Faster, safer and better catheter ablation?

Bruno Schwagten

Faster, safer and better catheter ablation?

Bruno Schwagten

Cover illustration: Jade Schwagten (‘Een hand die in het hart gaat om het hart te genezen en een verrekijker om in het hart te zien’)
Inside cover: Menno Schwagten (‘untitled, but with love’)
(He)artwork: Wendy De Moor & Glenn Van Langenhove (‘Bruno Schwagten train(s) with Glenn Van Langenhove to Rotterdam between the land-escapes from Wendy De Moor’)

Het werk van Wendy De Moor (Aalst 1973*) kenmerkt zich door abstracte en figuratieve landschappen, een confrontatie tussen droom en realiteit, chaos en orde, afstand en nabijheid.
Liefde in de kantlijn. De rode draad ook door de gedichten die ze schrijft.
Ze beweegt zich tussen vlakken in een onbewuste wereld die zich markeert met intense lijnen en een gevoelig kleurenpalet. Buigt zich over ronde vormen in contrast met verstilde landschappen.
De lichtgevende ‘bloementuin wachtend op de nachtvlinder’ is daar een voorbeeld van.
Fragmenten uit het leven, beelden uit het hart, een vlek op het doek.

* Wendy De Moor leeft en werkt in Antwerpen, haar opleiding heeft zij genoten in de Academie Sint-Lucas te Gent en de Academie voor beeldende kunst te Antwerpen

ISBN: 978-94-6169-198-9

Layout and printing: Optima Grafische Communicatie, Rotterdam, The Netherlands

Faster, safer and better catheter ablation?

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de rector magnificus
Prof.dr. H.G. Schmidt
en volgens besluit van het College voor Promoties.

De openbare verdediging zal plaatsvinden op
woensdag 25 januari 2012 om 13.30 uur

door

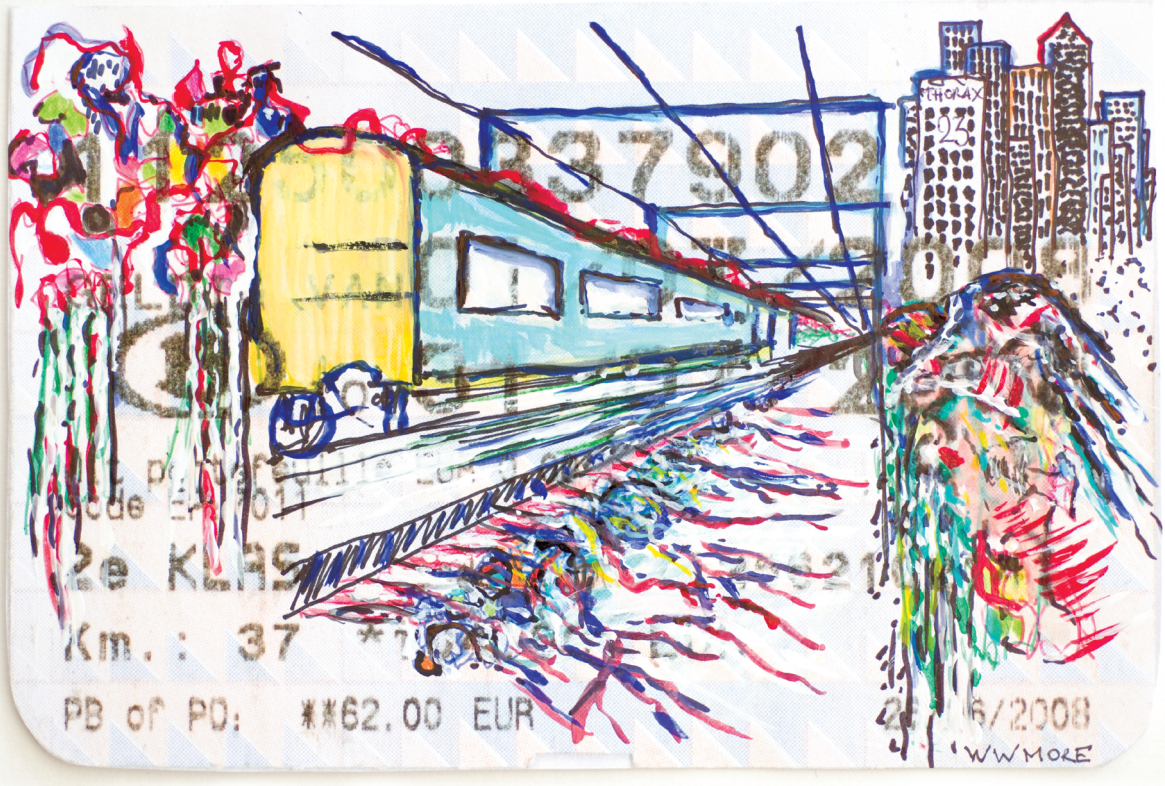
Bruno Schwagten
geboren op 16 december 1976
te Mortsel, België

PROMOTIECOMMISSIE

Promotor:	Prof.dr. L. Jordaens
Co-promotor:	Dr. T. Szili-Torok
Kleine commissie:	Prof.dr. F. Zijlstra Dr. R. van Domburg Prof.dr. R. Willems

Voor Ysabel, Jade en Menno

Contents


THORAX
Km. : 37
PB of PD: **62.00 EUR
WWMORE

Introduction

GENERAL INTRODUCTION

Undoubtedly the pace at which we are living increases step by step on a daily basis. Since this is a gradual process in general, this may go unnoticed to some, but the implications on healthcare are not to be taken too lightly.

Interventional electrophysiology as a distinct entity is a relatively young discipline. It has gone through several groundbreaking changes in a short time span. Although the first measurements of cellular currents date from the late 1800s, in general the birth of invasive clinical electrophysiology, associated with the use of programmed electrical cardiac stimulation combined with intracardiac activation mapping by the groups of Durrer and Coumel, is said to be no earlier than 1967. After having been used for several years as a diagnostic tool to evaluate the effect of anti-arrhythmic drugs, the therapeutic options of electrophysiology emerged in the early 1980s with the 'shock' ablation of the His bundle. At roughly the same time the pacing branch of electrophysiology experienced a comparable 'shock' with the introduction of the first implantable automatic defibrillator.

In the last decade, there has been a relentless innovation in the field of electrophysiology. The invasive electrophysiological armamentarium now consists of numerous diagnostic tools, multiple implantable devices aiming to pace, defibrillate or resynchronize the heart and a continuously growing number of manually and remotely navigated ablation catheters in various shapes and sizes.

In parallel to the aforementioned, the number of targeted arrhythmias expands. However, it is uncertain if our understanding of the underlying disease matures at the same velocity. Selection of patients suitable for an ablation or for device implantation, and timing of the intervention is crucial to achieve an optimal result. With regard to implantable defibrillators we need to optimize criteria to select patients who benefit most from this therapy: cost-efficacy is reasonable in secondary prevention, but still a whole lot of work needs to be done in identifying victims at risk for sudden cardiac death in primary prevention. In respect to cardiac resynchronization therapy we are able to improve functional status in about three out of four patients, however, one out of four is labeled as being a non-responder. We are ignorant to the exact cause of this therapy failure: did we select the wrong patient, are the current devices insufficient or do we lack consensus about reprogramming using mechanical or electrical synchronicity. The same applies to ablation for several complex arrhythmias. Atrial fibrillation and ventricular tachycardia are two hot topics in electrophysiology that currently illustrate our limitations in fully understanding their pathophysiology. Both arrhythmias tend to respond better when treatment is installed in an early phase of disease progression. However, we do not know the precise implications of the structural, functional, electric, metabolic and neurohumoral remodeling that occurs in the presence of these arrhythmias. Success rates of ablation are indisputably influenced by these limitations: we are still left with fundamental questions about optimal timing of intervention, precise ablation targets and uniform ablation endpoints.

Nevertheless, health care professionals tend to feel obliged to follow the new rhythm imposed by society. A swiftly increasing number of patients suffering from various arrhythmias in combination with regular cuts in financial resources by the Belgian government and a public opinion demanding a quick-fix treatment, form a potentially perilous combination.
Various questions need to be answered. When we strive to shorten procedural times, can we accept a trade-off in safety and efficacy? Is there still room for technologies that emphasize on safety without immediately shortening procedural times or increasing efficacy at the same time? How much effort should be made to first completely understand the pathophysiology of certain arrhythmias before developing treatment strategies that focus on swift and safe interventions?
Probably the true answer to these questions lies in a balanced approach combining different portions of speed, safety and success tailored to the needs of each single patient. In this thesis we aim to elucidate some determinants that could optimize our decision making using the currently available tools.
This thesis is composed of three parts each containing several chapters. The parts represent the past, present and future of catheter ablation. In each part we focus on techniques that were, are or could possibly be 'game changers' in the field of electrophysiology.
For starters, we take a look into the past comparing safety and efficiency of radiofrequency energy and cryothermal energy in treating atrioventricular nodal reentrant tachycardia. We try to find scientific evidence that justifies using one or the other energy form in certain circumstances. We also study basic principles of cryoenergy and learn how this knowledge can be of some help for less experienced users.
Secondly we evaluate some of the currently available novelties conceived to improve pulmonary vein isolation. Do these 'single shot ablation devices' really serve their goal or do they come with new threats? Can we consider treating new subgroups of patients that formerly were not suitable for catheter ablation? And can some new tools change the way we always thought about cryoablation?
Finally we take a thorough look at remote magnetic navigation and its implications for future electrophysiology.

Part I

Conventional AVNRT ablation: what do we learn from the past?

Chapter 1

Long-term follow-up after catheter ablation for AVNRT: a comparison of cryothermal and radiofrequency energy in a large series of patients

Bruno Schwagten MD, Paul Knops, Ing, Petter Janse, RN, Geert Kimman, MD, PhD, Yves Van Belle, MD, Tamas Szili-Torok, MD, PhD, Luc Jordaens MD, PhD, FESC

ABSTRACT

Background: Radiofrequency (RF) catheter ablation for atrioventricular nodal re-entrant tachycardia (AVNRT) is highly successful but carries a risk for inadvertent atrioventricular block (AVB). Cryoablation has the potential to assess the safety of a site before the energy is applied. Aim: to evaluate the long term efficacy and safety of cryothermal ablation in a large series of patients and compare it to RF. Methods: All consecutive routinely performed AVNRT ablations from our centre between 1999 and 2007 were retrospectively analysed. Results: In total 274 patients were elegible: 150 cryoablations and 124 RF. Overall procedural success was 96% (262/274), and equal in both groups, but 9 patients were crossed to another arm. Mean fluoroscopy time was longer in the group treated with RF (27 ± 22 min vs. cryo 19 ± 15 min; p=0.002). Mean procedure time was not different (RF 138 ± 71 min vs. cryo 146 ± 60 min). A permanent pacemaker was necessary in 2 RF patients. The questionnaire revealed a high incidence of late arrhythmia related symptoms (48%), similar in both groups, with improved perceived quality of life. The number of redo procedures for AVNRT over 4,3 ± 2,5 years follow-up was not statistically different (11% after cryo and 5% after RF). Conclusions: Our data confirm that cryo and RF ablation with 4 mm tip catheters for AVNRT are equally effective, even after long term follow up.

Key Words: arrhythmias; atrioventricular block; atrioventricular re-entrant tachycardia; catheter ablation; cryoablation, radiofrequency

INTRODUCTION

Catheter ablation is a successful and widely used approach for treatment of atrioventricular re-entrant tachycardia (AVNRT). (1,2) However, there is still debate about the choice of the most optimal energy. Radiofrequency (RF) catheter ablation is highly effective but carries the risk for creating inadvertent atrioventricular heart block (AVB). (3) Cryoablation (cryo) on the other hand can be performed very safely due to the possibility of `ice mapping` and `cryoadherence`. (4) We showed in the past in a randomised trial that both techniques had the same acute outcome. (5) However, conflicting data exist about the recurrence rate with this technique, ranging from 0 to more than 30%. (6-13) In this work, we evaluated not only the short term efficacy and safety of RF ablation and cryothermal ablation of AVNRT in a large series of patients, but also the long term outcome.

METHODS

All catheter ablations performed at our centre from 24/02/1999 to 19/12/2007 were analysed. In all procedures the antiarrhythmic agents were discontinued for at least 5 half-lives before the procedure. The ablation protocols were unchanged during the whole inclusion period, and were supervised by the same electrophysiologist. However, the team consisted of several experienced electrophysiologists, with their own training and preferences. All procedures were performed under local anaesthesia, implemented with sedation. The following data were collected: energy used, acute success, number of applications, ablation time, fluoroscopy time, procedural time, acute and late complications and need for redo procedures. Procedural time was measured from the time of puncturing the vein until the time of removal of the sheaths from the groin, including the 30 minutes waiting period after a successful ablation. The patients included in two previously published studies were not a part of this retrospective analysis. (5,14)

Ablation procedure

One bipolar catheter, one quadripolar and one decapolar catheter were inserted to perform a standard electrophysiological study. The catheters were advanced into the heart and positioned respectively in the right ventricular apex, on the His bundle and in the coronary sinus. At baseline the AH and HV intervals were recorded on the catheter in the His position, and with programmed electrical stimulation the presence of dual AV conduction was confirmed, defined as a AH jump of more than 50 ms. Subsequently tachycardia was induced by programmed electrical stimulation or by atrial burst pacing. If sustained tachycardia could not be induced, isoprenaline was used. Induction of AVNRT was performed at least 2 times before moving forward to ablation.

Cryoablation:
Cryoablation was performed by using a Freezor 3 catheter with a 4 mm tip (Cryocath Technologies, Montreal, Canada) and a CCT2 CryoConsole (Cryocath Technologies, Montreal, Canada). At the site of interest, ice mapping was performed by cooling to -30°C for a maximum of 60 s. Fluoroscopy was applied until a stable temperature of -30°C was reached. During these 60 s, atrial extrastimulus testing was performed. Termination or non-inducibility of AVNRT or disappearance of an AH-jump was considered to be an identification of a potentially successful ablation site. Ablation was subsequently performed using a freezing protocol by cooling to -75°C for a 6 min period to create a permanent lesion. If there was no clear AH-jump, and AVNRT was difficult to induce at baseline, prolongation of the anterograde AV refractory period during atrial extra stimulus testing during ice mapping was used to identify a target site. The endpoint was non-inducibility of AVNRT. This was tested after each application, and if non-inducible, repeated after a 30 min waiting period.

RF ablation:
RF catheter ablation was performed using a 4 mm, solid-tip, ablation catheter (Biosense-Webster Inc, Diamond Bar, CA, USA or an EPT Blazer, Boston Scientific, San Jose, CA, USA) in a temperature controlled mode (maximum temperature 55°C, maximum duration 60 s, maximum 40 W) with the use of a Stockert RF generator (Biosense-Webster Inc, Diamond Bar, CA, USA). Ablation of the slow pathway was guided by a combination of intracardiac electrograms and anatomical landmarks. When an optimal balance of a small fractionated A and large V signals were seen, RF energy was applied starting at a low energy level. Each application was started with the power set at 10 W and, if AV conduction was preserved, the power was progressively increased to 40 W until a maximum of 55°C was reached or junctional rhythm appeared. Fluoroscopy was used throughout each application.
With both techniques, retrograde conduction was continuously monitored. The endpoint was non-inducibility of AVNRT. This was tested after each application, and if non-inducible, repeated after a 30 min waiting period.

Follow-up

Before hospital discharge, all patients received a 12-lead ECG recording and echocardiographic examination. Three months after the procedure all patients were examined at the outpatient clinic and asked about recurrent palpitations. If longstanding palpitations occurred within the follow-up period, a new 24-hour holter monitor was performed or an effort was made to document the arrhythmia. Patients were then sent to their referring cardiologist, except when a redo procedure was necessary. For the purpose of this study, all patients were again personally approached by the investigators at the beginning of 2008 with a dedicated questionnaire, focusing on recurrence, duration and intensity of arrhythmias, antiarrhythmic drug use, cardioversion, readmission for cardiovascular reasons, for pacemaker implanta-

tion or reablation, also for other arrhythmias. This questionnaire was also sent to patients included in former trials as the obtained results were supposed not to be dependent on acute procedural outcomes. (5,14).

Statistical analysis

Continuous variables were expressed as mean ± standard deviation, if normally distributed, or otherwise by median. The Students t-test or analysis of variance were used when appropriate.

A Chi-square test with Yates correction was used for categorical data. The level of significance was set at $p < 0.05$. For efficacy and complications analysis, therapy as applied.

All statistics were performed using SPSS (16.0) for Windows (Chicago, Il, USA).

RESULTS

Patient data

Of the 389 consecutive procedures performed at our centre between 24/02/1999 and 19/12/2007, 81 were excluded as they were already part of other published studies.(5,14) Of the remaining 308 procedures, 16 were excluded because another arrhythmia was identified during the study before abalation, and 17 because of insufficient data (Figure 1). Patients

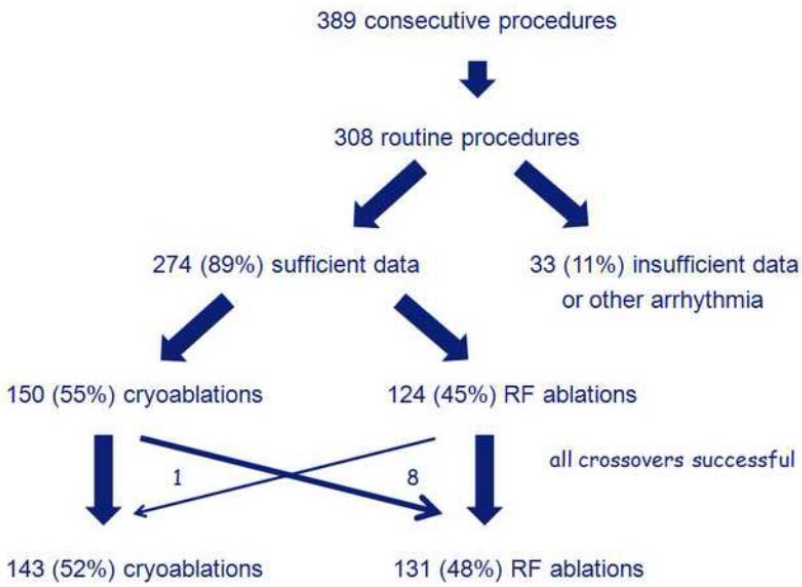


Figure 1. Patient flow chart. At the beginning, study patients were excluded, resulting in 308 routine procedures. AVNRT: atrioventricular nodal re-entrant tachycardia; RF: radiofrequency.

in whom AVNRT was ablated along with another arrhythmia (atrial flutter or atrial tachycardia) and redo procedures (28, of which 11 with cryo and 17 with RF) remained included. Eightyeight (32%) of 274 patients were male. The overall mean age was 51 ± 17 years, 50 ± 17 in the cryo group vs. 52 ± 17 years in the RF group (NS).

Procedure and ablation data

The initial approach was cryoenergy for 150 and RF for 124 ablations (55% vs. 45%). The overall acute success rate was 95% (262 patients). Of these procedures 246 were a first ablation for AVNRT, and 28 were redo procedures. Only 10/274 patients (3.6%) would fail the ablation (5 in each group had procedural failure), but this implied a cross-over of 8 cryo patients to RF, and 1 RF to cryo. The acute failure rate for the final delivered energy modality was similar for both approaches (cryo 3% vs. RF 4%; NS). The median number of applications was less in the cryo group (2 vs. 6) (Table I). The mean ablation time was longer in the cryo patients (522 ± 384 s vs. 371 ± 621 s). The mean fluoroscopy time was shorter in the cryo group (19 ± 15 min vs. 27 ± 22 min), while the procedure time was not different (cryo 146 ± 60 min vs. RF 138 ± 71 min). From the redo procedures, only one (cryo) failed acutely.

Table I. Procedural data (analysis including cross-overs)

	Cryoablation	RF ablation	*p* value
Nr (final approach)	143	131	
Application number (mean ± SD); median	2 ± 22	9 ± 86	<0.001
Ablation time (mean ± SD); s	522 ± 384	317 ± 621	<0.001
Fluoroscopy time (mean ± SD); min	19 ± 15	27 ± 22	<0.002
Procedural time (mean ± SD); min	146 ± 60	138 ± 71	NS
Acute success (nr)	138/143	126/131	NS
Temporary AVB (nr)	6	7	NS
Permanent AVB	0	2	NA
First procedure/Redo	132/11	114/17	NA

Analysis taking into account all patients as they were finally treated. AVB: atrio-ventricular block; NA: not applicable; nr: number; NS: not significant; RF: radiofrequency. SD: standard deviation

Acute complications

Thirteen patients had temporary AVB (6 cryo vs. 7 RF, including one cross-over patient; NS). Two patients had pericardial effusion needing acute intervention (both in the RF group). Further, two patients in the RF group received a permanent PM because of third degree atrioventricular block with narrow QRS complexes, without recovery before discharge.

Long term follow-up data

After a mean follow up of 4.3 ± 2.5 years, 20 of the 246 patients (8%) treated for the first time in this series did undergo a redo ablation. The number of redo AVNRT procedures divided by the number of first procedures was not statistically different for both groups (14/132 for cryo vs. 6/114 for RF). During 3 redo procedures the arrhythmia proved to be a left sided concealed accessory pathway.

Questionnaire

The overall response rate to the questionnaire was 235/389 (61%). Of all patients responding to the questionnaire, 49% initially underwent cryo and 51% RF ablation (NS). There was only one patient from the cross-over group to RF , and she is included in the RF group.
Arrhythmia related symptoms were reported in 55/115 (47.8%) in the cryo group versus 57/120 (47.5%) in the RF group (NS). Table II displays the distribution of the arrhythmia pattern and the reported duration of the arrhythmias as reported in the questionnaire. Whereas the majority of the patients initially reported monthly or weekly occurrence of palpitations with a typical duration of hours, rather than minutes, this changed to no palpitations or sporadic occurrence, sometimes lasting only seconds after the procedure (figure 2). No differences were seen between the groups. The perceived quality of life improved in 102/115 patients (89%) in the cryo vs 106/120 (88%) in the RF group (NS) (Figure 3); 12/115 patients (10%) in the cryo vs 12/120 (10%) in the RF group (NS) observed no difference in their

Table II. Reported arrhythmia pattern and duration (numbers) before and after ablation as answered in the questionnaire

	Cryoablation (N = 115)		RF (N = 120)	
Arrhythmia pattern	Before	After	Before	After
None	1	63	1	63
Sporadic	9	29	12	33
Monthly	40	15	43	12
Weekly	40	7	35	8
Daily	25	1	29	4
Arrhythmia duration	Before	After	Before	After
None	0	77	1	70
Seconds	2	18	3	23
Minutes	30	14	32	17
Hours	72	6	75	9
Days	11	0	9	1

The pattern and duration before and after ablation are different (p<0.0001); no differences are observed after ablation between the two treatment modalities. N: number; RF: radiofrequency ablation.

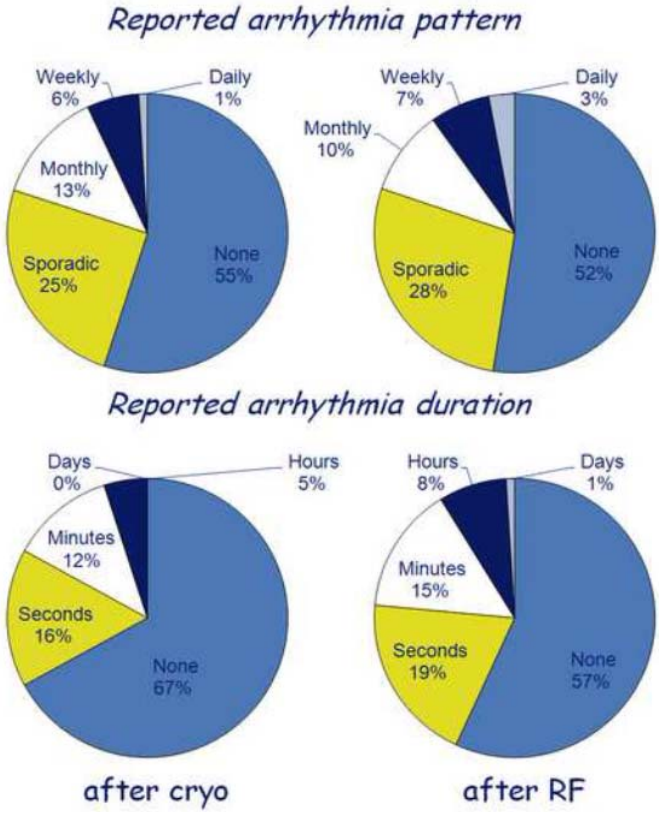


Figure 2. Reported arrhythmia pattern and duration in the questionnaire (N=235) after ablation (percentages) with cryoenergy (left) and RF (right). There are no differences in both parameters for the two approaches.

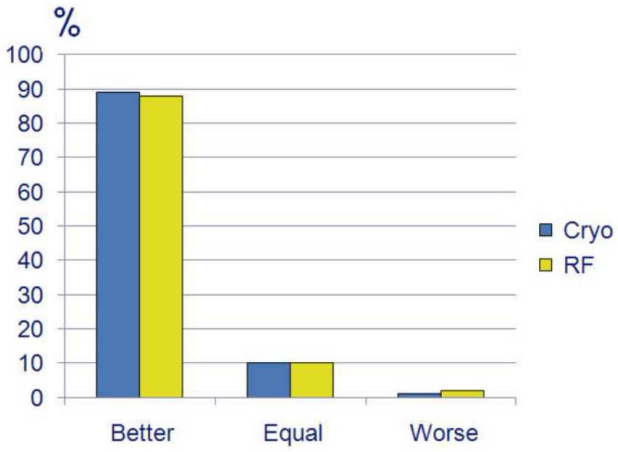


Figure 3. Percentage of patients indicating an improvement, no difference or deterioration in their quality of life before and after the cryoablation (cryo) or radiofrequency (RF) ablation.

quality of life; only 1/115 in the cryo and 2/120 in the RF group (NS) indicated a deterioration in perceived quality of life.

From the 235 responses, 66 (28%) patients reported a hospital readmission (Figure 4). From the 35 arrhythmia related admissions 19 (54%) were after cryo, 16 (46%) after RF (NS). Two patients were admitted for elective cardioversion (atrial fibrillation). Five patients received a device for arrhythmia management. The 2 late ICD's were implanted after anterior myocardial infarction and after development of heart failure in a patient with non-ischemic cardiomyopathy. No conduction disease, nor arrhythmias were recorded in these 2 patients. The 3 late pacemaker indications were sinus node disease (one from each group), and one second degree AVB with symptoms (RF group).

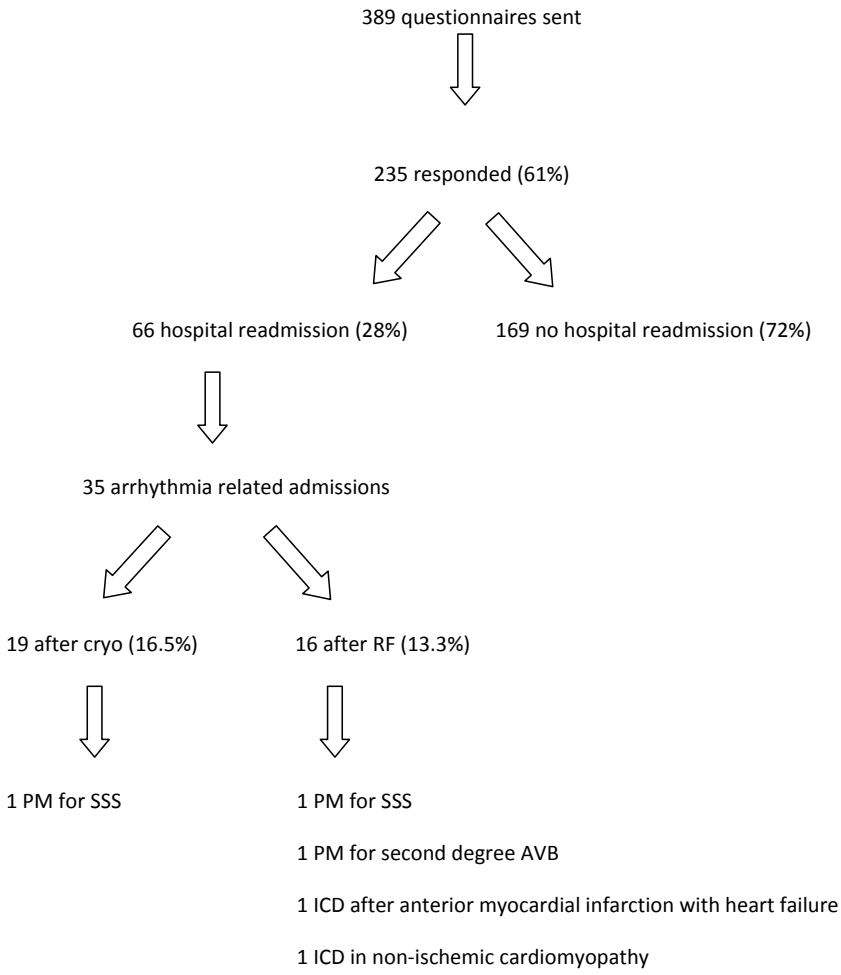


Figure 4. Hospital admissions according to the questionnaire. AVB, atrioventricular block; PM, pacemaker; SSS, sick sinus syndrome; ICD, implantable cardioverter defibrillator

DISCUSSION

The major finding of this study is that cryo and RF ablation for AVNRT are equally effective techniques, also in the long run. Cryoablation has a better safety profile.

Procedural efficacy

Both cryo and RF ablation are very successful techniques in AVNRT ablation. Acute success was very high in previous studies, and this is confirmed in our observations, which were also achieved with a 4 mm catheter tip.(5,6,7) We cannot completely explain the relatively high cross-over rate, but we suspect that physician preference played a role in this. Use of a 6 mm cryocatheter tip might improve the success rate, compared to a 4 mm tip, when applying on the right spot, but also might diminish the potential of ice mapping, as it yields larger lesions, and therefore might result in false positive conduction damage, so that no applications are given.(8-13)

The technique of RF ablation is well known: anatomical and electrical landmarks guide the procedure aimed to eliminate the slow pathway. The procedure is associated with some difficulties as the RF catheter tip moves during ablation due to changes in heart rhythm, respiratory movements and potential patient movements. For these reasons and also because of potential anatomic variations, damage to the fast pathway can occur in the triangle of Koch which is very small in comparison to a relatively large RF lesion. The need for careful imaging during RF ablation, which is not necessary during cryoablation, explains the shorter fluoroscopy time in our hands, confirming the data from other studies. (5,6,10)

Safety

The major potential advantage of cryoablation is its safety in preserving normal atrioventricular conduction. The ablation lesions formed by cryomapping probably always are reversible. Block during mapping at minus 30ºC, is a warning that no application should be given at this site.(4) However, even with short freezes at minus 75ºC on the compact AV node or on the His, the conduction seems to recover spontaneously almost always after waiting a short time. (8) With both the cryo and RF approach temporary heart block occurred in a similar amount. Further, we have seen unexpected temporary AVB occurring during real cryoablation, after cryomapping without blocking, but have never met inadvertent persisting heart block after such a procedure.(5) In contrast, in spite of a well trained group of electrophysiologists, we observed two times complete AVB requiring permanent pacing in the RF group, and detected one additional late conduction problem after RF.

Symptoms versus success

Although cryo and RF have very high acute and long-term success rates, a significant amount of patients still have some arrhythmia related complaints as shown by the questionnaire.

Nevertheless, most patients indicate an improvement in quality of life after the ablation. It is well known that palpitations after AVNRT ablation often bear no relationship with the original arrhythmia: some patient complain of sinus tachycardia, atrial premature beats, ventricular premature beats or have an associated arrhythmia. (3,15) Moreover, after AVNRT ablation atrial flutter might become present, or ectopic atrial tachycardia may arise due to the scarring.(3) It also has to be said when interpreting these results that atrial or ventricular premature beats, which often initiate AVNRT, are not treated by ablation of the slow pathway and may continue to provoke symptoms in both groups. An association with ventricular outflow tachycardia has been described, and is not uncommon. (16-18) Finally, it is known that in the long run, supraventricular tachycardia is associated with the development of atrial flutter or fibrillation. This indicates that judging the success of the AVNRT procedure merely by relying on symptoms is inefficient and can lead to incorrect conclusions. (15)

Late recurrence

Our study suggests that cryo and RF have a similar early and late failure rate, as reflected by the amount of redo procedures, even after a mean follow-up of over more than 4 years. When cryo is used on an intelligent way (i.e. with conventional pacemapping at -30°C), its success rate is equal to RF ablation in AVNRT (even when using a 4 mm tip). We always use pacing during cryomapping to prove that the AH-jump disappears, to see non-inducibility of AVNRT, or when cryomapping is performed during tachycardia, to witness termination of the AVNRT. Only after fulfilling at least one of the afore mentioned criteria we proceed to cryoablation.

Limitations

The major limitation of this study is its retrospective design. However, the early results are in line with all former trials trying to compare cryo with RF in a randomized fashion, (including our own study) or in a retrospective way. (5-13) Further, the high cross over rate created a discrepancy between the number intended to be treated with one approach, and the number really treated with one or another approach. However, this minor shift in numbers was taken into account in the interpretation of the data, so that the finally used energy modality took the benefit and the disadvantage.

The value of the questionnaire can be debated, as no standardized instrument to measure quality of life was used, and as no questionnaire was taken before the ablation. (19) On the other hand, patients indicated a perception of a better quality of life, indicating that some positive change occurred in a large majority after the treatment.

CONCLUSION

The overall success rate is very high and similar for both techniques. There is more need for fluoroscopy in the RF group, but procedures are equal in duration. There was no need to implant any pacemaker after cryoablation. Our data confirm that cryo and RF ablation for AVNRT are equally efficient, even after long term follow up, but still are associated with a high hospital admission rate during follow-up.

REFERENCES

1. Haissaguerre M, Warin JF, Lemetayer P, Saoudi N, Guillem JP, Blanchot P. Closed-chest ablation of retrograde conduction in patients with atrioventricular nodal re-entrant tachycardia. N Engl J Med 1989;320:426-33.
2. Jazayeri MR, Hempe SL, Sra JS, Dhala AA, Blanck Z, Deshpande SS, Avitall B, Krum DP, Gilbert CJ, Akhtar M. Selective transcatheter ablation of the fast and slow pathways using radiofrequency energy in patients with atrioventricular nodal reentrant tachycardia. Circulation 1992;85: 1318-28.
3. Kimman GP, Bogaard MD, van Hemel NM, van Dessel PF, Jessurun ER, Boersma LV, Wever EF, Theuns DA, Jordaens LJ. Ten year follow-up after radiofrequency catheter ablation for atrioventricular nodal reentrant tachycardia in the early days forever cured, or a source for new arrhythmias? Pacing Clin Electrophysiol 2005;28:1302-9.
4. Dubuc M, Roy D, Thibault B, Ducharme A, Tardif JC, Villemaire C, Leung TK, Talajic M. Transvenous catheter ice mapping and cryoablation of the atrioventricular node in dogs. Pacing Clin Electrophysiol 1999;22:1488-98.
5. Kimman GP, Theuns DA, Szili-Torok T, Scholten MF, Res JC, Jordaens LJ. CRAVT: a prospective, randomized study comparing transvenous cryothermal and radiofrequency ablation in atrioventricular nodal re-entrant tachycardia. Eur Heart J 2004;25:2232-7.
6. Zrenner B, Dong J, Schreieck J, Deisenhofer I, Estner H, Luani B, Karch M, Schmitt C. Transvenous cryoablation versus radiofrequency ablation of the slow pathway for the treatment of atrioventricular nodal re-entrant tachycardia: a prospective randomized pilot study. Eur Heart J 2004;25: 2226-31.
7. Collins KK, Dubin AM, Chiesa NA, Avasarala K, Van Hare GF. Cryoablation versus radiofrequency ablation for treatment of pediatric atrioventricular nodal reentrant tachycardia: initial experience with 4-mm cryocatheter. Heart Rhythm 2006;3:564-70.
8. Gupta D, Al-Lamee RK, Earley MJ, Kistler P, Harris SJ, Nathan AW, Sporton SC, Schilling RJ. Cryoablation compared with radiofrequency ablation for atrioventricular nodal re-entrant tachycardia: analysis of factors contributing to acute and follow-up outcome. Europace 2006;8: 1022-6.
9. Avari JN, Jay KS, Rhee EK. Experience and results during transition from radiofrequency ablation to cryoablation for treatment of pediatric atrioventricular nodal re-entrant tachycardia. Pacing Clin Electrophysiol 2008;31:454-60.
10. Chan NY, Mok NS, Lau CL, Lo YK, Choy CC, Lau ST, Choi YC. Treatment of atrioventricular nodal re-entrant tachycardia by cryoablation with a 6 mm-tip catheter vs. Radiofrequency ablation. Europace 2009;11:1065-70.
11. De Sisti A, Tonet J, Barakett N, Lacotte J, Leclercq JF, Frank R. Transvenous cryo-ablation of the slow pathway for the treatment of atrioventricular nodal re-entrant tachycardia: a single-centre initial experience study. Europace 2007;9:401-6.
12. Sandilands A, Boreham P, Pitts-Crick J, Cripps T. Impact of cryoablation catheter size on success rates in the treatment of atrioventricular nodal re-entry tachycardia in 160 patients with long-term follow-up. Europace 2008;10:683-6.
13. Rivard L, Dubuc M, Guerra PG, Novak P, Roy D, Macle L, Thibault B, Talajic M, Khairy P. Cryoablation outcomes for AV nodal reentrant tachycardia comparing 4-mm versus 6-mm electrode-tip catheters. Heart Rhythm 2008;5:230-4.

14. Thornton AS, Janse P, Theuns DA, Scholten MF, Jordaens LJ. Magnetic navigation in AV nodal re-entrant tachycardia study: early results of ablation with one- and three-magnet catheters. Europace 2006;8:225-30.
15. Jordaens L, Vertongen P, Verstraeten T. Prolonged monitoring for detection of symptomatic arrhythmias after slow pathway ablation in AV-nodal tachycardia. Int J Cardiol 1994;44:57-63.
16. Kazemi B, Arya A, Haghjoo M, Sadr-Ameli MA. Coincident atrioventricular nodal re-entrant and idiopathic ventricular tachycardia. Asian Cardiovasc Thorac Ann 2006;14:284-8.
17. Haghjoo M, Arya A, Dehghani M, Emkanjoo Z, Fazelifar A, Heidari A, Sadr-Ameli M. Coexistence of atrioventricular nodal reentrant tachycardia and idiopathic left ventricular outflow-tract tachycardia. Indian Pacing Electrophysiol J 2005;5:149-54.
18. Washizuka T, Niwano S, Tsuchida K, Aizawa Y. AV reentrant and idiopathic ventricular double tachycardias: complicated interactions between two tachycardias. Heart 1999;81:318-20.
19. Arribas F, Ormaetxe JM, Peinado R, Perulero N, Ramírez P, Badia X. Validation of the AF-QoL, a disease-specific quality of life questionnaire for patients with atrial fibrillation.Europace. 2010;12: 364-70.

Chapter 2

Cryoablation: how to improve results in atrioventricular nodal reentrant tachycardia ablation?

Bruno Schwagten, MD, Yves Van Belle, MD, and Luc Jordaens MD, PhD, FESC

ABSTRACT

Ablation for atrioventricular nodal reentry tachycardia is very effective, with a potential for damage to the normal conduction system. Cryoablation is an alternative, as it allows cryomapping, which permits assessment of slow pathway elimination at innocent freezing temperatures, avoiding permanent damage to the normal conduction system. It is associated with shorter radiation times and the absence of heart block in all published data. We discuss in this overview different approaches of cryoenergy delivery (focusing on spot catheter ablation), and how lesion formation is influenced by catheter tip size, application duration, and freezing rate. Some advantages of cryoenergy are explained. Whether these features also apply for an approach with a cryoballoon, e.g. for atrial fibrillation is unclear.

Key words: Arrhythmia, Atrial fibrillation, Atrioventricular nodal reentrant tachycardia, Catheter ablation, Cryoenergy, Radiofrequency

INTRODUCTION

In the past decade, a significant amount of basic and clinical research has been conducted regarding the use of cryoablation. The different clinical trials leave no doubt on the advantageous safety profile of this ablation technique, with not a single permanent heart block reported till now for atrioventricular nodal reentrant tachycardia (AVNRT).1 – 4 This has lead to the use of cryoablation as the technique of choice in medical or health care environments where safety is the primary concern, e.g. in pediatric patients, or when ablation is performed close to normal conduction system.5 Still, some debate remains about the long-term efficacy of cryoablation. Table 1 shows the average success rate and the long-term outcome of studies analysing cryoablation versus radiofrequency (RF) in AVNRT. Acute success is similar, but it cannot be denied that slightly more recurrences are observed with cryotherapy.1,2,5 – 10 However, it is possible that cryoablation procedures can be improved. Issues such as catheter tip size, application duration, and the temperature constant will be discussed in this paper. In Table 2, we show procedure and radiation times as reported by investigators, directly comparing cryoenergy, and RF, clearly demonstrating that less fluoroscopy is needed with AVNRT, with a similar procedure time as for RF.

Table 1 Acute procedural and long-term outcome data in studies comparing cryothermy vs. radiofrequency

Authors	Patient nr		Acute success (%)		Recurrences (%)	
	Cryo	RF	Cryo	RF	Cryo	RF
Kimman *et al.*[1]	30	33	93	91	10	9
Zrenner *et al.*[2]	100	100	97	98	8	1
Gupta *et al.*[6]	71	71	85	97	19.8	5.6
Collins *et al.*[5]	57	60	95	100	8	2
Avari *et al.*[7]	38	42	97	95	2	2
Chan *et al.*[8]	80	80	97.5	95	9	1.3
Schwagten *et al.*[9]	144	130	97	95	7.5	6.5
Opel *et al.*[10]	123	149	83	93	11	3
Total	643	665	93	96	10	4.2

Cryo, cryothermy; RF, radiofrequency

LESION FORMATION

The creation of a permanent cryolesion is characterized by three phases: (i) the freeze/thaw phase, (ii) the haemorrhagic and inflammatory phase, and (iii) the replacement of this acute lesion by fibrosis.11 In the first phase, intracellular and extracellular ice crystals are formed with variable size. Ice crystals formed more closely to the catheter tip are intra- and extracellular, in contrast to more peripheral ice crystals, which tend to appear only in the extracellular space. During the thawing phase, mitochondria develop irreversible damage due to increased membrane permeability. These changes are less marked towards the periphery.12

Table 2 Comparison of procedural parameters in studies using cryothermy vs. radiofrequency

Authors	Procedure time (min)		Fluoroscopy time (min)	
	Cryo	RF	Cryo	RF
Kimman *et al.*[1]	***142,5***	***144***	***29***	***35***
Zrenner *et al.*[2]	140	112	12	14
Gupta *et al.*[6]	***96***	***90***	***17***	***13***
Collins *et al.*[5]	146	112	20	21
Avari *et al.*[7]	***176***	***174***	***19***	***21***
Chan *et al.*[8]	150	159	19	26
Schwagten *et al.*[9]	149	152	22	29
Opel *et al.*[10]	90	90	16	14

Cryo, cryothermy; RF, radiofrequency.
Medians are in bold, italic; means are in a regular font.

The second phase, occurring within the first 48 h, is characterized by the development of haemorrhage, oedema, and inflammation.12,13 After 1 week, a sharply demarcated lesion is formed.12 The final phase of lesion formation takes place within 2–4 weeks. At this time, the lesion consists of dense collagen and is infiltrated by fatty tissue. At its border many small blood vessels are found. At 1 month, the lesion is composed of dense fibrosis.14 In summary, cryolesions are formed by consecutive freezing, inflammation, and fibrosis, leading to tissue with intact extracellular matrix. The advantage of preservation the endothelium is a decreased risk of thromboembolism.11 A theoretical advantage could be that cryolesions are less proarrhythmic as the lesion is more homogeneous. At this moment, cryoenergy is applied at the epicardium by surgeons and by spot, and balloon catheters by the cardiologist. It is evident that these methods will result in different ways of lesion formation. Most of what we will address in this review will be based on data from spot catheters, as used for AVNRT.

CRYOMAPPING

One of the major advantages of cryoablation is the possibility of cryomapping, a feature which was initially introduced by Dubuc.15 After cryoadhesion at -30°C, freezing is continued at this temperature, to evaluate the clinical effect of the application, and to proof that no collateral damage is present. Some authors reported that temporary AV block may happen, even after such cautious approach.16,17 Nevertheless, this should not lead to persisting block. Even fast freezing till -70°C on the target site was applied to perform cryomapping, and did not lead to permanent block in the hand of other investigators.6 However, it has to be pointed out that this 'aggressive' approach was associated with a lower procedural

success than for other groups, with substantially more recurrences (Table 1). One of the reasons might be that the 'stunned' area becomes larger, and that real (i.e. long-term) success becomes more difficult to predict. More moderate attempts, using -40°C resulted as well in local damage.18

CATHETER TIP SIZE

Catheter tip size can be a very important determinant of procedural success. Nowadays, 4, 6, and 8 mm tip catheters are available. In everyday practice, the 4 and 6 mm tip catheters are used most frequently for treating AVNRT, although the 8 mm tip catheter can be very useful in other areas as ventricular tachycardia, Wolff–Parkinson–White (WPW), and atrial flutter.19 The 4 and 6 mm tip catheters create a lesion size, which is smaller than the lesions of the 8 mm tip.12 The difference seems to be mostly dependent on the angle of the catheter tip in relation to the surface.20 Moreover, when comparing the 4 and 6 mm tip catheters in AVNRT in clinical practice (Table 3), there seems to be a difference in efficacy in favor of the 6 mm tip catheters: acute success is similar in both groups, but there is a higher recurrence rate in the 4 mm tip group.21,22 Apart from the lesion size and depth, lesion quality or degree of tissue damage created by cryoablation is influenced by the selected catheter tip size and by the tissue contact reached during the ablation, as shown in the recent experimental paper of Atienza et al.23

Table 3 Comparison of procedural and outcome data in studies comparing 4 and 6 mm tips for slow pathway ablation

Authors	Nr of cryoablation patients	Study design	Acute success	Follow-up (months)	Recurrences	Temporary AV block (first, second, third)	Complete, permanent AV block
De Sisti *et al.*[17]	8 (4 mm)	SC, cohort, prospective,	4/8	18[a]	4/4	NR (21/69)	0
	61 (8 mm)	4 and 6 mm	56/61		20/59		0
Sandilands *et al.*[21]	59 (4 mm)	SC, cohort, prospective,	54/59	18[a]	12/54	NR (13/160)	0
		4 vs 6 mm					
	101 (6 mm)		95/101		7/95		0
Rivard *et al.* (2007)[31]	152 (4 mm)	SC, 2 cohort, retrospective,	139/152	6	22/139	6/152	0
	137 (6 mm)	4 vs 6 mm	123/137	4.7	10/123	12/137	0

NR, not reported; SC, single centre.
[a]Subgroup not specified.

APPLICATION DURATION

It was shown in several experimental settings that lesion depth is determined by the duration of freezing. During the first minute a stable temperature gradient is reached, and a plateau phase is achieved at 5–6 min.11,13,21 This is reflected in most clinical settings, where cryoen-

ergy is applied for 4–5 min. A recent experimental paper describing the electrophysiologic and histologic changes in correlation to the duration of the cryoapplication using an 8 mm tip catheter on the compact AV node in pigs showed that recovery of AV nodal function was less likely if the application lasted longer.23 They observed that isolated viable cells surrounded by necrotic tissue in the compact AV node were associated with acute AV conduction recovery. Moreover, they witnessed a variation in the degree of myolytic changes between the animals with and without persistent AV block at 1 week. Some suggestions have been made to improve lesion formation by applying a double freezing cycle (freezing–thawing–freezing).24 First, a freezing phase of 4 min is applied. Then the catheter rewarms and immediately a new freezing cycle is performed at exactly the same site for 2 min. Data in hepatocellular ablation show that repetitive freeze–thaw cycles create larger lesions than those obtained by longer freezing at a certain temperature.25 The rate and extent of conduction of the cold front increases with repetitive exposure, what suggests a progressive increase in thermal conductivity of tissue. Although poorly understood, this could be related to basic cellular structure changes and/or modification of local microperfusion.26 So far, no cardiovascular data exist to support the routine use of this technique, which was tested in hepatic disorders.

TEMPERATURE TIME CONSTANT

Several suggestions have already been made to improve the quality of the lesion. Fast freezing, with a steep decrease in temperature is more effective than a slow progression to the target temperatures.27 It was demonstrated in a group of WPW patients that successful ice mapping attempts were characterized by a short time-constant. This parameter reflects the time interval between the onset of ice mapping and the steady-state mapping temperature of -30°C.

CATHETER ADHESION

The formation of ice during ablation at the tip of the catheter causes the catheter to adhere to the adjacent tissue(cryoadherence). This allows pacing manoeuvres in the atrium and the ventricle during ablation without the risk of catheter dislodgement, what is very useful to show persistence or absence of slow pathway conduction. Moreover, ablation can be performed during tachycardia without a risk of dislodging the catheter when normal rhythm is restored. Also, small patient movements and even deep breaths do not affect ablation catheter position during ablation. Unlike the ‘brush lesions’ formed by radiofrequency ablation, cryoablation creates very focal lesions. This is similar to lesions as described with magnetic navigation.28

RECURRENCE

It is not impossible that some of the recurrences are due to reconduction, a phenomenon which is well known in the pulmonary veins, where reconnection is often detected, and almost always when a patient is restudied because of recurrences.29 Asymptomatic reconduction is also seen in a recent study on cryoablation of the cavotricuspid isthmus in 23% of cases during restudy after several weeks.30 This might be a reason to strictly adhere to some observation time after ablation, and to ascertain that there is no more slow pathway conduction after this time.

CONCLUSION

In conclusion, cryoablation is a safe and effective approach for AVNRT, but care should be taken to use it in a way with full understanding of its possibilities and limitations, otherwise it could lead to disappointing results. This means that cryomapping should be performed to demonstrate that the catheter is over the slow pathway, which is impossible with RF techniques. Further, application times should be long enough to create full lesions. A 6 mm tip is probably better than the 4 mm tip, which still may have a place in some pediatric indications. Energy sources should allow very fast freezing to improve penetration of the cold in the tissue. Finally, waiting times should be respected, as recovery within a short time may indicate that more applications are necessary. In this way, cryoablation is an elegant technique, with few important side effects. The complete absence of AV nodal conduction defects in AVNRT, should make it a strategy of first choice. The small excess number of patients requiring a second approach makes the extra amount of radiation and catheterization related complications of a second procedure acceptable, due to the absence of the main RF related complication. Further studies should be undertaken to improve the long-term outcome, as the value of freeze–thaw–freeze cycles and different application times; more flexible catheters, e.g. steerable with robotics or magnetic navigation (and without pull wires) could make the procedure even more safe.

REFERENCES

1. Kimman GP, Theuns DAMJ, Szili-Torok T, Scholten MF, Res JCJ, Jordaens LJ. CRAVT: A prospective, randomised study comparing transvenous cryothermal, and radiofrequency ablation in atrioventricular nodal reentrant tachycardia. Eur Heart J 2004;25:2232–7.
2. Zrenner B, Dong J, Schreieck J, Deisenhofer I, Estner H, Luani B et al. Transvenous cryoablation versus radiofrequency ablation of the slow pathway for the treatment of atrioventricular nodal re-entrant tachycardia: a prospective pilot study. Eur Heart J 2004;25:2226–31.
3. Friedman PL, Dubuc M, Green MS, Jackman WM, Keane DTJ, Marinchak RA et al. Catheter cryoablation of supraventricular tachycardia: results of the multicenter prospective 'frosty' trial. Heart Rhythm 2004;1:129–38.
4. Bastani H, Schwieler J, Insulander P, Tabrizi F, Braunschweig F, Kenneba¨ck G et al. Acute and long-term outcome of cryoablation therapy of typical atrioventricular nodal re-entrant tachycardia. Europace 2009;11:1077–82.
5. Collins KK, Dubin AM, Chiesa NA, Avasarala K, Van Hare GF. Cryoablation versus radiofrequency ablation for treatment of pediatric atrioventricular reentrant tachycardia: initial experience with 4-mm cryocatheter. Heart Rhythm 2006;3:564–70.
6. Gupta D, Al-lamee RK, Earley MJ, Kistler P, Harris SJ, Nathan AWet al. Cryoablation compared with radiofrequency ablation for atrioventricular nodal re-entrant tachycardia: analysis of factors contributing to acute and follow-up outcome. Europace 2006;8:1022–6.
7. Avari JN, Jay KS, Rhee EK. Experience and results during transition from radiofrequency ablation to cryoablation for treatment of pediatric atrioventricular nodal reentrant tachycardia. Pacing Clin Electrophysiol 2008;31:454–60.
8. Chan NY, Mok NS, Lau CL, Lo YK, Choy CC, Lau ST et al. Treatment of atrioventricular nodal re-entrant tachycardia by cryoablation with a 6 mm-tip catheter vs. radiofrequency ablation. Europace 2009;11:1065–70.
9. Schwagten B, Knops P, Janse P, Kimman GJ, Szili-Torok T, Luc Jordaens L. Long term follow-up after catheter ablation for AVNRT: a comparison of cryothermal and radiofrequency energy in a large series of patients (abstract). Heart Rhythm 2009;6:53.
10. Opel A, Murray S, Kamath N, Dhinoja M, Abrams D, Sporton S et al. Cryoablation versus radiofrequency ablation for treatment of atrioventricular nodal reentrant tachycardia: cryoablation with 6-mmtip catheters is still less effective than radiofrequency ablation. Heart Rhythm. 2010;7: 340–3.
11. Lustgarten DL, Keane D, Ruskin J. Cryothermal ablation: mechanism of tissue injury and current experience in the treatment of tachyarrhythmias. Prog Cardiovasc Disease 1999;41:481–98.
12. Mikat E, Hackel DB, Harrison L, Gallagher JJ, Wallace AG. Reaction of the myocardium and coronary arteries to cryosurgery. Lab Invest 1977;37: 632–41.
13. Holman WL, Kirklin JK, Anderson PG, Pacifico AD. Variation in cryolesion penetration due to probe size and tissue thermal conductivity. Ann Thorac Surg 1992;53:123–6.
14. Harrison L, Gallagher JJ, Kasell J, Anderson RH, Mikat E, Hackel DB et al. Cryosurgical ablation of the A-V node-His bundle: a new method for producing AV Block. Circulation 1977;55:463–70.
15. Dubuc M. Transvenous catheter ice mapping and cryoablation of the atrioventricular node in dogs. Pacing Clin Electrophysiol 1999;22:1488–98.
16. Jensen-Urstad M, Tabrizi F, Kenneback G, Wredlert C, Klang C, Insulander P. High success rate with cryomapping and cryoablation of atriventricular nodal reentry tachycardia. Pacing Clin Electrophysiol 2006;29:487–9.

17. De Sisti A, Tonet J, Barakett N, Lacotte J, Leclercq JF, Frank R. Transvenous cryo-ablation of the slow pathway for the treatment of atrioventricular nodal re-entrant tachycardia: a single-centre initial experience study. Europace 2007;9: 401–6.
18. Jordaens L, Knops P, Schwagten B, Kimman GP, van Deel E, van der Giessen W et al. AVNRT Cryoablation and comparison with RF. In Bredikis A, Wilber DJ (eds), Cryoablation of Cardiac Arrhythmias. Philadelphia, USA: Elsevier Inc., in press.
19. Thornton AS, Janse P, Alings M, Scholten MF, Mekel JM, Miltenburg M et al. Acute success and short term follow-up of catheter ablation of isthmus-dependent atrial flutter; a comparison of 8 mm tip radiofrequency and cryothermy catheters. J Interv Card Electrophysiol 2008;21:241–8.
20. Khairy P, Rivard L, Guerra PG, Tanguay JF, MawadW, Roy D et al. Morphometric ablation lesion characteristics comparing 4, 6, and 8 mm electrode-tip cryocatheters. J Cardiovasc Electrophysiol 2008;19:1203–7.
21. Sandilands A, Boreham P, Pitts-Crick J, Cripps T. Impact of cryoablation catheter size on success rates in the treatment of atrioventricular nodal re-entry tachycardia in 160 patients with long-term follow-up. Europace 2008;10:683–6.
22. Rivard L, Dubuc M, Guerra PG, Novak P, Roy D, Macle L et al. Cryoablation outcomes for AV nodal re-entrant tachycardia comparing 4-mm versus 6-mm electrode-tip catheters. Heart Rhythm 2008;5:230–4.
23. Atienza F, Almendral J, Sa´nchez-Quintana D, Zaballos M, Murillo M, Gimeno C et al. Cryoablation Time-Dependent Dose Response Effect at Minimal Temperatures (2808C). An Experimental study. Europace 2009;11:1538–45.
24. Bredikis A, Sidhu J. Critical nitrogen cryo ablation: transmurality and effects of double freezing cycle in chronic experiment (abstract). Heart Rhythm 2007; (Suppl.):Po5–62.
25. Stewart G, Preketes A, Horton M, Ross W, Morris D. Hepatic cryotherapy: double-freeze cycles achieve greater hepatocellular injury in man. Cryobiology 1995;32:215–9.
26. Gill W, Frazer J, Canter DC. Repeated freeze thaw cycles in gery. Nature 1968; 219:410–3.
27. Theuns DAMJ, Kimman GP, Szili-Torok T, Res JCJ, Jordaens LJ. Ice mapping during cryothermal ablation of accessory pathways in WPW: the role of the temperature time constant. Europace 2004;6:116–22.
28. Thornton AS, Brito de Castro CA, Van Deel E, Van Beusekom HMM, Jordaens L. An in vivo comparison of radiofrequency cardiac lesions formed by standard and magnetically steered 4 mm tip catheters. Neth Heart J 2010;18:66–71.
29. Van Belle Y, Janse P, Theuns D, Szili-Torok T, Jordaens L. One year follow-up after cryoballoon isolation of the pulmonary veins in patients with paroxysmal atrial fibrillation. Europace 008;10: 1271–6.
30. Kuniss M, Vogtmann T, Ventura R, Willems S, Vogt J, Gro¨nefeld G et al. Prospective randomized comparison of durability of bidirectional conduction block in the cavotricuspid isthmus in patients after ablation of common atrial flutter using cryothermy and radiofrequency energy: the CRYOTIP study. Heart Rhythm 2009;6:1699–705.
31. Rivard L, Dubuc M, Guerra PG, Novak P, Roy D, Macle L et al. Cryoablation outcomes for AV nodal reentrant tachycardia comparing 4-mm versus 6-mm electrode- tip catheters. Heart Rhythm 2008;5:230–4.

Part II

Ablation: new developments

Chapter 1

Pulmonary vein stenosis after pulmonary vein ablation catheter–guided pulmonary vein isolation

Yves De Greef, MD, Bruno Schwagten, MD, Gilles De Keulenaer, MD, PhD, Dirk Stockman, MD

Key words: Atrial fibrillation; Pulmonary vein ablation catheter; Pulmonary vein stenosis

INTRODUCTION

We report the case of a patient with severe pulmonary vein (PV) stenosis of the left superior PV 5 months after PV isolation using a pulmonary vein ablation catheter (PVAC; Medtronic, Inc., Minneapolis, MN, USA).

CASE REPORT

The patient was a 44-year-old man with highly symptomatic paroxysmal atrial fibrillation (AF). The paroxysms of AF had started 6 years earlier and initially had been treated with Class IC and Class III antiarrhythmic drugs. He was referred for invasive treatment due to persistent symptomatic AF paroxysms despite medical therapy and after he developed severe side effects of amiodarone treatment (photosensitivity and thyroid dysfunction). No evidence of underlying cardiac disease was noted. Left atrial (LA) diameter on transthoracic echocardiographic parasternal long-axis view was 44 mm. Contrast-enhanced computed tomography (40 slices, Philips, Eindhoven, The Netherlands) was performed the day before ablation.

PV ABLATION PROCEDURE

The ablation procedure was performed with the patient under general anesthesia. A 6Fr decapolar catheter was inserted in the coronary sinus for pacing purposes. Immediately prior to transseptal puncture, an intravenous loading dose of 10,000 international units of heparin was given. Target activated clotting time throughout the procedure was maintained above 350 seconds. A 9.6Fr deflectable sheath (Channel sheath, Bard Electrophysiology, Lowell, MA) was positioned in the LA after a single transseptal puncture was performed using a modified Brockenbrough technique under transesophageal echocardiography, fluoroscopy, and pressure guidance. A multielectrode temperature probe (Esotherm Plus, Fiab, Florence, Italy) was used to monitor the luminal esophageal temperature and to delineate the anatomic position of the esophagus throughout the procedure. Selective PV angiography was performed for each PV and was used as a "template" during the ablation to anatomically delineate the PV ostia. The ablation procedure consisted of PV isolation of each PV using the PVAC catheter. Prior to radiofrequency (RF) application, template bipolar electrograms and corresponding fluoroscopic PVAC positions were carefully annotated in the Bard acquisition system, during both sinus rhythm and coronary sinus pacing (Figure 1). The ostia of the PVs were sequentially targeted with RF energy at all or at selected electrode pairs (60°C, 4:1 or 2:1, 60 seconds). Appropriate positioning of the PVAC catheter at the ostia was ensured by local electrogram interpretation and by comparing the position of the PVAC catheter with

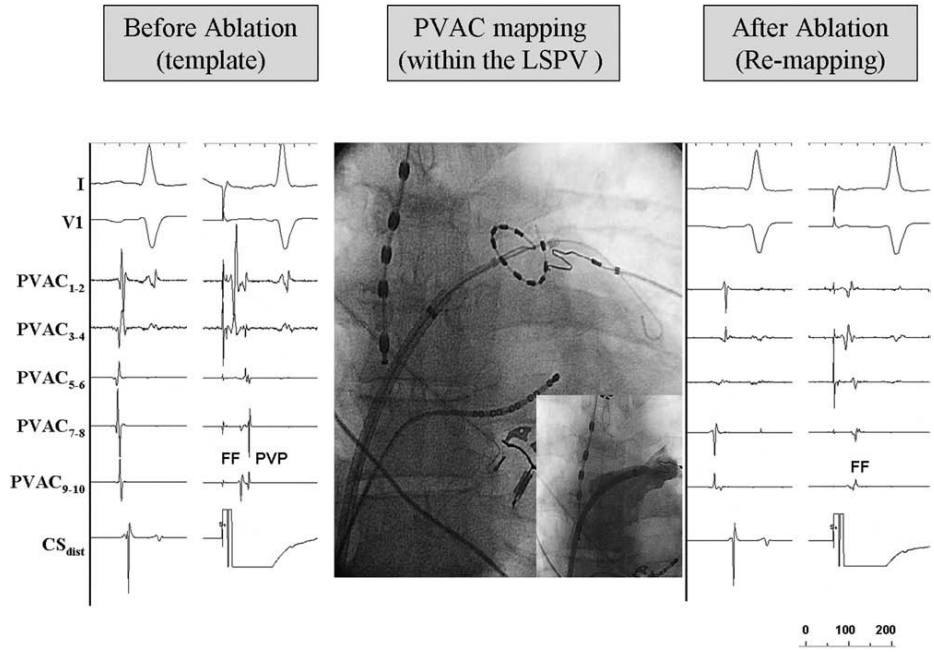


Figure 1 Pulmonary vein ablation catheter (PVAC)–guided ablation of the left superior pulmonary vein (LSPV). The PVAC catheter is circumferentially placed within the LSPV for mapping and validation of PV isolation (**middle**). A decapolar catheter positioned in the coronary sinus and a multielectrode esophageal temperature probe also can be observed. A selective PV angiogram is shown in the *inset*. Surface ECG leads I and V_1 and bipolar electrogram recordings before and after PVAC-guided ablation of the distal coronary sinus CS) and the PVAC catheter positioned within the LSPV are shown (**left** and **right**). At baseline, far-field (FF) and pulmonary vein potentials (PVP) can be clearly differentiated by distal CS pacing (**left**). After PVAC-guided ablation, remapping with the PVAC catheter at the same template position revealed only residual far-field potentials, thus confirming PV isolation.

the presumed LA–PV ostium seen on the selective PV angiogram. Between applications, remapping with the PVAC catheter at the same template position within the PV to check for PV isolation was repeatedly performed. Ablation was stopped when PV isolation was confirmed (Figure 1). The patterns of RF delivery for each PV are detailed in Table 1. Total procedure time was 180 minutes, with total RF time of 22 minutes.

Table 1 Pattern of energy delivery with PVAC for each pulmonary vein

PVAC energy modus	4:1 modus	2:1 modus
Left superior pulmonary vein	0	8
Left inferior pulmonary vein	0	3
Right superior pulmonary vein	3	2
Right inferior pulmonary vein	4	2

PVAC = pulmonary vein ablation catheter.

CLINICAL EVOLUTION POSTABLATION AND DIAGNOSIS OF PV STENOSIS

One month after the ablation procedure, the patient was free of AF paroxysms, with only residual symptomatic extrasystole recorded on 24-hour Holter monitoring. Treatment with antiarrhythmic drugs (except for beta-blockers) was interrupted, and a follow-up visit was scheduled for 6 months postablation. During the follow-up period, the patient developed progressive symptoms of exercise intolerance and fatigue. Five months after ablation, he was hospitalized with a 3-day history of pleuritic chest pain, shortness of breath, and fever. He was diagnosed with left lower and upper lobe pneumonia and severe secondary hypoxemia. Computed tomographic scan showed severely obstructed flow of contrast in the left superior PV with a "stop" image shortly postostially, suggesting severe PV stenosis. This diagnosis was confirmed by transesophageal echocardiography, which showed turbulent flow and high peak flow velocities (>2 m/s, normal 0.2 cm/s to 1 m/s) in the left superior PV (Figure 2). Normal laminar flow with low peak flow velocities was recorded in the left inferior PV (Figure 2).1 The patient's condition improved significantly during treatment with antibiotics.

Maximal cardiorespiratory exercise test performed prior to discharge showed slightly impaired VO2max (27 mL/kg/min, 76% of predicted value), near-normal maximal oxygen pulse (16.4 L/min, 80% of predicted value), and normal breathing reserve at peak exercise (>20%).

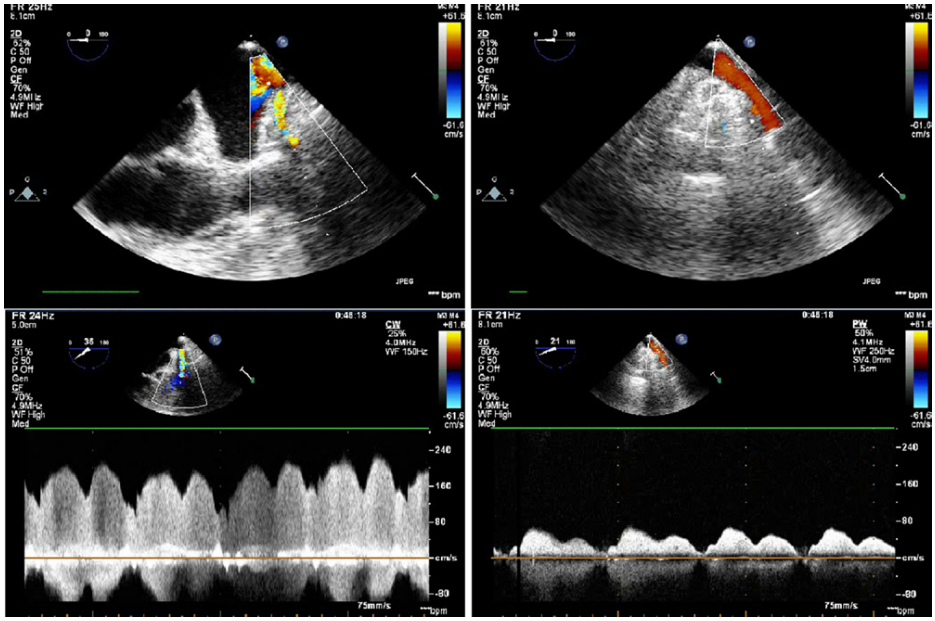


Figure 2 Transesophageal echocardiographic images of the left superior pulmonary vein (LSPV) (**right**) and left inferior pulmonary vein (LIPV) (**left**). Turbulent flow with high peak flow velocities (2 m/s, normal 0.2 cm/s to 1 m/s) is present in the LSPV compared to laminar flow with normal peak flow velocities in the LIPV.

Based on these results, PV angioplasty and stenting were not performed. The patient is scheduled for a follow-up visit 1 month after discharge. In addition to clinical evaluation, cardiorespiratory exercise test and transesophageal echocardiography will be performed at that time. In case of persistent functional impairment, recurrent pneumonia, and/or progressive elevation of left superior PV peak flow velocities (with risk for progression to total occlusion), PV angioplasty and dilation will be planned.

DISCUSSION

PV stenosis occurs in 1% to 3% of patients after catheter ablation for AF.2,3 Although frequently asymptomatic, it can be associated with severe respiratory symptoms. Since the development of three-dimensional mapping systems and the currently more extraostial ablation strategies, the reported incidence of PV stenosis is decreasing. 2,3 However, point-by-point catheter ablation procedures still remain complex, eliciting the need for "single-shot" devices to make AF ablation a more straightforward procedure. The PVAC catheter, a multielectrode over-the wire catheter using duty-cycled bipolar and unipolar nonirrigated RF energy, has recently provided promising results. Boersma et al4 studied the clinical outcome of PVAC ablation in patients with paroxysmal AF and found freedom from fibrillation (without antiarrhythmic drugs) in 83% of patients after 6 months. They found no evidence of PV stenosis on magnetic resonance imaging or angiography performed during a redo procedure in 11 patients.4 This is the first report of significant PV stenosis after PVAC ablation, which can represent a potential serious drawback of the technique. Due to its over-the wire design, the PVAC catheter can easily be torqued in and out of the PVs, inevitably harboring the tendency to again more closely approach the PV ostium. This approach may increase the risk for PV stenosis, especially when delineation of the PV ostia by a single "template" selective PV angiogram is not sufficiently accurate. Furthermore, PVAC ablation is performed in a circular fashion at multiple electrodes simultaneously. A circumferential cicatrization close to the PV ostium may lead to ostial PV stenosis during the subsequent healing process. Upon careful review of the bipolar electrograms recorded for this patient prior to each PVAC ablation of the left superior PV, combined atrial far-field circumferentially present) and PV potentials were always observed. No single application was performed on solitary local residual PV electrograms without any far-field signals. We believe, therefore, that all standard precautions to prevent PV stenosis were taken. The most likely explanations for PV stenosis in this patient are related to the methodology-based inaccuracy of ostial delineation with sole reliance on selective PV angiography and the high number of RF applications to the left superior PV with dominant use of a 2:1 ablation modus.

Of interest, the results reported by Boersma et al4 were established by energy delivery in a 4:1 modus only. Recent developments with the technique make energy applications in a 2:1

modus possible with the theoretical advantage of burning deeper lesions to enhance efficacy and limit the total number of applications. Limiting the total number and/or the number of 2:1 modus applications, avoiding ablations too close to the PV ostium, and improved imaging modalities to accurately delineate the PV ostia are potential ways to minimize the risk of PV stenosis.

CONCLUSION

This case report underscores the need to better evaluate the risk for PV stenosis after use of the PVAC catheter and to compare the incidence of PV stenosis with that observed after use of other RF ablation catheters.

REFERENCES

1. De Marchi SF, Bodemuller M, Lai DL, et al. Pulmonary vein flow velocity patterns in 404 individuals without cardiovascular disease. Heart 2001;85: 23–29.
2. Holmes DR Jr, Monahan KH, Packer D. Pulmonary vein stenosis complicating ablation for atrial fibrillation: clinical spectrum and interventional considerations. JACC Cardiovasc Interv 2009;2: 267–276.
3. Barrett CD, Di Biase L, Natale A. How to identify and treat patient with pulmonary vein stenosis post atrial fibrillation ablation. Curr Opin Cardiol 2009;24:42– 49.
4. Boersma LV, Wijffels MC, Oral H, et al. Pulmonary vein isolation by dutycycled bipolar and unipolar radiofrequency energy with a multielectrode ablation catheter. Heart Rhythm 2008;5: 1635–1642.

Chapter 2

Cryoballoon ablation for paroxysmal atrial fibrillation: a comparison of two age groups

B. Schwagten, MD, P. Janse, RN, R. Bhagwandien, MD, N.M.S. de Groot, MD, PhD, T. Szili-Torok, MD, PhD, Y. Van Belle, MD, L. Jordaens, MD, PhD, FESC

ABSTRACT

In elderly patients with atrial fibrillation (AF) the role of the substrate becomes more important and it can be questioned whether pulmonary vein isolation is as efficient as in younger patients. We evaluated the safety, feasibility and success rate of a cryoballoon ablation in an elderly population, and compared it to the younger patients.

A series of 241 patients with a subgroup of 52 patients aged ≥ 65 years was therefore analysed. Procedure, fluoroscopy time and hospital stay were similar in the 2 groups. There was a similar serious adverse event rate (4,5%). However, vascular complications occurred more frequently in the elderly (15% versus 5%). If the patients under intubation and general anaesthesia were considered (74 of the total group), the higher age group had significantly more serious adverse events (SAE), vascular and other adverse events (AE). In the older patient group, AF burden was reduced in the first 3 months from 15% to 3%; the Holter at 3 months showed AF in 11% as compared to 29% before the procedure. This was similar in both groups. AF free survival was similar for both groups with an event free survival of >60%, with only one procedure. After a mean follow-up of 884±414 days, a redo because of reconduction was performed in a similar number of patients in both groups (22%).

We conclude that the use of the cryoballoon is feasible in treating paroxysmal atrial fibrillation in elderly people, however special attention should be paid to possible vascular complications.

Key words: aging, anaesthesia, atrial fibrillation, complications, cryoablation, pulmonary vein isolation

INTRODUCTION

The prevalence of atrial fibrillation (AF) is high in the elderly and increases with time.[1] Pulmonary vein isolation (PVI) has become a useful rhythm control strategy in patients with lone AF, and aims to address the triggers of this arrhythmia.[2] In older patients, the substrate becomes more important, and it can be questioned whether PVI alone is sufficient, as in elderly patients the disease is often more advanced, with more dilation of the atria, and probably more fibrosis.[3] Especially for older patients, who are prone to more vascular complications, a technique is needed that combines safety and an acceptable success rate.[4] We evaluated the safety, feasibility and success rate of cryoablation with a double lumen cryoballoon, which is introduced through a quite thick venous sheath to treat paroxysmal or short-standing persistent AF in an elderly population, and compared it to the younger patients.

METHODS

After exclusion of our initial study group, which served as learning curve, we studied all consecutive patients treated with a first PVI, done with a cryoballoon, between November 1st, 2006 and December 1st 2010, with at least 3 months of follow-up till March 1st, 2011.[5] This resulted in a series of 241 patients, and allowed analysis of 52 patients aged ≥ 65 years, and 189 patients < 65 years (table 1).

Table 1. Demographics and procedure parameters

	Total	< 65 yrs	≥ 65 yrs	P
Number of patients	241	189	52	
Age (years)	56 ± 10	53 ± 9	69 ± 3	< 0,001
Male/Female	169/72	136/53	33/19	NS
Number transmitted events	124/218 (%)	95/172 (55%)	29/46 (63%)	NS
Holter with AF (baseline)	86/228 (38%)	71/175 (41%)	15/52 (29%)	0,041
Continuous AF	26/86 (30%)	21/71 (30%)	5/15 (33%)	NS
Balloon size				
23 mm	18 (7%)	14 (7%)	4 (8%)	NS
28 mm	223 (93%)	175 (93%)	48 (92%)	NS
Additional touch up	77 (32%)	64(34%)	13 (25%)	NS
Simultaneous Cavotricuspid flutter ablation	46 (19%)	39 (21%)	7 (13%)	NS
General Anesthaesia	72	57 (30%)	15 (29%)	NS
Procedure time (min)	193 ± 64	192 ± 63	196 ± 67	NS
Fluoroscopy time (min)	46 ± 32	47 ± 34	44 ± 23	NS
Hospital stay (days)	3,98 ± 1,99	3,96 ± 2,08	4,02 ± 1,6	NS
stay ≥ 4 days	111 (46%)	85 (45%)	26(50%)	NS

AF: atrial fibrillation

Procedure

Details of the procedure have already been described in a previous paper.[5]

Data collection and definitions

The patients had a baseline ECG and 24-hour Holter recording, repeated at 3-months and at one year after the procedure. Whenever necessary, unsolicited ECG`s were taken. All patients underwent daily transtelephonic Holter monitoring during one month before the ablation and during 3 months after the ablation. The number of days an arrhythmic event was transmitted, in relation to all transmitted recordings was used to calculate the burden of AF, symptomatic AF and other events.[6] Procedure duration, success rate, early and late recurrence of AF, fluoroscopy time and short and long term complications were prospectively registered. Vascular complications were groin haematomas, AV fistula and false aneurysms. All other potential procedure related complications (other adverse events – AE`s) were entered in a registry, and analysed by two of the authors, and kept for analysis when the relation to the procedure was possible, or when the hospital stay was prolonged. For hospital admission duration a partial day was considered as a day. Serious adverse events (SAE`s) were cardiac tamponade (requiring puncture or surgery), stroke, infarction, and cardiogenic shock.

Statistical methods

The Fisher exact test was used for the contingency tables. Non-parametric test were used when appropriate. SPSS was used for the Kaplan Meier survival curves. The Kaplan Meier curves were constructed for the total group and for both age groups, including all recurrence data obtained with all techniques, excluding the blanking period of 3 months, but included the 3 months Holter.

RESULTS:

Inclusion

Demographics

The mean age of all patients was 56 ± 10 years, the majority was male. Demographic data are shown in table 1. Before ablation 124/218 patients transtelephonically transmitted AF, 29/46 in the older group, and 95/172 in the younger group (figure 1). Median AF burden was 21% and similar in both groups (15% with IQR from 0-38% in the older, and 6% with IQR from 0-29% in the younger group). At baseline, 38% showed AF during the Holter, continuous in 39% of these.

AF was more often documented in the younger age group: 41% vs 29% in the older group (p=0.041).

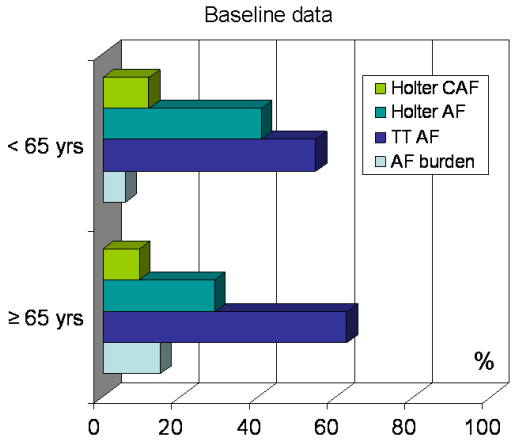


Figure 1. Percentage of patients showing AF at the base-line evaluation. Holter AF means paroxysmal, Holter CAF means continuous AF. TT: transtelephonic events.

Procedure

Procedural data

These are shown in table 1. Intubation with general anaesthesia was performed in 72 (30%) of the patients, the same proportion for both age groups. PVI was achieved in all patients. A touch-up with a spot catheter was required in 77 patients (32%); simultaneous cavotricuspid isthmus ablation was performed in 46 patients (19%). This was similar for both groups. Total procedure time (193 ± 64 min for all) did not differ in both groups, neither did total fluoroscopy time (46 ± 32 min for all). The average admission duration in hospital was 3,98 ± 1,99 days, and was also similar in both groups. The admission duration is shown in detail

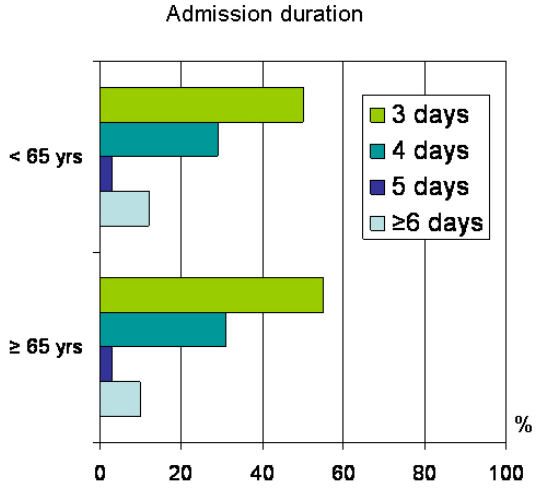


Figure 2. Hospital admission duration in both age groups.

in figure 2, for both groups. A total number of 111 patients stayed ≥4 days in the hospital (similar for both groups).

Complications

The major and minor complications are shown in table 2. There was no incidence of stroke (CVA and TIA) in both groups; nobody died. There was one tamponade in the higher age group, and 6 in the other group (NS). There were 4 other SAE`s: 2 peri-procedural infarctions (one in each group, once due to air embolism, once as a complication of retroperitoneal bleeding leading to hypovolaemia). One other retroperitoneal bleeding, and one cardiogenic shock due to aggravated mitral dysfunction after balloon insertion in the left atrium were noted as well. All these events were resolved without sequelae.

Table 2. Complications

	All	< 65 yrs	≥ 65 yrs	p
Number of patients	241	189	52	
Stroke	0	0	0	
Cardiac tamponade	7	6	1	
Other SAE	4	2	2	
Total SAE	11 (4,5%)	8 (4,2%)	3 (5,8%)	NS
Haematoma (groin)	13	7	6	
AV fistula/ Aneurysm	4	2	2	
Vascular AE	17 (7%)	9 (4,8%)	8 (15%)	0,0138
Phrenic nerve paralysis (transient)	9	5	4	
Other adverse events	8	5	3	
Total other AE	17 (7%)	10 (5%)	7 (13%)	0,0002

AE: adverse events; SAE: serious adverse events

Vascular complications (17) happened more frequently in the older group, where groin problems were present in 15% ($p<0,05$). Other adverse events (17) included transient phrenic nerve paralysis (PNP), similar in both age groups, ST segment changes suggestive for ischemia (1), hemoptysis (3), cystitis (1), a general allergic reaction (1), pacemaker lead damage (1), and leg oedema due to thrombosis (1). When all these events were counted, the elderly group had more complications ($p<0,0002$).

Anesthesia

There was a tendency to longer hospital duration in the higher age group if intubation and general anaesthesia (GA) was used ($p=0,052$). Moreover, if the patients under intubation and GA were considered, the higher age group had more serious or vascular AE`s and other AE`s

Table 3. General anaesthesia with intubation

	All	< 65 yrs	≥ 65 yrs	p
Number of patients	74	59	15	
Hospital stay (days)	4 ± 1,61	4 ± 1,76	4 ± 0,85	NS
stay ≥ 4 days	37(50%)	27 (46%)	11(73%)	0,052
Serious adverse / vascular events	8 (11%)	3 (5%)	6 (40%)	0,002
Other adverse events	7(9,5%)	3(5%)	4(27%)	0,028

(table 3). Similarily, a tendency towards more serious or vascular complications was present in the older group if anaesthesia was used (6/11 were under anaesthesia with intubation), while only 3/17 complications occurred in the younger under the same conditions (p=0,052).

Follow-up

Table 4 shows the follow up. The mean follow-up was 884 ± 414 days. Follow-up duration was shorter in the older group. Figure 3 shows a summary of the documented AF recurrences with the various follow up methods.

Table 4. Follow-up

		< 65 yrs	≥ 65 yrs	p
Number of patients	241	189	52	
Duration (days)	884 ± 414	924 ± 441	741 ± 414	<0,01
Event recording				
Number transmitting AF (months 1-3)	109/215 (51%)	82/167 (49%)	27/48(56%)	NS
Number transmitting > 1 AF event (months 1-3)	84/215 (39%)	62/167 (37%)	22/48 (45%)	0,069
Median burden (IQR)	1% (0-19)	0% (0-9)	3% (0-10)	NS
Holter with AF (3 months)	20/201 (10%)	15/156 (9,6%)	5/45 (11%)	NS
Continous AF	4	4	0	
Holter with AF (1 year)	16/155	13/119 (11%)	3/36 (8%)	NS
Continous AF	7	6	1	
Unsolicited ECG`s				
Incidental recording < 90 days	36	27 (14%)	9 (17%)	NS
Incidental recording > 90 days	43	35 (18,5%)	8 (15%)	NS
Clinical failure	69	58 (31%)	11 (21%)	NS
Redo	52	45 (24%)	7 (13%)	0,043

AF: atrial fibrillation; IQR: interquartile range

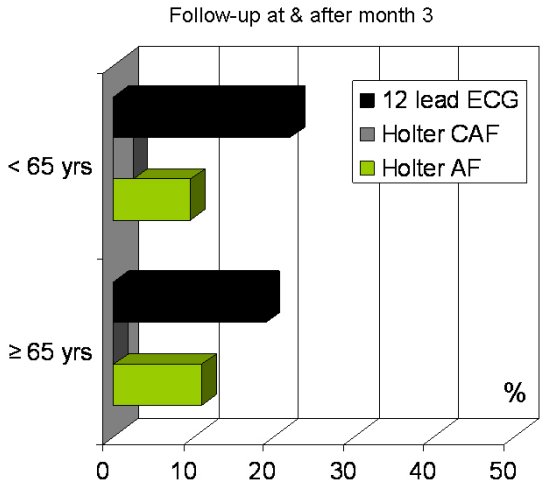


Figure 3. Percentage of patients showing atrial fibrillation (AF) on the 3 months Holter, or at a 12 lead ECG after 3 months. Holter AF: all AF; CAF: continuous AF.

Event recording

A total number of 215 patients transmitted daily events in the first 3 months. In the elderly, 27/48 transmitted AF, including 5 with only one episode; in the younger group, 82/167 transmitted AF, including 20 with only one episode. There was a tendency to have more AF transmissions in the elderly. Over the first 3 months median AF burden was 1% (IQR 0-19) with no difference between both groups (3%, with IQR from 0-10% in the older, and 0% with IQR from 0-9% in the younger).

Holter recordings

After the ablation, at month 3, without any further intervention, the number of patients with AF was reduced to 20/200, still including 4 continuous patients. Both age groups had a similar incidence of AF on the Holter, which was done at an average of 91 ± 16 days after the ablation. A redo was performed in 33 patients after the first control Holter.

A second control Holter was performed in 155 of the patients without a redo at a mean of 277±148 days after the procedure, with 16 showing AF (7 continuous).

AF on scheduled and unsolicited ECG`s – In the so-called blanking period of the first 3 months, 42 patients (17%) showed AF on a 12 lead ECG (12 from the older, 30 of the younger group). This occurred as well in 52 patients after month 3 (21%), 10 in the older and 42 in the younger group. These proportions were not different.

Clinical failure and redo procedures

All data and the clinical judgement at follow up, including the advice of the referring cardiologists determined whether clinical success was achieved after day 90. Clinical failure was

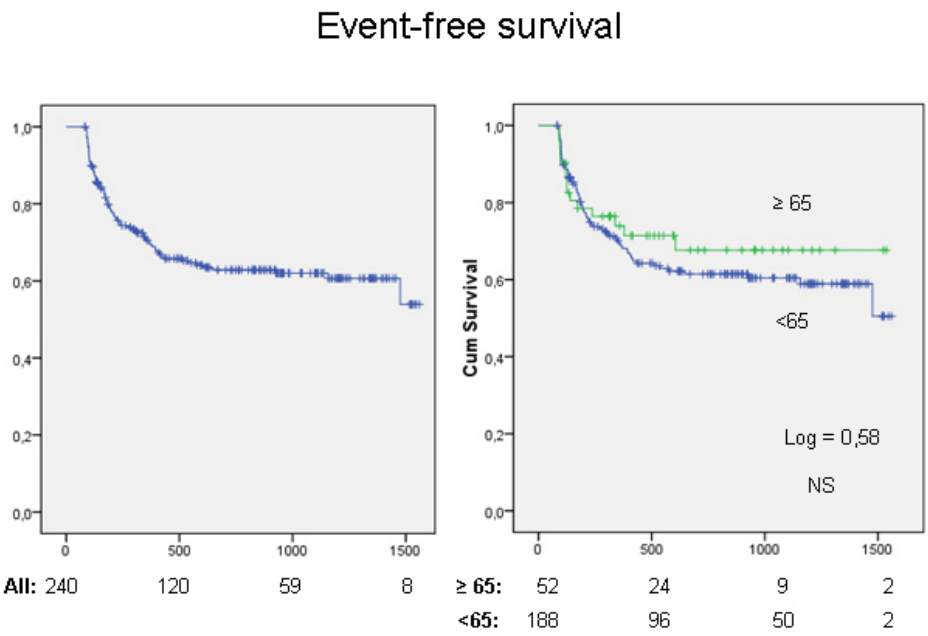


Figure 4. Kaplan-Meier curve showing event (atrial fibrillation) free survival; at the right for both age groups.

considered to be present in 84 patients (35%): 15/52 patients in the older group (29%), and 69/189 patients in the younger group (37%). This was not statistically different (p=0,079). The Kaplan Meier curves (figure 4) were constructed for the total group and for both age groups. There was no significant difference in AF free survival. Redo procedures were performed in 54 (23%) of all patients. This was in 2 young patients because of atrial tachycardia, without reconduction. Reconduction was observed in 2 other cases restudied for atrial tachycardia and in 15 in whom the reason for the redo was atrial flutter. This implies that 52 cases underwent redo, with PV reconduction. This happened in 7/52 patients in the older (13%), and 45/189 patients in the younger group (24%). There were more redo procedures in the younger age group with documented reconduction (p=0,043).

DISCUSSION

The nice observation in this study is that the outcome in the elderly was similar as in the younger patients. The number of clinical failures even tended to be lower. There were less redo procedures scheduled in the patients above 65 years, but it is not clear whether this was biased because we were reluctant to offer them a redo.

However the high number of complications was impressive. While the general number was acceptable (4,5%), the total number in the older age group became too high with 5,8%. This was not as was shown in similar studies.[7,8,9] Further the number of vascular events might have been due to the use of the thick sheath, and was also more prominent in the elderly. An excess of complications was observed when patients were treated under general anesthesia. This is not surprising, as patients who are awake can be very informative when complications should be prevented with insertion and positioning of catheters. Indeed regarding the latter, the opportunity of performing a PVI under conscious sedation is one of the possible advantages of this single shot ablation device. Except from the phrenic nerve stimulation to prevent phrenic nerve palsy, cryoablation is performed without any pain or discomfort for the mildly sedated patient, except maybe from the insertion of the catheters in the groin. Using a Doppler echo might be a way to facilitate to obtain vascular access and could even reduce vascular problems in the elderly.
Furthermore, not having any clinical stroke in this specific population of frail patients with a high risk of thromboembolic events can be considered as a major advantage for the cryoballoon technique. Unfortunately, no data on silent cerebral events were available.
A possible limitation for the interpretation of the results is that all procedures were performed by experienced Cryoballoon users.

CONCLUSIONS

Our data suggest that the use of the cryoballoon is feasible in treating paroxysmal atrial fibrillation in elderly people. These data also suggest that more attention should be paid to avoidance of vascular complications if one decides to invasively treat elderly patients. Moreover, our data encourage the use of conscious sedation specifically when performing a PVI using the cryoballoon in older patients.

REFERENCES

1. Kannel WB, Abbott RD, Savage DD, McNamara PM. Epidemiologic features of chronic atrial fibrillation: the Framingham study. N Engl J Med. 1982; 306: 1018-22.
2. Haïssaguerre M, Jaïs P, Shah DC, Takahashi A, Hocini M, Quiniou G, Garrigue S, Le Mouroux A, Le Métayer P, Clémenty J. Spontaneous initiation of atrial fibrillation by ectopic beats originating in the pulmonary veins. N Engl J Med. 1998; 339: 659-66.
3. Wyse DG, Gersh BJ. Atrial fibrillation: a perspective: thinking inside and outside the box. Circulation. 2004 ;109: 3089-95.
4. Haegeli LM, Duru F, Lockwood EE, Lüscher TF, Sterns LD, Novak PG, Leather RA.Ablation of atrial fibrillation after the retirement age: considerations on safety and outcome. J Interv Card Electrophysiol. 2010; 28: 193-7.
5. Van Belle Y, Janse P, Rivero-Ayerza MJ, Thornton AS, Jesserun ER, Theuns DAMJ, Jordaens L. Pulmonary vein isolation using an occluding cryoballoon for circumferential ablation: feasibility, complications, and short-term outcome. Eur Heart J 2007;18: 2231-7.
6. Janse PA, Van Belle YL, Theuns DAMJ, Rivero-Ayerz M, Scholten MF, Jordaens LJ. Symptoms versus objective rhythm monitoring in patiens with paroxysmal atrial fibrillation undergoing pulmonary vein isolation. Eur J Cardiovasc Nurs 2008; 7: 147-151.
7. Kusumoto F, Prussak K, Wiesinger M, Pullen T, Lynady C. Radiofrequency catheter ablation of atrial fibrillation in older patients: outcomes and complications.J Interv Card Electrophysiol. 2009; 25: 31-5.
8. Nademanee K, Schwab MC, Kosar EM, Karwecki M, Moran MD, Visessook N, Michael AD, Ngarmukos T. Clinical outcomes of catheter substrate ablation for high-risk patients with atrial fibrillation. J Am Coll Cardiol 2008; 51: 843-849.
9. Cappato R, Calkins H, Chen SA, Davies W, Iesaka Y, Kalman J, Kim YH, Klein G, Natale A, Packer D, Skanes A, Ambrogi F, Biganzoli E. Updated worldwide survey on the methods, efficacy, and safety of catheter ablation for human atrial fibrillation. Circ Arrhythm Electrophysiol. 2010; 3: 32-8.

Chapter 3

An apparent way of achieving proof of pulmonary vein disconnection during Cryoballoon ablation

B Schwagten, MD, Y De Greef, MD, WJ Acou, MD, D Stockman, MD

INTRODUCTION

Pulmonary vein isolation (PVI) has established itself as a standard therapy for paroxysmal atrial fibrillation (AF) (1). Still, the most widely performed procedure of point-by-point distaltip ablation using a 3D mapping system and a circular catheter to validate PVI, remains a complex, elaborative and time consuming procedure. This explains the many efforts being made over the recent years to simplify and shorten PVI procedures without compromising the efficacy nor the safety. The Cryoballoon (Ablation Frontiers, Medtronic, Inc., MN, USA) is a recently introduced 'single shot ablation tool' to facilitate PVI. Initial studies on efficacy and safety of this device are encouraging in patients with paroxysmal AF (2-4). However, several controversies remain such as the need for an additional circular mapping catheter to validate PVI and the lack of on-line PV recording during freezes. One of the most recent developments in this field is the Achieve circular mapping catheter (Ablation Frontiers, Medtronic, Inc., MN, USA). We describe an apparent case in which this tool is used in conjunction with the cryo-balloon.

Key words: Atrial fibrillation; Cryoablation; Achieve; Pulmonary vein isolation; Catheter ablation

CASE DESCRIPTION

A 59-year old male was scheduled to undergo PVI at our center. He had been suffering from paroxysmal AF for over 2 years. The paroxysms of AF were becoming more frequent despite treatment with class Ic anti-arrhythmic drugs in combination with a low dose of beta-blocking agent. There were no significant co-morbidities: patient did not suffer from arterial hypertension, there was no underlying structural or functional heart disease (ejection fraction on echocardiography was 75%). Coronary angiography performed in 2008 showed no significant coronary atheromatosis. A recent blood sample showed normal thyroid function, normal blood count, normal renal function, no signs of infection and no other abnormalities. The left atrial diameter measured 43mm (PS-LAX, Vivid 7, GE Healthcare, UK). Based on a 3-D reconstruction of the left atrium using a CT scan of the heart after contrast injection, patient was selected to have a Cryoballoon procedure: the image of the left atrium showed four separate pulmonary veins without a common ostium.

ABLATION PROCEDURE

The procedure was performed under general anaesthesia. Immediately prior to transseptal puncture, an intravenous loading dose of 10,000 international units of heparin was given. Target activated clotting time throughout the procedure was maintained above 350 seconds. The femoral vein was punctured twice: first a decapolar diagnostic catheter (Bard Electrophysiology, Lowell, MA, USA) was introduced through the vein and was positioned in the coronary sinus, subsequently a single transseptal puncture was performed under TEE guidance using a transseptal needle (BKR1, St Jude Medical, MN, USA) and a 14 Fr steerable sheath (FlexCath, Ablation Frontiers, Medtronic, Inc., MN, USA). An angiogram was made of all four pulmonary veins and was stored into the system (Figure 1). The presence of pulmonary vein potentials before ablation was confirmed using a decapolar steerable and adjustable lasso catheter (Inquiry Optima, St Jude Medical, MN, USA) (Figure 1).
Additionally exit pacing using the lasso catheter was successfully performed from all pulmonary veins.

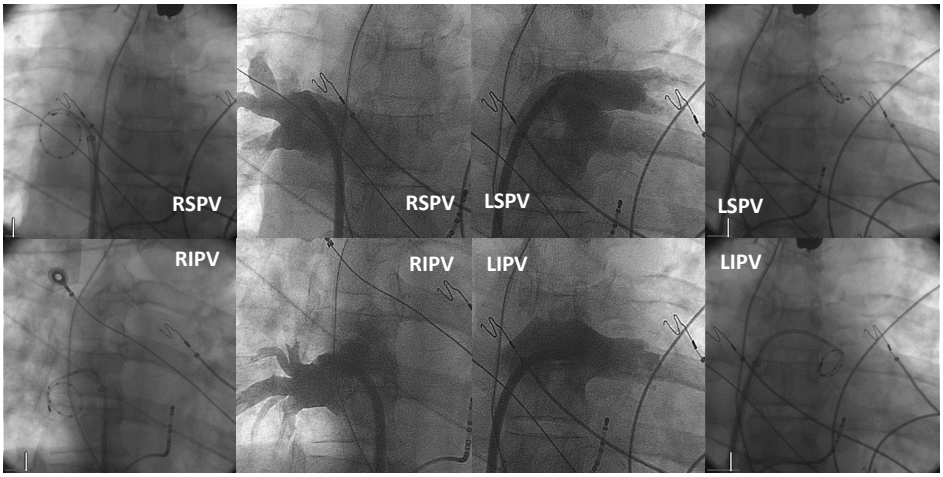


Figure 1. Selective positioning of the lasso catheter in the four pulmonary veins: LSPV (left superior pulmonary vein), LIPV (left inferior pulmonary vein), RSPV (right superior pulmonary vein) and RIPV (right inferior pulmonary vein). Together with the corresponding angiograms of the four pulmonary veins. All fluoroscopic images are taken in antero-posterior projection.

THE ACHIEVE CIRCULAR MAPPING CATHETER

The Achieve circular mapping catheter was introduced through the Cryoballoon system. This wire is conceived to combine both the properties of a wire for positioning of the Cryoballoon at the antrum of the pulmonary veins and the possibility of continuously checking the presence of pulmonary vein potentials throughout the ablation (Figure 2).

Cryoablation was started in the left superior pulmonary vein. Since this vein had a relatively late branching, it was possible to position the Achieve circular mapping catheter in the body of the pulmonary vein before its division into side-branches (Figure 2). The Cryoballoon was inflated thus occluding the left superior pulmonary vein at its ostium and cryoablation was started. Distinct sharp pulmonary vein potentials from the left superior pulmonary vein were clearly visible on the Achieve circular mapping catheter at the start of cryoablation (Figure 3). The temperature sensor on the proximal part of the Cryoballoon reached a minimal temperature of minus 45 degrees. During the first minute of cryoablation, the pulmonary vein potentials on the Achieve circular mapping catheter gradually delayed and eventually disappeared after 30 seconds (Figure 3). The cryoablation was continued for 300 seconds.

The pulmonary vein potentials did not reappear afterwards. A second cryoablation of 300 seconds was carried out in the same pulmonary vein. Subsequently the Achieve circular mapping catheter was positioned in the left inferior pulmonary vein and large pulmonary vein potentials were registered. Again the Cryoballoon was inflated and complete occlusion of the inferior pulmonary vein was realized. Cryoablation was started and gradual delay and disappearance of the pulmonary vein signals was seen after 105 seconds. The ablation was

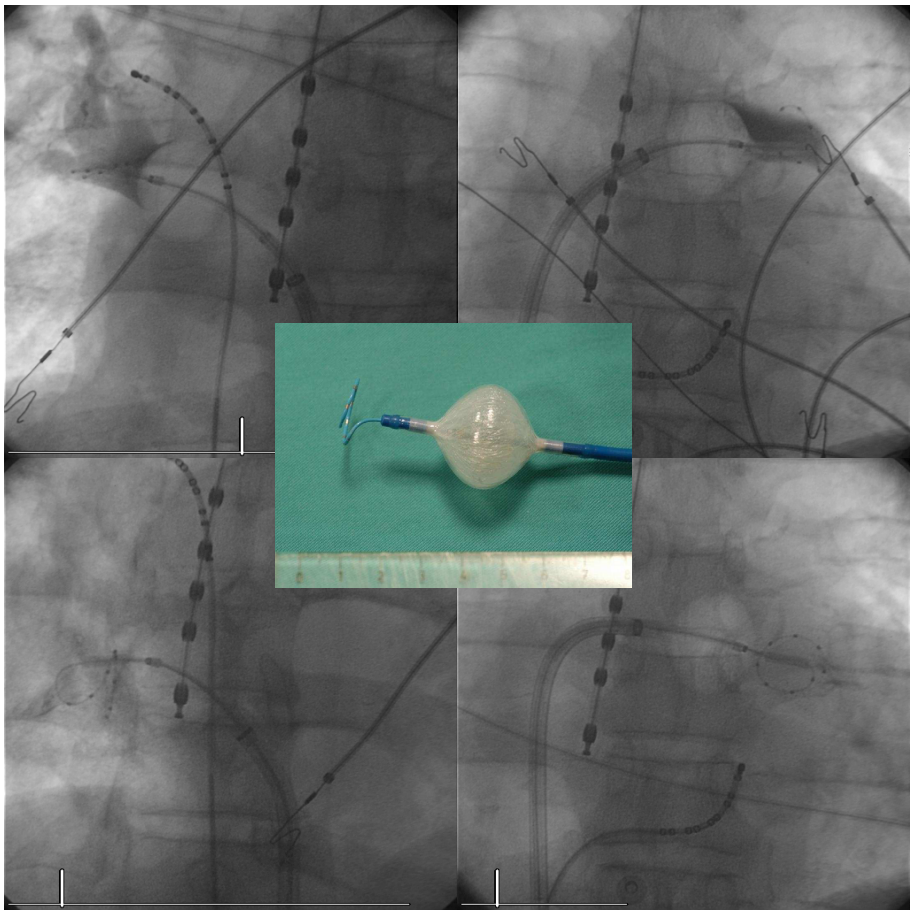


Figure 2. Selective positioning of the Cryoballoon over the Achieve circular mapping catheter in the four pulmonary veins while injecting contrast agent through the tip of the Cryoballoon: panel A: RSPV (right superior pulmonary vein), panel B: LSPV (left superior pulmonary vein), panel C: RIPV (right inferior pulmonary vein) and panel D: LIPV (left inferior pulmonary vein). Central image: the inflated Cryoballoon with the circular mapping end of the Achieve wire emerging from its tip.

completed after 300 seconds and also in this vein a second cryoablation was performed. In both right pulmonary veins similar ablations were performed. During ablation in the right pulmonary veins, phrenic nerve stimulation was performed from the tip of decapolar diagnostic catheter (which was repositioned in the right atrium) to prevent occurrence of phrenic nerve paralysis. At the end of the procedure all four pulmonary veins were checked with the lasso catheter during sinus rhythm and during pacing from the distal coronary sinus catheter (Figure 3). Elimination of all pulmonary vein potentials was confirmed in all pulmonary veins. Additionally exit pacing was performed from all pulmonary veins. This showed exit block in all veins. Catheters were removed from the heart, sheaths extracted from the groin and the patient was awakened. No complications occurred during the procedure. The patient

was discharged on the following day after a control echocardiography revealed no signs of pericardial fluid.

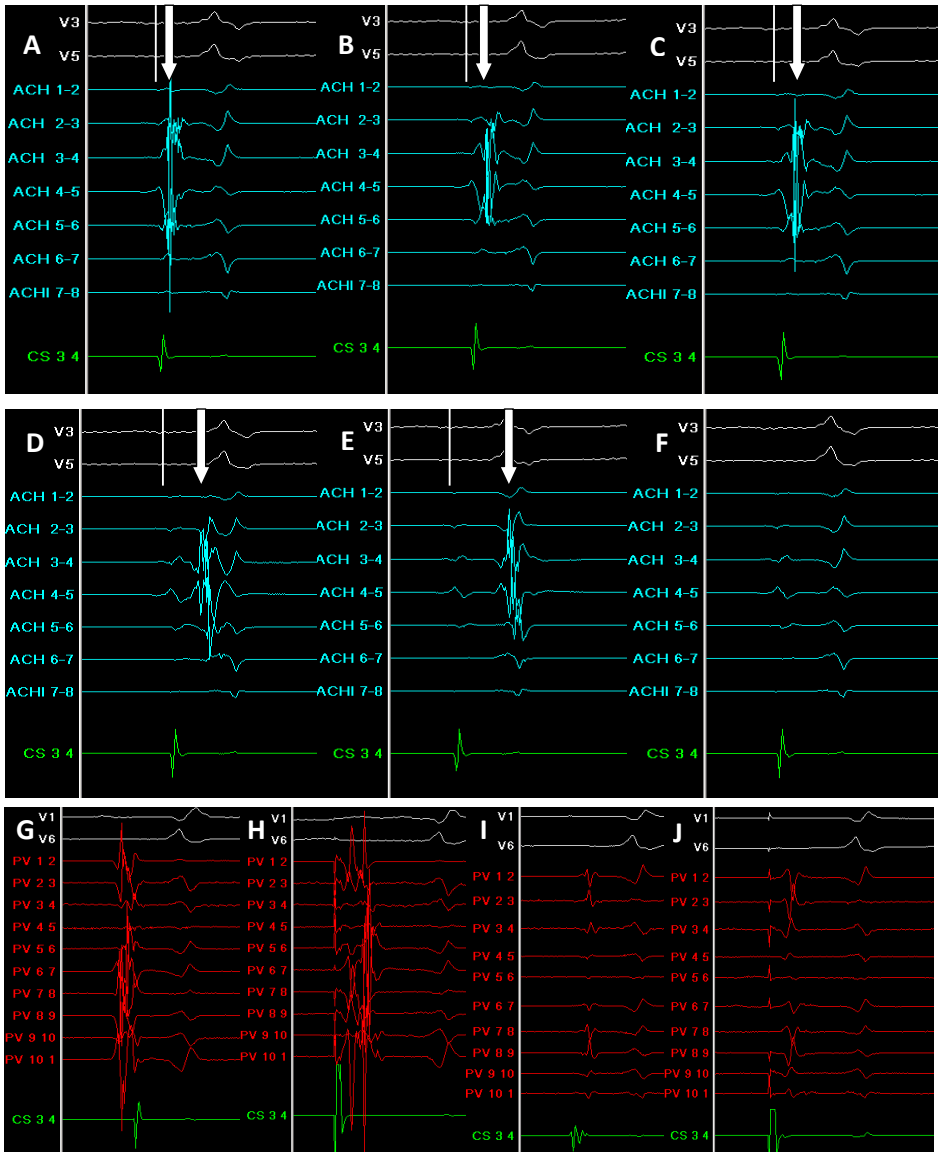


Figure 3. Panel A to F: Gradual delay and finally disappearance of pulmonary vein potentials (white arrow) on the Achieve circular mapping catheter in the LIPV (left inferior pulmonary vein) during the first 30 seconds of Cryoballoon ablation. Panel G to J: Recordings on the lasso catheter in the LIPV before (panel G and H) and after (panel I and J) ablation, without (panel G and I) and with (panel H and J) pacing from the distal CS catheter.

DISCUSSION

The Achieve circular mapping catheter seems to be a useful additional tool in PVI procedures using the Cryoballoon. Especially in pulmonary veins with late branching, delay and disappearance of pulmonary vein potentials can be monitored during cryoablation. However, in pulmonary veins with early branching local pulmonary veins potentials are hard to monitor during ablation as the Achive wire is advanced into the branches of the veins by the relatively long tip of the Cryoballoon. If the findings on the Achieve circular mapping catheter prove to be consistent in randomized trials in comparison to the mapping capabilities of the lasso catheter, this could speed up procedures. Moreover it could make procedures safer as this could obviate the need for a second transseptal puncture or render the need for switching of the Cryoballoon for the lasso catheter superfluous. Another peculiar finding with the Achieve circular mapping catheter was the definitive disappearance of pulmonary vein potentials only 30 seconds after the start of the ablation in some pulmonary veins. This raises some questions about the need for continuing the ablation for 300 seconds, a duration which was based on experimental findings about cryoablation that show reaching of a stable temperature gradient during the first minute and a plateau phase at 5 to 6 minutes(5,6). Of course, this needs to be studied in large randomized trials before it can be put into practice.

CONCLUSION

In conclusion, this technique demonstrates the possibility of on-line PV recording with the Achieve circular mapping catheter during cryoablation. This allows physicians to assess the timing of PV disconnection during ablation and could potentially obviate the need for a diagnostic circular catheter. Therefore these advantages offered by the Achieve circular mapping catheter have the potential to change the way we nowadays use the Cryoballoon to isolate the pulmonary veins.

REFERENCES

1. Camm, A. J., Kirchhof, P., Lip, G. Y., Schotten, U., Savelieva, I., Ernst, S., Van Gelder, I. C. et al. Guidelines for the management of atrial fibrillation: the Task Force for the management of Atrial Fibrillation of the European Society of Cardiology (ESC). Europace;12:1360-420.
2. Neumann, T., Vogt, J., Schumacher, B., Dorszewski, A., Kuniss, M., Neuser, H., Kurzidim, K. et al. Circumferential pulmonary vein isolation with the cryoballoon technique results from a prospective 3-center study. J Am Coll Cardiol 2008;52:273-8.
3. Ahmed, H., Neuzil, P., Skoda, J., D'Avila, A., Donaldson, D. M., Laragy, M. C., Reddy, V. Y. The permanency of pulmonary vein isolation using a balloon cryoablation catheter. J Cardiovasc Electrophysiol;21:731-7.
4. Van Belle Y, Janse P, Theuns D, Szili-Torok T, Jordaens L. One year follow-up after cryoballoon isolation of the pulmonary veins in patients with paroxysmal atrial fibrillation. Europace 2008;10: 1271-6.
5. Lustgarten DL, Keane D, Ruskin J. Cryothermal ablation: mechanism of tissue injury and current experience in the treatment of tachyarrhythmias. Prog Cardiovasc Dis 1999;41:481-98.
6. Sandilands A, Boreham P, Pitts-Crick J, Cripps T. Impact of cryoablation catheter size on success rates in the treatment of atrioventricular nodal re-entry tachycardia in 160 patients with long-term follow-up. Europace 2008;10:683-6.

Part III

The limits of remote magnetic navigation

Chapter 1

A randomized comparison of transseptal and transaortic approach in ablation of left-sided accessory pathways using magnetic navigation

Bruno Schwagten, MD, Luc Jordaens, PhD, Maximo Rivero-Ayerza, PhD, Yves Van Belle, MD, Paul Knops, MD, Andrew Thornton, PhD, Tamas Szili-Torok, PhD

ABSTRACT

Objectives: Radiofrequency catheter ablation of left-sided accessory pathways (AP) can be performed either by transseptal (TS) or transaortic (TA) approach. When performed manually, these techniques were found to be equally effective. The aim of this prospective randomized study was to compare these approaches using the magnetic navigation system (MNS) (Niobe, Stereotaxis, St. Louis, MO, USA). Methods: Twenty-two consecutive patients were randomized to undergo ablation of a left-sided AP by either a TS or a TA approach. MNS was used in all patients for catheter navigation and eventual ablation, after standard electrophysiology study confirmed the presence of left-sided APs. Crossover was allowed after failure of the initial approach. Success rate, procedure, fluoroscopy and ablation times were compared. Results: 10/11 procedures (91%) were successful in the TS group. The patient crossed over to the TA approach remained unsuccessful. A successful elimination of the AP was obtained in 9/11 (82%) of the TA procedures. Of the 2 patients who crossed over to a TS procedure in the same session, one was successful and one remained unsuccessful. Total procedure time did not differ in both groups (87,1 ± 30,8 vs 90,9 ± 26,5 min). When total procedure and patient fluoroscopy times were divided into electrophysiology study time, time to first application, to successful application and time to perform TS puncture or to retrogradely cross the aortic valve, only the last measurement differed significantly for both groups ($p<0.01$). Ablation times were comparable in both groups. No major complications occurred. Conclusions: Our data show that TS and TA approaches are equal in success rate and total procedure, patient fluoroscopy and ablation time when using the MNS for left sided AP ablation. However, crossing the aortic valve is faster than completing a transseptal puncture.

Key Words: Ablation, new technology, SVT/WPW

INTRODUCTION

Radiofrequency (RF) catheter ablation remains the first line of therapy for patients with symptomatic Wolff-Parkinson-White (WPW) syndrome and for selected patients with asymptomatic WPW syndrome.(1) Historically, the initial approach for catheter ablation of left sided accessory pathways (AP) used the retrograde, transaortic route.(2,3) The TS approach was later introduced for ablation with a high success rate and few complications. (4,5) However, surveys showed that AP ablation had a 2.1% complication rate both caused by the need for retrograde arterial left heart catheterisation and the transseptal puncture. (6) Results obtained from previously published retrospective and nonrandomized papers comparing these two manual approaches showed that both techniques had a comparable efficacy. RF ablation using the magnetic navigation system (MNS) (Niobe, Stereotaxis, St. Louis, MO, USA) has showed several advantages compared to manual ablation in more complex arrhythmias.(7-8) This study is the first prospective randomized open-label trial comparing the TS and the TA approach for RF ablation of left sided AP using the MNS.

METHODS

Patients

Twenty-two consecutive patients with WPW syndrome and pre-excitation on a rest ECG indicative of a left sided AP (9) were randomized to undergo RF ablation by either a TS or TA approach. MNS was used in all patients for catheter navigation and eventual ablation, after a standard electrophysiology study confirmed the presence of left-sided APs. Crossover was allowed after failure of the initial approach. Success rate, complications and procedure, fluoroscopy and ablation times were compared. All anti-arrhythmic drugs were discontinued for the duration of 5 half-lives. All patients signed informed consent.

Procedural information

In the TS group the right and left femoral vein were punctured. A decapolar coronary sinus catheter, a quadripolar right ventricular catheter and a quadripolar His catheter were introduced. Subsequently, an intracardiac echocardiographic catheter (ICE) was positioned in the right atrium to visualize the membranous part of the interatrial septum. A transseptal 8.5F sheath (SL1, St Jude Medical, Minneapolis, Minn) was inserted into the left atrium by means of a transseptal puncture or through a patent foramen ovale. Transseptal puncture was performed using fluoroscopic landmarks and ICE for guidance. As soon as echocardiographic contrast material appeared in the left atrium on ICE, successful transseptal puncture was confirmed. The transseptal sheath was then advanced and the dilator and needle were withdrawn. Finally the magnetic guided catheter (Celsius RMT 4mm,

Biosense-Webster, Diamond Bar, CA, USA) was positioned on the atrial side of the mitral annulus using the MNS.

In the TA group both the right femoral vein and artery were punctured. A decapolar coronary sinus catheter, a quadripolar right ventricular catheter and a quadripolar His catheter were introduced through the right femoral vein. Subsequently the magnetic guided catheter (Celsius RMT 4mm, Biosense-Webster, Diamond Bar, CA, USA) was introduced through the right femoral artery. Under fluoroscopic guidance the ablation catheter was advanced to the aortic root. With the aid of the MNS the magnetic vector was aimed at the apex of the left ventricle. The ablation catheter tip was advanced until the aortic valve was crossed. If it did not cross the aortic valve immediately, we further advanced the ablation catheter causing it to bend on the aortic valve, continuously making sure that the catheter tip did not enter a coronary artery. In the meantime the magnetic vector was changed to a position aiming in the complete opposite direction of the apex of the left ventricle. The catheter tip was then pointing in a cranial direction. We reduced the magnetic field and slowly retracted the ablation catheter a few centimeters causing it to drop into the left ventricle. If the ablation catheter still did not enter the left ventricle, the previous steps were repeated. After access to the left ventricle was achieved, the ablation catheter was positioned on the ventricular side of the mitral annulus using the MNS.

Magnetic navigation system

As previously described (10) the MNS consists of two permanent magnets situated on either side of the patient, which are computer-controlled via a workstation (Navigant, Stereotaxis, St. Louis, MO, USA) to allow for changes in the orientation of a stable magnetic field within the chest of the patient. A combined field strength of 0.08 Tesla is produced in navigation mode. As navigation is best performed with a fixed table position, this must be optimized prior to the start of magnetic navigation. When the magnets are positioned next to the patient, only limited angulation of the C-arm is possible (~28° in the right and left anterior oblique angulations with the magnets in the AP position and this can be increased by 15 degrees in either direction by tilting the magnets to either RAO or LAO). From the control room remote catheter advancement and retraction was performed using a catheter advancer system (CardiodriveTM, Stereotaxis, St. Louis, MO, USA), positioned on the high anterior thigh. Remote control of the fluoroscopy system was also performed from the control room. The mapping and ablation catheters are equipped with three small permanent magnets within the distal tip segment that align themselves with the direction of the externally controlled magnetic field, allowing effective catheter orientation. By changing the orientation of the outer magnets relative to each other, the orientation of the magnetic field changes and thereby leads to deflection of the catheter. After the magnets are brought in next to the patient, the physician is free to leave the room and performs the rest of the procedure from the control room. A nurse stays with the patient to monitor vital signs and administer drugs when required.

Ablation

Radiofrequency catheter ablation was performed with the 4-mm, solid-tip, three-magnet ablation catheter (Celcius RMT 4mm, Biosense-Webster Inc, Diamond Bar, CA, USA) in a temperature controlled mode (maximum temperature 55°C, maximum duration 60 seconds, maximum 40 W) with the use of a Stockert (Biosense-Webster Inc, Diamond Bar, CA, USA) radiofrequency (RF) generator. The target site for ablation was identified using standard electrophysiologic techniques: early local ventricular activation relative to the onset of a delta wave on surface electrocardiogram, continuous atrioventricular activity and a possible AP potential.(11,12) RF delivery was terminated within 10 seconds if conduction over the AP failed to block. If successful ablation of the accessory pathway was achieved, a waiting period of 30 minutes was initiated during which anterograde and retrograde accessory pathway conduction block was tested. If no reconduction occurred during this period, the procedure was considered successful. Antiarrhythmic drugs were discontinued and the patient received aspirin for a period of 4 weeks.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation. The Student t test was used to compare the two groups for continuous variables. All tests were two-tailed. The level of significance was set at $p < 0.05$.

RESULTS

Patient data

The patient group consisted of sixteen male and six female patients. Mean age was 42 ± 17 years. Fourteen patients had proven tachycardia, six patients presented with atrial fibrillation and rapid ventricular response through the accessory pathway, one patient had a near syncope and one was asymptomatic but had a short refractory period of the accessory pathway during exercise testing. Fourteen patients had an overt delta wave on surface ECG. Pathway location according to conventional and anatomic terminology is given in table I and was as follows: 16 left lateral, three left posteroseptal, one left posterolateral and two left posterior accessory pathways. (13)

Procedure and ablation data

Half of the patients were randomized to the TS group and half to the TA group. Ten (91%) out of the 11 procedures were successful in the TS group. The failing one crossed over to the TA approach but remained unsuccessful. Of the 11 TA procedures, 9 (82%) resulted in a successful elimination of the AP. Of the two patients who crossed over to a TS procedure in the same session, one was successful and one remained unsuccessful. Total procedure time did

Table I. Distribution of left sided pathway location according to the conventional and the anatomical terminology. Total number of pathways and number of pathways ablated by retrograde or transseptal approach.

Pathway location				
Conventional terminology	Anatomical terminology	Number	Retrograde approach	Transseptal approach
Lateral	Anterior	16	7	9
Posteroseptal	Inferoparaseptal	3	2	1
Posterolateral	Inferoposterior	1	0	1
Posterior	Inferior	2	2	0

not differ in both groups (87,1 ± 30,8 vs 90,9 ± 26,5 min). When total procedure time was divided into electrophysiology study time (26,5 ± 14,5 vs 20,8 ± 18,3 min), time to first application (53,7 ± 18,3 vs 59,6 ± 18,2 min), time to successful application (76,7 ± 24,7 vs 78,1 ± 28,6 min) and time to perform transseptal puncture or time to retrogradely cross the aortic valve, only the last parameter differed significantly (23,8 ± 19,2 vs 4,4 ± 3,6 min, $p<0.01$) (Table II). Total fluoroscopy times did not show a statistical significant difference between the two groups (14,4 ± 4,7 vs 15,5 ± 9,4 min). When total fluoroscopy time was divided into electrophysiology study fluoroscopy time (3,9 ± 2,5 vs 4,6 ± 3,2 min), fluoroscopy time to first application (11,2 ± 7,3 vs 11,8 ± 4,0 min), fluoroscopy time to successful application (13,8 ± 8,2 vs 13,6 ± 4,6 min) and fluoroscopy time to perform transseptal puncture or time to retrogradely cross the aortic valve, again, only the last parameter differed significantly (9,8 ± 4,8 vs 3,9 ± 2,7 min, $p<0.01$). Ablation times were comparable in both groups: 192 ± 107

Table II. Comparison of fluoroscopy and procedural times in the retrograde and the transseptal approach. Time for EP study and time to go transseptal or to cross the aortic valve are absolute times, the time to first RF, to first successful RF, to final successful RF and total time are presented in a cumulative fashion.

	Fluoroscopy time			Procedural time		
	Retrograde approach	Transseptal approach	p	Retrograde approach	Transseptal approach	p
Time for EP study	3.9 ± 2.5	4.6 ± 3.2	ns	26.5 ± 14.5	20.8 ± 18.3	ns
Time to go transseptal or to cross aortic valve	3.9 ± 2.7	9.8 ± 4.8	0.002	4.4 ± 3.6	23.8 ± 19.2	0.004
Time to first RF	11.2 ± 7.3	11.8 ± 4.0	ns	53.7 ± 18.3	59.6 ± 18.2	ns
Time to first successful RF	13.8 ± 8.2	13.6 ± 4.6	ns	74.5 ± 21.7	72.0 ± 16.5	ns
Time to final successful RF	13.8 ± 8.2	14.3 ± 4.7	ns	76.7 ± 24.7	78.1 ± 28.6	ns
Total time	15.5 ± 9.4	14.4 ± 4.7	ns	90.9 ± 26.5	87.1 ± 30.8	ns

vs 163 ± 101 seconds. The median number of RF applications in the successful procedures was 4. Time to block of the accessory pathway did not differ significantly in both groups: 5.3 ± 4.6 vs 5.4 ± 4.3 seconds. No major complications occurred.

DISCUSSION

The aim of this study was to evaluate if the navigation capabilities of the MNS would alter our approach in catheter ablation of left sided accessory pathways. The major finding is that success rate is high in both groups and does not differ significantly. However, performing the transseptal puncture takes longer than retrogradely crossing the aortic valve and causes a higher radiation burden for patient and operator.

TA versus TS approach

Catheter ablation of left sided accessory pathways can be done either by a retrograde TA or a TS approach. When performed manually, both techniques seem to have a comparable efficacy. On the other hand, different reports also showed some inconsistent findings regarding procedural and fluoroscopy time.(5,6,14,15) The most recently published randomized paper favoured the TS approach because of decreased procedural duration, radiation exposure and RF lesions.(16) However, nowadays some operators continue to prefer the TA approach because it is simpler and faster (17) and the TS approach is reserved only for patients who have a difficult arterial access or for cases in which the TA approach fails. One patient in this study failed in both the TA and TS approach using the magnetic navigation catheter. Figure 1 depicts the fluoroscopic images and corresponding tracings. Despite optimal continuous atrial and ventricular electrograms , ablation was unsuccessful. An attempt using a manually steered RF catheter transseptally positioned on the mitral annulus also was not successful. Finally the accessory pathway was successfully ablated from the coronary sinus using a manually steered RF catheter. In terms of success rate, this randomized prospective trial did not show any difference between the two groups. Only three patients crossed over, one from the TS to the TA approach but remained unsuccessful, two from TA to TS: one of which remained unsuccessful. Very importantly, no complications occurred with either technique.

Radiation exposure

One of the key advantages of the MNS is the reduction in radiation exposure for the operator. (8,10) A major finding in our study was that performing the transseptal puncture was accompanied by a higher radiation burden for the patient and the operator compared to retrogradely crossing the aortic valve (Figure 2). In our experience with the MNS, crossing the aortic valve with the floppy magnetic catheter is fairly easy when using the correct series

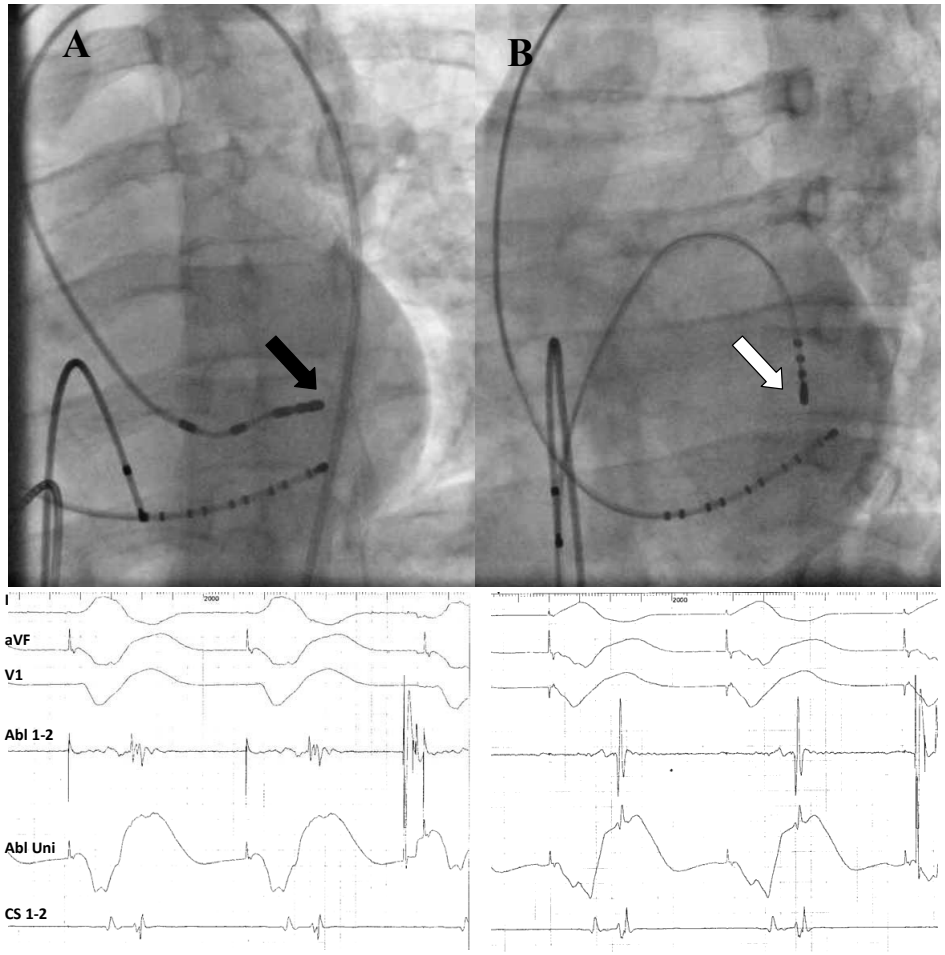


Figure 1. Upper panels: fluoroscopic views in LAO of the ablation catheter at the ablation spot. Panel A shows the magnetically navigated catheter (Celsius RMT 4 mm tip) that retrogradely crosses the aortic valve and is positioned on the mitral annulus (black arrow). A bipolar catheter was placed in de right ventricular apex and a decapolar catheter was positioned in de coronary sinus. Panel B shows an EPT Blazer 4mm tip catheter that crosses the interatrial septum and is positioned on the mitral annulus (white arrow). Lowers panels: ECG (I, aVF, V1) and intracardiac recordings (distal bipolar and unipolar, coronary sinus 1-2) during ventricular pacing directly before application of RF energy.

of consecutive vector movements in combination with temporary reduction of the magnetic field strength.

However, total radiation exposure time did not differ significantly in both groups, meaning that the difficult positioning of the magnetic catheter in the TA approach discards the gain in radiation exposure. As we did not separately measured patient and operator exposure time, we can only assume that the physician was exposed to less radiation in TA procedures, being placed remotely during the manipulation of the catheter across the aortic valve.

Procedural time

Despite the time difference in performing the transseptal puncture and retrogradely crossing the aortic valve, total procedure time does not differ significantly in both approaches. Careful examination of the time required to perform the different steps in the ablation process shows that the time gained by the TA approach seems to be lost by more difficult catheter positioning (Figure 2). Even when using the MNS, acquiring a stable catheter position using the TA approach is a daunting task. Transseptal positioning times tended to be shorter.

Magnetic navigation system

Like all major technological innovations, installing a MNS comes with a significant cost. The MNS hardware, shielding of the electrophysiology lab and the use of specifically designed

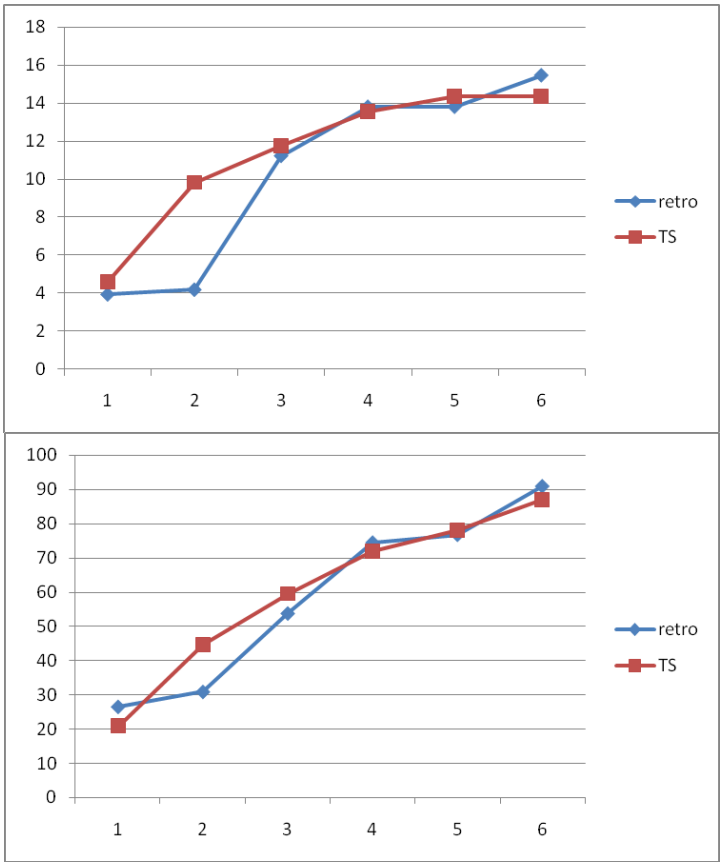


Figure 2. Comparison of fluoroscopy times (upper panel) and procedural times (lower panel) of transseptal and transaortic approach (minutes). Cumulative times are presented. Subdivision are 1: time to perform electrophysiological study, 2: time to perform transseptal puncture or to retrogradely cross the aortic valve, 3: time to first radiofrequency application, 4: time to first successful radiofrequency application, 5: time to final successful radiofrequency application, 6: total time.

catheters are the major determinants of the procedural cost. Fortunately the MNS serves a broad area of applications, both in the electrophysiological field and in the coronary interventional field. This favours the use of the MNS in high volume invasive centres from an economic point of view. However interesting, given the limited number of patients included in this trial, it is not possible to perform an analysis of the cost-effectiveness.

Limitations

This prospective randomized trial consists of only 22 patients. This relative small number of patients does not allow us to perform extensive statistical analysis and also reduces the power of the study results. The results discussed in this paper serve as a pilot study, larger studies including more patients need to be conducted to confirm the results obtained in our study.

CONCLUSION

In conclusion, our data suggest that when the MNS is used to perform RF ablation of left sided APs the TS and TA approaches are equal in success rate, procedure, patient fluoroscopy and ablation time. However, crossing the aortic valve by the MNS is faster and requires less fluoroscopy. This has implications for physicians who were not trained for transseptal punctures.

REFERENCES

1. Tischenko A, Fox DJ, Yee R, Krahn AD, Skanes AC, Gula LJ, Klein GJ. When should we recommend catheter ablation for patients with the Wolff-Parkinson-White syndrome? Curr Opin Cardiol 2008;23:32-7.
2. Jackman WM, Wang XZ, Friday KJ, Roman CA, Moulton KP, Beckman KJ, McClelland JH et al. Catheter ablation of accessory atrioventricular pathways (Wolff-Parkinson-White syndrome) by radiofrequency current. N Engl J Med 1991;324:1605-11.
3. Schluter M, Geiger M, Siebels J, Duckeck W, Kuck KH. Catheter ablation using radiofrequency current to cure symptomatic patients with tachyarrhythmias related to an accessory atrioventricular pathway. Circulation 1991;84:1644-61.
4. Swartz JF, Tracy CM, Fletcher RD. Radiofrequency endocardial catheter ablation of accessory atrioventricular pathway atrial insertion sites. Circulation 1993;87:487-99.
5. Lesh MD, Van Hare GF, Scheinman MM, Ports TA, Epstein LA. Comparison of the retrograde and transseptal methods for ablation of left free wall accessory pathways. J Am Coll Cardiol 1993;22: 542-9.
6. Linker NJ, Fitzpatrick AP. The transseptal approach for ablation of cardiac arrhythmias: experience of 104 procedures. Heart 1998;79:379-82.
7. Thornton AS, Rivero-Ayerza M, Knops P, Jordaens LJ. Magnetic navigation in left-sided AV reentrant tachycardias: preliminary results of a retrograde approach. J Cardiovasc Electrophysiol 2007; 18:467-72.
8. Schwagten B, Jordaens L, Witsenburg M, Duplessis F, Thornton A, van Belle Y, Szili-Torok T. Initial experience with catheter ablation using remote magnetic navigation in adults with complex congenital heart disease and in small children. Pacing Clin Electrophysiol 2009;32 Suppl 1:S198-201.
9. Xie B, Heald SC, Bashir Y, Katritsis D, Murgatroyd FD, Camm AJ, Rowland E, et al. Localization of accessory pathways from the 12-lead electrocardiogram using a new algorithm. Am J Cardiol 1994;74:161-5.
10. Ernst S, Ouyang F, Linder C, Hertting K, Stahl F, Chun J, Hachiya H, et al. Initial experience with remote catheter ablation using a novel magnetic navigation system: magnetic remote catheter ablation. Circulation 2004;109:1472-5.
11. Katritsis D, Bashir Y, Heald S, Poloniecki J, Ward DE. Radiofrequency ablation of accessory pathways: implications of accumulated experience and time dedicated to procedures. Eur Heart J 1994;15:339-44.
12. Bashir Y, Heald SC, Katritsis D, Hammouda M, Camm AJ, Ward DE. Radiofrequency ablation of accessory atrioventricular pathways: predictive value of local electrogram characteristics for the identification of successful target sites. Br Heart J 1993;69:315-21.
13. Cosio F, Anderson R, Becker A, Borggrefe M, Campbell RW, Gaita F, Guiraudon GM, et al. Living anatomy of the atrioventricular junctions. A guide to electrophysiological mapping. A Consensus Statement from the Cardiac Nomenclature Study Group, Working Group of Arrythmias, European Society of Cardiology, and the Task Force on Cardiac Nomenclature from NASPE. North American Society of Pacing and Electrophysiology. Eur Heart J. 1999;20:1068-75.
14. Natale A, Wathen M, Yee R, Wolfe K, Klein G. Atrial and ventricular approaches for radiofrequency catheter ablation of left-sided accessory pathways. Am J Cardiol 1992;70:114-6.
15. Manolis AS, Wang PJ, Estes NA, 3rd. Radiofrequency ablation of left-sided accessory pathways: transaortic versus transseptal approach. Am Heart J 1994;128:896-902.

16. Katritsis D, Giazitzoglou E, Korovesis S, Zambartas C. Comparison of the transseptal approach to the transaortic approach for ablation of left-sided accessory pathways in patients with Wolff-Parkinson-White syndrome. Am J Cardiol 2003;91:610-3.
17. Vora AM, McMahon S, Jazayeri MR, Dhala A. Ablation of atrial insertion sites of left-sided accessory pathways in children: efficacy and safety of transseptal versus transaortic approach. Pediatr Cardiol 1997;18:332-8.

Chapter 2

Remote magnetic navigation guided single catheter ablation of the slow pathway is feasible for the treatment of patients with slow-fast AVNRT

Bruno Schwagten MD, Luc Jordaens MD, PhD, FESC, Dominic A.J. Theuns, PhD, Marieke Takens, RN, Paul Musters, RN, Tamas Szili-Torok MD, PhD

ABSTRACT

Background: Ablation of AVNRT is a highly effective procedure both with radiofrequency (RF) and cryoenergy. Conventionally, it requires insertion of several diagnostic catheters and hospital admission.

Objectives: To test a highly simplified approach using RF ablation with the remote magnetic navigation system (MNS) and to compare its safety and efficacy to cryoenergy and manual RF ablation.

Methods: in the magnetic navigation (MN) group a single MN quadripolar catheter inserted through the internal jugular vein was used to perform ablation. In the cryoenergy group (cryo) ablation was done after cryomapping. In the manual RF group (ManRF) ablation was done conventionally.

Results: Of 69 eligible patients, 26 patients were treated using MN, 25 with cryo, and 16 with ManRF. Mean procedural time was 83 ± 25 min (MNS) vs 117 ± 47 (cryo), vs 117 ± 55 (ManRF)($p<0.01$). Physician radiation time was respectively 0.02 ± 0.07, vs 19 ± 17, and 22 ± 23 min ($p<0.001$). Patient radiation time was significantly reduced for MNS: 10 ± 7 min. The duration of applications was comparable for both RF groups: 357 ± 315 s (MNS) vs 266 ± 197 (ManRF). No major adverse events occurred. At 3 months, Holter recordings showed no recurrences, and similar PR intervals. During a mean follow-up of 26 ± 5 months, one recurrence occurred in each group.

Conclusions: MN guided single catheter approach is a feasible and safe technique in treating carefully selected patients with typical AVNRT.

Abbreviations:

AVNRT = atrioventricular nodal re-entry tachycardia
RF = Radiofrequency
MNS = Magnetic Navigation System
CS = Coronary Sinus
RV = Right Ventricle
AV = Atrioventricular
ERP = Effective Refractory Period

INTRODUCTION

Catheter ablation is the preferred therapy for atrioventricular nodal re-entry tachycardia (AVNRT), the most common regular supraventricular tachycardia(1). Although it is a highly effective treatment modality, with success percentages varying between 95 and 99%,(2) (3) conventionally it still requires the insertion of multiple diagnostic catheters into the heart both when RF or cryoablation is used. (4) Multiple catheters theoretically augment the risk for complications such as venous thrombosis, and perforation of the myocardium. Using multiple catheters also is more costly. Venous catheterization using the femoral vein is associated with haematomas, atrioventriculair (AV) fistulas, pain, vagal reactions, and temporary immobilization. Therefore, this procedure is typically performed in the setting of an overnight hospital stay. These disadvantages are not addressed by using cryoablation, which in our hands is judged as an otherwise safe procedure. (5,6) In order to simplify the procedure, we developed an alternative approach involving the use of only one catheter to diagnose and treat the AVNRT.

With remote magnetic navigation (NIOBE® Magnetic Navigation System, Stereotaxis, Inc., Saint Louis, MO, USA)(MNS) it might be possible to perform an easy, single catheter procedure, approaching the heart from the upper limb or a upper central vein, as a flexible and non-traumatic magnetic navigation catheter can be manoeuvred to all sites of interest.

We compared the safety and efficacy of this approach (MN group) to the use of conventional cryoablation (cryo) and standard manual RF (ManRF) ablation, in both groups using multiple diagnostic catheters. (7) So far, several studies have been conducted demonstrating the feasibility of the MNS in catheter ablation of AVNRT. (8,9) This is the first report that proves its feasibility and demonstrates further advantages of the MNS on conventional approaches.

METHODS

We prospectively screened 100 consecutive patients with recurrent narrow QRS-complex tachycardia and kept 69 patients with a 12-lead ECG suggestive for AVNRT (Figure 1). Patients were enrolled for the MN, cryo or ManRF treatment if they fulfilled following ECG criteria: a documented small QRS tachycardia on surface ECG with retrograde P waves in the inferior leads no further than 100 milliseconds after the ending of the QRS complex. All antiarrhythmic drugs were discontinued for the duration of 5 half-lives. All patients agreed to have the single catheter procedure performed as an outpatient treatment or the cryoablation and ManRF ablation as a conventional treatment, and signed after informed consent a treatment agreement. They were assigned to a procedure type in function of the availability of the lab.

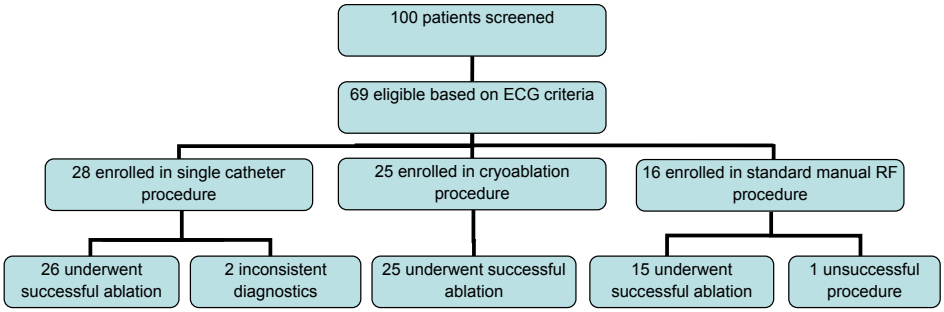


Figure 1. Flow chart of the study design, with the enrolment.

In the cryo and the ManRF group a standard electrophysiological study was performed. One bipolar catheter, one decapolar and one quadripolar catheter were inserted into the right femoral vein and advanced to the right ventricular apex, coronary sinus and His bundle position, respectively. Detailed measurements were taken and cryo or ManRF ablation was performed if diagnosis of dual AV nodal pathways (AH-jump) and AVNRT was made on the basis of standard diagnostic criteria.(5)

For the MN group we introduced a single magnetic navigation quadripolar catheter (Celcius RMT 4mm, Biosense-Webster, Diamond Bar, CA, USA) through the internal jugular vein under local anaesthesia. This catheter was remotely manoeuvred using the MNS (Figure 2). The principles and use of the MNS have already been extensively described. (10) Initially, the catheter was introduced into the right atrium (Figure 3). Using vectors to manoeuvre towards the lateral wall, a right atrial lateral position was achieved. At this position the atrial signal amplitude should be large, and stimulation threshold low. Subsequently, an attempt was made to reach the His position. The catheter was placed into this His region providing ventricular capture on the distal electrode pairs with wide paced QRS duration, while on the proximal pole a clear atrial signal should still be visible. The position of the His bundle was tagged on the MNS in the LAO and RAO views, through the fluoroscopic annotation option. A yellow dot was continuously displayed on fluoroscopy indicating the His bundle in all incidences. Subsequently, the coronary sinus was cannulated using the navigation system. All the magnetic vectors of the above mentioned anatomical locations were stored in the system. This allowed quick re-navigation of the catheter to a selected position using the system's target navigation option. Images of these positions were stored in two radiological views: right anterior oblique (RAO 30°) and left anterior oblique (LAO 30°). After registration of the important anatomical locations, programmed stimulation was performed. Incremental atrial and RV programmed stimulation and extra stimulus testing determined decremental conduction, the anterograde and retrograde effective refractory periods (ERP) of the AV node, as well as the Wenckebach point. RV and parahisian stimulation using the distal electrode pair at the His position and recording of an atrial signal on the proximal electrode pair was performed in order to exclude the presence of retrograde conducting parahisian accessory

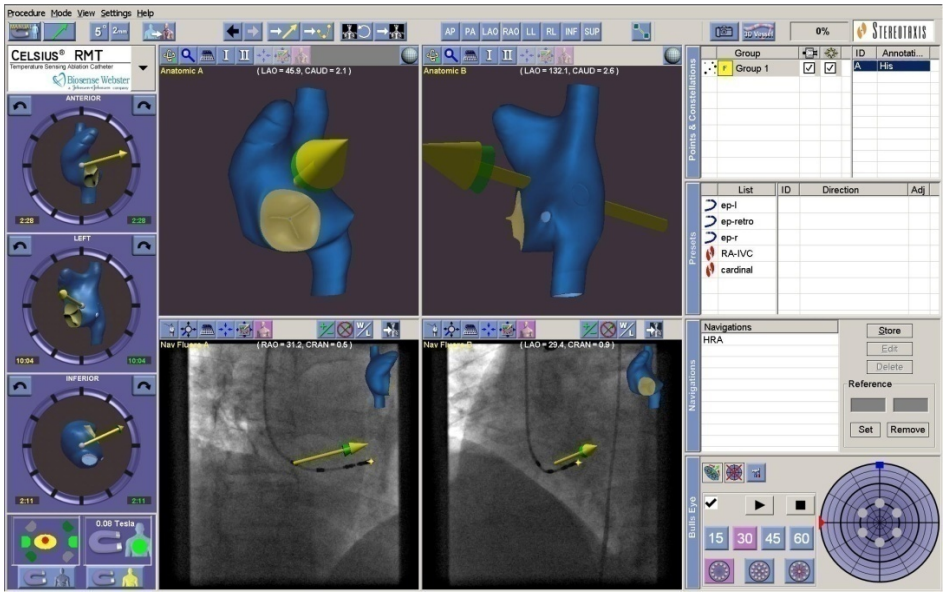


Figure 2. Part of the interface of the magnetic navigation system, displaying vector navigation and the ability to store magnetic vectors. A cast of the right atrium is displayed in the upper right corner, and the yellow arrow indicates the direction of the imposed vector on the catheter tip in the RAO and LAO 30 degrees views.

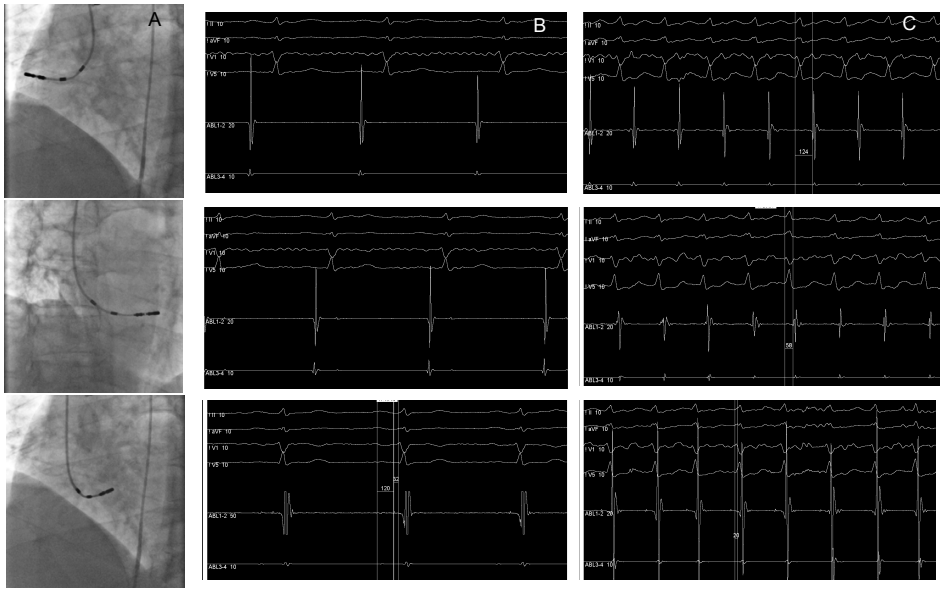


Figure 3. Fluoroscopic views (A) of the single catheter respectively in the high right atrium (LAO 30), coronary sinus (RAO 30) and His position (LAO 30). Corresponding electrograms during sinus rhythm (B) and during ongoing tachycardia (C).

pathways. During pacing from the right atrium an A-QRS jump was searched. Diagnosis of dual AV nodal pathways was made on the basis of standard diagnostic criteria modified according to the single catheter approach. (11)
Subsequently we tried to induce sustained tachycardia. During ongoing tachycardia the catheter was re-navigated using the stored magnetic vectors to the His position, into the CS proximal and distal part and subsequently VA measurements were taken (Figure 3). The VA time should be less than 90 ms at all of these locations. Based on the findings of the EP study the diagnosis of AVNRT was made: if the ventricular and atrial signals appeared almost simultaneously and the shortest VA time was measured at the His position, diagnosis of typical slow-fast AVNRT with an anterior exit point was made. (11) If sustained tachycardia could not be induced, isoproterenol and, if necessary atropine were infused to facilitate tachycardia. If any of the above-mentioned tests were not consistent with the diagnosis of AVNRT, the procedure was converted into a standard EP study by inserting diagnostic catheters in the standard locations in the heart, and ablation was performed according to the diagnosis.

Ablation endpoints

For the 3 groups, the endpoint was non-inducibility of AVNRT. Inducibility of AVNRT was tested after each application, and if non-inducible, repeated after a 30 min waiting period.

RF ablation with the MNS

RF catheter ablation in the MN group was performed with the 4-mm, solid-tip, magnetic ablation catheter (Celcius RMT 4mm, Biosense-Webster Inc, Diamond Bar, CA, USA) in a temperature controlled mode (maximum temperature 55°C, maximum duration 60 seconds, maximum 40 W) with the use of a Stockert RF generator. The target was the slow pathway guided by a combination of intracardiac electrogram criteria and anatomical landmarks. (12) Catheter positioning and handling was performed using the MNS and fluoroscopy. The target position was labelled using a hollow white dot on the fluoroscopic images in the two aforementioned radiological planes, with also a full white dot on the His bundle as a reference (Figure 4). When changing the angle of the fluoroscopy, these markings on the fluoroscopy screen moved concordantly. The fluoroscopy image was set at LAO 30°, and the navigation started at the His position. The magnetic vector was changed in the same plane inferior from the His, providing safe distance from the His bundle. Movement of the catheter was continuously monitored and recorded. When an optimal balance of a small fractionated A and large V signals was seen (Figure 4), RF energy was applied starting at a low energy level. Each application was started with the power set at 10 W and, if AV conduction was preserved, the power was progressively increased to 40 W until a maximum of 55°C was reached or junctional rhythm appeared. Fluoroscopy was used throughout each application. Procedure time was measured from the moment of puncturing the jugular vein in the EP lab until the removal of the sheath from the jugular vein, including the 30 min waiting period.

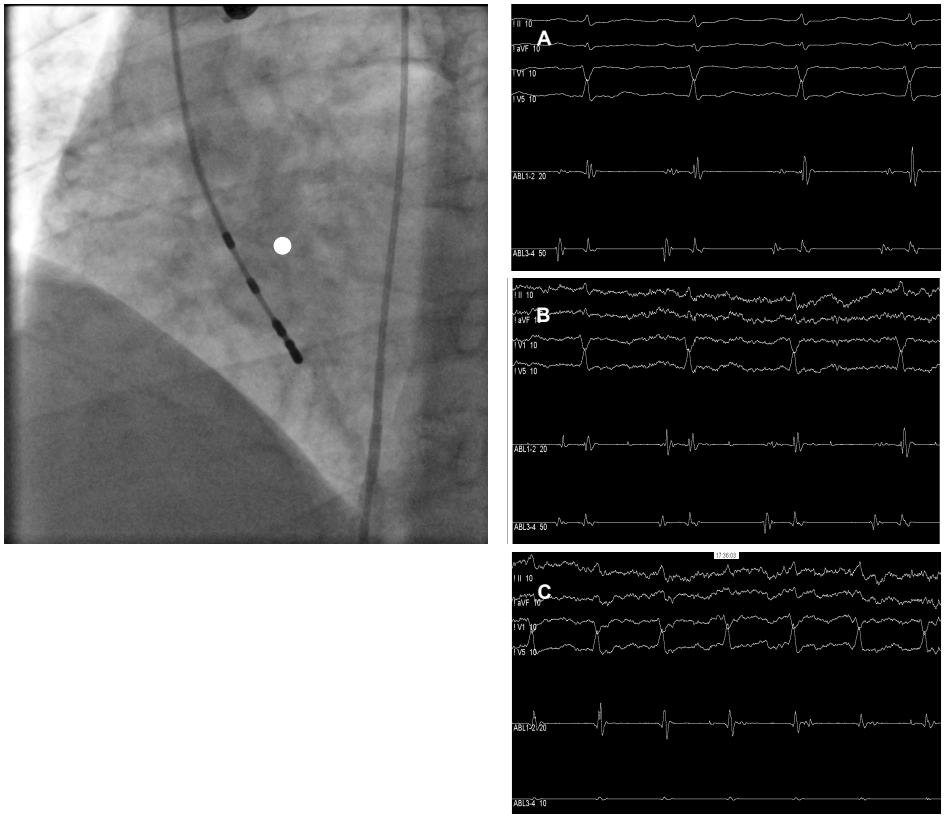


Figure 4. Left side: fluoroscopic view of the ablation spot (LAO) with labeling of the His by a white dot. Right side: the corresponding electrogram during sinus rhythm (A), during radiofrequency application (B) and during junctional rhythm (C), at the end of the tracing.

Cryoablation

Cryoablation was performed using a 4mm tip Freezor 3, catheter (Cryocath Technologies, Montreal, Canada) and a CCT2 CryoConsole (Cryocath Technologies, Montreal, Canada). Initially, ice mapping was performed by cooling to -30°C for a maximum of 60 s. If a potential successful site was identified cryoablation till -75°C was performed. (5)

Manual RF ablation

ManRF ablation was performed using an Alcath Gold FullCircle RF catheter (Biotronik Inc., Berlin, Germany) in a temperature controlled mode (maximum temperature 55°C, maximum duration 60 seconds, maximum 40 W) with the use of a Stockert RF generator. The target was the slow pathway guided by a combination of intracardiac electrogram criteria and anatomical landmarks. Catheter positioning was done manually. When an optimal balance of a small fractionated A and large V signals were seen and a stable catheter position was attained, RF energy was applied, starting at 10 W. If AV conduction was preserved, the power

was progressively increased to 40 W until a maximum of 55°C was reached or junctional rhythm appeared. Fluoroscopy was used throughout each application.

Follow-up

Immediately after ablation all patients received a 24 hour Holter monitor. MNS patients were discharged on the same day of the procedure. The following day all patients were seen at the outpatient clinic and an electrocardiogram and transthoracic echocardiographic examination were performed. Three months after the procedure all patients received a new 24 hour Holter monitor, were examined at the outpatient clinic and asked about recurrent palpitations. If longstanding palpitations occurred within the follow-up period, a 24 hour Holter monitor was performed and an effort was made to make an ECG at the time of complaints.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation, if normally distributed, or otherwise by median. The Students t test or analysis of variance was used when appropriate. A Chi-square test was used for categorical data. The level of significance was set at $p < 0.05$. All statistics were performed using SPSS (16.0) for Windows (Chicago, Il, USA).

RESULTS

Patient data

Of 100 patients screened 69 were found to be eligible based on documented ECG criteria. Two of the 28 patients enrolled for the single catheter MN approach were excluded due to inconsistent diagnostic results. Finally, 26 patients were ablated using the single catheter MN approach (Figure 1), 25 were treated using cryoenergy, and 16 with ManRF ablation (Table I). The mean age was similar in the 3 groups, with a female majority in the 3 groups. The mean number of total antiarrhythmic drugs used before the procedure was 1.0 ± 0.8 and decreased to 0.2 ± 0.5 for the entire group after the procedure ($p<0.001$), with only 3, respectively 2 and 2 patients in the groups continuing anti-arrhythmic drugs.

Procedure and ablation data

A right sided jugular venous access was achieved in all but 3 patients, in whom the left subclavian vein was used. Details of the electrophysiology procedure are shown in Table II. The mean procedural time was significantly shorter for MN than for cryo ($p=0.002$) and for ManRF ($p=0.008$). The mean physician radiation time was 0.02 ± 0.07 min for MN vs 19 ± 17 for cryo and 22 ± 23 for ManRF (both $p<0.001$). The mean patient radiation time was shorter for MN than for cryo ($p=0.01$) and ManRF ($p=0.02$). The mean patient radiation dose was 992 ± 759 μGym^2 vs 1273 ± 999 (NS) and 958 ± 778 (NS). The median application

Table I. Patient characteristics

	MN group	Cryo group	ManRF group
Number of patients	26	25	16
Male/female (n/n)	8/18	7/18	4/12
Mean age (years)	45 ± 10	51 ± 19	51 ± 15
Weight (kg)	78.8 ± 17.7	73.6 ± 14.9	69 ± 12
Length (m)	1.71 ± 0.10	1.64 ± 0.37	1.70 ± 0.10
Mean duration of symptoms (months)	166 ± 127	109 ± 108	78 ± 72
Mean symptoms/week (n)	1.8 ± 2.2	2.5 ± 2.5	1.8 ± 1.7
Mean number of AAD before procedure (n)	1.0 ± 0.4	0.8 ± 0.4	0.8 ± 0.5
Mean number of AAD after procedure (n)	0.2 ± 0.5	0.2 ± 0.5	0.2 ± 0.4
Number of patient taking AAD after procedure (n)	3	2	2
Underlying heart disease/hypertension (n)	3	4	2
Previous RF ablations (pts)	0	0	0

Table II. Electrophysiology study and ablation results

	MN group	Cryo group	Man RF group
Anterograde jump (≥50ms)	15 (57%)	16 (64%)	12 (75%)
Slow-fast AVNRT	26 (100%)	25 (100%)	16 (100%)
CL tachycardia (ms)	339 ± 51	343 ± 58	344 ± 51
Median application number	8.5	2	3.5
Mean application duration (s)	357 ± 315	605 ± 322	266 ± 197
Occurrence of junctional rhythm	26 (100%)	0 (0%)	16 (100%)
Residual jump after ablation	1 (4%)	3 (12%)	1 (6%)
Non-inducibility	26 (100%)	25 (100%)	15 (94%)
Procedure time (min)	83 ± 25	117 ± 47	117 ± 55
Patient radiaton time (min)	10 ± 7	19 ± 16	22 ± 23

Patient numbers, with % between brackets

number in the 3 groups was respectively 9.5; 2 and 3.5. The mean duration of applications was comparable for MN and ManRF, while it was longer in the cryo group (p=0.008) .

RF delivery was interrupted in two, respectively one patient in the MNS group because of the appearance of first and second degree AV block. The conduction disturbances spontaneously resolved within 6 ± 5 minutes. A transient third degree AV block was seen in two patients during cryomapping which spontaneously resolved, after 8 seconds and 10 minutes respectively. Transient VA block was seen in two patients during application in the ManRF group. After interrupting the application, normal AV conduction was seen. Acute success was achieved in all patients, except for one in the ManRF group. No major adverse events occurred.

Follow-up data

No major adverse events such as tamponade, high degree AV block or death were observed after the procedure. One patient suffered a haematoma in the neck which spontaneously resolved after a few weeks. The PR interval and the heart rates before and the day after the procedure are given in Table III. No differences were observed between groups, and between the two measurements in time.

Table III. Heart rate and PR intervals

	MN group	Cryo group	Man RF group
Heart rate at baseline (bpm)	75 ± 12	70 ± 14	69 ± 11
PR at baseline (ms)	149 ± 25	143 ± 33	155 ± 25
Heart rate after 24 hour (bpm)	75 ± 13	71 ± 13	70 ± 9
PR after 24 hour (ms)	148 ± 25	149 ± 24	153 ± 18
Heart rate after 3 months (bpm)	75 ± 12	78 ± 13	74 ± 9
PR after 3 months (ms)	152 ± 26	142 ± 24	152 ± 27

The heart rates and PR intervals three months after procedure were also comparable. No patient had a PR ≥ 220 ms nor significant arrhythmias at the three month Holter.
Mean follow-up was 26 ± 5 months without further documented bradycardia or conduction disturbance. Twenty-five (96%) vs 24 (96%) and 14 (93%) patients remained asymptomatic. Three patients, one in each group had a recurrence. The patient in the MN group had documented small complex tachycardia more than 3 months after the index procedure, probably AVNRT, but symptoms were no longer disabling. The 2 other patients underwent a redo procedure.

DISCUSSION

The major finding of this study is that RF ablation for AVNRT using the MNS, with a single catheter proves to be feasible.

MNS in AVNRT

Although ablation treatment modalities for AVNRT are highly efficient, with success rates ranging up to 95%, a conventional procedure requires the insertion of several diagnostic catheters into the heart. (12) These procedures were initially associated with a significant radiation exposure for both patient and investigator, (13) but in recent times radiation exposure dropped significantly. (14) This report supports the idea of using the different advantages of the advanced MNS technology to simplify and speed up RF ablation and reduce radiation exposure in a well-selected group of patients with AVNRT. (8,15)

Safety

In experienced hands, the incidence of inadvertent high degree heart block is low, with RF and cryo. (6,16) Compared to an extremely safe technique such as cryoablation, the single catheter approach also did not result in creation of inadvertent heart block, while this was temporarily present during the applications, which were interrupted at that moment.
To enhance safety, the position of the His bundle was tagged on the MNS in the LAO and RAO views and by means of the fluoroscopic annotation option. This feature makes the presence of a His catheter redundant, but this can also be performed with other navigation or mapping systems. Catheter stability, precise navigation capabilities and tagging of the His on fluoroscopy all contribute to the safety of this procedure. We did not search for slow pathway potentials; this might have allowed to tag the slow pathway region as well. Even though we observed two transient first degree and one transient second degree heart blocks during RF application, no permanent block remained after the procedure. At late follow up, where a large variation of arrhythmias may be discovered after AVNRT ablation, no conduction disturbances were observed. (17)

Advantages of the MNS in the trigonum of Koch

The soft and flexible magnetic navigation catheter permits easy manipulation. The possibility of perforating the myocardial wall with the extremely floppy catheter tip is very unlikely. Precise target or vector navigation can be achieved with accuracy of up to 1mm or 1 degree. A long as the magnetic field is applied the catheter will remain at the desired location, irrespective of patients taking deep breaths or even during accelerated junctional rhythm. This characteristic of the MNS is particularly important when mapping and ablating in small regions such as the triangle of Koch and in direct proximity of the compact AV node and His bundle. Additionally, different locations can be stored in the MNS workstation and exact re-navigation is accomplished by reapplying these vectors. (18) This feature of the MNS allows us to make the diagnosis of AVNRT quickly and with the use of one single catheter which is re-navigated to the right atrial lateral position, the His position and in the ostium of the CS. In this study overall procedure time was reduced by 52% to an average of 83 minutes in comparison to previous reported results and with 29% to conventional RF in this study. (10) Patient radiation exposure was reduced by 55% to an average of 10 minutes in comparison to the group reported in the same paper, and with a similar amount compared to the conventional RF group. (10) In comparison to the cryoablation group overall procedure time and patient radiation exposure are also significantly reduced. The decrease in overall procedure time is mainly due to the possibility of immediate and precise re-navigation to pre-stored positions facilitating diagnostics and therapy. The decrease in radiation exposure is supported by recent papers. (19,20)

Advantages of an upper limb or jugular access

The use of the jugular venous access literally allows the patient to walk in and out of the electrophysiology lab. A combination of the aforementioned advantages permits us to treat a much higher of patients with AVNRT in the same electrophysiology lab when compared to the conventional approach: all patients can be discharged on the day of the procedure. By using Doppler-echo techniques, it might have been possible to avoid the subclavian punctures as well, making the overall advantage more clear.

Limitations

A possible limitation to the current single catheter approach was the inconsistency in diagnostic findings in two patients, in whom a correct diagnosis was impossible with one catheter. Further, monitoring VA-conduction from the surface electrocardiograms was very difficult, and was potentially the reason of the short lasting block.

CONCLUSIONS

In conclusion, compared to cryoablation and manual RF catheter navigation, the use of the MNS is safe and offers further advantages for ablation of the slow pathway since procedural times are shortened, physician's radiation exposure is virtually zero and radiation exposure to the patient is lower. Moreover, this MN procedure can be safely done as an outpatient procedure. This is the first comparative study which shows real potential benefit of using the magnetic navigation system in AVNRT ablation. The present study also showed that in the large majority of patients suspected of AVNRT a complete, fast study can be done with a single catheter in this way.

REFERENCES

1. Denes P, Wu D, Dhingra RC, Chuquimia R, Rosen KM. Demonstration of dual A-V nodal pathways in patients with paroxysmal supraventricular tachycardia. Circulation 1973;48:549-55.
2. Calkins H, Yong P, Miller JM, et al. Catheter ablation of accessory pathways, atrioventricular nodal reentrant tachycardia, and the atrioventricular junction: final results of a prospective, multicenter clinical trial. The Atakr Multicenter Investigators Group. Circulation 1999;99:262-70.
3. Hindricks G. The Multicentre European Radiofrequency Survey (MERFS): complications of radiofrequency catheter ablation of arrhythmias. The Multicentre European Radiofrequency Survey (MERFS) investigators of the Working Group on Arrhythmias of the European Society of Cardiology. Eur Heart J 1993;14:1644-53.
4. Jackman WM, Beckman KJ, McClelland JH, et al. Treatment of supraventricular tachycardia due to atrioventricular nodal reentry, by radiofrequency catheter ablation of slow-pathway conduction. N Engl J Med 1992;327:313-8.
5. Kimman GP, Theuns DA, Szili-Torok T, Scholten MF, Res JC, Jordaens LJ. CRAVT: a prospective, randomized study comparing transvenous cryothermal and radiofrequency ablation in atrioventricular nodal re-entrant tachycardia. Eur Heart J 2004;25:2232-7.
6. Schwagten B, Knops P, Janse P, et al. Long-term follow-up after catheter ablation for atrioventricular nodal reentrant tachycardia: a comparison of cryothermal and radiofrequency energy in a large series of patients. J Interv Card Electrophysiol;30:55-61.
7. Kimman GJ, Theuns DA, Janse PA, et al. One-year follow-up in a prospective, randomized study comparing radiofrequency and cryoablation of arrhythmias in Koch's triangle: clinical symptoms and event recording. Europace 2006;8:592-5.
8. Ernst S, Ouyang F, Linder C, et al. Initial experience with remote catheter ablation using a novel magnetic navigation system: magnetic remote catheter ablation. Circulation 2004;109:1472-5.
9. Ernst S, Ouyang F, Linder C, et al. Modulation of the slow pathway in the presence of a persistent left superior caval vein using the novel magnetic navigation system Niobe. Europace 2004;6:10-4.
10. Thornton AS, Janse P, Theuns DA, Scholten MF, Jordaens LJ. Magnetic navigation in AV nodal re-entrant tachycardia study: early results of ablation with one- and three-magnet catheters. Europace 2006;8:225-30.
11. Heidbuchel H, Jackman WM. Characterization of subforms of AV nodal reentrant tachycardia. Europace 2004;6:316-29.
12. Haissaguerre M, Gaita F, Fischer B, et al. Elimination of atrioventricular nodal reentrant tachycardia using discrete slow potentials to guide application of radiofrequency energy. Circulation 1992;85:2162-75.
13. Rueter FG. Physician and patient exposure during cardiac catheterization. Circulation 1978;58:134-9.
14. Kesek M, Wallenius N, Ronn F, Hoglund N, Jensen S. Reduction of fluoroscopy duration in radiofrequency ablation obtained by the use of a non-fluoroscopic catheter navigation system. Europace 2006;8:1027-30.
15. Kerzner R, Sanchez JM, Osborn JL, et al. Radiofrequency ablation of atrioventricular nodal reentrant tachycardia using a novel magnetic guidance system compared with a conventional approach. Heart Rhythm 2006;3:261-7.
16. Kimman GP, Jordaens LJ. Transvenous radiofrequency catheter ablation of atrioventricular nodal reentrant tachycardia and its pitfalls: a rationale for cryoablation? Int J Cardiol 2006;108:6-11.

17. Jordaens L, Vertongen P, Verstraeten T. Prolonged monitoring for detection of symptomatic arrhythmias after slow pathway ablation in AV-nodal tachycardia. Int J Cardiol 1994;44:57-63.
18. Thornton AS, Jordaens L. A left-sided accessory pathway revisited with remote retrograde magnetic navigation. Pacing Clin Electrophysiol 2007;30:573-6.
19. Kim AM, Turakhia M, Lu J, et al. Impact of remote magnetic catheter navigation on ablation fluoroscopy and procedure time. Pacing Clin Electrophysiol 2008;31:1399-404.
20. Wood MA, Orlov M, Ramaswamy K, Haffajee C, Ellenbogen K. Remote magnetic versus manual catheter navigation for ablation of supraventricular tachycardias: a randomized, multicenter trial. Pacing Clin Electrophysiol 2008;31:1313-21.

Chapter 3

Flutter ablation with remote magnetic navigation: Comparison between the 8 mm tip, the irrigated tip and a manual approach

Wim Anné, MD, PhD, Bruno Schwagten, MD, Petter Janse, RN, Tamas Bauernfeind, MD, Yves Van Belle, MD, Natasja De Groot, MD, PhD, Paul Knops, BSc, Luc Jordaens, MD, PhD, Tamas Szili-Torok, MD, PhD.

ABSTRACT

Introduction: Remote magnetic navigated ablation has proven its feasibility in a large group of arrhythmias. Until now only scarce data are available on the use for atrial flutter. In this study we compared remote magnetic navigation (RMN), using non-irrigated and irrigated tip catheters, to manual radiofrequency ablation for ablating typical atrial flutter.

Methods: The 3 study groups consisted of 17 patients treated with RMN 8 mm tip; 14 patients with RMN irrigated tip; and 24 patients with a manual 8 mm tip. The primary outcome was the number of patients in whom bidirectional isthmus block could be obtained with ≤15 applications. Secondary endpoints were the median number of applications needed, the need to switch to a manual irrigated tip catheter, the procedural and fluoroscopy times.

Results: There was no significant difference in the primary endpoint (RMN 8 mm tip group: 59%, RMN irrigated tip group: 64% and manual group: 83%). The median number of applications needed to obtain block was higher in the RMN groups compared to the manual group. In 5 patients from the RMN 8 mm tip group, 1 in the RMN irrigated tip group and 1 in the manual group, a switch to a manually irrigated tip catheter was performed. There was no difference in fluoroscopy time, but procedural time was significant longer in the RMN groups compared to the manual group (p=0.03).

Conclusions: The use of magnetic navigation for the ablation of atrial flutter is feasible but not superior to a manual approach. There was no difference concerning the primary endpoint of acute success within 15 applications. Overall, more applications were needed and procedure times were longer with RMN, however RMN with the irrigating tip is promising.

Keywords: Atrial flutter; remote magnetic navigation; radiofrequency ablation; cavotricuspid isthmus

INTRODUCTION

Radiofrequency catheter ablation of the isthmus between the tricuspid annulus and the inferior vena cava has become a first-line treatment for patients suffering from recurrent atrial flutter 1. Since the introduction of the concept of bidirectional block over the isthmus, this method has evolved into a highly effective procedure. New treatment strategies are being developed with as major goals to further improve efficiency, efficacy and safety of this procedure.

Remote magnetic navigation (RMN) has proven its feasibility in a large group of arrhythmias such as atrial fibrillation 2, AV-node re-entry tachycardia 3, congenital heart disease 4 and ventricular tachycardia 5. The advantages of RMN are the very precise and accurate navigation possibilities, the reduced radiation exposure for the operator. The soft catheter makes cardiac perforation unlikely. The most often used catheter types, the 8 mm tip and the irrigated tip, are also available for RMN.

Nowadays, different strategies to ablate the cavotricuspid isthmus exist: some prefer to drag the ablation catheter while ablating; others use a point-by-point approach. Recently a third method has been described guided by the maximum voltage over the isthmus, based on the pathological observation that the cavotricuspid isthmus is composed of distinct muscular bundles, responsible for the electrical conduction 6. The maximum voltage technique aims to target only these muscular – electrical conducting – bundles and not the interlaying – non-conducting - connective tissue. This is achieved by sequentially ablating the highest voltages on the isthmus till bidirectional block is reached. This technique was assessed during coronary sinus pacing, sinus rhythm and during atrial flutter and proven to be a feasible method 7. This technique reduced the number of ablation lesions, the fluoroscopy and the procedure times needed to achieve bidirectional isthmus block. The primary aim of this project was to assess the feasibility and efficacy of the use of RMN (Stereotaxis, Niobe) in conjunction with the maximum voltage technique for ablating the cavotricuspid isthmus. We compared both the 8 mm remote magnetic navigated catheter, the irrigated remote magnetic navigated catheter with a manual approach using an 8 mm tip catheter.

METHODS

Patient characteristics

Between May 2007 and March 2010, 55 patients were included in this registry. Only patients with a first procedure were included. We excluded patients with congenital heart disease and heart transplantation. In total, 31 patients were treated with the aid of RMN: 17 with an 8 mm tip catheter, and 14 patients with an irrigated tip. The other 24 patients were treated with a manual 8 mm tip catheter. The choice whether a patient was treated with RMN or

with a manual approach was based on the availability of the RMN room. We started the RMN irrigated tip instead of the RMN 8 mm catheter from November 2008 on.

Ablation procedure

The procedures were performed in fasting state, under local anesthesia and light sedation with diazepam. Analgesia was given with IV fentanyl. A 20-pole catheter (Inquiry H, Boston Scientific) was advanced into the right atrium and positioned around the tricuspid annulus; a decapolar catheter (Polaris, Boston Scientific) was positioned in the coronary sinus. All patients were ablated while pacing the os of the coronary sinus. All procedures were carried out by a junior and senior electrophysiologist. Procedural times were measured from the puncture till 30 minutes after the last applications.

Manual group

Ablation in the conventional group was performed with an 8 mm Blazer catheter (Boston Scientific, Inc.). The isthmus between the tricuspid valve and the vena cava inferior was carefully mapped and the highest peak-to peak bipolar atrial electrograms were searched for. Ablation was first directed to the highest potential. If the ablation lesion did not result in bidirectional block, the next largest atrial electrogram was subsequently targeted for ablation until bidirectional block was present. Catheter settings were 60 s, 60 W, 60ºC. We used standard pacing maneuvers to verify bidirectional block. If bidirectional block could not be achieved within 15 applications a switch to a cooled-tip catheter was allowed (Thermocool, Biosense Webster, settings: 60 s, 35 W, 48ºC, cooling 20 ml/min).

RMN 8 mm tip group

All patients in the magnet group were ablated with the Navistar DS 8 mm catheter (Biosense Webster). The cavotricuspid isthmus was mapped with the aid of RMN (Stereotaxis, Niobe) and an electro-anatomical mapping system (CARTO, Biosense Webster). This was not used for activation mapping, but to tag the ablation line: the highest peak-topeak bipolar electrograms were indicated on the map. Ablation was first directed to the highest potential on this map. If the ablation lesion did not result in bidirectional block, the next largest atrial electrogram was subsequently targeted for ablation until bidirectional block was present. The magnetic navigation system was used to store the vectors into the system which allowed us to easily redirect the magnet catheter to the highest atrial electrogram, after the map of the cavotricuspid isthmus was made. The settings of the ablation were 60 s, 60 W, 50ºC. If we did not succeed in reaching bidirectional block within 15 applications; a switch to a manual guided cooled-tip catheter was allowed (Thermocool, Biosense Webster, settings cfr supra).

RMN irrigated tip group

The same protocol was used as for the RMN 8 mm tip group, but with a Thermocool (Biosense Webster) with 60 s, 55 W, 48ºC., 20 ml cooling.

Endpoints

The primary endpoint was defined as the presence of bidirectional block within 15 applications. Secondary endpoints were the median number of applications needed to obtain acute success, the ablation time, procedural time, fluoroscopy time.

Statistical analysis

Continuous, normally distributed, variables were compared with the ANOVA test and as post-hoc test the Fisher exact test. Continuous, not normally distributed variables were compared with the non-parametric Kruskal Wallis test. Not normally distributed variables are present as median ± interquartile range. A p-value of <0.05 was considered statistically significant.

RESULTS

Patient characteristics

The mean age of the patients was 59 ±10 years [range 25-84 years] and 27% was female. Thirty-six percent suffered from AF and 18% from hypertension. Five patients had valvular heart disease, 3 patients a pacemaker before ablation, 4 had known ischemic heart disease, one patient peripheral vascular disease and 2 patients had a history of transient ischemic attack.

Procedural parameters

There was no difference between the different groups concerning the primary endpoint. The proportion of patients who could successfully be treated within 15 applications was 59% for the RMN 8 mm tip group, 64% for the RMN irrigated tip group and 83% for the manual group (p=0.19). Patients treated in the magnet group (both 8 mm and irrigated tip) needed overall significant more applications to obtain bidirectional block compared to the conventional group. The median number of applications was 10 in the RMN 8 mm tip group, 13 in the RMN irrigated tip group and 8 in the manual group (p=0.03) (Fig. 1). The median application time was 570 seconds (RMN 8 mm tip group), 692 seconds (RMN irrigated tip group) and 465 seconds (manual group) (p=0.03). Five or less applications were needed in 12% of the patients in the RMN 8 mm tip group, 7% in the RMN irrigated tip group versus 17% in the conventional group (p=0.69). In 5 patients from the RMN 8 mm tip group (29%), the magnet catheter was switched to a conventional guided cooled-tip catheter. In 2 patients

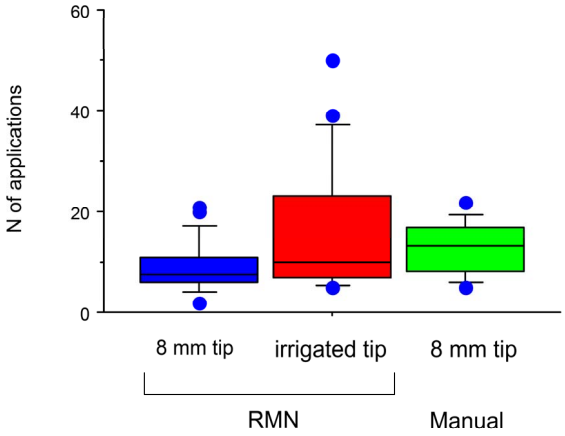


Figure 1. Box-plot of the total number of applications needed to achieve bidirectional cavotricuspid isthmus block.

bidirectional block could be achieved after 1 extra application; in another 2 patients after 4 and 15 extra applications with the cooled-tip catheter, while in 1 patient we could not create bidirectional block at all. In 1 patient of the RMN irrigated tip group (8%) there was a switch to a conventional irrigated tip catheter. In this patient, 3 extra applications were needed to obtain complete isthmus block. In the manual group there was also 1 patient which was

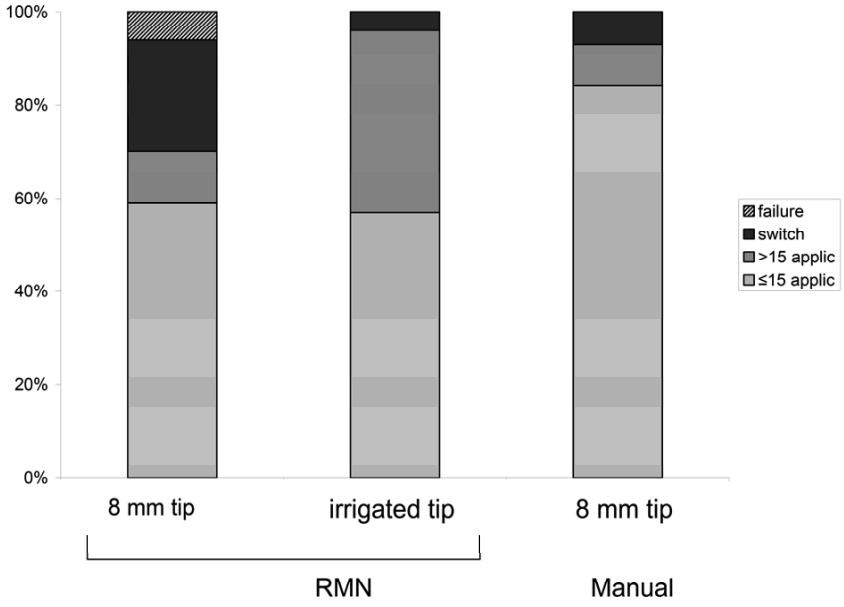


Figure 2. Graph depicting the percentage of patients in whom bidirectional block could be achieved with ≤15 applications, > 15 applications, and after a switch to a manual navigated cooled-tip catheter and were no bidirectional block could be obtained.

Table I. Procedural data

	Remote magnetic navigation		Manual navigation	
	8 mm tip (n=17)	irrigated tip (n=14)	8 mm tip (n=24)	p-value
Number of applications	10 ±16	13 ±9	8 ±5	0.03
Ablation times (seconds)	570 ±815	692 ±579	465 ±265	0.03
Switch to manual approach	5	1	1	0.04
Procedure time (min.)	148 ±44	143 ±40	106 ±53	0.03
Fluoroscopy time (min.)	23 ±12	22 ±7	20 ±11	0.62

switched to an irrigated tip catheter (4%). In this patient 8 extra applications were needed to obtain bidirectional block (p=0.04) (Fig. 2).

Procedural times were significantly longer in the magnet group compared to the conventional group: 148 ±44 min (RMN 8 mm tip group) 143 ±40 min (RMN irrigated tip group) versus 106 ±53 min (manual group) (p=0.03). There was no difference in fluoroscopy times: 23 ±12 min (RMN 8 mm tip group), 22 ±7 min (RMN irrigated tip group) and 20 ±11 min (p=0.62) (manual group) (Table 1).

There was 1 adverse event, consisting of a false aneurysm in a patient of the RMN irrigated tip group.

DISCUSSION

The main finding of this study is that for the primary endpoint (success within 15 applications) there was no difference between the 3 catheters. Secondary endpoints showed that more applications were needed with RMN compared to the manual approach, and that procedural times were longer. A third finding is that the maximum voltage technique is feasible with RMN.

Remote magnetic navigation

RMN proved to be a feasible technique for ablation of the majority of arrhythmias and has shown superiority in some difficult arrhythmias, such as in congenital heart disease 4. The major advantages are that it is a safe procedure since perforation with a floppy catheter is highly unlikely and that the amount of radiation for the operator substantially decreases, as he can operate the catheter remote from the patient 8. However, it is not impossible that these measures compromise efficacy.

Recently the irrigated tip catheter for RMN was introduced, making the advantages of catheter tip cooling possible in the magnetic environment.

In atrial flutter we did not see a statistical difference in the primary endpoint (success within 15 applications) compared to manual ablation. Nevertheless, the results with the RMN 8 mm tip were disappointing. We needed more applications compared to a conventional approach,

and we needed to switch 5 times to a manual irrigated tip catheter. Our results with the RMN irrigated tip catheter were encouraging since fewer switches to a cooled-tip manual catheter were needed (5 versus 1). Newer technologies which are emerging such as adjustable magnetic field strength might help to achieve even higher acute success rates.

There are several possible explanations for these mixed results. First of all, there are many anatomical variants in the cavotricuspid isthmus: the isthmus can vary in length, there may be pouch-like recessesses or a prominent Eustachian valve and the angle between the inferior vena cava and the isthmus have different degrees 9. Troublesome ablation of atrial flutter is associated with a longer cavotricuspid length and with a rectangular angle between the isthmus and the vena cava inferior 10. The maximum tissue force which can be applied by RMN is less than the average and significantly less than the maximal force which can be applied using a standard manual catheter 11. This can make it difficult to overcome some anatomical variations and to put the catheter parallel to the isthmus. When the catheter is placed more perpendicular than parallel to the tissue, the effective ablated contact area will decrease. When comparing lesions from magnetically steered catheters with standard manual catheters, the lesions from the former are more round or oval than elongated. The likelihood of seeing "brush lesions" as is common with the standard manual catheter is substantially less with the magnetically steered catheter. However, this "brush lesions" can actually be advantageous in the setting of flutter ablation12.

Particularly, when there is a rectangle between the isthmus and the vena cava inferior, it is sometimes difficult to have good wall contact at the transition of the isthmus and the vena cava inferior. Especially, an 8 mm magnetic catheter will have disadvantages both when the cavotricuspid isthmus is irregular, and when the angle with the vena cava inferior is sharp. The use of a RMN 8 mm tip catheter has been described in other studies. Vollmann et al. found that acute success rate was a reduced, more applications to obtain isthmus block were necessary, with longer procedural times and a reduced long-term success 13. Similar results have been presented with acute success ranging from 54% till 89% 14, 15. Only in one study a success rate of 100% was reported in a group of 24 patients 10. The use of the irrigated tip catheter could improve these results, since it is easier to titrate the energy, and as deeper lesions are formed.

The difference in procedural time is partly explained by the use of the electro-anatomical mapping system (CARTO) in the RMN group, even when activation was analysed. Since the EP recording system can not measure voltages, we needed to use this system to exactly measure the highest peak-to peak bipolar atrial electrograms. The combination of CARTO and RMN needs additional time for set-up and registering both systems and can explain a large part of the extra time needed in the RMN groups.

Maximum voltage technique

The approach using the maximum voltage technique led to a significant decrease in the number of applications compared to former approaches. In this series, we needed a median of 8 applications to achieve bidirectional block (conventional manual group). This is far less then the average of 23 applications when we created continuous lines as has been published before. 16. The procedural time decreased as well in the historical control group from 170 ±48 min to 106 ±53 min, fluoroscopy time from 29 ±15 min till 20 ±11 min 16. The aid of magnetic navigation however, did not add to a further decrease in the number of applications and fluoroscopy times as initially expected. This might be due as many of these procedures were done by in a training program, and because the set-up of the electromagnetic system required additional time in the RMN, which was shared with the intervention group.

Limitations

Whether a patient was appointed to the magnet group or the conventional group was based on the availability of the Stereotaxis room, and not to a randomization system. We did not perform angiography of the right atrium in order to assess the characteristics of the cavotricuspid isthmus. However, we have no reasons to presume that the distribution of the different anatomical variants is different between the 3 groups. Unfortunately, no comparison was made with a conventional irrigated tip group.

CONCLUSIONS

The use of magnetic navigation for the ablation of atrial flutter with the maximum voltage technique is feasible but not superior to a manual approach. Overall, more applications are needed and procedure times are longer (unfortunately influenced by other equipment in the two groups). Nevertheless, with RMN and irrigated tip technology, we required less often a switch to manual catheters, which is promising. Hopefully, further improvements in the catheter design and the magnetic navigation system such as an adjustable magnetic force can make this safe approach also more performing.

REFERENCES

1. Blomstrom-Lundqvist C, Scheinman MM, Aliot EM, Alpert JS, Calkins H, Camm AJ, Campbell WB, Haines DE, Kuck KH, Lerman BB, Miller DD, Shaeffer CW, Jr., Stevenson WG, Tomaselli GF, Antman EM, Smith SC, Jr., Faxon DP, Fuster V, Gibbons RJ, Gregoratos G, Hiratzka LF, Hunt SA, Jacobs AK, Russell RO, Jr., Priori SG, Blanc JJ, Budaj A, Burgos EF, Cowie M, Deckers JW, Garcia MA, Klein WW, Lekakis J, Lindahl B, Mazzotta G, Morais JC, Oto A, Smiseth O, Trappe HJ. ACC/AHA/ESC guidelines for the management of patients with supraventricular arrhythmias--executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Supraventricular Arrhythmias). Circulation. 2003;108(15):1871-1909.
2. Pappone C, Vicedomini G, Manguso F, Gugliotta F, Mazzone P, Gulletta S, Sora N, Sala S, Marzi A, Augello G, Livolsi L, Santagostino A, Santinelli V. Robotic magnetic navigation for atrial fibrillation ablation. J Am Coll Cardiol. 2006;47(7):1390-1400.
3. Thornton AS, Janse P, Theuns DA, Scholten MF, Jordaens LJ. Magnetic navigation in AV nodal re-entrant tachycardia study: early results of ablation with one- and threemagnet catheters. Europace. 2006;8(4):225-230.
4. Schwagten B, Cuypers J, Szili-Torok T. The magnetic navigation system allows avoidance of puncturing a baffle during ablation of a postincisional macroreentrant tachycardia. Cardiol Young. 2009:1-4.
5. Aryana A, d'Avila A, Heist EK, Mela T, Singh JP, Ruskin JN, Reddy VY. Remote magnetic navigation to guide endocardial and epicardial catheter mapping of scarrelated ventricular tachycardia. Circulation. 2007;115(10):1191-1200.
6. Cabrera JA, Sanchez-Quintana D, Farre J, Rubio JM, Ho SY. The inferior right atrial isthmus: further architectural insights for current and coming ablation technologies. J Cardiovasc Electrophysiol. 2005;16(4):402-408.
7. Redfearn DP, Skanes AC, Gula LJ, Krahn AD, Yee R, Klein GJ. Cavotricuspid isthmus conduction is dependent on underlying anatomic bundle architecture: observations using a maximum voltage-guided ablation technique. J Cardiovasc Electrophysiol. 2006;17(8):832-838.
8. Thornton AS, Maximo Rivero-Ayerza M, Jordaens LJ. Magnetic assisted navigation in electrophysiology and cardiac resynchronisation: a review. Indian Pacing Electrophysiol J. 2006;6(4): 202-213.
9. Heidbuchel H, Willems R, van Rensburg H, Adams J, Ector H, Van de Werf F. Right atrial angiographic evaluation of the posterior isthmus: relevance for ablation of typical atrial flutter. Circulation. 2000;101(18):2178-2184.
10. Kim AM, Turakhia M, Lu J, Badhwar N, Lee BK, Lee RJ, Marcus GM, Tseng ZH, Scheinman M, Olgin JE. Impact of remote magnetic catheter navigation on ablation fluoroscopy and procedure time. Pacing Clin Electrophysiol. 2008;31(11):1399-1404.
11. Faddis MN, Blume W, Finney J, Hall A, Rauch J, Sell J, Bae KT, Talcott M, Lindsay B. Novel, magnetically guided catheter for endocardial mapping and radiofrequency catheter ablation. Circulation. 2002;106(23):2980-2985.
12. Thornton AS, De Castro CA, van Deel E, van Beusekom HM, Jordaens L. An in vivo comparison of radiofrequency cardiac lesions formed by standard and magnetically steered 4 mm tip catheters. Neth Heart J.2010 18(2):66-71. 13. Vollmann D, Luthje L, Seegers J, Hasenfuss G, Zabel

M. Remote magnetic catheter navigation for cavotricuspid isthmus ablation in patients with common-type atrial flutter. Circ Arrhythm Electrophysiol. 2009;2(6):603-610.

14. Koektuerk B, Chun J, Schmidt B, Metzner A, Tilz R, Ernst S, Koester I, Ouyang F, Kuck KH. Remote controlled catheter ablation of typical atrial flutter: A preliminary comparison of the magnetic 8 mm tip catheter versus the novel 3.5 mm irrigated tip magnetic catheter (Abstract). Europace. 2008(10):i176.
15. Preminger M, Kamath G, Sichrovsky T, Arshad A, Mittal S, Steinberg J. Early experience with remote magnetic navigation ablation of cavotricuspid isthmus. Potential limitations (Abstract). Heart Rhythm. 2009;6:S61.
16. Thornton AS, Janse P, Alings M, Scholten MF, Mekel JM, Miltenburg M, Jessurun E, Jordaens L. Acute success and short-term follow-up of catheter ablation of isthmusdependent atrial flutter; a comparison of 8 mm tip radiofrequency and cryothermy catheters. J Interv Card Electrophysiol. 2008;21(3):2

Chapter 4

Initial experience with catheter ablation using remote magnetic navigation in adults with complex congenital heart disease and in small children

Bruno Schwagten, MD, Luc Jordaens, MD, PhD, Martin Witsenburg, MD, Frederik Duplessis, MD, Andrew Thornton, MD, PhD, Yves Van Belle, MD, and Tamas Szili-Torok, MD, PhD.

ABSTRACT

Background: The improved outcomes and increased availability of surgery for congenital heart disease (CHD) over the last three decades have created a small but steadily increasing subset of patients with unique needs: children and adults with complex arrhythmias in the setting of structural cardiac abnormalities. Radiofrequency catheter ablation (RFCA) in these patients, and in small children with normal cardiac anatomy, is effective but challenging. An understanding of specific anatomical and electrophysiological characteristics of these patients and the technical challenges in addressing them are critical to the success of this therapy. Tools specifically designed for intracardiac diagnosis and therapy in anatomically complex and/or small hearts remain scarce. Aims: We report single-center results from an ongoing registry of all patients with congenital heart disease and all children with complex arrhythmias in which the Magnetic Navigation System (MNS) was used. Results: Included in this report are 12 patients with CHD in whom 17 tachyarrhythmias were treated, and 11 pediatric patients with normal cardiac anatomy who each had a single arrhythmia. The procedures' duration and the duration of fluoroscopy time as well as arrhythmia recurrence rates were comparable to those found in previous reports of procedures performed in adults with structurally normal hearts, and the incidence of complications was quite low.
Discussion: In patients with complex congenital malformations, retrograde mapping of the pulmonary venous atrium was feasible, eliminating the need for puncture of the atrial septum, or surgically placed baffle in many cases. Moreover, the design of the catheter eliminated the need for multiple mapping and ablation catheters.
Conclusion: Our findings suggest that RFCA using the MNS for arrhythmias after surgery for congenital heart disease and in pediatric patients is safe and effective.

Key words: magnetic navigation, radiofrequency ablation, congenital heart disease, pediatrics

INTRODUCTION

The improved outcomes and increased availability of surgery for congenital heart disease (CHD) over the last three decades have created a small but steadily increasing subset of patients with unique needs: children and adults with complex arrhythmias in the setting of structural cardiac abnormalities. In these patients, arrhythmias may be related to suture lines, surgical scars, or myocardial abnormalities secondary to chronic chamber dilatation or increased wall stress.1,2,3 In addition, the use of radiofrequency catheter ablation (RFCA) has become more common for the treatment of arrhythmias in children with normal hearts. RFCA is effective in these patients,4 however, technically challenging. There are few tools specifically designed for intracardiac diagnosis and therapy in small and anatomically abnormal hearts. Believing that the use of the remote magnetic navigation system (MNS) could overcome some of the technical difficulties encountered in these patients, we evaluated the feasibility of its use in our patients with CHD and in small children presenting with complex arrhythmias. While the number of patients in our series is relatively small, it is of interest given the paucity of published information on the use of MNS in similar patients.

PATIENTS AND METHODS

All children with complex arrhythmias as well as all patients with CHD who were treated at our center with RFCA using MNS are included in this report. Information on these patients was obtained from an ongoing registry of such patients. The pediatric group consisted of 11 patients who ranged in age from 5 to 14 years (median = 10 years), in height from 103 to 161 cm (median = 130 cm), and in weight from 17 to 49 kg (median = 31 kg). The tachyarrhythmias treated were atrioventricular node reentry in one, atrial tachyarrhythmias in two, left-sided accessory pathways in four, and right-sided accessory pathways in four patients. All children had structurally normal hearts. The CHD group included 12 patients ranging in age from 16 to 61 years (median = 32.5 years). The underlying heart diseases were surgically repaired ventricular septal defect, surgically corrected tetralogy of Fallot, surgically repaired atrial septal defect, dextrocardia with anomalous pulmonary veins, pulmonary stenosis status postmyectomy, and pulmonary artery homograft each in one patient, transposition of the great arteries status post-Mustard's operation in two patients, and single ventricle status post-Fontan's operation in five patients. Ablation Procedures in Children
All procedures were performed under general anesthesia. A standard diagnostic electrophysiologic (EP) study was performed. After obtaining femoral venous access, heparin was given and diagnostic catheters were positioned in the coronary sinus, at the His bundle and in the right ventricular apex. Access to the left side of the heart, when necessary, was achieved using either a retrograde or transseptal approach. After standard EP measurements

were made, the magnetic-guided catheter (Celsius RMT, 4 mm, Biosense Webster, Diamond Bar, CA, USA) was introduced into the heart. The principles and use of the MNS have been described in detail previously by our group.5,6 The Niobe MNS (Stereotaxis Inc., St. Louis, MO, USA) consisted of two permanent magnets situated on either side of the patient, which were computer controlled via a workstation (Navigant, Stereotaxis Inc.) to allow for changes in the orientation of a stable magnetic field within the chest of the patient. A combined field strength of 0.08 T was produced in navigation mode. As navigation was best performed with a fixed table position, this was optimized prior to the start of magnetic navigation. When the magnets were positioned next to the patient, only limited angulation of the C-arm was possible (~28° in the right and left anterior oblique angulations). Remote catheter advancement and retraction from the control room were performed using a catheter advancer system, CardiodriveTM (Stereotaxis Inc.), positioned on the high anterior thigh. Remote control of the fluoroscopy system was also performed from the control room. The ablation catheters, with multiple magnets within the distal tip segment, aligned themselves with the field produced by the external magnets, allowing effective catheter orientation. The remote workstation in conjunction with the Cardiodrive unit allowed precise orientation of the catheter by 1° increments and by 1-mm steps in advancement or retraction. The system was controlled by joystick or mouse and allowed remote control of the ablation catheter from inside the control room. After the magnets were brought in next to the patient, the physician was free to leave the room and perform the rest of the procedure from the control room. A single nurse remained with the sedated patient to administer drugs, as needed. Vital signs were monitored from the control room by the anesthesiologist. The MNS catheter was used to determine the mechanism and chamber of origin of the tachyarrhythmia and the appropriate site for ablation; the same 4-mm tip magnetic-guided catheter was used to deliver the radiofrequency energy. The procedure was considered complete when the target arrhythmia could no longer be induced. Ablation Procedures in Patients with Congenital Heart Disease As in the pediatric patients, vascular access was obtained, heparin was given, and a standard diagnostic EP study was performed using both a screw-in electrode (Medtronic Inc., Minneapolis, MN, USA), attached to the septal area of the systemic venous atrium in most cases, and the magnetic-guided catheter (Navistar RMT DS, 8-mm, Biosense Webster). After induction of tachyarrhythmia by programmed stimulation, a voltage and activation map was created using the MNS in combination with the CARTO TM navigation system (Biosense Webster, Fig. 1). In all patients who had previously undergone Fontan's procedure for treatment of single ventricle-type CHD or Mustard's procedure for correction of transposition of the great arteries, a biatrial voltage and activation map was created. Whenever possible, we tried to avoid puncture of a baffle by using the retrograde transaortic approach to map the pulmonary venous atrium. In two patients, however, a baffle puncture had to be performed due to the presence of a mechanical valve prosthesis. We used transesophageal echocardiography in one patient and intracardiac echocardiography in the other, to guide

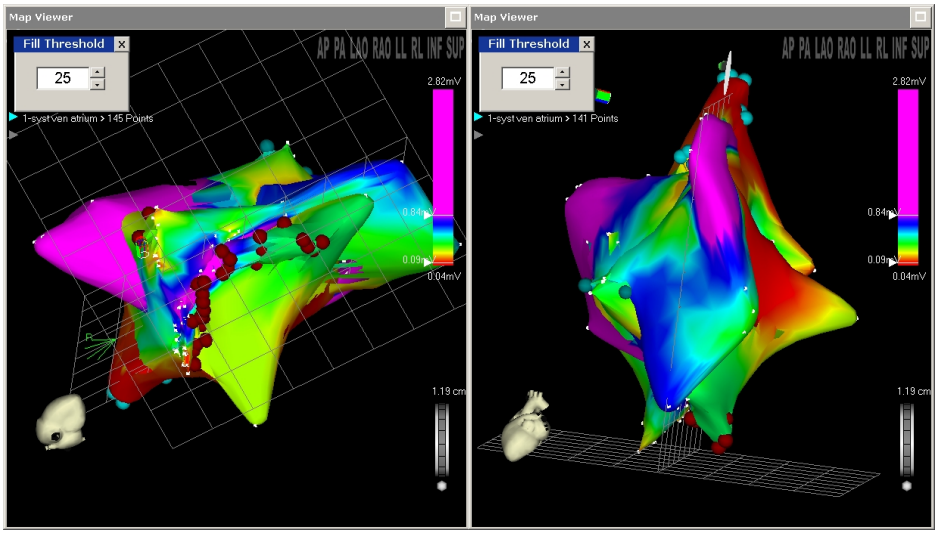


Figure 1. Biatrial voltage CARTO maps in a patient with transposition of the great arteries, status post-Mustard's operation (inferior and LAO views). The extremely floppy and maneuverable magnetic navigation catheter was used to map both atria, reaching the pulmonary venous atrium via an existing interatrial connection (baffle).

the transseptal puncture with a manually modified Brockenbrough needle. To determine the optimal ablation site in patients who had undergone these surgical procedures, we used the "no channel—no reentry" strategy. On the detailed CARTO map we could discern, among regions of scar tissue, different channels of conductive tissue with potential of becoming a substrate for macro-reentrant tachycardia. After identification of the arrhythmia substrate, ablation was performed using the same 8-mm tip magnetic-guided catheter. The procedure was considered complete when the target arrhythmia was no longer inducible.

Statistical Analysis

All results are descriptive, and are expressed as ranges and median.

RESULTS

In the pediatric group, the procedures ranged from 80 to 300 minutes in duration (median = 130 minutes), and fluoroscopy time ranged from 2 to 58 minutes (median = 16 minutes). Each patient was treated with one to 19 RF applications (median = three applications). All procedures were immediately successful, although tachyarrhythmias recurred in two patients at 3 and 12 months, respectively. In the CHD group, 17 tachyarrhythmias were treated in 12 patients, including two cavotricuspid isthmus-dependent flutters, five focal atrial tachyarrhythmias, and 10 incisional macro-reentrant tachyarrhythmias. Procedure times ranged

from 120 to 540 minutes (median = 240 minutes), and fluoroscopy time ranged from 12 to 85 minutes (median = 39.4 minutes). Each patient was treated with two to 105 applications (median = 26 applications) of RF energy. Among the 12 patients, 11 were free from inducible arrhythmias at the end of the procedure; three had recurrences of arrhythmia at follow-up of 4–6 months. None of the 23 patients developed pericardial effusion, tamponade, or embolic events in association with the procedure. A fever developed following the procedure in one patient who was diagnosed with Staphylococcus aureus bacteremia; therapy with antibiotics was initiated and the patient recovered without sequelae.

DISCUSSION

RFCA of tachyarrhythmias in patients with complex CHD and in small children requires considerable expertise, acquired through both training and practical experience. Although the number of such patients is increasing as a result of successful surgical and medical management of complex CHD and improved clinical diagnosis, they remain a very small minority among patients treated for arrhythmias, making it difficult for most electrophysiologists to become expert in their care. Another consequence of their small numbers is that there are few if any tools specifically designed for intracardiac diagnosis and treatment of electrophysiologic disorders in very small and/or structurally abnormal hearts.

MNS offers several potential advantages in treating these patients. The MNS catheter is floppy and a-traumatic, reducing the risk of perforation, and can easily pass through fenestrations associated with previous surgery. It can be passed retrogradely into the pulmonary venous atrium via the arterial approach, eliminating the need for transseptal puncture. At the same time, the catheter has excellent navigation characteristics, and is quite stable once positioned. In many cases, it can be used for complete mapping and RF delivery, eliminating the need for multiple catheters with different curvatures. These characteristics should result in more accurate and effective transmural lesions, especially when used with 3D imaging techniques such as computed tomography, magnetic resonance imaging, and ultrasound.

Our results reflect these advantages. The procedure and fluoroscopy times compare favorably with those reported previously when the MNS was used in adult patients with normal hearts.7,8 Immediate success was achieved in nearly all patients and the recurrence rate was fairly low. No major complications such as pericardial effusion, cardiac tamponade, or stroke occurred. One technical issue noted when using the Navistar RMT DS 8-mm tip catheter was frequent char formation on the tip during RF application, impairing energy delivery to the tissue, necessitating regular cleaning of the catheter tip after RF application.

CONCLUSION

Our experience suggests that RFCA using MNS for arrhythmias occurring after surgery for CHD and in pediatric patients is safe and effective. Procedure and fluoroscopy times were comparable to those previously reported, and no procedural complication occurred. The design of the MNS catheter offers multiple advantages in the treatment of these very challenging patients.

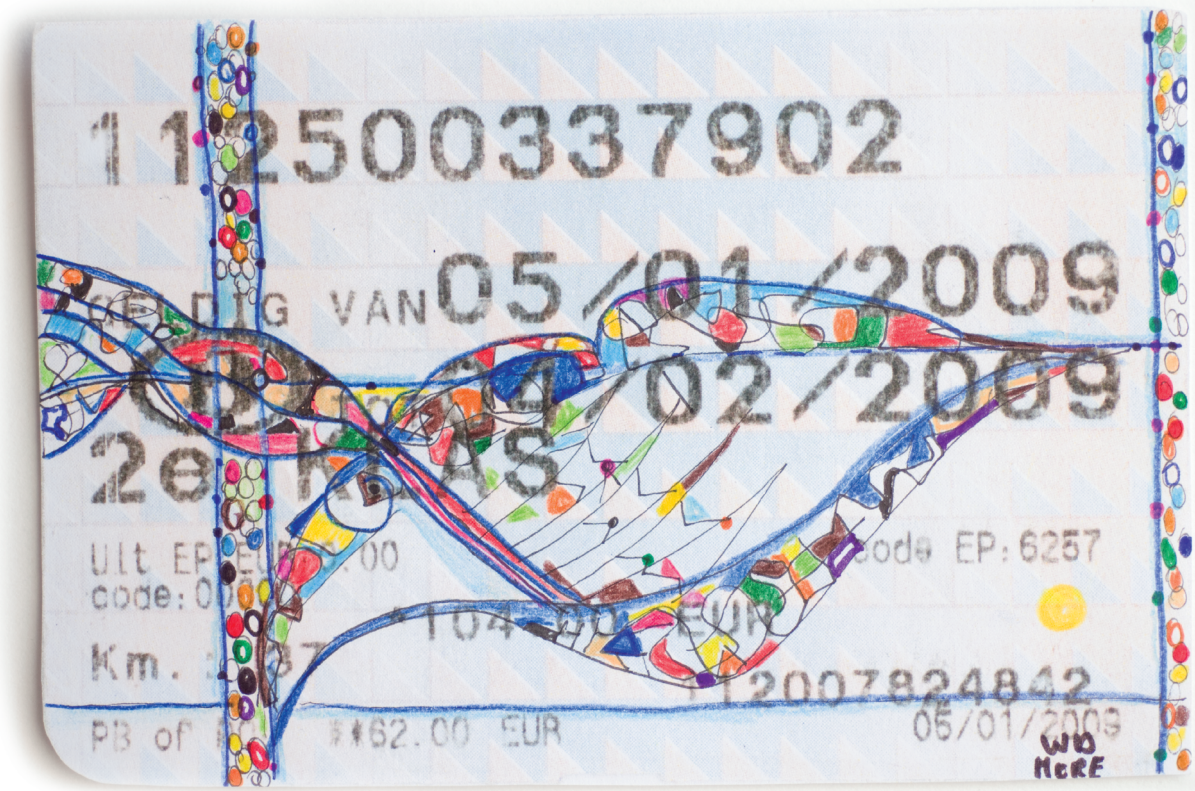
REFERENCES

1. Roos-Hesselink J, Perlroth MG, McGhie J, Spitaels S. Atrial arrhythmias in adults after repair of tetralogy of Fallot. Correlations with clinical, exercise, and echocardiographic findings. Circulation 1995; 91:2214–2219.
2. Balaji S, Harris L. Atrial arrhythmias in congenital heart disease. Cardiol Clin 2002; 20:459–468, vii.
3. Magnin-Poull I, De Chillou C, Miljoen H, Andronache M, Aliot E. Mechanisms of right atrial tachycardia occurring late after surgical closure of atrial septal defects. J Cardiovasc Electrophysiol 2005; 16:681–687.
4. Szili-Torok T, Kornyei L, Jordaens L. Transcatheter ablation of arrhythmias with congenital heart disease. J Interv Card Electrophysiol 2008; 22:161–166.
5. Thornton AS, Jordaens LJ. Remote magnetic navigation for mapping and ablating right ventricular outflow tract tachycardia. Heart Rhythm 2006; 3:691–696.
6. Thornton AS, Janse P, Theuns DAMJ, Scholten MF, Jordaens LJ. Magnetic navigation in AV nodal reentrant tachycardia study: Early results of ablation with one-and three-magnet catheters. Europace 2006; 8:225–230.
7. Thornton AS, Rivero-Ayerza M, Knops P, Jordaens LJ.Magnetic navigation in left-sided AV reentrant tachycardias: Preliminary results of a retrograde approach. J Cardiovasc Electrophysiol 2007; 18:467–472.
8. Chun JK, Ernst S, Matthews S, Schmidt B, Bansch D, Boczor S, Ujeyl A, et al. Remote-controlled catheter ablation of accessory pathways: Results from the magnetic laboratory. Eur Heart J 2007; 28:190–195.

Chapter 5

Effect of magnetic navigation system on procedure times and radiation risk in children undergoing catheter ablation

Bruno Schwagten MD, Maarten Witsenburg, MD, Natasja MS De Groot MD, PhD, Luc Jordaens MD, PhD, Tamas Szili-Torok MD, PhD



ABSTRACT

Background: Transcatheter ablation is an effective method to eliminate the arrhythmogenic substrate in symptomatic children with various types of arrhythmias. A reduction in procedure and fluoroscopy time decreases hazardous effects of ablation. The magnetic navigation system (MNS) utilizes atraumatic catheters and allows attainment of all targeted regions for mapping and treatment. Aim: to compare the efficacy and safety between a manual and MNS guided approach for mapping and ablation of arrhythmias in a general pediatric arrhythmia population and in a subgroup of young children aged less than 10 years. Results: 58 pediatric patients (mean age: 12,2 ± 3,2 years) were included into this study. Twenty-nine consecutive patients were treated with MNS system, while 29 consecutive patients underwent conventional manual ablation. There were no demographic differences between the groups. Acute success was achieved in 26 out of 29 vs. 27 out of 29 patients (p=NS). Mean procedure and fluoroscopy times were comparable in both study groups (168 ± 56 vs. 183 ± 52, p= NS, 22 ± 59 vs. 30 ± 29, p= NS). In young children (age under 10 years), success rate did not differ between the groups (10/11 vs. 6/8, p= NS). However, significant decrease in procedure and fluoroscopy times were achieved (139 ± 57 vs. 204 ± 49 min and 13 ± 7 vs. 31 ± 28 min, respectively, p=0,01 and p=0,04). Conclusion: Our data strongly suggest that using the MNS for treating young children is advantageous because it significantly reduces procedure and fluoroscopy times without compromising efficacy.

Key Words: Magnetic navigation system, children, ablation, reduction fluoroscopy time

INTRODUCTION

Transcatheter ablation is an effective method for eliminating the arrhythmogenic substrate in symptomatic children with various types of tachyarrhythmias [1-4]. Safety is without a doubt a crucial issue in these young and vulnerable patients. Unfortunately, in small-sized children only a limited number of dedicated devices (i.e.: significantly smaller in size and with specially designed curves) are available for ablation procedures. Reduction of procedure and fluoroscopy times decreases hazardous effects of ablation such as complications and the potential long-term effects of radiation exposure, such as leukemia and a whole spectrum of solid cancers [5 6 7]. The magnetic navigation system (Niobe, Stereotaxis, St Louis, MO, USA)(MNS) combines several possible advantages: it utilizes atraumatic catheters, with superior navigation capabilities and allows attainment of all targeted regions for mapping and treatment [8 9 10]. In our study we aimed to compare the efficacy and safety between manual and MNS guided approach for the mapping and ablation of tachyarrhythmias in a general pediatric population and in a subgroup of young children.

METHODS

Patients

In our centre patients were recruited from an ongoing registry of all children with complex arrhythmias. Patients treated using the MNS were included consecutively into this study from the time when the MNS was introduced into our hospital for ablation of paediatric patients. All paediatric patients were treated with the MNS from this moment on. A control group of manually ablated patients was accumulated in the same consecutive fashion in the period directly before the introduction of the MNS. This means that patients with different tachyarrhythmias were included into the study and only those with a parahisian substrate were excluded. Informed consent was obtained from the parents of the patients who were younger than 18 years old. Amiodarone was discontinued for at least 1 month and all other antiarrhythmic agents were discontinued for at least 5 half-lives before the procedure. The operators were the same for both groups. All procedures were performed under general anaesthesia. Data was collected regarding procedural time, use of fluoroscopy, acute success and procedure related complications. Procedural time was measured from the time of puncturing the vein until the time of removal of the sheaths from the groin, including the 30 minutes waiting period after a successful ablation.

Electrophysiologic assessment

The diagnosis of both dual AV nodal pathways, atrioventricular nodal reentrant tachycardia (AVNRT), circle mediated tachycardia (CMT) or atrial tachycardia (AT), was made on the basis

of standard diagnostic criteria. The earliest retrograde atrial activation during both tachycardia and premature ventricular complexes was registered. Single premature atrial and ventricular stimuli were applied during tachycardia while the His bundle was refractory to assess if tachycardia could be reset. This confirmed the presence or absence of an accessory pathway. In patients with manifest pre-excitation, the site that showed the earliest ventricular activation was identified. If sustained tachycardia could not be induced an infusion of isoprenaline was given. In case of an accessory pathway, the final classification was made according to the successful ablation site. In patients suspected of having an AT a 3D electroanatomical voltage and/or activation map (CARTO, Biosense-Webster Inc, Diamond Bar, CA, USA) was made.

Manual RF ablation

Manual RF catheter ablation was performed using a 4-mm, solid-tip, ablation catheter (Biosense-Webster Inc, Diamond Bar, CA, USA) in a temperature controlled mode (maximum temperature 55°C, maximum duration 60 seconds, maximum 40 W) with the use of a Stockert RF generator (Biosense-Webster Inc, Diamond Bar, CA, USA).

Magnetic navigation system ablation

Catheter ablation using the MNS was performed using a 4mm tip catheter (Celsius or Navistar RMT DS, Biosense-Webster Inc, Diamond Bar, CA, USA) with the use of the same Stockert RF generator (Biosense-Webster Inc, Diamond Bar, CA, USA). The principles and use of the MNS have already been extensively described previously by our group [8].

Atrioventricular nodal re-entrant tachycardia

In patients with AVNRT our target was elimination of the slow pathway. The ablation was guided using a combination of fluoroscopic images and electrograms (EGM). The procedural endpoint was defined as non-inducibility of the tachycardia. Inducibility was tested after each application. If non-inducible the test was repeated after a 30 min waiting period. Procedure time was recorded from the moment of puncturing the femoral vein in the EP lab until the removal of the sheath from the femoral vein, including the 30 minute waiting period.

Atrial tachycardia

In patients with an AT a 3D electroanatomical voltage and/or activation map (CARTO, Biosense-Webster Inc, Diamond Bar, CA, USA) was created. The procedural endpoint was again defined as non-inducibility of the tachycardia. Procedural time was measured in the same fashion and also included the 30 minute waiting period.

Accessory pathway

In patients with a CMT the objective of the ablation was abolition of conduction over the accessory pathway. Procedural time was measured in the same fashion and also included the 30 minute waiting period.

Follow-up

Twenty-four hours after receiving treatment patients were re-evaluated clinically and an electrocardiogram and a transthoracic echocardiographic examination were performed.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation, if normally distributed, or otherwise by median. The Students t-test or analysis of variance were used when appropriate. A Chi-square test was used for categorical data. The level of significance was set at $p < 0.05$. All statistics were performed using SPSS (16.0) for Windows (Chicago, Il, USA).

RESULTS

Patient data

Fifty-eight pediatric patients (mean age: 12,2 ± 3,2 years) were included into this study. Twenty-nine consecutive patients were treated with the MNS system, while 29 consecutive patients underwent conventional manual ablation. There were no demographic differences between the groups (MNS: age 12,1 ± 3,0, AVNRT: 4, AT: 3, RAP: 10, LAP: 12 pts vs. conventional group: age: 12,3 ± 3,4, AVNRT 7, AT 1, RAP 11, LAP 10, p= NS) (Table I).

Table 1 Patient and procedural data

Variable	MNS (n = 29)	Manual (n = 29)
Age (years)	12.1 ± 3.0	12.3 ± 3.4
Weight (kg)	28 ± 4.0	30 ± 4.5
Males	14 (48%)	16 (55%)
Atrioventricular nodal re-entrant tachycardia	4 (14%)	7 (24%)
Atrial tachycardia	3 (10%)	1 (3%)
Right-side accessory pathway	10 (34%)	11 (39%)
Left-side accessory pathway	12 (42%)	10 (34%)
Procedural time (min)	168 ± 56	183 ± 52
Fluoroscopy time (min)	22 ± 59	30 ± 29
Acute success	26 (90%)	27 (93%)
Complications	0	0

Data are presented as mean ± SD or numbers (%).
No significant differences were observed between 2 groups.

Procedure and ablation data

Acute success was achieved in 26 out of 29 vs. 27 out of 29 pts (p=NS). The mean procedure and fluoroscopy times were not different between the study groups (168 ± 56 vs. 183 ± 52, p= NS, 22 ± 59 vs. 30 ± 29, p= NS). No complications occurred. A subgroup analysis was performed selecting only young children aged less than 10 years (Table II). The success rate did not differ between the groups (10/11 vs. 6/8, p= NS). However, a significant decrease in procedure and fluoroscopy time was achieved (139 ± 57 vs. 204 ± 49 min and 13 ± 7 vs. 31 ± 28 min, respectively p=0,01 and p=0,04).

Table 2 Patient and procedural data of subgroup of young children (aged 10 years)

Variable	MNS	Manual
Patients (n)	11 (58%)	8 (42%)
Age (years)	8.9 ± 1.0	7.8 ± 3.0
Atrioventricular nodal re-entrant tachycardia	1 (9%)	0
Atrial tachycardia	3 (27%)	0
Right-sided accessory pathway	5 (45%)	3 (38%)
Left-sided accessory pathway	2 (19%)	5 (62%)
Procedural time (min)	139 ± 57*	204 ± 49*
Fluoroscopy time (min)	13 ± 7†	31 ± 28†
Acute success	10 (91%)	6 (75%)
Complications	0	0

Data are presented as mean ± SD or numbers (%).
* p = 0.01; † p = 0.04.

DISCUSSION

The major finding of this study is that using the magnetic navigation system in young children is advantageous because it significantly reduces procedure and fluoroscopy times without compromising efficacy.

The rationale of using the magnetic navigation system

Before the introduction of the MNS at our center, we had already developed a longstanding experience in ablation of arrhythmias in children. Nevertheless, to increase safety even more [11], we switched from manual ablation to MNS guided ablation for all pediatric patients shortly after the MNS became available.

The lack of dedicated devices for small hearts

Until now, dedicated devices designed especially for use in young children were very scarce. The different catheters which are at our disposition have been developed mainly for use in adults. When performing an electrophysiology study and ablation in children, we need to be

aware not only of the difference in scale between an adult heart and a paediatric heart, but also we need to realize that the morphology is somewhat different in children than in adults. For example the position of the ostium of the coronary sinus usually is far more caudal in children than in adults. These morphological differences compel us to be even more careful in treating these children. Even more so than in adult patients, this gives rise to the need to be extra cautious when manipulating these oversized and relatively stiff catheters inside the heart. As a consequence it is rather difficult to gain access to certain remote areas inside the heart of these young children. When using the magnetic navigation system, it is possible to gain access to even the most remote areas in the heart. The floppy magnetically steered catheter allows us to navigate freely inside the heart without fear of perforating the myocardium (Figure 1). Furthermore it is possible to make several consecutive bends in different directions with this extremely steerable catheter. The ease of this unrestricted

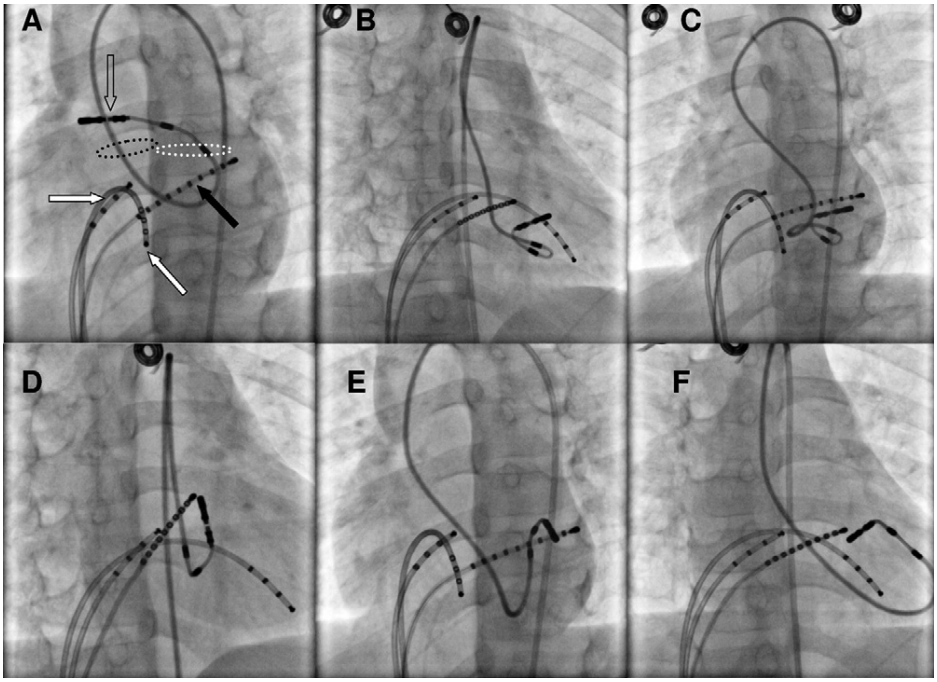


Figure 1. Different fluoroscopic views of the heart in a 9-year old child. A decapolar catheter is positioned in the coronary sinus, one quadripolar catheter is on the His and one is positioned in the right ventricular apex. The magnetically steered catheter is retrogradely advanced into the left ventricle in order to ablate a left sided accessory pathway. The different views depict the extreme flexibility of the magnetically steered catheter. Panel A: tip of the catheter is retrogradely advanced through the aortic valve via the left ventricle and the mitral valve into the ostium of the right inferior pulmonary vein. Panel B and C: the catheter can be navigated freely in the left ventricle without fear of perforating the myocardium. Panel D to F: finally the is positioned on left sided accessory pathway and a successful RF ablation was performed.

manoeuvrability is a possible explanation for the decrease in procedural and fluoroscopy times in young children.

Radiation hazard/vulnerability in young children

It has indisputably been proved that children are ten times more sensitive than adults to the induction of cancer by external radiation exposure [6]. Radiation exposure causes an excess incidence of leukemia and a whole spectrum of solid cancers. This risk varies dramatically with age. Young children are most vulnerable to the effects of radiation. The risk decreases with age. Particularly at early ages there seems to be also a gender difference with girls being more radiosensitive than boys. Iatrogenic induction of any form of cancer in children is without a doubt a major concern. Especially when the detrimental radiation is used to cure an in most cases benign disease. So every effort is needed to try to minimize effective radiation doses. Our data suggest that using the MNS for ablation in children and especially young children significantly reduces fluoroscopy times without compromising efficacy. Reduction of fluoroscopy times seems to be a general finding whenever the MNS is used [12].

Improved safety

Ever since RF catheter ablation established itself as an effective method to eliminate the arrhythmogenic substrate in symptomatic children with various types of arrhythmias, the challenge remained to avoid ablation-induced complications [13,14]. The use of the MNS in young children has several possible advantages. First of all our data suggest that using the MNS in young children results in shorter procedural and fluoroscopy times. This decreases hazardous effects of ablation such as complications and the potential long-term effects of radiation exposure in these very young patients. Secondly only a limited number of dedicated devices for young children are available for manual ablation procedures , the risk of perforating the myocardium when using these relatively stiff and oversized manually manipulated catheters remains. However, when using the MNS, creating a perforation of the myocardium with the floppy magnetically steered catheter is virtually impossible. Furthermore, absolute catheter stability during ablation decreases the risk of damaging vital areas of conduction.

Complications

Shorter procedural times when using the MNS decrease the chance for acute complications, which is without a doubt a definite advantage. The beneficial effects of reducing fluoroscopy times in these young children are not to be noticed acutely. Although there is no absolute proof, one can imagine the benefit of reducing the exposure to long periods of radiation of these young patients in the long run. Off course also the reduction of radiation exposure of the physician is a major step in the right direction. In most of our procedures performed with the MNS, the radiation exposure of the physician is virtually zero. The radiation dose caught by the physician is limited to the time needed to position the different electrophysiological

catheters inside the heart since the rest of the procedure is performed in a remote fashion from the workstation.

Cost- efficacy

Surely purchasing the MNS is a huge investment and the limited number of patients in our study do not allow us to perform a thorough cost-efficacy evaluation. On one hand ablation of tachycardia`s in young children should be preferably done in high volume centres with a longstanding experience in this field. The number of these kind of procedures performed in these high volume centres and the possibility of using the MNS for numerous other procedures could allow this technique to become cost-effective. On the other hand one can imagine this technique could lower the threshold to perform radiofrequency catheter ablation in young children even in low-volume centres equipped with a MNS, given the safety of catheter handling. However, we do not encourage this unless the operator has acquired a lot of experience in treating arrhythmias in young children.

Issues to be resolved

Acute success is high in both the manual and the MNS group. Whether these results remain in the long run needs to be investigated. Most diagnostic catheters used are still rather stiff and relatively large for use in young children. Downsizing of catheters and development of more specific tools for the paediatric population could be helpful.

CONCLUSION

In conclusion, using the MNS to treat tachyarrhythmias in children is effective and safe in comparison to manual RF ablation. But more specifically taking into account our data, we can strongly suggest using the MNS for RF catheter ablation in young children as this significantly reduces procedure and fluoroscopy times without compromising efficacy.

REFERENCES

1. Dick M, 2nd, O'Connor BK, Serwer GA, LeRoy, S. Armstrong, B. Use of radiofrequency current to ablate accessory connections in children. Circulation. Dec 1991;84:2318-2324.
2. Van Hare GF, Javitz H, Carmelli D, Saul J P, Tanel R E, Fischbach P S, Kanter R J, Schaffer M, Dunnigan A, Colan S, Serwer G. Prospective assessment after pediatric cardiac ablation: recurrence at 1 year after initially successful ablation of supraventricular tachycardia. Heart Rhythm. Jul 2004; 1:188-196.
3. Van Hare GF, Javitz H, Carmelli D, Saul JP, Tanel R E, Fischbach PS, Kanter RJ, Schaffer M, Dunnigan A, Colan S, Serwer G. Prospective assessment after pediatric cardiac ablation: demographics, medical profiles, and initial outcomes. J Cardiovasc Electrophysiol. Jul 2004;15:759-770.
4. Van Hare GF, Colan SD, Javitz H, Carmelli D, Knilans T, Schaffer M, Kugler J, Byrum C J, Saul JP. Prospective assessment after pediatric cardiac ablation: fate of intracardiac structure and function, as assessed by serial echocardiography. Am Heart J. May 2007;153:815-820, 820 e811-816.
5. Rueter FG. Physician and patient exposure during cardiac catheterization. Circulation. Jul 1978; 58:134-139.
6. Hall EJ. Lessons we have learned from our children: cancer risks from diagnostic radiology. Pediatr Radiol. Oct 2002;32:700-706.
7. Petridou E, Trichopoulos D, Dessypris N, Flytzani V, Haidas S, Kalmanti M, Koliouskas D, Kosmidis H, Piperopoulou F, Tzortzatou F. Infant leukaemia after in utero exposure to radiation from Chernobyl. Nature. Jul 25 1996;382:352-353.
8. Thornton AS, Janse P, Theuns DA, Scholten MF, Jordaens LJ. Magnetic navigation in AV nodal re-entrant tachycardia study: early results of ablation with one- and three-magnet catheters. Europace. Apr 2006;8:225-230.
9. Rivero-Ayerza M, Thornton AS, Theuns DA, Scholten MF, Mekel JM, Res J, Jordaens LJ. Left ventricular lead placement within a coronary sinus side branch using remote magnetic navigation of a guidewire: a feasibility study. J Cardiovasc Electrophysiol. Feb 2006;17:128-133.
10. Schwagten B, Jordaens L, Witsenburg M, Duplessis F, Thornton A, Van Belle Y, Szili-Torok T. Initial experience with catheter ablation using remote magnetic navigation in adults with complex congenital heart disease and in small children. Pacing Clin Electrophysiol. Mar 2009;32 Suppl 1: S198-201.
11. Ernst S, Ouyang F, Linder C, Hertting K, Stahl F, Chun J, Hachiya H, Bansch D, Antz M, Kuck KH. Initial experience with remote catheter ablation using a novel magnetic navigation system: magnetic remote catheter ablation. Circulation. Mar 30 2004;109:1472-1475.
12. Wood MA, Orlov M, Ramaswamy K, Haffajee C, Ellenbogen K. Remote magnetic versus manual catheter navigation for ablation of supraventricular tachycardias: a randomized, multicenter trial. Pacing Clin Electrophysiol. Oct 2008;31:1313-1321.
13. Bertram H, Bokenkamp R, Peuster M, Hausdorf G, Paul T. Coronary artery stenosis after radiofrequency catheter ablation of accessory atrioventricular pathways in children with Ebstein's malformation. Circulation. Jan 30 2001;103:538-543.
14. Schaffer MS, Silka MJ, Ross BA, Kugler JD. Inadvertent atrioventricular block during radiofrequency catheter ablation. Results of the Pediatric Radiofrequency Ablation Registry. Pediatric Electrophysiology Society. Circulation. Dec 15 1996;94:3214-3220.

Chapter 6

The magnetic navigation system allows avoidance of puncturing a baffle during ablation of a postincisional macroreentrant tachycardia

Bruno Schwagten, MD, Judith Cuypers, MD, Tamas Szili-Torok, MD, PhD

ABSTRACT

An 18-year-old female patient with tricuspid atresia, discordant ventriculo-arterial connections, a total cavo-pulmonary connection, and a Damus-Kaye-Stansel suffered with atrial tachycardia. Use of a magnetically navigated catheter made it possible to create an electro-anatomical map of both atriums using a retrograde approach. It then proved possible to ablate successfully the tachycardia in the left atrium thanks to the unique capabilities of the magnetic navigation system.

Key words: Arrhythmias; atrial tachycardia; radiofrequency catheter ablation

INTRODUCTION

Even for experienced operators, puncturing a surgically created intra-atrial baffle can be a challenging procedure.1–5 The magnetic navigation system, however, offers the advantage of using an extremely flexible, steerable, and non-traumatic catheter. 6,7 In this presentation, we describe the utility of such a system in structurally and functionally modified hearts.

CASE REPORT

An 18-year-old female was referred because of multiple recurrences of atrial tachycardia 2 years after an apparently successful catheter ablation. At birth, she had been diagnosed with tricuspid atresia, discordant ventriculo-arterial connections, and aortic coarctation. At an initial surgical procedure, the coarctation was corrected and a band placed on the pulmonary trunk. After a period of 1 year, a bidirectional Glenn shunt was created, and the ventricular septal defect was enlarged. After another 3 years, the pulmonary trunk was closed proximally, and the systemic venous atrium was connected directly to the pulmonary arteries. She then developed severe mitral valvar insufficiency at the age of 10 years, requiring surgical repair. At the same intervention, a total cavo-pulmonary connection was made using an intra-atrial tunnel, connecting the pulmonary trunk end-to-side to the aorta as the Damus-Kaye-Stansel procedure (Fig. 1). Subsequently, the patient developed multiple episodes of atrial tachycardia with a fast ventricular response, leading to near-syncope on many occasions, and necessitating frequent electrical cardioversions. Pharmacological treatment did not alleviate the symptoms, and caused unacceptable side-effects. An epicardial dual chamber pacemaker was implanted because of severe and symptomatic bradycardia. An electrophysiological study resulted in mapping and ablation of two scar-related tachycardias in the left atrium, using transoesophageal echocardiography to guide puncture of the intra-atrial baffle. The symptoms recurred 2 years later, and a new electrophysiological study was undertaken. Under general anesthesia, we punctured the right femoral artery and vein. A screw-in pacing lead (Medtronic, Minneapolis, MN, USA) was inserted into the right femoral vein and screwed into the lateral portion of the intra-atrial tunnel. A magnetically steerable catheter (Navistar RMT DS 8mm, Biosense-Webster, Diamond Bar, CA, USA) was also inserted into the right femoral vein, and the tip was positioned in the intra-atrial tunnel. With programmed atrial stimulation, and atrial burstpacing, multiple episodes of non-sustained atrial tachycardias could be induced with slightly different cycle lengths, suggesting a complex substrate for the arrhythmia. All tachycardias, nonetheless, had a centrifugal sequence of activation, suggestive for an origin in the intra-atrial tunnel. In the light of the history of arrhythmias in the left atrium, and using the CARTOTM navigation system (BiosenseWebster, Diamond Bar, CA, USA) in combination with the magnetic navigation system (MNS) (Niobe,

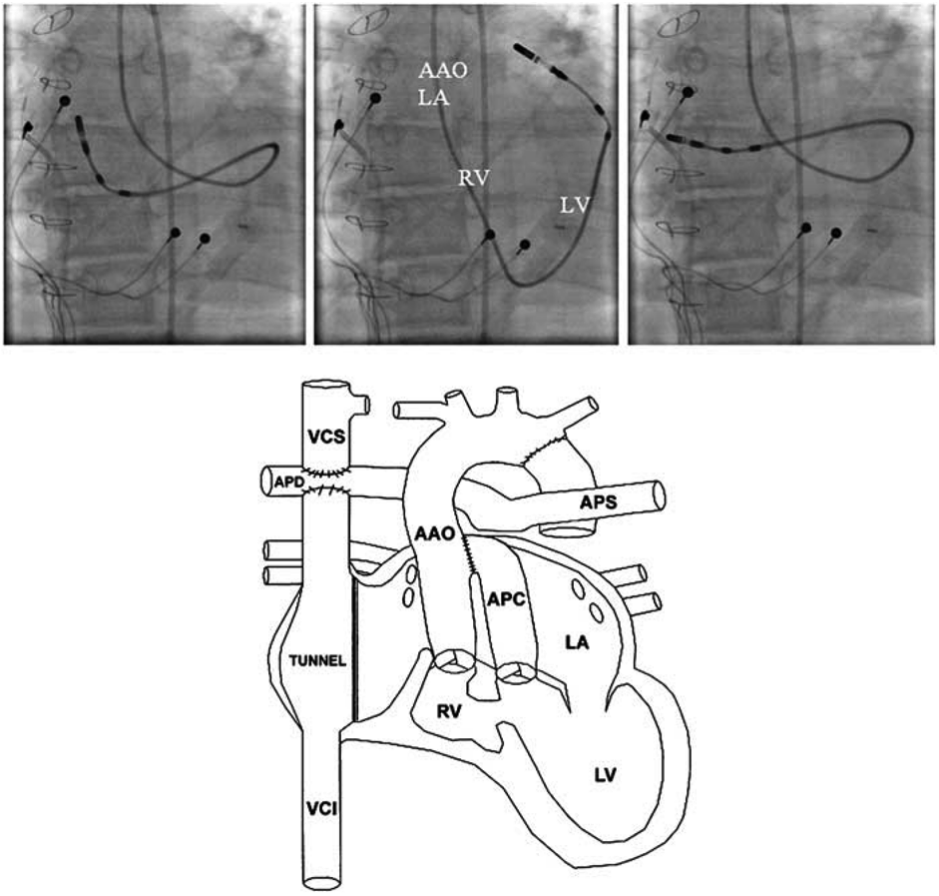


Figure 1. Top: Fluoroscopic images in the left anterior oblique projection of the magnetic navigation catheter retrogradely crossing the aortic valve, passing through the incomplete right ventricle, via the ventricular septal defect to the left ventricle, retrogradely through the mitral valve, and ending in the left atrium. The atrial and ventricular leads of an epicardial pacemaker are visible on all images. Bottom: Schematic reproduction of the heart after surgical repair. VCS superior caval vein, APD right pulmonary artery, APS left pulmonary artery, AAO ascending aorta, APC common pulmonary artery, TUNNEL intraatrial tunnel, LA left atrium, RV right ventricle, LV left ventricle, VCI inferior caval vein.

Stereotaxis, St. Louis, MO, USA), we were able to create safely a biatrial bipolar activation and voltage map (Fig. 2). We mapped the left atrium retrogradely using the femoral arterial access, a transseptal approach being deemed undesirable given the previous puncture of the baffle. The magnetically navigated catheter was piloted through the aortic arch, through the Damus-Kaye-Stansel shunt, into the incomplete morphologically right ventricle, through the ventricular septal defect into the morphologically left ventricle, and retrogradely through the surgically repaired mitral valve into the left atrium (Fig. 1). The voltage map showed high voltages in the intra-atrial tunnel, albeit without any channels or scars. In the left

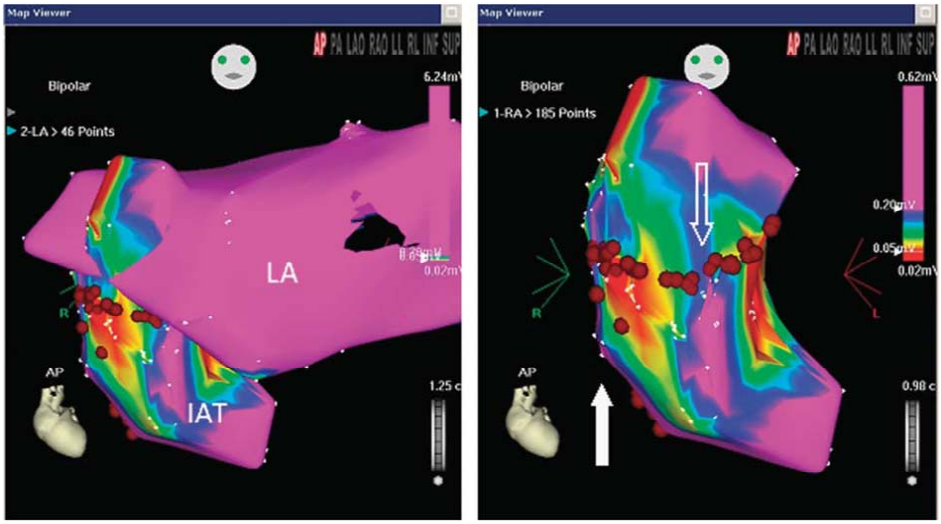


Figure 2.
Left panel: the biatrial CARTO voltage map shows only large potentials in the left atrium (LA), and different channels in the intra-atrial tunnel (IAT). Right panel: detail of CARTO voltage map in antero-posterior orientation (AP) of the intra-atrial tunnel with ablation points (red dots), with the first ablation line (hollow arrow) bisecting a channel, and the second ablation line (solid arrow) joining the first line to the inferior caval vein.

atrium, however, we found multiple channels capable of conducting re-entry tachycardia. We modified the substrate by creating 2 lines. The first line bisected a channel between the septal and lateral parts of the intra-atrial tunnel, while the second line joined the first line to the inferior caval vein (Fig. 2). Subsequent to creation of these lines, we were no longer able to induce the tachycardia. The patient remained haemodynamically stable during the procedure. During the period of follow-up thus far, the patient has suffered only very short episodes of palpitations.

DISCUSSION

Conventional manually steerable electrophysiological catheters nowadays are designed to reach even remote areas in the heart. These catheters, nonetheless, have a relatively stiff body, making it very difficult to generate different consecutive bends, and at the same time to maintain a stable position for the tip of the catheter. It is virtually impossible to use a retrograde approach with a manually steered catheter to ablate an atrial tachycardia, and to our knowledge this has never been performed, even in structurally normal hearts. In our patient, we were confronted with several challenges to gain access to the left atrium to create activation and voltage CARTO maps. Transseptal mapping through the femoral vein

was undesirable given the difficulties caused by the previous puncture of the atrial baffle. The likelihood of a possible cardiac perforation would put the patient at an unacceptable risk. A retrograde approach crossing the aortic valve, passing through the Damus-Kaye-Stansel shunt into the incomplete right ventricle, through the ventricular septal defect into the left ventricle, and retrogradely through the surgically repaired mitral valve into the left atrium was out of the question using a conventional manually steerable catheter. The magnetic navigation system, on the other hand, offers the opportunity to use extremely flexible and steerable catheters. The floppy tip of such catheters makes it possible to generate multiple consecutive bends. The soft and flexible nature of the catheter permits safe access to regions that are otherwise practically inaccessible. In addition, the chance of perforating the myocardial wall with the extremely floppy tip is very small. Another advantage is that as long as the magnetic field is applied, the tip remains stable at the desired position. Hence, we were able safely to generate a biatrial map, which provided valuable information about the origin of the postincisional macroreentrant tachycardia.

CONCLUSION

To our knowledge, this is the first report demonstrating successful retrograde mapping of the left atrium in a patient with complex congenital cardiac disease. Our experience, therefore, shows that such procedures can safely and effectively be performed, but we would suggest that they be attempted only in centers with extensive experience in magnetic navigation of congenitally malformed hearts.

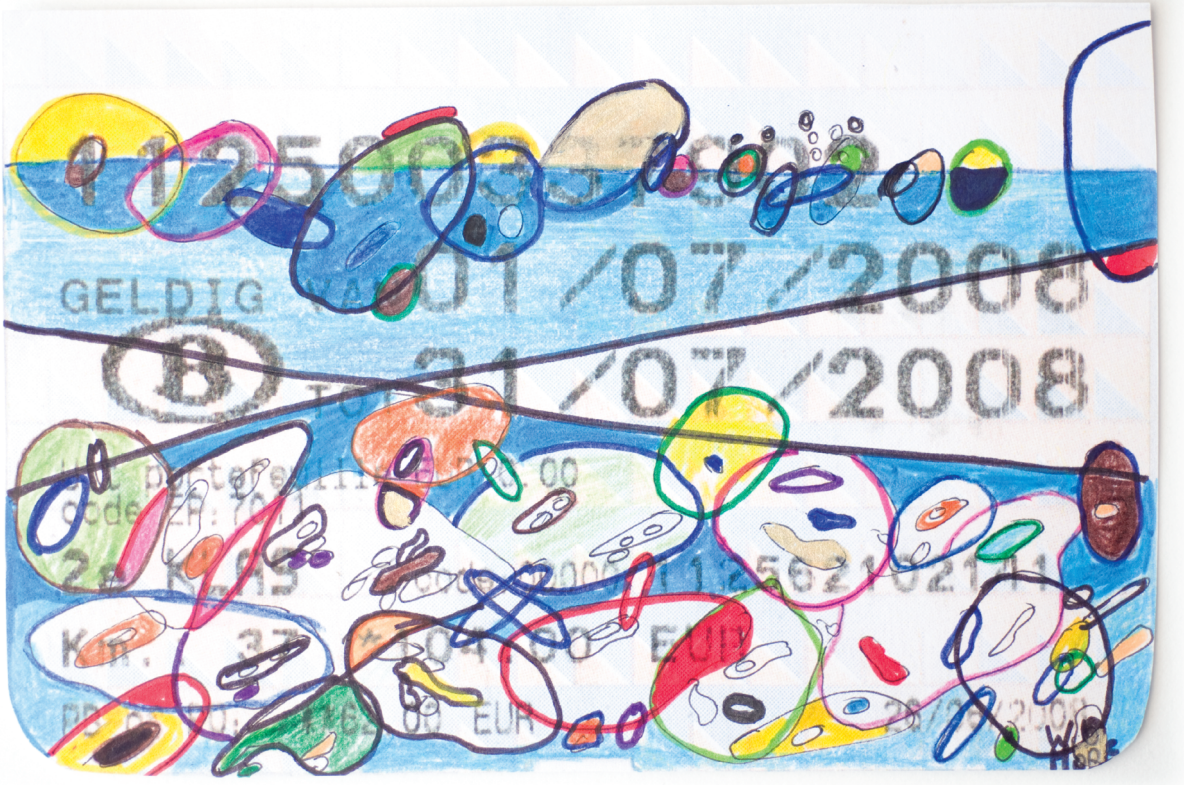
REFERENCES

1. Hahn K, Gal R, Sarnoski J, Kubota J, Schmidt DH, Bajwa TK. Transoesophageal echocardiographically guided atrial transseptal catheterisation in patients with normal-sized atria: incidence of complications. Clin Cardiol 1995; 18: 217–220. 2. El-Said HG, Ing FF, Grifka RG, et al. 18-year experience with transseptal procedures through baffles, conduits, and other intra-atrial patches. Catheter Cardiovasc Interv 2000; 50: 434–439.
3. Szili-Torok T, Kimman G, Theuns D, Res J, Roelandt JR, Jordaens LJ. Transseptal left heart catheterisation guided by intracardiac echocardiography. Heart 2001; 86: e11–e15.
4. Tucker KJ, Curtis AB, Murphy J, et al. Transoesophageal echocardiographic guidance of transseptal left heart catheterization during radiofrequency ablation of left-sided accessory pathways in humans. Pacing Clin Electrophysiol 1996; 19: 272–281.
5. Brockenbrough E, Braunwald E. A new technique for left ventricular angiography and transseptal left heart catheterization. Am J Cardiol 1960; 6: 1062–1067.
6. Thornton AS, Janse P, Theuns DA, Scholten MF, Jordaens LJ. Magnetic navigation in AV nodal re-entranttachycardia study: early results of ablation with one- and three-magnet catheters. Europace 2006; 8: 225–230.
7. Ernst S, Ouyang F, Linder C, et al. Initial experience with remote catheter ablation using a novel magnetic navigation system. Circulation 2004; 109: 1472–1475.

Chapter 7

Catheter ablation of ventricular tachycardias using remote magnetic navigation: a consecutive case-control study

Tamas Szili-Torok, MD, PhD; Bruno Schwagten, MD; Ferdi Akca, Tamas Bauernfeind, MD; Lara Dabiri Abkenari, MD; David Haitsma, MD, PhD; Yves van Belle MD, PhD; Natasja de Groot, MD, PhD; Luc Jordaens, MD, PhD



ABSTRACT

Background: Catheter ablation of ventricular tachycardia (VT) remains a challenging task. Recent studies support several advantages of the remote magnetic navigation system (MNS) (Niobe, Stereotaxis, Inc., Saint Louis, MO, USA) such as procedural safety, catheter manoeuvrability, improvements in electroanatomic mapping and reproducibility of catheter position. The aim of this study was to compare the acute and late outcome of VT ablation using the MNS to ablation using conventional manual techniques (MAN). Methods: Ablation data of 113 consecutive patients with ventricular tachycardia treated with catheter ablation at our centre were analyzed. MNS was used in combination with the CARTO RMT (Biosense-Webster Inc., Diamond Bar, CA, USA) system for catheter navigation, mapping and ablation for the MNS group. Patients in the manual group (MAN) were manually ablated using either the CARTO XP or the EnSite NavX system (St. Jude Medical, St. Paul, MN, USA). Success rate, complications, procedure, fluoroscopy and ablation times, and recurrence rates were systematically recorded for all patients. Results: Seventy-two patients were included in the MNS group and forty-one patients were included in the MAN group. Patient age, gender, aetiology, and right ventricular (RV) and left ventricular (LV) VT were equally distributed between the two groups. The investigators did not have input into treatment selection (MNS vs. MAN). Acute success was achieved in 59 patients in the MNS group (82%) vs. 27 (66%) patients in the MAN group ($p = 0.046$). Procedural time (177 ± 79 vs. 232 ± 99 minutes, $p < 0.001$), mean patient fluoroscopy time (27 ± 19 vs. 56 ± 31 min, $p < 0.001$), and recurrence rate (23.7% vs. 44.4%, $p = 0.047$) were all significantly lower in the MNS group when compared to the MAN group. No major complications occurred in the MNS group (0%) vs. 1 cardiac tamponade leading to patient demise and 1 significantly damaged ICD lead in the MAN group (4.9%, NS). After a mean follow-up of 20 ± 11 vs. 20 ± 10 months (NS), VT recurred in 14 pts (23.7%) in the MNS group vs. 12 pts (44.4%) in the MAN group ($p = 0.047$). Conclusions: The use of MNS offers major advantages for ablation of VT, including a higher acute success rate, reduced procedure time, lowered fluoroscopy exposure and fewer complications. Moreover, fewer recurrences of VT were observed in the MNS group.

Key words: ventricular tachycardia, catheter ablation, remote magnetic navigation

INTRODUCTION

Catheter ablation was introduced in clinical electrophysiology in the 1980s[1,2]. In the past decades, it has become well established as first line therapy for many types of arrhythmias, including ventricular tachycardia (VT)[3]. Further technological developments such as electro-anatomical mapping, integration of cardiac imaging and improved catheter design have been implemented to improve the consistency of the procedural outcome[4-6]. Until recently, all of the above mentioned techniques were based on manual navigation of catheters within the heart. The innovation of the remote magnetic navigation system (MNS) has offered important theoretical advantages in safety due to the atraumatic catheter design and less physical stress and radiation exposure for the physician[6-9]. Higher efficacy is also expected due to the unrestricted and reproducible catheter movement as well as improved catheter stability[7,10,11].

The objective of this prospective study was to evaluate the acute and long-term efficacy of MNS for ventricular tachycardia when compared to conventional manual ablation in the hands of the same operators at a single center. We hypothesized that the superior navigation capabilities of MNS tip delivery would lead to a superior and more consistent outcome with an improvement in procedural safety when compared to conventional methods.

METHODS

Patients

A total of 113 consecutive VT patients were included in this case series (consecutive VT patients from January 1, 2008 until August 31, 2010). Seventy-two patients were included in the MNS group and forty-one patients were included in the MAN group. Patient age, gender, etiology, and right ventricular (RV) and left ventricular (LV) VT were equally distributed between the two groups (p = NS, Table 1).

At our center, we have two separate electrophysiology laboratories: one equipped with the MNS system and one without a MNS system. A responsible person assigns individual patients to the one of the two laboratories without input from the investigators. Though this study was clearly not randomized, our internal policy does afford some of the scientific benefits of a formal randomization, as is evident by the homogeneity of the two groups. The reason for the lower number of manual ablations is that the electrophysiology laboratory where the manual ablations were performed serves as a device lab too, while in the magnetic room only ablations are performed.

Table 1. Comparison of ablation results between MNS and MAN groups.

	MNS – number	MNS – percentage	MAN – number	MAN – percentage	P-value
Total pts (n=113)	72 pts		41 pts		
Ptn age (years)	51±15		49±17		NS
Sex (male)	49	68.1%	33	80.5%	NS
Pediatric	2	2.8%	2	4.9%	NS
Hospital stay (days)	4.7		7.1		NS
NSHD-VT	3.5±2.9		4.4±4.5		NS
SHD-VT	7.4±9.0		9.9±12.1		NS
ASA	40	55.6%	21	51.2%	NS
Acenocoumarol	3	4.2%	5	12.2%	NS
Amiodarone	7	9.7%	14	34.1%	<0.01
Beta-blocker	16	22.2%	14	34,1%	NS
RV/LV Distribution					
RV: →	35	48.6%	16	39.0%	NS
LV: →	37	51.4%	25	61.0%	
VT Etiology					
NSHD: →	49	68.1%	21	51.2%	0.046
SHD: →	23	31.9%	20	48.8%	
Retrograde approach LV	32/37	86.5%	21/25	84.0%	NS
Overall Acute success	59	81.9%	27	65.9%	0.046
NSHD-VT	41/49	83.7%	13/21	61.9%	0.049
SHD-VT	18/23	78.3%	14/20	70.0%	NS
Procedural time (minutes)	177±79		232±99		<0.01
NSHD-VT	151±57		210±96		0.011
SHD-VT	237±91		250±101		NS
Number of RF applications	17.8±21.5		24.4±24.0		NS
NSHD-VT	10.2±8.1		12.4±9.3		NS
SHD-VT	33.3±30.8		34.0±27.8		NS
Application time (seconds)	816±902		1330±1289		0.024
NSHD-VT	494±402		652±541		NS
SHD-VT	1540±1254		1636±1412		NS
Fluoroscopy time (minutes)	26.9±19.3		55.9±31.5		<0.001
NSHD-VT	19.7±11.2		42.3±20.3		<0.001
SHD-VT	42.5±23.7		68.9±35.1		<0.01
Major complications	0	0%	2	4.9%	NS
Follow up (months)	20±11		20±10		NS
Recurrence	14	23.7%	12	44.4%	0.047
NSHD-VT	7	17.1%	4	30.8%	NS
SHD-VT	7	38.9%	8	57.1%	NS

Table 1. (*continued*)

	MNS – number	MNS – percentage	MAN – number	MAN – percentage	P-value
ICD	22	30.6%	22	53.7%	0.013
NSHD-VT	5	10.2%	4	19.0%	NS
SHD-VT	17	73.9%	18	90.0%	NS
ATP	0.94±2.19 [0-9]		1.18±2.21 [0-8]		NS
NSHD-VT	0.50±1.00 [0-2]		0.50±1.00 [0-2]		NS
SHD-VT	1.08±2.47 [0-9]		1.38±2.47 [0-8]		NS
ICD Shock	0.41±0.87 [0-3]		0.88±2.03 [0-7]		NS
NSHD-VT	0.75±0.96 [0-2]		0.50±1.00 [0-2]		NS
SHD-VT	0.31±0.85 [0-3]		1.00±2.27 [0-7]		NS

NSHD= non-structural heart disease, RV= right ventricle, LV= left ventricle, SHD= structural heart disease, VT= ventricular tachycardia, IHD= ischaemic heart disease, NIHD= non-ischaemic heart disease, RF= radiofrequency, ICD= implantable cardioverter defibrillator, ATP= antitachycardia pacing

Electrophysiology studies - ablations

The procedures were performed over the entire study duration by the same senior electrophysiologist group with the assistance of four fellows, trained for both manual catheter navigation and for remote MNS ablation. All catheter procedures were performed in accordance with institutionally approved local medical treatment protocols of the Erasmus MC, Thoraxcenter, Rotterdam. Prior written, informed consent for the ablation procedure was obtained from all patients. Resting 12-lead ECG, laboratory tests, an x-ray thorax image and a two-dimensional echocardiography were acquired from all patients within 48 hours of the procedure.

Standard peri-procedural medication protocols were followed in all patients. For planned procedures, patients were instructed to stop taking antiarrhythmic drugs for a period of at least four half lives prior to undergoing the procedure (except amiodarone). In cases of emergency VT ablation, medication remained unchanged. The procedures were performed during a fasting state, using local or general anesthesia. Market-approved diagnostic and ablation catheters were used as clinically indicated at the discretion of the operator. Investigators were not involved in the decision as to whether a patient was placed in our MNS laboratory or our MAN laboratory.

The left heart was accessed via retrograde aortic route or transseptal puncture based on the operator's preference. Generally, left sided ventricular arrhythmias were performed via retrograde approach (MNS 32/37, 87%; MAN 21/25, 84%; p = NS, Table 1). The use of a three-dimensional mapping system was mandatory in both groups for all patients. Intracardiac echocardiography (ICE) was used to guide transseptal punctures in all patients where applicable.

For patients with SHD, the procedure started with induction of VT and was followed by detailed mapping of the ventricle in order to localize of the myocardial scars as potential targets for catheter ablation. Programmed stimulation was performed using up to triple extrastimuli pacing from the right ventricular apex, right ventricular outflow tract or left ventricle. 12-lead ECG recordings were obtained for all inducible arrhythmias. If only VF or polymorphic VT was inducible the procedure was continued with electroanatomical substrate mapping using either the CARTO RMT (Biosense Webster, Inc., Diamond Bar, CA, USA) or the EnSite NavX system (St Jude Medical, Inc., St Paul, MN, USA). Bipolar contact electrograms were recorded and used to create a 3-dimensional map of the chamber based on the voltage amplitude. After creating a substrate map an extensive scar ablation (scar homogenization) was performed in all regions where scar tissue was identified. Scar was defined as a low voltage area under 1.5 mV. However, in order to minimize myocardial damage all lesions were made at the ≤ 1.0 mV border. In case of a hemodynamically stable VT the operators were allowed the tackle the VT by creating an activation map and identifying corridors as a part of the specific VT circuit. However, even after successful treatment of that particular VT, eventual scar homogenization was mandatory. For patients with idiopathic VTs standard ablation and mapping techniques were applied based on operator's choice. In principle, during hemodynamically stable VTs an activation map was created during the VT, usually followed by pace mapping (the site with a paced 12-lead QRS morphology identical to an inducible monomorphic VT was assumed to be the exit site or the site of origin of that particular VT) for confirmation. In patients where the VT was hemodynamically untolerable or was non-sustained, pace mapping was performed to identify the origin and/or exit of the tachycardia. If that was possible the VT was targeted during ongoing tachycardia in this group. There were no differences between treatment strategies in the MNS and manual ablation groups.

Crossover from the magnetic navigation catheter to manual navigation catheter was allowed at the discretion of the investigator. Any crossover was counted as an acute failure for the MNS group. Crossover from the MAN to the MNS group was not possible due to the fact that the MAN procedures were performed in another EP laboratory which was not equipped with MNS.

The endpoints of procedural success were defined as follows: if the VT was inducible, non-inducibility was the endpoint; if only ventricular extrasystoles (VES) were present, then the complete abolishment of VES as assessed by 24 hours telemetry was required for acute success. The presence of pacemaker (PM) or implantable cardioverter defibrillator (ICD) was not considered as a contraindication for MNS guided ablations, which is consistent with the product labeling for the MNS. There was a statistically greater percentage of implantable devices in the MAN group (22/41, 53.7%) when compared to the MNS group (22/72, 30.6%, $p = 0.013$, Table 1).

MNS-guided ablations

The procedures were performed in the MNS group using the Stereotaxis Niobe Magnetic Navigation System (Stereotaxis, Inc., Saint Louis, MO, USA) in an EP lab equipped with a Siemens Axiom Artis (Siemens, Erlangen, Germany) fluoroscopy system. All patients were treated with the NaviStar RMT ThermoCool catheter (Biosense Webster, Inc., Diamond Bar, CA, USA). Electroanatomical mapping was performed using the CARTO RMT (Biosense Webster, Inc., Diamond Bar, CA, USA) system.

Manual-guided ablations

The procedures in the MAN group took place in an EP lab equipped with a Siemens Megalix (Siemens, Erlangen, Germany) fluoroscopy system. Electroanatomical mapping was performed using the EnSite NavX system (St Jude Medical, Inc., St Paul, MN, USA). The following ablation catheters were used: Biosense Webster B, D and F curve Celsius Thermocool, St Jude Cool Path Duo.

Data collection and analysis

The following parameters were analyzed for both the MNS group and the MAN group: acute success rate, fluoroscopy time, procedure time, total RF time, RF applications and complications. Acute success rate was assessed according to the terms mentioned above. Fluoroscopy time was recorded from the fluoroscopy system in each room. Procedure time was defined as the interval between subcutaneous injection of lidocaine to the groin and removal of catheters from the patient's body including a 30 minutes waiting time for every case. Any adverse event recognized by the operator during the procedure, by the attending cardiologist prior to hospital discharge, or by the general physician during follow up was investigated by a trained electrophysiologist, and was considered as a complication if the event could be related to the procedure. Major complications were defined as pericardial effusion or/and tamponade, permanent AV block, PM/ ICD damage requiring device or electrode replacement, stroke, major bleeding, or death. Minor complications were defined as minor bleeding (groin hematomas), transient ischemic attack and temporary AV block.
Subgroup analyses were performed for patients with and without structural heart disease (SHD and NSHD) and for right-sided versus left-sided ablations.

Follow Up

Follow up visits were scheduled for all patients at the outpatient clinic of our department 3 months following the procedure and for every 3 months thereafter. For patients treated for idiopathic VT, 24-hours Holter recordings were scheduled during these clinic visits, while for scar-related VT patients the ICD interrogations served as primary source for documentation of recurrent arrhythmias. ICD shock and antitachycardia pacing (ATP) is reported as an event as well.

Statistics

All patient data was analyzed using SPSS 15.0 (SPSS Inc., Chicago, IL, USA). Patient demographic and baseline characteristics were presented as mean ± SD. The two-tailed Student's t-test was used for comparing continuous unpaired samples, assuming unequal variances. For categorical variables the χ^2 test or Fischer's exact test was performed. A two-sided p value < 0.05 was considered to be statistically significant.

RESULTS

Overall

The two groups were statistically homogeneous when comparing age, gender distribution, number of pediatrics, hospital stay, and RV/LV distribution (Table 1). Acute success was greater in the MNS group when compared to the MAN group (81.9% vs. 65.9%, p=0.046). After unsuccessful endocardial ablation an epicardial approach was considered necessary in 31% and 29% of the MNS and MAN procedures, respectively (NS). Patients received an ICD in 30.6% in the MNS group and 53.7% in the MAN group (p=0.013). In MNS pts the post-procedural amiodarone use was significantly lower than in MAN group (9.7% vs. 34.1%, p<0.01). Overall, the ablation procedures were shorter and fluoroscopy time was reduced in the MNS group: 177±79 vs. 232±99 min (p<0.01) and 27±19 vs. 56±31 min (p<0.001), respectively. Between MNS and MAN there was no difference in number of applications (17.8±21.5 vs. 24.4±24.0, p=NS), although in the MNS group there was significantly reduced total ablation time (816±902 vs. 1330±1289 seconds, p=0.024).

NSHD-VT

The success rate in the NSHD-VT subgroup was higher in MNS group (83.7% vs. 61.9%, p=0.049). For NSHD-VT in the RV and LV, no statistical difference was found between MNS and MAN (Table 2). MNS procedures for NSHD-VT were related to decreased procedure times (151±57 vs. 210±96 min, p=0.011) and less fluoroscopy use (19.7±11.2 vs. 42.3±20.3 min, p<0.001). Number of RF applications and total ablation time were not significant different: 10.2±8.1 vs. 12.4±9.3 (p=NS) and 494±402 vs. 652±541 seconds (p=NS). In the subgroup no difference in ICD implantation is noticed between MNS and MAN pts (Table 1).

SHD-VT

In VT subgroup with SHD acute success did not reach statistical significance (78.3% vs. 70.0%, p=NS). For the subgroups of SHD-VT no differences were observed in success rates, too (Table 2). In the MNS group less fluoroscopy was used compared to the MAN group (42.5±23.7 vs. 68.9±35.1 min, p<0.01). No statistical difference was found for procedural time (237±91 vs. 250±101 min, p=NS), RF applications (33.3±30.8 vs. 34.0±27.8, p=NS)

Table 2. Comparison of acute success and recurrence rates between all subgroups within MNS and MAN main groups.

Total Pts: N = 113	MNS Acute Success	MAN Acute Success	P-value	MNS Recurrence	MAN Recurrence	P-value
NSHD-VT						
RV	26/30 (86,7%)	8/13 (61,5%)	NS	5/26 (19,2%)	2/8 (25%)	NS
LV	15/19 (78,9%)	5/8 (62,5%)	NS	2/15 (13,3%)	2/5 (40%)	NS
SHD-VT						
IHD	15/16 (93,8%)	8/12 (66,7%)	NS	7/15 (46,7%)	3/8 (37,5%)	NS
NIHD	3/7 (42,9%)	6/8 (75%)	NS	0/3 (0%)	5/6 (83,3%)	0.048

NSHD= non-structural heart disease, RV= right ventricle, LV= left ventricle, SHD= structural heart disease, VT= ventricular tachycardia, IHD= ischaemic heart disease, NIHD= non-ischaemic heart disease

and ablation time (1540±1254 vs. 1636±1412 min, p=NS). There is no statistical significant difference for ICD implantation between both groups (Table 1).

Crossovers

In two MNS procedures the operator switched to a manual ablation catheter. During one operation the arterial sheath was dislocated resulting in inguinal bleeding (minor bleeding). In another patient the VT focus was closely located to the His bundle and for safety reasons cryo-ablation was applied.

Complications

There were no major complications in the MNS group (0%). In the MAN group, one patient suffered a cardiac tamponade that ultimately lead to the patient's demise and one patient suffered a significantly damaged ICD lead, thus yielding a major complication rate of 4.9% (Figure 1). These complication rates were not significantly different between the two groups. In MNS and MAN occurrence of groin hematomas was similar (6% vs. 7%, p=NS). In two patients in the MNS group, the ICD switched to magnet mode (asynchronous pacing). Neither of these patients was PM dependent, therefore temporary programming allowed electro-anatomical mapping without further problems. Of interest, both of these patients had an implant that was abdominally placed. No any long term effect on ICD or PM function was observed in any patient, including these two magnet mode switched patients.
No other complications were recorded in both groups.

Follow up

Patient follow up was obtained at a mean of 20±11 months in the MNS group and 20±10 months in the MAN group (p = NS). For the overall MNS group, 14/72 patients had a recurrence of their arrhythmia (23.7%) compared to 12/41 patients in the MAN group (44.4%). This difference was statistically significant (p = 0.047, Table 1). For the NSHD and SHD subgroups, no statistical differences were found for recurrence: 17.1% vs. 30.8% (p=NS) and

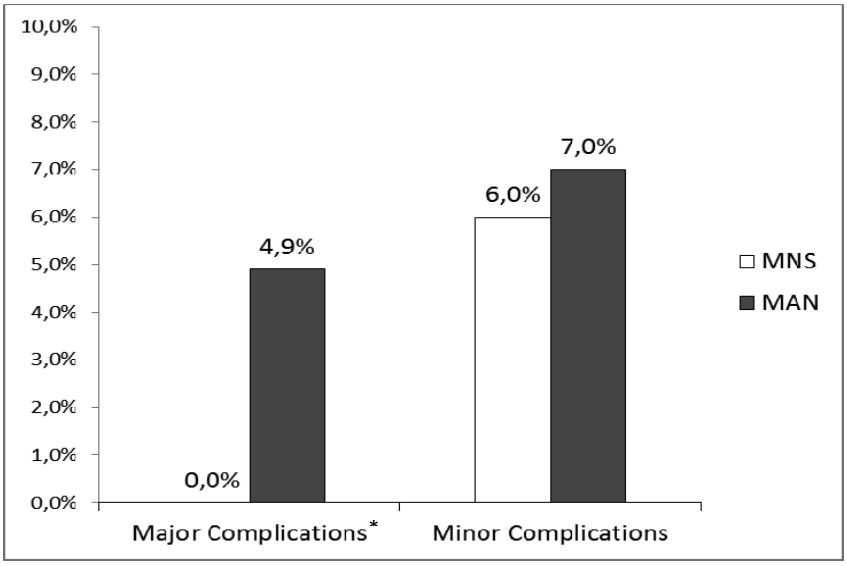


Figure 1. Comparion of major and minor complications * p<0.05

38.9% vs. 57.1% (p=NS), respectively. During follow up, fewer recurrences were observed in NIHD pts from the SHD subgroup (Table 2). No differences were found in ATP therapy and ICD shocks between the overall groups and the VT subgroups (Table 2). Furthermore, post-procedural use of amiodarone in the MNS group was significantly lower than in the MAN group (9.7% vs. 34.1%, p=0.002).

DISCUSSION

This is the first study which directly compares the efficacy and safety of VT ablation between remote magnetic and manual navigation involving statistically equivalent, large-scale patient groups and including both idiopathic and scar-related VT patients. The major finding of this study is that MNS was found to have a higher rate of acute success for catheter ablation of VT. Furthermore, this advantage remained apparent during the follow up, as fewer recurrences occurred in the MNS group as compared to the MAN group.

Rationale of MNS for VT ablation

The success of catheter ablation procedures depends on accurate substrate location, followed by optimal delivery of energy provided by good tissue contact[12]. Manual navigation of catheters in the human ventricles has limitations. Some regions are difficult to reach, and compromised catheter positioning may result in insufficient lesion formation[7,10,12]. Catheter movement in some positions is accompanied by the risk of major complications, in-

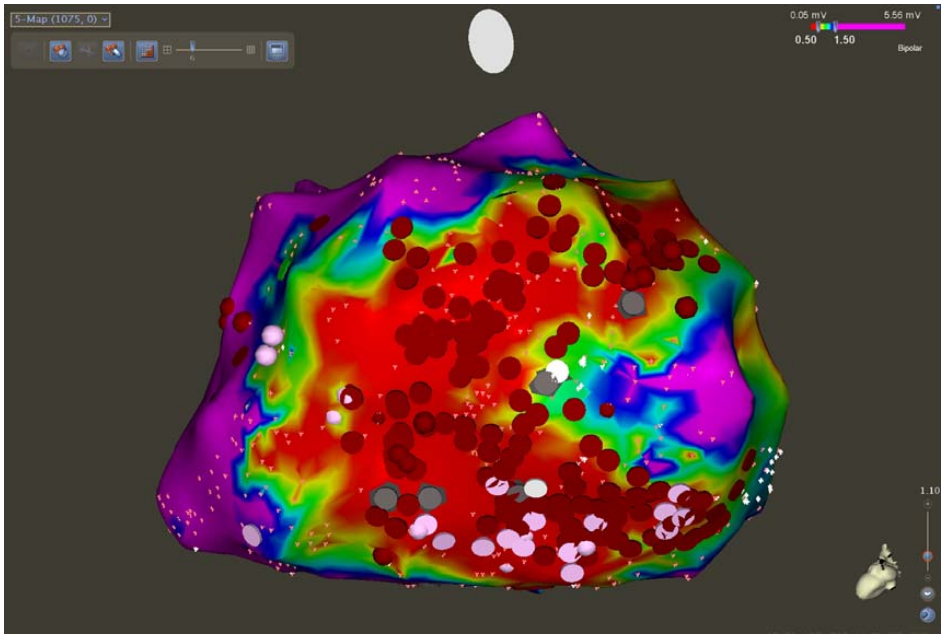


Figure 2.
Postero-inferior CARTO electroanatomical map view of the LV ventricle after MNS guided scar homogenization in a patient with electrical storm. The patient had more than 15 VT morphologies before the ablation procedure and became non-inducible after the ablation. The CARTO contains 958 mapping points (including radiofrequency ablation points-red dots). The white dots indicate regions with isolated late potentials. The patient became non-inducible and had no recurrences during the follow-up.

cluding pericardial effusion or tamponade[13). Although several pre-defined catheter curves were introduced to help appropriate lesion delivery, there are no optimal curves available for all subtypes of group of patients such patients with small hearts, patients with complex congenital heart defects, or for patients with extremely dilated hearts[14]. The introduction and utilization of MNS was aimed to surmount these difficulties. It provides improvement of safety by the flexible catheter design, and no pericardial effusion or tamponade was reported related to catheter navigation using MNS[6,15-19]. MNS also provides better navigation capability, which is not limited by preformed or evolved catheter curves[11,14,20].

In addition, non-fluoroscopic imaging and software-based automated functions such as auto-mapping and stored magnetic vectors may allow for reductions in fluoroscopy time to both operator and patient[21]. Stored magnetic vectors also make it possible to re-navigate to spots previously defined and stored during the procedure[11]. Promising initial results have been published concerning these capabilities of the MNS[6, 15,17-19].

Differences in mapping capabilities have also been noted between the MNS and conventional methodology. Latcu and colleagues reported on 20 patients with suspected arrhythmogenic right ventricular dysplasia who underwent RV mapping with both MNS and MAN techniques.

In this series, they reported higher RV volumes and surface areas and fewer, more defined low voltage areas and concluded that MNS maps were more accurate than MAN maps[22]. Other authors have shown a reduction in ventricular extrasystolies (VES) when using MNS for outflow tract tachycardias. Konstantinidou and colleagues recently published a series of 13 RVOT tachycardia patients who were treated with the MNS and concluded that the MNS was associated with a very low incidence of catheter-induced VES[23]. Our own group published a series of 3 cases with minimal ventricular extrasystolies and precise ablation in right ventricular outflow tract tachycardia ablation[7].

Ablation of VT: tip delivery vs. therapy delivery

This is the first larger-scale case-control study to prove superiority of MNS for ablation of VT when compared to manual navigation. This is demonstrated in most of the analyzed parameters, including acute success rate, procedure and fluoroscopy times, and recurrence rate. There are multiple reasons to explain this finding. The MNS guided catheter retains its maneuverability even in difficult positions, such as those encountered in cusp-related VT and papillary muscle originated VT, where the capabilities of manual navigation are seriously limited by the multiple curves of the catheter[7]. The MNS controls the tip of the catheter without the need for a predefined curve, which means that the unavoidable curves of the catheter do not hinder the positioning of the tip, and good contact can be achieved. This consistent contact results in appropriate lesion formation[10].

Acute success rates and recurrences

Based on the theoretical advantages mentioned above, MNS could be superior to manual navigation in the analyzed parameters. Reports until now focused more on feasibility rather than assessment of efficacy of MNS[24-27]. Our data showed a statistically significant increase in acute success in the MNS when compared to the MAN group. In our study, this acute difference lead to an improvement in recurrence rates in patients treated with remote magnetic navigation when compared to patients treated with manual methods.

Limitations of the study

This study is not a randomized, prospective trial, and the follow up interval was relatively short. To address this limitation, we included consecutive patients in both groups and did not exclude any patient from our study cohort. Also, at our center, patients are placed into either our MNS laboratory or our MAN laboratory by a responsible person who is not involved in clinical decision-making. This process effectively allows us to practically compare two disparate treatment groups without major bias, as is confirmed by the homogeneity between our two study groups. Furthermore, this study includes all consecutive VT patients from our hospital regardless the etiology of the tachycardias. This resulted in an obvious difference in the follow up method. For the ICD subgroup the ICD follow up provides extreme accuracy,

however, device follow up was not available for the idiopathic group, where Holter ECG monitoring served as a primary source for the follow up.

CONCLUSIONS

In conclusion our data strongly suggest that the MNS offers significant advantages for the ablation of both idiopathic and scar-related VT when compared to conventional methods. Prospective, randomized studies should be conducted to confirm the conclusions from our retrospective case-control study.

REFERENCES

1. Scheinman M. Transvenous AV junctional ablation. Am Heart J 1983;106:607-608.
2. Critelli G, Perticone F, Coltorti F, Monda V, Gallagher JJ. Antegrade slow bypass conduction after closed-chest ablation of the His bundle in permanent junctional reciprocating tachycardia. Circulation 1983;67:687-692.
3. American College of C, American Heart A, American College of Physicians Task Force on Clinical Competence and T, Heart Rhythm S, Tracy CM, Akhtar M, DiMarco JP, Packer DL, Weitz HH, Creager MA, Holmes DR Jr, Merli G, Rodgers GP. American College of Cardiology/American Heart Association 2006 update of the clinical competence statement on invasive electrophysiology studies, catheter ablation, and cardioversion: a report of the American College of Cardiology/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training: developed in collaboration with the Heart Rhythm Society. Circulation 2006;114: 1654-1668.
4. Khongphatthanayothin A, Kosar E, Nademanee K. Nonfluoroscopic three-dimensional mapping for arrhythmia ablation: tool or toy? J Cardiovasc Electrophysiol 2000;11:239-243.
5. Marchlinski FE, Callans DJ, Gottlieb CD, Zado E. Linear ablation lesions for control of unmappable ventricular tachycardia in patients with ischemic and non-ischemic cardiomyopathy. Circulation 2000;101:1288-1296.
6. Aryana A, d'Avila A, Heist EK, Mela T, Singh JP,Ruskin JN, Reddy VY. Remote magnetic navigation to guide endocardial and epicardial catheter mapping of scar-related ventricular tachycardia. Circulation 2007;115:1191-1200.
7. Schwagten BK, Szili-Torok T, Rivero-Ayerza M, Jessurun E, Valk S, Jordaens LJ. Usefulness of remote magnetic navigation for ablation of ventricular arrhythmias originating from outflow regions. Neth Heart J 2009;17:245-249.
8. Faddis MN, Blume W, Finney J, Hall A, Rauch J, Sell J, Bae KT, Talcott M, Lindsay Bl. Novel, magnetically guided catheter for endocardial mapping and radiofrequency catheter ablation. Circulation 2002;106:2980-2985.
9. Ernst. Robotic approach to catheter ablation Curr Opin Cardiol. 2008; 23:28-31
10. Davis DR, Tang AS, Gollob MH, Lemery R, Green MS, Birnie DH. Remote magnetic navigation-assisted catheter ablation enhances catheter stability and ablation success with lower catheter temperatures. Pacing Clin Electrophysiol 2008;31:893-898.
11. Ernst S. Magnetic and robotic navigation for catheter ablation: "joystick ablation". J Interv Card Electrophysiol 2008;23:41-44.
12. Wittkampf FH, Nakagawa H. RF catheter ablation: lessons on lesions. Pacing Clin Electrophysiol 2006;29:1285-1297.
13. Faddis MN, Chen J, Osborn J, Talcott M, Cain ME, Lindsay BD. Magnetic guidance system for cardiac electrophysiology: a prospective trial of safety and efficacy in humans. J Am Coll Cardiol 2003;42:1952-1958.
14. Schwagten B, Jordaens L, Witsenburg M, et al. Initial experience with catheter ablation using remote magnetic navigation in adults with complex congenital heart disease and in small children. Pacing Clin Electrophysiol 2009;32(Suppl 1):S198-201.
15. Di Biase L, Santangeli P, Astudillo V, Conti S, Mohanty P, Sanchez JE, Horton R, Thomas B, Burkhardt JD, Natale A. Endo-epicardial ablation of ventricular arrhythmias in the left ventricle with the Remote Magnetic Navigation System and the 3.5-mm open irrigated magnetic catheter: results from a large single-center case-control series. Heart Rhythm 2010;7:1029-1035.

16. Di Biase L, Burkhardt JD, Lakkireddy D, Pillarisetti J, Baryun EN, Biria M, Horton R, Sanchez J, Gallinghouse GJ, Bailey S, Beheiry S, Hongo R, Hao S, Tomassoni G, Natale A. Mapping and ablation of ventricular arrhythmias with magnetic navigation: comparison between 4- and 8-mm catheter tips. J Interv Card Electrophysiol 2009;26:133-137.
17. Arya A, Eitel C, Bollmann A, Wetzel U, Sommer P, Husser D, Piorkowsky C, Hindricks G. Catheter ablation of scar-related ventricular tachycardia in patients with electrical storm using remote magnetic catheter navigation. Pacing Clin Electrophysiol 2010;33:1312-1318.
18. Thornton AS, Jordaens LJ: Remote magnetic navigation for mapping and ablating right ventricular outflow tract tachycardia. Heart Rhythm 2006; 3:691-696.
19. Haghjoo M, Hindricks G, Bode K, Piorkowski C, Bollmann A, Arya A: Initial clinical experience with the new irrigated tip magnetic catheter for ablation of scar-related sustained ventricular tachycardia: a small case series. J Cardiovasc Electrophysiol 2009; 20:935-939.
20. Schmidt B, Chun KR, Tilz RR, Koektuerk B, Ouyang F, Kuck KH. Remote navigation systems in electrophysiology. Europace 2008;10(Suppl 3):iii57-61.
21. Kim AM, Turakhia M, Lu J, Badhwar N, Lee BK, Marcus GM, Tseng ZH, Scheinman M, Olgin JE. Impact of remote magnetic catheter navigation on ablation fluoroscopy and procedure time. PACE 2008;31:1399-1404.
22. Latcu DG, Ricard P, Popescu I, Arnoult M, Hugues T, Saoudi N. Endocardial voltage mapping for diagnosis of arrhythmogenic right ventricular dysplasia: remote magnetic navigation maps are more accurate than manual maps. Eur Heart J 2010;31:S_258.
23. Konstantinidou M, Koektuerk B, Wissner E, Schmidt B, Zerm T, Ouyang F, Kuck KH, Chun JK. Catheter ablation of right ventricular outflow tract tachycardia: a simplified remote-controlled approach. Europace 2011.
24. Burkhardt JD, Saliba WI, Schweikert RA, Cummings J, Natale A: Remote magnetic navigation to map and ablate left coronary cusp ventricular tachycardia. Journal of Cardiovascular Electrophysiology 2006; 17:1142-1144.
25. De Torres F, Szili-Torok T, Orellana FJ, Jordaens LJ: Ablation of idiopathic left ventricular tachycardia using remote magnetic navigation integrated with advanced mapping. Rev Esp Cardiol 2008; 61:1104-1106.
26. Thornton AS, Res J, Mekel JM, Jordaens LJ: Use of advanced mapping and remote magnetic navigation to ablate left ventricular fascicular tachycardia. Pacing Clin Electrophysiol 2006; 29: 685-688.
27. Latcu DG, Ricard P, Zarqane N, Yaici K, Rinaldi JP, Maluski A, Saoudi N. Robotic magnetic navigation for ablation of human arrhythmias: initial experience. Arch Cardiovasc Dis 2009; 102: 381-383.

Chapter 8

The magnetic navigation system allows safety and high efficacy for ablation of arrhythmias

Tamas Bauernfeind, MD, Ferdi Akca, MS, Bruno Schwagten, MD, Natasja de Groot, MD, PhD, Yves Van Belle, MD, PhD, Suzanne Valk, MD, Barbara Ujvari, MD, Luc Jordaens, MD, PhD and Tamas Szili-Torok, MD, PhD

ABSTRACT

Aims: We aimed to evaluate the safety and long-term efficacy of the magnetic navigation system (MNS) in a large number of patients. The MNS has the potential for improving safety and efficacy based on atraumatic catheter design and superior navigation capabilities. Methods and results: In this study, 610 consecutive patients underwent ablation. Patients were divided into two age- and sex-matched groups. Ablations were performed either using MNS (group MNS, 292) or conventional manual ablation [group manual navigation (MAN), 318]. The following parameters were analysed: acute success rate, fluoroscopy time, procedure time, complications [major: pericardial tamponade, permanent atrioventricular (AV) block, major bleeding, and death; minor: minor bleeding and temporary AV block]. Recurrence rate was assessed during follow-up (15+9.5 months). Subgroup analysis was performed for the following groups: atrial fibrillation, isthmus dependent and atypical atrial flutter, atrial tachycardia, AV nodal re-entrant tachycardia, circus movement tachycardia, and ventricular tachycardia (VT). Magnetic navigation system was associated with less major complications (0.34 vs. 3.2%, P ¼ 0.01). The total numbers of complications were lower in group MNS (4.5 vs. 10%, P ¼ 0.05). Magnetic navigation system was equally effective as MAN in acute success rate for overall groups (92 vs. 94%, P ¼ ns). Magnetic navigation system was more successful for VTs (93 vs. 72%, P , 0.05). Less fluoroscopy was used in group MNS (30+20 vs. 35+25 min, P , 0.01). There were no differences in procedure times and recurrence rates for the overall groups (168+67 vs. 159+75 min, P ¼ ns; 14 vs. 11%, P ¼ ns; respectively). Conclusions Our data suggest that the use of MNS improves safety without compromising efficiency of ablations. Magnetic navigation system is more effective than manual ablation for VTs.

Key words: Arrhythmias, Catheter ablation, Remote magnetic navigation

INTRODUCTION

Catheter ablation was introduced in clinical electrophysiology (EP) in the 1980s.1,2 In past decades, it became well established as firstline therapy for many types of arrhythmias, including atrioventricular (AV) nodal re-entrant tachycardia (AVNRT), circus movement tachycardia (CMT), and cavotricuspid isthmus (CTI)-dependent atrial flutter (AFl), and as therapeutic option for the treatment of atrial fibrillation (AFib), atrial tachycardia (AT), and ventricular tachycardia (VT).3 Further developments were implemented such as electroanatomical mapping, integration of cardiac imaging, and improved catheter design.4,5 Until recently, all of the abovementioned techniques were based on manual catheter navigation in the heart. The innovation of the remote magnetic navigation system (MNS) offered important theoretical advantages in safety due to the atraumatic catheter design and less physical stress and radiation exposure for the physician.6 – 11 Higher efficacy is also expected due to the unrestricted and reproducible catheter movement, and improved catheter stability.8,11 – 13 Numerous centres reported their initial experiences with MNS confirming its feasibility for ablation of most arrhythmias.14 – 23 However, these early reports included only small numbers of patients, the follow-up periods were short, and they failed to demonstrate superiority of MNS in safety and efficacy. The objective of the present study was to evaluate the safety and long-term efficacy of MNS as compared with conventional manual ablation techniques in a large number of patients with consistent technique and workflow.

METHODS

Patients

This study is an ongoing registry of the procedures performed in our clinic. Six hundred and ten consecutive patients underwent ablation from January 2008 to March 2010. All patients scheduled for EP study and ablation were distributed from the waiting list based on availability to the MNS-equipped or the conventional EP laboratory. Accordingly, ablation was performed either using MNS (group MNS, 292 patients, age 48+19 years, 166 males) or using conventional manual ablation (group MAN, 318 patients, age 52+16 year, 197 males). The procedures were performed over the entire study duration by the same senior electrophysiologist group with the assistance of four fellows, trained for manual catheter navigation and for MNS as well. The attending physicians performed MNS and MAN procedures in equal distribution.

Electrophysiology studies—ablations

Written, informed consent for the ablation procedure was obtained from all patients. Resting 12-lead electrocardiogram (ECG), and laboratory tests, an X-ray thorax image, and a

two-dimensional echocardiography were acquired from all patients within 1 month before and within 48 h following the procedure. Local peri-procedural medication protocols were followed in all patients. In short, AVNRT, CMT, AT, and elective VT patients were instructed to stop taking antiarrhythmic drugs for a period of at least four half-lives prior undergoing the procedure. In cases of AFib, AV junction (AVJ) and emergency VT ablation medication remained unchanged. The procedures were performed during a fasting state, using local or general anaesthesia. Market-approved diagnostic and ablation catheters were used as clinically required at the discretion of the operator. The left heart could be accessed via the retrograde aortic route or transseptal puncture (TSP) based on the operator's preference. Generally, left-sided ventricular arrhythmias were performed via the retrograde approach (MNS 93%, MAN 89%; P ¼ ns), left-sided atrial arrhythmias always via TSP, and left-sided accessory pathways distributed between the two methods (MNS 22% TSP, group MAN 20% TSP; P ¼ ns). The use of three-dimensional mapping system was allowed in both groups if necessary. Intracardiac echocardiography (ICE) was used to guide TSPs in both groups. Crossover from the magnetic navigation catheter to manual navigation catheter was allowed at the discretion of the investigator, although the crossover counted as an acute failure for the MNS group. Crossover from the MAN to the MNS group was not possible due to logistical reasons (see below).

The endpoints of procedural success were defined as the elimination of accessory pathway conduction for CMT, the elimination of inducibility and no more than single echo beats for AVNRT, complete AV block for AVJ ablation, bi-directional isthmus block for CTI dependent AFl, and complete electrical pulmonary vein isolation for AFib. For VT patients; if the VT was inducible, non-inducibility was the endpoint, if only ventricular extrasystoles (VES) were present, then the complete abolishment of VES assessed by 24 h telemetry counted as acute success. The presence of a pacemaker (PM) or an implantable cardioverter defibrillator (ICD) was not considered as contraindication for MNS-guided ablations. According to an institutional protocol for the treatment of patients with AFib, all paroxysmal AFib patients were ablated using the cryoballoon technique, the persistent AFib patients were ablated using cryoballoon or MNS, and all long-standing persistent (.12 months) AFib patients were ablated using MNS. Persistent and long-standing persistent AFib procedures included additional linear ablation in the left and/or right atrium. Whenever linear ablation was performed, conduction block was mandatory to be proven. Regardless of the type of AFib patients pulmonary vein isolation was mandatory in all patients. This was always controlled by a 'lasso-type' catheter. Also, atypical AFl and AT patients were ablated generally using MNS (50 of 56, 89%).

Magnetic navigation system-guided ablations

The procedures were performed in group MNS using the Stereotaxis Niobe II (Stereotaxis, Inc., St Louis, MO, USA) implemented in an EP lab equipped with a Siemens Axiom Artis (Siemens, Erlangen, Germany) fluoroscopy system. The following ablation catheters were used:

for AVNRT, CMT and AVJ Celsius RMT (4 mm) (Biosense Webster, Diamond Bar, CA, USA), and for AFib NaviStar RMT ThermoCool (Biosense Webster), AFl/AT and VT Navistar RMT DS (8 mm), NaviStar RMT ThermoCool (Biosense Webster), or Trignum Flux Gold-tip (Biotronik GMBH, Berlin, Germany). The use of an 8 mm tip RMT catheter was associated with a char formation in some patients. Therefore, after the thermocool RMT catheter became available the 8 mm tip catheter was no longer used. When needed, electroanatomical mapping was performed using the CARTO RMT (Biosense Webster) system.

Manual-guided ablations

The procedures in the MAN group took place in an EP lab equipped with a Siemens Megalix (Siemens) fluoroscopy system. Electroanatomical mapping was performed using CARTO (Biosense Webster) or EnSite (St Jude Medical Inc., St Paul, MN, USA) system. The following ablation catheters were used: for AVNRT, CMT, and AVJ Biosense Webster B–D curve 4 or 8 mm tip (Biosense Webster), for AFib, AFl/AT, and VT Biosense Webster Navistar ThermoCool (Biosense Webster). The Artic Front cryoballoon catheters (Medtronic Inc., Minneapolis, MN, USA) were used for cryo-isolation of the pulmonary veins; Freezor Max (Medtronic Inc.) catheters were used in cases when complete electrical isolation could not be achieved with the balloon.

Data collection and analysis

The following parameters were analysed both in group MNS and group MAN: acute success rate, fluoroscopy time, procedure time, and complications. Acute success rate was assessed according to the terms mentioned above. Fluoroscopy time and procedure time (latter began with subcutaneous injection application of lidocaine by the physician to the groin and ended when catheters were removed from the patient's body) were recorded in the clinical procedure log and included a 30 min waiting time. Any adverse event recognized by the operator during the procedure, by the attending cardiologist prior to hospital discharge, or by the general physician during follow-up was investigated by a trained electrophysiologist, and was considered as a complication if the event could be related to the procedure. Complications were categorized as major and minor [major: pericardial effusion or/and tamponade, permanent AV block, stroke, major bleeding (requiring blood transfusion or haemoglobin serum level drop of .20 g/L) or death; minor: minor bleeding, transient ischaemic attack, and temporary AV block.

Subgroup analysis of the above-mentioned parameters was performed for the following groups: AFib, AFl, atypical AFL (aAFl)/AT, AVNRT, CMT, AVJ, and VT. The AFib group was further divided into the following subgroups: paroxysmal, persistent, and long-standing persistent. Because different techniques were used for the treatment of paroxysmal and long-standing persistent AFib patients, paroxysmal and long-standing persistent AFib subgroups were not compared in efficacy; however, data from these groups were included into

Table 1 Patient demographics

	Group MNS	Group MAN	Total
Number	292	318	610
Age (years)	48 ± 19	52 ± 16	50 ± 18
Gender	166 male (57%)	197 male (62%)	363 male (60%)
AFib	56 (19%)	76 (24%)	132 (22%)
Paroxysmal	–	60 (19%)	60 (9.8%)
Persistent	23 (7.9%)	16 (5.0%)	39 (6.4%)
Long-standing persistent	33 (11%)	–	33 (5.4%)
AFl	40 (14%)	84 (26%)	124 (20%)
aAFl/AT	50 (17%)	6 (1.9%)	56 (9.2%)
AVNRT	29 (10%)	70 (22%)	99 (16%)
CMT	55 (19%)	45 (14%)	100 (16%)
AVJ	8 (2.7%)	8 (2.5%)	16 (2.6%)
VT	54 (18%)	29 (9.1%)	83 (14%)
VT-SHD	17 (5.8%)	15 (4.7%)	32 (5.2%)
VT-NSHD	37 (12%)	14 (4.4%)	51 (8.4%)

MNS, magnetic navigation system; MAN, manual navigation; AFib, atrial fibrillation; AFl, cavotricuspid isthmus-dependent atrial flutter; aAFl, atypical atrial flutter; AT, atrial tachycardia; AVNRT, atrioventicular nodal re-entrant tachycardia; CMT, circus movement tachycardia; AVJ, atrioventricular junction; VT, ventricular tachycardia; SHD, structural heart disease; NSHD, non-structural heart disease.

Table 2 Ablation results—acute success

	Group MNS	Group MAN	Total	*P* value
All arrhythmias	269/292 (92%)	298/318 (94%)	567/610 (93%)	0.904
AFib	52/56 (93%)	75/76 (99%)	127/132 (96%)	0.083
Paroxysmal	–	59/60 (98%)	59/60 (98%)	na
Persistent	22/23 (96%)	16/16 (100%)	38/39 (97%)	0.398
Long-standing persistent	30/33 (91%)	–	30/33 (91%)	na
AFl	38/40 (95%)	82/84 (98%)	120/124 (97%)	0.440
aAFl/AT	42/50 (84%)	4/6 (67%)	46/56 (82%)	0.295
AVNRT	29/29 (100%)	68/70 (97%)	97/99 (98%)	0.358
CMT	52/55 (95%)	39/45 (87%)	91/100 (91%)	0.075
AVJ	8/8 (100%)	8/8 (100%)	16/16 (100%)	–
VT	50/54 (93%)	21/29 (72%)	71/83 (86%)	0.013
VT-SHD	14/17 (82%)	10/15 (67%)	24/32 (75%)	0.306
VT-NSHD	36/37 (97%)	11/14 (79%)	47/51 (92%)	0.026

MNS, magnetic navigation system; MAN, manual navigation; AFib, atrial fibrillation; AFl, cavotricuspid isthmus-dependent atrial flutter; aAFl, atypical atrial flutter; AT, atrial tachycardia; AVNRT, atrioventicular nodal re-entrant tachycardia; CMT, circus movement tachycardia; AVJ, atrioventricular junction; VT, ventricular tachycardia; SHD, structural heart disease; NSHD, non-structural heart disease; na, not applicable.
P values listed were calculated based on a two-sample *t*-test assuming unequal variances between group MNS and group MAN.

the safety comparison (Tables 1 and 2). Patients included into the persistent AFib group were comparable (Tables 1 and 2). The VT group was further analysed in subgroups of patients with and without structural heart disease (SHD and NSHD).

Follow-up

Follow-up visits were scheduled for all patients at the outpatient clinic of the Department of Cardiology, Erasmus MC 3 months following the procedure, and every 3 months thereafter,

except for CMT, AFl, and AVNRT patients, when other than the first follow-up visit was scheduled only if the symptoms recurred. Atrial fibrillation patients were more rigorously followed at the AFib clinic of the department, including daily transtelephonic rhythm strips.

Statistics

Parameters obtained from the registry were analysed using SPSS 15.0 (SPSS Inc., Chicago, IL, USA). Patient demographic and baseline characteristics were presented as mean+SD. The two-tailed Student's t-test was used for comparing continuous unpaired samples, assuming unequal variances (age, fluoroscopy time, procedure time, and follow-up period). For categorical variables the x2 test was performed (number of patients with different arrhythmias, gender, success rate, recurrence rate, and number of complications). Two-sided P values ,0.05 were considered significant.

RESULTS

Patients

There were no differences in the gender and age between group MNS and MAN (Table 1). There were no differences in the number of patients enrolled into the subgroups based on the diagnosed arrhythmias, except for the subgroups mentioned in the Methods section—paroxysmal and long-standing persistent AFib and AFL/AT (Table 1). There was no difference in the presence of PMs or ICDs between the study groups (PM: 4 MNS vs. 6 MAN, P ¼ NS; ICD 20 MNS vs. 21 MAN, P ¼ NS). In, two patients (both in the VT group, both had abdominal implant) the ICD switched to magnet mode (asynchronous pacing). None of these patients were PM dependent; therefore, temporary programming allowed electro-anatomical mapping without further problems. No long-term effect on ICD or PM function was observed.

Ablation

Magnetic navigation system was equally effective as MAN in acute success rate for the overall groups (Table 2). In the subgroups only VT results were different, where MNS was more successful (Table 2). The success rate in the NSHD-VT subgroup was higher in MNS group, whereas the difference in VT subgroup with SHD did not reach statistical significance (Table 2). For the other subgroups no differences were observed in success rates (Table 2). Crossovers occurred only before the availability of irrigated tip MNS catheters, whereas one CMT patient and two AFl patients underwent crossover from MNS catheters (4 mm for CMT, 8 mm for AFl) to manual guided irrigation tip catheters. Following the crossover all the three patients were ablated successfully. However, the MNS still proved to be non-inferior for the ablation of AFl and CMT. Overall, less fluoroscopy was used in group MNS (Table 3). In the

Table 3 Summary of mean fluoroscopy and procedure times for group MNS and MAN

	Fluoroscopy time (min)			Procedure time (min)		
	MNS	**MAN**	***P* value**	**MNS**	**MAN**	***P* value**
All arrhythmias	30 ± 20	35 ± 25	0.009	168 ± 67	159 ± 75	0.119
AFib	44 ± 17	40 ± 22	0.278	248 ± 59	191 ± 81	0.001
Paroxysmal	–	36 ± 19	na	–	168 ± 52	na
Persistent	42 ± 15	54 ± 28	0.061	232 ± 41	276 ± 107	0.088
Long-standing persistent	46 ± 19	–	na	264 ± 70	–	na
AFl	27 ± 13	32 ± 24	0.198	152 ± 44	123 ± 47	0.005
aAFl/AT	37 ± 23	47 ± 20	0.361	188 ± 51	208 ± 53	0.464
AVNRT	12 ± 8.8	25 ± 20	0.001	114 ± 39	136 ± 55	0.068
CMT	28 ± 18	32 ± 27	0.428	134 ± 50	146 ± 57	0.314
AVJ	6.5 ± 2.4	7.7 ± 3.7	0.472	72 ± 7.5	86 ± 21	0.147
VT	27 ± 21	56 ± 31	0.001	166 ± 54	222 ± 97	0.009

MNS, magnetic navigation system; MAN, manual navigation; min, minutes; AFib, atrial fibrillation; AFl, cavotricuspid isthmus-dependent atrial flutter; aAFl, atypical atrial flutter; AT, atrial tachycardia; AVNRT, atrioventicular nodal re-entrant tachycardia; CMT, circus movement tachycardia; AVJ, atrioventricular junction; VT, ventricular tachycardia; na, not applicable. *P* values listed were calculated based on a two-sample *t*-test assuming unequal variances between group MNS and group MAN.

AVNRT and VT subgroups, less fluoroscopy was used in group MNS, otherwise there were no differences between the two groups (Table 3). There were no differences in procedure times between group MNS and MAN. Concerning subgroups, procedure times were higher using MNS in AFl, but were shorter in the VT subgroup.

Complications

The use of MNS was associated with a lower complication rate (4.5 vs. 10%; P ¼ 0.005). Moreover, concerning major complications the difference was also significant between the two groups (0.34 vs. 3.2%; P ¼ 0.01). One permanent AV block occurred in the MNS and one in the MAN group. The other nine major complications in the MAN group were either pericardial effusion or pericardial tamponade, whereas no effusion/tamponade occurred in the MNS group. There was a trend towards lower minor complications in the MNS group as well, but it did not reach statistical significance (4.1 vs. 6.4%; P ¼ ns) (Figure 1). Two temporary AV block were observed in the MNS group, one in the MAN group, the rest of the minor complications were femoral bleeding/haematoma in both groups.

Follow-up

There were no differences in follow-up periods between group MNS and MAN (15+9.5 vs. 14+9.5 months, P ¼ ns). There were no differences in recurrence rates between group MNS and MAN in overall (14 vs. 11%, P ¼ ns) or in any of the subgroups [(AFib persistent 14 vs. 19%) (AFib paroxysmal — vs. 16%) (AFib long-standing persistent 33 vs. 0%) (aAFL/AT 14 vs. 25%) (AFl 13 vs. 11%) (AVNRT 6.9 vs. 7.4%) (CMT 7.7 vs. 5.2%) (AVJ 0 vs. 0%) (VT 14vs. 14%), P ¼ ns].

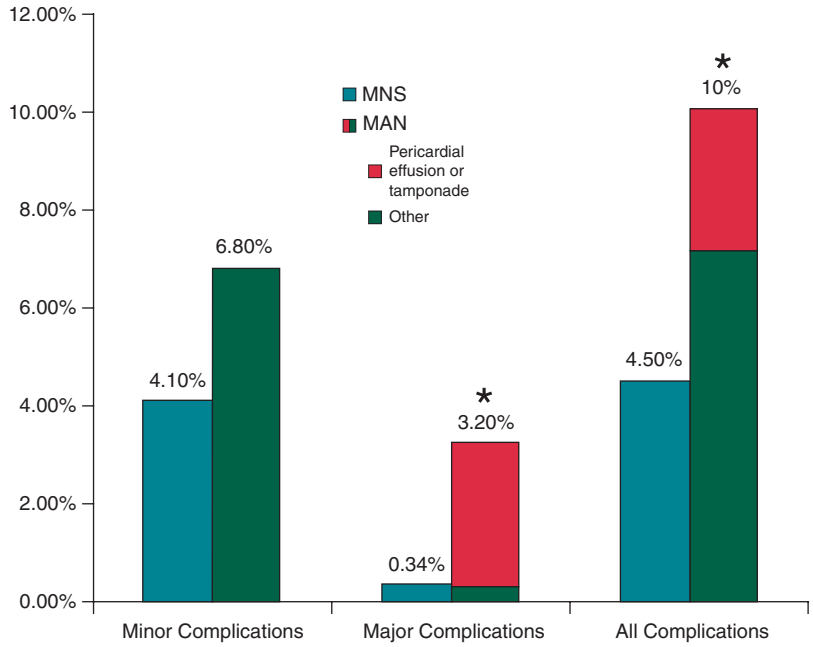


Figure 1 Complications Comparison of minor, major, and all complications between magnetic navigation system and manual navigation groups. Pericardial effusion/tamponade is coloured black. Asterisk indicates $P \leq 0.01$.

DISCUSSION

This is the first study that assesses the efficacy and safety of ablations using MNS vs. manual navigation involving statistically equivalent, large-scaled patient groups. Our series includes all types of arrhythmias, arising from all four heart chambers. There are three major findings of this study. First, MNS proved to be equal to manual ablation not only in acute success rate, but for a reasonable follow-up period in a broader aspect of arrhythmias. Second, MNS was superior in safety as compared with manual navigation resulting in lower number of complications as well as less fluoroscopy times. Third, MNS was found to be better for the ablation of VT.

Rationale of using MNS for ablations

The success of catheter ablation procedures depends on accurate substrate location, followed by optimal delivery of energy provided by good tissue contact.24 Manual navigation of catheters in the human heart has limitations: some regions are difficult to reach, and compromised catheter positioning may result in insufficient lesion formation.13,24 Catheter movement in some positions is accompanied by the risk of major complications, including pericardial effusion or tamponade.7,24 Although several pre-defined catheter curves were

introduced to help appropriate lesion delivery, there are no optimal curves available for the treatment of paediatric patients with small hearts, patients with complex congenital heart defects, or some type of VTs.25 The introduction and utilization of MNS was aimed at surmounting these difficulties. It provides improvement of safety by the flexible catheter design, and no pericardial effusion or tamponade was reported related to catheter navigation using MNS.20 Magnetic navigation system also provides better navigation capability, which is not limited by preformed or evolved catheter curves.19,25,26 Theoretically, nonfluoroscopic imaging and recently built-in automated functions (AutoMap, stored magnetic vectors) allow less fluoroscopy time (to both operator and patient).18 Stored magnetic vectors also make it possible to re-navigate to spots defined and stored during the procedure.26 Promising initial results were published concerning these above-mentioned issues.22,23,25,27 In our experience, automated map function was used in all AFib, aAFl/AT and VT patients undergoing MNS ablation. Manual correction was performed after automated mapping, which could be completed in 5–6 min on average.

Acute success rates and recurrences

Based on the theoretical advantages mentioned above, MNS could be superior to manual navigation in the analysed parameters. Reports until now focused more on feasibility rather than assessment of efficacy of MNS.10,11,15,17,23,25 – 30 Contrary to this, we aimed at comparing large groups of patients treated using MNS or MAN, with a long follow-up period. We confirm that MNS is feasible for ablation of different kinds of arrhythmias, and clearly demonstrate that it provides better safety and uses less fluoroscopy than manual navigation (see below). Furthermore, superiority in acute success rate can be achieved in the VT subgroup (see below). Certainly, some issues are still to be solved that may play a role in limiting of MNS. The delivered contact force is unknown relative to manual catheters in which it had been shown to affect adequate lesion formation. However, based on the high acute success and low recurrence rates found in all subgroups during the reasonably long follow-up period, it does not seem to effect patient outcomes. Preparation of the system consumes considerable time (isocentering, registration, merging with CARTO, checking magnet movement). However, it does not result in significant prolongation of the procedures in overall. Although improvements were made recently, we also lack of fully automated functions (no need or automated isocentering; reliable, well-defined automapping) yet.

Crossovers

In our series, we encountered only three patients, where crossover to manual navigation became necessary (one CMT and two AFl patients). Although the endpoint could be reached using manual navigation in all three cases, no difference was found in general between MNS and MAN concerning the acute success rates in these subgroups. Also, it is important to notice that these crossovers happened before the availability of irrigation tip catheters for MNS.

Safety of ablations

The use of atraumatic, flexible designed ablation catheters combined with magnetic field-guided navigation resulted in significantly reduced number of complications. No pericardial effusion or tamponade was observed in the MNS group, whereas in the MAN group these proved to be the most frequent major complications. All TSPs were guided by ICE, and none of these complications were related to them. This finding is consistent with previous reports, but these reports failed to substantiate it with significant statistical difference. Two atrioventricular blocks (AVB) occurred in the MSN group (one in a patient with parahisian AT; the risk was discussed with the patient after the diagnosis of the tachycardia was established. The other AVB occurred in a patient with AVNRT during an application near the ostium of the coronary sinus. In this case, our hypothesis is either an ectopic fast pathway or the occlusion of the AVN artery) Concerning minor complications—dominantly minor bleeding related to the femoral punctures, we also found somewhat higher number in the MAN group, which could be explained by the greater diameter of sheaths used for manual ablation such as cryo-balloon sheaths and decreased movement of the sheath at the puncture site during remote catheter manipulation. The high manoeuvrability and atraumatic design of the MNS-guided ablation catheter allows navigation without constant fluoroscopy control, while re-imaging is typically required after each repositioning of the manual-guided catheter.18 Furthermore, stored MNS vectors also help to navigate the catheter without repeated fluoroscopic pulses. As we mentioned in the Methods section, our clinic is an academic centre, and the fellows are taking part of the procedures, including femoral vein and artery punctures, and diagnostic catheter positioning. This significantly influences fluoroscopy or procedure times, and minor complication rates in both groups. Although our data may seem too high at first glance concerning these parameters, they are not really deviated from recently published available data.31

Transseptal puncture or retrograde aortic approach

In our centre, standard approach for left-sided VT is retrograde aortic ablation. Also, in case of left-sided accessory pathway the retrograde aortic approach is preferred. In our experience, this method helps to avoid the chance for serious complications (pericardial effusion/tamponade) and/or the need for expensive diagnostic tools (ICE).

Ablation of ventricular tachycardia

This is the first large-scale study to prove the superiority of MNS for ablation of VT compared with manual navigation. This is demonstrated in most of the analysed parameters, such as acute success rate, and procedure and fluoroscopy times. There are multiple reasons to explain this finding. The MNS-guided catheter retains its manoeuvrability even in difficult positions, e.g. in cusp-related VTs, papillary muscle-originated VTs, where the capabilities of manual navigation are seriously limited by the multiple curves of the catheter.11 The MNS

controls the tip of the catheter, which means that the unavoidable curves of the catheter do not hinder the positioning of the tip, and good contact can be achieved, resulting in appropriate lesion formation.13 An MNS-guided catheter has no pre-defined curve, which also contributes to the high manoeuvrability. Moreover, catheter stability using MNS is improved due to the constant magnetic force directing the tip unchanged during application.13 The above-mentioned capabilities are especially beneficial for patients in whom the arrhythmia substrate is located in a difficult position (i.e. posteroseptal wall in the right or left ventricular outflow tract) or where stability is the major issue (i.e. papillary muscle VTs). Two patients had papillary muscle-originated VT, and five patients had aortic cusp VT in the MNS group, all the seven patients were ablated successfully. This can explain the difference in success rates between the VT subgroups, whereas statistical significance could be only proven for the NSHD-VT subgroup.

Limitations of the study

Although this registry is not a randomized, prospective trial, there was not any difference between the two groups and the assignment of the patients to the groups was independent of the operators. However, because of local protocols for the treatment of AFib patients, there were no paroxysmal patients treated with the MNS, and there were no long-standing persistent AFib patients treated manually. This means that only persistent AFib subgroups were comparable, and these groups were not different indeed.

CONCLUSIONS

In conclusion, the MNS is equal in terms of acute and long-term success rates compared with MAN, whereas MNS-guided procedures can be performed with a lower complication rate and using less fluoroscopy. For the ablation of VT, MNS is superior to MAN.

REFERENCES

1. Scheinman M. Transvenous AV junctional ablation. Am Heart J 1983;106:607–8.
2. Critelli G, Perticone F, Coltorti F, Monda V, Gallagher JJ. Antegrade slow bypass conduction after closed-chest ablation of the His bundle in permanent junctional reciprocating tachycardia. Circulation 1983;67:687–92.
3. American College of C, American Heart A, American College of Physicians Task Force on Clinical Competence and T, Heart Rhythm S, Tracy CM, Akhtar M, DiMarco JP, Packer DL, Weitz HH, Creager MA, Holmes DR Jr, Merli G, Rodgers GP. American College of Cardiology/American Heart Association 2006 update of the clinical competence statement on invasive electrophysiology studies, catheter ablation, and cardioversion: a report of the American College of Cardiology/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training: developed in collaboration with the Heart Rhythm Society. Circulation 2006;114: 1654–68.
4. Khongphatthanayothin A, Kosar E, Nademanee K. Nonfluoroscopic threedimensional mapping for arrhythmia ablation: tool or toy? J Cardiovasc Electrophysiol 2000;11:239–43.
5. Marchlinski FE, Callans DJ, Gottlieb CD, Zado E. Linear ablation lesions for control of unmappable ventricular tachycardia in patients with ischemic and nonischemic cardiomyopathy. Circulation 2000;101:1288–96.
6. Faddis MN, Blume W, Finney J, Hall A, Rauch J, Sell J et al. Novel, magnetically guided catheter for endocardial mapping and radiofrequency catheter ablation. Circulation 2002;106:2980–5.
7. Faddis MN, Chen J, Osborn J, Talcott M, Cain ME, Lindsay BD. Magnetic guidance system for cardiac electrophysiology: a prospective trial of safety and efficacy in humans. J Am Coll Cardiol 2003;42:1952–8.
8. Ernst S, Ouyang F, Linder C, Hertting K, Stahl F, Chun J et al. Initial experience with remote catheter ablation using a novel magnetic navigation system: magnetic remote catheter ablation. Circulation 2004;109:1472–5.
9. Aryana A, d'Avila A, Heist EK, Mela T, Singh JP, Ruskin JN et al. Remote magnetic navigation to guide endocardial and epicardial catheter mapping of scar-related ventricular tachycardia. Circulation 2007;115:1191–200.
10. Katsiyiannis WT, Melby DP, Matelski JL, Ervin VL, Laverence KL, Gornick CC. Feasibility and safety of remote-controlled magnetic navigation for ablation of atrial fibrillation. Am J Cardiol 2008; 102:1674–6.
11. Schwagten BK, Szili-Torok T, Rivero-Ayerza M, Jessurun E, Valk S, Jordaens LJ. Usefulness of remote magnetic navigation for ablation of ventricular arrhythmias originating from outflow regions. Neth Heart J 2009;17:245–9.
12. Arentz T, von Rosenthal J, Blum T, Stockinger J, Burkle G, Weber R et al. Feasibility and safety of pulmonary vein isolation using a new mapping and navigation system in patients with refractory atrial fibrillation. Circulation 2003;108:2484–90.
13. Davis DR, Tang AS, Gollob MH, Lemery R, Green MS, Birnie DH. Remote magnetic navigation-assisted catheter ablation enhances catheter stability and ablation success with lower catheter temperatures. Pacing Clin Electrophysiol 2008;31: 893–8.
14. Pappone C, Vicedomini G, Manguso F, Gugliotta F, Mazzone P, Gulletta S et al. Robotic magnetic navigation for atrial fibrillation ablation. J Am Coll Cardiol 2006;47:1390–400.
15. Thornton AS, Jordaens LJ. Remote magnetic navigation for mapping and ablating right ventricular outflow tract tachycardia. Heart Rhythm 2006;3:691–6.

16. Chun JK, Ernst S, Matthews S, Schmidt B, Bansch D, Boczor S et al. Remote controlled catheter ablation of accessory pathways: results from the magnetic laboratory. Eur Heart J 2007;28: 190–5.
17. Di Biase L, Fahmy TS, Patel D, Bai R, Civello K,Wazni OM et al. Remote magnetic navigation: human experience in pulmonary vein ablation. J Am Coll Cardiol 2007; 50:868–74.
18. Kim AM, Turakhia M, Lu J, Badhwar N, Lee BK, Lee RJ et al. Impact of remote magnetic catheter navigation on ablation fluoroscopy and procedure time. PACE 2008;31:1399–404.
19. Schmidt B, Chun KR, Tilz RR, Koektuerk B, Ouyang F, Kuck KH. Remote navigation systems in electrophysiology. Europace 2008;10(Suppl 3):iii57–61.
20. Wood MA, Orlov M, Ramaswamy K, Haffajee C, Ellenbogen K. Remote magnetic versus manual catheter navigation for ablation of supraventricular tachycardias: a randomized, multicenter trial. PACE 2008;31:1313–21.
21. Di Biase L, Burkhardt JD, Lakkireddy D, Pillarisetti J, Baryun EN, BiriaMet al. Mapping and ablation of ventricular arrhythmias with magnetic navigation: comparison between 4- and 8-mm catheter tips. J Interv Card Electrophysiol 2009;26:133–7.
22. Vollmann D, Luthje L, Seegers J, Hasenfuss G, Zabel M. Remote magnetic catheter navigation for cavotricuspid isthmus ablation in patients with common-type atrial flutter. Circ Arrhythm Electrophysiol 2009;2:603–10.
23. Haghjoo M, Hindricks G, Bode K, Piorkowski C, Bollmann A, Arya A. Initial clinical experience with the new irrigated tip magnetic catheter for ablation of scar related sustained ventricular tachycardia: a small case series. J Cardiovasc Electrophysiol 2009;20:935–9.
24. Wittkampf FH, Nakagawa H. RF catheter ablation: lessons on lesions. Pacing Clin Electrophysiol 2006;29:1285–97.
25. Schwagten B, Jordaens L, Witsenburg M, Duplessis F, Thornton A, van Belle Y et al. Initial experience with catheter ablation using remote magnetic navigation in adults with complex congenital heart disease and in small children. Pacing Clin Electrophysiol 2009;32(Suppl 1):S198–201.
26. Ernst S. Magnetic and robotic navigation for catheter ablation: "joystick ablation". J Interv Card Electrophysiol 2008;23:41–4.
27. Miyazaki S, Nault I, Haissaguerre M, Hocini M. Atrial fibrillation ablation by aortic retrograde approach using a magnetic navigation system. J Cardiovasc Electrophysiol 2010;21:455–7.
28. Thornton AS, Rivero-Ayerza M, Jordaens LJ. Ablation of a focal left atrial tachycardia via a retrograde approach using remote magnetic navigation. Europace 2008;10:687–9.
29. Thornton AS, Rivero-Ayerza M, Knops P, Jordaens LJ. Magnetic navigation in leftsided AV reentrant tachycardias: preliminary results of a retrograde approach. J Cardiovasc Electrophysiol 2007; 18:467–72.
30. Thornton AS, Janse P, Theuns DA, Scholten MF, Jordaens LJ. Magnetic navigation in AV nodal re-entrant tachycardia study: early results of ablation with one- and three-magnet catheters. Europace 2006;8:225–30.
31. Pantos I, Patatoukas G, Katritsis DG, Efstathopoulos E. Patient radiation doses in interventional cardiology procedures. Current cardiology reviews 2009;5:1–11.

Overview

SUMMARY

Electrophysiologists have been performing catheter ablation over almost 30 years with varying success and complication rates. In this thesis we set out to determine where we stand after three decades of electrophysiological evolution.

Radiofrequency (RF) catheter ablation for atrioventricular nodal reentrant tachycardia (AVNRT) is highly successful but carries a small risk for inadvertent atrioventricular block (AVB). Cryoablation (Cryo) can assess the safety of a target site before energy is delivered. In chapter 1 of Part I we have evaluated the long term efficacy and safety of cryothermal ablation in comparison to RF in our series of patients treated between 1999 and 2007 excluding patients in former studies. We used for the first time a disease specific questionnaire to assess the late outcome. Results showed that overall success rate is comparable in Cryo and RF, even after a very long term follow-up, which has never been published before. Furthermore, Cryo is a safe technique regarding regarding preservation of atrioventricular conduction in AVNRT ablation since not a single permanent AVB occurred in the Cryo group.

The advantages offered by Cryo rely on the unique way of lesion formation. This is discussed in chapter 2 of Part I. Cooling the tip of the catheter creates a temperature gradient in the tissue. By cooling the catheter tip to no more than minus 30°C for less than 60 seconds, the targeted tissue will only temporarily lose its conduction capabilities. However, this 'functio laesa' is of a transient nature and no permanent damage is done. Once the catheter rewarms, the tissue regains its full function as if nothing happened. When the optimal ablation point is determined in this fashion by 'cryomapping', the operator can decide to move on to 'cryoablation' and the catheter tip is cooled to minus 80°C. Again a temperature gradient is created inside the tissue that reaches a steady state between 3 and 5 minutes. The cells within the proximity of the catheter tip permanently lose their function and an irreversible ablation lesion is created. At that time another exceptional characteristic of Cryo is revealed: on a cellular level the interior of the cells loses its function, but the exoskeleton remains intact. This makes cryolesions less thrombogenic and possibly less pro-arrhythmic in the long run. Of course we have to take into account that the quality and size of lesion formation is influenced by catheter tip size, application duration and freezing rate.

Recently several new tools have been introduced to perform ablation in a faster, easier and hopefully safer way. However, by introducing these new tools we sometimes are faced with unexpected disadvantages.

In chapter 1 of Part II we report on the case of a patient with severe PV stenosis of the left superior PV 5 months after pulmonary vein isolation (PVI) using a multipolar over-the-wire duty-cycled pulmonary vein ablation catheter (PVAC).
Unlike Cryo, RF application causes cells to disintegrate. This can lead to pulmonary vein stenosis whenever RF is applied inside the pulmonary veins (PVs). Despite current techniques targeting a more extra-ostial ablation, PV stenosis occurs in 1% to 3% of patients after catheter ablation for atrial fibrillation (AF). Although frequently asymptomatic, it can be associated with severe respiratory symptoms. Point-by-point catheter ablation remains a laborious task, this elicits the need for "single-shot" devices to make AF ablation a more straightforward procedure. The PVAC catheter, a multielectrode over-the wire catheter using duty-cycled bipolar and unipolar nonirrigated RF energy, has recently provided promising results.
We present the first report of significant PV stenosis after PVAC ablation, which can represent a potential serious drawback of the technique. Due to its over-the wire design, the PVAC catheter can easily be torqued in and out of the PVs, inevitably harboring the tendency to again more closely approach the PV ostium. This approach may increase the risk for PV stenosis, especially when delineation of the PV ostia by a selective PV angiogram is not sufficiently accurate. Furthermore, PVAC ablation is performed in a circular fashion at multiple electrodes simultaneously. A circumferential cicatrization close to the PV ostium may lead to ostial PV stenosis during the subsequent healing process. We advise to limit the total number and/or the number of 2:1 modus applications, to avoid ablations too close to the PV ostium, and to improve imaging modalities to accurately delineate the PV ostia as potential ways to minimize the risk of PV stenosis.

Continuous innovation seeks to increase success rates and diminish complications. However, we cannot influence the preexisting substrate and the risk associated with the `frailty` of the individual patient. In chapter 2 of Part II we study the safety, feasibility and success rate of a cryoballoon ablation in elderly patients as compared to younger patients. Our data suggest a similar serious adverse event (SAE) rate in both groups. However, vascular complications occurred more frequently in the elderly and if the patients under general anaesthesia were considered, the higher age group had significantly more SAE, vascular and other adverse events (AE). Success rates were similar in both groups. These data suggest that more attention should be paid to avoidance of vascular complications if one decides to invasively treat elderly patients.

Another novelty to speed up and possibly increase efficacy of cryoballoon procedures is the Achieve circular mapping catheter (Achieve). The Achieve is introduced through the Cryoballoon system. This wire is conceived to combine both the properties of a wire for positioning of the Cryoballoon at the antrum of the pulmonary veins and the possibility of continuously checking the presence of pulmonary vein potentials throughout the ablation. In chapter 3 of

Part II we describe an apparent case of real time disappearance of pulmonary vein potentials during Cryoballoon application. Judging by the first results the Achieve circular mapping catheter seems to be a useful additional tool in PVI procedures using the Cryoballoon. Especially in pulmonary veins with late branching, delay and disappearance of pulmonary vein potentials can be monitored during cryoablation. However, in pulmonary veins with early branching local pulmonary vein potentials are hard to monitor during ablation as the Achieve wire is advanced into the branches of the veins by the relatively long tip of the Cryoballoon. If the findings on the Achieve circular mapping catheter prove to be consistent in randomized trials in comparison to the mapping capabilities of the lasso catheter, this could significantly speed up procedures. This also could make procedures safer as it obviates the need for a second transseptal puncture and renders the need for switching of the Cryoballoon for the lasso catheter superfluous.

One particularly interesting new development is the magnetic navigation system (MNS). The MNS consists of two permanent magnets situated on either side of the patient, which are computer-controlled via a workstation that allows changing the orientation of a stable magnetic field within the chest of the patient. Combined field strength of 0.08 to 0.1 Tesla is produced in a navigation mode. From the control room, remote catheter advancement and retraction can be performed using a catheter advancer system, positioned on the high anterior thigh. Remote control of the fluoroscopy system was also performed from the control room. The mapping and ablation catheters are equipped with three small permanent magnets within the distal tip segment that align themselves with the direction of the externally controlled magnetic field, allowing effective catheter orientation. By changing the orientation of the outer magnets relative to each other, the orientation of the magnetic field changes and thereby leads to deflection of the catheter. After the magnets are brought as close as possible to the patient, the physician performs the rest of the procedure from the control room. A nurse stays with the patient to monitor vital signs and administer drugs when required.

In Part III we set out to evaluate the limits of the MNS in different clinical trials. In chapter 1 of Part III a prospective randomized study was conceived to compare RF catheter ablation of left-sided accessory pathways (APs) performed either by a transseptal (TS) or transaortic (TA) approach. Twenty-two consecutive patients were randomized to either a TS or a TA approach. The MNS was used in all patients for catheter navigation and eventual ablation, after the electrophysiologic study confirmed the presence of left-sided APs. Our data show that TS and TA approaches are equal in success rate and total procedure, patient fluoroscopy, and ablation time when using the MNS for left-sided AP ablation. However, crossing the aortic valve with the MNS is faster than completing a TS puncture.

In chapter 2 of Part III we take testing the limits of the MNS even one step further. We test a highly simplified approach using a single RF ablation catheter with the remote magnetic navigation system (MNS) to diagnose and treat AVNRT. In the magnetic navigation (MN) group a single MN quadripolar catheter inserted through the internal jugular vein is used to diagnose AVNRT through electrogram interpretation on different prestored positions of the catheter. Subsequently RF ablation is performed. The safety and efficacy of this approach was compared to cryoablation and manual RF ablation. Procedural times were shorter in the single catheter group and physicians were exposed to virtually no radiation. Success rates were similar in all groups. This proves that MN guided single catheter ablation of AVNRT is a feasible technique in treating carefully selected patients with typical AVNRT.

New techniques are developed with the intention to overcome limitations we are faced with in everyday practice. When evaluating these novelties, we discover there is still some room for improvement. Chapter 3 of Part III is dedicated to the use of the MNS in treating atrial flutter. In this study we compared MNS, using non-irrigated and irrigated tip catheters, to manual RF ablation for ablating typical atrial flutter. The primary outcome was the number of patients in whom bidirectional isthmus block could be obtained with ≤15 applications. Secondary endpoints were the median number of applications needed, the need to switch to a manual irrigated tip catheter, the procedural and fluoroscopy times. We found there was no significant difference in the primary endpoint. However, the median number of applications needed to obtain block was higher in the MNS group compared to the manual group. There was no difference in fluoroscopy time, but procedural time was significant longer in the MNS group. So, the use of magnetic navigation for the ablation of atrial flutter is feasible but not superior to a manual approach. Overall, more applications were needed and procedure times were longer with MNS.

A new and very interesting field of interest for using the MNS, are children and adults with complex arrhythmias in the setting of structural cardiac abnormalities. The improved outcomes and increased availability of surgery for congenital heart disease (CHD) over the last three decades have created a small but steadily increasing subset of patients with unique needs. RF catheter ablation in these patients, and in small children with normal cardiac anatomy, is effective but challenging. An understanding of specific anatomical and electrophysiological characteristics of these patients and the technical challenges in addressing them are critical to the success of this therapy. Tools specifically designed for intracardiac diagnosis and therapy in anatomically complex and/or small hearts remain scarce. In chapter 4 of Part III we report single-center results from an ongoing registry of all patients with congenital heart disease and all children with complex arrhythmias in which the MNS was used. Included in this report are 12 patients with CHD in whom 17 tachyarrhythmias were treated, and 11 pediatric patients with normal cardiac anatomy who each had a single arrhythmia. Procedure duration

and fluoroscopy time as well as arrhythmia recurrence rates were comparable to those found in previous reports of procedures performed in adults with structurally normal hearts, and the incidence of complications was quite low. In patients with complex congenital malformations, retrograde mapping of the pulmonary venous atrium was feasible, eliminating the need for puncture of the atrial septum, or surgically placed baffle in many cases. Moreover, the design of the magnetic catheter eliminated the need for multiple mapping and ablation catheters. Our findings suggest that RF catheter ablation using the MNS for arrhythmias after surgery for congenital heart disease and in pediatric patients is safe and effective.

More specifically we report in chapter 5 of Part III the use of the MNS in young children (<10 years old), especially because reduction in procedure and fluoroscopy time could decrease the hazardous effects of the ablation procedures. We compared the efficacy and safety between a manual and MNS-guided approach in this pediatric arrhythmia population and in a subgroup of young children aged <10 years old. Our data have strongly suggested that using the MNS for treating young children is advantageous, because it significantly reduced the procedure and fluoroscopy times without compromising efficacy.

The capabilities of the MNS are highlighted in chapter 6 of Part III by an exceptional case that could only be performed in this way using a MN catheter. An 18-year-old female patient with tricuspid atresia, discordant ventriculo-arterial connections, a total cavo-pulmonary connection, and a Damus-Kaye-Stansel suffered from atrial tachycardia. The extreme flexibility and maneuverability of the MN catheter made it possible to create a complete electro-anatomical map of both atria and ablate successfully the tachycardia in the left atrium using a retrograde approach. Even with the MN catheter shaft being twisted in numerous directions, precise catheter tip steerability remained intact and allowed for successful ablation. This would have been impossible using manual ablation.

Finally, the MNS has also been introduced for ablation of ventricular tachycardia (VT). In chapter 7 of Part III we describe our study that compared the acute and late outcome of VT ablation using the MNS to ablation using conventional manual techniques (MAN). Our results suggest that the use of MNS offers major advantages for ablation of VT, including a higher acute success rate, reduced procedure time, lowered fluoroscopy exposure and fewer complications. Moreover, fewer recurrences of VT were observed in the MNS group.
As a final overview and in order to evaluate the overall safety and long-term efficacy of the MNS, in chapter 8 of Part III we reviewed all patients treated with the MNS at our center between January 2008 and March 2010, being 292 consecutive patients in total. Patients were divided into two age- and sex-matched groups and were compared to conventional manual ablation. Subgroup analysis was performed for the following groups: AF, isthmus dependent and atypical atrial flutter, atrial tachycardia, AVNRT, circus movement tachycardia, and VT.

MNS was associated with less total and less major complications, it was equally effective in acute success rate for overall groups, but more effective than manual ablation for VTs, and it used less fluoroscopy. There were no differences in procedure times and recurrence rates for the overall groups. So we are confident that the use of MNS improves safety without compromising efficiency of ablations.

Conclusion


112500337902
KLAS
2e
TREINKAART
KONTICH
ROOSENDAAL-GRENS
SCHWAGTEN
VELDSTRAAT
2547 LINT
Geboren op : 16/12/1978
Laatste geldigmaking voor :
25/06/2018
MET GELDIG ZONDER
code:00000
Onze Algemene Vervoersvoorwaarden zijn van
toepassing. Info in onze stations
112562102040
26/06/2008
BRUNO
48.
Sec

Conclusion

When considering current literature and our contribution to it through these papers, faster, safer and better catheter ablation should indeed be followed by a question mark: not only for the mere sequence of these three adjectives, but also for the question if they all apply to current practice in electrophysiology.

With respect to the arrangement of those three words, we personally conclude that safety remains the critical determinant in the majority of patients treated for cardiac arrhythmias. Cryotherapy for AVNRT has undoubtedly proven to be the safest approach in treating this non-lethal arrhythmia without creating permanent atrioventricular block. Also in atrial fibrillation, cryoballoon therapy has earned its merits when the adequate patients are selected. But the new technique that is mostly linked to safety issues is without a doubt the magnetic navigation system. We are convinced that this association is appropriate and using remote magnetic catheter navigation is advantageous. New companies also investing in this concept only reinforce the belief that there is a future for magnetic navigation.

In order to improve both efficacy and speed a thorough knowledge of pathophysiology is paramount. Although a great deal of groundbreaking work has already been done, we are far from completely understanding complex arrhythmias. And despite the outside world pushing to increase numbers, we should try to keep focusing on uncovering the origin and progression of several arrhythmias.

To our knowledge, the key to success in invasively treating patients with cardiac arrhythmias lies in an approach tailored to the individual patient and flexible in balancing safety, success and speed. Different tools are already at our disposal and many more are being developed and tested. Fortunately, we have only just embarked on this tremendously innovative journey.

Besluit

Wanneer we de huidige literatuur bekijken en tevens de boodschap van de verschillende artikels in deze thesis in acht nemen, kunnen we niet anders dan besluiten dat het vraagteken achter 'faster, safer and better catheter ablation' er met recht en reden staat. Niet alleen de volgorde van deze drie woorden dient in vraag te worden gesteld, maar we moeten onszelf ook afvragen of deze drie termen allemaal van toepassing zijn op de manier waarop we electrofysiologie vandaag bedrijven.

Wat de volgorde van de woorden betreft, zijn wij ervan overtuigd dat veiligheid primordiaal is. Zo heeft vriestherapie onomstotelijk bewezen de veiligst mogelijke behandeling te zijn voor AVNRT gezien het risico op het creëren van een totaal atrioventriculair block quasi onbestaand is. Bij het behandelen van goed geselecteerde patiënten met voorkamerfibrillatie heeft de vriesballon ongetwijfeld ook zijn sporen verdiend. Maar wanneer het om nieuwe technieken gaat die ontwikkeld zijn met het oog op het veiliger maken van ablaties, dan spant het magnetisch navigatie systeem zondermeer de kroon. Omdat we zelf de veiligheid van de patiënt hoog in het vaandel dragen, zijn we absoluut voorstander om het magnetisch navigatie systeem zoveel mogelijk in de dagdagelijkse praktijk te gebruiken. Ons geloof in de toekomst van dit systeem wordt enkel nog maar versterkt door dat er momenteel nog andere systemen ontwikkeld worden die stoelen op hetzelfde mechanisme van magnetische navigatie.

Als we bovenop de veiligheid ook de efficiëntie en de snelheid van ablatieprocedures willen verhogen, is het belangrijk om het ontstaan van de verschillende ritmestoornissen te bestuderen. In de voorbije decennia is er al heel wat baanbrekend werk verricht op dit vlak, maar we kunnen nog niet stellen dat we vandaag het precieze mechanisme van de meer ingewikkelde ritmestoornissen volledig doorgronden. Het zou zinvol zijn om, in plaats van toe te geven aan de externe prestatiedruk om het aantal ablaties gestadig op te drijven, eerder onze aandacht toe te spitsen op het ontrafelen van de oorsprong en natuurlijke evolutie van ritmestoornissen.

Wij geloven dat de sleutel tot het succesvol invasief behandelen van ritmestoornissen ligt in een behandeling die op maat gemaakt is voor iedere patiënt afzonderlijk en die een perfect evenwicht biedt tussen veiligheid, efficiëntie en snelheid. We beschikken reeds over een heel arsenaal van hulpmiddelen hiervoor en quasi onophoudelijk worden er nieuwe ontwikkeld. En we mogen de toekomst met een gerust hart tegemoet zien, want deze ongelofelijk spannende en innoverende tocht is nog maar net begonnen.

Acknowledgements

THANKS A THOUSAND TIMES...

Jordaens LJLM, Szili-Torok T, Zijlstra F, van Domburg R, Willems R, Simoons M, de Groot N, Haitsma D, Res J, Jessurun E, Duplessis F, Thornton A, Witsenburg M, Roos J, Cuypers J, Theuns DAMJ, Janse P, Rivero-Ayerza M, Valk S, van der Heijden R, Scheffer M, Spierenburg H, Van Woerkens L, Anne W, Van Belle Y, Dabiri-Abkenari L, Caestecker D, Alloway R, Beurmanjer F, Brand R, Coenen A, Emilsdottir L, de Haan R, de Groot P, Kind-Huijskens C, Levens R, Saunders R, Peters E, Schilderman D, Chaitsing R, Knops P, Van De Rik I, Lopes M, Luijten R, Miltenburg M, van der Perk R, de Ruiter R, de Ruiter W, Veen D, Zandstra W, van Driel M, Genegel R, Kalkman Y, Leijdekker-Boer L, Orgers A, Muskens A, Takens M, Musters P, Vorm J, Dierckx R, Gielen WPMHIA, Kalkman Y, Orgers A, Barthelemy W, Kardos A, Bauernfeind T, Lovell J, Kaminski M, Rhakesh, Van Langenhove G, De Moor W, De Greef Y, Van den Branden F, Vanagt E, Stockman D, Mertens A, Van Walle M, Schwagten C, Schwagten E, Schwagten K, Schwagten D, Schwagten C, Schwagten V, Schwagten R, Schwagten J, Schwagten W, Schwagten J, Schwagten M, Smets K, Miljoen H, Schoenmaeckers Y, colleagues nurses and staff of EMC and Middleheim, family and friends, Jordaens LJLM, Szili-Torok T, Zijlstra F, van Domburg R, Willems R, Simoons M, de Groot N, Haitsma D, Res J, Jessurun E, Theuns DAMJ, Janse P, Valk S, van der Heijden R, Scheffer M, Spierenburg H, Van Woerkens L, Anne W, Van Belle Y, Dabiri-Abkenari L, Caestecker D, Alloway R, Beurmanjer F, Brand R, Coenen A, Emilsdottir L, de Haan R, de Groot P, Kind-Huijskens C, Levens R, Saunders R, Peters E, Schilderman D, Chaitsing R, Knops P, Van De Rik I, Lopes M, Luijten R, Miltenburg M, van der Perk R, de Ruiter R, de Ruiter W, Veen D, Zandstra W, van Driel M, Genegel R, Kalkman Y, Leijdekker-Boer L, Orgers A, Muskens A, Takens M, Musters P, Vorm J, Dierckx R, Gielen WPMHIA, Kalkman Y, Orgers A, Barthelemy W, Kardos A, Bauernfeind T, Lovell J, Kaminski M, Rhakesh, Van Langenhove G, De Moor W, De Greef Y, Van den Branden F, Vanagt E, Stockman D, Mertens A, Van Walle M, Schwagten C, Schwagten E, Schwagten K, Schwagten D, Schwagten C, Schwagten V, Schwagten R, Schwagten J, Schwagten W, Schwagten J, Schwagten M, Smets K, Miljoen H, Schoenmaeckers Y, colleagues nurses and staff of EMC and Middleheim, family and friends, Jordaens LJLM, Szili-Torok T, Zijlstra F, van Domburg R, Willems R, Simoons M, de Groot N, Haitsma D, Res J, Jessurun E, Theuns DAMJ, Janse P, Valk S, van der Heijden R, Scheffer M, Spierenburg H, Van Woerkens L, Anne W, Van Belle Y, Dabiri-Abkenari L, Caestecker D, Alloway R, Beurmanjer F, Brand R, Coenen A, Emilsdottir L, de Haan R, de Groot P, Kind-Huijskens C, Levens R, Saunders R, Peters E, Schilderman D, Chaitsing R, Knops P, Van De Rik I, Lopes M, Luijten R, Miltenburg M, van der Perk R, de Ruiter R, de Ruiter W, Veen D, Zandstra W, van Driel M, Genegel R, Kalkman Y, Leijdekker-Boer L, Orgers A, Muskens A, Takens M, Musters P, Vorm J, Dierckx R, Gielen WPMHIA, Kalkman Y, Orgers A, Barthelemy W, Kardos A, Bauernfeind T, Lovell J, Kaminski M, Rhakesh, Van Langenhove G, De Moor W, De Greef Y, Van den Branden F, Vanagt E, Stockman D, Mertens A, Van Walle M, Schwagten C, Schwagten E, Schwagten K, Schwagten D, Schwagten C, Schwagten V, Schwagten R, Schwagten J, Schwagten W, Schwagten J, Schwagten M, Smets K, Miljoen H, Schoenmaeckers Y, colleagues nurses and staff of EMC and Middleheim, family and friends, Jordaens LJLM, Szili-Torok T, Zijlstra F, van Domburg R, Willems R, Simoons M, de Groot N, Haitsma D, Res J, Jessurun E, Theuns DAMJ, Janse P, Valk S, van der Heijden R, Scheffer M, Spierenburg H, Van Woerkens L, Anne W, Van Belle Y, Dabiri-Abkenari L, Caestecker D, Alloway R, Beurmanjer F, Brand R, Coenen A, Emilsdottir L, de Haan R, de Groot P, Kind-Huijskens C, Levens R, Saunders R, Peters E, Schilderman D, Chaitsing R, Knops P, Van De Rik I, Lopes M, Luijten R, Miltenburg M, van der Perk R, de Ruiter R, de Ruiter W, Veen D, Zandstra W, van Driel M, Genegel R, Kalkman Y, Leijdekker-Boer L, Orgers A, Muskens A, Takens M, Musters P, Vorm J, Dierckx R, Gielen WPMHIA, Kalkman Y, Orgers A, Barthelemy W, Kardos A, Bauernfeind T, Lovell J, Kaminski M, Rhakesh, Van Langenhove G, De Moor W, De Greef Y, Van den Branden F, Vanagt E, Stockman D, Mertens A, Van Walle M, Schwagten C, Schwagten E, Schwagten K, Schwagten D, Schwagten C, Schwagten V, Schwagten R, Schwagten J, Schwagten W, Schwagten J, Schwagten M, Smets K, Miljoen H, Schoenmaeckers Y, colleagues nurses and staff of EMC and Middleheim, family and friends, Jordaens LJLM, Szili-Torok T, Zijlstra F, van Domburg R, Willems R, Simoons M, de Groot N, Haitsma D, Res J, Jessurun E, Theuns DAMJ, Janse P, Valk S, van der Heijden R, Scheffer M, Spierenburg H, Van Woerkens L, Anne W, Van Belle Y, Dabiri-Abkenari L, Caestecker D, Alloway R, Beurmanjer F, Brand R, Coenen A, Emilsdottir L, de Haan R, de Groot P, Kind-Huijskens C, Levens R, Saunders R, Peters E, Schilderman D, Chaitsing R, Knops P, Van De Rik I, Lopes M, Luijten R, Miltenburg M, van der Perk R, de Ruiter R, de Ruiter W, Veen D, Zandstra W, van Driel M, Genegel R, Kalkman Y, Leijdekker-Boer L, Orgers A, Muskens A, Takens M, Musters P, Vorm J, Dierckx R, Gielen WPMHIA, Kalkman Y, Orgers A, Barthelemy W, Kardos A, Bauernfeind T, Lovell J, Kaminski M, Rhakesh, Van Langenhove G, De Moor W, De Greef Y, Van den Branden F, Vanagt E, Stockman D, Mertens A, Van Walle M, Schwagten C, Schwagten E, Schwagten K, Schwagten D, Schwagten C, Schwagten V, Schwagten R, Schwagten J, Schwagten W, Schwagten J, Schwagten M, Smets K, Miljoen H, Schoenmaeckers Y, colleagues nurses and staff of EMC and Middleheim, family and friends, Jordaens LJLM, Szili-Torok T, Zijlstra F, van Domburg R, Willems R, Simoons M, de Groot N, Haitsma D, Res J, Jessurun E, Theuns DAMJ, Janse P, Valk S, van der Heijden R, Scheffer M, Spierenburg H, Van Woerkens L, Anne W, Van Belle Y, Dabiri-Abkenari L, Caestecker D, Alloway R, Beurmanjer F, Brand R, Coenen A, Emilsdottir L, de Haan R, de Groot P, Kind-Huijskens C, Levens R, Saunders R, Peters E, Schilderman D, Chaitsing R, Knops P, Van De Rik I, Lopes M, Luijten R, Miltenburg M, van der Perk R, de Ruiter R, de Ruiter W, Veen D, Zandstra W, van Driel M, Genegel R, Kalkman Y, Leijdekker-Boer L, Orgers A, Muskens A, Takens M, Musters P, Vorm J, Dierckx R, Gielen WPMHIA, Kalkman Y, Orgers A, Barthelemy W, Kardos A, Bauernfeind T, Lovell J, Kaminski M, Rhakesh, Van Langenhove G, De Moor W, De Greef Y, Van den Branden F, Vanagt E, Stockman D, Mertens A, Van Walle M, Schwagten C, Schwagten E, Schwagten K, Schwagten D, Schwagten C, Schwagten V, Schwagten R, Schwagten J, Schwagten W, Schwagten J, Schwagten M, Smets K, Miljoen H, Schoenmaeckers Y, colleagues nurses and staff of EMC and Middleheim, family and friends, Jordaens LJLM, Szili-Torok T, Zijlstra F, van Domburg R, Willems R, Simoons M, de Groot N, Haitsma D, Res J, Jessurun E, Theuns DAMJ, Janse P, Valk S, van der Heijden R, Scheffer M, Spierenburg H, Van Woerkens L, Anne W, Van Belle Y, Dabiri-Abkenari L, Caestecker D, Alloway R, Beurmanjer F, Brand R, Coenen A, Emilsdottir L, de Haan R, de Groot P, Kind-Huijskens C, Levens R, Saunders R, Peters E, Schilderman D, Chaitsing R, Knops P, Van De Rik I, Lopes M, Luijten R, Miltenburg M, van der Perk R, de Ruiter R, de Ruiter W, Veen D, Zandstra W, van Driel M, Genegel R, Kalkman Y, Leijdekker-Boer L, Orgers A, Muskens A, Takens M, Musters P, Vorm J, Dierckx R, Gielen WPMHIA, Kalkman Y, Orgers A, Barthelemy W, Kardos A, Bauernfeind T, Lovell J, Kaminski M, Rhakesh, Van Langenhove G, De Moor W, De Greef Y, Van den Branden F, Vanagt E, Stockman D, Mertens A, Van Walle M, Schwagten C, Schwagten E, Schwagten K, Schwagten D, Schwagten C, Schwagten V, Schwagten R, Schwagten J, Schwagten W, Schwagten J, Schwagten M, Smets K, Miljoen H, Schoenmaeckers Y, colleagues nurses and staff of EMC and Middleheim, family and friends, Jordaens LJLM, Szili-Torok T, Zijlstra F, van Domburg R, Willems R, Simoons M, de Groot N, Haitsma D, Res J, Jessurun E, Theuns DAMJ, Janse P, Valk S, van der Heijden R, Scheffer M, Spierenburg H, Van Woerkens L, Anne W, Van Belle Y, Dabiri-Abkenari L, Caestecker D, Alloway R, Beurmanjer F, Brand R, Coenen A, Emilsdottir L, de Haan R, de Groot P, Kind-Huijskens C, Levens R, Saunders R, Peters E, Schilderman D, Chaitsing R, Knops P, Van De Rik I, Lopes M, Luijten R, Miltenburg M, van der Perk R, de Ruiter R, de Ruiter W, Veen D, Zandstra W, van Driel M, Genegel R, Kalkman Y, Leijdekker-Boer L, Orgers A, Muskens A, Takens M, Musters P, Vorm J, Dierckx R, Gielen WPMHIA, Kalkman Y, Orgers A, Barthelemy W, Kardos A, Bauernfeind T, Lovell J, Kaminski M, Rhakesh, Van Langenhove G, De Moor W, De Greef Y, Van den Branden F, Vanagt E, Stockman D, Mertens A, Van Walle M, Schwagten C, Schwagten E, Schwagten K, Schwagten D, Schwagten C, Schwagten V, Schwagten R, Schwagten J, Schwagten W, Schwagten J, Schwagten M, Smets K, Miljoen H, Schoenmaeckers Y, colleagues nurses and staff of EMC and Middleheim, family and friends, Jordaens LJLM, Szili-Torok T, Zijlstra F, van Domburg R, Willems R, Simoons M, de Groot N, Haitsma D, Res J, Jessurun E, Theuns DAMJ, Janse P, Valk S, van der Heijden R, Scheffer M, Spierenburg H, Van Woerkens L, Anne W, Van Belle Y, Dabiri-Abkenari L, Caestecker D, Alloway R, Beurmanjer F, Brand R, Coenen A, Emilsdottir L, de Haan R, de Groot P, Kind-Huijskens C, Levens R, Saunders R, Peters E, Schilderman D, Chaitsing R, Knops P, Van De Rik I, Lopes M, Luijten R, Miltenburg M, van der Perk R, de Ruiter R, de Ruiter W, Veen D, Zandstra W, van Driel M, Genegel R, Kalkman Y, Leijdekker-Boer L, Orgers A, Muskens A, Takens M, Musters P, Vorm J, Dierckx R, Gielen WPMHIA, Kalkman Y, Orgers A, Barthelemy W, Kardos A, Bauernfeind T, Lovell J, Kaminski M, Rhakesh, Van Langenhove G, De Moor W, De Greef Y, Van den Branden F, Vanagt E, Stockman D, Mertens A, Van Walle M, Schwagten C, Schwagten E, Schwagten K, Schwagten D, Schwagten C, Schwagten V, Schwagten R, Schwagten J, Schwagten W, Schwagten J, Schwagten M, Smets K, Miljoen H, Schoenmaeckers Y, colleagues nurses and staff of EMC and Middleheim, family and friends, Jordaens LJLM, Szili-Torok T, Zijlstra F, van Domburg R, Willems R, Simoons M, de Groot N, Haitsma D, Res J, Jessurun E, Theuns DAMJ, Janse P, Valk S, van der Heijden R, Scheffer M, Spierenburg H, Van Woerkens L, Anne W, Van Belle Y, Dabiri-Abkenari L, Caestecker D, Alloway R, Beurmanjer F, Brand R, Coenen A, Emilsdottir L, de Haan R, ……

It does not come as a surprise that, after having finished this thesis, it is important to dedicate some attention to all those who have contributed (in every possible way).
A major contribution was made by the Belgian and Dutch railway system. This ingenious system allowed me to travel from my home to Rotterdam central station in approximately 2,5 hours…when I was lucky, that is. Here is the theory behind this endeavor: I would get up at 05.00am to leave the house at 05.30am. I would cycle towards the train station and catch the first train towards Antwerp central station at 05.45am. This train would reach its destination at 06.15am where I would have plenty of time to wait for the international train towards Rotterdam leaving hourly, at 5 minutes before the hour sharp. This direct connection would take about 60 minutes, so I should reach Rotterdam around 08.00am. There I would find my second bicycle and I would happily arrive at the Erasmus Medical Center around 08.20am (which is about 15 minutes late for the 'overdracht' of the cardiology department – which is attended by all cardiologists from the EMC without exception – a kind of punctuality that made me extremely popular amongst certain colleagues…).
The same ritual would take place every night in order to catch the train in Rotterdam central station, also leaving hourly, at 5 minutes before the hour sharp. This required a little more skills since I had to take into account the time to get changed, leave the hospital (unnoticed, preferably) and cycle (usually against a strong headwind) towards the station. I had to make sure to arrive in time because I needed another 5 minutes to allow me to walk from the bicycle storage location towards the train platform. Again, I would reach the front door of my house 2,5 hours later…in the ideal setting.
This fairly simple plan, however, contains a rather large amount of 'would's' and it was conceived without taking into account the unlimited number of variables provided by our friends at the railway department. I will not go into detail because this would lead us to far, but I would like to express my gratitude towards the Belgian and Dutch railway system using a simple example.
Punctuality. It seems virtually impossible to run the railway company with trains arriving and departing at their preset time. Either the tracks are too hot during summer or too cold during winter and this delays the trains. If leaves are on the track during autumn or if heavy rain wets them during spring, the trains are delayed. Sometimes a train would simply not show up (without any reason) and passengers needed to wait another hour until the next train arrived. The 40-year old locomotives broke down with the regularity of a Swiss watch, the railway staff had its monthly strikes and one time we even ended up in a traffic jam caused by several other trains (!!). By consequence, the preset timing of the travel plan could not always be guaranteed and this resorted in me arriving late at work on multiple occasions. Mostly this was due to the brilliant organization of the railway system, but once in a blue moon this was linked to me not answering my wake-up call. So I would like to thank the railway system for readily providing me every day with an generally accepted (even by most of my Dutch colleagues) excuse to arrive late at work.

Another important contribution was made by the person (whose name I will not disclose in writing) that made me aware of an important flaw in the security system of the EMC's parking facilities. During the last months of my fellowship, I ultimately switched from train to car or motorcycle to make the journey to Rotterdam and back. During the daytime, I parked on the premises of the EMC. This was charged by the hour and I realized soon enough that stalling my vehicle would cost me a small fortune every month. However, it seemed that the entrance of the emergency department had an unmanned barrier that opened automatically when approached both when entering and exiting the parking. Timing was crucial when performing the escape maneuver: one first had to be sure that no ambulances were on their way in as there was only a single driving lane, secondly the U-turn to get on this lane had to be made in one time in order not to lose precious time while being monitored by several cameras and finally it was of the utmost importance that the guards were patrolling the other side of the facilities. This last hurdle was sometimes hard to take and this prompted a guard jumping from behind a pillar in front of my car on several occasions. This usually only caused a delay of about half an hour before another attempt to escape the parking could be made. So again, my special thanks to my informant!

Finally I would very much like to thank the communication department for opening my window on the world, even long after I had already left the EMC.

Apart from this madness, I will make sure that those people who genuinely contributed to the thesis will be thanked appropriately and from the heart.

Curriculum Vitae, Bruno Schwagten

Bruno Schwagten was born in Mortsel, Belgium on December 16th 1976. After finishing his secondary school in Latin-Greek at the OLVE, Edegem, Belgium, he started his studies of Medicine in 1994 at the University of Antwerp, Belgium. In 2001 he graduated cum laude and started a specialisation in Cardiology. During this, he temporarily worked in a field hospital in Burkina Faso. He continued his clinical training in Cardiology in the Middelheim hospital Antwerp and the University hospital Antwerp, Belgium and he graduated as a cardiologist in September 2007. In Oktober 2007, he started his fellowship in clinical Electrophysiology at the Thoraxcenter, Erasmus MC, Rotterdam, the Netherlands under the supervision of Prof. Dr. L. Jordaens. In January 2012, he completed his PhD thesis entitled '*Faster, safer and better catheter ablation?*' under the auspices of Prof. Dr. L. Jordaens and Dr. T. Szili-Torok. He works as an electrophysiologist at the Middelheim hospital in Antwerp, Belgium. He is trained in working with all common tools used in electrophysiology such as cryotherapy, radiofrequency ablation, CARTO and Ensite systems, but his major expertise is performing electrophysiologic procedures remotely using the Magnetic Navigation System. He is a board member of the Belgian Heart Rhythm Association and the Cardiac Society of Robotic Navigation.

List of publications

1. Prevalence, Characteristics and Predictors of Pulmonary Vein Narrowing after PVAC Ablation. De Greef Y, Tavernier R, Raeymaeckers S, Schwagten B, Desurgeloose D, De Keulenaer G, Stockman D, De Buyzere M, Duytschaever M. Circ Arrhythm Electrophysiol. 2011 Nov 7.
2. An Apparent Way of Achieving Proof of Pulmonary Vein Disconnection during Cryoballoon Ablation.Schwagten B, De Greef Y, Acou WJ, Stockman D. Pacing Clin Electrophysiol. 2011 Aug 7. Epub ahead of print.
3. Flutter ablation with remote magnetic navigation: comparison between the 8-mm tip, the irrigated tip and a manual approach. Anné W, Schwagten B, Janse P, Bauernfeind T, Van Belle Y, De Groot N, Knops P, Jordaens L, Szili-Torok T. Acta Cardiol. 2011 Jun;66(3):287-92.
4. The magnetic navigation system allows safety and high efficacy for ablation of arrhythmias. Bauernfeind T, Akca F, Schwagten B, de Groot N, Van Belle Y, Valk S, Ujvari B, Jordaens L, Szili-Torok T. Europace. 2011 Jul;13(7):1015-21. Epub 2011 Apr 19.
5. Long-term follow-up after catheter ablation for atrioventricular nodal reentrant tachycardia: a comparison of cryothermal and radiofrequency energy in a large series of patients. Schwagten B, Knops P, Janse P, Kimman G, Van Belle Y, Szili-Torok T, Jordaens L. J Interv Card Electrophysiol. 2011 Jan;30(1):55-61.
6. Cryoablation: how to improve results in atrioventricular nodal reentrant tachycardia ablation? Schwagten B, Van Belle Y, Jordaens L. Europace. 2010 Nov;12(11):1522-5.
7. Effect of magnetic navigation system on procedure times and radiation risk in children undergoing catheter ablation. Schwagten B, Witsenburg M, De Groot NM, Jordaens L, Szili-Torok T. Am J Cardiol. 2010 Jul 1;106(1):69-72. Epub 2010
8. A randomized comparison of transseptal and transaortic approaches for magnetically guided ablation of left-sided accessory pathways. Schwagten B, Jordaens L, Rivero-Ayerza M, Van Belle Y, Knops P, Thornton IA, Szili-Torok T. Pacing Clin Electrophysiol. 2010 Nov;33(11):1298-303.
9. Pulmonary vein stenosis after pulmonary vein ablation catheter-guided pulmonary vein isolation. De Greef Y, Schwagten B, De Keulenaer G, Stockman D. Heart Rhythm. 2010 Sep;7(9):1306-8.
10. Usefulness of remote magnetic navigation for ablation of ventricular arrhythmias originating from outflow regions. Schwagten BK, Szili-Torok T, Rivero-Ayerza M, Jessurun E, Valk S, Jordaens LJ. Neth Heart J. 2009 Jun;17(6):245-9.
11. Initial experience with catheter ablation using remote magnetic navigation in adults with complex congenital heart disease and in small children. Schwagten B, Jordaens L, Witsenburg M, Duplessis F, Thornton A, van Belle Y, Szili-Torok T. Pacing Clin Electrophysiol. 2009 Mar;32 Suppl 1:S198-201.
12. The magnetic navigation system allows avoidance of puncturing a baffle during ablation of a postincisional macroreentrant tachycardia. Schwagten B, Cuypers J, Szili-Torok T. Cardiol Young. 2009 Apr;19(2):216-9.
13. Baffle puncture guided by transoesophageal echocardiography in a patient with dextrocardia and Mustard correction. Schwagten B, Jordaens L, Jessurun E, Witsenburg M, Scheffer M, Szili-Torok T. Eur J Echocardiogr. 2009 Jan;10(1):144-7.

14. Cardiac troponin I release after transcatheter closure of the interatrial septum: a prospective study. Vydt T, Vermeersch P, Schwagten B, Budts W. Acta Cardiol. 2007 Oct;62(5):467-71.

15. Combined systolic and diastolic heart failure as the first presentation of mixed connective tissue disease. Schwagten B, Verheye S, Van den Heuvel P. Acta Cardiol. 2007 Aug;62(4):421-3.

16. Postnatal cystic germinolysis and neonatal chronic lung disease: evaluation of risk factors and neurodevelopmental outcome. Smets K, Schwagten B. Acta Paediatr. 2000 Sep;89(9):1111-4.

17. Jordaens L, Knops P, Schwagten B, Kimman GP, van Deel E, van der Giessen W et al. AVNRT Cryoablation and comparison with RF. In Bredikis A, Wilber DJ 2010. In press

18. Focus Diagnostica 1999; Vol.7(3): 64-68. Erytropoëtine (EPO): a new wonderful remedy?

19. B. Schwagten, J Bosmans, T. Gillebert. Acta Clinica Belgica 2002; Vol 57, N°2. Valvular Aortic Stenosis: a Comparison between Invasive and Non-invasive Approach

20. B. Schwagten, D. Stockman, F. Van Den Branden, E. Vanagt. Acta Cardiologica 2007; Vol 62, N°1, Feb. Long-term follow-up after pulmonary vein isolation in paroxysmal atrial fibrillation in patients without underlying heart disease.

List of presentations on the subject of this PhD

1. Poster session at 29th Annual Scientific Sessions Heart Rhythm Society 2008, San Francisco, CA, USA, May 14-17. Baffle puncture guided by transoesophageal echocardiography in a patient with dextrocardia and Mustard correction
2. Oral presentation at Cardiostim 16th World Congress in Cardiac Electrophysiology and Cardiac Techniques. June 18-21, 2008, Nice, France 2008. Single catheter approach for AVNRT ablation using the magnetic navigation system
3. Oral presentation at European Society of Cardiology 30 Aug 2008 - 03 Sep 2008 , Munich, Germany. Single catheter ablation of AVNRT using the magnetic navigation system is a safe and feasible approach.
4. Poster at European Society of Cardiology 30 Aug 2008 - 03 Sep 2008 , Munich, Germany. Initial experience with catheter ablation using remote magnetic navigation in patients with complex congenital heart disease and in small children with arrhythmias
5. Poster at Second Belgian Heart Rhythm Meeting "Arrhythmias for every cardiologist", Brussels, Thursday 2, friday 3 en saturday 4 of october 2008. Single catheter ablation of AVNRT using the magnetic navigation system is a safe and feasible approach
6. Oral presentation at Second Belgian Heart Rhythm Meeting "Arrhythmias for every cardiologist", Brussels, Thursday 2, friday 3 and saturday 4 oktober 2008. Comparison of cryothermal and radiofrequency ablation in AVNRT in a large series of patients.
7. Oral presentation at 30th Annual Scientific Sessions Heart Rhythm Society, May 13-16, 2009, Boston, MA, USA. Long Term Follow-up after Catheter Ablation for AVNRT: A Comparison of Cryothermal and Radiofrequency Energy in a Large Series of Patients.
8. Poster at 30th Annual Scientific Sessions Heart Rhythm Society, May 13-16, 2009, Boston, MA, USA. Outpatient Single Catheter Ablation of the Slow Pathway in AVNRT using Remote Magnetic Navigation is Cost-effective in Comparison to a Conventional Approach
9. Oral presentation National congress of cardiogeriatrics, Rome, Italy, 16-18 april 2009. Catheter ablation vs AAD for AF: perspectives for aged subjects
10. Oral presentation at Europace 21 Jun 2009 - 24 Jun 2009 , Berlin, Germany. Randomized comparison of transseptal and transaortic approach in ablation of left-sided accessory pathways using the magnetic navigation system
11. Poster at Europace 21 Jun 2009 - 24 Jun 2009 , Berlin, Germany. Long Term Follow-up after Catheter Ablation for AVNRT: A Comparison of Cryothermal and Radiofrequency Energy in a Large Series of Patients.
12. Oral presentation 8th Conferinta Internationala de Cardiologie la Tirgu Mures 29 June - 4 July Tirgu Mures, Romania. Cryoballoon ablation of paroxysmal atrial fibrillation
13. Presenter of ECG course and posters at Third Belgian Heart Rhythm Meeting "Arrhythmias for every cardiologist", Brussels, friday 2 and saturday 3 of october 2009. AF ablation in the elderly using the cryoballoon technique.