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Assessment of the "Long Sheath" Technique for Percutaneous Aortic Balloon Valvuloplasty

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A 100 cm-long 16.5 F valvuloplasty catheter introducer was assessed as an adjunct for percutaneous transluminal aortic valvuloplasty (PTAV) via the femoral artery in 31 patients with severe aortic stenosis. Observed improvements in peak systolic gradient (81.6 ± 29.9 mm Hg vs. 35.5 ± 16.0 mm Hg, $P < 0.000001$) and aortic valve area (0.6 ± 0.4 cm^2 vs. 1.0 ± 0.6 cm^2, $P < 0.00001$) were similar to those achieved in a control group (C) of 17 patients in which no femoral sheath was used. However, a shorter procedure duration (211 ± 81 min vs. 117 ± 30 min, $P < 0.001$) and a reduced rate of vascular complications at the femoral puncture site (41% vs. 6.5%) were observed in patients in whom the long sheath (LS) technique was used. The frequency of other PTAV-related complications was comparable (C = 35%, LS = 29%, P = n.s.).

Other technical advantages of this device are: 1) prevention of looping and bending of the balloon catheter in tortuous vessels and easy positioning of the balloon across the aortic orifice provided by the LS trackability, 2) stabilisation of the balloon during inflation, 3) monitoring of supravalvular aortic pressure provided by the side-arm of the LS and reliable measurement of systolic gradient, and 4) the ability to perform aortograms without the need of another catheter in the ascending aorta. Thus, in our experience, the long sheath technique is a valuable adjunct for PTAV.

Key words: aortic balloon valvuloplasty, aortic stenosis, complications

INTRODUCTION

Percutaneous transluminal aortic balloon valvuloplasty (PTAV) is currently regarded as a palliative treatment for elderly patients with critical aortic stenosis (AS) not suitable for open-heart surgery [1,2]. Although the limited immediate hemodynamic improvement, inherent procedure-related complications, and possible development of late valve restenosis have decreased the initial enthusiasm for this alternative technique [3–6], PTAV remains the only therapeutical tool available for severely symptomatic patients with unacceptably high or prohibitive surgical risk. These current limitations of PTAV demand simplification of the technique in order to decrease the duration of the procedure and the rate of vascular complications and to facilitate passage of balloon catheters through tortuous vessels and across severely narrowed aortic orifices. The device described here has been developed in an attempt to achieve these objectives.

Long sheaths are currently used in catheterization laboratories for trans-septal catheterization and myocardial biopsy by the femoral vein. Recently, they have been used to help the performance of PTAV [7]. In a previous report [8], we have presented results of PTAV performed in 12 patients with severe AS obtained by using this 100 cm-long introducer especially designed for retrograde PTAV via the femoral artery. In this article, we report the results of PTAV procedures performed with this device in 31 patients and we compare the observed results and complications with our previous experience with the conventional percutaneous femoral artery approach.

MATERIALS AND METHODS

Introducer Design

The introducer consists of a polyurethane inner dilator and a 100 cm-long Teflon sheath (Schneider AG) with a

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15 F internal lumen and a 16.5 F external diameter, connected to a proximal valve system to prevent retrograde bleeding. This proximal adjustable adaptor is formed by a self-sealing diabolus-shaped silicon valve and a proximal screw-seal. A side-arm, connected to the transparent chamber in which the silicon valve is located, allows intermittent flushing of both the silicon valve and the internal lumen of the sheath and enables the recording of the hydraulically transmitted pressure from the distal tip of the sheath.

Patients

From March 1986 to April 1987, 17 patients (47% male; mean age ± SD: 73.2 ± 6.8 yr) underwent PTAV in our institution; a conventional technique of direct percutaneous introduction of the valvuloplasty balloon catheters through the femoral artery was used, as previously described [2]. These patients, in whom no femoral sheaths were used, served as our control group.

Thereafter, PTAV was performed with the use of the long sheath technique in 31 patients (42% male; mean age ± SD: 66.5 ± 22.5 yr) from two catheterization centers.[1] The AS etiology was presumed degenerative in 24 patients (77%) and congenital (bicuspid) in the remaining cases. Informed consent was obtained before each procedure.

Technique

In the 17 patients who served as our control group, a conventional approach was used, consisting of direct introduction and removal of various balloon catheters through the femoral artery. In the long sheath group, the valvuloplasty introducer was inserted through the femoral artery, following adequate positioning of a 0.035 in., 300 cm exchange guidewire across the aortic valve orifice. The guidewire is designed with a stiff proximal part to facilitate the insertion of the introducer and to provide a better trackability when attempting to cross the aortic orifice with the balloon catheter. The distal tip of the guidewire (7–12 cm) is soft and flexible to prevent ventricular wall trauma. The gradual tapering of the tip of the inner dilator combined with the support provided by the stiff guidewire allowed easy introduction into the femoral artery. Progression up the ascending aorta and positioning of the distal end of the sheath just above the aortic valve is also facilitated, despite the frequently tortuous iliac and femoral vessels commonly seen in elderly patients. After removal of the inner dilator, multiple balloon catheters were easily positioned across the aortic valve orifice, over the exchange guidewire with its tip in the left ventricular cavity. The side-arm was used for pressure monitoring, performance of aortograms, and for irrigation and intermittent flushing with heparinized solution; this was mandatory since blood clots can form rapidly in the large dead space of the sheath (Fig. 1). At the end of the procedure, after reversal of the residual effect of heparin, the sheath was removed and hemostasis achieved by careful inguinal compression.

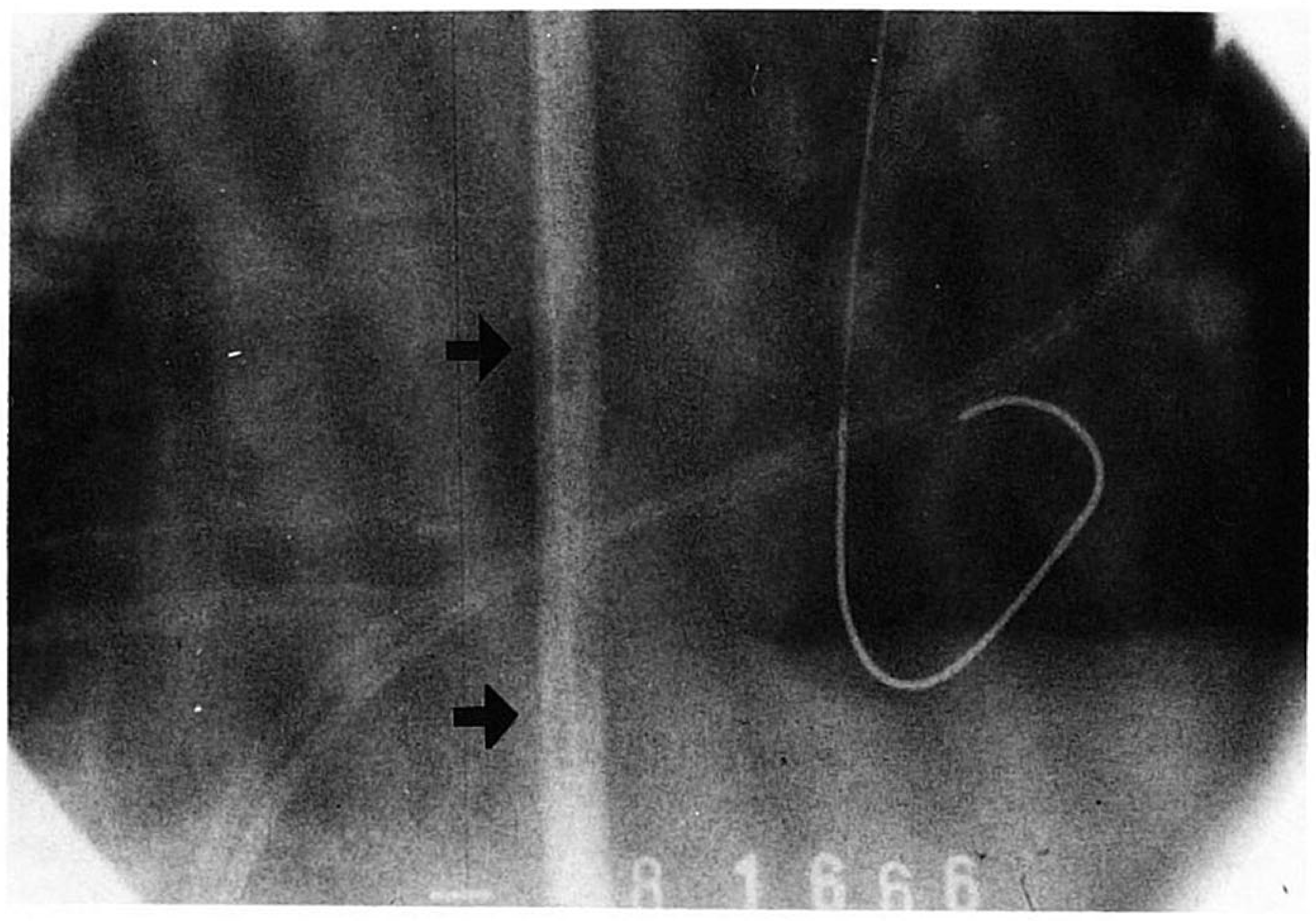

Fig. 1. Blood clots in the lumen of the long sheath. After two balloon dilatations, the contrast injector was connected to the side-arm of the long sheath, for the performance of an aortogram. During pre-filling by contrast medium, large clots were observed in the lumen of the long sheath (arrows). The screw-seal was removed, allowing spontaneous expulsion of the thrombi. Thereafter, the sheath was irrigated with heparinized solution and a supplementary dose of I.V. heparin was given. The procedure was continued without complications.

In the control group, the largest balloon catheter used was 15 to 20 mm in eight patients, trefoil 3 × 9 mm in one patient, and 3 × 12 mm in the remaining cases. In the long sheath group, the largest balloon catheter used was 23 to 25 mm in two cases, trefoil 3 × 8 in one, 3 × 9 mm in four, and 3 × 12 mm in 19 patients. In two cases, the bifoil 2 × 19 mm balloon was the largest balloon used.

Statistical Analysis

Means and standard deviations were calculated for each group of data. Unpaired and paired Student's t test, Chi square test, and Fisher's exact test were used whenever appropriate.

RESULTS

Table I shows the hemodynamic variables measured immediately before the procedure and after the last balloon dilatation in the two groups. The procedure duration is also tabulated. The two groups were comparable for

[1]Thoraxcenter, Rotterdam: 19 patients; University Hospital, Geneva: 12 patients.

TABLE I. Age, Sex, Hemodynamic Data, and Procedure Duration*

	Control group		Long sheath group		P
No. patients	17		31		
Age (yr)	73.2 ± 6.8		66.5 ± 22.5		(n.s.)
Sex (% male)	47 %		42 %		(n.s.)
Peak systolic gradient (mm Hg)					
Before	83.8 ± 28.8	A	81.6 ± 29.9	B	(n.s.)
After	39.6 ± 17.0		35.5 ± 16.0		(n.s.)
Aortic valve area (cm^2)[a]					
Before	0.5 ± 0.1	C	0.6 ± 0.4	D	(n.s.)
After	0.7 ± 0.2		1.0 ± 0.6		(n.s.)
Duration of procedure (min)[b]	211 ± 81		117 ± 30		< 0.001

*A: $P < 0.000001$; B: $P < 0.000001$; C: $P < 0.000001$; D: $P < 0.00001$.

[a]Assessed with the Gorlin's formula.

[b]The procedure duration (minutes) was calculated as the time elapsed from femoral puncture to the last recorded intra-aortic pressure, just before removal of the sheath and catheters. For some patients (see text), this included the time required for complete diagnostic catheterisation or transluminal coronary anglioplasty in the same session.

age, sex, peak systolic gradient, and aortic valve area before and after the procedure. Significant improvements in peak systolic gradient and aortic valve area were achieved in both groups.

However, the mean procedure duration was much shorter in the long sheath group (117 ± 30 min vs. 211 ± 81 min, $P < 0.001$), as reliably assessed in 14 patients (82%) of the control group and in 23 patients (74%) of the long sheath group. This was calculated as the time elapsed from femoral puncture to the last recorded intra-aortic pressure, just before removal of the sheath and catheters. This included the time required for complete diagnostic catheterization (control group: five cases; long sheath group: four cases) and transluminal coronary angioplasty (long sheath group: two cases) in the same session. To achieve hemostasis after removal of the long sheath, the mean inguinal compression time was 43 min (range 30–70 min, as assessed in the first 14 patients), which was comparable to the time usually required to achieve hemostasis after a conventional PTAV procedure.

In the control group, unsuccessful introduction of a 3 × 12 mm trefoil-shaped balloon catheter into the femoral artery or across the aortic valve occurred in three patients (17.6%), mainly due to tortuous vessels and lack of pushability. Such unsuccessful attempts were not encountered in any patient of the long sheath group; in only one case, we experienced a relatively difficult retrieval of a 2 × 19 mm bifoil-shaped balloon after rupture. The use of the long sheath technique in patients with tortuous vessels has facilitated the manipulation of the catheters and the exchange procedures, by preventing looping and bending of the balloon catheters. A good example of facilitated positioning of the balloon catheter across the aortic valve provided by the long sheath is shown in Figure 2.

The procedure-related complications observed in the two groups are summarized in Table II. Seven patients (41%) of the control group developed vascular complications at the femoral puncture site: three required surgical intervention (two for pseudoaneurysm formation and one for removal of a balloon remnant after balloon rupture) and large groin hematomas developed in four patients, requiring multiple blood transfusions in two cases. Vascular complications occurred only in two patients (6.5%) of the long sheath group. A 22 yr-old male patient needed surgical repair of the femoral artery for severe bleeding after unsuccessful attempts at introducing the long sheath over a conventional guidewire. The other vascular complication occurred in a 73 yr-old female patient in functional class IV (N.Y.H.A.). The procedure was uncomplicated with a single circular 19 mm balloon (two inflations) and a 23 mm balloon (three inflations). In an attempt to achieve better hemodynamic results, the balloon catheter was exchanged for a 2 × 19 mm bifoil-shaped balloon. After the second inflation with the latter, an aortogram showed severe aortic regurgitation with evidence of contrast extravasation around the left main coronary artery. In the following hours, her clinical condition deteriorated and she died 1 d after the procedure in a state of irreversible cardiogenic shock. Before death, signs of right leg ischemia were noted, suggesting a procedure-related complication. Postmortem examination showed congested lungs and liver, along with signs of hypoperfusion in both kidneys. Examination of the heart revealed a hypertrophied and dilated left ventricle, moderate atherosclerosis of the coronary arteries, and a calcified tricuspid stenotic aortic valve showing severe iatrogenic aortic insufficiency. An aortic intimal dissection was found, originating at the junction of the right and left coronary cusps, with exten-

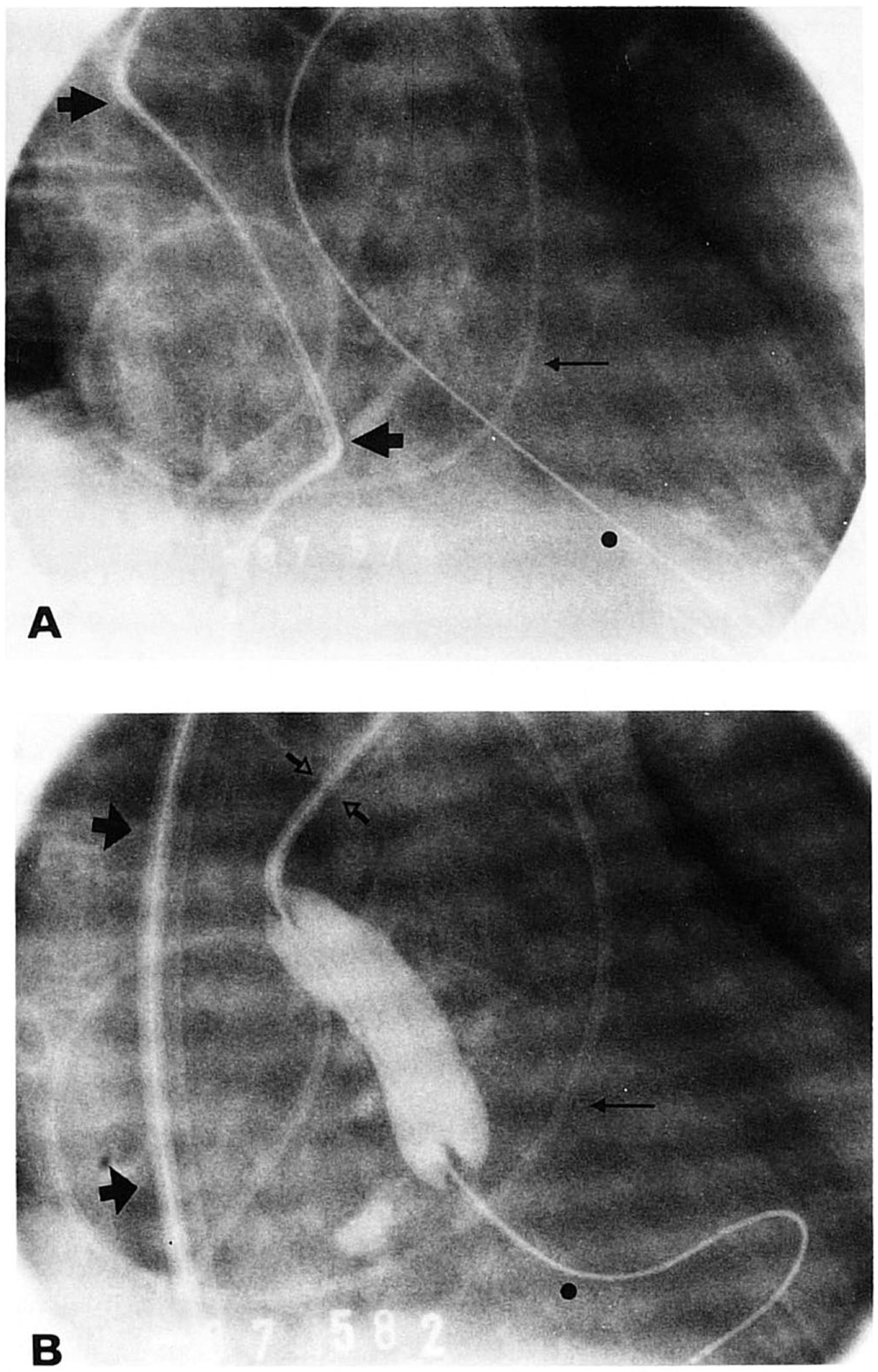

Fig. 2. A: This 80 yr-old female patient with severe aortic stenosis (aortic valve area: 0.4 cm^2; peak systolic gradient: 66 mm Hg) was scheduled for an elective PTAV. After introduction of a 23 cm 16.5 F sheath into the right femoral artery, a 0.035 in. exchange guidewire was positioned in the left ventricle. However, multiple attempts at crossing the stenotic valve with a 3 × 8 mm trefoil balloon catheter were unsuccessful, due to bending of the catheter in the descending aorta. The procedure was aborted, but the short sheath was left in place and irrigated with a heparinized solution. We urgently ordered a long sheath, which was provided by the manufacturer within 24 h. (Thick arrows: bendings of the shaft of the 3 × 8 mm trefoil balloon catheter in the descending aorta; thin arrow: Swan-Ganz catheter; black dot: exchange guidewire in the left ventricle.) B: The following day, a second PTAV was attempted. After positioning of the guidewire into the left ventricle, the short sheath was removed and replaced by a 100 cm-long sheath. The aortic orifice was easily crossed and consecutive dilatations with trefoil-shaped 3 × 8 mm and 3 × 12 mm balloon catheters were performed, without bending of the balloon catheters. The procedure was uncomplicated and satisfactory (aortic valve area: 0.7 cm^2; peak systolic gradient: 47 mm Hg). (Thick arrows: shaft of the 3 × 8 mm trefoil balloon catheter inside the long sheath; open arrows: distal tip of the long sheath above the inflated balloon; thin arrow: Swan-Ganz catheter; black dot: exchange guidewire in left ventricular cavity.)

sion to the proximal part of the left coronary artery. Inspection of the right leg vasculature revealed a mural dissection with occlusive thrombosis originating at the level of the right femoral artery puncture site.

The rate of other PTAV-related complications (cardiac, neurological, etc.) was similar in the two groups (35% vs. 29% for the long sheath group, P = n.s.). One intra-operative death (long sheath group) occurred in a 77 yr-old patient, with coexistent severe stenosis of the left main coronary artery, an occluded right coronary artery, and a left ventricular ejection fraction of 14%; the patient developed irreversible cardiogenic shock at the end of the first inflation. Post-mortem examination did not reveal any cardiac or vascular damage that could have been related to the procedure itself.

DISCUSSION

Cribier et al. [1] reported that tortuosity of the iliac arteries or aorta impeded balloon exchanging procedures in 16 of 82 patients (19.5%) in whom the femoral route was used, preventing further dilatations with larger-sized balloons, and possibly leading to suboptimal results. Drobinski et al. [4] also reported that a right axillary percutaneous arterial approach had to be used in four of 37 patients (11%) for the same reasons. We observed a similar rate of unsuccessful attempts in our control group (17.6%), but such difficulties were not encountered in the long sheath group.

It should be noted that, although many patients had tortuous iliac and femoral vessels, none of them had severe narrowings or subtotal occlusions, a condition which appears less amenable to the proposed technique. Nevertheless, the combined use of a stiff guidewire and a long sheath was able to straighten the vessels, allowing more easy passage of balloon catheters up to the ascending aorta. Stiffer guidewires were introduced almost simultaneously with the use of the long sheath and may have had an independent effect in facilitating negotiations of tortuous vessels and passages of balloon catheters across the aortic valve orifice.

The improvement in procedure duration observed in the long sheath group was mainly related to the facilitated balloon catheter manipulations and exchange procedures, especially in the presence of tortuous vessels. However, other factors may have influenced these results. For instance, the long sheath technique has been introduced after the performance of 17 conventional PTAV procedures in our institution. Therefore, the operator's previous experience (the "learning curve" effect) may have influenced favorably and independently the duration of the PTAV procedures in the long sheath group. Another bias may also arise from the small number of patients in the study and the incomplete data col-

TABLE II. Procedure-Related Complications

Control group	No.	Long sheath group	No.
Vascular complications at puncture site			
Femoral pseudoaneurysm	2	Surgical repair of damaged femoral artery	1
Surgical removal of balloon remnant	1	Femoral intimal dissection with mural thrombosis	1[a]
Groin hematoma	4[b]		
Total	7 (41%)		2 (6.5%) $P<0.05$
Other PTAV-related complications			
Left hemiplegia	1	Procedure-related death	2[a]
Left hemianopsia	2	Pericardial tamponnade	1
Grade 3 aortic insufficiency	1	Third degree AV block	1
Ventricular fibrillation	2	Grade 3 Aortic insufficiency	1[a]
		Stroke	1
		Acute pulmonary edema	1
		Embolic myocardial infarction	1
		Ventricular tachycardia	1
Total	6 (35%)		9 (29%) P = n.s.

[a]These complications occurred in the same patient (see text for details).
[b]Large groin hematomas requiring multiple blood transfusions in two patients.

lection, since it was not possible to reliably assess the procedure duration in all cases, for various reasons. Other groups have reported procedure duration of less than 2 hr with a standard approach [4,9], but the time interval used for the assessment of the procedure duration was not clearly defined. Nevertheless, we observed a dramatic reduction in the time required for performing PTAV with the long sheath technique in our institution. It should be emphasized that patients undergoing PTAV are often severely ill or in poor general condition, and improvement in procedure duration with easier and quicker access to the ascending aorta may be crucial in reducing the inherent complication rate.

Since the introduction of PTAV for calcific AS, the most frequently reported procedure-related complication has been related to local damage at the femoral puncture site, due to multiple insertions and removals of large balloon catheters and to the use of larger balloons required to achieve better hemodynamic results. The rate of vascular complications reported in the literature varies from 11.7% up to 32%, depending upon the severity of complications described [10–13]. According to data obtained from the French Registry (more than 600 patients) [14], this rate was approximately 12%. In the present series, we observed a rate of 41% in patients treated with the standard approach, compared to only 6.5% when the long sheath was used. A shorter sheath, of course, would suffice for reducing the rate of vascular complications at the femoral puncture site, since others have reported a reduction from 14.8% to 4.9% by using a shorter 14 F femoral sheath [9].

The observation of such a low frequency of vascular complications with a 16.5 F arterial sheath may be unexpected, since the reported incidence of peripheral vascular damage related to the use of insertion sheaths of similar size for intraaortic counterpulsation balloons varies from 10% to 20% [15]. However, this may be more related to the duration of use rather than the size of the catheter itself. On the other hand, the potential damage to the artery wall caused by multiple insertions and removals of balloon catheters frequently presenting irregular shapes and/or sharp edges after several inflations or after balloon rupture may be greater than that induced by the single insertion of a long sheath over its well-tapered inner dilator. Long sheaths with 14, 11.5, and 10 F diameter were also available at the time of our study. A 16.5 F sheath was selected in order to accommodate easily the shafts of the largest balloon catheters commercially available, to avoid difficult retrieval of deflated or ruptured balloons, and to avoid damping of the aortic pressure tracing when deflated balloon catheters were pulled back in the lumen of the sheath. In some cases, a 14 F sheath might have been of sufficient size, but after having experienced a relatively difficult retrieval of a ruptured 2 × 19 mm bifoil balloon in one of our first patients, it was decided not to use sheaths smaller than 16.5 F.

Other advantages of the long sheath technique should be emphasized. First, the long sheath provides stability during inflation (Fig. 3), allowing the use of shorter balloons and preventing the to-and-fro motion of the balloon across the aortic valve, which is frequently observed during inflation and may be implicated as a factor in ventricular perforation. Second, the side-arm located

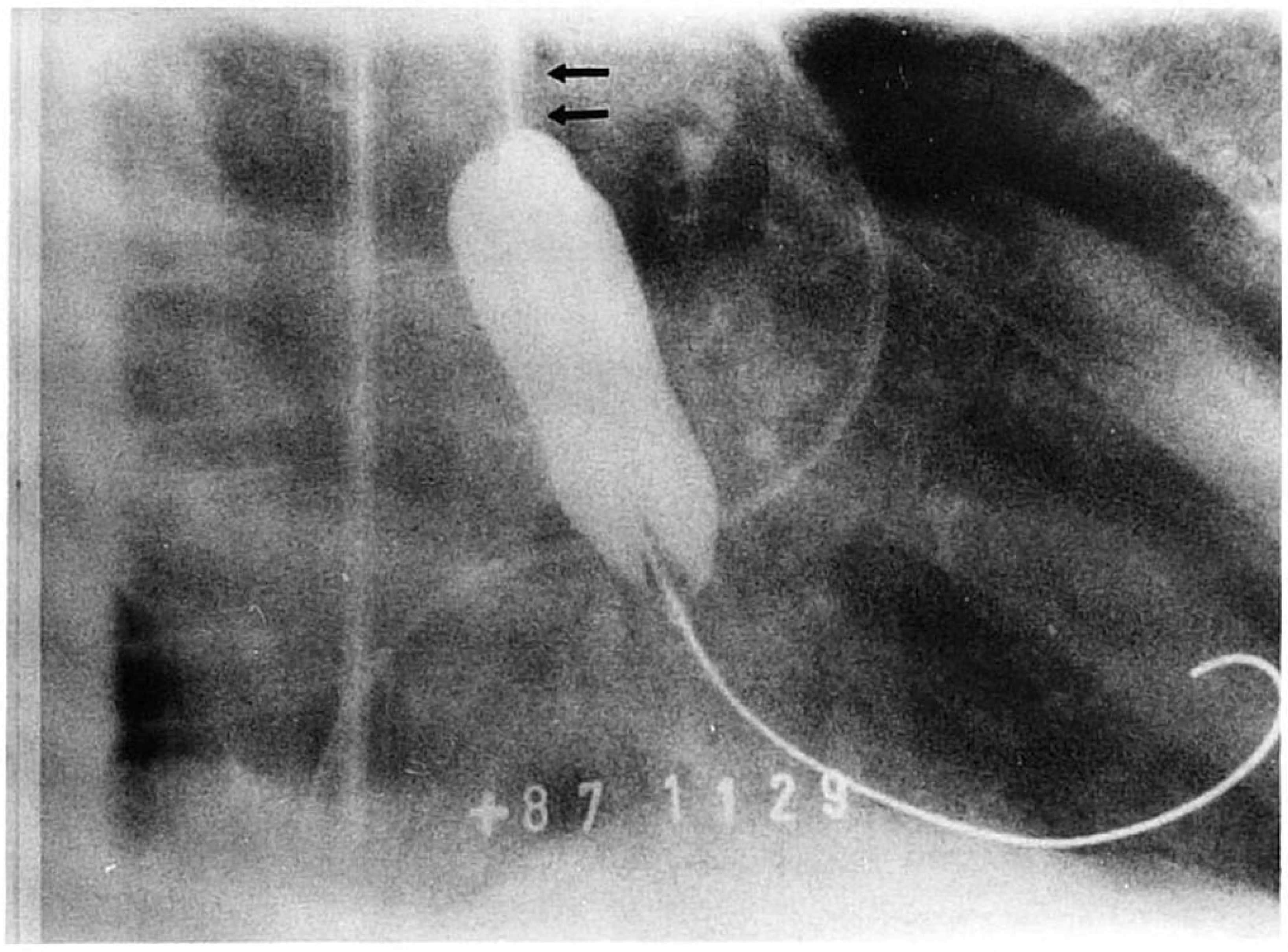

Fig. 3. Trefoil-shaped 3 × 12 mm, 40 mm-long balloon (Schneider AG) inflated across the stenotic aortic valve. The presence of the distal end of the sheath (arrows), just above the balloon, prevents possible to-and-fro motion during inflations.

in the proximal part of the sheath enables recording of the hydraulically transmitted supravalvular aortic pressure, allowing reliable measurement of the aortic gradient. Even during balloon inflation, high-quality pressure tracings were obtained. In a few cases, damped pressure curves were observed and obstruction of the distal tip of the sheath by the inflated balloon was suspected. In those cases, immediate injection of contrast via the side-arm revealed that the distal end of the sheath was free and that the recorded aortic pressure, which correlated with patient's symptoms, was rather related to aortic orifice obstruction by the inflated balloon. Third, iatrogenic aortic valve regurgitation can be assessed easily, since good-quality aortograms can be obtained by contrast injection either by the side-arm or via a pigtail catheter inserted through the long sheath. Finally, as with the use of shorter sheaths, the exchange procedures are performed without bleeding or the need of a second person to compress the punctured artery throughout the procedure.

A major disadvantage of the long sheath is the fact that its position in the ascending aorta provides a potential source for cerebral/peripheral air or clot embolism, although we observed more cerebrovascular complications in the control group (three patients) than in the long sheath group (one patient) (Table II). In the latter, air embolism from the balloon itself was more likely, since the patient had a stroke almost immediately after balloon rupture. This patient was discharged a few days later, after partial recovery. In another patient however, a clot embolization in the left circumflex coronary artery, resulting in a non-fatal myocardial infarction, was probably related to the use of the long sheath. Meticulous purging and adequate heparinization are thus crucial.

CONCLUSIONS

In our experience, the long sheath technique provides easier and quicker access to the aortic orifice, especially in patients with tortuous vessels. It gives additional support for the passage of the balloon catheters and offers a better stability during balloon inflation. In our hands, the long sheath technique has been associated with a decrease in the number of unsuccessful attempts, a decrease in procedure duration, and a reduction in the frequency of vascular complications at the femoral puncture site. However, since the two groups have been compared in a sequential way, a direct comparison with our previous experience may be misleading, as the improvements observed with the long sheath technique may be related in part to the "learning curve" effect.

With the commercially available balloons catheters, the long sheath technique is a valuable adjunct for the performance of PTAV, despite its large diameter. Technological improvements are needed for manufacturing balloon catheters with smaller shafts and with effective balloon cross-sectional area, in order to use femoral sheaths with a smaller diameter and eventually further decrease the rate of vascular complications related to the performance of PTAV.

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