Early detection of ventricular arrhythmias in adults with congenital heart disease using an insertable cardiac monitor (EDVA-CHD study)

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Abstract

Background: Sudden cardiac death (SCD) due to ventricular arrhythmias (VA) is an important mode of death in adults with congenital heart disease (CHD). Risk stratification is difficult in this heterogeneous population. Insertable cardiac monitors (ICM) may be useful for risk stratification. The purpose of the present study was to evaluate the use of ICM for the detection of VA in adults with CHD.

Methods: In this prospective single-center observational study we included consecutive adults with CHD deemed at risk of VA who received an ICM between March 2013 and February 2019. The decision to implant an ICM was made in a Heart Team consisting of a cardiac electrophysiologist and a cardiologist specialized in CHD.

Results: A total of 30 patients (mean age, 38 ± 15 years; 50% male) received an ICM. During a median follow-up of 16 months, 8 patients (27%) had documented nonsustained VA. Of these 8 patients, 3 (10%) received a prophylactic ICD. Furthermore, ICM-detected arrhythmias were present in 22 patients (73%) leading to a change in clinical management in 16 patients (53%). Besides the patients receiving an ICD, 10 patients (33%) had a change in their antiarrhythmic drugs, 6 patients (20%) underwent an electrophysiology study, and 1 patient (3%) received a pacemaker.

Conclusions: The detection of VA by the ICM contributed to the clinical decision to implant a prophylactic ICD. Furthermore, ICM-detected arrhythmias led to important changes in the clinical management. Therefore, long-term arrhythmia monitoring by an ICM seems valuable for risk stratification in adults with CHD.

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1. Introduction

Sudden cardiac death (SCD) is an important mode of death in adults with congenital heart disease (CHD) and is mainly driven by ventricular arrhythmias (VA) [1–4]. Identification of patients with CHD at risk for VA is important to determine which patients may benefit from a prophylactic implantable cardioverter-defibrillator (ICD). Risk stratification is hampered by the low predictive value of clinical risk factors [5]. This is not surprising considering Bayes theorem and the low absolute incidence of SCD in adults with CHD [6]. For patients with tetralogy of Fallot there is some guidance on selecting patients for a prophylactic ICD [7,8]. In other CHD lesions, the decision is challenging and the indication for an ICD is largely based on systemic ventricular dysfunction, syncope and/or documented VA. The decision to implant an ICD is also hampered by potential ICD complications, such as shocks, device or lead malfunction, inappropriate shocks, and psychological burden [9–11].

Considering the clinical relevance of documented VA for risk stratification, we adopted a strategy focusing on early detection of VA using insertable/implantable cardiac monitors (ICMs). ICM-detected VA may provide a tipping point in decision-making in patients who are considered at risk of SCD but who do not qualify for an ICD according to current guidelines. Long-term arrhythmia monitoring using ICMs already has an established role in patients with recurrent syncope [12]. In the most recent ESC Syncope guidelines there is an expanding role for ICMs for risk stratification in patients with primary cardiomyopathy or inheritable arrhythmogenic disorders, but not for patients with CHD [13]. The purpose of the present study was to evaluate the strategy of using ICMs for the early detection of VA in adults with CHD who are deemed at risk of VA based on their clinical profile.

2. Methods

2.1. Study design

The Early Detection of Ventricular Arrhythmias in adults with Congenital Heart Disease using an Insertable Cardiac monitor (EDVA-CHD) study is a prospective observational study which included consecutive adults...
with CHD who received an ICM between March 2013 and February 2019. The starting date was chosen based on the availability of the Re-veal LINQ (Medtronic Inc., Minneapolis, MN, USA) in our center. Patients who were deemed to be at risk of VA by their treating physician were eligible for an ICM. The reason for monitoring could be a combination of symptoms (e.g., (near) syncope, palpitations), prior nonsustained VA, wide QRS, and/or systemic ventricular dysfunction. The decision to implant an ICM was made in a Heart Team consisting of at least a cardiac electrophysiologist and a cardiologist specialized in CHD. The study was approved by the institutional review board of the Erasmus Medical Center. Our center is a tertiary referral center with the largest population of adults with CHD in the Netherlands.

2.2. Device programming and follow-up

All ICMs were implanted subcutaneously as recommended by the manufacturer using the incision and insertion tool. Furthermore, all patients received a handheld activator to indicate their symptoms when necessary. The ICM was usually programmed according to local settings: tachycardia-detection was set to 176 bpm for 16 beats; bradycardia-setting to 30 bpm for 8 beats; pause-setting to 4.5 s; and atrial fibrillation (AF) setting to ‘AF only’. Based on the implanting physician preferences other settings could be programmed. All devices were connected to the Medtronic CareLink network for remote monitoring. Patients were discharged on the same day of implantation. Ten days after im-plantation the patients were seen at the outpatient clinic to check their wound and to interrogate the ICM. Afterwards, the patients were seen regularly at the outpatient clinic according to routine patient care. ICM check-ups were performed at the outpatient clinic every 6 months or earlier when necessary based on symptoms or transmitted episodes. Remote monitoring was performed on a daily basis during weekdays.

2.3. Classification of episodes and endpoints

All patient activated episodes and automatically detected episodes were classified. In the case of an inappropriate automatically detected episode, the cause of inappropriate detection was specified, if possible.

The primary endpoint of the present study was the occurrence of VA. A regular broad complex tachycardia was considered a VA if there was a sudden onset and a change in the QRS morphology in comparison to the baseline rhythm (Fig. 1A). An irregular broad complex tachycardia was considered a VA if there was a sudden onset and a polymorphic QRS morphology. A regular broad or small complex tachycardia was consid-ered a supraventricular tachycardia (SVT) if there was a sudden onset and no change in QRS morphology (Fig. 1B). In the case of doubt, a sec-ond electrophysiologist was consulted for the final diagnosis.

The secondary endpoint was the occurrence of other arrhythmias during follow-up. Finally, it was established whether a detected ar-rhythmia resulted in a change in patient management (‘actionable event’).

2.4. Statistical analysis

Continuous data are presented as mean ± standard deviation or as median with corresponding 25th and 75th percentile, as appropriate. Categorical variables are presented by frequencies and percentages. Sta-tistical analyses were performed using SPSS version 21.

3. Results

3.1. Study population

A total of 30 CHD patients (mean age, 38 ± 15 years; 50% male) re-ceived an ICM during the study period. Baseline characteristics of the study population are listed in Table 1. The majority of patients had moderate or severe complexity CHD. The 3 most common diagnoses were aortic coarctation, tetralogy of Fallot (TOF) and d-transposition of the great arteries (d-TGA). The majority of patients had symptoms at the time of ICM implantation (93%). An impaired systemic ventricular function was present in 17 patients (57%). A previous nonsustained VA was documented in 20% of the study population. A detailed patient-level description of CHD diagnosis, previous cardiac surgery, and reason for ICM is presented in Appendix A. There were no ICM- or procedure-related complications.

3.2. ICM-detected episodes

During a median follow-up of 16 months (interquartile range 9–21 months), a total of 1689 episodes were transmitted to the CareLink network system (Table 2). There were 538 (32%) patient-activated episodes and 1151 (68%) automatically detected episodes. The majority of patient-activated episodes (88%) comprised sinus rhythm with or without ectopy, thus, only 12% of patient-activated episodes comprised a significant arrhythmia (Table 2).

3.3. Primary and secondary endpoints

During follow-up, 8 patients (27%) developed nonsustained VA. Four of 8 patients (50%) had a history of nonsustained VA, thus 4 patients (13%) had a de novo nonsustained VA and 4 patients (13%) had recurrent nonsustained VA. In 7 of 8 patients (88%) the VA episodes were de-tected by patient-activated episodes. Most patients had monomorphic VA episodes and 1 patient experienced polymorphic VA episodes. Of the 8 patients with VA, 3 patients had an impaired systemic ventricular function. Of the 8 patients with VA, 3 patients received a prophylactic ICD after consultation with their treating physician and 3 patients had a change in their antiarrhythmic drug therapy. The remaining 2 patients did not have a change in their clinical management.

A 19-year-old man with surgical corrected Shone’s complex (coarctation resection, subvalvular aortic membrane resection, mitral valve and aortic valve replacement) received a dual-chamber ICD after detection of recurrent symptomatic nonsustained fast polymorphic VA (mean CL 240–270 ms, maximal 7 beats) 3 months post-ICM implanta-tion. He received an ICM due to combination of palpitations, exercise-induced ventricular ectopy, signs of inferior wall infarction and mild im-paired systemic ventricular function. After ICD implantation, he experi-enced two episodes of nonsustained fast polymorphic VA without ICD therapy during a follow-up of 17 months.

The second patient who received a dual-chamber ICD was a 42-year-old woman with surgical corrected TOF who experienced recurrent symptomatic nonsustained monomorphic VA (mean CL 490–520 ms, maximal 11 beats) 3 months post-ICM implantation. She received an ICM for the combination of palpitations and near-syncope. She did not experience VA post-ICD implantation during a follow-up of 27 months.

The last patient who received a dual-chamber ICD was a 44-year-old man with congenital corrected transposition of the great arteries and tricuspid valvuloplasty who developed an asymptomatic nonsustained fast monomorphic VA (mean CL 280 ms, 27 beats) 18 months post-ICM implantation (Fig. 1A). He received an ICM for a combination of syncope and dilated systemic ventricle with moderate-to-severe systolic ventricular dysfunction. During a follow-up of 12 months post-ICD implantation he experienced one episode of nonsustained fast monomorphic VA without ICD therapy.

Any significant arrhythmia was detected in 22 patients (73%). Fig. 2 shows the proportion of patients with a specific arrhythmia and Appendix A provides an overview of detected arrhythmias per patient. In 16 patients (53%) the detected arrhythmia was considered an actionable event. Management included initiation or change of antiarrhythmic drug therapy (n = 10, 33%), electrophysiology study (n = 6, 20%), ICD implantation (n = 3, 10%), electrical cardioversion (n = 2, 7%), and pacemaker implantation (n = 1, 3%).

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4. Discussion

The incidence of ICM-detected VA in a selected CHD population was relatively high (27%). The ICM-detected VA contributed to the decision to implant a prophylactic ICD in 10% of the study population. Furthermore, the detection of other arrhythmias by the ICM resulted in a significant change in clinical management in a majority of patients. The present study is the first prospective study focusing specifically on the use of an ICM for risk stratification in adults with CHD.

4.1. Risk of sudden death

Although the risk of SCD is higher in patients with CHD than in the general population, the absolute risk is still relatively low (approximately 0.1% per year) [3]. This has stimulated the search for risk factors which may help identify patients at risk for SCD, who may benefit from a prophylactic ICD implantation. Important risk factors for SCD include among others (recurrent) (non)sustained VA, inducible VA, atrial tachyarrhythmias, prolonged QRS duration, systemic ventricular dysfunction.

Fig. 1. Example ICM-detected episode of (A) ventricular tachycardia, (B) supraventricular tachycardia with pre-existing intraventricular conduction delay.
and subpulmonary ventricular dysfunction [4,14–17]. Despite the multitude of identified risk factors, the indication for ICD implantation remains challenging in clinical practice, especially regarding the potential downside of ICD therapy [9–11]. Furthermore, risk stratification is not uniform for the CHD population. For example, inducible sustained VA during programmed ventricular stimulation is useful for risk stratification in patients with TOF [7,8], but has not been demonstrated to predict VA/SCD in other CHD populations [18].

4.2. Risk stratification using ICM

In patients with certain high-risk features presenting with symptoms (i.e., syncope, near-syncope, palpitations), it is of importance for both patients and caregivers to rule out VA. This can be attempted using short-term monitoring; however, when symptoms are infrequent longer arrhythmia monitoring is necessary. For this purpose, an ICM is a valuable diagnostic tool for detecting paroxysmal arrhythmias as well as establishing a symptom-rhythm correlation. We provide data on the diagnostic yield of an ICM in a selected adult CHD population deemed at risk for VA. The incidence of VA was high in this population and resulted in implantation of an ICD for primary prevention in 10% of the study population. This is slightly higher than previous retrospective studies in patients with CHD who received an ICM [19,20]. These studies focused on the overall diagnostic yield of an ICM and not specifically on

![Fig. 2. Proportion of patients with an ICM-detected arrhythmia.](image-url)

Data is presented as n (%). Abbreviations: AT, atrial tachycardia; AV, atrioventricular; PAC, premature atrial complex; PVC, premature ventricular complex.

a Episode classification by ICM.
the role of an ICM for risk stratification. Kenny et al. described the diagnostic outcomes in CHD (median age 15 years) [20]. In this study, 1 of 18 patients (6%) received an ICD during a median duration of follow-up of 19 months. The patient who received an ICD was known with Ebstein’s anomaly and developed monomorphic ventricular tachycardia (VA at the age of 16 years. A more recent retrospective study from Boston Children’s Hospital included 34 patients with CHD and an ICM (Reveal LINQ, Medtronic Inc., Minneapolis, MN, USA) [19]. In this study, 1 of 34 patients (3%) received an ICD during a median duration of follow-up of 11.8 months. The patient who received an ICD was a patient with Fontan circulation who received an ICM at the age of 32 years. Other series reporting the use of ICM in patients with CHD are smaller and mostly performed in a pediatric population [21–28].

4.3. Cost-benefit of ICMs for risk stratification

Besides the use of an ICM for risk stratification, the ICM detected a significant arrhythmia in 73% of the population and this led to a change in clinical management in 53% of patients. Therefore, an ICM can be used to titrate medication and identify candidates for an electrophysiologic procedure (i.e., pacemaker, ICD or electrophysiological study). An important aspect is the ability to differentiate between benign (near)syncope and arrhythmogenic (near)syncope. Providing reassurance to a symptomatic patient is valuable in daily clinical practice.

Although the use of ICMs for risk stratification seems promising, there are some factors which should be considered such as device costs, data overload, clinical relevance of device-detected VA and medical overuse. The issue of data overload is exemplified by the recording of >1600 episodes in 30 patients in a relatively short follow-up period in our study population. This requires a proper logistic organization with a dedicated telemonitoring staff. There is some controversy with regard to the clinical relevance of device-detected arrhythmias, especially for atrial fibrillation [12]. With regard to the clinical relevance of device-detected VA, it is important to stress that in our population the majority of VA episodes were detected as patient-activated episodes, indicating that the patient experienced symptoms. Koyak et al. previously identified that symptomatic but not asymptomatic nonsustained VA was associated with appropriate ICD therapy in TOF patients who receive an ICD for primary prevention [29].

4.4. Study limitations

A limitation of the present study is the small size and lack of a control group. Therefore, no conclusion can be made regarding the incremental value of an ICM compared to standard clinical practice with intermittent Holter monitoring. Ideally, a randomized clinical trial would be conducted where patients are randomized to an ICM or conventional follow-up. Obstacles for such a clinical trial are the heterogeneity of the population and challenges in defining appropriate endpoints. In this regard, it is important to stress that our study population was a highly selected population. The usefulness of an ICM may not apply to an unselected CHD population. Finally, the classification of broad complex tachycardia as either VA or SVT can be challenging considering that only a single surface EGM is available. To reduce the risk of misclassification, difficult EGMs were reevaluated by an electrophysiologist.

5. Conclusion

There was a high incidence of ICM-detected VA in adults with CHD who were deemed at risk of VA. ICM results led to implantation of an ICD in 10% of the study population. The detection of arrhythmias by the ICM led to important changes in the clinical management of patients. Our prospective pilot study suggests that the use of ICMs for risk stratification in selected adults with CHD is helpful.

Disclosures

Dr. Yap has received a research grant from Medtronic.

CRediT authorship contribution statement

Rafi Sakhi: Methodology, Formal analysis, Investigation, Writing - original draft, Visualization. Robert M. Kauling: Resources, Writing - review & editing. Dominic A. Theuns: Methodology, Formal analysis, Writing - review & editing. Tamas Szili-Torok: Conceptualization, Writing - review & editing. Rohit E. Bhagwandien: Investigation, Writing - review & editing. Judith A.A.E. Cuypers: Resources, Writing - review & editing. Jolien W. Roos-Hesselink: Conceptualization, Methodology, Writing - review & editing, Project administration. Sing-Chien Yap: Conceptualization, Methodology, Formal analysis, Writing - review & editing, Visualization, Supervision.

Declaration of competing interest

The authors report no relationships that could be construed as a conflict of interest

Appendix A

Overview of baseline characteristics and clinical outcome

<table>
<thead>
<tr>
<th>Underlying diagnosis</th>
<th>Surgical status</th>
<th>Age at repair (years)</th>
<th>QRS duration (ms)</th>
<th>Reason for ICM</th>
<th>Age at ICM implantation (years)</th>
<th>FU with ICM (months)</th>
<th>ICM-detected arrhythmia</th>
<th>ICM-guided therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic coarctation</td>
<td>Surgical repair, AVR</td>
<td>8</td>
<td>190</td>
<td>Syncope, bifascicular block with first-degree AV block</td>
<td>56</td>
<td>10</td>
<td>Sinus arrest</td>
<td>AAD</td>
</tr>
<tr>
<td>Aortic coarctation</td>
<td>Surgical repair</td>
<td>3</td>
<td>117</td>
<td>Prior NSVT (asymptomatic)</td>
<td>26</td>
<td>12</td>
<td>NSVT</td>
<td>Conservative</td>
</tr>
<tr>
<td>Aortic coarctation</td>
<td>Surgical repair, PDA closure</td>
<td>11</td>
<td>148</td>
<td>Syncope, mild systemic ventricular dysfunction</td>
<td>71</td>
<td>15</td>
<td>SVT, AF, AFL</td>
<td>Ablation ECV, AAD, DDD-ICD, AAD Ablation</td>
</tr>
<tr>
<td>Aortic coarctation</td>
<td>Surgical repair, AVR, MVR</td>
<td>&lt;1</td>
<td>109</td>
<td>Palpitations, exercise-induced PVCs, mild systemic ventricular dysfunction</td>
<td>19</td>
<td>3</td>
<td>NSVT, SVT, SA block, AF SVT</td>
<td>Ablation ECV, AAD, DDD-ICD, AAD Ablation</td>
</tr>
<tr>
<td>Aortic coarctation</td>
<td>Surgical repair, PDA closure</td>
<td>14</td>
<td>124</td>
<td>Palpitations, syncope, prior NSVT, mild systemic ventricular dysfunction</td>
<td>19</td>
<td>32</td>
<td>SVT</td>
<td>Ablation ECV, AAD, DDD-ICD, AAD Ablation</td>
</tr>
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<td>38</td>
<td>81</td>
<td>Palpitations</td>
<td>41</td>
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<tr>
<td>Aortic coarctation</td>
<td>Surgical repair, AVR</td>
<td>10</td>
<td>174</td>
<td>Palpitations, mild systemic ventricular dysfunction</td>
<td>55</td>
<td>21</td>
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<td></td>
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</tbody>
</table>

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<table>
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<tr>
<th>Underlying diagnosis</th>
<th>Surgical status</th>
<th>Age at repair (years)</th>
<th>QRS duration (ms)</th>
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<th>FU with ICM arhythmia (months)</th>
<th>ICM-detected arrhythmia</th>
<th>ICM-guided therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 TOF</td>
<td>Total repair, PVR</td>
<td>30</td>
<td>180</td>
<td>Palpitations, QRS 180 ms, mild systemic ventricular dysfunction</td>
<td>52</td>
<td>17</td>
<td>AF, AV block</td>
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<tr>
<td>9 TOF</td>
<td>Total repair (transannular patch), PVR</td>
<td>&lt;1</td>
<td>176</td>
<td>Palpitations, mild systemic ventricular dysfunction</td>
<td>33</td>
<td>17</td>
<td>SVT, Bradycardia</td>
<td>Conservative</td>
</tr>
<tr>
<td>10 TOF</td>
<td>Total repair (Hancock conduit)</td>
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<td>155</td>
<td>Palpitations, near syncope</td>
<td>41</td>
<td>3</td>
<td>NSVT</td>
<td>DDD-ICD</td>
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<tr>
<td>11 TOF</td>
<td>Total repair</td>
<td>8</td>
<td>176</td>
<td>Near syncope, prior NSVT</td>
<td>39</td>
<td>21</td>
<td>SVT</td>
<td>AAD, EPS</td>
</tr>
<tr>
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<td>Total repair (transannular patch)</td>
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<td>161</td>
<td>Palpitations, syncope</td>
<td>25</td>
<td>16</td>
<td>SVT, Bradycardia</td>
<td>AAD, EPS</td>
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<tr>
<td>13 ASD</td>
<td>Surgical closure ASD, PV repair</td>
<td>11</td>
<td>114</td>
<td>Palpitations, near syncope, mild systemic ventricular dysfunction</td>
<td>56</td>
<td>4</td>
<td>SVT</td>
<td>AAD, EPS</td>
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<td>AAD, EPS</td>
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<td>74</td>
<td>3</td>
<td>AF, SVT</td>
<td>Pacemaker</td>
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<td>AF, SVT</td>
<td>Conservative</td>
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<tr>
<td>17 ASD</td>
<td>TV repair</td>
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<td>Near syncope, moderate systemic ventricular dysfunction, exercise-induced PVCs</td>
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<td>15</td>
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<td>Arterial switch and VSD closure (patch)</td>
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<td>136</td>
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<td>36</td>
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<td>21 cc-TGA</td>
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<td>TV repair</td>
<td>97</td>
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<td>23 cc-TGA</td>
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<td>AAD</td>
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<td>26 Tricuspid atresia</td>
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<td>2</td>
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<td>8</td>
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<td>41</td>
<td>27</td>
<td>Symptomatic PVCs</td>
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<td>28 DIOV</td>
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<td>ECV</td>
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<td>153</td>
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<td>20</td>
<td>19</td>
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<td>30 Ebstein's anomaly</td>
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<td>24</td>
<td>16</td>
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Abbreviations: AAD, antiarrhythmic drug; AF, atrial fibrillation; AFL, atrial flutter; ASD, atrial septal defect; AV, atrioventricular; AVR, aortic valve replacement; cc-TGA, congenital corrected transposition of the great arteries; d-TGA, d-transposition of the great arteries; DOIV, double outlet left ventricle; ECV, electrical cardioversion; EPS, electrophysiology study; ICD, implantable cardioverter-defibrillator; ICM, insertable cardiac monitor; FU, follow-up; MVR, mitral valve replacement; NSVT, nonsustained ventricular tachycardia; PDA, patent ductus arteriosus; PV, pulmonary valve; PVC, premature ventricular complex; SA, sino-atrial; SVT, supraventricular tachycardia; TCPC, total cavopulmonary connection; TOF, tetralogy of Fallot; TV, tricuspid valve; VSD, ventricular septal defect.

References


