Long-term outcome of transvenous bipolar atrial leads implanted in children and young adults with congenital heart disease

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Received 18 November 2011; accepted after revision 26 January 2012; online publish-ahead-of-print 29 February 2012

Aims
Atrial leads are often implanted in paediatric patients needing a pacemaker (PM). The aim of this study is the evaluation of their outcome in young patients.

Methods and results
We evaluated transvenous atrial leads outcome in children and young adults from a single centre, with a retrospective analysis. A \( P < 0.05 \) was considered significant. Between 1992 and 2008, 110 patients, 75 with congenital heart defects (d-transposition of great arteries status/post, s/p, Mustard 41%, atrioventricular septal defect 11%, tetralogy 9%, ventricular septal defect 8%), aged 13.3 ± 5.3 years, underwent PM implantation with bipolar atrial transvenous leads for sinus node dysfunction (50%), atrioventricular block (38%), cardiomyopathies, and primary ventricular arrhythmias (12%). Leads are steroid-eluting (98%), tined (59%), screw-in (41%), polyurethane-insulated (72%), silicone-insulated (28%), and have been positioned by transcutaneous puncture of subclavian vein into right atrial appendage/remnant (RAA, 50%), right atrial free wall/septum (25%), left atrium (s/p Mustard, 25%). Follow-up duration is 6.4 ± 4.8 (range 0.1–18) years. At multivariate analysis, younger age at implant was a risk factor for lead failure (4 leads, 3.5%) (\( P = 0.03 \)); 16 leads (14%) dislodged post-implantation and 12 were successfully repositioned, the others extracted or abandoned. Dislocation occurred more frequently with screw-in leads (\( P = 0.03 \)) positioned outside RAA (\( P = 0.02 \)). Atrial threshold showed a small but significant increase, 0.002 V/month (\( P < 0.001 \)), impedance showed a decrease (0.6 \( \Omega \)/month, \( P < 0.001 \)). P-wave showed no significant difference.

Conclusions
Transvenous bipolar atrial leads have good long-term results in young patients, with a very low rate of lead failure. Older age at implant can further reduce this rate. Lead dislodgement is frequent in the post-operative period.

Keywords
Cardiac pacing • Children • Pacemaker • Endocardial pacing • Pacing leads • Pacing complications

Introduction
In children and young adults with bradyarrhythmias requiring a permanent pacemaker (PM), transvenous pacing is generally effective and safe but still carries significant risks of lead dislodgement, lead malfunction, and lead fracture.1–8 Single-chamber rate-responsive ventricular pacing (VVIR) is generally effective in children with atrioventricular block (AVB) and normal systemic ventricular function, and can be upgraded to dual-chamber (DDD) pacing in adolescence and young adulthood. Sinus node dysfunction (SND) is a post-operative late complication in patients with congenital heart defects (CHD), and often requires single-chamber atrial pacing (AAI/AAIR). Bipolar atrial leads are preferred for better performances. Few recent studies describe the outcome of transvenous pacing in children, generally in comparison with epicardial pacing,1–10 but to our knowledge there are no large or recent studies entirely dedicated to the outcome of endocardial atrial leads implanted in the paediatric age group. We sought to address this issue.

Methods
Between 1982 and April 2008, 443 patients underwent permanent PM implantation and are followed at the Arrhythmology Unit of Bambino Gesù Children’s Hospital, IRCCS Rome, Italy.
Gesú Paediatric Hospital. With a retrospective study we reviewed the records of these patients and identified all those who underwent an implantation of a transvenous bipolar atrial lead. We recorded the techniques used for the initial implantation, the pacing system characteristics, and any complication. We also recorded the clinical status at the most recent follow-up.

**Implantation procedure**

The implant technique used in our Institution has already been described. Briefly, the atrial lead was inserted by transcutaneous puncture of the subclavian vein, and positioned in the right atrium or in the left atrium in transposition of the great arteries (TGA), where adequate values of pacing threshold (pulse amplitude < 1 V at 0.50 ms of pulse duration), P-wave sensing (> 1 mV), and impedance (> 300 and < 1000 Ω) were achieved. Leads were fixed to the subcutaneous tissue with a slowly absorbable ligature in children and adolescents (< 16 years) and with a non-absorbable suture in patients > 16 years of age. A trial of high-output atrial pacing (10 V at 0.50–1.50 ms) was performed to exclude inappropriate diaphragmatic stimulation. After PM implantation patients were kept at bed rest in hospital for 48 h. Pre-discharge, patients underwent telemetric PM interrogation, standard electrocardiogram, two-dimensional-doppler echo, and chest X-ray.

**Definitions**

Pacing system implantation was defined as the placement of a new PM generator and leads. Pacemaker replacement was defined as the placement of the PM generator without the insertion of new leads. Lead repositioning was defined as when a dislodged lead (macroscopic dislodgement at chest X-ray with failure of atrial capture) underwent a reposition attempt. Lead re-implantation was defined as when a new lead was implanted in patients with a previous lead (either removed or abandoned). Lead failure requiring lead removal, abandonment, or re-implantation was defined in the presence of: (i) exit block, (ii) abnormal threshold increase with the need of high output values causing early battery depletion and/or partial loss of capture, (iii) lead fracture, (iv) insulation breach, (v) under- or over-sensing not reversible with programming.

System infection was defined according to published criteria. Follow-up was defined according to published criteria.

**Follow-up**

The follow-up schedule in use in our Institution has been described previously. Patients were generally followed up at 1, 3, and 6 months after implantation, and then every 6 months or as needed. During telemetric PM interrogation, pacing and sensing thresholds were generally measured manually; in the presence of PM with atrial capture management algorithm, automatic threshold measurements were used as a good correlation was demonstrated between automatically and manually measured thresholds.

**Statistical analysis**

Statistical analysis was carried out using the Stata package, version 8.0 (StataCorp. 2003 Stata Statistical Software: Release 8.0. College Station, TX, USA: Stata Corporation). Proportions or, when appropriate, means or medians together with standard deviation and range were computed. The median was specified if different from the mean. A P value < 0.05 was considered significant.

The Kaplan–Meier method and log-rank test were used to study the longevity of the atrial leads implanted considering lead failure, and the longevity of pacing systems implanted considering lead dislocation and pacing system infections or erosions requiring the extraction of the leads. Variables included in the model were patient’s age, presence or absence and severity of structural heart disease, number of procedures, lead model, mechanism of lead fixation, site of atrial lead positioning, and presence of a ventricular lead. Complications that did not require a new pacing system implantation (i.e. initial erosions treated only with pocket surgical revision or PM replacement, haemothorax at lead implantation) were recorded as complications but not included in the analysis of the outcome of the first pacing system implanted, as this was not replaced. Cases of lead removal because of extraneous causes (e.g. new cardiac surgery, cardiac transplantation, or patient’s death unrelated to pacing), were considered as ‘censored’. A Cox multivariate proportional hazard model was used to explore factors associated with the duration of the pacing system. Variables included in the model as predictors were patient’s age, presence or absence and severity of structural heart disease, number of procedures, lead type and model, presence of a ventricular lead, site of atrial lead positioning, and, as a continuous variable, year of implantation. Multivariate analysis was performed for lead failure and lead dislodgement. Electrical parameters were analysed with a multilevel model.

**Results**

**Population**

Between 1992 and April 2008, 110 children (36 girls) underwent PM implantation with an endocardial bipolar atrial lead at 13.3 ± 5.2 years of age (range 2–29 years); 29 patients were younger than 10 years.

Weight at implantation was 52 ± 20 kg (median 56, range 7–104).

In 18 patients (16%), a previous epicardial pacing system failed.

Structural heart diseases were present in 85 patients, including 75 patients with CHD (68%, Table 1), 5 patients with hypertrophic obstructive cardiomyopathy (HOCM), and 5 with dilated cardiomyopathy (DCM). For purposes of statistical analysis, patients were divided into three groups based on the presence and severity of CHD: Group 1, patients without CHD (25 patients) and with HOCM and DCM; Group 2, including 23 patients (31% of patients with CHD) with simple CHD (e.g. isolated atrial, ventricular and atrio-ventricular septal defect, pulmonary stenosis, tetralogy of Fallot); and Group 3, including 52 patients with complex CHD. Eight patients had trisomy 21.

**Table 1 Main congenital heart defect of the patients**

<table>
<thead>
<tr>
<th>Heart defects</th>
<th>No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>VSD</td>
<td>6</td>
</tr>
<tr>
<td>Tetralogy of Fallot, PA + VSD</td>
<td>7</td>
</tr>
<tr>
<td>AV septal defect</td>
<td>8</td>
</tr>
<tr>
<td>TGA status/post-Mustard</td>
<td>31</td>
</tr>
<tr>
<td>CCTGA</td>
<td>5</td>
</tr>
<tr>
<td>Ostium secundum atrial septal defect</td>
<td>4</td>
</tr>
<tr>
<td>Other CHD</td>
<td>14</td>
</tr>
</tbody>
</table>

AV, atrioventricular; CCTGA, congenitally corrected TGA (S, L, D); PA, pulmonary atresia; TGA, transposition of the great arteries (S, D, D); VSD, ventricular septal defect.
Indications
The main arrhythmias requiring PM implantation were: SND in 55 (50.0%) patients; complete AVB in 42 patients (38.2%), post-operative in 9 patients; and ventricular tachycardia requiring ICD implantation in 4 patients (3.6%). In the years 1994–1995, nine patients (8.2%) underwent DDD PM implantation with short AV interval in the presence of a DCM (n = 4 subjects) and HOCM (n = 5). When SND was the main arrhythmia requiring PM implantation, an AAI/AAIR PM was generally implanted. When AVB developed during the follow-up (n = 3 patients) the single-chamber system was upgraded to dual chamber. In the presence of SND and bradycardia–tachycardia syndrome, an anti-tachycardia anti-bradycardia dual-chamber PM was implanted (n = 7 patients).

Pacemaker and leads implantation
Pacemaker implanted are DDD/DDDR (n = 71, 65%) and AAI/AAIR (n = 39, 35%), with 110 bipolar atrial leads (Table 2): steroid-eluting (n = 108, 98%), mostly J-shaped (62/65, 95%), or straight screw-in (n = 45, 41%); polyurethane-insulated (n = 79, 72%) or silicone-insulated (n = 31, 28%). Screw-in leads were implanted since the year 2000. A total of 124 procedures were performed (see the Follow-up section below), including: lead implantation (110 procedures), the reimplantation of a screw-in and silicone-insulated lead in one patient following prior lead dislodgement and abandonment, and 13 procedures of lead repositioning (12 due to lead dislodgement, 1 due to exit block).

Leads were implanted in: right atrial appendage or appendage remnant (RAA, left atrium (LA), right atrial free wall and right atrial septum (RAFS)). There were 82 ventricular leads: 21 were implanted earlier than atrial leads (VVIR PM subsequently upgraded to DDD PM), 54 were implanted together with atrial leads (DDD PM implantation), and 7 were implanted later than atrial leads (AAIR PM upgraded to DDD PM).

Follow-up
Follow-up duration (until August 2010) was 6.4 ± 4.8 (median 6, range 0.1–18) years. Censored patients were 24: 15 patients died for causes unrelated to pacing, 8 underwent heart transplantation, and 1 had the lead removed and substituted with epicardial leads at the time of elective extracardiac Fontan operation; 10 patients were lost to follow-up. Forty-nine PM replacements occurred during follow-up (median 1, range 1–4 per patient).

Complications
Haemothorax at implantation occurred in three patients (2.7%) in the first years of our experience. In the last 10 years there was no implant-related complication.

Lead failure occurred in four (3.5%) tined, J-shaped leads (Table 2) implanted in significantly younger patients (5.2 ± 2.5 years, P = 0.027 at Cox regression/model): one due to exit block (lead abandoned), one due to abnormal threshold increase (lead was repositioned), and two due to insulation breach (one substituted at elective heart surgery with an epicardial lead, one still in site with acceptable function). Median time to lead malfunction was 7.5 years (range 2–14 years). None of the other variables examined (presence and severity of CHD, year of implant, lead model and insulation, fixation mechanism, presence of ventricular lead, atrial site of implantation) were significant. Also at multivariate analysis, younger age at implant was a risk factor for lead malfunction (P = 0.022, hazard ratio 0.7, 95% confidence interval 0.55–0.95).

A total number of 16 leads dislodged (13% of leads, 14% of procedures) (Table 2), always in the first year after implantation (10 in the first 15 days) except for 1 lead after 4 years. In three patients there were two consecutive dislocations. Twelve leads were successfully repositioned: two leads have been extracted after unsuccessful repositioning, and two leads have been abandoned without repositioning attempts due to anatomical characteristics. Dislocation occurred more frequently with screw-in (16%) than tined leads (7%) (P = 0.03 log-rank test (Figure 1), and for lead positioned in right atrial free wall and septum (RFWS) and LA (20% each) than in RAA (5%) (P = 0.03 log-rank test) (Figure 2). At multivariate analysis, the presence of a screw-in lead (P = 0.043, hazard ratio 2.8, 95% confidence interval 1.0–8.5) and the implantation in LA (P = 0.028, hazard ratio 4.5, 95% confidence interval 1.0–8.5) were significant. The implantation in LA (P = 0.028, hazard ratio 4.5, 95% confidence interval 1.0–8.5) was significant.
interval 1.2–17.6) were statistically significant, while the implantation in RFWS was nearly significant (P = 0.06, hazard ratio 3.7, 95% confidence interval 0.9–14.8). None of the other variables examined (presence and severity of CHD, year of implant, lead model and insulation, presence of ventricular lead) were significant.

System erosion/infection requiring system removal occurred in five patients (4.5%) with dual-chamber PM. Risk factors for infection were not identified (age at implantation, number of leads, or number of PM replacements). Two other patients developed initial pocket erosion treated with surgical revision and/or PM replacement.

No pericardial effusion was documented after screw-in atrial lead implantation.

**Electrical parameters**

At implantation the pacing threshold was 0.6 ± 0.3 V, P-wave-sensing 4.1 ± 2.6 mV, impedance 684 ± 244 Ω. At 10 years, the threshold was 0.9 ± 0.4 V; P-wave-sensing 3.4 ± 1.7 mV; impedance 518 ± 120 Ω (Figure 3). At multilevel model, atrial threshold showed a small and significant increase over time (0.002 V every month, P < 0.001, 95% confidence interval 0.001–0.002), P-wave sensing showed no significant difference (P = 0.5) and impedance showed a small and significant decrease during follow-up (0.6 Ω every month, P < 0.001, 95% confidence interval from −0.8 to −0.4). Fixation mechanism and insulation of the leads showed no significant influence on pacing parameters. No significant under/over-sensing occurred.

**Discussion**

Most of the complications of permanent pacing in children are lead related. As a general rule, the fewer leads that are implanted, the fewer complications that will occur.3 In children with AVB and normal ventricular function, VVIR pacing is adequate for children’s physiological needs,3–7 and DDD pacing with transvenous leads, which is technically feasible even in small children, may be postponed to adolescence.3 Atrial pacing, however, is indicated in the presence of SND, with good results,16 although initial reports described a significantly greater rate of failures for atrial leads.17 Recent and large papers about the outcome of atrial pacing in paediatric populations are lacking. In general, the use of bipolar leads for atrial pacing has significantly improved their outcome.18 In adult patients, J-shaped atrial leads seems to have more stability with fewer dislodgements but with a higher malfunction rate than straight leads,19,20 and a recent comparison of passive-fixation and active fixation J-shaped atrial leads demonstrated no significant difference in lead-related complications. However, the former demonstrated a better pacing threshold over 1 year of follow-up, probably due to the lack of an inflammatory response to the screw, while the latter showed a 6% rate of pericardial irritation or effusion.21 Other papers describe no significant modification of thresholds for active fixation leads in adults.22

Our data demonstrate that bipolar transvenous atrial pacing in young patients either with tined or screw-in leads has good results with a low rate of failure during a long follow-up, with a significant increase in risk of failure due to younger age at implantation. This failure rate, however, is lower than that described in ventricular lead (20%),9 as in our experience mean age at implantation of atrial leads is higher than that of ventricular leads.

Our findings suggest that one should postpone transvenous atrial lead implantation in children with AVB until adolescence, except in rare, selected cases. This study demonstrates that screw-in leads are safe and effective in a paediatric and young

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**Figure 1** Kaplan–Meier survival estimates of atrial leads considering lead dislocation, according to fixation mechanism (P = 0.03). CI, confidence intervals; No., number.

**Figure 2** Kaplan–Meier survival estimates of atrial leads (considering lead dislocation) according to the atrial site of implantation (P = 0.03) (see the text for further details). Confidence intervals were not displayed not to overwrite the different curves. RAA, right atrial appendage or appendage remnant; RFW, right atrial free wall and right atrial septum; LA, left atrium; No., number.

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adult population and can be used as an alternative to tined leads. Furthermore, screw-in leads might be easier to remove.

Lead dislodgement occurred in 13% of procedures. Age at implantation and year of implantation were not risk factors for dislocation. The latter excludes the impact of the operator learning curve on dislocation. Dislodgement occurred more frequently with screw-in leads than with tined leads, and more frequently when the lead was positioned in the LA and in RAFWS than in RAA. The reason is that tined J-shaped atrial leads are usually positioned in the RAA, a location that offers stability even in the absence of active fixation mechanisms because the tip is passively anchored to the pectinate muscles, and the distal part of the lead lies on the inferior wall of the RAA. On the contrary, the RAFWS and the LA wall are smooth and the distal part of the lead is floating inside the atrial cavity, conditions that may cause dislocation notwithstanding the active fixation mechanism in young subjects. One might speculate that the finding of a more frequent dislodgement rate with screw-in leads may reflect a selection bias, as active-fixation leads are preferred in patients with CHD after surgery who often show difficult access to RAA remnant, thus selecting a group at higher risk. However, in our study, presence and severity of CHD were not risk factors for lead dislodgement.

For these reasons, the RAA, when present, should be the preferred site of implantation.

Pacing threshold shows a significant increase over time; pacing impedance shows a decrease over time. Nonetheless, these variations appear clinically non-relevant, with good chronic pacing parameters at long-term follow-up (Figure 3). No significant under/or over-sensing occurred. Fixation mechanism and insulatin material had no significant influence on pacing parameters.

No pericardial effusion or irritation occurred with screw-in leads. The frequency of infections requiring system extraction is low (4.5%), as in previous reports. The number of procedures performed and that of leads implanted had no negative impact on system infections as previously described.

**Limitations**

The study has some limitations: it is a retrospective analysis, based on a single-centre experience and the number of patients is relatively small.

**Conclusions**

Bipolar endocardial atrial leads in children and young adults with CHD show good results, with a very low number of lead failures during the follow-up. Failures are related to low age at implantation. This finding suggests that one should postpone transvenous atrial lead implantation in children with AVB until adolescence, except in selected cases. Bipolar leads showed good electrical parameters during long-term follow-up, without significant atrial under/over-sensing requiring lead replacement. Straight screw-in atrial leads appear as safe and effective as J-shaped tined leads.

![Figure 3](https://academic.oup.com/europace/article-abstract/14/7/1002/476283/1006)
The most frequent complication is lead dislodgement, which generally occurs during the first days post-implantation, mostly for screw-in leads positioned outside the RAA where the stability may be impaired by anatomical characteristics.

As for all paediatric studies, larger populations and longer follow-up might give more information and other results.

Conflict of interest: none declared.

References