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CASE SERIES
Congenital heart disease

Case series of late lead dislodgement of Medtronic SelectSecure 3830 pacing leads in growing paediatric patients

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Background The SelectSecure lumenless 3830 pacing lead is often considered to be the pacing lead of choice for transvenous pacing in children because of its small diameter, lead strength, and reliable long-term sensing and pacing characteristics. One of the potential long-term pitfalls of a sturdy pacing lead is relative retraction with growth in children resulting in late lead dislodgement.

Case summary We report two cases of late SelectSecure 3830 lead dislodgement at 11.8 years (Case 1) and 8.8 years (Case 2), respectively, post the initial implantation. Case 1 was diagnosed with congenital complete heart block (CHB) at 9 months old when he presented with unconfirmed diphtheria infection. Case 2 was diagnosed with CHB at 14 weeks of age with positive maternal anti-Ro antibodies. Both patients underwent implantation of a transvenous permanent pacemaker implantation with Medtronic SelectSecure 3830 lead due to symptomatic bradycardia. Apart from a pulse generator change at 8.5 years (Case 1) and 7 years (Case 2), respectively, post-implant due to normal battery depletion, both patients are well in the interim.

Discussion As part of the pacemaker follow-up for rapidly growing children, we recommend more frequent surveillance of lead 'tautness' by chest radiography especially in children with CHB with no underlying heart rhythm.

Keywords Case report • Paediatric pacing • Pacemaker lead failure • Late lead dislodgement • Congenital heart block

Learning points

- The 4.1 Fr SelectSecure 3830 pacing lead is a sturdy lead that has reliable long-term sensing and pacing characteristics.
- One of the potential pitfalls of a sturdy pacing lead is relative retraction with linear growth in children leading to late lead dislodgement.
- The combination of the creation of atrial loop and the use of slow absorbing ligatures to anchor the lead has been reported to improve the longevity of the pacing leads.
- Regular chest radiograph and electronic performance check are essential to ensure optimum performance.

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Introduction

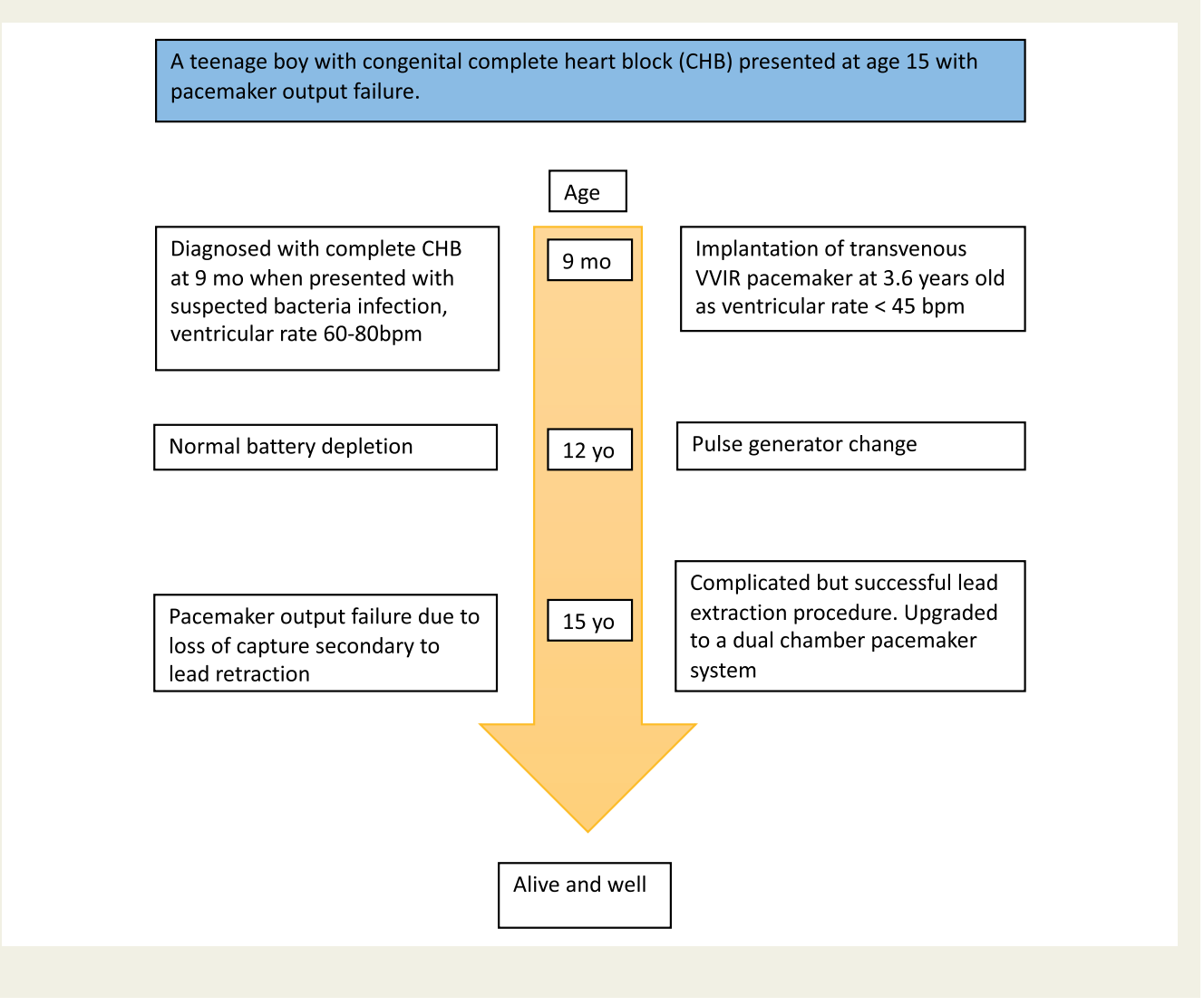
With the advances in pacemaker generator and lead designs over the past three decades, there has been a gradual shift towards placement of transvenous pacing systems in young children with encouraging short and medium to long-term outcomes.[1,2] However, the life-long pacing requirement in linearly growing paediatric patients presents ongoing unique challenges to lead selection and placement.

The SelectSecure 3830 lead (Medtronic Inc., Minneapolis, MN, USA) is often the pacing lead of choice for transvenous pacing in children because of its small diameter and reliable long-term sensing and pacing abilities, therefore, avoiding frequent lead revisions.[1,3–5]

This 4.1 French (Fr) bipolar lead is the thinnest lead available since 2000. It is lumenless with a cable cathode conductor and an anode conductor that is externally wound around in helical fashion. The conductors are separated by a layered insulation of ethylene–tetrafluoro–ethylene. The use of composite insultation materials allows this thin lead to have high crush resistance. The lead has active fixation with a steroid eluting non-retractable screw-in tip. The lead is easily delivered using the 8.4 Fr deflectable delivery catheter (SelectSite C304, Medtronic Inc., Minneapolis, MN, USA) or can be delivered through pre-shaped guiding catheters or even peel-apart introducer sheaths in small children and infants.[6]

One of the potential long-term pitfalls of this very sturdy pacing lead is retraction and lead dislodgement with linear growth in children. Several studies have reported complications related to other brands of leads dislodging in paediatric patients during early[3–5] and medium-term[1] follow-up. We report two cases of late lead dislodgement of 4.1 Fr SelectSecure 3830 in two patients with congenital complete heart block (CHB).

Timeline: Case 1

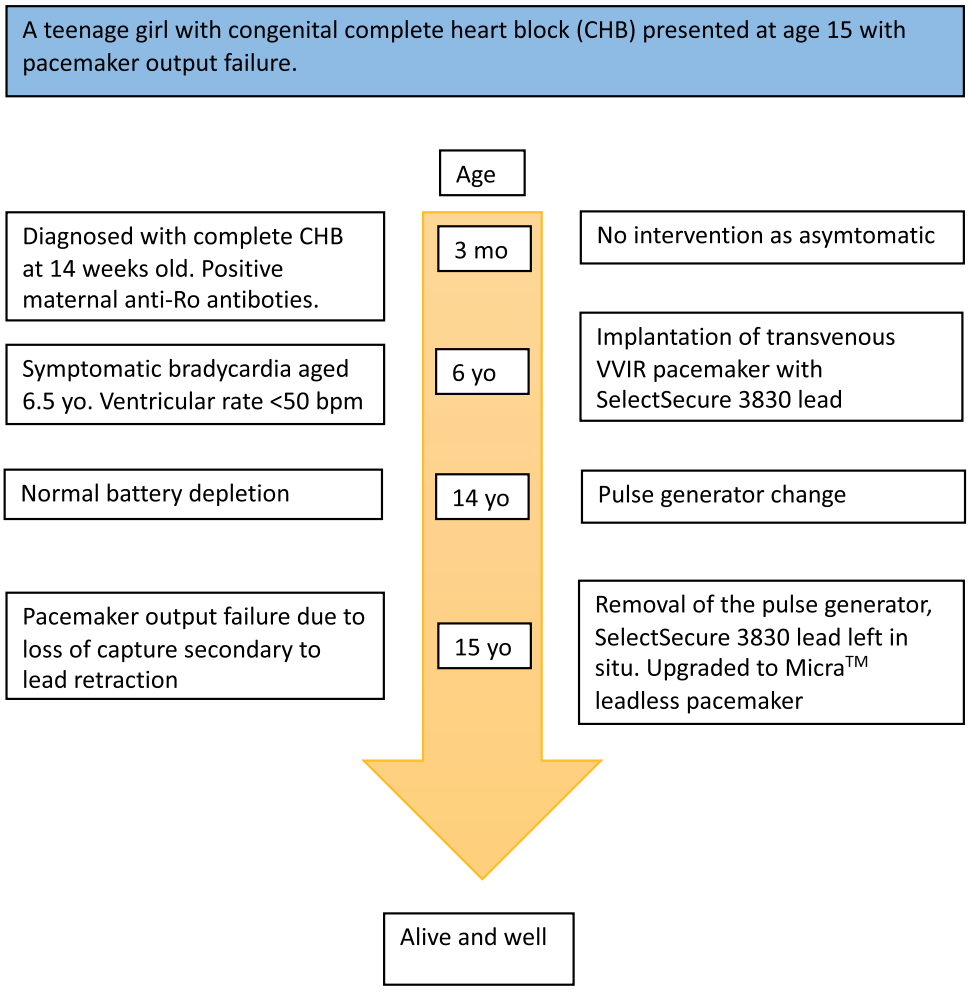


Case presentation

Case 1

A 15-year-old boy was diagnosed with congenital CHB at 9 months of age when he was admitted with a suspected but unconfirmed

Timeline: Case 2



diphtheria throat infection. During that admission, he was noted to be persistently bradycardic ranging from 60 to 80 b.p.m. with evidence of CHB on his electrocardiogram (ECG). He was otherwise healthy with no comorbidities. He underwent an implantation of transvenous VVIR pacemaker in 2004 when he was aged 3 years and 8 months as he became progressively bradycardic with resting ventricular rate below 45 b.p.m. He had a mild degree of lethargy but was otherwise well and his physical examination was normal with no evidence of heart failure.

The implantation procedure was performed under general anaesthesia. A sub-pectoral pocket was created. The left subclavian vein was punctured and a 59 cm SelectSecure 3830 lead was delivered to his right ventricular outflow tract (RVOT) septum using an 8.4 Fr deflectable sheath. The lead was tested for adequate sensing and pacing threshold. Of note, no atrial loop was created this time in order to potentially avoid loop migration (*Figure 1A*). The implanted lead was anchored in the sub-pectoral pocket with a non-absorbable suture and connected to the generator. The wound was closed with a subcuticular suture in a standard manner. The patient was reviewed in pacemaker clinic at 6 weeks post-initial implantation, then at 6 months interval within the 1st year of implantation and annually beyond 1st year.

He required a pulse generator change at 12 years of age due to normal battery depletion. During the box-change admission, the pacing lead was noted to be within the right ventricle but away from the RVOT septum on chest radiography (CXR) (*Figure 1B*). His ECG showed good ventricular pacing with appropriate ventricular capture (*Figure 2A*). No intervention was made to the lead as sensing and pacing thresholds were completely satisfactory at that time.

During a routine electrical performance check at 15 years and 5 months of age his pacemaker was noted to have loss of capture. The patient was asymptomatic with ventricular rate of 57 b.p.m., with normal blood pressure and no evidence of heart failure. The case was discussed at our Joint Cardiac Conference with agreement to proceed with lead extraction and pacemaker system upgrade. On admission, it was noted the pacing lead was withdrawn to right atrium (RA)

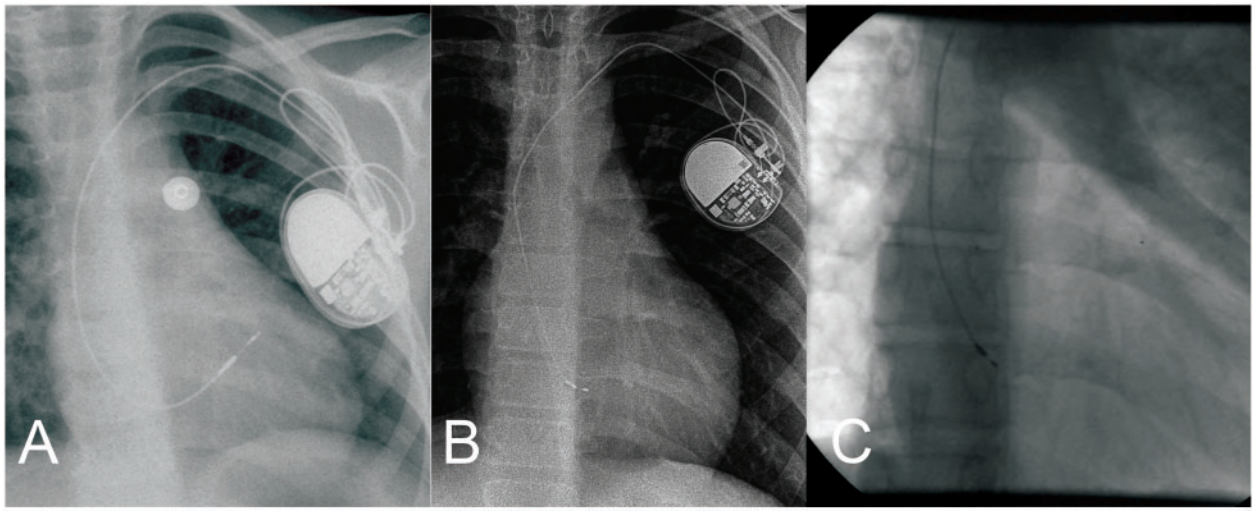


Figure 1 Serial chest X-rays/fluoroscopy images in Case 1. (*A*) At initial implantation of pacemaker system with no right atrial loop created with the redundant lead. (*B*) At interval pulse generator change, the pacing lead was noted to be within the right ventricle but away from the right ventricular outflow tract septum. (*C*) At lead extraction and pacemaker system upgrade, pacing lead was noted to have withdrawn to right atrium.

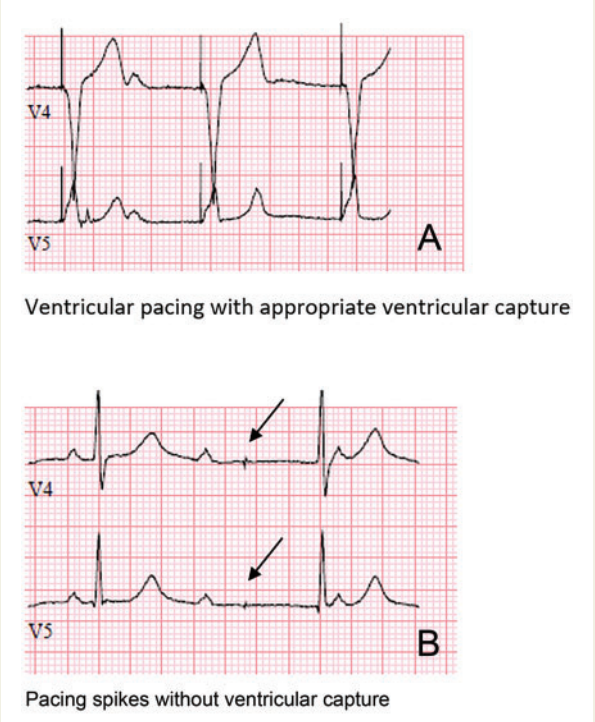


Figure 2 Serial electrocardiogram in Case 1. (*A*) Baseline electrocardiogram showing ventricular pacing spikes with appropriate ventricular capture. (*B*) Electrocardiogram at the presentation with pacemaker output failure showing pacing spikes without ventricular capture.

on an echocardiogram and as shown on fluoroscopy (*Figure 1C*), and his ECG showed pacing spikes without ventricular capture (*Figure 2B*).

Lead extraction procedure

After unsuccessful simple traction approach, we used a Bulldog Lead Extender (Cook Medical) and One-Tie Compression Coil (Cook Medical) for lead control. An 11 Fr, and 13 Fr Evolution Mechanical Dilator Sheath (Cook Medical), was advanced over the lead to dissect fibrous and periosteal adhesions up to the innominate vein and superior vena cava junction while applying constant traction on the lead. We had to resort to the femoral approach using a needle-eye snare to extract a calcified Select Secure lead completely. Haemostasis was achieved with a purse-string suture applied to the entry site. During the same procedure, he had an uneventful upgrade to a transvenous dual-chamber pacemaker system via the left subclavian vein.

At his latest follow-up, 3 years after the implantation of the dual-chamber pacemaker system, the patient is clinically well with normal cardiovascular exam. His pacing check was satisfactory with atrial threshold of 0.75V @ 0.4 ms, right ventricular threshold of 1.0V @ 0.4 ms with 99% ventricular pacing and 26% atrial pacing.

Case 2

A 15-year-old girl who was born prematurely at 30 weeks of gestation and was noted postnatally to have 2:1 atrioventricular block. She was subsequently diagnosed with CHB at 14 weeks of age with positive maternal anti-Ro antibodies. She was well and thriving with no sign of heart failure at that stage with a baseline ventricular rate of 80 b.p.m. However, she became progressively more bradycardic with resting ventricular rate between 45 and 50 b.p.m. along with near

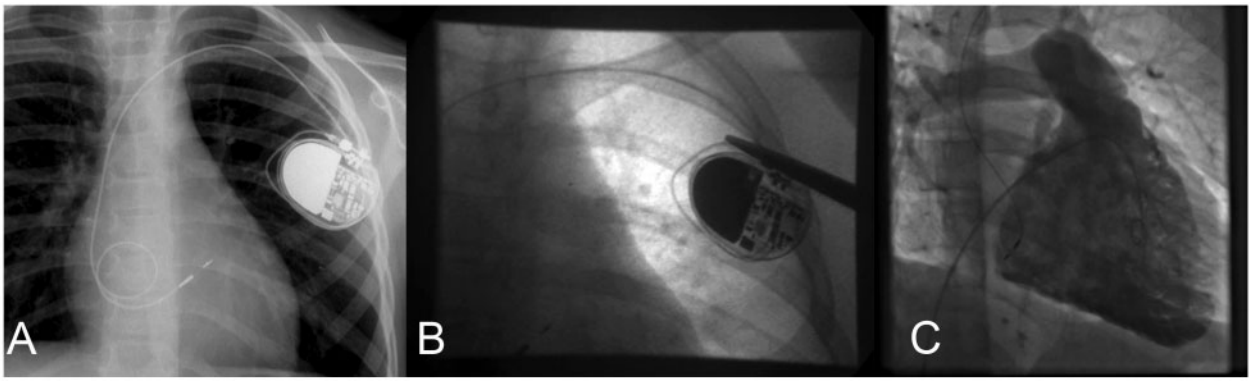


Figure 3 Serial chest X-rays/fluoroscopy images in Case 2. (*A*) At initial implantation of pacemaker system with a right atrial loop creation using the redundant lead. (*B*) At interval pulse generator change, note the tip of the lead at right ventricular outflow tract septum. (*C*) At pacemaker change, note the pacing lead has withdrawn to right atrium.

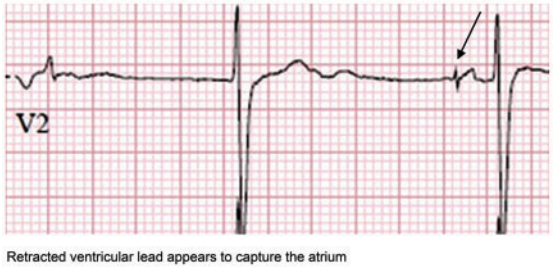


Figure 4 Electrocardiogram for Case 2 at the time of lead dislodgement showing the pacing spike appears to capture the atrium.

syncopal episodes and subjectively reduced energy levels. Her cardiovascular examination was normal with no evidence of heart failure. She underwent a transvenous VVIR pacemaker insertion with a 59 cm Select Secure 3830 pacing lead implanted on the RVOT septum in 2007 at the age of 6 years and 9 months. The redundant lead was pushed into create a loop in the RA (*Figure 3A*) and the implanted lead anchored in the sub-pectoral pocket with a non-absorbable suture. The patient was reviewed in pacemaker clinic at 6 weeks post-initial implantation, then at 6 months of interval within the 1st year of implantation and annually beyond 1st year.

She underwent a pulse generator change at 14 years of age due to expected battery depletion. Pacing check showed stable low lead capture threshold. Fluoroscopy image showed the position of the tip of the lead at RVOT septum; however, the extent of the RA loop was not imaged at this time (*Figure 3B*).

During a routine pacemaker check at 15 years and 6 months of age her pacemaker was noted to have lost ventricular capture. Her ventricular rate was 49 b.p.m. and the patient was asymptomatic. Fluoroscopy showed that the lead had dislodged and retracted to the RA (*Figure 3C*). The ECG showed that the retracted ventricular lead appears to capture the atrium (*Figure 4*). A month later, she opted to have implantation of a Medtronic Micra^{TM} leadless pacemaker so that she could engage in physical contact sports once the old box was explanted. The SelectSecure 3830 lead was left in situ after careful consideration of the risks vs. benefits of removing a near decade-old lead. After 2 years of follow-up, she remains well with a ventricular threshold of 0.63V @ 0.4 ms with 23% ventricular pacing and she is regularly involved in contact sports.

Discussion

About 1% of all pacemakers are implanted into children.[7,8] The epicardial pacemaker implantation is indicated in the presence of complex congenital heart defects with intracardiac shunts or absence of appropriate cardiac cavity, in small babies where the veins are too small to accommodate the passing of a pacing lead or in children with venous occlusion. Epicardial leads are traditionally associated with higher lead failure, shorter battery longevity, and rare but serious cardiac strangulation and coronary compression.[8–12] Traditional transvenous leads, on the other hand, carry a significant risk of venous thrombosis.[13–15]

The transvenous approach to pacemaker implantation in children and adolescents is an appealing alternative to the epicardial approach and has generally favourable outcomes.

Newer refined transvenous leads such as the bipolar, screw-in Medtronic SelectSecure 3830 with a smaller diameter may result in fewer long-term venous complications.[1–4,16] However, children are more prone to mechanical complications because of their active lifestyle, higher frequency of traumatic contacts, and somatic growth as shown in our cases.

Lead redundancy or loops were created where possible to allow for patient linear growth at the discretion of the operator. No atrial loop was created in Case 1 at the initial implantation as the loop migrated to the RVOT and required retraction. There was an atrial loop created in Case 2; however, a fluoroscopy image showing the

tip of the lead in desired position did not capture the atrial loop at subsequent pulse generator change.

The combination of the creation of an atrial loop to the ventricular lead and the use of slow absorbing ligatures to anchor the lead has been reported to improve the longevity of the pacing leads.[2,12,17,18]

However, the length of redundant lead introduced by creating a loop may still not be sufficient for linear growth in some patients as our cases show.[19] Furthermore, large atrial loops in addition to migrating into the right ventricle can also become adherent to the atrial walls. There have also been mixed results with late lead advancement to recreate atrial loop.[1,20] This may well be because of the lead being bound down by fibrous tissues intravascularly after many years.

Gasparini *et al*[21] suggested to leave redundant lead loop within the inferior vena cava (IVC) to allow for further growth by shortening excess loop. However, the IVC loop has been associated with IVC thrombosis and obstruction,[22] which may lead to Budd–Chiari syndrome hence we avoid that approach at our centre.

Conclusion

Our two case studies emphasize that over the longer term the Medtronic SelectSecure 3830 lead is subject to the usual problems related to transvenous leads. Long-term follow-up for patients with this lead should include pacemaker checks at regular intervals to ensure optimum pacemaker and pacing lead performance, and CXR every 2 years to pre-empt the problem of lead retraction and sudden loss of pacing. This matters most especially in children with CHB with no underlying heart rhythm. Further studies on the long-term outcome of SelectSecure 3830 leads in growing children are essential.

Lead author biography

Li Yen Ng graduated with an honoured medical degree from the Royal College of Surgeon in Ireland. I am currently a 3rd year specialist registrar training in the Paediatric Cardiology with the Royal College of Physician in Ireland. My area of interests in Paediatric Cardiology includes advanced cardiac imaging, cardiogenetics, and electrophysiology.

Supplementary material

Supplementary material is available at *European Heart Journal - Case Reports* online.

Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as Supplementary data.

Consent: The authors confirm that written consent for submission and publication of this case report, including images and associated text, has been obtained from the patients in line with COPE guidance.

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