

Lead Removal of Cardiac Implantable Electronic Device

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As more people are living longer with more significant cardiac disease, permanent pacemakers (PPMs) and implantable cardioverter-defibrillators (ICDs) are being inserted more frequently each year. Beginning early in the 21st century, there has also been an expansion in the indications for cardiac implantable electronic devices (CIED, a term which includes PPMs and ICDs), and device therapy has become more complex, frequently involving multiple leads per patient. In turn, there will be more occasion where the lead removal for these CIED will be necessary.

A 6 y.o. patient was incidentally found to have a fractured pacemaker lead during routine x-ray for his respiratory tract infection. The pacemaker was inserted 5 years ago, indicated for the permanent total atrioventricular block developed after total correction surgery in Tetralogy of Fallot. The lead fracture was thought to be caused by a phenomenon known as the subclavian crush syndrome. A transvenous lead extraction in this patient was only partially successful, leading to a surgical removal of the remaining lead. A new permanent pacemaker along with a new lead in the apex was successfully inserted before the surgery.

There are different levels of recommendations on whether a lead should be extracted or left behind. And in times where removal was needed, new specialized tool and techniques have developed in the last decade for the safe and successful retrieval of implanted pacemaker leads.

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(J Kardiol Indones. 2013;34:237-46)

Keywords: pacemaker, lead fracture, lead extraction

Pencabutan Kabel Pacu Alat Elektronik Kardiak Implan

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Makin baiknya harapan hidup pasien dengan penyakit jantung menyebabkan pemasangan alat elektronik kardiak implan (ALEKA) baik pacu jantung permanen maupun defibrilator semakin sering setiap tahunnya. Dimulai sejak abad 21 terjadi perluasan indikasi ALEKA juga terapi alat ini makin kompleks dengan kabel pacu yang multipel. Hal ini akan meningkatkan keperluan untuk melakukan pengangkatan kabel pacu di kemudian hari.

Disajikan kasus seorang anak umur 6 tahun dengan temuan fraktur kabel pacu pada saat pemeriksaan rontgen toraks untuk infeksi saluran nafas. Alat pacu jantung permanen (APJP) dipasang 5 tahun ke belakang atas indikasi blok AV total pasca operasi koreksi total Tetralogi Fallot. Fraktur kabel pacu diduga akibat subclavian crush syndrome. Pengangkatan kabel pacu secara transvenous tidak sepenuhnya berhasil sehingga memerlukan pengangkatan secara bedah. APJP baru berhasil dipasang dengan kabel pacu di apeks ventrikel kanan.

Terdapat beberapa rekomendasi yang berbeda mengenai keperluan ekstraksi kabel pacu. Alat-alat khusus dan teknik-teknik ekstraksi kabel pacu saat ini telah tersedia.

(J Kardiol Indones. 2013;34:237-46)

Kata kunci: alat pacu jantung permanen, fraktur kabel pacu, ekstraksi kabel pacu

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Introduction

As more people are living longer with more significant cardiac disease, permanent pacemakers (PPMs) and implantable cardioverter-defibrillators (ICDs) are being inserted more frequently. Beginning early in the

21st century, there has also been an expansion in the indications for cardiac implantable electronic devices (CIED, a term which includes PPMs and ICDs), and device therapy has become more complex, frequently involving multiple leads per patient. As such, there are occasions when it is necessary to remove a device and/or any associated leads. In National Cardiac Center Harapan Kita hospital, the trend for CIED implantations has been growing steadily each year, from a total of 101 in 2009 to 170 devices in 2011.^{1,2}

The most common indications for lead removal are infection, venous occlusion, advisory or recall as a result of (potential) lead malfunction, or mechanical lead failure. Lead management involves the assessment of risks and benefits of whether or not to remove the lead based on the individual clinical condition of the patient as well as lead characteristics.^{2,3}

Aim of Presentation

To discuss the identification and management for the mechanical failure of an implanted permanent pacemaker lead in a pediatric patient.

Case Report

A 6 years old boy was referred to the outpatient clinic for assessment of his pacemaker on 6th June 2012. The referring doctor found an anomaly by accident while diagnosing the patient for symptoms of coughing. A few days before he came to Harapan Kita, he had a chest x-ray taken to assess the lung for the

respiratory tract infection. The x-ray (image 1) showed a severed pacemaker cable around the clavicle region about 3 cm apart. Other than the cough, the patient was actually doing well without any other symptoms. The patient also did not report any possible rate-related symptoms such as shortness of breath or palpitations. He was said to remain active as ever by his parents.

Historically, the patient was diagnosed with Tetralogy of Fallot (ToF) back in late 2006 at the age of 6 months old, and had successfully underwent total correction surgery in National Cardiovascular Center Harapan Kita on early December 2006. Unfortunately he had a complication of permanent total atrio-ventricular block (TAVB) post-surgery

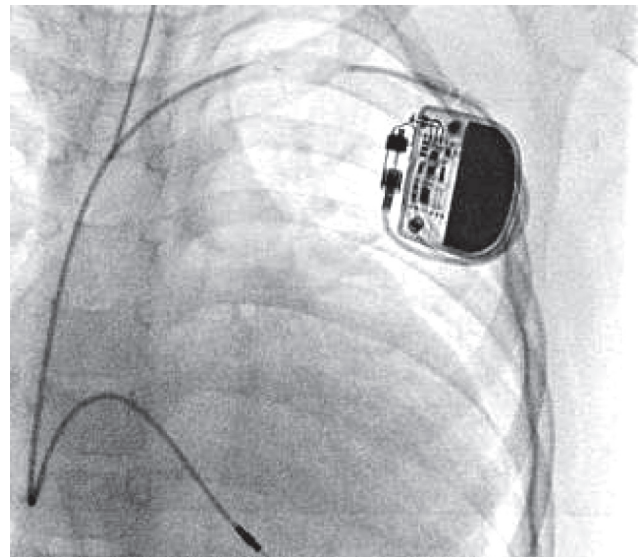


Figure 1. The chest x-ray that prompted the initial consultation; a clear gap of around 3 cm wide was visible between the severed lead.

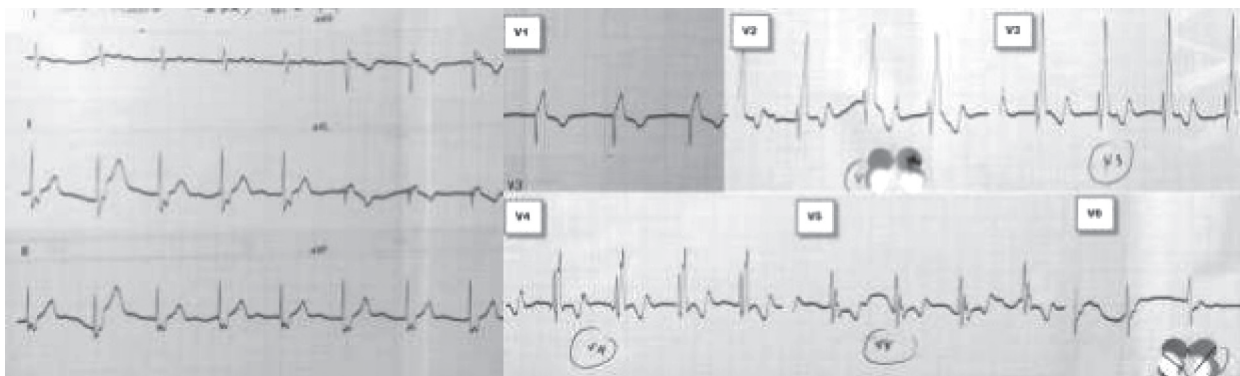


Figure 2 Initial ECG showing junctional escape rhythm with the absence of any pacing spikes

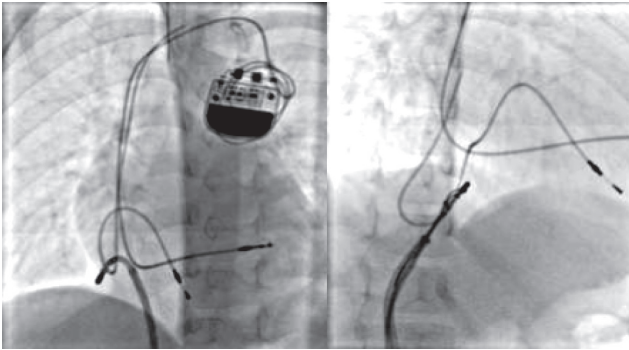


Figure 3 Efforts to move the proximal end of the fractured lead into the RA; new PPM & lead already in place.

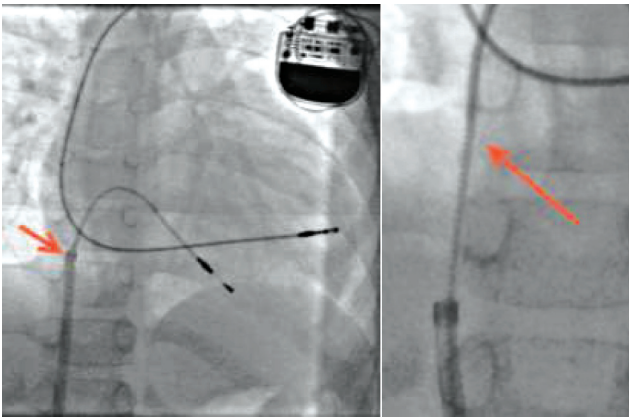


Figure 4 Left: Segment where the insulation was severed (arrow) and the conductor coil was exposed; the new generator and pacing lead was already in place. Right: zoomed view from another scene shows how the helical conductor coil was stretched out into the long sheath

and had a single chamber permanent pacemaker implanted shortly afterwards in early January 2007. His outpatient records noted good overall condition on the years before current admission, without any notable complaint or problems in growth or general health. The pacemaker function was also regularly evaluated at 6-12 months interval with good results.

Physical examination on the outpatient clinic was mostly unremarkable, his heartbeat was regular at 80 times/min; there were no audible murmurs upon auscultation; clear lung sounds; and no signs of peripheral congestion.

Outpatient surface electrocardiography (ECG) showed Junctional Escape Rhythm with a rate of 80 times/min, normal QRS axis, no distinct P wave, QRS duration of 0,16", no ST-T changes, complete RBBB, without any visible pacing spikes.

Based on the ECG and chest X-ray, it was concluded that he had an asymptomatic lead fracture with a normal heart rate from the junctional rhythm. He was then scheduled for elective PPM replacement and lead extraction, and was hospitalized on June 11th for the procedure. Physical and laboratory findings upon admission were all within normal limits. On June 12th, the patient underwent PPM replacement and lead extraction under general anesthesia. The PPM replacement procedure was performed without any significant problem; the old generator along with the proximal segment of the fractured lead was easily removed. A new lead was placed in the right ventricle (RV) apex via the left subclavian vein, and the generator was put in the same location as the previous generator. The baseline pacing rate was set at 80 times/



Figure 5 The fractured lead after surgical removal. Left: remains of the conductor coil and the fractured lead. Right (zoomed in): Residual tissue encapsulation near the severed lead insulation.

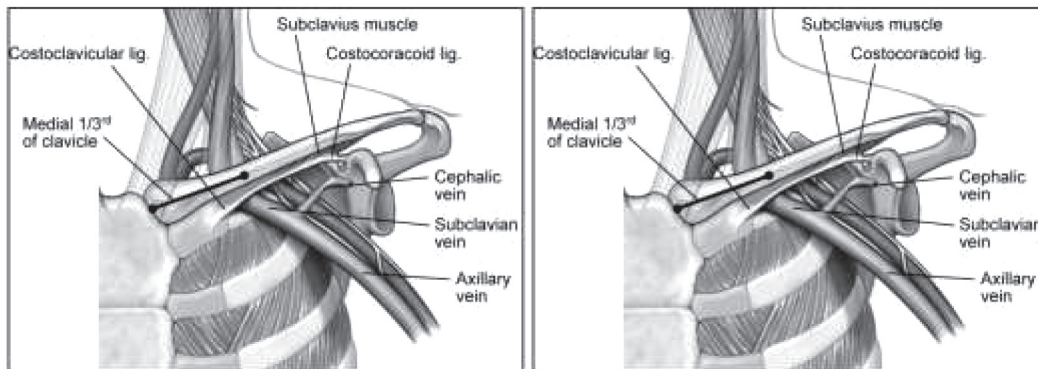


Figure 6 Left: Common lead introduction site. Right: Alternative lateral approach into the subclavian vein

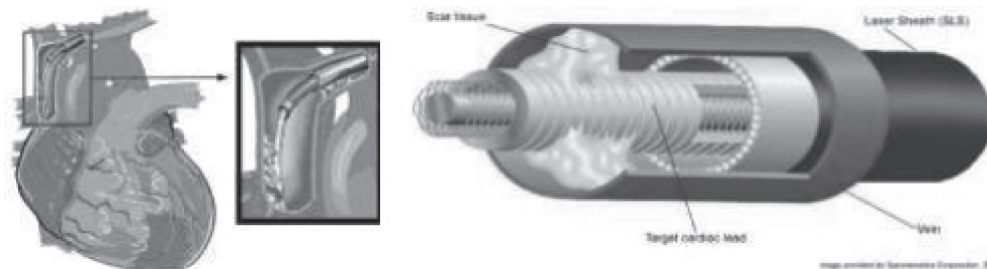


Figure 7 Laser-assisted lead extraction, where the Excimer laser sheath is advanced over the lead and photoablates the fibrous tissue that binds the lead to the surrounding tissue.¹⁵

min. The replacement part of the planned procedure was completed in about 90 minutes.

The next step of the procedure was the attempt to remove the distal part of the fractured lead with trans-venous approach from the right femoral vein. An 8 French Long Sheath was inserted as a support, along with a steerable lead. First step was to pull down the proximal end of the fractured lead from the subclavian vein into the right atrium for easier manipulation, using the steerable lead as a 'hook'. Initial attempts prove to be difficult as some encapsulation has occurred on the lead. Further attempts using both the steerable lead and a snare catheter successfully capture the proximal end of the fractured lead from the superior vena cava (SVC), pulling it into the RA, and then finally pulling it inside the long sheath with the snare catheter.

Further attempt to free the distal end of the fractured lead in the RV, however, was unsuccessful due to the strong attachment of the lead to the RV wall. It was thought that the lead was already encapsulated with fibrous tissue after 5 years of implantation. Further traction unfortunately severed the insulation in the middle segment of the partially retrieved lead, releasing and stretching the helical conductor coil

from the lead insulation. After careful attempt to further manipulate the remaining lead using the long sheath, it was decided to stop the procedure, leaving the distal part of the fractured lead along with the exposed conductor coil in the IVC.

Urgent surgery consult was then performed, and a decision was made (through a surgical conference) to perform urgent surgical lead extraction. Prior to the surgery, the patient was kept anticoagulated with heparin to prevent clot formation from the exposed conductor coil still present in the IVC. He successfully underwent the procedure on the next day using a right anterior thoracotomy approach and under cardiopulmonary bypass machine. The surgeon reported that the remaining lead was completely encapsulated with fibrous tissue in several points, confirming the reason why the previous trans-venous extraction had failed.

He was completely stable after the procedure, and was then discharged 4 days after the procedure.

On follow up in the outpatient clinic a month later, the patient was in good condition without any symptoms, and surface ECG showed regular pacing rhythm.

Discussion

Subclavian Crush Syndrome

Transvenous leads are introduced to the vasculature through different veins, including the right or left jugular, axillary, cephalic, and subclavian. While each venous approach has its advantages and disadvantages, selection is typically based on vein size to accommodate one or more transvenous leads. As illustrated in Figure 1, the most common entry sites are through the cephalic or subclavian vein. The medial (intrathoracic) portion of the subclavian vein may provide easier access to the venous system with the least amount of surgical complications. However, it may also increase the chance a lead will be compressed between the clavicle and first rib or even entrapped by soft tissue in this tight anatomical space. One alternative is to use the extrathoracic approach to introduce the lead using contrast venography.⁴⁻⁶

The fracture of lead in this patient was thought to be caused by the subclavian crush syndrome from the placement of the lead. Although rare, this risk is important to note and remember.

Definitions

Lead removal is a general term which encompasses removal of a cardiac implantable electronic device (CIED) lead using any technique, while lead explantation and lead extraction are terms with more specific definitions:⁷

- Lead explantation — Lead explantation is defined as removal of a lead that has been implanted for less than one year via the implant vein using only the tools typically supplied for lead implantation in combination with manual traction.
- Lead extraction — Lead extraction is generally a more complicated procedure which meets one of the following criteria:
 - o The lead is removed with the assistance of specialized equipment (e.g., laser sheaths) regardless of the implant duration.
 - o The lead is removed via a site other than the implant vein.
 - o The lead being removed has been implanted for more than one year.

The reported patient has the lead implanted for

more than five years, and was ultimately removed via surgery. Therefore the procedure qualifies as the term for lead extraction.

Indications for lead removal

The most common indications for lead removal are infection, venous occlusion, mechanical lead failure (often resulting in improper pacemaker function or inappropriate ICD shocks), or advisory or recall as a result of (potential) lead malfunction. As a result of the complex nature of these cases, recommendations for lead removal apply only to those patients in whom the benefits outweigh the risks when assessed on individual patient factors and operator specific experience and outcomes. Heart Rhythm Society (HRS) has released an expert consensus in 2009, outlining the indications for transvenous lead extraction along with their respective class of recommendations (see appendix).^{3,8}

This patient did not have any signs of infection nor venous occlusion, but the nature of the irregular shape of the severed lead was considered to have a high risk for thrombus formation; hence the indication and decision was made to perform transvenous lead extraction.

Contraindications for removal

In most patients, lead removal is associated with risks that are exceeded by the perceived benefits of the procedure. However, there are some relative contraindications to percutaneous transvenous lead removal, which include:^{3,7}

- Presence of calcification (visible by radiography) involving the lead in the atrium or superior vena cava
- Unavailability of required personnel or equipment
- The patient not being a suitable candidate for emergent thoracotomy
- Known anomalous placement of leads through structures other than normal venous and cardiac structures (e.g., subclavian artery, aorta, pleura, atrial or ventricular wall or mediastinum)
- Lead placement through a systemic venous atrium or systemic ventricle

In this reported case, there was no contraindication to perform the procedure.

Techniques

Currently there are a variety of techniques available for lead removal:⁹

- Direct (manual) traction — a stylet is inserted into the hollow center of the lead, extending close to the distal electrode. A stylet designed for lead extraction locks into place, providing support and allowing the application of direct traction to remove the lead. Leads that are isodiametric (the same diameter along the length of the lead) and less than one year old can potentially be removed by manual traction alone.
- Telescoping sheaths — specially designed sheaths extend over the lead, dissecting it away from the vascular wall and endocardium.
- Excimer laser sheaths — the laser in these sheaths dissolves, rather than tears, the fibrous attachments of the electrodes.
- Surgical removal — Cardiotomy with surgical removal is usually reserved for cases in which transcatheter approaches have failed. In some patients with large vegetations attached to the lead (e.g., >2.5 cm), surgical removal may be the preferred initial approach in order to minimize the risk of pulmonary embolism. Reports suggest that percutaneous removal even in the setting of large vegetations can be accomplished without clinically significant pulmonary embolism.

It is unfortunate that neither of those specialized devices was available to use in this patient. Instead, we tried doing a basic 'catch and pull' with currently available tools. After we successfully snare one end of the fractured lead into the long sheath, it was hoped that the distal end can be freed from the tissue using the long sheath as a guide. But the heavy encapsulation was stronger than the tensile strength of the lead insulation, leading to another fracture at the point of traction.

Complications

While CIED lead removal is performed without difficulty in most patients, complications can occur. Most of the complications are traumatic and related to the lead itself (i.e., vascular injury, cardiac perforation resulting in cardiac tamponade, tricuspid regurgitation), although embolization of thrombus or vegetation from the lead is also a concern. When performed by experienced operators, mortality is usually less than 1

percent of patients, with major complications seen only in 2 to 3 percent of patients.^{3,10}

Risk factors for a complication during lead removal include younger patient age, female sex, presence of calcification involving the leads on chest radiograph, and the presence of multiple leads. In general, implantable cardioverter-defibrillator (ICD) leads are more challenging to remove than pacemaker leads as a result of the presence of coils, which tend to be more adherent to vasculature and myocardium. In turn, dual coil ICD leads are more difficult to remove than single coil ICD leads. Leads with a passive fixation mechanism are more difficult to extract than those that are active.¹⁰⁻¹²

Outcomes

In 279 procedures involving the removal of 445 leads between 2000 and 2009 at a single center where all leads were removed via manual traction (without the assistance of extraction sheaths), clinical success was approximately 85 percent.¹³

Excimer Laser-assisted Lead Extraction

While most leads with shorter implantation time (less than 1 year) can be removed by simple manual traction, a higher proportion of longer implanted leads require the hands of experienced physicians by careful and extended traction. These procedures can also be very time consuming. This fact has generated interest in developing a specialized tool for lead extraction, and one of the most widely used today is the excimer laser sheath. Multiple registries have shown its effectiveness and good safety profile in lead removal, along with a shorter overall procedure time.^{3,10,14,15}

Summary

We have reported a case of 6 y.o. boy with an asymptomatic lead fracture which underwent successful pacemaker replacement but failed transvenous lead extraction. He eventually had a surgical procedure to remove the remaining lead from the right ventricle. The mechanism responsible for the lead fracture was thought to be the subclavian crush syndrome causing mechanical stress on the pacemaker lead. As more and more devices are implanted each year, lead removal will become a more frequent procedure,

requiring more specialized equipment and tools to successfully remove the lead with greater success rates and lower complications.

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