Treatment of permanent pacing infective complications in the reference centre. Necessary cooperation of the cardiologist and cardiac surgeon

Leczenie infekcyjnych powikłań stałej stymulacji serca. Konieczność ścisłej współpracy kardiologa i kardiochirurga

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Kardiochirurgia i Torakochirurgia Polska 2010; 7 (4): 376–382



Abstract

Some technical and organisational aspects of removal of infected pacemaker systems are presented in the experience of the reference centre for management of electrotherapy complications. The cardiac surgeon's role has evolved from single-person whole system extractor, to an important member of an interdisciplinary team for less invasive comprehensive treatment of complications. The presentday main role of the cardiac surgeon is readiness to prevent disaster caused by percutaneous lead extraction complications. In rare, precisely defined cases of lead extraction scheduled for open-chest surgery, the operation should be preceded by coronarography (excluding young patients) and removal of pacemaker, liberation of proximal part of leads and introduction of pocket suction drainage on the day before and outside the operating suite.

Key words: lead-dependent infective endocarditis, extraction of infected leads, open-chest lead extraction.

Introduction

Long ago, the cardiac surgeon alone performed whole pacing system removal in cases of severe system infection, but in that era systems were simple and (single) leads were not so strongly ingrown because of the short pacemaker (PM) lifetime [1, 2].

Only in the early 1990s was the transvenous (synonym: transcutaneous) concept of lead extraction delivered; the idea consisted of drawing on the proximal ending of the extracted lead slated catheter, pushing and rotating it accompanied by gentle lead tension which enabled separation of connecting tissue scar bridges fixating the

Streszczenie

W pracy przedstawiono wybrane aspekty organizacyjne usuwania zainfekowanych wrośniętych elektrod wewnątrzsercowych, wypracowane w krajowym centrum referencyjnym leczenia powikłań elektroterapii, jak również ewolucję roli kardiochirurga - od usuwającego samodzielnie operacyjnie cały układ stymulujący do ważnego członka wielodyscyplinarnego zespołu posługującego się technikami przezskórnymi. Dziś głównym zadaniem kardiochirurga jest gotowość zapobieżenia katastrofie w przypadku wystąpienia powikłań przezskórnego usuwania elektrod. W rzadkich przypadkach, gdy istnieją rzeczywiste wskazania do zabiegu w krążeniu pozaustrojowym, powinien on być poprzedzony koronarografią (za wyjątkiem młodych pacjentów), usunięciem stymulatora, uwolnieniem proksymalnych końców elektrod, jak również wdrożeniem aktywnego drenażu ssącego kieszonki stymulatora. Słowa kluczowe: odelektrodowe zapalenie wsierdzia, usuwanie zainfekowanych elektrod, kardiochirurgiczne usuwanie elektrod.

lead body to vein and heart walls from the lead body [3, 4]. In the mid-1990s double coaxial, telescopic pairs of Teflon and later polypropylene catheters (today called, after the name of the inventor, Byrd's dilators) were introduced [5, 6]. Since that time more and more leads have been extracted percutaneously and this method (including the use of new generations of catheters equipped with an energy source) permitted the extraction of over 8% of chronically implanted leads.

Introduction of a new generation of high quality ECHO machines for trans-thoracic echocardiography and wide use of transoesophageal echocardiography in every case of

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suspicion of lead-dependent infective endocarditis (LDIE) in the late 1990s, and the possibility of recognizing large, dangerous vegetations, created a situation in which some patients were sent directly for lead extraction by openheart surgery [7, 8].

During 2004-2010 a growing number of percutaneous lead extraction procedures in our centre were noted: from 10-15 annually during 2004-2005, to 22 in 2006, 61 in 2007, 115 in 2008, up to 206 in 2009, and 130 in the first half-year of 2010. The growing number of procedures

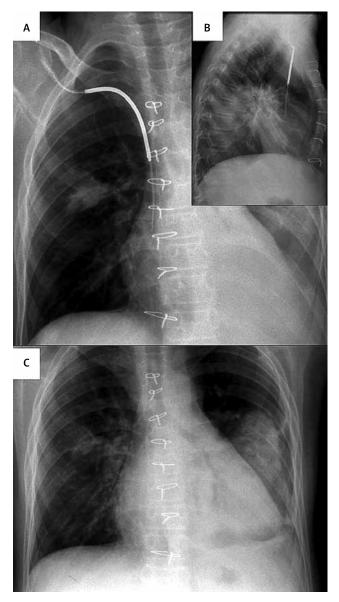


Fig. 1A–C. 13-year-old male patient after OHT. Long-term sepsis with purulent lung foci and general mixed infection (including fungal cerebral abscess) resistant to treatment. Abandoned during OHT part of ICD lead (A, B – PA and lateral view). Proximal coil of lead was prepared with conventional intravenous technique and extracted successfully (C). During long-term hospital rehabilitation the patient in good condition was discharged home. No recurrence of infection during 4-year FU

exposed another (dark) side of this method - an inevitable (fortunately low) percentage of serious and potentially dangerous complications such as tearing of the right atrial/ventricle or great vein wall - and the second (aside from large vegetation) indication for urgent cardiac surgical intervention thus arose. In our centre among 560 procedures, 3 acute cardiac tamponades were treated with direct small heart wall suture (0.5%). Amid over 500 procedures, we found some leads having no chance of being extracted percutaneously without complications, such as being strongly connected with the tricuspid valve or tricuspid apparatus or (in the past) a lead chronically implanted into the coronary sinus. The extraction of such leads had to be performed under direct vision and they showed the next, third, indication for lead extraction during the open-chest procedure. In such patients all the other leads were extracted percutaneously and the "dangerous lead" was prepared for easy removal from the venous system with direct pulling down. Such situations, when we left a potentially dangerous lead, happened in 4 of 560 procedures (0.7%). Our decision making to extract all leads which have to be extracted (we are a national reference centre) causes that the potential risk of complications is growing and cardiac surgery stand-by becomes a more and more essential element of the procedure [10].

Today, after 10 years of close cooperation and openchest removal of pacing systems in 32 patients we are able to present our everyday experience and to recommend our common, checked and confirmed in long-term practice technical and organisational measures concerning patient preparation, operation and postoperative management [10].

Patient preparation

Preoperative patients' preparation consists of: evaluation of pacemaker dependence, applying (if necessary) temporary pacing (using a screw-in lead introduced usually via the jugular vein), removal of pacemaker and preparation of all leads to become easy to draw down to the right atrium. The first stage of the procedure is ended by unit pocket drainage and sampling of suspected tissues for microbiological examination. This stage is performed outside of the operation suite [10] (Fig. 1).

In our opinion, pacemaker removal during openchest cardiac surgery is not an optimal solution due to: difficult operative approach, bleeding caused by heparin use, obstruction to untangle lead loops without X-ray visualisation and – very often – impossibility of leads' liberation from their adhesions with connective tissue scars surrounding leads and fixating them strongly to the subclavian, innominate and superior cava vein walls. Earlier performed suction drainage of pacemaker pocket enables its closure and prevents formation of haematoma during heparin use. Liberation of the venous course of very old permanently implanted leads (over 10 years old) and dual coil defibrillating leads is performed by typical percutaneous lead extraction techniques. This is the most important element of patients' preparation. Earlier pacemaker removal and liberation of extracardiac parts of leads is the most important in pocket infection cases. Usually, in spite of precautions, transient bacteraemia may occur, manifesting as chills during the final part of the procedure. At the moment of sternotomy and epicardial lead implantation bacteraemia occurrence threatens generalisation of infection with even chronic sternum infection. Completion of this first preparatory stage (mainly in case of local pocket infection) performed 2 or 3 days earlier, before open-chest surgery, may reduce the risk of infective complications following cardiac surgery [10].

If the clinical picture, including patient's age and gender, cannot exclude coronary artery disease and indications for lead removal are not urgent, coronarography should be performed because "by the way" or "on occasion" necessary aorto-coronary bypass grafts may be implanted.

Specific features of lead extraction using open-cardiac approach with extracorporeal circulation

Use of this approach and technique – if true indications exist – requires the evacuation of the blood from the right atrium and ventricle for good visualisation of vegetations and blood clots, and gentle liberation of intracardiac parts of leads. Thus, selective cannulation of both caval veins is necessary and the best approach is the incision on the antero-lateral wall of the right atrium [12, 13]. If evacuation of blood from the right atrium and ventricle for lead extraction was not necessary, it indicates that the leads could have been extracted without the cardiac surgery!

During the operation, after right atrium opening, the proximal parts of leads first should be shown and pulled down and a superior cava vein cannula may be clipped tightly [12, 13]. Careful removal of vegetations minimizes the risk of their comminution and later passage of fragments into the pulmonary circulation. Implantation of epicardial leads for temporary or permanent pacing is usually the final part of the operation. The unit may be implanted at the moment into the pocket formed from sternal incision laterally or the proximal lead ending may be dragged into the subclavian region and left subcutaneously for delayed unit connection for permanent pacing. In our centre the epicardial ventricular lead is placed on the left ventricle only, due to the very well known haemodynamic advantages of this electrode location (Fig. 2, 3).

Reference centre experience in open heart surgical extraction of chronically implanted endocardial leads

During 1998-2010 in the Department of Cardiac Surgery of the Medical University of Lublin, 30 procedures

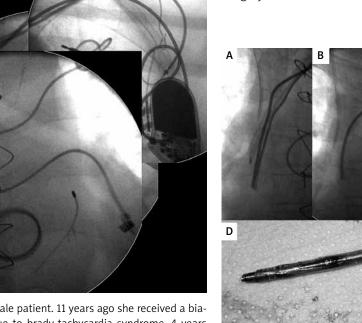


Fig. 2. 65-year-old female patient. 11 years ago she received a biatrial pacing system due to brady-tachycardia syndrome. 4 years ago an additional bipolar right atrial lead was implanted due to sensing problems. Severe endocarditis and anxiety of infection transmission toward artificial valve. Patient was sent for cardiac surgery, avoiding the cardiology department. Two central vegetations and atrial parts of lead were removed during open-chest operation using extracorporeal circulation. Parts of leads remained including cut-off anchoring strand of CS pacing designed atrial lead. Ventricular lead was implanted (2-year permanent AF with slow ventricular rate)

Fig. 3A-C. The same patient from figure 2. Second stage of proce-

Fig. 3A–C. The same patient from figure 2. Second stage of procedure – both cut-off atrial lead and abandoned unipolar atrial lead were extracted successfully using conventional intravenous technique with Byrd dilators after 3 days (A, B, C). In the atrial parts of extracted leads visible typical abrasions of external isolation, consisting of anchor of infection and place of vegetation formation

of chronically implanted endocardial leads' open surgical extraction with extracorporeal circulation were performed (< 0.5% of operations) in patients with lead-dependent endocarditis (in 12 patients local pacemaker pocket infection coexisted). There were 9 females and 21 males, aged 42-82 years (mean 62 ±9.2 y) in the group. Three patients required simultaneous tricuspid valve plasty. and in another three patients with earlier diagnosed significant narrowing of coronary arteries CABG was performed. Three operations were performed as urgent due to pericardial tamponade and one in accelerated mode due to growing symptoms of infection in spite of targeted antibiotic therapy. One patient received defibrillating epicardial leads and most of the operated patients received epicardial leads for permanent pacing. Three patients died in the perioperative period (within 24 hours of the operation).

Except for two patients with giant vegetations, qualification for the operation was based on presence of other indications (in former years underestimation of possibilities of transvenous lead extraction played a deciding role). In three patients operated on in the onset of close co-operation between the cardiac surgeon and cardiologist lead extractor, it was not possible to remove the proximal part of the leads during the operation and they were cut off high in the right atrium and then extracted using a mechanical system (Byrd dilators) from leads' venous entry approach several days later. For the last 6 years in cases of planned open-heart lead extraction, the dual stage procedure described above, which permits radical whole system extraction, was our mandatory standard (Fig. 4, 5).

Indications for open heart surgical extraction of chronically implanted endocardial leads

Finally, we want to emphasize that nowadays, in the face of growing effectiveness and safety of transvenous lead extraction, only four indications for surgical infected lead removal are accepted [11]:

- 1. presence of "large" vegetation > 3 cm; "modest sized" vegetations of 2-3 cm can be managed both ways after considering additional conditioning. There are many reports about successful and uncomplicated lead extractions in the presence of vegetations bigger than 2 or even 3 cm [12–14];
- 2. indication for lead extraction coexisting with the necessity of correctional operation of tricuspid valve (plastic repair of tricuspid valve due to tricuspid regurgitation) caused by inflammatory process. This indication includes the situation of strong connection of lead loop with tricuspid valve creating a risk of valve damage during percutaneous extraction;
- failure of percutaneous lead extraction usually the indication includes breakage of lead and lack of extraction lead fragment using different approaches and tools;
- 4. complications of percutaneous lead extraction: massive mediastinal bleeding, cardiac tamponade with ineffective pericardial drainage and significant damage of tricuspid valve during lead extraction.

There are no other indications! Keeping in mind the ten times higher (about 10% vs < 1%) peri-operative mortality and long-term after-effects of opening the pericardium in the aspect of future cardiac surgery due to other reasons, open heart surgical extraction of chronically implanted leads without the indications mentioned above should be considered as incorrect [11, 15].

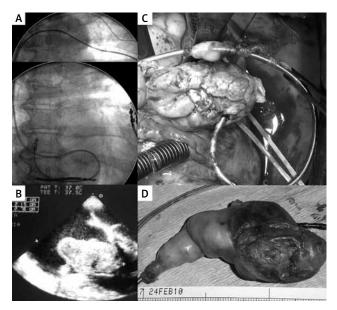


Fig. 4. Patient with LDIE sent for surgical open chest lead extraction; 3 weeks ago vegetation was 2 cm smaller but exceeded safety limit. Operation was performed with pacemaker removal and proximal part of lead liberation the day before



Fig. 5. Bleeding into pacemaker pocket after lead take-down (full heparinisation). Active suction prevents large haematoma formation

Final remarks

If the pacing / ICD system contains leads older than 10 years (borderline is arbitrary) or even an over two-yearold dual coil ICD lead, the most difficult part of system extraction is liberation of leads from surrounding connective tissue scars from venous entry down to the superior cava vein. Besides strong manual traction from atrial incision, the cardiac surgeon has no other possibilities of proximal part removal [16,17] and sometimes leaves the cut-off lead in the superior caval vein. The parts that remain, with lead fragments opened on both sides, provide an ideal (for bacteria) route connecting the infected pocket and endocardium, constituting a holder or excellent anchor for endocardial infection. Therefore proper lead preparation for further removal plays a crucial role and the whole procedure should be performed in a specialised centre, with good cooperation between the cardiologist and cardiac surgeon.

Opening of the chest creates a chance for implantation of epicardial lead(s) for permanent pacing and creation of a pacemaker pocket subcutaneously in the subclavian region, directly laterally from the sternal skin incision. The cardiologist should be present during the operation for proper unit pre-programming. Most important and unrepeatable for the pacemaker-dependent patient is the possibility of obtaining the optimal, from a haemodynamic point of view, ventricular, lead location. In our centre, the cardiologist always participates in surgical lead extraction or implantation.

Lead extraction in cases of LDIE (lead-dependent infective endocarditis) does not finish the problem definitely; the numerous vegetations remain a problem. In the majority of patients they remain and decrease in diameter gradually over weeks or even months. Control TEE examination is indicated in these patients and should be performed by the same echocardiographer. On the other hand, the decision about re-implantation of the system remains difficult (which chest side, and when) and should be taken by an experienced team.

The development of percutaneous / transvenous lead extraction techniques diametrically changed cardiac surgeons' role in the management of patients with leadrelated complications but in no respect lowered it [14-17]. The cardiac surgeon with his team and anaesthesiological team decides about the safety of such procedures in terms of immediate intervention when severe complications such as massive mediastinal bleeding, cardiac tamponade or pulmonary embolism with fatal haemodynamic consequences arise. For ten years it has been said that "one drunked perfusion pump (full cardiosurgical stand-by) saves one patient's life among 100 percutaneous lead extraction procedures", and it is strongly underlined that only an experienced surgeon, knowing the problematic aspects of percutaneous lead extraction, may meet the requirements, because incidents can occur outside out of the heart in the mediastinum [10, 11, 16-18].

The problem of severe lead-related complications was recognised in western European countries many years ago.

The two oldest national reference centres for treatment of permanent PM/ICD complications were organized in Italy (Bongiorni MG – Hospital, University of Pisa) [19] and in Sweden (Kennergren C – Sahlgrenska University Hospital) [20, 21] in the early 1990s thanks to direct government and health ministry support. Their exercise protection enables optimal patient management. Similar tendencies are visible in other European countries. Similarly in Poland, the official reference centre for complex management of patients undergoing lead extraction should consist not only of a cardiologist (an experienced lead extractor) but also of a cardiac surgeon, interventional radiologist and cardiologist well trained in echocardiography – all experienced with the problem. Another but similar solution may be the provision of several smaller centres.

Scale of the problem. In our country last year 27 thousand pacemakers (PM) and 5.5 thousand ICD were implanted / re-implanted. The number of CRT-P and CRT-D implantations / re-implantations is over one thousand. The absolute number of severe complications which need lead extraction is relatively low and will not exceed 400–500 annually in future. Informal but functioning, thanks to the group of enthusiasts (an experienced lead extractor but also a cardiac surgeon, interventional radiologist and cardiologist well trained in echocardiography) such a 'national' centre performs a duty for most patients from throughout Poland. An official systemic organising solution is a more and more burning issue [22].

Conclusion

The present-day main role of the cardiac surgeon is readiness to prevent disaster arising with percutaneous lead extraction complications. Only in rare, precisely defined cases of lead extraction should it be performed by open-chest surgery. The operation demands some technical and organisational efforts and should be performed by an experienced team. Shifting the whole problem of management of LDIE onto the cardiac surgeon is not an optimal solution.

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