Percutaneous extraction of endocardial leads – a single centre experience in 120 patients

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Abstract

Background: The expanding number of patients treated with pacing, especially resynchronisation therapy and pacing system upgrades as well as leads remaining inactive, and prolonged life expectancy are the causes of an increase of the number of electrodes in pacemaker patients. The growing problem with endocardial lead infections and excess leads has made percutaneous lead removal technology widespread as it is less invasive than cardiosurgery.

Aim: We present our experience in percutaneous lead removal in a single reference centre in Poland.

Methods: During 2.5 years, 236 leads in 120 patients were removed. The criterion for inclusion in the present analysis was the age of the oldest lead: >12 months in pacemaker patients and >6 months in patients with implantable cardioverter-defibrillators (ICD). All patients admitted to the hospital for lead removal underwent a percutaneous procedure. The age of the patients ranged from 18 to 87 (mean 65.7) years. The leads were removed using the Lead Extraction System (Cook) with the rotational cutting force only, notlaser or RF energy.

Results: Indications for lead removal were: local (pocket) infection (47%), endocarditis (27%) and lead excess (26%). Seventy six percent of patients had at least two pacemaker/ICD-related procedures whereas 24% had only one implantation procedure in the past. The median time from the preceding procedure was 12 months. In 38 patients there were 60 inactive electrodes. The majority of patients had two (62%) or three (19%) leads, followed by 12% with one lead and 7% of patients with more than three leads. In 27.5% of patients leads from the coronary sinus were removed. The complication rate was 4%.

Conclusions: Percutaneous lead removal procedures are performed in Poland for class I and II indications according to NASPE classification. In many cases patients had multiple leads, including in the coronary sinus. The majority of patients had two or more interventions in the past.

Key words: endocardial electrode removal, percutaneous lead extraction, endocarditis, pocket infection

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Introduction

The number of implanted pacemakers and cardioverters defibrillators (ICD) is increasing each year. The 18 077, 19 430 and 20 895 pacemakers and 1225, 1503 and 2050 ICD were implanted in Poland in years 2004, 2005, 2006, respectively [1]. Thanks to more effective treatment of coronary artery disease, heart failure and rhythm disorders the life expectancy is increasing. A progressive miniaturisation of the implanted devices decreased the battery capacity, which resulted in limitation of the functioning time of the devices despite the use of energy saving leads. As a result, the number of pacemaker and ICD exchange procedures is growing. Moreover, together with the growing understanding of the haemodynamic results of pacing, particularly in a impaired heart, the number of upgrading procedures (upgrade to dual-chamber DDD pacemakers or three-chamber CRT devices) is increasing. A considerable number of patients with pacemakers who survived a ventricular arrhythmia episode get an implanted defibrillator, and therefore there is a necessity of defibrillation lead implantation. In summary, an average patient with a pacemaker has currently more exchange, upgrade and repair procedures during a long period of time (for example in 10 years) than in the past. Therefore, an average patient with a pacemaker has more leads than would have been the case 20-30 years ago.

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From the beginning of the pacing era, there was a concept that one lead should work through the whole patient's life and only a pulse generator should be replaced. This is no longer true since the lead is currently the weakest and the most unpredictable element of the pacemaker system. Indeed, the number of patients with inactive leads retained in the cardiovascular system is increasing. It has been reported that the risk of infection of the stimulation system is higher during a re-do procedure than during the primary implantation. Subsequent procedures in patients with multiple (including those retained) leads are a potential source of infective complications [2].

Another problem is the damage of the defibrillator leads, which have a much higher malfunction rate than pacemaker leads. Intracardiac leads (in particular when multiple) stimulate fibrosis and connective tissue adhesions in the venous system, which can often cause complete obstruction of a subclavian or a brachiocephalic vein (and sporadically the superior vena cava), which makes the implantation of a new lead impossible [3]. All presented facts lead to the conclusion that the need for removal of pacemakers and defibrillating leads (both infected and inactive which obstruct transvenous access to the heart) is constantly growing and soon it will become a real problem. Intracardiac leads can also cause much more serious medical and therapeutic problems for doctors and patients, when left, damaged or broken leads migrate and form loops in cardiac chambers. The presence of the foreign body – a lead loop, its elements or a separated proximal lead end, which looks similar to a small wire brush – causes irritation of the vessels" endothelium and endocardium, and therefore it increases the risk of thrombosis, pulmonary embolism, tricuspid valve dysfunction and severe ventricular arrhythmias. There are two classes of indications for lead removal: class I (absolute) and class II (relative) [2, 4]. Class I indications include:

- lead dependent endocarditis, sepsis,
- arrhythmias or embolism secondary to the presence of a lead with it's proximal end located in the cardiovascular system,
- obliteration or occlusion of all usable veins for a new lead implantation,
- a lead that interferes with another lead.

Class II indications are the following:

- persistent localised infection of the pacemaker/ICD pocket (because of low long-term efficacy of the conservative therapy soon it will be a class I indication),
- recurrent fever in a patient with pacemaker/ICD without other evident cause,
- chronic pain at the pacemaker pocket site,
- inactive leads in a young patient.

Lead removal

For the last 15 years enormous progress in the lead extraction technique has been made. Instead of continuous traction, which is based on constant pulling (rubber or pulley systems) [5], a new technique is used. It is known as counter-traction, which led to the development of a mechanical system for removal of adhesions in the venous system and in heart chambers using a double sheath telescoping system. These telescopes, known as Byrd dilators (polypropylene colour sheaths produced by the Cook company), work together complementarily and their tips have an oblique cut. Systems of three locking stylets introduced into the central lumen of a lead were developed. They enable one to localise the pulling force directly around the distal electrode (Liberator Cook) or the force is spread through the whole lead length (LLD-EZ Spectranetics). In order to increase the efficacy and to shorten procedure duration new sheaths with an energy source [radiofrequency (RF) energy – Perfecta – Cook; or laser energy – Laser Sheath – Spectranetics] to ablate a variety of binding tissue were developed. Also new systems which enable catch, tension and release of the lead from adhesions via a femoral approach were developed: profiled loops system (Needle's Eye snare), catching basket (Dotter basket) and catching lasso catheters. Nevertheless, the principal method of percutaneous lead extraction is performed via an 'upper approach', which means the passage of a catheter over the lead and the use of this approach as the gate into a venous system [2].

Intracardiac leads can also be removed directly during cardiosurgical procedures with a cardio-pulmonary bypass. While in many centres it was the main or the only method of lead removal in the case of infective complications 20-30 years ago, for at least several years the role of cardiosurgery has changed dramatically. Nowadays the indication for cardiac surgery (sternotomy and cardio-pulmonary bypass) is limited only to the failure of the percutaneous approach or a severe complication during such a procedure. When it is known before the procedure that also a valve requires repair it is also an indication for surgical lead extraction. Further indications include truly large vegetations (proliferation of tissue on a lead) or thrombi in the heart chambers, which can provoke (spontaneously or during a percutaneous procedure) to lethal pulmonary embolism. Smaller vegetations below 1 or 1.5 cm (this limit is continuously increasing due to growing knowledge, an increasing number of studies and increasing experience) are not an indication for extensive cardiac surgery, which has a considerable number of complications [2, 6]. The role of a cardiac surgeon is limited to readiness for intervention when complications occur.

In recent years many leading cardiac centres which specialise in percutaneous lead extraction have presented the results of their experience [7-9]. So far there are no such publications in Poland. We have therefore decided to present our own experience. We believe that this paper will also have an important educational aspect. In Poland there are too many patients referred directly for cardiac surgery without consideration of much less invasive and

less expensive percutaneous procedures. The presented population consists of patients referred from the whole Poland and the procedures were performed in one tertiary centre.

Methods

The results of the present study are based on the experience of a centre in which percutaneous lead extraction has been performed for 30 years. Since 1995 Teflon Cook dilators have been used. All patients operatem in the last 2.5 years, fulfilling the inclusion criteria, were included in the present analysis. At this time (2.5 years ago) the method of lead removal was changed, which was due to introduction in Poland of the advanced Cook set which enables the removal also via a femoral approach. The inclusion criterion was also the time interval between the primary implantation and the extraction procedure; only patients with the period between implantation and removal of at least 1 year for a pacemaker system and 6 months for a defibrillating system (the 'oldest' lead was considered) were enrolled. However, this does not mean that all extracted leads stayed in the patient's body for more than 1 year or 6 months respectively. Some leads could remain in the heart for a shorter period of time. Finally, 120 patients (75 men and 45 women) at a mean age of 65.7±13.9 years (range: 18-87 years), in whom 236 leads were removed, were analysed.

The method of lead extraction

Some leads were removed with the direct traction technique, which is based on fixation of the lead with metal leader and the consequent strong rotation with gentle retraction. For this method an upper approach was used, which means that the site of introduction of the lead into the subclavian vein was used. The direct traction method was used as the first choice for active fixation lead with a constant external diameter. Some leads with passive fixation, implanted not later than one year before, were also extracted with this technique. In the case of failure of direct traction, the counter-traction technique was introduced using Byrd dilators. The method with ablation of the adhesions in the cardiovascular system using rotary cutting telescopic sheaths (mainly Byrd dilators) was the method of choice in the removal of the other types of leads. The only exception was the case when the dislodged proximal end of the lead was located in the cardiovascular system. In this case the procedure was started via a femoral approach. For economic reasons but also due to multiple cases of lead deformation with obstruction of the internal lumen of a lead, the looking-stylet or a similar type of catheter was introduced into the internal lumen of a lead only occasionally. However, in each case the whole length of the lead was fixed using the metal leader but without additional anchorage function.

In the case of leads with proximal end located in the venous system or in heart chambers, the lead was retracted with a pigtail catheter into the inferior vena cava. Then, it was pulled outside the workstation, introduced into the femoral vein, the lead was released and the distal tip was separated from the endocardium with a long Byrd dilator or its equivalent. This is our own modification of the procedure – there are no previous reports describing the use of a dilator via a lower approach.

All procedures were performed under local anaesthesia and deep sedation. In the most painful moments of the procedure brief intravenous narcosis was used (propofol). All procedures were performed in the operation room of the electrotherapy department and were assisted by the cardiac surgery and anaesthesiologist team ready for prompt intervention.

Sequential steps of the lead extraction procedure

The pacemaker dependency was checked in each patient before lead removal and temporary pacing was introduced whenever it was needed. Thereafter the pulse generator was removed and leads were mobilised from ligatures. Next, the metal leader was introduced into the lead lumen and the proximal end of the lead was attached with long, firm ligatures. The ligatures were also used for optimal tension of the lead during ablation of the connective tissue adhesions. To overcome the tissue resistance In the subclavian region stainless steel sheaths were used with the minimal needed diameter (Cook). All diameters of Byrd dilators (polypropylene telescopic catheters) were used. When significant resistance was met the catheters were changed for larger diameter ones (blue, yellow, green, white and orange). It was usually possible to remove unipolar leads using blue or yellow catheters, while for bipolar leads yellow or green ones were needed. For defibrillator leads green or white and in extreme cases orange catheters were used. In three cases in which breakage of the lead occurred, the adjacent leads were removed first and then the remaining part of the broken lead was removed via a femoral approach (the broken lead was caught with a Dotter basket or a lasso loop) (Figures 1-3).

Statistical analysis

The local database was used for a retrospective analysis. The following issues were studied: 1) indication for lead extraction, 2) time interval between lead implantation and its removal, 3) the number of leads and their characteristics – currently used and inactive (retained) leads, 4) the presence of leads in the coronary sinus and in cardiac veins, 5) the number of previous electrotherapeutic interventions, 6) the time since the last electrotherapeutic intervention. For the analysis an MS Excel 2000 spreadsheet was used. The results are presented as means ± SD or as numbers and percentages.

Results

The most common indication for lead removal was infection or purulent complication of the pacemaker pocket. The most common presentation was an open wound (bedsore), which enabled pus evacuation, without signs of infective endocarditis followed by so-called lead dependend endocarditis and the justified need for removal of an inactive lead. Seven patients (5.8%) had both inactive leads and a limited (to the pocket) or systemic infection. In the case of chronic infection of the pacemaker pocket or in the case of infective endocarditis all leads were removed from the heart. The inactive leads were removed when they were multiple or when their replacement was planned. In the latter situation the old lead from

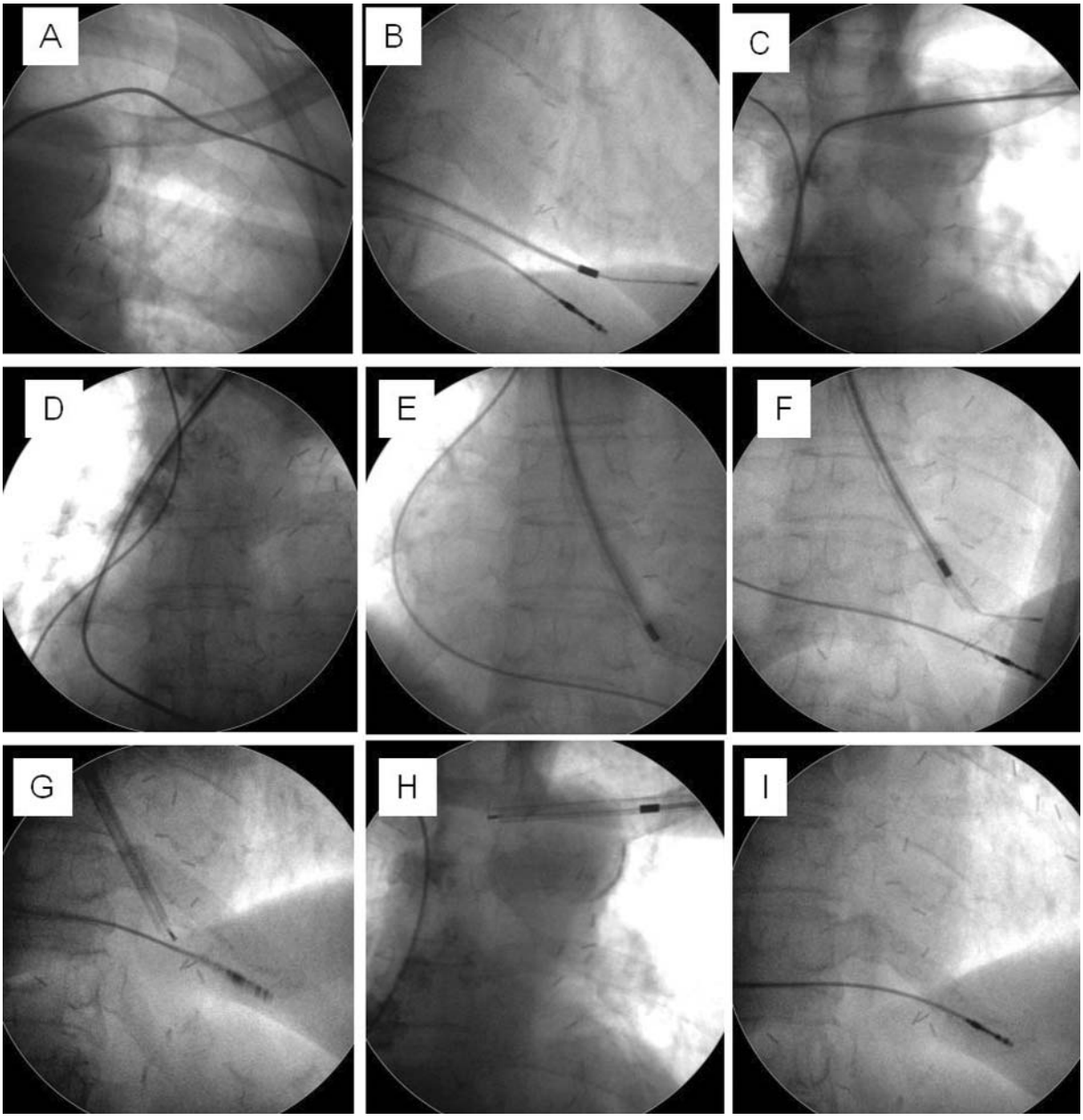

Figure 1. Typical images during lead extraction (inactive, broken) using Byrd dilators (Cook company) – intraoperative fluoroscopy. A pocemaker lead located in the left subclavian vein, before removal procedure (**A**). Distal tips of two leads in the right ventricle (the upper lead is to be removed) (**B**). Byrd dilator introduced along the lead at the left side; dilator end is located in superior vena cava (**C**). Further steps of the procedure: dilator end introduced into the right atrium (**D**) and in the right ventricle (**E**, **F**). Distal tip of the extracted lead is being separated from the endocardium (**G**). Removal of Byrd dilator together with the lead; the tip of the extracted lead located in the proximal part of superior vena cava (**H**). The right ventricle after lead removal. A retained lead in the right ventricle introduced via right subclavian vein (**I**)

the moment of the implantation of the new lead became inactive and was extracted (Table I). The mean time from lead implantation to lead removal was 82.7 months (range 2-248 months). We have also performed a subanalysis of the 120 leads with the longest time between implantation and removal – the extraction of the 'oldest" lead reflects true problems during the procedure. The mean interval between removal and implantation in this subgroup was 89.32 months (range 6-294 months); most leads were located in the heart for about 84 months.

Thirty eight from 120 patients had, apart from active currently used (connected with pulse generator or with ICD) leads, also inactive leads. It should be underlined that in the group of patients with inactive leads there were 8 cases of leads without a free end, which means that their proximal end was located in the cardiovascular system. The biggest group (82 patients – 68.3% of 120 individuals) comprised patients without intracardiac inactive leads. The remaining 38 patients had 60 inactive leads. A single inactive lead was present in 20 patients (16.7%), 14 patients (11.6%) had two inactive intracardiac leads and 4 patients (3.4%) had three inactive leads.

The number of intracardiac leads both currently used and inactive is presented in Table II.

The mean number of leads in the heart before removal was 2.25 per patient. The majority of patients (80.95) before the removal procedure had 2 or 3 leads. Thus, before the extraction procedure there were 270 leads, 236 leads were removed and 34 were left. Leads were not removed only in patients without infective indications for lead removal.

A slightly different technical issue is the extraction of the leads anchored in the coronary sinus and cardiac veins. Those cases formed a considerable numer of patients in the studied group (33 individuals – 27.5%).

Table I. Main indications for lead removal

Indication	Number of patients (%)	Number of leads (%)
Local infection	56 (46.7)	112 (47.5)
Endocarditis	33 (27.5)	76 (32.2)
Inactive lead	31 (25.8)	48 (20.3)
Total	120 (100)	236 (100)

Table II. Number of leads in the heart before removal*

Number of leads	1	2	3	4	5	6	Total
Number of patients (%)	14 (11.7)	74 (61.7)	23 (19.2)	7 (5.8)	1 (0.8)	1 (0.8)	120 (100)

** epicardial leads were not included*

Table III. Number of previous procedures before lead extraction

Number of previous procedures	1	2	3	4	5	6	Total
Number of patients (%)	29 (24.2)	51 (42.5)	21 (17.5)	7 (5.8)	10 (8.3)	2 (1.7)	120 (100)

The number of previous procedures (implantation, exchange, change of the stimulation type, inspection, reposition of the lead and other corrective and repair procedures) on the one hand reflects, the age of the leads, the severity of fibrosis in the pacemaker pocket and along the lead, and on the other hand it helps to establish the number of patients with the extraction procedure as the first intervention after implantation. These data are presented in Table III.

The mean number of interventions before extraction was 2.37; 60% of patients had two or three previous interventions (median 2) (Table III); 15.8% had more than 3 procedures and in only 24.2% of patients was lead removal the first intervention after implantation. The time

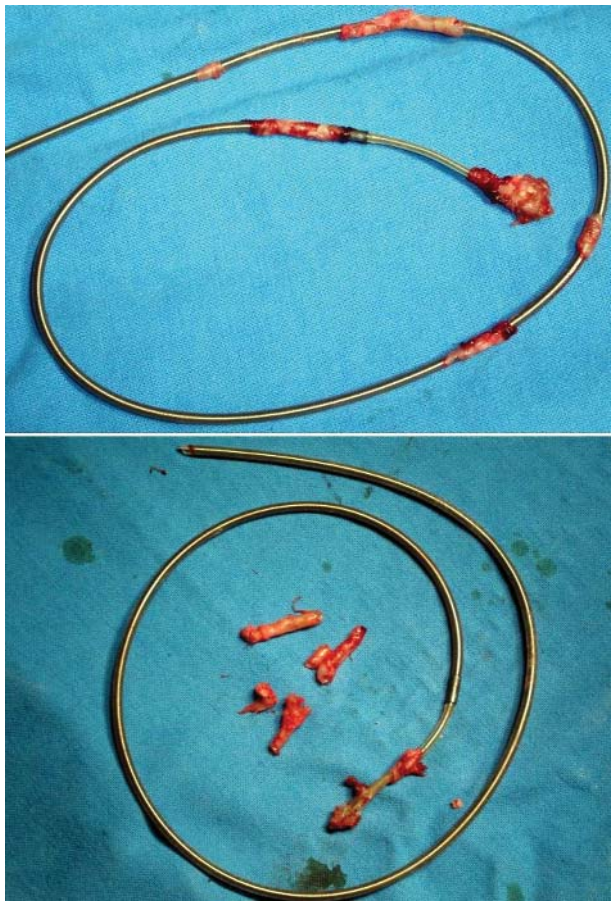

Figure 2. The extracted ventricular lead. Multiple strong connective tissue adhesions removed together with the lead using a Byrd dilator

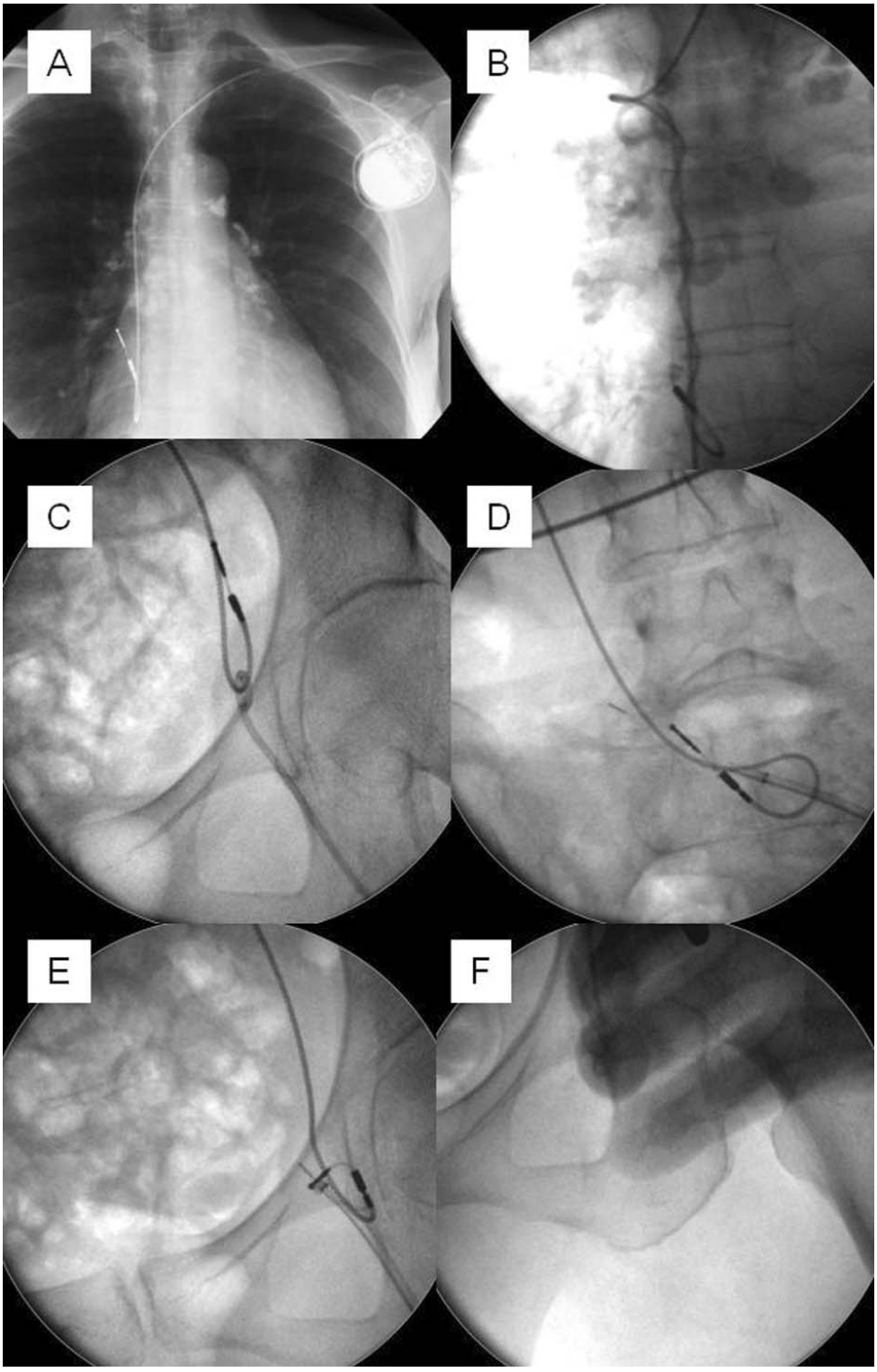

Figure 3. Intraoperative fluoroscopy. The removal of a broken and dislocated atrial lead using pigtail and Dotter basket catheters. The view before the removal of atrial lead – distal tip in the right atrium appendage, proximal end in the left subclavian vein (**A**). The extracted lead reeled on the pigtail catheter; distal tip of the lead is separated from the endocardium of the right atrium appendage (**B**). The separated distal tip of the lead is brought into the left iliac vein (**C**). The distal tip of the lead caught with Dotter basket (**D**). The further step of the procedure – retraction of the lead toward workstation placed in the left femoral vein (**E**). The left inguinal region after lead extraction procedure (**F**). It is interesting that an adhesion of the lead proximal end with the subclavian vein was stronger than an adhesion between the right atrium appendage endocardium and the lead tip. It is contrary to a previously described case [10]

from the last intervention can indicate the relationship between this procedure and the need for lead removal (especially in the case of infective complication). In most cases the last intervention before extraction was performed 1 year before lead removal (median 12 months, mean 21 months before the removal procedure; range 1-124 months).

Forty six leads (19.5%) were removed using direct traction. In the majority these were smooth, modern leads with active fixation, with the shortest time between implantation and removal (mean time 20.87±17.4 months).

Complications occurred in 5 patients (4%). In two patients cardiosurgical intervention was necessary due to bleeding into the pericardial space. In one patient symptoms of submassive pulmonary embolism occurred and disappeared after pharmacological treatment. One female patient developed symptoms of lobar pneumonia In the course of pulmonary embolism. She also had an atypical sign of large amounts of bloody exudates in the pleural space – therefore pleurocentesis was needed [10]. In the fifth patient papillary muscle rupture was detected by echocardiography after lead extraction with aggravation of the tricuspid regurgitation but without significant haemodynamic consequences and no need for cardiac surgery.

Discussion

We presented the experience of one of the centres specialising in endocavitary lead extraction via a transvenous approach. Indications, categorised as class I and class II indications by NASPE, were similar to those used in other centres in the world [4]. The analysis was performed in a group of patients with a lead removal procedure performed in the last 2.5 years. The analysis included 120 patients with multiple leads located in the heart, including leads in the coronary sinus and cardiac veins. The latter two locations make the procedure more difficult [2]. Leads with a dislodged proximal end into the heart chambers were also extracted. We introduced our own modifications of the currently used techniques as the use of a long Byrd dilator via a femoral approach and the sporadic use of internal locking stylet. These modifications of the approved methods were needed because of the various circumstances of the procedures. It should also be underlined that great experience is needed during such procedures and the whole team should be ready for detection of life-threatening complications and for a prompt change in the procedure strategy [2, 6-9].

The complication rate was low (4%) and there were no lethal complications. Ruttman et al. reported no deaths during percutaneous lead extraction in contrast to two cases of death during surgical lead removal [11].

Conclusions

1. Procedures of lead removal are performed in Poland in both types of indications: class I (sepsis) and class II (local infection, an inactive lead).
2. Procedures in patients with multiple (usually two) leads and leads located in cardiac veins (27.5%) are also performed.
3. Before lead removal usually two or sometimes more previous electrotherapeutic interventions were performed in the patient's history, which increases the risk of infective complications.
4. Before lead extraction usually an invasive procedure is performed about one year before (pulse generator exchange, system upgrading, lead reposition or repair). During this period a local infection can develop (treated with low efficacy with antibiotics) and it can progress to open wound or endocarditis.

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Przezskórne usuwanie wrośniętych elektrod wewnątrzsercowych – omówienie problemu, przedstawienie populacji 120 chorych i rodzaju zastosowanego leczenia

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Streszczenie

Wstęp: Stymulacje resynchronizujące, rozbudowy układów stymulujących i defibrylujących, pozostawianie nieczynnych elektrod oraz wydłużenie życia chorych spowodowały pojawienie się licznej grupy osób z wieloma elektrodami w sercu. Wzrost liczby komplikacji infekcyjnych, w tym zapaleń wsierdzia, i problemy z nadmiarem elektrod stały się przyczyną rozpowszechnienia przezskórnego usuwania elektrod jako znacznie mniej inwazyjnego zabiegu w stosunku do operacji kardiochirurgicznej w krążeniu pozaustrojowym.

Cel: Analiza własnego materiału dotyczącego przezskórnego usuwania elektrod endokawitarnych w jednym z referencyjnych ośrodków w Polsce.

Metody: W okresie 2,5 roku usunięto 236 wrośniętych elektrod u 120 chorych w wieku średnio 65,7 roku (18–87 lat). W prezentowanym materiale uwzględniono jedynie chorych z odpowiednio długą historią stymulacji, u których pierwszorazowa implantacja układu stymulującego była wykonywana przynajmniej przed rokiem, a defibrylującego przed pół rokiem. Usunięcie elektrody wykonano u wszystkich chorych, u których potwierdzono wskazania do tego typu zabiegu. Elektrody usuwano przy użyciu siły rotacyjno-tnącej cewników wchodzących w skład systemu Cooka bez wspomagania światła laserowego bądź energii wysokiej częstotliwości radiowej. Koniecznym warunkiem była obecność zabezpieczenia kardiochirurgicznego w razie wystąpienia powikłań krwotocznych.

Wyniki: Najczęstszym (47%) wskazaniem do usunięcia elektrod okazała się infekcja miejscowa loży stymulatora. Zapalenie wsierdzia i konieczność usunięcia nieczynnych elektrod stanowiły rzadsze wskazania (odpowiednio 27 i 26%). Zabieg usuwania elektrod był poprzedzony najczęściej (60%) dwoma lub trzema zabiegami w zakresie elektroterapii, a tylko 24% chorych przebyło wcześniej jeden zabieg. Poprzedzający zabieg elektroterapeutyczny miał miejsce na ogół przed rokiem. Większość (80%) chorych przed zabiegiem miała dwie (62%) lub trzy (19%) elektrody; chorych z jedną elektrodą bądź z licznymi elektrodami było znacznie mniej (odpowiednio 12 i 7%). Duża grupa chorych (27,5%) przebyła zabiegi usuwania elektrod z zatoki wieńcowej.

Wnioski: W Polsce wykonywane są zabiegi przezskórnego usuwania elektrod endokawitarnych z powodu wskazań klasy pierwszej – sepsa, i drugiej – infekcja miejscowa, zbędna elektroda. Duży odsetek stanowią chorzy z licznymi elektrodami (najczęściej dwiema), często w żyłach serca (27,5%). W prezentowanym materiale zabieg usuwania elektrod był najczęściej poprzedzony dwoma lub niekiedy większą liczbą zabiegów elektroterapeutycznych.

Słowa kluczowe: usuwanie elektrod endokawitarnych, przezskórne usuwanie elektrod, zapalenie wsierdzia, zakażenie loży

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