Lead extraction for device related infections: a single-centre experience

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Abstract

Aims We report a single-centre experience of extraction of infected pacing and ICD leads.

Methods Retrospective study of consecutive lead extractions for infection. Lead extraction was by traction, or, if unsuccessful, a laser sheath was used. All procedures were performed in the operating room.

Results Leads were extracted in 82 patients including 66 patients (80%) with infection occurring after replacement of the generator or revision of the leads. Previous treatment, without lead extraction, had failed in 51 patients (62%). Major complications (tamponade or haemothorax) occurred in 6 patients, 2 patients died despite emergency surgery. One patient succumbed to ongoing sepsis. Of the patients alive, a follow-up of at least 6 months (27 ± 17 months) was available in 76 patients. All patients were cured; none had a recurrence. In 31 patients (41%) pacing was abandoned after lead extraction; all remained asymptomatic.

Conclusion Lead extraction is effective in curing pacemaker or ICD related infection, even after failed conservative therapy, but with a significant complication rate. The routine replacement of the generator should be reconsidered in patients in whom the indication for pacing is no longer valid, as the majority of infections occurred after revision of the system.

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KEYWORDS

pacemaker; infection; lead extraction

Introduction

According to the NASPE policy statement on recommendations for extraction of chronically implanted transvenous pacing and defibrillator leads, systemic pacemaker related infection is a class 1 indication, localized pocket infections or erosions are a class 2 indication [1]. Endovascular extraction techniques including laser sheaths are reported to be effective for lead removal in multi-centre registries and this has stimulated the use of lead extraction in the treatment of device related infections [2]. We report a single-centre experience and follow-up of lead extraction in a referral population for device related infections.
Patients and methods

This is a retrospective study of the outcome of lead extraction for pacing or ICD system related infection in consecutive patients treated in a single referral centre. All patients had a follow-up of at least 6 months after lead removal.

There were 82 patients, 80 with a pacemaker and 2 with an ICD. Their mean age was 62 ± 17 years, 52 were male. Twelve patients had clinical signs of systemic infection. Fifty-two patients (62%) were referred after lead-conserving treatment, either with antibiotics or surgery, had failed. Infection had occurred after primary implant in 16 patients (20%) and after generator exchange or revision of the system for lead dysfunction in 66 patients (80%). One, 2, 3 and 4 leads were present in, respectively, 17, 53, 11 and 1 patients. Time from implant of all leads was 72 ± 62 months, range 0.5–342 months. Time from implant of the oldest lead present was 84 ± 68 months.

Lead extraction was performed by 2 operators. It was executed in the operating room under general anaesthesia with the patient prepared for thoracotomy and with a cardiac surgeon and extracorporeal circulation team present in the operating room. Transoesophageal echocardiography throughout the procedure was used to monitor possible complications. Only when all leads were implanted for less than 6 months was the extraction procedure performed in the catheterization laboratory, as in our experience simple traction sufficed to remove the leads [3]. A stepwise protocol for extraction was followed. Traction was first applied, if necessary with a locking stylet. If this failed, a laser sheath (SLS I, Spectranetics, Co) was inserted over the lead and locking stylet. Laser energy was provided by an Excimer Xenon chloride laser (Spectranetics, Co). The size of the sheath (12, 14 or 16 F) was chosen according to the recommendations of the manufacturer with a tendency to oversize in case of doubt, or if the chosen size stalled. If the tip of the lead was not yet free by the time the laser sheath reached the myocardium, counter-traction using the outer sheath was applied. In case of laser failure or if a lead dislocated but could not be pulled through the adhesions, a femoral approach with a femoral workstation and a retriever was attempted.

Statistical analysis was performed using a two-tailed Fisher’s test for contingency tables.

Results

Traction was sufficient for removal of all leads in 27 patients, and a laser sheath was used for at least 1 lead in the remaining 55 patients (Fig. 1). Major complications occurred in 6 patients, only during laser procedures. All these patients had a local infection of the pacemaker pocket and a history of previous unsuccessful conservative therapy. In 5 of these patients use of the laser caused a tear in the superior vena cava, the sixth patient had perforation of the atrium after counter-traction was applied to the atrial wall. All these patients showed haemodynamic instability almost immediately after detection of the complication and had to undergo emergency thoracotomy. Two of the patients with a tear in the superior vena cava died as a result of profound hypovolaemic shock: one of them could not be resuscitated during surgery, the other died post-operatively. Both patients were female and, respectively, 84 and 79 years old. In the other 4 patients surgery was successful without post-operative sequelae. Any leads still present at the time of the complication were removed during surgery. The patients with a tear in the superior vena cava had longer than average implant

![Figure 1](https://via.placeholder.com/150)

**Figure 1** Outcome of the lead extraction procedure. FWS: femoral workstation; † = patients who died.
times: 124 ± 66 months vs. 72 ± 62 months. No other complications were encountered in the study.

Laser sheath extraction was successful in 43 of the remaining, uncomplicated procedures. The laser failed in 6 patients. The leads were subsequently extracted via a femoral workstation in 5 patients, and in 1 patient a 28-year-old lead was removed during elective surgery. All leads were extracted completely except the tip of 1 electrode that dislocated from the lead body when the lead impacted in the subclavian vein during withdrawal.

Post-operatively, a 90-year-old female patient died from ongoing sepsis 1 month after an uneventful lead removal with traction.

Long-term follow-up could not be obtained in 3 patients (Fig. 2). All of the remaining 76 patients alive were cured from, and remained free of infection during a follow-up of 27 ± 17 months (range 6–70 months). Four patients died during follow-up of causes not related to the extraction procedure or pacemaker therapy (all had new pacemakers implanted and survived the extraction procedure for at least 6 months).

In 31 (41%) of these 76 patients it was considered that continuation of pacing therapy was not mandatory, and these patients did not receive a new pacemaker after lead extraction. All these patients remained asymptomatic during follow-up. The original indication for pacemaker implant was determined in 72 patients. Fifteen (32%) of 47 patients with atrio-ventricular conduction disturbances did not receive a new pacemaker in contrast to 15 (60%) of 25 patients with sick sinus or carotid sinus syndrome ($p = 0.03$).

**Discussion**

Lead extraction was highly effective in curing pacemaker or ICD related infection in this study. However, it was accompanied by major complications in 7% of patients including the death of 2 patients directly related to the procedure. In large registries of lead extraction, major complications are reported in 1.9–2.5% and mortality in 0.6–0.8% of procedures [2,4]. In these studies, complete extraction of the leads was obtained in 86–90% of patients. There may be several factors contributing to the higher complication rate in the present study. First, the implant times of the leads in patients with complications were longer than the rest of the study group. Byrd et al. reported an increased risk of failed or partial extraction with increasing implant duration, effectively doubling every 3 years [5]. Also the Accufix Research Institute reported an increase in complication rate of extraction of the Accufix lead (Teletronics Pacing Systems Inc., Englewood, CO, USA) from 2% at 1-year of implant time to 8.3% with implant duration of more than 5 years (http://www.accufix.com). Secondly, although physician’s experience has been associated with the risk of complications, it is interesting to note that the majority of

**Figure 2** Follow-up of the patients who survived lead extraction. FU: follow-up; AV: atrio-ventricular conduction defect; SSS: sick sinus syndrome; CSS: carotid sinus syndrome; PM: pacemaker; † = patients who died.
Complications occurred only late in our experience [4, 5]. Probably, our early results increased the confidence in the laser sheath and we persevered with the laser even when progress stalled. Finally, the first generation of laser sheaths that was used in all study patients was less flexible than the current model, and also lacked the bevelled tip making it more difficult to avoid the vessel wall.

Resulting from our experience we modified the approach when the laser sheath stalls, especially at the level of the superior vena cava—right atrial junction which is vulnerable to perforation. Rather than persevere, we continue extraction with a femoral approach. The proximal isodiametric part of the lead can easily be pulled down from the binding sites in the superior caval vein in most cases. Avoiding extensive traction at this vulnerable point greatly reduces the risk of perforation. If the lead cannot be mobilized from the femoral vein, we try to retrieve it through the internal jugular vein as described by Bongiorni et al. [6]. We surgically explore the internal jugular vein to obtain optimal haemostatic control whilst introducing sheaths or retrieving the leads as bleeding in this area can potentially be life threatening. In this situation also the laser can be applied again, now only having to negotiate the distal part of the lead with the laser.

It should be remembered that elective surgery could be an acceptable alternative for complicated endovascular extraction. However, mortality from surgical removal of infected leads is reported in 2.4–17% of patients [7–12].

This study again underlines the necessity to perform lead extraction only in the operating room with cardio-pulmonary bypass available on-site and the patient prepared for emergency surgery. General anaesthesia already instituted from the start of the procedure saved valuable time in case of complications. This approach saved the lives of 4 patients, nevertheless bleeding caused by superior vena cava tears can compromise the circulation beyond recovery, as happened in both elderly patients.

Localized pacemaker or ICD related infections are considered a class 2 indication for lead extraction in a NASPE policy statement [1]. The results of this study also contribute to a cautious approach in high-risk patients with local infections, and lead extraction may be deferred with an initial attempt at conservative therapy. Implant time, female sex, multiple leads and advanced age increase the risk of lead extraction [2, 4, 5, 13–15]. An additional consideration is a high operative risk, especially in the event of emergency surgery. Reports of successful conservative treatment have been mostly in relation to low-grade pocket infections or skin erosions [16–19]. Pacemaker or ICD related sepsis or endocarditis is class 1 indication for lead extraction [1]. In these patients and in frank pocket infections we also strongly favour lead extraction as therapy of choice.

Although no standard protocol to reassess the necessity of pacemaker therapy was used in this study, pacing was safely discontinued after lead extraction in 41% of patients, concordant with the 13–52% reported in the literature [12, 14, 20]. It happened significantly more in patients considered to have either sick sinus or carotid sinus syndrome than in those having atrio-ventricular block (60% vs. 32%).

It is noteworthy that 80% of patients were referred with infection occurring after a generator exchange or lead revision. Also Harcombe et al. reported that the overall rate of late complications, the majority of which consisted of infection or erosion, is significantly higher after elective unit replacement (6.5%) than after a first implant (1.4%) [21].

Even though the implant rate of pacemakers in the Netherlands is among the lowest in Western Europe (± 350 implants/million inhabitants), the above findings stress the importance of careful assessment of pacing indications not only at implant but also at the time of generator replacement or lead revision. Therefore, reassessment of the original indication should be made in any patient, when elective generator replacement approaches, to judge if pacing has to be continued. It can then be decided to leave the generator and leads in situ rather than replacing them with the risk of complications. However, leaving a generator with a depleted battery raises some concerns. Firstly, as the end of battery life approaches, one has to be sure that the pacemaker does not revert to unwanted pacing. This should be confirmed with the pacemaker manufacturer. Secondly, although run-away pacemaker behaviour, with high stimulation rates of more than 2000 bpm, has been described following battery depletion this is a rare condition in modern pacemakers and has resulted only in sub-threshold stimuli [22]. Thirdly, there is the possibility of battery leakage, but this is highly unlikely in modern pacemakers. As an alternative, only the generator may be removed, abandoning the leads properly insulated and fixed: this diminishes the risk of skin erosion, which is a main cause of infection after generator replacement. Although extraction of the leads has been advocated when pacing is abandoned, this should be heavily discouraged as the risk outweighs any potential benefit [19,23].

In conclusion, although lead extraction is highly effective for eradicating pacemaker or ICD lead
related infection, it is not without complications and the application of it as first line therapy should be tailored to the risk profile of both the extraction procedure and infection in a given patient. The automatic replacement of the generator when depleted has to be reconsidered given the frequent possibility of abandoning pacing therapy after lead extraction and the high incidence of infection occurring after generator replacement.

References


