Reflections of six years of lead extraction: influence on indications and technique

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Background. **Endovascular techniques have become the standard approach for extraction of pacemaker and ICD leads. However, with experience, the indications and technical approach have evolved.**
Indications. **In a population referred for lead extraction, we could not found a relation between the number of leads implanted and the incidence of occlusion of the access vein. Moreover, there is evidence that the lead extraction itself is accompanied with an increased risk of post-procedural venous occlusion. Electrical interference can be avoided in most cases, even in ICD patients. As complications of extraction have to be taken into account as well, it is therefore not in the patient's interest to extract chronically implanted non-functional superfluous leads. In contrast, lead extraction is a most effective way to cure pacemaker or ICD related infections, even if previous conservative therapy has failed. However, in patients at high risk, extraction might be deferred to attempt device saving therapy first.**
Technique. **Although leads can be removed with traction for almost all implant times, after six months additional tools are increasingly necessary to safely and completely extract them. No single technique suffices for all procedures: powered sheaths – as the laser sheath – and a femoral workstation with retrievers should be available when extraction is attempted.**
Complications. **Venous or myocardial perforation is a life-threatening complication of lead extraction. In these circumstances, time lacks to safely transfer a patient for emergency surgery and therefore the only safe environment to perform lead extraction is the operating theatre with cardiosurgical standby.**
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George Mallory said most famously in 1924 that he was climbing Mount Everest 'because it is there'. But if he ever reached the summit, he never lived to tell the tale as his body was found close to the top in 1999. Endovascular lead extraction has been shown to be technically feasible but not without complications and a careful assessment as to whether it is beneficial for the patient should be made before its application.[1,2] In this article we discuss the generally accepted indications for lead extraction and balance them against our own experience and how it has affected our indications and technical approach, tailoring both to minimise the risk for the patient.

Indications

Nonfunctional leads

In the opinion of many experts in the field, the extraction of superfluous malfunctioning (noninfected) leads is considered acceptable and even desirable. It has been stated that if too many leads are present, the resultant reaction has a high probability of obliterating the vein.[3,4] As it is, nonfunctional leads make up 31 to 40% of indications for lead extraction in published reports.[1,5,6] However, there is no evidence in the literature that these nonfunctional leads pose any risk for the patient, including venous obstruction (figure 1).

We therefore looked at the incidence of obstruction in 95 venous entry sites of 89 patients (17 patients with an ICD) scheduled for lead extraction.[7] Infection was the most important factor in the incidence of occlusion of the subclavian vein. It occurred in 18 out of 57 patients (32%) with infection: in patients with systemic infection in 5 out of 9 patients (p=0.01) versus 4 out of 32 patients (13%) with lead malfunction. The number of leads present per entry site was not related to the incidence of occlusion: 7 of 22 with one lead present, 17 of 61 with two leads, 0 of 11 with three leads and 0 of 1 with four leads (p=0.13). We consequently found no support for the concept that the

Figure 1. Occlusion of left brachiocephalic vein. Although the lead seemingly follows the course of the contrast at first sight, the tortuous path indicates this is actually a collateral. A second collateral connects both subclavian veins. A collateral of such a prominence would not be possible in case of an open brachiocephalic vein.

risk of venous occlusion increases in relation to the number of leads present. As all patients with three or four leads at one entry site had more than one implant procedure and no obstruction, it rather suggests that if the access vein is patent, it is very likely to remain so when additional leads are inserted. We concluded that venous obstruction seems to be more patient than lead dependent, but infection has a substantial risk of occluding the access vein.

Further, the incidence of venous thrombosis following lead extraction had not been investigated. We performed a follow-up study in the 65 patients with a patent access vein prior to extraction.[8] The indication for extraction was infection in 37 and lead malfunction in 28 patients. Extraction was performed with traction only in 13 patients and a laser sheath was used in 52 patients. During a follow-up of 29±14 months, oedema as a symptom of venous occlusion occurred in five patients (8%). It was temporary in three patients but led to Sudeck's atrophy in one patient. Although all complications occurred after the use of a laser sheath this was not statistically different from traction ($p=0.57$). Also the indication for extraction (infection vs. lead malfunction) did not influence the incidence of new symptoms ($p=0.15$). As most patients with venous obstruction are asymptomatic, the incidence of angiographic occlusion might still be higher and outnumber a – yet unproven – risk of occlusion resulting from multiple leads.

In ICD patients there may be concern about interference of abandoned leads with the proper function of the ICD. Mechanical contact between leads may lead to noise sensing and inappropriate therapy. To avoid this, new pace-sense or true bipolar ICD leads with active fixation can be positioned far enough from existing leads to avoid contact with the sensing electrodes. Effectiveness of defibrillation itself is not influenced by mechanical contact between coils of different leads, as long as the abandoned leads are properly insulated and the chance of a short circuit with the generator is avoided. Even if the leads have to be positioned in the septum or right ventricular outflow tract they can give satisfactory defibrillation thresholds.[9] In our experience, ICD leads do not pose an additional risk for venous occlusion compared with pacing leads.[9]

Importantly, major complications of lead extraction are reported in up to 3.3% of procedures including the death of 0.6 to 0.8% of the patients.[10] In contrast, properly abandoned nonfunctional leads have a very low complication rate.[11,12] Further, incomplete extractions have been described in 10 to 14% of procedures in large registries and these severed leads are more prone to complications, and can be regarded as therapy failures.[2,5,13]

Finally, lead extraction is expensive, and not only due to the necessary equipment (laser sheaths and console, electrosurgical sheaths, femoral workstation with retrievers and locking stylets). Extraction has to be carried out in an operating room with cardiothoracic surgical standby and is often more time-consuming than it is frequently professed to be.[14,15]

In conclusion, we can not find any evidence that lead extraction will be beneficial in case of properly abandoned, nonfunctional leads, either in the literature or in our own research. This led us to abandon lead extraction for nonfunctional superfluous leads. Even though extraction of ICD leads can be done as effectively as pacing leads, the lack of added risk for abandoning ICD leads also changed our approach, and we now prefer to insert additional pace-sense or shock leads as required.[9]

All these considerations are appropriate for the average, elderly, pacemaker patient. But one can argue that in young patients with a long life expectancy and a prospect of multiple lead revisions, extraction might still be beneficial. Such an assessment has been done for the Accufix leads as both the risk of injury from the retention wire and the risk of lead extraction for this specific lead are known (www.accufix.com). But even in patients younger than 50 years at the time of implant, the risk of extraction exceeded that of life-threatening or fatal complications of the retention wire at four years of implant for females (estimated risk 1.5 to 2%) and ten years of implant for males (estimated

risk ±1%). However, with the very low complication rate of properly abandoned nonfunctional leads as compared with the Accufix lead, the time from implant that extraction can be beneficial will be much shorter.[11,12] Therefore it is questionable that lead extraction will be more appropriate in young patients than in the general population.

In our opinion, extraction for nonfunctional leads should only be contemplated if the chance of removal with limited traction only is good. We have shown that in the first six months after implant almost all leads can be removed with simple traction.[16] If not directly successful, it is better to simply abandon the leads. Even in these circumstances, it can be useful to have a femoral workstation available to remove dislocated leads that become obstructed when removed from the site of insertion.

We make an exception to this rule for patients in whom the entry vein is occluded, which prohibits ipsilateral implantation of new leads. Extraction of a non-functional lead with a laser sheath can still provide access to the central venous circulation from the occluded site. During extraction, the laser sheath and its outer sheath are advanced beyond the occlusion.[17] New leads can then be inserted after an exchange procedure of the extraction sheaths for a lead introducer sheath. Lately, we no longer extract the lead but advance the laser and outer sheath just beyond the occlusion, just far enough to insert a guide wire through the obstruction.[18] The dysfunctional lead is then simply abandoned. This approach significantly reduces the risk of the procedure as the superior caval vein does not need to be negotiated with a laser sheath.

Infection

In contrast to nonfunctional leads there is ample evidence that the most effective cure for infected pacing or ICD systems is lead extraction. We reviewed the outcome of lead extraction in 82 patients referred to us because of infection. Previous treatment, with either antibiotics or surgery, had failed in 51 patients (62%). Traction was sufficient to remove the leads in 27 patients and a laser sheath was used for at least one lead in the remaining 55 patients. The laser sheath was not successful for at least one lead in six patients: the leads were subsequently extracted via a femoral work station in five patients and in the other patient a 28-year-old lead was removed during elective surgery. However, major complications (tamponade or haemothorax) during laser sheath extraction occurred in six patients, two of whom died despite emergency surgery. Any leads still present at the time of the complication were removed during surgery. All leads were extracted completely except the tip electrode of one lead. One patient died after an uneventful extraction from ongoing sepsis. Of the 79 patients alive, a follow-up of at least six months (27±17 months) was available in 76 patients: infection was cured in all, there were no recurrences.

Although effective for the treatment of device-related infection, the incidence of complications nuances the indiscriminate use of lead extraction and in high-risk patients lead extraction may be deferred. Long implant time is an important risk factor: Byrd et al. reported an increased risk of failed or partial extraction with increasing implant duration, effectively doubling every three years.[1] Also the Accufix Research Institute reported an increase in the complication rate of extraction of the Accufix lead (Telectronics Pacing Systems Inc. Englewood, Co, US) from 2% at one-year implant time to 8.3% with implant duration of more than five years (www. accufix.com). Female sex, multiple leads and advanced age are the other known risk factors for lead extraction and should be taken into account to determine the extraction risk.[1,2,5,19-21] Other considerations for primary conservative treatment include unavailability of alternative access sites, a lead configuration that technically compromises successful extraction and a poor general condition of the patient related to the risk of general anaesthesia and possible emergency thoracotomy. Conservative therapy is also best suited for skin erosion or low-grade pocket infections but can be even contemplated for systemic

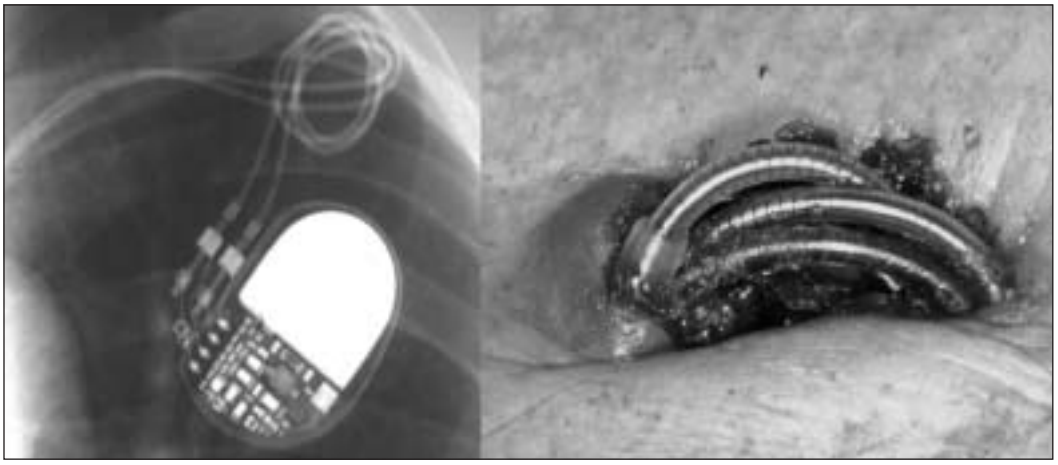

Figure 2. Low-grade infection following erosion of pacing leads. The excess part of the lead was not properly secured and eroded the skin from within (left panel). This led to a skin defect with protruding leads and low-grade infection (right panel).

infection when lead extraction has a high risk. Success of conservative therapy often depends on extensive debridement and disinfection of the pocket and reallocation of the pacemaker and the leads to a new uninfected site, if possible submuscular. Avoidance of any pressure on the skin from the device or leads is mandatory. Appropriate antibiotics should be prescribed: an intravenous course of antibiotic therapy comparable with endocarditis treatment may be required.

In our population, 80% of infection occurred after replacement of the generator or revision of the leads, and mostly after skin erosion from superficially positioned leads or generators (figure 2).[22] This stresses the importance of prevention. In primary implants, both the use of the cephalic vein together with a submuscular pocket will prevent skin erosion, especially in lean patients. During generator replacement or lead revision it can be necessary to create a new generator pocket below the original one or a submuscular pocket to prevent skin erosion, especially in emaciated patients.

Even not following a specific protocol, pacing therapy was not considered mandatory in 41% of our population after lead extraction for infection and a new system was not implanted. This occurred more often if the original indication was sick sinus or carotid sinus syndrome (60%) compared with atrioventricular conduction disturbances (32%). All patients with discontinued pacing therapy remained asymptomatic during follow-up.

Therefore, a reassessment of the pacing indication should be made in any patient when elective generator replacement approaches or lead dysfunction necessitates revision to judge if pacing can be discontinued. It can then be decided to leave the generator and leads in situ rather than replacing them to avoid complications. As an alternative only the generator may be removed, abandoning the leads properly insulated and fixed, to diminish the risk of skin erosion.

Left-sided leads

There are some rare indications for lead extraction. One of them is pacing leads inadvertently positioned endocardially in the left ventricle, most often through a patent foramen ovale. If not timely removed, lifelong anticoagulation with warfarin is recommended as first-choice therapy and lead extraction reserved in case of recurrent thromboembolic events or concomitant with cardiac surgery.[23] When necessary, lead extraction is preferably done surgically as the use of sheaths has a risk of cerebral embolisation.

Leads inserted through a subclavian artery into the left ventricle are preferably removed from the femoral artery: otherwise, debris from around the tip of the lead may embolise when the lead crosses the carotid artery during withdrawal.[23]

There is only incidental experience with the extraction of coronary sinus leads used for cardiac resynchronisation therapy. It appears that until now most of these leads can be removed by simple traction. However, implant times are still relatively short. Clearly, it is very doubtful if sheaths such as the laser can be applied safely inside the coronary sinus and its tributaries.

Extraction

Tools and technique

There are a number of tools available for endovascular lead extraction but none suffices to handle all extraction procedures. In our opinion, three systems are essential: locking stylets, power sheaths (laser or electrosurgical) and a femoral workstation including retrievers.

In practice, we use a stepwise protocol. It is useful to start with traction, considering the use of a locking stylet from the onset to prevent disintegration of the leads. Within six months, almost all leads can be removed with traction. Even from six months to one year, almost half of the leads need additional tools for extraction (figure 3). However, some of the leads with longer implant times respond to traction as well.[16] If traction is not successful after 10 to 15 minutes, we use a laser sheath (figures 4 to 7). Judiciously used, most leads can be removed completely with the laser sheath. However, one should be aware of its limitations. First, in an occasional patient there can be insufficient space between the clavicle and the first rib to pass the sheath. Second, with right-sided implants, a relatively sharp angle of the lead towards the brachiocephalic vein in conjunction with extensive fibrosis at this site can impede alignment and advancement of the relatively stiff laser sheath.[15] Third, the laser is not effective for disrupting calcified binding sites. This problem can sometimes be solved by oversizing the laser sheath to encompass the calcification and proceed through noncalcified scar tissue. Fourth, insulation defects, either pre-existent or caused by the extraction, can result in a plough effect, amassing the insulation in front of the sheath prohibiting any further advance.

As a result of our experience, we modified our approach when the laser sheath stalls at a binding site in the veins or atrium. Rather than persevere, we continue the procedure with a femoral approach. Using

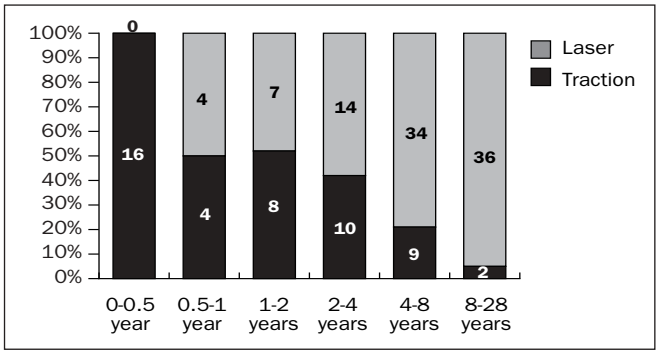

Figure 3. Relative distribution expressed as percentage of the use of either traction or laser sheath for lead extraction according to time from implant. Numbers inside bars indicate absolute numbers of leads extracted for each period of time from implant.

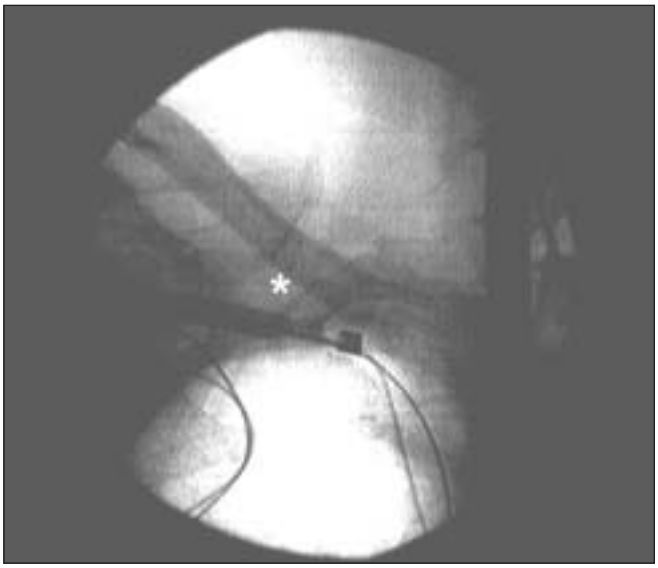

Figure 4. The laser sheath is inserted into the subclavian vein. The bevelled tip is directed to minimise the risk of perforation. The position of the outer sheath is indicated by the asterix.

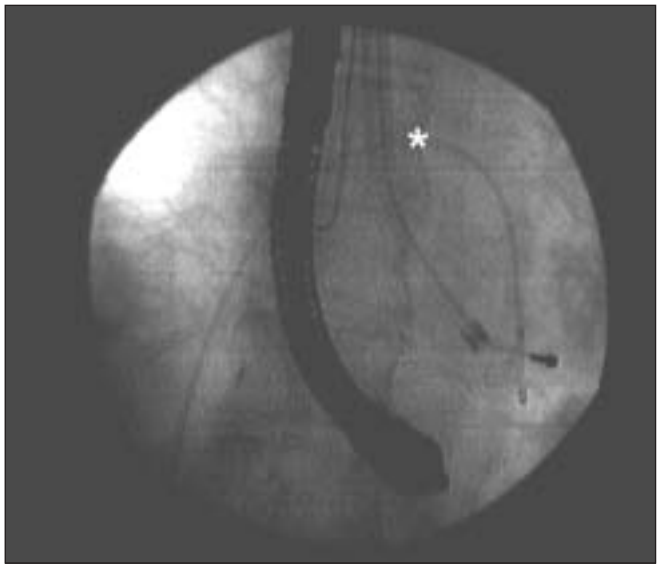

Figure 5. The laser sheath has reached the right ventricle. The outer sheath (*) follows the laser to facilitate its movement. Notice the probe of the transoesophageal echo to monitor for complications. A temporary pacing wire is in situ.

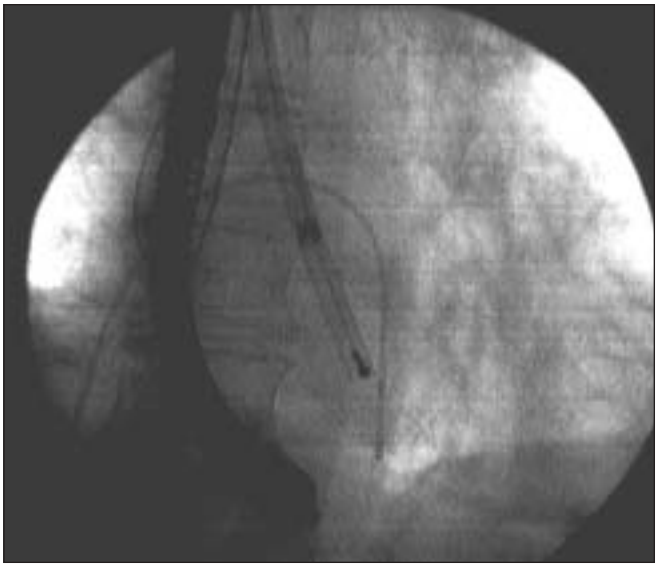

Figure 6. After the laser has reached the distal electrode, the outer sheath is advanced and positioned against the myocardium to prevent invagination during countertraction although some traction on the wall is present, indicated by the relative position of the lead tip to the temporary pacing wire. Traction is exerted directly at the tip via a locking stylet. The laser sheath is slightly withdrawn to allow unopposed traction on the tip of the lead.

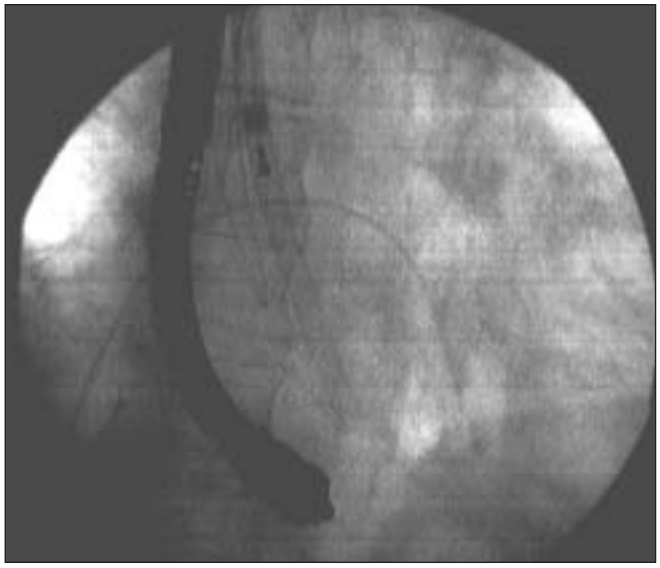

Figure 7. The lead tip has dislocated and is withdrawn inside the outer sheath. It can now be removed from the body together with the laser sheath.

a femoral workstation, the leads are grabbed in the atrium and the proximal isodiametric part of the lead can often be easily pulled down from the proximal binding sites greatly reducing the risk of extensive lasing at these sites (figure 8). If the distal part of the lead cannot be freed from the femoral vein, we try to retrieve it through the internal jugular vein and the laser can be applied again, this time only having to negotiate the distal intracardial part of the lead. This approach can be hampered by disrupted coils after application of a femoral workstation which prohibits the insertion of a locking stylet.

There are two situations in which we prefer to use a femoral workstation. First, when leads are severed

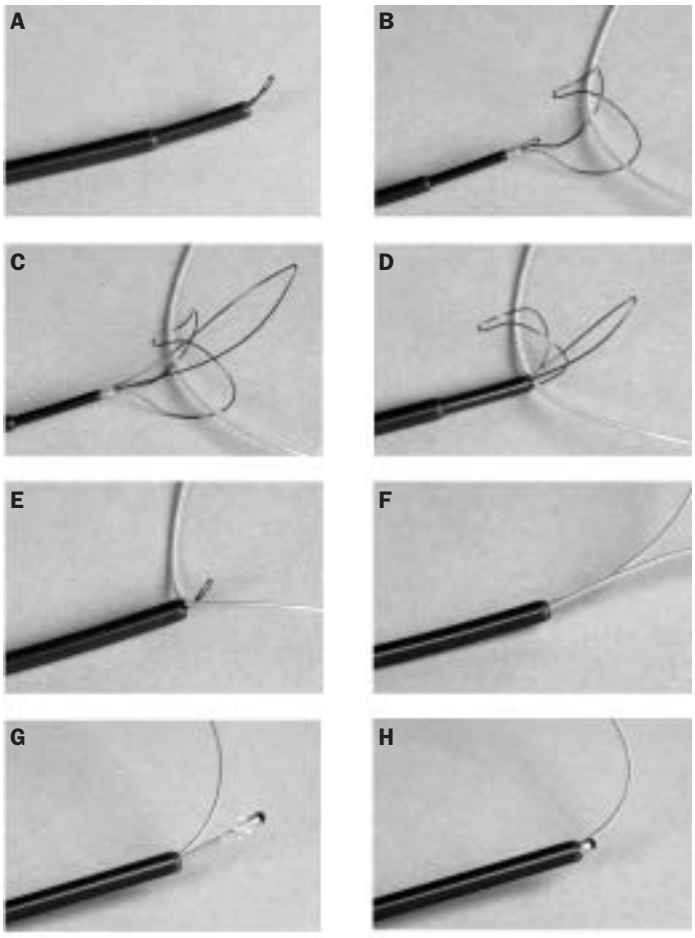

Figure 8. Mechanism of lead extraction with femoral workstation and Needle's Eye retriever.
A. The Needle's Eye is inserted withdrawn in its own sheath through a 16 F femoral workstation positioned close to the lead.
B. The Needle's Eye is deployed and hooked over the body of the lead.
C. A second, straight, loop is protruded from the sheath and through the Needle's Eye loop so the lead is captured between both intertwined loops.
D. By advancing the sheath of the Needle's Eye over both wires, the lead is secured as both wires interlock.
E. Once secured, the lead can be kept taut by pulling on the Needle's Eye, then the femoral workstation is advanced distally over the Needle's Eye and lead.
F. The lead doubles up inside the sheath as the femoral workstation is further advanced towards the distal end of the lead.
G. While the proximal end of the lead is simply pulled down from fibrous envelopes inside the veins, the distal part is freed mechanically through dissecting the fibrous scar tissue as the femoral workstation is advanced.
H. Once the distal electrode is reached, countertraction can be applied to free the tip of the lead. The lead is then further withdrawn through the femoral workstation.

and indwelling, it is easier to retrieve them with a femoral workstation. Second, when the tip of the lead has already dislocated from the myocardium and there is a risk of the lead being impacted in a proximal binding site during retrieval, they can be readily pulled down from the femoral vein.[15] A disadvantage of the femoral approach is less chance of completely removing the lead than with a laser sheath, which is important in case of infection.[10]

It is important to realise that for any of these techniques training and experience is essential to achieve good results, and we have shown that there is a clear learning curve for the laser sheath discouraging incidental attempts at lead extraction.[15]

Complications

As mentioned, lead extraction is not without the risk of major complications. The most life-threatening complications are vena cava superior laceration and perforation of the atrial or ventricular myocardium. As tears in the vena cava superior can occur above the pericardial fold, bleeding is unopposed at this site and can be profuse and not amendable with pericardial puncture. Profound hypotension or circulatory arrest may persist despite pericardial puncture.[24] In case of atrial or ventricular perforation, pericardial tamponade can limit the amount of blood loss. In both situations, if a patient has still to be transferred from a catheterisation laboratory to the operating room there is a high risk of serious morbidity or death as time is lost before thoracotomy can be performed. Therefore, all our extraction procedures are performed in the operating room during general anaesthesia with the patient prepared for thoracotomy.[14] Transoesophageal echo and invasive blood pressure registration are used to monitor the patient continuously. Cardiosurgical standby, including cardiopulmonary perfusion, are on stand-by in the operating room. Even though these precautions have proved to be lifesaving, patients can still succumb to profuse bleeding especially with venous rupture.[22]

The only exemption to performing lead extraction in the catheterisation laboratory is when pacemaker leads have been implanted for less than six months, as they can almost invariably be removed with simple traction.[16] However, if gentle traction fails and additional tools are necessary one should proceed to the operating room to complete the procedure. Further, a cardiosurgical centre also provides the option of surgically removing the leads: sometimes it is better to

Figure 9. Pacemaker lead-related endocarditis. Vegetations are attached to the tricuspid valve resulting from mechanical injury of the leaflets.

perform an elective surgical extraction, either primarily or when an endovascular extraction attempt stalls, than running too high a risk of complications and emergency surgery.

Minor complications of lead extraction include embolisation of either lead fragments or septic emboli to the lung. Embolisation of lead fragments usually remains asymptomatic. Septic lung emboli can cause a sudden drop in blood pressure during the procedure and can be differentiated from perforation by transoesophageal echocardiogram as they also typically show right ventricular dilation (figure 9). The septic lung emboli usually react well to antibiotic therapy.[25]

As leads can get attached with fibrous scar tissue to the tricuspid valve, extraction can damage the valve leaflets and chordae. We studied the incidence of new tricuspid regurgitation following lead extraction in 43 consecutive patients.[26] Transoesophageal echocardiography showed an increase in regurgitation by at least two grades in one out of 20 patients when the leads were removed without a laser sheath passing the tricuspid valve (forceful traction was used in that patient) and in four of 23 patients when a laser sheath was used beyond the tricuspid valve. Although this difference did not reach statistical significance it again cautions against indiscriminate extraction of superfluous leads, and provides doubts about the efficacy of lead extraction to alleviate tricuspid regurgitation related to pacing or ICD leads.

A rare complication of lead extraction was the laceration of the internal mammary artery with a laser sheath on entry of the subclavian vein. This gave rise to a mediastinal bleeding and formation of a false aneurysm requiring embolisation and ligation of both severed ends of the mammary artery.[27]

Venous angiogram

A venous angiogram has proven to give important information before lead extraction as well as before insertion of new pacing leads. When there is venous occlusion or extensive scar tissue visible around the leads, the leads can often be more reliably removed through the femoral vein with a retriever after they have dislocated from the myocardium. This avoids the risk of impacting the tip of the lead inside the scar tissue or occluded vein. Extensive fibrosis at particular sites can explain slow progress of the laser sheath. Also an outspoken tortuous course or sharp bend of the veins can be anticipated and this can help in choosing the appropriate extraction technique. As mentioned, a venous angiogram before any revision of a pacemaker or ICD system can reveal a nonsuspected occlusion and avoid futile attempts at catheterisation of the subclavian vein.

Conclusion

When results of lead extraction are presented, morbidity and mortality are often quoted to be acceptable. This results in a tendency to advocate lead extraction for nonmandatory indications such as superfluous nonfunctional leads. However, we have proved that there is insufficient evidence for either risk of superfluous leads or benefit of lead extraction for this condition. In contrast, lead extraction is acceptable and effective as first-line therapy for infected pacemaker or ICD systems in patients with an acceptable risk profile. The decision on lead extraction should be adapted for the individual patient, and a guideline for the indications is provided in table 1 and figure 10.

Niels Bohr stated that an expert is someone who has encountered all the complications in an ever narrower field. Lead extraction is certainly a narrow field of medicine. Although it is not necessary to experience all the complications, thorough knowledge

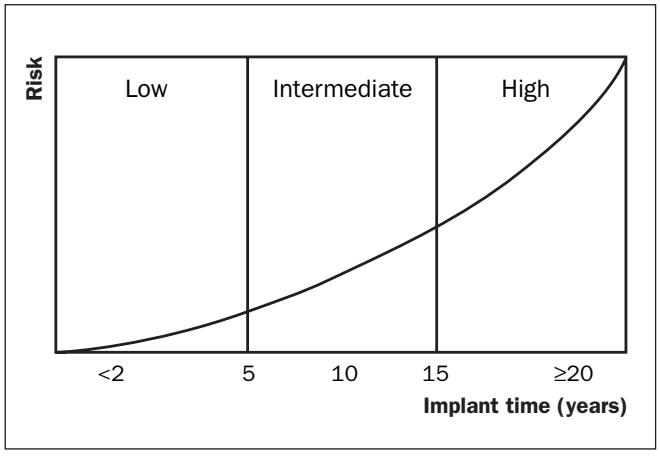

Figure 10. This graph gives an indication of combination of the risk and difficulty of lead extraction according to implant time as the authors perceive it to guide the choice of therapy as indicated in table 1.

Table 1. General indications for extraction of pacing or ICD leads.

Infection

A. Pacemaker- or ICD-related sepsis or endocarditis
   1. Lead extraction always first choice therapy
   2. Possible indications to defer lead extraction:
      a. Long implant times*
      b. No alternative pacing sites available and pacing dependent

B. Local pocket infection
   1. Factors favouring lead extraction
      a. Acceptable general condition of the patient
      b. Relatively short implant time*
      c. Alternative site for pacing available
   2. Factors in favour of lead-conserving therapy
      a. Elderly patients, especially female
      b. Long implant time*
      c. No alternative pacing sites available and pacing dependent
      d. Only skin erosion without frank infection
      e. Complex configuration of leads

Nonfunctional superfluous leads

1. In general no extraction advised
2. Exceptions:
   a. ICD: impossibility to avoid electrical interference
   b. Occlusion of entry vein (limited to recanalisation without extraction if leads can not be easily removed):
      - Favoured if:
        Obstruction distal to jugular vein
        Short obstruction
        Limited implant time
        Acceptable general condition of the patient

*Implant time and perceived risk of lead extraction depicted in figure 10.

of indications, techniques and complications is mandatory for safe implementation of this therapy. It should therefore only be carried out with cardiosurgical standby, by an experienced team and with the availability of all techniques necessary to cope with the often unexpected challenges encountered during these procedures. ■

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