The Needle’s Eye Snare as a primary tool for pacing lead extraction

Frank A. Bracke*, Lukas Dekker, and Berry M. van Gelder

Department of Cardiology, Catharina Hospital, Michelangelolaan 2, 5623 EJ Eindhoven, The Netherlands

Received 30 September 2012; accepted after revision 6 December 2012; online publish-ahead-of-print 30 December 2012

Aims
The femoral approach for lead extraction is typically used as a bailout procedure. We describe the results of a femoral approach with a Needle’s Eye Snare and Femoral Workstation as a primary tool for extracting pacing leads.

Patients and methods and results
Four hundred and seventy-six pacing leads implanted for >6 months were extracted in 229 consecutive patients (178 male, age 70.4 ± 12.7 years). First, traction was performed with a standard stylet, and if unsuccessful this was followed by the femoral approach with a Needle’s Eye Snare. Traction sufficed for 136 leads and a femoral approach was required in 340 leads, their respective implant times were 3.7 ± 2.9 and 9.2 ± 5.8 years. The Needle’s Eye Snare failed or was only partial successful (leaving a lead remnant of <4 cm) in, respectively, 1.8 and 3.8% of all leads, 2.7 and 7.1% of 182 right ventricular, 0.7 and 0% of 144 atrial leads, and in none of 14 coronary sinus leads. All leads implanted for <10 years were removed with a clinical success. Two patients were successfully operated after pericardial tamponade. There were no procedure-related deaths.

Conclusion
Needle’s Eye Snare lead extraction has a low complication rate. The technique should be considered as a primary tool for extraction of pacing leads, particularly atrial and coronary sinus pacing leads. The results for extracting ventricular leads might be improved if larger bore sheaths with a better cutting edge were available.

Keywords
Pacemaker lead • Lead extraction • Femoral approach • Needle’s Eye Snare

Introduction
Transfemoral approaches for lead extraction have been used mostly as a bail out procedure for a failed superior approach. However, we noticed that the femoral approach with a Needle’s Eye Snare (Cook Medical Inc.) was often effective when a superior approach with a laser sheath failed. Complications from lacerating the vena cava superior during laser sheath extraction accelerated the transition to a femoral approach to minimize the risk of damaging the upper thoracic veins. In this paper, we describe our single-centre experience with a Femoral Introducer Sheath and Needle’s Eye Snare as a primary tool for extraction of pacing leads in consecutive procedures.

Methods
Patient and lead selection
The Needle’s Eye Snare became the primary extraction tool for all pacing leads in our centre since mid-2006. The outcome of the extraction of atrial, right ventricular and coronary sinus pacing leads in consecutive patients until late 2011 is reported in this study. We used the definition of lead extraction according to the HRS Expert Consensus: lead extraction includes removal of a lead regardless of duration of implant requiring the assistance of specialized equipment or removal of a lead from a route other than via the implant vein. Therefore we included leads from 6 months on, as this was the shortest implant time of any pacing lead needing Needle’s Eye Snare extraction in the study period. Exactions of defibrillator leads during the same period or procedures were excluded from our results: there was a mixed use of a laser sheath and a Needle’s Eye Snare to extract these and they therefore did not constitute consecutive procedures or a homogeneous cohort.

Extraction procedure
All procedures were performed in the operating room under general anaesthesia with the patients prepared for thoracotomy with the exception of two patients in whom the risk of general anaesthesia and bailout surgery was considered prohibitive. Patients were continuously monitored by invasive blood pressure and trans-esophageal echo. A
cardio-thoracic surgeon and perfusionist were on standby, and a heart–lung machine and cell saver were present in the room. Two operators (F.B. and L.D.) performed all procedures.

Extraction was performed according to the following protocol. A standard stylet was first inserted if the lead was undamaged (we did not use locking stylets). For active fixation leads we attempted to unscrew the fixation mechanism. Traction was initiated, but if the lead remained immobile in the venous system after a few minutes, we proceeded to a Needle’s Eye Snare extraction. However, if the lead could be moved freely in the veins, and remained only attached to the myocardium, further traction was applied for \( \approx 10 \) min before proceeding to a femoral approach. When leads with a long implant time dislocated during traction from the myocardium and could be pulled up into the superior vena cava, we often removed these leads via the femoral vein employing an Atrieve Vascular Snare (Angiotech, Vancouver, Canada) or a Needle’s Eye Snare (if the latter was already employed for another lead). We started this practice after the experience that some leads got impacted in scar tissue in the brachiocephalic or subclavian vein during retrieval. For the purpose of the study we considered these leads as being removed by traction as most of them could have been removed with traction alone.

In case of a femoral approach we punctured the right femoral vein, and advanced a curved 16F Femoral Introducer Sheath (Cook Medical Inc.) over a 150 cm, 0.035” guidewire into the right atrium. Through this sheath, the smaller sized Needle’s Eye Snare retriever (13 mm) and the accompanying 12F sheath were introduced to snare the leads in the right atrium (Figure 1). Once the lead was secured with the Needle’s Eye Snare, we advanced the Femoral Introducer Sheath over the lead towards the myocardium (Figure 2). The leads had to double up inside the sheath to advance the sheath. We kept the lead taut, but did not pull on the lead to prevent inversion of the myocardium. Instead, we pushed the sheath over the lead. In this way, scar tissue was disrupted by advancing the sheath and not by pulling the lead out of the scar.

Once the distal electrode was reached, we applied counter traction to free the tip. For atrial leads, the distal electrode can be reached without pulling the proximal part of the lead down (Figure 2A). Ventricular leads are captured in the right atrium and the femoral workstation is curved to track the lead over the tricuspid valve downwards to the distal electrode in the right ventricle (Figure 2B). The proximal part of the lead has to be pulled down simultaneously to allow leeway in advancing the sheath towards the apex. If the proximal part could not be easily mobilized we released the lead and recaptured it more proximally to pull enough length into the right atrium providing a leeway to advance the sheath towards the apex. If the sheath got stalled over the doubled up lead, we also pulled the superior part down and recaptured the lead at the proximal end to advance the sheath over a single lead body. Breaking up scar over a single lead body proved to be more effective than over the doubled up lead.

**Outcome measures**

Complete success was defined as extraction of the entire lead or leaving only the distal electrode behind; partial success as leaving only a short lead remnant (\(<4\) cm of coil or insulation) that does not interfere with clinical result, and failure when leads or remnants needed surgical removal. To define a clinical result, we combined complete and partial success as this resulted in a clinical satisfactory outcome.

**Statistical analysis**

All time intervals are expressed as mean values ± the standard deviation.
Results

Study population

From 2006 till 2011, 229 patients had at least one pace-sense lead extracted with an implant time of >6 months. The mean age of the patients was 70.4 ± 12.7 years, 178 were male. The indication for extraction was device-related infection in 222 patients (other indications were pain, planned radiotherapy at the device location, and non-functional leads). We included 476 leads in the study (Table 1). Of these, 136 leads or 28.5% could be completely removed by traction alone (mean implant time 3.7 ± 2.9 years; range 0.6–15.6 years). A Needle’s Eye Snare was necessary in 340 leads or 71.5% (mean implant time of 9.2 ± 5.8 years; range 0.5–32 years; median implant time 7.8 years; 67.5% <10 years). Not included were 36 defibrillator leads that were also extracted in these patients and 16 leads that were removed after an implant time of <6 months.

Results of the Needle’s Eye Snare

With the Needle’s Eye Snare, failure or partial extraction occurred in, respectively, 1.8 and 3.8% of all leads, 2.7 and 7.1% of right ventricular leads, and 0.7 and 0% of atrial leads. All coronary sinus leads were successfully extracted. The overall clinical success rate for Needle’s Eye Snare lead extraction was 98.2%. Detailed results according to the location of the leads are shown in Table 1. We also stratified the outcome according to implant time (Table 2). This shows that leads implanted for <10 years were uniformly extracted with clinical success. The failure rate of leads implanted for >15 years was 6.4%.

The failed procedures included an atrial and a ventricular Helifix lead (Vitatron BV) in one patient. The closed looped helicoidal fixation mechanism of the atrial lead could not be dislodged with reasonable force despite adequate countertraction. When extraction of right ventricular leads failed, it was due to dense scar tissue in the right ventricle often located around the proximal electrode.

Table 1  Results of extraction

<table>
<thead>
<tr>
<th>Traction (136 leads)</th>
<th>Needle’s Eye Snare (340 leads)</th>
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<tbody>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td>All</td>
<td>62 (4.0 ± 2.8)</td>
</tr>
<tr>
<td>Complete success</td>
<td>–</td>
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<tr>
<td>Partial success</td>
<td>–</td>
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<td>Failure</td>
<td>–</td>
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Number of leads, implant time (in years, mean ± standard deviation) within brackets. A, atrium; RV, right ventricle; CS, coronary sinus.
that we failed to disrupt. All leads that failed extraction with the Needle’s Eye Snare were removed surgically. Three out of the five failed right ventricular leads were first exteriorized from the beating heart through a tobacco pouch suture in the right atrium, and then a laser sheath was used to release the lead from scar that could not be disrupted with the Femoral Introducer Sheath.

Sometimes prolonged gentle traction was needed to pull the proximal lead body down, and in a few cases we alternated traction from the femoral vein and the pocket before the lead body could be mobilized from scar in the veins.

Complications

Major complications occurred in two patients (0.7%): both perforations of the atrial wall after successful extracting the lead with a Needle’s Eye Snare. Both patients were immediately operated on and recovered completely. There were no other procedural cardiovascular complications.

Discussion

The Femoral Introducer Sheath and Needle’s Eye Snare proofed to be an effective tool for extracting pacing leads: clinical success was achieved in 98.2%, with 94.4% of leads completely extracted. The major complication rate was 0.7% and there were no deaths related to the procedure.

The Needle’s Eye Snare approach was particularly effective for atrial and coronary sinus leads (Figure 2A). Scar tissue seems to be less abundant in the atrium compared with the ventricle. Second, the lead can be freed from the myocardium before the proximal lead body has to be pulled down. Third, the sheaths are well aligned with atrial and coronary sinus leads resulting in effective transmission of the applied force. Although coronary sinus leads are usually easily removed with traction, we noticed that with increasing implant times the risk that they get trapped in scar tissue at the coronary sinus ost or in a tributary increases. It is sometimes necessary to advance the sheaths into the great cardiac vein to extract the lead.

Notwithstanding similar overall implant times, failure to extract right ventricular leads with a clinically satisfactory result occurred with implant times >10 years. The femoral workstation needs to be curved towards the apex, resulting in less efficient transmission of the applied force (Figure 2B). By curving, the sheath loses some of its radius resulting in increased friction with the lead. Further, scar tissue tends to be more abundant in the right ventricle. Also in order to advance the sheath towards the right ventricle, the proximal lead body has to be pulled down simultaneously to give leeway to the sheath. We did not routinely perform imaging of the upper thoracic veins before the extraction, so we do not know the influence of venous occlusion on the procedure. However, in some cases, resistance to pulling the lead down might have been aggravated by occlusion of the subclavian or brachiocephalic vein.

We did not include defibrillator leads in the study as we considered it important to describe the results in a homogeneous cohort. Although we used a femoral approach successfully in single coil 7F defibrillator leads, most of the 8F leads cannot be doubled up inside the Femoral Introducer Sheath because of the 12.8F inner lumen. Further, we normally pull the proximal lead body down from the scar in the veins. In case of dual coils, the lead is grasped in between the coils and the proximal coil cannot be simply pulled down when it is attached to the superior vena cava. We therefore often use a laser sheath to extract defibrillator leads.

The complication rate with the Needle’s Eye Snare approach is low in our experience (0.7%). Two patients developed pericardial tamponade from atrial perforation after successfully removing atrial leads. Both were operated on and recovered without sequelae. The femoral approach minimizes the risk of laceration of the superior vena cava as the sheaths do not have to enter the upper thoracic veins.

It should be stressed that we do not use the Needle’s Eye Snare as a pulling device, but instead push the Femoral Introducer Sheath forward over the lead. The role of the snare is only to keep the lead taut. In this way, considerable pressure can be exerted on the scar without direct traction on the myocardium and the risk of invagination or avulsion avoided. This approach demands that the Femoral Introducer Sheath is often bended up to 150° to direct it towards the right ventricular apex (Figure 2B). The curved femoral sheath tracks a ventricular lead much easier without kinking and it also facilitates roving the right atrium to snare the leads. We also preferred the smaller (13 mm) Needle’s Eye Snare size as it extends more easily to its full size in the atrium, making it more efficient in catching and securing the leads.

Comparison with the literature

There are two other reports on the femoral approach as a primary extraction method. Klug et al. reported the results of 70 leads extracted in 39 patients with the use of the Needle’s Eye Snare (with a time from implant of 113 ± 56 months). Eighty-seven per cent of leads were completely extracted, 4.3% incomplete and 8.5% of extractions failed. Two patients died after the extraction procedure, although their death was not related to the extraction technique. In contrast to our study there was no difference in success related to neither the location of the leads nor the implant times.
Bordachar et al.\textsuperscript{7} randomly assigned 101 patients either to a femoral approach or to a laser sheath extraction. The implant times were, respectively, 12 ± 6 and 13 ± 6 years. Unlike our study, the Needle’s Eye Snare group included patients in whom the leads were dislodged from the myocardium after traction with a locking stylet and the free-floating lead was snared and removed through the femoral vein. They reported 88% complete and 10% partial removal in both groups, with a 2% failure rate. Two patients in the laser group and one in the femoral approach group needed acute surgery for perforation. In the same paper, the authors compared the success rates of three centres using a laser sheath (218 patients) and three centres with a femoral approach (138 patients). Implant times were, respectively, 9 ± 5 and 10 ± 5 years. Complete success was reported in 85% of laser cases and 86% of femoral procedures, partial success in, respectively, 12 and 11%. There were two deaths in the laser group and one in the femoral group.

Bongiorni et al. described an internal transjugular approach that has similarities with femoral extraction. The proximal lead body was first pulled down with a femoral approach. Subsequently, the distal lead portion was freed with a sheath from superior after retrieval of the free floating lead through the jugular vein.\textsuperscript{9} Although the technique provides a better alignment of the sheath with right ventricular leads, one has to catheterize both the femoral and internal jugular vein and snare the lead a second time. Bongiorni et al. used the technique for 213 leads failing extraction from the venous entry site or for indwelling leads and completely removed 96.2%, partially 2.8%, and unsuccessfully 0.9% of the leads. The implant time of these leads was not provided.

Time from implant plays an important role in the published success rates. We could extract all leads with an implant time of <10 years with a good clinical result. But the failure rate was 3.6% for leads that were implanted between 10 and 15 years and increased to 6.4% when implanted for >15 years. An increase in failure rates with implant times >10 years has also been reported for the laser sheath as well.\textsuperscript{5,10}

The Lexicon study also reported a cumulative failure rate but only for extraction of non-functional and abandoned leads: from 0.75% at 5 years, 0.93% at 10 years, 1.2% at 15 years, 2.4% at 20 years to 10.9% at 25 years. This was significantly increased for leads implanted >10 years.\textsuperscript{9}

It should be noted that reported outcomes of lead extraction are greatly influenced by leads with a relatively short implant time: although the mean implant time of our Needle’s Eye Snare procedures was 9.2 ± 5.8 years, 67.5% of the leads had an implant time of <10 years. Similar observations can be made in other studies: Bongiorni et al.\textsuperscript{8} reported a mean implant time of 69.3 months, but the median was 50 months. Therefore, presentation of results stratified according to implant time would be more clinical relevant and improve comparing different extraction techniques. Ultimately, different approaches should be at hand when confronted with leads with longer implant times, and there should be a low threshold to switch between them, including surgery.

**Limitations**

We did not systematically record the duration of the extraction or of the fluoroscopy. In the randomized study of Bordachar et al.\textsuperscript{7} the duration of a femoral approach exceeded that of the laser procedures (86 ± 51 vs. 51 ± 22 min). Femoral lead extraction can be a demanding procedure, needing a lot of patience and sometimes a considerable amount of force to break up the scar. The latter may account for some of the 7.1% of right ventricular leads that severed at or in between the electrodes. Further, the proximal lead protruding from the sheath can obstruct progress as it absorbs part of the force intended to disrupt the scar (Figure 2B). If this happens, we sometimes release the lead and pull the proximal lead down first. The lead is then snared close to the proximal end and the sheath advanced over a single lead body; this was often effective when the first attempt failed. Procedure times and success rates could also greatly improve if the sheaths were equipped with a stiffer and better cutting edge: with the current Femoral Introducer Sheath, prolonged pressure on dense scar tissue may result in blunting or indentation of the tip with loss of cutting capability (Figure 3).

Bordachar et al.\textsuperscript{7} also reported longer fluoroscopy times (21 ± 17 vs. 7 ± 7 min). However, with a femoral approach the greater distance from the irradiated area compared with a superior approach ameliorates the radiation exposure for the operator.

Finally, though the indicated size of the sheath is 16F, the effective inner diameter is actually 12.8F. Larger doubled up pacing leads can get entrapped in the Femoral Introducer Sheath to a point that it is impossible to push them out again. Surgery may be necessary to recover both the lead and the extraction device. Other, larger

**Figure 3** Distortion of the Femoral Introducer Sheath. The tip of the Femoral Introducer Sheath after laborious extraction of a right ventricular lead. Note that the tip of the sheath is blunted and folded inwards. The lead body is wrinkled as a result of increasing force applied on the sheath in an attempt to disrupt the remaining scar. The lead has disintegrated partially, and the central coil has cut into the edge of the sheath (arrow). Although considerable force was used, we made sure to keep the lead taut but avoided pulling the myocardium.
Conductors externalization in a Riata ST Optim™ lead

Peerawut Deeprasertkul1,2*, Asim Yunus1, and Ranjan Thakur1

1Sparrow Thoracic and Cardiovascular Institute, Michigan State University, 1200 East Michigan Avenue, Suite 580, Lansing, MI 48912, USA; and 2Mid-Michigan Cardiovascular Institute, Saginaw, MI 48601, USA

* Corresponding author. Tel: +1 4154906314, E-mail: peerawut_d@hotmail.com

A 72-year-old man with a history of non-ischaemic cardiomyopathy in New York Heart Association III with an ejection fraction of 30% after optimized medical therapy. He underwent implantation of an implantable cardioverter-defibrillator (ICD) for primary prevention with dual-coil, passive fixation ventricular lead (Riata ST Optim™ Model 7070). Two years after implantation, the patient presented to hospital with infected defibrillator requiring defibrillator explantation.

After ICD removal, the ventricular lead was examined and showed evidence of conductor externalization just proximal to the distal coil (panel A) over a 1 cm length. We then carefully reviewed the chest X-ray and found evidence of conductor externalization (panel B).

Externalization of cables in the Riata and Riata ST leads has been reported. Optim™ coating was developed to prevent lead–lead abrasion. Inside-out abrasion of the silicone insulation, resulting in externalization of cables in the Riata and Riata ST leads has been reported.

The 7070 Riata lead has an Optim™ overlay that ends 1 cm proximal to the distal coil. We observed cable externalization only in the silicone-insulated segment of the lead. This could be good news for limiting externalization. However, this issue is not resolved and careful surveillance should be emphasized.

The full-length version of this report can be viewed at: http://www.escardio.org/communities/EHRA/publications/ep-case-reports/Documents/Conductor-externalization.pdf

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