Impact of a femoral snare approach as a bailout procedure on success rates in lead extractions

Christoph Thomas Starck,a,* Etem Caliskan,a Holger Klein,a Jan Steffelb and Volkmar Falka

a Clinic of Cardiac and Vascular Surgery, University Hospital Zurich, Zurich, Switzerland
b Clinic of Cardiology, University Hospital Zurich, Zurich, Switzerland

Abstract

OBJECTIVES: In cases of challenging transvenous lead extraction procedures, limitations exist for the subclavian approach (SCA). In case of absent alternative approaches, the procedure may end with failure. Therefore, we investigated the femoral snare approach (FSA) as bailout procedure.

METHODS: From December 2010 to August 2013, 114 patients with 190 leads were scheduled for transvenous lead extraction procedures [mean implant duration (MID): 74.7 (1–384) months]. In 28 leads [MID: 133.8 (36–384) months] the FSA was used. In 20 leads [MID: 127.5 (52–258) months] the FSA was performed as bailout approach and in 8 leads [MID: 149.6 (36–384) months] as first-line approach due to complete intravascular lead position.

RESULTS: In all FSA procedures (n = 28), clinical success was 85.7% and complete procedural success 64.3%. In SCA procedures as bailout approach (n = 20), clinical success was 80.0% and complete procedural success 55.0%. In first-line FSA procedures (n = 8), clinical success was 100.0% and complete procedural success 87.5%. Overall (n = 190) clinical success was 96.3%, complete procedural success 91.1%. By adding the FSA in cases of insufficient or impossible SCA, clinical success was increased by 12.6% (from 83.7 to 96.3%) and complete procedural success by 9.5% (from 81.6 to 91.1%). Comparison of leads extracted by SCA with leads extracted by FSA revealed that MID [133.8 (36–384) vs 64.4 (1–300) months; P < 0.0001] and the rate of passive fixation leads (67.9 vs 28.4%; P < 0.0001) were significantly higher in the SCA group.

CONCLUSIONS: In cases of failed or impossible subclavian approach, the femoral snare approach may improve overall success rates without relevantly increasing operative risk.

Keywords: Lead extraction • Femoral snare extraction • Pacemaker • implantable cardioverter defibrillator

INTRODUCTION

The need for transvenous lead extraction procedures is increasing and is estimated in the range of 1.5–6% of all newly implanted leads by the European Heart Rhythm Association [1].

The reported success rates are high and the complication rates low [2–5]. Extraction in long-term implanted leads remains challenging and success is not guaranteed [5]. The success rates decrease with increasing implant duration of a lead scheduled for extraction [6–8].

The most common approach for transvenous lead extraction procedures is the superior, subclavian approach (SCA) [9, 10]. In some cases this approach is not successful, for example in ruptured leads, completely intravascular leads or severely adhered leads. The femoral approach using a snare extraction device is an alternative in such situations and often allows finishing the procedure successfully. Some centres even use the femoral approach as their first-line approach in the extraction of pacemaker leads [8, 11].

To investigate the potential benefit of the femoral snare approach (FSA) as a bailout procedure in case of a failed or impossible superior approach, we performed this retrospective data analysis. As a hypothesis, the addition of an FSA increases success rates of lead extraction procedures in cases where an SCA has failed or is impossible.

METHODS

Patient population

From December 2010 until August 2013, 114 patients with 190 leads were scheduled for lead extraction procedures [mean age: 62.8 ± 14.5 years, mean implant duration (MID): 74.7 (1–384) months]. In 28 leads [MID: 133.8 (36–384) months] the FSA was used. In 20 leads [MID: 127.5 (52–258) months] the FSA was performed as bailout approach after failed SCA and in 8 leads [MID: 149.6 (36–384) months] it was used as first-line approach due to complete intravascular position of the targeted lead. All FSA procedures were performed via the right femoral vein using the Needle’s Eye Snare device (Cook Medical, Inc., IN, USA) (Fig. 1).
The preoperative patient and lead data are displayed in Table 1. Preoperative data of leads according to extraction approach (SCA versus FSA) are given in Table 2. Appropriate institutional review board approval was obtained. The results of the different groups were analysed and compared.

### Extraction procedure

If leads could not be extracted by simple traction, a staged approach was performed. Access of the lead scheduled for extraction was obtained by a superior, SCA in case the lead was accessible. For application of traction, a locking stylet was used (Liberator, Cook Medical or Lead Lock Device, Spectranetics, CO, USA). To apply counterpressure or countertraction, first polypropylene extraction sheaths (Byrd Dilator Sheath, Cook Medical, IN, USA) were used in telescoping sheath technique. In case of missing success in a further step, a mechanical dilator sheath (Evolution, Cook Medical, Limerick, Ireland) or a laser sheath (SLS II, Spectranetics, CO, USA) was used. In most cases, the mechanical dilator sheath was applied at this stage. In case of failure of the SCA or if the targeted lead was positioned completely intravascular, an FSA was performed using the Needle’s Eye Snare device (Cook Medical) via the right femoral vein.

Lead extraction procedures were performed in an operation theatre in general anaesthesia by a cardiac surgeon with standby of extracorporeal circulation. Patients were continuously monitored by ECG, invasive blood pressure measurement, pulse oximetry and transoesophageal echocardiography.

Success was defined either as complete procedural or as clinical success (CS) according to the definitions of the Heart Rhythm Society expert consensus on transvenous lead extraction. Complete procedural success (CPS) was characterized as removal of all lead material confirmed by fluoroscopy. CS was determined by removal of all targeted leads and lead material or retention of a small part of a lead that did not negatively affect the outcome goals of the extraction procedure [12].

### Statistics

Data were analysed using the SPSS Version 21 software (IBM Corporation, New York, NY, USA). Categorical variables are presented as numbers and percentages. Differences between groups were analysed using the $\chi^2$ test. Continuous variables are presented as mean ± standard deviation or as mean and range from minimum to maximum. To address clustering of leads within patients, linear and logistic regressions with robust standard error and patient-ID as cluster were performed to analyse the differences between groups in implant duration, indication for lead extraction, lead type and lead fixation. Linear and logistic regression was performed with the help of the Stata 11 software (StataCorp, College Station, TX, USA). A $P$-value of <0.05 was considered significant.
RESULTS

Overall CS was 96.3% and CPS 91.1%. The mean number of extracted lead per patient was 1.7 leads. Operative mortality was zero. Major complications were encountered in 2 cases (1.7%) (1 patient with asystole due to lead dislocation during extraction procedure, 1 patient with right ventricular avulsion). Both patients survived to hospital discharge. Minor complications were encountered in 4 cases (3.5%) (3 pocket haematomas requiring surgical drainage, 1 pneumothorax requiring chest tube placement).

Comparison of leads extracted by SCA with leads extracted by FSA revealed that MID [133.8 (36–384) vs 64.4 (1–300) months; \( P < 0.001 \)] and the rate of passive fixation leads (67.9% vs 28.4%; \( P < 0.001 \)) were significantly higher in the FSA group (Table 2).

In all FSA procedures (28 leads) CS was 85.7% and CPS 64.3%. In FSA procedures as bailout approach (20 leads) CS was 80.0% and CPS 55.0%. In first-line FSA procedures (8 leads) CS was 100.0% and CPS 87.5%. The rate of passive fixation leads in the bailout-FSA procedures was 80.0% (\( n = 16 \)) and 37.5% (\( n = 3 \)) in the first-line-FSA procedures, respectively. With regard to the complication rate, only one major complication was directly related to the FSA (Table 3). In this case of a pacemaker-dependent patient, a newly implanted right ventricular lead was dislocated by the manipulation of the femoral snare device during the extraction procedure. The patient required a short period of chest compressions until right ventricular pacing was re-established. The patient recovered uneventful and without any neurological sequelae.

By adding the FSA in cases where the SCA was not sufficient or possible, CS was increased by 12.6% (from 83.7 to 96.3%) and CPS was increased by 9.5% (from 81.6 to 91.1%) compared with the hypothetical success rates if the FSA would not have been available (Fig. 2).

DISCUSSION

Extracting leads using the same route as they were implanted is the most common approach in transvenous lead extraction procedures \([3, 6, 7, 10, 13, 14]\). In addition to this SCA, an internal jugular approach and a femoral approach are available \([3, 8, 11, 14]\).

The CS rates of transvenous lead extraction procedures are well above 90% \([3–5, 7]\). It is known that the availability of different extraction tools during a procedure improves success rates \([15]\).

### Table 2: Preoperative data of leads extracted by the subclavian approach versus the femoral snare approach

<table>
<thead>
<tr>
<th></th>
<th>Subclavian approach n = 162 (%)</th>
<th>Femoral snare approach n = 28 (%)</th>
<th>( P )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MID (months)</td>
<td>64.4 ± 56.8 (1–300)</td>
<td>133.8 ± 72.6 (36–384)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Indication for lead extraction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>68 (42.0)</td>
<td>13 (46.4)</td>
<td>0.693</td>
</tr>
<tr>
<td>Non-infectious indications</td>
<td>94 (58.0)</td>
<td>15 (53.6)</td>
<td></td>
</tr>
<tr>
<td>Lead type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pacemaker lead</td>
<td>112 (69.1)</td>
<td>21 (75.0)</td>
<td>0.554</td>
</tr>
<tr>
<td>ICD lead</td>
<td>50 (30.9)</td>
<td>7 (25.0)</td>
<td></td>
</tr>
<tr>
<td>Lead fixation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active</td>
<td>116 (71.6)</td>
<td>9 (32.1)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Passive</td>
<td>46 (28.4)</td>
<td>19 (67.9)</td>
<td></td>
</tr>
</tbody>
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ICD: implantable cardioverter defibrillator; MID: mean implant duration.

### Table 3: Success and complication rates

<table>
<thead>
<tr>
<th></th>
<th>All leads (( n = 190 ))</th>
<th>Femoral snare approach (( n = 28 ))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical success</td>
<td>96.3% (( n = 183 ))</td>
<td>85.7% (( n = 24 )) (first-line: 100.0%; bailout: 80.0%)</td>
</tr>
<tr>
<td>Complete procedural success</td>
<td>91.1% (( n = 173 ))</td>
<td>64.3% (( n = 18 )) (first-line: 87.5%; bailout: 55.0%)</td>
</tr>
<tr>
<td>Major complications</td>
<td>( n = 2 )</td>
<td>( n = 1 )</td>
</tr>
<tr>
<td>Minor complications</td>
<td>( n = 4 )</td>
<td>( n = 0 )</td>
</tr>
</tbody>
</table>

Figure 2: Contribution of the femoral snare approach (FSA) (red bar) to the overall success rates in cases of failed or impossible subclavian approach (SCA). The blue bar defines the success rates of the SCA, if the FSA would not have been available with the assumption that all 28 leads of the femoral snare group would have been extraction failures of targeted leads otherwise.
Therefore, we investigated the impact of an FSA as a bailout procedure on the success rates of lead extraction procedures.

We performed the FSA in cases of failed or impossible (due to intravascular position of a lead) SCA. In 20 out of overall 190 leads (10.5%), we switched to the FSA as a bailout procedure. In all these cases, the SCA did not facilitate a successful extraction. As a first-line approach, the femoral snare technique was used in 4.2% of all leads (8 of 190 leads) due to a complete intravascular position of the targeted lead and the impossibility to access the lead by the SCA. The differences in success rates between the first-line and the bailout procedure in the femoral snare group (CPS: 87.5 vs 55.0%; CS: 100.0 vs 80.0%) may be attributed to the fact that the percentage of passive fixation leads was higher in the bailout group than in the first-line group (80.0 vs 37.5%).

When comparing the leads in which the femoral approach was required with the leads that were extracted by the SCA, we were able to show that MID and the percentage of passive fixation leads were significantly higher in the femoral snare group. These two factors are known to be determinants of extraction failure or incomplete extraction [1, 6, 10, 16]. Thus, the femoral snare group contained the leads that were more challenging to extract, reflecting its use as a bailout procedure. This negative selection needs to be taken into account when interpreting the success rates of the femoral snare group. When comparing our success rates of the FSA with the success rates of an all-comer population, the rates were lower. In our study population, this was certainly caused by the fact that the leads, which were most difficult to extract and in which the SCA failed or was impossible, were assigned to the femoral approach group. These findings are hence not indicative that the FSA is inferior to a subclavian procedure. The non-inferiority of the femoral technique in a non-selective population is supported by several studies of the femoral extraction technique in centres where it was used as first-line approach, as well as in a comparative prospective study by Bordachar et al. [8] where leads were randomized either to extraction by a subclavian laser technique or to an FSA [8, 11, 17].

In our study, the addition of the FSA as a bailout option increased the success rates, which would have been below contemporary success rates of transvenous lead extraction procedures if the femoral snare technique had not been available (Fig. 2). The femoral approach did not come with an increased complication rate despite the negative selection of challenging target leads due to the bailout nature of the femoral extraction group. In the case of leads with completely intravascular position, an extraction would not have been possible without the femoral snare technique.

As an alternative to the FSA in cases of failed or impossible lead extraction by the SCA, the internal jugular approach as described by Bongiorni et al. [3] needs to be mentioned. This approach is technically more challenging than the FSA using the Needle’s Eye Snare device, but shows excellent results. As an alternative to the Needle’s Snare device, a deflection tip guidewire with a Dotter helical basket retriever, an Amplatz gooseneck snare or a Lasso snare catheter may be used to catch and control the lead [3, 9].

It is important to mention that when using a Needle’s Eye Snare device (Cook Medical) and advancing the outer sheath of the snare device over the lead to apply counterpressure, the lead is doubled (Fig. 3). This leads to friction between the outer sheath and the lead, which may lead to an irreversible entrapment of the lead in the sheath. In pacing leads with small lead body diameters, this is never a problem, but when extracting implantable cardioverter defibrillator (ICD) leads with larger lead body diameter, this needs to be kept in mind. Nevertheless, successful extraction of ICD leads is feasible with the Needle’s Eye Snare device as we were able to show in this study population.

The limitations of this study are its retrospective and single-centre study design. Furthermore, the uncontrolled nature of the data, the small sample size and the potential interdependence needs to be mentioned as limitations of this study. Besides, it needs to be outlined that selection bias might have subconsciously played a role in such a way that the FSA was used earlier in the procedure and that the SCA was considered failed at an earlier stage, as a consequence of an increased routine in the application of the femoral snare technique. Being aware of the possibility of a selection bias, we do not think it played an important role in our patient population. Nevertheless, we think that these findings do have important clinical impact for physicians performing lead extraction procedures. Further larger studies with a prospective and multicentre design should be performed to verify these findings.

CONCLUSION

The FSA in cases of failed or impossible SCA may increase overall success rates without increasing operative risk. Therefore, it should be available at centres that perform lead extractions in order to optimize patient outcome, particularly in challenging lead extraction procedures.

Conflict of interest: Christoph Starck and Jan Steffel received workshop honoraria from Cook Medical Europe Ltd. The other authors declare no conflict of interest.

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