**Non-Laser Percutaneous Extraction of Pacemaker and Defibrillation Leads: A Decade of Progress**

**Short Title:** Advances in non-laser lead extraction

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**INTRODUCTION**

Mechanical methods have demonstrated a better safety profile than laser in a meta-analysis of transvenous lead extraction (TLE),1 but in the past have not matched the high rate of success of laser procedures2 except for isolated high volume centres.3 New tools and techniques have been introduced to improve the efficacy and maintain the safety of mechanical extraction4 in response to an increasing need for TLE procedures of increasingly complexity.5,6 The Evolution® Mechanical Dilator Sheath (Cook Medical, Bloomington, IN, USA) is a hand-powered device for extracting chronically implanted leads.7-9 A rotational mechanism of the inner sheath is used to free the lead from the fibrous and calcified adhesions; an outer telescopic sheath provides support and can be used for blunt dissection.

In the 1990s our unit made a decision to avoid the use of laser techniques in lead extraction,10 relying instead on mechanical dissection sheaths, the Perfecta® Electrosurgical Dissection Sheath (Cook Medical) and femoral methods. The Perfecta® system was completely superseded by the Evolution® in mid-2010; this in turn was superseded by the Evolution® RL, a newer model characterised by bidirectional rotation and a less aggressive profile at the sheath tip. In this study we evaluated the clinical and procedural impact of evolving technologies on the outcome of TLE procedures.

**METHODS**

For all procedures performed at our centre in the decade to the end of 2014 that met the Heart Rhythm Society5 and European Heart Rhythm Association6 definition of a TLE, clinical details were collected prospectively by a cardiology technician dedicated to the task and present throughout each case. Institutional ethical committee approval was obtained.

Procedures were considered in 3 groups. Procedures performed up to mid-2010 were designated as group 1 TLEs. In this period a step by step approach was used , starting with simple traction followed by the use of a Liberator® Locking Stylet (Cook® Medical), then the use of Perfecta® Electrosurgical Dissection Sheaths (Cook® Medical), if required.

The Evolution® Mechanical Dilator Sheath was introduced in mid-2010 and immediately became the instrument of choice in all cases where difficulty was encountered during a TLE. It also led to a change in the approach to lead extraction: rather than progressing to this instrument after failure of traction alone, it was used from the start of the procedure whenever difficulty was anticipated. In early 2013, the Evolution® RL superseded the original version in our unit and the One-Tie® Compression Coil (Cook Medical) and the SteadySheath® Evolution® Tissue Stabilization Sheath (Cook Medical) were introduced (Figure 1). Procedures performed from the introduction of the Evolution® system to the switch to the Evolution® RL were classified as Group 2, subsequent procedures as Group 3.

All TLEs were performed in the cardiac catheterization laboratory with surgical backup available in an adjacent operating theatre. Throughout the study period, retrieval of fragmented leads was attempted when required using the Byrd Workstation™ Femoral Intravascular Retrieval Set (Cook® Medical) and/or Needle's Eye Snare® (Cook® Medical) via a femoral and/or jugular approach. Completeness of extraction was verified by radiological examination at the end of the procedure and by inspection including reassembly of the extracted fragments.

*Follow-up*

All patients were monitored for complications during hospitalisation and at one month post procedure. The severity of complications and the completeness of extraction were defined in accordance with the guidelines of the Heart Rhythm Society.5

*Statistical analysis*

Statistical analyses were performed using SPSS software (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as mean and standard deviation and compared using the unpaired Student’s t-test and the Mann-Whitney test, where appropriate. Chi-squared test and Fisher’s exact test were used for evaluating categorical variables. A p-value of less than 0.05 was considered statistically significant.

**RESULTS**

*Patient demographics*

In the 10 years to the end of 2014, 522 leads were extracted from 288 patients, with an increasing workload over the study period (figure 1). 133 leads were extracted from 76 patients Group 1, 221 leads from 115 patients in Group 2 and 168 leads from 97 patients in Group 3.

There was a significantly higher proportion of ICD patients in Group 2 and 3 vs. Group 1 (41%, 37% and 18% respectively, p = 0.002 Group 2 vs. Group 1 and p = 0.012 Group 3 vs. Group 1), whereas a higher prevalence of pacemaker patients was documented in Group 1 (57% vs. 35% in Group 2 and 45% in Group 3). No significant differences between groups were found in other clinical characteristics (table 1).

*Indications for extraction*

In all groups, the most common indication for TLE was infection, although the proportion of extractions performed for this reason declined over time from 64% in Group 1 to 57% in Group 2 and 38% in Group 3 (figure 1). There was a higher prevalence of local than of systemic infection in all groups with local infection accounting for 80% of infection in Group 1, 67% in Group 2 and 89% in Group 3.

Lead dysfunction was the second commonest indication , including 13 (of which 11 were in Group 2 and 3) malfunctioning Sprint Fidelis® leads Model 6931 and 6949 (Medtronic Inc, Minneapolis, MN, USA) and 6 (5 in Group 2 and 3) malfunctioning RiataTM ST leads Model 7000 and 7002 (St. Jude Medical, St. Paul, MN, USA).

In 9% of TLEs in Group 2 and 5% in Group 3, extraction was performed for Sprint Fidelis® advisory in the absence of any evidence of dysfunction, all at the time of generator substitution. In Group 1, no extraction was performed for an advisory alone (p = 0.037 compared to Group 2 and 3 together). In Group 3 there was a significantly higher prevalence of TLEs performed to obtain venous access to permit upgrade to CRT or ICD compared to Group 1 (3%, P = 0.003) and Group 2 (0.9%, p < 0.001).

*Lead characteristics*

The groups were similar in the number of extracted leads per patient (1.75 in Group 1 vs. 1.92 in Group 2, 1.73 in group 3, p = NS). The age of leads was significantly greater in Group 2 and Group 3 than in Group 1 (6.2±4.8, range 0.3-32.9 years vs. 4.7±4.5, range 0.3-30.8 years, p<0.001; table 2). All major manufacturers of pacing equipment were represented among the leads extracted (table 3). Passive fixation leads were more prevalent in Group 1 (68%, 91/133) vs. Group 2 and 3 (49% in each group, 108/221 and 82/168), p<0.001 (figure 2).

*Safety*

No death related to the TLE procedure occurred in either group; no patient required emergency surgery. The only complication requiring urgent intervention was a subacute pericardial tamponade in Group 1 that occurred at 6 hours after the extraction of 4 pacing leads, 2 of which had been in position for 18.6 years; pericardiocentesis was performed, but no other intervention was required. Two patients required transfusion for blood loss occurring from the access veins during the procedure. One patient in Group 3 suffered a non-fatal oesophageal perforation from a trans-oesophageal echocardiogram performed at the time of TLE. No other complication related to the extraction procedure occurred during follow up.

*Efficacy*

Incomplete extraction was recorded in 31 leads in 22 cases across the three groups. Surgical extraction was required after a failed TLE in two cases in Group 1; in one further case in Group 1, a redundant lead was abandoned after a failed attempt to extract it. Surgery was required in only one case in Group 2, for retrieval of a pacing lead chronically migrated to a pulmonary artery branch. One patient crossed over successfully to percutaneous extraction after a failed attempt at surgical extraction .11 All other cases incomplete extraction related to the retention of fragments of lead of <2cm in length, usually the tip electrode only.

In Group 2 the percentage of complete TLEs was significantly higher than in Group 1 (95.5% vs 88.0% of extracted leads, p = 0.016). The overall rate of complete success in Group 3 was also significantly higher than in Group 1 (97.6%, p = 0.002), but not significantly different to Group 2 (p = 0.395). The Evolution® Mechanical Dilator Sheath was used for 115 of the leads extracted in Group 2, the Evolution® RL for 109 of the leads in Group 3.

The percentage of complete extraction was higher for ICD leads than for pacing leads (98.5% [128/130] vs. 92.6 % [362/391], p=0.014). A trend toward higher percentages of complete extraction for ICD leads compared to pacing leads was confirmed in each of the groups separately.

*Efficiency*

Procedure duration, including the reimplantation when this occurred as part of the same procedure, was similar in all groups (114±70 minutes in Group 1, 91±49 minutes in Group 2 and 117±69 minutes in Group 3, p = 0.308 ).

The proportion of leads extracted completely using a secondary access point (femoral and / or jugular) in addition to the original access vein was significantly higher in Group 3 (11%, 18/164) than in Group 2 (3%, 7/211), p = 0.006. No difference was detected between Group 1 (6%, 6/117) and Group 3, p = 0.130 or between Group 1 and Group 2, p = 0.610. The 18 leads extracted by a secondary access site in the Group 3 included 5 ICD leads, 9 passive fixation leads; the mean dwell time of these leads was 10.1 yrs.

**DISCUSSION**

Our data show that advances in equipment have made it possible for a centre with a moderate volume to achieve a high rate of success in mechanical lead extraction without compromising safety.

*Safety*

In a recent structured meta-analysis of results, the risk of death or serious complication was more than twice as high when laser sheaths were used rather than mechanical methods in lead extraction.1 This compliments older but inconclusive data from trials that were not powered to measure mortality as an endpoint.4 A substantial majority (83%) of serious complications occurring during laser lead extraction relate to injury to the superior vena cava; these injuries are lethal in 40% of cases.12 This complication is seldom seen when mechanical techniques are used.13

*Efficacy*

In the past, mechanical methods have generally given lower success rates than laser.1,10 Isolated high volume centres have matched the success rates of laser,3 but this has been difficult to replicate in centres with a lower extraction volume.

Recent evidence suggests that the balance in efficacy may now have shifted in favour of mechanical methods.14 Several studies7-9 have been published documenting the safety and the efficacy of the Evolution® system in TLE procedures. Our data are in keeping with these, showing that a high level of safety can be maintained even with the achievement of a high rate of success and in a centre extracting fewer than 100 leads yearly.15

*ICD Vs. Pacing leads*

In our population, the rate of complete success was higher for ICD leads compared to pacing leads, suggesting that, in a population such as ours with a preponderance of active fixation single coil leads, ICD lead extraction may be safer and less difficult than is commonly expected.16 This supports the case for prophylactic extraction of leads that are subject to an advisory.17 In our experience, the Evolution® seems to be well suited to removing defibrillator coils.

The improved rate of success observed since adopting the Evolution® system may relate in part to an altered approach to the procedure: instead of resorting to the use of sheaths after failing with traction alone, the sheaths were brought into the procedure from the start in any case in which difficulty was anticipated. This helped to preserve the integrity of the lead so that it could be used as a rail for the extraction sheath. Ancillary tools such as the compression coil (figure 1) may have contributed to the increasing rate of success.18

*Evolution® Vs Evolution® RL*

The success rate in our series continued to increase after switching from the original model to the Evolution® RL, but the improvement stems entirely from improved success in using a femoral and / or jugular approach after failure of the mechanical sheath to advance or breakage of the lead. The success rate using an access vein only approach fell significantly after switching to the newer model. This was an unexpected finding.

Previous studies have shown a high rate of success with the Evolution® RL, but did not compare it to the original Evolution®.19 The apparent change may reflect a greater willingness on our part to switch to a femoral approach or may be a by-product of the less aggressive design of the cutting tip of the new model. Another mechanical extraction sheath has recently been introduced. Like the Evolution® RL, it has a less aggressive tip design than the original Evolution® sheath. Initial results with this have been favourable,20 but neither it nor the Evolution or Evolution RL has been subject to a substantial randomised comparison to any of the other extraction tools.

**STUDY LIMITATIONS**

Our comparison of different methods and equipment was non-randomised. Our results may have been influenced by the increasing experience of the institution during the period of the study, though individual operator experience was held relatively constant due to staff changes. The falling ratio of passive fixation to active fixation leads seen over the period in question and the increasing proportion of ICD leads may have influenced the rate of success.

**CONCLUSIONS**

We have shown a progressive improvement in the efficacy of non-laser percutaneous lead extraction over the past decade with a constant high level of safety. The Evolution® Mechanical Dilator Sheath and the Evolution® RL have been shown to be safe, efficient and effective tools when introduced early in the course of CIED lead extraction procedures, particularly with ICD leads.

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**FIGURE LEGENDS:**

**Figure 1**: Trends in the case load and in the indications for lead extraction over the study period and times of introduction of new technology. The graph represents the number of leads extracted in each six-month period of the decade. Leads that could not be extracted percutaneously or were extracted incompletely with a residual fragment of <2cm are represented respectively as a red or yellow marker for each lead. The increased workload of recent years largely reflects the need to extract old leads to create venous access to permit an upgrade to a CRT system and extraction of leads which have failed or carry an advisory.

**Figure 2:** Breakdown by leads extracted in each era by pacing site and fixation mechanism. For each bar graph, the length represents the number of leads in each category, the vertical dimension of each bar is proportional to the mean dwell time of the leads represented by the bar. Throughout the study period, the defibrillation leads encountered were predominantly active fixation models, the other lead types more evenly distributed between active and passive fixation. Dwell time was greater for groups 2 and 3 than for group 1.