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CLINICAL OUTCOMES FOLLOWING TRANSVENOUS LEAD EXTRACTION USING CONTEMPORARY TECHNIQUES

PhD Thesis

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PUBLICATIONS FORMING THE BASIS OF THE THESIS

I. Zsigmond EJ, Miklos M, Vida A, Benak A, Makai A, Schvartz N, Klausz G, Hegedus Z, Bogats G, Saghy L, Vamos M. Reimplantation and long-term mortality after transvenous lead extraction in a high-risk, single-center cohort. J Interv Card Electrophysiol. 2023 Jun;66(4):847-855. doi: 10.1007/s10840-021-00974-4. Epub 2021 Mar 16. PMID: 33723694.

II. Zsigmond EJ, Saghy L, Benak A, Miklos M, Makai A, Hegedus Z, Alacs E, Agocs S, Vamos M. A head-to-head comparison of laser vs. powered mechanical sheaths as first choice and second line extraction tools. Europace. 2023 Feb 16;25(2):591-599. doi: 10.1093/europace/euac200. PMID: 36352816; PMCID: PMC9935030.

1. INTRODUCTION

Transvenous lead extraction (TLE) is the gold standard therapy of cardiac implantable electronic device (CIED) related complications. Despite technological advancements, TLE is still considered a high-risk intervention with potential complications including death. Especially, cases with infection, longer dwelling time and previously failed extraction attempt can be challenging.

The biggest improvement of the TLE toolkit came with the advent of laser and mechanical powered sheaths. These devices have different characteristics; however, there is no recommendation regarding primary sheath selection. The use of diverse techniques may help to achieve more favorable results, although the exact impact of different methods on TLE outcomes remains unclear.

After extraction, reimplantation is not always necessary. However, the effect of reimplantation omission on patient survival is questionable.

Long-term follow-up data after TLE are scarce in the literature. Patients with device infection are thought to have a worse prognosis in general.

2. OBJECTIVES

In our study we wanted to analyze specific questions in the field of TLE with limited supporting data.

2.1. We aimed to investigated population characteristics and procedural outcomes in a tertiary referral Hungarian center, and to find risk factors for extraction failure.

2.2. We wanted to assess the efficacy and safety of different powered sheaths as primary and secondary tools.

2.3. In order to investigate the impact of different techniques on TLE outcomes, we analyzed the cumulative success rate through the levels of the stepwise approach.

2.4. We hypothesized that in appropriately selected patients the omission of reimplantation will not impact negatively long-term outcomes. Therefore, we compared long-term survival between patients with and without reimplantation.

2.5. We aimed to examine all-cause and cause-specific mortality during long-term follow-up after extraction, with a special focus on TLE indication.

3. METHODS

Clinical data were retrospectively collected from consecutive patients undergoing TLE between 2012 and 2021 at the University of Szeged. Indications of TLE were classified as pocket infection, systemic infection and non-infectious indications. Procedural outcomes and complications were defined concordant to international guidelines.

During TLE, a stepwise approach was applied. First, manual traction was performed with a conventional stylet. If this failed, traction was repeated with a locking stylet. The next step involved the use of powered sheaths. A laser or a mechanical powered sheath was used at the decision of the operator. If necessary, a crossover between powered sheaths was executed. Snare technique was used predominantly via femoral approach, to provide support traction or as a bailout extraction technique.

First, we performed descriptive analysis of population characteristics, procedural outcomes and complications.

After this, we analyzed the efficacy and safety of the primary powered extraction sheath, dividing leads into two groups according to powered sheath type (laser or mechanical). The need for crossover was also compared. Subgroup analysis of crossover procedures was performed, comparing outcomes with secondary tools.

We examined the amount of completely extracted leads at each level during the stepwise approach. The extraction process was divided into five levels: extraction without powered tools, primary powered sheath, crossover, bailout snare, and non-emergency surgery.

After extraction, the CIED indication was reassessed and the following decisions were reached: omission of reimplantation due to missing device indication or reimplantation of a device either with same or different properties (upgrade or downgrade). Survival data of patients with and without reimplantation was compared.

All-cause and cause-specific mortality was analyzed during hospitalization, within the first 30 days and during long-term follow-up. Mortality was classified as arrhythmia-related, cardiovascular, and non-cardiovascular. Survival of patients with infectious and non-infectious indications was also compared.

4. RESULTS

4.1. Cohort characteristics and procedural outcomes

Between May 2012 and August 2020 150 patients (66±14 years, 76% male) underwent extraction with 307 leads. Of these patients, 20% (n=30) already had a previous unsuccessful extraction attempt at other institutions. The indication of extraction was mainly infectious (93%, 105 pocket and 35 systemic infection). Dwelling time of the leads was 7.8±6.3 years (median 7 years, IQR 3–11), 69.7% having passive fixation.

In 225 cases (73%) powered extraction sheaths were used (laser in 55.8%, n=172; mechanical dilators in 28.6%, n=88). Snare technic was used in 25.3% (n=78) of the cases.

Complete procedural success was achieved in 87.3% (n=268), clinical success in 90.2% (n=277) of targeted leads. In 3.6% (n=11), residual leads were extracted during elective sternotomy. Minor complications occurred in 18, while major complications in 5 cases (4 superior vena cava injuries, 1 cardiac perforation). After multivariate analysis, lead dwelling time (OR 1.24, 95%CI 1.16–1.33), infectious indications (OR 12.12, 95%CI 2.9–50.63), and atrial fibrillation (OR 8.44, 95%CI 1.87–38.01) remained significant predictors of extraction failure.

4.2. Laser versus mechanical

Between May 2012 and February 2021 142 patients (65.4±13.7 years, 78% male) with 245 leads (dwelling time 9.4±6.3 years) underwent TLE with powered extraction tools. A laser device was used in 64.9% (n=159, 93 patients), a mechanical dilator in 35.1% (n=86, 49 patients) of the leads as primary extraction tool.

The efficacy of the primary extraction tool was not different in terms of complete procedural (85.5% for laser vs. 82.5% for mechanical) or clinical success (91.2% for laser vs. 86% for mechanical). Crossover was needed in a numerically higher percentage in the primary laser group (19.5 vs. 12.8%). However, only longer lead dwelling time (aOR: 1.12, 95% CI: 1.07–1.2) and defibrillation or coronary sinus lead type (aOR: 2.25 95% CI: 1.25–4.04) were found to be significant predictors of crossover.

Major complications occurred in 4.2% (n=6), minor complications in 11.4% (n=16) of the cases, without significant difference between primary laser and mechanical groups. Three procedural deaths were recorded, all in the primary laser arm, one being a crossover procedure.

Crossover was needed in case of 42 leads (31 from laser and 11 from mechanical sheaths). Laser sheaths needed crossover at extracardiac level, while mechanical sheaths

required crossover more often at intracardiac level. Complete procedural success was 80.6% with a secondary mechanical and 54.5% with a secondary laser tool, without significant difference (aOR: 0.16, 95% CI: 0.02–1.22). Secondary mechanical sheaths achieved significantly higher clinical success rate compared to laser devices (87.1% vs. 54.5%, aOR: 0.09, 95% CI: 0.01–0.79). Successful bailout snare rate was numerically higher in the secondary laser group (16% vs. 9%).

4.3. Stepwise approach cumulative success

Outcomes of 166 patients (337 leads) undergoing extraction between May 2012 and February 2021 were analyzed. In case of 92 (27.3%) leads no powered sheath was used. Of these procedures, procedural success was achieved by simple manual traction in 47.8% (n=44), traction with locking stylets in 32.6% (n=30) and with femoral snare in 19.6% (n=18) of the leads. The other 245 (72.7%) leads required the use of powered sheaths. Of these cases, the cumulative procedural success was 64.9% (n=159) with the first-line powered sheath, 75.1% (n=184) after crossover, 84.5% (n=207) with bailout femoral snare and 91.8% (n=225) after non-emergency surgery.

4.4. Reimplantation

Data on reimplantation were accessible for 94 (62.7%) patients who underwent TLE between May 2012 and August

2021. Seventy-five (79.8%) patients underwent a reimplantation: 61.7% (n=58) received a device with the same functions, in 13.8% (n=13) a downgrade, while in 4.3% (n=4) an upgrade procedure was performed. In 20.2% (n=19) of the patients, no new device was reimplanted, the most common initial indication being sick sinus syndrome. Long-term survival did not differ significantly between patients with and without reimplantation (HR: 1.09, 95%CI 0.46-2.57).

4.5. Short- and long-term survival

Mortality data were analyzed in 150 patients undergoing TLE between May 2012 and August 2021.

Periprocedural death occurred in 3 patients (2%). These patients already have experienced a failed extraction attempt at referral institutions and underwent TLE due to infectious indication. One death occurred during the 30-day follow-up due to overwhelming sepsis.

The mean follow-up time was 3.5±2.4 years, 44 (29.3%) patients died. There was no significant difference in survival of patients with different TLE indications. However, patients with infection tended to have poorer survival (HR 4.5, 95%CI 0.62–32.71). On multivariate analysis, deteriorated kidney function (aHR 1.01 95%CI 1.00-1.01) and major complications during TLE (aHR 6.36, 95%CI 1.76-22.96) were identified as predictors of mortality.

Cause-specific mortality was available in 30 cases of the 44 deaths. There was no death related to arrhythmia. The majority of the deaths were related to non-cardiovascular causes (59%), while heart failure was present in 33% of the cases.

5. CONCLUSIONS

5.1. Despite high-risk characteristics, we report favorable success and low complication rate. Dwelling time, infectious indications and atrial fibrillation were identified as independent predictors of extraction failure.

5.2. We observed no significant difference between the safety and efficacy of primary laser and mechanical sheaths. In crossover subgroup mechanical tools achieved a numerically higher procedural and significantly higher clinical success rate.

5.3. A quarter of targeted leads could be extracted using simple methods, while the remaining cases required advanced extraction techniques.

5.4. In one-fifth of the patients reimplantation was omitted and in another one-fifth an upgrade or a downgrade was necessary. Reimplantation status had no negative effect on long-term survival.

5.5. No significant difference was found in long-term survival of patients with different TLE indications. The analysis was underpowered by low patient number in the non-infectious group. Deteriorated kidney function and major complications were predictive for mortality.