Implementation of laser equipment in a center experienced in lead extraction: safety and efficacy within 1-year follow-up

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INTRODUCTION

As the use of cardiac implantable electronic devices (CIEDs) increases, so does the number of indications for their removal. Advancements in transvenous lead extraction (TLE) have brought physicians to use a variety of methods, including laser-assisted lead extraction (LALE) [1, 2].

The LALE procedure offers a potentially higher efficacy and the complication rate comparable to other TLE techniques. However, implementation of a new method is always associated with the risk of complications (learning curve) even in experienced teams [3].

METHODS

In this single-center registry we evaluated the safety and efficacy of LALE in our center that is highly experienced in TLE using a mechanical telescopic sheath. The study period involved two parts: June 27, 2009 through November 26, 2011, when the equipment was rented, and January 5, 2018 throgh January 29, 2019, when it was bought. It was a retrospective, observational study, and patients were treated according to the guidelines, hence there was no necessity to obtain consent from patients to take part in the study, nor to gain the approval of the Ethics Committee [1, 4]. All patients admitted to the hospital were eligible for TLE on elective judgement or as a bailout.

Before the surgery, informed written consent for the procedure was obtained, blood samples were collected for basic laboratory tests and for securing blood in case of transfusion, and also chest X-rays were taken in all patients. Transthoracic echocardiography (TTE) exams were performed using the GE *Vivid 6* on admission in the echocardiography examination room and during the procedure, with sterile probe cover, in the electrophysiology room. TLE surgeries were performed in the electrophysiology room equipped with high quality stationary fluoroscopy and medical gas supplies where in case of emergency on-site rescue procedures can be implemented. The cardio-surgical and anesthetic back-up, as well as transesophageal echocardiography were immediately available. Basic vital signs (heart rhythm, blood pressure, pulse oximetry) were continuously monitored during the procedure and for at least 4 hours after surgery. Transvenous temporary pacing lead was inserted through the femoral vein, if needed. LALE was the technique of choice, although conversion from mechanical extraction was necessary in 5 cases. The extraction technique is described in Supplementary material.

Endpoints were classified according to the guidelines [1, 4]. Complete procedural success was defined as the removal of all targeted leads from the vascular space, without any permanently disabling complications or procedure-related deaths. Clinical success in cases in which a small portion of the lead (less than 4 cm) remained in a vascular space and is not detrimental to the clinical outcome. Failure was defined as the inability to achieve either complete procedural or clinical success, or the occurrence of a major complication or procedure-related death.

Statistical analysis

Continuous variables are expressed as median values and 1st and 3rd quartiles (Q1–Q3) and categorical data are reported as frequencies and percentages. Statistics were completed using Statistica 13 software (Statistica, TIBCO Software Inc., Palo Alto, California, USA). The groups were compared using the Mann–Witney U test (W Shapiro–Wilk test showed non-nor-

mally distributed data), and a P <0.05 was considered to be significant.

RESULTS AND DISCUSSION

Laser-assisted lead extraction procedures were performed in 33 patients (24 men) at a median age of 64 years (57–74). We attempted to remove 49 leads. Detailed patient, lead and device characteristics are described in *Table S1* and *Table S2* in Supplementary material. Indications for lead extraction were: lead failure (15 [45.5%]), pocket infection (9 [27.3%]), cardiac device-related infective endocarditis (CDRIE) (5 [15.2%]), elective lead replacement (2 [6%]), and dislocation of the lead (2 [6%]).

Clinical success was achieved in 31 (94%) patients, whereas complete lead removal was achieved in 92% of lead extraction (45 leads). Complete procedural success appeared in 30 (91%) patients. TLE failure occurred in 3 patients with a dual-chamber pacemaker and was caused by inability to remove targeted leads from the vascular space in 2 cases and procedure-related death in 1 case. As a result, we noticed 4 failures of lead extraction (8%) in 3 patients. The mean lead dwell time of the failed extraction leads was 13.6 years (163 months [9–17 months]). The clinical success of the first 2 cases was confirmed during follow-up, and overall clinical success was 97% (32 out of 33 patients).

In-hospital complications related to procedure were divided, according to guidelines, into major (including death in 1 [3%] patient and cardiac avulsion in 2 [6%] patients) and minor (pericardial effusion not requiring surgical intervention in 2 [6%] patients and blood transfusion related to blood loss during surgery in 1 [3%] patient) [1, 4].

In 4 cases, a second procedure in the same patient was necessary to achieve procedural success, and in one situation, surgical removal of the lead was necessary.

It is worth noting that the last 9 out of all patients who underwent LALE did not have any complications. Those procedures were performed after purchase of the laboratory's own laser generator and after implementing the rule that a laser sheath was used only if the locking stylets reached the tip of the lead. Another factor that could have influenced that observation was the team's experience which had increased since the first use of LALE procedures.

During the follow-up, 11 out-of-hospital deaths were reported. There were three deaths between first and twelfth months after the procedure. The median time of death after 1 year was 53 months (range, from 17 to 86 months).

We performed an analysis of all-cause mortality, and the patients who died were older and had higher creatinine levels (Table 1).

The demographics, lead data, groups of indications for TLE are mostly comparable with other studies; however, there were some differences, for example the number of patients with pacemakers (45.4% vs 70%) [5, 6]. Also proportions of certain indications were different. In our study, the main indication for TLE was lead failure. The ELECTRa registry shows the same frequency of infectious and noninfectious indications in Europe [7]. Similarly, in the study by Ząbek et al. [8], both CDRIE and pocket infection together did not account for 20% of TLE indications.

In our study, the clinical success was achieved in 94% of cases, while Kennergren et al. [6] achieved an efficacy of 97.6% leads. Wazni et al. [9] described efficacy of 92.2% in operated patients, while Byrd et al. [10] reported complete success in 90% of leads. In our study, the mean lead dwell time was 150 months. In other studies it was much shorter, e.g. 91 months [6]. Byrd et al. [10] observed that removal of lead implanted more than 10 years prior to the procedure was a predictor of procedural failure. Kennegren et al. [6] also reported that a longer time from implanta-

Table 1. Comparison of survivors and non-survivors in the studied patients

	All-cause one-year mortality		
	Deaths (n = 13), median (IQR)	Alive (n = 20), median (IQR)	*P* value
Age, years	68 (64–77)	59.5 (50.5–70)	0.02
BMI, kg/m^2	25 (24–28)	28 (24.5–30.5)	0.12
WBC, k/µl	8.1 (6.3–8.9)	7.9 (6.7–9.1)	0.87
RBC, M/µl	4.3 (3.4–4.7)	4,5 (4.2–4.8)	0.74
Hemoglobin, mmol/l	8.4 (8.0–8.9)	8.9 (7.9–9.4)	0.59
Hematocrit, %	41.5 (37–43)	41.8 (38–44)	0.99
Platelets, K/µl	188.5 (161–219)	201 (172–245)	0.25
CRP, mg/l	7.8 (1.3–16.1)	4.7 (1.4–17.2)	0.84
Creatinine, µmol/l	122 (93–135.4)	90.1 (74.6–124.8)	0.03
LVEDD, mm	50 (43–70)	53.5 (47–58)	0.95
LA, mm	48.5 (39–52)	44.5 (38–47)	0.13
Ejection fraction, %	45 (25–60)	55 (35–60)	0.20
Age of the lead, years	7 (4–15)	8 (6–10)	0.91
Age of the oldest lead, years	7 (4–15)	8 (6–10)	0.57
Age of all extracted leads, years	14 (5–17)	9.5 (7–16.5)	0.61

Abbreviations: IQR, interquartile range; BMI, body mass index; CRP, C-reactive protein; eGFR, estimated glomerular filtration rate; LA, left atrium dimension; LVEDD, left ventricular end diastolic diameter; RBC, red blood cell count; WBC, white blood cell count

tion to removal was associated with a higher incidence of procedure failure, although it did not reach a level of statistical significance.

In the presented study the rate of major complications was 6%, while in other studies it ranged from 4% in the Wazni et al. [9] study, through 2.5% in the laser group in the PLEXES trial [11], through 2.1% in the Byrd et al. [10] study, to 1.7% in the ELECTRa Registry [7].

The analysis of all-cause mortality shows that older age and a higher creatinine level are predictors of a worse outcome of TLE. This result is similar to the study by Brunner et al. [12]. Also Jacheć et al. [13] demonstrated that heart failure, chronic kidney disease, and pacemaker infections together with minor complications influenced 30-day mortality.

CONCLUSIONS

It is unlikely to prove that introducing new procedures like the new method of lead extraction is safe and effective. The implementation of new surgical methods should be initiated in centers that are already highly experienced, and which initiate contemporary practice. It is important to apply a risk-benefit analysis, especially in patients with class II TLE indications, taking into consideration risk factors such as older age and kidney impairment, which are proven to worsen outcomes of patients after TLE.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/kardiologia_polska.

Article information

Conflict of interest: None declared.

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