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Transvenous Lead Extraction of Cardiac Implantable Electronic Devices Indications, Complications and Outcome: An Egyptian Two Years' Experience

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Abstract

BACKGROUND: The growing needs to extract cardiovascular implantable electronic devices warrants the need to improve the outcome and prevent complications.

AIM: This study aims to analyse the findings and identify factors associated with complications of Percutaneous Transvenous Lead Extraction in the Critical Care Department, Cairo University.

METHODS: We studied 52 candidates for Percutaneous Transvenous Lead extraction of a Permanent Pace Maker (PPM) regarding extraction indications, comorbidities, device type, complications and outcome. Extraction was first attempted by simple manual traction using regular non-locking stylet and if failed, locking stylet, and evolution dilator sheath were used.

RESULTS: We extracted 110 leads with a mean lead age of 4.67 ± 3.6 years. The most common extraction indication was an infection (71.15%). Indications correlated significantly with comorbidities ($p = 0.024$), the most common being Diabetes Mellitus (40.38%). Simple traction was successful in 31 % of the leads, while 69% were extracted using locking stylet and evolution dilator sheath. The method of lead extraction correlated significantly with lead age ($P \leq 0.001$). Complications were significantly higher with extraction by evolution dilator sheaths than by simple traction ($P = 0.003$) and in older patients ($P = 0.008$). Complications also correlated significantly with extractions indications ($p = 0.012$), type of PPM ($P = 0.037$), number of extracted leads ($P = 0.041$), and lead age ($p= 0.011$).

CONCLUSION: Among the studied variables, extraction indications particularly infection, was the only preventable factor significantly associated with complications. While focusing on preventable factors, improving, implantation and extraction techniques should also be addressed.

Introduction

In recent years, the number of Cardiac Implantable Electronic Device (CIED) complications has increased as a result of the increasing implantations. Concomitantly a rise in lead malfunctions and recalls accompanying the complex CIED procedures in high-risk patients has resulted in increased Transvenous Lead Extractions (TLE) [1], [2], [3], [4], [5]. Lead extraction is by far a complex procedure as it carries some risks for the patient [6], [7].

Age, sex, body mass index, lead implant duration, number of leads, even small calcifications or fibrosis along with the lead, venous thrombosis, systemic infection, presence of large vegetations, pacemaker dependency, and physical characteristics of the lead, e.g. intrinsic fragility are all factors associated with increased procedural risk. Infections, lead malfunction, actual or potential lead failure, interference between multiple leads, lead-induced life-threatening arrhythmias, lead interference with malignancy treatment, chronic pain and subclavian vein/superior vena cava thrombosis are clinical situations most commonly requiring lead extraction to be completely alleviated [6], [7].

Methods

From March 2016 to February 2018, 52 candidates for percutaneous Transvenous Lead Extractions (TLE) of Cardiac Implantable Electronic Devices (CIED), were enrolled in a prospective study conducted in Critical Care Department in Kasr Al-Ainy Hospital, Cairo University, Egypt. We aimed to analyse the findings and identify factors associated and can be predictive of complications of Percutaneous Transvenous Lead Extraction.

Patients were enrolled in the current study according to the Heart Rhythm Society (HRS) indications (2009) for lead extraction classes I & IIa [7]. All patients had undergone full medical history taking, body mass index (BMI) assessment, recording of indication, type, and functional status of CIED and indication of lead extraction. All patients were also subjected to full clinical examination & investigations in the form of full laboratory tests including blood culture and sensitivity, wound swab and blood typing, 12-lead surface ECG, Chest x-ray, Trans-thoracic echocardiography (TTE). Transesophageal echocardiography (TEE) was performed in every patient with suspected CIED-related infection to assess vegetations' place and size if present (Figure 1).

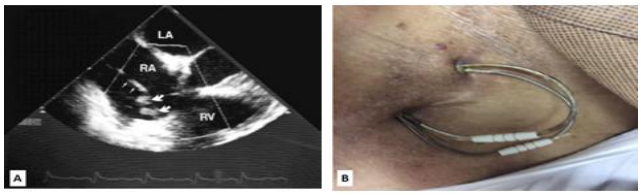

Figure 1: A patient with infective endocarditis secondary to pocket infection. A: TEE showing two large masses (bold arrows) attached to the pacemaker lead, B: A closed sinus of infected pocket and leads extrusion before extraction in our study

Lead extraction procedure

Following the induction of anaesthesia, proper skin preparation and sterile draping of the patient, a Temporary Pacing Lead was placed in the right ventricle via the right femoral vein. Invasive arterial blood pressure monitoring was connected via the right radial artery. Local anaesthesia and incision at the site of the pocket were done under deep sedation and analgesics. Extraction of the battery was done if present. Stylet wires were used to stiffen leads for removal and minimising the chance of lead breakage during traction and assist sheath advancement, which results in the extraction of a greater amount of intact lead. *Simple traction* Technique was initially tried for all patients in which manipulation of the lead was done so that the lead exits the vasculature via the implant vein using tools typically supplied for the lead implant, with the addition of traction. If the simple traction failed, traction with the help of Locking stylets and Evolution mechanical dilator sheath was attempted. A locking stylet is a special type of a traction device, designed to hold onto the inside of the conductor coil along its length or near the distal stimulating electrode. It improves the tensile properties and prevents elongation of the lead body during traction. We used Liberator *(Cook Vascular)* locking stylet.

Finally, after extraction of all leads, complete removal of all granulation tissue and necrotic material was done with adequate haemostasis and closure of the wound by properly interrupted suture.

Patients were kept postoperatively in the Cardiac Care Unit (CCU) under strict monitoring of vital signs, haematocrit and other labs with the adequate replacement of any blood loss during or after the procedure. Post-procedure chest X-ray & TTE were done within a few hours to detect any complications of TLE, *e.g. pericardial effusion*. Proper antibiotic therapy was instituted, and revision of the need for CIED reimplantation was done.

Procedure success was classified as; (1) Complete procedural success: if all targeted leads and lead material were removed from the vascular space, (2) Clinical success: if all targeted leads and lead material was removed, but with retention of a small portion of the lead that does not negatively affect outcome goals, or (3) Failure: if neither complete procedural nor clinical success could be achieved[(7)]. Complications were classified into *Intraprocedural*: Any event related to the performance of the procedure that occurs or becomes evident in the Cath. Lab. *Postprocedural:* Any event related to the procedure that occurs or becomes evident within the 30 days following the procedure. Events are classified as major or minor according to severity: *Major complications:* Those that create a life-threatening situation or require a major intervention for their resolution or result in death, e.g. cardiac avulsion and vascular tear requiring surgical repair. Then *Minor complications:* not life-threatening, but require an intervention, such as medication, for their resolution, e.g. pericardial effusion not requiring pericardiocentesis.

The study was approved by the ethical committee of the critical care department, Cairo University. Written informed consent was signed by the patient or his/her family.

Statistical Analysis

Data were coded and entered using the statistical package SPSS (*Statistical Package for the Social Sciences*) version 24. Data were summarised using mean, standard deviation, median, minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. Comparison between quantitative variables was made using the non-parametric Kruskal-Wallis and Mann-Whitney tests [8]. For

comparing categorical data, Chi-square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5 [9]. P-values less than 0.05 were considered as statistically significant.

Results

In total, 52 patients were included in our study; the baseline characteristics were shown in Table 1. Thirty-one males (59.6%) and 21 females (40.4%) with a mean age of 53.5 ± 14.1 years, the mean left ventricular ejection fraction (LVEF) was 51.7 ± 13.4%. The mean Body Mass Index (BMI) was 26.04 ± 3.95. Indications for TLE were infective in 37 patients (71.15%) and non-infective in 15 patients (28.85%). A total of 110 leads were extracted via the venous entry approach from 52 patients with a mean number of leads extracted per patient was 2.1. They included 106 pacing leads (96.36%) and 4 shock leads with dual coils (3.64%).

Table 1: Demographic and descriptive characteristics

Item		Number (%)
Age (mean)		53.56 ± 14.12
Sex	Male	31 (59.6%)
	Female	21 (40.4%)
Left Ventricle EF%		51.73 ± 13.47
Body Mass Index (mean)		26.04 ± 3.95
Indications	Infective indications	37 (71.15%)
	Pocket infection	26 (50%)
	Infective Endocarditis	11 (21.15%)
	Non-infective indications	15 (28.85%)
	Lead malfunction	7 (13.46%)
	Lead displacement or extrusion	5 (9.61%)
	Upgrading	3 (5.76%)
Type of implanted device	DDD	33 (63.5%)
	CRT-P	10 (19.2%)
	CRT-D	4 (7.7%)
	VVI	5 (9.6%)
Leads implanted	Total	110
	Active fixation	88 (80%)
	Passive fixation	22 (20%)
	Atrial leads	44 (40%)
	RV leads	48 (43.64%)
	Coronary sinus	14 (12.73%)
	Shock leads	4 (3.63%)
Extraction Technique	Simple traction	34 (31%)
	Evolution traction	76 (69%)
Mean implant duration (years)		4.67 ± 3.61
Mean procedure duration (minutes)		81.73 ± 38.4

Fixation mechanisms did not affect the method of TLE and its outcome. The method of the lead extraction showed a statistically significant relationship with the lead implant duration *(P-value < 0.001)* as shown in Table 2, where simple traction was more successful with shorter lead age. Also, the longer the leads' age, the longer was the procedure duration with a *P-value of < 0.001*.

Table 2: Method of extraction vs lead age

	Method of extraction				P-value
	Simple Traction		Evolution		
	Mean	SD	Mean	SD	
Lead age (years)	1.53	1.80	6.48	3.11	< 0.001

In our study, complications of TLE occurred in 28 patients (53.8%) and most of them were minor complications and managed conservatively and only one major complication (subclavian vein tear) which required surgical repair by a vascular surgeon.

The most common complication was hematoma formation in the pocket site (21.1%) and managed by proper compression and medical treatment after vascular surgery consultation. Patients with mild and moderate pericardial effusion (26.9%) were managed conservatively without the need for tapping. In our study, the rate of occurrence of complications was more in older age with a *P-value 0.008* where the mean age in the complicated patients was 58.43 ± 11.1 years, and the mean age in the non-complicated patients was 47.88 ± 15.25 years. The rate of complications showed statistically significant difference according to the method of extraction where complications were more in Evolution method with a P-value 0.003, as shown in Table 3.

Table 3: Complications

Parameter		Complications		P
		yes	No	
Extraction indications	Pocket Infection N (%)	14 (53.8%)	12 (46.2%)	0.012
	Infective endocarditis N (%)	10 (90.9%)	1 (9.1%)	
	Upgrade to ICD N (%)	1 (50.0%)	1 (50.0%)	
	Upgrade to CRT-D N (%)	1 (100%)	0 (0%)	
	Not connected old Lead extrusion N (%)	0 (0%)	1 (100%)	
	Malfunctioning RV lead N (%)	1 (20.0%)	4 (80 %)	
	Malfunctioning atrial lead N (%)	0 (0%)	2 (100%)	
	Lead displacement N (%)	1 (25.0%)	3 (75.0%)	
Patient's Age (Mean± standard deviation)		58.43 ±11.19	47.88±15.25	0.008
Lead Age (Mean± standard deviation)		5.73 ± 3.47	3.44 ± 3.44	0.011
Method of extraction	Simple Traction N (%)	5 (26.3%)	14 (73.7%)	0.003
	Evolution Method N (%)	23 (69.7%)	10 (30.3%)	
Type of PPM	VVI N (%)	2 (40.0%)	3 (60.0%)	0.037
	DDD N (%)	14 (42.4%)	19 (57.6%)	
	CRT-P N (%)	8 (80.0%)	2 (20.0%)	
	CRT-D N (%)	4 (100.0%)	0 (0 %)	
No. of extracted leads	1 N (%)	4 (36.4%)	7 (63.6%)	0.041
	2 N (%)	11 (44.0%)	14 (56.0%)	
	3 N (%)	12 (80.0%)	3 (20.0%)	
	4 N (%)	1 (100%)	0 (0%)	

The number of extracted leads was directly proportional to the occurrence of complications with a *P-value 0.041*. There was a statistically significant difference regarding the occurrence of complications and the type of CIED and the extracted leads *(P-value 0.037)*, where the percentage of complications in the form of subclavian vein tear, pericardial effusion and hematoma formation was more with extraction of shock leads in CRT-D devices due to presence of large and thick fibrous bands at shock lead binding sites, e.g. SVC coil as shown in Table 3. Our study showed that longer lead implant duration (lead age) reflects a higher incidence of complications of TLE with a *P-value 0.011,* as shown in Table 3.

Regarding procedure success, clinical success was achieved in all patients (52 patients) while complete procedure success (radiological and clinical) was achieved in 48 patients (92.3%) where a retained part of RV lead occurred in 4 patients (7.7%) and did not affect the patient outcome.

Discussion

In a European survey conducted by the European Heart Rhythm Association (EHRA) in 2012, the success rates and complications of TLE techniques showed that TLE was still under-developed across European countries with divergent practices between centres [3], [10]. *In our Critical Care Department, Cairo University*, the rate of CIED implantation increased over the years. This increase in rate was associated with increased risk of complications requiring TLE, especially with multiple generator replacements.

Many studies have been done in the last 10 years on CIED lead extraction techniques. Regarding indications of TLE, the most common indications of extraction in our patients were infection in 71.15% of patients (50% local and 21.15 % lead vegetations) while indications were non-infective in 28.85% of patients. In agreement with our study, *Andrzej et al.,* [11], also found that the most common indication for TLE was an infection. Similarly, indications of extraction in *Stylianos P et al.,* [12] study was an infection in 69.4% of the patients and led dysfunction in 30.6% of the patients. While in the EHRA survey 2012, the infection was the indication in 70% of the patients and non-infective indications in 30% of the patients [10]. In ELECTRa, the infection was the indication in 52.8% of the patients and non-infective indications in 47.2% of the patients [10]. On the other hand, in *Oto et al.,* [13] study in Turkey, the indications for lead extraction were primarily due to lead malfunction in 65.2% of the patients, cardiac device infection only in 30.4% of the patients and lead displacement in 4.4% of the patients.

In our study, there was no effect of lead fixation mechanisms on the method of extraction or the outcome of the procedure, only the *Andrzej et al., the* study stated that modern leads with active fixation could be easily extracted by traction [11].

The method of lead extraction showed a statistically significant relationship with the age of the lead (P-value < 0.001). The more the age of lead implantation; the more the difficulty of extraction by simple traction technique and the leads were extracted by locking stylet and evolution dilator sheath.

In *Andrzej et al*., [11] study, 19.5% of leads were removed by simple traction while other leads (80.5 %) were removed using the Lead Extraction System with the rotational cutting force only, with no laser or RF energy. In three cases in which breakage of the lead occurred, the remaining part of the broken lead was removed via a femoral approach.

Byrd et al., [14] reported that incomplete / failed extraction was more likely to occur in younger patients as the extent and quality of the scar tissue formed around the leads are inversely related to the age. However, our study failed to express this relation as younger patients were not significantly represented in our cohort (P-value 0.171).

In our study, older leads were associated with significantly prolonged procedure time compared to other leads (P-value < 0.001) and associated with a higher incidence of complications of TLE with a *P-value 0.011* with no effect on patient outcome. However, *Stylianos et al., a* study [12], [15] noted that lead age per se did not hurt lead extraction success rate or occurrence of complications.

Regarding complications of TLE, they occurred in 28 patients (53.8%) and most of them were minor complications and managed by conservative measures, the most common was hematoma formation (21.15% of patients), mild and moderate pericardial effusion and retained parts of leads and only one major complication (1.9% of patients) in which subclavian vein tear occurred and required surgical repair by a vascular surgeon. In *Andrzej et al., a study* [11], major complications occurred in 4 % of patients in the form of massive pericardial effusion, massive pulmonary embolism and papillary muscle rupture. While in *Oto et al.,* [13] study, minor complications occurred in 4.3 % of patients in the form of a hematoma. While in the *EHRA survey* [10], all 81 centres revealed major complications in their experience, where 10% of the centres experienced a death rate of 0.5-2% of patients. Other major complications like massive pericardial effusion requiring pericardiocentesis, vascular avulsion and hemothorax requiring chest tube, occurred in about 1-5 % of patients in all centres. In our study, the rate of occurrence of complications showed a statistically significant relationship with the type of CIED and the extracted leads *(P-Value 0.037),* where complications in the form of moderate pericardial effusion, subclavian vein tear and hematoma formation were more with the extraction of shock leads in CRT-D devices.

Our procedure success rate was high and comparable to other centres and in comparison, with the other studies, our rate and type of complications were relatively less, in spite of the relatively new experience of different methods of extraction in our department and restricted budget. This was most probably attributed to the good patient preoperative preparation and the skilled operator technique who was trained in a large centre of extraction in Europe.

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