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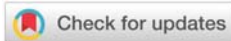
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Research Article

Interdisciplinary stepwise approach for an effective and safe Mechanical Transvenous Lead Extraction

Abstract

Aims: Mechanical force applied during leads removal is the main cause for major complications and cardiovascular injuries. Aim of this study was to retrospectively analyse safety and effectiveness of a stepwise interdisciplinary approach for mechanical transvenous lead extraction.

Methods: From February 2011 to December 2017, 71 patients (pts) underwent electronic leads extraction for Cardiac Implantable Electronic Devices (CIED) complications. Mean age was 70±11 years (range 34-92). A total of 160 leads were managed with a mean time from implantation to extraction of 33±39 months (range 4-300). Lead type were atrial (37%), Ventricular (49%) and Coronary sinus (14%). Indication for lead removal were pocket/lead erosion (73%), isolated lead infection (10%), dysfunction or upgrading (17%), respectively. Data on algorithm of treatment, procedural success, complications as well as 30 day mortality are reported.

Results: There were 152 leads extracted (95%) for a complete procedural success (CPS) in 90%, clinical success (CS) in 8.5%, and failure in 1.5% of pts, respectively. Associated procedures were aortic valve replacement (AVR) in 1 pt and AVR plus tricuspid valve repair in 1 pt. No major complications or cardiovascular injuries were detected whereas hemopericardium was reported in 2 pts and pocket bleeding in 1 pt, respectively. There were 3 in-hospital deaths (4.2%), but no one of them were procedure-related.

Conclusion: In our clinical experience we demonstrated that mechanical transvenous lead extraction is a safe and effective procedure also in small volume center providing that an interdisciplinary heart-team stepwise approach is applied.

Introduction

In the recent years, the extensive indications for cardiac electronic device implantation (CIED), has increased the probability to face with device-related complications during clinical practice [1]. Electronic system malfunction (device failure, lead fracture, contact defects), may represent a minor reason for complete or partial revision or replacement of components itself [2]. Nevertheless, large observational studies has shown that the incidence of infection is 1-7 % [3-5], being the most common indication for both device removal and lead extraction [6]. CIED infection significantly increases not only the number of hospitalizations but the risk of in-hospital death by more than 2-folds [7]. Therefore, prompt diagnosis and tailored therapeutic approach is mandatory for adverse outcome prevention, particularly for implantable cardioverter-defibrillators (ICDs) which have a higher rate of infection if compared with pacemakers (PMs) [8]. Despite explantation is not required for superficial or incisional

infection at the pocket site, complete removal of all hardware is the recommended procedure for patients with established device or lead infection [9]. However, extraction manoeuvres are still challenging, particularly in chronically implanted leads, with reported associated morbidity and mortality mainly ascribed to mechanical force applied during isolation procedures [10]. Accordingly, to reduce complications, several electronic extraction tools has been delivered by industry either employing electrosurgical dissection or laser energy which have led to an increase of procedural costs but with debatable clinical advantage when compared with mechanical approach [11,12]. In this paper we retrospectively analysed the effectiveness and safety of a multidisciplinary approach for mechanical lead extraction through the employment of our departmental algorithm of treatment.

Methods

From february 2011 to december 2018, 71 patients (pts) underwent electronic leads extraction for CIED complications.

Clinical characteristics of the whole group of pts are summarized in table 1. The main cause was pocket erosion and/or infection of both the device and the leads which was responsible for 83% of indications. All the pts were treated in operating theatre by a heart team including 2 electrophysiologists, 1 surgeon and 1 anesthetist. Surgical stand-by was contemplated for all the pts and a nurse's team for urgent sternotomy or thoracotomy was always arranged during the leads removal. On the base of the technical complexity and pts compliance, 63% of the procedures were performed under local analgesia and smooth sedation, whereas general anaesthesia and intubation were

employed in the latter 37%. Electronic devices (ICDs or PMs) were explanted in all the pts along with capsulectomy when the pocket site infection or erosion was detected. A total of 160 leads were managed for removal and all the extraction procedures were performed by transvenous approach.

Procedural description and stepwise approach

A subclavian approach (SCA) was used in all the patients. Once the pocket device was entered and the electronic system removed, the leads were untwisted and freed from the scar wrapping, using diathermy, in order to align every single catheter with the emerging point from subclavian vein. Figure 1 shows the algorithm we used as a step by step systematic approach. Before to initiate the extraction procedure, any active fixation system was unscrewed with a metallic clamp. All the pin-heads were cut, a thin stylet inserted into the lumen and a gentle traction applied for lead removal. This method was rarely effective, usually only in recently implanted leads or in active bacterial endocarditis. In almost all the leads the employment of a locking stylet (Liberator[®], Cook Medical, IN, USA) was necessary to anchor the lead-head just to avoid the risk for electronic catheter uncoiling. This method was most effective in terms of extraction probability because it allowed to tug on the lead structure reinforced by an inner metallic core. In the majority of cases a mechanical non-powered sheath (Byrd Dilator Sheath[®], Cook Medical, IN, USA) was necessary to unbridle the external catheter surface from the adhesions with the vein endothelium. Correct handling allow to apply counteraction keeping both the lead and the polypropylene pipe aligned with the subclavian vein and advancing the sheath through a rotational spinning motion. In case of missing success in a further step, a mechanical dilator powered sheath (Evolution[®], Cook Medical and Limerick Ireland) was used. This method was usually added when advancement beyond the junction between innominate vein and vena cava was impossible. When subclavian approach was unsuccessful a femoral snare approach (FSA) was performed using either the Lassos[®] or Catcher[®] device.

Table 1: Patients' clinical characteristics.

Patients number	71	
Demographics		
Age (years)	70±11	(range 34-92)
Gender	♂ 58	(81%)
	♂ 13	(19%)
Heart disease diagnosis		
Idiopathic DCM	21	(29.6%)
Ischemic DCM	16	(22.6%)
CAD	6	(8.5%)
Idiopathic complete A-V block	16	(22.6%)
SSS	9	(12.5%)
Brugada	1	(1.4%)
Congenital A-V block	1	(1.4%)
Ventricular tachycardia	1	(1.4%)
Left ventricular function		
Mean LVEF (%)	42±14	(range 22-64)
LVEF <30%	12	(17%)
LVEF 30-50%	30	(42%)
Associated pathologies		
COPD	11	(15.5%)
CRF	26	(36%)
Hemodialysis	1	(1.4%)
IDDM	6	(8.4%)
PVD	7	(9.8%)
Previous procedures		
PCI	4	(5.6%)
CABG	5	(7%)
Mitral valve surgery +/- CABG	2	(2.8%)
Aortic valve surgery	2	(2.8%)
Endocardial cushion defect	1	(1.9%)
Indication for lead removal		
pocket/lead erosion (w/o infection)	52	(73%)
lead infection (w/o BE)	7	(10%)
dysfunction or upgrading	12	(17%)

DCM= Dilative Cardiomyopathy; CAD= Coronary Artery Disease; A-V= Atrio-Ventricular; SSS= Sick Sinus Syndrome; LVEF= Left Ventricular Ejection Fraction; COPD= Chronic Obstructive Pulmonary Disease; CRF= Chronic Renal Failure; IDDM= Insulin Dependent Diabetes Mellitus; PVD= Peripheral Vascular Disease. PCI= percutaneous coronary intervention; CABG= coronary artery bypass grafting; BE= bacterial endocarditis.

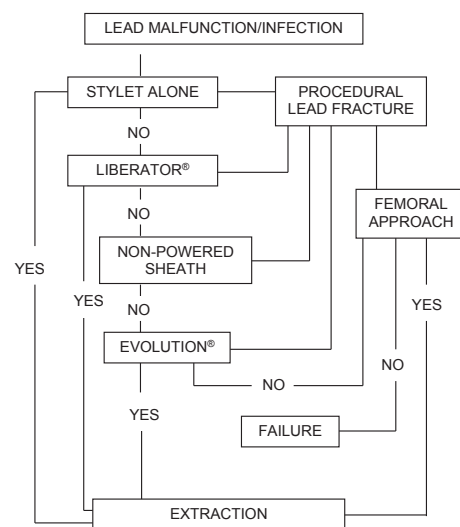


Figure 1: Stepwise approach for lead extraction.

On the base of the definitions of the Heart Rhythm Society expert consensus on transvenous lead extraction, complete procedural success (CPS) was characterized as removal of all material confirmed by fluoroscopy whereas clinical success (CS) was determined by removal of all targeted leads and lead material or partial retention that did not negatively affect the outcome goals of the extraction procedure [13].

Statistical analysis

All the values reported are expressed as mean ± standard deviation.

Results

The extraction procedures were managed through a SCA in 97% of cases. Leads demographics and results are listed in table 2. Range time from lead implantation to removal was extremely wide being from 4-months to 25 years. Leads type are identified as atrial or ventricular either implanted for pacing or ICD purposes, whereas only a minority of pts (14%) had a coronary sinus lead. Active lead fixation was prevalent (57.5%). In the majority of leads (96%), a locking stylet was necessary for catheter anchoring. Mechanical sheath were employed in a sequential approach, either non-powered or powered, in 82.5% and 30% of extractions, respectively. Only a minority of leads (3%) extractions need a conversion to FSA. Globally there were 152 leads extracted (95%) with a mean of 2.1 leads per pt. Successful of extraction ranged between 93-97% in all

Table 2: Leads demographics and results.

Total leads number	160	
Mean time from implantation (months)	33±39	(range 4-300)
Lead type, n (%)		
Atrial	59	(37%)
Ventricular PM	43	(27%)
Ventricular ICD	35	(22%)
Coronary Sinus	23	(14%)
Lead fixation, n (%)		
active	92	(57.5%)
passive	68	(42.5%)
Transvenous tools		
Stylet (direct extraction)	4	(2.5%)
Liberator ®	154	(96%)
Non-powered mechanical sheath	132	(82.5%)
Evolution ®	48	(30%)
Lassos/Catcher ®	5	(3%)
None (left in place)	2	(1.2%)
Successful lead extraction, rem./tot. (%)		
Atrial	55/59	(93%)
Ventricular PM	41/43	(95%)
Ventricular ICD	34/35	(97%)
Coronary Sinus	22/23	(95%)

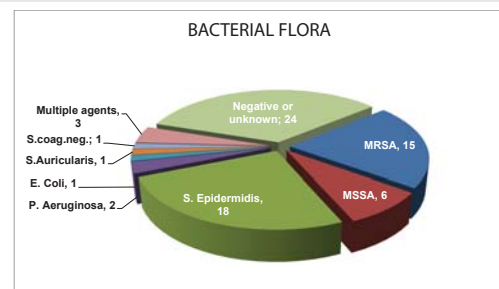
PM= pace-maker; ICD= implantable cardioverter defibrillator; rem= removed leads; tot= subgroup leads number; PM= Pace-Maker; ICD: Implantable Cardioverter Defibrillator.

the leads subgroups considered. Bacterial flora was identified in roughly 66% of pts as showed in figure 2. In the remaining 34% of pts, bacterial cultures were negative or unknown due to antibiotic treatment success or different causes of system failure out of infection.

Procedural data, mortality and complications are listed in table 3. Procedural success was complete in 90% (CPS) and partial in 8.5% (CS) of pts treated. There was only 1 complete failure of the extraction procedure with impossibility to remove any of the 2 leads.

In 2 pts leads infection was associated to an acute bacterial endocarditis (BE) on native cardiac valves which required open cardiac surgical procedures such as isolated aortic valve replacement (1 pt) and aortic valve replacement associated to tricuspid valve repair (1pt), respectively. Both pts received biological aortic valve prosthesis.

Mean hospital stay was 11±12 days (range 2-60 days). There were 3 in-hospital death but none of them was procedure related. One of the two pts submitted to cardiac surgery died for septic shock whereas multi-organ failure (MOF) was the cause in the other one during the 17th and 60th days of post-operative hospital stay respectively. A third pt who underwent to isolated lead removal died for MOF as a consequence of a right side acute bacterial endocarditis 48 days after the



MRSA= Methicillin-resistant staphylococcus aureus; MSSA= Methicillin-sensitive staphylococcus aureus.

Figure 2: Bacterial Flora.

Table 3: Procedural data, mortality and complications.

Patients number	71	
Procedural success, n (%)		
CPS	64	(90%)
CS	6	(8.5%)
Failure	1	(1.5%)
Associated surgical procedures n (%)		
AVR	1	(1.5%)
AVR+TVrep	1	(1.5%)
Mortality n (%)	3	(4.2%)
Complications n (%)		
Hemopericardium	2	(2.8%)
Urgent sternotomy	0	(0%)
Pocket bleeding	1	(1.4%)
TV or major RV injuries	0	(0%)

CPS=Complete Procedural Success; CS= Clinical Success; AVR= aortic valve replacement; TVrep= tricuspid valve repair; TV= tricuspid valve; RV= right ventricle.

procedure. There was no need for urgent sternotomy in anyone of the pts treated. Minor complications were detected only in 3 pts. In 2 of them a hemopericardium was recognized by post-procedural echocardiography without any hemodynamic consequence therefore pericardiocentesis was never necessary. The other pt showed an excessive bleeding at the pocket site requiring a drainage positioning for 2 days.

Discussion

Increasing age of pts affected by heart diseases is associated with a parallel prevalence of cardiomyopathies and conduction rhythm disturbances, either idiopathic or ischemic, which widens the indications for both PMK and ICD implantation. As a consequence, a growing number of electronic device failure or infection has to be removed along with the related leads. However, extraction of multiple and old implanted leads are getting more and more challenging especially when mechanical devices are employed. The US Food and Drug Administration's (FDA) Manufacturers and User Defined Experience (MAUDE) database, showed that device-assisted lead extraction is a high-risk procedure which could result in fatal cardiovascular injuries even if emergency surgery is carried out. The majority of deaths are caused to lacerations of the right atrium, superior vena cava or innominate vein either with excimer laser or mechanical dilator sheaths extractions [14]. Major injuries associated to transvenous procedures are mainly ascribed to mechanical forces applied during extraction manoeuvres therefore newly developed tools employing adjunctive source of energy has been delivered by industry. A recent randomized clinical trial showed a more effectiveness and safety of electrosurgical dissection compared with standard countertraction system for lead removal, in two groups of pts, with a 93% and 73% complete extraction, respectively. In their paper, the authors stated that standard mechanical system of extraction is an effective alternative as long as it is used in a highly experienced centers [15]. However, in our low volume activity, we treated only 71 pts and managed a total amount of 160 leads without any procedural related deaths and collecting a 90 % of CPS, 8.5% of CS and 4.2% of minor complications using standard mechanical tools by simply applying a stepwise approach for technique standardization. Procedural reproducibility achieved in our study could also be confirmed by the heterogeneity of pts we treated in terms of either, time from implantation to extraction, number of leads removed in a single pt and site of implantation, defining a wide range of lead demographics. More recently, despite a progressive devices sophistication, a real advantage of laser vs mechanical approach for transvenous lead extractions has not been demonstrated being the procedural success and safety absolutely comparable between the two techniques [12]. Moreover, our results in recipients with old or very old leads, equals those of percutaneous laser or femoral procedures, thus giving more importance to the team cooperation and steps observance instead of different endovascular entry site or extraction tools [16]. As a matter of the fact, in our experience successful lead extraction varies between 93% and 97%, depending on the type of lead considered, with a complete failure in only one patient. Validity of our approach

is also supported by the evidence that not even new devices with higher advancement rate do not reduce the risk of lead breakage, as showed in a recently published paper from Hakmi et al. who treated 76 pts for PM or ICD extraction by the use of the new GlideLight 80 hz laser sheaths [17]. On the other hand the development of hand-powered Evolution® mechanical dilator system allowed to improve global achievement for transvenous extraction also in small clinical experience, as reported by Oto et al. which showed an 87.9% of CPS and overall CS of 98.5% after the introduction of this device in their interventional practice using a step by step approach [18]. Therefore methodology coupled by a tailored algorithm seems to be the most important pathway to follow for best success. The importance of an interdisciplinary cooperation providing that a stepwise progression is respected, enhances safety limiting morbidity and death irrespectively of the site and type of lead considered. This is particularly true when old leads placed inside the coronary sinus have to be removed, being the venous wall extremely thin and delicate. Lisy et al. treated 41 pts for transvenous CoS lead extraction without any deaths or major periprocedural complications. In their escalating approach, manual traction was feasible in 13 pts, by locking stylets in 6, whereas mechanical sheaths was required in 17 pts and electrosurgical sheaths in 5 [19]. We never used electrosurgical dissection in our experience and 22 coronary sinus leads out of 23 were removed with no complications only using mechanical tools. Moreover, reliability of our method gain acceptance when compared with larger experiences recently published. As demonstrated by Sheldon et al. on 125 CoS leads removed percutaneously, those older than 4 yrs from implantation required complex extraction with significance incidence of complications. In their series they had CoS or tributary vessel thrombosis in 6.9% of pts, CoS dissection in 3.9% and 2 cases requiring surgical repair [20]. In no cases we need surgical lead removal neither in those pts who underwent surgery for valve replacement which had the percutaneous lead extraction before the surgical procedure. Mortality and morbidity in pts with CIED implantation should not only be considered as procedural related but mainly ascribed to preoperative patient's clinical conditions and device infection. Independent risk factors for mortality are systemic embolization, moderate or severe tricuspid regurgitation, abnormal right ventricular function and abnormal renal function [21]. Among the three pts who died in our series, excluding the two cardiac surgical pts, one of them had pre-procedural right side bacterial endocarditis with involvement of tricuspid valve and right ventricle, thus confirming the prognostic weight of pt clinical conditions.

Limits of the study

No informations about X-ray exposure and procedure duration are reported due to incompleteness of data collection. Therefore, it is not possible to make a comparison with electronic devices performance in terms of procedural radiological risk.

Conclusion

In conclusion, our clinical experience demonstrated that mechanical transvenous lead extraction is a safe and effective procedure also in small volume center providing that a

stepwise approach is applied. An interdisciplinary heart-team employment seems to be advantageous in terms of major complications avoidance maybe because integrated technical skills allow to share experiences coming from different field of work. Surgical stand-by for urgent sternotomy or thoracotomy seems to be not necessary but it is highly recommendable in pts with old leads implanted.

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