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Transvenous Lead Extraction by Using Tight Rail™ Mechanical Dilator Sheath: Single Center Experience

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ABSTRACT

Background: Implantable cardiac devices including pacemakers and implantable cardiac defibrillators have important therapeutic implications for the patients who have rhythm problems or the risk of sudden cardiac death. Despite the survival benefit and increase in quality of life, inappropriate shock therapies, macro or micro lead fractures or device infections are some of the devastating problems that can be encountered in such patients.

Methods: In this retrospective study, we reevaluated 153 patients who had undergone transvenous lead extraction using TightRail™ Mechanical Dilator Sheath (Spectranetics Corporation) between September 2014 and October 2017 in Hacettepe University Cardiology Clinic.

Results: 97 extracted devices were implantable cardiac defibrillator and 56 devices were pacemaker. Most common lead extraction causes were lead and/or pocket infection and lead dysfunction. Both causes were present in 69 patients. The total number of extracted leads were 275 (1.85 leads per patient). In the entire population 15 of 153 patients were died during the follow-up unrelated to extraction procedure.

Conclusion: Although cardiac devices can be implanted in many centers, lead extraction procedures can be performed in a very limited number of clinics. Our single center report is one of the largest series regarding lead extraction procedures. Our study showed that lead extraction procedure has its own serious morbidity and mortality risks.

Key Words: Cardiac devices, pacemaker Infection, pacemaker disfunction, percutaneous cardiac device extraction, lead extraction, infective endocarditis

INTRODUCTION

Implantable cardiac devices including pacemakers and implantable cardiac defibrillators have important therapeutic implications for the patients who have rhythm problems or the risk of sudden cardiac death [1]. These devices are commonly being used especially in the last 20 years [2]. Nowadays, over of one billion patients who live in European countries have an implanted cardiac device [2].

Despite the survival benefit and increase in quality of life, inappropriate shock therapies, macro or micro lead fractures or device infections are some of the devastating problems that can be encountered in such patients [3].

Transvenous lead extraction is a complex procedure that aims to remove the implanted leads and generator using percutaneous methods. Although transvenous method is the first-choice therapy in patients necessitating lead extraction, the procedure is not without significant complication risk. Cardiac or vascular rupture, cardiac tamponade, hemothorax, tricuspid valve damage or death are some of these complications related to the PROCEDURE [4].

In this this study, we aimed to report our experience regarding transvenous lead extraction in terms of procedural success and complications as well.

MATERIALS and METHODS

Study Population

In this retrospective study, we reevaluated 153 patients who had undergone transvenous lead extraction using TightRail™ Mechanical Dilator Sheath (Spectranetics Corporation) (figure 1) between September 2014 and October 2017 in Hacettepe University Cardiology Clinic. The written informed patient consent was signed by each patient before they were included in this study. The ethical approval of this research was confirmed by Hacettepe University Local Ethic Committee.

Figure 1: TightRail™ Mechanical Dilator Sheath (Spectranetics Corporation) (A) The system in original pocket including device and outer sheath seperately. (B) The higher flexibility of the TightRailTM shaft and (C) shielded distal metal blade.

Statistical Analysis

The continuous data is expressed as means+SD or median (ranges), and all categorical data is expressed as number and percentages. Statistical analysis is performed using SPSS statistical software (version 20; SPSS Inc., Chicago, IL, USA).

Periprocedural Assessment

Antiplatelet therapies including P2Y12 inhibitors were stopped 5 days ago, oral anticoagulant drugs were interrupted at least 2 days ago, and low molecular weight heparin was stopped at least 12 hours ago. If patients were using oral vitamin K antagonist, lead extraction procedures were performed when INR<2.0. Preprocedural erythrocyte suspension was prepared for each patient. Preprocedural and postprocedural transthoracic echocardiography was performed in all patients. If the lead extraction reason was device infection, transesophageal echocardiography was performed in order to evaluate possible vegetation on the leads.

Lead extraction procedures were performed under light sedation and local anesthesia. General anesthesia was not preferred because of conscious examination during the procedure. Invasive hemodynamic monitorization using femoral access was performed in all patients.

Complete blood count and transthoracic echocardiography were performed every 6 hours on the first day of post-procedural care.

Reimplantation of New Device

The devices which had been extracted because of noninfectious reasons(n:82) were re-implanted in the same procedure. In 3 cases only malfunctioning leads were changed and same batteries of the patients were reimplanted.
The extraction and re-implantation were done separately in the infection related patients (n:71). If there was not pacemaker dependency, the re-implantation procedures were postponed at least one month. The re-implantation was done at the opposite pectoral. Pacemaker dependent patients stayed at the intensive care unit with a temporary pacemaker inside until reimplantation. Their new devices were implanted after antibiotherapy was completed and culture negativity was achieved in the blood sample after the approval of the infectious diseases consultation.

RESULTS

The forty female patients and 113 male patients were included in our study group. Mean age of the population was 57 ± 40 years and median age was 60 (range between 17-91). Other baseline characteristics are listed in table 1.

Table 1: Baseline characteristics of patients

Parameters	Number
Age (mean/median) (range)	57 ±40 years / 60 years (17-91 years)
Male Gender (n/%)	113 / %73
Coronary artery disease (n/%)	74 / %48
Hypertension (n/%)	86 / %56
Diabetes Mellitus (n/%)	44 / %28
Chronic Kidney Disease (n/%)	13 / %8
Heart Failure (EF:<%50)/ (EF:<%35)	92(%60) / 75 (%49)
Ejection Fraction (mean) (range)	%42,5 ± 28,5 (%15-71)

The ninty seven extracted devices were implantable cardiac defibrillator (the number of biventricular devices, dual-chamber and single-chamber ventricular devices were 38, 34 and 25 respectively) and 56 devices were pacemaker (the number of biventricular devices, dual-chamber and single-chamber ventricular devices were 3, 35 and 18 respectively). The mean duration of implanted device 61.1 ± 340 months. Other device characteristics are listed in table 2.
Most common lead extraction causes were lead and/or pocket infection (figure 2) and lead dysfunction. Both causes were present in 69 patients. Other extraction causes were upgrading pacemaker to ICD, mastectomy on the same side due to malignancy, lead dysfunction and upgrade strategy in 11 patients (7 of them upgraded to CRT-D device and 4 of them upgraded to implantable cardiac defibrillator), 1 patient and 1 patient respectively. 2 patients presented with pocket infection and we realized that there were also lead disfunction. The total number of extracted leads were 275 (1.85 leads per patient). The total number of extracted atrial leads, ventricular pacemaker leads, ventricular shock leads, and coronary sinus leads was 90,59,93 and 33 respectively. There were 2 atrial leads in one patient. There were 2 ventricular pacemaker leads in 3 patients and 2 ventricular shock leads in 2 patients (Table 3).

Table 2: Characteristics of devices

Parameters	Number
Pacemakers Biventricular Dual-chamber Single-chamber ventricular	97 38 34 25
Defibrillators Biventricular Atrioventricular Single chamber ventricular	97 38 34 25
Age of leads (mean) (range)	61.1 months (1-420 months)
Indication of implantation	
Av block	29
Symptomatic bradicardia	27
Secondary prophylaxis	7
ARVD	2
Brugada	2
NI-DKMP	37
I-DKMP	38
HKMP	9
Long QT	1
Non-compaction CMP	1

Table 3: Characteristics of extracted leads

Parameters	Number
Lead Extraction Reasons	
Device infection	69
Lead Dysfunction	69

Table 3: Characteristics of extracted leads continued

Pacemaker upgrade to ICD • Biventricular ICD • Single ventricular ICD	11 7 4
Infection and lead dysfunction togetherness	2
Lead dysfunction and upgrade plan togetherness	1
Mastectomy plan due to malignancy	1
Numbers of Leads	
Total number	275 (1.85 leads per patient).
Atrial leads	90
Ventricular pacemaker leads	59
Ventricular shock leads	93
Coronary sinus leads	33

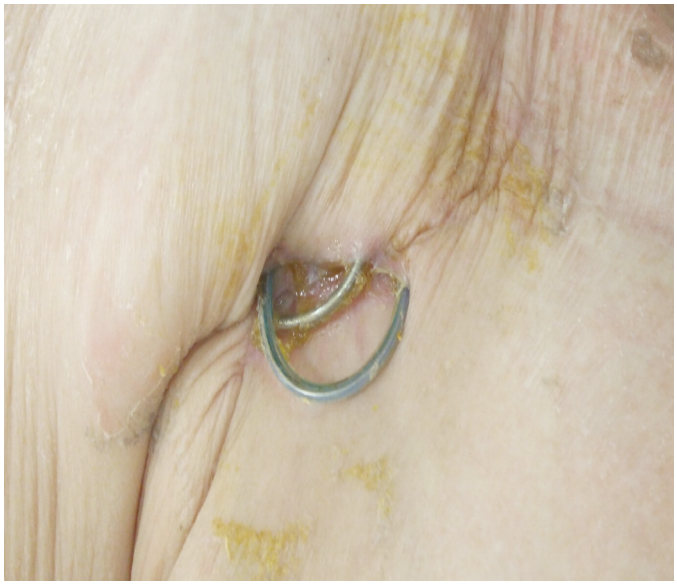

Figure-2: Cardiac device and pocket infection with skin perforation

Periprocedural Characteristics and Complications

The four of 275 leads couldn't be extracted percutaneously. In 3 patients, extractions of ventricular leads were failed. Two of them were shock leads and 1 of them was coronary sinus lead. Percutaneous approach was abandoned in these 3 leads and surgery was performed. In one patient, atrial lead was extracted percutaneously but cardiac tamponade occurred. Pericardiocentesis was performed, and after hemodynamic stabilization ventricular lead was removed percutaneously. A pigtail catheter was introduced into the pericardial space; however due to the continuous drainage from the pericardial space, surgery was needed.

In one patient, ventricular tachycardia was developed during the extraction procedure. In another patient, postprocedural pericardial effusion was detected; however, it was self-limited and pericardiocentesis was not required.

In 3 cases, incomplete extraction was performed. Right ventricular leads were extracted partially in 2 cases and epicardial left ventricular lead was left for surgical removal in another case.

Postprocedural Follow-up

The mean postprocedural hospitalization duration was 3 days. Only 1 patient who was sent to surgery because of intraoperative pericardial tamponade stayed at hospital for 32 days after the procedure. The patient was discharged uneventfully without any cardiologic sequela.

The mean hospitalization duration of these pacemaker dependent patients was 12 days (range between 10 - 18 days).

The mean follow-up duration of the study population was 18 months (range between 2 months to 78 months). In the entire population 15 of 153 patients were died during the follow-up unrelated to extraction procedure. There was 1 one re-extraction case due to the incomplete extraction in the index procedure. Second extraction procedure was done 13 months later after the index procedure. Seven months after the second procedure infective endocarditis was diagnosed in the same patient and the patient was consulted to surgery for complete device extraction (Table 4).

Table 4: Follow-up

Parameters	Number
Postprocedural hospitalization duration (mean) (range)	3 days (1-32 days)
Postprocedural hospitalization duration of pacemaker dependent patients (mean) (range)	12 days (10-18 days).
All-cause mortality	15
Re-extraction	1

DISCUSSION

Cardiac implantable devices comprise important therapeutic options for the patients who had sudden cardiac death risk or necessitating pacemaker or cardiac resynchronization therapy [1]. On the other hand, device implantation procedures are not free of complications, where infection and lead or device dysfunction can cause life threating conditions [3].

In case of lead dysfunction or device infection, device extraction should be thought as a first line therapeutic option [6]. Recent guidelines suggest that the indication of cardiovascular device extraction can be classified as an infectious and noninfectious reasons [7]. The lead failure to work properly, chronic pain that causes significant discomfort for the patient, is not manageable by medical or surgical techniques and for which there is no acceptable alternative, thrombosis or venous stenosis are the most common noninfectious indication of lead extraction [4,7,11]. The suggestions about infectious lead extraction indication in the recent guidelines are more clear than non-infection related indication [7]. Because we know that cardiac device related infective endocarditis is a life threating condition that is hard to treat unless complete device removal was performed[5]. On the other hand, some non-infectious problems, especially lead dysfunctions, could be solved without extraction of elder lead. Abandoning of dysfunctioned lead and new lead implantation could be an alternative therapeutic option[7]. But we also know that the extraction of elder leads are more related with periprocedural complication. Consecuently, leaving dysfunctioned lead and new lead implantation could result bigger complication risk when another lead extraction procedure needed. In lights of these knowledge, recent guidelines emphasize that lead extraction procedure should be performed after harm-benefit calculation[7].

Although lead extraction procedure is not free of complications, on time intervention in these patient groups is vital in order to prevent possible complications such as infective endocarditis or embolic complications. In addition, the dysfunction of ICD, CRT or pacemakers can cause inadequate anti-tachycardia therapy or inappropriate shock therapies, worsening of heart failure and inadequate anti-bradycardia pacing which can result with cardiac arrest, electro- mechanic dissociation or syncope. This also highlights the importance of standardized guideline oriented best practice approaches in these patients, mainly in the highly-experienced tertiary centers [8].

Percutaneous lead extraction can be performed using several techniques and lead extraction systems [9]. TightRail™ Mechanical Dilator Sheath (Spectranetics Corporation) is one of the rotating mechanical extraction systems. Our previous experience demonstrated that TightRail system is a safe and effective option for lead extraction procedures [10]. The main novelty of this system was flexible nature of the shaft of the sheath and the shielded distal blade which rotates 270 degrees in clockwise and counterclockwise with each trigger (figure 3). Our experience revealed that especially flexibility of this novel shaft in addition to better cutting performance of distal blade contributes to overcome serious fibrous attachments and calcifications around the leads. However, injury to the normal leads or dislodgement of the unplanned leads are still concerns in this mechanical approach that should be kept in mind.

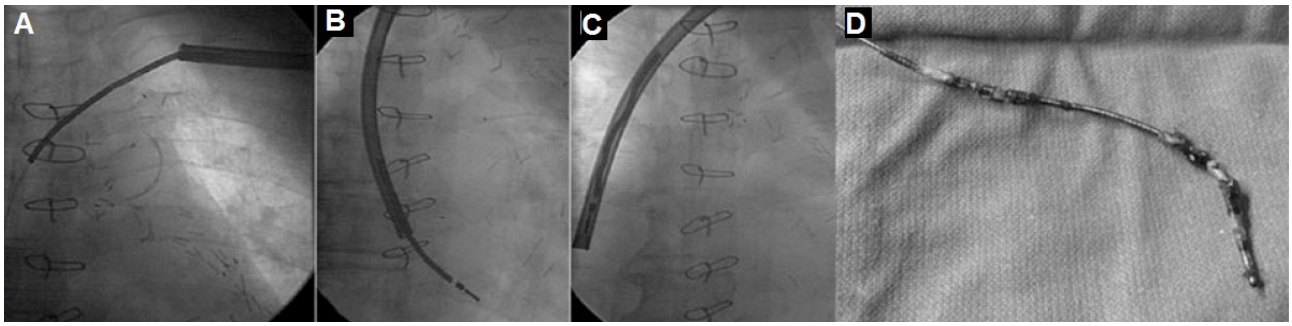

Figure-3: (A) Fluoroscopic image of ICD electrode covered by the TightRailTM sheath. (B,C) After the fibrous adhesions were eliminated by the cutting tip of TightRailTM sheath, ICD electrode was pulled back into the sheath and extracted successfully. (D) Fibrous material adherent to defibrillator coil at multiple sites.

Our study showed that lead extraction procedure has its own serious morbidity and mortality risks. Therefore, preprocedural planning has important implications in order to decrease periprocedural complications. Invasive hemodynamic monitorization is routinely performed in our clinic in order to foresee probable complications like pericardial effusion, tamponade or vascular rupture. As many patients undergoing lead extraction also have heart failure, lead removal should be performed when patients are in euvolemic status. In addition, erythrocyte suspension should be prepared for possible emergency situations that can be encountered. Anesthesia and cardiovascular surgery team should be informed before the procedure in order to intervene earlier as soon as possible when needed.

The device infection is one of the most common extraction reason in our series. Evaluation of device infection by infectious diseases department is mandatory for the patient's treatment plan as well as prognostic purposes. Moreover, the sterilization principles in the cardiac device implantation and extraction procedures are the most crucial factor to prevent procedure related

device infections [5]. In addition to the patient preparation, several sterilization measures should be taken by the operator as well. The education of the patients who have cardiac device could prevent lead fractures and dysfunctions also. Because of the possible devastating complications related to the implanted devices, general rules as indicated by international guidelines should be kept in mind and also put into action as a routine in every procedure [1,4].

Complete removal of device is one of the important negative predictors for recurrent device infection [9]. In 3 patients we were unable to remove leads completely using mechanical dilator sheath. In such situations, we usually use femoral snares in order to remove the remaining portion of the lead especially in case of device infections. On the other hand, surgery may also be needed in case of severe adhesions that renders percutaneous approach useless especially in passively fixated chronically implanted leads. Moreover, in case of epicardial leads, surgical extraction is the only option as one of our patients in whom epicardial left ventricular lead was removed by surgery.

Although our single center report is one of the largest series regarding lead extraction procedures, it has several limitations including the retrospective nature of the study, lacking comparison with other commercially available methods and reflection of a very highly experienced tertiary center results; therefore, not representing the real-world data in this specific patient group. On the other hand, we are not allowed to use laser extraction systems or other mechanical dilator tools due to reimbursement problems which limits the development in experience with these methods.

CONCLUSION

In the current era, although cardiac devices can be implanted in many centers, lead extraction procedures can be performed in a very limited number of clinics. As in line with our previous reports, lead extraction using TightRail mechanical dilator sheath is a safe and effective option in patients necessitating lead removal due to various indications. Further large-scale studies are needed to assess the safety of these devices.

CONFLICTS OF INTEREST AND SOURCE OF FUNDING

None.

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