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Prevention of sudden cardiac death in patients with chronic kidney disease, focusing on implantable cardioverter defibrillator therapy

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ABSTRACT

Aims: The number of implanted cardiac rhythm devices has rapidly increased in the past decade. Subsequently, the need for lead extraction has also increased. Several techniques of lead removal have been documented from manual traction of the lead to lead extraction assisted with mechanical or laser sheaths. The goal of this study was to review our experience with lead removal using manual traction without the assistance of extraction sheaths.

Methods and results: In the Leiden University Medical Center all leads are removed using manual traction without the assistance of extraction sheaths. We have retrospectively reviewed all lead removal procedures performed between 2000 and 2009. Procedures were reviewed for indication, success, complication rates, and mortality. In total, 279 lead removal procedures were included. During these procedures 445 leads were removed. Time since lead implantation: 4.2 ± 4.7 years. During extraction 53(11.9%) leads fractured, of which >50% could still be completely removed using a femoral approach. A longer implantation duration [odds ratio (OR) 1.16 per year, 95% confidence interval (CI) 1.09–1.23] and passive fixation (OR 2.52, 95%CI 1.17–5.45) significantly associated with the chance of lead fracture during lead removal. Clinical success, using the primary approach of manual traction from the pectoral area, was obtained in 228 (84.8%) procedures. Major complications occurred in 2(0.7%) and minor in 13(4.7%) procedures. One patient died within 24 h after the procedure due to septic shock. There was no further mortality within the first month after the procedure.

Conclusion: Lead removal using manual traction, without the assistance of lead extraction sheaths, is clinically successful in ~85% of the lead extraction procedures. Concomitant morbidity and mortality are low. The highest clinical success (~95%) was observed in patients with leads implanted less than 2.6 years.

INTRODUCTION

Due to rapidly expanding indications the number of implantations of cardiac rhythm devices has increased significantly over the last 20 years.¹⁻⁴ Subsequently, device and lead-related problems increased, also resulting in a growth of the need for lead extraction. Major indications for lead removal are infection, the desire for device upgrade, and lead failure.⁵ The latter is a high-profile topic given the growing concerns regarding the reliability of leads and the impact of lead failure.⁵⁻⁷

Transvenous lead removal can be performed manually with or without the assistance of traction devices including stylets, locking stylets, snares, and other devices used to engage and remove the lead or lead fragments. Furthermore, several extraction techniques have been developed applying laser, radiofrequency energy, or novel cutting techniques that can ablate or disrupt fibrous tissue in order to facilitate a safe lead removal.⁸⁻¹⁰

Recent studies regarding lead removal, for various indications, have documented high success rates of lead removal with low concomitant morbidity and mortality.¹¹⁻¹³ The usage of extraction sheaths ranges from 60 to 80% in these studies.¹¹⁻¹³ However, data regarding the success rates of manual lead removal, without the usage of extraction sheaths, are lacking. Given the costs and possible risks, associated with the use of extraction sheaths (especially those using laser, radiofrequency, and novel cutting techniques), manual lead removal, without the use of these sheaths may be a reasonable alternative, for leads with a limited dwell time.^{5,14,15}

The purpose of this study was to evaluate the results of lead removal procedures using manual traction without the assistance of extraction sheaths.

METHODS

Patients and study protocol

In the Leiden University Medical Center (LUMC) all data regarding pacemaker, implantable cardioverter–defibrillator (ICD) and cardiac resynchronization therapy (CRT) devices are prospectively collected in the departmental Cardiology Information System (EPD-Vision®, LUMC, Leiden The Netherlands). Patient characteristics at baseline, data regarding the implant procedure and all follow-up data regarding the implanted system are recorded. Between 2000 and 2009, 1640 pacemakers (including 86 CRT-P) and 3834 ICD (including 1560 CRT-D) were implanted.

In the LUMC all lead removal procedures are performed without the assistance of lead extraction sheaths. For the current study, all lead extraction procedures performed between January 2000 and December 2009 were evaluated. Lead extractions regarding leads that were not implanted in the LUMC were excluded from the current analysis. Furthermore, leads in situ <30 days and surgically implanted epicardial leads were excluded from the current analysis.

Indications for lead extraction

Indications for lead extraction were classified as infection, lead malfunction, upgrading of device, and miscellaneous.

Infective indications for extraction included endocarditis, with or without signs of vegetation on the leads, and generator pocket infections.¹⁶ Persistent fever or recurrent bacteremia without an apparent focus, despite profound examination, was also an indication for extraction of the entire system since a cardiac device infection could not be excluded.

Lead malfunctions were established on the basis of clinically significant alterations in pacing/sensing thresholds, and lead impedance. Malfunction was also diagnosed in case of muscular or diaphragmatic stimulation. Since the implantation of multiple leads could form a potential for noise, high defibrillation threshold and ipsilateral central venous obstruction, upgrading a pacemaker to an ICD or biventricular system was also an indication for lead removal in several patients.

Furthermore, lead extractions were also performed in case it was necessary to change the position of the device or to remove the system completely. Reason for lead extraction in case of an intact system included wish of the patient, the need for chest or breast radiotherapy, and/or ipsilateral venous occlusion.

Extraction technique

Lead extractions were performed in the catheterization laboratory under local anaesthesia and conscious sedation, with on-site cardiothoracic surgery back-up. After the leads were dissected free from the scar tissue in the pocket the sleeves were removed. The active fixation mechanism, if present, was retracted and manual traction was attempted. A stylet, or in a few cases a locking stylet, was placed to make traction more efficient (Figure 1A). When a thoracic approach was not sufficient to completely remove the lead, for instance, when a lead fractured during extraction, a femoral approach, using a variety of extraction tools, such as snares (but no sheaths), was applied (Figure 1B).

Definitions

Procedural success was defined according to Heart Rhythm Society recommendations as clinical success or failure. Clinical success: the removal of all targeted leads and lead material, or retention of a small portion of the lead that did not negatively impact on the outcome goals of the procedure. The latter being the tip of a small part of the lead when the residual part did not increase the risk of perforation, embolic events, perpetuation of infection or cause any undesired outcome.⁵

Failure: All procedures in which no clinical success was obtained were defined as failure. Complications were also scored according to the HRS recommendations.⁵

Statistics

Continuous data are expressed as mean \pm SD and compared with the Student's t-test for

unpaired data. Categorical variables were compared using the χ^2 test. Multivariable logistic regression was used in order to determine predictors of lead fracture. A P value of <0.05 was considered statistically significant. All analyses were performed using SPSS 15.0

RESULTS

Between 2000 and 2009, 279 consecutive lead removal procedures were performed. Patient characteristics are summarized in Table 1. Patients were predominantly male ($n=215$, 77%) with a mean age of 61 ± 16 years. The lead removal procedure was performed 4.2 ± 4.7 years after implantation of the lead. Median time since implantation was 2.6 years. An average of 1.6 leads was removed per procedure. Most leads were removed because of an infection ($n=124$, 44%) or a lead malfunction ($n=129$, 46%). A locking stylet was used in 9 (2%) leads and a femoral approach was necessary for 50 (11.2%) leads.

Table 1: Baseline characteristics, $n=279$

Average Age		61 ± 16 yrs
Male gender		215 (77%)
Nr. leads removed		1.6 ± 0.7
Time since implantation		4.2 ± 4.7 yr
Indication	Infection	124 (44.4%)
	-Systemic signs of infection	39(14.0%)
	-No systemic signs of infection	85(30.4%)
	Malfunction	129 (46.3%)
	Upgrade	17 (6.1%)
	Other	9 (3.2%)
Implanted device at time of procedure	AAI	6 (2.0%)
	VVI	17 (6.1%)
	DDDR	80 (28.7%)
	ICD	90 (32.3%)
	CRT-P	3 (1.1%)
	CRT-D	83 (29.8%)

In total, 445 leads were removed: 149 atrial leads, 102 right ventricular (RV) pacing leads, 127 right ventricular ICD leads and 67 left ventricular (LV) pacing leads (Table 2). Complete removal was accomplished in 377 (84.7%) leads with the use of manual traction alone. When switching to the femoral approach, the number of completely removed leads increased to 416 (93.5%) leads. In six (1.3%) cases the lead was left in place after an attempted lead removal procedure. Clinical success was obtained in 228 (84.8%) procedures using manual traction. After

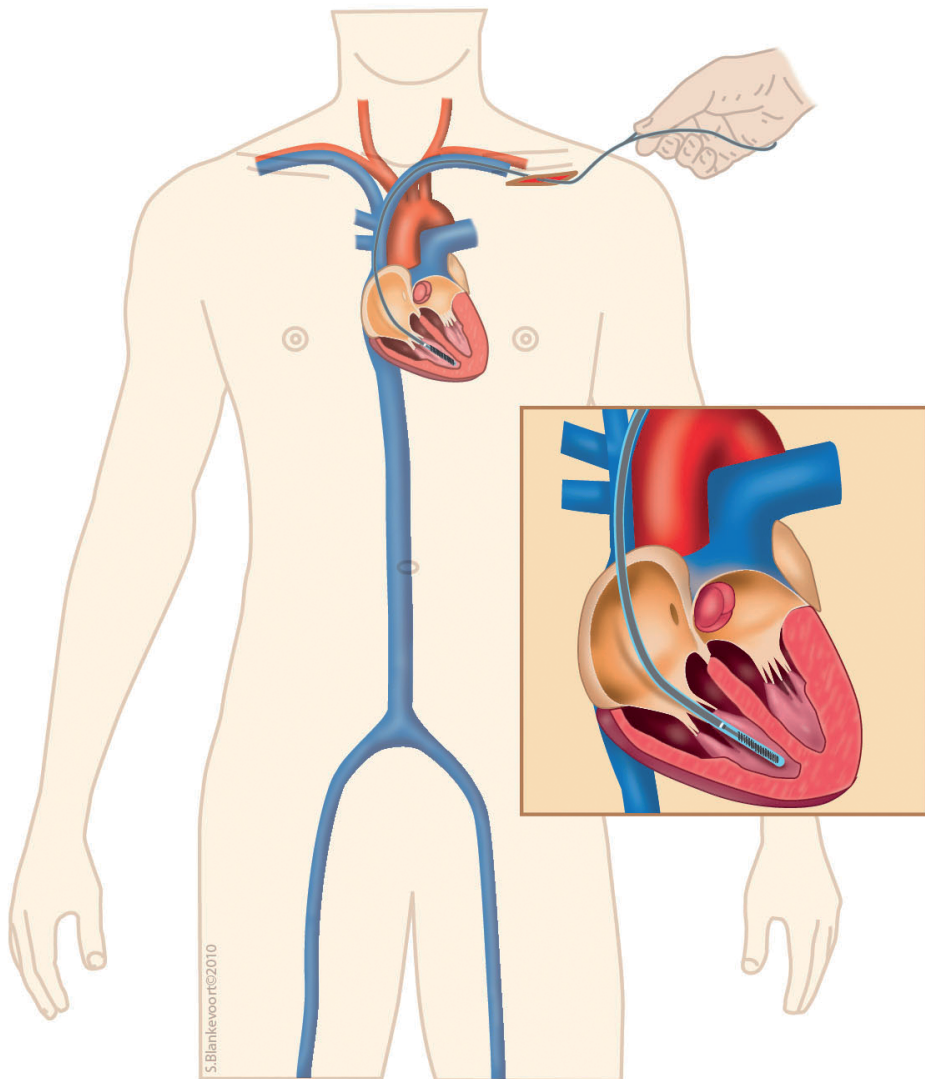


Figure 1. Thoracic approach: manual lead removal with a locking stylet in place.

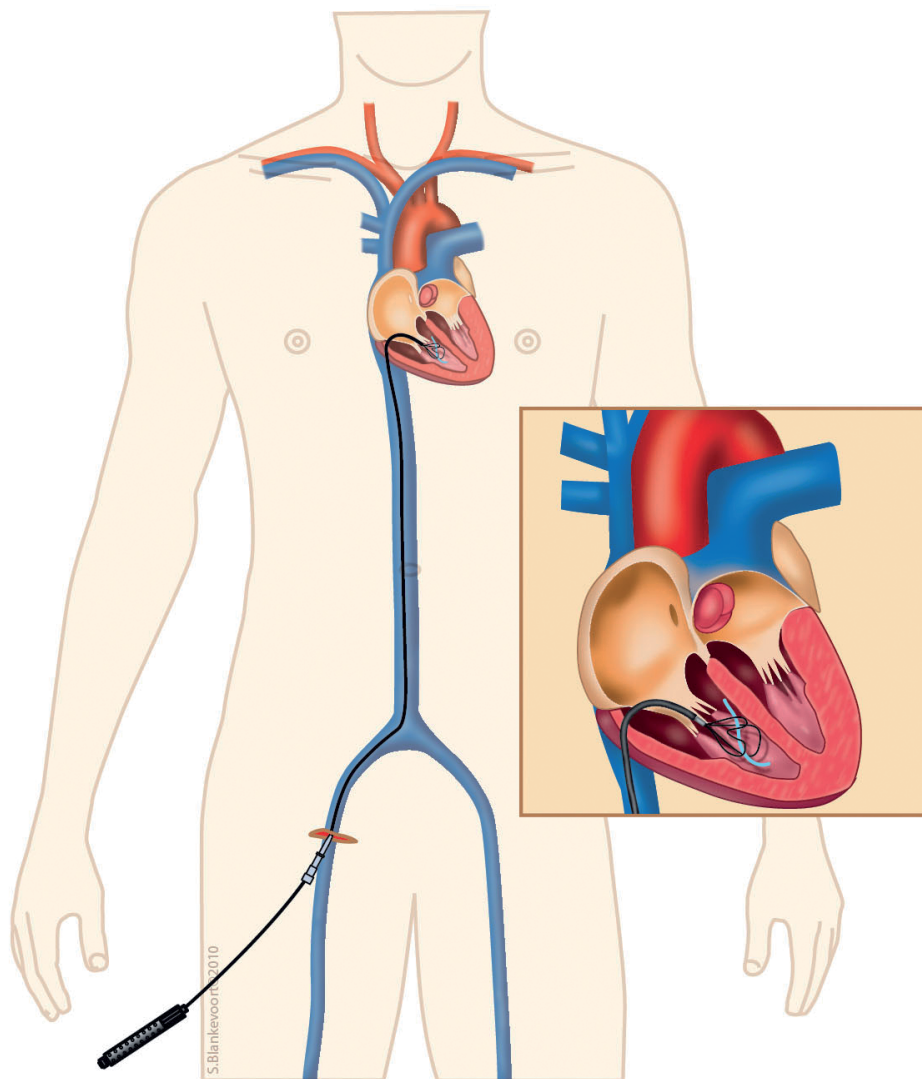


Figure 2. Femoral approach: lead removal using a needle's eye snare.

switching to a femoral approach, clinical success was obtained in 266 (95.3%) lead removal procedures. A femoral approach to remove one or more leads was necessary in 32 (11.5%) procedures. Most frequent causes for not obtaining clinical success were an unsuccessful attempt to extract the lead which was then aborted in five (1.8%), migration of the lead tip in four (1.4%), or combination (one lead left in place, one lead tip migration in the same procedure) in one procedure (0.35%). Furthermore, a second procedure was necessary after two (0.7%) procedures since a part of the lead was not entirely removed from the device pocket, causing the infective symptoms to persist. During one (0.35%) procedure a large portion (>3 cm) was left in the right ventricle.

Table 2: Lead characteristics, n=445

Leads	N = 445	Time	Fixation		Polarity*	
		Mean	Active	Passive	Uni	Bi
Atrial Pace/Sens	149	4.5 ±4.4	131	18	6	143
RV Pace/Sens	102	7.4 ±6.4	18	82†	14	88
RV Shock	127	2.7 ±2.4	76	51	37*	90*
LV Pace/Sens	67	1.3 ±1.5	0	67	13	54

* For RV Shock leads Single / Dual Coil; † information unavailable for 2 leads

An analysis was performed for leads implanted longer and shorter than the median implant duration of 2.6 years. In lead-removal procedures with leads implanted <2.6 years (~0.95 ± 0.74 years) clinical success rate was 94.9%. After switching to a femoral procedure, which was done in five (3.6%) procedures, the clinical success rate increased to 98.5%. For leads implanted >2.6 years (~7.4 ± 4.8 years) clinical success rate was 75.7% using manual traction. After switching to a femoral approach, which was done in 27 (19.3%) procedures, this increased to 92.1%.

Of the 67 removed LV-leads 64(95.5%) leads could be completely removed. In the three remaining cases the lead could be completely removed from the coronary sinus but got stuck in the area of the clavicle and consequently the tip fractured from the lead, which was left behind. A femoral approach was used during one (1.5%) procedure.

Lead fracture during removal

During traction, 53 (11.9%) leads fractured, of which 30 leads (>50% of all fractured leads) could be completely removed using a femoral approach. There was no statistically significant difference in the distribution of lead types (atrial/RV pace/sense lead, single-coil ICD lead, dual-coil ICD lead, and LV lead) between fractured leads and non-fractured leads. There was a difference in chance of fracture between single- and dual-coil leads, 2.7 vs. 12.2%, respectively. This difference, however, did not reach statistical significance (P= 0.18). Fractured leads, however, were more often passively fixated (73.6 vs. 45.7% P < 0.001)

and time since lead implantation was significantly longer (8.8 vs. 3.5 years, $P < 0.0001$). Indication of lead removal (infectious or non-infectious) was not significantly different between fractured and non-fractured leads (Table 3). Multivariable logistic regression analysis controlling for lead type, fixation and time since lead implantation demonstrated that time since lead implantation is an independent predictor for lead fracture [odds ratio (OR) 1.16, 95% confidence interval (CI) 1.09–1.23, per year]. Passive fixation also remained a significant independent predictor of lead fracture. Leads that were passively fixated had a 2.5-fold higher risk of fracturing (OR 2.52, 95%CI 1.17–5.45). Lead type was not predictive for the risk of lead fracture in this model.

Table 3: Characteristics of fractured and non-fractured leads

	Fractured Leads (n=53)	Non Fractured Leads (n=392)	
Lead Type			0.067
- Pace/Sense	69.8% (37)	54.6% (214)	
- ICD lead single coil	1.9% (1)	9.2% (36)	
- ICD lead duals coil	20.8% (11)	20.2% (79)	
- LV lead	7.6% (4)	16.1% (63)	
Passive Fixation	73.6% (39)	45.7% (179)	<0.001
Infection as indication	62.3% (33)	57.4% (225)	NS
Time since implantation (yrs)	8.8±5.9	3.5±4.1	<0.001

Complications and mortality

Procedure-related complications, major complications occurred in two (0.7%) patients, atrial rupture resulting in cardiac tamponade that was successfully treated in one patient and one patient developed tricuspid regurgitation which, after 2 years of conservative treatment, was treated surgically with success. Minor complications occurred in 13 (4.7%) patients: seven (2.5%) patients developed a pocket haematoma; one (0.35%) patient developed a pneumothorax requiring drainage; and a small part of the lead migrated to the pulmonary vasculature in five (1.8%) patients. In these patients lead tip migration did not result in further complications within the first year after follow-up.

One patient (0.4%) died within 24 h after the procedure due to septic shock. No other deaths occurred within 30 days after the removal procedure.

DISCUSSION

Key finding of the current study was that removal of pacemaker or ICD leads, using simple manual traction, was clinically successful in ~85% of all lead removal procedures. Especially

for leads with a short implant duration manual traction was associated with a high clinical success rate of ~95%. Furthermore, the incidence of major complications was relatively low, <1%.

Effectiveness of lead removal using manual traction

Marijon et al.¹⁷ concluded in their recent observational study that advanced extraction techniques substantially increased the number of complete lead removal, from 27% using only manual traction to 90% with the use of various advanced tools. This finding is in line with previous reports investigating lead removal procedures. These studies reported success rates for manual traction ranging from ~15–30%.^{11–13} Although comparison between different studies, especially retrospective studies, is difficult given the different designs, patient populations, and endpoints, it can be concluded that the clinical success rate for manual traction is substantially higher in the present study. This difference can probably, to some extent, be explained by the fact that in these studies cross over to another pectoral approach (i.e. using a laser sheath) was allowed when manual traction was considered not to be successful. Since it is not clearly defined when an attempt should be considered truly unsuccessful the decision to cross-over is rather subjective and may result in lower success rate for manual traction. Furthermore, the procedures in the current study were performed by operators with large experience in manual lead removal which could also lead to higher clinical success.

Switching to a transvenous femoral approach

When the transvenous pectoral approach was not successful, a secondary femoral approach was initiated to obtain clinical success. The necessity to switch to a secondary femoral procedure is associated with a longer and more complex lead removal procedure and therefore, if possible, should be avoided.

In the current study, the necessity to switch to a secondary femoral approach was 12% which is higher than reported by others using extraction sheaths. For instance, in the study by Jones et al.,¹² a secondary femoral approach was necessary in 5.6% of the cases and in the study by Bongiorno et al.¹³ a secondary transvenous femoral approach, mostly in combination with an internal transjugular approach, was necessary in 9.6%. Although, as mentioned previously, comparisons between various studies should be interpreted with some caution, this difference suggests that switching to a transvenous femoral approach can be avoided in some procedures by using extraction sheaths.

Risk of lead fracture

Fracturing of the lead was the major reason to switch to a femoral approach and furthermore resulted in an incomplete lead removal in ~45% of the procedures. For those leads that are at high risk of lead fracture, the necessity of a transvenous femoral approach could be reduced and the number of completely removed leads could be

increased by engaging another pectoral approach (for instance, using mechanical dilator sheaths), in an earlier phase of the lead removal procedure.

Especially in leads that have been implanted for a longer time, connective tissue that has grown around the lead might prohibit further extraction and could also possibly result in fracturing of the lead. This hypothesis was confirmed in this study, since the time a lead was implanted was a significant predictor for lead fracture. Furthermore, also passive fixation of a lead was significantly associated with a higher incidence of lead fractures. These factors could therefore be useful in the decision making regarding the approach for removal of a lead.

Complications

In this analysis, mortality (due to the procedure) and major complication rate were, respectively, 0.0 and 0.7%. In the recently reported lead removal series mortality ranged from 0.0 to 0.3% and major complication rate from 0.4 to 0.9%,¹¹⁻¹³ which are comparable to our results. However, higher complication rates, associated with extraction sheaths, have also been reported. For instance Wazni et al.¹⁸ recently reported the results for the LEXICON study, a large multicentre retrospective study evaluating laser lead extractions with the Spectranetics Laser Sheath II type sheath. They documented a major complication rate of 1.4%. Furthermore, previous data showed even higher complication rates. In the PLEXES trial, the major complication rate in the laser group was 1.96%^{8,14} and the authors concluded that laser-assisted pacemaker lead extraction is associated with significant risks.⁸ It should, however, be noted that in this study only the 12 Fr SLS I type sheath was used. Byrd et al.¹⁹ reported the results of the initial American experience with laser sheaths, which included 2561 pacing and defibrillator leads at 89 sites. They documented a major complication rate of 1.9% and an in-hospital death rate of 0.8%. Considering these results, further research is warranted regarding the safety of the different extraction techniques available.

Choosing lead removal strategy

Removing leads is a complex and potentially dangerous procedure which should be performed by experienced operators. Various techniques for lead removal have been described and choosing the most appropriate strategy is essential in order to minimize risks and costs of the procedure on one hand and to maximize success rate on the other hand. Based on the current results, we believe that manual traction would be appropriate in a large number of patients, especially those with leads implanted <2.6 years. However, this technique was also associated with a higher risk of switching to a secondary transvenous femoral approach compared with more advanced pectoral approaches. Especially leads with longer implant durations and leads with a passive fixation mechanism were at risk of fracturing and thus had an increased need for a secondary femoral approach. Since such a secondary approach is more complex, is associated with longer procedure times and

results in lower clinical success rates, engagement of more advanced techniques should be considered in these patients.

Study limitations

This study has some limitations. It is a retrospective analysis and therefore is subject to the selection bias associated with such studies. Furthermore, all lead removal procedures have been performed in a large tertiary centre with experienced operators. Success and complication rates may be different in less experienced operators.^{14,20} Finally, it is possible that leads in our institution are implanted in a way that facilitates manual traction, leading to a favourable outcome for manual traction.

In summary, this study demonstrates that lead removal using manual traction from the pectoral area, without the assistance of lead extraction sheaths is clinically successful in 85% of the lead extraction procedures. Concomitant morbidity and mortality are low. The highest clinical success (~95%) was observed in patients with leads implanted <2.6 years.

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