Cardiac implantable electronic device extraction in a non-surgical centre: a single centre experience

Bowers RW, Iacovides S, Foster WM, Balasubramaniam RN, Sopher SM, Paisey JR

Dorset Heart Centre, Royal Bournemouth Hospital, Bournemouth, BH7 7DW

Contact: robbowers12@doctors.org.uk

Abstract

Background: International guidance on transvenous lead extraction suggests that a cardiothoracic surgeon should be immediately available during all device extraction procedures. Our centre has provided a tertiary device extraction service without on-site cardiothoracic surgical cover for over 20 years.

Methods: Having identified all consecutive transvenous lead extraction procedures performed at our hospital from 1992 to 2013 we performed detailed analysis of those procedures from September 2005 onwards. We retrospectively reviewed the reports and lead data and cross referenced this with hospital date of death records. We identified demographics, procedural technique details and outcome data for all leads meeting the HRS definition for extraction.

Results: 658 leads were extracted during 421 separate procedures. There were no peri-procedural deaths or requirements for emergency cardiac surgery. In the 2005-13 data set of 385 leads in 226 procedures clinical outcomes were successfully achieved in 98% of procedures, with failure in the remaining 2%. 97% of leads were removed without leaving any retained material. This resulted in complete procedural success in 94% of cases.

Conclusions: These data suggest that, contrary to current international guidance, in selected patients with all forms of cardiac implantable devices, extraction can be performed safely and effectively in an established centre with appropriate experience without the need for on-site cardiothoracic surgical cover.

Introduction

Cardiac implantable electronic devices (CIEDs) are now used in the treatment of bradyarrhythmia, heart failure and additionally as prophylaxis against arrhythmic sudden cardiac death. With rising rates of implantation of cardiac devices[1], increasing complexity of the devices implanted and increasing longevity in patients in whom they are utilised, the requirement for transvenous lead extraction is growing worldwide[2]. It is estimated that between 10,000 and 15,000 leads are extracted worldwide annually[3].

Current European[2] and North American[3] guidance on transvenous lead extraction suggests that a cardiothoracic surgeon should be immediately available during all such procedures. The rationale behind the need for cardiothoracic surgical availability is to be able to perform open thoracotomy in the case of catastrophic haemorrhage whilst preventing "delays from the injury to having open access to the heart of more than 5-10 minutes" as delays longer than this "were often associated with a fatal outcome"[3].

Survey data from the UK[4], the US[5] and across Europe[6] confirm that the vast majority of centres regularly performing transvenous lead extractions have on-site cardiothoracic surgical cover. Interestingly, the survey data also suggest wide variation in what is meant by the practical application of cardiothoracic surgical "cover" and real world differences in accessibility to the on-site surgical assistance.

Our centre provides a tertiary device extraction service, utilising a full range of lead extraction techniques, with surgical cover provided by non-cardiothoracic surgeons on-site and off-site cardiothoracic specialist back up. We present a retrospective description of 20 year experience including detailed analysis of 8 years of outcome data following extraction of cardiac devices in this single centre.

Methods

All consecutive transvenous lead removal procedures meeting the 2009 Heart Rhythm Society (HRS) definition for lead extraction performed at the Royal Bournemouth Hospital between 1992 and September 2013 were identified. The group from September 2008 were subject to detailed investigation as part of a service evaluation. This period was chosen as it coincided with instigation of an effective, electronic database system to record cardiac procedures as well as the appointment of a second operating consultant and investment in powered sheaths. For the pre September 2005

cohort a basic data set of leads extracted and mortality was reported. The written procedure reports, lead data and hospital records for each case were retrospectively reviewed, the findings were then cross referenced with hospital coding and date of death records. Patient demographics, procedural technique details and outcome data for all leads meeting the HRS definition for extraction were identified and are presented; no records were excluded from the analysis. Definitions for extraction techniques, complications and procedural success conform to the HRS 2009 guideline. The analysis was performed as a service evaluation with appropriate local clinical governance and ethical approval.

Statistical Analysis

Normally distributed continuous variables are reported as mean ± SD, continuous variables with a skewed distribution are reported using the median and interquartile range. Proportions of populations are expressed as a percentage and where that proportion describes an outcome variable, the upper and lower boundaries of the 95% confidence interval for the proportion are also given. Univariate and multiple variable binary logistic regression was performed to determine if any factors were associated with a successful clinical outcome within our dataset.

Extraction Techniques

Lead extraction procedures were performed in a cardiac catheter laboratory with prearranged general surgical cover on site. The usual practice was for this to be a Vascular or Upper Gastrointestinal surgeon with expertise in procedures involving a thoracic approach. Expert Cardiothoracic surgical cover is provided by a neighbouring hospital with an estimated transfer time to cardiac theatre of approximately one hour. General anaesthesia with invasive haemodynamic monitoring was utilised in the majority of cases. All procedures were performed or supervised by one of three experienced operators. In general, the lead(s) to be extracted were identified and dissected away from the tissues in the pectoral region and extraction was then attempted by manual traction with or without the use of an appropriately sized locking stylet. Where the leads were felt likely to break down during simple traction, or if manual traction failed to remove the lead, more specialist equipment, including cutting, rotating threaded tip and laser sheaths were utilised at the discretion of the operator. Femoral extraction equipment was reserved for cases where techniques from the pectoral region had failed or the lead was not accessible from the top end.

Results

Patient characteristics [table 1] and summary results for the post 2005 cohort [table 2] are shown below.

Table 1: Patient Characteristics

Total Procedures	421
Post 2005 Procedures	226
Age	72 (range 20-95)
Gender	305 (72%) Male

Table 2: Post 2005 Cohort

Procedures	226
Leads	385
Systemic Infection	30 (13%)
Pocket infection	76 (34%)
Age of lead at procedure (months)	49 median (IQ 26-95)
Success by procedure	221 (98%)
Complete Success by procedure	212 (94%)
Complete success by Lead	373 (97%)
Procedural Mortality	0

In total 658 leads were extracted during 421 separate procedures. There were no procedural deaths but ten deaths within 30 days of the procedure. Over the 8 year period from September 2005 to September 2013, 385 leads were extracted during 226 separate procedures, an average of 28.3 cases each year. All subsequent analysis is of this cohort.

There were no peri-procedural deaths or requirement for emergency cardiac surgery. Procedural clinical outcomes were successfully achieved in 98% procedures, with failure in the remaining 2%. 97% of leads were removed without leaving any retained material. This led to attaining complete procedural success (removal of all parts of all extracted leads) in 94% of cases.

Patient and procedural characteristics

The patient population from which the leads were extracted had ages ranging from 20 to 95 years (median age 73 years, quartiles 63.75 to 80 years). There was a high burden of comorbid disease within the group. 66% of cases had 1 or more significant comorbidity including 47 cases performed on patients with severe impairment of left ventricular (LV) systolic function and an average LV ejection fraction in that group of 23%.

As with previous case series, the most common indication for extraction was infection, accounting for 47% of cases and 59.5% of leads. Thirty cases were performed in the context of systemic sepsis or demonstrable infective endocarditis. From the cases performed for an indication of infection, an organism was demonstrated in 71% with Staphylococcus species accounting for 79% of causative microbes identified.

The leads themselves included 129 atrial, 144 right ventricular, 63 high energy and 49 coronary sinus leads. The median number of leads extracted during a single procedure was two with a maximum of six. The median duration of implant prior to extraction was 49 months (quartiles 26 to 95 months). The lead implanted the longest time prior to extraction was in situ for 29 years and eight months. Nine leads were removed less than twelve months post implant but included in the dataset as they required specialist extraction equipment (locking stylets and/or sheaths) to facilitate their removal.

The length of stay associated with an extraction ranged from one to 155 day with a median of six days (interquartile range one to sixteen days). Intensive care was required in 2% of cases during their admission and 9.7% of cases were readmitted as a non-elective admission within 30 days. Data regarding specific complications was incomplete, especially post discharge. There were only two major complications (<1% of cases) recorded, both were cases of cardiac perforation causing Tamponade and requiring pericardiocentesis. Minor Complications (occurring in 9% cases overall) included four (1.7%) cases of post procedure pulmonary embolus, eleven (4.9%) cases of haematoma requiring evacuation or increase hospital length of stay, one requirement for vascular surgical repair of an access site, one case of pneumothorax requiring insertion of an intercostal drain, one migrated lead fragment without sequelae and two (<1%) reported cases of significant

post procedure arm swelling. In addition there was 1 case of phrenic nerve palsy complicating an extraction.

Of the five unsuccessful procedures, four were upgrades or lead revision procedures for malfunction in which tentative attempts to extract redundant leads were abandoned. The other procedure was for Acinetobacter sp. infection in an elderly patient with severe ischaemic cardiomyopathy. Although transfer for surgical extraction was discussed following the failed percutaneous extraction attempt, it was felt that the patient's premorbid state and co-morbidities meant that this was not in his best interests. His symptoms were palliated until his death some months later.

There were no intra-procedural deaths. No patients were transferred for emergency cardiothoracic surgery or required onsite chest opening. There were seven deaths within 30 days of the procedure. The indication for extraction was infection in three of these cases with the others being for malfunctioning or recalled leads. One patient developed overwhelming sepsis following the procedure, two suffered fatal myocardial infarctions, one developed post procedural metabolic acidosis thought secondary to medication, one died from massive upper GI haemorrhage on a background of endocarditis post procedure and the final two patients developed intractable heart failure.

Logistic regression analysis of single and multiple variables demonstrated no patient characteristics that were associated with a statistically significant increase in the chance of the procedure being a clinical success or of the patient dying within 30 days of the procedure. When analysing the data by each lead extracted, an increase in the time the lead was in situ prior to extraction was associated with a small but significant decrease in the chance of complete removal of that lead. This effect was consistently seen with both single and multiple variable analysis.

Discussion

This series represents the first description of outcomes from cardiac implantable electronic device extraction procedures performed in a non-cardiothoracic surgical centre. An overall clinical success rate of 98%, complete procedural success of 94% and 30 day mortality of 3.5% demonstrate outcomes comparable to other published, single centre series from units with cardiothoracic surgical cover on site. Also presented are data which demonstrate comparable practice with regard to patient selection and comorbidity, indication for device extraction, procedural techniques used and rate of both major and minor complications.

These data offer a unique insight into an alternative viewpoint to the current international guidance on the facilities required for the extraction of implanted cardiac devices. Our institution has offered a full device extraction service without on-site cardiothoracic surgical cover for over 20 years and, due to this historical skill-base, we continue to provide that service.

Percutaneous extraction of a cardiac implantable electronic device carries risk of catastrophic injury to the patient in a small proportion of those undergoing the procedure. Although it is clear that immediate cardiothoracic surgical intervention will salvage the situation in a percentage of these cases, others will undergo surgical intervention that may have been avoided by more conservative therapy, a proportion will succumb despite it and some will not have surgical intervention despite its availability[7]. Although conspicuous due to the fact we do not have on site cardiothoracic surgery or the facility to implement cardiopulmonary bypass, our centre takes the relatively widely held stance that there is no need for a surgeon to be immediately available during all extraction procedures. This is the case in a significant proportion of extracting centres where, although on site, either no cardiothoracic surgeon or an available theatre is identified prior to the procedure[4]. This would necessitate stabilisation of the patient, communication with a surgeon and transfer to the appropriate environment in the event of catastrophic complication. This is analogous to the situation in our facility. As in those centres, we accept that this system is a compromise to the sometimes advocated protocol of a surgical team and perfusionist on standby in the operating environment.

Many interventional cardiac procedures have made the transition from being performed only in tertiary, cardiothoracic surgical centres to being performed in surgical and non-surgical centres alike. Most notable amongst such is percutaneous coronary intervention (PCI). Originally felt to represent too high risk to perform without the safety of back-up cardiothoracic support, PCI had a quoted risk of a 6% chance of catastrophic complication[8]. Improvements in techniques and especially safety, coupled with a demand for intervention that could not be satisfied within the tertiary centre network capacity, have meant that the procedure is now established and accepted in the district general setting. Indeed, in the UK today, there are more centres performing PCI without cardiothoracic surgeons on site than with[9]. Pacing and complex device implantation[10] were once also regarded as the exclusive domain of surgical centres.

The data presented raises an important question as to whether surgical onsite backup is needed in the removal of all transvenous leads. This could be important for patients living at distance from a surgical centre allowing them access to treatment without the burden of significant travel. Whether rising rates of device extraction will necessitate more widespread application of the procedure being

performed in centres without on-site cardiothoracic surgical cover and whether setting up such a service *de novo* is possible, remains to be seen.

As a caveat to our stance, there are infrequent situations in which extraction without a surgeon available is felt too high risk. Specific examples for our centre include patients with congenital cardiac abnormalities, an instance where a patient had an arteriovenous fistula for haemodialysis on the side of their device requiring extraction and a patient in whom CT scanning had demonstrated an inflammatory mass associated with an infected coronary sinus (CS) lead within the main body of the CS. For such patients, transfer to our local cardiothoracic surgical centre and device extraction by the cardiologists or cardiothoracic surgeons there is arranged. This situation arises for our patient population less than once a year.

Data Limitations

These retrospective data are descriptive only. The analysis was not prospectively powered to reach any defined statistical significance and no firm conclusions can be drawn. The data presented do, however, represent a real world clinical experience. Whilst the absence of an intra-procedural death or requirement for emergency transfer within the case series could be due to chance rather than careful procedure planning and execution; the data on patient co-morbidity, indication for extraction and procedural success confirm that case selection and procedural techniques are appropriate. It is therefore likely that the upper limit of the confidence interval for the true proportion of cases associated with intra-procedural death or need for emergency transfer is valid at 1.7%.

Conclusions

It is our belief that in our established centre, with operators who have appropriate experience and a full range of techniques available, transvenous cardiac implantable electronic device extraction can be carried out safely and effectively in selected patients without on-site cardiothoracic surgical cover. These data support that practice, demonstrating patient and procedural outcomes comparable with other published results.

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