Deaths and cardiovascular injuries due to device-assisted implantable cardioverter–defibrillator and pacemaker lead extraction

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Aims

An estimated 10 000–15 000 pacemaker and implantable cardioverter–defibrillator (ICD) leads are extracted annually worldwide using specialized tools and techniques (personal communication with physicians and industry). These device-assisted procedures employ technologies that free leads from encapsulating fibrous tissue which binds them to major veins and cardiac structures and other implanted leads.1–6 Although infection has been the most common indication for device-assisted lead extraction, lead malfunction, the removal of abandoned and recalled leads, and the need to ‘upgrade’ existing systems to defibrillation or cardiac resynchronization devices have increased the number of extractions performed in recent years. The requirement to completely

Methods and results

We searched the US Food and Drug Administration’s (FDA) Manufacturers and User Defined Experience (MAUDE) database from 1995 to 2008 using the search terms ‘lead extraction and death’ and ‘lead extraction and injury’. Additional product specific searches were performed for the terms ‘death’ and ‘injury’. Between 1995 and 2008, 57 deaths and 48 serious cardiovascular injuries associated with device-assisted lead extraction were reported to the FDA. Owing to underreporting, the FDA database does not contain all adverse events that occurred during this period. Of the 105 events, 27 deaths and 13 injuries occurred in 2007–2008. During these 2 years, 23 deaths were linked with excimer laser or mechanical dilator sheath extractions. The majority of deaths and injuries involved ICD leads, and most were caused by lacerations of the right atrium, superior vena cava, or innominate vein. Overall, 62 patients underwent emergency surgical repair of myocardial perforations and venous lacerations and 35 (56%) survived.

Conclusion

These findings suggest that device-assisted lead extraction is a high-risk procedure and that serious complications including death may not be mitigated by emergency surgery. However, skilled standby cardiothoracic surgery is essential when performing pacemaker and ICD lead extractions. Although the incidence of these complications is unknown, the results of our study imply that device-assisted lead extractions should be performed by highly qualified physicians and their teams in specialized centres.

Keywords

Leads • Extraction • Complications • Pacemaker • Implantable defibrillator
remove infected leads encouraged manufacturers to develop extraction tools that can ablate or disrupt fibrous tissue. Such devices use laser \(^1\) and radiofrequency (RF) \(^2\) energy and novel cutting sheaths \(^3\) that have increased the proportion of leads completely removed compared with countertraction using non-powered or specialized sheaths. However, it is known that lead extraction with or without device assistance is a procedure that may be complicated by death, haemopericardium, and other life-threatening injuries.\(^1\)–\(^3\)

The controversy surrounding the management of patients who have Sprint Fidelis ICD leads \(^7\) and the report of deaths associated with Sprint Fidelis lead extraction \(^8\) prompted us to examine the worldwide adverse events that have been reported by manufacturers, hospitals, and health providers to the US Food and Drug Administration (FDA). The aim of this study was to determine whether complications due to device-assisted lead extraction might be more hazardous than available data suggest, and whether procedural safety precautions, including standby cardiothoracic surgery, are effective.

**Methods**

**United States Food and Drug Administration manufacturers and user-defined experience database**

The FDA’s Manufacturers and User Defined Experience (MAUDE) database contains reports of adverse events involving medical devices worldwide. The majority of reports originate from device manufacturers; \(5\,\text{–}\,7\%\) are submitted by user facilities, including hospitals and clinics.\(^9\)–\(^11\) The FDA has required device manufacturers to report adverse events that are communicated to them since 1995. Adverse events are filed as Medical Device Reports (MDRs), which are searchable online at www.fda.gov/cdrh/maude.html. The relevant data items for an MDR are: (i) device type and model, (ii) report source (e.g. hospital or manufacturer), (iii) event date and location, (iv) device age, (v) patient outcome, (vi) a narrative of the event, and (vii) the manufacturers evaluation of returned devices if available.

For this study, simple searches were conducted for the terms ‘lead extraction and death’ and ‘lead extraction and injury’; additional advanced manufacturer- and product-specific searches were performed for the search terms ‘death’ and ‘injury’. The searches were conducted in March 2009. These searches produced 123 MDRs that satisfied the search criteria. Although each MDR had a unique numerical identifier, 16 MDRs were clearly duplicate reports of the same events that were either submitted by a different party or were erroneously resubmitted by the manufacturer or user facility. Two MDRs described laser generator failure during lead extraction, which resulted in uncomplicated lead extraction by thoracotomy. After excluding the duplicate reports and the laser generator failures, we analysed 105 MDRs that reported deaths and injuries associated with device-assisted lead extraction.

**Techniques and devices**

The term ‘lead extraction’ applies to pacemaker and ICD leads that have been implanted \(>1\) year or that require special equipment to remove regardless of implant age.\(^12\) Lead removals via an access other than the original venous insertion site are also considered extractions. Pacemaker and ICD lead extraction is initially attempted by inserting a regular stylet to preserve the lead’s lumen, disengaging the active fixation mechanism if possible, and applying steady traction with or without the use of a specialized locking stylet that stabilizes the lead. Many leads—particularly those implanted \(<3\,–\,4\) years—can be removed by this basic countertraction method. If traction alone is unsuccessful, physicians may use one or several lead extraction devices as described in the following. Locking stylets are routinely used with these extraction devices. Leads that fracture or otherwise cannot be removed from the primary venous insertion site, e.g. cephalic or subclavian vein, may require extraction via the femoral vein using a variety of extraction tools such as snare. Surgical removal by thoracotomy is usually reserved for failed extractions and for infected leads with large vegetations. A successful extraction is complete lead removal, whereas a failed extraction has been defined as leaving \(>4\) cm of lead in situ.

**Excimer laser sheath**

The excimer laser sheath (SLS II, Spectranetics Inc., Colorado Springs, CO, USA) contains optical fibres that are arranged circumferentially between inner and outer polymer tubing.\(^13\) The optical fibres terminate in the distal tip where they produce a circle of pulsed eximer laser light consisting of high-energy short-duration pulses (135 ns) at low temperature (~50°C) and shallow tissue penetration (~100 μm). The resultant photoablation of non-calcified fibrous tissue yields water, gas, and small particles (90% <90 μm). During use, the laser sheath is placed in a 42 cm outer sheath that is cut at a 45° at one end with bevelled edges; this outer sheath is used to introduce and align the laser sheath and to serve as a conduit for removing the extracted lead. Some operators prefer not to use the outer sheath. The excimer laser generator interfaces with the laser sheath via a modular connector that delivers ultraviolet energy to the optical fibres. The manufacturer’s labelling specifies that its excimer laser products should not be used unless the procedure room is prepared for emergency thoracotomy or pericardiocentesis, that surgical back-up is arranged, and that the patient be prepped for thoracotomy with packed red blood cells immediately available for transfusion.\(^13\) Laser-assisted lead extraction \(^14\) (Figure 1) is performed under fluoroscopic control by (i) selecting a 12, 14, or 16 French laser sheath depending on the diameter of the lead to be removed; (ii) advancing the laser sheath and optional outer sheath over the lead and activating the laser as fibrous tissue is encountered; (iii) dislodging the lead tip by countertraction and removing the lead. Safety precautions include maintaining a coaxial orientation of the laser sheath to the lead and keeping the outer sheath’s long bevel from contacting the superior vena cava.

**Mechanical dilator sheath**

The Evolution™ mechanical dilator sheath (Cook Vascular Inc., Vandalgriff, PA, USA) is a rotationally powered telescoping device with an inner sheath that has a stainless steel bladed distal tip.\(^15\) The sheath is connected to a manually operated tool that rotates the bladed inner sheath so that fibrous tissue is disrupted as the sheath is advanced over the course of the lead.\(^5\,\text{–}\,6\)

**Electrosurgical dissection sheath**

This specialized sheath (Perfecta™, Cook Vascular Inc.) delivers RF energy via tungsten bipolar electrodes contained in the tip of a Teflon sheath set that is advanced over the lead inside an outer sheath.\(^16\) Fibrous tissue is ablated or dissected using a standard RF generator (Valleylab Force FX™, Valleylab, Boulder, CO, USA) that delivers 25 watts pulsed at 80 cycles per minute under operator control.\(^4\)
The electrosurgical and outer sheaths are applied using techniques similar to those used with other extraction sheaths.

**Polypropylene or Teflon dilator sheath**

The polypropylene or Teflon dilator sheath (Byrd, Cook Vascular Inc.) has been available for two decades. It is a telescoping sheath that ranges in size from 7 to 13 French and it is used in conjunction with a locking stylet that allows the operator to maintain traction on the lead while the sheath is advanced over the lead. As is true for all sheath-based techniques, keys to safety and successful removal include meticulous preparation of the lead and maintaining coaxial alignment of the sheath with the lead.

**Results**

Between 1995 and 2008, 57 peri-operative deaths and 48 serious procedural injuries associated with device-assisted lead extraction were reported to the FDA (Table 1); approximately a third of reports originated outside the USA. These 105 events involved the extraction of one or more pacemaker leads (n = 34), ICD leads (n = 42), pacemaker and ICD leads (n = 6), and unspecified leads (n = 23). The most frequently reported indication for extraction was lead malfunction, including 10 leads that had been subject to advisories by their manufacturers. Of the 105 events, 27 deaths and 13 injuries occurred in 2007–2008. During these 2 years, 23 deaths were linked to excimer laser or mechanical dilator sheath extractions. Overall, 62 patients underwent emergency surgical repair of myocardial perforations and venous lacerations and 35 (56%) survived.

**Excimer laser extraction**

The MAUDE data for 25 patients who died and 20 patients who sustained life-threatening injuries as the result of laser-assisted lead extraction are summarized in Table 2. The majority of deaths and injuries involved ICD leads and most were caused by lacerations of the right atrium, superior vena cava, or innominate vein (n = 31; 70%). Of the 34 patients who underwent emergency thoracotomy or sternotomy to repair venous lacerations or myocardial perforations, 17 (50%) died during or after surgery.
| Patient no./MDR Event Key | Outcome | Lead types | Lead age | Indication | Complication | Intervention |
|---------------------------|---------|------------|----------|------------|--------------|--------------|
| Table 2 Deaths and serious injuries associated with excimer laser and mechanical dilator sheath-assisted lead extractions | | | | | | |

**Excimer laser sheath**

| Patient no./MDR Event Key | Outcome | Lead types | Lead age | Indication | Complication | Intervention |
|---------------------------|---------|------------|----------|------------|--------------|--------------|
| 1/154622 | Death | PM | 9 months | Unspecified | SVC–RA laceration | Surgery² |
| 2/234845 | Death | ICD | NS | Lead malfunction | SVC–RA–innominate laceration | Surgery |
| 3/315195 | Death | NS | Unspecified | Unspecified | Unspecified | Unspecified |
| 4/374708 | Death | PM | NS | Unspecified | SVC–innominate laceration | Surgery |
| 5/630627 | Death | PM | 4 years | Lead malfunction | SVC laceration | Unspecified |
| 6/547246 | Death | ICD | Chronic | Infection | SVC laceration | Surgery |
| 7/967415 | Death | PM | NS | Unspecified | Innominate vein tear | Surgery |
| 8/893139 | Death | ICD | 10 years | Lead malfunction | SVC laceration | Expired before surgery initiated |
| 9/893137 | Death | ICD | 10 years | Lead malfunction | SVC–RA laceration | Surgery |
| 10/910339 | Death | ICD | NS | Unspecified | SVC laceration | Surgery |
| 11/958449 | Death | ICD | 5 years | Infection | SVC–RA laceration | Surgery |
| 12/94850 | Death | PM | NS | Upgrade to CRT | SVC laceration | Surgery |
| 13/973499 | Death | ICD | >10 years | Unspecified | Hypotension | Unspecified |
| 14/989544 | Death | ICD | 2.5 years | Lead malfunction | Hypotension | Unspecified |
| 15/1007232 | Death | ICD | 5 years | Infection | SVC laceration | Surgery |
| 16/1019345 | Death | NS | NS | Lead malfunction | Hypotension | Unspecified |
| 17/1046068 | Death | ICD | Chronic | Lead malfunction | SVC transection | Surgery |
| 18/1071466 | Death | ICD | 7 years | Infection | SVC laceration | Surgery |
| 19/1046069 | Death | ICD | 5 years | Lead malfunction | Haemopericardium | Surgery |
| 20/071467 | Death | PM | 8 years | Upgrade to ICD | SVC laceration | Surgery |
| 21/1074798 | Death | ICD | NS | Lead malfunction | Unspecified | Unspecified |
| 22/1198584 | Death | NS | NS | Infection | SVC laceration | Surgery |
| 23/1248243 | Death | ICD | NS | Infection | SVC laceration | Surgery |
| 24/1213923 | Death | PM A and V | 16 years | Unspecified | RV perforation | Surgery |
| 25/106917 | Death | ICD | Chronic | Infection | Pulmonary embolus | None |
| 26/44954 | Injury | PM | 4 years | Unspecified | Right atrial tear | Surgery |
| 27/264781 | Injury Survived | ICD | 4 years | Lead malfunction | SVC damage | Surgery |
| 28/684296 | Injury Survived | ICD | NS | Lead malfunction | SVC laceration | Unspecified |
| 29/273728 | Injury Survived | NS | NS | Unspecified | Haemopericardium | Surgery |
| 30/684495 | Injury Survived | ICD | 5 years | Lead malfunction | Haemopericardium | Surgery |
| 31/637729 | Injury Survived | ICD | NS | Unspecified | Haemotherax | Surgery |
| 32/543895 | Injury Survived | ICD | 7 years | Lead malfunction | Right atrial tear | Surgery |
| 33/544293 | Injury Survived | ICD | 6 years | Lead malfunction | SVC laceration | Surgery |
| 34/605731 | Injury Survived | ICD | NS | Infection | SVC laceration | Surgery |

*Continued*
Table 2  Continued

| Patient no./MDR Event Key* | Outcome | Lead types | Lead age | Indication | Complication | Intervention |
|----------------------------|---------|------------|----------|------------|--------------|--------------|
| 35/674412                  | Injury  | ICD        | 9 years  | Lead malfunction | Haemopericardium | Unspecified   |
| 36/785931                  | Injury  | NS         | NS       | Lead malfunction | Innominate vein tear | Surgery       |
| 37/930464                  | Injury  | NS         | 10 years | Unspecified   | SVC laceration | Surgery       |
| 38/930837                  | Injury  | NS         | 8 years  | Infection     | SVC laceration | Surgery       |
| 39/958245                  | Injury  | PM A and V | 14 years | Lead malfunction | Right atrial tear | Surgery       |
| 40/1007205                 | Injury  | ICD        | 4 years  | Unspecified   | SVC laceration | Surgery       |
| 41/1019437                 | Injury  | ICD        | 2 years  | Lead malfunction | SVC laceration | Surgery       |
| 42/1046003                 | Injury  | ICD        | NS       | Infection     | SVC–RA laceration | Surgery       |
| 43/1227551                 | Injury  | NS         | NS       | Unspecified   | SVC laceration | Surgery       |
| 44/1227550                 | Injury  | ICD        | NS       | Infection     | SC artery laceration | Surgery       |
| 45/1272964                 | Injury  | NS         | NS       | Unspecified   | SVC laceration | Surgery       |
| 46/1185004                 | Death   | ICD        | NS       | Unspecified   | Right atrial tear | Surgery       |
| 47/1032536                 | Death   | ICD        | NS       | Unspecified   | Haemorrhage    | Chest tube    |
| 48/1185003                 | Death   | ICD        | NS       | Unspecified   | Haemorrhage    | Surgery       |
| 49/1206484                 | Death   | NS         | NS       | Unspecified   | SVC laceration | Surgery       |
| 50/1222585                 | Death   | PM Multiple | 4 years  | Unspecified   | SVC laceration | Surgery       |
| 51/1273598                 | Death   | PM A and V | NS       | Lead malfunction | Haemopericardium | Surgery       |
| 52/978823                  | Injury  | PM Multiple | NS       | Infection     | Innominate vein tear | Unspecified    |
| 53/1264795                 | Injury  | ICD        | 3 years  | Lead malfunction | Innominate vein tear | Surgery       |

ICD, implantable cardioverter–defibrillator; PM, pacemaker; NS, not specified; SVC, superior vena cava; RV, right ventricle; SC, subclavian; A, atrial lead; V, ventricular lead.

*MDR, Medical Device Report. The MDR may be accessed at www.fda.gov/cdrh/maude.html by entering the MDR Event Key number into the simple search field.

*Surgery indicates thoracotomy or sternotomy.

Mechanical dilator sheath

Six peri-operative deaths were associated with the Evolution™ mechanical dilator sheath extraction, and the manufacturer reported all of them in 2008 (Table 2). Two deaths were caused by superior vena cava lacerations, one as the result of a right atrial tear, and three were due to haemorrhage. Three of the six deaths involved ICD leads that were being extracted for unspecified reasons. Two ICD patients survived innominate vein tears that were successfully treated surgically.

Electrosurgical dissection sheath

The manufacturer reported two deaths that were related to the use of a Perfecta™ electrosurgical dissection sheath to extract pacemaker leads, one of which had been implanted for 18 years. One death was due to haemopericardium, and the second patient died of unspecified reasons during the procedure.

Polypropylene or Teflon dilator sheaths

Between 1996 and 2000, the manufacturer reported 23 adverse events associated with this product, which was used during the extraction of 9 pacemaker leads, 1 ICD lead, and 13 unspecified leads. Our search found no further MDRs for Cook polypropylene or Teflon dilator sheaths from 2000 to 2008, when a single injury report was posted on MAUDE for an unspecified lead extraction. The 24 events associated with this extraction tool included 6 deaths and 18 injuries that were caused by subclavian, innominate,
or superior vena cava lacerations (n = 10), haemopericardium (n = 7), haemothorax (n = 2), lead entrapment in the sheath (n = 2), pneumothorax (n = 1), and embolic cerebrovascular accident (n = 1). Of the 16 patients whose intervention was recorded, 11 underwent surgery including 2 patients who died peri-operatively.

Unspecified extraction devices

Between 1995 and 2008, 26 MDRs were submitted by three pacemaker and ICD manufacturers and three health professionals describing 18 deaths and 8 injuries that occurred during an extraction procedure involving one of the manufacturer’s products or at the health professional’s facility. These events involved 15 ICD and 11 pacemaker leads that were being removed for malfunction (n = 19), infection (n = 3), prophylactically due to manufacturers’ advisory (n = 2), and unspecified reasons (n = 2). The 18 deaths were caused by superior vena cava lacerations (n = 5; 27%), haemorrhage (6; 33%), haemopericardium (n = 2; 11%), respiratory arrest (n = 1; 6%), and unspecified causes (n = 4; 22%). Of the 10 patients who underwent immediate thoracotomy or sternotomy, 8 survived, including one who required tricuspid valve repair.

Discussion

This study shows that device-assisted lead extraction has resulted in fatal cardiovascular injuries often despite emergency surgical intervention. Moreover, the majority of the reported deaths have occurred in the last 2 years, and most of them were caused by lacerations of major veins during laser or mechanical dilator sheath extractions. This finding is timely and important because more than 100,000 patients have undergone laser-assisted ICD leads that may require replacement. Medtronic has announced that 4 of the 13 deaths due to fractures of Sprint Fidelis leads were associated with the extraction of the failed lead. Byrd’s medical advisors have recommended that only physicians who have ‘extensive’ extraction experience should remove Sprint Fidelis leads. The results of our study and the known inverse relationship between extraction experience and procedural complications support this recommendation.

Byrd reported the first excimer laser-assisted pacemaker lead extraction in 1996. The multicentre randomized pacing lead extraction with the excimer sheath (PLEXES) trial found that laser-assisted extraction was more efficacious than non-laser techniques in 301 patients. Laser-assisted extraction resulted in a significantly higher proportion of complete lead removals than non-laser methods (94% vs. 64%; P < 0.001). However, even though there was no statistically significant difference in life-threatening complications between the laser and non-laser groups (P = 0.28), one death due to a right atrial laceration and three other major complications in the laser group prompted the investigators to conclude that laser-assisted pacemaker lead extraction was associated with significant risks. A subsequent non-randomized European multicentre study of excimer laser-assisted pacemaker and ICD lead extractions in 292 patients reported a 5.1% complication rate, including 10 non-fatal vascular and cardiac perforations.

Nevertheless, excimer laser-assisted lead extraction has been successful and reasonably safe in large single-centre experiences. Jones et al. recently reported their centre’s results for 975 pacemaker and ICD lead extractions in 498 patients over a 7-year period. Although the excimer laser was used for 77.6% of the leads, there were just two cases of tamponade and no procedural deaths. Importantly, 97.5% of leads were completely removed. Another single-centre study included laser-assisted extraction of 619 pacemaker and ICD leads that had been implanted for an average of 7.6 years with no device-related mortality. During the extraction of 277 pacemaker leads by Roux et al., the only death occurred when laser extraction was attempted on both left- and right-sided leads. A single-centre’s retrospective study reported one fatality during laser-assisted extraction of 91 ICD leads; this death was caused by a superior vena cava–right atrial tear despite immediate thoracotomy.

Byrd and Schaerf have reported their experiences with the mechanical dilator sheath that included 182 pacemaker and ICD leads which were removed by them without a death. Our study is the first to report major adverse events related to lead extraction with this device.

A multicentre historically controlled study of the electrosurgical dissection sheath reported six major adverse events in 166 patients (3.6%), including one death due to a superior vena cava tear and five cases of haemopericardium and haemothorax. A 160 patient randomized study of electrosurgical dissection sheaths found them to be more effective than standard counter-traction techniques, and the only complication was pacemaker pocket haemorrhage requiring transfusion in three patients.

It is apparent from our study that emergency surgical intervention to rescue patients who have suffered a venous laceration or myocardial tear may be unsuccessful even when all appropriate pre-procedure precautions have been taken. However, it is also clear that immediate surgical intervention was successful in many patients (Table 2), and hence competent cardiothoracic surgical standby is essential when performing pacemaker and ICD lead extractions. Still, it is vital that these injuries be avoided. As indicated by the MAUDE data and multiple studies, 19,24,25 the innominate vein—superior vena cava—right atrium is a region of great risk for fatal extraction injuries. Local tissue factors, such as calcification and infection, or the presence of other leads may confound the best available techniques, and operators must know when to stop the extraction and use a different approach such as another tool, surgery, or simply abandoning the lead.

Studies have shown that the risks of device-assisted lead extraction increase with the age and type of lead, presence of calcification around the lead, female patients, and the experience of the physician performing the procedure. Only the latter is a controllable risk factor, but a recent survey of Heart Rhythm Society members found that just 18% of physicians perform more than 50 extractions a year, and 25% of extraction procedures are done without a surgeon or operating room on standby. The Heart Rhythm Society’s recent expert consensus panel emphasized that the steepest decline in lead extraction complication rates occurs during the operator’s first 30 cases and that the decline continues up to 400 cases. The expert consensus panel also noted that an experienced physician’s success rate with
laser-assisted lead extraction declines when he or she averages less than 15 procedures per year.

This study has certain implications for research and development, physician training and credentialing, and the regulation of medical devices. Prospective studies are needed to determine the risks and benefits of extracting rather than abandoning non-infected leads. Regulatory agencies should consider limiting the sale of extraction devices to qualified physicians and institutions. Hospitals should apply strict criteria, such as those specified by the Heart Rhythm Society, for credentialing physicians who wish to perform device-assisted lead extraction.

Our study has certain limitations. Owing to underreporting, the MAUDE database does not contain all major adverse events involving lead extraction devices that occurred during the period of the study. Disparities may exist because events are not reported to the manufacturer, and users infrequently report deaths or serious injuries that occur at their facilities. Moreover, manufacturers may report adverse events to the FDA in annual product reports, which are generally unavailable to the public. For example, no MDRs exist for Teflon sheaths from 2000 to 2008 even though it is highly likely that adverse events with this sheath did occur during this period. Owing to these and possibly other limitations, no conclusion should be drawn regarding the incidence of device-assisted lead extraction deaths and cardiovascular injuries or the relative safety of the various extraction devices. Further, it is possible that more than one extraction device was used during some of the procedures.

In conclusion, device-assisted chronic pacemaker and ICD lead extractions have resulted in deaths and cardiovascular injuries due to catastrophic venous tears and myocardial perforations. Many of the deaths occurred despite emergency surgical intervention. However, immediate surgery was often successful, and competent standby cardiothoracic surgery is essential when performing pacemaker and ICD lead extraction with or without device assistance. The number of adverse events in the FDA MAUDE database underestimates the actual number of major complications associated with device-assisted lead extraction. These findings suggest that device-assisted lead extraction should be performed only in specialized centres by highly experienced physicians and their teams.

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