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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 that disrupt encapsulating fibrous tissue. Additional information is needed regarding the safety of the devices that have been approved for lead extraction. The aim of this study was to determine whether complications due to device-assisted lead extraction might be more hazardous than published data suggest, and whether procedural safety precautions are effective.

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

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

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remove infected leads encouraged manufacturers to develop extraction tools that can ablate or disrupt fibrous tissue. Such devices use laser[3] and radiofrequency (RF)[4] energy and novel cutting sheaths[6] 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; 5–7% 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 snares. 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., Vandergrift, 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.[5,6]

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]

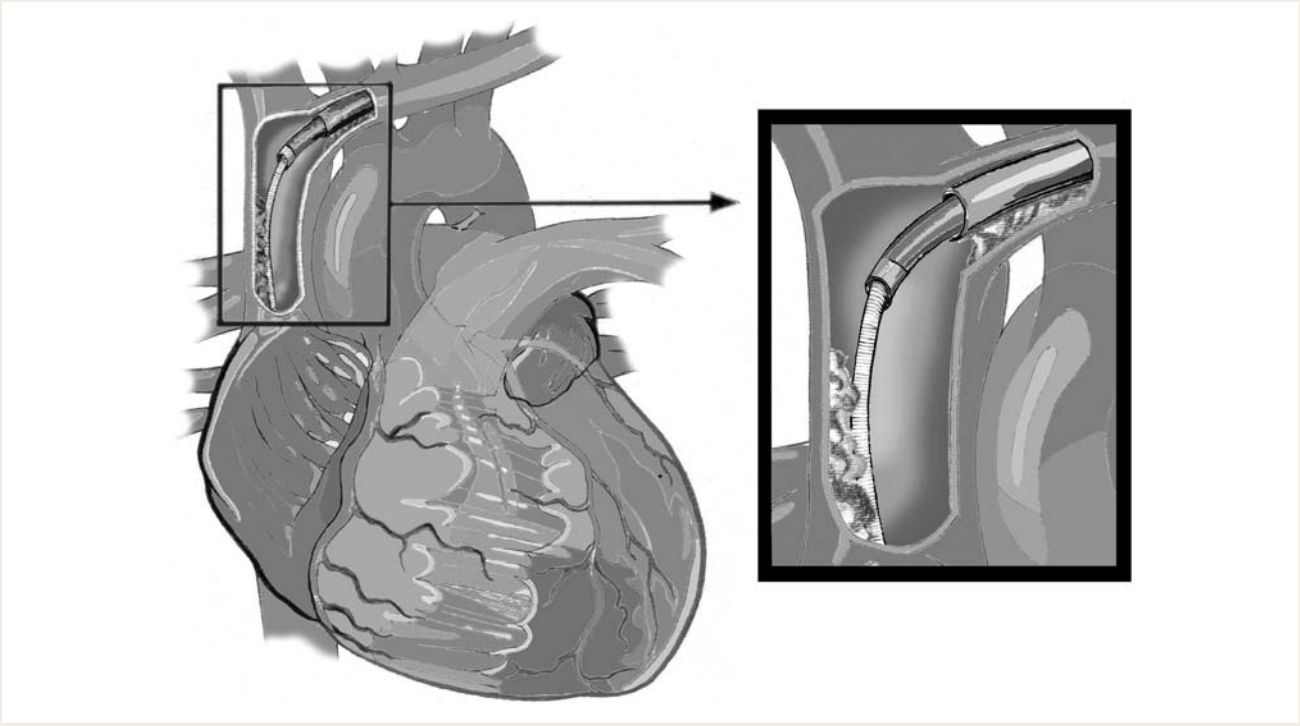

Figure 1 Laser-assisted lead extraction. The excimer laser sheath is advanced over the lead and photoablates the fibrous tissue that binds the lead to the superior vena cava.

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.[17] 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.[5]

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.

Table 1 Lead extraction devices associated with reported deaths and serious injuries in the FDA MAUDE database1995–2008

Lead extraction device	*n*	Number of events	
		Death	Injury
Excimer laser sheath	45	25	20
Mechanical dilator sheath	8	6	2
Electrosurgical dissection sheath	2	2	0
Polypropylene or Teflon dilator sheath	24	6	18
Unspecified extraction devices	26	18	8
Total	105	57	48

Owing to underreporting, all events that actually occurred during this timeframe are not in the FDA database, and hence are not represented in the table.

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.

Table 2 Deaths and serious injuries associated with excimer laser and mechanical dilator sheath-assisted lead extractions

Patient no./MDR Event Key[a]	Outcome	Lead types	Lead age	Indication	Complication	Intervention
Excimer laser sheath						
1/154622	Death	PM	9 months	Unspecified	SVC–RA laceration	Surgery[b]
2/234845	Death	ICD	NS	Lead malfunction	SVC–RA–innominate laceration	Surgery
3/314515	Death	ICD	NS	Unspecified	Unspecified	Unspecified
4/374708	Death	PM Leads	NS	Unspecified	SVC–innominate laceration	Surgery
5/630627	Death	PM	4 years	Lead malfunction	SVC laceration	Unspecified
6/547246	Death	ICD PM	Chronic	Infection	SVC laceration	Surgery
7/967415	Death	PM Leads	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 PM	NS	Unspecified	SVC laceration	Surgery
11/958449	Death	ICD PM	5 years	Infection	SVC–RA laceration	Surgery
12/946850	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 transsection	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 Multiple	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 Survived	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	Haemothorax	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 PM	NS	Infection	SVC laceration	Surgery

Continued

Table 2 *Continued*

Patient no./MDR Event Key[a]	Outcome	Lead types	Lead age	Indication	Complication	Intervention
35/674412	Injury Survived	ICD	9 years	Lead malfunction	Haemopericardium	Unspecified
36/785931	Injury Survived	NS	NS	Lead malfunction	Innominate vein tear	Surgery
37/930464	Injury Survived	NS	10 years	Unspecified	SVC laceration	Surgery
38/930837	Injury Survived	NS Multiple	8 years	Infection	SVC laceration	Surgery
39/958245	Injury Survived	PM A and V	14 years	Lead malfunction	Right atrial tear	Surgery
40/1007205	Injury Survived	ICD PM	4 years	Unspecified	Haemopericardium	Surgery
41/1019437	Injury Survived	ICD	2 years	Lead malfunction	SVC laceration	Surgery
42/1046003	Injury Survived	ICD	NS	Infection	SVC–RA laceration	Surgery
43/1227551	Injury Survived	NS	NS	Unspecified	SVC laceration	Surgery
44/1227550	Injury Survived	ICD	NS	Infection	SC artery laceration	Surgery
45/1272964	Injury Survived	NS	NS	Unspecified	SVC laceration	Surgery
Mechanical dilator sheath						
46/1185004	Death	ICD	NS	Unspecified	Right atrial tear	Surgery
47/1032536	Death	ICD	NS	Unspecified	Haemorrhage	Chest tube
48/1185003	Death	ICD PM	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 Survived	PM Multiple	NS	Infection	Innominate vein tear	Unspecified
53/1264795	Injury Survived	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.
[a]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.
[b]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 underperforming Sprint Fidelis 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.[8] Medtronic'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[1,2,12,18,19] support this recommendation.

Byrd[20] 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.[3] 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.[21]

Nevertheless, excimer laser-assisted lead extraction has been successful and reasonably safe in large single-centre experiences. Jones *et al.*[22] 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.[23] During the extraction of 277 pacemaker leads by Roux *et al.*,[24] 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.[25]

Byrd[26] and Schaerf *et al.*[27] have reported their experiences with the mechanical dilator sheath that included182 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.[16] 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.[4]

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–high 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.[5,28]

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.[1,2,19,22] 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.[29] 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.[12] 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,[30] and the regulation of medical devices. Prospective studies are needed to determine the risks and benefits of extracting rather than abandoning non-infected leads.[31] 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,[12] 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.

Conflict of interest: R.G.H. was responsible for analysing the data.

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References

1. Smith HJ, Fearnot NE, Byrd CL, Wilkoff BL, Love CJ, Sellers TD. Five years experience with intravascular lead extraction. *Pacing Clin Electrophysiol* 1994;**17**:2016–20.
2. Byrd CL, Wilkoff BL, Love CJ, Sellers TD, Turk KT, Reeves R *et al.* Intravascular extraction of problematic or infected permanent pacemaker leads: 1994–1996. *Pacing Clin Electrophysiol* 1999;**22**:1348–57.
3. Wilkoff BL, Byrd CL, Love CJ, Hayes DL, Sellers TD, Schaerf R *et al.* Pacemaker lead extraction with the laser sheath: results of the pacing lead extraction with the excimer sheath (PLEXES) trial. *J Am Coll Cardiol* 1999;**33**:1671–6.
4. Neuzil P, Taborsky M, Rezek Z, Volpalka R, Sediva L, Niederle P *et al.* Pacemaker and ICD lead extraction with electrosurgical dissection sheaths and standard transvenous extraction systems: results of a randomized trial. *Europace* 2007;**9**:98–104.
5. Love CJ. Lead extraction. *Heart Rhythm* 2007;**4**:1238–43.
6. Dello Russo A, Biddau R, Pelargonio G, Casella M, Frontera A, Camporeale A *et al.* Lead extraction: a new effective tool to overcome fibrous binding sites. *J Interv Card Electrophysiol* 2009;**24**:147–50.
7. Hauser RG, Hayes DL. Increasing hazard of Sprint Fidelis implantable cardioverter lead failure. *Heart Rhythm* 2009;**6**:605–10.
8. Samsel T. *Sprint Fidelis Lead Performance Update. 13 March 2009*. www.medtronic.com/product-advisories/physician/sprint-fidelis/PHYSLETTER-2009-03-13.htm (30 March 2009, date last accessed).
9. Hauser RG, Hayes DL, Almquist AK, Epstein AE, Parsonnet V, Tyers GFO *et al.* Unexpected ICD pulse generator failure due to electronic circuit damage caused by electrical overstress. *Pacing Clin Electrophysiol* 2001;**24**:1046–54.
10. Hauser RG, Kallinen L. Deaths associated with implantable cardioverter defibrillator failure and deactivation reported in the United States Food and Drug Administration Manufacturer and User Facility Device Experience Database. *Heart Rhythm* 2004;**1**:399–405.
11. Hauser RG, Kallinen LM, Almquist AK, Gornick CC, Katsiyiannis WT. Early failure of a small-diameter high-voltage implantable cardioverter–defibrillator lead. *Heart Rhythm* 2007;**4**:892–6.
12. Wilkoff BL, Love CJ, Byrd CL, Bongiorni MG, Carrillo RG, Crossley GH *et al.* Transvenous lead extraction: Heart Rhythm Society's expert consensus on facilities, training, indications, and patient management. *Heart Rhythm* 2009;**6**:1085–104.
13. *Spectranetics Instructions for Use: Laser Sheath Kit 2007*. www.spectranetics.com/pdf/IFU/7030-0253-13_SLSII.pdf (30 March 2009, date last accessed).
14. Feldtman RW. Intravascular lead extraction using the excimer laser: pitfalls and tips for success. *Semin Vasc Surg* 2007;**21**:54–6.
15. *Cook Vascular Inc. Instructions For Use: Evolution™ Mechanical Dilator Sheath Set*. www.cookmedical.com/di/content/mmedia/FM-2740-C.pdf (31 March 2009, date last accessed).
16. *Cook Vascular Inc. Instructions for Use: Perfecta™ Electrosurgical Dissection System*. www.cook-inc.com/di/content/mmedia/FM-1899-D.pdf (31 March 2009, date last accessed).
17. *Cook Vascular Inc. Instructions for Use: Byrd Dilator Sheath*. www.cookmedical.com/di/content/mmedia/FM-1403-C.pdf (31 March 2009, date last accessed).
18. Bracke FA, Meijer A, Van Gelder B. Learning curve characteristics of pacing lead extraction with a laser sheath. *Pacing Clin Electrophysiol* 1996;**21**:2309–13.
19. Byrd CL, Wilkoff BL, Love CJ, Sellers TD, Reiser C. Clinical study of the laser sheath for lead extraction: the total experience in the United States. *Pacing Clin Electrophysiol* 2002;**25**:804–8.
20. Byrd CL. Extracting chronically implanted pacemaker leads using the Spectranetics excimer laser: initial clinical experience. (Abstract). *Pacing Clin Electrophysiol* 1996;**19**:567.
21. Kennergren C, Bucknall CA, Butter C, Charles R, Fuhrer J, Grosfeld M *et al.* Laser assisted lead extraction: the European experience. *Europace* 2007;**9**:651–6.
22. Jones SO, Eckart RE, Albert CM, Epstein LM. Large, single-center, single-operator experience with transvenous lead extraction: outcomes and changing indications. *Heart Rhythm* 2008;**5**:520–5.
23. Kennergren CE, Bjurman C, Wiklund R, Gabel J. A thousand lead extraction experience. (Abstract). *Heart Rhythm* 2008;**5**:S339.
24. Roux JF, Page P, Dubuc M, Thibault B, Guerra PG, Macle L *et al.* Laser lead extraction: predictors of success and complications. *Pacing Clin Electrophysiol* 2007;**30**:214–20.
25. Saad EB, Saliba WI, Schweikert RA, AL-Khadra AS, Abdul Karim A, Niebauer MJ *et al.* Nonthoracotomy implantable defibrillator lead extraction: results and comparison with extraction of pacemaker leads. *Pacing Clin Electrophysiol* 2003;**26**:1944–50.
26. Byrd CL. Experience with the new Cook Evolution lead extraction sheaths. (Abstract). *Heart Rhythm* 2008;**5**:S30.
27. Schaerf RHM, Norlander BE, Goode L. Clinical experience with the Evolution mechanical dilator sheath set for intravascular lead extraction at a single center. *Heart Rhythm* 2008;**5**:S338.
28. Henrikson CA, Brinker JA. How to prevent, recognize and manage complications of lead extraction. Part III: procedural factors. *Heart Rhythm* 2008;**5**:1352–4.
29. Henrikson CA, Zhang K, Brinker JA. Lead extraction practice in the United States. (Abstract). *J Am Coll Cardiol* 2009;**53**:A129.
30. Naccarelli GV, Conti JB, DiMarco JP, Tracy CM. Task Force 6: training in specialized electrophysiology, cardiac pacing, and arrhythmias management: endorsed by the Heart Rhythm Society. *J Am Coll Cardiol* 2006;**47**:904–10.
31. Suga C, Hayes DL, Hyberger LK, Lloyd MA. Is there an adverse outcome from abandoned pacing leads? *J Interv Card Electrophysiol* 2000;**4**:493–9.