Classification and Surgical Repair of Injuries Sustained During Transvenous Lead Extraction

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***Background*—**Injuries to cardiac and venous structures during pacemaker and defibrillator lead extraction are serious complications that have been studied poorly. The incidence of these injuries is unknown but likely underestimated. No systematic multicenter review of these injuries or their management has been undertaken.

***Methods and Results*—**We interrogated our mandatory administrative database for all excimer laser extractions that sustained a cardiac or venous injury in the province of British Columbia. Injuries were classified according to presentation and compared with respect to nature of injury, type of repair, utilization of cardiopulmonary bypass, and outcome. Of 1082 excimer laser extractions over 19 years, 33 sustained an injury (3.0%). The majority of injuries occurred in women (21/33; 63.6%), and median age of oldest lead extracted was 10.8 (7.5, 12.2) years. A type 1 presentation, defined as circulatory collapse, was found in 12/33 patients (36.4%). A type 2 presentation, defined as progressive hypotension responsive to treatment, was found in 20/33 patients (60.6%). Over half the patients had a moderate or large injury, and cardiopulmonary bypass was required in 13 patients with extensive injury. Despite the presence of devastating injuries, the immediate availability of aggressive salvage measures resulted in a survival of 87.9% of patients at 30 days.

***Conclusions*—**The immediate availability of a cardiovascular surgeon, perfusionist, and cardiopulmonary bypass pump facilitates lifesaving repair of injuries sustained during laser lead extraction. The size and complexity of injury correlates closely with the presentation, blood loss, and need for cardiopulmonary bypass to facilitate repair. **(*Circ Arrhythm Electrophysiol*. 2016;9:e003741. DOI: 10.1161/CIRCEP.115.003741.)**

Key Words: cardiac surgery ■ cardiac tamponade ■ cardiopulmonary bypass ■ laser ■ lead extraction ■ pacemaker

Cardiac implantable electronic devices, particularly for the purpose of defibrillation or cardiac resynchronization, have seen dramatically expanded indications. This coupled with several high-profile device recalls and an increased rate of device infection have led to a greater need for transvenous lead extraction (TLE).[1–5] The consensus report from 2009 estimated that 10 to 15 000 TLEs occur globally per year, but this number is almost certainly larger now.[6]

TLE has the potential for infrequent but serious complications; in their worst form, these complications are characterized by cardiac or vascular perforation.[7] These injuries generally lead to either sudden-onset tamponade or hemothorax depending on the location of the perforation. These are often devastating injuries that carry a high risk of mortality if not treated appropriately. As a result, the most recent TLE consensus guidelines from 2009 mandate that cardiovascular surgical backup be immediately available (if the principal operator is not a cardiovascular surgeon) to facilitate repair of these injuries.[6]

The rate of injury varies from below 1% in highly experienced centers to over 3% with less experienced operators.[7–10] No data are available with respect to the population-based rate of complications or perforation. However, at a rate of 2%, an estimated 200 to 300 potentially fatal injuries may occur per year, though this number could be substantially higher. A provocative investigation from the MAUDE (Manufacturer and User Facility Device Experience) database revealed several perforations and fatalities related to TLE injuries, and valid concerns remain as to whether guidelines regarding surgical backup are being adequately followed.[11] The sporadic nature of these injuries is cited anecdotally as a likely contributor to the lack of awareness of surgeons to the critical issues at hand. Surgeons who represent the standby service may have limited exposure or experience with extraction, as well as its effects on the venous system.

Although 2 recent papers have appropriately described surgical management techniques in small series of injuries, there remains a paucity of information.[9,12] In the absence of a systematic examination of a large number of these injuries, a lack of consensus regarding management techniques is present. Even in centers that have the facility to immediately repair

Received October 17, 2015; accepted August 11, 2016.

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WHAT IS KNOWN

- Venous or cardiac injury with laser lead extraction can be a devastating complication with high mortality.

WHAT THE STUDY ADDS

- Retrospective review of a multicenter database supports the immediate availability of cardiac surgical back-up with the ability to implement cardiopulmonary bypass as the safest environment for laser lead extraction as most injuries can be readily fixed.
- The clinical presentation of patients with these injuries is correlated to the size of the injury and the type of repair required.
- Techniques for repair of these injuries are reproducible and can potentially be widely disseminated.

these injuries, the sporadic nature of these complications may leave the surgeon with no frame of reference or experience. This inexperience could easily lead to unnecessary and fatal delays in care. No systematic multicenter review of these injuries is published to our knowledge.

We performed a detailed review of all injuries sustained during transvenous laser lead extraction in the province of British Columbia (population 4.5 million), Canada, from 1996 to July 2015. In British Columbia, the vast majority of extractions are performed using the excimer laser (Spectranetics, Colorado Springs, CO), and all laser extractions were performed in 3 centers by cardiovascular surgeons. We identified all of the injuries in our total cohort of laser extractions followed by a careful review of the presentation, repair technique used, and its outcome. The primary objective was to examine the experience of a group of surgeons performing laser lead extraction (who have also, by necessity, developed experience in the repair of these injuries), with the ultimate goal of creating consensus on an effective management strategy for these injuries. The secondary goals were to classify the injuries by presentation and to determine the population-based rate of injury.

Methods

Laser-assisted lead extraction has been performed exclusively by cardiovascular surgeons in 3 institutions in the province of British Columbia since 1996. The British Columbia Cardiac Registry is a mandatory administrative database for all cardiac-related procedures that occur in the province, including all cardiac implantable electronic devices procedures and open-heart surgery. Data are collected prospectively for this database at the time of the procedure, and this data also forms the surgeons' operative report. This study was approved by the University of British Columbia Clinical Ethics Research Board.

Interrogation of this database (from the beginning of the laser extraction program in 1996 to July 2015) was undertaken to reveal all laser extraction procedures that were accompanied by any type of thoracotomy. Chart review was used to supplement this database and to confirm whether the thoracotomy was necessary to repair an injury that occurred during extraction or was used to supplement extraction procedures (to facilitate complete lead removal) as was occasionally done. Thoracotomies associated with laser extraction injuries were then subject to detailed chart review, with a particular emphasis on the location and size of injury, presentation, surgical management, and the outcome of each injury.

Injuries were primarily categorized according to size and location. The injury was described as small if ≤5 mm, moderate with an opening of 6 to 20 mm, and large if >20 mm. Locations of injury were described according to the anatomic cardiac or venous structure subtended by full thickness disruption.

The annotated section of the operative record was cross referenced with the anesthetic record and used to describe the presentation with respect to the onset of hypotension, the severity of hypotension, and anesthetic management. Detailed information was available in every case. Patients were then categorized according to the rapidity of onset of hypotension, the severity of hypotension, and its responsiveness to fluids and vasoconstrictors (as detailed in the anesthetic and operative record) into one of the 3 categories: type 1 presentation (circulatory collapse): immediate or rapid circulatory collapse where hypotension was essentially unresponsive to fluids and inotropes after 3 minutes; type 2 presentation (slow slider): hypotension that was responsive to fluids and inotropes but progressive such that the response to fluids and inotropes was less effective over time; type 3 presentation (dependent stability): delayed hypotension or hypotension that was readily treatable though the patient remained dependent on ongoing fluids or vasoconstrictors.

Based on the above mentioned stratification, comparisons were made between types to determine whether the presentation was predictive of the size of injury, as well as the repair technique, use of cardiopulmonary bypass (CPB), sucker bypass, and outcome.

Continuous variables were described using the mean±standard deviation or median (q1, q3). Categorical variables were described by frequencies and percentages. A generalized estimating equation logistic regression model or ordinal regression model for estimating the mortality rate or testing the associations between the variables with clustering on surgeon was used. Significant intraphysician correlation was not observed; therefore, independent outcomes were assumed. The small numbers involved and the fact that outcome depends on several factors makes it unlikely that the cluster effect, if any, is large. Thus, inference based on the assumption of independent outcomes is justified in this case. The association between female sex and risk of perforation was compared using the χ^2 test of the null hypothesis of no association. The dependence between size of injury and presentation of perforation, size of injury and use of CPB, and size of injury and units of packed red blood cells transfused was first compared using Fisher exact test or the Chi-square test of the null hypothesis of no association. Further, to capture the magnitude and direction of dependence between these ordinal variables, we calculated Spearman correlation coefficients and Kendall Tau correlation coefficients, respectively. All tests were 2-sided, and a *P* value <0.05 was considered statistically significant. All statistical analyses were performed using the SAS software version 9.4 (SAS Institute, Cary, NC).

Results

Between July 1996 and July 2015, 1082 patients had laser lead extraction performed in 3 centers in the province by 5 cardiovascular surgeons. All extractions were performed in an operating room or hybrid room with a CPB machine present and perfusionist standing by. Unexpected injuries related to laser extraction where a thoracotomy was performed as a rescue procedure were identified in 33 patients (3.0%). The baseline characteristics are described in Table 1, with a mean age of 58.8±18.7 in the patients with injury and 60.1±18.0 in the noninjured group. Females were significantly more likely to experience an injury than males (*P*<0.001), with women making up 63.6% (21/33) of the injured group and only 31.2% (327/1049) of those without injury. Pacemaker systems were more frequently extracted than implantable cardioverter defibrillator systems and had a higher but nonsignificant rate of injury (*P*=0.15).

Table 1. Baseline Characteristics

Variables	Extraction Injury	No Injury	*P* Value
Patients	33 (3.0%)	1049 (97%)	
Age at extraction	58.8±18.7	60.1±18.0	0.70
Male	12 (36.4%)	722 (68.8%)	<0.001
Female	21 (63.6%)	327 (31.2%)	
Pacemaker	23 (69.7%)	586 (55.9%)	0.15
Implantable cardioverter defibrillator	10 (30.3%)	463 (44.1%)	

Table 2 summarizes other variables in the injured cohort. In patients experiencing an injury, the median implant duration of leads undergoing extraction was 10.8 years (7.5, 12.2). Only 2 patients had an injury in the setting of previous open-heart surgery (2/33 [6.1%], one of which had the chest partially open during the extraction procedure). The indications for extraction in the injured group were pocket infection (13, 39.4%), failed leads and debulking (13, 39.4%), endocarditis (5, 15.2%), and other indications (2, 6.1%). The intent was to extract 2 leads in the majority of cases (21, 63.6%) that had a perforation.

Table 2. Characteristics of Patients With Extraction Injury

Variables	
Oldest lead, y*	10.8 (7.5, 12.2)
EF, %*	57.50 (50.00, 60.00)
Creatinine, μmol/L*	73.00 (65.00, 103.00)
BMI, kg/m²*	25.6 (23.3, 29.4)
Hemoglobin, g/L†	125.7±16.2
No previous open-heart surgery	31 (93.9%)
Previous open-heart surgery	2 (6.1%)
No cardiotomy sucker necessary	20 (60.6%)
Cardiotomy sucker necessary	13 (39.4%)
Indication for extraction	
Failed lead(s)	13 (39.4%)
Pocket infection	13 (39.4%)
Endocarditis	5 (15.2%)
Others	2 (6.1%)
Bled into left chest, no tamponade	1 (3.0%)
Bled into right chest, no tamponade	3 (9.1%)
Number of leads to be extracted (2)	21 (63.6%)
Tamponade	29 (87.9%)
Sternotomy	28 (84.8%)
Subxiphoid approach	4 (12.1%)
Right thoracotomy	1 (3.0%)
30-Day mortality	
No	29 (87.9%)
Yes	4 (12.1%)

BMI indicates body mass index; and EF, ejection fraction.
*Median (q1, q3).
†Mean±standard deviation.

A summary table of the injuries, repair techniques, and outcomes is found in Table 3. Injuries were characterized as small in 15 patients (45.5%), moderate in 6 patients (18.2%), and large in 12 patients (36.4%). A type 1 presentation with circulatory collapse and intractable hypotension occurred in 12 patients (36.4%), whereas the majority of patients (20, 60.6%) had a type 2 presentation with hypotension that was responsive to fluids and inotropes. Only 1 patient had a type 3 presentation, which only became evident at the end of a long reimplantation procedure. CPB was used in almost half the patients (16, 48.5%), but in 2 of these cases, the use of CPB was unnecessary for repair of the injury. In one case, coronary artery bypass was performed after sternotomy to fix a small right atrial (RA) injury. In the other case, the laser was used to remove leads in a patient with endocarditis and previous valve surgery having a concomitant open-heart repair of an aortic root abscess. This patient developed hypotension, and a tear was eventually discovered in the superior vena cava (SVC).

The use of a cardiotomy sucker to capture and control mediastinal shed blood in conjunction with CPB was necessary because of large injuries that were not easily controlled in 13 patients (39.4%). The vast majority of patients presented with tamponade (28, 84.8%), and sternotomy was the approach of choice in 28 patients (84.8%). In 4 stable cases with controllable hypotension (all type 2 presentations), a small subxiphoid approach, sparing the sternotomy, was all that was required to drain tamponade and repair the injury. The majority of patients required between 1 and 6 units of packed red blood cells (18, 54.5), whereas 6 patients required massive transfusion with over 6 units of packed red blood cells. A total of 8 patients were repaired without receiving any blood transfusion.

Despite the presence of devastating injuries, the 30-day mortality in our series included only 4 of the 33 patients (12.1%), with 95% confidence interval (8.1%, 23.4%). In 2 of the patients who died, no attempt was made at repairing extensive venous or cardiac injuries because of advanced age and multiple serious comorbid conditions. One patient with a large tear from subclavian vein to RA was the only patient to have severe brain injury and eventually died 2 weeks after surgery when care was withdrawn. Of the 29 survivors at 30 days, only one remained in hospital.

Independent comparisons between the size of injury and the presentation, use of CPB, and blood transfusion are described in Table 4. Patients who presented with circulatory collapse that was intractable to fluids and vasoconstrictors (a type 1 presentation) were much more likely to have large injuries and require CPB to resolve those injuries. This was highly statistically significant ($P<0.001$). Patients with a type 1 presentation were also more likely to require multiple blood products ($P=0.015$). Further, comparing size of injury to both presentation and use of CPB revealed a positive and medium degree of correlation such that it was significantly more likely for large injuries to present with circulatory collapse and to require CPB ($P<0.001$).

Discussion

Our experience with injuries sustained during lead extraction reveal these to be complex situations where, in the majority

Table 3. Summary of Injuries, Outcomes, and Repair Techniques Categorized by Size of Injury

Size	Location	Type of Presentation	Mechanism of Hypotension	Surgical Approach	Repair Technique	Cardiopulmonary Bypass	Sucker Bypass	30-Day Mortality
Small (15)	RA appendage (6); right ventricle (4); SVC (5)	Slow slider (14); delayed (1)	Tamponade (13); bleed into right chest (1); bleed into mediastinum (1)	Subxiphoid thoracotomy (4); sternotomy (11)	Simple suture (14); patch only (1)	3 Yes; 12 no	1 Yes; 14 no	1 Yes; 14 no
Moderate (6)	RA appendage (3); SVC (3)	Slow slider (4); circulatory collapse (2)	Tamponade (5); bleed into right chest (1)	Sternotomy (6)	Simple suture (4); multiple sutures (1); suture line (1)	2 Yes; 4 no	2 Yes; 4 no	0 Yes; 6 no
Large (12)	Free wall RA (2); large linear tear SVC (3); large tear SVC into RA (2); large linear tear from subclavian into RA (4); subclavian to innominate (1)	Circulatory collapse (10); slow slide (2)	Tamponade (10); bleed into left chest (1); bleed into right chest (1)	Sternotomy (11); right thoracotomy (1)	Suture line (2); not repaired (2); patch (8)	11 Yes; 1 not repaired	11 Yes; 1 not repaired	3 Yes; 9 no

RA indicates right atrial; and SVC, superior vena cava.

of cases, immediate and effective surgical treatment is a clear necessity to prevent mortality. Time is of the essence in the setting of cardiac tamponade because increasing pericardial pressure will prevent sufficient cardiac output to maintain neurological function, and irreversible neurological injury will generally occur within 5 to 10 minutes. Making matters worse, at the time of onset of hypotension and confirmation of cardiac tamponade, the location and severity of injury are often unknown.

In the worst case scenario, the situation necessitates immediate thoracotomy (usually sternotomy), evacuation of tamponade, and repair of the injury. Simultaneous aggressive maintenance of cardiac output and blood pressure with fluid and vasoconstrictors by the anesthesia team is critical. For large or complex injuries, ongoing blood loss from tears in the RA or SVC may make CPB and the use of a cardiotomy sucker an absolute necessity (39.4% of the patients in our series) because maintenance of cardiac output cannot be achieved otherwise. To be placed on CPB, the patient must be fully anticoagulated with unfractionated heparin, which may seem counterintuitive in the setting of trauma. However, in many cases, maintaining cardiac output and repairing the injury is not achievable without heparinization. Therefore, a CPB pump, and the personnel to operate it, must be immediately available at the location of the extraction because we do not feel it is feasible to transport a patient in this situation (though this strategy has been described).[13]

Although smaller injuries may not require CPB, these patients can still quickly develop a large tamponade that often involves both clotted and liquid blood. Therefore, although it may be appropriate to use pericardiocentesis as a temporizing measure for type 2 presentation patients, this is often only temporarily effective.[10] Despite a smaller injury, clotted blood cannot be evacuated by pericardiocentesis, and the resolution of the acute injury requires either that the injury be small and the injured structure seal itself spontaneously or that the tamponade be evacuated manually. It should be noted that although none of the surgeons in this series used pericardiocentesis as a therapeutic modality, it may be a useful

Table 4. Independence Test Between Size of Injury and Three Other Variables

Factor	All Patients (33)	Size of Injury			*P* Value*
		Large (12)	Moderate (6)	Small (15)	
Type 2 presentation (slow slider)	20 (63.6%)	2 (16.7%)	4 (66.7%)	14 (93.3%)	<0.001
Type 1 presentation (circulatory collapse)	12 (36.4%)	10 (83.3%)	2 (33.3%)	0 (0%)	
No CPB	17 (51.5%)	1 (8.3%)	4 (66.7%)	12 (80%)	<0.001
CPB used, other	2 (6.1%)	0 (0%)	0 (0%)	2 (13.3%)	
CPB used	14 (42.4%)	11 (91.7%)	2 (33.3%)	1 (6.7%)	
Packed red blood cells 0 U	8 (24.2%)	2 (16.6%)	0 (0%)	6 (40.0%)	0.015
Packed red blood cells 1–6 U	18 (54.5%)	5 (41.7%)	4 (66.7%)	9 (60.0%)	
Packed red blood cells >6 U	7 (21.2%)	5 (41.7%)	2 (33.3%)	0 (0%)	

CPB indicates cardiopulmonary bypass.

**P* values were obtained using Fisher exact test or the chi square test.

temporizing procedure when a thoracotomy cannot be immediately performed.

The overarching lesson from this experience is that despite the severity of some venous and right-sided cardiac tears associated with lead extraction, the vast majority can be safely resolved, provided that surgical expertise and a CPB pump and perfusionist are immediately available. In our series, where intervention was essentially immediate, we found a relatively low mortality (12.1%), given the acuity and magnitude of the injury. Comparative mortalities in recent publications are 27 out of 62 (44%) from the MAUDE database and 36% from another large single-center series.[11,13]

Certain patterns were evident from our analysis of location and extent of injury. Right ventricular injuries were universally small and easy to control as were RA appendage tears, which were never large in size and were only related to removal of the atrial lead. Therefore, almost one third of the injuries were easy-to-control tears that involved removal of the atrial lead from the appendage. This knowledge has changed our clinical practice with respect to the technical conduct of atrial lead extraction. In essence, we never pass the laser near the tip of the atrial lead; a concerted effort is always made to push the atrial lead off the atrium by pushing the sheath of the laser (or other tools) inferiorly against the distal angulation the atrial lead makes as it heads superiorly. This is frequently effective. Injuries that included the SVC occurred in over half the patients (17/33), though 6 of these were devastating injuries that included other structures. Large injuries were much more likely to require a patch repair. As described previously, women were substantially at higher risk for a lead extraction injury, and this was highly statistically significant ($P<0.001$).[7]

The 3.0% rate of injury in our series is greater than high-volume single-center experiences.[14] However, our study represents a population-based rate of extraction injury with multiple centers and multiple operators (5 learning curves) over many years. The true rate of injury in other populations is unknown and is almost certainly higher than represented in large single-center experiences. Our series involves only higher risk patients who required laser extraction because none of the leads could be removed with manual traction, regardless of how long they had been implanted.[15] As well, the age of leads in the perforated group were in a higher risk category, with a median of 10.8 years.[7,10] Finally, our rate of injury can largely be attributed to early inexperience; our data represents the total experience of these 5 surgeons, and the vast majority of the injuries occurred in the first 100 cases for each operator.[7,8,16] For the surgeons with over 100 cases experience, the subsequent rate of injury (excluding the first 100) was 6/632 or 0.95%.

Because of this, the authors feel that both the perforation rate and mortality rate can still be significantly lower. In the setting of circulatory collapse or a type 1 presentation, the sternum should be opened immediately, and provided that the injury found is indeed moderate to severe, heparin administered, an arterial cannula quickly placed, and preparation made for sucker bypass. Any fashion of venous drainage, including sucker bypass, can be used to restore the circulation, and the inferior vena cava–related lower atrium easily cannulated in most cases (except those where the lower RA is involved). Low pressure but high-volume right heart and central venous bleeding, even when the exact location of the tear cannot be rapidly determined, can usually be controlled with hand or sponge pressure.[12] When the patient is placed on bypass, the right side of the circulation is immediately decompressed, blood loss falls dramatically, and the cardiotomy sucker can be used to provide a clear field for the required repair. An umbilical tape around the inferior vena cava cannula, as used in cardiac transplantation or tricuspid valve surgery, can be used to prevent air entrainment from the opening in the venous system. Clamping the lower SVC can also be done to prevent air entrainment if the injury is above this area.

In the setting of a type 2 presentation where the defect is usually smaller, drainage of tamponade should be initiated, and the need for CPB will depend on the size of injury found. Smaller injuries can be easily repaired without CPB in the vast majority of cases in our experience. Finally, type 3 presentations can be managed expectantly or with pericardiocentesis (or a surgical subxiphoid approach to pericardium) as needed, provided that the patient remains stable. Some of these injuries may be related to reimplantation rather than extraction itself.[16]

A correlation between presentation and severity of injury was evident. In short, the larger the injury, the more rapid the onset of severe tamponade and intractable hypotension. Larger more complex injuries, for example, involving both SVC and RA, had rapid onset of circulatory collapse, more frequently required CPB, and had higher utilization of packed red blood cells ($P<0.001$). It is unlikely that these injuries would derive any benefit from pericardiocentesis. Immediate thoracotomy, evacuation of tamponade, and repair of the injury is essential to ensure survival. It should be noted that 3 of the 4 fatal injuries were large injuries with a type 1 presentation.

In addition to an arterial pressure monitoring line, our anesthesia team now places a below diaphragm large bore intravenous or central line in every case. The rationale is that injuries often involve the SVC and upper RA (also see Table 2).[11] The ability to administer fluid below the diaphragm can be helpful if inferior vena cava cannulation (or temporary SVC clamping) is used to isolate the injury, stop bleeding, and restore perfusion using blood returned only from the inferior vena cava. We also pass off a cell-saver suction on every case because this can salvage a large amount of the initial blood loss in case of injury and is inexpensive.

Some practitioners have anecdotally advocated the institution of peripheral veno-arterial CPB in the setting of these injuries. With our experience, we understand that veno-arterial CPB has significant disadvantages. Tamponade will prevent venous return to the pump in peripheral veno-arterial cannulation, as well as be significantly more time-consuming to implement. Also, injuries to venous structures can allow for air entrainment and air lock in the open reservoir CPB circuit once the chest is opened.

Interventional techniques to cover perforated venous structures, such as the SVC, have been reported.[13] Although promising, these could only be implemented in a type 2 or 3 presentation, and tamponade must still be relieved to render this technique useful.

In the presence of a perforation of the SVC that causes a right hemothorax and no tamponade, a right thoracotomy in the third interspace is a possible approach, though it does not provide for easy institution of CPB. This may also be useful in the setting of previous open-heart surgery where RA and SVC injuries are likely the most common, and opening the sternum is more complicated. Finally, injuries to the right ventricle should almost never require CPB. Because of the nature of electrode placement and the muscularity of the right ventricle, injuries here are usually isolated holes that can be easily sutured, and this was the case for all 4 of the injuries in our series. A midline subxiphoid incision of 10 to 15 cm was occasionally used in stable patients. With upward traction on the sternum, a good portion of the right ventricle and RA can often be visualized, and tamponade can be easily evacuated. This is not a suitable incision for SVC injuries but can be easily extended into a partial lower sternotomy or full sternotomy should that be necessary.

Limitations

It is likely that the frequency of type 3 injury is higher than described in our series because of the way patients were identified for study. Pericardiocentesis was not used routinely, and its clinical utility in smaller injuries has not been determined.

Disclosures

Dr Bashir is a consultant for Boston Scientific, St Jude, and Spectranetics and has research funding from Spectranetics; Dr Karim is a consultant for Boston Scientific; Dr Tyers is a consultant for Greatbatch. Drs Fedoruk and Ofiesh have no disclosures.

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Circ Arrhythm Electrophysiol. 2016;9:
doi: 10.1161/CIRCEP.115.003741
Circulation: Arrhythmia and Electrophysiology is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 1941-3149. Online ISSN: 1941-3084