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# Trial<sup>®</sup>

## THEME ARTICLES

# GETTING TO THE HEART OF WRONGFUL DEATHS IN CATHETERIZATION LABS

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October 2015 - Gerald D. Jowers Jr.

**When doctors remove pacemaker and defibrillator lead wires in catheterization labs instead of operating rooms, they put their patients at risk for complications or death. Plaintiff attorneys should be aware of this and know how to make a case for liability.**

Heart specialists engage in an alarming practice throughout this country: removing pacemaker and defibrillator lead wires in the catheterization (cath) lab.<sup>1</sup> Medical literature warns that this procedure carries serious risk of injury or death and should be done only in an operating room (OR) with a surgeon, surgical team, and bypass machine in the room so that systems are in place if complications arise.

Yet, many electrophysiologists (doctors who specialize in heart rhythm disorders) continue to do these procedures in a standard cath lab with a surgical team on-call and a bypass machine located elsewhere in the hospital. If a major complication such as a tear in a vein occurs, the patient likely would die. Patient rescue depends on immediate surgical intervention: Minutes are the difference between survival and death.

It is estimated that between 10,000 and 15,000 lead wires are extracted annually worldwide.<sup>2</sup> A lead

extraction is the most dangerous procedure in electrophysiology.<sup>3</sup> A lead is a wire that runs from a pacemaker or implantable defibrillator into the heart's chambers. It attaches to the heart muscle and provides electrical signals from the device as needed. Over time, scar tissue forms at the attachment point and around the lead. Pacemaker and defibrillator lead wires usually are removed with a laser sheath that slides over the wire and burns through the scar tissue that encapsulates it.

During the procedure, the laser travels through the major vein leading to the heart and into the chamber of the heart where the lead is attached. Regardless of the doctor's skill and experience in lead extractions, tearing the vein leading to the heart or tearing the heart itself is an unavoidable risk. These tears cause internal bleeding—if the tear is not repaired immediately, the blood loss is often fatal. Although only heart specialists—electrophysiologists or cardiothoracic surgeons—perform the procedure, the rate of major complications is between 1.4 percent and 5.1 percent.<sup>4</sup> This means that, statistically, any doctor who performs enough laser lead extractions will experience a major complication.

## Warnings in the Literature

In 2006, in response to patient deaths during lead extractions, Duke University Medical Center instituted a policy that required laser lead extractions to be performed in an OR with a cardiothoracic surgeon present.<sup>5</sup> Before Duke's policy change, major complications resulted in three patient deaths; after the policy change, there were no patient deaths.<sup>6</sup> Similarly, in 2014, another center reported five major complications in 140 laser lead extractions (3.6 percent) performed in the OR over a period of nearly seven years. Due to the immediate availability of a bypass machine, all five patients were saved.<sup>7</sup>

In 2009, the doctors at Duke cautioned that “although it is possible to perform these procedures in the cardiac catheterization laboratory, we, like others, believe that patients who require emergent intervention would likely die if this were attempted outside of the operating room.”<sup>8</sup> In a 2008 article in *Seminars in Vascular Surgery*, the author, a doctor, warned that “laser lead extraction carries the risk for immediate thoracotomy and thus should only be done in an OR environment.”<sup>9</sup> Another article reported that doing the procedure in an OR instead of a standard cath lab will save a life for every 100 to 200 procedures.<sup>10</sup>

## A Dangerous Practice

Still, many doctors continue to put their patients at needless risk. A 2010 article surveyed 1,000 doctors who perform lead extractions and found that 64 percent do the procedures in a cath lab.<sup>11</sup> Even more alarming is that 25 percent of the surveyed doctors reported that they perform lead extractions in a cath lab with no surgeon or OR identified.<sup>12</sup>

The Heart Rhythm Society's most recent consensus statement, while not mandating lead extraction be done in an OR, explains that in cases in which the superior vena cava is torn, delays of more than five to 10 minutes in being able to access the heart often are fatal.<sup>13</sup> The time needed to mobilize surgical and bypass teams and transfer a bleeding patient from the cath lab to another room in the hospital wastes those critical few minutes. This explains why Spectranetics, a laser lead removal system manufacturer, instructs that laser sheath use is contraindicated “when emergency thoracotomy with cardiopulmonary bypass cannot be

performed immediately in the event of a life threatening complication.”<sup>14</sup>

## Developing the Liability Case

Doctors and hospitals are resistant to changing their procedures, especially given the costs of using an OR and providing extra staff. But in light of the literature warning that these procedures should be performed only in an OR, lawyers representing families of patients who die from complications of lead removals performed in a standard cath lab can bring medical malpractice cases against both the doctor and the hospital. This is a new and emerging area of litigation, so it is important for plaintiff attorneys to know how to build a case for liability.

The doctor’s liability will stem from his or her choice to do the extraction in an unsafe environment. The hospital’s liability will be based on having inadequate facilities, equipment, and personnel to safely perform the extractions. Like any medical malpractice case, the standard of care will have to be established by expert testimony. The plaintiff will need to present the testimony of an electrophysiologist who is familiar with the literature and can explain to the jury why the standard of care would never allow extractions to be performed outside of the OR.

Additionally, the plaintiff will need to present a cardiothoracic surgeon to explain how performing the procedure in the OR would have allowed for timely intervention to save the patient. Critical issues in the case will include the reason for the extraction, the doctor’s and hospital’s experience with prior complications, and what information the doctor and hospital gave the patient, if any, about the risks of the extraction.

**Creating a timeline.** Evaluating a potential case begins with reviewing the medical records. These records can be complicated, but the attorney should look through them first to determine whether to hire an expert or decline the case. A cath lab typically uses a charting system that creates a timeline of events. Look for the following in the timeline:

- When was the complication recognized?
- When was the surgeon paged?
- When was the OR notified?
- How long did it take for the surgeon and surgical nurses to arrive?
- How long did it take to move the patient to the OR?

Given that delays in surgical intervention as short as five minutes are associated with patient death, any delay following signs of a major complication requiring surgery is unacceptable. The length of time it took for the surgeon and nurses to arrive and transfer the patient to the OR may demonstrate that they were unprepared to handle a complication, and, more importantly, that the inability to save the patient was foreseeable.

**Depositions.** When deposing the doctor, ask about prior complications and deaths in similar procedures. A prior poor outcome due to the time required to mobilize a surgical team and move a patient to the OR would be important evidence that the doctor—and hospital—were on notice that doing lead extractions in the cath

lab was not safe. Also, find out the reason for the extraction of the lead wires:

- Was the device malfunctioning, or was there an infection?
- Was the extraction elective, or was it mandatory?
- Was doing nothing an option for the patient, and was that option discussed?
- Could the lead have remained in place and a new one implanted alongside it?

Exposing the patient to lead extraction risks may have been unnecessary.

Ask whether the doctor was aware of other facilities in which lead extractions were performed only in an OR. Did the doctor choose to do the extraction in the cath lab, or did the hospital not give him or her another option? Find out whether the doctor, surgical team, and bypass team ever performed drills to evaluate their response time in an emergency situation.

You also should explore the informed consent issue: What was the patient told about the procedure's risks? It is unlikely that the patient was advised that if a major complication were to occur, life-saving people and equipment would not be in the room and probably could not be mobilized in time. No patient would knowingly accept that risk.

As trial lawyers, the cases we bring and the successes we achieve for our clients often are catalysts for change. By bringing malpractice cases against doctors and hospitals that continue to perform lead extractions in standard cath labs, we can end this practice and prevent patient deaths.

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## Notes

1. A cath lab is a specialized room in a hospital containing diagnostic and imaging equipment used in certain heart procedures that typically are performed by non-surgeon electrophysiologists. A cath lab is not equipped or staffed for open heart surgery.
2. Robert G. Hauser et al., *Deaths and Cardiovascular Injuries Due to Device-Assisted Implantable Cardioverter-Defibrillator and Pacemaker Lead Extraction*, 12 *Europace* 395 (2010).
3. See Charles A. Henrikson et al., *A Survey of the Practice of Lead Extraction in the United States*, 33 *Pacing & Clinical Electrophysiology* 721 (2010).
4. Charles Kennergren et al., *Laser-Assisted Lead Extraction: The European Experience*, 9 *Europace* 651 (2007); Oussama Wazni et al., *Lead Extraction in the Contemporary Setting: The LEXICon Study: An*

- Observational Retrospective Study of Consecutive Laser Lead Extractions*, 55 J. Am. College Cardiology 579 (2010); see also Wei Wang et al., *Cardiopulmonary Bypass Standby Avoids Fatality Due to Vascular Laceration in Laser-Assisted Lead Extraction*, 29 J. Cardiac Surgery 274 (2014).
5. Jeffrey G. Gaca et al., *Laser-Assisted Extraction of Pacemaker and Defibrillator Leads: The Role of the Cardiac Surgeon*, 87 Annals Thoracic Surgery 1446 (2009).
  6. *Id.*
  7. Wang et al., *supra* note 4.
  8. Gaca et al., *supra* note 5, at 1449.
  9. Robert W. Feldtman, *Intravascular Lead Extraction Using the Excimer Laser: Pitfalls and Tips for Success*, 21 Seminars Vascular Surgery 54, 55 (2008).
  10. Frank Bracke, *Complications and Lead Extraction in Cardiac Pacing and Defibrillation*, 16 Netherlands Heart J. S28, S29 (2008).
  11. See Henrikson et al., *supra* note 3.
  12. *Id.*
  13. Bruce L. Wilkoff et al., *Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management*, 6 Heart Rhythm 1085, 1092 (2009).
  14. Spectranetics, *SLS II Laser Sheath: Instructions for Use 2* (Jan. 2014), [www.spectranetics.com/resources/ifu-library/](http://www.spectranetics.com/resources/ifu-library/).

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