Laser Lead Extraction in the Octogenarian Patient

Running title: Rodriguez et al.; Laser extraction in the octogenarian

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Journal Subject Code: [39] CV surgery: other
Abstract:

**Background** - In the United States, patients over the age of 75 are the most rapidly growing segment in the population with an expected increase of 126% by 2050. These patients account for >70% of the pacemakers (PMs) and up to two-thirds of the implantable cardiac defibrillators (ICDs) implanted annually. Our aim was to explore the clinical outcomes of device complications in the octogenarian population.

**Methods and Results** - We performed a retrospective chart review of 506 patients undergoing laser lead extraction from January 2004 to September 2009. This population was divided into two groups based solely on age: octogenarians and non-octogenarians. These two groups were compared on the basis of several characteristics and clinical outcomes. There were 118 patients in the octogenarian group (78 males, 40 females) and 388 in the non-octogenarians group (301 males, 87 females) with an average age of 85±3.8 and 64.2±12.4. A total of 253 leads [atrial (A): 99, ventricular (V): 145, coronary sinus (CS): 9] were removed from 118 patients in the octogenarian group; 814 leads (A: 295, V: 442, CS: 77) were removed from 388 patients in the non-octogenarian group. The main indication for extraction for both groups was infection. The lead implant duration was 59.6±52.8 and 38.6±43.9 months for octogenarians and non-octogenarians, respectively. There was no significant difference with respect to the proportion of minor (p =.65), major (p =.56) and total (p =.50) complications.

**Conclusions** - Laser lead extraction demonstrated to be a safe and effective treatment method in octogenarian patients with multiple comorbidities.

**Key words:** octogenarian; aged; aged, 80 and over; pacemaker, artificial; defibrillators; intraoperative complications
Introduction

In the United States, the elderly are one of the fastest growing demographic groups. This impressive growth is reflected in the patient population as well: patients over the age of 75 are expected to increase by 125% by the year 2050.\textsuperscript{1} Moreover, this segment of the patient population currently accounts for a significant percentage of pacemaker (PM) and implantable cardioverter defibrillator (ICD) recipients in our health care system. The average age of a primary PM patient is 75.5 (±12.1 years);\textsuperscript{2} some estimates state that patients over the age of 75 account for over 70% of PMs implanted in this country.\textsuperscript{1} The average age of a primary ICD patient is 66.2 (±12.8 years), and has been trending upwards with a steady increase of .2-.3 years annually.\textsuperscript{2} Recent trends suggest that this segment of the patient population’s role as consumers of implantable cardiac devices will only grow with time.

As the technology associated with implantable devices continues to become more sophisticated, their role in medicine will continue to increase. This expanded role is reflected by both the increase in the number of indications and by its prevalence in the population. During the 1990s alone, the number of individuals with PMs increased by 22% and the number of patients with an ICD increased 11-fold.\textsuperscript{2} During 2006, an estimated 418,000 pacemaker-related procedures (195,000 PM implantations and 223,000 PM lead related procedures) and 114,000 ICD-related procedures were performed and it is estimated that over 2.4 million Americans currently live with an implantable cardiac device.\textsuperscript{3}

Despite improvements in technology and the development of infection prevention protocols and newer implantation techniques, device complications still remain a reality. The two most common complications requiring device extraction are lead-related problems and
infection. The number of lead-related problems can be expected to increase proportionally with
the increased use of implantable cardiac devices. On the other hand, a recent study demonstrates
that the number of device infections is increasing out of proportion to the increase in
implantation rates. This phenomenon might be attributed to the use of implantable cardiac
devices in sicker (and thus more susceptible) patients, as well as to the increasing use of more
complex procedures.5

The rate of device complications along with their associated clinical outcomes in the
general patient population has been well described in literature; however, there is an ever-
growing segment of the elderly population that has never been analyzed specifically – the
octogenarians. When dealing with device complications and clinical outcomes in an
octogenarian, clinicians traditionally had to base their decisions regarding management on
extrapolations from the general populations used in previous studies.

Due to the increasing change in age demographics, the increased use of implantable
devices, the prevalence and rise of complications and the lack of literature concerning this
specific group, we decided to analyze the clinical outcomes of device complication and laser-
assisted extraction in the octogenarian patient population. The goal of this study is to provide
clinicians with a source of reference when managing patients from this specific age segment.

Methods

Patient Population

We performed a retrospective chart review of 506 patients undergoing laser lead extraction at a
single high-volume tertiary cardiovascular referral center between January 2004 and June 2009.
These cases were obtained from a prospective registry and approved by our Institutional Review
Board. This comprehensive database contains patient demographics, co-morbidities, procedure characteristics, extraction techniques, hospital outcomes and 30-day office visits that were recorded by a trained data collector. Each patient was given a unique identifier to maintain privacy.

This population of 506 patients was divided into two groups based solely on age: octogenarians (age ≥ 80 years, n = 118) and non-octogenarians (age < 80 years, n = 388). Patient and lead characteristics, indications for extraction, associated medical conditions and clinical outcomes were analyzed.

**Study Protocol**

A prospective and well-defined care protocol was set up for patients undergoing laser lead extraction. All patients upon admission had chest x-rays, PA and lateral, and some had CAT scans. Transthoracic echocardiograms were done in all patients. Blood cultures and preoperative Transesophageal echocardiogram (TEE) were obtained in all the patients in whom a suspected device infection was the reason for admission. In the operating room, pacemaker pocket tissue samples and lead tip cultures were sent in all the patients with suspected infection.

**Definitions**

Extraction was defined in accordance with the Heart Rhythm Society Expert Consensus document from 2009: Removal of leads that have been implanted for more than a year or leads that required specialized laser equipment. The indications for transvenous extractions were also defined by the guidelines, examples were infection; chronic pain; thrombosis; venous stenosis and functional or non-functional leads. The infection category was further subdivided and defined: (1) pocket infection was defined as local signs of inflammation, device or lead erosion; (2) Device endocarditis was defined accordingly to the modified Duke criteria for endocarditis;
(3) Bacteremia where positive blood cultures were the only finding. The terms procedural clinical success, procedure failure, major complications, minor complications were taken from the aforementioned document.

Echocardiograms: Both transthoracic and transesophageal echocardiograms were all reviewed by a certified cardiologist echocardiographer.

**Laser Extraction**

Laser sheaths, (Spectranetics®, Colorado Springs, CO) were used in all the cases by a single operator. These sheaths were used due to the fact that traction had failed to explant the pacemaker or defibrillating leads. General anesthesia and intraoperative TEE were used in most cases. The incision was performed in the infraclavicular space. The device was then removed and the leads were dissected up to the subclavian ligament. En-bloc encapsulectomy was performed in all the cases. A lead locking device (LLE) was inserted in the inner channel of the multifilar coaxial conductor. Appropriately sized and calibrated laser sheaths were used under fluoroscopic guidance to release the binding sites. As the sheath got closer to the myocardial lead tip interface, counter traction was used to free the tip of the lead. In cases involving infections, the wounds were closed primarily with 2-0 nylon and subcutaneous drains were used.

**Statistical Analyses**

Variable distributions were determined. Continuous variables were expressed as mean values and standard deviations. Categorical variables were expressed as percents. Continuous variables were compared using t-tests for independent samples. Lead types were compared using Poisson regression adjusting for total number of each lead type. Nominal variables were compared using the Chi-square test or Fisher's exact test if expected cell values were less than 5. Ordinal variables were compared using the Cochran-Armitage test for trend. The level of significance
was set at alpha=0.05. All analyses were conducted using IBM SPSS Statistics v. 18 (Chicago, IL).

Results

Patient Population (Table 1)

The study population contained 506 total patients. This population was separated into two groups: the octogenarians (n = 118) and the non-octogenarians (n = 388). Table 1 contains more information regarding the demographics for and a comparison between both groups. There was a statistically significant difference between the proportion of males and females between both groups; there were more females in the octogenarian group and conversely more males in the non-octogenarian group. Aside from gender, there were no statistically significant differences with respect to any other demographic variable between the groups.

Comorbidities (Tables 1 and 2)

As shown in table 1, the distribution of comorbidities was relatively equal between both groups. The distribution of the number of comorbidities per patient was roughly similar between both groups as well; there was no statistically significant difference between the groups based on the number of comorbidities (P= 0.28). (Table 2).

Indications and Devices (Table 3)

The most common indication for extraction for both groups was infection. Although there was a difference in the proportion of patients with a device infection between the octogenarians and non-octogenarians, 99 (84%) and 295 (76%) respectively, this difference was not statistically significant (p = .07). There was a difference in the proportion of the type of devices between both populations. There were more pacemakers in the octogenarians (56%) than the non-
octogenarians (36%) and more implantable cardiac defibrillators in the non-octogenarians (47%) than the octogenarians (28%); these differences were statistically significant (p = < .001).

**Leads and Lead Time (Table 3)**

There were a total of 253 chronic endovascular leads (A: 99, V: 145, CS: 9) in the octogenarian group and 814 chronic endovascular leads (A: 295, V: 442, CS: 77) in the non-octogenarian group. There was no significant difference between the proportion of atrial, ventricular or coronary sinus leads. The mean lead time for the octogenarian group was longer than the non-octogenarian group, 59.6 ± 52.8 and 38.6 ± 43.9 respectively; this difference was statistically significant (p = .04).

**Extraction Approach and Complications (Table 3)**

The most common approach for both groups was via a Subclavian route; there was no statistically significant difference with respect to the approach used between both groups. There was no statistically significant difference in the proportion of minor (p = .65) and major (p = .56) complications between both groups. Both major and minor complications were grouped together for each population to create a composite of adverse events and this was further analyzed. There was no statistically significant difference with respect to composite adverse events between both groups (p = .5). There was one patient death in the non-octogenarian group; this particular patient was bacteremic and experienced a pericardial tamponade.

**Discussion**

Our findings demonstrate that laser lead extraction is a safe and effective treatment method in octogenarian patients with multiple comorbidities. The octogenarian group in our study was a sick population, reflected by their high rate of comorbidities, their advanced degree of heart
failure and by the fact that most of them had a device infection. Despite the fact that the octogenarian population in this study displayed these characteristics, they tolerated the extraction procedure well: all of these patients underwent successful extraction with a complication rate comparable to their younger counterparts. The clinical relevance of this finding is that clinicians can consider laser lead extraction as a safe and effective option when managing patients at the later extreme of life.

The projected and actual median age of individuals in this country continues to steadily increase; this change is mirrored in Medicare expenditure data. The elderly (age ≥ 65) are one of the fastest growing age groups in the United States, with individuals older than eighty comprising approximately 3.4% of the entire population. Although individuals over the age of 65 only amount to 12.5% of the total US population, they represent the majority of recipients of implantable cardiac devices in this country. Over 70% of the pacemakers implanted in the US are for patients over the age of 70 and up to two thirds of the ICDs in this country are for patients over the age of 65.\textsuperscript{1} Cardiac arrhythmia and conduction disorders currently ranks as one of the top areas of Medicare expenditure: in the 2009 fiscal year, an estimated $509,251,000 dollars were spent.\textsuperscript{8,9} As more resources are utilized in this field, it will become increasingly important to expand the literature concerning all aspects of implantable cardiac device usage.

There have been studies published that compare the complication rates associated with the implantation and use of implantable cardiac devices in the elderly with the complication rates in younger populations. Bailey and Wilkoff reviewed complications related to leads and venous access, surgical pockets and device function and concluded that there is no significant increase in complications with age.\textsuperscript{1} In the PASE study, Link at al. analyzed the complication rates associated with the implantation of single and dual chambered PMs in the elderly. Noseworthy et
al. studied the rate of complications associated with the implantation of ICDs in octogenarians compared to those of younger populations – both studies concluded that there was no significant increase in the complication rate with age.\textsuperscript{10,11}

The literature concerning the complication rate associated with laser lead extraction in different age groups is not as robust; this is likely a reflection of the fact that laser lead extraction is associated with a relatively low rate of complications – making accurate risk analysis difficult. There have been several proposed risk factors associated with complications, namely: long implantation time, lack of operator experience, lead type, female gender (patient size) and implantation route.\textsuperscript{12} Byrd et al.’s study in 2003 demonstrated an association between complications and lead implant duration along with female gender, which may have been a reflection of a lower body mass index.\textsuperscript{13} The association between lead implantation time and complications has been corroborated by several recent studies, whereas the association between female gender and complications has not been as clear.\textsuperscript{14-17} In all of these studies, the average age of the patients undergoing extraction has ranged around 65 (62.8 – 65).\textsuperscript{13-17} Clinical decisions regarding patients in the later extreme of life (age 80 and above) had to be based on extrapolations from this data.

All of the extractions in this study were performed in the same high-volume facility by a single experienced operator using the same laser extraction protocol. This scenario allowed us to create and compare two groups of patients, separated solely on the basis of age. The octogenarian group was on average approximately 20 years older than the non-octogenarian group with a mean age of 85 ± 3.8 compared to 64.2 ± 12.4. There was a significant difference (p = .01) in the proportion of females in the octogenarian group than in the non-octogenarian group, 40 (34%) compared to 87 (22%) respectively.
Both populations possessed several comorbidities, namely hypertension, diabetes, coronary artery disease and chronic renal failure. Although we were not able to apply a comorbidity score such as the Charleson index and its variants (i.e. D’Hoore-CI, Ghali-CI, or the Deyo-CI), or the ICD based indexes (i.e. the CDS and CDS-2 score), our team wanted to describe the proportion of measured comorbidities between both groups. The distribution of comorbidities between both groups and per patient was relatively equal (Tables 1 and 2). All of the patients in this study suffered from congestive heart failure, with an equal proportion of NYHA classifications between both groups – further reflected by their similar ejection fractions.

A total of 253 chronic endovascular leads (A: 99, V: 145, CS: 9) were removed from 118 patients in the octogenarian group. A total of 814 chronic endovascular leads (A: 295, V: 442, CS: 77) were removed from 388 patients in the non-octogenarian group. The implant duration was greater for the octogenarians than the non-octogenarians (p = .04), 59.6 ± 52.8 months (n = 101, range = 1-290) compared to 38.6 ± 43.9 months (n = 333, range = 1-263). A subclavian approach was used for nearly all patients. All patients experienced procedural success. There was no statistically significant difference with respect to overall complication rates between both populations. With respect to minor complications, the octogenarian group experienced 6 (5%) events, whereas the non-octogenarian group experienced 16 (4%) events (p = .65). With respect to major complications, the octogenarian group experienced 2 (2%) events, whereas the non-octogenarian group experienced 4 (1%) events (p = .56). In order to increase the sample size, we grouped together all complications for each group, labeling it as composite adverse events (CAEs). There was no statistically significant difference between the CAEs of both populations (p = .50).
Despite the fact that the octogenarian population in our study had a higher proportion of females and a longer lead implant duration than the non-octogenarian population, there was no statistically significant difference with respect to complication rates between both groups. Our overall complication rate and the proportion of both major and minor events are in line with the expected averages based on current literature.\textsuperscript{13-17} As in other studies, properly assessing differences in complication rates proved difficult in the sense that a large sample size is required due to the inherently low complication rate associated with laser lead extraction.

The aim of this study was to report our experience with this increasingly important portion of the elderly segment. Our elderly patients were not bedridden; they were functional individuals prior to experiencing these complications. Current literature has shown that age alone does not seem to be associated with an increased risk for complications in the implantation and use of cardiac devices. Our experience corroborates this idea with respect to octogenarians and laser lead extraction.

\textbf{Study Limitations}

A major limitation of this study is the fact that it is retrospective in nature. Only patients undergoing laser lead extraction were included; therefore, a selection bias could have been present. Even though the study population consisted of 506 patients, the sample size was limited and originated from a single center. A large population from several facilities could be used in order to better appreciate any differences that may exist between groups undergoing laser lead extraction and to increase the generalizability of the findings. Currently, the clinical methodology is limited with respect to objectively and accurately measuring a patient’s fragility.
Conclusion

Our findings demonstrate that laser lead extraction is a safe and effective treatment method in octogenarian patients with multiple comorbidities. Octogenarian patients experienced a procedural success rate and complication rate comparable to their younger counterparts.

Acknowledgements: The authors of this manuscript would like to thank James D. Wilkinson MD, MPH, Professor of Pediatrics and Epidemiology, and Robert S. O'Brien, MS, staff statistician, Division of Pediatric Research, University of Miami Miller School of Medicine, for their assistance with statistical analyses and for writing the corresponding section under Methods.

Conflict of Interest Disclosures: Dr. Carrillo is a consultant for Spectranetic®, Sorin®, Medtronic® and Sensormatic/TYCO®. No other author reports any conflict of interest.

References:


**Table 1.** Clinical characteristics for the non-octogenarian and octogenarian groups.

<table>
<thead>
<tr>
<th></th>
<th>Non-Octogenarians (n = 388)</th>
<th>Octogenarians (n = 118)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (mean ± SD)</strong></td>
<td>64.2±12.4</td>
<td>85±3.8</td>
<td>&lt;.001</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>301 (78)</td>
<td>78 (66)</td>
<td>.01</td>
</tr>
<tr>
<td>Female</td>
<td>87 (22)</td>
<td>40 (34)</td>
<td></td>
</tr>
<tr>
<td><strong>Comorbidities, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HTN</td>
<td>324 (84)</td>
<td>104 (88)</td>
<td>.20</td>
</tr>
<tr>
<td>DM</td>
<td>190 (49)</td>
<td>45 (38)</td>
<td>.09</td>
</tr>
<tr>
<td>CAD</td>
<td>261 (67)</td>
<td>72 (61)</td>
<td>.21</td>
</tr>
<tr>
<td>CRF</td>
<td>84 (22)</td>
<td>26 (22)</td>
<td>.93</td>
</tr>
<tr>
<td>Cr</td>
<td>1.80±1.8 (n = 385)</td>
<td>1.70±1.3 (n = 116)</td>
<td>.15</td>
</tr>
<tr>
<td>CHF, n (%)</td>
<td>388 (100)</td>
<td>118 (100)</td>
<td></td>
</tr>
<tr>
<td>NYHA I</td>
<td>107 (45)</td>
<td>36 (39)</td>
<td>.60</td>
</tr>
<tr>
<td>NYHA II</td>
<td>48 (20)</td>
<td>18 (29)</td>
<td>.46</td>
</tr>
<tr>
<td>NYHA III</td>
<td>44 (19)</td>
<td>9 (12)</td>
<td>.20</td>
</tr>
<tr>
<td>NYHA IV</td>
<td>35 (15)</td>
<td>11 (15)</td>
<td>.98</td>
</tr>
<tr>
<td><strong>Ejection Fraction</strong></td>
<td>35±19</td>
<td>42.3±16.6</td>
<td>.94</td>
</tr>
</tbody>
</table>

*HTN = Hypertension, DM = Diabetes Mellitus, CAD = Coronary Artery Disease, CRF = Chronic Renal Failure, Cr = Creatinine, CHF = Congestive Heart Failure, NYHA = New York Heart Association

*All patients had congestive heart failure, only a total of 311 patients (non-octogenarians, n = 237; octogenarians, n = 74) had a NYHA classification.*
Table 2. Distribution of comorbidities per patient between the non-octogenarian (n = 388) and octogenarian (n = 118) groups.*

<table>
<thead>
<tr>
<th>Number of Comorbidities</th>
<th>Non-octogenarians, n (%)</th>
<th>Octogenarians, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>32 (8)</td>
<td>8 (7)</td>
</tr>
<tr>
<td>2</td>
<td>67 (17)</td>
<td>27 (22)</td>
</tr>
<tr>
<td>3</td>
<td>122 (32)</td>
<td>45 (39)</td>
</tr>
<tr>
<td>4</td>
<td>122 (32)</td>
<td>22 (18)</td>
</tr>
<tr>
<td>5 or more</td>
<td>46 (11)</td>
<td>16 (14)</td>
</tr>
</tbody>
</table>

* P= 0.28, Cochran-Armitage test for trend

Table 3. Indications, device properties and extraction outcomes for the non-octogenarian and octogenarian groups.

<table>
<thead>
<tr>
<th>Indications, n (%)</th>
<th>Non-Octogenarians (n = 388)</th>
<th>Octogenarians (n = 118)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>296 (76)</td>
<td>99 (84)</td>
<td>.08</td>
</tr>
<tr>
<td>Malfunction</td>
<td>84 (21)</td>
<td>17 (14)</td>
<td>.09</td>
</tr>
<tr>
<td>Devices, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PM</td>
<td>141 (36)</td>
<td>68 (56)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>ICD</td>
<td>181 (47)</td>
<td>35 (28)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>CRT-ICD</td>
<td>65 (17)</td>
<td>13 (13)</td>
<td>.13</td>
</tr>
<tr>
<td>CRT-PM</td>
<td>1 (0)</td>
<td>2 (3)</td>
<td>.14</td>
</tr>
<tr>
<td>Leads, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total*</td>
<td>814</td>
<td>253</td>
<td>.49</td>
</tr>
<tr>
<td>Atrial*</td>
<td>295 (36)</td>
<td>99 (39)</td>
<td>.66</td>
</tr>
<tr>
<td>Ventricular*</td>
<td>442 (54)</td>
<td>145 (57)</td>
<td>.94</td>
</tr>
<tr>
<td>Coronary Sinus*</td>
<td>77 (10)</td>
<td>9 (4)</td>
<td>.93</td>
</tr>
<tr>
<td>Lead Time (mo.)</td>
<td>38.6±43.9 (n = 333)</td>
<td>59.6±52.8 (n = 101)</td>
<td>.04</td>
</tr>
<tr>
<td>Approach, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subclavian</td>
<td>379 (98)</td>
<td>116 (98)</td>
<td>.64</td>
</tr>
<tr>
<td>Femoral</td>
<td>9 (2)</td>
<td>2 (2)</td>
<td>.38</td>
</tr>
<tr>
<td>Complications, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minor</td>
<td>16 (4)</td>
<td>6 (5)</td>
<td>.65</td>
</tr>
<tr>
<td>Major</td>
<td>4 (1)</td>
<td>2 (2)</td>
<td>.56</td>
</tr>
<tr>
<td>Deaths</td>
<td>1</td>
<td>0</td>
<td>.50</td>
</tr>
<tr>
<td>Composite Adverse Events</td>
<td>20 (5)</td>
<td>8 (7)</td>
<td>.50</td>
</tr>
</tbody>
</table>

PM = Pacemaker, ICD = Implantable Cardiac Defibrillator, CRT-ICD = Cardiac Resynchronization Therapy Implantable Cardiac Defibrillator, CRT-PM = Cardiac Resynchronization Therapy Pacemaker

* Lead types compared using Poisson regression adjusted for total number of each lead type
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Circ Arrhythm Electrophysiol. published online October 17, 2011;
Circulation: Arrhythmia and Electrophysiology is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-3149. Online ISSN: 1941-3084

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