Laser Lead Extraction in the Octogenarian Patient

Yasser Rodriguez, MD, MBA; Juan D. Garisto, MD; Roger G. Carrillo, MD

Background—In the United States, patients aged >75 years 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 and up to two thirds of the implantable cardioverter-defibrillators 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 the following 2 groups based solely on age: octogenarians and nonoctogenarians. These 2 groups were compared on the basis of several characteristics and clinical outcomes. There were 118 patients in the octogenarian group (78 men) and 388 in the nonoctogenarians group (301 men) aged 85±3.8 and 64.2±12.4 years, respectively. A total of 253 leads (atrial, 99; ventricular, 145; coronary sinus, 9) were removed from the patients in the octogenarian group, and 814 leads (atrial, 295; ventricular, 442; coronary sinus, 77) were removed from the patients in the nonoctogenarian 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 nonoctogenarians, respectively. There was no significant difference with respect to the proportion of minor (P=0.65), major (P=0.56), and total (P=0.50) complications.

Conclusions—Laser lead extraction is demonstrated to be a safe and effective treatment method in octogenarian patients with multiple comorbidities. (Circ Arrhythm Electrophysiol. 2011;4:719-723.)

Key Words: aged ■ 80 and over ■ pacemakers ■ heart-assist device ■ intraoperative complications

In the United States, the elderly population is one of the fastest growing demographic groups. This impressive growth is reflected in the patient population as well: Patients aged >75 years are expected to increase by 125% by the year 2050.1 Moreover, this segment of the patient population currently accounts for a significant percentage of pacemaker (PM) and implantable cardioverter-defibrillator (ICD) recipients in our healthcare system. The average age of a primary PM patient is 75.5±12.1 years2; some estimates state that patients aged >75 years account for >70% of PMs implanted in this country.1 The average age of a primary ICD patient is 66.2±12.8 years and has been trending upward, with a steady increase of 0.2 to 0.3 years annually.2 Recent trends suggest that this segment of the patient population’s role as consumers of implantable cardiac devices will only grow with time.

Clinical Perspective on p 723

As the technology associated with implantable devices continues to become more sophisticated, the role of these devices in medicine will continue to increase. This expanded role is reflected both by 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.2 During 2006, an estimated 418 000 PM-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 >2.4 million Americans currently live with an implantable cardiac device.3

Despite improvements in technology and the development of infection prevention protocols and newer implantation techniques, device complications still remain a reality. The 2 most common complications requiring device extraction are lead-related problems and infection.4 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 demonstrated 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.

Because of the increasing chart in age demographics, the increased use of implantable devices, the prevalence and rise of complications, and the lack of literature about 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, comorbidities, 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 2 groups based solely on age: octogenarians (age ≥80 years, n=118) and nonoctogenarians (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 on admission had posteroanterior and lateral chest radiographs, and some had CT scans. Transthoracic echocardiograms were done in all patients. Blood cultures and preoperative transesophageal echocardiograms were obtained in all the patients in whom a suspected device infection was the reason for admission. In the operating room, PM pocket tissue samples were taken and lead tip cultures were done 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 were implanted for >1 year or that required specialized laser equipment. The indications for transvenous extractions also were defined by the guidelines. Examples were infection, chronic pain, thrombosis, venous stenosis, and functional or nonfunctional leads. The infection category was further subdivided as follows: (1) pocket infection (local signs of inflammation or device or lead erosion), (2) device endocarditis (according to the modified Duke criteria for endocarditis), and (3) bacteremia (positive blood cultures were the only finding). The terms procedural clinical success, procedure failure, major complications, and minor complications were taken from the consensus document.6

Echocardiograms

Both transthoracic and transesophageal echocardiograms were 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 because the incision had failed to explant the PM or defibrillating leads. General anesthesia and intraoperative transesophageal echocardiograms 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. An bloc encapsulectomy was performed in all the cases. A lead locking device 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, countertraction 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±SD or n (%). CAD indicates coronary artery disease; CHF, congestive heart failure; CRF, chronic renal failure; DM, diabetes mellitus; HTN, hypertension; NYHA, New York Heart Association.

<table>
<thead>
<tr>
<th>Definition</th>
<th>Nonoctogenarians (n=388)</th>
<th>Octogenarians (n=118)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>64.2±12.4</td>
<td>85±3.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>301 (78)</td>
<td>78 (66)</td>
<td>0.01</td>
</tr>
<tr>
<td>Female</td>
<td>87 (22)</td>
<td>40 (34)</td>
<td></td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HTN</td>
<td>324 (84)</td>
<td>104 (88)</td>
<td>0.20</td>
</tr>
<tr>
<td>DM</td>
<td>190 (49)</td>
<td>45 (38)</td>
<td>0.09</td>
</tr>
<tr>
<td>CAD</td>
<td>261 (67)</td>
<td>72 (61)</td>
<td>0.21</td>
</tr>
<tr>
<td>CRF</td>
<td>84 (22)</td>
<td>26 (22)</td>
<td>0.93</td>
</tr>
<tr>
<td>Creatinine*</td>
<td>1.80±1.8</td>
<td>1.70±1.3</td>
<td>0.15</td>
</tr>
<tr>
<td>CHF, n (%)†</td>
<td>388 (100)</td>
<td>118 (100)</td>
<td>0.60</td>
</tr>
<tr>
<td>NYHA I</td>
<td>107 (45)</td>
<td>36 (39)</td>
<td>0.46</td>
</tr>
<tr>
<td>NYHA II</td>
<td>48 (20)</td>
<td>18 (29)</td>
<td>0.20</td>
</tr>
<tr>
<td>NYHA III</td>
<td>44 (19)</td>
<td>9 (12)</td>
<td>0.98</td>
</tr>
<tr>
<td>NYHA IV</td>
<td>35 (15)</td>
<td>11 (15)</td>
<td>0.94</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>35±19</td>
<td>42.3±16.6</td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as mean±SD or n (%). CAD indicates coronary artery disease; CHF, congestive heart failure; CRF, chronic renal failure; DM, diabetes mellitus; HTN, hypertension; NYHA, New York Heart Association.

‡All patients had CHF. Only 311 patients (nonoctogenarians, n=237; octogenarians, n=74) had an NYHA classification.

Statistical Analyses

Variable distributions were determined. Continuous variables were expressed as mean±SD. 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 χ² test or Fisher exact test if expected cell values were <5. Ordinal variables were compared using the Cochran-Armitage test for trend. The level of significance was set at α=0.05. All analyses were conducted using SPSS version 18 (SPSS Inc; Chicago, IL) statistical software.

Results

Patient Population

The study population comprised 506 total patients. This population was separated into 2 groups: octogenarians (n=118) and nonoctogenarians (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 men and women in both groups; there were more women in the octogenarian group and more men in the nonoctogenarian group. Aside from sex, there were no statistically significant differences with respect to any other demographic variable between the groups.
Table 2. Distribution of Comorbidities per Patient Between the Nonoctogenarian (n=388) and Octogenarian (n=118) Groups

<table>
<thead>
<tr>
<th>No. of Comorbidities</th>
<th>Nonoctogenarians</th>
<th>Octogenarians</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>32 (8)</td>
<td>8 (7)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>67 (17)</td>
<td>27 (22)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>122 (32)</td>
<td>45 (39)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>122 (32)</td>
<td>22 (18)</td>
<td></td>
</tr>
<tr>
<td>≥5</td>
<td>46 (11)</td>
<td>16 (14)</td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as n (%). *P=0.28, Cochran-Armitage test for trend.

Comorbidities
As shown in Table 1, the distribution of comorbidities was relatively equal between groups. The distribution of the number of comorbidities per patient also was roughly similar between groups. There was no statistically significant difference between groups based on the number of comorbidities (P=0.28) (Table 2).

Indications and Devices
The most common indication for extraction for both groups was infection (Table 3). Although there was a difference in the proportion of patients with a device infection between the groups. There was no statistically significant difference in the proportion of patients with a device infection between the groups (P=0.5). This difference was statistically significant (P=0.07). There was a difference in the proportion of the type of devices between groups. There were more PMs in the octogenarians (56%) than in the nonoctogenarians (36%) and more ICDs in the octogenarians (47%) than in the octogenarians (28%). These differences were statistically significant (P≤0.001).

Leads and Lead Time
There were a total of 253 chronic endovascular leads (atrial, 99; ventricular, 145; coronary sinus, 9) in the octogenarian group and 814 chronic endovascular leads (atrial, 295; ventricular, 442; coronary sinus, 77) in the nonoctogenarian group (Table 3). 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 for the nonoctogenarian group (59.6±52.8 and 38.6±43.9, respectively). This difference was statistically significant (P=0.04).

Extraction Approach and Complications
The most common approach for both groups was through a subclavian route (Table 3). There was no statistically significant difference with respect to the approach used between groups. There was no statistically significant difference in the proportion of minor (P=0.65) and major (P=0.56) complications between 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 groups (P=0.5). There was 1 patient death in the nonoctogenarian group; this particular patient was bacteremic and experienced a pericardial tamponade.

Discussion
The present findings demonstrate that laser lead extraction is a safe and effective treatment method in octogenarian patients with multiple comorbidities. The patients comprising the octogenarian group was a sick population, as reflected by their high rate of comorbidities and their advanced degree of heart failure and because most had a device infection. Despite the fact that the octogenarian population 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, and this change is mirrored in Medicare expenditure data. The elderly population (aged ≥65 years) is one of the fastest growing age groups in the United States, with individuals aged >80 years comprising ~3.4% of the entire population. Although individuals >65 years only comprise 12.5% of the total US population, they represent the majority of recipients of implantable cardiac devices in this country. More than 70%...
of the PMs implanted in the United States are for patients aged >70 years, and up to two thirds of the ICDs in this country are for patients aged >65 years.1 Cardiac arrhythmia and conduction disorders currently rank as the top areas of Medicare expenditure. In the 2009 fiscal year, an estimated $509 251 000 were spent.8,9 As more resources are utilized in this field, it will become increasingly important to expand the literature with regard to 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 elderly patients with the complication rates in younger populations. Bailey and Wilkoff1 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. In the PASE (Pacemaker Selection in the Elderly) study, Link et al10 analyzed the complication rates associated with the implantation of single- and dual-chambered PMs in elderly patients. Noseworthy et al11 studied the rate of complications associated with the implantation of ICDs in octogenarians compared to those of younger populations. Both Link et al and Noseworthy et al concluded that there was no significant increase in the complication rate with age.

The literature regarding the complication rate associated with laser lead extraction in different age groups is not as robust, which likely is 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 sex (patient size), and implantation route.12 A study by Byrd et al13 demonstrated an association between complications and lead implant duration along with female sex, which may have been a reflection of a lower body mass index. The association between lead implantation time and complications has been corroborated by several recent studies, whereas the association between female sex and complications has not been as clear.12,14–16 In all of these studies, the average age of the patients undergoing extraction was 65 years (range, 62.8–65 years).12,13–16 Clinical decisions regarding patients in the later extreme of life (aged ≥80 years) had to be based on extrapolations from these data.

All 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 2 groups of patients separated solely on the basis of age. The octogenarian group was, on average, 20 years older than the nonoctogenarian group (85±3.8 versus 64.2±12.4 years, respectively). There was a significant difference (P=0.01) in the proportion of women in the octogenarian group than in the nonoctogenarian group (40 [34%] versus 87 [22%], respectively).

Both groups 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 Charlson index and its variants (ie, D’Hoore, Ghali, or Deyo Charlson indexes), or the ICD-based indexes (ie, the Chronic Disease Score and Chronic Disease Score 2),17 our team wanted to describe the proportion of measured comorbidities between groups. The distribution of comorbidities between groups and per patient was relatively equal (Tables 1 and 2). All the patients in this study had congestive heart failure, with an equal proportion of New York Heart Association classifications between groups, which was further reflected by their similar ejection fractions.

A total of 253 chronic endovascular leads (atrial, 99; ventricular, 145; coronary sinus, 9) were removed from 118 patients in the octogenarian group. A total of 814 chronic endovascular leads (atrial, 295; ventricular, 442; coronary sinus, 77) were removed from 388 patients in the nonoctogenarian group. The implant duration was greater for the octogenarians (59.6±52.8 months; n=101; range, 1–290) than for the nonoctogenarians (38.6±43.9 months; n=333; range, 1–263; P=0.04). 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 groups. With respect to minor complications, the octogenarian group experienced 6 (5%) events, whereas the nonoctogenarian group experienced 16 (4%) events (P=0.65). With respect to major complications, the octogenarian group experienced 2 (2%) events, whereas the nonoctogenarian group experienced 4 (1%) events (P=0.56). To increase the sample size, we grouped together all complications for each group, labeling it as composite adverse events. There was no statistically significant difference between the composite adverse events of both populations (P=0.50).

Despite the fact that the octogenarian group in the present study had a higher proportion of women and a longer lead implant duration than the nonoctogenarian population, there was no statistically significant difference with respect to complication rates between groups. Our overall complication rate and the proportion of both major and minor events are in line with the expected averages based on the current literature.12,13–16 As in other studies, properly assessing differences in complication rates proved difficult in the sense that a large sample size is required because of the inherently low complication rate associated with laser lead extraction.

The aim of the study was to report our experience with this increasingly important portion of the elderly segment. The elderly patients were not bedridden; they were functional individuals before experiencing these complications. The 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.

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 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.

Conclusions
The 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.

Acknowledgments
We 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.

Disclosures
Dr Carrillo is a consultant for Spectranetics, Sorin, Medtronic, and Sensormatic/TYCO.

References

CLINICAL PERSPECTIVE
In the United States, the elderly population is one of the fastest growing demographic groups. This segment of the patient population currently accounts for a significant percentage of pacemaker and implantable cardioverter-defibrillator recipients in the US healthcare system, a trend that will only increase with time. As the use of implantable cardiac devices increases in this population, the number of complications may increase proportionally. The rate of device complications along with their associated clinical outcomes in the general patient population has been well described in the 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. The goal of this study was to provide clinicians with a source of reference when managing patients from this specific age segment.
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