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Predictors of Fluoroscopy Time and Procedural Failure During Biventricular Device Implantation

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Abstract

Biventricular (BiV) device implantation with insertion of a transvenous left ventricular (LV) lead can be challenging. We sought to identify predictors of procedural difficulty measured by fluoroscopy time and predictors of LV lead implantation failure. We performed a single-center, retrospective study of 272 consecutive patients undergoing BiV device implantation between 2004 and 2011. We used multivariate linear regression to assess predictors of fluoroscopy time and logistic regression to identify predictors of LV lead implant failure. The median fluoroscopy time was 36.1 minutes (interquartile range [IQR] 24.2–51.6). After multivariable adjustment, independent predictors of longer fluoroscopy time included a right-sided approach (21.8 minutes longer, 95% confidence interval [CI] 6.8–36.9, $p=0.005$), prior congenital heart disease surgery (64.6 minutes longer, 95% CI 30.2–99.0, $p<0.001$), and previous failed attempt (30.3 minutes longer, 95% CI 6.0–54.5, $p=0.015$). Predictors of shorter fluoroscopy time included an LV lead upgrade (7.5 minutes shorter, 95% CI 0.6–14.4, $p=0.033$), electrophysiology fellow experience (5.4 minutes shorter/year, 95% CI 0.1–10.7, $p=0.047$) and attending physician experience (1.4 minutes shorter/year, 95% CI 0.01–2.9, $p=0.049$). Failed implantation occurred in 8% (22 of 272); inability to cannulate the coronary sinus (CS) and absent/atretic CS veins were the most common reasons (8 of 22 failed implants each). A previous failed attempt was the only significant predictor of LV lead implantation failure (odds ratio=33.5, 95% CI 3.2–352.6, $p=0.003$). In conclusion, six patient and operator characteristics predicted LV lead implantation difficulty measured by fluoroscopy time. LV lead implantation failed in 8% of cases, predicted only by a previous failed attempt.

Keywords

Biventricular pacing; Cardiac resynchronization therapy; Left ventricular lead; Pacemaker; Fluoroscopy

Introduction

Congestive heart failure is responsible for significant morbidity and mortality. Biventricular pacing (BiV) both with and without defibrillator therapy improves heart failure morbidity, quality of life, and survival in those with reduced left ventricular (LV) ejection fraction,

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heart failure symptoms, and increased QRS duration.^{1–5} However, BiV pacing requires placement of an LV lead, which is associated with increased procedural difficulty and a higher rate of complications.^{6,7} LV lead placement failure occurs in 6–12% of implants, despite continuous improvements of LV lead implantation techniques and tools.^{8–10}

Even in cases with successful LV lead implantation, procedural difficulty during attempted implantation leads to longer procedure times which increases the risk of device infection^{11–13} and expose the patient and operator to higher doses of radiation.¹⁴ With the premise that certain patient and operator characteristics may predict LV lead placement difficulty, our aim was to identify specific predictors of fluoroscopy time, a clinically relevant outcome measure. We also sought to identify predictors of LV lead implantation failure.

Methods

This was a single-center, retrospective cohort study of 272 consecutive patients undergoing LV lead implantation between 2004 and 2011. Patients undergoing *de novo* placement of a BiV device or upgrade to a BiV pacemaker or defibrillator were included.

Patient medical and surgical histories were obtained from chart review. Demographic data, including self-identified sex and race, were obtained from the electronic medical record. Lead, device and intra-procedural data including fluoroscopy time, procedure time, equipment used during LV lead placement, coronary sinus (CS) venography, and complications were extracted from nursing records and the report generated for the procedure. The study was approved by the Committee on Human Research of the University of California, San Francisco.

All BiV device and LV lead implantations were performed in dedicated electrophysiology laboratories by an electrophysiology fellow and attending physician, with the attending physician scrubbed during the procedure. After a subcutaneous pocket was created or re-accessed with blunt dissection, the axillary vein was accessed separately for each planned lead using a micropuncture introducer needle (Merit Medical, South Jordan, UT) attached to a 10 cc syringe. For *de novo* BiV lead and device implantations, the right ventricular lead was implanted first. For LV lead implantation, CS ostium cannulation was attempted through a splittable safety sheath using a CS outer guide sheath. Choice of CS outer guide sheath, as well as whether a guidewire, inner sheath and/or CS electrode catheter were used to aid cannulation, was at the operator's discretion. Once CS access was obtained, a CS venogram was performed at the discretion of the operators: a cine loop venogram was saved by fluoroscopy in movie format (Witt Biomedical Corp, Melbourne, FL) during infusion of 10cc of Visapaque™ (iodixanol, GE Healthcare, Princeton, NJ) through a balloon tipped catheter. The LV lead was then advanced to the selected CS branch with or without the use of a thin 0.014-inch guidewire. Once satisfactory pacing and capture thresholds were deemed acceptable by the operator, the LV lead was tested for diaphragmatic stimulation with 10V output. The CS sheath was then split and removed. In the absence of permanent atrial fibrillation or a pre-existing right atrial lead, a right atrial lead was subsequently implanted. The leads were sutured to the muscle layer, screwed into the device generator, and as a unit were placed in the pocket which was closed by suturing.

The primary outcome was the total fluoroscopy time used during biventricular device and lead implantation. Total fluoroscopy time represented the cumulative time, in minutes, that radiography was turned on by the operator using a dead-man foot pedal switch. Total procedure time was also recorded, and was measured from instillation of local anesthetic to pocket closure. To assess more specifically the types of procedural difficulty encountered

during LV lead placement, the total time devoted to LV lead placement was divided into two distinct intervals (secondary outcomes), called CS cannulation time (in minutes, from placement of the axillary vein sheath to stable engagement of the CS ostium with an outer guide sheath) and LV lead implantation time (in minutes, from stable engagement of the CS ostium with an outer guide sheath to anchoring of the LV lead with suture).

Continuous variables that are normally distributed (e.g., age, BMI) are expressed as means and standard deviations whereas continuous variables not normally distributed are expressed as medians and interquartile ranges (IQR). Categorical variables are expressed as percentages. Bivariate relationships between dichotomous predictors and continuous outcomes of interest were examined with linear regression analysis. For predictor variables with more than 2 categories, analysis of variance was used. Bivariate relationships between predictors and the dichotomous outcome of interest (LV lead implantation failure) were examined with logistic regression analysis. Multivariate linear regression analysis was performed to assess the independent predictors of the primary outcome (total fluoroscopy time), whereas multivariate logistic regression analysis was performed to assess the independent predictors of LV lead implantation failure. To determine which covariates to include in the stepwise algorithm for the final multivariate models, a group of likely predictors and confounders were specified *a-priori* and included for face validity. Other possible predictors and confounders were generated using a directed acyclic graph, which was constructed from general clinical knowledge and data from prior studies.¹⁵ A backward-selection procedure was performed for each multivariate regression analysis with a significance level for inclusion in the final model of <0.10. Only those covariates that remained independently associated with the outcome after adjustment in the final model were considered independent predictors. Two-tailed *p* values < 0.05 were considered statistically significant. Stata version 11 (College Station, Texas) was used for statistical analysis.

Results

A total of 272 patients were included in the analysis. Baseline patient and operator characteristics are shown in Table 1. The majority of patients were male and White. Most BiV placement attempts were performed on the patient's left side and in patients without previous device therapy. The median total fluoroscopy time for the cohort was 36.1 minutes (IQR 24.2–51.6), while the median total procedure time was 199.9 minutes (IQR 159.2–239.0).

Table 2 displays the unadjusted analysis of predictors of total fluoroscopy time during BiV device implantation. After adjustment for covariates in the final model, patients with a right-sided approach, a history of surgery for congenital heart disease, and a previous failed attempt required significantly longer fluoroscopy times during BiV device implantation (Figure 1A). An LV lead upgrade procedure, electrophysiology fellow experience, and attending physician experience were associated with shorter fluoroscopy time during LV lead implantation (Figure 1B). Calendar year of implant, left ventricular ejection fraction, and device manufacturer used at implant were not associated with fluoroscopy time in bivariate analysis (*p*=0.53, *p*=0.90, and *p*=0.12, respectively), and inclusion of calendar year of implant, left ventricular ejection fraction, and device manufacturer in the backward stepwise selection algorithm did not change the final predictors of fluoroscopy time. Additionally, a sensitivity analysis restricted only to *de novo* BiV implants (i.e., excluding the upgrade procedures) did not meaningfully change the overall results. In patients with additional leads implanted other than an LV lead, there was no statistically significant difference in fluoroscopy time for those implanted with both right ventricular and right atrial leads compared to those implanted with right ventricular leads only (*p*=0.28).

LV lead implantation failure occurred in 22 of 272 patients (8.1%) due to difficulty in cannulating the CS ostium (8 of 22, 36.4%), absent or atretic CS vein anatomy precluding lead placement (8 of 22, 36.4%), inability to achieve adequate pacing threshold (4 of 22, 18.2%), and lead instability (2 of 22, 9.1%). In 3 of 22 failed LV lead implants, a previous attempt had failed.

The only significant predictor of LV lead implantation failure in the final multivariate model was a previous failed attempt (adjusted odds ratio [OR] =33.5, 95% confidence interval [CI] 3.2–352.6; $p=0.003$). Although a higher BMI was associated with LV lead implantation failure in bivariate analysis, this was no longer significant after multivariable adjustment (adjusted OR=1.1, 95% CI 1.0–1.1; $p=0.55$).

The median CS cannulation time was 10.1 minutes (IQR 6.3–16.1) in the 203 patients with available data. In bivariate analysis, CS cannulation time was closely associated with fluoroscopy time; each 1 minute increase in CS cannulation time was associated with a 0.6 minute increase in fluoroscopy time (95% CI 0.4–0.7 minutes, $p<0.001$). In a multivariate model including the 6 predictors independently associated with the primary outcome of fluoroscopy time, only the side of implant affected CS cannulation time: a right-sided implant was associated with a longer CS cannulation time (26.6 minutes longer, 95% CI 9.5–43.8, $p=0.003$).

A CS electrode catheter was used to aid CS cannulation in 177 (69.4%) of patients. In the majority of patients ($n=219$, 85.9%), 1 outer guide sheath was used. For the rest of the population, a total of 2 ($n=21$, 8.2%), 3 ($n=8$, 3.1%), or 4 ($n=7$, 2.8%) outer sheaths were used. In bivariate analysis, each additional outer sheath used was associated with both an increased CS cannulation time (25.5 minutes longer, 95% CI 22.3–28.8, $p<0.001$) and fluoroscopy time (15.0 minutes longer, 95% CI 10.5–19.5, $p<0.001$). In a multivariate model including the 6 predictors associated with fluoroscopy time, only a right-sided implant was associated with use of additional outer sheaths (0.6 sheaths, 95% CI 0.2–1.0, $p=0.006$).

After CS cannulation, the median LV lead implantation time was 37.8 minutes (IQR 23.3–62.8) in the 201 patients with available data. In bivariate analysis, LV lead implantation time was also associated with fluoroscopy time; each 1 minute increase in LV lead implantation time was associated with a 0.4 minute increase in fluoroscopy time (95% CI 0.3 to 0.5 minutes, $p<0.001$). In a multivariate model including the 6 predictors associated with the primary outcome of fluoroscopy time, only a history of congenital heart disease surgery was associated with a longer LV lead implantation time (149.1 minutes longer, 95% CI 93.7–204.5, $p<0.001$).

A CS venogram was performed in 240 (88.6%) of patients. Use of CS venography was not associated with a difference in fluoroscopy time ($p=0.17$). During LV lead implantation attempts, 1 or less 0.014" wires were used in 162 patients (63.5%). In the rest of the cohort, 2–3 ($n=77$, 30.2%), 4–5 ($n=13$, 5.1%) or 6 ($n=3$, 1.2%) wires were used. In bivariate analysis, each additional wire used was associated with both an increased LV lead implantation time (12.6 minutes longer, 95% CI 8.1–17.0, $p<0.001$) and fluoroscopy time (7.0 minutes longer, 95% CI 4.6–9.4, $p<0.001$). In a multivariate model including the 6 predictors associated with fluoroscopy time, again, only a history of congenital heart disease surgery was associated with use of additional wires (2.4 wires, 95% CI 0.6–4.2, $p=0.008$).

Traumatic CS complications occurred in 10 patients, including CS perforation ($n=3$, 1.1%), CS dissection ($n=6$, 2.2%) and both CS perforation/dissection ($n=1$, 0.4%). None of these patients required pericardiocentesis or urgent cardiac surgery, and there were no deaths from traumatic CS complications. Failure of LV lead placement occurred in only 1 of these patients due to difficulty in stably cannulating the CS ostium.

Discussion

Cardiac resynchronization therapy with BiV pacing is commonly used to treat patients with heart failure, but in major clinical studies LV lead implantation failure rates are 6–12%.^{8–10} However, the proportion of failures does not capture important data regarding the relative difficulties in LV lead placement in those ultimately designated as successful implants. Prolonged fluoroscopy exposes both the patient and operator to radiation, which is associated with increased risk of cancer.^{16–18} Additionally, prolonged procedure times are associated with increased risk of device related infection.^{11–13} Long procedures also utilize valuable laboratory space and staff time, which could otherwise be used for other procedures. Our study found that a right-sided approach, a history of surgery for congenital heart disease, and a previous failed LV lead attempt were associated with longer fluoroscopy times during BiV device implantation whereas an LV lead upgrade procedure, electrophysiology fellow experience, and attending physician experience were associated with shorter fluoroscopy times.

While previous studies have evaluated predictors of total procedure time¹⁹ and LV lead implantation failure during BiV device and lead implantation,^{9,20,21} none have examined predictors of fluoroscopy time used during these procedures. Identifying predictors of LV lead procedural difficulty as measured by fluoroscopy time is important for several reasons. First, identification of specific populations at risk for difficult LV lead implantation may trigger measures to assure patient and operator protection from prolonged radiation exposure. Additionally, specific refinement of LV lead implantation techniques and equipment to facilitate the procedure might reduce procedure and fluoroscopy times.

We discovered that right chest implants were associated with both increased CS cannulation time and an increased number of outer guide sheaths necessary for CS cannulation. Since device implants are most commonly performed from the patient's left chest, the most likely explanations for these findings include lack of operator familiarity and poor performance of tools designed primarily for a left-sided approach. Future technology should focus on CS cannulation from a right-sided approach.

We also found that a history of surgery for congenital heart disease was associated with both increased LV lead implantation time and the number of thin guidewires required. Since cardiac resynchronization therapy can be helpful in surgically corrected congenital heart disease patients,^{22,23} BiV pacing should not be withheld. However, these patients on average required nearly 1 hour of additional fluoroscopy time. Moreover, patients with a history of surgical correction for congenital heart disease required more time during LV lead implantation *after successful CS cannulation* and, consistent with this finding, more 0.014 inch guidewires for lead placement. These findings suggest that additional preparation for congenital heart disease patients who have undergone surgical correction may be warranted, perhaps by reviewing previous operative reports and pre-procedural cardiac imaging.

Electrophysiology fellow and attending experience were each independently associated with shorter fluoroscopy times. The association between operator experience and BiV device implantation success has been well established.^{8,14,19} However, in many training institutions, the first operator for device implantation is a trainee, with a more experienced attending supervising the procedure. The association between longer abdominal surgery procedure times and trainee first operators has been described,²⁴ and this data demonstrates the same in cardiac rhythm device implantation. We found that for each 1 year increase in electrophysiology fellow experience, there was an approximate 5 minute decrease in fluoroscopy used for each LV lead implant. We also found that attending physician

experience was independently associated with less fluoroscopy time, demonstrating that experience of each implanter involved in the procedure is independently important.

Our study has several limitations. First, we relied on total fluoroscopy time, and although we believe that the main strength of this outcome is the avoidance of significant measurement error, fluoroscopy used during implantation for other reasons (e.g., right atrial and ventricular lead implantation) could introduce measurement bias when assuming that total fluoroscopy time pertains specifically to LV lead implantation. However, such measurement bias should be non-differential in respect to the predictor variables of interest, biasing results toward the null. To the contrary, we found statistically significant predictors. Because we focused on fluoroscopy time rather than total procedure time as the outcome variable, the time to obtain vascular access, make the device pocket and suture were likely excluded, which we believe is a strength of our study. Second, this was a single-center study at a university hospital that serves a referral population. Although the study environment provided a unique opportunity to investigate the association between electrophysiology fellow-in-training experience and LV lead implantation difficulty, our findings may not necessarily be generalized to all centers performing BiV device implantation. Finally, although it could be argued that certain statistically significant predictors only had a modest relationship with increased fluoroscopy time (such as 1–5 minutes less fluoroscopy for each year increase in fellow and attending experience), we believe these relatively small differences may actually be clinically significant, particularly when such factors are added together in a single case.

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Figure 1.

Panel A: Average increase in minutes of fluoroscopy for each statistically significant covariate associated with a longer fluoroscopy time after multivariate adjustment. Panel B: Average decrease in minutes of fluoroscopy for each statistically significant covariate associated with a shorter fluoroscopy time after multivariate adjustment. Error bars denote 95% confidence intervals.

Table 1

Baseline patient demographics, operator characteristics and intraprocedural data for all subjects at the time of attempted left ventricular lead implantation

Characteristic	Number (n=272)	Percentage
Age (years)	64 ± 14.6	--
Male	198	(72.8%)
Race		
White	173	(63.8%)
Black	20	(7.4%)
Asian	28	(10.3%)
Native American	1	(0.4%)
Other	49	(18.1%)
Body mass index (kg/m ²)	27.8 ± 6.6	--
Ischemic cardiomyopathy	118	(43.4%)
Previous myocardial infarction	47	(17.3%)
Hypertension	88	(32.5%)
Diabetes	54	(19.9%)
Atrial fibrillation	86	(31.6%)
Coronary artery bypass surgery	60	(22.1%)
Mitral valve replacement	9	(3.3%)
Mitral valve repair	4	(1.5%)
Congenital heart disease surgery	3	(1.1%)
Previous other cardiothoracic surgery	18	(6.6%)
ECG QRS duration (msec)	148 ± 33.8	--
Left ventricular ejection fraction (%)	29.9 ± 11.7	--
Attending physician experience (days)	1470.3 ± 902.8	--
Electrophysiology fellow experience (days)	356.3 ± 220.7	--
Failed previous left ventricular lead attempt	6	(2.2%)
Upgrade procedure		
Previous pacemaker	35	(12.9%)
Previous implantable cardioverter-defibrillator	58	(21.3%)
Right-sided implant	11	(4.0%)
Device and lead manufacturer		
St. Jude Medical	119	(43.8%)
Medtronic	80	(29.4%)
Boston Scientific	68	(25.0%)
Biotronik	5	(1.8%)

Table 2

Bivariate linear regression analysis of predictors of total fluoroscopy time during biventricular device implantation prior to multivariate adjustment

Variable	Bivariate Analysis	
	β^* (95% CI)	<i>p</i> value
Right-sided implant	19.6 (4.2 to 35.0)	0.013
History of surgery for congenital heart disease	60.6 (32.2 to 89.1)	<0.001
Previous failed left ventricular lead attempt	10.3 (−10.6 to 31.2)	0.33
Left ventricular lead upgrade procedure only	−6.8 (−13.4 to −0.3)	0.041
Electrophysiology fellow experience, per year	−4.6 (−9.8 to 0.06)	0.08
Attending physician experience, per year	−0.9 (−2.2 to 0.03)	0.15

CI = confidence interval

* The β coefficient represents the change in minutes of fluoroscopy time (positive values denoting more minutes of fluoroscopy time and negative values denoting less minutes of fluoroscopy time) per one unit increase of continuous predictor variables or as associated with individual categorical variables.