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Clinical Predictors of Successful Cephalic Vein Access for Implantation of Endocardial Leads

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Abstract. ***Background:*** **The purpose of this study was to determine whether there are any patient characteristics that predict successful use of the cephalic vein for endocardial lead implantation.**

Methods: **One-hundred fifty consecutive patients who underwent implantation of one or more endocardial pacemaker ($N = 63$) or defibrillator ($N = 87$) leads using a cephalic vein approach were included in this prospective study. The mean age of the patients was 63 ± 14 years, and 115 (77%) were men. Ninty-one patients (61%) had coronary artery disease, 77 patients (51%) had hypertension, and 42 patients (28%) had diabetes. The mean ejection fraction was 0.34 ± 0.17.**

Results: **At least one lead was successfully implanted using a cephalic vein approach in 96 patients (64%). The most common reason for failure of the cephalic vein approach was a small cephalic vein, found in 25 patients (17%). Independent predictors of successful cephalic vein use were diabetes ($p < 0.001$), ejection fraction ≤ 0.40 ($p < 0.05$), and male gender ($p < 0.05$). At least one endocardial lead was implanted in 19 of the 24 (79%) men who had an ejection fraction ≤ 0.40 and diabetes, compared to 4 of the 11 (36%) women who had an ejection fraction > 0.40 and did not have diabetes. The only independent predictor of successful cephalic vein implantation among nondiabetics was an ejection fraction ≤ 0.40 ($p < 0.01$). Body size was not an independent predictor of successful cephalic vein use.**

Conclusion: **Baseline patient characteristics influence the likelihood of successful endocardial lead implantation using a cephalic vein approach. Diabetes, ventricular dysfunction, male gender and are associated with an increased likelihood of a successful implant using the cephalic vein. Smaller leads and and better techniques are needed to improve the success rate of cephalic vein implantion in all patients.**

Key Words. **cephalic vein, pacemaker implantation, defibrillator, endocardial leads, defibrillation, cardiac pacing**

The cephalic vein is considered by many to be the preferred route for implantation of permanent, endocardial pacemaker and defibrillator leads [1–4]. However, the cephalic vein is not suitable for lead implantation in about 15%–35% of cases [5,6]. It is not known whether or not patient factors have an influence on the likelihood of successful lead implantation using the cephalic vein approach. Therefore, the pupose of this study was to determine if there are any patient characteristics that predict suitability of the cephalic vein for endocardial lead implantation.

Methods

Study Design

One-hundred fifty consecutive patients who underwent implantation of one or more endocardial pacemaker or defibrillator leads using the cephalic vein for access, at the University of Michigan Medical Center or Oakwood Medical Center, between July 1999 and March 2001 were prospectively included in this study.

In each patient an attempt was made to implant at least the ventricular endocardial lead using a standard cephalic vein approach [1]. If the pateint also required implantation of an atrial endocardial lead, an attempt was made to implant both leads using the cephalic vein. When the implanting phyiscian felt that it would be difficult to implant both leads using the cephalic vein, because the cephalic vein appeared inadequate, the subclavian or axillary vein was used for the second lead. Two patients underwent only atrial lead implantation. Leads that could not be implanted via the cephalic vein were implanted through the subclavian or axillary vein using standard techniques.

Regardless of the vascular access site, each lead was implanted through a peel-away introducer

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sheath placed over a separate guidewire. The technique of retaining the guide wire was not used. When two leads were implanted via the cephalic route, two guidewires were placed through the venotomy site. The size of the sheath that was used was the minimum French-size that could accommodate the lead without retaining a guidewire.

Patient Characteristics and Implantation Details

The mean age of the patients included in this study was 63 ± 14 years and 115 (77%) were men. Ninty-one patients (61%) had coronary artery disease, 77 patients (51%) had hypertension, and 42 patients (28%) had diabetes. The mean ejection fraction was 0.34 ± 0.17.

Eighty-seven (58%) patients underwent defibrillator implantation and the remainder underwent pacemaker implantation. Two endocardial leads were implanted in 84 patients (56%). Most patients (90%) underwent pacemaker and endocardial lead implantation on the left side of the chest. One-hundred fifty ventricular leads were implanted and 84 atrial leads were implanted. The sheath size used to implant the ventricular leads was 8 French in 3 patients (2%), 9 French in 52 patients (38%), 10 French in 4 patients (3%), 10.5 French in 6 patients (4%), and 11 French in 71 patients (52%). The sheath size used to implant the atrial leads was 7 French in 3 patients (4%), 8 French in 3 patients (4%), 9 French in 75 patients (89%), and 10 French in 3 patients (4%).

Data Analysis

Continuous variables are expressed as mean $\pm$ standard deviation and were compared using a Student's *t*-test. Nominal variables were compared using a Chi-square test or Fisher's Exact test. Univariate analysis was performed using the following prospectively-identified patient characteristics to determine predictors of cephalic vein suitability: age, gender, height, weight, body surface area, coronary artery disease, congestive heart failure, left ventricular ejection fraction, hypertension, diabetes, peripheral vascular disease, nitrates, beta-blockers, calcium channel blockers, angiotensin converting enzyme inhibitors, and alpha-blockers. Ejection fraction was analyzed as a continuous and as a categorical variable. Multivariate analysis was performed using binary logistic regression on variables that were associated with a p value <0.20 by univariate analysis. A p value <0.05 was considered statistically significant.

Results

At least one endocardial lead was successfully implanted using a cephalic vein approach in 96 patients (64%). Two leads were successfully implanted using a cephalic vein approach in 7 (9%) of the 82 patients who required a dual-chamber device. The remaining leads were successfully implanted through the subclavian vein.

There were several reasons for the failure to implant at least one lead via the cephalic vein: the cephalic vein was too small in 25 patients (17%); the vein could not be located in 11 patients (7%); the guide-wire could not be passed into the central veins in 5 patients (3%); the vein tore during sheath insertion in 1 patient (1%); other reasons were present in 12 patients (8%). There was no difference in successful use of the cepalic vein among the five different implanting electrophysiologists ($p = 0.5$). The introducer-sheath size used during implantation of the ventricular lead was slightly larger among patients who had a successful cephalic vein implantation compared to patients who did not have a successful cephalic vein implantation (10.3 ± 1.0 French vs. 9.8 ± 1.0 French, respectively; $p < 0.01$). There were no procedural complications.

The clinical characteristics and medications in patients who had at least one endocardial lead successfully implanted using the cephalic vein are compared to the patients who did not have any lead successfully implanted using the cephalic vein in Table 1. Variables that were entered into the multivariate regression model included gender, height, weight, body surface area, congestive heart failure, ejection fraction, an ejection fraction ≤ 0.40, diabetes, and the use of alpha-blockers. The three variables that were independent predictors of successful use of the cephalic vein were diabetes ($p < 0.01$), ejection fraction ≤ 0.40 ($p < 0.05$), and male gender ($p < 0.05$). At least one endocardial lead was implanted in 19 (79%) of the 24 men who had an ejection fraction ≤ 0.40 and diabetes, compared to 4 (36%) of the 11 women who had an ejection fraction > 0.40 and no diabetes.

A majority of patients (72%) did not have diabetes. Among nondiabetics, the only independent predictor of successful cephalic vein implantation was an ejection fraction ≤ 0.40 ($p < 0.01$).

Discussion

Main Findings

The main findings of this study are that endocardial lead placement via the cephalic vein is more likely to be successful among patients with diabetes, male gender, or an ejection fraction ≤ 0.40. At least one endocardial lead can be implanted using a cephalic vein approach in approximately 80% of men with diabetes and ventricular dysfunction.

Table 1. *Comparison of patient characteristics and medications among patients who had at least one endocardial lead placed using the cephalic vein compared to patients who had no lead successfully implanted using the cephalic vein*

Patient characteristic	Successful cephalic vein implant ($N = 94$)	Unsuccessful cephalic vein implant ($N = 56$)	p-value
Age (years)	62 ± 13	64 ± 15	0.430
Male	81%	67%	0.076[a,b]
Height (inches)	69 ± 4	67 ± 5	0.142[a]
Weight (pounds)	190 ± 38	177 ± 41	0.040[a]
Body Surface Area (m^2)	2.0 ± 0.2	1.9 ± 0.3	0.032[a]
Coronary artery disease	67%	50%	0.045[a]
Congestive heart failure	64%	50%	0.106[a]
LV ejection fraction	32 ± 16	37 ± 18	0.062[a]
LV ejection fraction <0.40	74%	52%	0.023[a,b]
Hypertension	55%	44%	0.206
Diabetes	35%	15%	0.007[a,b]
Peripheral vascular disease	12%	13%	0.591
Nitrates	35%	28%	0.631
Beta-blockers	57%	48%	0.549
Calcium channel-blockers	14%	11%	0.803
ACE inhibitors	62%	56%	0.471
Alpha-blockers	21%	6%	0.013[a]

Abbreviations: ACE = angiotensin converting enzyme; LV = left ventricle.

[a]Variables entered into the logistic regression model.

[b]Variables found to be independently significant after multivariate analysis.

Predictors of Cephalic Vein Suitability

Any condition that is associated with a large cephalic vein might facilitate transvenous lead implantation using the cephalic vein. In fact, the most common reason for failure of the cephalic vein approach in this study was that the cephalic vein was too small in 17% of patients. Male gender was found to be an independent predictor of successful cephalic vein use, however body surface area was not predictive. Therefore, relative to body size, men may have larger cephalic veins. The finding that height and weight were not independent predictors of successful cephalic vein use suggest that patients with small stature should still be considered candidates for a cephalic vein approach.

A depressed ejection fraction was found to be a strong independent predictor of cephalic vein suitability for endocardial lead placement among both diabetics and nondiabetics. Although the presence of congestive heart failure was not identified to be a predictor, there was a trend for heart failure to be more common among patients with suitable cephalic veins compared to patients without suitable cephalic veins (64% vs 50%; $p = 0.1$). Patients with ventricular dysfunction commonly have vasoconstriction due to neurohormonal activation, but also have venous hypertension which can lead to venous enlargement. Venous enlargement would allow for easier endocardial lead placement.

Because diabetes causes microvascular disease and atherosclerosis, it was surprising to find diabetes to be a positive predictor of cephalic vein suitablity in the present study. It is possible that diabetics have larger cephalic veins or that diabetes is a marker of more severe heart failure.

Previous Studies

Despite the fact that the cephalic vein has been used for implantation of endocardial pacing leads for over 15 years, no prior studies have examined the clinical predictors of success. A recent study by Calkins et al. compared the cephalic vein approach to an extrathoracic subclavian vein approach guided by contrast venography for endocardial lead placement [5]. The authors reported a success rate for the cephalic vein approach of 64%, which is identical to the success rate in the present study. Other investigators have described techniques to improve the success rate of cephalic vein implantation [6], including a recent study that reported an 84% success rate for single-chamber devices using cephalic venography [7].

Limitations

The results of this study only apply to the implant techniques used by the investigators. Although there was no difference in success rate between implanting physicians in the present study, it is possible that alternative techniques would have yielded a higher overall success rate of cephalic lead implantation. Experience and technique may influence the success rate of cephalic vein use for lead implantation. However, the results of the

present study suggest that patient factors are also relevant.

Clinical Implications

The cephalic vein approach is associated with a lower incidence of pneumothorax and lead failure compared to the subclavian vein approach [1–5]. Therefore, many implanting physicians first attempt to place endocardial leads through the cephalic vein and use the subclavian vein only if the cephalic vein is not suitable. The findings from this study demonstrate that baseline patient characteristics influence the likelihood of successful endocardial lead implantation using a cephalic vein approach. Although larger patients do not appear to be more likely to have a cephalic vein that is suitable for endocardial lead placement, patients with ventricular dysfunction or diabetes appear to be more likely to have a cephalic vein that can be used to implant an endocardial lead, compared to patients without these characteristics.

In the present study, approximately one-third of patients did not have a cephalic vein that is suitable for implantation of an endocardial lead. Given the advantages of the cephalic vein approach, it appears that smaller leads and better techniques are needed to improve the success rate of cephalic vein implantion in all patients.

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