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RESEARCH ARTICLE

Implantation of Biventricular Cardiac Devices Using a Double Venous Approach — An Alternative Implantation Technique

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Background: A standard technique regarding venous approach for implantation of biventricular cardiac electrical devices used for cardiac resynchronization therapy implementation has not yet been established. We analyzed the safety and efficiency of implanting these devices using a double venous approach (cephalic and subclavian) by comparing it with the simple approaches, in order to overcome some of their inconvenients.

Materials and methods: We retrospectively analyzed all 228 resynchronization patients implanted at the Timişoara Institute of Cardiovascular Medicine between January 1st, 2000 and January 1st, 2013. The 204 patients successfully implanted with biventricular pacemakers or defibrillators were divided according to the implantation techniques, and compared by complication rates and values of acute stimulation-detection thresholds. Group A featured a subclavian approach (48 patients), group B a cephalic approach (81 patients) and group C a double venous approach (76 patients).

Results: Adjusting for age, sex and device type there is no evidence in the data that complication rates are significantly different when using the different techniques: 6 complications (12.5%) in group A, 8 (9.87%) in group B and 5 (6.75%) in group C (p = 0.51). A slight downward trend was observed by using double venous approach. Values of acute stimulation-detection thresholds had no statistically significant differences neither (p = 0.36). Cephalic vein was of high quality in 59.8% of cases.

Conclusions: Subclavian and cephalic double venous approach implantation technique for biventricular devices proved to be feasible and at least as safe as single venous approach using subclavian or cephalic vein alone, and it can be used as a first resort technique.

Keywords: cardiac resynchronization therapy, biventricular device, complication, implantation technique, double venous approach

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Introduction

Electrical therapy for heart failure, namely cardiac resynchronization therapy, implemented by biventricular cardiac implantable devices (pacemakers or defibrillators), proved to be very important for patients with heart failure symptomatology, despite maximal pharmacological therapy, as shown in recent clinical trials. It induces regression of the left ventricle's pathological remodeling, reduction in mitral regurgitation if present, improvement in the left ventricle's ejection fraction, clinical and quality of life improvements, reduction in new hospitalizations for heart failure and also reduction in all-cause mortality [1–4]. It is a relatively new therapy (introduced in clinical practice for the first time in 1990 as a possible therapy) [4], still under development with regard to the implant techniques and programming.

The leads of these devices, as in the case of simple single or dual chambered devices, are routinely placed by exclusive puncture of the subclavian vein. Because of the possible complications linked directly to the puncture of this vein, explained by its tight anatomic relationship with the apical part of the lung, other techniques have also been comparatively analyzed lately, like cephalic vein or axillary vein approach, with good results. Most of the studies on venous approach referred however to simple single or dual chambered devices. Implantation of biventricular devices still remains a technical challenge, especially because of the necessity of placing the left ventricle's lead through the coronary sinus. It is possible that the stability of the leads to be affected by placing all of them using the same site of approach, especially when using triple chambered devices, with the increasing risk of acute or chronic dislodgement. On the other hand, puncturing the subclavian vein in different sites (for each lead), if possible, can increase the risk of complications even more [5]. Also, placing all leads by the subclavian route can increase the risk of lead fracture because of their compression by costo-clavicular tissue [6–8].

Theoretically, each technique carries advantages and disadvantages. So far, an ideal implantation technique for biventricular devices has not been established, the choice being at the discretion of the operator. Moreover, there are not many studies that analyze double venous approach technique in order to establish its feasibility and safety.

The purpose of this study is to analyze the feasibility, safety and efficiency of biventricular cardiac devices implantation (regarding the complication rate and the acute pacing and sensing thresholds), according to the implanta-

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tion technique, comparing subclavian approach, cephalic approach and double venous (both subclavian and cephalic) approach.

Methods

All 228 resynchronization patients from the Timişoara Institute of Cardiovascular Medicine between January 1st, 2000 and January 1st, 2013 were retrospectively included in the study. Two hundred and four patients were successfully implanted with biventricular pacemakers or defibrillators, meanwhile for the remaining 24 patients (10.5%), the coronary sinus failed to be cannulated or the coronary sinus lead failed to be placed. Patients successfully implanted with biventricular devices were divided according to the implantation techniques, and compared by complication rates, and values of acute pacing and sensing thresholds. They were split in 3 groups according to the implantation technique. Group A includes the procedures using the subclavian vein as single venous approach, group B the cephalic vein, and group C the double venous approach using both subclavian and cephalic vein.

Patients that underwent upgrade interventions were excluded because of the different timing of lead implantation.

All patients included in the study fulfilled the classic criteria recommended by current guidelines for implantation of the biventricular device in order to accomplish cardiac resynchronization therapy, meaning dilated cardiomyopathy with left ventricle ejection fraction ≤35%, NYHA class III, IV, QRS length ≥120 ms for sinus rhythm and ≥130 ms for atrial fibrillation [9].

The implant procedures were performed under local anesthesia with lidocaine 1% and antibiotic protection. For the cephalic approach, an incision usually in the left delto- pectoral groove was made, revealing the cephalic vein, and a small longitudinal venotomy was made with distal ligaturation in order to prevent bleeding. For the subclavian approach the modified Seldinger technique was used for puncturing the subclavian vein. For the double venous approach that will be described further on, usually a metallic guide wire (used for Seldinger type puncture) was first introduced using the cephalic vein. After that, the subclavian vein was punctured, using the guide wire in the cephalic vein as radiologic landmark, and then another metallic guide wire was placed. The right ventricle lead was introduced using the cephalic vein, maintaining the guide wire in place. Using the guide wire placed directly in the subclavian vein, a 9–9,5F peel away type sheath with valves was placed at this level, and a coronary sinus approach peel away sheath was placed through it. A venography of the coronary sinus and its branches was performed by using an Amplats type angiography guide wire catheter introduced through the coronary sinus sheath. The OTW (over the wire) type left ventricle lead was placed in the target vein, using an angioplasty guide wire, after withdrawal of the Amplats guide wire. Thereafter, the introducer system and the two peel away sheaths were withdrawn. Generally, the right atrium sheath was introduced by the cephalic vein route. In case of a too narrow cephalic vein, an introducer with peel away sheath was used. The leads were attached to the device and finally a two layer suture was performed.

The information regarding patients' characteristics, intervention parameters, as well as information regarding the complications that were encountered and needed intervention, were taken from the implant registers from the 2000–2013 period.

As for statistical analysis, characteristics of patients are expressed as mean ± 1 standard deviation or as a number and percentage, as appropriate. Variables were compared using Student's t-test. A multivariate logistic regression model was fitted in order to test the null hypothesis that there is no difference in the analyzed values between the groups. Covariables were used to control for confounders and effect modification. A p value <0.05 was considered significant. All analyses were performed by using STATA version 12.0 (STATACorp, College Station, TX).

All the investigations were in accordance with the Declaration of Helsinki.

Results

Patients included in the study received either biventricular pacemakers or biventricular defibrillators, with 2 (107, 52.45%) or 3 leads (97, 47.55%) respectively. From the 2 lead devices, 57.95% were implanted to patients with atrial fibrillation, and the remaining 42.05% to patients with sinus rhythm (VDD type). Their characteristics are described in Table I.

Regarding the double venous approach group, in 14 patients with 3 lead devices, the third lead was placed us-

Table I. Patient characteristics

Patients	Group A		Group B		Group C		p value
Number (Percent)	48 (23,53%)		81 (39.7%)		74 (36.27%)		p <0.05
Age	61,54 ± 9,89		61.2±9.4		61.27±10.23		p = NS
Sex	Men	Women	Men	Women	Men	Women	p <0.05
	62.5%	37.5%	93.82%	6.17%	85.13%	14.86%	
Device type	2 leads	3 leads	2 leads	3 leads	2 leads	3 leads	p <0.05
	39.58%	60.42%	72.84%	27.16%	37.83%	62.17%	
Pacemaker	37.5%	47.92%	70.37%	18.52%	35.13%	41.9%	p <0.05
Defibrillator	2.08%	12.5%	2.47%	8.64%	2.7%	20.27%	

Table II. Complications

Complications	Group A	Group B	Group C	Total
Total	6 (12.5%)	8 (9.87%)	5 (6.75%)	19 (9.31%)
Right atrial lead displacement	2 (4.16%)	–	–	2 (0.98%)
Right ventricular lead displacement	–	1 (1.23%)	–	1 (0.49%)
Coronary sinus lead displacement	2 (4.16%)	3 (3.70%)	3 (4.05%)	8 (3.92%)
Right atrial lead fracture	–	–	–	–
Right ventricular lead fracture	–	1 (1.23%)	–	1 (0.49%)
Coronary sinus lead fracture	–	1 (1.23%)	–	1 (0.49%)
Device exteriorization	1 (2.08%)	2 (2.46%)	1 (1.35%)	4 (1.96%)
Airway injury	–	–	1 (1.35%)	1 (0.49%)
Coronary sinus injury	1 (2.08%)	–	–	1 (1.49%)

ing the subclavian vein, because of the low quality of the cephalic vein.

Overall, the acute pacing threshold had a mean value of 2.03 ± 1.61 V (1.98 ± 1.63 for group A, 2.17 ± 1.82 for group B and 1.87 ± 1.24 for group C) and the acute sensing threshold 13.59 ± 6.27 mV (12.57 ± 4.95 for group A, 14.25 ± 6.57 for group B and 13.13 ± 6.52 for group C) (Figure 1). There is no evidence in the data that pacing values ($p = 0.15$) and sensing values ($p = 0.79$) are significantly different when using the different implantation techniques, after adjusting for age, sex and device type.
We encountered a number of 19 acute (during the intervention and until 48 hours after) and chronic complications that required intervention. These are presented in detail in Table II.

Adjusting for age, sex and device type, there were no statistically significant differences between the groups regarding the complication rate.

The cephalic vein had a high quality in 59.8% of the studied patients, a low quality in 13.23% and it was unapproachable in 12.25%. In 14.72% its approach was not tempted. Therefore in 8.81% of the studied patients, the subclavian vein approach alone was used as an alternative technique.

Fifty-four (73%) of the double venous approach implant procedures were accomplished between 2008–2013, representing 66.7% of the total number of interventions for cardiac resynchronization therapy in this period.

Discussion

The results of this retrospective study are consistent with the results of other studies. According to those studies, the cephalic vein single approach proved to be as safe as the routinely used subclavian vein single approach both for simple and for biventricular devices. Tse HF et al. [10] described the safety of the cephalic vein approach with cephalic venography for simple devices, and Calkins H et al. [11] obtained similar results by using the axillary vein with venography comparing with cephalic vein approach. Regarding cardiac resynchronization therapy, Romeyer-Bouchard C et al. [12] described the feasibility of biventricular device implantation using a modified right cephalic vein approach technique with 3 guide wires and one introducer. This triple cephalic vein access succeeded in 80% of the sinus rhythm patients included in the study. The authors report a number of 10 complications (10.1%), consisting in lead dislodgements, local infection, phrenic nerve stimulation, and pneumothorax. Ussen B et al. [13] compared biventricular devices' implantation using the cephalic vein approach (the usual unmodified technique, which we also used in our study) to the subclavian approach (with different punctures for each lead). Cephalic vein approach succeeded in 54 out of 61 patients in which this approach was tempted. The differences in complication rate — 3.3% in the cephalic group vs. 4.6% in the subclavian group — and in acute and chronic pacing and sensing thresholds — 1.6 ± 1.0 V vs 1.3 ± 0.8 V and 1.9 ± 1.6 V vs 1.4 ± 0.6 V, respectively — were statistically insignificant. The values of acute thresholds were similar in our study. The combined approach was mentioned in their study among both cephalic and subclavian approach groups in case of difficulty/failure when using one of the two techniques.

There is little data regarding the double venous approach, even if separate approach sites for each lead is mentioned in the specialty literature, in order to lower friction between the leads and to lower the risk of lead displacement [5,6]. To our knowledge, the use of double venous approach is reported in studies especially in case of failure of lead placement by single vein approach, for various reasons. The results of our study support the use of this technique as first resort technique, given the favorable theoretical data and the observation of a downward trend in the number of complications linked to this implantation technique in the study. This is important given the fact that complications of the implant procedures are still a problem nowadays. We described here a feasible and safe double venous approach implantation technique that was increasingly used in the past few years for patients implanted at the Timişoara Institute of Cardiovascular Diseases. The aim was to avoid pneumothorax while puncturing the subclavian vein by radiologic guidance controlled by the metallic guide wire placed in the cephalic vein, and also to avoid the tendency of lead destabilization, especially the coronary sinus lead.

The total percent of complications of 9.31% fits in the 4–10% interval described in the literature [14–16].

Study limitations

Given the fact that 3 venous approach techniques are considered in the study, the number of patients is limited. It is a single center experience. The implantation techniques described in this study were not compared by intervention time or radiation exposure.

Conclusions

Implantation of biventricular cardiac devices for cardiac resynchronization therapy using double venous approach (subclavian and cephalic) proved to be feasible and at least as safe as single cephalic or subclavian venous approach, considering the complication rate and it can be used as a first resort technique. This method mostly avoids the disadvantages of a blind (unguided) puncture as well as the risks of lead displacement when using single cephalic approach. On the other hand there are situations when this approach is difficult or even impossible, depending on the cephalic vein quality.

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