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Bifocal pacing in the right ventricle: An alternative to resynchronization when left ventricular access is not possible in end-stage heart failure patients

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Abstract

Background: *It has been reported that bifocal pacing (BiF) in the right ventricle might be an alternative to unsuccessful left ventricular lead implantation. This case report presents an assessment of the clinical and hemodynamic parameters during a three month follow-up in patients implanted with right ventricular BiF.*

Methods: *Eight patients who underwent unsuccessful left ventricular lead implantation were implanted with a bifocal system in the right ventricular. Leads were implanted in the right atrium appendage, the apex and the right ventricular outflow tract and connected to the cardiac resynchronization therapy pacemaker. All patients performed a sixminute walking test and underwent echocardiography after the implantation and after the three month follow-up.*

Results: *We found a significant performance increase in the six minute walking test and reduction in New York Heart Association class and mitral regurgitation in echocardiography study, as well as a significant increase in left ventricular ejection fraction, and cardiac output directly after the implantation, as well as at threemonth follow-up in patients after BiF implantation.*

Conclusions: *Right ventricular bifocal pacing in patients with cardiac resynchronization therapy indication and unsuccessful left ventricular lead placement seems to be a beneficial treatment for heart failure. Satisfactory hemodynamic and clinical results were observed directly after BiF implantation and during the three month follow-up.* (Cardiol J 2010; 17, 1: 35–41)

Key words: right ventricular bifocal pacing, resynchronization, heart failure

Editorial p. 1

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Introduction

Biventricular pacing has proven beneficial for patients with congestive heart failure in New York Heart Association (NYHA) functional classes III–IV, a bundle branch block with a QRS duration > 120 ms and a reduced left ventricular ejection fraction (LVEF) [1–4].

Despite continuous progress in left ventricular implantation technology, a completely successful biventricular pacemaker (BiV) implantation rate has not been achieved. Published data has shown a 6–12% rate of failed left ventricular lead insertion [5, 6]. Furthermore, these studies demonstrated that, if pacing at the target site (left or posterior veins) was not achievable, alternative pacing vessels (e.g. an anterior vein) should be used. Moreover, left ventricular lead placement has a relatively high (7–14%) risk of early and late dislodgement [7, 8]. Further complications linked to cardiac resynchronization include phrenic nerve stimulation and pocket infection [8]. A transthoracic epicardial approach may be an alternative for failed transvenous left ventricle implantation. Unfortunately, this method may be associated with some complications [9, 10]. Other methods for cardiac resynchronization therapy (CRT) implantation have been recently reported [11–14], but there is little published data so far. Some recently published studies show that right ventricular bifocal pacing (BiF) may be a feasible alternative to CRT [15–19]. First studies with BiF treatment patients with heart failure were published in nineteen years. However, it is one of the first published results of BiF in the end stage heart failure patients (in NYHA IV) with long term follow up.

The aim of our study was to assess clinical and hemodynamic parameters during a three month follow-up in patients with end-stage heart failure, implanted with BiF in the right ventricle in which standard transvenous BiV procedures were found to be ineffective or unsatisfactory.

Methods

The study was a single center study. Consecutive patients with CRT indications and unsuccessful left ventricular lead implantation were enrolled into this study. Inclusion criteria were as follows: NYHA functional class III or IV despite optimal management, LVEF < 40%, ventricular dyssynchrony defined as interventricular mechanical delay > 40 ms, sinus rhythm, QRS duration of > 120 ms due to left bundle branch block.

The implantation procedure

Access to the coronary sinus (CS) for left ventricular lead placement (Biotronik Corox LV-H 75-UP, used in every patient) was achieved either by using the Biotronik Introducer — Scout –8 F or directly via a stylet. A pacing site was considered satisfactory if the pacing threshold was below 5 V (0.5 ms width) with the absence of diaphragmatic stimulation at 10 V (0.5 ms width). If these criteria were not met, after a left lead dislodgement happened three times, or a fluoroscopy duration of more than 40 minutes, the patients underwent implantation of bifocal right ventricular leads. The screw-in endocardial lead (Biotronik Elox P) to the right ventricular outflow tract (RVOT) was defined according to Lieberman's rules [20]. To help differentiate the RVOT septum and free wall — the left oblique — and in determining high and low position right oblique, 40 degree fluoroscopic was used. A passive fixation lead (Biotronik Synox 60-BP) to the right ventricular apex was implanted in each patient. The third lead (Synox 53-JBP) was placed in the right atrial appendage. The Stratos left ventricular pacemaker was implanted in all patients.

The apical lead was connected to the right ventricle and the RVOT lead to the left ventricle port. The atrial lead was connected to the pacemaker's atrial channel.

Study protocol

All the patients performed a six minute walking test (6MWT) and underwent echocardiography before and after the pacemaker implantation (between the second and sixth days, mean 4.2 ± 3) and at the three month follow-up. NYHA functional class was evaluated before, and three months after, the BiF implantation. A 12-lead surface electrocardiogram (ECG) was done on all patients in the supine position before and after implantation in order to assess the QRS duration. All the ECGs were recorded at a paper speed of 100 mm/s and 4 mV/cm standarization.

Hemodynamic parameters were assessed before and after implantation by echocardiography, performed using Hewlett Packard Sonos 5500 before the implantation. The following parameters were evaluated: left ventricular end-diastolic diameter (LVDD) [mm]; left ventricular end-systolic diameter (LVSD) [mm], LVEF by Simpsons's method (%), cardiac output (CO) [l/min] and degree of mitral valve regurgitation.

The optimal atrioventricular (AV) delay was programmed according to the Ritter method [21]. DDD 70 beats/min mode with RVOT/RVA with 5 ms delay was programmed in all the patients.

Table 1. Baseline characteristics of studied patients.

No. of patients	Age	Male	NYHA class	LVEF (%)	QRS duration [ms]	Etiology of cardiomyopathy
1	52	Yes	IV	19	202	Non-ischemic
2	67	Yes	IV	25	153	Ischemic
3	54	Yes	IV	28	147	Non-ischemic
4	68	No	IV	13	175	Non-ischemic
5	45	Yes	III	27	159	Ischemic
6	72	Yes	IV	18	165	Non-ischemic
7	68	Yes	IV	15	224	Non-ischemic
8	69	No	III	30	212	Non-ischemic
Mean	61.8 ± 10	Total males: 6 (75%)		21.9 ± 6.4	179.6 ± 29	Total non-ischemic cardiomyopathy: 6 (75%)

NYHA — New York Heart Association, LVEF — left ventricular ejection fraction

Pharmacotherapy remained unchanged throughout the study.

The study was approved by the local bioethical committee and all patients gave their informed consent.

Statistical analysis

All numerical variables are reported as means ± standard deviation. Continuous variables were compared using a two-sided t-Student's test. P-values < 0.05 were considered significant.

Results

The left ventricular lead placement was not successful in eight patients (13%) out of the total 60 patient population with criteria for CRT implantation. This group of eight was implanted with the BiF system. The reasons for changing from the BiV to the BiF system were as follows: in one patient CS occlusion; in two patients an unacceptable pacing threshold (> 5.0 V; 0.5 ms width); in one patient diaphragmatic nerve stimulation; in another patient the intraoperative lead was dislodged three times; and in three patients X-ray exposure lasted over 40 minutes. The detailed clinical data of the studied BiF population is presented in Table 1.

Clinical data assessment

Six minute walking test. A significant increase in walking distance during the 6MWT was observed in all patients directly after implantation and at the three month follow-up. During the three month follow-up, the results from the 6MWT were even better compared to the results after implantation. However, the differences were not statistically significant. The results are shown in Figure 1.

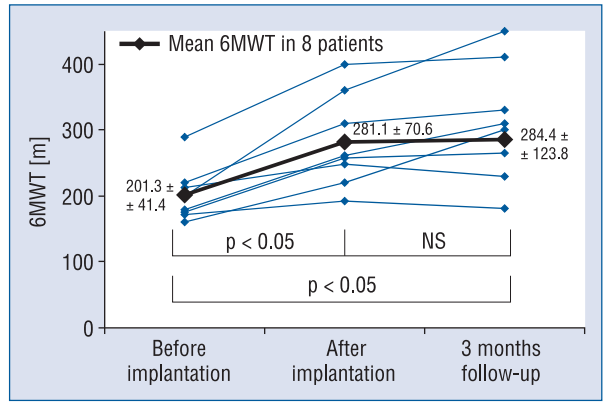

Figure 1. Comparison between six minute walking test (6MWT) before, after and at three month follow-up in eight patients with bifocal implantation.

NYHA class. The majority (six of the eight) of the patients were in NYHA class IV heart failure status. An improvement in the NYHA functional class status was seen in each patient. Six patients went from NYHA class IV to class III, and two patients went from class III to class II.

QRS duration. The mean duration of QRS complex was wider after implantation (QRS before 179.6 ± 29 *vs* QRS after 184 ± 46; NS). Only in three patients was a reduction in QRS duration observed. These results are presented in Figure 2.

Echocardiographic measurements

Echocardiographic evaluation revealed a significant increase in CO and LVEF after bifocal implantation. No differences were observed in LVDD. The mitral regurgitation was reduced after BiF, but significant differences were found only comparing the three month follow-up to the pre- and post-implant

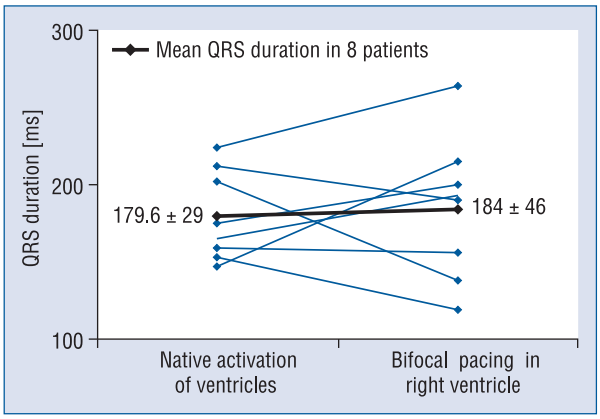

Figure 2. Comparison between QRS duration before and after right ventricular bifocal implantation in eight patients; p = non significant (NS).

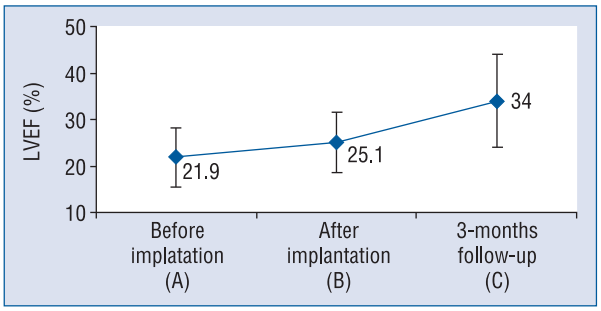

Figure 5. Left ventricular ejection fraction (LVEF) before, after and at three month follow-up in eight patients with right ventricular bifocal implantation; A *vs* B: p < 0.01, A *vs* C: p < 0.05, B *vs* C: p = NS.

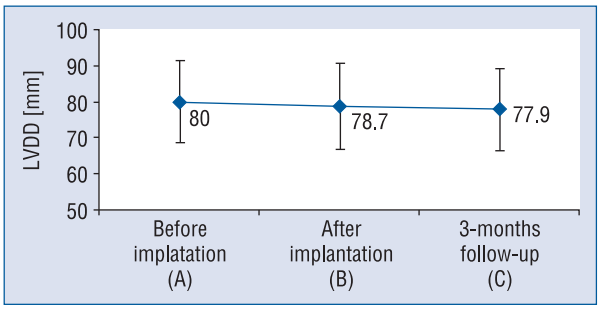

Figure 3. Left ventricular diastolic diameter (LVDD) before, after and at three month follow-up in eight patients with right ventricular bifocal implantation; A *vs* B: p = NS, A *vs* C: p = NS, B *vs* C: p = NS.

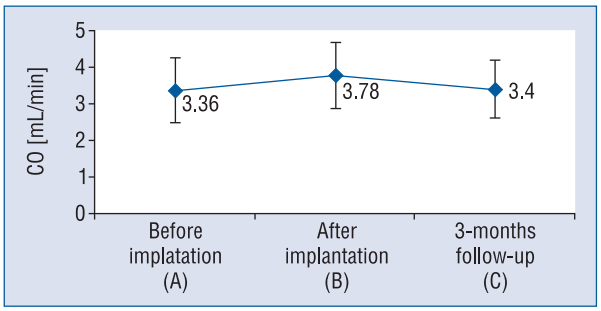

Figure 6. Cardiac output (CO) before, after and at three month follow-up in eight patients with right ventricular bifocal implantation; A *vs* B: p < 0.05, A *vs* C: p < 0.05, B *vs* C: p = NS.

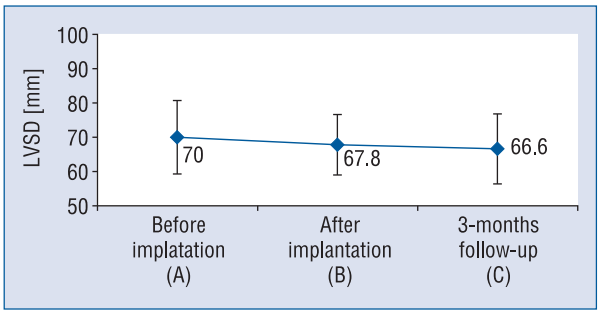

Figure 4. Left ventricular systolic diameter (LVSD) before, after and at three month follow-up in eight patients with right ventricular bifocal implantation; A *vs* B: p < 0.05, A *vs* C: p < 0.05, B *vs* C: p = NS.

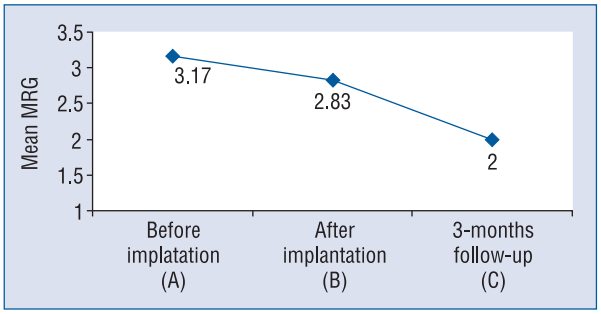

Figure 7. The mean mitral regurgitation grade (MRG) before, after and at three month follow-up in eight patients with right ventricular bifocal implantation; A *vs* B: p = NS, A *vs* C: p < 0.05, B *vs* C: p < 0.05.

periods. All other echocardiographic parameters were unchanged during the three month follow-up compared to the results directly after implantation. The results are shown in Figures 3–7.

Discussion

Nowadays, left ventricular lead implantation via a transvenous approach is a widely accepted method

for CRT. However, this technique, despite continued progress in the development of implantation tools, takes rather a long time, requires a high fluoroscopic exposure and does not guarantee success in all cases. Still today, publications on CRT report procedural failure in 10–20% of patients. The implantation success rate has been reported as follows: 89% in InSync Italian registry, 82% in EasyTrak Pre CE Mark Clinical Investigation and 87% in CONTAK registry [8, 22, 23]. Furthermore, a high percentage of left ventricular lead dislodgement is still reported: 7.4% in InSync Italian registry [8] and 6% in the Miracle study [2]. Even in the last year, published data with modern left ventricular leads is still high: a 6–8% of dislodgment has been reported [24]. The dissection or perforation of the coronary sinus directly associated with transvenous lead implantation was the other serious complication found in the MIRACLE study. This study reported two deaths related to this procedure.

Published studies prove that the beneficial effects of CRT are strictly associated with choosing the correct implantation site. Left ventricular lead positioning in the 'anterior veins' might explain the number of patients who do not respond to CRT [25, 26]. In the InSync Italian registry, only 71% of left ventricular leads were placed in the lateral or posterolateral vein [8]. In the EasyTrack Pre-CE Mark, only 50% of the leads were in the lateral vein [18]. Finally, even experienced cardiologists reported that the lateral vein was reached only in 80% of patients (MUSTIC trial) [1].

Furthermore, neither post-implantation QRS narrowing [27] nor acute hemodynamic response to CRT [28] proved to be a predictor for the improvement of symptoms and hemodynamic status.

Transvenous implantation procedure has certainly proved to be feasible, but it is highly dependent on the physician's level of experience, can last an unpredictably long time, and occasionally have severe complications.

Left ventricular epicardial implantation is an accepted method for CRT in case of an unsuccessful transvenous approach. The first CRT implantation with thoracotomy under general anaesthesia caused serious complications [9, 10]. Furthermore, left ventricular screw-in epicardial lead placement usually results in a high pacing threshold and loss of capture [11]. Limited thoracotomy decreases the number of complications, and the introduction of steroid eluting epicardial leads reduces the adverse events reported in previous series [29]. The advantage of this method, compared to transvenous left ventricular lead implantation, is in minimizing the length of the procedure, as well as the exposure to fluoroscopic time, and creating the possibility of placing the left ventricular lead at an optimal site. On the other hand, even limited thoracotomy can be performed only in a cardiosurgery department; it lengthens the duration of the patient's hospital stay and increases the costs of the procedure.

Bifocal stimulation in the right ventricle may be an alternative to unsuccessful left ventricular lead implantation. The first data about right ventricular bifocal pacing in five patients with Chagas disease and permanent atrial fibrillation with complete AV block was published in 1999 [30]. A significant increase in LVEF and CO during BiF was reported. Subsequent studies with a larger number of patients confirmed the previous results [31].

Until now, only a few publications about BiF have appeared. Kutarski et al. [32, 33] suggested in studies performed during implantation that BiF pacing might be beneficial in patients with unsuccessful left ventricular implantation. Vlay et al. [34] published three cases in 2003 in which BiF decreased the NYHA class, improved quality of life and some hemodynamic parameters. The first published long-term non-randomized study on BiF was performed by O'Donnell et al. [15]. He reported six patients in whom BiF increased the walking distance in 6MWT, increased LVEF, and resulted in the reduction in mitral regurgitation and in NYHA functional class. Additionally, these results were similar to changes observed in 44 patients with traditional biventricular CRT. Rocha et al. [18] compared the clinical, functional and echocardiographic parameters between BiF and BiV pacing mode. It was not a randomized study. They found favorable results of resynchronization were obtained with both techniques, with no significant differences between the two groups, except for a higher QRS narrowing in the BiV group, and a trend of a lower number or hospital admissions in the BiV group. Bulava et al. [16, 19] in two published studies examined echocardiographic parameters including tissue Doppler imaging and invasive measurement of hemodynamics in patients with BiF and BiV. They found that dp/dt significantly increased in both pacing modes compared to basal state, although higher values were obtained in BiV patients. Additionally, a significant correlation was found between the distance of the right ventricular apical and outflow tract leads and percentage of dp/dt (max) increase in idiopathic dilated cardiomyopathy patients. They also assessed that interventricular mechanical delay decreased in BiF patients. They concluded that BiF improves left ventricular hemodynamics by decreasing inter- and intraventricular conduction delays.

The BRIGHT was the first randomized, crossover study which assessed clinical status, NYHA classification, 6MWT, Minnesota Quality-of-Life Score and Hemodynamic status with LVEF in patients with BiF compared to a control group. All parameters were estimated prior to randomization and after three months of follow-up. Bifocal pacing: significantly improved LVEF, decreased NYHA classification from 2.8 ± 0.4 to 2.3 ± 0.7 ($p < 0.007$) and the 6MWT improved from 372 ± 129 m to 453 ± 122 m ($p < 0.05$). Minnesota Living with Heart Failure Scores decreased from 33 ± 20 to 24 ± 21 ($p < 0.006$). We found that, in cases where biventricular CRT could not be achieved, a right ventricular bifocal system seemed to be beneficial for patients with heart failure. The results showed a significant improvement in 6MWT and objective hemodynamic parameters such as LVEF, CO and reduction of mitral regurgitation in patients after BiF implantation. These positive results remained unchanged during the three month follow-up.

Our study is the first to assess bifocal pacing in patients with end-stage heart failure: six of the eight patients were in NYHA class IV. Compared to the aforementioned studies, in which most patients were in NYHA III, in our cases bifocal pacing provided an improvement in heart failure class in all patients. Although in our patients, LVEF and 6MWT distance were lower compared to patients in the BRIGHT study, during 3MFU we achieved significant improvements in these parameters.

There are two possible causes for the improved hemodynamic parameters through right ventricular bifocal pacing in the right ventricle. First of all, BiF as well as CRT increase AV synchrony [35, 36]. Additionally, as published in the study by O'Donnell et al. [15], BiF may decrease the degree of mitral regurgitation, perhaps by provoking greater interventricular synchrony, particularly at the level of the interventricular septum. Additionally Bulava et al. [16, 19] showed that BiF can also decrease interventricular dyssynchrony, suggesting that leads should be placed in the right ventricle as far as possible.

Limitations of the study

There is no comparison between BiF pacing and RVOT and/or right ventricular apex. It would be interesting to find out whether BiF gives better hemodynamic and clinical results compared to only RVOT pacing.

Conclusions

Right ventricular bifocal pacing in end-stage heart failure patients with CRT indication and unsuccessful left ventricular lead placement seems a beneficial treatment for heart failure. Satisfactory hemodynamic and clinical results were observed directly after BiF implantation and during the three month follow-up.

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