



Research Brief

Short term outcomes with dual chamber versus single chamber pacing for atrioventricular block - A crossover trial



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ABSTRACT

A total of 42 patients were studied for primary outcomes of quality of life and 6MWD between VVIR and DDD modes. At end of 2 months after device implantation, randomization was done and the device was programmed to VVIR or DDD modes. At the end of 2 months in this mode QOL and functional was assessed and the patient was switched to other mode. The same protocol was followed at the end of 2 months. We found no difference in functional capacity and quality of life between the two pacing modes. None of the patients developed pacemaker syndrome and there was no preference for any of the modes. © 2022 Cardiological Society of India. Published by Elsevier, a division of RELX India, Pvt. Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

1. Introduction

Patients with complete heart block can be treated with either a single chamber or a dual chamber pacemaker. Previous studies comparing them did not find any difference with respect to survival, QOL and functional capacity.^{1–4} The lack of a significant long term benefit with dual chamber pacemakers may be because the ventricular dyssynchrony with right ventricular pacing outweighs the benefits of atrioventricular synchrony.⁵ Despite this about 70–85% of the devices implanted are dual chamber in western countries.⁶ This study was designed to evaluate the difference in functional capacity between the two modes in the short term in patients with atrioventricular block.

2. Methods

This was a prospective randomized double blind cross over trial done at a single center. All patients over 40 years of age with acquired complete heart block and a resting heart rate of less than 50 for whom DDD pacemaker was to be implanted were included in the study. Implantation of pacemaker was done as per standard techniques. Active fixation leads were used in all patients. The

ventricular leads were preferentially positioned in the RV septal region above the level of the His bundle (high septal) or below the level of the His bundle (mid septal). Septal position was confirmed in multiple fluoroscopic views. When there was difficulty obtaining good septal position, the lead was placed in the apex. Devices were programmed to DDD mode after the implant. At the end of two months, after confirming normal device function and satisfactory parameters, randomization was done. Patients were assigned to group I or group II and the protocol was followed according to the study design (Fig. 1).

2.1. End points and outcomes

All outcomes were assessed by an observer who was blinded to the pacing mode. The primary outcomes were quality of life (WHO QOL-BREF score⁷) and effort tolerance (6 min walk distance). The secondary outcomes were ventricular pacing burden, pacemaker syndrome, atrial fibrillation and atrial lead malfunction.

By taking standard deviation of QOL score as 10 and considering a change in score of 5 as significant, we calculated that we need to study 42 subjects to be able to detect significant difference with a power of 0.85 and a type 1 error probability of 0.05 keeping a attrition rate of 4%.

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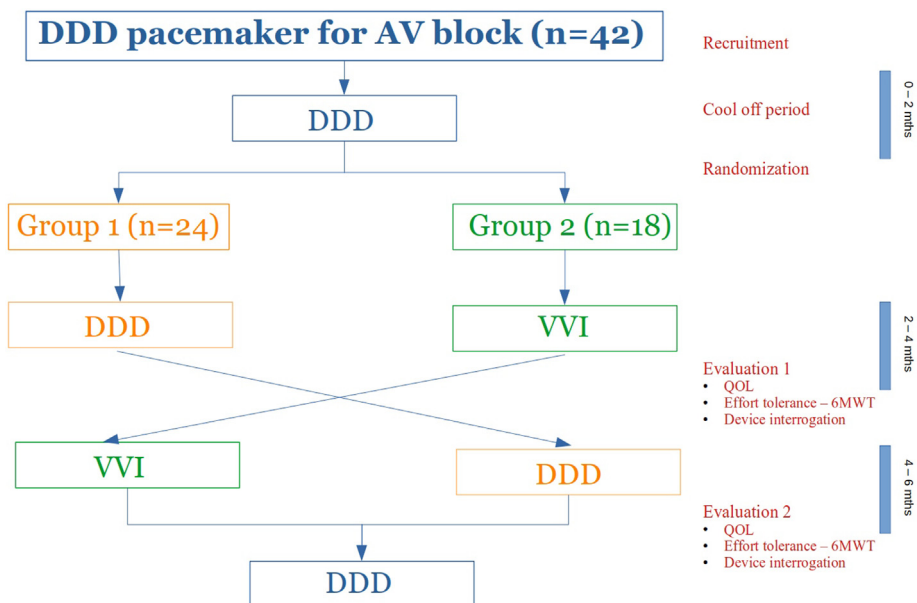


Fig. 1. Study design. A schematic representation of the cross over trial design.

3. Results

A total of 42 patients were recruited. There were no significant differences in the baseline characteristics of patients in the two groups (Table 1). The ventricular lead was placed in the right ventricular apex in three patients and in septal location in the others. All the patients completed the follow up. Eighteen patients were randomized to VVIR mode first followed by DDD mode while the other twenty-four patients were randomized to DDD mode first followed by VVIR mode.

There was no difference in the primary outcome between the two pacing modes. The quality of life scores for DDD mode vs VVIR mode were not different in the physical domain (52.8 ± 18.4 vs 51 ± 15, *p* value = 0.5), physiological domain (52.5 ± 17.4 vs 51.8 ± 16.9, *p* value = 0.8), social domain (52.5 ± 19.50 vs 56.9 ± 18.2, *p* value = 0.2) or the environmental domain (51.6 ± 14.4 vs 55.6 ± 14.1, *p* value = 0.1). There was no difference in 6 min walk distance between the two modes (396 ± 121.7 m for DDD mode vs 411.5 ± 112.9 m for VVIR mode, *p* = 0.07).

There was no significant difference in any of the secondary outcomes too (Table 2). None of the patients experienced any symptoms of pacemaker syndrome.

4. Discussion

In a group of patients with a dual chamber pacemaker implanted for atrioventricular block, we found that quality of life

Table 1
Baseline characteristics *n* = 42.

Age (mean ± SD)	62 ± 10 years
Male (%)	23 (55%)
Diabetes (%)	11 (26.2%)
Hypertension (%)	14 (33.3%)
Renal disease (%)	2 (4.8%)
Hb (mean ± SD)	11.4 ± 1.95
S creat (mean ± SD)	1.06 ± 0.47
RBS (mean ± SD)	118 ± 36.6
EF (mean ± SD)	59.5 ± 2.16

Table 2
Secondary outcomes *n* = 42.

	DDD	VVIR	<i>p</i> value
NYHA CLASS I	34 (81%)	34 (81%)	
NYHA CLASS II	7 (16.7%)	7 (16.7%)	
NYHA CLASS III	1 (2.3%)	1 (2.3%)	
NYHA CLASS IV	0	0	
PACEMAKER SYNDROME	0	0	
V PACING (MEAN/SD)	98.9 ± 2.08%	91.7 ± 17.1%	0.01
Atrial lead malfunction	0	0	

and functional capacity were not different in the short term between dual chamber pacing and single chamber rate responsive ventricular pacing. Our results on quality of life are consistent with the larger multicenter PASE study. However Ouali et al, in a cross over trial, reported better quality of life with dual chamber pacing³. The reason could be that the study population included people who were already in the dual chamber mode for a mean of 5.1 years. A sudden change to single chamber pacing might have resulted in the perceived reduced quality of life.^{1,3}

There was no difference in 6MWD between the two modes. This is consistent with other studies which also showed no difference in functional capacity between the two modes.^{1,3} Careful analysis of data in MOST provides us hints that benefits of AV synchrony might be mitigated by V–V dyssynchrony.⁹

None of our patients developed pacemaker syndrome during the course of the study. Our result was similar to CTOPP in which the occurrence of pacemaker syndrome was rare.⁸ The reason for low incidence of pacemaker syndrome in our study might be the low incidence of VA conduction in patients with AV block and the RV mid septal lead position in most patients leading to reduced V–V dyssynchrony.^{10,11}

Our trial is unique because of the younger age group of the patients studies when compared to other trials. Other studies have not specified the position of leads. In our study ventricular lead was placed in septal position in 39 patients out of 42 with an intention to reduce VV dyssynchrony.¹⁰

Pacing was 91.7 ± 17.1% in VVIR arm vs 98.9 ± 2.08% in DDD arm. The explanation for this is that complete third degree heart

block is dynamic in nature and during follow up, conduction can improve and heart block may be intermittent in a few patients. We found this in about a third of the patients during VVIR mode. Such intermittent conduction may not even be identified in DDD mode. Reduction in pacing burden might have resulted in improved functional capacity.

The results of this study are more important now with the approval of leadless pacemakers for the treatment of patients with complete heart block.

5. Conclusions

In patients with complete heart block, there was no difference in quality of life and functional capacity in the short term when programmed to DDD or VVIR modes.

Disclosures

None for any of the authors.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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