

Health-related quality of life in patients with Chagas' cardiomyopathy and complete atrioventricular block at elective pulse generator replacement: effects of pacing mode upgraded from VVI to DDD

Efeitos da mudança de modo de estimulação ventricular para atrioventricular sobre a qualidade de vida em pacientes com cardiopatia chagásica e bloqueio atrioventricular na troca eletiva do gerador de pulsos

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Abstract

Objective: Health-related quality of life in patients with Chagas cardiomyopathy and complete atrioventricular block at elective pulse generator replacement: effects of pacing mode upgraded from VVI to DDD.

Methods: From September 8, 2001 to March 18, 2004, at the Instituto do Coração da Medical School of the University of São Paulo and Hospital de Beneficência Portuguesa in Ribeirão Preto, a total of 27 patients with chronic Chagas cardiomyopathy, complete atrioventricular block and implanted ventricular pacemakers were upgraded to a dual-chamber pacing mode. At the beginning of the study and after 90-day periods under each pacing mode, the patients' quality of life was evaluated. Statistical analysis was made at basal, VVI and DDD conditions using an analysis of repetitive measures.

Results: No significant differences in the health-related quality of life, across the three studied variables (physical function, vitality and general health), were detected after the change of pacing mode from VVI to DDD. There were three cases of complications related to pacing mode upgrade: two cases of atrial tachycardia triggered to ventricles through DDD pacemaker and one atrial lead displacement.

Conclusions: No benefits no quality of life were detected after the change of pacing mode from VVI to DDD during elective replacement of pulse generator, in patients with Chagas cardiomyopathy and complete AV block.

Descriptors: Chagas' cardiomyopathy. Heart Block. Pacemaker, artificial. Cardiac pacing, artificial. Quality of life

Work performed in the Instituto do Coração – HCFMUSP, São Paulo and the Hospital Beneficência Portuguesa in Ribeirão Preto.

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Resumo

Objetivo: Avaliar os efeitos da mudança de modo de estimulação ventricular para atrioventricular sobre a qualidade de vida em pacientes com cardiopatia chagásica e bloqueio atrioventricular, na troca eletiva do gerador de pulsos.

Método: No período de 8 de setembro de 2001 a 18 de março de 2004, no Instituto do Coração da Faculdade de Medicina da Universidade de São Paulo e no Hospital de Beneficência Portuguesa de Ribeirão Preto, foram estudados comparativamente sob estimulação ventricular e atrioventricular 27 pacientes com cardiopatia chagásica e bloqueio atrioventricular, com indicação de troca eletiva do gerador de pulsos. Os pacientes foram analisados na inclusão do estudo e alternadamente no modo ventricular e atrioventricular em duas fases com duração de 90 dias, considerando-se o comportamento clínico, avaliado pela qualidade de vida. A análise estatística foi realizada na

condição basal, modo VVI e modo DDD, utilizando-se o teste de variância para medidas repetidas, considerando-se nível de significância de 0,05.

Resultados: Não foram detectadas diferenças de comportamento na qualidade de vida, avaliada pela capacidade funcional pelo estado geral e pela vitalidade, entre os dois modos de estimulação cardíaca estudados. Ocorreram três casos de complicações relacionadas à mudança de modo de estimulação: dois casos de taquiarritmias atriais conduzidas pelo marcapasso e um caso de deslocamento de eletrodo atrial.

Conclusões: A análise comparativa da estimulação ventricular com a atrioventricular, na troca eletiva do gerador, demonstrou que não houve diferença de comportamento clínico sobre a qualidade de vida.

Descritores: Miocardiopatia chagásica. Bloqueio cardíaco. Marcapasso artificial. Estimulação cardíaca artificial. Qualidade de vida.

INTRODUCTION

Sequential atrial and ventricular stimulation allows reconstitution of the atrioventricular synchronism in patients with atrioventricular blocks, providing, in relation to ventricular pacemakers, a greater ventricular filling, by the contribution of the atrial systole and the physiological control of the heart rate, by taking advantage of the spontaneous "P" waves of the patient.

There is evidence that atrioventricular stimulation is better than ventricular stimulation in patients with sinus node disease, offering greater longevity and a lower morbidity rate, which has not been demonstrated in patients with atrioventricular blocks [1]. The national and international guidelines, however, published from a consensus of medical societies, suggest an initial implantation of a dual-chamber pacemaker in patients with atrioventricular blocks, as these are theoretically more physiological than ventricular pacemakers [2,3].

For elective pulse generator replacement there is no consensus about the type of conduct to be adopted. The decision to maintain the ventricular mode or to change to an atrioventricular 'upgraded' mode is made depending on the routine of each professional. The upgrading of the stimulation mode at the moment of elective replacement, even though this can represent a theoretical benefit, implicates a higher cost for the healthcare system, a longer hospital stay, greater operative time and the risk of complications related to the introduction of an additional electrode lead.

In Brazil, Chagas disease represents a significant cause of atrioventricular blocks affecting a younger population than the patients with degenerative blocks. Theoretically

more physiological stimulation modes cause a greater impact in the quality of life of these patients [4,5].

The aim of the present study is to evaluate how an elective change in the stimulation mode affects the quality-of-life in patients with Chagas myocardialopathy and complete atrioventricular blocks at the moment of the pulse generator replacement.

METHOD

The study was performed in the Instituto do Coração, Medical School, University of São Paulo and in the Hospital of Beneficência Portuguesa in Ribeirão Preto from 8 September 2001 to 18 March 2004.

Twenty-five patients with Chagas cardiopathy, complete atrioventricular blocks and ventricular pacemakers, who needed to electively replace their pulse generators, were included. Patients who presented with any suggestion of fibrillation or atrial flutter, symptoms of pacemaker syndrome, pregnancy, disease associated with any kind of limiting factor or reduced life expectancy were excluded.

The patients were counseled about the procedure which was going to be performed, its risks and its potential benefits. After they agreed to participate in the research protocol and signed a consent form.

Patients

The age of the patients ranged from 29 to 79 years, with a mean of 55.9 ± 12.7 and median of 54 years old. Fifteen patients were women and twelve patients were men. The race of the patients was 14 white, 8 black and 5 mulattos. The patients used ventricular pacemakers for periods varying from 3 to 30 years with a mean of 11 ± 6 years and a

median of 10 years. For 13 patients, the procedure would replace the first implanted stimulation system; in seven patients the second pulse generator utilized; in three the third and the four their fourth replacement. The rhythm of all patients was sinusal for the atria with a complete block of the atrioventricular conduction, verified using a test to reduce the stimulation frequency of the pacemaker.

In the preoperative clinical evaluation, according to the criteria established by the New York Heart Association, 14 patients were in Functional Class I, 11 patients were in Functional Class II and two patients were in Functional Class III. Only seven patients were not taking medicine. The others took one or more drugs that acted on the cardiovascular system: anti-hypertensive drugs (14), diuretic drugs (13), digitalis (six) and antiarrhythmic drugs (six).

Echocardiograph measurements performed at the beginning of the study showed: ejection fraction (Teicholz) from 26 to 77% with a mean of 50.7% and standard deviation of 14.8; Left ventricle final diastolic diameter from 37 to 63 mm with mean of 51.8 mm and standard deviation of 7.6 mm and diameter of left atrium from 29 to 45 mm with mean of 37.6 mm and standard deviation of 4.4 mm.

Study design

This is a double-blind, randomized, prospective, controlled clinical study. All selected patients were submitted to the same type of surgical procedure: atrial electrode lead implantation and replacement of a single-chamber pulse generator for a dual-chamber pacemaker. After this, the generator was programmed for a pacing mode selected by randomization. To allow a comparison of two pacing modes and to minimize the effect of the tendency of the first programmed pacing mode, the patients were subdivided in two groups, according to randomization using a computer (Figure 1).

In Condition A, the patients stayed, after the surgery, in ventricular pacing mode for 90 days (Phase I), and after were reprogrammed to an atrioventricular mode for another 90 days (phase II).

In Condition B, the patients were programmed, after the surgery, in atrioventricular pacing mode for 90 days (Phase I) and after reprogrammed for the ventricular mode for another 90 days (Phase II).

Programming of the pacemaker

All the generators used for replacement were dual chamber, with telemetry to non-invasively change their programmable parameters. The pacing modes compared in the study were the ventricular and the atrioventricular pacing modes, identified according to the International Code of Standardization of Artificial Cardiac Pacing Modes by VVI and DDD, respectively. Mode VVI: The programmed

frequency was 70 bpm and as the patients had advanced atrioventricular block, AV synchronism never occurred. Mode DDD: The minimum frequency of pacing was 70 bpm without response to the frequency and the maximum frequency was calculated based on 80% of the maximum rate for the age. The AV interval was not individualized and was programmed at 120 ms after a spontaneous "p" wave and 180 ms after a stimulated "p" wave. The atrial sensitivity was programmed at 0.5 mV and the ventricular at 2.5 mV. At the end of the study all patients had their pacemaker reprogrammed to the atrioventricular mode.

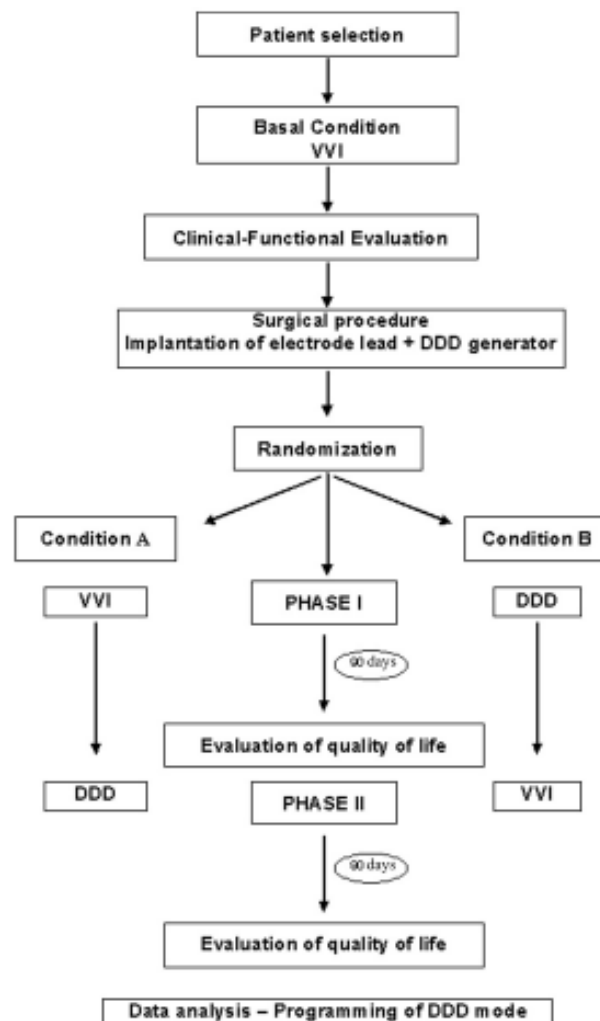


Fig. 1 – Study Design

Operative technique

The surgical technique was the same in the two centers with the incision performed in the same place as the previous surgery. After dissection by layers, the generator and the electrode lead were isolated. The generator was disconnected and the electrode lead submitted to routine evaluation tests. After confirming the good conditions of the ventricular electrode with chronic thresholds of stimulations less than 3.0V, sensitivity greater than 4.0 mV and impedance of from 400 to 1300 ohms, a new electrode lead was introduced (by subclavian or jugular vein puncture) and fixed in the right atrium. The electrode lead utilized, which is always actively fixed, was positioned in the auricula or in the most favorable region of the right atrium, according to the best pacing thresholds and sensitivity obtained. The acute thresholds of atrial stimulation considered satisfactory were less than 1.5 V, sensitivity greater than 1.0 mV and impedance from 300 to 1300 ohms. The measurements were performed in unipolar and bipolar situations when the electrodes had both configurations. After this, both the leads were connected to the pulse generator and any excess of the electrode leads was placed behind the generator and the pacemaker was fixed in a comfortable position without tension in the skin. Prophylactic antibiotic therapy was achieved with a single dose of cephazolin (2.0 g) administrated intravenously before starting of the procedure.

Six-minute walking test

The six-minute walking test, as it is similar to daily activities, was utilized for the functional evaluation of patients and the distance walked was a marker of the clinical condition. The heart rate was measured before the beginning and at the end of the test as was the distance that the patient walked in six minutes. The speed was controlled by the Borg's scale, which aims at evaluating the perceptible effort index of the patient during the test.

Quality of life

The generic instrument to assess the quality of life utilized in this study was the Medical Outcomes Study SF-36 Health Survey Protocol, which is an easily-used and understood multidimensional questionnaire. This questionnaire evaluates both positive aspects and negative aspects of health and well-being. It was developed in the United States and validated with Brazilian patients. It is one of the international tests most used in medicine [6,7]. The replies to the questionnaire were evaluated in a database (specific software) that measured the quality of life on a scale (Raw Scale) that varies from 0 (the worst state of health) to 100 (the best state of health). The questions were achieved in simple and understandable individual interviews with the

patients, in order that the answers did not suffer any kind of induction not even involuntary induction.

Statistic analysis

Statistic analysis of the effects of the change of pacing mode was made at pre (basal) condition, VVI mode and DDD mode. The quantitative variables were compared using variance analysis of repeated measurements. When significant, a complementary contrast test was used to discriminate the differences. P-values < 0.05 were considered significant.

RESULTS

The surgical procedures of pulse generator replacement, changing the pacing mode, were successfully performed in all study patients. No deaths occurred in the study period. The approach to introduce the atrial electrode was by puncturing the subclavian vein in 25 patients (92.5%) and the internal jugular vein in two (7.5%).

Four postoperative complications were observed: one displacement of the atrial electrode treated by repositioning; one atrial tachycardia and one episode of atrial flutter, both conduced to the ventricles by the pacemaker causing tachycardia; and one hematoma at the site of the generator, secondary to the use of anticoagulants, treated only by the suspension of the medicine.

No change of the functional status of the patients was observed when compared to basal conditions and following postoperative periods (VVI or DDD modes).

The six-minute walking test showed that the distance walked by the patients during the basal conditions was from 210 to 525 meters with a mean of 407.5 meters, with ventricular stimulation (VVI) it was 230 to 625 meters with a mean of 463.4 meters and with atrioventricular pacing (DDD) it was from 375 to 650 meters with a mean of 462.6 meters. No significant difference was observed between the mean walking distances of the two modes (P=0.945) but the walking distance in both cases was significantly greater than the basal condition (P=0.0006). The mean initial heart rate in the basal condition was 66.3 bpm, with VVI it was of 69.3 bpm and with DDD it was of 70.6 bpm, which did not give statistical differences between the two pacing modes, but the mean heart rate in the basal condition was significantly less than in the VVI and DDD Phases. The mean final heart rate was of 73.1 bpm in the basal condition, 75.1 bpm in the VVI condition and 77.8 bpm in the DDD condition (Table 1).

The quality of life, which was evaluated by the functional capacity, by the general state and by the vitality did not show significant differences in the means in any condition of the study. The mean functional capacity was of 68.0 (35 to 95) in the basal condition, 71.3 (20 to 100) in the VVI mode

Table 1. Data of the six-minute walking test in the basal conditions, VVI and DDD

Nº of Cases	Pre(basal)			VVI			DDD		
	HR (Initial)	HR (Final)	Distance (Meters)	HR (Initial)	HR (Final)	Distance (Meters)	HR (Initial)	HR (Final)	Distance (Meters)
1	56	72	360	70	76	450	76	96	400
2	62	68	350	60	64	460	60	68	435
3	69	78	280	64	69	495	84	92	435
4	72	76	420	70	77	430	68	80	480
5	56	64	435	64	68	450	65	72	465
6	72	76	420	70	72	372	72	76	420
7	70	72	435	70	72	490	70	76	460
8	68	72	210	64	70	230	68	74	420
9	62	68	378	70	72	450	74	78	470
10	74	80	225	70	75	420	72	76	420
11	68	68	435	70	70	465	67	70	460
12	74	78	420	80	85	450	82	86	465
13	70	74	415	64	70	440	69	73	480
14	72	76	300	70	76	450	70	80	400
15	68	68	300	76	76	400	70	76	375
16	60	64	375	70	84	375	70	80	375
17	60	68	450	70	76	450	70	76	400
18	70	88	500	70	84	625	70	80	650
19	70	76	450	70	76	550	70	76	450
20	60	68	450	70	76	450	70	80	475
21	60	68	450	70	80	450	70	78	400
22	60	64	525	70	76	500	70	80	550
23	64	76	500	70	80	600	70	76	550
24	74	80	450	70	76	350	70	80	500
25	68	80	450	76	84	576	70	80	550
26	72	84	500	72	78	615	74	76	540
27	60	68	520	60	67	520	64	66	465
Mean	66.3	73.1	407.5	69.3	75.1	463.4	70.6	77.8	462.6
Standard deviation	5.8	6.3	84.3	4.4	5.5	84.7	4.8	6.3	63.4
Minimum	56.0	64.0	210.0	60.0	64.0	230.0	60.0	66.0	375.0
Maximum	74.0	88.0	525.0	80.0	85.0	625.0	84.0	96.0	650.0

DDD: Patient condition after 90 days of atrioventricular stimulation; HR: Heart rate; PRE: Patient condition in exclusive ventricular stimulation at inclusion in the study; VVI: Patient condition after 90 days of ventricular stimulation

and 69.3 (30 to 95) in the DDD mode (Figure 3). Assessment of the general state gave a mean of 73.9 in the basal phase (35 to 97), 68.1 (10 to 97) in VVI mode and 69.4 (17 to 97) in DDD mode (Figure 4). The vitality had a mean of 63.5 (20 to 100) in the basal phase, 64.8 (0 to 100) in VVI mode and 67.6 (0 to 100) in DDD mode (Figure 5). The individualized data of the patients can be seen in Table 2.

There was no effect on the trend of the first programmed pacing mode, which was observed by an analysis separating Conditions A and B (Table 3). The results were similar in the analysis of patients with ejection fractions of more than, less than or equal to 40% and with time of pacemaker use of more than and less than or equal to 10 years (Tables 4 and 5).

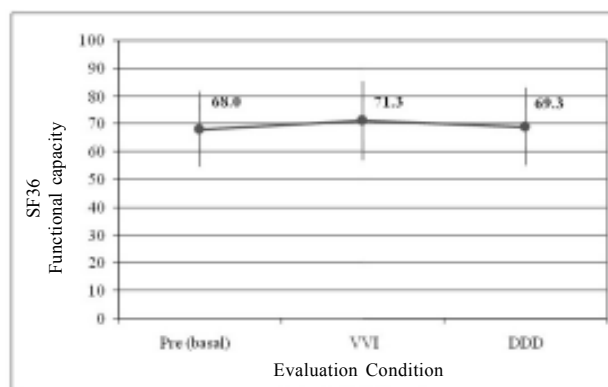


Fig. 2 - Quality of life evaluated by the functional capacity (p-value = 0.489) at the pre (basal), VVI and DDD conditions, of patients with chagasic heart disease and atrioventricular block. Total points (SF36) of the functional capacity evaluation represented as means and standard deviations; DDD: condition of patient after 90 days of atrioventricular stimulation; Pre (basal) condition of patient in exclusive ventricular stimulation at inclusion in the study; VVI: condition of patient after 90 days of ventricular stimulation

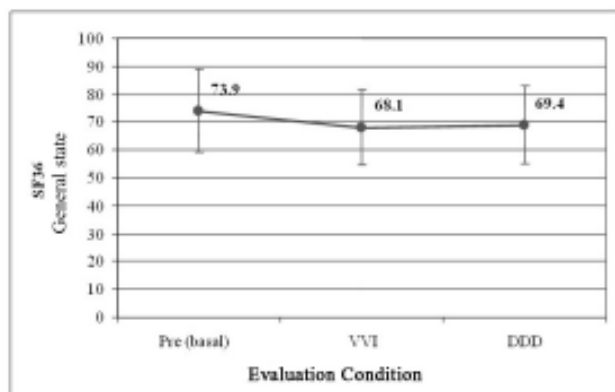


Fig. 3 - Quality of life evaluated by general state (P=0.546), in Pre (basal), VVI and DDD conditions, of patients with chagasic heart disease and atrioventricular block. Total of points (SF36) of evaluation of general state represented as a mean and standard deviation; DDD: condition of patient after 90 days of atrioventricular stimulation; P: descriptive level of variance test for repeated measures; Pre (basal) condition of patient in exclusive ventricular stimulation at inclusion in the study; VVI: condition of patient after 90 days of ventricular stimulation

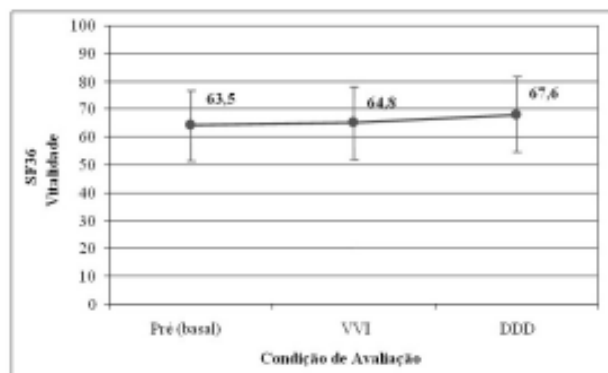


Fig. 4 - Quality of life evaluated by vitality (p=0.593), in Pre (basal), VVI and DDD conditions, of patients with chagasic heart disease and atrioventricular block. Total of points (SF36) of evaluation of vitality represented as means and standard deviation; DDD: patient condition after 90 days of atrioventricular stimulation; P: descriptive level of variance test for repeated measures; Pre (basal) patient condition in exclusive ventricular stimulation at inclusion in the study; VVI: patient condition after 90 days of ventricular stimulation

Table 2. Evaluation of dimensions of quality of life (Raw Scale) according the SF-36 protocol

N° of Cases	Pre(basal)			VVI			DDD		
	Functional Capacity	General state	Vitality	Functional Capacity	General state	Vitality	Functional Capacity	General state	Vitality
1	65	42	55	65	42	55	60	62	55
2	45	87	45	55	67	35	45	67	55
3	50	57	100	65	27	55	35	45	55
4	60	80	85	55	82	90	80	87	95
5	75	82	60	75	42	65	45	37	15
6	90	77	70	95	77	95	95	77	95
7	90	57	75	90	62	75	90	62	85
8	55	82	50	20	10	0	30	17	0
9	95	87	85	90	82	95	90	62	90
10	75	97	95	90	72	100	80	47	95
11	35	35	50	85	87	100	95	77	100
12	95	82	60	90	60	60	95	72	55
13	80	72	60	75	62	60	80	62	60
14	45	47	35	75	95	80	90	80	80
15	50	72	50	65	67	60	75	47	55
16	50	87	80	55	72	90	50	87	90
17	60	67	45	50	72	40	70	50	40
18	95	80	80	100	77	80	95	85	80
19	70	97	65	75	97	60	65	97	60
20	60	60	25	85	82	30	75	82	45
21	95	97	75	55	92	80	40	92	100
22	75	57	55	70	72	80	55	92	70
23	40	75	20	60	25	30	90	65	60
24	55	92	70	60	87	65	50	92	95
25	60	52	55	75	77	60	65	77	60
26	95	82	70	95	80	70	75	82	85
27	75	92	100	55	72	40	55	72	50
Mean	68.0	73.9	63.5	71.3	68.1	64.8	69.3	69.4	67.6
Standard deviation	19.1	17.5	20.7	18.2	21.8	24.6	20.4	19.4	25.5
Minimum	35.0	35.0	20.0	20.0	10.0	0.0	30.0	17.0	0.0
Maximum	95.0	97.0	100.0	100.0	97.0	100.0	95.0	97.0	100.0

DDD: Patient condition after 90 days of atrioventricular stimulation; PRE: Patient condition in exclusive ventricular stimulation at inclusion in the study; SF36: Short Form (questionnaire of quality of life with 36 questions); VVI: Patient condition after 90 days of ventricular stimulation.

Table 3. Evaluation of quality of life dimensions by randomization (situation A and B)

	Situation A			Situation B		
	N	Mean	Standard deviation	N	Mean	Standard deviation
SF36						
Functional capacity						
Pre (basal)	13	68	20	14	68	19
VVI	13	69	22	14	74	14
DDD	13	65	22	14	73	19
SF36						
General state						
Pre (basal)	13	77	16	14	71	19
VVI	13	68	21	14	68	23
DDD	13	72	22	14	67	17
SF36						
Vitality						
Pre (basal)	13	67	16	14	60	24
VVI	13	67	28	14	63	21
DDD	13	68	32	14	67	19

DDD: Patient condition after 90 days of atrioventricular stimulation; PRE: Patient condition in exclusive ventricular stimulation at inclusion in the study; SF36: Short Form (questionnaire of quality of life with 36 questions); VVI: Patient condition after 90 days of ventricular stimulation.

Table 4. Evaluation of quality of life dimensions by ejection fraction

	EF ≤ 40			EF > 40		
	N	Mean	Standard deviation	N	Mean	Standard deviation
SF36						
Functional capacity						
Pré (basal)	9	59	20	18	72	18
VVI	9	59	19	18	77	15
DDD	9	61	23	18	73	18
SF36						
General state						
Pré (basal)	9	75	20	18	73	17
VVI	9	63	27	18	71	19
DDD	9	68	22	18	70	19
SF36						
Vitality						
Pré (basal)	9	59	23	18	66	20
VVI	9	55	32	18	70	19
DDD	9	64	31	18	69	23

DDD: Patient condition after 90 days of atrioventricular stimulation; PRE: Patient condition in exclusive ventricular stimulation at inclusion in the study; SF36: Short Form (questionnaire of quality of life with 36 questions); VVI: Patient condition after 90 days of ventricular stimulation

Table 5. Evaluation of quality of life dimensions by time of use of pacemaker

	PM Time ≤ 10 years			PM Time > 10 years		
	N	Mean	Standard deviation	N	Mean	Standard deviation
SF36						
Functional capacity						
Pré (basal)	14	70	23	13	66	14
VVI	14	75	20	13	67	15
DDD	14	76	21	13	62	18
SF36						
General state						
Pré (basal)	14	72	19	13	76	16
VVI	14	71	25	13	65	18
DDD	14	71	20	13	68	19
SF36						
Vitality						
Pré (basal)	14	56	19	13	72	20
VVI	14	64	28	13	66	21
DDD	14	69	27	13	66	25

DDD: Patient condition after 90 days of atrioventricular stimulation; PRE: Patient condition in exclusive ventricular stimulation at inclusion in the study; SF36: Short Form Health Survey (questionnaire of quality of life with 36 questions); VVI: Patient condition after 90 days of ventricular stimulation.

DISCUSSION

The use of artificial heart pacemakers, which started in 1958 with right or left ventricular pacing, radically changed the natural evolution of the patients with atrioventricular blocks, by eluding their most fearful effects: Stokes-Adams crises and sudden death. The technological evolution that occurred over the last four decades, however, incorporated many resources in these devices. Among which, sequential atrioventricular pacing of the atria and ventricles was a memorable achievement in heart pacing, as it allows the reconstitution of the atrioventricular synchronism, lost with the installation of the conduction block.

There is clear evidence that the atrioventricular pacing mode is superior to ventricular pacing in patients with sinus node disease, providing greater longevity and lower morbidity rates. In patients with atrioventricular blocks, however, although some publications suggest there are advantages, there is no definitive evidence in respect to the benefits of using this type of pacemaker, which require the implantation of more than one electrode lead, resulting in a higher complications rate and a greater cost.

In respect to the absence of evidence, which would justify the indiscriminate use of atrioventricular pacemakers in patients with atrioventricular blocks, the national and international guidelines, published from a consensus of

medical societies, suggest for the initial implantation, the use of atrioventricular pacemakers, because theoretically they are more physiological than pacemakers with ventricular stimulation alone.

The upgrading of the pacing mode at the moment of elective replacements, although this may represent a theoretical benefit, as it allows a physiological increase in the heart rate during exercise and an improved ventricular filling, result in a higher cost of the implanted system, a longer hospitalization, longer operative time and higher risks of complications related to the introduction of a second electrode lead. The lack of knowledge of the true benefits of this conduct was the main reason for the present study.

The present series included only patients with Chagas cardiomyopathy, a differential characteristic and just one of among trials which compare the effects of varying artificial heart pacing modes. These patients presented essential differences when compared to patients with degenerative atrioventricular blocks: they are younger at the moment of the initial pacemaker implantation and as they have a greater survival rate, thus they are submitted to more pulse generator replacements [5].

Chagas disease also provokes intrinsic heart denervation, frequently to an unrecognizable degree [8,9]. Several studies, such as the one by GUZZETTI et al. [10], who studied the variability of the heart rate in patients with Chagas cardiomyopathy without heart insufficiency, demonstrated a

reduction in the sympathetic activity. The most significant clinical-functional consequence of this is chronotropic insufficiency which is the manifestation of the parasympathetic predominance on the atrial sinus node.

In the present study, the results obtained in the six-minute walking test, suggest that the studied patients presented different degrees of chronotropic insufficiency. It was possible to verify that during walking, under DDD stimulation, which allows ventricular stimulation synchronized with the spontaneous "P" waves, the variation of the heart rate was less than that expected for patients in the same age range. When they were asked to walk, at levels of difficulty subjectively defined as being relatively easy and slightly tiring, the patients reached up to 77% of the maximum heart rate [11]. The slightly significant variation of the heart rate may have been responsible for the absence of clinical improvement observed in the test of quality of life.

Taking in consideration the controversy about the central theme of this study, the results obtained in the present work may be of great value. Some authors understand that the procedure of changing the pacing mode during elective generator replacement should not be performed routinely because, in general, it involves older patients with a sedentary life style. The results of the present study suggest that even in younger patients with more intense physical activities, the change of pacing mode can be innocuous.

HILDICK-SMITH et al. in 1998, retrospectively evaluating 44 cases of upgrades from ventricular to atrioventricular pacemakers, observed that only symptomatic patients, the majority included in the study, benefited but presented with a complication rate of 45%, which was considered very high [12]. GRIBBIN et al. in an evaluation of their experience, also observed an rate of complications associated to the upgrade related to the implantation of the atrial electrode (36%) [13] and for this reason, concluded that the change in the pacing mode in elective generator replacement should be performed only for well-defined reasons.

The evaluation of quality of life using the SF-36 questionnaire, with the choice directed towards the functional capacity, general state and vitality, allowed consistent correlations in patients with good clinical evolution. The present study demonstrated, however, that when patients with Chagas cardiopathy, atrioventricular blocks and VVI pacemakers are involved, who are evolving clinically well and without intolerance to the ventricular mode, the implantation of an additional atrial electrode lead, apart from not being free from risk, does not give clinical-functional changes that justify its routine use. Recently, in 2003, NEWMAN et al., in the Canadian Trial of Physical

Pacing (CTOPP), with the same protocol for quality of life assessment, obtained similar results to ours [14].

In another study involving Brazilian patients, Martinelli et al., in 2001 (Brazilian Study on Physiological Pacemakers – ESBRAMAF – preliminary results) evaluated the potential benefits of artificial atrioventricular heart pacing compared to ventricular pacing, comparing the clinical-functional behavior of patients and concluded that, in the short-term follow up there was no difference between the modes [15].

On the other hand, some authors believe that the opportunity of generator replacement must be taken to perform atrial electrode lead implantation for supraventricular tachyarrhythmia prophylaxis. This procedure was proposed for the first time in 1992 by SULKE et al., after one randomized study involving 16 asymptomatic patients with VVI pacemakers implanted for more than three years because of sinus node disease and atrioventricular block. The DDD mode offered an improvement in the physical capacity and comfort (subjective evaluation), but it was not different from the echocardiographic point of view [16].

Recently, Hoijer et al. published their findings obtained from observing 19 patients submitted to the change from ventricular mode to atrioventricular mode. This randomized study showed that most the patients preferred the DDDR type, which also improved the quality of life and heart function [17]. The inclusion, however, of patients with pacemaker syndrome, gave a selection bias which compromised the comparison of the pacing modes. This effect can also be observed in the MOST study, in which the quality of life improved after MP implantation, with a slight advantage of atrioventricular pacing. The evaluation, except for the group that underwent crossover due to intolerance of the VVI mode, however, did not demonstrate a significant difference between the two situations [18]. In the present study, the patients were adapted to the ventricular pacing mode which eliminates this type of criticism.

Finally, it is important to stress that the change from the ventricular pacing mode to the atrioventricular pacing mode, is always indicated when there is intolerance to the first mode, which was not the subject of this current work. There are studies being carried out now, such as the STOPAF (Systematic Trial of Pacing to Prevent AF), the ADEPT (Advanced Elements of Pacing Trial), the UKPACE Trial and the DANPACE (Danish Pacemaker Trial) that may bring new light on this question.

CONCLUSIONS

The comparative analysis of ventricular pacing and atrioventricular pacing in the elective replacement of pulse generators in 27 patients with Chagas cardiopathy and

atrioventricular block, demonstrated that there was no significant difference in the clinical behavior, which was assessed by the quality of life and by the functional class. There are however, complications associated to the change of pacing mode. Taking into consideration that these are patients with Chagas disease and there is a possibility of associated chronotropic insufficiency due to the denervation provoked by this nosologic entity, a comparative study of the pacing modes is necessary with the correction of the chronotropism by the use of non-atrial sensors.

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BIBLIOGRAPHIC REFERENCES

1. Lamas GA, Lee KL, Sweeney MO, Silverman R, Leon A, Yee R et al. Ventricular pacing or dual-chamber pacing for sinus-node dysfunction. *N Engl J Med.* 2002;346(24):1854-62.
2. Sociedade Brasileira de Cardiologia. Diretrizes para avaliação e tratamentos de pacientes com arritmias cardíacas. *Arq Bras Cardiol.* 2002;79(suppl. 5):7-50.
3. Gregoratos G, Abrams J, Epstein AE, Freedman RA, Hayes DL, Hlatky MA et al. ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices—summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee to Update the 1998 Pacemaker Guidelines).. *J Am Coll Cardiol.* 2002;40(9):1703-19.
4. Rassi Jr. A, Rassi A, Little WC. Chagas' heart disease. *Clin Cardiol.* 2000;23(12):883-9.
5. Costa R, Rassi A, Leão MIP. Estudo clínico e epidemiológico de pacientes submetidos a implante de marcapasso cardíaco artificial permanente: comparação dos portadores da doença de Chagas com os de doenças degenerativas do sistema de condução. *Rev Bras Cir Cardiovasc.* 2004;19(2):107-14.
6. Linde C. How to evaluate quality-of-life in pacemaker patients: problems and pitfalls. *Pacing Clin Electrophysiol.* 1996;19(4 pt 1):391-7.
7. Seidl EMF, Zannon CMLC. Qualidade de vida e saúde: aspectos conceituais e metodológicos. *Cad Saúde Pública.* 2004;20(2):580-8.
8. Oliveira JSM. A natural human model of intrinsic heart nervous system denervation: Chagas' cardiopathy. *Am Heart J.* 1985;110:1092-8.
9. Marin-Neto JA. Cardiac dysautonomia and pathogenesis of Chagas' heart disease. *Int J Cardiol.* 1998;66(2):129-31.
10. Guzzetti S, Iosa D, Pecis M, Bonura L, Prosdócimi M, Malliani A et al. Impaired heart rate variability in patients with chronic Chagas' disease. *Am Heart J.* 1991 121(6 pt 1):1727-34.
11. Guimarães GV, Bellotti G, Bacal F, Mocelin A, Bocchi, EA. Pode o teste ergoespirométrico de caminhada de seis minutos ser representativo das atividades habituais de pacientes com insuficiência cardíaca? *Arq Bras Cardiol.* 2002;78(6):553-60.
12. Hildick-Smith DJ, Lowe MD, Newell SA, Schofield PM, Shapiro LM, Stone DL et al. Ventricular pacemaker upgrade: experience, complications and recommendations. *Heart.* 1998;79(4):383-7.
13. Gribbin GM, McComb JM, Bexton RS. Ventricular pacemaker upgrade: experience, complications, and recommendations.. *Heart.* 1998;80(4):420. [letter]
14. Newman D, Lau C, Tang AS, Irvine J, Paquette M, Woodend K et al. CTOPP Investigators. Effect of pacing mode on health-related quality of life in the Canadian trial of Physiologic Pacing. *Am Heart J.* 2003;145(3):430-7.
15. Martinelli Filho M, Grecco O, Atié J, Pêres A, Magalhães L, God EG et al.. Estudo Brasileiro de Marcapasso Fisiológico (ESBRAMAF): Resultados preliminares. In: XVIII Congresso Brasileiro do Departamento de Arritmias Cardíacas e Eletrofisiologia Clínica. Reblampa. 2001;14:189.
16. Sulke N, Dritsas A, Bostock J, Wells A, Morris R, Sowton E. "Subclinical" pacemaker syndrome: a randomized study of symptom free patient with ventricular demand (VVI) Pacemakers upgraded to dual chamber devices. *Br Heart J.* 1992;67(1):57-64.
17. Höjjer CJ, Brandt J, Willenheimer R, Juul-Möller S, Boström PA. Improved cardiac function and quality of life following upgrade to dual chamber pacing after long-term ventricular stimulation. *Eur Heart J.* 2002;23(6):490-7.
18. Montanez A, Hennekens CH, Zebede J, Lamas GA. Pacemaker mode selection: the evidence from randomized trials. *Pacing Clin Electrophysiol.* 2003;26(5):1270-82.