Long Term Experience with a Contractility (ANS) Driven Pacemaker Sensor in Patients with Chronic Chagasic Cardiomyopathy

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Summary

We analyzed performance of a VVIR pacemaker driven by autonomic nervous system activity sensor in chagasic patients with cardiac conduction system disturbances. Forty-seven chagasic patients have been studied (28 male, 19 female; age 24 - 68 years). Thirty-six patients had complete AV block, 8 had 2nd degree AV block and the remaining 3 patients had sinus node disease. Patients were divided into two groups according to their heart rate (HR) at rest; group 1, with HR > 65 bpm and group 2, with HR < 65 bpm. A comparative study that extended over the first 12 months after pacemaker implantation evaluated: 1) HR at rest and during various types of stress tests; 2) arterial blood pressure at rest and during exercise, 3) performance of the TIR 60 UP leads in conjunction with the sensor function as compared to the performance of other leads. Patients from group 1 had a higher HR at rest, and a smaller HR variation during stress test than patients from group 2. This indicates that with this type of rate adaptive system it is possible to control each patient individually. The blood pressure at rest and during stress tests did not differ between the two patient groups.With respect to the sensor function, the TIR 60 UP leads offered the same performance as others leads. The VVIR pacemaker equipped with the sensor of autonomic nervous system activity allowed chagasic patients to restore their physiological mechanisms. Seventy-four percent of the patients had the NYHA Functional Class improved by 1 or 2 steps, following the pacemaker implantation.

Key Words

Chagasic cardiomyopathy, cardiac pacing, ANS controlled pacing, contractility

Introduction

Heart contraction sequence is controlled by autonomous mechanisms that are subject to extracardiac influence. By means of the sympathetic system, these mechanisms allow inotropic and chronotropic adaptation of cardiac output (CO) during physical activities and in response to neurohumoral variations. These compensatory mechanisms are effective in healthy myocardium that exhibits an increase in HR during physical exercise, contributing to the adaptation of CO and reestablishing the physiological excitement. This is also evidenced by the artificial pacing utilizing sensors tied up to metabolic parameters, hemodynamical and cardiovascular [1].

In general, the vagal tone has antiarrhythmic effects, in view of its direct eletrophysiological actions in the heart as well as indirect actions, for antagonistic sympathetic activity can facilitate the appearance of ventricular arrhythmia provoked by bradyarrhythmia. Sympathetic activity can also be antiarrhythmic as it improves heart contractility and coronary flow in heart failure, but the increased demand for oxygen within the myocardium may lead to cardiac arrhythmia [2].

Based on quantitative studies on parasympathetic system activity, Amorin and co-workers established a chronology of events in the evolution of the chagasic cardiomyopathy and defined three phases:

a) pure neurogenic, with rhythm upset;

b) vascular, with relative coronary inadequacy; and

c) miogenic, with lesions post isquemics accentuated.

They believe that in the chronic chagasic cardiomyopathy the autonomic disturbance and/or the chronic myocardial fibrosis and ventricular dysfunction act as factors predisposing the largest risk of sudden death and deprive the diseased of their normal way of living [3].

A close relationship between sympathetic and parasympathetic activity and central hemodynamics has already been recognized. As it is directly linkedf to CO and its determinants, it is essential to consider sympathetic tone for rate-adaptive pacing. Intracardiac impedance, monitored by a unipolar lead, permits sensing of the heart's mechanical activity. In the physiological cardiovascular control circuit, the autonomic nervous system regulates the mean arterial blood pressure (MABP) by adjusting CO via the afferent pathways according to changes in the total peripheral resistance (TPR) and orthostatic loads. The ventricular impedance signal, measured during the isovolumetric contraction and pre-ejection phase, contains specific information regarding the changes in local geometry. After the lead has been placed in the apex of the right ventricle, the impedance signal will contain contractility information related to the right ventricle. The ventricular inotropic parameter (VIP) reflects the changes in the contraction velocity due to variations of the sympathetic tone. The VIP is sensitive to time shifts in the impedance waveform, due to shortening of the isovolumetric contraction during physical and physiological stress, which coincides with the pre-ejection period (PEP). Intracardiac impedance measurements using microprocessor-controlled signal processing provide a significant advantage in the reestablishment of the physiological control of the pacing rate and allow an automatic adjustment of pacemaker parameters to the patient's metabolic requirements during exercise.

Methods

Since August 1991, at the Instituto de Moléstias Cardiovasculares of São José do Rio Preto, we have regularly implanted a VVIR pacemaker driven by contractility sensor in chagasic patients with cardiac conduction disturbances. This paper reports on the evolution of the first 47 patients, 28 male (60%) and 19 female (40%), between 24 and 68 years old (mean age 49.9 and 45.7 years, respectively). Eighteen patients (38%) had a pacemaker previously. Unipolar fractal coated leads (TIR 60 UP, BIOTRONIK, Germany) were used in 26 patients (55%), and in the remainig 21 patients (45%) other leads were implanted.

The implant was indicated after nine clinical exams and bidimensional echocardiographs that revealed normal heart area in 35 patients (73%) and an altered area in 12 patients (27%). The cardiothoracic index varied from 0.35 to 0.62. The ejection fraction was altered in 30 patients (64%), varying from 40 to 55% (mean 49%), and it was normal in 17 patients (36%), varying from 56 to 62% (mean 58%). The pacemaker implantation was indicated by AV block in 44 (94%) of the cases, from which 36 (77%) had total AV block and eight (17%) a 2^{nd} degree AV block, and three patients (6%) suffered from sinus node disease. In accordance to the functional clinical classification of the New York Heart Association (NYHA), four patients (8%) were in Class I, 15 (32%) in Class II, 16 (34%) in Class III and 12 (26%) in Class IV.

The follow-up protocol began after patient discharge. For the first 15 days patients were in the VVI mode. At the first follow-up control, collection of data related to the sensor performance was initiated during several types of daily activities.

At each follow-up, the patient underwent a bidimensional echocardiography study, 24 h Holter HR monitoring (using the internal pacemaker memory), and two bicycle ergometries with changing workloads from 25 to 100W (according to the modified Bruce protocol), in order to compare data pertaining to the variation of the sympathetic nervous system activity. HR and BP were analyzed at rest and in exercise up to 12 months after pacemaker implantation. Due to different clinical behavior during pacing at rest, the patients were divided into two groups:

group 1: patients with HR > 65 bpm, and

group 2: patients with HR < 65 bpm.

The exploratory analysis of the gathered data consisted of comparative studies (applying the non parametric test of Mann-Whitney), that considered in particular:

a) differences between pacing leads, analyzing the difference in HR between exercise and rest in each patient;
b) HR changes with exercise, regarding patient groups 1 and 2;
c) BP variations, regarding groups 1 and 2.

Results

The clinical evaluation of 47 patients during 12 months after the VVIR pacemaker implantation considered values of HR and BP, both at rest and during physical exercise, with the workload changing from 25 to 100W. The pacemaker performance was also evaluated through analyzes of HR variations acwuired with the aid of the internal 24 h Holter function.

There is evidence of different behavior between the two patient groups with respect to HR in exercise (p = 0.0004). Group 1 exhibited lower HR during physical exercise - 75% of the patients reached up to 110 bpm, while nearly all patients from group 2 reached 120 bpm.

Figure 1 shows improvement in the NYHA Functional Classification Index: 35 patients (74%) moved from Class II (7; 15%), Class III (16; 34%) or Class IV (12; 25%) up to Class I (9; 26%), Class II (23; 66%) or Class III (3; 8%). Twelve patients (26%) remained in the same class, that is, Class I (4; 9%) and Class II (8; 17%).

In relation to the pacing leads used, the comparative study between TIR 60 UP and other leads revealed insignificant differences in sensor performance. A descriptive analysis of the data indicated a smaller variability of the difference in HR between exercise and rest for the TIR 60 UP than for other leads.

In general, patients reported an increased quality of life. They returned to a more active lifestyle and had a more confident approach to everyday life, with respect to their cardiac condition and pacemaker. Most patients reported on a significant decrease or absence of palpitations, which were in many cases present with their previous VVI or conventional activity-controlled pacemakers. Many patients are aware of their pacemaker activity, noticing increase in pacing rate with physical activity, states of anxiety or excitement.

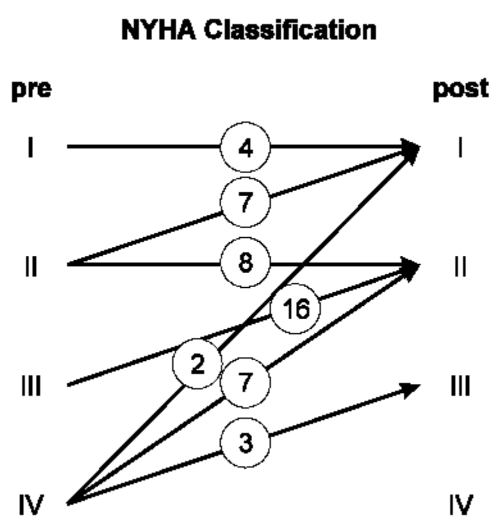

Figure 1. Evolution of NYHA Functional Class in 47 patients during 12 months follow-up of pacemaker.

Discussion

This study demonstrated benefits of appropriate cardiac pacing in chagasic patients. The clinical evaluation during 12 months of follow-up showed that all the patients exhibited a satisfactory evolution of their medical condition. Thirty-two patients (68%) reached NYHA Class I or II. Proper variations of the pacing rate were detected in response to routine physical activity.

A comparative study between patients with HR > 65 bpm at rest (group 1) and < 65 bpm (group 2) showed that the patients from group 1 exhibited a smaller pacing rate variation with exercise than the patients from group 2. This evidenced the importance of HR for the control of the pacing system in each patient. Thus, patients with higher HR values stayed under degree of reduced pacing, in comparison to those with lower HR, with incentive need in superior degree. Many factors are involved in the ventricular purpose, such as own intrinsic variations of the cardiovascular system of each patient, the patient's emotional stability, and the type of the undertaken activity. The sensor interferes with HR, depending on the variations of the autonomic nervous system activity, closing a circuit of information so that the heart maintains an appropriate beating rate.

Emotional and mental stress can lead to remarkable changes in the status of the cardiovascular system, particularly with respect to HR, provoking HR increase or decrease in an abrupt way, depending on the incentive type. The same effect appears when the patient is asked to accomplish arithmetic tasks. Such findings reflect sympathetic action in the cardiovascular system, taking into account the broadest metabolic demands. These episodes were accentuated in some of the studied patients and, often seen, after some minutes of rest and a tranquilizing dialogue, the patient progressively returned to lower pacing rates. This showed the real effect of the autonomic nervous system and the sensibility of this type of sensor [4, 5].

Conclusion

In the future, more details related to potential therapeutic effects of cardiac pacing driven by sensors capable of stimulating the heart under specific circumstances should be explored.

Our 12 months long evaluation of the evolution of 47 chagasic patients with cardiac conduction system disturbances, who were implanted with artificial cardiac pacemakers driven by the autonomic nervous system activity, allowed the following conclusions:

1) the VVIR pacemaker coupled to the variation of the autonomic nervous system activity reestablished the physiological mechanisms in chagasic patients with cardiac conduction disturbances;
2) the pacing systems allowed programming in the individual patients in the way that all of them reached a pacing answer in agreement with their physiological needs;
3) there was no relevant difference in sensor performance in conjunction with different pacing leads.

References

[1] Rossi P. Rate-responsive pacing: Biosensor reliability and physiological sensitivity. PACE. 1987; 10: 454-66.

[2] Sanchis J, Chorro FJ, Matamoros J, et al. Effect of site, summation and asynchronism of inputs on atrioventricular nodal conduction and refractoriness. Eur Heart J. 1993; 14: 1421-6.

[3] Amorin DS, Godoy RA, Manço JC, et al. Doença de Chagas. Enfermidade do Sistema Nervoso? Arq Bras Cardiol. 1968; 21: 203-204.

[4] Schaldach M. Progressos na estimulação cardíaca artificial. Rev Soc Cardiol Est SP. 1994; 1: 47-61.

[5] Greco OT, Ardito RV, Lorga AM, et al. Marcapasso com biosensor que analisa a atividade do sistema nervoso autonômico através da condutância ventricular. Estudo do período de pré-ejeção. Rev Bras Marcapasso Arritmia. 1995; 5: 55-61.