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Clinical and epidemiological characteristics of patients with Chagas' disease submitted to permanent cardiac pacemaker implantation

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

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Abstract

Objective: **To study patients with permanent cardiac pacemakers, comparing the clinical and epidemiological characteristics of patients with Chagas' disease versus those with degenerative or ischemic diseases.**

Method: **57,632 procedures performed from 1995 to 2003, registered in the Brazilian Pacemaker Register were analyzed: 25,648 patients with Chagas' disease and 31,984 with degenerative or ischemic bradyarrhythmias. The comparison of the characteristics of these two populations included Chi-square and Student T tests, with a 5% level of significance.**

Results: **There was a predominance of the Chagas' disease in the Central-west region, in the initial implants. In re-operations, the population with Chagas' disease represented the majority in the Southeast, too. Mean age was 59.3 ± 15.3 and 58.6 ± 14.8, respectively for initial implants and re-operations in Chagas' disease patients and 73.5 ± 12.6 and 73.7 ± 13.5, in non-Chagas' disease patients. There was no difference in respect to both genders and etiology. Syncope episodes and 3rd degree A-V blocks with wide QRS were more frequent in patients with Chagas' disease, and dizziness, heart failure and 3rd degree A-V blocks with in the other patients. Ventricular pacing systems were used in 60% and 63% in the initial implants and 77% and 76% of the reoperations, respectively for Chagas' and non-Chagas' disease patients. The need to change the batteries was the main reason for reoperations in 76.1% and 79.6% of these procedures, respectively for patients with Chagas' disease and the other causes of bradicardia.**

Conclusions: **The analysis of data of these two populations demonstrated significant differences in the clinical and demographic characteristics.**

Descriptors: **Cardiac Pacing, Artificial. Chagas' Disease. Bradycardia. Medical Records Systems Computerized.**

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Resumo

Objetivo: **Estudar os pacientes portadores de marcapasso cardíaco artificial permanente, comparando as características clínicas e epidemiológicas dos portadores da doença de Chagas com a dos portadores de doenças degenerativas do sistema de condução.**

Método: **Foram analisados 57.632 procedimentos cadastrados no Registro Brasileiro de Marcapassos, realizados no período de 1995 a 2003, sendo: 25.648 pacientes portadores da doença de Chagas e 31.984, de doenças degenerativas. A comparação das características dessas populações foi feita pelos testes do Qui-quadrado e t-Student com nível de significância de 5%.**

Resultados: **Houve predomínio da doença de Chagas na região Centro-Oeste, nos implantes iniciais. Nas reoperações, a população chagásica representou maioria também no Sudeste. A idade dos pacientes chagásicos foi 58,6 ± 15,3 e 59,3 ± 14,8 anos, respectivamente para implantes iniciais e reoperações, e, nos não chagásicos, 73,5 ± 12,6 e 73,7 ± 13,5. Não foi notada diferença na distribuição entre os dois sexos. Houve maior ocorrência de síncopes, pré-síncopes e bloqueio atrioventricular com QRS largo nos pacientes chagásicos e de tonturas, insuficiência cardíaca e QRS estreito nos não chagásicos. O modo de estimulação ventricular foi utilizado em 60% e 63% nos implantes iniciais e em 77% e 76% das reoperações, respectivamente para os pacientes chagásicos e não chagásicos. A depleção da bateria por desgaste normal foi o principal motivo para reoperação dos pacientes, tendo ocorrido em 76,1% e 79,6% das reoperações, respectivamente para chagásicos e não chagásicos.**

Conclusões: **Os dados analisados demonstraram diferenças significativas nas características clínicas e demográficas das populações estudadas.**

Descritores: **Estimulação Cardíaca Artificial. Doença de Chagas. Bradicardia. Sistemas Computadorizados de Registros Médicos.**

INTRODUCTION

Although its incidence has dropped significantly over the last decade thanks to adopted prophylactic measures, Chagas' disease is still highly prevalent in Brazil. According to the Brazilian Pacemakers Register (BPR), it has been responsible for around 25% of all indications of permanent artificial heart stimulation in our country [1-8].

Injury to the heart stimulation conduction system caused by this infection provokes bradyarrhythmias which are expressed as alterations in the sinoatrial node, as well as the atrioventricular conduction. Its clinical manifestations include syncope and sudden death. Variable degrees of heart insufficiency are present in the majority of patients. In these cases, permanent pacemaker implantation has been the treatment of choice.

The BPR is a source of national data that aims at registering procedures related to permanent artificial heart stimulation. Its implementation depends on the combined force of the medical community, the Health Ministry and manufacturers of pacemakers. It is compulsory as defined by Brazilian law [9,10].

The aim of this study is to analyze data obtained from the BPR in the period from January 1995 to December 2003, comparing the profile of two groups of patients, Chagas' disease sufferers and patients with degenerative diseases of the conduction system.

METHOD

This is a retrospective study which utilized information collected from the BPR. This database was developed by the Artificial Heart Stimulation Department of the Brazilian Society of Cardiovascular Surgery (DECA_SBCCV) with the help of manufacturers of permanent artificial heart stimulation systems. It was recognized by the Health Ministry on 17th December 1994 (Directive MS/SAS nº 41), which demands a standard form in all packages of pulse generators sold in Brazil to register particulars about their use. After being competed, this form is sent to the DECA-SBCCV, where the information it contains are processed.

The data of the BPR are registered using a tailor-made computer program written in Visual Basic 5.0 for IBM compatible microcomputers.

The information is distributed in three main groups, personal data of the patient, clinical data and surgical data. Support files with data of the hospitals, doctors and the implanted products are maintained and linked to the registration of each procedure.

Patients

The data of 106,071 surgical procedures performed in the period from January 1995 to December 2003 were analyzed. Patients suffering from acquired disorders of the conduction system of the heart were included and those suffering from congenital problems, secondary disorders caused by pharmacological agents or medical intervention and cases with undefined etiologies were excluded.

The patients were divided into two groups: the Chagas' Group, composed exclusively of patients with chagasic heart disease and the non-Chagas' Group formed of patients with degenerative diseases caused by fibrosis, ischemia or post-infarction.

The following data were analyzed:

1. The time of the procedure considering the year in which the initial implant or the reoperation were performed.
2. The location of the hospital that performed the initial implant or the reoperation in respect to the state and the

geographic region.
3. The age of the patients using different age ranges: one day to 20 years of age; 21 to 40 years; 41 to 60 years; 61 to 80 years and over 80 years old, both for the initial implant and reoperations.
4. The clinical state represented by the symptom that indicated the necessity of the use of pacemakers considering only the initial implants.
5. The functional classification of cardiac insufficiency utilizing the criteria of the NYHA (New York Heart Association) only for the initial implant.
6. The principal electrocardiographic finding that justified the indication of the pacemaker at the initial implant.
7. The type of pacing employed, whether pure atrial, ventricular (single chamber or ventricular synchronous with unique electrode) or atrioventricular (independent electrodes), both at the initial implant and subsequent reoperations.
8. The reason for reoperation grouped according to causes related to the pulse generation, related to the electrode lead, clinical or hemodynamic reasons, operative complications and other complications.

Statistical analysis

Statistical analysis was achieved utilizing the non-matched Student t-test to compare the quantitative data and the chi-squared test for qualitative data, with statistically significance considered with p-values less than 5%.

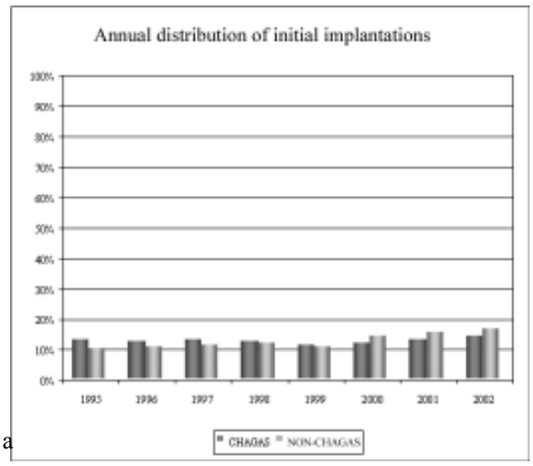
RESULTS

A total of 106,071 procedures were analyzed performed by 353 doctors who worked in 365 Brazilian hospitals. Of these, 57,632 procedures were included in the study with 25,648 in the Chagas' Group and 31,984 in the non-Chagas' Group. The data of 48,439 procedures were excluded. The field 'etiology' was not defined in 10,922 cases, the option was of 'unknown etiology' in 24,132 cases and data was not available in 2,279 cases. Also the data of 11,106 forms, whose etiologies did not fit the inclusion criteria of the study, were excluded.

The data analyzed refer to 16,788 (29.1%) initial implants in patients with Chagas' disease, 25,023 (43.4%) initial implants of non-Chagas' patients, 8,860 (15.4%) reoperations of patients with Chagas' disease and 6,961 (12.1%) reoperations in non-Chagas' patients (p-value = 0.001).

An analysis of Figures 1a and 1b show the distribution of the initial implants over the years. It is possible to confirm that in the Chagas' Group there is a homogeneous distribution of the initial implants (Figure 1a) ranging from 2,038 in 1995 to 2,223 cases in 2002 with a growth of only 9% in the period. On the other hand, in the non-Chagas' Group there was a constant growth in the number of new cases, from 2,288 in 1995 to 3,796 cases in 2002, giving a growth of 66% in the period (p-value = 0.001).

The annual distribution of cases of reoperation also differed between the two groups of patients, although there was an expressive growth in the number of reoperations in both populations. In the Chagas' Group the growth in the period from 1995 to 2002 was 44%, from 953 to 1,372 cases whilst in the non-Chagas' Group the number of cases in 1995 was 455 and in 2002 it was 1,246 with a growth of 174% (p-value = 0.001).



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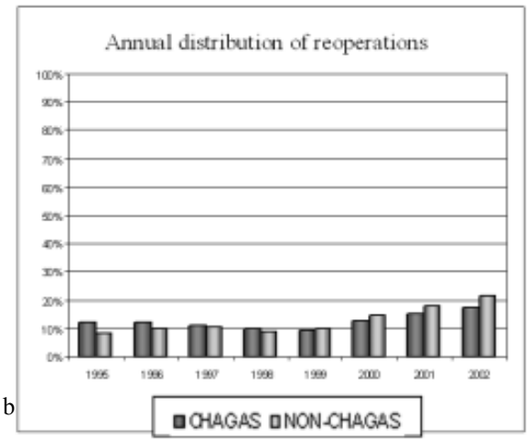

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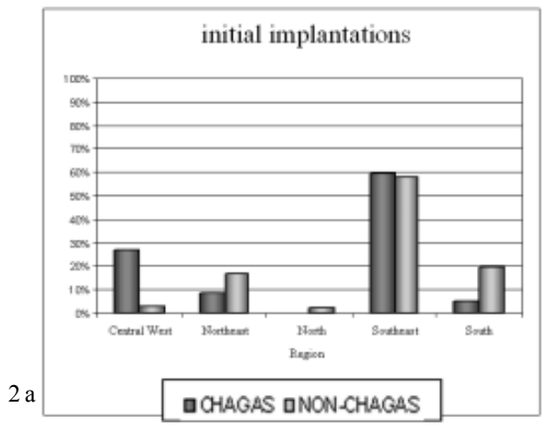
Fig.1 - Annual distribution of initial implantations (1a) and reoperations (1b).

The distribution of the procedures in the different areas around Brazil demonstrated a great regional difference. For the initial implantations, the highest proportional rate of Chagas' patients was in the Central-western region, where the patients suffering from this

disease constitute the absolute majority (85.2%) of the total cases. In the other regions this proportion is inverted, giving a chagasic population of 40.6% of the total patients in the Southeastern region, 26.2% in the Northeastern region, 14.7% in the Southern region and 1.7% in the Northern region. In absolute numbers, however, the greatest number of initial implants performed in patients suffering from Chagas' disease was in the Southeastern region (9,918 cases). In relation to reoperations, the proportion between the numbers of procedures in the groups differed in relation to the initial implants, representing a chagasic population majority in the Central-western region (93.1%) and Southeastern region (59.1%) (p-value = 0.001) as seen in Table 1 and Figures 2a and 2b.

Table 1. Absolute numbers of the procedures in relation to the Chagas' and Non-Chagas' groups subdivided in states for initial implantations and reoperations

State	Initial implantations		Reoperations	
	Chagas	Non-Chagas	Chagas	Non-Chagas
AL	144	255	98	78
AM	5	58	0	11
AP	0	53	0	2
BA	631	422	263	79
CE	85	777	36	233
DF	1779	468	740	75
ES	9	113	2	23
GO	2626	136	1068	34
MA	2	18	0	5
MG	4088	1907	2007	491
MS	28	91	5	18
MT	40	81	19	10
PA	3	424	0	58
PB	102	368	55	157
PE	352	1495	136	447
PI	118	122	46	29
PR	757	1719	370	451
RJ	65	1340	14	428
RN	33	523	11	74
RR	0	11	0	0
RS	70	2386	29	577
SC	11	775	3	255
SE	15	215	13	52
SP	5756	11126	3930	3341
TO	33	8	0	1



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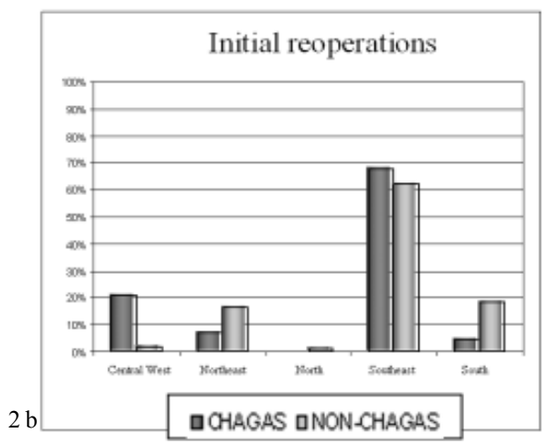

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Fig. 2 – Distribution of the procedures in the different regions of Brazil for initial implantations (2a) and reoperations (2b)

Caucasians represented the majority of the patients in both groups at 60.7% and 64.9% for the initial implants and reoperations, respectively, in the Chagas' Group and 71.1% and 78.5% in the non-Chagas' Group (p-value = 0.001).

The mean ages of the patients in the Chagas' Group were 58.6 ± 15.3 and 59.3 ± 14.8 years old for the initial implants and reoperations respectively. In the non-Chagas' Group, however, the mean ages 73.5 ± 12.6 and 73.7 ± 13.5 years old for the initial implants and reoperations respectively (p-value = 0.001). In the Chagas' Group the ages of the patients were mainly between 40 and 80 years old. Although this was observed both in the initial implants and the reoperations, the absolute number of chagasic patients was greater in the 60 to 80 age range for the reoperations (p-value = 0.001).

The distribution of the chagasic and non-chagasic

patients was similar in relation to gender, with a slightly smaller female population in initial implants of 47.8% of the chagasic population and 48.5% of the non-chagasic (p-value 0.186). In the reoperations, however, the number of procedures is greater for the female patients, representing 52.5% in the Chagas' Group and 52.7% in the non-Chagas' Group (p-value 0.939). These data are illustrated in Table 2.

The clinical state presented by the patients differed between the two groups. An analysis of Table 3 demonstrates that in the Chagas' Group the symptoms of syncope and pre-syncope were more frequent, while in the non-Chagas' population, symptoms of dizziness and heart insufficiency predominated (p-value = 0.001).

Thus, differences in the presentation of the symptoms of heart insufficiency between the two groups were noted. An analysis of Table 3 shows that patients in the Chagas' Group presented with a greater incidence of heart insufficiency in the functional classes II and III, while patients in the non-Chagas' Group presented a greater incidence in Class IV (p-value = 0.001).

Table 2. Distribution of the patients according to the demographic characteristics

	Chagas		Non-Chagas	
	Initial implantations	Reoperations	Initial implantations	Reoperations
Ethnic group				
• Caucasian	10068 (60.7%)	5401 (64.9%)	29438 (71.1%)	4995 (78.5%)
• Non- Caucasian	6514 (39.3%)	2917 (35%)	11954 (28.9%)	1366 (21.5%)
Gender				
• Female	8014 (47.8%)	4453 (53.1%)	12092 (48.5%)	2994 (46.9%)
• Male	8729 (52.1%)	3931 (46.9%)	12827 (51.5%)	3383 (53.1%)
Age				
• Mean ± standard deviation	58.6 ± 15.3	59.3 ± 14.8	73.5 ± 12.6	73.7 ± 13.5
• Median	60	60	75	75

Table 3. Clinical manifestation that indicated the initial implantation of the pacemaker

Clinical manifestation	Chagas		Non-Chagas	
Syncope	7,715	46.6%	10,691	43.1%
Pre-syncope	3,028	18.3%	3,536	14.2%
Dizziess	3,153	19.0%	6,161	24.8%
Congestive heart disease	1,130	6,8%	2,049	8.2%
Brain dysfunction / Bradypsychia	62	0.4%	193	0.8%
Asymptomatic bradycardia	939	5.7%	1,565	6.3%
Tachycardia	39	0.3%	65	0.25%
Arrhythmia secondary to bradycardia	136	0.8%	176	0.7%
Necessity of drugs	218	1.3%	182	0.7%
Prophylactic	97	0.6%	79	0.3%
Other indications not codified	51	0.3%	112	0.45%

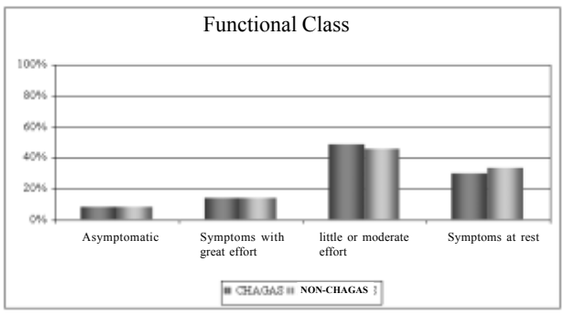


Fig. 3 - Cardiac insufficiency functional class of patients at initial implantation

The principal electrocardiographic finding that indicated the need of implantation of a stimulation system also differed between the two groups. An analysis of Table 4 Shows that 3rd degree atrioventricular blocks with wide QRS predominated in the Chagas' Group at 40.1% with only 29.8% seen in the non-Chagas' Group. Third degree atrioventricular blocks with narrow QRS were evidenced in 9.7% of the chagasic patients and 19.2% of the non-chagasic cases (p-value = 0.001).

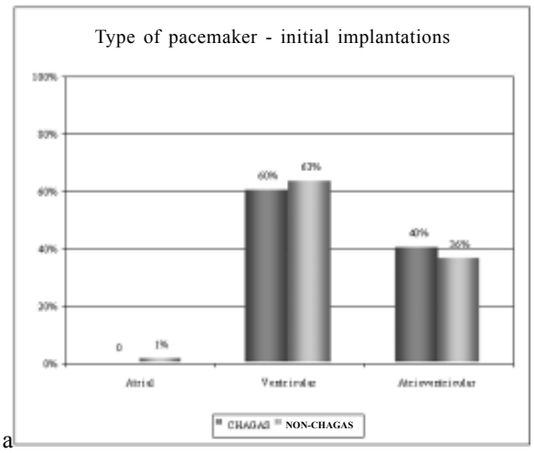
The criteria observed for the indication of the stimulation mode in this period justified ventricular pacing in 60% and 63% of the initial operations in the Chagas' and non-Chagas' Groups respectively.

Table 4. Electrocardiographic findings that justified the initial implantation of the pace maker

ECG findings	Chagas		Non-Chagas	
normal sinusal rhythm	35	0.2%	64	0.2%
1st degree AVB	119	0.7%	236	0.9%
2nd degree AVB - Wenckebach	143	0.8%	315	1.3%
2nd degree AVB - Mobitz II	637	3.8%	1,148	4.6%
2nd degree AVB 2:1	1,089	6.5%	2,258	9.1%
2nd degree AVB not specified	112	0.7%	283	1.1%
BAV de 3rd degree AVB narrow QRS	1,608	9.7%	4,778	19.2%
BAV de 3rd degree AVB wide QRS	6,678	40.1%	7,428	29.8%
BAV de 3rd degree AVB QRS not specified	749	4.5%	1,270	5.1%
BRD + PR normal	25	0.15%	20	0.1%
BRE + PR normal	39	0.2%	65	0.2%
BDAS + PR normal	8	0.05%	1	0.00%
BDPI + PR normal	1	0.01%	3	0.01%
BRD+BDAS + PR normal	39	0.2%	29	0.1%
BRD+BDPI + PR normal	8	0.05%	3	0.01%
BRD+BDAS+BDPI + PR normal	27	0.16%	15	0.06%
BRD + PR >0.20 s	18	0.1%	21	0.1%
BRE + PR >0.20 s	73	0.4%	129	0.5%
BDAS + PR >0.20 s	3	0.02%	6	0.02%
BDPI + PR >0.20 s	0	0.00%	0	0.00%
BRD+BDAS + PR >0.20 s	257	1.5%	131	0.5%
BRD+BDPI + PR >0.20 s	16	0.10%	8	0.03%
BRD+BDAS+BDPI + PR >0.20 s	96	0.6%	64	0.2%
Fascicular block not specified	31	0.2%	38	0.15%
bilateral alternant block	47	0.3%	63	0.2%
Sino-Atrial block	188	1.1%	312	1.2%
Sinusal arrest	406	2.4%	613	2.4%
Sinusal Bradycardia	1,356	8.1%	1,668	6.7%
Brady-Tachycardia syndrome	937	5.6%	1,059	4.2%
Atrial fibrillation + Bradycardia	1,505	9.0%	2,362	9.5%
Atrial flutter + Bradycardia	123	0.7%	176	0.7%
sinusal dysfunction non specified	112	0.7%	160	0.6%
Atrial Tachycardia	11	0.07%	12	0.05%
Pre-Excitation syndrome	3	0.02%	5	0.02%
Ventricular extrasystoles	13	0.08%	7	0.03%
Ventricular Tachycardia	73	0.4%	40	0.1%
Paroxistic Ventricular fibrillation	10	0.06%	9	0.04%
Other finding – not codified	52	0.3%	96	0.4%
Atrial fibrillation	5	0.03%	5	0.02%

Atrioventricular pacemakers were implanted in 40% of patients suffering from Chagas' Disease and 36% in the non-Chagas' cases. Atrial pacing in isolation was practically not employed in these groups of patients (Figure 4a). In the reoperations, the utilization of the three types of pacemakers studied was similar in the two groups. A greater use of ventricular pacemakers was seen however, when compared to the initial implants. In the reoperations, ventricular pacemakers were implanted in 77% of the chagasic patients and 76% of the non-chagasic cases (Figure 4b).

Problems related to the pulse generation were the cause of reoperations in the majority of the patients, occurring in 81.4% of the cases in the Chagas' Group and in 78.3% on the non-Chagas' Group. Battery replacement due to use was the main reason and occurred in 72.4% and 73.3% respectively.



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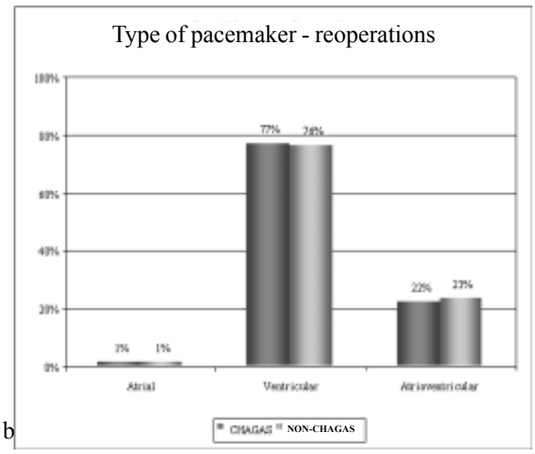

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Fig. 4 - Type of pacemaker used in the initial implantations (4a) and reoperations (4b).

COMMENTS

The study of the profile of the treated populations is of great importance to define health policies, as well as to compare their effectiveness. This has been the main interest of government organs in the BPR.

Within this scope, knowledge of the details of manifestations of Chagas' disease is important, principally due to the difficulty of obtaining this information in the international literature.

Analysis of these data also informs about in which circumstances it is possible to utilize knowledge of bradyarrhythmia originating from studies performed in populations of patients without Chagas' disease.

The great prevalence of degenerative causes in the genesis of disorders in electrical conduction of the heart is well known and so chronic ischemic processes are confused with simple fibrosis of the heart tissue affecting conduction or its invasion by fibrosis of fibrous structure of the heart. In Latin American countries, Chagas' disease is a frequent cause of injury affecting the electrical stimulus conduction in tissue. The exclusion of only 11,106 (10.4%) of the forms, which described etiologies not included in this study demonstrates the great prevalence of the studied causes.

The definition of the cause of bradyarrhythmia, however, is very difficult, especially in situations where multiple factors are associated, such as the case of a patient from a Trypanosomiasis endemic zone, with arterial hypertension and age that justifies chronic degenerative processes. The exclusion of 37,333 forms due to lack of definition of the etiology, which represents 35.1% of the total number of cases sent to the BPR, shows the difficulties of identifying the cause of bradyarrhythmia. The short stay of these patients in the hospital for pacemaker implantation should be added to the points already mentioned as, in the majority of cases, the blood tests are not ready when the form is filled in.

The study included a considerable number of procedures in both groups. Of these cases 25,648 (45.5%) belonged to the Chagas' Group and 31,984 (55.5%) to the non-Chagas' Group.

In absolute numbers, the states of São Paulo, Minas Gerais, Goiás and the Federal District presented with the greatest numbers of procedures in chagasic patients. Considering only the initial implants, in the states of Goiás, Tocantins, Federal District, Minas Gerais and Bahia, the population suffering from Chagas' disease constituted a majority with an amazing ratio of 19 to 1 in the state of Goiás. Considering only the reoperations, Mato Grosso, Alagoas, Piauí and São Paulo presented a majority of procedures in chagasic patients, in São Paulo with a ratio of 1.2 to 1.

Analysis of the data of this investigation may demonstrate that the clinical presentation of the patients in

the Chagas' Group, in relation to those where bradyarrhythmia indicated the first pacemaker, differ from the Non-Chagas' Group. An analysis of the symptoms of brain hypoflow, of the functional class for cardiac insufficiency and of the electrocardiographic expression show notable differences, with a greater incidence of syncope and pre-syncope in the chagasic population and of total atrioventricular block with narrow QRS in the non-chagasic population.

In the same way, the chagasic patients are younger when the first pacemaker implantation is performed. This seems to have influenced the postoperative evolution of the two groups: it was possible to see that, although the absolute number of chagasic patients is smaller than the non-chagasic patients for the initial implants, in the reoperations this number is inverted, demonstrating that the chagasic patients live longer after the pacemaker implantation, probably because they are younger at their first implantations.

On the other hand, the manifestation of the disease in both genders did not present with a significant difference when comparing the two groups. The number of initial implants in the male population is slightly greater in both groups, that is, 52.1% and 51.5% in the Chagas' and Non-Chagas' Groups respectively.

An analysis of the data related to reoperations also demonstrated that, although the number of reoperations was greater in the Chagas' Group, the cause of these reoperations was similar in both groups, with the main reason being the necessity of exchanging the pulse generator due to lack of current in the battery caused by its natural use. The choice of stimulation mode in the reoperations was similar in both groups and, apparently, accompanied the stimulation mode that the patient was already using remembering the utilization of the ventricular pacemaker was greater in the initial implants.

CONCLUSIONS

Marked differences between the two groups were observed, with the predominant occurrence of Chagas' Disease in the Southeastern and Central-western regions, in the clinical presentation of bradyarrhythmia, as in the symptoms of brain hypoflow, the functional class of cardiac insufficiency and in the electrocardiographic expression, as well as the age, where the chagasic patients are younger than the non-chagasic patients, both at the initial implantation and reoperations.

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