ORIGINAL ARTICLE

Braz J Cardiovasc Surg 2004; 19(3): 295-300

Randomized study of surgical correction of permanent atrial fibrillation: preliminary results

Estudo randomizado de correção cirúrgica de fibrilação atrial permanente: resultados parciais

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RBCCV 44205-697

Abstract

Objective: **To comparatively analyze the results of techniques in the treatment of atrial fibrillation: the Maze procedure and Isolation of Pulmonary Veins were compared together with a control group, to establish the best treatment for this arrhythmia.**

***Method*: All patients were referred for surgery for other cardiac lesions, which were treated concomitantly. From July 1999 to September 2003 fifty-one patients were randomly allocated to the different groups. No cryoablation or other source of energy was used. The following variables were initially analyzed: total bypass time, aortic clamping time, sinus rhythm at discharge and trans-operative and immediate postoperative complications.**

***Results*: There were two intra-hospital deaths, one in the Maze group and one in the Isolation of Pulmonary Veins group. The Maze group had the longest bypass time (p<0.001). The duration of follow-up of 28.4 ± 14 months was similar between the groups. The Isolation of Pulmonary Veins achieved the best results concerning reversion to sinus rhythm with 84.2% at hospital discharge and 88.9% after follow-up. In the Maze group, 78.5% of sinus rhythm was seen at discharge and 84.6% at the end of follow-up. In the Control group 87.5% of the patients had atrial fibrillation at discharge and after follow-up, atrial fibrillation remained at 56.3% of the patients. There was no difference in the NYHA class between the groups after follow-up (p=0.56) and Control group patients had more complications (p=0.017).**

Conclusion: **These results show that both techniques, the Maze and Isolation of Pulmonary Veins, have advantages over simple correction of cardiac lesions when associated to atrial fibrillation.**

Descriptors: **Atrial fibrillation. Mitral valve, surgery. Arrhythmia, surgery. Cardiac surgical procedures.**

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Support: CNPq, CAPES and FAPERGS.

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Article received on July, 2004
Article accepted on September, 2004

Resumo

Objetivo: **Analisar os resultados de dois modos de tratar a fibrilação atrial (FA): com cirurgia do Labirinto e com Isolamento de Veias Pulmonares (IVP), comparando com grupo controle, para estabelecer o melhor tratamento aos portadores desta arritmia.**

Método: **Todos os pacientes tinham indicação cirúrgica por outra lesão cardíaca, concomitantemente tratada. Foram randomizados 51 pacientes no período de julho de 1999 a setembro de 2003. Em nenhum paciente foi utilizada crioablação. Analisamos inicialmente as seguintes variáveis: tempo de circulação extracorpórea (CEC), pinçamento aórtico (ISQ), taxa de reversão a ritmo sinusal na alta hospitalar, e complicações do trans e pós-operatório imediato.**

Resultados: **Houve dois óbitos intra-hospitalares, um no grupo Labirinto e um no grupo IVP. O grupo Labirinto apresentou o maior tempo de CEC (p<0,001). Seguimento médio de 28,4±14,1 meses, sem diferença entre os grupos. O grupo IVP teve a maior taxa de sucesso com 84,2% de reversão a ritmo sinusal na alta e 88,9% após seguimento. No grupo Labirinto, 78,5% de ritmo sinusal à alta, e após seguimento, 84,6%. No grupo controle, 87,5% dos pacientes tiveram alta em FA, e após seguimento 56,3% seguem assim. A classe funcional pela NYHA não foi diferente entre os grupos após o seguimento (p=0,56), e os pacientes do grupo controle apresentaram mais complicações (p=0,017).**

Conclusão: **Estes resultados mostram que qualquer das técnicas empregadas para correção de FA, Labirinto ou IVP, apresenta vantagens sobre a operação tradicional de simples correção de cardiopatias quando associadas à FA.**

Descritores: **Fibrilação atrial. Valva mitral, cirurgia. Arritmias, cirurgia. Procedimentos cirúrgicos cardíacos.**

INTRODUCTION

Atrial fibrillation is the commonest sustained arrhythmia seen in clinical practice [1,2]. In over 60-year-old adults the incidence of atrial fibrillation is one case in every 25 individuals and in over 80-year-olds its incidence is one in ten. Because of its symptoms and because of the high risk of ischemic strokes, especially in elderly patients, this arrhythmia is a continuous concern. The impact of the disease tends to increase as the elderly population increases.

In patients who have surgical indication for mitral valve disease, atrial fibrillation is very common [3,4]. It is believed that the correction of a structural cardiac lesion may contribute to the treatment for atrial fibrillation. However, recent data have shown that persistent atrial fibrillation is the most significant risk factor for late strokes after mitral valve replacement [5]. This study demonstrated that reversal to sinusal rhythm using the Maze procedure practically eliminated the risk of late strokes. Thrombo-hemorrhagic events are less common in patients with sinusal rhythm after atrial fibrillation correction associated with mitral valve lesions [6]. In patients who receive surgical treatment for atrial fibrillation and obtain reversal to sinusal rhythm, the length of oral anticoagulant treatment is controversial.

In the 1980s and 1990s, more and more promising results in respect to conversion of atrial fibrillation to sinusal rhythm were published [7]. In 1991, COX [8] published his results with the Maze technique that gave the best hopes for a cure of atrial fibrillation up to that time thus this procedure became the gold standard [9]. The technique was modified by several teams who had adopted it. In our area cryoablation is not utilized [10]. The technique of pulmonary vein isolation may provide results as promising as the Maze procedure in the correction of atrial fibrillation associated with cardiac structural lesions [11].

This work was proposed to elucidate which treatment method for atrial fibrillation associated with cardiac structural lesions, among the most commonly used techniques used in Brazil, gives the most satisfactory results.

METHOD

The study was designed as a randomized controlled clinical trial, whose initial protocol aimed at allocating 20 patients in each of three groups giving a total of 60 patients.

Between June 1999 and December 2003, 51 patients were included in this study. All suffered from permanent atrial fibrillation secondary to a preexistent cardiac lesion and filled the clinical and hemodynamic criteria for elective mitral valve corrective surgery. The exclusion criteria established for the study were: age less than 18 years old, atrial fibrillation with less than six months of duration, ejection fraction less than 20%, pregnancy, reoperations, the presence of intrapericardial adhesions and refusal of the patient to participate. After completing the written informed consent, the patient was submitted to uni- and bidimensional Doppler echocardiography and taken for the operation.

The population of the study was randomized in three groups: Valve correction plus the simplified pulmonary vein isolation (PVI Group), valve correction plus the Cox-Maze III procedure without the use of cryoablation (Maze Group) or no procedure associated with mitral valve correction (Control Group).

All the patients were operated on by two principal surgeons. After anesthesia induction using thiopental, pancuronium bromide and maintenance with fentanyl, midazolam, which was occasionally supplemented with halothane, the patients were submitted to median sternotomy and a lengthwise opening of the pericardium. Cardiopulmonary bypass was established by cannulation of the ascending aorta and venous cannulation using metal-

tipped angled cannulae in the vena cavae, which were dissected and mobilized. Aortic clamping and infusion of routine hypothermic antegrade crystalloid cardioplegia were employed. The body temperature was maintained at 32 ºC during the cardiopulmonary bypass. Standard longitudinal left atriotomy was utilized in all the patients. In the Control Group, correction of the mitral valve was achieved at this point. In the Maze Group, the modified Cox-Maze III surgery was performed [10,11] without the use of cryoablation, which was substituted by ample dissection in the region of the coronary sinus and the adjacent tissues were cauterized. Before completing the suturing, the mitral valve was corrected. In the PVI Group, the atriotomy was extended to encircle the four pulmonary veins. At this point the mitral valve was corrected. A perpendicular incision was made from the margin of the atriotomy to the mitral valve annulus, dissecting the coronary sinus and performing cauterization as previously described [12]. The left auricle was always exercised in both the treated groups. After suturing the atrium using a single layer 3-0 monofilament polypropylene thread, other valves were corrected when necessary.

Before release from hospital, all the patients who did not have a regular rhythm were submitted to electric cardioversion and maintained on oral amiodarone when reversed to sinusal rhythm. The patients returned after two postoperative months and were submitted to an ECG and clinical evaluation in a specific outpatients' clinic attended by the same surgeon. The patients were counseled to return to the outpatients' clinic to perform another ECG, echocardiogram and stress tests at six-month intervals. Patients who did not present themselves were contacted by telephone or telegram. Medications prescribed by cardiologists were not modified.

This work was approved by the Research Ethics Committee of the institution and all the patients were only enrolled after signing written consent form was received. All data were stored in an Excel Database (Microsoft Corp.) and analyzed using Epi-Info (version 6.06, World Health Organization) and SPSS (SPSS Inc.). Continuous variables were expressed in means ± standard deviation. Comparisons for categorical variables were made using the chi-squared test and continuous variables using the Student t-test. An alpha error of 0.05 was adopted for these comparisons to be considered statistically significant.

RESULTS

Two deaths (4%) were registered during hospitalization. One, a 71-year-old patient from the PVI Group who also received a biological prosthesis implant, evolved with acute renal failure and septic shock and died on the fifteenth postoperative day and a 77-year-old patient from the Maze Group who in the immediate postoperative period presented with much bleeding with tamponade and cardiogenic shock died during the reoperation that followed. One third patient, also from the Maze Group, died due to complications of a coronary cineangiography in the 20th postoperative month (late mortality 2%).

According to Table 1, the groups were statistically similar in all the analyzed variables before the operation. The mean age of the operated patients was 53 ± 12.5 years and 66.7% were women. The mean preoperative functional class using the NYHA classification was 2.86 ± 0.74. Forty-nine percent of the patients presented with mitral insufficiency, 39.3% mitral stenosis and 11.8% double mitral lesions. Rheumatic disease was the etiology in 74.5% of the cases and 13.7% had already suffered from strokes.

Table 1. Clinical characteristics of the patients

Characteristics	PVI (n=20)	Maze (n=15)	Control (n=16)	total (n=51)	p-value
Age (years)	55.1±9.1	52.2±14.1	51.3±14.7	53±12.5	0.633*
Women (%)	70	73.3	56.3	66.7	0.554**
NYHA	2.85±0.67	2.73±0.88	3±0.73	2.86±0.74	0.826***
I	-	6.7%	-	2%	
II	30%	33.3%	25%	29.4%	
III	55%	40%	50%	49%	
IV	15%	20%	25%	19.6%	
Mitral lesion					
Stenosis	55%	46.7%	12.5%	39.2%	
Insufficiency	35%	46.7%	68.8%	49%	0.11**
Double lesion	10%	6.7%	18.8%	11.8%	
Etiology					
Rheumatic	80%	73.3%	68.8%	74.5%	0.738**
Degenerative	20%	26.7%	31.3%	25.5%	
Previous stroke	15%	13.3%	18.8%	15.7%	0.912**

NYHA: functional class
The data are presented as means ± standard deviation and frequency (%)
* variance analysis test. ** Chi-squared test. *** Kruskal-Wallis test

Mitral valvuloplasty was the most commonly used technique in all the groups with 64.7% of the patients being submitted to this procedure (Table 2). Associated operations included two cases of aortic valvuloplasty and seven of tricuspid valvuloplasty. As is shown in Table 2, the mean cardiopulmonary bypass time in the PVI Group was approximately 12 minutes less than in the Maze Group but this difference was not statistically significant (p-value = 0.305). Cardiopulmonary bypass and ischemia times were

significantly different between the treated groups and the Control Group (p-value < 0.001).

Table 2. Described data according to the surgical technique

	PVI (n=20)	Maze (n=15)	Control (n=16)	Total (n=51)	p-value
Technique	60%	66.7%	68.8%	64.7%	0.846**
mitral plasty	40%	33.3%	31.3%	35.3%	
mitral prosthesis	25%	6.7%	18.8%	17.6%	0.368**
Associated operation	1	-	1	2	
aortic plasty	4	1	2	7	
Tricuspid plasty	15	14	13	42	
none	99.8±23.8	111.6±21.4	60.1±23.6	90.8±31.2	<0.001*
CPB time (min)	b	b	a		
Ischemia time (min)	75.4±20	77.1±16.4	43±21.1	65.7±24.5	<0.001*
Rhythm at hospitalb		b	a		
release	n=19	n=14	n=16	n=49	
Sinusal	84.2%	78.6%	12.5%	57.2%	<0.001**
ACFA/ Flutter	15.8%	21.4%	87.5%	42.8%	
hospital mortality	5%	6.7%	-	3.9%	0.602**

CPB: cardiopulmonary bypass. The data are presented as means ± standard deviation and frequency (%)
* variance analysis test. ** Chi-squared test
Letter–index (a, b) non-coincident represent statistically significant differences by the multiple comparison technique of Duncan.

After the Maze procedure, the morphology of the electrocardiogram P wave can become much deformed. Owing to the difficulty of electrocardiographically identifying sinusal rhythm in this group, both sinusal and atrial rhythms were considered successful outcomes. At release from hospital, the PVI Group had a higher rate of success with 84.2% reversal to sinusal rhythm. The Maze Group reached a success rate of 78.6% and in the Control Group only 12.5% of the patients were released with sinusal rhythm (p-value < 0.001) – Figure 1.

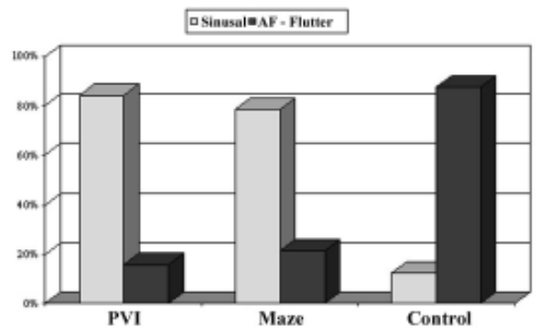

Fig. 1 – Rhythm at hospital release by groups

One patient from the Maze Group and another from the PVI Group did not complete the follow-up evaluations. Of the 51 patients enrolled in the study, 46 completed late follow-up evaluations with a mean of 28.5 ± 14 months. The follow-up period was homogeneous among the groups and at the end the PVI Group presented with the highest rate of conversion to a sinusal rhythm (88.9%) followed by the Maze Group (84.6%) and the Control Group (43.8%) giving significant differences among the groups (Table 3, Figure 2). At the end of the follow-up period, the NYHA mean functional class was 1.17 ± 0.43 without significant differences among the groups. In respect to the use of oral anticoagulants, 50% of the PVI Group, 30.8% of the Maze Group and 100% of the control Group received this treatment.

An analysis of the complications shows that 32.3% of the Control Group patients presented with some adverse event during the study period, which were: One case of nosebleed at 42 months of follow-up, one case of transient ischemic stroke at 30 months, one case of urethral bleeding in the second postoperative month, and two cases of reoperation with implantation of mechanical prostheses in patients who had originally been submitted to mitral valvuloplasties. No patient in the Maze Group presented with complications. In the PVI Group, one patient (5.3%) presented with trans-operative acute myocardial infarction detected by cardiac enzymes but without worse repercussions and the same patient, who received oral anticoagulants presented with a hemorrhagic stroke in the second postoperative month, underwent drainage by neurosurgery and had a good recovery.

COMMENTS

The absence at the moment of a widely accepted ideal treatment for atrial fibrillation encourages surgeons to look for answers. As the Maze procedure reported in 1991 [13] has had approved results it is considered as the gold standard for comparisons [14]. However, its complicated technique makes general acceptance unlikely. Several modifications of the Maze surgery have obtained success rates of around 85% in the maintenance of sinusal rhythm after the valve repair combined with the atrial fibrillation procedure [15-17]. These new techniques frequently utilize energy sources such as radiofrequency [18], ablation with microwaves [19] or cryoablation [20]. It is important to stress

that in our work, the use of available technology was stressed, electrocauterization was used without the use of other energy sources, which are sometimes expensive and with similar results in respect to reversal to sinusal rhythm.

Table 3. Follow-up of the patients

Characteristics	PVI (n=18)	Maze (n=13)	Control (n=16)	TOTAL (n=46)	p-value
time (months)	28.3±16.2	29.5±15.3	27.7±11.3	28.4±14.1	0.946*
Rhythm					
Sinusal	88.9%	84.6%	43.8%	72.3%	0.007**
AF	11.1%	15.4%	56.3%	27.7%	
NYHA	1.1±0.32	1.07±0.27	1.31±0.6	1.17±0.43	0.56**
I	88.9%	92.3%	75%	85.1%	
II	11.1%	7.7%	18.8%	12.8%	
III	-	-	6.3%	2.1%	
Anticoagulation	50%	30.8%	100%	61.7%	<0.001**
Complications	5.3%	-	31.3%	12.2%	0.017**
Deaths	5.3%	14.3%	-	6.1%	0.26**
Incomplete follow-up	1	1	-	2	NS

AF: atrial fibrillation; NYHA: functional class
CPB: cardiopulmonary bypass. The data are presented as means ± standard deviation and frequency (%)
*Variance analysis test. ** Chi-squared test

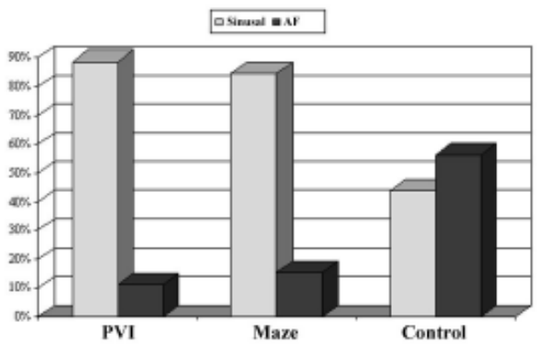

Fig. 2 – Late rhythm by groups

Ectopic foci originating from the pulmonary veins may act as a trigger reinitiating the chronic atrial fibrillation [21], and its ablation may impede the reappearance of arrhythmia. The isolation of these foci, performed in the PVI Group, perhaps was the factor responsible for our findings. There is a line of research that affirms that continuous atrial fibrillation does not depend on the pulmonary veins for its induction or perpetuation [22], and that simple isolation of the pulmonary veins would restrict only the trigger for intermittent atrial fibrillation. However, this was not observed in our series, where the obtained results in relation to the reversal to sinusal rhythm were statistically similar between the Maze and the PVI groups that received the complete surgery. As the PVI surgery did not include incisions of the right atrium, we could expect cases of atrial flutter in the postoperative period and this was observed in one patient, whose arrhythmia reverted to sinusal rhythm with the use of amiodarone.

The control Group were receiving more anticoagulant medicine compared to the other groups at the end of the study period and we believe that though the follow-up is too short to affirm that these techniques really do reduce the risk of thromboembolic events in the postoperative period, it is a real probability, both because of the greater maintenance of sinusal rhythm and because of the amputation of the left auricle.

From the clinical point of view, the patients of the three groups presented with significant improvement in the functional class, as only one patient was functional class I in the preoperative period and 85.1% were in this class at the end of the follow-up. This improvement is due to the correction of the valve disease and occurred in all three groups.

In respect to deaths, the complications presented can not be directly attributed to the operation for atrial fibrillation. The case of the patient who died during a reoperation for bleeding is open for discussion, but no line of sutures with active bleeding were reported in the atrium.

Many patients are excluded from the randomization as they arrived in the hospital with a recommendation of their cardiologist to be submitted to a specific treatment for atrial fibrillation, Maze or PVI, and this may constitute a bias in the selection process. Despite of this, all the patients without this specific indication were randomized as long as they fulfilled the selection criteria.

As in the outpatients' follow-up consultations the doctor knew which group the patient belonged to, this too could have caused a bias in the study. All the patients with atrial fibrillation were intensively checked on their reversal to sinusal rhythm and this contributed to a better rate of reversal in the Control Group, compared to what is reported in the literature [3].

The ischemia and cardiopulmonary bypass times were less in the Control Group compared to the others and the improvement in the functional class from the pre- to the postoperative periods were similar in all three groups.

CONCLUSIONS

Pulmonary vein isolation and the modified Maze

techniques, associated with surgical correction for mitral valve disease, were more effective to maintain sinusal rhythm than mitral valve repair in isolation.

The surgery of pulmonary vein isolation gives many options for the treatment of atrial fibrillation which are simpler and more acceptable for the surgeon without the necessity of special equipment, with less damage to the atrial myocardium and with very acceptable results. From our results and taking into consideration the morbidity of atrial fibrillation, we are happy about recommending this procedure to patients who need to be submitted to mitral valve surgery and that present with persistent atrial fibrillation. Further studies to evaluate the survival and the quality of life over the long-term should be conducted to confirm our findings.

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