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# Treatment of atrial fibrillation using ultrasonic cardiac ablation, during valvular heart surgery

***Tratamento da fibrilação atrial com ablação por ultrassom, durante correção cirúrgica de doença valvar cardíaca***

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***Abstract***

***Objective:*** **This study aims to evaluate the surgical treatment of atrial fibrillation with ultrasound ablation concomitant to mitral surgery in PROCAPE's patients with permanent atrial fibrillation.**

***Methods:*** **From March 2008 through January 2009 a prospective study was performed at the Pernambuco Cardiology Emergency Facility on 44 consecutive patients with a permanent atrial fibrillation and concomitant cardiac valvular surgery indication, from March 2008 through January 2009 at Pernambuco Cardiology Emergency Facility Twenty two patients underwent right atrium epicardial ultrasonic ablation and left atrium endocardial ultrasonic ablation performed concomitant with the valve procedure. The other 22 patients, the concurrent controls were submitted to valve procedure without ultrasonic ablation. Patients with serious diseases such as coronary and others were excluded of the research.**

***Results:*** **It was observed 90% restoration to sinus rhythm immediately after surgery in patients submitted to treatment of atrial fibrillation with ultrasound ablation simultaneous a mitral surgery. The evolution in late post operation showed that the maintenance of sinus rhythm drops although it was still 27% higher in the group which received ablation compared with the control group. 86.40% of the patients who received ablation had improved in functional class; they also have fewer complications than patients in the control group.**

***Conclusion:*** **The results showed that the patients who received treatment for atrial fibrillation simultaneously with valvar surgery had advantages related to the control group.**

***Descriptors:*** **Atrial Fibrillation. Ablation Techniques. Mitral Valve. Ultrasound, High-Intensity Focused, Transrectal. Arrhythmias, Cardiac.**

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***Resumo***

***Objetivo:*** **Este estudo visa avaliar a eficácia do tratamento cirúrgico da fibrilação atrial com ablação por ultrassom, concomitante à cirurgia valvar mitral, em pacientes do Pronto Socorro Cardiológico de Pernambuco (PROCAPE) portadores de fibrilação atrial permanente.**

***Métodos:*** **De março 2008 até janeiro 2009, foi realizado no PROCAPE um estudo prospectivo com 44 pacientes consecutivos, portadores de fibrilação atrial permanente e indicação de cirurgia valvar mitral. Vinte e dois pacientes foram submetidos à ablação com ultrassom no epicárdio do átrio direito (AD) e no endocárdio do átrio esquerdo (AE) concomitantemente ao reparo valvar. Os outros 22 pacientes foram submetidos ao procedimento valvar sem ablação por ultrassom. Pacientes com doença coronária diagnosticada e outras enfermidades graves foram excluídos da pesquisa.**

***Resultados:*** **Foi observada 90% de reversão da FA a ritmo sinusal no pós-operatório imediato dos pacientes que receberam ablação por ultrassom concomitante ao reparo mitral. A evolução no pós-operatório tardio mostrou queda na permanência da reversão a sinusal, porém o grupo que recebeu intervenção ainda apresentou percentual superior a 27% em relação ao grupo controle. Dos 22 pacientes submetidos à ablação com ultrassom, 86,40% apresentaram melhora da classe funcional e não foi constatado neste grupo maior ocorrência de complicações do que no grupo que foi submetido à correção valvar sem ablação.**

***Conclusão:*** **Os resultados apresentados pelo estudo demonstraram que os pacientes submetidos a tratamento cirúrgico da FA, com aplicação de ultrassom concomitante à correção valvar, apresentaram vantagens em relação ao grupo controle.**

***Descritores:*** **Fibrilação atrial. Técnicas de ablação. Valva mitral. Arritmias cardíacas.**

## INTRODUCTION

Atrial fibrillation (AF) is a common arrhythmia in clinical practice and affects approximately 2.5 million patients in the U.S. [1]. Often it occurs in patients with mitral valve disease from the second to the fourth decade of life [2]. It is related to a high occurrence of cerebral or pulmonary embolism, and heart failure, especially when it occurs in patients with valvular heart disease [3].

The medication/clinical treatment of AF is time consuming and high cost [4], and the related morbidity and mortality rate justify the interest in discovering some surgical technique that can reverse the FA, especially in cases of permanent AF, which does not reverse with antiarrhythmic drugs or electrical cardioversion [ 5,6].

From the 1980s, surgical techniques have been developed for treatment of permanent AF. The Maze III surgical technique that uses multiple incisions and sutures in the atrium has proven to be effective. However, due to its complexity, increasing the duration of cardiopulmonary bypass (CPB), as well as the time of anoxia, and being associated to an increased risk of bleeding, this technique has not been widely adopted by the surgical community [7,8].

Approaches that use alternative energy sources have been developed to speed up and simplify the treatment of AF [3].

Researchers from France, Spain, Belgium, and the United States have found that the use of ultrasound for AF ablation applied to the atrial epicardium showed significant number of reversion from AF to sinus rhythm [9].

In Brazil, Brick [2] has used the ultrasonic scalpel in the permanent AF intra-operative treatment in 27 patients. He has found that the technique was simple and that 81.4% of patients had sinus rhythm at discharge.

This study was developed in order to investigate if the application of ultrasound for ablation of permanent AF during surgical correction of mitral valve disease would be easy to perform and capable of converting the rate of permanent AF to sinus rhythm.

## METHODS

This study was carried out at the Pernambuco Luis Tavares da Silva (PROCAPE) Cardiologic Emergency Room, associated to the Federal University of Pernambuco (UPE). Patients were advised to repair or replace the mitral valve and permanent AF before surgery. The study was designed as a concurrent control, prospective clinical trial treatment.

**Inclusion Criteria**

a) To present permanent AF (PAF) with a duration of at least 1 month.

b) Present with valvular disease with indication for surgical treatment.

c) Age ³ 18 years and < 70 years.

d) Accept and sign the free written informed consent

**Exclusion Criteria**

a) To present FA never treated with drugs or electrical cardioversion before surgery.

b) Do not accept to take part in the study.

c) To be suffering from severe diseases such as kidney, liver, and respiratory insufficiency, advanced cancer, congestive heart failure with an ejection fraction below 35%.

d) To be pregnant.

e) To have chronic obstructive pulmonary disease.

f) To have hyperthyroidism.

g) To be a recipient or a candidate to be a recipient.

h) To have undergone coronary stenting; and to have acute or chronic myocardial infarction.

i) Contraindication to amiodarone

**Definition of Cases**

It will be considered to be a case only the patients with mitral valve disease with an indication for surgical treatment in accordance with the Guidelines of the Brazilian Cardiology Society [10] and those presenting permanent AF, as defined by the American College of Cardiology (ACC) [5]. The cases, besides being subjected to surgical correction of valvular heart disease, will undergo atrial compartmentalization through the ablation lines performed with an ultrasound scalpel in the RA epicardium and LA endocardium. Patients undergoing this kind of intervention will be designed as the treatment group (TG).

**Definition of the controls**

The controls have the same characteristics defined to the above cases, except for not being subjected to the application of ablation lines performed with an ultrasound scalpel. They will be called the control group (CG).

**Preoperative Characteristics of the Study Patients**

From March 2008 to January 2009, 128 patients have undergone surgical correction of mitral valve (at the study facility). Of the 128 operated patients, 44 patients (34.38%) met the inclusion and exclusion criteria established for the present study and constituted the total sample. Twenty-two of the patients (50%) underwent mitral valve repair associated with ultrasound ablation. The other 22 (50%) constituted the control group and undergone only mitral valve repair or replacement.

Of the 44 patients, 14 (31.82%) were male and 30 (68.18%) female. In the treatment group, seven (31.82%) were male and 15 (68.18%) female with an equal occurrence in the control group.

The mean age of the patients was 48 years (interquartile range from 27 to 69). In the control group the mean age of the patients was 45.77 ± 11.84 years. In the control group the mean age of the patients was 51.09 ± 10.16 years.

At admission, seven (31.82%) patients in the treatment group, were in NYHA functional class III and 15 (68.18%) in NYHA functional class IV. In the control group 13 (59.09) patients were in NYHA functional class III and nine (40.91%) in NYHA functional class IV. The mean dimensions of LA of the 44 patients postoperatively were 58.86 ± 8.95 mm. In the control group, the mean dimensions of preoperative LA were 57.31 ± 8.43 mm with a median of 56.00 mm. In the control group, the mean of LA was 60.4 ± 9.37 mm and the median was 56.00 mm.

The preoperative characteristics are summarized in Table 1.

Table 1. Preoperative characteristics of the study patients (TG n= 22) (CG n=22)

| Variables | TG | (%) ou SD | CG | (%) | *P* |
|---|---|---|---|---|---|
| Gender | | | | | |
| Female | 15 | 68.18% | 15 | 68.18 | 1.00 |
| Male | 7 | 31.82% | 7 | 31.82% | |
| Age (years) | 45.77 | ±11.84 | 51.09 | ±10.16 | 0.11 |
| | 7 III | | | | |
| Functional Class | 15IV | 31.82% | 13III | 59.09% | 0.13 |
| | 115IV | 68.18% | 9IV | 40.91% | |
| LA diameter | 57.31* | ±8.43 | 60.40* | ±9.37 | 0.25 |

TG: group treated with ablation; CG: control group

*Data presented as mean ±standard deviation and frequency (%). *Measure in milimeters*

In the treatment group, 15 (68.18%) of the patients underwent surgical repair of a valve (the mitral valve) and seven (31.82%) underwent surgical intervention simultaneously in both valves. In the control group, 17 patients underwent only surgical correction of mitral valve and five patients underwent correction of two valves.

**Preoperative Care**

Before undergoing surgery, all patients had already been given antiarrhythmic drugs or had already undergone electrical cardioversion and remained in AF. The NYHA functional class (FC) of each patient was identified as well as the diagnosis of permanent AF. Electrocardiograms and echocardiograms were performed preoperatively according to the same technical pattern.

Patients were evaluated by the same physician-investigator pre-and postoperatively.

**Ablation Techniques**

Right atrium epicardial ablation lines: 1st line around the superior vena cava (SVC), the 2nd line around the inferior vena cava (IVC) up to the tricuspid ring, the 3rd line connecting the lines from the superior and inferior vena cava, the 4th line in the base of the right auricle, which will not be excluded, and the 5th line between the base of the right auricle and the upper edge of the tricuspid valve ring.

Left atrium endocardial ablation lines were performed in similar locations to that of the Maze technique with the use of an ultrasound scalpel with the power set at level 3: the 1st ablation line should be placed around the openings of the pulmonary veins, the 2nd ablation line surrounds the pulmonary veins near the opening of the left superior pulmonary vein up to the base of the left auricle, the 3rd ablation line between the opening of the left inferior pulmonary vein and mitral valve annulus, excluding the left auricle through an internal suture, and the 4th ablation line in the base of the suture around its border (Fig. 1)

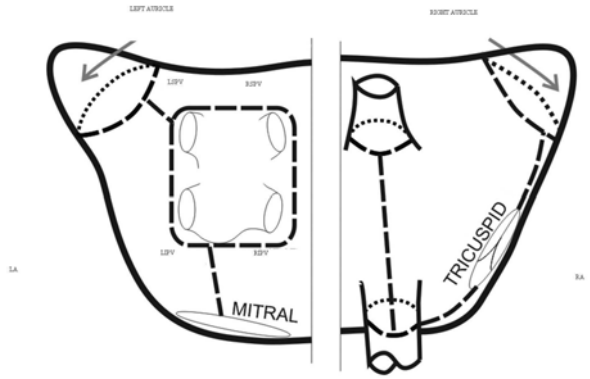


***Fig. 1** - Schematic drawing on ablation technique used at the study*

To perform the right atrium epicardial and left atrium endocardial ablation lines ultrasound, we used the UltraCision harmonic scalpel® (Ethicon Endo-Surgery Inc., Cincinnatti, Ohio).

After ICU discharge, patients in both groups (TC and CG) remained on amiodarone and oral anticoagulants until the reevaluation procedure, one month after surgery.

**Study Sample**

The sample calculation showed that to obtain adequate statistical power, with alpha and beta probabilities set at 5% and 20%, respectively. Each group should be composed of at least 22 patients to assess the possibility to accept or reject the null hypothesis, expecting that both types of treatment show a difference in the occurrence of reversion from AF to sinus rhythm around 39% between both groups.

**Statistical Analysis**

Continuous variables are presented as the mean ± SD. Differences between the two study groups were calculated using the unpaired Students's *t*-test for continuous variables. Differences in both study groups were assessed using $\chi^2$ test. All P values were two-tailed. A $P < 0.05$ was considered statistically significant.

RESULTS

Patient's distribution by gender in the both study groups was equal, with 15 females and seven males in each group; $P = 1.0$.

The mean age was lower in the group treated with ablation 45.77 ± 11.84 years compared to control group 51.09 ± 10.16 years; however, this difference was not statistically significant; $P = 0.11$.

The patients' functional class (FC) comparison at hospital admission in relation to the late postoperative course showed that 19/22 (86.40%) patients who received ultrasound ablation improved the functional class, while the control group the improvement occurred in 14/22 (63.63%) patients; $P > 0.05$.

The mean left atria diameters the treatment group and the measurements in the control group before surgery were 57.31 ± 8.46 mm vs 60.40 ± 9.37 mm (mm), respectively. Both groups were statistically similar before the operation; $P = 0.25$.

Patients undergoing ablation that reverted to sinus rhythm presented a mean left atrium diameter of 59 mm, and those who did not present reversal presented a mean left atrium diameter of 60 mm. Patients in the control group who also reverted presented a mean left atrium diameter smaller than those who remained in AF (54 mm vs 61 mm).

The average time (in minutes) of anoxia through aortic-clamping in the treatment group was 73.59 ± 26.74 minutes vs 84.86 ± 38.94 minutes in the control group. The median was 72.50 minutes in both groups. The average time of anoxia in those receiving ultrasound ablations did not differ significantly from the group that did not undergo ablation; $P = 0.2693$.

The average length of stay on cardiopulmonary bypass (CPB) in the treatment group 99.95 ± 22.14 minutes vs. 120.40 ± 51.7 minutes in the control group. The median of the treatment group was 100.5 minutes vs 103 minutes in the control group. The analysis of the significance test found no difference between the average CPB time in the treatment group compared to the control group; $P = 0.0955$.

The time spent with the application of lesion lines with ultrasound in the both RA and LA during surgery in the treatment group showed an average of 14 ± 4.11 minutes. The length of ICU stay in days) for the treatment group was 5.90 ± 2.54 days vs 5.80 ± 4.78 days compared to the control group. The median was 5.5 days in the treatment group vs 4.0 days in the group control group. By the analysis of the significance test, there is no difference between the average length of ICU stay in the treatment group compared to the control group; $P = 0.9320$.

In patients in the treatment group, the reversion of AF to sinus rhythm was 90.91% vs 13.64% on the control group in the immediate postoperative period. The comparison between these two groups with statistical analysis and significance level alpha of 0.05 allow us to reject the null hypothesis that considers the treatment with or without ultrasound ablation as equivalents.

In the late postoperative period, the non-permanence of sinus rhythm in the patients of the treatment group was 59.09% vs 86.36% in the control group. It was found a difference 27.27% greater permanence of conversion to sinus rhythm in favor of the patients in the treatment group.

The significance test showed that the treatment was better for the patients in the treatment group than for the patients in the control group concerning to the reversal of the AF rhythm to sinus rhythm in the postoperative late period; $P = 0.0422$.

As it was stipulated in the design of this study, the expected difference between both groups should be e" 39% of reversion to sinus rhythm, we were not able to reject the null hypothesis when the treatment with and without ablation in the late postoperative period was compared.

Regarding postoperative complications, there was a patient who presented severe complications. In addition to ultrasound ablation, the patient submitted to surgical treatment of both valves (mitral and tricuspid). This patient presented bleeding in the immediate postoperative period and the need to undergo mediastinotomy to correct the bleeding, but the patient died two days later due to cardiogenic shock.

Non-fatal complications not related to the ablation technique were observed in four patients in the treatment group.

A 65 year-old female patient presenting mitral stenosis with regurgitation undergoing mitral bioprosthesis implantation without previous cardiac surgery presented perforation of the left atrium. She was successfully re-operated and had an uncomplicated in-hospital course postoperatively. Three patients had an ischemic stroke in the postoperative period. A 63 year-old male patient after the implant of mitral bioprosthesis presented cerebral ischemia and were diagnosed with amaurosis. A 62 year-old female patient without previous operation, with a history of stroke without prior sequela to surgery was submitted to mitral valve bioprosthesis implantation and ablation technique with ultrasound had another stroke and remained with a motor deficit on the left. The third male patient, aged 32 years-old without previous surgery after mitral bioprosthesis had ischemia of two left toes.

In the control group eight deaths occurred. Of these, three occurred due to complications from bleeding. One patient died from complications due to mesenteric thrombosis, another one due to bacterial endocarditis and the sixth patient died, in consequence, of renal failure. Two other patients who died from heart failure had undergone previous surgery at the hospital for correction of both mitral and aortic valve dysfunction. At hospital admission the patients were functional class IV and were re-operated to correct the dysfunction of both prostheses.

## DISCUSSION

It is difficult to compare the results of several studies published in medical literature on the surgical treatment of permanent atrial fibrillation because of the large number of variables, FA different definitions and classifications, and treatment techniques as well.

The terminology used in the publications do not always identify whether the occurrence of AF is intermittent or continuous. The term *chronic AF*, is sometimes used to indicate that the arrhythmia is longstanding regardless of whether AF is intermittent or continuous. Other times, the term *chronic* is used to describe the continuous AF. This leads to misinterpretations when comparing results of different studies.

The persistent AF, defined as current, by the Atrial Fibrillation Guideline, published in 2003 [11] by the Brazilian Society of Cardiology, when treated, presents a higher percentage of reversal to sinus rhythm than the FA classified as permanent. When AF is paroxysmal, the success with the treatment is even greater, and the reversion to sinus rhythm and is more frequent than that observed with the treatment of persistent or permanent AF [12].

Several cardiology services are still researching methods to surgical correction of permanent AF. Nowadays, the Maze technique III, which presents a high efficacy in reversing the AF to sinus rhythm via application of multiple incisions and sutures to the atria, shows low effectiveness, since it is used by a limited number of surgical services [13, 14].

This study was designed so that the components of the treatment and control groups should present similar characteristics in order to allow an accurate comparison between both groups.

The choice of inclusion and exclusion was determined aiming at to avoid biasing comparisons. It has been excluded from the study patients with serious diseases that could result in a negative predictive factor for either group. We were extremely careful in standardizing the type of surgery concomitant to need to ablate AF. AF patients with congenital or coronary heart disease did not take part in the study.

The choice of a control group was important because it was possible to compare patients in situations of equality relative to the time the procedures were carried out, similar local conditions, same team involved in the assistance, and the quality standards of the complementary exams.

A series of case studies about the intra-operative treatment of AF using the ultrasonic scalpel was performed by Brick [15] in 27 patients from March 1999 to June 2000. According to the author, the patients were in functional class III or IV before surgery, which was also observed in present study.

According to Brick, the average age of the 27 participants was 36 years ranging from 18 to 64 years. In the present study, the mean age was 48.41 years, interquartile range from 18 to 69 years. Regarding gender, in Brick's study [15], 19/27 (70.37%) were women vs 8/27 (29.63%) were men; in the present study 30/42 (68.00%) were women vs 14/44 (32%) men.

In his series of case studies, Brick [15] have not reported the size of left atria.

In the brick's series, the anoxia average time was 39.7 minutes, interquartile range from 20 to 70 minutes. In the

present study, the anoxia time ranged from 20 to 210 minutes. The average time of anoxia of 22 patients in the treatment group was 73.59 minutes vs 84.86 minutes in the control group.

The mean CPB time in the study carried out by Brick [15] was 69.2 minutes, interquartile range from 45 minutes to 100 minutes. In the present study, 44 patients had a mean CPB time of 110 minutes.

The average time the patients remained on cardiopulmonary bypass in the group receiving ablation with ultrasound was 99.95 ± 22.14 minutes vs. 120.40 ± 51.71 minutes in the control group.

In the study carried out by Brick [15], the hospital length of stay ranged from 5 to 12 days with an average of 6.6 days.

In the present study, the average ICU length of stay was 5.85 days. The ICU length of stay in the treatment group was 5.90 ± 2.54 days vs 5.80 ± 4.78 days in the control group. No statistically significant difference between both groups was found.

There has not been found more complications or deaths in the early postoperative or postoperative period of patients who underwent ultrasound ablation than those who did not receive ultrasound ablation. It suggests that this technique which uses ultrasound as an energy source shown to be less invasive. The technique is not complex. The average time spent on application of ultrasound in both atria was 14 ± 4 minutes.

In the study carried out by Brick [15], it was observed reversion of AF rhythm to sinus rhythm in 24/27 (88.8%) of the patients in the immediate postoperative period; at the hospital discharge it was observed in 22/27 (81.4%) of the patients.

In the present study, the reversion of AF to sinus rhythm in the immediate postoperative period was 20/22 (90.91%) of the patients in the group receiving ablation vs 3/22 (13.64%) of the patients in the group that did not undergo ablation.

A prospective study involving 77 patients with permanent AF and mitral valve disease, who underwent surgical repair of this valve and surgical treatment of AF using the modified Maze technique III, radiofrequency, and cryoablation, showed that 84% of patients had reversal rhythm of AF to sinus rhythm. It was found that 65 patients who remained in sinus rhythm showed left atrial diameter significantly smaller than those who remained in AF (44.1 ± 7.6 mm vs 55.6 mm ± 11.5) [16]. In the present study, using ultrasound, the diameters of left atria in the treatment group measured 57.31 ± 8.46 mm.

A limitation of the present study was a short-term follow-up, which made the analysis of the prognosis and patient survival unfeasible.

Although the percentage of sinus rhythm in the immediate postoperative and late postoperative period has shown to be superior in the group receiving ablation in relation to the control group, percentage of responses in the late postoperative period was only 27% in the treatment group compared to the control group. One factor that may have contributed to the decrease of sinus rhythm permanence from the immediate postoperative to the late postoperative period was the occurrence of large left atria before surgery in the participants of the present study.

The increase in atrial diameters is considered a predictor of failure from the conversion to sinus rhythm after surgical treatment of AF [17]. Studies have shown that RA diameters larger than 52 mm present lower reversion rates to sinus rhythm [18]. Researchers in China have identified the diameter of preoperative LA greater than 56.8 mm had a significantly lower percentage of conversion to sinus rhythm [17]. The LA average diameter of the present study was greater than 57.31 mm [17].

The LA average diameter of the present study was greater than 57.31 mm.

There are published reports indicating a prolonged duration of AF as a factor that predisposes to the recurrence and even the maintenance of this arrhythmia after surgical treatment of AF [18-19]. Over 60% of the patients in the present study had a suggestive history of the atrial fibrillation over 5 years. This may have been a negative predictive factor that contributed to the reduction of the success treatment in the immediate postoperative period which was higher than 39% in the treatment group compared to the control group, highlighting a difference 27% higher over the treatment group in the late postoperative period.

It is possible that the energy applied to the ultrasonic scalpel with the power set at level 3 has been low and that some of the ablation lines aiming at to the transmural lesion were not sufficiently powerful. It is possible that an improvement of technique and an ultrasound power adjustment setting application can keep the reversion to sinus rhythm at a highest percentage in the late postoperative period.

## CONCLUSION

In the present study, there was a higher percentage of improvement in the functional class in the treatment group vs control group; however, it was not statistically significant. The variables: age ($P = 0.1175$), gender ($P = 1.0000$), sizes of preoperative atria ($P = 0.2569$) showed no significant difference between the treatment group and the control group, which shows that the groups presented homogeneous characteristics preoperatively.

Times of CPB, anoxia, and ICU length of stay postoperatively in both groups also showed no significant difference, which suggests that the use of an ultrasonic

scalpel for atrial ablation of AF does not act as a factor to worsen outcomes. It was not found more complications or deaths in early or late postoperative stages of patients undergoing ultrasound ablation than those who did not receive ultrasound ablation.

In the present research, the use of ultrasound as an energy source to create lines of ablation in the atria during cardiac surgery demonstrated a higher incidence of reversion to sinus rhythm in relation to the control group.

The findings observed in this study allow us to suggest that the application of ultrasound ablation technique can be applied in patients who have indications for surgical correction of mitral valve disease.

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