

Efficacy of intra-operative radiofrequency ablation in patients with permanent atrial fibrillation undergoing concomitant mitral valve replacement

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Abstract

Background: Permanent atrial fibrillation (AF) is present before operation and persists after surgery in 30-40% of patients undergoing mitral valve surgery. Using the maze procedure, 75-82% of patients can be cured of AF, but the procedure is difficult and long lasting. Percutaneous radiofrequency (RF) ablation has emerged as an effective therapy for AF in recent years.

Aim: To assess the efficacy of intra-operative RF ablation of AF in patients undergoing mitral valve surgery.

Methods: 100 adults with permanent AF underwent mitral valve replacement. Patients were divided into two groups: the RF group – 50 patients qualified for mitral valve replacement and RF ablation; and the control group – 50 patients selected for mitral valve replacement without ablation. Odds ratio and 95% confidence interval were examined to assess the influence of several factors on the outcome (free from AF during one-year follow-up based on symptoms and serial Holter ECG recordings).

Results: Baseline clinical, demographic and echocardiographic characteristics were similar in both groups. Electrical cardioversion following surgery was required in 76% of patients from the RF group compared with 94% from the control group ($p < 0.002$). In those who underwent cardioversion, sinus rhythm was restored more frequently in RF than control patients (32 vs. 16%, $p < 0.002$). Sinus rhythm at hospital discharge was present in 56% of RF patients compared with 22% of controls ($p = 0.0001$), and after one-year follow-up in 54 vs. 16% ($p < 0.001$), respectively. The use of amiodarone was significantly lower in RF patients compared with controls (32 vs. 70%, $p < 0.05$). NYHA class III (OR 8.5, CI 1.0-394) or IV (OR 36, CI 1.2-1958) and left atrial diameter > 6 cm (OR 9.3, CI 0.5-5230) were identified as predictors of AF.

Conclusions: Intra-operative RF ablation performed in the left atrium in patients with chronic AF undergoing mitral valve replacement significantly improves sinus rhythm restoration rate. Advanced heart failure (NYHA class IV) and left atrial diameter > 6 cm are negative prognostic factors for sinus rhythm maintenance.

Key words: permanent atrial fibrillation, mitral valve replacement, radiofrequency ablation

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Introduction

Atrial fibrillation (AF) is the third most frequent cardiac arrhythmia after supraventricular and ventricular extrasystolic beats [1]. As estimated AF is detected in approximately 75% of patients with severe mitral valve incompetence and 30-40% of subjects with significant mitral

stenosis [2]. In the majority of patients AF is permanent and it persists even after correction of the valvular disease.

The most effective surgical method of AF treatment is the maze operation developed by James Cox in the late 1980s [3, 4]. It was based on the assumption that AF resulted from multiple circulating re-entry loops and to terminate them it was mandatory to create many incisions

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of the atrial wall. Although maze operations were reported to offer exceptionally high success rates, they were time-consuming and technically demanding. Not surprisingly they stimulated development of cutting-edge medical technologies allowing much easier surgical treatment of the arrhythmia.

One of the most commonly employed invasive methods is radiofrequency ablation (RF ablation), which is also used during cardiac surgery.

The aim of this study was to assess the efficacy of intraoperative RF ablation in patients undergoing mitral valve operations. Several variables having a potential impact on the procedure efficacy were also analyzed.

Methods

The study involved 100 patients with permanent AF (lasting at least 1 year) with advanced and isolated mitral valve disease. In order to diagnose and document AF, 12-lead electrocardiography and 24-hour Holter ECG were performed in every patient. Mitral valve disease was confirmed using transthoracic echocardiography (TTE). Left ventricular ejection fraction (EF) was calculated by means of echocardiography using Simpson's method. Left atrial (LA) dimension was measured in the left parasternal view, from 2D mode. Coronary angiography was carried out in every patient. Patients with significant coronary disease were excluded. Presence of non-obstructive atherosclerotic coronary plaques was not an excluding criterion.

Patients were divided into two study groups: ablation group (RF) – 50 patients selected for mitral valve replacement and RF ablation; control group – 50 subjects undergoing mitral valve replacement without RF ablation.

Mitral valve operations accompanied by RF ablation were performed as part of a scientific programme and so were done in a predefined time period to accumulate a total of 50 RF ablation procedures. The control group consisted of 50 consecutive patients undergoing isolated mitral valve surgery. Table I summarises baseline demographic and clinical characteristics of patients enrolled.

All operations were done using cardio-pulmonary bypass in moderate systemic hypothermia (+28°C) using blood cardioplegia. RF ablation was performed before mitral valve replacement. Cold saline irrigated electrodes (Medtronic Cardioblate Device) were used for RF ablation. The generator power was set at 30 Watts and lesions were produced at a temperature of 70-80°C. Linear lesions were confined to the left atrium and produced according to the scheme presented in Figure 1.

Each 1 cm long segment of ablation line was done by moving the tip of the electrode forwards and backwards for about 20 seconds until the targeted endocardium became pale. As illustrated in Figure 1 the first ablation line was created around right (line no. 1) and left

pulmonary veins' (line no. 2) ostia, then both lines were connected (line no. 3). The next RF application line was extended downwards starting from the middle of the connecting line (line no. 4). The ablation path towards the LA auricle (LAA) was extended from the left upper pulmonary vein (line no. 5). The final ablation line

Table I. Preoperative demographic and clinical patient characteristics

Parameter	RF ablation group	Control group	P
Gender	F – 39 (78%) M – 11 (22%)	F – 38 (76%) M – 12 (24%)	NS
Age [years]	61.6±7.4 (50-76)	60.5±6.9 (46-74)	NS
NYHA class	II – 10 (20%) III – 35 (70%) IV – 5 (10%)	II – 17 (34%) III – 28 (56%) IV – 5 (10%)	NS
EF [%]	48.3 (35-60)	46.9 (25-72)	NS
Mean LA dimension [cm]	5.7 (4.5-9.8)	5.7 (4.4-8.3)	NS
DM [n/%]	4/8	4/8	NS
Thyroid disease [n/%]	8/16	6/12	NS
Thromboembolic complications [n/%]	2/4	6/12	NS
Hypertension [n/%]	16/32	14/28	NS
Coronary artery disease [n/%]	5/10	2/4	NS
Rheumatic disease [n/%]	6/12	5/10	NS
IM prevalence [n/%]	25/50	18/36	NS

Abbreviations: NS – non-significant, EF – ejection fraction, LA – left atrium, DM – diabetes mellitus, IM – mitral valve incompetence, n – number of patients

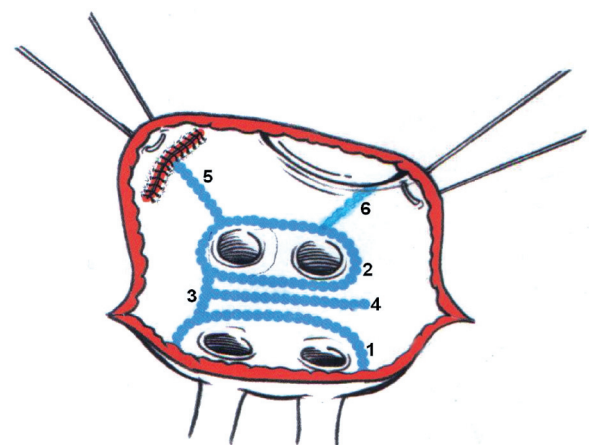


Figure 1. Scheme of ablation lines within the left atrium

connected the left lower pulmonary vein with the mitral annulus at the base of the posterior leaflet (line no. 6). The LAA was not electrically isolated but was ligated to prevent thrombus formation.

In the postoperative period, cardiac rhythm was evaluated by means of standard ECG and 24-hour ambulatory ECG monitoring. In case of AF recurrence antiarrhythmic medications were administered (amiodarone or in few cases sotalol) followed by monophasic DC electrical cardioversion when needed. The first employed energy was 200J; if found unsuccessful a DC shock of 360J was used for the second attempt. Patients in whom sinus rhythm was not restored were discharged from hospital on amiodarone unless contraindicated.

Statistical methods

The results are expressed as means $\pm$ SD or the number of cases and rates. Patient data of ablation and control groups were compared. Student's T test was applied for variables such as age, left ventricular EF, LA dimension and aortic cross clamping time. The χ^2 test for independent variables was used to compare prevalence of comorbidities, severity of heart failure expressed as NYHA functional class and gender distribution. Rates of electrical cardioversions in both groups were compared with χ^2 test. Impact of selected factors on early (at discharge) and late (after one year) outcomes within each group was analysed using χ^2 test for independent variables. The mean values of age, left ventricular EF and LA dimension were compared using Student's T test. Odds ratios and 95% confidential intervals were calculated

separately in RF and control groups for the variables found to be significantly associated with outcomes based on simple statistical tests. A p value ≥ 0.05 was considered statistically significant.

Results

Baseline characteristics (Table I)

Examined groups were similar with respect to baseline demographic, clinical and echocardiographic parameters. Prevalence of comorbidities and thrombo-embolic complications was also similar in both groups.

Intraoperative characteristics

Aortic cross-clamping time was longer by 12.5 min in the RF than in the control group (65.2 vs. 52.7 min, $p < 0.001$).

Postoperative period and outpatient follow-up

The two groups differed significantly with respect to the need for electrical cardioversion and cardioversion success rate (Table II). The need for electrical cardioversion was significantly lower in patients after surgical RF ablation than in the control group. Moreover, the cardioversion success rate was two times higher in the RF group.

Clinical outcome (sinus rhythm restoration) was significantly better in the RF group, both at discharge ($p = 0.001$) and at one year after the procedure ($p < 0.001$) (Figure 2). In the ablation group 16 (32%) patients and 35 (70%) patients in the control group were discharged on amiodarone ($p < 0.005$).

A permanent pacemaker was implanted in 4 (8%) patients in the RF group and in 1 (2%) in the control group (NS). All patients received VVI pacemakers mainly due to bradycardia and atrio-ventricular block.

Higher baseline EF and lower preoperative LA dimension were associated with higher chance of sinus rhythm restoration with RF ablation, particularly at the end of one-year follow-up (Table III).

Based on calculated odds ratios (OR) significant predictors of persistent AF during follow-up after initial success of ablation were identified. Among RF patients who were found in NYHA class III at baseline the risk of AF at discharge was 8 times higher than in patients in NYHA class II, and the risk of AF at one year was over three times higher in these patients (OR 3.4). Among patients in NYHA class IV at baseline the risk of persistent

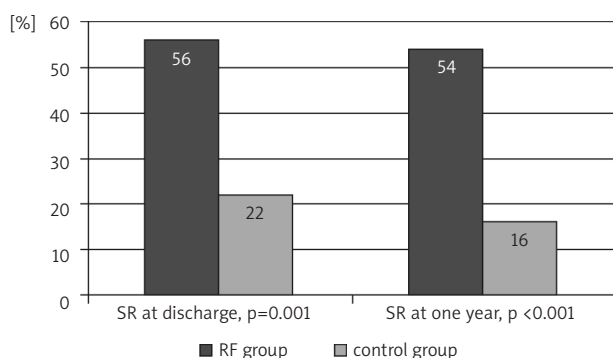


Figure 2. Outcomes at discharge and at 12 months postoperatively

Abbreviations: SR – sinus rhythm

Table II. Usage and success rates of electrical cardioversion

Group	n	Electrical cardioversion			p
		No cardioversion	Successful cardioversion	Failed cardioversion	
RF ablation [%]	50	12 (24)	16 (32)	22 (44)	0.002
Control [%]	50	3 (6)	8 (16)	39 (78)	

AF at discharge and after one year was 36-37 times higher than in NYHA class II patients. Preoperative LA dimension between 5.1 and 6 cm was not associated with increased risk of failure both at discharge and after one year when compared with subjects with LA dimension less than 5 cm. Meanwhile, LA dimension exceeding 6 cm resulted in a 5-fold increase in the risk at discharge and nine-fold at the end of one-year follow-up. The results are outlined in Table IV.

Discussion

The maze operation designed and developed by James L. Cox in the years 1987-1991 used to be a gold standard of surgical AF treatment [3-6]. Evidence of the importance of pulmonary vein ostia and the posterior atrial wall in the initiation and maintenance of AF together with technological advances led to abandoning the time-consuming, technically difficult Cox maze operation despite reported high efficacy of such treatment [7].

At the beginning of the surgical ablation programme our primary purpose was to restore the sinus rhythm and to show real efficacy of the ablation procedure. Thus we chose a group of 100 patients with permanent AF without any sinus rhythm spells for at least one year. Meeting this criteria seems to be of paramount importance. It is commonly accepted that in patients with paroxysmal AF or AF lasting less than 1 year, isolated surgery for mitral valve disease may be sufficient for sinus rhythm restoration [8-10].

The next purpose of our study was to determine the impact of LA size on RF ablation efficacy and attempt to answer the question of whether any particular LA dimension could serve as a prognostic threshold of successful ablation. The LA dimension exceeding 6 cm was found to be associated with elevated risk of arrhythmia persistence. Such a correlation was not seen by Raanani et al., who in 47 patients undergoing simultaneous mitral valve surgery and maze III operation did not find evidence for an impact of LA enlargement on outcomes of antiarrhythmic procedures (26% of patients had AF for less than 1 year) [11]. Geidel et al. did not perform ablation in patients with LA dimension exceeding 7.2 cm. They reported that in individuals with LA diameter >5.6 cm the results were significantly less favourable ($p=0.006$) [12]. On the other hand, Choo et al. performing Cox maze III operation managed to restore sinus rhythm in more than 95% of patients with LA dimension above 6 cm [13]. This may have resulted from aggressive LA size reduction carried out by these authors as well as other investigators [14]. However, reliable assessment of the impact of LA size on RF ablation efficacy is very difficult and requires detailed multivariable statistical studies. One should keep in mind that as mitral valve disease progresses not only atria become dilated, but also several other processes such as electrophysiological remodelling of cardiomyocytes, fibrosis, thickening and

Table III. Comparison of the preoperative ejection fraction and left atrial dimensions in the RF group at discharge and at the end of follow-up in relation to cardiac rhythm

Parameter	Sinus rhythm	AF	p
EF – discharge [%]	50.4	45.7	0.042
EF – at one year [%]	50.9	45.4	0.016
LA – discharge [cm]	5.4	6.0	0.05
LA – at one year [cm]	5.4	6.0	0.042

Abbreviations: as in Table I

Table IV. Odds ratio (OR) of failure (AF persistence) in early (at discharge) and late (at one year) follow-up in the RF group

AF recurrence predictor	Odds ratio (OR)	95% CI
NYHA III (vs. NYHA II) at discharge	8.5	1.0-394
NYHA III (vs. NYHA II) at one year	3.4	0.5-394
NYHA IV (vs. NYHA II) at discharge	36	1.2-1958
NYHA IV (vs. NYHA II) at one year	37.4	1.7 – infinity
Pacemaker implantation at discharge	13.9	0.9 – infinity
Pacemaker implantation at one year	1.2	0.7-17.7
LA dimension 5.1-6 cm (vs. LA 4-5 cm) at discharge	1.5	0.2-11.0
LA dimension 5.1-6 cm (vs. LA 4-5 cm) at one year	1.0	0.2-7.8
LA dimension >6 cm (vs. LA 4-5 cm) at discharge	5	0.4-76.0
LA dimension >6 cm (vs. LA 4-5 cm) at one year	9.3	0.5-5230

progressive necrosis of the atrial wall occur. The latter changes rather than LA size itself most likely play the crucial role in AF.

The critical condition of successful ablation seems to be transmural scar formation, which causes complete conduction block. Only during the maze operation was the surgeon sure the scar would be transmural as the whole thickness of the atrial wall was cut. Unfortunately in the case of RF ablation there is no way to check for the completeness of transmural. We are only capable of setting up appropriate parameters of the ablating device but cannot interfere with the patient substrate – the atrial wall. Mean thickness of the LA wall in healthy subjects is reported not to exceed 3 mm [15]. However, atrial wall thickness, and proportions of endo-, myo- and

epicardium, may vary between people. LA dilatation and thickening are especially pronounced in the course of mitral valve disease, and LA wall thickness may reach even 5-6 mm [15, 16].

A very interesting experimental study was carried out by Thomas et al. [16]. Based on histological examination they found atrial wall thickness in sheep to be similar to that in humans affected by cardiac disease. After application of endocardial RF ablation the depth of the ablation-induced scar was 3.9 ± 1.1 mm, suggesting that in the case of severe atrial hypertrophy the risk of incomplete transmural ablation is real. Portuguese investigators compared the results of RF ablation *in vitro* (fragments of atrial wall were harvested from transplant organ donors) and *in vivo* (specimens of atrial wall of patients with mitral valve disease) [15]. Of 12 *in vitro* specimens, in 10 transmural scars were documented. The findings in the second group were surprising: 5 *in vivo* specimens included changes confined only to the endocardium, in 3 cases the whole endocardium was involved, and only in 2 cases was the scar transmural. Paradoxically, in 2 patients with ablation-related changes confined only to the endocardium sinus rhythm was sustained at 6 months after operation and in patients with transmural lesions AF was persistent in 38%. Accord et al. investigated post mortem scars of microwave epicardial ablation in patients who in the early postoperative period presented sinus rhythm with documented intraoperative conduction block at the site of energy application [17]. It was shown that in some cases transmural scar was not achieved. It can be concluded that creation of the conduction block is not equivalent to transmural ablation of an ablation-produced scar.

From the cardiologist's point of view anti-arrhythmic management is of crucial importance in patients who develop recurrent arrhythmia in the postoperative period. Many surgeons claim that assessment of the ablation success should be postponed until at least 3 months postoperatively because frequent events of arrhythmia recurrence are typical in the early postoperative period [8, 12]. The majority of authors recommend amiodarone for the treatment of AF in this critical period. In case of pharmacotherapy failure or arrhythmia recurrence after a few months some experts recommend DC cardioversion [6, 18]. In our series we always attempted to restore sinus rhythm. Most of our patients had severe mitral valve disease and permanent AF. As could be expected pharmacotherapy failed almost in all cases. Meanwhile, the need for electrical cardioversion was significantly less frequent and success rate significantly higher in patients after surgical ablation than in the control group. Thus we can assume that ablation itself increases the efficacy of electrical cardioversion.

Of interest are the differences in efficacy of endocardial RF ablation reported by various teams. In our

series sinus rhythm was documented in more than 50% of patients in short-term or at one year. Although this rate was significantly higher than in the control group (sinus rhythm was seen in 22% of patients at discharge and only in 16% at one year) our findings are not consistent with results reported by other surgeons. For example, Sie et al., who carried out the highest number of ablation procedures in Europe, report a success rate of over 80% at one year [8]. They performed biatrial ablation in patients with significant mitral valve disease and AF lasting for at least 12 months. Mohr et al. reported efficacy of approximately 69% in a similar group of patients [19]. Williams et al. observed sinus rhythm restoration in 78% of patients at 9 months following ablation. However, they also ablated patients with AF lasting no longer than 6 months [20]. Geidel et al. reported outcomes of ablation not only in patients with permanent AF but also with persistent AF lasting for less than 1 year and excluding those with LA dimension exceeding 7.2 cm [12]. Wisser et al. documented sinus rhythm in 80% of patients, but not all of them were operated on for mitral valve disease [18]. In some of them arrhythmia screening was continued for 6 months only. Moreover, 21% of patients underwent DDD or AAI pacemaker implantation, which could also have a marked impact on the rate of sinus rhythm restoration. When adjusting for pacing, the percentage of patients with sinus rhythm was 59%.

Possibly the most appropriate management strategy would be simultaneous endo- and epicardial ablation resulting in the highest success rate of the treatment. Bipolar ablation is required to produce epicardial lesions, as reported by Suwalski and Doll, who showed that application of monopolar ablation failed to produce transmural scars [21]. In their opinion, a bipolar ablation device facilitates whole thickness of atrial wall compression, significantly increasing the probability of transmural energy application. Bipolar ablation may be assumed to greatly reduce the impact of unfavourable factors such as LA hypertrophy.

Finally it should be emphasised that reduced risk of AF recurrence is associated with better prognosis and improved quality of life, which is significantly depressed in the majority of patients suffering from AF [22].

Conclusions

1. Intraoperative RF ablation significantly increases probability of sinus rhythm restoration.
2. Isolated mitral valve surgery is insufficient to restore sinus rhythm in patients with permanent atrial fibrillation.
3. Particularly unfavourable predictors of ablation failure include symptoms of severe heart failure (NYHA class IV) and left atrial dimension exceeding 6 cm.
4. To reliably assess RF ablation efficacy large-scale studies with long-term follow-up are needed.

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Ocena skuteczności ablacji prądem o częstotliwości radiowej u chorych z utrwalonym migotaniem przedsionków poddanych operacji wymiany zastawki mitralnej

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Streszczenie

Wstęp i cel: Wśród chorych operowanych z powodu wady zastawki mitralnej 30–40% ma utrwalone migotanie przedsionków (AF). Arytmia utrzymuje się mimo korekcji wady zastawkowej. Najskuteczniejszą metodą chirurgicznego leczenia AF były operacje Coksa. Dawały one doskonałe wyniki, ale były czasochłonne i trudne technicznie. Alternatywną metodą jest ablacja prądem o częstotliwości radiowej (RF). Przeprowadziliśmy program badawczy, aby ocenić skuteczność ablacji RF.

Materiał i metody: Zbadano 100 chorych operowanych w naszej Klinice, u których stwierdzono wadę zastawki mitralnej oraz utrwalone AF. Wyróżniono dwie grupy: grupa RF – 50 chorych zakwalifikowanych do wymiany zastawki mitralnej i ablacji RF, grupa kontrolna – 50 chorych, u których zaplanowano wymianę zastawki mitralnej. Testem t-Studenta porównywano: wiek, frakcję wyrzutową, wymiar lewego przedsionka (LP), czas zakleszczenia aorty. Testem niezależności χ^2 porównywano występowanie chorób towarzyszących, stopień niewydolności krążenia wg NYHA, pęć oraz częstość wykonania kardiowersji elektrycznej. Test niezależności χ^2 posłużył analizie wpływu czynników ryzyka na wynik leczenia przy wypisie i po roku. Obliczono iloraz szans z 95% przedziałem ufności w grupie RF i kontrolnej oddzielnie dla tych czynników ryzyka, od których zależał wynik leczenia w prostej analizie statystycznej.

Wyniki: Grupy nie różniły się pod względem wieku i płci. Nie zanotowano różnic dotyczących wielkości frakcji wyrzutowej, wymiaru LP, stopnia zaawansowania niewydolności krążenia wg NYHA. Spośród parametrów przedoperacyjnych przeanalizowano obecność chorób towarzyszących (cukrzyca, choroby tarczycy, nadciśnienie tętnicze, choroba wieńcowa i reumatyczna), rodzaj wady zastawki mitralnej, częstość zatorów. Parametry te nie różnicowały obu grup. W grupie RF rytm zatokowy osiągnięto u 28 (56%) chorych, w kontrolnej u 11 (22%) chorych ($p=0,001$). Po roku rytm zatokowy stwierdzono u 27 (54%) chorych w grupie RF oraz u 8 (16%) chorych w grupie kontrolnej ($p<0,001$). Czas zakleszczenia aorty był dłuższy w grupie RF niż w kontrolnej ($p<0,001$). Po ablacji rozrzuśnik wszczepiono u 4 chorych, a w grupie kontrolnej u jednego. W przypadku nawrotu arytmii częstość wykonania i skuteczność kardiowersji elektrycznej różnicowała obie grupy ($p=0,002$). Średni wymiar LP chorych po ablacji, u których uzyskano rytm zatokowy, był mniejszy niż u osób, u których po roku od operacji pozostało AF ($p=0,042$). Frakcja wyrzutowa u tych chorych była znacząco wyższa ($p=0,016$). Wymiar LP powyżej 6 cm 5-krotnie przy wypisie i ponad 9,3-krotnie po roku zwiększał ryzyko utrzymania się arytmii. Zaawansowanie niewydolności serca w IV klasie wg NYHA 36-krotnie przy wypisie ze szpitala i 37-krotnie po 12 miesiącach zwiększało ryzyko nieskutecznej ablacji.

Wnioski: 1. Śródoperacyjna ablacja RF statystycznie znacząco zwiększa szansę przywrócenia rytmu zatokowego u chorych z utrwalonym migotaniem przedsionków. 2. Ablacja RF jest metodą bezpieczną. 3. Wydaje się, że szczególnie niekorzystnymi czynnikami prognostycznymi dla ablacji, oprócz czasu trwania arytmii, są niewydolność serca w IV klasie wg NYHA oraz wymiar LP przekraczający 6 cm.

Słowa kluczowe: utrwalone migotanie przedsionków, wymiana zastawki mitralnej, ablacja RF

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