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THE FIRST EXPERIENCE OF CRYOABLATION USING ARTICURE **CRYOICE IN KAZAKHSTAN FOR ATRIAL FIBRILLATION** IN COMBINATION WITH HEART VALVE REPLACEMENT

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Abstract

Introduction: Atrial fibrillation (AF) remains one of the most common arrhythmias worldwide, accounting for up to 30% of all cardiac rhythm disorders. It leads to impaired heart function and increased risk of systemic embolism and stroke[1]. Cryoablation is currently the only energy source that does not alter collagen tissue, preserving normal tissue architecture. This makes it an excellent energy source for ablation near valve tissue or the fibrous skeleton of the heart. Histologically, the damage shows dense formation of uniform scars and no thrombus formation over the lesions.

Aim: To analyze the early results of cryoablation in patients with valve pathology and rhythm disturbances.

Materials and Methods: The study was conducted at the Research Institute of Cardiology and Internal Medicine from 2019 to 2022. Fifty patients underwent cryoablation using ArtiCure cryoICE in combination with valve pathology and atrial fibrillation. All patients underwent echocardiography, transesophageal echocardiography, 24-hour Holter ECG, ECG, and cardiac CT before and after the procedure. The clinic used the innovative technique of left atrial appendage (LAA) clipping with AtriCLIP Flex. The cryoablation with ArtiCure cryoICE was performed in the left atrial and pulmonary vein cavities for 120 seconds, freezing the tissue to -70°C.

Results: The results were assessed through ECG and 24-hour Holter ECG readings taken at 2 days after the procedure, before discharge, and at 3 and 6 months. After 6 months, sinus rhythm was restored in 90% of the patients, 6% had persistent AF, and 4% (2 patients) required a permanent pacemaker implantation. The majority (80%) underwent LAA clipping with the AtriCure system of various sizes (No. 35, 40, 45, 50). A smaller portion (20%) had LAA sutured due to anatomical peculiarities.

Conclusions: The data from this small sample suggest a positive outcome of cryoablation using the ArtiCure cryoICE system for open-heart surgeries in patients with atrial fibrillation.

Keywords: Cryoablation of left and right atrium, left atrial appendage clipping, open-heart surgeries.

Резюме

ПЕРВЫЙ ОПЫТ В КАЗАХСТАНЕ КРИОАБЛЯЦИИ ARTICURE CRYOICE ПРИ ФИБРИЛЛЯЦИИ ПРЕДСЕРДИЙ В СОЧЕТАНИИ С ПРОТЕЗИРОВАНИЕМ КЛАПАНОВ СЕРДЦА

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Введение. На сегодняшний день, как и в прежние времена, фибрилляция предсердий (ФП) остается одной из самых распространенных аритмий в мире, до 30% всех нарушений ритма сердца, приводящих к ухудшению функции сердца и повышению риска системных эмболий, а также развитию инсультов [1]. Криоаблация является единственным доступным в настоящее время источником энергии, который не изменяет тканевой коллаген, т.е. сохраняется нормальная архитектура ткани. Это делает его отличным источником энергии для аблации вблизи

клапанной ткани или фиброзного скелета сердца. Гистологически, повреждения показывают плотное образование однородных рубцов и отсутствие образования тромба над повреждениями.

Цель исследования: Анализ ранних результатов криоабляции у пациентов с коррекцией клапанной патологии и нарушений ритма сердца.

Материалы и методы: В АО «Научно-исследовательском институте кардиологии и внутренних болезней» с 2019 по 2022 г. 50 пациентам выполнена криоаблация ArtiCure cryol CE при сочетании клапанной патологии и фибрилляции предсердий. Всем пациентам выполнялись исследования – ЭХОКГ, ЧПЭХОКГ, Суточный Холтер ЭКГ, ЭК, КТ сердца до и после операции. На сегодняшний день наша клиника имеет возможность применять последнюю инновационную технику клипирования ушка левого предсердия с помощью Атриоклипа «AtriCLIP Flex». Устройством ArtiCure cryo ICE выполняется криоаблация полости ЛП и ПП по линиям по 120 сек, с заморозкой ткани до -70*С.

Результаты: Результаты оценивались по ЭКГ и суточному Холтеру ЭКГ на 2-е сутки после операции, перед выпиской, через 3 и 6 мес. Через 6 мес после операции по данным Суточного холтера ЭКГ синусовый ритм восстановился у 90% пациентов, у 6% пациентов сохранилась постоянная форма ФП и 4% (2 пациентам) имплантирован ЭКС. В большей степени (80%) выполнено клипирование ушка ЛП системой «Atri Cure», различного размера (№35, 40, 45, 50). В меньшей степени ушивание ушка (20%), что связано с анатомическими особенностями ушка ЛП.

Выводы: данные на небольшом числе больных свидетельствуют о положительном результате криоаблации фибрилляции предсердий системой Arti Cure cryol CE при операциях на открытом сердце.

Ключевые слова: Криоабляция левого и правого предсердия, клипирование ушка ЛП, открытые операции на сердце.

Түйіндеме

ҚАЗАҚСТАНДА ЖҮРЕК ҚАҚПАҢДАРЫНЫҢ ПРОТЕТИКАСЫНЫҢ ҮЙЛЕСІНДЕГІ ЖҮРЕКТЕРДІҢ ФИБРИЛЛЯЦИЯСЫ АРНАЛҒАН ARTICURE CRIOICE КРИОАБЛЯЦИЯСЫНЫҢ АЛҒАШҚЫ ТӘЖІРИБЕСІ

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Кіріспе: Бүгінгі күні, бұрынғыдай, жүрек аритмиясы (ЖҚ) әлемдегі ең жиі кездесетін аритмиялардың бірі болып қала береді, бұл жүрек қызметінің нашарлауына және жүйелі эмболия қаупінің жоғарылауына әкелетін барлық жүрек аритмияларының 30% -на дейін. сондай-ақ инсульттің дамуы [1]. Криоабляция қазіргі уақытта қол жетімді жалғыз энергия көзі болып табылады, ол тіндік коллагенді өзгертпейді, яғни. қалыпты ұлпа архитектурасы сақталған. Бұл оны жүректің клапан тінінің немесе талшықты қаңқасының жанында абляция үшін тамаша энергия көзі етеді. Гистологиялық тұрғыдан зақымданулар тығыз, біркелкі тыртықты көрсетеді және зақымдану үстінде тромб түзілмейді.

Зерттеудің мақсаты: Қақпақша патологиясы мен жүрек ырғағының бұзылыстары түзетілген науқастардағы криоабляцияның алғашқы нәтижелерін талдау.

Материалдар мен әдістер: 2019 жылдан 2022 жылға дейін Кардиология және ішкі аурулар ғылыми-зерттеу институтында 50 пациент клапан патологиясы мен жүрекшелер фибрилляциясының комбинациясы бар ArtiCure cryoICE криоабляциясынан өтті. Барлық науқастар зерттеулерден өтті – ЭХОКГ, ТЭКОКГ, Күнделікті Холтер ЭКГ, ЭК, Операцияға дейін және одан кейін жүректің КТ. Бүгінгі таңда біздің клиникада AtriCLIP Flex Atrioclip көмегімен сол жақ жүрекше қосалқысын кесудің соңғы инновациялық техникасын қолдану мүмкіндігі бар. ArtiCure крио ICE құрылғысы 120 секундтық сызықтар бойымен LA және RA қуысының криоабляциясын орындайды, тіндерді -70*С дейін мұздатады.

Нэтижелер: ЭКГ және күнделікті Холтер ЭКГ операциядан кейінгі 2-ші күні, шығарар алдында, 3 және 6 айдан кейін бағаланды. Операциядан кейін 6 айдан кейін 24 сағаттық ЭКГ Холтер деректері бойынша синус ырғағы 90% науқастарда қалпына келді, науқастардың 6% тұрақты ЖФ түрі болды, ал науқастардың 4% (2 науқас) кардиостимуляторды имплантациялады. Көбінесе (80%) LA қосымшасы әртүрлі өлшемдегі (№ 35, 40, 45, 50) АtriCure жүйесімен кесілген. Аз дәрежеде құлақты тігу (20%), бұл LA құлақтың анатомиялық ерекшеліктерімен байланысты.

Корытынды: пациенттердің аз саны туралы деректер ашық жүрек хирургиясында ArtiCure cryoICE жүйесімен жүрекшелер фибрилляциясының криоабляциясының оң нәтижесін көрсетеді.

Түйінді сөздер: Сол және оң жүрекшенің криоабляциясы, LA қосымшасын кесу, ашық жүрекке операция.

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Introduction

Currently, atrial fibrillation (AF) remains one of the most prevalent arrhythmias worldwide, accounting for up to 30% of all cardiac rhythm disorders. It leads to impaired heart function, an increased risk of systemic embolisms, and the development of strokes, making it a matter of significant importance for the healthcare system [13].

AF is frequently associated with conditions such as arterial hypertension, rheumatic heart diseases, coronary artery disease (CAD), and hypertrophic cardiomyopathy. The appearance of AF often serves as a primary indication for surgical correction of heart valve defects, particularly mitral valve defects.

Based on global literature and recent analyses, the incidence of cardiac rhythm disorders is rising both among patients receiving medical treatment and those without it. At present, cardiac rhythm disorders have been identified in more than 2.2 million individuals in North America alone. In the European Union, despite its smaller population, over 4.5 million people are affected. While it is challenging to track precise data in Kazakhstan, recent estimates suggest that approximately 500,000 individuals require treatment for cardiac rhythm disorders.

Adhering to the latest recommendations regarding the treatment of cardiac rhythm disorders does not guarantee complete freedom from atrial fibrillation (AF) recurrences after various types of surgical correction of valve defects and cardiac rhythm disorders [12].

Persistent and long-standing persistent forms of AF in open heart surgeries require mandatory surgical treatment. The most effective treatment method for AF in patients with valve defects is the Maze procedure in its various modifications [7]. However, there is currently no consensus on the optimal tactical approach for patients with paroxysmal AF in the context of valve defects. Some authors advocate for the complete Maze IV procedure, while others, based on the understanding that the main triggers are located at the pulmonary vein ostia, limit the treatment to left atrial lesions or even pulmonary vein isolation.

In the early 2000s, the first few cases of cryodestruction using the Maze procedure were performed. Cryoablation was introduced to replace surgical ablation lines, which were associated with numerous complications, with the aim of preventing impulse conduction. Over time, the Maze procedure was refined into several variants: Maze III, and later it was modified into Maze IV. The latter technique showed the best results and became widely used by many surgeons for an extended period [15].

Cryoablation is currently the only available energy

source that does not alter tissue collagen, meaning the normal tissue architecture is preserved. This makes it an excellent energy source for ablation near valvular tissue or the fibrous skeleton of the heart. Histologically, the injuries show the formation of dense, homogeneous scars and the absence of thrombus formation over the lesions.

In Kazakhstan, the restoration of cardiac rhythm primarily occurs in electrophysiological and cardiothoracic surgery departments using radiofrequency ablation, which is considered an outdated technique worldwide. The use of the cryoablation system ArtiCure cryoICE has not been implemented in Kazakhstan, except in our clinic.

Aim. To analyze the early results of cryoablation in patients with valve pathology and atrial fibrillation.

Materials and Methods

From 2019 to 2022, cryoablation using ArtiCure cryoICE was performed on 50 patients with a combination of valve pathology and atrial fibrillation at the Research Institute of Cardiology and Internal Medicine. This study was conducted as part of the scientific and technical program BR 11065383, "Development of innovative and highly effective technologies to reduce premature mortality from cardiovascular diseases, chronic respiratory diseases, and diabetes." The patients had a history of atrial fibrillation for no more than 2 years. The method is based on lowering tissue temperatures to -70°C, leading to bimodal necrosis and scar formation. Cryoablation can be performed in any cardiothoracic operating room, as it requires minimal space. Any cardiothoracic surgeon can perform the procedure after appropriate training in standard cardiothoracic surgical operations. The ArtiCure crvoICE device, comprising a power module, a disposable probe (soft or rigid), and an N2Ofilled balloon, is required for cryoablation [1,2,5,7,10]. The procedure is conducted under conditions of artificial circulation and cardioplegia, with the heart in a "dry" state, as circulating blood is a powerful heat sink and absorbs cold energy. All patients underwent various pre- and post-operative examinations, including echocardiography, transesophageal echocardiography, 24-hour Holter monitoring, electrocardiography, and cardiac CT.

Results

The echocardiographic assessment provided valuable information regarding valve pathology and guided further treatment. Doppler imaging allowed for the evaluation of heart valves - regurgitation grade, orifice area, and gradients. Holter monitoring of ECGs helped detect heart rhythm, maximum and minimum heart rates, ventricular extrasystoles, supraventricular ectopic activity, pauses, and dynamic changes in the ST segment. Cardiac CT was particularly useful for assessing the internal structures of the heart, especially the left atrial appendage, its size, type, and the presence of thrombi. In our clinic, the latest generation of equipment is used, and the use of the AtriClip "AtriCLIP Flex" provides an innovative technique for clipping the left atrial appendage. The technique is relatively straightforward and involves measuring the base of the left atrial appendage with a special ruler under full artificial circulation to ensure that the appendage is empty. A range of clip sizes from 35 to 45 is available. A rigid clip is then applied to the orifice of the left atrial appendage, and proper placement is crucial to avoid thrombus formation below the orifice or coronary artery injury (wraparound), which could lead to ischemia. The system allows for unlimited opening and closing of the rigid ring in case of improper placement (Fig.1).



Figure.1. Left atrial appendage clipping device.

In all patients, valve pathology correction was performed, with 47 patients undergoing mitral valve replacement, and 45 patients undergoing tricuspid valve repair in conjunction with mitral valve surgery. Aortic valve replacement was carried out in 3 patients, but to a lesser extent. Left atrial appendage isolation was performed on all patients (50), with 40 patients undergoing AtriCure clip system isolation of various sizes, and 10 patients receiving left atrial appendage closure due to anatomical reasons (short left atrial appendage - 2 patients, presence of thrombi in the left atrial appendage - 8 patients), which contraindicated AtriCure clip system isolation.

The patients included in the study underwent transthoracic and transesophageal echocardiography (intraoperatively). Transesophageal echocardiography allowed for additional clarification and confirmation of the extent of the surgery, and in some cases, interesting anatomical findings were revealed.

The preparation of patients for cryoablation of atrial fibrillation does not fundamentally differ from existing openheart surgery procedures. After the operation begins, the first stage in parallel with artificial circulation involves ablation of the pulmonary vein ostia and ligation or clip application to the left atrial appendage. For cryoablation, the pulmonary vein ostia are identified on both sides, and the left and right atria are widely exposed. Cryoablation of the left atrial cavity is performed three times in different directions for 120 seconds each, freezing the tissue to -70°C. The first ablation line is from the right upper pulmonary vein to the left upper pulmonary vein. The second line is from the right lower pulmonary vein to the left pulmonary vein. The third line is from the right lower pulmonary vein towards the left atrial appendage, and the fourth line is from the right pulmonary veins towards the mitral annulus. Ablation of the right atrium (in the direction of the superior vena cava, inferior vena cava, from the anterior wall to the tricuspid valve) is performed for 120 seconds, and endocardial cryoablation is performed over the coronary sinus for 120 seconds [3,4,6,8,9,16]. No other ablation lines are created (Figure 2).

The majority of patients came from Almaty city (40%) and Almaty region (40%), followed by West Kazakhstan region (12%), and other regions (East Kazakhstan region, Kyzylorda region, etc.) accounting for 2%.

The anthropometric data revealed the following: patients' heights ranged from 152 to 178 cm, with an average of 165 cm. Patient weights ranged from 52 to 112 kg, with an average of 74 kg. The patients' ages ranged from 46 to 76, with a median age of 63 years. The distribution by gender is presented in Figure 3.



Figure2. ArtiCure cryoICE device.

The main complaint of the patients was dyspnea of varying severity, which was encountered in 100% of the cases. Dizziness was also reported by all patients. Edema

of the lower extremities was present in 56% of the patients (28 patients), considering the concomitant valve pathology and heart failure decompensation (Figure 4).



Considering the age of the patients, arterial hypertension was detected in 92% of cases (Figure 5). The duration of the disease varied significantly among patients, ranging from 1 to 20 years, with a median of 7 years.

The systolic blood pressure in the patients ranged from 120 to 200 mmHg, with a median of 161 mmHg. The diastolic blood pressure in the patients varied from 70 to 120 mmHg, with a median of 95 mmHg.

Frequency of occurrence of AH



The heart rate (HR) in the patients ranged from 56 to 150 beats per minute (bpm), with an average of 98 bpm. Based on this data, it can be noted that the patients exhibited a tendency towards tachycardia.

According to the results of the 24-hour Holter ECG monitoring, all 50 patients had heart rhythm disorders. In 93% of cases, a persistent form of atrial fibrillation was detected, while in 7% of cases, a paroxysmal form of atrial fibrillation was observed. None of the patients had implanted pacemakers at the time of the operation. In most cases, patients with a history of rhythm disturbance exceeding 24 months were excluded from the study, with only two cases having a duration of 28 months.

Anginoid chest pain was reported by 46% of the patients. 90% of the patients did not show any changes on the Holter ECG, while 4 patients experienced significant pain symptoms. After performing coronary angiography, pathological changes in the coronary vessels were detected



in 4 cases, necessitating additional coronary artery bypass grafting in addition to the main operation.

Echocardiographic assessment of the left atrium (LA) and left ventricle (LV) was crucial and could have influenced the final results. In all cases, there was noted an enlargement of the heart chambers, which was associated with both valve pathology and the prolonged duration of heart rhythm disturbances. Patients with left atrial enlargement (12 patients) were excluded from the study as, despite undergoing the procedure for restoring heart rhythm, they would not achieve the desired results in terms of rhythm restoration.

The results

The results were evaluated based on ECG and 24-hour Holter ECG monitoring at 2 days after the operation, before discharge, at 3 and 6 months (Table 1). In the first 24 hours, considering the post-operative heart edema in patients, the results were low: sinus rhythm was restored in 24% of patients, 70% of patients were under temporary external pacing, and 6 patients still had atrial fibrillation. The next assessment of rhythm was conducted at the time of discharge (on average, at 5-7 days). According to the 24hour Holter ECG monitoring, sinus rhythm was restored in 86% of patients, atrial fibrillation persisted in 14% of patients, and none of the patients required temporary external pacing. The third assessment of rhythm was carried out after 3 months during an outpatient consultation with the cardiac surgeon. According to the 24-hour Holter ECG monitoring, sinus rhythm was maintained in 86% of patients, atrial fibrillation persisted in 10% of patients, and patients) required permanent pacemaker 4% (2 implantation due to the development of AV block and bradyarrhythmias. The fourth and final evaluation of results was conducted after 6 months post-operation (patients underwent 2 stages of rehabilitation). According to the 24hour Holter ECG monitoring, sinus rhythm was restored in 90% of patients, persistent atrial fibrillation was present in 6% of patients, and 4% of patients (2 patients) had a pacemaker implanted.

Table 1.

Change in heart rhythm after performing open heart cryoablation surgery in combination with valvular pathology.

Cardiac rhythm	Sinus rhythm	Atrial fibrillation	Temporary pacing	Implanted pacemaker
After surgery	24%	6%	70%	0%
After discharge	86%	14%	-	0%
After 3 months after surgery	86%	10%	-	4%
After 6 months after surgery	90%	6%	-	4%

Given the rhythm disturbances and the risk of thrombus formation, all patients underwent left atrial appendage (LAA) isolation through either clipping or suturing (see Figure 6).

According to Figure 6, in the majority of cases (80%), left atrial appendage (LAA) occlusion was performed using the "AtriCure" clip system of various sizes (see Figure 7). In fewer cases (20%), LAA closure was achieved through suturing, which was due to anatomical peculiarities of the LAA and the impossibility of using a clip (e.g., in 2 patients, the LAA was too short and small to accommodate a clip,

Types of isolation of the LAA

 100%
 80%

 80%
 60%

 40%
 20%

 20%
 0%

 Clipping Suturing LAA
 LAA

Figure 6. Types of isolation of the left atrial appendage

Discussion of Results:

Cryoablation is one of the primary energy sources used in the surgical treatment of atrial fibrillation and offers several advantages. It causes minimal tissue damage at the periphery of the surgical intervention and carries the lowest risk of thrombosis compared to radiofrequency waves. Additionally, it does not harm endothelial cells. There is no or very low risk of damaging other organs, such as the esophagus and phrenic nerve.

The research involving 50 patients who underwent cardiothoracic surgeries with combined cryoablation of the left and right atria demonstrated a high effectiveness of this treatment method for atrial fibrillation (AF). After the operation, AF was absent in 90% of the patients after 6 months. Based on these findings, it is recommended to perform concomitant surgical cryoablation of AF during scheduled cardiothoracic surgeries. This approach myocardial contractility (positive inotropic effect) without increasing the myocardium's oxygen demand. It also induces reverse remodeling of the myocardium (improves ieft ventricular ejection fraction and enhances physical tolerance) and improves the heart's self-regulation.

This technique does not require the operating room to be re-equipped nor specialized personnel, as any cardiothoracic surgeon with operative skills can perform it after appropriate training. The method allows for use in minimally invasive procedures, reducing the duration of artificial circulation and aortic occlusion. Restoring sinus rhythm reduces the need for medication and the side effects of drugs (due to decreased intake). Additionally, the technique improves economic indicators by promoting more effective sinus rhythm restoration and reducing heart failure progression, thereby lowering the risk of rehospitalization and thromboembolic complications. It enhances and prolongs the quality of life by reducing the risk of stroke.

Although this method is being used for the first time in Kazakhstan, it has shown promising results, which are planned to be further analyzed in future studies.

and in 8 patients, the presence of thrombi in the LAA made clip placement an absolute contraindication). In all 50 cases, after the procedure, cardiac CT scans were performed to confirm the hermetic closure of the LAA by the AtriCure clip. In the majority of cases, the size 45 clip was used, while size 35 and 50 clips were used in a smaller proportion, depending on the anatomical characteristics of each patient (see Figure 7). This approach allowed for individualized treatment and ensured optimal results for patients with different LAA characteristics.



Figure 7. Shows the sizes of the clips used for LAA clipping.

Conclusions:

In summary, the data from a small number of patients indicate a positive outcome of cryoablation for atrial fibrillation using the ArtiCure cryoICE system during openheart surgeries. However, definitive conclusions regarding the efficacy and safety of this procedure will be formulated upon completion of further research.

Conflict of Interest:

The authors declare no conflicts of interest, and all authors made an equal contribution to the preparation of this material.

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