Int J Clin Exp Med 2018;11(12):13806-13812
www.ijcem.com /ISSN:1940-5901/IJCEM0069078

Original Article

Comparative study on efficacy of high-frequency electric knife and Cardioblate™ Pen for treatment of atrial fibrillation

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Received February 21, 2017; Accepted November 28, 2017; Epub December 15, 2018; Published December 30, 2018

Abstract: Objective: To compare the ablation efficacy of high-frequency electric knife and Cardioblate™ Pen for radiofrequency ablation in the treatment of atrial fibrillation. Methods: A total of 120 patients who suffered from rheumatic heart disease with atrial fibrillation were scheduled for valve replacement and atrial fibrillation ablation in our hospital during August 2012 to December 2014. Indices including length of postoperative hospitalization and complications incidences, the duration of postoperative mechanical ventilation, ICU retention time and postoperative hospital stay and hospital expense were compared between the Cardioblate™ Pen ablation group (pen group, n=60) and high-frequency electric knife group (knife group, n=60). Results: The differences in length of postoperative hospitalization and incidences of complications, the duration of postoperative mechanical ventilation, ICU retention time and postoperative hospital stay were insignificant between the two groups (all P>0.05), while the time of ablation in knife group was significantly shorter than pen group (P<0.01). Moreover, application of high-frequency knife for the treatment of atrial fibrillation in patients showed similar cure rate as Cardioblate™ Pen. Conclusions: High-frequency electric knife for the treatment of atrial fibrillation may be beneficial to patients in terms of safety and efficacy.

Keywords: High-frequency electric knife, atrial fibrillation, Cardioblate™ Pen, efficacy, radiofrequency ablation

Introduction

Atrial fibrillation is the most common persistent tachyarrhythmia, which shows increasing complications and mortality such as heart palpitations, non-synchronized atrioventricular contraction, and left atrial blood stasis [1, 2]. Meanwhile, the risk of stroke in patients with atrial fibrillation is 5 times of patients without [3, 4]. Besides, atrial fibrillation was also an independent predictor of increased mortality in 55-94 years old population, in which the mortality of patients with atrial fibrillation is 1.5 to 1.9 times higher than those without [5, 6]. As society ages, atrial fibrillation has increased the expenditure of health care and family's economic pressure, and seriously affected the life quality of patients.

First-line treatment of atrial fibrillation is pharmacotherapy. However, the existing long-term effects of drugs are limited, and there are numerous side effects, which a lot of patients cannot tolerate [7-15]. Therefore, the effective non-drug treatment has been a hotspot, including transcatheter and surgical treatment. The improvement and simplification of such surgical procedures finally allowed the establishment of Cox Maze III procedure for atrial fibrillation, which can reverse sinus rhythm and atrioventricular contraction, and can significantly reduce the risk of hemodynamic disorders and thrombosis [16, 17].

The clinical applications of various ablation devices have both advantages and disadvantages [17-22]. Radiofrequency ablation device, such as Cardioblate™ Pen, is the most common ablative method in clinic currently, which can achieve lasting and stable heat, reduce the heat loss, and is easy to obtain transmural ablation line. However, because of point-like

ablation, despite the good transmural effects, it has poor results in the continuity of ablation. In contrast, ablation clamp is a commonly used bipolar ablation in clinical settings. So far, it is always a goal to develop and improve the instruments and methods of ablation in clinical applications.

In this study, we enrolled patients with rheumatic valvular heart disease and atrial fibrillation at Qilu Hospital of Shandong University and the Fourth People's Hospital of Jinan. The efficacy of high frequency electric knife or Cardioblate™ ablation pen in valvuloplasty and atrial fibrillation ablation procedures was evaluated and compared for the treatment of atrial fibrillation.

Materials and methods

Patients

From August 2012 to December 2014, 120 patients with rheumatic valvular heart disease and atrial fibrillation (EuroScore ≥4) continued for more than 3 months that were admitted in Qilu Hospital of Shandong University and the Fourth People's Hospital of Jinan, Shandong Province, China, were recruited in this study. Patients were randomly divided into Cardioblate™ Pen ablation group (pen group, n=60) and high-frequency electric knife group (knife group, n=60).

All patients received routine preoperative electrocardiogram, chest lateral radiograph, echocardiography, liver and kidney function examination, and biochemical immunity, hematuria routine and other preoperative examinations. Elderly patients were asked about the history of angina. Patients with suspected coronary heart disease or above 50 years old underwent coronary angiography to confirm coronary artery disease. All patients and their families who participated in the study were fully informed of the risk of study and perioperative complications that may occur to patients, and had provided informed consent form before the surgery. And this study had been approved by our hospital Ethics Committee.

Surgical preparation

Routine preoperative preparation was performed. Cardiac and diuretic therapies were given to improve heart function before surgery. One or two days before the surgery, heart disease and heart valve lesions were reexamined. Intramuscular injection of scopolamine (0.3 mg) and dolantin (1 mg/kg) were given 30 min before procedure. After patients were admitted to the operating room, left radial artery catheter were placed and were connected to arterial pressure transducer to monitor arterial pressure. Oxygen mask was placed, and intravenous injection of midazolam (0.1 mg/kg), vecuronium (0.1 mg/kg), and sufentanil (10 μg/kg) were given. After tracheal intubation, machine-controlled breathing was set up. The right internal jugular vein catheterization was conducted, and central venous pressure was monitored. Anesthesia was maintained through the surgery. Blood pressure, venous oxygen saturation (CVP), blood oxygen saturation, blood gas, and urine output were monitored. Arterial oxygen saturation was maintained at 95%-100%, and CVP was kept at more than 65%. After routine disinfection, a thoracotomy was performed by a median and longitudinal incision. After heparinization, the extracorporeal tube intubation was established, and checked every 30 min. After the establishment of cardiopulmonary bypass and the blockage of blood flow of the upper and lower vena cava and ascending aorta, surgical incision was performed according to the valve condition. Coronary artery perfusion tube was prepared in advance for patients who needed aortic valve replacement. Surgeons, anesthesiologists, and nurses completed the safety checks before the operation. All the operations were performed by surgical teams with similar surgical skills and experience within similar length of time.

Extracorporeal circulation

Briefly, all patients underwent surgery at moderate low temperature (26-32°C) using a Stroker II cardiopulmonary bypass machine and an oxygenator with integrated arterial filter. Heparin was given at 3 mg/kg and ACT was maintained at 480-1000 s. The i.v. fluids composition included lactate Ringer's solution, albumin, plasma, mannitol (0.8-1.0/kg), 5% $NaHCO_3$ (5-10 ml/kg), and Dexamethasone (0.5 mg/kg). Hematocrit was 0.20-0.28. The aorta was blocked at 32°C after bypass. Cardiopulmonary bypass perfusion flow rate was 1.6-2.4 L/m^2/min. Myocardial protection was performed by

Table 1. Demographic data

Group	Sex		Age	Cardiac function		SVR	DVR	CPB	Aortic cross clamping duration
	Male	Female		III	IV				
Pen	34	26	47.3±10.2	45	15	37	23	102.7±40.94	69.07±40.41
Knife	28	32	48.6±11.3	49	11	31	29	102.4±10.30	63.28±36.40
t/χ^2	1.201		0.6615	0.7856		1.222		0.0550	0.8246
P	0.273		0.510	0.375		0.269		0.956	0.411

Note: SVR, Single valve replacement; DVR, Double valve replacement; CPB, Cardiopulmonary bypass.

perfusion of cold blood in ascending aorta. Potassium concentration was at 28 mmol/L, and the first infusion was 15-20 ml/kg, which was repeated once every 20 minutes at a half volume of the first perfusion at 14 mmol/L. Three to five minutes before the opening of the aorta, the hearts were perfused with oxygenated blood at 32°C. According to the situation, Dedeco water filter was used in some patients. Left upper pulmonary vein was catheterized. After the completion of valve replacement, the cardiac incision was sutured. Lidocaine (100-200 mg) or amiodarone (75-150 mg) was given 1 to 2 minutes before opening the aorta. Defibrillation (30 w/s) was used if the hearts cannot function. All patients had temporary epicardial pacemakers, and extracorporeal circulation was stopped after the patients had effective myocardial contractility, normal ECG, stable blood pressure, and good blood gas biochemical results.

Modified Cox Maze III procedure

In high-frequency electric knife group, Valleylab force II system and high-frequency electric knife in coagulation mode (80-100 w) were used with disposable electric knife head for ablation. In cardioblate™ Pen ablation group cardioblate™ Pen from Medtronic was used, with a power of 25-30 J and cold saline flush rate of 60 drops/min. Modified Cox Maze III surgical procedures included epicardial ablation, two pulmonary vein ring isolation, straight ablation line between pulmonary vein isolation and the top roof of the left atrium, straight ablation line between the midpoint of mitral annulus and the left pulmonary vein loop, atrial septal tangent, straight ablation line between the tricuspid and the lower end of atrial septal incision, straight ablation line between the tricuspid and the upper end of the right atrial appendage incision, right atrial tangent, and left atrial appendage ligation and resection.

Clinical parameters including intraoperative cardiac resuscitation, cardiopulmonary bypass time, ascending aortic occlusion time, mechanical ventilation time, ICU observing time, and complications, etc. are also recorded.

Perioperative management and follow-up

The time of intraoperative and postoperative ventilator-assisted respiration, ICU retention time, length of stay, and complications were recorded. All patients underwent continuous monitoring via 12-lead ECGs for 3 to 7 days. Atrial fibrillation was defined as persistent episodes of more than 5 minutes. Isoproterenol (0.02-0.05 μg/kg/min) and amiodarone (150 mg, bolus injection) were given before cardiac resuscitation. Amiodarone was given after surgery for three months to six months. The patients were followed up for 1, 3, 6, and 12 months, and the 12-lead electrocardiogram and echocardiography were recorded.

Statistical analysis

Continuous variables were expressed as means ± standard deviation, and t-tests were used for comparison between groups. The categorical data were expressed as percentage compared using a percentage and a chi-square test. PASW Statistic 18.0 statistical software was used, and $P<0.05$ was considered to be statistically significant.

Results

Demographic and clinical characteristics

There were no significant differences in the preoperative data including sex ratio, age, cardiac function degree, valve replacement condition, cardiopulmonary bypass and Aortic cross clamping duration between the pen group and knife group (all P>0.05, **Table 1**).

Table 2. Length of postoperative hospitalization and incidences of complications

Variable	Pen	Knife	t/χ^2	P
Length of postoperative hospitalization (days)	9.4±3.1	10.2±3.6	1.03	0.57
Incidences of complications			1.29	0.21
Operative death	0 (0)	0 (0)		
Abnormal sinus rhythm	1 (1.7%)	1 (1.7%)		
Left ventricular rupture	0 (0)	1 (1.7%)		
Aortic incision bleeding	2 (3.3%)	0 (0)		
Atrial rupture	0 (0)	0 (0)		
Atrioventricular block	0 (0)	0 (0)		

Table 3. Surgery data

Parameters	Pen group (n=60)	Knife group (n=60)	*P* value
Valve procedure			0.50
MVR	45 (41)	46 (42)	
MVR + TVR/repair	34 (31)	30 (27)	
MVR + AVR/repair ± TVR/repair	52 (53)	46 (41)	
Isolated	0	0	
MV repair	3 (3.6)	4 (3.7)	
Repair + TV repair	2 (2.7)	2 (2.2)	
Repair + AVR/repair ± TV repair	2 (2.2)	1 (1.1)	
Isolated	1 (1.1)	1 (1.1)	
Mitral valve procedure			
Mechanical valve	40 (41)	43 (41.7)	0.56
Bioprosthetic valve	15 (14.7)	11 (10.3)	0.87
Repair	5 (4.9)	6 (5.9)	0.5
Aortic valve procedure			
Mechanical valve	22 (24)	12 (16)	0.19
Bioprosthetic valve	3 (3.2)	5 (6.5)	0.25
Repair	0	0	0.99
Tricuspid valve procedure			
Mechanical valve	1 (1.3)	1 (1.1)	1
Bioprosthetic valve	1 (1.1)	0	1
Repair	45 (42)	39 (38)	0.84
ASD closure	1 (1.3)	0	0.25
CABG	5 (4.5)	7 (6.8)	0.96
CPB time, min	102.7±40.94	102.4±10.3	<0.0001
ACC time, min	69.07±40.41	63.28±36.40	0.002

Data are presented as the number (%) of patients or mean ± SD. MVR, mitral valve replacement; TVR, tricuspid valve replacement; AVR, aortic valve replacement; TV, tricuspid valve; ASD, atrial septal defect; CABG, coronary artery bypass grafting; LA, left atrium; CPB, cardiopulmonary bypass; ACC, aortic cross-clamp.

Incidence of postoperative hospitalization and complications

The length of postoperative hospitalization and incidences of complications were not significantly different between the two groups (P=0.57, P=0.21). There was no operative death in the 120 patients who were included in this study. See **Table 2**. In the two groups, 98% of the sinus rhythm for both pen and knife groups was reversed immediately after operation and only one patient was with abnormal sinus rhythm in postoperative period in each group. One patient had left ventricular rupture in knife group, and two patients had aortic incision bleeding in pen group. There was no atrial rupture in either group. Epicardial temporary pacemaker was placed in all patients. No atrioventricular block occurred in postoperative period in two groups of patients.

Application of high-frequency knife for the treatment of atrial fibrillation showed similar efficacy as Cardioblate™ Pen

There were no significant differences between the two groups in the duration of postoperative mechanical ventilation, ICU retention time and postoperative hospital stay as well (P=0.53, P=0.32, P=0.42). However, time of ablation in knife group was obviously shorter than that in pen group (P<0.001). See **Table 3**.

The patients were followed up for 1 to 30 months (average 7.4±4.7 months). Among them, 6 patients in the knife group and 5 in pen group withdrew. Therefore, the follow-up rate was 90.8%. The cure rate of atrial fibrillation was 74.07% (40/54) in knife group and 74.5% (41/

55) in pen group, and the difference had no statistical significance (P=0.955).

Discussion

With the development of surgery technology in past decades, Cox Maze surgery has become the standard surgical treatment of atrial fibrillation. However, the resulted sinus rhythm and prognosis varied in different patients. Previous studies have shown that the conversion rate of sinus rhythm after Cox Maze surgery is only 46-47% [17]. On the contrary, another study demonstrated that the maintenance rate of sinus rhythm can reach 98% in patients with rheumatic valvular disease and atrial fibrillation after Cox Maze surgery with simultaneous valve replacement. Our results showed that the maintenance rate of sinus rhythm was generally around 75% in patients who received surgeries with either high-frequency electrical knife or Cardioblate™ Pen.

Radiofrequency ablation is characterized by lasting and stable heat, which reduces heat loss caused by heat conduction to shorten the process of ablation, and increase the access to the wall of the ablation line. Bipolar pen ablation is currently the most widely used method in minimally invasive ablation. Several reports have shown that the overall effective rate of thoracoscopic bipolar pen ablation is around 99.5% [17, 20, 22]. Conversely, monopolar pen ablation is often difficult to obtain transmural ablation line [17, 20, 22]. Unipolar pen ablation with an assisted aspiration device has been used in animal studies, but its efficacy still need to be confirmed. Cryoablation is another commonly used ablation method, which usually requires operation under cardiopulmonary bypass to evacuate the heart. A study with 63 patients who underwent cryoablation at the same time during cardiac surgery showed that 88.5% of patients were free of atrial fibrillation at 1 year after surgery, however, the surrounding tissue may be damaged in cryoablation if the surgery is not properly performed [16, 17, 20].

High-frequency electric knife and Cardioblate™ Pen ablation pen have the same mechanisms, such as blocking the abnormal reentrant pathway by heat-induced denaturation and necrosis. During our clinical application of electric knife for ablation, we found that surgical field is clear without blood and the time of ablation can be significantly reduced. Since the electric knife head is directly connected to the electric knife, the electrode plates no need to be adhered to the patients. From our research, the time of ablation was 15.05±5.85 min (5-29 min) in pen ablation group and 21.87±6.90 min (17-32 min) in knife ablation group, respectively and the former was significantly shorter than the latter (t=4.01, P=0.0001). In general, electric knife ablation is faster and simpler than Cardioblate™ Pen ablation.

Previous studies have demonstrated that atrial fibrillation can increase the incidence of complications, such as patients with atrial fibrillation have a 5-fold increased risk of stroke compared with those without [1, 23, 24]. Cox and his colleagues showed that Cox Maze surgery significantly reduced the incidence of postoperative atrial fibrillation in a long-term follow-up study [22, 25]. We followed up two groups of patients for 1 to 30 months (mean, 7.4±4.7 months) via telephone or clinic visit (5 in Cardioblate™ Pen ablation group and 6 in high frequency knife group) with a follow-up rate of 90.8%. The results suggested that there was no statistically significant difference in the clinical effects between the high-frequency knife group and the Cardioblate™ Pen group at 30 months after surgery (P<0.05).

No patients were dead after surgery. It has been reported that in the traditional Cox Maze surgery the incidence rate of sinus node syndrome is around 6-23%, and such patients usually received implanted pacemaker. Even though patients with preoperative sinus node syndrome or atrioventricular block have been included in these studies, such incidence rate was still too high. While in this study, no patients developed postoperative sinus node syndrome and atrioventricular block. Additionally, 7 patients developed postoperative low cardiac output syndrome, and six had a serious preoperative cardiac dysfunction with admission to ICU. However, these patients recovered well after surgery. Two different ablation procedures immediately relieved sinus rhythm up to 98%. After 30 months of follow-up, we found that the success rate of in knife groups was 73.7%, and 74.5% in Pen group, which was not significantly different (P>0.05), indicating that electric knife ablation for the treatment of atrial fibrillation is

effective, and its efficacy is similar to or better than Cardioblate™ Pen.

In conclusion, applying high-frequency knife Cardioblate™ Pen in the treatment of atrial fibrillation could achieve almost the same efficacy, which still need to be verified in more patients and more surgeons.

Disclosure of conflict of interest

None.

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