

Radiofrequency Ablation for Patients with Hypertrophic Obstructive Cardiomyopathy Accompanied by Severe Left Ventricular Outflow Tract Obstruction

ABSTRACT

Background: Patients with hypertrophic obstructive cardiomyopathy (HOCM) have few available nonsurgical treatment options. The feasibility of CARTOSound-guided catheter radiofrequency ablation (RFA) has been reported previously; however, relevant data are limited. The objective is to retrospectively evaluate the effectiveness and safety of CARTOSound-guided RFA for patients with HOCM.

Methods: Thirty-seven patients with successive HOCM accompanied by severe left ventricular outflow tract (LVOT) obstruction underwent CARTOSound-guided RFA were reviewed. The intracardiac echocardiography (ICE) images obtained were merged with the CARTO system to create a shell of the left ventricle. The systolic anterior motion-septal contact area marked from the ICE images was considered the target area for the current delivery of RFA. Follow-up data of the LVOT gradient examined before, 1 month, 6 months, 1 year, and every year after catheter-mediated RFA were accessed.

Results: The symptoms of 30 patients (81.1%) improved during the follow-up after RFA. The symptoms of all 30 patients were alleviated from the New York Heart Association (NYHA) class IV/III/II to the NYHA class II/I. A sustained and significant gradient reduction was observed in 28 patients (75.7%). The invasive pressure gradient of LVOT was 84.43 ± 27.55 mm Hg before RFA and 42.78 ± 36.38 mm Hg after RFA ($P < .001$), with a decrease of 41.65 ± 19.72 mm Hg. The median drop in pressure gradient was 36.0% (1.0-67.0%).

Conclusions: Catheter-mediated RFA is an effective and safe treatment for patients with HOCM. However, its long-term efficacy and safety should be validated in the future by conducting multicenter clinical trials with large sample sizes.








Keywords: Hypertrophic obstructive cardiomyopathy, intracardiac echocardiography, radiofrequency ablation, left ventricular outflow tract obstruction

INTRODUCTION

Hypertrophic obstructive cardiomyopathy (HOCM) is a genetic disease that increases the left ventricular outflow tract (LVOT) gradient (LVOTG). It is an autosomal dominant hereditary disease with varying penetrance.^{1,2} The estimated prevalence of hypertrophic cardiomyopathy is 1 in 500, and HOCM due to LVOT obstruction (LVOTO) accounts for 20-30% of it. The obstruction prevalence may increase up to 70% with provocation maneuvers.³ In the majority of cases, basal septal hypertrophy and systolic anterior motion (SAM) of the mitral valve (MV) are the key components causing LVOTO.⁴ Left ventricular outflow tract obstruction is associated with the incidence of dyspnoea, stroke, and even be responsible for sudden death.^{5,6}

The evidence suggests that symptomatic patients who do not experience relief from medical therapy may benefit from septal myectomy and alcohol septal ablation (ASA) to improve hemodynamics and clinical symptoms.⁷⁻¹⁰ However, 5-15% of the patients do not have a septal vessel suitable for ASA.^{11,12} Radiofrequency ablation (RFA) has become the principal therapeutic approach for various cardiac arrhythmias, and radiofrequency septal ablation for HOCM has been used

ORIGINAL INVESTIGATION

Lu Xu¹ 
Chenglong Miao¹ 
Pin Wang¹ 
Yanwei Wang¹ 
Jue Wang² 
Ru Xing¹ 
Suyun Liu¹ 
Ruining Zhang¹ 
Yan Jia¹ 
Bingyan Guo¹ 

¹Department of Cardiovascular Medicine, The Second Hospital of Hebei Medical University, Shijiazhuang, China

²Department of Cardiovascular Medicine, Beijing Anzhen Hospital, Capital Medical University and National Clinical Research Center for Cardiovascular Diseases, Beijing, China

Corresponding author:

Bingyan Guo
✉ 27602603@hebmh.edu.cn

Received: April 3, 2024

Accepted: September 16, 2024

Available Online Date: November 21, 2024

Cite this article as: Xu L, Miao C, Wang P, et al. Radiofrequency ablation for patients with hypertrophic obstructive cardiomyopathy accompanied by severe left ventricular outflow tract obstruction. *Anatol J Cardiol.* 2024;28(12):599-605.

DOI:10.14744/AnatolJCardiol.2024.4486



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as an alternative method in many patients.¹³⁻¹⁶ If a precisely small amount of the tissue at the anterior mitral leaflet–interventricular septum (IVS) contact point is damaged via the endocardial route, the SAM-septal feedback mechanism can be interrupted to effectively reduce the LVOTG. Therefore, the location of tissue damage is as crucial as the lesion size.

CARTOSound system (Biosense Webster, Diamond Bar, CA, USA) is a technology that integrates both an electro-anatomic electrophysiology mapping system to guide and mark ablation lesions and intracardiac echocardiography (ICE) images to provide high quality images.¹⁴ CARTOSound system could provide the precise RFA target area, and thus progressively improve the success rate of the procedure.¹⁴ However, the data on the effectiveness and safety of CARTOSound-guided RFA for patients with HOCM are limited. This study aimed to summarize our experience of using CARTOSound-guided RFA for HOCM.

METHODS

Study Population

The patients diagnosed as symptomatic HOCM who received the CARTOSound (Biosense Webster, Diamond Bar, CA, USA)-guided RFA in our hospital from December 2018 to June, 2023 were retrospectively analyzed. The inclusion criteria were 1) patients with symptomatic HOCM who refused to undergo myectomy and ASA; 2) those who had a resting or provoked LVOTG ≥ 50 mm Hg associated with remarkable SAM; and 3) patients with drug-refractory symptoms (New York Heart Association (NYHA) class III or IV). Hypertrophic obstructive cardiomyopathy patients without outflow tract obstruction or incomplete data were excluded. The study procedures were approved by the Ethics Committee of our institution.

Evaluation of LVOTG

All patients underwent resting or provoked echocardiography (Phillips IE33 scanner, Phillips S5-1 probe) before RFA procedures. During the procedures, the pressure gradient of the LVOT was measured by inserting a pigtail catheter at apical and subaortic sites while the patient was at rest. The procedures were performed only when the gradient met the obstruction criterion. If the gradient did not meet the obstruction criterion (≥ 50 mm Hg), isoproterenol was administered to provoke the pressure gradient in the patient.

HIGHLIGHTS

- Radiofrequency ablation is an effective and safe treatment for patients with hypertrophic obstructive cardiomyopathy.
- The trans-atrial septal approach is a key factor in achieving the efficacy and safety of the procedure because of the stability of the catheter and the good tissue-catheter contact force.
- Due to the stability of the catheter and the relatively low ablation power, no serious complications occurred.

Establishment of a 3-Dimensional Anatomical Model

The SoundStar catheter (Biosense Webster, Diamond Bar, CA, USA) was inserted through the left femoral vein to access the right atrium and right ventricle (RV). The phased array probe was used to generate ICE images of the tricuspid annulus, RV, and left ventricle (LV), and the resulting images were merged with the CARTO system (Biosense Webster, Diamond Bar, CA, USA). Structural borders were manually contoured and reconstructed at the end of diastole. Next, a new map of the multiplanar contact area of the anterior MV leaflet and the hypertrophied septum during systole (SAM-septal contact area, Figure 1) was created. Further, the SAM contact map was superimposed on the LV shell and was regarded as the RFA target. Additionally, decapolar diagnostic catheters (Biosense Webster, Diamond Bar, CA, USA) were inserted into the coronary sinus to record the intracardiac electrogram and pace when necessary.

Ablation by the Retrograde Aortic or Trans-Septal Approach

Once the ablation catheter was inserted in the LV, the patient was administered heparin (100 U/kg) intravenously to maintain an activated clotting time between 300 seconds and 350 seconds. The His bundle locations and left bundle branch potentials were directly mapped and annotated on the CARTO shell with respect to the SAM-septal contact area. The NaviStar THERMOCOOL catheter (Biosense Webster, Diamond Bar, CA, USA) or the THERMOCOOL SMARTTOUCH catheter (Biosense Webster, Diamond Bar, CA, USA) was used for RFA as per the choice of the operator. The procedures were performed on the first 4 patients using the retrograde aortic access approach after the specialized conduction system was mapped on the LV septum. If there was difficulty in maintaining catheter stability and tissue-catheter contact force (CF) due to the dynamic septum and turbulent LVOT blood flow with the retrograde aortic access, the transatrial septal approach was used with the assistance of a steerable sheath (Agilis, St Jude Medical, St Paul, Minnesota, USA) with a large or medium curvature, which improved catheter stability and CF. Radiofrequency ablation energy lesions were placed over the SAM-septal contact area using the CARTO and ICE navigation combination (Figure 2). To avoid inducing a complete heart block, the tip of the ablation catheter was navigated as far away as possible from the His bundle, which was marked by the electrode catheter or by a "tag" in the CARTO map. Radiofrequency ablation power was set at 35-45 W with saline irrigation at 17-25 mL/min and the temperature did not exceed 43°C. A region of approximately 1.6-19.3 cm² was ablated to cover the SAM contact area. Myocardial edema was observed up to 6 mm from the endocardial LV surface after the cessation of energy delivery.

Acute and Long-Term Success

The acute success of RFA was achieved with an invasive gradient reduction of 50%. The long-term success was defined as the LVOTG being reduced to less than 50 mm Hg.

Follow-Up

To prevent a paradoxical increase in obstruction (PIO), all patients were administered beta blockers and/or calcium

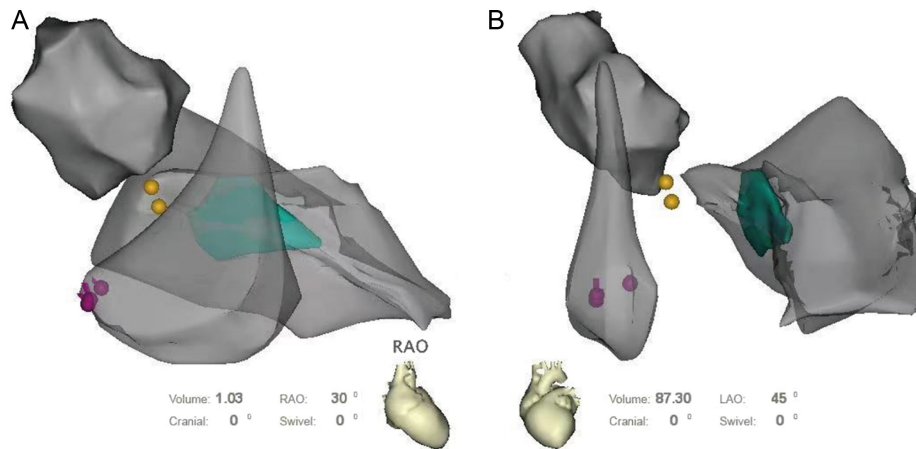


Figure 1. A 3-dimensional anatomical model was created with an ultrasound catheter. Several planes of ultrasound were used to create a complete image of the left ventricle (LV). Systolic anterior motion (SAM) septal contact in various intracardiac echocardiography (ICE) planes created a full SAM-septal contact map (green). The purple points indicate the tricuspid annulus; the yellow points indicate the area of the bundle of His or left bundle branch.

channel blockers after the procedure. Additionally, methylprednisolone sodium succinate was administered intravenously to avoid tissue edema at the end of the procedure. All patients were followed up by performing transthoracic echocardiography (TTE) at baseline, 1 month, 6 months, and every year thereafter. The documentation of the physical examination, 12-lead electrocardiogram, and TTE was reviewed. Echocardiography results at the last follow-up were considered to determine the long-term success of the procedure.

Statistical Analysis

Continuous variables were presented as means ± standard deviations or medians and interquartile ranges. Groups were compared using the *t*-test or the Mann–Whitney *U*-test based on the Shapiro–Wilks normality test. Categorical variables were represented as frequencies and percentages and

compared using Pearson’s chi-square test or Fisher’s exact test as needed. A Kaplan–Meier (K–M) survival curve showed the states of the patients during follow-up, and the log-rank statistic compared differences between the subgroups. Cox proportional hazard models were used to evaluate RFA outcome predictors, and hazard ratios (HR) and 95% confidence intervals (CI) were calculated. All tests were 2-sided, and values at *P* < .05 were considered statistically significant. All analyses were performed using IBM SPSS version 21.0.

Statement

DeepL was adopted for linguistic editing.

RESULTS

Baseline Data

Thirty-seven patients were included in this study, including 17 males and 20 females. Their ages ranged from 34 to

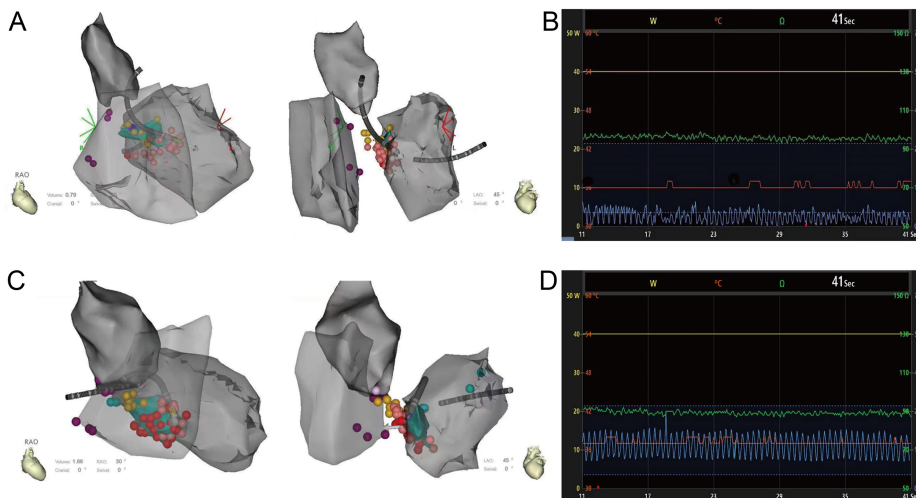


Figure 2. Different approaches of radiofrequency ablation to the SAM area. A, C: The right anterior oblique (RAO) and left anterior oblique (LAO) projection of the process of radiofrequency energy delivery over the SAM-septal contact area through retrograde aortic access (A) and trans-atrial septal access (C). The red and pink points indicate the ablation points; the purple points indicate the tricuspid annulus and the yellow points indicate the area of the bundle of His or the left bundle branch.

Table 1. Baseline Characteristics of Patients

Characteristics	Values
Age (years)	55.0 ± 10.0
Male, n (%)	17 (45.9)
NYHA class III/IV, n (%)	27 (73.0)
LVEF, (%)	67.4 (65.15-74.74)
Hypertension, n (%)	13 (35.1)
Diabetes, n (%)	4 (10.8)
Atrial fibrillation, n (%)	5 (13.5)
Atrial premature complex, n (%)	1 (2.7)
Coronary heart disease, n (%)	2 (5.4)
Atrial septal defect, n (%)	1 (2.7)
Stroke, n (%)	2 (5.4)
Myasthenia gravis, n (%)	1 (2.7)
Multiple site obstruction, n (%)	4 (10.8)
Multiple site hypertrophy, n (%)	5 (13.5)

Variables are represented as the mean ± standard deviation, medians and interquartile range, or frequencies and percentages. LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.

77 years, with a mean age of 55.0 ± 10.0 years. The baseline characteristics and complicated diseases are listed in Table 1. All patients received bisoprolol and/or diltiazem therapy. Six patients complicated with atrial fibrillation or atrial premature complexes underwent RFA for HOCM and arrhythmia simultaneously. Four patients were diagnosed with midventricular obstruction with/without subaortic obstruction. Moreover, 27 patients were in NYHA class III/IV before RFA.

Intracardiac Echocardiography-Guided RFA

Left ventricular ablation was performed on 33 (89.2%) patients using the transatrial septal approach, whereas the remaining 4 (10.8%) patients were treated using the retrograde aortic approach. The ablation area was 4.40 cm² (2.75-6.45 cm²). The invasive pressure gradient of LVOT was 84.43 ± 27.55 mm Hg before RFA and 42.78 ± 36.38 mm Hg after RFA (*P* < .001), with a decrease of 41.65 ± 19.72 mm Hg. The median pressure gradient drop was 36.0% (1.0-67.0%). Additionally, acute procedure success was achieved in 26 (70.3%) patients, with no less than a 50% pressure gradient decrease. During the procedure, 9 (24.3%) patients developed a left bundle branch block (LBBB) because of ablative damage.

Transthoracic Echocardiography Assessment and Follow-Up

The patients were followed up for 6-64 months, with a median follow-up of 36 months. They were followed up at 1 month, 6 months, and 12 months after RFA and every year thereafter. No patients were lost to follow-up.

The IVS before and after RFA was 20.27 ± 4.45 mm and 18.32 ± 4.10 mm, respectively (*P* = .054). The number of patients with the NYHA class III and IV decreased from 27 (73.0%) to 4 (10.8%) (*P* < .001).

The line chart presented the TTE pressure gradient before and after the procedure, at 1 month, 6 months, 1 year, and

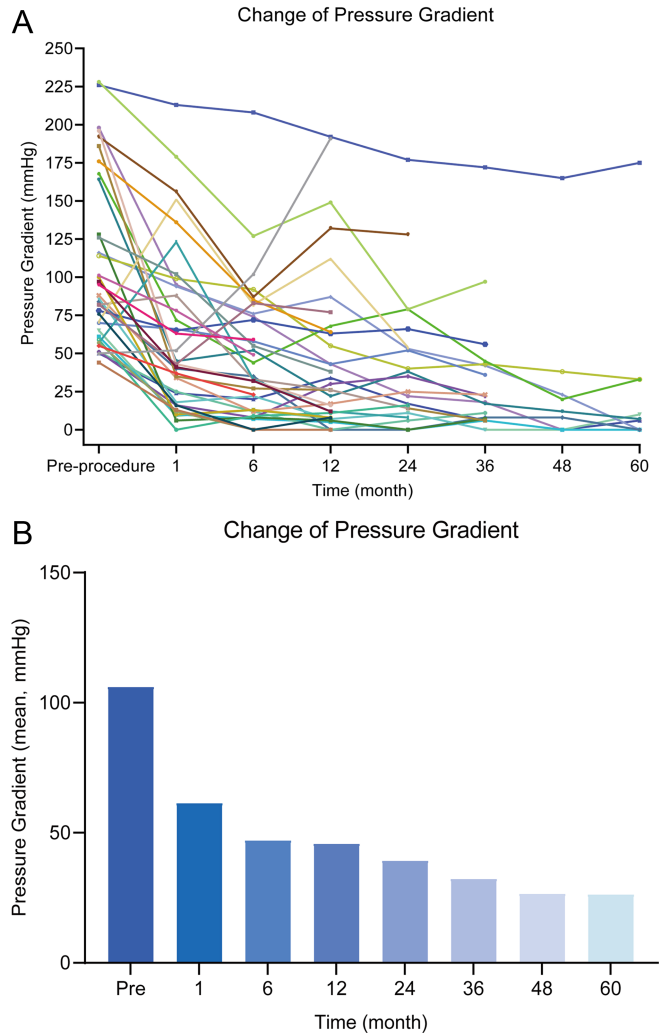


Figure 3. Changing of the pressure gradient before and after the procedure. (A) The line chart of the TTE pressure gradient before and after the procedure, at 1 month, 6 months, 1 year, and annually thereafter. Each line represents 1 patient. (B) The bar chart of the mean TTE pressure gradient level during follow-up.

every year thereafter, with the mean level shown in the bar chart (Figure 3).

The K-M curves of the results are presented in Figure 4. In 28 patients (75.7%), the pressure gradient decreased to 50 mm Hg or less at the last follow-up visit (Figure 4A), with a median pressure gradient of 16.0 mm Hg (7.5-51.5 mm Hg), and the median decrease in the pressure gradient was 64.0 mm Hg (41.5-102.0 mm Hg). Moreover, the number of patients classified as NYHA class I or II increased to 33 (89.2%, Figure 4B). Next, the patients were divided into 2 subgroups based on the long-term follow-up results: the success group and the failure group. At baseline, no statistical difference was observed between the 2 groups in terms of age, sex, hypertension, atrial fibrillation, coronary heart disease, NYHA class, IVS, and preoperative pressure stage. Intraoperative information such as the approach of the catheter entry, ablation area, and the development of LBBB

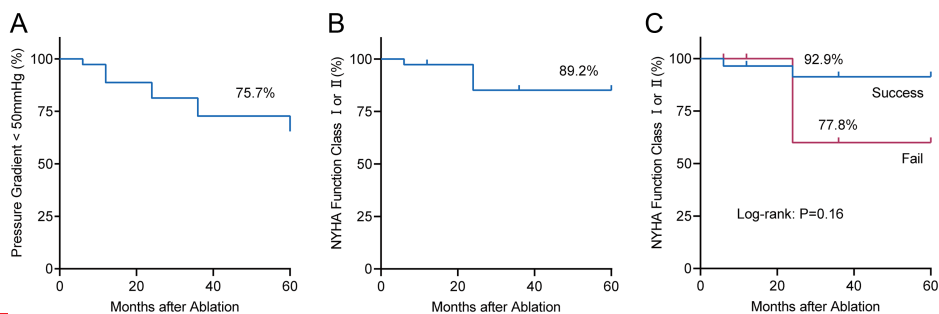


Figure 4. Kaplan-Meier curves. (A) 75.7% of the patients achieved the long-term success of RFA with the pressure gradient reduction to 50 mm Hg or below. (B) The proportion of patients classified as NYHA class I or II increased to 89.2%. (C) The patients were divided into 2 subgroups: success and failure, and the proportion of patients who achieved NYHA class I or II during follow-up was 92.9% vs. 77.8%, with a log-rank test *P*-value of .16.

was not statistically different between the 2 groups. The proportion of patients who achieved NYHA class I or II during follow-up was 92.9% and 77.8% in the success and failure groups, respectively. The *P*-value of the log-rank test was .156 (Figure 4C) and the HR was 0.17, 95% CI: 0.14-1.97. Cox proportional hazard models were used to evaluate the long-term success predictors of RFA, including the baseline data of patients and intraoperative parameters, and no statistically significant predictors were found.

Complications

Nine patients developed a complete LBBB during the ablation, 10 patients developed a left posterior fascicle block, and 2 patients developed a left anterior fascicle block. Nonetheless, no patient showed acute pericardial tamponade or PIO during the ablation.

DISCUSSION

For patients with drug-resistant, symptomatic HOCM, surgical myectomy is the most commonly used treatment approach.¹⁷ However, surgical myectomy is morbid and its success rate depends on the experience of operators. Alcohol septal ablation is an alternative non-surgical approach widely applied to patients who refuse to undergo surgery or are at high risk for surgery.^{18,19} But, ASA is constrained by septal arterial anatomy²⁰ and might result in unsatisfactory outcomes in a third of patients.²¹⁻²³ Radiofrequency ablation has been recently developed to alleviate LVOTO and was reported to achieve a >50% reduction in the resting gradient.²⁴ In this study, we retrospectively reviewed the patients who underwent CARTOSound-guided catheter RFA. The symptoms of 30 patients (81.1%) improved during the follow-up after RFA. The invasive pressure gradient of LVOT was 84.43 ± 27.55 mm Hg before RFA and 42.78 ± 36.38 mm Hg after RFA, with a decrease of 41.65 ± 19.72 mm Hg. No serious complications developed intra-procedurally or during follow-up.

The radiofrequency-generated energy was effective in improving the NYHA class and LVOTG in most patients in the present study. Thirty patients (81.1%) were alleviated from the NYHA class IV/III/II to the NYHA class II/I, and 28 patients (75.7%) were observed with sustained and significant gradient reduction. These results were similar to a previous study.²³

The efficacy of a procedure depends on 2 main aspects. First, the use of an intracardiac ultrasound catheter allows for precise ablation during the procedure. A study has shown that ICE is an effective tool during the procedure because even mild damage can interrupt the SAM-septal feedback mechanism, thereby effectively reducing LVOTGs.¹⁴ Tissue injury sites and locations are equally important, and real-time ICE images help operators precisely target the SAM-septal contact area and confirm tissue edema at the desired location on the septum. Although the tissue damage size may appear smaller compared to other forms of septal reduction, its accuracy is sufficient to affect the SAM and eventually reduce LVOTGs. Second, increasing the lesion size is a major goal of catheter-mediated ablation for HOCM. When RF duration and power are constant, lesion depth, diameter, and size can be increased proportionately with increasing CF.

Left ventricular ablation was performed on 33 (89.2%) patients using the transatrial septal approach, whereas the remaining 4 (10.8%) patients were treated using the retrograde aortic approach. During ablation, there was a risk of His bundle damage owing to catheter instability. To prevent the catheter from jumping to the His bundle, we adopted the transatrial septal approach instead of the retrograde aortic access approach. The transatrial septal approach improves the stability of the catheter, making the catheter tissue CF sufficient. Catheter stability is crucial for ensuring the effectiveness and duration of a single ablation. Herein, no cases of AV block, cardiac tamponade, or PIO were observed in the 37 patients, which indicated the transatrial septal approach has fewer complications and improves the catheter attachment pressure and effectiveness.²⁵

Ventricular ectopies originated from the mechanical effect of the catheter interrupted AV conduction observation. In this condition, the coronary sinus catheter was paced to confirm the intact AV conduction. Furthermore, to prevent cardiac tamponade induction, we manipulated the mapping and ablation catheters gently with the help of a fluoroscopy and 3-dimensional mapping system. Since outflow tract obstruction is the result of basal septal hypertrophy and SAM of the MV, we established an ultrasonic anatomical model to accurately mark the position of mitral valve and interventricular septum adhesion. The 3-dimensional

mapping system enables us to perform precise intervention, thus reducing the pressure stage difference and alleviating symptoms. Moreover, cardiac effusion was monitored by intracardiac echocardiology at any time. In contrast to previous results,^{13,14,16} none of the present patients experienced PIO, which occurs when ablation power is ≥ 50 W (maximum 75 W). The reason behind this may be that the power used in the present study did not exceed 45 W, as well as only a few audible steam pops were observed in all patients.

Study Limitations

The feasibility of CARTOSound-guided catheter RFA for HOCM has been reported in recent years. However, the sample size is always small, and follow-up time is generally short. Our preliminary results further suggest RFA as an alternative treatment in HOCM patients, especially in those who are unsuitable for ASA or surgical myectomy. The present study has several limitations that need to be acknowledged. First, Lawrenz and Kuhn²⁶ first reported the use of RFA by RV septal aspect in a 45-year-old patient with severe HOCM. Lawrenz et al¹⁶ reported no significant difference in the LVOTG after ablation between the LV aspect and the RV septal aspect ($P > .05$). However, herein, we used the left-sided approach in all patients, with no comparison to the RV septum approach. Second, this is a single-center study with a relatively small sample size. This may be the reason for the lack of major complications, and no long-term predictors of RFA success were observed. Third, this is a retrospective study, and selection bias or observer bias might exist. Besides, a causal relationship cannot be inferred from this study. Therefore, the present conclusions need to be further confirmed by conducting multicenter clinical trials with a large sample size and long-term follow-up.

CONCLUSIONS

Catheter-mediated RFA achieved an immediate decrease in the catheter pullback gradient and a further reduction of the gradient during follow-up. However, the long-term efficacy and safety of the procedure need to be validated by conducting multicenter prospective randomized controlled clinical trials with large sample sizes.

Ethics Committee Approval: Approval Letter of Research Ethics Committee was approved by the Research Ethics Committee of the Second Hospital of Hebei Medical University on January 8, 2004. Approval Letter Number is 2024-R002.

Informed Consent: Written informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: L.X., C.M., and B.G. designed the study. B.G. takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation. P.W. carried out the data analysis, and Y.W. provided support for Carto and screening and drawing of the figures in the article. R.X., R.Z., J.Y., J.W., and S.L. participated in the data collection and contributed to data analysis. All authors participated in the manuscript writing and the final approval.

Declaration of Interests: The authors have no conflict of interest to declare.

Funding: This study was supported by the Natural Science Foundation of Hebei Province (H202006504).

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