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Original Article

Comparison of automated fastener (Cor-Knot) versus manually tied knots in patients undergoing minimally invasive mitral valve replacement

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Abstract

Introduction: Automated knot fastener has been used in minimally invasive valve surgery to alleviate the longer total operating time and improve outcomes. Their advantages over manual knot tying remain questionable. This study aims to compare automated knot fasteners' efficacy with conventional knot-pushers in minimally invasive mitral valve replacements (MiMVR).

Methods: Between 2016 and 2020, 50 patients underwent isolated mechanical mitral valve replacement via right mini-thoracotomy in rheumatic or degenerative mitral valve disease. The patients were grouped into two groups. Group I (n= 25) included patients who had MiMVR using the Cor-knot device, and Group II (n= 25) had MiMVR using the conventional knot-pusher. Primary endpoints were cross-clamp, cardiopulmonary bypass, and total operative times and the secondary outcomes were paravalvular leak and reoperation. There were no significant differences in the demographic data between the two groups.

Results: Cross-clamp time (79± 1.11 vs. 98.88± 1.34 min; P<0.001), cardiopulmonary bypass time (132 (Q1- Q2: 129- 134) vs. 148 (140- 155) min; P<0.001) and operative times (206 (203- 209) vs. 228 (223- 234) min; P<0.001) were significantly shorter in Group I. There was no difference in postoperative complications between groups. The early paravalvular leak occurred in one patient (4%) in Group I and required valve re-exploration. In Group II, four patients (16%) had a paravalvular leak; 3 of them were severe and required valve re-exploration (P= 0.35). Transthoracic echocardiography at discharge revealed no evidence of a paravalvular leak in both groups.

Conclusion: Automated fastener device (Cor-knot) could reduce operative times during minimally invasive mitral valve replacement. Operative complications are comparable between both techniques, and follow-up studies are recommended.

KEYWORDS

Automated knot-fastener; Cor-Knot; Heart valves; Minimally invasive mitral surgery

Article History

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Introduction

Minimally invasive surgery is increasingly used for mitral valve replacement [1]. The minimally invasive mitral valve replacement (MiMVR) outcomes are comparable to those through full sternotomy [2]. Additionally, MiMVR has better cosmetic results, less pain and transfusion requirements, and shorter hospital stay. MiMVR provides better visualization of the mitral valve, facilitating various repair techniques that are technically demanding with the conventional approach [3].

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However, MiMVR is time-consuming, making it disadvantageous at high volume centers [4]. Many factors are responsible for a longer total operative time, which includes patient and operator factors. The use of video-assisted knot-tying with the knot pusher requires better hand-eye coordination, and it could be a reason for more prolonged cardiopulmonary bypass (CPB), ischemic, and operative times.

Automated knot fastener (Cor-Knot device, LSI Solutions, Victor, NY, USA) could reduce the operative times and affect the rate of postoperative complications [5]. This study aimed to compare the early outcomes of conventional knot-tying with automated knot-fastener systems in mitral valve replacement through right mini-thoracotomy in a single tertiary center.

Patients and Methods:

The Local Research Ethics Committee approved this study. Minimally invasive mitral valve surgery was introduced to our center in 2012 and Cor-Knot in 2015. We familiarized ourselves with the automated fastener, using it randomly for one year, and hence we did not include that year in this study. Between January 2016 and January 2020, all patients who received mitral valve replacement through right mini-thoracotomy were evaluated for possible inclusion in our research. We divided the patients into two groups. Group I had mitral valve replacement using an automated knot fastener (Cor-Knot device), and Group II had the same procedure with conventional knot tying with a knot pusher. Of the total patients evaluated, we included the first twenty-five patients in either group meeting the inclusion and exclusion criteria. We included patients less than sixty years of age with severe symptomatic mitral valve disease and normal sinus rhythm, who received isolated MiMVR for rheumatic or degenerative pathology. We excluded patients who had emergency surgery, infective endocarditis, concomitant cardiac procedure, or ischemic mitral valve disease. The primary outcomes were cross-clamp, cardiopulmonary bypass, and total operative times. The secondary outcomes were paravalvular leaks and early reoperation.

Operative technique

We implemented the standard techniques of mitral valve replacement through the right mini-thoracotomy in all patients. After establishing double-lumen endotracheal intubation, standard monitoring lines and transesophageal echocardiography probe were inserted. The patients were positioned in the semi-lateral position and to the left. A 5cm inframammary incision was carried out through the third or fourth intercostal space. The right hemithorax was insufflated with carbon dioxide. A combination of soft tissue retractor and small Finochito retractor was used to facilitate rib spreading (Figure 1).

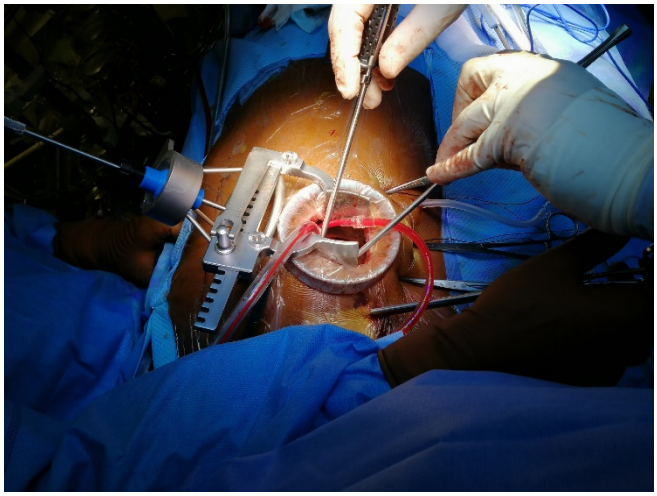

Figure 1: Exposure of the mitral valve through the right anterolateral mini-thoracotomy. A combination of soft and small Finochito retractors was used for a better view

A separate stab incision was made in the second intercostal space along the right anterior axillary line for the endoscopic camera (Karl Storz SE& Co. KG.Tuttigen, Germany). The pericardium was opened and retracted with sutures that were brought out through three separate one cm incisions. CPB was set up with femoral cannulation. We used a separate two cm incision for insertion and application of aortic cross-clamp, which was made medial to the anterior axillary line (Chitwood Aortic clamp – Cardiva Medical Inc, Sunnyvale, USA). Once CPB was established, the heart was arrested with an antegrade infusion of Custodial solution. A separate stab incision was also made in the fourth intercostal space in the right parasternal area for left atrial retraction with an atrial roof retractor (Aesculap, Inc. Centre Valley, USA). Mitral valve was replaced with

mechanical valve prosthesis appropriately either in an intra-annular or supra-annular fashion with interrupted Teflon pledgeted sutures secured either with the Cor-Knot device or with the conventional Knot pusher. Further to the prosthesis's satisfactory placement, the left atrium was closed and weaned off CPB after thorough deairing. Post CPB transesophageal studies were recorded and interrogated for paravalvular leak and other flow dynamics.

Statistical analysis:

Continuous data were expressed as mean and standard deviation if normally distributed or median and (25th and 75th percentiles) if non-normally distributed and binary data as numbers and percentages. We used the t-test to compare normally distributed continuous variables and the Mann-Whitney test for non-normally distributed variables. Chi-square or Fisher exact test was used to compare qualitative variables when appropriate. Linear regression analysis was used to identify factors associated with long cross-clamp time. A P-value of less than 0.05 was considered statistically significant. All analyses were performed using Stata 16 (STATA Corp-College Station- Texas- USA).

Results

Preoperative data

Age was 41 (33- 47) years in Group I and 41 (33- 52) years in Group II (P= 0.52). There was no difference in the preoperative data between both groups. (Table 1)

Table 1: Preoperative Data. Continuous data were presented as median (25th- 75th percentiles) and categorical data as numbers and percentages.

	Group I (n= 25)	Group II (n= 25)	P-value
Age (Years)	41 (33- 47)	41 (33- 52)	0.52
Male	20 (80%)	15 (60%)	0.12
Hypertension	17 (68%)	17 (68%)	>0.99
Diabetes mellitus	18 (72%)	20 (80%)	0.51
Stroke	2 (8%)	1 (4%)	>0.99
Renal failure	1 (4%)	3 (12%)	0.61
Ejection fraction (%)	49 (47- 52)	50 (48- 53)	0.27

Operative and postoperative data

Cross-clamp, cardiopulmonary bypass, and operative times were significantly shorter in Group I. There was no significant difference in postoperative complications between both groups (Table 2). The postoperative paravalvular leak was non-significantly higher in Group II. The early paravalvular leak occurred in one patient (4%) in Group I and required valve re-exploration. In Group II, four patients had a paravalvular leak (16%); three (12%) were severe and required valve re-exploration.

Cor-Knot was significantly associated with reduction in the cross-clamp time (coefficient (95% CI): -19.88 (-23.37- -16.39); P<0.001). (Table 3). In Group II, two patients developed postoperative heart block and required a permanent pacemaker. Group I had a shorter hospital stay than Group II. Both groups had the same rate of postoperative bleeding.

Discussion

Despite the clinical advantages of minimally invasive surgery, few constraints preclude many centers from adopting minimal access valve surgery program. The presumed benefits of minimally invasive mitral valve surgery through the right mini-thoracotomy include avoidance of sternotomy, less blood transfusion, shorter ICU, hospital stay, and early resumption of normal activities [6]. Mitral valve repair has been a challenging surgery for trainees who could not visualize the specific patho-anatomy and its correction by various techniques. Video-assisted MIMVS has now made it feasible for the operator and the other surgeons to perceive the level of resection of valve leaflets and preserve chords to maintain the left ventricle's integrity. However, as with any video-assisted minimal access surgery, the steep learning curve and the longer total operating time has resulted in many centers to retract this technique for a long time [7,8]. The equation of more prolonged CPB [9] and cross-clamp time to poor surgical outcomes, especially in patients with low ejection fraction, made a negative impact on this technique to a wide range of cohorts [10,11]. Other shortcomings with this procedure are cannulation and clamping related complications, including vascular damage [12].

Table 2: Operative and postoperative data. Continuous data were presented as median (25th- 75th percentiles) and categorical data as numbers and percentages.

	Group 1 (n= 25)	Group 2 (n= 25)	P-value
Cross-clamp time (min)	79± 1.11	98.88± 1.34	<0.001
Cardiopulmonary bypass time (min)	132 (129- 134)	148 (140- 155)	<0.001
Operative time (min)	206 (203- 209)	228 (223- 234)	<0.001
Paravalvular leak	1 (4%)	4 (16%)	0.35
Permanent pacemaker	0	2 (8%)	0.49
Valve re-exploration	1 (4%)	3 (12%)	0.61
Re-exploration for bleeding	3 (12%)	3 (12%)	>0.99
Stroke	0	1 (4%)	>0.99
Hospital stay (days)	5 (5- 6)	6 (6- 6)	0.004

With the transcatheter aortic valve replacement in intermediate-risk group reporting non-inferior results compared to surgical valve replacement, it has become imperative for the surgical fraternity to be innovative and less invasive without compromising the results [13, 14]. The perception of having a valve replaced through small incisions will pose a big challenge to the conventional surgeons who may not convince the patients in the future. Therefore, the key thing will be to keep the skills updated and be less traumatic to enhance early recovery.

Table 3: Factors associated with long cross-clamp time

Risk factors	Univariable analysis	
	Coefficient (95% CI)	P-value
Age	0.016 (-0.32- 0.34)	0.92
Gender	-4.28 (-11.52- 2.98)	0.24
Diabetes mellitus	2 (-5.67- 9.88)	0.61
Hypertension	-1.1 (-8.32- 6.12)	0.76
Renal failure	-0.75 (-13.18- 11.68)	0.90
Stroke	-3.13 (-17.3- 11.04)	0.66
Ejection fraction	0.48 (-0.52- 1.48)	0.34
Cor-Knot	-19.88 (-23.37- -16.39)	<0.001

The Cor-Knot device usage has been previously reported to reduce the CPB and total operating time in mitral valve repair and aortic valve replacement [15,16]. Our study's results demonstrated shorter cross-clamp time, CPB time, and total operative time compared to our control group. There was a time difference of twenty minutes in cross-clamp time, sixteen minutes in the CPB time, and twenty-two minutes in the total operating time, which were all significant. In one of the early reports of the ex vivo minimally invasive model, Lee and coworkers had demonstrated similar time savings [17]. After CPB, the immediate transesophageal echocardiogram showed comparable results and no significant difference in paravalvular leak or gradient across the valve. However, three in the knot-pusher group had re-intervention immediately due to severe paravalvular leak as opposed to one in the Cor-Knot group. This could also be due to the initial learning experience with MiMVR using knot pusher. Paravalvular leak as postoperative complication occurred mostly in our study's early two years, reflecting the importance of practical experience and training in this minimally invasive surgery field. Group I had a shorter hospital stay than Group II. There were no significant differences with other immediate clinical outcomes between the two groups.

One of the most challenging situations in minimally invasive surgery could be dealing with loose knots in valve replacements as opposed to valve repair. It will be challenging to get a loos knot after placing the valve, especially if it occurs towards the end. This did not happen with either of the groups during our study period. All the patients also underwent replacements of the mitral valve in the first run with good operative results. This could be due to the small number in both the groups during our study. The difference may become apparent if we power our study and then compare the postoperative results.

Although the Cor-Knot system's relative cost is assumed to be expensive than the conventional sutures, if we relate those patients with the shorter ICU stay and early discharge, it will give net cost-effectiveness in managing such patients [18]. Although not statistically significant, more patients had reintervention in Group II due to paravalvular leak. A second intervention incurred more consumables and human resources, which could be reduced if the first-time intervention was surgically effective.

Limitations

This is a retrospective observational study performed to assess the feasibility of Cor-Knot and compare it with the conventional knot-pusher and hence may be subjected to bias. We only compared the early postoperative outcomes. Further studies are required with an appropriate number of patients and more participating centers with longer follow-up to confirm our findings.

Conclusion

Our early results suggest a safe and reliable application of the automated fastener device (Cor-Knot) in minimally invasive mitral valve replacement with a possibility to reduce operative times. Operative complications are comparable between both techniques, and follow-up studies are recommended.

Conflict of interest: Authors declare no conflict of interest.

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