








Review article:

EFFICACY OF AUTOMATED FASTENERS VERSUS HAND-TIED KNOTS IN CARDIAC SURGERY: A SYSTEMATIC REVIEW AND META-ANALYSIS

Zoaib Habib Tharwani^a , Muhammad Abdul Qadeer^b , Ali Abdullah^b , Rubab Ali^b , Muhammad Ahmed Chaudhary^b , Shurjeel Uddin Qazi^a , Sameh M. Said^{c,d*} 

- ^a Department of Medicine, Dow University of Health Sciences, Karachi, Pakistan
- ^b Department of Medicine, Jinnah Sindh Medical University, Karachi, Pakistan
- ^c Division of Pediatric and Adult Congenital Cardiac Surgery, Maria Fareri Children’s Hospital, Westchester Medical Center, Valhalla, New York 10696, USA
- ^d New York Medical College, 100 Woods Road, Valhalla, New York 10595, USA

* **Corresponding author:** Sameh M. Said, Professor of Surgery and Pediatrics, New York Medical College, Chief, Division of Pediatric and Adult Congenital Cardiac Surgery, Maria Fareri Children’s Hospital, Department of Surgery, Westchester Medical Center, 100 Woods Road, Valhalla, New York, USA 10595; Department of Cardiothoracic Surgery, Faculty of Medicine, Alexandria University, Alexandria, Egypt.
Phone: 914-493-6696, Fax: 914-493-3853, E-mail: Sameh.Said@wmchealth.org

<https://dx.doi.org/10.17179/excli2023-6885>

This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0/>).

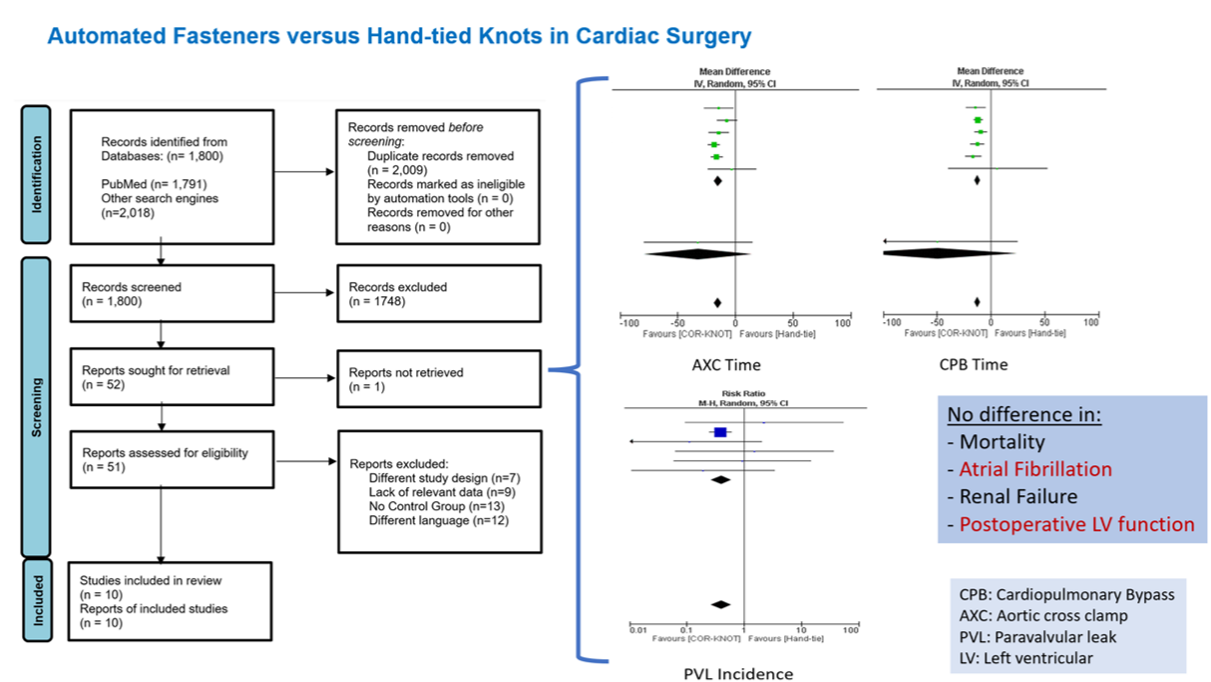


Figure 1: Graphical abstract

ABSTRACT

Valve surgery is common in cardiac procedures, with fasteners like COR-KNOT® and hand-tied knots used for knot securing. This study compares their efficacy in valve surgery patients. We searched PubMed, SCOPUS, and Cochrane Central until August 2023. Outcomes assessed included aortic cross-clamp time (AXT), cardiopulmonary bypass (CPB) time, valvular regurgitation, mortality, prolonged ventilatory support, atrial fibrillation, post-operative left ventricular ejection fraction (LVEF), and renal failure. Subgroup analysis was performed for minimally invasive and open cardiac surgery. We used a random effects model for analysis. We included eight observational studies and two randomized controlled trials (RCTs) with a total of 1.411 participants. COR-KNOT significantly reduced AXT [MD -15.14, 95 % CI (-18.57, -11.70), $P < 0.00001$] and CPB time [MD -12.38, 95 % CI (-14.99, -9.77), $P < 0.00001$]. Valvular regurgitation [RR 0.40, 95 % CI (0.26, 0.61), $P < 0.0001$] and need for prolonged ventilatory support [RR 0.29, 95 % CI (0.13, 0.65), $P = 0.003$] were significantly lower with COR-KNOT. There were no significant differences in mortality [RR 0.39, 95 % CI (0.09, 1.69), $P = 0.44$], atrial fibrillation [RR 1.03, 95 % CI (0.83, 1.27), $P = 0.81$], LVEF changes [MD 0.05, 95 % CI (-1.37, 1.47), $P = 0.95$], or renal failure [RR 0.87, 95 % CI (0.16, 4.80), $P = 0.87$]. COR-KNOT devices reduce operative time and valvular regurgitation without increasing mortality or adverse outcomes. This supports their use in enhancing surgical efficiency and patient outcomes. However, ongoing discussions about suturing techniques, especially in minimally invasive procedures, highlight the need for further research and consensus among practitioners.

Keywords: Cardiac valvular surgery, COR-KNOT, automated fasteners, hand-tied knots

INTRODUCTION

The incidence of degenerative valve disease is on the rise as the general population ages, leading to an increase in the need for surgical interventions to repair or replace these valves. The incidence of valvular diseases in the general population is 11.9 %, with mitral regurgitation being the most common, followed by aortic regurgitation (Matiasz and Rigolin, 2018). Surgery remains the mainstay of treatment for symptomatic patients with severe disease, with excellent long-term outcomes (Reddy and Punjabi, 2007).

A fundamental aspect of heart valve surgery is knot-tying. The traditional method of achieving secure knots is hand-tying (Jha et al., 2007). Hand-tying, however, has several potential drawbacks, such as longer aortic cross-clamp time (AXT) and cardiopulmonary bypass (CPB) time, especially when multivalvular procedures are needed. This may increase the risk of postoperative morbidity and mortality (Ler et al., 2021; Sazzad et al., 2021). Additionally, hand-tying, if insecure, may lead to higher rates of postoperative paravalvular leak or prosthetic dehiscence (Lee et al., 2018).

Automated fasteners, such as the COR-KNOT® by LSI Solutions® are used in heart

valve surgery to eliminate the need for manual tying during prosthetic implantation. It consists of an automated fixture with an articulating arm and a target device holder, as well as one or more additional automated fixtures with suturing arms and needle holders (Sazzad et al., 2021). The device can rotate the target device, allowing the suturing arms to perform operations such as forming sutures without the need for human intervention (Lee et al., 2018). The use of automated fasteners has been shown to reduce AXT and CPB time, leading to shorter overall operative time when compared with hand-tying (Salmasi et al., 2019; Sazzad et al., 2021; Cody et al., 2021).

While the benefits of automated fasteners are clear, it is crucial to be aware of the potential complications associated with them. Potential concerns include thrombi/clot formation with subsequent systemic embolization, coronary ostial obstruction, infective endocarditis, periprosthetic regurgitation and hemolysis (Sadeghian and Savand-Roomi, 2017).

There continues to be a lack of consensus regarding the role of automated suture fasteners, such as the COR-KNOT device, in the current era and if they are in fact a better technique compared to hand-tying, and therefore should be adopted on a larger scale. They

appear to be of greater value in minimally invasive valve surgery or when the surgical field is limited (Perin et al., 2019). Given these critical considerations, this study aims to assess the efficacy of using COR-KNOT devices over hand-tied sutures in valvular surgery.

METHODS

We followed the Preferred Reporting Items for Systematic review and Meta-Analyses (PRISMA) guidelines and the Risk of Bias in Systematic reviews and assessment of multiple systematic reviews (AMSTAR) 2 while performing this meta-analysis (Shea et al., 2017; Page et al., 2021).

Data sources and search strategy

MEDLINE, EMBASE and Cochrane CENTRAL were comprehensively searched from inception through July 2023 by two independent reviewers (MAC and RA). We extracted studies based on abstracts and titles. A full-text appraisal was sought when required. MeSH phrases and keywords were used to find keywords for “COR-KNOT”, “automated fastener”, “automated suture”, “automated suture fastening device”, “automated titanium fasteners” and “COR-KNOT heart valve surgery”.

Study selection

Data extraction and assessment of study quality

We included studies if they were: (1) randomized controlled trials (RCTs) or analysis of RCTs that determined the impact of automated sutures and hand-tied sutures in different interventional arms, (2) reported either of aortic cross-clamp time (AXT), cardiopulmonary bypass (CBP) time, valvular regurgitation, mortality, prolonged ventilatory support, atrial fibrillation, postoperative left ventricular ejection fraction (LVEF), and renal failure as one of their outcomes, (3) included patients with valvular disease(s) undergoing surgical replacement or repair. A third investigator (AA) was consulted in case of any disagreement regarding study selection. All articles

were then uploaded to Endnote Reference Library (Version X7.5; Clarivate Analytics, Philadelphia, Pennsylvania) software to remove any duplicates.

Two reviewers (ZHT and MAQ) independently extracted from the selected studies the characteristics of the studies, patient demographics, summary events, number of events, sample sizes and treatment type. Summary events were also extracted for outcomes of interest, and mean difference (MD) with standard deviation (SD) from baseline.

The quality assessment of included studies was conducted through Joanna Briggs’ Institute (JBI) critical appraisal checklist (Moola et al., 2020). Other studies included participants with similar baseline characteristics (Grapow et al., 2015; Plestis et al., 2018; Ler et al., 2021). The studies of Beute et al., Perin et al. and Grapow et al. did not provide information regarding strategies employed to reduce the effect of confounding factors (Beute et al., 2018; Perin et al., 2019; Grapow et al., 2015). All studies did not provide follow up details (Supplementary information, Tables 1, 2). The RCT by Etiway et al. did not provide information about blinding of the treatment allocators and outcome assessors (Etiway et al., 2018).

Statistical analysis

RevMan (version 5.4.1; Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration) was used to conduct the meta-analysis. The outcomes of interest were provided as Risk Ratios (RR) with 95 % confidence intervals (CIs) and were aggregated using an inverse variance weighted random-effects model. Forest plots were used to graphically display the pooled analyses. MD and 95 % CIs were used to present the continuous outcomes of interest. Inverse variance weighted random-effects model was used to pool MD and 95 % CI. We used the median value where mean was unavailable. Difference in means between the baseline and post-intervention measurement was calculated when the change from baseline was not reported. The SD for change was derived from

the baseline and the follow up, assuming their correlations were 0.5. The Higgins I^2 was utilized to assess heterogeneity between trials. A 25–50 % number was regarded as low, 50–75 % moderate, and >75 % serious. In all cases, a P-value less than 0.05 was considered significant.

RESULTS

Search results and baseline characteristics

The PRISMA flow chart below summarizes the search and study selection process (Figure 2). Initial search yielded a total of 1800 results. After screening and removal of duplicates, 51 articles were assessed for eligibility. Among those, seven of the studies had a different study design, nine studies did not report relevant outcomes of interest, thirteen of them did not have a control group, and twelve studies were not in English language. A total of 2 RCTs and 8 cohorts were included in the final analysis (Grapow et al., 2015; Beute et al., 2018; Etiwy et al., 2018; Lee et al., 2018; Loberman et al., 2018; Plestis et al., 2018; Sabik et al., 2018; Perin et al., 2019; Morgant et al., 2020; Ler et al., 2021).

A total of 1,411 participants were included in our study amongst which 721 were randomized to COR-KNOT while 690 participants were grouped into hand-tied knots. Table 1 and 2 summarize the baseline characteristics of included studies. Table 3 contains the baseline characteristics of the study population of Ler et al. (2021), as this particular study did not differentiate between minimally invasive cardiac surgery and open heart surgery. Table 4 summarizes the study details of the included studies, including the surgical procedure performed.

Outcomes

Aortic cross-clamp Time (AXT)

A total of six studies reported aortic cross-clamp time among patients with valvular disorder. We performed a subgroup analysis to compare the AXT, which included minimally invasive surgery and open cardiac surgery. Analysis revealed a significant difference in AXT between COR-KNOT versus hand-tied knots [MD -15.14, 95 % CI (-18.57, -11.70), $P < 0.00001$, $I^2 = 15\%$] (Figure 3).

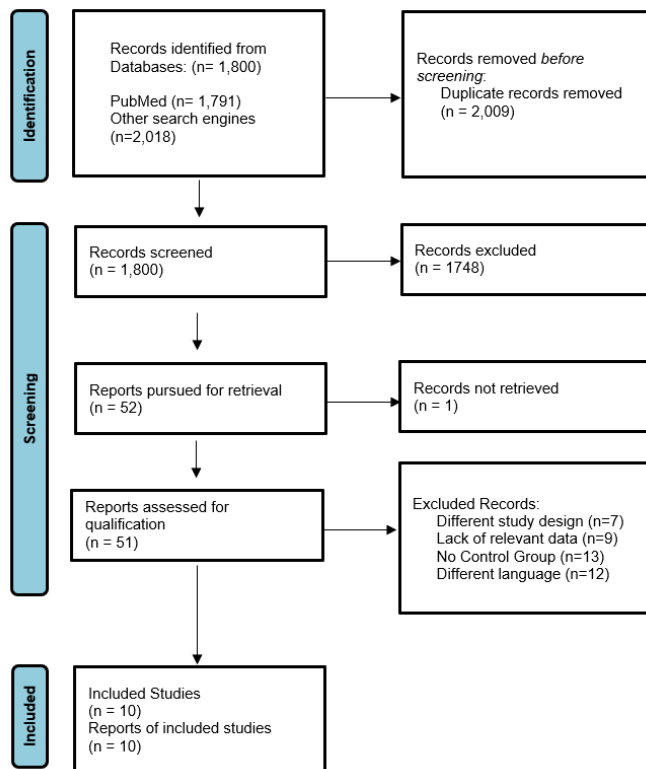


Figure 2: PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only (Page et al., 2021)

Cardiopulmonary bypass (CPB) Time

Six studies reported CPB time as an outcome. A subgroup analysis was done to compare the CPB time, which included minimally invasive surgery and open cardiac surgery. Our meta-analysis showed a significant difference in CPB time between COR-KNOT versus hand-tied knots [MD -12.38, 95 % CI (-14.99, -9.77), $P < 0.00001$, $I^2 = 0\%$] (Figure 4).

Valvular regurgitation

A total of eight studies reported valvular regurgitation as an outcome. A subgroup analysis was performed to compare the incidence of valvular regurgitation which included minimally invasive surgery and open cardiac surgery. Analysis yielded a significant difference in the incidence of valvular regurgitation between COR-KNOT versus hand-tied knots [RR 0.40, 95 % CI (0.26, 0.61), $P < 0.0001$, $I^2 = 0\%$] (Figure 5).

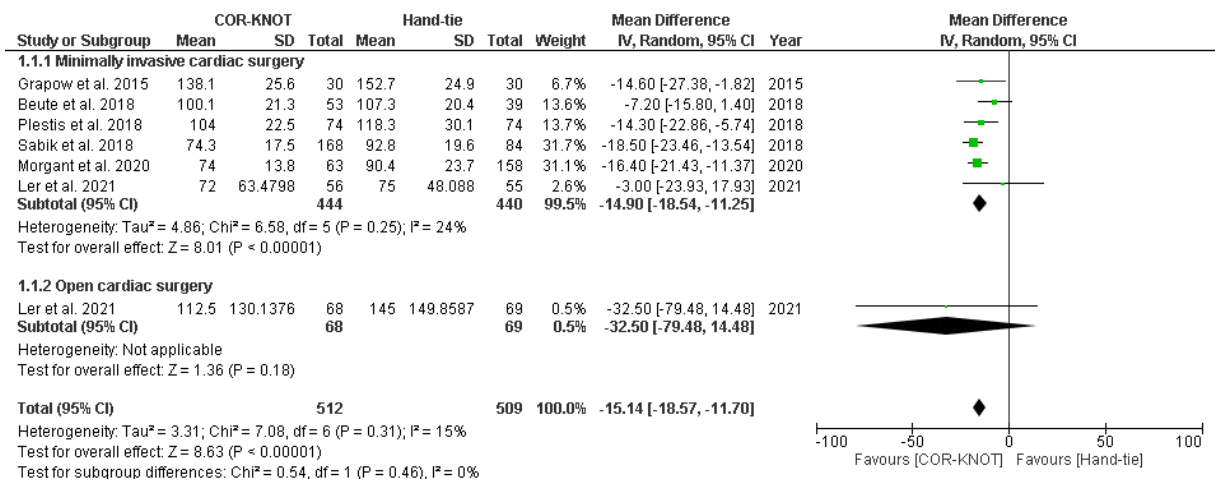


Figure 3: Forest plot comparing AXT in the COR-KNOT group vs Hand-tied

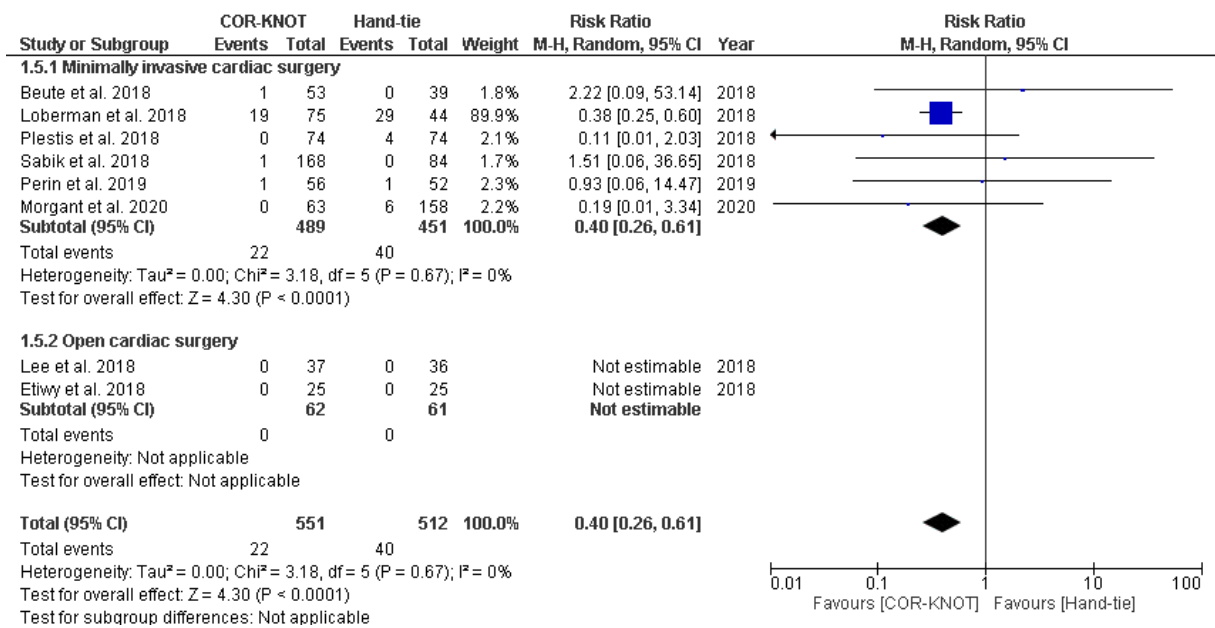


Figure 4: Forest plot comparing CPB time in the COR-KNOT group vs Hand-tied

Table 1: Baseline characteristics of the participants undergoing minimally invasive heart surgery (except Ler et al., 2021)

		Grapow et al., 2015	Beute et al., 2018	Loberman et al., 2018	Plestis et al., 2018	Sabik et al., 2018	Perin et al., 2019	Morgant et al, 2020
Patients, n	Cor-Knot	30	53	75	94	168	52	
	Hand tie	30	39	44	94	84	56	
Sex, male, n (%)	Cor-knot	17 (57)	38 (72)	61 (81)	50 (52)	120 (71)	44 (85)	42 (66.7)
	Hand-tie	24 (80)	23 (59)	33 (75)	47 (60)	48 (57)	39 (70)	99 (62.6)
Age, Year ± SD	Cor-knot	58.8 ± 13.8	66 ± 4	71 ± 3	72.5 ± 9.3	56.8 ± 10.9	60 ± 5	68.3 ± 10
	Hand-tie	56.1 ± 16.1	68 ± 4	75 ± 4	71.7 ± 9.6	55.1 ± 11.9	61 ± 4	69 ± 10.3
BMI, kg/m ²	Cor-knot	25 ± 6.38	29 ± 1.75	NA	NA	25.2 ± 3.88	25.9 ± 1.42	29.3 ± 5.3
	Hand-tie	26 ± 3.58	29 1.75	NA	NA	25.9 ± 4.41	26.0 ± 1.05	27.8 ± 5.1
Hypertension, n (%)	Cor-knot	22 (73)	39 (75)	NA	82 (87)	NA	14 (27)	42 (66.7)
	Hand-tie	15 (50)	28 (72)	NA	80 (85)	NA	17 (30)	105 (66.4)
Diabetes Mellitus, n (%)	Cor-knot	1 (3)	12 (23)	NA	25 (26)	NA	5 (10)	19 (30.1)
	Hand-tie	NA	8 (21)	NA	24 (26)	NA	0 (0)	33 (20.9)
LVEF (%), SD)	Cor-knot	NA	62 ± 3.8	63 ± 0.75	60.2 ± 9.5	NA	NA	61.5 ± 8.4
	Hand-tie	NA	61 ± 1.75	60 ± 3.5	60.5 ± 9.2	NA	NA	62 ± 10.7
Smoking history, n (%)	Cor-knot	2 (7)	NA	NA	39 (42)	NA	2 (4)	NA
	Hand-tie	4 (13)	NA	NA	34 (37)	NA	6 (11)	NA
Aortic Stenosis, n (%)	Cor-knot	NA	44 (83)	NA	NA	NA	NA	48 (76.2)
	Hand-tie	NA	31 (80)	NA	NA	NA	NA	127 (80.3)
Creatinine, mg/dL	Cor-knot	NA	1 ± 3	NA	0.99 ± 0.36	NA	NA	NA
	Hand-tie	NA	0.9 ± 3	NA	1.09 ± 0.57	NA	NA	NA

NA = not available

Table 2: Baseline characteristics of the participants undergoing open heart surgery (except Ler et al., 2021)

		Etiwy et al., 2018	Lee et al., 2018
Patients, n	Cor-Knot	25	37
	Hand-tie	25	36
Sex, male, n (%)	Cor-knot	15 (60)	23 (62)
	Hand-tie	16 (64)	24 (67)
Age, Year ± SD	Cor-knot	6.5 ± 7.8	72.9 ± 10.7
	Hand-tie	66 ± 11	71.5 ± 7.9
Hypertension, n (%)	Cor-knot	NA	27 (73)
	Hand-tie	NA	28 (78)
Diabetes Mellitus, n (%)	Cor-knot	NA	9 (24)
	Hand-tie	NA	10 (28)
LVEF (%), SD	Cor-knot	NA	55.5 ± 14.1
	Hand-tie	NA	54.0 ± 12.0
Smoking history, n (%)	Cor-knot	NA	21 (57)
	Hand-tie	NA	22 (61)
Aortic Stenosis, n (%)	Cor-knot	NA	23 (62)
	Hand-tie	NA	28 (79)
Creatinine, mg/dL	Cor-knot	NA	NA
	Hand-tie	NA	NA

NA = not available

Table 3: Baseline characteristics of the participants in Ler et al., 2021

Patients, n	COR-KNOT (n = 124)		Hand-tie (n = 124)	
	Minimally invasive heart surgery: 56	Open heart surgery: 68	Minimally invasive heart surgery: 55	Open heart surgery: 69
Sex, male, n (%)	85 (68.5)		75 (60.6)	
Age, Year ± SD	61.00 ± 3.8		58.00 ± 5.1	
Hypertension, n (%)	66 (53.2)		67 (54.0)	
Diabetes Mellitus, n (%)	5 (4.0)		4 (3.2)	
LVEF (%), SD	60.00 ± 3.2		58.00 ± 4.5	
Smoking history, n (%)	44 (35.5)		38 (30.6)	
Creatinine, mg/dL	91.88 ± 73.27		90.81 ± 102.73	

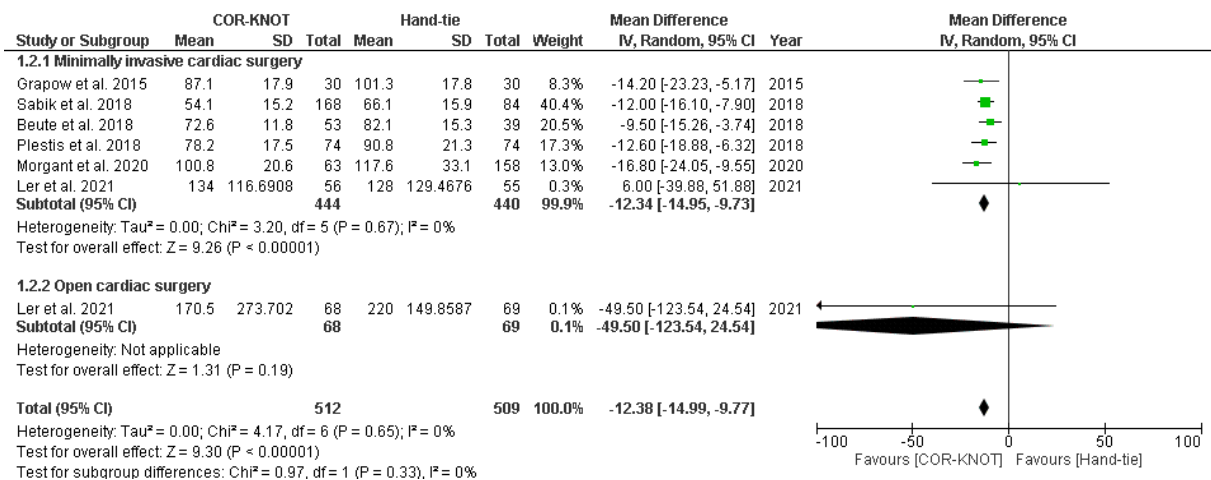


Figure 5: Forest plot comparing the incidence of valvular regurgitation in the COR-KNOT group vs Hand-tied

Table 4: Characteristics of included studies

Reference	Type of Study	Type of Surgery/ Procedure	Study Duration	Type of Knot used	Total Patients (COR-KNOT/ Hand-tie)	Surgical Technique
Minimally invasive heart valve surgery						
Grapow et al, 2015	Retrospective cohort study	Minimally invasive mitral valve repair	5/2013-6/2014	Cor-knot vs hand-tie (knot pusher)	60 (30/30)	Annuloplasty ring implantation combined with correction of the prolapsing leaflet using artificial chords (GoreTex CV4, W.L. Gore & Assoc, Newark, DE) was performed in all patients. Right mini-thoracotomy was done to perform the mitral valve surgery by minimal invasion. For cardioplegic arrest in all patients, antegrade Bretschneider HTK was used. There is a lack of data on the number of surgeons performing procedures.
Beute et al, 2018	Retrospective cohort study	Minimally invasive aortic valve replacement	5/2014-2/2017	Cor-knot vs hand-tie (standard manually tied knots)	92 (53/39)	Two surgeons performed the procedures through mini-right thoracotomy and mini-upper sternotomy using normothermic CPB. Administration of single-dose antegrade del Nido cardioplegia was done. Valves were implanted using pledgeted sutures placed through the left ventricle and aorta in all patients.
Loberman et al, 2018	Retrospective cohort study	Minimally invasive surgical aortic valve replacement	1/2014-12/2016	Cor-knot vs hand-tie (manually tied knots)	119 (75/44)	Attending surgeons with expertise performed all aortic valve replacements. There is a lack of data on the number of surgeons who performed the procedures.
Plestis et al, 2018	Retrospective cohort study	Minimally invasive aortic valve replacement	1/2008-12/2016	Cor-knot vs hand-tie (knot pusher)	188 (94/94)	Six-cm partial upper sternotomy approach with right lateral extension of incision into 3rd intercostal space was done to perform the surgery. Surgeons used antegrade Custodiol-HTK solution for cardioplegic arrest in all patients. To gain access to the aortic valve, transverse aortotomy was performed. The number of surgeons performing procedures is unknown.
Sabik et al, 2018	Retrospective cohort study	Minimally invasive mitral valve repair	2009-2016	Cor-knot vs hand-tie (knot pusher)	252 (168/84)	A 4 - 6-cm incision through the fourth right intercostal space was done to perform the mitral valve repair. For cardioplegic arrest, Buckberg or del Nido cardioplegia was used in all patients. Left posterolateral atriotomy was performed to expose the mitral valve. Standard techniques were used to carry out the repair. Procedures were performed by a single surgeon.

Reference	Type of Study	Type of Surgery/ Procedure	Study Duration	Type of Knot used	Total Patients (COR-KNOT/ Hand-tie)	Surgical Technique
Perin et al, 2019	Retrospective cohort study	Minimally invasive mitral valve repair	3/2011-3/2016	Cor-knot vs hand-tie (knot pusher)	108 (52/56)	Mini-thoracotomy, using femoral or internal jugular vacuum-assisted CPB, was done to carry out the procedure. Annuloplasty with either the loop technique or standard Carpentierian resection was done to perform the mitral valve repair. A single surgeon performed the procedures.
Open heart surgery						
Etiwy et al, 2018	Randomized controlled trial	Open mitral or tricuspid repair	8/2016-1/2017	Cor-knot vs hand-tie (conventional hand-tied knots)	50 (25/25)	Annuloplasty rings were used in all procedures to repair the valves and a single surgeon performed the procedures.
Lee et al, 2018	Randomized controlled trial	Open surgical aortic valve replacement	2/2013-5/2014	Cor-knot vs hand-tie (conventional hand-tied knots)	73 (37/36)	All prosthetic valves were sewn into the supraannular position following a standard pledgeted mattress suture technique using 2-0 coated polyester sutures. Single surgeon performed the procedures along with cardiothoracic surgery resident and fellow doctors.
Ler et al, 2021	Retrospective cohort study	Minimally invasive CABG + valve OR CABG + valve OR CABG + valve + other OR Valve only	1/2015-2/2020	COR-KNOT® and hand-tied groups	111 (56/55)	For mitral valve cases, the COR-KNOT® MIS device with diameter of 5 mm and length of 31 cm was used, whereas, for aortic valve cases, the COR-KNOT® Mini device with the diameter of 4 mm diameter and length of 14 cm length was used. The COR-KNOT® device used came with QUICK LOAD® UNITS, containing reloadable small metallic pellets. Every unit was exchanged after securing each knot. A single squeeze on the device was used to secure each not until the ergonomic feeling of knot security was achieved. In the end the sutures were trimmed. Where difficulty in releasing the device appropriately was felt, the operating surgeon released the lever fully and removed the device from the knot in order to check for suture break before proceeding further with the surgery.

Mortality

A total of seven studies reported mortality as an outcome. A subgroup analysis was performed to compare mortality which included minimally invasive surgery and open cardiac surgery. This meta-analysis reported no significant difference between the use of COR-KNOT versus hand-tied knot in preventing mortality [RR 0.39, 95 %CI (0.09, 1.69), P=0.44, I²=0%] (Figure 6).

Prolonged Ventilatory Support

Four studies with a total of 592 patients reported prolonged ventilatory support as an outcome of interest. Significantly lower rates of prolonged ventilator support were seen in patients sutured with COR-KNOT after valvular surgery when compared with those sutured with hand-tied knots [RR 0.29, 95 %CI (0.13, 0.65), P=0.003, I²=0%] (Figure 7).

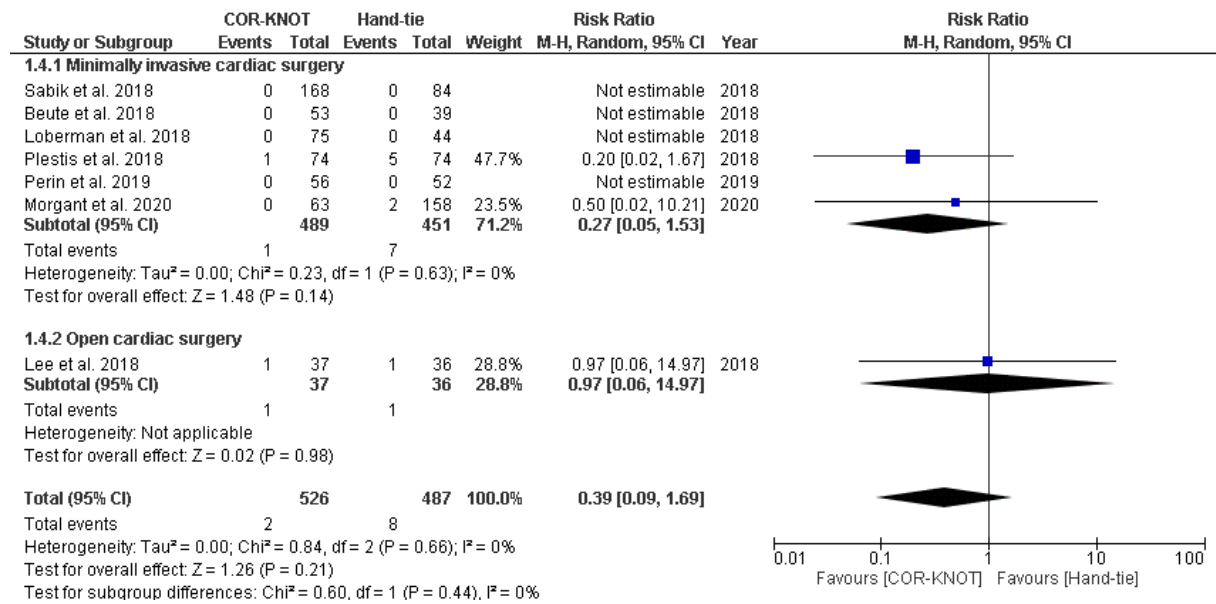


Figure 6: Forest plot comparing mortality in the COR-KNOT group vs Hand-tied

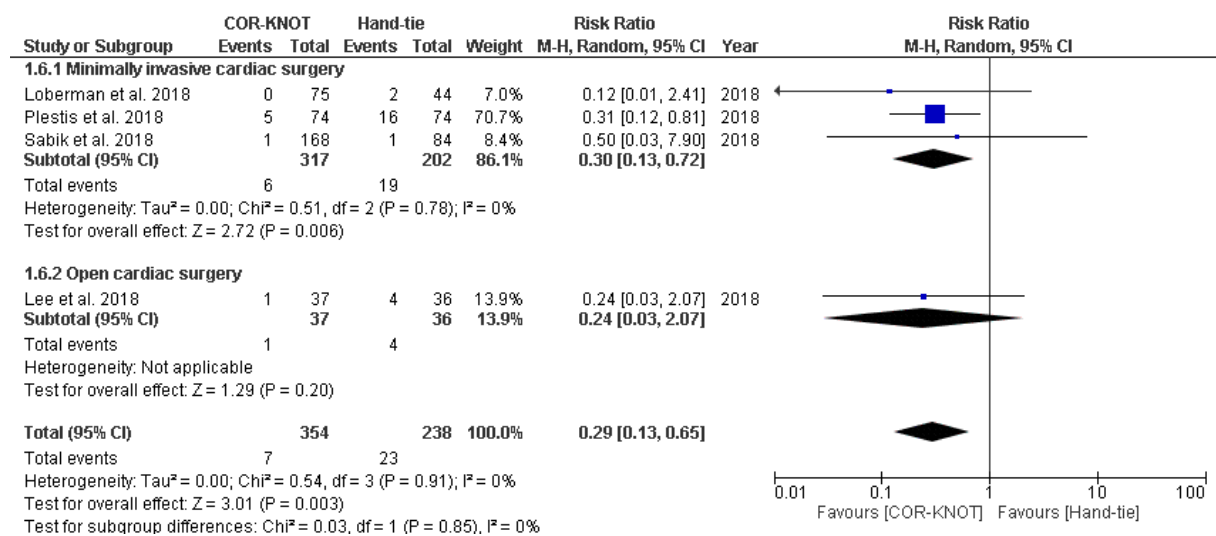


Figure 7: Forest plot comparing the need for prolonged ventilator support in the COR-KNOT group vs Hand-tied

Atrial Fibrillation

A total of five studies reported atrial fibrillation among patients undergoing valvular surgery. This meta-analysis reported no significant difference between the use of COR-KNOT versus hand-tied knot in preventing postoperative atrial fibrillation [RR 1.03, 95 %CI (0.83, 1.27), P=0.81, I²=0%] (Figure 8).

Changes in Postoperative Left Ventricular Ejection Fraction (LVEF)

Three studies with 492 patients reported no significant difference in postoperative

LVEF between COR-KNOT versus hand-tied knots [MD 0.05, 95 % CI (-1.37, 1.47), P = 0.95, I²=0%] (Figure 9).

Renal failure

A total of four studies comprising 600 patients reported renal failure as an outcome. No statistically significant difference was seen between COR-KNOT versus hand-tied knots in terms of incidence of renal failure [RR 0.87, 95% CI (0.16, 4.80), P = 0.87, I²=60%] (Figure 10).

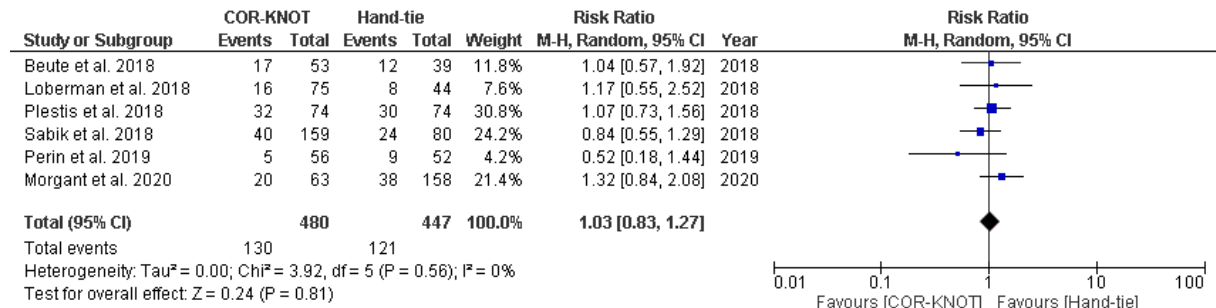


Figure 8: Forest plot comparing the incidence of atrial fibrillation in the COR-KNOT group vs Hand-tied

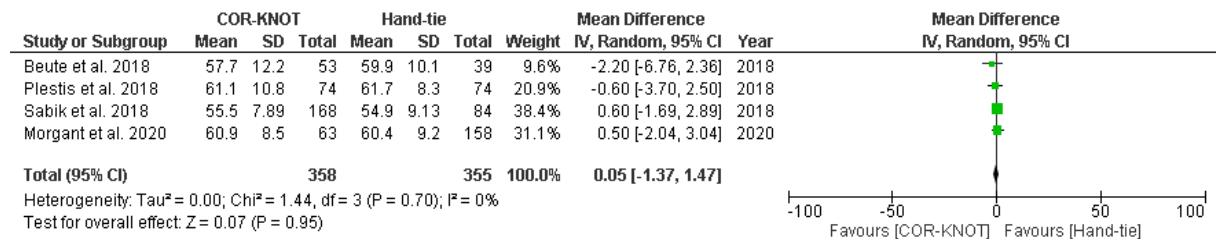


Figure 9: Forest plot comparing postoperative LVEF in the COR-KNOT group vs Hand-tied

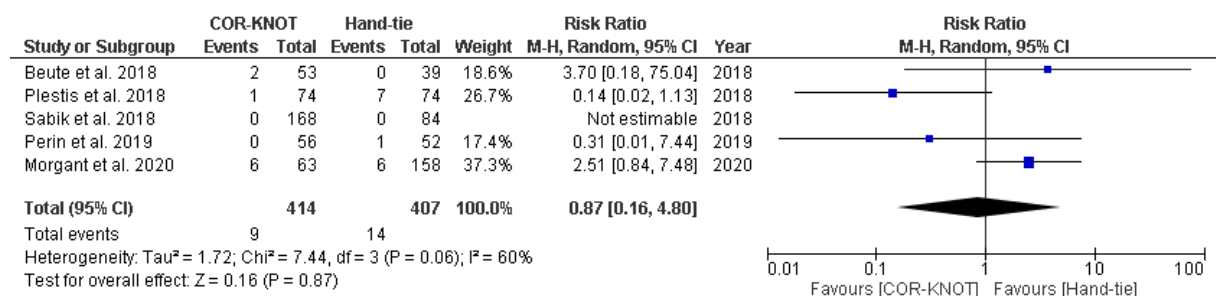


Figure 10: Forest plot comparing incidence of renal failure in the COR-KNOT group vs Hand-tied

DISCUSSION

Valve repair and/or replacement continues to be one of the most common procedures for adults undergoing cardiac surgery. Two techniques are available to secure prosthetic valves and rings: traditional hand-tying and automated fasteners. Automated fasteners, exemplified by the COR-KNOT[®] by LSI Solutions[®], have emerged as an innovative approach to shorten prosthetic valve implantation time (Sazzad et al., 2021). The present meta-analysis aimed at assessing the efficacy of COR-KNOT devices compared to hand-tied sutures in valve surgery.

Our findings demonstrated a significant reduction in both AXT and CPB times with the utilization of the COR-KNOT device, showcasing the potential for improved surgical efficiency. This reduction in operative time aligns with the benefits of automation (Loberman et al., 2018; Salmasi et al., 2019). Sazzad et al. also found a similar relationship between the use of COR-KNOT devices and reduction in AXT (MD = -14.36) and CPB time (MD = -11.74) (Sazzad et al., 2021). Importantly, this advantage could lead to decreased exposure to the potential risks inherent in longer operations, potentially mitigating postoperative morbidity and mortality risks (Salmasi et al., 2019; Sazzad et al., 2021; Cody et al., 2021).

Intriguingly, while the reduction in operative time was evident, our analysis did not reveal a significant difference in the incidence of atrial fibrillation between surgeries employing COR-KNOT devices and those using hand-tied knots. This suggests that the automated fasteners did not introduce an additional risk factor for postoperative atrial fibrillation, a common complication associated with cardiac surgeries. Therefore, practitioners can be reassured that the adoption of COR-KNOT devices does not appear to contribute to an increased risk of this particular complication. The previous meta-analysis by Sazzad et al. did not identify a correlation between postoperative atrial fibrillation and COR-KNOTs (Sazzad et al., 2021).

Notably, the most significant advantage of using the COR-KNOT device was observed in the context of valvular regurgitation. Our analysis revealed a significant decrease in the incidence of valvular regurgitation when COR-KNOT device was used. This finding is also supported by Sazzad et al. (2021) (RR = 0.40). It should also be noted, however, valve perforation followed by valvular regurgitation has been reported by two recent case reports following COR-KNOT devices use. Nevertheless, the failure was suspected to result from lack of experience with COR-KNOT deployment and can be prevented by being vigilant while operating with automated fastener and orienting and placing them away from native valve and or prosthetic leaflets (Salmasi et al., 2019).

In terms of mortality, our study did not identify a significant difference between the two techniques. This finding suggests that the use of COR-KNOT devices is not associated with an increased mortality compared to hand-tying. However, it is important to note that the study did not identify a significant advantage in terms of mortality prevention either, indicating that further investigation is necessary to comprehensively assess the impact of automated fasteners on other relevant outcomes. Salmasi et al. also concluded that there was no significant difference in terms of 30-day mortality rate between conventional knot-tying and COR-KNOT, after analyzing several RCTs and retrospective studies (Salmasi et al., 2019).

The reduction in the duration of ventilatory support among patients with COR-KNOT could be attributed to the reduced AXT and CPB time. Such benefits may contribute to shorter hospital stay and decrease other morbidities associated with prolonged intubation, which are essential factors in improving overall patient outcomes and resource utilization.

Our study's analysis of changes of postoperative LVEF did not reveal a significant difference between COR-KNOT and hand-tying. This suggests that both techniques main-

tain comparable cardiac function in the post-operative period.

Lastly, the analysis of renal failure also did not yield a statistically significant difference between COR-KNOT and hand-tying. While the incidence of renal failure did not significantly vary between the two techniques, it is essential to recognize that this outcome can be influenced by multiple factors beyond the suturing method, including pre-operative patient comorbidities and perioperative care.

Even though the study demonstrated compelling advantages, it is important to recognize the limitations and/or drawbacks that could be associated with both techniques. Thus, a comprehensive evaluation of the safety profile of both methods is needed prior to accepting the COR-KNOT on a wider scale.

Limitations

The current study has the following limitations. The study focused on RCTs and cohorts, which may introduce variability and heterogeneity. The study was also limited by the small amount of literature available on postoperative outcomes of COR-KNOT device use. Future research is needed before accepting the COR-KNOT device on a wider scale. It is also important to note that the included studies had some degrees of bias that may affect the quality of evidence presented.

CONCLUSION

In conclusion, this study contributes valuable insights into the ongoing discourse surrounding optimal techniques for knot securement during heart valve surgery. Our findings suggest that COR-KNOT device offers notable advantages in terms of reduced operative time and valvular regurgitation compared to hand-tying. However, we also recognize the need for caution in interpreting these results. The new studies have also not contributed to some of the outcomes (AXT, CPB time, valvular regurgitation, prolonged ventilator support, renal failure and postoperative LVEF) previously discussed in Sazzad et al's work,

thus, there continue to be a need for further investigation and research in this field to derive a better conclusion for these outcomes and determine the potential for wide-spread use of automated fasteners in cardiac surgery. As the field continues to evolve, future research could delve into long-term outcomes, patient-specific factors, and the learning curve associated with transitioning to automated fasteners, ultimately refining our understanding of their place in cardiac valvular surgery.

Conflict of interest

The corresponding author S.M.S is a consultant to Artivion, Abbott, and JOMDD.

Ethics approval

Not applicable.

Funding

No funding was available to the authors.

Acknowledgments

None.

Data availability statement

All relevant data are within the manuscript.

REFERENCES

- Beute TJ, Oram MD, Schiller TM, Goehler M, Parker J, Willekes CL, et al. Use of an automated suture fastening device in mini-mally invasive aortic valve replacement. *Ann Thorac Surg.* 2018;106:58–62.
- Cody JR 3rd, Shin P-Y, Tran TD. Automated heart valve manufacturing devices and methods. Patent US20210196456, 2021. <https://patents.justia.com/patent/11613834>, accessed 8 September 2023.
- Etiwy M, Javadikasgari H, Houghtaling P, Gillinov M. Automated titanium fasteners versus hand-tied knots: a randomized controlled trial. *Ann Thorac Surg.* 2018; 106:1160–3.
- Grapow MTR, Mytsyk M, Fassl J, Etter P, Matt P, Eckstein FS, et al. Automated fastener versus manually tied knots in minimally invasive mitral valve repair: impact on operation time and short-term results. *J Cardiothorac Surg.* 2015;10:146.

- Jha PK, Barabas AG, Sharma H. Surgical technique. The ambidextrous surgeon's knot: an alternate way to tie the surgeon's knot. *Can J Surg*. 2007;50:470–1.
- Lee CY, Johnson CA, Siordia JA, Lehoux JM, Knight PA. Comparison of automated titanium fasteners to hand-tied knots in open aortic valve replacement. *Innovations (Phila)*. 2018;13(1):29-34.
- Ler A, Wu D, Xian OZ, Sazzad F, Swee KG, Kofidis T. Automated suture fastener gaining complete commitment: cumulative propensity-matched comparison with hand-tied knot in heart valve surgery. *Innovations (Phila)*. 2021;16:334–42.
- Loberman D, Mohr R, Pirundini PA, Yazdchi F, Rinewalt D, Ziv-Baran T. Automated fastener (Core-Knot) versus manually tied knots in patients undergoing aortic valve replacement. *Medicine*. 2018;97:e11657.
- Matiasz R, Rigolin VH. Focused update for management of patients with valvular heart disease: summary of new recommendations. *J Am Heart Assoc*. 2018;7:1-16.
- Moola S, Munn Z, Tufanaru C, Aromataris E, Sears K, Sfetcu R, et al. Systematic reviews of etiology and risk. In: Aromataris E, Munn Z (eds): *JBIM Manual for evidence synthesis* (chapter 7). JBI, 2020.
- Morgant M-C, Malapert G, Petrosyan A, Pujos C, Jazayeri S, Bouchot O. Comparison of automated fastener device Cor-Knot versus manually-tied knot in minimally-invasive isolated aortic valve replacement surgery. *J Cardiovasc Surg (Torino)*. 2020;61(1):123-8.
- Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71.
- Perin G, Shaw M, Pingle V, Palmer K, Al-Rawi O, Ridgway T, et al. Use of an automated knot fastener shortens operative times in minimally invasive mitral valve repair. *Ann R Coll Surg Engl*. 2019;101:522-8.
- Plestis K, Orlov O, Shah VN, Wong J, Thomas M, Aharon A, et al. Facilitating technologies in minimally invasive aortic valve replacement: a propensity score analysis†. *Interact Cardiovasc Thorac Surg*. 2018;27:202–7.
- Reddy NS, Punjabi P. Heart valve surgery. *Surgery (Oxford)*. 2007;25:220–3.
- Sabik JF, Raza S, Chavin KD. Safety and benefits of new techniques and technologies in less invasive mitral valve repair. *J Card Surg*. 2018;33:609–19.
- Sadeghian H, Savand-Roomi Z. Malfunction and other complications after heart valve surgery. In: Sadeghian H, Savand-Roomi Z: *3D echocardiography of structural heart disease* (pp 327-68). Cham: Springer, 2017.
- Salmasi MY, Chien L, Hartley P, Al-Balah A, Lall K, Oo A, et al. What is the safety and efficacy of the use of automated fastener in heart valve surgery? *J Card Surg*. 2019;34:1598–607.
- Sazzad F, Ler A, Kuzemczak M, Ng S, Choong AMTL, Kofidis T. Automated fastener vs hand-tied knots in heart valve surgery: a systematic review and meta-analysis. *Ann Thorac Surg*. 2021;112:970–80.
- Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *BMJ*. 2017;358:j4008.