2772-9931 31
https://doi.org/10.1016/j.atssr.2024.07.020

Valve: Short Report

Acute Clinical Adverse Outcomes Associated With the Cor-Knot

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ABSTRACT

BACKGROUND Although an integral component of cardiac valve operations, manual knot tying has been linked with increased operative times and greater costs. The introduction of the Cor-Knot device (LSI Solutions) has eliminated hand-tied knots through an automatic titanium fastener system. However, adverse outcomes related to this device remain unknown. We thus used a nationally representative cohort to characterize adverse events of the Cor-Knot.

METHODS All adverse events for the Cor-Knot from 2015-2023 were tabulated from the Manufacturer and User Facility Device Experience database. Reports were screened to assess incident type and complication. Device and patient complications were categorized and reported as proportions to further ascertain factors contributing to the development of adverse incidents.

RESULTS Of an estimated 74 adverse events, the number of reported occurrences increased over the study period from 1 in 2015 to 13 in 2023. The greatest proportion of adverse events involved the Cor-Knot Mini (41.9%) or the Cor-Knot (37.4%), with malfunction representing the most frequent device incident (63.5%). Problems related to device usage (22.8%) or misfire (22.8%) constituted the most frequent complications after Cor-Knot usage. The most frequent complications included valve insufficiency (10.8%), presence of a foreign body (8.1%), or hemorrhage (2.7%).

CONCLUSIONS Of all reported adverse events, malfunction was most likely to occur due to misfire or device usage issues. Patient complications comprised valve insufficiency, foreign body presence, or hemorrhage. As adoption and utilization of the Cor-Knot increases, future work is necessary to ensure adequate device training and minimize the incidence of adverse events.

(Ann Thorac Surg Short Reports 2025;3:31-36)

Although knot tying remains an essential component of both open and minimally invasive cardiac valve operations, it has been linked with longer operative times and greater costs.[1,2] The recently introduced Cor-Knot device (LSI Solutions) has aimed to obviate the need for manually tied knots, allowing for accelerated prosthetic valve fixation using titanium fasteners in minimally invasive and open operations. Since its commercial market introduction in 2012, the Cor-Knot has reportedly been used in >450,000 patients, with >7.9 million

IN SHORT

- Of 74 adverse events associated with the Cor-Knot device (LSI Solutions), malfunction constituted the most frequent device incident and common complications included valve insufficiency, presence of a foreign body, or hemorrhage.
- With the increased utilization of automated suture devices such as the Cor-Knot, prospective randomized trials and registry data may better inform the actual device related rate of complications in order to better guide hospital, provider, and patient decision-making.

Accepted for publication Jul 22, 2024.

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fasteners delivered as of 2020.[3] Prior studies have demonstrated the use of Cor-Knot to be associated with 23- and 35-minute reductions in aortic cross clamp and cardiopulmonary bypass times, respectively.[4]

Although the efficacy of the Cor-Knot automated fastener is well documented,[4,5] concerns regarding device-related adverse events have emerged. A growing number of single-center series have reported device-related complications, including systemic embolization as well as prosthetic valve leaflet perforation or dehiscence leading to valvular insufficiency.[1,2,6] With increasing adoption of the Cor-Knot family of devices into clinical practice, a comprehensive report of such adverse events could better inform clinical decision-making as well as efforts towards device optimization. The present study queried the Manufacturer and User Facility Device Experience (MAUDE) database, maintained by the US Food and Drug Administration, to ascertain Cor-Knot-related adverse events across the United States.[7]

MATERIAL AND METHODS

This was a study of the MAUDE registry, a deidentified and publicly accessible repository of adverse outcomes related to medical devices; these reports are mandatory for device user facilities, but voluntarily reported by healthcare professionals. Upon the incidence of an adverse event, an open-ended description of the event including device and patient problem is recorded within the report. This database was developed by the US Food and Drug Administration and comprises ~2000 new daily entries and >4 million recorded events.[8]

All adverse events associated with the brand name "Cor-Knot" from 2015-2023 were tabulated from MAUDE. Adverse events were defined to comprise both potential and actual errors or quality issues, with or without related patient injuries. Data extraction was performed by individual review of each MAUDE record free-form text. Incident date, character, and ensuing complications were recorded. Device complications were subsequently categorized as Break/Jam, Failure to Cut, Failure to Fire, Insufficient Information, Misfire, Physical Resistance/Sticking, Use of Device Problem, and Other. Adverse events were further stratified by type of Cor-Knot device. The Cor-Knot is approved for "fixing and cutting the suture during cardiovascular surgery procedures performed by minimally invasive technique" while the Cor-Knot Mini is intended for "use in the approximation of soft tissue and prosthetic materials".[3]

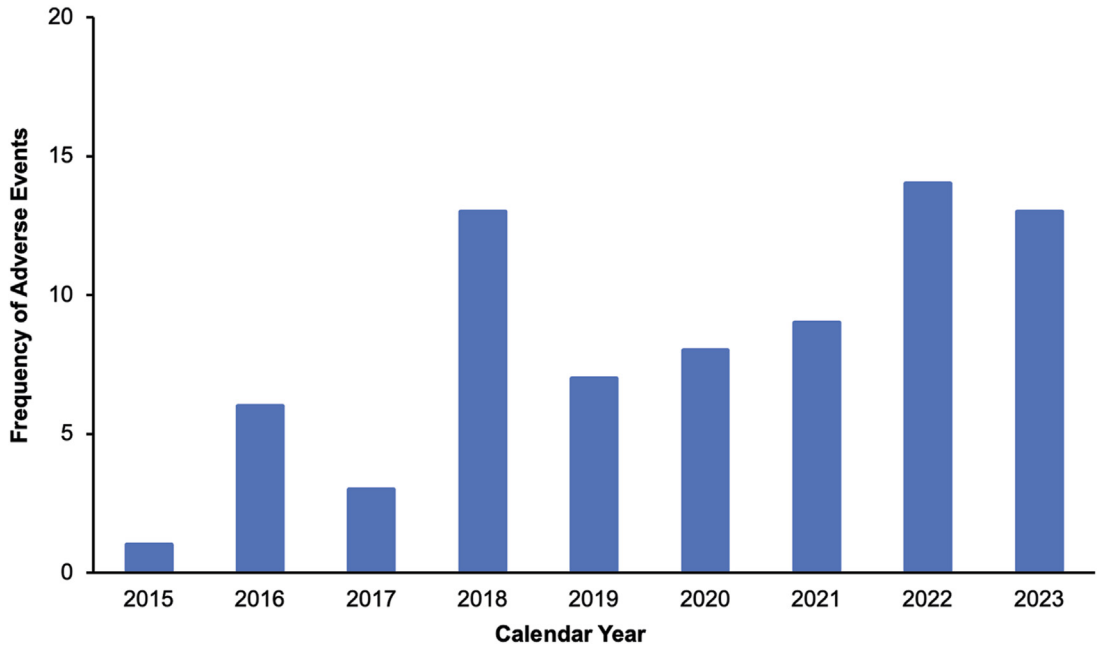

FIGURE 1 Adverse events associate with the Cor-Knot (LSI Solutions) device during 2015–2023 in the United States.

TABLE 1 Adverse Events by Category

Adverse Event	Instances N = 74
Event type	
Death	3 (4.1)
Injury	24 (32.4)
Malfunction	47 (63.5)
Device complication	
Break/Jam	4 (5.4)
Failure to cut	6 (8.1)
Failure to fire	5 (6.8)
Insufficient information	7 (9.5)
Misfire	17 (22.8)
Physical resistance/sticking	4 (5.4)
Use of device problem	17 (22.8)
Other	14 (18.9)
Patient complication	
Valve insufficiency	8 (10.8)
Cardiac perforation	1 (1.0)
Chest pain	1 (1.0)
Endocarditis	1 (1.0)
Foreign body	6 (8.1)
Hemorrhage	1 (1.0)
Ischemic heart disease	1 (1.0)
Laceration	1 (1.0)
No clinical symptoms/ No known impact	32 (43.2)
No information	17 (23.0)
Not otherwise specified	2 (2.7)
Vascular dissection	1 (1.0)
Operation type	
Aortic valve replacement	29 (39.2)
Combination (CABG/MVR or AVR)	6 (8.1)
MVR	10 (13.5)
Not reported	29 (39.2)
Version of Cor-Knot device[a]	
Cor-Knot	28 (37.4)
Cor-Knot Mini	31 (41.9)
Cor-Knot MIS device	9 (12.2)
Cor-Knot MIS Combo	6 (8.1)

[a]Core-Knot (LSI Solutions). Values are presented as n (%). AVR, aortic valve repair; CABG, coronary artery bypass grafting; MVR, mitral valve replacement.

Given the deidentified nature of the MAUDE, this study was deemed exempt from full review by the institutional review board at the University of California, Los Angeles.

RESULTS

From 2015 to 2023, 74 adverse events were reported across all commercially available Cor-Knot devices (Figure 1). The overall number of adverse events reported to MAUDE increased over the study period, from 1 in 2015 to 13 in 2023 (Table 1).

Most adverse occurrences involved the Cor-Knot Mini (41.9%) or the Cor-Knot (37.4%). Of those reported, the most common procedural indication was aortic valve replacement (31.1%), followed by mitral valve replacement (16.9%).

The most frequent device complications involved a problem related to device usage (22.8%) or misfire (22.8%). Among all MAUDE reports, 43.2% of cases involving a device complication were not clinically relevant. While clinical details were not available for all MAUDE-reported issues, the most frequent significant patient sequelae were valvular insufficiency (10.8%), presence of a foreign body (8.1%), or hemorrhage (2.7%).

Outcomes of adverse events were further stratified into mortality (4.1%), malfunction (63.5%), or a condition not otherwise specified (32.4%). The number of device malfunction events increased from 1.4% to 10.8% of all reported incidents over the study period (Figure 2). The 3 cases entailing mortality involved aortic cannulation site bleeding, punctate defects in the prosthetic valve leaflet, or development of cardiogenic shock. Upon further stratification of adverse events by Cor-Knot device type, the Cor-Knot demonstrated increased percentage of death (10.7%), and the Cor-Knot Mini exhibited the highest rate of malfunction (87.1%) (Table 2).

COMMENT

In the era of expanding transcatheter interventions, examination of outcomes for conventional and minimally invasive cardiac operations is warranted. Automated suture fixation devices, such as Cor-Knot, have been purported to reduce operative times and optimize knot-tying in minimally invasive procedures. Although the Cor-Knot device has experienced an exponential growth in utilization, literature evaluating the pragmatic safety of this device remains sparse. The present analysis used the US Food and Drug Administration-provided MAUDE database to evaluate the safety profile of the Cor-Knot device. Over an 8-year period, the number of adverse events reported increased 13-fold, with the majority of complications associated with device misfire or device dysfunction leading to valve insufficiency or a “foreign body” presence. A number of these findings warrant further discussion.

Over the study period, the reported number of adverse events associated with Cor-Knot increased from 1 to 13, annually. Although the exact utilization rate of Cor-Knot is not well characterized, the manufacturer has reported

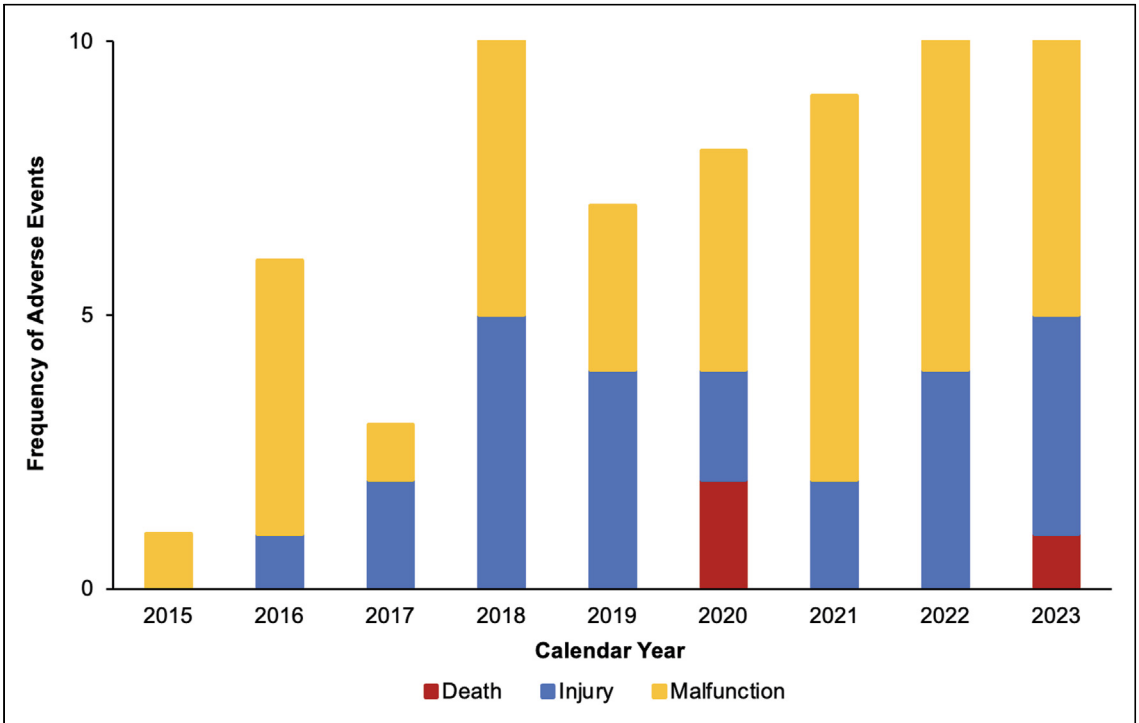

FIGURE 2 Incidence of adverse events reported each year from 2015–2023 stratified by event type.

>7.9 million fasteners to have been implanted in 64 countries since 2013.[3] Several single-institution studies have compared cardiopulmonary and aortic cross-clamp times for patients undergoing valve surgery with hand-tying versus automated fixation.[6] Adverse events appear to be rare with limited case reports regarding fastener embolization, valve perforation, and paravalvular leak.[2,9] The present analysis provides the first, pragmatic report of adverse events for this device. Consensus among cardiac surgeons is needed to determine a potential acceptable threshold for adverse event rates among patients with valvular heart disease.

Among reported adverse events, device misfire was one of the most common complications. Prior literature has shown the importance of the angulation of the Cor-Knot as well as wrist placement before application.[10] Furthermore, given the structure of the Cor-Knot device, the shaft may hinder full vision of the surgical field and the annuloplasty rings, thus leading to misfire. Additionally, handle jams may lead to device usage difficult and ultimately misfire due to incorrect loading of the wire snape. With widespread adoption of this technology, education and training in meticulous technique may serve as an opportunity for improvements in patient safety.

The present report has several limitations. MAUDE relies on consumer reports with free-form writing that may not capture clinical circumstances in totality. Compliance with reporting to MAUDE is unknown and lack of familiarity with operative technique may lead to underreporting of device-related adverse events. Additionally, events may be recorded by both device user facilities and healthcare professionals, resulting in duplicate reports. Furthermore, the information presented in the database may be incomplete and the registry is unable to formally verify incidents. Device and patient complication management is not reported within the MAUDE registry. Though the number of overall adverse events have increased in MAUDE, we are unable to quantify rate of adverse events given that the total use of Cor-Knot automatic fixation devices are unknown. Nonetheless, this remains the first nationwide analysis reporting adverse events associated with the Cor-Knot beyond institutional case reports and series.

In summary, the Cor-Knot device has widespread market penetration with 74 device-related adverse events over an 8-year period. Prospective randomized trials and registry data may better inform the actual device related rate of complications in order to better guide hospital, provider, and patient decision-making.

TABLE 2 Adverse Events Stratified by Cor-Knot Device Type

Adverse Event	Cor-Knot[a] n = 28	Cor-Knot Mini n = 31	Cor-Knot MIS Device n = 9	Cor-Knot MIS Combo n = 6
Event type				
Death	3 (10.7)	0 (0.0)	0 (0.0)	0 (0.0)
Injury	18 (64.3)	4 (12.9)	0 (0.0)	2 (33.3)
Malfunction	7 (25.0)	27 (87.1)	9 (100.0)	4 (66.7)
Device complication				
Break/Jam	1 (3.6)	0 (0.0)	2 (22.2)	1 (16.7)
Failure to cut	1 (3.6)	4 (12.9)	1 (11.1)	0 (0.0)
Failure to fire	1 (3.6)	4 (12.9)	0 (0.0)	0 (0.0)
Insufficient information	6 (21.4)	1 (3.2)	0 (0.0)	0 (0.0)
Misfire	6 (21.4)	5 (16.1)	4 (44.4)	2 (33.3)
Physical resistance/Sticking	0 (0.0)	2 (6.5)	2 (22.2)	0 (0.0)
Use of device problem	8 (28.6)	8 (25.8)	0 (0.0)	1 (16.7)
Other	5 (17.9)	7 (22.6)	0 (0.0)	2 (33.3)
Patient complication				
Valve insufficiency	6 (21.4)	0 (0.0)	0 (0.0)	2 (33.3)
Cardiac perforation	0 (0.0)	1 (3.2)	0 (0.0)	0 (0.0)
Chest pain	0 (0.0)	1 (3.2)	0 (0.0)	0 (0.0)
Endocarditis	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)
Foreign body	6 (21.4)	0 (0.0)	0 (0.0)	0 (0.0)
Hemorrhage	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)
Injury	1 (3.6)	1 (3.2)	0 (0.0)	0 (0.0)
Ischemic heart disease	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)
Laceration	0 (0.0)	1 (3.2)	0 (0.0)	0 (0.0)
No clinical symptoms/ No known impact	3 (10.7)	21 (67.7)	6 (66.7)	2 (33.3)
No information	6 (21.4)	6 (19.4)	3 (33.3)	2 (33.3)
Regurgitation	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular dissection	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)
Operation type				
AVR	17 (60.7)	8 (25.8)	4 (44.4)	0 (0.0)
Combination (CABG/MVR or AVR)	0 (0.0)	6 (19.4)	0 (0.0)	0 (0.0)
MVR	7 (25.0)	2 (6.5)	1 (11.1)	0 (0.0)
Not reported	4 (14.3)	15 (48.4)	4 (44.4)	6 (100.0)

[a]Core-Knot (LSI Solutions). Values are presented as n (%). AVR, aortic valve repair; CABG, coronary artery bypass grafting; MVR, mitral valve replacement.

FUNDING SOURCES

The authors have no funding sources to disclose.

DISCLOSURES

The authors have no conflicts of interest to disclose.

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