

Automated Titanium Fasteners Versus Hand-Tied Knots: A Randomized Controlled Trial

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Background. The relative benefits of automated titanium fasteners (LSI Solutions, Victor, NY) have not been examined in patients undergoing sternotomy. The aim of this study was to assess the time and cost required for suture fixation with the automated device versus conventional hand tying in sternotomy for mitral or tricuspid ring annuloplasty.

Methods. Fifty patients scheduled to undergo primary mitral or tricuspid, or both, ring annuloplasty–based valve repair operation by a single surgeon were randomly assigned to receive either conventional hand-tied knots or automated titanium fasteners, with 25 patients in each group. The primary outcome variable was the time required to affix the annuloplasty device to the valve annulus.

Results. The times taken to affix a mitral annuloplasty band or ring were 6.1 ± 0.9 min for manual tying versus 3.1 ± 0.4 min for automated fasteners ($p < 0.0001$); when calculated per annuloplasty stitch, the values were 22 ± 2 s versus 12 ± 1.1 s, respectively ($p < 0.0001$). The corresponding

values for tricuspid annuloplasty were 4.2 ± 1.2 min (hand tying) versus 2.2 ± 0.3 min (automated fasteners) ($p = 0.0005$), and the times for each suture were 20 ± 2.1 s versus 13 ± 2 s, respectively ($p = 0.0004$). The use of the automated fastener had no significant impact on aortic cross-clamp time or cardiopulmonary bypass duration. Total cost associated with annuloplasty fixation with automated titanium fasteners (device cost in addition to operating room time cost) was significantly higher than with hand tying ($\$1,190 \pm 374$ vs $\$164 \pm 60$; $p < 0.0001$).

Conclusions. Using the automated fastener to facilitate annuloplasty fixation through a sternotomy resulted in a small procedural time savings (average of 10 s/stitch) that had no overall impact on cardiopulmonary bypass or cross-clamp times but added an average cost of \$1,026 to the operation.

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The COR-KNOT device (LSI Solutions, Victor, NY) facilitates suture fixation and reduces operative times. Although the device presents clear ergonomic advantages during minimally invasive cardiac surgical procedures, it enjoys widespread use in sternotomy-based, standard heart surgical procedures. With a single squeeze of the lever, the device remotely and automatically secures sutures with a titanium fastener while also simultaneously cutting the suture and leaving a short suture tail. Clinical studies demonstrate that the use of this device has made suture fixation easier and faster and that it produces a consistent fixation that has greater strength than that of manually tied knots [1].

The COR-KNOT costs \$58 per application. Because the device facilitates less invasive surgical procedures, this may represent an acceptable cost in such instances; however, the relative advantage (if any) afforded by the device in traditional, sternotomy-based cardiac operations, is debatable. The objectives of this study were to determine

the time savings per knot for the COR-KNOT device versus standard, hand-tied knots and to quantify the relative cost of COR-KNOT versus that of standard, hand-tied knots in patients undergoing mitral or tricuspid annuloplasty repairs with traditional sternotomy.

Patients and Methods

Randomized Trial Design

The trial enrolled 50 adults 18 years of age and older who were scheduled to undergo primary mitral or tricuspid, or both, ring annuloplasty–based valve repair by a single surgeon using a standard median sternotomy at Cleveland Clinic in Cleveland, Ohio; all annuloplasty bands, whether hand tied or affixed with COR-KNOT, were applied by the senior surgeon (M.G.). The trial was

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approved by the Institutional Review Board and was registered at clinicaltrials.gov (NCT02720913). Screening and consenting of patients were done by the Cleveland Clinic Department of Cardiothoracic Surgery. Patients who consented and who met inclusion criteria were randomly assigned at the time of the surgical procedure to either COR-KNOT ($n = 25$) or hand-tied knots ($n = 25$) for fixation of the annuloplasty bands or rings. Randomization was performed using a computer program (Fig 1).

Intervention and Endpoints

Thirty-one (62%) patients had mitral valve repair alone, 14 (28%) had both mitral and tricuspid valve repairs, and 5 (10%) had tricuspid valve repair alone; there was no difference in distribution of procedures between the groups (Table 1). In both groups, sutures were passed through the annulus and then through the annuloplasty band or ring. In the conventional group, each suture was tied with six knots; the total time to affix the annuloplasty device was measured from the instant tying of the first suture commenced until the instant the final suture was cut. In the COR-KNOT group, measured time extended from the instant the first COR-KNOT was deployed until completion of the final COR-KNOT.

The primary endpoint was the time per suture fixation, which was calculated in each patient by dividing the total amount of time required to affix the annuloplasty band or ring by the number of sutures used. Cardiopulmonary bypass (CPB) and aortic cross-clamp times were recorded. The net cost associated with COR-KNOT use was calculated as the cost of the device minus the cost savings associated with reduced operating room time (on the basis of a rate of \$24/min for operating room time).

Sample Size

Preliminary pilot observations in 12 patients revealed that the time required per COR-KNOT application was

12 ± 2 s, and the time required to tie one knot manually was 19 ± 0.5 s for the same surgeon. On the basis of these observations, a sample size of 25 patients was required per arm of the study to identify an estimated difference of 5 s, with a type I error of 5% and power of 80%.

Presentation

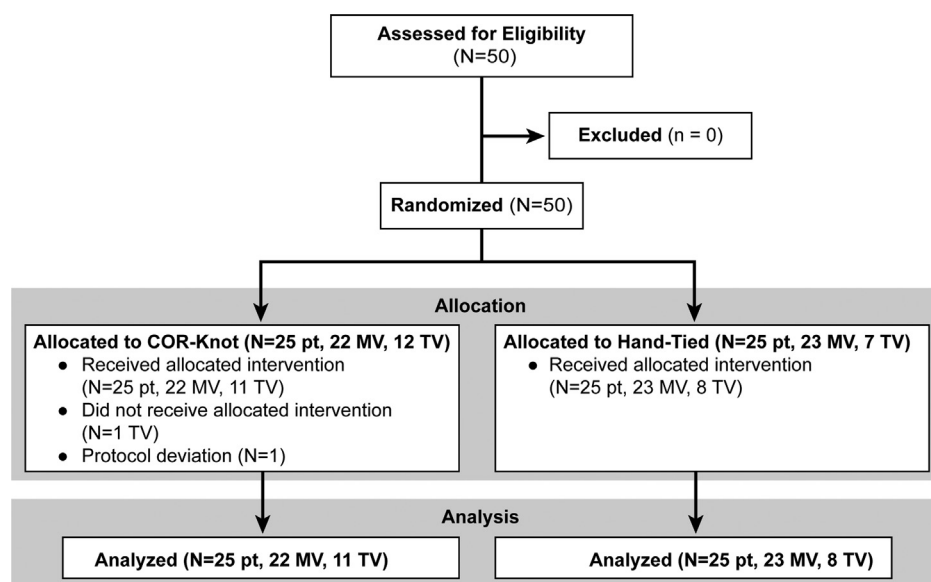
Analyses included all randomly assigned patients who underwent surgical treatment (Fig 1). An as-treated strategy was used to present the data when stratified by valve. Summary statistics are provided for categorical variables with frequencies and percentages, and group comparisons were made using the χ^2 test. Continuous data are presented with means \pm standard deviation, medians, and 15th and 85th percentile values; the nonparametric Wilcoxon rank sum test was used to compare groups. Statistical analyses were performed using SAS statistical software (SAS v9.4; SAS Institute, Inc, Cary, NC).

Results

From August 2016 to January 2017, 50 patients were randomized to undergo annuloplasty ring or band fixation using the COR-KNOT automated titanium fasteners or fixation with standard, hand-tied knots. In 1 patient assigned to the COR-KNOT group, COR-KNOT was used for mitral valve annuloplasty, but hand tying was used for tricuspid valve annuloplasty, depending on device availability. In this case, the outcome data for tricuspid annuloplasty are presented and analyzed as treated and in the hand-tied knot group.

The median number of sutures used to secure the annuloplasty ring to the mitral valve in the COR-KNOT group was 16 versus 17 sutures in the hand-tied knot group (means 16 ± 1.4 vs 17 ± 2 , respectively; $p = 0.055$).

Fig 1. Consolidated Standards of Reporting Trials (CONSORT; CONSORT Group, Ottawa, Canada) flow diagram. (MV = mitral valve; TV = tricuspid valve.)



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