Rigid Plate Fixation Versus Wire Cerclage for Sternotomy After Cardiac Surgery: A Meta-Analysis

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Background. **Traditionally, wire cerclage has been used to reapproximate the sternum after sternotomy. Recent evidence suggests that rigid plate fixation for sternal closure may reduce the risk of sternal complications.**

Methods. **The Medline and Embase databases were searched from inception to February 2017 for studies that compared rigid plate fixation with wire cerclage for cardiac surgery patients undergoing sternotomy. Random effects meta-analysis compared rates of sternal complications (primary outcome, defined as deep or superficial sternal wound infection, or sternal instability), early mortality, and length of stay (secondary outcomes).**

Results. **Three randomized controlled trials (n = 427) and five unadjusted observational studies (n = 1,025) met inclusion criteria. There was no significant difference in sternal complications with rigid plate fixation at a median of 6 months' follow-up (incidence rate ratio 0.51, 95% confidence interval [CI]: 0.20 to 1.29, $p = 0.15$) overall, but a decrease when including only patients at high risk for sternal complications (incidence rate ratio 0.23, 95% CI: 0.06 to 0.89, $p = 0.03$; two observational studies). Perioperative mortality was reduced favoring rigid plate fixation (relative risk 0.40, 95% CI: 0.28 to 0.97, $p = 0.04$; four observational studies and one randomized controlled trial). Length of stay was similar overall (mean difference −0.77 days, 95% CI: −1.65 to +0.12, $p = 0.09$), but significantly reduced with rigid plate fixation in the observational studies (mean difference −1.34 days, 95% CI: −2.05 to −0.63, $p = 0.0002$).**

Conclusions. **This meta-analysis, driven by the results of unmatched observational studies, suggests that rigid plate fixation may lead to reduced sternal complications in patients at high risk for such events, improved perioperative survival, and decreased hospital length of stay. More randomized controlled trials are required to confirm the potential benefits of rigid plate fixation for primary sternotomy closure.**

(Ann Thorac Surg 2018;106:298–304)

Median sternotomy remains one of the most commonly performed bone osteotomies globally, allowing for rapid access and excellent exposure to the intrapericardial and mediastinal structures. Sternal dehiscence and deep sternal wound infection (SWI) are serious complications after sternotomy and are associated with increased mortality and prolonged length of stay after cardiac surgery. Although Medicare has deemed mediastinitis a "never" event, the incidence ranges from 1% to 3% in the literature [1–3]. Risk factors include patient-related factors (smoking, lung disease, obesity, diabetes mellitus, renal failure) and procedure-related factors (eg, off-midline sternotomy and bilateral internal mammary artery [BIMA] harvest for coronary artery bypass graft surgery) [2].

In orthopedic surgery, rigid plate fixation (RPF) is the standard of care for the management of bone fractures and osteotomies, whereas wire cerclage (WC) remains the routine method of sternal closure in cardiac surgery for various reasons, including familiarity and ease of use. A recent randomized controlled trial (RCT) used a previously validated angiographic bone healing score as its primary outcome and demonstrated improved sternal healing scores and rates of sternal union with RPF compared with WC at 3 and 6 months [4]. In addition, as part of their safety outcomes, the same study also showed

Presented at the American College of Surgeon's Clinical Congress in San Diego, CA, Oct 2017.

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The Supplemental Material can be viewed in the online version of this article [https://doi.org/10.1016/j.athoracsur.2018.02.043] on http://www.annalsthoracicsurgery.org.

Published by Elsevier Inc.

0003-4975/$36.00
https://doi.org/10.1016/j.athoracsur.2018.02.043

Abbreviations and Acronyms

BIMA = bilateral internal mammary artery
CI = confidence interval
IRR = incident rate ratio
RCT = randomized controlled trial
RPF = rigid plate fixation
RR = relative risk
SWI = sternal wound infection
WC = wire cerclage

reduced sternal complications with RPF at 3 and 6 months; in contrast, some observational studies have shown no difference in sternal complications.

This meta-analysis seeks to determine whether RPF decreases the incidence of sternal complications (primary outcome), compared with WC in patients undergoing a median sternotomy for cardiac surgery. Our secondary outcomes include 30-day and inhospital mortality, late mortality, and hospital length of stay.

Patients and Methods

Systematic Review of the Literature

The Ovid versions of Medline and Embase were searched from 1946 to February 3, 2017, with the following key words: "rigid fixation," "bone plat*," "stern*," "fracture fixation," and "bone screws." Full details of the search strategy can be found in Appendix A. Study inclusion criteria included English language, direct comparison of RPF with WC, and at least one outcome of interest. Exclusion criteria for studies included non-English studies, conference abstracts and proceedings, and case reports and other noncomparative study designs. In addition, hand-searching of all selected references and review articles on this topic was performed. We also contacted the manufacturers of two rigid plate fixation systems (Sternalock Blue [Zimmer Biomet, Jacksonville, FL] and Depuy Synthes [Johnson & Johnson, West Chester, PA]) for any additional published or unpublished work. Titles and abstracts were screened by two investigators independently (D.Y.T. and R.N.). Full articles that met inclusion criteria were retrieved for further review. Disagreements between investigators were resolved by consensus. Furthermore, we screened all studies for possible overlap in patient population by examining the author list, study period, and institutions where the patients originated. When there was overlap between studies, we took the study with the larger sample size or the longer duration of follow-up.

Quality Assessment and Data Abstraction

Quality assessment of the selected studies for risk of bias was performed independently by two investigators (D.Y.T. and J.F.). Observational studies were assessed using the "grading of recommendations, assessment, development and evaluations" (GRADE) approach whereas RCTs were assessed using the Cochrane risk of bias tool [5, 6]. The following data were independently abstracted (by D.Y.T. and M.Y.): study details (sample size, country of origin, study period, duration of follow-up, plate system); patient characteristics; comorbidities and risk factors for sternal infections; operative details; and study outcomes. The primary outcome was defined as sternal complication and the secondary outcomes were 30-day or inhospital mortality, late mortality, and hospital length of stay. Sternal complications were defined as superficial SWI, deep SWI, sternal dehiscence, sternal instability, and reoperation for sternal complications.

Analysis

We used Review Manager (Revman version 5.2; Cochran Collaboration, Oxford, UK) to perform a random effects meta-analysis. For perioperative outcomes with similar follow-up, event rates were used to calculate relative risk ratios (RR) for binary outcomes, and mean differences were used to pool continuous outcomes. When the mean and standard deviation were not provided, they were estimated from the median and range, as described in the literature [7, 8]. For longer-term outcomes with potentially different follow-up between groups, the incident rate ratio (IRR) was pooled and analyzed using the generic inverse variance method on the logarithmic scale. When hazard ratios (assumed to be equivalent to IRR) were not provided, IRR for each study was calculated in one of two ways: (1) using Kaplan-Meier survival curve estimates for each group and the log-rank survival curve p value to estimate the standard error of the logarithm-transformed IRR, as previously described [9, 10]; or (2) using absolute events divided by patient-years of follow-up when group-specific mean follow-up durations were provided, as described in the literature [9, 11]. We reported heterogeneity as low ($I^2 = 0\%$ to 25%), moderate ($I^2 = 26\%$ to 50%), or high ($I^2 > 50\%$) [12]. All results were reported with 95% confidence interval (CI) as pooled weighted results of two subgroups (RCTs and observational studies) and overall. Statistical significance is assumed for p less than 0.05.

Post-Hoc Subgroup Analysis

We performed two post-hoc subgroup analyses. In the first subgroup analysis, we compared studies that used Sternalock (Zimmer Biomet, Warsaw, IN) for RPF to studies that used other RPF systems. In addition, as a sensitivity analysis, we compared rates of complication on study publication year (before 2016 versus after 2016) as a surrogate for potential use of newer generation of RPF systems as not all studies specified the generation of plating system used. In the second subgroup analysis, we grouped studies based on patient population risk for sternal complications as either high risk (three or more risk factors) or non–high risk (zero, one, or two risk factors). The reported risk factors included chronic obstructive pulmonary disease, body mass index greater than 30 kg/m^2, diabetes mellitus, chronic steroid use, BIMA grafting, and previous median (ie, redo) sternotomy.

Results

Description of Selected Studies and Quality Assessment

Our search of Medline and Embase yielded 454 citations after duplicates were removed. Eight articles were included in the analysis after title, abstract, and full article review (Supplemental Fig 1). Three studies were RCTs (n = 427) [4, 13, 14] and five studies were unmatched observational studies (n = 1,025) for a total of 1,452 patients [15–19]. There was overlap between an additional observational study, Song and associates [20], and one of the included observational studies, Raman and associates [19], that shared a common study period. We elected to include Raman and associates [19] as it matched our prespecified criteria of having the larger sample size. The quality of the RCTs was moderate (Supplemental Table 1). Two studies were of high quality [4, 14], whereas one study was at some risk of bias as there was incomplete details regarding blinding [13]. Furthermore, there was selective reporting of outcomes in two studies (30-day mortality was not reported) [13, 14]. The duration of follow-up for all three RCTs was 6 months.

All observational studies were retrospective and unmatched; overall study quality was low to moderate (Supplemental Table 2). Four studies provided concurrent control data whereas one study used historic controls [19]. We performed a meta-analysis of baseline risk factors (Supplemental Figs 2 and 3). Most observational studies did not have comparable baseline characteristics in the two groups; patients undergoing RPF were 5 years younger (95% CI: 3.4 to 6.7 years) and had 1.8 kg/m^2 lower body mass index (95% CI: 0.9 to 2.6 kg/m^2) but a higher incidence of BIMA harvesting (RR 2.6, 95% CI: 1.4 to 2.9; Supplemental Figs 2 and 3; Table 1). Two observational studies provided only early outcomes (hospital discharge) [16, 18] and three observational studies provided longer term outcomes [15, 17, 19].

The populations of the included studies varied in the patient's risk for sternal complications. The number of risk factors varied in the three RCTs; one specifically excluded high-risk patients [4] and the other two allowed patients with one or two risk factors [13, 14]. Two observational studies included patients with three or more risk factors for sternal complications (ie, high-risk patients) [17, 19], whereas the other studies included patients with only one or two risk factors. The reported risk factors for sternal complications also varied between studies. The risk factors commonly described in studies included being female, chronic obstructive pulmonary disease, body mass index greater than 30 kg/m^2, diabetes mellitus, chronic steroid use, previous sternotomy, and BIMA harvest. The definition of sternal complication also varied among studies, and the definitions by study are summarized in Supplemental Table 3. The sternal complications described in our studies included superficial SWI, deep SWI, dehiscence, sternal instability, sternal nonunion, and reoperation specific for sternal complications. There was heterogeneity in the number and pattern of plates used, number of wires used, and WC pattern between the studies (Supplemental Table 4). However, there was no difference in the pooled mean operating room time in the four studies that reported it (mean difference 12 minutes, 95% CI: −13 to 37, $p = 0.35$).

Early and Late Sternal Wound Complications

There was no difference in sternal complications at 30 days or hospital discharge (RR 0.40, 95% CI: 0.04 to 3.62, $p = 0.41$, $I^2 = 0\%$) between RPF and WC (Supplemental Fig 4), or at maximum follow-up (median 6 months [range, hospital discharge to 200 weeks], IRR 0.51, 95% CI: 0.20 to 1.29, $p = 0.15$, $I^2 = 56\%$; Fig 1).

Early and Late Mortality

Early mortality (30-day or at hospital discharge) was reduced in the RPF group compared with the WC group (RR 0.52, 95% CI: 0.28 to 0.97, $p = 0.04$, $I^2 = 0\%$) in five studies (Fig 2) but this was driven by the results of the four observational studies (RR 0.49, 95% CI: 0.25 to 0.93, $p = 0.03$, $I^2 = 0\%$). Longer-term mortality was similar at a median follow-up of 180 days in three studies (IRR 0.94, 95% CI: 0.32 to 2.75, $p = 0.92$, $I^2 = 14\%$; Supplemental Fig 5).

Total Length of Stay

There was no difference in the length of stay between RPF and WC in the RCTs and observational studies combined (mean difference −0.77 days, 95% CI: −1.65 to 0.12, $p = 0.09$, $I^2 = 64\%$). Length of stay was significantly lower with RPF (mean difference −1.34 days, 95% CI: −2.05 to −0.63, $p = 0.0002$, $I^2 = 12\%$) in the observational studies, and the treatment study type interaction was statistically significant (interaction $p = 0.04$; Fig 3).

Post-Hoc Subgroup Analyses

Six studies utilized the Sternalock system, and two studies used other devices. The rate of sternal complications was similar in Sternalock studies (IRR 0.54, 95% CI: 0.14 to 2.03, $p = 0.36$, $I^2 = 68\%$) compared with non-Sternalock studies (IRR 0.50, 95% CI: 0.19 to 1.29, $p = 0.15$, $I^2 = 0\%$, interaction $p = 0.94$; Supplemental Fig 6). In addition, there was no difference in sternal complication rates between early studies (before 2016) and late studies (after 2016 [interaction $p = 0.56$]). When the analysis was stratified by risk for sternal complications, patients at high risk did have a lower rate of sternal complications with RPF compared with WC (IRR 0.23, 95% CI: 0.23 to 0.89, $p = 0.03$, $I^2 = 73\%$; Supplemental Fig 7) whereas non–high risk patients did not (IRR 0.86, 95% CI: 0.29 to 2.51, $p = 0.78$, interaction $p = 0.14$).

Comment

This analysis represents the first systematic review and meta-analysis comparing RPF and WC for primary sternal closure after cardiac surgery. Overall, there was a trend toward lower rates of any type of sternal wound complications in the RPF group at last follow-up compared with the WC group. However, groups in the

Table 1. Baseline Demographics and Risk Factors for Sternal Complications of Included Studies

	Number		Age, Years			Male, %			Body Mass Index, kg/m^2		
First Author, Year	RPF	WC	RPF	WC	*p* Value	RPF	WC	*p* Value	RPF	WC	*p* Value
Randomized clinical trials											
Allen, 2016	116	120	65.3 ± 13	65.7 ± 11.4	0.78	74	76	0.76	28.8 ± 4.7	29.4 ± 4.6	0.28
Raman, 2012	70	70	66.3 ± 9.8	64 ± 8.9	0.14	73	74	1	31.8 ± 5.5	31.8 ± 4.6	0.98
Bennett-Guerrero, 2011	28	23	61.8 ± 10	63.0 ± 9.2	0.65	86	61	0.04	>30: 75%	>30: 65%	0.45
Unmatched observational studies											
Matsuyama, 2016	31	33	65.1 ± 7.1	70.5 ± 10.6	0.08	94	79	0.9	23.3 ± 3.1	24.0 ± 3.8	0.47
Park, 2016	30	45	59.6 ± 2.2	64 ± 1.7	0.11	50	33	0.16	33.9 ± 1.6	36.0 ± 1.1	0.26
Hirose, 2011	89	133	62 ± 9	69 ± 11	<0.001	84	48	<0.001	…	…	…
Snyder, 2009	30	99	61 (43–78)	59 (44–77)	0.8	100	98	1	33 (22–47)	32 (23–49)	0.50
Raman, 2006	320	215	…	…	…	…	…	…	…	…	…

Table 1. Continued

	Diabetes, %			Lung Disease, %			Smoker, %			Renal Failure, %			BIMA Use, %			Redo Sternotomy, %		
First Author, Year	RPF	WC	*p* Value	RPF	WC	*p* Value	RPF	WC	*p* Value	RPF	WC	*p* Value	RPF	WC	*p* Value	RPF	WC	*p* Value
Randomized clinical trials																		
Allen, 2016	30	37	0.29	19	18	0.58	12	8	0.34	0	2	0.16	6	3	0.37	7	4	0.36
Raman, 2012	69	61	0.48	21	27	0.55	…	…	…	27	27	1	13	17	0.64	14	14	1
Bennett-Guerrero, 2011	50	30	0.16	21	26	0.7	32	44	0.41	…	…	…	4	0	0.59	11	17	0.49
Unmatched observational studies																		
Matsuyama, 2016	71	48	0.067	0	0	0	61	73	0.33	23	24	0.13	65	24	0.001	…	…	…
Park, 2016	63	80	0.121	23	29	0.44	…	…	…	17	18	1	0	0	…	…	…	…
Hirose, 2011	30	38	0.2206	17	20	0.52	20	14	0.18	2	5	0.37	…	…	…	2	9	0.04
Snyder, 2009	10	18	0.401	…	…	…	43	20	0.01	…	…	…	0	1	1	3	4	1
Raman, 2006	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…

BIMA = bilateral internal mammary artery; RPF = rigid plate fixation; WC = wire cerclage.

Study or Subgroup	log[Incident Rate Ratio]	SE	RPF Total	WC Total	Weight	Incident Rate Ratio IV, Random, 95% CI
2.6.1 RCT						
Bennett-Guerrero 2011	−0.1967	1.4142	28	23	7.8%	0.82 [0.05, 13.13]
Raman 2012	0.9894	0.8165	70	70	14.8%	2.69 [0.54, 13.33]
Allen 2016	−2.531	1.4676	116	120	7.4%	0.08 [0.00, 1.41]
Subtotal (95% CI)			**214**	**213**	**30.0%**	**0.73 [0.09, 5.61]**
Heterogeneity: Tau^2 = 1.79; Chi^2 = 4.44, df = 2 (P = 0.11); I^2 = 55%						
Test for overall effect: Z = 0.30 (P = 0.76)						
2.6.2 Observational						
Raman 2006	−2.1204	0.4855	320	215	20.6%	0.12 [0.05, 0.31]
Snyder 2009	−0.7985	0.6155	30	99	18.2%	0.45 [0.13, 1.50]
Hirose 2011	1.6826	1.633	89	133	6.4%	5.38 [0.22, 132.06]
Matsuyama 2016	0.25	2	31	33	4.6%	1.28 [0.03, 64.71]
Park 2016	−0.7577	0.5123	30	45	20.1%	0.47 [0.17, 1.28]
Subtotal (95% CI)			**500**	**525**	**70.0%**	**0.39 [0.15, 1.03]**
Heterogeneity: Tau^2 = 0.56; Chi^2 = 8.40, df = 4 (P = 0.08); I^2 = 52%						
Test for overall effect: Z = 1.91 (P = 0.06)						
Total (95% CI)			**714**	**738**	**100.0%**	**0.51 [0.20, 1.29]**
Heterogeneity: Tau^2 = 0.85; Chi^2 = 16.06, df = 7 (P = 0.02); I^2 = 56%						
Test for overall effect: Z = 1.43 (P = 0.15)						
Test for subgroup differences: Chi^2 = 0.30, df = 1 (P = 0.58), I^2 = 0%						

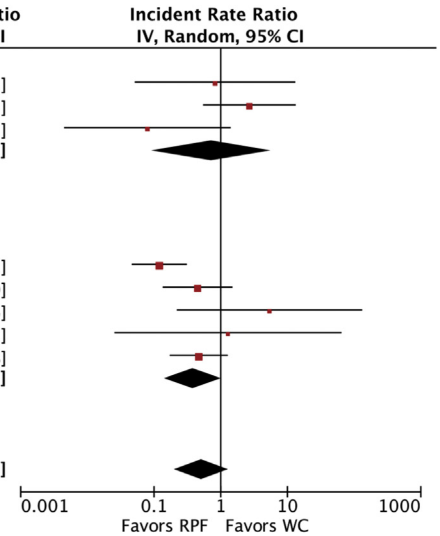

Fig 1. Forest plot for incident rate ratio for any sternal complication at the end of study follow-up for rigid plate fixation (RPF) versus wire cerclage (WC) in patients undergoing cardiac surgery. The median reported follow-up time was 6 months (range, hospital discharge to 200 weeks). (CI = confidence interval; IV = inverse variance; RCT = randomized controlled trial.)

observational studies were not balanced; patients were younger and had a lower body mass index in the RPF group, and there was also an increase in BIMA harvesting in the RPF group. We found that when studies were stratified by risk, high-risk patients had a significant 77% risk reduction in sternal complications with sternal plating compared with conventional WC. In addition, early mortality was lower and there was a trend toward decreased total hospital length of stay in the RPF group compared with patients undergoing WC. However, in all these cases the benefits observed for the RPF patients were dominated by the results of the unmatched observational studies.

The most recently published RCT of cardiac surgical patients undergoing sternotomy, included in this meta-analysis, compared 116 patients undergoing RPF with 120 patients undergoing WC and found that sternal healing was improved at 6 months using a previously validated computed tomography scoring tool [4]. In addition to early and improved bone healing by radiography, there was also a reduction in sternal complication events in the plating group (0% versus 5%; $p = 0.03$) by 6

Study or Subgroup	RPF Events	RPF Total	WC Events	WC Total	Weight	Risk Ratio M-H, Random, 95% CI
1.2.1 RCTs						
Allen 2016	2	116	2	120	10.0%	1.03 [0.15, 7.22]
Subtotal (95% CI)		**116**		**120**	**10.0%**	**1.03 [0.15, 7.22]**
Total events	2		2			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.03 (P = 0.97)						
1.2.2 Observational studies						
Raman 2006	12	320	18	215	75.2%	0.45 [0.22, 0.91]
Snyder 2009	1	30	2	99	6.8%	1.65 [0.15, 17.57]
Hirose 2011	1	89	4	133	8.0%	0.37 [0.04, 3.29]
Matsuyama 2016	0	31	0	33		Not estimable
Subtotal (95% CI)		**470**		**480**	**90.0%**	**0.49 [0.25, 0.93]**
Total events	14		24			
Heterogeneity: Tau^2 = 0.00; Chi^2 = 1.13, df = 2 (P = 0.57); I^2 = 0%						
Test for overall effect: Z = 2.18 (P = 0.03)						
Total (95% CI)		**586**		**600**	**100.0%**	**0.52 [0.28, 0.97]**
Total events	16		26			
Heterogeneity: Tau^2 = 0.00; Chi^2 = 1.65, df = 3 (P = 0.65); I^2 = 0%						
Test for overall effect: Z = 2.06 (P = 0.04)						
Test for subgroup differences: Chi^2 = 0.52, df = 1 (P = 0.47), I^2 = 0%						

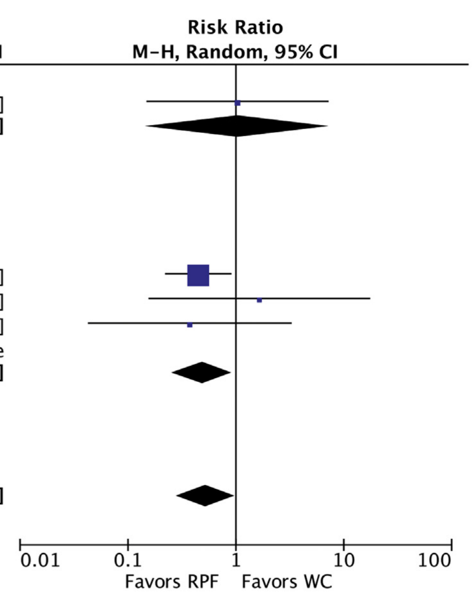

Fig 2. Forest plot for risk ratio of 30-day mortality for rigid plate fixation (RPF) versus wire cerclage (WC) in patients undergoing cardiac surgery. (CI = confidence interval; M-H = Mantel-Haenszel; RCT = randomized controlled trial.)

Study or Subgroup	RPF Mean	RPF SD	RPF Total	WC Mean	WC SD	WC Total	Weight	Mean Difference IV, Random, 95% CI
3.2.1 RCTs								
Bennett-Guerrero 2011	4.5	3.2	28	5.3	4	23	11.1%	−0.80 [−2.82, 1.22]
Raman 2012	13.3	9.8	70	10.7	6.3	70	7.5%	2.60 [−0.13, 5.33]
Allen 2016	6.9	2.4	116	6.9	2.7	120	23.3%	0.00 [−0.65, 0.65]
Subtotal (95% CI)			**214**			**213**	**42.0%**	**0.26 [−1.12, 1.64]**
Heterogeneity: Tau² = 0.79; Chi² = 4.06, df = 2 (P = 0.13); I² = 51%								
Test for overall effect: Z = 0.37 (P = 0.71)								
3.2.2 Observational Studies								
Snyder 2009	7	2.11	30	8	2.11	99	21.3%	−1.00 [−1.86, −0.14]
Hirose 2011	7	3.7	89	8.4	4.7	133	18.8%	−1.40 [−2.51, −0.29]
Matsuyama 2016	16	4	31	19.3	5.4	33	9.4%	−3.30 [−5.62, −0.98]
Park 2016	8	5.4	30	9	5.4	45	8.5%	−1.00 [−3.49, 1.49]
Subtotal (95% CI)			**180**			**310**	**58.0%**	**−1.34 [−2.05, −0.63]**
Heterogeneity: Tau² = 0.07; Chi² = 3.41, df = 3 (P = 0.33); I² = 12%								
Test for overall effect: Z = 3.70 (P = 0.0002)								
Total (95% CI)			**394**			**523**	**100.0%**	**−0.77 [−1.65, 0.12]**
Heterogeneity: Tau² = 0.76; Chi² = 16.71, df = 6 (P = 0.01); I² = 64%								
Test for overall effect: Z = 1.70 (P = 0.09)								
Test for subgroup differences: Chi² = 4.07, df = 1 (P = 0.04), I² = 75.4%								

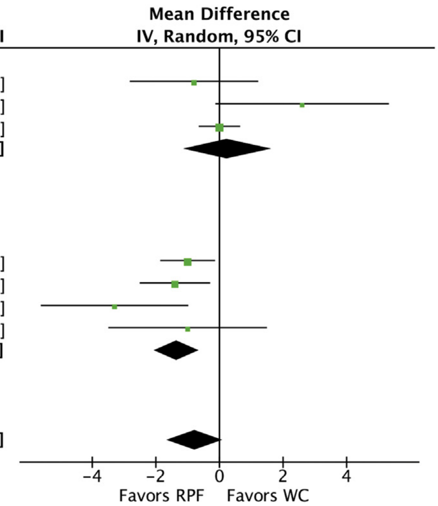

Fig 3. Forest plot for mean differences (in days) in total hospital length of stay for rigid plate fixation (RPF) versus wire cerclage (WC) in patients undergoing cardiac surgery. (CI = confidence interval; IV = inverse variance; RCT = randomized controlled trial.)

months. Following orthopedics principles, the cornerstone of fracture and osteotomy management is reapproximation and stabilization of the bone. These findings suggest that improved bone healing and bone immobilization may prevent infectious complications. Similarly, pooling all data in our meta-analysis we found significant trends toward lower sternal complications with RPF of the sternum. Interestingly, in our subgroup analysis, we found that there was a significant difference in sternal complication rates in the high-risk patient groups that were mainly derived from observational studies. This finding may be due to two of the randomized trials in our analysis excluding very high risk patients as part of their study protocol [4, 13]. These findings highlight the need for additional large high quality RCT in both average and very high risk patients to demonstrate the clinical efficacy of RPF.

Sternal complications, and in particular, deep SWI, are serious complications after median sternotomy. Although deep SWI is uncommon in the literature, ranging from 1% to 3%, readmissions related to this complication are no longer reimbursed by Medicare in the United States [1–3]. Efforts aimed to reduce the incidence of deep SWI and sternal complications are important from both a patient and a health system perspective. That is particularly true for the very high risk patients such as those with obesity, severe chronic lung disease, on immunosuppression regimens of chronic steroids, osteoporotic sternums, and diabetes. Our subgroup analysis of these patients was exploratory and hypothesis generating. We suggest that for such very high risk patients (ie, those with three or more risk factors) RPF may reduce the risk of sternal complications, and therefore, RPF should be considered.

Given the additional cost of RPF, further studies are required to determine whether its use is justified in all patients. An economic evaluation was performed alongside the recently published RCT comparing RPF to WC [4]. Costs from the time of sternal closure to follow-up at 6 months were compared between the two groups; findings suggest that although the initial hospitalization costs were higher in the RPF group ($23,437 versus $20,574), total cumulative costs through follow-up were numerically lower but not statistically different ($32,439 versus $34,085; $p = 0.61$). Our study suggests that reduced total hospital length of stay and future sternal complication events may serve as a mechanism to offset the higher initial costs associated with RPF. Further evaluation of cost effectiveness will be critical to setting reimbursement policies for RPF; that will require a formal cost-utility analysis that compares all relevant costs and health-related quality of life differences between the two treatment arms.

Study Limitations

This study must be interpreted in the context of several limitations. There were only eight studies in total that directly compared RPF with WC, of which only three were RCTs—despite a comprehensive literature search that included contacting manufacturers for published and unpublished data. Nonetheless, this remains the largest study that directly compares the two sternal closure strategies. The observational studies included in the analysis were of low to moderate quality; these studies had significant baseline differences and did not use any statistical techniques to match the two groups. Given the low event rate for any sternal complications and the different outcomes collected across studies, it was not possible to analyze outcomes individually. We grouped together some outcomes that are more severe, such as deep SWI and reoperation for sternal complications, with less severe complications such as superficial sternal infections and sternal instability. We performed a post-hoc analysis stratified by risk for complications; however, the reporting of risk variables was inconsistent in the individual studies, and the high-risk subgroup analysis was based on only two studies.

There also remains uncertainty whether there is a class effect that may be extended from one device manufacturer to another. We conducted a post-hoc analysis based on manufacturer and found no difference in rates of complications. In addition, different generations of devices exist from the same manufacturer, so we compared early studies (before 2016) to more recent studies and found no difference in sternal complications as a sensitivity analysis. However, as with the other comparisons, small numbers of studies in each subgroup limited the power to detect differences. Therefore, our analysis was not adequately powered to explore whether there exists a class effect from one device that can be generalized to all plating systems. Similarly, there was some heterogeneity among studies in how conventional WC was performed. Unfortunately, given the limited sample size, we were unable to perform a subgroup analysis on these data. However, these findings represent the real world variation in practice that may exist across institutions and even within institutions for WC closure. Finally, the comparison of the primary outcome was not statistically different between the RPF and WC groups; all secondary outcome and subgroup comparisons should be considered hypothesis generating and exploratory.

Conclusion

For patients at high risk for sternal complications, RPF was superior to traditional WC at the time of primary sternal closure, but that finding was derived from a small number of primarily unmatched observational studies. Although there was a trend toward lower sternal complications in all patients (high and average risk patients), there remains uncertainty regarding the true benefit for this population. Further research in the form of a large RCT is required to assess the potential benefit of RPF as the primary means of closure after median sternotomy.

Dr Tam is supported by the Ontario Ministry of Health Clinician Investigator's Program (Toronto, Ontario, Canada). Dr Fremes is supported by the Bernard S. Goldman Chair in Cardiovascular Surgery (Toronto, Ontario, Canada).

REVIEW

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