


# Surgical wound closure by staples or sutures?

## Systematic review

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### Abstract

**Aim:** To compare the effects of sutures and staples for skin closure of surgical wounds.

**Material and methods:** We included published and unpublished randomized controlled trials (RCTs) and cluster-randomized trials comparing staples with sutures. Patients were adults (aged 18 years or over) who had undergone any type of surgery. The primary outcomes were risk of overall and severe wound infection. Secondary outcomes included length of hospital stay, readmission rate, adverse events, patient satisfaction with cosmetic results, postoperative pain.

**Results:** Forty-two very low to low quality RCTs with a total of 11,067 patients were included. Sutures resulted in slightly fewer overall wound infections (4.90%) compared to staples (6.75%) but it is uncertain whether there is a difference between the groups (risk ratio [RR] 1.20, 95% confidence intervals [CI] 0.80–1.79; patients=9864; studies=34;  $I^2=70\%$ ). The evidence was also insufficient to state a difference in terms of severe wound infection (staples 1.4% vs sutures 1.3%; RR 1.08, 95% CI 0.61–1.89; patients=3036; studies=17;  $I^2=0\%$ ), grade of satisfaction (RR 0.99, 95% CI 0.91–1.07; patients=3243; studies=14;  $I^2=67\%$ ) and hospital stay. Staples may increase the risk of adverse events (7.3% for staples vs 3.5% for sutures; RR 2.00, 95% CI 1.44–2.79; patients=6246; studies=21;  $I^2=33\%$ ), readmission rate (RR 1.28, 95% CI 0.18–9.05; patients=2466; studies=5;  $I^2=66\%$ ) and postoperative pain (standardized mean difference [SMD] 0.41, 95% CI –0.35 to 1.16;  $I^2=88\%$ , patients=390 patients, studies=5).

**Conclusions:** Due to the lack of high quality evidence, we could not state if sutures are better than staples in terms of wound infection, readmission rate, adverse events, and postoperative pain. With a low quality of evidence, sutures reduce postoperative pain and improve grade of satisfaction with the cosmetic outcome.

**Abbreviations:** BMI = body mass index, CI = confidence intervals, OIS = optimal information size, RCTs = randomized controlled trials, RR = risk ratio, SMD = standardized mean difference.

**Keywords:** general surgery, infection, post-operative, staples, surgical, surgical site infections, sutures

Editor: Nikhil Jain.

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Supplemental Digital Content is available for this article.

The authors have no conflicts of interests to disclose.

Data sharing statement: All data relevant to the study are included in the article or uploaded as supplementary information.

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How to cite this article: Cochetti G, Abraha I, Randolph J, Montedori A, Boni A, Arezzo A, Mazza E, Vermandois JA, Cirocchi R, Mearini E. Surgical wound closure by staples or sutures? Systematic review. *Medicine* 2020;99:25(e20573).

Received: 3 June 2019 / Received in final form: 1 December 2019 / Accepted: 4 May 2020

<http://dx.doi.org/10.1097/MD.00000000000020573>

### Strengths and limitations of this study

- In this systematic review and meta-analysis, 42 studies comparing sutures with staples for skin closure of surgical wound were identified.
- This is the most comprehensive systematic review of these interventions to date.
- The study analyzes the outcomes related to the closure with sutures or staples according to the different types of surgical specialties.
- The main limitation of this systematic review is the low overall quality of the included studies.
- There was significant statistical heterogeneity.

## 1. Introduction

### 1.1. Description of the condition

Surgical wound closure aims to move close the skin flaps to favor rapid healing and a good cosmetic outcome with low risk of complications. Infection of surgical wound is a relevant

complication with an incidence of 1% to 3%; it is favored by age, underlying illness (American Society of Anesthesiologists score of three or more, diabetes, malnutrition, low serum albumin, radiotherapy, and steroid use), obesity, host immune status, smoking, site, level of wound contamination.<sup>[1,2]</sup> Further significant risk factors are related to type and complexity of the surgical procedure, duration of operation, type of surgical approach (laparotomic or laparoscopic or robotic).<sup>[3,4]</sup> Wound dehiscence is another complication of surgical procedures that may increase the inpatient stay, resulting in additional costs, and it has a 9.6% attributable mortality.<sup>[5]</sup> Further surgical wound complications are the formation of hypertrophic or keloid scarring. The cosmetic appearance of the scar after healing is a relevant outcome, which affects the satisfaction of patients. A meticulous surgical technique is needed to avoid local swelling, dehiscence of the wound, and a poor cosmetic result. Different methods and materials are used for wound closure and they are highly dependent on the type of surgery, the length and anatomical site of the wound.<sup>[6]</sup> Skin closure of surgical wounds is usually achieved with sutures. Sutures can be continuous or interrupted and the material used can be natural or synthetic, absorbable or non-absorbable, single filament or braided, depending on the length and anatomic location of the wound. The principal advantages of sutures are their flexibility, strength, non-toxicity, and in vivo degradation properties. Staples are a valid alternative to sutures and are mainly made of stainless steel, although staples using absorbable materials are now available.<sup>[6]</sup> Although the sutures are the most common technique of closure, they could increase the risk of wound infection. In fact, the sutures could cause the ischemia of the wound flaps and this hinders a regular healing. The potential advantage of staples in surgical wound closure is related to their low level of tissue reactivity.<sup>[7]</sup> This generates a higher resistance to infection in contaminated wounds, given the non-introduction of exogenous material, and consequent impairment of local immune response.<sup>[8–11]</sup> Furthermore, it is thought that the use of staples reduces the local inflammatory response, width of the wound, time to wound closure, and residual cross marks.<sup>[12,13]</sup> Even if the skin closure is conventionally performed by sutures, staples seem to be better in terms of efficacy of fixation, good cosmetic results and rapidity of application. However, in literature, it is unclear which is the best skin closure technique between sutures and staples. While some RCTs report that there is no difference between two methods in terms of overall wounds infections,<sup>[14,15]</sup> others report higher rates of wound complications following the use of staples.<sup>[16,17]</sup> Furthermore, evidence has begun to be synthesized within different surgery types, but often it is not conclusive due to small sample size and low quality of studies; then, it is important for the clinicians to evaluate the issue through the broad field of different surgical specialties. We believe that a systematic review of RCTs is required to compare sutures with respect to staples in terms of wound infections, length of hospital stay, rates of readmission, adverse events, pain, patient satisfaction with cosmetic results, in order to provide surgeons the optimal method for skin closure in different surgical specialties.

## 1.2. Objectives

To compare the effects of sutures and staples for the closure of surgical wounds in adults undergoing surgery in a hospital setting.

## 1.3. Methods

A protocol that describes the search strategy, screening, and inclusion criteria has been previously published.<sup>[18]</sup>

Ethics committee of University of Perugia approved the study.

## 1.4. Information sources

We searched the following electronic databases to identify reports of relevant clinical trials: Cochrane Wounds Specialised Register, Cochrane Central Register of Controlled Trials (CENTRAL), Ovid MEDLINE Ovid Embase, EBSCO CINAHL Plus. There were no date, language or publication status restrictions. We also searched the following clinical trials registries: ClinicalTrials.gov, World Health Organization International Clinical Trials Registry Platform, EU Clinical Trials Register (April 2018).

## 1.5. Selection of studies

One review author (RC) ran all the electronic searches, downloaded the references into bibliographic software and removed duplicates. Two review authors (RC and AR) independently assessed the titles and abstracts first and then only assessed in full text the studies that appeared to be relevant. Disagreements were resolved through discussion with the review team and the arbitrator (AM). One of the review authors (EM) contacted the corresponding author of the publications if data were missing or clarification was needed.

## 1.6. Data extraction and management

We constructed a data extraction sheet for the review and two review authors (RC and JR) used this independently for data collection. These authors were blinded to each other's data; however, they were not blinded to the journal of publication or the trial authors. Two review authors (AB and EM) independently extracted the following information from each included trial:

1. setting of the study
2. sample sizes
3. patients
4. baseline characteristics of patients interventions
5. type of surgery outcomes
6. follow-up points

If information was missing from the published paper, we contacted the trial authors. We compared results to check for inconsistencies and resolved disagreements by discussion or, if consensus could not be reached, through adjudication by a third review author (EM).

## 1.7. Outcomes

Primary outcomes were risk of overall wound infection within 30 postoperative days (including superficial, deep, or space infections), risk of severe wound infection (only deep or space infections) within 30 postoperative days. Secondary outcomes were length of post-operative hospital stay, rates of readmission for wound complication, adverse events within 30 postoperative days and patient satisfaction with cosmetic results.

## 1.8. Assessment of risk of bias

Two authors independently assessed the included studies using the Cochrane tool for assessing risk of bias.<sup>[19]</sup> This tool

addresses specific domains: random sequence generation (selection bias),<sup>[20,21]</sup> allocation concealment (selection bias),<sup>[20,21]</sup> blinding of patients and personnel (performance bias),<sup>[20,21]</sup> blinding of outcome assessment (detection bias),<sup>[20,21]</sup> incomplete outcome data (attrition bias),<sup>[22,23]</sup> selective reporting (reporting bias).<sup>[24,25]</sup> We assessed blinding and completeness of outcome data for each outcome separately. We completed a “Risk of bias” table for each eligible study (see Table 1, Supplemental Content, <http://links.lww.com/MD/E368>, which illustrates the “Risk of bias”).

We presented our assessment of risk of bias using “Risk of bias” summary figure (Fig. 1). For trials using cluster-randomization, we assessed the risk of bias using the following domains: recruitment bias, baseline imbalance, loss of clusters, incorrect analysis, and comparability with individually randomized trials.<sup>[19]</sup>

### 1.9. Measures of treatment effect

We expressed the treatment effects as RR with 95% confidence intervals (CI) for dichotomous outcomes. We analyzed continuous data as mean differences or standardized mean differences with standard deviations. When possible, we performed intention-to-treat analyses including all patients according to their original allocation. Where binary data were missing, we

performed a worst-case scenario analysis of the main outcome. In this case, we assumed that those participants who were lost to follow-up in the treatment group had the worse outcome, while participants lost to follow-up in the control group had the best outcome.

We compared the effects of the primary analysis with the worst-case analysis to explore whether they had the same direction and magnitude. No missing data were imputed.

### 1.10. Assessment of heterogeneity

We assessed heterogeneity both by a visual inspection of the forest plot and through examination of  $\chi^2$  test and  $I^2$  statistic. We considered outcomes with a statistically significant  $\chi^2$  value at the 0.10 level and  $I^2$  values >50% to be statistically heterogeneous. In the case of statistical heterogeneity, we then ensured that the data and effect sizes were correct. If they were, we attempted to explore heterogeneity through an analysis of the subgroups. If there was extreme unexplained heterogeneity (e.g., if  $I^2$  values are over 75% or if there is inconsistent direction of the effects), we did not perform pooling. If there were studies that appeared to be outliers, we conducted an analysis with and without the outliers. If heterogeneity could not be sufficiently explained, we accounted for the heterogeneity by using a random-effects model.

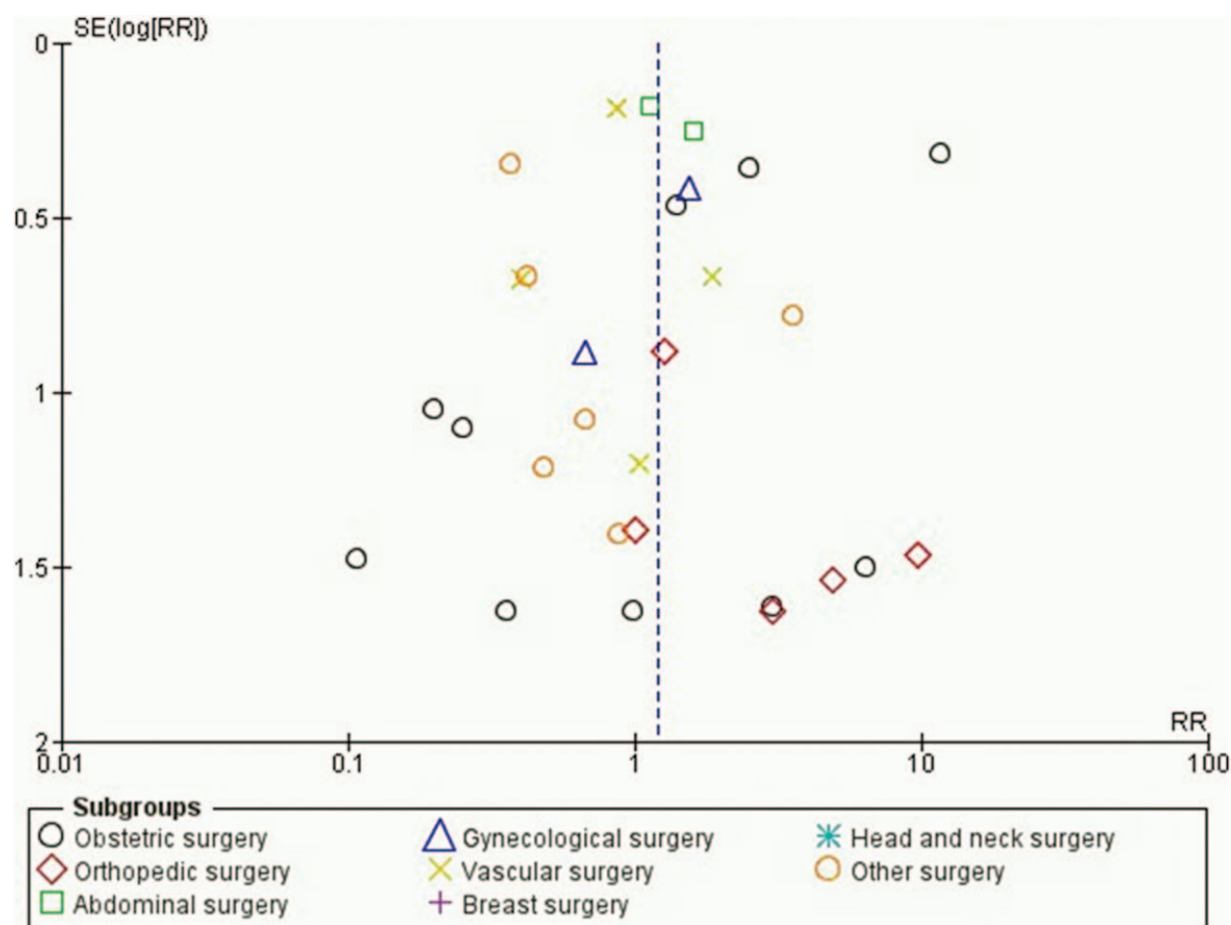


Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

### 1.11. Assessment of reporting biases

If there were 10 or more studies included for a particular outcome we produced a funnel plot using RevMan,<sup>[26]</sup> with the aim of looking for signs of asymmetry with respect to reporting bias.

### 1.12. Data synthesis

We summarized the main characteristics of included studies in Table 1 in Supplementary Material (see Table 1, Supplemental Content, <http://links.lww.com/MD/E368>, which illustrates the “Risk of bias”). In terms of data synthesis, we used a fixed-effect model for non-statistically heterogeneous outcomes. We used a random-effects model for statistically heterogeneous outcomes in which the heterogeneity could not be explained through a subgroup analysis. In the case of rare events (defined here as risks of 1 in 100 or less), we used the Peto one-step odds ratio method.

An exception to using the Peto method for rare events occurred when the risk ratio was  $<0.02$  or  $>5.00$  or when the event risk was about 1% and when the N size was two or more times greater in one condition than the other. In that case, we also reported logistic regression results.<sup>[27]</sup>

To summarize the methods and results, we included a PRISMA study selection flow chart,<sup>[28]</sup> Tables 1–3 and forest plots for each synthesized outcome (Tables 1–3). We used the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach to assess the quality of the evidence for each estimate of treatment effect.<sup>[19,28–30]</sup>

Where necessary the quality of evidence was downgraded by one (serious concern) or two (very serious concern) for the following reasons: risk of bias, imprecision, inconsistency, indirectness, and publication bias.<sup>[31,32]</sup> Quality of evidence was assessed for all the outcomes of the included studies (Table 1).

**Table 1**

**Staples compared to sutures for surgical wound closure in adults.**

**Patient or population: adult patients with surgical wound necessitating closure setting: hospital**

**Intervention: staples comparison**

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with sutures	Risk with staples				
Risk of overall wound infection	49 per 1,000	67 per 1,000 (42–89)	RR 1.20 (0.80–1.79)	9864 (34 RCTs)	⊕⊕⊕⊕ Low <sup>1</sup>	
Risk of severe wound infection	13 per 1,000	14 per 1,000 (8–24)	RR 1.08 (0.61–1.89)	3066 (17 RCTs)	⊕⊕⊕⊕ Low <sup>2</sup>	
Length of hospital stay			–	2774 (7 RCTs)	⊕⊕⊕⊕ Very low <sup>3</sup>	There was too high heterogeneity that hindered the possibility of performing a meta-analysis.
Rates of readmission	5 per 1,000	6 per 1,000 (1–45)	RR 1.28 (0.18–9.05)	2466 (5 RCTs)	⊕⊕⊕⊕ Low <sup>4</sup>	
Adverse events	35 per 1,000	70 per 1,000 (50–97)	RR 2.00 (1.44–2.79)	6246 (21 RCTs)	⊕⊕⊕⊕ Low <sup>5</sup>	
Patient satisfaction	625 per 1,000	619 per 1,000 (569–669)	RR 0.99 (0.91–1.07)	3243 (14 RCTs)	⊕⊕⊕⊕ Low <sup>6</sup>	
Pain	The mean pain was 0	SMD 0.41 higher (0.35 lower to 1.16 higher)	–	390 (5 RCTs)	⊕⊕⊕⊕ Very low <sup>7</sup>	A potential concern could be that of heterogeneity that resulted very high. The exclusion of one study (72) reduced significantly the heterogeneity to $I^2=32\%$ ( $P=.22$ ) without affecting substantially the final results (SMD 0.03 [–0.24, 0.31]). Compared to the other studies, this was an old trial.

GRADE Working Group grades of evidence.

High quality: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

CI=confidence interval, RR=risk ratio, OR=odds ratio.

\* The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

<sup>1</sup> We downgraded the evidence by two levels due to serious concern of risk of bias (58% of the trials reported unclear or inadequate allocation concealment and 80% reported unclear or inadequate blinding of the outcome assessor) and imprecision (the Optimal Information Size [OIS] criterion was met, however the 95% CI does not exclude no effect).

<sup>2</sup> We downgraded the evidence by two levels due to serious concern of risk of bias (59% of the trials reported unclear or inadequate allocation concealment; 70% did not report the blinding of the outcome assessor or were unclear) and imprecision (too few events and large confidence interval).

<sup>3</sup> We downgraded the evidence by three levels due to serious concern of risk of bias (5 of 8 trials were at high risk/unclear detection bias), inconsistency (very high heterogeneity that prevented from pooling the data), and imprecision (large confidence intervals in each of the trials).

<sup>4</sup> We downgraded the evidence by two levels due to serious concern of risk of bias (4/5 trials at high/unclear risk of detection bias) and imprecision (very few events and large confidence interval).

<sup>5</sup> We downgraded the evidence by two levels due to serious concern of risk of bias (11/14 trials reported inadequate or unclear allocation concealment; 13/14 trials were judged unclear or high risk of detection bias) and of imprecision (large confidence interval).

<sup>6</sup> We downgraded the evidence by two levels due to serious concern inconsistency (high and unexplained heterogeneity) and imprecision (large confidence interval).

<sup>7</sup> We downgraded the evidence by two levels due to very serious concern regarding imprecision (large confidence interval).

**Table 2****Outcome in different types of surgery.**

Outcome or subgroup	Studies	Participants	Statistical method	Effect estimate
1.1 Rates of overall wound infection	34	9864	Risk ratio (M-H, random, 95% CI)	1.20 [0.80, 1.79]
1.1.1 Obstetric surgery	10	2565	Risk ratio (M-H, random, 95% CI)	1.29 [0.46, 3.61]
1.1.2 Orthopedic surgery	7	672	Risk ratio (M-H, random, 95% CI)	2.22 [0.73, 6.80]
1.1.3 Abdominal surgery	2	2334	Risk ratio (M-H, random, 95% CI)	1.28 [0.92, 1.76]
1.1.4 Gynecological surgery	2	824	Risk ratio (M-H, random, 95% CI)	1.31 [0.62, 2.77]
1.1.5 Vascular surgery	4	2320	Risk ratio (M-H, random, 95% CI)	0.87 [0.62, 1.21]
1.1.6 Breast surgery	1	22	Risk ratio (M-H, random, 95% CI)	Not estimable
1.1.7 Head and neck surgery	2	130	Risk ratio (M-H, random, 95% CI)	Not estimable
1.1.8 Other surgery	6	997	Risk ratio (M-H, random, 95% CI)	0.64 [0.30, 1.35]
1.2 Rates of severe wound infection	16	3006	Risk ratio (M-H, fixed, 95% CI)	1.14 [0.62, 2.08]
1.2.1 Obstetric surgery	3	578	Risk ratio (M-H, fixed, 95% CI)	1.47 [0.62, 3.53]
1.2.2 Orthopedic surgery	5	413	Risk ratio (M-H, fixed, 95% CI)	3.69 [0.42, 32.01]
1.2.3 Abdominal surgery	1	1102	Risk ratio (M-H, fixed, 95% CI)	Not estimable
1.2.4 Gynecological surgery	1	78	Risk ratio (M-H, fixed, 95% CI)	0.67 [0.12, 3.77]
1.2.5 Vascular Surgery	2	237	Risk ratio (M-H, fixed, 95% CI)	0.40 [0.06, 2.65]
1.2.6 Head and neck Surgery	2	130	Risk ratio (M-H, fixed, 95% CI)	Not estimable
1.2.7 Other surgery	2	468	Risk ratio (M-H, fixed, 95% CI)	0.77 [0.16, 3.79]
1.3 Length of hospital stay	7		Mean difference (IV, random, 95% CI)	Subtotals only
1.3.1 Obstetric surgery	3	1274	Mean difference (IV, random, 95% CI)	0.55 [−1.40, 2.51]
1.3.2 Orthopedic surgery	3	268	Mean difference (IV, random, 95% CI)	0.09 [−1.37, 1.54]
1.3.3 Abdominal surgery	1	1232	Mean difference (IV, random, 95% CI)	0.00 [−6.21, 6.21]
1.4 Rates of readmission	5	2466	Risk ratio (M-H, random, 95% CI)	1.28 [0.18, 9.05]
1.4.1 Obstetric surgery	3	2262	Risk ratio (M-H, random, 95% CI)	3.18 [0.21, 47.23]
1.4.2 Vascular surgery	1	77	Risk ratio (M-H, random, 95% CI)	0.19 [0.01, 3.74]
1.4.3 Other surgery	1	127	Risk ratio (M-H, random, 95% CI)	0.34 [0.01, 8.16]
1.5 Adverse events	21	6246	Risk ratio (M-H, random, 95% CI)	2.00 [1.44, 2.79]
1.5.1 Obstetric surgery	7	2851	Risk ratio (M-H, random, 95% CI)	3.41 [2.35, 4.94]
1.5.2 Orthopedic surgery	5	407	Risk ratio (M-H, random, 95% CI)	1.09 [0.71, 1.67]
1.5.3 Abdominal surgery	2	2334	Risk ratio (M-H, random, 95% CI)	1.55 [0.70, 3.47]
1.5.4 Gynecological surgery	1	78	Risk ratio (M-H, random, 95% CI)	2.00 [0.39, 10.29]
1.5.5 Neck surgery	1	50	Risk ratio (M-H, random, 95% CI)	Not estimable
1.5.6 Vascular surgery	2	243	Risk ratio (M-H, random, 95% CI)	1.13 [0.33, 3.84]
1.5.7 Other surgery	3	283	Risk ratio (M-H, random, 95% CI)	1.76 [0.62, 5.01]
1.6 Patient satisfaction	14	3243	Risk ratio (M-H, random, 95% CI)	0.99 [0.91, 1.07]
1.6.1 Obstetric surgery	5	503	Risk ratio (M-H, random, 95% CI)	1.39 [0.84, 2.30]
1.6.2 Orthopedic surgery	1	60	Risk ratio (M-H, random, 95% CI)	1.00 [0.94, 1.07]
1.6.3 Abdominal surgery	2	2107	Risk ratio (M-H, random, 95% CI)	0.91 [0.73, 1.12]
1.6.4 Breast surgery	1	40	Risk ratio (M-H, random, 95% CI)	0.76 [0.53, 1.11]
1.6.5 Vascular surgery	1	83	Risk ratio (M-H, random, 95% CI)	0.95 [0.75, 1.20]
1.6.6 Head and neck surgery	3	247	Risk ratio (M-H, random, 95% CI)	0.99 [0.93, 1.06]
1.6.7 Other surgery	2	203	Risk ratio (M-H, random, 95% CI)	1.57 [0.57, 4.28]
1.7 Pain	5	390	Std. mean difference (IV, random, 95% CI)	0.41 [−0.35, 1.16]
1.7.1 Obstetric surgery	3	152	Std. mean difference (IV, random, 95% CI)	2.12 [−0.04, 4.28]
1.7.2 Orthopedic surgery	1	38	Std. mean difference (IV, random, 95% CI)	−0.58 [−1.23, 0.07]

**Table 3****Sensitivity analysis on rate of overall and severe wound infection.**

Outcome or subgroup	Studies	Participants	Statistical method	Effect estimate
2.1 Sensitivity analysis on rates of overall wound infection	34	9834	Risk ratio (M-H, random, 95% CI)	1.19 [0.80, 1.76]
2.1.1 Adequate allocation concealment	14	5540	Risk ratio (M-H, random, 95% CI)	1.49 [0.81, 2.76]
2.1.2 Unclear inadequate allocation concealment	20	4294	Risk ratio (M-H, random, 95% CI)	0.89 [0.56, 1.40]
2.2 Sensitivity analysis on rates of severe wound infection	16	2976	Risk ratio (M-H, fixed, 95% CI)	1.14 [0.62, 2.08]
2.2.1 Adequate allocation concealment	7	1995	Risk ratio (M-H, fixed, 95% CI)	1.06 [0.52, 2.20]
2.2.2 Unclear or inadequate allocation concealment	9	981	Risk ratio (M-H, fixed, 95% CI)	1.32 [0.45, 3.92]

1.13. Subgroup analysis and investigation of heterogeneity

We conducted subgroup analyses in relation to the type of surgery and the primary outcomes. We used Borenstein’s method and examined the  $I^2$  statistic to investigate heterogeneity across subgroups.<sup>[33]</sup>

1.14. Sensitivity analysis

We carried out sensitivity analyses to explore the effect of the following methodological characteristics:

- Allocation concealment: we re-analysed the data excluding trials with unclear or high risk of bias for allocation concealment.
- Random-effects versus fixed-effect models: we re-analysed the data using both random-effects and fixed-effect models to see if there are substantive differences in interpretation.

1.15. Patients and public involvement

The authors stated that patients and public were not involved.

2. Results

2.1. Study characteristics

The PRISMA flow diagram for systematic reviews is showed in Figure 2.

We identified 510 publications using the literature search strategy. Two reviewers (RC and AR) independently read the abstracts and applied the inclusion and exclusion criteria; 457 records were excluded after reviewing the titles and abstracts, there remained 53 abstracts eligible for full-text evaluation. After full-text assessment, we identified 42 publications that fulfilled the inclusion criteria (see Table 1, Supplemental Content, <http://links.lww.com/MD/E368>, which illustrates the “Risk of bias”).

We identified no ongoing trials following a search of the metaRegister ClinicalTrials.gov accessed on April 2018. 42 RCTs published between 1980 and 2016 were included in our analysis. Study sizes ranged from 11<sup>[34]</sup> to 1671<sup>[35]</sup> for a total of patients of 11,067. The trials concerned different surgical specialities: 13 about cesarean skin closure, 10 about orthopaedic surgery, 6 about abdominal surgery, 4 about vascular surgery, 3 about breast surgery, 2 about gynaecological surgery, 2 about head and neck skin closure, and 2 about lacerations closure.

2.2. Patients characteristics

All of the patients were 18 years old or over since three studies excluded patients younger than this.<sup>[36–38]</sup> Three studies<sup>[39–42]</sup> excluded patients with body mass index (BMI) > 35. Seven studies excluded participants with diabetes mellitus,<sup>[35,38,39,41–43]</sup> three excluded pre-pregnancy,<sup>[39,43,44]</sup> but none of the studies specified the number of patients excluded for any reason. Revision or previous incision was the most reported exclusion criteria.<sup>[14,45–48]</sup> In one study, four patients with a nickel allergy were excluded.<sup>[46]</sup> In one study,<sup>[49]</sup> the participants who need antibiotics were excluded from the analysis. Beyond gynaecological and obstetric procedures, 14 studies.<sup>[14,46–48,50–59]</sup> provided data on the gender of the patients included but in two of them<sup>[51,58]</sup> it was not specified the allocation based on



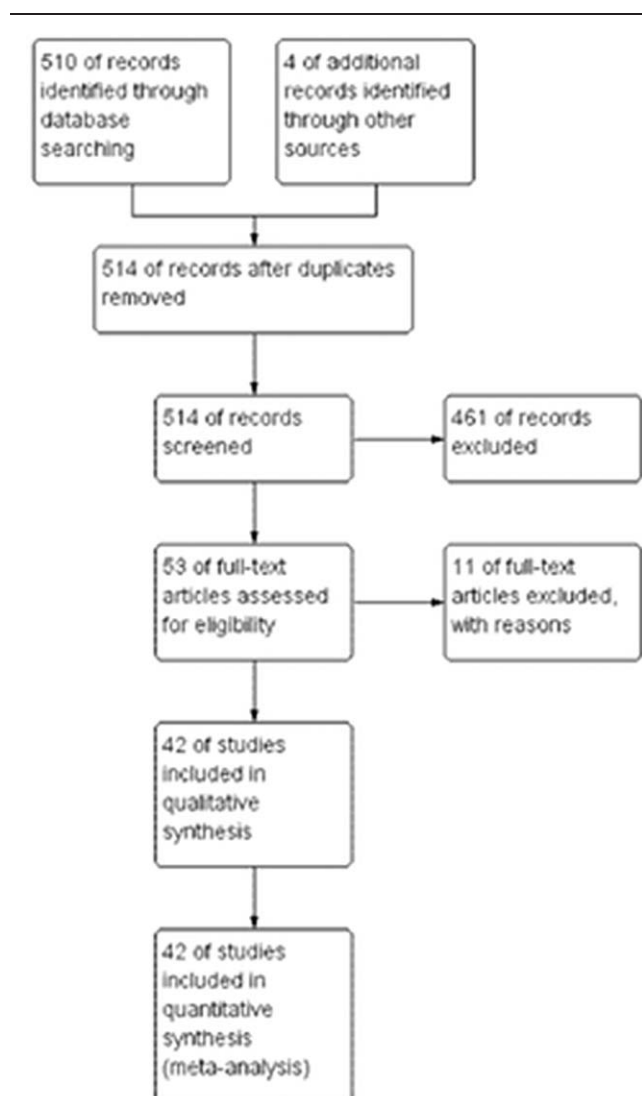
Figure 2. Study flow diagram.

sex. The use of routine antibiotics prophylaxis with cephalosporine was specified in ten studies,<sup>[36,39,42,45,46,48,55–57,59]</sup> while in six it was not clarified which antibiotics were used.<sup>[35,60–64]</sup>

### 2.3. Outcomes

All the informations concerning the outcomes of the trials are detailed in Tables 1–3.

All but 5 studies<sup>[65,66–70]</sup> reported the overall infection rate. Twenty studies also reported severe wound infection rate<sup>[36–40,42,43,45–48,50,52,54,57–59,61,62,68,71]</sup>; one study<sup>[60]</sup> reported this outcome without distinguishing between groups. In one case,<sup>[63]</sup> an overall infections rate was solely reported. Nine studies reported the length of hospital stay.<sup>[35–38,42,46,47,52,72,73]</sup> Six studies<sup>[35–38,46,57,65]</sup> showed the readmission rate for wound complications. Twenty-five studies<sup>[14,35–40,42,43,45–48,51,52,54,55,58,60,61,63,65,68,71,73]</sup> highlighted 30 post-operative days adverse events. Finally, 8 studies<sup>[34,37,47,50,55,60,69,70]</sup> reported the cost-analysis of their procedure, but this was not evaluated as an outcome in this study. Five studies reported private external funding sources.<sup>[35,37,45,54,69]</sup> Three study<sup>[48,53,74]</sup> was funded by public health internal authority.



**Figure 3.** Funnel plot of comparison: 1 Primary outcomes, outcome: 1.1 Rates of overall wound infection.

### 2.4. Effects of interventions

#### 2.4.1. Comparison: staples vs sutures—primary outcomes

**2.4.1.1. Risk of overall wound infection.** We pooled the results of 34 studies (9864 patients) using a random-effects model to compare the effects of sutures and staples on wound infection. Sutures resulted in slightly fewer overall wound infections (4.90%) compared to staples (6.75%) but it is uncertain whether there is a difference between the groups (RR 1.20, 95% CI 0.80–1.79; patients=9864; studies=34;  $I^2=70\%$ ). Results are shown in Figure 3. The certainty of evidence was low as the evidence was downgraded\*\* due to serious concern of risk of bias (58% of the trials were reported unclear or inadequate allocation concealment and 80% reported unclear or inadequate blinding of the outcome assessor) and imprecision (the Optimal Information Size [OIS] criterion was met, however the 95% CI does not exclude no effect).

**2.4.1.2. Risk of severe wound infection.** The evidence was insufficient to determine whether there was a difference between the two interventions in terms of rates of severe wound infection [staples 1.4% vs sutures 1.3%; (RR 1.08, 95% CI 0.61–1.89; patients=3036; studies=17;  $I^2=0\%$ ; low quality of evidence). The evidence was downgraded\*\* due to serious concern regarding risk of bias (58% of the trials reported unclear or inadequate allocation concealment; 80% did not report the blinding of the outcome assessor or were unclear) and imprecision (too few events and large confidence interval).

**2.4.1.3. Risk of bias.** For details on risk of bias of included studies see. Results for risk of bias assessment are resumed in Figure 4.

#### 2.4.2. Secondary outcomes

**2.4.2.1. Length of hospital stay.** Seven studies reported this outcome including 2774 patients. The evidence was insufficient to determine whether there was a difference between staples and sutures in terms of hospital stay. The presence of very high heterogeneity hindered the possibility of performing meta-analysis. The mean difference in hospital stay ranged from –2.05 days in favor of staples to 4.00 days in favor of sutures across the studies. The evidence was judged very low to determine whether there was a difference between staples and sutures in terms of hospital stay.

**2.4.2.2. Rates of readmission.** Wound closure with sutures slightly reduces the risk of readmission compared to wound closure with staples. Although the rate of readmission was slightly less for those with sutures (0.5%) than those with staples (1.7%) (RR 1.28, 95% CI 0.18–9.05; patients=2466; studies=5;  $I^2=66\%$ ; low quality of evidence), the evidence was downgraded\*\* by two levels due to serious concern of risk of bias (4/5 trials were at high/unclear risk of detection bias) and imprecision (very few events and large confidence interval).

**2.4.2.3. Adverse events.** The employment of staples may increase the risk of adverse events by two times compared to the use of sutures (7.3% for staples vs 3.5% for sutures; RR 2.00, 95% CI 1.44–2.79; patients=6246; studies=21;  $I^2=33\%$ ). However, the certainty of evidence was judged low as there were serious concern of risk of bias (11/14 trials reported inadequate or unclear allocation concealment; 13/14 trials were judged unclear or high risk of detection bias), and of imprecision (large confidence interval).

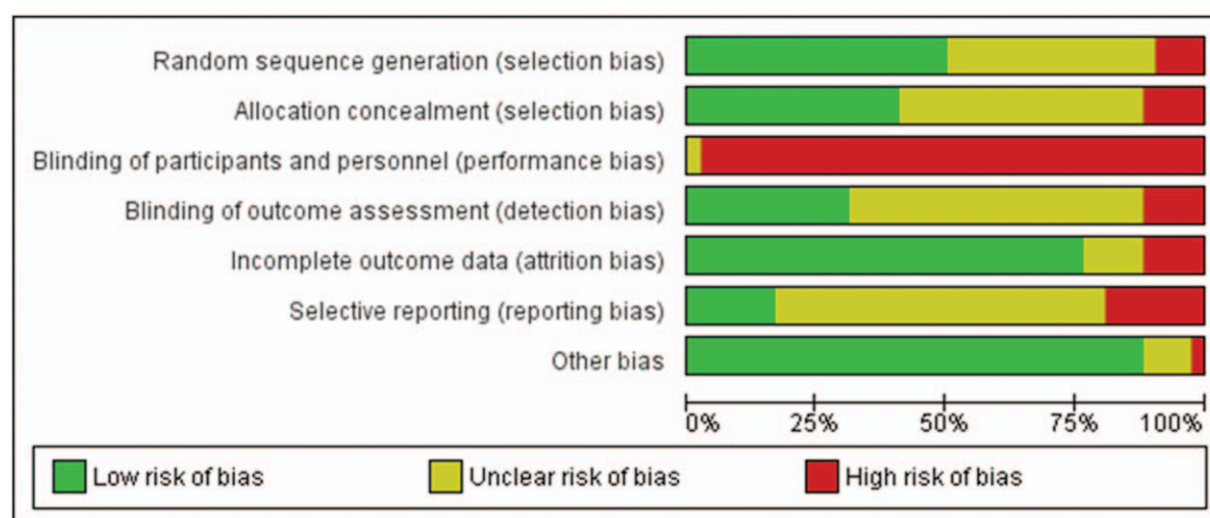


Figure 4. Risk of bias.

**2.4.2.4. Patient satisfaction with cosmetic results.** Patients with sutures were more likely to be satisfied with the cosmetic results of their surgery (63.7%) than patients with staples (60.5%) but there was no evidence of difference between the interventions (RR 0.99, 95% CI 0.91–1.07; patients = 3243; studies = 14;  $I^2 = 67\%$ ; low quality of evidence). The evidence was downgraded\*\* by two levels due to serious concern regarding inconsistency (high and unexplained heterogeneity) and imprecision (large confidence interval).

**2.4.2.5. Pain.** The employment of sutures may slightly reduce the post-operative pain compared to staples. In the trials that measured this outcome, patients with sutures reported having less pain than patients with staples (SMD 0.41, 95%CI –0.35 to 1.16;  $I^2 = 88\%$ , patients = 390 patients, studies = 5). A potential concern could be that heterogeneity was very high. The exclusion of one study<sup>[65]</sup> reduced significantly the heterogeneity to  $I^2 = 32\%$  ( $P = .22$ ) without affecting substantially the final results (SMD 0.03 [–0.24, 0.31]). Compared to the other studies, this was an old trial and this might explain the heterogeneity. Hence, the evidence was downgraded\*\* due to imprecision (large confidence interval).

## 2.5. Subgroup analysis

**2.5.1. Risk of overall wound infection according to type of surgery.** Subgroup analysis of risk of infection was performed according to type of surgery. There was no evidence of subgroup difference in the treatment effect between the trial according to the type of surgery ( $\chi^2 = 6.53$ , df = 5 [ $P = .26$ ],  $I^2 = 23.4\%$ ).

**2.5.2. Risk of severe wound infection according to type of surgery.** Similarly, we performed a subgroup analysis taking into account the type of surgery for the risk of severe wound infection. We did not find any subgroup difference according to the type of surgery ( $\chi^2 = 2.92$ , df = 4 [ $P = .57$ ],  $I^2 = 0\%$ ).

## 2.6. Sensitivity analysis

When we restricted the analysis to the studies with adequate allocation concealment, the results for overall wound infection

remained substantially the same (RR 1.49, 95% CI 0.81–2.76; patients = 5540; studies = 15;  $I^2 = 78\%$ ). The exclusion of a study by Chunder lower significantly the magnitude of the heterogeneity without affecting the estimate of the treatment (RR 1.21 [0.89, 1.65],  $I^2 = 16\%$ ). The population of this study, that assessed the differences in wound complications after cesarean section between skin closure with sutures or with staples, presented demographic and clinical characteristics very different from those of the other included studies. First, the study was conducted in South Africa, where infection rates associated with pregnancy are high and most cesarean deliveries are performed for prolonged labor and, often, many hours after rupture of membranes, that is a predisposing factor to develop wound infection. Secondly, the incidence of obesity in the population study was very high and this made challenging the staples placement. Thirdly, many participants were HIV-infected and this affects wound infection; moreover, all HIV-infected patients received therapeutic antibiotics compared with their noninfected counterparts, who only received prophylactic antibiotics. Finally, most of patients were from low socio-economic backgrounds and most of wound infections occurred after discharge. All of these factors, that are not present in other included studies, could influence the wound infection outcome. Similarly, when analysis for severe wound infection were restricted to the studies with adequate allocation concealment, the results remained substantially the same (RR 1.06, 95% CI 0.52–2.20; patients = 1995; studies = 8;  $I^2 = 0\%$ ). No relevant differences were observed when using a random versus fixed effects models for all the assessed outcomes (Table 3).

## 2.7. Publication bias analysis

An examination of funnel plots did not provide evidence of publication bias for any outcome (Fig. 3).

## 3. Discussion

### 3.1. Overall findings

We identified 42 trials comparing staples with sutures to wound closure in adult patients undergone any type of surgery in a hospital operating room. The number of patients varied from 11

to 1671 patients for a total of 11,067. The included studies showed wide heterogeneity in site, length and type of surgical wound. For these reasons, patients were divided into 8 groups according to the type of surgery: orthopaedic, abdominal, breast, vascular, head and neck, lacerations closure, caesarean skin closure, and gynaecological one. In each group, wound closures with staples were compared to wound closures with sutures. The primary outcomes of this review were the risk of overall and severe wound infection. Sutures resulted in slightly fewer overall wound infections (4.90%) compared to staples (6.75%) but it is uncertain whether there is a difference between the groups and the certainty of evidence was low. The evidence was insufficient to determine whether there was a difference between sutures and staples in terms of rates of severe wound infection (staples 1.4% vs sutures 1.3%) and the quality of evidence was low. These results for overall and severe wound infections were confirmed when we restricted the analysis to the studies with adequate allocation concealment. Similarly, subgroup analysis based on type of surgery did not find any subgroups difference between sutures and staples in risk of overall and severe wound infections. Secondary outcomes of this review were length of stay, readmission rate, adverse events, patient satisfaction with cosmetic results, and pain. Concerning the length of stay, the evidence was insufficient to determine whether there was a difference between two techniques. Compared to staples, sutures probably slightly reduce the risk of readmission (0.5% vs 1.7%), but the quality of evidence was low. The employment of staples for wound closure may increase the risk of adverse events compared to the use of sutures (7.3% for staples vs 3.5% for sutures), but the certainty of evidence was low. Furthermore, patients with sutures were more likely to be satisfied with the cosmetic results of their surgery (63.7%) than patients with staples (60.5%) but we found no evidence of difference between the interventions and the quality of evidence was low. Moreover, post-operative pain could be slightly less with sutures than staples, but the heterogeneity resulted very high and the evidence was downgraded\*\* due to imprecision (large confidence interval). All included studies were randomized trials and the evidence was rated as low or very low quality. The main reason for downgrading was that at least 60% of the studies were with unclear or high risk allocation concealment and only 30% of the trials clearly reported the blinding of the outcome assessor. Given that patients and personnel could not be blinded, it was not possible to avoid performance bias and we took in consideration only the presence of detection bias for our judgement. Hence, for almost all outcomes we downgraded for risk of bias due to the presence of selection bias and detection bias. A further downgrading was performed due to imprecision for all the assessed outcomes. In addition, for post-operative pain and readmission rates, unexplained heterogeneity was found and this caused a further downgrading of the evidence. There was no evidence of publication bias based on examination of a funnel plot.

The findings of this review are consistent with those of other published systematic reviews. The best technique for wound closure remains a matter still debated in the literature: many RCTs and investigated whether sutures or staples were associated with better wound outcomes, but they found no difference between two techniques. In 2008, the guidelines of National Institute for Health and Clinical Excellence (NICE) on surgical site infection identified 11 randomized controlled trials (RCTs) in 8 different surgery types, which had compared staples and sutures.<sup>[1]</sup> The guideline found no evidence of a difference

between the two methods of closure in rates of surgical site infection and recommended further RCTs to state the best closure technique. Recently, Hemming reported the first systematic review of systematic reviews of studies comparing staples and sutures following any operative skin to skin or internal wound closure. Similarly, concerning the wound infection and post surgical complication, the authors found no consistent evidence that one method outperformed the other across all surgery sites. Furthermore, the authors stated there was a clear indication, that although operating times varied considerably across specialties, on average, staples resulted in decreased length of operating time.<sup>[74]</sup> According to our findings, in a systematic review and meta-analysis of 10 RCTs and 3 observational studies focusing on comparing staples with sutures in orthopedic surgery, Krishnan reported no significant differences in infection and postoperative wound complications among participants who received staples and sutures for skin closure. Although the authors could not perform a quantitative analysis about post-operative pain, they reported more pain on removal of staples than sutures on the basis of qualitative analysis.<sup>[70]</sup> Also this findings is consistent with our results. However, in orthopaedic surgery a recent meta-analysis demonstrated a significantly higher risk of superficial wound infection associated with staple closure compared to sutures, but many of the included studies had methodological limitations.<sup>[17]</sup> In a meta analysis of 5 RCTs comparing the wound closure by sutures or staples outcomes at cesarean delivery, Clay reported both wound dehiscence and composite wound complication rates were significantly higher in skin closure by staples with respect to sutures.<sup>[73]</sup> However, these findings are due to a different inclusion criteria and to methodological limitation of the study. In addition, the study took into account all wound complications together as a single outcome.

### 3.2. Implications for practice

Staples are commonly used to skin closure mostly because they allow to reduce the operating time. However, it is unclear if staples should be preferred to sutures concerning wound outcomes. On the basis on our results, the skin closure by sutures may slightly reduce readmission rate, adverse events and postoperative pain compared to closure with staples; it is uncertain whether the employment of sutures may decrease the risk of overall and severe wound infections and whether it may improve the degree of satisfaction in cosmetic results with respect to application of staples. However, conclusive evidence cannot be stated due to the low quality evidence of the included studies.

### 3.3. Implications for research

Further studies comparing sutures with respect to staples should focus on conducting high-quality RCTs. Detailed demographic and pathological data should be presented as well as rigorous and standardized tools of evaluation of wound outcomes should be used in particular to evaluate postoperative pain and degree of satisfaction for cosmetic outcome. Such trials should follow a randomized, double-blind design. Finally, it could be useful that in each surgical specialties the research design takes into account the specific predisposing factor for wound complications in order to allow surgeons to choose the optimal skin closure technique on the basis on type of surgery as well as patient's clinical features.

### 3.4. Strengths and limitations

To the best of our knowledge, this systematic review and meta-analysis, that included 42 RCTs comparing sutures with staples for skin closure, is the most comprehensive systematic review of these interventions to date. Another strong point is that this study analyzes the outcomes related to the closure with sutures or staples according to the different types of surgical specialties. This is a relevant key point because different methods and materials are used on the basis on the type of surgery, the length and anatomical site of the wound; therefore, the type of surgery could be an important factor affecting the wound closure outcomes. The main limitation of this systematic review is the low overall quality of the included studies. Moreover, many outcomes such as length of post-operative hospitalization and readmission, length of scar, cosmetic result were not reported in any trials. There is insufficient evidence to report on patients who had preoperative antibiotics, for BMI, diabetes mellitus and peripheral vascular disease. Wide heterogeneity was evident among the published trials concerning the evaluation tools of cosmetic results and the degree of patients' satisfaction; another issue was the heterogeneity of reporting system of complications rate. Lastly, the influence of the skill of the surgeon performing the suture was not assessed.

### 4. Conclusion

The employment of sutures may reduce pain and provide better satisfaction with the cosmetic results than staples. It is uncertain whether using sutures for wound closure may decrease the risk of overall and severe wound infections, the readmission rate, the adverse events and the postoperative pain compared to wound closure with staples. Due to the lack of high quality evidence, further clinical research is needed to assess the effects of the sutures with respect to the staples in skin closure.

### Author contributions

All authors made a substantial contribution to this study. GC, RC, AA, and EM contributed to the conception and design of the review. AB and EIM screened the titles and abstracts, examined the full-text articles, extracted the data and assessed the risk of bias. GC, AB, EIM, RC, JARDV, JR, and IA were responsible for the analysis and interpretation of the data and the drafting of the manuscript. GC, IA, JR, AA, JARDV, RC, and EM critically revised the manuscript for the important intellectual content and suggested amendments before submission. All authors had access to all the data in the study and can take responsibility for the integrity of the reported findings. GC is the guarantor.

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