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## Staples versus sutures for closing leg wounds after vein graft harvesting for coronary artery bypass surgery. (Review)

Biancari F, Tiozzo V

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[Intervention Review]

# Staples versus sutures for closing leg wounds after vein graft harvesting for coronary artery bypass surgery.

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## ABSTRACT

### Background

Surgical site infection (SSI) after saphenous vein graft harvesting is a complication occurring in up to 18% of patients who undergo coronary artery bypass surgery (CABG). It is not known whether the method of skin closure influences the infection rate.

### Objectives

To compare the rates of SSI and wound dehiscence of staples and sutures for skin closure after saphenous vein graft harvesting for CABG.

### Search methods

For this first update we searched The Cochrane Wounds Group Specialised Register (searched 4 November 2011); The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2011, Issue 4); Ovid MEDLINE (2010 to October Week 4 2011); Ovid MEDLINE (In-Process & Other Non-Indexed Citations, November 3, 2011); Ovid EMBASE (2010 to 2011 Week 43); and EBSCO CINAHL (2010 to 28 October 2011).

### Selection criteria

Randomised controlled trials comparing staples and sutures for closing leg wounds after vein graft harvesting in patients undergoing CABG were eligible for inclusion in this review.

### Data collection and analysis

Two review authors independently assessed the titles and abstracts of references identified by the search strategy against the selection criteria and extracted data from eligible trials. Included trials were assessed for the following risks of bias: generation of random allocation sequence, allocation concealment, blinding, incomplete outcome data, selective reporting and freedom from other biases. For dichotomous variables, we calculated the risk ratio with 95% confidence intervals (CI).

### Main results

We included three prospective, randomised studies reporting on a total of 148 leg wounds closed with staples and 175 with sutures after vein graft harvesting in patients undergoing CABG. All trials were of sub-optimal methodological quality and all trials were at risk of bias. Leg wound infection rate was 10.8% (16/148) after leg wound closure with staples compared with 8% (14/174) with sutures (risk ratio 1.20, 95% CI 0.60 to 2.39). Leg wound dehiscence occurred in 9.3% (10/108) of patients after leg wound closure with staples compared with 8.8% (12/137) with sutures (risk ratio 1.05, 95%CI 0.43 to 2.53).

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**Authors' conclusions**

These results suggest that there is no evidence of a difference in the risk of SSI and wound dehiscence when staples rather than sutures are used to close leg wounds after vein graft harvesting during CABG, however more research is needed.

**PLAIN LANGUAGE SUMMARY****Staples versus sutures for closing leg wounds after vein graft harvesting for coronary artery bypass surgery**

Surgical wounds are usually closed by using either an interrupted or continuous suture using absorbable or non absorbable suture materials. Skin staples are an alternative to sutures and are usually used at the discretion of the surgeon. Skin wound closure with metallic clips is considered to be a fast and effective alternative to sutures. Furthermore, it is commonly believed that staples are less traumatic and may reduce wound complications. This makes the use of staples attractive as it may reduce the risk of postoperative wound complications.

Surgical site infection (SSI) after saphenous vein graft harvesting is a postoperative complication that may occur in up to 18% of patients who undergo coronary artery bypass surgery (CABG). We considered the effects of using either staples or sutures for closing the skin after saphenous vein graft harvesting for CABG on rates of wound infection and wound dehiscence. We included four studies reporting on a total of 148 leg wounds closed with staples and 174 with sutures after vein graft harvesting in patients undergoing isolated CABG.

There was no difference in leg wound infection rate or in leg wound dehiscence when wounds were closed with staples rather than with sutures.

## BACKGROUND

### Description of the condition

Despite the recognized advantages of using arterial grafts, saphenous vein grafts are still used in nearly all patients undergoing complete myocardial revascularization. Surgical site infection (SSI) after saphenous vein graft harvesting is a complication occurring in up to 18% of patients who undergo coronary artery bypass surgery (CABG) (Swenne 2004). It is associated with significant discomfort and prolonged treatment. Not infrequently multiple surgical revision procedures for treatment of SSI are needed. Lower limb revascularization is also indicated in a minority of patients with a SSI and coexistent lower limb ischaemia (Biancari 2008). The burden of such complications becomes more evident when we consider that in United States in 2004 to 2005 the annual rate of CABG procedures has been 11.6 per 10,000 population aged 18 years or more (Health, United States, 2007). The use of endoscopic vein graft harvest seems to be associated with fewer leg wound complications (Athanasίου 2004), but concerns about the quality of the harvested vein graft have prevented the widespread use of this technique (Rousou 2009). Thus, long skin incisions are still largely used by cardiac surgeons for saphenous vein harvesting.

### Description of the intervention

Skin closure for surgical wounds is usually accomplished with interrupted or continuous sutures employing either absorbable or non absorbable suture materials. Most cardiac surgeons use absorbable sutures for closing both the sternal and the lower limb surgical wounds. Skin staples represent an alternative to sutures and are usually used at the discretion of the surgeon.

### How the intervention might work

Skin wound closure with metallic clips is considered to be a fast and effective alternative to sutures. Whilst there is no evidence to support this, it is a common belief amongst cardiac surgeons that metallic clips are less traumatic and do not compromise blood flow to the wound edges. This makes the use of staples attractive as it may reduce the risk of postoperative wound complications.

### Why it is important to do this review

Although staples are commonly used to close surgical wounds, there is no evidence of their superiority over sutures. Evaluation of the potential clinical advantages of staples over sutures can have financial implications as the use of staplers and subsequent removal of clips is a more costly procedure than the use of subcuticular sutures. The calculated cost at our institution (Oulu University Hospital, Finland) for the intracutaneous suture of a leg wound 70 cm in length using 4-0 poliglecaprone 25 is €3.59 compared with a cost of €11.50 when two skin staplers are used to close a wound (typical when closing from above-the-knee to the ankle). The calculated incremental cost of using two skin staplers instead of 4-0 poliglecaprone 25 for 100 patients would be €791. Since the removal of clips costs approximately €114 for each patient, the overall incremental cost of using skin staples instead of sutures would be €12,191 for 100 patients. The impact of the more rapid closure with staples may only be marginal in the context of the overall duration of surgery and is often carried out simultaneously with harvesting of the internal mammary artery graft. Furthermore, removal of metallic clips may result in some discomfort to the patient. There are no current reviews on the evidence of using

staples and suture for skin closure after saphenous vein graft harvesting.

## OBJECTIVES

To compare the effects of using staples and sutures for skin closure after saphenous vein graft harvesting for coronary artery bypass grafting on rates of surgical site infection (SSI) and wound dehiscence.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomised controlled trials (RCTs) comparing staples with sutures as a method of closure after vein graft harvesting during CABG were eligible.

#### Types of participants

Studies involving any patients undergoing saphenous vein graft harvesting for CABG. Studies including other cardiac procedures combined with CABG would be eligible for inclusion because these patients share the same risk factors for leg wound infection as patients undergoing isolated coronary artery bypass surgery. Studies including patients undergoing endoscopic (minimally invasive) saphenous vein harvesting have been excluded as the resultant surgical wound after endoscopic saphenous vein harvesting is very small (about 1 cm).

#### Types of interventions

Studies recruiting patients undergoing CABG who were randomised to leg wound closure, after vein graft harvesting, with skin staples or with different methods of sutures. Studies or related data on any other method of wound closure such as sutureless technique (e.g. adhesive, glue, steric strips) have not been included in the review. We have considered the comparison of staples with any kind of suture.

#### Types of outcome measures

##### Primary outcomes

- Rates of surgical site infection (SSI) (as defined by trialists);
- Severity of SSIs (as defined by trialists);
- Time to wound healing.

##### Secondary outcomes

- Rate of wound dehiscence;
- Length of hospital stay;
- Pain - as measured by a validated scale;
- Cost;
- Patient comfort;
- Lower limb revascularization.

#### Search methods for identification of studies

For the search methods for the original version of this review see [Appendix 1](#)

## Electronic searches

For this first update we searched the following electronic databases to find reports of relevant RCTs:

- The Cochrane Wounds Group Specialised Register (searched 4 November 2011);
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2011, Issue 4);
- Ovid MEDLINE (2010 to October Week 4 2011);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations, November 3, 2011);
- Ovid EMBASE (2010 to 2011 Week 43);
- EBSCO CINAHL (2010 to 28 October 2011).

We searched The Cochrane Central Register of Controlled Trials (CENTRAL) using the following search strategy:

```
#1 MeSH descriptor Surgical Stapling explode all trees
#2 MeSH descriptor Surgical Staplers explode all trees
#3 stapl*:ti,ab,kw
#4 MeSH descriptor Sutures explode all trees
#5 MeSH descriptor Suture Techniques explode all trees
#6 sutur*:ti,ab,kw
#7 (#1 OR #2 OR #3 OR #4 OR #5 OR #6)
#8 MeSH descriptor Saphenous Vein explode all trees
#9 MeSH descriptor Tissue and Organ Harvesting explode all trees
#10 (vein NEXT graft* or saphenous NEXT vein* or harvest*):ti,ab,kw
#11 (#8 OR #9 OR #10)
#12 (#7 AND #11)
```

The search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in [Appendix 2](#); [Appendix 3](#) and [Appendix 4](#) respectively. The Ovid MEDLINE search was combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision) ([Lefebvre 2011](#)). The Ovid EMBASE and EBSCO CINAHL searches were combined with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN) ([SIGN 2009](#)). There were no restrictions on the basis of date or language of publication.

## Searching other resources

Reference lists of all included studies and any other related articles were searched for further studies.

## Data collection and analysis

### Selection of studies

Studies evaluating staples compared with sutures for closing leg wound after vein graft harvesting in patients undergoing isolated CABG has been considered for inclusion in this review.

The two review authors (FB, VT) have independently assessed the titles and abstracts of references identified by the search strategy according to the selection criteria. Full versions of the identified articles were obtained if, from the initial assessment, they appeared to satisfy the inclusion criteria. Full papers were checked independently to identify those that matched the inclusion criteria. Any disagreement was resolved by consensus. Trial details or authors of the trial report were not masked during study selection.

Reference lists of all retrieved studies were screened to identify further studies which were then retrieved.

### Data extraction and management

Data were extracted independently by both review authors and collected in an Excel file. All data were further reviewed and manually entered into RevMan (version 5.0). Any disagreement was resolved by consensus.

If data were missing from reports, the study authors were not contacted to obtain missing information, since most studies were conducted 10 or more years ago and it was thought unlikely that we would be able to trace authors.

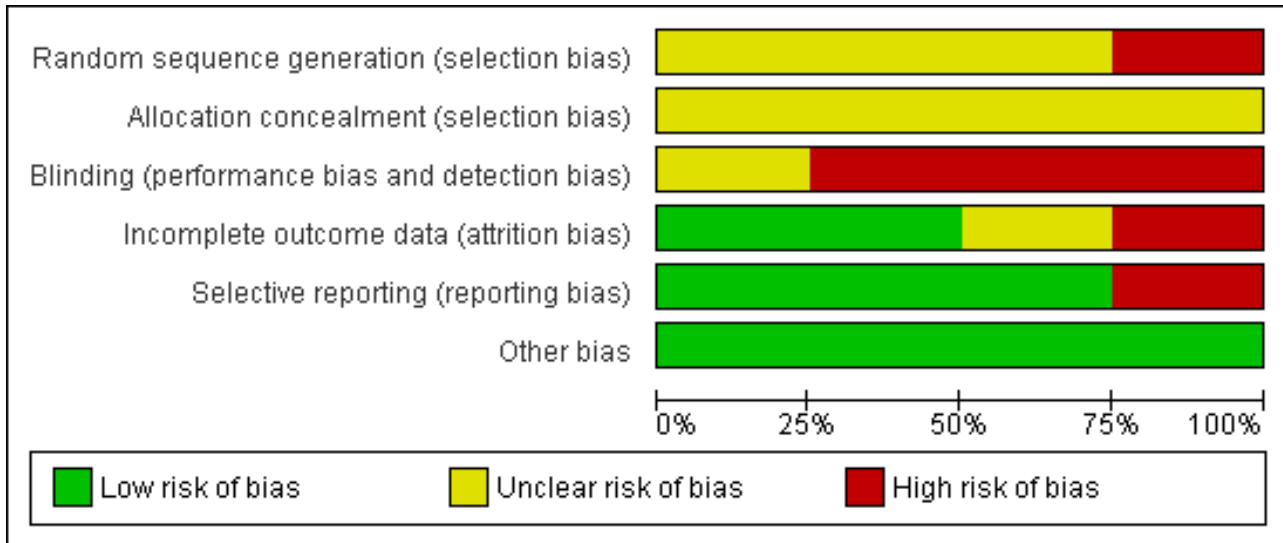
The following data were extracted from each study:

- type of study,
- study setting,
- number of participants,
- description of participants by treatment group at baseline for prognostic factors e.g., sex, age, body mass index, prevalence of diabetes, lower limb ischemia,
- type of intervention,
- all primary and secondary outcome descriptions and outcome measures reported, including infection rates and authors' conclusions.

### Assessment of risk of bias in included studies

The risk of bias was assessed independently by both review authors according to the Cochrane Collaboration criteria for assessing risk of bias ([Higgins 2011a](#)). Disagreement was resolved by consensus. Trials that met the eligibility criteria were assessed for generation of random allocation sequence, allocation concealment, blinding, incomplete outcome data, selective reporting and freedom from other biases ([Appendix 5](#)). We presented the assessment of risk of bias using a 'risk of bias summary figure', which presents all of the judgments in a cross-tabulation of study by entry. This display of internal validity indicates the weight the reader may give the results of each study ([Figure 1](#); [Figure 2](#)).

**Figure 1. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.**



**Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Angelini 1984	-	?	-	+	-	+
Chughtai 2000	?	?	-	?	+	+
Johnson 1997	?	?	-	+	+	+
Mullen 1999	?	?	?	-	+	+

**Measures of treatment effect**

For dichotomous variables (e.g., infection rates) we have calculated the risk ratio with 95% confidence intervals (CI). For continuous variables we would enter the mean and standard deviation data into RevMan and calculate the mean difference (MD) with 95% CI. For time to event data (e.g., time to wound healing) we would summarise the data using a hazard ratio with 95% CI.

**Unit of analysis issues**

If studies included patients with more than one vein graft harvesting site, and where these were randomised separately, we determined whether the data were appropriately analysed as paired data. Where this was not the case data were not included in the meta-analysis (Higgins 2011b).

**Dealing with missing data**

The trial authors have not been contacted to request missing data. The number of drop outs were recorded (where available) and if appropriate an intention-to-treat analysis was conducted using

available case analysis which would include data on only those whose results are known, using as a denominator the total number of people who had data recorded for the particular outcome in question. A drop-out rate of <5% was considered as acceptable.

**Assessment of heterogeneity**

Heterogeneity was assessed in the first instance by inspection of the graphical display of the estimated treatment effects from the included trials. The chi-squared statistic was used with significance set at  $p < 0.10$ . Any data below this threshold shows evidence of heterogeneity of intervention effects. In addition, the degree of heterogeneity was investigated by calculating the  $I^2$  statistic (Deeks 2011). Where pooling was appropriate a fixed effect model was used if  $I^2$  is less than 40%, a random effects model if  $I^2$  is greater than 40%. In addition to any statistical synthesis of data results are presented in narrative form.



## Data synthesis

Meta-analysis was conducted because there are RCTs sharing the same outcome end-points although having variable quality, design and heterogeneity.

## Sensitivity analysis

We have included all eligible trials in the analysis. The low quality of the included studies prevented any planned sensitivity analyses.

## RESULTS

### Description of studies

#### Results of the search

The searches for this review identified 24 citations of which 18 were irrelevant, 5 citations were retrieved in full text, one study was excluded on the basis that it was not an RCT (Swenne 2006) and the remaining four studies were included in the review.

#### Included studies

Four studies (Angelini 1984; Chughtai 2000; Johnson 1997; Mullen 1999) reported on a total of 839 leg wounds (in 581 patients). 406 wounds were closed with staples and 433 with sutures (intracutaneous sutures in 406 wounds and vertical mattress sutures in 27 wounds) after vein graft harvesting during CABG.

Among the primary and secondary outcome end-points pre specified for this review, trial authors reported only on the rates of SSI (four studies) and rates of wound dehiscence (two studies). Two studies reported on costs related with these two wound closure methods.

The studies were undertaken over the time period from the early eighties to the late nineties in single centers, all of them being University Hospitals. Two studies were based in Canada (Chughtai 2000; Mullen 1999), one in the USA (Johnson 1997) and one in Wales (UK) (Angelini 1984). Further details on these studies are reported in the [Characteristics of included studies](#) table.

#### Excluded studies

We excluded one study as it was prospective, but not randomised (Swenne 2006) (See [Characteristics of excluded studies](#)).

### Risk of bias in included studies

[Figure 1](#) and [Figure 2](#) summarizes the review authors' judgements about methodological quality of the included studies.

#### Allocation

Two studies did not report the method of generating the randomisation sequence (Chughtai 2000; Mullen 1999) and one did not report how the serial number used to allocate patients had been generated (Angelini 1984). None of these studies reported on the method of allocation concealment.

#### Blinding

None of these studies reported that blinding was successfully undertaken. Whilst both Angelini 1984 and Johnson 1997 appear to have blinded the outcome assessor it is the opinion of the review author that this would not be successful as the wound would indicate the presence (or absence of clips) by marks on the skin.

## Incomplete outcome data

One study (Mullen 1999) did not assess the outcome of one patient who was withdrawn because an intraaortic balloon pump was inserted in the index leg. It is unclear whether withdrawals or drop outs occurred in the study by Chughtai 2000. Neither withdrawals nor drop outs have been reported in the other studies.

## Selective reporting

The studies appeared to be free of selective reporting.

## Other potential sources of bias

The lack of data on major determinants of leg wound infection such as diabetes, lower limb ischaemia and body mass index are other potential biases in these analyses.

## Effects of interventions

### Comparison: suture compared with staples

#### Primary outcomes:

All four trials reported rates of SSI. Three trials were pooled using a fixed effect model ( $I^2 = 0\%$ ). The SSI rate was 10.8% (16/148) with staples compared with 8.0% (14/174) with sutures (RR 1.20, 95% CI 0.60 to 2.39) (Analysis 1.1). There was no statistically significant difference between the groups. To achieve this pooling we combined the data from two study groups which used two different suture materials, which maintains the randomisation but results in two unequal study groups (Angelini 1984). Similarly, Mullen 1999 reported data on wounds closed with staples (immediately and after protamine administration) and wounds closed with sutures (immediately and after protamine administration) and we combined these data into two groups (staples vs. sutures) irrespective of the timing of protamine administration. The third trial include in the pooled analysis was Chughtai 2000. We decided to exclude the study by Johnson 1997 from the pooled analysis because each wound experienced both methods of closure and there is the risk of a unit of analysis error. However the study reported that there was no statistically significant difference between the groups ( $p = 0.99$ ).

Two studies reported on the severity of the SSIs (Chughtai 2000; Mullen 1999). Chughtai 2000 reported one severe wound infection out of 81 cases (1.2%) in the staples group and in none in the suture group (81 wounds). Mullen 1999 reported two severe wound infections out of 37 wounds (5.4%) in the sutures group and in none in the staples group (40 wounds).

None of the studies reported on the time to wound healing.

#### Secondary outcomes:

Two trials (Angelini 1984; Chughtai 2000) reported the incidence of wound dehiscence; leg wound dehiscence occurred in 9.3% (10/108) of patients after leg wound closure with staples compared with 8.8% (12/137) of patients after closure with sutures (RR 1.04, 95% CI 0.47 to 2.30) (Analysis 1.2). There was no statistically significant difference between the groups.

No trials reported the length of hospital stay; pain as measured by a validated scale; patient comfort or the need for lower limb revascularization.

Regarding the costs of these wound closure methods, [Angelini 1984](#) reported that nylon (15 UK pounds/10 cm) as well as dextron (72 UK pounds/10 cm) sutures were cheaper than staples (360 UK pounds/10 cm). [Chughtai 2000](#) reported a cost of 4.5 \$ (US dollars) for each wound closed with sutures and 15 \$ for each wound closed with staples. Analysis of these data is not feasible as studies have been performed during different periods. Also calculation of the costs were likely different.

The heterogeneity of the type of suture materials as well as the small number of cases prevented any comparison of different types of suture.

## DISCUSSION

### Summary of main results

This review showed that according to currently available data there is no evidence that the use of staples or sutures to close leg wounds during CABG reduces the risk of leg wound infection and wound dehiscence. Two studies ([Angelini 1984](#); [Chughtai 2000](#)) reported increased costs with the use of staples but did so incidentally and not as a part of a cost benefit analysis. At our institution, the calculated incremental cost of using two skin staplers instead of 4-0 polyglactone 25 for 100 patients would be €791. Since the removal of clips costs approximately €114 for each patient, the overall incremental cost of using skin staples instead of suture would be €12,191 for 100 patients.

### Overall completeness and applicability of evidence

Only four studies addressed this issue and the number of patients included in the pooled analysis is small. In fact, it is likely that the total number of patients included in this meta-analysis is insufficient to detect a clinically relevant difference in the rates of leg wound complications. We have calculated that to achieve a reduction of leg wound infection rate from 10% to 5% a total of 870 patients should have been randomised ( $\alpha=0.05$ , power of 80%), a number much larger than the number of patients included in this meta-analysis.

### Quality of the evidence

Overall, the risk of bias of the included studies is high, particularly in terms of sequence generation and allocation concealment and the lack of blinding in the assessment of the outcome end-points. Indeed, estimation of the severity of these complications can be highly subjective.

In one study ([Johnson 1997](#)) half of each wound was closed with staples and the other half with sutures. This might lead to a bias in the correct evaluation of infection site as infection could develop in both halves of the wound, without knowing which part of the wound area was causative of the infection. This unit of analysis error will exaggerate the precision of the results.

There are sparse data on risk factors which are known to be associated with leg wound complications. Beside diabetes and obesity ([Sharma 2009](#)), lower limb ischaemia is likely to be a strong predictor of wound complication ([Haraden 2006](#)). However, no lower limb ischaemia was mentioned in these studies. A screening

for lower limb ischaemia by measurement of ankle/brachial index ([Haraden 2006](#)) would have provided important information about subclinical atherosclerosis of lower limb arteries and its impact on the development of wound complications.

There were no data regarding the experience of surgeons in closing the wound, it would be expected that experienced surgeons would carry out vein graft harvesting with careful handling of the vein graft and of the surrounding tissues, meticulous dissection, no excessive use of electrocautery, haemostasis, and débridement of devitalized tissue.

### Agreements and disagreements with other studies or reviews

Overall, the results of this review agree with those of the included single randomised studies. In a clinical study including patients who underwent abdominal incisions, blood flow measurements were performed by infrared laser Doppler flowmeter on either sides of abdominal incisions; there was a significantly higher blood flow in wounds sutured with subcuticular sutures compared with clips or mattress sutures ([Zografos 1992](#)). A decreased rate of wound infection with the use of skin sutures versus clips has been reported in hip surgery ([Shetty 2004](#)) and cranio-facial surgery ([Sidebottom 2003](#)). In an experimental study, subcuticular skin sutures were found to be more resistant to postoperative contamination than closure with clips ([Stillman 1980](#)). On the other hand, the use of clips could provide some benefits in contaminated operative fields ([Pickford 1983](#); [Stillman 1984](#)), but this is not the case of patients undergoing CABG.

## AUTHORS' CONCLUSIONS

### Implications for practice

These results suggest that there is no evidence of a difference in the risk of SSI and wound dehiscence with use of staples over sutures in closing clean leg wounds after vein graft harvesting during CABG.

### Implications for research

Further research should be well designed with an appropriate randomization method and allocation concealment. Studies should also consider the impact of risk factors known to be associated with postoperative leg wound complications such as lower limb ischemia, diabetes, obesity and any possible pre- and intraoperative condition resulting in ischemia/reperfusion injury such as critical condition, depressed cardiac function, prolonged cardiopulmonary bypass time and duration of surgery ([Sharma 2009](#)). The surgeon's experience may have a major impact on the rate of wound complications and must be taken into account. Because there is no evidence concerning the associated costs an appropriate costs analysis should also be carried out.

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vicryl suture: a prospective randomised trial. *Journal of Orthopaedic Surgery (Hong Kong)* 2004;**12**:191-3.

#### Sidebottom 2003

Sidebottom AJ, Grogan J, May P, Richardson D. Prospective comparison of methods of closure of the coronal flap after craniofacial surgery in children. *British Journal of Oral and Maxillofacial Surgery* 2003;**41**:309-11.

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#### Stillman 1980

Stillman RM, Bella FJ, Seligman SJ. Skin wound closure. The effect of various wound closure methods on susceptibility to infection. *Archives of Surgery* 1980;**115**:674-5.

#### Stillman 1984

Stillman RM, Marino CA, Seligman SJ. Skin staples in potentially contaminated wounds. *Archives of Surgery* 1984;**119**:821-2.

#### Swenne 2004

Swenne CL, Lindholm C, Borowiec J, Carlsson M. Surgical-site infections within 60 days of coronary artery by-pass graft surgery. *Journal of Hospital Infections* 2004;**57**:14-24.

#### Zografos 1992

Zografos GC, Martis K, Morris DL. Laser Doppler flowmetry in evaluation of cutaneous wound blood flow using various suturing techniques. *Annals of Surgery* 1992;**215**:266-8.

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

#### Angelini 1984

Methods	Randomized controlled trial performed in a single centre (University hospital setting). Study period was not reported.
Participants	One-hundred and thirteen patients undergoing CABG. No details about inclusion and exclusion criteria are reported.
Interventions	<p>Leg wound skin edges were closed with:</p> <p>Group 1: a continuous vertical mattress suture of 2/0 nylon (monofilament polyamide; Ethicon, Edinburgh) (27 patients);</p> <p>Group 2: a continuous subcuticular suture of 2/0 polyglycolic acid (Dexon; Davis and Geck, Fareham) (29 patients);</p> <p>Group 3: disposable metal skin staples (Premium; Autosuture UK, Ascot) (27 patients);</p> <p>Group 4: "Op-site" sutureless skin closure (Medium drape, Smith and Nephew Medical, Birmingham, UK) (30 patients).</p> <p>Leg wounds were closed by the same surgeon after protamine had been given and in all cases the deep layer of the wound was approximated with continuous 2/0 Dexon suture after the insertion of one or two drains.</p>
Outcomes	<p>Patients were checked for wound infection five days after surgery. The wound was considered infected if there was purulent discharge growing pathogenic organisms. Patients were checked also at 10 days and at 5 weeks, but authors did not report on wound infection at these study intervals.</p> <p>Number of patients with wound infection five days after surgery:</p> <p>Group 1 (sutures with nylon): 2 (7.4%)</p> <p>Group 2 (sutures with polyglycolic acid): 0 (0%)</p> <p>Group 3 (staples): 1 (3.7%)</p> <p>Group 4 (Op-site skin closure): 1 (3.3%).</p> <p>Number of patients with wound dehiscence 10 days after surgery:</p> <p>Group 1 (sutures with nylon): 4 (14.8%)</p> <p>Group 2 (sutures with polyglycolic acid): 0 (0%)</p> <p>Group 3 (staples): 3 (11.1%)</p> <p>Group 4 (Op-site skin closure): 1 (3.3%).</p>



**Chughtai 2000** (Continued)

Staples group: 7 (8.6%)  
Sutures group: 8 (9.9%).

Notes  
Location: Canada  
Setting: University hospital  
Source of funding: not reported.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not mentioned.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) All outcomes	High risk	Details about blinding of surgeons closing the leg wound has not been provided. All outcome assessment were performed by the same surgeon in a non blinded fashion.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	It is unclear whether there were any drop outs or withdrawals.
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

**Johnson 1997**

Methods	Randomized controlled trial performed in a single center (University hospital setting). Study period: from February 1993 to July 1994.
Participants	Two-hundred and fifty-eight saphenous vein harvest wound (516 leg segments) of patients undergoing CABG. Patients undergoing emergency operations or who were unable to complete follow-up at the authors' centre were excluded from the study.
Interventions	Half of each wound was closed with skin staples (Ethicon, Somerville, NJ, or USSC, Norwalk, CT) and the other half with subcuticular sutures (Polypropylene monofilament suture, Prolene; Ethicon, in 141 patients, or polyglecaprone 25/Monocryl; Ethicon, in 101 patients).
Outcomes	<p>Patients were checked up to three weeks after surgery.</p> <p>The wound was considered infected if there was purulent drainage, if antibiotics had been prescribed for wound cellulitis, or if any debridement or drainage procedure had been performed.</p> <p>The wound was considered complicated when it was judged to have greater-than-normal erythema, any drainage (regardless of character), wound separation, wound edge necrosis or infected.</p> <p>Number of patients with leg wound infection (p=0.99): Staples group: 23 (8.9%) Sutures group: 24 (9.3%).</p> <p>Number of patients with complicated leg wound (p=0.001): Staples group: 121 (46.9%)</p>



**Johnson 1997** (Continued)

Sutures group: 84 (32.6%).

Notes

Location: USA  
 Setting: University hospital  
 Source of funding: not reported.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The closure method was randomly allocated to either the upper or lower half of the wound.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding (performance bias and detection bias) All outcomes	High risk	The same surgeon closed both halves of any individual wound. Wounds were inspected by one of three persons not involved with any given patient's wound closures. However, complete assessment blinding is not possible as signs left by clips on the skin are still visible a few weeks after surgery.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There were neither drop outs nor withdrawals.
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

**Mullen 1999**

Methods	Randomized controlled trial performed in a single center (University hospital setting). Study period is unknown.
Participants	Eighty patients were randomly assigned to four study leg wound closure methods. Exclusion criteria were insertion of a drain, insertion of an intra-aortic balloon pump in the index limb and inability to complete follow-up at the authors' centre.
Interventions	<p>Patients were randomised to:</p> <ol style="list-style-type: none"> <li>1) wound closure with staples immediately;</li> <li>2) wound closure with staples after protamine administration;</li> <li>3) wound closure with subcuticular sutures immediately;</li> <li>4) wound closure with subcuticular sutures after protamine administration.</li> </ol> <p>Protamine is given at the end of the cardiac operation to reverse the effect of heparin. Since among these study groups there are two groups which have their wounds closed with no protamine administration and two groups that have their wounds closed after protamine administration. For analysis purposes Groups 1 and 2 were combined as were Groups 3 and 4, but the impact of a different protamine administration policy should be balanced. In the real world, the wound is closed any time during surgery (before and after protamine administration) and certainly before the activated coagulation time reaches baseline levels.</p>
Outcomes	Patients were checked for wound infection six to eight weeks after surgery.

**Mullen 1999** *(Continued)*

Minor infection was defined as erythema along the wound associated with one of the following symptoms: fever, elevated white blood cell count or purulent discharge, in the absence of another source of infection. Patients with minor wound infection were treated with oral or topical antibiotics.

Major infection was defined as any infection requiring the administration of intravenous antibiotics or surgical therapy.

Number of patients with any leg wound infection:

Staples group: 6 (15.0%, no major infection)

Sutures group: 3 (8.1%, two major infections occurred among patients whose wound was closed after protamine administration).

Notes	Location: Canada Setting: University hospital Source of funding: not reported.
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**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not mentioned.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding (performance bias and detection bias) All outcomes	Unclear risk	It is not stated who closed and assessed the leg wound.
Incomplete outcome data (attrition bias) All outcomes	High risk	Three patients were excluded after randomization. One patient in group 4 was excluded because they underwent intraaortic balloon pump insertion in the index limb and this may lead to an increased risk of wound infection. The outcome of this patient was not assessed. One patient in group 3 and one in group 4 were excluded as they underwent myocardial revascularization with arterial grafts and no leg wound was made.
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

**Characteristics of excluded studies** *[ordered by study ID]*

Study	Reason for exclusion
Swenne 2006	Non randomised study.

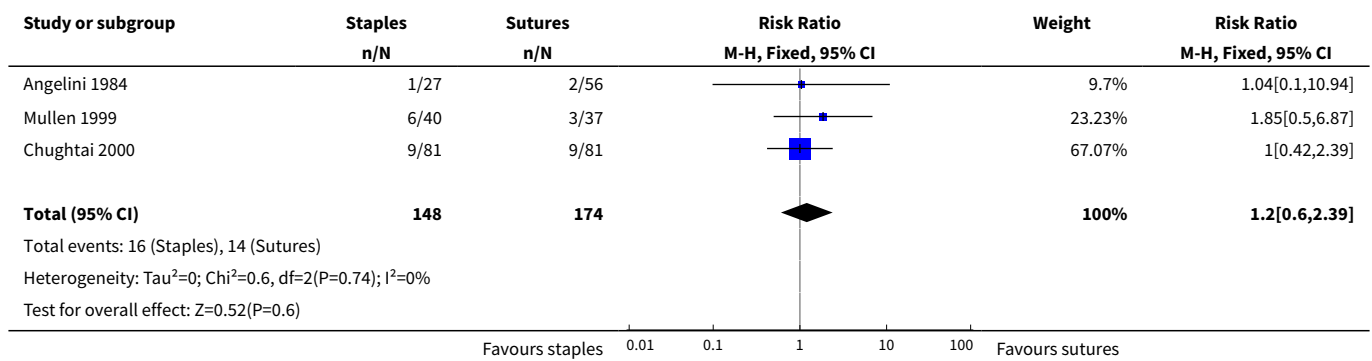
**DATA AND ANALYSES**



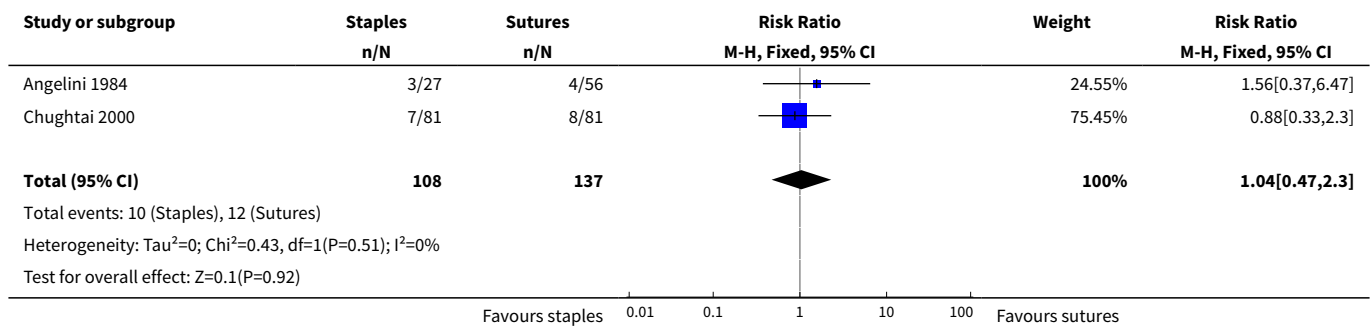
**Comparison 1. Staples versus sutures for closing leg wounds after vein graft harvesting**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Leg wound infection	3	322	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [0.60, 2.39]
2 Leg wound dehiscence	2	245	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.47, 2.30]

**Analysis 1.1. Comparison 1 Staples versus sutures for closing leg wounds after vein graft harvesting, Outcome 1 Leg wound infection.**



**Analysis 1.2. Comparison 1 Staples versus sutures for closing leg wounds after vein graft harvesting, Outcome 2 Leg wound dehiscence.**



**APPENDICES**

**Appendix 1. Search methods - Original version 2010**

We searched the following electronic databases to find reports of relevant RCTs:

- Cochrane Wounds Group Specialised Register (searched 11/3/10);
- The Cochrane Central Register of Controlled Trials (CENTRAL) - *The Cochrane Library* 2010 Issue 1;
- Ovid MEDLINE - 1950 to March Week 1 2010;
- Ovid MEDLINE - In-Process & Other Non-Indexed Citations (Searched 11/3/10);
- Ovid EMBASE - 1980 to 2010 Week 09;

- EBSCO CINAHL - 1982 to March 11 2010

We searched The Cochrane Central Register of Controlled Trials (CENTRAL) using the following search strategy:

- #1 MeSH descriptor Surgical Stapling explode all trees
- #2 MeSH descriptor Surgical Staplers explode all trees
- #3 stapl\*:ti,ab,kw
- #4 MeSH descriptor Sutures explode all trees
- #5 MeSH descriptor Suture Techniques explode all trees
- #6 sutur\*:ti,ab,kw
- #7 (#1 OR #2 OR #3 OR #4 OR #5 OR #6)
- #8 MeSH descriptor Saphenous Vein explode all trees
- #9 MeSH descriptor Tissue and Organ Harvesting explode all trees
- #10 (vein NEXT graft\* or saphenous NEXT vein\* or harvest\*):ti,ab,kw
- #11 (#8 OR #9 OR #10)
- #12 (#7 AND #11)

The search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in [Appendix 2](#); [Appendix 3](#) and [Appendix 4](#) respectively. The Ovid MEDLINE search was combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision). The Ovid EMBASE and EBSCO CINAHL searches was combined with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN). There were no restrictions on the basis of date or language of publication.

Reference lists of all included studies and any other related articles were searched for further studies.

### Appendix 2. Search strategy Ovid MEDLINE

- 1 exp Surgical Stapling/
- 2 exp Surgical Staplers/
- 3 stapl\$.mp.
- 4 exp Sutures/
- 5 exp Suture Techniques/
- 6 sutur\$.mp.
- 7 or/1-6
- 8 exp Saphenous Vein/
- 9 exp "Tissue and Organ Harvesting"/
- 10 (vein graft\$ or saphenous vein\$ or harvest\$).mp.
- 11 or/8-10

### Appendix 3. Search strategy Ovid EMBASE

- 1 exp Surgical Stapling/
- 2 stapl\$.ti,ab.
- 3 exp Suture/
- 4 exp Suturing Method/
- 5 sutur\$.ti,ab.
- 6 or/1-5
- 7 exp Saphenous Vein/
- 8 exp Saphenous Vein Graft/
- 9 (vein graft\$ or saphenous vein\$ or harvest\$).ti,ab.
- 10 or/7-9

### Appendix 4. Search strategy EBSCO CINAHL

- S12 S11 and S6
- S11 S10 or S9 or S8 or S7
- S10 AB vein graft\* or AB saphenous vein\* or AB harvest\*
- S9 T1 vein graft\* or T1 saphenous vein\* or T1 harvest\*
- S8 (MH "Tissue and Organ Harvesting")
- S7 (MH "Saphenous Vein")
- S6 S5 or S4 or S3 or S2 or S1
- S5 T1 sutur\* or AB sutur\*
- S4 (MH "Suture Techniques+")
- S3 (MH "Sutures")
- S2 T1 stapl\* or AB stapl\*

S1 (MH "Surgical Stapling")

## Appendix 5. Risk of bias - Criteria for judgement explanation.

### 1. Was the allocation sequence randomly generated?

#### *Low risk of bias*

The investigators describe a random component in the sequence generation process such as: referring to a random number table; using a computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots.

#### *High risk of bias*

The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number.

#### *Unclear*

Insufficient information about the sequence generation process to permit judgement of low or high risk of bias.

### 2. Was the treatment allocation adequately concealed?

#### *Low risk of bias*

Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomisation); sequentially-numbered drug containers of identical appearance; sequentially-numbered, opaque, sealed envelopes.

#### *High risk of bias*

Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

#### *Unclear*

Insufficient information to permit judgement of low or high risk of bias. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement, for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

### 3. Blinding - was knowledge of the allocated interventions adequately prevented during the study?

#### *Low risk of bias*

Any one of the following.

- No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

#### *High risk of bias*

Any one of the following.

- No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding.
- Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.

#### *Unclear*

Any one of the following.

- Insufficient information to permit judgement of low or high risk of bias.
- The study did not address this outcome.

#### 4. Were incomplete outcome data adequately addressed?

##### **Low risk of bias**

Any one of the following.

- No missing outcome data.
- Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size.
- Missing data have been imputed using appropriate methods.

##### **High risk of bias**

Any one of the following.

- Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size.
- 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

##### **Unclear**

Any one of the following.

- Insufficient reporting of attrition/exclusions to permit judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided).
- The study did not address this outcome.

#### 5. Are reports of the study free of suggestion of selective outcome reporting?

##### **Low risk of bias**

Any of the following.

- The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
- The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon)

##### **High risk of bias**

Any one of the following.

- Not all of the study's pre-specified primary outcomes have been reported.
- One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified.
- One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect).
- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis.
- The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

##### **Unclear**

Insufficient information to permit judgement of low or high risk of bias. It is likely that the majority of studies will fall into this category.

## 6. Other sources of potential bias

### *Low risk of bias*

The study appears to be free of other sources of bias.

### *High risk of bias*

There is at least one important risk of bias. For example, the study:

- had a potential source of bias related to the specific study design used; or
- had extreme baseline imbalance; or
- has been claimed to have been fraudulent; or
- had some other problem.

### *Unclear*

There may be a risk of bias, but there is either:

- insufficient information to assess whether an important risk of bias exists; or
- insufficient rationale or evidence that an identified problem will introduce bias.

## WHAT'S NEW

Date	Event	Description
17 November 2011	New search has been performed	First update, new search no new studies identified, no change to conclusions.

## CONTRIBUTIONS OF AUTHORS

Fausto Biancari coordinated the review update, extracted data, checked quality of data extraction, made an intellectual contribution to the review update, approved the final version prior to submission and performed previous work that was the foundation of the current review. Valentina Tiozzo performed previous work that was the foundation of the current review.

### Contributions of editorial base:

Nicky Cullum: edited the protocol and review; advised on methodology, interpretation and protocol content. Approved the final protocol and review prior to submission.

Sally Bell-Syer: coordinated the editorial process. Advised on methodology, interpretation and content. Edited and copy edited the protocol and edited the review and review update.

Ruth Foxlee: designed the search strategy and edited the search methods section and ran the searches.

## DECLARATIONS OF INTEREST

The authors do not have any conflicts of interest related to this review.

## SOURCES OF SUPPORT

### Internal sources

- None, Not specified.

### External sources

- NIHR/Department of Health (England), (Cochrane Wounds Group), UK.

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There were no differences between protocol and review.

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**INDEX TERMS****Medical Subject Headings (MeSH)**

\*Coronary Artery Bypass; \*Surgical Stapling [adverse effects]; \*Sutures [adverse effects]; Randomized Controlled Trials as Topic; Saphenous Vein; Surgical Wound Dehiscence [epidemiology] [\*etiology]; Surgical Wound Infection [epidemiology] [\*etiology]; Tissue and Organ Harvesting [\*adverse effects]

**MeSH check words**

Humans