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Effect of Skin Closure with Metal Staples *vs.* Intradermal Suture on Groin Infections after Vascular Surgery: A Randomised Controlled Trial

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WHAT THIS PAPER ADDS

In this randomised controlled trial in patients undergoing elective vascular surgery with primary isolated exposure of the femoral vessels, there was no significant difference in rates of inguinal surgical site infection or other incision related complications between skin closure with metal staples or intradermal suture.

Objective: Inguinal incision is the most common vascular surgery incision and is associated with a high rate of surgical site infections (SSIs). The objective of this study was to determine whether intradermal suture leads to a lower SSI rate than metal staples.

Methods: A multicentre, open label, superiority randomised controlled trial was conducted from March 2018 until November 2021 in three Finnish hospitals (ClinicalTrials.gov ID: NCT03468621). Patients with scheduled elective vascular surgery with isolated exposure of the femoral vessels from a longitudinal incision, i.e., femoral endarterectomy, femoral cutdown for endovascular aortic repair, and femoropopliteal or femorofemoral crossover bypass procedure using synthetic graft, were screened for eligibility. Patients were randomised with 1:1 allocation to undergo skin closure with metal staples or continuous intradermal suture. The primary outcome was 30 day SSI rate. SSI was defined according to the US Centers for Disease Control and Prevention (CDC). Secondary outcomes included incision dehiscence and lymphatic leak or seroma.

Results: Three hundred patients aged 54 − 94 years were enrolled (mean age ± standard deviation, 73.4 ± 8.0 years; 217, 72.3% male), with 148 patients randomised to skin closure with intradermal suture and 152 patients to skin closure with metal staples. The SSI rate was 10.1% (15/148) after intradermal suture and 15.8% (24/152) after metal staples (relative risk [RR] 0.64, 95% confidence interval [CI] 0.35 − 1.17; $p = .15$). The rate of seroma and lymph leak was 12.8% (19/148) and 21.1% (32/152) in the intradermal suture and metal staple groups, respectively (RR 0.6, 95% CI 0.4 − 1.0; $p = .060$). The rate of inguinal incision complications (infection or dehiscence) was 13.5% (20/148) and 19.7% (30/152) in the intradermal suture and metal staple groups, respectively (RR 0.7, 95% CI 0.4 − 1.2; $p = .15$).

Conclusion: In patients undergoing elective vascular surgery with primary isolated exposure of the femoral vessels, skin closure with intradermal suture did not reduce the SSI rate compared with the use of metal staples.

Keywords: Groin incision, Intradermal suture, Metal staples, Surgical site infection
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INTRODUCTION

According to the National Nosocomial Infection Surveillance (NNIS) system, the rate of surgical site infection (SSI) after clean surgery is approximately 2%.[1,2] Although the majority of lower limb vascular surgery procedures are considered clean surgery,[3] the rate of SSI after these procedures is much higher, with great variability in reported SSI rates ranging between 4% and 27.0%.[4,5]

Inguinal incision is the most frequently used incision in peripheral vascular surgery to gain access to the femoral vessels in a wide range of vascular procedures.[6,7] Inguinal incision is also particularly susceptible to developing SSIs

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due to the skin flora in the groin crease owing to the proximity to the external genitalia and anal canal.[8,9] In addition, the multiple comorbidities of vascular patients, such as diabetes, smoking, critical limb ischaemia, and frailty, contribute to this susceptibility, predisposing these patients to slow wound healing and SSIs.[10] Vascular SSIs cause major morbidity and death in addition to increased healthcare costs.[11] Fortunately, most SSIs are superficial and heal with appropriate antibiotic therapy.[4] Deeper SSIs and especially infections that involve a vascular graft increase the risk of graft failure,[12] amputation,[13] and death.[10] A previous retrospective study suggested that groin incision closure with intradermal absorbable suture was associated with fewer inguinal SSIs compared with commonly used transdermal closure.[14]

To the authors' knowledge, the impact of inguinal incision closure method on the SSI rate has previously been studied in only one prospective cohort study dating back to 1995.[15] The aim of the current randomised controlled trial (RCT) was to compare transdermal skin closure with metal staples with intradermal skin closure with an absorbable suture on the inguinal incision SSI rate at 30 days.

MATERIALS AND METHODS

Study design

This was a multicentre, open label, superiority RCT in vascular surgery patients undergoing scheduled elective vascular surgery with primary isolated exposure of the femoral vessels through a longitudinal skin incision, comparing the rate of inguinal incision SSI between transdermal metal staples and intradermal absorbable incision closure. The hypothesis was that intradermal suture closure would reduce the rate of inguinal incision SSIs. The three Finnish hospitals participating in the trial were Turku University Hospital, Turku (main research centre), Satakunta Central Hospital, Pori, and Hospital Nova of Central Finland, Jyväskylä. The catchment size for each hospital was 490 000, 214 000, and 272 000, respectively.

Patients

All patients with scheduled elective vascular surgery with primary unilateral or bilateral exposure of femoral vessels, i.e., femoral endarterectomy, femoral cutdown for endovascular aortic repair (EVAR), and femoropopliteal or femorofemoral crossover bypass procedure using synthetic graft, were screened for eligibility.

Exclusion criteria included ongoing infection in the inguinal area, previous ipsilateral femoral artery exposure, emergency surgery procedure (i.e., post-puncture bleed), and inability to cooperate and give informed consent. In addition, patients in whom the groin incision was part of a longer incision were excluded (i.e., patients having an autologous vein harvest incision).

Eligible patients received written study information and an informed consent form prior to their operation. Patients were given the opportunity to discuss the study with operating surgeon any possible concerns about participation. All patients gave written informed consent. The trial was performed in accordance with the Declaration of Helsinki. The trial was approved by the Research Ethics board of the Hospital District of Southwest Finland (ethical committee reference no. ETMK: 131/1801/2015) and was registered at ClinicalTrials.gov (NCT03468621).

Outcome measures

The primary endpoint of the study was the rate of SSI (superficial or deep infection) at 30 days; SSI was defined according to the US Centers for Disease Control and Prevention (CDC).[16] The severity of infection was graded according to the Szilagyi classification[17] as either superficial infection (Szilagyi grade 1) or deep infection (Szilagyi grades 2 and 3). In case of bilateral incisions, both incisions received the same intervention, and unilateral SSI assessment was defined as an infection. Pre-defined secondary outcomes included wound dehiscence and seroma and or lymph leak without SSI, which were evaluated clinically by the vascular surgeons. The primary and secondary outcomes were recorded at the four to six week post-operative follow up visit performed by a consultant vascular surgeon including five study surgeon investigators. If the patient was diagnosed with an infection requiring hospitalisation prior to the outpatient visit, patient follow up was arranged earlier, if needed, or these data were recorded at the latest at the time of the standard follow up visit.

Randomisation

Patients were randomised with a 1:1 allocation ratio to intradermal suture incision closure or transdermal metal staple closure. Randomisation was done by centre using random permuted blocks of 10 (SAS System for Windows Version 9.4; SAS Institute Inc., Cary, NC, USA). The randomisation blocks were blinded to the investigators. Randomisation was conducted using opaque randomisation envelopes that contained folded A4 sheets with the information of either intradermal suture or metal staples.

Interventions

The operations were performed by consultant vascular surgeons or by surgical residents under the supervision of consultant vascular surgeons. Ordinary surgical and operating room routines of each participating hospital were followed. Antibiotic prophylaxis was routinely given 30 − 60 minutes pre-operatively, with an additional dose after three hours for longer procedure durations. Intravenous cefuroxime 1.5 g or 3.0 g was used as the primary prophylactic antibiotic. Alternatively, intravenous clindamycin 900 mg was used for patients with renal failure. The World Health Organisation (WHO) surgical safety checklist[18] was used routinely in the operating room.

At the end of the operation, prior to incision closure, the randomisation envelope was opened by an operating room nurse and patients were randomly assigned to skin closure with an intradermal suture (V-Loc, Medtronic, Minneapolis,

MN, USA; Monocryl Ethicon, New Jersey, NJ, USA) or metal staples (Manipler AZ-35W, B. Braun, Bethlehem, PA, USA). The deep skin layers were closed according to the preference of the operating surgeon. No negative pressure wound therapy dressings were used.

Data collection

Data were entered prospectively into a Microsoft Excel (Microsoft Corp., Redmond, WA, USA) based study file in each participating centre. The study enrolment date, operation date, patient demographics, and medical data were collected.

Information about age, sex, body mass index (BMI), peripheral arterial disease (PAD), diabetes mellitus, hypertension, coronary artery disease, cerebrovascular disease, chronic obstructive pulmonary disease, rheumatoid disease, end stage renal disease (patients on dialysis treatment), systemic immunosuppressive medication, and surgical indication was recorded. Wound, Ischaemia, and foot Infection (WIfI) and Rutherford classifications[19,20] were used as determinants of PAD severity. Operation details (operating time, blood loss, antibiotic prophylaxis) and post-operative follow up data (antibiotics, post-operative complications including incision infection or dehiscence, seroma, or superficial or deep infections, and revisional procedures) were recorded.

Statistical analysis

Continuous variables were presented as the mean ± standard deviation or median (range). Frequencies and percentages were used for categorical variables. Differences between groups were tested with independent samples *t* test for continuous variables and with χ^2 test or Fisher's exact test for categorical variables. The univariable results of primary and secondary outcomes were quantified using relative risk (RR) with 95% confidence interval (CI).

According to the pre-defined statistical analysis plan, multivariable binomial logistic regression analyses were used to further analyse the infection rates in order to evaluate possible differences between the centres and to adjust the results with known risk factors for infections. The final model included the following variables: skin closure group; centre; age; BMI; and diabetes. Age, BMI, and diabetes are known risk factors for infections and were therefore included in the model to adjust the results. The interaction between group and centre was not included in the final model because it was not statistically significant ($p = .070$). The results of multivariable binomial logistic regression analyses were quantified using odds ratio with 95% CI. Two sided tests were used and a p value of $< .050$ was considered statistically significant. Statistical analyses were performed using SAS System for Windows Version 9.4.

Sample size calculation

The sample size calculation was based on clinically relevant difference of 15 percentage points between skin closure methods and the findings of a previous retrospective study[14] with an assumption that the infection rate would be reduced from 25% to 10% using intradermal incision closure. A 90% power and 5% significance level resulted in a minimum sample size of 133 inguinal incisions per treatment arm. To this number, an approximately 10% loss to follow up was added resulting in the final sample size of 300 patients in total.

Table 1. Baseline characteristics of patients ($n = 300$) in a randomised controlled trial of intradermal suture *vs.* metal staples for incision closure in isolated inguinal incisions.

Characteristic	Metal staples ($n = 152$)	Intradermal suture ($n = 148$)
Age − y	73.6 ± 8.3	73.3 ± 7.7
Sex, male	104 (68.4)	113 (76.3)
BMI − kg/m^2	26.4 ± 4.2	26.6 ± 4.1
Peripheral arterial disease	145 (95.4)	132 (89.2)
Diabetes mellitus	65 (42.8)	47 (31.8)
Hypertension	135 (88.8)	124 (83.8)
Coronary artery disease	73 (48.0)	72 (48.6)
Cerebrovascular disease	22 (14.5)	20 (13.5)
Pulmonary disease	38 (25.0)	38 (25.7)
Rheumatoid disease	9 (5.9)	15 (10.1)
Smoking	37 (24.3)	41 (27.7)
Dialysis	3 (2.0)	2 (1.4)
Immunosuppression	11 (7.2)	10 (6.8)
Study hospital		
TUH	99	97
SCH	35	35
HNCF	18	16

Data are presented as mean ± standard deviation or *n* (%). BMI = body mass index; TUH = Turku University Hospital; SCH = Satakunta Central Hospital; HNCF = Hospital Nova of Central Finland.

RESULTS

Recruitment was conducted between March 2018 and November 2021 enrolling a total of 300 patients aged 54 − 94 years in the trial (mean age, 73.4 ± 8.0 years; 217; 72.3% male), with 152 patients randomised to closure with metal staples and 148 patients randomised to closure with intradermal sutures. Patient baseline characteristics are presented in Table 1. Patients were enrolled from the centres as follows: 196 (65.3%) at Turku University Hospital; 70 (23.3%) at Satakunta Central Hospital; and 34 (11.4%) at Hospital Nova (Fig. 1). There were 265 (88.3%) patients with PAD and 35 (11.7%) EVAR patients (Table 2). The operation details according to the randomisation group is presented in Table 3.

Primary and secondary outcomes

The overall SSI rate was 13.0% (39/300). The rate of SSI was 10.1% (15/148) after intradermal suture and 15.8% (24/152) after metal staples (RR 0.64, 95% CI 0.35 − 1.17; $p = .15$). In the whole study population, there were five (1.7%) deep infections (Szilagyi grades 2 and 3), including one in the

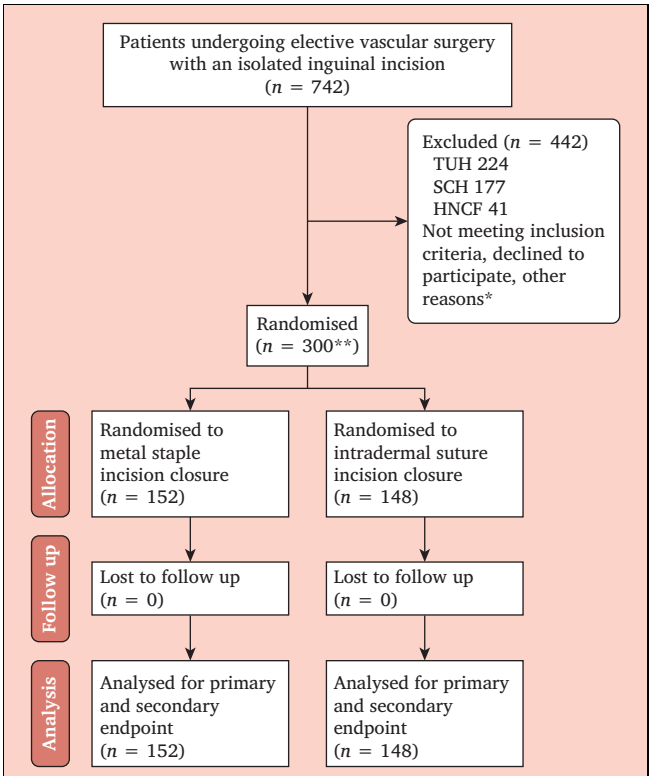

Figure 1. Consolidated Standards of Reporting Trials flowchart of patient selection for a randomised controlled trial of intradermal sutures *vs.* metal staples in isolated inguinal incisions. * A total of 442 patients were excluded from the study; the reason for exclusion was not documented for each patient. ** Randomised patients per centre: Turku University Hospital (TUH), $n = 196$; Satakunta Central Hospital (SCH), $n = 70$; Hospital Nova of Central Finland (HNCF), $n = 34$.

intradermal closure group and four in the metal staple group.

The rate of seroma and lymph leak was 17.0% (51/300) in the whole population; 12.8% (19/148) in the intradermal suture group and 21.1% (32/152) in the metal staple group (RR 0.6, 95% CI 0.4 — 1.0; $p = .060$). The overall rate of inguinal incision complications (infections or dehiscence) was 16.7% (50/300); 13.5% (20/148) in the intradermal suture group and 19.7% (30/152) in the metal staple group (RR 0.7, 95% CI 0.4 — 1.2; $p = .15$).

Table 2. Indication for operations in a randomised controlled trial of intradermal suture *vs.* metal staples for incision closure in patients ($n = 300$) undergoing isolated inguinal incisions.

Indication	Metal staples ($n = 152$)	Intradermal suture ($n = 148$)
Rutherford grade[*]		
0–1	85 (55.9)	85 (57.4)
2	38 (25.0)	14 (9.5)
3	19 (12.5)	24 (16.2)
Access for EVAR	10 (6.6)	25 (16.9)

Data are presented as *n* (%). EVAR = endovascular aortic aneurysm repair.
* Rutherford class was used to describe the severity of peripheral arterial disease.[19]

Table 3. Operation details according to randomisation group in a randomised controlled trial of intradermal suture *vs.* metal staples for incision closure in patients ($n = 300$) undergoing isolated inguinal incisions.

Detail	Metal staples ($n = 152$)	Intradermal suture ($n = 148$)
Hybrid operation[*]	74 (48.7)	81 (54.7)
Urgent operation[†]	13 (8.6)	15 (10.1)
Bilateral inguinal incision	9 (5.9)	10 (6.8)
Operation time — min	111.0 (46–317)	112.5 (40–272)
Peri-operative blood loss — mL	200 (10–1 600)	200 (10–2 000)

Data are presented as *n* (%) or median (range).
* Open surgery combined with endovascular procedures (in the present study femoral endarterectomy combined with iliac and or peripheral angioplasty and stenting or stent graft implantation from femoral cutdown).
† Operated within 72 hours.

Results by centre in the post hoc analysis

When analysed using multivariable logistic regression analysis, the effect of skin closure method on infections was not statistically significantly different between centres (interaction of group and centre, $p = .070$). The results of the final model for the primary endpoint are presented in Table 4.

DISCUSSION

Compared with previous studies,[4,5] the overall SSI rate of 13.0% in the present study is low. One possible explanation

Table 4. Multivariable analysis of the primary endpoint of surgical site infection rate at 30 days in a randomised controlled trial of intradermal suture *vs.* metal staples for incision closure in isolated groin incisions.

Variable	Point estimate of OR (95% CI)	*p* value
Skin closure		
Intradermal suture	0.65 (0.32–1.33)	.24
Metal staples	1.0 (ref.)	—
Centre		
SCH *vs.* TUH	1.40 (0.61–3.24)	.43
TUH *vs.* HNCF	0.33 (0.13–0.84)	.020
SCH *vs.* HNCF	0.46 (0.16–1.32)	.15
Diabetes		
Yes	1.92 (0.92–3.92)	.070
No	1.0 (ref.)	—
Age per one year increase	0.97 (0.92–1.01)	.12
BMI per one unit increase	1.04 (0.96–1.13)	.36

OR = odds ratio; CI = confidence interval; TUH = Turku University Hospital; SCH = Satakunta Central Hospital; HNCF = Hospital Nova of Central Finland; BMI = body mass index.

is that the current study also included patients undergoing a groin incision for exposure of the femoral vessels for EVAR. Patients with PAD are known to be at a higher risk of SSI than patients with abdominal aortic aneurysm.[12,21,22]

These results are in accordance with the only available prospective cohort study with a similar design but without randomisation and lacking statistical power calculations.[15] In that study published in 1995, Murphy *et al.* evaluated 114 patients with PAD (173 skin incisions) assigning patients to skin closure with subcutaneous Maxon, interrupted nylon, continuous nylon, or metal staples.[15] They found no difference in the number of SSIs in the different incision closure groups. The patients were considerably younger (67.3 years) and had more severe PAD[23] than the patients in the present study.

Intradermal sutures are used widely in elective surgery. There are very few RCTs available and no contemporary RCTs assessing vascular surgery patients. Recent reviews have not demonstrated a lower incidence of SSIs or other incision complications when using intradermal sutures.[24–27] A recent Cochrane review on subcutaneous skin closure for non-obstetric surgery showed no advantages in wound healing or number of SSIs compared with standard skin closure.[24] The review concluded that because the sutures do not need removal, they may improve patient satisfaction,[24] in agreement with other reports.[25,26] A meta-analysis of 19 RCTs (trauma, orthopaedic, gastrointestinal, gynaecological, and one lower limb bypass surgery) showed no statistical difference in incision infection between absorbable and non-absorbable skin closure groups, concluding that the advantage of absorbable sutures was both cost and time saving as no suture removal had to be scheduled.[27] This RCT addresses a clear knowledge gap in vascular surgery. Since this study started recruiting patients in 2018, at least one other similar RCT has been initiated (NCT05434182).[28]

There are limitations to the current RCT. First, there was unexpectedly high variance in the results of the primary and secondary endpoints between different centres. This is most probably partly explained by the inclusion of both EVAR and PAD patients. Turku University Hospital was the only centre to recruit EVAR patients in the study, and also the centre with the smallest amount of SSI and other wound complications. However, the number of EVAR patients was low in the whole study (35/300; 11.7%), and the rate of SSIs was slightly lower (3/35; 8.6%) compared with patients with PAD. These data have been analysed and discussed with the investigators, but no clear reason for these differences was identified. Second, metal staples chosen as the transdermal closure method may cause skin irritation and even an allergic reaction in some patients, interpreted as a local skin infection. The benefit of metal staples is that they are simple and fast to apply and easily reproducible. A third limitation of the study was that closure of the subcutaneous layers of the skin was not standardised. A tighter closure of the subcutaneous layers may help to reduce the dead space and reduce the prevalence of a seroma. On the other hand, a tight closure of the subcutaneous tissues may cause fat necrosis. A fourth limitation is that the demographics of the excluded or declined patients were not thoroughly documented, and only the total number of operations in the time of the investigation was recorded in the patient selection flowchart. A fifth limitation is that some of the wounds were evaluated post-operatively by study investigators, potentially increasing the risk of reporting bias.

Finally, a sixth limitation is the somewhat arbitrary power calculation as there were no RCTs available for evaluating the minimum clinically important difference, and the sample size calculation was performed according to a previous retrospective study with a markedly higher overall SSI rate and a difference of 15 percentage points between closure groups. A five percentage point difference in the rate of infections can be considered clinically very significant given the high cost and re-admission rate associated with SSIs. However, this study was underpowered to detect a five percentage point difference in the infection rates.

Conclusion

There was no statistically significant difference in the inguinal SSI rate between skin closure with metal staples or intradermal suture in patients undergoing elective vascular surgery with primary isolated exposure of the femoral vessels. The number of SSIs in vascular surgery remains high, warranting further trials to assess different skin closure methods with homogeneous inclusion criteria.

CONFLICTS OF INTEREST

None.

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DATA AVAILABILITY STATEMENT

The research data regarding the present cohort will not be available for public access because it contains confidential information. For inquiries or potential collaboration, please contact the corresponding author at veikko.nikulainen@utu.fi. The authors value transparency while ensuring patient confidentiality.

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