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Relation of skin closure method to groin wound infections after proximal femoral artery exposure, a randomized clinical trial

15.3.2018

M.D. Veikko Nikulainen
Turku University Hospital
Vascular Surgery Department

Research plan

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Veikko Nikulainen, MD
TYKS TO3, Verisuonikirurgisen potilaan hoito
PL52, FI-20521 Turku
veikko.nikulainen@tyks.fi
+358 2 313 0000

ABSTRACT

Background: According to published studies the frequency of groin wound infections after peripheral revascularization varies substantially depending on the source from 5% up to 27%.
Aims of the study: The aim of this randomized clinical trial is to evaluate whether the number of groin wound infections can be reduced with an intradermal skin suture compared to the commonly used metal staples skin closure method.
Methods and study design: We will perform a randomized clinical trial of patients undergoing a vascular procedure which includes an incision in the groin. The patients will be randomized (1:1) to two different wound closure techniques: subcuticular suture or metal staples. After the procedure the patients will be controlled for four to six weeks and the infection rate in each group is recorded. A clinical diagnosis of infection according to Centre for Disease Control (CDC) guidelines will be recorded, no microbiological samples will be routinely collected.
Statistical analysis: A power analysis has been conducted based on Finnish RCT studies and a retrospective study from our own hospital (submitted to Annals of Vascular Surgery 1/2018) which included all isolated groin wounds from Turku University Hospital Vascular Surgery clinic 2015-2016 and total of 626 patients, 313 per group will be enrolled in the study. Differences in infections between the groups will be evaluated using univariable and multivariable logistic regression analyses.
Time and schedule: This is a multicenter trial. Ethical committee approval was acquired in 2015. The randomization will start in the spring of 2018 in the University Hospital of Turku. Later in the year in the other hospitals that are participating in the study once the regional authorities have given their consent.
Ethical aspects: Ethical committee approval was obtained in 2015. The wound closure techniques are all in everyday use already, nothing new and experimental will be used.
Budget: This study is a critical part of quality control and improvement in vascular surgery. The funding will be applied from the Finnish Academy and EVO funding from the ERVA.

INTRODUCTION

The groin is a common site for arterial access in vascular surgery; it is also a frequently infected wound. According to published articles the frequency of groin wound infections after peripheral revascularization varies substantially depending on the source from 5% up to 27%[1-5].

Although the percentage of superficial groin infections is considerably high, the incidence of deep infections of the possibly prosthetic graft materials is significantly lower, between 0% and 3.1% [6-9]

Surgical wound infections (SWI) is defined as an infection that occurs within 30 days of surgery when autogenous material is used, but when prosthetic materials are used the incidence of SWI is calculated for one year after the initial operation. The infection occurs primarily as a result of contamination by skin organisms during or right after surgery. When these pathogens infiltrate deeper into the tissues they can cause an infection of the prosthetic material[6,10].

The high incidence of infection after peripheral vascular surgery compared to other clean surgery in both patient- and procedure related. Patients undergoing surgery for peripheral vascular disease are often frail and have typically multiple co-morbidities; they are in high risk for developing post-operative infections. They often have many pre-existing risk-factors for SWI and hospital acquired infections (HAIs) [11]. This risk is associated with cardiovascular risk factors, degree of ischemia in the operated limb and operative method[12]. Procedure related risks include long operation time[13], which is related to hypothermia, inadequate antibiotic prophylaxis and breaks in sterility. Critical ischemia, rest pain and ischemic ulcer are also independent risk-factors for SWI[14].

SWI causes additional costs for vascular surgery procedures as it lengthens the hospitalization period and requires additional treatments. The length of hospitalization is prolonged by 2-14 days due to SWI[15,16]. A recent Finnish article concluded that the cost for SWI after a revascularization operation was 3320e[2].

Numerous studies have been conducted investigating the best infection prevention schemes in vascular surgery. Andrew H. Stewart el al. [17]have done a meta-analysis of 34 studies to determine

the effectiveness of perioperative strategies in infection prevention. They reviewed 34 randomized controlled trials of these 22 were trial of prophylactic systemic antibiotics, 3 of rifampicin-bonded grafts, 3 of preoperative skin antisepsis, 2 of suction wound drainage, 2 of minimally invasive in situ bypass techniques and individual trials of intraoperative glove change and wound closure technique[18]. They concluded that systemic prophylactic antibiotics reduced the risk for infection but no significant reduction in other infection prevention methods was discovered

The surgical wound in the groin in vascular surgery is traditionally closed using transdermal closure techniques i.e. metal staples or traditional non-absorbable sutures. Gurusamy et al. [19] conducted a large Cochrane database review in 2014 on skin closure techniques in all non-obstetric surgery, they concluded that wound dehiscence may be reduced by using subcuticular absorbable sutures. This subcuticular wound closure method is widely adopted to use in for example plastic surgery.

AIMS OF THE STUDY

Patients undergoing peripheral revascularization procedures have many pre-existing risk factors for surgical wound infection. These cannot be reduced. Studies have shown that prophylactic antibiotics can reduce the number of surgical wound and infections and other hospital acquired infections. The above-mentioned Cochrane database review also stated that wound dehiscence can be reduced by using subcuticular wound closure methods.

The aim of this randomized clinical trial is to evaluate whether the numbers of surgical wound infections in patients undergoing peripheral vascular revascularization procedures can be reduced using the above-mentioned subcuticular wound closure method compared to the golden-standard metal staples.

METHODS AND STUDY DESIGN

Setting

This is a randomized multicenter clinical trial. The trial is coordinated from the University Hospital of Turku Vascular Surgery Department. The other participating hospitals are North Karelia Central

Hospital, Satakunta Central Hospital and Jyväskylä Central Hospital. These are all large volume central hospitals that manage demanding vascular surgery patients with a 24h on-call vascular surgery resource.

Corresponding researches in the other participating hospitals are:
MD Veikko Nikulainen, Turku University Hospital
MD, PhD Tuomas Koskinen, Satakunta Central Hospital(tuomas.koskinen@satshp.fi)
MD, PhD Johanna Turtiainen, North-Karelia Central Hospitaljohanna.turtiainen@siunsote.fi)
MD, PhD Tiia Kukkonen, Jyväskylä Central Hospital (tiia.kukkonen@fimnet.fi)

Patient recruitment

The patients enrolled in this trial are patients that have an isolated groin wound (i.e. the groin wound is not a part of a larger wound in the same limb). Only patients that are undergoing primary procedures are included. Emergency procedures (puncture site hematomas) are also excluded from the trial as are patients operated for surgical site infections and pseudoaneurysm.

Randomization

The patients will be randomized (1:1) to two different wound closure techniques: subcuticular suture or metal staples. The type of subcuticular suture material is not standardized, all participating hospitals use whatever suture they are accustomed to. After the procedure the patients will be controlled for four to six weeks and the infection rate in each group is recorded. A clinical diagnosis of infection according to Centre for Disease Control (CDC) guidelines will be recorded[20], no microbiological samples will be routinely collected.

Data recording

The following data will be collected from the operation monitoring system to an Excel-file: age, gender, diagnosis and body mass index (BMI) of the patient, indication and urgency of the operation and whether it was performed by the hybrid or a traditional approach. It will be recorded whether the prophylactic antibiotic was given accordingly. Known risk factors for SWI are recorded from the patient data system, these included peripheral artery disease (PAD), presence of critical limb ischemia (CLI), hypertension, diabetes, rheumatoid arthritis, smoking and

immunosuppressive medication. The condition of the patients' skin will also be recorded in the file.

Statistical analysis

A power analysis has been conducted based on a prospective Finnish study[2] and a retrospective study from our own hospital (submitted to Annals of Vascular Surgery 1/2018) which included all isolated groin wounds from Turku University Hospital Vascular Surgery clinic 2015-2016. Sample size calculations were based on two-sided Pearson's χ^2 -test for two proportions. Sample size was calculated from an estimated infection rate of 20% in the transdermal wound closure group. A decrease of 10 percentage points in infection rate is considered clinically important difference leading to estimated 10% infection rate in the intradermal wound closure group. To detect this difference with a power of 0.9 (1-β) and two-sided significance level (α) of 0.05 266 patients per group is needed. With an estimated drop-out rate of 15% total of 626 patients, 313 per group will be enrolled in the study. Sample size calculations were performed using Power procedure in SAS System for Windows, Version 9.4 (SAS Institute Inc., Cary, NC).

Categorical variables of the study will be characterized by group using frequencies and percents and for continuous variables means and standard deviations or medians with range and 25^{th} and 75^{th} percentiles will be used. Differences in patient characteristics between groups will be tested using two-sample t-test or Pearson's χ^2 –test. Differences in infections between the groups will be evaluated using univariable and multivariable logistic regression analyses. The study site differences will be evaluated in statistical models and if major differences are detected, then study site will be taken into account in the analyses. Two-sided p-values less than 0.05 will be considered statistically significant. The subjects with missing data will automatically be excluded from the analyses of the variables in concern. Statistical analyses will be performed using SAS System for Windows, Version 9.4 or later (SAS Institute Inc., Cary, NC).

TIME AND SCHEDULE

This is a multicenter trial. Ethical committee approval was acquired in 2015. The randomization will start in the spring of 2018 in the University Hospital of Turku. Later in the year in the other hospitals that are participating in the study once the regional authorities have given their consent.

Based on our retrospective material our clinic has ca. 130 patients annually undergoing a procedure with an isolated groin wound. Our estimates are that it will take approximately 2 years between the four participating centers to gather the needed patient material. By this calculation the material should be ready and analyzed during years 2020- 2021.

ETHICAL ASPECTS

Ethical committee approval was obtained already in 2015 for the University Hospital of Turku. The consent from the local ethical authorities has been filed for the other participating hospitals in the beginning of 2018. The wound closure techniques are all in everyday use already, nothing new and experimental will be used.

BUDGET

This study is a critical part of quality control and improvement in vascular surgery. The funding will be applied from the Finnish Academy and EVO funding from the ERVA.

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