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ORIGINAL RESEARCH

Observational Study on the Risk of Surgical Site Infection in Patients Undergoing Common Femoral Endarterectomy in Conjunction With an Endovascular Procedure Compared With Common Femoral Endarterectomy Alone

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WHAT THIS PAPER ADDS

This paper specifically compared surgical site infections in patients who had undergone common femoral endarterectomy compared with those who had undergone hybrid revascularisation procedures that included common femoral endarterectomy. It demonstrated that hybrid revascularisation can be undertaken without concern of an increased surgical site infection risk when compared with common femoral endarterectomy alone.

Objective: A hybrid approach is being employed increasingly in the management of peripheral arterial disease. This study aimed to assess the surgical site infection (SSI) incidence of hybrid revascularisation (HR) compared with common femoral endarterectomy (CFEA) alone.

Methods: This was a retrospective review of consecutive patients who underwent CFEA or HR alongside CFEA between 2017 and 2021 including one year of follow up. The primary outcome was SSI incidence. Secondary outcomes included length of surgery, duration of admission, further revascularisation surgery, limb salvage, and death. Differences in outcomes were assessed with the Student's unpaired *t* test, chi square test, and Fisher's exact test.

Results: A total of 157 groin incisions from 155 patients were included: 78 had CFEA procedures and 79 had HR procedures. No statistical difference was found between groups for age, sex, and indication for surgery. Surgical site infection occurred in five of the CFEA patients (6%) compared with seven of the HR patients (9%) ($p = 0.77$). The HR procedures took significantly longer, with an average of 299 minutes compared with 220 minutes for CFEA ($p < 0.001$). No statistically significant difference was identified for length of admission: median stay five days for CFEA *vs.* four days for HR ($p = 0.44$). Major amputation was performed within one year in five of the CFEA procedures (6%) and five of the HR procedures (6%) ($p = 1.0$). Further revascularisation surgery was attempted in two patients in the HR group and six patients in the CFEA group ($p =. 17$). No statistically significant difference was found in the one year mortality rate: eight CFEA (10%) and seven HR (9%) ($p = 0.77$).

Conclusion: Patients who underwent HR alongside CFEA did not have a statistically significantly increased incidence of SSI, despite increased surgical time. Using HR techniques enabled patients to have multilevel disease treated in one stage without an increased incidence of SSI.

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INTRODUCTION

The common femoral artery (CFA) is the target vessel for most surgical revascularisation procedures.[1] Common femoral artery disease in conjunction with proximal iliac or distal femoral vessel disease can result in lifestyle limiting claudication or chronic limb threatening ischaemia (CLTI).[2] Chronic limb threatening ischaemia is the leading cause of

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limb loss and a significant cause of premature death worldwide.[3]

Common femoral artery disease is predominantly treated by surgical means, including common femoral endarterectomy (CFEA) with patch repair. However, due to associated inflow and outflow disease, some patients additionally need adjunctive endovascular treatment such as angioplasty and or stenting of iliac or femoral vessels. These procedures can be performed sequentially. Alternatively, because patients with CLTI have multilevel disease, hybrid revascularisation (HR) techniques, combining inflow and or outflow angioplasty and or stenting alongside CFEA, are being used increasingly.[4,5]

Hybrid revascularisation surgery has the potential to reduce the number of procedures required for limb salvage, as well as future hospital admissions for endovascular procedures with low morbidity and mortality.[6] It has the benefit of managing multiple levels of disease in one stage, rather than arranging separate endovascular procedures. As an arterial hub for the regional vascular network, this institution has been utilising the hybrid suite since 2014, developing HR strategies to treat multilevel arterial disease.[7]

Both CFEA and HR for the treatment of CFA disease require groin incisions and therefore carry a significant risk of surgical site infection (SSI). The Groin wound Infection after Vascular Exposure (GIVE) multicentre cohort study[8] demonstrated that the SSI rate following groin incisions is as high as 8.6% and results in increased patient morbidity, length of stay, and healthcare costs. The GIVE study also identified increased operating time as an independent predictor of SSI.

This study aimed to assess the perceived advantage of HR compared with CFEA alone in terms of SSI rates and other complications.

METHODS

This single centre study and retrospective review included all consecutive patients who underwent CFEA and HR between January 2017 and January 2021. Inclusion criteria for HR included all patients who underwent CFEA in conjunction with an endovascular procedure of either inflow or runoff angioplasty and or stent. Patients who also underwent femoral or femoral crossover grafts or bypass surgery alongside CFEA were excluded from both groups. Patients received pre-operative antibiotics and chlorhexidine preparation. All operations were completed using a synthetic patch to close the CFA. All patients were followed up for one year. Each groin incision was included as a separate event for patients who underwent a bilateral procedure, with the total time of operation included for each groin.

Primary outcomes were SSI incidence, as pre-defined by the Centres for Disease Control and prevention (CDC) criteria (Table 1).[9] Secondary outcomes included length of surgery, duration of admission, further revascularisation procedures, limb salvage rate, and mortality rates at 30

Table 1. Centres for Disease Control and Prevention criteria for surgical site infections (SSI).[9]

Superficial SSI	Within 30 days of procedure Involves only skin/subcutaneous tissue of the incision	Patient has one of: 1. Purulent discharge 2. Organism identified from aseptic specimen 3. Incision deliberately re-opened by a surgeon	AND localised pain/tenderness/ swelling/erythema or heat.	The following do not qualify as superficial incisional SSI: 1. Diagnosis/treatment of cellulitis (redness/ warmth/swelling), by itself 2. A stitch abscess alone
Deep SSI	Within 90 days of procedure Involves deep soft tissues of the infection	Patient has one of: 1. Purulent discharge from the deep incision 2. Deep incision that dehisces or is deliberately opened	AND organism(s) identified from the deep soft tissues of the incision	AND patient has one of: fever (> 38 °C) localised pain An abscess or other evidence of deep infection detected on gross anatomical/histopathological exam/imaging test.

days and one year. Limb salvage was assessed by the need for major amputation, which included below, through, and above knee amputations. Patients who underwent foot debridement and or toe amputation were not classed as major amputation[10] and not included in the limb salvage analysis. Comparison of patient demographics and indication for surgery was undertaken between the two groups of patients. Data were obtained from operation notes, hospital business intelligence data, electronic health records, and radiology software.

Normality testing was undertaken using Kolmogorov–Smirnov test/Q–Q plot. Following this, Student's unpaired *t* test, chi squared analysis and Fisher's exact test were used for analysis of continuous and categorical data, respectively (SPSS V27; IBM, Armonk, NY, USA).

RESULTS

A total of 155 consecutive patients underwent revascularisation, two of whom underwent bilateral procedures; therefore, 157 groin incisions were included for analysis. Of these, 78 were CFEA and 79 were HR procedures. The median age was 72.5 years (range, 51–91) in the CFEA group and 73.5 years (range, 58–90) in the HR group ($p = 0.32$). Patients were predominantly male ($n = 123$, 78%), with no statistically significant difference between the two groups ($p = 0.97$). Indications for surgery were CLTI for 106 procedures and severe short distance claudication for 51 procedures. Chronic limb threatening ischaemia was the indication for 52 CFEA procedures (67%) and 54 HR procedures (68%) ($p = 0.82$). Table 2 provides a summary of baseline characteristics and patient comorbidities. Of the patients who underwent HR, the most common endovascular procedures performed alongside CFEA were: 64 iliac angioplasty and or stent (81%), 12 run off vessel angioplasty and or stent (15%), and three combined inflow and run off angioplasty and or stent (4%).

Hybrid revascularisation procedures were statistically significantly longer, with a mean average of 299 minutes compared with 220 minutes for CFEA alone ($p < 0.001$). There was no statistically significant difference in the median length of stay between the groups, with a median length of stay of five days for CFEA procedures and four days for HR procedures ($p = 0.44$).

Table 2. Baseline characteristics of patients.

Variable	CFEA ($n = 78$)	HR ($n = 79$)	*p* value
Age – years	72.5 (51–91)	73.5 (58–90)	0.32
Male	61 (78)	62 (78)	0.97
Female	17 (22)	17 (22)	0.97
CLTI	52 (67)	54 (68)	0.82
SDC	26 (33)	25 (32)	0.82
DM	34 (44)	24 (30)	0.086
HTN	37 (47)	33 (42)	0.48
IHD	28 (36)	25 (32)	0.57
AF	8 (10)	10 (13)	0.64
CKD	3 (4)	9 (11)	0.075
COPD	10 (13)	9 (11)	0.78
CVE	6 (8)	9 (11)	0.43

Data are presented as *n* (%) or median (range)
CLTI = chronic limb threatening ischaemia; SDC = short distance claudication; DM = diabetes mellitus; HTN = hypertension; IHD = ischaemic heart disease; AF = atrial fibrillation; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; CVE = cerebral vascular event.

Surgical site infection occurred following five CFEA procedures (6%) compared with seven HR procedures (9%) ($p = 0.77$). Indications for surgery did not significantly increase the risk of SSI: four procedures performed for short distance claudication resulted in SSI (8%), whereas eight procedures performed for CLTI resulted in SSI (8%) ($p = 1.0$).

Of the five infections recorded in the CFEA group, four were superficial and one was deep, according to CDC criteria.[9] The patient with a deep infection underwent a below knee amputation and died following general deterioration two months post-initial surgery. Of the four superficial infections, two patients returned to theatre for washout, with one undergoing a sartorius flap.

Of the seven infections recorded in the HR group, four were superficial and three were deep. Of the three deep infections, two patients underwent washout and sartorius flap and one patient underwent above knee amputation. Of the four superficial infections, one required vacuum assisted closure and none returned to theatre.

Major amputation was performed within one year in five patients who underwent CFEA procedures (6%) and in five patients who underwent HR procedures (6%) ($p = 1.0$). Three major amputations were performed within one month of surgery in both groups. Further revascularisation procedures were attempted in two patients in the HR group and six patients in the CFEA group ($p = 0.17$). This included one femoropopliteal bypass procedure and one further HR procedure in the HR group, and six patients underwent femoropopliteal bypass surgery in the CFEA group. One patient in the CFEA group underwent both a further revascularisation procedure (femoropopliteal bypass) and an amputation (below knee) on the same limb. The original indication for surgery in all patients who underwent major amputation or further revascularisation post-operatively was CLTI.

Within one year of surgery, eight of the CFEA group (10%) and seven of the HR group (9%) died ($p = 0.77$); two of these deaths occurred within 30 days and both were in the HR group. Causes of death were documented as multiorgan failure or heart failure and ischaemic heart disease.

DISCUSSION

This study has demonstrated that although HR increased operating time by an average of 79 minutes, it did not lead to a statistically significant increase in the incidence of SSI or length of stay. The results of this study show real world incidences of SSI in CFEA and hybrid groin revascularisation procedures. It also used validated criteria in the definition of SSI as per the CDC criteria,[9] which was also used in the GIVE study.[8] The overall SSI incidence in the current study was comparable with the GIVE study, which reported an SSI incidence of 8.6%. Furthermore, when HR alone was considered, the SSI incidence was lower than that reported

in the GIVE study (9% *vs.* 12.1%, respectively). The GIVE study is a multicentre study, whilst the current study was a single centre study and all cases were performed in a hybrid theatre, which may have had some impact on outcomes. Another previous multicentre study in 2022 found that of 128 patients who underwent hybrid revascularisation, 25% developed an SSI, although the criteria used for diagnosis of SSI were not stated.[11]

An alternative to hybrid revascularisation in treating multilevel arterial disease involving the CFA is to arrange a separate endovascular procedure; this was the case in six of the current patients who underwent CFEA. However, arranging a separate endovascular procedure to complement an open procedure carries its own risks; it would also result in repeat admissions for the patient and increased cost. Muller et al.[12] retrospectively analysed 676 cases of iliac endovascular procedures and identified a complication rate of 4.3%, which included vascular site complications, bleeding, and pseudoaneurysm.

There is increasing interest in the endovascular approach for CFA disease, but it remains predominantly being used in extremely high risk patients.[13] There is an ongoing multinational randomised control trial (SUPERSURG-RCT) being conducted to evaluate the role of endovascular therapy in CFA disease compared with CFEA, with an expected study completion date in 2025.[14] A recent systematic review and meta-analysis comparing endovascular procedures with open surgery alone in treating CFA disease has shown that endovascular procedures resulted in inferior long term arterial patency rates.[15] Until there is more evidence available, surgical repair of CFA disease remains the gold standard. Therefore, evaluating outcomes, especially of SSI, is important, as there are data to support increased morbidity and length of stay in patients developing SSI.[8]

Another consideration in reducing SSI incidence in patients undergoing open groin surgery is the use of closed incision negative pressure dressings at the index procedure. Studies have previously shown that these can reduce SSI rates, particularly in patients with recurrent groin incisions.[16] However, the dressings themselves are costly and recent studies have shown they have little effect in reducing wound infections and advocate for a risk factor based model when considering their use.[17]

Despite the increased operating time of HR procedures, this did not result in an increase in the SSI incidence, length of stay, amputation rate, or mortality rate in the current study. Therefore, HR procedures should be considered where appropriate for the management of multilevel CFA disease. Patients may also benefit from a single operation and avoid the risks associated with a separate endovascular procedure. There are also benefits in reducing the number of hospital admissions and costs associated with multiple procedures, as shown in patients with acute limb ischaemia.[18]

This study was limited by its retrospective nature and by being a single centre study. It used validated criteria in recording SSI using the CDC criteria[9] and all cases of SSI were diagnosed by a consultant vascular surgeon who may or may not have been the operating surgeon. However, these criteria contain an element of subjectivity, especially for the superficial SSI category, which may be diagnosed in the presence of purulent discharge without an identified organism or need for further surgery. Another limitation was regarding the follow up outcomes. Late complications or SSI that happened in the community after the patient was discharged and were managed in primary care would not have made it into the records; therefore, SSI data are more accurate in the short term, not the long term. However, this is a limitation of any observational study and is applicable even for the GIVE study.

Conclusion

Hybrid revascularisation for CFA disease is safe and has comparable rates of SSI, amputation, and mortality compared with CFEA alone. Wherever feasible, HR should be considered in patients with multilevel peripheral vascular disease involving the CFA.

CONFLICT OF INTEREST

None.

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