

Long-term results after femoral thrombendarterectomy combined with simultaneous endovascular intervention in intermittent claudication and critical ischemia

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Abstract

Objective: This population-based retrospective cohort study investigates long-term results of femoral thrombendarterectomy combined with simultaneous endovascular intervention of the iliac or femoropopliteal vessels, or both, with focus on freedom from recurrent intervention, limb salvage and survival.

Methods: All patients undergoing femoral thrombendarterectomy and simultaneous endovascular intervention between 1999 and 2013 were included. Stratification was according to clinical symptoms, intermittent claudication or critical ischemia, with subgroups for rest pain and ulcer/gangrene, and for type of endovascular intervention, iliac, femoropopliteal or both. We assessed technical success, 30-day complications, freedom from recurrent intervention, survival and amputation free survival in all patients. Limb salvage was assessed in patients with critical ischemia.

Results: We identified 151 operations in 143 patients with a total of 164 limbs treated. A total of 13 patients had bilateral and 8 patients had subsequent contralateral operations. Indication was intermittent claudication in 87 (57.6%) and critical ischemia in 64 (42.4%) operations. Thirty-day mortality, only observed in critical ischemia, was 5/64 (7.8%). Freedom from recurrent intervention after 5 years was 91% in intermittent claudication and 70% in critical ischemia. In total, 84% of the patients with claudication were improved at the end of the study. Limb salvage at 5 years was 75% in critical ischemia, 93% in rest pain and 64% in patients with ulcer or gangrene.

Conclusion: Femoral thrombendarterectomy combined with endovascular iliac or femoropopliteal intervention has good and durable results in intermittent claudication and critical ischemia, especially in patients with rest pain. In most cases, a single operation is sufficient.

Keywords

Hybrid operation, hybrid revascularization, intermittent claudication, critical limb ischemia, limb salvage, amputation free survival

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Introduction

Hybrid procedures combining open surgery and endovascular procedures for the treatment of multilevel atherosclerosis in the lower limb have become considerably more frequent in the last decades,^{1–13} and are being used for increasingly more complex lesions.^{1,4} This method is often used for complex vascular cases involving pathologies at both iliac and femoropopliteal level, necessitating simultaneous treatment of all levels to ensure sufficient inflow and runoff. However, the complexity of procedures with many consecutive steps and the involvement of interventional radiologists and vascular surgeons make

the approach resource demanding, both in terms of personnel and operating room time. Published series^{1–3,14} show excellent

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technical success rates and good short- and medium-term results; however, there are few published data regarding the long-term results. A PubMed search with the terms hybrid operation, hybrid revascularization, hybrid procedure and limb ischemia revealed one publication with observation time over 5 years for combined common femoral endarterectomy and iliac stenting,¹⁴ but no other studies with follow-up of more than 3 years. The primary aim of this study is to assess long-term results of femoral thrombendarterectomy (TEA), combined with iliac or femoropopliteal endovascular intervention, with focus on freedom from reintervention, limb salvage and amputation free survival.

Methods

Study patients were identified from our prospectively maintained local vascular registry, which is part of the Norwegian registry for vascular surgery (NORKAR).¹⁵ Complementary and long-term endpoints data were obtained from the patient records. The study protocol was approved by the regional ethical committee (REK midt, 2013/90). Informed consent was not required as the study was outcome analysis only without any influence on the treatment given. All patients who underwent revascularization by femoral TEA combined with simultaneous proximal or distal endovascular intervention between 1999 and 2013 were included consecutively. Due to the retrospective nature of the study and the paucity of published long-term results, no power calculations were performed. Hybrid techniques were used when significant atherosclerotic lesions affected more than one anatomic level. The most common disease pattern was affection of both iliac and common femoral artery, for example, occlusion of the common iliac artery and severe stenosis of the ipsilateral common femoral artery, treated by TEA and patching of the common femoral artery and thereafter endovascular recanalization and stenting of the common iliac artery.

Our institution is the only one performing vascular surgery in the catchment area, and hospital healthcare is free for the whole population. Therefore, all patients from the catchment area, treated with simultaneous hybrid operation in the study period, are included.

All study operations were performed by vascular surgeons and interventional radiologists as simultaneous hybrid procedures. Usually, femoral TEA was performed first, and endovascular intervention after completion of the patch angioplasty, except for iliac occlusion, where the intervention was performed before completion of the angioplasty. Arterial closure was usually performed with a vein patch, and the greater saphenous vein was used whenever available. Patients typically received 3000 units of unfractionated heparin prior to TEA, and 3000 units before the endovascular intervention. Repeated doses were usually given after 3 h. Activated partial thromboplastin time (APTT) measurement was not routinely used. Technical success was defined as patent vessel without significant stenosis.

Follow-up with clinical examination was performed at 1 and 12 months, unless earlier examination or imaging was indicated. Further follow-up was not standardized. However, both reintervention and amputation are documented in the hospital records. Mortality is directly obtained from the population registry and updated in the electronic patient records. No patient left the region, and patient records from all hospitals in the region were available for all study patients, resulting in complete follow-up regarding the study endpoints.

Stratification was according to clinical presentation with intermittent claudication or critical ischemia. Patients with critical ischemia were further stratified in subgroups with rest pain (Rutherford category 4)¹⁶ or ulcer/gangrene (Rutherford category 5–6).¹⁶ Procedures were stratified according to type of endovascular intervention with either iliac or femoropopliteal intervention or simultaneous iliac and femoropopliteal intervention.

Data analysis was performed with SPSS 23.0 (IBM Inc., Armonk, NY, United States). Demographic data were analyzed per patient, using the first entry in case of subsequent contralateral operation. Thirty-day local complications, freedom from reintervention, limb salvage in critical ischemia and clinical result in intermittent claudication were assessed per limb.

Systemic 30-day complications and early mortality were assessed per operation. Overall survival and amputation free survival were calculated per patient. In case of subsequent contralateral operation, the first entry was considered. Kaplan–Meier analysis and log rank test were used to compare groups for freedom from reintervention, limb salvage, survival and amputation free survival. Demographic comparisons were made with chi-square test for categorical variables and Mann–Whitney U test for continuous variables. P-values were considered significant if $<.05$.

Results

We identified 151 operations in 143 patients, 87 (58%) for intermittent claudication and 64 (42%) for critical ischemia, of which 23 operations for rest pain (Rutherford category 4)¹⁶ and 41 for ischemic ulcer or gangrene (Rutherford category 5–6).¹⁶ Eight patients had hybrid operations on the contralateral side later, and eight operations for intermittent claudication and five operations for rest pain were bilateral, resulting in 164 limbs treated in total, 95 for intermittent claudication, 28 for rest pain and 41 for ulcer or gangrene. Mean preoperative ankle-brachial pressure index (ABPI) was 0.62 in intermittent claudication, 0.45 in rest pain and 0.36 in patients with ulcer or gangrene. Table 1 shows the patient characteristics and comorbidities.

Intermittent claudication was most frequent in men, while critical ischemia was more frequent in female patients, especially in the group with rest pain. The difference in gender proportion between intermittent claudication and critical ischemia was significant with a chi-square of 14.1 ($p <.001$).

Table 1. Patient characteristics and comorbidities.

	Intermittent claudication		Rest pain		Ulcer/gangrene	
Gender	Male	58	Male	6	Male	18
	Female	24	Female	17	Female	20
Age (mean)	Male	70.5	Male	71.8	Male	69.3
	Female	72.2	Female	76.5	Female	76.6
Hypertension	M	55% (32/58)	M	50% (3/6)	M	72% (13/18)
	F	58% (14/24)	F	64% (11/17)	F	45% (9/20)
Cardiac disease	M	43% (25/58)	M	50% (3/6)	M	78% (14/18)
	F	33% (8/24)	F	29% (5/17)	F	40% (8/20)
COPD	M	12% (7/58)	M	33% (2/6)	M	11% (2/18)
	F	8% (2/24)	F	24% (4/17)	F	10% (2/20)
Smoker	M	41% (24/58)	M	67% (4/6)	M	50% (9/18)
	F	46% (11/24)	F	47% (8/17)	F	35% (7/20)
Diabetes	M	31% (18/58)	M	0% (0/6)	M	39% (7/18)
	F	4% (1/24)	F	18% (3/17)	F	20% (4/20)
Renal failure	M	5% (3/58)	M	17% (1/6)	M	6% (1/18)
	F	0% (0/24)	F	0% (0/17)	F	5% (1/20)
Cerebrovascular disease	M	5% (3/58)	M	50% (3/6)	M	17% (3/18)
	F	8% (2/24)	F	6% (1/17)	F	5% (1/20)
Vascular surgery prior to actual OP	M	24% (14/58)	M	33% (2/6)	M	33% (6/18)
	F	25% (6/24)	F	25% (5/17)	F	15% (3/20)
PTA/stent prior to actual OP	M	26% (15/58)	M	17% (1/6)	M	17% (3/18)
	F	29% (7/24)	F	35% (6/17)	F	10% (2/20)

COPD: chronic obstructive pulmonary disease; PTA: percutaneous transluminal angioplasty; OP: operation.

The difference in gender proportion between subgroups with rest pain and ulcer or gangrene was not significant, with a chi-square of 2.7 ($p = .099$). Women with intermittent claudication were significantly younger than women with critical ischemia ($p = .037$), but there was no significant age difference between women with rest pain and ulcer or gangrene ($p = .845$), and no significant age difference between any of the patient groups in men.

Femoral TEA was combined with iliac intervention in 101 cases, femoropopliteal intervention in 49 cases and with both iliac and femoropopliteal intervention in 14 cases. Iliac intervention was the most common procedure in all patients, while combined iliac and femoropopliteal interventions were more frequent in patients with critical ischemia. Table 2 shows the type of treatment in the different patient groups.

Mean length of stay after operation was significantly shorter for patients with intermittent claudication, compared with those treated for critical ischemia (3.2 vs 5.5 days, $p < .001$).

Technical success and early complications

Technical success. Primary technical success was 98% (99/101) for iliac revascularization, and 92% (58/63) for femoropopliteal revascularization. Two iliac occlusions in patients with critical ischemia could not be recanalized, necessitating femorofemoral crossover bypass. In two patients with intermittent claudication,

Table 2. Type of intervention depending on clinical presentation.

	Intermittent claudication	Rest pain	Ulcer/gangrene	Critical ischemia
Iliac intervention	59	20	22	42
Femoropopliteal intervention	32	4	13	17
Both	4	4	6	10
Total	95	28	41	69

recanalization of the superficial femoral artery (SFA) was not achieved, but no additional treatment was necessary. In three patients with critical ischemia, patency in the SFA could not be obtained due to intraoperative thrombosis. Bypass surgery was not feasible, leading to two amputations at knee level and one crural amputation. Technical failure was not associated with any 30-day mortality. Table 3 shows 30-day complications and mortality.

Thrombosis within 30 days. Thrombosis within 30 days occurred in nine patients (5%), intraoperatively in three cases as described previously and after operation in six cases. Of the latter, three patients were treated for critical ischemia. One of these was operated with successful thrombectomy, one had to be amputated at knee level and one deteriorated rapidly and died shortly after the thrombosis.

Table 3. Postoperative (30-day) complications and mortality.

	Intermittent claudication	Rest pain	Ulcer/gangrene
Return to theater within 30 days	2% (2/95)	14% (4/28)	12% (5/41)
Return to theater for bleeding	1% (1/95)	7% (2/28)	2% (1/41)
Return to theater for thrombosis	1% (1/95)	0% (0/28)	2% (1/41)
Return to theater for other reasons	0% (0/95)	7% (2/28)	7% (3/41)
Amputation within 30 days	0% (0/95)	7% (2/28) (all knee level)	10% (4/41) (all crural)
Thrombosis within 30 days	4% (4/95)	11% (3/28)	5% (2/41)
Superficial infection	1% (1/95)	0% (0/28)	2% (1/41)
Deep infection	0% (0/95)	4% (1/28)	0% (0/41)
Myocardial infarction	2% (2/87)	9% (2/23)	0% (1/41)
Non-fatal MI	2% (2/87)	4% (1/23)	0% (1/41)
Mortality	0% (0/87)	9% (2/23)	7% (3/41)
Pneumonia	0% (0/87)	4% (1/23)	2% (1/41)
Stroke	0% (0/87)	0% (0/23)	0% (0/41)

MI: myocardial infarction.

Local complications and amputations per limb (n = 164), systemic complications and mortality per operation (n = 151).

The remaining three patients were treated for claudication. Two had reocclusion of the SFA after 3 and 8 days without symptoms necessitating urgent treatment, while the third had an occlusion of a preexisting venous bypass graft after 26 days. Further reconstruction was not feasible, necessitating transfemoral amputation after 34 days.

Return to theater within 30 days. Return to theater within 30 days was necessary in 11 cases (7%), but was not associated with 30-day mortality. Four patients were operated for bleeding without subsequent complications. The other indications were wound necrosis and local infection in two cases, postoperative thrombosis in two cases, lymphatic leakage in one case and epidural hematoma after epidural analgesia in one case. One patient with small gangrenous lesions did not improve after iliac intervention and femoral TEA, and was operated with a femoropopliteal bypass below the knee (BK) with success, but this was part of a sequential treatment strategy, where one wanted to avoid simultaneous bypass operation in addition to the hybrid procedure.

Amputation within 30 days. Amputation within 30 days was necessary in six patients with critical ischemia (9%), but did not lead to any 30-day mortality. Of these, three were related to SFA occlusion as reported. In the remaining cases, there was progression of ischemic gangrene despite patent reconstruction. Amputation level was BK in four patients with ulcer or gangrene, while two patients in the group with rest pain had an amputation at knee level.

30-day mortality. The patients with critical ischemia suffered a 30-day mortality rate of 8% (5/61). One patient with primarily uncomplicated postoperative course died 2 days after discharge from unknown cause. The other causes of death

were myocardial infarction, progress of preexistent dilatative cardiomyopathy, septicemia with multiple organ failure and recurrent thrombosis.

Long-term results

Overview and summary of results. Mean observation time was 48 months in intermittent claudication and 31 months in critical ischemia. Reintervention after 30 days was performed in 19 cases (9 with claudication, 2 with rest pain and 8 with ulcer or gangrene). Limb salvage without 30-day mortality in critical ischemia was achieved in 49 out of 69 cases (71%), and improvement in intermittent claudication in 80 out of 95 cases (84%). Late amputation was necessary in 3 patients with intermittent claudication (3%) and 15 patients with critical ischemia (22%). Figure 1 shows treatment pathway and results for all limbs treated in this study.

Freedom from reintervention after 30 days. Kaplan–Meier estimate for freedom from reintervention after 5 years was 91% (standard error (SE)=.03) in intermittent claudication and 70% (SE=.09) in critical ischemia. In the subgroup with rest pain, the estimate was 87% (SE=.08), and in the subgroup with ulcer or gangrene, the estimate was 60% (SE=.12). Figure 2 shows Kaplan–Meier analysis for freedom from reintervention.

Log rank test shows a significant difference between the patient groups with intermittent claudication and critical ischemia (p=.035). Subgroup analysis shows a significant difference between intermittent claudication and ischemic ulcer/gangrene (p=.007), but no significant difference between intermittent claudication and rest pain (p=.708), and no significant difference between rest pain and ischemic ulcer/gangrene (p=.176).

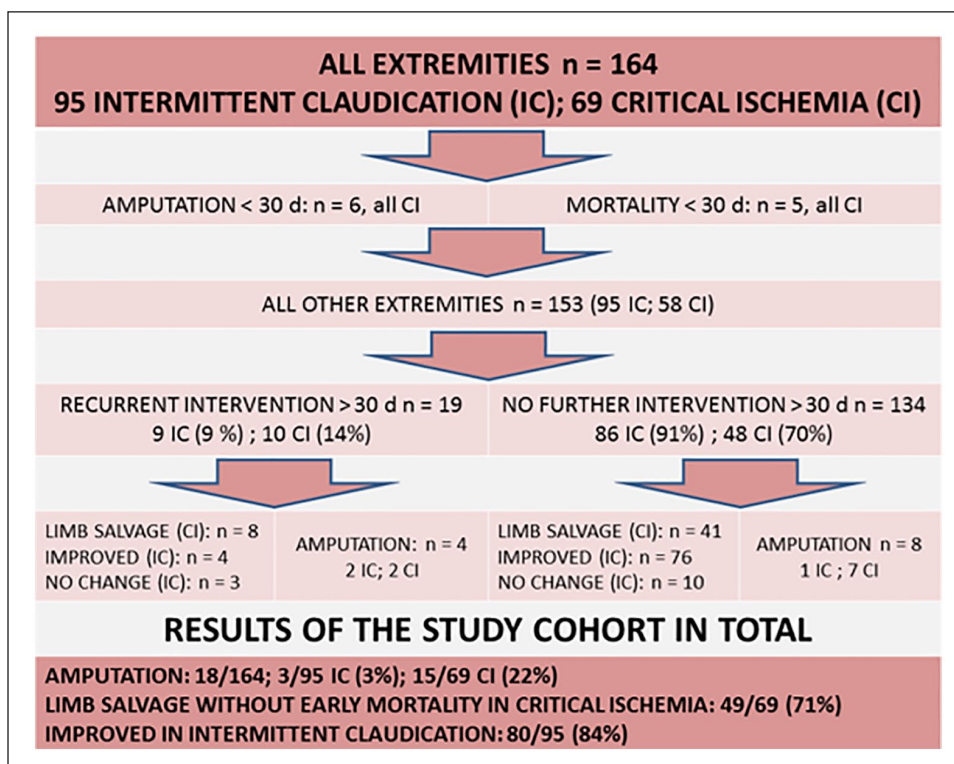


Figure 1. Treatment pathway and results for all limbs treated.

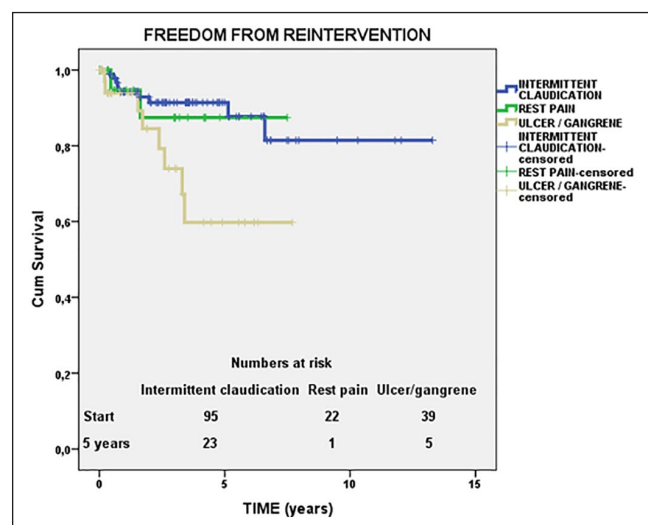


Figure 2. Freedom from reintervention depending on indication.

Reintervention was in all cases due to relapse of symptoms caused by either recurrent stenosis or occlusion in the actual limb. It was performed as endovascular intervention in 12 cases and open surgery in 7 cases, of which 2 redo hybrid and 5 bypass operations. Two of the secondary endovascular interventions failed, necessitating bypass surgery in one and repeated hybrid operation in the other patient. Subsequent bypass surgery was necessary in one patient after recurrent thrombosis.

Limb salvage. Limb loss occurred in 18 patients (15 with critical ischemia and 3 with intermittent claudication). Six patients with critical ischemia suffered limb loss within 30 days, associated with early occlusion in three cases and progression of ischemic gangrene despite patent reconstruction in the remaining cases. Limb loss after 30 days occurred in 12 patients (mean: 486 days, range: 34–1877 days). In nine patients with critical ischemia, all treated for ischemic ulcer or gangrene, limb loss was associated to loss of patency in four and progressive ischemic gangrene despite open reconstruction in five cases. In three patients with intermittent claudication, limb loss was associated to acute thrombosis of a preexisting bypass in one case, while the other two patients had secondary procedures because of recurrent stenosis, and developed critical ischemia after some years of follow-up. Subsequent bypass surgery was performed, but limb salvage was not achieved despite open reconstruction.

Kaplan–Meier estimate for limb salvage after 5 years was 75% (SE=.06) in patients with critical ischemia. Subgroup analysis revealed 93% limb salvage (SE=.05) for those with rest pain and 64% (SE=.09) for those with ulcer or gangrene. Log rank test shows a significant difference between the groups with rest pain and ischemic ulcer/gangrene (p=.032). Figure 3 shows Kaplan–Meier analysis of limb salvage depending on clinical presentation.

Kaplan–Meier estimate for limb salvage after 5 years in critical ischemia was 86% (SE=.06) for iliac intervention, 60% (SE=.16) for femoropopliteal intervention and 56%

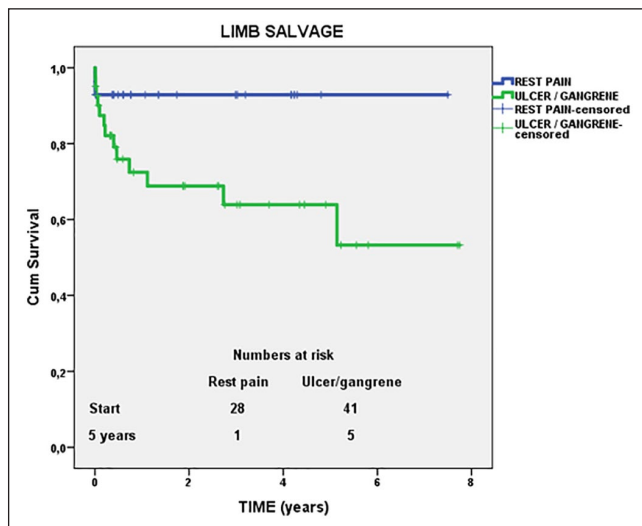


Figure 3. Limb salvage in after hybrid operation depending on indication.

(SE=.17) for simultaneous iliac and femoropopliteal intervention. Log rank test shows a significant difference between the treatment groups ($p=.043$). Subgroup analysis shows a significant difference between iliac intervention and femoropopliteal intervention ($p=.031$), but no significant difference between femoropopliteal intervention and simultaneous iliac and femoropopliteal intervention.

Survival and amputation free survival. Kaplan–Meier estimate for survival at 5 years was 76% (SE=.06) in intermittent claudication and 46% (SE=.08) in critical ischemia, 38% (SE=.18) in rest pain and 46% (SE=.10) in ulcer or gangrene. There is a significant difference between intermittent claudication and critical ischemia ($p<.001$), but not between rest pain and ischemic ulcer/gangrene ($p=.872$). Figure 4 shows Kaplan–Meier analysis of amputation free survival depending on clinical presentation.

Kaplan–Meier estimate for amputation free survival at 5 years was 73% (SE=.06) in patients with intermittent claudication and 38% (SE=.08) in critical ischemia, 41% (SE=.18) in rest pain and 33% (SE=.01) in ulcer/gangrene. Log rank test shows a significant difference between intermittent claudication and critical ischemia ($p<.001$), but no significant difference between rest pain and ischemic ulcer/gangrene ($p=.402$). Regarding the different treatment groups, there is no significant difference ($p=.109$) for any indication.

Discussion

The number of hybrid operations has increased considerably in recent years with a trend toward simultaneous treatment and toward treatment of more complex lesions.^{1–3} At our institution, the number of simultaneous hybrid operations has increased to several cases per month, constituting 29 of

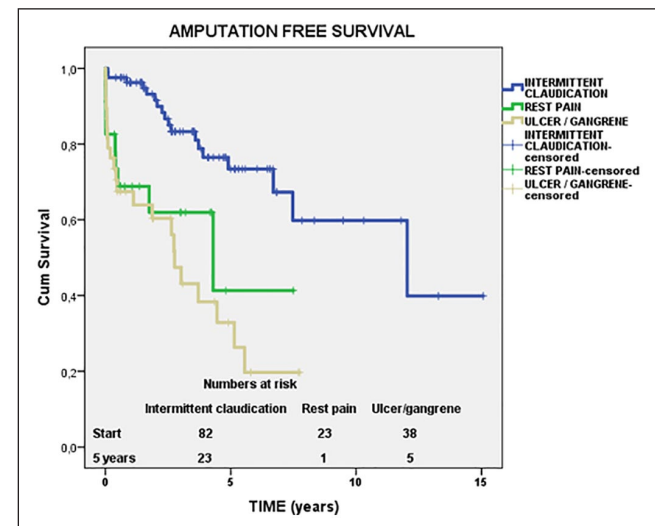


Figure 4. Amputation free survival after hybrid operation depending on indication.

342 (8.5%) of the reconstructions for limb ischemia in 2013.¹⁷ This is still lower than reported from other centers,^{1,4} but the trend is obviously the same.

Long-term follow-up in our study shows good efficiency and durability, both in intermittent claudication and rest pain. In most cases, hybrid reconstructions work well, without the need for secondary intervention. In total, 84% of the patients with intermittent claudication described improvement at the end of the study, and limb salvage was achieved in 71% of the patients with critical ischemia. Patients with rest pain had significantly better limb salvage than patients with ischemic ulcer or gangrene. This probably reflects the more advanced disease, and is in accordance with the results of Piazza et al.³ who found that tissue loss was a negative predictor for patency in hybrid repair for aortoiliacal and common femoral disease.

Limb salvage for the patient group with critical ischemia is comparable to other published results.^{1,18} The poorer results for patients with ischemic ulcer or gangrene may support a strategy with simultaneous bypass surgery, as proposed by Malgor et al.¹⁹ However, this increases operation time, and the perioperative mortality in patients with ulcer or gangrene is significant, which again favors an endovascular strategy for the SFA or a sequential approach that minimizes simultaneous surgical trauma. One can also speculate if primary amputation would have been beneficial in some patients, but this approach has a significant morbidity and mortality risk as well.^{20,21}

Only 9 of 95 cases with intermittent claudication, and 2 of 28 (7%) cases with rest pain needed additional treatment after 30 days in the study period. The corresponding figure for cases with ischemic ulcer or gangrene was 8/41 (20%). There was a significant difference regarding the need for reintervention between this group and patients with

intermittent claudication, but no significant difference between patients with rest pain and patients with intermittent claudication. This may again reflect the more advanced disease in patients with ulcer or gangrene, but subgroup analysis in a small sample mandates cautious interpretation. In critical ischemia, the need for secondary intervention was significantly lower in iliac intervention than in femoropopliteal intervention or the combination of both, which is in accordance with previously reported results.^{2,22}

In eight cases in this study, limb salvage was not achieved, despite open reconstruction. This sometimes occurs in the treatment of critical ischemia with tissue loss, and has been described after infrainguinal bypass as well. Simons et al.²³ report a rate of 10% of the patients in critical ischemia without improvement despite patent bypass, and an amputation rate of 2.7%, which is lower than our figures; however, follow-up in their study was only short term.

Two of the claudication patients had progression to critical ischemia, leading to amputation in spite of a patent reconstruction after reintervention and bypass surgery, which is comparable to results reported by Balaz et al.,² and in accordance with previous studies of the natural history in intermittent claudication, where a certain, yet small proportion of patients develops critical ischemia.²⁴ In our opinion, this does not indicate inferiority of the method or the treatment algorithm used, but rather reflects the natural history of the disease.

There is a significant difference between patients with intermittent claudication and patients with critical ischemia, regarding overall survival and amputation free survival, which was both expected and well known.^{2,3} The Kaplan–Meier estimate for amputation free survival at 5 years in rest pain was confoundingly longer than the estimate for survival, which was due to censoring of those who were amputated.

Another interesting observation is that patients with rest pain had a reintervention rate and amputation rate similar to patients with intermittent claudication, while overall survival was similar to patients with ischemic ulcer or gangrene. This may reflect that patients with rest pain have less severe disease regarding limb ischemia, but equally severe cardiovascular comorbidity, which is the main cause of death. Our findings are opposition to older results of Bertele et al.,^{25,26} who found better survival in patients with rest pain, compared to patients with ulcer or gangrene, but given the small sample size of this study this may as well represent a type 2 error.

A large subgroup of the patients in our study had previous vascular surgery or previous percutaneous transluminal angioplasty (PTA), but we did not find a significant effect on limb salvage in any of the clinical groups, which again may be due to the small sample size and represent a type 2 error. However, previous vascular surgery probably has positive and negative effects on outcomes, the positive being correction of impaired flow in other segments of the actual limb, the negative being scar tissue, making the approach to the

vessel more technically demanding and increasing the risk of damage to adjacent structures.

We have not assessed operation time, but our approach, where both vascular surgeons and interventional radiologists are involved, is obviously resource demanding. However, the multilevel disease necessitates simultaneous treatment of the actual lesions, in order to obtain both inflow and run-off. Ebaugh et al.⁹ have shown that performing simultaneous hybrids reduces costs, compared to staged hybrid treatment, which also favors a simultaneous approach in situations where a staged hybrid solution is technically possible. Performance of the entire procedure by vascular surgeons, as reported in a recent publication,⁴ certainly has the potential to optimize resource utilization.

The major weakness of the current study is the retrospective design without formal control after 1-year follow-up. Later assessment of patency was only performed when clinically indicated, that is, in patients with recurrent symptoms or clinical signs of critical ischemia. This precludes patency analysis and investigation of consequences of the loss of primary patency. Regarding the clinical results, a prospective trial would have the potential to stratify results more precise than the retrospective analysis permitted.

Conclusion

Femoral TEA combined with proximal or distal endovascular intervention has good and durable results in patients with intermittent claudication and rest pain. In most cases, a single procedure is sufficient. In critical ischemia, limb salvage is often achieved. Results are worse in patients with ulcer or gangrene. Patients with rest pain have a limb salvage rate similar to patients with intermittent claudication, but overall survival similar to patients with ulcer or gangrene.

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Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

This study was approved by the regional ethical committee of mid-Norway (REK midt 2013/90).

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Informed consent

Informed consent was not sought for the present study. The regional ethical committee did not require informed consent for the study, because it was outcome analysis only without any influence on the treatment given.

Trial registration

The current study was not a clinical trial, but outcome analysis only, without any influence on the treatment given. Therefore, registration as a clinical trial was not applicable.

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References

- Dosluoglu HH, Lall P, Cherr GS, et al. Role of simple and complex hybrid revascularization procedures for symptomatic lower extremity occlusive disease. *J Vasc Surg* 2010; 51(6): 1425–1435.
- Balaz P, Rokosny S, Wohlfahrt P, et al. Early and late outcomes of hybrid endovascular and open repair procedures in patients with peripheral arterial disease. *Vasa* 2013; 42(4): 292–300.
- Piazza M, Ricotta JJ II, Bower TC, et al. Iliac artery stenting combined with open femoral endarterectomy is as effective as open surgical reconstruction for severe iliac and common femoral occlusive disease. *J Vasc Surg* 2011; 54(2): 402–411.
- Aho PS and Venermo M. Hybrid procedures as a novel technique in the treatment of critical limb ischemia. *Scand J Surg* 2012; 101(2): 107–113.
- Joh JH, Joo SH and Park HC. Simultaneous hybrid revascularization for symptomatic lower extremity arterial occlusive disease. *Exp Ther Med* 2014; 7(4): 804–810.
- Matsagkas M, Kouvelos G, Arnaoutoglou E, et al. Hybrid procedures for patients with critical limb ischemia and severe common femoral artery atherosclerosis. *Ann Vasc Surg* 2011; 25(8): 1063–1069.
- Florenes T, Sandback G, Strandén E, et al. Surgical treatment of atherosclerosis in the lower limbs. *Tidsskr Nor Laegeforen* 2009; 129(21): 2252–2255.
- Nelson PR, Powell RJ, Schermerhorn ML, et al. Early results of external iliac artery stenting combined with common femoral artery endarterectomy. *J Vasc Surg* 2002; 35(6): 1107–1113.
- Ebaugh JL, Gagnon D, Owens CD, et al. Comparison of costs of staged versus simultaneous lower extremity arterial hybrid procedures. *Am J Surg* 2008; 196(5): 634–640.
- Kashyap VS, Pavkov ML, Bena JF, et al. The management of severe aortoiliac occlusive disease: endovascular therapy rivals open reconstruction. *J Vasc Surg* 2008; 48(6): 1451–1457.
- Reed AB. Endovascular as an open adjunct: use of hybrid endovascular treatment in the SFA. *Semin Vasc Surg* 2008; 21(4): 200–203.
- Dosluoglu HH, Harris LM and Cherr GS. Recanalization of concomitant iliac artery and common femoral artery occlusions using an antegrade hybrid (open/endovascular) approach. *Vasc Endovascular Surg* 2007; 41(2): 130–134.
- Qeral LA, Criado FJ and Patten P. Retrograde iliofemoral endarterectomy facilitated by balloon angioplasty. *J Vasc Surg* 1995; 22(6): 742–748; discussion 748–750.
- Chang RW, Goodney PP, Baek JH, et al. Long-term results of combined common femoral endarterectomy and iliac stenting/stent grafting for occlusive disease. *J Vasc Surg* 2008; 48(2): 362–367.
- Norwegian registry for vascular surgery, <http://www.stolav.no/norkar>
- Rutherford RB, Baker JD, Ernst C, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. *J Vasc Surg* 1997; 26(3): 517–538.
- Altreuther MBC, Halbakken E, Kjørstad KE, et al. *NORKAR Årsrapport*. Trondheim: St. Olav's Hospital, 2013.
- Fu X, Zhang Z, Liang K, et al. Angioplasty versus bypass surgery in patients with critical limb ischemia—a meta-analysis. *Int J Clin Exp Med* 2015; 8(7): 10595–10602.
- Malgor RD, Ricotta JJ 2nd, Bower TC, et al. Common femoral artery endarterectomy for lower-extremity ischemia: evaluating the need for additional distal limb revascularization. *Ann Vasc Surg* 2012; 26(7): 946–956.
- Jones WS, Patel MR, Dai D, et al. High mortality risks after major lower extremity amputation in Medicare patients with peripheral artery disease. *Am Heart J* 2013; 165(5): 809–15815.
- Swaminathan A, Vemulapalli S, Patel MR, et al. Lower extremity amputation in peripheral artery disease: improving patient outcomes. *Vasc Health Risk Manag* 2014; 10: 417–424.
- Antoniou GA, Sfyroeras GS, Karathanos C, et al. Hybrid endovascular and open treatment of severe multilevel lower extremity arterial disease. *Eur J Vasc Endovasc Surg* 2009; 38(5): 616–622.
- Simons JP, Goodney PP, Nolan BW, et al. Failure to achieve clinical improvement despite graft patency in patients undergoing infrainguinal lower extremity bypass for critical limb ischemia. *J Vasc Surg* 2010; 51(6): 1419–1424.
- Muluk SC, Muluk VS, Kelley ME, et al. Outcome events in patients with claudication: a 15-year study in 2777 patients. *J Vasc Surg* 2001; 33(2): 251–257; discussion 257–258.
- Bertele V, Roncaglioni MC, Pangrazzi J, et al. Clinical outcome and its predictors in 1560 patients with critical leg ischaemia. Chronic Critical Leg Ischaemia Group. *Eur J Vasc Endovasc Surg* 1999; 18(5): 401–410.
- Long-term mortality and its predictors in patients with critical leg ischaemia. The I.C.A.I. Group (Gruppo di Studio dell'Ischemia Cronica Critica degli Arti Inferiori). The Study Group of Critical Chronic Ischemia of the Lower Extremities. *Eur J Vasc Endovasc Surg* 1997; 14(2): 91–95.