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Differential Impact of Bypass Surgery and Angioplasty on Angiosome-Targeted Infrapopliteal Revascularization

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WHAT THIS PAPER ADDS
For the first time, the impact of angiosome-targeted revascularization has been studied in terms of wound healing and limb salvage. Unlike previous studies, the results of percutaneous transluminal angioplasty and bypass surgery were compared according to the angiosome concept. Differences in outcomes after bypass surgery and PTA were adjusted by estimating a propensity score, which was employed for one to one matching as well as adjusted analysis.

Objective: The aim of this study was to evaluate the impact of angiosome targeted revascularization according to the revascularization method.
Design: Retrospective observational study.
Materials and methods: This study cohort comprised 744 consecutive patients who underwent infrapopliteal endovascular or surgical revascularization between January 2010 and July 2013. Differences in outcomes after bypass surgery and PTA were adjusted by estimating a propensity score, which was employed for one to one matching as well as adjusted analysis.
Results: Cox proportional hazards analysis showed that angiosome-targeted revascularization (HR 1.29, 95% CI 1.02—1.65), bypass surgery (HR 1.79, 95% CI 1.41—2.27), C-reactive protein $\leq$10 mg/dL (HR 1.42, 95% CI 1.11—1.81), and the number of affected angiosomes (HR 0.85, 95% CI 0.74—0.98) were independent predictors of improved wound healing. When adjusted for the number of affected angiosomes and C-reactive protein $\leq$10 mg/dL, angiosome-targeted bypass surgery was associated with a significantly higher rate of wound healing than non-angiosome-targeted angioplasty (HR 2.27, 95% CI 1.61—3.20). This was confirmed in propensity score adjusted analysis (HR 1.72, 95% CI 1.35—2.16). Among patients who underwent angiosome-targeted revascularization, the propensity score adjusted analysis showed that bypass surgery was associated with a significantly better rate of wound healing (HR 154, 95% CI 1.09—2.16) but similar limb salvage rates when compared with angioplasty (HR 0.79, 95% CI 0.44—1.43).
Conclusion: Rates of wound healing and limb salvage in patients with critical limb ischemia (CLI) were significantly better after angiosome-targeted revascularization, bypass surgery achieving significantly better wound healing than angioplasty.

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INTRODUCTION

The angiosome concept, which has been successfully used in plastic surgery for years, has recently been the topic of lively discussion in the field of vascular and endovascular surgery. In 2006, Attinger et al. described six angiosomal regions in the foot and ankle, each supplied by one of the crural arteries and its terminal branches.[1,2] Based on this knowledge, several consecutive studies have been carried out applying the angiosome concept to the treatment of critical limb ischaemia (CLI) with tissue lesions.[3—17] Most of the studies have compared so called targeted versus non-targeted revascularization in patients who have undergone endovascular revascularization. Targeted revascularization is defined as a percutaneous transluminal angioplasty which achieves recanalization from the abdominal aorta to the angiosomal artery.[6] Two recent meta-analyses of angiosome-targeted versus non-targeted revascularization showed better results in terms of wound healing and limb salvage for angiosome-targeted revascularization procedures.[18,19] The main benefits of angiosome-targeted revascularization have been observed in patients with

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diabetes and renal failure.[10,20,21] The very few studies applying the angiosome concept in open surgical treatment of CLI suggested that better wound healing is dependent on the quality of the pedal arch rather than angiosome-guided revascularization.[11,17] No comparative analysis of surgical versus endovascular angiosome-targeted and non-angiosome-targeted revascularization of patients with CLI and tissue loss(/lesions) has been performed so far, thus this issue was investigated in the present study.

MATERIAL AND METHODS

The vascular surgical center in this study is the only provider of treatment of CLI in a population of 1.3 million inhabitants, with an annual number of about 1,000 revascularization procedures for CLI. About one third of the patients are treated on an emergency basis, and 60–70% of the patients are first referred to the outpatient clinic for evaluation and treatment of their CLI. The center has an active policy for the treatment of CLI, whereby a patient is declined for revascularization only if she/he is not mobile, has progressive dementia, extremely short life-expectancy, or no possibilities for revascularization. All patients undergo magnetic resonance imaging (MRI) angiography if not contraindicated, with the method for revascularization chosen on the basis of the results. Usual practice for revascularization is endovascular first, but in cases with extensive atherosclerosis and long occlusions, bypass is preferred as a first line treatment. Difficult cases are discussed in a daily meeting of vascular surgeons and interventional radiologists. A rough threshold for CLI is toe pressure $\leq$30 mmHg in patients without diabetes and $\leq$50 mmHg in diabetic patients, but in cases in whom there is an evident arterial stenosis and non-healing wound, intervention can be done at higher threshold pressure values. The operative techniques offered have been described in detail in previously published articles.[6,22,23]

This is a retrospective study including 744 consecutive patients with CLI and tissue loss (Fontaine IV), who underwent infrapopliteal endovascular or surgical revascularization between January 2010 and July 2013. The study plan was accepted by the ethical committee of the Helsinki University Central Hospital.

Data collection was performed using a prospectively collected database and scrutinized retrospectively by reviewing patient records as well as patients' angiograms. In patients who underwent endovascular treatment, the angiograms were reviewed before and after the revascularization to evaluate whether the procedure had been angiosome-targeted or not. In patients undergoing surgical bypass, the pre-operative MRI angiograms and digital subtraction angiograms, if available, were reviewed as well.

The patients' baseline characteristics and operative data are summarized in Table 1.

Glomerular filtration rate (eGFR) was estimated by the Modification of Diet in Renal Disease (MDRD) formula.[31] Angiosome-targeted revascularization was defined as any angioplasty or bypass surgery procedure of the source artery perfusing the affected area, therefore aiming to create direct flow from the abdominal aorta into the angiosomal source artery.[5,6]

Wound healing and limb salvage were the main outcome endpoints of the study. Survival and amputation free survival were secondary endpoints.

Statistical analysis

Statistical analysis was performed using SPSS statistical software (SPSS v. 22.0, SPSS Inc., Chicago, IL, USA). Continuous variables are reported as mean and standard deviation. Nominal variables are reported as absolute number and percentage. Pearson's chi-square test, Fisher's exact test, and the Mann–Whitney test were used for univariate analysis. Long-term outcome was assessed by Kaplan–Meier's method with the log-rank test and the Cox proportional hazards method.

Differences between study groups were adjusted by estimating a propensity score. The propensity score was calculated by non-parsimonious logistic regression. Hosmer-Lemeshow's test was used to assess the regression model fit. Receiver operating characteristic (ROC) curve analysis was used to estimate the area under the curve of the model predicting the probability of being included in the groups of patients with and without angiosome-targeted infrapopliteal revascularization. The calculated propensity score was employed for one to one matching, as well as to adjust for other variables in estimating their impact on the post-operative outcome. One to one propensity score matching between study groups was performed according to a caliper width equal to 0.2 times the standard deviation of the calculated propensity score's logit. Outcome in the propensity matched pairs was evaluated by Kaplan–Meier's methods as well as the Cox regression method. A $p < .050$ was considered statistically significant.

RESULTS

Wound healing

Univariate analysis showed that C-reactive protein $\leq$10 mg/dL ($p = .002$), bypass surgery as opposed to angioplasty ($p < .0001$), crural as opposed to pedal revascularization ($p = .001$), and a low number of affected angiosomes ($p < .0001$) were associated with improved foot wound healing. Angiosome-targeted revascularization was associated with a trend towards better wound healing ($p = .071$, Table 2). The Cox proportional hazards analysis revealed that angiosome-targeted revascularization ($p = .036$, HR 1.294, 95% CI 1.017–1.647), bypass surgery ($p < .0001$, HR 1.791, 95% CI 1.412–2.272), C-reactive protein $\leq$10 mg/dL ($p = .005$, HR 1.416, 95% CI 1.110–1.806), and the fewer angiosomes affected ($p = .024$, HR 0.854, 95% CI 0.744–0.979) improved wound healing. Actuarial analysis demonstrated the positive impact of angiosome-targeted bypass surgery on wound healing compared with angiosome-targeted angioplasty (Log-rank: $p < .0001$, Fig. 1). When adjusted for the number of affected angiosomes and C-

Table 1. Baseline characteristics and operative data on patients who underwent angiosome-targeted or non-angiosome-targeted infrainguinal revascularization for critical limb ischaemia.

Patients characteristics	Overall series Non-angiosome targeted 336 pts	Angiosome-targeted 408 pts	*p*	Propensity matched pairs Non-angiosome-targeted 252 pts	Angiosome-targeted 252 pts	*p*
Age, years	75.5 ± 11.2	73.6 ± 11.2	0.039	74.6 ± 11.2	74.8 ± 10.7	0.964
Age ≥80 years	142 (42.3)	153 (37.5)	0.186	99 (39.3)	107 (42.5)	0.469
Female sex	124 (36.9)	152 (37.3)	0.922	97 (38.5)	95 (37.7)	0.854
Smoking	48 (14.3)	60 (14.7)	0.871	37 (14.7)	35 (13.9)	0.799
Diabetes	201 (59.8)	258 (63.2)	0.340	160 (63.5)	157 (62.3)	0.782
C-reactive protein	46 ± 54	48 ± 54	0.703	47 ± 55	43 ± 51	0.326
Dyslipidaemia	78 (23.2)	116 (28.4)	0.107	65 (25.8)	67 (26.6)	0.839
Glomerular filtration rate (mL/min/1.73 m^2)	75 ± 35	76 ± 38	0.944	76.3 ± 36.8	74.7 ± 36.8	0.477
Chronic kidney disease class			0.109			0.952
3A	53 (15.8)	48 (11.8)		37 (14.7)	40 (15.9)	
3B	33 (9.8)	47 (11.5)		26 (10.3)	31 (12.3)	
4	10 (3.0)	9 (2.2)		6 (2.4)	8 (3.2)	
5	16 (4.8)	34 (8.3)	0.053	15 (6.0)	14 (5.6)	0.848
Dialysis	11 (3.3)	30 (7.4)	0.015	10 (4.0)	11 (4.4)	0.824
Kidney transplantation	6 (1.8)	9 (2.2)	0.685	4 (1.6)	5 (2.0)	1.000
Hypertension	222 (66.1)	248 (60.8)	0.137	163 (64.7)	165 (65.5)	0.852
Atrial fibrillation	106 (31.5)	111 (27.2)	0.195	72 (28.6)	75 (29.8)	0.769
Coronary artery disease	133 (39.6)	135 (33.1)	0.066	96 (38.1)	92 (36.5)	0.713
Heart failure	44 (13.1)	48 (11.8)	0.583	33 (13.1)	32 (12.7)	0.894
Stroke	49 (14.6)	54 (13.2)	0.596	37 (14.7)	39 (15.5)	0.803
Pulmonary disease	42 (812.5)	40 (9.8)	0.243	27 (10.7)	26 (10.3)	0.885
Foot gangrene	73 (21.7)	135 (33.1)	<0.0001	67 (26.6)	63 (25.0)	0.684
No. of affected angiosomes	2.2 ± 1.0	2.2 ± 0.7	0.723	2.2 ± 1.1	2.2 ± 0.7	0.768
Level of revascularization			<0.0001			1.000
Crural	320 (95.2)	346 (84.8)		237 (94.0)	237 (94.0)	
Pedal	16 (4.8)	62 (15.2)		15 (6.0)	15 (6.0)	
Type of revascularization			0.106			0.848
Endovascular revascularization	237 (70.5)	265 (65.0)		173 (68.7)	171 (67.9)	
Surgical revascularization	99 (29.5)	143 (35.0)		79 (31.3)	81 (32.1)	
Type of bypass graft			0.655			0.828
Single saphenous vein graft	52 (52.5)	84 (58.7)		43 (54.4)	50 (61.7)	
Other vein grafts	41 (41.4)	48 (33.6)		32 (40.5)	26 (32.1)	
Composite vein plus prosthesis graft	4 (4.0)	7 (4.9)		3 (3.8)	3 (3.7)	
Prosthesis graft	2 (2.0)	4 (2.8)		1 (1.3)	2 (2.5)	

Data are reported for the overall population and propensity score matched pairs.

reactive protein ≤10 mg/dL, angiosome-targeted bypass surgery was associated with a significantly higher rate of wound healing than non-angiosome-targeted angioplasty ($p < .001$, HR 2.265, 95% CI 1.605–3.196) (Fig. 2). Interestingly, non-angiosome-targeted bypass surgery also achieved better wound healing rates than angioplasty independently of the angiosome oriented strategy ($p = .001$, HR 1.890, 95% CI 1.292–2.766) (Figs. 1 and 2).

Limb salvage

Univariate analysis showed that C-reactive protein >10 mg/dL ($p < .0001$), CKD class 5 ($p = .005$), diabetes ($p = .020$), atrial fibrillation ($p = .030$), and an increasing number of affected angiosomes ($p < .0001$) were associated with decreased limb salvage rates. Angiosome-targeted revascularization was associated with a trend towards improved limb salvage ($p = .065$, Table 2). The Cox proportional hazards analysis demonstrated that an increasing number of affected angiosomes ($p < .0001$, HR 1.439, 95% CI 1.206–1.717), atrial fibrillation ($p = .028$, HR 1.499, 95% CI 1.046–2.149), C-reactive protein >10 mg/dL ($p = .002$, HR 1.952, 95% CI 1.271–2.997), CKD class 5 ($p = .002$, HR 2.285, 95% CI 1.354–3.856), and non-angiosome-targeted revascularization ($p = .014$, HR 1.531, 95% CI 1.088–2.154) were independent predictors of major amputation. When included in this regression model, non-angiosome-targeted angioplasty was associated with the highest risk of major amputation compared with non-angiosome-targeted bypass surgery ($p = .049$, HR 0.569, 95% CI 0.325–0.997), angiosome-targeted bypass surgery ($p = .033$, HR 0.589, 95% CI 0.362–0.958), and angiosome-targeted angioplasty ($p = .005$, HR 0.556, 95% CI 0.371–0.834).

Table 2. Outcome of patients who underwent angiosome-targeted or non-angiosome-targeted infrainguinal revascularization for critical limb ischaemia.

Outcome endpoint	Overall series Non-angiosome-targeted 336 pts	Angiosome-targeted 408 pts	*p*	Propensity matched pairs Non-angiosome-targeted 252 pts	Angiosome-targeted 252 pts	*p*
Wound healing			0.071			0.058
30-day	1.1%	2.3%		1.5%	2.8%	
6-month	37.8%	47.0%		36.9%	41.1%	
1-year	69.2%	72.1%		67.3%	71.6%	
Survival			0.364			0.741
30-day	96.1%	96.6%		96.0%	95.6%	
1-year	77.1%	78.5%		77.0%	76.0%	
2-year	66.8%	69.8%		65.0%	65.2%	
3-year	54.0%	57.2%		54.2%	51.1%	
4-year	47.6%	50.6%		46.7%	39.0%	
Limb salvage			0.065			0.019
30-day	89.1%	92.3%		87.1%	92.0%	
1-year	77.5%	82.7%		74.7%	84.1%	
2-year	74.7%	80.5%		71.5%	82.1%	
3-year	72.0%	78.3%		69.8%	77.7%	
4-year	69.8%	78.3%		69.8%	77.7%	
Amputation free survival			0.064			0.154
30-day	85.7%	89.2%		82.9%	87.7%	
1-year	62.2%	66.5%		59.9%	65.3%	
2-year	51.5%	58.4%		47.9%	55.7%	
3-year	41.4%	47.3%		39.6%	42.8%	
4-year	35.3%	43.8%		33.1%	36.0%	

Data are reported for the overall population and propensity score matched pairs.

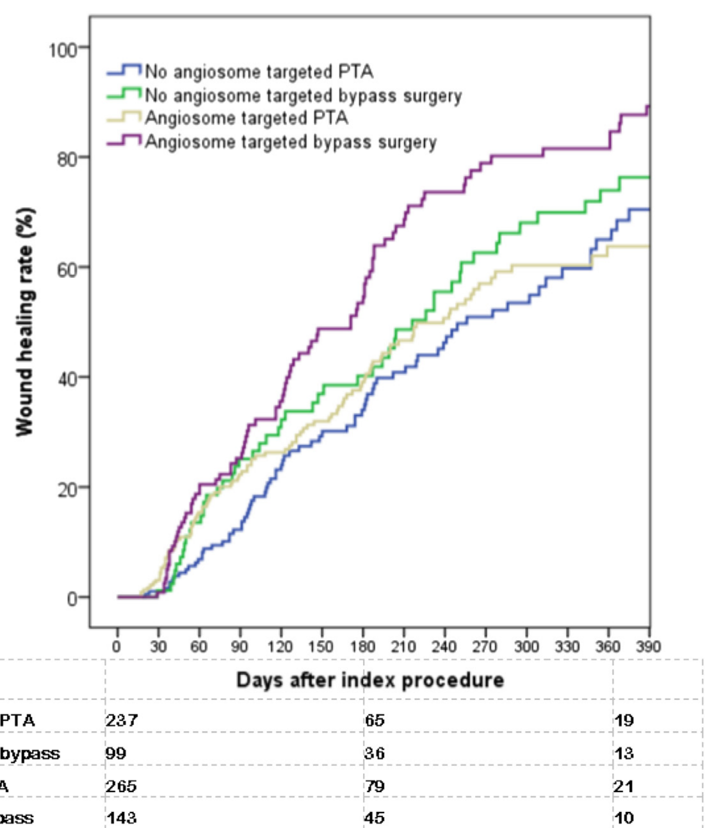

Figure 1. Kaplan–Meier estimates of wound healing according to treatment method and angiosome-targeted revascularization (log-rank: $p < .0001$).

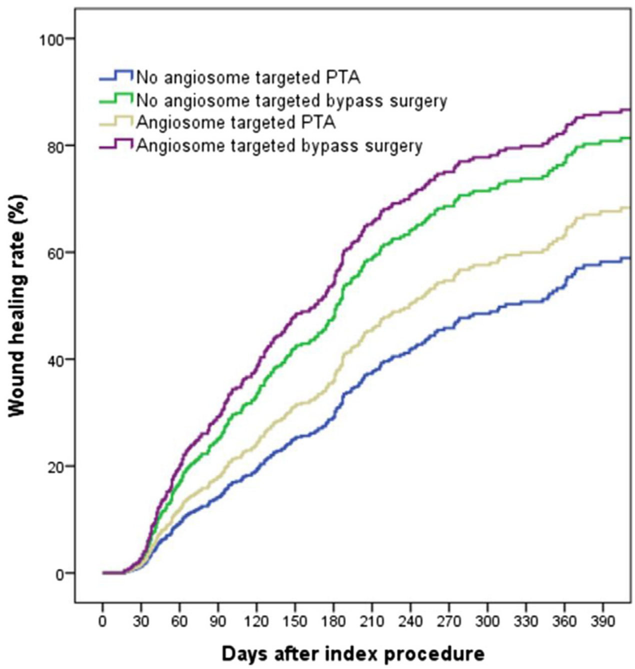

Figure 2. Adjusted Cox proportional hazards estimates of wound healing according to treatment method and angiosome-targeted revascularization ($p < .0001$).

Propensity score analysis

A propensity score for angiosome-targeted or non-angiosome-targeted revascularization strategy was calculated by means of logistic regression (Hosmer-Lemeshow's test: $p = .924$, area under the ROC curve 0.630, 95% CI 0.590–0.670).

Propensity score matching with a caliper width of 0.02 resulted in 252 pairs with similar baseline and operative characteristics (Table 1). Angiosome-targeted revascularization was associated with significantly better limb salvage and a trend towards improved wound healing (Table 2).

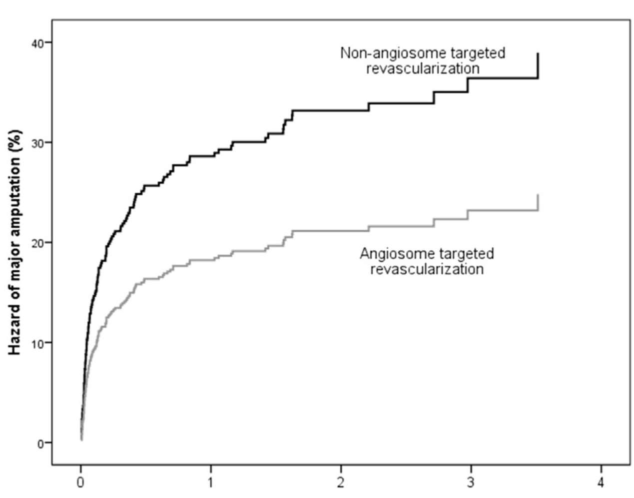

Figure 3. Propensity score adjusted hazard of major amputation according to angiosome-targeted and non-targeted revascularization ($p = .010$, HR 0.637, 95% CI 0.452–0.897).

The propensity score adjusted analysis showed that angiosome-targeted revascularization tended to lead to improved wound healing ($p = .058$, HR 1.275, 95% CI 0.992–1.639). When adjusted for propensity score and treatment method (bypass surgery vs. angioplasty), angiosome-targeted revascularization was associated with a significantly higher wound healing rate ($p = .046$, HR 1.295, 95% CI 1.005–1.668). It is worth noting that, in this regression model, bypass surgery was also an independent predictor of a higher rate of wound healing ($p < .0001$, HR 1.720, 95% CI 1.354–2.185).

Angiosome-targeted revascularization yielded a significantly lower risk of major amputation ($p = .010$, HR 0.637, 95% CI 0.452–0.897, Fig. 3) and better amputation free survival ($p = .037$, HR 0.788, 95% CI 0.630–0.986) in the propensity score adjusted analysis. When treatment strategy, that is bypass surgery versus angioplasty, was included in this regression model, bypass surgery yielded a lower risk of major amputation ($p = .070$, HR 0.703, 95% CI 0.480–1.029). Angiosome-targeted revascularization did not affect patient survival ($p = .601$, HR 1.071, 95% CI 0.828–1.384).

Bypass surgery versus angioplasty in angiosome-targeted revascularization

A propensity score was calculated to estimate the probability of being included in the bypass surgery or angioplasty group among patients who underwent angiosome-targeted revascularization. The obtained propensity score had an area under the ROC curve of 0.774 (95% CI 0.724–0.824) (Hosmer-Lemeshow's test: $p = .378$). Propensity score adjusted analysis showed that bypass surgery was associated with a significantly better rate of wound healing ($p = .014$, HR 1.536, 95% CI 1.091–2.162). However, angioplasty and bypass surgery achieved similar limb salvage rates ($p = .440$, HR 0.791, 95% CI 0.437–1.434).

DISCUSSION

The idea of applying the angiosome concept to the treatment of lower limb ischaemia with tissue lesions seems attractive, and during the last decade, a number of studies have been conducted to evaluate the efficacy of angiosome-targeted revascularization.[3–6,9,10,13,14,16,20,21,24–26] Two recent meta-analyses of the angiosome concept used in treatment of CLI agreed on the considerable potential for angiosome-orientated revascularization,[18,19] as confirmed by the present results. Herein, it is observed that better wound healing is associated with angiosome guided revascularization, low C-reactive protein, and a low number of affected angiosomes. Unlike previous studies,[3–17] endovascular revascularization was compared with surgical revascularization using multivariate analysis as well as by propensity score analysis in a large patient population. Interestingly, better wound healing was observed in open surgical revascularization, independently of the angiosome orientation, rather than in angiosome-targeted or non-targeted angioplasty. Limb salvage was significantly better if angiosome-targeted bypass was achieved, and non-angiosome-targeted angioplasty was associated with the highest risk of major amputation. When a comparison was made between 252 propensity score matched pairs, angiosome-targeted revascularization was associated with a lower amputation rate than non-angiosome-targeted revascularization.

It is clear that the patients who undergo angiosome-targeted revascularization as opposed to non-targeted revascularization are different regarding age, comorbidities, and maybe also the severity of peripheral arterial disease.[27] Many patients are too fragile for open surgery and the only option is endovascular revascularization. Furthermore, in a large proportion of patients, the anatomy of revascularization cannot be chosen as there may be only one crural vessel left and the wound affects several angiosomal regions.[28] Therefore, the number of patients in whom there is a real possibility to choose between angiosome-targeted and non-angiosome-targeted revascularization or between PTA and open bypass is limited. This study demonstrates the benefit of mastering both revascularization methods. The endovascular first strategy is good when there is a possibility of achieving angiosome-targeted revascularization. If not, however, the best option seems to be bypass surgery, regardless of the angiosomal orientation.

When choosing between surgical and endovascular revascularization, the completely different levels of invasiveness of the procedures must also be kept in mind. In light of the arrested inflow to the periphery and blood loss as a result of open surgery,[29] endovascular procedures are not just less invasive to the patient, but they also entail a lower risk of post-operative infection arising from the surgical wound as well as shorter hospitalization time.[30] Currently, the policy for clinical practice at the institution in this study is an endovascular first strategy whenever the pre-operative MR angiogram shows a sufficient probability of success. However, in cases in whom a high risk of failure is expected after endovascular revascularization, mostly patients with long arterial occlusions, open surgery is chosen first. The same decision is made if endovascular treatment fails repeatedly. The majority of patients with CLI and a tissue lesion are elderly women with diabetes mellitus and its complications.[27] In such cases, as non invasive an intervention as possible is recommended. But would “younger” patients with non-healing ulcers not benefit more from open surgery than angioplasty? The other important factors to be considered when planning the treatment are the number of affected angiosomes and C-reactive protein level. According to the findings of this study, in patients with several affected angiosomes and elevated C-reactive protein, if angiosome-targeted angioplasty is not possible, it seems to be significantly better to perform angiosome-targeted bypass as a first line treatment and skip non-targeted angioplasty.

This study provides evidence that angiosome-targeted revascularization results in higher wound healing and limb salvage rates than non-targeted revascularization.[3–7,9] To evaluate the differences between surgical and endovascular revascularization, a subanalysis was performed among patients who underwent angiosome-targeted revascularization. In this comparison, bypass surgery was associated with a better wound healing rate than endovascular revascularization, but the limb salvage rates were similar. This comparison included a limited number of patients and the results can be seen only as preliminary.

The possible reasons behind the differences between the surgical and endovascular groups can only be speculated upon. Most probably the patients in the surgery group had more extensive arterial occlusive disease, and thus they should not have better runoff and more limited tissue loss than patients in the endovascular group. After bypass, an arterial line with good diameter to perfuse the distal part of the lower limb is achieved. After angioplasty, the size of the arterial line is smaller and it is hypothesized that the pressure impact may be smaller even after a targeted PTA where an open line to the wound angiosome is achieved compared with the bypass. The poor outcome after non-targeted bypass is easier to understand: in these cases the distal arterial tree is probably very diseased and allows only limited revascularization, whereas in cases of non-angiosome targeted bypass, again, the pressure change is more dramatic compared with angioplasty.

A number of limitations may affect the results of this study. It is retrospective and, even though the data have been drawn from a prospectively collected database, determination of the affected angiosome can be difficult in some cases. Photographs were included in the case histories of many of the patients, and were found helpful in this regard. Moreover, in some cases, the evaluation of angiograms may be problematic because of poor image quality as regards limitations in the examined region. Furthermore, the definition of targeted revascularization in cases where the ulcer spans several angiosomes is unclear. In this study, the strategy was considered as targeted revascularization if direct flow was achieved to at least one of the angiosomal arteries. Furthermore, it was not possible to include ABI and toe pressures in the propensity score analysis. This was because ABI was available in only 440 patients and toe pressure in 516 patients. However, in comparison, there was no significant difference between ABI in the targeted and non-targeted groups (ABI 0.50 and 0.60 respectively, $p = .1$). Toe pressures were higher in the targeted group compared with the non-targeted group (36 mmHg and 32 mmHg, $p = .04$). The surgical group had significantly lower ABI and toe pressures than the endovascular group (ABI 0.37 vs. 0.67, $p < .001$; and 28 mmHg and 36 mmHg, respectively, $p < .01$). However, the analysis of these parameters does not weaken the results, on the contrary they strengthen the findings of different outcomes after surgical and endovascular revascularization. On the other hand, a strength of this study is the comprehensive follow up in the majority of the patients and reliable data on amputations and deaths. Furthermore, the number of patients included is high, allowing for a strong propensity score analysis and a high number of pairs matched by the propensity score.

In conclusion, rates of wound healing and limb salvage in patients with CLI were significantly better after angiosome-targeted revascularization. Bypass surgery seems to achieve significantly better wound healing than angioplasty.

CONFLICT OF INTEREST

None.

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