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J. Serna Santos, M.D., S. Laukontaus, M.D. PhD, M. Laine, M.D. PhD, P. Valledor Pellicer, Comput. Sci. PhD, A. Sonetto, M.D. PhD, M. Venermo, M.D. PhD, Prof., P. Aho, M.D. PhD, Ass. Prof.

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Hybrid revascularization for extensive iliofemoral occlusive disease

Serna Santos J[1] M.D., Laukontaus S[1] M.D. PhD, Laine M[1] M.D. PhD, Valledor Pellicer P[2] Comput. Sci. PhD, Sonetto A[3] M.D. PhD, Venermo M[1*] M.D. PhD Prof., Aho P[1*] M.D. PhD Ass. Prof.

[1]Department of Vascular Surgery, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

[2] PragmaTech AI Solutions, Asturias, Spain

[3] Department of Vascular Surgery, Vascular Surgery, Policlinico Sant'Orsola-Malpighi, Bologna, Italy

*Equal Contribution

ABSTRACT

Introduction: Total occlusion of the iliac-femoral tract can cause a variety of life limiting symptoms ranging from mild claudication to chronic limb-threatening ischemia (CLTI). Efforts should be made to revascularize the symptomatic ischemic limb. Currently there are different options in the vascular surgeon's armamentarium to achieve this. The aim of the study was to verify the feasibility and outcomes of inflow hybrid revascularizations combining femoral endarterectomy and recanalization of iliac atherosclerotic occlusion.

Methods: A retrospective review was conducted of all hybrid revascularizations involving femoral endarterectomy and endovascular treatment of iliac occlusion. The operations were performed in Helsinki University Hospital between 1/2013-12/2018. Firstly, information about patients' baseline characteristics, indications and details of surgery as well as technical/hemodynamic success, complications and mortality was obtained from the vascular registry and patients records. Secondarily, prospective assessment of mid-term patency was performed through follow-up (FU) in 11/2019. Immediate technical success, 30-day mortality, complications and patency were considered major outcomes. Hemodynamic improvement, amputation rate and overall mortality were also assessed.

Results: 163 ilio-femoral occlussions were performed on 147 patients during the period studied. Six patients (3.6%) had infrarenal aortic occlusion, 86 (52.7%) had common iliac and 128 (78.5%) external iliac artery occlusion. Technical success rate was 88.3% (n=144 occlusions recanalized). Primary technical success was somewhat lower in lesions $\geq$90 mm (87.1%) compared to lesions shorter than 90 mm (95.7%; χ^2 p=0.06). Iliac stent was deployed in 141 (94.6%) cases; 51 (34.3%) of which were covered stents. Significant residual stenosis remained in 1.2% of cases. Median operative time was 4 h 34 min (IQR 2h 43min), median estimated blood loss was 743ml (IQR 500ml). Five patients (3.0%) developed a deep groin infection and 12 (8.1%) suffered any major cardiovascular event or stroke perioperatively. Primary patency at 30 day, 6 months, 1 and 2 years was 98.7%, 98.1%, 96.6% and

93.7%, respectively. Hemodynamic success was documented in 107 patients (73%). By the end of the FU 7 iliofemoral tracts (11.1%) re-occluded, 2 limbs (1.2%) required amputation and 50 patients (3.0%) died.

Conclusions: Good immediate success rate and mid-term patency can be achieved by hybrid revascularization of ilio-femoral occlusions. Careful patient selection is mandatory since this population often suffers from universal atherosclerosis. The involvement of the aorta represents a significant determinant of worse long-term patency though it did not preclude technical success.

INTRODUCTION

Total occlusion of the iliofemoral arteries due to peripheral arterial disease (PAD) can cause a variety of life-limiting symptoms ranging from mild claudication to chronic limb-threatening ischemia (CLTI). Earlier the standard revascularization method was aorto-bifemoral bypass (ABFB), but nowadays endovascular techniques have replaced open surgery, and in many centers the majority of the patients are treated with recanalization, percutaneous transluminal angioplasty (PTA) and stenting of the occluded segments. Classically occlusions affecting the common femoral artery (CFA) were considered not suitable for a purely endovascular approach due anatomical challenges, stenting of this area has high risk of in-stent restenosis or secondary thrombosis of the deep femoral artery. (1,2) Recent reports on endovascular treatment are optimistic, however when it comes to thrombosis of the femoral bifurcation, open approach is in most vascular centers the rule since it provides longer patency(3,4). Hybrid procedures combining simultaneous femoral endarterectomy and endovascular recanalization of the occluded iliac arteries offer an alternative approach. The potential benefits of this intervention compared to ABFB are related to the minimal dissection and surgical trauma, less complications, length of hospital stay and quicker recovery after surgery.(5)

Traditional ABFB is a dependable option with a heavy body of evidence supporting its long-term patency and low rates of perioperative complications. (6–8) However, ABFB requires the patient to be fit enough to undergo a laparotomy. Extra-anatomical reconstruction in the form of femoro-femoral cross-over bypass or axillofemoral by-pass is an option for frail patients but is associated with lower patency rates and risk of graft infection in patients with CLTI and gangrene or tissue lesions. (9–12)

During recent years, preliminary reports on the hybrid approach have been promising. (13–16) European Guidelines on Peripheral Artery Diseases published in 2017 support hybrid approach

in iliofemoral lesions. (17) These reports are mostly based on TASC II classification focusing on C or D types thus reporting results on a variety of lesions including stenoses and usually few occlusions. Moreover, some reports define patency in terms of lack of re-intervention without adequate surveillance. (13) Because stenosis and occlusion might represent a different level of technical difficulty and long-term patency, it is important to analyze them independently in order to draw adequate conclusions and to be able to compare the results with ABFB.

We aimed to study the technical success and mid-term results in patients with total occlusion in the iliofemoral arteries treated with hybrid approach combining femoral endarterectomy and endovascular treatment of iliac occlusion.

METHODS

Data collection

Using the local vascular registry (HUSVASC) we identified all patients who underwent a hybrid procedure including femoral endarterectomy and endovascular treatment of the common or external iliac artery between 2013 and 2018. We selected only patients with occlusion in the iliac artery based on preoperative magnetic resonance angiography (MRA) or computer tomography angiography (CTA) scans. Baseline characteristics, The American Society of Anesthesiologists (ASA) score, Rutherford classification at the baseline and details on operative/perioperative treatment were acquired from the electronic patient records. Baseline characteristics included hypertension, smoking status, diabetes mellitus (DM), coronary artery disease (CAD), chronic kidney disease (CKD), chronic occlusive pulmonary disease (COPD) and cerebrovascular disease (CVD, history of TIA or stroke) as well as use of statin medication. ICD-10 codes, HUSVASC-registry, patient records were utilized in the data collection process.

Our primary outcome measures were:

1) Immediate technical (i.e. successful recanalization of the occlusion without significant (>30%) residual stenosis in the final angiogram)

2) 30-day mortality

3) Incidence of 30-day major complications: aortic dissection, AMI (troponin elevations and electrocardiography changes consistent with myocardial infarction), stroke (acute stroke in brain CT scan), renal complication (acute kidney injury needing dialysis), respiratory complication (pneumonia, acute respiratory insufficiency), bleeding or occlusion (leading to reoperations), and deep surgical site infection (only infetions involving the femoral vessels and needing debriding and coverage with sartorius muscle flap).

4) Patency during follow-up.

Our secondary outcomes were:

1) Hemodynamically significant improvement in ankle brachial pressure (ABI) (≥0.10) or toe pressure (TP) (>15 mmHg) at 30 days and in the late check up

2) Overall mortality

3) Overall amputation rate

Furthermore, we recorded the information on operation duration, intraoperative bleeding and the number of femoro-femoral of iliofemoral bypass operations due to unsuccessful endovascular revascularizations.

Operative technique

All operations were performed by a vascular surgeon or a supervised trainee in a hybrid operating room equipped with a floor-fixed C-arm (Artis Zeego, Siemens, Erlangen, Germany). Concomitant femoral endarterectomy was performed either prior to the endovascular procedure or thereafter at the surgeon's discretion. After full heparinization and arterial clamping, all occlusive material was removed from femoral bifurcation extending proximally up to the external iliac artery, paying special attention to the origin of the deep femoral artery. Vascu-Guard (Synovis, St. Paul, Minn, USA) or bovine pericardium patch (Xenosure©, LeMaitre Vascular Inc, Burlington, MA, USA) was used for the angioplasty. In most cases the endarterectomy was performed prior to the endovascular procedure, and access was obtained by direct puncture of the patch with an 18-gauge needle and subsequent placement of a 6F sheath over the wire. In a few cases endarterectomy was performed after recanalization of the iliac segment. The technique has been described earlier. (18)

All recanalizations were attempted first by retrograde access from the CFA. In case of failure, an antegrade access through either contralateral femoral artery (cross-over) or brachial artery was used. Covered stent (CS) or bare metal stents (BMS) were used. When also the distal aorta was involved, we used either 3-stent CERAB (Covered Endovascular Reconstruction of Aortic Bifurcation), or in case of short aortic lesion in distal aorta, two kissing stents to open the aortic bifurcation. (19). Finally, additional out-flow revascularizations were performed according to the preoperative MRA or intraoperative angiogram.

Postoperative follow-up (FU) and medication

Postoperative antithrombotic treatment included 1-3 months dual antiplatelet therapy (DAPT) (ASA 100 mg and clopidogrel 75 mg once daily) followed by single antiplatelet therapy with ASA 100 mg once daily. For patients who had permanent anticoagulation, only ASA 100 mg was added for 1-3 months. Follow-up extended until February 2020.

During the outpatient visit, all patients underwent clinical assessment, ABI and TP measurements and duplex ultrasound (DUS) examination. First follow-up was at 1-3 months. Patients with Rutherford classification 5-6 continued surveillance until the wound was healed. To evaluate the mid- and long-term success, all study patients were invited for an additional follow-up appointment by November 2019.

142 Statistical analysis

143 All the data were primarily collected and tabulated using Excel Version 2016 (Microsoft Corp,
144 Redmond, WA, USA). Categorical variables are presented as frequencies and percentages and
145 continuous variables as mean and range or median and interquartile range (IQR) depending on
146 the type of distribution. Estimated Kaplan-Meier survival curves were generated for primary and
147 secondary patency and survival. Multivariable binary logistic regression was used to elucidate
148 co-morbidities and factors affecting technical and hemodynamical success, patency, 30-day
149 mortality and complications. Pearson's Chi-square or Log Rank test were used to assess
150 statistically significant effects on each outcome at a significance level <0.05.

151 Comorbidities that were included in the univariate analysis were age, sex, DM, hypertension,
152 CAD, CVD, CKD, smoking status, and the use of statins. Variables were included in the Cox
153 proportional hazards model if they proved significant in the univariate analysis. Cox regression
154 analysis using iterative maximum likelihood algorithm was applied to examine the effect of
155 baseline characteristics as well as technical factors of interest (length of the lesion, stent type,
156 length and diameter of the stent) on the long-term patency. Fisher scoring was used to fit the
157 model and Hosmer-Lemeshow method was implemented to assess goodness of fit. Analysis
158 was carried out with the use of SPSS version 25.0 (SPSS I. 2017. IBM SPSS statistics 25. New
159 York: IBM Corp.) except for the proportional hazard model where R version 3.6.0 (Team R.C.,
160 2013. R: A language and environment for statistical computing) was used.

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RESULTS

The search identified 147 patients, who underwent hybrid procedure due to total occlusion in either one (n=131) or both (n=16) iliofemoral arteries. **Pictures I** and **II** exemplified the typical patients undergoing this type of procedure. Baseline characteristics and lesion lengths are presented in **Table I**. Concomitant outflow revascularization was performed in 28 limbs: 13 endovascular superficial femoral artery (SFA) revascularizations and 15 distal by-passes. Median operative time was 4 h 34 min (IQR 2 h 43 min). Median estimated blood loss was 500 ml (IQR 700 ml). Neither time nor bleeding correlated with the likelihood of developing complications. Other procedures details are presented in **Table II**.

Primary outcomes

1) Immediate technical success rate was 88.3% (n=144/163). In 15 (9.2%) cases satisfactory lesion crossing was not achieved and the operation was converted into an open procedure including 13 femoro-femoral cross-over bypasses and two ilio-femoral bypasses. In 4 cases (2.4%) successful recanalization was done, but residual stenosis remained (30-50% of normal vessel diameter). Longer occlusions extending to the distal part of aorta were more challenging and primary technical success was somewhat lower in lesions $\geq$90 mm (87.1%) compared to lesions less than 90 mm (95.7%; χ^2 p=0.06).

2) 30-day mortality. Twelve patients (8.2%) died during the first 30 days after the primary operation. There were six in-hospital deaths: In one patient (0.6%) iatrogenic dissection of the aortic arch led to cardiac tamponade and death, four patients (2.7%) died of acute myocardial infarction and one (0.7%) developed an acute stroke postoperatively. The rest of the early deaths (n=6, 4.1%) happened after the patient's discharge to different care/rehabilitation facilities due to reasons mostly related to baseline comorbidities. In univariate analysis, two factors increased the perioperative death risk: patient's age (p=0.006) and post-operative

complications (p<0.001). Risk of perioperative death was higher in patients operated on an emergency setting (χ^2 p=0.014)

Despite the fact that all early deaths except one happened among patients suffering from CLTI (n=12, 8.2%) no significant statistical difference was found between different Rutherford categories (χ^2 p=0.07).

3) 30-day complications. Within 30 days after surgery, five cases (3.0%) of acute thrombosis occurred, two (1.2%) of which were successfully rescued by emergency thrombectomy, while the other three (1.8%) underwent by-pass surgery. Overall complications were reported in 26 procedures (16%) and they are listed in **Table III.** The most common complication was AMI (n=11, 6.7%). The only covariate that showed significant correlation with the immediate postoperative complications in the multivariate logistic regression model was CAD (p=0.001).

4) Patency. All patients alive by November 2019 (n=97, 66.8%) were contacted by phone and invited to a follow-up visit. Fifty-eight patients refused to attend, all of them were asymptomatic. Thirty-nine patients (26.5%) underwent follow-up assessment including ABI, TP and DUS. The mean follow-up period was 28.8 months (range 1-94.8 months). DUS surveillance identified 4 re-stenoses of the iliac artery, 2 of which were asymptomatic. Seven iliofemoral arteries occluded during follow-up (all of which caused limb claudication). This yields a primary patency at 6 months, 1 and 2 years of 98.1%, 96.6%, 93.7%, respectively (**Table IV**). These patients required further revascularization: all re-stenosis (n=4, 2.4%) and 4 occlusions (2.4%) underwent successful endovascular recanalizations yielding a secondary patency of 98.7%, 97.3%, 96.3% at 6 months, 1 and 2 years, respectively (**Table IV**). The remaining 3 occlusions (1.8%) underwent bypass surgery.

After multiple binary logistic regression analyses for each outcome at 12 months follow-up primary patency failure rate was 21.8% higher when there was a concomitant aortic stenosis

compared to a healthy aorta (Log Rank p<0.001). The impact of the aortic status continued until the end of the follow-up (failure rate 21.3%, Log Rank p <0.001) survival analysis is presented in **figure I**. Neither the length of the stent nor the length of the occluded lesion affected patency significantly regardless of the number of stents deployed. Proportional hazard regression was consistent with these findings after adjusting with all the covariates and factors.

Impact of the stent type. A total of 10 patients treated with *any* stent (5 with bare metal stent *vs*. 5 with a covered stent, Log Rank p= 0.26) required target lesion revascularization (TLR) during follow up. Kaplan-Meier curve analysis disclosed a significant difference regarding Secondary Patency between patients with BMS *vs*. those with a CS in favor of BMS (Log Rank p<0.02). (**Figure II**)

Secondary outcomes

1) Median ABI improvement was 0.25 (IQR: 0.39) whereas median TP improvement was 9 mmHg (IQR: 37 mmHg). Hemodynamic success was therefore documented in 107 patients (73%).

2) Over the follow-up, 50 patients (34.0%) died. Mortality was higher among CLTI patients than among claudicants (40.4% vs 12.1%, p<0.001). Estimated survival at 6 months, 1 and 2 years was 86.4%, 83.0% and 74.6% respectively (**Table IV**). **Figure III** compares mortality over time between the two groups.

3) Only 2 amputations (1.2%) were performed, both on CLTI patients. By the end of the follow-up 8 more limbs (4.9%) required re-intervention on the run-off.

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DISCUSSION

In patients with aorto-iliac disease extending to the femoral segment, hybrid in-flow operation offers an interesting *third* option between traditional *open* and *endovascular*. Previous knowledge presents it as a feasible revascularization method (14,15,20,21) We explored the boundaries of the in-flow hybrid operations in a cohort of patients composed solely of occluded iliofemoral arteries.

Technical success:

Previous reports on hybrid revascularizations considered total occlusions only as part of the inclusion criteria, in other words reports tend to include a mix of lesions ranging from mild stenosis to complete occlusions. Conclusions from these reports can hardly be used on the occlusion subgroup. This is mostly because recanalization of completely occluded iliac arteries represents a bigger challenge than passing through stenosis. The largest series so far comes from a recent multicenter registry in Italy where 713 patients suffering from aorto-iliac occlusive disease underwent either endovascular or hybrid revascularization. The authors report an impressive 99.3% technical success rate regardless of the type of lesion. All the unsuccessful lesion-crossing happened in the TASC D subgroup (n=5, 1.8%) which comprises longer obstructions. (15) We found in our single-center experience a more modest immediate success rate of 88.3% which is consistent with the intuitive idea that occlusions of the iliofemoral segment represent more demanding lesions than stenoses. Moreover, in our series, longer lesions were more difficult to recanalize. Our results are in line with the report of Chang and colleagues where 171 patients, 41% of whom had occlusions, underwent an in-flow hybrid intervention. The authors stated that one obstacle to use this technique is inability to cross long iliac lesions, but this obstacle has largely been overcome by increased use of re-entry devices. (11) The success rate for the occlusion subgroup is not reported separately in neither of the above-mentioned studies.

Mortality and complications:

Perioperative complications are strongly dependent on patient's comorbidities and burden of disease. Surgery on claudicants tends to be uneventful whereas CLTI patients are at higher risk. This might explain the differences in reported complication rates varying from 2% to 22% (13,22) The proportion of patients with CLTI in our cohort is considerable (77.9%); despite of this, complications are not higher than those previously published.

Prolonged operative duration is a well-known risk factor for perioperative death and complications (23). Nevertheless, it is inconsistently reported in the literature. We found that the mean procedure time for an in-flow hybrid operation lies inside the margins published for ABFB.(6,24,25) The only publication on hybrid revascularizations reporting operative duration presents similar times than our series: 340min (20). In our series, in addition to the hybrid procedure many patients underwent distal bypass surgery, prolonging the duration of the procedure. Procedural bleeding on the other hand stays well under the reported 1091-1126 ml on average for ABFB. (6,24) Although in our series both time and bleeding were lower than with open repair, we found considerably high perioperative mortality (8.1%). Only older studies from the 80's report this level of perioperative mortality. (26,27) The rationale of this finding might be related to patients' baseline rather than to the operative technique: 59 patients in our cohort (40.1%) correspond to ASA IV category. We also found a statistically significant correlation between CAD and early death. Furthermore, a high prevalence of diabetes and renal insufficiency in the cohort also speaks for the patients' fragility. On the other hand, claudicants, who, by definition had less extensive arterial disease, had understandably lower mortality. In our cohort, emergency surgery also increases perioperative mortality as already presented in the literature. (28)

Aortic dissection is a very rare event during cardiovascular interventions and might be related to heavy calcifications or aggressive catheter manipulation. (29) The one patient who died of aortic

dissection in our cohort represents the only inside-the-OR death. The patient had calcified aortic arch and had a previous history of iatrogenic iliac dissection. In this particular case the recanalization was attempted from brachial artery access and the distal part of the long 5 fr sheath stuck in the iliac artery and broke into two pieces leaving a wire between them that caused the aortic dissection. According to the manufacturer's IFU, these sheaths should always be removed with the dilator inside the sheath in order to prevent sheath breakage.

Patency

Patients with stenotic or occluded aorta had poorer outcome in the mid- and long-term patency, this may be explained by heavier burden of disease. Interestingly, it did not impact the technical success.

Breaking down the patency results by type of stent discovered longer patency for patients with BMS *vs*. those with CS. This is not aligned with current evidence coming from multicenter studies as the COBEST trial(30) or the COBRA registry study(31). These two research works analyzed relapsing of the disease under a slightly different terms. Freedom binary restenosis in the case of COBEST, and freedom from TLR in the case of the COBRA study. Despite the differences in terminology both works found improved patency for complex iliac and aorto iliac occlusions when using CS *vs*. BMS. Why we did not observe improved patency with CS is unclear, total length of stent might have a role, stenting all areas affected by occlusion or accepting the use of only PTA in some, is something that in all these studies was left to the operator's discretion. Neither the length of the lesion nor the presence of diabetes seemed to affect patency, contrary to what was observed by Spanos and colleagues. (32) Women have high rates of PAD as well as worse outcomes after revascularization despite fewer cardiovascular disease risk factors (33,34). Our results, nevertheless, did not find neither gender related differences in patency after adjusting for age.

Interestingly among the patients that underwent the ad hoc clinical checkup, a small fraction developed re-stenosis (2.4%), and of them, only half were asymptomatic. This raises the question whether follow-up for this population group is necessary at all since relapsing of symptoms is rather rare. This however remain unclear, because over half of the patients did not attend the re-assessment and the patency couldn´t be verified. Further studies could explore whether so promising long-term results as we found here are the norm.

Over these years of complex hybrid revascularizations we have learned that that heavily calcified lesions are more difficult to cross with a wire, which is not a surprise. Also we tend to perform the femoral endarterectomy prior to endovascular part in order to be able to cross the lesion x-over and land always inside the true lumen despite subintimal recanalisation. Surprisingly to us chronic total occlusions hardly ever cause distal embolisation when treated endovascularly.

Limitations of the study

This is a retrospective study not designed to prospectively investigate the impact of stent characteristics or the status of the aorta and the results should be interpreted cautiously. Despite the lack of randomization and limitations inherent to the research methodology, vascular registries are nonetheless a valid alternative to achieving understanding of treatment feasibility and critical factors impacting outcomes. To our knowledge no other research has previously validated hybrid methods specifically for occluded iliofemoral lesions. The findings presented suggest that even in severe cases of complete lumen thrombosis the feasibility of the in-flow hybrid procedure is not compromised and long-term patency rates are commendable.

CONCLUSIONS

Hybrid revascularization of iliofemoral occlusions is a good option for patients with aortoiliac occlusion and concomitant significant lesion in femoral artery in terms of patency and perioperative complications. Patient selection is important since associated mortality in these procedures is not negligible, especially in CLTI patients. Long lesions (>90 mm) represent a bigger technical challenge although do not compromise the patency in the long term. The involvement of the aorta represents a significant determinant of worse long-term patency, but it did not preclude technical success.

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458 FIGURE'S LEGENDS

459 Picture I MRA of patient undergoing hybrid revascularization, both the common and external
460 artery are occluded.

461 Picture II MRA of patient undergoing hybrid revascularization. Iliac external artery is occluded.

462 Table I Demographics, nature of the lesion and perioperative risk score, n (%) or mean (SD).

463 Table II Procedural information n (%).

464 Table III <30 days complications, n (%)

465 Table IV Primary patency, secondary patency and survival over time

466 Figure I Cumulative hazard over time of patients with normal aorta (n=146 blue) and patients
467 with stenotic aorta (n=17 red). Multiple Cox regression analysis has shown that the presence of
468 aortic stenosis was associated with an increase hazard ratio of primary patency failure.

469 Figure II Survival of claudicants vs. patients with CLTI

470

Table I Demographics, nature of the lesion and perioperative risk score, n (%) or mean (SD).

Age in years	70 (9.4)
Men	91 (61.9)
Hypertension	110 (74.8)
Smoking (current / former)	80 (54.4) / 48 (32.6)
Dyslipidemia	117 (79.6)
COPD	39 (26.5)
Coronary artery disease	60 (40.8)
Diabetes (yes / insulin)	47 (31.9) / 29 (19.7)
Cerebrovascular disease	24 (16.3)
Chronic renal insufficiency (yes / dialysis)	17 (11.5) / 4 (2.7)
Chronic atrial fibrillation	24 (16.3)
ASA category	
2	7 (4.7)
3	81 (55.1)
4	59 (40.1)
Rutherford Indication	
2	34 (20.8)
3	32 (19.3)
4	51 (31.2)
5	37 (22.6)
6	9 (5.5)
TASC	
C	40 (24.5)
D	123 (75.5)
Occlusion	

length in mm	95 (48.8)
Involvement	
Aorta	6 (3.6)
Common iliac	86 (52.7)
External iliac	128 (78.5)
Elective/emergency	118/45

COPD: Chronic obstructive pulmonary disease; ASA: American Society of Anesthesiologists; TASC: transatlantic inter society consensus

Table II Procedural information n (%)

Recanalization access	
Retrograde	122 (82.4)
Antegrade (contralateral cross-over)	20 (13.5)
Antegrade (brachial)	6 (4.1)
Endarterectomy (EA) prior to endovascular procedure	126 (77.3)
Stent placed over the EA*	62 (44.2)
Stent employed in each segment treated**	
No stent	9 (6.8)
Bare metal stent (BMS)	88 (59.4)
Covered	34 (22.9)
Both types	17 (11.4)
Location of the stent	
CIA	32 (22.7)
EIA	39 (27.6)
Multiple***	69 (49.2)

**100% corresponds to 140 limbs that received a stent, **100% corresponds to number successful recanalizations, ***Includes any combination of locations: Aortic and common iliac, aortic and external iliac, common and external iliac...),*

Table III <30 days complications, n (%)

AMI	11 (6.7)
Aortic dissection	1 (0.6)
Stroke	1 (0.6)
Pneumonia/acute respiratory insufficiency	4 (2.4)
Acute kidney insufficiency	1 (0.6)
Acute thrombosis	5 (3.0)
Wound infection*	5 (3.0)
Death	12 (8.1)

**Deep infection requiring debridement in the operating theatre and Sartorius muscle flap. AMI: Acute myocardial infarction*

Table IV Primary patency, secondary patency and survival over time

	30 days	**6 months**	**12 months**	**24 months**
Primary Patency	98.7%	98.1%,	96.6%	93.7%
Secondary Patency	99.4%	98.7%	97.3%	96.3%
Survival	92.5%	86.4%	83.0%	74.6%

Fig. I Cumulative hazard over time of patients with normal aorta (n=146 blue) and patients with stenotic aorta (n=17 red). Multiple Cox regression analysis has shown that the presence of aortic stenosis was associated with an increase hazard ratio of primary patency failure.

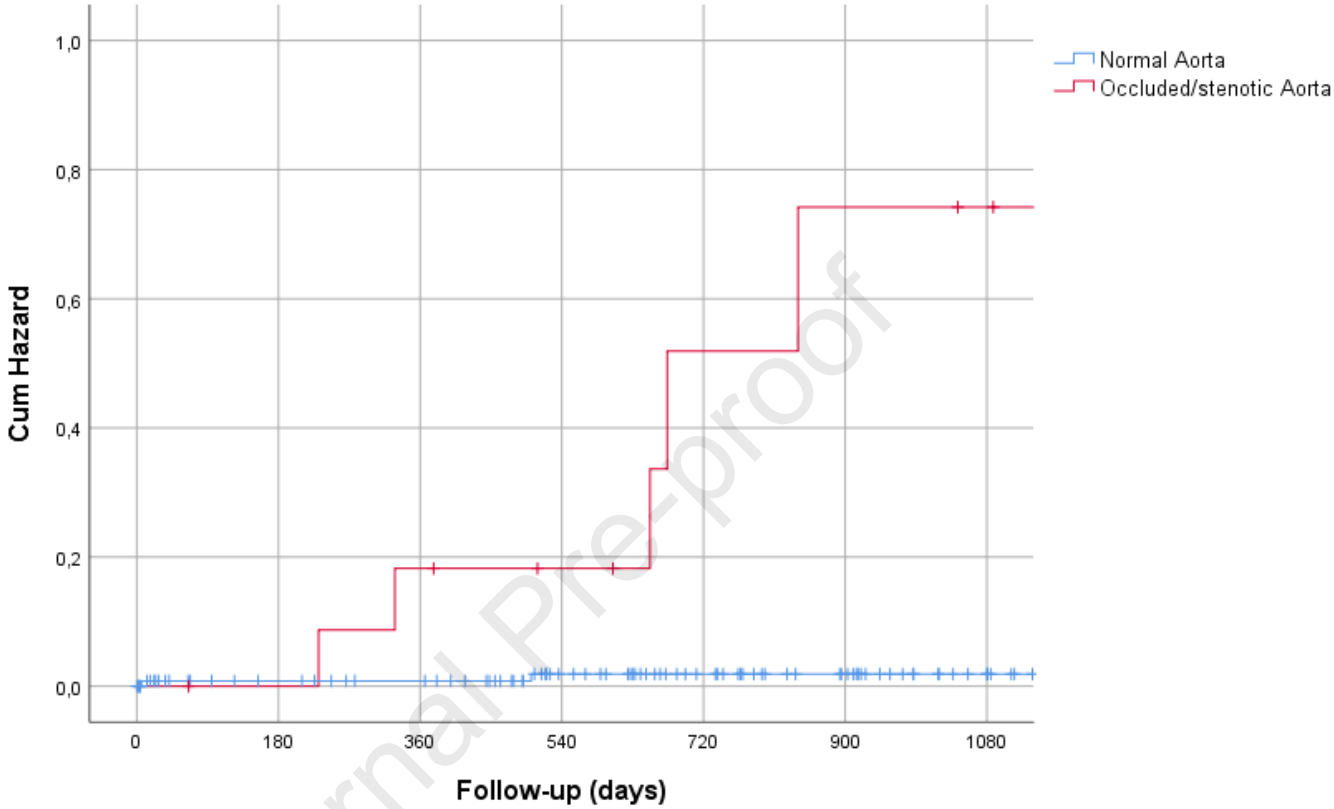


Figure II Secondary Patency of patients treated with BMS vs. CS (Log Rank p<0.02)

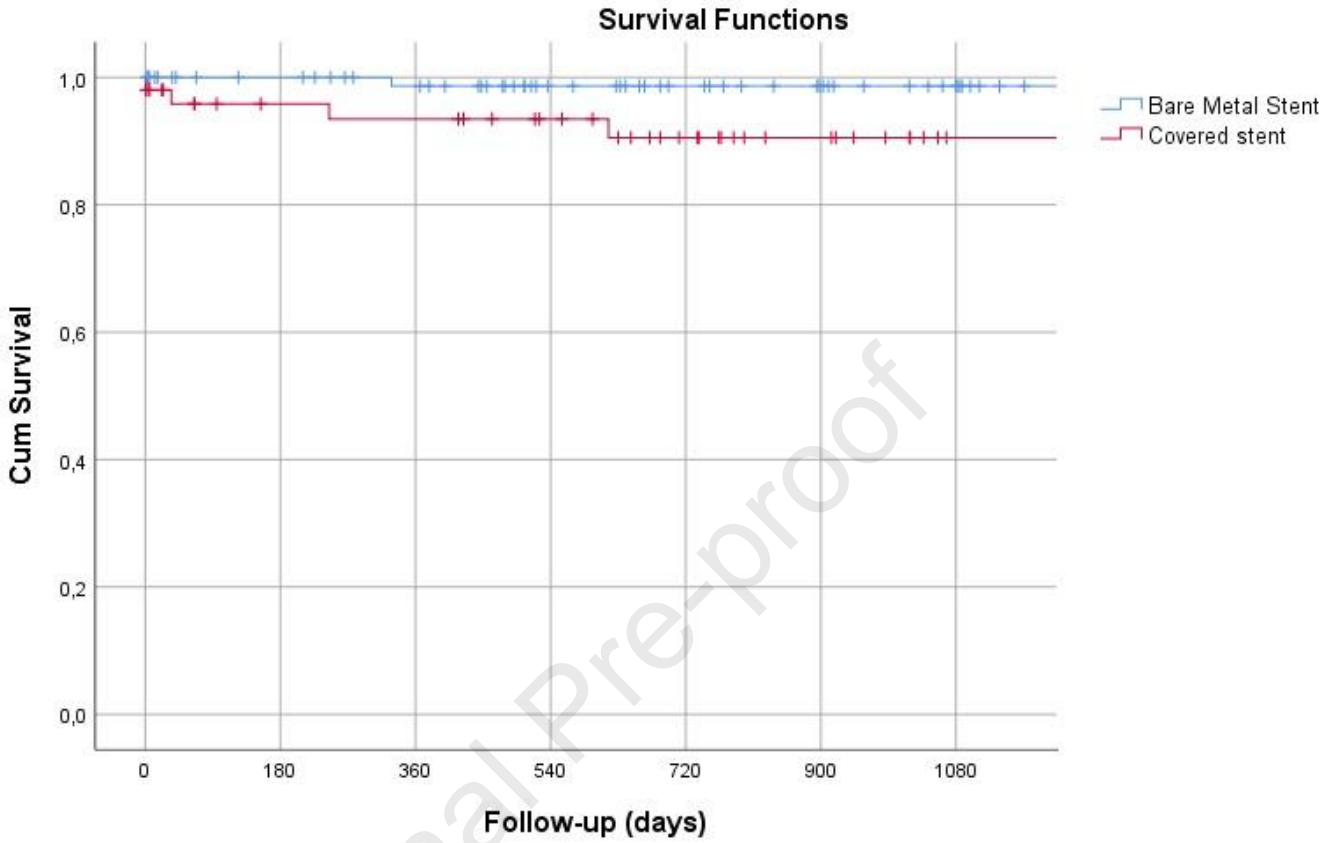
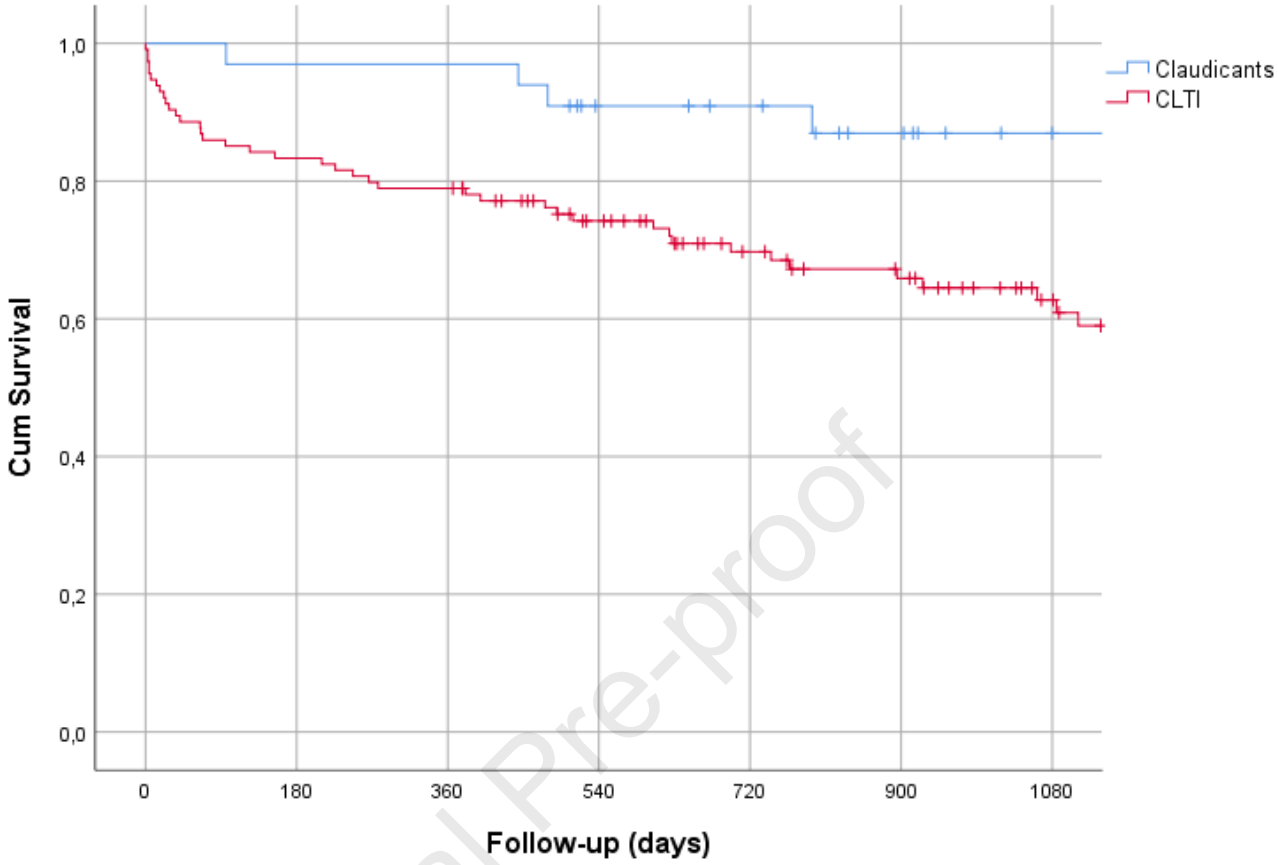


Fig. III Survival of claudicants vs. patients with CLTI



Picture I MRA of patient undergoing hybrid revascularization, both the common and external artery are occluded.

Picture II MRA of patient undergoing hybrid revascularization. Iliac external artery is occluded.