

# Early and late outcomes of hybrid endovascular and open repair procedures in patients with peripheral arterial disease

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## Summary

**Background:** Hybrid endovascular and open reconstructions are used increasingly often for multilevel revascularization for lower limb ischaemia. The aim was to evaluate outcomes after such procedures in a single-center non-randomized retrospective study.

**Patients and methods:** Consecutive patients with multilevel arterial disease who underwent single session hybrid procedures were analyzed depending on the type of ischaemia and the type of revascularization.

**Results:** 164 patients were included with a median follow up time of 14 months (range: 0–70). Indication was claudication (group 1, 47%), critical limb ischaemia (group 2, 33%) and acute limb ischaemia (group 3 20%). Technical success rate was 99.3%, perioperative mortality 2%. Primary, assisted-primary and secondary patency rates at one year were 60%, 61% and 64%, respectively. Primary, primary assisted and secondary patency were lower in group 2 and 3 compared to group 1 (all  $p < 0.05$ ). Results were better when endovascular repairs were performed above compared to below the open repair site (all  $p < 0.05$ ). Limb salvage at 1 year in groups 1–3 were 98%, 92% and 90%, respectively. The risk of major amputation was highest in group 3 compared to group 1 ( $p = 0.001$ ) or group 2 ( $p < 0.04$ ).

**Conclusions:** The results depend on the type of ischaemia and the localization of endovascular procedures.

**Key words:** Hybrid procedure, angioplasty, bypass, peripheral arterial occlusive disease, limb ischaemia

## Zusammenfassung

**Kurzzeit- und Langzeit-Ergebnisse von endovaskulären und offenen Hybridoperationen in Patienten mit peripherer arterieller Verschlusskrankheit**

**Hintergrund:** Endovaskuläre und offene Hybridoperationen werden immer häufiger bei mehrstufiger Ischämie der unteren Extremitäten eingesetzt. Das Ziel dieser Studie ist die Ergebnisse nach solchen OP-Verfahren in einer monozentrischen, nicht randomisierten retrospektiven Studie zu evaluieren.

**Patienten und Methoden:** Konsecutive Patienten mit mehrstufiger arterieller Verschlusskrankheit, die in einer einzigen Sitzung mit einer Hybrid-OP behandelt wurden, wurden in Abhängigkeit vom Ausmaß der Ischämie und Art der Revascularisation analysiert.

**Ergebnisse:** 164 Patienten mit einer medianen Beobachtungszeit von 14 Monaten (Bereich: 1–70) wurden ausgewertet. OP-Indikation waren belastungsabhängige Schmerzen mit Einschränkung der Gehstrecke (Claudicationsschmerz) (Gruppe 1, 47%), kritische Extremitätenischämie (Gruppe 2, 33%) und akute Ischämie (Gruppe 3, 20%). Die technische Erfolgsrate lag bei 99.3%, die perioperative Mortalität bei 2%. Primäre, primär-assistierte und sekundäre Raten nach einem Jahr waren 60%, 61% und 64%. Primär-assistierte und sekundäre Durchblutung waren niedriger in Gruppe 2 und 3 im Vergleich zu Gruppe 1 (alle  $p < 0.05$ ). Die Ergebnisse waren besser, wenn die endovaskuläre Reparatur oberhalb im Vergleich zu unterhalb der offenen Reparaturstelle durchgeführt wurde (alle  $p < 0.05$ ). Extremitätenerhaltsraten nach 1 Jahr in Gruppen 1, 2 und 3 waren 98%, 92% und 90%. Das Risiko einer größeren Amputation war höher in der Gruppe 3 im Vergleich zu Gruppe 1 ( $p = 0.001$ ) oder der Gruppe 2 ( $p < 0.04$ ).  
**Schlussfolgerungen:** Die Ergebnisse hängen von der Art der Ischämie und der Lokalisation der endovaskulären Eingriffen ab.

## Introduction

Treatment of patients with peripheral arterial disease (PAD) is usually

achieved with sole endovascular or open surgical procedures. A significant number of patients require a combined (hybrid) approach using

both techniques, however, preferably in one session. These hybrid procedures allow complete revascularization in patients with complex

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multilevel arterial disease [23]. From the first reported hybrid procedure in 1973 [17], the number of these procedures in contemporary practice has grown in the last decade contributing 5 to 21 % of the total number of arterial reconstructions [8]. To date, many reports of hybrid procedures include a variety of clinical presentations, timing of endovascular and open procedures, and technical aspects of the procedures, as well as differing terminology. This makes it difficult to compare results [6]. The aim of this study was to evaluate the patency and limb salvage rates in patients treated with hybrid procedures in one session, depending on the type of procedures and type of ischaemia.

### Patients and methods

#### Study design

A non-randomized retrospective study was undertaken including consecutive patients who had obstructive arterial disease at two levels or more among the abdominal aortoiliac, inguinal, femoropopliteal and infrapopliteal segments and were treated with a combination of endovascular and open arterial reconstruction. These procedures were performed in all patients in one single session. This type of study did not require the approval of the Institutional Review Board, and all patients provided informed consent before treatment.

#### Patients and data collection

All consecutive patients selected for hybrid procedures treatment on the basis of the presence of symptomatic lower extremity peripheral arterial disease as defined by the “recommended standards for reports dealing with lower extremity ischaemia” [18] between April 2006 and April 2012 were included in the study. Patients were divided into three groups, de-

pending on the indication for treatment: Group 1 had severe intermittent claudication group 2 had critical limb ischaemia and group 3 had acute limb ischaemia, definitions were according to the TASCII [16]. Patients who underwent perioperative on table thrombolysis as a part of thrombectomy were not included in this study. Preoperative (demographic data, risk factors for arteriosclerosis and previous ipsilateral lower limb revascularization), intra-operative (type of procedures, used graft material and type and localization of endovascular/open procedure) and follow-up information was retrospectively reviewed. All patients underwent preoperative peripheral arterial evaluation with physical examination according to the ESVS guidelines for critical limb ischaemia and diabetic foot [20]. All patients also underwent either digital subtraction angiography or computed tomography angiography (CTA). Patients with diagnosis of acute limb ischaemia received an intravenous bolus of 10000 UI of heparin immediately after admission to the hospital to reduce the propagation of thrombus and to prevent clinical deterioration. The measurement of ankle-brachial pressure index (ABI) was not undertaken in all patients, and two different measurement methods were used: manually or with an automatic device. Due to these limitations we decided not to include ABI in the analysis.

#### Revascularization procedures

These procedures were performed in the operating room equipped with a moveable radiolucent surgical table and a mobile digital angiographic system using a C-arm (OEC 9800, OEC 9900, General Electric). The procedures were performed under regional or general anesthesia with antibiotic intravenous prophylaxis. Patients typically received 5000 to 10000 UI of heparin before cross clamping of the artery. After the open part of the

procedures, usually a 7Fr sheath was placed in the common femoral artery or in the proximal anastomosis of the bypass when aortoiliac segments were operated on. For femoropopliteal and infrapopliteal endovascular procedures the 5Fr sheath was placed in the same positions, in an antegrade direction. The type of endovascular procedure (angioplasty with or without stenting) and the type of open surgical reconstruction was at the discretion of the operating surgeon. For the assessment of the degree of stenosis in the aortoiliac segment, catheter pressure measurements were made. Significant stenosis requiring treatment was defined as that causing more than 50 % luminal reduction and a pressure drop of >15 mmHg [16]. After completion of the endovascular intervention, the sheath was removed. Hemostasis was established by placing a suture at the puncture site and the effect of heparin was eliminated with Protamin®. Completion angiography including the pedal arteries was always performed. Most procedures were performed by a vascular surgeon alone, 16 % in cooperation with an interventional radiologist. After the procedure the patient received LMWH prophylactically during hospitalisation and thereafter clopidogrel for 3 months with low dose aspirin permanently.

#### Postoperative follow-up

The patients underwent postoperative surveillance, consisting of clinical examination, and either duplex ultrasonography or CTA at 1 and at 6-month intervals thereafter. Patients with worsening of clinical symptoms or abnormal physical examination were further assessed and decision on the type of re-intervention was made by the vascular surgeon.

#### Definitions and end-points

Technical success was defined as residual stenosis of less than 30 %

as demonstrated by intra-operative arteriography. Significant stenosis was defined by duplex ultrasonography as a systolic peak velocity gradient of at least 2.5 m/s and by digital subtraction angiography or CTA as a reduced vessel diameter of at least 50%. Early outcomes were defined as perioperative morbidity (complications) and mortality within 30 days following the hybrid procedure. In this study, patency refers to the status of both the endovascular and the open reconstructed arterial segments. Primary patency of the reconstructed arterial segments required the absence of restenosis or the necessity of re-intervention. Assisted primary patency was defined as a primarily restored artery that subsequently required at least one re-intervention to treat recurrent stenosis. Secondary patency was defined as an occluded artery that required at least one re-intervention to restore patency. Limb salvage was defined as preservation of a functional foot without the need of major amputation. Amputation-free survival was defined as the period from the date of the primary procedure to the date of the first major amputation of the leg on which bypass was performed,

or death from any cause, whichever occurred first [18].

### Statistical analysis

Descriptive statistics are expressed as mean ± SEM, median (interquartile range) or frequency (percent). Characteristics of groups with claudication, critical and acute limb ischaemia were compared using ANOVA and Kruskal-Wallis test for continuous variables, and by the  $\chi^2$  test for categorical variables. Patency and limb-salvage analyses were performed using the Kaplan-Meier method. Differences between groups were determined with the log-rank test. Calculations were done using SPSS 20 (IBM Corporation, Somers, NY, USA). A two-sided P-value  $\leq 0.05$  was considered statistically significant.

## Results

### Patients

One hundred sixty four patients underwent single session hybrid open and endovascular reconstruction for multilevel peripheral arterial disease. According to the Rutherford grading, 78(47%) patients were treated for severe intermittent

claudication (Rutherford category 3) (group 1), 55(33%) patients had signs of critical limb ischaemia (CLI) (group 2) and 31(20%) patients had signs of acute limb ischaemia (ALI) (group 3). In group 3, there were 21(68%) patients with acute limb ischaemia grade IIa and 10(32%) with grade IIb. Fifty one (31%) patients in group 1 or 2 and twenty seven (16%) in group 3 had previously undergone ipsilateral lower limb arterial reconstruction. In group 3, fourteen (45%) patients had a prosthetic graft occlusion. Individuals with CLI had significantly more often diabetes ( $p < 0.05$ ), while patients with ALI had more often had a history of previous ipsilateral arterial reconstruction ( $p < 0.001$ ). There were no statistically significant differences regarding other demographic characteristics and clinical presentation within groups (Table I).

### Revascularization procedures

The type of procedure, type of material used for revascularization and the frequency of open and endovascular procedures performed in the three groups are presented in Table II. The most common open

**Table I:** Patients characteristics

Characteristic	Claudication (group 1)	CLI (group 2)	ALI (group 3)	P
Number of patients (limbs)	78	55	31	-
Lost to follow up	0	4	2	-
Mean age (years)	65(range 41 – 88)	65(range 41 – 82)	64(range 55 – 88)	NS
Sex (male, female)	66(85%), 12(15%)	43(78%), 12(22%)	20(65%), 11(35%)	NS
Hypertension	67(85%)	46(84%)	23(74%)	NS
Diabetes	29(37%)	35(64%)	15(48%)	<0.05
Coronary artery disease	36(46%)	33(60%)	20(65%)	NS
Hyperlipidemia	38(48%)	32(58%)	16(51%)	NS
Renal insufficiency	4(1%)	6(11%)	2(4%)	NS
Chronic obstructive pulmonary disease	17(22%)	13(24%)	4(13%)	NS
Active smoker	53(68%)	36(65%)	24(77%)	NS
Previous ipsilateral arterial procedure	24(31%)	27(49%)	27(87%)	<0.001

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**Table II:** Types of procedures

Type of procedures	Claudication (group 1)	CLI (group 2)	ALI (group 3)	P
Number of procedures	78	55	31	-
Elective	78(100 %)	55(100 %)	0(0 %)	<0.001
Urgent	0(0 %)	0(0 %)	22(71 %)	<0.001
Emergent	0(0 %)	0(0 %)	9(29 %)	<0.001
<i>Type of open procedure</i>				
Aortic/iliac-femoral bypass	1	1	0	-
Femoral bifurcation EA	43	30	13	-
Femoro-femoral crossover bypass	0	1	2	-
SFA EA	2	0	0	-
Femoro-popliteal proximal bypass	31	13	3	-
Femoro-popliteal distal bypass	0	11	1	-
Femoro-crural bypass	0	2	1	-
TEA of native artery	0	0	11	-
TEA of graft	2	3	14	-
<i>Type of endovascular procedure</i>				
Angioplasty aorta/CIA/EIA	63	35	16	-
Angioplasty SFA	10	5	0	-
Angioplasty PA proximal	1	3	2	-
Angioplasty PA distal	1	1	0	-
Angioplasty crural artery	1	11	3	-
Angioplasty graft/ suprainguinal anastomosis	0	3	4	-
Angioplasty graft/infrainguinal anastomosis	2	0	7	-
<i>Graft/stent</i>				
Autovenous material	6	20	1	-
Prosthetic material	31	14	10	-
Stent deployment	57	37	18	-
<i>Localization of endovascular procedure</i>				
Above site of open procedure	63(81 %)	38(69 %)	20(65 %)	NS
Below site of open procedure	15(19 %)	17(31 %)	11(35 %)	NS

EA = endarterectomy; TEA = thrombectomy; CIA = common iliac artery; EIA = external iliac artery; PA = popliteal artery.  
An “urgent operation” is one that is intended to be performed as soon as the necessary preoperative preparation and diagnostic studies can be completed. An “emergency operation” is one that must be performed as soon as possible, often without time for adequate preoperative study or preparation, because of an immediate threat to limb or life.

procedure in patients with claudication and critical limb ischaemia was endarterectomy of the femoral bifurcation in 43 and 30 limbs, respectively. In patients with acute limb ischaemia, the most common open procedure was thrombectomy of the previous arterial reconstruction in 14 limbs, followed by endarterectomy of the femoral bifurcation and thrombectomy of native artery in 13 and 11 limbs, respective-

ly. The most common endovascular procedure in all groups was iliac angioplasty (CIA, EIA) with stent deployment. The majority of endovascular procedures in all groups were localized above the site of the open part, with no statistical significance difference between groups.

### Early outcomes

The immediate technical success rate was 99.3%. Complete pre- and

per-operative datasets were available for all 164 patients. There was one technical failure in a patient with a severely calcified iliac artery ruptured during balloon angioplasty. Postoperative complications within 30 days are listed in Table III. Overall perioperative complications occurred in 39(23 %) patients with no statistically significant difference between the groups (18 % in group 1, 25 % in group 2 and 35 % in group 3). The

**Table III:** Early postoperative complications

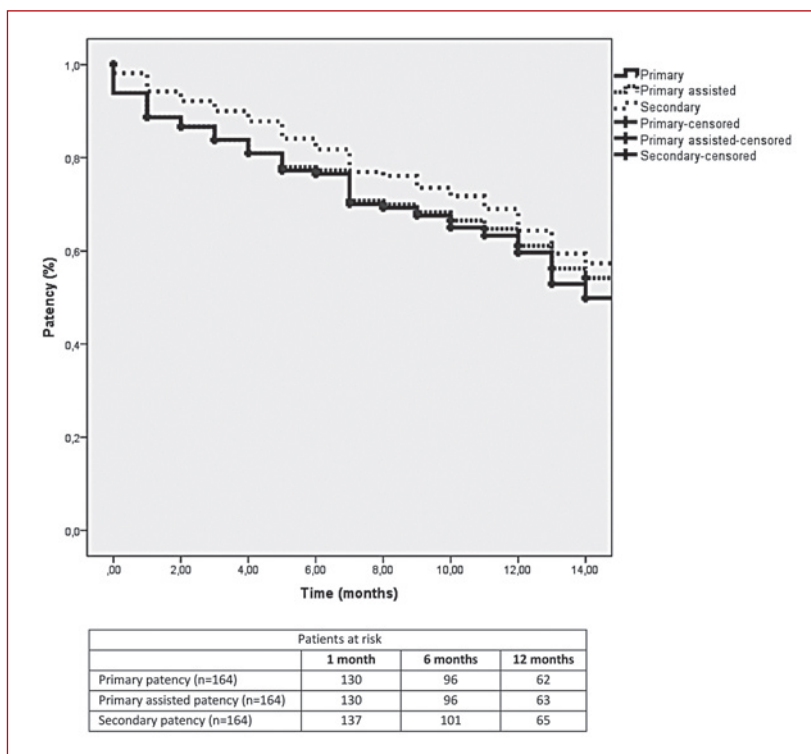
30 day postoperative complications	Claudication (group 1)	CLI (group 2)	ALI (group 3)	p
Technical success of the procedure	78(100%)	54(98%)	31(100%)	-
N° of patients with complications (without major amputation)	14(18%)	14(25%)	11(35%)	NS
N° of patients with major amputation	0(0%)	0(0%)	2(6%)	<0.05
Death	0(0%)	2(3%)	1(3%)	NS
Type of complications				
Local wound complications	12(15%)	8(8%)	6(19%)	-
Non-fatal cardiac complication	3(3%)	4(7%)	3(10%)	-
Acute renal failure	0(0%)	1(2%)	2(6%)	-
Occlusion of reconstruction	3(3%)	3(5%)	1(3%)	-
Graft infection	1(1%)	0(0%)	1(3%)	-
Fatal bleeding	0(0%)	1(2%)	1(3%)	-

risk of amputation was higher in individuals with ALI, while there was no difference of the complication or death rate between groups. Non-fatal cardiac complications occurred in 10(6%) patients, acute renal failure in 3(2%), wound local complication in 26(16%), occlusion of reconstruction in 7(4%), graft infection in 2(1%) and bleeding from reconstruction in 2(1%) patients. These complications were successfully managed except for three patients, resulting in a 2% perioperative mortality. One patient in group 2 died from myocardial infarction on the 20<sup>th</sup> postoperative day. Two patients, one from group 2 and one from group 3, died from hemorrhagic shock due to fatal bleeding: on the 6<sup>th</sup> postoperative day (bleeding from the proximal anastomosis of the bypass) and on the 14<sup>th</sup> postoperative day (bleeding from suture line after endarterectomy of the femoral bifurcation). No perioperative stroke, pulmonary embolism or deep venous thrombosis occurred in this study. Two amputations were performed in the 30 day postoperative period; both resulting from ongoing septic gangrene (2<sup>nd</sup> and 6<sup>th</sup> postoperative day) in acutely ischaemic limbs in which attempts of revascularization were unsuccessful.

**Late outcomes**

Complete data were available for 164 patients. The mean follow-up time was 14 months (range 0 – 70). Overall primary, primary assisted and sec-

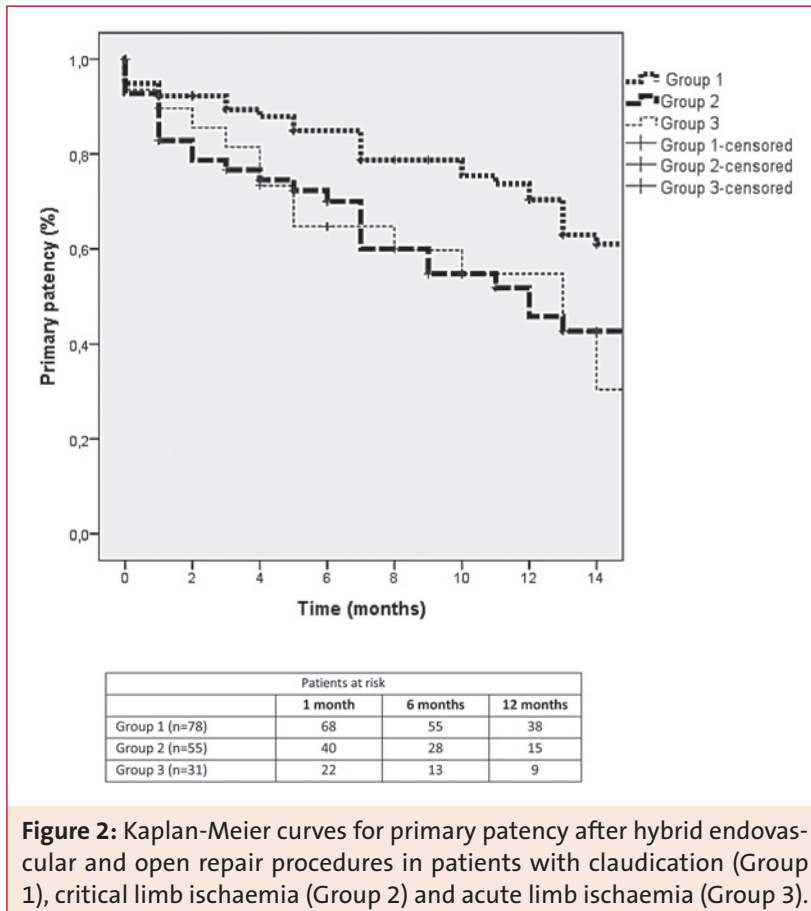
ondary patency rates at 6 months and one year after surgery were 77% and 60% for primary, 77% and 61% for primary assisted, 82% and 64% for secondary patency, respectively (Fig-



**Figure 1:** Kaplan-Meier curves for primary, assisted primary and secondary patency after hybrid endovascular and open repair procedures performed in patients with peripheral arterial disease.



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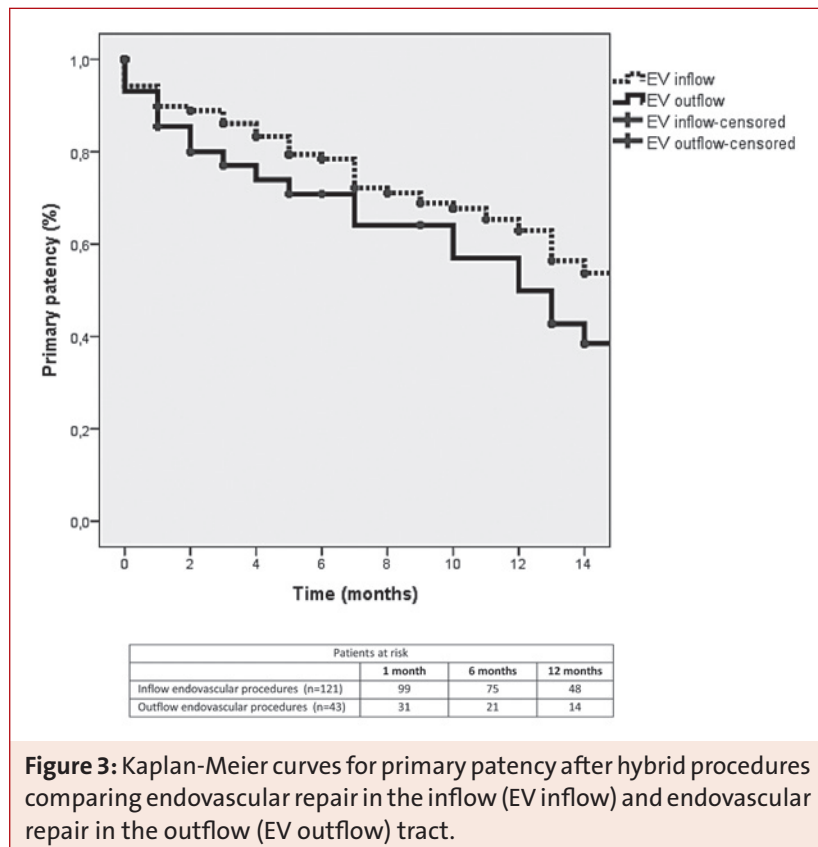


ure 1). Primary patency in group 1 at 6 months and one year after surgery were 85 % and 70 %, in group 2 70 % and 46 %, and in group 3 65 % and 55 %, respectively (Figure 2). The median primary patency rate was higher in group 1 as compared with group 2 ( $25.0 \pm 4.2$  vs.  $12.0 \pm 2.7$ ,  $p = 0.04$ ) and group 3 ( $25.0 \pm 4.2$  vs.  $13.0 \pm 3.2$ ,  $p = 0.03$ ) (Figure 2). Similarly, primary assisted and secondary patency were higher in group 1 as compared with group 2 and group 3. Individuals in group 2 and group 3 did not differ significantly in patency rates. Median primary patency among individuals with inflow endovascular procedures was higher than in individuals with outflow endovascular procedures ( $21.0 \pm 5.7$  vs.  $12.0 \pm 1.9$ ,  $p = 0.02$ ) (Figure 3). The median amputation-

free survival in group 1 was higher as compared with group 3 ( $57.5 \pm 3.7$  vs.  $39.1 \pm 4.5$ ,  $p = 0.04$ ) (Figure 4). Limb salvage rate at 6 months and one year after surgery in group 1 was 97 % and 97 %, in group 2, 98 % and 92 % and in group 3, 89 % and 84 %, respectively. The risk of major amputation was higher in the group with acute ischaemia as compared to the group with intermittent claudication ( $p = 0.001$ ) or the group with chronic ischaemia ( $p = 0.04$ ). Over the follow up period, 16 patients died, half of them of myocardial infarction, four of stroke, three of malignancy and one of pulmonary embolism. Out of these there were 15 patients with intact limbs.

## Discussion

Although the concept of combining angioplasty and surgery as a single procedure is not new (7), in the last decade this procedure has found a defined role in the treatment of multilevel arterial disease, allowing complete immediate revascularization in complex disease [23, 24, 20]. The performance of simultaneous hybrid procedures is associated with potential advantages. The length of hospital stay decreases, there is no delay in complete revascularization of the ischemic limb, open surgery can immediately repair inadequate endovascular results and vice versa, puncture complications related to angioplasty are eliminated, potential infectious complications of two separate interventions are minimized, adjustment of drug therapy between the procedures is not required and there is evidence of reduction of costs in comparison with the two-staged approach [5, 8, 23]. An increasing number of published series suggest safety and effectiveness of this procedure [3, 5, 7, 9, 22]. Furthermore, the proportion of hybrid revascularizations in relation to the total work-load is increasing [8]. The largest study was published by Madera in 1997, reporting on 239 lower extremity revascularization procedures in 200 patients [12]. Most of the combined procedures are nowadays performed by vascular surgeons with good results [1, 3, 6, 7, 9, 13, 22, 23], underlining the contemporary international trend in which vascular surgeons are trained in both open and endovascular techniques. A majority of the procedures in this study (84 %) were performed in the operating theater by vascular surgeons trained in endovascular techniques, open surgery was followed by an endovascular procedure. Some centers start with angioplasty and the site of puncture is then used for bypass anastomosis or endarterectomy



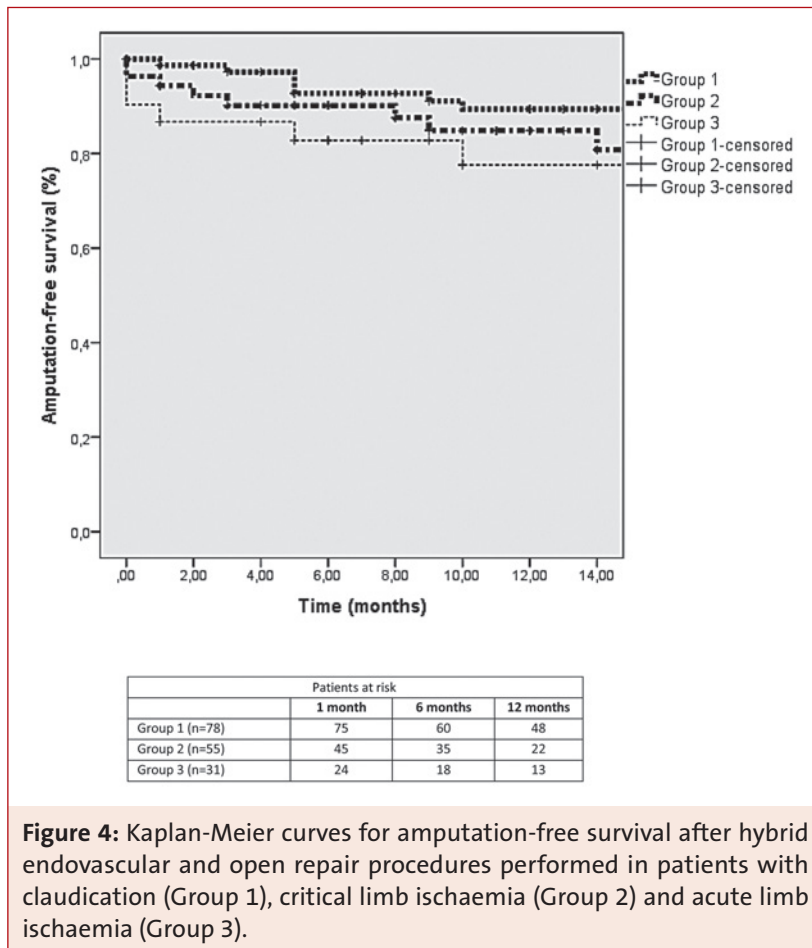
**Figure 3:** Kaplan-Meier curves for primary patency after hybrid procedures comparing endovascular repair in the inflow (EV inflow) and endovascular repair in the outflow (EV outflow) tract.

[22, 24], whereas other centers share the approach [2, 13, 22] of this investigation performing the open procedure first. The advantage of this approach is that when the endovascular is performed distal to the open procedure, no clamping is needed, and there is an automatic completion control with angiography. When, on the other hand, the endovascular act is proximal to the open procedure occlusion time is fairly short, and the patient is heparinized. Safety and efficacy of this approach is confirmed by the fact that we did not experience any perioperative thrombosis while immediate technical success rate was 99.3%. These results are comparable with other studies [3–6, 9, 13, 22]. In line with other recently published series [6, 11], femoral endarterectomy was a key component of complex hybrid procedures in this study, 47% of all open procedures. Endarterectomy

is the standard of care for common femoral artery occlusive disease [16, 20] and is also the ideal place for the introduction of endovascular instrumentation for aortoiliac or infrainguinal endovascular operations. Many studies report patency rates separately for the different reconstruction sites. In this study patency rates are reported considering both reconstructions together as recommended by Dosluoglu [6], which we also consider more appropriate when evaluating outcome. As expected, patients treated for claudication had higher patency rates at one year compared with patients with critical or acute ischaemia, 70% vs. 46% and 55%, respectively. These outcomes are comparable to those published in the literature, although it is very difficult to make meaningful comparisons due to the heterogeneity of studied populations and differences

in reporting standards of reconstructive patency. Patients treated with hybrid procedures have multilevel disease, which does affect the outcome negatively, in particular if patency of the combined procedure is analyzed. In a recent literature review, Schrijver et al. [23] analyzed outcomes of hybrid procedures performed for peripheral obstructive disease using data from Medline, EMBASE and Cochrane database published between years 2000 and 2010. For mixed hybrid procedures, similar to the patients studied in this investigation, the primary patency rates were 53–79% at 12 months follow up [3–5, 7, 15]. Recently Dosluoglu et al. [6] analyzed data from 108 patients treated by hybrid procedure with a mean follow-up time of  $30.3 \pm 20.7$  months. The 12-month primary patency rate in patients with TASC A,B lesions at the aortoiliac was  $80\% \pm 9\%$ . In this study patency rates of interventions at the aortoiliac and infrainguinal level were not significantly different. However in the present study, endovascular repairs performed above the open repair site were associated with better patency as compared to the repairs performed below the open repair site (all  $p < 0.01$ ). This result can be explained by the higher pressure gradient, and larger vessel diameter in the aortoiliac segment as compared to infrainguinal segment [10, 14]. Although this finding was expected, it has to our knowledge not been reported previously. The present study also analyzed a cohort of 31 patients with acute limb ischaemia due to multi-level disease treated with hybrid procedures (not including thrombolysis). This fact has negative influence on the overall limb salvage rate, since patients with ALI have a higher risk of amputation. In the literature, reported limb salvage at one year in patients with claudication is near to 100% and in patients with critical limb ischaemia it is in the

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range of 83–100% [1, 4, 5, 7, 9, 13, 15, 21]. In this study limb salvage at one year in patients with claudication and CLI was 97% and 92%, respectively, which is similar to previously published data. The difference in limb salvage rates between groups can be explained by a higher incidence of risk factors, especially diabetes [16]. As expected, multilevel arterial disease is more common among patients with CLI [16]. This was confirmed in this study where the presence of diabetes was higher in patients with CLI compared to other groups. This investigation has limitations. Although the procedures were registered prospectively in a database, analysis of the outcome was retrospective. Another limitation is the great variety of

open and endovascular procedures. Although three procedures dominate, such as femoral endarterectomy, fem-pop bypass and angioplasty, the number of treated patients did not allow for sub-group analysis, despite the fact that this is one of the largest studies performed. We consider it a strength that patients with both chronic and acute ischaemia were studied, and that outcome was based on combined patency of both reconstructions, thus having a clinical rather than a technical perspective.

### Conclusions

Hybrid procedures are important alternatives in the treatment of mul-

tilevel arterial disease among patients with chronic and acute limb ischaemia. Success of these procedures depends mainly on the type of ischaemia and on the location of the endovascular part of the procedure, with the best results achieved in claudicants with the endovascular repair being performed proximally to the open repair site. The increasing proportion of hybrid procedures, and their impact on outcome when treating complex patients with multilevel disease, is an important argument supporting the fact that modern vascular surgeons need to master both open and endovascular techniques.

### Conflicts of interest

There are no conflicts of interest existing.

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