

Outcomes of hybrid procedures for peripheral arterial disease: 5-year single center experience

Resultados de Procedimientos Híbridos para tratar Enfermedad Arterial Periférica: experiencia de un centro a 5 años

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Abstract

Objective: The objective of the study was to present patients with peripheral vascular disease (PWD) who underwent hybrid procedures at our institution, the results of these interventions for a 5-year period and determine patency, mortality, failure, and amputation rates compared to the literature. **Material and methods:** Observational, single center, retrospective, and cross-sectional study which analyzed data gathered from the vascular quality initiative from patients who had hybrid revascularization procedures from January 2010 to December 2015. **Results:** 87 patients were identified: 51 (58%) male, 36 (41%) female, 9 (10%) had critical limb ischemia (CLI), and 78 (90%) claudication. We analyzed results of hybrid interventions in their variations. Technical success rate was 100%, patency at 2 years 88.5% (primary 65%, primary-assisted 18.3%, and secondary 4.5%) and 11.49% failure rate (lost patency < 1 year, conversion to open or/and amputation). Predictors of failure were: Female, previous chronic heart failure, longer length of stay, and previously transferred from another hospital. Amputation rate was 12.6% (10.3% major and 2.2% minor amputation), the only significant predictor was age ($p = 0.035$, odds ratio = 0.89 (0.806-99)). **Conclusions:** Hybrid procedures are effective to treat patients with either CLI or claudication. Our study had outcomes comparable to the literature, with similar patency, amputation, and complication rates. We conclude it is a safe and effective option for PVD with multi-level disease.

Keywords: Peripheral vascular disease. Vascular Quality Initiative. Chronic heart failure. Length of stay. Common femoral artery. Superficial femoral artery.

Resumen

Objetivo: Presentar pacientes con EAP que requirieron procedimientos híbridos en nuestra institución, resultados en 1 periodo de 5 años y determinar permeabilidad, mortalidad, falla y rangos de amputación comparado con la literatura. **Material y métodos:** Estudio observacional un céntrico, retrospectivo y transversal que analizó datos obtenidos del VQI de pacientes post-revascularización híbrida de Enero 2010 a Diciembre 2015. **Resultados:** Se identificaron 87 pacientes: 51 masculinos (58%) y 34 femeninos (41%). 9 (10%) presentaron isquemia crítica, 78 (90%) claudicación. Se analizaron resultados de dichas intervenciones en sus variaciones, con éxito técnico 100%, permeabilidad a 2 años 88.5% (primaria 65%, primaria asistida 18.3%, secundaria 4.5%) y 11.49% de falla (pérdida de permeabilidad < 1 año, conversión a cirugía abierta y/o amputación). **Predictores de falla:** femenino, IC, larga EIH, traslado de hospital previo. El rango de amputación fue 12.6% (10.3% mayor, 2-2% amputación menor) y el único predictor significativo fue edad ($p = 0.035$,

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OR = 0.89) (0.806-99). Conclusiones: Los procedimientos híbridos son efectivos para tratar pacientes con isquemia crítica o claudicación. Nuestro estudio tuvo resultados similares a la literatura, permeabilidad, riesgo de amputación y complicaciones comparables con lo descrito. Concluimos que es una opción segura y efectiva para tratar pacientes con EAP multinivel.

Palabras clave: Enfermedad arterial periférica. Insuficiencia cardiaca. Estancia intrahospitalaria. Arteria femoral común. Arteria femoral superficial

Introduction

Peripheral arterial disease (PAD) is a highly prevalent atherosclerotic syndrome with an estimated worldwide incidence of approximately 200 million people¹. PAD Patients commonly present with a multilevel disease pattern and often require extensive operative and endovascular procedures. Although the number of patients treated purely with the endovascular procedure has grown, there is a significant number of patients that require a combined (hybrid) approach using both techniques, preferably in one session. This hybrid procedure allows complete revascularization of peripheral arteries in patients with significant co-morbidities and complex multilevel arterial repair². This procedure was first described by Porter in 1973 and has evolved³. Reports suggest that 5-21% of the total number of vascular reconstructions involve hybrid therapy (HT)⁴. The aim of the procedure is to minimize morbidity while continuing to provide a durable revascularization⁵.

The purpose of this study was to describe the prevalence, nature, and outcomes of hybrid procedures for symptomatic peripheral arterial disease (PAD) at a regional vascular center and compare our outcomes to the existing literature.

Methods

We performed an observational, single center, and retrospective cross-sectional study which analyzed data gathered from the vascular quality initiative (VQI) (www.svs-pso.org) at our local institution from patients who had hybrid procedures between January 2010 and December 2015. Outcomes, limb salvage rates, morbidity, mortality, comorbidities, patency, reintervention, success, and failure rates were analyzed and reported.

Major inclusion criteria were as follows: (1) 18 years of age or older, (2) Rutherford classification category 2-6, (3) resting ankle brachial index (ABI) of < 0.9 or abnormal exercise ABI, and (4) *de novo* lesion.

Exclusion criteria were applied as follows: (1) Procedures without combination of surgical and endovascular treatment, (2) previous vascular operation, (3) previous major amputation, (4) life expectancy < 1 year, (5) unsalvageable limb with extensive ischemic ulceration or gangrene, and (6) acute limb ischemia.

Patency rates were defined according to VQI criteria: (a) Primary (patency of the target lesion during follow-up), (b) primary-assisted (patency of the target lesion following endovascular therapy at the target vessel site in case of symptomatic restenosis, but without occlusion at any time), and (c) secondary (patency of the target lesion after treatment for [re]occlusion, with patency ending with untreated or surgically treated occlusion⁶.

We analyzed the results of peripheral vascular hybrid interventions with univariate analysis of data using Chi-square and Fisher exact test. Multicollinearity was assessed using variance inflation factor and tolerance and found to be within acceptable limits. This study was approved by the Institutional Review Board of our institution.

Results

Eighty-seven patients were identified who had undergone hybrid procedures for peripheral vascular disease. The majority were men (n = 51, 58%). Patient age ranged from 59 to 93 years-old with a mean age of 74.25. Most patients (n = 74, 85%) had hypertension, half of the patients (n = 47, 54%) had diabetes, and 48 (55.0%) had a history of past or current tobacco use. Patient demographics are shown in tables 1 and 2.

The majority (n = 78, 90%) presented with lifestyle-limiting claudication and the remainder presented with critical limb ischemia (n = 9, 10%). In-hospital stay ranged from 0 to 29 days with a mean of 5.26 days. Excluding the one outlier the average length of stay was 4.98 days. Most of the patients included in the study were American Society of Anesthesiologists (ASA) class 3 (34.4%) and 4 (62.3%).

Among patients treated, we found 70 (80.4%) with iliac lesions, 76 (87.3%) with femoral lesions and

Table 1. Patient demographics

Variable	Patients
Demographics	
Gender	M: 51 (58.6%); F: 36 (41.3%)
Age at surgery (mean)	74.2
Presurgical comorbidities	
Hypertension	77 (88.5%)
CAD	23 (26.4%)
COPD	20 (22.9%)
Diabetes	47 (54%)
Preop cholesterol (mean)	3.04
Preop Creatinine umol/L (mean)	94.62
Current smoker	10 (11.4%)
Non-smoker	39 (44.8%)
Former smoker	38 (81.6%)
Dialysis	4 (4.5%)
CHF	71 (81.6%)
Prior CABG	17 (19.5%)
Preop drugs	
Statin	69 (79.3%)
Antiplatelet	29 (33.3%)
Anticoagulants	7 (8%)
Ace Inhibitor	40 (45.9%)
Hospital variables	
LOS (mean, days)	5.26
Surgical time (mean, mins)	196.9
Surgical	
Fluoro time (mean, mins)	10.7
Largest sheath size (mean, French)	6.6
Total occlusion length (mean, cm)	2.46
ASA class	
1	0
2	2 (2.2%)
3	30 (34.4%)
4	53 (60.9%)

CHF: Common femoral artery, LOS: Length of stay, ASA: American Society of Anesthesiologists, CABG: Coronary artery bypass grafting, CAD: Coronary artery disease, COAD: Chronic obstructive pulmonary disease

6 (6.8%) with tibial lesions, which were classified according to TASC II (Table 3)^{6,7}. The most common procedure was common femoral endarterectomy and profundoplasty (n = 70, 80.4%), followed by iliac stenting (n = 55, 63.2%) for iliac lesions. Next was common femoral endarterectomy and profundoplasty followed by superficial femoral artery (SFA) angioplasty (n = 25, 28.7%) for superficial femoral lesions. A number of cases facilitated a bypass by iliac stenting, unilateral distal bypass (n = 8, 9.1%) or femoral-femoral crossover bypass (n = 10, 11.4%) (Table 4). OR time ranged between 90 and 370 min with a mean of 196.95 min and fluoroscopy time ranged between 1 and 37.2 min with a mean of 10.7 min.

Technical success rate was 100% for hybrid therapy. The mean follow-up period was 23.2 months, with a median of 12 months, ranging from 2 months to 4 years of follow-up. Two-year patency was 88.5% (primary 65%, primary-assisted 18.3%, or secondary 4.5%) and a failure rate of 11.49% (lost patency before 1 year, need for conversion to open procedure, or/and amputation). Amputation free-survival was 93.1% at 1 year and 87.3% at 2 years. We had a 13.7% morbidity, which included surgical site infection in 4.59%, acute limb ischemia in 5.74% and pseudoaneurysm in 3.44%, and a mortality rate of 1.1% at 30 days.

Univariate analysis of data showed the following predictors of failure: Female gender, preoperative antiplatelet therapy with P2Y12 receptor inhibitor and congestive heart failure. Age and surgical time were entered into a final logistic regression model predicting major amputation versus no amputation. After controlling for surgical time (p = 0.06, B = 0.01, OR = 1 (0.999-1.02), the only significant predictor of major amputation was age (p = 0.035, OR = 0.89 (0.806-0.99). The amputation rate was 12.6% (10.3% major and 2.2% minor).

Discussion

The first hybrid procedure was reported in 1973 and included a combination of dilation of pelvic arteries and femoro-femoral bypass⁴. Hybrid interventions have evolved since and now encompass a variety of simple and complex procedures to treat different anatomical regions⁸. In the present day, hybrid procedures accounted for 5-21% of vascular reconstructions and early analysis of hybrid interventions has shown promising results⁸, with clear benefits attributable to that simplified approach and cost savings of almost 50% compared to staged procedures^{4,5}. In our study, hybrid procedures composed 30% of open vascular reconstructions for PAD.

Patients with diagnosed chronic limb ischemia are often elderly and have multiple medical problems⁸. Our study cohort was consistent with this, with majority being ASA classes 3 and 4 (97.6%). These patients can present with intermittent claudication or critical limb ischemia and on investigation are often found to have multilevel lesions affecting inflow and outflow tracts (Fig. 1). Relief of rest pain or healing of ulcers or gangrene usually requires revascularization of all affected levels³. In these cases, endovascular interventions may be preferred to extensive open procedures because of the frail population and the high risk

Table 2. Patency rates

Variable	Primary (n = 57)	Primary assisted (n = 16)	Secondary (n = 4)	Failure (n = 10)
Demographics				
Gender (m) (%)	36 (63.2)	10 (62.5)	3 (75%)	2 (20%)
Age at surgery	75.4 (8.5)	73.6 (9.2)	67.5 (4.9)	71.5 (9.1)
Presurgical comorbidities				
Hypertension	50 (87.7)	15 (93.8)	3 (75)	9 (90)
CAD	12 (21.1)	5 (31.3)	4 (100)	2 (20)
COPD	14 (24.6)	4 (25.0)	1 (25.0)	1 (10)
Diabetes	33 (57.9)	7 (43.8)	1 (25)	6 (60)
Preop cholesterol	4.54 (1.04)	3.95 (1.52)	NA	3.67 (.79)
PreopCreatinine umol/L	90.1 (53.6)	101.6 (94.72)	89.0 (22.0)	97.8 (31.0)
Smoke	4 (7.0)	1 (6.3)	2 (50)	3 (30)
Non-smoker	28 (49.1)	7 (43.8)	1 (25)	3 (30)
Past smoker	25 (43.9)	8 (50.0)	1 (25.0)	4 (40.0)
Dialysis	3 (5.3)	0	0	1 (10)
CHF	50 (87.7)	16 (100)	1 (25)	4 (40)
Prior CABG	14 (38.9)	3 (30)	0	0
PreOp drugs				
Statin	50 (87.7)	14 (87.5)	4 (100)	1 (90)
Antiplatelet	14 (24.6)	4 (25)	3 (75)	8 (80)
Anticoagulants	3 (5.4)	2 (13.3)	0	2 (20)
Ace inhibitor	24 (66.7)	6 (60)	3 (75)	7 (70)
Hospital variables				
LOS	5.56 (7.4)	6 (7.7)	2.5 (2.1)	15.7 (12.5)
Surgical time (mins)	187.7 (59.1)	205 (64.7)	187.7 (59.1)	226 (72.3)
Surgical				
Flouro time	9.46 (7.06)	12.98 (8.02)	16.3 (15.47)	11.76 (15.86)
Largest sheath size	6.79 (1.16)	6.56 (0.727)	6.00 (1.41)	5.89 (.93)
Total occlusion length	1.32 (2.73)	4.93 (8.21)	3.67 (3.22)	5.33 (10.0)
ASA class				
1	-	-	-	-
2	2 (3.6)	-	-	-
3	19 (33.9)	5 (31.3)	2 (50)	4 (44.4)
4	35 (62.5)	11 (68.8)	2 (50)	5 (55.6)

CHF: common femoral artery; LOS: length of stay; ASA: American Society of Anesthesiologists; CABG: coronary artery bypass grafting; CAD: coronary artery disease; COAD: chronic obstructive pulmonary disease.

Table 3. Lesions classified according to TASC II

	Total	TASC II A	TASC II B	TASC II C	TASC II D
Iliac lesions	70 (80.4%)	12	21	14	23
Femoral lesions	76 (87.3%)	40	16	9	11
Tibial lesions	6 (6.8%)	0	3	3	0

TASC: Transatlantic inter-society consensus.

lesser open procedure with an endovascular adjunct thus diminishing the complications associated with extensive open surgical procedures^{3,8}.

Approximately 25% of patients that are diagnosed with multilevel arterial occlusive disease may require both aortoiliac and infrainguinal revascularization, both of which are used to treat patients with extensive tissue loss⁸. Surgical options include performing simultaneous bypasses (both aortofemoral and infringuinal) with good outcome for limb salvage. However, complication rates for these kinds of simultaneous surgeries have been reported to be as high as 61% morbidity and 19% mortality⁸. For hybrid procedures, morbidity can be as low as 11% and mortality 1.4% at 30 days, with comparable high limb salvage rates, improving efficiency in a single-stage intervention

of complications. However, a pure endovascular procedure may not always achieve optimal results due to anatomic challenges. Hybrid procedures offer a reasonable option for multilevel disease, combining a

Table 4. Hybrid procedures performed

Procedure type	# cases done
CFA repair+profundoplasty+iliac angioplasty±stenting	18
CFA repair+profundoplasty+iliac angioplasty±stenting+SFA angioplasty±stenting	6
CFA repair+profundoplasty+iliac kissing stents	21
CFA repair+profundoplasty+iliac kissing stents+SFA angioplasty±stenting	2
Iliac angioplasty±stenting+distal bypass	3
Iliac angioplasty±stenting±CFA repair+fem-fem crossover bypass	10
CFA repair+profundoplasty+SFA angioplasty±stenting	13
Iliofemoral bypass±CFA repair+profundoplasty+iliac angioplasty±stenting	5
Iliofemoral bypass±CFA repair+profundoplasty+SFA angioplasty±stenting	2
CFA repair+profundoplasty+SFA angioplasty±stenting+tibial angioplasty	4
Iliofemoral bypass+femoro-popliteal bypass+iliac angioplasty±stenting	2
CFA repair+profundoplasty+iliac angioplasty±stenting+distal bypass	1

CFA: Common femoral artery; SFA: Superficial femoral artery.

without adding risks⁸. In our study, morbidity was 13.7% and mortality was 1.1% both comparable to the literature reports.

Planning is of utmost importance for a successful hybrid intervention and deciding on which type of procedure will be performed for each segment to treat is based on both imaging and physiologic data⁸. Iliac intervention is the most common endovascular intervention reported in combination with femoral endarterectomy or infrainguinal bypass, which are the two most common open procedures performed in hybrid cases⁸. This is consistent with our results with the most common combination being common femoral artery repair + profundoplasty and iliac kissing stents. Other common hybrid procedures performed include: Femoral endarterectomy and distal catheter-based intervention, iliac artery stenting and crossover femoral-femoral artery bypass, SFA intervention and distal bypass to name a few, although there may be many possible combinations⁸. Reports have explained the important technical aspects of the hybrid procedure. Dosluoglu et al.⁹ emphasized that obtaining inflow

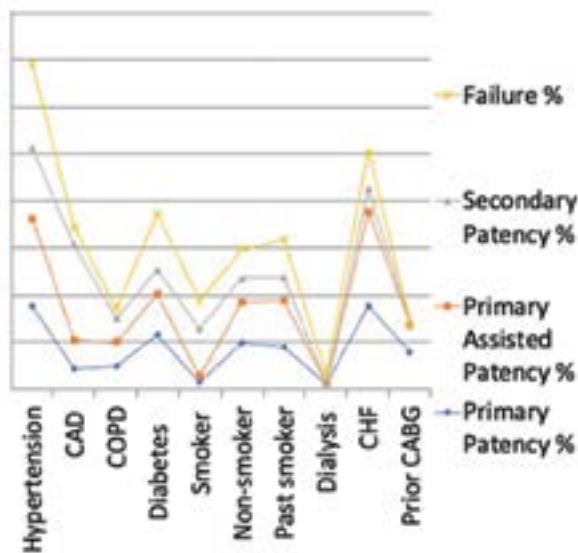


Figure 1. Risk factors and patency rates.

Patency Results (88.5% at 2 years)

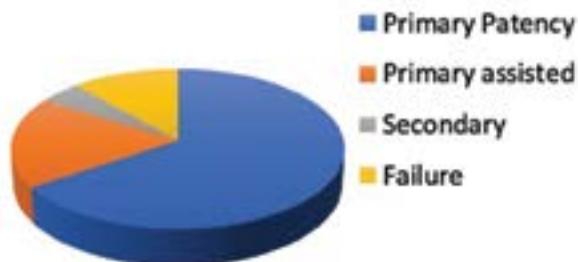


Figure 2. Patency results at 2 years.

and/or outflow guidewire access before performing the arteriotomy is a key maneuver in HT. At our institution this approach has been adopted. In addition, brachial access or multiple accesses (contralateral femoral and transbrachial) are not uncommon in these patients¹⁰. In our study, most common access was unilateral femoral (73.5%) followed by bilateral femoral access in 26.4% of patients.

Results for 12 and 36-month limb salvage rates were excellent in the patients in our study, ranging from 80% to 100%. Piazza et al.¹¹ reported similar results at the Mayo Clinic, with a 3-year patency of 91% for hybrid and 97% for open reconstruction^{2,3}. Another study performed by Nishibe et al.¹⁰ showed a primary patency of 94%, 70% and 70% at 6,12 and

24 months respectively for hybrid procedures performed in 21 limbs with a follow-up of 357 days for endovascular aortoiliac revascularization and common femoral artery endarterectomy². Chang et al.¹² showed improved 5-year primary patency for covered iliac stents compared to bare metal (87% and 53%, respectively) in combination with common femoral artery endarterectomy⁸.

In this study, we treated 87 patients who presented to our institution with multilevel arterial disease, 90% of whom had clinically incapacitating claudication and 10% who presented with critical limb ischemia. We observed patency rates of 88.5% at 2 years (Fig. 2), which compares favorably to the results reported in the literature for these interventions, ranging from 66 to 87%, at 2 years. We used bare metal stents for the iliac arteries treated and had a 5-year primary patency rate of 65%, which is comparable to the literature¹. Important variables to consider are the technical success rate, which was 100% (previous studies reporting rates ranging from 84 to 100%), and the limb salvage rate of 87.4% at 2 years (the literature reports range from 90 to 100%)¹.

There are many important advantages for these procedures, which include shorter operative time, less intraoperative morbidity and mortality, shorter in-hospital stay, and recovery times for patients. They demonstrate similar patency and limb salvage rates, which makes this option viable and effective. In our study, operative time ranged between 90 and 370 min with a mean of 196, which also compares to the literature that reports operative times ranging from 220 to 249 ± 35.378 min¹³⁻¹⁵. Length of stay was consistent with previous studies published¹³⁻¹⁵.

Interesting findings to consider further are the predictors of failure found in this study, especially female gender and congestive heart failure, which should be taken into consideration when deciding to perform a hybrid procedure and explaining the potential risks and benefits to patients and family members. When considering the finding that P2Y12 receptor inhibitor was a predictor of failure following these interventions this may a marker of a more aggressive multi vascular bed disease. Other authors have investigated predictors of failure. Zhou et al.¹⁶ recently reported a comparison between open surgery and hybrid procedures which concluded limb salvage rates at 3 years are similar (76.3 vs. 80.4% p = 0.579) and included 2 major risk factors, which were diabetes and renal insufficiency; these were independent risk factors for decreased primary patency for patients who underwent

hybrid procedures. These risk factors have been previously reported as predictors of failure following isolated endovascular interventions and need be taken into consideration when planning intervention^{16,17}. Our study numbers were likely too small to identify these factors.

The main limitations of our study are that it was a retrospective, nonrandomized analysis within a single institution. Our patient numbers were small however we wished to examine the longer follow-up post procedure.

Conclusions

Hybrid procedures have added to the armamentarium for treatment of patients with multilevel arterial disease and offer a less risky option for elderly patients with multiple comorbid conditions. Hybrid procedures are effective to treat patients with either CLI or claudication. Our study had similar outcomes compared to the literature, with effective patency, amputation and complication rates. We consider it is a safe and effective option for patients with multi-level disease.

Conflicts of interest

The authors declare that there are no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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