

EVT Guidelines: What Has Been Changed?

Aortoiliac Disease: EVT vs. Surgery



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2016 ACC/AHA Guidelines



Recommendations for Endovascular Revascularization for Claudication

COR	LOE	RECOMMENDATIONS
I	A	Endovascular procedures are effective as a revascularization option for patients with lifestyle-limiting claudication and hemodynamically significant aortoiliac occlusive disease (13,25,26,190,194,196,201).
IIa	B-R	Endovascular procedures are reasonable as a revascularization option for patients with lifestyle-limiting claudication and hemodynamically significant femoropopliteal disease (190,197-200,205,206).
IIb	C-LD	The usefulness of endovascular procedures as a revascularization option for patients with claudication due to isolated infrapopliteal artery disease is unknown (211-213).
III: Harm	B-NR	Endovascular procedures should not be performed in patients with PAD solely to prevent progression to CLI (186-189,214-216).

Recommendations for Surgical Revascularization for Claudication

COR	LOE	RECOMMENDATIONS
I	A	When surgical revascularization is performed, bypass to the popliteal artery with autogenous vein is recommended in preference to prosthetic graft material (226-234).
IIa	B-NR	Surgical procedures are reasonable as a revascularization option for patients with lifestyle-limiting claudication with inadequate response to GDMT, acceptable perioperative risk, and technical factors suggesting advantages over endovascular procedures (190,230,235-237).
III: Harm	B-R	Femoral-tibial artery bypasses with prosthetic graft material should not be used for the treatment of claudication (238-240).
III: Harm	B-NR	Surgical procedures should not be performed in patients with PAD solely to prevent progression to CLI (186-189,241).



2011 & 2017 ESC Guidelines



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ESC GUIDELINES

ESC Guidelines on the diagnosis and treatment of peripheral artery diseases

Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries

The Task Force on the Diagnosis and Treatment of Peripheral Artery Diseases of the European Society of Cardiology (ESC)

Endorsed by: the European Stroke Organisation (ESO)

Authors/Task Force Members: Michal Tendera (Chairperson)* (Poland), Victor Aboyans (Co-Chairperson)* (France), Marie-Louise Bartelink (The Netherlands), Iris Baumgartner (Switzerland), Denis Clément (Belgium), Jean-Philippe Collet (France), Alberto Cremonesi (Italy), Marco De Carlo (Italy), Raimund Erbel (Germany), F. Gerry R. Fowkes (UK), Magda Heras (Spain), Serge Kownator (France), Erich Minar (Austria), Jan Ostergren (Sweden), Don Poldermans (The Netherlands), Vincent Riambau (Spain), Marco Roffi (Switzerland), Joachim Röther[†] (Germany), Horst Sievert (Germany), Marc van Sambeek (The Netherlands), Thomas Zeller (Germany).



ESC

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2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)

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Authors/Task Force Members: Victor Aboyans* (ESC Chairperson) (France), Jean-Baptiste Ricco*[†] (Co-Chairperson) (France), Marie-Louise E. L. Bartelink (The Netherlands), Martin Björck[†] (Sweden), Marianne Brodmann (Austria), Tina Cohnert[†] (Austria), Jean-Philippe Collet (France), Martin Czerny (Germany),



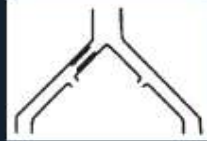
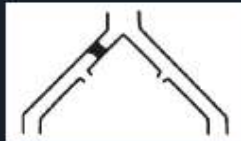
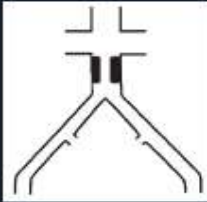
TASC II Classification of Iliac Artery Disease

Endovascular Treatment of Choice



Type A

Preferred Endovascular Treatment



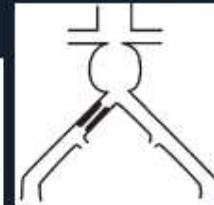
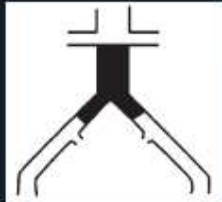
Types B

Preferred Surgical Treatment



Types C

Surgical Treatment of Choice



Type D



2011 ESC Guidelines



Recommendations	Class ^a	Level ^b
When revascularization is indicated, an endovascular-first strategy is recommended in all aortoiliac TASC A–C lesions.	I	C
A primary endovascular approach may be considered in aortoiliac TASC D lesions in patients with severe comorbidities, if done by an experienced team.	IIb	C
Primary stent implantation rather than provisional stenting may be considered for aortoiliac lesions.	IIb	C



2017 ESC Guidelines on Revascularization of Aorto-iliac Occlusive Lesions



Recommendations	Class ^a	Level ^b
An endovascular-first strategy is recommended for short (i.e. <5 cm) occlusive lesions. ²⁹¹	I	C
In patients fit for surgery, aorto-(bi)femoral bypass should be considered in aorto-iliac occlusions. ^{281,292,293}	IIa	B
An endovascular-first strategy should be considered in long and/or bilateral lesions in patients with severe comorbidities. ^{288,294,295}	IIa	B
An endovascular-first strategy may be considered for aorto-iliac occlusive lesions if done by an experienced team and if it does not compromise subsequent surgical options. ^{76,281–283,286}	IIb	B
Primary stent implantation rather than provisional stenting should be considered. ^{294–296}	IIa	B
Open surgery should be considered in fit patients with an aortic occlusion extending up to the renal arteries.	IIa	C
In the case of ilio-femoral occlusive lesions, a hybrid procedure combining iliac stenting and femoral endarterectomy or bypass should be considered. ^{297–300}	IIa	C
Extra-anatomical bypass may be indicated for patients with no other alternatives for revascularization. ³⁰¹	IIb	C

Level C: Consensus of opinion of the experts and/or small studies, retrospective studies, registries



Change in ESC Guidelines I



- No recommendations according to TASC II lesion types
- An endovascular-first strategy should be considered in long and/or bilateral lesions **in patients with severe comorbidities.** (Class IIa)
- An endovascular-first strategy may be considered for aorto-iliac occlusive lesions if done by an experienced team and if it does not compromise subsequent surgical options. **(Class IIa => IIb)**
- Primary stenting rather than provisional stenting **(class IIb => IIa)**



Change in ESC Guidelines II



- Recommendation of bypass surgery for aorto-iliac or aorto-bi-femoral occlusions (class IIa) **New!**
- In the case of ilio-femoral occlusive lesions, a hybrid procedure combining iliac stenting and femoral endarterectomy or bypass should be considered. (class IIa) **New!**
- Extra-anatomical bypass may be indicated for patients with no other alternatives for revascularization (class IIb) **New!**



2017 Guideline in Full Text



10.5.3. Revascularization for intermittent claudication. The anatomical location and extension of arterial lesions has an impact on revascularization options.

10.5.3.1. Aorto-iliac lesions. Isolated aorto-iliac lesions are a common cause of claudication. In the case of short stenosis/occlusion (<5 cm) of iliac arteries, endovascular therapy gives good long-term patency ($\geq 90\%$ over 5 years) with a low risk of complications.²⁸¹ In cases of ilio-femoral lesions, a hybrid procedure is indicated, usually endarterectomy or bypass at the femoral level combined with endovascular therapy of iliac arteries, even with long occlusions. If the occlusion extends to the infrarenal aorta, covered endovascular reconstruction of an aortic bifurcation can be considered. In a small series, 1- and 2-year primary patency was 87% and 82%, respectively.²⁸² If the occlusion comprises the aorta up to the renal arteries and iliac arteries, aorto-bifemoral bypass surgery is indicated in fit patients with severe life-limiting claudication.²⁸³ In these extensive lesions, endovascular therapy may be an option, but it is not free of perioperative risk and long-term occlusion. In the absence of any other alternative, extra-anatomic bypass (e.g. axillary to femoral bypass) may be considered.

References

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- 283 Anderson JL, Antman EM, Harold JG, Jessup M, O'Gara PT, Pinto FJ, et al. Clinical practice guidelines on perioperative cardiovascular evaluation: collaborative efforts among the ACC, AHA, and ESC. *Circulation* 2014;**130**:2213–4.



No RCT !

Limited large scale data!



Early Mortality: Endo vs. OP

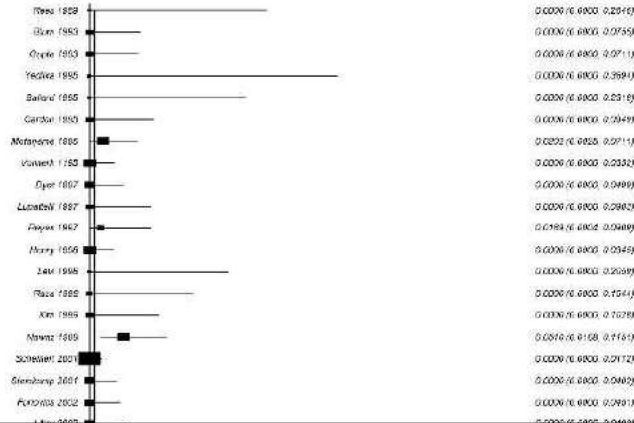


29 open bypass studies (n=3733) and 28 endovascular Tx (n=16250)

A

Endovascular Mortality

Proportion meta-analysis plot [random effects]

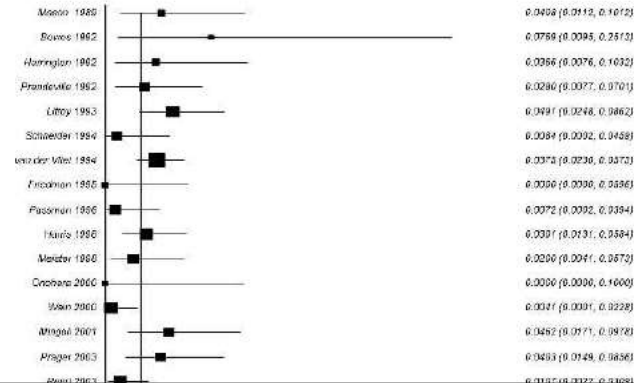


0.7% (95% CI 0.3% to 1.2%)

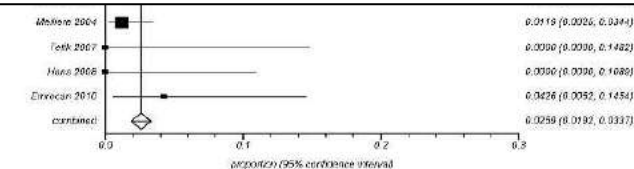
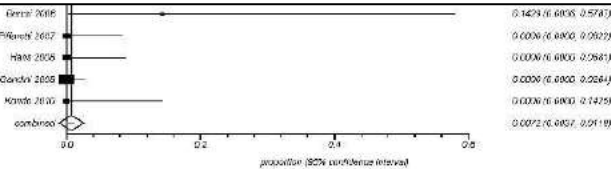
B

Direct Open Mortality

Proportion meta-analysis plot [random effects]



2.6% (95% CI 2.0% to 3.4%)



Complications: Endo vs. OP



	Endovascular Treatment	Direct/Open Bypass	p
Any complication	13.4% (10.4% to 16.7%)	18.0% (11.0% to 25.0%)	<0.001
Cardiac	1.7% (0.3% to 4.1%)*	4.2% (2.4% to 6.6%)	0.020
Gastrointestinal	—	4.9% (2.4% to 8.2%)	
Pulmonary	—	3.4% (1.8% to 5.5%)	
Stroke	—	1.1% (0.5% to 2.0%)	
Renal	2.4% (0.4% to 6.0%)*	2.6% (1.8% to 3.6%)	1.0
Bleeding	2.9% (0.5% to 7.2%)*	1.5% (0.6% to 2.7%)	1.0
Early thrombosis	4.9% (2.7% to 7.6%)	3.4% (1.9% to 5.4%)	0.358
Early stent/vessel occlusion	3.8% (1.2% to 7.8%)	—	
Graft failure	—	1.1% (0.3% to 2.3%)*	
Pneumonia	—	1.4% (0.5% to 2.7%)	
Wound infection	—	4.6% (2.7% to 7.0%)	
Graft infection	—	1.0% (0.3% to 1.7%)	
Wound seroma	—	0.6% (0.1% to 1.6%)*	
Pseudoaneurysm	2.6% (1.4% to 4.2%)	—	
Arterial perforation/rupture	2.4% (1.2% to 4.1%)	—	
Arterial dissection	3.6% (2.1% to 5.4%)	—	
Distal embolization	4.9% (2.9% to 7.3%)	1.2% (0.1% to 3.4%)	0.084
Hematoma	4.4% (3.3% to 5.6%)	—	
Fever	11.3% (2.5% to 25.2%)*	—	
Lymphocele	—	2.2% (0.5% to 5.1%)	



Danish Vascular Registry



Mortality and complications after aortic bifurcated bypass procedures for chronic aortoiliac occlusive disease

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Henrik Sillesen, MD, DMSc,^a Henrik Nielsen,^d and Jonas P. Eiberg, MD, PhD,^{a,b} *Copenhagen and Aarhus, Denmark*

Objective: Open surgery has given way to endovascular grafting in patients with aortoiliac occlusive disease. The growing use of endovascular grafts means that fewer patients with aortoiliac occlusive disease have open surgery. The declining open surgery caseload challenges the surgeon's operative skills, particularly because open surgery is increasingly used in those patients who are unsuitable for endovascular repair and hence technically more demanding. We assessed the early outcome after aortic bifurcated bypass procedures during two decades of growing endovascular activity and identified preoperative risk factors.

Methods: Data on patients with chronic limb ischemia were prospectively collected during a 20-year period (1993 to 2012). The data were obtained from the Danish Vascular Registry, assessed, and merged with data from The Danish Civil Registration System.

Results: We identified 3623 aortobifemoral and 144 aortobiliac bypass procedures. The annual caseload fell from 323 to 106 during the study period, but the 30-day mortality at 3.6% (95% confidence interval [CI], 3.0-4.1) and the 30-day major complication rate remained constant at 20% (95% CI, 18-21). Gangrene (odds ratio [OR], 3.3; 95% CI, 1.7-6.5; $P = .005$) was the most significant risk factor for 30-day mortality, followed by renal insufficiency (OR, 2.5; 95% CI, 1.1-5.8; $P = .035$) and cardiac disease (OR, 2.1; 95% CI, 1.4-3.1; $P < .001$). Multiorgan failure, mesenteric ischemia, need for dialysis, and cardiac complications were the most lethal complications, with mortality rates of 94%, 44%, 38%, and 34%, respectively.

Conclusions: Aortic bifurcated bypass is a high-risk procedure. Although open surgery has increasingly given way to endovascular repair, 30-day outcomes have remained stable during the past decade. Thus, it is still acceptable to consider an aortic bifurcated bypass whenever endovascular management is not feasible. (*J Vasc Surg* 2015;62:75-82.)

N=3767

30-day mortality: 3.6%

Major complication: 20%

Wound complication: 13%



Metaanalysis for TASC C/D lesions

Early and late outcomes of percutaneous treatment of TransAtlantic Inter-Society Consensus class C and D aorto-iliac lesions

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Objectives: The aim of this study was to analyze the technical success and long-term patency of the endovascular treatment of TransAtlantic Inter-Society Consensus (TASC) C and D aorto-iliac arterial lesions.

Methods: All studies reporting original series of patients published in English between 2000 and 2010 were enrolled into meta-analysis. Separate meta-analyses were performed for groups with immediate technical success, 12-month patency, and long-term outcomes. Subgroup analyses were performed to determine if there were differences in outcomes between patients with varying types of lesions (TASC C or D lesions) or between different stenting strategies, including primary or selective stenting.

Results: Sixteen articles consisting of 958 patients were enrolled in this meta-analysis. The pooled estimate for technical success was 92.8% (95% confidence interval [CI], 89.8%-95.0%, 749 cases). Primary patency at 12 months was 88.7% (95% CI, 85.9%-91.0%, 787 cases). Subgroup analyses demonstrated a technical success rate of 93.7% (95% CI, 88.9%-96.5%) and a 12-month primary patency rate of 89.6% (95% CI, 84.8%-93.0%) for TASC C lesions. For TASC D lesions, these rates were 90.1% (95% CI, 76.6%-96.2%) and 87.3% (95% CI, 82.5%-90.9%), respectively. The technical success and 12-month primary patency rates for primary stenting were 94.2% (95% CI, 91.8%-95.9%) and 92.1% (95% CI, 89.0%-94.3%), respectively; for selective stenting, these rates were 88.0% (95% CI, 67.9%-96.2%) and 82.9% (95% CI, 72.2%-90.0%), respectively. The long-term, primary patency rates for patients receiving primary stenting were significantly better than those receiving selective stenting. Publication bias was not significant for these analyses.

Conclusions: This study demonstrates that early and midterm outcomes of endovascular treatment for TASC C and D aorto-iliac lesions were acceptable, with a better patency for primary stenting than selective stenting. (J Vasc Surg 2011; 53:1728-37.)



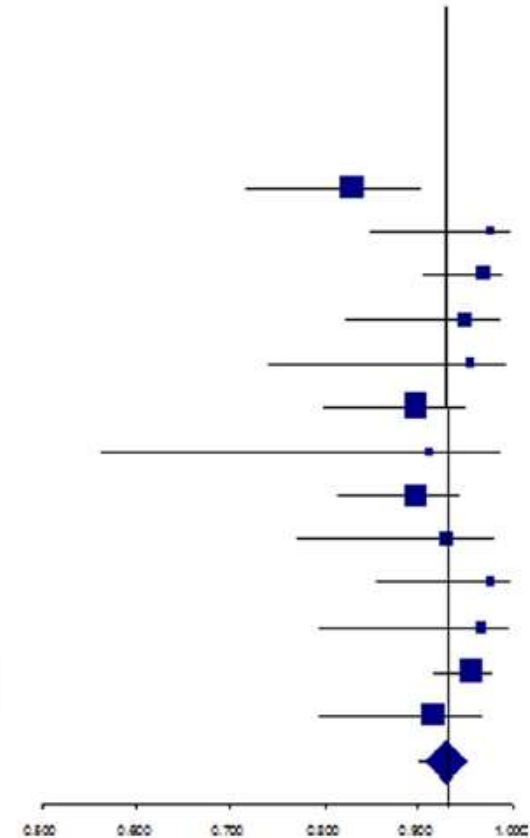
Technical Success



Studies	weight	Technical success rate (%)	95%CI (%)
AbuRahma [8]	14.60%	83.0	71.5 to 90.5
Ahn [9]	3.30%	97.6	84.6 to 99.7
Balzer [10]	7.50%	96.9	90.4 to 99.0
Hans [13]	5.80%	95.0	82.1 to 98.7
Jackson [14]	3.30%	95.5	73.8 to 99.4
Kashyap[15]	12.50%	89.6	79.7 to 95.0
Krankenbergl16]	3.10%	91.0	56.3 to 98.7
Kumakura [17]	14.30%	89.6	81.3 to 94.5
Moise [18]	6.10%	93.0	77.0 to 98.1
Piffaretti [20]	3.30%	97.7	85.2 to 99.7
Powell [21]	3.30%	96.6	79.2 to 99.5
Sebastian [22]	13.70%	95.6	91.4 to 97.8
Sharafuddin [23]	9.20%	91.5	79.4 to 96.8
total	100.00%	92.8	89.8 to 95.0

Heterogeneity: $\tau^2 = 0.15$; $\text{Chi}^2 = 18.12$, $\text{df} = 12$ ($P = 0.11$); $I^2 = 34\%$

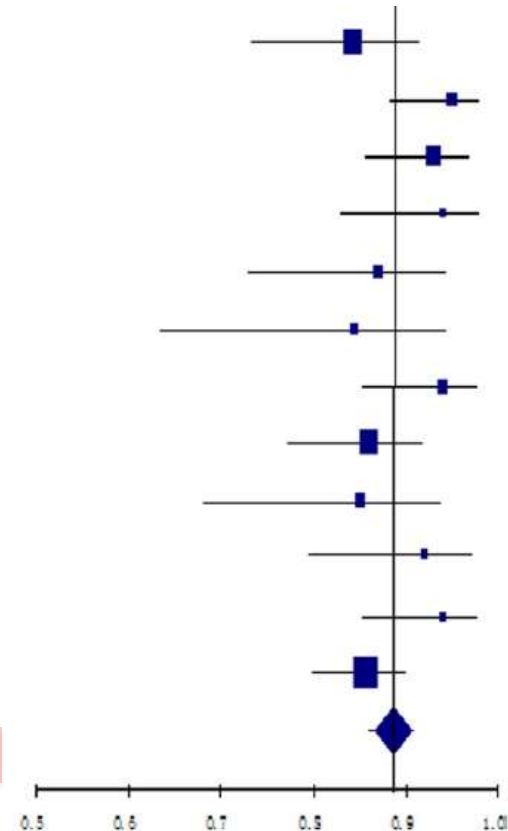
Test for overall effect: $Z = 12.92$ ($P < 0.00001$)



Primary Patency at 12 months



Studies	weight	Primary patency rate at 12 months (%)	95%CI (%)
AbuRahma[8]	11.30%	84.3	73.0 to 91.4
Balzer [10]	6.40%	95.0	88.0 to 98.0
Björnses [11]	8.40%	93.0	85.5 to 96.8
Do [12]	4.20%	94.0	82.6 to 98.1
Hans [13]	6.80%	87.0	72.7 to 94.4
Jackson [14]	4.50%	84.4	63.1 to 94.5
Kashyap [15]	5.80%	94.0	85.1 to 97.7
Kumakura [17]	13.80%	86.0	77.1 to 91.8
Moise [18]	6.00%	85.0	67.8 to 93.8
Piffaretti [20]	4.90%	92.0	79.3 to 97.2
Powell [21]	4.90%	94.0	85.1 to 97.7
Sixt [22]	23.10%	85.7	79.8 to 90.1
Total	100%	88.7	85.9 to 91.0



Heterogeneity: $\tau^2 = 0.03$; $\chi^2 = 12.76$, $df = 11$ ($P = 0.31$); $I^2 = 14\%$
 Test for overall effect: $Z = 15.86$ ($P < 0.00001$)



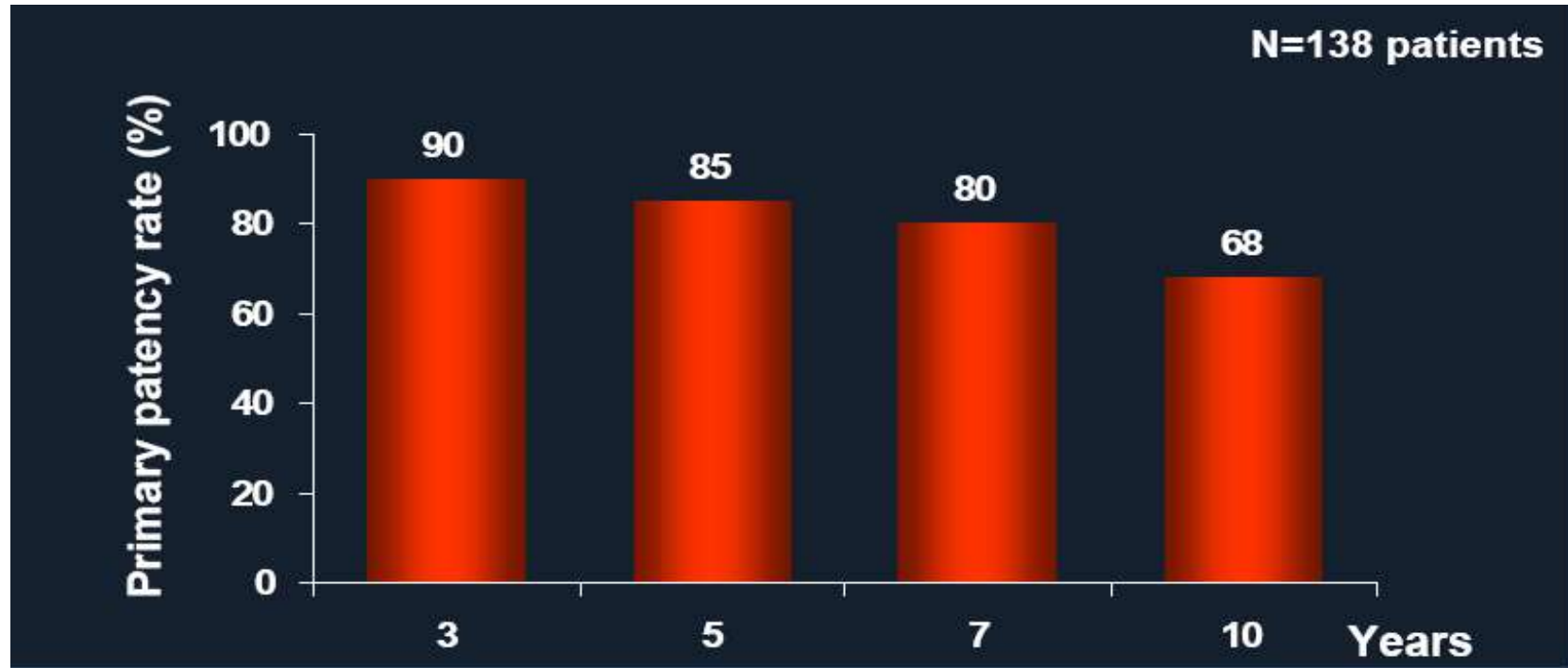
Long-term Patency



<i>Time period (months)</i>	<i>Subgroup analysis</i>	<i>Studies (n)</i>	<i>Patients (n)</i>	<i>Primary patency (%)</i>	<i>Primary patency (%) 95% CI</i>		<i>Significance</i>
12	TASC C	6	279	89.6	84.8	93.0	NS
	TASC D	7	266	87.3	82.5	90.9	
	PS	8	433	92.1	89.0	94.3	
	SS	5	354	82.9	72.2	90.0	
24	TASC C	5	166	87.5	73.3	94.6	NS
	TASC D	6	200	79.3	70.9	85.7	
	PS	7	404	87.3	83.7	90.3	
	SS	5	354	72.6	63.6	80.0	
36	TASC C	5	166	79.9	64.8	89.6	NS
	TASC D	6	200	76.0	65.0	84.4	
	PS	6	382	82.3	76.3	87.0	
	SS	5	354	64.9	63.5	74.7	
48	TASC C	3	99	79.2	43.8	94.6	NS
	TASC D	3	62	66.2	47.6	80.8	
	PS	2	88	79.1	55.8	91.9	
	SS	3	310	64.4	49.7	76.7	
60	TASC C	4	124	61.8	36.7	81.9	NS
	TASC D	4	109	66.6	55.2	76.2	
	PS	2	120	67.1	53.8	78.0	
	SS	3	310	63.0	48.2	72.7	



Percutaneous Treatment in Iliac Artery Occlusion: Long-term Results



Gandini R, Cardiovasc Intervent Radiol 2008;31:1069



Complications of Endovascular therapy

Perioperative Complications After Aorto-iliac Stenting: Associated Factors and Impact on Follow-up Cardiovascular Prognosis

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Objectives: To investigate factors associated with 30-day perioperative complications (POC) after aorto-iliac (AI) stenting, and to compare follow-up cardiovascular prognosis between patients with and without POC.

Materials and methods: This was a retrospective multicenter study. We used a multicenter database of 2012 consecutive patients who successfully underwent AI stenting for peripheral arterial disease in 18 centers in Japan from January 2005 to December 2009 to analyze independent predictors of POC and impact of POC on prognosis by logistic regression and a Cox proportional hazard regression model, respectively.

Results: Mean age was 71 ± 9 years (median: 72 years; range: 37–98 years), and 1,636 patients (81%) were men. POC occurred in 126 patients (6.3%). In multivariate logistic regression analysis, old age (≥ 80 years), critical limb ischemia (CLI), and Trans Atlantic Inter-Societal Consensus (TASC) II class C/D were independently associated with POC with adjusted odds ratios and 95% confidence intervals (CI) of 1.9 (1.3–2.9), 2.3 (1.5–3.4), and 2.4 (1.6–3.4), respectively. Out of 2012 patients, 1995 were followed up for more than 30 days (mean: 2.6 ± 1.5 years; range: 2–2,393 days). In a Cox hazard regression model adjusted for baseline clinical characteristics, POC was positively and independently associated with follow-up major adverse cardiac events (adjusted hazard ratio [HR]: 1.9; 95% CI: 1.3–2.8; $p = .002$), but not with major adverse limb events and target lesion revascularization (adjusted HR: 1.4; 95% CI: 0.7–2.7; $p = .25$; and adjusted HR: 1.2; 95% CI 0.6–2.6; $p = .568$), respectively.

Conclusions: Age >80 years, CLI, and TASC C/D lesion were positively associated with POC after AI stenting. Occurrence of POC appears to adversely affect follow-up cardiovascular, but not limb and vessel prognosis.

Table 1. Perioperative complications at 30 days.

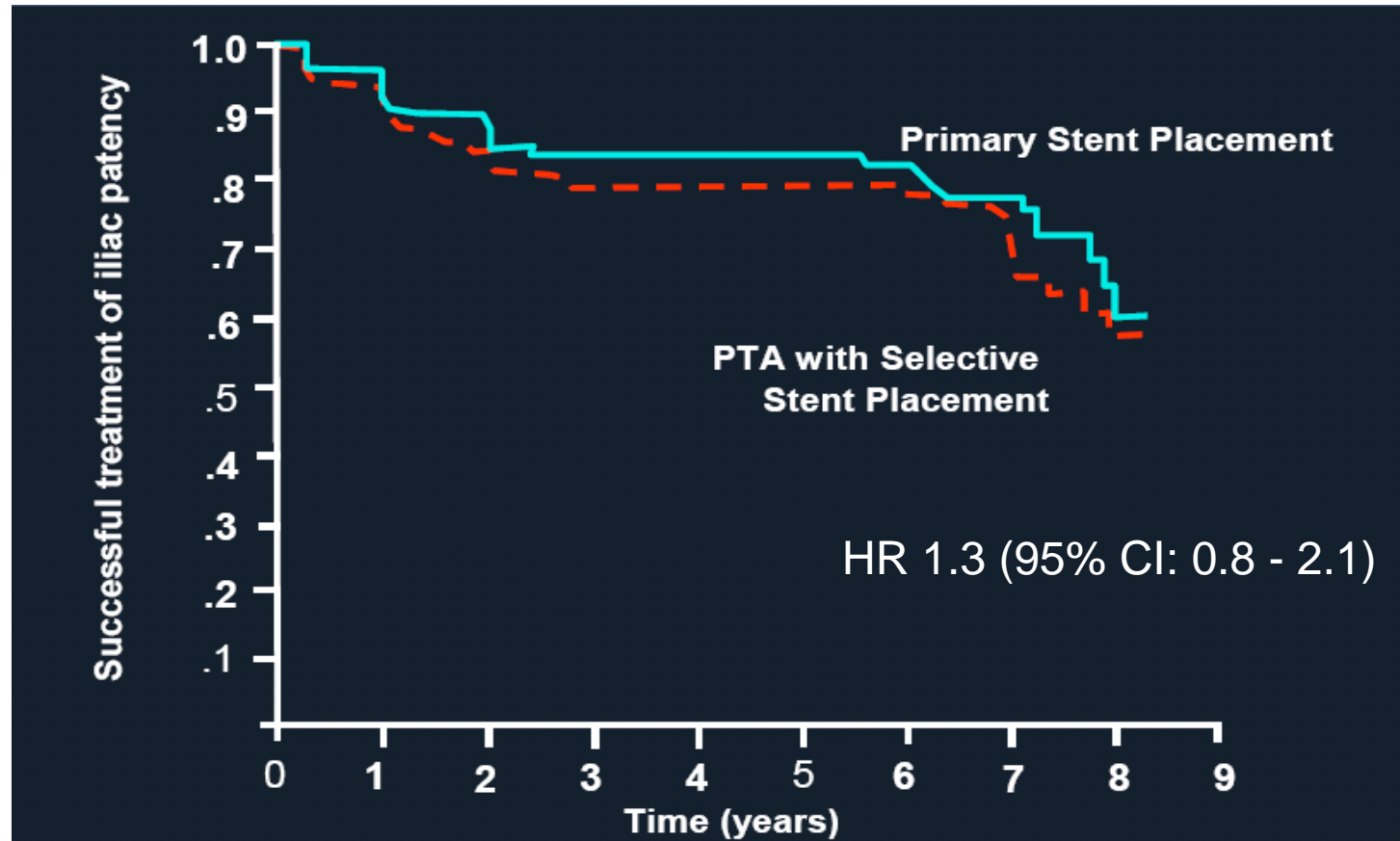
Variables % , n	6.3 (126/2012)
Death	0.3 (7)
Myocardial infarction	0.2 (3)
Stroke	0.4 (7)
Worsening of renal function	0.9 (17)
Intestinal bleeding	0.2 (4)
Stent thrombosis	0.3 (6)
Pseudoaneurysm	0.3 (6)
Vessel perforation	0.2 (4)
Distal embolization	1.6 (32)
Puncture site hematoma	1.6 (33)
Others	0.3 (7)



The Dutch Iliac Stent Trial



279 patients
with iliac a.
stenosis ≤ 10 cm
or
CTO ≤ 5 cm



STAG Trial: Stent vs. PTA



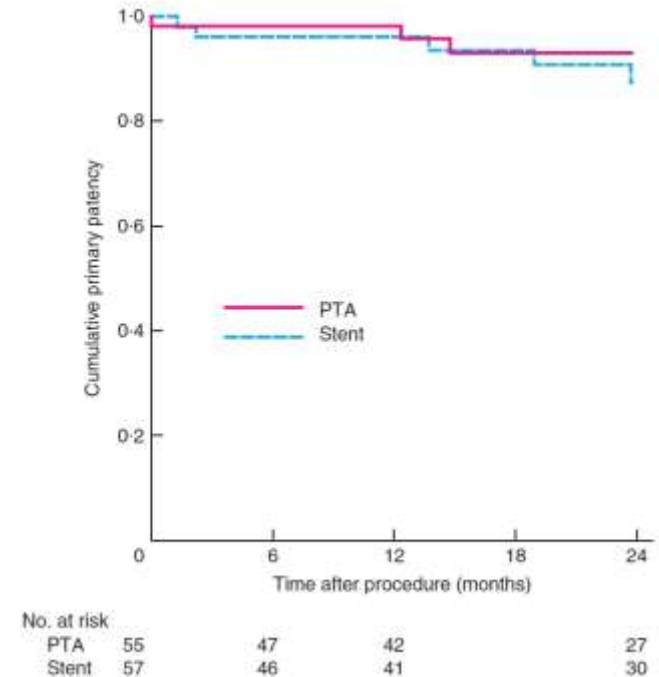
Randomized trial (n=112)

Total occlusions

Lesion length < 8cm

Mean length: ~5 cm

	PTA (n = 55)	Stent (n = 57)	P†
Technical success	46 (84)	56 (98)	0.007
Secondary stenting procedure*	9 of 57 (16)	1 (2)	0.007
Secondary non-stenting procedure	9 (16)	3 (5)	0.050
Complications			
Major	11 (20)	3 (5)	0.010
Minor	2 (4)	1 (2)	0.537



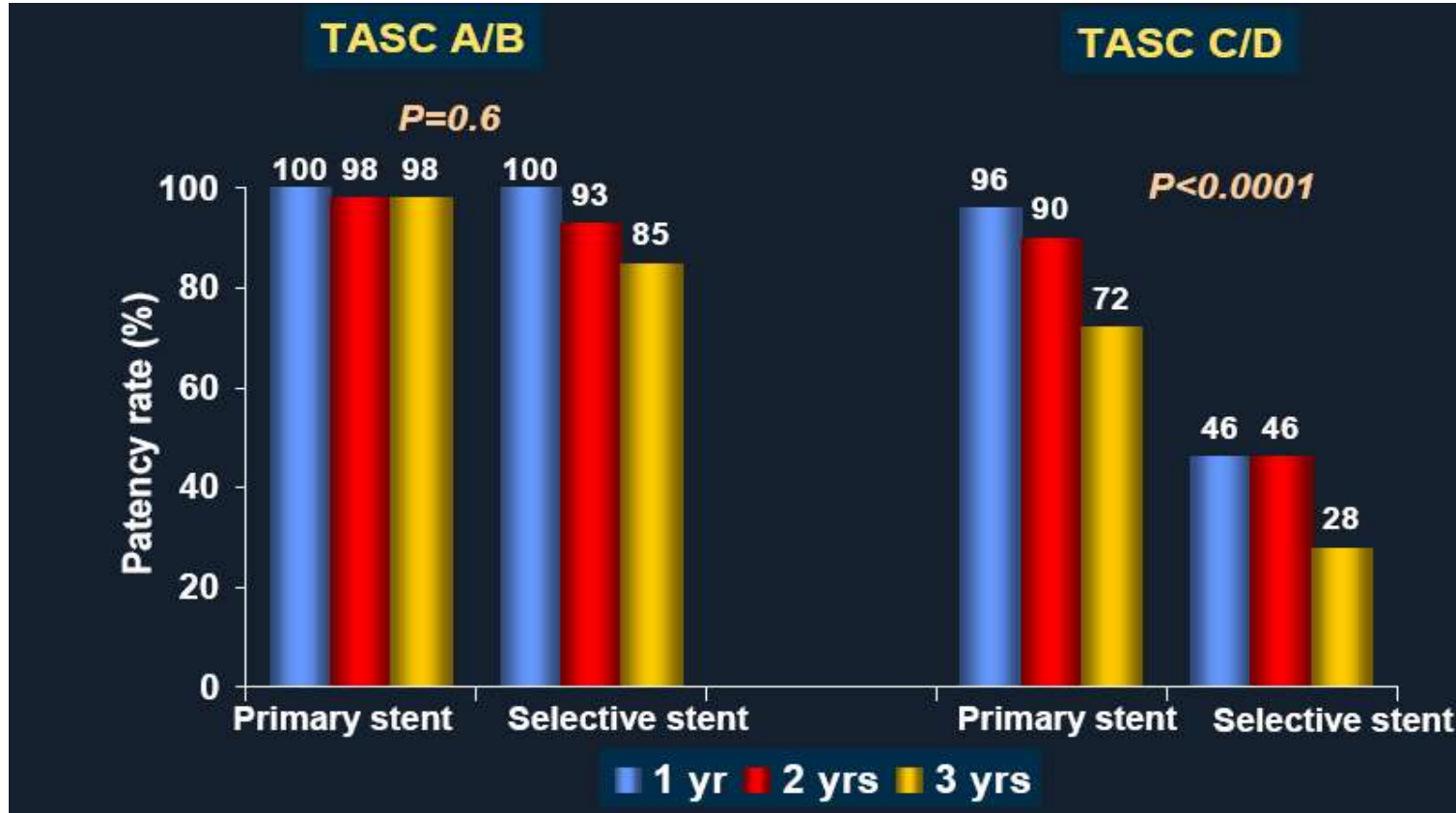
Primary vs. Provisional Stenting: Meta-analysis

<i>Technical success</i>							
<i>Subgroups</i>	<i>Subgroups</i>	<i>Studies (n)</i>	<i>Patients (n)</i>	<i>Technical success (%)</i>	<i>Technical success 95% CI</i>		<i>Statistics: Tests used and results</i>
TASC classification	TASC C	3	176	93.7	88.9	96.5	
	TASC D	3	158	90.1	76.6	96.2	Heterogeneity: $\tau^2 = 0.48$; $\chi^2 = 5.28$, $df = 2$ ($P = .07$); $I^2 = 62\%$ Test for overall effect: $Z = 4.24$ ($P < .0001$)
Stenting primary vs secondary	Primary	9	565	94.2	91.8	95.9	Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 6.31$, $df = 8$ ($P = .61$); $I^2 = 0\%$ Test for overall effect: $Z = 14.74$ ($P < .00001$)
	Selective	5	184	88	67.9	96.2	

<i>12 months primary patency</i>							
<i>Subgroups</i>	<i>Subgroups</i>	<i>Studies (n)</i>	<i>Patients (n)</i>	<i>12-month primary patency (%)</i>	<i>12-month primary patency 95% CI</i>		<i>Statistics: tests used and results</i>
TASC classification	TASC C	6	279	89.6	84.8	93.0	
	TASC D	7	266	87.3	82.5	90.9	Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 5.11$, $df = 6$ ($P = .53$); $I^2 = 0\%$ Test for overall effect: $Z = 10.02$ ($P < .00001$)
Stenting primary vs secondary	Primary stenting	8	433	92.1	89.0	94.3	Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 6.51$, $df = 7$ ($P = .48$); $I^2 = 0\%$ Test for overall effect: $Z = 13.18$ ($P < .00001$)
	Selective stenting	5	354	82.9	72.2	90.0	



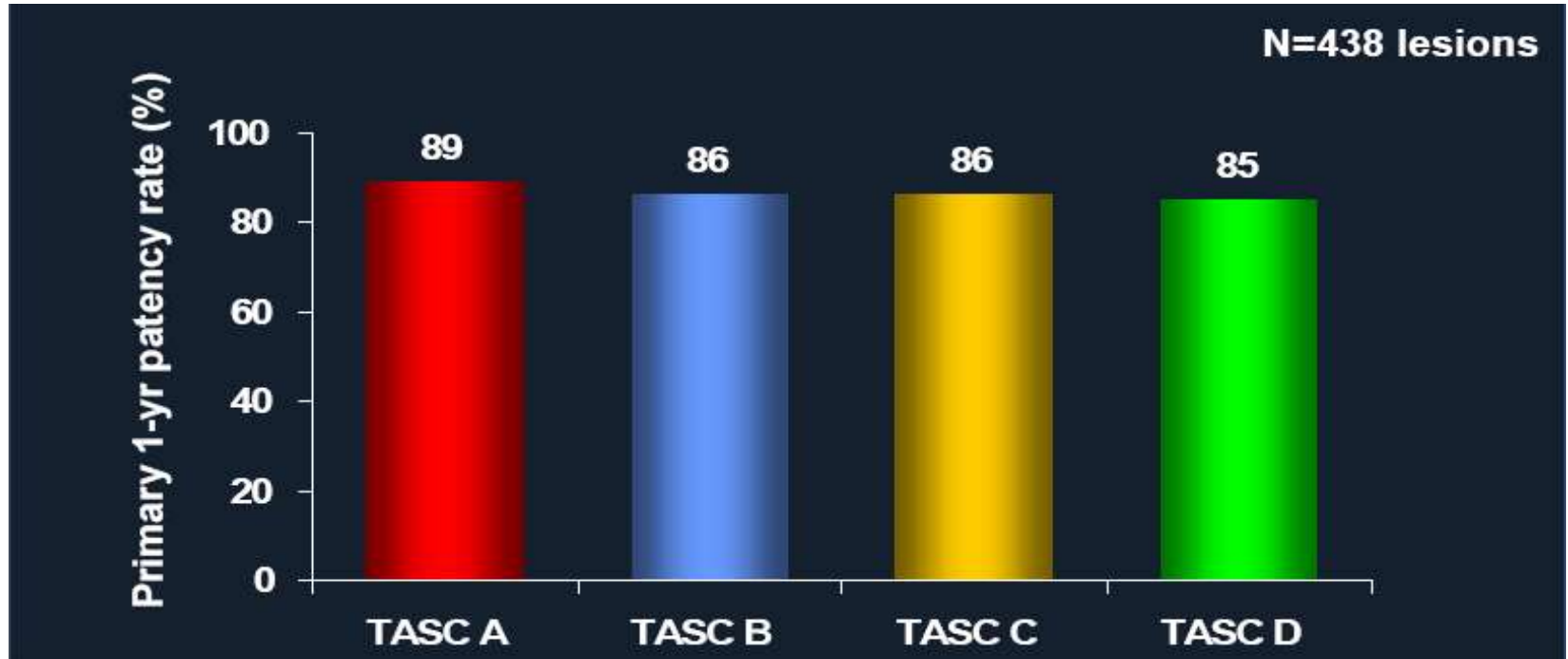
Primary Iliac Stenting vs. Provisional Stenting



AbuRahma AF, *J Vasc Surg* 2007;46:965



Endovascular Therapy for Aortoiliac Occlusive Disease



Sixt S, J Endovasc Ther 2008;15:408

BRAVISSIMO Registry:



24-Month Data from the BRAVISSIMO: A Large-Scale Prospective Registry on Iliac Stenting for TASC A & B and TASC C & D Lesions

Gianmarco de Donato,¹ Marc Bosiers,² Francesco Setacci,³ Koen DeLoose,³ Giuseppe Galzerano,⁴ Jürgen Verbitz,⁴ Patrick Peeters,⁴ and Carlo Setacci,¹ Siena and Rome, Italy; and Dendermonde and Bonheiden, Belgium

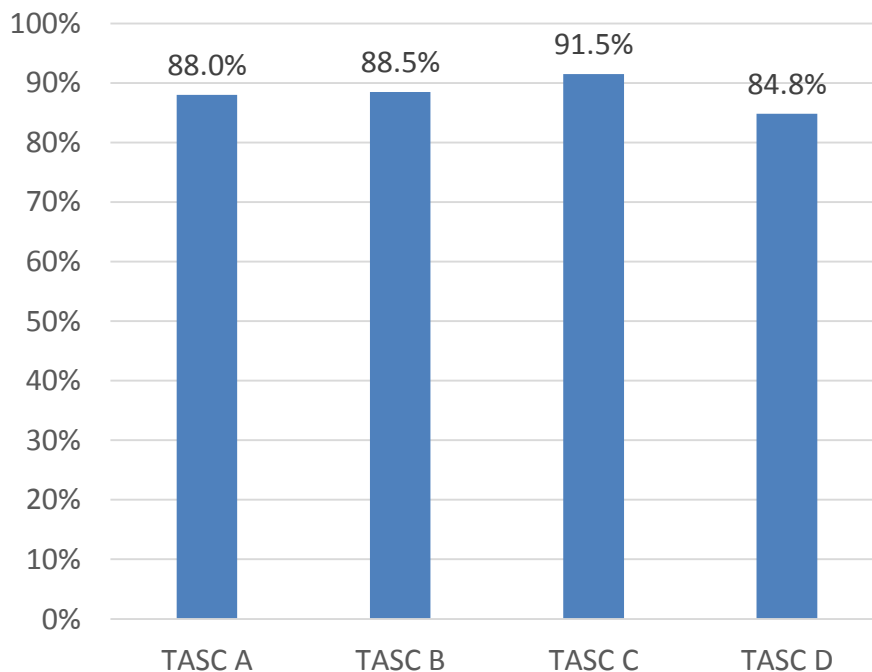
Background: To evaluate the 24-month outcome of stenting in Trans-Atlantic Inter-Society Consensus (TASC) A & B and TASC C & D iliac lesions in a controlled setting.

Methods: The BRAVISSIMO study is a prospective, nonrandomized, multicenter, multinational, monitored registry including 325 patients with aortoiliac lesions. The end point is the primary patency at 24 months, defined as a target lesion without a hemodynamically significant stenosis on duplex ultrasound (>50%, systolic velocity ratio >2.0). A separate analysis for TASC A & B versus TASC C & D population is performed.

Results: Between July 2009 and September 2010, 190 patients with TASC A or B and 135 patients with TASC C or D aortoiliac lesions were included. The demographic data were comparable for TASC A & B cohort and TASC C & D cohort. Technical success was 100%. Significantly more balloon-expandable stents were deployed in TASC A & B lesions, and considerably more self-expanding stents were placed in TASC C & D ($P = 0.01$). The 24-month primary patency rate after 24 months for the total population was 87.9% (88.0% for TASC A, 88.5% for TASC B, 91.8% for TASC C, and 84.8% for TASC D). No statistically significant difference was shown when comparing these groups. The 24-month primary patency rates were 92.1% for patients treated with the self-expanding stent, 85.2% for patients treated with the balloon-expandable stent, and 75.3% for patients treated with a combination of both stents ($P = 0.06$). Univariate and multivariable regression analyses using Cox proportional hazards model identified only kissing stent configuration ($P = 0.0012$) and obesity ($P = 0.0109$) as independent predictors of restenosis (primary patency failure). Interestingly, as all TASC groups enjoyed high levels of patency, neither TASC category nor lesion length was predictive of restenosis.

Conclusion: The 24-month data from this large, prospective, multicenter study confirm that endovascular therapy may be considered the preferred first-line treatment option of iliac lesions, irrespectively of TASC lesion category.

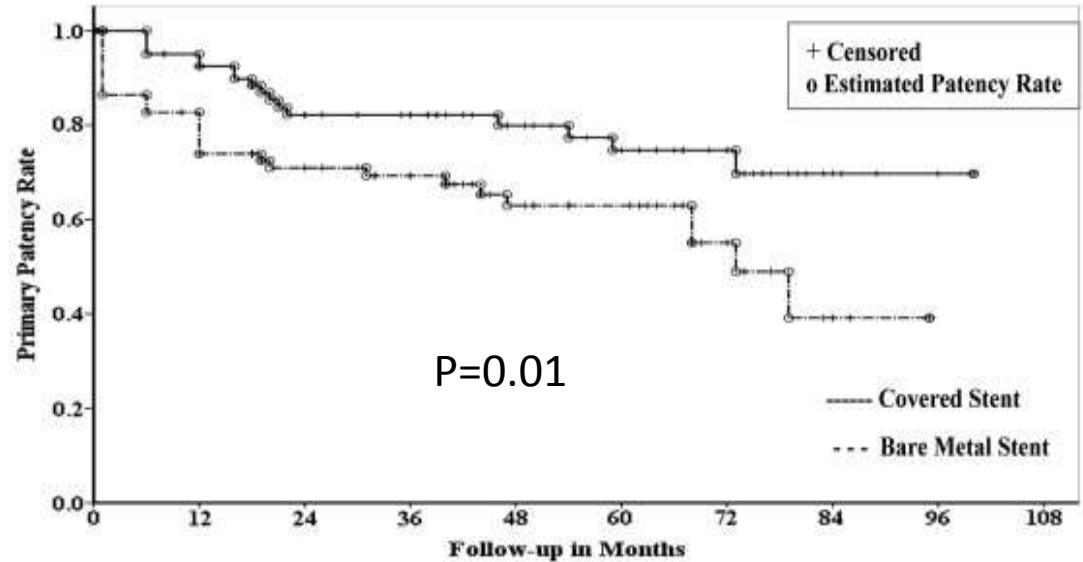
Primary Patency at 24 months



COBEST Trial: Covered Stent vs BMS



(Advanta V12; Atrium)



Time (Months)	0	12	24	36	48	60	72	84	96
Advanta V12 Stent (n. at risk)	83	74	52	47	35	28	17	5	2
Standard Error (%)	-	2.95	4.54	4.54	4.93	5.84	5.84	7.27	7.27
BMS (n. at risk)	85	66	46	40	28	23	10	3	1
Standard Error (%)	-	4.89	5.13	5.27	5.94	5.94	7.36	11.2	11.2



CERAB Technique



Three-year outcome of the covered endovascular reconstruction of the aortic bifurcation technique for aortoiliac occlusive disease

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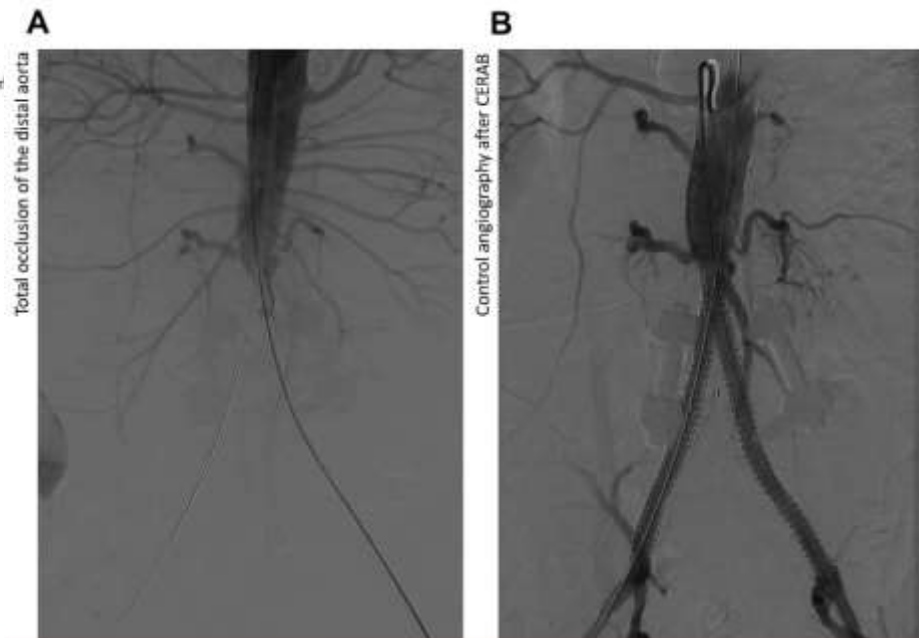
ABSTRACT

Objective: The objective of this study was to demonstrate the 3-year outcome of the covered endovascular reconstruction of the aortic bifurcation (CERAB) technique for the treatment of extensive aortoiliac occlusive disease (AIOD).

Methods: Between February 2009 and July 2016, all patients treated with the CERAB technique for AIOD were identified in the local databases of two centers and analyzed. Demographics and lesion characteristics were scored. Follow-up consisted of clinical assessment, duplex ultrasound, and ankle-brachial indices. Patency rates and clinically driven target lesion revascularization were calculated by Kaplan-Meier analysis.

Results: Of 130 patients (69 male and 61 female) treated, 68% were diagnosed with intermittent claudication and 32% suffered from critical limb ischemia. The majority (89%) were TransAtlantic Inter-Society Consensus II D lesions, and the remaining were B and C lesions (both 5%). Median follow-up was 24 months (range, 0-67 months). The technical success rate was 97%, and 67% of cases were performed completely percutaneously. The ankle-brachial index improved significantly from 0.65 ± 0.22 preoperatively to 0.88 ± 0.15 after the procedure. The 30-day minor and major complication rate was 33% and 7%. The median hospital stay was 2 days (range, 1-76 days). At 1 year and 5 years of follow-up, 94% and 96% of the patients clinically improved at least one Rutherford category (2% and 0% unchanged, 4% and 4% worsened). Limb salvage rate was 98% at 1 year and 97% at 3 years of follow-up. Primary, primary assisted, and secondary patency was 86%, 91%, and 97% at 1 year; 84%, 89%, and 97% at 2 years; and 82%, 87%, and 97% at 3 years. Freedom from clinically driven target lesion revascularization was 87% at 1-year follow-up and 86% at both 2-year and 3-year follow-up.

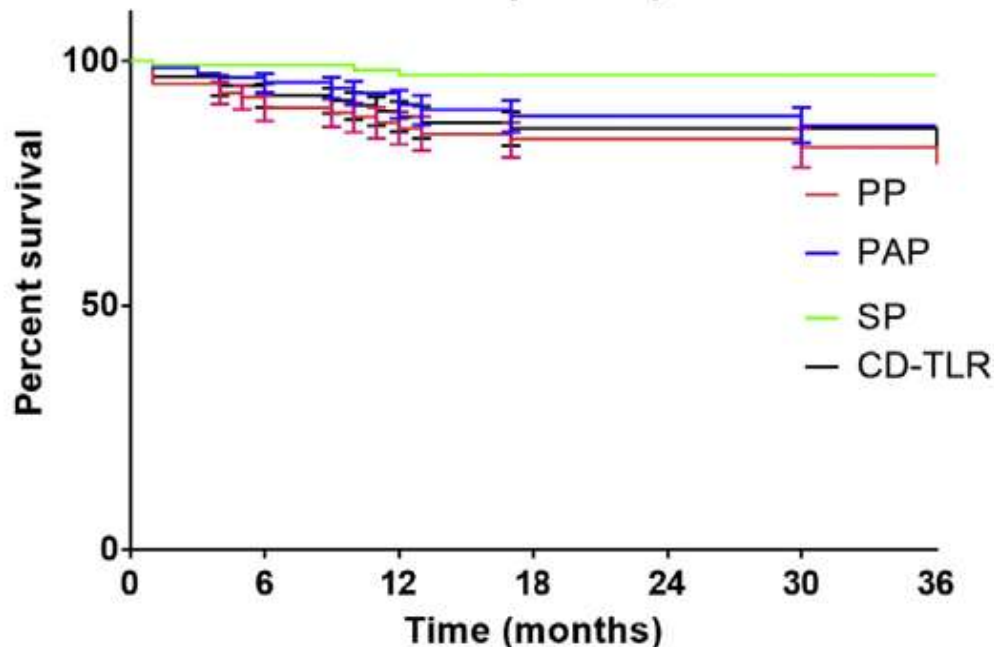
Conclusions: The CERAB technique is a safe and feasible technique for the treatment of extensive AIOD with good 3-year results regarding patency and clinical improvement. (J Vasc Surg 2018;67:3438-47.)



CERAB Techniqiue



Calculated patency rates



	0	6	12	18	24	30	36
Primary patency (PP)	0	6	12	18	24	30	36
No. At Risk	126	91	79	69	56	47	37
Patency (%)	100	90.4	86.2	83.9	83.9	82.1	82.1
SE (%)	0.0	2.8	3.3	3.6	3.6	4.0	4.0



Hybrid Procedures



N = 60

Role of simple and complex revascularization procedures in lower extremity occlusive disease

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Objective: Hybrid reconstructions have been increasingly used for lower extremity occlusive disease. The goal of this study was to compare the outcomes of hybrid and open treatment of severe multilevel lower extremity arterial disease.

Methods: All patients undergoing arterial revascularization (endoarterectomy, EV) or hybrid (HYBRID) procedures were stratified as limb salvage or amputation. Hybrid procedures were stratified as simple or complex. The study was performed in accordance with the principles of the May 2008 version of the TransAtlantic Inter-Society Consensus II (TASC) A/B, at

Results: Of the 654 patients, 770 limbs (67% critical limb ischemia) and 108 (14%) had hybrid procedures (56 sHYBRID, 52 cHYBRID). The sHYBRID group had significantly longer than the EV group, but less than the cHYBRID group, primary patency, limb salvage, and limb salvage in 83%, for runoff in 5%, and for both inflow and runoff in 5%. The sHYBRID group had significantly more frequent in cHYBRID (75% vs 23% in sHYBRID) and cHYBRID, the remainder being femoro-femoral bypasses (8% of interventions (91% in sHYBRID, 88% in cHYBRID). Thirty-day mortality was higher in the HYBRID than the EV group, with no difference with the cHYBRID and cHYBRID groups, and comparable to the disease complexity. Limb salvage in patients who presented with critical limb ischemia was similar in all groups.

Conclusion: Complex and simple hybrid procedures enable limb salvage in patients with severe multilevel lower extremity arterial disease. An increase in perioperative morbidity and mortality was observed in patients who presented with critical limb ischemia who underwent revascularization in higher risk patients. (*J Vasc Surg* 2010;51:1

N = 60

Hybrid Endovascular and Open Treatment of Severe Multilevel Lower Extremity Arterial Disease

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Available online 18 July 2009

OBJECTIVES: Hybrid therapy; Stents

Methods: Patients were divided into three groups: group 1 underwent endovascular reconstruction proximal and distal, whereas group 2 included patients who underwent endovascular reconstruction proximal and distal endovascular procedures. Patency and limb salvage were the primary end points. Univariate and multivariate analyses were performed to identify risk factors on primary patency.

Results: Complete data were obtained from 60 patients who underwent hybrid procedures. Technical and haemodynamic success rates were 91.7% and 88.3%, respectively. Primary patency at 1, 2, and 5 years were 71%, 58%, and 38%, respectively. Primary patency was significantly better in group 1 compared with groups 2 and 3 (log-rank test, $p = 0.001$). Diabetes mellitus and peripheral artery disease were independent predictors of decreased primary patency ($p = 0.014$, respectively).

Conclusions: Hybrid procedures provide an effective treatment for patients with multilevel lower extremity arterial disease. Diabetes mellitus and peripheral artery disease are associated with worse outcomes. © 2009 European Society for Vascular Surgery. Published by Blackwell Publishing, 108 Cowley Rd, Oxford OX4 1JF, UK and 350 Main St, Malden, MA 02148, USA

N = 40

Hybrid external iliac selective endarterectomy and outcomes

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Objective: Long or multilevel external iliac-to-femoral arterial lesions treated by angioplasty and stenting have achieved disappointing results. Conventional, open approaches are often complicated by significant morbidity, and endovascular stenting alone results in high rates of restenosis and need for additional outflow procedures. We hypothesized that a hybrid approach, combining selective external iliac endarterectomy, produces superior outcomes in patients with minimal associated morbidity.

Methods: All patients having undergone hybrid-based retrograde iliofemoral endarterectomy and stenting were included in this study. Patient demographics, presenting complaints, operative time, and primary patency were assessed by comparison of ankle-brachial index values and qualitative patient improvement. Data were analyzed by way of paired Student *t*-test with significance defined as $P < .05$.

Results: A total of 40 limbs were intervened upon on 33 patients. In 20 limbs, the procedure was performed for critical limb ischemia (rest pain, $n = 9$; tissue loss/gangrene, $n = 11$). By TransAtlantic Inter-Society Consensus II criteria, 83% of iliac lesions were class D. A more even distribution was noted in TransAtlantic Inter-Society Consensus II classification for femoral and popliteal disease. Seventeen percent of patients had one-vessel infragenicular runoff. In 21 limbs (54%), external iliac artery (EIA) stenting was performed at the time of procedure, 18 (46%) had common iliac artery (CIA) stenting, and 7 (18%) had a bridging stent from the CIA to EIA. The modal EIA stent diameter was 10 mm (range, 8–10 mm), modal CIA stent diameter 8 mm (range, 7–9 mm). The preintervention ankle-brachial index was 0.45 ± 0.24 ($n = 33$ limbs) and significantly improved to 0.75 ± 0.27 ($n = 29$ limbs; $P < .001$). In addition, preintervention toe pressure of 34 ± 28 mmHg ($n = 28$ limbs) improved to 58 ± 26 mmHg ($n = 23$ limbs; $P < .001$). No intraoperative complications occurred, which necessitated abdominal or retroperitoneal exposure. Average follow-up after the intervention was 13 ± 14.6 months. One limb (3%) required an additional outflow bypass. The incidence of ipsilateral hypogastric occlusion increased from 35% to 55% postoperatively; however, no patients reported pelvic or buttock ischemia. One patient who had the procedure done bilaterally presented 655 days after the procedure with bilateral iliac artery thrombosis and underwent aortobifemoral bypass. No other patient needed subsequent primary assisted patency or additional infrainguinal revascularization.

Conclusions: Hybrid-based external iliac and femoral endarterectomy provides a minimally invasive approach to EIA occlusive disease comparable with aortofemoral bypass. Dramatic inflow improvement was observed in our series, and the need for additional outflow revascularization was minimal. The procedure was deemed technically feasible and safe, with a low number of adverse sequelae and excellent primary patency achieved more than 1 year after the intervention. (*J Vasc Surg* 2010;64:1327-34.)

Only small-sized feasibility data!



Take Home Messages



- Basically, not much has changed!
- There has been no randomized trial directly comparing surgery vs. endovascular Tx.
- Surgery showed excellent late primary patency, however associated with relatively high complication rates
- Endovascular demonstrated high technical success rates and favorable primary patency rates even in complex aortoiliac lesions.
- Thus, endovascular therapy can be considered as the first-line therapy even in complex lesions, especially when performed in experienced centers.





**Thank you
for your attention!**

