Endovascular treatment as first line approach for infrarenal aortic occlusive disease

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Introduction: **The purpose of this study was to report the early and late results of primary stenting for focal atherosclerotic lesions of the infrarenal aorta.**

Methods: **A retrospective analysis of 52 consecutive patients treated for infrarenal occlusive aortic disease with primary stenting between January 2002 and November 2009 was performed. Original angiographic imaging, medical records, and noninvasive testing were reviewed. Primary stenting was the first line of treatment. Perioperative technical success and Kaplan-Meier estimates for patency and survival were calculated.**

Results: **The majority of the patients (43) were treated for severe claudication (Rutherford III; 82.7%), 5 for ischemic rest pain (Rutherford IV; 9.6%), and 4 for minor tissue loss (Rutherford V; 7.7%). Aortic stenosis was found in 40 cases (76.9%) and occlusion in 12 (23%). Perioperative hemodynamic success was 100%. All patients had an improvement of ankle brachial index (ABI) >0.10. Clinical improvement was found in 96%. Early surgical revision was necessary for aortic rupture in 1 patient. One death occurred for pneumonia. The mean follow-up time was 39.4 ± 27.2 months. Ten reinterventions (19%) were needed for symptom recurrence. The estimated assisted primary patency at 9 years was 96% and the mean survival time was 86.6 months.**

Conclusion: **Primary stenting offers safe and durable results and should be considered as the first line of treatment for focal aortic lesions. (J Vasc Surg 2011;53:1550-6.)**

Until the 1980s, the surgical approach was considered as the standard treatment for occlusive disease. Despite a good long-term patency rate, open surgery has a perioperative mortality rate between 3.3% and 4.4%, and perioperative complication rates between 8.3% and 12.2%.[1]

Percutaneous transluminal angioplasty (PTA) and lately primary stenting have been proposed as alternative solutions for lesions localized at the level of the infrarenal abdominal aorta.[2,3] However, few minor series have been published and no agreement has been found regarding which procedure should be considered as a first line treatment for focal aortic stenosis and occlusion.[3-9]

The purpose of this study was to report the early and late results of our experience with primary stenting for focal atherosclerotic lesions of the infrarenal aorta. Considering the limited number of publications on this topic, our data may contribute to up-to-date evidence.

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MATERIALS AND METHODS

All patients undergoing endovascular treatment between February 2002 and November 2009 for occlusive arterial disease and with atherosclerotic lesions localized at the level of the infrarenal abdominal aorta were reviewed. Patients with common iliac artery lesions without involvement of the aorta or with nonatherosclerotic aortic stenosis such as coartatio aortae abdominalis (mid aortic syndrome) were not included in this study. Indications for treatment were stenosis greater than 60% as determined by angiograms and with a pressure gradient through the lesion greater than 15 mm Hg. Treatment of concomitant iliac lesions were considered as associated procedures and reported.

Patient characteristics, comorbidities, operative data, and postoperative complications were prospectively gathered in a computer database. Follow-up was performed at 3, 6, and 12 months after treatment and at 12-month intervals thereafter. Physical examination, ankle brachial index (ABI) at rest, treadmill test, and Duplex scan were assessed.

Procedures. The majority of procedures were performed in the endovascular suite of our department with the patient under local anesthesia. Spinal anesthesia was performed when surgical reconstruction of the femoral vessels was necessary during the same procedure.

An intra-arterial bolus of heparin (100 UI/Kg) was given to every patient. The majority of lesions were recanalized with 0.035 hydrophilic J-type Terumo or Terumo stiff guide wires (Terumo Corp, Tokyo, Japan). In cases with demanding groin (eg, previous surgery, obesity, skin mycosis), the antegrade recanalization was performed through a left brachial approach using a 90-cm long sheath

(6 French Destination Straight CCV, Terumo Corporation, Tokyo, Japan, or Straight Flexible TBV KSAW, Cook, Bloomington, Ind).

In the case of challenging transfemoral punctures, vascular access was achieved under road map guide or using a Doppler ultrasound needle (PD Access, Vascular Solutions, Minneapolis, Minn).

The intraluminal technique was preferred to cross the lesion. In case of subintimal recanalization, we avoided re-entry close to the renal arteries. In chronic occlusion, it could be useful to place the sheath close to the lesion and use the funnelling effect of the hard plaque part. With this strategy, the wire is more likely to cross through the softer part intraluminally. Due to the duration of symptoms, locoregional thrombolysis or mechanical thrombectomy devices were not used.

Primary stenting was the first line of treatment. Predilation was performed for all cases with complete occlusion to achieve a smooth stent passage through the lesion. The stent selection was based on the characteristics of the lesion as found in the intraprocedural angiography. The length chosen was the shortest appropriate for complete coverage of the lesion. In the case of lesions just above the aortic bifurcation, kissing stent technique of the common iliac artery was used. Self-expandable stents were preferred for long lesions (Luminex, Austin, Tex; Bard, Covington, Ga; Protégé, ev3 Endovascular, Plymouth, Minn; Smart, Cordis Corporation, Miami Lakes, Fla; Wallstent, Boston Scientific, Natick, Mass). Alternatively, in lesions involving the aortic bifurcation, or when more radial force was needed, balloon-expandable systems were used (Genesis, Cordis Corporation; Omnilink, Abbott Laboratories, Abbott Park, Ill). Stent grafts (Talent, Medtronic Vascular, Santa Rosa, Calif; Zenith, Cook Medical, Bloomington, Ind) were used in the presence of a friable thrombus to prevent eventual embolization.

Post dilation was performed when self-expandable stents were implanted. To avoid risky over dilatation, the balloon size did not exceed an outer diameter of 14 mm, even if the aortic diameter proximal to the lesion was larger. Pressures from 5 atmospheres up to 12 atmospheres were applied over a mean time of 120 seconds. To avoid vessel rupture, pressure was reduced immediately in the event of remarkable pain.

The completion angiography always included a check of the below knee run off, to exclude eventual distal embolization.

Hemostasis was achieved using an Angioseal closure device (St. Jude Medical, St Paul, Minn) for sheaths up to 8F and with the Prostar XL device (Abbott Vascular, Redwood City, Calif) if larger sheaths were used. For the transbrachial puncture sites, manual pressure for 10 to 15 minutes and a pressure dressing for 24 hours were applied.

After the procedure, double antiplatelet treatment with aspirin (100 mg/day) and clopidogrel (75 mg/day) was administered for 6 weeks, and then monotherapy with aspirin (100 mg/day) was continued unless contraindicated.

Table I. Baseline patient characteristics

Variable	*Value*	*(n = 52)*
Age years old, median (IQR)	64.1	(14.7)
Male, no. (%)	22	(42.3)
Smoking, no. (%)	25	(48.1)
Hypertension, no. (%)	37	(71.2)
Diabetes, no. (%)	10	(19.2)
Hypercholesterolemia, no. (%)	30	(57.7)
Chronic renal failure, no. (%)	3	(5.8)
Previous MI no. (%)	12	(23.1)
Preoperative clinical status (by Rutherford Classification)		
III, no. (%)	43	(82.7)
IV, no. (%)	5	(9.6)
V, no. (%)	4	(7.7)

IQR, Interquartile range; *MI,* myocardial infarction.

Technical success was considered to have been attained for residual stenosis ≤30%. Immediate hemodynamic success was determined by an increase in ABI of >0.10 from baseline at the first clinical follow-up. Clinical success was defined as improvement in walking distance, absence of rest pain, and healing of trophic lesion changes after stent placement.

Patency was defined as stenosis <50% at color-coded duplex scan. Angiography was performed in the case of recurrence of symptoms, decrease in ABI measurements >0.1, or suspicion of restenosis in color-coded duplex scan because of an increase of peak systolic velocity ratio.

Statistical analysis. Median and interquartile range (IQR) values were calculated for all the continuous variables. Categorical variables were compared with the χ^2 or the Fischer exact test, and means were compared using the Kolmogorov-Smirnov test. The persistence of patency during follow-up was reported by Kaplan-Meier life-table analysis. The influence of the lesion type according to the TransAtlantic Inter-Society Consensus (TASC) classification on restenoses was tested with the log-rank test. All the analyses were performed using SPSS package, 17.0 version (SPSS, Chicago, Ill).

RESULTS

During the study period, a total of 52 patients matched the enrollment criteria. Demographic data, risk factors, and Rutherford classification are summarized in Table I. The majority of the patients presented with a stenosis (stenosis n = 40, occlusion n = 12; Table II) not involving the aortic bifurcation (n = 39; Fig 1). Associated atherosclerotic lesions were found at the level of the femoral bifurcation in 7 patients and of the iliac artery in 4 patients.

In 13 patients (25%), a kissing stent technique with bilateral stenting of the common iliac arteries was performed. In 2 patients, a self-expandable stent graft was used (Table III). Overall, only 2 patients, both treated with a self-expandable stent, required an adjunctive balloon-expandable stent for stent recoil. Completion angiography revealed no distal embolization.

Table II. Baseline lesions characteristic

Variable	*Value*	*(n = 52)*
Lesion type		
TASC B, no. (%)	40	(76.9)
TASC D, no. (%)	12	(23.1)
Lesion site		
Abdominal aorta, no. (%)	39	(75.0)
Aortic Carrefour, no. (%)	13	(25.0)
Associated peripheral lesion		
Iliac occlusions/stenoses, no. (%)	10	(19.2)
CFA stenoses, no. (%)	7	(13.5)

CFA, Common femoral artery; *TASC,* TransAtlantic Inter-Society Consensus.

In 16 patients, one or more associated procedures were necessary: femoral endarterectomy (n = 9), stenting of external iliac artery (n = 6), and femorofemoral cross-over bypass (n = 4). One patient with total aortic occlusion showed acute bilateral peripheral ischemia and was treated in an urgent setting. Bifemoral surgical approach, wire-guided Fogarty maneuver, and following stenting were performed.

Hemodynamic success was achieved in all the cases. All patients had an improvement of ABI >0.10 median increase from 0.5 (IQR 0.25) to 1.0 (IQR 2.2) ($P < .001$). Clinical improvement was found in all but 2 patients with Rutherford status in class III.

One major complication was related to an aortic rupture and required surgical conversion to aortoiliac bypass. One patient died within the first 30 days after the procedure due to pneumonia. One minor complication occurred − a groin hematoma requiring surgical revision. Univariate analysis showed no risk factors significantly correlated with major events (Table IV, online only).

The mean follow-up time was of 39.4 months (range, 1-117; SD ± 27.2). Nine patients experienced recurrence of symptoms. Eight in-stent restenoses were found and treated by re-PTA. One patient showed proximal progression of the disease and required an additional aortic stent (Fig 2). One patient developed an acute occlusion of the stent and required surgical treatment with aortic iliac bypass.

In total, 11 reinterventions were performed during the follow-up period. Eighty-five percent (n = 44) of the patients achieved unlimited walking distance during follow up. One amputation was performed in a patient with patent aorto iliac inflow caused by progressive distal disease (Table V, online only). Kaplan-Meier estimates an assisted primary patency of 96% at 9 years (Fig 3). The mean survival time estimated was 86.6 months (95% confidence interval 70.9-102.2). The log-rank test does not show statistical differences in primary and assisted primary patency rate between TASC B and D lesions (respectively, $P = .4$ and $P = .3$).

DISCUSSION

Isolated obstructive atherosclerotic pathology of the infrarenal aorta is a relatively rare entity, and few experiences have been published.[10] To increase the evidence relating to endovascular treatment, we reported our early and late results for primary stenting in this disease.

Consistent with the literature, our population was predominantly made up of young heavily smoking women with multisegmental atherosclerotic involvement as shown by the number of patients (n = 16; 31%) requiring one or more adjunctive procedures.[11]

According to TASC II, stenoses of the infrarenal aorta with a lesion length <3 cm (type B) should be treated by endovascular techniques. On the contrary, open surgery should be the treatment of choice for infrarenal occlusions (D category) because of more durable outcomes.[12] However, significant perioperative mortality and morbidity have been described.[13] A meta-analysis of 25 articles demonstrated a cumulative 4.4% mortality rate and 12.2% major complication rate.[1] A more recent analysis revealed a decrease in mortality and complication rates (3.3% and 8.3%, respectively). The overall 5-year patency rate was 91% for patients with claudication and 87% for patients with critical limb ischemia.[14,15] Patients not suitable for laparotomy underwent traditional extra-anatomic bypass revascularization. The results of these surgical strategies are not competitive to those proven by aortobifemoral bypasses and are affected by graft infection.[12]

Two major complications are present within our series. The first was a death at 30 days, due to an acute pneumonic event in a patient with chronic obstructive pulmonary disease and chronic limb ischemia Rutherford class 6. This was probably related to the severe comorbidities of the patient who was not eligible for an open procedure. The second was an early aortic rupture with abdominal pain and severe hypotension in a patient with aortic stenosis. An emergent computed tomography (CT) revealed active bleeding near the aortic bifurcation. Due to the site of the lesion, and the endovascular skills of the surgeon on call, an aorto-iliac bypass was preferred to a stent graft, and the patient made a good postoperative recovery. This second complication shows that surgical backup remains mandatory for the performance of this procedure.

One patient required surgical conversion 4 months later for a stent occlusion. This occurred in a 57-year-old patient at the beginning of our experience. The patient was initially treated for bifurcation aortic stenosis and uni-iliac occlusion by two kissing self-expandable stents with a diameter of 6 mm each. The probable reason for early treatment failure was the comparatively low diameter and low radial force of the chosen stents. The previous aortic stents did not compromise the surgical correction.

Most of the published retrospective series dealing with the endovascular treatment of aortic stenosis show good results with low perioperative complication rates. Recently, a large monocentric experience in endovascular aortic occlusion treatment showed excellent short-term results, but unfortunately one third of the patients had <1 month of follow-up.[16] Our results confirm this data for stenoses and occlusions also in the long term.

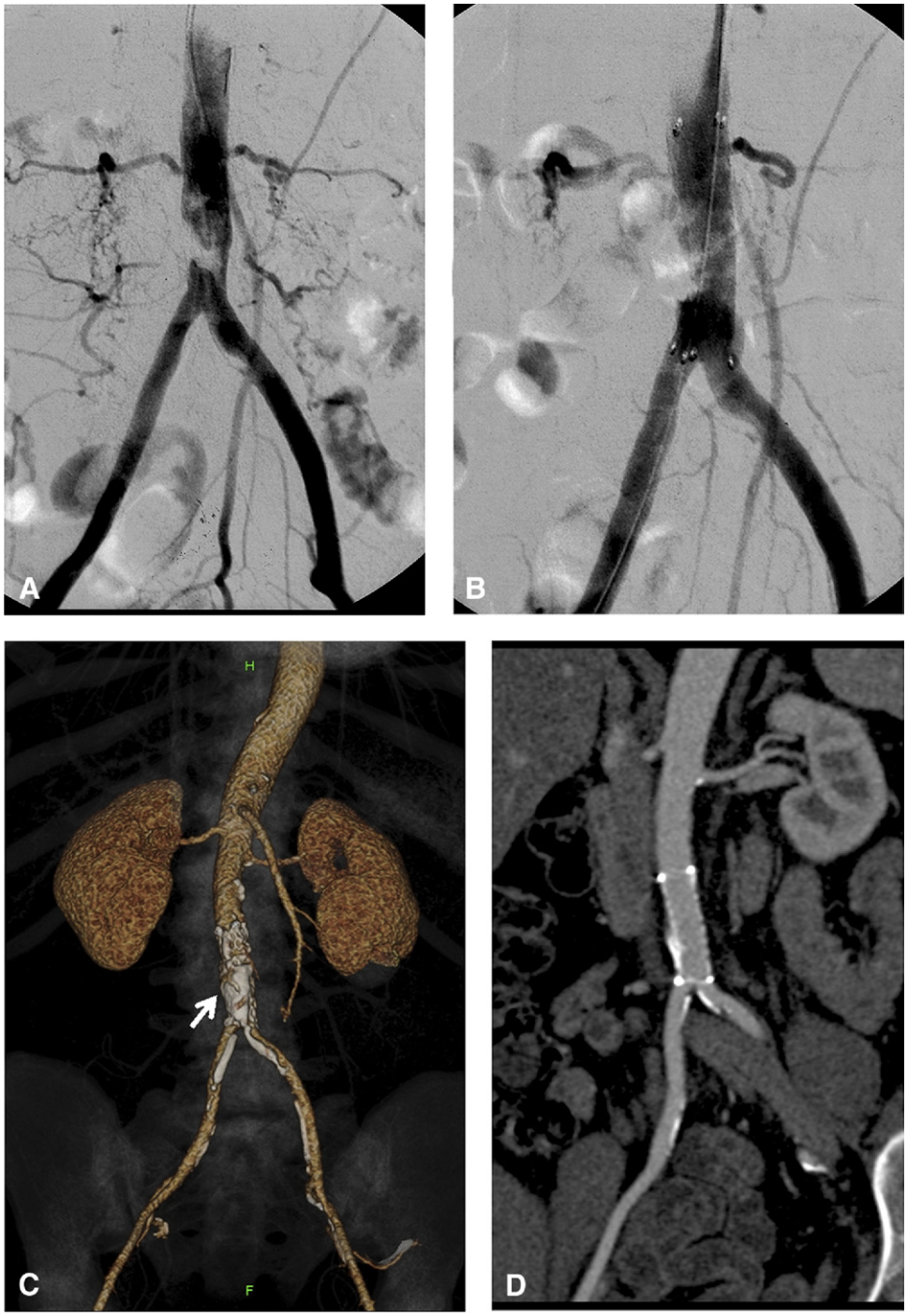

Fig 1. Angiography of a 70-year-old woman with focal aortic stenosis at the distal part of the aorta. **A** and **B,** Through a right femoral retrograde approach it was possible to cross and stent the lesion with a single self-expandable stent (Luminex, C.A. Bard). **C** and **D,** Computed tomography (CT) scan 2 years later shows the stent integrity and the calcified aortic plaque (3D volume rendering modality, *white arrow*). On the left, a curved planar reformation passing through the aortic lumen shows the absence of a restenosis.

Table III. Material details based on the site of the lesion and the related technique

Technique	*Variable (mm)*	*Median*	*IQR*	*Minimum*	*Maximum*
Aortic tube stent (n = 39)	Balloon diameter	9	3	8	14
	Stent diameter	14	2	6	28
	Stent length	50	20	10	122
Aorto-iliac kissing stent (n = 13)	Balloon diameter	6.3	1.2	5	8
	Stent diameter	7.5	1	6	9
	Stent length	40	58.2	28	150

IQR, Interquartile range.

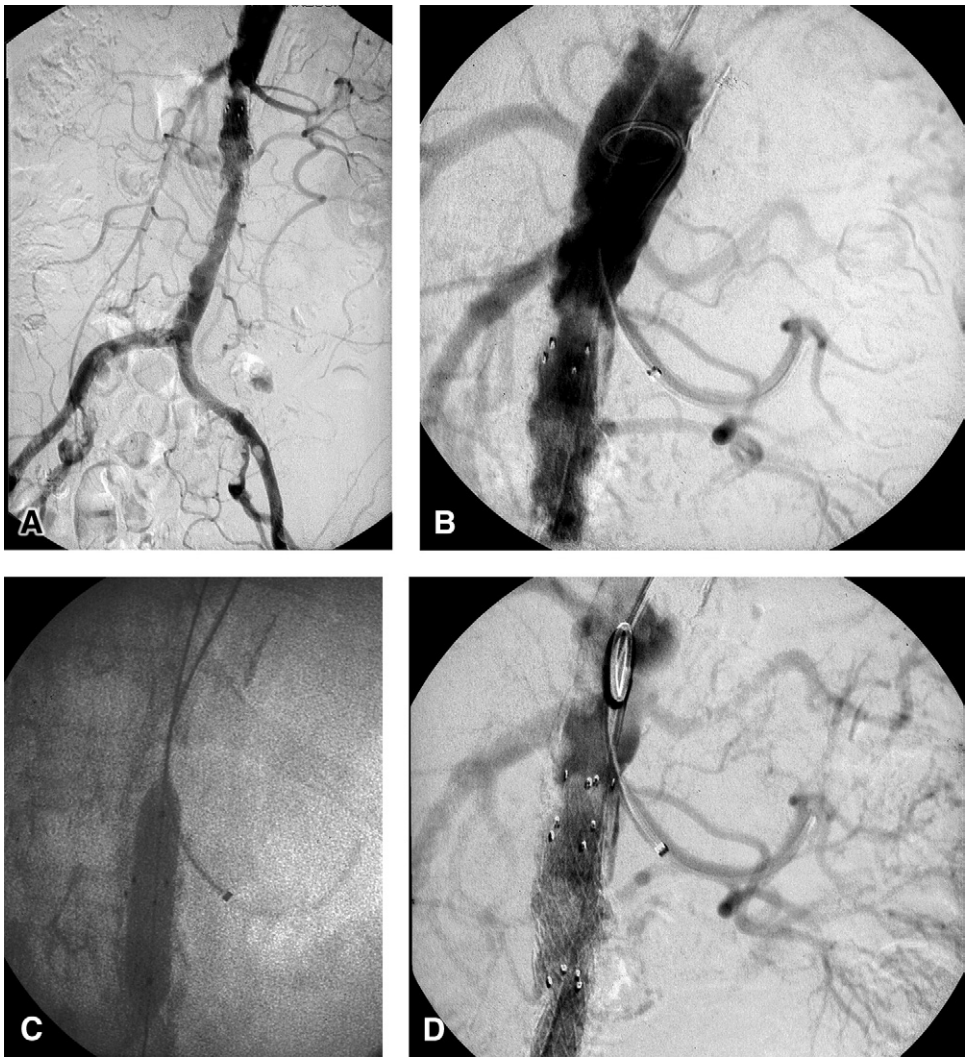

Fig 2. Secondary procedure in a patient with recurrence of symptoms 75 months after implantation of a self-expandable stent. The intraoperative angiography shows de novo stenosis below the origin of the left renal artery **(A)**. A 7F introducer sheath was placed to protect the lower left renal artery through a left brachial access **(B)**. A new self-expandable stent was deployed and postdilated **(C)** while patency of the left renal artery was preserved **(D)**.

In our series, assisted primary patency at 9 years was 96% and 9 patients required a secondary endovascular procedure for in-stent restenosis. Redo-PTAs of this type are not technically demanding and can be performed with a high success rate.

The TASC lesion type did not significantly predict the long-term outcome (Fig 3). In contrast with TASC II recommendations, our results suggest primary stenting as a viable option also for focal aortic occlusion. This

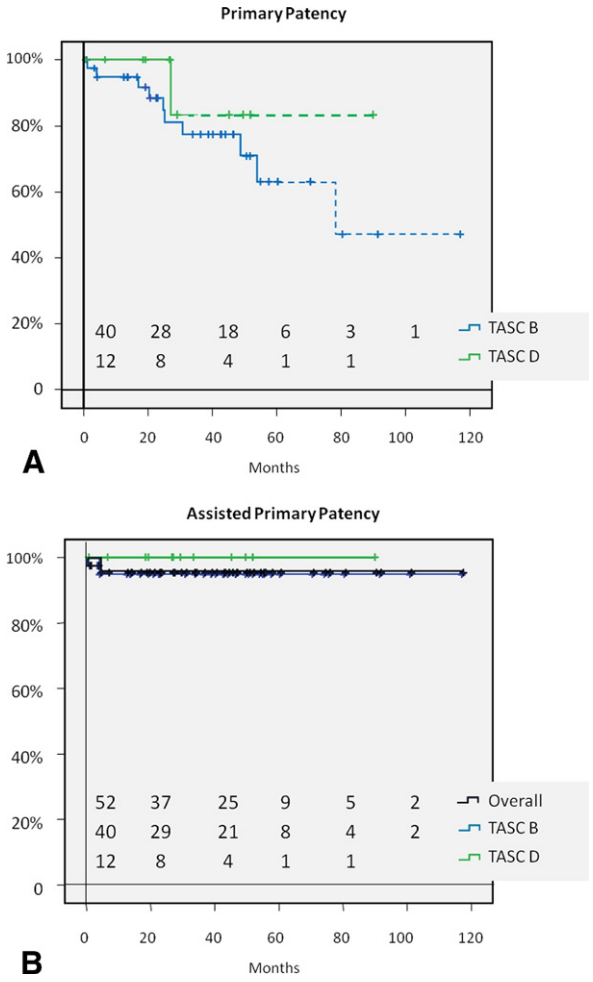

Fig 3. Primary patency **(A)** and assisted primary patency **(B)** in 52 patients with numbers at risk for each period (Kaplan-Meier). Subgroup for occlusions (green line) and stenoses (blue line) are also depicted. Dashed lines show SE value >10%.

is probably explained by the lack of a specific classification for short aortic occlusions, which are included with the extensive aorto-iliac occlusions in group D.

Despite the absence of direct scientific evidence for the superiority of the primary stent over the simple aortic PTA, it is broadly accepted that primary stenting may help to create a smooth cylindrical lumen thus minimizing thrombus formation and recoil in a relatively large vessel such as the aorta where the possible neo-intimal hyperplasia seems not to be crucial.[9,17,18]

After an aortic rupture in the beginning of our series, we reduced our post-ballooning diameter. Previous articles consider as target diameter the first aortic segment above the lesion "free from disease," instead of considering the hemodynamic necessity of the run-off. In case of surgical aorto-iliac reconstruction, the main body diameter of the prosthesis is commonly 14 to 16 mm, giving good clinical results. In our opinion, it is not necessary to exceed this diameter regardless of how large the proximal aorta is. This strategy could reduce the risk of dangerous aortic overdilation without compromising the clinical outcome.

There is also debate about the stent choice. As mentioned in the Method section of this article, our indications for the use of balloon-expandable vs self-expandable stents are mainly dictated by the localization of the lesion, and intergroup comparison was therefore not reasonable. Self-expandable stents offer several advantages such as the smaller French profile, and a delivery system that reduces the risk of losing the stent. However, in 2 patients, the radial force of the stent was insufficient, and an additional balloon-expandable stent was needed. The recent introduction into the European market of a stent pre-mounted on an angioplasty catheter with two concentric balloons could further improve the deployment of balloon-expandable stents (NuMED, Hopkinton, NY).

In 2 cases, self-expandable stent grafts were used in the suspicion of a higher risk of embolic event due to the appearance of the thrombus at the preoperative CT scan. In both cases, an adjunctive balloon-expandable stent was needed to expand the graft. These devices are dedicated for aneurysmatic disease, and the recoil may be explained by low radial force. Only recently, balloon-expandable covered stents long enough (maximum 61 mm) to completely cover the segment involved (Advanta, Atrium, NH) have become available. However, despite the widespread use of bare metal stents and intensive imaging of the postoperative runoff vessel, no symptomatic or asymptomatic embolic events have been found in this series. In accordance with previous publications, this result suggests a low risk of embolic events for these patients and reduces the indication for stent grafting. In our opinion, the use of these devices is intended as a bailout technique in the case of aortic rupture and should always be available. Bifurcated stent grafts for a narrow lumen with high radial force are not yet available.

In addition to the limitation related to the retrospective nature of the study, the small sample size could affect the predictive value of univariate analyses. Furthermore, advances in endovascular technology and surgeons' experience during the 7 years of the study were not taken into account.

CONCLUSIONS

Endovascular and combined treatment of focal occlusive aortic disease is a safe method with excellent clinical outcomes. Bare metal stents should represent the standard device for treatment. Secondary procedures are needed but are safe and effective, leaving the surgical option uncompromised. The feasibility of a randomized study comparing endovascular treatment to open surgery is low because of the rarity of the disease. However, more data could help to perform meta-analyses. Short aortic occlusions are not a risk factor for the early and late patency rate and should be downgraded from group TASC D. Advances in technology have already been made and are likely to improve future results.

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AUTHOR CONTRIBUTIONS

Conception and design: AS, GP, GT
Analysis and interpretation: AS, GP, GT
Data collection: AS, GP, KD
Writing the article: AS, GP, LF, GT
Critical revision of the article: AS, GP, LF, KD, MA, GT
Final approval of the article: AS, GT
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Additional material for this article may be found online at www.jvascsurg.org.

Table IV, online only. Univariate analysis of the association between major complications and risk factors

Variable	*Major complications*		P *value*
	Yes (n = 2)	*No (n = 50)*	
Age years, median (IQR)	73.3 (15.4)	63.5 (14.5)	.8
Male, no. (%)	1 (50)	21 (42)	1
Smoking, no. (%)	1 (50)	24 (48)	1
Hypertension, no. (%)	2 (100)	36 (72)	1
Diabetes, no. (%)	0 (0)	10 (20)	1
Hypercholesterolemia, no. (%)	2 (100)	30 (60)	.5
Chronic renal failure, no. (%)	0 (0)	3 (6)	1
Previous MI, no. (%)	0 (0)	12 (24)	1
Chronic limb ischemia, no. (%)	1 (50)	8 (16)	.3
TASC D, no. (%)	1 (50)	11 (22)	.4
Adjunctive procedures, no. (%)	1 (50)	15 (30)	1

IQR, Interquartile range; *MI,* myocardial infarction; *TASC,* TransAtlantic Inter-Society Consensus.

Table V, online only. Perioperative and late complications

	Value	*(n = 52)*
Perioperative		
Mortality	1	(1.9)
Groin complication (%)	1	(1.9)
Aortic rupture (%)	1	(1.9)
Late		
Re-PTA (%)	8	(15.4)
Additional stent (%)	1	(1.9)
Aorto-iliac bypass (%)	1	(1.9)
Limb lost	1	(1.9)

PTA, Percutaneous transluminal angioplasty.