

# Endovascular treatment of complex atherosclerotic lesions of the aortoiliac segment

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**Aim.** Endovascular surgery is the first choice method for the treatment of iliac occlusive lesions. Its role in complex lesions of the aortic bifurcation and terminal aorta is still debated. The aim of this retrospective study is to analyze the treatment outcomes in a group of patients.

**Methods.** Forty-two consecutive patients who underwent an aortoiliac bilateral endovascular procedure between January 1994 and December 2001 were analyzed. The patient population was subdivided into 4 groups according to the Trans-Atlantic Inter-Society Consensus (TASC) 2001 criteria. Twelve patients with type A lesions, 2 with type B, 4 with type C, and 24 with type D were treated. Stents were placed in 26 patients.

**Results.** Global early patency was 100%, 1-year patency 91%, and 5-patency 79%. In the group with the largest lesions (type D), early patency was 100%, 1-year patency 91%, and 5-patency 65%. In the group with stent placement, early patency was 100%, 1-year patency 91.6%; this value remained unchanged at 5-year follow-up but was not statistically significant.

**Conclusion.** Endovascular surgery appears to be a valuable treatment option also in bilateral lesions of the iliac-femoral axis and/or those involving the aortic bifurcation and terminal aorta. Failed treatment attempts do not preclude eventual conversion to conventional revascularization with abdominal or extra-anatomic access.

**KEY WORDS:** Aorto-iliac arteriopathy - Aorto-iliac endovascular surgery - Stents.

Aortoiliac occlusive disease was conventionally treated with aortic endarterectomy (AE) or aorto-bifemoral bypass<sup>1</sup> until the early 1980s, when endovascular surgery and early diagnosis revolutionized the surgical approach, providing the option of minimally invasive surgery in this anatomic segment.

Percutaneous transluminal angioplasty (PTA) is a technique of proven efficacy in the treatment of localized stenosis of the aortoiliac axis; some case series reported an early success rate of 95%.<sup>2-4</sup> The efficacy and reliability of the procedure have improved with the concomitant use of stents to treat long or complex stenoses likely to occlude or to revise technical defects that are otherwise difficult to repair with PTA alone. The endovascular approach has also demonstrated effective long-term results, obtaining 5-year patency rates of 80-90% in small stenosing lesions comparable to those obtained with conventional surgery.<sup>5-6</sup> Surgical treatment of aortoiliac disease is characterized by 5-year patency rates between 80% and 95%. Even so, mortality and perioperative morbidity range from 1% to 5%.

Generally, endovascular surgery is the treatment of choice for localized disease of the common or exter-

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TABLE I.—*Lesion classification.*

<i>Type A lesion (Iliac axis)</i>
— Single stenosis (<3 cm long) of the common or external iliac artery (unilateral or bilateral)
<i>Type B lesion (Iliac axis)</i>
— Single stenosis (3—10 cm long) not external to the common femoral artery
— Two stenoses (< 5 cm long) of the common and/or external iliac artery not involving the common femoral artery
— Unilateral obstruction of the common iliac artery
<i>Type C lesion (Iliac axis)</i>
— Stenosis (5-10 cm long) of the common and/or external iliac artery not involving the common femoral artery
— Unilateral obstruction of the external iliac artery extending to the origin of the common femoral artery
— Bilateral obstruction of the common iliac arteries
<i>Type D lesion (Iliac axis)</i>
— Unilateral, diffuse, multiple stenoses of an iliac artery involving the common and external iliac arteries and the common femoral artery
— Unilateral iliac obstruction involving the common and external iliac arteries
— Bilateral obstruction of the external iliac arteries
— Diffuse disease involving the aortoiliac axis
— Iliac stenosis in a patient with an aneurysm of the abdominal aorta or other lesions that require aortoiliac surgery
Recommendation 32: Endovascular treatment is the procedure of choice for type A lesions; surgery is the treatment of choice for type D lesions.

nal iliac arteries, whereas conventional surgery remains the procedure of choice in treating large, complex, multifocal lesions or complete obstruction of the sub-renal abdominal artery and the iliac arteries.

To help code procedural indications and types of lesions, the Trans-Atlantic Inter-Society Consensus (TASC) stratified obstructive lesions of the aortoiliac axis into 4 categories (A, B, C, D) in 2000<sup>7</sup> (Table I). PTA and/or stenting is considered the treatment of choice for type A lesions and surgery for type D lesions. While no definite rules were given for the treatment of type B or C lesions, leaving the choice between conventional and endovascular surgery to the surgeon's discretion, endovascular procedures were to be preferred in the treatment of type B lesions and conventional surgery for type C lesions.

Our retrospective study analyzes a case series of 42 consecutive interventions using endovascular procedures in the treatment of bilateral aortoiliac lesions performed at our unit from January 1994 to December 2001. All stenosing lesions were caused by atherosclerosis of the aortoiliac axis and were classified as type A or B according to the TASC criteria.

## Materials and methods

The intervention was performed in 42 symptomatic patients, 38 of which presented with stage 2 peripheral arterial disease and walking distance <150 m (90.4%), 2 with pain at rest (4.8%) and 2 with trophic lesions (4.8%). Patients treated for limb salvage conditions were 4 (9.6%).

The mean age was 59.7 years [30 men (mean age 63.5 years; range 43-78) and 12 women (mean age 56.1 years; range 30-75)].

Risk factors for the disease included cigarette smoking in 35 patients (83.3%), diabetes in 10 (23.8%), a positive history of coronary heart disease in 14 (33.3%), and hypertension in 32 (76.2%).

All patients underwent preoperative arterial catheter aortography to determine the indication for an endovascular procedure. The types of lesions were stratified according to the TASC classification<sup>7</sup> into 12 type A (28.5%), 2 type B (4.7%), 4 type C (9.5%), and 24 type D (57.3%).

All interventions were performed in the operating room using a C arm (O.E.C. Medical System, Salt Lake City, UT, USA). Intra-vascular ultrasonography (IVUS) has been performed in 5 patients (12%), limited to the beginning of our experience.

In 32 cases (76.2%) the procedure was performed completely under local anesthesia while in 10 patients (23.8%) we preferred spinal anesthesia to perform surgical isolation of the femoral artery. This was necessary in 7 cases to treat concomitant lesions at the level of the femoral tripod, while mixed access was used in 3 cases (percutaneous on one side and surgical on the other).

The lesion was negotiated using a hydrophilic guide (0.035", 180 cm long) (Radiofocus, Terumo, Tokyo, Japan). The stenosing lesion was dilated using balloon catheters (10-16 mm in aortic PTA; 7-9 mm in iliac PTA) (Marshall, Smash, Synergy, Centurion or Opta P, according to which type was available). The stenosis was dilated for 45-60 min at pressures from 5 atm to 12 atm.

The lesions of the terminal aorta and the origin of the iliac arteries were successfully treated with the kissing balloon or kissing stent technique, wherein the proximal end of the stent is positioned in the terminal aorta and the distal end in the first segment of the common iliac artery to reconstruct an aortic bifurcation.<sup>8</sup> The kissing balloon/stenting technique was

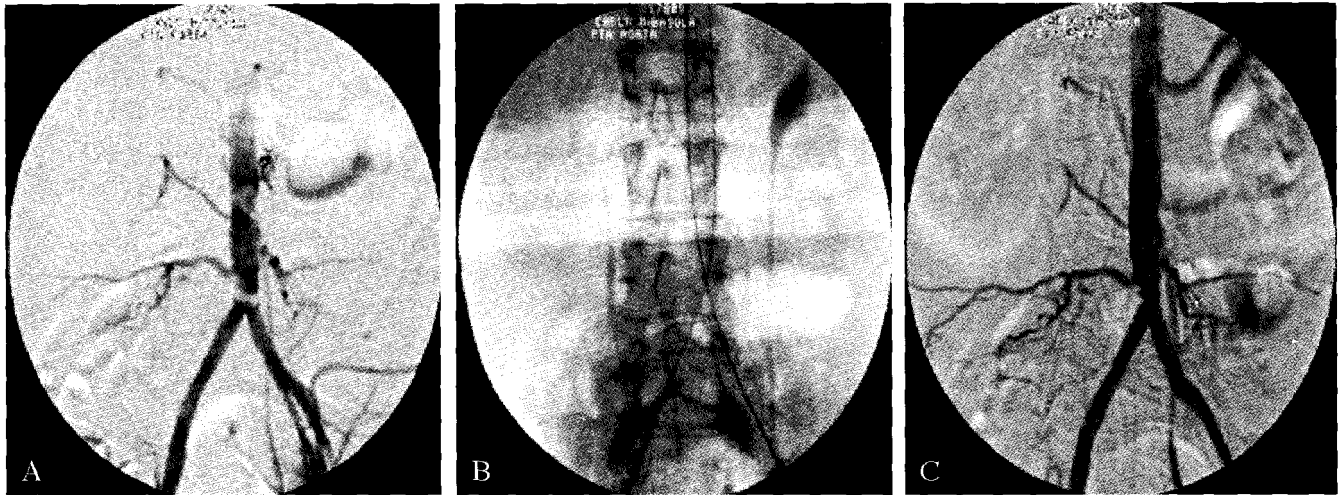


Figure 1.—Kissing balloon of terminal aorta: A) Intraoperative fluoroscopy shows a short occlusion of the terminal aorta; B) Bilateral passage of the occlusion with two 0,035" guidewires; C) Final result after balloon dilatation.

preferred in the treatment of stenosis of the terminal abdominal aorta and bilateral stenosis of the common iliac arteries to prevent contralateral embolism caused by dislodgement of cholesterinic or thrombotic material (Figure 1). This technique was used in 14 cases (33.3%), in 4 of which (9.5%) primary kissing stent placement was carried out (2 with short iliac obstruction; 2 with plaque at a high risk of occlusion).

The selection of PTA catheters and stents (length, diameter, compliance) was based on the morphologic features of the plaque as visualized by preoperative color Doppler imaging studies and intraoperative angiography.

Placement of one or more stents was necessary in 26 cases (61.9%) for chronic obstruction, complex or large plaques or because of unsatisfactory technical results (residual stenosis >30%) and translesional pressure  $\leq 5$  mm Hg, vessel rebound or plaque dissection. The type and number of stents were: 14 Palmaz in 9 patients, 11 Memotherm in 6 patients, 5 Jomed in 3 patients, 1 Corinthian in 1 patient and 1 Saxx in 1 patient. Stratified according to type of lesion, stent placement was performed in 7 patients with type A lesions, 2 patients with type B, 4 patients with type C and 13 patients with type D (Figure 2).

Primary stenting was necessary in complex lesions with a high probability of distal occlusion.

Stent characteristics (self-expanding, thermal mem-

ory, balloon expandable) were selected based on plaque features and availability from hospital supplies, except for the first 10 patients in whom expandable balloon-mounted stents were regularly used.

Outcome assessment was based on findings from postoperative angiography and measurement of the translesional pressure, wherein technical success was defined as residual stenosis <30% and translesional pressure  $\leq 5$  mm Hg.

The patients received preoperative anticoagulation therapy with low molecular weight heparin, calcic heparin or sodic heparin, then for 3 days in the postoperative period, followed by routine antiplatelet therapy (acetylsalicylic acid or ticlopidine).

At follow-up visits (at 3, 6, 12 months and then every 12 months thereafter), physical examinations and color Doppler imaging studies were performed. Technical success was determined according to the presence or absence of aortoiliac stenosis by analysis of ultrasonography images and spectral wave morphology; clinical success was defined as improvement in the stage of the arterial disease (absence of claudication, healing of trophic lesions) and, where findings were available, as improvement in the Winsor index compared with preoperative occlusion pressure.

Statistical analysis was performed using the  $\chi^2$  test, Student's t test and actuarial curves according to the Kaplan-Meier method calculated with Excel for Windows statistics program.

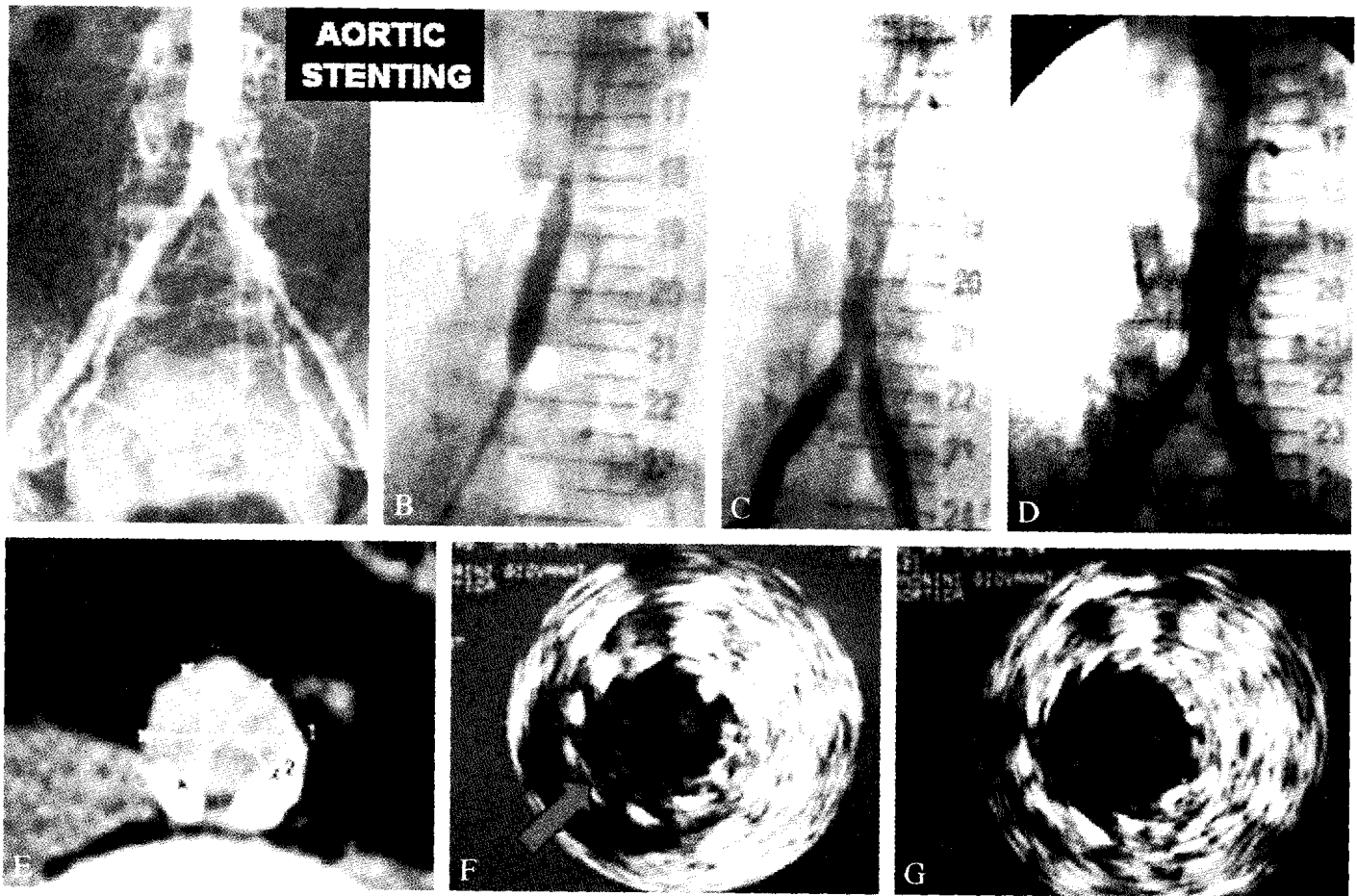


Figure 2.—Severe stenosis of abdominal aorta: A) Preoperative aortography; B) Preoperative computed tomography scan shows heavy calcification of posterior aortic plaque and thrombotic material; C) PTA of the abdominal aorta with a 14 mm balloon catheter and an Extra-Jarge Palmaz stent; D) Intraoperative fluoroscopy with an apparently good result; E) Intravascular ultrasound (IVUS) shows incomplete adhesion of the stent to the aortic wall; F) Final result after a supplemental dilatation of the stent; G) Final IVUS control.

## Results

The analysis of the results took into account the hemodynamic parameters and the clinical outcomes of all 42 patients who received endovascular treatment.

The 5-year mortality rate was 7% (Figure 3) due to diseases unrelated to the pathology in question (2 cases of acute myocardial infarction and 1 lung cancer). Limb salvage was 50% in patients with critical limb ischemia. Leg amputation was performed in 2 patients with pre-existing femoropopliteal-tibial disease and Fontaine stage IV type I diabetes mellitus at intervention.

Early patency was 97.6%. Immediate thrombosis of one iliac axis occurred in 1 patient (2.4%) with type A lesions; this thrombosis was immediately corrected by means of a femoro-femoral bypass crossover.

A major complication occurred in only 1 case (2.4%) following the appearance of an inguinal pseudoaneurysm at the puncture site. Since echo-guided compression could not be performed, surgical removal and raphing of the femoral artery were carried out. Minor complications developed in 4 cases (9.5%). Three hematomas at the puncture site were treated conservatively; a stent was placed in 1 case of dissection of the external iliac artery in a patient who received kissing balloons. Early thrombosis of the iliac axis occurred in 1 patient (2.4%) with a type A lesion and was resolved with a femoro-femoral crossover bypass.

Global 5-year patency was 79%. Clinical success as defined by the SVS/ISCVS Joint Council was 100%, as was hemodynamic outcome according to 3-phase

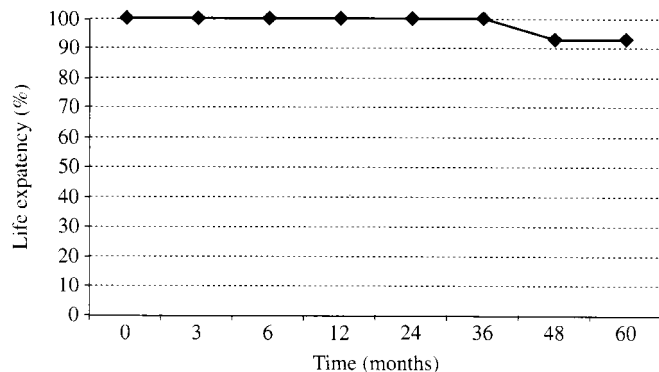


Figure 3.—Life expectancy rate at 5 years.

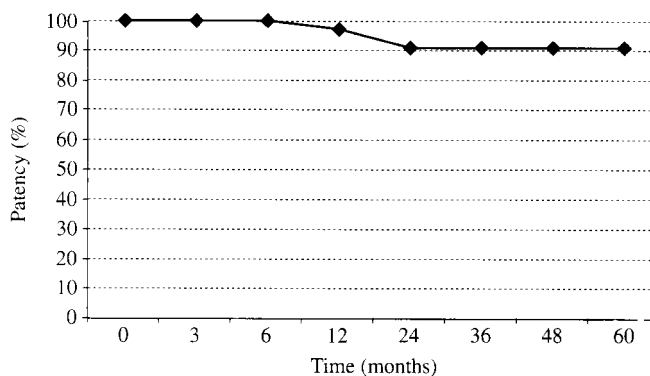


Figure 5.—Cumulative patency rate at 5 years considering patency of almost one iliac-femoral axis.

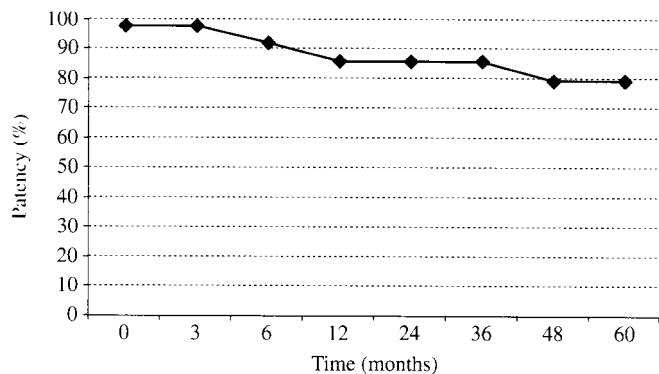


Figure 4.—Cumulative patency rate at 5 years in bilateral interventions.

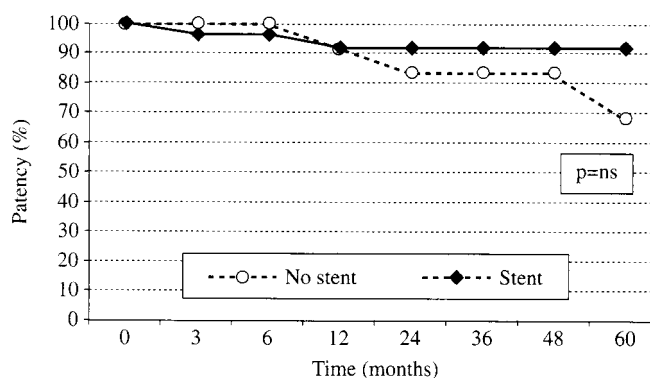


Figure 6.—Comparison of stenting vs no stenting intervention: cumulative patency rate at 5 years.

wave Doppler ultrasonography study of the common femoral artery (Figure 4).

Failures at 6 months occurred in 2 cases (4.8%); in the first case the patient had a type D lesion and received an aorto-bifemoral bypass at another institution; in the other case, again a patient with a type D lesion, a femoro-femoral crossover bypass was performed. Failures at 12 months occurred in 2 cases (2.4%); in the first case the patient was not reoperated because of residual intermittent claudication of the thigh with walking distance >250 m; in the other case the patient received an aortobifemoral bypass. One failure occurred at 48 months due to restenosis at the site of previous aortic PTA, which was resolved with revision PTA.

Five-year patency of at least 1 of the 2 iliac axes was 90.1% (Figure 5).

Stents were placed in 26 patients because of plaque

characteristics or to repair a technical defect. Early stent patency was 100%; 5-year patency was 91.6%; early patency with angioplasty alone was 100%; 5-year patency was 68%. This difference was not statistically significant, however (Figure 6).

### Discussion

Surgical treatment of aortoiliac atherosclerotic disease has advanced notably with greater operator experience, refinement in anesthesia techniques and improvement in the quality of the materials. Conventional revascularization procedures include thromboendarterectomy (TEA) and aorto-bifemoral bypass. TEA affords optimum results particularly in patients with localized arterial disease of the terminal aorta with or without involvement of the iliac arteries.

Nevelsteen *et al.*<sup>9</sup> reported a cumulative 5-year patency rate of 86% and operative mortality of 3%. Aortobifemoral bypass is currently the standard technique in diffuse lesions of the aortoiliac axis (TASC classification type D lesions). Studies report 5-year patency rates between 85% and 90% and from 75% to 80% at 10 years, with perioperative mortality between 1% and 5%.

In the various case series, the associated morbidity ranges from 95% to 20%.<sup>9, 10</sup> The most common complications are bleeding (1-2%), limb ischemia in thrombosis of the bypass or of side branch (1-10%), renal insufficiency (4-8%), bowel ischemia (1-2%), formation of anastomotic pseudoaneurysms at the proximal or distal anastomotic site (1-5%), spinal cord lesions (rare), urethral damage and sexual dysfunction (25%), prosthesis infection (1-2%).<sup>11</sup>

In recent years, endovascular surgery has gained importance in the treatment of occlusive disease because of its minor invasiveness, lower surgical risk, and results comparable with those of conventional surgery. This has led to its indication in the treatment of isolated lesions of the aortoiliac axis.<sup>7</sup>

In a review of 6 620 patients who underwent aortoiliac PTA, Long *et al.*<sup>12</sup> reported a complication rate of 8.1%; major complications occurred in 2.7% of cases and required surgical revision in 1.2%, with a mortality rate of 0.2%. In most cases, management of thrombotic complications eventually requires another endovascular procedure, *e.g.* thrombolysis, thromboaspiration or stent placement.<sup>13</sup> Other common complications in endovascular surgery include hematomas at the puncture site, pseudoaneurysms, arterovenous fistulas, distal emboli and postoperative renal insufficiency.

In our series of 42 patients, the population was subdivided into 4 groups according to the TASC 2000 classification of aortoiliac lesions: 12 patients with type A lesions, 2 with type B, 4 with type C, and 24 with type D.

No deaths occurred during the perioperative period. Global patency immediately following the procedure was 97.6% across all types of lesions and modes of stent placement; primary patency at 5 years was 91.6%. Early patency was 100% in procedures treating the terminal aorta (type D lesions).

The number of episodes of complications (2.4% major complications, 9.5% minor complications) was in line with the rates reported in the literature, most of

which concern populations of patients with simple lesions (mainly type A or B). In a review by Nyman *et al.*<sup>14</sup> on 280 patients who underwent aortoiliac axis PTA, primary patency was 85% and secondary patency was 90% over a follow-up period between 4 and 52 months. Yakes *et al.*<sup>15</sup> and Ravimandalan *et al.*<sup>16</sup> reported early patency to vary from 93% to 100% in aortoiliac PTA and/or stenting.

The use of endovascular surgery also in lesions involving the terminal aorta and the 2 iliac axes simultaneously (type D lesions) contrasts with the current chief guidelines set forth in the literature.<sup>7</sup> This approach was, however, partly warranted by the demographics of the population; the mean age of 59.7 years was relatively lower compared to the mean of European survival.

The aim of endovascular intervention was to repair bilateral occlusive lesions involving the terminal aorta in order to avoid the need for aortobifemoral bypass (ABF), which is more invasive and carries the risk of highly invalidating complications. Early or late failure of an endovascular procedure does not preclude an eventual conversion to bypass operation.

Moreover, from an analysis of the global data and the postoperative assessment of each of the 42 patients in our study, it can be said that the outcome was positive for patency of at least one side. A treatment that permits effective recanalization even in only 1 of the 2 iliac axes and its use as a donor axis for femoro-femoral crossover bypass may, in fact, be considered successful therapy. This type of patency was estimated to be 100% in the early postoperative period, 97% after 1 year, and 90.9% at 5 years. A mixed procedure combining endovascular and late extra-anatomic interventions may be considered an operation with reduced operative risk and limited sequelae.

In our case series, stents were placed in 26 patients, the first 10 of which received expandable balloon-mounted stents. In most cases, the indication for this type of stent was correlated with an unsatisfactory result of PTA, the presence of eccentric plaque with a high calcium component, a PTA pressure >5 mmHg, post PTA residual stenosis >30%, plaque dissection, intimal flaps or vessel obstruction. Primary stent placement was performed only if the lesion was at a high risk for distal embolism or for small obstructions of the iliac axis (5 cases). Five-year stent patency was 91.6% compared with 83.1% for PTA alone; however, this difference was not statistically significant.

Several authors have described routine use of primary stenting, regardless of the occurrence of the conditions mentioned above. Primary stenting has been proposed for aortic stenosis and iliac stenosis when the axis is used as a donor for a femoro-femoral bypass. Stent placement reduces the risk of aortic rupture, thus permitting the vessel to be dilated wide enough to create a lumen that ensures the remission of symptoms.<sup>14, 17, 18</sup> Schedel *et al.*<sup>19</sup> supported the use of primary stenting in infrarenal aortic stenosis reporting 15 cases with a primary patency at 2 years of 85% and secondary patency of 100%.

Meta-analysis has shown that in most cases stents are placed to treat stenosis and not occlusion, with an improvement in results in early patency of 5% and in 4-year primary patency between 7% and 11% compared with PTA alone.<sup>20</sup> In the Dutch Iliac Stent Trial Study Group, a randomized study was conducted on patients with aortoiliac occlusive disease to compare primary stenting with selective stent placement. The results showed that late patency was similar in both groups, with lower costs accrued by the selective stenting group.<sup>21</sup> In some case series,<sup>4, 22, 23</sup> routine stenting was reported to reach up to 15%, with major complication rates ranging between 3.4% and 10.5% due to the need for larger introducers, high heparin doses and prolonged operation times.

The results of our study confirm the data reported in the international literature on the validity of endovascular treatment of type A and B lesions; the patency rate of type D lesion (81.4% at 5 years) does not appear to contraindicate the use of endovascular procedures. Routine stenting could be theoretically preferable in presence of larger lesions (type D). Results after stent placement appear to be better than those with PTA alone, although the difference (91.6% vs 83.1% at 5 years) was not statistically significant.

### Conclusions

Since its introduction, endovascular surgery has advanced markedly, particularly in the development of innovative materials and the increased ease of use that have helped to make it the procedure of choice in selected anatomopathologic conditions. Furthermore, endovascular surgery soon became a valuable alternative to conventional revascularization surgery because of its minor invasiveness, reduced number of side effects and optimum learning curve. In aortoiliac

diseases, it has become the gold standard, especially in the treatment of small, localized lesions, while certain authors have also advocated its use in the treatment of larger, bilateral lesions, including the aortic bifurcation and the terminal aorta.

The results obtained in our series have been encouraging and prefigure ever wider use of endovascular surgery. Future development of materials and the possibility to use advanced design stents, endoprostheses or to associate the procedure with fibrinolytic therapy even in patients with chronic lesions could further extend the indications for endovascular treatment of this anatomic area.

Another advantage of endovascular surgery is that even when the outcome does not meet expectations, patients undergoing endovascular surgery can later be referred for conventional surgery. For operators and patients alike, this provides the benefit of an additional option for therapeutic treatment.

Moreover, patients with bilateral stenosing aortoiliac lesions are generally young. A minimally invasive procedure affords advantages in reduced mortality and morbidity, thus avoiding the sequelae associated with conventional surgery.

Simplicity of performance and repeatability of the procedure have made endovascular surgery the method of choice in the treatment of aortoiliac diseases, while conventional surgical revascularization continues to maintain its fundamental role in the revascularization of large chronic occlusions.

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