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Surgical internal iliac artery preservation associated to endovascular repair of infrarenal aortoiliac aneurysms to avoid buttock claudication and distal type I endoleaks.

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Abstract

Objectives

To assess outcomes of a hybrid technique consisting in treating abdominal aortic aneurysm (AAA) associated with iliac aneurysm without distal neck, by combining an AAA endovascular repair approach with open surgery for preserving internal iliac artery (IIA).

1 Methods

2 The files of 51 patients operated between 1998 and 2017 in a single vascular surgery department
3 were retrospectively analyzed. Inclusion criteria were patients with AAA associated with uni- or
4 bi-iliac aneurysm without suitable distal sealing zone. Surgery consisted in deploying an aorto-
5 uni-iliac stent-graft combined with an extra-anatomical crossover prosthetic bypass. Using a
6 limited retroperitoneal approach, the contralateral proximal common iliac aneurysm was
7 surgically excluded and the IIA revascularized by direct ilio-iliac anastomosis or terminal
8 common iliac suture preserving the iliac bifurcation.

9 Results

10 Patient mean age was 74 years (58-88) and 92% were men. The mean follow-up was 5.8 years
11 (0.1-18). Twenty-nine patients (57%) had one or more high-risk criteria for open surgery.
12 Nineteen patients (37.3%) had aorto-uni-iliac aneurysms, 19 (37.3%) aorto-bi-iliac aneurysms, 5
13 (10%) isolated iliac aneurysms and 8 (15.7%) bi-iliac aneurysms without aortic location. Four
14 patients (7.8%) also had IIA aneurysms. Surgery was successful in all cases. Two patients (4%)
15 died during the 30 days after surgery. One surgically-preserved IIA occluded within the first
16 month resulting in buttock claudication. The 5-year IIA primary patency rate was 96%. Type I
17 proximal endoleaks occurred in 2 patients requiring additional surgery 3 and 13 years after the
18 initial surgery, respectively.

19 Conclusion

20 This hybrid technique, consisting in AAA endovascular exclusion combined with open IIA
21 revascularization, is safe and effective to preserve pelvic vascularization. It is associated with
22 long-term patency and low morbidity rates. We have been using this technique before the advent
23 of branched dedicated devices allowing to the preservation of IIA with good results. And this

technique should continue to be proposed, especially in patients not eligible for endovascular iliac branch repair due to anatomical contraindications, to avoid pelvic ischemia if IIA has to be sacrificed.

Introduction

Endovascular repair of abdominal aortic aneurysms (AAA) results in a lower early morbidity in high-risk patients compared to open surgery¹⁻³. However, endovascular repair is sometimes limited by anatomical constraints resulting in the inability of the stent-graft to properly exclude the AAA because of high-flow endoleaks. AAA endovascular repair extended to common iliac arteries requires dedicated devices to preserve internal iliac arteries (IIA) or IIA embolization to avoid distal type I endoleaks. The loss of one or both IIA exposes to a higher risk of pelvic ischemia such as colonic ischemia, buttock claudication and erectile dysfunction⁴. The hybrid technique we present combines an endovascular approach to treat the AAA and an open technique to preserve at least one IIA. The aim of this study was to assess the morbidity and mortality associated with the use of this hybrid technique and its efficacy in maintaining IIA long-term patency.

Material and methods

A retrospective study was conducted to analyze outcomes of endovascular repair in a series of patients who underwent AAA endovascular repair combined with surgical preservation of at least one IIA. Surgery was performed in a single tertiary vascular surgery referral center. Clinical and demographic data as well as aneurysm features and surgical techniques were analyzed.

Indication for aneurysm surgery was either an AAA diameter larger than 50 mm or a common iliac artery diameter larger than 30 mm. No emergency cases were included. Follow-up visits were planned 1 and 6 months after surgery and annually thereafter. They included clinical examination, CT-scan and Doppler ultrasonography. Technical success rate and early or late complications were reported according to reporting standards of the Ad Hoc committee for Standardized Reporting Practices in Vascular Surgery/International Society for Cardiovascular Surgery^{5,6}. In this reporting, mortality was defined as "early" when it occurred before day 30. Three types of complications were defined (systemic, local non-vascular or vascular and implant-related) and three severity grades were used (mild, moderate or severe). Statistical analyzes were carried out using SAS 9.4 software. All tests were two-sided and P-values less than 0.05 were considered statistically significant. Descriptive analysis was performed and data are presented as a mean \pm standard deviation or frequencies (percent) depending of variable nature. Survival data were assessed using Kaplan Meier curves.

Surgical technique

When one of the two distal iliac necks was unfit for bifurcated endograft use, AAA endovascular exclusion was performed with aorto uni-iliac stent-graft. The stent-graft was always inserted on the side which had an adequate common iliac sealing zone (iliac neck length greater than 10 mm, non-conical and with a maximum diameter less than 20 mm), using a short longitudinal groin incision, allowing preserving the ipsilateral IIA. The contralateral limb was revascularized through a prosthetic crossover femoro-femoral or femoro-external iliac bypass. In case of iliac anastomosis, graft was tunneled through the Retzius space and described a large loop in the retroperitoneum to avoid kinking. In order to preserve contralateral IIA, a retroperitoneal

approach was used on the other side. The contralateral femoral approach was extended to a pararectal incision without transecting the inguinal ligament. Then, the iliac bifurcation was controlled (figure 1). The proximal common iliac clamping was facilitated by the low pressure inside the aneurysmal sac obtained after proximal exclusion by the stentgraft. And the common iliac aneurysm was transversally cut off above the bifurcation. The proximal end was sutured with 3/0 back-and-forth suture on a felt strip (figure 2). When the iliac bifurcation was spared by aneurysm dilation, a simple suture of the distal end was performed (AAA class D, according to EUROSTAR classification⁷) (figure 3). When the iliac bifurcation was included in the aneurysm dilation (AAA class E), the external iliac and IIA were divided and end-to-end anastomozed (figure 4a and b).

Ethical Approval for Research and informed consent were obtained for the whole series as well as for every individual patient.

Results

From 1998 to 2017, 51 patients (92% of men) with a mean age of 74 years (58-88) were included. During the study period, 3173 AAA were treated at our centre, including 2230 treated with open repair and 943 with endovascular repair. Clinical and demographic data are shown in table I.

Twenty-nine patients (57%) had one or more high-risk criteria for open surgery. Thirteen patients (25%) were more than 80 years old. Twenty-three patients (45%) had preoperative renal failure with an estimated glomerular filtration rate less than 60 mL/min (Cockroft formula). Nineteen patients (37.3%) had aorto-uni-iliac aneurysm, 19 (37.3%) aorto-bi-iliac aneurysm, 5 (10%) isolated iliac aneurysm and 8 (15.7%) bi-iliac aneurysm without aortic location. The mean

1 abdominal aortic diameter was 47.5 mm (range 16 to 71). The mean diameter of the common
2 iliac artery, ipsilateral to the stent-graft, was 17.9 mm (range 10 to 26). All ipsilateral common
3 iliac arteries had a distal landing zone of more than 10 mm. The mean diameter of the
4 contralateral common iliac artery, that was surgically excluded, was 29.5 mm (range 18 to 62).
5 Four patients (7.8%) also had proximal IIA aneurysm and in these cases the crossover prosthetic
6 bypass was directly anastomosed on the distal IIA after aneurysm exclusion and the external iliac
7 artery was re-implanted into the crossover bypass. Only one patient had a non-patent ipsilateral
8 IIA prior to surgery; in this later case, the contralateral IIA was surgically preserved.

9 Home-made devices have been developed in our unit since the beginning of the endovascular
10 experience. Briefly the device consisted in aorto mono iliac stentgraft including stents and textile
11 of variable diameter designed to fit with the aneurysmal sac⁸. These homemade endografts used
12 commercially available textile and stents. The aim was to use surgical-like textile to avoid
13 porosity of thinner ones and to provide a morpho-adjusted device to fill the empty space of the
14 aneurysmal sac, as last generations of endovascular aneurysm sealing system do. Forty-two
15 stent-grafts were home-made devices based on Gianturco Z stents (Z stent, Cook Inc,
16 Bloomington, Ind) coated with vascutek Gelweave fabric (Terumo company, Glasgow, United
17 Kingdom). These devices were used until year 2010. Then, seven aorto-uni iliac Endurant and 2
18 aorto-uni iliac Talent stent-grafts (Medtronic, Dublin, Ireland) devices were used during the last
19 period (from 2010 to 2017) (figure 5). The mean proximal stent-graft diameter was 26 mm (20-
20 36) and the mean distal stent-graft diameter was 18 mm (9-24). An extra-anatomical bypass was
21 performed in all patients: ilio-external iliac in 11 patients, femoro-femoral in 14, femoro-external
22 iliac in 24, and femoro-IIA in 2. A Dacron tube with a mean diameter of 10 mm (8-12) was used
23 for the bypass.

In 27 cases (53%), the iliac bifurcation was preserved and the distal common iliac artery was only sutured. In the remaining 24 cases (47%), the iliac bifurcation was aneurysmal and an end-to-end anastomosis was performed between the external iliac artery and the IIA prior to the extra-anatomical bypass.

Surgery was successful in all cases. On completion angiography, the IIA was patent in all cases.

Short-term complications (day 30)

The 30-day postoperative mortality rate was 4%: 2 patients died from massive heart attack within 2 days of surgery, one after a pace-maker dysfunction and one after acute respiratory failure secondary to complete lung atelectasis.

One patient developed acute mesenteric ischemia due to a cholesterol embolization syndrome and required cholecystectomy and colectomy with ileostomy at day 7. Two patients had a wound infection requiring secondary surgical intervention for drainage and Sartorius myoplasty. In another patient, a preserved IIA occluded within the first month resulting in buttock claudication. Finally, 2 patients (4,1%) experienced type II endoleak identified on post op CT scan.

Long-term follow-up and patient evolution

The mean follow-up was 5.8 years (0.1-18). The 5-year IIA primary patency rate was 96%.

No secondary dilation was observed in the neo-iliac bifurcation during follow-up.

One aortic stent-graft occluded 15 years after surgery and was treated with an axillo-bifemoral bypass.

An endoleak occurred in 7 patients (14.3%) at various time points after surgery. Five endoleaks were type II, of which 4 were successfully embolized. Embolization was indicated when

aneurysm diameter increased by more than 1 cm or more than 5mm per 6 months. Two type I proximal endoleaks occurred in 2 patients and required additional surgery. In one patient, the stent-graft was only partially removed and an aortic bypass between the infra-renal aortic neck and the previous stent-graft was performed 3 years after implantation. In the other patient, the stent-graft was totally removed and an open surgical aorto bi-iliac bypass was performed 13 years after the initial surgery. In these two cases no endovascular conversion was available. During follow-up, 31 patients (60.1%) died from non-vascular causes in addition to the 2 patients who died during the peri-operative period. The 5-year survival rate was 52.1% (figure 6). Four patients were lost to follow-up at 0.1, 3.4, 3.6 and 3.9 years.

Discussion

In this study, we used a hybrid technique combining AAA endovascular exclusion to IIA open revascularization and demonstrated its long-term efficacy on patency and safety on pelvic revascularization.

It is usually accepted that endovascular treatment is less invasive than open surgical repair⁹⁻¹¹, especially when iliac arteries are involved¹². However, the endovascular treatment of AAA extended to iliac aneurysms may be responsible for inadequate distal sealing resulting in high-flow endoleaks precluding AAA exclusion success. This issue is not uncommon since iliac aneurysms are associated with AAA in 20-30% of cases¹³. Several studies have shown that an inadequate distal sealing zone was responsible for a high re-operation rate during follow-up of patients who underwent endovascular aneurysm repair (EVAR). For instance, when common iliac aneurysm extends to the bifurcation, AAA-related complications occur more commonly and

secondary interventions are more frequently needed. Distal type 1 endoleak and stent-graft thrombosis are more common in these patients^{14,15}.

Moreover even when the aneurysm does not involve the iliac bifurcation, the common iliac artery tends to significantly dilate after EVAR, especially in case of ectatic iliac arteries¹⁶.

Other endovascular techniques have been proposed to overcome the risk of endoleak in case of inadequate sealing zone, including short, tortuous or conical distal neck.

The most common technique consists in embolizing and then covering IIA with stent-graft to reach an external iliac sealing zone. This technique has well-known complications. Buttock claudication occurs in about 28% of cases^{4,17} and its resolution has been reported in only 48.0% of cases after 21.8 months in a recent meta-analysis⁴. The proportion of buttock claudication may reach 42% in case of bilateral embolization¹⁷.

To prevent IIA occlusion, other techniques have been developed but endoleaks may still occur in some cases: the Bell-bottom technique consists in deploying an iliac flared endograft limb in large common iliac arteries. But it may only be performed in case of moderately dilated common iliac arteries (20 mm for the Cook Zenith Flex® and 25 mm for the Gore Excluder® and Endurant II®). Although ectatic iliac arteries appear to be suitable sealing zones in the short term, the long-term follow-up is of concern. Indeed, the dilation of ectatic common iliac arteries is frequent after EVAR¹⁶. Recent studies have shown that these techniques are associated with a significant risk of iliac limb complication (type I or III endoleaks: 4%)¹⁸ and the long-term outcomes are uncertain.

Other totally endovascular techniques using non specific dedicated devices have been described.

For instance, retrograde endovascular IIA preservation is a hybrid technique consisting in performing an endovascular external-to-internal iliac artery bypass with a covered stent

1 associated with an aorto-mono-iliac stentgraft procedure and a femfem bypass. It has been shown
2 to be associated with a 4-year rate of endoleaks or occlusion of 14.3%¹⁹. A limited number of
3 cases are described in the literature and the long term outcomes are of concern.

4 New dedicated devices are commercially available to ensure a good distal sealing zone while
5 preserving IIA patency, including the Zenith Branch Endovascular Graft Iliac Bifurcation device
6 (Zbis, Cook medical Boominghton, Ind) and the Iliac branch Excluder (IBE, Gore, Flagstaff,
7 AZ).

8 These two devices are strongly dependent on iliac aneurysm morphology as described in the
9 instructions for use (IFU). They are indicated in aorto-iliac aneurysms without distal neck. In
10 France, their indication is restricted to the preservation of only one IIA when both IIA may
11 undergo occlusion.

12 The Z-bis stent-graft (Cook) requires a non-aneurysmal external iliac artery with a diameter large
13 enough (8-11 mm) to get through a 20 Fr sheath and a landing zone length of at least 20 mm.

14 The IIA should have a distal neck of at least 10 mm and a diameter compatible with the
15 commercially available bridging stents. Moreover, the iliac bifurcation should be larger than 16
16 mm to avoid a conflict between the two legs of the bifurcated stent-graft.

17 The IBE (Gore) requires a common iliac artery diameter larger than 17 mm, an external iliac
18 artery with a diameter ranging between 6.5 and 13.5 mm, and an IIA diameter ranging between
19 6.5 and 13.5 mm. The IIA and external iliac artery landing zone should be longer than 10 mm.

20 The exclusive endovascular approach is thus restricted to selected cases²⁰ to be effective
21 ((minimal iliac tortuosity, minimum length and diameter of the common iliac artery, non stenotic
22 IIA).

Indeed, two studies have reported that the anatomical suitability for one of the two iliac branched devices available was limited to 35-39.8% of patients based on the IFU^{21,22}. For IBE (Gore) or Zbis (Cook) stent-graft alone, the anatomical suitability was of 25.3% and 18.2%, respectively²². However in patients who could receive this branched stent-graft, the technical success reached 85-100%^{20,23-25}. This technique has good initial results when anatomical recommendations are respected. But when the IFU are not respected, in case of peroperative technical difficulties or IIA proximal stenosis, Delay et al have shown that thrombosis may occur²⁶. In the long term, IIA branch occlusion has been reported in 9.3% of patients after a mean follow-up of 26.6 months and secondary surgery was needed in 24.1% of cases at 5 years²⁴. In another study, a significative rate of limb occlusion of 12% was reported during follow-up, responsible for buttock claudication in half of the cases²⁰.

It thus appears that although the importance of preserving the IIA while preventing the occurrence of endoleaks has been shown²⁷, there is no consensus about the best technique (endovascular or open repair) to be used to achieve these results.

The strategy we describe was implemented before emergence of branched devices dedicated to IIA. Branched devices have been available in France with reimbursement only since March 2013, that is why the majority of cases were fulfilled before this date. The acceptable results we obtained led us to continue to use this technique when anatomical contraindications avoided us to use branched devices. Its use has made it possible to develop a simple technique. It requires 2 vascular approaches: a scarpa approach and a retroperitoneal iliac pathway. These classical vascular approaches are regularly used in open surgery and make them a reproducible technique. Considering the good results of dedicated branched devices we should advise to use endovascular technique first when IFU are respected, and to consider hybrid surgical

preservation technique when they are not, instead of embolization or non dedicated devices use.

The technique we describe showed a mortality rate of 4% but the patient we treated were high risk patients: 51% were ASA 3 or more, mean age was 74 (+/-8) y and 25% were older than 80 y.

In this context, we considered that this technique resulted in a low morbidity rate and appeared to be especially indicated in patients who are not eligible for endovascular iliac repair due to anatomical contraindications.

Our hybrid procedure consisted in simple common iliac closure in half of cases where aneurysm ended just above the iliac bifurcation (figure 3). In the other cases, the external iliac and IIA were divided and end-to-end anastomosed with minimal IIA mobilization (figure 4b) in order to exclude any pathologic tissue. With this technique, no secondary iliac bifurcation dilation occurred.

Our study has some limitations, including its retrospective design, and the fact that we did not verify a posteriori which cases would have benefited from an iliac bifurcated device. This experience was initiated before the advent of iliac branched stent-grafts for which the results now appear to be promising, although their long-term patency should be assessed and compared to that achieved with open repair in further studies.

However, our follow-up was long (5.8 years), only four patients were lost to follow-up and the rate of non-aorto-iliac complication-related mortality was in the normal range in this specific population after surgery and reflected the disease severity of our patients. Furthermore, unlike iliac bifurcated stent-graft, our hybrid technique allowed revascularizing the IIA regardless of the anatomical pattern of iliac arteries.

Conclusion

The hybrid technique we described, consisting in AAA endovascular exclusion combined with open IIA revascularization, is safe and effective on pelvic vascularization. It results in a high long-term patency rate and low morbidity. This technique is a simple alternative. It is accessible to any vascular center and should continue to be proposed in patients who are not eligible for endovascular treatment due to anatomical contraindications to preserve both IIA.

Conflict of interest

None

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- 6

Legends for illustrations

Figure 1

CT scan reconstruction (volume rendering technique) showing:

(a): femoral and iliac approaches (the midline scar corresponds to a previous approach for visceral surgery performed several years ago)

(b): right aorto-mono-iliac stentgraft with femoro-femoral bypass and left iliac bifurcation reconstruction.

Figure 2

Surgery overview. An aorto-mono-iliac stent-graft was deployed and a femoro-femoral crossover bypass performed to revascularize the left limb and the left internal iliac artery. Left common iliac artery aneurysm is clamped and divided after proximal exclusion by the stent graft.

Figure 3

In case of EUROSTAR class D aneurysm, common iliac aneurysm is proximally and distally sutured just above the bifurcation, allowing to easily preserving the iliac bifurcation.

Figure 4a

In case of EUROSTAR class E aneurysm, the dilated iliac bifurcation must be divided.

Figure 4b

In case of EUROSTAR class E aneurysm, an end-to-end anastomosis between IIA and external iliac artery is performed allowing maintaining the internal iliac artery patent, and avoiding to maintain the distal aneurysmal arterial wall.

Figure 5

Year and number of endografts implantations with IIA preservation.

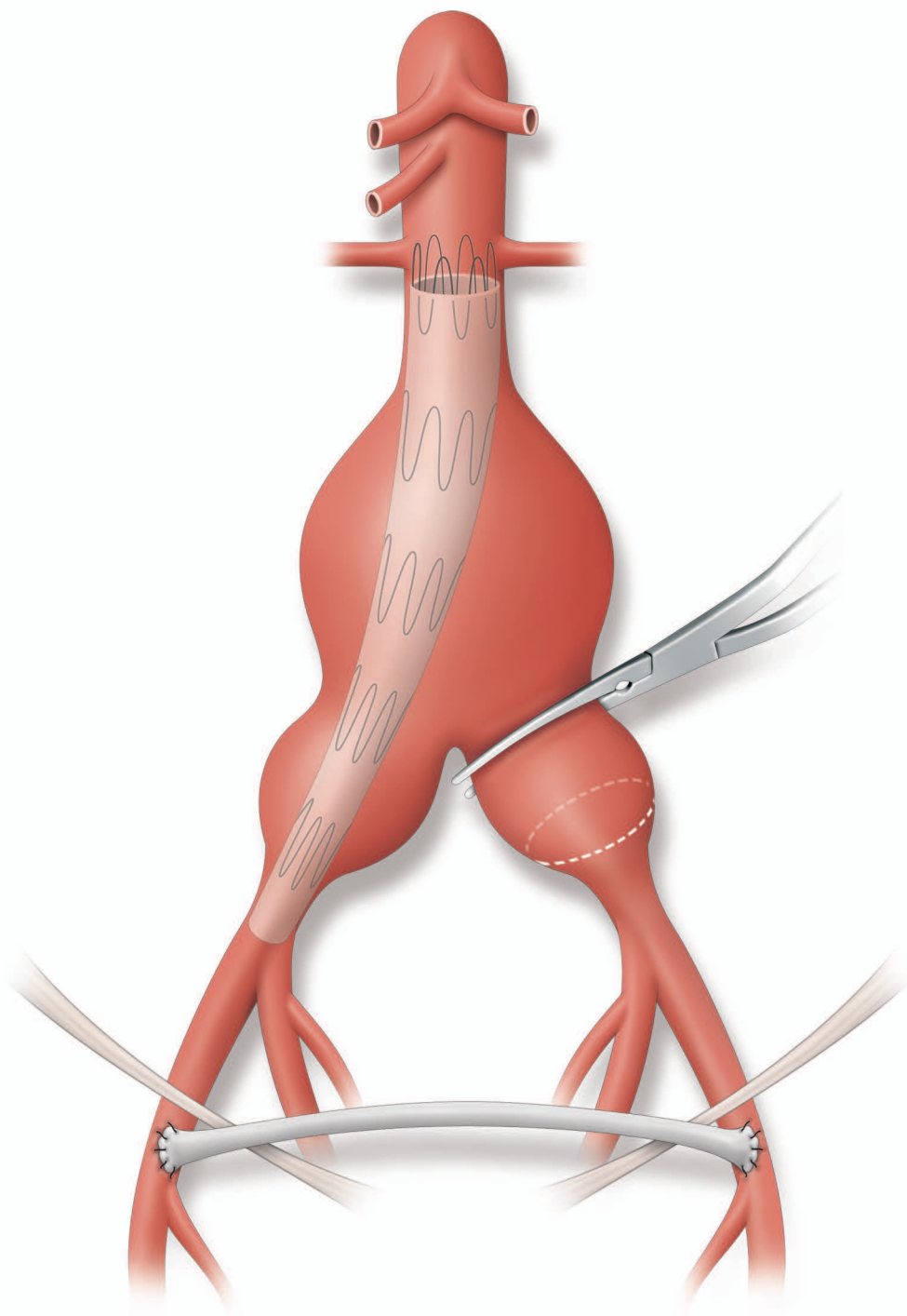
Figure 6

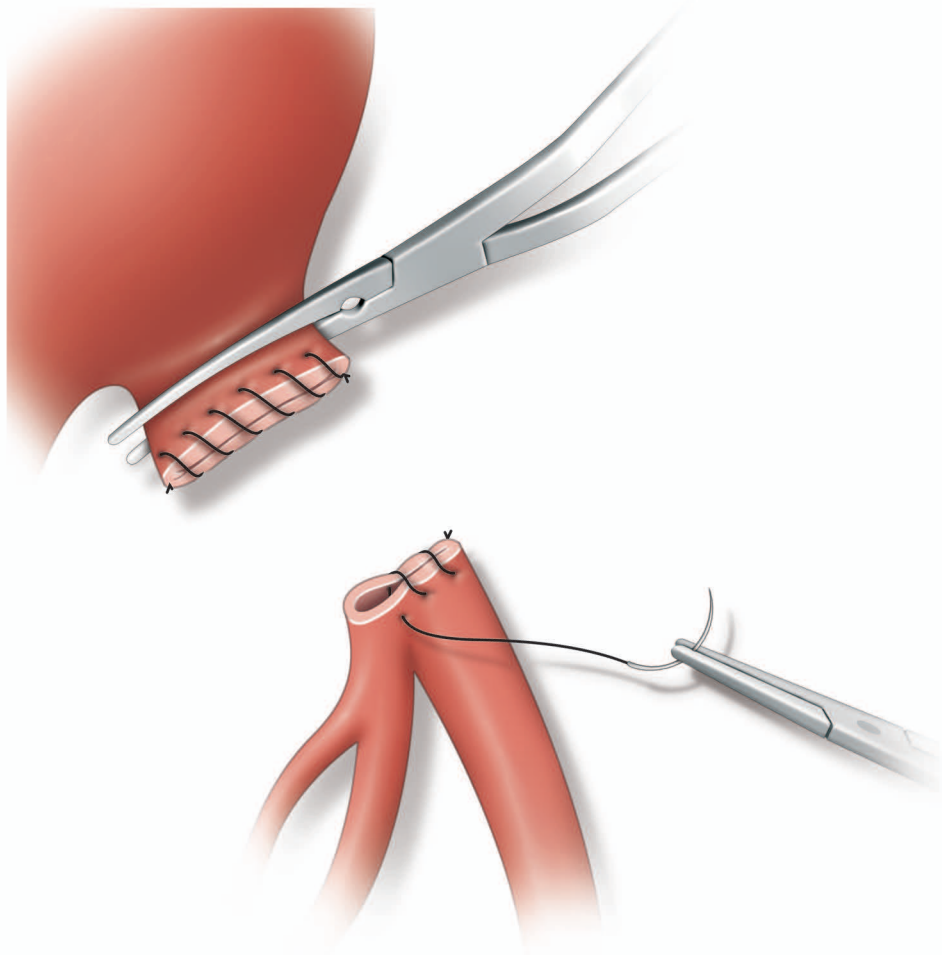
Long term survival rates (number at risk are mentioned above the horizontal axis)

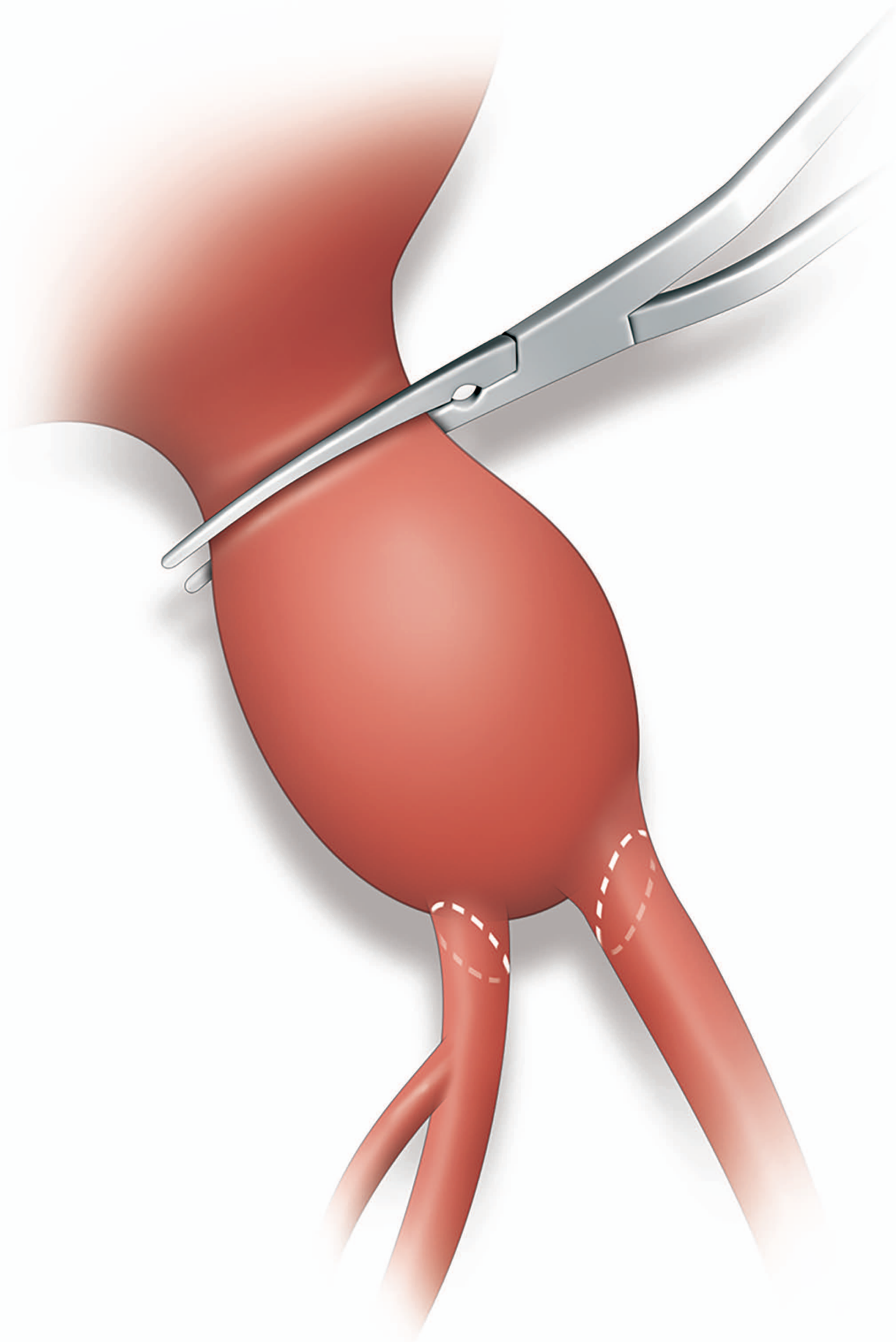
Table 1

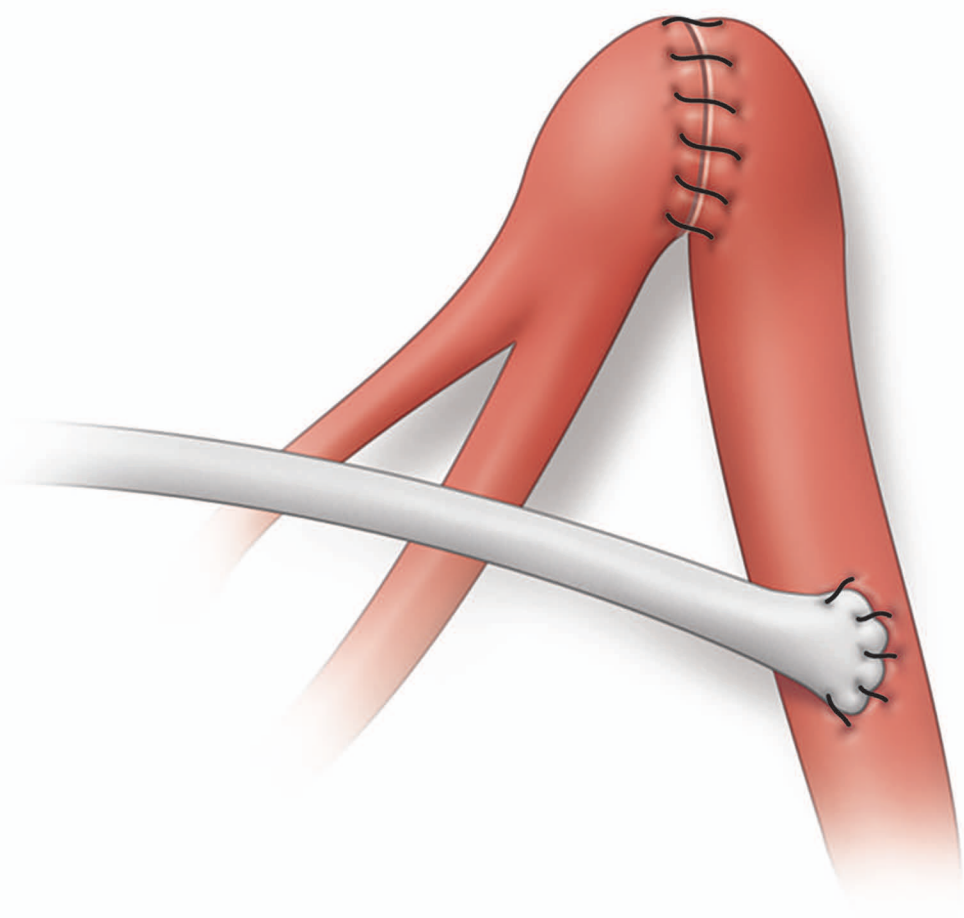
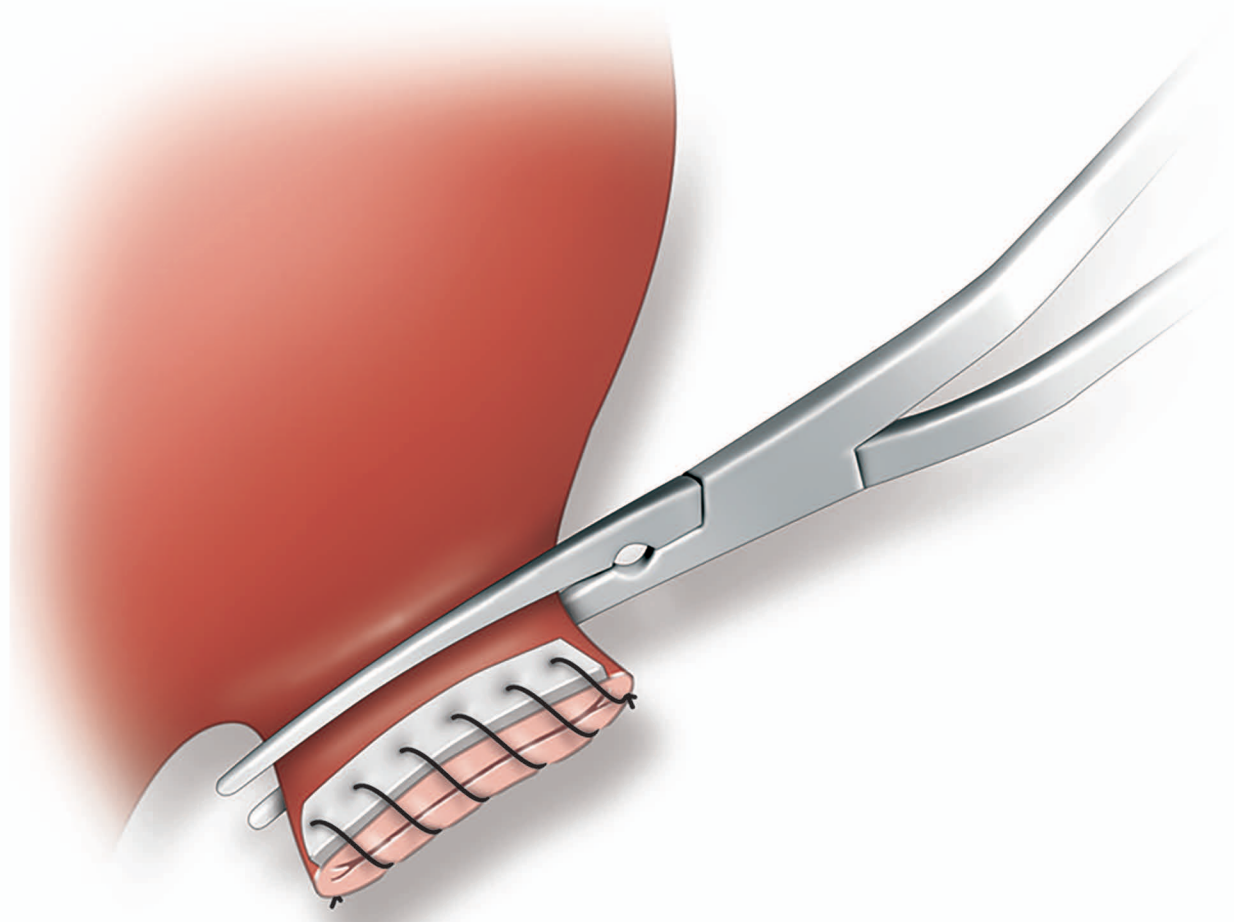
Clinical and anatomical characteristics of patients with internal iliac artery surgical preservation











■ Number of patients

10

9

8

7

6

5

4

3

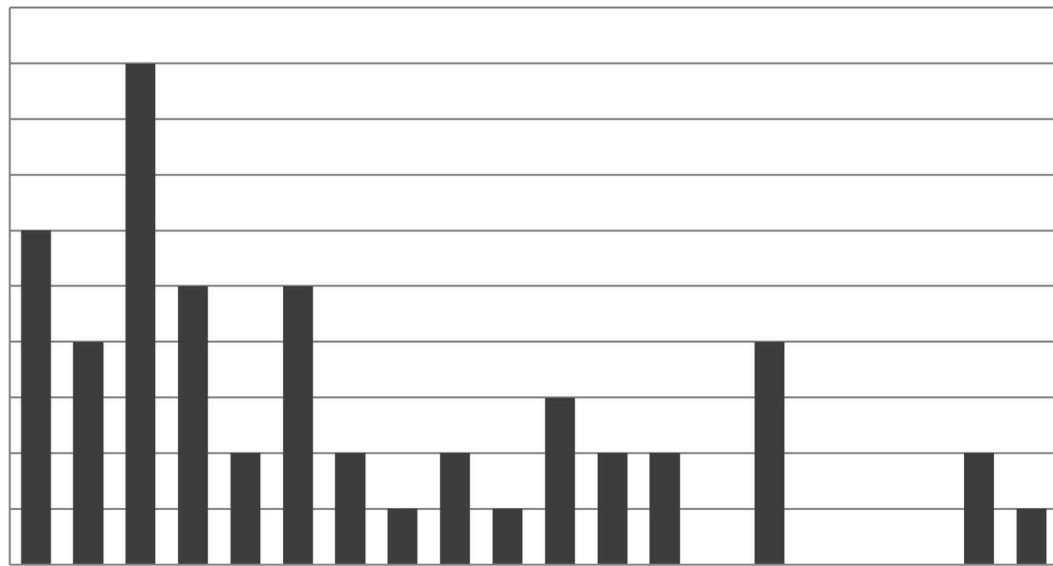
2

1

0

1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017

Year



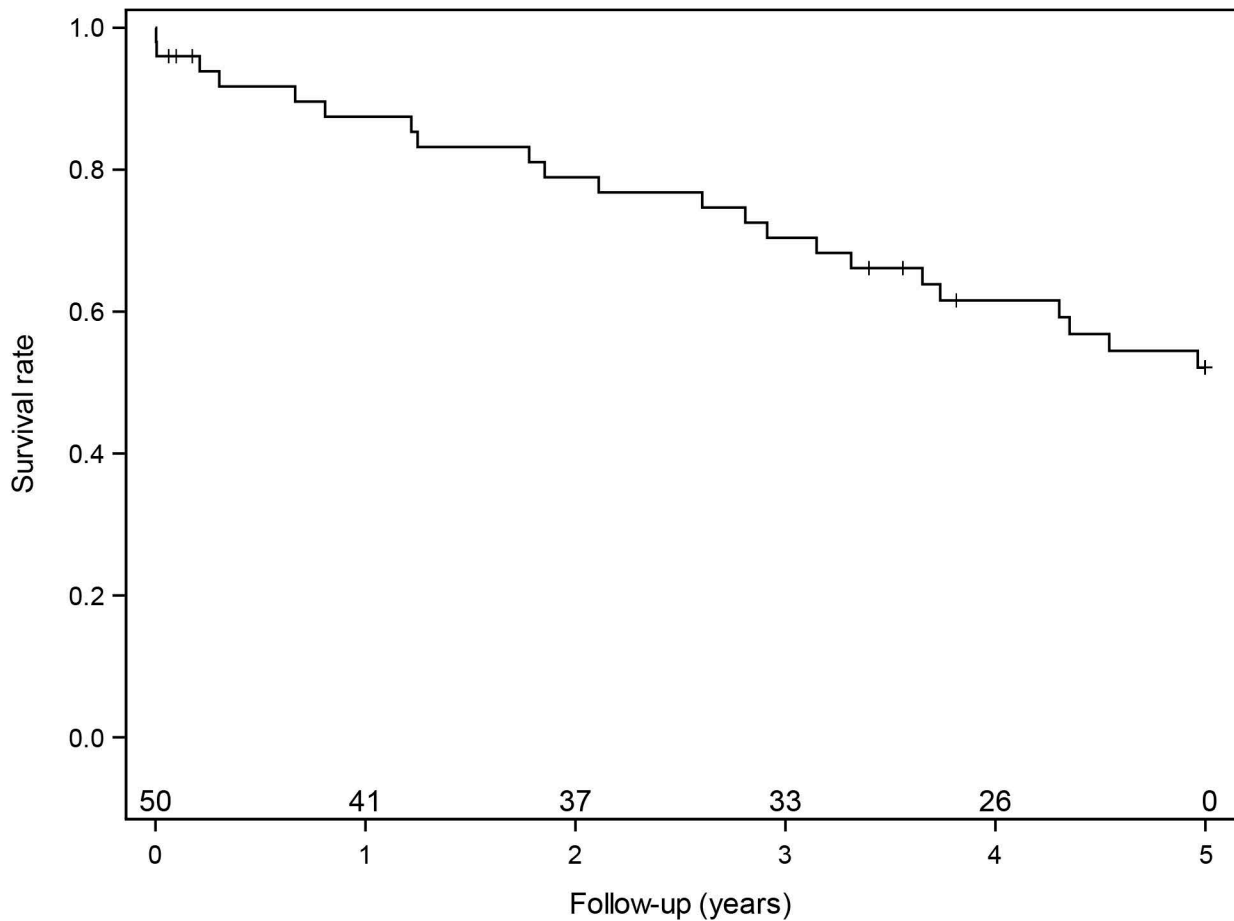


Table I

	n=51
Mean age, years (+/-SD)	74 (+/-8)
Age >80 years, n (%)	13 (25)
Men, n (%)	47 (92)
Diabetes, n (%)	8 (16)
Smoker, n (%)	41 (80)
Hypertension, n (%)	39 (77)
Coronary artery disease, n (%)	21 (41)
Mean LVEF, % (+/-SD)	59 (+/-8)
LVEF <40%, n (%)	2 (4)
Hostile abdomen*, n (%)	10 (20)
Mean BMI, kg/m ² (+/-SD)	28.7 (+/-2)
COPD, n (%)	16 (31)
Renal clearance, mL/min. (+/-SD)	66 (+/- 10)
ASA	
1 (%)	2
2 (%)	47
3 (%)	43
4 (%)	8
Mean common iliac diameter surgically excluded, mm (+/-SD)	29.5 (+/-9)
Mean common iliac diameter ipsilateral to the SG, mm (+/-SD)	17.9 (+/-9)
Uni-iliac aneurysm, n (%)	24 (47)
Bi-iliac aneurysm, n (%)	27 (53)

LVEF: Left Ventricle Ejection Fraction, BMI: Body Mass Index, COPD: Chronic Obstructive Pulmonary Disease, SG:stent graft.

*: history of laparotomy