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ORIGINAL ARTICLE

Preliminary experience with the use of ultra-low profile endografts

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PURPOSE
We aimed to report a preliminary single-center experience of elective endovascular aortic repair (EVAR) using ultra-low profile (ULP) endografts of 14 F outer diameter.

METHODS
Data of 67 consecutive patients who underwent EVAR using either Ovation (group A, n=30) or Incraft (group B, n=37) endografts were retrospectively analyzed.

RESULTS
Aorto-iliac anatomy was significantly different between the two groups, as patients of group A had a greater thrombotic apposition on proximal aortic neck (thrombus thickness: 7.2±1 mm vs. 3.3±1.6 mm, $P = 0.042$; percentage of the circumference covered by thrombus: 45.2%±10.4% vs. 18.7%±10.6%, $P = 0.0003$), while patients of group B had a more angulated proximal neck in the coronal axis (35.9°±6.4° vs. 16.7°±5°, $P = 0.012$). Procedural success was 93.3% and 97.3%, respectively, in groups A and B. One patient in group A required an immediate conversion to open surgery for persistent occlusion of both iliac limbs. Another patient required implantation of a conical endograft with a femoro-femoral right-to-left bypass for occlusion of the contralateral gate during the cannulation. In group B, one intraoperative type Ia endoleak was immediately corrected. Neither deaths nor major adverse events were recorded within 30-days. During a median follow-up of 15.2 months (range, 1–56.7 months) two type Ia endoleaks in group A required open conversion after 12.1 and 40.5 months, respectively. Three patients in group B required a reintervention after 30 days. Neither deaths nor aortic ruptures were recorded during follow-up.

CONCLUSION
Both ULP endografts showed satisfying early and mid-term results.

Since Parodi's first experience (1), the technologic development of new materials for the endovascular treatment of infrarenal abdominal aortic aneurysms (AAA) has moved towards the creation of highly flexible devices which could combine minimal invasiveness of the procedure without affecting safety and effectiveness.

Moreover, the advent of low-profile endograft (ULP) with a 14 F outer diameter has allowed the endovascular aortic repair (EVAR) of infrarenal AAA in patients who have previously been excluded because of challenging aortic anatomies and small and tortuous access vessels.

In our institution, the Trivascular Ovation (2) and Cordis Incraft (3) endografts have been both used for the treatment of these kinds of patients with good results.

In particular, from October 2011 to October 2014 the Trivascular Ovation endograft was the only ULP device available in our hospital. Since November 2014, the Cordis Incraft endograft has been introduced in our clinical practice.

Both endografts have similar instructions for use; however, in our experience we noticed some differences that drive our decision making on the choice of the appropriate ULP endoprosthesis.

In this retrospective study, we aimed to report our experience about the use of both ULP devices.

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Methods

Data of all patients who underwent elective EVAR in our Division of Vascular Surgery using the Cordis Incraft AAA Stent Graft System and the Trivascular Ovation endografts from October 2011 to June 2016 were retrospectively collected in a database and the outcomes were reviewed. All procedures performed in this study were in accordance with the ethical standards of our institutional research committee and with the 1964 Helsinki declaration and its later amendments. Our Internal Review Board approved each procedure and informed consent was obtained from all participants.

Patients

Patients were considered suitable for endovascular repair according to anatomical criteria on a preoperative thoracic-abdominal computed tomography angiography (CTA). According to the current guidelines, infrarenal AAA repair was performed when the diameter exceeded 4.5 cm in women and 5 cm in men, or when the diameter was >4 cm with an increase of more than 0.5 cm during the preceding 6 months. Patients with saccular aneurysms were eligible for inclusion irrespective of the sac diameter.

We specifically opted for the use of a ULP endograft in case of small and tortuous iliac vessels or short proximal aortic neck. In particular, a ULP device was chosen when the suitable proximal aortic neck was shorter than 15 mm and/or the external iliac-femoral arteries were smaller than 7 mm in caliber. From October 2011 to October 2014, the Ovation endograft was the only ULP device available in our institution. Since November 2014, the Incraft endograft has been introduced in our clinical practice, and preferred, according to our experience, in case of more angulated proximal neck in the coronal axis, where we had the opinion that the Ovation could conform worse due to the presence of the polymer and the long free-flow.

Patients with a dissecting or ruptured aneurysm were excluded, as well as patients with history of connective tissue disease (e.g., Marfan's or Ehler's-Danlos syndrome).

Patient records were reviewed for demographics, medical history and aorto-iliac morphology via CTA. Procedural data included fluoroscopy time, operation time, amount of procedural contrast medium, blood loss, and any complications. Follow-up data were analyzed to evaluate primary success, survival, complications, and device-related events, both at 30 days and in the mid-term. Primary success was defined as successful access, delivery and implant of the endograft with absence of immediate surgical conversion, mortality, type I or III endoleak, or graft limb occlusion.

After treatment, all patients were discharged on single antiplatelet therapy (lifelong use of either acetylsalicylic acid 100 mg daily or Clopidogrel 75 mg daily) unless they were already on anticoagulant therapy for preoperative comorbidities.

Postoperative surveillance protocol included a duplex ultrasonography (DUS) scan at discharge, at 1, 6, and 12 months, and annually thereafter. A CTA was performed at 12 months and in case of non-diagnostic DUS scan (i.e., for hostile abdomen) or if either graft thrombosis or endoleak was suspected at DUS scan.

Statistical analysis

Statistical analysis was performed using JMP® 5.1.2 (SAS Institute, Inc.). Continuous variables were reported as mean ± 2 standard deviations (SD) for normally distributed data; median and interquartile range (IQR) were reported otherwise. Categorical variables were presented as frequency and percentage. The comparisons of the two groups were performed using the nonparametric Fisher's exact test for dichotomous nominal variables. Student's t test was performed to compare continuous normally distributed data with homogeneous variances, while Mann-Whitney U test was used for not normally distributed continuous data. Assuming a standard type I error rate α=0.05, a P value <0.05 was considered statistically significant.

Main points

- The advent of ultra-low profile endograft (ULP) with a 14 F outer diameter has allowed endovascular aortic repair (EVAR) of infrarenal abdominal aortic aneurysms in patients who were previously excluded because of challenging aortic anatomies and small and tortuous access vessels.
- To our knowledge, there is no study in the literature comparing the outcomes of the two types of ULPs (Ovation, TriVascular Inc. and Incraft, Cordis Corp).
- Both ULP endografts showed satisfying early and mid-term results. However, they harbor some technical differences that influence our preference for individual cases.

Results

From October 2011 to June 2016, 67 patients (9 females; median age 75.5 years, IQR, 68–81.7 years) underwent elective exclusion of a infrarenal AAA with a challenging iliac anatomy (minimum access vessel, 4.5 mm) using either Trivascular Ovation (group A) or Cordis Incraft (group B) endoprostheses.

As described in Table 1, patients were mainly affected by hypertension (82.1%), current or previous smoking (71.6%), coronary artery disease (CAD, 52.2%), and dyslipidemia (43.3%). No patient presented with severe renal failure; 15 patients had either a slight or a mild increase of serum creatinine level (maximum serum creatinine detected 1.52 mg/dL) at preoperative lab tests.

The two groups were different in terms of aorto-iliac anatomy, as patients of group A had a proximal aortic neck which was affected by a greater presence of thrombus (thrombus thickness: 7.2±1 mm vs. 3.3±1.6 mm, P = 0.042; percentage of the circumference covered by thrombus: 45.2%±10.4% vs. 18.7%±10.6%, P = 0.0003). On the other side, patients of group B had a more angulated proximal neck in the coronal axis (35.9°±6.4° vs. 16.7°±5°, P = 0.012).

Primary infrarenal AAA etiology was atherosclerotic and degenerative in all cases. There were 66 AAAs and a left common iliac artery aneurysm 50 mm in diameter, involving the internal iliac artery.

All procedures were performed by vascular surgeons in the operating theatre. EVAR was mainly performed using regional anesthesia, with an increasing use of local anesthesia and conscious sedation in the recent months rather than general anesthesia, which was the alternative to regional anesthesia in the first part of our experience, when the Cordis Incraft was not yet used (Table 2).

EVAR was performed preferably through a bilateral surgical exposure of common femoral arteries; however, in the last few months we have been opting for a total percutaneous access when femoral arteries are not calcified. A percutaneous additional humeral access was performed in case of extreme difficulty in the cannulation of contralateral gate from both femoral accesses (2 cases in group A only).

Primary success was achieved in 93.3% of cases in group A and 96.1% in group B. In one patient of group A, the device twisted and opened incompletely at the gate,

Table 1. Patient characteristics and anatomical data

	Group A - Ovation (n=30)	Group B - Incraft (n=37)	*P*
Male sex, n (%)	26 (86.7)	32 (86.5)	0.98
Age (years), median (IQR)	74.5 (69.7–79.2)	74.5 (66–83)	0.97
Comorbidities, n (%)			
Current or previous smoking	25 (83.3)	23 (62.2)	0.07
COPD	7 (23.3)	7 (18.9)	0.71
CAD	17 (56.7)	18 (48.6)	0.82
Hypertension	24 (80)	31 (83.8)	0.68
Dyslipidemia	17 (56.7)	12 (32.4)	0.041*
Diabetes	5 (16.7)	5 (13.5)	0.75
Renal failure	8 (26.7)	7 (18.9)	0.45
Obesity	3 (10)	3 (8.1)	0.87
Neoplasm	2 (6.7)	2 (5.4)	0.34
Previous stroke	1 (3.3)	1 (2.7)	0.18
Oral anticoagulants	3 (10)	5 (13.5)	0.68
Anatomical data (mm), (mean±2SD)			
Proximal aortic neck diameter (AP)	28.5±2	25.6±3.6	0.07
Proximal aortic neck diameter (LL)	29.6±1.6	28.2±3	0.31
Proximal aortic neck length	12.2±8.6	13±5	0.61
Proximal aortic neck angulation (coronal axis)	16.7°±5°	35.9°±6.4°	0.012*
Proximal aortic neck angulation (sagittal axis)	52.6°±42.2°	49.1°±71.6°	0.21
Thrombus thickness (aortic neck)	7.2±1	3.3±1.6	0.042*
% of circumference covered by thrombus (aortic neck)	45.2%±10.4%	18.7%±10.6%	0.0003*
Aortic bifurcation diameter (mm)	21.2±0.8	22.5±1.6	0.61
Proximal RCIA diameter (mm)	11.1±0.4	9.2±0.2	0.28
Distal RCIA diameter (mm)	9.1±1	9.6±0.8	0.18
Proximal LCIA diameter (mm)	10.2±1	9.8±3	0.27
Distal LCIA diameter (mm)	10.8±1.6	9.5±2.8	0.35
Smaller EIA diameter (mm)	5.9±1.8	6.1±1.6	0.28
Smaller CFA diameter (mm)	5.2±0.2	5.9±0.8	0.24
Sac diameter (mm), median (IQR)	54 (52–55)	51.5 (50–60)	0.71

IQR, interquartile range; COPD, chronic obstructive pulmonary disease; CAD, coronary artery disease; SD, standard deviation; AP, anterior-posterior; LL, lateral-lateral; RCIA, right common iliac artery; LCIA, left common iliac artery; EIA, external iliac artery; CFA, common femoral artery.
*$P < 0.05$.

so cannulation of the contralateral leg was not possible. A conical stent graft (Talent, Medtronic) was then placed, with an occluder at the level of the left common iliac artery, and a femoro-femoral right-to-left bypass was performed. In a second patient of group A, immediate open conversion was necessary because of a persistent steno-occlusion at the origin of the left iliac limb, which at angiographic control appeared shrunk due to extrinsic compression by the contralateral limb. Kissing ballooning of both iliac limbs at their origin was performed, but did not yield a valid flow throughout both iliac-femoral axes, so open conversion was indicated. Considering the good proximal sealing of the endovascular graft, proximal control of the hemostasis was achieved placing the aortic clamp in the soft part of the main body, below the two polymer rings. Both iliac legs were easily removed but the main body was left in place. Two 8 mm tubular grafts (Fusion) were anastomosed between the legs of the main body and the common femoral artery on both sides, after suturing common iliac arteries at their origin (4). In group B, one patient presented an immediate type Ia endoleak which was resolved by the placement of a proximal aortic cuff.

Intraoperative complications occurred in 3 patients overall. In one patient of group A, retrieval of the sheath at the end of the procedure caused rupture of a heavily calcified right femoral artery, which was reconstructed using a short Dacron tubular 8 mm graft. One more patient required a left femoral endarterectomy with patch angioplasty due to failure of a percutaneous closure system. In group B, one patient at the end of the procedure required a left popliteal Fogarty thrombectomy which successfully resolved an acute leg ischemia. Postoperative course was uneventful and the patient was discharged in postoperative day (POD) 3.

Accidental hypogastric artery coverage occurred in 2 patients of group A, but not in group B (6.7% vs. 0%, $P = 0.18$), without any complication.

Postimplantation syndrome was noted in group B only (18.9% vs. 0%, $P = 0.011$). However, patients were discharged in POD 3 (n=4) and in POD 4 (n=3), respectively.

During in-hospital stay, 7 patients required blood transfusion for postoperative anemia (4 in group A and 3 in group B), with a median of 1.2 packs of red blood cells. One patient in group B required a surgical revision of the groin for a hematoma which occurred in POD 2. No other complications occurred during in-hospital stay. Patients' median length of in-hospital stay for both groups was 2 days (IQR, 2–4 days for patients in group A and 2–3 days for patients in group B, $P = 0.35$).

During follow-up (median, 15.2 months; range, 1–56.7 months), neither deaths nor AAA rupture occurred for both groups.

Two type Ia endoleaks in group A required late open conversion and partial graft explant after 12.1 and 40.5 months, respectively. In the former case, the proximal part of the endograft with its long free-flow was successfully kept in place, trimmed just below the polymer ring and packed with the aortic wall and a Dacron 18 mm tubular graft. Distally, the Dacron graft was anastomosed to the distal end of the endoprosthesis, keeping the iliac branches in

Table 2. Perioperative data and long-term results

	Group A - Ovation (n=30)	Group B - Incraft (n=37)	*P*
Anesthesia			
Regional	23 (76.7)	31 (83.8)	
Local + conscious sedation	0 (0)	5 (13.5)	0.006[a]
General	7 (23.3)	1 (2.7)	
Vascular access			
Percutaneous femoral	7 (23.3)	4 (10.8)	
Percutaneous brachial (additional)	2 (6.7)	1 (2.7)	0.14
Surgical femoral	23 (76.7)	33 (89.2)	
Time of operation (min), mean±SD	59.1±3.4	49.6±2.8	0.16
Amount of contrast (mL), mean±SD	49.1±3.2	44.3±2.8	0.24
Fluoroscopy time (min)	17.8±1.4	16.1±1.8	0.63
Blood loss (mL), mean±SD	167±16	154±12	0.48
Procedural success	28 (93.3)[b]	36 (97.3)[c]	0.41
Accidental hypogastric artery coverage	2 (6.7)	0 (0)	0.18
Intraoperative complications	2 (13.3)[d]	1 (2.7)[e]	0.17
Length of stay (days), median (IQR)	2 (2–4)	2 (2–3)	0.38
30-days complications	4 (13.3)[f]	4 (10.8)[g]	0.86
Post-implantation syndrome	0 (0)	7 (18.9)	0.011[a]
Long-term results			
Death	0 (0)	0 (0)	NC
Major adverse events	0 (0)	1 (2.7)	0.47
Endoleak	2 (6.7)	1 (2.7)	0.45
Aortic rupture	0 (0)	0 (0)	NC
Reintervention	2 (6.7)	3 (8.3)	0.79
Follow-up (months), median (IQR; range)	40 (24.9–50.2; 1–56.8)	10.8 (2.1–15.1; 1–18.8)	-

Data are presented as n (%), unless otherwise noted.
[a]*P* < 0.05; [b]One conical stent graft with a femorofemoral right-to-left bypass due to unsuccessful cannulation of the contralateral gate and one immediate conversion due to persistent steno-occlusion of iliac limb; [c]One intraoperative type Ia endoleak; [d]One case of rupture of the femoral artery at the retrieval of the sheath and one failure of the percutaneous vascular closure system; [e]One case of acute left lower limb ischemia; [f]Four cases of postoperative anemia with blood transfusion; [g]Three cases of postoperative anemia with blood transfusion and one groin hematoma.
NC, not calculated; IQR, interquartile range.

site (Fig. 1). In the latter case, the main body was cut below the polymer ring, leaving in place the proximal part, which was packed with the aortic wall with the interposition of a Dacron 16 mm bifurcated graft. Both iliac limbs had a good distal sealing and the proximal soft part of each limb was used for the distal anastomoses of the bifurcated graft (Fig. 2).

One type II endoleak in a patient of group B required endovascular placement of a covered stent to exclude a collateral branch of the left hypogastric artery, 12.5 months after the operation.

Two more patients in group B required reintervention during the follow-up: a bilateral iliac angioplasty for a residual buttock claudication due to severe stenosis at the distal end of both iliac limbs (after 11 months) and an endovascular recanalization and stenting for a left limb thrombosis (after 6 months). Also, one patient in group B developed acute renal failure, which completely resolved.

Freedom from reintervention at 1 year was 100% in group A and 91.6%±5.7% in group B (28 and 19 patients at risk, respectively).

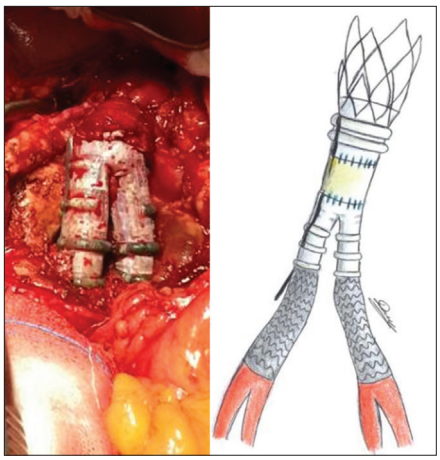

Figure 1. Intraoperative result after late open conversion in one case in group A. The tubular Dacron graft was anastomosed just below the collar rings, all together with the soft part of the main body and the aortic wall.

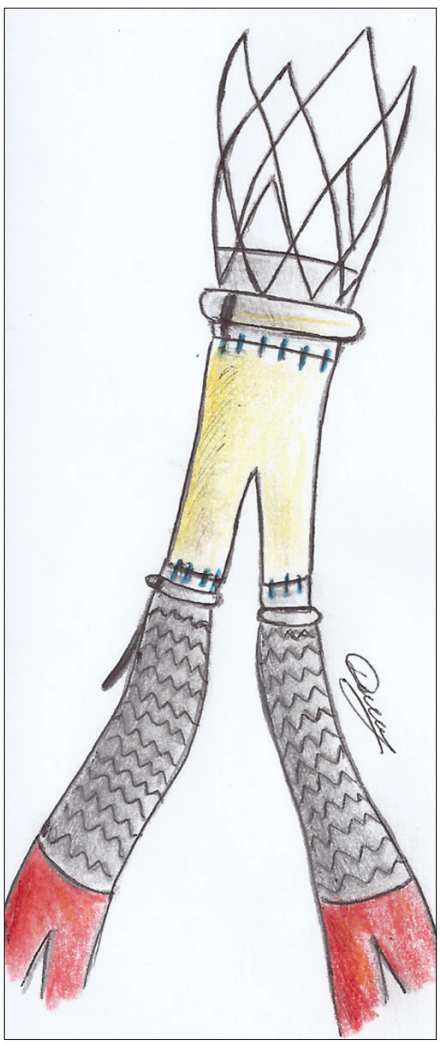

Figure 2. The second case of late intraoperative conversion in group A. The main body was cut below the polymer ring, leaving in place the proximal part. A Dacron 16 mm bifurcated graft was anastomosed with the proximal soft part of each iliac limb.

Table 3. Instructions for use for Trivascular Ovation and Cordis Incraft endografts

	Trivascular Ovation	Cordis Incraft
Pathology	Asymptomatic iAAA	Asymptomatic iAAA
Proximal aortic neck diameter (mm)	16–30	17–31
Proximal aortic neck length (mm)	≥7, if angle <45° ≥10, if 45°<angle<60°	≥10
Aortic bifurcation diameter (mm)	NR	≥18
Iliac-femoral access diameter (mm)	≥4.7	≥4.7
Iliac landing zone length (mm)	≥10	≥15
Iliac landing zone diameter (mm)	8–20	7–22
% of circumferential calcification/thrombus in the suprarenal aorta, proximal aortic neck and iliac landing zones	≤50%	≤50%
Suprarenal/infrarenal neck angulation (°)	<60°	<60°
Length from the lowest renal artery to the distal landing zone (mm)	≥130	≥128

iAAA, infrarenal abdominal aortic aneurysm; NR, not reported.

Discussion

The evolution of endografts for endovascular repair of abdominal aortic aneurysms has allowed physicians to expand the indications to the treatment of those patients who previously would have been excluded due to presence of a challenging aortic anatomy and small access vessels.

The benefits of reducing the endograft profile are well known (5). However, technologic development aims to find the right balance between the profile and performance, as reducing the profile may lead to the possible loss of proximal sealing, which can compromise the overall performance and durability of the device. The next generation of ULP endografts (14 F) has been designed and engineered with the goal of meeting or even exceeding the performance characteristics of the current second-generation devices, with a three-piece modularity, a lower number of stent crowns per circumference, and a redesign of the stent-fabric interaction.

Both Trivascular Ovation and Cordis Incraft endografts have special features to address these issues. The Ovation stentgraft combines a large free-flow with hooks with a ring inflated via polymers, which provides sealing to the arterial wall. By eliminating the need for a metallic endoframe entirely, the Ovation can keep a lower profile while achieving a good proximal seal and likely good durability over time.

The Cordis Incraft AAA has a trimodular stent-graft system, which is designed and engineered with the undeniable advantage of combining navigability in difficult access with adaptability to most anatomies, ensuring durability, conformability, and sealing without the need for polymers.

The experiences described so far have reported excellent results in terms of safety and efficacy for both endografts (6, 7), without any particular difference between the two types of endografts in terms of patients' selection and outcomes. Also, both endografts have quite similar instructions for use (8), as described in Table 3.

In our experience, both endoprostheses showed good results in terms of safety and effectiveness, with no reported aortic rupture during follow-up. The aim of our retrospective analysis was not to compare the results of the two ULP devices, since they were used generally in non-overlapping periods and in different patient groups. However, technical differences observed between the endoprostheses influences our choice for individual cases.

The first technical difference concerns the long free-flow of the Trivascular Ovation, which increases the sealing to the aortic wall along with the polymer. It may represent a major challenge if the graft needs to be removed entirely, so in case of open surgical conversion we suggest to keep the proximal part of the main body whenever possible, as indeed also reported by Georgiadis and Coll (9). No experiences of late conversion after EVAR with Incraft endograft have been reported up to now (10).

The second technical difference addresses the lack of columnar support of the Ovation graft due to a reduction of the prosthetic structure. This technical aspect can affect the occurrence of limb collapse and thrombosis, particularly in case of narrow aortic bifurcation (11), leading even to surgical conversion as happened in our experience. Moreover, intraoperative cannulation of the gate can be more challenging (12). However, this latter problem can be fixed using an additional transbrachial antegrade approach (13). Similarly, some troubles with the cannulation of the contralateral gate were noticed also with the Cordis Incraft. When the main body of the Incraft is deployed, there is not much space between the opening of the contralateral gate and the release of the ipsilateral leg. This fact can make cannulation of the contralateral gate difficult in case of accidental opening of the ipsilateral leg. Moreover, according to the instructions for use, the prosthesis must be released up to the opening of the contralateral gate. Then, the free-flow should be released to allow suprarenal fastening and deployment of the endograft can be completed. However, during deployment of the first stent, the free-flow is still closed and the graft may dislocate downwards under the thrust of systolic blood pressure which exerts on a "cul de sac". This fact increases the risk of distal migration with consequent formation of an immediate type Ia endoleak, as happened in one of our cases. To overcome this problem, we suggest to open the free-flow immediately after deploying the first stent of the main body.

The third difference concerns precise placement of the iliac limb of the Incraft endograft: the risk of accidental coverage of the hypogastric artery is minimized by the ability to perform an in-situ adjustment of 3 cm on ipsilateral and 2 cm on contralateral limb.

As for patient selection, in our experience we retrospectively noted that the Ovation endograft was primarily used in patients with proximal aortic neck affected by a greater thrombotic apposition, while the Incraft endograft was preferably used in case of more angulated proximal neck in the coronal axis. We have no evidence to support this choice, it simply reflects our opinion that Incraft can better adapt to angulated proximal necks, while we have the opinion that Ovation could conform worse due to the presence of the polymer and the long free-flow. This feeling was supported by data reported in 2015 by Georgakarakos

and Coll (14), who noted greater postoperative reduction in the suprarenal AAA neck angulation after EVAR using the Ovation graft compared with an endograft with stent-supported graft seal. Moreover, in our experience the two cases of late surgical conversion in group A were needed for type Ia endoleaks in patients who had an angulated proximal neck (greater than 45° on both sagittal and coronal axes). In these cases, we could have used the Incraft stent-graft if it had been available at that time.

Finally, yet importantly, a significant difference in the incidence of postimplantation syndrome was recorded after the use of the Incraft endograft compared with the Ovation graft, which could be due to the manufacture of nitinol stents of the former, as it has been reported with the use of other endografts (15). This occurrence did not affect neither postoperative course nor in-hospital stay, which was similar for both groups, but it should be kept in mind and especially stressed to the patient, who must be informed on the possibility of this complication after the Incraft implantation.

In our experience both endografts showed good navigability throughout small and tortuous vessels, allowing for a totally percutaneous approach under local anesthesia.

The main limitation of our study is represented by its retrospective nature, along with its small sample size. Moreover, in the first part of our experience Ovation was the only ULP endograft available. Further studies will help improving the knowledge about this topic.

In conclusion, both ULP endografts were safe and effective in early and mid-term results. However, some technical differences were noted, which are actually driving our clinical practice in the choice of the right device for the right patient.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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