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ORIGINAL ARTICLE
VASCULAR SECTION

Open repair *versus* EVAR with parallel grafts in patients with juxtarenal abdominal aortic aneurysm excluded from fenestrated endografting

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ABSTRACT

BACKGROUND: We compared the outcomes of open surgical repair (OSR) *versus* endovascular aortic repair (EVAR) with parallel graft technique (PG) in patients with juxtarenal abdominal aortic aneurysm (JAAA) excluded from fenestrated endovascular aortic repair (FEVAR) due to clinical, anatomical, technical or manufacturing time reasons.

METHODS: A single-center analysis of consecutive patients who underwent elective and urgent (within 24-48 hours) repair of JAAA from January 2010 to January 2019 was performed. Two groups were compared: patients excluded from FEVAR and respectively treated by OSR or by PG for JAAA. Perioperative clinical, anatomic and operative data were collected in a dedicated database. The endpoints were primary technical success, changes in renal function, early and long-term mortality, freedom from aortic related reinterventions (ARRs) and aortic related mortality (ARM).

RESULTS: Overall, 118 consecutive patients were treated for JAAA, 32 of whom (27.1%) with FEVAR. Eighty-six patients were enrolled in the study (OSR group, N.=61; PG group, N.=25). The mean age was 77.4±6.5 years for PG group and 71.1±6.7 years for OSR group (P=0.0001); the average comorbidity score of the Society for Vascular Surgery was higher for patients treated by PG (10.2±4.8 *vs.* 5.5±0.4, P=0.0001), with no differences for hypertension and renal score. After propensity score matching, 42 patients (27 OSR, 15 PG) without differences in the preoperative risk factors were selected. Conical shape and neck mural thrombus were respectively more represented in the OSR group (95.1% *vs.* 56.0%; 63.9% *vs.* 36.0%). Aortic clamp site was supraceliac for 12 patients (19.7%), suprarenal for 21 (34.4%) and trans-renal for 28 patients (45.9%). In the PG group, 16 patients (64%) were treated with a single renal chimney. Primary technical success was similar in the two groups (100.0% *vs.* 92.0%, P=0.08), with a higher rate of procedure achieved by assisted technical success for the PG group after propensity score matching analysis (20.0% *vs.* 0%, P=0.04). Deterioration of renal function occurred for both groups of patients, with a significant creatinine increasing 12 months after surgery in the PG group compared with OSR group (1.72±0.66 *vs.* 1.18±0.40, P=0.006). Multiple logistic regression shows no independent predictor of peri-operative medical complication among demographics and pre-operative relevant clinical factors between the two cohorts. No difference in terms of early mortality was observed between the groups (1.6% *vs.* 0%, P=1.00). At 5 years, overall survival was lower for patients treated by PG (53.5% *vs.* 70.2%, P=0.007), such as freedom from ARRs (64.6 *vs.* 90.5%, P=0.03). Freedom from ARM at 5 years did not show significant differences among the two groups (100% *vs.* 98.4%, P=1.00).

CONCLUSIONS: PG represents a feasible procedure for patients excluded from FEVAR due to clinical, anatomical, technical or device manufacturing time reasons, ensuring low rates of ARM. However, ARRs during the follow-up remain the Achilles heel of this technique. OSR is still the most durable procedure in the endovascular era, allowing the treatment of proximal "hostile necks" with low rates of reoperation and a similar impact on the renal function compared to PG.

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KEY WORDS: Abdominal aortic aneurysm; Vascular grafting; Conversion to open surgery; Endovascular procedures; Aorta.

Juxtarenal abdominal aortic aneurysms (JAAAs) are traditionally treated through open surgical repair (OSR), with higher mortality and morbidity rates than surgery for infrarenal abdominal aortic aneurysms (AAAs) and with an average rate of postoperative renal dysfunction of 14%.[1, 2] Since its introduction, endovas-

cular aneurysm repair (EVAR) has become a reliable modality to treat AAAs, extending the opportunity to treat those patients considered unfit for OSR; however, hostile proximal aortic neck anatomy or aneurysmal extension into the renal arteries segment represent a contraindication for the use of commercially available infrarenal standard devices.[3]

Chimney technique, described by Greenberg as a bail-out procedure to preserve an aortic branch after an unintentional coverage, has been used to extend the proximal landing zone above the lowest renal artery.[4] Nowadays, endovascular aneurysm repair associated with parallel graft (PG) has been rapidly adopted for the treatment of patients with JAAA and recently this technique was included in the latest European Society for Vascular Surgery AAA practice guidelines.[2] Long term-experience from PERICLES registry reported a chimney graft branch vessels patency of 92% at five years, with more than half of the patients surviving over this time.[5]

A specific open issue regarding chimney technique is still the occurrence of gutters related endoleak (EL), due to an unfilled space between the main graft, the chimney and aortic wall: gutters are associated with the development of type IA EL, potentially leading to aneurysm rupture.[6] Also the type of stents used may influence technical success and outcomes of PG: balloon expandable stent-grafts offer higher radial strength and a "one step" procedure for both deployment and molding, while self-expanding stent-grafts have been increasingly used with success for the navigability of the devices, especially in case of tortuosity of the target vessels.[7]

PG has gained increasing popularity during the last years and the advantages of this technique include off-the-shelf and widespread availability. At the same time, the advent of fenestrated endograft has broadened the technical solutions for patients with a JAAA, however fenestrated endovascular aortic repair (FEVAR) usually have to be customized to the patient's anatomy, following strict anatomic criteria and making this procedure unsuitable in 12-18% of cases.[8, 9] Moreover the waiting time for the production of the custom made devices (CMDs) allowed to treat only elective cases, physician-modified endografts (PMEs) are an effective alternative for treating JAAAs in patients deemed unsuitable for traditional open surgical repair or for urgent settings, although long-term results are not available.[10]

The aim of this study was to compare the outcomes of OSR *versus* PG in patients with JAAA excluded from FEVAR.

Materials and methods

Patient selection

A single-center analysis of consecutive patients admitted to the Vascular and Endovascular Surgery Division (Padua University Hospital, Padua, Italy) who underwent JAAA repair from January 2010 to January 2019 was carried out. All patients treated for a JAAA in elective and urgent setting (within 48 hours for symptomatic non-ruptured AAA) by OSR or PG and excluded from FEVAR due to clinical, anatomical, technical or manufacturing time reasons (generally up to 4-12 weeks for CMD) were included in the study (Figure 1). No patients with JAAA were treated with PMEs during the study in the Center. Indications for surgery was JAAAs with a diameter ≥55 mm, JAAAs with a rapid enlargement (≥0.5 cm within 6 months or ≥1 cm within a year), symptomatic non-ruptured JAAAs or JAAAs with a saccular shape.[2] Patients were classified into two groups: patient who underwent PG and patients who underwent OSR. Data were retrospective collected in a dedicated database. Informed consent was obtained from all patients. Institutional Review Board requirements and ethical approval were waived for the present study.

Definitions

Patients' demographics and cardiovascular risk factors were evaluated. Operative comorbidity risk was evaluated using the Society for Vascular Surgery (SVS) comorbidity grading system and the America Society of Anesthesiologists (ASA) score. Patients affected by CKD were classified according to KDIGO guidelines into five stages (G1-G5), determined by eGFR levels, in patients with abnormalities of kidney structure or function present for more than 3 months.[11] Kidney function was monitored by measuring serum creatinine (mg/dL) and estimated glomerular filtration rate (eGFR) before surgery and 6, 12 and 24 months later. The diagnosis of AAA was carried out after physical examination, findings supported by duplex ultrasound. Computed tomography angiography (CTA) has been performed for all patients for diagnosis confirmation and careful evaluation of disease severity and extension. JAAA was defined as an aneurysm extending up to but not involving the renal arteries, necessitating transrenal or suprarenal aortic clamping for OSR (e.g. a short neck < 10 mm or sealing zone ≤4 mm).[12] Anatomic data, in particular regarding the aortic and the visceral vessels diameters, the presence of iliac/renal stenosis or the aortic neck characteristics were obtained by CTA images. Aortic and vessels diameter was

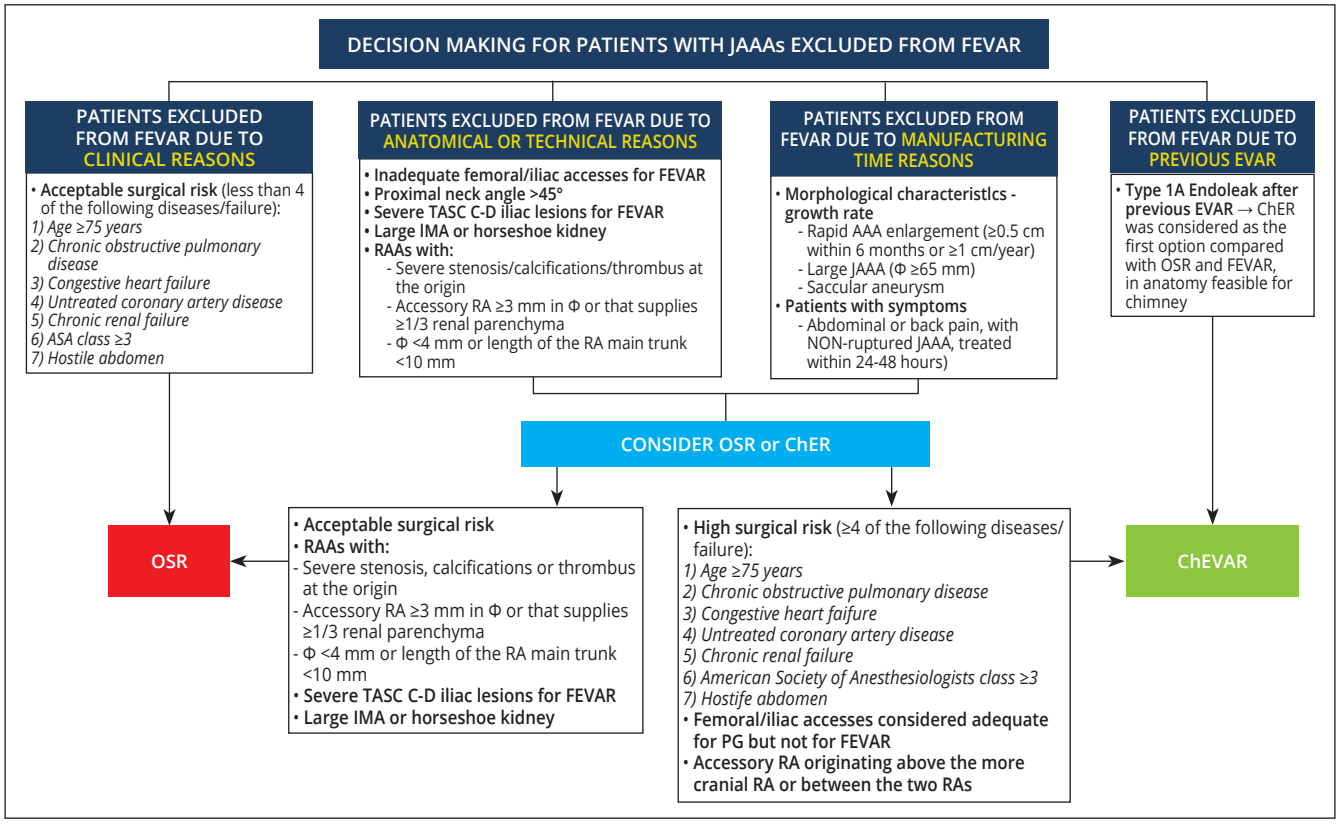


Figure 1.—The chart explains the decision process for the treatment of patients with JAAA, excluded from FEVAR.

measured on the preoperative CTA images using multiplanar reconstructions. The diameter was measured from outer wall to outer wall. Aortic anatomy parameters were obtained in accordance with the standards reported by Oderich *et al.*[13] The shape of the neck was defined conical for those necks with an increase >2 mm for each centimeter of length, according to Dias *et al.* definition.[14]

According to reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries, primary technical success was defined on an "intent-to treat" basis and required the successful introduction and deployment of the device in the absence of surgical conversion or mortality, type I or type III EL, branch occlusion or graft limb occlusion. Primary technical success was also claimed for procedures which involved additional modular components, stents or angioplasty. A special clarification is needed for "gutter" EL, which should be considered type IA EL. The gutter ELs may be present at initial angiography and spontaneously resolve in the first 30 days on evaluation by CTA, otherwise these will be considered as a failure of primary technical success. For those patients who needed unplanned endovascular or surgical procedures, assisted primary technical success or secondary technical success were respectively claimed.[13] Primary technical success for OSR requires the replacement or bypass of the aneurysmal segment with a prosthetic graft in the absence of mortality or graft thrombosis either during surgery or during the initial 24-hour postoperative period. If an unplanned surgical procedure is necessitated, such as re-exploration for bleeding, the term secondary technical success was used.[15] The study endpoints were primary technical success, changes in renal function, early mortality and freedom from ARR. RIFLE classification was considered in order to define and stratify the severity of acute kidney injury (AKI) after surgery:[16] risk was defined as increasing in serum creatinine ×1.5 or eGFR decreased >25%; injury was defined as doubling of creatinine or >50% decline in eGFR; failure was defined as a threefold increase in creatinine, a >75% decline in renal function, or a serum creatinine of >4 mg/dL with an acute rise of 0.5 mg/dL; there were no findings of postoperative loss of function or end-stage renal disease.

Operative technique

All OSR and PG procedures (Figure 2) were performed by Vascular Surgeons in the Department of Vascular and Endovascular Surgery, in an operating room equipped with a C-arm (Eurocolumbus srl, Milan, Italy). For both PG and OSR a standard dose of intravenous heparin 5000 IU was routinely administered. During the procedure the activated clotting time (ACT) is monitored every 45 minutes, in order to ensure a target ACT >300.[17] Protamine reversal was not usually performed.

Open surgical treatment

Surgical aneurysm repairs were performed through midline laparotomy, with 16×8 mm or 18×9 mm Dacron grafts. Aortic proximal clamping was performed above one renal artery (transrenal), above both renal arteries (suprarenal) or even above the celiac trunk (supraceliac). Supraceliac aortic clamping was performed in patients who had atherosclerotic debris in the non-aneurysmal juxtarenal aortic segment, reducing the risk of renal or peripheral atheroembolization, thus achieving adequate proximal control of the infra and juxtarenal aorta. Clamping time was recorded. In all patients, intravenous mannitol (12.5 g) was injected before performing suprarenal aortic cross clamping for renal protection. Excluding patients with documented allergy, patients treated received single antiplatelet therapy with aspirin 100 mg/day indefinitely. Imaging follow-up protocol included abdominal color-flow Doppler ultrasonography at 6 months and then annually.

Endovascular treatment

General anesthesia or local anesthesia with conscious sedation were usually performed. The preferred vascular accesses were the common femoral arteries (CFA) for the main body and the brachial arteries for renal/visceral stents (left side was preferred if a single access was sufficient). The femoral access was percutaneous if the CFA was free from stenotic plaque (<50%) and with a non-calcified anterior wall. In contrast, a minimal groin cutdown was performed for visual access to the vessel. The main body size was determined by the native diameter of aortic neck and by the number and the diameter of the chimney grafts (about 25-30% for a single chimney stent-graft and about 30-35% in case of two or more chimney stent-grafts).[18, 19] Iliac limbs diameter was determined by common iliac arteries (CIA) native diameter (usually with no more than 10% oversizing). The renal/visceral stent size was determined by the native diameter of target vessel with a ratio of 1.1. Both covered/uncovered and self-expandable/balloon-expandable stents were used. The choice for the type of stent was generally determined by the renal artery anatomy and the type of main graft. When a Medtronic Endurant II/IIs Endograft (Medtronic, Minneapolis, MN, USA) was chosen, a balloon expandable covered stent (CS) was used as indicated in the endograft instruction for use (IFU). In the case of longer chimneys or tortuous arteries, Viabahn stent graft (W.L. Gore & Associates, Inc., Flagstaff, AZ, USA) or Fluency stent graft (Bard Peripheral Vascular, Inc., Tempe, AZ, USA) were preferred because of their major adaptability; in case of residual stenosis or kinking, they were reinforced with self-expandable stents (SES). For arteries with calcific associated lesions, or in case of a short vessel (early bifurcation), balloon-expandable stent (BES) grafts were used due to their precise deployment. CS were generally preferred over uncovered bare metal stents, however used in case of unavailability of CS or to reinforce a SES.[20] The standard procedure includes the target visceral vessels cannulation from the brachial accesses and then the aortic main body deployment. After these steps, iliac limbs are released and then the visceral reperfusion is completed with stent-grafts proximal deployment and molding. Key point of the procedure is to balloon simultaneously the chimneys and the endograft's body to achieve a good sealing between the stent grafts and the aortic lumen. Excluding patients with documented allergy, dual antiplatelet therapy was started postoperatively for patients treated by endovascular surgery and consisted of clopidogrel (75 mg/day) and aspirin (100 mg/day) for 1 month, followed by aspirin 100 mg/day, indefinitely. Imaging follow-up protocol included CTA at 3 months and yearly thereafter.

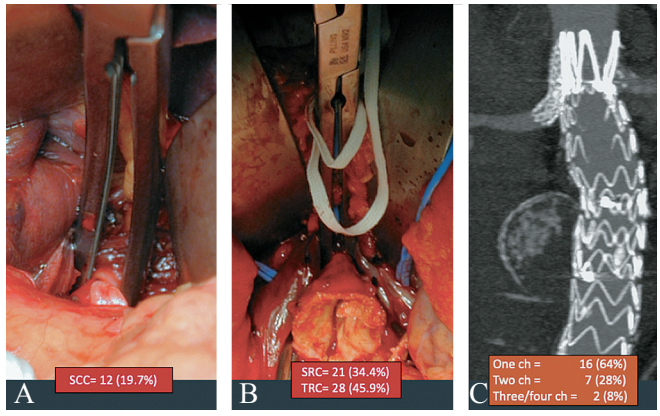


Figure 2.—Open JAAA treated with OSR by supraceliac (SCC), suprarenal (SRC) or transrenal (TRC) aortic clamping (A-B). Saccular JAAA treated by ChEVAR with single chimney for the right renal artery (C).

Statistical analysis

Continuous data are presented as mean and standard deviation and categorical data as n (%). Continuous variables were compared with the Wilcoxon rank sum test or the Student's *t*-test as appropriate. Pearson's chi square test and Fisher's Exact test were used for the analysis of categorical variables. To reduce bias and make both groups uniform and comparable, patients of the OSR group were matched to patients of the PG group based on propensity score analysis. The baseline covariates included age, gender, diabetes, smoke, CKD, CHD and SVS Score. The covariates included in the analysis were than used to generate the score and a score-based matched control group. Early and late outcomes were compared in the two matched groups. A multiple logistic regression was used to determine the association of relevant clinical factors with peri-operative medical complication. Kaplan-Meier survival curves were used to compare long term survival and freedom from reintervention; the log rank test was used to compare the two groups. Results data are to be reported to unmatched cohorts, unless specified. All analyses were carried out with GraphPad Prism v. 9.0 (GraphPad Software, Inc., San Diego, CA, USA). A two tailed P value <0.05 were considered statistically significant.

Results

During the study period, 118 consecutive patients were treated for JAAA. 32 patients (27.1%) were treated by a FEVAR implantation, while 86 patients were included in the study: 25 patients in the PG and 61 patients in the OSR group. At the presentations, the two groups were similar in terms of demographics data, but PG patients were older (77.4±6.5 *vs.* 71.1±6.7, P=0.0001) and there were less males represented in the PG group (72.0% *vs.* 96.7%, P=0.002). SVS score analysis revealed as expected a significant difference between PG *vs.* OSR in term of cardiac (1.04±1.0 *vs.* 0.44±0.6, P=0.0009), pulmonary (0.56±0.9 *vs.* 0.16±0.5, P=0.01) and age score (2.24±0.6 *vs.* 1.69±0.5, P=0.0001), with a higher overall SVS score for PG group (10.2±4.8 *vs.* 5.5±4.0; P=0.0001). Renal and Hypertension SVS score did not result as significantly different between the two groups. After propensity score matching, no differences were observed in the two cohorts

TABLE I.—*Demographics, cardiovascular risk factors and preoperative risk assessment at presentation in the two groups.*

Variable	Unmatched cohort			Matched cohort		
	PG (N.=25)	OSR (N.=61)	P value	PG (N.=15)	OSR (N.=27)	P value
Demographic data / risk factors						
Age, years	77.4±6.5	71.1±6.7	0.0001	74.7±5.5	74,00±4.3	0.65
Male	18 (72.0%)	59 (96.7%)	0.002	14 (93.3%)	25 (92.6%)	1.00
Hypertension	25 (100%)	50 (82%)	0.03	15 (100%)	25 (92.6%)	0.53
Diabetes	5 (20.0%)	9 (14.8%)	0.54	3 (20.0%)	6 (22.2%)	1.00
CHD	10 (40.0%)	18 (29.5%)	0.45	7 (46.7%)	12 (44.4%)	1.00
CKD	10 (40.0%)	14 (22.9%)	0.12	5 (33.3%)	8 (29.6%)	1.00
COPD	8 (32.0%)	6 (9.8%)	0.02	3 (20.0%)	5 (18.5%)	1.00
Preoperative renal function						
Serum creatinine	1.1±0.4	1.1±0.4	1.00	1.1±0.4	1.1±0.5	1.00
eGFR	63.8±24.3	72.4±18.8	0.08	66.8±28.7	68.6±20.7	0.82
GFR category G1	-	-	-	-	-	
GFR category G2	-	-	-	-	-	
GFR category G3	6 (24.0%)	10 (16.4%)	0.54	3 (20.0%)	5 (18.5%)	1.00
GFR category G4	4 (16.0%)	3 (4.9%)	0.18	2 (13.3%)	2 (7.4%)	0.61
GFR category G5	0 (0.0%)	1 (1.6%)	1.00	0 (0.0%)	1 (3.7%)	1.00
Specific and overall SVS Score						
Cardiac SVS score	1.04±1.0	0.44±0.6	0.0009	1.07± 1.10	0.81±0.79	0.38
Pulmonary SVS score	0.56±0.9	0.16±0.5	0.01	0.33±0.72	0.30±0.67	0.89
Renal SVS score	0.44±0.5	0.25±0.4	0.07	0.4±0.51	0.33±0.55	0.69
Hypertension SVS score	1.80±0.7	1.39±0.9	0.045	1.60±0.74	1.70±0.91	0.72
Age SVS score	2.24±0.6	1.69±0.5	0.0001	2.00±0.53	1.96±0.52	0.81
Overall SVS score	10.2±4.8	5.5±4.0	0.0001	9.3±5.2	8.2±4.5	0.48

Data are presented as mean±SD or as number (percentage).
CHD: chronic heart disease; CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease; eGFR: estimated glomerular filtration rate; SVS: Society for Vascular Surgery.

in term of risk factors or SVS score values (Table I). Exclusion criteria for FEVAR in patients underwent OSR or PG are listed in Table II. The production delay was the reason for ineligibility of FEVAR for 64% of patients in PG group, while in OSR group most patients were excluded for clinical reasons (39.3%). Comparing anatomical aortic factors, patients treated by OSR presented respectively a large proximal and distal neck diameter compared with PG group (proximal 27.6±9.0 *vs*. 23.1±2.8 mm, P=0.02; distal 30.5±8.2 *vs.* 23.8±3.7 mm, P=0.0002). Rates of conical necks were also higher in OSR patients (95.1% *vs.* 56.0%, P≤0.0001). OSR patients were also more likely to present parietal thrombus (63.9% *vs.* 36.0%, P=0.03). Presence of neck calcification was not statistically different between the groups (Table III). There were no significant differences regarding general operative data and the days in ICU or of hospitalization between the two groups, such as for the mean surgical duration time of the procedures. A clear difference in the type of anesthesia was obtained considering that 12% of patients in the PG group were treated with locoregional anesthesia (Table IV). Regarding OSR operative data, proximal clamp position was transrenal in 28 patients (45.9%), suprarenal in 21 patients (34.4%) and supraceliac for 12 patients (19.7%). The overall mean visceral ischemia time due to aortic clamping was 21.9±5.8 min, 22.0±5.8 min for suprarenal or transrenal aortic clamping and 21.4±6.2 min for supraceliac aortic clamping. For 12 patients (19.7%), an adjunctive procedure was performed during JAAA open surgical repair, including five renal artery bypass/transposition and an inferior mesenteric artery reimplantation (Table V). Operative data and technical details of PG procedures are listed in the Table VI. Medtronic Endurant II endograft was used in most patients (88%). Endograft proximal mean diameter was 28.4±5.5 mm and 16.0±2.1 mm for the iliac limbs. Renal stents' mean diameter was 6.9±1.0 mm for the LRA, 7.1±1.0 mm for the RRA, 8±0.8 mm for the two SMA stents and 10 mm for the only CT stent. The average rate (%) of proximal oversizing was 28.4±5.5; in patients with a single chimney stent it was 27.7±6.1, whereas it was 29.9±5.7 if two renal chimneys were deployed. 36 vessels were stented overall in patients treated by PG. Most used stents were covered SES (N.=16, 44%), while covered BES were deployed in 14 patients (38.9%); 64% patients had a single renal vessel stented (32% LRA, 32% RRA) and 28% both RAs. Heli-FX Endoanchors were used successfully in two cases to treat an intraoperative type IA EL. Early outcomes (<30 days) are showed in Table VII. Primary technical success

TABLE II.—*Exclusion for FE device.*

Variable	PG (N.=25)	OSR (N.=61)
Clinical	-	24 (39.3%)
Anatomical-technical	4 (16.0%)	21 (34.4%)
Renal stenosis/calcifications/thrombose	-	7 (11.4%)
Accessory renal artery	1 (4.0%)	3 (4.9%)
Horseshoe / ectopic kidney	-	2 (3.2%)
Large IMA	-	2 (3.2%)
Inadequate accesses	2 (8.0%)	1 (1.6%)
Iliac aneurysm	-	3 (4.9%)
Neck > 45°	1 (4.0%)	3 (4.9%)
TASC D	-	3 (4.9%)
Manufacturing time reasons	16 (64.0%)	18 (29.5%)
Aneurysm diameter > 65 mm	13 (52.0%)	13 (21.3%)
Saccular aneurysm	-	3 (4.9%)
Symptomatic patient	1 (4.0%)	2 (3.2%)
Rapid growth	2 (8.0%)	1 (1.6%)
Previous EVAR	8 (32.0%)	-

Data are presented as number (percentage).
IMA: inferior mesenteric artery.

TABLE III.—*Anatomical aortic factors.*

Variable	PG (N.=25)	OSR (N.=61)	P value
Max AAA diameter, mm	67.0±13.8	64.8±20.5	0.63
CIAs diameter, mm	15.5±4.1	19.6±9.4	0.04
Proximal neck length, mm	6.8±3.2	5.5±5.8	0.30
Proximal diameter, mm	23.1±2.8	27.6±9.0	0.02
Distal diameter, mm	23.8±3.7	30.5±8.2	0.0002
Angle, degrees	53.8±14.0	52.0±25.5	0.75
Conical neck	14 (56.0%)	58 (95.1%)	< 0.0001
Presence of thrombus	9 (36.0%)	39 (63.9%)	0.03
Mild	9 (100.0%)	12 (30.8%)	0.0003
Moderate	0 (0.0%)	24 (61.5%)	0.002
Severe	0 (0.0%)	3 (7.7%)	1.00
Presence of calcification	16 (64.0%)	34 (55.7%)	0.63
Mild	14 (87.5%)	24 (70.6%)	0.29
Moderate	2 (12.5%)	7 (20.6%)	0.70
Severe	0 (0.0%)	3 (8.8%)	0.54

Data are presented as mean±SD or as number (percentage).

TABLE IV.—*General operative data.*

Variable	PG (N.=25%)	OSR (N.=61%)	P value
Duration time, min	244.2±88.1	214.9±78.7	0.13
Anesthesia			
General	22 (88.0%)	61 (100.0%)	0.02
Spinal	3 (12.0%)	0 (0.0%)	0.02
Hospitalization			
Days in ICU	1.2±2.0	2.6±7.1	0.16
Hospitalization days	10.3±10.2	8.±6.9	0.38

Data are presented as mean±SD or as number (percentage).
ICU: intensive care unit.

TABLE V.—*Open surgical treatment operative data.*

Variable	OSR (N.=61)
Type of aortic graft	
Aorto-aortic	32 (52.4%)
ABI	17 (27.9%)
ABF	5 (8.2%)
AI+AF	7 (11.5%)
Adjunctive procedures	12 (19.7%)
Bypass/transposition RA	5 (8.2%)
CFA/PFA endarterectomy	4 (6.5%)
Accessory renal artery reimplantation	2 (3.3%)
IMA reimplantation	1 (1.6%)
IIA bypass	1 (1.6%)
Proximal clamp position	
Transrenal	28 (45.9%)
Suprarenal	21 (34.4%)
Supraceliac	12 (19.7%)
Mean visceral ischemia time (min)	21.9±5.8
Transrenal/Suprarenal	22.0±5.8
Supraceliac	21.4±6.2

Data are presented as mean±SD or as number (percentage).
ABI: aorto-bi-iliac; ABF: aorto-bi-femoral bypass; AI: aorto-iliac; AF: aorto femoral; CFA: common femoral artery; PFA: profunda femoral artery; IMA: inferior mesenteric artery; IIA: internal iliac artery.

TABLE VI.—*Chimney endovascular treatment operative data.*

Variable	PG (N.=25)
Aortic endograft	
Medtronic Endurant II	22 (88.0%)
Cook Zenith	1 (4.0%)
Gore Excluder	1 (4.0%)
Endologix Nellix	1 (4.0%)
Proximal oversizing (%)	28.4±5.5
1 renal chimney stent	27.7±6.1
2 renal chimney stents	29.9±5.7
3 chimney stents	30.8±4.2
Chimney stents types	
Self-expandable, covered	16 (44.4%)
Fluency	11 (30.6%)
Viabahn	5 (13.8%)
Balloon-expandable, covered	14 (38.9%)
Advanta	1 (2.8%)
Lifestream	13 (36.1%)
Self-expandable, uncovered	5 (13.8%)
Flype	2 (5.5%)
Protege GPS	3 (8.3%)
Balloon-expandable, uncovered	1 (2.8%)
Express	1 (2.8%)
Chimney stent target vessels	
Single RA only	16 (64.0%)
Both RAs	7 (28.0%)
Both RAs and SMA	1 (4.0%)
RRA + SMA + CT	1 (4.0%)
Endoanchors	2 (8.0%)

Data are presented as mean±SD or as number (percentage).
RAs: renal arteries; SMA: superior mesenteric artery; CT: celiac trunk.

rate was obtained for all OSR patients, with no statistically significant differences comparing OSR and PG patients (100% *vs.* 92.0%, P=0.08). Patients who achieved technical success after an assisted/secondary procedure were more numerous, with a statistically significant difference, in the PG group, even after propensity score analysis (matched cohorts 20% *vs.* 0%, P=0.04). Cumulative medical early complications rates (including cardiac, pulmonary and all stages of acute renal complications according to RIFLE criteria) were similar among the two groups (matched cohorts PG 53.3% *vs.* OSR 48.1% P=1.00). One patient from PG group suffered from respiratory failure (4.0%), while one from OSR group suffered from AMI (1.6%). No statistically significant differences were observed for surgical complications (PG 0% *vs.* OSR 3.3%, P=0.55). Perioperative mortality rates were similar for the two groups (PG 0%; OSR 1.6%, P=1.00). No difference in terms of early ARRs were observed in the two cohorts (PG 4.0% *vs.* OSR 3.2%, P=1.00). Regarding late outcomes (Table VIII), cumulative complications were more represented in the PG group (unmatched cohorts 40% *vs.* 9.8%, P=0.002; matched cohorts 46.7% *vs.* 11.0%, P=0.02), such as the ARR rates (OSR 4.9% *vs.* PG 24.0%, P=0.016). Among PG specific complications, 60% were related to an EL/gutter, while 40% due to a chimney stent-graft thrombosis. Variation in renal function is represented in Figure 3. A postoperative deterioration in mean serum creatinine and eGRF was found for both groups 6 months after surgery, with a significant difference 12 months after the procedures for patients treated with PG compared with those treated by OSR (creatinine: 1.72±0.66 *vs.* 1.18±0.40, P=0.006; eGFR: 41.2±25.2 *vs.* 67.7±21.4, P=0.0003). The gap in renal function status between the groups decreased 24 months after the procedure, without significant difference between the two cohorts.

Kaplan-Meier curves are represented in Figure 4. Regarding freedom from ARR (Panel A), the analysis showed a significant difference among the two group at 5 years (OSR 90.5% *vs.* PG 64.6%, log rank P=0.03). The reoperations for the OSR patients included two relaparotomies and three reinterventions at the groin, one for an anastomotic pseudoaneurysm, one for prosthetic graft thrombosis and one for a stenosis at the distal anastomosis level in a patient underwent ABF reconstruction. Six patients in the PG group underwent to different ARRs, one patient for a PG thrombolysis, one for a chimney relining, three for a sac or for lumbar arteries embolization and a patient to treat a type IB EL. Also, the overall survival rates at 5 years (Figure 4B) were significant higher for OSR group

TABLE VII.—*Early outcomes (<30 days).*

Variable	Unmatched cohort			Matched cohort		
	PG (N.=25)	OSR (N.=61)	P value	PG (N.=15)	OSR (N.=27)	P value
24-h technical success						
Primary	23 (92.0%)	61 (100.0%)	0.08	14 (93.3%)	27 (100%)	0.36
Assisted/secondary	4 (16.0%)	2 (3.2%)	0.06	3 (20.0%)	0 (0.0%)	0.04
Medical complications	12 (48.0%)	22 (36.1%)	0.33	8 (53.3%)	13 (48.1%)	1.00
Cardiac	0 (0.0%)	1 (1.6%)	1.00	0 (0.0%)	1 (3.7%)	1.00
Pulmonary	1 (4.0%)	0 (0.0%)	0.29	1 (6.7%)	0 (0.0%)	0.36
Neurological	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Renal (RIFLE)	11 (44.0%)	21 (34.4%)	0.46	7 (46.7%)	12 (44.4%)	1.00
Risk	6 (24.0%)	15 (24.6%)	1.00	3 (20.0%)	6 (22.2%)	1.00
Injury	3 (12.0%)	5 (8.2%)	0.69	2 (13.3%)	5 (18.5%)	1.00
Failure	2 (8.0%)	1 (1.6%)	0.20	2 (13.3%)	1 (3.7%)	0.28
Loss of function	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
ESR disease	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Surgical complication	0 (0.0%)	2 (3.3%)	0.55	0 (0.0%)	2 (7.4%)	0.53
Intraperitoneal bleeding	0 (0.0%)	1 (1.6%)	1.00	0 (0.0%)	1 (3.7%)	1.00
Bowel infarction	0 (0.0%)	1 (1.6%)	1.00	0 (0.0%)	1 (3.7%)	1.00
PG specific complications	5 (20.0%)	-	-	3 (20.0%)	-	-
EL (gutter – type 1A/B)	3 (12.0%)	-	-	2 (13.3%)	-	-
Chimney compression	1 (4.0%)	-	-	0 (0.0%)	-	-
Chimney occlusion	1 (4.0%)	-	-	1 (6.7%)	-	-
General outcomes						
Medical and surgical complications (sum)	12 (48.0%)	24 (39.3%)	0.48	8 (53.3%)	15 (55.6%)	1.00
Aortic related reinterventions	1 (4.0%)	2 (3.2%)	1.00	1 (6.7%)	2 (7.4%)	1.00
Overall perioperative mortality	0 (0.0%)	1 (1.6%)	1.00	0 (0.0%)	1 (3.7%)	1.00

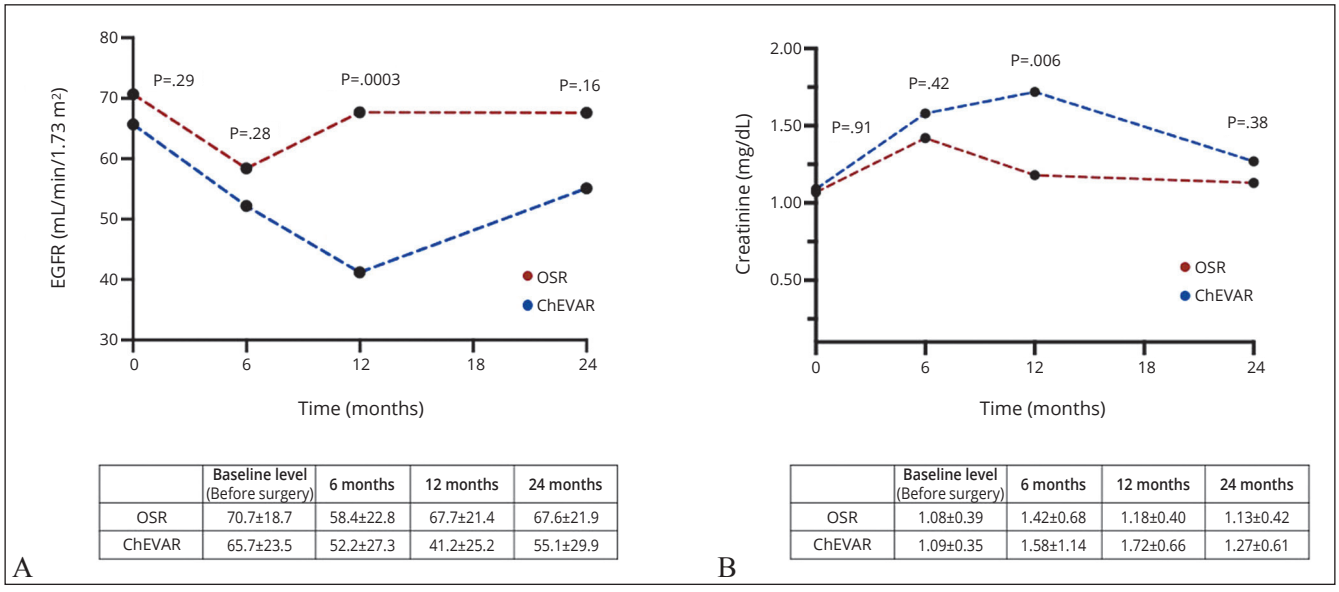
Data are presented as mean±SD or as number (percentage).
AKI stage 1 was defined as increasing in serum creatinine x 1.5 or eGFR decreased >25%. AKI stage 2 was defined as doubling of creatinine or >50% decline in eGFR. AKI stage 3 was defined as a threefold increase in creatinine, a >75% decline in renal function, or a serum creatinine of >4 mg/dL with an acute rise of 0.5 mg/dL.

TABLE VIII.—*Late outcomes (>30 days).*

Variable	Unmatched cohort			Matched cohort		
	PG (N.=25)	OSR (N.=61)	P value	PG (N.=15)	OSR (N.=27)	P value
Overall complications	10 (40.0%)	6 (9.8%)	0.002	7 (46.7%)	3 (11.0%)	0.02
OSR specific surgical complications	-	6 (9.8%)	-	-	3 (11.1%)	-
Graft thrombosis	-	1 (1.6%)	-	-	0 (0.0%)	-
Anastomotic Pseudoaneurysm	-	1 (1.6%)	-	-	1 (3.7%)	-
Laparocele	-	3 (4.9%)	-	-	2 (7.4%)	-
Femoral anastomosis stenosis	-	1 (1.6%)	-	-	0 (0.0%)	-
PG specific complications (overall)	10 (40.0%)	-	-	7 (46.7%)	-	-
Endoleak	6 (24.0%)	-	-	5 (33.3%)	-	-
Type IA	3 (12.0%)	-	-	3 (20.0%)	-	-
Type IB	0 (0.0%)	-	-	0 (0.0%)	-	-
Type II	2 (8.0%)	-	-	1 (6.7%)	-	-
Type III	1 (4.0%)	-	-	1 (6.7%)	-	-
Type IV	0 (0.0%)	-	-	0 (0.0%)	-	-
Chimney stent graft occlusion	4 (16.0%)	-	-	2 (13.3%)	-	-
General outcomes						
Aortic-related reinterventions	6 (24.0%)	3 (4.9%)	0.016	5 (33.3%)	1 (3.7%)	0.016
Aortic-related mortality	0 (0.0%)	1 (1.6%)	1.0	0 (0.0%)	1 (3.7%)	1.00

Data are presented as number (percentage).
IMA: inferior mesenteric artery.

compared with PG group (70.2% *vs.* 53.5%, log rank P=0.007). Both techniques showed a good result in terms of freedom from ARM (Figure 4C), with no statistically significant differences between the two groups (100% *vs.* 91.8, log rank P=0.49). The medium follow-up for the two groups was 42.7±35.6 months. Despite age and burden of baseline cardiac and pulmonary comorbidity were different in the two cohorts, multiple logistic regression analysis



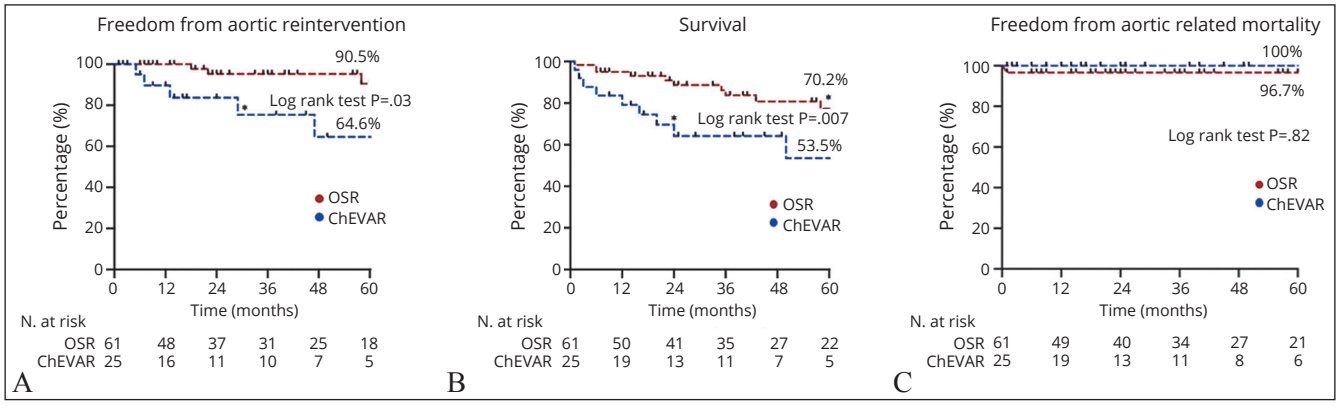
	Baseline level (Before surgery)	6 months	12 months	24 months
OSR	70.7±18.7	58.4±22.8	67.7±21.4	67.6±21.9
ChEVAR	65.7±23.5	52.2±27.3	41.2±25.2	55.1±29.9

A

	Baseline level (Before surgery)	6 months	12 months	24 months
OSR	1.08±0.39	1.42±0.68	1.18±0.40	1.13±0.42
ChEVAR	1.09±0.35	1.58±1.14	1.72±0.66	1.27±0.61

B

Figure 3.—Graphs show changes in GRF (A) and serum creatinine level (B), from baseline over 24 months period.



A B C

Figure 4.—Kaplan-Meier curves for freedom from aortic reintervention (A), overall survival (B) and freedom from aortic related mortality (C) in the OSR and PG groups. * Standard error <10% at 12 months.

shows no independent predictor of peri-operative medical complication among demographics and pre-operative relevant clinical factors between the two groups (Supplementary Digital Material 1: Supplementary Table I).

Discussion

Involvement of the juxtarenal aorta in the treatment of AAA is not an infrequent occurrence, representing about 20% of the aortic cases in our experience. Open surgical repair is still considered a durable and well-established treatment for JAAAs, however the widespread application of endovascular techniques has resulted in a proportionate increase in endovascular repair of JAAA.[21] Durability and safety of the OSR seems to confirmed by the data from our experience, with high rates of freedom from ARRs regarding early (96.8%) and long term outcomes (96.8%), with minimal perioperative mortality rate (1.6%).

New devices allow more frequently to treat by mini-invasive procedures patients with challenging anatomy or poor clinical features for open repair. FEVAR is now extensively performed as technique for endovascular repair of JAAA, but long-term results are still discussed, especially concerning reintervention rates and main graft/

bridging-stents failure. Rao *et al.* reported 4.1% rate for 30-day mortality and 11% for renal complications after FEVAR procedure.[22] A retrospective study based on Globalstar Registry reported 99% for technical success rate, with 4.1% for perioperative mortality and 7% for early re-intervention rate (<30 days); in this study, freedom from late reintervention was 90%, 86% and 70% respectively at 1, 2 and 3 years.[23] However, when the anatomy is not favorable for FEVAR or in emergency setting, parallel graft or chimney during EVAR has proved to be another effective technique for endovascular JAAA repair. As for other endovascular techniques, PG has shown its safety in the perioperative period, with low mortality and morbidity, and it is effective also in urgent cases, but its overall efficacy remains questionable on long-term.[24] Pericles Registry reported a 3.7% rate for 30-day mortality in case of PG technique performed as elective treatment; transient kidney injury (less than 4 weeks) has been reported in 17.5% patients.[25]

FEVAR is often seen as a safe and customized solution for JAAA, but specific anatomic criteria must be satisfied for the effectiveness of this procedure: in the present authors' experience, 86 patients with JAAA were excluded from FEVAR for clinical, anatomical or technical reasons, including "manufacturing time" reasons. Patients excluded due to clinical reasons were patients with an acceptable surgical risk, then treated by OSR with transrenal, suprarenal or supraceliac aortic clamping. Anatomical or technical reasons included inadequate femoral/iliac accesses for FEVAR, inadequate proximal landing zone (proximal neck angle >45°), severe TASC C-D iliac lesions for FEVAR and large IMA or horseshoe/ectopic kidney candidate to surgical reimplantation/transposition (Figure 5). Also, RAAs with severe stenosis/calcifications/ thrombus at the origin, accessory RA≥3 mm in diameter or that supplies ≥1/3 renal parenchyma or with a diameter <4 mm/a length of the RA main trunk <10 mm were considered a contraindication for FEVAR. Patients with type IA EL after may have a complex aortic anatomy that limits their endovascular treatment options; furthermore, many of these patients are not candidates for surgical repair. As stated in the recent European guidelines, a re-intervention, primarily by endovascular techniques, is recommended in patients with type IA EL after EVAR.[2] In our study, eight patients were treated due to this reason and in these cases the extension of the sealing zone more proximally was considered the first choice, compared to FEVAR, in patients with feasible anatomy to one or two chimneys deployment or with aneurysms larger than 65 mm. ChEVAR also may requires less aortic coverage in most cases compared to a fenestrated endograft, theoretically decreasing the risk of SCI due to extensive aortic involvement. Regarding manufacturing time reasons, in addition to patients with rapid AAA enlargement (≥0.5 cm within 6 months or ≥1 cm within a year), saccular aneurysm or patients with symptoms treated within 24-48 hours, an AAA with 65 mm of maximum diameter was considered a contraindication because the delayed time for the CMD production has to be considered with the risk of AAA rupture of large aneurysms. All patients with an aortic aneurysm who are hospitalized at Padua Vascular Surgery Department are discussed in a weekly meeting with surgical trainees, staff grade surgeons and surgical consultants, to assess the safest and most durable and suitable therapeutic solution for the patient.

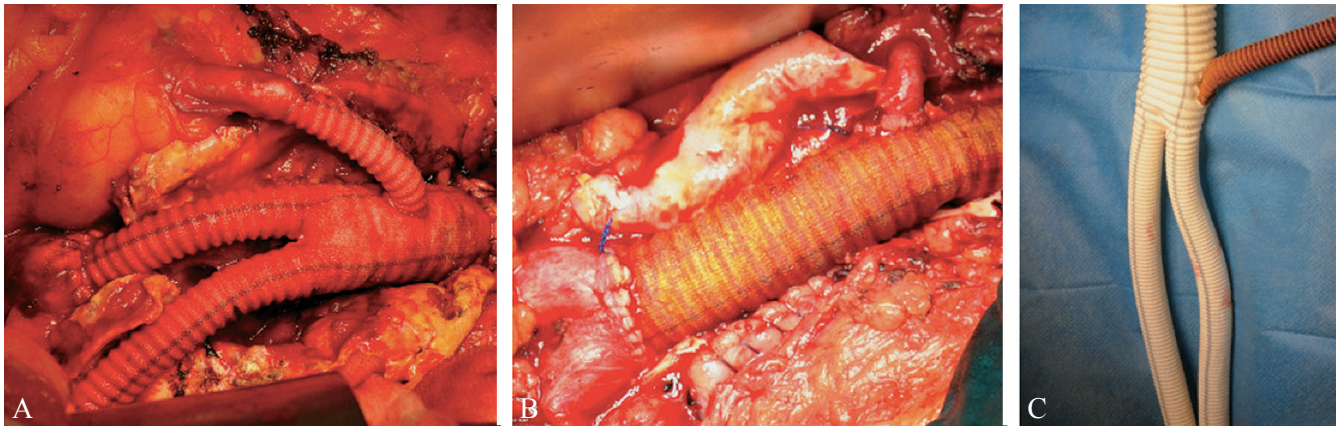


Figure 5.—Open surgical repair details: Renal artery bypass (A) or transposition (B). " On-bench " modified Dacron graft with a dedicate branch for the left renal artery (C).

In the endovascular era, many patients are more often candidates to endovascular therapy due to more inclusive criteria for new devices, which allow to treat them in an elective setting even in presence of hostile necks, but at the same time patients who are selected for open surgical repair present a constantly more challenging aortic anatomy.[26] This means that it is crucial to maintain or even improve the skills for open surgical repair in the endovascular era, as the cases that a vascular surgeon must face are increasingly complex.

In this experience, PG and OSR patient cohorts had a similar primary technical success (92.0% *vs.* 100%, P=0.08). Two OSR procedures (3.2%) achieved technical success with a secondary/assisted procedure, but no patients suffered from a technical failure. On the other hand, PG technique was performed with secondary/assisted success in 16% patients and two more patients did not benefit from a rescue re-intervention.

After propensity score matching analysis, a statistically significant difference was observed between OSR and PG groups (20.0% *vs.* OSR 0%, P=0.04); these data could indicate that PG technique may have significant limitations, especially in circumstances which involve a short or hostile neck such as for JAAA, while open repair has shown its excellent success rates. In details, the presence of conical neck is strongly associated with proximal failure for endovascular techniques:[27-29] patients who underwent endovascular procedures had a consistently lower rate of conical necks (56% *vs.* 95%, P<0.0001), with smaller neck diameters, despite a significantly higher early failure rate. Medical early complications rates (including cardiac, pulmonary and renal) were similar among the two groups. OSR confirmed an acceptable perioperative mortality (1.6%), which was comparable to other studies and reviews (5.3%);[30] no perioperative deaths were observed in the PG group. Long term survival was also satisfying for OSR, while PG patients had a lower survival rate (at 5 years 53.5% *vs.* 70.2%, P=0.007); this difference is probably the result of a higher mean for age and SVS score for PG cohort.

OSR confirmed to be a safe and effective technique, supported by a low complications rates regarding late outcomes compared with PG: in patients treated by endovascular repair, late complications occurred in ten patients (40%), while complications due to open surgical repairs in six (9.8%) patients (P=0.002). Many of PG related complications are often followed by re-intervention, primarily by endovascular technique when feasible. However, it should be noted that no PG patients underwent open surgical conversion due to graft-related complications, even considering a long-term period. No differences were observed in the groups regarding the ARM, with no aortic rupture in the cohorts.

Although PG proved its safety in terms of perioperative mortality rate and ARM; despite conflicting results in literature, PG was burdened by similar renal complication rate to OSR, with the two groups of patients having a comparable pre-operative renal status. Even considering those results, an increase in serum creatinine level was observed in the post-operative time for both cohorts, as well as a simultaneous decrease in eGRF: however, OSR patients recovered from this condition more quickly than patients with PG, with a significant difference in the two groups at 12 months after surgery. Intuitively, renal stent occlusions (N.=4 for mid- to long-term follow-up) would contribute for the slowest recovery of renal function in PG group; however, most of our patients did not "re-present" with symptomatic occlusion. Other reasons for an increased renal morbidity in patients with PG could include distal embolization caused by renal catheterization during the procedures, especially in case of renal arteries or aortic aneurysms with thrombotic apposition. Moreover, chimney instability, defined by a composite of any stent stenosis or stent occlusion, occurred in different patients both for perioperative and postoperative period, may also have influenced renal status outcome, as well as the use of iodinated contrast.[31]

The alternative of PMEs is certainly valid in the case of JAAA, however in our center we have no experience with this technique at the aortic perivisceral level, even if we have successfully treated a patient who was referred in urgency with a thoracic isthmic rupture an a congenital anomalous origin of the left vertebral artery directly from the aortic arch.[32] PMEs offer a considerably faster repair time considering the 4-12 week wait for CMD and this gives PMEs the advantage of being a feasible repair strategy for symptomatic aneurysms (and potentially ruptures). PMEs is also an attractive option for those surgeons who do not have access to fenestrated or branched CMDs. However, these types of solutions are probably burdened by high reintervention rates.[33] Therefore, as well as PG, long-time durability of the results remains questionable.

Limitations of the study

Clear limitations exist to this study and our conclusions. This was a single center retrospective analysis and the characteristics of the two groups, especially regarding the preoperative performance status, are different, in particular in terms of age, cardiac and pulmonary comorbidities, and this condition may have certainly influenced mortal-

ity and medical complications; however, in terms of outcomes, there were no differences between the two groups before and after the propensity score analysis. Multiple logistic regression analysis shows no independent predictor of perioperative medical complication among demographics and preoperative relevant clinical factors between the two group. A cost effectiveness analysis among the two cohorts was not available and the lower number of patients, especially for PG group, may have limited the statistical analysis.

Conclusions

PG represents a feasible procedure for patients excluded from FEVAR due to clinical, anatomical, technical or "device manufacturing time" reasons. This procedure ensures low rates of ARM, even if ARRs during the follow-up remain the Achilles heel of this technique. Despite age and burden of baseline cardiac and pulmonary comorbidity were different in the two cohorts, OSR with trans or suprarenal clamping for JAAA still appears to be a safe and durable procedure in the endovascular era, allowing the treatment of proximal "hostile necks" with low rates of aortic reoperation in the medium and long term. The impact of clamping one or both renal arteries does not appear to have a worse influence than PG on the renal function, which has been shown to have a greater impact on the recovery of renal function in the postoperative period.

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