Initial Experience with Chimney EVAR for the Treatment of Para- and Juxta-Renal Aneurysms

Miltiadis Matsagkas[1],Petroula Nana[1], Georgios Kouvelos[1], Konstantinos Spanos[1], Aikaterini Bouzia[2], Konstantinos Mpatzalexis[1], Eleni Arnaoutoglou[2], Athanasios Giannoukas[1]

[1]Department of Vascular Surgery, Faculty of Medicine, School of Health Sciences, University of Thessaly, Larissa, Greece
[2]Department of Anesthesiology, Faculty of Medicine, School of Health Sciences, University of Thessaly, Larissa, Greece

Abstract:

Introduction: Endovascular aortic aneurysm repair using parallel grafts (chimney technique, ChEVAR) is an off-the-shelf alternative technique in patients with challenging aortic anatomy when fenestrated or branched devices are contraindicated or unavailable. This study reports the outcomes of ChEVAR for para-renal abdominal aortic aneurysm (AAA) treatment in a single center.

Methods: This is a retrospective analysis of prospectively collected data. All patients suffering from a pararenal AAA and treated with ChEVAR between May 2016 and February 2019, wereincluded.Proximal landing zones precluded any standard endovascular intervention and all patients were considered as high risk for open aortic surgery. As main outcomes technical success, endoleak type Ia, overall mortality, freedom from target vessel occlusion,as well as reinterventions were recorded and analyzed.

Results: Thirty patients (28 males; mean age 72 years) underwent Ch-EVAR.In 23 cases, patients were primarily treated while 7 patients had a previous aortic procedure. Target vessels (TVs) included 51 renal and 11 superior mesenteric arteries. 11 patients received three chimneys, 10 patients two chimneys and 9 patients one chimney. The median preoperative proximal neck length increased from3mm (range, 0-8mm), to 24.5 mm (range, 18-34 mm)using the chimney technique. Technical success was 100%. Thirty-day mortality was 10% (3/30), whileno early re-intervention was needed. During follow-up (range, 1-30 months), the survival rate was calculated at 73% (SE 9.9%), TVs primary patency rate at 95% (SE 5%) and freedom from chimney graft-related re-interventions was 94.7% (SE 5.1%) at 24 months. In three cases, a gutter endoleak was detected on the initial CTA and spontaneously resolved in all patients. In 2 cases, a type Ia endoleak was detected (93.3% at 24 months, SE 4.6%). These patients are under close surveillance (2nd and 3rd post-operative month respectively).

Conclusion: The chimney techniqueallowsthe endovascular treatment of para-renal aneurysms according to each patient's specific anatomy. It seems a feasible and safe option at least during the early follow-up period. Despite the minimal invasive nature of the procedure, these patients remain fragile and need a meticulous perioperative care.

INTRODUCTION

Nowadays, the numerous advanced endovascular treatment techniques offer a minimal approach in patients with complex aortic aneurysm anatomy.[1] Chimney technique (chimney EVAR, ChEVAR) using parallel grafts is an endovascular approach that hasincreased its popularity during last decade.[2] ChEVAR is an off-the shelf technique in the treatment of pararenal abdominal aortic aneurysms (AAA), initially used in emergent cases or as a bailout technique. Furthermore, when proximal or distal anatomy rules out a treatment with fenestrated or branched devices, ChEVAR is an alternative management in complex aneurysms.[3,4]

Despite the wider application andincreasing experience in the use of ChEVAR in complex aortic aneurysm treatment, there are persistingdilemmas concerning overall technical success, endoleak Ia and chimney stent patency, as well as long-term ChEVAR's durability and safety.[2] In clinical aspects, occurrence of adverse events during the early follow-up is associated with renal impairment or fatal superior mesenteric artery occlusion.[4]

The aim of this study was to report the early-outcomes of ChEVAR for the treatment of para-renal AAAs at a single tertiary vascular center.

Author for correspondence:

Miltiadis Matsagkas, MD, PhD, FEBVS

Department of Vascular Surgery, Medical School, University of Thessaly, Larissa University Hospital, Mezourlo, Larissa, Greece
Tel: +30 6945585876, E-mail: milmats@gmail. com
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METHODS

Study Cohort

From May 2016 to February 2019, 30 consecutive high-risk patients (28 men; mean age 72 years) with AAAs extending to or involving renal arteries were treated using the chimney

technique. All patients had proximal landing zones precluding any standard endovascular intervention and were at high risk for open aortic surgery.

All cases were electively treated. In cases where FEVAR or branched devices were indicated, patients' decision to deny a long waiting of 4 to 8 months for the fenestrated or branched endograft was considered. A preoperative CTA of the thoracic and abdominal aorta down to femoral arteries was performed in all patients. During preoperative planning, CTAs were assessed using center lumen line measurements for both the aorta and the TVs, usingdedicatedsoftware (3Mensio Medical Imaging BV, Bilthoven, Netherlands). Patients' demographics, preoperative and postoperative anatomic parameters, perioperative characteristics and outcome data were collected prospectively. Informed consent was obtained from all patients. The study was approved by the Institutional Review Board.

Periprocedural characteristics

Intraoperative management

All operations were realized under general anesthesia. After the insertion of the sheaths, 50-100IU/kg of unfractionated heparin were administrated to the patient. After the first operative hour, activated clotting time (ACT) was calculated and repeated each 30 minutes. In the case that ACT target (200-300%) was not achieved, a further bolus administration of heparin was demanded (50IU/kg). Cerebral oximetry was applied in all cases as a standard of care.

Access

In all cases, bifemoral access was used for the insertion of the main endograft. Concerning the parallel grafts, in cases of one chimney a left brachial access was preferred with percutaneous puncture under ultrasound guidance, of the peripheral brachial artery. Left axillary artery was dissected and two parallel sheaths were inserted when two chimneys were applied. Right axillary artery was additionally used in cases of three chimneys. In all cases, a complete CTA of the aortic vessels, thoracic, abdominal aorta and iliac arteries was preoperatively demaned and the anatomy of the upper and lower access was carefully evaluated and taken into consideration.

Type of stents

A balloon expandable covered stent was preferred in all cases where patient's anatomy permitted a successful stenting with a maximal stent length up to 57 mm. In any other case, whenlonger stents were demanded, a self-expanding covered stent was used. Relining with self-expanding stents was applied according to surgeon's preference or in cases where an inadequate angulation of the inserted stent was detected in the intra-operative angiography.

Antiplatelet therapy

Double antiplatelet therapy, clopidogrel 75mg and aspirin 100mg,was initiated in all patientsat least for the first post-operative month, except those under anticoagulant regiment with DOACs or VKA antagonist, where single antiplatelet treatment was preferred. The duration of the double antithrombotic therapy was reevaluated in 1st and 6th month of follow-up according to patient's characteristics and surgeon's preferences.

Follow-up

A standardized follow-up protocol including CTA of the abdominal aorta and iliac arteries and laboratory testing was performed between 2nd and 30th post-op day, at 12 months and yearly, thereafter. Duplex ultrasonography with plain x-rays was used as standard follow-up method at 6-month follow-up, as well as in cases of uncomplicated CTA at discharge, at 1st month. In any other case, a CTA was demanded.

Outcomes

As main outcomes technical success, presence of endoleak type Ia, overall mortality, freedom from target vessel occlusion, as well as reinterventions were recorded and analyzed. Endoleak type Ia was considered as any high flow endoleak provoked by an inadequate proximal sealing between the main graft and the aortic wall. On the other hand, as gutter endoleaks were considered all low flow endoleaks created between the main and the parallel grafts.

Statistical Analysis

Continuous data were reported as a mean ± standard deviation. Categorical data were expressed as absolute numbers and percentage of prevalence (%) in the study cohort. In the statistical analysisfor continuous variables the independent t-test for normally distributed data and the Mann-Whitney U test for nonparametric data were used. The Pearson x2 test or the Fisher exact test was used for categorical variables, as appropriate. Survival times were initially compared among groups with the log-rank test and Kaplan- Meier curves were generated. P value was considered significant when it was <0. 05. Statistical analysis was performed by SPSS 22. 0 for Windows software (IBM Corp, Armonk, NY).

RESULTS

Patients' demographics and anatomic characteristics

A total of 30 patients (28 men, age 72 years, range 68-81 years old) underwent chimney procedures. In 23 cases, chimney technique was used as primary treatment (Image 1, 2) while in 7 patients a previous aortic procedure has been recorded (Image 3). One patient underwent previous open repair for AAA and was re-operated with ChEVAR for a para-anastomotic aneurysm. In the remaining 6 cases, a previous failed EVAR with endoleak type Ia was the indication of treatment. The preoperative aneurysm diameter was calculated at 67 mm (range 51-91mm) with a preoperative proximal neck length at 3mm (range, 0-8mm)while the neck length using the chimney technique changed to 24. 5 mm (range, 18-34 mm).

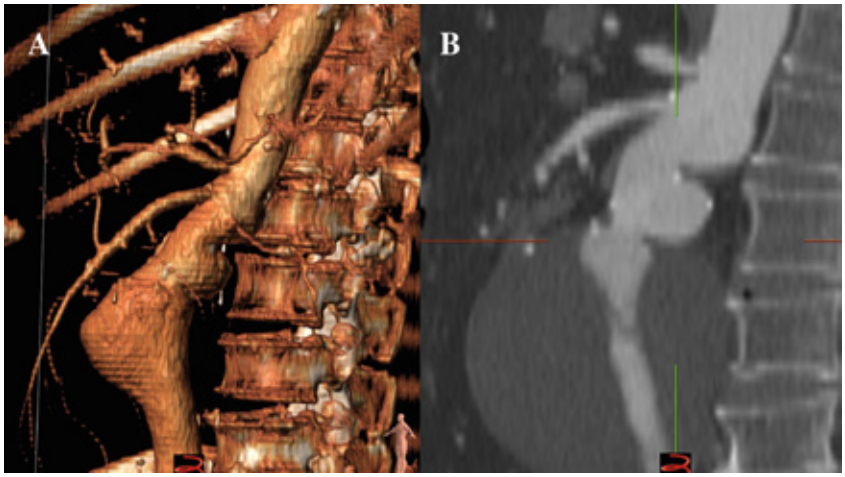


Image 1. Preoperative CTA: 8cm pararenal AAA with complex proximal neck anatomy (Panel A, 3D reconstruction, Panel B, Longitudinal axis)

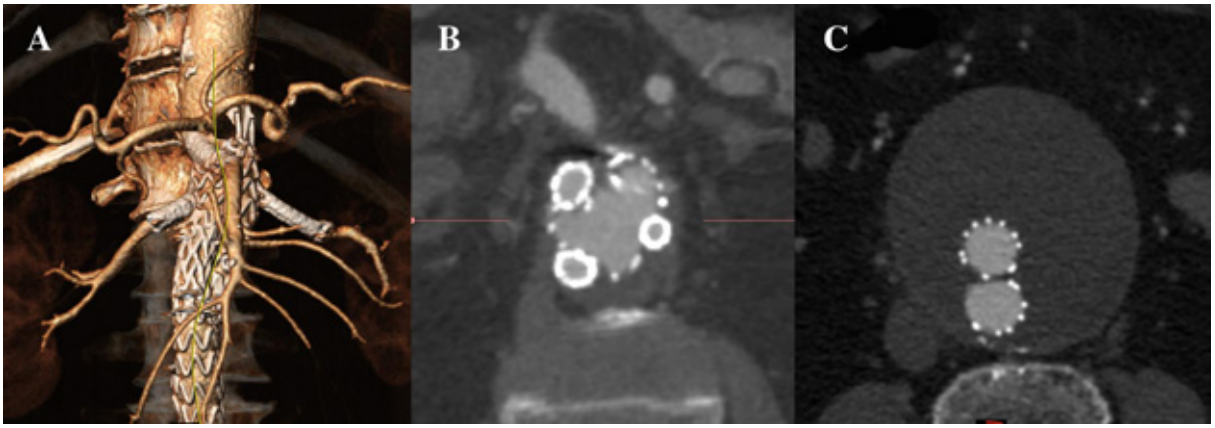


Image 2. Post-operative CTA: The patient presented in Image 1 was treated with a triple chimney. All grafts are patent (Panel A & B). The post-operative CTA revealed no endoleak (Panel C).

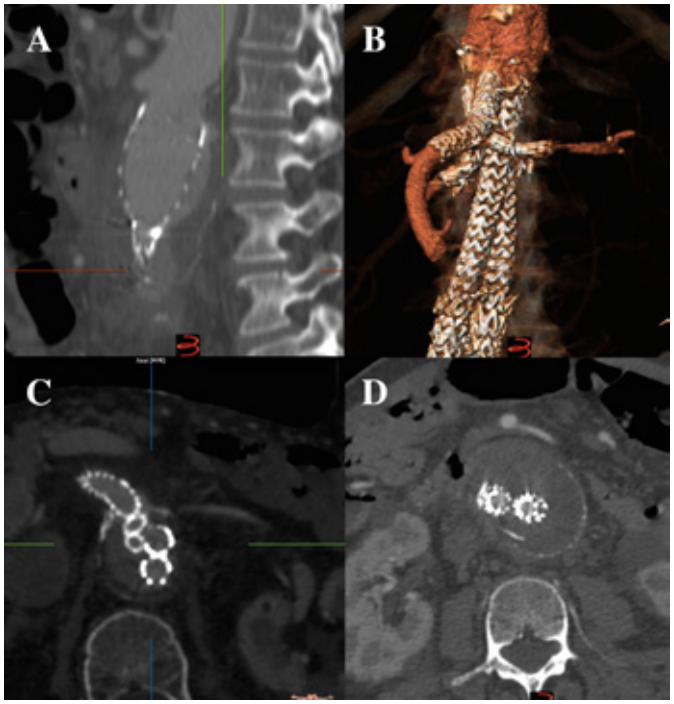


Image 3. Preoperative CTA of a patient with failed EVAR (Panel A, EndoleakIa). The patient was treated with a triple chimney and a Nellix device (Panel B & C). ChEVAR resolved the endoleak as presented in the post-operative CTA (Panel D).

Perioperative characteristics

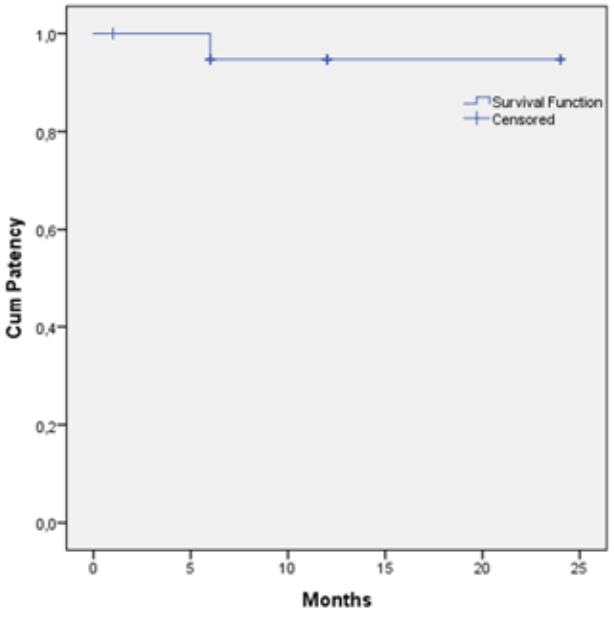
Target vessels were51renal (RA) and 11superior mesenteric arteries (SMA). 11 patients treated usingthree chimneys, 10 patients two chimneys and 9 patients one chimney. 18 patients received an Endurant endograft (Medtronic Inc, Minneapolis, MN), 9 patients a Nellix sealing device (Endologix-Inc, Irvine, CA),2 patients an Incraft device (Cordis, Cardinal Health, Dublin, UK) and 1 patient a Bolton Relay endograft (Vascutek, Terumo Aortic, Glasgow, UK). The decision for the endograft used was according to patient's specific anatomic characteristics and surgeon's preference. The oversizing of the main aortic graft was varied between 23% and 30% (mean: 26,7%). Totally, we used for primary stenting 11 covered balloon expandable stents for the SMA and 49 for the RAs (14 BeGraft,Bentley Innomed,GE, 7 Atrium V12, Maquet SAS, FR, 28 LifeStream, C. R. Bard, USA), and 2 self-expanding covered stents for the RA (Viahban, W. L. Gore, USA) with a range between 5 and 10mm. Additionally, we used for relining self-expanding covered stents, 6 for the SMA and 15 for the RA (E-luminex, C. R. Bard, USA). Completion angiography showed no type Ia endoleak in any of the patients at the end of the procedure. Technical success was 100%.

Median perioperative time was calculated at 214 minutes (range 180-360 minutes) while the median radiation exposure time was 43. 5 minutes (range 30-102 minutes). The median contrast volume used was 200ml (range 120-300ml). Blood loss was within acceptable limits as median transfusion volume was 535ml (2RBC/patient). After the procedure, patients were usually transferred directly to the ward. However, some patients had to be admitted to the ICU, usually due to pre-existing comorbidities. For these patients, median stay at the Intensive Care Unit (ICU) was 1day (range 0-10 days).

The overall 30-day mortality was 10% (3/30). An aneurysm related death was recorded due to severe systemic inflammatory response syndrome (SIRS). The patient expressed an extensive SIRS, a few hours after the end of the operation (an Endurant endograft was used in this case), admitted immediately in the ICU, but unfortunately, he never recovered and eventually died10 days later due to multi-organ failure. All 3 chimneys remained patent without any endoleak at 6th postoperative day when he underwent a CTA. Two patients (an 80-year-old and a 57-year-old male patient) died due to myocardial infarction on the 2nd and the 5th post-operative day, respectively. Both suffered from severe coronary artery disease, even though with preserved EF preoperatively. During hospitalization, 3 myocardial infarctions (2 fatal) and 2 strokes were recorded. One patient suffered a left ischemic stroke due to embolization probably from the aortic arch. 3 target vessels were stented in this patient, via both axillary arteries. A second patient suffered a stroke associated with visual blurriness and mild instability due to embolization from the vertebral artery. Left renal artery was the target vessel in this patient. Left axillary artery was used the catheterization.

Kaplan-Meier estimation forTVprimary patency rate was 95% at24months (SE 5%) (Figure 1). One renal stent occlusion was detected at 6th month follow-up. The patient remained asymptomatic with a creatinine at 1. 7mg/dl during follow-up. After extended discussion with him, he refused any further intervention. He is under nephrological surveillance. Two target vessel stenoses were diagnosed during the 1st month follow-up, concerning 1 renal and 1 superior mesenteric artery. The SMA stenosis was treated successfully by endovascular means during the 2nd post-operative month using a balloon expandable stent (Image 4).

Figure 1



Months	0	1	6	12	24
Patients at risk	30	29	18	12	3
Events	0	0	1	1	1
Percentage			95%		95%
SE			5%		5%

Figure 1: The cumulative patency rate was 95% at 24 months according to Kaplan Meier

The patient with the renal stenosis was treated conservatively ashe remained asymptomatic. A mild renal impairment was identified with amaximum post-stenosis creatinine at 1. 7mg/dl with a preserved GFR >60ml/kg/1. 73m^2 and urine output (creatinine baseline at 0. 9). Threegutter endoleaks werediagnosed with CTA before patient's discharge. All of themresolved spontaneouslyduring the 1st month. Furthermore, at the initial CTA, type Ia endoleaks were identified in 2 patients treated with triple chimney and they are still under surveillance (2nd and 3rd month respectively). The cumulative endoleak type Ia and freedom from chimney graft-related re-interventions rate was 93. 3% (SE 4. 6%) and 94. 7 % (SE 5. 1%) at 24 months, respectively.

Three patients died during the follow-up period and the overall survival rate during follow-up was calculated at 73%at 24 months (SE 9. 9%, Figure 2). A patient died the 6th post-operative month due to pneumonia. This patient suffered a stroke with left hemiparesis the 2nd post-operative day (1 of the 2 patients that suffered a post-operative stroke). An em-

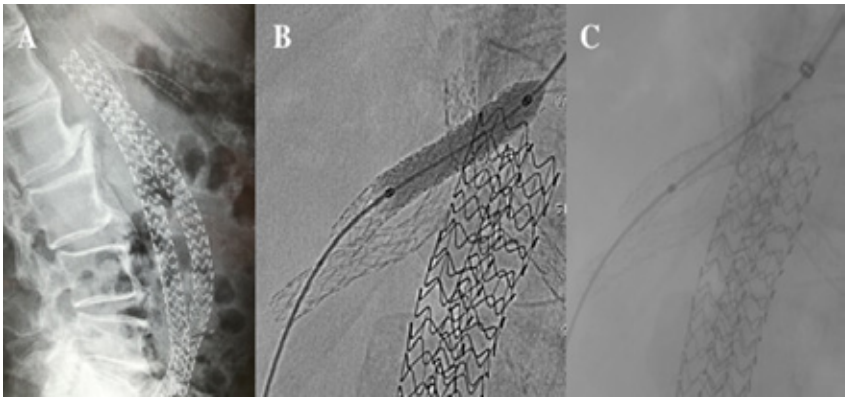
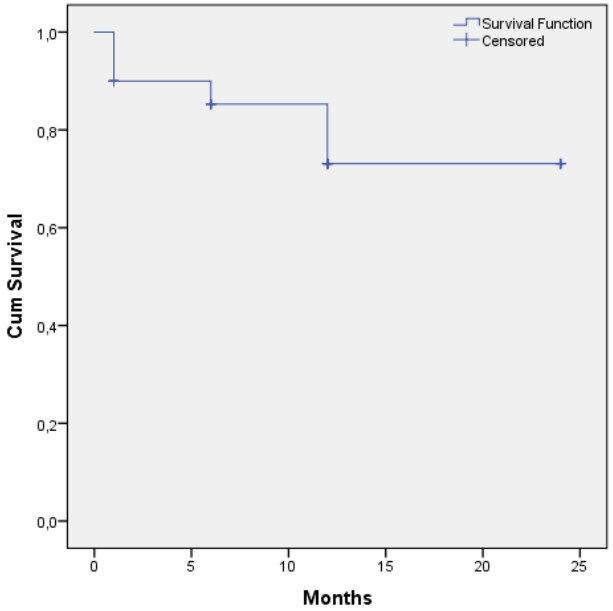


Image 4. Plain X-rays revealed a post-operative SMA stenosis in a patient treated with ChEVAR (Panel A). The patient was treated with a balloon expandable stent (Panel B & C).

bolic etiology is the most possible diagnosis, as the patient had a mild aortic arch atheromatosis and both axial artery accesses were used during a triple-chimney procedure. The second patient suffered a fatal myocardial infarction the 5th post-operative month. He had a medical history significant for coronary artery disease. Another patient died two years after the procedure because of alcoholic cirrhosis. No late aneurysm related death was recorded.

Figure 2



Months	0	1	6	12	24
Patients at risk	30	27	18	12	3
Events	0	3	4	6	6
Percentage		90%	85. 3%	73%	73%
SE		5. 5%	6. 9%	9. 9%	9. 9%

The cumulative survival rate was 73% at 24 months according to Kaplan-Meier

DISCUSSION

Endovascular repair of pararenal abdominal aortic aneurysms has gain popularity as an attractive alternative to open repair.[5] ChEVARincreases the eligibility of endovascular aneurysm repair in complex aneurysm anatomy with acceptable mortality rates and less morbidity than open repair.[6] ChEVAR seems a safe option, with comparable morbidity and mortality to FEVAR, especially in emergent cases or when custom-made grafts are unavailable or contraindicated.[5] In high volume centers, early mortality is as low as 1. 17% for the chimney technique and 0. 58% for fenestrated EVAR.[5]

In this study technical success was 100%. Along this line, in PERICLES registry and PROTAGORAS study, the intraoperatively technical success rate was 97. 1% and 100%, respectively.[2,7] With more than 500 patients treated with the chimney technique and 898 parallel grafts implanted in target vessels in PERICLES registry, ChEVAR seems a feasible option in pararenal aneurysm repair.[2] Despite of the encouraging perioperative results, long-term durability and stent patency is an oft-debated issue in these cases. During median follow-up, patency achieves acceptable rates, more than 95%.[8] Similarly, in our study the cumulative TV primary patency rate was 95% at24 months (SE 5%).

TVs graft occlusion seems a rare condition, mostly occurring the early post-operative period, within the first 4 months in the current literature.[4] In most renal cases, it is a silent complication, associated with mild or reversible renal impairment. Otherwise, superior mesenteric artery occlusion could be a lethal event, demanding urgent laparotomy.[4] In this study, one renal occlusionseen at 6 months associated with mild renal injurywas treated conservatively. During the follow-up, freedom from reinterventions was 94. 7%at 24 months (SE 5. 1%), which consort with the current literature.[9, 10]

Type Ia endoleak is characterized as the Achilles's heel of the chimney technique. Excessive or insufficient main stent-graft oversizing as well as an inadequate seal zone length (<20mm) are the main factors associated with high flow Ia endoleak in ChEVAR.[11] This classification of endoleak type Ia according to its mechanism may instigate a more appropriate management, as in these cases a further intervention is obliged.[11] Lindblad et al report an incidence of 13%endoleak type Ia in patients treated with parallel grafts in abdominal aortic aneurysms during early follow-up.[12] In this study, two patients were diagnosed with type Ia endoleak and they are under close surveillance (2nd and 3rd post-operative month re-

spectively). In both cases, an inadequate proximal seal zone (<20mm) is recorded. The cumulative freedom from endoleak type Ia was 93. 3% at 24 months (SE 4. 6%)

On the other hand, the challenging issue regarding the inevitable formation of "gutters" between the parallel and main grafts provides more uncertainty regarding the technical and clinical role of these type Ia endoleak. 13Gutter endoleaks are physically low-flow endoleaks, not associated with sac enlargement, with a tendency to disappear during early follow-up. 13Only a few patients, presenting this probably benign type of endoleak, seem to require reintervention. 13In PERICLES registry, the persistence rate of gutter endoleaks at 17. 1 months follow-up was eliminated at 2. 9%. 11 Also, in this study, all gutter-related type Ia endoleaks (3/3) were resolved spontaneously within first month. 13. 3% of patients presented a gutter endoleak. With the wider use of the chimney technique, more technical aspects, as stent graft position and angulation, are investigated, promising an amelioration of the current results. 14More studies are needed to identify the role of gutter endoleaks, as in the current literature they are generally described and included in type Ia endoleaks, despite their different natural history and clinical impact.

Chimney technique is a readily dispensable solution for the treatment of not only intact pararenal aneurysms but also type I endoleaks in failed EVAR.[15] Especially in this series, two Nellix devices were used in previous failed EVAR. No complication was recorded in technical or clinical aspects. Nellix device seems to offer a good adaptation in previous endografts and was associated with no endoleak (type Ia, or gutter) in our series. In ASCEND registry, 3 endoleaks within 154 patients and 90 days of follow-up were detected (1type Ia and 2 type Ib). The freedom from type Ia endoleaks was 95. 7% and the freedom from all endoleakswas 94. 2% at 1 year.[16] Youssef et al reported also encouraging results with 100% technical success rate and no endoleak[17], while other small series also support these results.[18,19] Even in cases of failed ChEVAR with Nellix, a more proximal extension with a second Nellix is already described with encouraging results in the 2-year follow-up.[20]

As perioperative mortality in ChEVAR is similar to open repair and fenestrated EVAR, within the acceptable rate of 3. 1%, the parallel graft technique remains an attractive alternative in the treatment of pararenal aneurysms.[10] Especially, in elder patients, late outcomes, including overall mortality, are similar to standard EVAR.[21] High early mortality rate (10%) in this series may be explained by the small number of high-comorbidity patients during the primary period of the learning curve. Analogous results are presented also by Coscas et al during their early experience report (4/16).[22] During the follow-up period, 3 non–aneurysm related deaths were recorded. The fragility of these patients is an aspect that should not be disregarded. All patients were characterized as unfit for open repair while a complex aneurysm anatomy remains an independent factor of progressed disease. A high major adverse event rate up to 8. 5% is described in the literature.[1] In this study, 2 patients suffered a stroke (2/30, 6. 6%). In the current literature, bilateral upper extremity access, aneurysm rupture and an operation time >290 minutes are associated with a significantly increased risk for adverse events, with an incidence of clinical cerebrovascular events at 1. 9%.[1] Stroke after ChEVAR is associated with a high mortality rate.[1]

The major limitation of this study was its retrospective nature. The quite small number treated with ChEVAR and the short-term follow-up may also lead to bias. The high early post-operative mortality rate (3/30) represents an acceptable number when the age and comorbidities of these patients are kept in mind. Furthermore, the heterogeneity of endografts, devices and stent grafts used during the procedures influence the conformability of our results and hamper disciplinarian conclusions.

CONCLUSION

Chimney technique permitsthe management of para-renal AAAs according to each patient's specific anatomy. It seems a feasible and safe option at least during the early follow-up period. Despite the minimal invasive nature of the procedure, these patients need a meticulous perioperative care. Patients suffering from extended aortic aneurysm disease remain fragile during early follow-up, needing a close surveillance.

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