Endovascular repair of juxta- and para-renal abdominal aortic aneurysms

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Abstract:

Introduction: During the last two decades endovascular approach has been extensively adopted for the treatment of juxta-renal abdominal aortic aneurysm (jAAA) and para-renal aneurysms (pAAA). The aim of the current study was to evaluate the early and mid-term outcomes of endovascular treatment of jAAA and pAAA in a tertiary vascular center.

Methods: A retrospective study was undertaken of consecutive high-risk patients presenting with complex aortic aneurysm (jAAA or pAAA) and treated electively with either chimney endovascular aneurysm repair (ChEVAR), fenestrated (FEVAR) or branched (BEVAR) technique between 2016 and 2019. The primary end point was technical success rate, survival and target vessel patency during 30 post-operative days. Secondary outcomes were survival, target vessel patency and re-intervention rate during the study period.

Results: A total of 41 patients with presentation of complex aortic aneurysm were treated electively; 36 ChEVAR, 4 FEVAR and 1 BEVAR. The mean age of the patients was 71.2±6.7 years (95% male [39/41]), with mean aneurysm diameter of 64±14mm. Ninety-eight splanchnic arteries were targeted; 76 renal arteries, 19 superior mesenteric arteries and 3 coeliac trunk arteries. The technical success rate was 95% (39/41; 2 patients had a gutter endoleak intra-operatively). The overall 30-day mortality was 10% (4/41); only one aneurysm related. No patient presented spinal cord ischemia. The median follow-up was 6 months (1-36 months). Survival was 85% (SE 6%) and 80% (SE 7%) at 6 and 12 months, respectively. The freedom from re-intervention was 98% (SE 2.4%) and 89% (SE 5%) at 1 and 12 months, respectively. The freedom from target vessel occlusion was 98% (SE 2.4%) at 6 and 12 months. At 1st month computed tomography, 4 patients had gutter endoleak, which disappeared at the 6-month follow up.

Conclusion: Endovascular approach of pAAA and jAAA is an effective treatment option with high technical success rate. Early and mid-term outcomes are good in terms of mortality, target vessel patency and re-intervention rate.

INTRODUCTION

Juxta-renal abdominal aortic aneurysm (jAAA) is defined as an AAA with an infra-renal short proximal neck of <10 mm that may require suprarenal cross-clamping during open repair,[1] while para-renal AAA (pAAA) involves the renal arteries and always require a supra-renal cross-clamping.[2] JAAA and pAAA pathology are diagnosed in up to 15% of all AAA.[3,4] Traditionally, during the past decades open repair was the treatment of choice of such AAAs. Open repair is technically challenging due to the involvement of reno-visceral vessels, the potential renal or even visceral ischemia due to the proximal clamping, the advanced age of the patients, and the commonly coexisting severe comorbidities. Additionally, similar pathology represents the para-anastomotic aneurysms (PAA) after open repair, that may present in 0.5% to 15% in various reports.[5] Open repair of jAAA and pAAA has showed quite low perioperative mortality rates, however the morbidity rates are not insignificant.[6-8] In particular, the open repair of PAAs has demonstrated even higher morbidity (70% to 83%) and mortality rates (8% to 70%).[5,9,10]

On the other hand, during the last two decades endovascular approach has been extensively adopted for the treatment of jAAA and pAAA.[5,11] Fenestrated stent-grafts (FEVAR; fenes-

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trated endovascular aneurysm repair) incorporates the renal or all of the visceral branches in order to expand the proximal sealing zone.[3] Custom made branched devices or standardized off-the-shelf multibranched devices, such as the t-Branch (Cook Medical, Bloomington, IN, USA), has also been used in order to expand the proximal sealing zone to a healthy aorta.[12] Another endovascular technique that has been broadly used is the chimney technique (ChEVAR) that has also showed good aneurysm exclusion and patency rates.[13]

The aim of the current study was to evaluate the early and mid-term outcomes of endovascular treatment of jAAA and pAAA in a tertiary vascular center.

METHODS

Patients selection

A retrospective study was undertaken of consecutive high-risk patients presenting with complex aortic aneurysm (jAAA or pAAA) and treated electively with either ChEVAR, FEVAR or BEVAR (Branched EVAR) technique between 2016 and 2019. Proximal landing zone precluded any standard EVAR. Patients were classified as high risk for open aortic surgery. This was a single-center retrospective study, with all data being acquired prospectively. According to the local authorities, Institutional Review Board approval for informed consent of the patient was not deemed necessary for this retrospective study.

End points- Definition

The primary end point was technical success rate (absence of surgical conversion or mortality, type I or III endoleaks, or graft limb obstruction), survival and target vessel patency during 30 post-operative days. Secondary outcomes were survival, target vessel patency and re-intervention rate during the study period. Endoleak type Ia and gutter's endoleak were defined and reported separately as has been described previously.[14]

Peri-procedural characteristics

Demographic data, pre-operative comorbidities such as hypertension (HT), hyperlipidemia (HL), diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), cerebrovascular disease (CVD), coronary artery disease (CAD), smoking, intraoperative and perioperative details were recorded. Blood test results, such as hemoglobin (Hb) level, white blood cell count and creatinine levels were also recorded.

Sizing and planning were performed based on the pre-operative computed tomography angiography (CTA) using a 3Mensio workstation (Medical Imaging B.V., Bilthoven, the Netherlands) with dedicated reconstruction software. All but 4 ChEVAR procedures were performed in an adequately equipped operating room, using a moveable radiolucent surgical table and a mobile digital angiographic system (Philips BV Endura, Philips Medical Systems, the Netherlands). The last 4 ChEVAR patients were treated with the new mobile digital angiographic system (Ziehm Vision RFD 3D, Ziehm Imaging GmbH, Nuremberg, Germany). The FEVAR and BEVAR cases were undergone in the angio-suite of the radiology department (Allura Xper FD 20, Philips, USA).

Standard Intra-operative management

All operations were undergone under general anesthesia. After the insertion of the sheaths, 50-100IU/kg of unfractionated heparin was administrated to the patient. After the first operative hour, activated clotting time (ACT) was calculated and repeated every 30 minutes. In the case that ACT target (200-300 sec) was not achieved, a further bolus administration of heparin was administered (50IU/kg). Cerebral oximetry (INVOS™ 5100C Cerebral/Somatic Oximeter, Medtronic, Minneapolis, MN, USA) was also applied in all cases as a standard of care.

Access

In all ChEVAR cases, bi-femoral 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. 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 the B/FEVAR cases bi-femoral access was used for the insertion of the main endograft. The branches (t-Branch) were cathererized by right axillary artery because of the setup of the angio-suite, while in FEVAR cases, the splanchnic vessels were catheterized by the femoral access, except one case that upper extremity access was needed for the catheterization of coeliac trunk (CT) and superior mesenteric artery (SMA).

Type of stent-graft and stents

Stent grafts with either supra-renal fixation system (Endurant; Medtronic Ave, Inc, Santa Rosa, Calif or Incraft, Cordis, Cardinal Health, Santa Clara, California, US) or Nellix system, Endologix, Irwin, California, US) were used in ChEVAR procedures; in one patient a thoracic endograft from Bolton (Medical, Sunrise Florida, U.S) was also used. The oversizing of the main aortic graft was varied between 23% and 30%. The choice type of endografts were selected according to personal preferences of each surgeon taking into consideration the anatomical characteristics of the aneurysm. In the BEVAR case the t-Branch (Cook Medical, Bloomington, IN, USA) was used, and in the FEVAR cases a custom made device also from Cook was used.

In all cases a balloon expandable covered stent was preferred where patient's anatomy permitted a successful stenting. When longer stents were demanded, either a self-expanding covered stent was used or in the recent cases the VBX (W.L. Gore & Associates, Flagstaff, AZ, USA) that can be up to 79mm. Relining with self-expanding bare metal 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.

Dual antiplatelet therapy with clopidogrel 75 mg and aspirin 100 mg, was administered in all patients for at least the first post-operative month. Patients that were under antico-

agulation with DOACs or VKA antagonist, received single antiplatelet treatment additionally.

Follow-up

All patients have been under follow up protocol including CTA before discharge, duplex ultrasonography with plain x-rays was used as standard follow-up method at 6-month follow-up, CTA at 12 months and yearly thereafter. All data derived from CTAs were analyzed and registered in a xl file.

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. 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 characteristics

Between 2016 and 2019, a total of 41 patients with presentation of complex aortic aneurysm were treated electively in our department. The mean age of the patients was 71.2±6.7 years (95% male [39/41]), with mean aneurysm diameter of 64±14mm. The mean length of AAA neck was 4±2mm in jAAA patients (28/41) and 0mm in 13 patients who had pAAA. Table 1 shows the most common co-morbidities of the patients; all patients were classified as ASA 3 or 4.

Co-morbidities	
HT	61% (25/41)
HL	34% (14/41)
CAD	46% (19/41)
Smoking	46% (19/41)
COPD	42% (17/41)
CRD	5% (2/41)
CVD	2.5% (1/41)
ASA classification	
ASA 3	90% (37/41)
ASA	10% (4/41)

Table 1. This table demonstrates the co-morbidities. HT: hypertension; HL: hyperlipidemia; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; CRD: chronic renal disease; CVD: cerebrovascular disease; ASA: American Society of Anesthesiologists.

Intra-operative details

All patients were treated under general anesthesia. Table 2 shows the devices that have been used for ChEVAR (Figure 1), FEVAR (Figure 2) and BEVAR (Figure 3). Seven patients (17%; 7/41) were a secondary procedure after previous aortic repair (6 after EVAR and 1 for para-anastomotic aneurysm after open repair); for the 6 redos after EVAR, 2 patients have been treated with ChEVAR using an Endurant Cuff, 3 with ChEVAR using Nellix and 1 with FEVAR, while the one patient with the para-anastomotic AAA was also treated with ChEVAR using the Nellix device. Ninety-eight splanchnic arteries were targeted; 76 renal arteries, 19 superior mesenteric arteries and 3 coeliac trunk arteries. In terms of type of stents for target vessels (TVs) 74 balloon expandable covered stents were used for the renal arteries (35 BeGraft, Bentley Innomed, GE, 7 Atrium V12, Maquet SAS, FR, 28 LifeStream, C. R. Bard, USA, 4 VBX, W. L. Gore, USA) and 2 self-expanding covered stents (Viahban, W. L. Gore, USA). Additionally, 19 balloon expandable covered stents were also used in SMA (18 BeGraft, Bentley Innomed, GE and 1 VBX) and 3 in CT (2 BeGraft, Bentley Innomed, GE and 1 VBX). Additionally, we used for relining self-expanding stents, 6 for the SMA and 15 for the RA (E-luminex, C. R. Bard, USA).

	Number of target vessels	1	2	3	4	Total
Type of endograft in ChEVAR	Nellix*	4	3	3	0	10
	Endurant**	4	6	12	0	22
	Incraft	0	3	0	0	3
	Relay	0	0	1	0	1
	FEVAR***	0	0	2	2	4
	BEVAR	0	0	0	1	1
	Total	8	12	18	3	41

*3 cases after previous EVAR, 1 case for para-anastomotic aneurysm

**2 cases with Cuff after previous EVAR

***1 case after previous EVAR

Table 2. This table shows the devices that have been used. ChEVAR: chimney endovascular aneurysm repair; FEVAR: fenestrated EVAR; BEVAR: branched EVAR.

Median perioperative time was recorded at 235 minutes (range 180-360 minutes) while the median radiation exposure time was 49 minutes (range 30-102 minutes). The median contrast volume used was 194ml (range 72-400ml). Blood loss was within acceptable limits as median transfusion volume was 1.6 RBC/patient (0-3). The technical success rate was 95% (39/41; 2 patients had a gutter endoleak intra-operatively). 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).

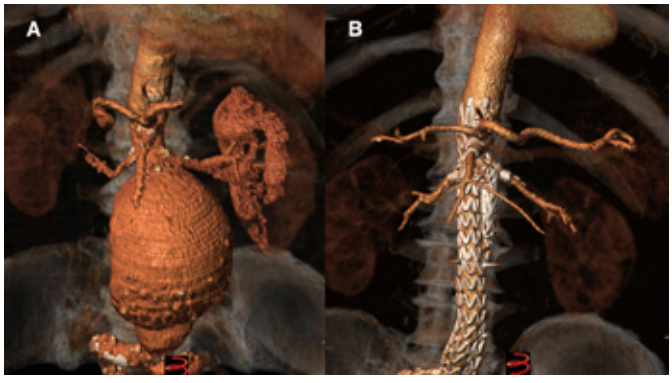

Figure 1. A pre-op and post-op computed tomography angiography of a chimney endovascular aneurysm repair case.

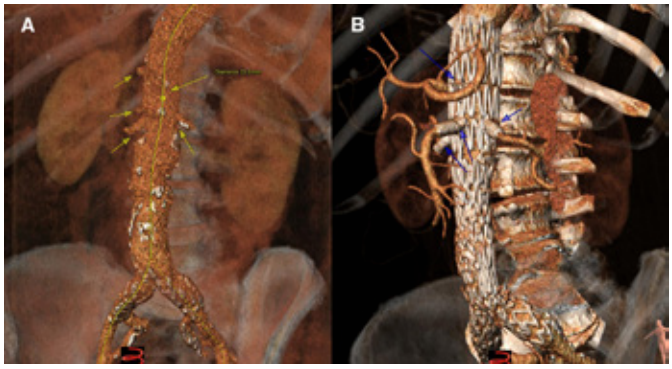

Figure 2. A pre-op and post-op computed tomography angiography of a fenestrated endovascular aneurysm repair case.

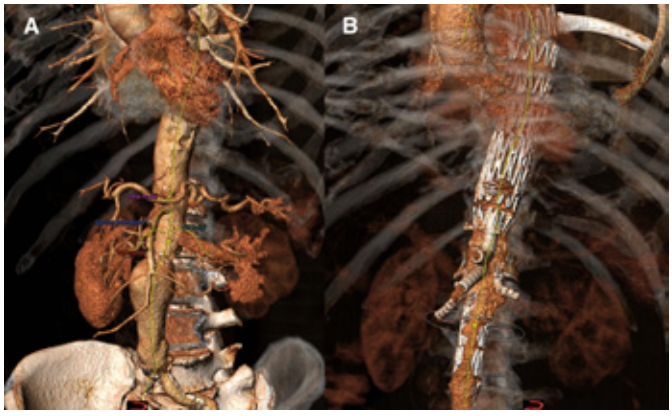

Figure 3. A pre-op and post-op computed tomography angiography of a branched endovascular aneurysm repair case.

Early outcomes

The overall 30-day mortality was 10% (4/41); all patients after ChEVAR. A patient died after severe systemic inflammatory response syndrome and multi-organ failure in the 10th post-operative day (without Endoleak and with patent splanchnic vessels in post-op CTA). Two patients died due to myocardial infarction on the 2nd and the 9th post-operative day. One aneurysm related death was attributed to an injury of a renal artery branch probably due to the stiff wire needed in this particular anatomy (severe aortic atherosclerosis and angulation of the aorta and the renal artery) that caused severe hemorrhage and retroperitoneal hematoma, despite the immediate re-intervention with subsequent embolization of the branch the same day. During hospitalization, 1 more patient had a non-fatal myocardial infarction and 2 patients had a non-disabling stroke (1 hemorrhagic and 1 ischemic). Two patients had a respiratory infection (pneumonia), 3 had a paralytic ileus and 1 patient presented with a transient upper limb paralysis due to brachial plexus injury. No patient presented spinal cord ischemia. All patients were discharged in good condition. One patient after the discharge presented gastro-intestinal bleeding the 20th post-operative day that was successfully treated conservatively.

Follow up outcomes

The median follow-up was 6 months (1-36 months). Two patients died during follow up. One patient at 6 months due to chest infection and one patient at 2 years because of liver cirrhosis. No patient presented a renal insufficiency. The KM analysis showed that survival was 85% (SE 6%) and 80% (SE 7%) at 6 and 12 months, respectively (Figure 4). Additionally, 3 patients needed a re-intervention, one patient had a type III endoleak at 1st month and a new stent graft was inserted, one patient had a limb occlusion at 6 months and underwent a fem-fem bypass, and one patient had a in-stent stenosis of the SMA at 6 months of follow up, and a re-intervention was undertaken with a covered balloon expandable stent. The patient with the t-Branch treatment had a small endoleak type III between the branch device and the distal graft and he is still under surveillance (Figure 3). KM analysis showed that freedom from re-intervention was 98% (SE 2.4%) and 89% (SE 5%) at 1 and 12 months, respectively (Figure 5). During follow up, only one right renal artery stent was thrombosed during the 6th follow-up month after ChEVAR. KM analysis showed that freedom from target vessel occlusion was 98% (SE 2.4%) at 6 and 12 months (Figure 6). An in-stent stenosis was noted in 3 patients (all ChEVAR patients; 2 RRA and 1 SMA; that was treated as mentioned above) during the 1st month CTA without any clinical presentation, and patients with the RRA in-stent stenosis were treated conservatively. At 1st month CTA, 4 patients had an endoleak type Ia (all defined as gutter endoleaks), one patient type III (that was treated with a limb extension) and the patient with the t-Branch mentioned above had also type III endoleak between the main graft and the distal one. In all 4 patients the gutter endoleak disappeared at the 6-month follow up.

DISCUSSION

During the last decades, endovascular interventions have been constantly increasing for the treatment of complex aortic aneurysms.[15] The recent ESVS (European Society for Vascular Surgery) guidelines,[16] highlighted that in complex endovascular repair of jAAA, FEVAR should be considered the preferred treatment option when feasible (IIa, C), while the use of parallel graft techniques may be considered as an alternative in the emergency setting or when fenestrated stent grafts are not indicated, not available, and as a bailout (IIb, C). This is more pronounce for patients that have severe comorbidities, that usually are turned down for open repair. However, with the relatively novel endovascular techniques, the treatment of those patients is now feasible. In this study, the technical success rate was 95%, with no intra-operative death. Although, those were patients with ASA 3 and 4, most of them were treated without any severe peri-operative complication. Along this line, a recent systematic review showed that endovascular treatment of pAAA and jAAA was a safe and efficient treatment with high technical success rate and low mortality.[17] Li et al.[18] presented another systematic review and pooled analysis comparing FEVAR with ChEVAR techniques, showing that both fenestrated and chimney techniques are attractive options for jAAA treatment with encouraging early and mid-term outcomes.

The mortality rate of this study's cohort was 10%. Howev-

er, only one death was absolutely aneurysm-related, after an injury of a renal artery branch probably due to the stiff wire needed in this particular anatomy, while other causes were mainly myocardial infraction and chest infection. A recent study analyzed custom made devices and physician modified devices for the treatment of complex aneurysms also showed an early mortality rate of 4% and 14%, respectively.[19] In another large systematic review on FEVAR and ChEVAR, it was highlighted that no statistically significant differences were found between the two endovascular approaches for pararenal aortic pathologies in terms of 30-day mortality, renal impairment, or endoleak.[20] Thus, different endovascular approaches present similar results in terms of mortality. In this study, most of the patients were treated with ChEVAR technique, because of logistic and economical reason that exist in our country. Another important reason was that some patients had a large aneurysm and could not wait for a custom-made device that could be available up to 12 weeks; although this situation is changing. Although, those are complex aneurysm requiring complex endovascular approach, it is apparent that the main cause of mortality is the frailty of those patients. Most of them, they are not candidates of open repair, thus endovascular treatment for them might be the only option. In this study, the outcome during follow up is encouraging, with the survival rate at 12 months period was 80%. Literature evidence has shown that survival during follow up can be 90% at 12 months to 73% at 48 months of follow up.[3]

A recent propensity score analysis in patients with pAAA undergoing F/BEVAR or open surgical repair suggested that although no difference was noted in terms of 30-day mortality, dialysis, or organ-specific postoperative complications, the incidence of acute kidney injury was higher after open repair.[21] In our study, no patient presented either early or late renal insufficiency, even the patients with the renal stent occlusion or the renal stent stenosis. Another study highlighted, that postoperative acute kidney injury might be more common after BEVAR and its prevention was based on staged procedures, early interventions for renal side branch complications, and regular surveillance.[22]

Seventeen percent of our patients were treated as a redo procedure after EVAR or open repair with good technical success rate and good clinical outcome. Previous studies have also showed that fenestrated and branched stent-grafting represents a feasible option for the repair of jAAA after prior endovascular or open aortic surgery. Despite increased technical difficulties it was associated with high technical success rate and was advantageous in terms of mortality and morbidity compared to redo open aortic surgery.[23] Reyes et al.[24] reported a study on the use of FEVAR, BEVAR, and ChEVAR on postsurgical pararenal aneurysms showing that those less invasive endovascular approaches allow effective treatment approaches. Additionally, the treatment of patients with Endoleak type I repair after previous EVAR appeared generally feasible, with good early to midterm outcomes. Different endovascular treatments options are available, and the choice should be based on endoleak characteristics, aortic anatomy, and the patient's surgical risk.[25]

Two points of consideration in patients with complex endovascular treatment, are the incidence of endoleak, mainly type Ia in ChEVAR and type III in FEVAR and BEVAR, along with the stent patency of the splanchnic vessels. Recently Donas et al.[19] have reported that there was no significant differences recorded in the endoleak Ia rate: 1.93% of the chimney patients vs. 2.06% for the FEVAR group (p=0.939). In another study, Lachat et al.[26] also highlighted nearly all of the aneurysms showed no increase in diameter over a >2-year mean follow-up with few endoleaks or branch occlusions. Generally, a low rate of chimney graft occlusions has been noted, which appeared to occur generally a few months after placement. Involvement of the renal artery had no severe clinical consequences[13]; along this line, in our study we have identified one early stent occlusion and two renal stent stenosis but without any clinical implication. Similar good results have been demonstrated in FEVAR patients even during long term period. The pooled TV patency rates during 12, 24, 36, 48 and 60 months were 95.4, 92, 91, 88 and 87%, respectively.[3]

Recently, devices with visceral inner branches might represent another feasible option to address selected target vessels in F/BEVAR. Stent grafts with inner branch(es) in combination with fenestrations seem to be a better configuration than stent grafts with inner branches alone. Estimated survival at 1 year was 80.0%, while the estimated inner branch target vessel stent patency at 1 year was 91.9%. % ± 8.9%.[27] Additionally, percutaneous upper extremities access has been used for F/BEVAR procedures showing low incidence rate stroke (2%). However, there is still some doubt on higher access-related complication rate compared with open access.[28]

The main limitation of this study was its retrospective nature. The number of patients is relatively small, however these cases concerned endovascular treatment of complex abdominal aortic aneurysms. Additionally, there was a heterogeneity in terms of treatment methods, although the indication was similar in all patients (pAAA or jAAA). Longer follow up and larger equal number for each approach might demonstrate clearer and more solid evidence for the endovascular approach of pAAA and jAAA.

CONCLUSION

Endovascular approach of pAAA and jAAA is an effective treatment option with high technical success rate. Early and midterm outcomes are good in terms of mortality, target vessel patency and re-intervention rate taking into consideration that many of those patients are unfit for open repair with severe co-morbidities.

No conflict of interest.

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