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Comparison of fenestrated stentgrafts and open repair for juxtarenal aortic aneurysms using a propensity score matching.

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Declarations of interest. None

Key words. Juxtarenal aortic aneurysm, pararenal aortic aneurysm, open surgery, fenestrated stent graft, propensity score matching

ABSTRACT

Objectives: The purpose of this study was to compare post-operative morbi-mortality and medium-term follow-up of fenestrated stentgrafting (FEVAR) and open repair (OR) for patients with juxtarenal aortic aneurysms (JRAAs).

Materials and Methods: All consecutive patients who underwent custom-made FEVAR or open repair for complex abdominal aortic aneurysm (AAA) between 2005 and 2017 in two tertiary centers were scrutinized. Patients with JRAA constituted the study group. Suprarenal and thoracoabdominal aortic aneurysms were excluded. The groups were made comparable through the use of a propensity score matching.

Results: 277 patients with JRAAs were included, 102 (36.8%) in the FEVAR group and 175 (63.2%) in the OR group respectively. After propensity score matching, 54 FEVAR patients (52.9%) and 103 OR patients (58.9%) were included for analysis. In-hospital mortality rates were 1.9% (n=1) in the FEVAR group vs. 6.9% (n=7) in the OR group (p=.483). Postoperative complications were less common in the FEVAR group (14.8% vs. 30.7%; p=.033). Mean follow-up was 42.1 months in the FEVAR group and 40 months in the OR group. Overall mortality rates at 12 and 36 months were 11.5% and 24.5% in the FEVAR group vs. 9.1 % (p=.691) and 11.6% (p=.067) in the OR group. Late reinterventions were more frequent in the FEVAR group (11.3% vs. 2.9%; p=.047). However, freedom from reintervention rates were not significantly different at 12 months (FEVAR: 86% vs. OR: 90%; p=.560) and 36 months (FEVAR: 86% vs. OR: 88.4%, p=.690). In the FEVAR group, persistent endoleak during follow-up was identified in 11.3% of cases.

Conclusion: In the present study, there was no statistical difference in terms of mortality, in-hospital, at 12 or 36 months, between FEVAR and OR groups for JRAA. FEVAR for JRAA was associated with a significant reduction of overall postoperative major complications compared with OR. There were significantly more late reinterventions in the FEVAR group.

INTRODUCTION

Fenestrated endovascular aortic repair (FEVAR) is currently the most commonly used alternative to open repair (OR) to treat complex abdominal aortic aneurysms (AAA). Recent systematic reviews derived from high volume centers series have provided excellent short-term and encouraging mid-term results(1),(2),(3). Long-term results remain poorly known. Expert centers have reported low rates of aneurysm-related mortality during follow-up, at the cost of substantial reintervention rates, mainly for endoleaks or branch instability(4). Data comparing FEVAR and OR are scarce. In the absence of randomized study, they are based on few meta-analyses(1),(2) and retrospective studies(5),(6),(7) leading to conflicting conclusions. These studies included heterogeneous patients with heterogeneous anatomies. There is a need for subgroup analyses reporting specific results for juxtarenal (JRAA) and suprarenal (SRAA) aortic aneurysms. Although these two entities are often mixed and reported as "pararenal AAA" or "complex AAA", SRAA have been associated with increased mortality and morbidity, especially when treated by OR(8),(9),(10). OR for JRAA has shown acceptable operative risk with durable results in terms of both graft integrity and preservation of renal function(11).

The purpose of this study was to compare postoperative morbi-mortality, the short-term, defined as in-hospital, and mid-term, defined as after hospital stay, results of FEVAR and OR for JRAAs in order to provide the best patient-specific therapy option.

METHODS

Definitions

In this study, juxtarenal and suprarenal aortic aneurysms were defined according criteria used for open surgery.

Juxtarenal AAAs were defined as requiring suprarenal, supramesenteric or supraceliac aortic cross clamping and infrarenal proximal aortic suture without separate renal revascularisation. Suprarenal AAA were defined as requiring suprarenal, supramesenteric or supraceliac aortic cross clamping and a suprarenal proximal aortic suture and/or a bevelled proximal aortic suture encompassing at least one renal artery and/or a separate renal or splanchnic revascularization.

Study population

This retrospective study was conducted in two tertiary centers (Rangueil Hospital, Toulouse, France and Henri Mondor Hospital, Créteil, France) between January 2005 and December 2017. Both centers frequently perform both FEVAR and OR of complex AAA. Indications for FEVAR or OR were discussed during multidisciplinary meetings and based on clinical condition, comorbidities, anatomic criteria and patients' preferences.

All consecutive patients who underwent FEVAR or open repair for complex AAA between 2005 and 2017 were scrutinized. Only patients with JRAA treated by custom-made FEVAR and OR were selected.

Selection of JRAA treated by FEVAR was based on preoperative computed tomography angiography (CTA) analysis. CTA of patients with complex AAA who underwent FEVAR were reviewed by two senior surgeons (XC, FC) having an expertise in both endovascular and open repairs. Patients deemed to fulfil the anatomic criteria of JRAA were included. Patients who were thought to fulfil the definition of SRAA were excluded. In case of disagreement, decision to include patients was made after discussion between the two senior surgeons.

For selection of JRAA treated by OR, operating reports were reviewed. Patients fulfilling the definition of JRAA were included.

Suprarenal or thoracoabdominal aneurysms, infrarenal AAA requiring renal artery reconstruction for occlusive lesions, inflammatory or infectious aneurysms, symptomatic or ruptured aneurysms were excluded.

The follow-up was the usual protocol of our institutions. In the FEVAR group, it consisted in CTA within one month, at six months and every year. In the OR group, it consisted in CTA or duplex ultrasound (DU) at one month, DU at six months and every year. A CTA was performed if abnormalities were detected on DU. The 1 and 6-month control is to confirm the technical success of the surgery, to look for an eventual technical complication and to verify the good healing of the patient. The 2019 ESVS clinical practice guidelines(12) recommend every 5-year surveillance to detect para-anastomotic aneurysm, recurrent aortic aneurysm and peripheral aneurysm. This recommendation is based on an old study from 1970 to 1976 published in 1985. We believe a more robust surveillance is needed to ensure the absence of complications and to provide regular follow-up for our patients with yearly DU, with yearly DU, which is non-invasive, non-irradiating and inexpensive. In Henri Mondor Hospital, preoperative, intraoperative and postoperative data were collected prospectively in a dedicated software (Safir, Opale, Paris). In Rangueil Hospital, data were collected retrospectively from patients' files. For survival assessment, telephone interviews were conducted.

This study was declared compliant with the reference methodology provided by the CNIL (Commission Nationale de l'Informatique et des Libertés), declaration number: 2209803 v 0. Individual consent for this retrospective analysis was not required by the ethics committee. Risks and benefits of FEVAR and OR were explained to all patients before they gave their consent to the procedure.

Operative techniques

Fenestrated Endovascular Aneurysm Repair

Patients were treated using various but only custom-made stent grafts (Zenith (Cook Medical, Bloomington, Ind), Ventana (Endologix, Inc, Irvine, CA, USA) or Anaconda (Vascutek, Inchinnan, UK), depending on availability, planning centers recommendations and surgeon's preference. In one centre, most of procedures were performed in a dedicated hybrid room using fusion techniques whereas in the other centre, most of patients were treated in an operating theatre equipped with a C-arm. Femoral access was obtained via a percutaneous approach or a surgical cutdown, depending on surgeon's preference. During the study period, cone beam CT scans were not performed at the end of the procedure. Technical success was defined according to the Society of Vascular Surgery (SVS) criteria(13) as successful insertion and deployment of the device in the absence of surgical conversion, death, type I or III endoleaks, obstruction of graft limbs or target vessels within the first 24 hours after surgery.

Open Repair

Surgical approach was a left lumbotomy or a median laparotomy. The level of aortic cross clamping depended on anatomic characteristics and surgeon's preferences. A suprarenal aortic cross clamping was performed whenever possible. In some patients with thrombus at the visceral level or heavily calcified visceral aortas, a supramesenteric or a supraceliac aortic cross clamping was preferred. All proximal anastomoses were performed below the renal arteries in an end-to-end fashion. Distal reconstructions were performed according to standards in vascular surgery. Technical success was achieved when the aortic reconstruction was patent and patients were alive within the first 24 hours.

Endpoints

The primary endpoint was overall survival. Secondary endpoints included moderate to severe complications occurring during hospital stay, length of hospital stay, reinterventions and target vessel patency. In the FEVAR group, endoleaks and aortic rupture were also reported.

Acute kidney injury (AKI) was defined as an increase in serum creatinine to ≥ 1.5 times the baseline level during the first 7 days, as defined by the clinical practice guidelines for acute kidney injury of the KDIGO (Kidney Disease Improving Global Outcomes) program(14). The KDIGO classification combines the RIFLE and AKIN classifications(15). Severe AKI is defined as stages 2 and 3 of the KDIGO classification. Since mild AKI is regressive and do not lead to complications(11), that was the case in our population. Only moderate to severe grade complications, as defined by the SVS criteria(13), were considered for analysis. Moderate complication indicates the need for significant intervention, prolongation of hospitalization more than 24 hours, and at most, minor permanent disability that does not preclude normal daily activity. A severe complication necessitates major surgical or medical intervention, may be associated with prolonged convalescence, is usually accompanied by prolonged or permanent disability, and may result in death. This was determined by analyzing all patients' complications, then classified them in minor and major (moderate to severe) complications (**Table 1**). These included severe AKI.

The limit for early or late reinterventions was the date of discharge from hospital.

Statistical analysis

Patient characteristics were expressed in n (%) and mean (standard deviation) or median (Q1-Q3) according to the variable (categorical or continuous).

A propensity score was built by a logistic regression model to account for the indication bias.

Explanatory variable was surgical strategy (FEVAR vs. OR). Independant variables were age, sex, smoking, diabetes, obesity, coronary artery disease, heart/renal/respiratory failure, American Society of Anesthesiologists (ASA) score, aortic surgery history, aneurysm diameter and hospital centre. Characteristics with a p value <0.20 in univariate analysis (Table 2) were included in the model to build the propensity score.

One patient in the FEVAR group was matched for 1 to 4 patients in the OR group based on the value of the propensity score.

Characteristics of patients in the unmatched and matched OR groups were compared to FEVAR. For an unmatched comparison, exact Pearson or Fischer tests and T-test or Wilcoxon test were used according to the nature and distribution of the variables. The comparison of the matched groups was done using a mixed logistic regression model that considered the paired nature of the data.

The analysis of the outcomes was conducted on paired groups. A descriptive analysis was carried out. Survival analysis was performed using Kaplan-Meier survival curves for death and reintervention outcomes. For the latter outcomes, a mixed proportional Hazard Cox Model was used to compare the FEVAR and OR groups. For other outcomes, a mixed logistic regression model was used.

Missing data on outcomes were not imputed. Missing data are displayed in each table.

Two-tailed tests were used. A 0.05 threshold was used for significance. The analysis was done using Stata SE v15.0 (College Station, TX, USA).

RESULTS

Demographics

Between January 1st 2005 and December 31th 2017, 548 patients were treated for complex AAA of which 277 were treated for asymptomatic JRAA, either by FEVAR (n=102) or OR (n=175) (**Figure 1**). Before propensity score matching, ten baseline characteristics were significantly different between the two groups (**Table 2**).

After propensity score matching, 157 patients were included in the analysis. There were no significant differences in baseline characteristics between the two groups (**Table 2**).

Intraoperative data

Technical success (FEVAR: 94.4%, OR: 100%; *p*=.992) and median procedure length (FEVAR: 180 min, OR: 185 min; *p*=.076) were no statistically different.

Intraoperative details of matched patients who underwent FEVAR are given in **Table 3**.

There was no open conversion. There were 139 fenestrations (average of 2.6 fenestrations per patients) and 35 unstented scallops.

Intraoperative data of matched patients who underwent OR are given in **Table 4**.

Early post-operative results

Group comparison for early postoperative outcomes are detailed in **Table 5**.

There were four 30-day mortality events in the OR group, one in the FEVAR group (*p*=.510). In-hospital mortality rates were similar in both groups (FEVAR: 1.9%; OR: 6.9%; *p*=.483). In the FEVAR group, one patient died from pneumonia. In the OR group, one patient died during the procedure from haemorrhagic shock, four patients died from multi-visceral failure, one patient died from colic ischemia. For another patient, cause of death remained unclear.

The overall complication rate was significantly lower in the FEVAR group (*p*=.033).

The AKI and severe AKI rates were similar in both groups (*p*=.232 and *p*=.09, respectively). Twelve patients (FEVAR group: n=2; OR group: n=10) required transient dialysis after the procedure during the hospital stay, with no statistical difference between groups. No patient required permanent dialysis.

Two FEVAR patients occluded a renal artery stent during the postoperative course. One patient had a control CT scan eleven days after the surgery, that made discover the renal stent occlusion, he was asymptomatic so no salvage was attempted. For the second one we have unfortunately no data about how it was discovered or why was there no salvage attempted. One of them had a persistent stage 1 AKI at discharge, the other one required temporary dialysis and was discharge with persistent stage 2 AKI.

Two early-reinterventions for two FEVAR patients and twelve early-reinterventions for eight OR patients (p=.345) were performed.

In the FEVAR group, both patients required an early-reintervention for an acute limb ischemia. There was no significant statistical difference in terms of in-hospital mortality (p=.883), overall complication (p=.203), early reintervention (p>.99) and endoleak at discharge (p>.99) between the different type of endografts used (Supplemental files: ***Table 7***).

In the OR group, reinterventions consisted in: haemostasis for haemorrhage (n=4), acute limb ischemia (n=4) and bowel resection (n=4). In one of the patients reoperated for acute limb ischemia, a right ilio-renal bypass was performed during the same procedure, we do not have any information about why this bypass was performed.

Midterm results

Mid-term results are detailed in **Table 6**.

There was no statistical difference about overall survival rates in the OR group at 12 months (FEVAR: 88.5%, 95% confidence interval (CI): 76.2-94.7; OR: 90.9%; 95%CI: 83.2-95.2; p=.691) and 36 months (FEVAR: 75.5%, 95%CI: 60.7-85.3; OR: 88.4%, 95%CI: 79.9-93.4; p=.067) (**Figure 2**).

During follow-up, eighteen deaths occurred in the FEVAR group from cancer (n=8), stent graft infection (n=2), cardiac disease (n=1), respiratory failure (n=1), stroke (n=1) and unknown cause (n=5). Twenty deaths occurred in the OR group from unknown cause (n=9), cancer (n=4), stroke (n=1), end-stage Parkinson's disease (n=1), aortic arch rupture (n=1), secondary to heart surgery (n=1), endocarditis (n=1) and critical ischemia of the lower limbs (n=1).

No statistical difference in terms of renal function decline could be identified (**Table 6**).

Freedom from reintervention rates were not significantly different at 12 months (FEVAR: 86%, 95% CI:72.8-93.1; OR: 90%, 95% CI: 82.1-94.5; *p*=.560) and 36 months (FEVAR: 86%, 95% CI: 72.8-93.1; OR: 88.4%, 95% CI: 79.7-93.5; *p*=.690) (**Figure 3**).

Apart from early reinterventions mentioned above, ten late reinterventions were performed in six patients of the FEVAR group and three in three patients of the OR group.

In the FEVAR group, late reinterventions consisted in endovascular treatment (n=2) or open ligation of the inferior mesenteric artery (n=1) for type II endoleaks, drainage of access site complications (n=4), bypasses for graft limb thrombosis (n=2) and peripheral stenting for acute limb ischemia (n=1). There was no significant statistical difference in terms of late reintervention between the different type of endografts used (*p*=.645) (Supplemental files: ***Table 8***).

In the OR group, two late endovascular reinterventions were required, one to treat a growing iliac aneurysm due to a dissection on the recipient artery from the suture line and the other to treat an ectatic primary iliac artery responsible of distal embolisms. One late open reintervention was required to treat a false distal aneurysm.

In the matched FEVAR group, no aortic rupture occurred during follow-up. However, two aortic ruptures were recorded in the unmatched FEVAR group. Six patients presented with persistent endoleak (n= 2 type Ia, n= 4 type II). Two of them required reintervention, as mentioned above. Two patients with type Ia endoleaks died during follow-up, one from a stent graft infection, the other one from unknown cause after he was lost from follow-up.

In the OR group, no renal artery occlusion was reported but most of DU did not focus on renal artery patency.

DISCUSSION

In this retrospective comparative cohort study with propensity score matching, there was no statistical difference in terms of mortality, between FEVAR and OR groups for JRAA,

although a trend towards higher mortality rates was observed at 36 months in the FEVAR group. FEVAR for JRAA was associated with a significant reduction of all major postoperative complications compared with OR, but no significant difference was found when considering individual complications. Only the length of stay was statistically different, which was longer in the OR group (p=.012). There was no statistical difference between groups in terms of early-reintervention rates, but significantly more late-reinterventions were observed in the FEVAR group (p=.047). Eleven-point three percentage of the FEVAR patients had a persistent endoleak during the follow-up.

To the best of our knowledge, it is the first study to compare FEVAR and OR specifically for juxtarenal AAA, that is suprarenal and type IV TAAAs excluded. Previous comparative studies have reported on so called "complex" AAA or "pararenal" AAA, which typically refers to a mix population of JRAA, SRAA, type IV thoracoabdominal aortic aneurysms and sometimes infrarenal AAA with occlusive lesions of renal arteries. Without subgroup analysis, results of these studies can hardly be extrapolated to JRAA. Recent data showed that OR of JRAA provides excellent short-term and long-term results, with low rates of graft-related complications during follow-up(11),(16). In contrast, there is a reasonable amount of data in the literature suggesting that OR of SRAA is associated with increased risks of mortality and morbidity compared to OR of JRAA(8),(9),(10). When treated by FEVAR, differences between JRAA and SRAA in terms of postoperative outcomes are not so clear. There is a need for comparative studies with a standardized definition of JRAA and SRAA.

So far, no randomized study comparing FEVAR and OR for juxta and suprarenal AAA has been published. It is unlikely that such a trial will be conducted in the coming years since practice in each centre is based on surgeon skills or preferences, and intensive care unit expertise. Most of consistent comparative data in the literature comes from meta-analysis(1),(2),(17),(18), registries(5),(19),(20),(21),(22) and retrospective studies with

propensity score matching(6),(7). Again, these studies included heterogeneous patients with heterogenous anatomies. They provided conflicting results in terms of early mortality. Some studies reported similar postoperative mortality rates(1),(17),(5),(7) which is consistent with our results. Others reports suggested that FEVAR is associated with reduced postoperative mortality rates(2),(18),(19),(20),(22),(6) especially in octogenarians(21). However, almost all comparative studies reported a reduced complication rate in the FEVAR group, which is in line with our finding.

Comparative data on mid-term results remain scarce in the literature. In the present study, late-reintervention rates were significantly higher in the FEVAR group. Indeed, with endovascular treatment of AAA, the disease is not cured but only contained. The tissue evolves and the aorta may expend, leading to endoleaks and therefore reinterventions. Stent patency as well as acute limb ischemia due to EVAR/FEVAR embolization may also be a cause of reinterventions. These results are consistent to those of the most recent meta-analysis comparing FEVAR and OR for juxta and suprarenal AAA. At a mean follow-up of 31 months, estimated survival was similar for FEVAR and OR but the rate of late reintervention following FEVAR was higher(1).

There is also a lack of comparative data on renal function decline during follow-up. To our knowledge, only one retrospective study with a propensity-matched comparison found no difference in terms of renal function decline(7). The contribution of our study to provide more data on that matter is poor. We did not find any significant difference in terms of renal function decline but creatine levels at last follow-up were only available in half of the patients.

Our study has the advantage of providing specific data on juxtarenal AAA but several limitations are worth mentioning. It is a non-randomised study and matching ended up with limited numbers for group comparison. Propensity score matching mainly selected the most

fragile patients in the OR group and the less fragile patients in the FEVAR group. Thus, results are only applicable to patients at intermediate risk. A significant proportion of patients were included before 2010, period during which the FEVAR technique in both centers had not reached a state of maturity. We performed a sensitivity analysis with the inclusion of the date of surgery in the propensity score. It reduces our numbers and the results were similar except for length of stay which was no longer statistically different and late reinterventions which could no longer be compared due to the lack of events in the OR group. Therefore, we choose not to consider year of surgery in our propensity score. Devices were inserted via femoral cutdowns in half of the patients whereas most of procedures are currently performed percutaneously. Ventana and Anaconda devices were used during the study period. Ventana are not available anymore. We choose to include them anyway in our study. The Cook device was by far the most commonly used, given limited numbers of Anaconda and Ventana devices, one can hardly expect that statistical comparison of mortality and complication rates according to the type of device can lead to a valid and informative conclusion. Furthermore, we believe such a comparison would be out of the scope of this specific study. We did not observe any significant difference in the primary or secondary endpoints between the different endografts used in our population (Supplemental files: *Table 7* and *Table 8*). Most of patients were implanted two fenestrated-vessel devices. Even for juxtarenal AAA, due to improved technical skills and better patient selection, there is a current trend in both centers to promote devices with three or four fenestrations. Indeed, in order to reduce the risk of type Ia endoleak that may occur during follow-up, there is a current trend to treat JRAA using devices with three or four fenestrations instead of two. Whether this strategy is truly beneficial for patients remains controversial. Some studies have shown increased risks when devices with three or four fenestrations were used(23),(24),(4). Other studies suggested after the learning curve is reached, procedure complexity does not influence outcomes significantly(25),(26). Thus, the

rationale of treating JRAA with three or four fenestrated stent grafts rather than with a durable open repair is questionable. However, one could argue that with enhancement of anaesthetic and surgical techniques, OR for juxtarenal AAA also improved over the last decade. For example, we currently tend to cross-clamp the aorta in an infrarenal position whenever possible the time to ligate lumbar arteries. The clamp is subsequently moved to a suprarenal position to perform the proximal anastomosis. This allows to reduce the clamping time of renal arteries to 10-20 minutes. Finally, because of the retrospective design, there is lack of data on cause of deaths in both groups and long-term target artery patency in the OR group.

CONCLUSION

In the present study, there was no statistical difference in terms of mortality, between FEVAR and OR groups for JRAA. FEVAR for JRAA was associated with a significant reduction of postoperative overall major complications compared with OR. During follow-up, even if there was a non-significant trend towards higher mortality rates in the FEVAR group, the survival rates after FEVAR and OR at 12 and 36 months were statistically non-significant. There were significantly more late reinterventions in the FEVAR group compared with the OR group. And 11.3% of the FEVAR patients had a persistent endoleak during the follow-up. This is why open surgery still has its place in the management of JRAA in fit patients.

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TABLES AND FIGURES LEGENDS

Table 1. Classification of complications according to SVS criteria.

Table 2. Demographic characteristics and comorbidities of 277 consecutive patients who underwent FEVAR and OR for JRAAs, before and after propensity score matching.

Table 3. Intraoperative data in the propensity score-matched cohort of patients who underwent FEVAR for JRAAs.

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Figure 1. Flow diagram between January 1st 2005 and December 31th 2017.

Figure 2. Survival after FEVAR and OR, in matched groups.

Figure 3. Freedom from reintervention after FEVAR and OR, in matched groups.

SUPPLEMENTAL FILES

Table 7. *Early post-operative results in FEVAR patients used in propensity score-matched cohort, depending on the type of endograft.*

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