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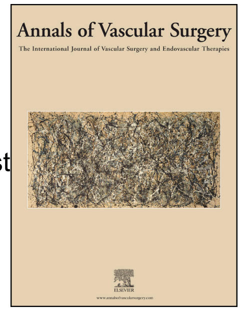

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ONE-YEAR OUTCOMES AFTER RUPTURED ABDOMINAL AORTIC ANEURYSMS REPAIR: IS EVAR THE BEST CHOICE? A SINGLE-CENTER EXPERIENCE

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CONFLICT OF INTEREST STATEMENT

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Abstract

Objective: Treatment of ruptured abdominal aortic aneurysms (rAAAs) is still burdened by high morbidity and mortality. Although endovascular aortic repair (EVAR) offers encouraging results in elective setting, its role as first line strategy to treat rAAA is still debated. Our aim was to compare early and late outcomes in patients undergoing open surgical repair (OSR) compared with those submitted to vs EVAR for rAAAs.

Methods: A retrospective review of data extracted from medical records identified 105 consecutive patients with rAAA who were submitted to open or endovascular repairs from 2008 to 2016.
Primary endpoint was to assess the rAAA-related mortality in the immediate postoperative, within 1 month and 1 year after ORS and EVAR Secondary endpoints included: length of stay, AAA-related postoperative complications such as acute limb ischemia, myocardial infarction, renal and respiratory failure and rAAA-related re-interventions. Statistical analysis was performed using the Fisher exact test, χ^2 test and logistic regression calculations. Early and midterm survival rates were assessed with Cox model.
Results: Of the 105 patients with rAAA 70.48% underwent OSR including 41.89% which was hemodynamically (Hd) unstable and the remaining 29.52% was submitted to rEVAR. (all Hd stable). Compared EVAR group, the OSR group had a higher RAAA-related mortality rate for both Hd stable and Hd unstable patients: 18.92% vs 6.45% at 24 hours; (P = .185) 39.19% vs 19.35% at 30 days (P = .082); 44.59% vs 38.71% at 1 year (P = .734) If only Hd stable patients were considered, mortality following OSR and EVAR was: 6.98% vs 6.45% at 24 hours (P = .703); 27.91% vs 19.35% at 30 days (P = .567); 32.56% vs 38.71% at 1 year (P = .764). Mean length of stay for patients was 15 days after OSR and 10 days after rEVAR (P = .002). At 1-year follow-up, the overall rAAA-related complications incidence was higher in the rEVAR group than in the OSR group (47.85% vs 18.33%; P = .008); re-interventions were 18.33% in OSR group vs 21.82% in EVAR group (P = .917). Cox model showed that instability and coronary artery disease were predictors of overall mortality of rAAAs.

Conclusions: EVAR does not independently reduce 1-year mortality in comparison with OSR in Hd-stable patients. Urgent EVAR for rAAAs in unstable patients can be limited by logistical problems. It follows that patients selected for OSR have a more complex aortic anatomy and worse Hd status than those sumitted to rEVAR. rEVAR burdened by a higher incidence of procedure-related complications than OSR.
Reconfiguration of acute aortic services and establishment of standardized institutional protocols might be advisable for improvements in the management of ruptured AAA.

A carefully evaluation of whether the benefits of an endovascular strategy translate into longer term benefit is needed before definitive conclusions can be drawn about the advantages of EVAR as first-line strategy for ruptured aneurysms.

Introduction

The treatment of ruptured abdominal aortic aneurysm (rAAA) is still challenge with a reported operative mortality rate between 42% and 48%[1–4]. Despite the improvements in critical care and anesthesia management and the development of modern surgical techniques and materials to treat the AAAs, the operative mortality rate has just slightly decreased in the last decades[2]. Endovascular repair (EVAR) was introduced in 1991 by Parodi[5] as an alternative to open surgical repair (OSR) to treat electively patients with high operative risk. Three years later, April the 21st of 1994, Marin et al.[6] described the first endovascular repair of rAAA (rEVAR). Since that, endovascular approach for rAAA has been increasing worldwide (in USA from 6.6% in 2001 to 42.1% in 2010)[7–9]. Although EVAR has an established role in the elective treatment of aneurysms, the evidence supporting its use as the primary treatment for patients with rAAAs remains controversial[8]. In many centers, rEVAR has recorded very encouraging results in diminishing peri-operative mortality rates[10–17]. According to some recent studies, rEVAR is associated with a diminished 30-days mortality but its superiority in long-term results in term of mortality and morbidity is still to be defined[8,18–20]. The aim of this study was to assess outcomes of patients undergoing open repair (OSR) vs EVAR for all rAAAs. Primary endpoints were to compare OSR and rEVAR in terms of perioperative, 30-days and 1-year mortality and morbidity rates. Secondary endpoints included: length of hospital stay, incidence of perioperative complications such as acute limb ischemia, myocardial infarction, renal and respiratory failure and rAAA-related re-interventions rate, following OSR and EVAR. We also focused on investigating which variables might have influenced the early and 1-year mortality after ORS and after EVAR for rAAA.

Methods

A retrospective review of medical records identified 105 consecutive patients with rAAA who were submitted to open or endovascular repairs from 2008 to 2016. Thoracic and thoraco-abdominal aortic aneurysms as well as the isolated common iliac artery aneurysms were excluded. Rupture was defined as the clear presence of blood outside the aortic wall on preprocedural contrast computed tomographic (CT) scans or intraoperatively[21]. Clinical features of patients undergoing OSR and rEVAR were compared including: demographic variables (age and sex); comorbidities (hypertension, dyslipidemia, coronary artery disease, chronic obstructive pulmonary disease, diabetes mellitus, chronic renal insufficiency as glomerular filtration rate < 60 mL/min/1.73 m^2 or creatinine> 150 µmol/L and cerebro-vascular insufficiency).

AAA characteristics (mean diameter and morphology) and hemodynamic status; patients were considered Hd-unstable if their systolic blood pressure was <80 mmHg for >10 minutes. All the Hd stable patients and 50% of the Hd unstable patients underwent preoperative CT scan; in the remaining cases, clinical evidence, hemoperitoneum by ECO-FAST and explorative laparotomy has been settled for rAAA diagnosis. Follow-up controls were at 30 days and 1 year by ultrasounds and by CT scan, whenever needed.

Statistical analysis

Univariable analysis was performed using the Pearson $\chi 2$ test of the Fisher exact test for categoric variables and the t-test or F test for continuous variables. Forward stepwise multiple logistic regression analyses along with Cox model were performed to assess factors associated with the primary and all of the secondary study outcomes. A P value of < .05 was considered significant. Statistical analysis was performed using SPSS 17.0.

Results

From January 2008 to December 2016, 105 patients (mean age 73 years, SD 10.06) were enrolled, 91 males (86.67%) and 14 females (13.33%). The RAAA: supra-renal in four cases (3.81%), juxta-renal in 14 (13.33%) and infra-renal in 87 patients (82.86%). Seventy-four patients (70.4%; 62 males) underwent OSR. Operative characteristics and comorbidities of patients undergoing OSR and rEVAR are listed in **Table I**. Comorbidities did not differ significantly between the two groups, whereas instability was 41.89% for OSR vs 0% for rEVAR (P = < .001); rAAA diameter was larger for OSR group (P = < .001). Thirty-one Hd stable patients underwent rEVAR (29,6%; 23 males). In the open repair group, 31 cases were Hd-unstable (41.89%) and 43 were Hd-stable (58.11%). In rEVAR group the endograft release was performed under controlled hypotension (100 mmHg) when the maximum systolic pressure was superior to 130 mmHg. Intraoperative aortic occlusion balloon was never required because the treated patients were all hemodynamically stable.Overall, the time from rAAA diagnosis to treatment was different in the Hd unstable cases compared to stable ones; for unstable patients directly transferred to the operating room for OSR without a preoperative CT scan, the average time from diagnosis to treatment was 35 minutes. In stable patients submitted either to rEVAR or OSR, the average time from diagnosis to treatment was 70 minutes.

Table II reports the details of univariable analysis of postoperative outcomes. Mean follow-up was 41 months (SD 31.78). By comparing all patients submitted to ORS, both stable and unstable with those, all Hd-stable, treated with EVAR, the mortality was 18.92% vs 6.45% (P = .185) at 24 hours 39.19% vs 19.35% (P = .082) at 30 days and 44.59% vs 38.71% (P = .7341) at 1 year. Three Hd-unstable patients (9.6%) submitted to OS died during the first 30 days due to abdominal compartment syndrome (ACS). When only Hd-stable rAAA cohort were considered (Table II.) there were no significant differences in mortality rate between the OSR and rEVAR groups at 24 hours (6.98% vs 6.45%; P = .703), at 30 days 27.91% vs 19.35% (P = .567) and at 1 year follow-up. (32.56% vs 38.71% (P = .764). One-year mortality in both stable and unstable patients undergoing OSR or rEVAR was: 44.59% and 38.71% respectively (P = .734), Three OSR procedure (4.0%) were complicated by an acute limb ischemia that occurred within the first 24 hours and was successfully treated with a lower extremity thrombectomy. Limb salvage was achieved in two cases, whereas a minor limb amputation was performed in one case. Two rEVAR procedures were complicated by acute intraoperative limb ischemia (6.4%), which required a femoro-femoral crossover bypass following an unsuccessful thrombectomy attempt.

Early postoperative complications (within 30 days), including acute renal failure (ARF) requiring hemodialysis, ventilator-dependent respiratory failure (VDRF), myocardial infarction, acute limb ischemia and mean lengths of hospital stay after OSR and EVAR are reported in **Table III.** At 1-year follow-up, the overall rAAA-related complications incidence was higher in the rEVAR group than in the OSR group (47.85% vs 18.33%; P = .008). ACS was never observed after EVAR due to the lower extent of aortic rupture. The rEVAR complications were: 1 branch stenosis and 11 endoleaks (3 type IA, 6 type II, 1 type III and 1 type IV). All type I and type III endoleaks (ELs) and the limb stenosis required a reintervention. An adjunctive proximal cuff in 3 cases and a distal stent-graft in 2 cases (1 for limb stenosis and 1 covered stent for type III endoleak). In the open group, the 1-year complications occurred in 3 cases (4.0%): were: 2 laparoceles which required an abdominal wall reconstruction and 1 stenosis of the distal anastomosis at the level of a common iliac artery that was treated by iliac stenting. The rAAA-related reintervention rates at 1-year after the first procedure were: 18.33% in OSR group vs 21.82% in rEVAR group (P = .917).

Discussion

AAA management is hardworking, and its results are heavily dependent on a timely diagnosis and an appropriate therapeutic choice. Although EVAR is increasingly used in the treatment of intact AAA due to the proved elower early mortality than OSR, the actual advantages of this approach for rAAA compared with OSR are still questioned[22,23].

The superior outcomes of EVAR for rAAA showed by previous trials and retrospective studies like that of Sweeting and coll.[24] may be an effect of case selection thus limiting the comparability the comparison between EVAR and OSR.

In current series, patients submitted to OSR or EVAR had similar comorbidities. Furthermore, rEVAR was performed, after a CT scan investigation only stable and anatomically suitable rAAAs. Although this approach represents a limitation of our study, yet, it emphasizes the feasibility problem of the endovascular approach for this particular setting in the contemporary practice of our high volume vascular center[25]. The “EVAR- first approach for all rAAAs” can be limited by logistical problems (e.g., an adequate imaging, performed often in other centers to evaluate the aorto-iliac morphology; a hybrid operating room equipped in order to perform ORS as well as rEVAR and, a wide selection of grafts readily available). Proof of this, from an international perspective, only 25% of all rAAAs underwent EVAR in Sweden[26] and in USA[1], with significant rate variations of EVAR between these centers. Some of these organizational limitations could be overlooked eg r-EVAR in HD-unstable patients could be performed without a preoperative CT imaging using intraoperative imaging[27]. Anyhow, an endovascular planning based on angiography alone may not be as adequate as that based on CT.

It is also reasonable to believe that the hemodynamic instability may have a negative impact on outcomes of rEVAR[28]. Thus, reconfiguration of acute aortic services and establishment of standardized institutional protocols might be advisable for feasibility of the EVAR approach for ruptured AAA[29].

As far as the early results, we found rEVAR superiority was not statistically significant as regard in-hospital and 30-days mortality rates, compared with overall OSR cohort (stable and unstable patients). Likewise, even analyzing the OSR 30-days mortality adjusted for patients' hemodynamic stable condition, rEVAR does not offer survival benefits over open surgery. Our results harmonize with the IMPROVE trial findings: this large randomized trial showed that the 30-days mortality was similar in the endovascular strategy and open repair group (35.4 vs 37.4%, P = 0.62)[30].

From our data, 30-day mortality after OSR was 39,19% for unstable rAAA and 27,91 for stable RAAA stable; 30-day mortality was 19,35% for stable rAAA treated with EVAR group. The higher mortality after OSR may be related to the more complex and technical challenging aorto-iliac anatomy of patients selected of open surgery. Our findings are also comparable to some recent study that show no difference in early mortality rates between EVAR and OSR after ruptured abdominal aortic repair[9,31,32]. Reimerink et al.[23] describe no significant difference in 30-day mortality in the EVAR and open repair group (21% vs 25%). Our study has some inherent weaknesses. It is a retrospective non-randomized analysis of collected data from a single center. EVAR was performed just in case of HD stability status and contemporary suitable anatomy, whereas OSR was carried out to treat more complex anatomy. It follows that the outcomes of OSR with favorable EVAR anatomy have not been proven. However, in most studies and randomized trials, mid-term and long-term morbidity and mortality are not available, thug they are important indicators of treatment success.

Thus, the main strength of this study was the evaluation of whether the results of EVAR and OSR for ruptured AAA translate into longer term. We found that EVAR did not independently reduce 1-year mortality. The main explanation has to be searched to those co-morbidities and pre-operative hemodynamic status that negative affect patient's survival more than the operative strategy the type of emergency treatment. As proof of this, the multivariate analysis of our overall entire study population showed that mortality is subject to the following factors: hemodynamic instability, CAD and AAA diameter for all-time follow-up (24 hours, 30 days and 1 year) and advanced age for 30-days and 1-year follow up, independently by the OSR or EVAR approach. Secondary endpoints analysis confirmed that an endovascular strategy was associated with shorter critical care stay and overall in-hospital stay as showed the IMPROVE Trial Investigators[31].

This can offset the higher cost of the endovascular device and consumables showed by van Beek et al.[33] and IMPROVE TRIAL[30] which calculated a similar average costs within 30 days in the two groups.

Although ACS may occur after EVAR more frequently than after OSR, this complication didn't occur in our cohort because all patients underwent endovascular repair had stable rAAA surrounded by small hematoma. The ORS strategy was associated with a higher risk of VDRF and myocardial infarction while ARF and acute limbs ischemia were more frequent in EVAR group. However, the difference in incidence of these complications between the two groups was not statistically significant as reported in previous studies[13]. From our experience, endovascular strategy for treatment of ruptured abdominal aortic aneurysm does not offer a survival benefit over 1 year (38.71% vs 44.59% in OSR group; P = .734). Similar results can be figured out in one-year outcomes from IMPROVE trial[31].

Furthermore, at 1-year follow-up, complications were more frequent in rEVAR cohort than in the OSR group (P = .002). These data are consistent with the results reported by van Beek et al. [33]. The higher incidence of complications after rEVAR is due to onset of Type 2 ELs. No type 2 ELs of our series required secondary intervention and this explains that the reintervention rate was similar in both groups. Although most of these endoleaks are innocuous and transient as occurred in this series, sac enlargement may accompany persistent type II ELs and prompts reinterventions[34]. It follows that the mere presence of a type II EL after rEVAR requires a more rigorous imaging surveillance with additional health care costs.

Our data suggest that EVAR for rAAA is beneficial in appropriate candidates. Therefore, the suitability of ruptured aneurysm for EVAR should be carefully defined by the aortic morphology in order to minimize the risks of procedure-related complications. The compliance with post-EVAR surveillance is an important factor in longer term outcomes of rAAA endovascular strategy. EVAR outcomes have been also shown to be dependent on the institutional volume and experience with this strategy[35,36].

Conclusions

This single-center experience suggests genuine concerns and impediments to the adoption of an “EVAR-first” policy for all rAAAs.

Our data show that EVAR to treat Hd rAAA does not independently reduce 1-year mortality even if compared with the entire study population submitted to OSR (both stable and unstable patients). Though rEVAR reduces the length of hospital stay of the patients, this is burdened by a higher incidence of complications than OSR. A carefully evaluation of whether the benefits of an endovascular strategy translate into longer term benefit is needed before definitive conclusions that can be drawn about the advantages of the endovascular approach for ruptured aneurysms. Further studies are necessary to figure out key selection factors in order to improve better outcomes of rAAA repair, regardless the primary treatment strategy. Regardless of the treatment modality, a reconfiguration of acute aortic services and establishment of standardized institutional protocols are needed to improve our abilities in the rAAA management.

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Table I. Pre-operative characteristics and comorbidities of patients undergoing rEVAR and OSR for ruptured abdominal aortic aneurysms (rAAAs).

Features[*]	**OSR (n=74)**	**rEVAR (n=31)**	**P *value***
Age, years (SD)	73 (10.01)	75 (10.22)	.35
Male	83.78	93.55	.304
Female	16.22	6.45	.304
Hemodynamic stability	58.11	100	<.001
Hemodynamic instability[†]	41.89	0	<.001
Hypertension	86.49	96.77	.223
Hyperlipidemia	75.67	70.97	.796
Coronary artery disease	44.59	38.71	.734
Chronic obstructive Pulmonary disease	40.54	29.03	.372
Diabetes mellitus	25.67	35.48	.436
Chronic renal insufficiency[‡]	28.38	25.81	.977
Cerebro-vascular Insufficiency	18.92	22.58	.873
rAAA diameter, mm (SD)	83.04 (15.32)	66.06 (12.01)	<.001
Suprarenal rAAA	2.7	6.45	.721
Juxtarenal rAAA	14.87	9.68	.69
Infrarenal rAAA	82.43	83.87	.916

[*]Continuous data are listed as mean (SD) and categoric data as percentage.

[†]Defined as systolic blood pressure <80 mm Hg for >10 minutes.

[‡]Defined as glomerular filtration rate < 60 mL/min/1.73 m^2 or creatinine> 150 µmol/L

Table II. Univariable Analysis of the postoperative events in both stable and unstable patients with rAAA (n = 105) and in Stable rAAA population. Mortality and 1-year outcomes (complications and re-interventions).

Outcomes[*]	***rAAA (n = 105)***			***Stable rAAA (n = 74)***		
	OS (*n* = 74)	**EVAR (*n* = 31)**	**P *value*[†]**	**OS (*n* = 43)**	**EVAR (*n* = 31)**	**P *value*[†]**
24-hours mortality,%	18.92	6.45	.185	6.98	6.45	.703
30-days mortality,%	39.19	19.35	.082	27.91	19.35	.567
1-year mortality,%	44.59	38.71	.734	32.56	38.71	.764
AAA-related complications[‡],%	18.33	47.85	.008	11.46	47.85	.002
AAA-related re-interventions[‡],%	18.33	21.82	.917	11.46	21.82	.407
Length of stay, days (SD)	15.23 ± 7.72	10.44 ± 5.60	.002	14.45 ± 7.81	10.44 ± 5.60	.017

rAAA, ruptured abdominal aortic aneurysm; *OS*, open surgery; *EVAR*, endovascular aortic repair.

[*]Categoric data are shown as percentage and continuous data as mean ± standard deviation (SD).

[†]P *value* reflects univariate analysis: Pearson χ^2 test and analysis of variance F test comparing mortality rates and 1-year complications/re-intervention (within 30-days outcomes) between OSR and rEVAR. P < .05 is significant.

[‡]It referred to complications and re-interventions onset within the first year follow-up.

Table III. Univariable Analysis of perioperative outcomes for patients undergoing open surgical repair (OSR) and endovascular repair (rEVAR) for ruptured abdominal aortic aneurysms (rAAAs)

Perioperative outcomes[*]	OSR (n = 74)	rEVAR (n = 31)	*P* value
ARF requiring dialysis	3.33	10.35	.39
VDRF	10.00	3.45	.51
Myocardial infarction	6.67	3.45	.89
Acute limb ischemia	5.00	3.45	.83

ARF, acute renal failure; VDRF, ventilator-dependent respiratory failure.

[*]Categoric data are shown as percentage.

Table IV. Cox multiple regression with Stepwise technique, conducted on the entire study population (*n*=105) at three times of follow up. Patients undergoing OSR or rEVAR for rAAAs between 2006 and 2014. *P value* was significant for mortality predictors.

Features	24 hours	30 days	1 year
Sex	NS	NS	NS
Age	NS	P = 0.032	P = 0.001
Hemodynamic Instability*	P = 0.001	P = 0.042	P = 0.027
Hypertension	NS	NS	NS
Hyperlipidemia	NS	NS	NS
Coronary artery disease	P = 0.004	P < 0.001	P < 0.001
Chronic obstructive Pulmonary disease	NS	NS	NS
Diabetes mellitus	P = 0.077	P = 0.014	P = 0.001
Chronic renal insufficiency†	NS	NS	NS
Cerebro-vascular Insufficiency	NS	NS	NS
rAAA diameter	P = 0.067	P = 0.001	P = 0.001
AAA morphology	NS	NS	NS
rEVAR – OSR‡	NS	NS	NS

*Defined as systolic blood pressure <80 mm Hg for >10 minutes

†Defined as glomerular filtration rate < 60 mL/min/1.73 m^2 or creatinine> 150 μmol/L

‡Defined as the kind of emergency procedures for treatment of ruptured abdominal aortic aneurysm