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Article

Real world short and mid-term outcomes of EVAR and open repair of ruptured AAA in the post-IMPROVE era: A retrospective cohort (Real world outcomes of EVAR and OSR of rAAA)

Mohamed Elahwal, MS FRCS [1,2] , Raafat Naga MD [1], Mamdouh Kotb MD [1], Wael Shaalan MD[1]

[1] Vascular Surgery Department, Alexandria Faculty of Medicine, Alexandria, Egypt; [2] Vascular Surgery Department, University Hospitals Sussex NHS Foundation Trust, Brighton, UK

Correspondence: Mohamed Elahwal. Vascular Surgery Department, Alexandria Faculty of medicine, Al-khartoum sq, Alexandria, Egypt; Vascular Surgery Department, Royal Sussex County Hospital Eastern Rd, Brighton, United Kingdom. BN2 5BE

Abstract

Objectives: We aimed to study the real-world outcomes of EVAR and open repair (OSR) of ruptured AAA to further clarify the optimal management strategy for this difficult cohort.
Methods: We studied short term (30 day) and mid-term (2 year) outcomes of 120 patients with ruptured AAA who underwent EVAR(n=60) or OSR(n=60) between June 2015 – November 2021 in terms of technical aspects, 30-day all cause mortality rates, mid-term survival rates (up to 24 months) and post-operative complication rates (peri-operative and mid-term). Data was analyzed using IBM SPSS version 20.0. (Armonk, NY: IBM Corp).
Results: Successful aortic repair was achieved in 90% of OSR cases, the majority of these being tube graft repairs (81.5%) vs 98% of EVAR cases. The 30-day all-cause mortality was significantly higher in the OSR group (38.3%) compared to the EVAR group (13.3%). At 2 year followup, 2 and 3 further deaths were reported in OSR and EVAR groups, respectively. No significant differences were found in terms of cardiovascular, respiratory or renal complications between both groups. However, significantly higher renal complications were noted in cases requiring suprarenal clamping in OSR and significantly higher mortality was noted in cases requiring aortic occlusion balloons in EVAR. Length of ICU stay was significantly shorter with EVAR, but total hospital stay was not.
Conclusions: Our study shows that EVAR for ruptured AAA, when anatomically suitable, offers a significant survival benefit in the short and medium-term, especially if done under local anesthetic. Furthermore, in patients who are not anatomically suitable for EVAR and who receive an open surgical repair, all efforts should be made to use an infrarenal clamp site.

Despite the advances in peri-operative and ICU care, mortality rates for open repair of ruptured AAA have remained consistently high.

Keywords: Ruptured, AAA, EVAR, OSR

Introduction

Rupture of an abdominal aortic aneurysm (AAA) is one of the most serious vascular emergencies, and essentially a fatal condition if left untreated. The reported incidence of this condition has been variable over the years, although considerably low, reported at around 10-15 per 100,000.[1, 2] The overall perioperative mortality ranges from 40 – 60%[3]. Many patients with ruptured aneurysms die in the community. Half, or more, of those patients who make it to the emergency department may not reach the operating theatre alive. [4]

These patients are usually old aged, with multiple co-morbidities and present with cardiovascular collapse and systemic instability. The urgency and impact of their condition cannot be overstated, and this makes their management very challenging.

Historically, among patients who reach the operating theatre (for open surgical repair under general anaesthesia), only about half will leave hospital alive. These stark figures have changed little over the last 50 years.[5] [6]

Decision of Open Surgical Repair vs EVAR

Multiple studies have argued that there remains no significant benefit for EVAR over open repair in terms of postoperative mortality and morbidity.[7-10]

Other studies, including recent systematic reviews and meta-analyses have advocated the superiority of EVAR, when anatomically feasible, over open surgical repair in the treatment of ruptured AAA. [11, 12]

The IMPROVE trial was the most significant study to encourage the use of local anaesthetic for endovascular repair of ruptured AAA (rEVAR), reporting lower mortality rates with this technique, and this has since been adopted by many centers as a routine practice.[13]

Furthermore, the most recent draft NICE guidelines in the UK have recommended endovascular repair as the first line strategy for repair of ruptured aortic aneurysms if anatomically suitable. This same stance was adopted by the SVS and ESVS.[14, 15]

However, some of the obstacles to EVAR for ruptured AAA are anatomical constraints, availability of equipment and well-trained staff out of hours. All these factors need to be taken into consideration.

Considering all the above, a decision is made to proceed with open repair under general anesthesia or EVAR under local or general anesthesia, and the patient is transferred to the operating room as soon as possible.

We aimed to study the outcomes of open surgical repair and EVAR for ruptured AAA in a real-world setting, in hopes to further clarify the optimal management strategy for this difficult cohort.

Methods

This study included 120 patients presenting with ruptured Abdominal Aortic Aneurysms (AAA) at University Hospitals Sussex, UK and Alexandria Main University Hospital, Egypt; 60 consecutive patients receiving open repair and 60 consecutive patients receiving EVAR for treatment of ruptured AAA in the period between 15/6/2015 and 16/11/2021

Ethics approval was obtained from the ethics committee at Alexandria University

All patients had ruptured AAA confirmed on MDCT angiography and received immediate endovascular repair if they were found to be anatomically suitable for standard infrarenal EVAR. Patients who were outside IFU for EVAR received immediate open surgical repair.

Patients who were not within IFU for EVAR and deemed unfit for open repair due to comorbidities were excluded. Ruptured thoraco-abdominal aortic aneurysms, isolated iliac aneurysms or secondary ruptures following previous EVAR were also excluded.

We studied the outcomes in terms of:

1. Technical aspects, including operative technique, technical success rate, mode of anaesthesia, intraoperative complications.
2. 30-day all cause mortality rates
3. Mid-term survival rates (up to 24 months)
4. Post-operative complication rates (peri-operative and mid-term)

Data was analyzed using IBM SPSS version 20.0. (Armonk, NY: IBM Corp). Qualitative data was described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution. Quantitative data was described using range (minimum and maximum), mean and standard deviation. Significance of the obtained results was judged at the 5% level. The used tests were

1. Chi-square test: For categorical variables, to compare between different groups

2. Fisher's Exact or Monte Carlo correction: Correction for chi-square when more than 20% of the cells have expected count less than 5
3. Student t-test: For normally distributed quantitative variables, to compare between two studied groups
4. Mann Whitney test: For abnormally distributed quantitative variables, to compare between two studied groups

Results

Patient characteristics

The studied group included 53 males (88.3%%) and 7 females (11.7%%) patients in the OSR group, compared to 48 males (80%) and 12 females (20%) in the EVAR group.

The patients' ages ranged from 60-84 years in the OSR group, with the mean age (± SD) being 74.23 (± 5.94). In the EVAR group, this ranged from 36-92 years, with the mean age (± SD) being 75.28 (± 10.43).

Only one patient was under 50 years of age, who was a patient with known Marfan's disease and presented with a ruptured AAA, treated with EVAR.

One hundred and eighteen aneurysms were fusiform in nature and two (1.7%) were saccular AAA at the site of a penetrating aortic ulcer. The mean size (± SD) was significantly larger in the group receiving OSR: 7.93 (± 1.91) when compared to the group receiving EVAR: 6.85 (± 1.32).

The patients in both groups were similar in terms of background medical history, particularly when studied from a diabetes, cardiovascular, respiratory and renal comorbidity perspective (Table (1)).

Table (1): Baseline characteristics of the studied patients

Past medical history	OSR (n = 60)		EVAR (n = 60)		p
	No.	%	No.	%	
Cardiac	24	40.0	31	51.7	0.200
COPD/Asthma	9	15.0	14	23.3	0.246
CKD	0	0.0	4	6.7	^{FE}p=0.119
DM	9	15.0	7	11.7	0.591
HTN	39	65.0	34	56.7	0.350

Legend: COPD: Chronic Obstructive Pulmonary Disease; **CKD:** Chronic Kidney Disease; **DM:** Diabetes Mellitus; **HTN:** Hypertension; **FE:** Fisher Exact; **p:** p value for comparing between the two studied groups

Technical Aspects

Of the 60 patients included in the open repair group, six succumbed prior to achieving an aortic repair. In the remaining 54 patients; 44 (81.5%) received a tube graft repair and the remaining ten (18.5%) received bifurcated repairs.

Fifty nine patients in the EVAR group underwent technically successful aortic repair, with 56 (94.9%) receiving infrarenal EVAR. Two patients (3.4%) received an aorto-uniiliac repair with contralateral common iliac artery plugging and fem-fem crossover bypass and one patient (1.7%) received a single aortic stent.

Details of the technical aspects are outlined in Table (2).

Table (2): Technical aspects in EVAR and OSR groups

OSR group		**n (%)**
Clamp site	**Infrarenal**	**38 (63.3%)**
	Inter-renal	**5 (8.3%)**
	Suprarenal	**10 (16.7%)**
	Supra-celiac	**5 (8.3%)**
	Died before control	**2 (3.3%)**
EVAR group		
Access	**Bilateral percutaneous**	**36 (60%)**
	Bilateral cutdown	**19 (31.7%)**
	One percutaneous, one cutdown	**4 (6.7%)**
	Intraoperative conversion	**1 (1.7%)**
Aortic occlusion balloon	**Required**	**22 (36.7%)**
	Not required	**38 (63.3%)**
Anesthetic	**Local anesthesia**	**45 (75%)**
	General anesthesia	**9 (15%)**
	Conversion LA-GA	**6 (10%)**

Mortality

The 30-day all-cause mortality was significantly higher in the OSR group, with 23 patients (38.3%) dying as opposed to eight patients (13.3%) in the EVAR group (p=.002).

Ten patients (16.7%) in the OSR group died intraoperatively, compared to three patients (5%) in the EVAR group.

Seven patients (11.7%) in the OSR group died of multi-organ failure on ICU, all within the first 48 hours postoperatively. This was similar in the EVAR group, resulting in four mortalities (6.7%).

Six further patients (10%) in the OSR group died of myocardial infarctions, ranging from day 8-15 postoperatively. One patient in the EVAR group died 18 days post-procedure (10 days post-discharge) due to a Type A aortic dissection involving the coronary buttons. This was in the context of known Marfan's disease.

Two further patients in the OSR group passed away within the two year follow-up period (total of 25 patients 41.7%); one died following a myocardial infarction 20 months later and one of respiratory failure following a prolonged ICU stay after the initial procedure (day 42).

Three further patients in the EVAR group passed away between the 30-day and 2-year marks (total of 11 patients (18.3%)). One passed away following a myocardial infarction, and two passed away at home during the COVID pandemic.

The mortality rate at 2 years remained significantly lower in the EVAR group (p=.005).

Postoperative complications

Postoperative complications were reported in all patients who survived the initial procedure; which were 48 patients in the OSR group and 58 patients in the EVAR group. Details of post-operative complications are outlined in Table (3).

- *Cardiovascular*

Eight patients (16.7%) in the OSR group and eight patients (13.8%) in the EVAR group experienced postoperative cardiovascular complications.

Although the incidence of myocardial infarctions was doubled in patients undergoing open repair, this was not found to be statistically significant, neither was the overall cardiovascular morbidity.

- *Respiratory*

Respiratory complications were more common in the EVAR group, with 18 patients (31%) developing some form of respiratory insult compared to eight (16.7%) in the OSR group. However, there was no statistically significant difference found.

- *Renal*

There were no statistically significant differences between both groups when analyzing postoperative renal dysfunction and need for long-term dialysis.

In the OSR group, when comparing infrarenal clamping to any clamping above one or both renals, we found that there was a significantly higher incidence of renal dysfunction if the clamp was applied above a renal artery (13.2% vs 53.3%, p=0.02)

Two of 38 (5.3%) of patients receiving infrarenal clamping went on to require dialysis and 2/5 (40%) patients receiving inter-renal clamping required dialysis. This was also found to be statistically significant (p=0.012)

- *Lower Limb*

There were significantly fewer lower limb complications in the EVAR group (p=0.026)

- *Endoleaks*

Two patients (3.4%) had persistent Type Ib endoleaks on conclusion of the EVAR procedure. This was successfully treated by internal iliac embolization and extension into the external iliac artery in one patient. The second patient unfortunately succumbed on table before a satisfactory seal could be achieved.

Over the two year follow-up period, 17 patients (29.3%) were found on surveillance duplex to have Type II endoleaks. This did not require further intervention in any of the patients.

- *Length of stay*

Patients who survived the index procedure and arrived to ICU were compared in terms of length of stay on ICU and total length of stay in hospital. The length of ICU stay was significantly longer in the OSR group (p=.001)

However, the length of total hospital stay was not found to be significantly different in both groups (p=.096).

Table (3): Post-operative complications

		OSR group n (%)	EVAR group n (%)	P value
Cardiovascular	**Total**	8 (16.7%)	8 (13.8%)	0.861
	MI	5 (10.4%)	3 (5.2%)	0.309
	Rapid AF	2 (4.2%)	5 (8.6%)	
	Acute pulmonary edema	1 (2.1%)	0	
Respiratory	**Total**	8 (16.7%)	18 (31%)	0.087
Renal	Renal dysfunction*	13 (27.1%)	15 (25.9%)	0.887
	Long-term dialysis	4 (8.3%)	2 (3.4%)	0.278
Lower limb	**Total**	6 (12.5%)	1 (1.7%)	0.026
	Embolectomy + fasciotomy	3 (6.25%)	0	
	Fem-fem crossover	1 (2.1%)	0	
	Above knee amputation	1 (2.1%)		
	Femoral pseudoaneurysm	0	1 (1.7%)	

*Increase in serum creatinine by >0.3 mg/dL

Factors influencing mortality in EVAR and OSR groups

In the EVAR group, there was a significantly lower mortality among patients who had the procedure under LA when compared to GA (p=0.046).

Furthermore, there was a significantly higher mortality rate in patients who required the use of aortic occlusion balloons. 27.3% of the patients who required the use of occlusion balloons passed away, as opposed to only 5.3% of patients who did not (p=.042).

In the OSR group, infrarenal clamping was associated with a significantly lower mortality rate compared to suprarenal clamping (23.6% vs 70%, p=.024).
The mortality rate in patients who were hemodynamically unstable on presentation was significantly higher than those who were stable on presentation [19/30 (63.3%) vs 4/30 (13.3%), p=<.01]

Discussion

We aimed to compare the mortality rates following OSR and EVAR for ruptured AAA, both at 30 days and at 2 years, as well as post-operative complications and technical factors that could contribute to these outcomes. Our results showed a significantly lower mortality rate at 30 days and 2 years for patients undergoing EVAR, with a 30-day mortality rate of 13.3% in the EVAR group as opposed to 38.3% in the OSR group.

A similar conclusion was reported in the study by Mehta et al(2), a meta-analysis by Kontopodis et al(3), the VQI analysis by D'Oria et al(4) as well as an earlier systematic review by Mastracci et al (5). However, this was not a universal finding when examining the literature, with many studies showing no survival benefit for EVAR over OSR, such as the Swedvasc population-based study(6), the AJAX(7), ECAR(8) and IMPROVE(9) trials.

Our 30-day results were similar in terms of the OSR mortality rates as reported in the IMPROVE trial (37.4%)(9), but were higher than the ECAR trial (24%)(8) and the AJAX Trial (25%)(7). However, in the EVAR group, our results were lower than the IMPROVE trial (35.4%)(9), the AJAX trial (21%)(7) and the ECAR trial (18%)(8). The IMPROVE trial also noted that half the deaths in each group were within the first 24 hours (11).

We suspect that this significant discrepancy in outcomes is multi-factorial but could be due to the fact that the AJAX and ECAR trials only randomized patients suitable for both EVAR and OSR, thus all juxtarenal/short neck aneurysms were excluded. Also, patients who were hemodynamically unstable and failed to stabilize following endoclamping were excluded from randomization in ECAR. Furthermore, the IMPROVE trial was analyzed on an intention-to-treat basis, and when the

subgroup of "endovascular first" patients actually receiving EVAR was studied, it showed a 25% mortality at 30-days, not 35.4% (9).

We acknowledge the differences in study design between our study and the previously quoted trials; as we did not have an element of randomization and relied on the anatomical suitability for EVAR as the main determining factor for choice of repair. This does carry a risk of selection bias, but we believe that it conveys a real-world perspective.

In the AJAX and ECAR trials, however, patients were only included if they were anatomically suitable for EVAR, thus excluding short-neck and juxtarenal aneurysms and they predominantly employed aortouni-iliac repairs. In the IMPROVE trial, patients were randomized prior to CT assessment of anatomy.

When comparing the EVAR group in our study with other trials, 85% of our patients received a standard infrarenal EVAR, with only 3.3% receiving an AUI. Similarly, in IMPROVE, 74.7% were bifurcated and 21.4% were AUI repairs(20). This was different when compared to ECAR, with 73.2% receiving AUI and only 22.6% received a bifurcated graft(8). All cases in AJAX received AUI repairs as per protocol(7).

We utilized local anesthesia as the primary anesthetic technique for our EVAR group, with 75% of our cases receiving their repairs in that fashion. This was in contrast to the IMPROVE trial (21%), the ECAR trial (14.3%) and the AJAX trial (22.8%). We believe this also contributed to the lower mortality rates in our study, as it has been shown that local anesthesia confers a survival benefit in these cases (21-23).

In terms of post-operative cardiovascular complications, we found no statistically significant differences between the OSR and EVAR groups, however we did note that about a quarter of the patients who died following OSR died of myocardial infarctions, which was not the case in the EVAR group. We also noted that the incidence of MI in patients who survived OSR was double that of those who survived EVAR. This appears to be in line with the higher operative insult due to hemodynamic effects of OSR. This was not the case in the AJAX or ECAR trials. We believe this discrepancy might be explained by the much larger adoption of local anesthesia for EVAR in our group when compared to the other trials.

There were no significant differences between the OSR and EVAR groups in terms of respiratory complications, which was also the case in ECAR and AJAX.

We found no significant difference in the overall renal complications between both groups, but we did note that the number of patients requiring RRT following OSR was double that in the EVAR group, which was still not statistically significant. Similar results were reported in ECAR and AJAX, although AJAX reported a significantly higher moderate-severe renal insufficiency rate following OSR(7). It is, however, interesting to note that we found a significantly higher risk of renal dysfunction and dialysis requirement when OSR was performed with clamping

above one or both renal arteries. This echoes the recent results of the VQI review by Natour et al(24).

The incidence of post-operative endoleaks in our EVAR group (29.3%) was similar to that reported in AJAX (28%). The reported incidence was lower in ECAR (16%). It is of note that most of these did not require further interventions, for example IMPROVE reported a 3% reintervention rate for endoleaks at 1 year.(11)

Factors affecting mortality rates

- **EVAR**

We attempted to explore the factors that could contribute to an increased mortality in both patient groups, and on studying the EVAR group, we found that patients requiring the use of aortic occlusion balloons had higher mortality rates. The number of patients requiring occlusion balloon use in our study was higher than that reported in any of the three trials (36.7%) as opposed to 12.5% in ECAR, 6.1% in IMPROVE(20) and 7% in AJAX. We attribute this effect to the worse baseline condition of these patients and higher technical complexity of their repairs, as well as the physiological effects of (effectively) supraceliac aortic clamping.

Interestingly, we noted a significantly lower mortality rate in patients undergoing EVAR under LA as opposed to GA, which is similar to the results of a subgroup analysis of the IMPROVE trial, which showed a four-fold reduction in 30-day mortality with this strategy.(21) These findings strengthen the argument that LA should be the preferred modality for EVAR in ruptured AAA.

- **OSR**

In terms of the level of aortic clamping, our results (78.4% infrarenal, 16% above one or both renals) were similar to the results of the ECAR trial, which reported 80.3% infrarenal and 15.7% suprarenal clamping. Furthermore, we did note that infrarenal aortic clamping carried significantly lower risks of mortality than suprarenal clamping.

This is not surprising, as it is well known from the results of elective AAA repairs that suprarenal/supraceliac clamping exerts a much higher physiological effect than infrarenal clamping.(24) This highlights that an infrarenal clamp should be the preferred site whenever possible.

Limitations:

We acknowledge the limitations of our study, which include its retrospective design and risk of selection bias. We also acknowledge the lack of randomization of patients into both groups, which is a significant difference compared to the previously mentioned trials.

Conclusions:

Ruptured AAA remains a significant challenge facing vascular surgeons, and despite the declining incidence of AAA in the general population, patients presenting with aortic aneurysms tend to be older than previously reported.

Our study shows that EVAR for ruptured AAA, when anatomically suitable, offers a significant survival benefit in the short and medium-term, especially if done under local anesthetic.

The long-term survival benefit offered by OSR especially after more than 2 years is a significant factor that requires further studies, which contributes to the lack of consensus around the optimum treatment modality for these patients.

Furthermore, in patients who are not anatomically suitable for EVAR and who receive an open surgical repair, all efforts should be made to use an infrarenal clamp site.

Despite the advances in peri-operative and ICU care, mortality rates for open repair of ruptured AAA have remained consistently high.

Conflict of Interest: None

Author Contributions:

Mohamed Elahwal: Conceptualization; Data curation; Formal analysis; Investigation; Writing - original draft

Raafat Naga: Conceptualization; Methodology; Project administration; Supervision; Validation; and Writing - review & editing.

Mamdouh Kotb: Conceptualization; Methodology; Project administration; Supervision; Validation; and Writing - review & editing.

Wael Shaalan: Conceptualization; Methodology; Project administration; Supervision; Formal analysis; Validation; and Writing - review & editing.

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