Original Article

Short Term Outcomes of Endovascular Vs Open Repair of Ruptured Infrarenal Aortic Aneurysms

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Abstract

Purpose: The purpose of this study is to summarize scientific evidence regarding patients undergoing Endovascular Abdominal Aortic Repair (EVAR) for ruptured of Abdominal Aortic Aneurysm (rAAA). Particular aspects of the procedure which have clinical impact are highlighted. Furthermore, the mortality rate of a single center is investigated retrospectively.
Methods: Electronic information sources and bibliographic lists of relevant publications were investigated. Also, a retrospective study was performed in a consecutive series of patients presenting with rAAA, one year before and one year after the implementation of a protocol in a single center (Vascular Department, General Hospital Nicosia, Cyprus).
Results: From this single center study, a moderate quality evidence was found suggesting that there is an improved thirty-day mortality using a protocol based endovascular-first approach for the treatment of rAAAs.
Conclusions: Overall, there is a relevant evidence that the use of a protocol based endovascular-first approach appears necessary in the treatment of the rAAAs, as it gives lower 30-day mortality rates.

Key Words: Ruptured Aortic Aneurysm, Endovascular Repair, Thirty-day mortality

Introduction

Well established evidence has shown that the majority of patients with ruptured Abdominal Aortic Aneurysm (rAAA) will die before they can be operated. In addition, open surgery carries high mortality (35-55%) and morbidity rates (Bown et al., 2002, Dillavou, Muluk and Makaroun, 2006). However, treatment options have been advancing, as endovascular approaches to repair Abdominal Aortic Aneurysms (AAAs) were introduced in the early 90s.

After decades of negligible improvements in open surgical survival rates, advances in endovascular technology, perioperative management and centralization of health services, improved outcomes and decreased the mortality rate (Veith and Ohki, 2002).

Furthermore, public health measures such as aneurysm screening and smoking cessation regulations, contributed to a decrease in the incidence of rAAA (Veith et al., 2009). Observational studies, systemic reviews, and administrative databases have indicated that ruptured Endovascular Aneurysm Repair (rEVAR) is associated with lower operative mortality compared to Open Surgery Repair (OSR). Despite favorable data, some investigators claim that all this evidence is flawed by patient selection (von Allmen, Schidli and Dick, 2013, Saqib et al., 2012). Therefore, health care providers require better evidence in order to invest in organizational changes.

The main purpose of this retrospective review is to showcase the experience of a single center (Vascular Surgery Department of the Nicosia General Hospital, Cyprus) that provides 24/7

vascular care for the whole island of Cyprus, after the implementation of an endovascular-first approach to treating ruptured abdominal aneurysms.

Ruptured Abdominal Aortic Aneurysm Repair Outcomes

Open Surgical Repair

Despite advances in anesthesia, critical care, and open surgical techniques, the overall mortality of rAAA patients undergoing OSR has remained at approximately 50% on the basis of an accumulation of data from national data bases, statewide audits, and single center studies. A meta-analysis of studies during a 15-year period between 1991and 2006 that included more than 60,000 patients found an overall OSR mortality rate of 48.5% and that tertiary centers had a lower mortality (Hoornweg et al., 2008).

Endovascular Repair

Worldwide, more rAAAS are now treated by EVAR. The endovascular approach is less invasive and, in some reports, decreases mortality (Mayer et al., 2012).

Multicenter Results

In a multicenter study, authors from university hospital of Zurich and Orebro reported their combined 14 year-experience of EVAR and OSR of rAAAs to address the impact of complete replacement of OSR for rAAA by EVAR. *Mayer et al* evaluated their data retrospectively, in two time periods: during the initial period (1998-2009), all rAAA patients were offered EVAR and OSR; during the later period (2009-2011), all patients were offered EVAR only (Mayer et al., 2012). Their overall results indicated a significantly lower 30-day mortality for EVAR compared with OSR of rAAA (17.9% vs. 37.4%; OR, 3.3; 95% CI, 1.4-7.5; P = 0.004). The study limitations were that the authors did not analyze outcomes in the 24.3% of EVAR patients who required secondary procedures, which might have resulted in a higher mortality.

Randomized Trials

The first multicenter randomized trial completed to date has been the Dutch multicenter randomized trial known as the Amsterdam Acute Aneurysm trial (**AJAX trial**). The participants decided to randomize only those patients who were eligible for both open repair and EVAR, which evaluated death and severe complications as its primary endpoints. The trial showed no difference in 30-day mortality between the two groups of patients. The 30-day mortality for all patients was low: 21% for EVAR to 25% for OSR.

In addition, AJAX findings indicate that death and severe complications occur in 42% of patients after EVAR and in 47% after OSR of rAAA, which was not significantly different. However, the trial was small and didn't randomize more than one third of the ruptures reported to the trial centers (Hoornweg et al., 2007).

The **ECAR trial** is a French prospective multicenter Randomized Controlled Trial (RCT) including consecutive patients with ruptured Aorto-Iliac Aneurysms. In this study, EVAR was found to be equal to OSR in terms of 30-day mortality (24% to 25%). However, EVAR was also a small trial since decided to randomize only those patients who were eligible for both procedures. ECAR trial excluded hypotensive or unstable rAAA patients who were not offered EVAR and were treated by OSR or have no reparative treatment. Fatefully, these patients at high risk are precisely the ones who might have better outcomes if treated with EVAR.

The **IMPROVE trial** was a larger RCT, conducted in 29 high-volume centers in the United Kingdom and one Canadian hospital. It was well organized, and much useful information was collected (Powel and Sweeting et al., 2014). Analysis of outcomes at 30 days and one year found no difference in survival rate between the two groups.

The overall 30-day mortality rate in the endovascular group was 35%; in the open repair group, it was 37% (P=0.67). Nonetheless, the main conclusion of IMPROVE's trial on 30-day outcomes is not supported by data because more than half of the patients who were randomized to EVAR group did not actually undergo endovascular treatment. Several investigators consider that a better conclusion is justified by IMPROVE's data; patients with rAAA who can be treated with EVAR, have a higher 30-day-survival to that of patients treated with open repair (Veith and Rockman, 2015). Also, after three years, the endovascular surgery emerges as a better care pathway for patients as it is not associated with a greater rate of serious late reinterventions (Veith and Rockman, 2015).

Meta-Analyses

A meta-analysis of 23 published studies on EVAR versus OSR of rAAA analyzed outcomes in 7040 patients who underwent EVAR (n=730, 10%) or OSR (n=6310, 90%). The findings depicted that EVAR of rAAA was associated with a significant reduction in 30-day mortality and operative duration, mean intensive care unit length of stay was lowered by 4 days and mean hospital length of stay by 9 days (Qin, Chen and Xiao, 2014).

These findings suggest that centers with adequate expertise and recourses available for these emergent EVAR procedures provide a benefit for patients in lowering morbidity and mortality.

Current Recommendations for Ruptured AAA Repair

"For those patients with rAAA, where appropriate facilities, personnel, equipment, and expertise are available for EVAR, we suggest EVAR rather than open AAA repair, provided that is anatomically feasible (Grade 2C). In appropriately selected patients, endovascular repair of rAAA appears to be associated with lower perioperative (30-day) morbidity and mortality. For patients with symptomatic but not rAAA who have multiple risk factors for poor prognosis, we also suggest EVAR rather than open repair (Grade 2C). Where EVAR for emergency AAA repair is not an option (due to anatomical challenges, lack of facilities or expertise, excessive time for transfer), open repair at the initial facility by an experienced surgeon is appropriate. If no such surgeon is available, or the patient is a poor candidate for open repair, transfer to a vascular center is appropriate" (Jeffrey and Thompson, 2019).

Objectives: Consistent with international trends, the use of EVAR for rAAA has steadily increased at our institution during the past two years. The objective of the present review was to investigate whether the implementation of our Endovascular-first emergency protocol for the treatment of a rAAA would translate into improved clinical outcomes compared to conventional OSR.

Materials and Methods: The study included all patients diagnosed and treated for a rAAA at Nicosia General Hospital under the Department of Vascular Surgery from January 2017 to 2019. We implemented our endovascular-first protocol for the management of patients with rAAA, which included an initial eligibility evaluation for an "intension to treat with EVAR" protocol.

The present review serves as a retrospective nonrandomized intension-to-treat review of patients with rAAA who were treated after application of the protocol (January 2017–2019), compared with pre-protocol patients (January 2016-2017).

The commercially available endograft system used was the Endurant II by Medtronic, (Sunrise, FL, USA). It was used according to anatomic characteristics and device availability. Aorto-uniiliac grafts were preferred in critically unstable patients. If an aorto-uniiliac stent was placed, an occluder device (Talent^{TM}Occluder) was deployed in the contralateral iliac artery (Figure 2). The procedure was completed with a femoro-femoral bypass graft (Vascular/Propaten,W.L. Gore). In stable patients, a bifurcated device was preferred to restore direct flow in both lower limbs (Figure 3).

Protocol Application: Endovascular as the First Approach

Our current treatment protocol for patients with rAAA is similar to those previously published (Mehta et al., 2006, Oyague et al., 2015) and is highlighted in Figure1 (Ullery, Tan and Chandra, 2016).

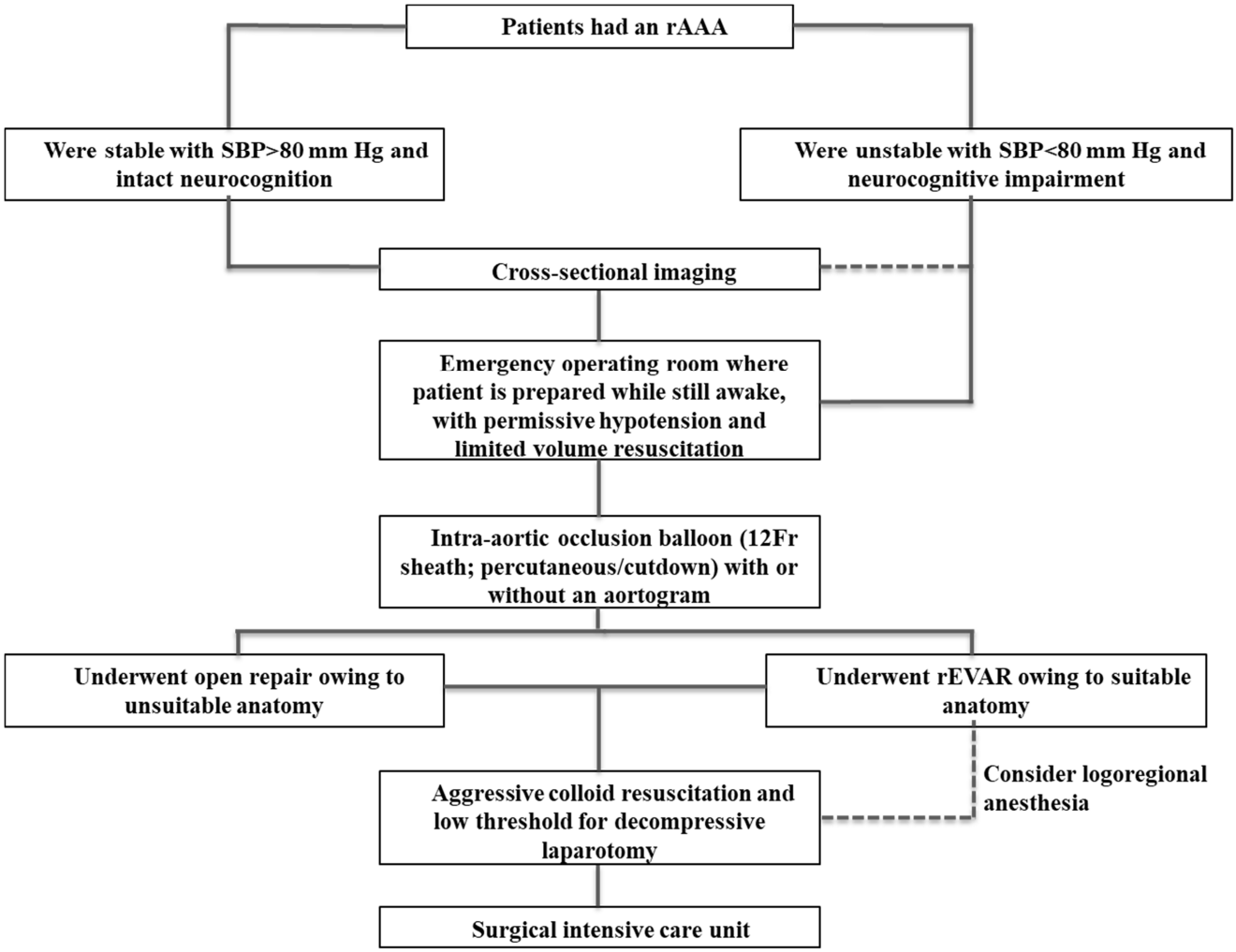
All cases were performed in a standard hybrid operating room. In hemodynamically unstable patients, a trans-femoral intra-aortic occlusion balloon (CODA balloon; Cook Medical) with 12Fr sheath support, was inserted into the suprarenal aorta. If patients exhibited significant hypotension, the occlusion balloon was inflated to profile in order to optimize hemodynamics. Heparin was used selectively in all cases.

Conversion to open repair was performed using a transperitoneal approach. Postoperative follow-up included a clinical examination and a CTA at 1, 6, and 12 months, and yearly thereafter for the patients underwent EVAR for rAAA.

Statistical Analysis

Primary outcome measures were intraoperative mortality and 30-day mortality. Incidence of post-operative complications was recorded as a secondary outcome. Descriptive statistics were used to assess demographics, baseline comorbidities, and aneurysm characteristics. Univariate analyses were calculated using the

independent samples t-test and the Pearson $\chi 2$ test for continuous and categorical variables, respectively. A logistic regression model was subsequently employed to identify independent predictors of 30-day mortality. A $P < .05$ was considered statistically significant for all analyses. All calculations were performed in SPSS version 21.0.



rEVAR indicates Ruptured Endovascular Aneurysm Repair;SBP, systolic blood pressure.

Figure 1. Management of ruptured abdominal aortic aneurysm: Contemporary Endovascular-First Approach for the Treatment of Patients with a Ruptured Abdominal Aortic Aneurysm (rAAA).

Results

A total of 58 patients were treated during the study period, including 24 in the pre-protocol and 34 in the post-protocol groups. Both groups were similar based on baseline patient demographics and comorbidity status (Table 2).

A rEVAR was performed with significantly greater frequency during the post-protocol period than during the pre-protocol period (70.6% vs. 25.0%; $P < .001$).

Table 2. Baseline Patient Characteristics and Perioperative Data

	PatientsN%										
	Preprotocol				Post Protocol						
	All (n=24)		Open Repair (n=18)		EVAR (n=6)		All (n=34)		Open Repair (n=10)		EVAR (n=24)		P value
	N	%	N	%	N	%	N	%	N	%	N	%	
Age													
<70	4	16.70 %	4	22.2%	0	0.0%	2	5.90%	2	20%	0	0.0%	
70-79	15	62.50 %	10	55.6%	5	83.3%	30	88.20%	8	80%	22	91.7%	0.068
≥80	5	20.80 %	4	22.2%	1	16.7%	2	5.90%	0	0%	2	8.3%	
Male sex	23	95.80 %	18	100.0 %	5	83.3%	34	100.00 %	10	100%	24	100.0 %	0.23
Comorbidities													
CAD	11	45.80 %	8	44.4%	3	50.0%	12	35.30%	3	30%	9	37.5%	0.419
Hypertension	23	95.80 %	18	100.0 %	5	83.3%	26	76.50%	8	80%	18	75.0%	0.045
CRI	4	16.70 %	4	22.2%	0	0.0%	2	5.90%	1	10%	1	4.2%	0.184
COPD	5	20.80 %	4	22.2%	1	16.7%	5	14.70%	2	20%	3	12.5%	0.543
Tobacco use	18	75.00 %	14	77.8%	4	66.7%	28	82.40%	8	80%	20	83.3%	0.496
Prior stroke	0	0.00%	0	0.0%	0	0.0%	2	5.90%	0	0%	2	8.3%	0.227
Prior MI	8	33.30 %	5	27.80 %	3	50.00 %	11	32.40%	3	30%	8	33.30 %	0.938
Hyperlipidemia	16	66.70 %	14	77.8%	2	33.3%	19	55.90%	5	50%	14	58.3%	0.408
Diabetes mellitus	7	29.20 %	5	27.8%	2	33.3%	8	23.50%	3	30%	5	20.8%	0.629
Preoperative Data													
Hospital transfer	15	62.50 %	12	66.7%	3	50.0%	13	38.20%	5	50%	8	33.3%	0.069
Diameter of AAA,mean(SD), cm	6.92 (0.82)		7.02 (0.86)		6.6 (0.67)		6.85 (0.84)		6.96 (0.99)		6.81 (0.79)		0.775
SBP<80 mmHg	8	33.30 %	6	33.3%	2	33.3%	7	20.60%	4	40%	3	12.5%	0.275
Hematocrit<25 %	6	25.00 %	4	22.2%	2	33.3%	7	20.60%	4	40%	3	12.5%	0.692
Creatinine level ≥2mg/dl	1	4.20%	1	5.6%	0	0.0%	1	2.90%	1	10%	0	0.0%	0.801
Free rupture	8	33.30 %	6	33.3%	2	33.3%	7	20.60%	4	40%	3	12.5%	0.275

Mortality

Perioperative morbidity and mortality are noted in Table 3. In total, 4 patients died intraoperatively (3.3% who underwent an EVAR vs. 10.7% who underwent an open repair; *P* = .27). The percentage of intraoperative deaths was not significantly different between the pre-protocol and post-protocol groups (8.3% vs. 5.9%; *P* = .72). Eight (10.7%) survived open or endovascular rAAA repair but died within 30 days.

Thirty-day mortality irrespective of treatment type, during the pre-protocol was higher compared to post-protocol periods (16.7% vs. 11.8%) but not within the statistical significance threshold (*P* = .59), respectively. Similarly, irrespective of protocol, 30-day mortality for open repair was higher compared to EVAR, (17.9% for open repair vs. 10% for EVAR; *P* =0 .39) although not within statistical significance limits.

Table 3. Perioperative Morbidity and Mortality

	Patients(N - %)												
	Preprotocol						Post Protocol						
	All (n=24)		Open Repair (n=18)		EVAR (n=6)		All (n=34)		Open Repair (=10)		EVAR (n=24)		P value
Variable	N	%	N	%	N	%	N	%	N	%	N	%	
Complications													
Myocardial Infraction	2	8.30%	2	11.1%	0	0,0%	0	0.00%	0	0%	0	0.0%	0.087
Acute renal failure	1	4.20%	1	5.6%	0	0.0%	1	2.90%	0	0%	1	4.2%	0.801
Need for hemodialysis	1	4.20%	1	5.6%	0	0.0%	1	2.90%	0	0%	1	4.2%	0.801
Respiratory failure	2	8.30%	2	11.1%	0	0.0%	1	2.90%	1	10%	0	0.0%	0.361
Stroke	0	0.00%	0	0.0%	0	0.0%	0	0.00%	0	0%	0	0.0%	N/A
Hemorrhage	4	16.70%	3	16.7%	1	16.7%	3	8.80%	2	20%	1	4.2%	0.366
Mesenteric ischaemia	0	0.00%	0	0.0%	0	0.0%	0	0.00%	0	0%	0	0.0%	N/A
Lower extremity ischaemia	1	4.20%	0	0.0%	1	16.7%	0	0.00%	0	0%	0	0.0%	0.23
Mortality													
Intraoperative	2	8.30%	2	11.1%	0	0.0%	2	5.90%	1	10%	1	4.2%	0.717
30-Day	4	16.70%	3	16.7%	1	16.7%	4	11.80%	2	20%	2	8.3%	0.594

Table 4: 30-day mortality across protocol in EVAR and Open Repair Patients

		N	%	TOTAL patients
EVAR	POST	2	8.3%	24
	PRE	1	16.7%	6
Open Repair	POST	2	20.0%	10
	PRE	3	16.7%	18

Pre-protocol versus Post-protocol Mortality in EVAR and Open Repair (OSR)

Among patients who underwent EVAR treatment (n=30), pre-protocol 30-day mortality (16.7%) was higher than that of post-protocol (8.3%), however without reaching statistical significance (p=0.543). Among patients who underwent open repair (n=28), pre-protocol 30-day mortality (16.7%) was lower than that of post-protocol

(20%), however without reaching statistical significance (p=0.825) (Table 3 and 4).

Open Repair versus EVAR Mortality in Pre-protocol and Post-protocol

Among patients in the pre-protocol (n=24), 30-day mortality was similar for open repair and EVAR (16.7%). Among patients in the post-protocol (n=34), 30-day mortality for the open repair (20%) was higher than that of EVAR (8.3%), however without reaching statistical significance (p=0.336) (Table 3 and 4).

Overall, the lowest mortality rate is observed among the 24 patients who underwent EVAR operation with the post-protocol (2/24=8.3%) (Table 4).

Discussion and Conclusions

Endovascular repair of AAAs is evolving through the new generations of the aortic stent-grafts and the better learning curves and expertise of vascular practitioners worldwide.

It is recommended that a standardize protocol for endovascular treatment of rAAAs should be established and includes a multidisciplinary approach and adequate equipment including an immediately available stock of endografts prone to use in an emergency setting. This was feasible in the General Hospital of Nicosia that provides endovascular care in a 24/7 setting. The resulting treatment algorithm can minimize delays and even lead to treatment of hemodynamically unstable patients (Mehta et al., 2006).

Hence, for patients with ruptured AAA, where appropriate facilities, personnel, equipment, and expertize are available for endovascular repair (EVAR), it is suggested EVAR rather than OSR provided that this is anatomically feasible (Grade 2C). In appropriately selected patients, endovascular repair of ruptured abdominal aortic aneurysms appears to be associated with lower perioperative morbidity (30-day) and mortality (non statistical significance though overall). For patient with symptomatic but not ruptured AAA who have multiple risk factors and poor prognosis, it is also suggested EVAR rather than open repair (Grade 2C) (Jeffrey and Thompson, 2018).

A recent review by *Badger et al.*, assessed the advantages and disadvantages of emergency endovascular abdominal repair on comparison with conventional repair for the treatment of ruptured abdominal aortic aneurysm (rAAA). They included four studies with a total of 868 participants. They conclude, from the data available, there is no difference in thirty day mortality between rEVAR and open repair for ruptured abdominal aortic aneurysms (Badger et al., 2007).

Also, in an original article from *Veith FJ et al*, the collected experience with the use of EVAR for rAAA treatment from 49 centers was examined. The authors concluded that EVAR is more beneficial in augmenting survival even when it is used in the high risk patients who are unlikely to survive OSR. These are patients with hemodynamic instability, circulatory collapse, and hostile abdomen. They finally found a reduced 30-day mortality compared with patients treated with open repair (Veith et al., 2009).

Furthermore, in a review article by *Mastracci et al* it was also concluded that short term mortality after endovascular repair of ruptured aneurysms appears promising in the selected patients who have undergone the procedure (Mastracci et al., 2008).

A systematic review and meta-analysis of the current literature with information on EVAR mortality rates for rAAAs demonstrated mortality from rEVAR of 24.5%. Hence, endovascular repair of ruptured AAAs, is associated with lower mortality rates (Rayt et al., 2008).

The IMPROVE trial was valuable. It has provided useful information regarding the treatment of ruptured AAAs and will undoubtedly provide more in the future (Powell and Sweeting, 2014). However, the main conclusion of IMPROVE's key article on 30-day mortality is not supported by its data (Powell and Sweeting, 2014). According to *Vieth and Rockman* the conclusion of IMPROVE trial that "an endovascular repair was not associated with a significant reduction in 30-day mortality" is misleading (Veith and Rockman, 2015).

In concurrence with international literature data, EVAR has become the first line treatment for rAAAs in our department (Lesperance et al., 2008, Veith and Ohki, 2002, Karkos et al., 2011).

In a systematic review comparing EVAR to OSR, *Visser et al.*, observed postoperative 30-day mortality rates of 22% for EVAR and 38% for OSR (Visser et al., 2006). Similar results were presented by *Resch et al.* (Resch et al., 2003). In the present study it is noted that 30-day

mortality rate of rEVAR was lower compared to open repair (10 % for EVAR vs 17.9% for OSR). Even though this result does not appear to be within statistical limits, probably because of the small sample used for this particular review, it is still in agreement with the international literature data.

Likewise, in the present review, pre-protocol 30-day mortality was higher (16.7%) than that of post-protocol (8.3%) suggesting the need for establishing an algorithm for the treatment of ruptured abdominal aortic aneurysms. This will lead to rapid decision making regarding further treatment and it will help to overcome confusing and stressful circumstances.

Finally, we found that Coronary Arterial Disease (CAD) and hypotensive status of the patients due to hypovolemia are independent risk factors for 30-day mortality. Hence, cardio vascular comorbidity may play an important role on the survival rate of these patients. Furthermore, the role of hypotension preoperatively on the mortality rates is well determined, affecting the survival rate of the patients with ruptured AAA (Antonopoulos et al., 2014).

Overall, in this review, the lowest mortality was observed among the 24 patients who underwent EVAR for ruptured aneurysms within the post protocol period (even though not statistically significant). This highlights the two principal concepts for the treatment of ruptured AAAs emerging from the present study: firstly, the adaptation of a protocol in high volume centers that provide vascular and endovascular services and secondly, the concept of "endovascular first approach" to the treatment of rAAAs in order to achieve the best we can in this vascular emergency situation.

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Figures

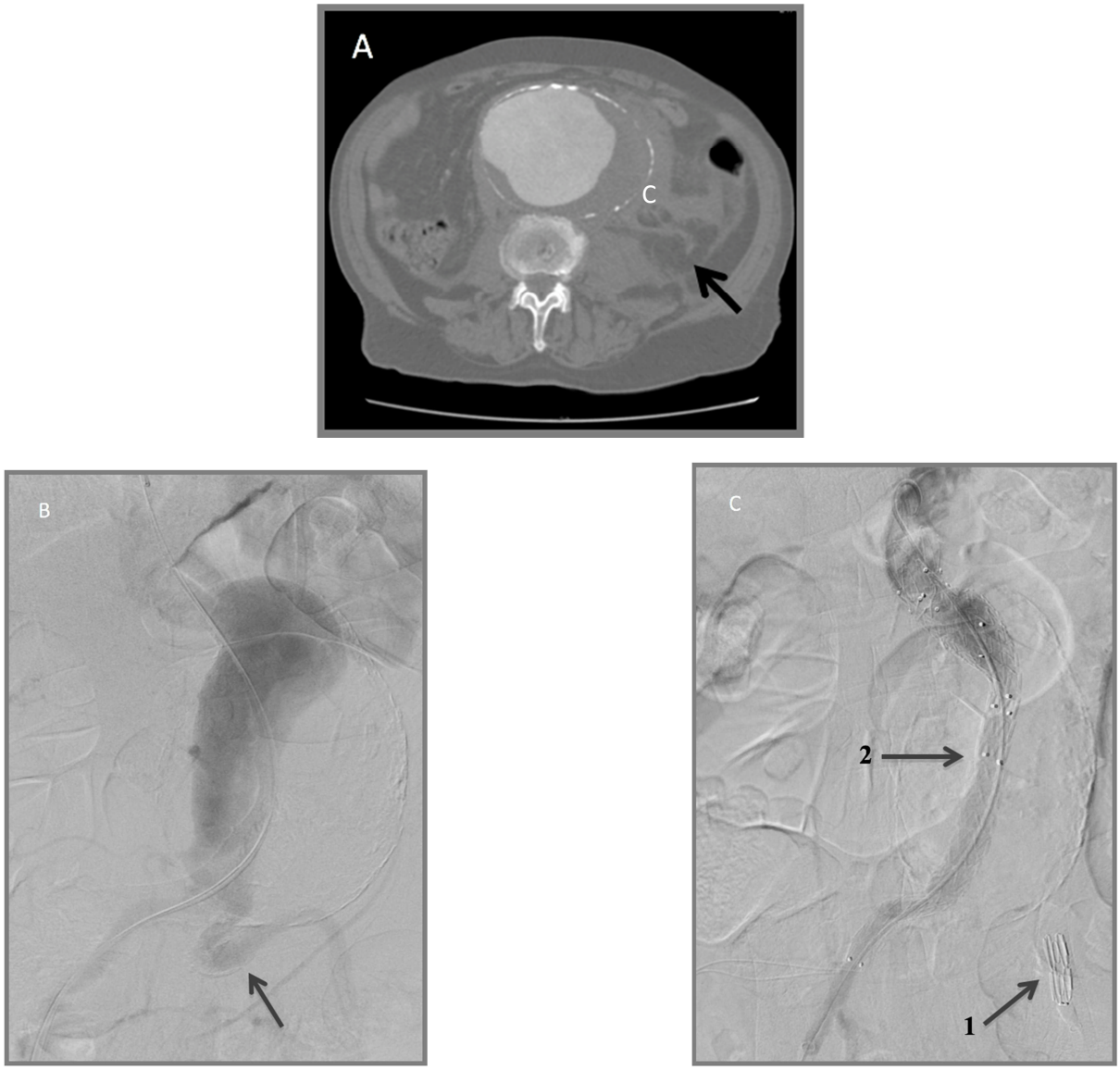

Figure 2. Endovascular treatment of rAAA: (A) Computed Tomography Angiography (CTA) showing the presence of a ruptured aneurysm of the abdominal aorta with retroperitoneal hematoma (arrow). (B) Intraoperative angiogram showing severe angulation of the left iliac artery (arrow). (C) Intraoperative angiogram showing an aorto-uniiliac stenting with Medtronic's Edurant II device (arrow 2) and the Talent^{TM}Occluder device (arrow 1)

Figure 3. Completion angiogram: The image shows the repaired ruptured abdominal aortic aneurysm with an Endurant II Medtronic's device. The stent graft deployment covers the main body and contralateral limb with an added extension graft to the left.