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ORIGINAL ARTICLE

Comparison Between Surgical and Endovascular Repair of Infra-renal Abdominal Aortic Aneurysm

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ABSTRACT

Background: Elective open repair (OR) and endovascular aneurysm repair (EVAR) are the 2 methods of infra-renal abdominal aortic aneurysm (AAA) repair. Each method has advantages and disadvantages. Aim of study was to compare both methods. **Patients and methods:** Prospective study was conducted at vascular surgery departments, Zagazig University Hospitals, Egypt and Alnoor Specialist Hospital, Makkah, Saudi Arabia from February 2015 to January 2020. Included patients were with asymptomatic AAA with diameter ≥ 5.5 cm or symptomatic. Patients underwent computerized tomographic angiography, echocardiogram, cardiac and chest consultation. **Results:** 14 patients underwent OR and 9 underwent EVAR. No statistically significant difference between both groups regarding demographics or aneurysm characteristics. In OR group mean age was 65.54 ± 4.44 years and mean aneurysm maximum diameter was 6.92 ± 0.55 cm, while in EVAR group mean age was 67.03 ± 5.31 years and mean aneurysm maximum diameter was 7.1 ± 0.3 cm. EVAR group had statistically significant less duration of procedure ($p < 0.001$), blood loss ($p < 0.001$), blood transfusions ($p = 0.003$), less ICU ($p < 0.001$) and hospital stays ($p < 0.001$). **Conclusion:** EVAR group had statistically significant less duration of procedure, blood loss, blood transfusions, ICU and hospital stay than OR group. No statistically significant difference between 2 groups regarding mortality. Second interventions were more in EVAR but did not reach statistical significance. Our study was limited by small number of patients and only 2 years follow-up. However, there is an evolving concept in literature that in low-risk patients, both procedures have nearly similar results with less reinterventions in OR, but for high risk patients EVAR may be preferred. So, selection between EVAR and OR should be tailored for each patient according to surgical risk, life span, aneurysm anatomy and patient choice.

Keywords: open surgical; endovascular; repair; abdominal aortic aneurysm.

1. INTRODUCTION

Abdominal aortic aneurysm (AAA) is dilatation of abdominal aorta by more than half its diameter or exceeding 3 cm. Annual risk of rupture was reported as 1–3% with diameter of 4–5 cm, 6–11% with diameter of 5–7 cm and 20% with diameter exceeding 7 cm. Predisposing factors for AAA comprise aging, hypertension, ischemic heart disease, hypercholesterolemia and smoking [1]. Surgical repair was the traditional management and indicated when diameter ≥ 5.5 cm, ≥ 2.5 times proximal diameter, annual growth > 1 cm, rupture or symptomatic aneurysm. Surgery requires long time of anesthesia and also for recovery, while

Endovascular aneurysm repair (EVAR) is safer for elderly patients especially with comorbidities e.g. ischemic heart disease and lung diseases [2]. In their study on 22,830 patients, Schermerhorn and colleagues found that mortality was less in EVAR patients than open repair (OR) patients especially in elderly patients, with better outcome for EVAR in chronic obstructive pulmonary disease (COPD) patients and less myocardial infarctions (MIs) in the first month postoperatively [3]. Indications for EVAR are the same as OR; but contraindications and success depend mainly on individual vascular anatomy. As EVAR is less invasive than OR, it results in less morbidity, more rapid recovery, and

shorter hospital stay. So EVAR is suggested to be more suitable for risky cases. But compared to OR proven durability and long-run results, still there are concerns about EVAR especially re-interventions rates and long-term advantage on survival [4]. The study aimed to compare results of elective EVAR and OR for patients of infra-renal AAA.

2. THE PATIENTS AND METHODS

We conducted our prospective study after approval of ethical committee at vascular surgery departments, Zagazig University Hospitals, Egypt and Alnoor specialist Hospital, Makkah, Saudi Arabia from February 2015 to January 2020. Our patients underwent history taking, physical examination, laboratory investigations, computerized tomographic angiography (CTA), echocardiography, cardiac, chest consultation. Patients were given fully informed consent.

Inclusion criteria

Asymptomatic AAA of 5.5 cm or more in diameter by CTA, or Symptomatic AAA.

Exclusion criteria:

We excluded suprarenal AAA, ruptured AAA and cases with unfavorable anatomy were excluded from EVAR (i.e. AAA with neck diameter <10 mm or > 40 mm or neck length <10 mm).

Endovascular Repair

Meticulous sizing and proper planning and are crucial for ideal EVAR. The size of stent-graft is determined by overestimating proximal and distal landing zones diameters by 10–20% for better sealing and prevention of endoleak. Under general anesthesia, 2 groin incisions were done for bilateral common femoral arteries (CFAs) exposure then IV heparin (5000 IU) were given. Insertion of main body delivery system (Endurant II stent graft (Medtronic, Inc., Minneapolis, MN, U.S.A.) over stiff guidewire (after exchange of hydrophilic guide wire), then contrast injection (through contralateral pigtail catheter with suitable projection) for accurate positioning just below the lower renal artery, then main body stent-graft was deployed. Then through contralateral CFA, cannulation of the gate by hydrophilic wire (and verifying its position surely) to be exchanged by stiff wire for contralateral limb insertion and deployment, then extension of ipsilateral limb with sparing both internal iliac arteries by ending just above. Then proximal and distal ends and overlap of stent-grafts were ballooned for better sealing and prevention of endoleak. Then completion angiography was done to exclude endoleaks (**Figure 1**).

Open Repair:

Under general anesthesia, the infrarenal abdominal aorta is approached through a transperitoneal approach through a midline laparotomy. The aneurysm neck is exposed by packing the bowel in the right abdomen and dividing the ligament of Treitz. IV heparin (5000 IU) was given before aortic clamping. Proximal vascular control is obtained by infrarenal aortic cross-clamping. Distal control is obtained by clamping both CIAs. Then sac is opened, removing thrombi, securing back-bleeding from inferior mesenteric artery (IMA) and lumbar vessels. The choice of graft configuration either tube (woven polyester (Dacron) collagen coated grafts (FlowWeave Bioseal, JOTEC GmbH, Hechingen, Germany) or bifurcated (Knitted polyester (Dacron) collagen coated grafts (FlowNit Bioseal, JOTEC GmbH, Hechingen, Germany) relies on the distal extension of the aneurysm. For prevention of colon ischemia, if an anastomosis distal to the CIA bifurcation is required, internal iliac artery (IIA) blood flow can be maintained by end-to-side anastomosis to the external iliac (EIA) or CFA allowing retrograde flow to IIA. After the aortic reconstruction is complete, the sac is closed around synthetic graft. Then after extubation, patient was transferred to Intensive Care Unit (ICU) till stabilization then to ward (**Figure 2**).

Follow up

Patients were followed up for 2 years, coming for clinical and aortic duplex assessment at 1,6,12,18,24 months. CTA was done for OR cases when suspecting graft occlusion or pseudoaneurysm but was routinely done for cases of EVAR at 1 month, 1 and 2 years.

3. STATISTICAL ANALYSIS

Continuous variables were expressed as mean \pm SD while categorical variables were expressed as number (percentage). Continuous data were checked for normality by using Shapiro Walk test. Independent samples Student's t-test was used to compare two groups of normally distributed data. Percent of categorical variables were compared using Pearson's Chi-square test or Fisher's exact test when was appropriate. Overall Survival (OS) was calculated as the time from procedure to death. A p-value <0.05 was considered significant. All statistics were performed using SPSS 22.0 for windows (SPSS Inc., Chicago, IL, USA) and MedCalc windows (MedCalc Software bvba 13, Ostend, Belgium).

4. RESULTS

From February 2015 to January 2020, 23 cases underwent elective repair of infrarenal AAA, 14 underwent OR and 9 underwent EVAR. No statistical difference between both groups regarding demographics, comorbidities, or aneurysm characteristics. In OR group there were 9 (64.3%) males, mean age was 65.54 ± 4.44 years and mean aneurysm maximum diameter was 6.92 ± 0.55 cm, while in (EVAR) group there were 6 (66.7%) males, mean age was 67.03 ± 5.31 years and mean aneurysm maximum diameter was 7.10 ± 0.30 cm. Patients demographics and comorbidities are summarized in (table 1) and aneurysm characteristics are summarized in (table 2).

In OR patients, aorto-aortic tube Dacron graft was used in 1(7.1%) patient, bifurcated aorto-biiliac grafts were used in 4(28.6%) patients and aorto-bifemoral were used in 9(64.3%) patients. While straight aorto-aortic stent-graft was used in 2(22.2%), bifurcated aorto-biiliac stent-graft was used in 7(77.8%) patients of the EVAR group.

EVAR group had statistically significant less operative time (153.23 ± 2.95 versus 298.00 ± 17.15 minutes; $p < 0.001$), less blood loss (190.89 ± 7.62 versus 945.00 ± 34.97 mL; $p < 0.001$) and less patients needed blood transfusions (33.3% versus 92.9%; $p = 0.003$), less ICU (2.10 ± 0.51 versus 6.30 ± 0.93 days; $p < 0.001$) and less hospital stays (4.70 ± 0.64 versus 17.01 ± 3.74 days; $p < 0.001$) (Table 3).

Technical success was 100% in both groups. Postoperative complications occurred in 3 patients

(21.4%) in OR group: (2 patients had acute MI and one of them died), and (one patient had bronchopneumonia). While postoperative complications occurred in 2 patients (22.2%) in EVAR group: one of them had acute lower limb ischemia and underwent embolectomy and the other had type Ib endoleak (defect of distal sealing) and was treated with stent-graft (table 4).

Primary outcome was all-cause mortality. Secondary outcomes were all-cause mortality and related second interventions. No patient died during the procedure. Overall (2 years) mortality was 21.4% (3 patients) in OR group; 1 patient died postoperatively during hospital admission (2 days postoperative due to myocardial infarction (MI)), while the remaining 2 patients died 5th and 16 months postoperative (i.e., 2 patients (14.3%) in the first year and 1 patient (7.1%) in the second year in OR group during the follow up period). While overall (2 years) mortality was 22.2% (2 patients) in EVAR group; no patients died during hospital admission or during the first month, while 2 patients died 7 and 18 months postoperative (i.e. one patient (11.1%) in the first year and 1 patient (11.1%) in the second year in EVAR group). There was no statistically significant difference between the 2 groups regarding mortality (table 5). Second interventions were more in EVAR but did not reach statistical significance (table 5).

Table 1; Patients demographics

Characteristics	OR (Number=14)		EVAR (Number =9)		p-value
	No.	%	No.	%	
<u>Gender</u>					
Male	9	64.3%	6	66.7%	1.000‡
Female	5	35.7%	3	33.3%	
<u>Age (years)</u>					
Mean \pm SD	65.54 \pm 4.44		67.03 \pm 5.31		0.475*
<u>Comorbidities</u>					
Hypertension	13	92.9%	7	77.8%	0.538‡
Smoking	11	78.6%	8	88.9%	1.000‡
Diabetes mellitus	10	71.4%	6	66.7%	1.000‡
Dyslipidemia	9	64.3%	5	55.6%	1.000‡
Coronary artery disease	4	28.6%	5	55.6%	0.383‡

Characteristics	OR (Number=14)		EVAR (Number =9)		p-value
	No.	%	No.	%	
COPD	3	21.4%	3	33.3%	0.643‡
Quantitative data were expressed as mean \pm SD (standard deviation), Qualitative data were expressed as number (percentage), ‡ Chi-square test or Fisher's exact test, * Independent samples Student's t-test.					

Table 2; Characteristics of the aneurysm

Characteristics	OR		EVAR		p-value
	(Number =14)		(Number =9)		
	No.	%	No.	%	
<u>Iliac aneurysm</u>					0.838‡
Unilateral	6	42.9%	5	55.6%	
Bilateral	2	14.2%	1	11.1%	
Absent	6	42.9%	3	33.3%	
<u>Maximum diameter of AAA (cm)</u>					0.404*
Mean ± SD	6.92 ± 0.55		7.10 ± 0.30		
<u>Proximal neck length (mm)</u>					0.179*
Mean ± SD	17.93 ± 0.68		18.71 ± 1.51		
Quantitative data were expressed as mean ± SD (standard deviation), Qualitative data were expressed as number (percentage). ‡ Chi-square test or Fisher's exact test; * Independent samples Student's t-test.					

Table 3; The perioperative data

Perioperative data	OR (Number =14)		EVAR (Number =9)		p-value
	No.	%	No.	%	
<u>Duration (min.)</u>					
Mean ± SD	298.00 ± 17.15		153.23 ± 2.95		<0.001*
<u>Blood loss (ml)</u>					
Mean ± SD	945.00 ± 34.97		190.89 ± 7.62		<0.001*
Blood transfusion needed	13	92.9%	3	33.3%	0.003‡
<u>ICU stay (days)</u>					
Mean ± SD	6.30 ± 0.93		2.10 ± 0.51		<0.001*
<u>Hospital stay (days)</u>					
Mean ± SD	17.01 ± 3.74		4.70 ± 0.64		<0.001*
Quantitative data were expressed as mean ± SD (standard deviation), Qualitative data were expressed as number (percentage), ‡ Chi-square test or Fisher's exact test, * Independent samples Student's t-test.					

Table 4; Postoperative complications

Postoperative complications	OR (Number =14)		EVAR (Number =9)		p-value‡
	No.	%	No.	%	
Acute MI	2	14.3%	0	0%	0.502
Bronchopneumonia	1	7.1%	0	0%	1.000
Acute lower limb ischemia	0	0%	1	11.1%	0.391
Type Ib endoleak			1	11.1%	
Qualitative data were expressed as number (percentage), ‡ Chi-square test or Fisher's exact test.					

Table 5; Clinical outcomes

Clinical outcomes	OR		EVAR		p-value	
	(Number =14)		(Number =9)			
	No.	%	No.	%		
Secondary interventions	0	0%		2	22.2%	0.142‡
<u>Mortality</u>						
1-month mortality	1	7.1%		0	0%	1.000‡
1-year mortality	2	14.3%		1	11.1%	1.000‡
Over all (2-year) mortality	3	21.4%		2	22.2%	1.000‡
<u>Overall Survival (OS)</u>						
Mean OS (days) (95%CI)	610.85 days (491.13–730.57)			643.33 days (536.73–749.93)		0.964§
1-month OS	92.9%			100%		
1-year OS	85.7%			88.9%		
Over all (2-year) OS	78.6%			77.8%		
Qualitative data were expressed as number (percentage), ‡ Chi-square test or Fisher’s exact test, § Log rank test.						

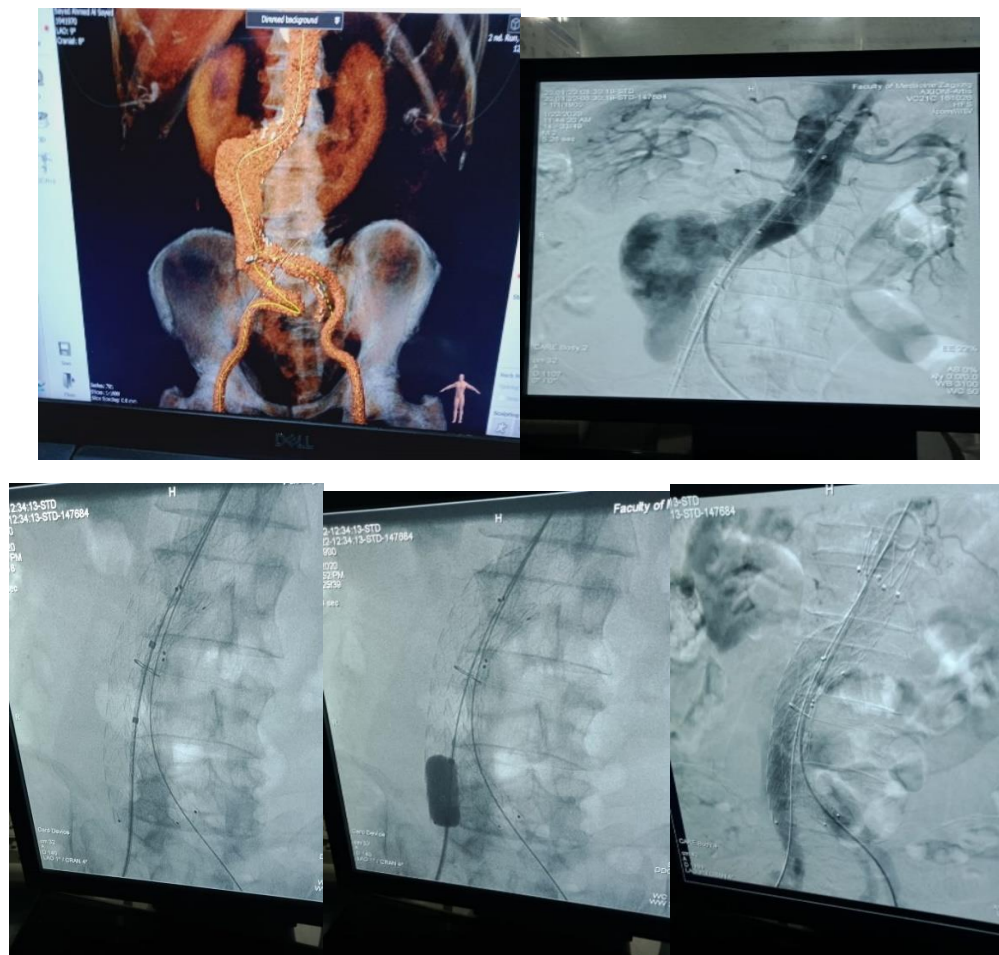


Figure1. A case of EVAR. (a): preoperative CTA. (b): aortogram for accurate positioning of main body below lower renal artery. (c): after deployment of main body and contralateral limb. (d): balloon dilatation of distal end for better sealing. (e): completion aortogram with no endoleak.

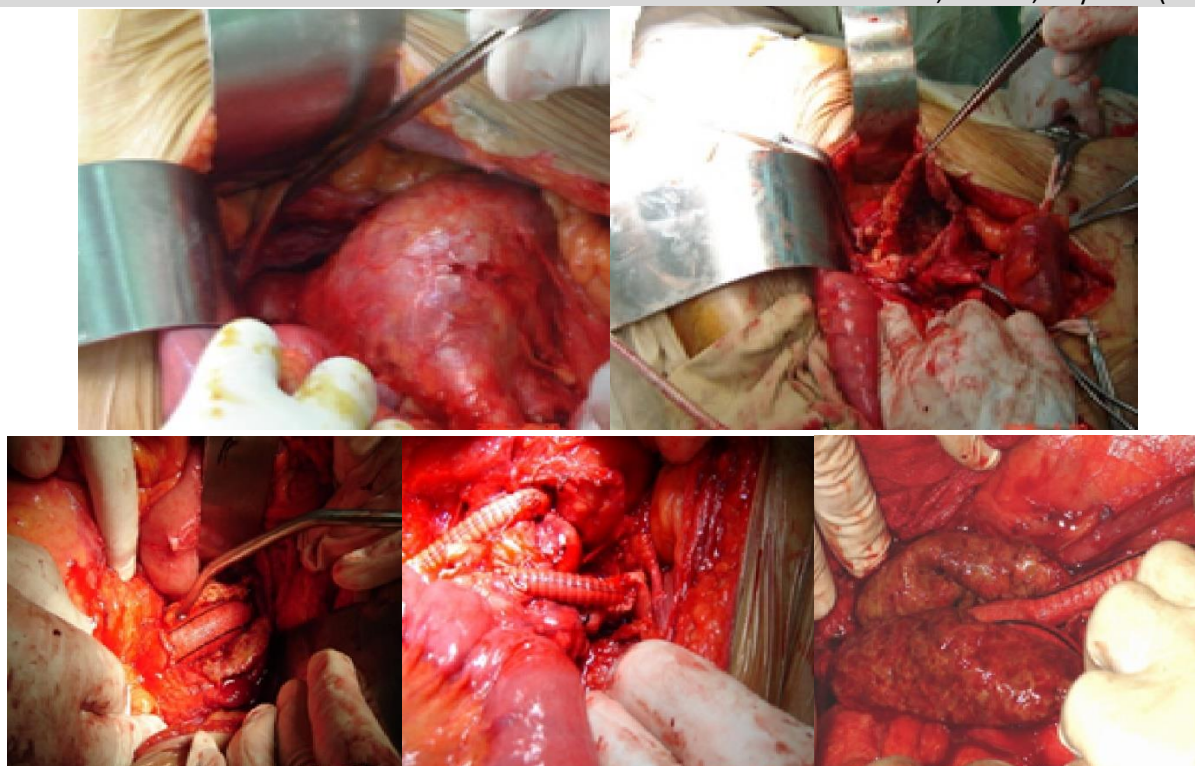


Figure 2: A case of open repair of AAA (Aorto-biiliac bypass). (a): before opening retroperitoneum. (b): opening of aneurysm after proximal and distal clamping. (c): after performing proximal anastomosis. (d): after performing distal anastomoses. (e): before closure of sac over synthetic graft.

5. DISCUSSION

Aim of AAA repair is to avoid fatal rupture. In 1991, EVAR was first presented by Parodi et al. as a less invasive technique, followed by continuous advancements of stent-grafts [5]. No significant difference in mortality or complications was found between endovascular and open repairs in patients of low or moderate risk. Selection between EVAR and OR should be tailored for each patient according to surgical risk, life span, aneurysm anatomy and patient choice, because each procedure has its risks. OR has longer procedure duration, hospitalization, and incision related sequelae, while EVAR needs CTA follow-up and possible reinterventions [6].

This study showed that there was no statistically significant difference between the 2 groups regarding mortality. Second interventions were more in EVAR but did not reach statistical significance. But endovascular repair had statistically significant less operative time (153.23 ± 2.95 versus 298.00 ± 17.15 minutes; $p < 0.001$), less blood loss (190.89 ± 7.62 versus 945.00 ± 34.97

mL; $p < 0.001$) and less patients needed blood transfusions (33.3% versus 92.9%; $p = 0.003$), less ICU (2.10 ± 0.51 versus 6.30 ± 0.93 days; $p < 0.001$) and less hospital stays (4.70 ± 0.64 versus 17.01 ± 3.74 days; $p < 0.001$). Postoperative complications were not significantly different between EVAR and OR groups over the 2 years.

Regarding UK EVAR 1 trial (UK Endovascular Aneurysm Repair 1) which involved 1082 cases (1999 - 2003), it showed statistically significant less first month mortality in endovascular repair (1.7% versus 4.7%, $P = 0.009$), and statistically significant less median procedure duration (180 vs 200 min, $P < 0.0001$) and hospital stay (7 vs 12 days, $P < 0.0001$) in endovascular repair [7]. At 4 years, endovascular repair had statistically significant less disease-specific mortality (4% vs 7% in OR, $P = 0.04$), but similar all-cause mortality (26% vs 29%, $P = 0.46$). But 4-8 years after the procedure, endovascular repair had statistically significant more aneurysm-related mortality (2.1% in EVAR vs 0.4% in OR, $P = 0.05$) [8]. Along the whole 8 years, all-cause mortality was similar, but second

interventions were more in endovascular group (5.1% vs 1.7%, $P < 0.001$) [9].

DREAM trial (Dutch Randomized Endovascular Aneurysm Management), which was done on 351 cases (2000 - 2003), demonstrated that 30-day mortality was 1.2% in endovascular repair and 4.6% in OR ($P = 0.1$). But endovascular repair had statistically significant shorter hospital stay (6 vs 13 days, $P < 0.001$), less first month complications (11.7% versus 26.4%, $P < 0.001$), but no statistically significant difference for combined severe complications and mortality (4.7% in endovascular repair and 9.8% in open repair ($P = 0.1$) [10]. Survival rates were similar after six years (68.9% in endovascular repair and 69.9% in open repair), but after six years, second interventions were significantly higher in endovascular repair than in open repair (29.6% vs 18.1%, $P = 0.03$), mostly were associated with stent-graft in endovascular repair and repair of incisional hernia and wound dehiscence in open repair [11].

In USA OVER (Open Versus Endovascular Repair) randomized trial, which was done on 881 cases (2002 - 2008), endovascular group had statistically significant less first month mortality (0.5% vs 3.0%, $P = 0.004$), less procedure duration (2.9 vs 3.7 hours, $P < 0.001$) and hospital stay (3 vs 7 days, $P < 0.001$). But after two years there was no significant difference in mortality (7% vs 9.8% in OR, $P = 0.13$), quality of life or second interventions. In spite that allover (up to 9 years; mean 5.2 years) mortality was similar between the 2 groups, EVAR subgroup <70 years had statistically significant less mortality than OR ($P = 0.04$) [12,13].

In French ACE (Anevrisme de l'aorta abdominale, Chirurgie vs Endoprothese) randomized trial, which was done on 316 cases (2003 - 2008), no significant difference in mortality after 3 years (endovascular 11.3% vs open repair 8%). But endovascular group had statistically significant higher second interventions (endovascular 16% vs open repair 2.7%, $P < 0.0001$) [14].

In a study done by Schermerhorn et al. in 2008 which was done on 61,598 Medicare beneficiaries (2001 - 2004), endovascular group had statistically significant lower mortality (1.2% vs 4.8%, $P < 0.001$) than open repair allover 3 years (especially for cases ≥ 85 years), but later no significant difference [15]. In spite that second interventions were more in endovascular patients all over four

years (9% vs 1.7%, $P < 0.001$), but open repair patients underwent much more hospitalizations without surgery for intestinal obstruction or hernia (14.2 % in OR vs 8.1% in EVAR, $P < 0.001$) and incision-related interventions (9.7% in OR versus 4.1% in EVAR, $P < 0.001$) [16]. Endovascular group had statistically significant shorter hospital stay (3.4 vs 9.3 days, $P < 0.001$) [17].

Eurostar (European Collaborators on Stent-graft Techniques for Abdominal Aortic Aneurysm Repair) registry showed that the 3% early survival advantage is lost after four years and surprisingly OR has survival advantage from 8 to 14 years, may be explained by late sac ruptures (may be due to employing the devices outside instructions for use) and abdominal malignancies (may be accused by repeated CTA). This, besides the higher costs for repeated CTA and second interventions, may resulted in draft NICE (National Institute for Health and Care Excellence) guidelines in May 2018 that do not recommend EVAR for unruptured infra-renal AAA when OR is suitable. This draft led to debates especially that it recommends EVAR in ruptured AAA [18].

It is claimed that mentioned studies were done earlier with older devices, but with continuous improvement of EVAR by time, better results regarding lower mortality and second interventions have been achieved [19].

Improvement includes development of new devices and advancement of imaging technology enabling CTA thinner slices and 3D reformation software allowing more accurate sizing and planning, moreover improvement of physicians learning curve. All of this resulted in improvement of outcomes when compared with results more than 10 years ago [20,21].

6. CONCLUSION

EVAR group had statistically significant less duration of procedure, blood loss and less patients needed blood transfusions, less ICU and hospital stay than OR group. No statistically significant difference between the 2 groups regarding mortality. Second interventions were more in EVAR but did not reach statistical significance. Our study was limited by small number of patients and only 2 years follow-up.

However, there is an evolving concept in literature that in low-risk patients with suitable anatomy for EVAR, both procedures have nearly similar results with less reinterventions in OR, but for high-risk patients EVAR may be preferred. So,

selection between EVAR and OR should be tailored for each patient according to surgical risk, life span, aneurysm anatomy and patient choice, because each procedure has its risks. OR has longer procedure duration, hospitalization, while EVAR needs CTA follow-up and possible reinterventions.

Conflict of interest

Authors report no conflict of interest.

Financial Disclosure

Authors report no financial Disclosures

Ethical approval

Institutional review boards' approval was obtained.

All authors shared all steps of research participation and article preparation. All authors have approved the final article.

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