

# Cost-effectiveness comparison between open repair (OR) and endovascular technique (EVAR) in AAA: 11 years follow-up of personal experience

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**Aim.** Clinical and economic analysis of perioperative and long-term results in EVAR vs. OR.

**Methods.** We have considered 373 AAA (204 OR and 169 EVAR) treated in elections between 1997 and 2008; all information about pre-operative and peri-operative outcome of patients were collected. For a specific long term analysis only 265 patient with 48 months follow-up were considered. Clinical outcome and mean cost of every radiological and therapeutical procedure were evaluated.

**Results.** In our experience perioperative morbidity and mortality was higher in OR vs. EVAR (10% vs. 3% and 2.5% vs. 0.4%, respectively), hospital stay was longer (13 days vs. 6 days) and rate of 30-days reoperation greater (6% vs. 2%). Perioperative cost of the procedures was 8 572 euro for OR and 15 917 euro for EVAR.

During 11-year follow-up none OR patient died for AAA related causes and 20 (13%) needed a re-operation for complications. Six EVAR patients (5%) died for problem related to the aneurysm and 32 (27%) underwent a second procedure. Six patients (5%) had a rupture. Mean cost of follow-up per year resulted 117euro for OR vs. 763 euro for EVAR.

**Conclusion.** EVAR appears better than OR in the perioperative period. Some doubts come out in consideration of different complications and reoperation that EVAR can present in long term follow-up. Peri- and post-operative mean costs are clearly in favour of OR. Perplexities about EVAR are evident and prudent indications to this procedures are necessary yet.

**KEY WORDS:** EVAR - Costs and cost analysis - Follow-up studies.

Since 1990s up today EVAR has demonstrated to be a safe and effective technique in the short-medium

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term follow-up. Randomized and controlled trials (RCTs) have shown endovascular procedure to be superior than the traditional surgical one (open repair, OR) in terms of morbidity and mortality.

Long-term results are not clear yet. None RCT with long term followup is available in the literature. Small and heterogeneous studies describe high risk of complications and re-operations, included surgical conversions; further doubts develop if high perioperative and postoperative costs are considered.

In this study we have analyzed our 11-years EVAR experience vs. the OR one; an accurate attention was focused on the perioperative and postoperative costs.

## Materials and methods

Since January 1994 to December 2008, 635 abdominal aorta aneurysms (AAA) were treated in our Vascular Institute in Verona, Italy.

Of these 518 were treated in election (284 OR and 234 EVAR). In this study we have considered 373 cases (204 OR and 169 EVAR) that underwent all pre-operative investigations in our hospital and that had all information about follow-up.

Demographic data, all preoperative investigations, kind of intervention, short and long-term follow-up have been considered, with all complications and endovascular and surgical re-operations; mean preoperative, operative and postoperative costs have been accurately calculated.

Each patient (OR or EVAR) underwent the same preoperative controls:

- angio-CT or in particular cases angio-MRI;
- Carotid and legs arteries Duplex Scan;
- ECG, Ultrasound Cardiologic Evaluation, Cardiologic Visit;
- chest X-Ray, Spirometry, and Pneumologic Visit;
- anaesthesia evaluation.

Indications to the surgical or endovascular treatment were given on AAA-characteristics, clinical status of patients and their preference and the skills of the surgeons, of course.

#### OR

All surgical procedures were conducted into general anaesthesia, with median laparotomy and the interposition of a straight or bifurcated graft, often in Dacron or sometimes in PTFE. Only in case of important comorbidities, patient was transferred in ICU (Intensive Care Unit) for a safe reawakening.

After the operation, all OR patients were followed with this program:

- Vascular visit after two months;
- Ultrasound in case of any complications;
- Other investigations only if necessary.

In consideration of the clinical and radiological reports, indications to re-operation were given

#### EVAR

At the beginning endovascular procedure was conducted in the operating theatre; afterwards a specific radiological theatre was preferred.

Different devices were used: AneuRx Medtronic, Edwards Lifepath, Quantum Cordis, Vanguard Boston Scientific, Talent Medtronic, Excluder Gore and Zenith Cook.

All EVAR patients were followed with this program:

- Angio-CT (with a previous blood check: hemochrome, renal and hepatic function) at one, six and 12 months and than once per year.

TABLE I.—OR vs. EVAR patients characteristics and comorbidities.

	OR N./%	EVAR N./%
<i>Patient characteristics</i>		
Total	204	169
Mean age	70,2 (50-85)	72,6 (52-89)
Male	194 (95%)	162 (96%)
Mean AAA-diameter (mm)	65,5 (40-110)	55 (32-110)
<i>Comorbidities</i>		
Cardiac	76/204 (37%)	89/169 (53%)
Respiratory	30/204 (15%)	39/169 (23%)
Renal	19/204 (9%)	18/169 (11%)
Tumor	21/204 (10%)	41/169 (24%)
Cerebrovascular disease	15/204 (7%)	15/169 (9%)
Previous laparotomy	12/204 (6%)	43/169 (25%)

- Closer follow-up in case of complications.

- Angio MRI if CT was contraindicated.

- Angiography only in case of particular complications or of a re-operation.

- Ultrasound for patients with long term follow-up without any previous radiological problems.

- Vascular visit after each radiological investigation.

All type I and III endoleak were treated with a cuff. Type II endoleak were treated in  $\geq 55$  mm aneurysms significantly increased ( $\geq 5$ mm) in diameter and in stable but big aneurysms ( $\geq 60$  mm): a percutaneous embolizations was tempted and a surgical conversion was conducted in case of failure with a continuous grove of the sac or of rupture.

Other endovascular or surgical treatments were performed on the bases of clinical and radiological reports.

For each technique peri-operative costs were calculated; in particular we have analysed mean costs of all instrumental investigations, surgical and endovascular procedures, hospital stay both in ward and in ICU (Intensive Care Unite), medical staff employed and management of short and long term follow-up.

With the aim to be specific as much as possible in the long term results we considered only 265 patients with a minimum 48-month follow-up, treated between 1997 and 2004.

In according with our Administration Offices, with the purpose to calculate the real sanitary costs including all the other general expenditure (offices and med-

TABLE II.—Complications and re-operations OR vs. EVAR.

Complications	OR (204- pts) Total complications	OR (204 pts) Re-operations	EVAR (169pts) Total complications	EVAR (169 pts) Re-operations
Respiratory	8	—	—	—
Cardiac	4	—	—	—
Renal	2	—	1	—
Neurologic	3	—	1	—
Abdominal	7	5 abdominal plastics 1 intestinal resection 1 intestinal de-rotation	—	—
Distal ischemia	3	3 embolectomy	1	1 embolectomy
Bleeding	2	2 surgical hemostasis	3	3 surgical hemostasis

In OR group 29 complications in 20 patients happened; 12 re-operations were necessary. In EVAR group 6 patients developed one complication; 4 re-interventions were done.

TABLE III.—Peri-operative mean OR costs in Euro.

Preoperative costs (clinical, radiological and laboratory diagnosis)	442
Operative costs (materials, staff and theatre)	2305
Hospital stay costs	3747
General company costs (32%)	2078
Total costs	8572

TABLE IV.—Peri-operative mean EVAR costs in Euro.

Preoperative costs (clinical, radiological and laboratory diagnosis)	442
Operative costs (materials, staff and theatre)	10247
Hospital stay costs	1086
Post-operative Angio-CT	284
General company costs (32%)	3858
Total costs	15917

ical facilities management, cleaning services etc.), it was necessary to add another 32% to our resulting costs.

## Results

### Perioperative results

Similar demographic data were found among both groups, with a superior pre-operative aneurysm mean diameter in the OR one (65 mm vs. 55 mm); EVAR patients had more comorbidities (Table I).

Mean hospital stay was six days in EVAR (range 2-29) of whom 0 in ICU vs. 13 (range 6-61) in OR of whom two in ICU.

Twenty OR-patients (10%) developed at least one post-op complication: 12 of them (6%) needed a re-operation.

Six EVAR-patients (3%) presented one complication: four of them (2%) needed a re-operation (Table II)

Peri-operative AAA-mortality was 2.5% in OR (7/284) vs. 0.4% in EVAR (1/234).

In consideration of preoperative investigations, recently available grafts, hospital stay and management of 30-days complications, mean cost for each patient resulted 8572 euro for OR vs. 15917euro for EVAR; each graft had got a specific weigh in the total expenditure (508euro vs. 8587euro respectively) (Tables III, IV).

### Long term results

In order to study long term results we considered only 265 patients (146OR and 119EVAR) treated between 1997 and 2004; in this way patients presented a 48-months minimum follow-up; maximum was 135, mean resulted 77 months.

### OR

Between 146 OR-cases, 20 (13%) underwent at least one re-operation; totally 24 re-operations were performed: in particular 14 laparocoele treated with abdominal plastic, 4 false-aneurysms treated with 2 bypass and 2 endovascular cuffs, 3 femoral hemody-

TABLE V.—Long term complication and reoperations in OR.

Complications	N. of patients	Re-interventions	Results
Laparocoele	14/146	14 abdominal plastic	ok
False aneurysms	4/146	2 endovascular cuffs 2 surgical bypass	ok
Critic limb ischemia	3/146	3 endoarterectomy (2 underwent abdominal plastic for laparocoele)	ok
Abdominal Occlusions	2/146	2 laparotomy and lysis (1 underwent endovascular exclusion of false aneurysm)	ok
Acute limb Ischemia	1/146	1 embolectomy (he also underwent abdominal plastic for laparocoele)	ok

In OR, 20 patients had at least one re-operation: 4 of them underwent two procedures in different time. Totally 24 re-operations were done.

TABLE VI.—Long term complications and re-operations in EVAR.

Complications	N. of patients	Notes
Endoleak	60/119	15EL I, 43EL II, 1EL III, 9 ELV (some pts had more than one EL)
Migrations	21/119	We have considered only $\geq 10$ mm migrations
Endovascular re-operations	27/119	12 cuffs, 12 embolizations, 2 PTA*, 1 regional fibrinolysis
Surgical re-operations	15/119	13 conversions, 1by-pass, 1 embolectomy
Ruptures	6/119	Only 3 with real 48mths fup
Deaths	6/119	Only 3 with real 48mths fup

32 patients underwent at least one re-operation; 8 patients had more than one re-operation: in particular 2 had two different endovascular procedures and then a surgical conversion, 2 had one endovascular procedures and then a conversion and 4 had two different endovascular procedures. Totally 42 re-operations were done. \*PTA: Percutaneous Tranluminal Angioplasty.

namic stenosis treated with surgical endarterectomy, 2 intestinal obstructions treated with laparotomy and lysis of adhesions, 1 acute limb ischemia treated with urgent embolectomy. Four patients underwent two procedures in two different moments (Table V).

None of 29 deaths (20%) was AAA-related.

Each patient had 3.36 surgical visits and 1.8 ultrasound investigations; only in few cases a CT was conducted.

In this group mean cost of follow-up was per year was 108euro, included the management of all complications occurred; total expenditure of the procedure up to the first year is 8689 euro and up to 11years of follow-up is 9 859 euro/patient.

#### EVAR

Into the group of 119 EVAR patients treated between 1997 and 2004 we had 68 endoleak in 60 patients (50%): in particular 15 type I, 43 type II, 1 type III and 9 type V-Endotension. All kinds of endoleak were counted also in case of transient one or uncertain image.

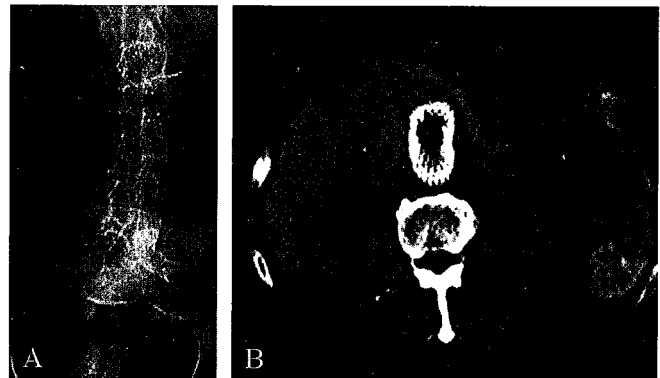


Figure 1.—Late AneuRx migration (A) and subsequent aneurysm rupture (B).

Significant migration ( $\geq 10$ mm) was observed in 21 cases (17%) (Figure 1A).

Six ruptures (5%) occurred but only three (2.5%) had a real 48-months follow-up (Figure 1-B).

32 patients (27%) needed at least one re-intervention: totally 27 endovascular procedures and 15 surgical operations were conducted; 13 conversions (11%)

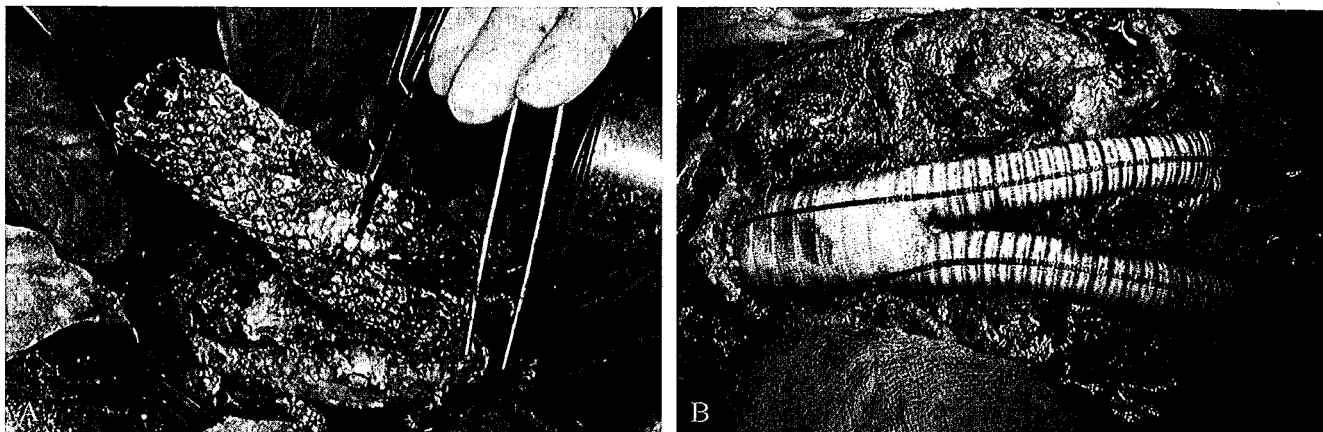


Figure 2.—Late surgical conversion for type I EL (A) and Dacron aorto-bisiliac interposition (B).

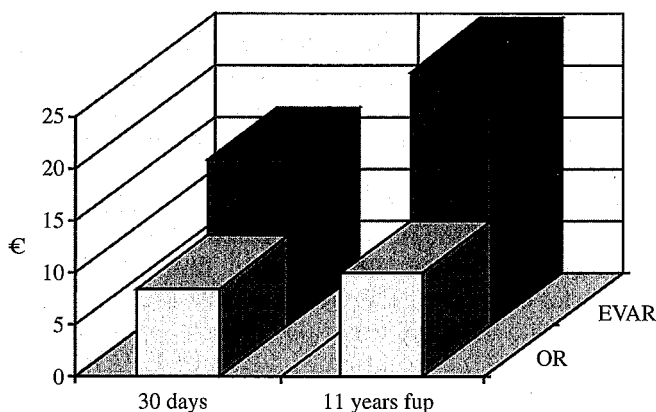


Figure 3.—Thirty days and 11 years follow up cost per patient of OR vs. EVAR.

were necessary: 8 in election and 5 in emergency for rupture (Figure 2). Only one patient died for complication after elective conversion while four died during emergent conversion for rupture.

Eight patients underwent more than one re-operation: in particular 2 had two different endovascular procedures and then a surgical conversion, 2 had one endovascular procedures and then a conversion and 4 had two different endovascular procedures (Table VI).

From 1997 to 2004 26 patients (22%) died of non AAA-related causes; in the same period we had six (5%) AAA-related deaths but only three (2.5%) with a real 4-years follow-up.

Each patient underwent one ultrasound, six angio-CT with a previous blood and urinary test (nitrogen,

creatinine, bilirubin and urinary Bence-Johns protein) and one vascular visit after any radiological investigation.

Mean follow-up cost per year was 763 euro/patient, included management of possible complications. Total expenditure of the procedure after the first year is 16 680 euro and after 11 years is 24 310 euro (Figure 3).

## Discussion

Up today perioperative morbidity and mortality benefit of EVAR vs. OR is clear; it is more evident if the hospital stay and psychological impact on patient are considered.

Different RCTs largely demonstrated superiority of the endovascular technique: lower morbidity (4.7% vs. 9.8%) and mortality (1.9% vs. 4.5%); shorter ICU and hospital stay (16 hours vs. 72 hours and 6 days vs. 12 days, respectively).<sup>1-5, 9, 10, 14</sup>

Perioperative satisfaction and psychological impact on the patients are on favour of EVAR.<sup>6-8</sup>

In this study we have obtained similar perioperative results.

Immediate EVAR advantage decreases if we consider perioperative costs: Blackhouse *et al.* estimate 22 791euro for endovascular technique vs. 13 230 euro for traditional surgery;<sup>28</sup> in a similar way EVAR 1 reports 13 524 euro vs. 11 505 euro respectively; this obvious difference is due to the relevant cost of the endovascular device (from 5 000 up to more than

10 000 euro) that can represent up to 50% of total procedure expenditure.<sup>1, 13</sup>

In our study we have considered only patients that underwent all preoperative investigations in our Hospital of whom we had all information about operation and 30 days outcome: we obtained 15 917 euro for EVAR vs. 8 572 euro for OR; mean endovascular device cost was 8 587 euro, 60% of total perioperative spending.

Further doubts come out if long term results are analyzed: AAA-related mortality remains apparently lower in EVAR (4% EVAR vs. 7% OR) but general mortality becomes equivalent in both techniques (26% EVAR vs. 29%OR);<sup>1</sup> it is probably due to important comorbidities that patients can develop during follow-up and to the usually compromised clinical conditions of EVAR patients.

In our groups we found equivalent rate of non AAA-related mortality (20% OR vs. 22% EVAR) but a peculiar aspect has been obtained in the related one: among patients with long follow-up (treated between 1997 and 2004) none of OR group died whereas six died in the EVAR one.

This result emphasizes that endovascular treatment is safe in the first period but the rupture and death can happen also after long time from the procedure. It looks like different from OR in which the risk of major complications and death is high only in the perioperative period.

Not only risk the of rupture and death increase during the years after EVAR but also the rate of other complications and re-operations: in our 11 years record 13% of OR group vs. 27% of EVAR group underwent at least one re-intervention and 11% were converted.

In literature rate of migration, rupture, re-intervention and conversion can be up to 4%, 2%, 20% and 8%, respectively.<sup>11, 12, 15-17</sup>

Some authors write that re-interventions are often endovascular and have low surgical risk and psychological impact for the patient.<sup>12</sup> We partially agree with this concept: it is important to underline that sometimes patients undergo more than one re-treatment and that their comorbidities increase during follow-up; these aspects expose them to a significant stress, a part from the kind of procedure. We must not forget that also elective surgical conversion, with its high risk of complications, can be necessary: one of our patients died peri-operatively after one of this.

On the other hand in the OR group a surgical re-operation is the usually required; in spite of this none of our patients died or developed severe complications after it.

It is necessary to underline that patients demonstrate a progressive difficulty to continue the controls, specially who develops complications and requires closer follow-up. High number of radiological investigations, risk of complications and the possible second or third procedure can cause fair, tiredness and disillusion in the patient who can finally refuse the follow-up.

Different papers are available in which a rapid convergence of quality of life between OR and EVAR patients is shown;<sup>6-8, 32</sup> not even from this point of view long term advantage of EVAR has been demonstrated.

Considerations about EVAR become worse if the long term management cost is analyzed: high number of complications and re-operations, high number of radiological investigations and the specific materials used in endovascular procedures make EVAR extremely expensive, more than OR. Hayter *et al.* calculated a mean cost of 713 euro/pt for EVAR vs. 40 euro/pt for OR;<sup>18</sup> Prissen *et al.* found out 2 594 euro after 5 years of EVAR vs. 6 949 euro of OR.<sup>29</sup> Similar data in many other papers<sup>4, 13, 28</sup> and in our record: 24 310 euro after 11 years of EVAR vs. 9 859 euro of OR.

Probably our results are influenced by outcome of old generation devices, AneuRx in particular: many complications and re-operations have been necessary in this group of patients.

Different authors reported disastrous results with old generation devices: Sampaio *et al.* have shown a direct relationship between AneuRx and risk of migration; Vaaramai *et al.* reported up to 90% of complications in EVAR patients.<sup>31</sup>

Up today none study with long term follow-up is available for new generation devices and a real comparison with OR is not possible yet.

Alternative radiological investigations for EVAR follow-up have to be defined: angio-TC remains the gold standard technique but possible long term effects of its ionizing radiations have to be cleared.<sup>19-22</sup>

In our Institute one study on Contrast Enhancement Ultrasound (CEUS) role is in progress: preliminary data show good sensitivity and accuracy on looking for

endoleak, especially in the dynamic evaluation, although a specific morphological image of aneurysm and the device is not possible.

Different authors consider CEUS a rapid, cheap, non-invasive and accurate investigation in EVAR follow-up, better than the traditional ultrasound.<sup>23-27</sup>

### Conclusions

On the bases of perioperative data, EVAR represents a sure and effective technique, better than OR in morbidity and mortality.

Nevertheless high rate of complications and re-operations during long term follow produces many perplexities.

Old patients, sometimes affected by different comorbidities, develop difficulties to continue follow-up and sometimes are exposed to one or more re-treatments, even the surgical conversion.

Finally costs of peri- and postoperative management of EVAR are extremely higher respect OR.

Old generation devices negatively influenced outcome, of course; clear long term results of new generation ones and reduction on costs are indispensable.

Meanwhile prudent indications to endovascular treatment are necessary.

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