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ABDOMINAL AORTIC ANEURYSM TREATMENT IN EMILIA ROMAGNA REGION

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ABSTRACT

Introduction

Elective endovascular repair (EVAR) of abdominal aortic aneurysm (AAA) has been performed with increasing frequency due to lower 30-day morbidity and mortality compared with open surgical repair(OSR). Similar advantages are reported for ruptured AAAs.

Aim of the study was to report the frequencies of EVAR/OSR in elective and acute setting and 30-day outcomes, in two Italian Vascular Surgery of Emilia-Romagna-Region(VS-ERR).

Methods

All patients undergoing AAA repair in two VS-ERR (2015-2019), were prospectively collected. Pre-operative, procedural and post-operative data were retrospectively analyzed.

Percentage of EVAR/OSR were evaluated for overall, elective and acute patients. Technical-success (TS), intra-operative mortality and procedure-related adverse events (PAE) were assessed. Reinterventions, mortality&morbidity were assessed at 30-day. Results of EVAR and OSR were compared. Reasons of EVAR ineligibility were also investigated and compared.

Results

Overall 878 patients underwent AAA repair, 736 in elective (EVAR/OSR:80.4%/19.6%) and 142 in acute setting (EVAR/OSR:71.1%/28.9%).

Overall TS was 95.8%, PAE were reported in 9.1% of patients. Overall intraoperative mortality was 0.5%. Post-operative medical complications were reported in 21.2% patients. The mean hospitalization was 6.7±11.08 days. Overall 30-day-reinterventions and mortality were 3.9% and 4.2%, respectively.

In elective-setting, TS was similar between groups(P=.18). OSR had more PAE(P<.001) vs EVAR. There was no difference of intraoperative mortality(P=.62). EVAR had shorter hospitalization(P<.001), less 30-day reintervention(P<.001) and mortality(P<.001) vs OSR.

In acute-setting, no significant differences of TS(P=.56) and PAE(P=.18) between groups were observed. OSR had more perioperative medical complications(P<.001) and higher rate of 30-day mortality(P<.001) vs EVAR.

The main reason of EVAR exclusion was anatomical unsuitability(94.4%) in elective-setting while logistic cause(61%) in acute-setting.

Conclusion

EVAR has progressively increased for elective more than for acute setting. The misalignment of the VS-ERR from literature evidence in acute setting is principally due to logistic reason. According our data, the management of this subgroup of patients, should be improved.

INTRODUCTION

In the last decades, elective endovascular repair (EVAR) of abdominal aortic aneurysm (AAA) has been performed with increasing frequency [1] due to lower 30-day morbidity and mortality compared with those of open surgical repair (OSR) [2 - 6]. According to these results, there is a wide consensus to favour of elective EVAR in elderly and high-risk patients while its role in young patients is still debated [8 - 10]. However, one should consider that most of the randomized controlled trials report long-term results of first generations endografts, which have been replaced by more efficient devices [11].
Similar advantages are reported for the endovascular management of ruptured AAAs (r-AAAs). International Societies of Vascular Surgery (American, European) recommend EVAR over OSR for treatment of a r-AAA, if it is anatomically feasible [12, 13]. Unfortunately, this is not always possible in the real life due to hospitals logistic organization and costs. The aim of the present study was to report the frequencies of EVAR / OSR in elective and acute setting and their 30-day outcomes in two Italian University Vascular centers of Emilia Romagna Region.

METHODS

Study design and patient' selection

It was a voluntary, observational, multicenter and retrospective study. Between January 2015 and June 2019, all patients undergoing EVAR or OSR for elective and acute AAAs in two Italian Vascular Surgery Centers of Emilia Romagna Region (Bologna, Parma) were prospectively collected in local databases. Cases were clustered in a dedicated shared electronic database and retrospectively evaluated. According to the European General Data Protection Regulation (GDPR), all cases were deidentified with a coding number. The study was approved by the local Institutional Review Board. Demographics, pre-operative co-morbidities, anatomical features, procedural and post-operative data were retrospectively analyzed. No funding was obtained from companies or other institutions for conducting the present study.

Endpoints and definitions

Percentage of EVAR and OSR cases were evaluated for overall, elective and acute patients, respectively. Technical success, intra-operative mortality and procedure-related adverse events were assessed as procedural outcomes. Reinterventions, mortality, cardiac, pulmonary and nephrological morbidity were assessed at 30-day. EVAR and OSR results were compared.

Reasons of EVAR ineligibility were also investigated and compared between elective and acute setting.

Acute cases were defined as patients treated in urgent or emergency setting. Urgent repair was performed for symptomatic (abdominal / back pain) patients, radiological contained AAA ruptures or rupture with stable hemodynamic parameters. Emergency repair was defined in presence of hemodynamic instability.

Technical success was defined as a completed procedure with no 24-h mortality or reinterventions, correct endograft positioning with the absence of type I-III endoleak and stenosis/occlusion of iliac limb.

Procedural related adverse events (PAE) were any complications required unplanned adjunctive maneuvers or reinterventions.

Endoleaks were defined according with the classification reported by White and May [14].

Chronic kidney disease (CKD) was defined as eGFR < 60 mL/min/1.73 m^2 based on the National Kidney Foundation/Kidney Disease Outcome Quality Initiative (NKF/KDOQI) [15]. Perioperative renal function worsening was defined as e-GFR reduction >25% of the preoperative value according

with the RIFLE (Risk, Injury, Failure, Loss of kidney function, End-stage renal disease) classification [16].

Cardiac and pulmonary morbidity was defined as any cardiac or pulmonary events that required adjunctive surgical or medical therapies or a prolonged hospitalization.

Statistical analysis

Continuous variables were reported as a mean and standard deviation (SD). Categorical variables were expressed as frequencies. Fisher's exact and Mann-Whitney tests were used to compare technical success, 30-day outcomes and any differences between the EVAR and OSR groups. All the statistical tests were two-sided and p values ≤ 0.05 were considered as statistically significant. Statistical analysis was performed by SPSS 23.0 for Windows (SPSS Inc, Chicago, IL, USA).

RESULTS

Overall patients

During the study period, overall 878 patients underwent treatment for Abdominal Aortic Aneurysm in two Vascular Surgery Unit of the Emilia Romagna Region. Among those, 535 (61%) patients were treated by the Vascular Surgery Unit of the Policlinico S.Orsola - Malpighi of Bologna and 343 (39%) were treated by the Vascular Surgery Unit of the Azienda Ospedaliero - Universitaria of Parma.

Overall, 693 (79%) patients underwent EVAR and 185 (21%) patients underwent OSR, treatments distribution is shown in **Figure 1**.

Elective AAA repair were performed in 736 (84%) patients, while urgent/emergent treatments were performed in 142 (16%) patients, 51 (5.8%) of whom were hemodynamically unstable at the time of the operation. The treatment setting is shown in **Figure 2**.

Mean age was 75.5 ± 7.7 years (range 49-100), male patients were 786 (89%) and mean AAA diameter was 58.6 ± 15.5 cm. All demographics and clinical details were reported in Table 1.

Technical Success was achieved in 840 (95.8%) cases. Procedure related adverse events (PAE) were reported in 79 (9.1%) patients.

Overall intraoperative mortality was 0.5% (4 patients). Post-operative medical complications were reported in 186 (21.2%) patients, in particular Cardiac, pneumological and nephrological complications were detected in 45 (5.1%), 50 (5.7%) and 37 (4.2%) patients, respectively.

The overall mean length of stay was 6.7 ± 11.08 days.

Overall 30-day reintervention and 30-day mortality were 3.9% (34 patients) and 4.2% (37 patients).

Elective treatments

Overall, 736 patients underwent AAA elective repair, 592 (80.4%) patients by EVAR and 144 (19.6%) patients by OSR technique, treatments distribution in elective patients is shown in **Figure 3**. Among those, 435 (59.1%) patients were treated by the Vascular Surgery Unit of the Policlinico S.Orsola - Malpighi of Bologna and 301 (40.9%) were treated by the Vascular Surgery Unit of the Azienda Ospedaliero - Universitaria of Parma.

Mean age was 74.9 ± 7.4 years, male patients were 668 (90.8%) and mean AAA diameter was 57.4 ± 12.8 mm. All demographics and clinical details were reported in Table 1.

Technical success was achieved in 713 (96.9%) cases and procedure related AE were reported in 54 (7.3%) of patients.

Overall intraoperative mortality was 0.1% (1 patient). Post - operative medical complications were reported in 126 (17.1%) patients, in particular cardiac, pneumological and nephrological complications were detected in 32 (4.3%), 34 (4.6%) and 24 (3.3%) patients, respectively.

The overall mean length of stay was 6.19 ± 10.1 days.

Overall 30-day reintervention and 30-day mortality were 2.9% (21 patients) and 2.0% (15 patients), respectively.

Intra and perioperative results were reported in Table 3.

Comparison between OSR and EVAR repair in elective setting

The rate of Open/EVAR repair in elective setting in Bologna and Parma was significantly different, 12.9% (56 patients) and 87.1% (379 patients) respectively, underwent Open repair and EVAR AAA repair in Bologna and 29.2 (88 patients) and 70.8% (213 patients) respectively, underwent Open repair and EVAR AAA repair in Parma (P < .001).

There was not significant difference of age between groups, patients underwent EVAR repair had a smaller AAA diameter (56.4 ± 11.6 mm vs 61.1 ± 16.1 mm, P < .001), were more affected by atrial fibrillation (13.2% vs 4.9%, P = .005), chronic renal failure (33.3% vs 22.9%, P = .01) and obesity (21.3% vs 13.2%, P = .02) if compared with Open repair. Comparison of demographics and comorbidities was summarized in Table 1.

No significant difference in term of technical success (98.6% in Open repair and 96.5 in EVAR, P= .18) between groups were observed. Patients underwent OSR had more procedure related AE (15.3% vs 5.5%, P < .001), required more post-operative intensive care (100% vs 13.5%, P < .001) and had more perioperative medical complications (40.3 % vs 11.5 %, P < .001), in particular they had more cardiac (9.0 % vs 3.2 %, P=.002), pneumological (15.3 % vs 2 %, P<.001) and nephrological (11.1 % vs 1.4 %, P<.001) complications if compared with EVAR repair.

There was no difference between groups in term of intraoperative mortality (P = .62). Patients underwent elective EVAR had shorter length of stay (4.6 ± 6.5 days vs 12.5 ± 17.2, P < .001), less 30 - day reintervention (1.4 % vs 9.0 %, P < .001) and 30 - day mortality (0.8 % vs 6.9 %, P < .001).

Comparison of intra and perioperative results between groups were reported in Table 3.

Urgent / Emergency treatment

Overall, 142 patients underwent AAA urgent / emergent repair, of those 51 (35.9%) patients were hemodynamic unstable and were treated in emergency.

Endovascular repair was performed in 101 (71.1 %) patients and Open repair in 41 (28.9 %) patients, treatments distribution in acute patients is shown in **Figure 4**.

Among those, 100 (70.4%) patients were treated by the Vascular Surgery Unit of the Policlinico S.Orsola - Malpighi of Bologna and 42 (29.6 %) were treated by the Vascular Surgery Unit of the Azienda Ospedaliero - Universitaria of Parma.

Mean age was 78.68 ± 8.9 years, male patients were 118 (83.1%) and mean AAA diameter was 65.5 ± 24.9 mm. All demographics and clinical details were reported in Table 1.

Technical success in urgent / emergent AAA treatment was achieved in 127 (90.1%) cases. Procedure related AE were reported in 25 (17.6%) patients.

Overall intraoperative mortality was 2.1% (3 patients). Post-operative medical complications were reported in 61 (43.0 %) patients, in particular cardiac, pneumological and nephrological complications were detected in 13 (9.2%), 16 (11.3%) and 13 (9.2%) patients, respectively.

The overall mean length of stay was 9.85 ± 14.8 days.

Overall 30-day reintervention and 30-day mortality were 9.2% (13 patients) and 15.5% (22 patients), respectively.

All intra and perioperative results were summarized in Table 3.

Comparison between OSR and EVAR repair in urgent / emergent setting

The rate of OSR / EVAR repair in urgent / emergent setting was similar in Bologna and Parma (P = .64), 30% and 26.2 % of patients underwent OSR and 70% and 73.8 % underwent EVAR, respectively.

There were not significant differences of age and AAA diameter between groups. Patients underwent EVAR repair were more affected by hypertension (90.1% vs 73.2%, P = <.001). Comparison of demographics and comorbidities between groups was summarized in Table 1.

No significant differences in term of technical success (87.8% in OSR and 91% in EVAR, P= .56) and of procedure related AE (24.4% in OSR and 15% in EVAR, P= .18) between groups were observed.

Patients underwent OSR required more post-operative intensive care (100% vs 58.4%, P < .001) and had more perioperative medical complications (80.5 % vs 27.7 %, P < .001), in particular they had more pneumological (22.0 % vs 6.9 %, P<.01) complications if compared with EVAR repair.

There was no difference between OSR and EVAR in terms of intraoperative mortality (4.9 % vs 1.0 %, P= .14) length of stay (13.4 ± 14.3 days vs 8.0 ± 14.0, P<.22) and 30 - day reintervention (12.2 % vs 7.9 %, P.42). Patients underwent urgent / emergent OSR had higher rate of 30 - day mortality (31.7 % vs 8.9 %, P<.001) if compared with EVAR.

Comparison of intra and perioperative results between groups were reported in Table 3.

Emergency treatment in hemodynamic instable patients

Overall, 51 patients underwent emergency AAA repair and were hemodynamic unstable at the time of the operation, 52.9% (27 patients) and 47.1% (24 patients) respectively, were treated in Bologna and Parma.

EVAR was performed in 23 (45.1 %) and OSR in 28 (54.9 %) patients.

Mean age was 78.5 ± 9.4 years, male patients were 43 (84.3%) and mean AAA diameter was 68.2 ± 28.2. All demographics and clinical details were reported in Table 1.

Technical success in hemodynamic unstable patients was achieved in 42 (82.4%) cases. Procedure related AE were reported in 18 (35.3%) patients.

Overall intraoperative mortality was 5.9% (3 patients). Post-operative medical complications were reported in 39 (76.5 %) patients, in particular cardiac, pneumological and nephrological complications were detected in 6 (11.8%), 112 (23.5%) and 7 (13.7%) patients, respectively.

The overall mean length of stay was 16.5 ± 9.4 days.

Overall 30-day reintervention and 30-day mortality were 15.7% (8 patients) and 39.2% (20 patients), respectively.

Intra and perioperative results were reported in Table 3.

Comparison between emergency OSR and EVAR repair in hemodynamic unstable patients

The rate of ORS / EVAR repair in hemodynamic unstable patients in Bologna and Parma was significantly different (P < .004), 74.1% (20 patients) and 25.9% (7 patients) underwent OSR and EVAR respectively in Bologna, and 33.3 % (8 patients) and 66.7 % (16 patients) underwent OSR and EVAR respectively, in Parma.

Comparison of demographics and comorbidities between groups was summarized in Table 1.

No significant difference in term of technical success (82.1% in OSR and 82.6 in EVAR, P= 1.00) and procedure related AE (32.1% in OSR and 40.9 in EVAR, P= .52) between groups were observed.

Patients underwent OSR required more post-operative intensive care (100% vs 82.6%, P = .02) and had more perioperative medical complications (89.3 % vs 60.9 %, P = .01) but there were no differences between groups in term of intraoperative mortality (7.1% in Open repair and 4.3 in EVAR, P= .63), 30 - day reintervention (17.9 % in Open repair vs 13.0 % in EVAR, P<.63), 30 - day mortality (46.4 % in Open repair vs 30.4% in EVAR, P<.24) and length of stay (14.4 ± 17.05 days vs 19.2 ± 29.03, P=.30)

Comparison of intra and perioperative results between groups were reported in Table 3.

Overall EVAR treatment

During the study period, 693 patients underwent EVAR, 449 (64.8%) patients were treated in Bologna and 244 (35.2%) in Parma.

Among those, 592 (85.4%) patients underwent elective and 101 (14.6%) underwent urgent /emergent EVAR. Urgent/emergent EVAR in condition of hemodynamic instability was performed in 23 (3.3%) patients.

Mean age was 76.5 ± 7.4 years, male patients were 620 (89.5%) and mean AAA diameter was 57.4 ± 13.8 mm. All demographics and clinical details were reported in Table 2.

Technical Success was achieved in 662 (95.7%) cases. Procedure related AE were reported in 49 (6.9 %) patients.

Overall intraoperative mortality was 0.3% (2 patients). Post-operative medical complications were reported in 196 (13.9%) patients, in particular cardiac, pneumological and nephrological complications were detected in 29 (4.2%), 19 (2.7%) and 15 (2.2%) patients, respectively.

The overall mean length of stay was 5.18 ± 8.3 days.

Overall 30-day reintervention and 30-day mortality were 2.3% (16 patients) and 2% (14 patients).

Comparison between elective repair and urgent/emergent EVAR

Female sex was significantly more frequent in urgent / emergent (18.8%) than in elective (9.1%) cases (P = .007). Statin therapy was less common in patients underwent urgent/emergent EVAR (50.5% vs 64.9%, P = .007). Patients underwent elective EVAR were significantly younger (75.9 ± 7.1 years vs 79.9 ± 8.5 years, P= .03) and had a smaller AAA (56.4 ± 11.6 mm vs 63.9 ± 22.4 mm, P< .001) at the time of the operation if compared with patients in urgent/emergent setting. Comparison of demographics and comorbidities was summarized in Table 2.

Technical success was significantly different between groups (91.0% in urgent/emergent EVAR and 96.5% in elective EVAR, P=.01). Patients underwent urgent/emergent EVAR had more procedure related AE (15.0% vs 5.5%, P = .002), required more post-operative intensive care (58.4% vs 13.7%, P < .001) and had more perioperative medical complications (27.7 % vs 11.5 %, P <.001), in particular they had more cardiac (9.9 % vs 3.2 %, P=.005), pneumological (6.9 % vs 2 %, P=.013) and nephrological (6.9 % vs 1.4 %, P=.003) complications if compared with elective EVAR.

There was no difference between groups in term of intraoperative mortality (1% in urgent/emergent EVAR and 0.2% in elective EVAR, P= .27). Patients underwent elective EVAR had shorter length of stay (4.6 ± 6.5 days vs 8.3 ± 14.8 days, P<.001), less 30 - day reintervention (1.4 % vs 7.9 %, P=.001) and 30 - day mortality (0.8 % vs 8.9 %, P<.001) if compared with acute EVAR.

Comparison of intra and perioperative results between groups were reported in Table 4.

Overall OSR treatments

During the study period, 185 patients underwent OSR for AAA, 99 (53.5%) patients were treated in Bologna and 86 (46.5%) in Parma.

Among those, 144 (77.8%) patients underwent elective and 41 (22.2%) urgent/emergent OSR. Emergent OSR in condition of hemodynamic instability was performed in 28 (15.1%) patients.

The reasons of EVAR exclusion were anatomical in 154 (83.2%) patients and logistic in 26 (14%) patients.

Mean age was 71.6 ± 7.5 years, male patients were 166 (89.7%) and mean AAA diameter was 62.9 ± 20.1 cm. All demographics and clinical details were reported in Table 2.

Technical Success was achieved in 178 (96.2%) cases. Procedure related AE were reported in 32 (17.3 %) patients.

Overall intraoperative mortality was 1.1% (2 patients). Post-operative medical complications were reported in 90 (48.6%) patients, in particular cardiac, pneumological and nephrological complications were detected in 16 (8.6%), 31 (16.8%) and 22 (11.9%) patients, respectively.

The overall mean length of stay was 12.6 ± 16.6 days.

Overall 30-day reintervention and 30-day mortality were 9.7% (18 patients) and 12.4% (23 patients).

Comparison between elective and urgent / emergent OSR

The rate of elective OSR repair was significantly higher in Parma (73.2%) then in Bologna (38.9%) while urgent / emergent OSR repair was significantly more frequent in Bologna (61.1%) then in Parma (26.8%), ($P < .001$).

Elective patients were more affected by dyslipidemia (63.9% vs 39%, $P = .007$) by hypertension (88.9% vs 70.7%, $P = .01$) and had a smaller AAA at the time of operation (61.1 ± 16.1 mm vs 69.5± 30.1 mm, $P < .001$) if compared with urgent/emergent cases. Comparison of demographics and comorbidities was summarized in Table 2.

Patients underwent OSR in elective setting were excluded by EVAR treatment more frequently for anatomical reason (94.4%) than logistic reason (43.9%) ($P< .001$), while in urgent/emergent setting patients were excluded by EVAR treatment more frequently for logistic reasons (61%) than anatomical reason (0.7 %) ($P < .001$).

Technical success was higher in elective OSR (98.6%) than in urgent/emergent OSR (87.8%, $P=.006$). No difference of procedure related AE was observed between elective and urgent/emergent OSR (15.3% vs 24.4%, $P =.24$). Patients treated in urgent/emergent setting had higher rate of

intraoperative mortality (4.9% vs 0%, P= .04), had more perioperative medical complications (80.5 % vs 40.3 %, P < .001), if compared with elective OSR.

No differences in terms of length of stay (12.5 ± 17.2 days vs 13.4 ± 14.3, P = .70) and 30 - day reintervention (9.0 % vs 12.2 %, P = .55) were observed between elective and urgent/emergent treatments, respectively.

Patients underwent urgent/emergent OSR had significantly higher rate of 30 - day mortality (31.7 % vs 6.9 %, P < .001).

Comparison of intra and perioperative results between groups were reported in Table 4.

Distribution of treatments during the study period

Overall EVAR / OSR rate remained nearly stable between 2015 and Jun 2019, as shown in Figure 5. During the study period, overall number of EVAR procedure has been slight increased and we observed a mild growth from 4% to 25% of EVAR procedure performed in acute setting (see **Figure 6**).

Overall number of OSR procedures performed per year remained stable, but the percentage of urgent / emergent OSR has been progressively reduced during the time, from 35% to 18% (see **Figure 7**).

Procedures in urgent / emergent setting were performed mostly by OSR in 2015 (OSR: 67% vs EVAR: 33%), while mostly by EVAR in 2019 (OSR: 19 % vs EVAR:81%) (See **Figure 8**).

DISCUSSION

In this study we reported the perioperative results of all patients underwent EVAR and OSR for elective and acute AAAs in two Italian Vascular Surgery Centers of Emilia Romagna Region, between 2015 and 2019.

Our result showed that in elective setting, the overall EVAR / OSR rate is 80% and 20%, respectively. EVAR patients had better results in terms of perioperative procedure related adverse events, medical complications, shorter hospitalization, 30-day reinterventions and 30-day mortality, then OSR.

The advantage of EVAR in perioperative mortality is in line with literature results, as reported also by Greenhalgh RM at al.[6] Differently from EVAR1 trial [6] we also reported less perioperative reinterventions in EVAR than in OSR.

The worst perioperative results in OSR could be due to the more complex anatomy of those patients. In our study in fact, patients underwent elective OSR had significantly bigger AAA than elective EVAR group and the anatomic unfeasibility was the main reason (94.4%) of EVAR exclusion in this subgroup of patients.

In urgent / emergent setting, the overall rate EVAR / OSR is 70% and 30% respectively. The rate has progressively grown during the years from 33% and 67% in 2015 to 81% and 19% in 2019.

The EVAR group showed better results in terms of perioperative medical complication and 30 – day mortality, compared with OSR.

Some studies [17, 18] in literature suggest the benefit of EVAR in urgent / emergent condition, even if the conclusions on this topic are currently limited by the paucity of data [19].

Nevertheless, a real advantage in literature is represented by the use of EVAR in hemodynamic unstable patients, associated with the use of the endo-clamping balloon technique. [20] A meta-analysis of 39 studies documented that a total of 200 of 1277 patients (14.1%) required endo-clamping balloon. Mortality was significantly lower in studies with a higher rate of endo-clamping balloon use, suggesting that the use of an endo-clamping balloon in unstable ruptured AAA patients undergoing EVAR may improve the results. According these results, the ESVS guidelines [12] suggest EVAR with aortic endo-clamping as first line treatment in ruptured AAA with hemodynamic instability.

In our experience, if we look to the subgroup of hemodynamic unstable patients, patient underwent EVAR had significantly lower incidence of perioperative medical complication but we didn't observe a true advantage of EVAR in terms of 30 - day mortality and 30 - day reintervention.

A possible reason could be the small sample of patients of this subgroup, moreover in our experience the rate EVAR /OSR in ruptured AAA in unstable patients is 45% and 55%, respectively.

The major part of the patients in emergency has been treated by OSR and the main reason of exclusion from EVAR treatment for this subgroup of patients was due to logistic causes.

This data suggests that some improvement in the diagnostic therapeutic process is required in order to ameliorate the treatment of this particular subgroup of patients.

LIMITS

This is a multicentric retrospective observational studies with the aim to reflect the real-world experience. The strongest limitation is given by the retrospective nature that may carry possible selection bias, another limit is the absence of information about the specific details of the anatomies of patients.

CONCLUSION

The overall EVAR /OSR ratio is 80% vs 20%, respectively. In the study we observed a progressive increase of the EVAR and a reduction of the OSR treatment over the years. This trend is justified by the improved peri-operative mortality results of EVAR treatment compared with OSR.

In elective setting, the trend is in line with the literature data, on the contrary in urgent/emergent setting, although we reported a progressive increase of the EVAR treatments, the management of the AAA is not entirely in line with the indications of the guidelines of the European and American Societies of Vascular Surgery (ESVS and SVS).

The analysis of the causes of exclusion of emergency EVAR treatment showed that the main reason was logistic. This can suggest that an improvement in the management of this subgroup of patients, is needed.

TABLES

Table I. Preoperative demographics, clinical and morphological characteristics of patients treated for Abdominal Aortic Aneurysm in Elective, Urgent /emergent and hemodynamic unstable setting

Characteristic	**Overall**	**Elective**				**Urgent / Emergent**				**Emergency (hemodynamic unstable)**			
		Overall	EVAR	OSR	p	Overall	EVAR	OSR	p	Overall	EVAR	OSR	p
No. of patients	878	736	592	144		142	101	41		51	23	28	
	(mean ± SD)	(mean ± SD)	(mean ± SD)	(mean ± SD)		(mean ± SD)	median (IQR)	median (IQR)		median (IQR)	median (IQR)	median (IQR)	
Age (years)	75.5 ± 7.7	74.9 ± 7.3	75.9 ± 7.1	70.5 ± 6.6	.22	78.6 ± 8.9	79.9 (8.5)	75.4 (9.3)	.96	78.5 (9.4)	81.4 (8.7)	76.0 (9.5)	.76
AAA diameter (mm)	58.6 ± 15.5	57.4 ± 12.8	61.1 ± 16.1	56.4 ± 11.6	**< .001**	65.5 ± 24.9	63.9 (22.4)	69.5 (30.1)	.10	68.2 (28.2)	67.5 (32.7)	69.0 (22.9)	.10
	N - %	N - %	%	%		N - %	%	%		N - %	%	%	
Bologna	535 - 61	435 – 59.1	87.1	12.9	**< .001**	100 – 70.4	70	30	.64	27 – 52.9	25.9	74.1	**.004**
Parma	343 - 39	301 – 40.9	70.8	29.2	**< .001**	42 – 29.6	73.8	26.2	.64	24 - 47.1	66.7	33.3	**.004**
Male	786 - 89	668 – 90.8	90.9	90.3	.82	118 – 83.1	81.2	87.8	.34	43 – 84.3	87	82.1	.63
PAOD	89 - 10	79 – 10.7	9.8	14.6	.09	131 – 92.3	6.9	9.8	.56	5 – 9.8	8.7	10.7	.80
COPD	340 - 38.7	288 – 39.1	38.7	41	.61	90 – 63.4	35.6	39	.70	21 – 41.2	39.1	42.9	.78
CAD	272 - 31	230 – 31.3	32.5	26.4	.15	100 – 70.4	30.7	26.8	.64	16 – 31.4	34.8	28.6	.63
Dyslipidemia	559 - 64	12.5 ± 17.2	65.7	63.9	.68	64 – 45.1	60.4	41.5	**.04**	21 – 41.2	43.5	39.3	.76
DM	140 - 16	481 – 65.4	17.1	11.1	.08	119 – 83.8	19.8	7.3	.06	6 – 11.8	13	10.7	.79
AF	109 -12	85 – 11.5	13.2	4.9	**.005**	118 – 83.1	17.8	14.6	.64	7 – 13.7	8.7	17.9	.34
Active Smoker	288 - 33	259 -35.2	30.9	52.8	**< .001**	29 – 20.4	11.9	41.5	**< .001**	14 – 27.5	13	39.3	.07
Hypertension	760 - 87	639 – 86.8	86.3	88.9	.41	121 – 85.2	90.1	73.2	.01	39 – 76.5	87	67.9	.11
ICV	130 - 15	111 – 15.1	14.2	18.8	.17	19 – 13.4	14.9	9.8	.21	5 – 9.8	4.3	14.3	.30
CRF	285 - 32.5	230 – 31.3	33.3	22.9	**.01**	55 – 38.7	40.6	34.1	.47	15 – 29.4	21.7	35.7	.27
Dialysis	12 - 1.4	10 – 1.4	1.4	1.4	.97	2 – 1.4	1	2.4	.50	1 – 2	4.3	0	.26
Obesity (BMI >30)	171 - 19.5	145 – 19.7	21.3	13.2	**.02**	26 -18.3	21.8	9.8	.09	7 – 13.7	21.7	7.1	.13
Dual Ag	41 - 4.7	33 – 4.5	5.1	2.1	.12	8 – 5.6	5.9	4.9	.80	2 – 3.9	8.7	0	.11
OAT	105 - 12	83 – 11.3	13	4.2	**.007**	19 – 13.4	15.8	7.3	.17	3 – 5.9	4.3	7.1	.63
Statin therapy	538 - 61	473 – 64.3	64.9	61.8	.49	65 – 45.8	50.5	34.1	.07	19 – 37.3	39.1	35.7	.80

PAOD: Peripheral Arterial Obstructive Disease; COPD: Chronic Obstructive Pulmonary Disease, CAD: Coronary Artery Disease, DM: Diabetes Mellitus; AF: Atrial Fibrillation, ICV: Cerebra - Vascular Insufficiency; CRF: Chronic Renal Failure, BMI: Body Max Index; Dual Ag: dabble antiaggregating therapy, OAT: oral anticoagulant therapy;

Table 2. Preoperative demographics, clinical and morphological characteristics of patients treated for Abdominal Aortic Aneurysm by EVAR and OSR

Characteristic	**EVAR**	**ORS**

	Overall	Elective	Acute	p	Overall	Elective	Acute	p
No. of patients	693	592	101		185	144	41	
	(mean ± SD)	(mean ± SD)	(mean ± SD)		(mean ± SD)	median (IQR)	median (IQR)	
Age (years)	76.5 ± 7.4	75.9 ± 7.1	79.9 ± 8.5	**.03**	71.6 ± 7.5	70.5 (6.6)	75.4 (9.3)	.06
AAA diameter (mm)	57.4 ± 13.8	56.4 ± 11.6	63.9 ± 22.4	**< .001**	62.9 ± 20.1	61.1 (16.1)	69.5 (30.12)	**< .001**
	N - %	%	%		N - %	%	%	
Bologna	449 – 64.8	379 (84.4)	70 (15.6)	.30	99 – 53.5	56 (38.9)	88 (61.1)	**< .001**
Parma	224 – 35.2	213 (87.3)	31 (12.7)	.30	86 – 46.5	30 (73.2)	11 (26.8)	**< .001**
Male	620 – 89.5	90.9	81.2	**.003**	166 – 89	90.3	87.8	.64
PAOD	65 – 9.4	9.8	6.9	.36	23 – 12.4	14.6	7.3	.22
COPD	265 – 38.2	38.7	35.6	.55	74 – 40	41.0	36.6	.61
CAD	223 – 32.2	32.5	30.7	.72	48 – 25.9	26.4	24.4	.79
Dyslipidemia	450 – 64.9	65.7	60.4	.30	108 – 58.4	63.9	39	**.007**
DM	121 – 17.5	17.1	19.8	.50	18 – 9.7	11.1	4.9	.23
AF	96 – 13.9	13.2	17.8	.21	12 – 6.5	4.9	12.2	.09
Active Smoker	195 – 28.1	30.9	11.9	**< .001**	92 – 49.7	52.8	39.0	.17
Hypertension	602 – 86.9	86.3	90.1	.29	157 – 84.9	88.9	70.7	**.01**
ICV	99 – 14.3	14.2	14.9	.86	31 – 16.8	18.8	9.8	.17
CRF	238 – 34.3	33.3	40.6	.15	47 – 25.4	22.9	29.3	.40
Dialysis	9 – 1.3	1.4	1	.76	3 – 1.6	1.4	2.4	.63
Obesity (BMI >30)	148 – 21.4	21.3	21.8	.91	23 – 12.4	13.2	9.8	.55
Dual Ag	36 – 5.2	5.1	5.9	.71	5 – 2.7	2.1	4.9	.14
OAT	93 – 13.4	13	15.8	.58	9 – 4.9	4.2	7.3	.15
Statin therapy	435 – 62.8	64.9	50.5	**.006**	103 – 55.7	61.8	34.1	**.002**
EVAR exclusion								
Anatomical reason	-	-	-	-	154 – 83.2	94.4	43.9	**< .001**
Logistic reason	-	-	-	-	26 – 14.1	0.7	61	**< .001**

PAOD: Peripheral Arterial Obstructive Disease; COPD: Chronic Obstructive Pulmonary Disease, CAD: Coronary Artery Disease, DM: Diabetes Mellitus; AF: Atrial Fibrillation, ICV: Cerebra - Vascular Insufficiency; CRF: Chronic Renal Failure, BMI: Body Max Index; Dual Ag: dabble antiaggregating therapy, OAT: oral anticoagulant therapy;

Table 3. Intraoperative and perioperative characteristics of patients treated for Abdominal Aortic Aneurysm in Elective, Urgent /emergent and hemodynamic unstable setting

Characteristic	**Overall**	**Elective**				**Urgent / Emergent**				**Emergency (hemodynamic unstable)**			
		Overall	EVAR	OSR	p	Overall	EVAR	OSR	p	Overall	EVAR	OSR	p
No. of patients	878	736	592	144		142	101	41		51	23	28	
Intraoperative	N - %	N - %	%	%		N - %	%	%		N - %	%	%	
Technical Success (TS)	840 – 95.8	713 – 96.9	96.5	98.6	.18	127 – 90.1	91	87.8	.56	42 – 82.4	82.6	82.1	1.00
0 - day Mortality	4 – 0.5	1 – 0.1	0.2	0	.62	3 – 2.1	1	4.9	.14	3 – 5.9	4.3	7.1	.63
Procedure related AE	79 – 9.1	54 – 7.3	5.5	15.3	**< .001**	25 – 17.6	15	24.4	.18	18 – 35.3	40.9	32.1	.52
ICU	225 - 29		13.5	100	**< .001**		58.4	100	**< .001**	47. 92.2	82.6	100	**.02**
Perioperative	N - %	N - %	%	%		N - %	%	%		N - %	%	%	
Medical Complication	186 – 21.2	126 – 17.1	11.5	40.3	**< .001**	61 - 43	27.7	80.5	**< .001**	39 – 76.5	60.9	89.3	**.01**
Cardiac	45 – 5.1	32 – 4.3	3.2	9.0	**.002**	13 – 9.2	9.9	7.3	.62	6 – 11.8	26.1	0	**.004**
Pneumological	50 – 5.7	34 – 4.6	2	15.3	**< .001**	16 – 11.3	6.9	22	**.01**	12 – 23.5	13	32.1	.11
Nephrological	37 – 3.9	24 – 3.3	1.4	11.1	**< .001**	13 – 9.2	6.9	14.6	.14	7 – 13.7	17.4	10.7	.49
30 – day Reintervention	34 – 3.9	21 – 2.9	1.4	9	**< .001**	13 – 9.2	7.9	12.2	.42	8 – 15.7	13	17.9	.63
30 – day Mortality	37 – 4.2	15 – 2.0	0.8	6.9	**< .001**	22 – 15.5	8.9	31.7	**< .001**	20 - 39.2	30.4	46.4	.24
	(mean ± SD)	(mean ± SD)	(mean ± SD)	(mean ± SD)		(mean ± SD)	(mean ± SD)	(mean ± SD)		(mean ± SD)	(mean ± SD)	(mean ± SD)	
Length of hospitalization (days)	6.7 ± 11.08	6.19 ± 10.1	4.6 ± 6.5	12.5 ± 17.2	**< .001**	9.8 ± 14.8	8.0 ± 14.0	13.4 ± 14.3	.22	16.5 ± 22.9	19.2 ± 29.03	14.4 ± 17.05	.30

Procedure related AE: procedure related adverse events; ICU: intensive care unit;

Table 4. Intraoperative and perioperative characteristics of patients treated for Abdominal Aortic Aneurysm by EVAR and OSR techniques

Characteristic	**EVAR**	**OSR**

	Overall	Elective	Acute	p	Overall	Elective	Acute	p
No. of patients	693	592	101		185	144	41	
Intraoperative	N - %	%	%		N - %	%	%	
Technical Success (TS)	662 – 95.7	96.5	91	**.01**	178 – 96.2	98.6	87.8	**.006**
0 - day Mortality	2 – 0.3	0.2	1	.27	2 – 1.1	0	4.9	**.04**
Procedure related AE	47 – 6.9	5.5	15	**.002**	32 – 17.3	15.3	24.4	.24
ICU		13.7	58.4	**< .001**		100	100	1.00
Perioperative	N - %	%	%		N - %	%	%	
Medical Complication	96 – 13.9	11.5	27.7	**< .001**	90 – 48.6	40.3	80.5	**< .001**
Cardiac	29 – 4.2	3.2	9.9	**.005**	16 – 8.6	9	7.3	1.00
Pneumological	19 – 2.7	2	6.9	**.01**	31 – 16.8	15.3	22	.34
Nephrological	15 – 2.2	1.4	6.9	**.001**	22 – 11.9	11.1	14.6	.58
30 – day Reintervention	16 – 2.3	1.4	7.9	**.001**	18 - 9.7	9	12.2	.55
30 – day Mortality	14 - 2	0.8	8.9	**< .001**	23 – 12.4	6.9	31.7	**< .001**
	(mean ± SD)	(mean ± SD)	(mean ± SD)		(mean ± SD)	(mean ± SD)	(mean ± SD)	
Length of hospitalization (days)	5.8 ± 8.3	846 ± 6.5	8.3 ± 14.8	**< .001**	12.7 ± 16.6	12.5 ± 17.2	13.4 ± 14.3	.70

Procedure related AE: procedure related adverse events; ICU: intensive care unit;

FIGURES

Figure 1 - Overall treatments

	n	%
EVAR	693	79
OSR	185	21
Total	878	100

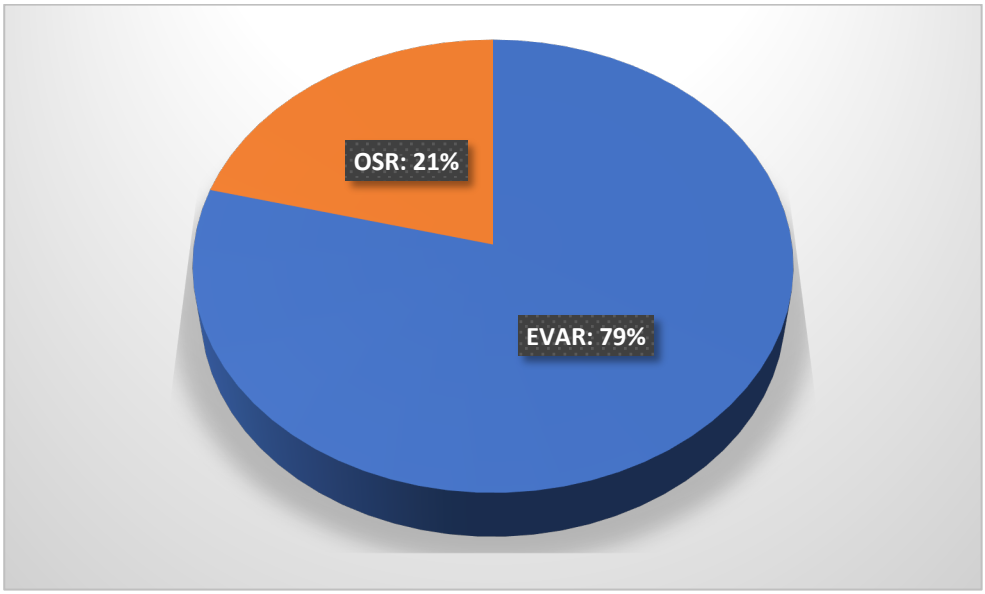


Figure 2 - Overall AAA clinical presentation

	n	%
Elective	795	84
Urgent/emergent	142	16
Total	878	100

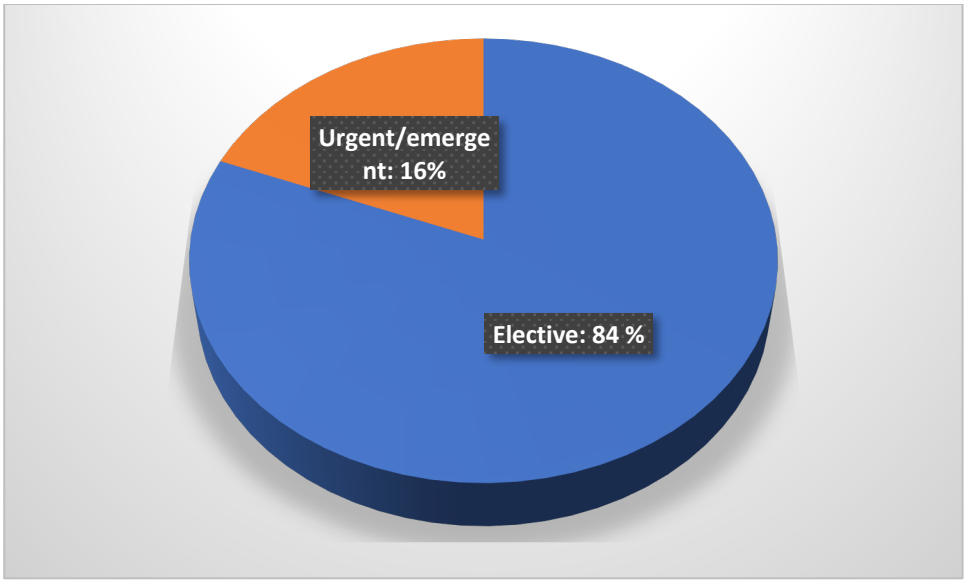


Figure 3 - Type of treatment in Elective cases

Elective	n	%
EVAR	592	80.4
OSR	144	19.6
Total	736	100

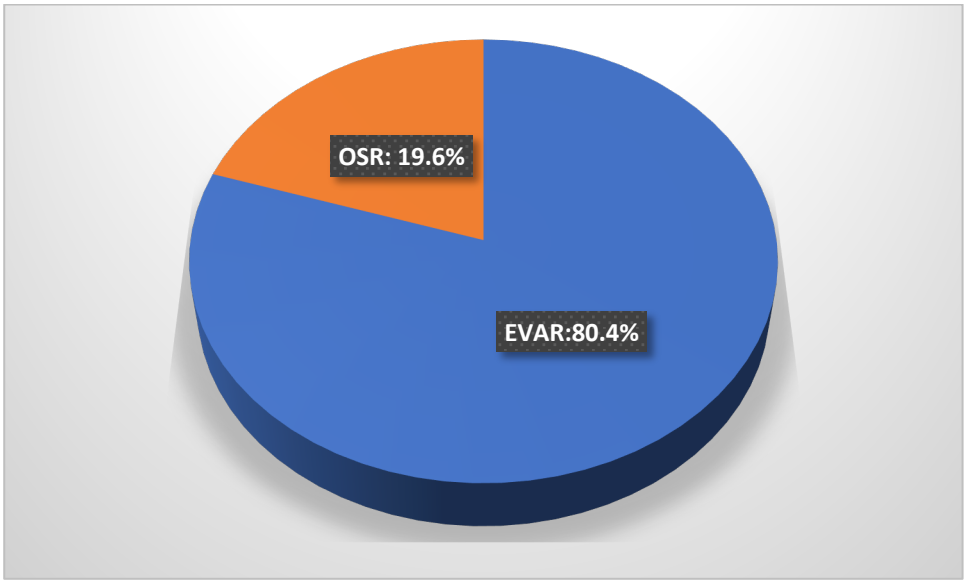


Figure 4 - Type of treatment in urgent / emergent cases

Urgent / emergent	n	%
EVAR	101	71.1
OSR	41	28.9
Total	142	100

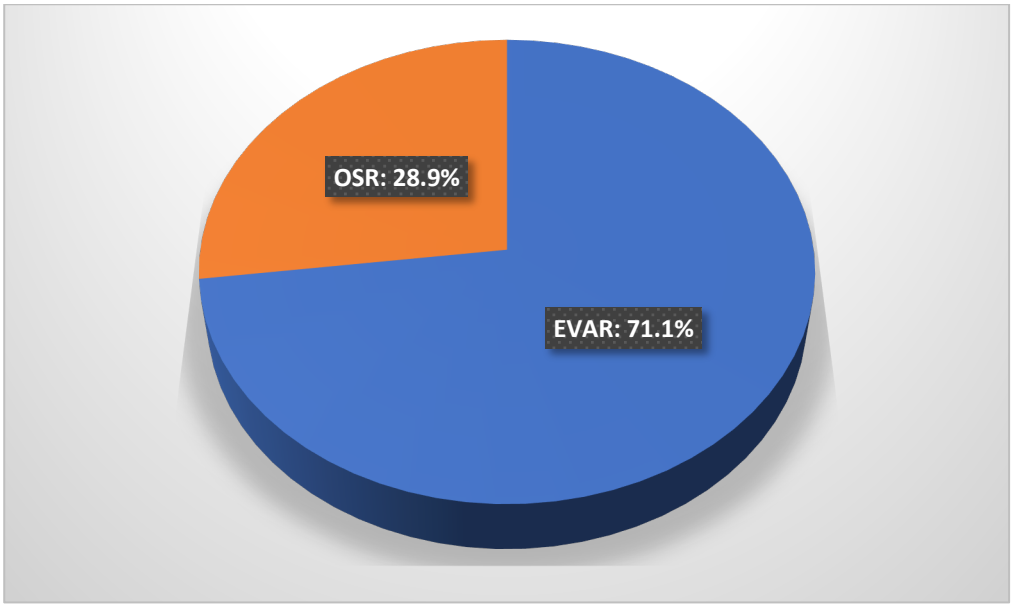


Figure 5 - Time table of EVAR and OPEN treatment

Treatment	2015 n (%)	2016 n (%)	2017 n (%)	2018 n (%)	2019 June n (%)
EVAR	110 (82)	165 (78)	170 (79)	161 (79)	87 (76)
OSR	23 (18)	47 (22)	44 (21)	43 (21)	28 (24)
Total	134 (100)	212 (100)	214 (100)	204 (100)	115 (100)

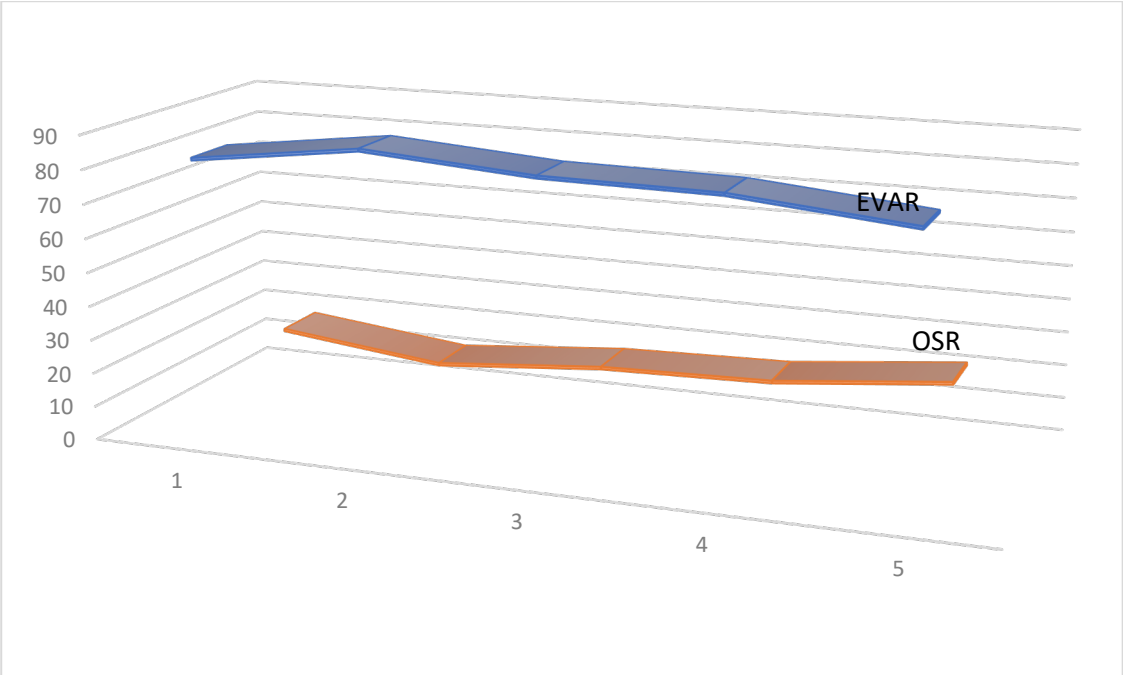


Figure 6 - Time table of EVAR in Elective and Urgent /emergent setting

EVAR	2015 n (%)	2016 n (%)	2017 n (%)	2018 n (%)	2019 June n (%)
Elective	106 (96)	140 (85)	141 (83)	140 (87)	65 (75)
Urgent/emergent	4 (4)	25 (15)	29 (17)	21 (13)	22 (25)
Total	110 (100)	165 (100)	170 (100)	161 (100)	87 (100)

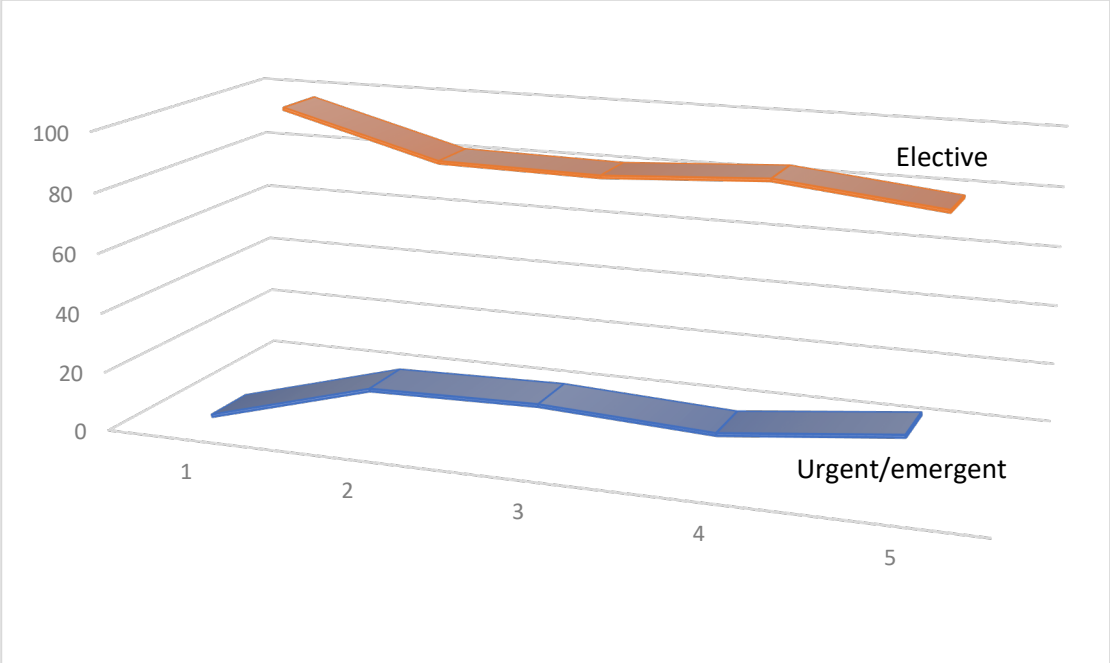


Figure 7 - Time table of OSR in Elective and Urgent /emergent setting

OSR	2015 n (%)	2016 n (%)	2017 n (%)	2018 n (%)	2019 June n (%)
Elective	15 (65)	40 (85)	32 (73)	34 (79)	23 (82)
Urgent/emergent	8 (35)	7 (15)	12 (27)	9 (21)	5 (18)
Total	23 (100)	47 (100)	44 (100)	43 (100)	28 (100)

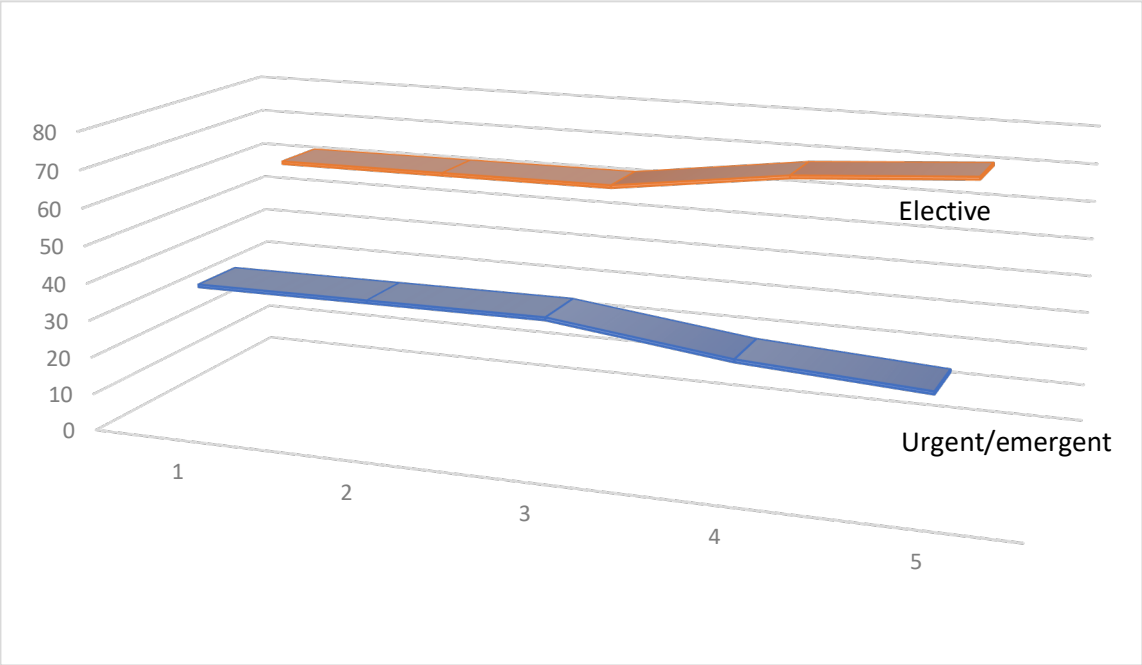
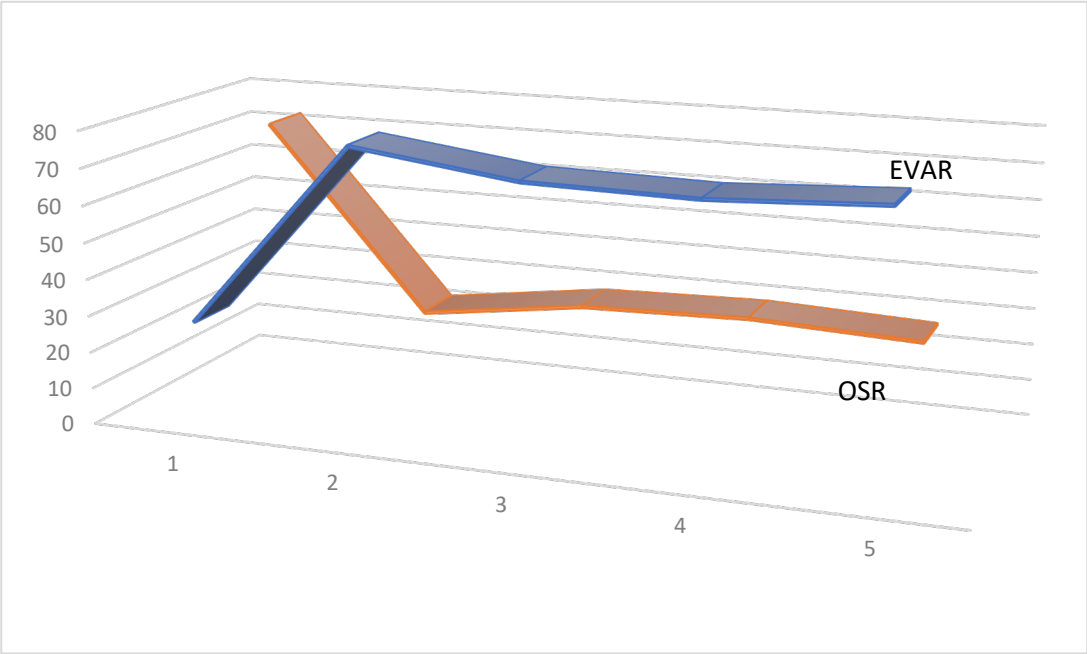


Figure 8 - Time table of treatments (EVAR and OSR) in urgent /emergent setting

Treatment in urgent /emergent	2015 n (%)	2016 n (%)	2017 n (%)	2018 n (%)	2019 June n (%)
EVAR	4 (33)	25 (78)	29 (71)	21 (70)	22 (81)
OSR	8 (67)	7 (22)	12 (29)	9 (30)	5 (19)
Total	12 (100)	32 (100)	41 (100)	30 (100)	27 (100)



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