Accepted Manuscript

The outcome of technical intraoperative complications occurring in standard aortic endovascular repair

A. Vacirca, G. Faggioli, R. Pini, E. Gallitto, C. Mascoli, L.M. Cacioppa, M. Gargiulo, A. Stella

PII: S0890-5096(18)30860-4

DOI: https://doi.org/10.1016/j.avsg.2018.08.092

Reference: AVSG 4098

To appear in: *Annals of Vascular Surgery*

Received Date: 2 June 2018

Revised Date: 3 August 2018

Accepted Date: 8 August 2018

The outcome of technical intraoperative complications occurring in standard aortic endovascular repair

A. Vacirca, G. Faggioli, R. Pini, E. Gallitto, C. Mascoli, L.M. Cacioppa, M. Gargiulo, A. Stella.

Vascular Surgery, Department of Experimental, Diagnostic and Specialty Medicine,
University of Bologna, Policlinico Sant'Orsola-Malpighi,
Bologna-Italy

Category of Manuscript: Clinical Paper

Corresponding Author
Prof Gianluca Faggioli
Vascular Surgery, University of Bologna,
Policlinico S. Orsola-Malpighi
via Massarenti 9, 40138 Bologna, Italy.
Tel. +39 051 2143288 - +39 051 2144244
Fax: +39 051 214 4305
gianluca.faggioli@unibo.it

The outcome of technical intraoperative complications occurring in standard aortic endovascular repair

Objectives **-** Technical intraoperative complications (TIC) may occur during standard EVAR with possible effects on the outcome. This study evaluates the early and mid-term effects of TIC on EVARs.

Methods **-** All EVARs (from 2012 to 2016) were analysed in order to identify all TIC: endoluminal defects (stenosis/dissection/rupture/compression of native arteries or endograft); type I-III endoleaks; unplanned artery coverage; surgical access complications. Follow-up was performed by DUS/CEUS/CT-Scan at yearly intervals. Outcome was compared with that of uneventful cases (UC) through Fisher's test and Kaplan-Maier curve.

Results **-** TIC occurred in 68 (18%) of 377 patients undergoing EVAR. Thirty-two endoluminal defects were relined endovascularly; 24 type I-III endoleaks were treated with cuff deployment/forced ballooning (23) and surgical conversion (1); 3/8 unplanned artery coverages were revascularized (2 renal, 1 hypogastric), 5 hypogastric had an unsuccessful correction; 4 access artery injuries were repaired. Although fluoroscopy time and contrast employed were significantly higher in TIC compared with UC (309 cases), 30-day outcome was similar for death (1.4% TIC vs 0% UC, P=0.18), reintervention (0% TIC vs 0.3% UC, P=1), type I-III endoleak (0% TIC vs 0.9% UC, P=1), steno-occlusions (0% TIC vs 0.3% UC, P=1), buttock claudication and renal failure (0% in both groups). At 24 months, TIC and UC had similar survival (91.7 ± 8% vs 96.2 ± 2.1%, P=0.5), freedom from reintervention (81.4±9.9% vs 96±2.2%, P=0.49), overall complication rate (13.4±7.6% vs 11.4±3.5%, P=0.49), type I-III endoleak (11.2±7.5% vs 7±2.9%, P=0.8), buttock claudication (0% vs 2±2% P=0.6) and haemodialysis (0% in both). Mid-term iliac leg occlusion was significantly higher in TIC (26.9±12.3% vs 3 ± 2.1%, P=0.01).

Conclusions **-** TIC may affect several aspects during EVAR, leading to the necessity of adjunctive maneuvers, which have no impact on early outcome, but may cause an increased rate of mid-term iliac leg occlusion.

Keywords - Endovascular aortic treatment; abdominal aortic aneurysm; intraoperative complication; unexpected event; adjunctive maneuver.

Background

Endovascular repair (EVAR) is presently the mainstay in the treatment of Abdominal Aortic Aneurysm (AAA)[1], since technical expertise and endograft evolution has allowed to reach high standards of care, with reduced procedure time, and low intraprocedural and perioperative complications[2]. Nevertheless, several technical intraoperative complications (TIC) may occur in daily clinical practice, even in highly standardized procedures, since EVAR has been used more frequently in challenging anatomies.

These events may include unplanned coverage of important arteries such as renal or hypogastric artery, injury to the access or target arteries, incomplete sealing either at the proximal or distal endograft site, with possible consequences on the early or late outcome of the procedure.

Several studies have addressed the influence of adjunctive procedures performed during standard EVAR[3-8]; Ultee KH et al[3] analyzed patients undergoing concomitant procedures during EVAR in terms of perioperative outcome and found that those adjunctive procedures were associated with increased postoperative morbidity and mortality; however, a specific analysis of the overall impact of TIC occurring during the procedures and a mid-term follow-up of patients is lacking. Thus, the aim of our study is to describe TIC and their treatment, in order to evaluate their perioperative and mid-term effect.

Methods

All standard EVAR procedures performed in our center from January 2012 to December 2016 were retrospectively analyzed in order to identify all TIC, which were classified as follows:

- <u>Group a) endoluminal defect</u>: diameter stenosis of the endograft limb or iliac artery >50%, angiographic visible dissection or rupture of common or external iliac artery, extrinsic compression of an endograft element, such as the main body or the iliac leg. Iliac limb stenosis was defined as the detection of an incomplete expansion of the endograft iliac stents at the final angiogram either due to the presence of a severe wall calcification or a tight angulation of the iliac artery. A very high dose of suspicion towards any possible cause of stenosis is used when examining the completion angiography after each procedure. In the presence of any endoluminal defect, adjunctive imaging with different projections was performed as well as intraoperative duplex scanning.

- Group b) high flow endoleak: type I or III endoleak
- Group c) unplanned artery coverage: inadvertent coverage of a renal or a hypogastric artery
- Group d) surgical access complication: thrombosis or plaque dissection of the femoral artery.

Type II Endoleaks were not considered as an intraoperative complication, since they do not represent a real intraprocedural failure, but a paraphysiological condition, which requires only a strict follow-up[9].

Standard EVAR procedure was defined as aorto-bi-common-iliac endograft implantation for unruptured AAA, following the instructions for use of the appropriate manufacturer. We considered patients suitable for standard EVAR treatment according to Chaikof EL[10] classification criteria, such as length, diameter, amount of calcium, thrombus and angulation of aortic proximal neck and common iliac arteries. If during planning and sizing of every single case those criteria were not satisfied, the patient was excluded from standard EVAR treatment.

All patients submitted to intentional embolization or coverage of the hypogastric artery were excluded from the analysis.

The procedure was performed with bilateral surgical exposure of the common femoral arteries in all cases.

Patients who had a TIC were analyzed in terms of preoperative characteristics (age, sex, anesthesiological and cardiovascular risk factors, and medical therapy) and type of endoprosthesis used, in order to identify risk factors for TIC occurrence and compared with the consecutive uneventful cases (UC) treated in the same period. Preoperative peripheral artery disease was considered in case of IIb to IV stage according to Leriche-Fontaine classification. Mean fluoroscopy time and amount of iodinated contrast medium used during the procedure were also analyzed.

TIC and UC patients were also compared in terms of 30-day and mid-term results, considering the presence of type I-III endoleak, iliac leg occlusion/thrombosis, buttock claudication, renal failure, haemodialysis, mortality and reintervention rate.

Follow-up

Follow-up was performed by duplex ultrasound, contrast enhanced ultrasound or computed tomography (CT) scan. Every patient submitted to standard EVAR undergoes duplex scanning before discharge. If no high flow endoleak or any other postoperative complication such as iliac leg thrombosis is detected, a follow-up duplex scanning is planned at 6 and 12 months and yearly thereafter. If some significant change is suspected at any of the duplex assessments, a CT scan is performed. If an endoleak of uncertain origin is detected, contrast-enhanced ultrasound is also performed. This strategy is not modified in case of TIC occurrence. At each follow-up interval, every patient was encouraged to report any change in life-style or any new pain during walking after the intervention, in order to detect any possible steno-occlusive event responsible for buttock, thigh or calf claudication.

Statistical Analysis

Frequencies were expressed with percentages and continuous variables with means ± standard deviation. The independent samples *t*-test was used to compare all means of continuous variables. Risk factors for TIC occurrence were identified comparing preoperative differences between TIC and UC patients by Fisher’s test, odd ratio (OR) and 95% confidence interval (C.I.); the results were confirmed by multivariate analysis (including factors significant or with trend to significance, $p<.20$

at the univariate analysis) Fisher's test was also used to analyze perioperative results between the two groups.

Comparison between TIC and UC mid-term outcome was performed by survival function (Kaplan-Meier with log-rank evaluation). SPSS Statistics 21.0 for Mac Os (Chicago, Illinois) was used for statistical analysis.

The study was performed following the rules of the local Institutional Review Board, which approved protocol and informed consent. All subjects gave informed consent for this study.

Results

From January 2012 to December 2016, 377 standard EVAR were performed in our center with different types of infrarenal 177/377 (47%) or suprarenal fixation endografts 200/377 (53%). Preoperative characteristics of patients are reported in Table Ia.

TIC occurred in 68/377 (18%) and a corrective treatment was always attempted. Technical complications were divided into 4 groups, depending on the pathophysiology.

Group a) endoluminal defect, included 32 (8.5%) cases, which were all treated with endovascular relining. Ten cases of iliac leg stenosis, compression or kinking, 18 cases of residual stenosis (15 cases), dissection (2 case) or rupture (1 case, as shown in fig.1) of external iliac arteries and 4 cases of tight or compressed aortic bifurcation were all stented with unilateral or bilateral-kissing procedures.

Group b) high flow endoleak, included 24 (6.3%) cases, which were all (100%) immediately treated. Thirteen cases of type Ia endoleak were successfully treated with forced ballooning (9 cases), proximal cuff deployment (3 cases, as shown in Fig.2) and in one case surgical conversion (1 case) due to infolding of the proximal stent of endoprosthesis at final angiogram; 10 cases of type Ib endoleak were treated with forced ballooning (3 cases) or iliac extension of the endograft (7 cases) with a complete endoleak resolution at final angiogram. One case of type III endoleak from the contralateral leg gate was successfully treated with iliac leg relining.

In group c) unplanned artery coverage, there were 8 (2.1%) cases. Two cases of inadvertent renal artery coverage, during EVAR with suprarenal fixation device, were treated with renal artery cannulation through the free flow of the endograft and subsequent stenting (Fig. 3); One case of unplanned hypogastric artery coverage was successfully revascularized by cannulating it with a floppy guidewire from ipsilateral access using an angulated catheter, on a Rosen guidewire, a sheath was advanced into the artery and a covered stent was deployed to maintain patency of the hypogastric artery; the other 5 cases of hypogastric artery coverage had an unsuccessful correction and were left untreated.

In group d) surgical access complication, there were 4 (1%) cases of thrombosis or plaque dissection of the common femoral artery, which were all surgically treated with femoral interposition graft.

Risk factors for technical intraoperative complications occurrence

The preoperative evaluation of risk factors for TIC occurrence (as shown in Tab. Ia) showed a higher prevalence of female gender and PAOD in TIC patients. Specifically, female sex had a higher prevalence in TIC group (17.6%) compared with UC (8.4%) (OR 2.3, 95% CI 1.1-4.9, p=0.04). The most common TIC type in women was high flow endoleak (group B) with 6/12 TIC cases (50%), followed by endoluminal defect (group A) with 4/12 TIC cases (33.3%) and surgical access complication (group D) with 2/12 TIC cases (16.6%). The prevalence of peripheral artery disease was higher in the TIC group (14.7%) compared with the UC group (6.2%), with OR 2.6 (95% CI 1.5-5.8) and p=0.02. These results were also confirmed by multivariate analysis of risk factors for TIC occurrence, as shown in Tab. Ib

The mean fluoroscopy time was significantly higher in TIC patients compared with UC (30.5 ± 9.4 min for TIC vs 9.5 ± 6.2 min for UC, P=0.001), as well as the mean amount of iodinated contrast medium (198.36 ± 80.1 ml for TIC vs 97 ± 32.7 ml for UC, P=0.001) during the procedure.

Perioperative Outcome

At 30 days outcome, there were no significant differences between TIC and UC patients, as shown in Table II. In TIC patients 1 (1.4%) perioperative death occurred: after an intraoperative external iliac artery rupture, the artery was repaired by an iliac artery endograft with a hypogastric artery embolization. Subsequently to the internal iliac embolization, intestinal ischemia occurred leading to death 9 days after EVAR despite wide patency of the contralateral iliac arteries (common, internal and external).

Among the UC patients, 1 (0.3%) iliac leg occlusion occurred. Three cases (0.9%) of UC had perioperative type I-III endoleak, 1 of which (endoleak type Ia) was treated within the same admission with the deployment of a proximal cuff. The other two cases were left untreated and monitored at three months intervals, with no increase in sac diameter (Table II).

Mid-term Outcome

The mean follow-up time was 25.63 ± 10.53 months (median 27 months, range 15-58 months). At 24 months, overall complications rate (death, freedom from reintervention, persistent type I-III endoleak, iliac leg occlusion, buttock claudication and renal insufficiency requiring haemodialysis) was 13.4±7.6% for TIC versus 11.4±3.5% for UC, P=0.49 (Fig.4); as shown in table III there was no significant difference in terms of mid-term survival, freedom from reintervention, persistent type I-III endoleak, buttock claudication and renal insufficiency requiring haemodialysis between TIC and UC groups. However, iliac leg occlusion/thrombosis at 24 months was significantly higher in TIC compared with UC (26.9±12.3% vs 3±2.1%, P=0.01), as shown in Fig.5. Patients who developed iliac occlusion after TIC at follow-up were 4 males. In one of them a moderate calcification of the left common iliac artery was present, which determined a stenosis of the iliac component and was consequently treated with an intraoperative iliac stenting. A second patient showed mild calcification of the common iliac arteries; a bilateral iliac stenting was performed during EVAR because of a stenosis of aortic bifurcation seen at the completion angiogram; after several months a right iliac leg thrombosis occurred. A third patient showed no particular narrowing or calcification, but was intraoperatively treated for a left iliac type IB endoleak, with iliac endograft extension; an acute ipsilateral iliac leg thrombosis occurred 37 months after surgery. The fourth patient had no significant iliac disease at the preoperative CT-Scan; a type IB endoleak from the right iliac leg was treated intraoperatively with an iliac extension, and 1 year later a thrombosis of the same iliac leg occurred. In TIC population, 3/4 patients with iliac leg occlusion were treated with fibrinolysis for 24-48 hours and subsequent iliac relining (2 with covered and 1 with uncovered stent) in order to correct the endoluminal defect; 1/4 patients underwent femoral to femoral crossover bypass after unsuccessful thrombolysis. In UC group, 2/3 patients with acute iliac leg thrombosis, underwent iliac relining (both with covered stent) after fibrinolysis; 1/3 patients underwent femoral to femoral crossover bypass. No patient developed postoperative reperfusion injury or neurological deficit after the iliac leg thrombosis correction.

Discussion

Some type of technical intraoperative complications can occur in as much as 18% of standard EVAR procedures, even when performed in a high-volume center with a very high caseload of advanced endovascular procedures, as shown by the present study. These unexpected events require adjunctive maneuvers in order to repair or prevent from negative outcomes; this can be achieved in the majority of cases, however a small percentage of these TIC are not amenable to repair (i.e. the unplanned coverage of a hypogastric artery).

In the considered series, the occurrence of TIC during the EVAR procedures is quite similar of that of other studies in literature. Naslund et al[8] reported a technical complication rate of 26% in patients submitted to EVAR with both bifurcated and non-bifurcated grafts. Ultee et al[3] showed a 29% complication of one or more concomitant procedures during elective endovascular aneurysm repair. Similarly, Hobo et al[4] reported 29.2% of adjuvant procedures during standard EVAR procedures. Although only a limited number of recent papers is available in the literature[2,3,11], it appears that TIC occur quite often during standard endovascular aneurysm repairs, despite meticulous preoperative planning and high surgical expertise.

By analyzing the preoperative and intraoperative characteristics possibly associated with the early and late results, we have found that female sex is an independent risk factor in technical intraoperative complications occurrence (female sex rate was 17.6%, in TIC patients vs. 8.4%, in UC patients, OR 2.3 (1.1-4.9) and p=0.04). The reason for this feature is unknown. This data is in agreement with Wolf et al[12], who showed a higher incidence of access-related complications for women due to smaller arteries, as well as Ouriel et al[13], who observed a greater frequency of iliac leg occlusion in female patients, and Chung et al[14], who demonstrated that women experienced more endoleaks and arterial complications and consequently required more adjunctive procedures.

In addition, preoperative peripheral artery disease was an independent risk factor for TIC occurrence (peripheral artery disease in TIC group was 14.7%, in UC was 6.2%, OR 2.6 (1.5-5.8) p=0.02). These data can be strictly related with the high rate of endoluminal defects (group a) occurrence (47%), which was the most numerous subgroup of TIC population, and consequently with the higher rate of iliac leg occlusion at 24 months compared with UC group in the considered series.

TIC are not influenced by the type of device used, as shown also by previous papers[15-19], therefore their occurrence appears to be linked more to misplanning or other intraprocedural casualties rather than to technical features of the endograft. In our series, the most frequent cause of TIC was the presence of endoluminal defects (Group a), including stenosis of the iliac artery or leg, dissection or rupture of common or external iliac artery or extrinsic compression of the endograft elements, accounting for 47% of TIC cases. These occurrences may be easily addressed with the adjunct of intraluminal stents or endograft.

Similarly, the occurrence of an intraprocedural type I and III endoleak (Group b) can be managed effectively with intraoperative forced ballooning, proximal cuff or iliac leg deployment. As shown in literature, patients with short, heavily calcified or angled necks have an increased risk of intraand postoperative type I and type III endoleaks, therefore an accurate patient's selection and procedure's planning for standard EVAR is very important[11,20,21].

The unplanned hypogastric or renal artery coverage (Group c) occurs less frequently. The two cases of unplanned renal artery coverage were treated performing a renal artery stenting through the free flow of the suprarenal fixation endograft; this kind of maneuver needs a specific expertise in complex aortic procedures and visceral vessels treatment, such as fenestrated or branched endovascular aortic repair. Moreover, the treatment of hypogastric artery coverage is even more challenging and often infeasible. In our series, one case of unplanned hypogastric artery coverage was successfully revascularized with hypogastric artery stenting, however the other 5 cases had an unsuccessful correction and consequently were left untreated.

Surgical access complication (Group d) is usually a minor problem, both in terms of overall incidence and of technical bailout.

Operation time in TIC patients was significantly increased, as shown by the longer fluoroscopy time and greater amount of iodinated contrast media. This aspect can be explained with the longer arterial manipulation and the consequent longer procedure time in an attempt to correct complications, when TIC occurred.

As a matter of facts, the perioperative outcome was not influenced by TIC with results comparable to uneventful cases, in terms of perioperative complications, such as stenocclusions, high flow endoleak, renal insufficiency requiring haemodialysis, reintervention or death. These data are in contrast with those of Ultee et al[3] and Hobo et al[4]. In the first one, EVAR procedures requiring adjunctive maneuvers had a worse postoperative outcome, in terms of morbidity and mortality: particularly femoral endoarterectomies and renal artery stenting were associated with an increased perioperative mortality[3]. In the second one, endovascular adjuvant maneuvers were associated with a higher rate of perioperative complications, as well as adjunctive surgical peripheral arterial procedures, with significant higher early perioperative mortality and morbidity[4].

We have been interested also in the mid-term impact of TIC, differently from previous studies[3-4]. As a matter of fact, the mid-term outcome was not influenced by TIC in terms of late type I-III endoleak, buttock claudication, renal failure requiring haemodialysis, reintervention and mortality rate. The iliac leg occlusion at 24 months was significantly higher in TIC (26.9 ± 12.3% vs 3 ± 2.1%, P=0.01) compared with UC group and was possibly due to peripheral embolization or iliac leg/artery thrombosis. The reason for the higher rate of late iliac leg and artery occlusion can be related with the significantly higher rate of preoperative peripheral artery disease in TIC population. As a confirmation for this, Mantas GK et al[22] analysed all patients presenting with endograft limb occlusion after EVAR and found that severe iliac artery angulation and calcification are independent predictors of endograft limb occlusion.

The present study has some limitations, such as the retrospective design, which can lead to less reliable results compared with prospective studies. The series considered is composed of a limited number of patients (377) and offers little statistical power. In the period examined, four different types of endoprosthesis were used in our center, with no data on TIC possibly occurring with other types of endografts. In addition, surgeons performing EVAR had different surgical expertise, with possible different procedure results. Duplex ultrasound, used as procedure of choice for follow-up evaluation, is an operator-dependent examination with possible variability in the endograft evaluation. The mean follow-up time (25 months) was rather limited, therefore further studies will be needed to validate our conclusion.

Conclusions

Technical intraoperative complications may arise for a variety of reasons and in a significant number of cases during standard EVAR. Female sex and preoperative peripheral artery disease appear to be independent risk factors for TIC occurrence, therefore an accurate preoperative anatomical evaluation of these patients is particularly important, in order to prevent a possible TIC.

TIC occurrence requires adjunctive manoeuvres, which lead to a more demanding procedure, in terms of fluoroscopy time spent and iodinated contrast medium used.

Although early outcome is not influenced by TIC occurrence, the mid-term follow-up of these patients may be affected by a higher rate of iliac leg occlusion/thrombosis, as a possible effect of intraoperative longer arterial manipulation.

References

1. Dua A, Kuy S, Lee CJ, Upchurch GR Jr, Desai SS. Epidemiology of aortic aneurysm repair in the United States from 2000 to 2010. J Vasc Surg. 2014 Jun;59(6):1512-7.

2. Tadros RO, Faries PL, Ellozy SH, Lookstein RA, Vouyouka AG, Schrier R et al. The impact of stent graft evolution on the results of endovascular abdominal aortic aneurysm repair. J Vasc Surg. 2014 Jun;59(6):1518-27.

3. Ultee KH, Zettervall SL, Soden PA, Darling J, Siracuse JJ, Alef MJ et al. The Impact of Concomitant Procedures during Endovascular Abdominal Aortic Aneurysm Repair on Perioperative Outcomes. J Vasc Surg. 2016 June; 63(6): 1411–1419.e2.

4. Hobo R, Van Marrewijk CJ, Leurs LJ, Laheij RJ, Buth J. Adjuvant Procedures Performed During Endovascular Repair of Abdominal Aortic Aneurysm. Does it Influence Outcome? Eur J Vasc Endovasc Surg. 2005 Jul;30(1):20-8.

5. Yano OJ, Faries PL, Morrissey N, Teodorescu V, Hollier LH, Marin ML. Ancillary techniques to facilitate endovascular repair of aortic aneurysms. J Vasc Surg. 2001 Jul;34(1):69-75.

6. Fairman RM, Velazquez O, Baum R, Carpenter J, Golden MA, Pyeron A et al. Endovascular repair of aortic aneurysms: critical events and adjunctive procedures. J Vasc Surg. 2001 Jun;33(6):1226-32.

7. Kalliafas S, Albertini JN, Macierewicz J, Yusuf SW, Whitaker SC, Macsweeney ST et al. Incidence and treatment of intraoperative technical problems during endovascular repair of complex abdominal aortic aneurysms. J Vasc Surg. 2000 Jun;31(6):1185-92.

8. Naslund TC, Edwards WH, Neuzil DF, Martin RS, Snyder SO, Mulherin JL, et al. Technical complications of endovascular abdominal aortic aneurysm repair. J Vasc Surg 1997;26:502-10.

9. Piazza M, Squizzato F, Zavatta M, Menegolo M, Ricotta JJ 2nd, Lepidi S et al. Outcomes of endovascular aneurysm repair with contemporary volume-dependent sac embolization in patients at risk for type II endoleak. J Vasc Surg 2016; 63:32-8.

10. Chaikof EL, Fillinger MF, Matsumura JS, Rutherford RB, White GH, Blankensteijn JD, et al. Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair. J Vasc Surg 2002;35:1061-6.

11. Millen AM, Osman K, Antoniou GA, McWilliams RG, Brennan JA and Fisher RK. Outcomes of persistent intraoperative type Ia endoleak after standard endovascular aneurysm repair. J Vasc Surg. 2015 May;61(5):1185-91.

12. Wolf YG, Arko FR, Hill BB, Olcott 4th C, Harris Jr EJ, Fogarty TJ et al. Gender differences in endovascular abdominal aortic aneurysm repair with the AneuRx stent graft. J Vasc Surg 2002;35(5):882–886.

13. Ouriel K, Greenberg NK, Clair DG, O’hara PJ, Srivastava SD, Lyden SP et al. Endovascular aneurysm repair: gender-specific results. J Vasc Surg. 2003 Jul;38(1):93-8.

14. Chung C, Tadros R, Torres M, Malik R, Ellozy S, Faries P et al. Evolution of gender-related differences in outcomes from two decades of endovascular aneurysm repair. J Vasc Surg 2015;61:843-52.

15. Freyrie A, Gallitto E, Gargiulo M, Faggioli G, Bianchini Massoni C, Mascoli C et al. Results of the endovascular abdominal aneurysm repair using the Anaconda aortic endograft. J Vasc Surg 2014;60:1132-9.

16. Mertens J, Houthoofd S, Daenens K, Fourneau I, Maleux G, Lerut et al. Long-term results after endovascular abdominal aortic aneurysm repair using the Cook Zenith endograft. J Vasc Surg 2011;54:48-57.

17. Sobocinsky J, Briffa F, Holt PJ, Martin Gonzalez T, Spear R, Azzaoui R et al. Evaluation of the Zenith low-profile abdominal aortic aneurysm stent graft. J Vasc Surg 2015;62:841-7.

18. Pratesi C, Piffaretti G, Pratesi G, Castelli P and the ITalian Excluder Registry (ITER) Investigators. ITalian Excluder registry and results of Gore Excluder endograft for the treatment of elective infrarenal abdominal aortic aneurysms. J Vasc Surg 2014;59:52-7.

19. Singh MJ, Fairman R, Anain P, Jordan WD, Maldonaldo T, Samson R et al. Final results of the Endurant stent graft system in the United States regulatory trial. J Vasc Surg 2016;64:55-62.

20. Sampaio SM, Panneton JM, Mozes GI, Andrews JC, Bower TC, Karla M et al. Proximal type I endoleak after endovascular aortic aneurysm repair: predictive factors. Ann Vasc Surg 2004; 18(6):621-8.

21. Antoniou GA, Georgiadis GS, Antoniou SA, Kuhan G and Murray D. A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy. J Vasc Surg 2013; 57(2):527-38.

22. Mantas GK, Antonopoulos CN, Sfyroeras GS, Moulakakis KG, Kakisis JD, Mylonas SN et al. Factors Predisposing to Endograft Limb Occlusion after Endovascular Aortic Repair. Eur J Vasc Endovasc Surg. 2015 Jan;49(1):39-44.

Tables

Table Ia - Risk factors for technical intraoperative complications occurrence

	Tot(n=377) No (%)	TIC (n=68) No (%)	UC (n=309) No (%)	OR (95% C.I.)	P
Age ≥ 80 years	103(27.3%)	16(23.5%)	87(28.1%)	0.8 (0.4-1.4)	.54
Female Gender	38(10.7%)	12(17.6%)	26(8.4%)	2.3 (1.1-4.9)	.04*
ASA >3	355(94.2%)	67(98.5%)	288(93.2%)	4.9 (0.6-37)	.14
PAD	29(7.8%)	10(14.7%)	19(6.2%)	2.6 (1.5-5.8)	.02*
COPD	142(38%)	27(40.3%)	115(37.5%)	1.1 (0.6-1.9)	.68
CAD	127(34%)	28(41.2%)	99(32%)	1.4 (0.8-2.5)	.2
Dyslipidemia	230(61%)	42(61.8%)	188(60.8%)	1 (0.6-1.8)	.1
Diabetes Mellitus II	60(15.9%)	10(14.7%)	50(16.1%)	0.9 (0.4-1.8)	.8
Atrial Fibrillation	39(10.3%)	7(10.2%)	32(10.3%)	0.9 (0.4-2.3)	1
Smoke	180(47.7%)	34(50%)	146(47.2%)	1 (0.6-1.8)	.78
Hypertension	330(87.5%)	62(91.2%)	268(86.7%)	1.4 (0.6-3.5)	.53
Cerbrovascular Disease	40(10.6%)	7(10.3%)	33(10.6%)	0.9 (0.4-2.2)	1
Chronic Kidney Disease	103(27.3%)	19(27.9%)	84(27.2%)	1 (0.5-1.8)	.88
Haemodialysis	6(1.6%)	0	6(1.9%)	-	.59
BMI >25	70(18.5%)	9(13.2%)	61(19.7%)	0.6 (0.2-1.3)	.23
Neoplasia	69(18.3%)	16(23.5%)	53(17.1%)	1.4 (0.7-2.7)	.23
Double Antiaggregant Th.	9(2.3%)	4(5.9%)	5(1.6%)	3.7 (0.9-14)	.06
Oral Anticoagulant Th.	39(10.3%)	6(8.8%)	33(10.6%)	0.8 (0.3-2)	.82
Statin	227(60.2%)	47(69.1%)	180(58.2%)	1.5 (0.8-2.6)	.16
Endoprosthesis Manifacturer				-	.38
Medtronic	93(24.6%)	14(20.5%)	79(25.5%)		
Cook	106(28.1%)	25(36.7%)	81(26.2%)		
Vascutek	82(21.7%)	13(19.1%)	69(22.3%)		
Gore	96(25.4%)	16(23.5%)	80(25.9%)		

Table Ib – Multivariate analysis of risk factors for technical intraoperative complications occurrence

	OR (95% C.I.)	P
Female Gender	2.5 (1.1-5.4)	.02*
ASA >3	3.3 (0.4-25)	.25
PAD	2.5 (1-5.8)	.03*
Dyslipidemia	0.8 (0.4-1.5)	.55
Double Antiaggregant Th.	3.8 (0.9-15)	.06
Statin	1.4 (0.7-2.8)	.24

Table II - 30 Days Outcome

30 Days Events	TIC (n=68) No	UC (n=309) No	P
Death	1 (1.4%)	0	.18
Steno-occlusive Event	0	1 (0.3%)	1
Type I-III Endoleak	0	3 (0.9%)	1
Mean GFR	65.1 ± 21.4 ml/min	67.6 ± 20.7 ml/min	.6
Haemodialysis	0	0	-
Buttock Claudication	0	0	-

Table III - Mid-term Outcome

Mid-term Events	TIC (n=68) %	UC (n=309) %	P
Overall Complications	13.4 ± 7.6%	11.4 ± 3.5%	.49
Type I-III Endoleak	11.2 ± 7.5%	7 ± 2.9%	.8
Iliac leg occlusion/thrombosis	26.9 ± 12.3%	3 ± 2.1%	.01*
Buttock Claudication	0	2 ± 2%	.6
Haemodialysis	0	0	-
Survival	91.7 ± 8%	96.2 ± 2.1%	.5
Freedom from Reintervention	81.4 ± 9.9%	96 ± 2.2%	.49

Figure legends

Figure 1 - Rupture of right external iliac artery and treatment with covered stent

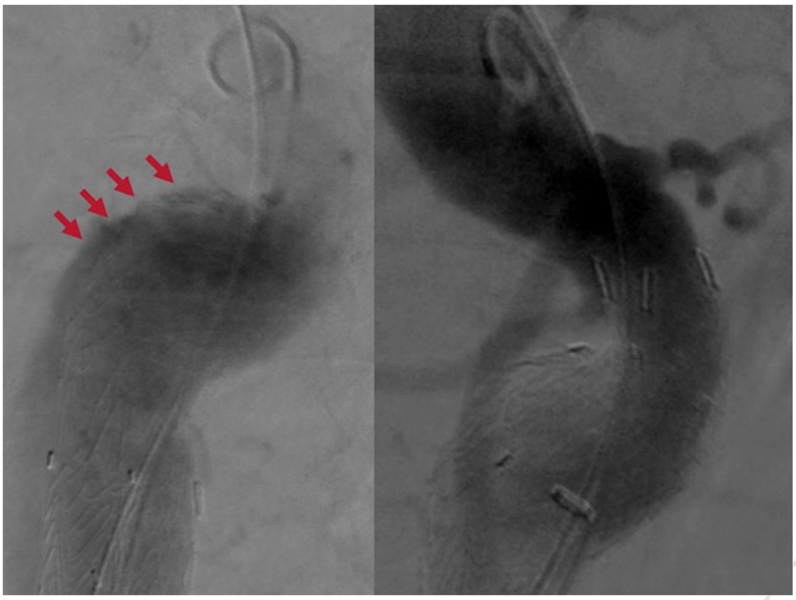
Figure 2 - Endoleak Ia and correction with proximal cuff deployment

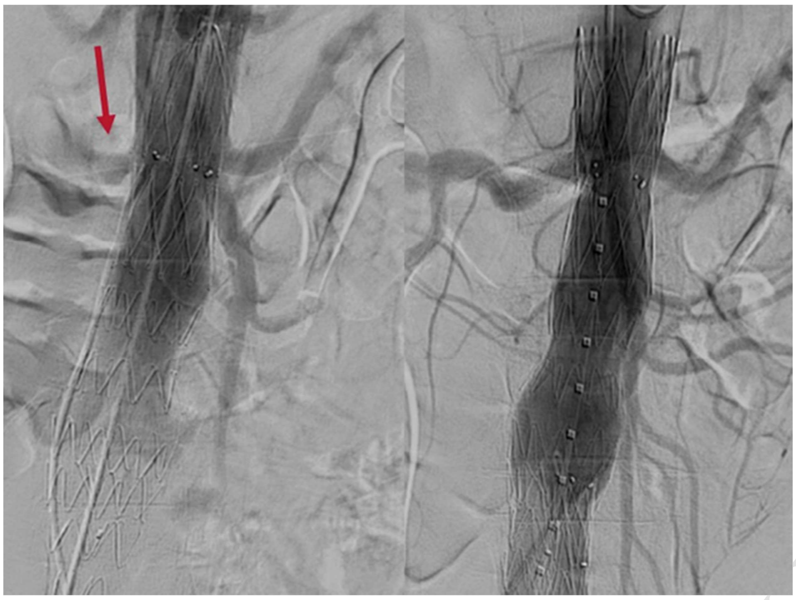
Figure 3 - Unplanned coverage of right renal artery and treatment with renal artery cannulation through the free flow of a suprarenal fixation endograft and subsequent stenting

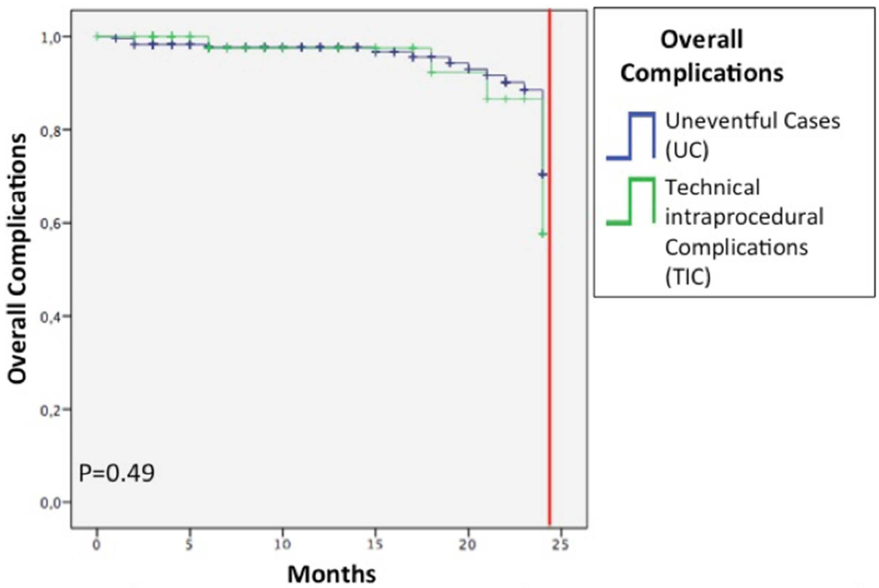
Figure 4 - 24-months overall complications rate

Figure 5 - 24-months iliac leg occlusion

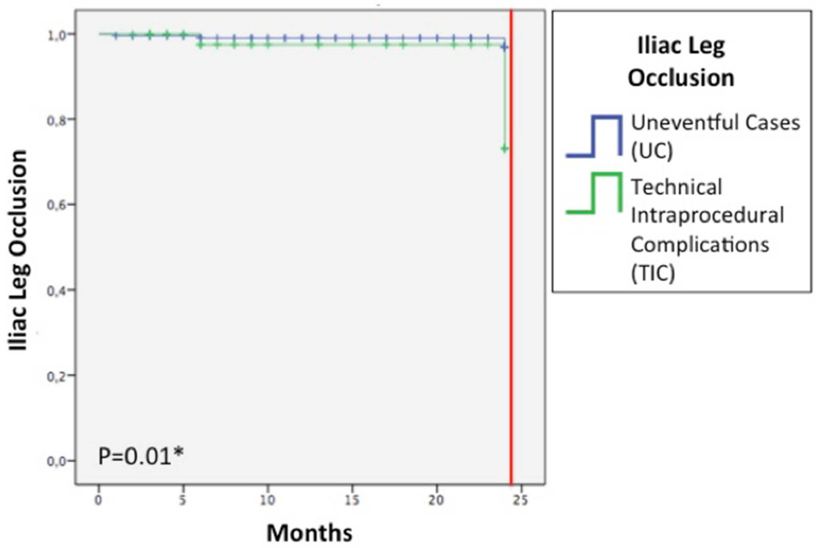

1940
256







	UC					TIC				
Months	5	10	15	20	25	5	10	15	20	25
K-M Estimate	.98	.97	.96	.93	.70	1.00	.97	.97	.92	.57
Standard error	.00	.01	.01	.02	.05	.00	.02	.02	.05	.12
N at risk	183	133	95	72	0	41	27	22	16	0



	UC					TIC				
Months	5	10	15	20	25	5	10	15	20	25
K-M Estimate	.99	.99	.99	.99	.97	1.00	.97	.97	.97	.73
Standard error	.00	.00	.00	.00	.02	.00	.02	.02	.02	.12
N at risk	183	133	95	72	0	41	27	22	16	0