The Outcome of Technical Intraoperative Complications Occurring in Standard Aortic Endovascular Repair

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Background: Technical intraoperative complications (TICs) may occur during standard endovascular repair (EVAR) with possible effects on the outcome. This study evaluates the early and midterm effects of TICs on EVARs.

Methods: All EVARs (from 2012 to 2016) were analyzed to identify all TICs: (1) endoluminal defects (stenosis, dissection, rupture, compression of native arteries, or endograft); (2) type I-III endoleaks; (3) unplanned artery coverage; and (4) surgical access complications. Follow-up was performed by Doppler ultrasound/ontrast enhanced ultrasound/computed tomography scan at yearly intervals. The outcome was compared with that of uneventful cases (UCs) through Fisher’s exact test and Kaplan-Maier curve.

Results: TICs 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 of 8 unplanned artery coverages were revascularized (2 renal and 1 hypogastric); 5 hypogastric coverages had an unsuccessful correction; and 4 access artery injuries were repaired. Although fluoroscopy time and contrast usage were significantly higher in the TIC group than those in the UC group (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 groups 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 hemodialysis (0% in both). Midterm iliac leg occlusion was significantly higher in the TIC group (26.9 ± 12.3% vs 3 ± 2.1%, \( P = 0.01 \)).

Conclusion: TICs 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 midterm iliac leg occlusion.

BACKGROUND

Endovascular repair (EVAR) is presently the mainstay in the treatment of abdominal aortic aneurysm (AAA) because technical expertise and endograft evolution have allowed to reach high standards of care, with reduced procedure time and low intra procedural and perioperative complications. Nevertheless, several technical intraoperative complications (TICs) may occur in daily clinical practice, even in highly standardized procedures, because 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, and 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 EVAR3–8; 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 TICs occurring during the procedures and a midterm follow-up of patients is lacking. Thus, the aim of our study is to describe TICs and their treatment to evaluate their perioperative and midterm effects.

METHODS

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

- **Group A**, endoluminal defect: 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 is used toward any possible cause of stenosis 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 as they do not represent a real intraprocedural failure, but as a parophysiological condition, which requires only a strict follow-up.9

A standard EVAR procedure was defined as aorto-bi-common-iliac endograft implantation for unruptured AAAs, following the instructions of the appropriate manufacturer for use. We considered patients suitable for standard EVAR treatment according to Chaikof EL10 classification criteria, such as length, diameter, amount of calcium, thrombus, and angulation of aortic proximal neck and common iliac arteries. If those criteria were not satisfied during planning and sizing of every single case, the patient was excluded from the 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 to identify risk factors for TIC occurrence and compared with the consecutive uneventful cases (UCs) treated in the same period. Preoperative peripheral artery disease was considered in case of Leriche-Fontaine classification IIb to IV stage. Mean fluoroscopy time and amount of iodinated contrast medium used during the procedure were also analyzed.

Patients with TICs and UCs were also compared in terms of 30-day and midterm results, considering the presence of type I-III endoleaks, iliac leg occlusion/thrombosis, buttock claudication, renal failure, hemodialysis, mortality, and reintervention rate.

Follow-up

Follow-up was performed by duplex ultrasound, contrast-enhanced ultrasound, or computed tomography (CT) scan. Every patient submitted for 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 changes are 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 lifestyle
or any new pain during walking after the intervention, to detect any possible steno-occlusive event responsible for buttock, thigh, or calf claudication.

Statistical Analysis

Frequencies were expressed in percentages and continuous variables in 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 patients with TICs and UCs by Fisher's exact test, odds ratio (OR), and 95% confidence interval; the results were confirmed by multivariate analysis (including factors significant or with trend to significance, \( P < 0.20 \) at the univariate analysis). Fisher’s exact test was also used to analyze perioperative results between the two groups.

Comparison between TIC and UC midterm outcomes was performed by survival function (Kaplan-Meier with log-rank evaluation). SPSS Statistics 21.0 for Mac Os 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 EVARs were performed in our center with different types of infrarenal (177 of 377 [47%]) or suprarenal fixation endografts (200 of 377 [53%]). Preoperative characteristics of patients are reported in Table I.

TICs occurred in 68 of 377 (18%) EVARs, 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 cases), 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 surgical conversion (1 case) due to infolding of the proximal stent of endoprosthesis at the 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 the 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 using a 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 hypogastic 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 TIC Occurrence

The preoperative evaluation of risk factors for TIC occurrence (as shown in Table I) showed a higher prevalence of peripheral arterial occlusive disease in patients with TICs and higher number of female patients. Specifically, a high number of female patients were found in the TIC group (17.6%) compared with those in the UC group (8.4%) (OR: 2.3; 95% confidence interval [CI]: 1.1–4.9, \( P = 0.04 \)). The most common TIC type in women was high-flow endoleak (group B) with 6 of 12 TIC cases (50%), followed by endoluminal defect (group A) with 4 of 12 TIC cases (33.3%) and surgical access complication (group D) with 2 of 12 TIC cases (16.6%). The prevalence of peripheral artery disease was higher in the TIC group (14.7%) than that in the UC group (6.2%), with OR of 2.6 (95% CI: 1.5–5.8) and \( P = 0.02 \). These results were also confirmed by a multivariate analysis of risk factors for TIC occurrence, as shown in Table II.

The mean fluoroscopy time was significantly higher in patients with TIC than that in patients.
Fig. 2. Endoleak Ia and correction with proximal cuff deployment. Red arrows show type Ia endoleak.

Fig. 3. Unplanned coverage of the right renal artery and treatment with renal artery cannulation through the free flow of a suprarenal fixation endograft and subsequent stenting. Red arrow shows the unplanned coverage of right renal artery.
with UCs (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-day outcome, there were no significant differences between patients with TICs and UCs, as shown in Table III. In patients with TIC, 1 (1.4%) perioperative death occurred: after an intraoperative external iliac artery rupture, the artery was repaired by an iliac artery endograft by 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 patients with UC, 1 (0.3%) iliac leg occlusion occurred. Three UCs (0.9%) 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-month intervals, with no increase in the sac diameter (Table II).

**Midterm Outcome**

The mean follow-up time was 25.63 ± 10.53 months (median: 27 months; range: 15-58 months). At 24 months, the overall complications rate (death, freedom from reintervention, persistent type I-III endoleak, buttock claudication, and renal insufficiency requiring hemodialysis) was 13.4 ± 7.6% for TIC versus 11.4 ± 3.5% for UC, \(P = 0.49\) (Fig. 4); as shown in Table IV, there was no significant difference in terms of midterm survival, freedom from reintervention, persistent type I-III endoleak, buttock claudication, and renal insufficiency requiring hemodialysis between TIC and UC groups. However, iliac leg occlusion/thrombosis at 24 months was significantly higher in TIC than in UC (26.9 ± 12.3% vs 3 ± 2.1%, \(P = 0.01\)), as shown in Figure 5.

Patients who developed iliac occlusion after TIC at follow-up were 4 men. 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 intraoperative iliac stenting. The second patient showed mild calcification of the common iliac arteries; a bilateral iliac stenting was performed during EVAR because of stenosis of aortic bifurcation seen at the completion angiogram. After several months, a right iliac leg thrombosis occurred. The 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 of 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) to correct the endoluminal defect; 1 of 4 patients underwent femoral to femoral crossover bypass after unsuccessful thrombolysis. In the UC group, 2 of 3 patients with acute iliac leg thrombosis underwent iliac relining (both with covered stent) to correct the endoluminal defect; 1 of 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 TICs 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 in the present study. These unexpected events require adjunctive maneuvers to repair or prevent negative outcomes. This can be achieved in most cases; however, a small percentage of these TICs are not amenable to repair (i.e., the unplanned coverage of a hypogastric artery).

### Table II. Multivariate analysis of risk factors for technical intraoperative complications occurrence

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>OR (95% CI)</th>
<th>(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender</td>
<td>2.5 (1.1–5.4)</td>
<td>0.02*</td>
</tr>
<tr>
<td>American Society of Anesthesiologists classification &gt; 3</td>
<td>3.3 (0.4–25)</td>
<td>0.25</td>
</tr>
<tr>
<td>Peripheral arterial occlusive disease</td>
<td>2.5 (1–5.8)</td>
<td>0.03*</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>0.8 (0.4–1.5)</td>
<td>0.55</td>
</tr>
<tr>
<td>Double antiaggregant Th.</td>
<td>3.8 (0.9–15)</td>
<td>0.06</td>
</tr>
<tr>
<td>Statin</td>
<td>1.4 (0.7–2.8)</td>
<td>0.24</td>
</tr>
</tbody>
</table>

*\(P < 0.05\), statistically significant.
In the considered series, the occurrence of TICs during the EVAR procedures is quite similar of that of other studies in literature. Naslund et al. reported a technical complication rate of 26% in patients submitted to EVAR with both bifurcated and nonbifurcated grafts. Ultee et al. showed a 29% complication of one or more concomitant procedures during elective endovascular aneurysm repair. Similarly, Hobo et al. reported 29.2% of adjuvant procedures during standard EVAR procedures. Although only a limited number of recent articles are available in the literature, it appears that

Table III. Thirty-day outcome

<table>
<thead>
<tr>
<th>Thirty-day events</th>
<th>TIC (n = 68), no.</th>
<th>UC (n = 309), no.</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1 (1.4%)</td>
<td>0</td>
<td>0.18</td>
</tr>
<tr>
<td>Steno-occlusive event</td>
<td>0</td>
<td>1 (0.3%)</td>
<td>1</td>
</tr>
<tr>
<td>Type I-III endoleak</td>
<td>0</td>
<td>3 (0.9%)</td>
<td>1</td>
</tr>
<tr>
<td>Mean glomerular filtration rate</td>
<td>65.1 ± 21.4 mL/min</td>
<td>67.6 ± 20.7 mL/min</td>
<td>0.6</td>
</tr>
<tr>
<td>Hemodialysis</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Buttock claudication</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>

Table IV. Midterm outcome

<table>
<thead>
<tr>
<th>Midterm events</th>
<th>TIC (n = 68) %</th>
<th>UC (n = 309) %</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall complications</td>
<td>13.4 ± 7.6%</td>
<td>11.4 ± 3.5%</td>
<td>0.49</td>
</tr>
<tr>
<td>Type I-III endoleak</td>
<td>11.2 ± 7.5%</td>
<td>7 ± 2.9%</td>
<td>0.8</td>
</tr>
<tr>
<td>Iliac leg occlusion/thrombosis</td>
<td>26.9 ± 12.3%</td>
<td>3 ± 2.1%</td>
<td>0.01*</td>
</tr>
<tr>
<td>Buttock claudication</td>
<td>0</td>
<td>2 ± 2%</td>
<td>0.6</td>
</tr>
<tr>
<td>Hemodialysis</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Survival</td>
<td>91.7 ± 8%</td>
<td>96.2 ± 2.1%</td>
<td>0.5</td>
</tr>
<tr>
<td>Freedom from reintervention</td>
<td>81.4 ± 9.9%</td>
<td>96 ± 2.2%</td>
<td>0.49</td>
</tr>
</tbody>
</table>

*P < 0.05, statistically significant.

In the considered series, the occurrence of TICs during the EVAR procedures is quite similar of that of other studies in literature. Naslund et al. reported a technical complication rate of 26% in patients submitted to EVAR with both bifurcated and nonbifurcated grafts. Ultee et al. showed a 29%
TICs 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 TIC occurrence (female sex rate was 17.6% among TIC patients vs. 8.4% among UC patients; OR: 2.3 [1.1 e 4.9] and P = 0.04). The reason for this feature is unknown. These data are in agreement with those provided in a study by 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 occurrence in the TIC group was 14.7% and that in the UC group was 6.2%; OR: 2.6 [1.5 e 5.8]; P = 0.02). These data can be related with the high rate of occurrence of endoluminal defects (group A) (47%), which was the most populous subgroup of TIC population, and consequently the one with the higher rate of iliac leg occlusion at 24 months compared to the UC group in the considered series.

TICs are not influenced by the type of device used, as shown also by previous articles;15e19 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 intraoperative and postoperative type I and type III endoleaks; therefore, an accurate patient selection and procedure 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 patients with TICs 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 TICs occurred.

As a matter of fact, the perioperative outcome was not influenced by TICs with results comparable to UCs, in terms of perioperative complications such as stenocclusions, high-flow endoleaks, renal insufficiency requiring hemodialysis, 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 endarterectomies and renal artery stenting were associated with an increased perioperative mortality.5 In the second one, endovascular adjunctive maneuvers were associated with a higher rate of perioperative complications and adjunctive surgical peripheral arterial procedures, with significant higher early perioperative mortality and morbidity.4

We have been interested also in the midterm impact of TIC, differently from previous studies.3,4 As a matter of fact, the midterm outcome was not influenced by TICs in terms of late type I-III endoleak, buttock claudication, renal failure requiring hemodialysis, reintervention, and mortality rate. The iliac leg occlusion at 24 months was significantly higher in the TIC group (26.9 ± 12.3% vs 3 ± 2.1%, P = 0.01) than that in the 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 the TIC population. Confirming this, Mantas GK et al.22 analyzed 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 than 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 TICs 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 the 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

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

Although an early outcome is not influenced by TIC occurrence, the midterm 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