Reprinted Article “Endovascular Repair with Bifurcated Stent-Grafts under Local Anaesthesia to Improve Outcome of Ruptured Aortoiliac Aneurysms”☆

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Abstract Introduction: Acute haemodynamic changes and/or loss of abdominal muscle tone can occur during induction of general anaesthesia and may be the Achilles’ tendon in endovascular aneurysm repair (EVAR) of ruptured aortoiliac aneurysms (rAIA). The purpose of this study was to evaluate the use of local anaesthesia (LA) for EVAR to overcome these limitations. Methods: Twenty-one consecutive patients with rAIA are included in this study. Twenty patients underwent EVAR under LA, and 1 patient was treated under general anaesthesia. Haemodynamics were stabilised during assessment of EVAR feasibility by CT-scan and during the procedure itself by controlled hypotension (MAP 50-60 mmHg) and moderate fluid resuscitation. Results: Median procedure time was 120 min. Haemodynamics remained stable in all but 3 patients who required transfemoral balloon occlusion of the supra-renal aorta. Perioperative intubation was necessary in 5 patients because of respiratory distress (n = 3), or retroperitoneal access (n = 2). Temporary deterioration of renal function occurred in 6 patients, with 2 requiring hemofiltration. CT-scan confirmed sealing of the rAIA in all patients at discharge. 30-day mortality was 9.5% (2 deaths). In the median follow-up of 19 months, there were no deaths, but 3 endovascular re-interventions, 1 crossover femoro-femoral bypass, and 1 open surgical graft repair. Discussion: Our series is the first to show that EVAR for rAIA can be safely performed under LA. This approach allows implantation of commercially available bifurcated SG and improves patient outcome.

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Introduction

Despite significant improvements in anaesthetic and surgical techniques, the mortality and morbidity rates of ruptured aortoiliac aneurysms (rAIA) treated by conventional open surgery remains as high as 30-70%.1,2 Promising results with the less invasive endovascular technique have been reported.3,4 However, in these studies, stent-grafting was performed under general anaesthesia and haemodynamic instability occurring during induction of general anaesthesia remains an important issue.4 It seemed to us that local anaesthesia, which has been demonstrated to provide more stable haemodynamics in elective EVAR,5,6 might be the more appropriate approach in patients with ruptured aortoiliac aneurysm.

We report here our results in a consecutive series of 21 patients treated with this technique.

Materials and Methods

Prospective study in 57 consecutive patients with ruptured AIA treated between August 1998 and September 2001. Of these 57 patients 21 (37%) were treated by stent-grafting, and 36 patients (63%) were treated by conventional open surgery. During the same time period another 262 non ruptured were treated - 64 open and 198 by stent-graft. The mean age of the 4 female and 17 male EVAR patients was 74 years (range: 53-88 years). An abdominal aortic aneurysm had been previously diagnosed in 10/21 patients (47%) prior to rupture. Most of these 10 patients were treated conservatively, because the morbidity risk associated with open surgery was considered to be too high. Other patients had refused surgery. Nevertheless, as rupture occurred, all of the patients asked for a rescue procedure and were transferred to our unit. Because of the experimental aspect of stent-grafting in that situation, informed consent was obtained in all cases, either from the patient or their family.

Initially, only open surgery was considered in patients presenting with one or more of the following contraindication for EVAR: (a) persistent marginal haemodynamics despite resuscitation (n = 10); (b) abdominal pains (n = 5); (c) sub-optimal infrarenal anatomy with short and/or tortuous neck and/or kinking, and/or small sized iliac vessel (n = 5); and (d) intraperitoneal haematoma or ongoing retroperitoneal bleeding (n = 7). A total of 35 patients were treated using these criteria. Of these 35 patients, 10 (17%) underwent EVAR, and 25 (83%) underwent conventional open surgery. Impressed by the excellent results in the first 10 EVAR patients, we decided to re-evaluate our inclusion/exclusion criteria. As a result, we changed the protocol to tolerate a systolic blood pressure of about 80 mmHg and restrict fluid infusion to a minimum until the aneurysm is sealed (by EVAR or cross-clamping). Moreover, because patients remained haemodynamically stable under these conditions, patients with intraperitoneal haematoma or on-going retroperitoneal bleeding were no longer excluded. Since then, an additional 22 patients have been treated. Of these, 11 patients (50%) underwent conventional open surgery (COS), and 11 patients were treated by EVAR. In 5/11 patients (45%) CT scan was not performed because of severe shock and/or abdominal distension requiring immediate open surgery without further investigation. In 6/11 patients (55%) EVAR was not performed because of anatomical contraindications (short proximal neck and/or unfavourable anatomy of the access vessel). In summary, EVAR could not be performed because of an anatomical contraindication in 15/36 patients (42%) and an haemodynamic contraindication in 21/36 patients (58%) treated by conventional open surgery.

According to the American Society of Anesthesiologists (ASA) classification, patients were classified as ASA IV. In addition to the risk represented by the rescue procedure, all of the patients had other risk factors such as chronic heart failure, coronary vessel diseases, cerebrovascular and peripheral vascular disease, renal insufficiency, chronic obstructive lung disease, and cancer.

Assessment of feasibility

Early in our experience, imaging consisted of ultrasound of the abdomen to confirm the diagnosis and to rule out presence of free intraabdominal fluid, which seemed to us to be a contraindication to EVAR. Following the ultrasound, angio CT-scan was performed to assess the rupture and the anatomical feasibility of stent-grafting, according to accepted criteria. Retroperitoneal haematoma was confirmed in all the 21 patients (Fig. 1) and in 9/21 (43%) patients, intraperitoneal haematoma was observed. The mean aneurysm diameter was 71mm.
(range: 50-95 mm). The proximal aneurysm neck had a median length 26 mm (range: 7-34 mm) and a median diameter of 25 mm (range: 18-30 mm). The median distal iliac diameter was 12 mm (range: 10-14 mm).

Anaesthetic management

Immediately after confirmation of anatomical feasibility of stent-grafting, patients were transferred to the operating theatre and prepared for the EVAR procedure. Simultaneously, they received a central venous catheter, radial artery catheterisation for continuous blood pressure monitoring and blood gas analysis, and a diuresis catheter. EVAR was performed under local anaesthesia with 0.5% lidocaine combined with i.v. analgosedation (Remifentanil), in order to increase patient comfort and avoid movements during implantation of the stent-graft (SG). Controlled hypotension (systolic blood pressure under 100 mmHg) and permissive hypovolemia were maintained until the aneurysm was sealed. Once the SG was correctly implanted, blood pressure and blood volume were corrected to more physiological values. (Fig. 2 and Table 1).

Stent-grafting

All the patients were treated by implantation of commercially available premounted self-expanding SG. Of these, 20/21 SGs were of the modular type (trunk-ipsilateral
component with an attachment site for the contralateral component), and one was a single-piece tubular SG (Vanguard (Boston Scientific), \( n = 7 \); Talent (Medtronic), \( n = 1 \); and Excluder (Gore), \( n = 13 \)).

The Vanguard and Talent stents are coated with polyester (Dacron) fabric, and the Excluder stent is coated with a Teflon (ePTFE) fabric. Both Vanguard and Talent stents have a proximal uncovered stent (bare spring) allowing transrenal fixation in case of a short proximal neck. The Excluder SG does not have this feature and therefore cannot be implanted when the proximal aortic neck is shorter than 10 mm. The delivery system of the Vanguard and Talent SG are very similar. These SGs are pre-mounted within a delivery system. The SG is deployed by retracting the introducer sheath while holding the supporting catheter stationary. A totally different system has been developed by Gore. An ePTFE sleeve is used to constrain the SG on the leading end of the delivery catheter prior to deployment. The deployment line connects to a deployment knob located on the other end of the delivery catheter. The device opens instantaneously when the deployment line is withdrawn from the sleeve.

The diameter and length of the endovascular prostheses was determined by measurements of the normal aortic section proximal to the aneurysm and of the iliac arteries. The SG was oversized by 15%. The median size of the prostheses was 28 mm (range: 24-34 mm) for the proximal diameter and 14 mm (range: 10-14 mm) for the distal diameter. After surgical exposure of one or, when contra lateral sheath was > 14 mm both femoral arteries, guide wires, catheters and sheaths were introduced endoluminally under fluoroscopic guidance (Sirimobil 2000, Siemens). After the aortic SG was advanced up to the desired position, location of the renal arteries and SG deployment was performed under angiographic control. After catheterization of the contralateral iliac orifice, the SG extension was implanted in order to complete the bifurcated fabric. Catheterization of the iliac orifice was achieved using a transfemoral retrograde approach in 12 patients or with a crossover catheter (EasyCross®, Fumedica, CH), when the latter procedure could not be completed within 2-5 minutes. In 3 patients with increasing haemodynamic instability, transfemoral suprarenal balloon occlusion (large occlusion balloon catheter, Boston Scientific Corp., Meditech, U.S.A.) above a super-stiff guidewire allowed haemodynamic stabilization and completion of SG implantation (Fig. 3). In one patient haemodynamic deterioration occurred acutely during anesthetic instrumentation and the occlusion balloon was implanted urgently as a salvage procedure. In the 2 other patients, haemodynamics deteriorated continuously and suprarenal balloon occlusion had to be performed as a first step too, but not on an urgent basis. The balloon was removed after the short time period when the aortic SG was delivered and then re-inflated within the main body of the SG (Fig. 3). At the end of the procedure, a completion angiogram was performed to confirm sealing. Two patients required an open surgical procedure on the hypogastric artery. In one case open ligation was performed in order to avoid retrograde filling of the abdominal aortic aneurysm. In the other case with a type D abdominal aortic aneurysm, a bypass to one hypogastric artery was performed in order to avoid hypogastric hypoperfusion after bilateral overstenting of the iliac bifurcation.

### Postoperative management

Directly after EVAR, a control CT-scan was performed to assess correct positioning of the SG, complete sealing of the aneurysm and dimension of any retro- and/or infrarenal haematoma.

All the patients were then transferred to the ICU. Most of the patients required blood, fresh frozen plasma, or platelets transfusion postoperatively (Fig.2). As long as blood transfusions were necessary, systolic blood pressure was maintained below 120 mmHg. Before discharge from hospital an additional CT-scan was performed. Additional CT-scans were performed at 6 weeks (Fig. 4), 6 months, and yearly postoperatively.

### Results

The technical success of this procedure was 100% with complete sealing in 21/21 cases and no conversion to open graft repair. Primary anesthetic management of the SG patients was with local anaesthesia in all but one case when the patient was already intubated. Switching to general anaesthesia was necessary in 5 patients (19%) because of a retroperitoneal approach (\( n = 2 \), ligation and/or revascularization of the hypogastric branch after stent-grafting). As long as respiratory insufficiency was maintained below 120 mmHg. Before discharge from hospital an additional CT-scan was performed. Additional CT-scans were performed at 6 weeks (Fig. 4), 6 months, and yearly postoperatively.

### Table 1

<table>
<thead>
<tr>
<th>Fluids (ml)</th>
<th>Preoperative</th>
<th>Intraoperative</th>
<th>Postoperative</th>
</tr>
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<tr>
<td>Median (range)</td>
<td>1245 (500-1750)</td>
<td>2200 (800-3500)</td>
<td>2500 (1000-3500)</td>
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<td>FFP (package)</td>
<td>1 (0-4)</td>
<td>2 (0-11)</td>
<td>2 (0-12)</td>
</tr>
<tr>
<td>Tc (package)</td>
<td>0 (0)</td>
<td>0 (0-9)</td>
<td>1 (0-6)</td>
</tr>
<tr>
<td>Ec (package)</td>
<td>0 (0)</td>
<td>0 (0-6)</td>
<td>0 (0-6)</td>
</tr>
</tbody>
</table>

Among of fluids and transfusions required pre-, intra- and postoperative (24 h).
Figure 3  Stent-grafting in instable haemodynamics. Once both guide-wires are placed endoluminally, transfemoral supra-renal balloon occlusion is performed from the left side (a). For the delivery of the SG, the balloon is briefly deflated, removed and then rapidly replaced from the right side and re-inflated below the renal arteries within the SG. Catheterisation of the left iliac ostium is performed from the left side, with a standard transfemoral approach (b). When catheterisation becomes time-consuming, a cross-over technique with special catheters (EasyCross) from the right side can be considered (c). Finally the left iliac leg is implanted and the aneurysm excluded (d).
The in-hospital mortality rate was 9.5% (2/21 patients). One patient suffering from type B dissection died on post-operative day (POD) 7 after additional "de novo rupture" of the right iliac artery distal to the SG. In one case autopsy revealed no cause of death. Renal failure or deterioration of renal function occurred in 6/21 cases (28%), but haemofiltration for a median duration of 3.5 days was necessary in only 2 patients. Mechanical ventilation was necessary for a median duration of 5 days (range 1-10 days). In-hospital endovascular re-intervention was necessary in 2 patients (9.5%) with attachment endoleaks. Two patients developed an abdominal compartment syndrome due to a huge retroperitoneal haematoma. Intubation, relaxation and haemofiltration were sufficient interventions in these patients, and no surgical decompression was necessary (Figs 1 and 4). Before discharge from hospital (median hospital stay of 6 days (range 3-10 days)) the correct position of SG and complete sealing of aneurysm was confirmed in all cases by CT-scan.

During the 3 year follow-up (median: 19 month, range: 4-37 months) there were no additional deaths. Control CT-scans showed localized aneurysm reperfusion (type II endoleak) in 4/20 patients (20%). As the haematoma was resorbed and aneurysm diameter did not increase, a conservative approach was taken. Re-interventions had to be performed in 7/20 patients (35%). One patient with a distal reperfusion was treated by a distal SG extension. The patient that was primarily treated with a tubular SG was converted to a bifurcated SG because of a distal reperfusion. A third patient developed a distal migration with untreatable kinking of the SG. He was treated by open removal of the SG and implantation of a conventional surgical bifurcated Dacron graft. Two patients developed a thrombosis of the iliac SG limb. Of these, one was treated with thrombolysis, while the other required a surgical cross-over bypass. Two patients developed a groin infection. The one with superficial infection was treated by local revision. The second patient with an infection who previously had a graft replacement of the common femoral artery, and presented with a deep infection with graft involvement, required graft replacement with a homograft.

Discussion

Despite significant improvements in resuscitation, anaesthetic and surgical techniques morbidity and mortality rate of ruptured aortoiliac aneurysms remains unchanged up to 70%. When using the open approach, patient outcome is impacted negatively by the intensive resuscitation necessary to achieve physiological or supra-physiological volume balance and blood pressure. The use of fluids and catecholamines seems to be counterproductive. Continuing haemorrhage and coagulation disorders are the consequences. General anaesthesia inhibits the sympathetic tone that can induce a difficult to control hypotension in these often hypotensive and hypovolemic patients. Myorrelaxation, opening the abdomen and dissection of the retroperitoneal space can precipitate a free rupture. The acute increase in left ventricular after-load due to aortic cross-clamping can induce subendocardial ischaemia and acute or delayed myocardial infarction. Finally, the
ischaemia-reperfusion injury may lead to severe arrhythmia and/or multiple organ failure. Aortic stent-grafting that is performed without laparotomy, retroperitoneal dissection, and aortic cross-clamping is a very attractive alternative for patients with rupture, despite long-term concerns. Therefore, it is not surprising that several authors have reported their experience with stent-grafting of ruptured aneurysms. In these limited studies, general anaesthesia is the uncontested choice for anaesthetic management and, not surprisingly, haemodynamic instability occurring during induction of general anaesthesia remains an issue. Haemodynamic stability is of prime importance for the endovascular technique as it can affect the time required to seal the aneurysm, and consequently, the duration of cross-clamping. It seemed to us that local anaesthesia, which has no systemic effects and does not affect abdominal tone, might be the more appropriate approach in patients with ruptured abdominal aortic aneurysm. Our series has confirmed this hypothesis since none of the patients here presented with the acute haemodynamic changes, normally seen during induction of general anaesthesia. Three patients with deterioration of haemodynamics required temporary transfemoral suprarenal balloon occlusion. This manoeuvre allowed the haemodynamics to be stabilised, and to complete the stent-grafting. Intraoperative intubation was necessary in 3 patients. In 2 of these patients, the aneurysm was already sealed, and in one, transfemoral suprarenal balloon occlusion had already been performed. Acute haemodynamic instability subsequent to the intubation was not observed in any of these 3 patients.

The selection of bifurcated modular stent-grafts for implantation, instead of unilateral aortoiliac prosthesis, which require an additional occluder to seal the contralateral side, was motivated by the fact that we wanted to achieve an anatomic reconstruction. In considering on the one hand the time needed to place an occluder, such as in the case of a unilateral aortoiliac SG, and on the other hand the time needed for the completion of a modular bifurcated SG with the help of a cross-over system (EasyCross, Fumedica, CH), we did not see any advantage of the unilateral aortoiliac SG, and gave our preference to the bifurcated one. Our series shows that this approach is a valuable option. With regards to the number and dimensions of the prostheses that are necessary to treat most ruptured aneurysms, we feel that a stock of three prostheses covering the following proximal aortic and distal iliac diameters of 24-14, 28-14, and 34-14 mm is enough. In case of a short proximal infrarenal neck, a large Palmaz stent can be implanted to achieve optimal proximal anchorage.

Because of the high mortality rate of ruptured abdominal aortic aneurysms, a straightforward surgery, without additional time-loss for imaging, seems to be justified in cases of clinical suspicion of a rupture. Nevertheless, a more deliberate approach, including an intra-abdominal screening with ultrasonography or CT scanning is usually performed. Transabdominal ultrasonography helps to confirm the diagnosis, but examination can be time-consuming, is highly operator-dependant, and the definitive extension of the aneurysm cannot be seen in all cases. Alternatively, on-table angiography combined with intravascular ultrasonography seems to be an attractive option for diagnostic management in stent-grafting for ruptured aneurysm. The costs of the disposable catheters and availability may be limiting factors. We decided to use CT scanning because, with use of contrast-medium, it is a fast and not operator-dependant procedure that gives extensive information about intra-abdominal pathologies and aortic and access vessel anatomy. Acquisition time of a spiral CT-scan is about 80 s with an overall procedure time, including image reconstruction, of 4-6 min. Moreover, with regards to stent-grafting, the decision about feasibility of this approach can be made on-line during image processing. Finally, we do have a CT machine integrated in our emergency room, minimizing transportation time.

For the first 10 cases, only patients whose haemodynamics were stable or could be stabilised after a short resuscitation were considered as suitable candidates. Based on our early results and the extraordinary haemodynamic stability, when stent-grafting was performed under local anaesthesia, we extended the indication to patients who could be stabilised with only slight fluid transfusion at a systolic blood pressure level around 70-80 mmHg. At such a level of arterial blood pressure, a haemostatic state is achieved in most of the patients. No deterioration of the haemodynamic state occurred during the scanning procedure with this management. Once the patient is in the OR, if there is a deterioration of the haemodynamics, transbrachial or transfemoral balloon-occlusion of the supra-renal aorta is possible and helps to control the haemodynamic situation during stent-grafting. All in all, permissive hypovolemia and/or hypotension, the use of local anaesthesia, and/or supra-renal balloon occlusion in case of haemodynamics deterioration, allowed the procedure to be performed in all cases without conversion to conventional open surgery, despite a relatively long overall procedure duration of up to 3 h.

Two patients developed a perioperative abdominal compartment syndrome. Both of them developed abdominal distension, respiratory distress syndrome, and decrease in urinary output, due to a huge retroperitoneal haematoma. Most authors agree that the treatment of choice should be the decompression of the abdomen by laparotomy, and temporary haemofiltration. This allowed us to maintain urinary bladder pressure < 25 mmHg and to avoid additional surgery with its bleeding and infectious complications.

**Conclusion**

Our series, which to our knowledge is the first such series, shows that general anaesthesia can be avoided in ruptured aortoiliac aneurysms. Moreover, the combination of stent-grafting with the less-invasive anaesthetic method allows implantation of commercially available modular bifurcated endografts and improves the outcome of patients suffering from ruptured abdominal aortic aneurysm.
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References