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Present and Future of Branched Stent Grafts in Thoraco-abdominal Aortic Aneurysm Repair: A Single-centre Experience

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Abstract *Background:* Recent developments with fenestrated and branched stent grafts have opened the way to treat complex aortic aneurysms involving the visceral arteries. Early reports on endovascular treatment of thoraco-abdominal aneurysms have demonstrated the feasibility of the technique. Given the sparse literature, its safety has not been established yet.
Methods: A literature review was conducted, and the results of our own series of 30 patients treated with a custom-made Zenith device with fixed branches are presented. Most of the patients were refused open surgery mainly for the extent of the disease combined with co-morbidity, which included in most patients a combination of several risk factors. The mean aneurysm size was 70 mm and the extent of the aneurysm was type I in eight cases, type II in five, type III in 12 and type IV in five patients.
Results: Technical success in our series was achieved in 93% (28/30). Two out of 97 (2%) targeted vessels were lost. In one patient, a renal artery ruptured during insertion of the bridging stent graft. In a second patient, a coeliac artery could not be catheterised and was lost. The 30-day mortality was 6.7% and corroborated with 5.5% in the largest series reported so far. The 6 months and 1-year survival were 89.3% and 76.0%, respectively.
Conclusion: The results of fully endovascular repair of selected thoraco-abdominal aneurysms are promising. A learning curve should be expected. Anatomical limitations such as extremely tortuous vessels and access problems should be taken into account, as well as the quality of the targeted side branches. Although longer-term results need to be awaited, it is likely that endovascular repair of thoraco-abdominal aneurysms will become a preferential treatment option for many patients in the future.
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Thoraco-abdominal aortic aneurysms (TAAAs) involve both the thoracic and abdominal aorta and are relatively uncommon. If left untreated, these patients are at risk of aneurysm rupture and death.[1] Conventional open treatment, however, is still associated with high mortality and morbidity rates. This remains true despite advancements in perioperative management, such as application of intra-operative adjuncts, and improved postoperative care.[2] These complex aneurysms still represent a real challenge to the surgeon. In 2003, Cowan Jr. et al. reported the results from a nationwide discharge database representing 20% of the US hospitals and including 1542 patients with TAAA.[3] The in-hospital postoperative mortality rate after elective repair was 22.3%, with higher rates in surgeons and hospitals with lower volumes. Postoperative complications are often severe and include myocardial infarction and ischaemia, respiratory insufficiency with prolonged ventilation and acute renal failure. One-year survival was reported to be as low as 69% in a population-based study.[4] In addition, there is an inherent risk for paraplegia depending on the extent of the aneurysm and its repair. All these factors, and paraplegia as a separate factor, have been identified as predictors for mortality, also at the longer term.[5] In recent years, a few specialised high-volume centres have achieved operative mortality rates with open repair as low as 5–12%, with good performance scores as well.[6,7] Nevertheless, due to the major impact on the patient, open surgery is only justified in those patients who are in reasonably healthy condition and present with larger aneurysms. Therefore, there is an obvious need for improvement, and alternative treatment options have been explored.

After its first introduction in 1991, endovascular repair (EVAR) of aortic abdominal aneurysm (AAA) has become standard medical care in many centres. Still, a major limitation of EVAR was the necessity of a suitable proximal portion of normal aorta (i.e., proximal neck) to serve as a sealing zone for the stent graft. The solution to this problem was the introduction of customised stent grafts with fenestrations and branches to incorporate the vital side branches of the aorta. Advances in fenestrated endovascular repair techniques (F-EVAR) over the past 10 years opened the way to treat short-necked and juxtarenal aneurysms. The F-EVAR technique has reached maturity with over 2000 cases having been performed worldwide. Published results, albeit from selected centres, are excellent, and durability of the technique equally seems good.[8–15] The development of branched grafts (i.e., grafts with directional side branches) resulted in the first attempts to treat TAAA.[16] The specific advantages, disadvantages and features of the fenestrated versus branched grafts have been elaborated before.[17]

In this article, we review the current literature on fenestrated and branched stent grafts for endovascular TAAA repair, present the results of the first 30 cases performed and discuss shifts in paradigms for future treatment of TAAA.

Current Literature on Fenestrated and Branched Endovascular TAAA Repair

Up to now, EVAR of TAAA has primarily been reserved to a few pioneering centres, but widespread in larger and experienced endovascular centres throughout the world is ongoing. Chuter et al. were the first to treat a TAAA with a multi-branched stent graft.[16,18] In 2001, they published the case of a 76-year-old man with a type III TAAA and a contained rupture of a supracoeliac ulcer treated using this novel approach. The aneurysm was treated with a custom-made device with two 25-mm downward branches for the coeliac trunk and the superior mesenteric artery, as well as two 5-mm stumps for the renal arteries. On the first postoperative day, two additional stents were placed to prevent kinking. Despite technical success, the patient developed paraplegia on the second postoperative day. The repair covered the entire abdominal and half of the descending thoracic aorta, which was ulcerated and ruptured, and the rupture was believed to have contributed to the development of paraplegia.

The largest series reported so far includes a cohort of 73 patients, as published in 2007 and operated on in The Cleveland Clinic Foundation, Cleveland, Ohio, USA.[19] In that series, there were 28 types I, II or III and 45 type IV TAAAs. The mean aneurysm size was 7.1 cm (range: 4.5–11.3 cm). General anaesthesia was used in 47% of the patients and regional anaesthesia in 53%. The devices used were all variants of the Zenith device (Cook Medical Inc., Bloomington, IN, USA). There were no conversions to open surgery nor ruptures post-treatment. Technical success was achieved in 93% of patients (68 out of 73). The 30-day mortality rate was 5.5% (four out of 73). Of the total of 73 patients, major perioperative complications occurred in 11 (14%) patients and included paraplegia in two (2.7%), new onset of dialysis in one (1.4%), prolonged ventilator support in five (6.8%), myocardial infarction in four (5.5%) and minor haemorrhagic stroke in another (1.4%). A majority of patients had no complications. The mean length of stay was 8.6 days. At follow-up, six deaths had occurred. There were no instances of stent migration nor aneurysmal growth.

These 73 patients were also included in a larger series of patients also comprising repair of descending thoracic aneurysms.[20] In a direct comparison with open repair, no significant difference in the incidence of mortality or spinal cord ischaemia was found between EVAR and open repair. Multivariate analysis showed that the extent of the disease (types I–IV) was the primary factor in the development of spinal cord ischaemia in both the treatment modalities.

The results of other published cases/series with endovascular TAAA repair are summarised in Table 1.[21–27]

Groningen Series

Patient characteristics and technical details

Up to April 2009, experience included a total of 245 fenestrated and branched stent grafts for aneurysmal disease. The indications for treatment were short-necked AAA ($n = 86$), juxtarenal AAA ($n = 74$), suprarenal AAA ($n = 11$), TAAA ($n = 34$), arch aneurysm ($n = 7$) and iliac aneurysm ($n = 33$).

Experience with regards to endovascular repair of TAAA is limited to 34 patients, of which four patients were treated in another hospital under supervision, and follow-up not complete. From the remaining 30 patients, complete

Table 1 Results with branched and fenestrated endovascular repair for TAAA in the literature.

Authors	Year	No	Extent of disease	Technical success	30-day mortality	1-Year survival
Chuter[16,18]([a])	2001	1	TAAA III	100%	—	—
Bleyn[21]	2002	1	TAAA IV	100%	0%	—
Anderson[22]	2005	4	TAAA II ($n = 2$), IV ($n = 2$)	75%	25%	75%
Greenberg[23]([b])	2006	9	—	89%	0%	78%
Simi[24]	2007	1	TAAA III	100%	—	—
Roselli[19]([b])	2007	73	TAAA I, II, III ($n = 28$), IV ($n = 45$)	93%	5.5%	81%
Chuter[25]	2008	22	—	100%	9.1%	77%
Gillling-Smith[26]	2008	6	TAAA II ($n = 2$), TAAA III ($n = 2$) TAAA IV ($n = 2$)	100%	0%	100%
Bicknell[27]	2009	8	TAAA I ($n = 2$), TAAA III ($n = 2$) TAAA IV ($n = 4$)	100%	0%	—

[a] Same case.
[b] same series.

follow-up was available. These 30 patients included 23 men and seven women with a mean age of 71.5 years (range: 58–86 years). Twenty (67%) patients were refused open surgery mainly for the extent of the disease combined with co-morbidity. Thirteen (43%) patients had previous aortic surgery (open ($n = 11$), EVAR ($n = 2$)). Ten (33%) patients had a hostile abdomen due to multiple previous laparotomies. The type of the aneurysm was as follows: TAAA I, $n = 8$; TAAA II, $n = 5$; TAAA III, $n = 12$; and TAAA IV, $n = 5$. The mean ($\pm$SD) diameter of the aneurysm was 70 ± 9 mm (range: 55–100 mm). Further patient demographics are shown in Table 2.

The devices used were all individually tailored Zenith stent grafts (Cook Medical Inc., Brisbane, Australia). All types of fenestrations, scallops and branches were used, dictated by the individual anatomy. For TAAA type I, scallops were sometimes used distally for the coeliac and superior mesenteric artery, in order to land the distal edge of the graft just above the renal arteries. Similarly, when branches were used for TAAA type I, scallops were sometimes used to incorporate the renal arteries. Fenestrations were preferentially used if the main body of the stent graft had contact with the wall of the aorta and the orifice of the target vessel, or only a short gap to be bridged. Branches were mainly used in those situations where a longer gap had to be bridged from the branch towards the orifice of the target vessel.[17]

Table 2 Patient demographics own series.

Diabetes mellitus	3	(10%)
Hypertension	27	(90%)
Hypercholesterolaemia	25	(83%)
Smoking	18	(60%)
Cardiac disease	20	(67%)
Carotid disease	2	(7%)
Pulmonary disease	24	(80%)
Renal disease	16	(53%)
Previous aorta surgery	13	(43%)
Hostile abdomen	10	(33%)
ASA class 2	3	(10%)
3	22	(73%)
4	5	(17%)

In total 97 fenestrations/branches for a possible 120 visceral vessels were targeted: 45 branches directed downwards, six branches directed upwards, 27 fenestrations and nine scallops. Fourteen aortic side branches were already occluded at the time of diagnosis: three right renal arteries, five left renal arteries, one superior mesenteric artery and five (three complete, two near occlusions) coeliac arteries. The remaining nine visceral vessels, all renal arteries in type I TAAA, did not require incorporation of the stent graft. Coverage of the descending thoracic and abdominal aorta was an estimated 50% in eight patients, 75% in 15 patients and 100% in the remaining seven patients. In the majority of cases, balloon-expandable stents (Advanta, Atrium Medical Corporation, Hudson, NH, USA, or Jomed Covered Stent Graft, Jomed International AB, Helsingborg, Sweden) were used to bridge the branches of the stent graft to the target vessels. Additional support to prevent kinking was usually achieved with self-expandable stents (Zilver Stent, Cook Medical Inc., Bloomington, IN, USA, or Smart Stent, Cordis, Miami, FL, USA). All but one operation were performed under general anaesthesia, and in 19 (63%) cases a spinal catheter was inserted for drainage of the spinal fluid. Access was gained through the groins and in 23 (77%) cases also through an upper access site, including the brachial artery ($n = 3$), the axillary artery ($n = 14$), the subclavian artery (supraclavicular approach, ($n = 2$), infraclavicular approach ($n = 3$)) and the left common carotid artery ($n = 1$).

Results

Technical success was achieved in 28 (93%) patients. In two patients target vessels were lost. In the first patient a renal artery ruptured during inflation of the bridging stent graft, which was inadvertedly positioned inside a smaller side branch of the renal artery. This unfortunately happened in a patient with a single kidney, therefore resulting into dialysis. In the second patient it proved impossible to catheterise a heavily stenosed coeliac artery. Due to catheterisation attempts, the coeliac artery occluded; the branch on the main stent graft was covered with a cuff in order to seal the endoleak.

Adjunctive manoeuvres were required in seven (23%) patients. Rupture of a vessel (aortic arch ($n = 1$), external iliac artery ($n = 1$)) occurred in two patients: both were immediately treated with additional stent grafts. In further two patients laparotomies were needed for access, one planned for catheterisation of a left renal artery, one unplanned to create an aortic conduit in view of an impossible iliac access. In two cases arteriosclerotic complications had to be resolved: in the first case by stenting a stenosed external iliac artery, in the second case by repairing a damaged common femoral artery. Finally, in one patient, torsion occurred in the distal stent of the proximal fenestrated graft due to repositioning inside a previous surgical graft. This resulted in an insufficient overlap between the fenestrated tube graft and the bifurcated graft, and was treated with an additional cuff.

Two (6.7%) patients died within 30 days. The patient with the ruptured arch died on the first postoperative day as a result of multiple organ failure. A second patient died on postoperative day 8 due to massive gastro-intestinal bleeding. Autopsy revealed ulcers in the stomach and an ischaemic distal oesophagus. The patient had an open repair for TAAA type IV 10 years before this procedure.

Complications were seen in 13 (43%) patients, including three cardiac complications (STEMI ($n = 2$), atrial fibrillation ($n = 1$), two respiratory complications and one urinary tract infection. One patient required dialysis as mentioned above, and one patient had a glomerular filtration rate decrease of more than 30%. Two retroperitoneal haematomas were managed with transfusion and conservative measurements. Symptoms of paraparesis/paraplegia were seen in five (16.7%) patients, of which two had previous open aortic surgery (abdominal ($n = 1$), type IV TAAA ($n = 1$). In two patients, continued drainage of spinal fluid and raise of systolic blood pressure resulted in resolution of the symptoms; in two more patients spinal catheters were immediately inserted: one patient was discharged home without symptoms; the second patient died on postoperative day 8 as mentioned above. The last patient had his spinal catheter removed on day 1, but an acute onset of paraplegia occurred later that day in concert with a systolic blood pressure drop. A spinal catheter was immediately reinserted, which relieved the symptoms. The following day, he underwent a sigmoid resection for ischaemic colitis. There were otherwise no re-interventions during the admission period.

The mean operation time was 286 ± 78 min (range: 135–480 min); median blood loss was 570 ml (range: 100–5500 ml). The mean contrast used was 277 ± 92 ml (range: 80–480 ml) and the mean fluoroscopy time was 74 ± 29 min (range: 15–140 min). Half of the patients required admission to the intensive care unit after the procedure. The median stay in intensive care unit was 1 day (range: 0–28 days). The median hospital stay was 8 days (range: 3–50 days).

The mean follow-up was 12 months (range: 1–57 months), during which five patients died: two as a result of myocardial infarction, one after pneumonia and in two cases the patients died in poor general condition without a specified cause of death. Six months and 1-year survival were 89.3% and 76.0%, respectively, as shown in Fig. 1. On univariate analysis, previous aortic surgery (EVAR) and occlusion of one or both renal arteries were predictors for mortality (Figs. 2 and 3). On multivariate analysis, however, these factors turned out not to be independently predictive for mortality.

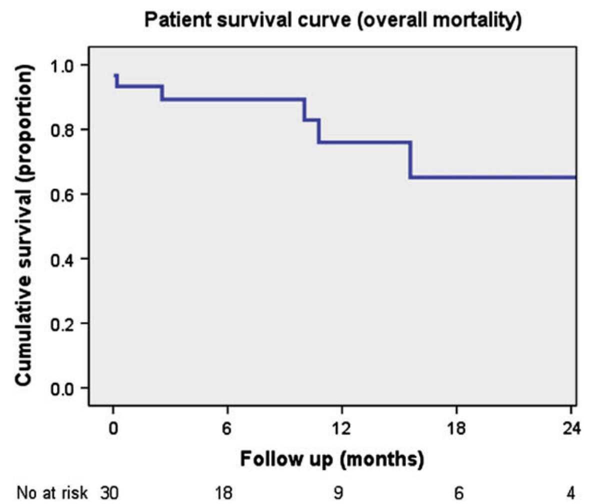

Figure 1 Kaplan–Meier survival curve of TAAA patients treated with branched endovascular repair.

During follow-up, one patient suffered occlusion of both renal arteries at 3 months, which required dialysis. This late event occurred in the second patient of our series due to kinking of the two renal artery branches (Fig. 4). In this patient, the balloon-expandable bridging stent grafts were not relined with additional self-expandable stents. One additional target vessel occluded at 30 months but without symptoms (coeliac artery covered by a scallop in a type I TAAA). One more patient experienced renal function deterioration of more than 30%, but his single kidney renal artery showed to be fully open. Overall patency estimate of target vessels is shown in Fig. 5, and has remained well over 90% over time. Kaplan–Meier analysis of patency stratified after type of bridging stent graft showed excellent results for downward-facing branches relined with self-expandable stents (Figs. 6 and 7).

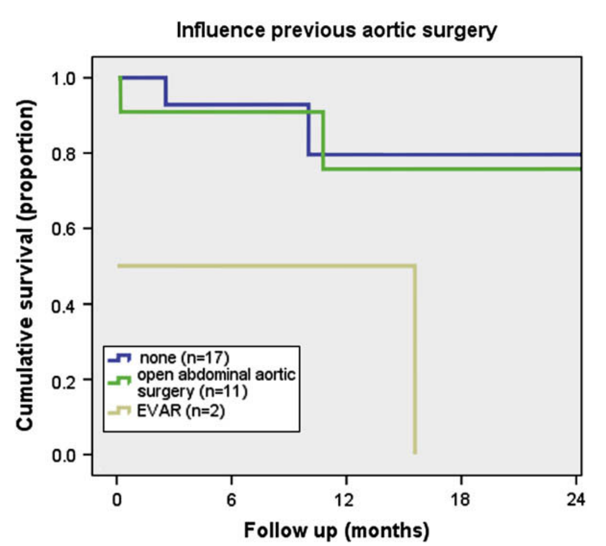

Figure 2 Influence of previous aortic interventions on patient survival rate after branched endovascular TAAA repair. (log rank test: 0.032.)

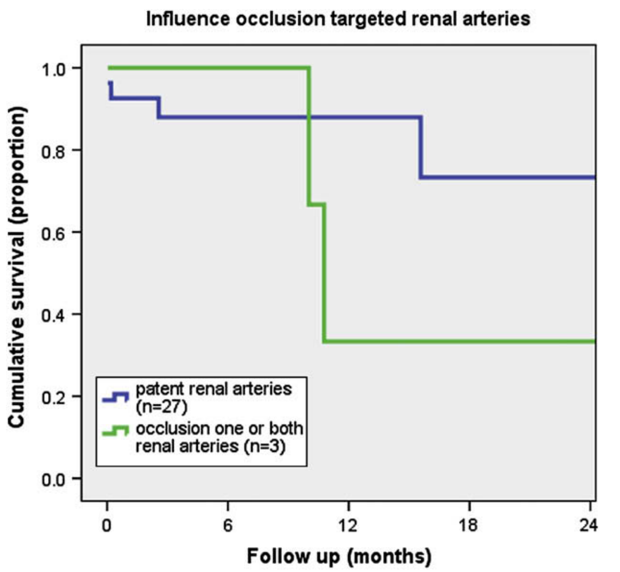

Figure 3 Influence of occlusion of one or both targeted renal arteries on patient survival rate after branched endovascular TAAA repair. (log rank test: 0.048.)

During follow-up, two re-interventions were performed, including endovascular treatment of a stenosis in the coeliac trunk at 3 months, and a femoro-femoral crossover bypass after occlusion of a prosthetic limb at 14 months in the same patient.

Discussion and future perspectives

At this moment, patients with TAAA are still mostly offered open repair. However, many patients are rightfully not

Figure 4 Postoperative angiography of 76-year-old female with TAAA type III treated with a four branched stent graft, which resulted in kinking (arrows) of both renal artery branches.

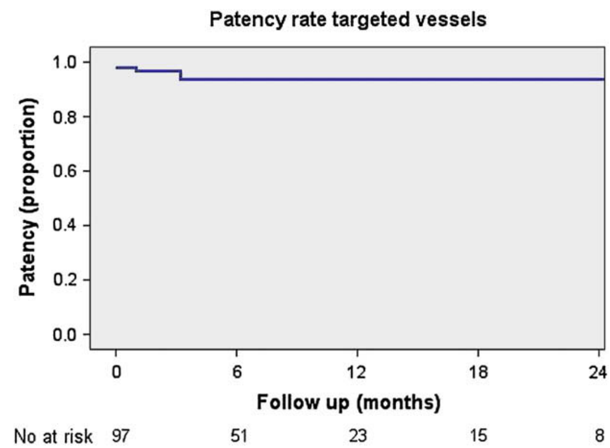

Figure 5 Overall target vessel patency curve.

considered for treatment because of age and/or co-morbidity. Alternative treatment techniques have emerged over the last years. Some favour a 'hybrid approach' combining surgical de-branching of the visceral side branches of the aorta with an endovascular relining of the aorta.[28–30] This method is less invasive than a standard open repair, but still requires a laparotomy and temporary interruption of visceral artery blood flow. A fully endovascular repair has the potential to overcome these problems and to be less invasive.

Our results are promising in view of the high-risk group that was treated, and are in concordance with the other publications. In addition, a learning curve has to be taken into account, with a technique in full evolution. With dedicated bridging stent grafts, the procedure would gain in simplicity and probably efficacy. At this moment, we have to resort to stiffer balloon-expandable bridging stent grafts that have the advantage of accurate positioning, and relining with self-expandable stents to prevent kinking. However, this technique seems to work as demonstrated by the patency rates (Fig. 7).

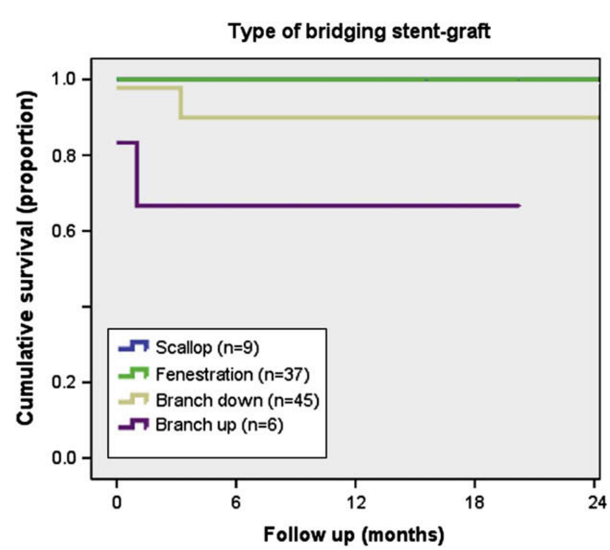

Figure 6 Target vessel patency curves stratified after type of bridging stent graft (log rank test 0.004).

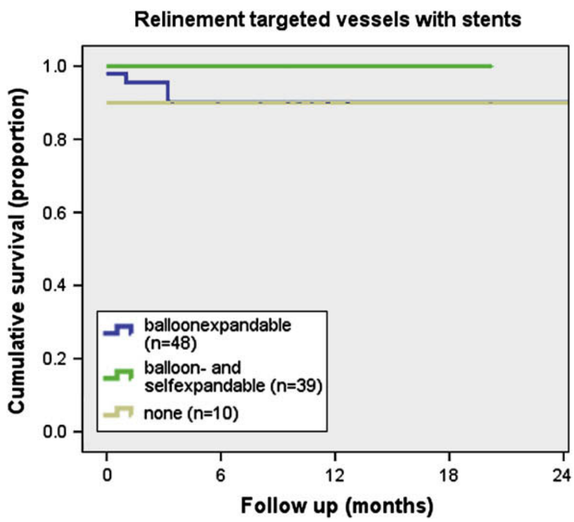

Figure 7 Target vessel patency curves stratified after type of relinement of the targeted vessels with stents (log rank test 0.196).

Planning is probably even more important than execution. Each graft should be designed according to the unique anatomy of the patients' aneurysm. Fenestrations work well when they can be approached from the contralateral femoral artery, and when the gap between the graft and the target vessel is small. After deployment, the bridging stent graft is flared on the inside of the main graft with a larger-diameter balloon, and should remain in a stable position. When the gap to bridge becomes bigger, this connection becomes instable. A directional branch has the advantage of providing a longer fixation and sealing zone. We do customise our grafts to the patients' anatomy, but have found a mix of branches and fenestrations very appealing. This can include fenestrations for the renal arteries and downward-facing branches for the coeliac and superior mesenteric arteries. This also allows for a more natural angle and position for the bridging stent grafts in view of the take-off angle of the respective vessels. Upward-facing branches are sometimes useful for the renal arteries but seem to be inferior to downward-facing branches (Fig. 6)

A selection bias is undoubtedly present in all the published endovascular series, including the present series, and should be acknowledged, but more challenging cases were successfully managed with increasing experience. This is the most probable explanation for the rising numbers in our centre. There is indeed a clear increase of cases (2004 ($n = 4$), 2006 ($n = 3$), 2007 ($n = 5$), 2008 ($n = 10$), 2009/4 ($n = 8$)), which cannot be explained by referral patterns only. This selection bias is true for any of the treatment options for TAAA. Where open treatment preselects the patients more on the absence of severe co-morbidity and age below 75, rather than on anatomical difficulty, fully endovascular repair and to a lesser extent the hybrid procedure have to comply to inclusion criteria such as access and suitable landing zones. In our series, nine patients were over 75, and 20 patients were refused open surgery. As mentioned above, we gradually take on more challenging cases, for example, with severe angulations or stenosed target vessels.

The future will probably see an increase of endovascular procedures for TAAA, even without level I evidence, in view of the major impact of open repair, which will remain an option for some younger and healthier patients, and patients who are not suitable for EVAR. The hybrid approach will be reserved for some specific anatomies only, in patients who cannot have an EVAR, or patients who need urgent repair. Finally, it is to be expected that a fewer patients will be refused treatment at all in view of the increasing technical options.

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