Endovascular repair of aortic aneurysms: Critical events and adjunctive procedures

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Objective: **We sought to define the learning curve relative to the incidence and range of intraoperative problems and to establish guidelines for troubleshooting during the endovascular repair of infrarenal aortic aneurysms.**
Methods: **We prospectively evaluated our first 75 consecutive cases over a 12-month period and focused on perioperative critical events and adjunctive procedures as categorical outcome measures collected during the operation. Patients were separated into three groups on the basis of the date of their operation, such that group 1 consisted of our first 25 cases, group 2 our next 25 cases, and group 3 our last 25 cases.**
Results: **At least one critical event and adjunctive procedure marked 67 (89%) of 75 cases. In 51%, there were at least two critical events and adjunctive procedures. There were no immediate open conversions or intraoperative deaths. Access problems occurred in 28% of the 75 cases and were addressed by use of brachial-femoral artery access (30%), iliac artery/aortic bifurcation balloon angioplasty (8%), and iliofemoral conduits (4%). Graft foreshortening was the most common deployment event (44%), necessitating distal covered extensions. Iliac graft limb twists and kinks occurred in 12% of cases and were managed with balloon angioplasty and uncovered stents. General incidents included balloon ruptures (10%), arterial dissections (6%), iliac artery rupture (2.6%), and lower extremity ischemia (4%). The two cases of iliac artery rupture were managed with distal covered extensions, and there were no cases of atheroemboli. Intraoperative endoleaks were encountered in 44% of the cases and included proximal attachment sites (15%), distal attachment sites (9%), type 2 sources, and "blushes." Management of intraoperative endoleaks included proximal/distal covered extensions and re-ballooning. Our 30-day endoleak rate was 20%. The incidence of critical events did not decrease in the latter one third compared with the first two thirds of cases.**
Conclusions: **Critical events occur frequently during endovascular repair of aortic aneurysms. The intraoperative problems range from the common endoleaks, access and deployment issues, and balloon ruptures, to rare but life-threatening complications such as iliac artery rupture. A toolbox of accessories that includes wires, catheters, large balloons, covered proximal and distal extensions, and uncovered stents is essential given the frequency of adjunctive procedures. Successful aortic endografting requires more than mere familiarity with basic endovascular techniques. (J Vasc Surg 2001;33:1226-32.)**

A number of institutions in the United States are now participating in multicenter Food and Drug Administration–approved phase 1 and 2 investigational device exemption clinical trials to evaluate a variety of endovascular devices to repair abdominal aortic aneurysms. This technology mandates the use of standard interventional radiologic techniques, which for many established vascular surgeons also represents an educational process. These devices require a variety of tools for successful deployment, including more than mere familiarity with guide wires, catheters, balloons, and stents. Regardless of whether one chooses to implant a unitary device such as the Ancure system (Guidant/Endovascular Technologies, Menlo Park, Calif) or a modular one such as the Talent graft (Medtronic/World Medical Inc, Sunrise, Fla), a host of adjunctive interventional procedures will become part of the operation in most cases. The aim of this prospective study is to define the learning curve associated with successful endovascular implantation of abdominal aortic stent grafts specifically as it pertains to the incidence and range of serious intraoperative problems or critical events that we have encountered during our consecutive cases. We have sought to identify whether unanticipated critical intraoperative events occur only during the early phase of one's experience with this new technology or alternatively continue to occur as case volume and experience grows. We have learned that a number of critical events occur with some degree of consistency and predictability. Similarly the adjunctive bailout procedures, which are required to successfully manage these problems, do ultimately become routine. This article will also suggest guidelines for troubleshooting these events, which we hope will be instructive to other vascular surgeons who are anticipating an aortic stent graft program.

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METHODS

Over a 12-month period from January 1998 to January 1999, we enrolled 77 patients in Food and Drug Administration–approved trials with endovascular devices

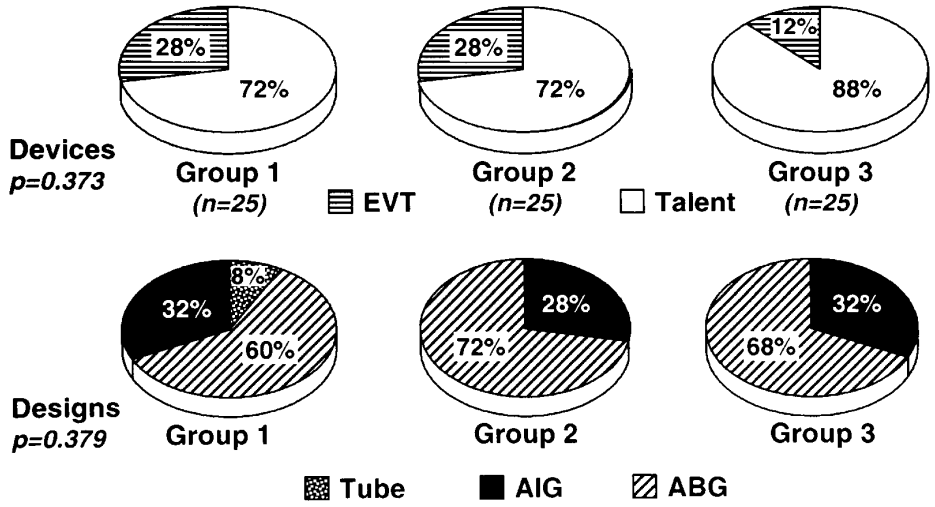

Fig 1. Devices and designs: most cases were performed with modular bifurcated endografts throughout all three phases of experience.

used to repair abdominal aortic aneurysms. Two different devices were used throughout this study period. All study patients were initially evaluated for the Ancure Guidant/Endovascular Technologies system. However, if their anatomy was not amenable to this unitary design, they were subsequently enrolled in a modular customized device trial with an endograft from Talent Medtronic/World Medical Inc. Seventy-five consecutive patients were separated into three mutually exclusive groups on the basis of the date of their operation. Group 1 consisted of our first 25 cases; group 2 our next 25 cases; and group 3 our last 25 cases. Three different aortic stent graft designs were available throughout the trial including tube, aortouniiliac, and aortic bifurcation grafts. Fig 1 depicts both the devices and designs that were deployed in each of the three groups. The overwhelming majority of devices were Talent designs consistently throughout the study period. Because all patients were first screened for an Ancure device (unitary design), the preponderance of Talent grafts reflects our ability to enroll and treat more patients with a modular customized design at this point in time. The three groups did not differ statistically with regard to device and design. The customization feature of the Talent design, particularly the option for suprarenal fixation, enabled us to treat patients with more anatomic complexity in these trials. By definition these were all high-risk patients who were turned down for conventional open repair with more complicated aortic neck features such as short (< 1 cm) or dilated (> 28 mm) necks, angulated (> 45 degrees and ≤ 60 degrees) necks or bifurcations (> 60 degrees), as well as tortuous, calcified, and diffusely diseased iliac arteries. This category accounted for 50% of our case enrollment and has been analyzed independently to define whether critical incidents correlate with anatomic complexity.

All 75 endograft procedures were performed in the operating room by the same team of physicians, consisting of both a vascular surgeon (R.M.F.) and an interventional radiologist (R.B.) with considerable experience and expertise in endovascular procedures. All data were recorded prospectively. Groups were evaluated by several categorical outcome measures collected during the operation. The χ^2 or Fisher exact test was used to evaluate differences and compute the *P* values for descriptive and numerical data, respectively. Statistical significance was accepted as a *P* value of .05 or less.

Critical events have been defined as unanticipated technical difficulties that occurred during the course of the operation and threatened the success of the procedure. These included general access and deployment problems, graft foreshortening, as well as device/design–specific issues. Also, general incidents such as balloon ruptures, endoleaks, arterial dissections, iliac artery rupture, and lower extremity ischemia were included. Balloon rupture has been included as a critical event because these large, compliant balloons are a built-in design feature of both the Ancure and Talent delivery systems and are required to successfully complete the deployment and attachment procedure. The consequence of balloon rupture is inadequate ballooning of the attachment sites and junctions, resulting in endoleaks. Large, compliant balloons were not commercially available during this phase of our endograft trials.

Intraoperative endoleaks were anatomically localized to proximal/distal attachment sites, or perfusing inferior mesenteric/lumbar arteries, and compared with persistent endoleaks at 30 days. "Blushes" were defined as slow filling of the aneurysm sac in the absence of an attachment site or perfusing vessel leak at the completion of the case while the patient was still receiving anticoagulants with a markedly prolonged activated clotting time. Additional outcome variables were evaluated, including the total volume of contrast material used and the length of time fluoroscopy was required.

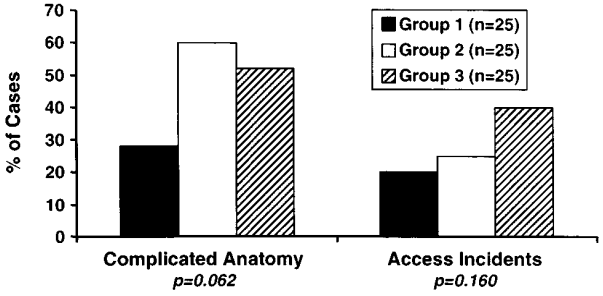

Fig 2. Case complexity and access incidents: 50% of cases were characterized as anatomically complex. Most access incidents occurred in these cases.

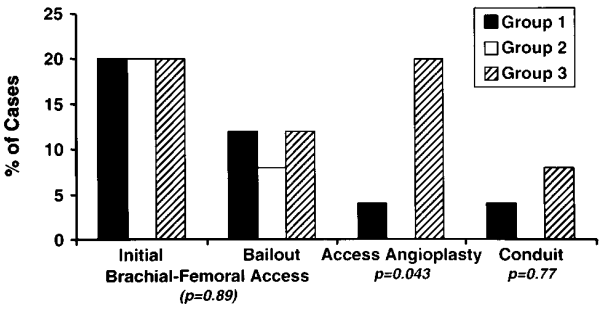

Fig 3. Adjunctive procedures to manage access incidents: Brachial-femoral access was used frequently (30%) in this series, although recent commercial availability of stiffer wires has greatly reduced need for this intervention in our subsequent practice.

Adjunctive procedures have been defined as unanticipated, salvage, or bail-out interventions with supplemental techniques and accessories such as large balloons, brachial-femoral artery access, uncovered stents, proximal and distal covered extensions, surgical conduits, as well as standard vascular surgical procedures, which were required to deal successfully with critical incidents. By way of further explanation, if an iliac artery stenosis was identified before operation and balloon angioplasty was anticipated, this was not included as a critical event or adjunctive procedure. Similarly, repeat ballooning a residual stenosis in the limb of an endograft was not recorded as either a critical event or adjunctive procedure. Our intent was to accurately record serious unanticipated events and supplemental procedures but not artificially inflate the incidence by including routine procedural hurdles.

Brachial-femoral artery access describes the technique whereby a guide wire was passed percutaneously from the left brachial artery down the descending aorta and into the abdominal aorta by use of fluoro chase. This guide wire was directed down through the iliac arteries and retrieved by creating a small arteriotomy in the common femoral artery. This through-and-through technique created a "clothes-line" effect, which was useful to deal with highly tortuous and angulated iliac arteries and aortas. It did require the use of a protective catheter to prevent shear injury to the origin and proximal left subclavian artery.

Conduits refer to surgically placed iliofemoral bypasses with 10-mm polyester fabric prosthesis, which were performed through a limited retroperitoneal exposure. This technique essentially created a larger iliac access channel through which one could then advance the catheter-based delivery system up into the aneurysm.

RESULTS

At least one critical event and adjunctive procedure marked 67 of 75 (89%) cases. Furthermore, 38 (51%) of 75 cases were notable for at least two critical events and adjunctive procedures. There were no immediate open conversions or intraoperative deaths.

Fig 2 documents our experience with complicated anatomy throughout the three groups. There is a trend toward more patients with complicated anatomy in groups 2 and 3. Access issues are also described in Fig 2. Difficulty in obtaining catheter-based delivery system access occurred in 20% of the cases in group 1 and 25% in group 2 and in both groups was due to iliac artery anatomy, such as tortuosity, calcification, and small size. In group 3, 40% of the patients had either iliac artery or aortic bifurcation access issues, but this difference was not statistically significant. Access issues were therefore a consistent event occurring in 28% of the 75 cases. Furthermore, the overall incidence of access issues correlated with anatomic complexity ($P = .007$). Within group 1, 66% of the access incidents occurred in the anatomically complex subgroup.

Within group 2, all access incidents occurred in this subgroup, and within group 3, 88% of the access incidents occurred in this subgroup. Access issues were addressed by use of a variety of adjunctive procedures, including brachial-femoral artery access, iliac artery/aortic bifurcation balloon angioplasty, and iliofemoral conduits. Three cases were aborted, one in each group, because of access problems that were underestimated before operation. These were not device specific. Brachial-femoral access was used in two fashions; either as an initial procedure when we anticipated an access problem on the basis of the anatomy (20%), or as a bailout, salvage technique when we had not anticipated access difficulty (10%). These data are presented in Fig 3. Brachial-femoral artery access has been consistently used throughout all three groups and has been a valuable tool in our early endograft experience. Balloon angioplasty to achieve access was performed with greater frequency (20%) in group 3 ($P = .043$), perhaps reflecting our growing experience in dealing with more complicated anatomic situations. Iliofemoral surgically placed conduits were rarely used (one patient in group 1 and two patients in group 3), although we view this as a useful technique until such time as the delivery systems decrease in profile such that we can access external iliac arteries less than 7 mm in diameter.

Deployment incidents and adjunctive procedures are defined in Table I. *Suprarenal deployment* describes that we inadvertently deployed the stent graft above one or

both renal arteries. *Infrarenal deployment* describes that we deployed too low or the device migrated distally into the aneurysm sac during deployment. *Graft foreshortening* describes the phenomenon whereby the implanted design was not long enough to land at the proposed distal attachment site.

The frequency of deployment incidents, including graft foreshortening, did not correlate with anatomic case complexity. Some deployment incidents were clearly related to the engineering features of the devices/delivery systems themselves. Ancure iliac limbs not reinforced with stents were vulnerable to development of twists or kinks during deployment that were successfully managed with uncovered stents and balloon angioplasty. The Ancure pull-through wire commonly became trapped on the proximal attachment hooks, necessitating catheter techniques to salvage the deployment. The modular Talent bifurcated grafts commonly demonstrated an element of graft foreshortening necessitating distal covered extensions.

Fig 4 quantitates the incidence of adjunctive procedures needed to effectively manage deployment incidents in all three groups. Distal covered extensions to manage graft foreshortening was the most common event, and the incidence increased in groups 2 and 3 patients to 44% (P = .21). We have hypothesized that graft foreshortening may be tied to the more complicated anatomy we were encountering in groups 2 and 3.

Balloon traction to manage inadvertent suprarenal deployment was used to drag the device down below the renal arteries in one patient in each group. Proximal extensions were successfully used when we deployed the devices too low or they migrated distally during deployment. The ability to address deployment problems successfully with both proximal and distal extensions points to the need for a "toolbox" consisting of covered stent graft extensions. Device-related iliac limb twists/kinks occurred in 28% of group 2 patients, which is a statistically significant difference compared with the other two groups (P = .008). Although these twists and kinks occurred in unreinforced Ancure limbs, as well as in the fully supported Talent limbs, Fig 4 does not reflect the fact that twists/kinks complicated 85% of Ancure cases compared with 8% of the Talent cases in group 2. Pull-through wire entrapment on the proximal attachment hooks of the Ancure device occurred in 57% of the Ancure group 2 cases. The frequency and predictability of these events, including the foreshortening issues encountered above, resulted in a familiarity such that intervention to resolve these incidents ultimately became rather commonplace and routine.

Other general incidents less commonly encountered, included balloon ruptures, arterial dissections, iliac artery ruptures, and lower extremity ischemia. The incidence of these events is depicted in Table II. Balloon ruptures were clearly learning curve related and occurred in 28% of group 1 patients, 4% of group 2 patients, and were no longer an issue in group 3 patients (P = .004). Arterial dissections were rarely encountered, but they were always successfully treated by uncovered stents. Early on in our experience, there were two instances of life-threatening iliac artery rupture; both were successfully treated by covered distal extensions. Both these events could be attributed to overzealous ballooning across the bare springs of a Talent bifurcated design at the distal attachment site. We believe this is also learning curve related. There were no instances of atheroemboli, and all cases of lower extremity ischemia were noted to occur in group 2 and were related to iliac artery or graft limb abnormalities; all were successfully treated by uncovered stents and balloon angioplasty.

Table I. Deployment incidents and adjunctive procedures

Deployment incidents	*Adjunctive procedures*
Suprarenal	Balloon traction
Infrarenal/migration	Proximal covered extensions
Graft foreshortening	Distal covered extensions
Device-related	
Limb twists/kinks	Stents and balloon angioplasty
Pull-through wire issues	Catheter techniques

Endoleaks (Table III) were divided into intraoperative and 30-day (persistent) categories and were anatomically classified. Intraoperative endoleaks were localized by arteriography to the proximal attachment site in 15% of cases and the distal attachment site in 9% (type 1).[1] Attachment site endoleaks were encountered in all three groups during the study and were managed by repeat ballooning the appropriate attachment site when identified as the source, although in some instances, proximal and distal covered extensions were also deployed at that time. Although every effort was made to methodically characterize and correct the precise source of every intraoperative endoleak; when the origin was still uncertain, the entire device underwent reballooning with particular attention to junctions (in modular designs). Intraoperative endoleaks arising from proximal/distal attachment sites, perfusing inferior mesenteric artery/lumbar sources, and "blushes" occurred during 44% of our cases. Endoleaks were considered persistent if they were still evident by 30 days. All persistent endoleaks identified by computed tomography angiography or magnetic resonance angiography were subsequently studied by use of standard selective angiographic techniques. Persistent 30-day endoleaks were identified in 20% of our patients. These were all based on communicating inferior mesenteric and lumbar arteries (type 2),[2] except for two cases that were type 1. One persistent distal attachment site endoleak was repaired with a covered distal extension, whereas one proximal endoleak was repaired by placing a covered proximal extension. Both the incidences of intraoperative and persistent 30-day endoleaks did not correlate statistically with case complexity.

Two additional categorical outcome measures are described in Fig 5 and include the volume of contrast material and the length of time fluoroscopy was used. Contrast volume was clearly learning curve related (P = .002). Only 16% of cases in group 3 required ≥150 mL contrast as contrasted with 56% and 60.9% in groups 1 and 2, respectively.

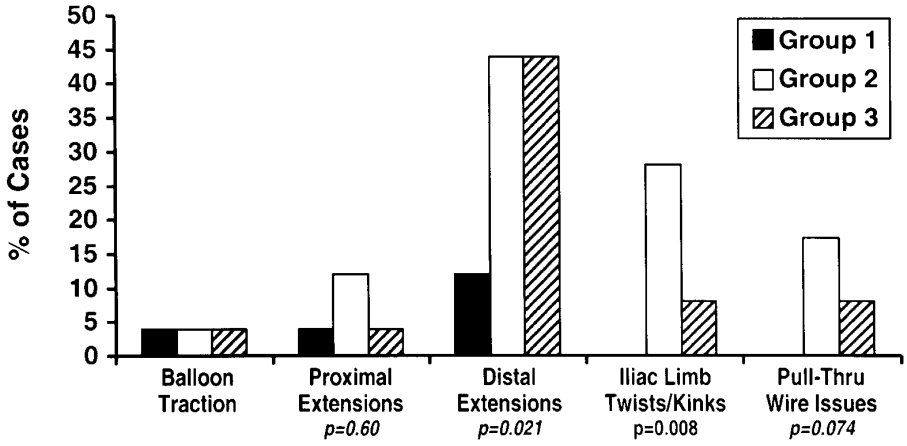

Fig 4. Incidence of deployment issues: Graft foreshortening was most common deployment incident necessitating distal covered extensions.

Table II. General incidents

	Group 1 (n = 25)	*Group 2 (n = 25)*	*Group 3 (n = 25)*
Balloon ruptures ($P = .004$)	28%	4%	0
Arterial dissections	8%	8%	4%
Iliac artery rupture	4%	4%	0
LE ischemia ($P = .10$)	0	12%	0

Table III. Endoleaks

	Group 1 (n = 25)	*Group 2 (n = 25)*	*Group 3 (n = 25)*
Intraoperative			
Proximal attachment site ($P = .77$)	12%	20%	12%
Distal attachment site ($P = .48$)	16%	4%	8%
Total (including blushes)	48%	40%	44%
Persistent (30 d) ($P = .36$)	30.4%	13%	16.7%

The volume of contrast material and the fluoroscopy time did not correlate with case complexity. Although we had anticipated a learning curve, we did not improve with regard to "fluoro time" over the course of the 75 cases. Most of our cases (62%) required more than 30 minutes of fluoroscopy, and 30% of the cases used greater than 45 minutes.

DISCUSSION

This study was undertaken in a prospective fashion to define the incidence and range of unanticipated intraoperative critical events and to establish adjunctive procedures for troubleshooting. Naslund et al[2] reported technical complications in 26% of 34 endovascular repairs that seemed to be associated with the use of a preponderance of tube grafts, short distal necks, small iliac arteries, tortuous iliac arteries, and atherosclerosis at the aortic bifurcation. May et al[3] identified a similar incidence of adverse events during two consecutive periods of time over a 5.5-year period. The adverse events were defined as follows: a death within 30 days, a conversion to open repair, the need for further intervention (either open or endovascular), the need for hemodialysis, a failure to cure the abdominal aortic aneurysm, and wound complications. These authors concluded that there are inherent risks in the endograft method rather than iatrogenic complications that occur as a learning curve phenomenon. Buth et al[4] reporting collaborative data from the EUROSTAR registry assessed risk factors for adverse advents in 1554 patients who underwent endovascular abdominal aortic aneurysm repair over a 5-year period at 56 European centers. The authors reported open con-

version in 2.5%, device-related or procedure-related complications in 10%, and arterial complications in 3%. Risk factors for failure to complete the procedure included an aneurysm diameter of 60 mm or more and the need for adjuvant procedures. Factors predicting device-related and arterial complications were the experience of the team and the need for adjuvant procedures.

Looking at different outcome variables, we have demonstrated that intraoperative critical events occur with a degree of consistency and predictability during endovascular repair of abdominal aortic aneurysms. The overwhelming majority of these events are access and deployment related; however, routine adjunctive interventional procedures will result in salvage of these cases. The incidence of access-related events correlates with case selection and anatomic complexity. Because 50% of our cases were defined as anatomically complex, this serves to explain why the incidence of critical events was so high in our series. Similarly, Chuter et al[5] reported 33 patients with high-risk anatomy who were successfully treated with aortic endografting, but necessary adjunctive maneuvers included additional uncovered and covered stent graft placement and balloon dilation. We believe that there are events that are clearly learning curve related, such as balloon/iliac artery ruptures and volume of contrast material used during each case. Access issues will remain a problem for this technology until the profile of the delivery systems are downsized so that we may reliably and atraumatically access external iliac arteries less than 7 mm in diameter. Alternatively, access balloon angioplasty, brachial-femoral artery (through and through) wire access, and surgically placed iliofemoral conduits are valuable and essential adjunctive techniques to manage diminutive external iliac arteries, marked tortuosity, angulation, and intrinsic stenoses. With this in mind, in this series we routinely included the left antecubital area as part of the prepared surgical field, such as to have access for potential left brachial artery puncture. Although we used brachial-femoral access in approximately 30% of our cases, we recognize that others have avoided this technique in virtually all cases. Subsequent to this series of patients, we obtained stiffer commercially available guide wires, and our need for through-and-through access has been nearly eliminated.

A number of critical events are device/design specific, which points to the need to truly understand the basic engineering features of differing endografts. Device/design–specific incidents tend to occur with some degree of regularity, and therefore one learns to anticipate these events. The unsupported limbs of the Ancure bifurcated system were vulnerable to development of twists or kinks during deployment that could be successfully managed by balloon angioplasty and uncovered stents. Allen et al[6] reported a series of 34 patients with abdominal aortic aneurysms that were repaired with three different types of Ancure endografts, necessitating additional endovascular procedures in 32.4% at the initial procedure or during follow-up to correct graft or arterial stenoses. We found that the Ancure pull-through wire would occasionally

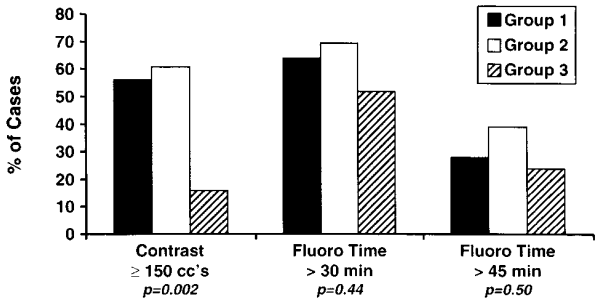

Fig 5. Contrast volume and fluoro time: Contrast volume appeared to be learning curve related, but there were no trends with regard to fluoro time.

catch on the proximal attachment hooks and require the use of a catheter to successfully bring the contralateral limb down into the iliac position. The modular self-expanding Talent system seemed vulnerable to graft foreshortening necessitating the availability of distal covered extensions. This phenomenon has also been reported by other investigators using self-expanding modular devices. White et al[7] identified a high incidence of intraprocedural graft shortening with the self-expanding Vanguard (56%) and AneuRx (44%) endografts. Additional distal covered extensions were needed to correct endoleaks caused by inadequate graft length in 14% of patients.

Endoleaks are a reality of the current technology.[8] Zarins et al[9] reported a 21% discharge endoleak rate during the AneuRx multicenter prospective clinical trial, which decreased to 9% at 1 month. We have perhaps been overzealous in reporting our incidence of intraoperative endoleaks by including "blushes." On the other hand, our 30-day endoleak rate of 20% is generally reflective of type 2 issues that are not likely to be device or learning curve related. Additionally our endoleak rate was not influenced by anatomic complexity. One needs to develop a consistent interventional strategy to identify the source of an endoleak detected on the completion intraoperative arteriogram. We typically perform selective antegrade and retrograde arteriograms at the proximal and distal attachment sites respectively, as well as injections within the neck below the proximal attachment site. For the Ancure and Talent endografts, it is appropriate to repeat ballooning the entire device, with particular attention to attachment sites and junctions. In general, a toolbox of accessories that includes the usual interventional items is essential, but covered proximal and distal extensions and large angioplasty balloons (which are now commercially available) are also necessary. Although it is our belief that the learning curve for aortic endografting is protracted, there were no open conversions or intraoperative deaths in this initial consecutive series of 75 cases. These results contrast with those reported in earlier series and are most likely indicative of how rapidly the technology is

improving. Heilberger et al[10] performed endovascular procedures on 137 patients with aortic aneurysms between 1994 and 1996. With largely Mintec and Endovascular Technologies devices, 8% required open conversion because of defective devices (n = 5 patients), device-related occlusion of a renal artery (n = 2), aortic dissection (n = 1), occlusion of iliac outflow (n = 1), proximal endoleak (n = 1), and retroperitoneal bleeding (n = 1).

Although there would seem to be a potential risk of cholesterol embolization after repetitive instrumentation and manipulation of an aneurysmal aorta,[11] we did not observe this in any of our 75 cases. Not reflected in this report is the frequency of local femoral artery injury from the repetitive insertion, deployment, and withdrawal of the stent graft delivery systems. Heavily calcified femoral arteries were particularly vulnerable to plaque disruption, necessitating standard yet meticulous vascular surgical interventions at the completion of the cases. Femoral artery trauma occurred commonly, and the incidence should diminish in frequency as the profile of the delivery systems comes down in size. The lack of improvement with regard to the length of time that fluoroscopy was required may be indicative of the trend to tackle more anatomically complex cases over time.

CONCLUSION

In summary, this report outlines the incidence and range of intraoperative critical incidents that we have encountered during our first 75 consecutive cases using the Ancure and Talent aortic endografts. Although some events were learning curve related, such as balloon/iliac artery ruptures and high volume of contrast material used, other incidents occurred with some degree of consistency and predictability throughout the study interval, such as access and deployment issues. We have learned that each endograft design will demonstrate particular idiosyncrasies, and it is important for the Investigator to have an understanding of the basic engineering features of each device. In general, the adjunctive procedures became routine, but successful troubleshooting necessitated a toolbox of wires, catheters, large balloons, uncovered stents, as well as proximal and distal covered extensions. Brachial-femoral artery access and iliofemoral conduits were important adjuncts that enabled salvage of difficult access cases. Although this report represents our initial experience with aortic endografting, there were no immediate conversions or intraoperative deaths.

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