Impact of intraoperative adverse events during branched and fenestrated aortic stent grafting on postoperative outcome

Frédéric Cochennec, MD,[a] Hicham Kobeiter, MD,[b] Manj S. Gohel, MD,[c] Marek Majewski, MD,[a] Jean Marzelle, MD,[a] Pascal Desgranges, MD,[a] Eric Allaire, MD, PhD,[a] and **Jean Pierre Becquemin, MD,[a]**
Créteil, France; and Cambridge, United Kingdom

Objective: **Fenestrated and branched endovascular devices are increasingly used for complex aortic diseases, and despite the challenging nature of these procedures, early experiences from pioneering centers have been encouraging. The objectives of this retrospective study were to report our experience of intraoperative adverse events (IOAEs) during fenestrated and branched stent grafting and to analyze the impact on clinical outcomes.**

Methods: **Consecutive patients treated with fenestrated and branched stent grafting in a tertiary vascular center between February 2006 and October 2013 were evaluated. A prospectively maintained computerized database was scrutinized and updated retrospectively. Intraoperative angiograms were reviewed to identify IOAEs, and adverse events were categorized into three types: target vessel cannulation, positioning of graft components, and intraoperative access. Clinical consequences of IOAEs were analyzed to ascertain whether they were responsible for death or moderate to severe postoperative complications.**

Results: **During the study period, 113 consecutive elective patients underwent fenestrated or branched stent grafting. Indications for treatment were asymptomatic complex abdominal aortic aneurysms (CAAAs, n = 89) and thoracoabdominal aortic aneurysms (TAAAs, n = 24). Stent grafts included fenestrated (n = 79) and branched (n = 17) Cook stent grafts (Cook Medical, Bloomington, Ind), Ventana (Endologix, Irvine, Calif) stent grafts (n = 9), and fenestrated Anaconda (Vascutek Terumo, Scotland, UK) stent grafts (n = 8). In-hospital mortality rates for the CAAA and TAAA groups were 6.7% (6 of 89) and 12.5% (3 of 24), respectively. Twenty-eight moderate to severe complications occurred in 21 patients (18.6%). Spinal cord ischemia was recorded in six patients, three of which resolved completely. A total of 37 IOAEs were recorded in 34 (30.1%) patients (22 CAAAs and 12 TAAAs). Of 37 IOAEs, 15 (40.5%) resulted in no clinical consequence in 15 patients; 17 (45.9%) were responsible for moderate to severe complications in 16 patients, and five (13.5%) led to death in four patients. The composite end point *death/nonfatal moderate to severe complication* occurred more frequently in patients with IOAEs compared with patients without IOAEs (20 of 34 vs 12 of 79; $P < .0001$).**

Conclusions: **In this contemporary series, IOAEs were relatively frequent during branched or fenestrated stenting procedures and were often responsible for significant complications. (J Vasc Surg 2014;60:571-8.)**

Fenestrated and branched endovascular aneurysm repairs (FEVAR and BEVAR) have become an attractive alternative to open repair for complex abdominal aortic aneurysms (CAAAs) and thoracoabdominal aortic aneurysms (TAAAs). In many countries, these complex procedures are still under evaluation and generally available only in tertiary centers. In France, fenestrated and branched Cook devices have been approved for reimbursement from the national health care system. However, intraoperative difficulties and complications are not rare.[1] Safe target vessel cannulation and stenting is a concern, particularly in the presence of stenotic ostial lesions and small or angulated target vessels. Malpositioning of stent graft components can also have devastating consequences. As delivery devices are larger than in standard infrarenal endovascular aneurysm repair (EVAR) and the procedure duration is generally longer, patients are more prone to access complications. The real incidence of those intraoperative adverse events (IOAEs) and their impact on the postoperative course are poorly documented.

In this retrospective study, we report the incidence of IOAEs during fenestrated or branched stent grafting and analyze to what extent these adverse events may influence early postoperative outcomes.

METHODS

Study setting. Consecutive patients undergoing FEVAR or BEVAR between February 2006 and October 2013 in a tertiary vascular unit (Henri Mondor Hospital, Créteil) were included. Patients were treated for CAAAs and TAAAs. CAAAs included short-necked infrarenal,

From the Department of Vascular Surgery[a] and Department of Radiology and Medical Imaging,[b] Henri Mondor Hospital, Créteil; and the Department of Vascular Surgery, Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust, Cambridge.[c]

Author conflict of interest: none.

Reprint requests: Frédéric Cochennec, MD, Department of Vascular Surgery, Henri Mondor Hospital, 51 avenue du Maréchal de Lattre de Tassigny, 94000 Créteil, France (e-mail: cochennecf@gmail.com).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214/$36.00

http://dx.doi.org/10.1016/j.jvs.2014.02.065

Table I. Clinical and anatomic data

	CAAA (n = 89)	*TAAA (n = 24)*	*Overall (N = 113)*
Clinical data			
Males	80 (90)	21 (87)	101 (89)
Age, years	73 ± 9	72 ± 9	73 ± 9
Diabetes mellitus	17 (19)	2 (8)	19 (17)
Tobacco use in last 10 years	52 (58)	15 (62)	67 (59)
Hypertension	62 (70)	17 (71)	79 (70)
Hyperlipidemia	46 (52)	10 (42)	56 (50)
Coronary artery disease	46 (52)	7 (29)	53 (47)
Myocardial infarction	21 (24)	3 (12)	25 (22)
Congestive heart failure	22 (25)	8 (33)	30 (27)
Arrhythmia	14 (16)	3 (12)	17 (15)
Cerebrovascular disease	19 (21)	1 (4)	20 (18)
Chronic renal insufficiency	17 (19)	4 (17)	21 (19)
Pulmonary disease	35 (39)	9 (37)	44 (39)
Peripheral vascular disease	13 (15)	4 (17)	17 (15)
Cancer	14 (16)	5 (21)	19 (17)
Obesity	18 (20)	3 (12)	21 (19)
Anatomic data			
Maximal diameter, mm	59 ± 10	60 ± 10	59 ± 10
Type of aneurysm	Short neck/juxtarenal: 63 (71) Pararenal: 20 (22) Suprarenal: 6 (7)	Type II: 8 (33) Type III: 9 (37) Type IV: 7 (29)	

CAAA, Complex abdominal aortic aneurysm; *TAAA,* thoracoabdominal aortic aneurysm.
Continuous data are presented as mean ± standard deviation and categorical data as number (%).

Table II. Details of stent graft configurations

Stent graft configuration	*No. (%)*
Fenestrated stent grafts	96 (85)
One fenestration	4 (4)
Two fenestrations	43 (38)
Three fenestrations	36 (32)
Four fenestrations	13 (12)
Branched stent grafts	11 (10)
Three branches	1 (1)
Four branches	10 (9)
Stent grafts with fenestrations and branches	6 (5)
Three target vessels	1 (1)
Four target vessels	5 (4)

juxtarenal, pararenal, and suprarenal abdominal aortic aneurysms, considered unsuitable for conventional EVAR. TAAAs were classified according to the Crawford classification.[2] In our institution, all patients with CAAAs and TAAAs are considered for open, hybrid, or endovascular repair in a multidisciplinary meeting including vascular surgeons, interventional radiologists, and anesthesiologists. Demographic, anatomic, intraoperative, and postoperative data were recorded by means of a prospectively collected database.

Preoperative assessment and device sizing. All patients underwent a high-resolution computed tomography scan preoperatively and before discharge. Procedure planning and device sizing were performed with a dedicated three-dimensional vascular imaging workstation (Aquarius WS; TeraRecon Inc, Mateo, Calif) with centerline luminal reconstructions. The aneurysm morphology was assessed by a vascular surgeon (M.M.) and an interventional radiologist (H.K.), both with considerable experience with EVAR. Device designs proposed by the implanting physicians were systematically reviewed and approved by the planning center of the corresponding device manufacturer.

Details of procedures. Procedures were performed in an angiography suite (Philips FD20; Philips Healthcare, Cleveland, Ohio) in a sterile environment. An experienced proctor physician was present during the procedure for the first five Cook fenestrated cases, the first two Cook branched cases, and the first fenestrated Anaconda and Ventana cases. Eight physician-modified fenestrated stent grafts were excluded. For each device, the implantation techniques have been described previously.[3-9] Control angiograms were obtained once each target vessel was cannulated with a long sheath, after deployment of bridging covered stents in each target vessel, and at the end of the procedure. Each control angiogram was saved and images were stored in a database. Technical problems and subsequent IOAEs were also recorded in the database.

Definitions. IOAEs were defined as any intraoperative complication or technical problem occurring during stent graft implantation that required additional and unexpected endovascular manipulations. IOAEs were classified in three distinct types:

Type 1: Problems with target vessel cannulation;
Type 2: Malpositioning of one of the following graft components: bridging stents, bifurcated component, or iliac extensions; and
Type 3: Difficulty with intraoperative access.

Complications were defined according to the Society for Vascular Surgery criteria.[10] Only moderate and severe complications were reported in the current series.