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Preloaded Catheters and Guide-Wire Systems to Facilitate Catheterization During Fenestrated and Branched Endovascular Aortic Repair

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Abstract

Objective The aim of this study was to review the clinical outcomes for patients treated for pararenal (PRA) and thoracoabdominal aortic aneurysms (TAAAs) by fenestrated–branched endovascular aortic repair (F-BEVAR) using preloaded systems (PLS).

Methods We reviewed clinical data of 83 patients (64 male, mean age 75 ± 7 years) enrolled in a prospective study to investigate F-BEVAR. All patients had PLS, which included two catheters or two through-and-through guide wires with 12-Fr trans-brachial sheaths positioned in the descending thoracic aorta. Outcome measurements were technical success defined as successful deployment of the main fenestrated stent graft and cannulation of all target vessels, total endovascular time, total lower extremity ischemia time and complications, 30-day mortality, and major adverse events (MAEs).

Results Aneurysm extent was PRA in 27 patients and TAAA in 56 (35 extent IV and 21 extent I–III). A total of 333 target vessels were incorporated with an average of 4 ± 0.4 vessels per patient. Technical success was 99.7%. Total endovascular time was 160 ± 51 min. Sixty-five (78%) patients had motor and somatosensory evoked potentials monitoring, and lower extremity ischemia time was 115 ± 42 min. There were no 30-day mortalities. Fifteen patients (18%) had MAEs, including three (3.6%) minor ischemic strokes. There were no upper extremity complications. All ischemic strokes occurred in female patients (3.6% vs. 0%, P = .001). One (1.2%) patient had paraplegia.

Conclusion This study shows high technical success and early lower limb reperfusion using PLS with trans-brachial access. The risk of stroke, especially in female patients, should be carefully assessed by review of preoperative arch imaging.

Keywords Fenestrated and branched endovascular repair · Preloaded catheter · Complex aortic aneurysm · Thoracoabdominal aortic aneurysm

Introduction

Fenestrated and branched endovascular repair (F-BEVAR) of complex abdominal and thoracoabdominal aortic aneurysms (TAAAs) has been increasingly reported with high technical success and excellent mid- and long-term results [1–4]. Over the last decade, advances in stent graft design and physician learning curve have been key to the advancement of this treatment modality. Nevertheless, these cases remain technically challenging and are often

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prolonged for several hours. The standard technique for target vessel cannulation is tedious, requiring sequential catheterization of each branch/fenestration followed by access into the target vessel itself. The continued presence of large (20–22 Fr) device delivery sheaths impairing pelvic blood flow has a theoretical impact in postoperative morbidity, most notably spinal cord ischemic complications [5–8]. The use of preloaded catheter and guide-wire systems (PLS) has been proposed as device adjuncts providing direct access to branches and fenestrations. This technique decreases catheter manipulations to access the vessels, hence expediting the procedure and minimizing lower extremity and collateral network ischemia [9–11]. However, routine brachio-femoral access is required for a preloaded system to be utilized, which may be associated with a higher risk of neurologic complications. The objective of this study was to review the clinical outcomes of patients treated for pararenal (PRA) and thoracoabdominal aortic aneurysms (TAAAs) by F-BEVAR using preloaded catheter and guide-wire systems.

Methods

The study was approved by the Mayo Clinic Institutional Review Board. All patients were enrolled in a prospective, non-randomized investigational device exemption study to investigate F-BEVAR (NCT1937949 and NCT2089607) and consented to participation in this study. All patients treated with customized patient-specific fenestrated–branched stent grafts designed with PLS addressing two or more target vessels from 2013 to 2016 were included in the analysis. All stent graft designs were based on the Cook Zenith Fenestrated platform (Cook Medical Inc, Brisbane, Australia).

Device Design

Aneurysm morphology was determined by high-resolution CTA datasets. Aneurysm morphology was determined by high-resolution CTA datasets. A minimum proximal sealing zone of at least 25 mm was selected in normal supraceliac aortic segments, defined by parallel aortic wall with no evidence of thrombus, calcium, or diameter enlargement $> 10\%$. Specific device design varied depending on aneurysm extent, vessel angulation, and inner aortic diameter, and included customized patient-specific devices with up to five fenestrations or branches. Selection of design was tailored by the primary investigator depending on aneurysm extent and diameter of aortic lumen. For renal targets, fenestrations were preferred. For extent I–III TAAAs, directional renal branches were used if the aortic lumen was large (> 40 mm) and vessel orientation was down-going without excessive tortuosity.

Technique

Preoperative planning and sizing are performed in an identical manner as with standard fenestrated–branched devices without PLS. Our perioperative spinal cord ischemia protocol has been previously described [8]. All patients required brachial access in addition to bilateral femoral access, unless unilateral iliac occlusion was present, in which case unilateral brachio-femoral access was performed. At the time of this study, we routinely surgically access the brachial artery at the level of the axillary hairline, preferentially on the left arm. A 12-French Gore DrySeal sheath (WL Gore, Flagstaff, Arizona) is advanced over a super-stiff Amplatz wire (Boston Scientific, Marlborough, Massachusetts) across the aortic arch and into the distal thoracic aorta. The preloaded catheters are positioned in the stent graft by the manufacturer entering the fenestration or branch and exit the device through an access scallop (Fig. 1). The main device is advanced via the femoral approach into its intended deployment position over a 0.035-in. Lunderquist wire (Cook Medical, Bloomington, IN), and 0.021-in. 480-cm Tracer Metro® Direct™ wires (Cook Medical, Bloomington, Indiana) are advanced into the preloaded catheters and subsequently snared using an Indy snare (Cook Medical, Bloomington, Indiana) via brachial approach. The wires are labeled according to its respective branch/fenestration (i.e., celiac axis, superior mesenteric artery, and renal arteries), and brachio-femoral access is secured with clamps in both ends of the wire. A 7- or 8-French x 90-cm Flexor® Raabe sheath (Cook Medical, Bloomington, IN) is advanced over the through-and-through wire via the brachial access inside the 12-French DrySeal and into the branch/fenestration. A 130-cm Kumpe (Boston Scientific, Marlborough, Massachusetts) or Van Schie 3 (Cook Medical, Bloomington, IN) catheter is then advanced in the sheath as a "buddy" catheter and used to cannulate the target vessel. After access is secured, the through-and-through wire is removed and the same procedure is performed in the additional preloaded catheters [9]. The standard wire-sheath configuration may vary based on the number of vessels accessed via the brachial sheath.

Outcome Measurement

Clinical results were analyzed based on aneurysm extent, with three groups divided into pararenal, extent IV TAAA, and extent I–III TAAA. Outcome measurement were technical success, defined as successful deployment of the main fenestrated stent graft and cannulation of all target

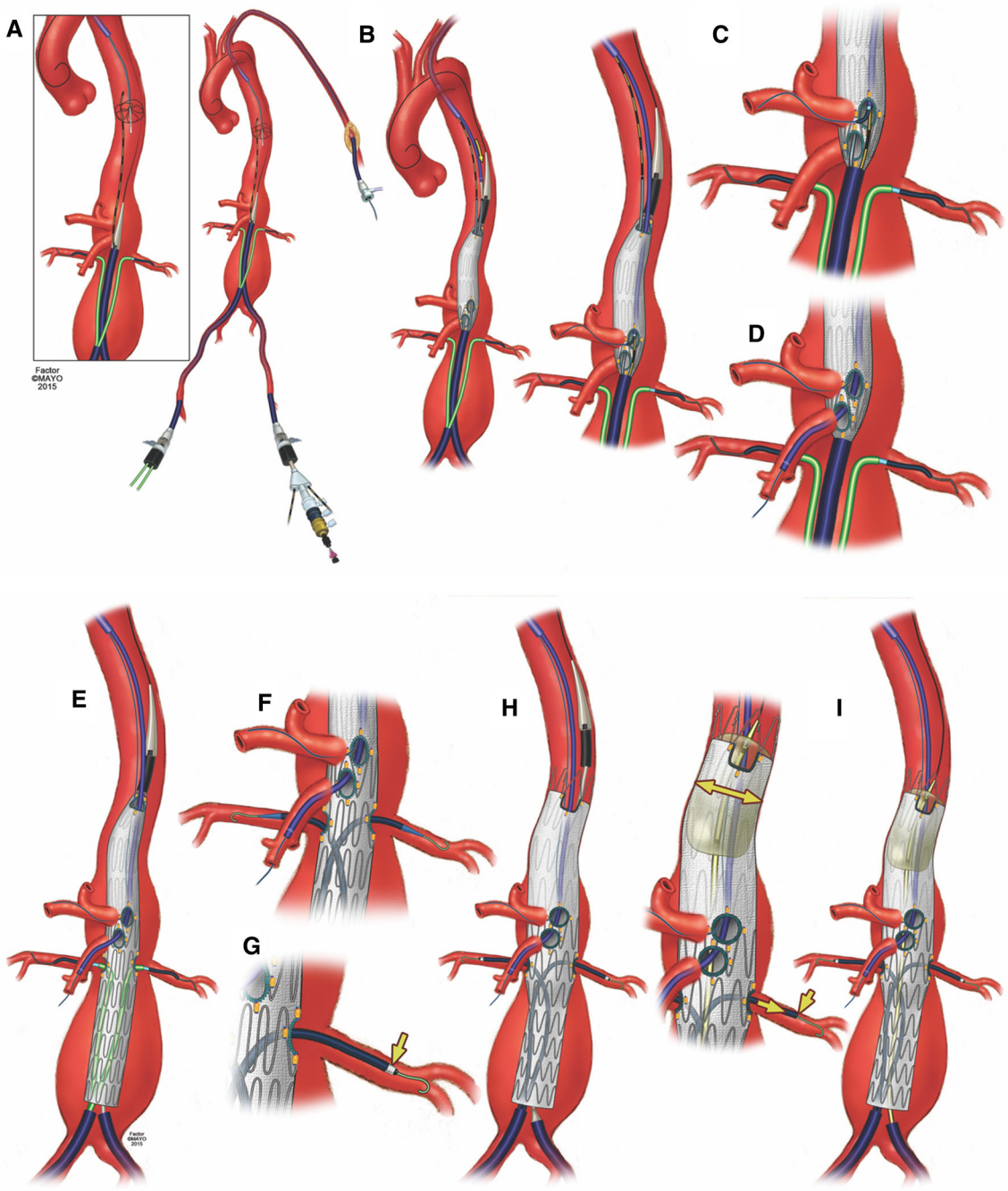

Fig. 1 Illustration depicts the technique used for four-vessel fenestrations with preloaded catheters into the celiac and SMA fenestration. These catheters exit via an access scallop in the top of the device (**A**). The catheters allow guide wires to be advanced and snared via the brachial approach using an Indy Snare (Cook Medical). Once both guide wires are snared, the device is deployed to the level of the SMA fenestration (**B**). First, a 7-Fr sheath is advanced over the celiac fenestration (**C**) and a buddy catheter is used for catheterization of the celiac axis. A 0.035-in. Amplatz guide wire is left in the celiac axis. The sheath is then advanced over the SMA fenestration, and the SMA is sequentially catheterized in similar fashion (**D**). The distal portion of the device is deployed once the celiac and SMA are catheterized by the brachial access (**E**). The guide catheters are sequentially removed from the renal arteries and used to regain access into the renal fenestrations and renal arteries from the femoral approach. Seven-French sheaths are advanced over a Rosen guide wire into each of the renal arteries (**F**). The renal alignment stents may be positioned inside the sheath with the tip of the stent serving as a dilator (single arrows) to protect the vessel from a dissection (**G**). Before deployment of the alignment stents (**H**), the proximal sealing zone is dilated (double arrow, I). By permission of Mayo Foundation for Medical Education and Research. All rights reserved

vessels; total fluoroscopy time; lower extremity ischemia time; access-related complications; early (30-day or in-hospital) mortality; and major adverse events (MAEs), defined as a composite endpoint including any mortality, severe acute kidney injury, myocardial infarction, respiratory failure, paraplegia, stroke, bowel ischemia requiring surgical intervention, and estimated blood loss > 1 L [12, 13]. Outcomes were reviewed and adjudicated by an independent clinical event committee and data safety monitoring board.

Statistical Analysis

All clinical data were collected prospectively and stored on case report forms and MEDIRAVE database and analyzed using SAS v 9.4 software [1]. Differences were determined by the log-rank test. Results were reported as a percentage for categorical variables and mean ± standard deviation for continuous variables. The Pearson's chi-square or Fisher's exact test was used for the analysis of categorical variables. Differences between means were tested with two-sided Student's t test, Wilcoxon rank-sum test, or Mann–Whitney test. A P value of less than .05 was used to determine statistical significance. Data are presented as median values or mean and standard deviation with 95% confidence interval (CI), as appropriate.

Results

During the study period, a total of 127 patients were treated with F-BEVAR. Preloaded systems were used in 83 patients (65%, 74 male, mean age 75 ± 7 years), which comprised the study population. There were seven different types of PLS configuration. The most common design, which was selected in 65 patients (78%), consisted of two preloaded catheters for the celiac axis and superior mesenteric artery (Table 1) Extent IV TAAAs were present in 35 patients (42%), pararenal AAAs in 27 (21%), and 21 patients (25%) had extent I–III TAAAs. Demographics and cardiovascular risk factors were typical for the patient population and similar among the groups (Table 2). Overall mean aneurysm diameter was 58 ± 16 mm. Patients with extent I–III TAAA more frequently had a history of prior aortic repair (67% vs. 19% and 23% for pararenal and extent IV TAAA, respectively; $P < .001$).

Table 1 Type of preloaded systems configuration of 83 patients treated with customized patient-specific device

n = number of patients	Overall n = 83 (%)
Configurations	
2 preloaded catheters	65 (78)
1 preloaded catheter	8 (10)
2 preloaded catheters with wires	4 (5)
2 preloaded wires	2 (2)
4 preloaded wires	2 (2)
2 preloaded catheters with wires/2 preloaded wires	1 (1)
1 preloaded catheter/2 preloaded wires	1 (1)

Procedural Details

All procedures were performed under general anesthesia. There were 333 renal/mesenteric arteries incorporated in the repair (mean 4 vessels per patient). Fenestrations were preferentially used in patients with pararenal and extent IV thoracoabdominal aortic aneurysms (94% and 96%, respectively), while directional branches were used in slightly over half of the patients with extent I–III TAAA (53%). A cerebrospinal fluid drain was used in 75% of the patients, more often in the extent I–III group. Brachial access approach was used in all patients, and the left brachial access (88%) was more often used than the right brachial access (12%, $P < .001$). Technical success, defined by deployment of the aortic stent graft and all intended side branch components, was achieved in 98.8% (82/83) of patients and 99.7% (332/333) of the vessels. Mean utilized contrast volume was 154 ± 48 mL and was significantly higher in the extent I–III group as compared to the pararenal group (172 ± 56 mL vs. 136 ± 35 mL; $P = .03$). Mean fluoroscopy time and radiation exposure were 78 ± 24 min and 3457 ± 1769 mGy, respectively, and were similar among all groups. Mean estimated blood loss was 461 ± 516 mL, also similar in all groups; EBL $>$ 1L occurred in four patients (5%). Total lower extremity ischemia time was 115 ± 42 min. Procedural details are summarized in Table 3.

Early Outcomes

The median length of hospital stay was 6.1 ± 3.6 days (intensive care unit stay was 2.3 ± 1.5 days). There were no 30-day or in-hospital deaths. Major adverse events were recorded in 15 patients (18%), with no differences among the three groups. Acute kidney injury (eGFR decline $>$ 50% baseline) was more common in the extent IV TAAA group (17% vs. 0 for pararenal and I–III TAAA; $P = .01$), with no patient requiring hemodialysis. Additional major adverse events are summarized in Table 4. There were three minor ischemic strokes (3.6%) all in patients with thoracoabdominal aneurysms (two in extent IV TAAA patients and one in extent I–III TAAA). Two patients had bilateral posterior and anterior circulation small

Table 2 Clinical characteristics of 83 patients treated by fenestrated and branched endovascular aortic repair for pararenal and thoracoabdominal aortic aneurysms (TAAAs) using preloaded catheters

Variable *n* = number of patients	All *n* = 83 *n* (%) or mean ± SD	Pararenal *n* = 27	Extent IV TAAA *n* = 35	Extent I–III TAAA *n* = 21	*P* value
Demographics					
Age (years old)	75 ± 7	77 ± 6	76 ± 7	72 ± 6	.04
Age > 80 years old	21 (25)	10 (37)	10 (29)	1 (5)	.09
Male gender	64 (77)	21 (78)	27 (77)	16 (76)	.99
Cardiovascular risk factors					
Hypertension	70 (84)	21 (78)	30 (86)	19 (90)	.47
Cigarette smoking	73 (88)	24 (89)	29 (83)	20 (95)	.38
Hypercholesterolemia	69 (83)	21 (78)	30 (86)	18 (86)	.66
Coronary artery disease	43 (52)	12 (44)	20 (57)	11 (52)	.61
COPD	28 (34)	7 (26)	10 (29)	11 (52)	.11
Myocardial infarction	31 (37)	9 (33)	15 (43)	7 (33)	.68
arrhythmia	8 (10)	1 (4)	6 (17)	1 (5)	.14
Diabetes mellitus	15 (18)	5 (19)	8 (23)	2 (10)	.45
Congestive heart failure	9 (11)	1 (4)	6 (17)	2 (10)	.23
CKD stage III–V	16 (19)	4 (15)	7 (20)	5 (24)	.73
Stage III	14 (17)	3 (11)	7 (33)	4 (11)	
Stage IV	2 (2)	1 (4)	0	1 (3)	
Stage V	0	0	0	0	
Prior stroke/TIA	7 (8)	3 (11)	3 (9)	1 (5)	.73
Peripheral arterial disease	24 (29)	4 (15)	12 (34)	8 (38)	.14
Other medical history					
Prior aortic repair	27 (33)	5 (19)	8 (23)	14 (67)	< .001
History of malignancy	15 (18)	6 (22)	6 (17)	3 (14)	.76
Family history of aortic aneurysm	7 (13)	3 (19)	1 (5)	3 (16)	.42
Preoperative evaluation					
Positive cardiac stress test	17 (21)	5 (19)	9 (28)	3 (14)	.14
Ejection fraction (%)	57 ± 12	60 ± 12	55 ± 11	58 ± 11	.17
Serum creatinine (mg/dl)	1.2 ± 0.4	1.2 ± 0.3	1.1 ± 0.2	1.3 ± 0.6	.37
eGFR (mL/min/1.73 m^2)	62 ± 19	61 ± 18	64 ± 19	60 ± 19	.73
Body mass index (kg/m^2)	28 ± 5	28 ± 5	29 ± 6	27 ± 4	.43
Risk assessment and comorbidity scores					
ASA classification					.42
Class II	44 (53)	12 (44)	20 (57)	12 (57)	
Class III	32 (39)	11 (41)	12 (34)	9 (43)	
Class IV	7 (8)	4 (15)	3 (9)	0 (0)	
SVS total score (0–30)	12 ± 4	12 ± 3	13 ± 4	12 ± 4	.65
Cardiac score	14 ± 7	12 ± 6	15 ± 7	13 ± 7	.16
Pulmonary score	13 ± 9	14 ± 9	12 ± 10	14 ± 9	.71
Renal score	3 ± 5	3 ± 5	2 ± 4	3 ± 6	.70
Hypertension score	17 ± 10	15 ± 9	17 ± 11	18 ± 8	.46
Age score	21 ± 6	23 ± 6	21 ± 7	18 ± 5	.03
Vessels per patient	4.0 ± 0.4	4.0 ± 0.5	4.0 ± 0.5	4.1 ± 0.3	.67
≥ 4 target vessels	76 (92)	24 (89)	18 (86)	34 (97)	.27

Table 2 continued

n = total target vessels (%)	*n* = 333	*n* = 108	*n* = 142	*n* = 83	
Fenestrations	276 (83)	101 (94)	136 (96)	39 (47)	< .001
Directional branches	52 (16)	2 (2)	6 (4)	44 (53)	< .001
Doublewide scallops	5 (2)	5 (4)	0 (0)	0 (0)	.004
Total celiac axis	81 (24)	27 (25)	35 (25)	19 (23)	< .001
Doublewide scallop	5 (2)	5 (5)	0 (0)	0 (0)	
Large fenestration	56 (17)	21 (19)	32 (23)	3 (4)	
Directional branch	20 (6)	1 (1)	3 (2)	16 (19)	
Total superior mesenteric artery	83 (25)	27 (25)	35 (25)	21 (25)	< .001
Large fenestration	64 (19)	26 (24)	33 (23)	5 (6)	
Directional branch	19 (6)	1 (1)	2 (1)	16 (19)	
Total right renal artery	80 (24)	26 (24)	34 (24)	20 (24)	< .001
Small fenestration	74 (22)	26 (24)	34 (24)	14 (17)	
Directional branch	6 (2)	0 (0)	0 (0)	6 (7)	
Total left renal artery	82 (25)	27 (25)	35 (25)	20 (24)	.06
Small fenestration	78 (23)	27 (25)	34 (24)	17 (20)	
Directional branch	4 (1)	0 (0)	1 (1)	3 (4)	
Other vessels	7 (2)	1 (1)	3 (2)	3 (4)	
Small fenestration	4 (1)	1 (1)	3 (2)	0 (0)	
Directional branch	3 (1)	0 (0)	0 (0)	3 (4)	

ASA American Society of Anesthesiologists, *CKD* chronic kidney disease, *COPD* chronic obstructive pulmonary disease, *eGFR* estimated glomerular filtration rate, *SVS* Society for Vascular Surgery

infarctions, and one patient presented an occipital infarct ipsilateral to the trans-brachial access. Among stroke cases, two patients had a type 2 aortic arch and one patient had a type 3 arch. Aortic arch debris varied from moderate to severe with significant calcification in all cases. All stroke patients were discharged from the hospital to home/rehabilitation with no minor sequelae. All ischemic strokes occurred in female patients (3.6% vs. 0%; $P = .001$) and in patients with left brachial access (4% vs. 0%, $P = .51$). One (1.2%) patient had spinal cord injury grade 3a. The brachial artery was surgically exposed in all cases, with no access-related upper extremity ischemic or neurologic complications.

Discussion

Endovascular repair of complex abdominal and thoracoabdominal aortic aneurysms with fenestrated and branched endografts has been reported with low mortality and adverse events, and high technical success [1, 4, 14, 15]. Despite the many advances in the past decade, these cases still remain technically demanding. In this study, we reported the use of preloaded catheter systems in endovascular repair of PRA and TAAAs with high technical success (99.7%), low perioperative major adverse events, and no mortality.

Preloaded systems and guide wires were incorporated into complex aortic repair earlier in our experience and are now planned and utilized with most repairs [9]. Preloaded systems allow for immediate access to branches and fenestrations through a 12-Fr trans-brachial sheath positioned in the thoracic aorta. This expedites the procedure by avoiding additional time to catheterization of fenestrations or branches, which translated into a mean endovascular time of 160 ± 51 min, decreasing fluoroscopy time, patient and surgical crew radiation exposure, and contrast utilization. Moreover, utilizing a PLS, the device can be fully deployed prior to target vessel catheterization, with subsequent retrieval of the large femoral access sheath, therefore reducing pelvic and lower extremity ischemia time. This has the benefit of lowering the risk of paraplegia and distal ischemic complications [5, 16]. In this study, we report a lower extremity ischemia time of 115 ± 42 min, and only one patient presented postoperative spinal cord ischemia.

Preloaded systems are particularly useful in patients with challenging visceral vessel anatomy, such as ostial

Table 3 Procedural details in 83 patients treated by fenestrated and branched endovascular aortic repair for pararenal and thoracoabdominal aortic aneurysms (TAAAs) using preloaded catheters

Variable *n* = patients	All *n* = 83 *n* and (%) or mean ± SD	Pararenal *n* = 27	Extent IV TAAA *n* = 35	Extent I–III TAAA *n* = 21	*P* value
General anesthesia	83 (100)	27 (100)	35 (100)	21 (100)	1.0
Cerebrospinal fluid drainage	62 (75)	12 (44)	29 (83)	21 (100)	< .001
Somatosensory evoked potential (SSP)/motor evoked potentials	65 (78)	13 (48)	32 (91)	20 (95)	< .001
Percutaneous femoral approach	57 (69)	19 (70)	24 (69)	14 (67)	.96
Upper extremity approach	83 (100)	27 (100)	35 (100)	21 (100)	1.0
Left	73 (88)	25 (93)	32 (91)	16 (76)	.16
Right	10 (12)	2 (7)	3 (9)	5 (24)	.16
Total endovascular time (min)[a]	160 ± 51	146 ± 32	164 ± 63	171 ± 47	.08
Amount of contrast used (ml)	154 ± 48	136 ± 35	158 ± 48	172 ± 56	.03
Total fluoroscopy time (min)	78 ± 24	71 ± 17	82 ± 30	79 ± 21	.26
Radiation exposure (mGy)	3457 ± 1769	3478 ± 1808	3556 ± 1962	3264 ± 1808	.80
Estimated blood loss (ml)	461 ± 516	332 ± 198	465 ± 583	621 ± 642	.16
Transfusion of blood products					
PRBC	18 (22)	3 (11)	7 (20)	8 (38)	.08
FFP	4 (5)	0	3 (9)	1 (5)	.30
Platelets	3 (4)	0	2 (6)	1 (5)	.46
Cryoprecipitate	3 (4)	0	2 (6)	1 (5)	.46
Iliac conduit	17 (20)	3 (11)	7 (20)	7 (33)	.17
Technical success[b]	82 (99)	27 (100)	35 (100)	20 (95)	.22
Follow-up (months)	34 ± 14	36 ± 15	34 ± 15	33 ± 13	.76

PRBC packed red blood cell, *FFP* fresh frozen plasma

[a]Total endovascular time was defined as the difference between the initial catheter insertion time and the final catheter removal time

[b]Technical success was defined by implantation of aortic component and all intended side branch components

Table 4 Early mortality and major adverse events < 30 days in 83 patients treated by fenestrated and branched endovascular aortic repair for pararenal and thoracoabdominal aortic aneurysms (TAAAs) using preloaded catheters

	All *n* = 83 *n* (%) or mean ± SD	Pararenal *n* = 27	Extent IV TAAA *n* = 35	Extent I–III TAAA *n* = 21	*P* value
Any cause of mortality	0	0	0	0	
Any major adverse event	15 (18)	3 (11)	9 (26)	3 (14)	.29
Estimate blood loss higher than 1000 ml	4 (5)	0	2 (6)	2 (10)	.30
Acute kidney injury (> 50% decrease in eGFR)	6 (7)	0	6 (17)	0	.01
Myocardial infarction	6 (7)	2 (7)	4 (11)	0	.28
Respiratory failure	1 (1)		1 (3)	0	.50
Paraplegia (SCI grade 3a–3c)	1 (1)	1 (4)	0	0	.35
Stroke	3 (4)	0	2 (6)	1 (5)	.46
Bowel ischemia requiring intensification of medical therapy	1 (1)	0	1 (3)	0	.50
Postprocedure transfusion	1 (1)	1 (4)	0	0	.35

eGFR estimated glomerular filtration rate, *SCI* spinal cord injury

stenosis, tortuosity, difficult angulation, or in cases of chronic post-dissection aneurysms [10, 11]. In such cases, the importance of expedited repair with early pelvic and lower extremity flow restoration cannot be overemphasized. Additionally, in patients with unilateral iliac occlusions in which the procedure will almost invariably involve brachial access, PLS can be utilized to assist access into all involved fenestrations or branches. Similarly, when treating thoracoabdominal aneurysms with grafts including multiple directional down-going branches, the use of PLS eliminates the procedural time required for catheterization of the directional branches prior to target vessel catheterization. This becomes significantly helpful in cases of previous endovascular aortic repair with failed thoracic/abdominal or even fenestrated stent grafts, as the identification and visualization of fenestrations and branches will be impaired by the previously existing hardware in the aorta.

One concern with the use of brachio-femoral through-and-through access, required with the described preloaded systems, is the risk of central neurologic events associated with crossing the aortic arch. At the time of the study, our preference was to utilize left brachial surgical access in order to avoid a longer path in the arch from the right brachial artery. Since then, we changed our practice to utilizing right brachial approach in the majority of cases as it has been previously demonstrated to be associated with lower radiation exposure without an increase in cerebrovascular events, in addition to a subjective improvement in the overall ergonomics for the operative team [17]. In the present study, there were three cases of minor ischemic strokes (3.6%), which were all in females with thoracoabdominal aneurysms. In our current practice, patients with severe ascending, arch, or descending thoracic aorta debris have been counseled against endovascular repair due to the risk of cerebrovascular, visceral, or distal embolic events. In order to facilitate assessment of aortic wall thrombus, we have proposed a novel classification system using a scoring system from 0–10 to quantify thrombus type, thickness, area of involvement, circumference, and number of affected segments [18]. A second point that deserves mention is the need for larger delivery systems when preloaded guide wires and/or catheters are included in the preoperative planning. Current device technology and low-profile fabrics allow a four-vessel fenestrated or branched stent graft to be delivered through an 18-French system when no PLS is included. Addition of one or two preloaded catheters will likely result in a 2-French increase in the system profile, similar to two or four preloaded wires. This should be taken into consideration while planning repair in patients with suboptimal iliac anatomy and diameters. Finally, surgical access to the brachial artery remains a concern; despite the use of large (12-French) sheaths in high brachial exposure in this series, there were no cases of access-related upper extremity ischemia or neurological complications in this patient population. Our group recently reported outcomes of 243 patients treated with upper F-BEVAR and brachial access, with 88% undergoing primary arterial repair and 12% requiring patch repair. Postoperatively, two patients presented with transient median nerve neuropraxia (1%), one patient developed an access site hematoma (1%) with no pseudoaneurysms, occlusions, or distal embolization events. We continue to employ surgical brachial access routinely in these cases [19].

This study has several limitations. It does not provide a direct comparison between patients treated without preloaded systems. The patient population selected has an inherently more complex anatomy as this is one of the possible indications for the use of PLS in the original graft planning. There were significant changes in the technique since the original collection of these data including new preloaded systems, which could have impacted results positively. Our upper extremity approach has shifted from left to right brachial artery surgical access with no clear impact in cerebrovascular events; however, we have not yet reviewed this specifically at this moment.

Conclusion

The use of preloaded systems in F-BEVAR is presented with high technical success, no mortality, and low rates of major adverse cardiovascular events. The greatest concern remains the risk of ischemic stroke due to brachial artery access. Case selection should be based on the risk of stroke, particularly in female patients.

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Compliance with Ethical Standards

Conflict of interest Dr. Oderich has received consulting fees and grants from Cook Medical, W. L. Gore, and GE Healthcare (all paid to Mayo Clinic with no personal income). The other authors declare no conflict of interest.

Consent for Publication Consent for publication was obtained for every individual person's data included in the study.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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