Comparison of single- and multistage strategies during fenestrated-branched endovascular aortic repair of thoracoabdominal aortic aneurysms

Marina Dias-Neto, MD,[a] Emanuel R. Tenorio, MD,[a] Ying Huang, MD,[a] Tomasz Jakimowicz, MD,[b] Bernardo C. Mendes, MD,[c] Tilo Kölbel, MD,[d] Jonathan Sobocinski, MD,[e] Luca Bertoglio, MD,[f] Barend Mees, MD,[g] Mauro Gargiulo, MD,[h] Nuno Dias, MD,[i] Andres Schanzer, MD,[j] Warren Gasper, MD,[k] Adam W. Beck, MD,[l] Mark A. Farber, MD,[m] Kevin Mani, MD,[n] Carlos Timaran, MD,[o] Darren B. Schneider, MD,[p] Luis Mendes Pedro, MD,[q] Nikolaos Tsilimparis, MD,[r] Stéphan Haulon, MD,[s] Matt Sweet, MD,[t] Emília Ferreira, MD,[u] Matthew Eagleton, MD,[v] Kak Khee Yeung, MD,[w] Manar Khashram, MD,[x] Andrea Vacirca, MD,[a] Guilherme B. Lima, MD,[a] Aidin Baghbani-Oskouei, MD,[a] Katarzyna Jama, MD,[b] Giuseppe Panuccio, MD,[d] Fiona Rohlffs, MD,[d] Roberto Chiesa, MD,[f] Geert Willem Schurink, MD,[g] Charlotte Lemmens, MD,[g] Enrico Gallitto, MD,[h] Gianluca Faggioli, MD,[h] Angelos Karelis, MD,[i] Ezequiel Parodi, MD,[m] Vivian Gomes, MD,[m] Anders Wanhainen, MD,[n] Anastasia Dean, MD,[n] Jesus Porras Colon, MD,[o] Felipe Pavarino, MD,[o] Ryan Gouveia e Melo, MD,[q,r] Sean Crawford, MD,[s] Rita Garcia, MD,[u] Tiago Ribeiro, MD,[u] Kaj Olav Kappe, MD,[w] Samira Elize Mariko van Knippenberg, MD,[w] Bich Lan Tran, MD,[w] Sinead Gormley, MD,[x] *and* Gustavo S. Oderich, MD,[a] on behalf of the International Aortic Research Consortium, *Houston, TX; Warszawa, Poland; Rochester, MN; Hamburg, Germany; Lille, France; Milan, Italy; Maastricht, The Netherlands; Bologna, Italy; Malmö, Sweden; Worcester, MA; San Francisco, CA; Birmingham, AL; Chapel Hill, NC; Uppsala, Sweden; Dallas, TX; Philadelphia, PA; Lisbon, Portugal; Munich; Germany; Paris, France; Seattle, WA; Boston, MA; Amsterdam, The Netherlands; and Auckland, New Zealand*

ABSTRACT

Objective: The aim of this study was to compare outcomes of single or multistage approach during fenestrated-branched endovascular aortic repair (FB-EVAR) of extensive thoracoabdominal aortic aneurysms (TAAAs).

From the The University of Texas Health Science Center at Houston, Houston[a]; the Medical University of Warsaw, Warszawa[b]; the Division of Vascular and Endovascular Surgery, Mayo Clinic, Rochester[c]; the University Medical Center Eppendorf (UKE), Hamburg[d]; the Vascular Surgery, Aortic Centre, Université de Lille, CHU Lille, France; Université de Lille, INSERM, CHU Lille, Lille[e]; the Vita Salute San Raffaele University, San Raffaele Hospital, Milan[f]; the Maastricht University Medical Center, Maastricht University, Maastricht[g]; the Department of Vascular Surgery, University of Bologna, University Hospital Policlinico S. Orsola, Bologna[h]; the Vascular Centre, Department of Thoracic Surgery and Vascular Diseases, Skåne University Hospital and Department of Clinical Sciences Malmö, Lund University, Malmö[i]; the University of Massachusetts Medical School. Worcester[j]; the University of California San Francisco, San Francisco[k]; the University of Alabama at Birmingham, Birmingham[l]; the Division of Vascular Surgery, Department of Surgery, University of North Carolina, Chapel Hill[m]; the Department of Surgical Sciences, Division of Vascular Surgery, Uppsala University, Uppsala[n]; the Clinical Heart and Vascular Center, University of Texas Southwestern, Dallas[o]; the Division of Vascular Surgery and Endovascular Therapy, Perelman School of Medicine, University of Pennsylvania, Philadelphia[p]; the Department of Vascular Surgery of the Hospital Santa Maria (CHULN) and Faculty of Medicine of the University of Lisbon, Lisbon[q]; the Department of Vascular Surgery, Ludwig-Maximilians-University Hospital, Munich[r]; the Aortic Centre, Hôpital Marie Lannelongue, Groupe Hospitalier Paris Saint-Joseph, Université Paris Saclay, Paris[s]; the Division of Vascular Surgery, Department of Surgery, University of Washington, Seattle[t]; the Department of Angiology and Vascular Surgery, Hospital de Santa Marta, Centro Hospitalar Universitário de Lisboa Central; NOVA Medical School, Universidade NOVA de Lisboa, Lisbon[u]; the Division of Vascular and Endovascular Surgery, Massachusetts General Hospital, Boston[v]; the Department of Vascular Surgery, Amsterdam Cardiovascular Sciences, Amsterdam UMC, VU Medical Center, Amsterdam[w]; the Department of Vascular Surgery, Waikato Hospital, Hamilton, New Zealand; Department of Surgery, The University of Auckland, Auckland.[x]

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Correspondence: Gustavo S. Oderich, The University of Texas Health Science Center at Houston – Memorial Hermann Texas Medical Center, 6400 Fannin St, Ste 2850, Houston TX 77030 (e-mail: gustavo.oderich@uth.tmc.edu).

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Methods: We reviewed the clinical data of consecutive patients treated by FB-EVAR for extent I to III TAAAs in 24 centers (2006-2021). All patients received a single brand manufactured patient-specific or off-the-shelf fenestrated-branched stent grafts. Staging strategies included proximal thoracic aortic repair, minimally invasive segmental artery coil embolization, temporary aneurysm sac perfusion and combinations of these techniques. Endpoints were analyzed for elective repair in patients who had a single- or multistage approach before and after propensity score adjustment for baseline differences, including the composite 30-day/in-hospital mortality and/or permanent paraplegia, major adverse event, patient survival, and freedom from aortic-related mortality.

Results: A total of 1947 patients (65% male; mean age, 71 ± 8 years) underwent FB-EVAR of 155 extent I (10%), 729 extent II (46%), and 713 extent III TAAAs (44%). A single-stage approach was used in 939 patients (48%) and a multistage approach in 1008 patients (52%). A multistage approach was more frequently used in patients undergoing elective compared with non-elective repair (55% vs 35%; $P < .001$). Staging strategies were proximal thoracic aortic repair in 743 patients (74%), temporary aneurysm sac perfusion in 128 (13%), minimally invasive segmental artery coil embolization in 10 (1%), and combinations in 127 (12%). Among patients undergoing elective repair (n = 1597), the composite endpoint of 30-day/in-hospital mortality and/or permanent paraplegia rate occurred in 14% of single-stage and 6% of multistage approach patients ($P < .001$). After adjustment with a propensity score, multistage approach was associated with lower rates of 30-day/in-hospital mortality and/or permanent paraplegia (odds ratio, 0.466; 95% confidence interval, 0.271-0.801; $P = .006$) and higher patient survival at 1 year (86.9±1.3% vs 79.6±1.7%) and 3 years (72.7±2.1% vs 64.2±2.3%; adjusted hazard ratio, 0.714; 95% confidence interval, 0.528-0.966; $P = .029$), compared with a single stage approach.

Conclusions: Staging elective FB-EVAR of extent I to III TAAAs was associated with decreased risk of mortality and/or permanent paraplegia at 30 days or within hospital stay, and with higher patient survival at 1 and 3 years. (J Vasc Surg 2023;77:1588-97.)

Keywords: Fenestrated-branched endovascular aortic repair; Multistage approach; Single stage; Spinal cord injury; Thoracoabdominal aortic aneurysm

Open or endovascular repair of extensive thoracoabdominal aortic aneurysms (TAAAs) requires multidisciplinary expertise to minimize the risk of mortality and disabling complications. These procedures pose formidable technical challenge irrespective of the approach. One of the most devastating complications is spinal cord injury (SCI), particularly when associated with permanent paraplegia, which can lead to severe decline in quality of life and decreased patient survival.[1] The risk of developing SCI after fenestrated-branched endovascular aortic repair (FB-EVAR) varies widely in the literature, reaching up to 40% in some reports.[2] Although the risk is directly related to the extent of aortic coverage, potential explanations for the wide variation in reported rates include the lack of reporting standards, patient heterogeneity, and variations in the use of preventive strategies.[3]

Most of the strategies to prevent SCI during endovascular repair focused on maneuvers to optimize spinal cord perfusion by increasing systemic pressure and oxygen delivery, and decreasing cerebrospinal fluid (CSF) pressure, while promoting collateral flow.[4-8] The spinal cord collateral network includes not only the segmental aortic branches, but also extensive collaterals from the vertebral, intercostal, hypogastric, and paraspinal muscular branches.[9,10] Results from experimental models have demonstrated that single-stage ligation of the segmental aortic branches is associated with significant reduction in the spinal collateral network perfusion pressure, slower recovery to baseline values, and increased rates of paraplegia as compared with a multistage approach.[11,12] In the clinical setting, several strategies have been proposed to achieve staged occlusion of segmental aortic branches. These strategies include proximal thoracic aortic repair (PTAR), temporary aneurysm sac perfusion (TASP), and minimally invasive staged segmental artery coil embolization (MIS ACE).[13-19] A limitation of staged approaches is the inherent risks of intervening rupture between procedures and the morbidity of multiple procedures. The aim of this study was to compare outcomes of FB-EVAR for treatment of TAAAs using a single- or multistage approach.

METHODS

Study design. The study is a retrospective review of all consecutive patients treated by FB-EVAR for TAAAs in 24 centers from the United States, Europe, and New Zealand (2006-2021). In all participating centers, the study was approved by the Institutional Review Boards or waived for ethical approval in accordance with local ethical committees. Patients consented for participation in minimal risk retrospective studies, where required. We included in the analysis all consecutive patients treated for Extent I, II, and III TAAAs using a single brand manufactured patient-specific or off-the-shelf fenestrated-branched stent grafts. Patients who had Extent IV TAAAs or complex abdominal aortic aneurysms, defined as aneurysms that involve the renal or mesenteric arteries and extend up to the level of the celiac axis or diaphragmatic hiatus but do not extend into the thoracic aorta, were excluded. Patients were classified into single-stage and multistage groups according to the use of any of the staging strategies for

FB-EVAR. In each group, patients were further divided into elective and non-elective subgroups according to the urgency of the index procedure. The clinical data were obtained from institutional prospective or retrospective databases and/or from electronic medical records. Patient information was de-identified and recorded in a standardized electronic database.

Procedure. Stent design was based on centerline of flow analysis of preoperative computed tomographic angiography as previously reported.[20] Options included off-the-shelf multi-branch stent graft (Cook t-Branch, Cook Medical Inc, Bjaeverskov, Denmark) or patient-specific company manufactured device (Cook Medical Inc) with any combination of fenestrations and/or directional branches. A single-stage repair was defined as TAAA exclusion using FB-EVAR in a single procedure, without prior thoracic aortic repair. A multistage approach was defined as aneurysm exclusion using one or more staged procedures besides FB-EVAR. These staging strategies included intentional staged thoracic repair, PTAR unrelated to the current TAAA repair using either open or endovascular repair (unrelated PTAR), MISACE, TASP, or combinations of these approaches. TASP could be performed by use of perfusion branches designed for this purpose, delayed insertion of the bridging stents, or the contra-lateral limb of the bifurcated stent-graft.[15-18] All these are followed by a later exclusion that can be preceded by a balloon occlusion test to examine the tolerance of the spinal cord to definite sac perfusion. Prior infrarenal aortic repair was not considered a staging strategy. The perioperative protocol to prevent SCI was not the same for all centers but generally included, following the United States Aortic Research Consortium consensus, to keep mean blood pressure >90 mmHg, serum hemoglobin >10 g/dL, and to use CSF drainage in high-risk patients.[21] Rescue maneuvers in case of SCI included to place a CSF drainage if not already present, to reduce the target CSF drain pop-off pressure (<10 mmHg), to increase CSF drainage volume, the mean arterial pressure goal and the hemoglobin goal, and to perform imaging the spine via computed tomography or magnetic resonance imaging.[21]

Definitions. Clinical variables and study endpoints were defined in accordance with the Society for Vascular Surgery reporting standards for endovascular repair involving incorporation of renal and mesenteric arteries.[22] Major adverse events (MAEs) include all-cause mortality, myocardial infarction, respiratory failure requiring prolonged (>24 hours from anticipated) mechanical ventilation or reintubation, renal function decline resulting in >50% reduction in baseline estimated glomerular filtration rate (eGFR) or new-onset dialysis, bowel ischemia requiring surgical resection or not resolving with medical therapy, major stroke, and paraplegia (grade 3).

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter prospective and retrospective cohort study
- **Key Findings:** From patients undergoing fenestrated-branched endovascular repair of extensive thoracoabdominal aortic aneurysms, a single-stage approach was used in 939 patients (48%) and a multistage approach in 1008 patients (52%). For elective repair (n = 1597), the composite endpoint of 30-day/in-hospital mortality and/or permanent paraplegia rate occurred in 14% of single-stage and 6% of multistage approach patients ($P < .001$).
- **Take Home Message:** Staging elective fenestrated-branched endovascular repair of extent I to III thoracoabdominal aortic aneurysms was associated with decreased risk of mortality and/or permanent paraplegia at 30 days or within hospital stay, and with higher patient survival at 1 and 3 years.

SCI was considered independent of cause or mechanism and graded as none (0), resolved with minimal sensory deficit, able to walk independently (1), minor motor deficit, able to walk with assistance or independently (implies the ability to move against gravity) (2), or nonambulatory (wheelchair bound) (3 A-C). Paraplegia was defined by any grade 3 spinal cord injury (A-C) in a patient who is nonambulatory. Permanent injury was defined by any injury that has partial or no improvement compared with baseline examination.

The primary endpoint was a composite of all-cause mortality and/or permanent paraplegia within the first 30 days or within hospital stay if longer than 30 days. Secondary endpoints were mortality within the first 30 days or within the hospital stay if longer than 30 days, MAEs, any SCI, patient survival, and freedom from aortic-related mortality (ARM).

Statistical analysis. Continuous data were assessed for normality with histogram. Continuous variables were expressed as mean ± standard deviation when normally distributed, otherwise as median and interquartile range. Categorical variables were expressed as number (percentages). Time-dependent variables were evaluated using Kaplan-Meier curves. Patients who underwent elective FB-EVAR were further analyzed. We reported early and intermediate outcomes comparing single-staging with different staging strategies. Differences between groups were assessed using χ^2 tests for categorical variables and the t test or non-parametric tests for continuous variables in which a normal distribution could or could not be assumed, respectively. Logistic regression models were developed to examine the predictive role of staging in the development of early

Table I. Demographics and comorbidities of patients undergoing elective endovascular thoracoabdominal aortic aneurysm (TAAA) repair

	N	Single-stage (n = 713)	Multi-stage (n = 884)	Total	Unadjusted *P* value	Adjusted *P* value[a]
Male sex	1597	506 (71.0)	543 (61.4)	1049 (65.7)	**<.001**	.973
Age, years	1597	71.5±8.0	70.0±8.6	70.7±8.4	.057	.847
Hypertension	1597	609 (85.4)	783 (88.6)	1392 (87.2)	.060	.947
Hyperlipidemia	968	261 (58.7)	289 (55.3)	550 (56.8)	.288	.601
Diabetes mellitus	1597	81 (11.4)	109 (12.3)	190 (11.9)	.552	.950
Coronary artery disease	1596	284 (39.9)	252 (28.5)	536 (33.6)	**<.001**	.935
Chronic heart failure	1595	98 (13.8)	132 (14.9)	230 (14.4)	.516	.951
Peripheral arterial disease	1456	182 (29.5)	142 (16.9)	324 (22.3)	**<.001**	.939
Stroke or TIA	1596	72 (10.1)	104 (11.8)	176 (11.0)	.295	.993
GFR, mL/min/1.73m^2	1544	63.2±25.2	64.9±24.5	64.1±24.8	**.014**	.955
COPD	1595	226 (31.8)	324 (36.7)	550 (34.5)	**.042**	.914
ASA ≥III	1498	557 (85.7)	763 (90.0)	1320 (88.1)	**.011**	.844
Genetically triggered aortic disease	1504	11 (1.7)	32 (3.7)	43 (2.9)	**.022**	.782
Family history of aortic disease	1277	68 (12.9)	85 (11.3)	153 (12.0)	.395	.986

ASA, America Society of Anesthesiologists Physical Status Classification System; *COPD*, chronic obstructive pulmonary disease; *GFR*, glomerular filtration rate; *TIA*, Transient ischemic attack.
Data are presented as number (%) or mean ± standard deviation.
Boldface *P* values indicate statistical significance.
[a]After adjustment with a propensity score.

outcomes. The odds ratios (ORs) with 95% confidence intervals (95% CIs) were reported when appropriate. The Kaplan-Meier method was used to assess patient survival and freedom from ARM. To estimate the effect of multistage strategies on study outcomes, we performed propensity score (PS) adjustment analysis.[23] A multivariable logistic regression model was used to calculate the predicted probability of undergoing a multistaged approach (vs a single-stage approach) based on demographics, comorbidities, and anatomic variables. Variables associated with staging with a *P* value bellow .250 and/or considered clinically relevant were added to the multivariable logistic regression model. Using the PS adjustment, the outcome variable is regressed on an indicator variable denoting treatment status (single- vs multi-stages) and the estimated PS. Logistic models were developed to determine the impact of the single- vs multistage approach in early outcomes, adjusting to the PS, whereas Cox proportional hazard models were used in intermediate outcomes adjusting with the PS. All analyses were conducted using IBM SPSS version 28 software (IBM Inc, Chicago, IL), and a *P*-value of $< .05$ was considered statistically significant.

RESULTS

Study patients. A total of 1947 patients, including 1260 male (65%) and 687 female (35%) patients, with mean age of 71±8 years were treated by FB-EVAR for 195 extent I (10%), 895 extent II (46%), and 857 extent III (44%) TAAAs. Of these, 1597 patients (82%) underwent elective repair of asymptomatic aneurysms, and 350 patients (18%) required urgent or emergent repair of symptomatic or ruptured TAAAs. A single-stage approach was used in 939 patients (48%) and a multistage approach in 1008 patients (52%). The most common staging strategy was PTAR in 741 patients (74%), followed by TASP in 128 (13%) and MISACE in 10 patients (1%) from three centers. A combination of multiple staging strategies was applied in 127 patients (12%).

Use of the multistage approach was more common among patients undergoing elective procedures (55% vs 35%; $P < .001$). Seventy-five percent of these patients had staging with PTAR based on previous open or endovascular procedures and unrelated to the current TAAA repair (Supplementary Fig 1, online only).

The distribution of the single-stage vs multistage cases among the study sites is presented in Supplementary Fig 2 (online only).

Among 1597 patients undergoing elective FB-EVAR, there were significant differences in baseline characteristics between the single- and multistage groups (Table I). Compared with patients who had a single-stage approach, those who had a multistage approach had a lower proportion of male sex, coronary artery disease, and peripheral arterial disease, but higher rates of chronic obstructive pulmonary disease, American Society of Anesthesiologists score ≥III, genetically-triggered

Table II. Prior aortic history and anatomic features of patients undergoing elective endovascular thoracoabdominal aortic aneurysm (TAAA) repair

	N	Single-stage (n = 713)	Multi-stage (n = 884)	Total	Unadjusted *P* value	Adjusted P value[a]
Prior open aortic repair	1597	250 (35.1)	389 (44.0)	639 (40.0)	**<.001**	–
Prior endovascular aortic repair	1597	52 (7.3)	388 (43.9)	440 (27.6)	**<.001**	–
Maximal aortic diameter, mm	1588	67.4±12.5	65.7±11.5	66.5±12.0	**.004**	.900
Crawford classification	1597				**<.001**	.784
Extent I		56 (7.9)	99 (11.2)	155 (9.7)		
Extent II		207 (29.0)	522 (59.0)	729 (45.6)		
Extent III		450 (63.1)	263 (29.8)	713 (44.6)		
Chronic aortic dissection	1504	53 (8.0)	215 (25.4)	268 (17.8)	**<.001**	.533
Hypogastric arteries, one or both occluded	1377	46 (8.0)	78 (9.7)	124 (9.0)	.270	.992
One		31 (5.4)	58 (7.2)	89 (6.5)		
Both		15 (2.6)	20 (2.5)	35 (2.5)		
Vertebral arteries, one or both occluded	1385	51 (8.8)	67 (8.3)	118 (8.5)	.732	.906
One		43 (7.4)	65 (8.1)	108 (7.8)		
Both		8 (1.4)	2 (0.2)	10 (0.7)		

Data are presented as number (%) or mean ± standard deviation.
Boldface *P* values indicate statistical significance.
[a]After adjustment with a propensity score.

Table III. Procedural features of patients treated by elective fenestrated-branched endovascular aortic repair (FB-EVAR) in a single-stage procedure or any of the staging strategies

	N	Single-stage (n = 713)	Multistage (n = 884)	Total	*P* value
Ilio-femoral conduit	1532	54 (7.8)	57 (6.8)	111 (7.2)	.453
Bilateral percutaneous femoral access	1411	230 (34.1)	396 (53.7)	626 (44.4)	**<.001**
Upper access	1562	542 (77.2)	574 (66.7)	1116 (71.4)	**<.001**
Iliac branch device	1518	54 (8.2)	92 (10.8)	146 (9.7)	.081
One side		42 (6.4)	80 (9.4)	122 (8.1)	
Both sides		12 (1.8)	12 (1.4)	24 (1.6)	
Prophylactic lumbar drain	1592	460 (64.9)	610 (69.1)	1070 (67.2)	.076
MEP and/or SSEP	1587	110 (15.5)	202 (23.0)	312 (19.6)	**<.001**
SVS proximal implantation zone	958				**<.001**
Zones 0-3		115 (31.0)	367 (62.5)	482 (50.3)	
Zones 4-6		256 (69.0)	220 (37.5)	476 (49.7)	
SVS distal implantation zone	827				.243
Zone 9		123 (40.3)	188 (36.0)	311 (37.6)	
Zone 10		155 (50.8)	271 (51.9)	426 (51.5)	
Zone 11		27 (8.9)	63 (12.1)	90 (10.9)	
Technical success	1596	678 (95.1)	834 (94.5)	1512 (94.7)	.569

MEP, Motor evoked potentials; *SSEP*, somatosensory-evoked potentials; *SVS*, Society for Vascular Surgery.
Data are presented as number (%).
Boldface *P* values indicate statistical significance.

aortic disease, and higher eGFR ($P = .014$). Patients who had multistage FB-EVAR also had higher proportion of Extent I and II TAAAs and chronic post-dissection TAAAs ($P \leq .001$), but shorter maximal aortic diameter ($P = .004$) (Table II).

Procedural data. Procedural results are present in Table III. Compared with patients who underwent a single-stage approach, those who had multistage procedures more often had bilateral percutaneous femoral access (multistage, 53.7% vs single-stage, 34.1%; $P < .001$),

Table IV. Thirty-day outcomes after elective fenestrated-branched endovascular aortic repair (FB-EVAR) using single- or multi-stage approaches

	N	Single-stage (n = 713)	Multistage (n = 884)	Total	*P* value
Death or permanent paraplegia	1502	92 (13.7)	52 (6.3)	144 (9.6)	**<.001**
MAE	1478	189 (29.5)	165 (19.7)	354 (24.0)	**<.001**
Death	1594	49 (6.9)	37 (4.2)	86 (5.4)	**.017**
Myocardial infarction	1594	24 (3.4)	18 (2.0)	42 (2.6)	.099
Respiratory failure	1595	31 (4.3)	35 (4.0)	66 (4.1)	.705
AKI	1473	94 (14.8)	84 (10.0)	178 (12.1)	**.005**
Bowel ischemia	1597	13 (1.8)	6 (0.7)	19 (1.2)	**.036**
Major stroke	1597	24 (3.4)	19 (2.1)	43 (2.7)	.135
Paraplegia	1597	71 (10.0)	38 (4.3)	109 (6.8)	**<.001**
Any SCI	1597	108 (15.1)	92 (10.4)	200 (12.5)	**.004**
Permanent SCI	1501	59 (8.8)	33 (4.0)	92 (6.1)	**<.001**
Permanent paraplegia	1500	56 (8.3)	25 (3.0)	81 (5.4)	**<.001**

AKI, Acute renal injury; *MAE*, major adverse event; *SCI*, spinal cord injury.
Data are presented as number (%).
Boldface *P* values indicate statistical significance.

but less often had upper extremity access (multistage, 66.7% vs single-stage, 77.2%; $P < .001$). The use of prophylactic CSF drainage was similar in patients with multistage or single-stage procedures (69% vs 65%; $P = .076$), but neuromonitoring with motor and sensory evoked potentials was more frequent in the multistage repair (23% vs 16%; $P < .001$). Patients with multistage procedures less frequently underwent proximal implantation in Society for Vascular Surgery zones 4 to 6 (37% vs 69%; $P < .001$). Overall technical success averaged 95%, with no difference between the two groups (95% vs 94%; $P = .569$).

Early outcomes. Among the 1594 patients treated by elective FB-EVAR, there were 86 early deaths (5.4%) and 81 permanent paraplegias (5.4%), resulting in an overall composite all-cause mortality and/or permanent paraplegia rate of 9.6%, 6% for the multistage approach and 14% for single-stage patients ($P < .001$) (Table IV). The rates of the composite outcome did not differ among patients with TAAA extent I, II, and III (Supplementary Fig 3, online only). Early mortality was higher in the multistage group (n = 37; 4.2%) compared with the single-stage group (n = 49; 6.9%; $P < .001$). Major adverse events occurred in 354 of 1478 patients (24%) who had events recorded. There were significantly lower rates of MAEs among patients treated by the multistage approach compared with the single-stage approach (19.7% vs 29.5%; $P = .017$). The multistage approach was associated with lower rates of acute kidney injury (AKI) (10.0% vs 14.8%; $P = .005$), bowel ischemia requiring resection (0.7% vs 1.8%; $P = .036$), and paraplegia (4.3% vs 10%; $P = .046$). After PS adjustment, a multistage approach was associated with one-half the risk of having early mortality and/or permanent paraplegia than a single-stage approach (adjusted OR, 0.446; 95% CI, 0.271-0.801) (Table V).

Specific staging strategy vs single-stage repair. Outcomes of staging using PTAR and TASP were similar, except for the rate of major stroke, which was higher in patients with TASP compared with those with PTAR (5.9% vs 1.8%; $P < .05$) (Supplementary Table, online only). Compared with single-stage repair, staging with PTAR was associated with decreased rates of composite all-cause mortality and permanent paraplegia (PTAR, 6.4% vs single stage, 13.7%; $P < .001$), MAEs (PTAR, 19.8% vs single-stage, 29.5%; $P < .001$), AKI (PTAR, 10.1% vs single-stage, 14.8%; $P < .039$), paraplegia (PTAR, 3.3% vs single-stage, 8.3%; $P < .001$), any SCI (PTAR, 10% vs single-stage, 15.1%; $P = .008$), and permanent paraplegia (PTAR, 3.6% vs single-stage, 8.8%; $P < .001$); staging with TASP was associated with decreased rate of paraplegia (2.0% vs 10.0%; $P < .05$). Rates of composite all-cause mortality and/or permanent paraplegia (6% vs 14%; $P > .05$), as well as MAEs, were similar for patients having TASP or a single-stage approach (19% vs 30%; $P > .05$).

TASP. There were 203 patients (23%) who were treated with TASP as part of a multi-stage strategy during elective FB-EVAR, including 102 patients who also had PTAR or MISACE. The rate of any SCI in this group of patients after FB-EVAR was 10.8%, and the rate of paraplegia was 4.4%. Complete clinical data on techniques and outcomes of the TASP closure procedure was available in 124 patients. The TASP technique consisted of incomplete aorto-iliac coverage in 75 patients (60%), unstented perfusion or directional branch in 42 patients (34%), and unstented fenestration in six patients (5%). Completion FB-EVAR with successful closure of TASP was achieved in

Table V. Early outcomes after elective fenestrated-branched endovascular aortic repair (FB-EVAR) in a single-stage or multiple stages after adjustment with the propensity score

	P-value	aOR	95% CI
Death or permanent paraplegia	**.006**	**.466**	**.271-.801**
MAE	.54	.703	0.492-1.006
Death	.106	.594	.316-1.117
Myocardial infarction	.387	.679	.283-1.631
Respiratory failure	.758	.887	.415-1.898
AKI	.797	.940	.589-1.502
Bowel ischemia	.444	.616	.177-2.135
Major stroke	.302	1.779	.596-5.307
Paraplegia	**.046**	**.515**	**.268-.988**
Any SCI	.436	.828	.515-1.331
Permanent SCI	**.009**	**.397**	**.198-.798**
Permanent paraplegia	**.018**	**.407**	**.193-.857**

AKI, Acute renal injury; *aOR*, adjusted odds ratio; *MAE*, major adverse event; *SCI*, spinal cord injury.
Boldface *P* values indicate statistical significance.
Single-stage, n = 360; multistage, n = 635; Total, N = 995.
Reference = single-stage.

194 patients (95.6%) at a median of 20 days (interquartile range, 8-49 days). Upon closure, seven patients (3.6%) developed SCI, including one patient (0.5%) who had permanent paraplegia. Nine patients (4.4%) died prior to closure of TASP. Among these, six patients died early; the remaining three died from non-aortic-related causes after hospital dismissal. No aortic aneurysm ruptured after TASP.

Intermediate outcomes. The median follow-up for patients undergoing elective FB-EVAR was 14 months (interquartile range, 3-36 months). Patient survival was significantly higher ($P = .005$) for patients who had multistage compared with single-stage approach at 1 year (86.9% ± 1.3% vs 79.6% ± 1.7%) and 3 years (72.7% ± 2.1% vs 64.2% ± 2.3%), respectively (Fig, *A*). Freedom from ARM was 94.8% ± 0.8% vs 91.1% ± 1.2% at 1 year, and 93.5% ± 1.1% vs 89.0% ± 1.4% at 3 years ($P = .017$) (Fig, *B*), respectively. After PS adjustment, patients treated by a multistage approach had significantly lower all-cause mortality (adjusted hazard ratio [aHR], 0.714; 95% CI, 0.528-0.966; $P = .029$) and similar ARM (aHR, 0.558; 95% CI, 0.310-1.007; $P = .053$).

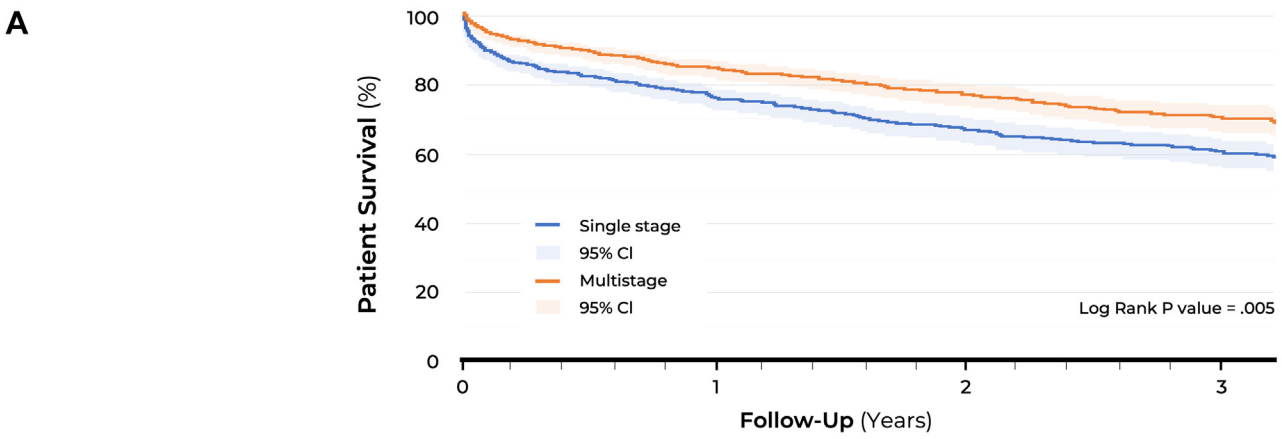
This benefit was observed in patients that developed grade 3 SCI. Among those, the aHRs for all-cause mortality and ARM were 0.412 (95% CI, 0.157-1.079; $P = .071$) and .190 (95% CI, 0.053-0.686; $P = .011$), respectively. Among patients that did not develop grade 3 SCI, the aHRs for all-cause mortality and ARM were 0.802 (95% CI, 0.579-1.111; $P = .184$) and .779 (95% CI, 0.388-1.562; $P = .572$), respectively.

DISCUSSION

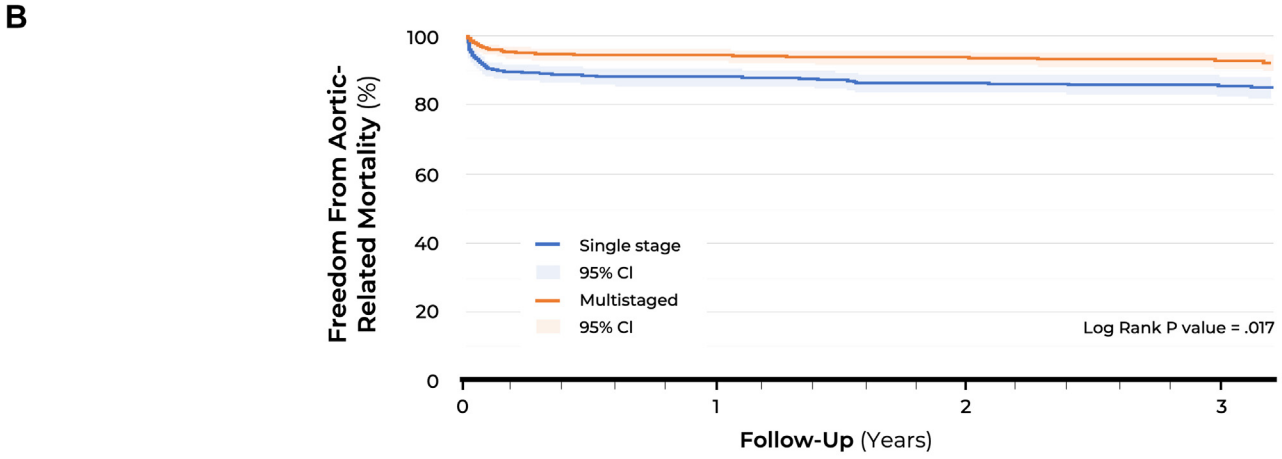
This large multicenter observational study of patients treated for extent I to III TAAAs demonstrated that the overall composite all-cause mortality and/or permanent paraplegia after elective FB-EVAR was low (9.6%) within the first 30 days or within hospital stay, and that a multistage approach resulted in a 52% reduction in the primary endpoint. Staging was also associated with increased patient survival by 29% at 3 years after adjustment with a PS for differences in baseline clinical and anatomical characteristics.

The rationale for staging emerged from translational and clinical research. The perfusion of the spinal cord was once considered to be primarily determined by terminal segmental aortic branches such as the artery of Adamkiewicz. A better understanding of the complex and dynamic collateral network concept derived from animal studies and from clinical anatomical imaging after extensive open surgical repair.[24-26] The comprehensive elements of the collateral network rely on: (1) the existence of an axial network of small arteries in the spine canal, paravertebral tissue, and musculature that anastomose among themselves and tributers to the spinal cord[27]; (2) contributions not only from segmental intercostal and lumbar arteries, but also from the vertebral (cephalic input) and hypogastric arteries (distal input); and (3) vessel remodeling and reorientation of flow within the collateral network from one source to another upon reduction of selective inflow source.[11] Thus, the collateral network allows for some degree of adaptation to the loss of individual contributors to perfusion until a point beyond which dysfunction is inevitable. Moreover, in experimental studies of animals submitted to sacrifice of segmental arteries, enlargement and redirection of flow in the intraspinal and paraspinous arteries and arterioles occurred, providing the anatomic substrate for preservation of the spinal cord blood flow via collateral pathway. This adaptive change occurred very early; in fact, the anterior spinal artery had an increased diameter after 24 hours from the procedure, and after 5 days, the anterior spinal and epidural arterial network improved in diameter by 80% to 100% ($P < .001$). Although there is no guarantee that these animal models are an accurate reflection of what happens in humans, they show very well the process of spinal arterial network change in mammals after covering aortic segments.[12]

The first evidence that staging may reduce the risk of mortality and SCI was the observation of more favorable outcomes among patients who had staged open surgical repair of Extent II TAAAs.[28-31] Multistage endovascular repair has gained popularity in the last decade, but evidence remains limited to a few single-center reports. Bertoglio and associates analyzed 80 high-risk patients treated by multistage FB-EVAR with mortality of 8%



—	**Number at risk**	**709**	**370**	**263**	**195**
	Kaplan – Meir estimate survival rates	100	80	71	64
	Standard error	0	2	2	2
—	**Number at risk**	**882**	**485**	**311**	**190**
	Kaplan – Meir estimate survival rates	100	87	79	73
	Standard error	0	1	2	2



—	**Number at risk**	**667**	**336**	**242**	**182**
	Kaplan – Meir estimate survival rates	100	91	90	89
	Standard error	0	1	1	1
—	**Number at risk**	**791**	**419**	**262**	**164**
	Kaplan – Meir estimate survival rates	100	95	94	94
	Standard error	0	0.8	0.9	1

Fig. Kaplan-Meier survival estimates for patient survival (**A**) and for freedom from aortic-related mortality (**B**) after elective fenestrated-branched endovascular aortic repair (FB-EVAR) of extensive thoracoabdominal aortic aneurysms using a single-stage vs multistage approach. *CI*, Confidence interval.

and permanent paraplegia in 5%.[31] The Cleveland group reported the largest single-center comparison of single- and multistage strategy in 87 patients treated for Extent II and III TAAAs by FB-EVAR. In that study, any SCI occurred in 38% of single-stage and 11% of multistage procedures.[32] Furthermore, unintentional (OR, 0.02; 95% CI, 0.001-0.46; $P = .014$) and intentional staging (OR, 0.01; 95% CI, 0.02-0.7; $P = .019$) were both effective in reducing risk of SCI.[33] Among patients who had unintentional staging, there was no added benefit for

intentional staging, with a risk of SCI of 1% and 2%, respectively.

The risk of SCI is directly related to the extent of coverage, which is low with Extent IV TAAAs and complex abdominal aneurysms. The pooled rates for SCI for all TAAAs is 4.0% (95% CI, 3.0%-5.0%), ranging from 15.0% (95% CI, 10.0%-22.0%) with extent II and 2.0% (95% CI, 2.0%-4.0%) with extent IV TAAAs.[3] The highest potential benefit for multistage approach is observed with more extensive aneurysms. Therefore, in this study, we focused on patients with Extent I to III TAAAs and excluded the lower risk groups. Although staging was also used in 33% of non-elective procedures, our analysis focused on elective cases who can wait the extended period required for staged exclusion of the aneurysm sac.

Reduction in the rates of SCI with staging occurred along with a positive effect on patient survival but no changes in 30-day and/or in-hospital mortality nor ARM. The impact of the severity of the SCI in the 30-day mortality was described before.[34] In a German study based on insurance claims data, the 30-day mortality was significantly higher in the SCI group than the overall patient cohort (23% vs 8%; $P < .001$) and varied by the SCI deficit level: paraplegia, 46%; paraparesis with <50% muscle function, 13%; and paraparesis with >50% muscle function, 0% ($P = .001$). The occurrence of SCI was also associated with higher 90-day mortality (15% vs 1%; $P < .05$) and with decreased long-term survival after FB-EVAR for TAAA (hazard ratio, 2.54; 95% CI, 1.37-4.73; $P < .003$).[35]

A limitation of multistage repair is the risk of interval aneurysm rupture. Even among patients undergoing elective repair, multistage approach is not suitable to all patients. Patients with excessively large or rapidly expanding aneurysms may be better suited for a single-stage procedure to avoid the risk of rupture.[32] Some patients may not be candidates for final completion or may be lost to follow-up. Kasprzak and colleagues reported that five of 40 patients (13%) undergoing TASP were not able to complete the repair due to death, complications, patient refusal, or technical difficulty.[15] In this study, we were not able to obtain an accurate account of patients who failed final completion of the repair.

The risk of interval aneurysm rupture was reported in a study of 235 patients treated with patient-specific devices.[36] There were 10 patients with interval aneurysm rupture (4.2%), of whom six had emergent repair with 0% mortality and four who died from aneurysm rupture. The risk of rupture was estimated on 6% ± 2% at 6 months. Therefore, eligibility for multistage approach, as well as the ideal staging strategy and timing for completion, need to be tailored based on the anticipated risk of aneurysm rupture.

This study has several limitations that need to be discussed. The most important limitation is that the comparison of the single- and multistage approach was not performed in intention-to-treat manner, and results of failed first-stage attempts were not uniformly reported by participating centers. Therefore, the findings need to be analyzed with caution, as the benefit of multistage may be lost with high mortality during the first-stage procedure. Second, although PS adjustment was applied to minimize selection bias and minimize potential measured confounders, it is likely that patient selection was affected by unmeasured confounders not considered in the analysis. Third, the classification of the TAAA extent (based on the anatomy or on the repair) may have not been consistent among the centers. Finally, the risk of bias due to the learning curve of each center could not be eliminated, that is, the possibility that the single stage was used more often during the early years of experience and hence had worse outcomes than in the later years.

CONCLUSIONS

A multistage approach was associated with lower risk of any cause mortality and/or permanent paraplegia and with improved patient survival at 1 and 3 years follow-up among patients treated by FB-EVAR for Extent I to III TAAAs. The composite of any cause mortality and/or permanent paraplegia was low in patients who underwent elective multistage repair (6%).

AUTHOR CONTRIBUTIONS

Conception and design: MD, ET, YH, TZ, BCM, TK, JS, LB, BM, MG, ND, AS, GW, AWB, MAF, KM, CT, DB, LMP, NT, SH, MS, EF, ME, KKY, MK, AV, GBL, AB, GO

Analysis and interpretation: MD, ET, YH, AB, GBL, AB, GO

Data collection: MD, ET, YH, TZ, BCM, TK, JS, LB, BM, MG, ND, AS, GW, AWB, MAF, KM, CT, DB, LMP, NT, SH, MS, EF, ME, KKY, MK, AB, GBL, AB, KJ, GP, FR, RC, GWS, CL, EG, GF, AK, EP, VG, AW, AD, JP, FP, RGM, SC, RG, TR, KOK, SK, BLT, SG, GO

Writing the article: MD, YH, GO

Critical revision of the article: MD, ET, YH, TZ, BCM, TK, JS, LB, BM, MG, ND, AS, GW, AWB, MAF, KM, CT, DB, LMP, NT, SH, MS, EF, ME, KKY, MK, AB, GBL, AB, KJ, GP, FR, RC, GWS, CL, EG, GF, AK, EP, VG, AW, AD, JP, FP, RGM, SC, RG, TR, KOK, SK, BLT, SG, GO

Final approval of the article: MD, ET, YH, TZ, BCM, TK, JS, LB, BM, MG, ND, AS, GW, AWB, MAF, KM, CT, DB, LMP, NT, SH, MS, EF, ME, KKY, MK, AB, GBL, AB, KJ, GP, FR, RC, GWS, CL, EG, GF, AK, EP, VG, AW, AD, JP, FP, RGM, SC, RG, TR, KOK, SK, BLT, SG, GO

Statistical analysis: MD, ET, YH, AV, GO

Obtained funding: Not applicable

Overall responsibility: GO

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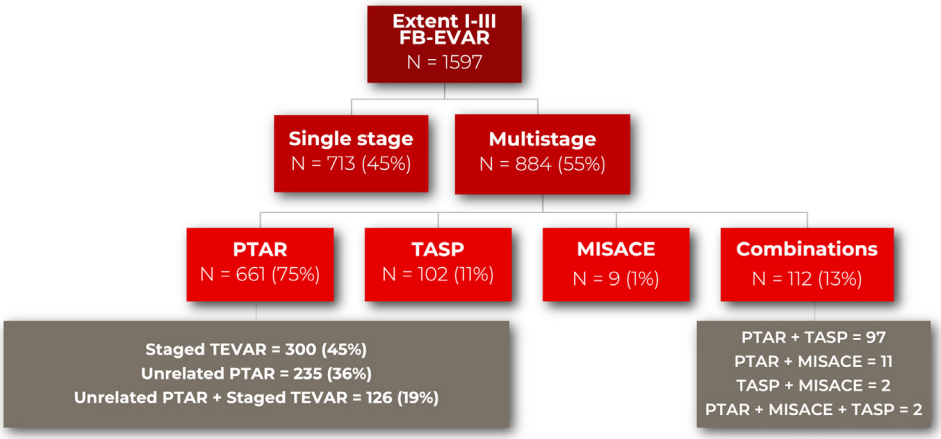
Additional material for this article may be found online at www.jvascsurg.org.

APPENDIX (online only).

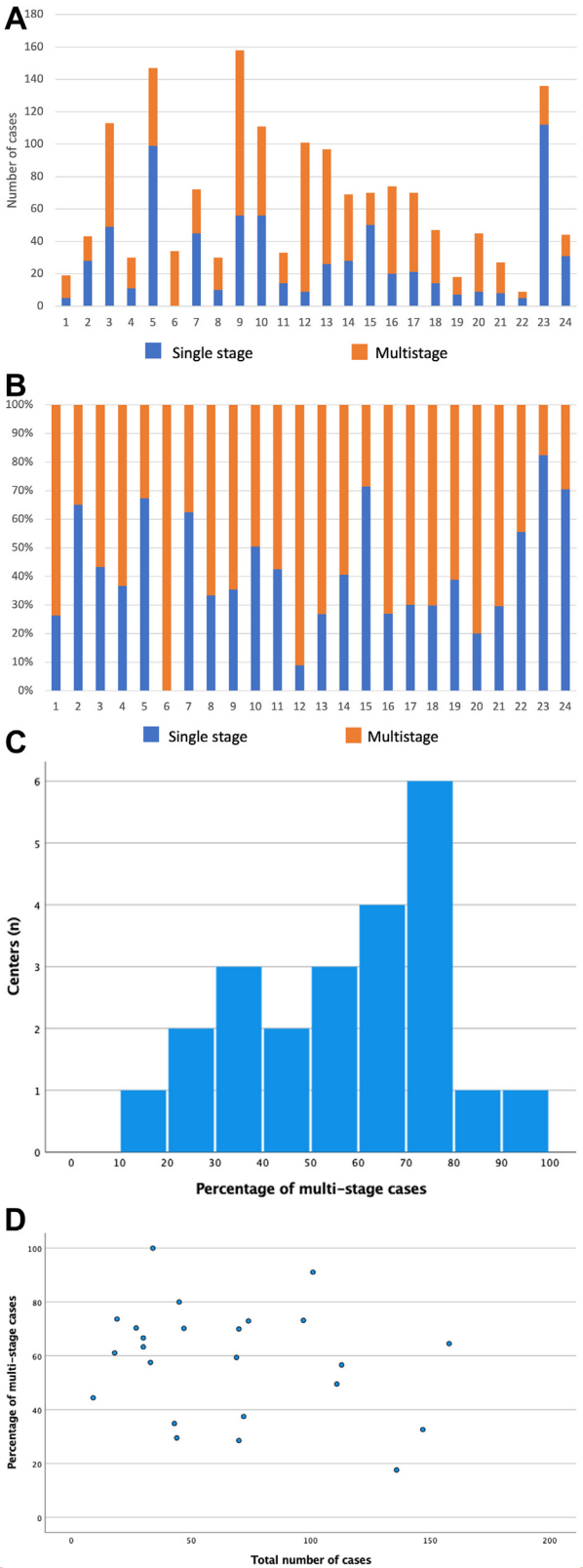
Supplementary Table (online only). Thirty-day mortality, major adverse events (MAEs), and onset of spinal cord injury (SCI) in patients treated by elective fenestrated-branched endovascular aortic repair (FB-EVAR) in single-staged or multi-staged fashion using proximal thoracic aortic repair (*PTAR*) or temporary aneurysm sac perfusion (*TASP*)

	Single-stage (N = 713)	PTAR (N = 661)	TASP (N = 102)	*P*-value	*P* value <.05 for multiple comparisons
Any MAE	189 (29.5)	122 (19.8)	19 (18.8)	**<.001**	[a]
Death	49 (6.9)	28 (4.2)	4 (3.9)	.074	–
Myocardial infarction	24 (3.4)	10 (1.5)	3 (3.0)	.085	–
Respiratory failure	31 (4.3)	26 (3.9)	4 (4.0)	.925	–
AKI by RIFLE criteria	94 (14.8)	62 (10.1)	13 (12.7)	**.039**	[a]
Bowel ischemia	13 (1.8)	4 (0.6)	2 (2.0)	.111	–
Major stroke	24 (3.4)	12 (1.8)	6 (5.9)	**.036**	[c]
Paraplegia	71 (10.0)	27 (4.1)	2 (2.0)	**<.001**	[a, b]
Any SCI	108 (15.1)	66 (10.0)	9 (8.8)	**.008**	[a]
Any permanent SCI	59 (8.8)	22 (3.6)	4 (3.9)	**<.001**	[a]
Permanent paraplegia	56 (8.3)	20 (3.3)	2 (2.0)	**<.001**	[a]
Death/permanent paraplegia	92 (13.7)	39 (6.4)	6 (5.9)	**<.001**	[a]

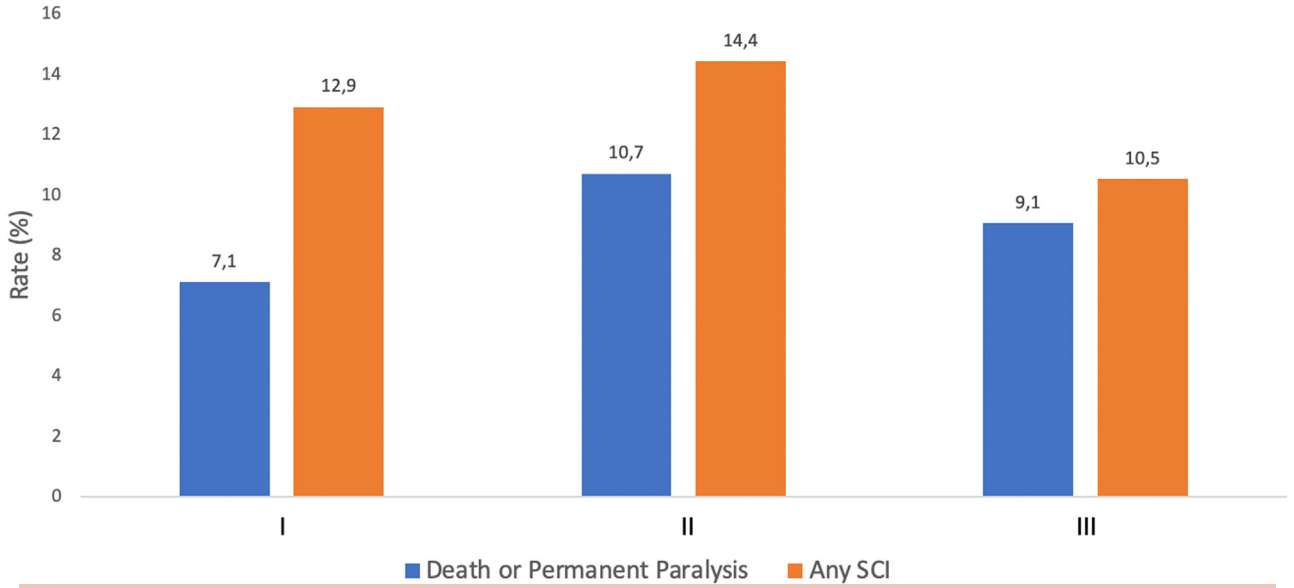
AKI, Acute renal injury; *MAE*, major adverse event; *SCI*, spinal cord injury.
Data are presented as number (%).
Boldface *P* values indicate statistical significance.
[a]Single-stage vs PTAR.
[b]Single-stage vs TASP.
[c]PTAR vs TASP.



Supplementary Fig 1 (online only). Patient distribution regarding the different staging strategies for elective fenestrated-branched endovascular aortic repair (*FB-EVAR*) of extensive thoracoabdominal aortic aneurysms. *MISACE*, Minimally invasive segmental artery coil embolization, *PTAR*, proximal thoracic aortic repair previous; *TASP*, temporary aneurysm sac perfusion; *TEVAR*, thoracic endovascular aortic repair.



Supplementary Fig 2 (online only). Distribution of single-stage versus multistage cases among the study sites: number of cases **(A)**, proportion of multistaging **(B),** and histogram with the percentage of multistage cases per each center **(C)**. There was no correlation between total number of cases and the percentage of multistaging (Pearson correlation coefficient −0.252; $P = .235$) **(D)**.



Supplementary Fig 3 (online only). Rates of death of permanent paralysis (*P* = .337) and of any spinal cord injury (*SCI*) (*P*=.083) according to the thoracoabdominal aortic aneurysm (TAAA) extent (Crawford classification).