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Results of a multidisciplinary spinal cord ischemia prevention protocol in elective repair of Crawford's extent I-III thoracoabdominal aneurysms by fenestrated and branched endografts

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Abstract

Aim: Fenestrated/branched endografting (F/B-EVAR) is an established technique to treat thoracoabdominal aortic aneurysms (TAAAs) in high-risk patients. Spinal cord ischemia/infarction (SCI) is a possible postoperative complication leading to deterioration in quality of life and decreased survival. Several strategies have been suggested in order to minimize its occurrence. The aim of this study was to report the outcomes of a dedicated multidisciplinary SCI prevention protocol for elective F/B-EVAR in Crawford's extent I-III TAAAs.

Methods: All consecutive Crawford's I-III TAAAs undergoing elective F/B-EVAR from 2010 to 2022 (March) in a single center were prospectively collected and retrospectively analyzed. A dedicated SCI prevention protocol was always adopted. The protocol included several surgical precautions, such as the collateral arterial network optimization, the adoption of a staged repair, and the early limbs reperfusion. Routine use of cerebral spinal fluid drainage (CSFD) was embraced. More anesthesiological measures were the maintenance of perioperative mean arterial pressure > 80 mm Hg, and blood hemoglobin levels > 10 mg/dL. Neurological measures were constituted by intraoperative monitoring with motor-evoked (MEPs) and somatosensory-evoked potentials (SSEPs) plus hourly bedside neurological evaluation during ICU stay. Preoperative comorbidity and postoperative complications were classified according to the Society of Vascular Surgery Reporting Standards. SCI, cardiac/pulmonary

morbidities, postoperative hemodialysis, and 30-day/in-hospital mortality were assessed as early outcomes. Survival was evaluated during follow-up.

Results: Out of 104 patients, there were 6 (6%), 51 (49%), and 47 (45%) Crawford's extent I, II, and III TAAAs, respectively. A staged TAAA repair, according to endograft design, anatomical and clinical characteristics, was performed in 83 (80%) cases. The mean hospital stay was 25 ± 22 days. Eight (8%) patients developed SCI, 2 (2%) transitory, and 6 (6%) permanent. Among those with permanent deficits, only 3 (3%) patients had permanent paraplegia with inability to walk. Out of 104 patients, 5 (5%) had cerebral hemorrhage, two among SCI patients. Postoperative cardiac and pulmonary morbidity was reported in 6 (6%) and 6 (6%) cases, respectively. Hemodialysis was necessary in 3 (3%) patients. Three patients died within 30 postoperative days and other 4 during a prolonged/complicated hospitalization, for an overall in-hospital mortality of 7%. The mean follow-up was 30 ± 18 months. The overall estimated 3-year survival was 62%, with a significant difference in survival at 2 years between patients with and without postoperative SCI (SCI: 18% *vs.* no-SCI: 69%; $P < 0.001$).

Conclusions: A dedicated multidisciplinary SCI prevention protocol in elective F/B-EVAR for Crawford's I-III TAAAs is feasible and safe, with encouraging rates of SCI (8% overall SCI, 6% permanent impairment, and 3% paraplegia). The 30-day mortality (3%), cardiopulmonary morbidities (6%), and dialysis rate (3%) were satisfactory, as well as the estimated survival at 3 years (62%). Patients with SCI had a significantly lower survival (18% *vs.* 69%) at 2 years.

Keywords: Thoracoabdominal aortic aneurysm, endovascular repair, spinal cord ischemia, paraplegia, prevention protocol, cerebrospinal fluid drainage, motor-evoked potentials, somatosensory-evoked potentials

INTRODUCTION

Fenestrated and branched endografting (F/B-EVAR) is an established technique to treat thoracoabdominal aortic aneurysms (TAAAs) in patients at high surgical risk with specific anatomical characteristics[1,2]. Satisfactory results in terms of technical and clinical success have been reported in the literature at mid-term follow-up, even in very challenging scenarios, such as urgent situations or in cases with previous aortic repair[3].

Despite the progress in overall postoperative results, spinal cord ischemia/infarction (SCI) remains a possible catastrophic complication after F/B-EVAR for TAAAs, leading to a significant reduction in quality of life and survival[4]. In a recent systematic review and meta-analysis, the pooled incidence of SCI after F/B-EVAR was found to be 13%[5]. Previous studies reported an incidence of SCI up to 35%[6], with a higher risk related to factors such as urgent/emergent repair, previous aortic surgery, Crawford's extent I-III TAAAs, and loss of subclavian/hypogastric arteries[7-9].

In the last decades, a number of preoperative, intraoperative and postoperative strategies including surgical, anesthesiological and medical adjuncts have been proposed in order to reduce the incidence of SCI after F/B-EVAR in TAAAs[10-14]. CSFD[15] and intraoperative neuromonitoring with SSEPs/MEPs[1,16-17] have also been extensively investigated, but their efficacy is still debated in the literature.

The aim of the present study was to report the results of a dedicated multidisciplinary SCI prevention protocol, consisting of surgical, anesthesiological and neurological measures, for elective endovascular repair of Crawford's extent I-III TAAAs by F/B-EVAR.

METHODS

Study design and patient selection

Between January 2010 and March 2022, data on all consecutive patients receiving an endovascular repair of a complex aortic pathology in a single tertiary center, were prospectively collected into a dedicated electronic database. Once the anatomical feasibility for the endovascular treatment was established, the F/B-EVAR was offered to subjects at high risk for open surgical repair, according to the SVS reporting standards[18]. The choice of the device configuration was made based on the patient's vascular anatomy, using either an off-the-shelf device or a custom-made device of the Cook Zenith platform (Cook Medical, Cook Inc, Bloomington, IN, USA). All patients signed a dedicated consent for both the complex endovascular procedure and the analysis of their anonymous data. For the present study, only patients with a TAAA extent I to III (according to Crawford's classification[19]), aged > 18 years, treated in an elective setting with a custom-made or off-the-shelf thoracoabdominal stent-graft were included. The relative data were extrapolated in a second electronic database and retrospectively analyzed. Exclusion criteria were emergent/urgent setting, TAAA extent IV, pararenal and juxtarenal aortic aneurysm as underlying treated pathology. The study was performed with the approval of the ethical review board of IRCCS - Azienda Ospedaliero-Universitaria di Bologna, (T.Ev.AAA-155/2015/U/Oss).

SCI prevention protocol

For each patient, a SCI prevention protocol including intra/perioperative surgical, anesthesiological, and neurological adjuncts was applied, as shown in Table 1.

Surgical measures

(1) Staging technique

In our series, a multi-staged TAAA repair was realized whenever possible. Depending on aortoiliac anatomy and specific characteristics of the endografts of choice, a different staging technique was chosen. With branched endograft, temporary aneurysm sac perfusion (TASP)[20] was preferably adopted. TASP was preferentially achieved leaving one of the directional branches patent into the aneurysm sac, generally the one destined to the celiac trunk. In the case of stenotic target visceral vessel, the "bare branch" technique was performed to guarantee the sac perfusion. This technique, which involves the connection of the target visceral vessel (TVV) to the branch through a bare metal stent, prevents the thrombosis of the TVV during the interstep period[21].

When a custom-made fenestrated-only device was used, the staging technique usually included a first isolated thoracic step, possibly with supra-aortic surgical debranching, and subsequent deployment of the fenestrated graft. In the case of bifurcated grafts, one of the two iliac limbs could serve as an unsealed branch for aneurysm sack perfusion. In all cases, the aneurysm exclusion was completed within two or three weeks.

(2) Collateral arterial network

Preservation of collateral spine network has always been pursued. Excluding urgent cases, revascularization of subclavian and hypogastric arteries was performed, both in a surgical or endovascular fashion, prior to extensive aortic coverage.

Table 1. Dedicated multidisciplinary SCI prevention protocol

Multidisciplinary SCI prevention protocol	
Surgical measures	Staged TAAAs repair
	Patency of subclavian and hypogastric arteries (revascularization, if needed)
	Early pelvic and limbs reperfusion
Anesthesiological measures (within 72 postoperative h)	Routine use of cerebrospinal fluid drainage
	Maintenance of a mean arterial pressure > 80 mmHg
	Maintenance of a hemoglobin concentration > 10 g/dL
Neurological measures	Preoperative clinical evaluation
	Intraoperative motor and somatosensory evoked potential monitoring*
	Postoperative clinical evaluation

*Since 2019.

(3) Early limbs reperfusion

Despite the introduction of low-profile devices, sheaths needed to perform complex aortic procedures still have large calibers (18-20 Fr), which may be occlusive, especially in the narrowest anatomies. Femoral sheaths were always withdrawn as soon as possible during the procedure, for pelvic and lower limb restoration of blood flow.

Anesthesiological measures

CSFD is obtained by the insertion of a catheter in the lumbar subarachnoid space. The deliquoration aims to reduce the compression on spinal cord, which may present post-ischemic edema, and facilitate its perfusion thanks to the lowering of the positive pressure inside the canal. A key point of this protocol consisted of the routine use of CSFD (Liquogard, Moller Medical GmbH, Fulda, Germany) in all Crawford's extent I-III TAAAs patients. The only cases excluded from the use of CSFD were urgent settings (not included in the presented study), patients under non-suspendable ADP-inhibitors or dual antiplatelet therapy (DAPT) or with excessive prolonged activated partial thromboplastin time (aPTT > 1.5 s), or even the presence of prohibitive spine diseases. Acetylsalicylic acid was introduced for every patient submitted to F/B-EVAR if no contraindications were present, while oral anticoagulants and new oral anticoagulants were shifted to low-molecular-weight heparin (LMWH) dosed on patient's weight. LMWH was suspended 24 h prior to the surgery to permit CSFD insertion, which was always performed in operating room the day of the procedure, just before starting surgery. It was inserted by an anesthesiologist and without fluoroscopic guidance. Cerebrospinal fluid pressure was maintained through CSFD deliquoration of no more than 20 mL/h, < 10 mm Hg during operation and for at least 72 postoperative hours. CSFD was kept on site for a longer time in case of SCI symptoms onset, increased cerebrospinal fluid pressure, or aPTT > 1.5 s. For staged F/B-EVAR, CSFD was maintained or repositioned for every step, whenever possible. Additionally, a CSFD was also positioned emergently in case of SCI symptoms onset at any time. In case of SCI onset in patients already under DAPT/ADP-inhibitors or anticoagulants, the insertion of a CSFD is discussed depending on the grade of SCI and the response to the optimization of all the other hemodynamic factors, mainly hemoglobin level and mean systolic pressure. If an urgent CSFD positioning is needed, the optimization of the patient's coagulation condition is attempted.

Finally, the CSFD was always removed only after a "clamping test" of 24 h negative for SCI symptoms onset. It was removed with an aPTT < 1.5. At discharge, or at least 72 h after the CSFD removal, dual antiplatelet therapy was introduced and continued for at least 3 months. For patients under oral anticoagulants or new oral anticoagulant therapy, only acetylsalicylic acid was added (or Clopidogrel, in case of acetylsalicylic acid contraindications).

To ensure good spinal cord perfusion, two more anesthesiological measures were adopted in all cases: the maintenance of perioperative high mean arterial pressure > 80 mm Hg, and blood hemoglobin levels > 10 mg/dL.

Every patient was continuously monitored in the Intensive Care Unit (ICU) for at least 24 h in the postoperative period.

Neurological measures

Each patient received a neurological evaluation on admission, after every step, and before discharge. Neurologic evaluation was performed every hour at the bedside by specialized nurses in the ICU, and every 4 h by medium care nurses until the removal of the CSFD. Thereafter, a physician of the vascular team evaluated the patient at least every 12 h.

If there were signs of neurological deficits, they received promptly further evaluated by a neurologist. Following this evaluation, and typically upon the prescription of the neurologist him/herself, a magnetic resonance imaging (MRI) was usually conducted.

Intraoperative neuromonitoring via SSEPs/MEPs represents a way to detect SCI prior to irreversible damages occurring and to promptly initiate corrective measures[11,17]. SSEPs/MEPs were introduced in 2019 in our department. Its use is limited by the availability of the service, provided by a specialized team of neurologic technicians. In case of SSEPs/MEPs decrease during the procedure, immediate rescue maneuvers include the optimization of blood pressure and hemoglobin levels, downsizing of femoral sheaths as soon as possible to restore pelvic circulation, drainage of cerebrospinal fluid through CSFD, and, most importantly, staging of the procedure if not already planned for the specific case.

Endpoints and definitions

The primary endpoint was the incidence of SCI after F/B-EVAR. SCI was defined as the onset of transient paraparesis or paraplegia after TAAA repair, not explained by other causes. SCI was considered permanent in the presence of any residual neurologic deficit (motor or sensitive). Neurological deficits were classified according to Tarlov's Modified Scale.

The secondary endpoints were the rate of cardiac and pulmonary morbidities, the need for hemodialysis, and the combined 30-day/in-hospital mortality after F/B-EVAR. Survival was also evaluated during follow-up.

Preoperative comorbidity and postoperative complications were classified according to the Society of "Vascular Surgery Reporting Standards[18].

Several clinical characteristics were collected for every patient, including sex, history or current tobacco use, hypertension (systolic blood pressure > 140 mm Hg and/or diastolic pressure > 90 mm Hg or antihypertensive drugs use), dyslipidemia (total cholesterol > 200 mg/dL or low-density lipoprotein > 120 mg/dL or lipid-lowering drugs use), coronary artery disease (history of angina pectoris, myocardial infarction, or coronary revascularization), diabetes mellitus (medical treatment with insulin or oral hypoglycemic drugs), chronic kidney disease (CKD) (estimated glomerular filtration rate < 60 mL/min), chronic obstructive pulmonary disease (chronic bronchitis or emphysema), peripheral artery obstructive disease (lower limb claudication or rest pain or ischemic ulcer with confirmation of arterial disease at duplex ultrasonography or previous peripheral artery revascularization). Single or double antiplatelet therapy and oral anticoagulant therapy were also registered.

Each patient received a preoperative evaluation by an anesthesiologist of a dedicated team, with the assignment of a score according to the American Society of Anesthesiologists (ASA) scoring system[22].

Statistical analysis

Continuous variables are reported as mean ± standard deviation (SD) or median (interquartile range), when the sample number was insufficient to allow a gaussian distribution. Categorical variables are expressed as frequency. Survival was estimated by the Kaplan-Meier method. Statistical analysis was performed using SPSS 25.0 for Windows software (SPSS, Inc., Chicago, IL).

RESULTS

A total of 104 patients underwent elective endovascular repair in the period of study, with 6 (6%) presenting with Crawford's extent I, 51 (49%) with extent II, and 47 (45%) with extent III. Table 2 provides a summary of demographic and clinical characteristics of the population (71% male, mean age 73 ± 6 years). Aneurysm characteristics and procedural details are reported in Table 3. Forty-eight (46%) patients have had a previous aortic procedure, mostly a surgical aortic repair (39 out of 48 patients). All the procedures were performed under general anesthesia. A single-stage repair was performed in 20% of cases, with 80% undergoing a staged repair, according to endograft design, anatomical and clinical characteristics. A fenestrated device was used in 18% and a branched device in 68% of cases, with a custom-made device with fenestrations and branches chosen in the remaining 14% of cases. To ensure an adequate proximal and distal sealing zone, a thoracic endograft was deployed in 95 cases, 22 during a previously planned step and 73 simultaneously with the thoracoabdominal module release. Thirteen supra-aortic trunks debranching were also needed, and an iliac branch device was used in 18 patients. Prophylactic spinal drainage was performed overall in 90% of cases; and in 81% of staged repairs, it was also used in the second stage. The mean ICU stay was 5 ± 5 days and the mean hospital stay was 25 ± 22 days.

Postoperative events are reported in Table 4. Eight patients developed SCI: 2 transitory, with complete regression of symptoms, and 6 with different severity degrees of permanent deficits. Among the latest, 3 cases had permanent paraplegia. Details of the 8 patients with SCI are specified in Table 5. Five cases of cerebral hemorrhage were detected, 2 among SCI patients (one having a post-traumatic cerebral hemorrhage that occurred after the aortic repair). Postoperative cardiac and pulmonary morbidity were reported in 6 cases, respectively. A renal function worsening of any degree occurred in 21 (20%) of the patients, 3 requiring hemodialysis (2 permanently).

Three patients died within 30 postoperative days, while other 4 during a prolonged/complicated hospitalization (overall in-hospital mortality 7%). The mean follow-up was 30 ± 18 months. Overall estimated 3-year survival was 62%, with a significant difference in survival at 2 years of follow-up between patients with and without postoperative SCI (SCI: 18% *vs.* no-SCI: 69%; $P < 0.001$), as shown in Figure 1.

DISCUSSION

The dedicated multidisciplinary SCI prevention protocol in elective F/B-EVAR for Crawford's I-III TAAAs analyzed in this paper led to encouraging rates of SCI (8% overall SCI, 6% permanent impairment with 3% paraplegia).

Table 2. Demographic and CLINICAL CHARACTEristics of 104 patients receiving F/B-EVAR for Crawford's I-III TAAAs

Variable	Overall *N* = 104	SCI *N* = 8 (7.7%)	Non-SCI *N* = 96 (92.3%)	*P* value
Male gender	74 (71.2)	6 (75.0)	68 (70.8)	1.000
Age	72.6 ± 6.3	73 (78-68)	72.5 ± 6.2	1.000
Hypertension	102 (98.1)	8 (100)	94 (97.9)	1.000
Tobacco use	72 (69.2)	4 (50.0)	68 (70.8)	0.433
Dyslipidemia	70 (67.3)	4 (50.0)	66 (68.8)	0.277
Diabetes	10 (9.6)	0 (0.0)	10 (10.4)	1.000
BMI > 31	13 (12.6)	0 (0.0)	13 (13.7)	0.591
Chronic renal impairment	52 (50.0)	3 (37.5)	49 (51.0)	0.715
Hemodialysis	5 (4.8)	1 (12.5)	4 (4.2)	0.335
Coronary artery disease	38 (36.5)	4 (50.0)	34 (35.4)	0.459
Chronic obstructive pulmonary disease	46 (44.2)	2 (25.0)	44 (45.8)	0.297
Peripheral artery occlusive disease	18 (17.3)	1 (12.5)	17 (17.7)	1.000
Cerebrovascular disease	7 (6.7)	0 (0.0)	7 (7.3)	1.000
History of stroke/TIA	11 (10.6)	0 (0.0)	11 (11.5)	0.595
Atrial fibrillation	11 (10.6)	2 (25.0)	9 (9.4)	0.200
Anticoagulant medication	11 (10.6)	1 (12.5)	10 (10.4)	1.000

BMI: Body mass index. Continuous data are presented as the means ± SD or median (IQR); categorical data are given as the counts (percentage).

The beneficial effect of a bundled protocol for SCI prevention was already shown by Scali *et al.*, who compared the results of F/B-EVAR before and after the introduction of a dedicated protocol for SCI prevention, including cerebrospinal fluid drainage, blood pressure control, transfusion strategy, and pharmacological adjuncts (steroids, naloxone)[23]. They found a significant reduction in SCI rate from 13% to 3% (P = 0.007), with even more significant results in Crawford's extent I-III TAAA (19% *vs.* 4%, P = 0.004). Moreover, a subsequent beneficial effect on 1-year survival was obtained, with an increase from 90% to 99% after the introduction of the protocol (P = 0.05), although a possible influence by a combination of factors such as the natural learning curve of the surgeons may have occurred.

As a matter of fact, a study on Vascular Quality Initiative data published in 2021 by Aucoin *et al.* also showed a decrease in SCI rates over the study period (2014-2019), despite an unchanged use of prophylactic CSFD[4]. This finding suggests that other measures included in the protocols over the years may contribute to better outcomes.

In our series, the combined 30-day/in-hospital mortality was significantly higher in patients with SCI (*P*:0.032). Moreover, patients with SCI had a lower survival rate than patients without SCI at follow-up (18% and 69% at 2 years, respectively).

Similar results were reported by Heidemann *et al.* In their multicenter retrospective cohort study including 877 patients treated with F/B-BEVAR for a juxta-/para-renal aneurysm or a TAAA, SCI occurred in 10.7% of cases[24]. Among all the SCI cases reported, 37% occurred after 30 days from the endovascular treatment. In their study, SCI was not associated with a higher in-hospital/30-day mortality, but with later mortality (14.7% of 90-day mortality in patients presenting SCI compared to 1.1% of those without SCI, P > 0.05). The authors suggest that these results may be due to the effectiveness of the intensive care units, with a worse outcome occurring in the patients transferred to other clinical settings.

Table 3. Aneurysm characteristics and procedural details of 104 patients receiving F/B-EVAR for Crawford's I-III TAAAs

Variable	Overall *N* = 104	SCI *N* = 8 (7.7%)	Non-SCI *N* = 96 (92.3%)	*P* value
Previous aortic procedures	48 (46.2)	0 (0.0)	48 (50.0)	**0.007**
Previous aortic surgery	39 (37.5)	0 (0.0)	39 (40.6)	**0.024**
Previous EVAR	14 (13.5)	0 (0.0)	14 (14.6)	0.594
Aneurysm maximum diameter (mm)	71.5 ± 15.4	71.5 (83.8-68.5)	70.6 ± 15.4	**0.045**
Crawford's extent I	6 (5.8)	0 (0.0)	6 (6.3)	0.520
Crawford's extent II	51 (49.0)	3 (37.5)	48 (50.0)	
Crawford's extent III	47 (45.2)	5 (62.5)	42 (43.8)	
Need of supra-aortic trunk debranching	13 (12.5)	2 (25.0)	11 (11.5)	0.262
Previous planned TEVAR	22 (21.2)	0 (0.0)	22 (22.9)	0.346
Concomitant TEVAR and f/bEVAR	73 (70.2)	7 (87.5))	66 (68.8)	0.438
Occlusion of one hypogastric artery	7 (6.8)	1 (12.5)	6 (6.3)	0.442
Occlusion of both hypogastric arteries	5 (4.9)	0 (0.0)	5 (5.3)	1.000
Iliac branch devices	18 (17.3)	1 (12.5)	17 (17.7)	1.000
Single stage repair	21 (20.2)	4 (50.0)	17 (17.7)	**0.051**
Staged repair	83 (79.8)	4 (50.0)	79 (82.3)	
CSFD I/unique step	94 (90.4)	8 (100)	86 (89.6)	1.000
CSFD last step	39 (81.3)	3 (75.0)	35 (79.5)	1.000
Intraoperative SEPs/MEPs	6 (5.8)	2 (25.0)	4 (4.2)	0.067
F-EVAR	19 (18.3)	0 (0.0)	19 (19.8)	0.346
B-EVAR	71 (68.3)	5 (62.5)	66 (68.8)	1.000
CM F/B-EVAR	14 (13.5)	3 (37.5)	11 (11.5)	0.073
Inverted Limb	5 (4.8)	0 (0.0)	5 (5.2)	1.000
Visceral targets/patient	3.8 ± 0.6	4.0 (4.0-4,0)	4.0 (4.0-4.0)	0.562
Blood units transfusion	2.8 ± 2.4	3.0 (4.0-1.0)	3.0 ± 2.3	0.743
Total surgical time (min)	554 ± 197	445 (338-386)	560 ± 198	0.192

EVAR: Endovascular aneurysm repair; TEVAR: thoracic endovascular aneurysm repair. Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage). Bold form was used for $P < 0.05$.

Table 4. Postoperative outcome

Variable	Overall *N* = 104	SCI *N* = 8 (7.7%)	Non-SCI *N* = 96 (92.3%)	*P* value
ICU stay (days)	5.2 ± 5.0	6.0 (15.0-4.8)	4.4 ± 3.5	**0.003**
Hospitalization (days)	25.0 ± 21.5	35.0 (48.0-17.0)	23.2 ± 21.0	**0.010**
Cardiac complications	6 (5.8)	1 (12.5)	5 (5.2)	0.389
Pulmonary complications	6 (5.8)	0 (0.0)	6 (6.3)	1.000
Renal function worsening	21 (20.2)	2 (25.0)	19 (19.8)	0.661
Postoperative dyalisis	3 (2.9)	1 (12.5)	2 (2.1)	0.215
Cerebral hemorrhagic event	5 (4.8)	2 (25.0)	3 (3.1)	**0.046**
Mesenteric events	2 (1.9)	2 (25.0)	0 (0.0)	**0.005**
Stroke/TIA	0 (0.0)	0 (0.0)	0 (0.0)	-
In-hospital/30-day mortality	7 (6.7%)	2 (25.0%)	5 (5.8%)	**0.032**

TIA: Transient ischemic attack. Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage). Bold form was used for $P < 0.05$.

Table 5. Main characteristics of the patients who presented SCI

Case	Crawford 's extent	CSFD	*MEPs SSEPs*	Staging	SCI-timing	SCI-grade @Onset	SCI-grade @Discharge*	Cerebral hemorrhage	30-day/in-H mortality
1	III	Yes	No	No	1st POD	0	0	No	No
2	III	Yes	No	Yes	@Awakening, After I Step	3	4	No	No
3	II	Yes	No	Yes	@Awakening, After I Step	3	-	No	Yes
4	III	Yes	No	No	@Awakening	2	2	No	No
5	II	Yes	No	Yes	@Awakening, After II Step	4	4	Yes	No
6	II	Yes	Yes	Yes	@Awakening, After I Step	0	-	Yes	Yes
7	III	Yes	Yes	No	> 24 h	4	5	No	No
8	III	Yes	No	No	> 24 h	4	5	No	No

POD: Post-operative day. *According with the Tarlov's Modified Scale.

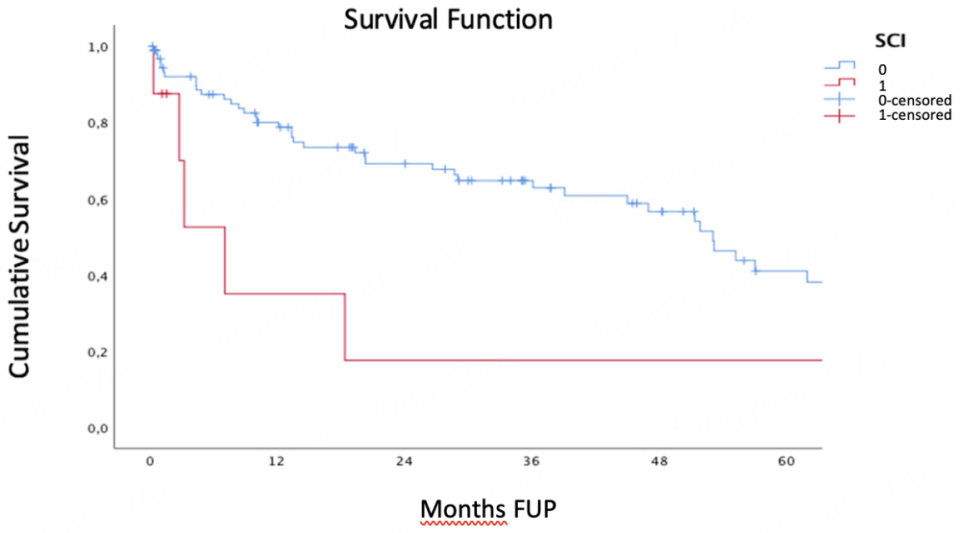

Figure 1. Kaplan-Meier estimate of survival in patients treated for Crawford's extent I-III patients, with or without SCI.

Our results failed to demonstrate a clear correlation between prophylactic CSFD and SCI (*P*:1.0).

The effectiveness of prophylactic CSFD has been recently questioned even in TAAA at high SCI risk[4], due to the incidence of CSFD complications, usually divided into major and minor. Major complications include intracranial hemorrhage, spinal hematoma, meningitis, and CSFD fracture requiring neurosurgical intervention. The main minor complications are reflex hypotension during catheter insertion, spinal headache, minimal presence of blood in the CSFD catheter, and non-functional CSFD.

In the 2023 multicenter retrospective study, Marcondes *et al.* reported the results of 541 patients with TAAA extent I-III endovascularly treated without the use of prophylactic CSFD[25]. The authors reported an overall incidence of SCI of 8%, with 2% of permanent paraplegia. A rescue CSFD was used only in 4% of all patients, with only 0.3% of major drain-related complications.

In 2018, Dijkstra *et al.* published a review of preventive strategies for SCI after thoracic and thoracoabdominal aortic repair[12]. They included 43 studies for a total of 7,168 patients, all retrospective cohort studies, mainly non-comparative, based on very heterogeneous populations of thoracic or thoracoabdominal aneurysms, dissections, penetrating aortic ulcers, and traumatic injuries. Overall, a specific SCI prevention protocol was used in about 77% of the studies included in the review. Generally, SCI is more often transient than permanent (5.7% *vs.* 2.2%, respectively), with the transient SCI rate ranging from 0.3% to 31% and the permanent SCI rate from 0.3% to 21%, without a time trend[12]. Permanent SCI was 3.6% in the thoracoabdominal aneurysm subgroup at pooled analyses. The more counterintuitive result reported by this study was the high rate (8%) of SCI affecting TAAA repairs with CSFD. The Authors suggest that this may be related to a subgroup of patients at very high risk for SCI. Also counterintuitive was the finding of an association between a permissive endoleak and a rather high (5%) transient SCI rate. The final suggestion was to selectively use CSFD only in high-risk patients and to promote international multicenter prospective and high-quality studies to define a universally accepted preventive protocol for SCI.

To assess risks and benefits related to the use of selective CSFD in F/B-EVAR for Crawford's extent I-IV TAAA, Kitpanit *et al.* analyzed 106 consecutive patients treated from 2014 to 2019 in a prospective physician-sponsored investigational device exemption study[8]. Despite an overall low rate of SCI (3.8%), the authors found a high incidence of CSFD-related major complications, including spinal hematoma, subarachnoid and cerebellar hemorrhage, and a spinal drain fracture. There was a significant increase in intensive unit care and hospital length of stay for patients with CSFD. The authors concluded by discouraging a routine use of prophylactic CSFD and instead emphasized the need for prospective randomized trials on the use of CSFD in the endovascular treatment of TAAA.

Recently, the US Aortic Research Consortium (US-ARC)[26] published the results of a 65-question survey on the methods and protocols to prevent SCI in high-risk patients. These high-risk patients were identified in the presence of Crawford's extent I-III, a shaggy aorta, a previous EVAR or open infra-renal aortic repair, or an abnormal pelvic or vertebral perfusion. The 8 principal investigators differed in the answers principally on the timing of the resumption of antihypertensive medications, on the duration of the hemoglobin goals, and on the management of CSFD. Particularly, the investigators using prophylactic CSFD in high-risk patients for SCI were 6 of 8 (75%), with one of the 6 changing the practice during the study to only CSFD placement as a rescue maneuver for SCI onset. The US-ARC concluded with a consensus on the beneficial role of the CSFD for the prevention of SCI, although underlying the need for clinical trials to obtain rigorous scientific data on its preoperative prophylactic use.

On this point, Aucoin *et al.* reported worse neurologic outcomes and lower survival with the therapeutic CSFD for SCI symptoms onset compared with prophylactic CSFD[26]. These findings again highlight the necessity of randomized controlled trials to compare prophylactic and therapeutic CSFD. Conversely, in the systematic review of Pini *et al.*, the pooled SCI rate was 13% for symptomatic CSFD and 14% for prophylactic CSFD (*P*:0.87)[5].

Among major complications, intracranial hemorrhage affected 5 patients in our series (2 also presenting SCI). Previous research conducted by our group[27] already indicated that ICH after F/B-EVAR does occur mainly in patients with CSFD, and that a platelet count reduction greater than 60%, chronic kidney disease, and a liquor drainage higher than 50 mL are strongly associated with ICH, independently from the urgent or selective setting. Statistical analysis failed to show a difference between manual or auto-draining, which have always been selected according to anesthesiologists' preference and availability of the devices.

Although 50 mL seemed to be an unrealistic threshold already in 2021 when these findings were published, our group focused on strict and careful CSFD management.

Permissive endoleak was first described by Reilly and Chuter in 2010[28], when they successfully reversed the symptoms of SCI in a patient who received an endovascular repair of a type II Crawford's extent TAAA. The authors obtained a Ib endoleak by placing a balloon-expandable stent between the distal portion of the infrarenal endograft and the aortic wall. Three months later, a Palmaz stent was used to solve the endoleak and complete the procedure. Thereafter, this idea was developed[29] to leave an interstep intentional endoleak, and to avoid abrupt cessation of spinal cord perfusion through intercostal and lumbar arteries, while enhancing collateral circuit formation. The main techniques to stage a TAAA endovascular repair are three: a first isolated thoracic endograft placement[30], a minimally invasive segmental artery coil embolization[31,32], and a TASP[20]. Depending on aneurysm anatomical characteristics, in our series, a multi-staged TAAA repair was realized whenever possible. Not-staged cases were usually patients with a higher anesthesiological risk or with larger aneurysmal diameters. Among the preventive measures introduced by the present multidisciplinary protocol, treatment staging reached a statistical significance, in accordance with previous reports in the literature[33,34]. Given the positive effect of staging in preventing SCI, the absence of TAAA rupture between the two steps in the presented series, and also considering that the second stage can often be performed under local anesthesia, further prospective studies about this preventive strategy should be performed, in order to validate these conclusions.

In their 2021 systematic review and meta-analysis on the occurrence of SCI after TAAA endovascular repair, Pini *et al.* reported a lower pooled SCI rate after staged compared with non-staged repair (9% *vs.* 18%, respectively; $P = 0.02$), independently from the method and timing of staging[5]. More recently, Dias-Neto *et al.* published an analysis of the data from 24 centers of the ARC, with 1947 extent I-III TAAA electively treated with a staged approach from 2006 to 2021[35]. The staging strategies (proximal thoracic endografting, TASP, MISACE, and combinations of these) allow lower rates of mortality and/or permanent paraplegia at 30 days or within hospital stay, and higher 1- and 3-year survival.

Recent studies focused on the results of different anesthesiological choices in the endovascular repair of TAAA give us several insights into the different available possibilities[35-36]. A detailed discussion of every aspect of a SCI prevention protocol together with the anesthesiology team for each patient is fundamental for clinical success[36].

In 2022, Monaco *et al.* compared first the short-term results of F/B-EVAR performed under general anesthesia with sedation with those performed under monitored anesthesia care (MAC) in addition to local anesthesia, finding that the type of anesthesia seemed to have no effect on procedure success, perioperative morbidity, or mortality in patients undergoing F/BEVAR, despite a higher need of inotropes/vasopressors to treat intraoperative hypotension with general anesthesia[37]. In 2023, Monaco *et al.* compared the results of F/B-EVAR under MAC with remifentanil-based sedation with those using dexmedetomidine instead, finding a worse patient satisfaction with the latter. Moreover, remifentanil was associated with less hemodynamic effect than dexmedetomidine[38].

Considering the high complexity of F/BEVARprocedures and their potential long surgical time, general anesthesia was used in all cases reported in the present study.

Concerning intraoperative SSEPs/MEPs monitoring, no large randomized controlled trials are currently available, at the best of our knowledge. In a retrospective review of 1,214 thoracic and TAAA[16] treated

either in open fashion or endovascularly between 2000 and 2013 in 12 Japanese centers, 631 patients received intraoperative MEPs monitoring and the outcome was compared with the outcome of 583 patients treated without neuromonitoring. MEPs failed to improve the outcome. The low number of cases performed under SSEPs/MEPs until 2022 in our department precludes a meaningful consideration of its role in the secondary prevention of SCI.

This study has limitations primarily concerning its retrospective nature, which includes potential biases related to data collection and incomplete medical records, and the small size of SCI group that may not fully represent the broader SCI population, potentially limiting general conclusions. Further research with larger and more diverse SCI groups is necessary to validate and extend these findings.

In conclusion, dedicated multidisciplinary SCI prevention protocol in elective F/B-EVAR for Crawford's I-III TAAAs is feasible and safe, with encouraging rates of SCI (8% overall SCI, 6% permanent impairment with 3% paraplegia). The 30-day mortality (3%), cardiopulmonary morbidities (6%), and dialysis rate (3%) were satisfactory, as well as the estimated survival at 3 years (62%). Patients with SCI had a significantly lower survival (18% *vs.* 69%) at 2 years.

Further high-quality scientific data are needed to define the role of prophylactic or therapeutic CSFD. Although defining the efficacy of individual SCI prevention measures is not easy, treatment staging has been widely associated with lower rate of SCI.

DECLARATIONS

Authors' contributions

Conception and design: Sufali G, Faggioli G
Analysis and interpretation: Sufali G, Gallitto E, Pini R, Vacirca A
Data collection: Sufali G, Mascoli C
Writing the article: Sufali G
Critical revision of the article: Faggioli G, Vacirca A, Gargiulo M
Final approval of the article: Sufali G, Faggioli G, Gallitto E, Pini R, Vacirca A, Mascoli C, Gargiulo M
Statistical analysis: Sufali G, Pini R
Overall responsibility: Gargiulo M

Availability of data and materials

Not applicable.

Financial support and sponsorship

None.

Conflicts of interest

Gargiulo M, Faggioli G and Gallitto E are consultants for Cook Medical. The remaining authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

All patients signed a dedicated consent for both the complex endovascular procedure and the analysis of their anonymous data. For the present study, data of all patients were extrapolated in a second electronic database and retrospectively analyzed. The study was performed with the approval of the ethical review board of IRCCS - Azienda Ospedaliero-Universitaria di Bologna (T.Ev.AAA-155/2015/U/Oss).

Consent for publication

Not applicable.

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