Safety of cerebrospinal fluid drainage for spinal cord ischemia prevention in thoracic endovascular aortic repair

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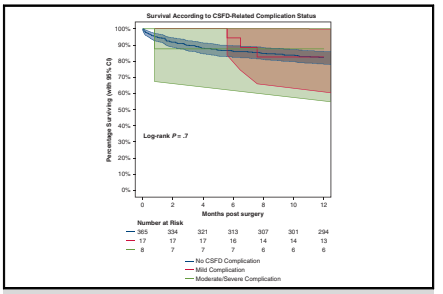
ABSTRACT

Objective: Spinal cord ischemia (SCI) after thoracic endovascular aortic repair (TEVAR) is associated with permanent neurologic deficit and decreased survival. Prophylactic cerebrospinal fluid (CSF) drainage (CSFD) in TEVAR is controversial. We evaluated the usage of CSFD in TEVAR at our tertiary aortic center.

Methods: Our institutional TEVAR database was reviewed to determine the frequency of CSFD usage/complications. Complications were categorized as mild (headache/CSF leak not requiring intervention, urinary retention), moderate (headache/CSF leak requiring intervention, drain malfunction requiring replacement), or severe (intrathecal hemorrhage, CSFD-attributable neurologic deficit). The relationships between CSFD complications and patient/procedural characteristics, CSFD placement timing, and survival were analyzed.

Results: Nine hundred thirty-six TEVAR procedures were performed in 869 patients from 2011 to 2020. Three hundred ninety CSFD drains were placed in 373 (41.7%) TEVAR patients. Most CSFD drains (89.5%) were pre-TEVAR. Most post-TEVAR drains were placed for new SCI symptoms (n = 21). Twenty-five patients (6.4%) suffered 32 CSFD complications. Most (n = 17) were mild in severity. Severe CSFD complications occurred in 5/432 (1.1% CSF drains) patients. No patient/procedural characteristics were predictive of CSFD complications. Post implant CSFD placement for new SCI symptoms conferred an increased risk of CSFD complication (odds ratio, 6.9; 95% CI, 2.42-19.6; $P < .01$). The long-term survival of the CSFD complication cohort did not differ from the overall population.

Conclusions: Post-TEVAR CSFD placement for new SCI symptoms was associated with substantially greater risk of CSFD complications. Avoidance of post-implant therapeutic drain placement might be the key to prevention of CSFD complications, favoring a strategy of selective pre-implant drain placement in patients at higher risk for SCI. (JTCVS Techniques 2022;14:9-28)



Survival at 12 months after TEVAR was not affected by CSFD complications in our cohort.

CENTRAL MESSAGE

Dedicated providers can provide CSFD with minimal morbidity, which supports the selective use of CSFD in patients deemed at higher risk for SCI.

PERSPECTIVE

Several aorta centers have reported complications with spinal drain placement during TEVAR; and have curtailed their indications for placement. We still find value in prophylactic CSF drainage for extended length TEVAR and have experienced a low rate of major complications; the purpose of this report was to review the historical safety profile of drain placement at our center to validate its use for prophylactic drainage.

Thoracic endovascular aortic repair (TEVAR) is a valuable tool for treating thoracic aortic pathology and carries less morbidity and mortality than open techniques.[1-4] However, TEVAR carries a 2%-15% risk of spinal cord ischemia (SCI) and resulting paraplegia/paraparesis associated with decreased quality of life and long-term

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Abbreviations and Acronyms

APS	= acute pain service
B/FEVAR	= branched/fenestrated endovascular aortic repair
CSF	= cerebrospinal fluid
CSFD	= cerebrospinal fluid drainage
CT	= computed tomography
EDH	= epidural hematoma
ICH	= intracranial hemorrhage
PDPH	= post dural puncture headache
SCI	= spinal cord ischemia
TAA	= thoracic aortic aneurysm
TEVAR	= thoracic endovascular aortic repair

survival.[5-8] Numerous risk factors for post-TEVAR SCI have been identified, including distal landing in Ishimaru zones 5-10, landing in close proximity to or covering the celiac ostium, long segment (>150-200 mm) aortic coverage, previous aortic surgery, nonelective procedures, history of tobacco use, and acute/chronic kidney disease.[9,10] Lumbar cerebrospinal fluid (CSF) drainage (CSFD) allows intrathecal pressure monitoring and drainage that can augment spinal cord perfusion pressure by decreasing CSF pressure. It is an established therapy in the prevention and treatment of SCI in open and endovascular thoracic aortic repair and is frequently used prophylactically in patients considered to be at increased risk for SCI.[11-16]

However, there is growing interest in minimizing CSFD usage in TEVAR.[17-19] Notwithstanding its utility in managing symptomatic SCI, no consistent link between routine prophylactic CSFD use and decreased SCI rates after TEVAR has been shown. Relevant evidence is hampered by inconsistent protocols for CSFD usage and lack of broadly-accepted "high-risk" criteria for SCI.[19-21] Furthermore, CSFD is associated with several potential complications ranging in severity from minor self-limited headache to hemorrhage causing permanent neurologic injury.[22,23] Although the reported incidence of CSFD complications is relatively low (6.5% overall; 2.5% severe), these events can be associated with long-term disability and decreased survival.[7,22]

Our team has previously reported reduced rates of SCI using a bundled prevention protocol in branched/fenestrated endovascular aortic repair (B/FEVAR), particularly in patients with Crawford extent I to III thoracoabdominal aneurysm.[11] This protocol was introduced to promote "bundled" usage of many of the SCI prevention and treatment measures already in use at our institution and to facilitate the education of trainees and other team members. Components of the protocol involve measures to optimize spinal cord oxygen delivery, passive hypothermia, and pharmacologic interventions (Table E1). Central to this protocol, however, was the routine use of prophylactic CSFD in patients deemed to be high anatomic risk for post-TEVAR SCI. The purpose of this current study was to: (1) examine long-term trends in CSFD usage in TEVAR and associated rate of CSFD complications, (2) identify demographic and/or clinical predictors of post-TEVAR CSFD complications, and (3) determine if the use of a bundled SCI prevention protocol that relies heavily on CSFD was associated with an increase in the rate of post-TEVAR CSFD complications.

METHODS

Study End Points

The primary end point was the rate of any complication directly attributable to CSFD placement and postprocedural use in patients who underwent TEVAR. We sought to examine the association of patient factors, timing of CSFD placement, and procedural characteristics/urgency with the risk of CSFD complications. We further evaluated the relationships between CSFD utilization, CSFD complications, and time-dependent survival and determined if implementation of our SCI prevention protocol involving CSFD use (initiated May 1, 2015) was associated with increased rates of CSFD complications.

Patients and Database

All patients who underwent TEVAR and/or B/FEVAR (henceforth referred to globally as "TEVAR") from 2011 to 2020 were identified from a prospectively maintained institutional endovascular aortic database. This study interval coincides with the implementation of the current electronic medical record at our institution and with the creation of the current iteration of our database. Patients who underwent endovascular aortic repair without a thoracic aortic component or any open thoracic aortic reconstruction were not included. CSFD utilization was prospectively recorded in the database and the true rate of CSFD usage was further verified by a query of hospital billing records and chart review. Demographic characteristics, comorbidities, preoperative oral anticoagulant use, preprocedural coagulation studies, previous aortic surgery, TEVAR indication, and procedural characteristics were obtained from the database and chart review. Long-term survival was verified by a query of the Social Security Death Index (August 1, 2020). The electronic medical record was queried for International Classification of Diseases, 10th Revision codes associated with a broad list of potential CSFD-related complications generated for the purpose of this study. Records of patients who underwent CSFD for TEVAR were individually reviewed to determine the presence/exact nature of CSFD-related complication(s). Chart review was performed by 3 investigators (J.R.S., T.J.W., K.L.W.) and all possible and actual CSFD complication events were reviewed by 1 investigator (J.R.S.) to ensure consistency in data collection and event interpretation. All variables examined were complete in our database and no statistical interpolation was required. This study was approved by the University of Florida College of Medicine institutional review board (UF-IRB #917-2020; April 8, 2020).

SCFD Placement Procedure

Timing of CSFD placement was distributed among 3 categories. "Preimplant" CSFD placements were before TEVAR in patients thought to be high-risk for postprocedure SCI, typically including patients with >150 mm of planned aortic coverage, planned zone 5 coverage within 5 cm of the celiac artery, previous open/endovascular aortic surgery, and/or presence of an unrepaired infrarenal aneurysm.[7] CSFD placements after TEVAR in patients deemed high-risk for SCI but who were unsuitable for pre-implant placement because of urgent/emergent presentations and

without SCI symptoms were considered "post-implant prophylactic." CSFD placements after TEVAR for new SCI symptoms were considered "post-implant therapeutic."

Before anesthesia induction, patients were placed into either a sitting (using an epidural positioning device) or lateral decubitus position for drain placement and sedation was administered. Lateral positioning was reserved only for emergent drain placement. A 14-gauge Tuohy neuraxial needle was passed into the subarachnoid space at the L2 to L5 level. A 1.5-mm outer diameter hermetic lumbar catheter was advanced 10-15 cm with or without a wire stylet, with intended catheter tip location in the intrathecal space at the T10 to T12 level, on the basis of the level of needle entry. During placement, patients were closely monitored for the development of paresthesia, bloody CSF, and early-onset dural puncture headache. CSFD placements were made by a dedicated anesthesia acute pain service (APS) except in a small number (<10) of isolated instances of obesity for which fluoroscopy and neurosurgical consultation were required. For all nonemergent CSFD, drains were placed by an APS fellow with an attending physically present in the room, whereas emergent drains were placed by the attending APS anesthesiologist. Ultrasound guidance was used in patients with significant obesity, scoliosis, and previous back surgery with hardware present at the intended level of drain placement.

Intraoperatively, CSFD drains were connected to a closed drainage system at a default pressure of 10 mm Hg with continuous monitoring. Postoperatively, a lower extremity motor exam was obtained as soon as feasible. Drains remained at 10 mm Hg for a minimum of 24 hours with hourly neurologic exams performed by bedside staff. If no neurologic symptoms were present during that period, the drain was clamped for 18-24 hours with continued hourly exams and then removed if the patient remained asymptomatic. If neurologic changes occurred, the drain was kept in place for ≥72 hours after symptom onset. A pressure of ≤10 mm Hg was maintained during this period at surgeon discretion to alleviate symptoms.[24] Details of the evolution of our institutional SCI prevention protocol to its current form, including prescribed CSFD rates, are shown in Table E1.[25] Anticoagulant medications were held for drain placement/removal according to a standardized protocol concordant with the American Society of Regional Anesthesia guidelines (Online Data Supplement).

SCFD Complication Definitions and Classification

Although no standardized grading system for severity of CSFD-related complications exists, a composite classification schema was developed for this study on the basis of numerous recent publications on this topic (Table 1).[22,23,26,27] CSFD-related complications that were self-limited or managed with medication only (eg, post dural puncture headache [PDPH] and/or CSF leak not requiring procedural intervention) or requiring minor non-neurologic intervention (eg, urinary retention) were considered "mild" in severity. Complications requiring premature drain removal or drain replacement (eg, drain occlusion) and any headache and/or CSF leak requiring intervention (eg, blood patch) but without evidence of intracranial/neuraxial hemorrhage were considered "moderate." Any occurrence of neuraxial hemorrhage (eg, intracranial hemorrhage [ICH], epidural hematoma [EDH]) or neurologic impairment determined to be attributable to CSFD was considered a "severe" complication. Patients with post-TEVAR neurologic impairment determined to be due to stroke or other non-CSFD etiologies were not considered CSFD-related complications. SCI was clinically defined by presence of any new lower extremity motor or sensory deficit not attributable to other etiologies (eg, EDH, intracranial pathology, stroke, peripheral neuropathy, and/or neuropraxia).

Statistical Analysis

Summary statics are reported as mean ± SD or n (%) and are reported across all TEVAR procedures rather than among all patients because primary interest was in characterizing the hospital experience with CSFD utilization. Mixed effects logistic regression models were used to make bivariate comparisons between no CSFD versus CSFD, no SCI versus SCI, and pre- versus post-protocol groups on patient and procedure characteristics. In all models, group membership was the outcome, the variable of interest was the fixed factor, and a random factor for patient was included to account for the patients who received more than 1 operation. Because of the exploratory nature of many of our reported analyses and small number of CSFD complication events, a Bonferroni correction for multiple comparisons was not applied to prevent the penalization of potentially notable associations. Model results are reported as odds ratios for being in the CSFD, SCI, or post-protocol group. Kaplan–Meier methods with log rank testing were used to compare groups on long-term survival. Tests of normality were performed for all continuous variables and used to determine appropriate statistical tests for between group comparisons. All statistical analyses were performed using the R software package (version 4.0.5, the R Foundation for Statistical Computing) by our departmental biostatistician (D.N.).

RESULTS

Study Cohort Characteristics

During the study interval, 936 TEVAR procedures were performed in 869 patients. Demographic, historical, and clinical characteristics of the overall cohort are summarized in Table 2. A total of 390 CSFD placements were made in 373 patients (41.7% of all TEVAR procedures). Patients who received CSFD had higher rates of chronic obstructive pulmonary disease (39.2% vs 33.5%) and peripheral arterial disease (97.9% vs 94.0%) but lower incidence of diabetes (14.6% vs 19.2%) compared with those who did not; these groups otherwise had similar comorbidity burdens. Patients with CSFD were more likely to have undergone previous aortic surgery (44.1% vs 35.9%), but this difference largely disappeared with the exclusion of previous ascending/arch procedures.

The most common TEVAR indications were thoracoabdominal aneurysm (n = 300; 32.2%) and thoracic aortic aneurysm (TAA; n = 217; 23.3%). TEVAR indications with the highest rates of CSFD utilization were chronic aortic dissection (64.7%), TAA (50.2%), and acute aortic dissection (45.4%). CSFD use was marginally higher in elective procedures (43.3% vs 39.6% nonelective). Among patients who received TEVAR alone, CSFD placement was similar among subjects who did or did not have left subclavian artery coverage (44.5% for both groups). Patients who underwent B/FEVAR received CSFD at lower rates overall compared with those who received TEVAR (33.8% vs 44.7%) and there was no clear association between B/FEVAR complexity (eg, 1-vessel vs 4-vessel) and CSFD utilization. The complete distribution of patients among CSFD groups is shown in Figure 1 and demographic/procedural characteristics of each of the CSFD groups is shown in Table E2.

SCFD-Related Complications

Overall rates of CSFD complications and associated patient clinical and procedural characteristics are shown in Table 3. The per-patient CSFD complication rate of any

TABLE 1. CSFD complication severity classification

Severity	Description
Mild	PDPH not requiring procedural intervention
	CSF leak not requiring procedural intervention
	Any CSFD-related issue requiring minor non-neurologic intervention (eg, urinary retention requiring Foley catheter placement)
Moderate	Need for premature drain removal/replacement (eg, drain occlusion) without evidence of neuraxial hemorrhage
	PDPH or CSF leak requiring procedural intervention (eg, blood patch) without evidence of neuraxial hemorrhage
Severe	Any neuraxial hemorrhage (eg, ICH or EDH)
	Any neurologic impairment related to CSFD

CSFD, Cerebrospinal fluid drain; *PDPH*, post dural puncture headache; *CSF*, cerebrospinal fluid; *ICH*, intracranial hemorrhage; *EDH*, epidural hematoma.

severity was 6.4% (25/390 TEVAR patients). Eight patients (2.1% of the overall cohort) suffered complications categorized as moderate or severe and are explained in the final two paragraphs of this subsection. The complication and complication-free groups were similar with regard to demographic characteristics, comorbidities, aortic surgical history, preoperative anticoagulant use, TEVAR indication, or procedural urgency. Most (89.5%) CSFD drains placed in our cohort were pre-implant. Post-implant prophylactic (4.9%) and post-implant therapeutic drains (5.6%) were placed at similarly low rates.

The main predictors of CSFD complications identified in our entire analysis pertained to the timing of drain placement. The per-patient CSFD complication rate was higher when drains were implanted in the post-implant therapeutic setting (27.3%) compared with in the post-implant prophylactic (5.3%) and pre-implant (5.2%) setting. This difference correlated with a sevenfold increase in CSFD-related complication risk with post-implant therapeutic placement (odds ratio, 6.9; 95% CI, 2.42-19.6; $P < .01$). Conversely, pre-implant placement was associated with an approximately fourfold reduction in CSFD complication risk (odds ratio, 0.26; 95% CI, 0.10-0.68; $P < .01$).

Details regarding CSFD complications are shown in Table E3. Among the 25 patients who suffered CSFD complications, 17 (65.3%) were mild in severity. All but 2 of these consisted of PDPH with (n = 5) or without (n = 10) CSF leak that resolved with various combinations of oral butalbital, acetaminophen, caffeine supplementation, oral or intravenous hydration, supine positioning, and observation. One patient had urinary retention requiring Foley catheter placement and another had a self-limited asymptomatic CSF leak.

Three patients (0.8% of total cohort) suffered complications of moderate severity. One required premature drain removal because of drain occlusion. Another required drain replacement because of external catheter fracture. The third had a persistent CSF leak requiring bedside skin-level suture closure.

Severe CSFD complications occurred in 5 patients (1.3% of overall CSFD cohort), 3 of whom suffered suspected/actual neuraxial hemorrhage. There were no episodes of CSFD-related meningitis in our series. One of these patients had a complex presentation and pre-TEVAR course and subsequently died during the same hospitalization. She was 78 years old with history of cirrhosis from nonalcoholic steatohepatitis and previous endovascular aortic repair with bilateral renal artery snorkel reconstruction who presented with a type 1 endoleak and underwent open conversion with left aortorenal bypass, at which time qualitative coagulopathy and liver nodularity were observed. She recovered satisfactorily and underwent TEVAR for a synchronous TAA with pre-implant CSFD 12 days later. New bilateral lower extremity paralysis and concurrent CSFD occlusion occurred immediately after TEVAR. The CSFD drain was replaced with subsequent return of bloody CSF. An initial thoracolumbar computed tomography (CT) scan was unrevealing but head CT imaging showed a combined intraparenchymal/subdural/subarachnoid hemorrhage. The patient received nonoperative management of this combined ICH and died after withdrawal of care 23 days after TEVAR.

Bundled SCI Management Protocol and CSFD Complications

A bundled protocol for SCI prevention in TEVAR was implemented at our institution on May 1, 2015, which included routine pre-implant CSFD placement in patients considered to be high-risk for SCI.[11] Patient and procedural characteristics, rates of CSFD usage, implantation timing, and rates of CSFD complications before and after SCI protocol implementation are shown in Table E4. As expected, the pre- and post-protocol groups were similar regarding demographic and historical characteristics. The overall rate of CSFD usage increased after activation of the protocol (36.9% vs 50.6%). Timing of CSFD placement was similar among groups (pre-implant in 88.9% pre- vs 90.3% post-implementation). The rates (6.7% vs. 6.1%) and individual levels of severity of CSFD

TABLE 2. Patient factors and procedural characteristics according to CSFD status

	Overall	CSFD	No CSFD	OR (CSFD vs no CSFD)	*P* value
Demographic characteristics					
Patients	936	390 (41.7)	546 (58.3)		
Age, y	67.1 ± 13.7	67.6 ± 12.1	66.8 ± 14.6	1	.394
Male sex	652 (69.7)	269 (69.0)	383 (70.1)	0.95	.698
Comorbidities, aortic surgical history, preoperative anticoagulant use, and preoperative laboratory values					
ASA class	3.7 ± 0.55	3.7 ± 0.52	3.7 ± 0.57	1.1	.367
Current smoker	231 (24.7)	96 (24.6)	135 (24.7)	0.99	.97
Ever smoker	684 (73.1)	289 (74.1)	395 (72.3)	1.1	.554
Previous MI	125 (13.4)	48 (12.3)	77 (14.1)	0.85	.425
Congestive heart failure	145 (15.5)	59 (15.1)	86 (15.8)	0.95	.801
Cerebrovascular disease	113 (12.1)	44 (11.3)	69 (12.6)	0.88	.531
Peripheral arterial disease	895 (95.6)	382 (97.9)	513 (94.0)	3.1	<.01
COPD	336 (35.9)	153 (39.2)	183 (33.5)	1.3	.074
Diabetes mellitus	162 (17.3)	57 (14.6)	105 (19.2)	0.72	.066
Renal insufficiency	222 (23.7)	84 (21.5)	138 (25.3)	0.81	.192
Any liver disease	41 (4.4)	15 (3.8)	26 (4.8)	0.8	.502
Any previous aortic surgery	368 (39.3)	172 (44.1)	196 (35.9)	1.4	<.05
Previous nonascending/arch aortic surgery	292 (31.2)	133 (34.1)	159 (29.1)	1.3	.108
NOAC	23 (2.5)	9 (2.3)	14 (2.6)	0.9	.808
Warfarin	30 (3.2)	12 (3.1)	18 (3.3)	0.93	.852
Antiplatelet	93 (9.9)	32 (8.2)	61 (11.2)	0.71	.137
Aspirin	572 (61.1)	258 (66.2)	314 (57.5)	1.4	<.01
Platelet count, × 1000/mL	182 ± 86	181 ± 77	184 ± 91	1	.59
INR	1.2 ± 0.22	1.2 ± 0.22	1.2 ± 0.22	0.91	.775
Serum hemoglobin, g/dL	11.6 ± 2.2	11.7 ± 1.9	11.5 ± 2.4	1	.306
TEVAR indication					
TAAA	301 (32.2)	109 (27.9)	192 (35.2)	0.72	<.05
TAA	221 (23.6)	109 (27.9)	112 (20.5)	1.5	<.01
Acute dissection	142 (15.2)	65 (16.7)	77 (14.1)	1.2	.285
Chronic type B dissection	102 (10.9)	66 (16.9)	36 (6.6)	2.9	<.01
PAU/IMH	68 (7.3)	18 (4.6)	50 (9.2)	0.48	.01
Post surgical	38 (4.1)	14 (3.6)	24 (4.4)	0.81	.538
TAT	34 (3.6)	2 (0.5)	32 (5.9)	0.08	<.01
Other	30 (3.2)	7 (1.8)	23 (4.2)	0.42	.045
Urgency					
Elective	517 (55.2)	224 (43.3)	293 (56.7)	1.2	.26
Nonelective	419 (44.8)	166 (39.6)	253 (60.4)	0.86	.26
TEVAR characteristics					
TEVAR with LSCA coverage	362 (38.7)	161 (44.5)	201 (55.5)	1.2	.171
TEVAR without LSCA coverage	311 (33.2)	140 (45)	171 (55)	1.2	.145
Any TEVAR alone	673 (71.9)	301 (44.7)	372 (55.2)	1.6	<.01
4-Vessel FEVAR	170 (18.2)	60 (35.3)	110 (64.7)	0.72	.065
3-Vessel FEVAR	51 (5.4)	17 (33.3)	34 (66.7)	0.69	.22
2-Vessel FEVAR	33 (3.5)	7 (21.2)	26 (78.8)	0.37	<.05
1-Vessel FEVAR	9 (1.0)	5 (55.6)	4 (44.4)	1.8	.405
Any FEVAR	263 (28.1)	89 (33.8)	174 (66.1)	0.63	<.01

ORs and *P* values reflect the results of mixed effects logistic regression analysis. Data are presented as n (%) or mean ± SD, except where otherwise noted. *CSFD*, Cerebrospinal fluid drain; *OR*, odds ratio; *ASA*, American Society of Anesthesiologists; *MI*, myocardial infarction; *COPD*, chronic obstructive pulmonary disease; *NOAC*, novel oral anticoagulant; *INR*, international normalized ratio; *TEVAR*, thoracic endovascular aortic repair; *TAAA*, thoracoabdominal aortic aneurysm; *TAA*, thoracic aortic aneurysm; *PAU*, penetrating atherosclerotic ulcer; *IMH*, intramural hematoma; *TAT*, traumatic aortic transection; *LSCA*, left subclavian artery; *FEVAR*, fenestrated endovascular aortic repair.

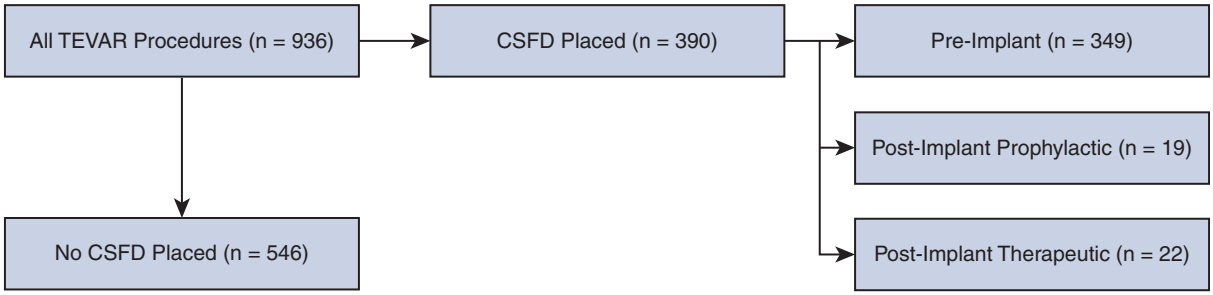

FIGURE 1. Consolidated Standards of Reporting Trials diagram showing CSFD use in TEVAR patients. *TEVAR*, Thoracic endovascular aortic repair; *CSFD*, cerebrospinal fluid drain.

complications were similar before and after protocol implementation.

SCI

Overall rates of post-TEVAR permanent neurologic deficit (paraparesis or paraplegia) are shown in Table 4. The rate of permanent deficit was higher in the CSFD group compared with the non-CSFD cohort (5.4% vs 2.9%), reflecting the higher preoperative SCI risk in patients who received CSFD. Patients who had a CSFD complication had higher rates of permanent deficit (16.0% vs 3.6%). Similar rates of permanent deficit were observed before and after implementation of the SCI protocol (3.9% vs 4.0%). Notably, in this subanalysis we report raw data only, it is not intended to evaluate the effectiveness of the SCI protocol for rescue therapy for new post-TEVAR SCI symptoms, and does not reflect rigorous risk adjustment.

Annual CSFD Utilization, Complication Rates, and Survival

Overall annual rates of CSFD utilization and complications compared with TEVAR volume and SCI rates are shown in Figure 2. From 2011 to 2015, TEVAR volume increased whereas CSFD utilization initially increased and then became relatively stable between 2013 and 2015. As TEVAR volume declined from 2015 to 2017, CSFD utilization remained stable, indicating an increase in the proportion of CSFD usage during this period. The overall annual rate of CSFD complications remained between 2.0% and 3.2% during this period with the exceptions of 2011 (5.6%), 2016 (0.0%), and 2019 (5.8%).

The relationship between CSFD complications and 1-year survival post-TEVAR is depicted in Figure 3. Survival was similar between patients who suffered mild vs. moderate/ severe complications. No survival difference among the overall TEVAR cohort that did not have a CSFD complication versus those with a CSFD-related complication was evident. Notably, the analogous 12-month survival among the moderate/severe complication cohort and the CSFD-complication-free cohort was driven entirely by the single mortality described previously.

DISCUSSION

The routine use of prophylactic CSFD for SCI prevention in TEVAR is controversial because of concerns about drain-related complications and lack of strong evidence supporting its use in this setting.[17,19,22] Historically, our institutional preference has favored the use of prophylactic CSFD in TEVAR and its use has increased in recent years after the implementation of our SCI prevention protocol.[11,28] We performed the present study to characterize our experience with and patterns of CSFD usage in a large contemporary TEVAR cohort. Further, we quantified CSFD complication rates, identified predictive factors, and determined if a bundled SCI prevention protocol that increased the use of CSFD was associated with an increase in drain-related complications.

There were three principal findings of our study. Rates of overall (6.4%) and moderate/severe (2.1%) CSFD-related complication rates were low. The main clinical predictor of CSFD complications was timing of drain placement; post-implant therapeutic placement substantially increased risk of complications and pre-implant placement substantially decreased risk. Finally, implementation of a bundled SCI prevention protocol was not associated with increased CSFD-related complications (Figure 4).

In a recent meta-analysis Rong and colleagues[23] reported the combined rates of CSFD complications in open and endovascular aortic repairs in 34 studies from 1990 to 2017. An overall complication rate of 6.5% was reported (vs 6.4% in the current study). Comparisons of the rates of minor/moderate complications are challenging because of differing severity classification of some post-CSFD events. As an example, PDPH managed medically was classified as mild in our study and moderate by Rong and colleagues, whereas drain occlusion/dislodgement was considered moderate in our study (because of potentially increased SCI risk caused by premature cessation of drainage) but was classified as mild in the meta-analysis. However, the

TABLE 3. Patient factors and procedural characteristics according to CSFD complication status

	Overall	CSFD complication	No CSFD complication	OR	*P* value
Demographic characteristics					
Patients, n (%)	390	25 (6.4)	365 (93.6)		
Age, y	67.6 ± 12.1	65.7 ± 14.6	67.7 ± 11.9	0.99	.429
Male sex	269 (69.0)	17 (68.0)	252 (69.0)	0.95	.913
Multiple CSFDs placed	16 (1.7)	2 (8.0)	14 (3.8)	2.2	.274
Comorbidities, aortic surgical history, preoperative anticoagulant use, and preoperative laboratory values					
ASA class	3.7 ± 0.52	3.8 ± 0.47	3.7 ± 0.52	0.65	.303
Current smoker	96 (24.6)	4 (16.0)	92 (25.2)	0.57	.307
Ever smoker	289 (74.1)	15 (60.0)	274 (75.1)	0.5	.102
Previous MI	48 (12.3)	2 (8.0)	46 (12.6)	0.6	.502
Congestive heart failure	59 (15.1)	2 (8.0)	57 (15.6)	0.47	.315
Cerebrovascular disease	44 (11.3)	5 (20.0)	39 (10.7)	2.1	.163
Peripheral arterial disease	382 (97.9)	24 (96.0)	358 (98.1)	0.47	.487
COPD	153 (39.2)	12 (48.0)	141 (38.6)	1.5	.356
Diabetes mellitus	57 (14.6)	6 (24.0)	51 (14.0)	1.9	.176
Renal insufficiency	84 (21.5)	5 (20.0)	79 (21.6)	0.91	.847
Any liver disease	15 (3.8)	1 (4.0)	14 (3.8)	1	.967
Any previous aortic surgery	172 (44.1)	12 (48.0)	160 (43.8)	1.2	.685
Previous nonascending/arch aortic surgery	133 (34.1)	9 (36.0)	124 (34.0)	1.1	.836
NOAC	9 (2.3)	0 (0)	9 (2.5)	N/A	N/A
Warfarin	12 (3.1)	0 (0)	12 (3.3)	N/A	N/A
Antiplatelet	32 (8.2)	2 (8.0)	30 (8.2)	0.97	.969
Aspirin	258 (66.2)	12 (48.0)	246 (67.4)	0.45	.052
Platelet count, × 1000/mL	181 ± 77	176 ± 94	181 ± 76	1	.769
INR	1.2 ± 0.22	1.3 ± 0.19	1.2 ± 0.20	4	.132
Serum hemoglobin, g/dL	11.7 ± 1.9	12.0 ± 2.0	11.6 ± 1.9	1.1	.362
TEVAR indication					
Acute dissection	64 (16.5)	5 (7.8)	59 (92.2)	1.3	.622
Chronic dissection	66 (17.0)	7 (10.6)	59 (89.4)	2	.135
TAAA	109 (28.0)	5 (4.6)	104 (95.4)	0.62	.36
PAU/IMH	18 (4.6)	1 (5.5)	17 (94.4)	0.85	.877
TAA	109 (28.0)	5 (4.6)	104 (95.4)	0.62	.36
TAT	2 (0.5)	1 (50)	1 (50)	15.1	.058
Other	8 (2.1)	1 (12.5)	7 (87.5)	2.1	.489
Post surgical	12 (3.1)	0 (0)	12 (100)	N/A	N/A
Hybrid	1 (0.3)	0 (0)	1 (100)	N/A	N/A
Urgency					
Elective	224 (57.4)	12 (5.3)	212 (94.6)	0.67	.327
Nonelective	166 (42.6)	13 (7.8)	153 (92.2)	1.5	.327
TEVAR characteristics					
TEVAR with LSCA coverage	161 (41.3)	9 (55.9)	152 (94.4)	0.79	.58
TEVAR without LSCA coverage	140 (35.9)	11 (7.9)	129 (92.1)	1.4	.385
Any TEVAR alone	301 (77.2)	20 (66.4)	281 (93.4)	1.2	.729
4-Vessel FEVAR	60 (15.4)	3 (5)	57 (95)	0.74	.629
3-Vessel FEVAR	17 (4.4)	1 (5.9)	16 (94.1)	0.91	.928
2-Vessel FEVAR	7 (1.8)	1 (14.3)	6 (85.7)	2.5	.406
1-Vessel FEVAR	5 (1.3)	0 (0)	5 (1)	N/A	N/A
Any FEVAR	89 (22.8)	5 (5.6)	84 (94.3)	0.84	.729
CSFD placement timing					
Before implant	349 (89.5)	18 (5.2)	331 (94.8)	0.26	<.01
After implant, prophylactic	19 (4.9)	1 (5.3)	18 (94.7)	0.8	.835
After implant, therapeutic	22 (5.6)	6 (27.3)	16 (72.7)	6.9	<.01

(Continued)

TABLE 3. Continued

	Overall	CSFD complication	No CSFD complication	OR	*P* value
CSFD complication severity					
Mild	17 (4.4)	17 (68)	N/A	N/A	N/A
Moderate	3 (0.8)	3 (12)	N/A	N/A	N/A
Severe	5 (1.3)	5 (20)	N/A	N/A	N/A

ORs and *P* values reflect the results of mixed effects logistic regression analysis. Data are presented as n (%) or mean ± SD, except where otherwise noted. *CSFD*, Cerebrospinal fluid drain; *OR*, odds ratio; *ASA*, American Society of Anesthesiologists; *MI*, myocardial infarction; *COPD*, chronic obstructive pulmonary disease; *NOAC*, novel oral anticoagulant; *N/A*, not applicable; *INR*, international normalized ratio; *TEVAR*, thoracic endovascular aortic repair; *TAAA*, thoracoabdominal aortic aneurysm; *PAU*, penetrating atherosclerotic ulcer; *IMH*, intramural hematoma; *TAA*, thoracic aortic aneurysm; *TAT*, traumatic aortic transection; *LSCA*, left subclavian artery; *FEVAR*, fenestrated endovascular aortic repair.

definition of a severe complication used by Rong and colleagues (any ICH, EDH, meningitis, or CSFD-related neurologic deficit) was consistent with that used in the current study. The reported rate of severe complications in the meta-analysis was 2.5%, compared with 1.3% in this report.

Despite the large number of patients available for meta-analysis, relatively few studies directly examined and provided granular data pertaining to CSFD complications in open and endovascular aortic repair.[22,29,30] In the largest of these dedicated studies, Wynn and colleagues[30] reported complication data in 724 patients who received CSFD while undergoing open (n = 622) and endovascular (n = 102) aortic repair. The most common complications reported were CSF leak (4.4%) and headache (3.6%), with most of these patients receiving an epidural blood patch. A strong relationship between volume of CSF drained, bloody CSF (10.1%), and ICH (5.2%) with an overall rate of CSFD-related neurologic dysfunction of 0.8%. Youngblood and colleagues[29] reported their experience in 504 patients who received CSFD related to open or endovascular TAA repair with an overall complication rate of 12.7%, consisting mostly of PDPH (9.7%) and ICH (2.8%). Notably, patients with connective tissue disorders of any age were at greater risk of PDPH. There were no cases of neuraxial hematoma/abscess or meningitis reported. Kärkkäinen and colleagues[22] reported an overall complication rate of 10% in 187 patients who underwent endovascular repair of pararenal (n = 20) or thoracoabdominal (n = 167) aortic aneurysms. Similar to other reports, the most frequent complication was PDPH (5%) but the rate of CSF leak (1%) was notably lower and the rate of neuraxial hematoma (3%) notably higher.

Most recently, Plotkin and colleagues[26] reported 268 patients who received CSFD for endovascular aortic repair with an overall complication rate of 8.1% (4.2% major). In contrast to previous reports, timing of drain placement was evaluated: 95.5% of drains were placed before TEVAR (vs 89.5% in our experience) and 4.2% were placed for new neurologic symptoms after TEVAR (vs 4.9%). There was no relationship between timing of drain placement and rate of CSFD complications, but increased body mass and history of previous CSFD placement were predictive of complications. In a notable departure from previous work on the topic, PDPH not requiring procedural intervention was not counted as a complication and asymptomatic neuraxial hematoma was considered only a minor complication.

Citing concerns about uncertain utility and risk for CSFD-related complications, Hanna and colleagues[18] previously reported low rates of SCI in TEVAR with a restrictive strategy for prophylactic CSFD. Weissler and colleagues[17] subsequently reported success with complete avoidance of prophylactic CSFD in 223 consecutive TEVAR patients, placing emphasis on a bundle of non-CSFD interventions (left subclavian artery revascularization, permissive postprocedural hypertension, and evoked potential monitoring), with no reported episodes of clinically apparent SCI. The combination of the risk of CSFD complications and these and other reports suggesting an absence of clear benefit to prophylactic CSFD in TEVAR question the necessity of its routine use.[9,17,18]

Our current study is the largest TEVAR-specific examination of CSFD complications to date and differs from previous work by describing a strong relationship between post-implant therapeutic CSFD placement and CSFD complications, along with the corresponding finding that pre-implant CSFD placement is associated with lower rates of CSFD complications (Figure 3). Previous studies showed

TABLE 4. Spinal cord ischemia and CSFD usage

	No SCI (n = 864; 92.3%)	Any permanent deficit (n = 37; 4.0%)
CSFD status		
No CSFD	522 (95.6)	16 (2.9)
CSFD	342 (87.7)	21 (5.4)
CSFD complication status		
No CSFD Complication	846 (97.9)	33 (3.6)
CSFD Complication	18 (2.1)	4 (16.0)
SCI protocol status		
Pre-protocol	565 (92.6)	24 (3.9)
Post protocol	299 (91.7)	13 (4.0)

Data are presented as n (%). "Permanent deficit" refers to any new post-TEVAR bilateral lower extremity paralysis or paraparesis present at discharge. *CSFD*, Cerebrospinal fluid drain; *SCI*, spinal cord ischemia; *TEVAR*, thoracic endovascular aortic repair.

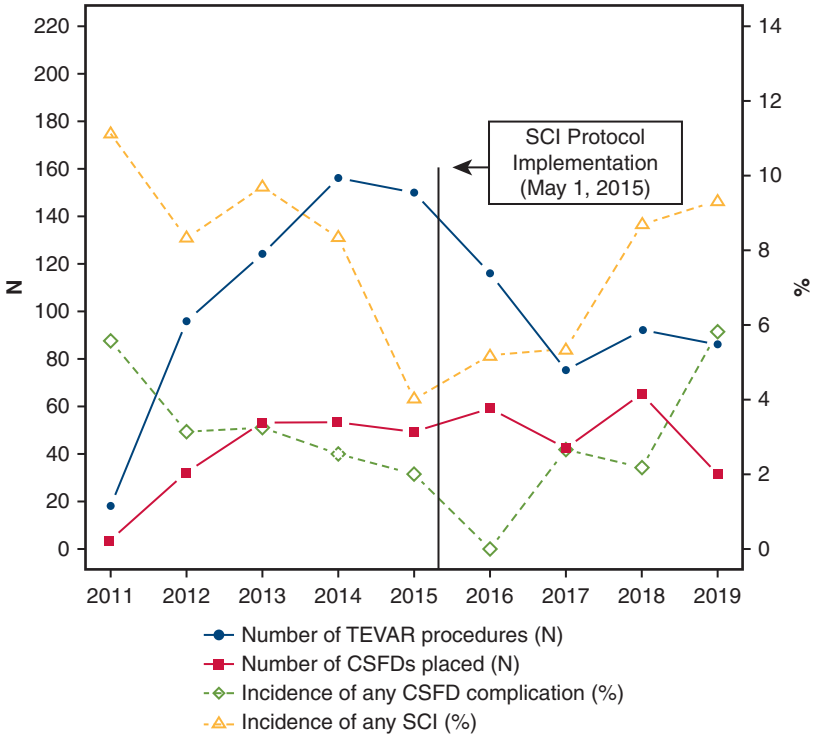

FIGURE 2. Overall annual rates of cerebrospinal fluid drain (*CSFD*) use and complications compared with thoracic endovascular aortic repair (*TEVAR*) volume and spinal cord ischemia (*SCI*) rates. Cumulative incidence plot showing annual TEVAR volume, annual CSFD volume, annual CSFD complication rate (as percentage of all CSFDs), and SCI incidence (as percentage of TEVAR procedures). The implementation of our SCI protocol in May 2015 was associated with a relative increase in CSFD usage. Increased CSFD use was not associated with an increase in the rate of CSFD complications.

the relationship between post-implant therapeutic CSFD placement and comparatively worse SCI functional outcomes but this relationship between post-implant therapeutic placement and increased risk of CSFD complications has not been previously reported.[31-33] At our institution, the standard protocol is for pre-implant CSFD to be placed by a dedicated anesthesia team in a procedure room with appropriate lighting and equipment, including ultrasound, while the patient is awake, sitting upright, and leaning forward onto an epidural positioning device. In rare circumstances, CFSD has been placed using CT guidance in patients with challenging anatomy. Post-implant therapeutic drains, however, are not placed in the same controlled setting as pre-implant drains and are subject to several adverse factors. Chief among these is coagulopathy that is often present after TEVAR despite adequate heparin reversal with protamine, which might be exacerbated by periprocedural hypothermia. Because of the emergent need for CSFD in the presence of new SCI symptoms, such coagulopathy might not be accurately captured by postoperative coagulation studies, which were not consistently available in our series, and might not be amenable to complete correction because of the emergent need for CSFD. Emergent CSFD placement is typically performed in a patient with numerous lines/tubes in an intensive care unit bed, making even lateral positioning challenging. Finally, performance of these procedures during nondaytime hours might also increase complication risk. Notably, the complication rate for post-implant prophylactic drains was lower than for post-implant therapeutic drains. Although the former are still subject to many of the suboptimal environmental factors as the latter, the nonemergent nature of placement might allow for correction of any residual post-TEVAR coagulopathy and is by definition performed in a more stable patient population.

Implementation of our SCI protocol in May 2015 was associated with an increase in the gross number of CSFD drains placed and in the per-procedure utilization rate, an effect magnified by decreased TEVAR volume after protocol implementation. Long-term survival was similar for the group with CSFD complications and those with no complications. The combination of this observation with the findings of increased rates of CSFD complications with post-implant therapeutic placement and overall and diagnosis-specific complication rates that compare favorably with others in the literature reinforces our current institutional preference for routine pre-implant CSFD

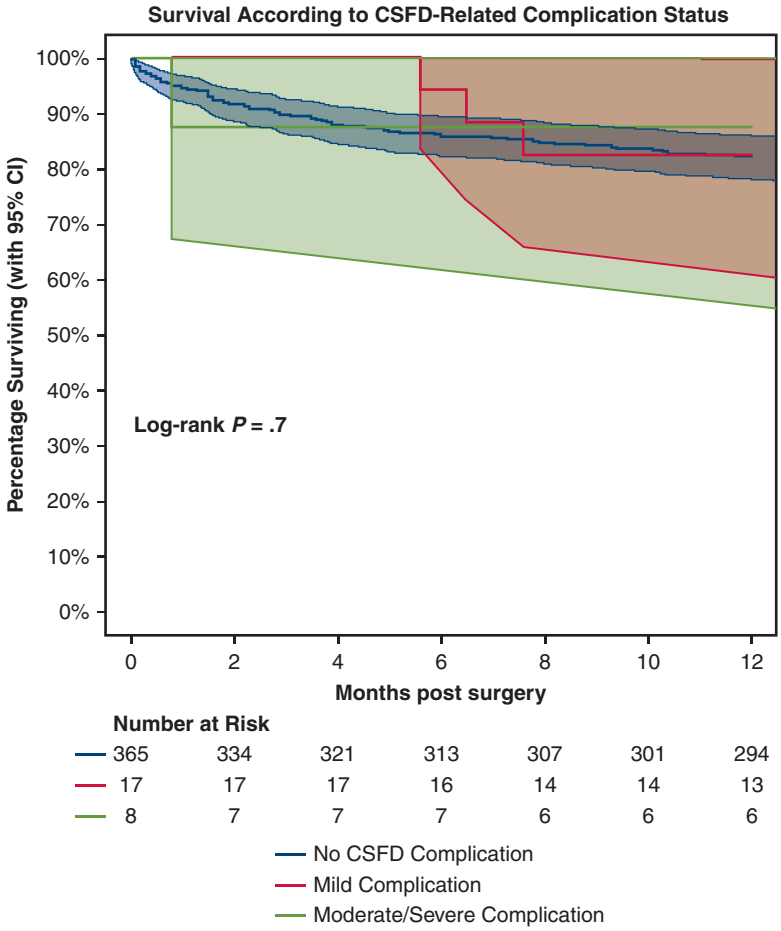

FIGURE 3. Cerebrospinal fluid drain (*CSFD*) complication and post thoracic endovascular aortic repair survival. Kaplan–Meier plot showing 12-month survival according to CSFD complication status (95% CI displayed). *P* value obtained from log rank testing. There was no difference in survival at 12 months among patients with CSFD-related complications and those without.

utilization in patients considered high-risk for SCI after TEVAR.

Limitation

Limitations to this study include its retrospective, single-center nature and associated inherent selection bias regarding the use of endovascular approaches to particular pathology and the use of CSFD. Because of the small number of CSFD complication events in our data, multivariate comparison was not possible and, as such, all of our reported associations are on the basis of univariate analysis. As stated previously, our institutional preference has been in favor of the routine use of prophylactic CSFD in TEVAR. Despite the implementation of our SCI protocol, the patient-level decision-making regarding the usage of CSFD in "high-risk" settings remains influenced by surgeon judgement. Although there is clear consensus that neuraxial hemorrhage and new neurologic deficits related to CSFD use are considered "severe" complications, there is a high degree of heterogeneity among previous reports on this topic regarding the definition of "mild" and "moderate" complications, making comparisons between these studies difficult. Although many contemporary studies report detailed data on volume of CSFD and specific drainage pressure settings, this information was not consistently available in our database. Furthermore, some technical details of CSFD placement, including operator experience, number of needle passes, and patient position were not consistently available.

CONCLUSIONS

Low rates of overall and severe CSFD complications were observed in a large institutional TEVAR experience with a preference for pre-TEVAR CSFD placement in patients thought to be at high risk for SCI. In our analysis, post-implant therapeutic CSFD placement for new SCI symptoms was associated with a sevenfold increased risk of CSFD complications. The implementation of our bundled SCI protocol including the routine use of pre-implant CSFD for patients at high risk for SCI was not

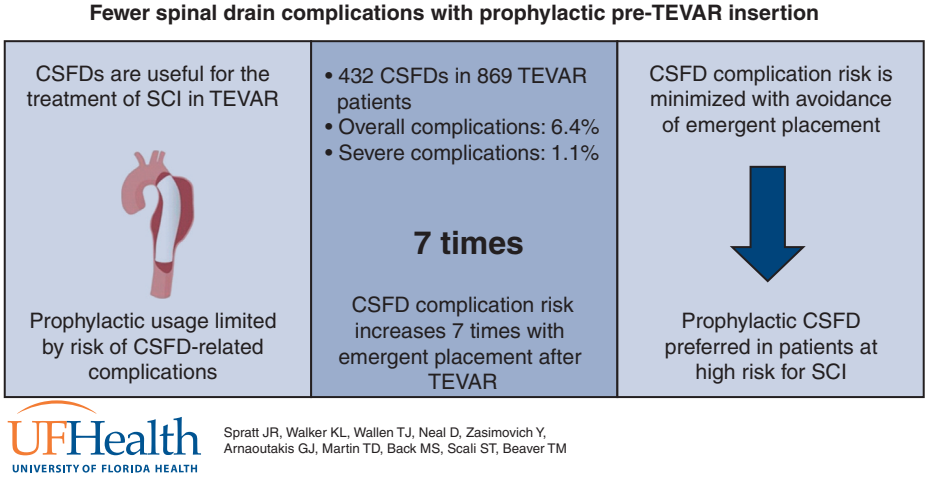

FIGURE 4. Emergent post-TEVAR CSFD placement for new SCI symptoms is associated with an increased risk of CSFD-specific complications, favoring prophylactic CSFD placement in patients at high risk for SCI after TEVAR. *TEVAR*, Thoracic endovascular aortic repair; *CSFD*, cerebrospinal fluid drain; *SCI*, spinal cord ischemia.

associated with an increase in CSFD-related complications. Although the use of CSFD in TEVAR is associated with a low but relatively fixed risk of complications, the key to their prevention might be avoiding emergent drain placement after TEVAR, favoring a strategy of routine pre-implant drain placement in patients at higher risk for SCI.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Key Words: thoracic endovascular aortic repair, spinal cord ischemia, cerebrospinal fluid drain, aortic aneurysm, perioperative management

TABLE E1. Evolution of University of Florida Spinal Cord Ischemia Prevention and Management Protocol

	2000-2008	2009-April 2015	May 2015-present
Preoperatively	Pre-implant CSFD at surgeon discretion	Pre-implant CSFD at surgeon discretion	Oral antihypertensive therapy held 2 days preoperatively (except β-blockers, clonidine, and ACEI/ARB in patients with heart failure)
			Preoperative statin therapy
			Routine pre-implant CSFD placement in patients at high SCI risk
Intraoperatively	No standard protocol	No standard protocol	One-time methylprednisolone bolus (30 mg/kg) after induction of anesthesia
			Naloxone infusion (1 μg/kg/h) started preoperatively and continued for 48 hours, long-acting narcotics avoided
			Mannitol 12.5 g I.V. pre- and post endograft deployment if concerns about CSFD patency
			Mild (approximately 34°C) passive hypothermia (no active warming or warmed IVF administered)
			MAP $\geq$90 mm Hg intraoperatively, arterial vasodilators avoided
			Serum Hgb $\geq$10 g/dL
			CSFD open at 10 mm Hg
Postoperatively all	Cardiac ICU admission for hourly neurological checks	Cardiac ICU admission for hourly neurological checks	Cardiac ICU admission for hourly neurological checks (patient must lift legs off bed)
			Goal SBP 120-150 mm Hg (antihypertensive therapy with β-blockers and nitroglycerin; arterial vasodilators avoided)
			CVP $\geq$8-10 mm Hg with bedside TTE as needed to optimize volume status
			Serum Hgb $\geq$9 g/dL for 5 days
			Continue naloxone infusion for 48 hours, long-acting narcotics avoided
			Continued mild passive hypothermia x24H postop
Postoperatively with SCI symptoms	MAP $\geq$90-100 with fluid and vasopressors	MAP $\geq$90-100 with fluid and vasopressors	MAP $\geq$100 mm Hg with fluid and vasopressors (norepinephrine preferred)
	CSFD placement if not already present	Optimize spinal cord oxygen delivery (goal cardiac index $\geq$ 2.0, SpO2 $\geq$ 96%, Serum Hgb $\geq$ 10 g/dL)	Optimize spinal cord oxygen delivery (goal cardiac index $\geq$ 2.0, SpO2 $\geq$96%, serum Hgb $\geq$10 g/dL)
	CSFD approximately 10 mm Hg, limited to 15 mL/h or 350 mL per 24 hours	Emergent CSFD placement if not already present	Emergent CSFD placement if not already present
	If CSFD effective, continue drainage for 72 hours, clamp for 24 hours, then remove	CSFD approximately 10 mm Hg, limited to 15 mL/h or 350 mL per 24 hours	If CSFD present, lower to 5 mm Hg, maximum drainage 40 mL/h
			Mannitol 12.5 g I.V. over 15 minutes
			Methylprednisolone 1000 mg I.V. over 30 minutes

(Continued)

TABLE E1. Continued

	2000-2008	2009-April 2015	May 2015-present
			Initiate naloxone infusion (1 μg/kg/h) if not already running
Postoperatively with no SCI symptoms	Remove CSFD within 36-48 hours postoperatively	If CSFD effective, continue drainage for 72 hours, clamp for 24 hours, then remove	CSFD drainage at 10 mm Hg for 24 hours postoperatively, clamp CSFD and continue hourly neurological checks, remove CSFD in 18-24 hours if no SCI symptoms

CSFD, Cerebrospinal fluid drainage; *ACEI*, angiotensin-converting enzyme inhibitor; *ARB*, angiotensin receptor blocker; *SCI*, spinal cord ischemia; *I.V.*, intravenous; *IVF*, intravenous fluid; *MAP*, mean arterial pressure; *Hgb*, hemoglobin; *ICU*, intensive care unit; *SBP*, systolic blood pressure; *CVP*, central venous pressure; *TTE*, transthoracic echocardiogram; *SpO2*, percent blood oxygen saturation; *CSF*, cerebrospinal fluid.

TABLE E2. Patient factors and procedural characteristics according to CSFD placement timing

	Pre-implant CSFD	Post implant prophylactic CSFD	Post implant therapeutic CSFD	*P* value
Demographic characteristics				
Patients	350 (89.7)	19 (4.9)	21 (5.4)	
Age, y	67.5 ± 11.9	65.7 ± 16.6	70.3 ± 10.4	.461
Male sex	239 (68.3)	14 (73.7)	16 (76.2)	.764
Comorbidities, aortic surgical history, preoperative anticoagulant use, and preoperative laboratory values				
ASA Class	3.7 ± 0.51	3.9 ± 0.57	4.1 ± 0.45	.26
Current smoker	88 (25.1)	3 (15.8)	5 (23.8)	.732
Ever smoker	267 (76.3)	8 (42.1)	14 (66.7)	<.01
Previous MI	38 (10.9)	2 (10.5)	4 (19.0)	.46
Congestive heart failure	51 (14.6)	2 (10.5)	3 (14.3)	1
Cerebrovascular disease	20 (5.7)	3 (15.8)	4 (19.0)	.02
Peripheral arterial disease	4 (1.1)	0 (0)	0 (0)	1
COPD	130 (37.1)	2 (10.5)	10 (47.6)	<.05
Diabetes mellitus	51 (14.6)	0 (0)	5 (23.8)	.072
Renal insufficiency	345 (98.6)	18 (94.7)	19 (90.5)	<.05
Any liver disease	12 (3.4)	1 (5.6)	0 (0)	.555
Any previous aortic surgery	158 (45.1)	6 (31.6)	8 (38.1)	.448
Previous nonascending/arch aortic surgery	121 (34.6)	4 (21.1)	8 (38.1)	.48
NOAC	7 (2.0)	0 (0)	2 (9.5)	.142
Warfarin	11 (3.1)	1 (5.3)	0 (0)	.534
Antiplatelet	32 (9.1)	0 (0)	0 (0)	.21
Aspirin	238 (68.0)	11 (57.9)	9 (42.9)	<.05
Platelet count, × 1000/mL	180 ± 75	198 ± 87	167 ± 106	.439
INR	1.2 ± 0.19	1.3 ± 0.22	1.4 ± 0.27	<.01
Serum hemoglobin, g/dL	11.7 ± 1.8	11.8 ± 2.5	10.4 ± 2.6	<.01
TEVAR indication				
TAAA	99 (28.3)	4 (21.1)	6 (28.6)	.85
TAA	104 (29.7)	3 (15.8)	2 (9.5)	.066
Acute dissection	54 (15.4)	7 (36.8)	4 (19.0)	.053
Chronic type B dissection	62 (17.7)	2 (10.5)	2 (9.5)	.586
PAU/IMH	12 (3.4)	2 (10.5)	4 (19.0)	<.01
Post surgical	13 (3.7)	1 (5.3)	0 (0)	.6
TAT	0 (0)	0 (0)	2 (9.5)	<.01
Other	6 (1.7)	0 (0)	1 (4.8)	.534
Urgency				
Elective	216 (61.7)	5 (26.3)	3 (14.3)	<.01
Nonelective	134 (38.3)	14 (73.7)	18 (85.7)	<.0001
TEVAR characteristics				
TEVAR with LSCA coverage	145 (41.4)	9 (47.4)	7 (33.3)	.643
TEVAR without LSCA coverage	124 (35.4)	6 (31.6)	10 (47.6)	.488
Any TEVAR Alone	269 (76.9)	15 (78.9)	17 (81.0)	.955
4-Vessel FEVAR	52 (14.9)	4 (21.1)	4 (19.0)	.597
3-Vessel FEVAR	17 (4.9)	0 (0)	0 (0)	.837
2-Vessel FEVAR	7 (2.0)	0 (0)	0 (0)	1
1-Vessel FEVAR	5 (1.4)	0 (0)	0 (0)	1
Any FEVAR	81 (23.1)	4 (21.1)	4 (19.0)	.955

Data are presented as n (%) or mean ± SD, except where otherwise noted. *P* values corresponding to differences in descriptive statistics were calculated using analysis of variance for continuous variables and Fisher exact test for categorical variables. *CSFD*, Cerebrospinal fluid drain; *ASA*, American Society of Anesthesiologists; *MI*, myocardial infarction; *COPD*, chronic obstructive pulmonary disease; *NOAC*, novel oral anticoagulant; *INR*, international normalized ratio; *TEVAR*, thoracic endovascular aortic repair; *TAAA*, thoracoabdominal aortic aneurysm; *TAA*, thoracic aortic aneurysm; *PAU*, penetrating atherosclerotic ulcer; *IMH*, intramural hematoma; *TAT*, traumatic aortic transection; *LSCA*, left subclavian artery; *FEVAR*, fenestrated endovascular aortic repair.

TABLE E3. Granular description of consecutive CSFD complications

Age, years	Sex	Major comorbidities	Indication	Urgency	CSFD placement timing	Complication(s)	Management	Severity	SCI?	Disposition
77	M	COPD, PAD, CKD	TAAA	Elective	Pre-implant	Headache, CSF leak	Butalbital/ acetaminophen, limited opiates, oral caffeine, hydration	Mild	Yes	Discharge to inpatient rehabilitation, ambulating with assistance
64	M	HTN, chronic pancreatitis, former smoker	TAA	Nonelective	Pre-implant	Headache	Oral caffeine	Mild	No	Discharged home, ambulating
70	M	AF, COPD, PAD	CTBAD	Elective	Pre-implant	Headache	Butalbital/ acetaminophen, oral caffeine, hydration	Mild	No	Discharged home, ambulating
69	F	PAD, CKD, previous repair of DeBakey type 1 dissection	CTBAD	Elective	Pre-implant	CSF leak	Self-limited	Mild	No	Discharge to long-term acute care facility
66	M	HTN, PAD, CVD	CTBAD	Elective	Pre-implant	Headache	Self-limited, transient	Mild	No	Discharged home, ambulating
29	F	HTN, suspected Marfan, previous repair of DeBakey type I dissection	ATBAD	Nonelective	Post implant prophylactic	Headache	Empiric medical therapy for migraine	Mild	No	Discharged home, ambulating
77	M	HTN, CAD, previous MI	TAAA	Elective	Pre-implant	Questionable epidural hematoma	Observation	Severe	Yes	Discharge to skilled nursing facility, ambulating
78	F	HTN, COPD, cirrhosis, former smoker, recent EVAR explant for endoleak	TAA	Nonelective	Pre-implant	Bloody CSF, drain occlusion with progressive bilateral lower extremity weakness, combined IPH/ SAH/SDH	Drain replacement for initial occlusion, nonoperative ICH care	Severe	Yes	Died after withdrawal of care
76	M	CVD, DM, PAD, CKD	TAAA	Elective	Pre-implant	Epidural hematoma (no mass effect or focal deficit)	Drain removal, observation	Severe	No	Discharged home, ambulating

(Continued)

TABLE E3. Continued

Age, years	Sex	Major comorbidities	Indication	Urgency	CSFD placement timing	Complication(s)	Management	Severity	SCI?	Disposition
67	M	DM, PAD, CVD	CTBAD	Elective	Post implant therapeutic	Drain site bleeding resulting in subdural clot without epidural hematoma	Observation	Severe	Yes	Discharged to rehabilitation, residual left lower extremity dorsiflexion palsy
41	M	Childhood AVR twice and repair of aortic coarctation	Other	Nonelective	Pre-implant	Headache	Butalbital/ acetaminophen, limited opiates	Mild	No	Discharged home, ambulating
62	M	Acute blunt polytrauma: sternal and rib fractures, lung laceration, pelvic and thoracic spine fractures	TAT	Nonelective	Post implant therapeutic	Drain fracture/ dislodgement	Fractured drain catheter removed, new drain placed	Moderate	Yes	Discharged to rehabilitation, 2/5 strength in bilateral lower extremities
75	F	CHF, CVD, COPD, DM, PAD, CKD AI	PAU	Nonelective	Post implant therapeutic	Urinary retention	Foley catheter placement	Mild	Yes	Discharged to inpatient rehabilitation with Foley, movement of toes in bilateral lower extremities
62	M	COPD, PAD, severe, previous repair of DeBakey type I dissection	CTBAD	Elective	Pre-implant	Headache, CSF leak	Topical compression, hydration, I.V. caffeine	Mild	No	Discharged home, ambulating
74	M	HTN, PAD	AD	Nonelective	Pre-implant	Headache, CSF leak from inadvertently disconnected drainage tubing	Hydration, flat positioning	Mild	No	Discharged home, ambulating
68	M	HTN, PE, COPD, PAD, former smoker, previous repair of DeBakey type 1 dissection	TAA	Nonelective	Pre-implant	Headache	Butalbital/ acetaminophen, oral caffeine, hydration	Mild	No	Discharged home, ambulating
65	F	COPD, CKD, former smoker	TAAA	Elective	Pre-implant	Headache, CSF leak	Site closure with skin glue, hydration, oral caffeine, NSAIDs, acetaminophen, flat positioning	Mild	Yes	Discharged to rehabilitation with paralysis in bilateral lower extremities

(Continued)

TABLE E3. Continued

Age, years	Sex	Major comorbidities	Indication	Urgency	CSFD placement timing	Complication(s)	Management	Severity	SCI?	Disposition
78	M	PAD, CKD, previous open AAA repair	TAA	Elective	Pre-implant	Headache	Hydration, oral caffeine, flat positioning	Mild	No	Discharged home, ambulating
79	M	CAD, previous MI, PAD	ATBAD	Nonelective	Pre-implant	Spinal headache, CSF leak	Hydration, oral caffeine, flat positioning, direct suture closure of drain site	Moderate	No	Discharged home, ambulating
75	M	COPD, PAD, DM	TAAA	Elective	Pre-implant	Headache, CSF leak	Site closure with skin glue, flat positioning, acetaminophen	Mild	No	Discharged home, ambulating
84	M	HTN, AF, PAD, CKD	ATBAD	Nonelective	Post implant therapeutic	Drain occlusion with bilateral lower extremity weakness	Drain replacement	Severe	Yes	Discharged home, ambulating
57	M	HTN, daily smoker, COPD, PAD, CKD, previous repair of ruptured intracranial aneurysm	ATBAD	Nonelective	Pre-implant	Headache	Butalbital/ acetaminophen, hydration	Mild	No	Discharged home, ambulating
32	F	Marfan, NICM, previous mechanical MVR	CTBAD	Nonelective	Pre-implant	Headache	Butalbital/ acetaminophen, oral caffeine, flat positioning for comfort	Mild	No	Discharged home, ambulating
43	F	HTN, daily smoker, COPD	CTBAD	Elective	Pre-implant	Headache	Self-limited	Mild	No	Discharged home, ambulating
66	F	Poorly controlled DM, CKD	TAA	Nonelective	Pre-implant	Drain occlusion	Drain removal	Moderate	No	Returned to referring hospital, ambulating

CSFD, Cerebrospinal fluid drain; *SCI*, spinal cord ischemia; *M*, male; *COPD*, chronic obstructive pulmonary disease; *PAD*, peripheral artery disease; *CKD*, chronic kidney disease; *TAAA*, thoracoabdominal aortic aneurysm; *CSF*, cerebrospinal fluid; *HTN*, hypertension; *TAA*, thoracic aortic aneurysm; *AF*, atrial fibrillation; *CTBAD*, chronic type B aortic dissection; *F*, female; *CVD*, cerebrovascular disease; *ATBAD*, acute type B aortic dissection; *CAD*, coronary artery disease; *MI*, myocardial infarction; *EVAR*, endovascular aortic repair; *IPH*, intra-parenchymal hemorrhage; *SAH*, subarachnoid hemorrhage; *SDH*, subdural haemorrhage; *ICH*, intracranial hemorrhage; *DM*, diabetes mellitus; *AVR*, aortic valve replacement; *TAT*, traumatic aortic transection; *CHF*, congestive heart failure; *AI*, aortic insufficiency; *PAU*, penetrating atherosclerotic ulcer; *I.V.*, intravenous; *AD*, aortic dissection; *PE*, pulmonary embolism; *AAA*, abdominal aortic aneurysm; *NSAID*, nonsteroidal anti-inflammatory drug; *NICM*, nonischemic cardiomyopathy; *MVR*, mitral valve replacement.

TABLE E4. Patient factors and CSFD complications before and after SCI protocol implementation

	Pre-protocol	Post protocol	OR	*P* value
Demographic characteristics				
Patients	620 (65.5)	326 (34.5)		
Age, y	68.0 ± 12.8	65.4 ± 15.0	0.99	.01
Male sex	428 (69.0)	232 (71.2)	1.1	.558
Comorbidities, aortic surgical history, preoperative anticoagulant use, and preoperative laboratory values				
ASA class	3.7 ± 0.53	3.7 ± 0.57	1	.959
Current smoker	144 (23.2)	91 (27.9)	1.3	.144
Ever smoker	467 (75.3)	225 (69.0)	0.73	.051
Previous MI	85 (13.7)	40 (12.3)	0.87	.511
Congestive heart failure	91 (14.7)	54 (16.6)	1.1	.506
Cerebrovascular disease	76 (12.3)	38 (11.7)	0.94	.802
Peripheral arterial disease	583 (94.0)	312 (95.7)	1.4	.303
COPD	215 (34.7)	123 (37.7)	1.1	.378
Diabetes mellitus	112 (18.1)	50 (15.3)	0.82	.322
Renal insufficiency	136 (21.9)	86 (26.4)	1.3	.182
Any liver disease	23 (3.7)	19 (5.8)	1.6	.176
Any previous aortic surgery	245 (39.5)	128 (39.3)	0.99	.966
Previous nonascending/arch aortic surgery	196 (31.6)	101 (31.0)	0.97	.868
NOAC	6 (1.0)	17 (5.2)	5.9	<.01
Warfarin	21 (3.4)	9 (2.8)	0.82	.634
Antiplatelet	68 (11.0)	26 (8.0)	0.71	.188
Aspirin	374 (60.3)	204 (62.6)	1.1	.529
Platelet count, × 1000/mL	178 ± 75	190 ± 103	1	.067
INR	1.3 ± 0.24	1.2 ± 0.18	0.19	<.01
Serum hemoglobin, g/dL	11.4 ± 2.2	11.8 ± 2.3	1.1	.039
TEVAR indication				
Acute dissection	81 (13.2)	60 (18.4)	1.5	.044
Chronic dissection	72 (11.7)	30 (9.2)	0.77	.277
TAAA	238 (38.8)	67 (20.6)	0.4	<.01
PAU/IMH	36 (5.9)	34 (10.4)	1.9	.018
TAA	120 (19.5)	98 (30.1)	1.8	<.01
TAT	22 (3.6)	13 (4.0)	1.1	.77
Other	28 (4.6)	5 (1.5)	0.33	<.05
Post surgical	17 (2.8)	15 (4.6)	1.7	.191
Hybrid	0 (0)	4 (1.2)	NA	<.05
Urgency				
Elective	355 (57.3)	167 (51.2)	0.78	.093
Nonelective	265 (42.7)	159 (48.8)	1.3	.093
TEVAR characteristics				
TEVAR with LSCA Coverage	225 (36.3)	140 (42.9)	1.3	.059
TEVAR without LSCA Coverage	158 (25.5)	154 (47.2)	2.7	<.01
Any TEVAR alone	383 (61.8)	294 (90.2)	5.8	<.01
4-Vessel FEVAR	157 (25.3)	18 (5.5)	0.17	<.01
3-Vessel FEVAR	43 (6.9)	9 (2.8)	0.38	<.05
2-Vessel FEVAR	28 (4.5)	5 (1.5)	0.33	<.05
1-Vessel FEVAR	9 (1.5)	0 (0)	N/A	<.05
Any FEVAR	237 (38.2)	32 (9.8)	0.17	<.01
CSFD usage and placement timing				
CSFD used	225 (36.9)	165 (50.6)	1.8	<.01
Pre-implant	200 (88.9)	149 (90.3)	1.2	.662
Post implant prophylactic	13 (5.8)	6 (3.6)	0.61	.349
Post implant therapeutic	12 (5.3)	10 (6.1)	1.1	.767

(Continued)

TABLE E4. Continued

	Pre-protocol	Post protocol	OR	*P* value
CSFD complication severity				
Any complication	15 (6.7)	10 (6.1)	0.9	.811
Mild	11 (4.9)	7 (4.2)	0.86	.766
Moderate	1 (0.4)	2 (1.2)	2.8	.424
Severe	3 (1.3)	2 (1.2)	0.91	.918

Data are presented as n (%) or mean ± SD, except where otherwise noted. ORs and *P* values reflect the results of mixed effects logistic regression analysis. *CSFD*, Cerebrospinal fluid drain; *SCI*, spinal cord ischemia; *OR*, odds ratio; *ASA*, American Society of Anesthesiologists; *MI*, myocardial infarction; *COPD*, chronic obstructive pulmonary disease; *NOAC*, novel oral anticoagulant; *INR*, international normalized ratio; *TEVAR*, thoracic endovascular aortic repair; *TAAA*, thoracoabdominal aortic aneurysm; *PAU*, penetrating atherosclerotic ulcer; *IMH*, intramural hematoma; *TAA*, thoracic aortic aneurysm; *TAT*, traumatic aortic transection; *LSCA*, left subclavian artery; *FEVAR*, fenestrated endovascular aortic repair.