# A systematic review of spinal cord injury and cerebrospinal fluid drainage after thoracic aortic endografting

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*Background:* **The use of thoracic endovascular aneurysm repair (TEVAR) is increasing. Similar to open repair, TEVAR carries a risk of spinal cord ischemia (SCI). We undertook a systematic review to determine whether preoperative cerebrospinal fluid (CSF) drainage reduces SCI.**

*Methods:* **PubMed, the Cochrane Library, and conference abstracts were searched using the keywords** *thoracic endovascular aortic repair***,** *cerebrospinal fluid***,** *spinal cord ischaemia***,** *TEVAR***, and** *aneurysm***. Studies reporting SCI rates and CSF drain rates for TEVAR patients were eligible for inclusion. SCI rates across studies were pooled using random-effects modeling. Study quality was evaluated using the Downs and Black score.**

*Results:* **Study quality was generally poor to moderate (median Downs and Black score, 9). The systematic review identified 46 eligible studies comprising 4936 patients; overall, SCI affected 3.89% (95% confidence interval, 2.95.05%- 4.95%). Series reporting routine prophylactic drain placement or no prophylactic drain placement reported pooled SCI rates of 3.2% and 3.47%, respectively. The pooled SCI rate from 24 series stating that prophylactic drainage was used selectively was 5.6%.**

*Conclusions:* **Spinal chord injury is uncommon after TEVAR. The role of prophylactic CSF drainage is difficult to establish from the available literature. High-quality studies are required to determine the role of prophylactic CSF drainage in TEVAR. ( J Vasc Surg 2012;56:1438-47.)**

Thoracic endovascular aneurysm repair (TEVAR) has emerged as an alternative to traditional open repair.<sup>[1](#page-7-0)</sup> Although morbidity and mortality rates are lower with TEVAR, there remains a risk of neurologic complications, including stroke and spinal cord ischemia  $(SCI).<sup>2</sup>$  The precise pathophysiology of SCI after TEVAR is unclear but is probably multifactorial. Contributing factors may include occlusion of multiple intercostal vessels by longsegment stenting, occlusion of the left subclavian or hypogastric arteries, perioperative hypotension resulting in watershed ischemia in the midthoracic spinal cord, and previous abdominal aortic surgery.[2](#page-7-1) SCI may be ameliorated through the use of cerebrospinal fluid (CSF) drainage (CSFD). Experimental studies $3-6$  showed that CSF pressure reductions led to an increase in spinal cord perfusion pressure.

At present, there is little consensus regarding the role of CSFD in TEVAR. Some units routinely use prophylactic CSFD in all patients undergoing TEVAR, whereas others

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<http://dx.doi.org/10.1016/j.jvs.2012.05.075>

rescue CSFD as required. We undertook a systematic review with two aims: to establish the overall incidence of SCI after TEVAR in published series and, if possible, to determine the effect of routine prophylactic CSFD on SCI rates among patients undergoing TEVAR. However, we recognized from the outset that clinical heterogeneity within and between reported TEVAR series, combined with a lack of data regarding SCI risk factors within individual study cohorts, would limit the ability to draw robust conclusions regarding the role of prophylactic CSFD. In particular, it was unlikely that the generation of pooled odds ratios comparing the three possible strategies of no drain, routine drain, or selective drain placement would be appropriate.

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# **METHODS**

The systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.<sup>7</sup> The PubMed and Medline databases were searched for series from 1991 to 2011 reporting outcomes after thoracic aortic endografting. The following search terms were used: *thoracic endovascular aortic repair*, *cerebrospinal fluid drainage*, *spinal cord ischaemia*, *thoracic*, and *aneurysm*. These terms were searched using Boolean operators in five separate blocks:

- Block 1: *thoracic aneurysms* **and** *spinal* **and** *aortic repair*
- Block 2: *thoracic* **and** *aneurysms* **and** *spinal*
- Block 3: *thoracic endovascular* **and** *cerebrospinal fluid*

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Author conflict of interest: none.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest. 0741-5214/\$36.00

<span id="page-1-0"></span>*Reporting (10 items)*

- $\hat{\bullet}$  Is the hypothesis/aim/objective of the study clearly described?
- Are the main outcomes to be measured clearly described in the introduction or methods section?
- Are the characteristics of the patients included in the study clearly described?
- Are the interventions of interest clearly described?
- Are the distributions of principal confounders in each group of subjects to be compared clearly described?
- Are the main findings of the study clearly described?
- Does the study provide estimates of the random variability in the data for the main outcomes?
- Have all important adverse events that may be a consequence of the intervention been reported?
- Have the characteristics of patients lost to follow-up been described?
- Have actual probability values been reported (eg,  $P = .035$  rather than  $P < .05$ ) for the main outcomes, except where the probability value is  $< .001$ ?

*External validity (3 items)*

- Were the subjects asked to participate in the study representative of the entire population from which they were recruited?
- Were those subjects who were prepared to participate representative of the entire population from which they were recruited?
- Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive? *Internal validity (bias) (7 items)*
	- Was an attempt made to blind study subjects to the intervention they have received?
	- Was an attempt made to blind those measuring the main outcomes of the intervention?
	- If any of the results of the study were based on "data dredging," was this made clear?
	- In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?
	- Were the statistical tests used to assess the main outcomes appropriate?
	- Was compliance with the intervention/s reliable?
	- Were the main outcome measures used accurate (valid and reliable)?

*Internal validity (confounding) (6 items)*

- Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?
- Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?
- Were study subjects randomized to intervention groups?
- Was the randomized intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?
- Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?

● Were losses of patients to follow-up taken into account?

*Power (1 item)*

- Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?
- Block 4: *thoracic* **and** *endovascular* **and** *spinal* **and** *paraplegia*
- Block 5: *thoracic* **and** *aneurysms* **and** *paraplegia*

No language restrictions were used. Reference lists from articles obtained through the electronic search were scrutinized for further relevant publications. A manual search was conducted for relevant abstracts presented at the Vascular Society of Great Britain and Ireland, the European Society of Vascular Surgery, and the Society for Vascular Surgery (2000 to 2011). One author (C.S.W.) screened potentially eligible abstracts identified by the systematic review.

Articles were eligible for inclusion if the following criteria were satisfied: case series, case-control study, cohort study, or randomized clinical trial that reported SCI rates (permanent or transient, early or delayed, paraplegia or paraparesis) after elective or emergency TEVAR, including hybrid procedures. Any patient reported to develop permanent or transient or early or delayed paralysis or paraparesis was deemed to have sustained SCI for the purpose of the review.

Only prophylactic CSFD was considered. Thus, data regarding prophylactic CSFD were extracted for three

groups of studies: those reporting that no form of prophylactic CSFD was used, those reporting a policy of routine CSFD placement, and those reporting a policy of selective prophylactic CSFD, whereby drains were placed preoperatively in high-risk patients. Patients who received drains for the treatment of SCI (ie, rescue drains) were not included in the drain group totals from the selective series. We excluded series reporting SCI rates after open thoracic or thoracoabdominal aneurysm repair and studies reporting the results of experiments in animal models.

In addition to publishing their own center's results, a number of units also contributed patients to multicenter reports. Consequently, the analysis was restricted to singlecenter series to avoid double-counting patients reported by the responsible clinical center and as part of a multicenter collaboration.

Data for SCI rates were extracted from the eligible studies and entered into a computerized spreadsheet. Prophylactic CSFD policy (routine, never, or selective) was recorded for each study. When studies reported SCI rates according to placement or otherwise of a prophylactic drain, SCI rates for both subgroups were extracted.

Random-effects models were used to generate an overall pooled rate of SCI after thoracic endovascular interventions.

Heterogeneity was assessed by means of the Cochran  $Q$  test, a null hypothesis test in which values at  $P < .05$ indicate the presence of significant heterogeneity. Heterogeneity, also referred to as *inconsistency*, is a measure of the degree of noncombinability of studies included in a meta-analysis and is calculated as the weighted sum of squared differences between individual study effect sizes and the overall pooled effect estimate. The greater the differences, the more likely it is that significant clinical differences exist among the patient cohorts studied or that significant methodologic differences exist among the individual studies.

Bias was assessed by visual inspection of a funnel plot. Funnel plots exploit the observation that, in the absence of small sample bias, the effect size estimates for small studies should vary to a much greater degree than those from larger studies due to natural random variation. Therefore, plots of sample size against effect size variation should result in funnel-shaped plots. Asymmetry in such plots implies the existence of bias, which is usually publication bias due to nonpublication of small studies with negative results.

The statistical analyses were undertaken using Statsdirect 2.7.8 software (Statsdirect Ltd, Altrincham, UK). The 5% level was taken as significant throughout. Study quality was assessed by means of the Downs and Black score,<sup>[8](#page-8-1)</sup> which uses 27 criteria to evaluate the quality of nonrandomized studies with respect to five quality domains (reporting, external validity, bias, confounding, and power). The scoring was performed by answering all

questions in the checklist, which were scored 0 to 2. Possible total scores range from 0 (poor quality) to 31 (high quality). Full details of the checklist are provided in [Table I.](#page-1-0)

## **RESULTS**

The systematic review identified 15,528 citations, of which 46 were included in the final pooled analysis [\(Fig 1\)](#page-2-0). No randomized trials to date have evaluated the role of prophylactic CSFD in TEVAR. Details of the 46 eligible series are summarized in [Table II.](#page-4-0) Although all 46 reported postoperative SCI rates, only 26 studies documented a clear policy regarding prophylactic CSFD (ie, routine drainage, no drainage, or selective drainage). The eligible studies generally comprised heterogenous cohorts of patients undergoing elective or emergency treatment of a wide range of thoracic aortic pathologies, including dissection, degenerative aneurysm, penetrating aortic ulcer, and traumatic transection, as well as patients undergoing complex hybrid and fenestrated repairs.

**Quality evaluation.** All 46 series were evaluated using the Downs and Black template. The median score was 9 (range, 5-12), indicating that the general quality of the included studies was poor to moderate. The reporting domain, which evaluates factors such as clear statement of aims, reporting of baseline characteristics, outcome definitions and confounding, had a median score of 4 (range, 2-7) of a possible 11.

**Overall SCI rate.** Spinal cord injury was reported by all 46 eligible studies.<sup>9-54</sup> SCI occurred in 206 patients, yielding a pooled incidence rate of 3.88% (95% confidence interval [CI], 2.95%-4.95%). There was evidence of significant heterogeneity (Cochran  $Q = 129.08; P < .0001$ ).



<span id="page-2-0"></span>**Fig 1.** Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram summarizes the systematic review.

The funnel plot was asymmetric on visual inspection [\(Fig 2\)](#page-6-0), and there was statistical evidence of bias (Egger  $=$  $1.40; P < .001$ ).

**SCI after routine prophylactic drainage.** Three studies (404 patients)<sup>[34,44,48](#page-8-3)</sup> reported SCI rates after routine placement of a prophylactic spinal drain. SCI occurred in 12 patients. The pooled rate was 3.2% (95% CI, 1.7%- 5.1%). There was no evidence of heterogeneity (Cochran  $Q = 1.58$ ;  $P = .45$ ). There were insufficient studies to reliably evaluate bias.

**SCI without routine prophylactic drainage.** Eight studies (451 patients) stated<sup>[14,25,27,28,32,38,43,53](#page-8-4)</sup> that no prophylactic drains were placed. SCI occurred in 18 patients. The pooled SCI rate was 3.47% (95% CI, 1.98%- 5.37%). There was no evidence of heterogeneity (Cochran  $Q = 8.34$ ;  $P = .303$ ) or bias (Egger = 1.02;  $P = .18$ ).

**SCI with selective prophylactic drainage.** A policy of selective prophylactic drainage was used in 15 studies (2569 patients)[.15,29,30,33,35,39-42,45,46,49,50,52,54](#page-8-5) All studies reported prophylactic drain placement in patients deemed at high risk for SCI, although definitions of high risk varied. The pooled rate of SCI in this group was 5.60% (95% CI, 4.00%-7.40%). There was evidence of significant heterogeneity (Cochran  $Q = 44.43; P < .001$ ). The funnel plot was skewed (Fig  $3$ ), and there was evidence of bias (Egger = 1.76;  $P = .06$ ). Among the 15 selective series, six studies  $(1168 \text{ patients})^{33,39,46,49,50,54}$  $(1168 \text{ patients})^{33,39,46,49,50,54}$  $(1168 \text{ patients})^{33,39,46,49,50,54}$  reported a breakdown of SCI rates with respect to prophylactic drain placement. SCI occurred in 29 of 424 patients (6.8%) with a prophylactic drain vs 53 of 764 patients (6.9%) without a drain. Random-effects modeling showed there was no significant difference in SCI risk between patients who did and did not have a prophylactic CSFD placed in the subgroup reporting this outcome (pooled odds ratio, 0.67; 95% CI, 0.22-2.08;  $P = .49$ ). There was no evidence of heterogeneity (Cochran  $Q = 8.66$ ;  $P = .07$ ).

#### **DISCUSSION**

Spinal cord injury is a well-recognized complication of open and endovascular thoracic aortic interventions. SCI may complicate up to 20% of open thoracic aortic procedures. Numerous strategies to reduce SCI risk have been devised, including cooling, CSFD, and intercostal vessel reimplantation. The use of prophylactic CSFD in open surgery has been the subject of two meta-analyses.<sup>55,56</sup> Although based on small patient samples, both concluded that prophylactic drainage significantly reduces the risk of perioperative paraplegia or paraparesis. To date, three randomized controlled trials $57-59$  have examined the benefits of lumbar CSFD in open thoracoabdominal aortic aneurysm repairs. The largest and most recent randomized controlled trial, by Coselli et al,<sup>[59](#page-9-2)</sup> reported that prophylactic CSFD significantly reduced the risk of paraplegia (13% vs  $2.6\%$ ;  $P = .03$ ). The role of prophylactic CSFD in endovascular procedures is more contentious. Level 1 evidence that supports the role of CSFD is still lacking in the era of endovascular repairs.

SCI risk after TEVAR is generally lower, although individual case series report rates of between 0% and 20%.<sup>52</sup> Perioperative SCI after thoracic aortic interventions is associated with impaired medium-term survival.<sup>40</sup> It also represents a potentially avoidable burden on health care economies because this complication renders many patients dependent for most activities of daily living. A recent largescale comparison of patients undergoing open and endovascular thoracic aortic procedures in the United States noted that the TEVAR patients had greater comorbidities than the open repair patients, rendering them at increased risk of complications[.60](#page-9-4) TEVAR is now an established component in thoracic aortic therapy. Increasingly, attention must focus on methods to reduce complications after TEVAR.

The current systematic review establishes the overall pooled incidence of SCI after TEVAR. Random-effects modeling yielded a pooled SCI rate of 3.88% (95% CI, 2.95%-4.85%). Two major caveats should be noted:

- First, significant statistical heterogeneity exists among the included studies. This is not surprising, because the sample mixes emergency and elective patients undergoing a range of thoracic aortic procedures covering various aortic lengths to treat a range of pathologic processes. Attempting to refine the sample, for example, by only focusing on single pathologies or elective cases, would have been extremely difficult because most authors only report pooled results from very mixed cohorts.
- Second, the funnel plot for the overall SCI rate is asymmetric [\(Fig 2\)](#page-6-0). No studies are left in the bottom left corner of the plot, where one would expect a number of small series reporting a high SCI rate. This appearance of the plot, together with the statistically significant Egger test for bias, is very suggestive of publication bias. Thus, the pooled SCI rate of 3.7% produced in our metaanalysis may underestimate the true risk of SCI after TEVAR.

The utility of prophylactic CFSD is difficult to establish from the available literature. Analysis of the three studies reporting routine drain placement produced a pooled SCI rate of 3.2% compared with 3.47% among the eight studies in which no drains were placed. The 15 series reporting a selective policy yielded a pooled rate of 5.6%, higher than either of the other two groups. In the subgroup in which SCI rates were reported according to drain placement, prophylactic drain use did not appear to reduce SCI (pooled odds ratio, 0.22-2.08).

We point out, however, that in all of these series, prophylactic CSFDs were placed only in patients deemed at high risk of perioperative SCI. Thus, there is an inherent bias in the analysis, in that the CSFD group was at increased risk of SCI. Given this context, it could be argued that the similar SCI rates achieved in the highrisk and low-risk groups in these studies represent successful use of CSFD. However, the risk of SCI is influenced by a host of factors, among them hypogastric

# <span id="page-4-0"></span>**Table II.** Characteristics of included series







#### **Table II.** Continued.

*CSFD,* Cerebrospinal fluid drainage; *LSA,* left subclavian artery; *MAP,* mean arterial pressure; *SCI,* spinal cord ischemia; *SSEP*, somatosensory-evoked potential; *TAA,* thoracic aortic aneurysm; *TAAA,* thoracoabdominal aortic aneurysm.



<span id="page-6-0"></span>**Fig 2.** Funnel plot shows the spinal cord injury rate after thoracic endovascular aneurysm repair (TEVAR).

artery patency, intercostal vessel occlusion, length of thoracic aorta stented, and previous infrarenal aneurysm repair. The current data are insufficient to allow any corrections for these confounding factors, thus limiting the conclusions that can be drawn from the literature regarding prophylactic CSFD.

CSFD placement is not without complications, which include spinal canal hematomas, neurologic injury, and postdrainage headache, which is the most common reported complication.<sup>61,62</sup> The included studies did not report a systematic evaluation of complications arising from prophylactic drains. The benefit of any intervention must be weighed against the risks. Currently, there are insufficient data to allow meaningful evaluation of the risks vs the benefits of prophylactic CSFDs in TEVAR.

### **CONCLUSIONS**

Overall, the available literature regarding prophylactic CSFD in TEVAR patients is of only moderate quality, as indicated by the Downs and Black scores [\(Table I\)](#page-1-0). Data regarding complications are lacking. The influence of confounding factors is impossible to evaluate. Level 1 evidence from open surgery suggests that prophylactic CSFD is of benefit, but the risks and benefits cannot be accurately estimated from the current available TEVAR literature. An adequately powered clinical trial, in which patients are stratified for pre-existing risk factors, is likely to be the only means by which the role of prophylactic CSFD can be ascertained with reasonable confidence in patients undergoing TEVAR.

## **Table II.** Continued.





<span id="page-7-3"></span>**Fig 3.** Funnel plot shows the spinal cord injury rates in series reporting selective prophylactic drainage.

# **AUTHOR CONTRIBUTIONS**

Conception and design: CW, DH, CC Analysis and interpretation: JC, SW Data collection: CW Writing the article: CW, SW Critical revision of the article: JC, JB, SW Final approval of the article: SW Statistical analysis: SW Obtained funding: Not applicable Overall responsibility: SW

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Submitted Feb 15, 2012; accepted May 16, 2012.