New Experimental Work In Avoiding SCI After TAAA Repair: How Can A Sheep Model Of TEVAR Be Helpful

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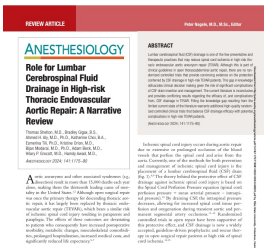
Objectives

- 1. Current Evidence and Best Practice of CSF Drainage in TEVAR in our review
- 2. The need for a randomized controlled clinical trial
- 3. The need for a large animal model of TEVAR

Role for Lumbar Cerebrospinal Fluid Drainage in High-risk Thoracic Endovascular Aortic Repair: A Narrative Review


REVIEW ARTICLE

ANESTHESIOLOGY

Role for Lumbar Cerebrospinal Fluid Drainage in High-risk Thoracic Endovascular Aortic Repair: A Narrative Review

ABSTRACT

Anesthesiology December 2024

Definition of High Risk TEVAR

?

Table 3: Defining High-Risk Patients for SCI in TEVAR

Authors	Year	Defined High-Risk for SCI	High-Risk Definition
Khan et al.[17]	2016	No	NA
Mazzaffi et al.[19]	2018	Yes	≥15 cm coverage, previous aortic repair, poor pelvic perfusion, or occluded abdominal aorta
Suarez-Pierre et al.[18]	2019	No	NA
Yang et al.[26]	2019	Yes	>20 cm coverage, previous thoracic or abdominal aortic repair, bilateral internal iliac artery occlusions
Mousa et al.[16]	2020	Yes	Raw score ≥7.0 from Mousa SCI risk calculator
Aucoin et al.[15]	2021	No	NA
Pan et al.[24]	2022	No	NA
Scott et al.[23]	2021	Yes	Proximal coverage extension zones I-IV and spinal collateral network, ultimately up to surgeon
Weissler et al.[27]	2021	Yes	>20 cm coverage or prior distal aortic repair
Antoniou et al.[25]	2022	Yes	High-risk for preoperative anatomy, aortic device, procedure performance, and postoperative surveillance
Spratt et al.[28]	2022	Yes	>150 mm coverage, planned zone 5 coverage within 5 cm of celiac artery, previous aortic repair, unrepaired infrarenal aneurysm, and surgeon discretion
Zarrintan et al.[29]	2023	No	NA

TEVAR: Thoracic Endovascular Aortic Repair; SCI: Spinal Cord Injury

Shelton T, et al. *The Role for Lumbar Cerebrospinal Fluid Drainage in High-Risk Thoracic Endovascular Aortic Repair: A Narrative Review*; Accepted for Publication Aug 20, 2024

Role of Prophylactic CSF Drainage in TEVAR

YES

Study	Year	Database	Sample Size	Incidence of SCI with CSF Drain	Incidence of SCI without CSF Drain	*P*-value
Weigang et al.[17]	2006	local	31	0%	Unavailable	Not Assessed
Heath et al.[26]	2008	local	121	0%	7.7%	< 0.05
Arnaoutakis et al.[27]	2014	local	90	3.3%	3.3%	1.00
Rodos et al.[28]	2015	local	142	14.1%	18.8%	0.604
Okup-Neto et al.[30]	2017	local	9	0%	Unavailable	Not Assessed
Mazzaffi et al.[19]**	2019	local	102	2%	Unavailable	Not Assessed
Suarez-Pierre et al.[18]	2019	VQI	4,287	1.5%	2.5%	0.022***
Yang et al.[31]	2019	local	130	7.0%	3.4%	0.455
Mousa et al.[16]****	2020	VQI	7,889	1.2% - Moderate-Risk 4.9% - High Risk	1.3% - Moderate-Risk 5.3% - High-Risk	Not Significant – Moderate-Risk Not Significant – High-Risk
Aucoin et al.[15]	2021	VQI	3,406	4.6%	0.7%	Not Assessed
Kitpanit et al.[32]	2021	local	106	3.8%	0%	Not Assessed
Spratt et al.[28]	2022	local	869	7.8%	2.4%	Not Assessed
Loukeli et al.[33]	2023	local	100	7.3%	5.1%	0.660
Zarrintan et al.[29]*****	2023	VQI	2,683	4.3%	7.1%	0.026

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Role of Prophylactic CSF Drainage in TEVAR

Evidence Against CSF Drainage

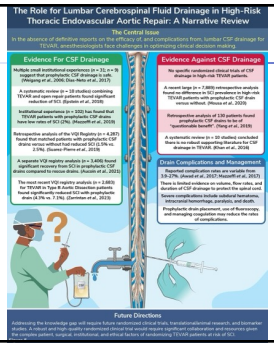
No specific randomized clinical trials of CSF drainage in high-risk TEVAR patients.

A recent large (*n* = 7,889) retrospective analysis found no difference in SCI prevalence in high-risk TEVAR patients with prophylactic CSF drain versus without. (Mousa *et al.*, 2020)

Retrospective analysis of 130 patients found prophylactic CSF drains to be of "questionable benefit". (Yang *et al.*, 2019)

A systematic review (*n* = 10 studies) concluded there is no robust supporting literature for CSF drainage in TEVAR. (Khan *et al.*, 2016)

Shelton T, et al. *The Role for Lumbar Cerebrospinal Fluid Drainage in High-Risk Thoracic Endovascular Repair: A Narrative Review*; December 2024



Conclusion of Review

1. The risks and benefits of spinal drain in TEVAR are undefined
2. Existing studies struggle with sample size issue
3. Definition of high risk TEVAR
4. Variation in surgical technique across the globe
5. Reliance on self-reporting database
6. Spinal drain management protocol without firm basis in clinical evidence

Future Directions

Future Directions

- A need for a randomized controlled clinical trials to answer the clinical question
- A need for a large animal model of TEVAR

Future Directions – Clinical Trial

- 30 Potential Centers in North America and Europe
- Duration: 5 years
- Potential Cost: $9 Million

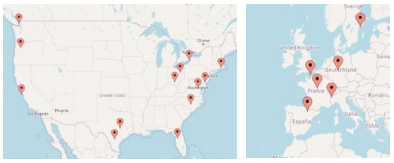


Figure 2: Potential locations of participating centers in North America and Europe

Future Directions – Clinical Trial

Primary Endpoint	Secondary Endpoint	Sample Size
Presence of motor deficit attributable to SCI within 30 days after TEVAR in high-risk patients with prophylactic CSFD versus no drain	Overall mortality rate at 6 months and 1 year after TEVAR in high-risk patients with prophylactic CSFD versus no drain	A sample size of n=1301 (n=391 in the prophylactic CSFD group, n=910 in the no drain group) will achieve 90% power to detect a difference between the group proportions of 0.036

Why the need for a large animal model of TEVAR?

- We believe that ISCI in open and TEVAR is 2 separate diseases with 2 separate mechanisms of action and pathophysiology.

Canine Model of Endovascular Repair

OPEN Endovascular repair and open repair surgery of thoraco-abdominal aortic aneurysms cause drastically different types of spinal cord injury

Hamdy Awad[1,2,*], Esmerina Till[1,2], Gerard Nuovo[3], Hesham Kelani[1], Mohamed Ehab Ramadan[4], Jim Williams[5], Katherine Binzel[1], Jayanth Rajan[1], David Mast[6], Alexander A. Efanov[7], Kareem B. Rasul[1], Sarah Moore[8], Michele Basso[9], Adel Mikhail[9], Mostafa Eltobgy[1], Raphael A. Malbrue[10], Eric Bourekas[3], Michael Oglesbee[11], Valerie Bergdall[12], Michael Knopp[3], Jean-Jacques Michaille[1,13] & Hosam El-Sayed[13]

Nature Scientific Reports - 9 April 2021

Global Response

Dear Hamdy,

I think you are right that these two mechanisms are different, and that maybe many of us have failed to recognize the fundamental difference. The mapping of the pathophysiology might help us to better design the preventive strategy.

Do you have human studies in pipeline too?

Kind regards,

Martin
Martin Björck
Professor (em) in Vascular Surgery
Dep. Surgical sciences, Uppsala University
Senior Editor Eur J Vasc Endovasc Surg
Past president Eur Soc Vasc Surgery
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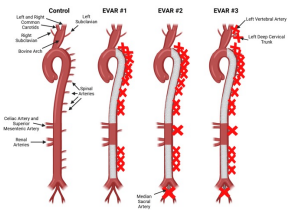
"Interesting work and likely to be very impactful" - Joseph Coselli, MD, @JCoselli_MD

Our Sheep Models

Dr. Kristine Orion and Dr. Joseph Bozzay

Experimental Work



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3D Reconstruction photos

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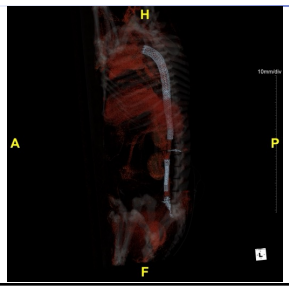
3D Reconstruction photos



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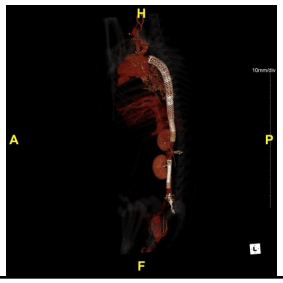

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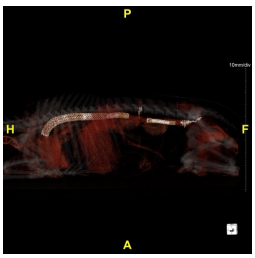

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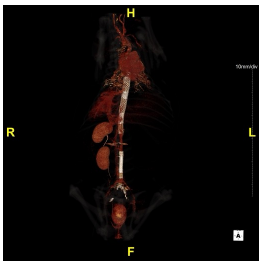

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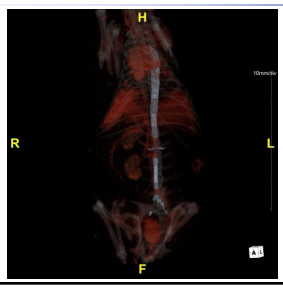

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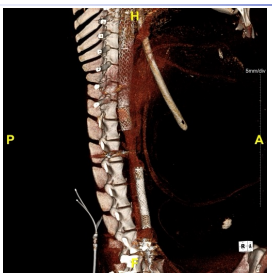

Post Mortem

Why failure?

Our Team

Thank You

- Questions?