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# Stroke, spinal cord ischemia and upper limb ischemia in patients undergoing TEVAR with coverage of the left subclavian artery: a case series study

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## Abstract

**Background:** We performed routine spinal fluid drainage for patients who underwent TEVAR for thoracic aortic pathology together with left subclavian artery coverage, which was needed for achievement of a safe proximal sealing zone. We assessed the occurrence of spinal cord ischemia as well the rate of occurrence of other complications such as stroke, and upper limb ischemia.

**Results:** This was a case series study done between July 2014 and April 2020, in them all the left subclavian artery was covered to ensure a proximal safe seal zone. Routine spinal fluid drainage was done, keeping the spinal fluid pressure < 10–15 mmHg with catheter in place for 48 h. Data was obtained from twenty-three patients who underwent TEVAR for thoracic aortic dissection (73.91%), thoracic aortic aneurysm (21.74%), or ulcer (4.35%). Planning was based upon multi-slice computed tomographic angiography and covering the left subclavian was mandatory to achieve a proximal sealing zone. Technical success was achieved in 100% of cases. 4.35% of patients had three endograft, 56.52% had two endografts, 39.13% had one endograft. All patients lost their radial pulsations immediately after implantation, 8.70% developed post implantation syndrome (fever) that was managed conservatively, 4.35% developed stroke related to the anterior circulation, 4.35% developed signs of spinal cord ischemia. During the follow up, one patient died within 6 h after the procedure due to extensive myocardial infarction (patient was scheduled for CABG after our procedure). 17.40% developed upper limb symptoms that were tolerable and were managed conservatively.

**Conclusion:** By adopting routine spinal cord drainage and pressure monitoring, we can consider not to revascularize the left subclavian artery prior to TEVAR if it will be covered.

**Keywords:** Thoracic aorta, Stroke, Spinal cord ischemia, Spinal drainage, Left subclavian coverage, Revascularization

## Background

Since Dake et al. demonstrated their preliminary results for treating thoracic aortic aneurysms using endovascular stent graft, TEVAR became an essential treatment modality for treating thoracic aortic dissections and

aneurysms [1]. the introduction of this technique has widely replaced open technique and increased the target population to be treated especially ruptured cases [2]. During this procedure it is mandatory to keep perfusion of the innominate artery and the left common carotid artery while maintain antegrade flow of the left subclavian is still controversial [3–5]. In order to have a safe sealing zone the left subclavian artery is covered in almost 40% of cases [6–8]. In 2007, Buth et al. reported a fourfold increase in the incidence of postoperative

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paraplegia with intentional coverage of the left subclavian artery [9]. Also Chung et al. showed an increased risk of stroke by 2.17 fold [10]. But up till now there was no consensus regarding revascularization of the left subclavian artery, other investigators concluded that it is safe to cover the left subclavian artery without revascularization such as, Lee et al., who concluded that it is safe to cover the left subclavian artery without revascularization in patients having bilateral patent vertebrobasilar junctions [11]. Another notion by Maldonado et al., who noted that revascularization of the left subclavian artery carried a higher incidence of cerebrovascular accidents [12]. But what about CSF drainage during TEVAR?. Drainage of CSF has been widely practiced during open thoracic aortic repair, as well it has been accepted and recommended during open repair of thoracic aortic pathology [13, 14].

On the contrary, the role of CSF drainage in TEVAR is less defined due to the lack of randomized studies or high quality observational studies [15, 16].

Although the endovascular option for management of thoracic aortic pathology eliminates the need for aortic cross clamping needed in open surgery but the risk of spinal cord ischemia remains [9, 17].

The reported incidence of spinal cord ischemia and associated complications in TEVAR ranges from 1 to 10% [18–20].

There is a wide range of varying protocols as regard the employment of CSF drainage during TEVAR procedures with no formal guidelines as regard placement of a CSF drain or not [21–23].

However, to date, no consensus has been reached regarding the timing, indication, and use of CSF drainage in patients undergoing endovascular repair of the thoracic and thoracoabdominal aorta [24].

The aim of our study was to record the rate of spinal cord ischemia, stroke, and upper limb ischemia in patients with routine spinal fluid drainage and monitoring in whom there is a necessity to cover the left subclavian artery during deployment of the stent graft in TEVAR procedures.

## Methods

Between July 2014 till April 2020, twenty-three (23) patients have had thoracic aortic lesion that was treated by applying a stent endograft, the anatomic morphologic characteristics of the lesion (the dissection flap was starting at the origin of the left subclavian artery and/or retrograde extension of the dissection plane beyond the safe sealing zone) made it necessary to cover the left subclavian artery to achieve a safe sealing zone (presence of 2 cm of healthy aortic wall for proximal sealing). All patients were referred due to suspicion of thoracic aortic pathology and were treated on elective basis.

All patients were subjected to careful history taking, examination, routine preoperative laboratory investigations including echocardiogram, cardiologic and anesthesiologic assessment. We excluded patients with history of CABG using the internal mammary artery to avoid occurrence of myocardial infarction due to decreased flow in this internal mammary due to blockage of the left subclavian artery. Informed consent was obtained from patients for data collection and for the procedure as is standard according to the local institutional review board's approval (IRB 00006379).

## Pre-interventional imaging and landing zones

The decision of intervention was based upon a multi-slice contrast enhanced computed tomography with three-dimensional reconstruction. The scans of patients were studied using the OsiriX software ([www.osirix-viewer.com](http://www.osirix-viewer.com)) to identify the proximal and distal landing zones necessary to cover the whole pathology, the diameter and length of the aortic segment needed to be covered and the diameter of both common femoral arteries to determine the best access site for the delivery system. Endografts were oversized by 10–20% according to the pathology needed to be treated.

Proximal landing zone was identified using “TEVAR reporting standards” made by “Society for Vascular Surgery Ad Hoc Committee” [25].

## Pre-interventional spinal drainage

We adopted a routine spinal drainage protocol. A spinal catheter was inserted, and initially 10 ml were drawn slowly upon insertion of the catheter, another 10 ml were drawn slowly upon deployment of the stent graft. We always kept CSF Pressure < 10–15 mmHg.

## Procedure

After spinal catheter insertion, all patients were subjected to general endotracheal anesthesia, exposure of the right or left common femoral artery was done surgically according to the planned access site. A 6F sheath was inserted in the common femoral artery through which a hydrophilic 0.035 guide wire was positioned in the ascending aorta, upon which a pig tail supporting catheter was advanced. We exchanged the hydrophilic wire with an extra stiff one (Lunderquist®, Cook Medical).

Another 6F sheath was inserted through a right brachial access, through which a diagnostic catheter is advanced over a hydrophilic wire and positioned in the arch of the aorta for angiography.

The femoral sheath was exchanged with the endograft delivery system (Zenith TX2 or Zenith Alpha, COOK MEDICAL), the system was advanced to the arch of aorta, angiography was done to identify the proximal

sealing zone (zone 2) with origin of the left subclavian arising from it. Deployment of the endograft was done under fluoroscopy to ensure perfect positioning.

Completion angiography was done, and according to the preoperative plan another stent could be applied with attention to the distal seal zone.

#### Post procedural care and follow up

Patients were awakened checked for signs of stroke, upper limb ischemia, spinal cord ischemia. Then were transferred to intensive care unit for close observation, with the spinal catheter in place to continue monitoring of spinal fluid pressure keeping it < 10–15 mmHg.

The catheter was left in place for 48 h and patients were followed up neurologically for development of weakness of the lower limbs and drainage was done then.

Follow up computed tomographic angiography was done at two month and 6 months for follow up.

Technical success was considered when completion angiography showed precise deployment of the stent graft as planned with complete exclusion of the target pathology (covering of the proximal tear with no type 1a endoleak, exclusion of the aneurysm or ulcer). Freedom from procedure related complications and the need for reintervention was considered as a clinical success.

All procedures were done by skilled vascular surgeons with endovascular capabilities and experience.

#### Results

This was a case series study with data obtained from 23 patients with demographics shown in Table 1, from the period of July 2014 till April 2020, patients underwent placement of an aortic endograft to treat a thoracic aortic pathology (Table 2) either dissection or aneurysm.

From the five patients with coronary artery disease only one has had CABG not using the internal mammary as a graft.

**Table 1** Patient demographics

	Number	%
Sex		
Male	22	95.65
female	1	4.35
Age (mean $\pm$ SD)	52.95 $\pm$ 6.35	
Co-morbidities		
Hypertension	21	91.30
Diabetes mellitus	9	39.13
Coronary artery disease	5	21.74
stroke	1	4.35
End stage renal disease	1	4.35

**Table 2** Thoracic aortic pathology

Aortic pathology	Dissection	Aneurysm	Ulcer
Number	17 (73.91%)	5 (21.74%)	1 (4.35%)

Exposure of the left common femoral artery was done in 18 patients (78.26%), while the other 5 (21.74%) patients, we did expose the right common femoral artery. The whole procedure time ranged from 50 min to two hours with a mean time of 85 min. Patients were transferred to the intensive care unit post procedural. All procedures were uneventful except for one patient, in whom the proximal sealing zone was not achieved and another endograft was inserted to achieve this goal immediately.

Three endograft stents were used in one patient (4.35%), two endograft stents were used in 13 patients (56.52%), and only one endograft stent was used in the rest of patients (39.13%). The choice of the number of stents were based upon preoperative planning to cover the whole thoracic aortic pathology.

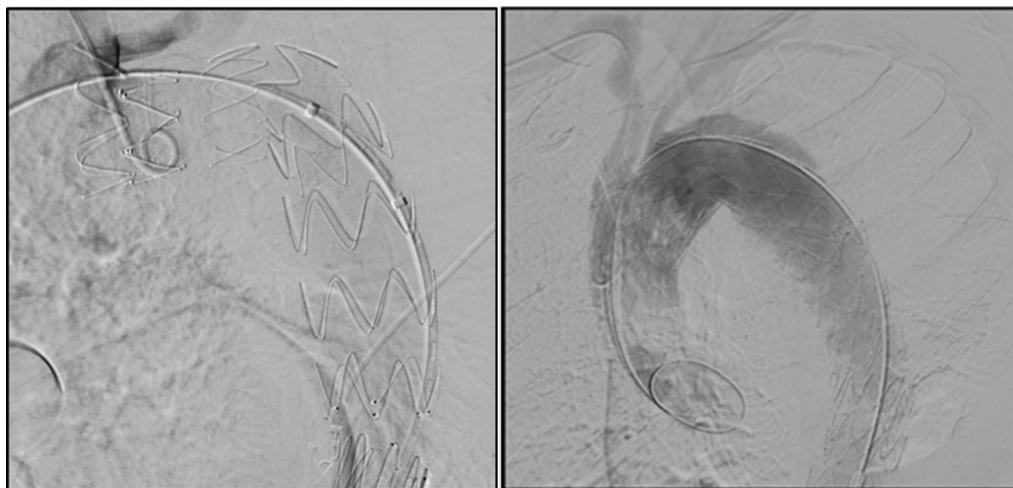
Technical success was achieved in 100% of cases (Fig. 1).

Patients were transferred to the intensive care unit fully conscious, with no signs of spinal cord ischemia. All patients had lost their left radial pulsations, with slight coldness of the left upper limb but with full motor power.

Patients were observed in the intensive care unit for 48 h with the spinal catheter in place keeping the CSF pressure < 10–15 mmHg. As regard the adverse events (Table 3), only one patient developed signs of Spinal cord ischemia after four hours of the procedure then this patient developed severe chest pain then arrested with failure to resuscitate him (the patient died 6 h after the procedure). This patient had a thoracic aortic aneurysm, his preoperative cardiological assessment showed an ejection fraction of 35% with multiple segments of segmental wall motion abnormalities, and his pre-procedural coronary angiography showed multivessel disease for CABG, and cardiac surgery opinion was to postpone the bypass till after treatment of his aneurysm.

Two patients (8.70%) developed post implantation syndrome, fever that was managed conservatively and subsided within two weeks from the procedure.

Neurological assessment of patients was done to assess for development of stroke or not. All patients did not show any sign for development of stroke either related to the anterior or posterior circulation except for one patient who developed left sided hemiparesis three months after the procedure. This patient was investigated and was found to have minute infarcts in the right temporal and parietal lobes. This was a stroke



**Fig. 1** The left subclavian artery was covered during deployment of a thoracic endograft

**Table 3** Major adverse events

	Major adverse events	Remarks
Death	1 (4.35%)	The same patient, two endografts were deployed in this patient
Spinal cord ischemia	1 (4.35%)	
Stroke	1 (4.35%)	
Acute upper limb ischemia	0 (0%)	
Total	2 (8.70%)	

related to the anterior circulation. The patient was managed conservatively, and his symptoms improved.

As regard the upper limb symptoms, immediately after deployment of the endograft, the patients lost their left radial pulsations. After the patient was awakened, his left upper limb was examined for signs of acute ischemia. All patients did not complain of pain, showed good power of movement comparable to the right side, with slight temperature difference. During follow up, left upper limb symptoms were noted in four patients (17.40%) in the form of upper limb claudication or tingling sensation upon elevation of the upper limb. These upper limb symptoms were tolerable, were managed conservatively. Conservative management was in the form of Cilostazol which is an antiplatelet and vasodilator together with Naftidrofuryl which is a vasodilator drug, both are used in case of claudication and chronic limb ischemia.

Follow up contrast enhanced computed tomography was done after two and six months, showed no signs of endoleak (Fig. 2). The origin of the left subclavian from the arch of aorta was not visualized in three patients

(3/22) (13.63%), with refilling of the distal part of the left subclavian.

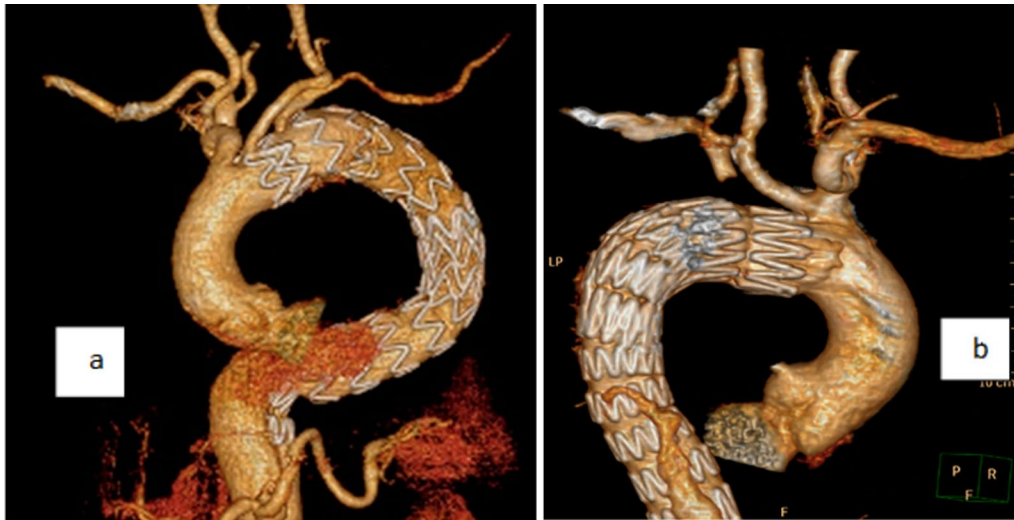
**Discussion**

To achieve a successful TEVAR procedure, we must have an adequate proximal seal zone, in one third of the patients this seal zone will not be reached unless we covered the left subclavian artery [8]. But what about the complications related to such maneuver? It is the same with spinal drainage during TEVAR procedures, CSF drainage has proven its efficacy during open surgical repair of thoracic aorta but with TEVAR, it is still under studying. By reviewing literature, we found lack of clear evidence on either spinal fluid drainage or revascularization of the left subclavian artery in the prevention of both spinal cord ischemia and stroke, The Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS) on management of Descending Thoracic Aorta Diseases stated that it should be considered giving it level C evidence, and grade IIa recommendation [26].

In this case series there was a necessity to cover the left subclavian artery to achieve a safe sealing zone. We adopted a policy of routine spinal catheter placement and monitoring of spinal fluid pressure keeping it below 10–15 mmHg. We recorded the occurrence of spinal cord ischemia, stroke, and upper limb ischemia in this case series and we found that 0% of our patients developed acute upper limb ischemia, 4.35% of patients developed stroke related to the anterior circulation 3 months post-procedure, and 4.35% developed signs of spinal cord ischemia.

The rate of spinal cord ischemia during TEVAR, though it is less than open surgery, but it ranges from 3 to 5% [27, 28].





**Fig. 2** 6 months follow up showing the left subclavian covered with the endograft. **a** patient with two endografts. **b** Patient with three endograft, the origin of left subclavian was not visualized white arrow, **c** a patient with a single endograft, **d** a patient with two endografts with non-visualization of the origin of the left subclavian artery

Mazzeffi et al., performed routine spinal fluid drainage in high risk patients undergoing TEVAR and the overall rate of paraplegia was 2% [29].

In the study by Suarez-Pierre et al., which was done over 4287 patients who underwent TEVAR it was found that the rate of spinal cord ischemia was 2.5% in patients who underwent TEVAR without spinal drainage versus 1.5% in patients with spinal drainage [30].

Some adopted a selective protocol for spinal fluid drainage keeping it to the high risk group for developing spinal cord ischemia to spare the low risk group the complications of spinal drainage [31, 32]. But the role of this adjunctive procedure is less defined due to the lack of high quality observational evidence or randomized studies [15, 16].

There is a general agreement that patients with focal descending thoracic pathology and can be treated with short endograft (< 15 cm) are at lower risk of spinal cord ischemia [33, 34]. While the EUROSTAR registry showed increased incidence of spinal cord ischemia in patients without revascularization of the left subclavian artery versus patients who underwent prior revascularization (8.4% vs 0%;  $P=0.049$ ) [9].

In our study the incidence of spinal cord ischemia was 4.35% with coverage of the left subclavian artery and routine spinal fluid drainage. On the contrary Maldonado et al. reached a conclusion that with covering the left subclavian artery, there is no increased risk of spinal cord ischemia or stroke if a selective revascularization strategy was adopted [12].

As for left subclavian artery coverage, in the beginning it was mandatory to revascularize the left subclavian artery prophylactically if it will be covered during TEVAR procedures [35]. But this did not become a common practice. In the “meta-analysis by Rizvi et al.,” there was a low-quality evidence suggesting that covering the left subclavian artery is associated with significant increase in arm ischemia, vertebrobasilar ischemia, and possibly spinal cord ischemia and anterior circulation stroke [36].

Other studies showed that covering the left subclavian artery during endograft deployment is well tolerated without a revascularization procedure and carries no additional morbidity [37–39].

In the series by Antonello et al. for treating traumatic descending thoracic aortic transection, intentional coverage of the left subclavian artery without revascularization, it was found that patients did not develop signs of vertebrobasilar insufficiency, paraplegia, or stroke [40].

Another meta-analysis comparing the outcomes of intentional coverage of the left subclavian artery during TEVAR procedures with or without revascularization, showed nonsignificant trends with revascularization in preventing stroke and spinal cord ischemia [41].

Delafontaine et al. found in his retrospective analysis of the “Nationwide Inpatient Sample Database” that the rates of spinal cord ischemia and upper extremity ischemia were similar between patients who underwent revascularization of the left subclavian artery versus those without while the peri-operative cardiac complications, stroke, pulmonary complications were significantly

higher in patients who underwent TEVAR with left subclavian artery revascularization [42].

In is known that the overall incidence of stroke during TEVAR ranges from 3.2 to 6.2% [43]. In our study the rate of stroke was 4.35%, which was related to the anterior circulation and occurred after 3 months of the procedure.

As for upper limb ischemia, in our study 0% of patients had upper limb ischemia. While Youssef et al., concluded that covering the left subclavian artery without revascularization was justifiable in their cohort. The study included 40 patients who underwent TEVAR with complete coverage of the left subclavian during the procedure, only 2.5% developed critical upper limb ischemia that was in need of revascularization by transposition of the left subclavian artery, 2.5% developed anterior spinal artery syndrome, and none developed new neurological symptoms during follow up [44].

In a meta-analysis of 1161 patients of whom 444 underwent revascularization of the left subclavian artery versus 717 who did not, it was found that revascularization was associated with a similar risk of stroke (OR 0.70, 95% CI 0.43–1.14,  $P=0.15$ ), spinal cord ischemia (OR 0.56, 95% CI 0.28–1.10,  $P=0.09$ ), and mortality (OR 0.87, 95% CI 0.55–1.39,  $P=0.56$ ) compared with no revascularization [45].

Varkevisser et al. in their analysis of 2346 cases from the “National Surgical Quality Improvement Program registry” found that left subclavian artery revascularization was not associated with lower incidence of stroke [46].

## Conclusions

Revascularization of the left subclavian artery is a procedure that carries an increased rate of morbidity, and it is done to decrease the risk of stroke or spinal cord ischemia. But as we can see from the above results and discussion that the benefit of this procedure is still debatable, as well as the need for routine prophylactic spinal fluid drainage, using either methods have a class c evidence recommendation which is not backed up by randomized controlled studies. The need for these studies is mandatory to end up the debate.

## Abbreviations

CABG: Coronary artery bypass graft; CSF: Cerebrospinal fluid; TEVAR: Thoracic endovascular aorta repair.

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## Authors' contributions

MR was involved in the study design, collection, analysis, and interpretation of data. Also, writing and revising and approving the final paper draft. MI was involved in study design, collection of data. Also, revision and approval of the

final paper. KG was involved in data collection and revising and approving the final paper draft.

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## Availability of data and materials

The data sets used and/or analyzed during this study will be available from the corresponding author on reasonable request.

## Declarations

### Ethics approval and consent to participate

We had the approval of the ethics committee for research of general surgery department, faculty of medicine, Ain shams university (IRB 00006379). All patients were consented for sharing the data in a scientific research.

### Consent for publication

Not applicable.

### Competing interests

The authors declare that they have no competing interests.

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