**Early outcomes after Left Subclavian Artery revascularisation in association with Thoracic Endovascular Aortic Repair.**

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**Abstract**

*Background*

Approximately 40-50% of patients undergoing Thoracic Endovascular Aortic Repair (TEVAR) require left subclavian artery (LSA) coverage in order to achieve an adequate proximal landing zone. LSA coverage has been associated with increased risk of strokes, spinal cord and left arm ischaemia. Despite this, routine prophylactic LSA revascularisation remains controversial. Better understanding of outcomes following LSA revascularisation is needed in order to balance associated risks against potential benefits.

*Methods*

70 LSA revascularisation procedures, performed at a tertiary hospital between 2004-2015, were retrospectively reviewed. Perioperative and 30-day outcomes data were analysed in patients undergoing staged and simultaneous LSA revascularisation with TEVAR. Outcomes data were censored at point of TEVAR for those who underwent staged procedures so as to identify revascularisation-related outcomes.

*Results*

46 (66%) carotid-subclavian bypass, 17 (24%) carotid-carotid-subclavian bypass and 7 (10%) aorto-inominate-carotid-subclavian bypass procedures were performed. Median age was 69 years and majority of patients were male (67%). 29 (41%) of the revascularisation procedures were staged prior to TEVAR with a median staging interval of 46.5 days. There were no strokes or mortalities following LSA revascularisation procedures alone. Three (10%) minor complications occurred including a seroma, a haematoma and a temporary neuropraxia.

*Conclusions*

Separation of complications following LSA revascularisation, from those resulting from the associated TEVAR procedure, can be fraught with difficulty. Early outcomes data from 29 patients who underwent LSA revascularisation in isolation indicate that the procedure is safe with low complication rates.

**Introduction**

Thoracic Endovascular Aortic Repair (TEVAR) is gradually overtaking open approaches in the management of pathologies affecting the descending thoracic aorta.1,2 This change in practice has been supported by evidence of reduced early complications and mortality rates after endovascular repair of thoracic aortic aneurysms, type B aortic dissections and traumatic aortic injuries.3-5 Approximately 40-50% of patients undergoing TEVAR require coverage of the left subclavian artery (LSA) in order to achieve an adequate proximal landing zone during stent deployment.6,7 The LSA contributes significantly to perfusion of the left arm, spinal cord and the posterior circulation of brain. The risks associated with LSA coverage during TEVAR has been well characterised in literature and they include increased risk of strokes, spinal cord ischaemia and left arm ischaemia. There is also evidence of a risk reduction following LSA revascularisation in these patients. 6,8,9

Current guidelines from the Society of Vascular Surgery recommend routine revascularisation in cases where the LSA is covered during TEVAR, although this is admittedly based on weak evidence.10 There are also proponents of selective LSA revascularisation in patients at higher risk of complications from LSA coverage. These include patients with dominant left vertebral arteries, incomplete circle of Willis, left arm arterio-venous fistula and those with existing left internal mammary artery – coronary circulation bypass.11 The decision to revascularise the LSA is a balance of risks, and the risk of neurological complications following LSA coverage needs to be weighed up against risk of complications from the revascularisation procedure. Adequate understanding of outcomes following LSA revascularisation is therefore crucial to such decision-making. Outcomes data following LSA revascularisation procedures are very limited and the risk profile of LSA revascularisation, in the context thoracic aortic pathology, remains poorly understood. This study reports our experiences and early outcomes following LSA revascularisation in patients undergoing TEVAR procedures at a tertiary referral institution.

**Patients and methods**

*Study design*

All consecutive LSA revascularisation cases were identified from operating theatre and procedure records and retrospectively reviewed. Data pertaining to patients’ demographics, medical history, drugs history, operative procedure, imaging reports and 30-day perioperative outcomes were collated from clinical notes and the hospital’s electronic records system. Outcomes data for all the LSA revascularisation procedures were reported. Patients who underwent revascularisation procedures separately from their TEVAR procedures represented the group of interest for the study. Outcomes data for staged LSA revascularisation procedures (prior to TEVAR) were reported up to 30 post-operative days but censored at the time of TEVAR in order to capture revascularisation-related outcomes only. Outcomes of interest were 30-day mortality, morbidities and re-interventions.

*Preoperative preparation and revascularisation decision*

All patients undergoing TEVAR with anticipated LSA coverage were imaged pre-operatively via Computed Tomography Angiography (CTA) +/- Colour duplex ultrasound scan in order to assess the anatomy and pathology of the aorta and head/neck vasculature. Decision to revascularise the LSA and the choice of procedure was made by a multidisciplinary team of vascular surgeons and interventional radiologists based on assessment of individual patients’ risk factors and potential benefits from the procedure. Patients undergoing elective TEVAR with LSA coverage, who were perceived to be at high risk of brain, spinal cord or left arm hypoperfusion, were scheduled for prophylactic LSA revascularisation (staged) or simultaneous LSA revascularisation during their TEVAR procedures. In emergency cases, LSA revascularisation was performed at the discretion of the operating surgeon.

*Procedures and perioperative care*

LSA revascularisation procedures performed include aorta-inominate-left common carotid-left subclavian artery bypass (AICSB), right carotid-left carotid-left subclavian artery bypass (CCSB) and left carotid-left subclavian artery bypass (CSB). The procedures were chosen based on the aortic arch vessels requiring coverage for achievement of an adequate landing zone. Proximal landing zones were defined based on the Ishimaru classification system12. The surgical procedures were performed according to previously described techniques13 All patients were assessed preoperatively for the presence of a transcranial doppler (TCD) acoustic window. Intraoperative monitoring for middle cerebral artery hypoperfusion was performed in all suitable patients. All patients, except those already on long-term anticoagulation or where contraindicated, were commenced on lifelong anti-platelet therapy postoperatively. Patients with suspected neurological complications were assessed by a neurologist post-operatively and all necessary imaging performed.

**Results**

*Patient demographics and procedures*

70 patients underwent LSA revascularisation in association with thoracic aortic surgery, over a 12-year period (2004 – 2015) at our institution. The majority of patients were male (67%) and the median age at LSA revascularisation was 69 (IQR 60-76). Main risk factors for aortic diseases were hypertension, smoking and dyslipidaemia. Majority of the procedures were performed electively (83%) Indications for TEVAR with LSA coverage were thoracic aortic aneurysms (38%), Chronic type B dissections (26%), thoracoabdominal aneurysms (16%), Acute type B dissections (10%) and type A dissection (6%). 29 (41%) of the LSA revascularisations were staged prior to TEVAR thus allowing observation of revascularisation-specific outcomes. The remaining 41 (59%) had simultaneous TEVAR and LSA revascularisation. Patient demographics and indication for TEVAR for both groups are described in Table 1. All of the staged revascularisation procedures were performed electively. Median interval between LSA revascularisation and TEVAR for staged patients was 46.5 days (IQR 28-68). Most patients required LSA coverage only (proximal landing zone 2; 55%) while the remaining required additional coverage of the left common carotid artery (proximal landing zone 1; 30%) and the innominate artery (proximal landing zone 3; 15%). In line with the number of arch vessels covered, the most common procedures performed were CSB (66%) followed by CCSB (24%) and AICSB (10%). Table 2 summarises the procedure details.

*Outcomes*

There were no strokes, spinal cord ischaemia or deaths following LSA revascularisation alone among the staged cases. All grafts remained patent after 30 post-operative days. There were three complications (10%). One patient developed a seroma that was managed with antibiotics. Another patient developed a hoarse voice (likely secondary to neuropraxia of the recurrent laryngeal nerve). This resolved prior to discharge. The last patient had neck haematoma that was managed conservatively. All patients experienced full recovery prior to their TEVAR procedures. Conversely, there were four mortalities, one paraplegia, one stroke and three haematomas following 41 simultaneous LSA revascularisation and TEVAR. Two patients died of myocardial infarction, one developed pneumonia and died of sepsis and the last patient died following mesenteric ischaemia. Two of the haematoma cases affected the neck wounds and one patient required re-intervention in theatre for haemorrhage control. The third haematoma occurred in the groin and also required re-intervention in the operating theatre. The postoperative complications are summarised in table 3. While the study focused on early outcomes, two patients were noted to develop graft infection at three and 18 months post-operatively thus requiring graft removal.

**Discussions**

LSA revascularisation in TEVAR patients represent a balance of complications risks from the additional procedure, against risks of neurological complications associated with LSA coverage. However, the risks and outcomes associated with LSA revascularisation in the context of TEVAR is poorly understood. A vast majority of available evidence in this area come from retrospective studies of revascularisation in the context of occlusive LSA disease. Outcomes from these studies are not always relevant to TEVAR patients due to differences in procedures and risk profiles of the patients studied. This study set out to report 30-days perioperative outcomes following LSA revascularisation in association with TEVAR at a single tertiary institution. Among 70 reviewed LSA revascularisation procedures, 29 were performed separately from the TEVAR thus allowing observation of outcomes associated with the revascularisation procedure rather than those secondary to TEVAR. Evidence from these 29 patients indicates a low early complications rate of 10%. The observed complications were also relatively minor or transient. Notably, there were no strokes or mortality following the LSA revascularisation procedures.

Separation of LSA revascularisation-related complications from those resulting from the associated TEVAR procedure can be fraught with difficulty. This is particularly pertinent to the patients who undergo simultaneous revascularisation and TEVAR procedures. The nature of the observed complications (strokes and mortalities) among these patients suggest that they are likely due to the TEVAR procedures rather than the LSA revascularisation, with the exception of the two neck haematomas reported within this group. There are limited studies to which our findings can be compared due to differences in procedures performed, study methodologies and durations of follow-up. A recent study, by Saouti et al, of LSA revascularisation outcomes among 51 patients who underwent TEVAR with LSA coverage reported an overall complications rates of 22.6%. Majority of the complications reported were nerve injuries (15%). They reported no strokes or deaths14. Complications from TEVAR could not be separated from those of LSA revascularisation in this study. Also, varied follow-up periods and procedures make comparisons difficult.

 Other available studies have focused on comparison of outcomes after TEVAR procedures with and without LSA revascularisation with little emphasis on outcomes specifically associated with the LSA revascularisation procedure.11,15,16 Nerve injuries, especially phrenic nerve injuries, have also been commonly reported in these studies. Furthermore, a meta-analysis of complications associated with LSA revascularisation among TEVAR patients reported a phrenic nerve injury rate of 4.40% (CI: 1.60%-12.20%).9 No phrenic nerve damage was recorded among the patients reviewed in our study. Numerous studies have investigated outcomes following CSB or Carotid-Subclavian transposition (CST) procedures in the context of occlusive LSA disease with reported complication rates ranging from 8-23% and Stroke rates up to 10.8%.13,17-20 Complications, especially those secondary to occlusive or embolic phenomena, cannot be directly extrapolated from patients with occlusive LSA disease to TEVAR patients. The underlying LSA disease and the intraoperative endarterectomy among the former patients can potentially predispose them to higher complication rates.18 Also, CST accounts for majority of the procedures performed in these studies.

This study is limited by the retrospective approach to data collection and small sample size. However, focus on the window between LSA revascularisation and TEVAR procedures allowed for specific identification of complications associated with the LSA revascularisation procedure alone. The aim of the study was to identify early post-operative outcomes, late complications of the procedure were therefore not captured. However, the risk of longer term complications does exist. For example, two of the CSB grafts required removal at three and 18 months after the initial operation due to infection. This highlights that a risk of future graft infection exists and the LSA revascularisation graft should be monitored together with the routine surveillance of the TEVAR endograft.

In conclusion, our experience indicates that LSA revascularisation in patients undergoing TEVAR is associated with low complication rates. However, a longer term risk of graft infection exists. Current research priorities include further definition of the risk profile and risk-reduction associated with LSA revascularisation in order to guide patient selection and help establish ideal revascularisation protocols.

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Table 1: Patient demographics and preoperative details

|  |  |  |
| --- | --- | --- |
| **Variable** | **Staged LSA revascularisation (N=29)****No (%)** | **Simultaneous LSA revascularisation (N=41)****No (%)** |
| Age, median (IQR) | 70 (62-77) | 69 (60-76) |
| Male | 20 (79) | 30 (73) |
| **Risk factors & comorbidities** |  |
| Hypertension | 19 (66) | 26 (63) |
| Myocardial Infarction | 7 (24) | 7 (17) |
| COPD | 5 (17) | 4 (10) |
| Smoking history | 18 (62) | 31 (76) |
| Diabetes Mellitus | 3 (10) | 5 (12) |
| Dyslipidaemia | 14 (48) | 21 (51) |
| ASA, median (IQR) | 3 (2-4) | 3 (2-4) |
| Elective surgery | 29 (100) | 29 (71) |
| **Indications for TEVAR** |  |
| Acute type A dissectionAcute type B dissection | 0 (0)2 (7) | 2 (5)5 (12) |
| Chronic type B dissection | 11 (38) | 8 (20) |
| Thoracic aortic aneurysm | 10 (34) | 18 (44) |
| Thoracoabdominal aneurysmTrauma | 6 (21)0 (0) | 6 (15)2 (5) |

COPD: Combined Obstructive Pulmonary Disease; ASA: American Society of Anaesthesiology grade.

Table 2: Indications for LSA revascularisation and procedures performed

|  |  |
| --- | --- |
|  | **No (%)** |
| **Proximal landing zone** |
|  0 | 10 (15) |
|  1 | 21 (30) |
|  2 | 38 (55) |
| **Procedure** |  |
| Carotid-Subclavian bypass  | 46 (66) |
| Rt Carotid-Lt Carotid-Lt Subclavian artery bypass | 17 (24) |
| Aorta-Inominate-Lt Carotid-Lt Subclavian artery bypass  | 7 (10) |

Table 3: Postoperative complications

|  |  |  |
| --- | --- | --- |
|  | **LSA revascularisation****N=29 (%)** | **Simultaneous LSA revascularisation & TEVAR****N=41 (%)** |
| Mortality | **0** | 4 (10) |
| Stroke | **0** | 1 (2) |
| Spinal cord Ischaemia (SCI) | **0** | 1 (2) |
| Haematoma | **1 (4)** | 3 (7) |
| Hoarse voice(temporary neuropraxia) | **1 (4)** | 0 |
| Seroma  | **1 (4)** | 0 |
| **\*** 2 grafts required removal at 3 and 18 months for infection;  |