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## Best evidence topic - Aortic and aneurysmal

# Is it safe to cover the left subclavian artery when placing an endovascular stent in the descending thoracic aorta?

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### Summary

A best evidence topic in cardiac surgery was written according to a structured protocol. The question addressed was whether the left subclavian artery may be safely covered with a descending thoracic aortic stent without a prior carotid-subclavian artery bypass or transposition procedure. Altogether 2612 abstracts were identified. Forty-five non-randomized control trials and 213 non-controlled papers were found using the reported search and all these were read in full to search for coverage of the left subclavian artery. From these papers, 20 represented the best evidence to answer the clinical question. The authors, journal, date and country of publication, patient group studied, study type, relevant outcomes and results of these papers are tabulated. We identified 20 studies with more than 10 cases of left subclavian artery coverage without prior revascularisation. Aggregating the data from all these studies we found 498 covered left subclavian arteries. Complications included 13 strokes (2.6%), 8 cases of paraplegia or paraparesis (1.6%) and 6 endoleaks due to subclavian backflow (1.2%). Of note there were 51 cases of ischaemia or other symptoms attributable to poor blood flow (10%), which resulted in 20 post-procedural revascularisations (4%). In three studies the mean pressure drop in the left arm was between 36 and 48 mmHg after left subclavian occlusion. We conclude that coverage of the left subclavian artery has a low, but not insignificant, incidence of side-effects. This incidence must be balanced with the urgency of the procedure and may be acceptable in emergency or salvage situations. However, in non-emergency cases we recommend that the carotid arteries, the vertebral arteries and the Circle of Willis are fully assessed by tests such as duplex ultrasound, angiography, CT or MRI scanning. An absent right vertebral artery, diseased carotid arteries or an incomplete Circle of Willis is a contraindication to left subclavian artery coverage without prior transposition or bypass grafting of the left subclavian artery.

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**Keywords:** Thoracic aortic stents; Aortic aneurysm; Aortic dissection; Left subclavian artery

### 1. Introduction

A best evidence topic was constructed according to a structured protocol. This is fully described in the ICVTS [1].

### 2. Three-part question

In [patients undergoing a descending thoracic aortic stent] does [coverage of the left subclavian artery] cause an unacceptable rate of [vascular complications]?

### 3. Clinical scenario

You are assisting a vascular radiologist with a 77-year-old gentleman who has suffered a contained rupture of his descending thoracic aorta after a road traffic accident 24-h ago. He had been intubated and ventilated immediately on admission to hospital, but on assessment, his age and smoking history persuaded you that his surgical risk

was too high. Therefore, you asked your radiologist to place a descending thoracic aortic stent. During the procedure the radiologist who previously thought that he could land the stent below the subclavian now feels that he must place the stent across this artery and asks you if you are happy with this. You say yes, but resolve to check that this is safe in the literature after the case.

### 4. Search strategy

Medline, Cochrane CENTRAL, EMBASE, NICE, CADTH, INAHTA databases, MSAS were searched from date of inception to February 2008.

[TEVAR.mp OR GORE.mp OR Vanguard.mp OR Braile.mp OR EGS.mp OR TALENT.mp OR Zenith.mp OR Aneurx.mp OR Medtronic.mp OR (endovasc\$.mp AND thorac\$.mp) OR (stent\$.mp AND thorac\$.mp)] AND [aneury\$.mp OR dissect\$.mp OR rupt\$.mp OR penetrate\$.mp OR intramural.mp OR trauma\$.mp]

### 5. Search outcome

Two thousand six hundred and twelve abstracts were identified for screening. Forty-five non-randomised control

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Table 1  
Best evidence papers

Author, date and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Buth et al., for the Eurostar registry, (2007), Holland and UK, [2]  Registry report (level 2b)	606 patients with urgent or elective thoracic aortic pathologies, aneurysm, dissection, trauma, false aneurysm and infection from July 2000 to July 2006  58 participating institutions  Talent, Excluder, Zenith, Valiant, Endofit, AneuRx Relay or other devices used	Complications among all patients	Stroke 19 (3.1%) Paraplegia/paraparesis 15 (2.5%)	Coverage of the left subclavian was not a risk factor for stroke
		Risk factors for spinal cord injury	Non-revascularised left subclavian artery coverage OR 3.9 95% CI 1.17–13.3 P=0.027	None of the 40 patients who had coverage of the left subclavian but with revascularisation had any complications
		Number of patients with left subclavian intentionally covered without revascularisation	119 (an additional 40 had coverage with revascularisation)	
		Complications	6 had spinal cord injury 5 had stroke	
		Complication rate	6/119 for SCI 5% 5/119 for stroke 4.2% 10/119 for either or both 8.4%	
Riesenman et al., (2007), J Vasc Surg, [3]  Non-controlled cohort study (level 2b)	112 patients receiving a thoracic endovascular stent for a variety of indications. Cases retrospectively searched for complete intentional occlusion of the left subclavian artery without revascularisation  7-month follow-up	Number of patients with left subclavian intentionally covered	24	19 had complete cessation of antegrade flow through the left subclavian
		Complications	3 upper limb symptoms but no intervention 1 had rest pain requiring stenting. 3 CVAs	Unknown if CVAs caused by left subclavian coverage
		Complication rate	4/24 17%	
Gorich et al., (2002), J Endovasc Ther, Germany, [4]  Non-controlled cohort study (level 2b)	23 patients with aortic rupture, type B dissection or aneurysm  All used Gore-TAG stents except one Talent stent  Follow-up at 1 week and 3-month intervals	Number of patients with left subclavian intentionally covered	23	18 had the patency of both vertebral arteries documented prior to subclavian coverage
		Complications	3 (1 paraesthesia – arm pressure drop of 95 mmHg, 1 dizziness – 50 mmHg drop, 1 temperature difference in upper limb – 50 mmHg pressure drop)	5 patients had an asymptomatic pressure drop of more than 60 mmHg
		Complication rate	3/23 13%	
		Pressure drop in left subclavian artery	Mean drop 48 ± 23 mmHg	
		Endoleaks	4 patients had a type 1 endograft leak due to incomplete seal of the proximal end of the prosthesis	
Bergeron et al., (2006), Eur J Vasc Endovasc Surg, Italy, [17]  Non-controlled cohort study (level 2b)	25 patients with aortic aneurysms or dissections, treated with total arch or hemi arch transposition then stenting  The 15 cases of total arch transposition did not have the left subclavian transposed and thus was covered by the stent	Number of patients with left subclavian intentionally covered	15	The 10 patients having hemi arch transposition did have subclavian transposition
		Complications	0	
		Complication rate	0/15 0%	

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Table 1 (Continued)

Author, date and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Buffolo et al., (2002), Ann Thorac Surg, Brazil, [18]	191 patients with a type B dissection treated with a tailor-made stent	Number of patients with left subclavian intentionally covered	14	
Non-controlled cohort study (level 2b)		Complications	1, a carotid shunt was necessary due to weakness in the left arm post- operatively	
		Complication rate	1/14 7%	
Criado et al., (2005), Ann Thorac Surg, USA, [5]	186 patients with either thoracic aneurysms or dissection	Number of patients with left subclavian intentionally covered	44	Stent coverage from left subclavian to celiac was a risk factor for spinal cord injury
Non-controlled cohort study (level 2b)	77 patients had proximal site of stent proximal to left subclavian. The vessel was occluded in 66 patients but 18 has revascularisation	Complications	One LSA required embolization to prevent an endoleak 15/44 35% developed left arm claudication 1 death due to bilateral cerebellar infarcts and absent vertebral arteries	
		Complication rate	2/44 serious complications, 17/44 any complication	
Eggebrecht et al., (2005), Eur Heart J, Germany, [19]	38 patients with type B aortic dissections	Number of patients with left subclavian intentionally covered	13	Diminished flow in 7 and occlusion in 6 on postoperative assessment of the left subclavian artery
Non-controlled cohort study (level 2b)	Talent stent	Complications	1 subclavian steal syndrome which did not require treatment	
		Complication rate	1/13 7%	
Fattori et al. for the TALENT registry, (2006), J Thorac Cardiovasc Surg, Italy, [6]	457 consecutive patients undergoing endovascular stenting with the Talent stent graft from 1996 to 2004. Minimum 1-month follow-up	Number of patients with left subclavian intentionally covered	32	22 patients also had subclavian coverage but after revascularisation
Registry report (level 2b)		Complications	Numbers not given  17 of all patients had a stroke and this was significantly associated with occlusion of subclavian without revascularisation ( $P=0.004$ )  Left subclavian was not a predictor of death ( $P=0.60$ ) or in hospital complications ( $P=0.51$ )	
Kaya et al., (2006), Ann Thorac Surg, Holland, [20]	28 patients undergoing endovascular stenting for a range of aortic vascular conditions	Number of patients with left subclavian intentionally covered	12	
Non-controlled cohort study (level 2b)	Talent and Excluder stents	Complications	3 (one coiling of origin of LSA due to type II endoleak and 2 subclavian- carotid transposition due to forearm ischaemia)	
		Complication rate	3/12 25%	

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Table 1 (Continued)

Author, date and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Khoynezhad et al., (2007), Ann Thorac Surg, USA, [7]	153 patients undergoing endovascular stenting for a variety of indications	Number of patients with left subclavian intentionally covered	41	8 strokes in all patients 8 paraplegia in all patients
Non-controlled cohort study (level 2b)	Mainly Talent, although 37 had AneuRx or 2 had Excluder or TAG	Complications	2 strokes $P=0.59$ 2 paraplegia $P=0.59$	
		Complication rate	4/41 10%	
Leurs et al. for the EUROSTAR and United Kingdom Thoracic Endograft registries, (2004) J Vasc Surg, UK and Europe, [8]	443 patients undergoing endovascular repair of the thoracic aorta  249 degenerative aneurysms 131 aortic dissections 13 false anastomotic aneurysms 50 traumatic injuries	Number of patients with left subclavian intentionally covered  Complications	Degenerative aneurysms 20 aortic dissections 22  22 patients had symptoms of sidebranch occlusion, 5/62 elective and 17/60 emergency procedures but this included paraplegia, paraparesis, intestinal ischaemia, renal insufficiency and limb ischaemia	An additional 22 had pre-procedural subclavian revascularisation in the degenerative aneurysm group, 15 in the dissection group  Overall incidence of stroke was 3%
Registry report (level 2b)	Data from August 1997 to August 2003  340 patients from EUROSTAR Registry and 103 from the UK registry			We do not know the true incidence of complications due to left subclavian occlusion in this paper as these complications are reported together with all symptoms of side-branch occlusion  Note EUROSTAR REGISTRY 2007 [2] is also reported above
Orend et al., (2007), Eur J Endovasc Surg, Germany, [9]	34 patients with traumatic lesions of the descending aorta to a single centre. March 1999 to December 2006	Number of patients with left subclavian intentionally covered	23	22/34 patients had the tear directly opposite the left subclavian on CT scanning and 10–20 mm distal in a further 11 patients
Non-controlled cohort study (level 2b)	Excluder, Talent and Zenith stents used	Complications	1 required revascularisation of the LSA	State in the discussion that they have now performed over 100 left subclavian occlusions without further problems in their practice
		Complication rate	1/23 4%	
Palma et al., (2002), Ann Thorac Surg, Brazil, [10]	198 patients with a descending aortic dissection treated by endovascular stenting from 1996 to 2001	Number of patients with left subclavian intentionally covered	14	
Non-controlled cohort study (level 2b)	Individually manufactured stents	Complications	1 patient required carotid to subclavian bypass 8 months after TEVAR due to arm weakness	
		Complication rate	1/14 0%	
Patel et al., (2006), Ann Thorac Surg, USA, [21]	Retrospective review of 73 patients undergoing thoracic endovascular stenting for a range of pathologies, from 1993 to 2005	Number of patients with left subclavian intentionally covered	13	An additional 3 had coverage but prior carotid to subclavian bypass grafting
Non-controlled cohort study (level 2b)	Excluder, Talent, Zenith, AneuRx and custom made stents used	Complications	1 required a stent hours post-procedure and 1 bypass 7 months later for arm ischaemia	
		Complication rate	2/13 15%	
Peterson et al., (2006), J Vasc Surg, USA, [1]	Retrospective analysis of 30 of 70 patients who had a thoracic endovascular stent placement close or over the left subclavian artery  2001–2005	Number of patients with left subclavian intentionally covered  Complications	8  5 acute complications after coverage [4 strokes (3 posterior circulation strokes), 1 subclavian-vertebral steal requiring	20 had subclavian to carotid artery transposition and 2 had carotid to subclavian bypass  2 revascularised patients experienced left vocal chord palsy, and one suffered lower extremity paraparesis

(Continued on next page)

Table 1 (Continued)

Author, date and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
	Either industry provided or custom-made devices used		revascularisation (arm pain, fatigue and syncope)]	Paper included in table as it specifically addressed this issue, although it is left out of the summary table 2 as it contained < 10 patients with LSA coverage
		Complication rate	5/8 63%	
Reece et al., (2007), Ann Thorac Surg, USA, [12]	Retrospective review of 27 patients who required exclusion of the left subclavian artery	Number of patients with left subclavian intentionally covered	20	7 patients had preoperative revascularisation for the following reasons: 1 LIMA to LAD, 3 aberrant right subclavian arteries, 2 incomplete circle of Willis', 1 dominant left vertebral artery
Non-controlled cohort study (level 2b)	1999–2006	Complications	4 patients required late revascularisation at 3, 9, 10 and 26 months for arm claudication or steal syndrome	
		Complication rate	4/20 20%	
Rehders et al., (2004), J Endovasc Ther, Germany, [13]	22 patients retrospectively identified from a review of 171 patient who had undergone thoracic endovascular stenting	Number of patients with left subclavian intentionally covered	22	All patients had a balloon occlusion test – 30 min balloon occlusion when patient was awake and unanaesthetised
Non-controlled cohort study (level 2b)	1997–2003	Complications	No revascularisation 7 mild symptoms	
	Candidates were evaluated with TOE, angiography, CT or MRI	Complication rate	0/22 serious complications 7/22 mild complications	
		Blood pressure difference	Right arm 138 ± 14.0 mmHg Left arm 101.8 ± 21.0 mmHg P < 0.05	
Rodriguez et al., (2007), J Vasc Surg, USA, [14]	324 patients undergoing thoracic aortic stenting at a single centre for a variety of pathologies	Number of patients with left subclavian intentionally covered	24	13 had prior revascularisation and then LSA ligation
Non-controlled cohort study (level 2b)	1998–2006	Complications	None Coverage of left subclavian not a risk factor for paraplegia or paraparesis (n=8)	
	Gore Excluder stent			
	Pre-op examination included: carotid/vertebral artery duplex USS, CT chest			
Sunder-Plassman et al., (2003), J Cardiac Surg, Germany, [15]	45 patients having a thoracic aortic stent for aneurysmal disease	Number of patients with left subclavian intentionally covered	12	
Non-controlled cohort study (level 2b)	1995–2002	Complications	1 patient required subclavian to carotid transposition	
	Corvita, Stenford, Vanguard, AneuRx, Talent, Excluder	Complication rate	1/12 (8%)	
		Blood pressure drop	Left radial blood pressure drop was 48 ± 12 mmHg	
Di Tommaso et al., (2006), Interact Cardiovasc Thorac Surg, Italy, [22]	51 patients undergoing TEVAR for a variety of indications. In a single institution	Number of patients with left subclavian intentionally covered	10 patients	
Non-controlled cohort study (level 2b)	2001–2005	Complications	No complications from LSA coverage	

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Table 1 (Continued)

Author, date and country Study type (level of evidence)	Patient group	Outcomes	Key results	Comments
Wheatley et al., (2006), Ann Thorac Surg, USA, [23]	158 patients undergoing Gore-TAG thoracic aortic stenting for a range of pathologies	Number of patients with left subclavian intentionally covered	20	8 had prior revascularisation
Non-controlled cohort study (level 2b)	2000–2004	Complications	2 patients required bypass for left upper extremity ischaemia	
		Complication rate	2/20 10%	
Zipfel et al., (2007), Ann Thorac Surg, Germany, [16]	Retrospective review of 172 patients who required thoracic aortic stenting for a variety of pathologies. 57% emergencies. 1999–2005	Number of patients with left subclavian intentionally covered	35	13 had concurrent or prior revascularisation
Non-controlled cohort study (level 2b)	All performed in the operating room by Cardiothoracic Surgeons	Complications	7 had revascularisation after the stent procedure, but uncertain as to the reason for this revascularisation	
	Talent or E-vita stents	Complication rate	7/35 20%	

trials and 213 non-controlled papers were found using the reported search and all these were read in full to search for coverage of the left subclavian. Only papers documenting coverage of at least 10 left subclavian arteries without a prior carotid subclavian procedure were included. Also, uncovered stenting across the subclavian was excluded. From these, 20 papers were identified that provided the best evidence to answer the question. These are presented in Table 1.

## 6. Results

The Eurostar registry [2] in 2007 collected data from 58 institutions with 606 thoracic endovascular aortic stent procedures (TEVAR) in total. They reported 119 cases of coverage of the left subclavian artery (LSA), with an additional 40 having prior revascularisation. While there were only 15 cases of spinal cord injury on their database, they identified non-revascularised LSA as being a risk factor for this complication with an odds ratio of 3.9 which was significant ( $P=0.027$ ). The incidence of stroke was not increased in this group.

Riesenman et al. [3] reported a cohort of 112 patients, of whom 24 had LSA coverage. One of these patients required LSA stenting due to rest pain in the arm and a further three had mild upper limb symptoms.

Gorich et al. [4] documented the patency of both vertebral arteries prior to coverage of the LSA in 23 patients. There were no serious complications, although five patients had a pressure drop of more than 60 mmHg in the left arm and three patients had some mild arm symptoms.

Criado et al. [5] documented 186 patients having TEVAR of either an aneurysmal or dissected aorta. Forty-four patients had intentional coverage of the left subclavian without revascularisation. One patient had significant back-flow from the LSA to cause an endoleak which required embolisation. In addition, one patient died as they were

later found to have had absent vertebral arteries and suffered a bilateral cerebellar infarct. In addition, 15 patients suffered from left arm claudication but did not require any intervention.

The TALENT Registry [6] contained 457 patients up to 2004 and of these 32 had coverage of the left subclavian artery. They reported that 17 of all 457 patients suffered a stroke and that this was significantly associated with occlusion of the LSA without prior revascularisation ( $P=0.004$ ). Unfortunately, they did not give the exact number of strokes that these 32 patients suffered.

Khoynezhad et al. [7] covered the left subclavian in 41 patients. Two of these suffered a stroke and two suffered paraplegia, but this incidence was no higher than in the total cohort of 153 patients.

The Eurostar registry combined with the UK thoracic endovascular stenting registry to report their results [8]. They reported that 42 patients had the subclavian artery covered without prior revascularisation and a further 37 had coverage but with prior revascularisation. They also report that 22 patients had complications relating to side-branch occlusion but this category included mesenteric and renal ischaemia as well as limb ischaemia. Also, they did not report how many of these complications occurred in the uncovered LSA stented group.

Orend et al. [9] reported their experience with 34 emergency stenting procedures for traumatic descending aortic injuries. They covered the left subclavian on 23 occasions and only one patient required revascularisation for arm hypoperfusion (4%). They also stated in their discussion that they have now covered the left subclavian in over 100 cases in their practice without any further complications, although these data have not been published.

Three studies specifically looked at the issue of left subclavian artery coverage: Peterson et al. [11] reported their experience in 30 patients. Eight had coverage without revascularisation but four of these patients had a stroke.

Table 2  
Summary of left subclavian artery (LSA) stenting without prior revascularisation and its complications

Author	Year	Covered LSA without revasc	Stroke	Revascularisation	Endoleak	Ischaemia/ claudication/ or steal syndrome	Paraplegia/ Paraparesis	Mean pressure drop mmHg
Buth	2007	119	5				6	
Riesenman	2007	24	3	1		4		
Gorich	2002	23			4	3		48 mmHg
Rehders	2004	22				7		36 mmHg
Bergeron	2006	15						
Buffolo	2002	14		1		1		
Criado	2005	44	1		1	15		
Eggebrecht	2005	13				1		
Fattori	2006	(32)	*					
Kaya	2006	12	2		1	2		
Khoynezhad	2007	41	2				2	
Orend	2007	23		1		1		
Palma	2002	14		1		1		
Patel	2006	13		2		2		
Reece	2007	20		4		4		
Rodriguez	2007	24						
Sunder-Plassman	2003	12		1		1		48 mmHg
Tommaso	2006	10						
Wheatley	2006	20		2		2		
Zipfel	2007	35		7		7		
Total		498	13 (2.6%)	20 (4%)	6 (1.2%)	51 (10%)	8 (1.6%)	

\*Exact figures not given.

CT confirmed that three of these were posterior circulation strokes and two patients had absent contralateral vertebral arteries. A fifth patient suffered subclavian-steal, requiring revascularisation seven months later.

Reece et al. [12] documented 20 patients who underwent coverage of the left subclavian artery without prior revascularisation. Four patients required subclavian bypass for arm claudication or steal syndrome. Furthermore, of the seven patients that were revascularised preoperatively, all were due to preoperative CT-scan findings, including three aberrant right subclavian arteries, one dominant left vertebral artery, and two incomplete circle of Willis'.

Rehders et al. [13] also specifically looked at this issue and reported that there were no significant complications in 22 patients who had left subclavian artery occlusion, other than four patients who had minor sensations of cold in the outdoors in the months following the procedure. However, their preoperative evaluation was meticulous, including not only TOE, angiography and CT or MRI but also a 30-min balloon occlusion test of the left subclavian while the patient was awake and unanaesthetised.

Sunder-Plassmann et al. [15] found a mean blood pressure drop of 48 mmHg in the left radial artery after left subclavian artery coverage. Twelve patients underwent this procedure with only one requiring subsequent subclavian transposition.

## 7. Clinical bottom line

Aggregating the data from all these 20 studies we found 498 covered left subclavian arteries (Table 2). Complications included 13 strokes (2.6%), 8 cases of paraplegia/paraparesis (1.6%) and 6 endoleaks due to subclavian backflow (1.2%). Of note there were 51 cases of ischaemia

or other symptoms attributable to poor blood flow (10%), which resulted in 20 post-procedural revascularisations (4%). In three studies the mean pressure drop in the left arm was between 36 and 48 mmHg after left subclavian occlusion.

We conclude that coverage of the left subclavian artery has a low, but not insignificant, incidence of side-effects. This incidence must be balanced with the urgency of the procedure and may be acceptable in emergency or salvage situations. However, in non-emergency cases we recommend that the carotid arteries, the vertebral arteries and the Circle of Willis are fully assessed by tests such as duplex ultrasound, angiography, CT or MRI scanning. An absent right vertebral artery, diseased carotid arteries or an incomplete Circle of Willis is a contraindication to left subclavian artery coverage without prior transposition or bypass grafting of the left subclavian artery.

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**Is it safe to cover the left subclavian artery when placing an endovascular stent in the descending thoracic aorta?**

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