The effect of left subclavian artery coverage on morbidity and mortality in patients undergoing endovascular thoracic aortic interventions: A systematic review and meta-analysis

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Objectives: **Thoracic endografts (stent grafts) have emerged as a less invasive modality to treat various thoracic aortic lesions. The intentional coverage of the left subclavian artery (LSA) during the placement of these endografts is associated with several complications including stroke, spinal cord ischemia, and arm ischemia. In this review, we synthesize the available evidence regarding the complications associated with LSA coverage.**

Methods: **We searched electronic databases (MEDLINE and EMBASE) from January 1990 through February 2008 for studies that included patients who received thoracic endografts and had intentional LSA coverage. Eligible studies had a control group that either received the endograft without LSA coverage or had primary revascularization prior to coverage. Two independent reviewers determined trial eligibility and extracted descriptive, methodological and outcome data from each eligible study. Meta-analyses estimated Peto odds ratio (OR) and 95% confidence intervals (CI) to describe the strength of association between coverage and complications; the I^2 statistic described the proportion of inconsistency of treatment effect among studies not due to chance.**

Results: **We found 51 eligible observational studies. LSA coverage was associated with significant increase in the risk of arm ischemia (OR 47.7; CI, 9.9-229.3; I^2 = 72%, 19 studies) and vertebrobasilar ischemia (OR 10.8; CI, 3.17-36.7; I^2 = 0%; eight studies); and nonsignificant increase in the risk of spinal cord ischemia (OR 2.69; CI, 0.75-9.68; I^2 = 40%; eight studies) and anterior circulation stroke (OR 2.58; CI, 0.82-8.09; I^2 = 64%, 13 studies). There were no significant associations between LSA coverage and death, myocardial infarction, or transient ischemic attacks. The incidence of phrenic nerve injury as a complication of primary revascularization was 4.40% (CI, 1.60%-12.20%). Data on perioperative infection were sparse and rarely reported.**

Conclusions: **Very low quality evidence suggests that LSA coverage increases the risk of arm ischemia, vertebrobasilar ischemia, and possibly spinal cord ischemia and anterior circulation stroke. (J Vasc Surg 2009;50:1159-69.)**

Over the past decade, the use of thoracic endografts (stent grafts) has emerged as a less invasive modality to treat various thoracic aortic pathologies, including aneurysm, dissection, trauma, fistula, and penetrating ulcer. To expand the anatomic limits of this technology, intentional coverage of the left subclavian artery with the proximal aspect of the endograft without revascularization (carotid-subclavian artery bypass or transposition) has been performed.

Intentional covering of the left subclavian artery may lead to a higher incidence of extremity ischemia, spinal cord ischemia, or stroke. A few studies report that intentional coverage without revascularization is not associated with additional morbidity,[1-3] whereas other studies report a higher incidence of postoperative arm ischemia and posterior circulation strokes compared with patients that did not undergo intentional coverage.[4,5] The discrepancy in the outcomes of intentional LSA coverage may be due to the primary etiology being treated, underlying patient comorbidities, or other patient and/or anatomic factors.

The Society for Vascular Surgery has formed a committee of experts in the treatment of thoracic aortic lesions to formulate clinical practice guidelines to guide patients and surgeons in making treatment decisions. This committee commissioned us to conduct a systematic review and meta-analysis to support the formulation of evidence-based recommendations. Thus, we sought to summarize the best available evidence about the effect of intentional LSA coverage on patients' morbidity and mortality.

METHODS

The report of this protocol-driven systematic review was approved by the Committee on Thoracic Aortic Disease from the Society for Vascular Surgery and is in adherence with the standards for reporting Meta-analyses of

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Competition of interest: none.

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Observational Studies in Epidemiology (MOOSE).[6] The quality of evidence was rated using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methods.[7]

Eligibility criteria

Eligible studies were controlled studies that enrolled patients receiving an endovascular device to repair descending thoracic aortic pathologies such as transection, aneurysm or dissection. Eligible studies enrolled patients in whom the LSA was intentionally covered to extend the proximal seal-zone for endovascular repair. Eligible studies included a comparison group including patients in whom the endograft placement did not cover the LSA or patients who underwent a primary revascularization procedure such as carotid-subclavian bypass or transposition.

We included studies that measured the outcomes of interest including death, arm ischemia, vertebrobasilar ischemia, anterior circulation stroke, transient ischemic attack (TIA), spinal cord ischemia, myocardial infarction, phrenic nerve paralysis, and infection. We defined spinal cord ischemia as permanent decrease or loss of lower extremity neurological function in the immediate postoperative period. Vertebrobasilar ischemia was defined as permanent loss of neurological function related to the posterior circulation. Arm ischemia was defined as any symptoms of hand ischemia that occurred at rest or with arm exertion and required revascularization. Studies were included regardless of their language, sample size, or duration of patient follow-up. Single cohort studies (ie, studies in which all patients received coverage without a concurrent comparison group) were excluded.

Study identification

An expert reference librarian (P.J.E) designed and conducted the electronic search strategy with input from study investigators with expertise in conducting systematic reviews. To identify eligible studies, we searched electronic databases (MEDLINE and EMBASE) from January 1990 through February 2008. We chose the year 1990 as the start point for literature search because the use of thoracic endografts started in the late 1990s in Europe and in the early 2000s in the US; and because surgical techniques, device technology, and peri-operative care have likely changed sufficiently to decrease the relevancy of literature published prior to this date. We also sought references from experts, bibliographies of included trials, and the ISI (Institute for Scientific Information) Science Citation Index for publications that cited included studies.

MeSH and EMBASE subject headings were primarily used to describe the aorta, with subheadings to focus upon surgery or repair: aorta, thoracic/sugery, therapy, aortic surgery, therapy, aortic aneurysm/surgery, therapy, aortic disease, or aorta dissecting aneurysm or aortic rupture. A combination of subject headings and text words were used for the type of intervention: stent* or stentgraft, in conjunction with endograft, endovascul*, endolumin*, intralumin*, endoprosth*, blood vessel prosthesis implantation, or blood vessel prosthesis. Text words were used to describe the placement: covered, uncovered, anchor*, planned within 2 words of transpos*, subclavian*, lsa. The outcomes of concern (risk*, postoperative complications, mortality, brain ischemia, cerebrovascular accident, cerebrovascular trauma, hypoxia, intracranial embolis and thrombosis, bacterial infections, intracranial hemorrhages, or paralysis) were combined with all terms, and limited to clinical trials, comparative studies, practice guidelines, and other clinical studies. Detailed search strategy is available from study authors upon request.

Paired reviewers working independently screened all titles and abstracts for eligibility. References that were deemed potentially relevant were retrieved in full text for full text evaluation against eligibility criteria. The chance adjusted inter-reviewer agreement (kappa statistic) about study eligibility was 0.96 (95% confidence interval (CI) 0.96-1.0). Disagreements were resolved by consensus (the two reviewers discussed the study and reached a consensus), and when disagreement continued, by arbitration (a third reviewer adjudicated the study).

Data collection

Two reviewers working independently and using a standardized form extracted data from all eligible studies. We extracted descriptive data (number of patients in each study arm, patients' age, gender, indication for endograft placement, urgency of procedure, control group description, type of endograft, comorbidities such as diabetes, coronary artery disease, hypertension, and history of a previous stroke); methodological data (study design, randomization procedures if any, bias protection measures, proportions of patients lost to follow up, funding source, the prognostic comparability of the two study groups, ascertainment of exposure and outcome, and blinding of outcome assessors); and outcome data (death, arm ischemia, vertebrobasilar ischemia, anterior circulation stroke, TIA, spinal cord ischemia, myocardial infarction, phrenic nerve paralysis, and infection). We contacted authors of included studies by e-mail for clarification and to obtain missing data.

Statistical analysis

Meta-analyses. Anticipating that studies will have rare events and report sparse data, we used Peto odds ratio (OR)[8] as the measure of effect for dichotomous outcomes and estimated the 95% confidence intervals (CI) for each outcome to reflect the uncertainty of point estimates of effect. When data are sparse and events are rare, Peto odds ratio method is associated with less bias, more power, and better confidence interval coverage than other methods, provided that study arms are balanced and treatment effects are not large,[9] which we anticipated to be the case in this meta-analysis. In this review, OR of 1.0 indicates no association between LSA coverage and a particular outcome whereas OR above 1.0 indicates that coverage without revascularization increased the risk for this outcome. If the confidence interval of the OR overlaps the value of

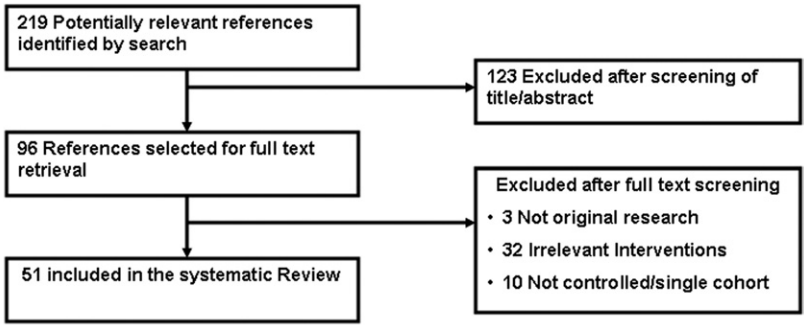


Fig 1. Process of study selection.

1.0, this would indicate that the results are not statistically significant.

We used the I^2 statistic, which estimates the percentage of heterogeneity across studies that is due to heterogeneity rather than chance (ie, the percentage of variability in treatment effects across trials that is not due to chance or random error, but rather due to real differences in study patients, design or interventions).[10] I^2 values of $\leq$ 25%, 50%, and $\geq$ 75% represent low, moderate, and high inconsistency, respectively. Statistical analysis was conducted using Comprehensive Meta-Analysis, Version 2 (Biostat Inc., Englewood, New Jersey, USA).

Subgroup and sensitivity analyses. We established a priori hypotheses to explore subgroup interactions and explain inconsistency in the direction and magnitude of effect among studies. These subgroup analyses were based on the indication for aortic repair (aneurysm vs. dissection vs. transsection) and the urgency of repair (urgent vs. elective), and the control intervention (no coverage vs. coverage after primary revascularization). We tested the hypotheses of a subgroup effect using a test of interaction.[11] We also planned to conduct meta-regression using the effect size as the dependent outcome variable and the duration of follow up as the independent continuous variable.

Anticipating that the outcomes of interest would be rare and that many studies would report zero events in both arms, we planned to conduct sensitivity analysis using the risk difference (RD) as the measure of effect. RD value of 0 indicates that the absolute risk of a particular outcome is similar between the two study arms. RD >0 indicates that coverage without revascularization increased the risk for this outcome. If the confidence interval of the RD overlaps the value of 0, this would indicate that the results are not statistically significant.

Using RD allows the inclusion of these "no event" studies, which increases sample size, improves precision, and includes the totality of evidence in generating meta-analytic estimates. RD has the shortcomings of being associated with higher inconsistency among studies and is very dependent on the control group event rates in the different studies.[12,13] We planned to explore whether study conclusions were sensitive to the choice of outcome measure used.

RESULTS

Study identification

Fig 1 depicts our search and selection procedures. Table I summarizes the characteristics of the 51 eligible studies in terms of patients' age, gender, comorbidities, type of endograft, indications for placement, and elements of study quality. These studies enrolled 3365 patients with a mean study size of 70 patients. The majority of patients (75%) were males and the mean age was 58 years.

Study quality

All eligible studies were observational, comprising five prospective cohort studies and 46 retrospective chart reviews. Researchers ascertained the outcomes, which were mostly death or major morbidities, and the exposure, by reviewing medical charts and perioperative records. Reviewers determining the quality of the eligible studies had perfect agreement on study design, exposure and outcome ascertainment; however, the prognostic comparability of study cohorts at baseline was difficult to assess because there were multiple indications for endograft placement and these indications conferred variable prognosis given in part by the original aortic pathology regardless of the procedure patients received. Loss of follow-up was in general low and only exceeded 10% in two studies. Study funding was often not reported but on two occasions was provided by endograft manufacturers.[14,15] Outcomes were poorly described in the included studies and we had to accept the definitions of the original studies; therefore, it was not always clear whether cases of spinal cord, vertebrobasilar, and hand ischemia were permanent or that they required interventions/revascularization.

Meta-analysis

LSA coverage was associated with significant increase in the risk of arm ischemia (OR 47.69; CI, 9.92-229.34; I^2 = 72%, 19 studies; Fig 2) and vertebrobasilar ischemia (OR 10.78; CI, 3.17-36.69; I^2 = 0%; eight studies; Fig 3); and nonsignificant increase in the risk of spinal cord ischemia (OR 2.69; CI, 0.75-9.68; I^2 = 40%; eight studies; Fig 4) and anterior circulation stroke (OR 2.58; CI, 0.82-8.09; I^2 = 64%, 13 studies; Fig 5).

Table I. Description of included studies

Author, Year	*No.*	*Endograft*	*Indication*	*Age (Years)*	*% Females*	*% CAD*
Mitchell 1996[18]	44	Homemade device	Trauma (4), pseudo aneurysm (4), aneurysm (24), penetrating ulcer (8), ductus aneurysm (4), dissection (1); all elective	66	18	50
Kato 1997[19]	10	Homemade device	Trauma; 7 urgent	56	40	NR
Hausegger 2001[20]	29	Talent	Dissection; elective	55-81	3	3
Criado 2002[21]	47	Talent	Aneurysm (31), dissection (16)	33-88	30	NR
Fattori 2002[22]	19	TAG (18), Talent (1)	Trauma; Urgent (11), delayed (8)	39	NR	NR
Orend 2002[23]	8	Talent, TAG	Trauma and urgent	17-59	0	NR
Pamler 2002[24]	14	TAG, Talent	Dissection; urgent (1), elective (13)	60	14	43
Totaro 2002[25]	32	TAG	Dissection (25), aneurysm (7); urgent (5), elective (25)	62	31	NR
Balzer 2003[26]	26	TAG, Talent	Aneurysm (18), dissection (8)	61	46	12
Lambrechts 2003[27]	26	Aneurx (1), Talent (13), TAG (12)	Trauma (3), Dissection (11), Aneurysm (12)	64	69	19
Matravers 2003[28]	24	TAG, Talent, Aneurx	Aneurysm, dissection, penetrating ulcer, pseudoaneurysm	71	NR	NR
Orford 2003[29]	9	Zenith	Trauma; elective (1), urgent (8)	52	33	NR
Scharrer-Palmer 2003[30]	45	Talent, TAG, Corvita, Aneurx, Vangaurd	Aneurysms; urgent (11), elective (34)	69	27	NR
Sunder-Plassman 2003[31]	45	Aneurx, Talent, TAG,	Aneurysms; elective (30), urgent (15)	69	27	NR
Tiesenhausen 2003[32]	10	Talent, TAG	dissection (7), aneurysm (3)	NR	NR	NR
Amabile 2004[33]	9	Talent, TAG	Trauma; delayed 6, urgent 3	15-51	11	NR
Leurs 2004[34]	443	Talent, TAG, Zenith, Endofit	Aneurysm (249), dissection (131), pseudoaneurysm (13), Trauma (50); Elective (263), Urgent (180)	63	25	17
Nemes 2004[35]	31	Vangaurd, Talent	Aneurysms	60	35	NR
Tse 2004[36]	34	NR	Trauma, dissection, aneurysm	73	54	46
Dagenais 2005[37]	24	Talent	Aneurysm (10), penetrating ulcer (6), trauma (4), dissection (2), fistula (1), psuedoaneurysm (1); Urgent (3), elective (21)	63	33	33
Dong 2005[38]	10	Talent	Dissection (9), aneurysm (1)	42-65	NR	40
Doss 2005[39]	32	Talent, TAG	Ruptured aneurysm (15), perforated dissection (10), Trauma (7)	61	47	22
Fu 2005[40]	10	Talent	Dissection (9), aneurysm (1)	45	30	90
Guo 2005[41]	178	Talent	Dissection; acute (76), chronic (102)	50	17	NR
Lawlor 2005[42]	7	Talent	Trauma; all urgent	42	14	NR
Melissano 2005[43]	21	Talent, TAG, Zenith, Endomed	Aneurysm, dissection, trauma; all elective	71	17	NR
Pogorzekski 2005[44]	42	NR	Dissection	22-81	NR	NR
Amabile 2006[45]	17	Talent or TAG	Trauma and aneurysm; elective (7), Urgent (10)	42	12	NR
Caronno 2006[46]	19	TAG (12), Talent (4), Zenith (3)	Trauma (7), dissection (5), penetrating ulcer (4), symptomatic aneurysm (3); all urgent	54	10	16
Ferrari 2006[47]	18	Talent	Trauma; all urgent	41	NR	NR
Kaya 2006[48]	28	Talent (26), TAG (2)	Dissection (12), intramural hematoma (4), ruptured aneurysm (7), trauma (2), fistula (2), penetrating ulcer (1); all urgent	64	39	14
Marchiex 2006[49]	45	Talent (27), TAG (17)	Aneurysm; elective (37), Urgent (8)	68	NR	53
Patel 2006[50]	73	Talent, TAG, Zenith, Aneurx	Aneurysm, dissection, trauma	67	NR	43
Petersen 2006[4]	30	NR	Aneurysm, dissection, trauma; 2 had abberrant subclavian origins underwent prior subclavian transposition	58	37	NR
Schoder 2006[51]	58	Talent (30), TAG (27), Endofit (1)	Aneurysm (32), Dissection (20), trauma (4), penetrating ulcer (2); Urgent (19), elective (39)	62	22	12
Song 2006[14]	42	Aneurx (5), Talent (37)	Thoracic dissection; Elective (17), Urgent (28)	64	43	21
Verhoye 2006[52]	54	Talent, TAG Zenith	NR	63	19	NR
Buth 2007[53]	606	Talent (386), TAG (119), Zenith (39), Valiant (28), Endofit (12), Aneurx (4), Relay (2), unknown (16)	Aneurysm (291), dissection (215), pseudoaneurysm (24), trauma (67); chronic (379), acute (205), unknown (22)	63	22	25

Table I. Continued

% HTN	*% Renal failure*	*% Previous stroke*	*% DM*	*F/U (Months)*	*% Loss to F/U*	*Funding*	*Design*
82	14	NR	18	13	0	NR	OB, R, S
NR	NR	NR	NR	15	0	NR	OB, R, S
100	3	3	NR	2-36	0	NR	OB, R, S
NR	NR	NR	NR	18	6	NR	OB, R, S
NR	NR	NR	NR	20	0	NR	OB, R, S
NR	NR	NR	NR	11	0	NR	OB, R, S
83	NR	NR	43	14	NR	NR	OB, R, S
NR	NR	NR	NR	12	0	NR	OB, R, S
85	12	8	NR	UC	0	NR	OB, R, S
69	23	12	4	UC	NR	NR	OB, R, S
NR	NR	NR	NR	UC	NR	NR	OB, R, S
NR	NR	NR	NR	21	0	NR	OB, R, S
NR	NR	NR	NR	24	NR	NR	OB, R, S
NR	NR	NR	NR	UC	NR	NR	OB, R, S
NR	NR	NR	NR	UC	NR	NR	OB, R, S
NR	NR	NR	NR	15	0	NR	OB, R, S
NR	NR	NR	NR	UC	66	NFP	OB, P, M
NR	NR	NR	NR	UC	NR	NR	OB, R, S
73	24	5	22	10	NR	NR	OB, R, S
67	25	NR	17	13	0	NR	OB, R, S
10 of 10	NR	10	30	3-12	0	NR	OB, R, S
44	6	NR	NR	36	NR	NR	OB, R, S
NR	NR	NR	20	UC	NR	NR	OB, R, S
NR	NR	NR	NR	9	10	NR	OB, R, S
NR	NR	NR	NR	18	14	NR	OB, R, S
NR	NR	NR	NR	23	NR	NR	OB, R, S
100	NR	NR	NR	UC	NR	NR	OB, R, S
NR	NR	NR	NR	13	6	NR	OB, R, S
63	16	10	NR	25	NR	NR	OB, R, S
NR	NR	NR	NR	21	NR	NR	OB, R, S
68	29	NR	NR	11	0	NR	OB, R, S
76	22	9	27	25	2	NR	OB, P, S
63	17	NR	11	23	0	NR	OB, R, S
NR	NR	NR	NR	18	NR	NR	OB, P, S
74	26	3	21	22	2	NR	OB, R, S
88	10 of 42	10	10	11	12	FP	OB, R, S
NR	NR	NR	NR	23	0	NR	OB, R, S
69	18	NR	10	UC	NR	NR	OB, P, M

Table I. Continued

Author, Year	*No.*	*Endograft*	*Indication*	*Age (Years)*	*% Females*	*% CAD*
Feezor 2007[54]	196	TAG (156)	Aneurysm, trauma, dissection, pseudoaneurysm; elective (138), urgent (30)	NR	NR	NR
Ferreira 2007[55]	81	NR	aneurysm, dissection, penetrating ulcer	NR	NR	NR
Juszkat 2007[56]	13	NR	pseudoaneurysm (6), dissection (3), trauma (4); urgent (7), elective (6)	21-56	30	NR
McPhee 2007[57]	8	Anuerx and Gore	Trauma; all urgent	31	NR	NR
Neschis 2007[58]	20	Talent, Aneurx and Gore	Trauma; all urgent	40	15	NR
Orend 2007[59]	36	TAG (23), Zenith (6), Talent (5)	Trauma; all urgent	17-79	13	NR
Reece 2007[5]	64	Aneurx, Talent, TAG	aneurysm, trauma, dissection, pseudoaneurysm	60	NR	NR
Rehders 2004[60]	171	Talent	dissection (128), aneurysm (39), pseudoaneurysm (4)	60	25	NR
Riesenmen 2007[1]	24	Talent, TAG, Zenith	trauma, dissection, aneurysm, pseudoaneurysm, aortobronchial fistula; elective (19), urgent (9), note that 4/28 were arch repairs, not included in data	63	32	NR
Rodriguez 2007[61]	324	TAG	Aneurysm (157), dissection (82), penetrating ulcer (34), psuedoaneurysm (26), trauma (11), aortobronchial fistula (9); elective (224), urgent (100)	72	38	36
Saratzis 2007[62]	9	Endofit	Trauma; all urgent	29	0	NR
Thompson 2007[15]	180	Valiant	Aneurysm (66), thoracoabdominal aneurysm (22), acute aortic syndrome (19), dissection (52), trauma (21); elective (173), urgent (63)	64	NR	23
Woo 2008[3]	70	TAG, Talent, TX2	Aneurysm (47), dissection (16), transection (4), pseuodoaneurysm (2), right subclavian aneurysm (1); 5 had patent LIMA; 47 elective and 23 emergent operations	67	24	63

LSA coverage did not significantly affect the risk of death (OR 1.14; CI, 0.49-2.67; I^2 = 28%, 17 studies), myocardial infarction (OR 0.47; CI, 0.02-9.26; I^2 = 11%, two studies), or TIA (OR 0.94; CI, 0.19-4.74; I^2 = 12%, six studies). The incidence of phrenic nerve injury as a complication of primary revascularization was 4.40% (CI, 1.60%-12.20%). The baseline risks of outcomes of interest in patients who underwent LSA coverage are presented in Table II. Data on perioperative infection were sparse and rarely reported.

Subgroup and sensitivity analysis

When RD was used as the measure of effect instead of Peto OR, study conclusions did not change in terms of the outcomes of death (RD −0.49%; CI, −3.94%-2.96%; I^2 = 0%, 32 studies), myocardial infarction (RD −0.45%; CI, −3.41%-2.52%; I^2 = 0%, 31 studies), anterior circulation stroke (RD 1.76%; CI, −0.45%-3.97%; I^2 = 0%, 40 studies), TIA (RD −0.15%; CI, −2.07%-1.76%; I^2 = 0%, 41 studies), spinal cord ischemia (RD 1.18%; CI, −0.79%-3.14%, I^2 = 0%, 47 studies) or arm ischemia (RD 2.14%; CI, 0.15%-4.13%; I^2 = 4%, 31 studies). However, the outcome of vertebrobasilar ischemia became less precise due to the inclusion of numerous studies with zero events in both arms (RD 0.64%; CI, −1.15%-2.43%).

We found no significant subgroup interactions across subgroups defined by whether the aortic intervention was done on an urgent or elective basis or whether the indication for the intervention was aneurysm or dissection. Data on trauma/transsection was insufficient for subgroup analysis. When we tested for subgroup interaction based on the control group in the included studies (patients received aortic endograft without coverage vs. they received primary revascularization before coverage), we found no significant interaction for all outcomes except arm ischemia (*P* value for interaction = 0.01). This interaction means that the magnitude of increased risk of arm ischemia due to LSA coverage was greater when coverage is compared with no coverage; than when coverage is compared with coverage preceded by primary revascularization. Several other subgroup analyses were not conducted due to insufficient data. Table III depicts all these subgroup analyses. Meta-regression showed no significant association between the length of study follow-up (expressed in days) and outcomes of interest ($P > .05$ for all outcomes).

DISCUSSION

Our findings

We conducted a systematic review of the literature to evaluate the effect of the intentional coverage of the left subclavian artery associated with endograft placement in the descending thoracic aorta. We found very-low-quality

Table I. Continued

% HTN	% Renal failure	% Previous stroke	% DM	F/U (Months)	% Loss to F/U	Funding	Design*
NR	NR	NR	NR	UC	NR	NR	OB, P, S
NR	NR	NR	NR	28	NR	NR	OB, R, S
NR	NR	NR	NR	UC	3	NR	OB, R, S
NR	NR	NR	NR	17	NR	NR	OB, R, S
NR	NR	NR	NR	UC	NR	NR	OB, R, S
NR	NR	NR	NR	44	NR	NFP	OB, R, S
NR	NR	NR	NR	19	NR	NFP	OB, R, S
NR	NR	NR	NR	NR	NR	NR	OB, R, S
NR	NR	NR	NR	7	NR	NFP	OB, R, S
87	17	10	11	20	NR	NFP	OB, R, S
NR	NR	NR	NR	12	0	NFP	OB, R, S
58	25	NR	NR	5	10	FP	OB, R, M
77	21	NR	19	11	NR	NR	OB, R, S

CAD, Coronary artery disease; *DM,* diabetes mellitus; *FP,* for profit; *HTN,* hypertension; *M,* multi-center study; *NFP,* not-for-profit; *NR,* not reported; *OB,* observational or nonrandomized study; *P,* prospective study; *R,* retrospective study; *S,* single center study; *UC,* unclear.

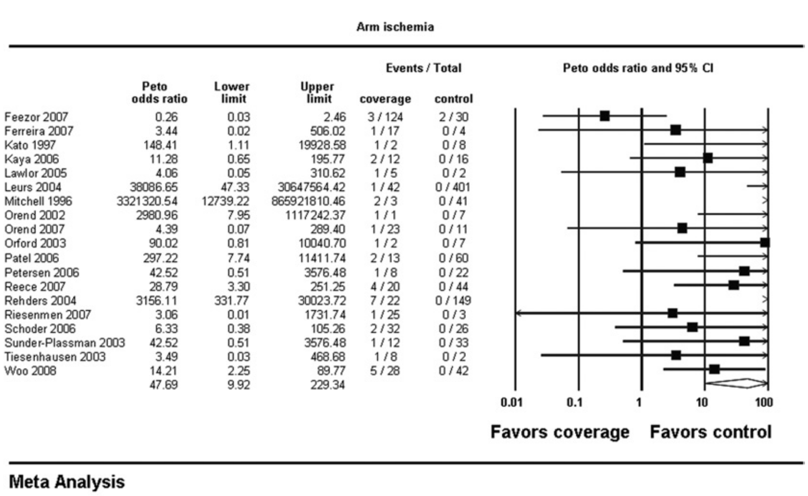
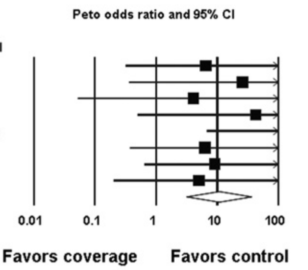


Fig 2. Arm ischemia: random-effects meta-analysis. Squares are odds ratios of individual studies, lines are 95% confidence intervals, diamond represents the pooled effect, and the width of the diamond is the 95% confidence interval of the pooled estimate.

evidence suggesting that coverage increased the risk of arm ischemia and vertebrobasilar ischemia with a strong trend for increased risk of spinal cord ischemia and anterior circulation stroke. We found no difference in other outcomes such as death, myocardial infarction, or TIA. The incidence of phrenic nerve injury associated with primary revascularization was fairly low. Data on perioperative infection were sparse and inconclusive.

Vertebrobasilar ischemia

	Peto odds ratio	Lower limit	Upper limit	Events / Total Coverage	Events / Total control
Fu 2005	6.52	0.32	131.05	2 / 6	0 / 4
Juszkat 2007	25.79	0.37	1801.89	1 / 4	0 / 9
Lawlor 2005	4.06	0.05	310.62	1 / 5	0 / 2
Petersen 2006	42.52	0.51	3576.48	1 / 8	0 / 22
Rehders 2004	2374.94	6.81	827820.95	1 / 22	0 / 149
Schoder 2006	6.33	0.38	105.26	2 / 32	0 / 26
Song 2006	9.04	0.65	126.48	2 / 11	1 / 31
Tiesenhausen 2003	4.99	0.20	123.33	3 / 8	0 / 2
	10.78	3.17	36.69		

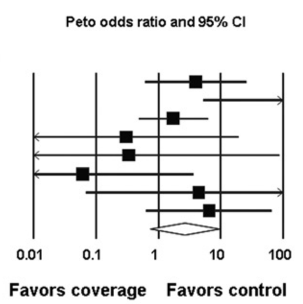


Meta Analysis

Fig 3. Vertebrobasilar ischemia: random-effects meta-analysis. Squares are odds ratios of individual studies, lines are 95% confidence intervals, diamond represents the pooled effect, and the width of the diamond is the 95% confidence interval of the pooled estimate.

Spinal cord ischemia

	Peto odds ratio	Lower limit	Upper limit	Events / Total coverage	Events / Total control
Buth 2007	3.97	0.61	25.89	6 / 119	0 / 40
Dagenais 2005	184.45	5.36	6352.92	2 / 5	0 / 20
Feezor 2007	1.73	0.49	6.16	15 / 124	2 / 30
Marchiex 2006	0.31	0.00	18.98	0 / 6	2 / 39
Mitchell 1996	0.33	0.00	86.90	0 / 3	2 / 41
Pamler 2002	0.06	0.00	3.63	0 / 9	1 / 5
Rodriguez 2007	4.48	0.07	286.49	1 / 12	0 / 6
Schoder 2006	6.54	0.65	66.34	3 / 32	0 / 26
	2.69	0.75	9.68		

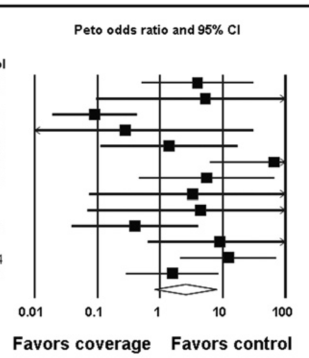


Meta Analysis

Fig 4. Spinal cord ischemia: random-effects meta-analysis. Squares are odds ratios of individual studies, lines are 95% confidence intervals, diamond represents the pooled effect, and the width of the diamond is the 95% confidence interval of the pooled estimate.

Anterior circulation stroke

	Peto odds ratio	Lower limit	Upper limit	Events / Total coverage	Events / Total control
Buth 2007	3.94	0.51	30.48	5 / 119	0 / 40
Dong 2005	5.29	0.10	289.29	1 / 6	0 / 4
Feezor 2007	0.09	0.02	0.43	5 / 124	6 / 30
Ferrari 2006	0.28	0.00	30.84	0 / 4	1 / 14
Marchiex 2006	1.38	0.11	16.87	1 / 6	5 / 39
Petersen 2006	65.54	6.31	680.70	4 / 8	0 / 22
Reece 2007	5.49	0.46	65.60	2 / 20	1 / 44
Riesenmen 2007	3.35	0.07	150.16	3 / 25	0 / 3
Rodriguez 2007	4.48	0.07	286.49	1 / 12	0 / 6
Schoder 2006	0.40	0.04	4.06	1 / 32	2 / 26
Song 2006	9.04	0.65	126.48	2 / 11	1 / 31
Thompson 2007	12.26	2.12	70.79	5 / 56	1 / 124
Woo 2008	1.57	0.29	8.54	3 / 28	3 / 42
	2.58	0.82	8.09		



Meta Analysis

Fig 5. Anterior circulation stroke: random-effects meta-analysis. Squares are odds ratios of individual studies, lines are 95% confidence intervals, diamond represents the pooled effect, and the width of the diamond is the 95% confidence interval of the pooled estimate.

The evidence in this review is of very low quality due to several reasons. First, the included studies are observational; hence, patients were assigned to the different interventions based on their morbidity and surgeon's preferences/expertise. Second, it is apparent that the patients within each study are heterogenous in terms of diagnoses, morbidity, and aortic pathology. It is possible that the underlying aortic pathology, rather than the procedure itself, had

Table II. Baseline risk of outcomes of interest in patients who underwent LSA coverage

Outcome	*Overall risk*	*Aneurysm*	*Dissection*	*Trauma*
Arm ischemia	38/687 (6%)	2/82 (2%)	7/127 (6%)	5/57 (9%)
Spinal cord ischemia	27/673 (4%)	NR	NR	NR
Vertebrobasilar ischemia	7/442 (2%)	1/82 (1%)	6/127 (5%)	1/47 (2%)
Anterior circulation stroke	33/676 (5%)	1/26 (4%)	3/99 (3%)	NR
Death	29/447 (6%)	2/18 (11%)	1/60 (2%)	4/50 (8%)

LSA, Left subclavian artery; *NR,* no events reported/incalculable.
Data on myocardial infarction, infection, transient ischemic attacks are sparse and not well-reported.

Table III. Subgroup analyses

Outcome	*Peto OR (95% CI)*	P *value for interaction*
Death		
Control group: revascularization	0.76 (0.18-3.29)	.50
Control group: no coverage	1.43 (0.46-4.42)	
Elective procedure	327.20 (0.28-∞)	.61
Urgent procedure	38.74 (0.61-∞)	
Indication: aneurysm	1.25 (0.05-30.93)	.78
Indication: dissection	2.41 (0.10-56.32)	
Arm ischemia		
Control group: revascularization	3.05 (0.26-35.99)	.01
Control group: no coverage	144.43 (27.86-748.08)	
Elective procedure	0.87 (0.24-3.19)	.31
Urgent procedure	2.36 (0.55-10.09)	
Indication: aneurysm	786.70 (1.08-∞)	.79
Indication: dissection	3156.10 (1.23-∞)	
Anterior circulation stroke		
Control group: revascularization	1.84 (0.35-9.74)	.59
Control group: no coverage	3.48 (0.72-16.67)	
Elective procedure	1.44 (0.10-21.43)	.65
Urgent procedure	0.28 (0.00-228.00)	
Indication: aneurysm	1.39 (0.11-16.87)	.31
Indication: dissection	7.68 (0.85-69.55)	
TIA		
Control group: revascularization	0.58 (0.05-7.44)	.59
Control group: no coverage	1.53 (0.14-17.13)	
Vertebrobasilar insufficiency		
Control group: revascularization	7.73 (1.54-38.68)	.67
Control group: no coverage	17.02 (2.58-112.14)	
Indication: aneurysm	25.79 (0.16-∞)	.92
Indication: dissection	19.18 (1.45-254.21)	
Spinal cord ischemia		
Control group: revascularization	3.38 (0.64-18.02)	.74
Control group: no coverage	1.57 (0.14-18.27)	
Indication: aneurysm	0.31 (0.01-18.98)	.59
Indication: dissection	0.06 (0.00-3.63)	

CI, Confidence interval; *OR,* odds ratio; *TIA,* transient ischemic attack.

played a significant role in the overall outcome. Third, data are in general sparse with low number of events. Fourth, the outcomes were poorly described in many cases; therefore, transient or less clinically important outcomes (eg, a case of hand ischemia that is not severe or does not require revascularization) may have been included in the analysis, adding an element of indirectness to this evidence. Thus, the quality of the evidence is downgraded due to methodological limitations of included studies, heterogeneity, imprecision, and indirectness.

Strengths, limitations, and comparison with other systematic reviews

A systematic review and meta-analysis conducted by Cooper et al[16] found that LSA coverage, with or without revascularization, was associated with increased risk of stroke, whereas the risk of spinal cord ischemia is only increased when revascularization is not done. In this report, we differentiated between anterior circulation stroke, transient ischemic attacks and vertebrobasilar ischemia; and assessed several additional outcomes such as arm ischemia, death, and myocardial infarction. Our findings are also in agreement with a narrative review by Noor et al;[17] our review, however, explicitly describes the search process as well as the eligibility criteria and offers a meta-analytic estimate to assist decision makers in balancing the risks and benefits of this procedure. In addition to these strengths, our team reviewed evidence in blinded pairs of reviewers with adequate inter-reviewer agreement. Also, we have shown that our findings are robust to the use of different statistical pooling methods and consistent across several subgroups of patients, interventions, and study designs. The inferences drawn are weak given the very low quality of the best available evidence. Indeed, the primary studies summarized here enrolled a heterogeneous patient population, have important methodological limitations, and report inconsistent findings. Furthermore, the overall data is sparse and the estimates imprecise even after pooling.

Implications for practice and research

The increased risk of arm ischemia, vertebrobasilar ischemia and, possibly, spinal cord ischemia and anterior circulation stroke associated with LSA coverage need to be weighed against other factors such as urgency of aortic repair, availability of surgical expertise, feasibility of carotid-subclavian bypass or transposition before coverage, patient anatomy, and other risks and burdens associated with these procedures. The accompanying guideline document prepared by the Committee on Thoracic Aortic disease from the Society for Vascular Surgery contains the practical and clinical implications of our results.

Considering that some of the indications for these procedures, such as dissection or transsection, are rare and data is overall sparse, it is apparent that future studies are needed to confirm or dispute the weak inferences we have drawn from the available very-low-quality evidence. Multicenter research with collaboration among surgeons and researchers is paramount to accrue the large number of patients and events necessary to improve the precision of future studies and the overall evidence base. Random or protocol-driven allocation stratified by procedure urgency and aortic pathology will decrease the heterogeneity of future evidence and improve its quality.

CONCLUSION

Very low quality evidence suggests that the intentional coverage of the left subclavian artery during placement of an endovascular stent graft in the descending thoracic aorta increases the risk of arm ischemia, vertebrobasilar ischemia, and possibly of spinal cord ischemia and anterior circulation stroke. When feasible, primary revascularization procedures may reduce this risk.

AUTHOR CONTRIBUTIONS

Conception and design: AR, MM, RF, PE, VM
Analysis and interpretation: MM, VM
Data collection: AR, MM, PE
Writing the article: AR, MM, RF, PE, VM
Critical revision of the article: AR, MM, RF, PE, VM
Final approval of the article: AR, MM, RF, PE, VM
Statistical analysis: MM
Obtaining funding: MM, VM
Overall responsibility: MM

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