

Long-term results of left subclavian artery coverage during thoracic endovascular aortic repair: A single center study

Kemal Karaarslan¹, Ayşe Gül Kunt¹, Onur Saydam², Deniz Şerefli³, Burçin Abud¹

¹Department of Cardiovascular Surgery, Health Sciences University, Tepecik Training and Research Hospital, Izmir, Turkey

²Department of Cardiovascular Surgery, Hacettepe University Faculty of Medicine, Ankara, Turkey

³Department of Cardiovascular Surgery, Başkent University Faculty of Medicine, Ankara Turkey

ABSTRACT

Objectives: In this study, we aimed to evaluate the results of patients with or without left subclavian artery (LSA) coverage during thoracic endovascular aortic repair (TEVAR) in terms of type IA endoleak.

Patients and methods: Between December 2011 and March 2020, a total of 50 patients (42 males, 8 females; mean age: 65.2±12.0 years; range, 53.2 to 77.2 years) who underwent TEVAR in our clinic were retrospectively analyzed. The patients were divided into two groups Group 1 (n=34) including patients whose LSA was not covered and Group 2 (n=16) whose LSA was covered by an endograft during the procedure. Primary outcome measures were all-cause mortality and type IA endoleak.

Results: Indications were mostly type B aortic dissection (n=15, 30%) (Group 1 n=7, Group 2 n=8) and descending thoracic aortic aneurysms (n=15, 28%) (Group 1 n=11, Group 2 n=4) (p=0.605). The mean follow-up for all patients was 18±12.2 months (p=0.26). Overall mortality was 10% (5/50) and all were in Group 1 (n=5/0), indicating no statistically significant difference between the groups (p=0.11). During follow-up, type IA leak was detected in five patients and was found to be more frequent in Group 2 (n=1/4) (p=0.02). None of the patients had a cerebrovascular accident and spinal cord ischemia during follow-up.

Conclusion: The coverage of the LSA during TEVAR may pose a risk for type IA leakage. Left-arm ischemia can be treated with carotid-subclavian bypass surgery after LSA occlusion.

Keywords: Left subclavian artery, mortality, thoracic endovascular aortic repair, type IA endoleak.

Thoracic endovascular aortic repair (TEVAR) for the treatment of thoracic aortic diseases has gained broad acceptance in high-risk patients.^[1-5] The procedure requires a healthy anatomical landing zone in the aortic arch to ensure optimal clinical outcomes and minimize the complications including endoleak.^[6,7] However, in the presence of a complex aortic arch pathology, a significant proportion of patients have the lesion adjacent or even proximal to the left subclavian artery (LSA) and, to achieve complete sealing during TEVAR, coverage of LSA with a TEVAR graft can be crucial.^[8]

The LSA arises as the third branch of the aortic arch after the left common carotid artery and branches arising from LSA provide flow to posterior cerebral, spinal cord, and upper extremity circulation. Therefore, cessation of antegrade blood flow with LSA coverage during TEVAR procedure may lead to neurological and vascular complications up to 40% in patients with insufficient collaterals circulation.^[9] However, there are still debates regarding the prophylactic treatment approaches for patients whose LSA would be covered. The 2009 Society for Vascular Surgery guidelines recommended routine preoperative revascularization

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Correspondence: Kemal Karaarslan, MD. SBÜ Tepecik Eğitim ve Araştırma Hastanesi Kalp ve Damar Cerrahisi Kliniği, 35020 Konak, İzmir, Türkiye.
e-mail: karaarslan4@hotmail.com

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in patients who need LSA coverage, with 2C evidence to prevent cerebrovascular accident (CVA), spinal cord ischemia (SCI) and upper extremity ischemia. However, some authors have advocated a selective revascularization strategy due to the high mortality and morbidity rates in insistent LSA coverage.^[10-12] In addition, most of the aforementioned risks, which may arise by closing the LSA, can be eliminated after the risk of endoleak, particularly type IA endoleak, is reduced following the procedure. However, there are not enough data about type IA endoleak occurring after TEVAR with LSA coverage.^[13]

The development of neurovascular (spinal) ischemia after the closure of the LSA during the TEVAR procedure is controversial in cases with and without subclavian revascularization. The requirement of closing the LSA for the proximal landing zone in TEVAR is extremely important, particularly in terms of preventing type IA endoleak. In the present study, we aimed to compare the outcomes of patients with or without coverage of LSA during TEVAR with special attention to the development of type IA endoleak.

Increased endoleak rates are reported after LSA closure. In our study, does the increase of endoleak in the group we closed LSA mean statistically? Is the type I endoleak significantly associated with LSA closure?

PATIENTS AND METHODS

This single-center, retrospective study was conducted at Health Sciences University, Tepecik Training and Research Hospital, Department of Cardiovascular Surgery between December 2011 and March 2020. A total of 50 patients (42 males, 8 females; mean age: 65.2±12.0 years; range, 53.2 to 77.2 years) who underwent TEVAR procedure for a descending thoracic aortic pathology were included. Demographic and clinical characteristics of the patients and pre-, intra-, and post-procedural and follow-up data were obtained from hospital records, archival images, or phone calls. A written informed consent was obtained from each patient. The study protocol was approved by the Tepecik Training and Research Hospital Ethics Committee (date/no: 08.06.2020/2020/7-38). The study was conducted in accordance with the principles of the Declaration of Helsinki.

The patients were divided into two groups. Group 1 (n=34) consisted of patients whose LSA was not covered by a TEVAR graft and Group 2 (n=16) consisted of patients whose LSA was covered by a TEVAR

graft during the procedure (Figure 1). Indications for TEVAR were aortic intramural hematomas, penetrating aortic ulcer, type B aortic dissection and descending thoracic aortic aneurysms including fusiform, saccular, traumatic aneurysms, and anastomotic pseudoaneurysms. Elective, urgent, and emergent procedures were included; however, patients who underwent alternative revascularization methods, such as a fenestration or a chimney procedure, were excluded. In cases that required TEVAR due to lesions in the subclavian artery proximal (Zone 0, 1, 2) were excluded. The patients who underwent coronary artery bypass surgery with a left mammary artery were also excluded.

Preoperative planning with computed tomography angiography (CTA) of the neck was performed in all patients to assess the arch vessel, carotid, and vertebral artery anatomy. Preoperative carotid and vertebral artery Doppler ultrasonography was also performed to evaluate the cerebrovascular anatomy. For endovascular graft access, the femoral artery was cut down and retrograde endovascular graft was sent. However, in unsuccessful attempts with these techniques, they are combined with an antegrade approach via the axillary artery. In all cases, a ≥10-mm proximal aortic neck was considered appropriate not to cover LSA. In cases with a shorter neck, LSA was covered. The TAG™ (W.L. Gore and Associates, Flagstaff, AZ, USA) and the Talent™ (Medtronic, Minneapolis, MN, USA) were used as endovascular grafts. The proximal diameter of the stent-graft was adjusted to the target aortic diameter in aneurysms by increasing by 20%

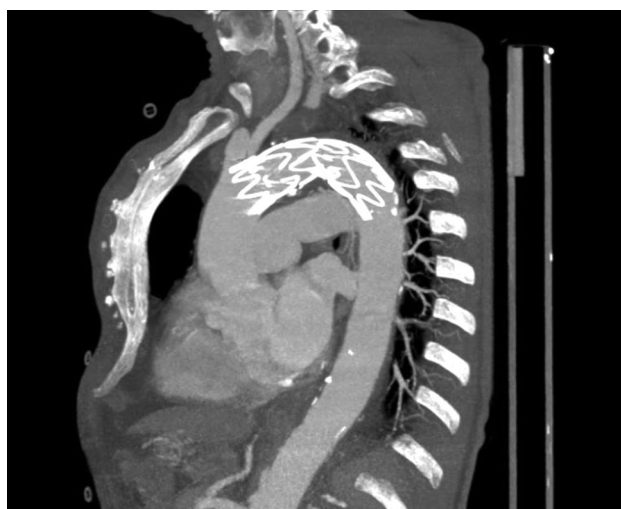


Figure 1. Coverage of left subclavian artery with endograft.

and by 15% in type B aortic dissection. The drainage catheter of the cerebrospinal fluid was routinely placed preoperatively by the neurosurgeons in all patients, except for ruptured aneurysms. Drains were kept in place until 72 h after the operation. Spinal drainage was removed, if no neurological signs or symptoms developed.

In patients who underwent TEVAR with LSA coverage, selective revascularization strategy was adopted for LSA. The patient who had postoperative left upper extremity ischemic symptoms was considered a candidate for carotid-subclavian bypass.

In patients without any symptom, postoperative clinical and imaging follow-up was performed with CTA at six months after the procedure and annually thereafter; otherwise, on the date when the first symptom occurred. The CTA was used to detect endoleak, changes in the aneurysmal sac size or thrombosis formation and structural orientation of the stent graft. The endoleaks seen within the first 30 days were defined as early and those seen after 30 days were defined as late.^[14]

Primary outcome measures were all-cause mortality and type IA endoleak. Late mortality was defined as death that occurred after ≥ 30 days or during hospital stay or follow-up. For early endoleak, first conservative management was followed. In case of prolonged early endoleak or late endoleak, endovascular treatment was carried out with balloon angioplasty or stent graft extension.

Statistical analysis

Statistical analysis was performed using the IBM SPSS for MAC version 20.0 software (IBM Corp., Armonk, NY, USA). Continuous variables were expressed in mean \pm standard deviation (SD) or median (min-max), while categorical variables were expressed in number and frequency. The Student t-test was used for normally distributed data measured on a continuous/interval scale, while the Mann-Whitney U test was used for non-normally distributed data. The Pearson correlation test was used to analyze significant relationships between continuous variables. A *p* value of <0.05 was considered statistically significant.

Table 1. Baseline patient data

	Group 1 (n=34)			Group 2 (n=16)			<i>p</i>
	n	%	Mean \pm SD	n	%	Mean \pm SD	
Age (year)			65.4 \pm 11.8			64 \pm 12.9	0.88
Sex							0.64
Male	28	56		14	28		
Diabetes mellitus	8	16		1	2		0.14
Hypertension	25	50		10	20		0.43
Coronary artery disease	10	20		4	8		0.75
Ejection fraction			56.2 \pm 9.4			55.4 \pm 9.8	0.80
Chronic obstructive pulmonary disease	17	34		6	12		0.41
Chronic renal insufficiency-dialysis dependent	0	0		2	4		0.04
Peripheral artery disease	2	4		0	0		0.32
Acute	28	56		7	14		0.005
Mean diameter of the sac (mm)			53.9 \pm 13.6			61.3 \pm 15.6	0.8
Aortic pathology							0.60
Type B aortic dissection	7	14		8	16		
Descending thoracic aortic aneurysm	11	20		4	8		
Saccular aneurysm	3	6		2	4		
Pseudoaneurysm	1	2		0	0		
Traumatic transection	1	2		0	0		
Intramural hematoma	4	8		0	0		
Penetrating aortic ulcer	3	6		1	2		
Ruptured descending thoracic aortic aneurysm	3	6		1	2		
Ruptured type B dissection	1	2		0	0		

SD: Standard deviation.

Table 2. Procedural and follow-up data

	Group 1 (n=34)				Group 2 (n=16)				p
	n	%	Mean±SD	Length (mm)	n	%	Mean±SD	Length (mm)	
Anesthetic management									0.002
General	2	56			5	10			
Spinal	2	4			5	10			
Local	4	8			6	12			
Stent graft length				18.9				18.5	0.74
Mean follow-up (months)			17.6±11.7				21.7±12.4		0.26
Mortality	5	20			0	0			0.11
Type IA endoleak	1	2			4	8			0.02

SD: Standard deviation.

RESULTS

Among a total of 50 patients included in the study, the origin of the LSA was covered to obtain an adequate proximal landing zone or to exclude a pathology in 16 (32%) patients. The TEVAR was most commonly performed to treat type B aortic dissection (n=15, 30%) (Group 1 n=7, Group 2 n=8) and descending thoracic aortic aneurysms (n=15, 28%) (Group 1 n=11, Group 2 n=4). No significant difference was found between the groups in terms of indications (p=0.605). Baseline patient data are summarized in Table 1.

Thirty-five (70%) patients underwent TEVAR for acute aortic pathologies and Group 1 more commonly underwent an intervention due to acute aortic pathologies (n=28 *vs.* n=7, respectively) (p=0.005). The mean preoperative aortic diameters were similar between the groups (p=0.99). General anesthesia was performed in 33 (66%), spinal anesthesia in seven (14%) and, local anesthesia in 10 (20%) patients (Table 2). General anesthesia was mostly used in Group 1 (n=28 *vs.* n=5, respectively), while local anesthesia was mostly used in Group 2 (n=4 *vs.* n=6, respectively) (p=0.002).

The overall mean follow-up was 18±12.2 (range, 5.8 to 30.2) months, indicating no significant difference between the groups (p=0.26). Major complications were seen in five (21.3%) (Group 1 n=3/Group 2 n=2) patients including left hand ischemia (n=0/1), monoplegia in lower extremity (n=1/0), left iliac artery dissection (n=1/0), and left iliac pseudoaneurysm (n=1/0) and contrast nephropathy (0/1), indicating no significant difference between the groups (p=0.69). Immediately after the procedure, the left upper extremity pulses were detected; however, it was weaker compared to

the contralateral extremity in the patient with hand ischemia. The ischemia process developed slowly, and carotid-subclavian artery bypass was performed on postoperative Day 7 (Figure 2). The patients who were diagnosed with iliac artery dissection and pseudoaneurysms required an additional endovascular reintervention with balloon-expandable covered stents.

Peripheral artery disease was accompanied by severe stenosis in both common iliac arteries in two (4%) patients. Both lesions were treated with a balloon-expandable bare-metal stent in the beginning of the TEVAR procedure. Type IA endoleak was detected in five (10%) patients during follow-up and was found to be more common in Group 2 (n=1 *vs.* 4) (p=0.02). No significant difference was found between the patients who developed type IA endoleak or in terms of indications (p=0.89). Although no significant difference was observed, the mean diameter of the aorta was slightly larger in patients with type IA endoleak (56.8 mm *vs.* 59.2 mm, respectively; p=0.74). Two (40%) patients who had type IA endoleaks were detected on the initial postoperative computed tomography (CT) scan on Days 19 and 20, respectively. Both patients belonged to Group 2 and one patient was treated with conservative treatment, while reintervention was needed in the other patient. Totally, 60% of endoleaks 3 of a total of 5 endoleaks were detected later on Days 31, 55, and 95. No open surgery was performed for the treatment of type IA endoleaks. All late endoleaks and one prolonged early type IA endoleak were treated with endovascular approach. Balloon angioplasty was used in two (40%) and stent graft extension was used in three (60%) patients. No diameter extension was observed in patients after the treatment of type IA endoleak during follow-up. The Talent™ device was used in 31 (62%) patients, and the



Figure 2. (a) Left-hand ischemia after TEVAR procedure. (b) Healed after carotid subclavian bypass graft interposition.

Gore TAG™ device was used in 19 (38%) patients. No significant differences were found between the groups and patients diagnosed with type IA endoleak in terms of devices which were used during the procedure ($p=0.11$ and $p=0.47$, respectively).

Overall survival at six and 12 months were 88% and 86%, respectively. Although Group 1 had better survival rates at two time points (88.2% *vs.* 87.5%, respectively and 85% *vs.* 57%, respectively), no statistically significant differences were found ($p=0.31$).

Overall mortality was 10% (5/50) and all were found in Group 1 (5 *vs.* 0, respectively); however, it did not reach statistical significance ($p=0.11$). Early in-hospital mortality was observed in one patient who was diagnosed with ruptured type B dissection. No mortality was detected in the patients diagnosed with type IA endoleak and also there was no CVA-related mortality.

DISCUSSION

Although LSA coverage is recommended to prevent type IA endoleak in patients having inadequate landing zone,^[15] in our study, the patients whose LSA was covered with a TEVAR graft had a higher incidence of type IA endoleaks. The relationship between coverage of LSA and type IA has not completely elucidated yet; however, the group of

patients whose LSA are needed to be covered consists of those with more complex aortic pathologies. The LSA revascularization may be required to reduce major neurological complications which may be associated with the left vertebral artery.^[16]

Occlusion of the LSA with a covered stent may result in catastrophic neurological and vascular complications, including left upper ischemia, CVA and SCI.^[17-19] Stroke following TEVAR with LSA coverage frequently occurs in the real-world setting, and concurrent LSA revascularization is not associated with a lower stroke incidence.^[20] Hypogastric hypoperfusion due to visceral atherosclerosis may be eliminated by collateral circulation from the subclavian artery. The LSA closure in these cases may cause stroke and spinal ischemia. In contrast, our study showed no significant differences in term of major complications including neurological and vascular between patients whose LSA was covered or not. Maldonado et al.^[21] revealed that LSA revascularization may even be harmful to certain patients. Similarly, most authors have advocated a selective revascularization strategy based on absolute indications for revascularization to avoid these complications. There are also studies showing that there are similar rates of CVA and SCI, when selective revascularization is performed.^[9,18] About 2 to 3% of the patients with LSA covered without revascularizations may result in left upper extremity ischemic symptoms.^[10,22] Vertebral artery hemodynamic changes that would

occur when Zone 2 is closed with TEVAR may be an important determinant of postoperative neurological events.^[23] In our study, one (2%) patient underwent carotid-subclavian bypass due to left arm ischemia. This finding is consistent with the other results. Multivariable analysis adjustment identified an independent association between LSA coverage without revascularization and the incidence of SCI. Although the incidence of stroke was also higher for the group with a covered and non-revascularized LSA, this difference was not statistically significant after multivariable analysis.^[24]

Endoleaks are the most common complications reported with an incidence as high as 23.3 to 32.9%.^[25-28] The presence of an endoleak may lead to significantly less sac regression and, thus, to rupture regression. In parallel with our study, LSA coverage was significantly associated with an increased type IA endoleak rate in a previous study.^[29] Although there was no significant difference between the graft type and type IA endoleaks in our study, endograft type may affect the outcomes of endoleaks.^[29,30] Although early endoleaks may be treated conservatively, prolonged or late endoleaks need immediate reintervention to halt enlargement of the aneurysm and, finally, prevent the rupture.^[31] Reintervention with balloon angioplasty or stent graft extension are primary choices for repair of endoleaks. In addition to these conventional techniques, there are several new devices for better proximal sealing, such as endostaples that fixate the proximal stent-graft to the aortic neck wall, for better proximal sealing promising early results for both prophylaxis and treatment of type IA endoleaks.^[31] Despite all these efforts, open repair may be still required and open repair of endoleak in the aortic arch is a challenging issue due to the existence of endograft. However, in our cohort, all patients who were diagnosed with type IA endoleak were successfully treated conservatively or by using endovascular techniques.

Due to the patient's comorbid conditions and ongoing thoracic aortic pathologies, inadequate intervention is adversely effective in the long term. Surprisingly, in our study, in both groups, no CVA was detected. However, monoplegia was observed due to SCI in one (2%) patient whose LSA was not covered by the TEVAR graft. Routine use of lumbar drainage catheter insertion and maintenance of mean arterial pressure over 90 mmHg during and after the procedure may have affected our results in a positive manner for SCI. Although SCI and

postoperative neurological deficit are more commonly seen with surgical repair, they can be also seen after TEVAR.^[32,33] The risk of SCI mostly stands out due to the deterioration of blood flow in T8-L2 intercostal arteries, which may be crucial to spinal cord perfusion.^[34] Using longer devices instead of short devices may result in the increased incidence of involvement of T8-L2 intercostal arteries. In addition, the patient who had postoperative SCI in our study had one of the longest graft lengths. Major aortic pathologies requiring LSA closure during the TEVAR procedure are frequently encountered. Complications that may occur after LSA closure, particularly type IA endoleaks, can be successfully treated.^[35-37]

The single-center, retrospective design, relatively small sample size, and heterogeneous aortic diseases which may have an effect on the outcomes of LSA coverage on mortality and endoleak rates are the main limitations of this study.

In conclusion, coverage of the LSA during TEVAR may be considered a risk for type IA endoleaks. Left arm ischemia can be seen after occlusion of LSA with a low incidence, and, if needed, patients can be treated with carotid-subclavian bypass surgery without any sequelae during follow-up. Although modern reintervention techniques for patients diagnosed with type IA endoleak are still under investigation, reintervention with conventional endovascular technique currently seems to be safe and effective.

Declaration of conflicting interests

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