

## Clinical Outcomes and Quality of Life Following TEVAR with or without Revascularization of the Left Subclavian Artery

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### Abstract

**Objectives:** This study aims to evaluate the clinical outcomes and quality of life of patients with or without the left subclavian artery (LSA) revascularization in patients with thoracic aortic diseases undergoing endovascular repair of the ishimaru zone 2.

**Methods:** A total of 48 patients with the closure of the LSA after thoracic endovascular aortic repair (TEVAR) were enrolled in the study between 2014 and 2018, of whom 21 had undergone the LSA (revascularization group), and the remaining 27 cases (non-revascularization group). The study was planned as a single-center retrospective design. Data were retrieved from the patients' files. Short form-36 scales were administered to assess quality of life.

**Results:** There was no difference between the two groups with and without LSA revascularization in 30-day paraplegia (4.8% vs. 0.0%,  $p=0.449$ ), 4-year cerebrovascular events (0.0% vs. 3.8%,  $p=0.998$ ), upper extremity ischemia (9.6% vs. 0.0%,  $p=0.207$ ), death (28.6% vs. 25.9%,  $p=0.887$ ), rate of endoleak (23.8% vs. 29.6%,  $p=0.896$ ), and length of intensive care unit stay ( $2.3\pm 2.1$  days vs.  $2.1\pm 1.8$  days,  $p=0.645$ ). Regarding the quality of life, only physical functioning was improved slightly more in the group that underwent LSA without revascularization ( $90.7\pm 26.7$  vs.  $82.3\pm 14.9$ ,  $p=0.032$ ).

**Conclusion:** The current study showed no significant differences with respect to neurological outcomes, upper extremity ischemia, quality of life, and mortality among patients undergoing TEVAR with or without revascularization of the LSA.

**Keywords:** Quality of life; subclavian arteries; thoracic aorta.

## Sol Subklavian Arter Revaskülerizasyonu Yapılan ve Yapılmayan TEVAR Sonrası Klinik Sonuçlar ve Yaşam Kalitesi

### Özet

**Amaç:** Bu çalışmada, isthimaru zone 2 endovasküler aortik onarım yapılan hastalarda, sol subklaviyan arter revaskülerizasyonu yapıp yapılmamasının klinik sonuçlara ve yaşam kalitesine etkisi araştırılmaktadır.

**Gereç ve Yöntem:** Bu çalışmaya 2014-2018 yılları arasında torasik endovasküler onarım (TEVAR) sonrası sol subklaviyan arteri kapatılan 48 hasta dahil edildi. Bu hastaların 21'inde sol subklaviyan arter revaskülerize edildi (revaskülerizasyon grubu), geri kalan 27 hastaya revaskülerizasyon yapılmadı (revaskülerizasyon yapılmayan grup). Çalışma tek merkezli retrospektif olarak planlandı. Veriler hastaların dosyalarından alındı. Yaşam kalitesini değerlendirmek için kısa form-36 (SF-36) kullanıldı.

**Bulgular:** Sol subklaviyan arter revaskülerizasyonu yapılan ve yapılmayan gruplar arasında 30 günlük parapleji (%4.8 karşı %0.0,  $p=0.449$ ), 4 yıllık serebrovasküler olay (%0.0 karşı %3.8  $p=0.998$ ), üst ekstremitte iskemisi, (%9.6 karşı %0.0,  $p=0.207$ ), ölüm (%28.6 karşı %25.9,  $p=0.887$ ), endoleak oranı (%23.8 karşı %29.6,  $p=0.896$ ),

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ve yoğun bakım kalış süresi ( $2.3 \pm 2.1$  gün karşı  $2.1 \pm 1.8$  gün,  $p=0.645$ ) bakımından fark yoktu. Yaşam kalitesi açısından sol subklaviyan arter revaskülarize edilmeyen grupta sadece fiziksel fonksiyon biraz daha iyiydi ( $90.7 \pm 26.7$  karşı  $82.3 \pm 14.9$ ,  $p=0.032$ ).

**Sonuç:** Sol subklavian arter revaskülarizasyonu yapılan TEVAR hastaları ile revaskülarizasyon yapılmayan hastalar arasında nörolojik sonuçlar, üst ekstremitte iskemisi, yaşam kalitesi ve mortalite açısından anlamlı farklılık saptanmamıştır.

**Anahtar sözcükler:** Yaşam kalitesi; subklavian arter; torasik aort.

## Introduction

The repair of the thoracic endovascular aorta is a treatment option performed by implantation of a stent grafting in the thoracic aorta. The diseases of the thoracic aorta include aneurysm, dissection, intramural hematoma, penetrating aortic ulcer, and blunt aortic injury, with a mortality rate of up to 18%.<sup>[1]</sup> The thoracic endovascular aortic repair (TEVAR) was first performed by Dake et al.,<sup>[2]</sup> in 1994. TEVAR is a method of choice in that it is associated with fewer complications and a shorter hospital and intensive care unit stay than open surgery.<sup>[3]</sup> Safe placement of a TEVAR grafting requires an aortic diameter to be <40 mm and a landing zone length of 20 mm, for which procedure the occlusion of the left subclavian artery (LSA) may become necessary, which may lead to ischemia of the left upper extremity, of the spinal cord, claudication, and neurological symptoms because of vertebrobasilar hypoperfusion.<sup>[4]</sup> Therefore, the presence of obstruction in LSA may increase the burden of complications caused by the procedure, and therefore, it seems that simultaneous revascularization of the LSA can bring much better procedural consequences and minimize the aforementioned complications.<sup>[5]</sup> The available evidence indicates a significant improvement in the clinical outcome of patients undergoing the TEVAR technique. In this regard, a significant reduction in mortality due to aortic abnormalities, improvement in the physical ability of patients, and finally improvement in the quality of life of patients have been reported.<sup>[6–8]</sup> The current study aimed to evaluate the clinical outcomes and quality of life of patients who had undergone endovascular repair of the landing zone 2 and to compare patients undergoing revascularization of the LSA (the revascularization group) with those not undergoing revascularization of the LSA (the non-revascularization group).

## Materials and Methods

This single-center study recruited 48 patients (10 females and 38 males) who had undergone occlusion of the LSA by performing TEVAR; of whom 21 (one woman 4.8% and 20 men 95.2%) had undergone left carotid-subclavian artery bypass operation (revascularization group) and the remaining 27 cases who had not undergone revascularization (non-revascularization group). The criteria for carotico-subclavian bypass were the dominance of the left vertebral artery, hypoplasia or stenosis of the right vertebral artery, the left vertebral artery terminating in the posterior inferior cerebellar artery, the use of long segment grafts (>20 cm) in the descending aorta, functioning left internal mammary artery (LIMA)-LAD anastomosis in patients undergoing coronary artery bypass graft, the presence of an A-V fistula in the left arm for dialysis, the dominance of the left hand, bilater-

al carotid artery stenosis, and prior abdominal aortic surgery. In this regard, the exclusion criteria for left carotico-subclavian artery bypass included requiring emergency operations, the presence of moderate-to-severe chronic obstructive pulmonary disease (COPD), or respiratory failure. The patients' data were retrieved from the patients' files. Demographic characteristics, cardiovascular risk factors, comorbidities, and echocardiographic findings were recorded. Data about paraplegia within 30 days, long-term cerebrovascular events (CVE), ischemia of the upper extremity, endoleak, length of ICU stay, length of hospital stay, and death were also retrieved. Patients who underwent TEVAR and who were over 18 years of age were included in the study. Exclusion criteria were age  $\geq 80$  years; prior valvular surgery, severe aortic regurgitation or stenosis; inotropic dependency; multiorgan failure; a history of moderate or severe COPD; and a serum creatinine level of  $\geq 2.5$  mg/dL.

The short form-36 (SF-36) was administered to assess the quality of life of patients. The patients were informed about the questionnaire. This tool evaluated the quality of life in the form of eight components including physical functioning, physical role limitation, pain, general health perceptions, vitality, social functioning, emotional role limitation, and mental health with scores for each of these scales (or dimensions) ranging from 0 to 100. Higher scores indicate a higher quality of life level.<sup>[9]</sup> The study protocol was approved by the local institutional review board and all participants gave their written informed consent (2018.3/2-94).

## Statistical Analysis

Categorical data were presented as percentages, and the quantitative data were presented as the mean and standard deviation. The comparison of categorical variables between the two groups was made with the Chi-square test. Since the number of patients was fewer than 50, the Shapiro–Wilk test was used for the compliance of the quantitative data; the Student's t-test was used for the normal distribution of the data between groups, and the Mann–Whitney U-test was used for the non-normal distribution. A p-value of 0.05 was considered significant, and IBM SPSS Statistics 22 was used in the analysis of the data.

## Results

The study included 48 patients with LSA coverage, of whom 21 (one female and 20 males) underwent left carotid-subclavian artery bypass, and of the remaining 27 patients, nine were females (33.3%) and 18 males (66.7%) (Table 1). A total of 39 patients (81.2%) presented with back pain and received a diagnosis of thoracic aortic disease. Of patients in the revascularization group, nine received a diagnosis of the aneurysm (42.9%) and

**Table 1. Demographic and clinical characteristics of the patients at baseline**

Characteristics	LSA with revascularization (n=21)		LSA without revascularization (n=27)		p
	n	%	n	%	
Age (Mean±SD)	52.5±12.1		58.1±14.1		0.151
Male	20	95.2	18	66.7	0.029
BMI (kg/m <sup>2</sup> ±SD)	27.2±4.5		26.3±4.8		0.489
Hypertension	17	81	22	81.5	0.999
Diabetes mellitus	3	14.3	1	3.7	0.306
COPD	5	23.8	3	11.1	0.272
Creatin level >1.7 mg/dL	3	14.3	1	3.7	0.306
Non-critical coronary lesion	19	90.5	23	85.2	0.726
PCI	1	4.8	3	11.1	0.726
CABG	1	4.8	1	3.7	0.726
EF (%±SD)	64.3±3.9		63.3±4.6		0.217

Data are presented as mean±SD or number (%). LSA: left subclavian artery; SD: Standard deviation; BMI: Body mass index; COPD: Chronic obstructive pulmonary disease; PCI: Percutaneous coronary intervention; CABG: Coronary artery bypass graft; EF: Ejection fraction.

12 patients received a diagnosis of dissection (57.1%). Of 22 patients in the non-revascularization group, 5 (18.5%) received a diagnosis of aneurysm and 22 patients (81.5%) received a diagnosis of dissection. One patient (4.8%) in the revascularization group had a history of prior coronary bypass operation and one patient who underwent LSA coverage (3.7%) had a history of prior coronary bypass. The LIMA was not used as a graft in both of them. Five patients without LSA bypass and two patients in the revascularization group underwent cerebrospinal fluid drainage. TEVAR was performed in all patients who electively underwent revascularization of LSA, and seven patients without revascularization underwent immediate TEVAR. There was no difference between the groups with respect to the diameter of the aorta. The two groups had pre-operative measurements of the diameter of the aortic annulus, sinus valsalva, ascending aorta, aortic arch, and descending aorta with CT angiography, with no statistical difference in diameters. Patients in the non-revascularization group had statistically higher pre-operative hemoglobin levels ( $p=0.05$ ) and higher post-operative white blood cell count ( $p=0.005$ ). Three patients (14%) in the revascularization group and 7 patients (25%) in non-revascularization had erythrocyte suspension replacement. Patients in the revascularization group and those in the non-revascularization group had similar TEVAR graft sizes. One patient (4.8%) in the revascularization group developed paraplegia within the first 30 days after the left carotid-subclavian artery bypass surgery, who died due to respiratory failure and sepsis and 1 patient (3.8%) in the non-revascularization group had a CVE 4 years after TEVAR. No ischemia of the upper extremity was noted in the non-revascularization group. Two patients in the revascularization group had ischemia of the right upper extremity, which was caused by an arterial catheter used for arterial monitorization. The signs of ischemia resolved completely after vascular surgery. The rates of endoleak did not differ significantly between the two groups ( $p=0.729$ ). Eight patients in the non-revascularization group had endoleak, of whom, five underwent reinterven-

tion of TEVAR. The five patients in the revascularization group had endoleak, of whom, two underwent reintervention of TEVAR, with the remaining patients continued receiving medical treatment. Patients in the non-revascularization group had statistically longer extubation time. The length of ICU stay of the revascularization group was  $2.3\pm 2.1$  days; which was  $2.1\pm 1.8$  days in the non-revascularization group, being no statistically significant difference ( $p=0.645$ ). Patients in the revascularization group had  $8.8\pm 5$  days of hospital stay; those in the non-revascularization group had  $7.8\pm 4.2$  days of hospital stay, not being a statistically significant difference ( $p=0.645$ ) (Table 2). Because nine patients rejected to fill in the questionnaire and 13 had died after discharge, the SF-36 questionnaire was limited to 26 people, of whom, 11 were in the revascularization group and 15 patients in the non-revascularization group. The mean value of physical function of those in the non-revascularization group was statistically higher ( $p=0.032$ ). No statistical difference was found in the remaining seven parameters (Table 3).

## Discussion

TEVAR has recently become a more preferred technique in the treatment of thoracic aortic pathologies<sup>[2]</sup> which was first performed by Bilgen et al.,<sup>[10]</sup> in 2001 for thoracic aortic aneurysms in Türkiye, becoming gradually more common in the following years. In the TEVAR procedure, the LSA may be closed for the appropriate proximal landing zone area. While left carotico-subclavian artery bypass and transposition techniques were previously applied for the treatment of occlusive diseases of the LSA, they have become two techniques more frequently performed by surgeons together with TEVAR. The difference between the left carotico-subclavian artery bypass and the transposition technique is that no graft is used in the transposition technique. While there was no difference in the rates of mortality between the two techniques, the rate of stroke was lower in left carotico-subclavian artery bypass surgery.<sup>[4]</sup> There have been also two percutaneous

**Table 2. Post-operative complications in revascularization and non-revascularization groups**

Item	LSA with revascularization (n=21)		LSA without revascularization (n=27)		p
	n	%	n	%	
Paraplegia within 30 days	1	4.8	0	0.0	0.449
Long-term cerebrovascular event	0	0.0	1	3.8	0.998
Ischemia of the upper extremity	2	9.6	0	0.0	0.207
Endoleak	5	23.8	8	29.6	0.896
Length of ICU stay, day	2.3±2.1		2.1±1.8		0.624
Length of hospital stay, day	8.8±5.0		7.8±4.2		0.645
Death	6	28.6	7	25.9	0.887

Data are presented as mean±SD or number (%). LSA: Left subclavian artery; ICU: Intensive care unit.

**Table 3. Scores of the SF-36**

Item	LSA with revascularization (n=11)		LSA without revascularization (n=15)		p
	Mean	SD	Mean	SD	
Physical functioning	82.3	14.9	90.7	26.7	0.032
Physical role limitation	75.0	38.7	81.7	38.3	0.384
Emotional role limitation	81.8	27.3	82.2	35.3	0.760
Vitality	70.5	13.5	70.0	19.6	0.721
Mental health	76.5	10.9	62.1	21.2	0.069
Social functioning	80.7	28.2	80.8	25.4	0.799
Bodily pain	78.4	18.0	85.7	20.4	0.237
General health perceptions	68.6	15.0	70.7	18.0	0.683

Data are presented as mean±SD. LSA: Left subclavian artery.

methods for revascularization of LSA, such as chimney and fenestration.<sup>[5]</sup> In a study comparing left carotico-subclavian artery bypass and the chimney technique, the rate of endoleak was higher in patients who had undergone left subclavian revascularization with the chimney technique.<sup>[6]</sup> Therefore, we preferred to perform carotico-subclavian among patients with LSA coverage. In the current study, there were 48 patients whose LSA was closed after the TEVAR procedure, of whom, 21 underwent left carotico-subclavian artery bypass before the TEVAR procedure. In our study, we compared the clinical outcomes of revascularization and its effects on quality of life between the two groups.

A meta-analysis of five observational studies involving a total of 1161 patients showed that LSA revascularization did not improve TEVAR outcomes. Although the risk of CVE, spinal cord ischemia, and perioperative mortality was low among patients who underwent LSA revascularization before or during TEVAR, in which the LSA was closed, this decrease was not statistically significant between the groups with or without revascularization.<sup>[11]</sup> We also found no significant difference between the groups. In our study, one patient in the revascularization group developed paraplegia within the first 30 days after left carotid-subclavian artery bypass surgery, and one patient in the non-revascularization group had CVE 4 years after TEVAR.

In a meta-analysis of 16 cohort studies involving a total of 2591 patients, the rates of perioperative CVE and spinal cord ischemia were significantly lower in TEVAR patients who under-

went LSA revascularization as compared to patients without revascularization; however, no significant difference was found in terms of perioperative mortality and paraplegia. Based on this analysis, revascularization is recommended if the subclavian artery is covered in patients undergoing TEVAR.<sup>[12]</sup>

In the meta-analysis conducted by Chen et al.,<sup>[13]</sup> perioperative CVE and spinal cord ischemia rates were observed significantly lower in the revascularized group; however, no significant difference was found in terms of perioperative mortality and paraplegia. Based on this meta-analysis, LSA revascularization should be evaluated individually for each patient because revascularization techniques can also be associated with CVE and local complications. Similar to this meta-analysis, we found no significant difference with regard to perioperative mortality and paraplegia.

In another study, the 30-day stroke and upper extremity ischemia rates were higher in the group whose LSA was not revascularized, with no significant difference in mid-term spinal ischemia and mortality.<sup>[14]</sup> Our study found no significant difference between the two groups in terms of neurological events, upper extremity ischemia, and mortality (p=0.252, p=0.101, and p=0.252, respectively).

LSA coverage can be associated with type II endoleak. The endoleak may occur associated with the location of the LSA ostium, graft diameter, proximal landing zone, and whether or not the LSA is revascularized.<sup>[15]</sup> In the study of Lee et al.,<sup>[16]</sup>

no difference was found between the groups with and without LSA revascularization in terms of endoleak. In our study, there was no statistically significant difference in the rate of endoleak between the two groups.

The SF-36 is a tool that is filled in line with the information received from the patient and gives information about the general health status of the patient.<sup>[9]</sup> Eight health concepts are evaluated by the survey. The current study detected that the group in which LSA was not revascularized had a significantly increased mean of physical capacity, being statistically significant ( $p=0.032$ ). The mean physical function in the group undergoing surgical intervention is expected to be limited. Our study found that patients who had undergone surgical revascularization had no decreased mean physical capacity with pain. There was no difference in physical function, emotional role vitality, mental health, social functionality, bodily pain, or overall health perception between the two groups.

In a study by Klocker et al.,<sup>[17]</sup> in which the LSA was covered and its effects on quality of life were evaluated, the short form-12 was used in evaluating the quality of life, with no significant difference being found between the two groups. In a study in which the quality of life of patients with and without covered LSA after TEVAR, involving a total of 82 patients, were compared, the patients were evaluated with the short form-12. There was no statistically significant difference in the life functions of both groups. In patients whose LSA was closed, the mental health score was slightly higher.<sup>[18]</sup>

### The Limitations of Our Study

It is a retrospective study, and the number of cases is limited. The SF-36 form was completed and evaluated only after discharge. Further comprehensive studies are required to evaluate the need for revascularization in patients with LSA occlusion.

### Conclusion

The current study showed no significant differences with respect to neurological outcomes, upper extremity ischemia, quality of life, and mortality among patients undergoing TEVAR with or without revascularization of the LSA.

### Disclosures

**Ethics Committee Approval:** The study was approved by the University of Health Sciences Kartal Koşuyolu Yüksek İhtisas Training and Research Hospital Non-Interventional Clinical Research Ethics Committee (no: 2018.3/2-94, date: 25/04/2018).

**Authorship Contributions:** Concept – M.Ş., M.A., S.T., M.Şi; Design – M.Ş., M.A., S.T., M.Şi; Supervision – M.Ş., M.A., S.T., M.Şi; Funding – M.Ş.; Materials – M.Ş.; Data collection and/or processing – M.Ş., M.A.; Data analysis and/or interpretation – M.Ş., S.T.; Literature search – M.Ş., M.A.; Writing – M.Ş., M.A.; Critical review – M.Ş., S.T.

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