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Subclavian steal syndrome – surgical or endovascular treatment

Sindrom krađe krvi potključne arterije – hirurško ili endovaskularno lečenje

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Abstract

Background/Aim. A phenomenon of subclavian steal is caused by occlusion or stenosis of the proximal subclavian artery with subsequent retrograde filling of the subclavian artery via the ipsilateral vertebral artery. The aim of this research was to compare surgical method [carotid-subclavian bypass grafts (CSBG)] and endovascular methods [percutaneous transluminal angioplasty (PTA) and stenting of subclavian artery] from the aspect of immediate and long-term results. **Methods.** Thirty patients [16 (53.33%) males], of average age between 60.1 ± 8.25 years were treated with CSBG and compared with a group of forty patients [18 (45%) males], of the average age between 57.75 ± 6.15 years treated by PTA and stenting of subclavian artery. Immediate and long-term results were determined clinically and confirmed by Doppler pressures and duplex ultrasound/angiography. All patients were followed-up after 1, 6 and 12 months post-procedure, and annually thereafter. **Results.** The average follow-up for both groups was 22.37 ± 11.95 months. There were 2 (6.67%) procedural complications in the CSBG group (transient ischemic attack in 2 patients) and 3 (7.5%) ones in the PTA/stent group (dissection and distal embolization in one patient and puncture site hematoma in one patient). Systolic blood pressure difference between the two brachial arteries in CSBG group was: 42.6 ± 14.5 mmHg *vs* 4.75 ± 12.94 mmHg ($p < 0.05$). In the PTA/stent group it was: 41.2 ± 15.35 mmHg *vs* 3.58 ± 5.83 mmHg ($p < 0.05$). Long-term success was 93.33% in the CSBG group and 92.5% in the PTA/stent group ($p > 0.05$). **Conclusions.** Both, the CSBG and PTA/stenting of subclavian artery are safe, efficacious and durable procedures. They have similar immediate and long-term results. PTA and stenting are the methods of choice for high grade stenosis, near total occlusions and segment occlusions of subclavian artery. CSBG is indicated in case of diffuse occlusive lesions and when the PTA and stenting do not succeed or cause complications.

Key words:
subclavian artery; subclavian steal syndrome; angioplasty; stents; blood vessel prosthesis; endovascular procedures; vascular procedures, operative.

Apstrakt

Uvod/Cilj. Sindrom "krađe" krvi potključne arterije uzrokovan je okluzijom ili stenozom proksimalnog segmenta potključne arterije sa njenim posledičnim retrogradnim punjenjem putem ipsilateralne vertebralne arterije. Cilj ovog rada bio je poređenje hirurške [karotido-supklavijalni bajpas (KSBP)] i endovaskularne metode [perkutana translumenska angioplas-tika (PTA) i stenting] sa aspekta ranih i udaljenih rezultata. **Metode.** Trideset bolesnika [16 (53,33%) muškaraca, prosečne starosti 60,1 ± 8,25 godina tretirano je KSBP i poređeno sa grupom od 40 bolesnika [18 (45%) muškaraca], prosečne starosti 57,75 ± 6,15 godina koji su tretirani PTA i stentingom potključne arterije. Rani i udaljeni rezultati su verifikovani razlikom u segmentnim pritiscima ruku, kliničkim i ultrasonografskim/angiograf-skim pregledom. Svi bolesnici su praćeni nakon mesec dana, 6 meseci i 12 meseci, a jednom godišnje nakon toga. **Rezultati.** Prosečni period praćenja iznosio je 22,37 ± 11,95 meseci. Utvrđene su 2 (6,67%) periproceduralne komplikacije u KSPB grupi (tranzitorni ishemijski atak kod 2 bolesnika) i 3 (7,5%) u PTA i stenting grupi (disekcija i distalna embolizacija kod jednog bolesnika, i hematom na mestu punkcije takođe kod jednog bolesnika). U KSPB grupi razlika u sistolnim pritiscima dve brahijalne arterije iznosila je: 42,6 ± 14,5 *vs* 4,75 ± 12,94 mmHg ($p < 0,05$), a u PTA i stenting grupi: 41,2 ± 15,35 *vs* 3,58 ± 5,83 mmHg ($p < 0,05$). Udaljeni uspeh u bypass grupi bio je 93,33%, a u PTA i stenting grupi 92,5% ($p = 0,83$). **Zaključak.** Obe metode, KSBP i PTA i stenting potključne arterije su bezbedne, efikasne i trajne. Imaju slične rane i udaljene rezultate. Tehnika PTA i stenting metod su izbora kod hemodinamski značajnih stenoza, subokluzija i segmentnih okluzija potključne arterije. KSBP je indikovan u slučaju difuznih okluzivnih lezija, ukoliko je PTA i stenting neuspešan ili ako se iskomplikuje.

Ključne reči:
a. subclavia; a. subclavia, sindrom promene toka krvi; angioplastika; stentovi; krvni sud, proteza; endovaskularne procedure; hirurgija, operativne procedure.

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Introduction

A phenomenon of subclavian steal is caused by occlusion or stenosis of the proximal subclavian artery with subsequent retrograde filling of the subclavian artery via the ipsilateral vertebral artery. Contorni was the first to recognize and describe this retrograde flow in 1960 using angiography in a patient who had an absent radial pulse [1]. In 1961, Reivich et al. [2] showed that there is a relationship between cerebral ischemic attack and retrograde vertebral flow. The term "subclavian steal syndrome", was coined by Fisher [3], after he reviewed Reivich et al. [2] article and observed that the anomaly caused the ipsilateral subclavian artery to receive retrograde flow from the contralateral circulation at the expense of the vertebro-basilar circulation.

The management of subclavian artery disease has evolved a great deal over the years, and a variety of therapeutic options are now available, including transthoracic bypass grafting or an endarterectomy, subclavian-carotid transposition, carotid-subclavian bypass and carotid-axillary bypass. The transthoracic approach is invasive and is rarely used in elderly population because of the high incidence of complications. Subclavian-carotid transposition and carotid-subclavian bypass grafts (CSBG) are the interventions used by most surgeons [4].

Percutaneous transluminal angioplasty (PTA) and stenting of the subclavian artery provides another tool for treating patients who have stenosis or occlusion. Endovascular treatment of subclavian artery is now commonly used for treating subclavian artery stenosis (total occlusion of the subclavian artery poses a special challenge and is technically demanding).

The aim of this study was to compare surgical CSBG and endovascular methods (PTA and stending) for subclavian artery disease from the aspect of immediate and long-term results.

Methods

Study design

This single center study included 70 patients treated at the Clinic for Vascular and Endovascular Surgery of Clinical Center of Serbia in Belgrade from January 1st, 2010 to March 1st, 2014. Thirty patients were treated by the surgical (CSBG) procedure, while 40 were treated endovasculary using the PTA and stent implantation. Data were collected prospectively with retrospective analysis. The indication for treatment was made on the basis of clinical and ultrasound examination of vertebral, carotid and upper limb arteries.

The clinical examination was used in order to determine the difference between radial arterial pulse. Arterial pressure gradients were measured on both arms and the following parameters were evaluated: the presence of symptoms of vertebrobasillar insufficiency (VBI) (vertigo and loss of consciousness while using the arm for physical activity, gait instability, amaurosis fugax) and disabling arm ischemia (functional weakness and paresthesia related to arm exercise, sensation of cold, rest pain, arm claudication discomfort), presence of anginal disturbances (in cases of mammary graft), need for repeated PTA and stenting or surgery.

PTA/Stent and bypass procedures

Endovascular procedures were performed under local anesthetic. Arterial access was obtained via common femoral and/or axillary arteries. A 6 F sheath was used during the procedures. The lesions were crossed using a 0.035-inch hydrophilic wire with a curved catheter providing directional control and support. The reference vessel diameter was determined with quantative angiography. Self-expandable and balloon-expandable stents were used. Neptun (Balton Medical) balloon-expandable stent was implanted in 7 (28%) patients. The following types of self-expandable stents were used: ev3 GPS (eV3) – 8 (32%) patients; SMART (Cordis) – 4 (16%) patients; Jaguar (Balton Medical) – 24% of patients; and Wallstent (Boston Scientific) – 24% of patients. Technical success for endovascular procedures was defined as residual diameter stenosis < 30% on the post-intervention arteriogram. After the procedure, all patients were prescribed lifelong aspirin (100 mg/d), whereas, clopidogrel (75 mg/d) or ticlopidine (100 mg twice a day) was continued for at least 1 month.

The carotid-subclavian bypass procedures were performed by 6 and 8 mm diameter polytetrafluoroethylene grafts (3 patients) and Dacron grafts (27 patients). In 20 (66.67%) patients the procedure was performed in general anesthesia, while regional anesthesia was used in 10 (33.33%) patients. A skin incision was made 1 cm above the clavicle, extending from the sternoclavicular joint to the lateral portion of the supraclavicular region for about 6 to 8 cm. An exposure of the carotid artery and subclavian artery was then carried out. Next, the carotid artery was isolated and surrounded with vessel loops. After systematic heparinization, the distal subclavian anastomosis was first performed in an end-to-side fashion to minimize the amount of graft material used. The carotid anastomosis was completed in end-to-side fashion. Lifelong aspirin (100 mg/d) therapy was prescribed after open surgery treatment. In 6 (20%) patients, ipsilateral eversion carotid endarterectomy was performed simultaniously with carotid-subclavian bypass in the same act.

Follow-up examinations

Graft and PTA-stent patency were determined by the presence or absence of peripheral pulses and confirmed by duplex ultrasound evaluation of vertebral arteries and upper limb arteries performed 1 month, 6 months, 12 months for the first year and annually thereafter. It included: determining segment systolic arm pressures, qualitative and quantitative analysis of doppler spectrums, duplex and color duplex scan. In symptomatic patients, angiographic examination in multiple projections was performed as well. Perioperative complications were any sequel that took place within 30 days following the procedure.

Statistical analysis

Perioperative complications, relief of symptoms, primary patency, and overall survival were compared

between the endovascular and surgical groups. Data were statistically analyzed using Exact Wilcoxon Rank Sum Test, Fisher exact test and Exact Wilcox Signed Rank Test for testing the difference between the treated groups and within the groups, as well as Log-rank test and Kaplan-Meyer product-limit method for testing patency difference and for presenting patencies within the two patient groups during the follow-up period. The results were considered statistically significant at level of $p < 0.05$. Calculations were performed using the statistical package STATA, version 8.2.

Results

The average age of both groups of patients was comparable. The proportion of women was higher in the group of endovasculary treated patients. In both groups, more than 50% of patients were smokers and had arterial hypertension, while diabetes mellitus was observed in 6 (20%) of surgically treated and 10 (25%) endovascular treated patients respectively. In 8 (26.67%) surgically treated patients previous carotid endarterectomy was performed, and within the group of endovasculary treated patients, there were 6 patients with previous carotid surgery. In both surgically and endovasculary treated groups, carotid lesions were symptomatic, and because of that these patients were treated with open surgery procedures. There was no significant difference between the two groups regarding cardiovascular comorbidities and previous surgeries (Table 1).

Symptomatic lesions were present in 67 (95.71%) of all patients. They included VBI during physical activity involving the arm, and disabling arm ischemia, as well as the combination of the two. In all three (4.29%) asymptomatic patients, hemodynamically significant subclavian stenosis was found accidentally during preparations for aorto-coronary bypass surgery using internal thoracic artery. There was no significant difference between the two treated groups regarding patient distribution by symptoms ($p = 0.254$).

The average length of a lesion was 17.33 ± 6.26 mm in the group of patients with CSBG, and 16 ± 7.77 mm in patients in which PTA and stenting had been performed. There was no significant difference between the two groups of patients ($p = 0.177$). The left subclavian artery was more commonly involved than the right in both groups (90% in both groups).

In the CSBG group, 29 patients had complete subclavian artery occlusion. Among patients treated endovasculary, 1 patient had subclavian artery occlusion, 25 patients had near total occlusion, while 14 patients had hemodynamically significant subclavian stenosis. Significant difference was observed between the two groups regarding patient distribution by grade of stenosis/occlusion ($p < 0.05$).

There were no fatal outcomes within the initial 30 days or during the follow-up period. Both methods significantly improved patient condition regarding pre-procedure complaints. The rate of remaining pre-procedure symptoms was insignificant. In the group of surgically treated patients, only one (3.33%) patient still had VBI, and the same was found in the group of endovasculary treated patients where only one (2.5%) patient still had arm-related complaints. During the early post-procedure period, within the CSBG group, 29 (96.67%) patients had palpable radial pulse. This ratio was 38 (95%) *vs* 2 (5%) within PTA/stenting group. No significant difference was found by comparing the two groups of patients regarding radial pulse palpability during early post-procedure period ($p = 1$). The difference between brachial pressure of the healthy and treated arm was significantly smaller when compared before and after the procedure, both in surgically and endovasculary treated groups.

Immediately after the procedure, 2 (6.67%) surgically

Table 1

Demographic characteristics, risk-factors and associated diseases in patients with subclavian steal syndrome

Parameter	Treatment		*p*
	surgical	endovascular	
Gender			
males, n (%)	16 (53.33)	18 (45)	0.489
females, n (%)	14 (46.67)	22 (55)	
Mean age (years), $\bar{x}$ ± SD	60.1 ± 8.25	57.75 ± 6.15	0.268
Risk factors, n (%)			
arterial hypertension	26 (86.67)	29 (72.5)	0.239
cigarette smoking	20 (66.67)	23 (57.5)	0.435
diabetes mellitus	6 (20)	10 (25)	0.622
hyperlipidemia	4 (13.33)	3 (7.5)	0.451
Associated diseases, n (%)			
PVD	10 (33.33)	17 (42.5)	0.435
ischemic heart disease	9 (30)	18 (45)	0.201
carotid endarterectomy	8 (26.67)	6 (15)	0.227
AAA	5 (16.67)	5 (12.5)	0.622
CVI	4 (13.33)	3 (7.5)	0.451
CABG	1 (3.33)	1 (2.5)	1

PVD – peripheral vascular disease; AAA – abdominal aortic aneurysm; CVI – cerebrovascular insult; CABG – coronary artery bypass grafting; n (%) – number (%) of patients; $\bar{x}$ – mean value; SD – standard deviation.

treated patients developed transient ischemic attack (TIA), and the symptoms disappeared after 24 hours. One endovasculary treated patient developed dissection. The repeated angioplasty was unsuccessful. The same patient was also diagnosed angiographicaly with distal axillary artery embolization. Both complications were successfully managed using carotid-subclavian and subclavian-axillary bypass grafts. One endovasculary treated patient developed groin hematoma requiring surgical treatment. No significant difference was observed between the two treatment groups regarding total number of early complications (Table 2).

The follow-up period after the procedure ranged from 6 months to 3 years, while the average follow-up time was 22.37 ± 11.95 months. During the follow-up period, no significant rate of symptom reappearance was observed (2 surgically and 3 endovasculary treated patients). The comparison of the efficacy of the methods did not show any significant difference. When comparing two treatment groups, no significant difference was found regarding palpability of radial arterial pulse at the long-term follow-up. After the follow-up period, the difference between brachial pressure of healthy and treated arm was significantly smaller when compared to the time before the procedure in both groups.

Graft occlusion was observed in 2 (6.66%) surgically treated patients. One patient underwent new bypass surgery, while the other did not undergo surgery because of the symptoms, age, clinical presentation, and comorbidity. Within the group of endovasculary treated patients, 3 (7.5%) restenosis were observed. In 1 case, stent was implanted primarily, while in 2 cases, only PTA without stent implantation. Balloon dilatation was performed in 1 out of these 3 patients, while the stent was implanted in 2 patients. No significant difference was found between the two groups regarding patient distribution by localization and frequency of long-term complications (Table 3).

Also, no significant difference in primary patency was found between the two groups of patients (Figure 1).

Table 2

The results during the initial 30 postoperative days in surgically and endovasculary treated patients with subclavian steal syndrome

Parameter	Treatment		*p*
	surgical	endovascular	
Clinical characteristics, n (%)			
asymptomatic	29 (96.67)	39 (97.5)	0.677
Radial pulse palpability			
palpable	29 (96.67)	38 (95)	1
The difference in systolic brachial pressure on healthy and treated arm (mmHg), $\bar{x}$ ± SD			
pre-procedure	42.6 ± 14.5	41.2 ± 15.35	0.959
post-procedure	4.75 ± 12.94	3.58 ± 5.83	0.371
Early complications, n (%)			
TIA	2 (6.67)	0 (0.0)	
dissection	0 (0.0)	1 (2.5)	1
distal embolization	0 (0.0)	1 (2.5)	
groin hematoma	0 (0.0)	1 (2.5)	

TIA – transient ischemic attack; n (%) – number (%) of patients; $\bar{x}$ – mean value; SD – standard deviation.

Table 3

Follow-up results in surgically and endovasculary treated patients with subclavian steal syndrome

Parameter	Treatment		*p*
	surgical	endovascular	
Clinical characteristics, n (%)			
asymptomatic	28 (93.3)	37 (92.5)	0.494
VBI	0 (0)	2 (5)	
disabling arm ischemia	2 (6.67)	1 (2.5)	
Radial pulse palpability, n (%)			
palpable	27 (90)	36 (90)	1
The difference in systolic brachial pressure on healthy and treated arm (mmHg), $\bar{x}$ ± SD			
pre-procedure	42.6 ± 14.5	41.2 ± 15.35	0.959
after (22.37 ± 11.95) months	6.45 ± 15.41	5.33 ± 8.48	0.835
Long-term complications, n (%)			0.715
graft occlusion	2 (6.66%)	0 (0.0%)	
restenosis	0 (0.0%)	3 (7.5%)	

VBI – vertebrobasillar insufficiency; n (%) – number (%) of patients; $\bar{x}$ – mean value; SD – standard deviation.

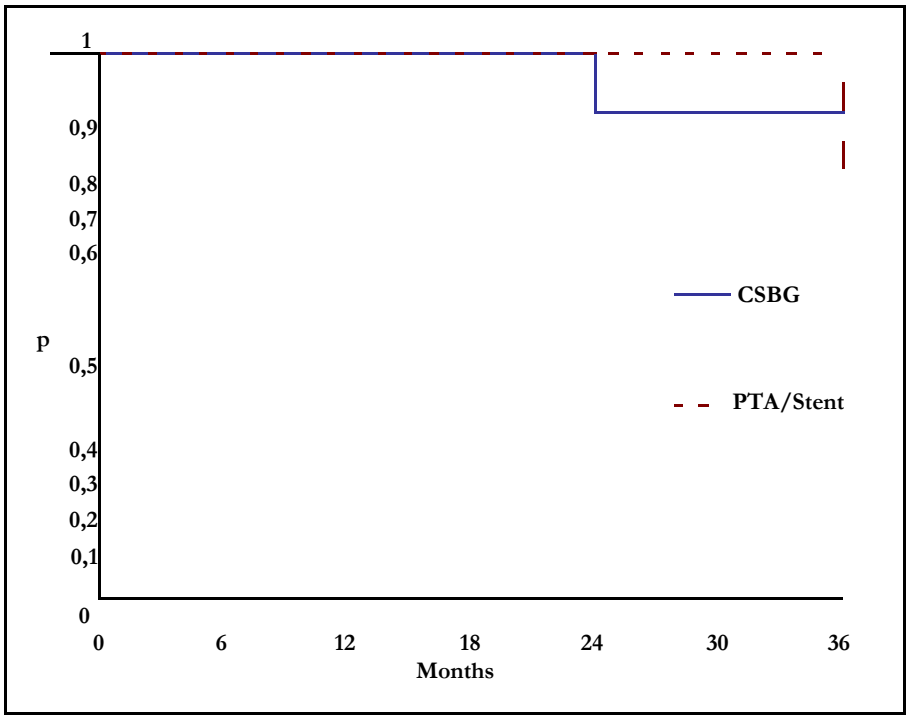

Fig. 1 – Long-term patency in treatment groups (Kaplan-Meyer curve).
CSBG – carotid-subclavian bypass grafts; PTA/Stent – percutaneous transluminal angioplasty and stenting of subclavian artery.

Discussion

The incidence of subclavian artery obstructive disease is difficult to determine as most of the lesions appear asymptomatic. Based on the available data, the incidence ranges from 0.5–2% and is mostly present in polyvascular patients [5–7].

Initially, subclavian artery lesions were treated surgically. Transthoracic approach was primarily used that is now abandoned method due to high complication and mortality rates [8]. In 1964, Parrott [9] was the first to describe subclavian artery transpositioning technique. In 1967, Diethrich and Koopot [10] presented extraanatomical bypass from carotid to subclavian artery. Today, the CSBGs and subclavian artery transposition are characterized by similar early and long-term results [7, 11, 12]. In 1980, Bachman and Kim [13] performed the first subclavian artery PTA. The numerous studies showed significant increase in success rates in early and long-term results in endovasculary treated patients, especially in those undergoing stent implantation [14]. Therefore, the opinions about the choice of treatment for this region changed, and PTA, with or without stent implantation, became method of choice besides extrathoracic surgical revascularization [5, 15]. Endovascular procedures are important especially in high risk patients. The majority of patients included in this study were polyvascular patients with numerous risk factors and comorbidities. Taking risk factors into account, AbuRahma et al. [16] treated patients with several comorbidities using PTA and stenting, considering their risk was too high to be treated surgically. Patients with high grade stenosis/near total occlusion and those with subclavian artery occlusion cannot be considered equal, nor can those with segmental and diffuse lesions. In our study, as many as 29 (96.67%) patients with subclavian artery occlusion were treated surgically. Over the past years, numerous studies showed significantly increased technical success rate of endovascular treatment of chronic occlusions [6, 17].

In the PTA/stenting group, we mostly used transfemoral approach (92%), while transaxillary approach (8%) was used in cases of changes in aorto-iliac region and in cases of total arterial occlusion of proximal segment of subclavian artery. Apart from these two approaches used to treat most of their patients, Sagić et al. [18, 19] and Babic et al. [20] described patients treated with "snare" technique using combined axillary and femoral approach. A bidirectional approach is mostly used for chronic total occlusions and much calcified lesions [21]. Within the proximal segment of subclavian artery, stents have to be implanted carefully in order to prevent blockage of vertebral artery ostium [6]. Balloon-expandable stents enable more accurate implantation compared to self-expandable stents. Therefore, in the study published by Brountzos et al. [22] balloon-expandable stents were used in the majority of patients (90%). Conversely, Wang et al. [23] implanted self-expandable stents in all 60 (100%) of their patients. Within our study, in 7 (28%) patients we used balloon-expandable stents, while 18 (72%) patients received self-expandable stents. In some recent studies, the use of balloon expandable covered stents to treat occlusive disease has been proposed as a method to reduce intimal hyperplasia and improve patency rate [24].

Although PTA and stenting is a minimally invasive technique, a comparable complication rate is seen in the PTA and stenting group (2.9–14.9%) [25], vs. the bypass group (5.9–14.2%) [12, 16, 26]. In a group of surgically treated patients, there was no case of graft infection, nor pseudoaneurysms were found in the PTA/stenting group. No significant difference regarding complications was found between the two groups.

Only five studies have been published so far comparing the results of CSBG and endovascular procedure at the same institution [16, 25–28]. Farina et al. [26] analyzed 15 patients with CSBG and 21 patients treated by balloon dilatation without stent implantation. Periprocedural complications were similar in both groups, while the long-term success, in contrast to our study, was significantly higher in the group of patients treated with bypass grafts (84% compared to 54%, respectively). Modarai et al. [25] compared early and long-term results of PTA and stenting of subclavian artery with extraanatomical bypass procedures on supraaortic branches and obtained more favorable long-term results in surgically treated patients. AbuRahma et al. [16] compared 121 patient treated with PTA and stenting, and 51 patient with CSBG, and confirmed better long-term results in CSBG patients. Linni et al. [27] compared 34 patients with subclavian-to-carotid artery transposition with 40 patients treated by stent supported PTA. According to their experience, they recommend endovascular treatment for subclavian stenosis and surgery for subclavian occlusions. The most recent comparative study was established in 2012 by Song et al. [28]. They analyzed the immediate and long-term outcomes in 148 patients treated with balloon-expandable stents, and 104 patients treated with extrathoracic surgical bypasses and concluded that both endovascular stenting and extrathoracic surgical bypass are safe and effective treatments for subclavian steal syndrome in the short and medium term, however, extrathoracic surgical bypasses are more durable in the long term. In our study, we showed similar long-term patency in both groups; stents were as durable as bypass grafts (Table 4).

Endovascular treatment, such as PTA and stenting, may have several advantages over surgical approach, including its minimally invasive nature, avoidance of general anesthesia and shorter length of hospital stay. Also, most in-stent restenosis can be treated with endovascular therapy. Today, we routinely select subclavian artery stenting first for subclavian steal syndrome. When, endovascular therapy is unsuccessful, surgical revascularization can provide durable treatment option.

Our study has some limitations. First, more occlusions were treated in the bypass surgery group, that can be partially based on selection bias by the endovascular specialist, and also it has to be noted that endovascular procedure was tried in some of them and abandoned due to difficulties in passing wire through the lesion after which they were treated surgically. Second, this was a retrospective, nonrandomized study. Prospective randomized studies are needed to compare the current treatment modalities for subclavian steel syndrome.

Conclusion

Both CSBG and PTA/stenting of subclavian artery are safe, efficacious and durable procedures. Using the PTA/stenting procedures is a method of choice in the treatment of hemodynamically significant stenosis, near total occlusions and segmental occlusions of subclavian artery. CSBG is indicated in case of diffuse occlusive lesions and when PTA and stenting do not succeed or cause complications.

Table 4

Studies comparing surgical and endovascular subclavian artery procedure

Author (year of publication)	Patients (number)		Follow-up period		Periprocedural complications		Long-term success/period	
	PTA/stent	Surgical	PTA/stent	Surgical	PTA/stent	Surgical	PTA/stent	Surgical
Farina et al. [26] (1989)	21	15	30 ± 24 months	40 ± 25 months	4.76	13.33	54% (5 years)	87% (5 years)
Modarai et al. [25] (2004)	41	35 (14 CSBG)	20 years		9.75	14.3	82% (4 years)	97% (5 years)
AbuRahma et al. [16] (2007)	121	51	41 (12–108) months	92 (12–80) months	14.9	5.9	70% (5 years)	96% (5 years)
Linni et al. [27] (2008)	40	34	50.1	52.6 months	5	11.7	95% (5 years)	100% (5 years)
Song et al. [28] (2012)	148	104	67 months	101 months	6.1	9.6	67% (5 years)	95% (5 years)
Our study Cvetic et al. (2017)	40	30	22.37 ± 11.95 months		6.67	7.5	92.5%	93%

PTA – percutaneous transluminal angioplasty; CSBG – carotid-subclavian bypass grafts.

Conflict of interest statement

The authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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