

ЕНДОВАСКУЛАРНО ЛЕЧЕНИЕ НА СТЕНОЗИ НА АРТЕРИЯ СУБКЛАВИЯ

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ENDOVASCULAR TREATMENT OF SUBCLAVIAN ARTERY STENOSIS

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Резюме.

Най-честата локализация за атеросклерозата на горните крайници са артерия субклавия и трункус брахиоцефаликус. Сигнификантната стеноза на артерия субклавия се среща приблизително при 2% от популацията и в 7-11% от пациентите с манифестно сърдечно-съдово заболяване. Реваскуларизацията е показана при симптомни пациенти или асимптомни с коронарно заболяване с планирана оперативна реваскуларизация. Освен атеросклероза други причини за изязвата на стеноза на артерия субклавия включват дисекция, предизвикана от радиация, възпаление на фибромускулатурата и различни васкулити, особено артериит на Такаясу. Лявата подключична артерия е около четири пъти по-вероятно да бъде засегната, отколкото дясната. Среща се обикновено на възраст над 50 години и в 1,5-2 пъти по-често при мъжете, отколкото при жените. Заболяването на подключичната артерия обикновено е огнищно и лезията е предимно в първите 2 cm проксимален сегмент от началото на аортата. Между 2016-2021 г. в Клиниката по кардиология и ангиология ние лекувахме ендоваскуларно 81 пациенти (41 мъже и 40 жени, средна възраст 64 ± 11) чрез балонна дилатация и/или първично стентирание последвано от балонна пост-дилатация. Постигнахме висока техническа успеваемост (93.8%) и незабавен клиничен успех със само няколко минимални усложнения.

Ключови думи:

артерия субклавия, ендоваскуларно, интервенционално, стент, оклузия, атеросклероза

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Abstract.

The most common localizations for upper extremity atherosclerosis are the subclavian artery and the brachiocephalic trunk. Significant stenosis of the subclavian artery occurs in 2% of the population and in 7-11% of patients with manifest cardiovascular disease. Revascularization is indicated in symptomatic or asymptomatic patients with coronary disease with planned surgical revascularization. In addition to atherosclerosis, other causes of the appearance of subclavian artery stenosis include dissection, radiation-induced inflammation of the fibromusculature, and various vasculitides, especially Takayasu arteritis. The left subclavian artery is about four times more commonly affected than the right. It usually occurs over the age of 50 years and in 1.5-2 times more common in men than in women. Disease of the subclavian artery is usually focal and the lesion is predominantly in the first 2 cm proximal to the origin of the aorta. Between 2016-2021 in the clinic of cardiology and angiology we treated endovascularly 81 patients (41 men and 40 females, median age 64 ± 11) with either intraluminal balloon dilatation and/or primary stent implantation followed by balloon post dilatation. We achieved a high technical success rate (93.8%) and immediate clinical success, with only a few minor complications.

Key words:

subclavian artery, endovascular, interventional, stent, occlusion, atherosclerosis

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INTRODUCTION

Symptomatic subclavian artery stenosis (SAS) is uncommon, clinically manifesting after a long subclinical period. SAS is present in approximately 2% of the world's population and up to 7% among population with known cardiovascular disease. Symptoms, when they occur, include brief vertigo due to decreased blood flow in the posterior part of the brain, and circulatory problems in the arms and hands. On physical examination, subclavian artery stenosis is usually suspected when a difference between the systolic arterial pressures of the two arms (> 15 mm Hg) is found [1]. Smoking, high blood pressure, lower levels of „good“ high-density lipoprotein, and peripheral arterial disease are associated with an increased risk of subclavian artery stenosis [2]. The most common underlying etiology of SAS is atherosclerosis. It is multifocal disease that leads to plaque formation and subsequent ischemia in the arteries of the body. Treatment may be surgical, endovascular or with medical therapy. In many patients, who are having discrete symptoms, they tend to improve over time without treatment, because of the efficient collateralization and that is why surgical and interventional methods are not usually indicated for asymptomatic subclavian stenosis/occlusion. Even though medical therapy is advocated as the first line treatment, endovascular revascularization is emerging as an alternative [1-3]. Intervention is usually indicated for upper extremity ischemia, vertebro-basilar symptoms, subclavian steal syndrome, and coronary steal syndrome. In symptomatic patients the most common surgical approach is the extra thoracic revascularization - carotid-subclavian bypass, or subclavian to carotid transposition. The preferred method of treatment for subclavian stenosis in the last years is endovascular, which is remarkable with low complication rate and a high success rate [3]. It includes angioplasty alone or followed by stent implantation. In 1980 Bachman and Kim first reported successful endovascular treatment of subclavian artery stenosis [4]. Since then there have been numerous publications showing varying degrees of procedural success and long-term patency rates.

In this article, we report our experience with endovascular treatment of the subclavian artery. The purpose of this study is to evaluate the results of primary stenting of the subclavian artery pathology and the long-term data.

AIMS

Our aim is to investigate the immediate technical and clinical success rate of the procedure. To calculate and analyze the intraprocedural complications – mortality, morbidity, vascular complications, stroke,

renal impairment. We aim to describe our intraprocedural details: X-ray time, procedural time and amount of contrast used, and to follow our patients for future patency of the technique and late minor and major complications.

MATERIAL AND METHODS

Our analysis included 81 patients (41 men and 40 females, median age 64 ± 11), from January 2016 to December 2021 who were treated by endovascular approach for severe stenosis/occlusion of the subclavian artery. Patients were referred for invasive evaluation and treatment in the presence of high-grade subclavian artery stenosis, unilaterally or bilaterally on standard ultrasonographic examination of the vessels. We defined symptomatic patients as those presenting with upper extremity ischemia, vertebro-basilar symptoms, subclavian steal syndrome, and coronary steal syndrome. In this study, 7.5% of the studied patients had a symptom of subclavian steal, while 92.5% had symptoms of upper limb ischemia. All patients included in the analysis were informed in detail about the nature of the procedure and signed an informed consent.

All of the patients underwent intraluminal balloon dilatation and/or primary stent implantation followed by balloon postdilatation. Follow up of the patients included in the study was done by hospital checkup (for the first 6 months post procedurally) and after that by contacting with them or with their relatives. The mean follow-up period was 40 ± 21 months. With regard to rehospitalizations, we distinguished several groups: for intervention of the other subclavian artery (if it had bilateral involvement); target lesion revascularization (TLR) found at the target lesion site, or stenosis of the same vessel but with localization outside the target lesion (TVR). Survival was calculated according to the number of months survived after dehospitalization. Mortality was classified as cardiovascular, cerebrovascular, or death from another disease unrelated to those listed so far or with no established cause.

Procedural protocol

In all patients, procedures were performed in the catheterization laboratory under local anesthesia, and in rare cases under additional conscious sedation. No switch to general anesthesia was registered. Femoral access was used in 26 (33.3%) cases and radial access in 45 (57.7%) cases. In chronic total occlusion (CTO) cases we have used double vascular approach (mostly femoral and ipsilateral radial). In total we had 7 patients (8.6%) who required double vascular approach. Once arterial access was established, 70 IU/kg heparin was administered intravenously. In subclavian artery intervention, the choice

of guidewire was based on the characteristics of the lesion and the catheter planned to be used. Typically, steerable 0.035" wire (at least 260 cm in length) supported by curved diagnostic catheter (Judkins right in most of the cases) is used. Our work horses among the "standard" wires are steerable floppy tip wires, namely Cordis STORQ™ – Cardinal Health and angulated Guidewire (Terumo). For subtotal stenoses and CTOs, we have used specialty microcatheters (Trailblazer .035" and .018", Medtronic) for additional support and CTO dedicated wires (.018" and .035" Advantage, Terumo; Asahi Gladius, Asahi Gaia PV). Balloon predilatation was done in 68 patients (83.9%). The selection of the stent type and size was based on the length of the lesion, the size of the subclavian artery and the affected segment of the artery (prevertebral, ostium, or postvertebral segment). Because the main anatomical localization of the target stenosis was aorto-ostial, requiring exact implantation without big protrusion in the aorta we have used mainly balloon-expandable Visi-Pro Stent (Medtronic, USA) (43.2% of the procedures). In non-ostial and long lesions, we utilized self-expanding stents, and the EverFlex stent (Medtronic, USA) (22.2% of the procedures). Three Wallstents (Schneider, Minneapolis, MN) were utilized in long lesions. Self-expandable stents were implanted in 66 patients (81.5%) and balloon dilatations alone were performed in 12 patients (15.0%) who were with shorter and/or concentric stenosis. Technical success was defined as adequate stent deployment at the appropriate site with a satisfactory angiographic result and residual translesional pressure gradient less than 15 mm Hg. After completion of the procedure, patients were transferred to the cardiology care unit and monitored overnight for vascular access and renal complications.

RESULTS

Table 1 presents the clinical characteristics of the patients included in the analysis. The mean age of the patients was 64 ± 11 years, and 40 (49.4%) were women and 41 were men (50.6%). Regarding the risk profile in this population, dyslipidaemia was observed in 70 patients (87.5%), diabetes mellitus in 21 patients (26.6%), hypertension in 78 patients (97.5%), family history in 21.9% and smoking in 50 patients (66.7%). Patients included in the analysis had current and/or past angina or angina-like symptoms (53.8%), with 32% having multivessel coronary disease. Peripheral vascular disease affecting the aorta and lower extremity arteries occurred in 38.8%. All were symptomatic, with subclavian steal syndrome in 7.5%, upper limb claudication in 77.8%.

Tabel. 1. The clinical characteristics of the patients included in the analysis

| Clinical parameter | (n = 85), number (%) |
|--|----------------------|
| Age | 40 ± 21 |
| Sex, male | 41 (50.6) |
| Arterial hypertension | 78 (97.5) |
| Tabaco | 50 (66.7) |
| Dyslipidemia | 70 (87.5) |
| Diabetes | 21 (26.6) |
| Past Myocardial infarction | 3 (3.8) |
| Prior percutaneous coronary intervention | 28 (35) |
| Prior hear surgery | 11 (13.8) |
| Peripheral artery disease | 31 (38.8) |
| Prior transitory ischemic attack (TIA) | 27 (33.8) |
| Prior ischemic cerebral infarction | 12 (15) |
| Carotid artery stenosis, known before intervention | 37 (46.3) |
| COPD (chronic obstructive pulmonary disease) | 7 (8.8) |

Figure 1 shows the preprocedural medical treatment of the patients in our group. Of note is the high rate of statin use in all patients (78%) and the non-high rate (about 40%) of ACE inhibitor or sartan use. Significantly higher was the frequency of beta-blocker administration (70.9%). Regarding antiplatelet therapy, it is seen that the majority of patients were pre-treated with clopidogrel, and 24.1% (19) of the patients were taking anticoagulant. The incidence of atrial fibrillation was 16.3%. Sixty of the 81 patients (74,1%) had a subclavian artery occlusion, which was successfully treated in 55 of them (91.6% CTO success rate). In the 5 (6,2%) patients with the unsuccessful first intervention, we did a reintervention using different arterial approach (double vascular approach: femoral and radial), because of their vessel's anatomy. The reintervention was successful in all of the patients. Localization of the target lesion was in the left subclavian artery in 73 (90.1%) of patients. Bilateral stenosis was found in 3.7% of patients. The mean hospitalization stay was 1.68 days. Complications rate was 6,17% (5 patients) with 4 patients who had access site hematoma and 1 patient (1,2%) with thromboembolic ischemic brain infarction with lesional thrombus migration to the tip of the basilar artery. The patient with the cerebral infarction was successfully treated with immediate thrombaspiration during the hospitalization that resulted in complete neurological restoration. All of the puncture site hematomas were timely managed with manual compression and then closely followed with doppler ultrasonography during the first month postintervention. None of them required surgical interference, and only one required hemotransfusion. During the study period

of 40 ± 21 months, 20 patients (24.7%) died. In 11 patients (13.5%), due to restenosis found in the stented area, a repeat intervention was necessary, which was successful in all of them. In ten of the reinterventions we have performed successful balloon dilation with final drug eluting balloon inflation for better secondary outcome, and stent-in-stent implantation was needed in only one case, because of significant residual gradient after the balloon inflation.

DISCUSSION

Surgical revascularization is the preferred treatment option for SAS in the clinical guidelines because of the excellent long-term outcomes. In recent years, percutaneous endovascular approaches have come to the force due to high success rates, low complication rates, shorter hospital stays and significantly lower cumulative costs compared to the surgical treatment [5,

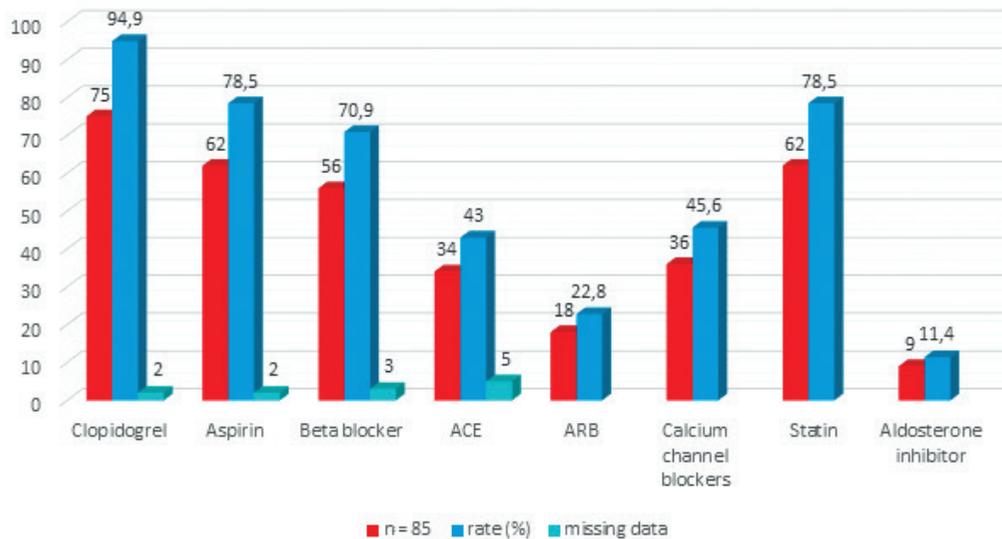


Fig. 1. Medication treatment of patients from our analysis

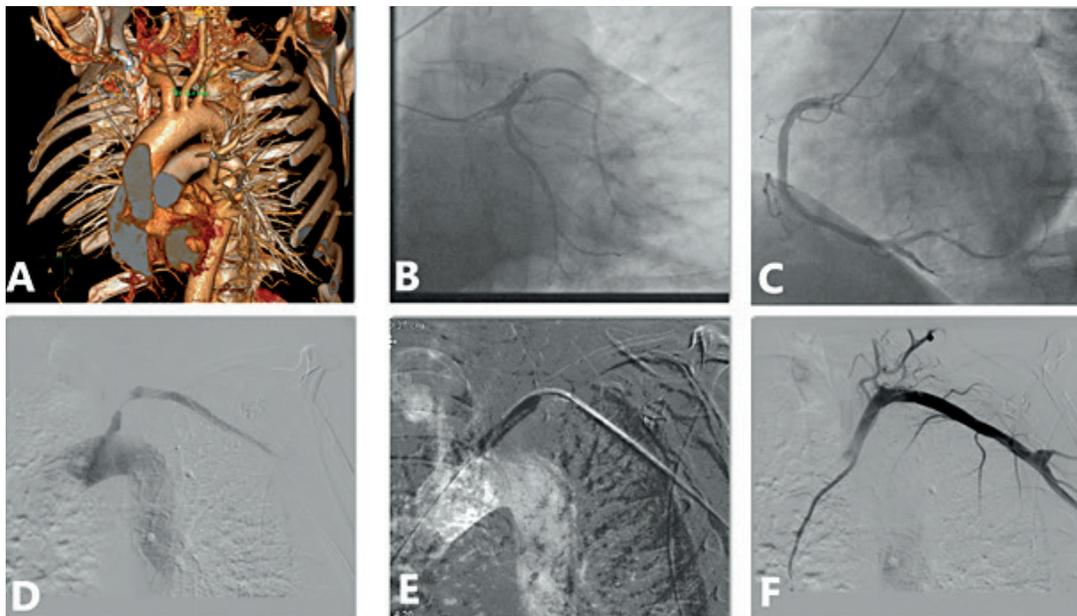


Fig. 2. A 43-year-old man presented with complaints of weakness, pain, numbness of the left arm, and nonpalpable pulsations of the left hand. Difference in arterial pressure of both arms over 15 mm Hg. With known arterial hypertension and dyslipidemia, smoking. From Doppler sonography with critical stenosis on the left subclavian artery. A computed tomography scan was performed which confirmed stenosis of the left subclavian artery (A). We proceeded with endovascular treatment. An invasive study was performed via radial access with coronary and peripheral angiography. Coronary angiography showed coronary arteries without significant stenosis (B, C). Peripheral angiography with 90% non-ostial stenosis of a left subclavian artery. Direct stenting with 2 balloon-expandable stents was undertaken (D, E, F). Postprocedural with restored left arm pulsations and ischemic symptoms were resolved

6]. The technical success rate of endovascular therapy for subclavian artery stenosis has been reported to be very high. Song et al. reported a technical success rate of 97.3% in 148 patients with balloon-expandable stents [7]. However, the technical success of endovascular treatment of subclavian artery occlusions was lower. Babic et al. reported a successful recanalization rate of 82.1% [8]. De Vries et al. reported in their case series of 110 patients over 10 years that stenting was accomplished in 58% of patients with a 93% technical and clinical success rate and a 1% complication rate [9]. In our case series, 76 patients (93.8%) of 81 patients with subclavian artery stenosis were successfully treated with endovascular methods. The success rate in CTO cases was relatively high (90.1%). As a whole, we achieved a high technical success rate and immediate clinical success, with only a few minor complications. In five patients, the procedure was unsuccessful the first time, due to total calcium occlusion and difficult vessel anatomy. One of the common concerns of stent implantation is the restenosis. In the present study, 11 (13,6%) restenosis were found and all of them needed further intervention, that resulted successful. One of the quoted risks of subclavian artery intervention is with or without stent implantation, a vertebral artery occlusion or distal embolization with subsequent stroke. This possible complication is mostly seen when performing angioplasty for subclavian steal syndrome. Because of the stroke risk, there are some technique modifications, such as balloon insertion into the ipsilateral vertebral artery with temporary occlusion of flow, or additional filter insertion [14, 15, 16]. In our study, only one patient suffered an ischemic stroke, as a complication of the procedure, successfully treated by immediate thromb aspiration. As a protocol, for embolic risk reduction, we ask our patients to actively exercise the forearm (rapid fist formation and relaxation) during the balloon disinflation, in order to redirect the flow mainly to the forearm and not to the vertebral artery.

Left subclavian artery stenosis are more common than right subclavian artery stenosis [16]. Most lesions in our study were also in the left subclavian artery. Because of the unique anatomic features, endovascular treatment of right subclavian artery stenosis is always associated with additional difficulties and risks because of the ipsilateral carotid artery proximity. Stent implantation, stent placement, and risk of right-sided cerebral infarction has to be evaluated in details in order to avoid complications. Embolic protection devices placed in the distal segment of the right internal carotid artery before dilatation could reduce infarction [5, 18]. In one case of Takayasu arteritis we successfully recanalized the brachiocephalic trunk and stented the trunk, the stenotic ostium of the subclavian artery, and the stenotic ostium of the carotid artery with cu-

lotte technique under cerebral protection with Spider (Medtronic) carotid embolic protection.

Depending on the location and severity of the lesion, antegrade (femoral), retrograde (radial) or combined approaches may be preferred for endovascular treatment. Femoral artery access is preferred for subtotal lesions with sufficient stump nose in the proximal subclavian artery. Because of the high fibrocalcification of the lesion and the rich collateral circulation, it is difficult to penetrate antegrade through a chronic occlusion. Therefore, the retrograde approach from the radial/ brachial artery may be preferred in complete occlusions without an ostial "nose", in long lesions, in the presence of a highly tortuous aorta, and in cases where the angle of exit of the subclavian artery from the aortic artery is abnormal [10, 16, 17].

There is no definitive evidence whether stenting is more effective than balloon angioplasty alone in occlusive disease of the subclavian artery. However, in a systematic review (544 patients) comparing the two strategies, stenting was found to be superior, with a higher patency rate compared with stand-alone angioplasty [11]. Balloon-expandable stents were preferred over self-expandable stents for lesions in the ostial and proximal regions because of the possibility of stent dislodgement and migration with self-expandable and undersized stents. Furthermore, in severely calcified ostial lesions, in addition to easier and more precise implantation, the balloon-expandable stent provides greater radial force [19, 20].

In the literature, although long-term follow-up data are insufficient, the long-term patency rate (3-5 years) is 84%. This rate has been reported to be 64% in complete occlusion. In-stent restenosis is a major problem in endovascular procedures. Because the subclavian artery is an elastic and large vessel, the recurrence rate is relatively low and ranges from 5 to 7%. Despite that, there are some risk factors for restenosis. According to Bates et al., females tend to have a higher risk for in-stent restenosis, which actually correlates with our data – 72,7% of the restenosis were found in women [21]. Of course, the typical risk factors for in-stent restenosis like smoking and severe dyslipidemia are relevant here, but also a baseline vessel size of ≤ 7 mm is a predictive for restenosis. Interestingly enough, younger age is found to be an independent risk factor for secondary intervention [22]. The complication rate ranges from 3 to 11% in endovascular treatment of subclavian artery stenosis. Reported complications include subclavian artery thrombosis, axillary artery thrombosis, stent migration, stent dislocation, arterial flow limitation dissection, distal embolization, arterial extravasation, arterial access complications, hematoma requiring transfusion, restenosis, and neurological complications (transient ischemic attack, stroke, hemiplegia, diplopia, etc.) [11-15].

CONCLUSION

Endovascular treatment of subclavian artery is highly successful, safe and feasible method with very good short and mid-term patency. Intravascular stenting of the subclavian artery has an advantage in terms of patency, but more evidence is needed in this regard.

No conflict of interest was declared

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