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Original Article

Application of cobalt chromium stents in the subclavian arterial disease

Subklavian arter hastalığında kobalt krom stentlerin uygulaması

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ÖZ

Amaç: Üst ekstremiteyi etkileyen iskemik problemlerden biri subklavian arter darlığıdır. Son zamanlarda endovasküler tedavi, cerrahi tedaviye alternatif bir tedavi olmuştur. Bu çalışmanın amacı hastalıkla baş etmede yeni bir yol olarak sol subklavian arter hastalığında (LSAH) kobalt krom stentin endovasküler tedavide etkinliğini araştırmaktır.

Gereç ve Yöntemler: Nisan 2011 ile Aralık 2014 yılları arasında LSAH nedeniyle endovasküler tedavi yapılan 30 hasta geriye dönük olarak incelendi. Hastaların vertebrobaziler yetmezlik (16 hasta, %53), sol kol iskemisi (5 hasta, %17) ve anjina (4 hasta, %13,3) semptomları mevcuttu. Tüm hastalarda sol subklavian arter proksimal bölgesi etkilenmişti.

Bulgular: 25 hastada (%72) sol subklavian arter darlığı, 5 hastada (%28) ise tam tıkalı lezyon mevcuttu. Ortalama lezyon uzunluğu 21,60 ± 4,58 mm idi. Ortalama damar çapı 8,7 ± 3,8 mm ve lezyon tipi %40 hastada egzantrikti. Tüm hastalarda kobalt krom balonla genişleyen stent kullanıldı. Teknik başarı %100 idi. Endovasküler tedavi sonrası bir yıllık takipte yeniden daralma izlenmedi.

Sonuçlar: Kobalt krom balonla genişleyen stent avantajlı özellikleri nedeniyle LSAH da başarılı sonuçlara sahiptir.

Anahtar kelimeler: Subklavian arter, tıkayıcı arter hastalığı, endovasküler, kobalt krom, stent

ABSTRACT

Aim: One of the ischemic problems influencing the upper extremities is subclavian artery stenosis. Recently, endovascular management has become a therapy alternative to surgical treatment. This study aims to investigate the effectiveness of the endovascular therapy with cobalt chromium stent in the left subclavian arterial disease (LSAD) as a novelty.

Material and Methods: 30 patients who underwent endovascular therapy because of LSAD were retrospectively investigated from April 2011 to December 2014. They have symptoms of vertebrobasilar insufficiency (16 patients, 53%), arm ischemia (5 patients, 17 %), and angina (4 patients, 13.3%). All patients had proximal region stenosis or total occlusion in the left subclavian artery.

Results: 25 patients (72%) had left subclavian artery stenosis, whereas five patients (28%) had left subclavian artery total occlusion. The average lesion length was 21.60 ± 4.58 mm. The average vessel diameter was 87 ± 3.8 mm. Eccentric types of lesions were encountered in stenotic cases (n= 12, 40%). Predilatation was performed in 7 patients. Average stent length was 33.1±12.2 mm. Cobalt chromium stent balloon-expandable stents were used for all patients. Technical success in the endovascular treatment was 100%. One year after the endovascular intervention, no seen restenosis were observed.

Conclusion: Due to the advantageous features, cobalt chromium balloon-expandable stents have produced successful results in LSAD.

Keywords: Subclavian artery, arterial occlusive disease, endovascular procedure, cobalt chromium, stent

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Introduction

The left subclavian artery, one of the aortic arch branches, can be adversely affected by steno-occlusive process. One of the ischemic problems influencing the upper extremities is subclavian artery stenosis [1]. Atherosclerosis is the major reason for upper extremity artery steno-occlusive process [2]. Although left subclavian arterial disease (LSAD) is usually well-tolerated by patients, LSAD can cause a number of symptoms. One of the symptoms is related with vertebrobasilar insufficiency, including effort-induced dizziness, dizziness at rest, blurred vision, and even nausea and vomiting [3]. The second one is claudication owing to arm ischemia. The third is embolization to the fingers [4]. The final symptom is angina pectoris caused by coronary-subclavian artery steal syndrome [5], especially in the patients who previously undergone coronary by-pass surgery. For the treatment, there are medical, endovascular, and surgical options. Surgical revascularization has been used as treatment modality in LSAD so far [6]. However, recently, endovascular management has become a therapy alternative to surgical treatment [7,8]. This study aims to investigate the effectiveness of the endovascular therapy with cobalt chromium stent in the left subclavian arterial disease (LSAD) as a new way of dealing with the disease.

Materials and methods

30 patients who underwent endovascular therapy from April 2011 to December 2014, because of symptomatic LSAD were retrospectively investigated. We declare that the study was performed in accordance with the ethical standards laid down in the Helsinki Declaration of 1975, as revised in 1983. All patients had a proximal region stenosis or a total occlusion of the left subclavian artery (Figure 1).

Figure 1. Proximal region stenosis in the left subclavian artery

The cause of stenosis or occlusion was considered as atherosclerosis in all of the patients. The previous medical history and smoking habits were investigated in detail. The initial physical examination recorded a blood pressure difference between left and right arm measurements. Duplex ultrasound imaging had been done in all.

In angiography, left subclavian artery narrowing greater than or equal to 70% was accepted as significantly subclavian artery disease. The endovascular intervention had been planned in patients who had symptomatic and severe subclavian artery narrowing.

The Endovascular Therapy

All patients received 300 mg acetylsalicylic acid and 600 mg clopidogrel 6 hours before the intervention. The endovascular intervention was performed through bilateral common femoral arterial access under local anesthesia. Eight French (8 Fr) sheath was placed in the common femoral artery using Seldinger technique. A catheter (Right Judkins, Boston Scientific) was advanced into the aortic arc then selective catheterization and angiography of left subclavian artery was performed. A 0.035 inch guide-wire was passed through the catheter distally and beyond the lesion. Moreover, before stenting, a balloon predilatation was performed in seven of the patients due to severe critical stenosis. Afterwards, the cobalt chromium balloon-expandable stent (Abbott Vascular, Omnilink Elite Vascular Balloon-Expandable Stent System) was implanted through guide-wire in the target lesion under nominal pressure. During the intervention, arteriography with hand injection of contrast dye through the other femoral access was carried out. During stenting, the vertebral artery ostium was well-protected, considering the likelihood of vertebral artery occlusion. Left internal mammary artery orifice was carefully protected during intervention as well (Figure 2). Standard (unfractionated) heparin was intravenously given 100 Unit/kg.

Figures 2. Appearance of the left subclavian artery after stent implantation

After the implantation, pre-stent and post-stent region gradient was found to be less than 10 mmHg. The procedural success was 100%.

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Follow-up

In the endovascular intervention group, acetylsalicylic acid and clopidogrel were registered up to the third month follow. Afterwards, only acetylsalicylic acid were continued with annual follow-up. At annual controls all patients underwent a physical examination (especially, bilateral arm arterial pressure measurement) and questioned about the complaints. In addition, they underwent ultrasound examinations.

Statistical Analysis

The categorical data percentages and continuous variables were presented as mean ± standard deviation (SD). All data were analyzed using SPSS version 13.0 software for Windows (SPSS, Chicago, IL, USA). A $P < 0.05$ was considered statistically significant.

Results

The mean age of the patients were 65.54 ± 6.0. They had hypertension (18 patients, 60%), diabetes mellitus (15 patients, 50%), coronary artery disease (CAD) (total 11 patients, 36.7%, including 4 CABG patients), hypercholesterolemia (17 patients, 56.7%), carotid stenosis (7 patients, 23.3%), and the habit of smoking (15 patients, 50%). Four of 11 with CAD patients had coronary by-pass surgery history before LSAD (Table 1).

Table 1. Patient characteristics

Variable	Value	Frequency	%
Gender	Female	10	33.3
	Male	20	66.7
Diabetes	No	15	50.0
	Yes	15	50.0
Hypertension	No	12	40
	Yes	18	60
Hyperlipidemia	No	13	43.4
	Yes	17	56.6
Coronary artery disease	No	19	63.3
	Yes	11	36.7
Smoking	No	15	50.0
	Yes	15	50.0
Symptoms	Vertebrobasilar insufficiency	16	53.3
	Left arm ischemia	5	16.6
	Chest pain (angina)	4	13.3
Carotid stenosis		7	23.3

The patients had symptoms of vertebrobasilar insufficiency (16 patients, 53.3%, vertebral artery subclavian steal phenomenon), arm ischemia (5 patients, 16.6%, emboli), and angina (4 patients, 13.3%, with coronary artery bypass (CABG), coronary left internal mammary artery steal phenomenon).

In duplex ultrasound imaging, the bunny waveform (subclavian stenosis sign) was seen 22 of all the patients, reversed flow in diastole was seen in severe stenosis or occlusion cases (8/30).

25 patients (72%) had left subclavian artery stenosis, whereas five patients (28%) had left subclavian artery total occlusion. All of the lesions were in pre-vertebral artery region. The average lesion length was 21.60 ± 4.58 mm, vessel diameter (mm) 8.7 ± 3.8. Lesion type of stenotic cases was eccentric (n= 12, 40%) (Table 2).

Table 2. Clinical, laboratory and angiographic features

Duplex ultrasound Bunny waveform Reversed flow in diastole	 22/30 8/30
Physical examination Blood pressure difference (mmHg)	 42.0 ± 21.0
DSA Lesion length (mm) Vessel diameter (mm)	 21.60 ± 4.58 8.7 ± 3.8
Left subclavian artery stenosis	25/30
Left subclavian total occlusion	5/30
Lesion type	Eccentric (12/30)

Technical success in the endovascular treatment was 100%. Predilatation (balloon angioplasty) was performed 7 patients. Cobalt chromium stent balloon-expandable stents were used for all of the patients. Average stent length was 33.1 ± 12.2 mm average stent diameter was 82 ± 1.4 mm (Table 3).

Table 3. Procedural characteristics

Success rate	30/30 (100%)
Stent (cobalt chromium balloon-expandable stents)	30/30
Predilatation (balloon angioplasty)	7/30 (23.3%)
Stent length (mm)	33.1 ± 12.2
Stent diameter (mm)	8.2 ± 1.4
Max. Pressure (Atm)	9.8 ± 3.2
Complications (femoral pseudoaneurysm)	3/30 (10.0%)

Three of all the patients developed complications, which were femoral pseudoaneurysm. Those complications was resolved by manual compression. During the checks after the intervention, all of the patients underwent physical examination (bilateral arm arterial pressure measurement) and were asked if they had any complaints. Evaluation of restenosis was performed in all of the patients on ultrasound, and diagnostic angiography was performed in one patient, which was normal artery patency (Table 4).

Table 4. Follow-up information of the patients

Follow-up periods	3 months and 12 months
Percentage of follow up the patients	30/30
Restenosis (12 months)	none
BP difference (mmHg)	10 ± 3.2
Ultrasound follow	30/30
Angiography check	1 patient

Discussion

The incidence of subclavian artery disease is 3-4% in angiographic prevalence [9]. Atherosclerosis is the most common cause of subclavian artery disease. In addition, arteritis, inflammation due to radiation exposure, compression syndromes, fibromuscular dysplasia and neurofibromatosis may cause subclavian artery disease [1]. LSAD is diagnosed four times as frequently as right subclavian artery or innominate arteries [10-12].

In LSAD diagnosis, many techniques and measurements are used, among which are physical examination (absent or decreased left arm pulses), duplex ultrasound with color flow (waveform dampening or monophasic changes), CT angiography, magnetic resonance angiography and digital substraction angiography (DSA).

In LSAD therapy, in addition to medical therapy, surgical therapy or endovascular intervention can be performed. The patients without symptoms should be given medical therapy [11], including anti-platelet therapy, statins with blood pressure control and cessation of smoking. Surgical revascularization has long been performed as a treatment in LSAD [6]. Some studies using carotid–subclavian bypass and subclavian transposition have reported a low mortality (<1%), low stroke rates (0.5–5%) and high patency rates (92%-98%, within a 5-year period) [13-17].

Endovascular management has recently become a therapy alternative to surgical treatment [7,8]. Al- Mubarak et al reported in 1999 that the primary patency in 38 patients was 91% during a 20-month period [18]. The largest stent series (with 170 patients) were reported in 2008 with a technical success of 98%. No procedural deaths were reported and the rate of major complications were 0.6% (one stroke occurred). Primary patency rate was 83% during a 66-month period [19]. Wang et al stated in 2010 that, primary patency rate in 59 patients was 82% during a 60-month period, and technical success was 95.1% [20].

Cobalt chromium stents have good tissue tolerance and safe for human body. They are feasible due to their improved safety profile together with their high radial strength, low profile, and excellent elasticity. These stents have advantageous features, including thin struts designed to minimize vessel wall injury absence shortening for excellent accuracy, strong yet flexible to conform to the natural anatomy of the subclavian artery [21, 22]. These stents may have less restenosis rate in subclavian artery endovascular interventions. In our study, the success with cobalt chromium stents used in subclavian artery disease was 100%, with no major complications.

Current guidelines recommend the endovascular-first strategy in patients with atherosclerotic lesions of the upper extremities because of the effectiveness of subclavian endovascular intervention, and long-term patency [23].

There is no need for either general anesthesia and/or long hospitalization after endovascular therapy. On the other hand, such complimentary variables as experienced team, more effective and handy tools, and drugs for intervention help achieve enormous success (100%), low complication rates (<1%), and long-term primary patency. Consequently, endovascular intervention should be the preferred option in LSAD.

As a conclusion the endovascular management has recently become a popular therapy in subclavian arterial disease. Due to advantageous features, such as thin struts, absence shortening, strong yet flexible, cobalt chromium balloon-expandable stents have produced successful results in LSAD. Randomized prospective studies with larger samples are needed.

Declaration of conflicting interests

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References

1. Ochoa VM, Yeghiazarians Y. Subclavian artery stenosis: a review for the vascular medicine practitioner. Vasc Med 2011; 16: 29-34.
2. Shadman R, Criqui MH, Bundens WP, et al. Subclavian artery stenosis: Prevalence, risk factors, and association with cardiovascular diseases. J Am Coll Cardiol 2004; 44: 618 -23.
3. Sueoka BL. Percutaneous transluminal stent placement to treat subclavian steal syndrome. J Vasc Interv Radiol 1996; 7: 351-6.
4. Bryan AJ, Hicks E, Lewis MH. Unilateral digital ischaemia secondary to embolisation from subclavian atheroma. Ann R Coll Surg Engl 1989; 71: 140-2.
5. Olsen CO, Dunton RF, Maggs PR, Lahey SJ. Review of coronary-subclavian steal following internal mammary artery-coronary artery bypass surgery. Ann Thorac Surg 1988; 46: 675-8.
6. Wang KQ, Yuan C, Zhang WD, et al. Endovascular therapy and arterial bypass for subclavian artery occlusion. Chin J Surg 2006; 44: 584-7.
7. Motarjeme A, Gordon GI. Percutaneous transluminal angioplasty of the brachiocephalic vessels: guidelines for therapy. Int Angiol 1993; 12: 260-9.
8. Rutherford RB, Baker JD, Ernst C, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997; 26: 517-38.
9. English JA, Carell ES, Guidera SA, Tripp HF. Angiographic prevalence and clinical predictors of left subclavian stenosis in patients undergoing diagnostic cardiac catheterization. Catheter Cardiovasc Interv 2001; 54: 8-11.
10. Rodriguez-Lopez JA, Werner A, Martinez R, Torruella LJ, Ray LI, Diethrich EB. Stenting for atherosclerotic occlusive disease of the subclavian artery. Ann Vasc Surg 1999; 13: 254-260.

11. Schillinger M, Haumer M, Schillinger S, Mlekusch W, Ahmedi R. Outcome of conservative versus interventional treatment of subclavian artery stenosis. J Endovasc Ther 2002; 9: 139-46.
12. Williams SJ. Chronic upper extremity ischemia: current concepts in management. Surg Clin North Am 1986; 66: 355-75.
13. Vitti MJ, Thompson BW, Read RC, et al. Carotid–subclavian bypass: a twenty-two-year experience. J Vasc Surg 1994; 20: 411-18.
14. Perler BA, Williams GM. Carotid–subclavian bypass: a decade of experience. J Vasc Surg 1990; 12: 716-23.
15. Kretschmer G, Teleky B, Marosi L, et al. Obliterations of the proximal subclavian artery: to bypass or to anastomose? J Cardiovasc Surg 1991; 32: 334-9.
16. Cinà CS, Safar HA, Laganà A, Arena G, Clase CM. Subclavian carotid transposition and bypass grafting: consecutive cohort study and systematic review. J Vasc Surg 2002; 35: 422-9.
17. Van der Vliet JA, Palamba HW, Scharn DM, van Roye SF, Buskens FG. Arterial reconstruction for subclavian obstructive disease: a comparison of extrathoracic procedures. Eur J Vasc Endovasc Surg 1995; 9: 454-8.
18. Al-Mubarak N, Liu MW, Dean LS, et al: Immediate and late outcomes of subclavian artery stenting. Catheter Cardiovasc Interv 1999; 46: 169-72.
19. Patel SN, White CJ, Collins TJ, et al. Catheter-based treatment of the subclavian and innominate arteries. Catheter Cardiovasc Interv 2008; 71: 963-8.
20. Wang KQ, Wang ZG, Yang BZ, et al. Long-term results of endovascular therapy for proximal subclavian arterial obstructive lesions. Chin Med J 2010; 123: 45-50.
21. Kastrati A, Mehilli J, Dirschinger J, et al. Intracoronary stenting and angiographic results strut thickness effect on restenosis outcome (ISAR-STEREO) trial. Circulation 2001; 103: 2816-21.
22. Kolandaivelu K, Swaminathan R, Gibson WJ, et al. Stent thrombogenicity early in high-risk interventional settings is driven by stent design and deployment and protected by polymer- drug coating. Circulation 2011; 123:1400-9.
23. Brogneaux C, Sprynger M, Magnée M, Lancellotti P. European Society for Cardiology. 2011 ESC guidelines on the diagnosis and treatment of peripheral artery diseases. Rev Med Liege 2012; 67: 560-5.