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Patency rate and factors affecting the clinical outcome of patients with aortoiliac artery occlusion undergoing intra-arterial stenting

Tasa de permeabilidad y factores que afectan el resultado clínico de pacientes con oclusión de la arteria aortoiliaca sometidos a endoprótesis intraarterial

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ABSTRACT:

Background Occluding plaques are commonly found in the infrarenal aorta and the iliac artery in patients with peripheral arterial disease (PAD). Aortoiliac occlusive disease (AIOD) occurs commonly in patients with PAD.

Methods: This is a prospective study was carried out between 2015 and 2017 in Sina hospital. Patients with occlusion in aortoiliac artery and its branches were included. Stent was placed for patients, if they had any obstruction or stenosis in aortoiliac artery in angiography. Patients were examined in terms of clinical status and ABI calculation and underwent Color Doppler ultrasound of aortoiliac artery to determine patency rate at 1, 3, 12, and 24 months after stent placement.

Results: The mean age of patients was 64.60 (± 10.41). The main symptoms of the patients were claudication (41.8%), ulcer (27.3%), pain at rest (20%), and gangrene (20%). The lesion was bilateral in 21 patients (38.2%). According to TASC stratification, lesions were of type A in 26 patients (47.3%), type B in 4 patients (7.3%), type C in 5 patients (9.1%), and type D in 20 patients (36.4%). The six-month, one-year, and two-year patency rates were 89.1%, 83.6%, and 72.7%, respectively. The mean annual ABI of patients was 0.79 (± 0.11) and two year ABI was 0.68 (± 0.1).

Conclusion: It seems that stenting and angioplasty are effective in improving patients' conditions and result in a good short and medium-term patency.

KEYWORDS: Aortoiliac artery occlusion, patency rate, endovascular stenting, intraarterial stenting.

RESUMEN:

Antecedentes Las placas oclusivas se encuentran comúnmente en la aorta infrarrenal y la arteria iliaca en pacientes con enfermedad arterial periférica (EAP). La enfermedad aortoiliacoclusiva (AIOD) ocurre comúnmente en pacientes con EAP.

Métodos: Este es un estudio prospectivo realizado entre 2015 y 2017 en el hospital de Sina. Se incluyeron pacientes con oclusión en la arteria aortoiliaca y sus ramas. Se colocó un stent para pacientes, si tenían alguna obstrucción o estenosis en la arteria aortoiliaca en la angiografía. Los pacientes fueron examinados en términos de estado clínico y cálculo de ABI y se les realizó un ultrasonido Doppler color de la arteria aortoiliaca para determinar la tasa de permeabilidad a los 1, 3, 12 y 24 meses después de la colocación del stent.

Resultados: La edad media de los pacientes fue de 64,60 ($\pm 10,41$). Los síntomas principales de los pacientes fueron claudicación (41,8%), úlcera (27,3%), dolor en reposo (20%) y gangrena (20%). La lesión fue bilateral en 21 pacientes (38,2%). Según la estratificación TASC, las lesiones fueron de tipo A en 26 pacientes (47,3%), tipo B en 4 pacientes (7,3%), tipo C en 5 pacientes (9,1%) y tipo D en 20 pacientes (36,4%). Las tasas de permeabilidad de seis meses, un año y dos años fueron 89,1%, 83,6% y 72,7%, respectivamente. El promedio anual de ABI de los pacientes fue de 0,79 ($\pm 0,11$) y el de dos años fue de 0,68 ($\pm 0,1$).

Conclusión: Parece que el stent y la angioplastia son efectivos para mejorar las condiciones de los pacientes y dan como resultado una buena permeabilidad a corto y mediano plazo.

PALABRAS CLAVE: oclusión de la arteria aortoiliaca, tasa de permeabilidad, endoprótesis endovascular, endoprótesis intraarterial.

INTRODUCTION

Occluding plaques causing atherosclerotic obstructive disease are commonly found in the infrarenal aorta as well as iliac artery in patients with peripheral arterial disease (PAD). Atherosclerotic plaques can cause symptoms in distal vessels, due to blockage of blood flow, detachment and embolization of atherosclerotic or thrombotic debris. If the plaques become large enough to affect the arterial lumen, blood flow to the distal organs will be decreased^{1,2}.

Aortoiliac occlusive disease (AIOD) occurs commonly in patients with PAD. Significant lesions in the aortoiliac arterial wall can be easily detected by checking femoral pulses. Any reduction in the femoral palpable pulse suggests that the blockage is proximal to the femoral pulses. Occlusive lesions can be present in the infrarenal aorta, common iliac, internal iliac (hypogastric), external iliac or any or all of these arteries^{3,4}.

Surgical treatment of AIOD has remained the corner stone of treatment for many years and had somewhat favorable outcomes. Techniques such as percutaneous transluminal angioplasty (PTA) and stenting can be considered as alternative to open surgery for patients who are not proper candidates for surgical repair. Catheter-based endovascular therapies for AIOD have more benefits in terms of morbidity, faster recovery, and shorter hospitalization. In fact, most endovascular interventions are easily performed in outpatient settings^{3,4}.

Regarding the mentioned issues, the present study aims to determine the survival rate and possible contributing factors in the clinical outcomes of patients with aortoiliac artery occlusion undergoing intra-arterial stenting.

MATERIAL & METHODS

This prospective study was carried out on patients presented at outpatient vascular surgery clinic of Sina hospital from 2015 to 2017 with occlusion of aortoiliac artery and its branches, and subsequently, they were selected for angiography. CO. angiography was considered for those who had raised creatinine level. Stent was placed for patients, if they had any obstruction or stenosis in aortoiliac artery in angiography. In this study, the exposure refers to patients with stenosis and obstruction of the common iliac or external iliac arteries, or both, diagnosed after angiography and the outcome refers to patients who underwent stenting during angiography after diagnosis. Variables include smoking, disease manifestations, comorbidities, symptoms onset to treatment onset interval, signs of limb ischemia, degree of artery stenosis and obstruction, anatomical site of stenosis, TASC II stratification, patency rate, 1-year prognosis, and ABI were gathered. Patients with poor compliance, rheumatologic diseases, due to the possible misdiagnosis of pain, were excluded from the study. The inclusion criteria were the eligible patients aged from 50 to 80 years with manifestations of arterial obstruction. The patients were examined clinically, ABI was calculated for each one, and patients underwent Color Doppler Ultrasound of aortoiliac artery for patency rate at 1, 3, 12, and 24 months after stent placement. Patency rates at four intervals and one- and two-year ABI were considered as the final outcomes of the study and the relationship of these variables with other parameters of the study was determined.

Statistical analysis was accomplished using the Statistical Package for Social Sciences (SPSS 16, SPSS Inc., Chicago, US). Data are expressed as number (%) or mean $\pm$ standard deviation (SD).

RESULTS

The mean age of patients, including 48 males (87.3%) and 7 females (12.7%), was 64.6 (± 10.41) years. Forty-three patients (78.2%) had a history of smoking. The underlying diseases were hypertension in 19 (34.5%), diabetes mellitus in 26 (47.3%), hyperlipidemia 7 (12.7%), heart failure 8 (14.5%), and renal failure 1 (1.8%).

The drugs used were Aspirin 29 (52.7%), warfarin 2 (3.6%), Beta-blockers 5 (9.1%), Plavix 8 (14.5%), Statins 18 (32.7%), Glibenclamide and Metformin 53 (96.4) and insulin 2 (3.6%).

The main symptoms of the patients were claudication, ulcer, rest pain, and gangrene in 23 (41.8%), 15 (27.3%), 11 (20%), and 11 (20%), respectively. The lesion aortoiliac artery occlusion was on the right side in 21 patients (38.2%), on the left side in 12 patients (21.8%), and bilateral in 21 patients (38.2%). The interval between symptoms onset and treatment was less than 3 months in 6 patients (10.9%) whereas

more than 3 months in 43 patients (78.2%). In patients whose symptoms had started more than 3 months, the mean interval between symptoms onset and treatment was 8.15 (± 2.54) months. According to TASC stratification, lesions were type A, type B, type C, type D in 26 (47.3%), 4 (7.3%), 5 (9.1%), and 20 (36.4%) patients, respectively. The mean diameter of the vessel was 7.82 (± 1.16) mm and the mean length of the lesion was 6.34 (± 6.42) cm. The mean minimum stenosis was 81.18 (± 8.86) percent prior the treatment.

The type of stent used was self-expanding in 37 patients (67.3%) and balloon-expanding in 18 patients (32.7%). The largest diameter of the stent was averaged 70.86 (± 45.25) mm. The mean number of stents used was 1.83 (± 0.97). The initial success was achieved in 98.70% of the cases (number of patients should be mentioned 54). Ultrasound performed after a month, 6 months, 1 year, 2 years, revealed that 0 (0.0%), 5 (9.1%), 8 patients (14.5%), 2 years, 11 patients (20%) had developed stenosis or obstruction, respectively. The mean 1 and 2-year calculated ABI of the patients was 0.79 (± 0.11) and 0.68 (± 0.1).

There was a significant difference between HLP and one-year ABI (p-value: 0.011). There was significant difference between claudication and one-year patency (p-value: 0.008). There was significant difference between two-year patency (p-value: 0.044). There was significant difference between and one-year ABI (p-value < .001). There was significant difference between gangrene and six-month patency (p-value: 0.021) and one-year ABI (p-value: 0.005). There was significant difference between TASC stratification and six-month patency (p-value: 0.010). There was significant difference between number of lesions with six-month patency (p-value: 0.011). There was significant difference between the maximum lesion diameter and six-month patency (p-value: 0.042). There was significant difference between and the number of stents and six-month patency (p-value: 0.042). The location of the disease was significantly differed among different TASC groups (p=0.015), so that 61.9% were bilateral TASC D and 57.1% unilateral TASC A. The relationship of between one and 2-year ABI and patency rate was statistically significant (p-value < 0.001). (Table 1).

Table 1. Showing correlation between all studied variables and 6 month 1 year and 2 year patency rate as well as 1 year ABI.

TABLE 1
Showing correlation between all studied variables and 6
month 1 year and 2 year patency rate as well as 1 year ABI

Parameter	6-month patency	1-year patency	2-year patency	1-year ABI
Age	0.635	0.493	0.945	0.469
Gender	0.374	0.245	0.636	0.078
Smoking	0.902	0.731	0.480	0.051
HTN	0.516	0.885	0.935	0.156
DM	0.708	0.329	0.487	0.752
HLP	0.631	0.967	0.636	0.011*
HF	0.738	0.845	0.622	0.866
Renal Failure	0.753	0.681	0.056	0.702
ASA	0.708	0.597	0.794	0.752
Warfarin	0.653	0.557	0.459	0.479
Betablocker	0.394	0.337	0.301	0.115
Plavix	0.374	0.845	0.141	0.130
Statin	0.649	0.595	0.439	0.862
Insulin	0.653	0.159	0.328	0.479
Claudication	0.053	0.008*	0.044*	0.000*
Ulcer	0.924	0.004*	0.860	0.932
Rest Pain	0.243	0.126	0.764	0.725
Gangrene	0.021*	0.139	0.241	0.005*
Unilateral/Bilateral	0.029*	0.624	0.639	0.423
Symptom to therapy interval	0.559	0.729	0.786	0.774
TASC	0.010*	0.580	0.254	0.511
Reference vessel diameter	0.446	0.843	0.246	0.056
Lesion length	0.311	0.947	0.886	0.381
Occlusion severity	0.431	0.385	0.472	0.582
Number of lesions	0.011*	0.388	0.283	0.878
Stent Type	0.516	0.218	0.237	0.643
Highest diameter of stent	0.042*	0.315	0.681	0.747
Number of stents	0.042*	0.705	0.254	0.830

* shows statistically significant values

DISCUSSION

As expected, the disease is most prevalent at a particular age. Accordingly, in the study of Van Haren RM et al.⁵ in 2017, the mean age of patients was 59 years. In the study of Rzucidlo Em et al.⁶, the mean age of patients was 63 years. Indes JE et al. stated that patients undergoing stenting are more likely to be over 65 years (54%), and to be female. The latter study is the only study in which the number of females was more than males.

There was a history of smoking in 43 (78.2%) of patients. The most common underlying diseases were diabetes mellitus (47.3%) and hypertension (34.5%). In the study of Rzucidlo Em et al.⁶, 71% of patients were active smokers and hypertension was observed in 91%, diabetes in 26%, and renal failure in 21% of patients. The rate of renal failure in the present study was 1(1.8%). In current study, there was a relationship between hyperlipidemia and one-year ABI ($p=0.011$), so that, the higher levels of lipid profile, the lower one year ABI. Despite hyperlipidemia, the probability of ABI of less than 0.9 increased after one year. In a study by Kashyap VS et al.⁸ (2008), hyperlipidemia and smoking led to poor outcomes in stenting and

angioplasty compared to ABI. In the study of Kashyap VS et al.⁴, diabetes mellitus had an inverse relation with patency rate⁸.

The main symptoms in the present study were claudication, ulcer, resting pain, and gangrene, in descending order. In the study of Kashyap VS et al., claudication was observed in 53%, resting pain in 28%, and gangrene and limb ischemia in 19% of patients; the findings of this study are similar to that of ours. In the study of Van Haren RM et al.⁵, 100% of patients had resting pain and 40% had gangrene, which is completely in contrast with our findings. In a study by Rzuicldo Em et al.⁶, resting pain was observed in 65% of patients and gangrene and limb amputation in 35% of patients.

The relationship of the number of symptoms with other parameters was statistically significant in the present study. Claudication was statistically significant with one-year and two-year patency and one-year ABI, worsening the prognosis of the patient. Ulcers, also, significantly reduced the one-year patency, while gangrene significantly reduced the six-month patency as well as one-year ABI. In this study, 38.2% of cases were bilateral and 60% were unilateral and there was a significant relationship between bilateral disease and less significant six-month patency rate, which is similar to the results of a study by Lun Y et al.⁹.

The most common lesions in our study were TASC A, type D, type C, and type B, in descending order. In the study of RevueltaSuero et al.¹⁰, as with the present study, TASC A lesions were the more common lesion. In the study of Rzuicldo Em et al., TASC C and D lesions were the common lesions in 85% of cases. The TASC type had a significant relationship with six-month patency in our study, so the more severe TASC group, the less patency rate. In numerous studies, TASC types had statistically significant relationship with the procedure and its clinical outcomes. Accordingly, Benetis et al.¹¹ found that endovascular procedure in TASC A lesions can lead to more complications compared to other interventions, and it is not a preferred method, while endovascular procedure can bring beneficial clinical outcomes in the other three types of TASC.

The mean length of lesions was 6.34 cm in the present study. In the study of Rzuicldo Em et al.⁶, the mean length of lesions was 13.7 cm. The study by RevueltaSuero et al.¹⁰ reported a mean lesion length of 42 mm. There was no correlation in the present study between the lesion length and other parameters of the study, but Karpenko AA et al.¹² concluded that increasing the lesion length to more than 100 mm was associated with restenosis or subsequent thrombosis.

The largest stent diameter in our study was averagely 70.86 mm. This diameter has a significant relationship with the six-month patency and larger stent diameter has led to lower patency rate. In a study by Kavaliauskienė et al.¹³, stents smaller than 61 mm had 12-month and 24-month patency rates of 90.6% and 86.6%, respectively, while stents larger than 61 mm had 12-month and 24-month patency rates of 67.7% and 60.2%, respectively.

In the present study, the initial success rate was 98.70%. In the study of Kashyap VS [8], the success rate was 96%. Van Haren RM⁵ reported a success rate of 100%. This was 95% in the study of Yuan L¹⁴. In general, the findings of most studies are to a great degree similar in terms of primary success rate.

Patency was the most important indicator in this study, which was 100% in the first month, 89.1% in 6 months, 83.6% in 1 year, and 72.7% in 2 years. One-year and 3-year patency rates were 86% and 80%, respectively in the study of Indes JE et al.⁴. In a study by Jongkind V et al.³, the 4-year/ 5-year patency rates were 80%-98%. The three-year patency in the study of Kashyap VS et al.⁸ was 74%. One-year and 2-year patency rates were 92.7% and 81.9%, respectively in the study of Karpenko AA et al.¹². The one-year patency reported by Van Haren RM et al.⁵ in 2017 was 80%. Lun Y⁹ reported one-year, 3-year, and 5-year patency rates as 91.4%, 81.8%, and 64.2%, respectively. The 6-month, 18-month, and 24-month patency rates were 93.3%, 83%, and 66.4%, respectively in the study of Yuan L et al.¹⁴. The one-year patency was

91% in the study of Psacharopulo D et al.¹⁵. In our study, the number of stents was significantly associated with a decrease in six-month patency rate.

Changes in ABI have been recorded as one of the most important indicators after the procedure in various studies. In here, ABI was evaluated 1 and 2 years after the trial, which was 0.79 and 0.68. The study by Van Haren RM et al.⁵ has shown that ABI is improved in both left and right legs by 0.5. In the study of Rzucidlo Em et al, ABI was increased from 0.3 to 0.59. In the study of Kashyap VS et al.⁸, ABI reached from 0.48 to 0.84.

Limitations

Failure to measure ABI prior to the procedure was one of the drawbacks of the present study, which should be considered in future studies in order to allow its comparison before and after intervention and to calculate recovery after the procedure.

CONCLUSION

According to the findings of this study, it seems that stenting and angioplasty (irrespective of the stent type, i.e. self-expanding or balloon-expanding) are effective in improving patients, resulting in a good short- and medium-term patency. In addition, due to the strong association between patency rate and symptoms (i.e. claudication, gangrene, and ulcer) patients should be further evaluated in terms of these symptoms.

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