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TurboHawk plaque rotation system for treatment of arteriosclerosis occlusion in lower extremities

A pilot retrospective study

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Abstract

This pilot study retrospectively assessed the feasible efficacy of TurboHawk plaque rotation system (THPRS) for treatment of arteriosclerosis occlusion in lower extremities (AOLE).

A total of 36 eligible patients with AOLE were included in this pilot retrospective study. We divided all those patients into a treatment group and a control group, each group 18 patients. All patients in both groups administered conventional therapy. Additionally, all patients in the treatment group received THPRS, while all patients in the control group received percutaneous transluminal angioplasty (PTA) and percutaneous transluminal stenting (PTS). All outcomes were evaluated and analyzed at 3-month after surgery.

At 3-month postsurgery, there were not significant statistical differences in clinical manifestations (intermittent claudication, $P = .49$; resting pain, $P = .28$), ankle brachial index change ($P = .07$), 6-minute walk distance ($P = .43$), and complications between 2 groups.

This pilot study did not show better outcome improvement of THPRS for patients with AOLE. We cautiously draw the present conclusion, because it suffers from several major restrictions. Thus, further studies with larger sample size and longer term follow-up are still needed to warrant the current conclusion.

Abbreviations: ABI = ankle brachial index, AOLE = arteriosclerosis occlusion in lower extremities, PTA = percutaneous transluminal angioplasty, PTS = percutaneous transluminal stenting, THPRS = TurboHawk plaque rotation system.

Keywords: arteriosclerosis occlusion, efficacy, lower extremity, TurboHawk plaque rotation system

1. Introduction

Arteriosclerosis obliterans in lower extremities (AOLE) is a common disease in vascular surgery department.[1,2] It occurs more frequently in the elderly, and the incidence rate is increasing with the changes in dietary habits and age.[3,4] Its morbidity rate is about 10%, and it is approximately 20% in people over 70 years old.[5–7] It affects over 200 million around the world, and 2 to 4 times frequency in diabetes patient than the general population.[8,9] The mainly risk factors are associated with age, gender, smoking, hypertension, hyperlipidemia, and high cholesterol.[10–13]

Medications are reported to treat AOLE, including antiplatelet medications and Cilostazol.[14–20] Antiplatelet medication, such as aspirin is responsible for the management of relief in risk of heart attack and stroke.[14–17] Cilostazol is reported to enhance walking distance.[18–20] However, not all patients are eligible to take those medications. In addition, their overall efficacy is still limited.[21–23] Thus, it is very necessary to find alternative treatment for this disorder. Fortunately, surgery is reported to treat AOLE effectively.[24,25]

Studies suggest that percutaneous transluminal angioplasty (PTA) and percutaneous transluminal stenting (PTS) have been used in the treatment of AOLE.[7,26] However, its long-term patency rate is still not satisfied,[7,26] with 2-year patency rate of 64.2%.[7] Although TurboHawk plaque rotation system (THPRS) is report to achieve better efficacy in patency rate in patients with AOLE,[27,28] there is still insufficient evidence to support THPRS for AOLE. Thus, this pilot retrospective study assessed the feasible efficacy and complications of THPRS for the treatment of patients with AOLE.

2. Methods

2.1. Design

This pilot study was approved by the Medical Ethical Committee of Second Affiliated Hospital of Xuzhou Medical University (General Hospital of Xuzhou Mining Group). All patient records were conducted and completed in this hospital between January

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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2018 and December 2019. All of them signed informed written consent.

This study was designed as a pilot retrospective study. It included 36 patients with AOLE. They were divided into 2 groups according to the different treatments they received. Eighteen eligible patients were assigned to a treatment group and the other 18 participants were allocated to a control group. All patients in both groups received conventional therapy. Then, patients in the treatment group received THPRS, while subjects in the control group administrated PTA and PTS. All outcomes were measured at 3-month after surgery. All patients and researchers were not blinded to the treatment allocation. However, data analyst was blinded to this study.

2.2. Inclusion and exclusion criteria

Eligible patients should meet the following inclusion criteria:

1. all patients were diagnosed as AOLE according to the Guidelines for the Diagnosis and Treatment of Arteriosclerosis Obliterans of the Lower Extremities;[29]
2. aged between 18 and 80 years old; and
3. signed written informed consent.

Patients were excluded if they were:

1. below 18 or over 80 years old;
2. pregnant women;
3. acute thrombosis; and
4. severe diseases, such as cancer.

2.3. Intervention schedule

Patients in both groups administered conventional therapy.[29] It included oral aspirin (100 mg/time, once daily) and clopidogrel (75 mg/time, once daily) until 3 months postsurgery.

In addition, patients in the treatment group received THPRS. After local anesthesia with 2% lidocaine, the lateral femoral artery with Cook 7F anti-folding sheath was inserted, and we applied 4000U heparin intravenously. Under the guide of roadmap, VER catheter and Terumo 0.035 hydrophilic guide wire reached to popliteal artery lesion. Then, THPRS were placed in the target narrowed vessel and plaque resection was performed in multiple quadrant of artery. After manipulation, THPRS was withdrawn from the target vessel.

Patients in the control group administrated PTA and PTS. The same approach was applied to guide wire through the popliteal artery lesion. Then, a 3 mm balloon dilatation catheter was inserted to pre-dilate the target vessel. A matching balloon catheter was placed according to the diameter of the attacked vessel for postdilation. After dilation, the target vessel was observed by angiography, and the stent was placed at the most narrow and severe calcification.

2.4. Outcome measurements

Number of major clinical manifestations (intermittent claudication, resting pain), ankle brachial index (ABI), 6-minute walk distance, and complications (major amputation, postoperative thrombosis rate, number of patients needed resurgery). All outcomes were measured and analyzed at 3-month after surgery. Data analyst was blind to the treatment schedule and patient allocation.

2.5. Statistical analysis

This study occupied SPSS software (SPSS 17.0, IBM Corp., Armonk, NY) for statistical analysis. Continuous data was analyzed using t test for normally distributed data or Mann–Whitney U test for non-normally distributed data. Categorical data was analyzed using χ^2 test or Fisher exact test. A 2-side $P < .05$ was defined as having statistical significance.

There is insufficient evidence to base the sample size calculation. Thus, this pilot retrospective study assessed feasible efficacy and compilations of THPRS for patients with AOLE according to the published study about how to calculate sample size for a pilot study.[30] A minimum of 36 patients (18 in each group) is supposed to appraise the feasible efficacy of THPRS for AOLE with expected dropout rate of 20%.[30]

3. Results

We summarized the general characteristics and clinical symptoms of all patients in both groups (Table 1). There were not significant statistical differences between 2 groups (Table 1). These general characteristics and clinical symptoms include age, gender, race, risk factors, body mass index, ABI, 6-minute walk distance, intermittent claudication, resting pain, antihypertensive, antidiabetic, and antilipid medications.

At 3-month postsurgery, all patients in the treatment group did not show better improvement in clinical manifestations (intermittent claudication, $P = .49$; resting pain, $P = .28$; Table 2), ABI change ($P = .07$, Table 3), and 6-minute walk distance ($P = .43$, Table 4), than patients in the control group.

As for safety, only 2 patients reported treatment-related complications 3 months after surgery (Table 5). One reported thrombosis, and the other one needed secondary surgery

Table 1

General characteristics and clinical symptoms of all patients between 2 groups.

Characteristics	Treatment group (n = 18)	Control group (n = 18)	*P*
Age (years)	65.4 (8.3)	68.1 (9.3)	.36
Gender			
Male	11 (61.1)	13 (72.2)	.48
Female	7 (38.9)	5 (27.8)	.48
Race (Han ethnicity)	18 (100.0)	18 (100.0)	-
Risk factors			
Diabetes mellitus	12 (66.7)	11 (61.1)	.73
Hypertension	13 (72.2)	15 (83.3)	.43
Hyperlipidemia	10 (55.6)	13 (72.2)	.30
High cholesterol	11 (61.1)	9 (50.0)	.50
Family history of atherosclerosis	5 (27.8)	6 (33.3)	.72
Smoking	8 (44.4)	10 (55.6)	.51
Drinking	6 (33.3)	4 (22.2)	.46
BMI (kg/m^2)	25.3 (3.7)	25.8 (3.3)	.67
ABI	0.52 (0.09)	0.50 (0.11)	.55
6-minute walk distance (m)	191.9 (32.4)	201.6 (36.0)	.40
Intermittent claudication	14 (77.8)	12 (66.7)	.46
Resting pain	7 (38.9)	8 (44.4)	.74
Antihypertension medication	13 (72.2)	15 (83.3)	.43
Antidiabetes medication	12 (66.7)	11 (61.1)	.73
Antilipid medication	11 (61.1)	13 (72.2)	.48

Data are present as mean ± standard deviation or number (%).
ABI = ankle-brachial index, BMI = body mass index.

Table 2

Comparison of clinical manifestations after 3-month treatment between 2 groups.

Clinical manifestations	Treatment group (n = 18)	Control group (n = 18)	P
Intermittent claudication	0 (0)	1 (5.6)	.49
Resting pain	0 (0)	2 (11.1)	.28

Data are present as number (%).

(Table 5). However, there were not significant differences regarding complications between 2 groups in this study (Table 5).

4. Discussion

AOLE is a very common disorder in the elderly, with increasing prevalence rate annually.[1,2,5,6] Previous similar studies suggested THPRS for the treatment of patients with AOLE.[27,28] One study reported THPRS in the treatment of patients with superficial femoral atherosclerosis (SFA).[27] It retrospectively analyzed 60 patient case records (including 50 males and 10 females) of superficial femoral atherosclerotic stenosis and occlusion treated by THPRS.[27] Its findings showed that THPRS may be effective for the management of SFA in a short period. In addition, it exerts less trauma and satisfied safety.[27] The other study appraised the efficacy and safety of directional atherectomy with Silver HawkTM device in the management of in-stent restenosis of femoropopliteal artery.[28] The results of this study found that atherectomy of in-stent restenosis showed promising initial success rate.[28] However, its long-term patency rates are still low. Additionally, this study did not yield prevention of recurrent intimal hyperplasia.[28]

In this pilot retrospective study, we included 36 patients with AOLE. Of those, 18 patients were treated with THPRS, while the other 18 patients were treated with PTA and PTS. The results of this pilot study showed that there were not significant differences regarding intermittent claudication, resting pain, ABI change, 6-minute walk distance, and treatment-related complications between 2 groups. It indicates that THPRS may be not efficacious in outcome improvement and complications reduction at 3 months postsurgery. There may be significant differences between 2 groups at long term follow-up, such as 1 year or 2 year. However, this retrospective study only reported outcome data at 3-month after surgery.

This pilot retrospective study suffers from several limitations. First, it has pretty small sample size, which may affect the results of this study. Second, this pilot study only analyzed outcome data at 3-month postsurgery, and no longer term follow-up outcome data was collected and analyzed. Third, this pilot study did not apply approaches of randomization and blind to patients and researchers, except data analyst, which may impact selection risk of this study. Fourth, the outcomes of this pilot study may be not comprehensive, which may also affect the efficacy of THPRS. Finally, all patient data was only harvested from 1 hospital, which may affect its generalization to other hospitals. The future studies should warrant current findings, and avoid all above limitations.

Table 3

Comparison of ABI change from baseline after 3-month treatment between 2 groups.

Outcome measurements	Treatment group (n = 18)	Control group (n = 18)	P
After 3-month treatment	1.05 (0.09)	0.99 (0.11)	
Change from baseline	0.53 (0.38, 0.62)	0.49 (0.36, 0.58)	
Difference between two groups		0.04 (0.02, 0.07)	.07

Data are present as mean ± standard deviation (range).

Table 4

Comparison of 6-minute walk distance change after 3-month treatment between 2 groups.

6-minute walk distance (m)	Treatment group (n = 18)	Control group (n = 18)	P
After 3-month treatment	378.6 (89.8)	354.1 (96.0)	
Change from baseline	186.7 (149.5, 212.0)	152.5 (133.3, 181.6)	
Difference between 2 groups		34.2 (23.1, 46.3)	.43

Data are present as mean ± standard deviation (range).

Table 5

Comparison of complications 3-month after treatment between 2 groups.

Adverse events	Treatment group (n = 18)	Control group (n = 18)	P
Major amputation	0 (0)	0 (0)	-
Thrombosis	0 (0)	1 (5.6)	.49
Patients needed re-surgery	0 (0)	1 (5.6)	.49

Data are present as number (%).

5. Conclusion

The results of this study did not show that THPRS may benefit more in patients with AOLE. We cautiously draw this conclusion because of the several major limitations. Future studies should warrant current findings.

Author contributions

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