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Clinical Research

Early Diagnosis and Intervention Are Needed for a Reasonable Prognosis of Thromboangiitis Obliterans

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Background: Thromboangiitis obliterans (TAO) poses a higher risk of amputation than atherosclerosis obliterans. It is characterized by onset at a relatively young age. There are currently no clear treatment guidelines for TAO other than smoking cessation. In this study, we aimed to identify factors that could influence a favorable prognosis of TAO.
Methods: From January 2009 to December 2019, we retrospectively reviewed the initial symptoms, characteristics, treatments, and disease course of 37 patients (45 limbs) with TAO. Logistic regression analysis was performed to investigate factors affecting the course of symptoms that persisted or worsened despite treatment.
Results: Patients' mean age was 37.2±11.4 years, and all patients were men. The mortality rate was 0% during the follow-up period (76.9±51.1 months). All patients were smokers at the time of diagnosis, and 19 patients (51.4%) successfully quit smoking during treatment. When comparing the Rutherford categories before and after treatment, 23 limbs (51.1%) showed improvement, the category was maintained in 11 limbs (24.4%), and 11 limbs (24.4%) worsened. Symptom persistence or exacerbation despite treatment was associated with a higher initial Rutherford category (odds ratio [OR], 1.59; 95% confidence interval [CI], 1.04–2.42; p=0.03) and a higher score of the involved below-knee artery at the time of diagnosis (OR, 2.26; 95% CI, 1.10–4.67; p=0.03).
Conclusion: The degree of disease progression at the time of diagnosis significantly affected patients' prognosis. Therefore, early diagnosis and intervention are important to improve the course of TAO.

Keywords: Thromboangiitis obliterans, Arterial occlusive diseases, Vascular grafting, Endovascular procedures, Prognosis

Introduction

Thromboangiitis obliterans (TAO) is a disease that affects small and medium-sized arteries and veins and causes stenosis or occlusion of blood vessels due to chronic inflammatory reactions [1]. In 1908, Buerger [2] reported other types of vascular occlusion, different from atherosclerosis obliterans (ASO), in Polish and Russian patients who underwent amputation for spontaneous gangrene. However, in 1960, researchers began to describe TAO separately from ASO [1]. TAO poses a higher risk of amputation than ASO and is characterized by onset at a relatively young age. Furthermore, TAO tends to be concentrated in certain regions. It is common in the Middle East, Asia, the Mediterranean region, and Eastern Europe along the Silk Road. However, it is rare in Africa, Central Europe, and the United States [3,4].

TAO is characterized by distal extremity ischemia and mainly occurs in smokers aged <50 years of age. Symptoms appear in the feet, legs, hands, and arms, and as the disease progresses, the proximal arteries become involved. Symptoms range from mild coldness, burning pain, redness, cyanosis, migratory superficial thrombophlebitis, and the Raynaud phenomenon to trophic nail change, ischemic ul-

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ceration, and digital gangrene as the disease progresses [1].

Smoking is a risk factor for TAO [5]. The relationship between smoking and the pathogenesis, onset, and course of TAO is well established. Furthermore, genetic predisposition [6], immune-mediated mechanisms [7], hypercoagulable states [8], oral infection-inflammatory pathways [9], and endothelium-dependent vasorelaxation [10,11] have been suggested as underlying factors. There are currently no clear treatment guidelines for TAO other than smoking cessation. Considering the catastrophic course of the disease, analyzing the factors affecting prognosis would be helpful.

In this study, we investigated the characteristics, symptoms, treatment methods, progress, and prognosis of patients diagnosed with TAO during 10 years of follow-up at a single institution, and we analyzed factors associated with improvement.

Methods

This retrospective study was approved by the Institutional Review Board of the Pusan National University Hospital (IRB no., 2105-001-102). The requirement for informed consent was waived. The study adhered to the principles of the Declaration of Helsinki.

Patients

From January 2009 to December 2019, 72 patients were treated for TAO at the Pusan National University Hospital. If 4 or more of the Shionoya criteria were satisfied [12], TAO (Buerger's disease) was diagnosed: (1) smoking history, (2) onset before the age of 50 years, (3) infrapopliteal arterial occlusions, (4) upper limb involvement or phlebitis migrans, and (5) absence of atherosclerotic risk factors other than smoking.

Cases in which initial image data were lost (n=18) because of the hospital's policy regarding the image retention period or where the description of the diagnostic criteria was insufficient, even with the diagnosis of TAO (n=17), were excluded. The medical records of the remaining 37 patients were retrospectively reviewed. Baseline characteristics, including age, sex, smoking history, comorbidities, affected limbs, date of diagnosis, last follow-up date, and initial symptoms, were investigated.

The Rutherford classification was used to investigate patients' initial symptoms and course after treatment at the time of diagnosis and 6 months after treatment [13]. Additionally, the patency of the involved artery was investigated using angiography and computed tomography (CT). Involvement of the anterior tibial artery, posterior tibial artery, and peroneal artery was recorded using CT or angiography at the time of diagnosis. If patency was not confirmed owing to invasion, 1 point was recorded. The sum was calculated, and the score ranged from 0 to 3 points for each patient.

The type and dose of drugs used for treatment, whether or not smoking cessation was successful, type of intervention or surgery, the number of interventional procedures or operations performed, and whether symptoms improved after treatment were checked. During the follow-up period, amputation and mortality rates were investigated.

Treatment and clinical outcomes

Smoking cessation treatment and medication were concurrently administered to all patients. For Rutherford categories 1 to 3, lifestyle changes, including smoking cessation treatment and exercise therapy, were attempted first. In some cases of Rutherford categories 3 to 5, in which the target vessels could be specified on CT or conventional angiography, revascularization was attempted with surgery or endovascular procedures. Additionally, in some cases of Rutherford categories 3 to 5, sympathectomy or stem cell therapy was performed as an adjunctive treatment with or without revascularization.

Surgeons rechecked the Rutherford category after treatment. If it decreased, the condition was considered as improved; if there was no change, it was considered as maintained; and if it increased, it was considered as worsening. When amputation was performed, the level of amputation and the number of trials were investigated. Major amputation was defined as that performed over the ankle. Minor amputation included removing smaller areas, such as a toe or part of the foot.

Statistics

Patient characteristics are expressed as numbers and percentages. Categorical data are described using the mean and standard deviation following a normal distribution. It was hypothesized that severe initial status of limbs and vessels, the modality of treatment, and smoking cessation would be significantly positively correlated with worse progression of TAO. Multivariate logistic regression analysis was performed to investigate factors affecting the course of symptoms that persisted or worsened despite treatment. The included factors were the initial status, such as the

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Rutherford classification and involved artery score, the treatment modality performed (surgery, endovascular procedure, or stem cell therapy), and the success of smoking cessation. A p-value <0.05 was considered statistically significant. The results were calculated using MedCalc Statistical Software ver. 20.0 (MedCalc Software, Ostend, Belgium).

Results

Patients

In total, 45 extremities in 37 patients were included. The median follow-up duration was 58.8 months (interquartile range, 38–106.6 months). Table 1 shows the patient characteristics. Two patients (5.4%) had arm involvement, and both arms and legs were involved in 1 (2.7%) of them. In addition, 3 patients were treated for either deep vein (n=2) or superficial vein (n=1) thrombophlebitis.

Table 2 shows the Rutherford categories at the time of diagnosis and after treatment. Among the 21 ulcer cases (category 5), 18 occurred on the toes and 3 on the fingers. The median duration of ulcers before diagnosis was 60 days (range, 3–240 days). Table 3 shows the anatomical location of the involved artery.

Most patients were diagnosed as having TAO on a preoperative examination; however, 6 were diagnosed after surgery. Among those patients, 4 had acute limb ischemia with Rutherford category 4, and emergent surgery or endovascular therapy was performed first. Then, the patients were diagnosed using postoperative angiography after revascularization due to repeated thrombosis. The other 2 patients had Rutherford category 3 and were thought to have ASO of a femoral lesion that occurred at a relatively young age. Initial CT images showed insufficient imaging of the artery below the knee due to slow arterial flow. Early thrombosis repeatedly occurred after femoropopliteal bypass, and they were later diagnosed with TAO based on angiography.

Table 1. Patient demographics (N=37)

Characteristic	Value
Sex (male)	37 (100.0)
Age (yr)	41.8±11.4
Leg involvement	36 (97.3)
Arm involvement	2 (5.4)
Venous involvement	3 (8.1)
Comorbidities	
Hypertension	5 (13.5)
Diabetes	1 (2.7)
Coronary artery disease	1 (2.7)
Cerebrovascular accident	1 (2.7)
Smoking history	
At diagnosis	
Current	37 (100.0)
Pack-years	23.9±13.3
During treatment	
Cessation smoking	18 (48.6)
Continuous smoking	19 (51.4)

Values are presented as number (%) or mean±standard deviation.

Treatment and clinical outcomes

All patients were current smokers at the time of diagnosis, with histories varying from 1.5–60 pack-years, with an average of 23.9±13.3 pack-years. Additionally, 19 patients (51.4%) successfully quit smoking during treatment, and 18 patients (48.6%) continued to smoke.

Comparing the Rutherford categories before and after treatment, among the 45 limbs, 23 (51.1%) showed im-

Table 2. Rutherford classification at the time of diagnosis (initial) and 6 months after treatment (N=45 limbs)

Rutherford classification	Initial	Post-treatment
Category 0	1 (2.2)	10 (22.2)
Category 1	7 (15.6)	18 (40.0)
Category 2	2 (4.4)	3 (6.7)
Category 3	7 (15.6)	3 (6.7)
Category 4	7 (15.6)	0
Category 5	21 (46.6)	5 (11.1)
Category 6	0	6 (13.3)

Values are presented as number (%). Category 0, asymptomatic; category 1, mild claudication; category 2, moderate claudication; category 3, severe claudication; category 4, ischemic rest pain; category 5, minor tissue loss non-healing ulcer, focal gangrene with diffuse pedal ischemia; category 6, major tissue loss extending above the transmetatarsal level, functional foot no longer salvageable.

Table 3. Locations of the involved arteries (N=45)

Involved artery	Location	No. (%)
Proximal artery	Iliac artery	2 (4.44)
	Superficial femoral artery	10 (22.2)
	Deep femoral artery	0
	Popliteal artery	17 (37.8)
	Brachial artery	0
Distal artery	Anterior tibial artery	27 (60.0)
	Posterior tibial artery	25 (55.6)
	Peroneal artery	31 (68.9)
	Dorsal artery	45 (100.0)
	Ulnar artery	2 (4.44)
	Radial artery	0

provement, 11 (24.4%) were maintained, and 11 (24.4%) worsened. Additionally, 9 limbs (20%) underwent amputation: 3 below-knee amputations (6.7%), 1 metatarsophalangeal joint disarticulation (2.2%), and 5 toe amputations (11.1%). In 2 cases (4.7%), toe-level amputation was performed first, followed by below-knee amputation. The mortality rate was 0% during the follow-up period. Fig. 1 shows a flow chart of the treatment modalities performed and their outcomes.

Medical treatment

The treatment modalities, including the prescribed medications, are shown in Table 4. Four patients (8.9%) underwent anticoagulation therapy together with antiplatelet therapy.

Revascularization

Revascularization was attempted in 14 of 45 limbs (31.1%). There were 1, 2, 6, and 3 cases of Rutherford categories 2, 3, 4, and 5, respectively. In addition, 2 patients had Rutherford category 1 at the initial diagnosis but deteriorated to category 4 during follow-up.

Of the revascularization cases, 7 patients underwent surgical bypass or thrombectomy, and 7 underwent endovascular treatment. Additionally, 7 maintained patency, but 3 required additional revascularization. The additional revascularization procedures included repeated thrombectomy (n=1) and thrombolysis (n=2). Amputation was performed in 4 of 7 cases where vessel patency was not preserved.

Surgical bypass or thrombectomy was performed in 7 cases (7/14, 50%), of which 3 maintained patency (3/7, 42.8%) and 2 underwent amputations (2/7, 28.6%). The other 2 cases did not maintain patency, but the symptoms did not worsen.

Furthermore, 7 patients (7/14, 50%) underwent endovascular treatment, 4 maintained patency (4/7, 57.1%), and 2 underwent amputations (2/7, 28.6%). The other case did not maintain patency, and the symptoms worsened, resulting in resting pain and gait disturbance.

According to the anatomical location where revascularization was attempted, the femoral arteries were the first target. Bypass surgery was performed in 6 cases and endovascular treatment in 5 cases. Two patients with iliac artery involvement were admitted to the emergency department with acute limb ischemia. One patient underwent stent insertion, and the other underwent surgical thrombectomy. However, both cases did not maintain patency; therefore, a femoro-femoral bypass was also performed. Subsequently, post-procedural conventional angiography confirmed the

Table 4. Treatment modalities (N=45)

Treatment	No. (%)
Medication	45 (100.0)
Antiplatelet	
Aspirin	33 (73.3)
Clopidogrel	6 (13.3)
Phosphodiesterase: cilostazol	18 (40.0)
Prostaglandin analog: beraprost	22 (48.9)
Anticoagulant: warfarin	4 (8.9)
Revascularization	14 (31.1)
Surgery	7 (15.6)
Intervention	7 (15.6)
Stem cell therapy	11 (24.4)
Lumbar sympathectomy	8 (17.7)
Hyperbaric oxygen therapy	3 (6.6)

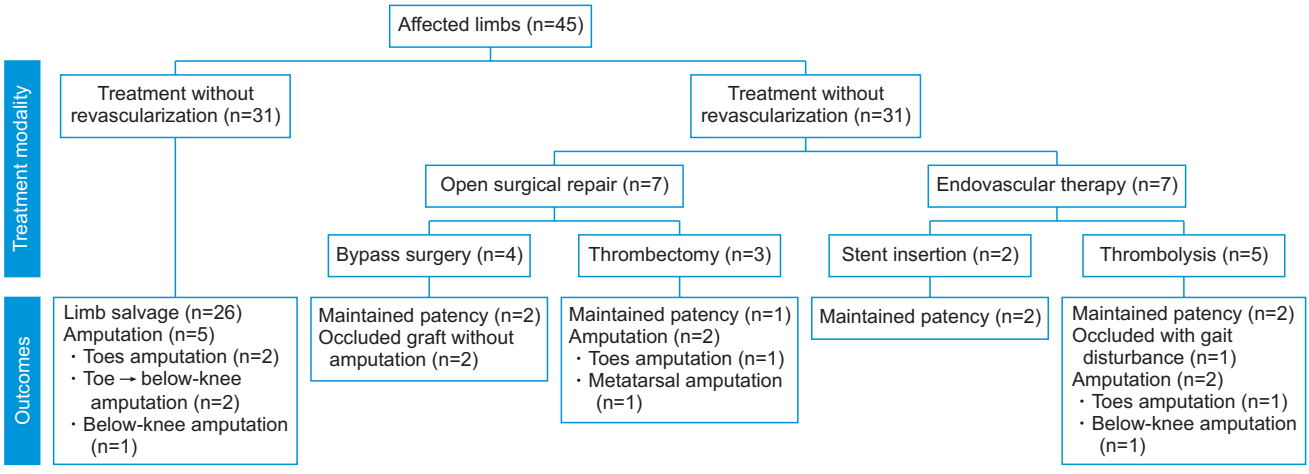

Fig. 1. Flow chart of treatment modalities and outcomes.

below-knee lesions, and the patients changed the diagnosis from ASO to TAO. One patient underwent thrombectomy with isolated popliteal artery occlusion.

There were no statistically significant differences between the surgical and non-surgical therapy groups in the incidence of amputation (27.3% versus 17.6%, respectively; p=0.67) and major amputation (9.1% versus 5.9%, respectively; p>0.99). Similarly, the endovascular and non-endovascular therapy groups showed no statistically significant differences in the incidence of amputation (25.0% versus 18.9%, respectively; p=0.65) and major amputation (25.0% versus 2.7%, respectively; p=0.77). Additionally, the revascularization (surgery and endovascular therapy) and non-revascularization groups did not present statistically significant differences in the incidence of amputation (28.6% versus 16.1%, respectively; p=0.43) or major amputation (14.3% versus 3.2%, respectively; p=0.22).

Other therapies

Stem cell therapy was performed once on average in 11 cases (25.6%). All patients were referred to a cardiologist; amputation was performed in 5, with major amputations in 2 limbs. The overall amputation rate was significantly higher in the group that received stem cell therapy than in the group that did not (45.5% versus 11.8%, p=0.028). However, there was no significant difference in major amputations (18.2% versus 2.9%, p=0.143).

The Department of Anesthesiology and Pain Medicine performed sympathectomy as an adjuvant treatment to alleviate pain in 8 cases (18.6%). In three cases, hyperbaric oxygen therapy was also used as an adjuvant for ulcer treatment (7%).

Table 5. Comparison of initial factors and treatment modalities according to prognosis

Variable	Improvement (n=22)	Persistence or deterioration (n=23)	p-value
Initial Rutherford classification	3.45	4.04	0.28
Involved artery score	2.77	4.04	0.01
Surgical treatment	4 (18.1)	3 (13.0)	0.64
Endovascular treatment	2 (9.0)	5 (21.7)	0.48
Stem cell therapy	6 (27.2)	5 (21.7)	0.67
Continuous smoking during treatment	11 (50.0)	14 (60.9)	0.47

Values are presented as number or number (%).

Factors affecting prognosis

A comparison of initial factors and treatment modalities according to prognosis is shown in Table 5.

Multivariate logistic regression analysis was used to analyze the factors that affected the disease course (Table 6). A higher initial Rutherford classification category at the time of diagnosis was significantly associated with symptoms persisting or worsening despite treatment (odds ratio [OR], 1.59; 95% confidence interval [CI], 1.04–2.42; p=0.03). Additionally, a higher score for the involved below-knee artery at the time of diagnosis was associated with a worsening disease course despite treatment (OR, 2.26; 95% CI, 1.10–4.67; p=0.03). However, a lower initial Rutherford classification category at the time of diagnosis was associated with symptom improvement (OR, 0.64; 95% CI, 0.43–0.96; p=0.03).

Discussion

Revascularization in TAO was performed only in patients with Rutherford category 4 or higher, for which the target blood vessels were specified. However, the symptoms improved after treatment in 51.1% of patients, while 20% underwent amputations. Despite treatment, the factors that affected the course of the disease (i.e., presenting an association with worsening or persisting symptoms) were an initially higher Rutherford classification category and a

Table 6. Factors affecting resistance to treatment (persisting or deteriorative progression) by logistic regression analysis (p=0.03)

Covariate	Improvement		Persistence or deterioration	
	p-value	OR (95% CI of HR)	p-value	OR (95% CI of HR)
Surgical treatment	0.43	1.99 (0.36–11.05)	0.27	0.34 (0.05–2.31)
Endovascular treatment	0.25	0.3 (0.04–2.36)	0.16	4.77 (0.54–42.39)
Stem cell therapy	0.32	2.3 (0.45–11.82)	0.17	0.3 (0.05–1.67)
Continuous smoking during treatment	0.59	0.69 (0.18–2.61)	0.5	0.61 (0.15–2.53)
Initial Rutherford classification	0.03	0.64 (0.43–0.96)	0.03	1.59 (1.04–2.42)
Involved artery score	0.45	0.86 (0.57–1.28)	0.03	2.26 (1.10–4.67)

OR, odds ratio; CI, confidence interval; HR, hazard ratio.

higher involved arterial score at the time of diagnosis.

The prevalence of TAO has recently fallen because of a decrease in the smoking population and the use of stricter criteria [14,15]. According to data published by the Mayo Clinic, the incidence decreased from 104 per 100,000 in 1947 to 12.6 per 100,000 people in 1986 [5]. In Japan, the TAO-to-ASO incidence ratio declined from 1:3 in the 1990s to 1:10 in the 2000s [5]. In Korea, the incidence of TAO decreased from 6.07 per 100,000 in 2006 to 3.38 per 100,000 people in 2017 [16].

In TAO, ischemia of the distal extremity causes forefoot or lower calf claudication. Foot claudication is a characteristic symptom [17]. In this study, 46.6% of the patients visited the hospital for non-healing wounds on the toes and fingertips; data on foot claudication before visiting the hospital were not accurate, precluding further investigation. Most wounds were accompanied by bacterial infection, which led to peripheral necrosis and progression to gangrene. The pain was very severe, and the patients reported having sleep disorders, anxiety, depression, and amputation-related fears.

Several studies have reported a correlation between smoking cessation and prognosis [18-20]. The overall amputation rate is 0%–25%. In reports with a smoking cessation rate >50%, the amputation rate was 0%–12.5%, whereas, in studies with a smoking cessation rate <50%, the amputation rate was 8.3%–33% [21]. In this study, the smoking cessation rate was 51.4%, and the overall amputation rate was 20%. Amputation occurred in 4 patients who successfully quit smoking. However, these were minor amputations limited to the toes.

In this study, the effect of smoking cessation on the symptom progression that persisted or worsened despite treatment was not statistically significant. The presumed reason is that the number of enrolled patients was insufficient due to the low disease prevalence. Additionally, smoking cessation was not confirmed based on thorough examinations, but was determined based on the patients' reports.

Arterial revascularization is not commonly considered a treatment in TAO because of the diffuse thrombotic segment involvement. However, treating TAO accompanied by critical limb ischemia with only smoking cessation is sometimes challenging; thus, revascularization may be needed [21,22].

In this study, 12 of 45 cases (26.7%) involved the proximal artery beyond the femoral artery (iliac artery: 4.4%; superficial femoral artery: 22.2%). Dsouza et al. [22] showed that the proximal artery over the popliteal artery was invaded in 56.7% of cases, the iliac artery in 14.5%, the superficial femoral artery in 46.9%, and the popliteal artery in 37.3%. Therefore, when a patient with TAO visits the emergency room owing to acute ischemia, misdiagnosis as ASO can occur owing to occlusion of the above-knee arteries and nonvisible below-knee arteries in CT imaging, resulting in an incorrect intervention by the surgeon.

In this study, surgical or endovascular treatment was performed in 14 of 45 patients (31.1%), and re-occlusion occurred in 6 of those 14 patients (43%). Revascularization can increase distal blood flow to promote wound healing, thereby avoiding amputation. However, blood flow can accelerate endothelium damage and worsen the disease course [7,11]. This may be why revascularization did not have a statistically significant effect on overall progression.

In some cases, conventional therapy (cessation of smoking and drugs) did not control the patients' symptoms, and the surgeon could not determine target blood vessels suitable for revascularization. Therefore, stem cell therapy was performed in 11 cases (25.6%), amputations in 5 cases, and major amputations in 2 limbs. The amputation rate was significantly higher in patients who received stem cell therapy than in those who did not. However, this should be attributed to disease progression rather than the treatment modality. Therefore, the choice of the treatment method (surgery, endovascular revascularization, or stem cell therapy) did not significantly affect the overall course. Nevertheless, revascularization is helpful if it focuses on controlling short-term symptoms, such as pain or wound healing.

Le Joncour et al. [23] collected data from 224 people over 46 years and reported that milder disease was associated with a lower amputation rate and better prognosis. The present study also showed similar results—namely, a higher Rutherford classification and a larger number of involved below-knee arteries were associated with persistent or worsening symptoms despite treatment.

Thus, young individuals who smoke should be better informed about TAO (Buerger's disease). They can visit the hospital early and consult a doctor when the symptoms are mild. Unfortunately, young patients with TAO often overlook the early signs and are diagnosed at an advanced stage. However, an earlier diagnosis, more appropriate medication, smoking cessation, and aggressive revascularization may delay disease progression and help salvage the limb before the disease progresses to more vessels.

This study had some limitations. It was a retrospective, single-center study with a small cohort and was not a randomized controlled study. Additionally, although the Shio-

noya criteria were followed, there were cases where the laboratory tests for a differential diagnosis had not been performed, and thus, autoimmune disease could not be completely ruled out. As approximately half of the patients were excluded due to insufficient evidence to satisfy the inclusion criteria or because initial imaging data were lost, the results may have been affected by selection bias. Moreover, data from 3 different surgeons were synthesized, and the date of the first visit spanned between 2004 and 2018. Therefore, the treatment method may have needed to be more consistent. Additionally, data on smoking cessation may be inaccurate, as they were based solely on patients' reports.

In conclusion, patients with TAO with a higher Rutherford category at the time of diagnosis and a higher involved artery score had a worse prognosis. Initial involvement of more vasculature was associated with a higher likelihood of the disease persisting or worsening. Furthermore, the treatment method did not significantly affect the overall course, but it helped control short-term symptoms.

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Conflict of interest

No potential conflict of interest relevant to this article was reported.

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