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Case Report

Experience of using coronary perfusion balloon catheter for acute middle cerebral artery occlusion

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ABSTRACT

Background: We present the case of an individual with acute occlusion of the middle cerebral artery caused by atherosclerosis. The patient underwent angioplasty using a coronary perfusion balloon, which resulted in a favorable clinical outcome.

Case Description: A 66-year-old male patient presented with an acute onset of right hemiplegia and dysarthria. Magnetic resonance imaging revealed an occlusion of the left middle cerebral artery, and alteplase was administered, followed by a mechanical thrombectomy and intracranial balloon catheter angioplasty. Due to restenosis, a coronary perfusion balloon catheter was used for a 15-minute angioplasty procedure while maintaining the perfusion. This treatment approach led to the recanalization of the artery and favorable clinical outcomes.

Conclusion: The coronary perfusion balloon may represent a viable therapeutic alternative for the management of refractory intracranial atherosclerotic large vessel occlusion.

Keywords: Angioplasty, Intracranial atherosclerotic disease, Perfusion balloon

INTRODUCTION

A meta-analysis of several randomized controlled trials[4] has shown the efficacy of percutaneous thrombus retrieval therapy for stroke associated with large vessel occlusion (LVO). The LVOs are frequently attributed to cardiogenic or carotid-source embolisms, and conventional thrombectomy modalities involving stent retrieval and aspiration catheters have demonstrated efficacy in the removal of these embolic particles.

However, restenosis and reocclusion are highly prevalent due to residual plaque in the vessel wall of patients with intracranial atherosclerotic disease (ICAD). An additional angioplasty is considered for the atherosclerotic lesions.

Perfusion balloons, which allow a prolonged balloon dilation while maintaining peripheral perfusion, can be used during angioplasty for coronary artery lesions.

In this case, the patient had an acute middle cerebral artery occlusion and underwent thrombus retrieval and angioplasty using a cerebrovascular balloon catheter. However, a restenosis

was observed. Therefore, a prolonged angioplasty was performed using a coronary perfusion balloon to maintain recanalization, ultimately leading to favorable outcomes.

CASE PRESENTATION

Case

66-years-old male.

Chief complaint

A sudden onset of the right hemiplegia and dysarthria.

Medical history

Nothing significant.

Life history

Smoked 30 cigarettes/day for 45 years.

History

At 7:30 a.m. while driving, the patient suddenly experienced right hemiplegia and dysarthria and was rushed to our hospital.

Neurological findings

Right facial paralysis, dysarthria, right upper extremity paralysis, right upper and lower extremity paresthesia, and National Institutes of Health Stroke Scale (NIHSS) score 6/42.

Neuroradiological findings

Magnetic resonance imaging (MRI) diffusion-weighted imaging (DWI) showed slightly high signal areas in the left putamen, corona radiata, and part of the middle cerebral artery region. Magnetic resonance angiography (MRA) showed an occlusion of the left middle cerebral artery [Figures 1a and b]. The T2-weighted images showed no obvious thrombi in the occluded area.

Clinical course

The patient was admitted to the hospital at 8:25 a.m. Based on the MRI findings, we determined that there was a mismatch between the perfusion area of the left middle cerebral artery and the high signal DWI lesion. An intravenous alteplase therapy was deemed appropriate without any cautionary or contraindicated items as per the guidelines. Alteplase was administered at 9:27 a.m. following the management of hypotension with nicardipine. The primary strategy was to pursue an endovascular recanalization.

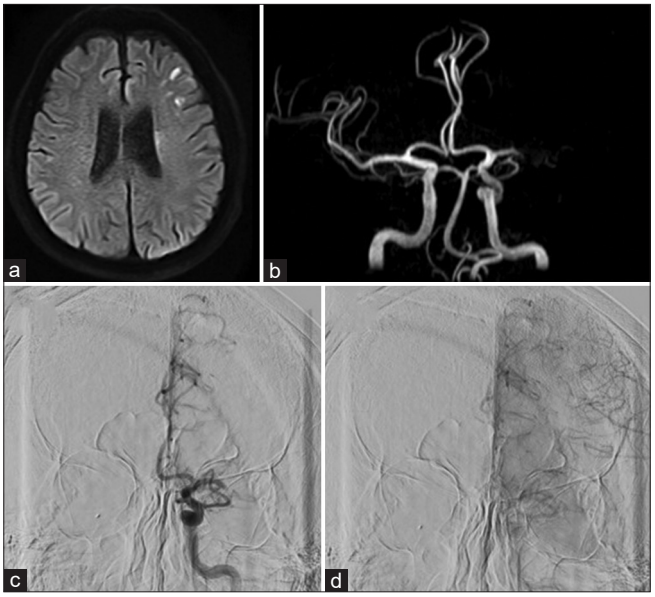

Figure 1: (a) Magnetic resonance imaging diffusion weighted imaging at initial onset. Diffuse high-intensity signals are observed in the left corona radiata and middle cerebral artery. (b) Magnetic resonance angiography, left middle cerebral artery occlusion. (c and d) Digital subtraction angiography, left internal carotid angiography, (c) is the early phase, and (d) is the late phase. Occlusion of the left middle cerebral artery and collateral blood flow from the left anterior cerebral artery through the leptomeningeal anastomosis.

Endovascular treatment

A 9 Fr sheath was placed in the right femoral artery, and a 9 Fr OPTIMO (Tokai Medical Products, Aichi, Japan) was guided into the left internal carotid artery. Internal carotid arteriography revealed that the left middle cerebral artery was distally occluded [Figure 1c]. In the delayed phase, an anastomosis of the cerebral pia mater provided the collateral blood flow from the anterior to the middle cerebral arteries [Figure 1d]. The rebar (Medtronic, Minneapolis, MN, USA) was guided distal to the occlusion with a CHIKAI 14 200 cm (Asahi Intec, Aichi, Japan) to secure the distal vessel, and a Trevo XP ProVue Retriever 4.0 × 30 mm (Stryker, Kalamazoo, MI, USA) was deployed. The post deployment imaging showed an immediate flow restoration but poor stent dilation in the occluded area, suggestive of arterial stenosis [Figure 2a].

The proximal and distal diameters of the stenosis were 2.6 mm and 2.1 mm, respectively [Figure 2b]. After retrieving the Trevo, a 1-min amount of thrombus was retrieved. Although reperfusion was achieved, a significant degree of stenosis persisted [Figure 2c]. A diagnosis of ICAD was established, and an angioplasty using a balloon catheter was proposed.

Crushed aspirin and clopidogrel (300 mg each) were administered orally. A 6 Fr Cerulean catheter DD6 113 cm (Medikit, Tokyo, Japan) was guided to the pyramidal segment

of the internal carotid artery as a distal access catheter. Subsequently, a Gateway 2.0 × 12 mm monorail (Stryker, Kalamazoo, Michigan, USA) was placed at the stenosis region using a CHIKAI. A gradual dilatation and retraction were performed under nominal pressure [Figure 3a]. Subsequent imaging revealed a temporary recanalization [Figure 3b]; however, restenosis was observed after 7 min [Figure 3c].

The strategy was to use a coronary perfusion balloon for prolonged angioplasty while maintaining the peripheral perfusion. Ryusei 2.5 × 20 mm monorail (Kaneka Medix, Osaka, Japan) was navigated toward the stenotic lesion. After dilating to 2 atm, the wire was drawn anterior to the proximal perfusion hole, and the perfusion lumen was subsequently unsealed [Figure 4a].

The angiography performed in this state showed that peripheral perfusion was achieved using balloon dilation [Figures 4b and c]. The patient was maintained in this state for 15 min, during which intermittent angiography was performed to monitor the patency of the perfusion lumen. Ozagrel sodium 80 mg was administered intravenously. The Ryusei was then deflated and adequate vascular dilation was observed [Figure 4d]. After an additional waiting period of 20 min, we confirmed the absence of restenosis and concluded the procedure.

Heparin was administered while monitoring activated clotting time (ACT) during the procedure, with a minimum ACT value of 200. The total dose was 6,000 units.

Postoperative course

The patient's symptoms resolved to an NIHSS score of 0 on the day after the procedure. Postoperative echocardiography and electrocardiography revealed no evidence of cardiogenic cerebral embolism. Based on the intraoperative findings, the patient was diagnosed with ICAD. Postoperatively, aspirin 100 mg and clopidogrel 75 mg prescriptions were continued, and cilostazol 200 mg and atorvastatin 10 mg were added. Postoperative MRI showed a clearly defined high signal DWI without significant enlargement of the infarcted area [Figure 5a] and although a mild stenosis remained, the MRA also showed a satisfactory peripheral perfusion [Figure 5b].

The patient was discharged without a neurological deficit on the 7th day.

Clopidogrel medication was discontinued at discharge. Three months later, the MRA indicated an improvement in the stenosis [Figure 5c], and the patient was prescribed antithrombotic therapy with cilostazol as a single agent. No

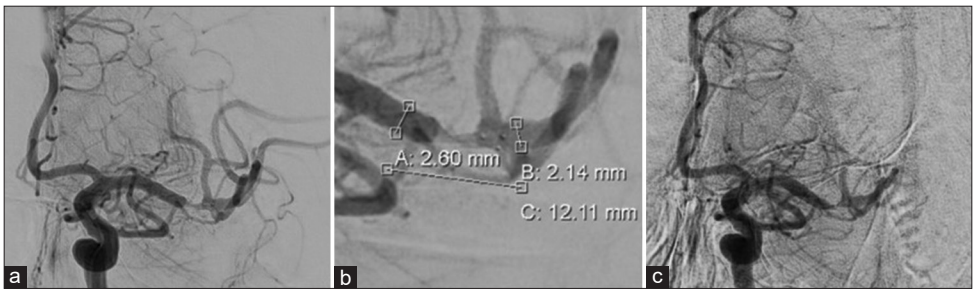

Figure 2: (a and b) Left internal carotid angiography after Trevo deployment. Immediate flow restoration is confirmed. The lesion is at the distal middle cerebral artery. Dilation with Trevo is inadequate distal to the stenosis. (c) Left internal carotid angiography after Trevo retrieval. Recanalization has been achieved; however, severe stenosis remains, and peripheral perfusion is delayed.

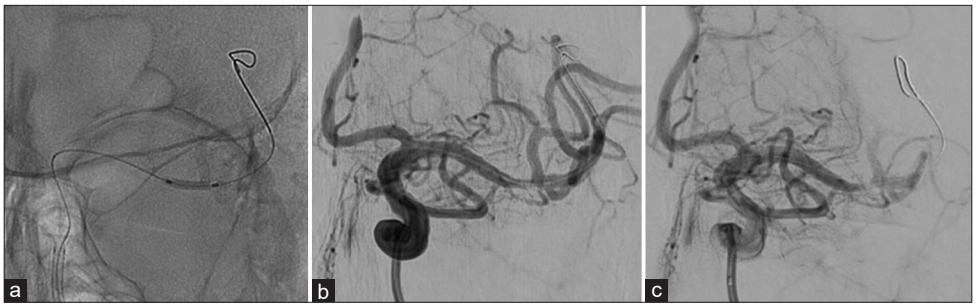

Figure 3: (a) Gateway 2.0 × 12 mm monorail (6 atm) is inflated at the center of the lesion. (b) Left internal carotid angiography after percutaneous transluminal angioplasty at the Gateway. Stenosis has improved. (c) Left internal carotid angiography 7 min after B. Restenosis has appeared.

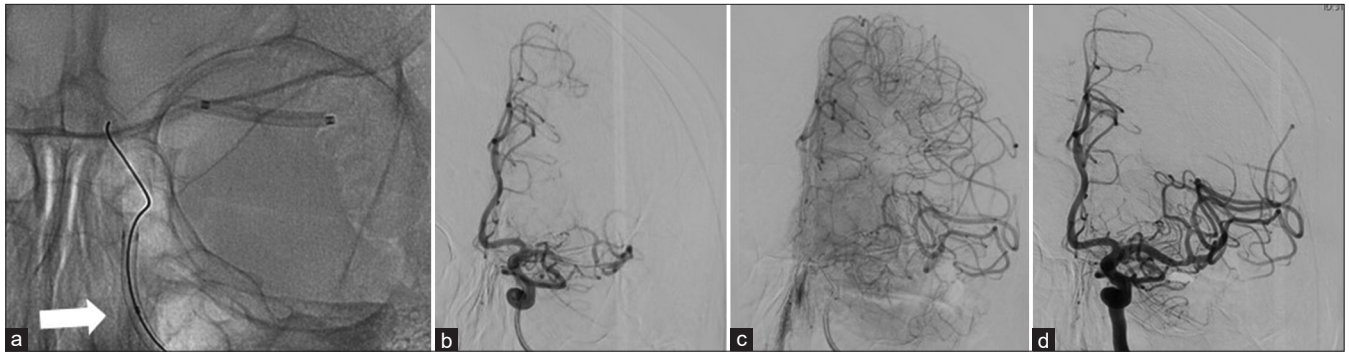

Figure 4: (a) Ryusei 2.5 × 20 mm monorail (2 atm) inflated at the center of the lesion. The white arrow indicates the perfusion marker. (b and c): Left internal carotid angiography during Ryusei inflation. (b) is the early phase, (d) is the late phase. Perfusion lumen enables the blood flow to traverse toward the distal of the balloon. (d) After angioplasty at Ryusei, the stenosis has improved.

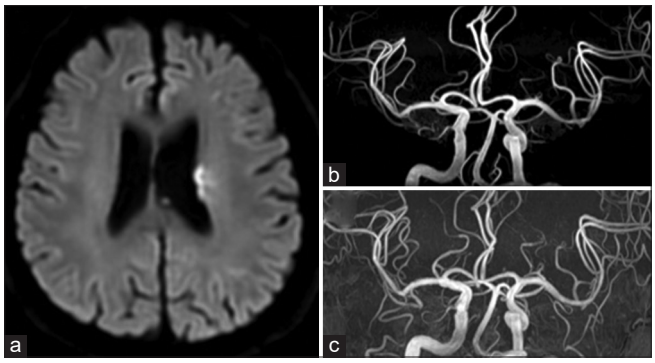

Figure 5: (a) Magnetic resonance imaging diffusion weighted imaging on day 7. High-intensity signals are indicated in the left corona radiata. There is no enlargement compared to preoperative. (b) Magnetic resonance angiography on day 7. Mild stenosis is observed in the left middle cerebral artery; however, the recanalization findings are maintained. (c) Magnetic resonance angiography 3 months postoperatively. Improvement of the stenotic lesion is observed.

specific events were observed for more than 1 year after the procedure.

An ethical measure for off-label use

An application for an unapproved new medical device was submitted to the hospital's committee for the evaluation of highly difficult new medical technology, and approval was obtained. Furthermore, during patient consultations regarding surgical procedures, we explicitly conveyed that we may employ nonconforming medical devices if adequate substitutions proved arduous and secured informed consent accordingly.

DISCUSSION

This case involved an intracranial LVO with a severe and sudden onset. The MRI DWI showed that the infarction was confined to a part of the perfusion area at the middle cerebral artery, suggesting a clinical diffusion mismatch or perfusion-diffusion mismatch, which required acute reperfusion therapy. There was no evidence of atrial fibrillation, other arrhythmias, or thrombosis on MRI, suggesting a cardiogenic cerebral embolism and the etiology of the occlusion was unknown at this point.

A preoperative diagnosis of ICAD was speculated based on the calcification on computed tomography and thrombotic findings on MRI magnetic susceptibility-enhanced images,[8,9] although without any definitive diagnostic criteria. The diagnosis of ICAD was confirmed when there was a ≥50% residual stenosis after thrombectomy, intraoperative restenosis, reocclusion, or severe stenosis with hypoperfusion (pseudo-occlusion), provided that the differential diagnoses, such as vasospasm or dissection, had been ruled out.[10]

The digital subtraction angiography findings, in this case, revealed the development of a collateral blood flow through the leptomeningeal anastomosis, indicating the potential presence of ICAD. Initially, the lesion was crossed with a microcatheter, and a stent retriever was deployed. Following the stent retriever deployment, angiography revealed an immediate flow restoration with no evidence of thrombus in the stent or poor stent dilation, thereby suggesting a diagnosis of ICAD.

No effective endovascular therapy has been reported for LVO caused by ICAD. Tsang *et al*. reviewed 11 articles and 1,967 cases of thrombectomy for intracranial LVO, regardless of the pathophysiology.[10] The review, which included a comparative analysis between atherosclerotic occlusions and cardiogenic emboli, revealed that atherosclerotic occlusions required additional angioplasty at a higher frequency (46.8% vs. 3.9%). However, no significant difference in the final recanalization rate, rate of symptomatic bleeding, or clinical outcome was observed.

Furthermore, most thrombectomy approaches in the evaluated studies involved the use of a stent retriever as the primary option. In the present case, as the etiology

was difficult to predict, the deployment of Trevo with high strut visibility allowed visualization of the lesion and a temporary restoration of the blood flow. This facilitated the establishment of the etiology, and it was highly probable that an additional treatment would be required after thrombectomy, as previously reported.[5,10]

A minute volume of thrombus volume was retrieved using the stent retriever, and the subsequent angiography revealed a residual severe stenosis, as predicted. Therefore, the administration of antiplatelet agents and angioplasty were deemed necessary.

In Japan, the angioplasty devices indicated for acute intracranial lesions include Gateway and Unryu xp (Kaneka Medix, Osaka, Japan). These two devices possess slender and pliant tips and are attainable with balloon diameters as minute as 1.5 mm. In this case, we selected a 2 mm diameter Gateway, which was slightly slenderer than the diameter of the dilated site. However, this treatment was insufficient, and an elastic recoil manifested after the angioplasty procedure.

Two options were considered at this point. One was stenting, and the other was redilation using different balloons. The use of a Wingspan stent (Stryker, Kalamazoo, MI, USA), an aneurysmal stent, and a coronary stent was considered, although all stents would be used off-label. Perioperative complications in the stenting and aggressive medical management for preventing recurrent stroke (SAMMPRIS) trial[1] using the Wingspan stent were observed to be as elevated as 14.7%. This is because a considerable number of patients underwent treatment during the acute to subacute phases of the disease, and the inherent instability of their condition and insufficient efficacy of antithrombotic therapy at the time of treatment were deemed to be the underlying reasons for this situation. We were, therefore, reluctant to perform stent placement during the acute phase.

In a study by Mori *et al*.[6] regarding the balloon dilation for symptomatic lesions with >70% stenosis, the treatment had greater efficacy in cases of short lesion lengths with afferent and unbent lesions, and the lesion in the present case fulfilled these criteria. Regarding the dilation technique, Ohman *et al*.[7] reported a study on angioplasty using a perfusion balloon in the coronary artery region and compared two to four standard (1 min) dilatations with one or two prolonged (15 min) dilatations after a perfusion balloon. The prolonged dilatation group demonstrated a higher success rate (89% vs. 95%, $P = 0.016$) and fewer dissection complications (9% vs. 3%, $P = 0.003$). Connors and Wojak[2] reported similar results with balloon dilation of the cerebral vessels. A comparative analysis was performed to assess the balloon dilation techniques for symptomatic intracranial artery stenosis across three distinct periods, each utilizing a different procedural method. The group of patients treated with rapid dilation lasting 15–30 s during the early- and mid-term periods exhibited a dissection rate exceeding 50%. Conversely, the group treated with slow dilation lasting 2–5 min during the late period had a dissection rate of 14%.

Based on these reports, we attempted a prolonged dilation procedure using different balloon catheters. Ryusei is a perfusion balloon catheter used for coronary angioplasty procedures; its structure is shown in [Figure 6a]. Despite its monorail design, the Ryusei catheter has a wire lumen (0.014 inches) with perfusion apertures preceding and following the balloon. This facilitates the direction of blood flow from the proximal balloon through the wire lumen (perfusion lumen) to the distal end of the catheter by simply pulling the wire adjacent to the perfusion marker during balloon dilation. In essence, the wire lumen serves as a perfusion channel, enabling blood flow through the proximal end of the balloon to its distal end even during balloon dilation, thus facilitating angioplasty to be performed over an extended period while preserving the peripheral perfusion. The perfusion volume flow from the proximal balloon through the perfusion lumen is 32 mL/min.

As the minimum balloon diameter of this device was 2.5 mm, the dilatation conducted in this case was restricted to 2 atm, which resulted in an approximate dilation diameter of 2.35 mm. The subsequent imaging demonstrated satisfactory peripheral perfusion through the perfusion lumen [Figures 4b and c], thus signifying the feasibility of sustaining dilation over a prolonged duration. The duration for the onset of the antiplatelet efficacy of aspirin was 30 min, and that of clopidogrel at the loading dose ranged from 3 h to 6 h.[3] In this case, the duration from antiplatelet drug administration to the conclusion of the first balloon dilation procedure at the Gateway was approximately 20 min. At that time, it was conjectured that ample antiplatelet activity had not been realized. On completion of the prolonged dilation procedure using the perfusion balloon, approximately 60 min had elapsed since administration, and we believed that the partial antiplatelet effect obtained might have been conducive to maintain patency. The perfusion balloons might have been effective in maintaining the peripheral perfusion and "buying time" for antiplatelet agents to take effect.

We demonstrated a successful recanalization using a perfusion balloon. However, this device is intended for use in the coronary arteries, and its distal end exhibits greater thickness and reduced flexibility than cerebrovascular balloons [Figures 6b and c]. In our case, resistance was encountered while traversing the curvature of the blood vessel. The potential for vascular injury and the requirement for sufficient backup of the intermediate catheter to access the lesion were the limitations of this device. The efficacy of this catheter has been reported in the coronary artery region, but there are no reports of its efficacy in the cerebrovascular region,[7] and it is unclear whether the perfusion volume flow

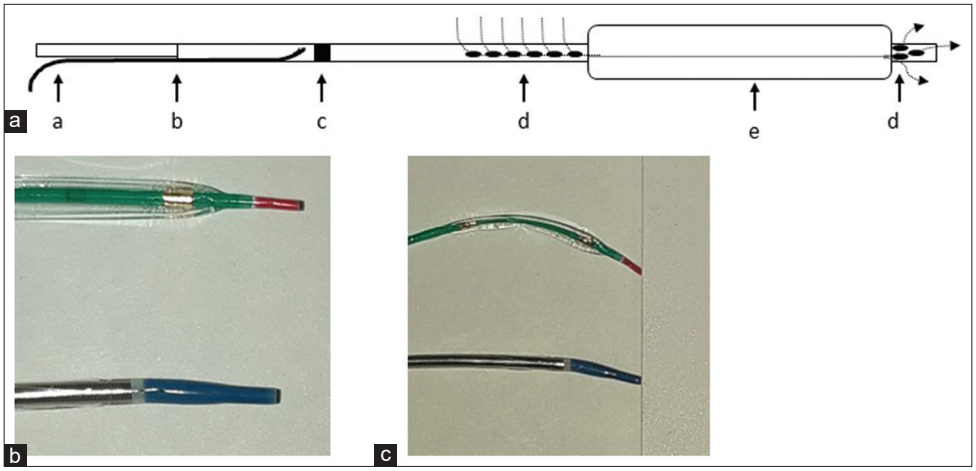

Figure 6: (a) Schematic of Ryusei balloon inflation. a: micro guidewire; b: guidewire entrance; c: perfusion marker; d: perfusion hole; e: balloon; dotted arrow: blood flow dynamics during balloon inflation. (b) Tip shape of both catheters: top, Gateway 2.0 × 12 mm; Bottom, Ryusei 2.5 × 20 mm. (c) Tip flexibility of both catheters.

from the proximal balloon through the perfusion lumen is sufficient to perfuse the middle cerebral artery, which is also a limitation.

It should be noted that the perfusion lumen is <1 mm in diameter, and there was a risk of thrombus formation or occlusion inside the lumen. Adequate antithrombotic therapy, confirmatory angiography, and heparin flushing every 5 min during balloon occlusion were used to prevent this.

In this case, the patient underwent a conventional mechanical thrombectomy for LVO. During the procedure, ICAD was identified, prompting treatment with antiplatelet agents and an angioplasty using a cerebrovascular balloon. However, this method is resistant to cerebrovascular balloon treatment. As such, the perfusion balloon was utilized with the utmost care, eventually resulting in favorable recanalization and outcomes.

Although it is off-label and requires proficiency, a perfusion balloon can potentially be used as an effective treatment for LVO due to refractory ICAD.

CONCLUSION

At present, there is no established endovascular treatment for LVO secondary to ICAD. Treatment with antiplatelet agents and angioplasty with cerebrovascular balloons are frequently insufficient.

The coronary perfusion balloons may serve as a potential therapeutic option for refractory ICAD.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The author(s) confirms that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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