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CEREBROVASCULAR DISEASE AND STROKE

FIRST-IN-HUMAN/EARLY REPORTS

FullBlock-Assisted Percutaneous Carotid Artery Revascularization

A Novel Approach for Enhanced Neuroprotection

Bo Yu, MD, PhD,[a,b,c,*] Kristine J.S. Kwan, MD,[a,b,*] Jiong Zhou, PhD,[a,b,*] Jin-Dong Tong, MD, PhD,[a,b] Shuai Jiang, PhD,[a,b] Jin-Yun Tan, MD, PhD,[b,c] Wei-Hao Shi, MD, PhD,[b,c] Jing-Dong Tang, MD, PhD[a,b]

ABSTRACT

This report describes a first-in-human case of percutaneous carotid artery revascularization (PCAR) using FullBlock, a neuroprotective system that consists of a dual-occlusion balloon and reverse-flow neuroprotective system. The patient was a 77-year-old woman with severe left internal carotid artery stenosis and multiple cardiovascular comorbidities. She was deemed unsuitable for carotid endarterectomy. PCAR with stenting was performed successfully with general anesthesia. Neuroprotection depended on controllable reverse hemodynamics established with the femoral vein and communicating intracranial arteries. Atherosclerotic plaques were filtered in the extra-anatomic reverse flow tube. One-month follow-up was favorable. This case demonstrates the feasibility of FullBlock-assisted PCAR with stenting as a promising alternative for high-risk patients. Transradial and femoral access can be avoided, adding potential benefits of reduced operative complexity and enhanced neuroprotection. (JACC Case Rep. 2025;30:103629)

Symptomatic moderate or severe carotid stenosis (≥50%) significantly increases the risk of recurrent ischemic stroke.[1] Surgical interventions recommended for prevention include mechanical thrombectomy for acute ischemic stroke and transfemoral carotid stenting (CAS) or carotid endarterectomy (CEA) for recurrence prevention.[2] The widespread and unstable distribution of atherosclerotic plaques increases the risk of perioperative stroke.[3,4]

TAKE-HOME MESSAGES

- FullBlock offers enhanced neuroprotection with its dual-occlusion balloon and extra-anatomic reverse flow with built-in filtering system during PCAR.
- PCAR potentially eliminates the need for transradial and femoral access in future intracranial revascularization procedures.

Transcarotid arterial revascularization (TCAR), using the ENROUTE transcarotid neuroprotection system, has been established as a promising alternative.[5] This approach involves occluding the common carotid artery (CCA) through open exposure and creating an extra-anatomic reverse flow to facilitate carotid stenting. TCAR has shown perioperative outcomes similar to CEA and demonstrated advantages over transfemoral CAS.[6]

From the [a]Department of Vascular Surgery, Fudan University Pudong Medical Center, Shanghai, China; [b]Shanghai Key Laboratory of Vascular Lesions Regulation and Remodeling, Shanghai, China; and the [c]Vascular Surgery Division, General Surgery Department, Huashan Hospital Affiliated to Fudan University, Shanghai, China. *These authors contributed equally to this work.
The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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ABBREVIATIONS AND ACRONYMS

CAS = carotid artery stenting

CCA = common carotid artery

CEA = carotid endarterectomy

ECA = external carotid artery

ICA = internal carotid artery

PCAR = percutaneous carotid artery revascularization

TCAR = transcarotid artery revascularization

The Mo.Ma Ultra Proximal Cerebral Protection device, equipped with a double-occlusion balloon system, simultaneously blocks retrograde blood flow from the external carotid artery (ECA) and antegrade flow from the CCA during transfemoral CAS.[7] However, intolerance to occlusion remains a concern.[8]

Recently, a novel dual-occlusion balloon and reverse flow system, the FullBlock (HeartCare), was introduced in China as an on-label treatment option. Combining both neuroprotective systems into a single device, FullBlock can be percutaneously inserted into the CCA to treat intracranial internal carotid artery (ICA) stenosis. Here, we report the first-in-human case of percutaneous carotid arterial revascularization (PCAR) using FullBlock, highlighting key technical aspects.

HISTORY OF PRESENTATION

A 77-year-old woman was referred to our center after an incidental finding of left-side severe carotid stenosis on a preoperative ultrasound 2 months before. She reported occasional tinnitus in recent years but was otherwise in good health, with no signs of neurologic deficit on physical examination.

PAST MEDICAL HISTORY

The patient had a history of recurrent cardiovascular events from multivessel coronary artery disease, with multiple interventions over the past 8 years, including percutaneous coronary intervention, coronary artery bypass grafting, and stenting. She was last hospitalized 3 months before and recovered well.

INVESTIGATIONS

Echocardiography revealed mild mitral and tricuspid regurgitation with a left ventricular ejection fraction of 53%. Computed tomographic angiography showed mild stenosis in the left CCA and an isolated severe tortuosity in the proximal internal carotid artery (ICA) (Figure 1). Apart from an elevated B-type natriuretic peptide level (574 pg/mL), other biochemicals were normal. Given her comorbidities and preferences, the vascular team deemed her unsuitable for CEA, opting instead for PCAR with stenting.

MANAGEMENT

Under general anesthesia, the patient was positioned supine with her neck extended and turned away from the surgical side. Right femoral artery access was obtained using a 6-F sheath, followed by the insertion of a 4-F J-curve guidewire into the right CCA for angiography. After heparinization, a 6-F sheath was placed in the left femoral vein as standby for potential flow reversal.

A 1-cm vertical incision was made at the left neck. The left CCA was then punctured under ultrasound guidance, and a loach guidewire was advanced into the distal left ECA. A 6/8-F dilatation catheter was gradually expanded to accommodate a 9-F sheath (11 cm; Pinnacle; Terumo Medical Co). Bilateral CCA angiography was performed to assess vascular conditions before introducing a 0.035-inch J-curve loach

FIGURE 1 Preoperative Computed Tomographic Angiography Assessment of the Carotid Arteries

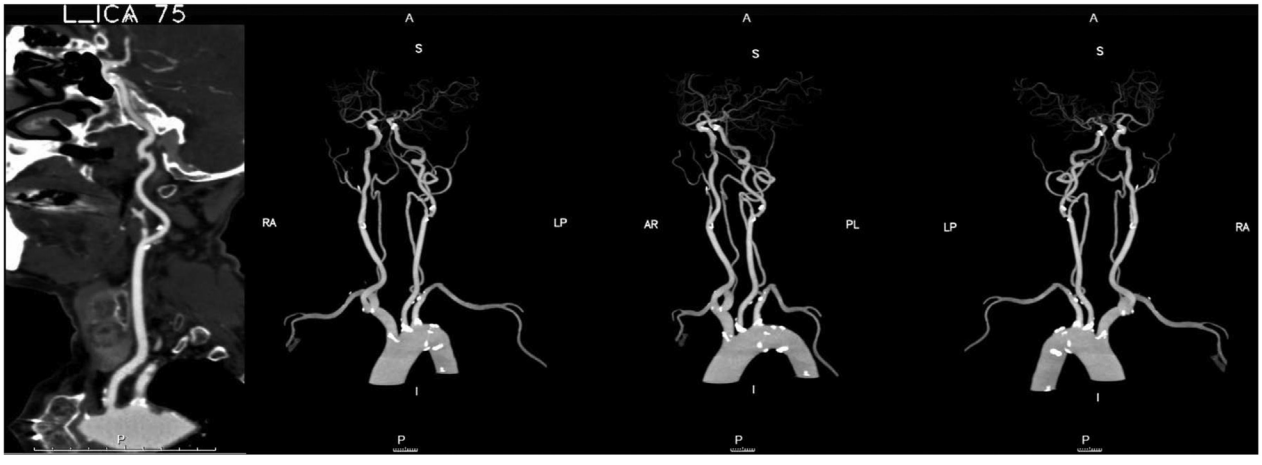
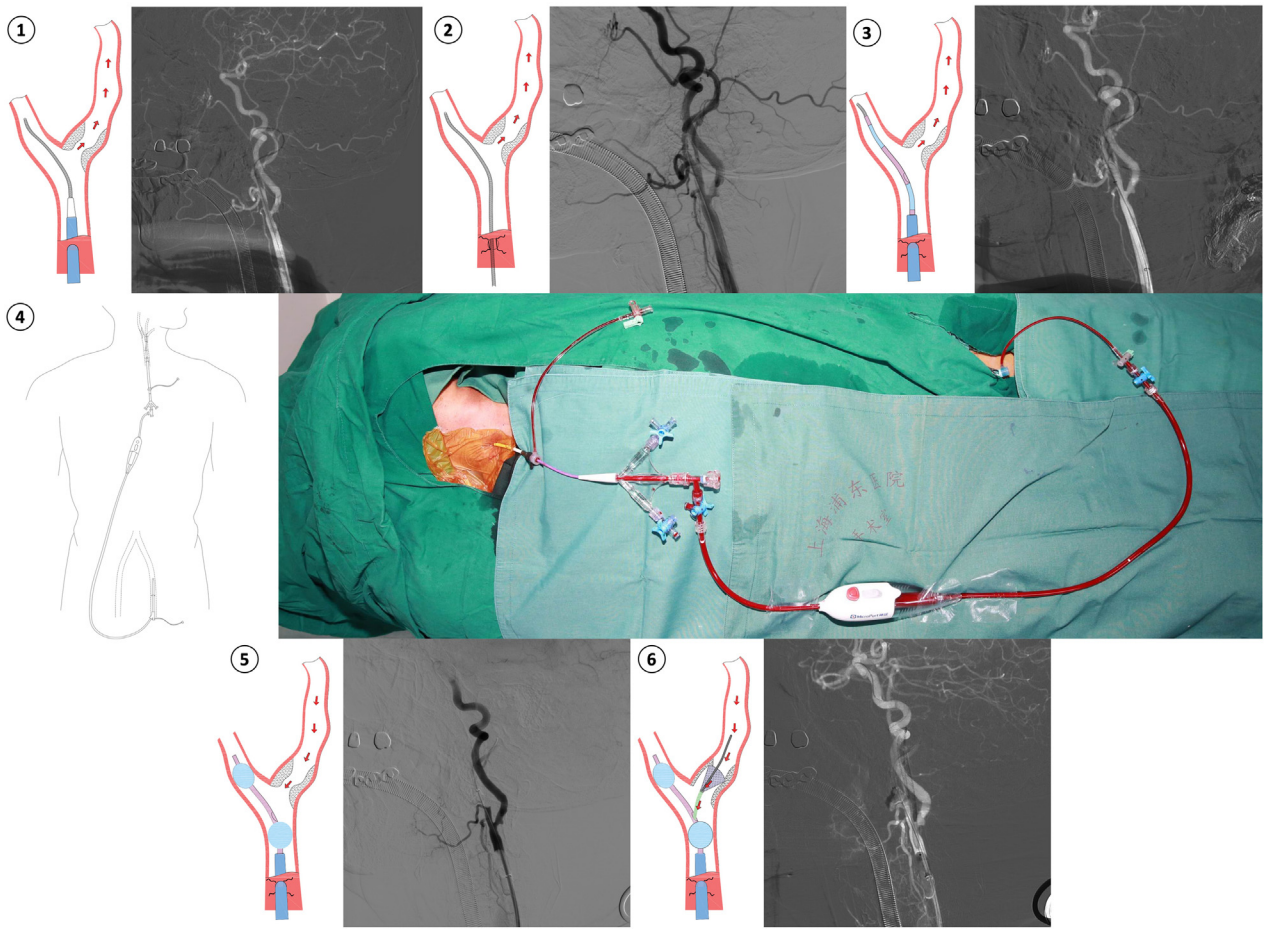


FIGURE 2 **Figurative Descriptions of the Percutaneous Carotid Arterial Revascularization and Stenting Procedure With Intraoperative Angiographic Visualizations**



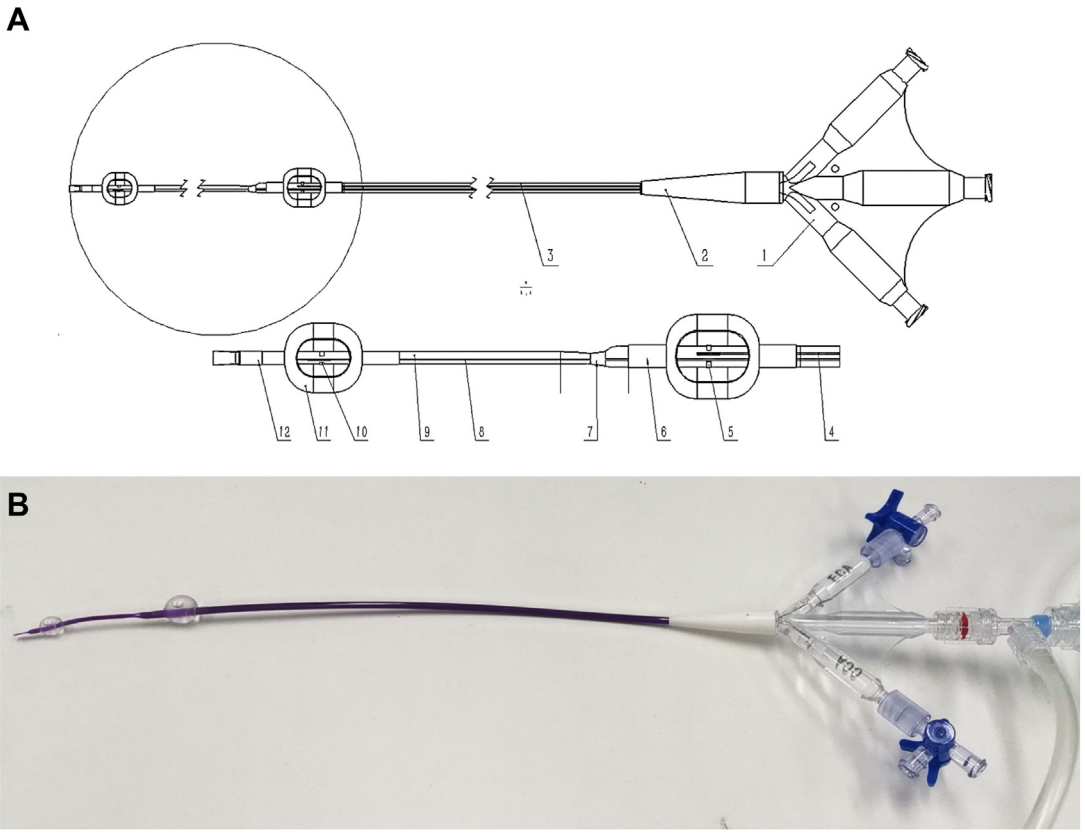
Red arrows represent the direction of arterial flow. (1) Direct puncture and insertion of the catheter and guidewire to the common carotid artery. (2) Withdrawal of the catheter sheath with or without preclosure of the puncture site (not shown in angiography). (3) Introduction of the dual-occlusion catheter following the preplaced guidewire. (4) Connecting the disposable extra-anatomic reverse flow establishment device (off). (5) Dilation of the occlusion balloon, occluding first the common carotid artery followed by the external carotid artery, and turning on the flow reversal system. (6) Once reverse blood flow is established, internal carotid artery stenting was performed.

guidewire for placement of the FullBlock catheter, equipped with a Y globe valve. Dual occlusion of the left ECA and CCA was performed. A disposable reverse flow tube was connected to the Y valve, with its output directed to the left femoral vein catheter. This setup allowed for control over the speed (high or low) and volume of the reverse flow before proceeding with ICA revascularization.

For the ICA stenting, a 0.014-inch micro guidewire was introduced through the FullBlock catheter to dilate the stenosed ICA segment with a 4 × 30 mm balloon. A 7 × 40 mm Wallstent (Boston Scientific) was then implanted. After successful stenting, the Y valve was closed and the occlusion balloons deflated. The neuroprotection device was withdrawn, and a final angiography confirmed patent cerebral flow. All equipment was removed. Puncture sites were sutured and compressed. A final ultrasound was performed to check for hematomas or bleeding. **Figure 2** illustrates the FullBlock-assisted PCAR with stenting. **Figure 3** presents a comparison between the conceptual design and the actual model of the device.

The patient was returned directly to the ward after the procedure, which lasted a total of 135 minutes, with 30 mL of blood loss and 160 mL of contrast media used. She was discharged 4 days later.

FIGURE 3 Illustrated Design and Real-World Model of the Dual-Occlusion Device



(A) Illustration of the dual-occlusion device: (1) Y globe, (2) stress diffusion tube, (3) catheter, (4) proximal end of drainage tube, (5) proximal development ring, (6) proximal/common carotid artery balloon, (7) attachment, (8) distal end of drainage tube, (9) external carotid artery segment of catheter, (10) distal development ring, (11) distal/external carotid artery balloon, (12) tip. (B) Actual model of the dual-occlusion device.

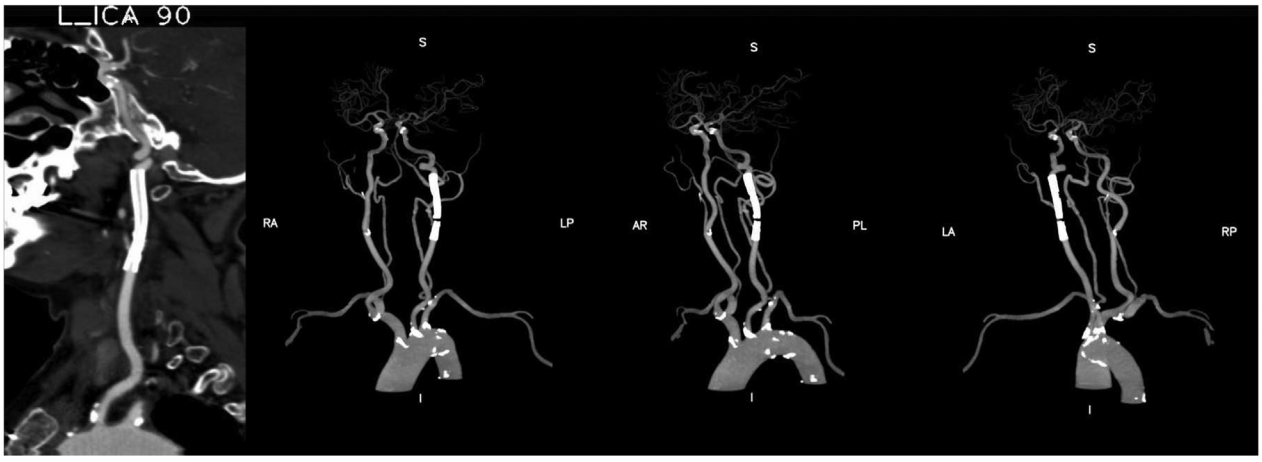
DISCUSSION

This report outlines the first experience using PCAR in conjunction with FullBlock, a neuroprotection device designed to optimize safety during revascularization procedures. FullBlock operates through occlusion of the ECA and CCA, combined with dynamic extra-anatomic flow reversal and a built-in plaque filtration system, and it yielded excellent immediate and early outcomes in this case. By allowing adjustable reverse flow speed, the device prevents complications such as turbulent flow and steal syndrome. High-speed reverse flow can also flush unstable plaques into the extra-anatomic tube, where they are filtered, further minimizing the risk of perioperative stroke.

Several precautionary measures were implemented in this case, including the use of general anesthesia, direct percutaneous access via an incision for the double-occlusion catheter, and a full angiogram of the circle of Willis. As a result, total operating time and contrast media volume exceeded typical requirements. However, in a cooperative patient, PCAR with CAS can be performed under local anesthesia. The procedural complexity is reduced, and it is estimated that PCAR with CAS alone can be completed in just 20 minutes from puncture to closure with the use of a preplaced suture-mediated closure device. In contrast, revascularization of the ICA and deeper intracranial lesions in a single session would require more time, making general anesthesia and stringent cerebral function monitoring preferable.

The FullBlock device integrates elements of the EnRoute and Mo.Ma systems into an enhanced neuroprotection solution for intracranial arterial

FIGURE 4 One-Month Follow-Up Computed Tomography Assessment of the Carotid Arteries



revascularization. Although this case report is limited in its ability to fully capture the outcomes and prognosis of PCAR, it is expected that results will align with those of TCAR, including smaller incisions, shorter hospital stays, and lower mortality rates.[9] Percutaneous access accuracy can be further improved with ultrasound guidance, minimizing the risk of cranial nerve injury.[10] In addition, perioperative stroke and transient ischemic attack rates are anticipated to be lower compared with TCAR and CEA, because intracranial atherosclerotic plaques are removed and stent patency is maintained.

Currently, PCAR is recommended for patients requiring endovascular revascularization of the intracranial ICA owing to ischemic or hemorrhagic events. Candidates must meet 2 specific criteria: 1) the carotid bifurcation is at least 4.5 cm above the clavicle; and 2) the circle of Willis is complete. Contraindications include: 1) ipsilateral ECA occlusion and contralateral CCA occlusion; 2) bilateral femoral vein occlusion; 3) infection at the puncture site; 4) a recent history (within 1 week) of ipsilateral proximal CCA puncture; and 5) lesions in the CCA within 2 cm of the puncture site.

The primary procedure associated with FullBlock involves ICA stenting, though it is unsuitable for lesions extending into the CCA. The outer and inner diameters of the device are 3.0 mm and 2.1 mm, respectively, allowing accommodation of any carotid stent with a 2 mm diameter. In this case, treatment was feasible owing to the patient's isolated ICA tortuosity distinct from mild tortuosity of the proximal CCA. This patient was carefully selected for PCAR, given that the risk of myocardial infarction, coronary events, and cardiovascular death is up to 22% higher in patients with severe carotid stenosis.[11] By avoiding transradial or femoral access, the aorta is bypassed, simplifying the overall instrument delivery route. No perioperative complications were observed. Future outcomes are expected to improve as experience with the procedure grows. Upcoming multicenter studies (ref. YXLL-2024-002) will further assess the safety, feasibility, and long-term efficacy of PCAR with the use of FullBlock.

FOLLOW-UP

The patient made an uneventful recovery. One-month follow-up computed tomographic angiography revealed a patent ICA stent with no migration. Carotid and intracranial arterial blood flow remained patent with no restenosis (**Figure 4**).

CONCLUSIONS

FullBlock-assisted PCAR offers a promising, minimally invasive alternative for high-risk patients with severe carotid stenosis. With the combination dual-occlusion neuroprotection and controlled reverse flow with built-in filtering system, safety of intracranial revascularization is enhanced.

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ADDRESS FOR CORRESPONDENCE: Dr Bo Yu, 9th floor, Block 9, Shanghai Key Laboratory of Vascular Lesions Regulation and Remodeling, Fudan University Pudong Medical Center, 2800 Gongwei Road, Pudong New District, Shanghai 201399, China. E-mail: YBxg0306@163.com.

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