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Proximal Penumbra Pump Aspiration in Carotid Stenting

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Pervinder Bhogal, Vamsi Gontu, Patrick A Brouwer

Abstract

There is a lack of consensus on indications for carotid stenting in the field of neurointervention, despite the widespread use of this intervention for a variety of reasons including inoperability. A number of publications have addressed the use of distal protection devices, and have concluded that these devices do not benefit the (imaging) outcome of patients. A potential explanation may be that the devices used are not adequately functioning or that the passage through the stenosed portion in itself carries risk. Furthermore, the use of proximal protection devices has to date resulted in highly complicated procedures and involves very expensive equipment. We describe two cases in which a proximal protection and aspiration with the Penumbra pump was utilized with only limited minimal modification to the usual procedure.

Keywords: thrombectomy, carotid stenting, proximal balloon protection, flow reversal

Introduction

The results of the recent carotid stenting trials are mixed, but this intervention is currently employed for a variety of reasons including for patients unsuitable to undergo carotid endarterectomy. The use of protection devices, either proximal or distal to the stenosis can effect outcome, both radiological and clinical, in patients undergoing carotid artery stenting (CAS). A common criticism of several recent trials is the failure to insist upon the use of a protection device during the procedure. A number of publications address the use of distal protection devices and some believe these devices do not benefit to (imaging) outcome of patients. A potential explanation may be that the devices used are not adequately functioning or that the passage through the stenosed portion in itself already carries risk.

We describe two cases in which a proximal protection and aspiration with the Penumbra pump was utilized with only minimal modification to the usual procedure.

Case Presentation 1

A previously healthy 71-year-old male patient attended hospital after waking with an acute mild right-sided mouth droop and dysarthria (NIHSS 2). He was previously well with only gastric reflux for which he intermittently took omeprazole 20 mg. On admission he was afebrile and in sinus rhythm, 61 bpm, with a blood pressure of 160/80 mmHg. There were no abnormalities on routine blood work.

An emergency CT scan and CT angiogram were performed. This did not demonstrate a proximal vessel occlusion and there was no definite infarction seen on the CT scan. The CT angiogram showed a long, heterogenous stenosis of the left internal carotid artery that began approximately 1.5 cm above the carotid bifurcation and extended for approximately 4 cm. This resulted in 70 % stenosis (according to NASCET criteria) (Fig. 1).

Dr Pervinder Bhogal (Corresponding Author) — Department of Neuroradiology, The Karolinska University Hospital, Stockholm, 17176, Sweden *Email:* bhogalweb@aol.com *Tel:* +44 7815 937220

Dr Vamsi Gontu, **Dr Patrick A Brouwer** — Department of Neuroradiology, The Karolinska University Hospital, Stockholm, 17176, Sweden

After discussion, the multi-disciplinary team meeting determined that endarterectomy would not be feasible due to the length of the stenotic segment and the difficulty in access to the cranial portion of the cervical ICA for haemostatic control. Therefore, carotid stenting was determined to be the best option for stabilising plaque and reducing stenosis.

The patient was loaded on clopidogrel 300 mg with maintenance daily dose of 75 mg. The patient was already taking daily aspirin 75 mg. After local anaesthesia and using a standard right common femoral approach, an 8Fr Arrow long sheath (Teleflex Medical, Athlone, Ireland) was tracked into the left common carotid artery. A bolus dose of 5000 IU of heparin was given as well as continuous heparinised saline flush on the long sheath. Following this an 8Fr Merci balloon guide catheter (Concentric Medical, Mountain View, CA, USA) was tracked into the common carotid artery. Angiography through the balloon guide catheter confirmed the stenosis seen on the CT angiogram. The main lumen of the Merci balloon catheter was connected to the Penumbra aspiration pump (Penumbra, Inc., Alameda, CA, USA), which is routinely used for endovascular stroke treatment. Under balloon inflation and continuous aspiration by the Penumbra system, two Precise stents (Cordis Corporation, Bridgewater, New Jersey, USA) were telescopically placed over the stenosis. This resulted in good coverage of the stenosis and reasonable improvement in the calibre of the vessel. Post-stent balloon angioplasty was not performed. The balloon remained inflated and the aspiration continued until the guidewire was removed (Fig. 2).

Following deployment of the stents, angiography of the brain confirmed no thromboembolic events. An 8Fr Angioseal was used to achieve haemostasis at the groin. The patient did not suffer from any clinical events.

Case Presentation 2

A 53-year-old man was admitted to his local hospital with acute onset left side weakness, sensory disturbance, dysphasia and visual disturbance. His NIHSS score at the time of attending his local hospital was 11. He was a Type 2 non-insulin dependant diabetic and hypertensive, for which he took metformin and enalapril. He was a heavy smoker with a 50 pack/yr history. He had never suffered a stroke or ischaemic neurological event.

His admission CT head and CT angiogram demonstrated a subtle small infarction within the posterior insular cortex and a terminal M1 and M2 occlusion. He was immediately transferred to the regional neurological hospital for emergency thrombectomy. He received full dose rtPA en route to our hospital.

On arrival to hospital, a repeat plain CT of the head, CT angiogram and perfusion CT was performed. This demonstrated a larger area of infarction and large ischaemic penumbra of salvageable tissue (Fig. 3). In the internal carotid artery there was a large atherosclerotic plaque with what appeared to be “floating thrombus” (Fig. 4).

After discussion with the stroke physicians and the family, an emergency thrombectomy and carotid stenting procedure was performed. Using a standard right common femoral approach, a 9Fr Arrow long sheath was tracked into the right common carotid artery. A 9Fr Merci balloon guide catheter was then tracked into the distal common carotid artery. Angiography confirmed a markedly irregular atherosclerotic plaque with associated floating thrombus. In order to cross the stenosis with the least risk, the balloon on the guide catheter was inflated and continuous aspiration with the Penumbra pump was applied as the lesion was crossed with a Transend microwire, over which was tracked a Velocity microcatheter and 5Max Ace distal aspiration catheter. Once across the lesion and in the cavernous internal carotid artery, aspiration was concluded and the balloon deflated. A continuous heparinised saline drip was then

attached to the main lumen of the Merci balloon guide catheter as is our standard practice. The thrombus was successfully navigated with the Velocity microcatheter and a Solitaire 4 x 20 mm stent retriever was deployed. With the stent retriever in situ across the thrombus, the 5MAX Ace was tracked into the mid-M1 segment. With balloon inflation and continuous pump aspiration on the 5MAX Ace, distal access catheter flow was restored. A final TICI 2c end result was achieved with a single small M4 embolus but excellent collateral flow (Fig.5).

Following this procedure, we decided to place a carotid stent over the carotid plaque in order to "tack" the plaque and against the wall. Using a Transend Floppy 300 cm wire to maintain distal access the Velocity microcatheter and 5MAX Ace catheters were removed. The pump aspiration was then reconnected to the balloon catheter. After inflation of the balloon and with continuous pump aspiration, a 9x40 mm Precise stent was placed in the carotid. Unfortunately, during placement of the stent, the patient suddenly moved resulting inappropriate placement. Therefore, the procedure was repeated and a second stent (Precise 8x40 mm) placed more distally resulting in double layer coverage over the plaque. The balloon inflation was maintained during preparation of the second stent but aspiration was stopped. A half-bolus dose of IV abciximab (Reopro) was given at the time of stent placement. The patient was started on 75 mg Aspirin and Clopidogrel per day 24 h later. Follow up CT imaging of the head showed no extension of the infarct and CT angiogram showed good coverage of the plaque and good flow in the internal carotid artery (Fig. 6).

Angiography at the end of the carotid stenting procedure showed no new distal emboli and excellent flow through the carotid stents. An 8F Angio-Seal was used to achieve haemostasis. The patient made a good recovery NIHSS score of 6 on discharge back to his base hospital 24 h later.

Discussion

Carotid artery stenting (CAS) is an evolving technique and despite numerous trials comparing CAS to carotid endarterectomy (CEA), consensus has been difficult to reach because of significant heterogeneity in trial design, population, operator experience, etc. However, studies have shown a progressive improvement in the stroke rates and 30 day mortality over the last 10-15 years [1]. Furthermore, there is evidence that the embolic burden is related to the experience of the operators and the technique used [2] and this lack of experience was one criticism of both the SPACE and EVA-3S trials. The more rigorous inclusion criteria applied to operators in CREST may partially explain the improved outcomes seen in this study.

Embolic protection devices (EPD) were designed to improve the safety profile of the CAS. These EPD can be subdivided into distal embolic protection devices and proximal embolic protection devices. Several studies comparing the different approaches to embolic protection have been performed. The PROFI study was a prospective randomised trial that compared proximal and distal EPD [3]. This study demonstrated an almost 50 % reduction in the incidence of new cerebral ischemic lesions in those patients undergoing proximal balloon embolic protection, an argument used to discourage distal protection devices. Cano et al. [4] compared the Mo.Ma (Medtronic Vascular Inc., Santa Rosa, California, USA) proximal EPD with the Angioguard (Cordis Corporation, Bridgewater, New Jersey, USA) distal EPD. They found that approximately 60 % of patients undergoing carotid stenting demonstrated new foci of restricted diffusion on postoperative MRI scans; however, the total number of new lesions was significantly reduced in the Mo.Ma proximal EPD group. Bersin et al. [5] conducted a systematic review of 2397 CAS cases using proximal embolic protection. They showed the incidence of stroke was 1.7 %, with a composite endpoint of stroke, myocardial infarction and death at 30 days of 2.25 %. A meta-analysis by Benjo et al. also demonstrated the benefit of proximal embolic protection compared to distal embolic protection [6]. However,

contradictory to evidence suggesting that proximal protection is safer, are the results of the recent randomised controlled trial of Castro-Afonso et al. [7]. In this trial there was a statistically significant increase in the incidence, overall number and mean diameter of new DWI lesions in the group undergoing CAS with proximal protection compared to distal protection. Therefore, it has not been conclusively proven which is the best method of cerebral protection.

Until recently, the Mo.Ma system and Gore Flow Reversal system were commercially available. The ARMOUR Pivotal US trial enrolled 257 patients and evaluated the Mo.Ma system with an all-stroke and death rate of 2.7 % [8]. The EMPIRE US trial evaluating the Gore Flow Reversal system recruited 245 patients with a stroke and death rate of 2.9 % [9]. The Gore system is no longer commercially available; however, the MICHI Neuroprotection System (Silk Road Medical Inc., Sunnyvale, California, USA) is currently undergoing evaluation with very promising results. This new device employs a direct surgical cut down to the common carotid artery and does not require a balloon in the external carotid artery. Instead, it uses very high flow reversal to prevent distal emboli to the brain. The PROOF study found that using this novel flow reversal system with access via the common carotid artery had a low incidence of new restricted diffusion lesions (16 %) [10]. The ROADSTER trial has shown similarly impressive findings with a 30 day stroke rate of 1.4 % in the pivotal cohort. It is likely that as technological advances are made, the exact approach, be it transfemoral or transcervical, will be adjusted depending on individual patient factors such as aortic arch morphology, atheromatous burden, physician experience etc.

In order to test the flow rate achievable by the Penumbra pump, we connected the aspiration pump to the main lumen of the 9Fr Merci balloon guide catheter via the standard aspiration tubing. With the aspiration pump set to aspirate at -29 Hg, the distal tip of the balloon guide catheter was placed in a large cylinder filled with room temperature water and aspirated for 60 s. This gave a flow rate of 398 ml/min. A similar technique was used by Hu et al. to test the aspiration tip force and flow rate of different aspiration catheters [11]. Given that the mean flow rate within the ICA in normal individuals is approximately 320 ml/min as measured by power Doppler [12], the use of the Penumbra aspiration pump connected to 9 Fr Merci balloon catheter should theoretically provide more than adequate flow reversal. This may be especially true in patients with atherosclerotic stenosis where the flow rate will be significantly reduced. This system is similar to that employed by the MICHI device in that it relies on a very high rate of flow reversal in order to prevent distal embolisation.

We believe that the minimal change to the normal carotid stenting procedure, by using the Penumbra aspiration system in conjunction with proximal balloon occlusion, represents a viable and cheap option for physicians whom do not have access to either the Mo.Ma or MICHI systems. The successful use of the Penumbra aspiration system in acute thrombectomy has previously been reported and we believe that this widely used apparatus can, in major stroke centres, be a simple and cost effective adaptation for stenting procedures.

Ethical standards and consent

We declare that our study adheres to the ethical principles outlined in the 1964 Declaration of Helsinki and later amendments. We declare that we did not request ethics approval for this study and we requested and received informed consent from one patient prior to enrollment.

Conflict of interest

We declare that we have no conflict of interest.

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Figures

Figure 1

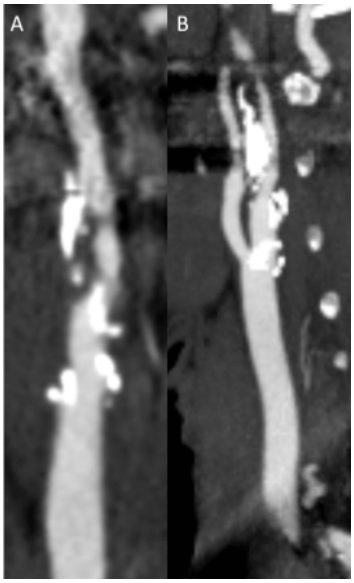


Figure 1A shows a curved reformat from the CT angiogram performed at the time of admission. Figure 1B is a magnified sagittal image from the same CT angiogram. Both images show a heterogenous heavily calcified plaque in the left ICA that extends for several centimetres. This resulted in approximately 70% stenosis (NASCET criteria)

Figure 2

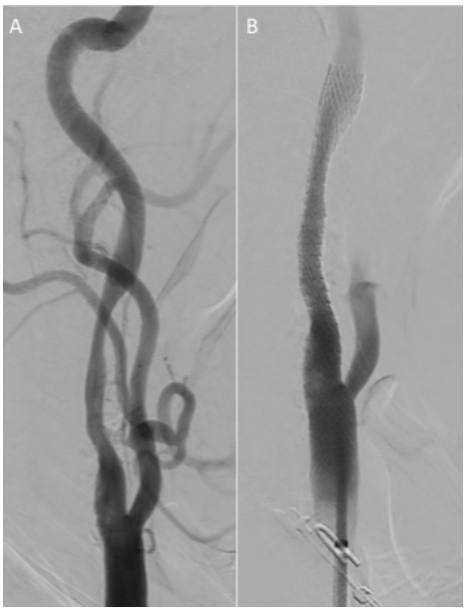
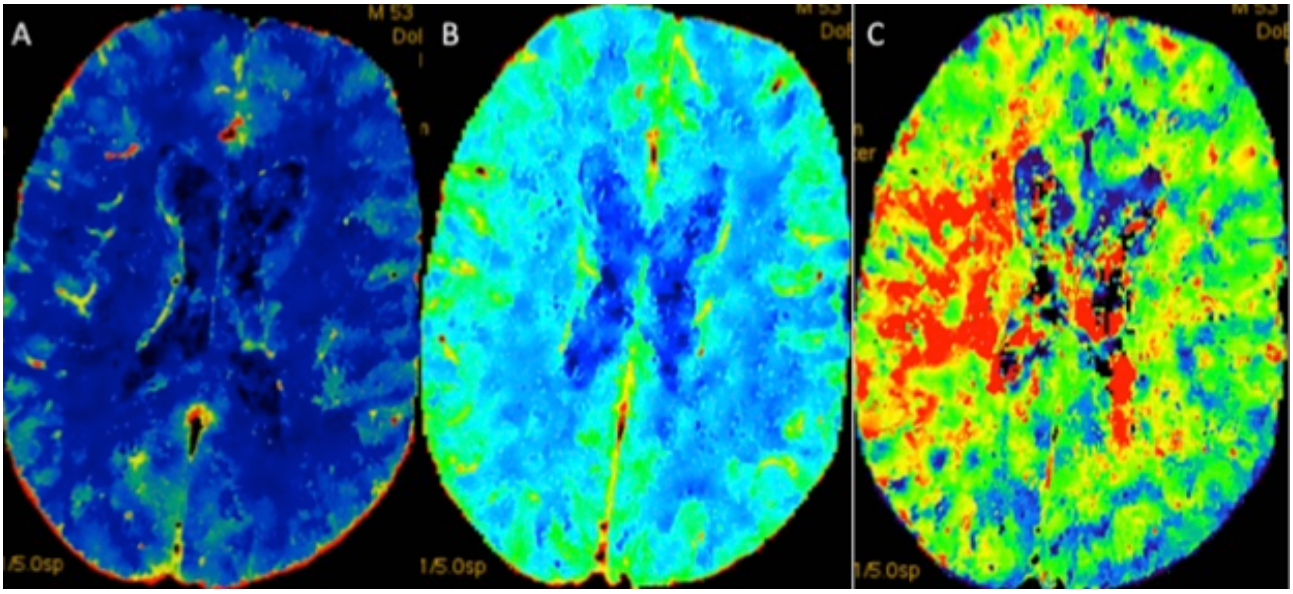


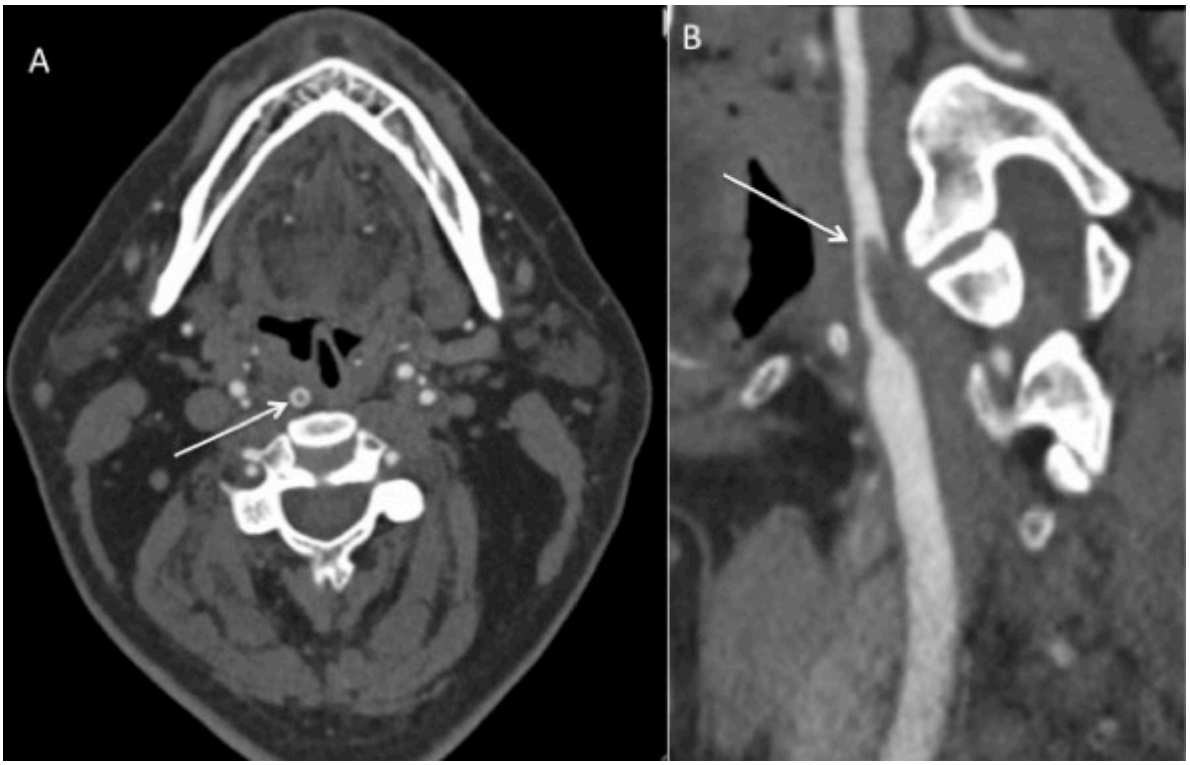
Figure 2A is a lateral angiographic image taken pre-operatively with the patient awake. Figure 2B is taken immediately after the deployment of both stents. The stents cover the entire diseased segment and there was an improvement in the calibre of the vessel therefore, post-operative balloon angioplasty was not performed. The flow reversal using the balloon guide catheter and Penumbra aspiration pump was maintained during the time the stenosis was crossed and until both stents were placed and the guidewire removed.

Figure 3



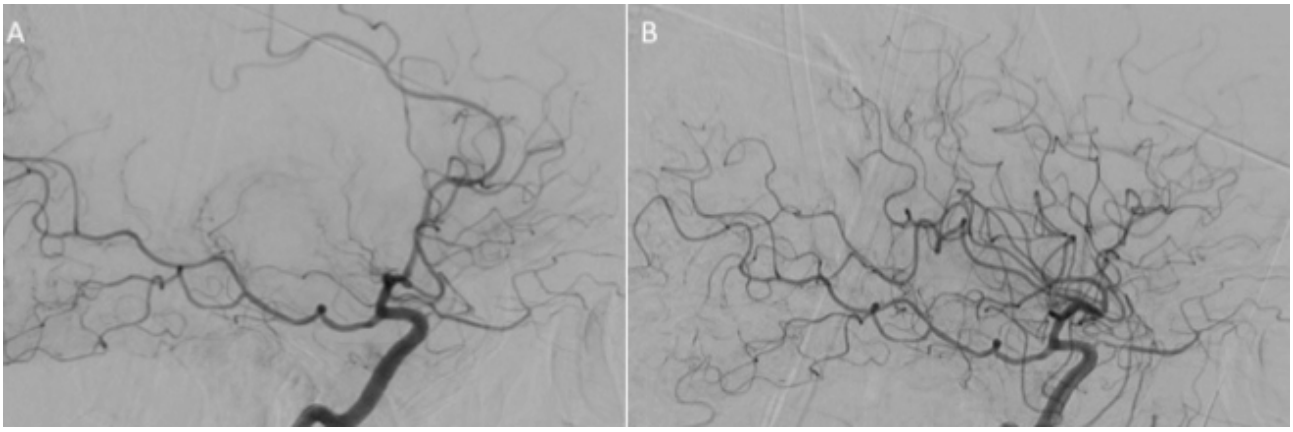
The blood flow (Fig. 3A), blood volume (Fig. 3B) and TMax (Fig. 3C) demonstrate a large ischaemic penumbra on arrival to our hospital.

Figure 4



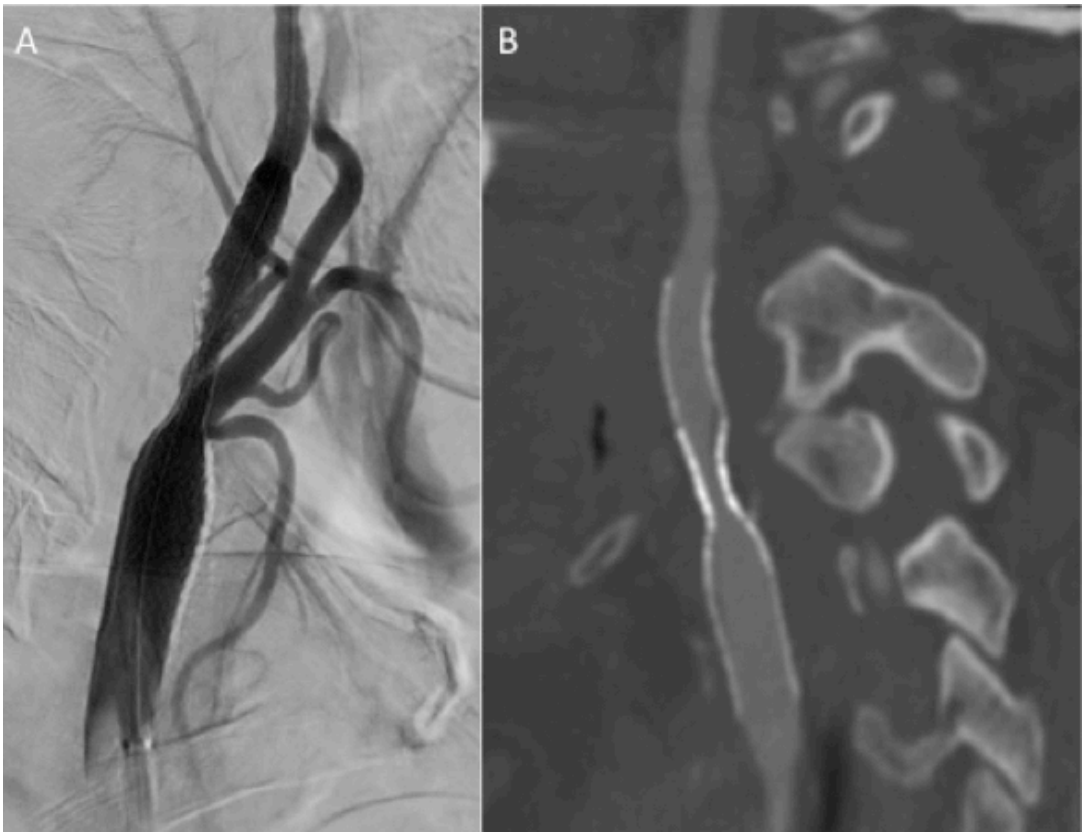
CT angiogram demonstrated a stenosis with atherosclerotic plaque and floating thrombus seen on axial images in Fig. 4A (white arrow). A curved reformat of the ICA and CCA also demonstrate the floating thrombus distally (white arrow).

Figure 5



The initial catheter angiogram (Fig. 5A) shows a large defect within the MCA territory. After mechanical thrombectomy there was restoration of flow with the MCA territory only a single small embolus in a distal M4 branch (Fig. 5B).

Figure 6



Catheter angiography at the end of the procedure (Fig. 6A) demonstrate good flow in the ICA and effective 'tacking' of the thrombus against the wall of the ICA by the stents. A CT angiogram performed 24 hours (Fig. 6B) later show persistent good flow through the stents.