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Rescue Angioplasty with Drug-Eluting Balloon (DEB) in Symptomatic Intracranial Atherosclerotic Stenosis Large Vessel Occlusion (ICAS-LVO): A Case Report and Thematic Literature Review

CASE REPORT

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ABSTRACT

Intracranial atherosclerotic stenosis (ICAS) is an important cause of acute ischemic stroke, particularly in the Asian population. The mainstay of treatment is largely medical; however, despite aggressive medical management, the recurrence rate remains high. Recently, balloon angioplasty, in addition to aggressive medical management, has emerged as a viable interventional treatment to manage this neurovascular disease entity effectively. The utilization of drug-eluting balloons (DEB) compared to conventional balloons has shown promise, with some early studies demonstrating superiority. Larger-scale studies are underway to prove this theory. We attempt to discuss this topic with an illustrated case in our center. The rationale of this interventional approach, as well as related issues, will also be highlighted.

KEYWORDS

intracranial atherosclerotic stenosis (ICAS), stroke, endovascular thrombectomy (EVT), thrombolysis, angioplasty, drug eluting balloon (DEB)

INTRODUCTION

ICAS is a major cause of acute ischemic stroke worldwide, particularly in Asian countries [1]. However, at present, there is no effective approach to manage this disease entity, which is known to have a high recurrence rate. Previous large, randomized trials have attempted to prove the efficacy of percutaneous transluminal angioplasty and stenting in patients with ICAS, without success [2,3].

A viable therapeutic alternative, which is gaining more traction of late, is the use of DEB. In this paper, we aim to discuss the available literature, specifically its use in the neurovascular setting, in particular acute ischemic stroke, the rationale behind DEB, as well as describing a case that we managed in our center.

CASE DESCRIPTION

A 73-year-old lady with underlying hypertension and dyslipidemia presented to our center with a complaint of left-sided body weakness and difficulty in speech. Symptoms had started about 1 hour prior to presentation. On assessment, the power of the left upper and lower limbs was found to be 4/5, with slurred speech and a weak gag reflex. Her initial National Institutes of Health Stroke Scale (NIHSS) was scored as 7/42. An urgent magnetic resonance imaging (MRI) stroke protocol was done, which showed evidence of right-sided middle cerebral artery (MCA) territory infarct, with evidence of DWI-FLAIR mismatch, as well as an occluded proximal right MCA [Figure 1]. A decision was made to administer intravenous (IV) thrombolysis with Tenecteplase 0.25 mg/kg, considering the patient's early presentation, with MRI evidence of DWI-FLAIR mismatch. Post-IV thrombolysis, she was taken to the angiography suite for endovascular thrombectomy (EVT), after discussion with the family members and managing teams. Preliminary angiogram showed persistent occlusion of the proximal right MCA [Figure 2]. Following this, EVT was attempted with a direct aspiration first-pass technique (ADAPT), using a Sofia aspiration catheter (6 French, 125 cm). After one pass, it was realized that this patient had an underlying critical stenosis of the proximal right MCA, with delayed perfusion distally to the right MCA territory [Figure 3]. After discussion between the managing teams in the angiography suite, a decision was made to perform a rescue balloon angioplasty, with a drug-eluting coronary balloon (DEB), in view of an underlying ICAS. This was achieved using a paclitaxel-coated drug-eluting coronary balloon (Essential Pro,

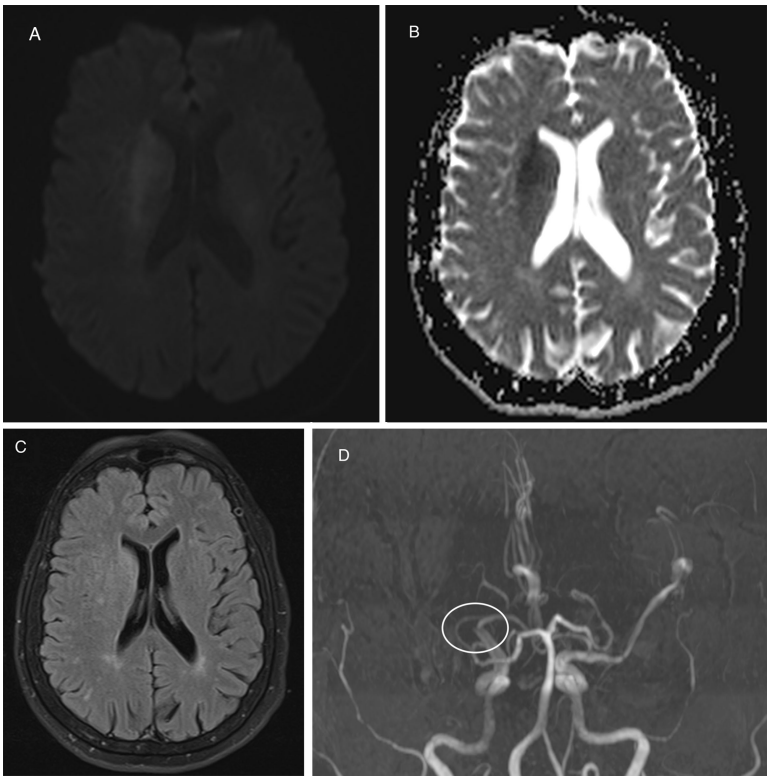

FIGURE 1. (A) DWI MRI b1000 sequence showing hyperintensity in keeping with hyperacute infarct, at the right MCA territory. (B) The corresponding ADC MRI sequence showing hypointensity at the same region, which confirms a hyperacute infarct. (C) The FLAIR sequence showing no signal changes at the affected region, in keeping with evidence of DWI-FLAIR mismatch. (D) The MRA sequence shows truncation of the proximal right MCA vessel, in keeping with MCA occlusion/large vessel occlusion (white circle). ADC, apparent diffusion coefficient; DWI, diffusion-weighted imaging; FLAIR, fluid-attenuated inversion recovery; MCA, middle cerebral artery; MRI, magnetic resonance imaging.

142 cm, 2.0 × 15 mm^2), which was inflated sub-maximally for 30 seconds. Following this, distal perfusion was restored, with no delay compared to the unaffected cerebral territory. No venous phase/washout delay was exhibited. Immediately post-revascularization, the patient was given IV Tirofiban (infusion) for 6 hours (loading dose of 0.4 mcg/kg/min, followed by maintenance dose of 0.1 mcg/kg/min). The immediate post-EVT NIHSS score was 2/42, which improved to 0/42 the following day. Post-EVT surveillance non-contrasted plain computed tomography (CT) scan showed no evidence of hemorrhage, with no progression of the initially seen acute infarct. A surveillance MRI a few days afterward showed a small hemorrhage at the right high parietal region (Heidelberg class 3a); Magnetic resonance angiography (MRA) showed patency of the right MCA vessel, with a similar signal compared to the unaffected contralateral side [Figure 4]. The patient was clinically stable with no neurological deficits. She was allowed home after 5 days in the hospital, with a single antiplatelet therapy (with aspirin).

DISCUSSION

ICAS is a neurovascular condition characterized by long-standing, repeated inflammation, lipid deposition, and plaque formation in the cerebral vasculature, which consequently leads to steno-occlusion. It is recognized as a major cause of acute ischemic stroke, particularly in the Asian population. At present, the recommendation is to manage this disease primarily via aggressive medical therapy with antiplatelet medications, lipid-lowering therapy, and blood pressure/sugar control—for stroke prevention. Unfortunately, despite our best efforts at aggressive medical therapy, the recurrence rate remains high, with estimates between 7.2% and 15.1%, per year [2–4]. In view of this, effective interventional strategies, when patients present with acute ischemic stroke in the presence of an associated ICAS, are vital.

Previous large, randomized trials, namely SAMMPRIS (Stenting vs. Aggressive Medical Management for Intracranial Arterial Stenosis) and VISSIT (Vitesse Intracranial Stent Study for Ischemic Stroke Therapy) have attempted to prove the effectiveness of percutaneous transluminal angioplasty and stenting compared to aggressive medical management in patients with ICAS. Unfortunately, what these trials demonstrated was a higher risk of early ischemia, increased peri-procedural complications, and no clear benefit or superiority of intervention compared to aggressive medical management. In fact, long-term data from the SAMMPRIS trial showed early benefit of aggressive medical management in patients with high-grade ICAS; this effect was persistent throughout an extended median follow-up period of 32.4 months [5].

More recently, the BASIS (Balloon Angioplasty for Symptomatic Intracranial Artery Stenosis) trial managed to show that in patients with ICAS, opting for balloon angioplasty in addition to aggressive medical management may be an effective therapeutic approach [6]. Considering the results of the BASIS trial, as well as previous trials using the combined angioplasty and stenting approach, an alternative interventional method via DEB was explored. Some of these studies have shown the superiority of DEB compared with conventional balloons used in patients

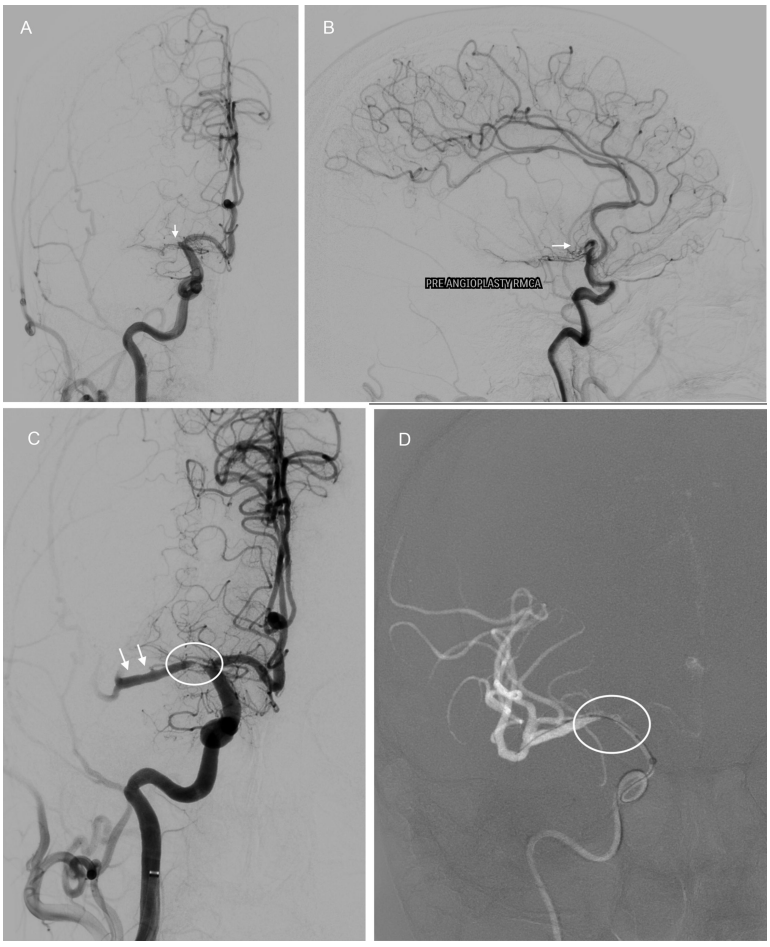

FIGURE 2. (A) Preliminary angiogram (prior to EVT) showing evidence of proximal right MCA occlusion (white arrow). (B) Preliminary angiogram in lateral view, demonstrating the right MCA occlusion. (C) Post-ADAPT/aspiration thrombectomy single pass shows evidence of critical stenosis (white arrow). Delayed contrast filling/perfusion is also noted (white arrows) distal to this critical stenosis. (D) DEB catheter is seen on this angiogram (roadmap) crossing the lesion/critical stenosis, aided by microwire. ADAPT, a direct aspiration first-pass technique; DEB, drug-eluting balloon; EVT, endovascular thrombectomy; MCA, middle cerebral artery.

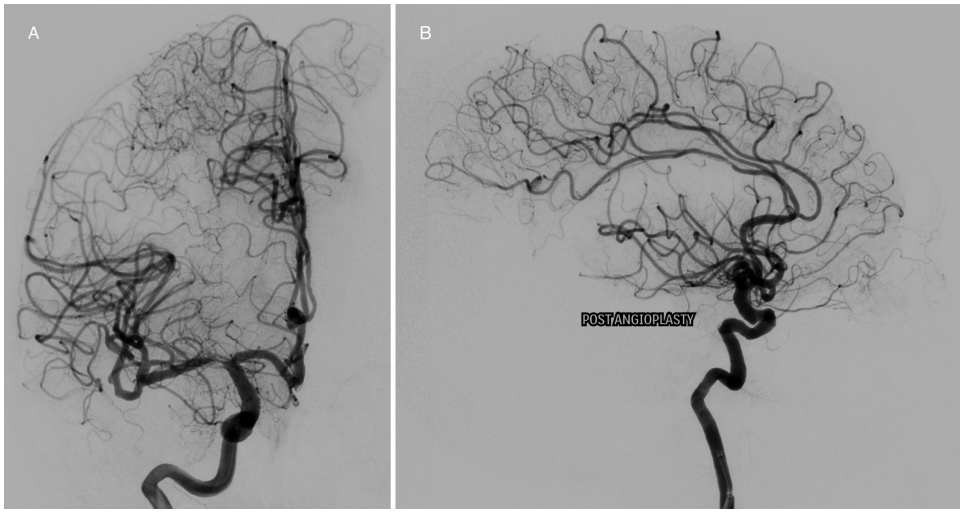

FIGURE 3. (A) Post-DEB angioplasty angiographic run shows restoration of perfusion distal to the critical stenosis, with no delay compared to the unaffected territory (TICI 2 C/3 revascularization). (B) Post-DEB angioplasty lateral view angiography, showing no perfusion defects. DEB: drug-eluting balloon.

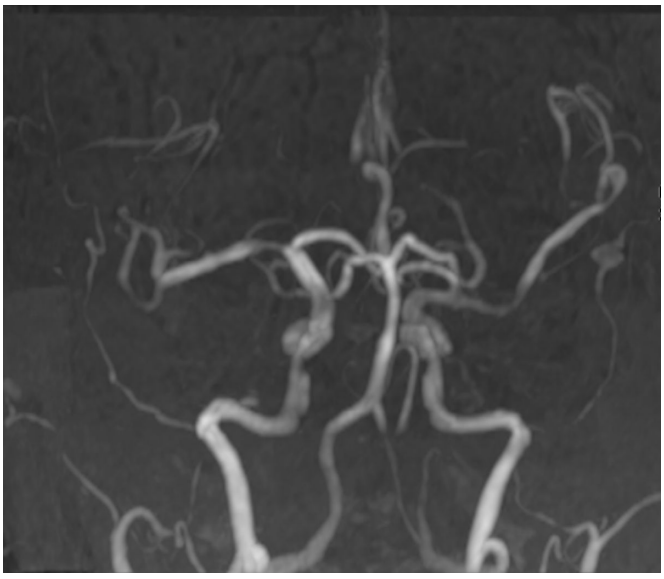

FIGURE 4. Surveillance MRA showing patency of the previously occluded right MCA vessel, which displays a similar signal compared to the contralateral, unaffected MCA vessel. MCA, middle cerebral artery.

with ICAS [7–9]. The idea behind the use of DEB is that coating the balloon with anti-proliferative drugs, such as paclitaxel or sirolimus, and deploying it onto the lesion/stenotic site releases the drug directly onto the vessel wall, which in turn inhibits endometrial hyperplasia and re-stenosis.

Our case is an example of how complex it is to manage this neurovascular entity. Our patient presented early, with an NIHSS score of 7/42. Urgent stroke MRI demonstrated a right MCA territory infarct, with evidence of DWI-FLAIR mismatch, and an occluded proximal right MCA. The decision to administer IV thrombolysis was based on the patient presenting within the thrombolytic window, with imaging evidence of a DWI-FLAIR mismatch, which suggests, at least theoretically, that the tissue time is still very early. After successful thrombolytic therapy, a preliminary angiogram prior to EVT showed persistent occlusion of the proximal right MCA, which was managed via aspiration thrombectomy. However, after the first pass, it was noted that the patient had a critical stenosis of the proximal right MCA, with impaired perfusion distally. A consensus among the neurologist, the interventional neuroradiologist, and the family was reached intra-procedurally to attempt a rescue angioplasty, using a DEB. This therapeutic approach managed to restore distal perfusion, with the patient improving drastically post-procedurally, with no neurological deficits. However, surveillance imaging post-intervention showed a small hemorrhage at the right high parietal region (Heidelberg class 3a), remote from the ischemic/infarcted tissue. This could possibly be secondary to the patient's underlying small vessel disease, (advanced) age, or gender, which are known risk factors for developing remote parenchymal hematoma post-IV thrombolysis in patients with acute ischemic stroke—occurring in a third of patients [10]. Antiplatelet monotherapy via aspirin was prescribed, considering the presence of hemorrhage post-treatment.

Despite procedural success and good immediate clinical outcomes, questions remain regarding the long-term outlook. Studies have looked at the timing of intervention in relation to the outcome. Early intervention, they argue, confers a higher risk of long-term cerebrovascular events, namely the total rates of transient ischemic attack (TIA), any ischemic stroke, hemorrhagic stroke, and death [11]. A recent study demonstrated that in patients with symptomatic ICAS, it may be beneficial to delay intervention via DEB (between 21 and 42 days from event) compared to intervening early (<21 days) [12]. Their study showed that in the delayed intervention group of patients, significantly lower post-operative residual stenosis, restenosis rates, lower peri-procedural complication rates, and recurrence rates were seen. However, in our case, delaying the angioplasty while knowing the intra-procedural angiographic findings is not feasible. Thus, a decision was made to intervene early.

A recently published study [13] looking at the use of drug-eluting/coated balloon angioplasty for the treatment of medically refractory intracranial atherosclerotic disease, both in the emergency/rescue and elective setting, showed that in their cohort of consecutively identified patients (11 patients), 9 patients underwent successful DEB angioplasty, without major complications and a combined technical success rate of 78%. They found a mean stenosis reduction rate of 53.6%, while restenosis was seen primarily in patients whom angioplasty was done in an elective setting, and not those done in the emergency/rescue setting, at follow-up imaging (mean of 64 days post-procedure). However, they reported that none of these patients experienced recurrent or symptomatic ischemic events.

CONCLUSION

ICAS is a complex neurovascular disease entity and an important cause of acute ischemic stroke, with no effective management strategy at present. The addition of balloon angioplasty as a possible interventional approach on top of aggressive medical management provides an avenue with which further research can be done to manage this condition. The usage of DEB shows promise as a viable option; however, more data are needed to validate this strategy, to better manage patients with ICAS.

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Consent

Informed consent was obtained from the patient/family for the publication of this case report.

Author Contributions

All authors contributed to this study.

Disclosure

All authors read and approved the final manuscript for submission.

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Data Availability Statement

Data sharing is not applicable to this article as no datasets were generated or analyzed, during the study.

Ethics Statement

No ethical approval is required for a retrospective, anonymized, single case study.

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