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# Intracranial Stenting for Acute Ischemic Stroke

Ahmad Khaldi and J. Mocco  
University of Florida,  
USA

## 1. Introduction

Stroke is the third major cause of death in the US. In the past decade there has been an exponential growth in modalities to treat acute stroke with acute recanalization therapies, including intravenous thrombolysis, intra-arterial chemical thrombolysis and mechanical thrombectomy, thromboaspiration, or angioplasty. While these new modalities of therapy have been promising, there remains a very real limitation to the overall rate of successful recanalization for current standard interventions. As a result, extrapolation from the cardiac literature has lead to early efforts using primary intracranial stenting to achieve safe recanalization. A major advantage of intracranial stenting is immediate flow restoration, as time to recanalization has repeatedly been shown to be a strong predictor of outcome in stroke. We will provide a cursory review each of the major established methods of acute stroke recanalization therapy, followed by a detailed review of intracranial stenting for acute stroke recanalization.

## 2. Intravenous tPA thrombolysis

Recombinant tissue-plasminogen activator (rt-PA) has been approved by the FDA for the use as a medical therapy in acute stroke. However, only 1% of acute stroke patients' patients in the US receive rt-PA (Barber 2001). The rate of recanalization using intravenous rt-PA is around 10%-30% when used within 3 hours of symptoms onset (Wolpert et al 2007). The rates of recanalization of large vessels are modest at best. Recanalization of a large internal carotid artery occlusion using intravenous rt-PA is around 10% and it can be as high as 30% of Middle Cerebral artery occlusion (Wolpert et al 2007) (Saqqur 2007). Recent studies, including European Cooperative Acute Stroke Study 3 (ECASS 3), have demonstrated that there may be a benefit in administering intravenous rt-PA up to 4.5 hours from the time of onset (Hacke 2008).

## 3. Intraarterial tPA thrombolysis

Large proximal intracranial arteries can be recanalized more effectively with intra-arterial rt-PA than with intravenous rt-PA (Tomsick 2008). The Prolyse in Acute Cerebral Thromboembolism (PROACT) II trial revealed that intra-arterial proukinase within 6 hours of onset has 66% recanalization rate but with a higher intracranial hemorrhage 10% versus 2%. In other words, for every 7 patients that are treated with intraarterial rt-PA, 1 patient will benefit (Furlan Jama 1999). Following the IMS (Interventioanl Managemenet of Stroke) I

and II pilot trials, where the combined intervention of both intravenous and intraarterial rt-PA was more effective than the standard intravenous rt-PA alone for patients with NIH stroke scale of 10 or worse (IMS II 2007), the IMS III trial is currently underway. The aim of the IMS III trial is to enroll 900 patients with NIH stroke scale of 10 or higher and to randomize them to IV tPA therapy alone or IV tPA plus intra-arterial rt-PA infusion, MERCI thrombus-removal device (see below), Penumbra Aspiration Device (see below) or infusion of rt-PA with low intensity ultrasound at the site of the occlusion (Khatri 2008).

#### **4. Mechanical thrombectomy**

There are multiple mechanical thrombolysis techniques on the market today that treat acute stroke. They include Merci retriever (Concentric Medical, Mountain View, CA), snares and Alligator (EV3, Irvine, CA). Mechanical Embolus Removal in Cerebral Ischemia (MERCI) trial in 2004 revealed a recanalization rate of 64% within 6 hours of onset of stroke when used with or without intra-arterial rt-PA (Gobin 2004). Advancement in device design has lead to improved outcome with rate of recanalization exceeding 69% when using intra-arterial rt-PA as an adjunct to MERCI device (Smith 2008). The use of Snare (Medical Device Technologies, Gainesville, Fl) and alligator devices has been limited. Case report and small case series have been noted in the literature. For example, Hussain et al (Hussain 2009) describes a case series of 7 patients where alligator device was used to remove a clot in a straight segment vessels. Of the 7 patients, 5 attempts were successful in retrieving the clot with 1 complete recanalization and 4 with partial recanalization.

#### **5. Thromboaspiration**

Penumbra system (Penumbra, Alameda, CA) has shown to be very effective in acute stroke in early studies. One small series reported a revascularization rate of 100% in 21 vessels (20 patients) (TIMI 2 or 3) when using the Penumbra device (Bose 2008). At 30 days post-procedure, 45% of the patients had an improvement of 4 point or better on the NIH stroke scale with a modified Rankin scale of 2 or better. The mortality rate was high (45%) but was not unexpected as the initial NIH stroke scale had a mean of 21 (Bose 2008). Importantly, more comprehensive studies have revealed less successful revascularization rates of 81.6% and an increased rate of intracranial hemorrhage, 28% (Penumbra Pivotal Stroke Trial Investigators 2009). Additionally concerning was that only a modest number of patients did achieve independent outcome at 90 days. Of interest, there was a higher recanalization rate in both internal carotid artery (82.6%) and middle cerebral artery (83%) clots, which suggest that the penumbra device might be particularly useful for large vessel occlusions.

#### **6. Angioplasty**

Balloon angioplasty can augment thrombolysis especially in cases of proximal middle cerebral artery occlusion. There are two retrospective studies with 16 total patients revealing that the use angioplasty was successful in 10 patients when used followed failure of chemical thrombolytic agents (Mori 1999). Complications of angioplasty include arterial dissection and “snow plowing” effect (occlusion of vessel perforators at the ostium by plaque displacement) (Levy 2006). Inflating the balloon to 90% of the parent vessel diameter has been suggested as a angioplasty technique in order to reduce the potential risk the intracranial vessel walls (Levy 2007).

## 7. Intracranial stents

The use of intracranial stent provides a great benefit of restoring immediate flow to the effected area. The evolution of using intracranial stenting for recanalization is a concept that is adopted from the cardiac literature.

Early successful use of balloon-mounted coronary stents, in the setting of acute stroke, has advanced the field of intracranial stenting (Levy 2009). Self-expanding stents were first introduced in 2002 with a modification designed for intracranial atherosclerosis became available later in 2005. Until recently, intracranial stents have been viewed as a reasonable “last resort” technique in acute stroke revascularization, however increasing interest has developed around using stents as a first-line modality for stroke treatment.

Despite acute stentings origins being found in the cardiac literature, it is important to note that intracranial pathology differs from cardiac pathology in two major ways. First, cerebral arteries lack an extensive external elastic lamina and are relatively fixed in position because of small branching and perforating arteries (Lee 2009). Therefore, any technology used intracranially, must be appropriately navigable and atraumatic. Second, cerebral occlusion is often the result of emboli lodged in a healthy vessel, whereas coronary artery occlusion is more commonly a product of local vessel disease. This may mean that stenting is of less value in acute stroke; however, an alternative hypothesis is that stent placement allows the opening of a channel in an embolus while limiting distal emboli and perforator occlusion.

The first reports of using stents for acute stroke were retrospective series utilizing balloon-mounted cardiac stents. These achieved a high recanalization rate (79% had TIMI grade 2 or 3 flow) (Levy 2006). Of the 19 patients that were treated within 6.5 hours of the onset of symptoms, 6 died and 1 had asymptomatic intracranial hemorrhage. While these results were excellent, in general, balloon-mounted stents are relatively inflexible and are difficult to deploy in the anterior circulation.

The introduction of self-expanding stents has provided, at least a theoretical advantage, by decreasing the risk of vessel dissection or rupture and reducing the barotrauma to the parent’s vessel (Levy 2006). Advantages of self-expanding stents include easier navigation to the target vessel, adaptation to the shape and anatomy of the affected vessel, and reduce rate of parent vessel rupture or dissection. The intracranial stents that are currently on the market in the US are Neuroform (Stryker Neurovascular, Fremont, CA), Wingspan (Stryker Neurovascular, Fremont, CA), and Enterprise (Codman, Raynham, MA). Only Wingspan is FDA-approved for the treatment of symptomatic intracranial stenosis, while others are indicated for coil assistant treatment. The Neuroform and the wingspan stents are open cell design while the Enterprise is a closed cell design.

Early case reports using the self expanding intracranial specific stents for arterial recanalization in 2 adults patients were first published in 2006 (Fitzsimmons 2006, Sauvageau 2006). This was followed by a multicenter, retrospective review of intracranial stenting for acute stroke in 2007 (Levy 2007) that demonstrated a successful recanalization rate of 79% (TIMI 2 or 3) in 18 patients (19 lesions). The use of self -expanding stents (Neuroform 16, wingspan 3) with a combination of thrombolysis and angioplasty, MERCI device, and/or glycoprotein IIb/IIIa inhibitor had no increased intraprocedural complication, however, there were 7 deaths with 4 due to progression of stroke, 2 from intracranial hemorrhage and an additional patient suffered respiratory failure. Of note, 7 patients had an improvement in their NIH scale within 24 hours from the procedure of 4 or greater points (Levy 2007).

A similar retrospective study of 9 patients who underwent placement of intracranial self-expanding stent intervention in the setting of acute stroke had recanalization rate of 89% (TIMI 2 or 3) (Zaidat 2008). The mean time to treatment was 5.1 hours with successful deployment of 9 stents (4 Neuroform, 5 Wingspan). Complications included 3 deaths, 1 intracranial hemorrhage and 1 acute in-stent thrombosis that were treated with glycoprotein IIb/IIIa inhibitor. All the surviving patients had a good clinical outcome have modified Rankin Scale of 2 or better at 90 days follow-up appointment.

Breckenfeld et al., in a single center retrospective study of self-expanding stents for acute stroke achieved 92% recanalization (TIMI 2 or 3) in 12 patients (Breckenfeld 2009). Treatment also included the use of thrombolysis, thromboaspiration, thromboembolectomy, and angioplasty as well stent placement. Complications included 1 vessel dissection and 4 deaths but no intracranial hemorrhages. The overall outcome was good in 3 patients (modified Rankin Scale of 0-2) and moderate in 3 patients (modified Rankin Scale 3) and poor in 6 (modified Rankin Scale of 4-6) at 90 days follow-up.

Stent-Assisted Recanalization in Acute Ischemic Stroke (SARIS) trial was the first FDA approved prospective trial for the use of stenting in the treatment of acute stroke (Levy 2009 stroke). The patients that were included had poor NIH Stroke scale (mean 14) and were treated within 5.5 hours of onset of symptoms. Adjuvant therapy included angioplasty (8), intravenous rt-PA (2) and intra-arterial thrombolytics (10). There was 100% recanalization in 20 patients (Wingspan 17, Enterprise 2, No Deployment 1) and three intracranial hemorrhages occurring within 24 hours with one symptomatic hemorrhage. An improvement of 4 points or more on NIH stroke scale was achieved in 65% of the patients. Sub-acute outcomes demonstrated that 12 patients (60%) had a modified Rankin Scale of 3 or better at 30 days and additional 5 patients (25%) died of complications related to the stroke. More recently Mocco et al. revealed similar results in 20 patients with acute stroke were treated with Enterprise stent (Mocco 2010). Of the 20 patients, 10 had received intravenous rt-PA, which was unsuccessful. In addition, 12 patients had MERCI retrieval attempted, 7 had angioplasty, and 12 had administration of glycoprotein IIb-IIIa administration. Three patients had Wingspan stents deployed and one that had an Xpert Stent (Abbott, Abbott Park, and IL) deployed. Following the deployment of the Enterprise stent there was 100% recanalization with 75% of the patients having improved NIHSS (National Institute of Health Stroke Scale) > 4 points. There were 2 patients (10%) with symptomatic intracranial hemorrhage.

## 8. Intracranial stenting as a temporary measure:

The use of self-expanding stents as a temporary bypass, thereby allowing vessel recanalization while limiting the potential long-term complications that are associated with deploying a permanent stent such as in-stent stenosis or complications related to antiplatelet therapy. There are early case reports of using this technique in order to re-establish flow in a proximal Middle Cerebral artery occlusion despite failure of mechanical thrombolysis and chemical thrombolytics administration (Kelly 2008). The partial sheathing of an Enterprise stent allows for immediate revascularization of the artery without committing the patient for a permanent stent placement. After 20 minutes of blood flow, the stent was removed. The patient had a seven point's improvement to his NIH Stroke Scale following the procedure. A similar case was described using partially deployed Enterprise stent for a vertebrobasilar occlusion at 9 hours following onset. The patient did have 8 points improvement in their NIH stroke scale (Hauk 2009).



These early temporary deployment measures have led to further work in developing stent based thrombectomy tools, often referred to as “stent-on-a-stick”. The most utilized of these rapidly expanding technology is the Solitaire device (EV3, Irvine, CA).

The Solitaire was first developed for assistance with wide-neck cerebral aneurysms (Lubicz 2010). Solitaire stent is a self-expanding stent that can be completely retrieved even when fully deployed (Lubicz 2010). A recent European study of 20 anterior circulation stroke patients treated within 8 hours of symptom onset with the Solitaire demonstrated a 90% revascularization rate, of which 16 had immediate restoration of flow following stent deployment (Castano 2010). Complications included 2 (10%) patients with intracranial hemorrhage, 4 (20%) died within 90 days. The 90 day follow up revealed that 45% of patients had a modified Rankin Scale score of 2 or better. There is also a recent randomized clinical trial of Solitaire Stent versus MERCI device, which has been completed, and the data is expected shortly. Additionally, there is an ongoing trial to evaluate a newer “stentriever” device called the Trevo (Concentric, Mountain View, CA). It is unknown, at this time, when this trial will be completed.

## 9. Conclusion

Acute stroke treatment has developed dramatically over the past decade and a half. Endovascular therapies have led to improved recanalization rates, while simultaneously extending the therapeutic time window. Recent publications suggest that intracranial stents effectively recanalize occluded cerebral blood vessels refractory to traditional techniques and, perhaps more excitingly, prospective data collected on the use of intracranial stents as a first line therapy have reported recanalization rates approaching 100%, and excellent clinical outcomes. While these data, from a highly selected series of patients, are certainly encouraging, significant concerns remain regarding the use of intracranial stents for acute stroke recanalization. These include the need for prolonged double antiplatelet therapy and continued limitations in the navigability of the current generation of intracranial stents. In the coming years we will doubtless see many further advances on the concepts of stent based acute stroke recanalization.

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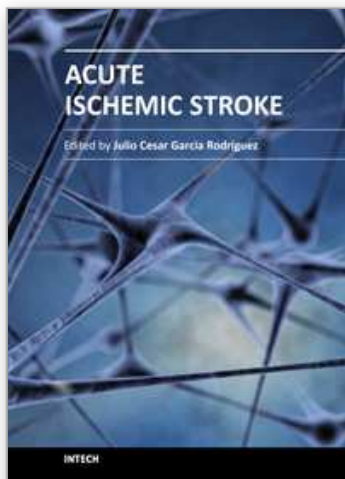
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### **Acute Ischemic Stroke**

Edited by Prof. Julio Cesar Garcia Rodriguez

ISBN 978-953-307-983-7

Hard cover, 236 pages

**Publisher** InTech

**Published online** 18, January, 2012

**Published in print edition** January, 2012

Despite significant technological advances in recent years, their impact on our overall health and social, well-being is not always clear to see. Perhaps, one of the best examples of this can be highlighted by the fact that mortality rates as a result of cerebrovascular diseases have hardly changed, if at all. This places cerebrovascular diseases as one of the most prominent causes of both disability and death. In Cuba, for instance, a total of 22,000 cases of cerebrovascular diseases are reported each year in a country where life expectancy should increase to 80 years in the near future. In such a situation, to have a book that includes in a clear and summarized way, a group of topics directly related to the preclinical investigations advances and the therapeutic procedures for the cerebrovascular disease in its acute phase constitutes a useful tool for the wide range of the contributors to this affection's problems solution. In this group is included students, professors, researchers, and health policy makers whose work represents one of the greatest social and human impact challenges of the XXI century basic and clinical neurosciences.

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Ahmad Khaldi and J. Mocco (2012). Intracranial Stenting for Acute Ischemic Stroke, *Acute Ischemic Stroke*, Prof. Julio Cesar Garcia Rodriguez (Ed.), ISBN: 978-953-307-983-7, InTech, Available from: <http://www.intechopen.com/books/acute-ischemic-stroke/intracranial-stenting-for-acute-ischemic-stroke>

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