

# Acute Combined Revascularization in Acute Ischemic Stroke with Intracranial Arterial Occlusion: Self-expanding Solitaire Stent during Intravenous Thrombolysis

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## ABSTRACT

**Purpose:** To investigate the safety and efficacy of the self-expanding Solitaire stent used during intravenous thrombolysis (IVT) for intracranial arterial occlusion (IAO) in acute ischemic stroke (AIS).

**Materials and Methods:** Consecutive nonselected patients with AIS with IAO documented on computed tomographic angiography or magnetic resonance angiography and treated with IVT were included in this prospective study. Stent intervention was initiated and performed during administration of IVT without waiting for any clinical or radiologic signs of potential recanalization. Stroke severity was assessed by National Institutes of Health Stroke Scale (NIHSS), and 90-day clinical outcome was assessed by modified Rankin scale (mRS), with a good outcome defined as an mRS score of 0–2. Recanalization was rated by thrombolysis in cerebral infarction (TICI) scale.

**Results:** Fifty patients (mean age,  $66.8 \pm 14.6$ ) had a baseline median NIHSS score of 18.0. Overall recanalization was achieved in 94% of patients, and complete recanalization (ie, TICI 3 flow) was achieved in 72% of patients. The mean time from stroke onset to maximal recanalization was  $244.2 \pm 87.9$  minutes, with a median of 232.5 minutes. The average number of device passes was 1.5, with a mean procedure time to maximal recanalization of  $49.5 \pm 13.0$  minutes. Symptomatic intracerebral hemorrhage occurred in 6% of patients. The median mRS score at 90 days was 1, and 60% of patients had a good outcome (ie, mRS score 0–2). The overall 3-month mortality rate was 14%.

**Conclusions:** Combined revascularization with the Solitaire stent during IVT appears to be safe and effective in the treatment of acute IAO.

## ABBREVIATIONS

AIS = acute ischemic stroke, CI = confidence interval, IAO = intracranial arterial occlusion, ICA = internal carotid artery, IMS = Interventional Management of Stroke [trial], IVT = intravenous thrombolysis, MCA = middle cerebral artery, mRS = modified Rankin scale, NIHSS = National Institutes of Health Stroke Scale, OR = odds ratio, rt-PA = recombinant tissue plasminogen activator, TICI = thrombolysis in cerebral infarction

The early recanalization of an occluded cerebral artery is crucial for clinical improvement and good outcome in

patients with acute ischemic stroke (AIS) (1). Although intravenous thrombolysis (IVT) is a safe and effective

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therapy for acute stroke when used within the first 4.5 hours from symptom onset, it has a relatively low recanalization rate for large vessel occlusions, and therefore is associated with poor outcomes (2–4). Intra-arterial thrombolysis has been shown to be more effective than IVT in the treatment of occluded cerebral vessels (5–7); however, it might be associated with an increased frequency of early symptomatic intracerebral hemorrhage (5,6).

In the past decade, several small series (8–11) showed promising data with respect to the use of mechanical devices in the treatment of AIS. Subsequent, larger prospective trials confirmed the previous positive results not only in patients eligible for IVT, but also in combination with IVT or intraarterial thrombolysis (12–14).

During the past few years, stent retrievers, which allow simple thrombus extraction, have been introduced (15) and tested in several small pilot studies involving patients treated within 8 hours of stroke onset (16–18). Our center began to use the self-expanding stent retriever (Solitaire AB; ev3, Irvine, California) because of its unique ability to achieve immediate flow restoration when deployed and its easy retrieval if not detached.

Waiting for the effect of IVT (ie, the lysis of thrombus) may significantly delay endovascular treatment, and it therefore may be reasonable to simultaneously initiate intraarterial therapy (19). With the target of reaching the shortest possible interval from stroke onset to successful recanalization, and respecting the guidelines for IVT administration, the concept of combined therapy was implemented in our center as a standard treatment approach, which included initial IVT followed directly by endovascular treatment with the use of the stent retriever without a period of waiting for clinical improvement or radiologic signs of early recanalization during intravenous infusion of recombinant tissue plasminogen activator (rt-PA).

The aim of the present prospective study was to report the safety and efficacy of combined revascularization therapy with a stent retriever (Solitaire AB; ev3) used during IVT for acute intracranial arterial occlusion (IAO) in patients with AIS.

## MATERIALS AND METHODS

### Patients

A prospective observational single-center study was conducted. Consecutive nonselected patients with AIS with baseline computed tomographic (CT) angiography– or magnetic resonance (MR) angiography–documented occlusion of the middle cerebral artery (MCA; segment M1 or M2) or distal part of the internal carotid artery (ICA) or basilar artery treated between June 2010 and April 2012 at our stroke center were included in the

study. All patients were initially treated with standard full-dose IVT within 4.5 hours from symptom onset according to present guidelines (20). The study protocol was in compliance with the Declaration of Helsinki (1975) and was approved by the ethical committee of our hospital. All patients or their relatives provided informed consent for study participation and the intervention procedure.

On admission, the blood pressure was measured, an electrocardiogram was recorded, and standard blood samples were obtained. Clinical status was evaluated per the National Institutes of Health Stroke Scale (NIHSS) by a certified neurologist. A brain imaging examination followed immediately. All patients underwent CT including CT angiography (LightSpeed RT, GE Medical Systems, Milwaukee, Wisconsin) or MR imaging including MR angiography (Symphony; Siemens, Erlangen, Germany) of the arteries comprising the circle of Willis.

### Procedure

The preparation of endovascular intervention was initiated immediately after the detection of an occluded artery on CT angiography or MR angiography. After the initiation of a standard full-dose rt-PA infusion, all patients were transferred directly to the angiographic room without any period of waiting for eventual clinical improvement and without any subsequent radiologic control (including transcranial Doppler studies) to detect signs of early recanalization. Patients underwent sedation or general anesthesia according to present clinical status and stroke severity. In patients with a risk of aspiration, loss of consciousness, or severe aphasia with poor cooperation, general anesthesia was preferred. To maximally economize time, the intervention procedure was initiated earlier (groin puncture, guiding catheter insertion) during the preparation of general anesthesia. All interventions were performed by using a single-plane interventional suite (Allura Xper FD 20; Philips, Amsterdam, The Netherlands). The full-dose infusion of rt-PA was continued during the intervention until the planned end of rt-PA administration, even if the intervention was successful before then. Presence of arterial occlusion and achievement of recanalization were rated according to the thrombolysis in cerebral infarction (TICI) scale (21).

In patients with an occlusion in the anterior circulation (ie, MCA or ICA), an 8-F guiding catheter (Guider Softip XF; Boston Scientific, Natick, Massachusetts) was placed into the proximal ICA. In patients with basilar artery occlusion, a 6-F guiding catheter (Guider Softip XF; Boston Scientific) was placed into the vertebral artery. Heparin 2,500 IU was administered in saline solution through the guiding catheter to prevent thromboembolization. The site of occlusion was reached by using a microcatheter system (Progreat 2.7-F;

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