The eJournal of the European Society of
Minimally Invasive Neurological Therapy

Mechanical thrombectomy in acute embolic stroke: results of a single centre retrospective analysis of 36 patients treated with the Solitaire™ FR device

EJMINT Original Article, 2013: **1305000102** (28th January 2013)
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Abstract

Introduction: Stent-based recanalisation techniques are increasingly used in stroke caused by large vessel occlusion. In this retrospective case series, we report our experience with 36 patients including technical and clinical results and complications with the Solitaire™ FR device

Methods: 36 consecutive patients (mean age 60.5 years, range 36-80) with acute ischaemic stroke were treated by thrombectomy with the Solitaire™ FR device between January 2010 and January 2012. The Thrombolysis in Cerebral Infarction (TICI) scale and clinical outcome was assessed using the modified Rankin scale (mRs) at 3 months (mRs ≤ 2 considered as good clinical outcome). We examined the correlation between outcomes and National Institutes of Health Stroke Scale (NIHSS) score, number of passes of the Solitaire™ FR device, TICI score, time to recanalisation and rt-PA application if performed.

Results: The mean NIHSS score to initial management was 16. The number of solitary passes was 1.7 (range 1-5). Recanalisation was successful in 32 cases (89 %) and the clinical outcome at 3 months showed revascularisation was good in 21 cases (58.5 %). Per procedural complication rate was 11 % (4 cases): 3 thromboembolic events and 1 subarachnoid haemorrhage (SAH). Intracerebral bleeding was found in 5 patients (14 %) without clinical complications. Initial NIHSS and number of passes of the device were associated with bad outcome.

Conclusion: Mechanical thrombectomy in cases of occlusion of large intracranial vessels with the Solitaire™ FR device appears to be safe and allows for a high recanalisation rate (89 %) with a good clinical outcome (58.5 % at 3 months). Easier retrieval generates better clinical results. A reliable imaging evaluation of the brain viability (MRI or CTP) remains critical to improving patient selection..

Keywords: neuroradiology, stroke, thrombectomy

Introduction

A rapid and complete recanalisation is a major factor in good clinical outcomes in treatment of acute cerebral ischemia [1]. Stent-based recanalisation techniques are increasingly used in stroke caused by large vessel occlusion, with promising results. Recanalisation rate may be achieved in 80 % of cases

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particularly with the Solitaire™ FR device (Covidien, Irvine, California, USA) [1-8]. This device is a self-expanding, non-detachable stent with closed cell design, retrievable after full deployment. Solitaire™ FR With the Intention for Thrombectomy (SWIFT) [9] and Trevo (Stryker Neurovascular, Mountain View, California, USA) versus Merci Thrombectomy Revascularisation of Large Vessel Occlusions in Acute Ischaemic Stroke (TREVO 2) [10] are 2 randomised studies which compared the MERCI Retriever, an FDA approved device for thrombectomy (Stryker Neurovascular, Mountain View, California, USA), with stent retrievers. Stent retrievers demonstrated significantly better results (recanalisation, outcome and mortality). We report our experience with 36 patients including technical and clinical results and complications with the Solitaire™ FR device.

Materials and methods

Patients

36 consecutive patients (mean age 60.5 years, range 36-80 years, 22 male) with acute ischaemic stroke were treated with thrombectomy between January 2010 and January 2012. Inclusion criteria were: occlusion of large intra cranial vessel within 6 h of stroke with National Institutes of Health Stroke Scale (NIHSS) score > 7; in cases of anterior circulation stroke, within less than 12 h of onset stroke symptoms in posterior circulation and no bleeding lesion (Table 1).

Technique

Depending on the availability of the diagnostic modality, patients were examined using either MRI (Axial slice in DWI, FLAIR, T2*, 3DTOF) (n=15) or CT (n=21) (plain CT scan, followed by AngioCT). Eight of 21 patients had CT perfusion (CTP). Retrospectively, the extent of initial ischaemic damage was assessed by the Alberta Stroke Program Early CT (ASPECT) score (11) based on diffusion weighted images (DWI) for patients examined by MRI or based on perfusion maps.

Patients were evaluated by a neurologist and received intravenous recombinant tissue Plasminogen Activator (rt-PA, 0.9 ml/kg) if no contraindication was present. All procedures were performed under general anaesthesia. After setting up an 8F catheter balloon (Merci Balloon Guide Catheter, Stryker Neurovascular, Mountain View, California, USA) in the internal carotid artery (ICA) or a 6F catheter Envoy (Codman Neurovascular, Raynham, Massachusets, USA) in the vertebral artery, the occluded vessel was catheterised with a microcatheter (Rebar 27, Covidien, Irvine, California, USA) and microwire. When the clot was crossed by the microcatheter, an injection was performed through the microcatheter to assess the length of the clot. The Solitaire™ FR (Size: 4 * 20 mm) was used in all cases. The device was opened and left in place for 5 min across the clot. To help thromboaspiration, we always inflated the balloon catheter at the level of the upper cervical carotid artery and performed aspiration through the main lumen of the catheter.

All patients were extubated at the end of procedure to evaluate neurologic status. A follow-up CT scan at 24 h was performed in all patients.

Rating

The result of the recanalisation was assessed according to the Thrombolysis in Cerebral Infarction (TICI) scale [12] (grade ≥ 2b was considered a good result). During the procedure, the number of passes attempted with the device was noted as well as presence of any embolic fragments (defined by the occurrence of thromboembolic occlusion in a remote territory). Bleeding complications were classified as follows: haemorrhagic infarction (HI 1 and HI 2) and parenchymal haematoma (PH1 and PH2) [13]. Symptomatic haemorrhage was defined as an increase of the NIHSS ≥ 4 [12]. The clinical course was assessed by the modified Rankin scale (mRs) at 3 months (score ≤ 2 considered as good clinical outcome).

We examined the correlation between outcomes (Good: mRs ≤ 2 vs. Bad: mRs ≥ 3) and the following factors: initial NIHSS score, number of passes of the device, final TICI score and time to necessary to achieve recanalisation (Mann-Whitney non-parametric test). In addition, we studied the impact of administration of IV injection of rt-PA before thrombectomy (Chi-squared test).

Results

Clinical presentation

The mean NIHSS score prior to treatment was 16 (range: 7-24). The occlusions involved the first segment of the middle cerebral artery (M1) in 25 cases (69.5 %), basilar artery in 6 cases (16.5 %), terminal ICA in 3 cases (8.5 %) and tandem occlusion (M1 + ICA in a case of dissection) in 2 cases (5.5 %) (Table 1). Aetiology was atrial fibrillation in 14 cases (38.75 %), atheroma in 8 cases (22 %), a patent foramen ovale in 3 cases (8.5 %), thrombosis of prosthetic cardiac valve in 3 cases (8.5 %), carotid or vertebral artery dissection in 3 cases (8.5 %) and thrombosis above a M1 stenosis in 1 case (2.75 %); in 4 cases (11 %) no aetiology was found. Eighteen patients (50 %) received IV rt-PA, and 18 patients (50 %) did not receive thrombolytic agent due to contraindications.

Procedure characteristic

The mean time between onset of symptoms and arterial puncture was 220 min, time to recanalisation was 290 min and duration of the procedure was 70 min. The mean number of device passes was 1.7 (range: 1-5) (Table 2). In 5 cases (14 %) an additional technique was used: detachment of the Solitaire™ FR in 1 case and insertion of a balloon expandable stent (Pharos Vitesse, Codman Neurovascular, Raynham, Massachusetts, USA) in another case. In 3 cases, an additional dilation balloon (Gateway, Boston Scientific, Fremont, California, USA) was used after revascularisation to treat atheromatous residual stenosis on the vertebro-basilar system. All patients showed complete occlusion at the beginning of the procedure (TICI 0). Recanalisation was successful in 32 cases (89 %) (TICI 3 and 2b), in 2 cases a TICI 2a was achieved (5.5 %), in 1 case a TICI 1 (2.75 %) and in 1 case no recanalisation could be achieved: TICI 0 (2.75 %) (Table 3).

Complication

Procedural complication rate was 11 % (4 cases): 3 embolic fragments (anterior cerebral artery (ACA): n= 2, multiple: n= 1) and 1 subarachnoid haemorrhage (SAH). The 24 h CT scan showed high density in 5 cases (14 %): HI 1 in 3 cases (8.5 %), HI 2 in 2 cases (5.5 %) and 0 were symptomatic (Table 2).

Follow-up

The clinical outcome at 3 months was good in 21 cases (mRs ≤ 2) (58.5 %). Mortality was 19.5 % (7 cases) (Table 3).

Discussion

The technical data concerning our procedures are similar to those reported in a recent analysis by Koh et al. [6] from 13 papers reporting stent retriever recanalisation including a total of 262 patients (Tables 1, 2 and 3).

We have the opportunity to perform procedures under general anaesthesia because an anaesthesiologist is always available for interventional neuroradiology. Sedation without intubation is excluded from practice in our institution. General anaesthesia is used in most studies in the literature to decrease risks associated with patient movement and to protect the airway. Alternate techniques of sedation without intubation for mechanical thrombectomy are proposed and a review of the literature [14] on this modality of sedation seems to show excellent results. Additionally, in a prospective study of 36 patients [15], Soize et al. found thrombectomy feasible under conscious sedation in 86.1 % of cases, with good functional outcome in 61.1 %.

Pragmatically, the neuroradiologist has to take into account the availability and practice of anaesthesia in their institution. Due to lack of randomised studies, it seems difficult today to raise guidelines. The time necessary to perform general anaesthesia may be considered as "time consuming". In an aim to shorten the time to thrombectomy, once the procedure is confirmed, we prepare the devices. Whatever technique used, we aim to achieve acceptable immobility of the patient and to avoid a drop in arterial blood pressure during the procedure (mainly under general anaesthesia).

Recanalisation

The recanalisation rate in our patients was successful (TICI ≥ 2b) in 89 %, similar to the mean successful results in the review of Koh et al. [6] (89.7 %).

In 2 cases, we had failure (TICI 1 n=1; TICI 0 n=1). For these patients, the origin of the occlusion was cardio-embolic. Despite expansion of the device, no circulation could be restored and clot withdrawal was unsuccessful, with mRs at 3 months of 3 and 5 respectively.

In 1 patient (origin of the clot: atheroma), despite reperfusion during device expansion, clot removal remained impossible and reocclusion occurred following all attempts. However, even though the device is not designed to be detached, we left the Solitaire™ FR in place across the lesion and obtained a TICI 2a recanalisation and mRs 3 at 3 months. Detachment of a permanent stent in a major intracranial vessel during acute ischaemia has been proposed [16, 17] with fair results. On the other hand, intra-stent thrombosis may occur and use of antiplatelets drugs may be complicated by haemorrhage [16, 17]. When recanalisation with stent retriever is unsuccessful, permanent insertion of a stent may be an additional procedure necessary to obtain mechanically the patency of the vessel as recently pointed out by Egashira et al. [18].

Outcome

Good outcome was observed at 3 months in 58.5 % of patients (mRs ≤ 2). These results are good when compared to the review by Kohl et al. [6]; however, our occlusion sites show a higher percentage of middle cerebral artery (MCA) occlusion (69.5 % vs. 56.9 %). This location is known to have a better prognosis than other locations such as posterior circulation or tandem lesions. A statistically significant correlation was found in our study between initial NIHSS and outcome at 3 months (Table 4). These data are consistent with the results of a prospective paper by Costalat et al. examining prognostic factors [19] with 50 thrombectomies in which a better outcome (70 %) was associated with MCA location. Furthermore, in the same paper, initial NIHSS was an independent predictive factor of prognosis. In our series, the number of attempts required to achieve reperfusion was inversely correlated with good outcome. It appears that easier thrombectomy may lead to shorter and safer procedures. To our knowledge this has not been reported in previous series (Table 4). Unlike other studies [20-21], we found no statistically significant correlation with the TICI recanalisation score and IV rt-PA administration; however, the size of our sample was smaller. Another possible bias might be that at the beginning of our series, patients were included following CT and CT angio without CTP.

Procedural complication rate (11 %)

We observed embolic fragments in 3 cases (8.5 %). In 2 cases these occurred at the second segment of the anterior cerebral artery (A2) and ACA + posterior cerebral artery (PCA);no ischaemic lesions were observed on follow-up CT scans suggesting minimal deleterious effect (the mRs at 3 months was 2 and 3 respectively). The third patient had an embolic occlusion of A2 and died of malignant MCA infarction within 48 h. This embolic rate is consistent with some previous reports concerning 56 [22] and 108 [23] patients. We think that balloon inflation during clot retrieval may reduce the number of embolic events. Indeed, we observed in some cases that the embolic material was retrieved not only within the stent but also from the blood aspirated from the balloon catheter, as also reported by Costalat et al. [22]. Special attention to introduce further injections via the guiding catheter (angio control or new attempt) may be advisable at the time of procedure. Vascular perforation complicated the opening of a permanent stent in 1 case. After successful thrombectomy, the underlying calcified residual stenosis (M1) required permanent stenting (Pharos Vitesse, Codman Neurovascular, Raynham, Massachusetts, USA) . This stenting procedure was complicated by an arterial injury of the MCA bifurcation. A transient leak of contrast was observed within the sylvian fissure, but bleeding ceased after temporary inflation of the balloon and complete clinical recovery occurred (mRS at 3 months: 0). This bleeding did not complicate the thrombectomy itself, but did complicate the additional procedure. In our series, the Solitaire™ FR did not cause vascular injury. In a published series, SAH complicated primarily distal thrombectomy (M2) and balloon angioplasty, but were usually asymptomatic [6, 22, 23].

Haemorrhages (14 %)

In 5 patients bleeding was observed within the territory of the recanalised artery. In 3 cases (HI 1 n=2; HI 2 n=1) no clinical impairment was noted. The 2 remaining patients died at 48 and 72 h respectively. The volume of haemorrhage (HI 1 n=1; HI 2 n=1) compared with the mass effect of ischaemic tissue did not explain the clinical deterioration [24]. In other publications [6, 22-23] symptomatic haemorrhages are reported in 2-6 %, and are associated with poor prognosis. [19].

Mortality (18.5 %)

Mortality in our series is consistent with early papers by Castano et al. (20 %) [2] and Roth et al. (18 %) [3], but is higher than in the study of Koh et al. (11 %) [6].

In our series, 7 patients died, all of malignant infarction. The procedure was always technically successful (TICI 3), raising the question of the accuracy of inclusion criteria and evaluation of brain viability. Indeed, tolerance to large vessel occlusion is very different from one patient to another. Large lesions may complicate the arterial obstruction. Among these 7 patients, 3 were studied by MRI and 2 had an initial ASPECT score of 4. This is consistent with the Costalat et al. paper [19] which shows that a DWI ASPECT score less than 5 was a reliable value to predict poor results (lack of salvageable ischaemic areas and risk of complications) when thrombectomy is performed. Similar values in IV thrombolysis are found by Nezu et al. [25]: an ASPECT score of less than 4 was associated with death and an ASPECT score less than 5 associated with intracerebral haemorrhage.

The remaining 4 dead patients were only explored by angioCT without CTP (2 occlusions of the basilar artery and 2 occlusions of the MCA). In regard to the MCA occlusions, we retrospectively observed a poor retrograde filling of the distal MCA branches on both DSA and angioCT.

These results highlight the importance of imaging viability selection criteria as compared with the single time-based criteria, which appeared insufficient. Diffusion Weighted Imaging Evaluation for Understanding Stroke Evolution Study-2 (DEFUSE 2) [26], a prospective multicentre cohort study enrolling 99 patients within 12 h of stroke onset, demonstrated persistent clinical improvement after thrombectomy performed after 6 h in patients with an MRI mismatch. These results point out the relative weakness of time criteria. Turk et al. [27-28] in a single centre and multi centre study included 140 and 247 patients respectively based on perfusion CT maps and demonstrated that patients fulfilling criteria showed similar neurological recovery if treated before or after 7 h following onset of stroke.

The series we report reflects a retrospective, single centre experience. This is a consecutive series including all patients treated for large vessel occlusion during this period. Some patients included at the beginning of our series lacked a reliable evaluation of brain viability by MRI or CTP. Nevertheless, in our experience, the procedure of thrombectomy with the Solitaire™ FR appears safe (no symptomatic haemorrhage, no mortality per procedure), prompt (mean operating time of 70 min) and effective (successful recanalisation in 89 % of cases, good outcome in 58.5 % of cases). These results are consistent with other published series using the Solitaire™ FR [3] or other “stent retriever” devices [29-30].

Conclusion

Solitaire™ FR recanalisation of acutely occluded large intracranial vessels appears to be an effective (TICI ≥2b, 89 %; mRs ≤ 2 at 3 months, 58.5 %) and safe procedure. Easier clot retrieval generates better clinical results. A good imaging evaluation of the brain viability (MRI or CTP) remains critical to improve selection mainly because the viability of underlying brain tissue may be maintained by collateral flow and permits an increased time to recanalisation.

Conflict of interest

We declare that we have no conflict of interest.

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Tables

Table 1 - Patient characteristics

Patient Characteristics		*Koh JS and all. [6]*
Number	36	*262, (13 studies)*
Age (range)	60,5 (36-80)	*58,9-76,4*
Male/Female	22/14	*149/113*
NIHSS (range)	16 (7-24)	*14-21,4*
Occlusion site :		
MCA	25 (69,5%)	*56,9%*
Terminal ICA	3 (8,5%)	*22,5%*
Tandem (ICA + MCA) (dissection)	2 (5,5%)	*21,6%*
Basilar artery	6 (16,5%)	*20,6%*

NIHSS : national institute of health stroke score
MCA : middle cerebral artery
ICA : internal carotid artery

Table 2 - Clinical and angiographic results

Results		*Koh JS and all. [6]*
TICI		
3 + 2b	**32 (89%)**	*89,7%*
3	25 (69,5%)	
2b	7 (19,5%)	
2a	2 (5,5%)	
1	1 (2,75%)	
0	1 (2,75%)	
Rankin score at 3 month		
≤ 2	**21 (58,5%)**	*50,8%*
0	7 (19,5%)	
1	9 (25%)	
2	5 (14%)	
3	6 (16,5%)	
4	0	
5	2 (5,5%)	
6	7 (19,5%)	*11,1%*

TICI : Thrombolysis in cerebral infarction

Table 3 - Procedure characteristics

Characteristics procedure		*Koh JS and all. [6]*
Number of passes	1,7 (1-5)	*1,4-2,5*
Time (min)		
Puncture (range)	220 (90-160)	*160-460*
Duration (range)	70 (30-150)	*37-95*
Recanalization (range)	290 (180-510)	*233-588*
Complication	**4 (11%)**	
Embolic fragments	3 (8,5%)	
ACA	*2*	
Multiple	*1*	
SAH	1 (2,75%)	
Hemorrhage	**5 (14%)**	
HI 1	3	
HI 2	2	
PH1	0	
PH2	0	*6,8%*

ACA : anterior cerebral artery
SAH : sub arachnoid hemorrhage
HI : hemorrhagic infarction
PH : parenchymal hematoma

Table 4 - Outcome correlation

	Good outcome	**Bad outcome**	**P**
NIHSS*	13	19	**0,02**
Rt-PA**	52%	46,5%	NS
Number of passes*	1,4	2,7	**0,001**
TICI > = 2b*	100%	73%	0,1
Time to recanalization (min)*	290	300	NS

Rt-PA : recombinant tissue Plasminogen Activator
TICI : Thrombolysis in cerebral infarction
* Mann whitney non parametric test
** Chi2 test