Mechanical Thrombolysis Using a Solitaire Stent

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SUMMARY – *Mechanical offers several advantages over drug thrombolysis: in particular, the haemorrhagic risk may be not significantly increased while working out the indications got intravenous drug thrombolysis. Available tools were in our hands inefficient, stiff and dangerous. We found a retrievable stent efficient and easy to handle for this purpose. This experience is described.*

Introduction

Several tools are used to mechanically recanalize acutely occluded cerebral arteries: we have direct experience of multiple catheter and guidewire passing through the thrombus, variously shaped retrievers [1], balloon angioplasty and stenting [2,3], temporary [4] or permanent stent delivery [5], dedicated systems, including aspiration [6], nitinol baskets [7], and helical retrievers [8] (see 9 for a comprehensive review of all available tools). None of the above tools were easy, effective, fast and safe to use in our hands. While using a Solitaire stent (SAB 4×20, EV3, Irvine, CA, US) as a temporary bypass [4] in a patient with acute MCA occlusion, we serendipitously were able to retrieve the embolus. In accord with other experiences (Liebig T and Castano C, oral communications, ABC-WIN meeting, Val d'Isere, January 11th, 2009), we used this tool as retriever to recanalize acutely occluded arteries in six consecutive patients as first-choice treatment, without using thrombolytic drugs. This experience is presented.

Material and Methods

In our hospital, mechanical recanalization is the first-choice treatment for severe ischaemic strokes not suitable for - or after unsuccessful - intravenous thrombolysis, according to an experimental protocol approved by ethical committee. We use an ordinary 6F guiding catheter (Envoy, Cordis, Miami, FL, USA), without extracranial balloon inflation for flow arrest, inserted in a 7F 80 cm long introducer sheath for carotid procedures. No heparin apart from flushing solution of the guiding catheter (5 IU/ml) is administered. Salicylate 300 mg is given before the procedure to all patients, except when r-TPA was given. A 021 microcatheter is placed into or at the distal end of the thrombus, and the stent is pushed in the vessel, then it is slowly resheathed. If a resistance is felt, the thrombus is caught through the meshes, and the system may be retrieved. If nothing is caught the microcatheter with the stent inside it is gently pushed and the manoeuvre may be immediately retried. Before the Solitaire enters the guiding catheter a contrast injection will allow us to estimate the thrombus size, and to decide whether to retrieve the whole system, including the guiding catheter, or to aspirate the thrombus through the guiding catheter. Consecutive patients submitted to this procedure from February to December 2009 were retrospectively reviewed.

Results

Six patients were treated, out of 13 submitted to intra-arterial treatment for ischaemic stroke. Reasons not to treat the remaining seven patients with the Solitaire were: unavailable tool (three patients), operator with no experience of the tool (two patients), purely ex-

Table 1

Pat.	*Sex, Age*	*Presumed etiology*	*Main symptoms*	*Time to needle*	*Systemic thrombolysis excluded*	*Occlusion site*	*Procedure time*	*N° of passes*	*Outcome (MRS)*
1	F, 52	embolic	hemiplegia, oculo-cephalic deviation	90	recent surgery	extracranial ICA + MCA	90	2 (plus stenting of extra cranial ICA)	2
2	M, 65	plaque thrombosis	tetraparesis, impaired consciousness	120	stroke severity	vertebral, lower basilar	90	1 (plus PTA)	1
3	F, 74	atero embolic	hemiplegia, aphasia, oculo-cephalic deviation	240	done at 130 minutes	carotid "T"	70	3	6
4	F, 68	atero embolic	anarthria, skew deviation, impaired consciousness	230	stroke severity	basilar tip	50	1	1
5	M, 72	atero embolic	tetraparesis, impaired consciousness	230	stroke severity	mid basilar	60	1	3
6	M, 53	ateroma	tetraplegia, coma, vertical nystagmus	480	large occipital infarction >24 h	basilar, upper 2/3	130	> 6	5

tracranial vessel occlusion (one case), distal middle cerebral artery occlusion (one patient). Demographic, clinical characteristics and outcomes are summarized in table 1. Briefly, in all but one patient treatment was technically successful; a single embolus was lost in the distal circulation. In three patients a single passage retrieved the embolus and restored the flow. In one case two passages – first unsuccessful – were required. In one case the vessel reopened after three passages successful in retrieving portions of a large carotid "T" thrombus; the distal middle cerebral artery was occluded by an embolus. In the unsuccessful case, an extended occlusion of the middle third of the basilar artery did not reopen after several passages. Clinical results were good in four patients. Unsuccessful recanalization lead to a locked-in syndrome. A single patient, previously submitted to intravenous thrombolysis, died due to sudden haemorrhage six hours after the procedure.

Illustrative Case

Patient 3. A 74-year-old women was submitted to systemic thrombolysis with r-TPA, two hours after onset of right hemiparesis, aphasia (NIHSS 26). Treatment was unsuccessful and the patient worsened (consciousness disturbances, oculo-cephalic deviation, difficulties in breathing, NIHSS 32). Angiography four hours after onset demonstrated right carotid "T" occlusion (figure 1). A microcatheter was placed in the carotid siphon. A Solitaire stent was deployed and retrieved, catching a very large thrombus (figure 2), that did not pass through the guiding catheter nor the introducer sheath, and was lost in the descending aorta. A second Solitaire stent was deployed in the left M1 segment, retrieving a second thrombus (not shown). It was not possible to pass a very hard occlusion of the distal M1, and the procedure was stopped. Final angiogram showed recanalization of carotid "T", anterior cerebral arteries, M1 segment, with residual distal occlusion of distal M1 (figure 3). CT scan showed contrast extravasation in the basal ganglia (figure 4). The patient recovered to an NIHHSS of 12 in the following two hours. Six hours later she became agitated and confused: a CT scan showed a large intraparenchymal left haematoma and the patient finally died.

Discussion

The scientific bases of intra-arterial thrombolysis are weak. A single trial (pro-ACT) demonstrated better outcomes in patients with

B

← A

Figure 1 *Patient* 3 (all angiographic images of this patient are unsubtracted, due to movement artifacts). Extracranial left internal carotid artery (A) and siphon (B) injection. Arrow marks the catheter tip.

middle cerebral artery occlusion treated by intra-arterial thrombolysis compared to a sham procedure [10]. Concerns remain if results apply to different vessels – meaning different anatomy and different stroke severity – or to different drugs.

Mechanical recanalization offers several advantages over pharmacological thrombolysis with r-TPA: in particular, patients with severe strokes due to large emboli and over the three hour time-window may be theoretically managed [9]. No randomized trials on mechanical intra-arterial procedure have been published to date. In spite of this, to our knowledge at least three different systems to perform mechanical recanalization have been cleared in Europe and used by our team: Merci (Concentric Medical, Mountain View, CA, USA), Catch (Balt, Montmorency, France), and Penumbra (Chestnut Medical, Alameda, CA, USA). Our experience with these tools was limited, but negative: our results have not improved since the introduction of such new tools, and we were unable to replicate the published results. This

Figure 2 *Patient* 3. A) The Solitaire stent is placed in the thrombus (arrow). Contrast injection through the guiding catheter shows a large filling defect corresponding to the thrombus (arrowheads mark the proximal end of the thrombus). B,C) Successive phases of clot retrieval.

Figure 3 *Patient* 3. Final angiogram. MCA occlusion could not be passed by the microcatheter and the vessel was left occluded.

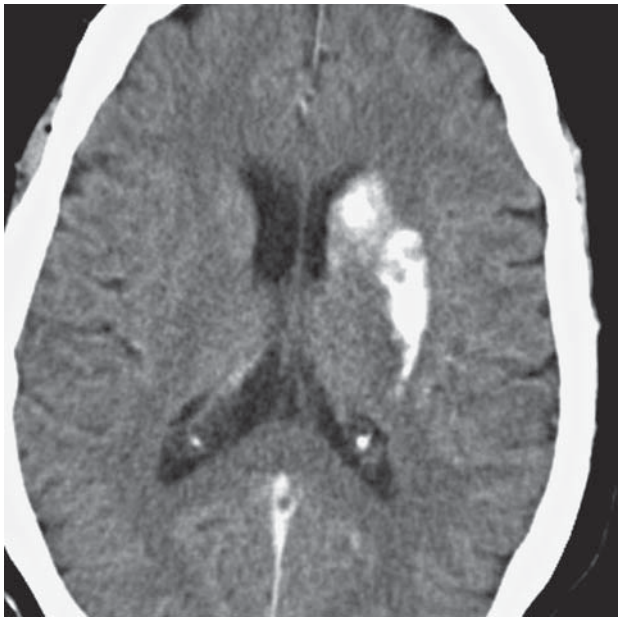

Figure 4 *Patient* 3. Immediate post-operative CT scan shows contrast media - and possibly blood - extravasation into the basal ganglia. The cerebral cortex shows no evident lesions.

is because none of the tools are user-friendly, and no tool is definitely more efficient than the others, in spite of differences seen *in vitro* [11] or *in vivo* [12]. In particular, multiple passes of both Merci and Catch systems are usually needed, requiring multiple removal and replacement of a stiff system. In our experience the Penumbra system is efficient in a large vessel only, less or not at all useful in supra-willisian arteries. Generic lazoo-shaped retrievers are softer, but also less efficient. Balloons are easy to use and efficient, but they may be extremely dangerous and, more relevant, distal embolization is the rule. Balloon-mounted stents are stiff compared with ordinary neurointerventional tools.

Because of the above, we did not consider clearance of a system a mandatory reason to use it, since the scientific evidence of the efficacy of the treatment itself is lacking. Then, we adopted as internal policy for mechanical thrombolysis the use of a tool that the operator knows well, and that may be carried to the occlusion site with ordinary maneouvres, namely balloons, stents and retrievers.

The Solitaire stent is a self-expandable intracranial stent, originally designed to treat wide-necked aneurysms, delivered through a 021 microcatheter. The stent expands when it exits from the catheter, and it may be retrieved since it is attached to a steel wire, or eventually released by electrolysis. When the stent is open in front of the embolus, it is pressed against the vessel wall, restoring the flow. Resheathing of the stent led to thrombus catching in the majority of cases. In our experience, if the stent is resheathed in front of a coiled aneurysm, even coils are frequently caught.

We found this tool easy to handle: seven out of eight passages in successful cases retrieved some thrombus. Two patients had contrast media extravasation in ischaemic areas: in our experience this is a frequent finding in patients submitted to selective intra-thrombus contrast injection, and it is not necessarily due to vessel wall damage during mechanical maneuvers. *Patient 2* died from basal ganglia delayed haemorrhage. Although a vessel rupture during manoeuvres may not be excluded, bleeding may have been due a late recanalization of M1 in a patient with previously administered r-TPA and large basal ganglia infarction. We attributed the single unsuccessful procedure to an atheromatic plaque occluding the vessel. Both clinical (minor pontine strokes some weeks before; large occipital infarction one day before) and CT findings (extensive calcification on the wall of the basilar artery) suggested the diagnosis.

The most difficult portion of the procedure is to place a microcatheter into the thrombus

– basically, the first step for every kind of intra-arterial thrombolysis. This blind navigation into occluded arteries probably remains the most dangerous step of the whole procedure, and contrast injection through the microcatheter is required to avoid inadvertent catheterization on small vessels.

The self-expandable nature of the stent allows small diameter vessels and tortuous anatomies to be treated. The manoeuvre may be rapidly repeated in unsuccessful cases by re-advancing the microcatheter.

Finally, the stent may be detached from the pusher if excessive strength is applied. In this case the final result will be stenting of an occluded artery that may eventually be considered a therapeutic alternative per se.

This limited series obviously does not allow a direct comparison with different devices, possible even more effective. On the other hand, in our opinion the use of ordinary, instead of "dedicated" materials in a relatively uncommon procedure allows faster, easier and finally less dangerous interventions.

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