Journal of Neuroradiology xxx (2017) xxx–xxx

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Original Article

Multicenter initial experience with the EmboTrap device in acute anterior ischemic stroke

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ARTICLE INFO

Article history:
Available online xxx

Keywords:
Stroke
Embotrap
Endovascular
Anterior
Acute
Thrombectomy

ABSTRACT

Background and purpose. – Mechanical thrombectomy predominantly using stent retrievers effectively restores cerebral blood flow and improves functional outcomes in patients with acute ischemic stroke. We sought to determine the safety and efficacy of mechanical thrombectomy using the EmboTrap device.
Materials and methods. – We identified 80 consecutive patients from 4 centers with acute ischemic stroke treated with EmboTrap from June 2015 to December 2016. All patients had confirmed large vessel occlusions in the anterior circulation using CT or MR angiography with salvageable tissue. We assessed baseline characteristics and treatment related parameters including onset-to-treatment time, recanalization success (mTICI 2b or greater), complications, and good clinical outcome (mRS 0 to 2).
Results. – Successful recanalization was achieved in 72 patients (90%). When considering the use of a second thrombectomy device as failure, the EmboTrap successfully recanalized 65 patients (81%), with complete (mTICI 3) recanalization in 40 patients (50%) within 1 or 2 passes. Median procedure time (groin to recanalization) was 35 minutes (8–161 minutes). During the procedure, distal emboli in previously unaffected territories were found in 5 (6%) patients. There were 3 vasospasms (4%) and no vessel perforations. Intracranial hemorrhage on CT at day 1 was found in 18 17 (2321%) patients, none with subarachnoid hemorrhages, and 5 were symptomatic (6%). Good clinical outcome occurred in 4749/68 78 patients (6963%).
Conclusions. – In this multicenter retrospective study, the EmboTrap device achieved high recanalization rates, good clinical outcomes and was safe in treating acute stroke patients with large vessel occlusions.
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Introduction

Large randomized control trials have shown significant benefits of endovascular thrombectomy (EVT) predominantly using stent-retrievers in combination with intravenous tissue-plasminogen activator (IV tPa) compared to IV tPa alone in acute ischemic stroke (AIS) particularly in the anterior circulation [1]. Good reperfusion rates in the five positive trials published in 2015 (MR CLEAN, ESCAPE, EXTEND-IA, SWIFT PRIME and REVASCAT) ranged from 59 to 88% [2–6]. More recently, large single or multiple center series of stent-retriever thrombectomy patients reveal good reperfusion rates ranging from 67 to 94% together with low procedure times less than 1 hour, although final angiograms are not core-lab validated like clinical trials [7–12]. This wide range likely reflects the variation of patient selection (i.e.–ASPECTS, perfusion, stroke severity), intervention technique (i.e.–using balloon guide catheters or distal intracranial catheters), and thrombectomy devices used in the clinical trials and large cohort patient series, and remains an open questions even today [13,14]. Of note, the ASTER trial recently published failed to show superiority of direct contact aspiration compared to stent-retrievers [15]. With the use of EVT becoming more widespread, technical improvements to these devices are

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https://doi.org/10.1016/j.neurad.2018.01.052
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Please cite this article in press as: Bourcier R, et al. Multicenter initial experience with the EmboTrap device in acute anterior ischemic stroke. J Neuroradiol (2017), https://doi.org/10.1016/j.neurad.2018.01.052

needed to achieve recanalization in fewer attempts and to successfully recanalize the remaining 15 to 35% of cases [11,15].

Stent-retriever designs differ in size, shape and physical properties, such as radial force, ease of deployment, friction, radio-opacity and interaction with vessel wall [16,17]. Neuravi (Galway, Ireland) developed the EmboTrap Revascularization Device based on in-vitro stroke models that incorporate realistic clot analogs derived from animal blood that represent the wide range of human clots retrieved from stroke patients [18]. Studies of clots suggest particularly challenging retrievals may be due to softer, erythrocyte rich clots that tend to fragment easily, and the firmer, fibrin rich clots that have a significantly higher coefficient of friction [19]. As described elsewhere, the segmented outer cage of the EmboTrap is designed to trap a wide range of clot compositions inside the device and an inner channel to stabilize the clot during retrieval. The articulated body allows the segments to remain open and apposed to the vessel wall while retracted through challenging vessels [20]. Here, we report the initial experience in 4 high volume centers (more than 100 cases a year) with this novel device in terms of efficacy and safety.

Materials and methods

Patient selection

All consecutive patients with AIS in anterior circulation [including distal internal carotid artery (ICA), carotid T, middle cerebral artery (MCA) segments M1 and M2] treated with EVT using the EmboTrap Revascularization Device (Galway, Ireland) as first or second line device, were retrospectively included from June 2015 to December 2016 across four different centers. There were no specific criteria prescheduled to choose EmboTrap rather than another mechanical thrombectomy device in this study. According to the availability of the material and as in this period, there were not any recommendation regarding a preferred type of stent retriever, EmboTrap were used randomly in the flow of patients. 8 experienced INR-Operators (at least 5 years) used the device.

For each included patient, we recorded age, gender and cardiovascular risk factors (diabetes mellitus, obesity, smoking, high blood pressure, hyperlipidemia).

Initial imaging was brain CT with cervical and intracranial angiography or brain MRI with time of flight angiography, depending on hospital protocol. The ASPECT (Alberta Stroke Program Early CT) score was evaluated by experienced neuroradiologists on either modality, and the NIHSS score by neurologists. Patients were treated up to 12 hours from time of stroke onset or time last known well in case of wake-up stroke. We included tandem occlusions, but excluded occlusions in the posterior circulation.

Endovascular treatment

All patients with confirmed large-vessel occlusion and no hemorrhage on noncontrast CT were treated with mechanical thrombectomy. If patients arrived within 4.5 hours of stroke onset, IV tPa was administered with a dosage of 0.9 mg/kg of body weight unless contraindicated. Access techniques, the use of balloon guide catheters, the use of intermediate catheters, and co-aspiration techniques were left to the discretion of the physician. Typically, a 0.014″ guidewire and a 0.021″ microcatheter were advanced through the occlusion, the guidewire was then removed and the EmboTrap 5×21 was advanced through the microcatheter and positioned as distal as possible with the start of the outer cage aligned with the proximal face of the occlusion. Some operators waited for at least 3 minutes for embedding, while other times the device was retracted into an intermediate or guide catheter without any additional waiting time. The device was used as first-line or second-line device (in only those cases where another first-line device failed to recanalize) and the number of attempts using the EmboTrap were also left to the discretion of the treating physician.

Study endpoints

In accordance with recent data suggesting fewer passes to recanalization may offer better clinical outcomes [21], we specified the primary endpoints as:

- successful recanalization after one or two attempts, defined by the modified thrombolysis in cerebral infarction (mTICI) score $\geq$ 2b [22];
- successful recanalization independently of the number of attempts. mTICI score was evaluated at the end of the procedure by the neuroradiologist who performed the intervention.

When a second stent retriever followed EmboTrap, recanalization was considered to be futile (ie, mTICI < 2b).

The secondary endpoints were:

- to evaluate procedural efficacy for successful recanalization of all patients including those treated with a second device;
- good clinical outcome as defined by a modified Ranking Score (mRS) $\leq$ 2 at 3 months.

Safety was assessed by recording procedural complications:

- distal embolism to previously unaffected territory;
- vessel perforations;
- vasospasms;
- intracranial hemorrhage (ICH).

ICH was determined on a CT control at 24 hours, and included all types of hemorrhagic transformations (HI1, HI2, PH1, PH2), and defined as symptomatic if associated with a worsening of the NIHSS score $\geq$ 4 points at day 1, as per ECASS-3 criteria [23].

Influence of balloon guide catheter technique on outcomes was also explored.

Statistical analysis

Continuous variables are represented as median (range) or mean (standard deviation) and categorical variables as the number and percentage (%) of patients. Statistical analysis was performed using Student's *t*-test, Mann–Whitney test or Fisher's exact test, as appropriate, for each variable. A 2-sided *P*-value of < 0.05 was considered statistically significant. Minitab version 17.1.0 statistical software was used.

Results

Patient and procedure characteristics

Eighty consecutive patients (44 men and 36 women; median age: 72 years; range: 34–93 years) were treated with EmboTrap from June 2015 to December 2016. Baseline characteristics are summarized in Table 1 and intra-procedural characteristics are summarized in Table 2.

Median NIHSS at admission was 15 (range: 5–30) and median initial ASPECT score was 8 (1–10). Occlusion was proximal i.e. from the ICA in 19 cases (23.7%) and involved the MCA (M1, M2) in 79 cases (99%). Seven patients (9%) had tandem (proximal ICA) occlusions. Forty-five patients (56.2%) received IV tPA before EVT.

Please cite this article in press as: Bourcier R, et al. Multicenter initial experience with the EmboTrap device in acute anterior ischemic stroke. J Neuroradiol (2017), https://doi.org/10.1016/j.neurad.2018.01.052

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