CASE SERIES

The Trevo XP 3×20 mm retriever ('Baby Trevo') for the treatment of distal intracranial occlusions

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ABSTRACT

Objective To report our single-center initial experience using the Trevo XP ProVue Retriever 3×20 mm ('Baby Trevo') for distal intracranial occlusions.

Methods We performed a retrospective review of our interventional database for consecutive patients who underwent treatment for acute ischemic stroke with the Baby Trevo device between February and December 2014.

Results Of 134 patients treated during the study period, 8 underwent treatment with the Baby Trevo for distal occlusions. Their mean age was 51 ± 20 years, 5 (62.5%) were male, mean baseline National Institutes of Health Stroke Scale was 19±5. The mean interval between the time the patient was last-known normal to groin puncture was 527±285 min, and the overall procedural length was 110±26 min. Intra-arterial tissue plasminogen activator was used in 5 (62.5%) cases. The device was used for a total of 10 branches: five middle cerebral artery (four superior M3 and one inferior M3), three anterior cerebral arteries (two pericallosal and one callosomarginal), and two posterior cerebral arteries (one P2 and one P3) occlusions. All patients achieved complete recanalization of the artery targeted by the Baby Trevo (arterial occlusive lesion 3). Good capillary reperfusion (TICI 2b-3) was noted in 6 (75%) cases. One pass was performed in 7 vessels and 2 passes in three branches. Vasospasm was noted in 5 (62.5%) of the vessels and fully responded to intra-arterial vasodilator infusion. Follow-up MRI revealed no infarct within the territory vascularized by the artery targeted by the Baby Trevo in 4 cases, partial infarct in 5, and complete infarct in 1. Two patients had parenchymal hematomas (one PH1 and one PH2). No vessel perforations, dissections, or subarachnoid hemorrhage were noted.

Conclusions Our initial data suggest that treatment of distal cerebrovascular occlusions with the Trevo XP 3×20 mm Retriever is feasible. Although this device emerges as a promising technology for small and tortuous distal intracranial vessels, larger studies are still necessary to establish its safety and clinical benefit.

INTRODUCTION

Mechanical thrombectomy of distal cerebral vessels may lead to complications such as subarachnoid hemorrhage (SAH), vessel perforation, and dissection.¹ The FDA-cleared stent retrievers (eg, Trevo Retriever, Stryker Neurovascular and Solitaire Retriever, Covidien) have been shown to be safer than the older coil retriever mechanical thrombectomy technology, resulting in less vessel perforation and device-related SAH.² ³ However, there are concerns about their use in smaller vessels.⁴ A Trevo retriever with a smaller diameter has been recently approved; however, its performance has not been described in the medical literature. We aim to report our local initial experience with the use the Trevo XP ProVue Retriever 3×20 mm ('Baby Trevo') for distal intracranial occlusions.

MATERIALS AND METHODS

We retrospectively reviewed our interventional database for consecutive patients who underwent endovascular therapy for acute ischemic stroke (AIS) and were treated with the Baby Trevo device. The study period encompassed February 2014-December 2014 at the comprehensive stroke center Marcus Stroke and Neuroscience Center/Grady Memorial Hospital. Demographic, radiologic, and procedural variables were collected. Anterior cerebral artery (ACA), middle cerebral artery (MCA), and posterior cerebral artery specific segments were in accordance with standard definitions.⁵ Overall reperfusion rates and the specific reperfusion rate for the vessel approached with the Baby Trevo were graded according to the modified Thrombolysis In Cerebral Infarction (TICI) classification.⁶ Moreover, we collected the arterial occlusive lesion (AOL) score for each occlusion treated with the Baby Trevo.⁶ Vasospasm after retraction of the Baby Trevo was considered present if >50% stenosis was noted on follow-up angiography. The brain tissue vascularized by the artery approached with the Baby Trevo was evaluated for the absence or presence of a complete or partial infarct. Hemorrhagic transformation was scored by the ECASS (European Cooperative Acute Stroke Study) criteria.⁷ Symptomatic intracerebral hemorrhage was defined as in the ECASS-3 trial-for example, any apparently extravascular blood in the brain or within the cranium associated with clinical deterioration, as defined by an increase of ≥ 4 points in the National Institutes of Health Stroke Scale (NIHSS) score, or that leads to death and is identified as the predominant cause of the neurologic deterioration.8

Device description

Similarly to its 4×20 counterpart, the Trevo XP 3×20 is a laser-cut, closed-cell, nitinol stent retriever specifically built to retrieve intracranial clots in patients with AIS. The 3×20 device was uniquely designed to target smaller vessels. According to the manufacturer, in comparison with a 4 mm diameter stent retriever, the Baby Trevo was shown in bench testing to have much larger cell sizes when deployed in small vessels (217%)

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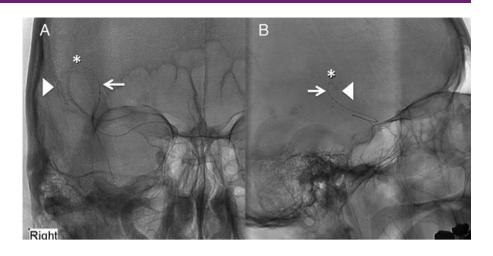
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Figure 1 Use of the Baby Trevo for a distal middle cerebral artery (MCA) occlusion (case No 1). (A) unsubtracted anteroposterior view demonstrating the Baby Trevo unsheathed within the superior division of the MCA. Note that the distal stent is at the opercular MCA segment (arrow), the mid-part at the circular sulcus (asterisk), and the proximal part at the insular segment (arrowhead); (B) lateral unsubtracted view.



larger cell size in a 2 mm vessel and 57% larger cell size in a 3 mm vessel); larger cells in smaller vessels maximize clot integration. Deployment and retrieval safety have also been optimized to allow for a more distal use. The distal tip of the Trevo XP 3×20 is at least 48% softer than the 4×20 versions of other stent retrievers. The device also has less radial force than larger stent retrievers across all vessels diameters. These differences should minimize the chances of vessel perforation and endothelial damage in smaller vessels. Similarly to the Trevo XP and ProVue retrievers, the Baby Trevo is fully radiopaque allowing for continuous visual feedback during all phases of its use and has a vertical stent strut alignment theoretically promoting better clot integration. The overall device has a total length of 190 cm, which includes a 0.015 in diameter pusher wire and the stentriever itself (3 mm diameter; 36 mm length; 20 mm clot capture area). The stentriever portion is marked with one proximal and two distal radiopaque markers (figure 1). Given its small profile, the device can be navigated and deployed through a smaller microcatheter (minimum ID: 0.017 in).

Technique

For every case in which the Baby Trevo was used, a Trevo Pro 14 microcatheter (ID: 0.017in/OD: proximal-distal 2.4-2.0F/ length: 157 cm) was navigated under roadmap guidance over a

0.014 in microwire into the desired position distal to the occlusion. A micro-run through a 10 cc syringe was typically performed to confirm the intravascular position. The Baby Trevo devices were systematically unsheathed, and 3-5 min of waiting time was allowed to promote better device-clot integration. The balloon guide catheters were inflated at the proximal cervical internal carotid artery and the device was very slowly retracted into the balloon under manual aspiration.

RESULTS

Of 134 patients receiving endovascular therapy for AIS within the study period, eight underwent treatment with the Baby Trevo for distal occlusions (in branches that were considered to vascularize eloquent brain or that were judged to have poor collaterals). Their mean age was 51 ± 20 years, five (62.5%) were male, mean baseline NIHSS score was 19±5, and the Alberta Stroke Program Early CT Score (ASPECTS) was 7.8 ± 1.0 . These were mostly complex thrombectomy cases in which individuals had one or more distal branch occlusions either at baseline or as a residual occlusion within the same territory after thrombectomy of the primary lesion. Only three patients received intravenous thrombolysis; the remaining five (62.5%) had had either a wake-up or unwitnessed stroke. The baseline occlusion level and thrombectomy approach for each patient are described in

Table 1	1 Demographics and treatment variables								
Case No	Age (years)	NIHSS	Baseline occlusion	Treatment	Residual occlusion	Treatment	Overall reperfusion	Baby Trevo reperfusion	
1	64	12	MCA M1	Trevo 4×20	MCA M3 (sup div)	Baby Trevo	TICI 2b	TICI 2a/AOL3	
2	39	18	MCA M1	Trevo 4×20	MCA M3 (sup div)*	Baby Trevo	TICI 2b	TICI 2b/AOL3	
3	17	15	MCA M3 (sup div)†	Baby Trevo (larger M3)	MCA M3 (smaller M3)	IA tPA	TICI 2b	TICI 2b/AOL3	
4	57	25	ICA terminus	Solitaire 6×30	MCA M3 (sup and inf div)	Baby Trevo	TICI 2b	TICI 2b/AOL3‡	
5	26	26	BA proximal	Trevo 4×20	PCA P3	3 Max/Baby Trevo	TICI 2b	TICI 2b/AOL3	
6	70	14	BA proximal	Trevo 4×20	PCA P2-3	Baby Trevo	TICI 2b	TICI 2a/AOL3	
7	76	21	ACA A4	Baby Trevo (ACA)	-	_	TICI 3	TICI 3/AOL3	
			MCA M1	Solitaire (MCA)	MCA M3 (inf div)	3 Max			
8	63	25	ACA A3 MCA M3s§	Baby Trevo (ACA)	ACA Callosomarginal	IA tPA/Baby Trevo	TICI 2b	TICI 3/AOL3	

*Inferior division completely infarcted at baseline (not approached).

†Two M3 occlusions

‡TICI 2b/AOL 3 in both divisions.

SICA terminus per CT angiogram. Upon angiography, ACA occlusion and multiple MCA M3 occlusions (MCA not approached owing to established infarct). ACA, anterior cerebral artery; AOL, arterial occlusive lesion; BA, basilar artery; div, division; middle cerebral artery; IA tPA, intra-arterial tissue plasminogen activator (alteplase); ICA, internal carotid artery; inf, inferior; MCA, middle cerebral artery; NIHSS, National Institutes of Health Stroke Scale; PCA, posterior cerebral artery; sup, superior; TICI, Thrombolysis In Cerebral Infarction

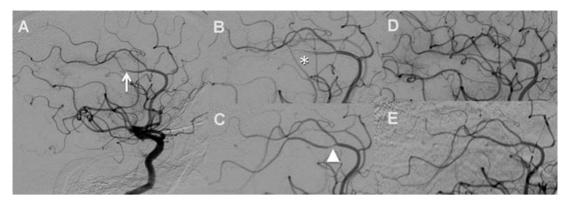


Figure 2 Use of the Baby Trevo for a pericallosal anterior cerebral artery occlusion (case No 7). (A) lateral subtracted view revealing an occlusion of a distal anterior cerebral artery branch (arrow); (B) Baby Trevo unsheathed across the occluded segment (asterisk); (C) Significant vasospasm after retraction of the stent retriever; (D) improving vasospasm on follow-up angiography (arrowhead); (E) final angiogram after infusion of milrinone.

table 1. Some cases had residual occlusions after treatment of the primary lesion, and the corresponding thrombectomy approach is also noted. The mean time interval from the time the patient was last-known normal to groin puncture was 527 ± 285 min and the overall procedural length was 110 ± 26 min. Intra-arterial tissue plasminogen activator was used in five (62.5%) patients, but never concomitantly with the use of the Baby Trevo.

The Baby Trevo was used in a total of 10 branches: five MCA branches (four superior M3 and one inferior M3) (figure 1), three ACA branches (two pericallosal and one callosomarginal arteries) (figures 2 and 3), and two posterior cerebral arteries (one P2 and one P3) occlusions.

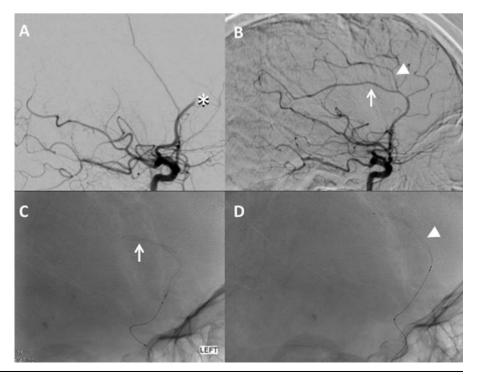
Complete recanalization and restoration of the artery targeted by the Baby Trevo with any distal flow (AOL 3) was achieved in all patients, while good capillary reperfusion (TICI 2b–3) was noted in six (75%) patients (table 1). One pass was used in seven vessels approached by the Baby Trevo and two passes were required in three. Significant vasospasm after the device pass was noted in five (62.5%) patients and all responded to infusion of an intra-arterial vasodilator (table 2). Follow-up MRI disclosed no new infarct within the territory vascularized by the artery targeted by the Baby Trevo in four cases, partial infarct in five, and complete infarct in one. Three patients had petechial hemorrhage after treatment (HI1 and HI2). Two patients had parenchymal hematomas (one PH1 and one PH2). None of the intracerebral hemorrhages were symptomatic and both involved areas that were infarcted on follow-up imaging. No cases of vessel perforation, dissection, or subarachnoid hemorrhage were noted.

DISCUSSION

We report on a series of patients who underwent thrombectomy with the Trevo XP 3×20 mm Retriever ('Baby Trevo') for the treatment of distal intracranial occlusions. Despite using the Baby Trevo in small diameter vessels, we observed good reperfusion rates and no intraprocedural complications.

Distal occlusions due to residual thrombus, emboli to new territory or due to downstream embolization within the initially affected territory are not uncommon and may have an important clinical impact.² ⁹⁻¹¹ However, considering the scarce

Figure 3 Use of the Baby Trevo for pericallosal and callosomarginal anterior cerebral artery (ACA) branch occlusions (case No 8). (A) lateral subtracted view revealing a distal ACA branch (asterisk) occlusion; (B) final lateral angiogram revealing full reperfusion of ACA territory; (C) Baby Trevo deployed within the pericallosal artery (arrow); (D) Baby Trevo unsheathed within the callosomarginal branch (arrowhead).



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Table 2 Radiological and clinical outcomes

Case No	Baby Trevo passes (n)	Baby Trevo spasm (>50%)	Baby Trevo territory—MRI outcome	Parenchymal hemorrhage	Vessel perforation	SAH	mRS
1	1	No	Partial infarct	No	No	No	0 @3 m
2	1	Yes	No new infarct	No	No	No	2 @3 m
3	2	No	Partial infarct	No	No	No	3 @1 m
4	3*	Yes (inf div)	No new infarct	PH2	No	No	4 @3 m
5	2	Yes	No new infarct	No	No	No	5 @3 m
6	1	No	Complete infarct	PH1	No	No	6 @3 m
7	1	Yes	Partial infarct	No	No	No	4 @3 m
8	1 each artery	Yes	Partial infarct	No	No	No	4 @3 m

*Two passes in the superior and one in the inferior division.

div, division; inf, inferior; m, months; mRS, modified Rankin Scale; PH, parenchymal hemorrhage; SAH, subarachnoid hemorrhage.

literature, the benefits of targeting smaller arteries for thrombectomy needs to be very carefully considered against the risks in carefully selected patients.

In the TREVO 2 trial, the incidence of vessel perforation was low for stent retrievers (1%).² In contrast, a substantially higher rate of vascular perforations (10%) was seen with the older thrombectomy technology (eg, Merci Retriever).² Similarly, the SWIFT trial revealed a sizable difference in vessel perforations favoring stent retriever technology (1.7% vs 5.5% for the Merci Retriever).¹² Additionally, cases of SAH were also less common with stent retrievers (1.1% vs 7.3% for the Merci Retriever).¹² However, these trials treated larger vessels with MCA M2s, encompassing only 16% of the Trevo arm patients in the TREVO 2 study and 10% of the SWIFT trial cases, and neither trial investigated the use of these devices to treat more distal occlusions. Although standard stent retriever delivery microcatheters can be easily navigated into distal vessels, there is at least a theoretical concern about deploying these devices in smaller and more tortuous distal arteries. Smaller diameter thromboaspiration catheters, such as the Penumbra 3 Max, may represent a good option for less tortuous distal anatomy, especially when ADAPT (A Direct Aspiration first Pass Technique) is used.¹³ However, smaller and more tortuous distal sites (such as loopy superior division opercular branches) or occlusions with challenging access, such as distal ACA branches, may not be optimal recipients for this device owing to its relatively large diameter (ID: 0.035 in/OD: proximal-distal 4.7-3.8F/length: 153 cm) and lower flexibility. These limitations seem to be overcome with the use of the Trevo 3×20 system, as much smaller profile microcatheters (OD: 2.0F) are required to navigate and deploy this smaller stentriever

Vessel vasospasm on angiography was noted in a significant number of patients (22.5%) who underwent treatment with a stent retriever in the SWIFT trial.¹² However, no clinical sequelae were seen, possibly indicating that this may not be a hazardous event. Although the Baby Trevo is the smallest stent retriever with lower radial force across all vessel diameters, it generated spasm in more than half of our patients. This may relate to the very small caliber and tortuous course of the vessels approached. We infused IA vasodilators (eg, milrinone and/or nicardipine) either prophylactically or to treat angiographic vasospasm, with good response.

Parenchymal hematomas were seen in 2/8 (25%) of our small series. This compares favorably with the 23% of PH1 or PH2 reported in the TREVO 2 trial despite our focus on refractory and distal occlusion cases.² In comparison with recently published thrombectomy trials, the number of parenchymal

hemorrhages was relatively high (EXTEND-IA 11%, ESCAPE 5.4%, and MR CLEAN 6%), and our results should be interpreted with caution.^{14–16} The reperfusion rates of the branches treated with the Baby Trevo were relatively high, achieving TICI \geq 2b reperfusion in 75% of cases compared with 68% of the overall population studied in the TREVO 2 trial.²

CONCLUSION

Our initial data suggest that treatment of distal cerebrovascular occlusions with the Trevo XP 3×20 mm Retriever is feasible. Although this device emerges as a promising technology for small and tortuous distal intracranial vessels, larger studies are still necessary to establish its safety profile and clinical benefit.

Contributors DCH: design of the work, acquisition of data, interpretation of data, drafting of the manuscript. AL: data acquisition, critical revision of manuscript. RGN: study conception, data acquisition, interpretation of data, critical revision of manuscript. All authors gave final approval of the version to be published, and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Competing interests RGN has the following disclosures: Stryker Neurovacular (Trevo-2 Trial PI, DAWN Trial PI), Covidien (SWIFT and SWIFT-PRIME Steering Committee, STAR Trial Core Lab), and Penumbra (3-D Separator Trial Executive Committee).

Ethics approval Local institutional review board.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The unpublished data from this dataset are held by Grady Memorial Hospital/Emory University and RGN. Requests for data sharing would be required to be discussed with them directly.

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