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Original Article

Mechanical thrombectomy with a novel device: initial clinical experience with the ANA thrombectomy device

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ABSTRACT

Introduction. – The ANA™ (Anaconda Biomed) thrombectomy system is a novel stroke thrombectomy device comprising a self-expanding funnel designed to reduce clot fragmentation by locally restricting flow while becoming as wide as the lodging artery. Once deployed, ANA allows distal aspiration in combination with a stentretriever (SR) to mobilize the clot into the funnel where it remains copped during extraction. We investigate safety and efficacy of ANA™ in a first-in-man study.
Methods. – Prospective data was collected on 35 consecutive patients treated as first line with ANA™ at a single centre. Outcome measures included per-pass reperfusion scores, symptomatic intracerebral hemorrhage (sICH), NIHSS at day 5, and mRS at 90 days.
Results. – Median NIHSS was 12(9–18). Sites of primary occlusion were: 5 ICA, 15 M1-MCA, 15 M2-MCA. Primary performance endpoint, mTICI 2b-3 within 3 passes without rescue therapy was achieved in 91.4% (n = 32) of patients; rate of complete recanalization (mTICI 2c-3) was 65.7%. First pass complete recanalization rate was 42.9%, and median number of ANA passes 1(IQR: 1–2). In 17.1% (n = 6) rescue treatment was used; median number of rescue passes was 2(1–7), leading to a final mTICI2b-3rate of 94.3% (n = 33). There were no device related serious adverse events, and rate of sICH was 5.7% (n = 2). At 5 days median NIHSS was 1 (IQR 1–6) and 90 days mRS 0–2 was achieved in 60% of patients.
Conclusions. – In this initial clinical experience, the ANA™ device achieved a high rate of complete recanalization with a good safety profile and favourable 90 days clinical outcomes.

Introduction

Endovascular treatment (EVT) has become the mainstay of treatment in acute ischemic stroke due to large vessel occlusion (LVO).[1,2] Rapid[3] and complete[4] reperfusion with a minimum number of attempts[5,6] is the principal objective to achieve best clinical outcomes.

The final rate of successful reperfusion (modified thrombolysis in cerebral ischemia (mTICI) 2b/3) in the recent largest series varies from 60 to 92%.[7] However, the rate of excellent procedural outcome or first-pass effect (mTICI 2c/3 after first pass) has been reported to be 30–40%.[8] Failure to achieve successful recanalization has been associated with different variables such as composition and length of the clot,[9] vascular tortuosity,[10] or procedural factors such as clot fragmentation, distal embolization[11] or early reocclusion.[12] Specific device features such as flow arrest with balloon guide catheter (BGC) or the catheter-to-vessel diameter ratio[13] have been linked to

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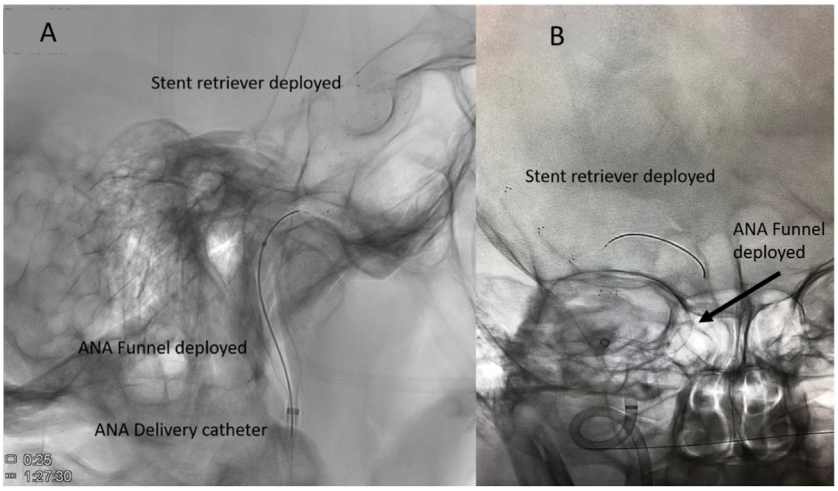

Fig. 1. Thrombectomy setting with devices deployed. ANA funnel was deployed and could be visualized either at extracranial (A) or intracranial (B) segments of internal carotid artery.

higher successful recanalization[14] by reducing distal embolization or allowing complete clot ingestion into the catheter.[15]

The Advanced Neurovascular Access (ANA device or ANA catheter system. Anaconda Biomed, Barcelona Spain) is a new stroke thrombectomy device comprising a self-expanding funnel component designed to reduce clot fragmentation by locally restricting blood flow while becoming as wide as the diameter of the lodging artery. Once deployed, ANA allows distal aspiration in combination with a stent retriever (SR) to mobilize the clot into the funnel where it remains trapped during extraction. In *in vitro* phantom models of middle cerebral artery (MCA) occlusion, ANA device showed better recanalization rates than SR in combination with distal aspiration or BGC, both after first and third passes.[16] A second study performed in a swine model replicated the efficacy findings with no safety concerns in terms of induced endothelial damage.[17]

We aimed to describe the safety and efficacy profile of the ANA catheter in a first-in-human study.

Methods

The SOLONDA study ("SOL"itaire in combination with the ANA Catheter system as manufactured by Anac"ONDA"), study title "Prospective, Single-Arm, Multi-center Study to Assess the Safety and Performance of the ANA catheter system, in combination with a Stent Retriever in Patients with Acute Ischemic Stroke", aims to assess Safety and Performance of the ANA Catheter System, Combined With a Stent Retriever in Acute Ischemic Stroke (NCT04095767). The study was designed to collect clinical evidence on safety and efficacy for the ANA Catheter system. We present the preliminary results of the first 35 consecutive patients recruited in one of the participating centers. Patients were treated by four different neurointerventionalists.

The investigational use of the ANA device was approved by the national regulatory agency, the clinical protocol was approved by the institutional ethics committee (07 Jun 2019 - Study number 5482), and informed consent to participate in the trial was obtained from all patients or next of kin before treatment.

Description of ANA device and procedure

ANA is a thrombectomy device, comprised of two coaxial catheters: the funnel catheter and the delivery catheter, made from variable stiffness sections (Fig. 1). The funnel catheter comprises highly flexible polymers on a braided metallic structure. It is intended to restrict the blood flow locally during the intervention, and it can provide effective aspiration that serves as a complementary mechanism combined with a SR. The delivery catheter is the outermost catheter of the device, which navigates until reaching the target vessel. The total usable length of the ANA device is 1210 mm, the outer diameter of the delivery catheter is 2.11 mm, the diameter of the fully expanded funnel is 5.2 mm, and the internal diameter of the funnel catheter is 1.04 mm (Fig. 2).

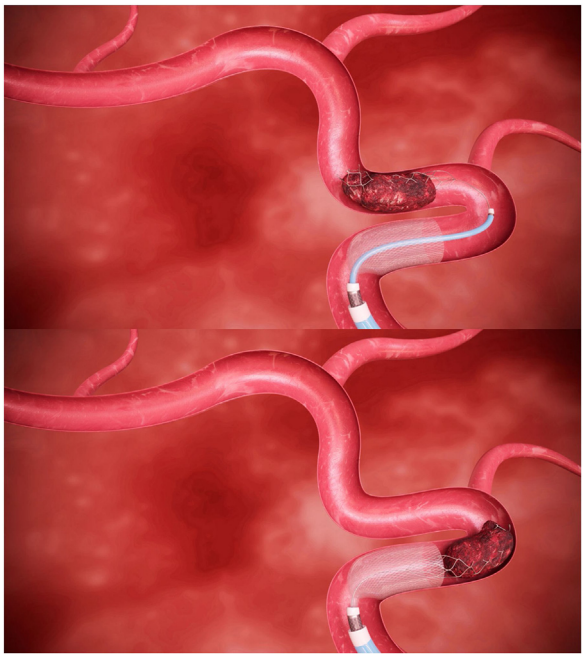

Fig. 2. Schematic drawing of thrombectomy using ANA device.

In all patients, once the guide catheter (6F NeuronMax, Penumbra) was placed at the level of the internal carotid artery, in a triaxial setting, a microcatheter (preferably Phenom 21 (160 cm length), Medtronic) was advanced over a micro guidewire to the clot. The ANA catheter, in its retracted position, was then positioned as close as possible to the proximal aspect of the clot (terminal ICA or MCA), and the funnel was deployed to restrict flow locally. The microcatheter was then advanced through the occlusion site, and the SR (Solitaire family, Medtronic) deployed as in usual practice. At this point, the microcatheter was completely withdrawn to increase the

aspiration lumen and manual aspiration (60cc VacLok® syringe) was applied through the ANA funnel catheter. The SR was then, slowly pulled into the funnel while applying aspiration. When the distal ends of SR and ANA funnel catheter are aligned, assuming that the clot was mobilized and copped into the funnel, both the ANA + the SR were simultaneously pulled out. The braided stent nature of the funnel allows lengthening that compresses the clot holding it inside as a Chinese finger trap while being pulled out through the guiding catheter.

Population

The first 35 consecutive patients in a single, large volume stroke center, intended to be treated with the ANA catheter to perform the thrombectomy have been included in this study. Patients with anterior circulation LVO (terminal internal carotid artery, M1 or M2 segment of the middle cerebral artery) treated within 8 h of symptom onset were eligible for inclusion if they were 18–85 years and presented National Institute Health Stroke Scale (NIHSS) score 8–25 at onset, pre-stroke modified Rankin Scale (mRS) score 0–1, and ASPECTS score>5.The use of standard-dose thrombolysis was at the discretion of the treating physician following current guidelines. A standard clinical research form was used to chart baseline characteristics including age, sex, comorbidities, medications, timing of medical and interventional treatments, reperfusion and clinical outcomes, and imaging results.

Outcome measures

Primary efficacy outcome was defined as the ability of ANA + SR to achieve successful reperfusion (mTICI ≥2b) with ≤3 passes without the use of rescue therapy (intention to treat population). Rescue therapy with alternative commercially available devices was allowed after at least one attempt with the ANA device. In cases in which rescue therapy was used before TICI2b was achieved, primary outcome was considered as not achieved. Secondary efficacy outcomes were: the ability of the ANA catheter to reach the occlusion allowing navigation and deployment of the SR, procedural times, neurological status at day 5 or discharge, and mRS at day 90. The local interventionalist and an independent central core lab(Neurovascular Imaging Research Core, UCLA) assessed the rate of recanalization according to the eTICI scale,[4] including first-pass complete recanalization (mTICI2c-3) and rate of successful recanalization (TICI 2b-3)after each pass and at the end of procedure including rescue therapy. Sudden recanalization[18] was considered when mTICI increased from 0–1 to 2b–3 in a single pass. Only central core-lab readings are presented as the main results. An independent Clinical Research Organization was responsible for the monitoring of the clinical data.

Safety was defined as the occurrence of any serious adverse device effects up to 90-days post-procedure, including symptomatic intracranial hemorrhage (sICH), neurological worsening defined as NIHSS increasing ≥4 points (24 h and 5 days or discharge), rate of embolization to distal or new territories, rate of procedural complications (arterial perforation, dissection, vasospasm in target vessel, and procedure related mortality. All reported adverse events were reviewed by an independent data safety monitoring board that adjudicated their potential relationship with the ANA device.

Results

Baseline and imaging characteristics

The mean age of the patients in the study (n = 35) was 74.6 years (standard deviation (SD) 8.3), 54.3% (n = 19) of them were women. Median admission NIHSS score was 12 (interquartile range (IQR) 9–18), left hemisphere was affected in 21 (60%) patients and median ASPECTS score on initial CT was 9 (IQR 9–10). Sites of primary occlusion were: 5 (14.3%) terminal internal carotid artery (ICA), 15 (42.9%) M1 middle cerebral artery (MCA) and 15 (42.9%) M2-MCA. Other baseline characteristics are shown in Table 1.

Table 1
Baseline characteristics, treatment workflow and clinical outcome measures (SD: standard deviation, IQR: inter quartile range, NIHSS: National Institute of Health Stroke Scale, ASPECTS: Alberta Stroke Programme Early CT Score, ICA: internal carotid artery, MCA: middle cerebral artery, mRS: modified Rankin Scale).

Demographic	
Age (mean +/- SD; years)	74.6 +/−−8.3
Gender (female)	19 (54.3%)
prestroke mRS (median, IQR)	1 (0.5−1)
Current/previous Smoker	7 (20%)
Hypertension	28 (80%)
Diabetes mellitus	12 (34.3%)
Dyslipidemia	20 (57%)
Atrial fibrillation	5 (14.3%)
Clinical and radiological	
NIHSS score (median, IQR)	12 (9−18)
ASPECTS (median, IQR)	9 (9−10)
Side of occlusion (left)	21 (60%)
Occlusion site:	
ICA	5 (14.3%)
M1-MCA	15 (42.9%)
M2-MCA	15 (42.9%)
Treatment	
Intravenous thrombolysis	8 (22.9%)
Onset to groin time (median, IQR; minutes)	240 (149−345)
Door to groin time (median, IQR; minutes)	51 (34−87)
Procedural time (groin to end- all sheets removed) (median, IQR; minutes)	41 (25−57)
Angiographic outcomes without rescue treatment	
mTICI 2b-3 within 3 passes	32 (91.4%)
mTICI 2c-3 within 3 passes	23 (65.7%)
First pass mTICI 2b-3	20 (57.1%)
First pass mTICI 2c-3	15 (42.9%)
Sudden recanalization	29 (82.9%)
Number of passes (median, IQR)	1 (1−2)
Safety outcomes	
Intracranial vessel perforation	1 (2.9%)
New territory embolization	1 (2.9%)
Extracranial ICA dissection	2 (5.7%)
Symptomatic hemorrhagic transformation	2 (5.7%)
Clinical outcome	
NIHSS at 24 h (median, IQR)	5(1−16)
NIHSS at 5 days (median, IQR)	1 (1−6)
mRS at 90 days (median, IQR)	1 (1−3)
Symptomatic hemorrhagic transformation	2 (5.7%)
Dissection	2 (5.7%)
Embolization to new territory	1 (2.8%)

Procedural data

Of the 35 consecutive cases (intention to treat population), ANA could be successfully deployed in 97.1% of patients (n = 34). In the remaining case, excessive vascular tortuosity led to difficult navigation and instability precluding deployment and first recanalization attempt with the ANA device. The median procedural time was 41(IQR 25−57) min.

Table 2
Recanalization rates in the Solonda study and other published series. (pts: patients, Rec: Recanalization, ITT: Intention To Treat, SR: Stent retriever).

Study name	# of pts	Device	First pass	mTICI 2b/3			mTICI 2c/3			mTICI 3		Sudden Recanalisation	mRS 0–2 at 90 days
				Last pass with study device	Final	First pass	Last pass with study device	Final	First pass	Last pass with study device	Final		
Hermes[7]	634	Multiple			75.4%			31.4%			8.6%		46.0%
SEER[27]	401	Solitaire			71.1%						32.9%		54.0%
SWIFT[28]	58	Solitaire		69%	89%								36%
Sudden Rec[18]	609	Multiple	41%		83.6%						45.6%	62.1%	44.8%
Solonda (ITT)	35	ANA + Solitaire	57.1%	91.4%	94.3%	42.9%	65.7%	74.3%	40%	51.4%	54.3%	82.9%	60%

Intention to treat analysis

Primary endpoint, defined as successful reperfusion (mTICI 2b-3) within 3 passes without rescue therapy, was achieved in 91.4% (n = 32) of patients with a rate of complete reperfusion (mTICI 2c-3) of 65.7%. Rate of first pass complete recanalization (mTICI≥2c) was 42.9%, and the rate of sudden recanalization was 82.9%. Median number of ANA passes was 1 (IQR: 1–2).

In 17.1% (n = 6) patients, rescue treatment was used; median number of rescue therapy passes was 2(1–7), leading to a rate of final successful reperfusion of 94.3% (n = 33) patients.

Table 2 shows a detailed analysis of the per-pass recanalization rates and comparison with previously published series by the same center or multicentric trials. Correlation in reperfusion grade between site vs. central core assessment was strong (kappa = 0.87).

Safety and clinical outcomes

Rate of symptomatic intracranial hemorrhage was 5.7% (n = 2). One patient, in which stroke etiology was presumed to be intracranial atherosclerotic disease, presented an intracranial vessel perforation while receiving rescue angioplasty treatment. In two other patients a periprocedural dissection of the extracranial ICA was observed (one required stenting); first case was related with the 0.035″ guidewire used to catheterize ICA and observed before ANA catheter was inserted. The second case was observed at the end of the procedure at the level of an ICA curve. One patient presented an embolization into a new vascular territory. Data safety monitoring board reviewed all reported adverse events and concluded that there are no safety concerns related to the use of the ANA device.

At 5 days or discharge median NIHSS was 1 (IQR 1–6). At 3 months, favourable functional outcome, defined as mRS 0–2, was achieved in 60.0% patients (n = 21) and mortality rate was 20% (n = 7).

Discussion

This first-in-human clinical study of ANA device shows that the combination of ANA with a SR achieves a high rate of successful recanalization and first-pass effect with a good safety profile. These results replicate the preliminary efficacy profile observed in 3D-printed phantom[16] and swine models.[17] The theoretical advantages offered by the design of ANA include the combination of local flow arrest and maximized catheter-to-vessel diameter ratio that allows protected extraction of the clot minimizing the risk of fragmentation and distal embolization. These features are now supported by the initial results of this first in man study. Reported rates of successful recanalization with the ANA device were >90% and could only be marginally improved with rescue treatment. Procedure time, from groin puncture to all sheets were removed (Table 1), was similar to previously published studies of new devices[19,20] and to historical Solitaire series.[21,22]

The fact that rescue treatment with multiple passes of different thrombectomy devices did not lead to significantly higher success may indicate that in case of failure to achieve recanalization with ANA, ICAD should be suspected and stenting considered.

Repeated passes of thrombectomy device either by inducing vessel damage, extending procedural time, or generating microemboli, are associated with worse clinical outcomes despite successful reperfusion. Previous studies have reported the benefit of achieving reperfusion in a single attempt[19] (first-pass effect) or minimizing clot fragmentation[18] (sudden recanalization). The present study shows promising high rates of both indicators when the ANA device is used as compared with previously published experiences. Embolization into a new territory was observed in one patient (2.8%), suggesting that the mentioned features of the device might confer protection against this periprocedural complication since previously reported rates range from 6.6 to 8.5%.[19,23,24] Longer series should explore this trend. Although one of the two dissections was unrelated to the ANA device, this event should be monitored to confirm that it remains in line with previously published rates (2%).[25]

The ANA device was originally conceived to be deployed intracranially, very proximal to the clot. However, as recruitment of patients progressed, we observed that funnel deployment at lower levels did not seem to reduce the efficacy.

Preclinical models showed that efficacy results obtained with the ANA catheter were substantially better than with other devices when attempting to retrieve hard fibrin-rich clots.[17] In the future, available information of clot composition before treatment[26] could be used to select the appropriate first-line device. However, until this is not possible, tools with wide efficacy profile should be considered as first-line options to ensure a minimum number of attempts.

The present study aims to describe the initial safety and efficacy profile of a novel ANA device in a first in man study. Data were obtained at a single center with a limited number of cases and need to be confirmed when the SOLONDA study will be completed in other participating centers. Efficacy data were however evaluated by an independent imaging core lab. An independent, combined Clinical Events Committee/Data Safety Monitoring Board (CEC/DSMB) did not find any safety concerns related to the device. This was also the advice that the CEC/DSMB communicated to the Trial Steering Committee (TSC), members being the study PI, a neurologist, and three interventional radiologists, allowing the TSC to conclude, after each of the CEC/DSMB meetings, that the study could be continued without changes. To reduce variability and ease interpretation of the results, the clinical protocol only allowed the use of the Solitaire stent-retriever in combination with ANA. However, bench testing showed compatibility of ANA with most commercially available SR with similar efficacy rates. As opposed to what might happen in registries, the present study describes the intention to treat the results of all patients prospectively included in the study. Patients in which, due to anatomic challenges, ANA could not be advanced and/or deployed were not excluded.

Conclusion

In this initial clinical experience, the ANA™ device achieved a high rate of complete reperfusion, sudden recanalization, a good safety profile, and favourable 90 days clinical outcomes.

Disclosures

Dr Tomasello and Dr Hernández have a consulting agreement with Anaconda Biomed. Dr Liebeskind receives support as a consultant as imaging core lab for Stryker, Medtronic, Cerenovus, Genentech and Rapid Medical. Dr Nogueira reports funding from Stryker Neurovascular (DAWN Trial [DWI or CTP Assessment With Clinical Mismatch in the Triage of Wake-Up and Late Presenting Strokes Undergoing Neurointervention With Trevo], Trevo Retriever Registry-no compensation, Trevo-2 Trial-modest compensation), Medtronic (SWIFT Trial [SOLITAIRE FR With the Intention for Thrombectomy]–modest; SWIFT-Prime Trial-no compensation; STAR Trial [Solitaire FR Thrombectomy for Acute Revascularisation]– significant), Penumbra (3D Separator–no compensation), Cerenovus/Neuravi (ENDOLOW Trial, EXCELLENT Registry, ARISE-2 [ARISE Analysis of Revascularization in Ischemic Stroke With EmboTrap]-no compensation, Physician Advisory Board [PAB], modest), Phenox (PAB, modest), Anaconda (PAB, modest), Genentech (PAB–modest), Biogen (PAB–modest), Prolong Pharmaceuticals (PAB–modest), Allm, Inc (PAB–no compensation), Brainomix (research moderate compensation), Sensome (Research Device Use–no compensation), Viz-AI (PAB, stock options), Corindus Vascular Robotics (PAB, stock options), research consultation with modest compensation from Vesalio and Ceretrieve. Dr Jovin is a consultant at Cerenovus (steering committee/DSMB -modest), Stryker Neurovascular (Principal Investigator DAWN-unpaid), holds stock at Anaconda, Blockade Medical, Route 92, Corindus, FreeOx Biotech, Vizai. Tommy Andersson is clinical consultant for Anaconda, Ablynx, Amnis Therapeutics, Cerenovus/Neuravi, Medtronic, and Rapid Medical. Dr Cognard receives funding from Stryker, Microvention, Medtronic, Cerenovus, MIVI. Dr Ribo has a consulting agreement with Medtronic, Stryker, Cerenovus, CVAid, Methinks, Anaconda Biomed, and Apta Targets. The other authors report no conflict.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.neurad.2020.11.003.

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