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Original Article

Mechanical thrombectomy with a novel stent retriever with multifunctional zones: Initial clinical experience with the NeVa™ thrombectomy device

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ABSTRACT

Background and purpose. – The NeVa™ (Vesalio, Nashville, Tennessee) thrombectomy device is a CE-approved novel hybrid-cell stent retriever with offset enlarged openings coupled with functional zones and a closed distal end. The device was designed to incorporate and trap resistant emboli. The purpose was to determine the safety and efficacy of the NeVa™ stent.

Methods. – Prospective data was collected on the first thirty consecutive patients treated at four stroke centers with NeVa™ as first line treatment between December 2017 and May 2018. Clinical outcome measures included re-perfusion scores after each pass, complications (per-procedural complications, device related adverse events, all intracerebral hemorrhage (ICH) and symptomatic ICH (sICH) on follow up imaging), 24 hour NIHSS, mRS at discharge and 90 days. Baseline data as well as treatment parameters were documented.

Results. – Mean presenting NIHSS was 16. Sites of primary occlusion were 10 ICA, 16 M1-MCA, 3 M2-MCA and one basilar. There were five tandem occlusions. Reperfusion outcomes after each NeVa pass; TICI ≥ 2b after first pass 63%, after 1 or 2 passes 83%, after 1 to 3 passes 90%. TICI 2c-3 after first pass 47%, after 1-2 passes 57%, after 1–3 passes 60%. TICI ≥ 2b after final pass 93%; TICI 2c-3, 63%. There were no device related serious averse events and no sICH. Clot material was partially or completely incorporated into the device after 70% passes. The mean 24 hour NIHSS was 7 and the 90 day mRS was 0–2 in 53%.

Conclusions. – The NeVa™ device demonstrated a high rate of first pass complete reperfusion effect, a good safety profile and favorable 90 day clinical outcomes in this initial clinical experience.

Introduction

Mechanical thrombectomy is the current standard of care for acute stroke associated with large vessel occlusions [1–5]. Stent retriever mechanical thrombectomy has been the most widely studied technique with multiple prospective, randomized trials demonstrating a clear clinical benefit [1–5]. Successful and rapid recanalization has been demonstrated to correlate with improved clinical outcomes [6]. Rates of successful recanalization (modified thrombolysis in cerebral ischemia [mTICI) 2b/3) vary widely and range between 58–92% from the prospective literature [1–5,7,8]. Recent efforts have been put forth to understand the mechanism of failure in stent-retriever thrombectomy [9]. Resistant clot, which adheres more strongly to itself and the vessel wall than to the stent retriever, coupled with inadequate incorporation into the openings of the stent retriever has been shown experimentally to be one mechanism of failure [9–12]. Beyond the difficulties posed by resistant emboli, multiple passes to achieve a satisfactory reperfusion outcome and fragmentation of emboli remain major challenges to stent-retriever re-perfusion success [8].

The NeVa™ thrombectomy device was designed to be effective against both resistant and more typical thrombus [13,14]. Pre-clinical data demonstrated superiority in the removal of 'white'

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Table 1
Baseline characteristics. NIHSS- national institute of health stroke scale score, IQR- interquartile range, mRS- modified Rankin scale score, ICA T- intracranial carotid T occlusion, M1-MCA- middle cerebral artery M1 segment occlusion, M2- M2 middle cerebral artery occlusion, LKW- last known well, ASPECTS Alberta Stroke Program Early CT Score, ED- emergency department.

Age (mean)	72 years
Male sex (%)	16 (53)
Presenting NIHSS- mean (IQR)	16 (13-20)
Pre-stroke mRS	
0	18
1	10
2	2
Medical history (%)	
Hypertension	19 (63)
Diabetes	5 (17)
Atrial fibrillation	8 (27)
Dyslipidemia	12 (40)
Smoking	8 (30)
Coronary artery disease	3 (10)
ASPECTS score median (IQR)	10 (8-10)
Proximal occlusion location	
Occlusion side left	16
Extra-cranial carotid	3
ICA T occlusion	7
M1 MCA	16
M2 MCA	3
Basilar	1
Symptom Onset or LKW to arterial puncture minutes	
Mean (IQR)	326 minutes (134-388)
Balloon Guide catheter	6/30
Intermediate catheter	24/30
Procedural Time (groin puncture to final reperfusion) median (IQR)	52 minutes (37-79)
Direct ED admission (%)	15 (50)
IV thrombolytics (%)	12 (40)

Table 2
Clinical outcomes and safety measures.

24 hour NIHSS- mean (IQR)	7 (1-11)
Discharge mRS (%)	
0–1	9 (30)
0–2	12 (40)
3	6 (20)
4	5 (17)
5	3 (10)
6	2 (7)
90 day mRS (%)	
0–1	12 (40)
0–2	16 (53)
3	3 (10)
4	4 (13)
5	2 (7)
6	5 (17)
Intracerebral hemorrhage	
sICH	0
All ICH (%)	7 (23)
All cause mortality at 90 days	5 (17)
In hospital mortality	2
Serious device adverse events	0
Procedure related adverse events[a]	3

NIHSS- national institute of health stroke scale score, IQR- interquartile range, mRS- modified Rankin scale score, sICh- symptomatic intracerebral hemorrhage (ECASS II classification).
[a] One wire perforation, two incidences of contrast extravasation on immediate post procedure CT scan.

Table 3
Reperfusion outcomes.

Neva First Pass Effect	
mTICI 2b and above (%)	19/30 (63 %)
mTICI 2c-3 (%)	14/30 (47%)
Total passes (avg.)	30 (1)
Two or less NeVa passes	
mTICI 2b and above (%)	25/30 (83%)
mTICI 2c-3 (%)	17/30 (57%)
Total passes (avg.)	41 (1.4)
Three or less NeVa passes	
mTICI 2b and above (%)	27/30 (90%)
mTICI 2c-3 (%)	18/30 (60%)
Total passes (avg.)	47 (1.5)
After final NeVa pass	
TICI 2b and above (%)	28/30 (93%)
TICI 2c-3 (%)	19/30 (63%)
Total passes (avg.)	50 (1.7)
End of procedure (includes rescue therapy[a])	
mTICI 2b and above (%)	28/30 (93%)
mTICI 2c-3 (%)	21/30 (70%)
Total passes (avg.)	64 (2.1)
Clot incorporation inside of device (%)	28/40 (70)[b]

mTICI- modified thrombolysis in cerebral ischemia.
[a] Rescue therapy included use of direct aspiration or other stent retrievers.
[b] Clot incorporation data was available for forty NeVa passes.

resistant thrombus compared to other stent retriever designs in an established in vitro model [13,14]. The purpose of the current study was to determine the safety and efficacy of the NeVa™ thrombectomy device in a consecutive series of patients presenting with ischemic stroke related to large vessel occlusion.

Methods

Patient variable

The first thirty consecutive patients treated with the NeVa™ thrombectomy device as a first line therapy between December 2017 and May 2018 at four centers were included in the study. Patients were eligible for inclusion if they presented with an NIHSS ≥ 4, an ASPECTS Score > 5 and had a large vessel occlusion on DSA immediately prior to treatment. Extended window patients (beyond 6 hours) were included if they had a favorable profile on CT-perfusion maps as described in previous studies [28,29]. The use of standard dose IV thrombolytics was at the discretion of the treating physician for eligible patients. A standard clinical research form (CRF] was used to chart baseline characteristics including age, sex, comorbidities, medications (antiplatelet, anticoagulants, thrombolytics), timing of medical and interventional treatments, reperfusion outcomes, flow control strategies, NIHSS, imaging results and mRS scores (Table 1).

Outcome measures

Treatment related parameters including onset to treatment time (last seen normal to groin puncture), procedural time (groin puncture to final reperfusion), reperfusion grade after each NeVa™ pass and end of all treatments (mTICI), per-procedural complications and device related adverse events, all intracerebral hemorrhage (ICH) and symptomatic ICH (sICH) on follow up imaging as well as functional outcome at 24 hours, discharge (NIHSS/mRS) and 90 days (mRS) were charted prospectively using the standard CRF [15–18]. The treating physician determined the mTICI Scores and functional outcome scores. Near full re-perfusion was defined as being mTICI 2b or greater and full as being mTICI 2c/3. Good functional outcome was defined as mRS 0-2 (Table 1–3).

NeVa device and technique

The NeVa™ thrombectomy device includes three sizes (M1-s 4 × 22, M1 4 × 30 and T 4.5 × 37). The stent scaffolding pattern results in three distinct zones when moving from proximal to distal. The initial segment is a closed cell stent structure which compresses thrombus and provides immediate flow restoration, the second segment consists of two large offset hybrid cell areas of minimal

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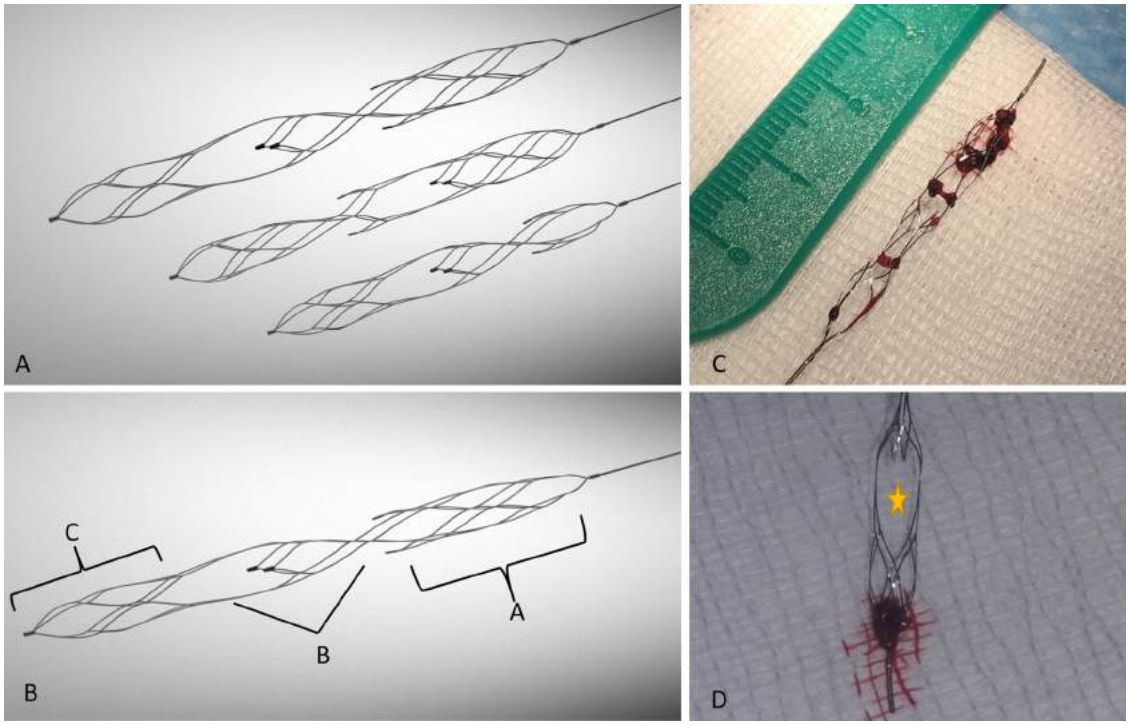

Fig. 1. A. Three sizes of NeVa, from top to bottom; T (4.5 × 37 mm), M1 (4.0 × 30 mm) and M1-s (4.0 × 22 mm). Note how M1-s lacks the proximal stent zone seen in M1 and T. B. Functional zones: (A) is flow restoration zone, (B) 'drop zone' with large offset openings for clot entry and (C) closed distal end for clot capture. C. M1-s with incomplete clot entry into the device. D. NeVa T with complete clot entry retained in the distal basket. Note enlarged opening with minimal metal coverage allowing entry of clot (star).

metal coverage, termed 'drop zones', which provide entry points for resistant thrombus. The final segment is a closed ended basket, which retains thrombus entering through the enlarged 'drop zone' openings. The M1-s differs from the M1 and T in that there is no proximal flow restoration zone (Fig. 1).

The NeVa^{TM} device was deployed with the proximal marker (junction of device to pusher wire) at the leading edge of the occlusion. In general, the M1 or M1-s was utilized for M1 and M2 MCA occlusions while the T was utilized for ICA and proximal M1 occlusions. After deployment, the device was left in place for up to 60 seconds and then slowly retrieved, either into a distal access catheter or into a proximal balloon guide catheter. The choice of proximal flow control (DAC vs balloon guide vs DAC + balloon guide) was left up to the discretion of the interventionalist. The flow control strategies were charted for each case (Table 1).

The operators were asked to comment on clot location after each pass, with four options: completely inside device, partially inside device, on the outside surface of the device or no thrombus identified.

This study was approved by the local ethics committee and all patients or next of kin signed the written informed consent.

Results

Baseline data

Among 30 included patients, 16 (53%) were men with mean age of 72 years. Mean presenting NIHSS was 16 (interquartile range (IQR), 13-20) and sites of primary occlusion were 10 ICA, 16 M1-MCA, 3 M2-MCA and one basilar. Baseline patient demographics and characteristics data can be found in Table 1.

Procedural data

The median procedure time was 52 minutes (IQR 37-79). A balloon guidecatheter was used without a DAC in 6 cases. A distal access catheter (intermediate catheter) without a balloon guide-catheter was used in the remaining 24 cases. The re-perfusion rates according to number of NeVa^{TM} passes and total number of passes are as follows: First pass TICI 2b or greater (19/30) 63%, TICI 2c-3 (14/30) 47%, total passes 30 (avg.1); Two or less passes TICI 2b or greater (25/30) 83%, TICI 2c-3 (17/30) 57%, total passes 41 (avg.1.4), Three or less passes TICI 2b or greater (27/30) 90%, TICI 2c-3 (18/30) 60%, total passes 47 (avg. 1.5), After final NeVa^{TM} pass TICI 2b or greater (28/30) 93%, TICI 2c-3 (19/30) 63%, total passes 50 (average 1.7). The end of procedure final reperfusion score (includes direct aspiration and the addition of other stent retrievers after last NeVa^{TM} pass) TICI 2b or greater (28/30) 93%, TICI 2c-3 (21/30) 70%, total passes 64 (avg.2.1) (Table 3). The addition of direct aspiration and stent retrievers compatible with distal location emboli (vessels less than 2 mm) resulted in an increase in TICI Score from 2b to 2c-3 in two patients and from 2c to 3 in a third. The NeVa^{TM} device performed well regardless of occlusion location or flow control strategy (BGC or DAC). The NeVa^{TM} device was designed to incorporate and retain thrombus inside the device [13]. Data about clot location after each pass was provided for forty of forty eight total passes and revealed that thrombus was found partially or completely incorporated into the device after 70% (28/40) of passes (Table 3).

Safety and performance data

There were no device related intra-procedural complications and all devices were noted to track through .021 (minimum compatible ID) microcatheters to the site of occlusion in all cases. There was one instance of a wire perforation during microcatheter placement unrelated to the deployment of the NeVa^{TM} device. The perforation required the procedure to be terminated after obtaining a TICI 2a reperfusion result. There were no instances of sICH and there were seven instances of asymptomatic petechial re-perfusion (HI 1) hemorrhage identified on follow up CT scans [18]. There were two instances of contrast extravasation seen on immediate

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post intervention follow up CT, which were both asymptomatic (Table 2).

Clinical outcomes

The mean 24 hour NIHSS score was 7 (IQR 1-11), which represented an average decrease of nine points compared to presentation. The discharge mRS score was 0-2 in 12/30 (40%) patients treated. The 90 day mRS was 0–2 in 16/30 (53%) of patients. There were five deaths in the series (17%), two of which occurred during hospitalization from malignant edema related to large volume strokes (Table 2).

Discussion

The use of stent retriever mechanical thrombectomy for stroke associated with large vessel occlusion has become the standard of care after multiple randomized trials have conclusively proven benefit over medical management [1–5]. The most studied and widely used stent retrievers, Trevo® and Solitaire®, share common features including a uniform cylindrical structure, uniform relatively small openings (5×4 and 4×4 mm respectively), uniform radial force and an open distal end [19–23]. Almost all current stent retrievers function in a similar manner, exerting force against the clot to trap the clot between the outer surfaces of the stent-retriever and the vessel wall [19–27]. Consensus is that when stent retrievers fail to open the vessel it is due to organized, firm thrombus [9–12]. Stent retrievers traverse the space between the clot and vessel wall without engaging the thrombus in a manner to allow extraction [9]. Incomplete penetration of organized thrombus into the stent openings due to a mismatch between the size of the thrombus and the size of the openings is postulated as another mechanism of failure [9–12].

The NeVa™ device is a novel thrombectomy device with multiple functional zones moving proximal to distal. The proximal third of the device is analogous to Solitaire® and Trevo®, having a uniform cylindrical shape, stent openings and radial force. The middle third of the device is comprised of a hybrid cell design with offset regions of minimal metal coverage to encourage the entry of resistant, organized clot into the inside surface of the device. The enlarged 'drop zone' openings measure 12×4.5 mm and 10×4 mm in the NeVa™ T and M1 devices. The third segment consists of a closed ended basket to retain clot fragments, which enter the inside of the device (Fig. 1). Having features of both a typical stent retriever coupled with a segment of very large, offset openings was postulated to be effective against a wide variety of clot types, including resistant or organized thrombus. Pre-clinical results with the NeVa™ supported the hypothesis and demonstrated efficacy against resistant and more typical clot morphology [13,14].

In this first in man clinical experience with the NeVa™ thrombectomy device, thirty consecutive patients treated at four stroke centers in two countries were evaluated. The inclusion criteria was broad and the series included a significant number of patients with time to groin puncture beyond six hours (8/30) as well as a range of occlusion sites (ICA, M1 and M2 MCA, Basilar) and five patients with tandem extracranial occlusions/stenosis which required treatment at the time of the procedure (Table 1). A high percentage of first pass effect was identified with (19/30) 63% achieving TICI 2b and nearly half (14/30) achieving full reperfusion (TICI 2c-3). First pass effect has been shown to correlate with improved clinical outcomes [17]. In this small series, a similar relationship was identified where 11/16 patients with a mRS of 0–2 at 90 days had a TICI 2b or greater first pass reperfusion result. After three or less passes with NeVa™ (27/30) 90% achieved at least TICI 2b with (18/30) 60% achieving full reperfusion (TICI 2c-3) (Table 3).

In (22/30) 73% of cases, NeVa™ was the only thrombectomy device or strategy employed. In the eight cases where additional strategies were performed, minimal improvements were seen in final reperfusion score. There were no device related adverse events identified in the series and the clinical outcomes compare favorably to other stent-retriever studies [21–26]. The in-hospital mortality was 7% (2/30) and the 90 day mortality 17% (5/30). In summary, the Neva™ stent retriever that previously presented encouraging results in preclinical in-vitro evaluation, has shown to be a safe and effective thrombectomy device in this first in man study.

Limitations

The non-randomized study design, small number of patients and non-core lab adjudicated reperfusion and clinical outcome measurements are valid criticisms against generalizing the results of the study. However, the positive results observed in this initial, consecutive, multi-center clinical experience using NeVa™ as a first line therapy, warrant further investigation in larger patient populations and randomized design study to determine the comparative efficacy of this unique design.

Conclusions

The NeVa™ thrombectomy device is a novel stent retriever, which demonstrated high rates of first pass efficacy, a good safety profile and favorable clinical outcomes in this initial clinical experience.

Disclosures

Marc Ribó has a consulting agreement with Stryker, Medtronic, Cerenovus, Apta, Perflow, Anaconda, Vesalio and he is founder and shareholder of Anaconda biomed.

The other authors report no conflicts.

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