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Mechanical thrombectomy using the Nimbus stent-retriever – initial experiences in a single-center observational study

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Abstract

Background: The Nimbus stent-retriever (NSR) was developed for mechanical thrombectomy of wall-adherent thrombi in cerebral arteries. It features a novel geometry with a proximal spiral section and a distal barrel section. The new device is designed to retrieve tough clots with a micro-clamping technique. In the first case series reporting on the NSR, we share our initial experience about the first 12 treated cases.

Methods: In total, 12 patients (5 men, 7 women; mean age 78 years) with occlusion of the internal carotid artery or the middle cerebral artery (M1 or M2 segment) were treated with the NSR, 11 after unsuccessful recanalization attempts with conventional stent-retrievers or aspiration thrombectomy.

Results: Retrieving maneuvers with the NSR recovered a thrombus in 7 patients (58%), of which 6 resulted in vessel recanalization mTICI $\geq$ 2b. Successful recanalization improved the mTICI score by a median of 3 points. In 5 of 7 cases, this required only one thrombectomy maneuver. In 5 cases, no improvement of recanalization could be achieved with the NSR (1–3 attempts). No NSR-related complications occurred in this case series.

Conclusions: In our initial experience, the NSR appeared to be a safe and effective second-line stent-retriever after unsuccessful MT with conventional stent-retrievers or aspiration thrombectomy allowing for mTICI $\geq$ 2b rescue thrombectomy in ab 50% of cases. No NSR associated complications occurred in our case series.

Keywords

mechanical thrombectomy, stroke, stent-retriever, second-line device, Nimbus

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Introduction

Stroke is the leading cause of disability worldwide and the second leading cause of death.[1] Due to demographic developments, the number of strokes is likely to increase significantly in the coming years.[2] The majority (87%) of strokes are caused by the occlusion of a cerebral artery with hypoxia and consecutive damage to the brain tissue.[3] In about 40% of cases, a large vessel is affected.[4] Treatment of acute ischemic stroke is based on intravenous lysis therapy and additional mechanical thrombectomy in case of large vessel occlusion.[5] Currently, second-generation stent-retrievers are often used in combination with aspiration catheters[6] using different techniques. The Stent-retriever Assisted Vacuum-locked Extraction (SAVE) has been shown to be fast and effective in regard to first pass reperfusion.[7] Another effective technique is known as "Solumbra", which is the combination of a distal aspiration catheter and a stent-retriever.[8] Stent-retrievers were the first medical devices to contribute not only to pure embolectomy but also to the reduction of disability after ischemic stroke.[9] Stent-retrievers are self-expanding devices made of nickel-titanium alloys (nitinol). Major advantage of this material is the superelasticity and the shape-memory effect. Due to these properties, stent-retrievers can be inserted into the occluded vessel through a microcatheter and unfold distally or at the level of the thrombus before the retrieving

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maneuver.[9] The composition of the thrombus has a major impact on the likelihood of success of endovascular clot retrieval.[10,11] Fibrin-rich clots of rubbery consistency with low red blood cell count[12–14] and mainly calcified thrombotic material[15] remain a challenge for conventional stent-retrievers (CSR) and require special endovascular devices.[16] The CERENOVUS NIMBUS geometric clot extractor (Nimbus stent-retriever, NSR, Cerenovus Johnson & Johnson Medical Ltd, Wokingham, United Kingdom) was developed for treatment of thrombotic fibrin-rich large vessel occlusions in patients with ischemic stroke.[17] Currently, there are no clinical application studies available in regard to the NSR for MT. Thus, we are reporting our initial clinical experience in the first 12 cases with this retrospective single center observational study.

Methods

Patient selection and procedure

The first 12 patients with acute ischemic stroke in whose therapy the NSR was used for MT of an internal carotid artery (ICA) or middle cerebral artery (MCA) occlusion were retrospectively included in the present study. The occlusion of the MCA refers to the M1 or M2 segment. Recanalization outcomes were analyzed using modified treatment in cerebral ischemia (mTICI) scores assessed before and after deployment of the NSR.

On admission, the National Institute of Health Stroke Scale (NIHSS) and modified Ranking Scale (mRS) were determined in each patient by neurological specialists. For primary imaging, each patient underwent native cranial computed tomography (CCT) followed by computed tomography angiography (CTA). The extent of irreversibly damaged brain parenchyma in the MCA territory was determined by Alberta Stroke Programm Early Computed Tomography Score (ASPECTS).[18] Subsequently, patients received either intravenous lysis therapy using recombinant tissue-type plasminogen activator (rtPA) for recanalization of the occluded artery followed by MT, or primarily MT in case of contraindications to lysis therapy.

In all 12 cases MT was performed by a femoral 9 French sheath, a proximal 8 French guiding catheter, a microcatheter with 0.021 inch inner diameter and a 0.014 inch steerable micro guidewire. Trevo and/or Embotrap III were used as CSR. Thrombectomy procedures were carried out using standard of care recommendations using either SAVE or "Solumbra" techniques.

To monitor the outcome of therapy, a CCT scan was performed one day after the intervention and the ASPECTS was determined again. Clinical outcome was finally evaluated at discharge using the mRS and NIHSS.

All cases were reviewed by two board-certified neuroradiologists (C.M., J.B.).

The CERENOVUS NIMBUS geometric clot extractor

The NSR was invented for treatment of large vessel occlusions by wall-adherent and tough clots in patients with acute ischemic stroke. The device consists of a laser cut nitinol stent-retriever connected to a nitinol shaft.[16] It has a 0.021 inch microcatheter compatibility and a working length of 28 mm. The indicated vessel diameter for the device ranges from 1.5 to 5 mm. Its design features two geometrically distinct sections: The proximal "spiral" section of 2.25 mm cage diameter is configured with a two-cell design with wide angles, large openings and a short strut length. The distal "barrel" section is designed with a four-cell design and a cage diameter of 4.5 mm. Radiopaque markers are located at the proximal and distal end of the stent-retriever as well as between the two sections, allowing to locate them under fluroscopy[19] (Figure 1).

To recanalize recalcitrant clots, a micro-clamping technique has been proposed,[20] which means the microcatheter is partially advanced over a stent-retriever before retrieving. The NSR should be positioned in the clot ideally such that the proximal radiopaque coil marker is aligned with the proximal face of the clot. Prior to clot retrieval, the microcatheter is re-advanced to the clot while holding the NSR push wire static until resistance is met, as a sign that the clot is pinched between the struts of the device and the microcatheter.[21] The special design of the spiral section allows to grip tough clots within the struts and to generate a consistent pinch force to improve clot clamping between the spiral section and the microcatheter. Because of that mechanism, the device is not suitable for performing bare wire thrombectomies with removal of the microcatheter immediately before the stent-retriever maneuver. Under aspiration, the NSR and microcatheter are withdrawn as a single unit to the guide catheter or intermediate catheter, maintaining the position relative to each other. The barrel section is designed to funnel the clot into either catheter while maintaining wall apposition and clot engagement during deployment and retrieval. The novel design has shown improvement in capturing tough clots in-vitro[16] and in-vivo[22] in situations where other CSR are unsuccessful.

Results

Twelve patients (mean age 78 years, range: 69–83, 5 male, 7 female) with known time of symptom onset (<6 h) or with wake-up-stroke were treated with the NSR between February and November, 2021. Details about the baseline demographics, the medical histories and information about the current stroke event, therapy and outcome of all included patients is given in Tables 1 and 2.

MT was performed by 5 different, experienced interventionalists. The large-vessel occlusions in this patient population were localized exclusively in the anterior cerebral circulation. Two patients presented with distal ICA occlusion, 8 patients with M1 occlusion and 2 patients with M2 occlusion. The median ASPECTS on initial CCT was 7 (range: 3–9). On admission, the mean NIHSS was 16.7 (range: 6–32) and median mRS was 3 (range: 0–5). Symptom onset remained unclear in 4 patients with wake-up strokes. Five of 12 patients were

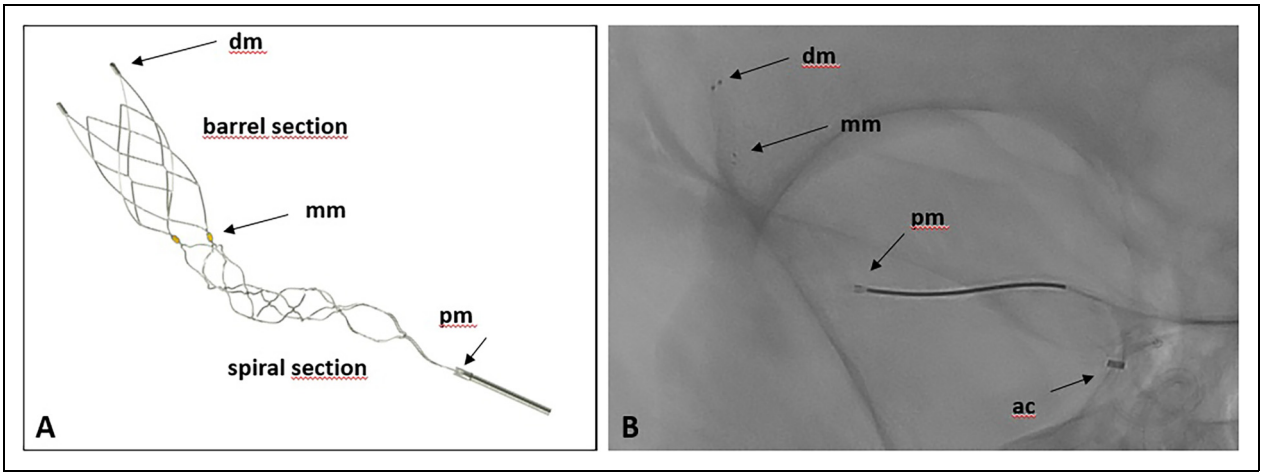

Figure 1. Image (A) of the Nimbus stent retriever (NSR; Courtesy of Cerenovus Johnson & Johnson Medical Ltd, Wokingham, United Kingdom) with a proximal marker (pm) followed by a spiral section of helically wound eyelets designed to pinch thrombus material with the distal microcatheter ostium upon retraction of the stent retriever. Spiral and barrel section are combined by two radiopaque middle markers (mm). Two distal markers (dm) indicate the end of the barrel section, which is designed to funnel the thrombus into the guide or intermediate catheter. Fluoroscopy view (B).

treated with intravenous lysis therapy using rtPA prior to thrombectomy with a mean time from symptom onset to start of lysis of 157 min (range: 80–267). The average time from symptom onset to groin puncture in the 8 patients with known symptom onset was 178 min (range: 95–286). The mean time from groin puncture to recanalization or final abortion averaged 70 min (range: 21–136). The median number of thrombectomy maneuvers until final recanalization or termination of the intervention was 4 (range: 2–7). In one of the 12 patients, the thrombus was imaged as predominantly calcified on CCT. In this case, we chose the NSR as the first thrombectomy device with the intention to test its potential of removing calcified clots. In the other 11 patients, the NSR was used after a median of 2 (range: 1–5) unsuccessful thrombectomy maneuvers using CSR or after unsuccessful aspiration thrombectomy (mTICI 0/1) as a second line thrombectomy device (Figure 2). Except for one patient (initial mTICI score 2a), all initial mTICI scores (prior to the use of the NSR) were 0 or 1. In 7 cases, the occluded artery could be recanalized by the NSR. Improvement of the mTICI score was achieved in one case from mTICI 0/1 to mTICI 2a, in 2 cases from mTICI 0/1 to mTICI 2b, in 3 cases from mTICI 0/1 to mTICI 2c, and in one case from mTICI 0/1 to mTICI 3. In 5 cases, no improvement of the mTICI score was achieved with the NSR.

The median number of thrombectomy maneuvers with the NSR was 1 (range: 1–3). In 5 of the 7 cases, in which improvement in recanalization was achieved, it was accomplished with the first pass of the NSR. In the remaining 2 cases, 2 passes were required.

In one case, in which recanalization could not be achieved after two initial unsuccessful attempts of a CSR, followed by a single pass with the NSR, a CSR was used again in the fourth maneuver. By doing this, the vessel could finally be recanalized; the mTICI score improved from 2a to 3.

In the second case, in which the NSR also failed to achieve recanalization, NSR was deployed after two unsuccessful maneuvers with a CSR. After three subsequent unsuccessful passes with the NSR, the intervention was finally terminated.

In the third unsuccessful case, the NSR was deployed after 5 ineffective conventional maneuvers. A sixth attempt with the NSR was also unsuccessful.

In the fourth case, two attempts of MT with the NSR were unsuccessful after four ineffective attempts of MT with CRS.

In the fifth case, in which severe calcification of the thrombus was already evident on native CCT, the NSR was used as the first-choice device. Recanalization could not be achieved after two maneuvers. A subsequent third maneuver with a CSR improved the mTICI score from 0/1 to mTICI 2a.

No specific complications that could be related to the use of the NSR occurred in the present study.

CCT controls performed on the first day after the intervention revealed a worsening of the ASPECTS in 10 patients to a median of 6 points (range 2–8). Three patients showed no further worsening of the ASPECTS compared to the initial CCT.

At discharge, the overall median mRS deteriorated from 3 to 5. Six of the 12 patients died during their hospital stay. Five of the 6 severely disabled patients died under palliative conditions within the framework of the living will. The sixth patient died due to multi organ failure after aspiration pneumonia. The median mRS of the 6 surviving patients at discharge was mRS 3 (range: 2–5).

Regarding the NIHSS, we have information on 5 of the 6 surviving patients at discharge. In one case, the NIHSS deteriorated from 17 to 18. In all other cases, the NIHSS improved from 13 to 4, from 14 to 10, from 15 to 3 and from 6 to 4.

Discussion

The present study is the first investigation reporting on clinical experience with the novel NSR. Overall, in our

Table 1. Information on patient data, current stroke event and initial imaging.

Patient data & current stroke event												
Patient	1	2	3	4	5	6	7	8	9	10	11	12
Sex	F	M	M	F	M	F	F	F	F	M	F	M
Age	81	79	79	78	72	77	69	81	78	80	83	83
Occluded vessel (L = left; R = right)	MCA M1 R	MCA M1 R	MCA M2 R	MCA M1 L	MCA M2 L	ACI R	MCA M1 L	MCA M1 R	MCA M1 L	MCA M1 L	MCA M1 L	ACI R
Risk factors & medication												
Aetiology	Unknown	Cardioembolism	Atherosclerosis	Cardioembolism	Atherosclerosis	Cardioembolism	Unknown	Unknown	Neurosarcoidosis	Unknown	Unknown	Unknown
Atrial fibrillation	No	Yes	No	Yes	No	Yes	No	No	Yes	Yes	No	Yes
Previous stroke event	No	No	No	No	No	Yes	No	No	Yes	No	Yes	O
Arterial hypertension	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes
Diabetes mellitus	No	No	Yes	No	Yes	No	No	No	Yes	No	No	No
Acetylsalicylic acid	Yes	No	Yes	No	No	No	No	No	No	Yes	Yes	No
Clopidogrel	No	No	No	No	No	No	No	No	No	No	No	No
Marcumar	No	No	No	Yes	No	No	No	No	Yes	No	No	Yes
DOAC	No	No	No	No	No	Apixaban	No	No	No	No	No	No
i.v.Lysis:	50 mg rtPA	63 mg rtPA	81 mg rtPA	no lysis	no lysis	no lysis	no lysis	60 mg rtPA	no lysis	70 mg rtPA	no lysis	no lysis
CT-Imaging												
Initial ASPECTS	8	9	7	7	8	5	8	3	6	9	7	7
ASPECTS 24 h control	8	9	4	6	8	2	3	NA	5	5	6	NA
Hyperdense artery sign	Yes	Yes	Calcified	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No

Table 2. Information therapy and outcome (SAH: subarachnoid hemorrage).

Timeframes (minutes)												
Patient	1	2	3	4	5	6	7	8	9	10	11	12
Symptom onset to lysis	267	80	134	no lysis	no lysis	no lysis	no lysis	182	no lysis	120	no lysis	no lysis
Onset to groin puncture	301	95	170	unknown	unknown	136	unknown	195	286	95	unknown	145
Onset to recanalisation	322	167	243	unknown	unknown	221	unknown	298	372	210	unknown	281 (aborted)
Groin puncture to recanalisation	21	72	73	69	80	85	38	103	86	115	77 (aborted)	136 (aborted)
Thrombectomy data												
Overall maneuvers	2	3	3	4	6	4	4	3	7	6	5	6
Maneuvers using CSR	1	1	1	3	4	2	2	2	4	4	2	5
Maneuvers using NSR	1	1	2	1	1	2	1	1	1	2	3	1
Maneuver 1	Aspiration	Embotrap III	NSR	Embotrap III	Trevo	Embotrap III	Trevo	Embotrap III	Aspiration	Embotrap III	Trevo	Embotrap III
Maneuver 2	NSR	NSR	NSR	Embotrap III	Trevo	Embotrap III	Trevo	Embotrap III	Aspiration	Embotrap III	Trevo	Embotrap III
Maneuver 3		Aspiration	Embotrap III	Embotrap III	Embotrap III	NSR	NSR	NSR	Aspiration	Embotrap III	NSR	Embotrap III
Maneuver 4				NSR	Embotrap III	NSR	Trevo		Aspiration	Embotrap III	NSR	Embotrap III
Maneuver 5					NSR				Embotrap III	NSR	NSR	Embotrap III
Maneuver 6					NSR				Embotrap III	NSR		NSR
Maneuver 7									NSR			
Outcomes												
mTICI prior use of NSR	0/1	0/1	0/1	0/1	0/1	0/1	2a	0/1	0/1	0/1	0/1	0/1
mTICI after use of NSR	2c	2b	0/1	2c	2b	2a	2a	2c	3	2a	0/1	0/1
mTICI final	2c	3	2a	2c	2b	2a	3	2c	3	2a	0/1	0/1
mRS admission	4	0	2	3	2	1	3	5	5	5	2	5
mRS discharge	4	2	5	6	3	6	5	6	6	6	4	6
NIHSS admission	13	13	14	19	15	15	17	32	21	18	6	17
NIHSS discharge	NA	4	10	NA	3	NA	18	NA	NA	NA	4	NA
Intracranial hemorrhage						SAH						

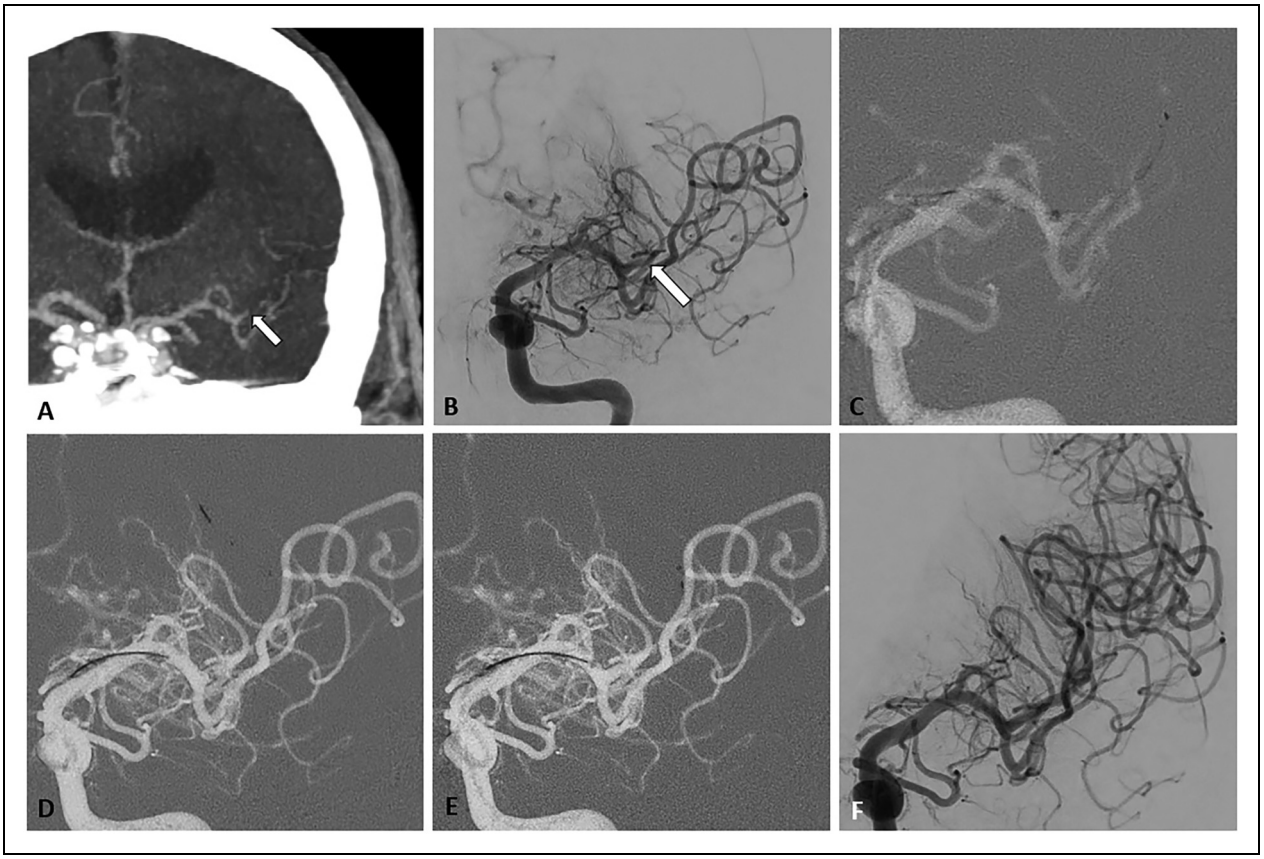

Figure 2. 72-year old male patient with wake up stroke (initial NIHSS 15; mRS 2; ASPECTS 8) due to an M2 occlusion of the left middle cerebral artery (MCA). The coronal CT angiography (A) and digital subtraction angiography in p.a.-view (B) depict an occlusion (mTICI 0) of the M2 branch (superior trunk) of the MCA (white arrow). Two unsuccessful mechanical thrombectomy attempts were performed with a conventional stent retriever (CSR) of 4 mm × 22 mm size (C) followed by another 2 futile maneuvers with another CSR of 5 mm × 37 mm size (D). After two recanalisation attempts with the NSR (E), successful recanalisation (mTICI 2b) was achieved within a groin-to-recanalisation time of 80 min (F). Patient recovered with an NIHSS of 3 and mRS of 3 at discharge with an unchanged ASPECT score of 8.

limited initial experience the NSR turned out to be a useful rescue device in the treatment of ischemic stroke after unsuccessful MT with CSR or unsuccessful aspiration thrombectomy.

In cases of unsuccessful MT with the NSR, this was mainly due to the inability to remove the thrombus from the cerebral artery, rather than the inability to penetrate the thrombus with the guidewire and microcatheter. This finding is in line with the observations of other studies using modern stent-retriever devices. Piasecki et al., for example, describing their experience with the Tigertriever™, did not encounter a case in which it was impossible to cross the thrombus with the device. The cases of failure were all related to failed attempts to remove the thrombus, which is similar to our experiences with the NSR.[23] In one case of a severe calcified thrombus, the NSR was ineffective because it was not possible to pinch it to the microcatheter ostium. However, subsequent MT was successful using a CSR.

It has been shown that complete wall-stent apposition facilitates a higher recanalization rate and lower embolism rate.[24] In case of the NSR, the complex geometry is intended to cover a maximum of the vessel lumen and to improve the contact between particularly adherent clots and device, which should reduce the number of required passages.[17] This is underlined by the cases presented in this study. Except for two cases, successful recanalization was achieved by only one maneuver, which improved the mTICI score by a median of 3 points. This first pass success rate (5 out of 11, 45%) seems to be in a similar range compared to previous studies describing the efficiency of other second line stent-retriever devices. For example, Piasecki et al. report on an first pass success rate of 55% using the Tigertriever™ as a rescue therapy in 20 cases.[23] The Tigertriever™ uses manual expansion and contraction of the stent by movement of a core wire connected to a handle,[23] which is an alternative method to achieve an enhanced wall-stent apposition. Akpinar et al. report on a first pass success rate of 56.8% using the NeVa™ thrombectomy device as a first line thrombectomy device in 118 cases.[25] The special design of the NeVa™ device with large drop down zones and a closed distal tip, applying enhanced expansive radial force, may be more efficient in retrieving all clot types.[25,26] Moreover, studies have shown that a higher first pass success can be achieved by using longer devices.[27,28] Only one size of NSR (4,5 × 20 mm) is currently available and used in our study population. In case of the Tigertriever™ XL device, for example, a longer, adjustable device with a maximum length of 53 mm is available.[29] In comparison, the NeVa™ device has 4

alternative configurations with different diameters and working lenghts.[26]

Another approach to improve the first pass success of MT in general would be the ability to estimate the thrombus composition prior to MT to select the suitable primary thrombectomy device. Magnetic Resonance Imaging and unenhanced CT can be used to identify a red blood cell-rich thrombi by the presence of a hyperdense artery sign or gradient-echo blooming artifact.[30] Kim et al. showed that the proportions of fibrin and platelets were significantly higher in clots without a susceptibility vessel sign, whereas the proportion of red blood cells was significantly higher in clots with a susceptibility vessel sign.[31] A recent study by Fitzgerald et al. demonstrated a significant correlation between platelet-rich clots and the absence of hyperdensity in unenhanced CT.[32] A study by Niesten et al. demonstrated that lower absolute and relative Hounsfield Units in unenhanced CT are independently related to persistent occlusion.[33] Another study has shown that higher thrombus density in unenhanced CT is an independent predictor for secondary embolism.[34]

A promising future approach to characterize clot composition prior thrombectomy could be Electrical Impedance Spectroscopy (EIS). EIS based sensors integrated on catheters or guidewires could be used to measure the electrical response of different clots over a frequency range, leading to a characteristic impedance spectra that is determined by clot structure, dimension, arrangement and components.[35,36] For example, in a recent study Santorelli et al. investigated the dielectic profile of 32 physiologically relevant blood clot analogues, combined with a subsequent histologic analysis of the red blood cell content. Based on EIS measurement, it was possible to classify the blood clot analogues in RBC rich or platelet and fibrin rich clots.[37] Süselbeck et al. sucessfully used a conventional coronary balloon catheter system with an integrated polyimide-based microelectrode structure for 3D mapping and detection of atherosclerotic lesions in a rabbit model.[38]

The main limitation of this case series is the small number of patients treated with the NSR and the retrospective design with a lack of standardization, due to heterogenity of treatment by 5 different interventionalists, conducted with no defined inclusion criteria, methodology or standardized thrombectomy procedure in clinical routine. Each interventionalist could gain only little experience with the device and especially the pinching technique. It is possible that recanalization rates will improve as interventionalists become more experienced with the NSR.

Further investigation with a larger population is required to fully determine the role of the NSR in rescue thrombectomy, to assess long-term clinical outcomes and to support our first experiences regarding safety and efficacy, especially in comparison to other second line stent-retrievers like the Tigertriever™ or NeVa™ devices.

Conclusions

The NSR was able to achieve mTICI $\geq$ 2b recanalization of the occluded vessel in 6 of 12 cases (50%) after unsuccessful MT with CSR or unsuccessful aspiration thrombectomy. Only one thrombectomy maneuver was required for recanalization with the NSR in 5 cases. The mTICI score was improved by a median of 3 points in case of successful recanalization. NSR-specific complications did not occur in any of the treated patients.

Abbreviations

ac	aspiration catheter
ADAPT	A Direct Aspiration First Pass Technique
ASPECTS	Alberta Stroke Programm Early CT Score
CCT	cranial computed tomography
CSR	Conventional stent-retriever
CTA	computed tomography angiography
DOAC	direct oral anticoagulants
dm	distal markers
EIS	Electrical Impedance Spectroscopy
Fig.	Figure
ICA	internal carotid artery
mRS	modified Rankin Scale
MCA	middle cerebral artery
mm	middle markers
MT	mechanical thrombectomy
mTICI	modified Treatment In Cerebral Infarction
NIHSS	National Institute of Health Stroke Scale
No.	Number
NSR	Nimbus stent-retriever
pm	proximal marker
rtPA	recombinant tissue-type plasminogen activator
SAH	subarachnoid hemorrhage
SAVE	Stent-retriever Assisted Vacuum-locked Extraction

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Credit autor statement

Jan Boriesosdick: Investigation, Writing – Original Draft, Formal analysis, Data Curation, Visualization. Arwed Elias Michael: Writing – Original Draft. Jan-Robert Kröger: Investigation. Julius Henning Niehoff: Formal analysis. Saher Saeed: Investigation. Marc Pflug: Investigation. Peter Schellinger: Investigation. Volker Maus: Writing – Review & Editing. Jan Borggrefe: Conceptualization, Resources, Writing – Review & Editing. Christoph Mönninghoff: Supervision, Project administration, Writing – Review & Editing.

Declaration of conflicting interests

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Ethics approval

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Ethics Committee of the Ruhr-University Bochum (19 July 2021, reference number 2021-827).

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