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First clinical multicenter experience of the new NeVa NET 5.5 thrombectomy device

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ABSTRACT

Background Mechanical thrombectomy for the treatment of acute ischemic stroke has undergone relevant technical improvements over recent years. However, distal emboli and incomplete reperfusion after mechanical thrombectomy are still shortcomings in the care of patients with endovascular acute ischemic stroke. The NeVa NET 5.5 thrombectomy device (Vesalio, Nashville, Tennessee, USA) is the first stent retriever featuring an integrated clot micro-filtration system, aiming to enhance first pass efficacy and reduce distal embolization. This study evaluates the safety and efficacy of the NeVa NET 5.5 thrombectomy device.

Methods Patients with acute anterior circulation occlusions and vessel diameters >2 mm treated with the NeVa NET 5.5 stent retriever as a first-line approach were retrospectively included in this study. Data were collected from three European comprehensive stroke centers between October 2022 and April 2024. Patient data, occlusion details, clinical outcomes, and procedure-related parameters were analyzed.

Results A total of 51 patients were included. The most common occlusion locations were the internal carotid artery terminus and intradural internal carotid artery (70.6%). The mean±SD clot length was 25.1±13.3 mm (range 4–50 mm). First pass reperfusion (eTICI 2b–3) was achieved in 78.5%, with a final reperfusion rate of eTICI 2b–3 in 98.1%. Distal embolization in new territories occurred in 3.9%. No device-related adverse events were reported, and procedure-related adverse events occurred in 7.6% of the overall included cases.

Conclusion The NeVa NET 5.5 stent retriever has a high first pass reperfusion rate in large vessel occlusions of the anterior circulation, with a good safety profile and low rate of distal embolization.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Distal embolization and incomplete reperfusion remain significant challenges in mechanical thrombectomy for acute ischemic stroke.

WHAT THIS STUDY ADDS

⇒ This study provides the first multicenter evaluation of the novel NeVa NET 5.5 stent retriever, demonstrating high rates (54.9%) of first pass near-complete to complete reperfusion in large vessel occlusions, including a substantial proportion of intradural internal carotid artery (ICA-I, ICA-T) occlusions with extensive thrombus burden, accompanied by low distal embolization rates.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Particularly in ICA-I and ICA-T occlusions with large thrombi, the NeVa NET 5.5 stent retriever represents an effective option to achieve high first pass reperfusion rates with a favorable safety profile, potentially influencing procedural strategies and guiding device selection in clinical practice.

INTRODUCTION

Besides ischemic heart disease, acute ischemic stroke (AIS) is the second most common cause of death and serious long-term disability; 80% of strokes are ischemic strokes due to vessel occlusion. Mechanical thrombectomy (MT) has become the standard of care for AIS due to large vessel occlusions (LVO), particularly in the anterior circulation.[1] The favorable outcome depends on time to reperfusion, the final result of recanalization, the first pass effect (FPE), and the occlusion location.[2–5] The clot composition, especially fibrin-rich hard clots, and the presence of distal embolization influence the FPE negatively.[6–10] Specifically, internal carotid artery terminus (ICA-T) and intradural internal carotid artery (ICA-I) occlusions are associated with a worse clinical outcome and a high rate of secondary embolization in a new territory during MT.[11–13] To target these predictors, the NeVa stent retriever (Vesalio, Nashville, Tennessee, USA) was developed and showed high rates of first pass efficacy and safety with all types of clots.[14 15] To lower distal embolization, the new NeVa NET 5.5 stent retriever includes an integrated clot micro-filtration system in the distal tip. The aim of this study is to evaluate the safety and efficacy of the NeVa NET 5.5 stent retriever.

MATERIALS AND METHODS

Study design

We retrospectively analyzed all patients treated with the NeVa NET 5.5 stent retriever as the first-line use for occlusions of the anterior circulation with a vessel diameter >2 mm in the ICA-I, ICA-T, and M1 segment of the middle cerebral artery

(MCA) between October 2022 and April 2024 at three European comprehensive stroke centers.

Clinical data and outcomes

Demographics included gender and age at presentation. The Alberta Stroke Program Early CT Score (ASPECTS) was evaluated using non-enhanced cranial computed tomography (NECT).[16] The National Institutes of Health Stroke Scale (NIHSS) score was measured at presentation and 24 hours following MT by a board-certified stroke neurologist. The modified Rankin Scale (mRS) was documented pre-stroke and at discharge (0–2 favorable outcome; 3–5 major morbidity; 6 dead).[17] Intracerebral hemorrhage (ICH) and symptomatic intracerebral hemorrhage (sICH) were classified according to the Heidelberg bleeding classification as described previously.[18]

Data evaluation

The occlusion characteristics and reperfusion grading were assessed and evaluated independently on-site at each center by two board-certified neuroradiologists or neurointerventionalists, each with 5–15 years of experience. In cases of disagreement, the assessment was reviewed by a third board-certified neuroradiologist or neurointerventionalist and the final rating was determined by majority consensus.

Occlusion characteristics

The occlusion site and location were determined using CT angiography (CTA), magnetic resonance angiography (MRA), or digital subtraction angiography (DSA). The length of the clot was measured in thin-sliced (0.5–1 mm) axial images from the pre-mechanical thrombectomy NECT if available.[19 20] The collateral status was assessed according to Tan *et al* based on the single-phase CTA (sCTA) (0: absent collateral supply to the occluded MCA territory; 1: collateral supply filling ≤50% but >0% of the occluded MCA territory; 2: collateral supply filling >50% but <100% of the occluded MCA territory; 3: 100% collateral supply of the occluded MCA territory).[21]

Device details

The NeVa NET 5.5 thrombectomy device is designed with an outer laser-cut nitinol frame and an internal dual-layered nitinol braid. The outer frame, measuring 5.5 mm in diameter, includes three 90 degree offset 'drop zones' optimized for capturing both soft and resistant thrombi. Distally, the frame tapers to a closed end that secures the clot. An integrated micro-filter at the tip of the device, constructed from 32 braided nitinol strands, provides a dual-layer filtration mechanism, effectively capturing particles <400 microns. This micro-filter further enhances clot retention by reducing the risk of distal end collapse. The NeVa NET 5.5 has a working length of 37 mm, is compatible with 0.027 inch ID microcatheters, and is indicated for use in vessels of 2 mm or larger.[22] A comparison between the NeVa NET 5.5 stent retriever and the NeVa stent retriever is shown in figure 1.

Procedure

Time intervals were recorded from onset or last seen well (LSW) to groin puncture, from presentation to groin puncture, and from groin puncture to final reperfusion. First-line use of the NeVa NET 5.5 stent retriever was mandatory. The choice of technique, whether to use a stent retriever alone or in combination with an aspiration catheter, was left to the discretion of the treating physician. The grade of reperfusion for each pass was evaluated according to the expanded Thrombolysis in Cerebral Infarction (eTICI) scale.[23] Successful reperfusion was defined as eTICI 2b50–3, while near-complete or complete reperfusion was defined as eTICI 2c–3.[24 25] The distal access catheters, proximal flow arrest, any switch to a different stent retriever, embolization in another downstream territory, and intraprocedural complications were documented.

Statistical analysis

For the statistical analysis, SPSS 29 (IBM, Redmond, Washington, USA) was used. The clinical and patient data, occlusion characteristics, and outcome parameters were analyzed descriptively. Continuous variables are listed as mean±SD and range or median and IQR. Binary variables are listed as total numbers and percentage. Differences between two groups of binary variables were calculated with the χ^2 test. Depending on the normal distribution, the unpaired t-test or the Mann–Whitney U-test was used for differences between two groups for continuous variables. The Kruskal–Wallis test was used to compare dependent variables across independent groups, as the data did not meet the assumptions of normality and homogeneity of variances. The unpaired t-test was used to compare the means between two independent groups. In cases where the assumption of homogeneity of variances was violated, Welch's t-test was applied. The correlation between clot length and grade of reperfusion was

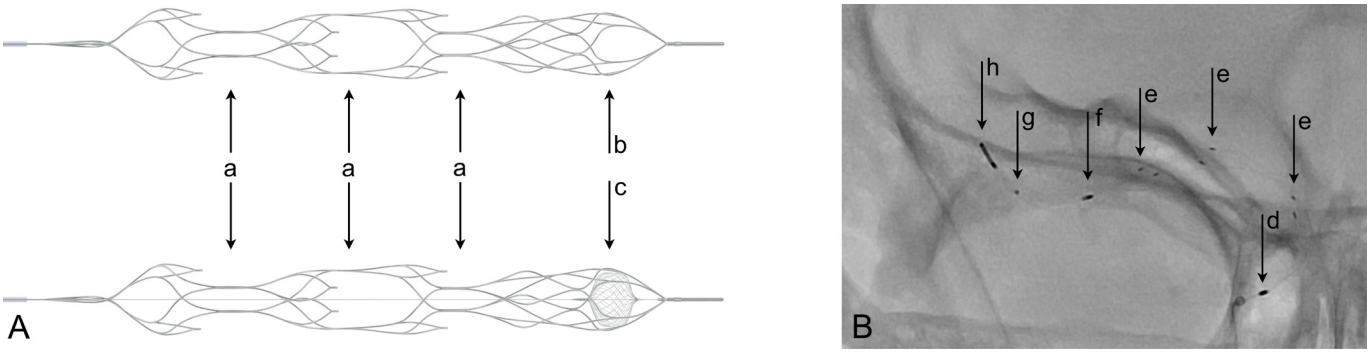

Figure 1 (A) Detailed comparison of the NeVa stent retriever (top) and the NeVa NET 5.5 stent retriever (bottom). Both devices feature three large offset openings (a), referred to as 'drop zones'. The NeVa NET stent retriever includes a dual-layer micro-filter at the distal tip (c), made from 32 braided nitinol wires, distinguishing it from the conventional NeVa stent retriever with a closed distal tip (b). (B) Single-shot unsubtracted DSA frame after deployment showing the proximal radiopaque marker (d). The three 'drop zone' markers (e) indicate the complete opening of each segment. At the distal end, the dual-layer micro-filter is attached proximally (f) to the pusher wire, extending to the distal marker (g) and transitioning to the distal tip marker (h).

Table 1 Baseline and occlusion characteristics

Characteristics	Values
Age (years), mean±SD (range)	75±13.5 (48–92)
Sex, n (%)	
Female	22 (43.1)
Male	29 (56.9)
Pre-stroke mRS, n (%)	
0	40 (78.4)
1	4 (7.8)
2	1 (2)
3	6 (11.8)
NIHSS at presentation, mean±SD (range)	17±5.5 (7–28)
Use of IVT n (%)	25 (49)
Occlusion location, n (%)	
ICA-T	28 (54.9)
ICA-I	8 (15.7)
M1 MCA	15 (29.4)
Occlusion site, n (%)	
Left	19 (37.3)
Right	32 (62.7)
Clot length (mm), mean±SD (range))	25.1±13.3 (4–50)
ASPECTS, median (IQR)	8 (7–10)
Single-phase CTA collateral score, n (%)	
0	16 (31.4%)
1	11 (21.6%)
2	12 (23.5%)
3	7 (13.7%)
Symptom onset/LSW to groin puncture (min), mean±SD (range)	356±247 (75–935)
Presentation to groin puncture (min), mean±SD (range)	74.2±33.6 (5–173)

ASPECTS, Alberta Stroke Program Early CT Score; CTA, CT angiography; ICA-I, intradural internal carotid artery; ICA-T, internal carotid artery terminus; LSW, last seen well; MCA, middle cerebral artery; mRS, modified Rankin scale; NIHSS, National Institutes of Health Stroke Scale.

assessed using Spearman's rank correlation coefficient. Statistical significance was described as $P<0.05$.

RESULTS

Patient characteristics

A total of 51 patients were included. The mean±SD age was 75±13.5 years (range 48–92). Of these, 56.9% (n=29) were male. The pre-stroke mRS score was 0–2 in 45 patients (88.2%) and 3 in six patients (11.8%). The mean±SD presenting NIHSS score was 17±5.5 (range 7–28).

Occlusion characteristics

The most recent occlusion location was the ICA-T in 28 cases (54.9%), followed by the M1 segment of the MCA in 15 patients (29.4%) and the ICA-I in eight (15.7%). 53% of the patients presented with a poor sCTA collateral status classified as 0–1. A detailed breakdown is shown in table 1.

Procedure characteristics

The mean time from groin puncture to final reperfusion was 38 min. In 13 cases (25.5%) a stent retriever was used alone, while in 38 cases (74.5%) a stent retriever was combined with an aspiration catheter. The mean±SD number of passes was 1.7±1.1 (range 1–5). There was no significant difference in the number of passes required across occlusion locations (ICA-T, ICA-1, M1 MCA) (P=0.94). The NeVa NET 5.5 stent retriever was used for all passes in 40 cases (78.4%). In 11 cases (21.6%) a different stent retriever was used as a bail-out procedure. In the stent retriever-only group, a balloon-guiding catheter (BGC) was used in nine cases (69.2%) compared with 18 (47.4%) in the combined group. The number of passes required to achieve final reperfusion was significantly lower in the stent retriever-only group with a mean of one pass compared with the stent retriever plus aspiration catheter group (mean±SD 1.9±1.1; range 1–5) (P<0.001). A moderate negative correlation was observed between clot length and grade of reperfusion (ρ=0.33, P=0.031). A summary of the data is shown in table 2.

First pass reperfusion (FPR) with complete reperfusion (eTICI 2c–3) was observed in 28 cases (54.9%). Successful reperfusion (eTICI 2b50–3) was achieved in 40 cases (78.5%). Final reperfusion with an eTICI 2b50–3 after the exclusive use of the NeVa NET 5.5 was 92.2% (n=47), and 98.1% (n=50) when including rescue therapy. A detailed overview of the reperfusion results is provided in table 2 and figure 2.

Procedure-related adverse events were reported in four cases (7.6%). In one of these cases, a rupture of an aneurysm which had been obscured by the clot occurred at the apex of the ICA-T. Embolization in a new territory occurred in two patients (3.9%), all of them having been localized in the anterior cerebral artery, and occurred after a thrombectomy pass in an ICA-T occlusion without using a BGC. Any ICH was observed in 12 patients (23.5%), with two patients classified as sICH up to 24 hours after the procedure. The most common ICH types, according to the Heidelberg bleeding classification, were type 1a (HI1) and type 2 (PH2), each accounting for 25% of the cases. A detailed summary is provided in table 2.

Clinical outcomes

The mean±SD NIHSS score after 24 hours was 13±9.3 (range 1–35), which represents a decrease of 4 points compared with the NIHSS score at admission. The mRS score at discharge was 0–2 in 13 cases (25.5%) and 3–5 in 23 cases (45.1%). Fifteen patients (29.4%) died (mRS 6) during the inpatient stay following the procedure.

The median collateral status at admission was 2 (2–3) in the mRS at discharge 0–2 group, 1 (0–2) in the mRS 3–5 group, and 0 (0–1) in the mRS 6 group. The differences between the mRS 0–2 group and the mRS 3–5 group (P=0.03), as well as the mRS 0–2 group and the mRS 6 (dead) group (P<0.001), were statistically significant.

DISCUSSION

The NeVa Net 5.5 stent retriever is an advanced iteration of the NeVa thrombectomy device. The outer frame also features three large openings, known as 'drop zones'. This design facilitates the integration of clots ranging from resistant to soft compositions.[14 15] Beyond clot composition, the FPE is a critical predictor of clinical outcomes.[5] In the prospective CLEAR study conducted by Yoo *et al*, 139 patients with an LVO were treated using the NeVa stent retriever. Reperfusion in this cohort achieved an eTICI 2c–3 in 48.6% and an eTICI 2b–3 in 73.8% on the first pass. In our retrospective study the FPR rates were higher, achieving an eTICI 2c–3 in 54.9% and an eTICI 2b–3 in 78.5%. Final reperfusion measures in the study by Yoo *et al* were comparable to ours, with an eTICI 2b–3 achieved in 99.1% compared with 98.1% in our study.[24] In the MASTRO I meta-analysis by Zaidat *et al*, the three commonly used stent retriever models Trevo (Stryker, California, USA),

Table 2 Procedure and reperfusion characteristics

Characteristics	Values
Groin puncture to final reperfusion (min), mean±SD (range)	38±27.2 (8–125)
Technique, n (%)	
Stent retriever alone	13 (25.5)
Stent retriever+aspiration catheter	38 (74.5)
Balloon guiding catheter, n (%)	27 (52.9)
Number of passes, mean±SD (range))	1.7±1.1 (1–5)
All passes with NeVa NET 5.5, n (%)	40 (78.4)
Safety measures (n=51), n (%)	
Any ICH	12 (23.5)
1a HI1	3 (25)
1b HI2	2 (16.7)
1c PH1	1 (8.3)
1c PH1, 3c	1 (8.3)
2 PH2	2 (16.7)
2 PH2, 3b, 3c	1 (8.3)
3c	2 (16.7)
sICH	2 (3.9)
Embolization new territory	2 (3.9)
Vasospasm	1 (1.9)
Retroperitoneal hematomaa	1 (1.9)
Microwire perforation	1 (1.9)
Aneurysm rupture	1 (1.9)
Reperfusion, % (n)	
NeVa NET first pass reperfusion (eTICI)	
1	9.8 (5)
2a	11.8 (6)
2b50	11.8 (6)
2b67	11.8 (6)
2c	5.9 (3)
3	49 (25)
NeVa NET only final (eTICI)	
0	1.9 (1)
1	1.9 (1)
2a	3.9 (2)
2b50	13.7 (7)
2b67	11.8 (6)
2c	11.8 (6)
3	54.9 (28)
NeVa NET final including rescue therapy (eTICI)	
2a	1.9 (1)
2b50	9.8 (5)
2b67	5.9 (3)
2c	15.7 (8)
3	66.7 (34)
NeVa NET first pass reperfusion ICA-T (eTICI)	
1	7.1 (2)
2a	14.3 (4)
2b50	10.7 (3)
2b67	14.3 (4)
2c	10.7 (3)
3	42.9 (12)
NeVa NET first pass reperfusion ICA-I (eTICI)	
1	12.5 (1)
2a	0 (0)
2b50	12.5 (1)
2b67	12.5 (1)
2c	0 (0)
3	62.5 (5)
NeVa NET first pass reperfusion MCA M1 (eTICI)	
1	9.8 (5)
2a	11.8 (6)
2b50	11.8 (6)
2b67	11.8 (6)
2c	5.9 (3)
3	49 (25)

eTICI, expanded Thrombolysis in Cerebral Infarction; ICA-I, intradural internal carotid artery; ICA-T, internal carotid artery terminus; ICH, intracerebral hemorrhage; MCA, middle cerebral artery; sICH, symptomatic intracerebral hemorrhage.

Solitaire (Medtronic, California, USA), and EmboTrap (Johnson & Johnson MedTech, California, USA) were evaluated. A total of 9804 patients were included. The FPR for achieving an eTICI 2c–3 ranged from 23.1% to 40.1% while, for an eTICI 2b–3, it ranged from 41% to 50.8%. Final reperfusion rates achieving an eTICI >2b were between 81.7% and 86.6%.[25] All three reperfusion outcomes reported in this meta-analysis were lower than those observed in our retrospective study. A major difference between our data and the studies mentioned is the high proportion of ICA-T and ICA-I occlusions, observed in 70.6% of cases in our study compared with 16.6–27.1% in the MASTRO I study and 10.1% in the CLEAR study.[24 25] Riegler *et al* reported in a cohort of 2312 patients with ICA-T and ICA-I occlusions that the FPR rate achieving mTICI 2b–3 was 32.6%, which was lower compared with other anterior circulation occlusions.[26] Our subgroup analysis of FPR depended on ICA-T and ICA-I occlusions, resulting in a higher eTICI 2b–3 FPR at 83%. Another important factor influencing clinical outcomes negatively is a high rate of distal embolization.[27] To minimize distal embolization rates, the NeVa NET stent retriever contains a dual-layer micro-filter at the distal tip, braided out of 32 nitinol wires, differentiating it from the conventional NeVa stent retriever. In an in vitro comparison of different tip designs (open tip, closed tip, and filter tip), the NeVa NET stent retriever with the filter tip design demonstrated the lowest rate of distal embolization >1 mm at 56% (open tip: 84%; closed tip: 80%).[28] In the MASTRO I study by Zaidat *et al*, the overall rates of distal embolization into new territories across all locations ranged between 5.3% and 7.7%. Subgroup analysis by occlusion location was not conducted.[25] Ota *et al* investigated procedural and clinical outcomes in 81 patients undergoing MT for ICA-T and ICA-I occlusions, concluding that distal embolization was more frequent with a reported rate of 18.2%.[13] In comparison, the distal embolization rate in our study was lower at 3.9%. Pilato *et al* reported in an investigation of clot characteristics and distal embolization in 327 patients that longer clots (M=14.39±7.93 mm) increase the risk of distal embolization, negatively impacting

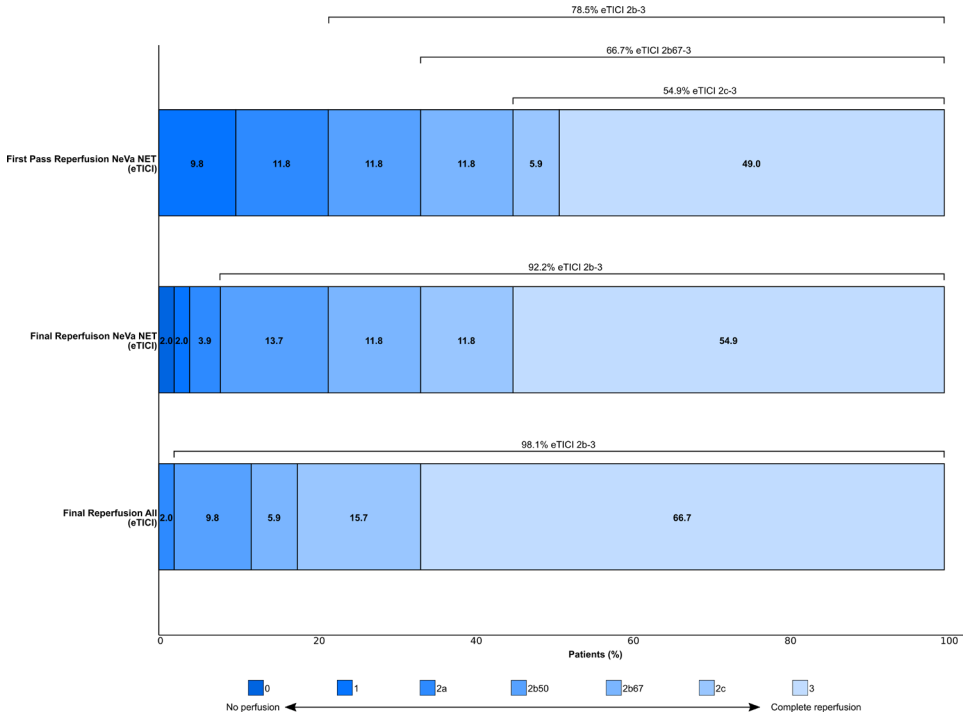

Figure 2 Reperfusion results. Distribution of expanded Thrombolysis in Cerebral Infarction scale (eTICI) after the first NeVa NET 5.5 pass, after all NeVa NET 5.5 passes (without rescue therapy), and after all passes including rescue therapy.

patient outcomes.[29] These findings were corroborated in a substudy of the ESCAPE-NA1 trial by Bala *et al*, who analyzed 496 patients. Overall, any distal embolization was observed in 50.6% of the patients. They showed that longer thrombi (median (IQR) 28.5 (20.8–42.3) mm) were associated with a higher risk of distal embolization. Conversely, their analysis showed that fewer thrombectomy passes were associated with a lower risk of distal embolization. Furthermore, they concluded that the presence of distal embolization significantly decreases the likelihood of achieving functional independence. They explain that longer thrombi tend to be more prone to fragmentation and dislocate more frequently from the distal part of the stent retriever.[30] The low rate of distal embolization in a new territory observed in our study, despite clot lengths of up to 50 mm, could potentially be explained by the low number of necessary passes (mean±SD 1.7±1.1) in combination with the protective mechanism of the integrated micro-filter in the distal tip of the NeVa NET stent retriever, potentially preventing clot fragments from migrating distally, as previously described by Li *et al*.[28] The rate of ICH in ICA-T and ICA-I occlusions is reported to be between 11% and 28%. The rate of sICH ranges from 4.1% to 4.9%, which is consistent with our data, showing an ICH rate of 23.5% and an sICH rate of 3.9%.[13 26] As previously published, poor collateral status has a negative impact on clinical outcomes.[21 31] This is also reflected in our data. The mRS score following MT in studies with a dominance of ICA-T and ICA-I occlusions typically shows an mRS of 0–2 in 27.3–39.7% of cases, an mRS of 3–5 in 35.7% of cases, an mRS of 6 in 37% of cases and an mRS of 5–6 in 54% of cases.[13 26] These results are in line with our findings. No device-related adverse events were observed. The rate of procedure-related adverse events in our study was 7.6%, which is in line with the recent stent retriever studies (4.8–10%).[24 32–34]

Limitations

The retrospective study design and small sample size are primary limitations. No 90-day clinical follow-up data were available, limiting the assessment of long-term outcomes. Additionally, the image data were not evaluated by an independent core laboratory so the generalizability of our findings is restricted. On the other hand, we present the first multicenter data on the use of the NeVa NET 5.5 stent retriever. These results require further validation in prospective randomized studies for more robust conclusions.

CONCLUSION

In our initial multicenter experience, the NeVa NET 5.5 stent retriever achieved high FPR rates in large vessel occlusions of the anterior circulation, with a good safety profile and low rate of distal embolization in long thrombi.

Contributors All listed authors provided a substantial contribution to the work. RS acquired, analyzed and interpreted data for the work, designed the study, drafted the manuscript and is the guarantor. JARP, BK, BAR, JSG, KH, SJM, EK, and MT acquired data for the work. EF provided linguistic revision/editing. DB provided critical revision of the manuscript. All authors approved the final version of the manuscript.

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Patient consent for publication Not applicable.

Ethics approval Ethical approval was obtained as required according to the guidelines of the local ethics committees (Ethics Committee, Medical Faculty of Otto-von-Guericke-University Magdeburg, Magdeburg, Germany). The data have been legally collected in accordance with paragraph §15, subsection 5 (University Hospital Magdeburg).This anonymous retrospective study, which was conducted in accordance with the Declaration of Helsinki, fulfills the guidelines of the federal state of Saxony-Anhalt.

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