ORIGINAL RESEARCH

Ultra-distal access of the M1 segment with the 5 Fr Navien distal access catheter in acute (anterior circulation) stroke: is it safe and efficient?

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ABSTRACT

Background and aim The importance of mechanical thrombectomy in acute stroke treatment has grown over recent years. Mechanical thrombectomy comprises many different techniques. Technical improvements in the catheter material have led to the development of large-bore distal access catheters which can enter tortuous intracranial vessels. This has promising applications for endovascular stroke treatment. This study evaluated the safety and success rate of ultra-distal access of the middle cerebral artery (MCA) M1 segment with the 5 Fr Navien 58 distal access catheter in the treatment of acute stroke in combination with stent retrievers.

Methods We retrospectively analyzed 81 patients with an acute stroke of the anterior circulation in whom ultra-distal access to the M1 segment was carried out using the Navien 58 catheter with an anchoring technique with a stent retriever for mechanical thrombectomy. Technical complications, success rates of catheter placement, success rates of thrombectomy using the modified Thrombolysis In Cerebral Infarction (mTICI) score, and the procedure times were evaluated.

Results Ultra-distal access with the Navien 58 was successful in 75% (61/81) of cases. Recanalization success with a mTICI score of 2b and better was achieved in 83% overall (67/81), in 90% (55/61) of cases with successful ultra-distal access and in 60% (12/20) of cases without ultra-distal access. No severe adverse effects such as dissections or perforations occurred as a result of the ultra-distal catheter placement in the M1 segment. In 4% (3/81) of the cases a reversible MCA vasospasm occurred.

Conclusions Ultra-distal placement of the Navien 58 distal access catheter into the M1 segment in acute anterior circulation stroke can be achieved consistently, is safe in practice, and results in good recanalization success rates.

INTRODUCTION

Over the past decades intravenous thrombolysis (IVT) has been established as the standard treatment for acute ischemic stroke.[1] Recent publications have shown that recanalization of occluded vessels cannot be expected after IVT alone in cases with proximal occlusions and a high thrombus load.[2] Several randomized controlled trials showed a benefit in the overall outcome for patients who had undergone endovascular recanalization procedures in severe acute stroke.[3–7] Today, stent retrievers are state of the art devices for mechanical thrombectomy in acute stroke treatment.[8–10] Improved device designs have also led to better recanalization rates.[9–11]

In addition to the development of different thrombectomy devices, different concepts of the recanalization procedure have been described. There are two main concepts of mechanical thrombectomy: proximal occlusion and distal access. For the proximal occlusion technique in the anterior circulation,[12] a large-bore guiding catheter with a distal balloon collar is placed in the proximal internal carotid artery (ICA). Antegrade blood flow is restricted by balloon inflation, resulting in flow reversal under aspiration in the distal ICA. After deployment of a stent retriever within the thrombus, the stent and clot are retracted under aspiration into the balloon-guiding catheter, trying to avoid loss and fragmentation of thrombus material.

In a different approach without proximal occlusion, the goal is to rapidly access the thrombus or site of occlusion directly with an aspiration catheter in order to shorten the distance the thrombus has to be pulled uncovered through the vessel by the stent retriever. To achieve this rapid and distal access, these catheters need extremely good distal flexibility combined with a large bore. Furthermore, the catheter must not collapse when underpressure is applied during thrombus aspiration. Different applications in endovascular procedures for such distal access catheters have been published.[13] As reported in the literature, these catheters are mainly used to gain access to the distal ICA segment.[14 15] Since catheter technology has improved rapidly in recent years, different access catheters have been used for distal access in mechanical thrombectomy.[16 17]

Our standard procedure in mechanical thrombectomy comprises bringing the 5 Fr Navien 58 catheter further than the distal ICA segment by placing the catheter tip around the 90° angle of the terminal carotid bifurcation up into the M1 segment of the middle cerebral artery (MCA). We regard this to be ultra-distal access (UDA). To date, the term 'UDA' has been used differently in the literature and has mainly described every catheter position distal to the origin of the ophthalmic artery.

In 2013 the catheter was renamed from Reflex to Navien after acquisition by ev3 Neurovascular (Irvine, USA). The outer diameter of the Navien 58 is 5 Fr or 0.070 inch (ie, 1.8 mm) and the inner diameter is 0.058 inch (ie, 1.5 mm). The catheter is available in 115 and 125 cm lengths and has a radiopaque tip marker that makes it visible under fluoroscopy.

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Our aim was to evaluate whether the method of routine ultra-distal placement of the Navien 58 catheter in the M1 segment in combination with the use of a stent retriever for acute anterior circulation stroke is feasible and safe. We also wanted to study the number of case in which UDA to the M1 segment of the MCA was successful with a large 5 Fr catheter like the Navien 58.

METHODS

The institutional review board approved the retrospective study and waived requirement for informed consent. We identified 117 patients retrospectively who had undergone mechanical thrombectomy for acute stroke at our hospital between January 2012 and March 2014. We included in the study all 81 patients with an MCA occlusion (n=64), a combined terminal carotid and M1 occlusion (n=16), or an A1 occlusion (n=1) in which a Navien 58 distal access catheter was used. Patients with combined terminal carotid and M1 occlusions were considered as one group, since the thrombotic M1 component necessitated UDA to the M1 segment. We excluded 13 patients who were treated with different distal access catheters and 23 patients who had acute basilar thrombosis. In all 81 included cases, catheters with a straight tip were used. To make sure that reaching the M1 segment was not inhibited by a combination of contorted vessel anatomy and insufficient catheter length, the 125 cm catheter was chosen in all cases. The diagnosis of mainstem occlusion had been established in all patients by non-contrast CT (NCCT) and CT angiography with multiplanar reformations. For all patients the mechanical thrombectomy was indicated by consensus of the neurointerventionalist and the neurologist on duty. In all 81 cases, mechanical thrombectomy was performed in addition to IVT. All patients underwent immediate post-procedural NCCT to detect interventionally-induced intracerebral hemorrhage.

Procedure

Cases were either performed under general anesthesia or, whenever deemed appropriate by the interventionalist and the anesthesiologist, under conscious sedation. All procedures were performed in an angiosuite on a biplane angiography unit (Siemens Axiom Artis, Siemens Healthcare, Erlangen, Germany) using a triaxial approach. After groin puncture of the femoral artery an 80–90 cm sheath was positioned in the distal common carotid artery. Subsequently, the ICA and occluded MCA segment were accessed with a 0.014 inch microguidewire and a 0.021 inch microcatheter capable of delivering a 4 mm diameter standard stent retriever. After positioning a microcatheter distal to the thrombus, and after confirmation by microinjections, a stent retriever was deployed within the occluded vessel segment. The stent retrievers used in this study were Solitaire (ev3 Neurovascular, Irvine, USA), Preset (phenox GmbH, Bochum, Germany), and Trevo (Concentric Medical Mountain View, USA) devices. After deployment the stent retriever and the microcatheter established a path to support the access of the Navien catheter into the M1 segment adjacent to the thrombus. In order to increase the Navien cross-section usable for aspiration, the microcatheter was carefully removed from the Navien without dislocating the developed stent retriever. Vacuum was then applied in the Navien catheter by manual aspiration through the side port of a firmly closed hemostatic valve with a 30 mL syringe. Under the applied vacuum the deployed stent retriever was pulled back into the Navien catheter and pulled out into the hemostatic valve. When free aspiration was possible through the Navien catheter after retracting the stent retriever, the distal access catheter was left in place. If the clot was apparently stuck in the catheter it was removed through the sheath under continuous aspiration, both on the catheter and on the sheath. To specify recanalization success, all procedures were classified using the modified Treatment In Cerebral Ischemia (mTICI) scale[18] where Grade 0 represents persistent occlusion without perfusion distal to the thrombus, Grade 1 shows only little distal reperfusion, in Grade 2a antegrade reperfusion of <50% of the affected territory is seen, Grade 2b shows reperfusion of ≥50%, and Grade 3 represents complete antegrade reperfusion of the territory without distal branch occlusions.

Statistics

We performed all statistical analyses using SPSS Statistics V.22 (IBM, Armonk/New York, USA). Comparison between groups was evaluated using the χ^2 test. Significance was assumed at a p value of <0.05.

RESULTS

Using the Navien catheter, mechanical thrombectomy was performed in 81 patients (43 women with a mean (SD) age of 71.3 (12.6) years and 38 men with a mean (SD) age of 66.4 (13.8) years). Clinical data were researched retrospectively from the patients' records. Vessel occlusion was located in the M1 segment in 75 cases (93%), in the M2 segment in 5 cases (6%), and in the A1 segment in 1 (1%) (table 1). For the latter case, UDA was also performed with placement of the aspiration catheter in the A1 segment instead of the M1 segment (figure 1).

Patient baseline characteristics are summarized in table 2. UDA of the Navien catheter in the M1/A1 segment was successful in 61 cases (75%; group 1) and in 20 cases the attempt failed for various reasons (group 2, table 2). A major hindrance was a very tortuous course of vessels with elongation that led to failure of ultra-distal placement in 15 cases. In four cases M1 placement was impeded by a stenosis and in one case by thrombus material in the distal ICA that was too firm to be passed by the Navien catheter. In all cases DSA control series of the whole hemisphere were acquired to affirm recanalization success and to detect potential vessel injuries. In three cases vasospasm occurred after UDA in the M1 segment that was reversible under diluted nimodipine application via the catheter flush (2 mg in 500 mL NaCl). No case of dissections or visible permanent vessel damage occurred after catheter placement in the M1 segment. In one case UDA was performed with catheter placement in the A1 segment without complications. In no case could post-interventional hemorrhage be detected on the NCCT carried out immediately following the procedure.

Recanalization of the M1/A1 segment was successful in 72 patients. Our technique of mechanical thrombectomy failed to reopen the occluded vessel in nine patients. Of those, three

Table 1 Distribution of occlusion sites

Location	All	Group 1*	Group 2*
M1 segment	75 (93%)	57 (93%)	18 (90%)
M2 segment	5 (6%)	3 (5%)	2 (10%)
A1 segment	1 (1%)	1 (2%)	0
All	81	61	20

*Group 1, successful UDA; Group 2, not successful UDA.
UDA, ultra-distal access.

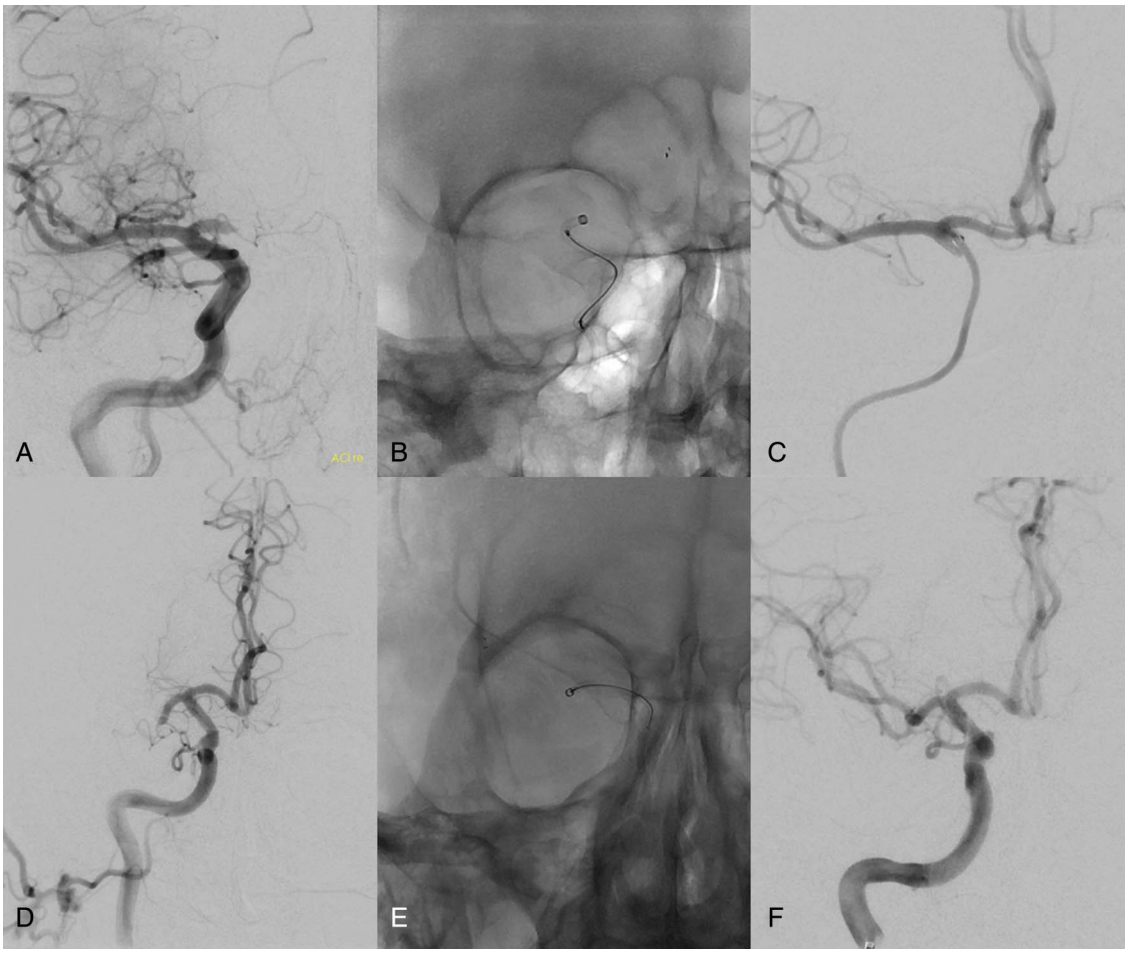

Figure 1 Examples of ultra-distal access (UDA) with the Navien 58 distal access catheter in one case with A1 occlusion (A–C) and one case with M1 occlusion (D–F) and successful recanalization.

patients were in group 1 with successful UDA (3/61; 5%) and six patients were in group 2 with failed UDA (6/20; 30%).

According to the standard in published trials, mTICI scores of 3 and 2b were considered as good recanalization results and mTICI scores of 2a, 1 and 0 were considered as poor results. Overall, good recanalization of mTICI 3 and 2b was achieved in 83% (67/81). In the patients in group 1 with successful UDA, a good recanalization result (mTICI 3 and 2b) was achieved in 90% (55/61 cases) and a poor outcome was found in 10% (6/61 cases). In patients in group 2 without successful UDA, a good recanalization result (mTICI 3 and 2b) was achieved in 60% (12/20 cases) and a poor outcome was found in 40% (8/20 cases). Table 3 shows the recanalization results of groups 1 and 2 in detail.

The time between the first DSA series and the first image series after revascularization of the vessel was calculated to determine the duration of the procedure. In cases of recanalization failure, the time was calculated up to the last of the imaging series obtained during the intervention. In patients in group 1 with successful UDA, mean (SD) procedure time was 38 (22) min and in patients in group 2 without successful UDA, mean (SD) procedure time was 76 (55) min. Mean (SD) duration of all interventions was 47 (36) min (table 2). Overall, the mean (SD) number of passes with the stent retriever in cases with successful recanalization was 1.9 (0.9) compared with 2.6 (1.3) in cases without successful recanalization. In cases with successful UDA the mean (SD) number of passes was 2.1 (1.0) compared with 2.6 (1.3) in those without successful UDA.

DISCUSSION

UDA of the M1 segment with the 5 Fr Navien distal access catheter was successful in 75% of all patients. There were no cases of permanent vessel injury caused by this approach. In three cases (4%) reversible vasospasm of the M1 segment was visible after accessing the vessel. After successful UDA, good recanalization results of mTICI 2b and better were achieved in 90% but only in 60% of those in whom UDA failed (table 3).

Our concept of UDA in mechanical thrombectomy is based on the idea of combining two recanalizing procedures. The mechanical extraction of the thrombus was accomplished first by a state of the art stent retriever and, second, by aspiration with a large-bore catheter directly at the site of thrombotic occlusion. Using a combination of both techniques, the distance the thrombus is pulled uncovered through the vessels is reduced to a minimum. The stent retriever is supposed to ensnarl the thrombus material in its mesh so, during withdrawal without UDA, movement through curves and tortuous vessels like the cavernous segment of the carotid artery may disrupt thrombus particles and induce distal embolization. We believe that our approach can reduce the problem of thrombus fragmentation by reducing the distance through the vessels. The other advantage of our approach is that aspiration is directly applied at the thrombus site, not being reduced by simultaneous backflow from the anterior cerebral artery and so diminishing the effectivemess of aspiration. A similar technique has already been

described with the Penumbra 54 aspiration catheter.[19] We also remove the microcatheter from the Navien catheter to improve the aspiration effect. The high stability of the Navien 58 allows this maneuver without loss of the catheter or stent position.

Previously, the ADAPT technique has been described in which only distal aspiration is applied at the thrombus.[20–22] However, recent in vitro studies have shown that, by using the Navien 58 catheter, a relevant vacuum can be generated in an aspiration maneuver and the combined use of aspiration and a stent retriever improves recanalization rates.[23 24] Apart from in vitro models, the outer size of the Navien distal access catheter is only negligibly smaller than the average MCA luminal diameter, therefore an ideal vacuum can be achieved and only little cross-flow from other vessels is aspirated.[25 26]

Comparing our results with a recent report of a similar technique using a different distal access catheter, the favorable recanalization rate in our cohort using the Navien 58 was comparable, although UDA was achieved in fewer cases in our study.[17] In addition, the overall procedure times in our study were distinctly shorter.

In our study we were able to demonstrate that advancing a Navien 58 5 Fr catheter into the M1 segment in patients with acute stroke does not pose a relevant risk of vessel damage such as dissections or perforations. In none of our cases did such severe adverse effects occur. Only a small number of patients (n=3; 4%) showed reversible vasospasm after UDA, as can be observed in many different kinds of endovascular interventions, which is treatable with intra-arterial spasmolysis.

Our recanalization success rates with UDA are higher than those in other published reports.[10 12 27] In particular, the rate of good recanalization was clearly higher in our study than in the technique with proximal balloon occlusion.[12] We found that good recanalization results of mTICI ≥2b could be achieved significantly more often in combination with a stent retriever when UDA was successful. Various methods of mechanical stroke treatment are available for sufficient revascularization and each interventionalist relies on his or her own technique and experience. Since mechanical thrombectomy is now well established in the treatment of acute stroke, we believe it is important to highlight the advantages of different stroke procedures so that interventionalists can gain comprehensive data on different approaches. From our experience, we believe our technique is at least equal to or even potentially superior to other methods in terms of recanalization rates. In any case, our primary intention was not to favor our method compared with others but rather to show that UDA with the Navien 58 is a safe and extremely efficient method of stroke treatment. Whether the UDA approach is superior in terms of better clinical outcome for patients should be further evaluated in prospective randomized trials.

CONCLUSION

We have shown that using the Navien 58 distal access catheter ultra-distal placement in the M1 segment in acute anterior circulation stroke can be achieved in most cases, is safe in practice, and results in excellent recanalization success rates.

Contributors HJ, JL: study conception and design, interventions, acquisition of data, analysis and interpretation of data, drafting of the manuscript. MP, GB: acquisition of data, critical revision of the manuscript. MK-O: study conception and design, critical revision of the manuscript.

Competing interests MK-O received a research grant from MicroVention and is consultant for Medtronic and MicoVention.

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Data sharing statement Additional data may be made available on request.

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