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ORIGINAL ARTICLE

The SAVE Technique

Large-Scale Experience for Treatment of Intracranial Large Vessel Occlusions

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Abstract

Background The stent retriever assisted vacuum-locked extraction (SAVE) technique was introduced as an effective thrombectomy method in stroke patients suffering from intracranial large vessel occlusion (LVO). This article presents our multicenter, large-scale experience with SAVE.

Methods The study involved a retrospective core team analysis of 200 patients undergoing mechanical thrombectomy using the SAVE technique due to intracranial LVO at 4 German centers. Primary endpoints were first-pass and overall complete/near complete reperfusion, defined as a modified thrombolysis in cerebral infarction (mTICI) score of 2c and 3. Secondary endpoints were the number of passes, time from groin puncture to reperfusion, embolization to new territories (ENT), postinterventional symptomatic intracranial hemorrhage (sICH), and favorable outcome at discharge, defined as a modified Rankin Scale (mRS) score ≤ 2.

Results The median age was 78 years (interquartile range IQR 68–85). Median National Institutes of Health stroke scale (NIHSS) at admission was 16 (IQR 12–20). Occlusions sites were: internal carotid artery (ICA-T) in 39/200 (19.5%), M1 in 126/200 (63%), M2 in 30/200 (15%), and others in 5/200 (2.5%) cases. The primary endpoints were documented in 114/200 (57% first pass mTICI 2c or 3) and 154/200 (77% overall mTICI 2c or 3) patients, respectively. The overall median time from groin puncture to reperfusion was 34 min (IQR 25–52) with a median of 1 (IQR 1–2) attempts. An ENT was observed in 3 patients (1.5%) and the rate of sICH was 2.6%. The rate of successful reperfusion (mTICI ≥ 2b) on final angiograms was 95%. At discharge, 73/200 (36.5%) patients revealed a favorable outcome.

Conclusion Mechanical thrombectomy using the SAVE technique seems to be effective, fast and safe. First-line use of SAVE leads to high rates of complete and near complete reperfusion.

Keywords Ischemic stroke · Mechanical thrombectomy · Stent-retriever · SAVE · Large vessel occlusion

A. Mpotsaris and M.N. Psychogios contributed equally.
A small part of the analyzed cases has been published before and another small part concerning a specific technical variation is currently under review in another journal.

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Background

The state of the art treatment of patients suffering from intracranial large vessel occlusion (LVO) in the anterior circulation nowadays is mechanical thrombectomy (MT) with concomitant intravenous thrombolysis (IVT). This is based on the publication of five randomized controlled trials in 2015, which demonstrated that endovascular therapy of LVO using stent retrievers was shown to be more effective compared to IVT alone [2, 3, 6, 10, 25]. In recent years the development of new techniques and improvements of existing methods were evaluated to improve the rate of successful reperfusion and minimize the occurrence of distal embolization, including the use of local aspiration via large-bore distal access catheters, balloon-guide catheters (BGC) and stent retrievers or a combination of them [5, 9, 12, 14, 15, 17, 21, 27].

The stent retriever assisted vacuum-locked extraction (SAVE) technique was recently described as a method for achieving favorable angiographic results concerning a high rate of successful and complete reperfusion and a low rate of downstream embolization based on the principle of a distal (stent retriever) and proximal (aspiration catheter) capture of the clot [16]. The purpose of the present study was to report our ongoing experiences with SAVE.

Methods

Study Design and Patient Selection

A retrospective analysis of data was performed to identify all patients who consecutively underwent MT with SAVE at the participating centers between November 2015 and January 2018. All consecutive cases with LVO were included from center A (Göttingen, 95 cases), center B (Aachen, 42 cases), center C (Cologne, 38 cases), and center D (Kiel, 25 cases). Baseline, clinical, and angiographic parameters were extracted from a prospectively acquired database in centers A and C. The National Institute of Health Stroke Scale (NIHSS) parameter and the modified Rankin Scale (mRS) at discharge were assessed by a certified stroke neurologist in each center. Inclusion criteria were: clinical diagnosis of acute ischemic stroke, intention to perform endovascular stroke treatment (i.e. initiation of endovascular procedure) with complete angiographic documentation of the SAVE maneuver and patient age ≥ 18 years. Tandem occlusion was an exclusion criterion in this study. Ischemic stroke was diagnosed with non-contrast computed tomography (CT) or flat panel detector CT (FDCT) in cases of one-stop management and CTA (or multiphase FDCTA; [23]). All eligible patients received IVT based on the judgment of the attending neurologist according to the guidelines of the German Neurological Society. Non-contrast CT or magnetic resonance imaging (MRI) was regularly performed within 24 h after treatment, or immediately in symptomatic patients. Symptomatic intracranial hemorrhage (sICH) was defined as any extravascular blood in the brain or within the cranium that was associated with clinical deterioration, as defined by an increase of ≥4 points in the NIHSS score. Primary endpoints were first pass and overall complete or near-complete reperfusion, defined as a modified thrombolysis in cerebral infarction (mTICI) score of 2c and 3. Secondary endpoints were number of passes, time from groin puncture to reperfusion, embolization to new territories (ENT), postinterventional sICH, and favorable outcome at discharge, defined as a modified Rankin Scale (mRS) score ≤ 2.

Of significance, all images from digital subtraction angiography were re-evaluated in accordance with the recommendations of the Cerebral Angiographic Revascularization Grading Collaborators [30] from an internal core team that was not involved in the evaluated procedures consisting of a senior neuroradiologist (M.P. or I.T.) and a medical student (S.H.). The core team was blinded to the clinical outcome, presentation or any demographic data to assess the preinterventional initial state and extent of tissue reperfusion after each thrombectomy attempt [30]. The preinterventional collateral status was assessed using the American Society of Interventional and Therapeutic Neuroradiology / Society of Interventional Radiology (ASITN/SIR) collateral grading system [8]. According to the guidelines of the respective local ethics committees, ethical approval was given when necessary (University Medical Center Göttingen) for this anonymous retrospective study, which was conducted in accordance to the Declaration of Helsinki. A patient's consent for treatment was obtained according to the individual institutional guidelines. Due to the retrospective nature of the study additional informed consent was deemed unnecessary.

Thrombectomy Technique with SAVE

The SAVE technique has been described previously [16]. Briefly, based on a triaxial approach, access to cerebral vasculature is obtained with an 8 French (F) guide catheter (8 F Cordis Vista, Johnson & Johnson, New Brunswick, NY, USA) or a long 8 F sheath (8 F Destination, Terumo Medical, Somerset, NJ, USA) distally in the internal carotid artery (ICA) or in cases of a posterior circulation stroke with a 7 F guide catheter (Mach 1, Boston Scientific, Marlborough, MA, USA) in the vertebral artery (Fig. 1). During the study period some operators introduced the use of an 8 F BGC (FlowGate[2], Stryker Neurovascular, Fremont, CA, USA) for selected cases with anterior LVO. A microcatheter is advanced through a 5 F/6 F aspiration catheter (AXS Catalyst, Stryker Neurovascular, Fremont, CA, USA; Sofia/ Sofia Plus, Microvention, Tustin, CA, USA) past the occlusion site in an M2/A2/P1 vessel under continuous aspiration or with the help of a 0.014″ inch microwire. A stent retriever (Trevo variants, Stryker Neurovascular, Fremont, CA, USA; Solitaire AB/FR; Covidien, Irvine, CA, USA; EmboTrap, Neuravi, Galway, Ireland) is then advanced and placed primarily distally to and with the proximal third across the occlusion site by using the active push deployment technique [29]. The stent retriever is deployed over 2–8 min, which in each case was left to the attending neuroradiologist's discretion. The microcatheter is slowly retracted (bare wire technique) in order to maximize the internal volume

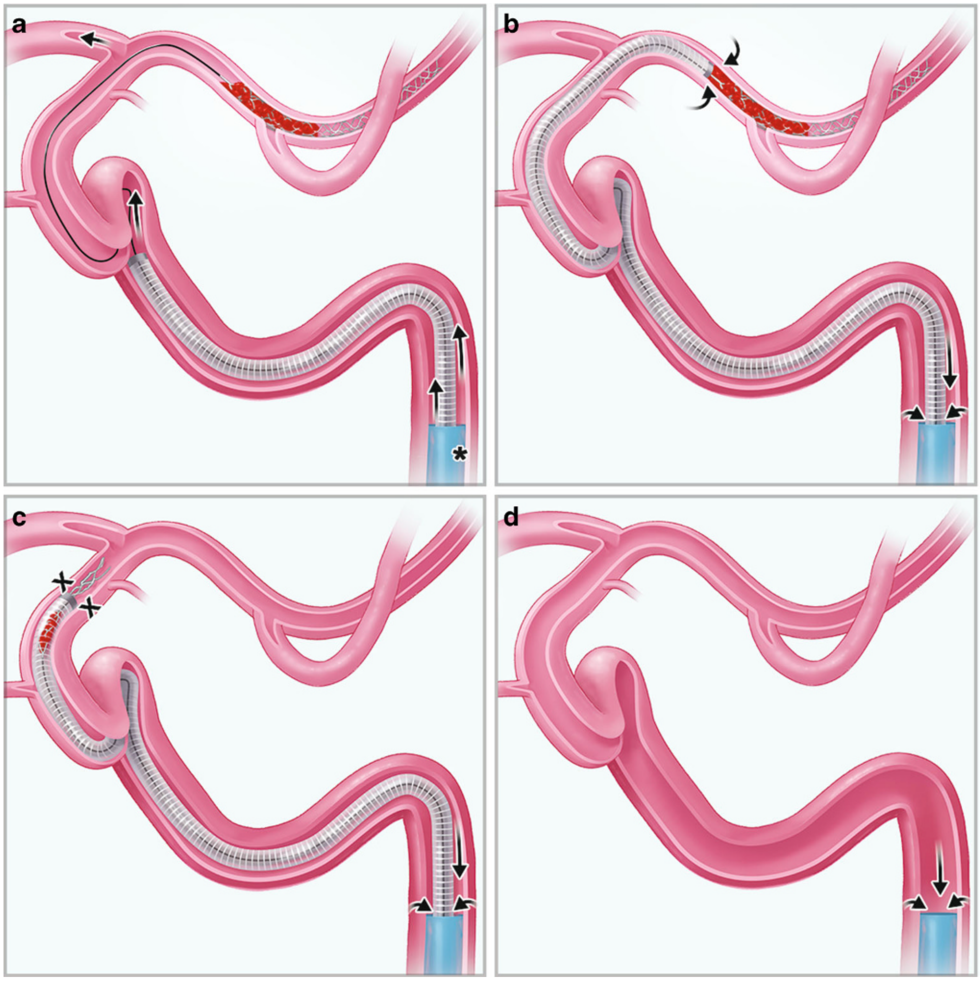

Fig. 1 SAVE technique. **a** A guiding catheter (*Asterisk*) is placed distally in the internal carotid artery. The stent retriever is advanced and deployed primarily distally to the clot and only the proximal one third interacts with the clot. **b** The aspiration catheter is then advanced to the face of the clot and aspiration with the pump is started. The stent retriever is carefully retrieved while the aspiration catheter is pushed simultaneously until a wedge position is reached. The vacuum within the aspiration catheter is preserved with a negative pressure syringe and the permanent aspiration with the pump is connected to the guide catheter. **c, d** Stent retriever and aspiration catheter are then withdrawn into the guide catheter as a unit. (© Campbell Medical Illustration)

of the aspiration catheter. The aspiration catheter is then advanced to the proximal face of the clot and the aspiration pump is connected and activated. The stent retriever is gently retracted, while the tip of the aspiration catheter is further advanced until a wedge position is reached. The negative pressure within the aspiration catheter is then retained with the use of a 60 ml vacuum syringe (VacLok, Merit Medical, South Jordan, UT, USA) and the aspiration pump is connected to the guide catheter or long sheath. Stent retriever and aspiration catheter are then withdrawn into the guide catheter as a unit (https://vimeo.com/245744122). In exceptional cases, where no back-flow is observed within the guide catheter, the guide catheter is also retrieved under permanent aspiration to remove the entrapped thrombus.

Statistical Analysis

Statistical analysis was performed using MedCalc Statistical Software version 18 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2018). Descriptive statistics of normally distributed data are stated as mean and standard deviation; not normally distributed data are summarized as median and interquartile range (IQR). The Mann-Whitney test was performed for assessing statistical differences between groups. Statistical significance was defined as $p \leq 0.05$.

Results

The median age was 78 years (IQR 68–85) and 78 patients were male (39%). The median NIHSS at admission was 16 (IQR 12–20) and rate of IVT was 58%. Occlusion sites were: ICA-T in 39/200 (19.5%), M1 in 126/200 (63%), M2 in 30/200 (15%), and others in 5/200 (2.5%) cases. Median Alberta stroke program early CT score (ASPECTS) on initial imaging was 8 (IQR 7–9).The pretreatment mTICI score was 0 in 189/200 (94.5%), 1 in 7/200 (3.5%), and 2a in 4/200 (2%). The median ASITN/SIR collateral status was 3 (IQR 2–4). First pass complete or near complete reperfusion (mTICI ≥ 2c) was achieved in 114/200 (57%) with complete reperfusion (mTICI 3) in 90 patients (45%). An overall rate of mTICI 2c and 3 on final angiogram was reached in 154 patients (77%) with 111 individuals

Table 1 Angiographic results after core team analysis

	ICA-T	M1	M2	Overall result	Self-reported
No. of patients	39	126	30	200	200
First-pass reperfusion					
mTICI 3	10 (26%)	66 (52%)	9 (30%)	90 (45%)	–
mTICI ≥ 2c	15 (38%)	80 (64%)	14 (47%)	114 (57%)	–
mTICI ≥ 2b	23 (59%)	94 (75%)	26 (87%)	148 (74%)	–
Final reperfusion					
mTICI 3	19 (49%)	77 (61%)	10 (33%)	111 (56%)	126 (63%)
mTICI ≥ 2c	29 (74%)	104 (83%)	16 (53%)	154 (77%)	–
mTICI ≥ 2b	38 (97%)	120 (95%)	27 (90%)	190 (95%)	192 (96%)
No. of passes, median (IQR)	2 (1–3)	1 (1–2)	1 (1–1)	1 (1–2)	–
Groin puncture-reperfusion time (min), median (IQR)	51 (34–68)	32 (25–48)	28 (24–44)	34 (25–52)	–

ICA internal carotid artery; *mTICI* modified thrombolysis in cerebral infarction; *IQR* interquartile range

(56%) completely reperfused (mTICI 3). The rate of successful reperfusion (mTICI ≥ 2b) after 1 attempt was 74% and 95% at the end of the procedure with a median of 1 (IQR 1–2) attempt and a maximum of 6 passes. The self-reported rate of complete reperfusion on final angiogram was 63% with a successful reperfusion of 96%. The overall median time from groin puncture to reperfusion was 34 min (IQR 25–52), ENTs were observed in 3 patients (1.5%) and the rate of sICH was 2.6%. The median NIHSS at discharge was 4 (IQR 2–11) and 73/200 (36.5%) patients revealed a favorable outcome (mRS ≤ 2).

A subgroup analysis investigating the angiographic results with respect to the occlusion site revealed that the use of SAVE tended to be more effective in M1 occlusions compared to ICA-T occlusions in terms of complete reperfusion after a single pass (66/126, 52% vs. 10/39, 26%, $p = 0.084$) and complete or near-complete reperfusion (80/126, 64% vs. 15/39, 38%, $p = 0.154$). This trend was not observed for M2 occlusions as this cohort showed a first pass mTICI ≥ 2c and 3 rate of 47% and 30%, respectively. The final rate of complete reperfusion was higher in M1 vs. ICA-T occlusions (61% vs. 49%, $p = 0.538$). The median time from groin puncture to reperfusion was significantly faster in patients suffering from M1 occlusions (32 min) compared to ICA-T occlusions (51 min, $p < 0.001$) with a median number of 1 pass (M1) vs. 2 passes (ICA-T). The reperfusion time did not differ between M1 and M2 occlusions. The details of the angiographic results are summarized in Table 1.

Discussion

Since multiple randomized controlled trials in 2015 have demonstrated success in neurothrombectomy, endovascular therapy using stent retrievers should primarily be considered in acute stroke patients with LVO in the anterior circulation (grade A, level 1a; [28]); however, there is no distinct recommendation on which thrombectomy technique should be used as first-line therapy. The central requirement of neurothrombectomy comprises a fast recanalization of the occlusive lesion with a complete reperfusion of the downstream territory and prevention of ENT. Several approaches have been published including the use of a BGC, a large-bore aspiration catheter, and/or stent retrievers (Table 2, a more comprehensive table is available online). The combined utilization of such devices led to the development of new techniques beside SAVE such as Solumbra, continuous aspiration before intracranial vascular embolectomy (CAPTIVE), aspiration–retriever technique for stroke (ARTS), a stent-retrieving into an aspiration catheter with proximal balloon technique (ASAP), or proximal balloon occlusion together with direct thrombus aspiration during stent retriever thrombectomy (PROTECT; [5, 9, 14, 15, 17]).

We have previously reported our initial experience using SAVE as first-line method with promising reperfusion results in patients with intracranial LVO [16]. In this multicenter, large-scale study we were able to confirm that using the SAVE technique yields in a high rate of core team evaluated, complete/near complete reperfusion (mTICI ≥ 2c) of 77% with an overall successful reperfusion rate (mTICI ≥ 2b) of 95%. A possible reason for the high efficacy of SAVE is the combination of a stent retriever placed distally to the thrombus center and a proximally placed aspiration catheter which leads to an increased clot entrapment by wedging the thrombus between the aspiration catheter tip and stent retriever while simultaneous withdrawal of the unit is executed under continuous proximal aspiration.

First-pass rates of complete (mTICI 3) and complete/near complete (mTICI ≥ 2c) reperfusion achieved with SAVE are still high after 200 cases, with 45% and 57%, respectively. The rates are superior to the self-reported first pass complete reperfusion rates of up to 26% when using

Table 2 Overview of studies using different techniques for mechanical thrombectomy

Reference	Strategy	BGC	First-pass reperfusion rate, (%)	Final reperfusion result, TICI (%)					Time from puncture to recanalization (median, min.)	No. of passes (median)	ENT (%)	SICH (%)
				2b	2c	3	2b/3	2c/3				
Humphries et al. 2015 [9]	Solumbra	No	37, TICI 2b/3	–	–	–	88	–	54	2.3 (mean)	3.8	4.6
Goyal et al. 2015, ESCAPE[a] [6]	SR mainly + BGC	Yes	–	–	–	–	72.4	–	30	NR	NR	3.6
Mocco et al. 2016, THERAPY[a,b] [18]	ADAPT	No	–	–	–	–	70	–	NR	NR	NR	9.3
Mueller-Kronast et al. 2017, STRATIS[a,b] [20]	SR only	NR	–	–	–	–	87.9	–	36	NR	0.8	1.4
Lapergue et al. 2017, ASTER[a,b] [13]	ADAPT	No	–	–	–	37.5/28.7[c]	85.4/63.0[c]	56.3/43.2[c]	38	2	3.7	5.3
	SR + BGC	Yes	–	–	–	38.6/35.5[c]	83.1/67.7[c]	56.6/49.7[c]	45	2	2.7	6.5
This study[a,b] 2018	SAVE	Optional	45, mTICI 3 57, mTICI 2c–3 74, mTICI 2b–3	18	22	56	95	77	34	1	1.5	2.6

BGC balloon guide catheter, *TICI* thrombolysis in cerebral infarction, *ENT* embolism to new territory, *SICH* symptomatic intracranial hemorrhage, *SR* stent retriever, *NR* not reported, *ADAPT* a direct aspiration first pass technique

[a]Assessed by core laboratory

[b]Modified thrombolysis in cerebral infarction

[c]After first-line strategy alone

a direct aspiration first pass technique (ADAPT) strategy alone [19]. A comparison to studies focusing on stent retriever with respect to first pass complete reperfusion is elusive as in most of the studies this information is missing. The first results of the ARISE II study, which exclusively used one type of stent retriever, demonstrated a first pass complete reperfusion of 30% and a near complete/complete reperfusion of 40% [31].

With respect to the successful reperfusion rate (mTICI ≥ 2b) after a single pass (74%) and on the final angiogram (95%), SAVE is also very effective when compared to the results reported in the literature. While studies using stent retrievers in conjunction with BGC exhibited first pass mTICI 2b/3 rates up to 64% [27], the studies including the combination of distal aspiration and stent retrieving achieved successful reperfusion rates between 37–59% after a single pass [9, 14, 15, 17]. The ASAP technique described by Goto et al. is a method with similar first pass successful reperfusion rate (77.5%) and identical overall reperfusion (95%); however, these data are self-reported and might be lower after core laboratory [5]. The high rate of overall successful reperfusion in our study is comparable to recent studies which used a combination of aspiration catheters/stent retrievers or BGC [7, 14, 15, 17, 27]; however, our results are slightly better compared to the Aster trial which exhibited no difference between ADAPT and stent retriever/BGC use with final mTICI ≥ 2b rates of 85% and 83%, respectively, and the STRATIS registry with a successful reperfusion rate of nearly 88% after stent retrieval [13, 20].

It must be emphasized that first pass reperfusion with the SAVE technique tended to be more effective in M1 occlusions compared to ICA-T occlusions. This might be due to a higher clot burden within the intracranial ICA, which is known as an independent factor of successful reperfusion [1]. The higher rate of thrombectomy attempts in ICA-T occlusions is in line with this assumption and explains the longer reperfusion time compared to MCA occlusions; however, the overall reperfusion results between the groups at the end of the procedure were similar, suggesting that SAVE finally led to a high rate of successful reperfusion regardless of the occlusion site in proximal LVO. Interestingly, in more distal occlusions (M2) the first pass and final complete/near complete reperfusion rates were inferior compared to those in M1 occlusions. Possible explanations are (a) a suboptimal positioning of the stent retriever more proximally than desired due to narrow vessel diameter behind the occlusion and insular tortuosity and (b) the possible complexity of advancing the aspiration catheter tip through the MCA bifurcation which might reduce the force during the wedge procedure and diminish the proximal capture of the clot. It is already known that vessel curvature significantly influences the results of stent retriever-based MT [26].

In comparison to our initial experiences with SAVE, the rate of first pass complete reperfusion decreased from 72% to 45%, which could be explained by the introduction of the technique to less experienced neurointerventionalists and inclusion in our study of MTs performed by them; however, the high successful reperfusion rate on final angiogram (95%) and the median number of passes (1) were similar to our initial experience, demonstrating a good learning curve for a relatively complex maneuver [16].

The median time from groin puncture to reperfusion could be decreased by about 11 min in comparison to our initial study down to 34 min which is explained by the growing experience with SAVE in the participating institutes, although some operators meanwhile allow an increased stent retriever dwell time up to 8 min, which might be have a beneficial effect on the reperfusion result [11]. The duration of the procedure lies at the lower range of comparable stent retriever studies (14–120 min) due to the high rate of first pass complete reperfusion [4–6, 9, 13–15, 17, 20, 21]; however, meaningful comparisons with other studies are impossible to draw as the term 'time to reperfusion' sometimes is defined from different starting points, which results in a concomitant reduction of the procedure time, e.g. in SWIFT and STAR from guide catheter placement (36 min and 20 min, respectively) and in the study of Velasco et al. from first angiogram (20.5 min) [22, 24, 27]. It must be emphasized that our procedure time is similar to the ADAPT technique in the Aster trial (38 min), which up to now is seen as an advantage for this method [13].

The very low rate of ENT (1.5%) is a further advantage of the SAVE technique as new emboli negatively impact clinical outcome. This rate is lower than other studies describing combined approaches (CAPTIVE 5%, ASAP 4.8%). This can be explained by the omission of proximal aspiration via the guide catheter in CAPTIVE as no control over clot fragments during retrieval of the clogged aspiration catheter/stent retriever unit within the guide catheter is achieved [17]. With ASAP, the distal protection via stent retriever is missing and proximal aspiration is not regularly executed during retrieval [5]. The rate of ENT in MR CLEAN or when using ADAPT is higher and reported to be up to 9%; however, even the rate of ENT in the Aster trial was 3.7% [2, 12, 13].

One drawback of this technique (as with all stent retriever-based techniques) might be the potentially higher cost of this method by using more materials; however, a) analyzing costs goes further than this retrospective study, which did not focus on cost analysis and b) in our view an effective thrombectomy method is justifiable if the probability of clinical outcome might be improved due to high rates of first pass complete/near complete reperfusion as this may decrease the long-term costs of patient care.

A promising aspect seems to be the introduction of BGC in conjunction with distal access catheters and stent retrievers. Maegerlein et al. recently demonstrated the results of a primary combined approach with additional use of a BGC (PROTECT technique) with manual aspiration via syringe on the BGC during withdrawal of aspiration catheter and stent retriever. Reperfusion was successful in all treated individuals with a first pass successful reperfusion rate of 48% and an ENT rate of 2.5% [14]. The results of this study were inferior to SAVE, possibly demonstrating the importance of a concomitant distal positioning of the stent retriever and wedging position. As recently demonstrated that the first pass complete reperfusion rate is more frequently associated with the use of BGC, some operators in the participating centers started introducing the use of a BGC with SAVE ("protected SAVE"; [32]).

The strength of our study is the large number of patients included and the re-evaluated angiographic data by the internal core team. A limitation of our study is the retrospective design with the attendant selection bias. A prospective trial is warranted. A further selection bias is that some participating centers rarely used this technique. The heterogeneity of our cohort with respect to the equipment used (e.g. BGC) might be a further limitation. Clinical outcome after 90 days is missing; however, this study primarily focused on angiographic techniques and results and there is no doubt that complete reperfusion is a basic requirement for favorable clinical outcome. The very low rate of ENT has to be interpreted with caution as the safety of a technique is also dependent on the individual center's experience. A comparison to randomized trials might be affected due to performance differences as operators have to choose a certain technique, which not might be the preferred one. Furthermore, individual factors, e.g. clot composition have an impact on the technical success. The goal of future studies should address these individual characteristics, which may predict first-pass success of SAVE.

Conclusion

Mechanical thrombectomy using the SAVE technique seems to be effective, fast and safe. The use of SAVE leads to high rates of complete/near complete reperfusion in patients with intracranial LVO and should therefore be aspired as first-line therapy.

Compliance with ethical guidelines

Conflict of interest D. Behme Consultant: Phenox; speakers fees: Siemens, Styker, Penumbra. M. Wiesmann worked as a consultant and received reimbursement for lectures or travel support: Stryker Neurovascular; received reimbursement for lectures or travel support: Bracco Imaging, Medtronic, Siemens Healthcare, Abbott. A. Mpotsaris consultancy (modest fees): Neuravi, Penumbra, Sequent Medical. M.-N. Psychogios: travel grant, fees: Styker, Phenox, Penumbra, Acandis, Siemens. V. Maus, S. Henkel, A. Riabikin, C. Riedel, I. Tsogkas, A.C. Hesse, N. Abdullayev and O. Jansen declare that they have no competing interests.

Ethical standards According to the guidelines of the respective local ethics committees, ethical approval was given when necessary (University Medical Center Göttingen) for this anonymous retrospective study, which was conducted in accordance to the Declaration of Helsinki. A patient's consent for treatment was obtained according to the individual institutional guidelines. Due to the retrospective nature of the study additional informed consent was deemed unnecessary.

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