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ORIGINAL ARTICLE

Mechanical Thrombectomy Using the new Solitaire™ Platinum Stent-retriever

Reperfusion Results, Complication Rates and Early Neurological Outcome

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Abstract

Background and Purpose The application of radiopaque markers to the Solitaire™ stent-retriever for better visibility during mechanical thrombectomy (MT) has the potential to alter the well-known characteristics of the device; however, it is uncertain whether this adjustment influences efficacy or safety of the enhanced stent-retriever.

Methods Retrospective analysis of stroke databases of three comprehensive stroke centers. Our investigation was focused on technical and angiographic parameters, including procedure times, reperfusion results (thrombolysis in cerebral infarction, TICI), periprocedural complications and favorable early neurological recovery at discharge (modified Rankin scale ≤ 2 or National Institutes of Health Stroke Scale, NIHSS = 0 or ΔNIHSS ≥ 10), from consecutive patients with acute anterior circulation ischemic stroke treated with a Solitaire™ Platinum stent-retriever between October 2016 and March 2017.

Results A total of 75 patients (male: $n = 27$, 36%, age in years: mean (SD): 75 (±12), median baseline NIHSS: 17 (interquartile range IQR: 11–21), $n = 41$, 54.7% received additional i. v. thrombolytics) were treated with a median number of 2 device passes (range: 1–5). The median time from groin puncture to final TICI was 56 min (IQR: 41–79). In 69 patients (92%) TICI 2b-3 was achieved. Early neurological recovery was seen in 47 (62.7%) patients. The following periprocedural complications occurred: vasospasms ($n = 7$, 9.3%), emboli into a new territory ($n = 4$, 5.3%), symptomatic intracranial hemorrhage ($n = 3$, 4%), difficulties during device delivery/deployment ($n = 1$, 1.3%).

Conclusion The usage of the Solitaire™ Platinum stent-retriever for MT in acute ischemic stroke patients was highly effective and was not accompanied by an increased periprocedural complication rate.

Keywords Mechanical thrombectomy · Acute ischemic stroke · Solitaire™ Platinum · Stent-retriever · Visibility

Abbreviations

AIS	Acute ischemic stroke
CT	Computed tomography
DSA	Digital subtraction angiography
ICA	Internal carotid artery
M1	Main branch of middle cerebral artery
mRS	modified Rankin Scale
NIHSS	National Institutes of Health Stroke Scale
RCT	Randomized controlled trial
sICH	Symptomatic intracranial hemorrhage
TICI	Thrombolysis in cerebral infarction

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Introduction

Intracranial large vessel occlusions in acute ischemic stroke, usually caused by cardioembolic or arteriosclerotic thrombi, are a predictor and cause for morbidity and mortality [1, 2]. While i. v. thrombolytics in general are an effective treatment for ischemic stroke, they have been proven to be less effective if the clot exceeds a certain length [3]. Since i. v. thrombolytics are supposed to dissolve the thrombi, the main principle of mechanical thrombectomy (MT) is based on immediate retrieval of the clot. Early non-stent-retriever recanalization devices (e. g. Merci retriever) have shown promising reperfusion results [4] but failed to prove clinical superiority compared to i. v. thrombolytics in the past [5, 6].

Building on the encouraging reperfusion results of previous non-stent-retriever recanalization devices, the Solitaire™ AB stent (manufactured and distributed by ev3, Irvine, CA, USA) was used as the first stent-retriever device for mechanical thrombectomy in acute ischemic stroke less than a decade ago [7]. Because it was initially intended and used as a neck bridging device for endovascular treatment of intracranial aneurysms, the Solitaire™ AB stent was developed further to the Solitaire™ FR (flow restoration) device and subsequently to the Solitaire™ 2 revascularization device (see Figs. 1 and 2b). Solitaire™ stent-retrievers are laser-cut, nitinol stents with a closed cell scaffolding design attached to a push-wire.

From early on, patients treated with stent-retrievers showed better reperfusion rates, better clinical outcome and lower complication rates than patients treated with non-stent-retriever devices [8–10]. The paradigm shift to mechanical thrombectomy as first line treatment for large intracranial vessels was finally completed after several randomized controlled trials (RCT) showed superior clinical outcomes compared to best medical care and i. v. thrombolytics (if eligible) alone [11–15]. In these RCTs self-expanding retrievable stents have been used in 78.8–100% of patients assigned to the endovascular treatment arm. Moreover, Solitaire™ stent-retrievers have been used in most patients who underwent mechanical thrombectomy in these RCTs (see Table 1).

While the advantages of Solitaire™ stent-retrievers for mechanical thrombectomy have been studied in several single and multicenter trials, one major disadvantage remains: its limited visibility in fluoroscopic images. Solitaire™ stent-retrievers have been equipped with radiopaque platinum markers to the very distal end and a radiopaque guiding wire. These radiopaque sections, however, do not allow a complete visualization of the device on digital subtraction angiographic images. Especially in patients with a curved vasculature, visualization of the device during introduction, deployment and retrieval was unsatisfactory. For this reason, additional radiopaque markers or wires have already been added to the designs of other stent-retrievers, e.g. the Trevo ProVue (Stryker Neurovascular, Fremont, CA, USA). An improved structural radiopacity might facilitate the interventional procedure due to a more secure deployment of the stent-retriever or a more targeted placement of the retriever with regards to the clot [16].

As next step of technical evolution of the Solitaire™ stent-retriever, radiopaque platinum markers, evenly spaced 10 mm apart, have been added to the device, which is now called Solitaire™ Platinum (see Figs. 1 and 2e); however, any adjustments to medical devices have the potential to alter the previously well-known characteristics of the device. It remains uncertain whether the adjustments influence efficacy or safety of the stent-retriever.

The purpose of this study was to investigate whether the new Solitaire™ Platinum stent-retriever has comparable reperfusion and complication rates and similar effects on clinical outcome than preceding generations of the device.

Methods

Setting and Interventional Treatment Rational

This retrospective analysis was conducted using patient data from stroke databases from two university hospitals and a maximum care facility with 24 h/7 days neurological and neuroradiological attendance. Of the centers two were co-investigators within the SOLITAIRE with the intention for thrombectomy (SWIFT) prime trial. Consecutive patients with acute ischemic stroke in the anterior circulation who received mechanical thrombectomy using a Solitaire™ Platinum stent-retriever between October 2016 and March 2017 were included in this analysis. Treatment rational for patients with acute ischemic stroke was the same in all three institutions, i. e. treatment was intended if there was a significant neurological deficit as defined by a National Institutes of Health Stroke Scale (NIHSS) >2, caused by a large vessel occlusion in the anterior circulation, verified by computed tomography (CT) angiography and pre-interventional imaging, e.g. non contrast-enhanced computed tomography (NCCT) of the brain, ruled out intracranial hemorrhage, mass effect or advanced early ischemic changes, i. e. Alberta Stroke Program Early CT Score (ASPECTS) <5. Treatment was intended for all patients presenting with a time between symptom onset to estimated groin puncture of less than 12 h; however, patients presenting later or patients with unknown symptom onset (e.g. wake-up strokes) were offered treatment if the criteria mentioned above were met. There was no lower or upper age limit as exclusion criterion for mechanical thrombectomy. Intravenous thrombolytic drugs were administered and dosed at the discretion

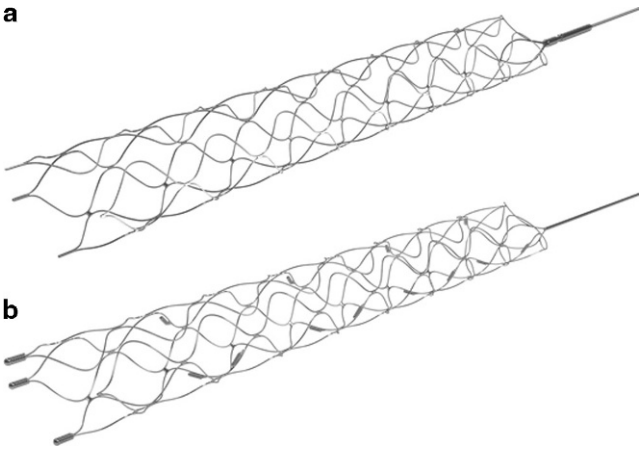

Fig. 1 Shows a close-up image of a 6×40 mm Solitaire™ 2 stent-retriever (**a**) and a 6×40 mm Solitaire™ Platinum stent-retriever (**b**). Please note the 3 radiopaque markers spaced 10 mm apart from each other added to the Solitaire™ Platinum stent-retriever (source: Medtronic, Dublin, Ireland)

of the treating neurologist following national and international guidelines. An exclusion criterion for this analysis was posterior circulation ischemic stroke.

Data Acquisition and Processing

Data acquisition was performed using a standardized electronic data entry form and included baseline demographics (sex and age) and previous medical history (e.g. hypertension, atrial fibrillation, diabetes mellitus, coronary artery disease and previous stroke). Furthermore, time of symptom onset and stroke severity as measured with the NIHSS was recorded. In the case of unknown symptom onset, the time the patient was last seen healthy was documented. Time of admission to the hospital where MT was performed was determined based on data from the admission charts.

Interventional times, e.g. start of the interventional procedure (groin puncture time), time of first flow restoration as the first antegrade flow of contrast medium in arteries distal to the occlusion on digital subtraction angiographic images (DSA) images, usually following placement

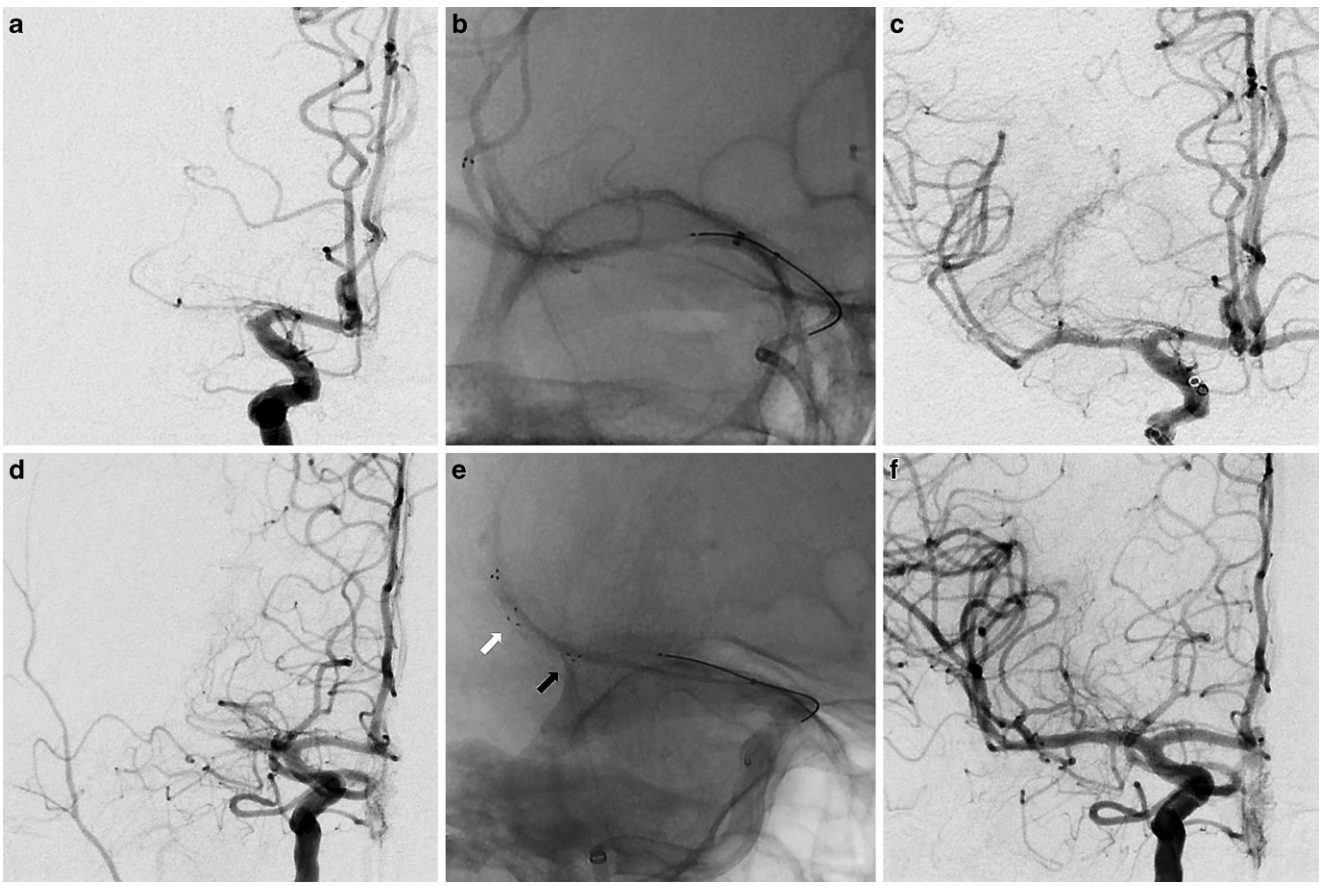

Fig. 2 The images **a**–**c** and **d**–**f** show two different patients with a middle cerebral artery (MCA) occlusion: **a**, **d** show the occlusion on digital subtraction images (DSA) prior to mechanical thrombectomy, **b** shows a non-subtracted image of a deployed 4× 20 mm Solitaire™ 2 stent-retriever with its typical radiopaque push-wire and three distal radiopaque markers, **e** demonstrates a deployed 4× 20 mm Solitaire™ Platinum stent-retriever with added 3 proximal (*black arrow*, delineating the proximal end of the working length of the device) and 3 middle (*white arrow*) radiopaque markers, **c**, **f** show complete reperfusion of the MCA on DSA images after one thrombectomy maneuver

Table 1 Usage of retrievable stents for mechanical thrombectomy in a selection of randomized controlled trials

Trial name	No. of patients in the trial	Patients assigned to interventional arm, *n* (%)	Patients within interventional arm treated with a stent-retriever, *n* (%)	Patients within interventional arm treated with a Solitaire stent-retriever, *n* (%)
MR CLEAN [15]	500	233 (46.6)	190 (81.5)	n.a.
SWIFT Prime [14]	196	98 (50)	98 (100)	98 (100)
REVASCAT [13]	206	103 (50)	103 (100)	103 (100)
ESCAPE [12]	316	165 (52.2)	130 (78.8)	100 (60.6)
EXTEND-IA [11]	70	35 (50)	35 (100)	35 (100)

EXTEND-IA extending the time for thrombolysis in emergency neurological deficits—intra-arterial, *ESCAPE* endovascular treatment for small core and anterior circulation proximal occlusion with emphasis on minimizing CT to recanalization times, *SWIFT Prime* solitaire with the intention for thrombectomy as primary endovascular treatment for acute ischemic stroke, *REVASCAT* randomized trial of revascularization with solitaire FR device versus best medical therapy in the treatment of acute stroke due to anterior circulation large vessel occlusion presenting within 8 hours of symptom onset, *MR CLEAN* multicenter randomized clinical trial of endovascular treatment for acute ischemic stroke in the Netherlands

of a stent-retriever, time of final angiographic result (time of DSA images after the final mechanical recanalization maneuver/attempt) and end of the procedure (time of digital subtraction angiographic images showing the last angiographic contrast run, immediately prior to removal of the catheter(s) and introducer sheath and closure of puncture site) were captured based on acquisition time stamps created automatically by the angiography systems. Location of the occlusion was evaluated on the pre-therapeutic DSA contrast runs. Medication and devices used during the intervention procedures, thrombectomy maneuvers count and intraprocedural complications were evaluated according to the treatment protocols. Complications (e.g. vessel perforation, dissection, emboli into a previously unaffected territory, unintended device detachment) and final perfusion result as by thrombolysis in cerebral infarction (TICI) were assessed based on DSA images. Interventional data were independently assessed by the institutions where the procedure was performed and by an experienced stroke neurointerventionalist during a monitoring visit. In the case of discrepancy, consent was reached in a consensus reading. The incidences of hemorrhage were assessed using the routinely performed follow-up imaging within 24 h after the procedure following the Heidelberg bleeding classification [17].

Because this analysis was designed to focus on technical and angiographic parameters, clinical mid-term or long-term follow-up data were not recorded; however, early neurological outcome was assessed based on NIHSS scores at discharge of the patients. Favorable early neurological recovery was graded following SWIFT trial criteria (i.e. at hospital discharge: modified Rankin Scale [mRS] = 0–2 or ΔNIHSS $\geq$ 10) [18]. Furthermore, patients initially admitted with a stroke severity of NIHSS 3–9 were rated as favorable early neurological recovery if NIHSS at discharge was 0.

Evaluation Questionnaire to the Operators

Data concerning the technical performance of the Solitaire™ Platinum stent-retriever was collated by a questionnaire survey to the neurointerventionalists in the three participating centers. Feedback was requested with respect to the individual neurointerventionalist's cumulative experience with the device. Basic, mandatory questions were scaled by a five point scale (ranging from "much less resistance" and "less resistance", over "no difference" to "more resistance" and "much more resistance", or "much better performance", "better performance", "no difference", "worse performance", "much worse performance") and included assessment of delivery and deployment of the Solitaire™ Platinum stent-retriever through the typically used microcatheter, as well as clinical performance of the device compared to the a Solitaire™ 2 stent-retriever.

We additionally asked the operators to comment (free text comment) on the visibility of the Solitaire™ Platinum stent-retriever and the possible influence on their interventional technique. These questions were targeted to capture information with respect to a possible change of placement strategy due to the additional markers, visualization of clot-device engagement, measurement of clot length, and visualization of a device elongation or deformation during so-called hard pull retrieval maneuvers.

Ethical Approval and Statistical Analysis

The stroke database was approved by the ethics committee. Due to the retrospective character of data collection and analysis written informed consent was waived.

Data are shown as mean with standard deviation (SD) or median with interquartile range (IQR), as appropriate. All statistical analyses were performed using IBM SPSS Statistics 21.0.0.0 (Armonk, NY, USA).

Table 2 Baseline clinical and therapeutic characteristics and radiological findings before the first thrombectomy maneuver of patients treated with a Solitaire™ Platinum stent-retriever

Patient characteristics		$n=75$
Baseline clinical characteristics		
Age (years), mean (SD)		75 (12)
Male, (%)		27 (36)
Hypertension, (%)		56 (74.7)
Diabetes mellitus, (%)		21 (28)
Atrial fibrillation, (%)		39 (52)
Coronary artery disease, (%)		11 (14.6)
Previous stroke, (%)		17 (22.7)
Initial NIHSS, median (IQR)		17 (11–21)
Intravenous rtPA, (%)		41 (54.7)
Unknown time of symptom onset, (%)		9 (12)
Radiological findings before mechanical thrombectomy		
ASPECTS, median (IQR)		8 (7–9)
CT angiographic collateral score[a], median (IQR)		2 (1–3)
Occlusion site[b]	Intracranial ICA (excluding carotid T), (%)	1 (1.3)
	Tandem occlusion (cervical ICA and carotid T, M1 or M2)[c], (%)	5 (6.7)
	Carotid T, (%)	11 (14.7)
	M1, (%)	42 (56)
	M2, (%)	16 (21.3)
	Occlusion site right, (%)	33 (44)

ASPECTS Alberta Stroke Program Early Computed Tomography Score, *ICA* internal carotid artery, *M1* main trunk of middle cerebral artery, *M2* segment arising distal to the main trunk of the middle cerebral artery, *NIHSS* National Institutes of Health Stroke Scale, *rtPA* recombinant tissue plasminogen activator

[a]CT angiographic collateral scoring according to Tan et al. [19]

[b]On DSA images before the first thrombectomy maneuver

[c]Patients received additional cervical carotid artery stenting during the procedure

Results

Baseline Clinical Characteristics and Radiological Findings Before Mechanical Thrombectomy

Between October 2016 and March 2017 MT with a Solitaire™ Platinum stent-retriever was performed in 75 patients due to an acute ischemic stroke in the anterior circulation at the three institutions participating in this analysis. Baseline clinical characteristics and pre-interventional imaging data reflect a typical stroke population (see Table 2). Mean patient age was 75 years (SD 12 years). There was a slight female predominance in this patient cohort (male: $n=27$, 36%). Patients with known time of symptom onset were admitted to the interventional hospital after a median time window of 179 min (IQR: 90–285 min) and presented with a median NIHSS of 17 (IQR: 11–21). Of the patients 41/75 (54.7%) were eligible and received intravenous thrombolysis. Although it was not a prerequisite for inclusion in this analysis, all patients received a NCCT prior to MT and scoring of early ischemic changes could be performed (ASPECTS, median IQR: 8, 7–9). In 72/75 (96%) patients CT angiography was assessable for scoring of intracranial collaterals according to Tan et al. (median score 2, IQR 1–3) [19]. The majority of patients had an occlusion of the middle cerebral artery ($n=42$, 56%), an occlusion of a M2 branch ($n=16$, 21.3%) or a carotid-T occlusion ($n=11$, 14.7%).

Procedural Aspects and Interventional Complications

Initiation of the procedure (groin puncture) was performed within a median time window of 238 min (IQR 177–356 min) in patients with known time of symptom onset. For all patients, median time from groin puncture to the first intracranial flow restoration was 35 min (IQR 24–47 min) and the final angiographic result could be reached within a median time of 56 min (IQR 41–79 min). In 39/75 (52%) patients TICI 3 was achieved. Overall, in 69 (92%) patients TICI 2b-3 could be achieved with a median stent-retriever maneuver count of 2 (IQR: 1–2, range: 1–5, mean: 1.9). Final angiographic result of TICI 2b-3 was achieved in 29/75 (38.6%) patients after 1 retrieval maneuver. In additional 28/75 (37.3%) patients, reperfusion grade TICI 2b-3 could be achieved following a second thrombectomy maneuver.

Vasospasm following a stent-retrieval maneuver was observed in 7/75 (9.3%) patients. Of the patients with middle cerebral artery vasospasms 2/75 (2.7%) were treated successfully with prophylactic intra-arterial administration of a calcium channel blocker because vasospasms were deemed to have the potential of significantly reducing the flow in the downstream vasculature. In the other cases vasospasms were minimal and resolved spontaneously. An embolism into a new, previously unaffected territory was observed in 4/75 (5.3%) patients following a stent-retriever thrombectomy maneuver. In 2/75 (2.7%) cases these emboli occluded a proximal vessel (A2 and M2 segments) and were subsequently removed without causing any sequelae. In 6 (8%) patients an additional Solitaire™ Platinum stent-retriever was used. Change of the stent-retriever was deemed necessary by the treating neuroradiologist for better adjustment of the primary occlusion to the vessel size (upsizing from a 4 × 20 mm to either 6 × 20 mm or 6 × 40 mm Solitaire™ Platinum stent-retriever in $n=5$, 6.7%). In 1/75 (1.3%) cases a 4× 20 mm Solitaire™ Platinum stent-retriever was used because of residual thrombus in a proximal M2 branch following a single stent-retriever of a carotid-T and middle cerebral artery occlusion with a 6 × 40 mm

Table 3 Procedural aspects, interventional complications and early outcome parameters following treatment with a Solitaire™ Platinum stent-retriever

Procedural aspects		$n = 75$
Treatment in general anesthesia, (%)		37 (49.3)
Onset to groin puncture time[a], min, median (IQR)		238 (177–356)
Groin puncture to first intracranial flow restoration, min, median (IQR)		35 (24–47)
Groin puncture to final angiographic result (final TICI) time, min, median (IQR)		56 (41–79)
Duration of interventional procedure[b], min, median (IQR)		64 (51–85)
No. of device passes, median (IQR; min–max; mean)		2 (1–2; 1–5; 1.9)
Total no. of device passes (no. of patients treated) by size of Solitaire™ Platinum stent-retriever used	4 × 20 mm	99 (55)
	4 × 40 mm	17 (9)
	6 × 20 mm	8 (5)
	6 × 40 mm	18 (12)
Angiographic results	TICI 0–1, (%)	6 (8)
	TICI 2b, (%)	30 (40)
	TICI 3, (%)	39 (52)
Interventional complications		
Vasospasm, (%)		7 (9.3)
Emboli into a new territory, (%)		4 (5.3)
Dissection, (%)		0
Vessel perforation, (%)		0
Device related complication, (%)		1 (1.3)
Early outcome parameters		
Favorable early neurological recovery[c], (%)		47 (62.7)
In-house mortality, (%)		10 (10.7)
Incidence and anatomic distribution of intracranial hemorrhages on follow-up NCCT[d]	1a, (%)	2 (2.7)
	1b, (%)	2 (2.7)
	1c, (%)	1 (1.3)
	2, (%)	2 (2.7)
	3a, (%)	0
	3b, (%)	0
	3c, (%)	6 (8)
	3d, (%)	0
Symptomatic intracranial hemorrhage[d], (%)		3 (4)

NCCT non-contrast-enhanced computed tomography, *TICI* thrombolysis in cerebral infarction

[a]Data provided for patients with known symptom onset only

[b]Time from groin puncture to removal of the catheter(s) and introducer sheath and closure of puncture site

[c]Improvement of stroke symptoms at hospital discharge: modified Rankin scale (mRS) = 0–2 or ΔNIHSS ≥ 10 (SWIFT trial criteria [18]) or NIHSS = 0

[d]According to the Heidelberg bleeding classification [17]

Solitaire™ Platinum stent-retriever. In 4 cases, it was possible to improve reperfusion results to TICI 2b or 3 using the rescue device.

In 75 patients, a total number of 142 stent-retriever placements and retrieval maneuvers were performed. There was only 1 out of the 142 (0.7%) where technical difficulties were reported. During deployment of the stent-retriever, stretching of the device was suspected. In this case the stent-retriever was easily recaptured with the microcatheter. Visual inspection of the device revealed no apparent damage. The stent-retriever was subsequently used for retrieval of the clot without causing damage to the vessel detectable on DSA runs. The follow-up NCCT after 24 h revealed a clinically silent subarachnoid hemorrhage limited to the ipsilateral Sylvian fissure in this patient. The patient was discharged with an NIHSS of 2 and a mRS of 2. We did not observe any device malfunction, such as an unintended device detachment. Furthermore, no vessel dissections or perforations occurred.

Early Outcome Parameters

In 13/75 (17.3%) patients any kind of intracranial hemorrhage was detected on follow-up NCCT 24 h after treatment according to Heidelberg bleeding classification criteria (anatomical description and distribution see Table 3; [17]). Most often these hemorrhages were asymptomatic, minimal, ipsilateral, subarachnoid hemorrhages ($n = 6$, 8%). A total of 3/75 (4%) symptomatic, but non-fatal intracranial hemorrhages were observed.

In 47/75 (62.7%) patients early neurological recovery was observed at hospital discharge. In-house mortality was 10.7% ($n = 10$).

Performance Evaluation

A total of 11 full questionnaire replies were received and analyzed. For delivery of a Solitaire™ Platinum stent-retriever, the most commonly used microcatheter was a Rebar™ 18 microcatheter (ev3 Neurovascular, Irvine, CA, USA), which was used in 70 of the abovementioned 75 patient cases (93.3%). In only 5/75 (6.7%) of the cases a Prowler® Select® Plus microcatheter (Codman & Shurtleff, Raynham, MA, USA) was used for delivery and deployment of a Solitaire™ Platinum stent-retriever.

The passage of a Solitaire™ Platinum stent-retriever through a standard microcatheter was deemed to be associated with less resistance in 6/11 (54.5%) or no difference in 4/11 (36.6%) of replies. A similar experience was reported for the deployment of the Solitaire™ Platinum stent-retriever as neurointerventionalists assessed this interventional step to be associated with either less resistance (5/11, 45.5%), or no difference (4/11, 36.6%). Only one

neurointerventionalist reported more resistance in passage of a Solitaire™ Platinum stent-retriever through a microcatheter, 2/11 (18.2%) replies indicated more resistance on deployment of the stent-retriever. The clinical performance of the new stent-retriever was assessed to be comparable to a Solitaire™ 2 stent-retriever in 9/11 (81.8%) or even better according to 2/11 (18.2%) replies.

According to the 5/11 (45.5%) replies, the better visibility of the Solitaire™ Platinum stent-retriever was deemed to have no effect on placement strategy; however, 6/11 (54.5%) neurointerventionalists appreciated the better visibility of the stent-retriever and attributed this to a more precise placement of the device with respect to the thrombus length and location. Visualization of clot-device engagement, as indicated by increasing distance of the markers within the thrombus after deployment, and the possibility to measure the clot length, as indicated by a close distance of the markers, was reported from 2/11 (18.2%) neurointerventionalists. Visualization of device elongation or deformation during retrieval maneuvers was not reported.

Discussion

In several multicentric RCTs mechanical thrombectomy using a Solitaire™ stent-retriever has been proven to be an effective treatment for acute ischemic stroke caused by large intracranial vessel occlusion [11, 13, 14]. In these trials successful reperfusion, as per TICI 2b-3, was achieved in 66–88% of patients who received endovascular stroke treatment. In this multicentric, retrospective, non-randomized analysis of consecutive patients with acute ischemic stroke in the anterior circulation, reperfusion grade TICI 2b-3 was achieved in 69 (92%) patients following mechanical thrombectomy with a Solitaire™ Platinum stent-retriever. The number of device passes (median: 2), time between groin puncture and first intracranial flow restoration (in minutes, median, IQR: 35, 24–47) and time from groin puncture to final angiographic result (56, 41–79 min) were comparable to data from the previously published RCTs [11, 13, 14].

Of the patients 47 (62.7%) had a favorable early neurological recovery at hospital discharge, i. e. mRS = 0–2 or ΔNIHSS $\geq$ 10 or NIHSS = 0. This result is similar compared to the results of the SWIFT trial (58%) [20]. Unfortunately, 10 (10.7%) patients died within the hospital stay due to the suffered stroke. This in-house mortality rate, however, is comparable to the results of the REVASCAT trial (death at $\leq$7 days: n = 10, 9.7%) [13]. Likewise, the rate of any kind of asymptomatic (13.3%) and symptomatic (4%) intracranial hemorrhages (ICH) corresponds to the REVASCAT trial results (asymptomatic ICH: 16.5%; symptomatic ICH: 4.9%) [13]. An additional stent-retriever was used in only 6 (8%) patients. This rate appears relatively low, compared to other publications (e. g. Kabbasch et al. 22%) [16]. In our patient cohort all rescue devices used were likewise Solitaire™ Platinum stent-retrievers, which were adjusted in size to fit the caliber of the targeted vessel more properly. This underlines the need for proper sizing of a stent-retriever with respect to the vessel diameter [21].

There was a very low rate of typical procedure-related complications. Vasospasms and vessel dissection are closely related to shear stress applied to the vessel wall by the stent-retriever during MT. While we did not experience a case of vessel dissection, vasospasm was noted in 7 (9.3%) patients, of which 2 (2.7%) required medical treatment. This occurrence is relatively low and well within the line of previously published data reporting vasospasms in 4.1–23% of patients following MT, making treatment necessary in 3.9% of cases [13, 14, 22].

Embolization of thrombus fragments into a previously unaffected vascular territory is a potential adverse event in mechanical thrombectomy. This adverse event is known to happen in 3.5–6% of endovascular stroke treatments [11, 13, 22, 23]. We observed embolization of thrombus fragments in 4 (5.3%) patients although distal aspiration through an intermediate catheter was used in all cases. A combination of distal aspiration with additional proximal internal carotid artery occlusion using a balloon guiding catheter might be a method to reduce the occurrence of this adverse event [24, 25].

The radiopaque platinum markers added to the Solitaire™ stent-retriever are intended to help in a more targeted deployment of the device with regard to the clot. Additionally, the markers should better delineate the stent-retriever in the vasculature after delivery and are thought to show clot migration into the device through expansion of the markers. Based on a narrow majority of replies to our questionnaire to the neurointerventionalists, the new proximal markers identifying the proximal end of the working length of the stent-retriever, were helpful in aligning the retriever to the clot more precisely; however, visualization of clot-device engagement was not detected very often. Since it appears that there is almost no effect on clinical performance, reperfusion results or complication rates, compared to years of experience with the Solitaire™ 2 device, the newly added markers could be considered “nice to have” rather than “must have”. On the other hand, colleagues treating only a few cases per year or starting in the field of endovascular stroke treatment might appreciate the increased visibility of the Solitaire™ Platinum stent-retriever.

In an international survey performed among the members of the World Federation of Interventional and Therapeutic Neuroradiology friction of the stent-retriever in the microcatheter was the most reported limitation of stent-retrievers (reported by 26% colleagues in more than 10% of their

cases) [26]. The results of our survey show that there is a disagreement among neurointerventionalists whether the added markers increase the resistance during delivery and deployment of the Solitaire™ Platinum stent-retriever via a microcatheter. Either way, possible alterations in favor of more, or less resistance appear to be limited, since there was no reply stating a "much more resistance" or "much less resistance" during delivery and deployment of the new device. In all patients included in this analysis, a Solitaire™ Platinum stent-retriever was deployed successfully; however, we experienced one technical difficulty during deployment of a device which did not cause any sequelae. Furthermore, we did not need to switch to a different type of stent-retriever and no procedure was terminated because of increased friction of the device. Furthermore, no adverse interaction between the new stent-retriever and a microcatheter, distal access catheter or guiding catheter, such as abnormal wear or tear leading to replacement of a device or catheter, was reported.

Limitations

There are a few limitations to this analysis. Due to the retrospective character of data collection, possible difficulties with delivery and deployment of a Solitaire™ Platinum stent-retriever could be underestimated; however, if there would have been any serious difficulties with the device (e. g. unintended detachment of the device, vessel perforations) they would have been documented in the angiographic reports or patient records.

Although consecutive patients treated with a Solitaire™ Platinum stent-retriever were included in this analysis, other stent-retriever devices have been used in the participating institutions during the observation period; therefore, there might be a certain degree of selection bias to our patient population. Nonetheless, we believe that our findings are to some extent applicable to other settings since our patient baseline characteristics reflect a typical patient population and our findings are comparable to previous trials.

To our knowledge, there are currently no technical or in vitro test results available focusing on friction of the Solitaire™ Platinum stent-retriever in comparison to other stent-retrievers during passage through a microcatheter. Against this background, the results of the user questionnaire reflect the first experience and opinion of a relatively small group of neurointerventionalists. Hence, our results might not be applicable to other settings, might differ in a larger survey and certainly cannot replace first-hand experiences with the new stent-retriever.

Conclusion

In this retrospective, multicenter analysis the usage of the Solitaire™ Platinum stent-retriever for mechanical thrombectomy in acute ischemic stroke patients was highly effective and was not accompanied by an increased periprocedural complication rate compared to previous Solitaire™ revascularization devices. From the investigators point of view, the newly added radiopaque platinum markers and the associated increased visibility of the stent-retriever was deemed to be helpful for alignment of the device with the clot. A final assessment of friction or resistance during delivery and deployment of the device, or abnormal wear of concurrently used material (e. g. microcatheters), should be subject to a prospective evaluation, for example within a register trial and perhaps supported by in vitro tests.

Conflict of interest J. Pfaff: activities related to the present article: disclosed no relevant relationships. Activities not related to the present article: travel and meeting expenses from Stryker, and MicroVention Deutschland. Other relationships: disclosed no relevant relationships. S. Rohde: activities related to the present article: disclosed no relevant relationships. Activities not related to the present article: payment for Lectures including service on speakers bureaus: <€1000, MicroVention, ev3; travel/accommodation/meeting expenses unrelated to activities listed: <€1000, MicroVention, Stryker Neurovascular. Other relationships: disclosed no relevant relationships. M. Bendszus: activities related to the present article: grants and personal fees from Medtronic. Activities not related to the present article: grants and personal fees from Bayer, Codman, Guerbet, and Novartis; grants from the Hopp Foundation, Siemens, and Stryker; personal fees from Braun, Böhringer Ingelheim, Roche, Teva, and Vascular Dynamics. Other relationships: disclosed no relevant relationships. M.A. Möhlenbruch: activities related to the present article: consultancy for Medtronic. Activities not related to the present article: board membership for Codman, and payment for lectures from MicroVention, Phenox, and Stryker. Other relationships: disclosed no relevant relationships. T. Engelhorn and A. Doerfler declare that they have no competing interests.

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