Outcome of Standard and High-Risk Patients With Acute Anterior Circulation Stroke After Stent Retriever Thrombectomy

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**Background and Purpose**—Stent retrievers have become an important tool for the treatment of acute ischemic stroke. The aim of this study was to analyze outcome and complications in a large cohort of patients with stroke treated with the Solitaire stent retriever. The study also included patients who did not meet standard inclusion criteria for endovascular treatment: low or high baseline National Institutes of Health Stroke Scale score, ≥80 years of age, extensive ischemic signs in middle cerebral artery territory, and time from symptom onset to endovascular intervention >8 hours.

**Methods**—Consecutive patients with acute anterior circulation stroke treated with the Solitaire FR were analyzed. Data on characteristics of endovascular interventions, complications, and clinical outcome were collected prospectively. Patients who met standard inclusion criteria were compared with those who did not.

**Results**—A total of 227 patients were included. Mean age was 68.2±14.7 years, and median National Institutes of Health Stroke Scale score on admission was 16 (range, 2–36). Reperfusion was successful (thrombolysis in cerebral infarction, 2b–3) in 70.9%. Outcome was favorable (modified Rankin Scale, 0–2) in 57.7% of patients who met standard inclusion criteria and 30.3% of those who did not. The rates for symptomatic intracranial hemorrhage were 3.7% and 13.1%, for death 11.4% and 33.8%, and for symptomatic intraprocedural complications 2.5% and 4.8%, respectively.

**Conclusions**—Patients <80 years of age, without extensive pretreatment ischemic signs, and baseline National Institutes of Health Stroke Scale score ≤30 had high rates of favorable outcome and low periprocedural complication rates after Solitaire thrombectomy. Successful reperfusion was also common in patients not fulfilling standard inclusion criteria, but worse clinical outcomes warrant further research with a special focus on optimal patient selection. *(Stroke. 2014;45:152-158.)*

**Key Words:** stroke ■ thrombectomy

Stent retrievers have become valuable as thrombectomy devices for the treatment of acute ischemic stroke. The reasons for this are 3-fold. First, stent retrievers restore perfusion in the occluded vascular territory immediately after insertion. Second, they can readily be retrieved and achieve a high rate of vessel recanalization, and third, unlike traditional stents, they are not permanently deployed and do not have device-related adverse events in the long term. The Solitaire FR (ev3-Covidien, Irvine, CA) was the first dedicated stent retriever, commercially introduced in Europe in November 2009. The percentage of patients with successful reperfusion with the Solitaire retriever was higher (64%–100%) compared with that of patients with anterior circulation strokes. However, most studies using the Solitaire excluded patients with expected high risk for adverse outcome and patients with only mild stroke symptoms (ie, patients whose treatment was not advised according to contemporary guidelines). Thus, safety and outcome of stent retriever thrombectomy in patients who do not meet standard inclusion criteria for endovascular stroke treatment are not known. The aim of this study was to analyze safety and outcome of Solitaire treatment in a large cohort of patients with anterior circulation stroke and to compare patients with and without risk factors that presumably predict adverse outcomes.

**Patients and Methods**

Patients with acute stroke admitted to our stroke center are continuously recorded in the Bernese Stroke Registry. In this analysis, we...
assessed clinical outcome, procedural characteristics, and peri-
procedural complications in all patients with anterior circulation stroke
who were treated with the Solitaire FR stent retriever. Part of the data
of 49 patients has been included into retrospective and prospective
international studies on thrombectomy. The study was approved
by our institutional review board.

Preinterventional Patient Assessment

Neurological deficits were scored by a neurologist using the National
Institutes of Health Stroke Scale (NIHSS). Baseline demographic and
clinical data were recorded prospectively.

Computed tomography (CT) or MRI of the head was performed
before therapy, including CT angiography or contrast-enhanced MR
angiography depicting the aortic arch and the neck and intracranial
vessels. Images were assessed for extensive early ischemic signs in
the middle cerebral artery (MCA) territory, defined as an Alberta
Stroke Program Early CT Score (ASPECT) of ≤6 on CT, or <5 on
diffusion-weighted imaging on MRI. When both pretreatment CT
and MRI were available, the MRI ASPECT score was used for clas-
sification of infarct size.

Therapy

Criteria for endovascular therapy were an acute neurological deficit
of ≤24 hours duration and an NIHSS score ≥4 or isolated aphasia. In
addition, the causative vessel occlusion had to be accessible by an
endovascular route, intracranial hemorrhage had to be excluded on
admission CT or MRI, and clinical and laboratory findings advising
against endovascular therapy had to be absent. Endovascular strategy
was based on clinical data and multimodal CT or MRI.

Endovascular therapy was performed under general anesthesia or
conscious sedation with monitored anesthesia care. High-resolution,
biplane flat panel diagnostic 4-vessel cerebral angiography was per-
formed before endovascular treatment (Axiom Artis zee; Siemens,
Erlangen, Germany). The site of vessel occlusion was categorized as
internal carotid artery (ICA), tandem (ICA in combination with MCA
and/or anterior cerebral artery), carotid-T, M1 segment of MCA, M2
segment of MCA, and multiple (MCA in combination with anterior
cerebral artery). Characteristics from endovascular therapy were
assessed by review of digital subtraction angiography series and writ-
ten reports.

Leptomeningeal collaterals supplying the occluded vessel territory
were graded as poor if no angiographically relevant collaterals were
visualized, as moderate if minimal leptomeningeal anastomoses were
visualized, and as good if leptomeningeal anastomoses were filling
the occluded vessel territory by more than half.

Retrieval of the stent was performed in flow arrest using a balloon-
mounted guiding catheter placed with its tip as close as possible to
the skull base, to prevent the ICA from collapsing during aspiration.
Triple-access catheter technique was used if the artery to access the
thrombus was extremely tortuous or large arterial branches origi-
nated between the balloon catheter and the thrombus (Figure). Using
this technique, a high volume 5 or 6F distal access and aspiration
catheter was advanced over the wire of the stent retriever in front
of the occlusion site. The extraction of the clot and stent was per-
formed under simultaneous aspiration at the distal access and infla-
tion of the balloon catheter. In addition to thrombectomy with the
Solitaire, thromboaspiration with a distal access catheter and simul-
taneous aspiration with a balloon catheter if applicable, intra-arterial
thrombolysis, percutaneous transluminal angioplasty, or intracranial
or extracranial stent placement were used in individual patients as
deemed necessary.

In patients with tandem occlusions, we preferentially performed
stenting after distal thrombectomy as the last step, using a distal pro-
tection system. In this way, distal thrombectomy of the MCA or distal
ICA can be performed in flow arrest caused by the more proximal
ICA occlusion. To avoid stent-associated complications, we usually
performed percutaneous transluminal angioplasty alone and contin-
ued with stenting only, if rapid reocclusion occurred. Patency of the
carotid bifurcation, with or without stenting, was closely bedside
monitored in the stroke unit using Doppler ultrasound.

Intraprocedural complications included vessel wall dissection, ves-
sel perforation, severe vasospasm, in-stent thrombosis, device failure,
embolization, and immediate reperfusion hemorrhage. Severe vaso-
spasm was defined as vasospasm necessitating intra-arterial spasmol-
ysis using nimodipine or papaverine. Symptomatic intraprocedural
complications were defined as adverse events associated with an in-
crease in NIHSS score of ≤4 points or death at 24 hours.

Figure. A 53-year-old woman with proximal right middle
cerebral artery (MCA) occlusion with dysarthria and left-sided
hemiparesis (National Insti-
tutes of Health Stroke Scale
[NIHSS] score, 15). Preinter-
ventional MR perfusion shows
decreased cerebral blood flow
and increased time to peak of
apparent diffusion coefficient
(A, A') and diffusion-
weighted imaging (B) and
apparent diffusion coefficient
maps (B'). Digital subtraction
angiography (lateral projection;
C) confirms proximal M1 occlu-
sion and persistent trigeminal
artery (black arrow). Roadmap
with deployed Solitaire stent
(white arrow at distal end)
and 5F aspiration catheter
in the proximal M1 segment
(anterior projection; D), pro-
ecting the trigeminal artery from any displacement of thrombotic
material during stent retrieval. NIHSS score after 1 day was 4 and outcome
at 3 months was favorable
(modified Rankin Scale, 1).
Cerebral reperfusion was assessed at the end of the endovascular procedure, using biplane or 3-dimensional rotational angiography, according to the thrombolysis in cerebral infarction grading system.23

**Postinterventional Patient Assessment**

A CT or MRI was obtained 24 to 72 hours after treatment, or earlier in case of clinical deterioration. The occurrence of symptomatic intracranial hemorrhages (sICH) or asymptomatic intracranial hemorrhages within 72 hours from stroke onset was recorded according to the Prolyse in Acute Cerebral Thromboembolism (PROACT) II criteria.24 Clinical outcome was assessed 3 months after stroke using the modified Rankin Scale (mRS).

**Statistical Analysis**

Categorical variables were compared with the 2-tailed Fisher exact test. To determine the predictors of clinical outcome, death, and reperfusion success, a forward stepwise logistic regression including all variables with a \( P < 0.2 \) in univariate analysis was performed. These variables were age, sex, baseline NIHSS score, occlusion site, degree of collaterals, ASPECT score, time from symptom onset to arterial puncture, anesthesia type, reperfusion success, symptomatic intraprocedural complication, peri-interventional intramural arterial dissection, atrial fibrillation, diabetes mellitus, arterial hypertension, hypercholesterolemia, coronary artery disease, previous stroke, current or previous smoking, and family history of stroke. Successful reperfusion was defined as thrombolysis in cerebral infarction grades 2b and 3. Clinical outcome was dichotomized into favorable functional outcome (mRS, 0–2) and poor outcome (mRS, 3–6). Patients with baseline NIHSS score <8 or >30, patients aged ≥80 years, patients with extensive ischemic signs in the MCA territory, or patients with time from symptom onset to endovascular intervention >8 hours were assigned to the group who did not meet standard inclusion criteria for endovascular stroke treatment. Hundred forty-five patients (63.9%) did not fulfill all criteria, and 35 of them violated ≥1 criterion. Vascular risk factors were similar in patients meeting standard inclusion criteria and those who did not.

Baseline ASPECT scores and extent of leptomeningeal collaterals are given in Table I in the online-only Data Supplement. Collateral status could not be determined in 1 patient with carotid-T occlusion because angiograms of the contralateral side were missing. Patients presenting with a baseline NIHSS score <8 had significantly better collateral supply than patients with an NIHSS score ≥8 (\( P = 0.028 \)), and patients with extensive ischemic signs in the MCA territory had significantly worse collaterals compared with those with less extensive ischemic changes (\( P < 0.001 \)).

**Procedural Characteristics**

Of the 227 patients included in the study, 105 (46.3%) were treated with the Solitaire alone. In 122 patients (53.7%), additional techniques were used. In patients treated with the Solitaire alone, the median procedural time was 44 minutes (range, 15–171) versus 114 minutes (range, 31–282) in patients receiving multimodal endovascular therapy. In 225 patients (99.1%), the Solitaire could be deployed over the thrombus. In 2 patients, the Solitaire could not be completely passed over the thrombus because of elongated vessels. The median number of passes by the stent retriever was 1 (range, 1–6). An immediate bypass effect, restoring at least a trickle of flow through the occluded vessel after temporary deployment of the stent retriever, was seen in 184 patients (81.4%).

**Table 1. Baseline Characteristics of 227 Patients Treated With the Solitaire**

<table>
<thead>
<tr>
<th>Overall (n=227)</th>
<th>Patients Meeting Standard Criteria (n=81)</th>
<th>NIHSS &lt;8 (n=27)</th>
<th>NIHSS &gt;30 (n=11)</th>
<th>Age ≥80 y (n=50)</th>
<th>Extensive Ischemic Signs in MCA Territory (n=69)</th>
<th>Time From Symptom Onset to Arterial Puncture &gt;8 h (n=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y, mean (SD)</td>
<td>68.2 (14.7)</td>
<td>66.5 (12.5)</td>
<td>65.5 (14.5)</td>
<td>59.4 (13.8)</td>
<td>83.6 (2.6)</td>
<td>65.1 (16.0)</td>
</tr>
<tr>
<td>Women, n (%)</td>
<td>111 (49.9)</td>
<td>35 (43.2)</td>
<td>15 (55.6)</td>
<td>7 (63.6)</td>
<td>30 (60.0)</td>
<td>32 (46.4)</td>
</tr>
<tr>
<td>Baseline NIHSS score, median (range)</td>
<td>16 (2–36)</td>
<td>15 (8–26)</td>
<td>6 (2–7)</td>
<td>36 (36–36)</td>
<td>17.5 (4–36)</td>
<td>20 (6–36)</td>
</tr>
<tr>
<td>Extensive ischemic signs in MCA territory, n (%)</td>
<td>69/226 (30.5)</td>
<td>0 (0.0)</td>
<td>2 (7.4)</td>
<td>6 (54.5)</td>
<td>13 (26.0)</td>
<td>69 (100)</td>
</tr>
<tr>
<td>Occlusion site, n (%)</td>
<td>Internal carotid artery</td>
<td>2 (0.9)</td>
<td>1 (1.2)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td>Carotid-T</td>
<td>42 (18.5)</td>
<td>11 (13.6)</td>
<td>1 (3.7)</td>
<td>3 (27.3)</td>
<td>11 (22.0)</td>
<td>22 (31.9)</td>
</tr>
<tr>
<td>Tandem occlusion</td>
<td>25 (11.0)</td>
<td>11 (13.6)</td>
<td>3 (11.1)</td>
<td>0 (0.0)</td>
<td>3 (6.0)</td>
<td>6 (8.7)</td>
</tr>
<tr>
<td>MCA M1</td>
<td>135 (59.5)</td>
<td>55 (67.9)</td>
<td>18 (66.7)</td>
<td>6 (54.5)</td>
<td>29 (58.0)</td>
<td>34 (49.3)</td>
</tr>
<tr>
<td>MCA M2</td>
<td>12 (5.3)</td>
<td>1 (1.2)</td>
<td>5 (18.5)</td>
<td>1 (9.1)</td>
<td>4 (8.0)</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td>Multiple occlusions</td>
<td>11 (4.8)</td>
<td>2 (2.5)</td>
<td>0 (0.0)</td>
<td>1 (9.1)</td>
<td>3 (6.0)</td>
<td>5 (7.2)</td>
</tr>
</tbody>
</table>

MCA indicates middle cerebral artery; and NIHSS, National Institutes of Health Stroke Scale.
In 85.5% of all interventions, the Solitaire FR 4×20 mm was used, in 10.1% the Solitaire FR 6×30 mm, and in 4.4% both were used. In 161 patients (70.9%), successful reperfusion (thrombolysis in cerebral infarction, 2b–3) was achieved (Table 2; Table I in the online-only Data Supplement).

In multiregression analysis, more extensive leptomeningeal collaterals (P=0.011; odds ratio [OR], 1.716; 95% confidence interval [CI], 1.131–2.604) predicted successful reperfusion independently.

In the majority of patients, endovascular interventions were performed under general anesthesia (n=196 [86.3%]). Good outcome (mRS, 0–2) was more often in patients undergoing treatment with conscious sedation compared with patients receiving general anesthesia (n=193/31 [61.3%] versus n=53/190 [36.3%]; P=0.010).

Intraprocedural Complications
In 74 patients (32.6%), 84 intraprocedural complications occurred (Table III in the online-only Data Supplement). Nine patients (4.0%) had clinically symptomatic complications. Most of the symptomatic complications were related to problems in the cervical ICA such as iatrogenic dissection (n=3) or in-stent thrombosis (n=3).

Vessel perforation was observed in 2 patients (1 M1 and 1 M2 perforation). Bleeding stopped spontaneously in the patient with the M1 perforation after retraction of the stent retriever, and we were able to stop the bleeding in the patient with the M2 perforation by superselective occlusion of the MCA branch with a drop of glue (Histoacryl; B. Braun Melsungen AG, Melsungen, Germany). In both patients, follow-up CT on the next day showed no extension of the subarachnoid hemorrhage. Material failure occurred in 1 patient in whom the stent was lost from the push wire during retraction in the M1 segment. Treatment with aspirin and Plavix was initiated. The vessel remained open, and the patient experienced no new symptoms. After recanalization and stent placement in ICA occlusions, immediate in-stent thrombosis was seen in 8 of 36 patients (22.2%; Precise; Cordis, a Johnson & Johnson company, Miami Lakes, FL, and Cristallo Ideale; Invatec S.p.A., Roncadelle, Italy). In-stent thrombosis was successfully treated in all patients with intra-arterial Abciximab (ReoPro; Centocor B.V., Leiden, The Netherlands) or heparin. No in-stent thrombosis occurred after permanent Solitaire deployment. Distal clot embolization was observed in 15 patients (6.6%). Six embolizations occurred in a previously uninvolved vascular territory.

Clinical Outcome and Bleeding Complications
Follow-up imaging with CT or MRI within 72 hours was performed in 225 patients (99.1%). sICH occurred in 22 patients (9.7%) and symptomatic intracranial hemorrhage in 34 (15.0%; Table 3). Of 18 anticoagulated patients with an international normalized ratio ≥1.7, sICH occurred in 4 (22.2%), whereas only 18 of 207 patients (8.7%) with an international normalized ratio <1.7 had an sICH. At 3 months, 221 patients (97.4%) underwent assessment of the mRS. Outcome was favorable (mRS, 0–2) in 88 patients (39.8%) and poor (mRS, 3–6) in 133 patients (60.2%).

Multiregression analysis demonstrated successful reperfusion (P=0.012; OR, 2.790; 95% CI, 1.254–6.209), higher ASPECT score (P=0.037; OR, 1.190; 95% CI, 1.011–1.402), younger age (P=0.001; OR, 0.935; 95% CI, 0.908–0.963), lower NIHSS score on admission (P=0.001; OR, 0.834; 95% CI, 0.781–0.890), and absence of diabetes mellitus (P=0.018; OR, 0.284; 95% CI, 0.100–0.806) to be independent predictors of favorable clinical outcome.

Mortality at 3 months was 25.7% (n=57/222). Failed reperfusion (P=0.005; OR, 0.354; 95% CI, 0.172–0.729), advancing age (P=0.001; OR, 1.056; 95% CI, 1.023–1.091), higher NIHSS score on admission (P<0.001; OR, 1.120; 95% CI, 1.062–1.181), and diabetes mellitus (P=0.001; OR, 4.375; 95% CI, 1.855–10.320) were independent predictors of death. Carotid-T occlusions showed the highest mortality rate (39.0%).

Comparison of Patients Who Met Standard Inclusion Criteria With Those Who Did Not
Successful reperfusion was achieved in 71% of patients not fulfilling standard inclusion criteria, which is similar to the 70.4% in the group who met the criteria (P=1.000). Outcome was favorable (mRS, 0–2) in 57.7% of patients who met standard inclusion criteria and in 30.3% of those who did not (P<0.001). The rates for sICH were 3.7% and 13.2% (P<0.001), for death 11.4% and 33.8% (P<0.001), and for

Table 2. Treatment Details

<table>
<thead>
<tr>
<th>Overall (n=227)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Time from symptom onset to arterial puncture, min, median (range)</td>
<td>235 (64–1426)</td>
<td>222 (110–472)</td>
<td>253 (115–437)</td>
<td>218 (155–370)</td>
<td>233.5 (120–594)</td>
<td>229 (120–778)</td>
</tr>
<tr>
<td>Time from arterial puncture to final reperfusion, min, median (range)</td>
<td>79 (15–282)</td>
<td>81 (16–213)</td>
<td>54 (23–173)</td>
<td>86 (26–282)</td>
<td>61 (21–261)</td>
<td>84 (23–241)</td>
</tr>
<tr>
<td>Successful reperfusion (TICI, 2b–3), n (%)</td>
<td>161 (70.9)</td>
<td>57 (70.4)</td>
<td>23 (85.2)</td>
<td>7 (63.6)</td>
<td>37 (74.0)</td>
<td>43 (62.3)</td>
</tr>
<tr>
<td>Multimodal endovascular therapy, n (%)</td>
<td>122 (53.7)</td>
<td>44 (54.3)</td>
<td>13 (48.1)</td>
<td>6 (54.5)</td>
<td>24 (48.0)</td>
<td>39 (56.5)</td>
</tr>
</tbody>
</table>

MCA indicates middle cerebral artery; NIHSS indicates National Institutes of Health Stroke Scale; and TICI, thrombolysis in cerebral infarction.
symptomatic intraprocedural complications 2.5% and 4.8% (P=0.709), respectively.

Patients of old age (≥80 years) reached a favorable outcome in a low percentage (n=5/49 [10.2%]; P<0.001). Low rates of good outcome were also observed in patients with extensive ischemic signs in the MCA territory on admission (n=14/68 [20.6%]; P<0.001) and patients with baseline NIHSS score >30 (n=1/10 [10.0%]; P=0.054). The highest mortality rates occurred in patients of old age (n=22/49 [44.9%]; P=0.001), those, who had extensive ischemic lesions on initial imaging (n=29/68 [42.6%]; P<0.001), and patients with high baseline NIHSS score (n=5/10 [50.0%]; P=0.129). Figures I and II in the online-only Data Supplement give an overview of the distribution of mRS scores in patients of old age compared with those who were younger and of patients with extensive ischemic signs in the MCA territory compared with those without, respectively. The percentage of patients with moderately severe to severe disability (mRS, 4–5) was not significantly different from that in younger patients (n=10/49 [20.4%] versus 25/173 [14.5%]; P=0.375). Similar rates of moderately severe to severe disability were observed in patients with extensive ischemic signs compared with those without (n=11/68 [16.2%] versus 24/152 [15.8%]; P=1.000).

Patients who received endovascular treatment >8 hours after stroke onset had comparable rates of good outcome (P=0.821) and mortality (P=0.607) as those whose treatment began ≤8 hours after ictus.

### Discussion

Thrombectomy with the Solitaire proved to be highly effective in our 81 patients with acute ischemic stroke of the anterior circulation and a median baseline NIHSS score of 15 who met standard inclusion criteria for endovascular stroke treatment. Reperfusion was successful in 70.4%, outcome was favorable in 57.7%, survival at 3 months was 88.6%, and symptomatic intraprocedural complications occurred in only 2.5%.

Successful reperfusion in patients fulfilling standard inclusion criteria was similar to previous studies (64%–100%).1-14 Previously reported favorable clinical outcomes ranged from 29% to 77%, depending mainly on whether patients with posterior circulation strokes were included. The median NIHSS scores in these studies were generally high (median NIHSS scores, 15–38).2-4,7,11,12,14,16,17,21

Several previous studies with the Solitaire stent retriever excluded patients with an expected low chance of a favorable outcome (ie, patients with baseline NIHSS score >30, patients ≥80 years, patients with extensive ischemic signs in the MCA territory and patients treated >8 hours after symptom onset).3-5,9,11,14,16-19 Notably, more than half of the patients in our series (64.1%) did not meet standard criteria. As this patient population generally constitutes a large part of patients treated at high-volume stroke centers, findings on outcome in this group are of particular importance.

Successful reperfusion rate in elderly patients was similar to that in younger patients. This indicates that age-related atherosclerotic changes do not influence technical success with the Solitaire, but favorable outcome (10.2%) and survival (55.1%) in patients ≥80 years of age were lower than in the younger cohort. Similar results were found in a retrospective comparison of patients ≥80 years of age and younger patients undergoing endovascular treatment for acute ischemic stroke.25 It remains unknown what effect successful reperfusion in the elderly has on clinical outcome. IST-3 revealed similar treatment effects of intravenous thrombolysis in patients ≥80 years of age compared to younger patients, despite a generally worse outcome in the elderly.26 It also has to be noted that in our series more than a third of patients of old age achieved a mRS score ≤3. Although mortality was markedly higher in the elderly, the percentage of patients with moderately severe to severe disability (mRS, 4–5) was not significantly different compared to that in younger patients (20.4% versus 14.5%; Figure I in the online-only Data Supplement). Apart from a significantly higher prevalence of atrial fibrillation in the elderly (n=32/44; 72.7%; P=0.002), we did not find any significant difference in imaging or clinical baseline characteristics, which could have acted as possible confounders on outcome.

Fewer patients with extensive ischemic signs in the MCA territory showed favorable outcomes (20.6%) and survival at 3 months (57.4%) compared with those who met standard inclusion criteria, and their sICH rates were markedly increased (19.1% versus 3.8%). Percentages of patients with moderately severe to severe disability (mRS, 4–5) were still similar in patients with extensive ischemic signs and those without (16.2% versus 15.8%; Figure II in the online-only Data Supplement). In our study, none of the patients with an MRI ASPECTS ≤3 or a CT ASPECTS ≤4 on pretreatment imaging reached a favorable outcome. This is in line with a previous report.27 No unequivocally accepted definition of extensive ischemic signs in the MCA territory exists in literature. For reasons of comparability, we used the ASPECTS-based definition from the STAR trial.14
Outcome and survival in patients treated >8 hours after symptom onset did not differ from those treated ≤8 hours. This is most likely the result of patient selection and emphasizes the importance of imaging for treatment decision. We treated patients beyond 8 hours only when a considerable perfusion-diffusion mismatch and none or only minor signs of early ischemic changes were present. Despite the small size of this patient subgroup, which precludes from drawing firm conclusions, our results are in line with findings from previously published retrospective studies that showed that endovascular therapy might be used with acceptable safety >6 and 8 hours, respectively, after stroke onset.28,29

Symptomatic intraprocedural complications occurred in only 9 of 227 patients (4.0%). As in other studies with stent retrievers, vasospasm necessitating pharmacological spasmolysis was the most common complication, but it was not associated with an elevated risk for sICH or asymptomatic intracranial hemorrhage. Distal clot embolization was rarely observed (n=15/227 [6.6%]). In 4 of 11 patients (36.6%) with emboli directly associated with stent retriever thrombectomy, a distal access catheter (Outreach DAC; Concentric Medical, Mountain View, CA and VASCOSTENT; Balt, Montmorency, France) was used. In 1 of these 4 patients, flow arrest was not achieved during stent retrieval because the balloon guiding catheter could not be inflated because of previous ICA stenting. First, distal access catheters were used with the intention to minimize the risk of embolic events by shortening the distance, the thrombus had to be retracted through the vessel and by providing additional aspiration during stent retrieval. Second, they were used to facilitate access in patients with tortuous or ectatic vascular anatomy.

In our study, the majority of endovascular interventions (86.3%) were performed under general anesthesia. Controversy exists about whether general anesthesia or conscious sedation should be preferred in endovascular stroke treatment.30–32 In our series, patients undergoing treatment with conscious sedation had a significantly higher rate of good outcome compared with patients receiving general anesthesia. This finding could have been biased by the fact that almost all patients with severe stroke (NIHSS score >30 or extensive ischemic signs in the MCA territory) received general anesthesia. After exclusion of these patients, the difference in favorable outcome between the conscious sedation and general anesthesia group was no longer significant. It has to be noted, that in more than half of the patients, other endovascular techniques apart from the Solitaire were used to achieve final revascularization. This emphasizes that traditional techniques such as intra-arterial thrombolysis or thromboaspiration still remain important complementary components of endovascular stroke treatment.

Limitations of our study are that data from imaging were partly analyzed retrospectively, although clinical data were collected prospectively. Moreover, our nonrandomized single-center study has the inherent limitation of a potential selection bias. Furthermore, this is not a randomized study, and only indirect comparisons with results of other studies are possible. Nevertheless, despite limited comparability attributable to different revascularization techniques, favorable outcomes in patients who met standard inclusion criteria were more frequent than in the active arm of PROACT II as well as the endovascular and intravenous thrombolysis arms of Interventional Management of Stroke–3.24,33 This finding further supports the preferential use of stent retrievers compared with older thrombectomy devices or isolated intra-arterial thrombolysis.

Conclusions

Patients <80 years of age, without extensive pretreatment ischemic signs on brain imaging, and with a baseline NIHSS score ≤30 had high rates of favorable outcome and low peri-procedural complication rates with Solitaire thrombectomy for ischemic stroke. Technical success was also high in patients not fulfilling standard inclusion criteria, but worse clinical outcomes in most of the nonstandard subgroups warrant further research to determine more precisely which individuals may benefit from stent retriever treatment.

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We thank Laurie von Melchner for her editorial assistance.

Disclosures

Dr Gralla reports receiving consulting fees from Covidien as the global principal investigator for the Solitaire FR Thrombectomy for Acute Revascularization trial. Dr Mattle has received speaker’s honoraria from Covidien and is in the steering committee of SWIFT PRIME.

References


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Outcome of standard and high risk patients with acute anterior circulation stroke after stent retriever thrombectomy

Pascal P. Gratz¹, MD*; Simon Jung¹,², MD*; Gerhard Schroth¹, MD; Jan Gralla¹, MD; Pasquale Mordasini¹, MD; Kety Hsieh¹, MD; Mirjam R. Heldner², MD; Heinrich P. Mattle², MD; Marie-Luise Mono², MD; Urs Fischer², MD; Marcel Arnold², MD†; Christoph Zubler¹, MD†

¹ Department of Diagnostic and Interventional Neuroradiology, ² Department of Neurology, Inselspital, Bern University Hospital and University of Bern, Bern, Switzerland

* Pascal P. Gratz and Simon Jung contributed equally to this study.
† Marcel Arnold and Christoph Zubler contributed equally to this study.
### SUPPLEMENTAL TABLES

#### Supplementary Table I.  Additional Baseline Imaging Characteristics of 227 Patients Treated With the Solitaire

<table>
<thead>
<tr>
<th></th>
<th>Overall (n=227)</th>
<th>Patients meeting standard criteria (n=81)</th>
<th>NIHSS &lt;8 (n=27)</th>
<th>NIHSS &gt;30 (n=11)</th>
<th>Age ≥80 years (n=50)</th>
<th>Extensive ischemic signs in MCA territory (n=69)</th>
<th>Time from symptom onset to arterial puncture &gt;8 hours (n=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI ASPECTS, median</td>
<td>6 (0–10)</td>
<td>7 (5–10)</td>
<td>7 (4–10)</td>
<td>5 (4–6)</td>
<td>7 (3–10)</td>
<td>3.5 (0–4)</td>
<td>6.5 (3–10)</td>
</tr>
<tr>
<td>CT ASPECTS, median</td>
<td>8 (2–10)</td>
<td>9 (7–10)</td>
<td>10 (9–10)</td>
<td>6 (4–8)</td>
<td>8 (4–10)</td>
<td>5 (0–6)</td>
<td>8.5 (5–10)</td>
</tr>
<tr>
<td>Leptomeningeal collaterals</td>
<td>n=226</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Good</td>
<td>74 (32.7)</td>
<td>30 (37.0)</td>
<td>14 (51.9)</td>
<td>2 (18.2)</td>
<td>18 (36.0)</td>
<td>9 (13.2)</td>
<td>10 (45.5)</td>
</tr>
<tr>
<td>Moderate</td>
<td>110 (48.7)</td>
<td>41 (50.6)</td>
<td>12 (44.4)</td>
<td>5 (45.5)</td>
<td>19 (38.0)</td>
<td>38 (55.9)</td>
<td>7 (31.8)</td>
</tr>
<tr>
<td>Poor</td>
<td>42 (18.6)</td>
<td>10 (12.3)</td>
<td>1 (3.7)</td>
<td>4 (36.4)</td>
<td>13 (26.0)</td>
<td>21 (30.9)</td>
<td>5 (22.7)</td>
</tr>
</tbody>
</table>

NIHSS indicates National Institutes of Health Stroke Scale; MCA, middle cerebral artery; ASPECTS, Alberta Stroke Program Early CT Score.
### Supplementary Table II. Additional Endovascular Treatment Details

<table>
<thead>
<tr>
<th></th>
<th>Overall (n=227)</th>
<th>Patients meeting standard criteria (n=81)</th>
<th>NIHSS &lt;8 (n=27)</th>
<th>NIHSS &gt;30 (n=11)</th>
<th>Age ≥80 years (n=50)</th>
<th>Extensive ischemic signs in MCA territory (n=69)</th>
<th>Time from symptom onset to arterial puncture &gt;8 hours (n=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reperfusion grade</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>TICI 3, n (%)</td>
<td>84 (37.0)</td>
<td>32 (39.5)</td>
<td>11 (40.7)</td>
<td>3 (27.3)</td>
<td>16 (32.0)</td>
<td>24 (34.8)</td>
<td>7 (31.8)</td>
</tr>
<tr>
<td>TICI 2b, n (%)</td>
<td>77 (33.9)</td>
<td>25 (30.9)</td>
<td>12 (44.4)</td>
<td>4 (36.4)</td>
<td>21 (42.0)</td>
<td>19 (27.5)</td>
<td>8 (36.4)</td>
</tr>
<tr>
<td>TICI 2a, n (%)</td>
<td>32 (14.1)</td>
<td>12 (14.8)</td>
<td>3 (11.1)</td>
<td>2 (18.2)</td>
<td>7 (14.0)</td>
<td>13 (18.8)</td>
<td>3 (13.6)</td>
</tr>
<tr>
<td>TICI 1, n (%)</td>
<td>13 (5.7)</td>
<td>7 (8.6)</td>
<td>1 (3.7)</td>
<td>1 (9.1)</td>
<td>0 (0.0)</td>
<td>3 (4.3)</td>
<td>2 (9.1)</td>
</tr>
<tr>
<td>TICI 0, n (%)</td>
<td>21 (9.3)</td>
<td>5 (6.2)</td>
<td>0 (0.0)</td>
<td>1 (9.1)</td>
<td>6 (12.0)</td>
<td>10 (14.5)</td>
<td>2 (9.1)</td>
</tr>
<tr>
<td><strong>Use of distal access catheter</strong></td>
<td></td>
<td></td>
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<tr>
<td>Multimodal endovascular therapy</td>
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<tr>
<td>Thromboaspiration, n (%)</td>
<td>63 (27.8)</td>
<td>19 (23.5)</td>
<td>7 (25.9)</td>
<td>2 (18.2)</td>
<td>11 (22.0)</td>
<td>23 (33.3)</td>
<td>10 (45.5)</td>
</tr>
<tr>
<td>Intraarterial thrombolysis with urokinase, n (%)</td>
<td>52 (22.9)</td>
<td>20 (24.7)</td>
<td>8 (29.6)</td>
<td>2 (18.2)</td>
<td>10 (20.0)</td>
<td>17 (24.6)</td>
<td>2 (9.1)</td>
</tr>
<tr>
<td>Stent intracranial (Solitaire), n (%)</td>
<td>8 (3.5)</td>
<td>3 (3.7)</td>
<td>0 (0.0)</td>
<td>1 (9.1)</td>
<td>2 (4.0)</td>
<td>2 (2.9)</td>
<td>3 (13.6)</td>
</tr>
<tr>
<td>Stent intracranial (other), n (%)</td>
<td>4 (1.8)</td>
<td>2 (2.5)</td>
<td>0 (0.0)</td>
<td>1 (9.1)</td>
<td>1 (2.0)</td>
<td>1 (1.4)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Stent extracranial, n (%)</td>
<td>33 (14.5)</td>
<td>13 (16.0)</td>
<td>6 (22.2)</td>
<td>1 (9.1)</td>
<td>0 (0.0)</td>
<td>9 (13.0)</td>
<td>5 (22.7)</td>
</tr>
<tr>
<td>Anesthesia</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>General anesthesia, n (%)</td>
<td>196 (86.3)</td>
<td>70 (84.4)</td>
<td>16 (59.3)</td>
<td>11 (100)</td>
<td>44 (88.0)</td>
<td>67 (97.1)</td>
<td>19 (86.4)</td>
</tr>
<tr>
<td>Conscious sedation, n (%)</td>
<td>31 (13.7)</td>
<td>11 (13.6)</td>
<td>11 (40.7)</td>
<td>0 (0.0)</td>
<td>6 (12.0)</td>
<td>2 (2.9)</td>
<td>3 (13.6)</td>
</tr>
</tbody>
</table>

NIHSS indicates National Institutes of Health Stroke Scale; MCA, middle cerebral artery; TICI, Thrombolysis in Cerebral Infarction.
**Supplementary Table III. Overview of Intra-Procedural Complications**

<table>
<thead>
<tr>
<th>Patients with symptomatic intra-procedural complications, n (%)</th>
<th>Overall (n=227)</th>
<th>Patients meeting standard criteria (n=81)</th>
<th>NIHSS &lt;8 (n=27)</th>
<th>NIHSS &gt;30 (n=11)</th>
<th>Age ≥80 years (n=50)</th>
<th>Extensive ischemic signs in MCA territory (n=69)</th>
<th>Time from symptom onset to arterial puncture &gt;8 hours (n=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with symptomatic intra-procedural complications, n (%)</td>
<td>9 (4.0)</td>
<td>2 (2.5)</td>
<td>2 (7.4)</td>
<td>0 (0.0)</td>
<td>1 (2.0)</td>
<td>4 (5.8)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Total of patients with intra-procedural complications, n (%)</td>
<td>74 (32.6)</td>
<td>25 (30.9)</td>
<td>8 (29.6)</td>
<td>5 (45.5)</td>
<td>13 (26.0)</td>
<td>23 (33.3)</td>
<td>9 (40.9)</td>
</tr>
<tr>
<td>Occurrence rate of different complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dissection, n (%)</td>
<td>11 (4.8)</td>
<td>3 (3.7)</td>
<td>1 (3.7)</td>
<td>0 (0.0)</td>
<td>2 (4.0)</td>
<td>4 (5.8)</td>
<td>1 (4.5)</td>
</tr>
<tr>
<td>Vessel perforation, n (%)</td>
<td>2 (0.9)</td>
<td>1 (1.2)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (1.4)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Severe vasospasm, n (%)</td>
<td>43 (18.9)</td>
<td>16 (19.8)</td>
<td>6 (22.2)</td>
<td>2 (18.2)</td>
<td>4 (8.0)</td>
<td>11 (15.9)</td>
<td>7 (31.8)</td>
</tr>
<tr>
<td>In-stent thrombosis, n (%)</td>
<td>8 (3.5)</td>
<td>1 (1.2)</td>
<td>3 (11.1)</td>
<td>1 (9.1)</td>
<td>2 (4.0)</td>
<td>3 (4.3)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Device failure (Solitaire), n (%)</td>
<td>1 (0.4)</td>
<td>1 (1.2)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Device failure (other), n (%)</td>
<td>2 (0.9)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>2 (2.9)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Embolization, n (%)</td>
<td>15 (6.6)</td>
<td>5 (6.2)</td>
<td>0 (0.0)</td>
<td>2 (18.2)</td>
<td>5 (10.0)</td>
<td>6 (8.7)</td>
<td>1 (4.5)</td>
</tr>
<tr>
<td>Immediate reperfusion hemorrhage, n (%)</td>
<td>1 (0.4)</td>
<td>1 (1.2)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Other, n (%)</td>
<td>1 (0.4)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1 (2.0)</td>
<td>1 (1.4)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

NIHSS indicates National Institutes of Health Stroke Scale; MCA, middle cerebral artery.
Supplementary Figure I. Comparison of 3-month modified Rankin Scale scores of disability between patients ≥80 (n=49) and those <80 years of age (n=173).
Supplementary Figure II. Comparison of 3-month modified Rankin Scale scores of disability between patients with early extensive ischemic signs in the MCA territory (n=68) and those without (n=157).