Vessel Patency at 24 Hours and Its Relationship With Clinical Outcomes and Infarct Volume in REVASCAT Trial (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 Eight Hours of Symptom Onset)

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Background and Purpose—Higher rates of target vessel patency at 24 hours were noted in the thrombectomy group compared with control group in recent randomized trials. As a prespecified secondary end point, we aimed to assess 24-hour revascularization rates by treatment groups and occlusion site as they related to clinical outcome and 24-hour infarct volume in 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 Eight Hours of Symptom Onset).

Methods—Independent core laboratory adjudicated vessel status according to modified arterial occlusive lesion classification at 24 hours on computed tomographic/magnetic resonance (94.2%/5.8%) angiography and 24-hour infarct volume on computed tomography were studied (95/103 patients in the thrombectomy group versus 94/103 in the control group, respectively). Complete revascularization was defined as modified arterial occlusive lesion grade 3. Its effect on clinical outcome was analyzed by ordinal logistic regression.

Results—Complete revascularization was achieved in 70.5% of the solitaire group and in 22.3% of the control group (P<0.001). Significant differences in complete revascularization rates were found for termination internal carotid artery, M1, and tandem occlusions (all P<0.001) but not for M2 occlusions. In the thrombectomy group, 2 out of 63 patients (3.1%) with modified Thrombolysis in Cerebral Infarction 2b/3 after thrombectomy showed arterial reocclusion (modified arterial occlusive lesion grade 0/1) at 24 hours. Complete revascularization was associated with improved outcome in both thrombectomy (adjusted odds ratio, 4.5; 95% confidence interval, 1.9–10.9) and control groups (adjusted odds ratio, 2.7; 95% confidence interval, 1.0–6.7). Revascularization (modified arterial occlusive lesion grade 2/3) was associated with smaller infarct volumes in either treatment arm.

Conclusions—Complete revascularization at 24 hours is a powerful predictor of favorable clinical outcome, whereas revascularization of any type results in reduced infarct volume in both thrombectomy and control groups.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01692379.

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Key Words: angiography ◼ computed tomographic angiography ◼ magnetic resonance angiography ◼ reocclusion ◼ stroke ◼ thrombectomy
Recently, completed randomized endovascular stroke trials have established mechanical thrombectomy as an effective immediate revascularization therapy for acute intracranial large anterior vessel occlusion resulting in increased rates of functional independence compared with best medical therapy. To assess whether the revascularization advantage of mechanical thrombectomy is sustained, vessel patency at 24 hours has been evaluated in follow-up computed tomographic (CT) or magnetic resonance (MR) angiography in most of these studies. Overall, successful revascularization rate was significantly higher for endovascular thrombectomy compared with medical treatment, ranging 75% to 94% versus 32% to 43%, respectively. However, limited data are available on the impact of successful revascularization at 24 hours on clinical outcome both after endovascular and after medical treatment alone. As a prespecified secondary outcome measure, we aimed to assess the 24-hour revascularization rates by treatment groups and arterial occlusion site as they related to clinical outcome and 24-hour infarct volume in the REVASCAT trial (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 Eight Hours of Symptom Onset).

Methods

The REVASCAT trial studied the safety and efficacy of thrombectomy with the Solitaire device compared with best medical treatment in patients with anterior circulation stroke who could be treated within 8 hours after symptom onset. Main study design and results have been published elsewhere. An Alberta Stroke Program Early CT Scores ≥6 on MR and a documented tandem internal carotid artery/middle cerebral artery (ICA/MCA), terminal ICA, or M1-MCA occlusion on prerandomization CT/MR angiography (CTA/MRA) were the main inclusion criteria for this trial. The protocol also included CTA or MRA at 24 hours (−2, +12). Vessel occlusion site on prerandomization CTA, vessel status at 24 hours according to modified arterial occlusive lesion classification (mAOL grade 0: primary occlusive lesion remains same, 1: debulking of thrombus without recanalization, 2: partial or complete recanalization of the primary lesion with thrombus/occlusion in the distal vascular tree, and 3: complete recanalization of the primary occlusion with no thrombus in the vascular tree or beyond the primary occlusive lesions), and infarct volume on 24-hour CT were adjudicated by an independent core laboratory blinded to clinical data. Quantomo (Cybertrial Inc, Calgary) was used to delineate infarct and measure infarct volume (in milliliters). Manual adjustments to delineate infarct boundaries where necessary. If the infarct showed hemorrhagic conversion, the hemorrhage regions were incorporated within the boundaries of infarct. Complete revascularization (CR) at 24 hours was defined as the presence of a mAOL grade 3 and revascularization of any type at 24 hours as the presence of mAOL 2 or 3 at follow-up CTA/MRA. Recollimation was defined as the presence of mAOL 0 or 1 at 24 hours in those patients who achieved modified Thrombolysis in Cerebral Infarction (mTICI) 2a, 2b, or 3 after thrombectomy. The primary outcome was the severity of disability according to the central blinded evaluation of modified Rankin scale (mRS) scores at 90 days. Favorable outcome was defined as mRS 0 to 2 and excellent outcome as mRS 0 to 1 at day 90.

Statistical Analysis

Statistical data were obtained using a SPSS statistics version 23.3 software. Continuous variables are shown as mean (SD) or median (interquartile intervals) and were compared with the Student t test, ANOVA, Mann–Whitney, or Kruskal–Wallis tests as appropriate.
was a nonsignificant trend toward smaller infarcts in patients who achieved CR in both thrombectomy and control arms (Table 2). However, large and significant differences were found in median infarct volume when any type of revascularization was considered in comparison with absence of revascularization (mAOL grade 0/1) in both treatment groups (12 versus 92 cc; \( P = 0.019 \) and 14 versus 52 cc; \( P = 0.001 \), respectively). There was a gradual reduction in the median infarct volume with increasing degrees of revascularization at 24 hours in the thrombectomy and control groups, although comparable infarct volumes were found in patients who achieved mAOL grade 2 or 3 (Figure 3). The small number of patients with absence of revascularization at 24 hours (mAOL grade 0) in the thrombectomy group had nonsignificant larger infarct volumes (136.6 cc; 95% confidence interval, 17.4–255.8) compared with control arm (93.5 cc; 95% confidence interval, 59.1–127.8).

In the thrombectomy group, arterial reocclusion (mAOL grade 0/1) at 24 hours was found in 2 out of 63 patients (3.1%) with complete revascularization (mTICI 2b/3) and 6 out of 23 patients (26%) with partial revascularization (mTICI 2a) after thrombectomy. Arterial reocclusion was associated with higher infarct volume and worse functional outcome at 3 months compared with those patients with

### Table 1. Complete Revascularization Rate at 24 h According to the Baseline Occlusion Site by Treatment Groups and tPA Administration

<table>
<thead>
<tr>
<th>Baseline Occlusion Location</th>
<th>Thrombectomy (n=95)</th>
<th>Control (n=94)</th>
<th>( P ) Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVP A</td>
<td>No IV P A</td>
<td>Total</td>
<td>IVP A</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------</td>
<td>----------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Terminus ICA</td>
<td>6/11 (54.5)</td>
<td>9/12 (75)</td>
<td>15/23 (65.2)</td>
</tr>
<tr>
<td>Tandem (ICA+MCA)</td>
<td>9/13 (69.2)</td>
<td>2/4 (50)</td>
<td>11/17 (64.7)</td>
</tr>
<tr>
<td>M1-MCA</td>
<td>32/44 (72.7)</td>
<td>14/17 (82.4)</td>
<td>46/61 (75.4)</td>
</tr>
<tr>
<td>M2-MCA</td>
<td>3/8 (37.5)</td>
<td>2/2 (100)</td>
<td>5/10 (50)</td>
</tr>
<tr>
<td>Total population</td>
<td>42/64 (65.6)</td>
<td>25/31 (80.6)</td>
<td>67/95 (70.5)</td>
</tr>
</tbody>
</table>

Values are presented as number (proportions). ICA indicates internal carotid artery; MCA, middle cerebral artery; and tPA, tissue-type plasminogen activator.

*\( P \) values are given for differences in total patients between treatment groups.

### Table 2. Baseline Characteristics and Outcome Variables by the Presence of 24-h Complete Revascularization in the Entire Population and Treatment Subgroups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Entire Population (n=189)</th>
<th>Thrombectomy (n=95)</th>
<th>Control (n=94)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>65±11</td>
<td>66±13</td>
<td>0.794</td>
<td>66±10</td>
</tr>
<tr>
<td>Male sex</td>
<td>59.1</td>
<td>45.5</td>
<td>0.063</td>
<td>55.2</td>
</tr>
<tr>
<td>Hypertension</td>
<td>65.9</td>
<td>65.3</td>
<td>0.935</td>
<td>62.7</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>25</td>
<td>15.8</td>
<td>0.117</td>
<td>20.9</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>54.5</td>
<td>54.5</td>
<td>0.990</td>
<td>50.7</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>14.8</td>
<td>9.9</td>
<td>0.307</td>
<td>14.9</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>39.8</td>
<td>33.7</td>
<td>0.384</td>
<td>41.8</td>
</tr>
<tr>
<td>NIHSS score</td>
<td>15 (13–18)</td>
<td>19 (14–22)</td>
<td>0.371</td>
<td>16 (13–19)</td>
</tr>
<tr>
<td>Glucose levels, mg/dL</td>
<td>6.7 (5.7–8.1)</td>
<td>6.4 (5.9–7.6)</td>
<td>0.192</td>
<td>6.8 (5.9–8.3)</td>
</tr>
<tr>
<td>Systolic BP, mm Hg</td>
<td>145±18</td>
<td>135±21</td>
<td>0.788</td>
<td>143±18</td>
</tr>
<tr>
<td>Diastolic BP, mm Hg</td>
<td>78±12</td>
<td>73±7</td>
<td>0.693</td>
<td>78±12</td>
</tr>
<tr>
<td>ASPECTS score</td>
<td>7 (6.5–9)</td>
<td>8.5 (7–10)</td>
<td>0.873</td>
<td>7 (6–9)</td>
</tr>
<tr>
<td>tPA use</td>
<td>67</td>
<td>76.2</td>
<td>0.161</td>
<td>62.7</td>
</tr>
<tr>
<td>Stroke-onset tPA, min</td>
<td>113 (85–149)</td>
<td>131 (94–172)</td>
<td>0.133</td>
<td>111 (85–148)</td>
</tr>
</tbody>
</table>

Values are presented as number (proportions), proportions, mean±SD, or median (quartiles). ASPECTS indicates Alberta Stroke Program Early CT Score; BP, blood pressure; mAOL, modified arterial occlusive lesion classification; mRS, modified Rankin scale; NIHSS, National Institutes of Health Stroke Scale; and tPA, tissue-type plasminogen activator.
Discussion
The main findings of this secondary analysis from the REVASCAT trial were that, at 24 hours post-randomization, rates of successful revascularization remained significantly higher in the intervention group compared with control group. Furthermore, both control and thrombectomy patients who achieved successful revascularization had significantly better clinical outcome and reduced infarct volume than those who did not.

The magnitude of the thrombectomy effect on successful revascularization at 24 hours compared with the control group (70.5% versus 22.3%) in the REVASCAT trial was comparable to MR-CLEAN (Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands; 75.4% versus 32.9%), EXTEND-IA (Extending Time for Thrombolysis in Emergency Neurological Deficits—Intra-Arterial; 94% versus 43%), and SWIFT-PRIME (Solitaire With the Intention for Thrombectomy as Primary Endovascular Treatment; 86% versus 40%). Interestingly, higher rates of revascularization at 24 hours were noted in the control groups of SWIFT PRIME and EXTEND-IA compared with MR CLEAN and REVASCAT confirming previous statements that these trials enrolled different patient populations with respect to resistance to recanalization. The fact that all patients in the control group of SWIFT PRIME and EXTEND-IA were treated with IV tPA may not entirely account for these differences because, according to our findings, IV tPA does not seem to influence recanalization rates at 24 hours in a significant way neither in the thrombectomy group nor in the control group. However, in contrast to ESCAPE (Endovascular Treatment for Small Core and Anterior Circulation Proximal Occlusion With Emphasis on Minimizing CT to Recanalization Times), REVASCAT did not use a bridging approach; so, early tPA recanalizers within the first 30 minutes after tPA infusion with no occlusion at prerandomization CTA were not included. This distinct methodological approach may explain in part that ESCAPE found higher revascularization rate in control patients who received IV tPA than that in those who did not as opposed to REVASCAT. This issue is compounded further by the fact that different methodologies to assess recanalization at 24 hours were used across trials (TIMI in Myocardial Infarction 2/3 in EXTEND-IA and reperfusion >90% in SWIFT PRIME). Regarding the occlusion site, complete revascularization rate at 24 hours was significantly higher, favoring thrombectomy for M1-MCA, and especially for terminus ICA and tandem occlusions, but no differences

Figure 1. Distribution of functional scores at 90 d. Bars show the proportion of patients in each score of modified Rankin score when achieved complete revascularization (modified arterial occlusive lesion classification [mAOL] 3) or did not (mAOL grade 0–2) in the thrombectomy (A) and control group (B). A significant difference between mAOL3 vs mAOL 0 to 2 was noted in the overall distribution of scores independently of treatment modality. The model was adjusted for tissue-type plasminogen activator administration and minimization factors: age (≤70 or >70 years), baseline National Institutes of Health Stroke Scale score (≥6–16 or ≥17), randomization window (≤4.5 or >4.5 h), and vessel occlusion site (intracranial internal carotid artery or M1).

Figure 2. Distribution of each modified Rankin score by modified arterial occlusive lesion (mAOL) grades in all patients included in REVASCAT trial (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 Eight Hours of Symptom Onset). The higher the grade of revascularization at 24 h, the better the functional outcome at 90 d.
were found for the M2-MCA occlusions. Although there are limited data on the benefit of endovascular therapy in M2-MCA occlusions,\textsuperscript{12} the lack of statistically significant evidence of benefit from endovascular treatment recently shown in an individual level meta-analysis from 5 randomized trials\textsuperscript{13} for this occlusion location might be determined in part by comparable rates of revascularization between mechanical thrombectomy and IV tPA. It should be noted, however, that the small number of patients in the M2 category precludes any definitive conclusions regarding differences in recanalization rates between endovascular and medical treatment. Furthermore, because M2 occlusions were excluded from enrollment in REVASCAT, the small number of patients included in this analysis was considered M1 occlusions by the enrolling investigators and M2 occlusions by core laboratory (ie, misclassified as M1 at enrollment) and, thus, may not represent the typical M2 segment patient population. Finally, just like in this meta-analysis, in REVASCAT, the majority of patients included in the control group were treated with IV tPA, which is known to have higher recanalization efficacy with decreasing vessel size and is likely to be responsible for the higher rates of recanalization at 24 hours in M2 occlusions compared with M1 and ICA occlusions noted in the control groups. Our data does not rule out the possibility that thrombectomy may be associated with higher rates of recanalization at 24 hours in patients with M2 occlusions not treated with tPA.

Importantly, patients who achieved complete revascularization in both thrombectomy and control group had similar distribution of the Rankin scores at 90 days, with equivalent proportion of patients with favorable outcome and mortality, supporting the fact that revascularization within 24 hours poststroke onset is a powerful independent predictor of favorable functional outcome irrespective of treatment modality. However, excellent outcome was only significantly higher in those patients with complete revascularization after mechanical thrombectomy. Although the precise time when revascularization occurred in control arm cannot be determined, it is likely that higher rates of early revascularization in the intervention group compared with control group could explain this finding because longer onset to reperfusion time has been associated with a reduced likelihood of good outcome in most trials examining the clinical benefit of reperfusion (intravenous or endovascular).\textsuperscript{14–16} Our results are similar to those observed in SWIFT PRIME where patients who achieved successful reperfusion at 27 hours had more favorable clinical outcome than those who did not reperfuse regardless of treatment allocation with a trend toward better outcomes in successfully reperfused patients in the intervention group compared with controls.\textsuperscript{11} Importantly, REVASCAT has shown a strong association between the degree of revascularization and the probability to become functionally independent at 90 days (Figure 2). Because of the clear shift in disability across the entire mAOL spectrum, trials examining new thrombolytics or ancillary treatments to tPA could consider using an ordinal analysis for evaluating mAOL as a revascularization end point.

Table 3. Vessel Patency at 24 h (mAOL Classification) by Postendovascular Revascularization mTICI Grade in the Thrombectomy Group

<table>
<thead>
<tr>
<th>mAOL at 24 h</th>
<th>Postendovascular mTICI Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mTICI 0/1 (n=9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>mAOL 0/1, n (%)</th>
<th>Infarct volume (mL)</th>
<th>mRS 90 d</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 (44.4)</td>
<td>233 (95–311)</td>
<td>6 (3–6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>mAOL 2/3, n (%)</th>
<th>Infarct volume (mL)</th>
<th>mRS 90 d</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 (55.6)</td>
<td>17 (73.9)</td>
<td>2 (2–2)</td>
</tr>
</tbody>
</table>

Infarct volume and mRS at 90 d are expressed as median (quartiles). mAOL indicates modified arterial occlusive lesion; mRS, modified Rankin scale; and mTICI, modified Thrombolysis in Cerebral Infarction.

*These 2 patients were scanned rapidly after reocclusion within 24±12 h before the new infarct lesion appeared. Further CT scans showed large infarct volumes.
Revascularization of any type (and not complete revascularization) at 24 hours was associated with a significantly lower median infarct volume on 24-hour CT scan in both treatment arms, as has been shown in SWIFT PRIME and ESCAPE trials, supporting evidence that any degree of revascularization limits brain damage. Although there was a gradual decrease in the infarct volume with increasing grades of revascularization, no statistically significant differences in 24-hour infarct volumes were found between mAOL 2 and 3 grades both in thrombectomy and control groups, suggesting that either grade (mAOL grade 2 or 3) could represent successful revascularization. The relationship between posttreatment infarct volume and clinical outcome at 90 days is well established, but the fact of mAOL 2 and 3 had equivalent infarct volumes but different probability to achieve favorable outcome may be explained because the location of the brain infarct in an eloquent area and not only the infarct size determines functional outcome after stroke. Another explanation for this observation could be that because of several reasons (delayed infarct growth, infarct being overcalled because of edema, etc), infarct volumes at 24 hours as measured by CT do not reflect accurately enough the true extent of poststroke infarct volume. Patients in the thrombectomy group with an absence of revascularization (mAOL grade 0) at 24 hours showed a nonsignificant higher infarct volume than nonrecanalizers in the medical group, finding that has also been observed in the SWIFT-PRIME study.

Little is known about the incidence of arterial reocclusion after successful endovascular revascularization and its effect on clinical outcome, and no data are available to date from the recent large endovascular clinical trials. In REVASCAT, arterial reocclusion was infrequent (3.1%) in patients with complete postprocedural revascularization (mTICI 2b/3), whereas reocclusion rate was significantly higher (26%) in those patients who only achieved partial revascularization (mTICI 2a). A potential underlying intracranial atherosclerotic disease has been hypothesized as reason of delayed arterial reocclusion, especially when residual stenosis remains at the target vessel immediately after thrombectomy. Patients with arterial reocclusion had similar poor outcome to those with lack of recanalization after the procedure and significantly worse than those with partial or complete revascularization at 24 hours, supporting the fact that vessel status at 24 hours strongly determines clinical outcome. The effect of arterial reocclusion on functional recovery should be addressed in further meta-analysis because of the small sample of arterial reocclusion in the intervention group of REVASCAT.

This study has limitations. The relatively small sample size and the fact that some patients did not undergo follow-up CT/AMR angiography might not provide sufficient power for highly reliable subgroup analysis and might increase susceptibility of false-positive/negative findings. We do not have information about the specific time of revascularization within 24 hours in the control group, so, we cannot elucidate the impact of achieving early revascularization on clinical outcomes in patients treated with medical therapy compared with those who achieved early revascularization during the procedure in the thrombectomy group. Finally, infarct volume was measured using a noncontrast CT scan at 24 hours (−2, +12 h) after stroke, which is fraught with limitations outlined above.

Conclusions

Mechanical thrombectomy with solitaire increases the rate of complete revascularization at 24 hours compared with medical therapy (which includes high proportions of patients with IV tPA). Regardless whether patients are treated with thrombectomy or best medical therapy, complete revascularization at 24 hours is a powerful predictor of favorable clinical outcome while revascularization of any type results in reduced infarct volumes.

Acknowledgments

We thank all REVASCAT investigators and coordinators and especially the patients enrolled and their families for their invaluable contribution to the successful completion of REVASCAT.

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Disclosures

Dr Demchuk reports receiving honorarium from Medtronic for CME events. It is consulted for Pulse Therapeutics. Dr Jovin reports receiving personal fees as consultant from Neuravi (steering committee-modest), Cephalon Neurovascular (DSMB-modest), Stryker, and Neurovascular (PI DIWN-unpaid). He has stock ownership in Anaconda, Silk Road Medical, and Bloackade Medical (all modest). Dr Dávalos reports receiving personal fees from Medtronic outside the submitted work. The other authors report no conflicts.

References


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