Influence of Device Choice on the Effect of Intra-Arterial Treatment for Acute Ischemic Stroke in MR CLEAN (Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands)

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Background and Purpose—Intra-arterial treatment by means of retrievable stents has been proven safe and effective. In MR CLEAN (Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands), the choice of the type of thrombectomy device was left to the discretion of the interventionist. The aim of this study was to explore the differences in functional outcome, neurological recovery, reperfusion, extent of infarction, and adverse events according to stent type and make.

Methods—The primary outcome was functional outcome at 90 days, assessed with the modified Rankin Scale (mRS). Neuroimaging outcomes included occlusion on computed tomographic angiography at 24 hours, infarct volume at 5 to 7 days, and modified thrombolysis in cerebral infarction scores. Safety outcomes included death within 90 days and any symptomatic intracerebral hemorrhage. We analyzed possible interactions between stent type and treatment with multiple regression models. Treatment effects were adjusted for patient age, stroke severity, and collateral score.

Results—Of the 500 patients included in the trial, 233 were allocated to intervention. Of these, 124 (53%) were first treated with Trevo (adjusted common odds ratio for shift on the mRS [acOR, 1.98; 95% confidence interval, 1.30–2.92]), 31 (13%) with Solitaire (acOR, 1.90; 95% confidence interval, 0.97–3.73), 40 (17%) with other retrievable stents or mechanical devices (acOR, 0.96; 95% confidence interval, 0.51–3.93), and 38 (16%) could not be treated. There was no interaction between device and treatment effect on functional outcome and all other secondary and safety outcomes.

Conclusions—We found no evidence for a differential effect of thrombectomy for acute ischemic stroke by type of stent.

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Key Words: cerebral hemorrhage ■ infarction ■ odds ratio ■ reperfusion ■ stroke

Intra-arterial treatment has been proven safe and effective for a wide range of patients with acute ischemic stroke caused by intracranial large vessel occlusion.1–6 In the MR CLEAN trial (Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands), there were no restrictions to the choice of arterial treatment modality or device, apart from the requirement that the device should be Food and Drug Administration or Conformité Européenne approved and allowed in the trial by the steering committee, on the basis of proven safety and efficaciousness in cases series.1,7 The vast majority of patients were treated with retrievable stents. This setting provides a unique opportunity to compare treatment effects reached with the most commonly used retrievable stents.

Stents differ in size, shape, and physical properties, such as radial force, ease of deployment, friction, and radio-opacity. The

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*A list of all MR CLEAN investigators is given in the Appendix.

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extent to which these properties are important in clinical practice and whether they lead to better clinical outcomes is unknown. Experience with different stent types has led researchers and interventionists express the opinion that one type of stent may cause more damage to the vessel wall than the other. The apparently smaller treatment effect and rate of revascularization in MR CLEAN have been attributed to the type of stent used in this trial, instead of other factors, such as broader inclusion criteria.8

The aim of this post hoc study is to explore the differences in functional outcome, neurological recovery, extent of infarction, and adverse events according to treatment type and modality within the framework of the MR CLEAN trial.

Methods
Study Design and Participants
Patient eligibility and methods of MR CLEAN have been reported previously. In short, MR CLEAN was a randomized clinical trial of intra-arterial treatment versus no intra-arterial treatment in patients with a proximal intracranial arterial occlusion in the anterior circulation demonstrated on vessel imaging and treatable within 6 hours after symptom onset. In almost all treated patients, retrievable stents were used as a first approach.

Treatment Modalities
Intra-arterial treatment was categorized by the first treatment modality used. This could be (1) Trevo retrievable stent, (2) Solitaire retrievable stent, (3) other types of stent or mechanical devices or intra-arterial thrombolytics, and (4) no treatment or mechanical device. Treatment modalities or stent types used in <10% of patients were lumped into group 3. The fourth group consisted of patients who either recovered or had no (treatable) occlusion after reaching the angiosuite, or deteriorated neurologically before treatment.

Patients
All 500 patients from the trial were included in the primary analysis. We report demographics and baseline characteristics, including comorbidity, stroke severity, and baseline neuroimaging by treatment modality.

Outcomes
The primary outcome was functional outcome at 90 days, assessed with the dichotomized mRS (0–2 versus 3–6), NIHSS score at 24 hours, and infarct volume at 5 to 7 days on noncontrast computed tomography,9 and modified thrombolysis in cerebral infarction (mTICI) score in patients who underwent intra-arterial treatment. Safety outcomes included death within 1 week, 1 month, and 90 days, any parenchymal hematoma ECASS (European Cooperative Acute Stroke Study) type 2, and any symptomatic intracerebral hemorrhage. We also report procedural adverse events, including vessel perforation, subarachnoid hemorrhage, and dissection. Logistics parameters included (1) time from onset to reperfusion or end of procedure, (2) time from door to reperfusion or end of procedure, (3) duration of procedure, and (4) number of attempts per device.

Statistical Analysis
The primary analysis consisted of assessment of interaction between device and treatment effect by introducing a categorical variable indicating stent type, other mechanical or no treatment in a multivariable ordinal regression model, with a multiplicative effect on the treatment variable. Next, secondary outcomes were tested with regression models against treatment modality in a similar way.

Results
Treatment Modalities
Of all 233 patient allocated to intervention, 38 (16%) could not be treated, 124 (53%) were first treated with the Trevo device, 31 (13%) with the Solitaire device, and 40 (17%) with other retrievable stents or mechanical devices, or with intra-arterial thrombolytics. These other treatment modalities included aspiration or clot disruption with the guidewire (3/40, 7.5%), CAPTURE device (1/40, 2.5%), CATCH device (11/40, 27.5%), Lazarus device (1/40, 2.5%), MERCI device (2/40, 5.0%), Penumbra 3D device (1/40, 2.5%), REVIVE device (19/40, 47.5%), and unspecified retrievable stents (2/40, 5%). In 24 patients (10.3%), a second treatment modality was used. This happened in 11 of 124 patients treated with Trevo (8.9%), in 1 of 30 patients treated with Solitaire (3.2%), and in 12 of 40 (30%) patients treated with other devices (P<0.001).

Baseline Characteristics
Of the 500 patients included in the trial, 233 were allocated to intervention. Baseline characteristics were distributed evenly over subgroups defined by treatment modality (Table 1). Moderate to good collaterals were seen more often in patients treated with the Trevo device (83/124, 67%), but this was not statistically significant in comparison with all other treatment subgroups (68/109, 62%, P=0.53) or with the Solitaire subgroup (17/31, 55%, P=0.19). Time to groin was 25 to 30 minutes longer in the Solitaire compared with the Trevo or other treatment modalities, but the difference was not statistically significant. General anesthesia was used more often in Trevo-treated patients than those treated with the Solitaire (P=0.10).

Effect on the Primary Outcome by Treatment Modality
The overall effect of intervention on the primary outcome was positive; the common odds ratio (cOR) was 1.66 (95% confidence interval [CI], 1.21–2.28); after adjustment for age, NIHSS, and collateral score, the adjusted common odds ratio (acOR) was 1.74 (95% CI, 1.26–2.41). In the group of 124 (53%) patients who were first treated with Trevo, the acOR was 1.98 (95% CI, 1.30–2.92) and among the 31 (13%) patients who were treated with Solitaire, the acOR was 1.90 (95% CI, 0.97–3.73; Table 2). In the 40 (17%) patients treated with other retrievable stents or mechanical devices, the acOR was 0.96 (95% CI, 0.51–1.93). There was no statistically significant interaction between device and effect on the primary outcome (Solitaire P=0.42, other devices P=0.06). The distribution of primary outcomes was similar for Trevo and Solitaire (Figure 1).
Effect on the Secondary Outcomes

The proportions of patients with favorable scores on the Barthel Index at 90 days, the NIHSS scores at 24 hours and 5 to 7 days, were similar for each treatment modality (Table I in the online-only Data Supplement). Of the neuroimaging outcomes, infarct volume and absence of occlusion on CTA were similarly distributed, again without interaction. The proportion of patients with mTICI score 2b/3 was lower for patients treated with other mechanical devices than for patients treated with Solitaire or Trevo, but the difference was
not significant (Figure 2). Treatment effects for clinical and neuroimaging outcomes were similar for Trevo and Solitaire and seemed worse for other devices, but there was no statistically significant interaction (Table 2), except for persistence of occlusion on CTA, which was seen less often after treatment with Trevo (p<0.01) and Solitaire devices (p<0.03). Finally, no interaction was seen between stent type and general anesthesia or center on outcome (data not shown).

Safety Outcomes
Rates of any symptomatic intracerebral hemorrhage did not vary significantly by device type and in comparison with controls. The rate of deaths within 7 days and 3 months was increased for patients treated with other devices (11/40, 27.5% to 16/40, 40.0%), and this was statistically significant (Table 3). No statistically significant differences in occurrence of parenchymal hematoma types 1 and 2 and of new infarct in different territory were noted.

Timing and Work Flow
We estimated time to successful reperfusion, which was defined as mTICI 2b/3. We noted no differences in time from start of the treatment to reperfusion between patients treated with Trevo and those treated with Solitaire (−2 minutes,
Discussion

We explored functional outcome, neurological recovery, reperfusion, extent of infarction, and adverse events according to stent type and make, within the framework of the MR CLEAN trial. Our study suggests that the 2 most commonly used stents, Trevo and Solitaire, perform equally well. We observed no statistically or clinically significant differences in effect on functional outcome, neurological recovery, recanalization, final infarct volume, or adverse events. Effectiveness and safety should, therefore, not be an argument in the choice of these devices.

Other Studies

The large majority of other randomized trials of stent thrombectomy have predominantly used one particular device. We found one other study that directly compared the performance of different stent types. However, it included only 33 patients, and therefore lacked precision. A recent systematic review of revascularization and functional outcomes by stent type also found no significant differences between studies using Trevo and studies using Solitaire. Studies that used only one type

Table 3. Safety Parameters by Treatment Modality

<table>
<thead>
<tr>
<th>Clinical events</th>
<th>Control, n=267 (%)</th>
<th>Trevo, n=124 (%)</th>
<th>Solitaire, n=31 (%)</th>
<th>Other, n=40 (%)</th>
<th>None, n=38 (%)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic intracerebral hemorrhage</td>
<td>17 (6.4)</td>
<td>9 (7.3)</td>
<td>3 (9.7)</td>
<td>3 (7.5)</td>
<td>3 (7.9)</td>
<td>0.90</td>
</tr>
<tr>
<td>Death within 7 d</td>
<td>27 (10.1)</td>
<td>12 (9.7)</td>
<td>5 (16.1)</td>
<td>11 (27.5)</td>
<td>5 (13.2)</td>
<td>0.04</td>
</tr>
<tr>
<td>Death within 1 mo</td>
<td>49 (18.4)</td>
<td>18 (14.5)</td>
<td>7 (22.6)</td>
<td>13 (32.5)</td>
<td>6 (15.8)</td>
<td>0.15</td>
</tr>
<tr>
<td>Death within 90 d</td>
<td>59 (22.1)</td>
<td>19 (15.3)</td>
<td>7 (22.6)</td>
<td>16 (40.0)</td>
<td>7 (18.4)</td>
<td>0.03</td>
</tr>
<tr>
<td>Radiological findings</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subarachnoid hemorrhage</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>2 (5.0)</td>
<td>0 (0)</td>
<td>0.02</td>
</tr>
<tr>
<td>Parenchymal hemorrhage type 1</td>
<td>15 (5.9)</td>
<td>15 (12.4)</td>
<td>4 (12.9)</td>
<td>1 (2.5)</td>
<td>0 (0)</td>
<td>1.0</td>
</tr>
<tr>
<td>Parenchymal hemorrhage type 2</td>
<td>21 (8.2)</td>
<td>11 (9.1)</td>
<td>1 (3.2)</td>
<td>2 (5.0)</td>
<td>4 (10.5)</td>
<td>0.79</td>
</tr>
<tr>
<td>New infarct in different territory</td>
<td>13 (4.9)</td>
<td>15 (12.1)</td>
<td>2 (6.5)</td>
<td>5 (12.5)</td>
<td>1 (2.6)</td>
<td>0.14</td>
</tr>
<tr>
<td>Procedural events (DSA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vasospasm</td>
<td>…</td>
<td>49 (39.5)</td>
<td>10 (32.3)</td>
<td>14 (35.0)</td>
<td>…</td>
<td>0.75</td>
</tr>
<tr>
<td>Vessel perforation</td>
<td>…</td>
<td>0 (0)</td>
<td>1 (3.2)</td>
<td>1 (2.5)</td>
<td>…</td>
<td>0.13</td>
</tr>
<tr>
<td>New clot in different vascular territory</td>
<td>…</td>
<td>17 (13.7)*</td>
<td>1 (3.2)</td>
<td>2 (5.0)</td>
<td>…</td>
<td>0.14</td>
</tr>
</tbody>
</table>

*In 3 cases, the embolism occurred before the attempted mechanical thrombectomy, and in 2, it could be attributed to the second device that was used in the procedure.

Figure 2. Modified thrombolysis in cerebral infarction (mTICI) distribution for Trevo, Solitaire, and other devices in MR CLEAN (Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands). Other devices comprise stent-retrievers, MERCI, aspiration devices, guidewire manipulation, and other thrombectomy devices.
of device were included in the review. No within study comparisons and no adjustments for prognostic factors could be made.15

Previously, comparisons have been made of retrievable stents with the first generation devices.16–18 The observation that both the Solitaire and the Trevo outperformed the first generation devices, corroborates our findings.17,18

**Limitations**

The MR CLEAN trial was not designed for the purpose of comparing device types. The baseline characteristics and prognostic factors were well balanced between the 2 most commonly used stent types; this suggests that systematic bias is negligible. The findings in the category other devices are difficult to interpret. The experience of the interventionists with these relatively new devices was probably limited; moreover, confounding by indication may have played a role. From these data, it cannot be readily concluded that other devices are inferior to the 2 most commonly used retrievable stents. Our study does not provide a definite answer to the question “is any device for thrombectomy better than another one?” , because (1) our study was not powered to analyze the differences in outcome according to device type, (2) the comparison was not randomized, and (3) the data stem from a trial setting and not from the real world. In our opinion, however, MR CLEAN was a trial that approached the real world as close as possible, whereas real-world data often do not provide a clear-cut comparison that is easy to interpret.

**Overall Conclusions**

In this randomized clinical trial of endovascular thrombectomy versus usual care for patients with acute ischemic stroke caused by proximal intracranial occlusion, we found no evidence for a differential treatment effect by stent type or make.

**Appendix: The MR CLEAN Investigators**

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Disclosures

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References


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### Table I: Secondary outcomes by treatment modality

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Control (N=267)</th>
<th>Trevo (N=124)</th>
<th>Solitaire (N=31)</th>
<th>Other (N=40)</th>
<th>None (N=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Modified Rankin Scale 0 to 2</strong></td>
<td>51 (19.1%)</td>
<td>42 (33.9%)</td>
<td>10 (32.3%)</td>
<td>11 (27.5%)</td>
<td>13 (34.2%)</td>
</tr>
<tr>
<td><strong>Barthel index 19 to 20</strong></td>
<td>73 (30.2%)</td>
<td>52 (45.2%)</td>
<td>14 (48.3%)</td>
<td>16 (43.2%)</td>
<td>17 (50.0%)</td>
</tr>
<tr>
<td><strong>NIHSS score at 24 hrs</strong></td>
<td>16.1 (7.5)</td>
<td>13.4 (8.6)</td>
<td>12.8 (8.3)</td>
<td>15.4 (8.4)</td>
<td>12.2 (10.1)</td>
</tr>
<tr>
<td><strong>NIHSS score at 5-7 days</strong></td>
<td>13.0 (7.9)</td>
<td>9.9 (8.4)</td>
<td>8.6 (6.5)</td>
<td>10.7 (7.9)</td>
<td>10.1 (9.5)</td>
</tr>
<tr>
<td><strong>Infarct volume at 5 to 7 days</strong></td>
<td>93.4 (73.5)</td>
<td>75.6 (75.2)</td>
<td>66.8 (58.7)</td>
<td>78.7 (83.7)</td>
<td>61.9 (71.2)</td>
</tr>
<tr>
<td><strong>mTICI 2b/3</strong></td>
<td>-</td>
<td>80 (64.5%)</td>
<td>19 (61.3%)</td>
<td>16 (40.0%)</td>
<td>-</td>
</tr>
<tr>
<td><strong>No occlusion on CT at 24 hrs</strong></td>
<td>68 (32.9%)</td>
<td>84 (80.8%)</td>
<td>20 (83.3%)</td>
<td>21 (70.0%)</td>
<td>16 (55.1%)</td>
</tr>
</tbody>
</table>

* Mean (SD);