STRA TIS STROKE REGISTRY
Systematic Evaluation of Patients Treated with Neurothrombectomy Devices for Acute Ischemic Stroke (STRA TIS)
Registry

CAUTION: Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

The Solitaire™ Revascularization Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and clinical evidence who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset.

The Solitaire™ Revascularization Device is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV t-PA or who fail IV t-PA therapy are candidates for treatment.

The Capture™ LP Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) therapy are candidates for treatment.

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Système Evaluation of Patients Treated with Neurothrombectomy Devices for Acute Ischemic Stroke (STRATIS) Registry

REAL-WORLD STUDY
CONFIRMS RESULTS FROM FOUR RCT'S (SEER)
BASELINE CHARACTERISTICS

TARGET INTRACRANIAL OCCLUSION LOCATION

TREATMENT n=982**

- IV t-PA + MT (MT only 56.0%)

BASELINE + CLINICAL CHARACTERISTICS BY ADMISSION TYPE**

CHARACTERISTIC

ADMISSION TYPE

TRANSFER - DIRECT (n=539)

TRANSFER - TRANSFER (n=445)

p VALUE

Age, mean (SD), y

46.9 (15.6)

Males

245 (45.5%)

Atrial flutter/ Atrial fibrillation

165 (31.7%)

Diabetes mellitus

108 (21.2%)

Hyperlipidemia

121 (27.2%)

Peripheral artery disease

184 (41.3%)

Pre-stroke mRS

0

66.9 (14.6)

0245 (55.1%)

1165 (37.1%)

2321 (72.1%)

3108 (24.3%)

1121 (27.2%)

1184 (41.3%)

414 (3.1%)

39 (8.8%)

326 (73.3%)

104 (23.4%)

15 (3.4%)

Initial Qualifying NIHSS Score, mean (SD)

18.0 (5.5)

Baseline ASPECTS – per image core lab*, mean (SD)

66.9 (14.6)

** IV t-PA data not available for 2 patients

** Baseline imaging reviewed for 982 patients of which 72 were not evaluated for ASPECTS.

The STRATIS Registry is a prospective, multi-center, observational, single-arm registry that was designed to investigate the ‘real-world’ stroke care questions and build a comprehensive representation of the patient population being treated with Medtronic stent retrievers.

The STRATIS Registry tracked the system of care data including transfer distances, referral patterns, times and location of stroke onset to ultimate interventional treatment. Patient images were core lab adjudicated. STRATIS is the first registry to enroll 982 patients within 8 hours from stroke onset with a focus on systems of care on clinical outcomes.

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**BASELINE CHARACTERISTICS**

**TARGET INTRACRANIAL OCCLUSION LOCATION**

<table>
<thead>
<tr>
<th>Location</th>
<th>M1</th>
<th>M2</th>
<th>ICA-T</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>54.7%</td>
<td>17.3%</td>
<td>22.6%</td>
</tr>
</tbody>
</table>

**TREATMENT n=982**

- *In-office, evidence-based medical treatment* 35%
- *Minimally invasive, evidence-based medical treatment* 76%
- *Evidence-based device* 7%

**IV t-PA + MT**

64.0% (TICI 2b-3) after first device pass

**MT only**

56.0% (TICI 2b-3) after mechanical thrombectomy

**BASELINE + CLINICAL CHARACTERISTICS BY ADMISSION TYPE**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Direct Admission</th>
<th>Transfer (n=445)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>66.3 (14.4)</td>
<td>68.5 (14.8)</td>
<td>0.044</td>
</tr>
<tr>
<td>Male Sex</td>
<td>245 (45.1%)</td>
<td>288 (53.4%)</td>
<td>0.10</td>
</tr>
<tr>
<td>Initial Qualifying NIHSS Score, mean (SD)</td>
<td>18.0 (5.5)</td>
<td>16.7 (5.5)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**ANGIOGRAPHIC OUTCOMES**

93.6% SUCCESSFUL REVASCULARIZATION (TICI 2b-3) per site**

87.9% SUCCESSFUL REVASCULARIZATION (modified TICI 2b-3) per image core lab**

**SUCCESSFUL REVASCULARIZATION (TICI 2b-3)**

- **TICI grading scale as per site’s standard practice**
- **Implantation site:**
  - **n=984**
  - **Enrolling Hospitals = 55**
  - **Participants = 982**

**SYSTEMS OF CARE – What are the key variables affecting time to treatment?**

**INTERVENTIONAL TECHNIQUE – How do procedural techniques impact clinical outcomes?**

**PRIMARY OUTCOMES – What are the clinical outcomes in the real world and how does this compare to the RCT’s?**

**CLINICAL OUTCOMES1,6**

60.3% FIRST PASS SUCCESS RATE6

56.5% INDEPENDENT FUNCTIONAL (mRS 0-2) at 90 days

**60.3% FIRST PASS SUCCESS RATE6**

**1.4% sICH**

**93.6% SUCCESSFUL REVASCULARIZATION (TICI 2b-3) per site**

**87.9% SUCCESSFUL REVASCULARIZATION (modified TICI 2b-3) per image core lab**

**85% of patients were treated with IV t-PA.**
STROKE ONSET TO 911 CALL TO EMS SCENE ARRIVAL TO DOOR (INITIAL HOSPITAL) TO PICTURE TO IV t-PA (INITIAL HOSPITAL) TO DEPARTURE (INITIAL HOSPITAL)

SYSTEMS OF CARE: TIME TO TREATMENT IS AN IMPORTANT PREDICTOR OF OUTCOME

DIRECT ADMIT VS. TRANSFER: INTERHOSPITAL TRANSFER WAS ASSOCIATED WITH MEAN DELAYS OF 124 MINUTES FROM ONSET TO REVASCULARIZATION

DIRECT ADMIT: 16 8 29 13 23 52 34 311.5 min

TRANSFER: 11 8 23 14 42 47 35 15 42 37 311.5 min

mRS 0-2 at 90 Days

DIRECT ADMIT: 60.0%

TRANSFER: 52.2%

p VALUE: 0.02

OVERALL DIRECT ADMIT VS. TRANSFER p VALUE: <0.0001
SYSTEMS OF CARE: TIME TO TREATMENT IS AN IMPORTANT PREDICTOR OF OUTCOME

Median time from symptom onset to revascularization IV t-PA + MT subgroup

DIRECT ADMIT VS. TRANSFER: INTERHOSPITAL TRANSFER WAS ASSOCIATED WITH MEAN DELAYS OF 124 MINUTES FROM ONSET TO REVASCULARIZATION

Onset to revascularization (per image core lab)*

- DIRECT ADMIT: mRS 0-2 at 90 days: 60.0%
- TRANSFER: mRS 0-2 at 90 days: 52.2%

* Overall median (IQR) minutes
STRAITIS showed that results from four Solitaire™ RCT’s (SEER 1) can be replicated in US centers in a real-world setting. In this large, real-world study, inter-hospital transfer was associated with significant delays to treatment and significantly lower chance of functional independence at 90 days (mRS 0-2 60.0% vs. 52.2%, p=0.02).

CONCLUSION

Time delays to endovascular treatment due to inter-hospital transfers have shown to decrease the rate of functional independence at 90 days, reflecting the impact of routing and transfer protocols.
STRATIS showed that results from four Solitaire™ RCT’s (SEER) can be replicated in US centers in a real-world setting.

In this large, real-world study, inter-hospital transfer was associated with significant delays to treatment and significantly lower chance of functional independence at 90 days.

(\textit{mRS} 0-2 60.0\% vs. 52.2\%, \textit{p}=0.02)

**CONCLUSION**

TIME DELAYS TO ENDOVASCULAR TREATMENT DUE TO INTERHOSPITAL TRANSFERS HAVE SHOWN TO DECREASE THE RATE OF FUNCTIONAL INDEPENDENCE AT 90 DAYS, REFLECTING THE IMPACT OF ROUTING AND TRANSFER PROTOCOLS.


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