Results Of The Systematic Evaluation Of Patients Treated With Neurothrombectomy Devices For Acute Ischemic Stroke (STRATIS) Registry: Key Messages

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DISCLOSURE

- STRATIS IS A MULTI-CENTER ACUTE ISCHEMIC STROKE LVO SOLITIARE AND MINDFRAME DEVICES REGISTRY SPONSORED AND COORDINATED BY MEDTRONIC
OVERALL STRATIS KEY RESULTS

BACKGROUND AND OVERVIEW

- Since the publication of 5 seminal randomized controlled trials (RCTs) in 2014-15, mechanical thrombectomy (MT) with stent-retrievers has become standard of care for treatment of acute ischemic stroke patients due to large vessel occlusion (LVO), recommended by various scientific societal guidelines across the world.

- Given the highly selected patient population in some of these RCTs, questions remain whether process timelines, technical and functional outcomes can be achieved in a “real world” setting.

- Here we present the preliminary STRATIS registry results;
  - Overview of the primary STRATIS results
  - Overview of the system of care outcomes (transfer vs direct)
  - Difference in outcomes between various adjunctive MT techniques
## OVERALL STRATIS KEY RESULTS

### METHODS

| Design/Objective | ▪ Independent Steering Committee, imaging and core lab, & statistician  
▪ Prospective, multi-center, observational, single-arm registry designed to capture a “real world experience” without requirement of specialized triage imaging, age limits or technique exclusions at academic and non-academic centers in the USA.  
▪ Patients with large vessel occlusion (LVO) acute ischemic stroke (AIS) were enrolled within 8 hours from symptom onset. |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Endpoints & Evaluations | **Performance**  
▪ Time from puncture to revascularization (mTICI ≥ 2b)  
▪ Revascularization assessment at the end of the procedure using TICI score  
**Clinical Efficacy**  
▪ mRS at 90 days  
**Safety**  
▪ All-cause mortality (up to 90 days post procedure)  
▪ Incidence of symptomatic ICH  
**Reproducibility:**  
▪ A patient-level comparison with SEER database was performed |
| Devices | ▪ First neurothrombectomy device use must be:  
▪ Solitaire™ Revascularization Device  
▪ MindFrame Capture™ LP Device |

Stratis Registry Key Primary Results
### OVERALL STRATIS KEY RESULTS

#### METHODS: SPECIFIC ADDITIONAL AIMS

**TARGET**

Answering the “real world” stroke questions and building a comprehensive representation of the patient population being treated with Medtronic stroke devices

<table>
<thead>
<tr>
<th></th>
<th>SYSTEMS OF CARE</th>
<th>ROLE OF IMAGING</th>
<th>INTERVENTIONAL TECHNIQUE</th>
<th>GENERAL ANESTHESIA</th>
<th>BASELINE CHARACTERISTICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>What are the key variables affecting time to treatment?</strong></td>
<td><strong>How does imaging selection method impact clinical outcome?</strong></td>
<td><strong>How does interventional technique (proximal vs. lesional aspiration) affect technical efficacy and clinical outcome?</strong></td>
<td><strong>What are the effects of general anesthesia on workflow and clinical outcome? Will not be discussed (ESOC 2017)</strong></td>
<td><strong>What are the key baseline characteristics that affect clinical outcome? Will not be discussed</strong></td>
</tr>
</tbody>
</table>
OVERALL STRATIS KEY RESULTS

PRIMARY RESULTS

- AUGUST 2014 TO JUNE 2016
  - 1,000 PATIENTS WERE ENROLLED AT 55 US CENTERS
  - 16 PATIENTS WERE IDENTIFIED TO BE SCREEN FAILURES AND EXCLUDED FROM THE ANALYSIS
  - TOTAL OF 984 PATIENTS

- DEVICES USED
  - SOLITAIRE™ WAS THE FIRST MT DEVICE USED IN 954 PTS (96.9%)
  - MINDFRAME CAPTURE™ LP IN 30 PTS (3.1%)
## OVERALL STRATIS KEY RESULTS

**COMPARISON OF BASELINE & WORKFLOW CHARACTERISTICS, CONTINUED**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>SEER Intervention</th>
<th>STRATIS</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Qualifying NIHSS Score</td>
<td>16.6 ± 4.9 (398)</td>
<td>17.3 ± 5.5 (984)</td>
<td>0.042</td>
</tr>
<tr>
<td>IV t-PA delivered</td>
<td>80.5% (323/401)</td>
<td>64.0% (628/982)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ASPECTS – per imaging core lab†</td>
<td>8.3 ± 1.7 (388)</td>
<td>8.2 ± 1.6 (763)</td>
<td>0.091</td>
</tr>
<tr>
<td>Target Intracranial Occlusion Location‡</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Not reported</td>
<td>2.5% (10/401)</td>
<td>0.8% (8/984)</td>
<td></td>
</tr>
<tr>
<td>Internal Carotid Artery Terminus</td>
<td><strong>18.2% (73/401)</strong></td>
<td><strong>22.6% (222/984)</strong></td>
<td></td>
</tr>
<tr>
<td>MCA – First segment (M1)</td>
<td>71.1% (285/401)</td>
<td>54.7% (538/984)</td>
<td></td>
</tr>
<tr>
<td>MCA – Second segment (M2)</td>
<td>8.2% (33/401)</td>
<td>17.3% (170/984)</td>
<td></td>
</tr>
<tr>
<td>MCA – Third segment (M3)</td>
<td>0.0% (0/401)</td>
<td>0.2% (2/984)</td>
<td></td>
</tr>
<tr>
<td>Posterior Circulation</td>
<td>0.0% (0/401)</td>
<td>4.5% (44/984)</td>
<td></td>
</tr>
</tbody>
</table>

Data are % (n/N), or mean±SD (N), [median] (IQR). Abbreviations: ASPECTS, Alberta Stroke Program Early CT Score; mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale. The protocol was amended to restrict enrollment to mRS 0-1 to ensure consistency with SWIFT PRIME enrollment criteria. †Baseline imaging received for 835 patients, of whom 72 were not evaluated for ASPECTS (38 Posterior stroke, 30 no non-contract CT, 4 not evaluable), resulting in 763 patients evaluable for ASPECTS. ‡For STRATIS, assessed by the Techniques Core Lab based on operative reports.
## OVERALL STRATIS KEY RESULTS

### COMPARISON OF BASELINE & WORKFLOW CHARACTERISTICS, CONTINUED

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>SEER Intervention</th>
<th>STRATIS</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process Metrics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke onset to enrolling hospital arrival (door)</td>
<td>143.5 ± 122.2 (400)</td>
<td>149.3 ± 101.0 (907)</td>
<td>0.030</td>
</tr>
<tr>
<td>Stroke onset to alteplase initiation</td>
<td>122.9 ± 49.2 (322)</td>
<td>113.3 ± 50.5 (622)</td>
<td>0.001</td>
</tr>
<tr>
<td>Hospital arrival to alteplase initiation</td>
<td>28.7 ± 66.0 (265)</td>
<td>42.1 ± 26.5 (336)</td>
<td>0.503</td>
</tr>
<tr>
<td>Stroke onset to puncture</td>
<td>263.1 ± 194.7 (394)</td>
<td>226.4 ± 100.0 (976)</td>
<td>0.011</td>
</tr>
<tr>
<td>Hospital arrival to puncture</td>
<td>122.0 ± 173.7 (392)</td>
<td>80.1 ± 49.4 (901)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Imaging to puncture</td>
<td>68.9 ± 34.7 (394)</td>
<td>71.2 ± 46.4 (824)</td>
<td>0.642</td>
</tr>
<tr>
<td>Alteplase to puncture</td>
<td>107.2 ± 206.5 (259)</td>
<td>102.0 ± 73.5 (613)</td>
<td>0.001</td>
</tr>
<tr>
<td>Puncture to TICI 2b/3 or completion</td>
<td>45.9 ± 31.0 (348)</td>
<td>45.6 ± 29.0 (939)</td>
<td>0.740</td>
</tr>
<tr>
<td>Stroke onset to TICI 2b/3 or completion</td>
<td>293.6 ± 126.5 (349)</td>
<td>271.1 ± 105.7 (945)</td>
<td>0.020</td>
</tr>
</tbody>
</table>

Data are % (n/N), or mean±SD (N). Abbreviations: ASPECTS, Alberta Stroke Program Early CT Score; mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale. The protocol was amended to restrict enrollment to mRS 0-1 to ensure consistency with SWIFT PRIME enrollment criteria.
OVERALL STRATIS KEY RESULTS

PRIMARY CLINICAL EFFICACY OUTCOME: MODIFIED RANKIN DISTRIBUTION AT 90 DAYS

mRS at 90 days

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
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<tbody>
<tr>
<td>21</td>
<td>22</td>
<td>13</td>
<td>14</td>
<td>10</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>14</td>
<td>22</td>
<td>18</td>
<td>16</td>
<td>12</td>
<td>7</td>
<td>12</td>
</tr>
</tbody>
</table>

Shift analysis favored STRATIS over SEER Intervention. OR 1.38 (95% CI 1.11-1.71); p=0.004.

56.5% vs. 54%; p = 0.002.
OVERALL STRATIS KEY RESULTS

KEY FINDINGS

DESPITE ENROLLING A NONSELECTIVE POPULATION WITH SIGNIFICANTLY HIGHER MEAN BASELINE NIHSS, HIGHER PERCENTAGE OF ICA OCCLUSION, INCLUSION OF POSTerior CIRCULATION STROKES AND LONGER MEDIAN ONSET TO ARRIVAL TIME,

FAVORING SEER; STRATIS ACHIEVED SIMILAR TECHNICAL, SAFETY AND CLINICAL OUTCOMES.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>SEER</th>
<th>STRATIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Lab mTICI 2b-3</td>
<td>76.6%</td>
<td>87.9%</td>
</tr>
<tr>
<td>sICH</td>
<td>2.5%</td>
<td>1.4%</td>
</tr>
<tr>
<td>mRS 0-2 at 90 Days</td>
<td>54.0%</td>
<td>56.5%</td>
</tr>
</tbody>
</table>

WORKFLOW

- **MEAN TIME FROM ONSET TO ARRIVAL** WAS SIGNIFICANTLY LONGER IN STRATIS (5.8 MIN) COMPARED TO SEER.
- **MEAN ONSET TO PUNCTURE TIME** WAS 36.7 MINUTES SHORTER IN STRATIS, PRIMARILY DRIVEN BY A 41.9 MINUTE SHORTER MEAN DOOR TO PUNCTURE TIME.
II. STRATIS SYSTEM OF CARE OUTCOME; TRANSFER VS. DIRECT

SYSTEMS OF CARE: DIRECT VS. TRANSFER AND SHOULD WE BYPASS?

INTERHOSPITAL TRANSFER PRIOR TO THROMBECTOMY IS ASSOCIATED WITH DELAYED TREATMENT AND WORSE OUTCOME IN THE STRATIS REGISTRY
## II. STRATIS SYSTEM OF CARE OUTCOME; TRANSFER VS. DIRECT

### DEMOGRAPHICS: DIRECT 539/984 (55%) TRANSFER 445/984 (45%)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ALL (984)</th>
<th>Transfer (445)</th>
<th>Direct (539)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>67.8 (14.7)</td>
<td>66.9 (14.6)</td>
<td>68.5 (14.8)</td>
<td>0.10</td>
</tr>
<tr>
<td>Atrial flutter/Atrial fibrillation</td>
<td>369 (37.5)</td>
<td>165 (37.1)</td>
<td>204 (37.8)</td>
<td>0.80</td>
</tr>
<tr>
<td>Systemic Hypertension</td>
<td>712 (72.4)</td>
<td>321 (72.1)</td>
<td>391 (72.5)</td>
<td>0.89</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>252 (25.6)</td>
<td>108 (24.3)</td>
<td>144 (26.7)</td>
<td>0.38</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>414 (42.1)</td>
<td>184 (41.3)</td>
<td>230 (42.7)</td>
<td>0.68</td>
</tr>
<tr>
<td>Current or former tobacco use</td>
<td>465 (47.3)</td>
<td>222 (49.9)</td>
<td>243 (45.1)</td>
<td>0.13</td>
</tr>
<tr>
<td>Baseline mRS 0</td>
<td>748 (76.0)</td>
<td>326 (73.3)</td>
<td>422 (78.3)</td>
<td></td>
</tr>
<tr>
<td>Baseline mRS 1</td>
<td>209 (21.2)</td>
<td>104 (23.4)</td>
<td>105 (19.5)</td>
<td></td>
</tr>
<tr>
<td>Initial Qualifying NIHSS Score, mean (SD), median (IQR)</td>
<td>17.3 (5.5), 17.0 (13-22)</td>
<td>18.0 (5.5), 18.0 (13-22)</td>
<td>16.7 (5.5), 17.0 (12-21)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Baseline ASPECTS – per core lab*</td>
<td>N=763</td>
<td>N=306</td>
<td>N=457</td>
<td></td>
</tr>
<tr>
<td>Mean (SD), median (IQR)</td>
<td>8.2±1.6, 8.0 (8-9)</td>
<td>7.9 (1.8), 8.0 (7-9)</td>
<td>8.4 (1.4), 9.0 (8-9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Treatment with IV-tPA, No. (%)</td>
<td>628 (63.8)</td>
<td>299 (67.2)</td>
<td>329 (61.0)</td>
<td>0.044</td>
</tr>
</tbody>
</table>

*Baseline imaging received for 835 pts, of which 72 were not evaluated for ASPECTS (38 Posterior stroke, 3 CT not available, 4 not evaluable), resulting in 763 pts evaluable for ASPECTS.
II. STRATIS SYSTEM OF CARE OUTCOME; TRANSFER VS. DIRECT

TIME DIFFERENCES FOR TPA + MT: 120 MINUTES TIME DIFFERENCE IN ONSET TO REVASC (<0.0001)

(Transfer 445 pts (45%), Direct 539 pts (55%)

- Stroke Onset to 911 call
- 911 call to EMS Scene Arrival
- EMS Scene Arrival to Door [Initial Hospital]
- Door to Picture [Initial Hospital]
- Picture to IV t-PA [Initial Hospital]
- IV t-PA to Departure [Initial hospital]
- Transfer time (Departure initial hospital to Door Enrolling Hospital)
- EMS Scene Arrival to Door [Enrolling Hospital]
- Door to Picture [Enrolling Hospital]
- Picture to IV t-PA [Enrolling Hospital]
- IV t-PA to Puncture [Enrolling Hospital]
- Puncture to Revascularization [Enrolling Hospital]

Transfer: 311.5 minutes
Direct: 192 minutes

\( P < 0.0001 \)
II. STRATIS SYSTEM OF CARE OUTCOME; TRANSFER VS. DIRECT

TIME DIFFERENCES FOR MT ALONE

Median Times from Stroke Onset to Revasc: 82.5 min delay

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Stratis Registry Key Primary Results
II. STRATIS SYSTEM OF CARE OUTCOME; TRANSFER VS. DIRECT

MRS AT 90 DAYS

**mRS 0-2:**
- 60.0% direct
- 52.2% transfer
- OR 1.38 (1.06-1.79)

**mRS 0-1:**
- 47.4% direct
- 38.0% transfer
- OR 1.47 (1.13-1.92)

**Mortality:**
- 15.0% direct
- 13.7% transfer
- p=0.56

Shift analysis favored direct presentation (p=0.012 by Cochran-Mantel-Haenszel test).
II. STRATIS SYSTEM OF CARE OUTCOME; TRANSFER VS. DIRECT
TIME DELAY ACCOUNTS FOR DIFFERENCE IN OUTCOMES

Across all patients, the absolute rate of functional independence decreased by 5.5% per hour from alarm (911 call) to puncture.
After accounting for differences in outcome related to time to endovascular treatment, the administration of IV-tPA did not have a significant effect on outcome, either overall or in interaction with time.
II. STRATIS SYSTEM OF CARE OUTCOME; TRANSFER VS. DIRECT

SHOULD WE BYPASS?

BYPASSING THE COMMUNITY HOSPITAL MAY REDUCE TIME TO MT, BUT MAY INCREASE TIME TO IV-TPA OR MISSING THE IVTPA DUE TO BYPASS PSC.

WE PERFORMED VIRTUAL BYPASS SIMULATION ROUTING TO CALCULATE EFFECT ON TIMES DELAY TO TREATMENT: IDEA, TO_ASSUME THAT TRANSFER PATIENTS WOULD BYPASS THE CLOSEST HOSPITAL:

WHAT WOULD BE THE TIME DELAY TO IVTPA

HOW MANY WOULD MISS IVTPA

INCLUSION ON THE VIRTUAL MODEL
FOR GROUND TRANSPORT ONLY. AIR TRANSPORT EXCLUDED GIVEN LONGER DISTANCES AND HIGHER VARIABILITY.

BYPASS ANALYSIS PERFORMED FOR TWO SUBSETS:
ALL TRANSPORTED VIA GROUND, AND ONLY THOSE WITHIN 20 MILES OF ENDOVASCULAR CENTER (TO SEE THE EFFECT ON SPECIFIC DISTANCE FROM EC)
All patients transferred via ground (n=209) = virtual population assuming bypassing

1. Onset to EMS arrival
2. 15 min EMS on scene
3. Calculated drive time
   - Distance to EC
   - Actual Average Transport Velocity

- IV-tPA before transfer (n=122)
- Door-to-needle at CSC
- tPA ineligible (n=87)

Still < 270 min?

6 no longer tPA eligible (2%)

Virtual bypass time (onset-to-puncture)
## II. STRATIS SYSTEM OF CARE OUTCOME; TRANSFER VS. DIRECT

### VIRTUAL BYPASS: DELAY IN TPA: 17 MIN, 6 NO TPA, DECREASE IN ONSET TO PUNCTURE: 81 MINUTES

**All patients transferred via ground (n=209, 122 w tPA)**

<table>
<thead>
<tr>
<th></th>
<th>Actual</th>
<th>Bypass</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset-to-tPA</td>
<td>106</td>
<td>123</td>
</tr>
<tr>
<td>(Median time)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Onset-to-puncture</td>
<td>169</td>
<td>250</td>
</tr>
<tr>
<td>(Median time)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Patients within 20 miles (n=130, 71 w tPA)**

<table>
<thead>
<tr>
<th></th>
<th>Actual</th>
<th>Bypass</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset-to-tPA</td>
<td>100</td>
<td>102</td>
</tr>
<tr>
<td>(Median time)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Onset-to-puncture</td>
<td>148</td>
<td>240</td>
</tr>
<tr>
<td>(Median time)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### VIRTUAL BYPASS IN STRATIS

**FULL COHORT:**

- 6 no longer tPA eligible (5%)
- 17 min IVTPA Delay
- GAIN: 81 min shorter Median Onset to Puncture time (250 to 169 min)

### VIRTUAL BYPASS IN STRATIS 20 miles radius to EC Yielded:

- 2 no longer tPA eligible (3%)
- 2 min Delay in IVTPA
- GAIN: 92 min shorter Median Onset to Puncture time (240 to 148 min)
II. STRATIS SYSTEM OF CARE OUTCOME; TRANSFER VS. DIRECT

3-5% MISS TPA IF BYPASSED (ALL VS 20 MILES BYPASS)

• *If tPA is missed* due to bypassing nearer hospital in favor of direct routing to endovascular care, there is *no predicted difference* in outcome.

• **Outcome** remains dependent on time-to-treatment.
III. STRATIS ADJUNCTIVE TECHNIQUE OUTCOMES

INFLUENCE OF BALLOON, CONVENTIONAL, OR DISTAL CATHETERS ON ANGIOGRAPHIC AND CLINICAL OUTCOMES IN THE STRATIS REGISTRY
## III. STRATIS ADJUNCTIVE TECHNIQUE OUTCOMES
### METHODS

<table>
<thead>
<tr>
<th>Objective</th>
<th>To evaluate the influence of thrombectomy adjunctive devices/techniques on angiographic and clinical outcomes from the STRATIS Registry: BGC+SR, DLBC with local or lesional aspiration, CGC</th>
</tr>
</thead>
</table>
| Outcomes  | - Modified First pass effect (FPE) defined as successful reperfusion of ≥TICI2b after first device pass  
- True FPE defined as TICI 2c or 3 after first pass  
- Number of passes  
- Rate of good clinical outcome defined as mRS 0-2 at 90 days |
| Independent Evaluation | - A Technique Core Lab blinded to clinical outcome extrapolated the techniques and assessed FPE and True FPE based on procedural reports.  
- An Image Core Lab blinded to clinical outcome assessed final angiographic reperfusion status. |
| Analysis Population | - Included anterior circulation target vessel occlusion  
- Excluded subjects in whom combined BGC and DLBC approach was used |
## III. STRATIS ADJUNCTIVE TECHNIQUE OUTCOMES

### INTERVENTIONAL TECHNIQUES

<table>
<thead>
<tr>
<th>Interventional Techniques</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Balloon Guide Catheter (BGC)</strong></td>
</tr>
<tr>
<td>• BGC with proximal aspiration, no DLBC used (n=503)</td>
</tr>
<tr>
<td><strong>Conventional Guide Catheter (CGC)</strong></td>
</tr>
<tr>
<td>• Conventional guide/sheath with proximal aspiration, no DLBC used (n=77)</td>
</tr>
<tr>
<td><strong>Distal Large Bore Catheter (DLBC)</strong></td>
</tr>
<tr>
<td>• CGC with BOTH lesional aspiration and retrieval with DLBC (n=72)</td>
</tr>
<tr>
<td>• CGC with lesional aspiration (DLBC) and proximal retrieval into CGC (n=229)</td>
</tr>
<tr>
<td>• CGC with DLBC with aspiration via CGC (n=1)</td>
</tr>
</tbody>
</table>

Technical approaches as assessed by the Technique Core Lab based on procedural reports.
III. STRATIS ADJUNCTIVE TECHNIQUE OUTCOMES

STUDY POPULATION & BASELINE CHARACTERISTICS

- A total of 936 patients were included in the analysis.
- Baseline characteristics were well balanced across groups with the exception of current or previous tobacco use.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>BGC (503)</th>
<th>CGC (77)</th>
<th>DLBC (302)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>67.7±15.22 (503)</td>
<td>68.8±14.66 (77)</td>
<td>68.7±14.29 (302)</td>
<td>0.7943</td>
</tr>
<tr>
<td>Sex - Male</td>
<td>261/503 (51.9%)</td>
<td>43/77 (55.8%)</td>
<td>162/302 (53.6%)</td>
<td>0.7635</td>
</tr>
<tr>
<td>Medical History</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>210/503 (41.7%)</td>
<td>26/77 (33.8%)</td>
<td>110/302 (36.4%)</td>
<td>0.1919</td>
</tr>
<tr>
<td>Hypertension</td>
<td>360/503 (71.6%)</td>
<td>58/77 (75.3%)</td>
<td>230/302 (76.2%)</td>
<td>0.3350</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>119/503 (23.7%)</td>
<td>14/77 (18.2%)</td>
<td>89/302 (29.5%)</td>
<td>0.0617</td>
</tr>
<tr>
<td>Current or previous tobacco use</td>
<td>260/503 (51.7%)</td>
<td>33/77 (42.9%)</td>
<td>127/302 (42.1%)</td>
<td>0.0203</td>
</tr>
</tbody>
</table>

Data are % (n/N), or mean±SD (N). The protocol was amended to restrict enrollment to mRS 0-1 to ensure consistency with SWIFT PRIME enrollment criteria.
III. STRATIS ADJUNCTIVE TECHNIQUE OUTCOMES

STUDY POPULATION & BASELINE CHARACTERISTICS, CONTINUED,

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>BGC (503, 54%)</th>
<th>CGC (77, 8%)</th>
<th>DLBC (302, 32%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-Procedural</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial Qualifying NIHSS Score</td>
<td>17.1±5.34 (503)</td>
<td>17.5±5.73 (77)</td>
<td>17.5±5.50 (302)</td>
<td>0.7489</td>
</tr>
<tr>
<td>IV t-PA delievered</td>
<td>328/503 (65.2%)</td>
<td>51/77 (66.2%)</td>
<td>195/302 (64.6%)</td>
<td>0.9489</td>
</tr>
<tr>
<td>ASPECTS – per imaging core lab†</td>
<td>8.3±1.59 (415)</td>
<td>8.5±1.28 (66)</td>
<td>8.1±1.59 (235)</td>
<td>0.0685</td>
</tr>
<tr>
<td><strong>Intracranial Vessel treated on First Pass‡</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.1967</td>
</tr>
<tr>
<td>Internal Carotid Artery Terminus</td>
<td>105/503 (20.9%)</td>
<td>18/77 (23.4%)</td>
<td>89/302 (29.5%)</td>
<td></td>
</tr>
<tr>
<td>Middle Cerebral Artery – First segment (M1)</td>
<td>300/503 (59.6%)</td>
<td>43/77 (55.8%)</td>
<td>164/302 (54.3%)</td>
<td></td>
</tr>
<tr>
<td>Middle Cerebral Artery – Second segment (M2)</td>
<td>97/503 (19.3%)</td>
<td>16/77 (20.8%)</td>
<td>48/302 (15.9%)</td>
<td></td>
</tr>
<tr>
<td>Middle Cerebral Artery – Third segment (M3)</td>
<td>1/503 (0.2%)</td>
<td>0</td>
<td>1/302 (0.3%)</td>
<td></td>
</tr>
</tbody>
</table>

Data are % (n/N), or mean±SD (N). Abbreviations: ASPECTS, Alberta Stroke Program Early CT Score; mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale. The protocol was amended to restrict enrollment to mRS 0–1 to ensure consistency with SWIFT PRIME enrollment criteria. †759 patients evaluable for ASPECTS. ‡Assessed by the Techniques Core Lab based on operative reports.
III. STRATIS ADJUNCTIVE TECHNIQUE OUTCOMES

DISTRIBUTION OF TECHNICAL APPROACHES USED ON 1ST PASS

- 54% BALLOON GUIDE CATHETER (BGC)
- 32% DISTAL LARGE BORE CATHETER (DLBC)
- 8% CONVENTIONAL GUIDE CATHETER (CGC)
- 6% OTHER

Stratis Registry Key Primary Results
III. STRATIS ADJUNCTIVE TECHNIQUE OUTCOMES

PROCEDURAL OUTCOMES

- **Mean number of device passes** was significantly lower in the BGC group when compared to either CGC or DLBC groups.
- **Mean time from puncture to revascularization** was significantly shorter in both the BGC and DLBC groups when compared to the CGC group.
III. STRATIS ADJUNCTIVE TECHNIQUE OUTCOMES

REPERFUSION OUTCOMES: TFPE AND MFPE WERE SIGNIFICANTLY HIGHER WITH BGC, FINAL REVASC WAS NOT DIFFERENT

First Pass Effect: Technique Core Lab
(TICI ≥2b after first device pass)

True First Pass Effect: Technique Core Lab
(TICI 2c-3 after first device pass)

Successful Reperfusion Imaging Core Lab
(Final mTICI ≥2b)

Stratis Registry Key Primary Results
III. STRATIS ADJUNCTIVE TECHNIQUE OUTCOMES

SAFETY OUTCOMES

Emboli to New Vascular Territory (per Imaging Core Lab)
- BGC: 0.9%
- CGC: 1.4%
- DLBC: 0.8%

Incidence of Symptomatic ICH at 24h
- BGC: 1.8%
- CGC: 0.0%
- DLBC: 1.2%

All-Cause Mortality at 90 Day Follow-up
- BGC: 16.1%
- CGC: 17.9%
- DLBC: 14.9%

P-values for comparisons:
- Emboli: P=0.8666 (BGC vs CGC), P=0.6973 (BGC vs DLBC), P=0.6331 (CGC vs DLBC)
- Incidence of Symptomatic ICH: P=0.7543 (BGC vs CGC), P=0.6056 (BGC vs DLBC), P=1.000 (CGC vs DLBC)
- All-Cause Mortality: P=0.5501 (BGC vs CGC), P=0.9138 (BGC vs DLBC), P=0.6501 (CGC vs DLBC)
III. STRATIS ADJUNCTIVE TECHNIQUE OUTCOMES

GOOD CLINICAL OUTCOME: TECHNIQUE CORE LAB WAS BLINDED TO mRS

- **MFPE AND TRUE FPE WERE SIGNIFICANTLY HIGHER IN THE BGC GROUP WHEN COMPARED TO EITHER THE CGC OR DLBC GROUPS.**
- **OVERALL:** MFPE 60.3%, TRUE FPE 47.7%
- **FINAL SUCCESSFUL REPERFUSION RATES WERE SIMILAR AMONG THE GROUPS.**
- **NO DIFFERENCES WERE OBSERVED IN ENT, SICH OR ALL-CAUSE MORTALITY RATES.**
- **RATE OF GOOD CLINICAL OUTCOME WAS SIGNIFICANTLY HIGHER IN THE BGC GROUP WHEN COMPARED TO EITHER THE CGC OR DLBC GROUPS**

![mRS 0-2 at 90 day Follow-up](image)
STRATIS CONCLUSIONS

- STRATIS DOCUMENTS THAT THE TECHNICAL AND CLINICAL OUTCOMES OF THE LANDMARK TRIALS USING THE SAME DEVICE CAN BE REPRODUCED IN A REAL-WORLD SETTING. DESPITE ENROLLING A POPULATION WITH HIGHER MEAN BASELINE NIHSS AND MORE RISK FACTORS THAN SEER, RESULTS DEMONSTRATE THAT MT WITH A MEDTRONIC STENT RETRIEVER IS BOTH SAFE AND EFFECTIVE.

- THE SHORTER DOOR TO PUNCTURE INTERVALS IN STRATIS MAY SUGGEST AN INCREASING AWARENESS OF THE IMPORTANCE OF RAPID HOSPITAL WORKFLOW SINCE PUBLICATION OF THE SEER TRIALS.

- DIRECT PATIENTS IN STRATIS HAD BETTER CLINICAL OUTCOMES AND SHORTER ONSET TO PUNCTURE TIME VS. TRANSFER PTS. VIRTUAL BY PASS PROVIDED HIGHER GAIN IN SHORTENING ONSET PUNCTURE TIME WITH 3-5% LOSS OF TPA WITH LESS THAN 17 MIN DELAY.

- DESPITE HAVING SIMILAR FINAL SUCCESSFUL RECANALIZATION RATES, BGC USE AS THE FIRST APPROACH IN STRATIS DEMONSTRATED A HIGHER RATES OF FPE AND GOOD CLINICAL OUTCOME AT 90 DAYS COMPARED TO CGC AND DLBC.
STRATIS
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GEOGRAPHIC DISTRIBUTION OF ENROLLING HOSPITALS

55 US Centers

Stratis Registry Key Primary Results
THANK YOU