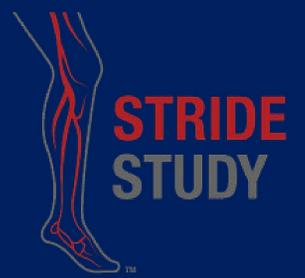


Safety and Performance of Aspiration Thrombectomy for Lower Extremity Acute Limb Ischemia: STRIDE Interim Analysis

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Background and Purpose

Reported rates of 30-day limb salvage in patients with acute limb ischemia (ALI) following surgical intervention can reach 83.1%.¹

The purpose of this interim analysis is to report safety and performance data from STRIDE (A Study of Patients with Lower Extremity Acute Limb Ischemia to Remove Thrombus with the Indigo® Aspiration System) and to evaluate the benefits of thromboaspiration in the setting of lower extremity (LE) ALI.

Methods

- **Study design:** Global, prospective, real-world, multi-center study
- **Patients included:** LE-ALI treated frontline with mechanical thrombectomy using the Indigo Aspiration System
- **Primary Endpoint:** Target limb salvage, 30 days post-procedure
- **Secondary Endpoints:** Technical success, peri-procedural
 - Flow restoration (core-lab adjudicated TIMI 2/3 flow) rate
 - Change in modified SVS runoff score, major bleeding, and device-related SAEs

Results - Baseline

- **Enrollment:** 96 Participants, 14 sites (US 12, EU 2)
- **Baseline Characteristics:**
 - Ischemic severity (n=95):
 - Rutherford I in 5.3%,
 - Rutherford IIa in 57.9%,
 - Rutherford IIb in 36.8%.
 - Mean target thrombus length:
 - 109.9±115.8mm.
 - Prior to procedure:
 - 94.5% (69/73) of patients had no flow (TIMI 0) through the target lesion.
 - Most common thrombus location was the popliteal in 66.0% (62/94) of patients, followed by the superficial femoral in 44.7% (42/94).

Results (continued) - Baseline

Demographics (All Subjects, N=96)	% (n/N) or mean ± SD
Age, years	65.9 ± 13.54
Sex, female	46.9% (45/96)
Ethnicity, Hispanic or Latino	17.6% (16/91)
Race, White	68.1% (62/91)
Race, Black or African American	24.2% (22/91)
Race, Asian	1.1% (1/91)
Medical History (N=95)	% (n/N) or mean ± SD
BMI	27.9 ± 6.13
Hypertension	83.2% (79/95)
Hyperlipidemia	73.7% (70/95)
Previous intervention on the affected limb	54.7% (52/95)
Tobacco use within last 10 years	52.6% (50/95)
Diabetes mellitus	40.0% (38/95)
Previous graft > 6 months	17.9% (17/95)
Cancer	17.9% (17/95)
Baseline Thrombus & Lesion Evaluation (All Subjects, N=96)	% (n/N) or mean ± SD or median [IQR]
Target Thrombus Length, mm	109.9 ± 115.8; 60.0 [30.0, 150.0]
Target Lesion Diameter, mm	6.0 [4.0, 7.0]
Tandem Lesion	25.8% (24/93)

Results (continued) – Primary and Secondary Outcomes

Target limb salvage rate at 30 days was 97.9% (94/96). The rate of peri-procedural major bleeding was 4.2% (4/96) and the rate of device-related SAEs was 1.0% (1/96). Technical success was achieved in 94.4% (67/71) of patients immediately post-procedure. Median [IQR] improvement in the modified SVS runoff score (pre- to post-procedure) was 5.0 [0.0, 10.0]. All-cause mortality at 30 days was 3.3% (3/92).

Primary Endpoint	n (%)
Target Limb Salvage 30-Day	97.9% (94/96)
Secondary Endpoints	% (n/N) or median [IQR]
TIMI 2/3 flow rate post procedure ¹ (Core lab assessed)	94.4% (67/71)
Improvement in Modified SVS runoff score (post- vs. pre-procedure) ²	5.0 [0.0, 10.0]
Major bleeding peri-procedure ³	4.2% (4/96)
Fasciotomy related	1 of 4
Access site related (pseudoaneurysm, retroperitoneal hematoma, access site hemorrhage)	3 of 4
Device Related SAEs ⁴	1.0% (1/96)

Conclusions

This interim analysis of STRIDE study patients demonstrated high rates of technical success and limb salvage, and low rates of periprocedural complications. Based on these results, mechanical aspiration thrombectomy provided a powerful endovascular treatment option for LE-ALI patients