High Limb Salvage Rate and Improved QoL Following Aspiration Thrombectomy with Indigo for LE ALI: 365-day Results from the STRIDE Study

Thomas Maldonado, MD[1] on behalf of the STRIDE Investigators

[1]New York University Langone Health, NY, USA

Co-authors

Thomas Maldonado, MD	New York University Langone Health, NY, USA
Alex Powell, MD	Baptist Hospital of Miami, FL, USA.
Heiko Wendorff, MD	Iinikum rechts der Isar, Munich, Germany
Jarrad Rowse, MD	University of Alabama at Birmingham, AL, USA
Khanjan H. Nagarsheth, MD	University of Maryland, MD, USA
David J. Dexter, MD	Sentara Norfolk General Hospital, VA, USA
Alan M. Dietzek, MD	Danbury Hospital, CT, USA
Patrick E. Muck, MD	TriHealth, OH, USA
Frank R. Arko, MD	Sanger Heart and Vascular Institute, NC, USA
Jayer Chung, MD	Baylor College of Medicine, Texas, USA

Presenter's Disclosures

- Consultant for Penumbra. National PI of STRIDE

Objective: Collect safety and performance data on the Indigo Aspiration System in a patient population with lower extremity acute limb ischemia (LE-ALI)

ClinicalTrials.gov ID: NCT04144959

- PI: Thomas Maldonado (NYU Langone Health, New York, USA)
- 16 sites (13 US, 3 EU)
- 119 patients (55 female, 64 male)
- Primary safety endpoint:
  - Target limb salvage (TLS) at 30 days post-procedure
- Key secondary safety and performance endpoints:
  - Technical success, patency at 30 days, TLS at 365 days, periprocedural major bleeds, mortality at 365 days
- 365-day follow-up

Indigo Aspiration System
Computer Assisted Vacuum Thrombectomy (CAVT) with Lightning

Penumbra ENGINE® pump with Lightning Aspiration Tubing

- Continuous aspiration when engaged in thrombus
- Intermittent aspiration in patent vessel to minimize blood loss

In the STRIDE Study, Lightning was used in 43.7% (52/119) patients.*

*CAT6 usage was 31.9% (38/119) and CAT8 usage was 35.3% (42/119).

Key Eligibility Criteria

Key inclusion criteria

- Acute (≤14 days) occlusion of lower limb artery(ies) (below inguinal ligament)
- Rutherford Category I, IIa or IIb score
- Firstline treatment with Indigo Aspiration System
- ≥18 years old

Key exclusion criteria

- Target vessel size <2 mm
- Amputation in the ipsilateral limb
- Target thrombus in a saphenous vein bypass graft
- Absolute contraindication to contrast administration
- Life expectancy of <1 year

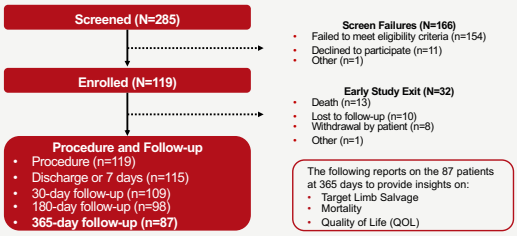
Primary & Secondary Endpoints

Primary performance endpoint
- Target limb salvage at 30 days post-procedure

Secondary performance endpoints
- Technical success (TIMI 2/3 flow rate immediately post-procedure)
- Improvement in modified SVS runoff score immediately post-procedure
- Improvement of Rutherford classification
- Patency at 30 days
- Target limb salvage at 365 days

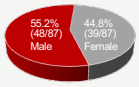
Secondary safety endpoints
- Device-related serious adverse events
- Periprocedural major bleeding
- Mortality at 365 days

Patient Enrollment



Baseline | Demographics & Medical History
365-day Cohort

- **Similar demographics between 30-day (N=119) and 365-day (N=87) cohorts**
- **Near equal sex distribution**

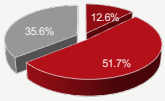


Demographics	(N=87)
Age (yrs, mean ± SD)	65.0 ± 13.31
Sex, female	**44.8% (39/87)**
Medical History	**(N=87)**
BMI (kg/m^2, mean ± SD)	28.1 ± 6.52 (N = 86)
Hypertension	85.1% (74/87)
Coronary Artery Disease	33.3% (29/87)
Atrial Fibrillation	19.5% (17/87)
Hyperlipidemia	83.9% (73/87)
Previous intervention on the affected limb	58.6% (51/87)
Tobacco use within last 10 years	52.9% (46/87)
Diabetes mellitus	36.8% (32/87)
Renal failure/ insufficiency	6.9% (6/87)
Previous graft > 6 months	21.8% (19/87)

Baseline | Thrombus, Lesion, & Clinical Severity
365-day Cohort

Thrombus & Lesion Evaluation	Mean ± SD or % or range (min, max)
Target Thrombus Length (N=82)	126.9 mm ± 130.18 range (3.0, 627.0)
Target Lesion Diameter (N=73)	5.4 mm ± 1.91 range (1.0, 10.0)
Tandem Lesion	17.2% (15/87)

Baseline Rutherford

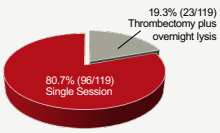


- I- Viable
- IIa- T hreatene d Marginally
- IIb- T hreatene d Immediately

Peri-Procedural Characteristics

Procedural Characteristic	
<400 cc Estimated Blood Loss Volume[1], % (n/N)	82.7% (96/116)
Median Indigo Aspiration Time[2] [IQR] (minutes) (n=83)	22.0 [12.0, 47.0]
Overnight IA rtPA, % (n/N)	19.3% (23/119)
Hospital Stay	
Patient had an ICU stay, %(n/N)	30.3% (36/119)
Median length of ICU stay [IQR] (days) (n=36)	2.5 [1.5, 4.4]

Adjunctive thrombolytics permitted at the discretion of the treating physician



60.5% (72/119) of STRIDE patients received no lytics at all

[1] Estimated blood loss was calculated by subtracting the amount of saline flush used from the total amount of aspirated material in the canister.
[2] Time from first Indigo Aspiration Catheter insertion to last Indigo Aspiration Catheter removal.

Results – 30-day Outcomes Summary

Primary Endpoint	% (n/N)
Target Limb Salvage at 30 days	**98.2% (109/111)**
Secondary Endpoints and Other Outcomes	**% (n/N) or Mean ± SD or range (min, max)**
Technical Success	**96.3% (105/109)**
Patency at 30 days	89.4% (101/113)
Improvement in Modified SVS runoff score (pre- vs. post-procedure)	6.3 ± 5.49 Range (-1.0, 18.0)
Major bleeding, peri-procedural[1]	4.2% (5/119)
Device-related SAEs[2]	0.8% (1/119)
Mortality at 30 days	3.4% (4/119)

[1] Major bleeding, peri-procedural: defined as bleeding w/n 2d of procedure, which is fatal or leads to drop in hemoglobin of ≥5 g/dL or significant hypotension requiring inotropes, or requires surgery (other than vascular site repair), or symptomatic intracranial hemorrhage, or requires transfusion of 2 or 3 units of RBC or equivalent whole blood. Events (3) include: (i) retroperitoneal bleed on heparin, (ii) access site hemorrhage, (iii, iv) anemia requiring transfusion 2x, (v) pseudoaneurysm.
[2] Related is Definite or Probable relatedness. All events until study exit noted.

Primary endpoint of TLS met at 30 days.

Published in *JVS*:

Results – 365-day Outcomes

Efficacy endpoint	% (n/N)
Target Limb Salvage at 365 days	88.5% (77/87)
Safety endpoint	**% (n/N)**
Mortality at 365 days	12.0% (12/100)
Patient-reported Quality of Life	**Median (p-value)**
VascuQoL-6 overall score improvement	7.0 (p < 0.001)

- Higher TLS rate at 365 days than historical literature rates for CDT and open surgery (57.5%-87%; 65.4%-82%)[1,2,3]
- 76.6% (49/64) patients achieved an important benefit (VascuQol-6 improvement of at least 3.0 points)

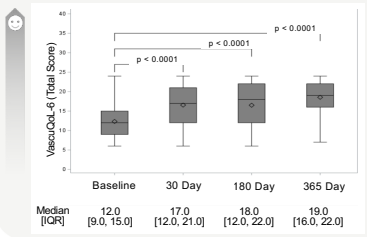
[1] Investigators TS. Results of a prospective randomized trial evaluating surgery versus thrombolysis for ischemia of the lower extremity. The STILE trial. Ann Surg. 1994;220(3):251-66; discussion 66-8.
[2] Durial K, Veith FJ, Sasahara AA. Thrombolysis or peripheral arterial surgery: phase I results. TOPAS Investigators. J Vasc Surg. 1998;23(1):64-73; discussion 4-5.
[3] Taha AG, Byrne RM, Avgerinos ED, Marone LK, Makaroun MS, Chaer RA. Comparative effectiveness of endovascular versus surgical revascularization for acute lower extremity ischemia. J Vasc Surg. 2015;61(1):147-54.

Historical control surgical outcomes vs. STRIDE

Outcome	Open Surgery	STRIDE
Target Limb Salvage at 30 days	83.1%[1]	**98.2% (109/111)**
Target Limb Salvage at 365 days	65.4%-82%[2,3,4]	**88.5% (77/87)**
Patency at 30 days	78.6%[5]	**89.4% (101/113)**
Mortality at 30 days	13.2%[6]	**3.4% (4/119)**
Mortality at 365 days	4.9%–42%[2,3,4]	**12.0% (12/100)**
Major bleeding	21.0%[7]	**4.2% (5/119)**

[1] Veenstra EB, van der Laan MJ, Zeebregts CJ, de Heide EJ, Kater M, Bokkers RPH, et al. A systematic review and meta-analysis of endovascular and surgical revascularization techniques in acute limb ischemia. J Vasc Surg. 2020 Feb;71(2):654–668.e3. doi: 10.1016/j.jvs.2019.05.031. [2] Grip O, Wanhainen A, Michaelsson K, Lindhagen L, Björck M. Open or endovascular revascularization in the treatment of acute lower limb ischaemia. Br J Surg. 2018 Nov;105(12):1598-1606. doi: 10.1002/bjs.10954. [3] Taha AG, Byrne RM, Avgerinos ED, et al. Comparative effectiveness of endovascular versus surgical revascularization for acute lower extremity ischemia. J Vasc Surg. 2015 Jan;61(1):147–54. doi: 10.1016/j.jvs.2014.08.109. [4] Kolte D, Kennedy KF, Shishehbor MH, Mamdani ST, Stangenberg L, Hyder ON, et al. Endovascular Versus Surgical Revascularization for Acute Limb Ischemia: A Propensity-Score Matched Analysis. Circ Cardiovasc Interv. 2020;13(1):e008150.

Results – Overall VascuQoL-6 score



- Overall score improvement of 7.0 points driven by improvements across all 6 domains
- 76.6% exceeded minimal important difference threshold* for important benefit

VascuQoL Overall Improvement
Activity I | II Improvement
Symptom | Pain Improvement
Social | Emotional Improvement

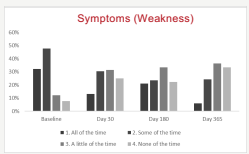
*Utilizing a distribution-based approach to determining MID for VascuQoL-6 in STRIDE ALI population, an important benefit was calculated to be an increase of 3 or more points.

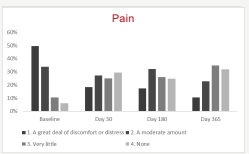
Results – Overall VascuQoL-6 score

VascuQoL Overall Improvement
Activity I | II Improvement
Symptom | Pain Improvement
Social | Emotional Improvement

Severity of activity limitations improved from baseline though 365-days.

Results – Overall VascuQoL-6 score

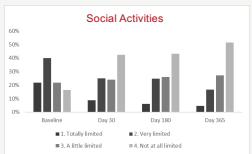




VascuQoL Overall Improvement
Activity I | II Improvement
Symptom | Pain Improvement
Social | Emotional Improvement

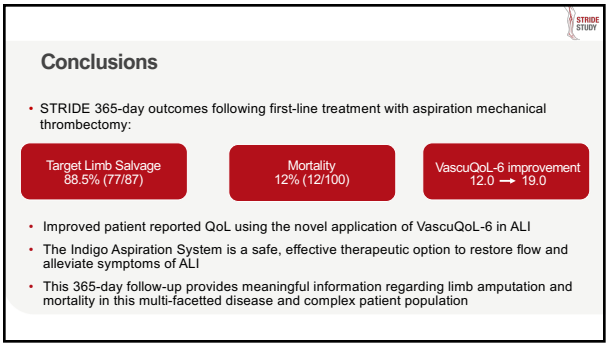
Severity of symptoms and pain improved from baseline though 365-days.

Results – Overall VascuQoL-6 score



VascuQoL Overall Improvement
Activity I | II Improvement
Symptom | Pain Improvement
Social | Emotional Improvement

Severity of emotional or social impact improved from baseline though 365-days.


STRIDE STUDY
Conclusions
• STRIDE 365-day outcomes following first-line treatment with aspiration mechanical thrombectomy:
Target Limb Salvage 88.5% (77/87)
Mortality 12% (12/100)
VascuQoL-6 improvement 12.0 → 19.0
• Improved patient reported QoL using the novel application of VascuQoL-6 in ALI
• The Indigo Aspiration System is a safe, effective therapeutic option to restore flow and alleviate symptoms of ALI
• This 365-day follow-up provides meaningful information regarding limb amputation and mortality in this multi-facetted disease and complex patient population