

Kosmas I. Paraskevas, MD, PhD

Department of General and Vascular Surgery
Central Clinic of Athens
Athens, Greece

On behalf of the RIV "Red de Investigación Vascular de la SEACV"

REFERENCES

1. Lin JH, Jeon SY, Romano PS, Humphries MD. Rates and timing of subsequent amputation after initial minor amputation. *J Vasc Surg* 2020;72:268-75.
2. Kumbhani DJ, Steg PG, Cannon CP, Eagle KA, Smith SC Jr, Goto S, et al; REACH Registry Investigators. Statin therapy and long-term adverse limb outcomes in patients with peripheral artery disease: insights from the REACH registry. *Eur Heart J* 2014;35:2864-72.
3. Baubeta Fridh E, Andersson M, Thuresson M, Sigvant B, Kragsterman B, Johansson S, et al. Editor's choice—impact of comorbidity, medication, and gender on amputation rate following revascularisation for chronic limb threatening ischaemia. *Eur J Vasc Endovasc Surg* 2018;56:681-8.
4. Vogel TR, Dombrovskiy VY, Galinanes EL, Kruse RL. Preoperative statins and limb salvage after lower extremity revascularization in the Medicare population. *Circ Cardiovasc Interv* 2013;6:694-700.
5. Kokkinidis DC, Arfaras-Melainis A, Giannopoulos S, Katsaros I, Jawaid O, Jonnalagadda AK, et al. Statin therapy for reduction of cardiovascular and limb-related events in critical limb ischemia: a systematic review and meta-analysis. *Vasc Med* 2020;25:106-17.

<https://doi.org/10.1016/j.jvs.2020.07.099>

Reply



Thank you Paraskevas et al for your thoughts considering this subject. Given that our study used an administrative database from the state of California allowing us to identify amputation rates among different patient populations, it is limited by the lack of granular patient level data pertaining to statin use among these different patient groups. Although we are not able to contribute an answer to your question with our data, we believe that a subgroup analysis with patients taking statins would demonstrate a higher limb salvage rate as there are data supporting its use in patients with peripheral artery disease (PAD) with and without diabetes. Specifically, Arya et al¹ conducted a retrospective study using Veterans Affairs data in which they compared the mortality and amputation outcomes in 155,647 patients with PAD who were treated with high- and low-intensity statins with patients treated with antiplatelet medication alone. On adjusted Cox modeling, any use of statins was associated with lower risk of mortality (high: hazard ratio [HR], 0.74; confidence interval [CI], 0.70-0.77; low: 0.83; CI, 0.81-0.86) and amputation (high: HR, 0.67; CI, 0.61-0.74; low: 0.81; CI, 0.75-0.86). Further, on subgroup analysis, any statin use in patients with PAD and diabetes

mellitus (DM) was associated with lower risk of mortality (high: HR, 0.76; CI, 0.72-0.8; low: 0.84; CI, 0.81-0.87) and amputation (high: HR, 0.75; CI, 0.68-0.82; low: 0.86; CI, 0.81-0.93). There was a similar benefit observed in patients without diabetes.¹ In addition, in another retrospective study using Veterans Affairs data evaluating 83,593 patients with DMI or DMII, the authors observed that the use of statins was associated with a lower risk of major amputation (HR, 0.645; CI, 0.420-0.991) after adjusting for comorbid conditions including PAD.² To close, the 2016 AHA/ACC guidelines give a strong recommendation for the addition of statin therapy to all patients with PAD given its benefits in both cardiovascular and limb outcomes, and it is our current practice to work closely with the primary care providers to ensure that these patients are on an optimal dose of statins.³

Jonathan H. Lin, MD

Misty D. Humphries, MD, MAS

Division of Vascular Surgery
Davis Medical Center
University of California
Sacramento, Calif

On behalf of the RIV "Red de Investigación Vascular de la SEACV"

REFERENCES

1. Arya S, Khakharia A, Binney ZO, DeMartino RR, Brewster LP, Goodney PP, et al. Association of statin dose with amputation and survival in patients with peripheral artery disease. *Circulation* 2018;137:1435-46.
2. Sohn MW, Meadows JL, Oh EH, Budiman-Mak E, Lee TA, Stone NJ, et al. Statin use and lower extremity amputation risk in nonelderly diabetic patients. *J Vasc Surg* 2013;58:1578-85.e1.
3. Gerhard-Herman MD, Gornik HL, Barrett C, Barshes NR, Corriere MA, Drachman DE, et al. 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation* 2017;135:e726-79.

<https://doi.org/10.1016/j.jvs.2020.08.026>

Indigo aspiration thrombectomy for treating acute lower limb ischemia: Technical considerations



We have read with great interest the recently reported article by Lopez et al¹ regarding their experience with Indigo System (IS; Penumbra, Alameda, Calif) aspiration thrombectomy for acute lower limb ischemia (ALLI) with a technical success rate of 52%.

The study by Lopez et al¹ is one of the first single-center experiences after the well-known PRISM trial.² In the PRISM trial, the success of the procedures was reported using the Thrombolysis in Myocardial Infarction score,³ allowing for an objective evaluation. In contrast, Lopez

et al¹ selected the definition of technical success as blood flow restoration to the ischemic limb with <50% residual thrombus, and as they stated, this measurement could be perceived as subjective.

The IS consists of an aspiration pump, five different aspiration catheters ranging from 3.4F to 8F, and a separator wire. These intrinsic characteristics lead to some technical considerations that were not described in their report, such as the type of device used in different vessels and whether they had used the separator wire. In our experience, the choice of the caliber of the CAT device is of crucial importance for clot removal and, in particular, in the femoral district in which a mismatch can be present between the vessel diameter and device size. Regarding the separator, our impression has been that it can help in the case of a larger clot by allowing for catheter patency during the aspiration maneuver.

Another technical aspect we would like to focus on is the vascular access to be used: the antegrade or retrograde approach with short or long sheaths. We think that the antegrade common femoral artery approach, even for the CAT8 catheter, should be preferred when possible because it increases overall control of the endovascular devices.

A main issue when treating patients with ALLI is symptom onset. Using the IS, we can observe the benefits of early treatment after symptoms have appeared.

In conclusion, the IS device is very promising for treating ALLI; however, the optimal treatment time and standardization of the techniques should be determined.

Marcello Andrea Tipaldi, MD

Florindo Laurino, MD

Michele Rossi, MD, PhD

Division of Interventional Radiology
Department of Surgical and Medical Sciences and Translational Medicine
Sapienza University of Rome – Sant'Andrea University Hospital
Rome, Italy

On behalf of the RIV "Red de Investigación Vascular de la SEACV"

REFERENCES

1. Lopez R, Yamashita TS, Neisen M, Fleming M, Colglazier J, Oderich G, et al. Single-center experience with Indigo aspiration thrombectomy for acute lower limb ischemia. *J Vasc Surg* 2020;72:226-32.
2. Saxon R, Benenati J, Teigen C, Adams G, Sewall L. Utility of a power aspiration-based extraction technique as an initial and secondary approach in the treatment of peripheral arterial thromboembolism: results of the multicenter PRISM trial. *J Vasc Interv Radiol* 2018;29:92-100.
3. Chesebro JH, Knatterud G, Roberts R, Borer J, Dalen LS, Dodge HT, et al. Thrombolysis in Myocardial Infarction (TIMI) trial, phase I: a comparison between intravenous tissue plasminogen activator and intravenous streptokinase. *Clinical findings through hospital discharge. Circulation* 1987;76:142-54.

<https://doi.org/10.1016/j.jvs.2020.08.024>

Reply



We appreciate the important comments by Tipaldi et al and thank them for their interest in our work. We acknowledged the limitation of technical success for acute lower limb ischemia with the Indigo aspiration mechanical thrombectomy device in our paper. Technical success was defined as restoration of blood flow to the ischemic limb with <50% residual thrombus, without the need to initiate catheter-directed thrombolysis or proceed to open surgery. We recognize that this may be perceived as subjective, because it is our interpretation of the available clinical documentation. Thrombolysis in Myocardial Infarction score was not defined by the proceduralists at the time and therefore was not used in our research because of lack of key data such as blood flow velocity. Intravascular ultrasound was not performed in many cases. However, we feel that our end point is equivalent to Thrombolysis in Myocardial Infarction score grade 3 or higher, and can be used by the readership to assess the outcomes reported and the degree of flow restoration.

Our study was focused on our initial clinical outcomes and complications for treatment of acute lower limb ischemia with Indigo aspiration mechanical thrombectomy. Technical considerations were not the primary focus of our study. Nevertheless, we briefly discussed a few technical aspects such as selection and availability of catheter size at the time of our study (ie, CAT 3, CAT 5, CAT 6, and CAT 8). Separator use was not specifically recorded to accurately report. However, nearly all cases are from retrograde femoral access. Also, over time larger catheters were used as they became available for better thrombus removal. Tipaldi et al point out several technical considerations in their letter that may be of clinical benefit. We agree that with all new technology, techniques will evolve and outcomes will improve as it is used to its maximum potential.

Ricardo Lopez, MD

Department of Radiology
Mayo Clinic
Rochester, Minn

Randall R. DeMartino, MD, MS

Division of Vascular and Endovascular Surgery
Mayo Clinic
Rochester, Minn

On behalf of the RIV "Red de Investigación Vascular de la SEACV"

<https://doi.org/10.1016/j.jvs.2020.08.025>