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New data adds to body of research demonstrating safety and effectiveness of atherectomy

Comparative data and systematic literature review released at VIVA 2024 show breadth and depth of data supporting atherectomy as a treatment for peripheral arterial disease

Medtronic, the global leader in healthcare technology, today announced results from two studies evaluating the utility of atherectomy for peripheral endovascular interventions. Results from both analyses were released at the Vascular InterVentional Advances (VIVA) 2024 conference in Las Vegas.

The Total REALITY study, a late-breaking presentation, retrospectively compared directional atherectomy (DA) versus balloon predilatation prior to drug-coated balloon (DCB) treatment of long, calcified femoropopliteal lesions. Additionally, results from a systematic literature review and meta-analysis, including 305 published clinical studies on atherectomy, were released.

"The data presented at VIVA this week helps to reinforce the use of atherectomy in appropriately selected lesions, and further affirms the breadth of data demonstrating its safety and effectiveness," said Dr. John Laird, chief medical officer of the Peripheral Vascular Health business, which is part of the Cardiovascular Portfolio at Medtronic. "This adds further documentation on directional atherectomy that our clinical community has been seeking and supports our commitment to providing evidence to inform treatment decisions."

Total REALITY Study

The Total REALITY study combined data from the VIVA REALITY[1] study and the Total IN.PACT[2] dataset, in order to address the need for more comparative data regarding atherectomy for femoropopliteal lesions. The results, which were presented by Dr. Venita Chandra, director of vascular surgery, Stanford University School of Medicine, showed that DA followed by DCB achieved a significantly lower provisional stent rate with comparable safety and efficacy outcomes compared to standard predilatation prior to DCB, making it a viable alternative for treating long and highly calcified lesions.

REALITY patients treated with DA+DCB (n=84) were propensity score matched to eligible patients treated with PTA+DCB from the Total IN.PACT dataset (n=143). While the groups were mostly well-matched on other patient and lesion characteristics, there were significant differences in severe calcification (PACSS 4) even after matching (71.4% DA+DCB versus 5.9% PTA+DCB, P <0.001).

Key findings include:

- One-year primary patency (freedom from both clinically driven target lesion revascularization and duplex ultrasound-derived restenosis) did not differ between groups, despite the significant difference in baseline calcification.
- In the DA+DCB arm, there was a trend toward higher stent-free patency through 12 months (79.1% versus 68.1%,
- *P*=0.09) and a significantly lower provisional stenting rate (9.5% versus 21.1%, *P* =0.014).
- Major adverse limb events (target vessel revascularization, major target limb amputation, and target lesion thrombosis) through 12 months did not differ between groups.

Total REALITY underscores the complexity and high calcification burden of lesions included in the REALITY study. Despite having significantly greater baseline calcification, DA+DCB achieved a significantly lower provisional stent rate with comparable safety and efficacy outcomes compared to PTA+DCB. These results show that DA followed by DCB is a viable, safe, and effective alternative to DCB with standard predilatation, even when treating long and highly calcified lesions, while reducing the need for permanent implants.

Atherectomy Systematic Literature Review

The atherectomy systematic literature review and meta-analysis evaluated the amount and rigor of published data on atherectomy. The analysis identified 305 original research papers reporting outcomes on atherectomy for endovascular treatment of occlusive or stenotic disease in native, infrainguinal, peripheral arteries through May 2024. The highest levels of evidence were represented, including 11 meta-analyses, 19 papers on randomized trials, and 94 papers on prospective observational studies; in addition; there were 136 retrospective observational study papers and 45 case study papers.[†] Most studies (86%) evaluated atherectomy in addition to an adjunctive definitive therapy, most commonly uncoated balloons and DCBs.

Key findings from the literature review include:

- One-year patency (defined as freedom from target lesion revascularization [TLR] or freedom from restenosis determined by angiography or duplex ultrasound) was 76.5% among 42 observational studies (4,195 patients) and 72.7% among 6 randomized controlled trials (RCTs) (172 patients), comparing favorably to published meta-analysis rates for uncoated balloon angioplasty (47.4% across 10 RCTs),[3] and DCB without atherectomy (67.6% in observational studies and 67.9% in RCTs).[3]
- One-year rates of TLR (16.6% in 56 observational studies, 10.8% in 10 RCTs), major amputation (1.7% in 58 observational studies, 0.9% in 11 RCTs), and mortality (2.8% in 52 observational studies, 2.2% in 11 RCTs) were also similar or better than meta-analysis rates for balloon angioplasty or DCB, with variations based on study design and artery level.[3-6]
- Compared to uncoated balloon or DCB rates ranging from 9.1% to 20.2%,[3,4] bailout stenting rates were low following atherectomy in both observational studies (9.3% across 112 studies with 11,731 patients) and RCTs (8.9% across 13 studies with 721 patients).

“These results show that published evidence supports the use of atherectomy as part of the endovascular treatment algorithm for peripheral arterial disease with publications at the highest level of evidence,” said Jeffrey Carr MD, CHRISTUS Health Heart and Vascular Institute, Tyler, TX.

References

[1] Rocha-Singh KJ, et al. Catheter Cardiovasc Interv. 2021;98:549-558.

[2] Shishehbor MH, et al. J Vasc Surg. 2019;70:1177-1191 e1179.

[3] Caradu C, et al. J Vasc Surg. 2019;70:981-995 e910.

[4] Mustapha JA, et al. Circ Cardiovasc Interv. 2016;9:e003468.

[5] Cai H, et al. J Surg Res. 2022;278:303-316.

[6] Dinh K, et al. J Endovasc Ther. 2021;28:755-777.

† Meta-analyses and case studies (single-patient, or series with <10 patients with no aggregate data) were included in the literature review but excluded from the meta-analysis. Database studies (e.g., Medicare, Vascular Quality Initiative) on identical patient cohorts were excluded from the meta-analysis to prevent redundant reporting. Papers included directional atherectomy (119 papers), rotational atherectomy (67 papers), laser atherectomy (42 papers), and orbital atherectomy (30 papers). An additional 47 papers evaluated multiple atherectomy classes in the same study.

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https://news.medtronic.com/New-data-adds-to-body-of-research-demonstrating-safety-and-effectiveness-of-atherectomy