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Review and commentary of key non-JVS articles

Absence of Long-term Benefit of Revascularization in Patients With Intermittent Claudication: Five-Year Results From the IRONIC Randomized Controlled Trial



Djerf H, Millinger J, Falkenberg M, Jivegard L, Svensson M, Nordanstig J. *Circ Cardiovasc Interv* 2020;13:e008450.

Study design: Open-label, prospective, randomized trial from Sweden (Invasive Revascularization or Not in Intermittent Claudication [IRONIC]) enrolled between March 2010 and November 2012.

Key findings: After 5 years, there were no differences in quality of life or treadmill walking distance for 116 patients with mild to severe claudication randomized to revascularization plus best medical therapy plus structured exercise therapy (revascularization group) vs best medical therapy plus structured exercise (nonrevascularization group) who completed the primary end point. Medical therapy included cilostazol (Pletal) in both groups. Revascularization was associated with twice the cost per patient compared with noninvasive treatment (\$13,000 vs \$7000).

Conclusion: Revascularization lost its early benefit after 5 years and did not result in long-term improvement in quality of life or walking capacity compared with noninvasive treatment. Revascularization is not a cost-effective treatment option.

Commentary: If the findings of this study are to be believed, we should not perform endovascular or surgical interventions for claudication. I question the conclusions of this study. If a patient undergoes endovascular therapy or an arterial bypass for disabling claudication, subsequently walks as far as he or she wants for 4 years, and then the stent or graft occludes, wouldn't the patient say the intervention greatly improved his or her quality of life for 4 years but not at 5 years? The authors admit that intervention resulted in improved quality of life at least during the first 2 years. Since the COVID-19 crisis, I have been sitting in front of my computer for many hours for many days and my lower back is killing me. If spine surgery would completely relieve my low back pain for 4 years but not 5, I think I would do it. The real question is how much intervention improved patients' quality of life *during* the 5 years after intervention, not necessarily *at* 5 years.

There are four significant weaknesses of this paper. First, the authors point out that their study targeted patients with "mild to severe" claudication. Obviously, mild claudicants will not benefit from intervention, just as patients with "mild" carotid artery disease will not benefit from carotid intervention. None of us, it is to be hoped, would offer intervention to patients with mild claudication anyway. Second, the authors excluded patients with "very severe claudication." These are patients most likely to benefit from intervention. Third, TransAtlantic Inter-Society Consensus (TASC) A to C lesions were treated only with endovascular intervention and TASC D lesions only with surgery. I question how many patients with TASC C lesions might have done better with surgery. Fourth, patients were allowed to crossover to the intervention arm after 6 months if their claudication continued to be disabling. Were these patients considered to have complete failure of conservative treatment?

I concede we should encourage smoking cessation and supervised exercise programs more than we do. But I have felt very rewarded after performing vascular intervention for claudicants who could not walk a block but who later returned for surveillance studies grateful they could walk as far as they wanted for 5 and, dare I say, even for 10 years after the intervention.

Prognostic Value of Clinical and Morphologic Findings in Patients With Type B Aortic Intramural Hematoma



Li Z, Liu C, Wu R, Zhang J, Pan H, Tan J, et al. *J Cardiothorac Surg* 2020;15:49.

Study design: Retrospective single-center study from China between September 2013 and October 2017.

Key findings: Of 71 patients admitted with type B intramural hematoma (IMH), 29% (6/21) with only IMH underwent endovascular intervention compared with 80% (40/50) of patients with penetrating aortic ulcers (PAUs). Approximately one-quarter of patients with PAU underwent repair for asymptomatic ulcers with a width >15 mm or depth >10 mm. Based on multivariate analysis, PAU and maximum aortic diameter were independent risk factors for death. For patients with PAU-IMH, aortic diameter was an independent risk factor and intervention was an independent protective factor.

Conclusion: Independent risk factors for type B IMH are PAU and maximum aortic diameter. Intervention may improve outcomes for type B IMH in association with PAU.

Commentary: Acute aortic syndrome is defined as an acute aortic lesion with symptoms <14 days old. This entity includes aortic dissection, IMH, limited intimal tear, and PAU. IMH is a crescentic or circumferential thickening of the aortic wall without an entry point, such as an intimal tear. IMH may progress to aortic dissection and aneurysm formation. Depending on the population, the frequency of IMH compared with typical aortic dissection varies from 10% (North America/Europe) to 32% (Japan/Korea). PAU is a focal disruption in the intima protruding into the media and appears as a localized outpouching of the endoluminal border.

Optimal medical therapy in this study consisted of beta blockers and other antihypertensive drugs. Patients with hemodynamically stable type B IMH were treated only with medical therapy. For PAU-IMH, intervention was considered if the ulcer was >15-mm wide or >10-mm deep, which was the sole indication in about a quarter of these patients. The authors are suggesting that patients with type B PAU-IMH should be strongly considered for intervention. Because of small sample size, the authors could not establish a cutoff value for aortic diameter to determine increased risk. This study included only Chinese patients, so these findings may not apply across populations.

I previously reviewed an article for *Venous Vantage Point* (November 2018) confirming that management of acute aortic syndrome, regardless of type, includes urgent surgical repair for type A lesions (ascending aorta) and optimal medical management for uncomplicated type B lesions (not involving the ascending aorta).¹ The authors of this paper suggest a more aggressive approach, specifically for asymptomatic PAUs with a width >15 mm or depth >10 mm. I would lean toward the more conservative approach.

REFERENCE

1. Chin AS, Willeminck MJ, Kino A, Hinostrroza V, Sailer AM, Fischbein MP, et al. Acute limited tears of the thoracic aorta. *J Am Coll Cardiol* 2018;71:2773-85.

Long-term Efficacy of EVAR in Patients Less Than 65 Years With an Infraarenal Abdominal Aortic Aneurysm and Favourable Anatomy



Gallitto E, Faggioli G, Mascoli C, Spath P, Pini R, Ricco JB, et al. *Ann Vasc Surg* 2020 Apr 10. [Epub ahead of print]

Study design: Retrospective single-center study between 2005 and 2013.

Key findings: In 115 patients <65 years with infraarenal abdominal aortic aneurysms, 58 patients underwent endovascular aneurysm repair (EVAR) according to instructions for use (IFU) and 57 underwent open surgical repair (OSR) with infraarenal aortic clamping. There were no significant differences in 30-day mortality rates (EVAR, 0%; OSR, 2%), 10-year survival (EVAR, 79%; OSR, 70%), or 10-year freedom from reintervention rates (EVAR, 81%; OSR, 74%). Compared with OSR, patients who underwent EVAR were significantly more obese (38% vs 19%) and less likely to require intensive care unit (ICU) stay (19% vs 79%) or to receive blood transfusions (236 mL vs 744 mL); they had significantly shorter hospital stays (4 vs 9 days), fewer 30-day reinterventions (0% vs 8%), and lower rates of postoperative retrograde ejaculation (2% vs 31%).