Managing the Claudicant: Are We Too Aggressive?

Some healthy introspection based on the current literature.

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Think about your typical day and the activities for which you rely on your legs to get you from one place to the next, whether for work, exercise, or routine tasks such as grocery shopping, work around the house, or event attendance. Now imagine doing the same daily activities with some degree of pain in one or both of your legs. The limitations that even moderate discomfort or pain might impose on our daily routines make it easy to empathize with patients who are experiencing intermittent claudication.

This understanding of our patients' daily hardships increases our desire to lessen or, ideally, resolve the lower extremity vascular disease that can sometimes be the source. A patient reporting relief of symptoms at follow-up visits is rewarding and encouraging, but a variety of factors compounding long-term outcomes provide reason for considering when these treatments are truly warranted.

This is a dilemma that has plagued the vascular interventionist since the emergence of percutaneous angioplasty as an alternative to bypass (or no therapy at all, in noncandidates). Interventionists have become the providers of many different treatment options, such as angioplasty, atherectomy, laser, cutting balloons, stents, drug-eluting stents, drug-coated balloons, and more. Although it is gratifying to provide effective patient care using these therapies—a gratification often reinforced by amazing angiographic results—the overapplication of these procedures can inflate the cost and decrease the quality of care for what is a relatively benign disease process in the majority of patients. Further compounding the issue is the lack of clearly demonstrated long-term benefits compared to conservative approaches in some lesion and symptom presentations.

In many ways, the technology has usurped the patient's role in his/her own care, which we know can be a more significant factor in long-term outcomes than the device we choose and how well we perform the procedure.

Let's consider a hypothetical case: A patient returns to the office for follow-up, walking much more comfortably after placement of a superficial femoral artery (SFA) stent. However, he continues to smoke and lead a sedentary lifestyle. How many times have we witnessed this either in our own practices or while giving a second opinion? Next, consider the patient who returns to the office with a new SFA stent and no improvement. In our practice, we see many patients who seek second opinions for failed interventions with an eventual diagnosis of lumbosacral spine disease and other musculoskeletal processes causing leg discomfort. Each of these cases demonstrates a situation when the ability to "do something" superseded an evaluation of the necessity to intervene in the first place.

Many cases are difficult to define or remediate, but some interventions performed are baseless and concerning. Somewhere along the way, our ability has overshadowed our patients' real needs. With this article, we do not intend to define standards for when peripheral arterial disease (PAD) patients should or should not be treated, but rather, to look at what we currently know and ask ourselves which cases require invasive treatment before deciding what that treatment should be. Let's consider this issue in its basic elements.

THE BASICS

In the claudicant, blood flow that supports skeletal muscle metabolism at rest becomes inadequate during exertion secondary to stenoses or occlusions to flow. Specific symptoms arise from lesions at each level only when oxygen demand of the muscle bed increases (walking, running, climbing stairs, etc.). One can often predict a lesion's location or severity based on symptoms alone. For example, iliac occlusive disease

TABLE 1. CATEGORIES OF PAD[1]	
Rutherford Category	Presentation
0	Asymptomatic
1	Mild claudicant
2	Moderate claudicant
3	Severe claudicant
4	Ischemic rest pain
5	Minor tissue loss
6	Ulcer/gangrene

is thought to primarily be associated with buttock, hip, and thigh pain. Femoral-level disease is classically associated with thigh and calf pain, whereas tibial disease can present as calf or foot pain and numbness.

The well-defined natural history of claudication, as we must first reassure patients, does not progress to limb loss.[1] However, the atherosclerotic disease process is systemic, and more patients with claudication die from cardiac events and suffer nonhemorrhagic CVA than age-matched controls.[1]

The workup of the claudicant begins with a history and physical exam, including documentation of the quality of all pulses and listening for bruits in the femoral, carotid, and abdominal regions. Noninvasive testing can then be ordered for further workup or as a baseline for the patient at follow-up.

Ankle-brachial indices (ABIs) should be measured in all patients presenting with intermittent claudication–type symptoms, although ABI correlates weakly with actual walking distance in treadmill-based testing secondary to the typical comorbidities within the vascular patient population.[2] Toe pressures in the diabetic patient, pulse volume recordings, and an accurate symptom history are usually enough to delineate the patient's issues.

HOW DO WE MEASURE SEVERITY?

Rutherford categories describe the spectrum of PAD (Table 1). Among these patients, claudicants present the most significant challenges to management, because symptom severity is subjective. To translate "severity" from qualitative to quantitative requires careful and directed discussion at the initial clinic visit. Khaira et al showed that in 100 patients matched between claudicants and controls, the former group presents with lower scores in energy, pain, sleep, mobility, and emotional health ($P < .05$).[3] The inability to perform Activities of Daily Living reliably correlates with the worst quality-of-life (QOL) scores. Table 2 lists some sample questions to help delineate severity and QOL impact. It is surprising how many patients are actually reassured that pressing on, in the midst of their active claudication, is not dangerous and can often be therapeutic when combined with risk-factor modification.

TABLE 2. QUESTIONS TO GUIDE DETERMINATION OF SEVERITY		
Sample Questions	Mild-Moderate Claudicant Answer	Severe Claudicant Answer
Can you do what you need to for your employment?	Yes	No
Can you maintain Activities of Daily Living (eg, cooking, cleaning, self-care)?	Yes	No
Does worrying about your walking ability interfere with your sleep/mood/energy levels?	No	Yes
Do you consider this discomfort disabling?	No	Yes
Are you willing to accept the risks of major surgery to be free of this discomfort?	No	Yes
Are you willing to accept that reintervention is expected?	No	Yes
Will you follow-up regularly?	Yes/No	Yes
Are you willing to commit to an exercise program?	Yes	Yes
Are you willing to quit smoking?	Yes	Yes

TABLE 3. COMPONENTS OF MEDICAL MANAGEMENT	
Absolute	Relative
Smoking cessation	Smoking cessation (ie, no change)
Exercise program	Supervised exercise program
Blood pressure management	Beta blocker for HR (60–70 range when possible)
Optimization of HDL/LDL ratio	Statin use preferable when tolerated
Daily aspirin	Daily clopidogrel
Optimal blood glucose control when applicable (diabetics HbA1c < 6%–7%)	Dietary modifications

TABLE 4. VASCULAR AGGRESSIVENESS SCORE		
	Yes	No
Do I have a standard exercise program to recommend for claudicants?	–5	+5
Do I insist on risk factor modification before recommending intervention?	–5	+5
Have I ever intervened on a lesion without: a. Knowing degree of ambulatory impairment? b. Without knowing what other limitations to ambulation are comorbid?	 +3 +3	 –3 –3
Do I regularly diagnose lumbosacral spine disease?	–2	+2
Do I use an IAC Vascular Testing–accredited vascular lab?	–3	+3
Do I use arteriography for delineating anatomy in claudicants?	+5	–5
Do I study my patients routinely and periodically after an intervention?	–3	+3
Do I intervene on active smokers?	+5	–5
Total		
Score: > 12, intensely aggressive interventionist; 0–12, moderately aggressive; < 0, conscientious and conservative interventionist.		

"Mild" claudicants, or those presenting with abnormal noninvasive studies in the setting of a relative lack of symptoms, should be counseled toward medical management. The components of medical management, unfortunately, vary greatly by patient, provider, location, and availability of support systems. Ideal medical management (Table 3) includes smoking cessation, which is shown to be optimized by frequent physician follow-up, establishment of a timeline and accountability model,[4] optimization of blood pressure and cholesterol (statin use), antiplatelet therapy, and an exercise program (preferably supervised). The successful enforcement of all these arms to optimal medical management is reliably lacking when interventions are tracked.[5]

INTERVENTION VERSUS MEDICAL THERAPY

Even patients with moderate to severe claudication are known to benefit from comprehensive behavior, medical, and lifestyle modifications but are often quickly moved to intervention under the pretense of being able to provide maximal benefit as soon as possible. We know from the CLEVER trial, however, that the systemic benefits of exercise and lifestyle modification included a greater improvement in HDL levels in the exercise group than the intervention group, as well as peak walking time at 6 months in the exercise group, which exceeded the intervention group.[6] Acknowledging the difference in aortoiliac disease, as studied therein, to femoropopliteal disease, the systemic benefits of exercise and medical therapy cannot be ignored.

To more concretely justify their use, we must investigate whether our interventions are truly better than best medical therapy (BMT). Can we honestly say that the benefits of early intervention outweigh the risks? Do we have a tendency to doubt our patient's ability to change in a manner that better sustains their outcomes? These doubts move

the onus of responsibility from the patient and places it unto ourselves, changing the natural history of a known process with conservative success into a reliably inferior long-term outcome. We must do a better job in sharing the responsibility for the patient's improvement and delineate accountability. We can reflect on our own habits by utilizing Table 4, which scores our aggressiveness in treating vascular disease, and consider whether medical therapies and more preintervention discussion might be warranted should we fall into the moderately or intensively aggressive groups.

LITERATURE REVIEW

Turning to the MIMIC trial to help further guide our decision making, the investigators looked at 93 patients, 48 of whom were randomized to balloon angioplasty with BMT and the remainder underwent BMT alone. The BMT group was all-inclusive of the previously described arms (although only 62% were compliant with supervised exercise). At 24 months, the angioplasty group had a 38% increase in walking distance compared to the BMT alone group. Both groups had equal improvement in ABI and QOL.[4] As previously discussed, the impact of claudication on self-reported QOL cannot be underestimated. If it is the deciding factor for intervention in the claudicant, then an improvement in absolute walking distance without improving QOL is not sufficient to overcome the small number of procedure-related morbidities reported.

Certainly, studies with such small numbers cannot be the only data to help guide our treatment of these challenging patients, so allow us to discuss a meta-analysis of nine randomized control trials.[7] Trial patients were comparable in terms of ABI, but pretrial maximum walking distance (MWD) and initial claudication distance (ICD) varied. To reiterate: ABI is rarely the sole determining factor in walking distance, so we must remain attuned to comorbid conditions when considering intervention.

Three questions were asked in comparing trials:

- How does endovascular therapy compare to medical therapy alone?
- How does endovascular therapy compare to supervised exercise programs?
- How does endovascular therapy with supervised exercise compare to supervised exercise alone?

Endovascular therapy (mostly balloon angioplasty) had better outcomes than medical therapy alone when measuring improvements in ABI, MWD, and ICD. Endovascular intervention showed an early improvement in ABI that was better than supervised exercise alone ($P < .05$), but the advantage was lost by later follow-up. MWD improvement was the same for the intervention and the supervised exercise groups at all time points.

Most importantly, combining intervention with supervised exercise had a better and longer-lasting effect on ABI, MWD, and ICD over supervised exercise alone. The combination of an intervention with a commitment on behalf of the patient to an exercise regimen is integral to ensuring realistic expectations and the longevity of the outcome.

CONCLUSION

In patients with severe claudication, requiring proof of commitment to an exercise program and lifestyle modification before an intervention allows us to select the patients whose QOL drives them to change their own behaviors. The result is a much more effective and systemic improvement after intervention.[8] Keep in mind that once an intervention has been performed, the benign natural history of claudication has been altered, and close follow-up with *prn* investigation is mandatory.

Although head-to-head comparisons of different modes of intervention are ongoing, there is no expectation that a definitive comparison will ever be made between each newer technology and medical therapy with supervised exercise. Regardless of which intervention might outduel the other, success should be predicated on the interventionist's ability to judge whether intervention is truly necessary and to remind our patients that the power to improve their overall survival still depends highly on their behaviors. ■

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