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INTERVIEW

Did BASIL-2 Miss the Mark?

An Interview With Nicolas J. Mouawad, MD, MPH, MBA

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At this year's SIR Annual Scientific Meeting, *Vascular Disease Management* spoke with Nicolas J. Mouawad, MD, MPH, MBA, from McLaren Health in Bay City, Michigan, to discuss his presentation entitled "BASIL-2 Missed the Mark." The BASIL-2 trial measured amputation-free survival (AFS) in patients with chronic limb-threatening ischemia (CLTI) after undergoing either angioplasty or bypass, and its results showed that an endovascular-first revascularization strategy was associated with higher AFS. Dr. Mouawad spoke about the differences between the BASIL-2 and BEST-CLI trials, and what the BASIL-2 trial failed to consider.

Your presentation is titled "BASIL 2 Missed the Mark"—can you elaborate on what you believe the trial overlooked or failed to address, particularly in light of the improved AFS with endovascular treatment?

BASIL-2 was a bit of a different patient population as compared to BEST-CLI in that BASIL-2 required all patients to undergo infrapopliteal artery interventions, whereas only around 60% of BEST-CLI patients had infrapopliteal artery interventions; also, the endpoints in these 2 studies were different. For BASIL-2, the primary outcome was AFS, which was higher in the endovascular treatment group as compared to the surgical cohort. But what was the reason for this? On specific evaluation, there was no difference in major amputation rates between the endovascular and bypass groups within the study period. The difference, driving higher AFS in the endovascular group, was mainly due to higher mortality in the bypass group (53% vs 45%). So this better AFS needs to be understood in the light that in fact the limb events were similar, and lower mortality in the endo group drove this difference.

Given that limb-related outcomes were similar between the 2 groups, do you think the trial design sufficiently captured the nuances of limb salvage vs overall survival?

That's a very good question. From a bird's-eye view, the 2 trials of BASIL-2 and BEST-CLI results look completely discordant and conflicting. However, when we really look at them, I believe that it is an apples-vs-oranges type of analysis. BASIL-2 was underpowered for limb outcomes. In my opinion, it should be a patient-centered approach rather than an endovascular approach or a surgical bypass approach, because patients with CLTI are not homogeneous; they are very heterogeneous, and there are more specifics and granular information about tibial runoff, anatomy, etc., that make it challenging to compare the 2 trials.

The big driver behind the difference in AFS seemed to be fewer deaths in the endovascular group. Do you think this was a reflection of the procedure itself, patient selection, or other systemic factors?

We know that patients with peripheral arterial disease, in particular CLTI, have coronary and cerebrovascular disease—which is what they usually succumb to. The increase in mortality seen in the bypass group was primarily not a limb-related event, it was a cardiac or a cardiorespiratory event. So I think that is what the driver was; I don't think it was a result of the procedure. I think it was just systemic patient factors. And we need to be better at managing their non-limb comorbidities.

How do you think BASIL-2 should (or shouldn't) influence current decision-making for CLTI patients with infrapopliteal disease? Do you believe this trial shifts the balance toward endovascular-first strategies?

I think a lot of people still prefer to proceed with endovascular-first therapy in patients who are older and frailer, which is what we saw in BASIL-2. The difference, again, is in the patient population. I think where we are all missing the mark is that no CLTI patient is technically the same—they are not homogenous. Some patients need endovascular treatment, some need open bypass, some need a combination of both, and some need nothing. We should be able to integrate the data into the patient-specific factors to achieve best outcomes. Therefore, what I take from all this is that treatment decisions for CLTI should be based on the patient first, and a patient-centered approach is what probably should happen rather than pushing a bypass-first or an endovascular-first strategy. ■