

## EDITOR'S CORNER

# Addressing the New York Times Controversy: Eroding Patient Trust

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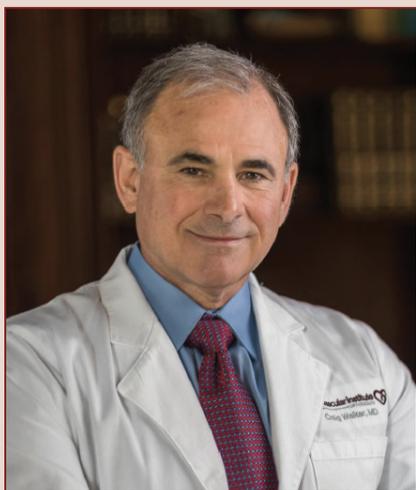
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Hello and welcome to the September issue of *Vascular Disease Management*. In this month's journal there are several articles worthy of editorial comment. I have chosen, however, to address the controversy around the *New York Times* publication in which interventionists working in outpatient labs were criticized as doing unnecessary and dangerous peripheral vascular interventions with finances as the sole motivation. The article cites payments made to the centers for procedures performed as physician income without any explanation that there are substantial costs in procedures that may make certain procedures net financial loss. No mention is made by the criticizing physicians that the payments for these procedures are substantially less than the technical payments to their hospitals plus their professional fees with no fear of financial loss on complex procedures. The accusations are that the cited physicians with outpatient labs utilized atherectomy in a higher percentage of cases than hospital-based interventionists. No objective evaluation of patient status at presentation or of outcomes across all the treated patients was cited. This was immediately followed by an editorial suggesting that only

vascular surgeons are ideally trained to treat patients with peripheral vascular disease. The author of the editorial also noted that no vascular surgeons were cited in error, as one was cited in that article. That article also inferred that FDA-approved atherectomy is experimental and inherently more dangerous than other procedures. It failed to note that there are level 1 randomized controlled data via the EXCITE trial that 308 nm laser atherectomy was safer and resulted in better patency than percutaneous transluminal angioplasty (PTA) when treating in-stent restenosis. I freely admit that although atherectomy devices are FDA approved, there is a lack of additional randomized controlled data. There is a publication by Mustapha et al, looking at Centers for Medicare and Medicaid Services (CMS) claims data in 36,000 patients, that atherectomy as initial therapy in treating chronic limb-threatening ischemia (CLTI) resulted in better outcomes than a surgery, stent, or PTA-first approach.

I am very concerned that controversies like these in a public forum will negatively impact patient care. Goodney clearly demonstrated that as interventions increased and open surgery decreased, major amputations declined. BEST-CLI and BASIL-2 had completely different conclusions as to how patients presenting with CLTI should be treated. Controversy and debate are the vehicles by which medical advances occur. No great breakthrough has occurred without profound criticism. My concern is that these attacks are far more personal and caustic.

I have been treating peripheral vascular disease for 4 decades and have willingly trained others from all disciplines as I firmly believe that we can do far more to help patients. I have worked closely with all specialties and have learned much from them as well. The treatment of vascular disorders is complex,

and it is difficult to accurately and scientifically compare therapies as there are so many variables present in each and every patient. Some of the notable variables include:

1. Patient fragility and general health
2. Total occlusion vs stenosis
3. Dense vascular calcification
4. Length of occluded segments
5. Access options
6. Wound characteristics (size, infection, age, etc.)
7. Fresh or chronic thrombus
8. Thrombophilia
9. Prior grafts (and types)
10. Prior stents (and types)
11. Renal status
12. Neurological health
13. Infection
14. Vessel size
15. Nutritional status
16. Gender
17. Ability to tolerate antiplatelet agents or anticoagulation
18. Patient compliance
19. Guideline-directed medical therapy
20. Access to comprehensive wound healing teams
21. Etc, etc, etc, etc

This list is not complete. It is easy to understand how difficult it is to get meaningful randomized controlled data in anything but small numbers of highly specific matched controlled sets of individuals, as there are countless variables.

In my practice, I manage multiple hospital cath labs and I also practice in an office-based lab/ambulatory surgery center (OBL/ASC). My practice pattern is no different in one from the other. I am more able to retain key cath lab personnel in my OBL/ASC than in the hospital. Patient charges are far less. My patients prefer and ask for the outpatient setting. There are, nonetheless, cases where hospitalization is preferable, particularly if overnight observation is needed. When I utilize drug-coated balloons or drug-eluting stents (DES) in my OBL/ASC, there is increased cost but no additional compensation; nonetheless, I utilize these technologies. I sincerely believe that outpatient care offers many advantages. An outpatient facility does not choose who to treat or how to treat.

Obviously, I do not condone bad practices in hospitals or in outpatient centers. I sincerely believe that the overwhelming majority of physicians have a moral compass and try to the best of their ability to help patients. It must also be stated that physicians working in hospitals have also been cited in prior publications. I do not believe that one can equate a higher percentage of atherectomy use as a wrong practice unless one can accurately evaluate the outcomes with these procedures and the status of the patients at presentation. Unfortunately, many are equating accusations with proof that atherectomy is dangerous. There is no stratification as to the varying mechanisms of action of the very different atherectomy devices or the risk of the different devices for embolization and perforation. There is no mention of patients who achieved limb salvage after having been recommended to undergo major amputation.

I fear we are taking a step backwards in patient care with the acrimony that has occurred following this publication. I fear this may lead to less cooperation between disciplines. There are many patients who are given no alternative options to amputation at this time, even in cases where viable options exist. Unfortunately, there are societies refusing to endorse legislation that major amputation secondary to chronic ischemia should require a vascular assessment unless it is urgently required to save life. Why? I don't understand.

The only thing worse than no data is bad data. Despite several obvious concerns in Katsonis's article suggesting that DES resulted in increased mortality, reimbursement for balloon cost was discontinued and it took 5 years for the FDA to remove the warning when data ultimately demonstrated no increased mortality and better patency. At this time, almost 5 years later, there is still no compensation for these highly studied, and proven to reduce restenosis, devices. Will this happen with other treatment tools? I fear it may. There are already some insurers contemplating limiting intravascular ultrasound assessment in peripheral intervention, despite multiple large studies demonstrating better outcomes.

I have participated in debates with others at large medical conferences about what constitutes best therapies in treating patients. I have presented my case and have listened to their case. There was no ill will following the debate. I sincerely believe that disagreement in strategies and civil discourse about those strategies is a force for positive change. I condone these debates. In these debates each side can present data supporting beliefs. I do not, however, condone one-sided criticism without a chance for rebuttal. I believe that articles like the one in the *New York Times* will lead to a further erosion of patient trust in all physicians. We can and should be much better than this. ■