Improving the CHEST Guidelines for VTE Care

Suresh Vedantham, MD, shares his perspective on how the current CHEST guidelines serve the endovascular community and how they might be improved in the next edition.

How would you briefly summarize the current American College of Chest Physicians Evidence-Based Clinical Practice (CHEST) guidelines for thrombus management and venous thromboembolism (VTE) prevention? What were the goals of this publication, and how were they assembled?

The chapters in the CHEST guidelines on VTE prevention and treatment are intended to guide the practicing physician by rigorously synthesizing the available clinical studies on VTE care into a series of evidence-based clinical practice recommendations that are graded by the strength of the recommendation and the quality of the supporting evidence.

What do you consider to be the strengths and weaknesses of the current guidelines?

The methodological rigor of the CHEST guidelines process is outstanding, and the people involved in developing them are truly experts in the field who are dedicated to great patient care. Many are esteemed colleagues with whom I work closely, and I can personally vouch for their excellence as clinical scientists and methodologists. This is a "labor of love" in the truest sense—the amount of work that goes into analyzing the literature is astounding, and the scientific rigor of the finished product is excellent. Looking at the guidelines from the perspective of a time-crunched practicing physician, the "CliffsNotes" style of the recommendation summaries for each chapter is particularly helpful.

With all that said, I can think of two important areas of improvement for future CHEST guidelines. First, the breadth of subspecialty expertise that has been included in the writing groups has sometimes been lacking. For example, the CHEST panel that develops recommendations on endovascular thrombolysis for deep vein thrombosis (DVT) and pulmonary embolism had never included an interventional radiologist (IR) or vascular surgeon before its 8th (2008) edition and still does not include an IR in any chapter dealing with endovascular procedures. The Society of Interventional Radiology has twice requested that IRs be included, but this has not occurred. That may partially explain why the credibility of the CHEST guidelines is limited within the endovascular community. This is unfortunate because the CHEST guidelines are an excellent resource.

Second, the CHEST guidelines understandably, but excessively, emphasize the results of randomized controlled trials (RCTs). No one doubts that RCTs are the optimal clinical study design in terms of minimizing bias. However, RCTs have tight patient selection criteria—many patient groups that are seen in daily clinical practice would not be eligible for the RCTs that form the basis of the guidelines. Most RCTs are performed in Europe and Canada, but there are differences in real-world thrombosis practice (often stemming from socioeconomic disparities and poor delivery of care) in the United States. Some of the RCTs that are cited in the guidelines are simply outdated. Also, there are many decisions faced by physicians for which RCT results are not available, and some CHEST guidelines have erred by viewing an absence of RCT data to be somehow equivalent to negative RCT data. In the endovascular DVT arena, the CHEST guidelines have historically dismissed procedures lacking RCT data, even when the preponderance of available evidence favored their use. This was somewhat improved in the 8th edition—for example, the recommendation on catheter-directed DVT thrombolysis was more balanced and reflective of the available non-RCT data than were pre-

vious editions. But overall, this is particularly troublesome because the inherent publication bias seems not to have been considered.

The truth is that some therapies (eg, anticoagulant drugs) are sponsored by large, well-resourced companies with a financial interest in conducting RCTs. Also, medical thrombosis trials are relatively easy to complete. On the other hand, RCTs comparing endovascular therapy versus drug therapy offer much more complex considerations and are difficult to complete, so there are fewer. Together, these issues result in a more cursory and less-informed handling of topics (in particular, endovascular therapies) that do not fall within the core strength areas of the panel members. Some therapies are judged negatively due to the lack of available RCTs.

Other important topics (eg, the use of retrievable inferior vena cava [IVC] filters for primary pulmonary embolism prophylaxis) are simply omitted, as if failing to recognize these practices might discourage their use. In still other areas, a lack of familiarity with a particular treatment may contribute to its omission. For example, although I was pleased to see some content on the treatment of established postthrombotic syndrome (PTS) in the 8th edition, the use of stents is not discussed. To be clear, I do not think the committee should feel compelled to issue recommendations on topics with poor scientific foundation, but stating that there is insufficient information to support an evidence-based recommendation is certainly preferable to outright omission or, worse, taking an unfounded position against therapies for which RCT evidence is not available.

Overall, the CHEST guidelines are a wonderful resource on many aspects of VTE care, and all endovascular physicians should be familiar with their recommendations. However, the above issues reduce their impact and credibility outside the world of internal medicine. I continue to hear rumblings about different organizations joining together to develop an alternative set of consensus guidelines. If the CHEST organizers do not address these issues, particularly the issue of inclusiveness, that type of project will inevitably occur.

How have the guidelines influenced current practice patterns in DVT referral and treatment?

The CHEST guidelines are viewed by many physicians as the leading source of rigorous analysis of the evidence in clinical thrombosis studies and are relied upon heavily. I believe that they have had a favorable impact on patient care in their areas of strength. For example, the foundation of many hospitals' DVT prevention programs is rooted in the CHEST guidelines. Regarding the adoption of catheter-based thrombolytic procedures for DVT treatment, I suspect that the changes in the 2008 guidelines made some medical physicians more comfortable with referring selected patients for treatment. However, we did not see seismic changes in referral patterns—most patients with acute iliofemoral DVT are still not even told about the option of catheter-directed thrombolysis—which, to me, highlights the fact that the impact of even a neutral or favorable guideline is ultimately limited by the quality of the underlying evidence. The medical community would still like to see a rigorously designed RCT to guide clinical practice on this particular question.

How have technological advances impacted the field since the CHEST guidelines were released?

Certainly, endovascular DVT practice is affected by the advent and continued evolution of new devices that are designed to disperse thrombolytic drugs, eliminate thrombus, provide caval filtration, and open and close veins. Since the last CHEST guidelines, two articles (including one single-center RCT) have been published describing an association between successful pharmacomechanical catheter-directed thrombolysis and reduced PTS, with few bleeding complications. So, the use of thrombectomy devices may be having some effect. On the other hand, the recent US Food and Drug Administration (FDA) advisory on IVC filters has illustrated some downsides to the rapid introduction of new technology before the completion of large-scale studies. In my opinion, the use of a new FDA-approved technology in an individual patient should be judged by weighing the risks and benefits as estimated from the available data, even when those studies are methodologically limited. However, I also believe that the physicians who use such new technology bear a responsibility to actively push for and strongly support better studies.

Have updated guideline editions kept up with technology and publications regarding best practices and clinical study data?

The current system in the United States has major limitations in enabling clinical practice guidelines to keep pace with technological advances. First, the FDA approval process for devices can be quite fast. Second, when a device is approved by the FDA, physicians are not provided with the data on which the approval was based. Therefore, the time when physicians actually see data on a particular device's use depends largely upon whether or not the company sees a financial incentive to publicize its preapproval data or sponsor postmarketing studies. This explains why some devices have been used for many years (eg, nearly 40 years for some IVC filters) without a single RCT based in the United States. So, to answer the

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question, no, the guidelines do not keep up with technology, but in all fairness, how could they?

What are the current plans to revise the CHEST guidelines for venous thromboembolism?

The 9th edition of the CHEST guidelines is currently being finalized and is expected to be published in late 2011 or early 2012. The CHEST guidelines undergo periodic revision every 4 years or so. Given the truly immense work that their production entails, I think it would be difficult to revise them much more frequently.

Based on technological developments, published studies, and your own experiences since the guidelines were originally published, in which ways do you think the guidelines should be revised?

First, I think that much greater emphasis should be placed on broadening the definition of "multidisciplinary" to move beyond internal medicine and truly incorporate all relevant expertise domains into the panels. One way to go about this would be to first query a broad range of subspecialty organizations for key clinical practice changes and publications they have observed over the preceding few years. This list should be compiled, carefully reviewed, and then used to develop a list of topics and key expertise domains that should be included. I think this type of process could help the CHEST guidelines move to the next level in terms of achieving broader impact across the medical community.

Second, the guidelines should address some important disease areas that the previous edition missed—specifically, the endovascular treatment of PTS and the use of retrievable IVC filters. Regarding acute DVT therapy, I do not see a strong basis yet to modify the current guidelines. However, recent literature (the Venous Thrombosis Outcomes [VETO] study) has increased our confidence that acute iliofemoral DVT is a high-risk condition relative to lesser proximal DVT or calf DVT. Therefore, I think it would be worthwhile for the writing groups to consider some type of recommendation in favor of assessing each DVT patient's risk of developing long-term complications such as PTS. This could encourage the use of evidence-based PTS prevention measures in these patients. ■

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