Updated Radial Guideline Classification Supports the Importance of Bleeding Avoidance in PCI

For over a decade, the scientific literature regarding bleeding avoidance during percutaneous coronary intervention (PCI) has pointed to the importance of radial access in mitigating access-site bleeding and the potential vascular complications common to the femoral approach. In this month's article, we have asked Dr. Michael Martinelli, CMO, Terumo Medical Corporation, and his physician guests to address the importance of the recent American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) guideline change[1] and how it might be viewed not only from a clinical/procedural perspective but from a quality/outcomes perspective, and how hospitals and ultimately, payers, may view its importance and role in the future of endovascular access.

— Gary Clifton, VP Care Pathways

Introduction

By Michael Martinelli, MD

Over the past decade, radial artery access for coronary intervention has grown dramatically in the United States, primarily as a major bleeding avoidance strategy. Over the years, the literature has supported this strategy and demonstrated significant reductions in access-site bleeding when compared with femoral access, resulting in shorter hospital/ICU stays, fewer transfusions, improved patient satisfaction[2], reduced hospital costs, and in the case of acute coronary syndromes and ST-elevation myocardial infarction, reductions in mortality. Some of the initial work in evaluating radial access as an important bleeding avoidance strategy was conducted at Saint Luke's Mid America Heart Institute in Kansas City, Missouri. This work led to prospective deployment of the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) bleeding risk model[3] in routine clinical care at Mid America Heart Institute through personalized consent forms[4], so that patients at higher risk for bleeding could be readily identified and bleeding risk reduction strategies, such as radial access, prioritized. Ultimately, incorporating the ACC-NCDR bleeding risk model led to a marked reduction in bleeding complications.[5] This process was facilitated by the integration of the ePRISM clinical decision software to collect the elements of the ACC-NCDR bleeding risk model, and to then calculate the risk and provide the results in the informed consent for patient and physician review. As radial artery access is now classified Class Ia according to ACC/AHA/SCAI guidelines[1], the incorporation of the ePRISM tool in clinical practice has the potential to enhance shared decision-making and address the important interplay between provider, hospital, and payers in significantly improving outcomes for patients.

Dr. Spertus, your group at Mid America Heart Institute conducted some of the seminal work around bleeding avoidance over a decade ago. How did that guide your eventual incorporation of radial into the ePRISM software and its emphasis on quality?

John Spertus, MD, MPH: One of the great challenges in medicine today is that despite calls for precision medicine and the use of evidence, it has been exceedingly difficult for healthcare to actually implement these strategies into routine clinical care. ePRISM removed many of the logistical barriers, and by integrating ePRISM with The Joint Commission-mandated informed consent process, we were able to alter our routine practice to embrace both evidence-based and precision medicine into routine care, while markedly improving our outcomes and patient satisfaction.

"ePRISM's data visualization tools help facilitate shared decision-making between patients and providers by allowing for simultaneous projections of outcomes and risks for various treatment pathways."

— Gabe Soto, MD, PhD

Dr. Soto, you were one of the principal architects of ePRISM. How did the clinical body of work around bleeding guide your initial construct of ePRISM?

Gabe Soto, MD, PhD, MHCDS: Major bleeding events — or any other periprocedural complication — are the result of a complex interplay of patient-specific and periprocedural factors. Although these events are inherently probabilistic and occur with some degree of randomness, we knew the data existed to identify those patients who were at highest risk. We also recognized that in the rapidly evolving field of interventional cardiology, we needed to build a system that could be continuously updated with a minimal turnaround time, so as to provide clinicians with actionable risk projections based on contemporary treatments and trends.

Dr. Spertus, how do you see this recent guideline classification affecting or influencing physicians in their current use of radial access?

Dr. Spertus: These guidelines merely codify the well-accepted practice of prioritizing radial access. However, there are many other components of performing PCI, including reducing the risks of acute kidney injury and safely triaging patients to same-day discharge, that could benefit from the precision medicine approaches used to mitigate bleeding risk. Our profession needs to prioritize the use of these techniques to improve all aspects of PCI care.

How do you view the use of radial as a mechanism to promote greater shared decision-making (referring physician, hospital, payer)?

Dr. Spertus: From my perspective, the access site is a process of care that should not necessarily be a key focus of shared decision-making. Whether or not to have a procedure at all, given the recent results of the ISCHEMIA trial[6,7], the decision for elective procedures, and whether the patient should be discharged on the day of the procedure[8] are richer opportunities for shared decision-making. Strategies that can objectively describe the risks and benefits of these decisions offer great promise for realizing guideline goals of shared decision-making.

Dr. Soto: To further Dr. Spertus' points, ePRISM's data visualization tools help facilitate shared decision-making between patients and providers by allowing for simultaneous projections of outcomes and risks for various treatment pathways (Figure 1).

How do you see the role of clinical decision software such as ePRISM as a tool to assist physicians and hospitals in improving outcomes and reducing costs? Do you see ePRISM as an important adjunct to personalized health care as it pertains to personalized risk assessment and informed consent?

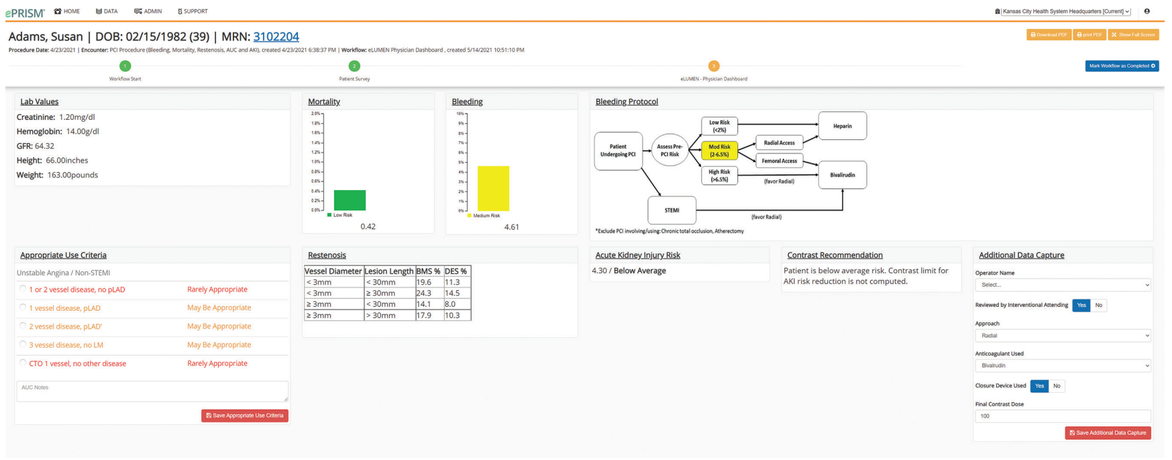

Figure 1. Risk calculation output available to the physician and cath lab team on the boom prior to the start of the procedure.

"Tools, like ePRISM, that can translate risk models (the foundation of precision medicine) into routine clinical practice are the future of healthcare."

— John Spertus, MD, MPH

Dr. Spertus: I am confident that tools, like ePRISM, that can translate risk models (the foundation of precision medicine) into routine clinical practice are the future of healthcare. A key advantage of this initial approach is that ePRISM uses exceedingly well-validated risk models that are already used for quality assessment, enabling these risk models to be used at the time of healthcare delivery to improve care. While these risk models have already been proven to work in bleeding reduction[9], this is only the first step. Moreover, as healthcare transitions from volume- to value-based reimbursement, hospitals will increasingly need tools to better tailor treatment to risk so as to reduce their costs and improve their economic viability.

Dr. Soto: ePRISM can help hospitals and organizations drive paradigm shifts in care delivery by giving clinicians the opportunity to preview the impact of process changes on patient outcomes. By modeling the impact of such a change on a hospital's specific patient population, and then giving providers the tools to optimize care delivery to those patients who are most likely to benefit from the change, hospitals can take the lead in providing cutting-edge, value-based care.

As we look into the crystal ball of healthcare, do you see payers potentially focusing more on the use of radial access?

Dr. Spertus: I believe payers are primarily focused on obtaining the best outcomes at the lowest costs. There is great potential to accomplish this goal by minimizing the costs of care associated with complications. To the extent that hospitals can innovatively develop strategies to improve the safety of care, they can minimize both their costs and those of their payers. My suspicion is that as new strategies for engaging patients in shared decision-making are developed, such as those that arise from the ISCHEMIA trial, payers will be incentivized to support (and pay for) shared decision-making.

Conclusion

By Michael Martinelli, MD

Dr. Spertus, Dr. Soto, on behalf of Terumo Medical Corporation, I would like to express my appreciation for your insights. Your valuable comments around the benefit of radial access as essential to a bleeding avoidance strategy in PCI are not only highly relevant given the recent guideline updates, but underscore the importance of incorporating this strategy in patients undergoing PCI as it will contribute to improvements in outcomes, reductions in cost, and optimize shared decision-making. Certainly, ePRISM is all that you described and we at Terumo are confident that as more physicians and hospitals become aware of its capabilities to provide important pre-procedural personalized risk data and informed consent, in combination with the incorporation of backend quality metrics, it will be a valuable tool within cardiac programs as they continue to strive to deliver increasingly cost effective, clinically driven outcomes. We believe this to be a win-win for patients, providers, hospitals, and payers. ■

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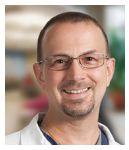

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