

The SCAI Expert Consensus Statement on the Management of Calcified Coronary Lesions

Dr. Robert F. Riley discusses the genesis of the SCAI expert consensus statement, using an algorithmic approach to calcium modification of coronary lesions in practice, how the consensus statement might be modified in the future, matching device decisions with clinical scenarios, and his hope for the algorithm's use in the interventional community.



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What was the genesis of developing an algorithmic approach for calcium modification of coronary lesions?

Dr. Riley: A few different treatment modalities had been available for a while, and once intravascular lithotripsy (IVL) came to the market, we really saw renewed interest in calcium modification, first in Europe and then in the United States. Looking at the number of publications on PubMed, we could see that it wasn't just a blip—this was a significant shift, and it was timely because it dovetailed with a considerable rise in the incidence of coronary calcium.

Considering that we now had a multitude of devices, we had to figure out in which cases we should consider using each option, which led us to the need for a consensus document. We don't have the data to create true guidelines, so we devised this consensus document as a living, breathing thing—it's a first pass and will be

an evolving field over the coming years. As Chair of the Society for Cardiovascular Angiography & Interventions (SCAI) Ischemic Heart Disease Council, I took the idea to the society leadership. Then, we went through a vetting process to ensure it was reasonable to move forward.

How were the coauthors chosen for this document?

Dr. Riley: After we pitched it to the SCAI Publications Committee and it was accepted, the Publications Committee was tasked with finding experts in the field to serve as coauthors. Ultimately, SCAI has its own internal processes for author selection.

What were some challenges in reaching a consensus on the specific elements of the algorithm?

Dr. Riley: Generating consensus was essential, especially in instances when there are good data for certain devices in certain scenarios but not as much head-to-head data. There are vetting systems for expert consensus documents to ensure that the majority agree, and the mechanism we employed to achieve consensus, detailed in the document, allowed us to have the majority on board as we made decisions on the use of certain devices in certain situations. The key central algorithm is the focus, but we also included tips and tricks for each device, ensuring everyone was on the same page throughout.

There was a public feedback period prior to the publication of the consensus document. How was industry involved in that period to ensure all stakeholders had a voice in what they thought the algorithm should include?

Dr. Riley: Although not actively partners per se in developing these kinds of documents, industry has

important perspective to add. They know their products better than anyone else, and giving them the opportunity to look at what's been developed and add comments is beneficial. There will be inherent bias, but there may be important data that have been overlooked and could be additive. It was critical to ensure everyone who had a stake in this type of document could provide feedback.

Over the past decade, we've seen a shift in perspective regarding industry collaboration. Industry is now seen more as partners, with a mission of helping physicians take better care of patients.

You've participated in a few algorithmic consensus documents in your career. How do algorithms help improve the quality of care and train fellows, and how do you teach an algorithm?

Dr. Riley: An algorithm is an educational tool to help physicians identify and practice within the existing data. In my mind, there are two different ways of educating. One is to look at the experts and mimic what they do, with the goal of getting everybody to be an expert in the field. The other is to raise the tide for everyone to be at a certain level of expertise, realizing there will be variation in abilities. Over time, I've shifted to more the latter, believing there are ways for us to really raise the tide for everyone to a certain level based on the data.

That's where algorithms can come into play. We've seen time and time again through multiple aspects of medicine that algorithms can help improve patient care. We want to create a framework that can help identify the problem at hand and put it into clinical context, understanding that it is a framework with which to operate, not the end all be all. We believe offering a framework will help improve identification and treatment; then, as it matures and evolves, it will only continue to improve.

Algorithms are a great tool for complex procedures because the more variables there are, the harder it is to make a decision, and these days, there's a multitude of options to consider. When you have an increasing number of variables when you teach or practice, it's difficult to make a decision because every time a new variable comes up, there's that much more uncertainty around the final decision. The more variables and options you add, the more ambiguous the relationship to the outcome becomes. Algorithms help alleviate some of this because they give you a framework. One of the things that I truly believe is that to become really great at your craft, you have to understand an algorithmic approach to a problem in order to develop a deep enough understanding of the issue to move beyond the algorithm.

You use an algorithm to understand the minutiae of what you're doing, but once you get really good with it where you don't have to think about every step, that's where the artistry and the true mastery come into play—you see beyond the edges, beyond all those other variables.

That said, I think that algorithms are like anything else—they're a tool. Not everything can be taught by algorithms. Certain elements are hard to quantify, and that's why training takes so long. It's why case volume is so important—the more you do, the better you are, and we can't quantify all aspects.

With each device having a unique mechanism of action, does the algorithm include how specific types of calcium should be addressed? Is there a risk of inadequate modification if the optimal mechanism of action is not applied to a particular type of calcium?

Dr. Riley: I think the importance of the algorithm is twofold. One, if not identified or treated properly, our patients have a major risk for adverse events. Our primary goal as physicians is to keep patients safe and try to alleviate either symptoms or risk of major events down the road. Second, all treatment options have pros and cons, associated risks, cost considerations, etc. When you have disease that adversely affects patients if not treated appropriately and several different treatment options each with its own pros and cons, that's where we see the importance of creating a framework of how to identify the appropriate scenario and type of calcium for each option. An algorithmic evaluation and treatment will help us get more consistent results.

This algorithm's key focus is matching devices to specific calcium morphologies, but how often is this analysis done in real time in the lab?

Dr. Riley: First and foremost, in my opinion, you really can't make a decision unless you use intravascular imaging. Using only angiography, your ability to discriminate the presence of significant calcium and type of calcium is lower. We know that each device works differently in different types of calcium, whether it's atherectomy, IVL, etc. If you're not using imaging, it doesn't mean we can't have some sort of algorithm, but it's less definitive and more of a user experience. When using imaging, I think physicians are trying to match up devices with the type of calcium present. For example, we understand that nodular calcium is very different from eccentric or concentric calcium and that certain devices have more data or have been shown to either work or not in those scenarios. There is still enough

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overlap that several devices can be used in certain scenarios, and there's also a lack of comparative data. This goes back to my first point that calcium modification will continue to be a work in progress.

If intravascular imaging is not obtained, can this algorithm still be of value?

Dr. Riley: We wanted to make it very apparent that the data show you should image no matter what—with or without calcium. We also had the understanding that imaging is obtained in only about 20% of cases, so that left us at a crossroads. There are two different schools of thought for education, and we wanted to have the document speak to both of those. On the one hand, the algorithm starts with, you should obtain imaging. Then, the middle segment of the algorithm delineates steps if imaging is not available, and it speaks to the understanding that some physicians just aren't going to image. Although our beliefs about the need for imaging are clear, we still wanted the algorithm to provide some guidance for these operators.

The algorithm describes what to do when nothing passes (eg, balloons) and when you probably need to do atherectomy. On the other hand, if you're not going to image, you should at least test with a noncompliant balloon and see if it's inflated 1:1 fully in two different views. That's the best you're going to do if you're not going to image, and it's probably okay to perform percutaneous coronary intervention (PCI). If not, you need to choose something else (eg, IVL, specialty balloon).

None of these pathways exist in a vacuum, and we know concomitant strategies, whether rotational atherectomy, IVL, or something similar, have a role. How do you go about addressing those specific evaluations algorithmically? What are the challenges in doing so?

Dr. Riley: Right now, the biggest challenge is that we have no real-time means of measuring vascular compliance during PCI. As a result, we cannot definitively know when there is ideal vessel preparation. We can take extrapolatory analyses such as intravascular imaging to look for fractures or a 1:1-size fully inflated noncompliant balloon, but these are extrapolations, not direct measurements. For example, one of the current limitations of IVL is the ability to deliver the device in tight, tortuous lesions. That's where atherectomy is still going to be most effective. After atherectomy, how do we know if

we need something else? We can do the noncompliant balloon test or intravascular imaging, but the problem with intravascular imaging is we don't always see all the fractures. We can see if big, thick pieces of calcium are left, but again, it's all extrapolatory. In these instances, we simply use these extrapolatory measures to see if we need another option, whether IVL, a specialty balloon, etc. The reason we can't be more prescriptive about these additive measures—when they're needed and when they're not—is because we simply don't have that ability to measure what we really need, which is vascular compliance and vessel preparedness for PCI.

You mentioned that the expert consensus statement is a living document. What future iterations do you predict might alter, shape, or change the algorithm?

Dr. Riley: As we see more data published with device use, whether it's head-to-head or use in certain subsets, these data will continue to mature, and this will influence how the document changes in the future—whether it's subset selection, one device over the other in certain scenarios, or in general. As devices evolve and new tools come into the market, data will also be associated with those iterations that could change the algorithm.

What's your hope for this algorithm? How do you hope the interventional community receives it?

Dr. Riley: There are a lot of other algorithms out there, so we don't pretend that this is the only one every single operator will use. My hope is that we made the algorithm simple enough for physicians to recognize when they need a specific approach, with enough of a framework to help them choose what they need when they need it. Ultimately, it needs to be simple enough to understand so that physicians will use it. Other algorithms are a little more circuitous, and I always found myself thinking, these are really good—they're so prescriptive, but I don't know how I would ever remember all of this. We wanted to create something that could simply either hang in your cath lab or just be intuitive enough to look at and know what makes sense. With that, we would get improved recognition and treatment of these lesions with the ultimate desire to reduce major adverse events in patients with calcified coronary lesions. ■