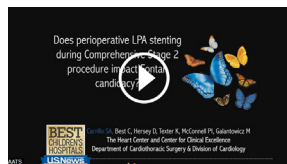


most and understand potential long-term consequences of this novel but controversial technique. Figure 6 provides a visual summary of the study and Figure 7 is a visual summary of the surgical technique.

Webcast

You can watch a Webcast of this AATS meeting presentation by going to: <https://www.aats.org/resources/1468>.



Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Key Words: HLHS, pulmonary artery stenting, Fontan, hybrid palliation, preemptive stenting

Discussion

Presenter: Dr Sergio Carrillo



Dr James Hammel (*Grand Rapids, Mich*). I'd like to thank the moderators for the opportunity to discuss this important and interesting paper and also give my congratulations to Dr Carrillo and his colleagues at Nationwide Children's Hospital for their innovation and continued refinement of the [inaudible] for hypoplastic left heart syndrome. Present study reports an apparently further refinement of their technique for comprehensive stage 2 procedure, and just to sort of summarize and clarify to make sure I have the groups correct, in the first 15 years of your experience, 120 patients had no indication for stenting the left pulmonary artery at the time of their stage 2, but 17% did need that and were stented, and that's called the unplanned group. And then in your more current experience, the past 5 years, you've just put a stent in everybody because by making it part of the standard operation, it allowed you to really simplify the case, shorten the pump time, and shorten the crossclamp, and the outcomes have been much, much better in the last 5 years. But if I understand correctly, in the first era, 17 patients would be 12%

of patients had an indication for stenting, the others did not, and your data show that those did not have stenting had good growth of their pulmonary arteries, and those who did have stenting didn't have any reduced need for subsequent intervention and stenting. So I guess my question to you is there are excellent results in the current era which coincides with the adoption of this technique, but is this just an era effect or a demonstration of your learning curve and continued perfection of the technique?



Dr Sergio Carrillo. Yeah. Thank you for your question. Yes. I think the era effect, it is a possibility that could lead to some bias. However, as I said, we started dabbling into pulmonary artery stenting intraoperatively or perioperatively back in 2006. However, we did not do it routinely, as you

mentioned, since 2017, so the last 5 years or so. So we do think that it, yeah, has some era effect, but those patients that had perioperative stenting that were unplanned were because they had pulmonary artery programs that were seen during the [inaudible] or had a torrid postoperative course immediately following the comprehensive stage 2 procedure that went back to the catheterization lab or in the operating room for either surgical reconstruction with the addition of a pulmonary artery stent.

Dr Hammel. Thank you. So, moving forward, you've showed enlargement of the left pulmonary artery with the intraoperative stenting, which isn't really the same as growth—the artery doesn't have much choice but to enlarge—and that was effective. But that diameter was preserved up until the time of pre-Fontan evaluation, as you showed. However, there wasn't really significant growth from stenting to Fontan, so what's the future hold for these vessels? Is the stent that you're placing dilatable to adult sizes? Is it a fracturable stent? What do you think is going to be the effect long-term of having that stent in that position as far as vascular biology or just technically as far as working in the hilum, for example in the case of cardiac transplantation?

Dr Carrillo. Yeah. It's a great point. We believe that this technique somewhat is going to define not only the comprehensive stage 2 technique but also the Fontan, and allow for pulmonary artery growth. Because as we all know, the pulmonary artery's growth is with flow, and just preserving the diameter, the nominal diameter of the pulmonary artery, does help. We also believe that by having a rigid structure there, potentially a variable of having a ductal arch, which all these patients have, in the reconstruction, all of that could play a role in obstruction of the left pulmonary artery, as we all have seen and have been frustrated with those results. So we do think that this will provide some of that protection. And it's just a matter of getting sort of comfortable with having a stent there to begin

with. We haven't seen any problems or any concerns at the time of Fontan. So it's actually quite far away, so you just don't want it to be anything that surgically cannot be dealt with.

Dr Hammel. Thank you. Your answer, actually, leads me perfectly into my final question, which is this: I would say that your program has been part of a paradigm shift, a change in thinking about managing first stage in these patients. Does this report represent a further change in understanding or attitude to stenting? We as surgeons tend to think of a stent or the need for a stent as a complication. We don't want them in our blood vessels if we can avoid it, typically. And yet, in this case, you've stented mostly patients who—unless there was a change in the rate of stenosis, mostly patients who didn't need 1. So should we consider these stents to be benign? And to generalize it out to procedures that are performed, probably, by more of the audience, should we be preemptively stenting the bifurcation and left pulmonary artery when we're taking down a Sano to do a cavopulmonary shunt, for example? What are your thoughts?

Dr Carrillo. Yeah. Great points. So to take what you said last about either the Norwood approach or the conventional therapy, in looking at the literature—and if you look at the single ventricle reconstruction (SVR) trial results both in the three and the six-year report - up to 43% of the patients have had already an left pulmonary artery stent at 6 years. And we've also been in the operating room when are doing a 15-year-old Fontan that has failed, has had multiple operations, multiple dimensions, and lo and behold, there's an left pulmonary artery stent there as well. So I agree with you that we see stenting as a surgical failure, if you will. I certainly do. And having trained at Stanford, having worked with one of the world-renowned pulmonary artery gurus, if you will, I felt a little bit torn in between what, really, to do. But just looking at these outcomes and working with these vessels with a stent in place, it hasn't really been a problem, again. And so far, we've seen appropriate hemodynamics, and none of the patients have had progression to either Fontan—sorry, to transplantation due to Fontan failure or pulmonary artery problems.

Dr Hammel. Thank you. Provocative idea, and excellently presented. Thank you.

Dr Carrillo. Thank you.

Dr Ignacio Cornejo (*Cordoba, Argentina*). Hello. Ignacio Cornejo from Cordoba, Argentina. Congratulations for the excellent presentation. We've been doing hybrid procedures for the last 7 years. My question is, first, if you know about the stent dimensions, the size, and diameter to use? The second 1 is, we have reviewed some sutureless patches to the left pulmonary artery sometimes. If you can comment on that, and if you have experience? Thank you.

Dr Carrillo. Yes. Thank you for that question. We've utilized a stent called the Mega LD stent (Medtronic), which is a

16-mm in length. And that stent can be dilatable up to 12 mm without having any reduction or shortening of the length. And that is, at the time of the comprehensive stage 2 is balloon dilated with a nonpliable balloon to 6 mm, which is a score of +1 for these patients. Those stents are not fracturable but they are dilatable up to 18 mm in diameter, which should be more than enough for an adult pulmonary artery. But once you go beyond 12 mm it shortens slightly and when you reach 18 mm in diameter it reduces its length by 25%. So those are really the technical points and these are made out of stainless steel so they're very pliable. They're made of strength 2, that is quite good and then lastly, the last point I will make about the stent is that the edges are rounded so it creates less intimal injury and as a matter of fact when reviewing all of these angiograms, there has been very little intimal hyperplasia if any at all.

Dr John Meyer (*Boston, Mass*). John Meyer, from Boston. I just had a couple of questions sort of related to the physiologic effects, if you will, of this. Do you have any follow-up data via lung scan or anything else about how you have affected the distribution of blood flow between the right and the left lungs?

Dr Carrillo. No, Dr Meyer, we have not looked into that. Some of those patients have undergone magnetic resonance imaging but it has not been protocolized so I cannot comment on that. Certainly, something to look at.

Dr Meyer. I mean, ultimately what's going to make at least 1 component of what makes or breaks a Fontan is how is the distal pulmonary arterial level development, and cross-sectional capillary area. And I think 1 of the important questions, I think, I don't expect an answer but I think just put it on everyone's agenda is we really need to have a better way of assessing the pulmonary vascular bed in these patients. And if I may, I may make 1 other comment about the preceding discussion about Down syndrome kids and single ventricle. I think I remember this correctly. There is old histologic morphometric data that suggests that Downs kids actually have fewer arterials per

gas exchange unit than an otherwise normal child. So now at the macrovascular level you have an explanation for why the Fontan or other single ventricle approaches might not do so well.

Unidentified Speaker 1. David, last question.

Dr David Barron (*Toronto, Canada*). Thank you. I think it's so important the work you do because we learn so much about the hybrid from the fact you've been so successful with it and used it so widely. But I guess it comes back to this issue or saying it doesn't feel right to be putting stents into infant pulmonary arteries. Would you not consider simply just routinely patch enlargement of the left pulmonary artery? It's an easy time to do it because you've got the good exposure before you've done the Damus-Kaye-Stansel and yeah, go ahead.

Dr Carrillo. Yes, sorry. Yes, great point. So we've transitioned from multiple surgical techniques, again sometimes we've left the operating room frustrated. I think that maybe the reconstruction was not extensive enough. We've gone from hilum to hilum on the pulmonary artery reconstruction, single patch, 2 patches, multiple patches, so and it is very difficult to tell who is going to actually have a problem on the left pulmonary artery, right? So I think it's difficult to tell and predict who will have a problem. We've done everything that we can, surgically. One thing that I will mention is that when you put the left pulmonary artery stent we do minimal dissection on the left pulmonary artery obviously as I mentioned or as I showed. The pulmonary bypass time and crossclamp time are decreased by just nature of less dissection, less surgical time burn there, so.

Dr Barron. Are the bands of the Achilles heel potentially, I couldn't convince you to change over to an award at 6 weeks and then I might not have a problem with the sclerosis on the bands, and then do your irregular stage 2 at 8 months.

Dr Carrillo. Yes, absolutely. That's another pathway, absolutely right.