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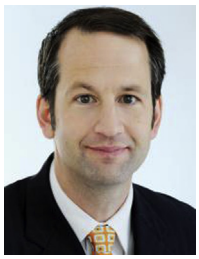
Key Words: aortic valve replacement, randomized controlled trial, sutureless

Discussion

Presenter: Dr Theodor J. M. Fischlein



Dr Michael A. Borger *(New York, NY)*. Cardiac surgery is unfortunately in the area of heart valve therapy relatively sparse in our randomized trial evidence thus far, but there's no doubt about it: As we've learned from our interventional cardiology colleagues, this is the way of the future to more accurately determine if the therapy that we are applying for our patients is the appropriate one. Again, I would just like to congratulate you on bringing a very important trial here to publication. Just as a fine point, it is a noninferiority trial and the conclusions state that the 2 treatment options are equivalent, just statistically proving equivalence is basically impossible. But what you can say is that the one therapy is noninferior to the other, just as a fine critique.

First of all, the implant success rate: there were 5 Perceval patients who were not successful with the implant, and interestingly, 10 conventional bioprosthetic valve

patients who did not receive a successful implant. Can you give us a few more details on those patients, please?

Dr Theodor J. M. Fischlein *(Nürnberg, Germany)*. Well, it was interesting that in the standard valve group, we had some cases with problems in sizing and positioning. We had 2 cases due to valve overlapping the coronary ostia. We also had 2 cases with strong calcification of the annulus area and of the root. There was also 1 case that required replacing the ascending aorta and an instance of congenital abnormality in the standard group. In the Perceval group, it was a problem with the deployment or, let's say, dislodgment of the stent of the Perceval valve.

Dr Borger. Some 35% of the conventional bioprosthetic group patient received a 19 or 21 valve size. Especially in this age group, we tend to try to avoid this, because they may need a TAVI valve-in-valve in the future. Do you think that may have affected the hemodynamic performance in the conventional group? Also, do you have experience with TAVI in a Perceval valve?

Dr Fischlein. To the first part of your question, yes, you are absolutely right. I am not a friend of the size 19. We don't actually use size 19 in our institution; we always do a root enlargement in those cases. And of course, if I look to the gradients, then they have been quite high as you can assume, especially the size 19. If you have to do a valve-in-valve procedure to implant a TAVI prosthesis—yes, we have done this already for the Perceval valve, so it's possible to do that. But of course, if you have to use a 19 standard valve, that could be a problem in the future, absolutely.

But what I always say is, open reoperation for AVR or, let's say, replacement of the prosthesis, I actually view this as not being very high-risk to perform. So also surgery would be a possible situation to do.

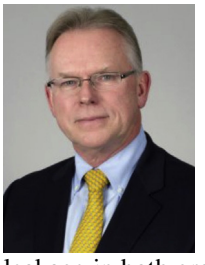
Dr Borger. My last question is: The shorter cardiopulmonary bypass and crossclamp times that you demonstrated and that have been shown and in several other studies as well on sutureless and rapid-deployment valves: Usually we expect that to be associated with less bleeding, maybe shorter ventilation times, maybe shorter intensive care unit, hospital length-of-stay. Did you find that in your study?

Dr Fischlein. We plan do a lot of sub-studies. This is what we are looking forward to as well. Up to now, I couldn't really find any big differences in both groups in regard to bleeding. We had somewhat better results in the Perceval group, and intubation time was also a little bit shorter in the Perceval group. But as you know, in some multicenter studies, and from our center, we could already show a reduction of bleeding postoperatively. Eventually this is also much influenced by the surgical access. If you do just minimal, let's say a ministernotomy or a right anterior minithoracotomy, you have less bleeding. But we will have to look to our cohorts closer as well, and up to now, we had not found any statistical significance between both groups.

Dr Vinod H. Thourani *(Atlanta, Ga)*. I was a little surprised that one of the benefits that people have talked about sutureless valves is being able to do more minimally invasive surgery, and I saw no difference between the stented versus the sutureless. In fact, it was about 50% for both. Could you explain that a little bit? I know the company has advocated that we are able to do more of those with this technique. Did you not find that was not the case?

Dr Fischlein. Well, there was a difference. I hope I understood your question fully, but there was a difference in clamping time and cardiopulmonary bypass time. For the ministernotomy, you're right, it's not like a wow effect. But with Perceval, you could achieve a shorter clamping time as well.

Experienced centers using sutureless devices—especially in isolated AVR cases, always do a ministernotomy. In some cases, we also do a right anterior minithoracotomy. What I want to say is that even with conventional valves experienced surgeons are quite fast using a minimal invasive access. But if I do a right anterior minithoracotomy, I'm happy to have a sutureless valve as well. Much better to have it, and it's much easier to do than with a conventional valve.



Dr Vaughn A. Starnes *(Los Angeles, Calif)*. Given the short follow-up: Did you do echo follow-ups, and did you have any degree of differences of aortic insufficiency in the 2 groups?

Dr Fischlein. Yes, as I've shown, it's interesting: There is no difference in paravalvular leakage and central leakage in both groups.