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Tricuspid Regurgitation – A new prospect in the management of patients with TR

Q&A – Part 1 Dr. Katharina Kiss

Q: Dr. Kiss, you said the valve is made of bovine pericardium. Was there a certain reason why that was selected?

A: Well, first of all we think bovine pericardium has a better durability and especially this is a low pressure system so we need a thinner pericardium of a slightly different consistency than what we would use in a TAVI. Also we believe that the bovine pericardium will show better results and also with the dry tissue technology, this was the better selection.

Q: Sometimes the question pops up, do we need to have 2 valves both in the superior and inferior vena cava or could one be enough?

A: Well, I think from the first animal trial and then also from the patient data and the pre-clinical testing, we could show that there is like 2/3 to 1/3 of the flow between the superior vena cava and inferior vena cava. So we had a few patients where only the inferior vena cava was implanted first for different reasons and we could see that the patients developed a superior vena cava syndrome so they had increased circular pressure, they have been complaining about headaches. And when we went and implanted the SVC valve through the IVC valve, which is easily possible, we could see that all of these symptoms were abolished. So I strongly believe we need the 2 valves in order to have a complete solution.

Q: What are the essential, if people are looking for candidates for this technology, what is the essential imaging technology to be used in order to identify whether a patient is suitable for TricValve?

A: Of course, first it is always ECHO. We have to be sure that the patient has a severe torrential TR. We have to understand whether the right ventricle is still viable. I mean the right ventricle doesn't need to be perfect but it should have the potential to cope with at least the closure of the backflow, although here is much more forgiving than if you put, for example, orthotopic valve for you, because you will have the right atrium as a reservoir. For the imaging, aside from only needing CT, we are working on an MRI protocol for patients with severe kidney dysfunction. But in general you need the CT to understand the sizing of the valves.

Q: Is there any special aspect of the CT? How and when to do it? How much contrast to inject or is it just a standard CT?

A: It is a standard low-dose CT where we want to see the superior and inferior vena cava, that's all that needs to be shown.

Q: Regarding dialysis patients, since you mentioned now working on a protocol to avoid renal impairment, what is your take on patients in a pre-existing dialysis through a fistula or a permicath. What do you think should we go with?

A: Those patients are doable, of course it is always a question. Of course we have to be aware that the dialysis probably changes the calcium metabolism and it might change the durability of the valve. But I think in general those patients are severely ill, if we can help them to ease their symptoms then it is possible. So the dialysis is no contraindication.

Q: Is there any kind of strict contraindication from upfront viewing when you search for patients, where TricValve will not work?

A: For me, personally I would say the anticoagulation is something we should really ensure that we can give it lifelong, because it is a low-flow system and I think this is an important factor. Other than that, pacemaker leads are no contraindication, prior valve surgery is no contraindication because you don't intervene with the native valve, so that of course whatever has happened there before, it does not bother you anymore because you put your valves outside the right heart.

Q: I think maybe the sizing might be an issue?

A: Yes.

Q: Are they working on a bigger size or smaller size, something like that?

A: Bigger size. This was really an interesting observation that in the beginning we did not realize how big the covers can be because you have covers up to 60 mm, so huge vessels.

Q: What about the presence of the pacing leads or ICD leads or does it prevent future implant of such devices?

A: No. Because the maximum that can happen is if you already have a TricValve in place, so first the pre-existing leads are not a problem because they're simply sealed between the vessel wall and the stent frame. But even if you want to go in with ICD CRT lead, you still can go through the SVC valve you might lose a little bit of function because you again have a central lead through the valve but otherwise it is perfectly well doable.

Q: Sometimes people will extend the question: if you have 2 leads for pacing and 1 lead for the ICD or a CRT system so 3 leads. Do the 3 leads also allow you to have adequate stability to fix the part of the superior valve?

A: Our maximum up to now was 5 leads as far as I remember.

Q & A – Part 2 Dr. Sondos Samargandy

Q: Dr. Samargandy, you nicely showed your case and how you did it. Can you maybe summarize again for us what are your main landmarks you look at when you go through your procedure?

A: So as we mentioned at the beginning, we go with the 3 axis. This is like the standard, we are talking about going by the book and then having a pigtail to illuminate for you the innominate vein, where are you exactly, because this is your landmark. And the PA catheter to show you where your RPA is because you aim with the superior vena cava implantation to be as high as possible and because you have a long skirt you don't want to obscure something. And the contrast injection will give you exactly where the innominate vein is and you can work around it. And this doesn't need any imaging support at this stage. You can go at all the fluoroscopy and once you go to the inferior vena cava, you might

need again some injection. You can remove at that stage the PA catheter because you don't need it anymore. And then you go with the pigtail to show where exactly the hepatic vein is in relation to right atrium. And the TEE can help you with this, how much of a protrusion you are having. And I think we did it. We spoke about that briefly and mentioned we can have up to 6 to 8 mm because you might have a tendency to jump up a bit, so you have to have a very good grip of the valve when you are deploying the IVC valve. Then we have a short skirt and this is why CT is very important, to illuminate the distance – because I had one screening failed because there was no existing space to allow us to implant at inferior vena cava. And the whole notion of having a pigtail at the end to show immigrating of the regression volume back to the liver or the kidneys and demonstrating a good reduction in the IVC dynamics. And that is one of the key factors why you have to have v-wave of 15 and above in the beginning of the case and allowing to have more stroke volume of the RV going back to pulmonary circulation. Therefore, may increase the cardiac output. You have to have a good RV to some extent. We have them inserted by TAPSE. In addition to that, to have acceptable RV LV function.

Q: The beauty of the system is that it allows you to reposition the device if it is not completely opened. Is there any experience how often that is used, a repositioning?

A: As far as I know with a device like we have, even up to 80 % you can re-sheath and reposition again. I didn't need anything in my case. It was simple, straightforward because we were practicing very slow deployment with a good traction.

Q: Dr. Alenezi, do you have any requirement for re-sheathing or something in your case?

A: From our limited experience, the big size of the delivery system and the slow release makes the system very stable so there is very little movement when you are deploying the valve.

Q & A - Part 3 Dr. Abdullah Alenezi

Q: You showed us the case not done under general anaesthesia for certain reason in this particular patient. In general, is that a procedure that should be done under general anaesthesia or in the learning phase done under general anaesthesia? Or you think you can liberally use contrasedation or even local anaesthesia?

A: To be honest, the cases we've done so far are all under local anaesthesia. And I don't think the failure in this case or the reason they made it complicated was the absence of TEE. I think it's just we don't have extensive experience with the interpretation of the hemodynamic assessment after the valve. So what was really concerning for us is that the pressure in the IVC did not drop. The TTE showed that the hepatic vein reversal has disappeared after we deployed the valve. So I think that was the key learning point that the pressure may not drop. But if you see the hepatic vein flow reversal improved significantly – then you should be happy with that. And the leak, even if you have a little bit of leak – this is a self-expandable valve; over time, it might continue to expand and find its position and seal itself. So that's a learning point.

Q: Is this a common observation that you see the improvement in hemodynamics immediately when both of the valves are implanted?

A: I think the issue was that this was the 2nd case of the day and the 1st was perfect. We had a drop of pressure on live IVC. So in our mind, that's what we were expecting. We are TAVI operators, when you put in the new valve, you expect the gradient to go down. So that's what swayed our decision in this case. But in retrospect, we have been happy with the 1st implant which was great. The flow reversal

went away and the 2nd valve we implanted at the IVC was exactly the same position we implanted the 1st one.

Q (to Dr. Kiss): Regarding the general anaesthesia because usually it's driven by requisite by the TEE. So do you think the TEE can make or break your case or you can just consider the TTE as I did.

A: I think you can try if you have a good ECHO window or most of the patients are rather cachectic. You can if you have a good subcostal view. Then I think this is good enough because you really need it for let's say 3 to 5 min during the implantation. And so I think it's safe to move. If you have a good ECHO window, it's safe to move with the TTE.

Q (to Dr. Samargandy): We have seen 2 cases now where TricValve was used as the last resolve of the option. We have seen 2 failures for the tricuspid clipping. What do you see? Or where do you see the role of the technology? Is that the role at the very end of the pathway of technologies we can apply to the disease? Or should we try to bring that at an earlier stage because of its safety, because of its ease of use?

A: Not the very early stage because those are tissue valves. We know the durability from what we have from the surgical data we know for 8 years, 10 years. What if a patient is in his 40's, DCM like old carcinoid for example. Maybe we can put bicaval. After 8 years, 10 years what's going to happen. So I don't know to be honest with you. Like you know lifelong management, and maybe I don't want to push it just for people who are desperate, demented, bedridden. We want to give it to someone who can add quality in their life. Actually we are still not very early and still not very late because both treatment option commercially available, edge to edge repair versus bicaval, both of them are very early stages. We can't say who is durable. Even though clip was successfully initially, it open at the end.