

Solution for Paravalvular Leak Room Michelangelo Friday 11 February 7.00–8.00

New updates fill the void in paravalvular leak closure

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in Europe, then that I would think would be the preferential device. In the United States, we only have the rounder plugs, the AVP 2 plugs...and we use those side by side now."

To that end, we asked Dr Rihal if he thought the AVP3 plugs would find their way into the US market any time soon? "I doubt it – the FDA [Food and Drug Administration] so far does not seem predisposed to approve it," he said, adding that this is an all-too-common occurrence that is very frustrating to bear.

"I know they are trying to do their job and ensure that they are approving safe devices, but we're still frustrated that the devices aren't always approved as quickly as we would prefer," said Dr Rihal. "There's always this tension between rapid approval and ensuring absolute safety. I'm not sure we can ever ensure absolute safety, but it is what it is and we have to deal with it."

Moving on to discuss the flourishing use of percutaneous techniques for paravalvular leak closure, once again *JIM Today*

posed the question as to whether such techniques would surpass open surgery, and just how, in Dr Rihal's experience, it really is spreading throughout centres in the world.

"Yes, it is spreading, but it is spreading to centres that are very experienced with

know. This paravalvular closure business is an order of magnitude more complicated."

He added: "So I know I've taught a number of people in the United States, and around the world, how to perform this procedure, and the ones that have the skills of transseptal catheterisation, snaring, device deployment – sometimes apical puncture – these are skills or techniques that most interventional cardiologists do not do in their day-to-day practise. So those centres and those operators that have these skill sets I think are very capable of learning these procedures."

In fact, the choice of team members and skill sets for interventional procedures is a hotly-debated topic that has, often, a core reason behind any concerns, which is that these are relatively new procedures after all, which haven't had time to fully form in centres yet.

Dr Rihal added his thoughts on the specific case of paravalvular leak closure, saying that, in addition to interventional cardiologists, congenital paediatric interventionalists should also be incorporated as part of the team: "The congenital

interventionalist brings certain skill sets to the table, and the adult interventional cardiologist brings certain skill sets to the table," he said.

"Together, that team will have the skills that are necessary to perform this procedure. And this is how we started here initially, so I think there is a real synergy between the adult structural interventional cardiologist and a paediatric interventional cardiologist in working together in these procedures. That's a good way for a new programme to start."

To that end, in his closing remarks to *JIM Today*, Dr Rihal mentioned an upcoming paper he has authored that will hope to address some of the issues with procedural techniques via a "step-by-step" guide on the percutaneous paravalvular leak closure technique.² "Our centre will be publishing a pretty detailed paper on the technical execution of this procedure," said Dr Rihal.

"Now, our colleagues in Europe are more fortunate as they have a plug that's more suited to an oblong leak, which is the AVP3 plug. We don't have that available in the United States. If the AVP3 plug is available like it is in most places in Europe, then that I would think would be the preferential device."

Charanjit S Rihal (Mayo Clinic, Rochester, USA)

structural heart disease and have very experience and skilled operators," he said.

He continued: "This procedure is probably the most complex procedure I am doing. It is more complex than TAVI [Transcatheter Aortic Valve Implantation] or MitraClip [Abbott Vascular] for example, which are themselves rather complex structural interventional procedures as we

Dr Garcia and Dr Rihal will present their approaches and results during the Solution for Paravalvular Leak breakfast session; 7.00-8.00, Saturday 11 February, Room Michelangelo

References

1. Sorajji P. Long-Term Follow-Up of Percutaneous Repair of Paravalvular Prosthetic Regurgitation. *Journal of the American College of Cardiology* (2011); 58(21)
2. Rihal C et al. *JACC interventions* (2012); 2(5):121 [In press]

Win-win situation with the TAVI female registry

A novel registry that will focus on the outcomes and prospects of women undergoing transcatheter aortic valve implantation (TAVI), which promises to be one of the most exciting and pioneering projects in recent years in interventional cardiology, became the subject of much discussion at JIM 2012.

Alaide Chieffo (St Raffaele Scientific Institute, Milan, Italy), who has been a constant presence at JIM 2012 thanks to her participation in the live case transmissions from Milan, is spearheading the project alongside Roxanna Mehran (Mount Sinai School of Medicine, New York, USA), and they both spoke to *JIM Today* to talk about the reasons for setting up the registry and their hopes for what can be learned from its findings.

Dr Chieffo began by outlining the details of the Women in Innovations (WIN)-TAVI Registry. She said: "We are planning to have a TAVI registry of women. It will be a 1000-patient registry

focused on females undergoing TAVI, and it will be a multinational, European study. We have done a survey, which is on our website, and 26 centres from all over Europe have already answered positively that they are willing to participate in this registry. It will be focused on female patient characteristics."

She continued: "The difference between this registry and other ongoing registries, such as industry or national registries, is that we going to ask specific questions regarding female patient characteristics, in order to know better if there are significant differences between females and males. We have seen that women bleed more, have a smaller annulus diameter and we need to know any differences in the choice of valve.

"We want to focus on this problem, because, in contrast to other studies in the cardiac field, half of our TAVI patients are females. So I think there is a large clinical need. We really have to focus on this subgroup, which is



Patrizia Presbitero

technically not even a 'subgroup', as 50% of the patients we are going to treat will be female."

Dr Mehran added her feelings about setting up this groundbreaking registry. "We feel very proud to be able to bring together these incredibly strong in-

vestigators who have committed themselves to collecting specific data for women," she said. "The outcomes may be very different in men versus women, and there are many women afflicted with aortic valve stenosis.

"In the trials, for the first time, we see more than 50% of the patients being female, which gives us an incredible opportunity to actually study their outcomes, and we know that the pathobiological disease process will be very different in men versus women. We know that size mismatch could be a very big issue in women. Yet, unless we study this in a prospective way, with complete focus on the female patient, we really aren't going to know the answer."

Dr Mehran explained: "So this WIN-TAVI registry is, I think, a win-win situation, because we will be able to study women in a prospective fashion who undergo this procedure. We're very, very thrilled to have this announced at JIM, especially given that Alaide

Chieffo is leading this project."

She continued: "The registry will include any female patient who is undergoing transcatheter aortic valve replacement, using any of the approved devices. One of the things we're very thrilled about is that both Edwards and Medtronic have expressed tremendous interest in this area. Both companies are very devoted to understanding the outcomes in the female patient population.

"Our mission is not to focus on one device versus another but to try to understand the pathology of women with aortic stenosis and their short and long-term results. One of the areas that we are most interested in is prevention of stroke, bleeding complications and renal complications, because they are most prone to these important complications. It could very well be that, in the female population, the causes of stroke are very different. Women have much more calcification, and it could be more related to debris that has embolised, rather

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than clots. It may well be that calcific aortic stenosis is much more prevalent in the female population, especially in older age, because they live longer. So, very importantly, that's what we want to understand. If that's the

case, then maybe the embolic protection devices are going to be important."

JIM Today also spoke to Patrizia Presbitero (Istituto Clinico Humanitas), who gave some background to the genesis of the project, and why initial investiga-

tions that preceded the registry gave added impetus to its establishment. She said: "Already, we have done some work in TAVI and women. Alaide [Chieffo] presented results at PCR from four hospitals, in 450 patients, to see if there are differences between men and women. At the beginning, we thought that there was a difference in the immediate results. It was a bit worse in women mainly because of

peripheral vascular access problems, but the long-term results are better in women, because...I don't know. Because they are stronger, or because they have less coronary disease, or less carotid disease. We are looking into that and I think we need more work on it. Because of that, we are now trying to do a registry about TAVI and women."

She added: "Because of the economic situation, and because

women have less mortality than men, perhaps we should implant valves only in women! To treat women is more cost-effective, so gender cost-effectiveness must be evaluated."

Manuela Piccaluga (Luigi Sacco Hospital, Milan) also lent her support to the registry. She said: "I think that this registry will give more insight into the treatment of women. This is a great

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opportunity, due to the fact that women are such a prevalent part of the patient population and we will learn more about their treatment and the differences from men."

The registry has also generated a great deal of interested outside of Italy. Ghada Mikhail (Imperial College Healthcare NHS Trust, London, UK) said: "TAVI certainly is a very exciting area. Women, as we know, continue to be under-investigated, under-treated and under-researched when it comes to cardiovascular disease.

"And what is exciting is that TAVI is the first area in interventional cardiology where women are equally treated as men. We

are currently looking at the UK database not only in terms of gender differences but also as part of the women's innovation group (WIN). We are also designing a TAVI registry for women, in order to study females receiving TAVI and hopefully be able to ascertain clinical outcomes."

Liliana Grinfeld (Italian Hospital, Buenos Aires, Argentina) added: "We are treating TAVI patients in Argentina and women represent more than 50%, as everywhere else. We have problems with access sites, so some of the patients should have the subclavian or the transaortic approach. All of those that did are women, and they were all successful, so women do very well

with TAVI, and we hope that, in the near future, we will be part of the registry."

JIM Today also spoke to Marie-Claude Morice (Institut Cardiovasculaire Paris-Sud, France), who explained that TAVI is not the only area where there are gender differences in response to therapy. "I think that, for most diseases, the responses of women to treatment are very often different. For example, cardiovascular prevention with aspirin doesn't work as well for women as for men.

"And usually because women are under-represented in the trials, we have never had that information; because they are not powered for gender analysis. In TAVI, it is half and half, male and female, and we really want this registry to identify the specificity of TAVI in women.

"It's of particular importance



Marie-Claude Morice

first to improve results and, second, women have a longer life expectancy. So, if we treat a woman of 80 years, for example, her life expectancy is longer than a man of 80, making it even more useful for society."

For more information on the WIN-TAVI Registry, please visit: www.scai.org/WIN/

Additional contributions by Holly Whitin.

Live from JIM

'Why I use IVUS in the cath lab'

Intravascular ultrasound (IVUS) is a simple, cost-effective and extremely useful tool to complement traditional angiographic measurements in the cath lab, delegates heard on Friday evening during a session dedicated to imaging and functional evaluation.

IVUS has been previously met with some scrutiny, including suggestions that it is too expensive and time consuming. However, there are fervent supporters of the technology that are keen to stress that, in their opinion, IVUS should take pride and place in any cath lab.

One such supporter is Antonio Bartorelli (Centro Cardiologico Monzino, Milan, Italy), who spoke to *JIM Today* ahead of his presentation on IVUS during the Friday evening session. "Let me tell you first of all that our cath lab is the one that used the highest number of IVUS catheters not only in Italy but also in Europe, so we are very convinced that IVUS is a good to help us achieve the best results in PCI [percutaneous coronary intervention]," he said.

Dr Bartorelli then moved on to discuss his presentation as a whole: "My talk is really a practical one," he said. "I don't want to touch base too much on the literature and things like that. JIM is a meeting for the interventionalist, so I will really [just] show an example of why we think IVUS could be of help."

Again, the time aspect is one of the components of IVUS that seems to separate opinion, but Dr Bartorelli has a clear standpoint: "The first slide is just a slide

that shows how much time is needed to prep and IVUS catheter and to have the image," he said. "And I show that in three minutes in a trained lab, you have your image on the screen. So the myth that IVUS makes you lose time is not true. It is very fast and easy."

Dr Bartorelli continued to say that the "main backbone" of his talk would be to discuss the classic and new indications for IVUS imaging. "Among the classic indications [are] intermediate and equivocal lesions and any time that angiography doesn't tell you if that lesion is really critical for the patient," he said.

"The other point is uncertain capillary lesions. Sometimes you have a patient with acute coronary syndrome, and by angiography sometimes you don't know which is the culprit lesion, and IVUS can help you find the more severe lesions, or lesions with ruptured plaque."

He added that the third and fourth points to consider were correct lesion sizing for stenting, and optimisation of the stent implantation itself. "It has been demonstrated more and more and more than you can optimise the stent implantation," said Dr Bartorelli.

He continued: "The fifth point is in assessing complications. Sometimes after angiography you have fuzzy images and you don't know what they mean and what you should do, and IVUS can help you in detecting dissection and things like that."

"The sixth point is the evaluation of in-stent restenosis. Mainly that you have



Antonio Bartorelli

to differentiate between very aggressive proliferative responses."

In terms of new indications for IVUS, Dr Bartorelli detailed his thoughts on what areas warrant more usage of IVUS in the current time. "In my view the new indications are bifurcations lesions – and I put the biggest bifurcation lesions in this subset: the left main. The left main is very important," he said.

He added: "[Also important] is chronic total occlusion lesions, and the guidance from chronic total occlusions. I will show a few examples of how IVUS can help you. And some cases of primary PCI and STEMI [segment elevation myocardial infarction] patients."

Given the support that Dr Bartorelli has for IVUS in improving his clinical outcomes, what does he feel are the main barriers still holding IVUS back from being ubiquitously adopted? "My feeling is that

the studies that demonstrate the benefits of IVUS are underpowered," he said.

"To have a power study in patients undergoing DES [drug-eluting stenting], you need a study that is larger, and the cost of this study would be over 10 million dollars. I doubt that a study of this size will be done, for cost issues, so we have to live with what we have."

Returning to the issue of cost, we asked Dr Bartorelli as to his thoughts on how often IVUS should be used. Is it cost-effective to use IVUS in every procedure, or are there specific cases where it is unnecessary? And how do costs factor in?

"In my lab every time we have a diagnostic doubt that is not solved by the angiographic images alone, we go for IVUS," said Dr Bartorelli. "I think there is an upfront increase of the cost that pays off along the way. A stent thrombosis or a stent restenosis has its own cost, not only for the patient themselves, but also in terms of the economical costs for the hospital and society."

He added: "Don't forget that if you have a large usage of IVUS you can negotiate a much better price with the company."

In his closing remarks to *JIM Today*, Dr Bartorelli stressed that a common mistake made by centres was to use IVUS only in a few cases, which doesn't allow the development of skills properly, and ultimately, and ironically, leads to even less usage. "Forget about using IVUS in 3% of your patients: you will never be proficient in understanding what you are looking at," he said.

"You have to use it [regularly] to understand what the images mean, and how they can help."