Thinking ‘out of the box’ in mitral valve-in-ring case

The audience packed into Main Hall Washington on Friday morning for a series of live cases from the Interventional Cardiology Unit at the San Raffaele Scientific Institute in Milan. Kicking off the first case were operators Antonio Colombo, Azeem Latib, Matteo Montofano and the rest of their team, who were gearing up to address severe mitral regurgitation (MR).

The patient, a 72-year-old man, had a medical history of hypertension, dyslipidaemia, paroxysmal atrial fibrillation (treated with warfarin), COPD and severe chronic kidney disease. In 2014, he was diagnosed with severe left ventricular dysfunction, with normal coronary arteries and severe MR. As such, he underwent mitral valve repair with a Medtronic (USA) Profile 3D Annuloplasty System – a 28 mm fully rigid ring designed to repair the mitral valve annulus.

Having had ‘frequent’ >1-month admissions for heart failure in the last year, at the time of the case the patient was still symptomatic, with effort dyspnoea (NYHA III). Echo showed recurrence of cerebral emboli. Does the mainstream join cerebral embolic protection devices? Continued on page 2

OCT brings atherosclerosis into sharp focus

Page 6

Lithoplasty runs circles around calcium

Page 7

Evidence to date on no-predilatation TAVI

Page 10

Cerebral embolic protection devices: joining the mainstream?

Page 11

DEBATE: Is imaging during PCI so important? Main Hall Washington Thursday 09:45–10:15

Great debates at JIM 2017

Stepping up to the podium first was Dr Prati, who gave his opening gambit for the audience. “First of all, it is very important indeed to use an imaging modality, particularly OCT, when we want to really understand what is going on in patients with ambiguous lesions in the setting of acute coronary syndromes.”

He added that given OCT has such a high resolution, it gives superior ability to identify thrombi – thereby allowing the pinpointing of ruptured vessels and lesions that could cause acute events. Clinically, it allows better understanding of what syndrome the patient has, and therefore aids in drug choice.

Importantly, Dr Prati also stressed that imaging modalities can be used to help decide when best not to treat a patient. Similarly, he added: “I think it is very important sometimes to use IVUS, to use OCT, to decrease the Syntax score: i.e. to be less aggressive. It is difficult, however, to

Continued on page 12
### Programme

**Saturday, February 11 2017**

**Main Hall Washington**

Chairmen: Eberhard Grube, Alexandre Abizaid

**8.30** **LIVE CASES FROM MILAN, ITALY**

*Columbus Hospital Heart Center*

Commentators: Cosmo Godino, Omer Goktekin, Roxana Mehran, Francesco Versaci, Alan Yeung

Operators: Antonio Colombo, Azeem Latib, Gloria Melzi

On-line factoids relevant to the cases presented: Lorenzo Azzalini, Francesco Giannini (Coordinators), Luciano Candilio, Antonio Mangieri, Akihito Tanaka

**9.30** **CASES PRESENTATION AND DEBATE**

Chairmen: Eberhard Grube, Alexandre Abizaid

Marco Ancora  Milan - Italy

Francesco Giannini  Milan - Italy

Ioannis Iakovou  Athens - Greece

Nikolaos Konstantinidis  Thessaloniki - Greece

Mohammad Hassan Namazi  Tehran - Iran

Francesco Tomassini  Rivoli, TO - Italy

Orsola Valtecechi, Angelina Vassaleva  Bergamo – Italy

**11.00** **LIVE CASES FROM MILAN, ITALY**

*Columbus Hospital Heart Center*

Commentators: Carlo Di Mario, Ghada Mikhail, Augusto Pichard, Patrizia Presbitero, Mohamed Ahmed Sobhy

Operators: Antonio Colombo, Azeem Latib, Gloria Melzi

Guest Operator: Sunao Nakamura

On-line factoids relevant to the cases presented: Lorenzo Azzalini, Francesco Giannini (Coordinators), Luciano Candilio, Antonio Mangieri, Akihito Tanaka

**12.00** **Closing remarks and JIM 2018 announcement**

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**Thinking ‘out of the box’**

*Thinking ‘out of the box’ in mitral valve-in-ring case of severe MR, severe left-ventricular systolic dysfunction (LVEF 25%), and moderate-severe pulmonary hypertension.*

Session Chairman Gregg W. Stone commented: “This is a typical scenario, and it is increasing. These rings fail in patients with dilated cardiomyopathy, and this is why surgeons are moving away from putting rings in.” He added that disease recurrence rates after using such rings are expected in as much as 35%-50% of cases.

“There are interesting issues here. Do you predilate? Do you straighten out some of the three-dimensional geometry?”

Co-chairman Nicholas Van Mieghem weighed in to discuss the approach moving forward, noting: “In this particular case there is a poor left ventricle, so I would not go transapically. I would try for a transseptal approach.”

**“There are interesting issues here. Do you predilate [a rigid mitral annuloplasty ring]? Do you straighten out some of the three-dimensional geometry?”**

Gregg W. Stone
in mitral valve-in-ring case

With plans to implant a valve prosthesis, choice and sizing of the device was also up for debate. While consensus was to use an Edwards (USA) SAPIEN 3 valve, the sizing was more tricky to decide, despite indication for a 23 mm prosthesis from app calculation. “We have discussed this case a lot, and the challenges with this ring, and a 23 mm valve, are two-fold,” commented Dr Latib. “One, because [the ring] is so eccentric, we may get paravalvular leak at the edges of the ring. And, it may deform the valve as well, so we could end up with a residual gradient … so we wondered if we should use a 26 mm valve.”

Importantly, to be more confident in their valve sizing, the team used a benchtop test with a new, ‘out of the box’ ring of equal size, and evaluated its structure after dilation with either a 22 mm or a 26 mm non-compliant balloon. They discovered that the 22 mm balloon did not impart any structural changes to the ring (even at rupture pressures), thus large gaps remained in the eccentrically-shaped ring, which would leave it rife for paravalvular leak. The 26 mm valve, however, was able to re-form the ring to a circular profile, and as such the 26 mm valve was deemed the best sizing to utilise.

“That is a great demonstration,” said Dr Stone. “It will also get rid of some of the three-dimensionality of the ring (which may or may not be beneficial), but it clearly makes it more circular, and that will decrease the chance of paravalvular leak.”

Using a Safari® guidewire (Boston Scientific, USA), the team placed the 26 mm Sapien 3 valve prosthesis – after which the panel commented on how fast and ‘easy’ they made it look. On Echo, there was some minor paravalvular leak still remaining, owing to incomplete apposition of the device frame to the ring, thus the team employed dilatation with a TRUE Dilatation balloon catheter (Loma Vista Medical), a fibre-reinforced valvuloplasty balloon complete with diameter control (within 1.5%).

Inflating to 10 ATM, the dilatation was able to reduce paravalvular leak down to trace levels – which was deemed perfectly acceptable from the point of view of the operators, and panel.

Live from Bonn: “Even in experienced centres, hypertrophied ventricles pose a challenge.”

Commentators Oscar Mendiz (Buenos Aires, Argentina), Giuseppe Musumeci (Cuneo, Italy), Augusto Pichard (Washington DC, USA), Horst Sievert (Frankfurt, Germany), Mohamed Ahmed Sobhy (Alexandria, Egypt) and Robert J. Van Geurs (Rotterdam, the Netherlands) joined Gregg Stone (New York, USA) and Nicolas Van Mieghem (Rotterdam, the Netherlands) to discuss yesterday morning’s live case from University Hospital Bonn, Germany, where operators Eberhard Grube, Georg Nickenig, Nikos Werner, and Fritz Mellert carried out a transfemoral TAVI in bicuspid aortic stenosis.

The patient was a 76-year-old female with no severe past medical history and no coronary artery disease. Her clinical presentation was dyspnea (NYHA III) due to severe heart failure, and she also had recurrent syncope. A severe aortic valve stenosis (log EuroScore 6.19%, STS score 1.56%) was identified, accompanied by severe calcification and left ventricular (LV) hypertrophy. The valve was a bicommissural raphe-type bicuspid aortic stenosis type I. Echo revealed ejection fraction at 60%, and a peak-to-peak gradient of 176 mm hg. The sizing of the annulus was very challenging. Three different measurements, at different heights, were taken: at the aortic annulus, the average diameter was 26.0 mm with a perimeter of 81.8 mm and area of 521.5 mm²; at 5 mm above the annulus, the average diameter was 23.4 mm, perimeter 80.5 mm and area 425.1 mm²; at 8 mm above the annulus, the average diameter

Continued on page 4
JIM today  Issue 3  Saturday  11 February 2017

Live from Bonn: “Even in experienced centres, hypertrophied ventricles pose a challenge.”

Continued from page 3

was 22.5 mm, perimeter 79.6 mm and area 354.9 mm². The team were in agreement that landing at the annulus was probably too deep.

“Because you have his bicuspid situation and almost a reverse doming, 5 mm above the perimeter is smaller,” said Dr Nickenig. “8 mm above is where we think will be our landing zone. We will try to re-evaluate that using a balloon dilatation later on.”

Dr Nickenig pointed out the significance of the distance to the coronaries, especially in patients with bicuspid aortic valve stenosis, because the leaflets are longer — such factors favouring a smaller prosthesis sizing.

Thus an attempt was made with the Lotus valve 23 mm (Boston Scientific), along with cerebral protection with the Sentinel device (Claret Medical).

Reviewing the diagnostic information gathered so far, Dr Grube continued, “First of all, the 250 mmHg gradient — that is huge, and accounts for the massive LV hypertrophy which also poses a challenge in terms of placing wires. For that purpose, I think it is good that we have a Safari Extra Small (Boston Scientific), just to make sure that we are not irritating the ventricle too much.

“The other thing is the massive calcification. Calcifications pose a risk for placing, sizing, embolism, coronary obstruction — all these things are in one bundle in this particular patient. That is why I think, when we look at bicuspid valves, the classic way of looking at the annulus doesn’t work anymore. Usually, we downsize the valve size by at least one. It is really up to you to decide which downsize to take. In the classic way, it would probably be 25 mm, but we are doing a 23 mm.”

After advancing a 23 mm predilatation balloon at the level of the stenosed valve, Dr Nickenig recapped: “We had a hard time to pass this valve. There is also some aortic regurgitation. It was very difficult to get the catheter to the ventricle. So we decided, unusually enough, to give always contrast dye, because sometimes you can end up out of papillary muscle.”

“Even in experienced centres, hypertrophied ventricles pose a challenge,” added Dr Grube.

Back at the JIM auditorium, Dr Stone added some context to this particular presentation: “Obviously this is a new burgeoning indication for TAVR. There have been hundreds of cases done now for bicuspids — the results seem pretty good. Perhaps there is a higher pacemaker rate than in non-bicuspid.”

“The most important thing is downsizing the valve,” offered Dr Pichard. “There is so much calcium there; there is no room. Especially when using balloon-expandable, I’ve seen annular rupture when you go by the annulus size.”

Dr Pichard added that the Shock-
wave Lithoplasty device (Shockwave Medical) would achieve softening of the calcium, possibly making this case easier to manage. “It is a very, very challenging case,” agreed Dr Van Mieghem. “The advantage of Lotus is that it is completely repositionable and retrievable so you can completely deploy it and then take it out. This is quite unique. You can do it with the Direct Flow valve [Direct Flow Medical Inc.] and Lotus, but that’s it. But I’m still not convinced that you need to size 5-8 mm above the annulus. It depends on the patient-by-patient evaluation. But I must admit that this piece of calcium is really impressive. I would still use a 25 mm valve, though.”

“I can see your point,” responded Dr Grube. “But I disagree. In all my experience with bicuspid valves, the valve is not anchored in the annulus; it is anchored in the leaflets. Therefore, for sizing of the bicuspid valve, the annulus really doesn’t help much. Besides that, we have to pay attention to the coronaries, because if the calcium flips up we may have an issue. But again, the valve choice means that if we do have an issue we can collapse the valve and if we see there is any flow disturbance in the left main, we could keep the valve there, protect and put a stent in.”

“If you do careful planning, then you are prepared. That doesn’t mean that you are avoiding complications, but we are prepared for having them and we know how to deal with them.”

Returning to the tricky balloon passing into the valve, Dr Nickenig inflated the positioned balloon and applied contrast, revealing no leakage. Commenting on the result, Dr Van Mieghem still felt 25 mm would serve the patient better. “A balloon inflation and additional contrast gives you a piece of information, but it’s not the gold standard.”

The patient was insistent on TAVR rather than surgery, explained Dr Grube. Given the heavily calcified aortic arch, noted Dr Van Mieghem, surgical reconstruction of the arch may have been demanded if surgery had been opted for. After a few positioning attempts with the 23 mm Lotus valve, aortic insufficiency was repeatedly noted due to the particular expansion of the valve frame against its calcified surroundings. Dr Van Mieghem pointed out that, while the case was clearly challenging, it also illustrated the benefits of the Lotus prosthesis: “It is very controlled, the patient is very stable. I must say, I really appreciate that there is embolic protection in place. You can imagine that the manoeuvring in the annulus will dislodge quite some material.”

“I would also predict that there will be substantial material at the end of this case,” said Dr Stone. “Even if we don’t have a lot of criteria for using it, I think in these cases it makes a lot of sense. That is going to be the question when the [Claret Sentinel] device is more widely available, at least in the US: which patients do you use it in (assuming it is approved)? I think the safety is going to be its saving grace at the advisory board panel, although it didn’t show efficacy in terms of clinical outcomes. But its purpose is really to capture material, and in 100% of cases it caught material. And it is visible – not what you would see in STEMI – big chunks of material.”

On the recently-published Sentinel trial results, Dr Van Mieghem added: “There was a 42% reduction in lesion volume by MRI, which was not significant – so it tells you that it was underpowered. Also, 20% of the patients did not have a follow-up MRI.”

After some unsatisfying results of repositioning, discussion began as to how to proceed. Suggestions included sizing up the prosthesis to 25 mm (which would achieve a greater opening force), or performing further and more extensive predilatation. After revisiting IVUS and angiography revealing moderate aortic insufficiency, the team opted to switch to a 25 mm prosthesis, with no further balloon predilatation.

“It’s a challenge, these heavily calcified bicusps – the geometry and forces are so different to the tricuspid valve,” commented Dr Stone, as the team repositioned the valve a number of times, finally achieving a better position to avoid both insufficiency and valve regurgitation. The case concluded with final angiogram confirming the absence aortic insufficiency.
During Thursday’s symposium focusing on the use of coronary imaging for guidance of coronary interventions, Enrico Romagnoli (Centro per la Lotta contro L’Infarto - CLI Foundation, Rome, Italy) walked the audience through the use of optical coherence tomography (OCT) to reduce procedural complexity.

Speaking to JIM Today, Dr Romagnoli summarised some of his key messages.

OCT has been lauded as having ‘unparalleled’ spatial resolution. But what can you tell us about its clinical utility?

OCT is an innovative intracoronary imaging technique designed for a better definition of coronary atherosclerosis and its functional consequences. The current OCT systems are rapid with unprecedented spatial resolution allowing high-definition visualisation of intraluminal and endothelial structure. In particular, it permits semi-automated accurate insights regarding stent apposition, struts coverage and neointimal growth.

However, OCT may provide operators with an excess of information that may lead to an overreaction, and an effort to correct innocent but ominous-looking anatomic issues. Thus, the clinical utility of OCT to improve percutaneous coronary intervention (PCI) techniques, and clinical outcomes, remains to be defined.

OCT-defined suboptimal stent deployment was an independent predictor of worse clinical outcome (HR=3.53, p<0.001). These data seemed to corroborate the rationale for an OCT-guided strategy during PCI.

How does OCT sit in with IVUS?

When compared to IVUS, OCT’s unprecedented spatial resolution allows a more accurate quantitative, and also qualitative, assessment of coronary disease. OCT is capable of visualising superficial plaque components at a high resolution (in the range of 10-15 microns) and can depict all the features of plaque vulnerability (e.g. presence of macrophages) or thrombogenicity.

The identification of these plaque features with imaging modalities is potentially a valid approach to identify patients at increased risk of future events (i.e. myocardial infarction).

Are there cost/reimbursement issues?

Unfortunately OCT penetration into daily practice is still low, basically for reimbursement reasons. We hope that our efforts to identify the correlation of some OCT findings and clinical outcomes will stimulate the design of larger, accurate randomised controlled trials aiming to validate OCT use during PCI.

“OCT may provide operators with an excess of information that may lead to an overreaction, and an effort to correct innocent but ominous-looking anatomic issues.”

Enrico Romagnoli
Lithoplasty system makes waves in DISRUPT CAD study

The latest study updates for a unique therapy were laid bare yesterday in a session dedicated to drug-eluting stents (DES) and optimisation technology.

Known as Lithoplasty Technology (Shockwave Medical, USA), the device combines lithotripsy and angioplasty, thus merging the calcium-disrupting power of lithotripsy, and the simplicity of a standard balloon catheter platform. “Unlike traditional focused lithotripsy, Lithoplasty uses unfocused lithotripsy to provide a circumferential impact on calcium,” said Todd J. Brinton, Clinical Associate Professor of Medicine (Cardiology) and Adjunct Professor of Bioengineering at Stanford University, Stanford, CA, USA. Dr Brinton is co-founder of Shockwave Medical, and serves as Medical Advisor.

“The device requires no special guidewires. It is a standalone technology for addressing both the superficial calcium that may obstruct the artery, and deep calcium that restricts vessel expansion.”

While the platform is based on decades of safety experience in renal lithotripsy, its efficacy is being tested in DISRUPT CAD, a pre-market, prospective multi-centre single arm study conducted at seven centres in Europe and Australia. DISRUPT CAD has evaluated the use of Lithoplasty as a treatment for calcified coronary arteries prior to DES implantation. Sixty patients with complex calcified obstructive coronary artery disease were enrolled, with 80% of these classified as having ‘severe’ calcification.

Dr Brinton presented results from DISRUPT CAD yesterday at JIM, commenting: “The primary endpoint – the ability to dilate calcified lesions with less than 50% residual stenosis, without in-hospital MACE – was 95%. And the study demonstrated a residual stenosis of 13% in these very hard to treat lesions, and acute gain of 1.7 mm (Figure 1).”

He added that the MACE rate was 5%, with only three biomarker-positive non-Q wave myocardial infarctions, and no angiographic procedural complications such as perforations, slow flow or no-reflow were observed from core-lab review.

References

“Unlike traditional focused lithotripsy, Lithoplasty uses unfocused lithotripsy to provide a circumferential impact on calcium.”

Todd J. Brinton

Procedural Angiographic Outcomes

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<tr>
<th>Diameter Stenosis</th>
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<td>60±13%</td>
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<td>13±15%</td>
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Cumulative Frequency Distribution

DON’T MISS!...
Pay a visit to the wine corner at JIM for a refreshing chance to try delicious wines from the Colombo vineyard!
The miniature approach to CTO

Speaking during Thursday’s CTO session, Andrea Gagnor (Ospedale degli Infermi, Rivoli, Italy) examined the trend towards miniaturised interventions that is gaining ground in the cardiovascular community. New devices, he explained to JIM Today, are an opportunity to reduce vascular complications and patient discomfort – but they come with their own unique set of strategies for dealing with complexity.

“In CTO PCI, the most complex procedure in the coronary tree, it’s important to maintain the correct balance between miniaturisation and safety and efficacy of the procedure,” noted Dr Gagnor before contrasting miniature with standard sizing: “New devices offer the opportunity to perform very complex procedures with small devices. But larger guiding catheters offer the possibility to perform complex procedures with simultaneous utilisation of different devices, and to change strategy according to the problems you have to face during the procedure.”

In a 2015 paper, Kiemeneij et al. described the miniaturised – or ‘slender’ – technique as any that is associated with less trauma to the radial artery, primarily through the use of reduced French sizes. It is proposed that this could improve outcomes and reduce costs – although this remains unvalidated1 – “There is no position, and there is no analysis,” confirmed Dr Gagnor. “It is just a personal attitude to perform the procedure in one way or another. From the cost point of view, even if you use a slender introducer rather than a conventional introducer, you are not changing the cost of the procedure in a very important way.”

Miniature introducers tend to possess smaller outer diameters accompanied by a decreased wall thickness, allowing the insertion of larger guiding catheter without compromising the radial approach. Matsukage et al. demonstrated successful tapered soft or stiff 0.010” guidewire passage in 60% of 141 CTOs in 2010.2 Smaller compatible balloons, as well as diagnostic catheters, have also been developed.

For simple procedures, the benefit to risk ratio is rather high, as complications are fewer, explained Dr Gagnor. Back up techniques, such as loops, anchor wire or balloon, parallel wiring, mother and child, are associated with a learning curve1.

“When things get more complex, you might have to change your strategy or device. So maybe you start with a 6 Fr guiding catheter, and you may have to change to a device that requires an 8 Fr guiding catheter.”

Small catheter sizes, like sheathless introduction, are also more difficult to manipulate, explained Dr Gagnor. Lack of back-up support is an issue, too: “With a lesser level of support you sometimes have to perform very aggressive manoeuvres in order to advance your equipment into the CTO body, which can cause damage to the arterial wall.”

References
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No predilatation in TAVI

The TAVI discussion continued yesterday afternoon with Oscar Mendiz (Hospital Universitario, Fundación Favaloro, Buenos Aires, Argentina) examining the case for no predilatation in TAVI. While in most cases it is feasible and safe, he said, gentle predilatation can still be required where there is doubt, or in cases of extreme calcification.

Dr Mendiz answered some of the key questions in predilatation in TAVI during an interview with JIM Today.

You described the rationale for omitting predilatation steps in TAVI procedures from your single-centre experience with the CoreValve. Could you describe this cohort?

We didn’t use routine predilatation from the very beginning of our series. After one multicentre experience conducted by Professor Grube in which we also participated, we kept on doing TAVI without predilatation for almost all our cases (more than 95%). We published this experience in 2013, and then we continued.

It is important to remark that due to some commercial restrictions, the balloon-expandable valve was introduced in my country of Argentina only very recently. Thus most of our team experience, and also proctoring in the Centros de Investigación LATAM, was done with the self-expandable valve. However, Dr Eulogio Garcia has published a pioneer series with balloon-expandable transcatheter heart valve.

What is your experience in no predilatation with respect to choice of valve?

Well, I have some limitations answering this question, because CoreValve was the only valve available for many years in my country (and it is by far the most commonly used device nowadays due to some commercial reasons), until the introduction of JenaValve, then Accurate Neo (TA and TF), Lotus and now Edwards.

However, we have used almost all of the self-expandable valves without predilatation except for the first cases with Evolut R, where we followed companies’ recommendations, and for transapical implantation of the JenaValve.

What is the current state of the data on this question of valve choice, particularly when it comes to postprocedural transprosthetic gradient, and the long-term effects of inclusion or omission of predilatation?

The available data is not enough and quite contradictory, because in our series – and also in other TAVI series – using no predilatation was feasible and safe. However we have to point out that most of the series were single centre experiences and not well designed clinical trials, but there a reduction of the stroke rate and permanent pacemaker implantation was observed.

Moreover some of these data belong to the beginning of the experience in many centres, using first generation valves. Thus is quite difficult to extrapolate to current practice. In addition, the complication rates are so low in current series that it is going to be quite complicated to get a significant reduction when comparing with or without predilatation.

For the few cases where we used the JenaValve by a transapical approach, we used predilatation because we were not so sure about safety.

We never had a case without predilatation where the THV did not cross, and (then because of this) we had to use predilatation. However, we had a case with extreme calcification that, after valve deployment and before final delivery, the THV was so asymmetric with almost a total antero-posterior collapse that we decided to retrieve the valve and predilate.

In other cases we had some difficulties retrieving the nose cone of the delivery system but we are not so sure if it was due to not using predilatation, aortic angulation or both.

Regarding gradient, I have not found any significant differences, neither have other series, but regarding the concern about durability, I would say that in my opinion it would affect late outcomes if we have had worse initial outcomes, which we do not, and a higher need of postdilatation, which has not been conclusively observed.

Are there cases in which no predilatation is unfeasible?

I would say that if we have extreme calcification, with a difficult threshold (8.000UA was used in one series) and we are not sure about the implantation without predilatation, we should use it without any doubt – but gently to prevent potential complications due to S-Schneider (embolisation or acute-severe AR with haemodynamic deterioration).

Of course, having an adequate randomised clinical trial would have been the best option to answer almost all these questions, but with the current experience of the operators and new repositionable devices, I am not so enthusiastic about the possibility of having such a trial in the near future.

Operators will continue trying to simplify the procedure as much as they can, and not using predilatation is part of that.

Oscar Mendiz

“Operators will continue trying to simplify the procedure as much as they can, and not using predilatation is part of that.”

Oscar Mendiz

References


Complete cerebral protection during TAVI

Cerebral embolic protection (CEP) with the TriGuard Cerebral Protection Device (Keystone Heart, Israel) was addressed during the TAVI 2 session, held yesterday, including a discussion of the REFLECT trial currently underway in Europe and the US.1 While CEP trials to date of have provided hope amid few hard numbers, this remains an area of interest due to the growing awareness of the significance of peri-procedural brain lesions. REFLECT commenced enrolment in June 2016, anticipating a total of 285 patients, and is expected to complete in October of this year.

In their recent editorial accompanying the release of the analysis of the randomised trial of the Sentinel system (Claret Medical, USA), Azeem Latib and Matteo Pagnesi discussed a motive for continuing the investigations into CEP in transcatheter aortic valve replacement (TAVR), especially given an era which is seeing increasing numbers of intermediate- and low-risk patients undergoing the procedure.2

The authors noted that cerebral events, including those clinically silent, are evidenced as contributing to memory loss, cognitive decline, and dementia. The filters of 99% of patients contained histopathological debris generated around the TAVR procedure; thus an appeal to reason suggests CEP devices hold merit despite insufficient evidence.3 While the Sentinel system was deemed safe it was not found to convey significant differences in terms of post-procedural diffusion-weighted (DW) MRI lesion volume relative to no protection in TAVR (despite it trending), possibly due to its small sample size.3

Numerous other difficulties in Sentinel’s design and interpretation were described by Latib and Pagnesi, including the fact that the Sentinel only offers protection to 9 out of 28 brain regions due to the exposure of the left vertebral vessel.2 In contrast, REFLECT’s predecessor DEFLECT demonstrated complete cerebral vessel coverage in 89% of its 85 subjects with the TriGuard system.4 The TriGuard device departs from the Sentinel in that it deflects material rather than capturing it, and is introduced via the femoral artery rather than the right radial.

During an interview with JIM Today, Dr Latib (San Raffaele Scientific Institute, Milan, Italy) described the significance of silent brain infarct and the issues within trials to date that may explain why CEP is not currently a standard part of the TAVR procedure for every patient.

“There are a lot of patients who are having cerebral events during these TAVI procedures that are subtle,” he began. “Now that we go to the lower risk patients, this becomes important: silent brain infarction has become important.”

And silent brain infarctions are frequent in TAVI, occurring in about 80% of cases according to the pooled analysis carried out by Latib and Pagnesi.2 Younger patients may possess a greater cognitive reserve, whereby cerebral events have less of an impact on cognition – but such events are nonetheless significant in the context of a lifetime: “From birth to 100 years old, there will be a slight decrease in brain function and cognition with time, which will be very subtle. During the lifespan, there will be little events that cause that straight line to drop down, until it gets to a level where you start seeing dementia.”

“You get to that line quicker if you have bigger events, such as either clinical strokes – or even silent strokes. This is really our concern: are we giving patients silent strokes?”

“We as cardiologists are not great at diagnosing strokes. There have been a couple of studies looking at stroke rates as reported by the physicians – when you get neurologists to examine the same patients, stroke rates can more than double. Furthermore, there were no standardised or uniformed definitions for stroke after interventional procedures until the recent publication of the Neuro-ARC definitions. We probably underdiagnose clinical stroke, and we don’t have a reproducible and easy way of measuring or defining the subclinical ones.”

Around 60% of TAVR-associated cerebrovascular events occur around the 24-48 hour period procedural window, noted Dr Latib. Cerebral protection, therefore targets this 60% majority of clinical events. By extension, it is logical to suggest that silent infarcts occurring during this 24-48 hour period are therefore also prevented by CEP.

“We are impacting all patients, then,” concluded Dr Latib. “I think we are having beneficial long-term negative impact on all patients.

Honestly, I would not want to have a TAVR procedure, without cerebral protection!

“The hope is that the TriGuard will demonstrate efficacy data where other trials have not.”

Azeem Latib

References


Great debates at JIM 2017

Continued from page 1

“Translate this important concept into numbers.”

He went on to note that “How to stent?” is a pertinent question to be addressed, noting several factors that have an impact on early thrombosis and restenosis, including: small minimum stent area, underexpansion, edge problems (geographic miss, secondary lesions, large plaque burden, dissections etc.). “So I think it is important to deploy a stent, in some cases, looking [with IVUS] from the inside, to make sure you have done a good job,” said Dr Prati.

He continued, turning to studies and various meta-analyses evaluating IVUS-guided DES: “The question is do we have sufficient data to further address this issue? I would say yes, because in the last five years we have seen many studies with analyses that show that IVUS is a very reasonable solution to improve the outcome ... not only target lesion revascularisation, but also the incidence of myocardial infarction, and death.”

ADAPT-DES1 was a particular focus, with two-year follow-up – from 3,361 patients treated with IVUS-guidance versus 5,221 treated with angiographic guidance – showing that the use of IVUS significantly decreased MACE rates, definite/probably stent thrombosis and myocardial infarction. “The curves tend to diverge month by month, so it very possible that the longer the follow-up, the greater the benefit,” said Dr Prati.

In ADAPT-DES, when IVUS was used, it translated to larger stent/balloon use, higher pressures, longer stents, as well as a more “aggressive” approach with post-dilation or additional stenting.

Moving on to OCT, Dr Prati underlined that while it is a relatively new modality, thus has less data, traction is gaining, including Dr Prati’s own CLI-OPCI studies (see page 6 also on this topic). The multi-centre CLI-OPCI study concluded that OCT plus angiography can improve clinical outcomes of patients undergoing PCI, specifically a reduction in the one-year rate of cardiac death or myocardial infarction.

He also touched upon the ILUMIEN I trial, a key finding of which he relayed: ‘Physician decision-making was influenced by pre-PCI OCT findings in 55 % of patients (57% of lesions) and by post-PCI in 25% of patients (27% of lesions) with a total of 66% of all patients and 67% of all lesion treatment decisions influenced by OCT’.

As Dr Prati described, the DOCTORS trial2 – a multicentre study involving 240 STEMI patients randomised to either OCT-guided or angio-guided PCI – showed that OCT use can significantly improve FFR rates. “It is nice to see in a randomised study that we can definitely improve our way of stenting,” he said.

Going back to the ILUMIEN family of trials, he noted that in the randomised controlled ILUMIEN III trial,1 OCT-guided PCI was safe, and resulted in a similar minimum stent area to that of IVUS-guided PCI. The second CLI-OPCI study, published in 2015,4 used OCT to...

Continued on page 14
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demonstrate that suboptimal stent implantation was present in 31% of its PCI cases, and was associated with an increased risk of MACE during follow-up. What’s more, the CLI-OPCI ACS study (507 patients, 588 lesions, mean follow-up 284 days) showed that “thrombus inside the stent is an additional factor that can impact the outcome,” as Dr Prati noted.

He went on to stress that it was “obvious” that you can’t use IVUS or OCT in all cases, rather you need to be selective, using them wherever angiographic results are unacceptable. “And, I would say, we have to use OCT or IVUS when we have complex cases,” he added.

The IVUS-XPL randomised clinical trial, which Dr Prati also emphasised, concluded that ‘IVUS-guided everolimus-eluting stent implantation, compared with angiography-guided stent implantation, resulted in a significantly lower rate of the composite of major adverse cardiac events at one year. These differences were primarily due to lower risk of target lesion revascularization.’

Offering his conclusions for the audience, Dr Prati pondered on the original question of ‘Is imaging during PCI so important?’, stressing that we still do not have a definitive answer, and including some possible explanations. First, he argued that it is not imaging itself that makes a difference, but the correct interpretation and consequent action. In addition, because imaging is not FFR, it does not give a “black and white” answer, thus it is a struggle to find a practical algorithm to apply.

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“Also, another point is that now we are applying very nice stents, and I think that the event rate is very low indeed,” he said. “Every time we tackle a stent thrombosis, we save a patient’s life, so I think it is very difficult to translate this important concept to statistics. I do think, therefore, that we have to use imaging modalities any time we are not confident we have done a good job using angiography, and then any time we start complex lesions, such as left main, bifurcations (etc.)”

He concluded: “Lastly, and it is an important message again, is that while it is difficult to translate into numbers, I do think the use of OCT is of great importance to better understand what is going on, and to make a good diagnosis.”

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