Optimal care for your patient before and after TAVR

Martin Leon MD: Hello. My name is Martin Leon from Columbia University Medical Center and the New York Presbyterian Hospital in New York City. It's my pleasure to welcome you to this editorial discussion, which is entitled "Optimal Care for Your Patient Before and After TAVR or in Europe TAVI.

I am joined by my colleagues David Hildick-Smith from the Brighton and Sussex University Hospitals in the UK, and Jeroen Bax from the Leiden University Medical Center in the Netherlands. First, welcome, David and Jeroen.

David Hildick-Smith MD: Thank you.

Jeroen Bax MD: Hi.

TAVR: Hot new procedure

Dr Leon: As I'm sure you all know, one of the hottest new procedures in the interventional cardiology universe is the transcatheter aortic valve replacement procedure. In Europe alone in the past five years, there have been more than 35,000 cases. In the United States, where we're going a little bit slowly because of the delay in regulatory approval, in the last year there have been about 8,000 cases. So this is increasing very rapidly.

So it's important for us to inform the entire medical community on the best way to prepare patients for this procedure TAVR and also how to best care for the patient after TAVR. And that will be the focus of this editorial discussion.

Appropriate image screening

So let's begin by talking about the typical patient that presents to us who may be a candidate for this new procedure. And let me ask Jeroen, from the esteemed point of imaging, if you have a patient that you feel has severe aortic stenosis who is now developing symptoms, what would be the appropriate screening imaging evaluations?

Dr Bax: Well, thanks Martin. I think what is important when you look at these patients is that first you have to confirm the aortic stenosis severity. I think that's the key issue. And if there is a good LV function and you look for the maximum gradient and mean gradient and the surface area, basically a standard transthoracic echocardiography is good enough for that.

If the function is not good, then you can enter into the discussion whether this is a pseudo stenosis or a true stenosis. And I think then you can do a low dose dobutamine challenge. Or you can also look at the CT scan and just see if there's lots of calcium because it was demonstrated recently that if there's lots of calcium in the valve, then frequently this is a true stenosis. And with the low dose dobutamine, you can also find out if this is a true stenosis or it's secondary to the poor LV function.

Once you have determined that the case is let's say a normal ventricle or a bad ventricle with true stenosis, then I think the important thing is that you look for the geometry of the valve. And one of the first things is to look at the bicuspid valve. Or is it a tricuspid valve?

And if it is a bicuspid, I think that the discussion that's evolving also is is this a true bicuspid or is this like a degenerative bicuspid?

Dr Leon: What we call functionally bicuspid—

Dr Bax: Exactly. So that is something that you can also easily find out usually on transthoracic echocardiography. Well, once you have identified this information—which usually comes from the CT scan that is routinely performed in most centers nowadays—you can look for the valve a little better and also for the aortic root, the annulus, and the ascending aorta.

For the valve, we like to look at if there is a lot of calcium and where the calcium is. If there's a lot of calcium and it's specifically in the annulus or in the walls towards where the valve is originating, that's where your prosthesis is going to anchor. So if there's a lot of calcium there, that may have a higher likelihood to result in regurgitation afterwards because it's difficult then to deploy sometimes the valve exactly in these positions.

You take a look at the annulus. From that you can do sizing. For the sizing you need a three-dimensional technique. So during the procedure, people can do a transesophageal echocardiography. But in the routine workup, we don't do a transesophageal, but we do transthoracic which is a 2-D technique. So we rely here on the CT scan.

And it's important to realize that sometimes the annulus can be very oval-shaped. So you have a short dimension and a long dimension. We like to take—we like to put more emphasis on the long dimension than on the short dimension. And also with the three-dimensional approach just like CT, we can assess the parameter, which is like tracing around. But you can also assess the area.

Dr Bax: And I think these things are the most accurate for sizing the annulus and giving you the indication for what size of valve you need.

Dr Leon: So I think what's clear is that for this procedure—it's very clear to me at least—that the intensity of the noninvasive imaging is crucial. It's unlike what we do commonly in interventional procedures. So the quality and the care in interpreting the echocardiogram, the effort that goes in to looking at the CT is extremely important. So that's a fundamental part of the screening evaluation.

Further screening

So David, what other screening and clinical tests do we need to be concerned about?

Dr Hildick-Smith: I think there are a number of things that [you need], as someone who receives referrals, and that you're hoping that the referral will contain information about. So obviously the severity of the aortic stenosis, and hopefully, whether the patient is symptomatic or not—that's obviously rather critical, but it's sometimes left out.

But beyond that, I think the main things that I look for in the letter is any indication of cognitive impairment or cognitive decline on the part of the patient because I think if that's present, then you have to think very carefully about whether this is the right thing to be doing for somebody. And that's in a sense top of my list of red flags.

After that is probably kidney function. I'd be hoping to get something about that, because obviously we know that those patients don't do very well in medium terms If their kidney function is poor, that's something that's nice to hear about.

Beyond that, very commonly a composite, if you like, of mobility on the one hand and overall frailty assessment, however it's done, on the other, is nice to see—

Dr Leon: This is again something new for us. We have not been accustomed to really looking at frailty as an entity, as a phenotype, for patients and try to account for that in terms of a patient's candidacy for a procedure.

Dr Hildick-Smith: Absolutely. And I think that we probably don't have the right tools for it yet either. There are all these indices of frailty, but I'm not sure that any of them is exactly what we're looking for yet.

Dr Leon: I think it's a work in progress.

Dr Leon: I think we do a lot of tests, but we're not quite certain which objective parameter is most important.

Dr Leon: Although some people think that the five-meter walk test, if you're going to do one test, is probably a good one to do.

What about risk profiling? Are you calculating scores? How are you deciding if a patient is, you've talked a little bit about it before if a patient is too sick and might fall into what we call the futility category. What about those patients that might be a better candidate for surgery?

Dr Hildick-Smith: Surgery. No, absolutely. I mean what you hope is that in the referral letter you have enough information to go to the MDT so that you can at least do a kind of triage of the MDT and say, well, it sounds as though this patient may actually be a candidate for surgery, so the surgeon should see them in clinic. Or it sounds as though this patient is a good candidate for TAVI so the TAVI cardiologist or surgeon should see them in clinic.

So, yes, you're looking for those kinds of things including chronic obstructive airways disease, that's a very important one, vascular disease burden, previous strokes, carotid disease, peripheral vascular disease, all of these things. And I guess what we do is—hopefully if we have all that information in the referral letter, then we can make that decision in the meeting and start to point the patient in the right direction. But obviously that all gets modified by them actually being seen in clinic.

The heart team

Dr Leon: Yes, exactly. And that's what I wanted to get to next, which is that we're used to working a little bit in isolation as interventionalists, as surgeons, even as imaging specialists. But this procedure in this whole scenario of these elderly, ill patients is a little bit different. So we've now invoked this concept which began with coronary disease, but now it's taken a whole new dimension with valvular heart disease: the heart team.

So Jeroen, do you have a heart team in Leiden? And how do you approach when you actually see the patient making these decisions?

Dr Bax: In Leiden, there is a weekly meeting. And the meeting is attended by cardiac surgeons, by heart failure specialists, by imaging specialists, and by interventionalists. And one of the attending cardiologists is presenting the patient describing all the different things. And the "imager" shows the images, and the heart failure specialist indicates how severe the heart failure is, for example. And based on all this information, then the team decision is taken. So all these complex patients are discussed on a weekly basis. And then a consensus decision for treatment is taken.

Dr Leon: So the idea of the heart team is not really a notion of convenience. It has, in most large referral centers, become a fundamental component to make decisions for patients, which brings the surgeons and the interventionalists and the imaging specialists finally together in the best interest of the patient, which I think is exciting.

Now another responsibility of the heart team is to decide, what is the best access? Now we have many options. So David, how do you and how does the heart team make the decision for access?

Dr Hildick-Smith: I think initially what we do is much as Jeroen has been describing. We look at the imaging. We will tend to have angiography, CT scan, and an echocardiogram as our tools. So we will look at the imaging modalities and decide based on this information. Perhaps the femoral is or isn't the best approach. And then we'll have to take into account the other factors if the femoral is not looking good because it's too tortuous, too calcified, too small caliber etc. then other diseases processes will have to be taken into consideration. If we're going to use another site, for example transaortic, it's a very good approach, but not so great if somebody has bad chronic obstructive airways disease. Subclavian is very nice, but if the iliac vessels are too small caliber, the subclavian is likely to be too small caliber as well. And it's a friable vessel.

So I think this, as you were saying, is also a work in progress I think because nearly everybody would choose to go by the femoral approach as the least invasive access route and the one which the patients respond to and recover from the quickest.

But in decreasing order of merit, if you like, we head then through the subclavian and then through the transaortic, and finally perhaps to the transapical, this would be the current strategy certainly in our unit.

Dr Leon: Yeah, I think it varies from place to place based upon preference with respect to valve type and familiarity with one approach or another. But certainly it's necessary to have alternative access beyond the transfemoral because we understand the consequences of significant vascular complication. So we want to certainly make the right decisions for patients where the common femoral and iliac access may not be optimal.

Dr Hildick-Smith: Yes.

Preparing the patient

Dr Leon: So one of the aspects of this procedure that fascinates me is that there clearly is this level of preplanning where you have to go through a very intense imaging phase. You have to assess many clinical aspects of the patient's overall condition in ways that are different than what we would normally. And we need to actually prepare ourselves for what is the access and what size valve we're going to use. And this requires a very coordinated effort and a lot of communication with the patient and the family.

So once you've made the decision, you've gone through this effort, and we have a patient that's going to go through the procedure, what do you tell the patient about what they should expect as they go through the procedure? Jeroen, how do you prepare them?

Dr Bax: Well, usually the patient is being informed by the referring physician. And the physician indicates the procedure and how long the hospitalization is expected to last. Usually the ins and outs of the procedure make up most of the discussion taking place.

Dr Hildick-Smith: So in your unit, will the MDT— because for us the MDT, if you like, makes a provisional decision, a decision based only on the clinic-pathological features. And, of course, then the decision is only really made with the patient. So in your unit that's not made by the people who are going to be implanting, that's largely made by the referring—

Dr Bax: It's a discussion between the referring. But we have actually one physician who is seeing those patients at specific outpatient clinics. So most of them are centered in that outpatient clinic. So they always have the same information and we ensure that the same discussion is taking place.

So I think that's a good approach that you have. And he's also doing most of the implants. So he's seeing all the patients before and also seeing them back after, so… And Holland is a relatively small country, so the patients, they are usually coming from the neighborhood and not from very far so they can easily come back. And they usually stay with us for further follow up.

Post-procedure management

Dr Leon: I think it is important to emphasize that there usually is a valve clinic that is organized to be able to see these patients and their families because there are many social issues—these are elderly patients—in terms of their postprocedural care that have to be sorted out. And I think many of these things can be discussed with the family and the patient during the valve clinic.

So we've gotten the patient ready. We've done what we think is proper communication. They understand the risks, the benefits, and what to expect in terms of recovery. And we get through the procedure and we have what we think is a good result.

And now we have to manage the patient after the procedure. And it can be a bit tricky certainly in the first several days after the procedure because these are elderly patients that are high risk for surgery, many with heart failure, many with poor LV function, and many with other comorbidities. So I think that the postprocedure management is quite critical.

In fact, we've had to construct our own valve service, clinical valve service, which rounds just on the valve patients because we think that there's such sensitivity to many of the aspects of their care.

How do you manage the inpatient phase postprocedure? Do you have a special team or certain things that you worry about that need to be considered?

Dr Hildick-Smith: Well, we don't have a special team and I like the sound of your setup. I suppose to be fair, it's probably an area that overall we handle less well as interventional cardiologist than the preplanning. So post-procedure the patients are obviously seen every day that they're in—it may be three days, it may be seven days or whatever—and at those stages, we're looking immediately, of course, for any potential complications and then for return of simple body functions, the urine output et cetera, being able to get up and go to the bathroom et cetera, the next day ambulation and all these things.

But at the same time, of course, we're looking for the more practical aspects specific to the valve. So is the valve working okay? So they'll have an echocardiogram at some stage. Is there any issue with atrial ventricular block?—
we would be monitoring that for at least 48 years depending on the valve type.

But I think much of it is just supportive if you like. And this is driven more by good nursing than the doctors in sort of gently chivvying the patients to get up out of bed and get going again quickly because, as you've said, if some of these patients stayed too long in the hospital because of their general infirmity, they can subside rather and be slow to get going. So you have to a little bit bold.

Dr Leon: That's a very good point. Rapid mobilization and being able to get the patients with physical therapy and social work involved for disposition, because sometimes they don't stay in the hospital very long but they go to a secondary facility that would assist them to get more fully mobilized.

But we worry about all of those things, of course, kidney function with the contrast load. We worry about, of course, stroke. The first thing you want to do is see the patient wake up and act normally. That's very important. You worry about vascular complications and bleeding. We worry about new onset atrial fibrillation. We worry about heart failure, which can occur if we don't watch carefully the volume status. So we—

Dr Bax: [interposing] AV conduction.

Dr Leon: Exactly, AV conduction. So all of these things are important.

Post-procedure imaging

Also pre-discharge, we do some imaging. And it seems to me that it used to be if you're an interventionalist that angiography is king.

Dr Bax: And in this procedure?

Dr Leon: Angiography is secondary and echo is king. So maybe, Jeroen, you can explain what we do in terms of just looking at the echocardiograms afterwards and how we follow these patients?

Dr Bax: Yes. Well, the way it's being done in our hospital is that the routine echoes are being performed, so no transesophageals. Those are really not needed. We do routine transthoracic. You look for the valve positioning. You look for the opening. You look specifically for the regurgitation. You look for LV function whether that's recovering or not. And sometimes you can also see combined valve disease that there is in severe aortic stenosis with secondary mitral regurgitation. And sometimes you see that improve quite rapidly. And sometimes that takes quite some time.

My idea about it is that the pressure overload results in a quite rapid recovery and the reverse remodeling. Sometimes you see that results in a later recovery of mitral regurgitation. So we look for that also.

But basically a routine standard transthoracic echocardiography; the way we do it is immediately after and then at discharge one more, and then usually at about several months after—the patient comes back to this outpatient clinic and is seen by the specific physicians. And then the echo is being done the same day and we look at that specifically for these features.

Sometimes one can consider doing a CT scan if you don't understand exactly what the leakage is causing to see the deployment and what that looks like. But routinely transthoracic echo I think is the tool of choice.

Followup post-discharge

Dr Leon: Yes. Clearly the idea of seeing the patient again, at least in our environment, is an important one, even though we, of course, will send the patient back to the referring doctor for the day-to-day and the chronic post care. In that respect communication is essential, to have direct communication so that they understand exactly what's happened, what to look out for, and what medications and other things to consider.

But we also have a routine where we always bring the patients back. No matter where they're from, they have to come back somewhere around 30 days. It's been shocking to me—in a nice way—that unlike coronary disease, people's lives are transformed, from a symptom standpoint, within 30 days.

You have elderly women who were frail and could barely walk across the room who come back with makeup and absolutely with a completely different affect. Frankly for me, it's very reassuring to see that. It's one of the things that's nice for a physician to see.

But also I think you can pick up things. And you become very acutely aware and sensitive to some of the medical problems. And you can help the referring doctor in their chronic care. But it's essential to have this communication with the referring doctor so that the post-procedure care is optimized, especially in these high-risk patients with so many comorbidities.

Dr Hildick-Smith: And it's a great educational tool for the physicians themselves because if you do procedures on patients and you never see them again, you never

know whether you made a good choice or whether you had the wrong patient entirely. So seeing them at least once afterwards is so important, isn't it?

Dr Leon: Essential. And one of the things that's also been important is that we're very enamored with a new procedure. Sometimes interventionalists can suffer the fate of being too excited to be more proceduralists than physicians. And we tend to emphasize some of the good results. Some of the patients don't improve that much from a clinical standpoint. And it's important for us to see that so we can become more discriminating I think in terms of how to select patients in the future. So we've had patients that have had chronic congestive heart failure due to ischemic cardiomyopathy who don't get that much better or other patients with such severe chronic obstructive pulmonary disease where frankly they haven't improved.

Dr Bax: Exactly. And it's very difficult sometimes to determine what is now causing the symptoms, or the fatigue or the low exercise capacity. Is that related to pulmonary disease or is that really the valve that's causing that?

And we've also seen these cases where you do not see the expected improvement. Although the valve is functioning quite well, the symptoms do not get so much less.

Aortic regurgitation

Dr Hildick-Smith: Yeah. It's been a bit of an education for us I think that, certainly initially when we did this procedure, we thought, oh, that's only a little bit of a leak, that'll be fine. We've cured the obstruction—they're going to be much better. And a good portion of them come back and actually they're *not* that much better.

And there's quite an issue with assessing the degree of aortic regurgitation both clinically and echocardiographically, which I think we haven't worked out yet.

Dr Bax: Not sorted at all. It's very difficult to precisely quantify the aortic regurgitation because all of the nice echocardiographic and other imaging tools that you have to assess the severity of your aortic regurgitation, they don't work after TAVI because it's very hard to apply these. So usually it comes down to visual assessments of the leakage on a short access view. And then they say if it's more than 20%, it's significant. But what does that mean?

Dr Leon: Exactly, yes.

Durability

One last question that I get posed many times is that these are new valves, in a sense. They may be made from biologic materials that are common to surgeons but we're still testing a new technique. And it has to do with how durable these valves are. Perhaps it impacts, in fact, our sensitivity with regard to what patients to treat. If there are younger patients, should we subject them to a technology where we don't have very long-term durability data?

Jeroen, you've seen as many of these patients and valves and echoes as anyone. Do you have any early insights from the standpoint of durability, anything that is different from these valves than surgical valves so far?

Dr Bax: No. I think for the medium term followup that's available, we do not see any specific features. So they look good so to speak. But it is really the long-term followup that is anticipated to tell us really what the durability will be. But as far as I can see now in the followup and we see all the patients back, as I indicated. And most of them come directly from the neighborhood, so we see all of them back and also for a longer-term followup. And so far, it looks quite good.

Dr Leon: So I think we can say that it's encouraging what we're seeing from midterm followup. But we need more data and we need a longer time to be definitive about that.

Conclusions

Well, this has certainly been a very interesting discussion. I've learned a lot. And I think the emphasis again is on the clinical care of the patient: to be able to properly screen patients, to get the right tests, to communicate avidly with the referring doctor both pre-procedure and then after the procedure; and then to try to provide an environment where the patients and their families can have more than adequate postprocedure care.

I think the emphasis on the multidisciplinary heart team is very important to us in the United States. In fact, it's mandated for us to even receive reimbursement for a procedure. It has to be both surgeons and interventional physicians and imaging physicians working together. And I think that's a good thing. I think we've now learned to become partners in care as opposed to at times competitors.

So with that, I'd like to thank both of you for your sage comments. And hopefully this editorial discussion will be meaningful to many of the physicians who are with us today.