Yves Louvard

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Taking a closer look at bifurcations: A conversation about Visible Heart®

The Visible Heart® model is a novel tool to visualize the internal workings of a beating heart. *Confluence* spoke with Dr Yves Louvard, Institut Hospitalier Jacques Cartier, Massy, France, and Dr Francesco Burzotta, Catholic University of the Sacred Heart, Rome, Italy, who pioneered the use of this model for imaging the stenting of bifurcation lesions.

Can you tell us how the Visible Heart initiative began?

Dr Yves Louvard (YL): The Visible Heart initiative is supported by the European Bifurcation Club, which I helped to found 10 years ago and Medtronic (Medtronic, Inc., Minneapolis). Within the Club, we have been working to improve stenting of bifurcation lesions for many years and we have had many discussions about theory, cases and data to try and do so. One of our key challenges is trying to show what is invisible in the clinic – that which cannot be seen with X-rays while deploying of stents. To date we have done this by modelling simulations of virtual bifurcations coming directly from the anatomy of a patient.

The Visible Heart is based on the work of the Visible Heart Lab, which houses a beating heart model that enables us to gain a greater perspective on interventions than if we performed an angioscopy in the clinic. Last year, Medtronic proposed that we use this pre-existing model developed by the University of Minneapolis to help visualize a stent implantation in a bifurcation lesion.

Dr Francesco Burzotta (FB): Our ability to work in the Visible Heart Lab, whose work focussed on electrophysiology and structural heart disease, has now allowed us to provide more information about coronary interventions. While the Visible Heart Lab had been used up until then for anatomical studies by the team at the University of Minnesota, no studies had been performed by this lab to investigate coronary circulation. Since the European Bifurcation Club is a working group of experts in percutaneous treatment of coronary bifurcations, the idea was for them to test how bifurcation prevention could be visualized using the Visible Heart Lab.

Can you explain the concept behind the Visible Heart Lab and what the technique entails?

FB: The Visible Heart Lab has pioneered a unique system in which a recently harvested beating pig heart is suspended in a clear blood-like solution and is connected to a resuscitation machine. This enables the visualization of a beating heart and gives you have the opportunity to place interventional devices inside the heart, allowing you to investigate the parameters in different chambers – for example, the pressure. With the use of optical probes, you can also monitor how the heart behaves during beating.

It is extremely interesting to have high-quality pictures from inside the coronary artery since this is not possible routinely. This means it is very difficult to imagine the end result of percutaneous interventions, especially complex interventions like bifurcations, where the interactions between the stent and the coronary artery wall are less predictable.

YL: This system enables us to use a probe to enter the coronary arteries and visualize what we want to see. In this case, we are using this model to look specifically at the bifurcations. We are able to enter each of the tree arteries simultaneously and visualize how the stents are deployed in a coronary bifurcation following different insertion techniques. We can also use this system for many other situations, not just bifurcation stenting; for example, I have seen a registered case of valve implantation with double angioscopy from the aorta and from the apex (videos from the Visible Heart Lab can be found at **www.vhlab.umn.edu/atlas** and **http://www.visibleheart.com/index.shtml**).

Can you describe your personal involvement in the project?

YL: I was asked to propose some other operators from the European Bifurcation Club, or elsewhere, to perform the stent implantations using the Visible Heart Lab. I recommended Francesco Burzotta because he is very involved in the practical management of patients. Within the European Bifurcation Club, he has very frequently presented different bifurcation stenting techniques.

FB: When I was invited by Yves Louvard to take part in the initiative, I was the first interventional cardiologist to perform stent implantations in the Visible Heart Lab. I performed a double-stenting implantation in the Visible Heart model according to my preferred bifurcation intervention, the T And Protrusion (TAP) technique. This is an established technique that enables the implantation of an additional stent into a side branch, even if you start by stenting the main vessel. During this first day, we worked on two hearts from two pigs, which had been harvested sequentially.

The Visible Heart Lab is specially equipped for these experiments, to allow us to perform our intervention exactly as we do in our routine practice in the catheterization labs. This meant that we could visualize on an angiographic machine our interventions and manipulations as we were performing the procedure. We were able to insert the guide-wires and the guiding catheter through the aorta, so that the method of cannulation of the coronary artery was exactly as we do in our coronary patients, using the trans-femoral approach. After the coronary angiography, we decided which bifurcations were suitable to receive stents, and we continued with the procedure, recording everything with multiple cameras.

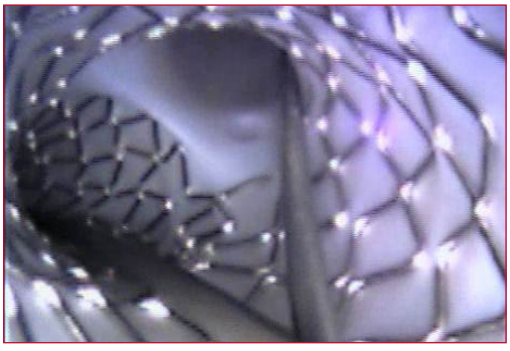

IMAGE: ©Medtronic, Inc.

fig. 1

Visible Heart image. Resolute

What is the clinical application of the Visible Heart initiative?

YL: The first time I was able to see a stent deployed using Visible Heart Lab really was an outstanding experience. Using the Visible Heart Lab we are able to show different methods of stent implantation, performed by different interventionalists and we are able to see the outcomes of these stenting procedures. A sample image is shown in figure 1.

In the clinic, we have radiological tools like the StentBoost (Philips Healthcare), angioscopies, intravascular ultrasounds (IVUS) or optical coherence tomography (OCT), to enhance visualization of the stent, but these tools do not let us see inside the vessels to visualize the stent position. Using the Visible Heart model, I have now seen stent deployment. Furthermore, I have seen the implantation of a CoreValve (Medtronic, Inc.) in an aortic pig valve imaged from both sides – the back of the ventricle and through the angle of the aorta; you can see how the valve is moving and whether the deployment is eccentric or not.

FB: The unique feature of the Visible Heart Lab is that it allows for the insertion of another probe, an angioscopy probe, inside the coronary artery. This means we can record each step of the stent insertion visually. The procedure is performed using angio-guidance, as in the clinical practice, but each step is checked with this endoscopic device.

Performing the TAP technique myself, it personally allowed me to observe the morphological associations of my routine stenting practices. Normally, when we implant the stent in the coronary artery we don't know the exact anatomical aspect of the stent – the interaction between the stent and the wall. The Visible Heart model allows us to do this in a wonderful way because the system is perfused not by blood but by a saline solution, specifically designed to accommodate the optical tools.

How will it benefit the wider cardiology community?

YL: My colleagues, especially younger operators, will probably view the images from the Visible Heart Lab with such surprise and wonder because they probably don't really know what is actually occurring to their stent inside the coronary artery. A website is currently being developed to store the uploaded

images of different stent implantations that have been performed using different techniques on living pig hearts.

This model will help provide a link between the radiology data and cardiac morphology; if we see a protrusion in some techniques in the middle of the other branch in the results then I hope that if we are collecting the data we will see the consequences of this. This is what is important for the treatment of patients. People interested in the topic of bifurcation stenting will then be able to see what they are doing and what the outcome will be if they use one of these techniques.

FB: All the main images will be put on the Medtronic Visible Heart Lab website (**http://www.visibleheart.com/index.shtml**) and made freely available to registered doctors. This project was carried out with the specific aim of allowing everybody to have access to, and reap the benefit from, these images.

This Visible Heart is really useful to check if different techniques are associated with specific problems or benefits and may therefore be very informative for investigating different stenting interventions. As I mentioned previously, we don't know exactly, at the anatomic level, the nature of the interaction between the stent and the vessel. We perform our chosen intervention based on the angiography and sometimes we also use an imaging device, but there is no way to check exactly how the stent is positioned inside the artery. I think this experimental technique will be very useful to better understand the nature of the different stenting techniques and to evaluate these methods. I think this may be an important application of this technology; if you have a new technique, or if you have a new device for coronary intervention, then why not check the result – how the device is associated with the vessel – with the Visible Heart?

Do you think the Visible Heart Lab is likely to influence clinical practice?

YL: There are a number of different strategies available for stent implantation in bifurcation lesions. We aim to have images from a variety of different stenting techniques and I believe that by showing cardiologists the outcomes of different stenting techniques, this will inform clinical practice.

From the studies carried out in Europe[1] for example, we learned that it is better, if possible, to put only one stent in a bifurcation, even if there are two diseased branches. It is considered best practice in Europe to insert a stent in one of the branches and a 'kissing' balloon in the other.[1] In the US, however, they frequently use systematic double stenting and frequently begin stenting by the side branch. Despite European data showing that it is probably better to insert only one stent, many US cardiologists believe that we probably don't see the same lesions as they do, and that perhaps the lesions seen in the US are more complex. Thus, there is still some controversy as to best practice for stenting bifurcated lesions.

I think the Visible Heart initiative will help cardiologists to understand the impact of their interventions, particularly when using some exotic techniques, such as the classical crush technique or simultaneous kissing stents. This latter technique involves the simultaneous deployment of two stents with a double barrel in the proximal main part of the bifurcation. If we show this kind of technique with an angioscope, you will see an impressive neo-carena in the middle of the main vessel proximal to the bifurcation, but this is a true vessel, a moving vessel in a living heart. Using the Visible Heart Lab, US cardiologists may appreciate the concerns raised regarding this technique and they may choose to follow the advice from Europe, where many studies and meta-analyses show that one stent is better. Conversely, if the US patients are really different, it will help the US cardiologists to design their own clinical studies on their own patients to investigate single stent implantation in US patients with different anatomies and different severities of lesions. The Visible Heart initiative will help cardiologists make an informed decision about clinical practice having viewed how the stent looks in a real coronary artery. I am convinced it will change the vision of the operators about what they are doing in the patient.

What are the limitations of the Visible Heart Lab?

FB: One of the main limitations is the fact that the pig hearts we tested were from a healthy animal, whose coronary arteries were not diseased. Using Visible Heart, you are testing a theoretical condition, which is never encountered in clinical

practice – you are treating a normal coronary artery. A clear progression of this technology could be testing hearts that are unhealthy, in an experimental condition that allows you to have coronary arteries which are diseased. Looking to the future, I believe that the relevance this technique will continue to improve if diseased hearts are used.

Another limitation is that the beating heart doesn't last in this condition for ever. This means that you have a limited timeframe to perform your test. For example, very complex situations for which you have very long interventions may be affected by the fact that there is a time limitation issue.

YL: There are limitations with all simulation projects. A clear limitation in this living pig heart is that there is no stenosis, so not the problem we encounter in patients with stenosis. What we propose with the Visible Heart is lesion-free bifurcation stenting, so it's not exactly the same as the patient; but does provide an idea of what we are doing in patients.

What are the future applications of the Visible Heart Lab?

YL: For the moment, the aim of the Visible Heart initiative is for operators with different ideas about bifurcation stenting to investigate these various techniques, allowing them to see the end results and make informed decisions. Following this, we may ask other operators to go to Minneapolis and use the Visible Heart Lab to perform even more exotic techniques, to populate a visual library of simulated cases.

With the images obtained from the Visible Heart Lab, we will try to help people learn stent bifurcation practices. This model could definitely be used for teaching purposes. Indeed, we have already experienced some mistakes while performing stenting using the Visible Heart Lab, which are useful for teaching purposes; we know why these mistakes occurred and we want to teach people about the practical problems of bifurcation stenting using the images produced. The Visible Heart can help cardiologists to understand why the problems occurred and how to correct them. I always say to my Fellows that the best way to learn the job is to go and discuss the complications with colleagues, so they can see exactly how to avoid the problems. With the Visible Heart, we can see the problem and then try to solve it. As this is a pig heart and not a patient, we have to create the problem first and then explain how it can be solved, but I believe this is definitely a worthwhile process.

In the future, we want to use the Visible Heart to compare different imaging techniques, such as angioscopy, with OCT or IVUS to help us better plan operations.

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REFERENCE:
1. Katritsis DG, et al. *Circ Cardiovasc Interv* 2009;2:409-15.

DISCLOSURES: FB is involved in advisory board meetings for Medtronic, Inc. YL has no conflicts of interest.

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If you are attending EuroPCR 2014, be sure not to miss Dr Louvard and Dr Burzotta discuss the Visible Heart initiative!

Their seminar **'Stent behavior in bifurcations like you have never seen before – A first look comparing intravascular Visible Heart videoscope versus computational modeling and traditional imaging techniques'** will take place on **Tuesday 20 May, 2014** in room 242AB, **17:00–18:00**