A long-standing history of innovation for cardiovascular pathologies, Marie-Lannelongue hospital

With its colorful logo created by famous painter Joan Miro in 1972 as a tribute to the 1000th open heart surgery, the Marie Lannelongue hospital in Le Plessis Robinson, near Paris, thrives to continuously innovate in the field of cardiovascular pathologies, and decided therefore to invest in a Discovery hybrid operating room in 2017.

The Marie-Lannelongue hospital

The Marie Lannelongue hospital (HML) was founded in 1909 by Professor Odilon Lannelongue, member of the academy of medicine and the academy of sciences, and his wife Marie. Odilon was famous for his work on congenital malformations and bone pathologies, in particular tuberculosis.

Since then, the HML has become a center of excellence for thoracic, vascular and heart surgery, dedicated both to pediatric patients and adults. In addition, it is the reference center nationwide for complex congenital cardiopathies. Some of the most important innovations which have built its international reputation include the first pediatric open heart surgery in Europe in 1955 or the first European implantation of a mechanical valve in 1962. In 1986, HML performed successfully the first French heart-lung transplant. ■

SOME KEY NUMBERS ABOUT THE HML

201 beds

960 members of staff

8377 hospital stays, split in 40% surgical, 35% interventional and 25% medical stays

6213 interventional procedures, among which 51% are coronary interventions, 26% vascular interventions, and 23% other types of interventions

3750 surgeries, including 776 on pediatric patients

The hybrid OR project

In 2017, the HML invested in a hybrid operating room (HOR), equipped with the Discovery IGS 740 system. The HOR opened part time this summer and full time in September, and patient recruitment is increasing since then. The room was co-financed by the hospital and by Medtronic, as part of a collaboration on implantable cardiac valves.

Pr. Elie Fadel, medical director of the HML, cardio-thoracic-vascular surgeon, tells us all about this project.

Where did the hybrid operating room project come from?

The project was born about 18 months ago and was pushed by an increase in our endovascular and TAVI (Transcatheter Aortic Valve Implantation) treatment activities. We also started to collaborate with Pr. Stéphan Haulon, head of the aortic center in the University hospital of Lille at that time, and he later decided to join us here when we invested in the Discovery IGS 740 hybrid OR. We aim to be constantly at the spearhead of surgical innovation, so we need to have the very latest high-end equipments to continue to lead in the percutaneous treatment of cardiac pathologies such as mitral clip and valves, as well as thoraco-abdominal aneurysms. This is why a hybrid operating room was a must.

How is the hybrid OR currently used?

This room is used mainly for complex interventions that we would not be able to do without such an equipment, and is shared between all departments in the hospital. Currently, the room is dedicated to percutaneous cardiac interventions two days per week, aortic endovascular interventions another two days per week, and the last day is for pediatric cases. It is also used for open surgeries, as it truly works like a standard operating room when the

Discovery is parked. We had for instance a case of open aortic repair last week with cardiopulmonary bypass.

We also anticipate to use it in the future for other applications, such as spinal tumors or lung tumor resections. Indeed, it is key to be able to locate precisely the extent of such tumors for the safety of the intervention and also to avoid removing healthy tissue that could be preserved. But in some cases, like for instance for ground-glass opacity pulmonary nodules, it can be hard to assess the tumor margins, so they are usually operated with video-assisted thoracoscopy, partly blindly with regards to tumor extension. Therefore, I anticipate that image fusion technologies brought by the Discovery HOR will allow us to treat these cases more effectively and safely, by enabling to highlight and remove only the lesion itself.

How was the learning curve for the staff?

We were a bit worried initially about the learning curve, but were positively surprised as the staff adapted very quickly to the technical use of the system. This was even easier thanks to the involvement of Pr. Stéphan Haulon and Pr. Dominique Fabre from the vascular surgery department who were both familiar with the Discovery system. In the end, the main challenge was the re-organization of staff, in particular access to the room for all departments and anesthetists' rotations between rooms. We also had to redesign OR circulation, hygiene and sterility rules as the hybrid room is installed in the interventional radiology department and not in surgery. Now, after two months of use, we are over that learning curve and the room is fully occupied.

Why did you choose the Discovery hybrid OR from GE?

We felt the Discovery room was the most suited solution for our specialties, such as percutaneous valve repairs and endovascular interventions. In addition, we started a collaboration with Pr. Stéphan Haulon on aortic repairs, and he was very satisfied with his own Discovery room in Lille. Our hospital also has a strong collaboration with the GRCC (Gustave Roussy Cancer Campus), as we work like a virtual common entity by mutually taking care of each other's patients in our specialties, and Pr. Thierry de Baère, head of interventional radiology at GRCC, also promoted the choice of the Discovery HOR.

Finally, we have a close collaboration with GE on research as well, as we will soon have the same Discovery equipment in the animal lab to validate future applications and run basic research projects.

What are the main benefits of this Discovery HOR?

I would say that there are two main benefits. The first one is to be able to do what we did before in a simpler and safer way, with less radiation dose and contrast media. So, we are improving the security and results of procedures for patients, thanks to image fusion technology in particular. The second benefit is that we can now perform cases that we could not do before, we are enlarging our surgical indications and treating patients that were previously contra-indicated because they are too fragile. Now, thanks to the HOR and image fusion, we can offer an alternative to these patients.

In terms of economic benefits, it is too early to quantify them, but I am convinced that with better results we will be able to reduce the length of hospital stay thus decreasing costs. Between that and the overall increase in patients treated thanks to this room, we should see an increase in our revenues.

In conclusion, this technology is first and foremost for the patient, as we can offer safer surgeries, and propose minimally invasive surgical alternatives to more patients. It represents a true progress in our cardiothoracic and vascular specialties, both in terms of image quality and advanced applications, and it will continue to improve in the near future without any doubt. ■

Dr. Saïd Ghostine, Interventional Cardiologist and Chief of the Cardiology department at Marie Lannelongue Hospital.

Please introduce the scope of activity in your interventional cardiology department

"Our cardiac activity is above 1100 PCI, 200 TAVI, 20 Mitraclip a year so far. The department is also performing Left Atrial Appendage Closure procedures.

In our new hybrid environment, we are specifically performing TAVI, Mitraclip and LAAC procedures.

The indication criteria for these percutaneous procedures are decided within the heart team at the clinical staff. It includes our cardiac surgeon, anesthesiologist, and interventional cardiologist. If we take TAVI as an example, we also define together the access route, the measurements of the annulus and finally the choice of the valve."

What is the benefit of such an hybrid OR environment ?

"The main benefit is the security for the patient, and also the sterile environment that conforms to the latest french regulation for TAVI.

Our TAVI procedures being performed together with a surgeon, he is ready to intervene in case of a procedure conversion to open surgery: thus the patient does not move and definitely benefits from this additional security.

The sterility is not compromised as the robot is made free from ceiling rails and enabling all different positioning we need.

95% of our TAVI are performed with a trans femoral access, and we are using the carotid access for the other procedures[1], enabled by the complete team set-up and the hybrid OR environment.[1]

The quality of imaging is really good and helps us look at all the details we need. A better field of view enabled by the 40x40 flat panel enables us to do our TAVI with a single injection, lowering our contrast media use, which is very suitable for these patients suffering from moderate to severe renal failure.

We've also seen the radiation doses decrease, thanks to the use of collimation and the low-dose design of the system.

The structural heart field is expanding with important growth of TAVI procedures, as well as mitral annulus repairs, and sooner or later mitral and tricuspid valves replacements.

TAVI is growing between 20-25% a year in France. Registries show a positive curve with 7000 TAVI in 2015, 9200 in 2016 and we expect around 12000 in 2017.

We will be able to grant TAVI access to more patients, as we expect to include patients with intermediate risk (Partner II and SURTAVI studies). If clinical evidences supports extending the indication to low risk patients, we forecast 20000 patients in total.

As a reference, 15000 aortic valve replacement surgeries are performed each year in our country.

Between 2016 and 2017 our activity has grown 26%, with high risk patients that have been discussed at the clinical staff."

What are the remaining challenges?

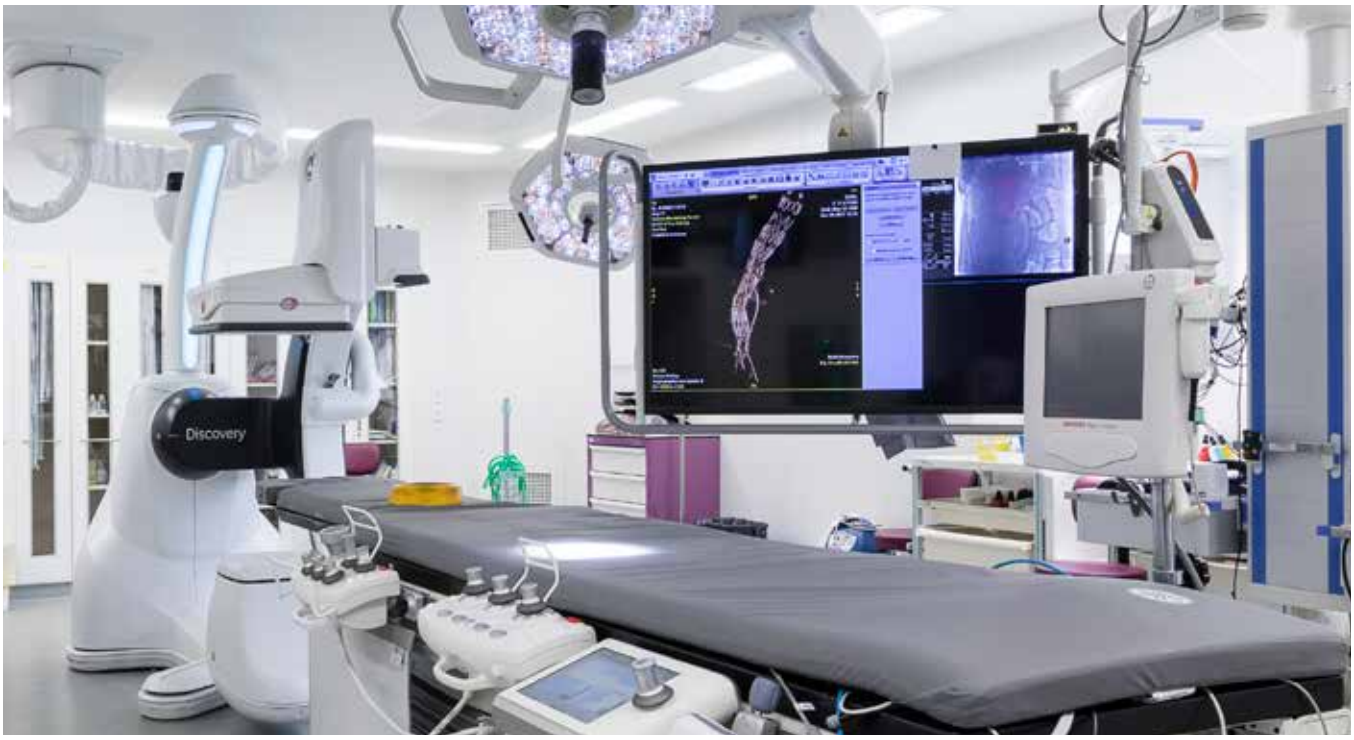
"TAVI is a well mastered procedure nowadays. The remaining challenge is mainly to simplify the whole procedure while keeping it safe.

Our patients are now under conscious sedation, as we moved away from general anesthesia.

We are now using hypnosis at Marie Lannelongue to enable a faster discharge of the patient, who is able as a consequence to recover faster than in the past.

We are using devices from the two main players, and they are still working on some improvements to decrease the size of the catheters, and valve technologies with skirt to reduce further the paravalvular leaks." ■

1 Reference: Eur J Cardiothorac Surg. 2014 Oct;46(4):693-8; discussion 698. doi: 10.1093/ejcts/ezt619. Epub 2014 Jan 14. Transcatheter aortic valve implantation through carotid artery access under local anaesthesia.



The benefits of 3D CTHD for immediate assessment of EVAR

Pr. Stéphan Haulon is a vascular surgeon and has specialized over the years in complex endovascular repairs of aortic aneurysms. He has recently moved to HML where he is the head of the aortic center. He explains to us the benefits of using a hybrid OR, in particular completion 3D angiography, for aortic endovascular repairs.

The Achilles heel of EVAR

The treatment of aortic aneurysms has switched in recent years from open repair to primarily endovascular repairs. Endovascular aortic aneurysm repair has lower early mortality and morbidity rates compared to open surgical repair, with equivalent technical success. For complex repairs, high technical success (over 95%) has been reported by large tertiary centers, encouraging the development and adoption of the endovascular technique, with early mortality ranging from 1% to 5% for pararenal and 4% to 10% for thoraco-abdominal repairs[1234567].

However, with the increasing volume and complexity of aortic endovascular repairs, stent graft–related early

1 Mastracci TM, Eagleton MJ, Kuramochi Y, et al. Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms. J Vasc Surg. 2015;61:355-364.
2 Greenberg R, Eagleton M, Mastracci T. Branched endografts for thoracoabdominal aneurysms. J Thorac Cardiovasc Surg. 2010;140:S171-178.
3 De Souza LR, Oderich GS, Banga PV, et al. Outcomes of total percutaneous endovascular aortic repair for thoracic, fenestrated, and branched endografts. J Vasc Surg. 2015;62:1442-1449.e3.
4 Amiot S, Haulon S, Becquemin JP, et al. Fenestrated endovascular grafting: the French multicentre experience. Eur J Vasc Endovasc Surg. 2010;39:537-544.
5 Oderich G, Ribeiro M, Hofer J, et al. Prospective, nonrandomized study to evaluate endovascular repair of pararenal and thoracoabdominal aortic aneurysms using fenestrated-branched endografts based on supraceliac sealing zones [published online December 13, 2016]. J Vasc Surg.
6 Oderich GS, Ribeiro M, Reis de Souza L, et al. Endovascular repair of thoracoabdominal aortic aneurysms using f enestrated and branched endografts [published online October 22, 2016]. J Thorac Cardiovasc Surg.
7 Eagleton MJ, Follansbee M, Wolski K, et al. Fenestrated and branched endovascular aneurysm repair outcomes for type II and III thoracoabdominal aortic aneurysms. J Vasc Surg. 2016;63:930-942.

complications due to technical issues during the initial procedure may occur, which potentially require re-intervention. The most common early complications include endoleak at the sealing zone and compression of side branches of the stent, putting the collateral arteries at risk or leading to potential aneurysm rupture in the case of an endoleak[8] . Therefore, these complications need to be monitored closely through follow-up post EVAR.

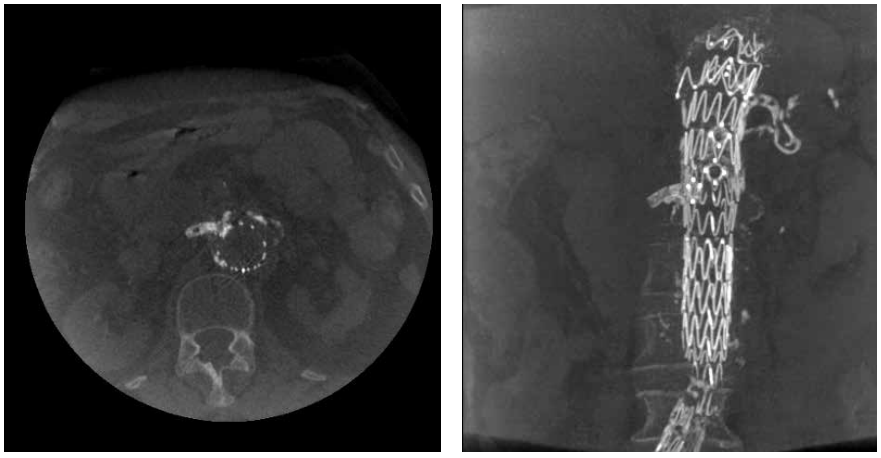
Value of CBCT post EVAR for early complications

Traditionally, follow-up includes a 2D angiogram immediately after stent deployment to verify the correct position of the endograft and patency of connecting arteries, as well as a post-op CTA (Computed Tomography Angiography) 48hours to one month after EVAR. However, 2D angiography has limitations to correctly assess the potential presence of an endoleak or a kink in the stent. The sensitivity and specificity of completion angiography to detect endoleaks have been estimated respectively at 63% (range 60-70%) and 77% (range 58-100%), while it is 92% (range 80-100%) and 90% (range 85-92%) for CTA[9]. If such complications are missed by completion 2D angiography, detection at the follow-up CTA might be too late to avoid a devastating complication, such as renal failure. Therefore, immediate assessment of the repair with intra-operative 3D imaging, namely cone-beam CT (CBCT), is more and more widely used and effective thanks to the recent advances in CBCT image quality. The benefits of immediate CBCT include the possibility to avoid secondary re-intervention if a complication is detected while the patient is still on the operating table. In the case of a compression or kink of a side-branch, endovascular maneuvers will re-open on the spot the connecting stents.

Post-operative surveillance protocol with CBCT and US

Another concern of endovascular repair compared to open repair is the long-term durability of endografts. Therefore, life-long surveillance is still required with CTA or duplex ultrasound. At his institution, Pr. Stephan Haulon has changed the surveillance protocol for EVAR patients, moving from immediate DSA at the end of the deployment and post-operative CTA to immediate CBCT and post-operative Ultrasound (US). Not only has this strategy shown an improved detection of complications and decreased rate of re-intervention consequently[8] , but it has also been shown to be much more effective dose & contrast wise.

Indeed, repeated radiation exposure and contrast-induced nephrotoxicity are major concerns for EVAR patients given the lifelong surveillance that is needed. In his previously published study[8], median exposure due to CBCT was 7.0 Gy cm^2, which represented important additional radiation exposure during bifurcated cases, but less than 10% of the total procedure in the most complex cases. According to this study, on the total hospital stay, the follow-up strategy of doing an immediate post-operative CBCT plus a contrast-enhanced ultrasound before patient discharge saved 50% radiation dose and 68% contrast media, compared to doing an immediate DSA followed by a post-op CTA.



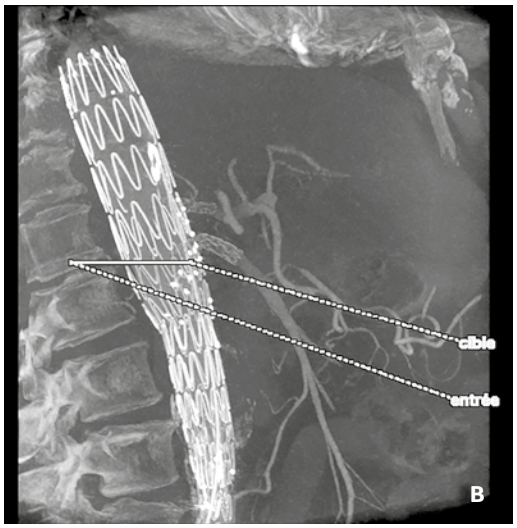
3DCT HD cross-sections with excellent spatial resolution to control endograft deployment.

New 3D CTHD for enhanced image quality at the same low dose

Recently, Pr. Stéphan Haulon noted an improvement in image quality of his CBCT acquisitions. Indeed, a new protocol called 3D CTHD, was introduced to improve the visualization of small devices and soft tissues.

8 Hertault A, Pontana F, Martin-Gonzalez T, Spear R, Sobocinski J, Sediri I, Gautier C, Azzaoui R, Rémy-Jardin M, Haulon S. Benefits of Completion 3D Angiography Associated with Contrast Enhanced Ultrasound to Assess Technical Success after EVAR. Eur J Vasc Endovasc Surg (2015) 49, 541e548

9 Armerding MD, Rubin GD, Beaulieu CF, Slonim SM, Olcott EW, Samuels SL, et al. Aortic aneurysmal disease: assessment of stent graft treatment-CT versus conventional angiography. Radiology 2000;215(1):138e46.



A: Translumbar approach to access the kinked renal stent
B: Trajectory planned on 3DCT HD with Needle ASSIST

Using high frame rate acquisition and an advanced scatter reduction algorithm, 3D CTHD reduces streak artifacts, brings uniform images for soft tissue visualization and higher spatial resolution for improved visualization of small devices, without increasing dose.

For 3D CTHD acquisitions, patient is under general anesthesia with arms along the side, and an easy spin acquisition over 200 degrees at 40 degrees per seconds is performed. A spin test is done just before to verify that there is no risk of collision between the patient and the C arm, and to check that the acquisition volume is well centered on the anatomy of interest. Patient centering is performed with the fusion mask only, saving unnecessary radiation dose due to fluoroscopy. Thanks to the wide bore C-arm of the Discovery, collision-free CBCT is easily performed and the spin test only takes a few seconds. In patients with impaired renal function, an antero-posterior (AP) fluoroscopy shot of diluted contrast media is performed to check for potential endoleaks, and then a non-injected CBCT is acquired to verify in detail the endograft placement.

Compared to his previous CBCT protocol, Pr. Haulon noted an enhanced visualization of bridging stent struts and small endoleaks, and less artifacts in cross-sections.

Translumbar repair with 3D CTHD and Needle ASSIST

Another application of 3D CTHD which has been more recently utilized by Pr. Haulon is to repair a kinked renal stent or a type 2 endoleak through translumbar puncture using Needle ASSIST. Upon completion of a 3D CTHD acquisition, the kink or endoleak is localized and a needle trajectory is virtually created on the 3D model from the skin entry point to the target. This trajectory is then superimposed on top of fluoroscopy to guide the needle until the target. Finally, two fluoroscopy views are used to precisely assess the real-time position of the needle tip and compare to the planned trajectory by reconstructing the automatically-detected needle into the initial CBCT. Once correct placement of the needle has been assessed, the translumbar embolization of the endoleak can be performed. In the case of a kinked renal stent, the translumbar approach may help to access the renal artery retrogradely if access from the aortic lumen has failed. ■

"Thanks to post-operative CBCT, we are able to immediately assess the technical success of the procedure and potentially avoid re-interventions, while reducing radiation dose and contrast. The new 3D CTHD protocol shows significant improvement for visualization of small details such as stent kinks and has the same low-dose features as our previous protocol."

Case Report
using Valve ASSIST 2

Stenting of the left pulmonary artery at the anastomosis with a left superior vena cava in a young boy with total cavo-pulmonary connection

Courtesy of Dr S. Hascouët, Hôpital Marie Lannelongue, France

Clinical challenge

One of the main challenges in complex congenital heart diseases is to understand the anatomical lesions before planning treatment either by surgery or interventional catheterization. Multimodal accurate preoperative imaging is thus essential.

Pulmonary valve atresia with intact ventricular septum and severe hypoplasia of the right ventricle leads to impaired arterial blood oxygen saturation and ventricle overload. Such cases require the same patient care strategy as single ventricle cases: the Fontan's intervention, a palliative pediatric cardiac surgery which allows deriving the systemic venous blood return by connecting the right atrium to the pulmonary artery. This technique has evolved to the total cavopulmonary bypass, connecting the vena cava directly to the pulmonary arteries, without interposition of the right atrium.

This cavopulmonary bypass allows to separate the pulmonary and systemic circulation and to restore a circulatory system "in series", leading to a non-pulsed blood flow to the pulmonary vascular system. In the present case, the patient has a pulmonary artery stenosis, compromising the flow through the pulmonary vascular tree.

Clinical case

Patient History

A young boy, with a pulmonary atresia with an intact septum and severe hypoplasia of the right ventricle, had multiple surgeries to achieve a total cavo-pulmonary assembly (connection of the inferior vena cava to the pulmonary artery with an extra cardiac tube and connection of right and left superior vena cava to the pulmonary arteries). The patient later developed a thrombosis of the right superior vena cava.

A severe stenosis at the bifurcation between the left superior vena cava and the left pulmonary artery was also diagnosed. After medico-surgical evaluation and given a high surgical risk, it was decided to perform stenting of the left pulmonary artery stenosis.

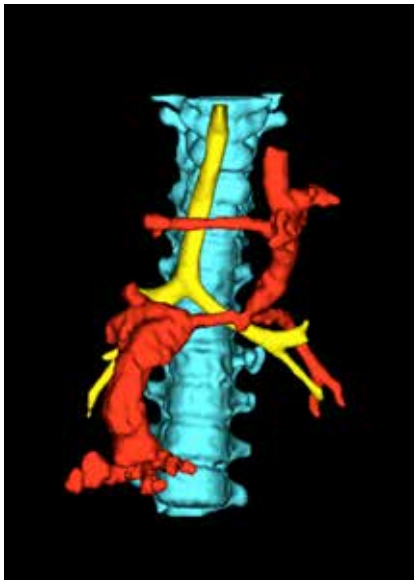


Fig. 1: 3D volumes extracted from pre-operative CT

Procedure

Planning

Before the procedure, an injected preoperative CT was studied and visualized to better understand the anatomy of the patient. Using EP Xpress, various anatomical structures were segmented to have a better representation in 3D and plan the procedure. The cavo pulmonary bifurcation and pulmonary artery were segmented to visualize precisely where to catheterize, as well as non-moving anatomical structures such as the bronchus and the spine, so as to use them during the registration phase. EP Xpress allowed to analyze multi-oblique views to opt for the best approach and to perform measurements to choose the right device. In this case, the stenosis was sub occlusive and the left pulmonary artery was nearly occluded. Measurements, landmarks and 3D volumes coming from the preoperative CT were recorded and fused with live fluoroscopy imaging during the procedure using Valve ASSIST 2.

Guidance

The procedure was performed in the Discovery IGS 740 hybrid room, with the patient under general anesthesia. As the two femoral veins of the patient were occluded, the procedure had to be performed with a trans-hepatic approach. The catheterization was performed using two vessels access. The right hepatic vein and the left internal jugular vein were punctured under ultrasound guidance. Angiography was performed to confirm the T-stenosis of the bifurcation between the superior vena cava and the left pulmonary artery. A 7x36 mm pre-mounted balloon expandable stent was chosen based on the measurements made.
The fusion of 3D volumes from the preoperative CT on the live fluoroscopy with Valve ASSIST 2 helped the team to delineate the lesions and to minimize radiation dose.

Fig. 2: Procedure planning with EP Xpress

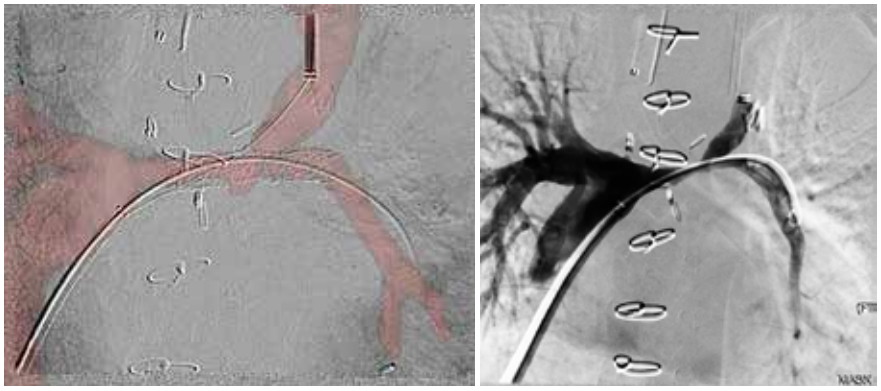


Fig. 3: Live guidance with Valve ASSIST 2 (left), injected DSA to visualize the stenosis of the pulmonary artery (right)

The stent was placed in the left pulmonary artery covering the cavo-pulmonary anastomosis. After the assessment of the right position of the stent with a DSA acquisition, balloon opening of the stent was performed towards the stenotic part of the left superior vena cava.

Conclusion

This case illustrated how multimodality imaging tools and image fusion can help perform complex congenital heart disease treatments.

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