The hybrid OR of the future

VIDEO-ASSISTED THORACIC SURGERY OF LUNG NODULES

UROLOGY & INTERVENTIONAL RADI OLOGY COLLABORATION

DOSE REDUCTION RESULTS FROM THE REVAR STUDY
FLEXIBILITY FOR DIVERSE CLINICAL SETUPS
Mobile robotic gantry with customizable parking positions to position the gantry where you need it, so it works around you, not the other way around.

DESIGNED TO MEET STRINGENT OR HYGIENE STANDARDS
Rail-free ceiling provides flexibility to design the location of the laminar flow, monitors, surgical lights and rad-shield without any interference.

MAXIMISE OR UTILISATION
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IMPROVE OUTCOMES WITH AUGMENTED REALITY 3D GUIDANCE
Intuitive ASSIST solutions help to significantly reduce radiation dose and contrast media, while reducing procedural time.

5 reasons why Discovery IGS 7 OR is a highly flexible Hybrid OR solution

Dear Reader,

The fields of Interventional Imaging and Minimally-Invasive Surgery have never been so close. Hybrid Operating Rooms (HOR) are spreading at a fast rate across hospitals in the world, and more and more specialties are discovering the benefits of such innovative environments. HOR are evolving from dedicated CardioVascular ORs to multidisciplinary environments, where Thoracic Surgery, Urology, Interventional Radiology and other specialties are performing advanced Precision Therapy.

Key considerations for building an HOR, such as having a flexible imaging solution to enable diverse clinical setups, meet stringent OR hygiene standards, maximize OR utilization, and improve clinical outcomes through intra-operative 3D imaging and augmented reality 3D guidance are driving hospitals investments.

In this edition of the ASSIST magazine, dedicated to the future of the hybrid OR, we aim to highlight innovative practices and novel usages from our customers around the world using GE advanced solutions, such as the Discovery IGS 7 and Discovery IGS 7 OR, as well as ASSIST Augmented Reality Image Guidance. From combining two procedures in one, or bringing together two specialties for the benefit of the patient, to finding cutting-edge solutions to address clinical challenges, these articles are highlighting how Surgeons, Interventional Radiologists and other healthcare providers are pushing the boundaries of imaging today to drive better patient care.

We would like to thank our clinical partners for sharing their best practices in this ASSIST magazine, and wish you a good reading!

Jean-François Drouet and France Schwarz
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EVAR ASSIST 2 *

Designed by surgeons and interventional radiologists, EVAR ASSIST 2 provides a fully integrated workflow to plan, guide, and assess complex EVAR procedures. EVAR ASSIST 2 consists of a dedicated planning application to perform and save key anatomical information and measurements for sizing, along with a dedicated image fusion application to provide 3D guidance during the procedure.

Vessel ASSIST **

Designed by surgeons and interventional radiologists, Vessel ASSIST provides easy to use and accurate planning and guidance tools. For example, Vessel ASSIST enables you to create and edit a vessel centerline, trace through an occlusion, and fuse it on the live fluoroscopy with 2D/3D fusion.

Needle ASSIST ***

With Needle ASSIST, you can perform complex percutaneous procedures in the angio room. It provides real-time visualization of needle positions in the 3D space by automatically fusing CBCT data over live fluoroscopic images. This enables precise needle trajectories, with over 1mm accuracy. With the guided-workflow instructions, you can reconstruct a needle in 3D with only two fluoroscopic images in less than 1 minute.

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Liver ASSIST V.I. significantly improves sensitivity of identifying tumor feeding vessels so you can diagnose and perform sophisticated TACE procedures with far greater confidence. With Virtual Injection, Liver ASSIST V.I. simulates in real-time your injection before you treat. This real-time simulation helps you to define your injection points thus aiding injection strategy decision making.

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Valve ASSIST 2 ******

Valve ASSIST 2 provides enhanced planning and real-time visualization enabling you to position the valve and guide devices with precision. 3D contour rendering further improves intra-aortic visualization. You can choose the appropriate x-ray projection with no use of contrast media and minimal radiation dose.

Fostering Team Collaboration and Medical Innovation in a Hybrid Room

The CHU d’Angers experience

A world premiere was achieved at the CHU d’Angers hospital in France on July 4th 2015. A patient was treated for his renal tumor in a two-stage hybrid procedure combining hyper-selective renal embolization and laparoscopic partial nephrectomy (LPN) on the same day. The patient was discharged two days later, tumor-free, with no complication and with two functional kidneys. Since then, Dr. Antoine Bouvier and Pr. Pierre Bigot, respectively Interventional Radiologist and Urological Surgeon at the CHU d’Angers, have been using this revolutionary technique to improve outcomes for more than a hundred patients with renal tumors and promoted their approach through several peer-reviewed publications. This medical innovation and the collaborative effort between teams were made possible thanks to a hybrid operating room equipped with the Discovery™ IGS 730 mobile robotic gantry (GE Healthcare).

Hybrid and collaborative approaches

The multiple challenges of renal tumors

Renal cell carcinoma accounts for 2-3% of all cancers. Incidence has been growing with a 2% increase over the past twenty years\(^5\). Every year, 84,400 new renal tumors are diagnosed in Europe causing 34,700 deaths\(^5\). The majority of these tumors\(^5\) are discovered incidentally by radiologists on abdominal imagery. At the time of detection, most of the tumors are small and localized (e.g., less than 7cm in diameter), and guidelines recommend partial nephrectomy for such tumors\(^5\). Partial nephrectomy has been proven to have similar oncological outcomes compared with larger resection\(^6\). In terms of functional outcomes however, partial nephrectomy is superior, as Pr. Bigot highlights: "The risk of renal insufficiency is divided by four, associated with better survival of patients by diminishing cardiovascular events". Traditionally, partial nephrectomy was performed through an open surgical approach, by lumbotomy. Pr. Bigot explains that these are major interventions for the patients: "We need to make an incision in oblique and transverse muscles, sometimes even resect a rib. It is a painful surgery, and patients need almost three months for full recovery". For these reasons, a laparoscopic approach was developed over time to have a minimally invasive alternative. However, according to Pr. Bigot, laparoscopic partial nephrectomy is a complex intervention which has technical limitations. "The kidney is a very vascularized organ, it can bleed a lot during surgery. To avoid this, the traditional technique in open surgery is to clamp the renal artery during tumor resection and parenchymal repair. But the clamping, resection and particularly the renal parenchymal repair are difficult through a laparoscopic approach". Robotic-assisted partial nephrectomy was developed to answer the challenges of the laparoscopic technique. "Nowadays, most of the minimally invasive partial nephrectomies are performed with a robot, which greatly simplifies the surgical technique. Laparoscopic partial nephrectomy is hardly performed at any institution anymore" adds Pr. Bigot.

Towards a minimally-invasive approach

But there was no robot at the CHU d’Angers, so for many years, open surgery was the only option that Pr. Bigot could propose to most of his patients with renal cancer. Until the advent of the hybrid room. When the Discovery IGS 730 hybrid OR was installed in 2014, he started to look for a solution using this brand-new hybrid room, and turned to his colleague from Interventional Radiology, Dr. Antoine Bouvier.

"Instead of clamping the renal artery, we decided to embolize selectively the artery going to the tumor to avoid bleeding during subsequent resection" adds Dr. Bouvier. Such a preoperative selective embolization approach had been tried before by an Italian team who was able to demonstrate positive clinical outcomes, such as limited bleeding and decrease in operating time\(^8\). "In addition, renal artery clamping may cause renal ischemia..."
leading to renal insufficiency in some patients, so this approach has the benefit of avoiding risks of renal ischemia” adds Pr. Bigot. However, the Italian team was using a fixed interventional room with no OR possibilities, so they had to do two separate interventions, embolization being performed the day before resection. Beside operational disadvantages of this approach, a clinical limitation was that an edema was created around the tumor after embolization, making subsequent resection more difficult.

In our approach, since we are doing the resection right after the embolization in the same hybrid room, we do not have the edema” emphasizes Pr. Bigot. In the Discovery IGS hybrid operating room, both interventions are performed back to back. Dr. Bouvier starts with the selective embolization of renal arteries feeding the tumors, and then Pr. Bigot enters the HOR for the laparoscopic partial nephrectomy. This collaboration also brings other advantages to the surgeon, such as facilitating the localization and enucleation of the kidney tumor. “Another difficulty is often the localization of the tumor, especially for obese patients with a lot of perirenal fat, or for endophytic tumors”, says Pr. Bigot. “This is why we developed interventional techniques to help with that as well. Initially we used a breast tumor hook wire device placed percutaneously in the tumor under ultrasound guidance. But quickly we switched to the use of patent blue mixed with lipiodol to fix the tumor and give a blue color, easily visible for the surgeon” adds Dr. Bouvier. The concept and exact formula of this mix, which is the result of a collaboration with the hospital’s pharmacy, has been submitted as a patent, and the detailed technique submitted for publication.

A true benefit for the patients

Traditional renal artery clamping is meant to avoid bleeding during partial nephrectomy but it carries some risks as highlighted before, as it might cause kidney ischemia and lead to irreversible damage to kidney healthy tissue. “One says that every minute counts and that you are not supposed to clamp the artery longer than 25 min. Actually, post-operative risks linked to renal ischemia depend mostly on the patient’s renal function. If the patient has a poor renal function, then indeed ischemia time can be a problem. Now, there is no risk of renal ischemia, since we don’t need to clamp the renal artery anymore.” Complication rates after renal nephrectomy also vary depending on tumor complexity, and can be as high as 50% for grade three complexity tumors, as explained by Pr. Bigot. Main complications are peri-operative bleeding, urinary fistula, and renal ischemia, and if such complications occur, an additional surgical intervention might be needed. “When we were performing open surgical approaches in the past, my main fear was the post-operative bleeding. Our surgeries were on Friday, and I would worry over the week-end about a suture going to rupture or create a false aneurysm. Now, I do not need to worry anymore, as we have not had any case of peri-operative bleeding with the selective embolization approach in the hybrid room since the beginning”.

Overall, the team emphasizes that the key benefits of this new approach for the patients are two-folds. First, clinical outcomes are improved thanks to the clampless technique leading to zero ischemia laparoscopic partial nephrectomy and operative bleeding divided by two. Second, minimizing such operative and post-operative complications brings operational benefits with mean surgical operating time reduced to 150 min, and median hospital stay shortened to 3 days. “Our patients usually leave on Monday, three days after surgery and when we see them again for post-operative consultation, they do not have any pain or complication from the surgery anymore” adds Pr. Bigot. Lastly, it is important to note that oncological outcomes for the patient remain as good as for traditional or robotic approaches. In particular, the use of a blue dye during embolization allows to more easily spot the tumor for the resection.

A clinical and financial alternative to the robot?

There is no clear guideline on which partial nephrectomy approach between open (OPN), laparoscopic (LPN) or robotic (RPN) is recommended. Studies comparing OPN and RPN have shown clear clinical benefits for the second approach, which in turn is considered more and more the gold standard. Dr. Bouvier and Pr. Bigot claim that the technique they have developed in the hybrid room is proving to be a very interesting alternative to the robotic approach for centers not equipped with robots, and which have access to a hybrid room. “We performed a prospective study comparing fifty-seven patients undergoing LPN at our center in the hybrid room and forty-eight undergoing RPN at Diaconesses Croix Saint-Simon hospital group”. There was no difference between oncological and functional outcomes in both techniques. With our LPN technique, there is a 7% loss of renal function after surgery, which is comparable with results published with the robot. Our operative times are shorter and blood loss is reduced. This is very promising for LPN.”

“From an economic point of view, once you have amortized your hybrid room, there is almost no consumable costs. Our only costs are the 200€ catheters, whereas with the robot, you need to spend some 2000€ consumables for each surgery.”

Expanding the usage of the hybrid room

Renal tumor patients are not the only ones who have benefitted from team collaboration fostered by the hybrid room at the CHU d’Angers. Cardiology and cardiac surgery departments commonly use the room to perform TAVI procedures, as well as complex cardiac interventions, such as Left Atrial Appendage Closure (LAAC) or percutaneous Mitral Valve Repair (MVR). The interventional cardiology team was already performing TAVI cases in their fixed cath lab before, but they have developed their activity towards LAAC or percutaneous MVR thanks to the hybrid environment. Dr. Bouvier also worked initially with the vascular surgery team to develop the aneurysm repair practice, and they are now autonomous. “We are also developing combined thermoablutions and embolizations in the liver for patients who have tumors slightly over 3 cm who could normally not benefit from such curative interventions”.

Recently, a young patient with a benign spleen tumor was operated in the hybrid room by the digestive surgery team. “Digestive surgeons now have a conservative approach for splenectomies and try to do partial splenectomy whenever possible, as the spleen plays an important role for immunity. However, since there was a high risk of bleeding for this patient’s splenectomy, I performed a pre-operative embolization in the hybrid room, just before the laparoscopic procedure. It all went very well for the patient, who had no bleeding and was able to leave the hospital very quickly” says Dr. Bouvier.

Last but not least, babies are born in the hybrid room! The Gynecology & Obstetrics department also started a collaboration with Interventional Radiology for the sake of pregnant women with placenta accreta and their babies. Placenta accreta is a serious and rare pregnancy condition where the placenta has an abnormal implantation in the uterus, leading to a risk of severe blood loss after child delivery. C-section is the recommended approach. Dr. Bouvier explains how he was able to help: “We perform a few cases of preventive or post-operative embolization in pregnant women with placenta accreta every year. The gynecology team performs the C-section in the hybrid room, and I embolize arteries leading to the placenta either before or right after the surgery, if there is an important bleeding”. For such cases, up to twenty medical staff can be in the room at the same time, from the pediatrics team to the gynecology team to anesthesia and interventional radiology. “The ample space that we have in the hybrid room and around the patient is a true benefit during these cases” concludes Dr. Bouvier.

In an era where cost pressure on healthcare systems is growing, and operating rooms utilization must be maximized, a sophisticated and highly flexible hybrid room, such as the Discovery IGS 7 series, allowing for open and minimally invasive approaches, involving several surgical and medical departments, and fostering team collaboration for the benefit of patients is becoming the new standard of care. [1]

The key benefits of this new approach are the following:4

Key clinical outcomes:
- Minimized operative & post-operative complications, in particular:
  - Decreased renal ischemia to a strict minimum
  - Decreased bleeding: mean estimated blood loss of 185 mL for LPN compared to 345 mL for RPN (p=0.04)
  - Similar oncological outcomes with 4.4% positive surgical margins for LPN compared to 10.3% for RPN (p=0.12)

Clampless laparoscopic partial nephrectomy after superselective arterial embolization, made possible by new generation hybrid rooms, is a safe and reproducible minimally invasive procedure for the treatment of localized renal tumors. This expands HOR usage to new hybrid techniques in minimally invasive surgery, thanks to multidisciplinary collaboration between Urology & Interventional Radiology.

The CHU d’Angers, has developed a new approach of laparoscopic partial nephrectomy using the Discovery IGS Hybrid OR. The principle is to perform a single session, staged hybrid procedure:

First, selective embolization of renal arteries feeding the renal tumor is performed by the Interventional Radiologist, Dr. Antoine Bouvier, using Vessel ASSIST image fusion. In addition, a blue dye is injected selectively before embolization to help with tumor identification during surgery.

In a second step, laparoscopic partial nephrectomy is performed by the Urology Surgeon, Pr. Pierre Bigot, in the same hybrid OR.
Case Report using Vessel ASSIST

Partial Nephrectomy after Selective Embolization of Tumor Vessels in a Hybrid Operating Room

Courtesy of Pr. Pierre Bigot & Dr. Antoine Bouvier, CHU Angers, France

Patient history
This is a case of a 77-year-old male patient with a lesion of the inferior pole on the left kidney, which was discovered incidentally during an examination for left lumbar pain. Pre-operative CT showed a lesion of 53 mm in diameter with tissue density enhanced after injection, which was suspicious for a malignant tumor (Fig. 1 et 2). A biopsy of the lesion was performed but the pathological result was inconclusive.

Clinical Challenge
The kidney is a hyper-vascularized organ, leading to a risk of bleeding during or after surgery. Additionally, for overweight patients with very adherent fat on kidneys and a tumor without relief, it is difficult to identify intra-operatively the tumor. Therefore, a two-staged procedure was performed: first, selective embolization of tumor vessels together with patent blue dye injection, and then partial nephrectomy.

Procedure
First stage: renal embolization
The embolization procedure was performed under general anesthesia, with the patient placed in the supine position. Femoral puncture was performed on the tumor side (left side) and the renal artery was catheterized with a 4F probe.

Plan
A subtracted CBCT acquisition was performed at 40°/s with selective injection in the renal artery. 35 cc diluted at 50% were injected at 4 cc/s with 5 s of X-ray delay (Fig.3). The subtracted acquisition allowed to have a precise map of the arterial tree of the kidney and the tumor at the beginning of the intervention.

Guide
The 3D volume of the feeders was fused with live fluoroscopy to optimize the guidance, using Vessel ASSIST™ (Fig. 4).

- Patent blue was mixed with lipiodol and injected selectively in order to highlight the tumor for subsequent laparoscopic resection.
- Feeders were catheterized using a microcatheter, and glue diluted to 1/5 with lipiodol was injected to embolize selectively and avoid reflux. At the end of the embolization, the femoral introducer attached to the skin was left in place, in case a re-intervention per or postoperatively was necessary.

Assess
After the renal embolization, a subtracted CBCT acquisition was performed, with the same injection parameters as the initial CBCT, in order to evaluate the success of the intervention. The CBCT highlighted a complete devascularization of the tumor (Fig 5).

Dose levels
Total DAP (Gy.cm²) | 63.41
Total AK (mGy) | 313
Fluoroscopy time (min) | 08:17

Second stage: partial nephrectomy
Prior to surgery, the Discovery IGS 730 system was moved back to its parking position. The patient was positioned in lateral decubitus, to optimize surgical access to the kidney by having all intestinal loops fall. Laparoscopy was performed without approaching the renal pedicle but directly with an incision of the Gerota’s fascia in order to cut into the parenchyma. The tumor highlighted with patent blue (Fig.6) was immediately visible and resected.

Conclusion
After the resection, sutures were not necessary because there was no bleeding, thanks to the vessel embolization.
Treatment of Peripheral Arterial Occlusive Disease (PAOD) and Bowel Ischemia in a single session using Discovery™ IGS 740

Courtesy of Prof. Bob Geelkerken (Vascular Surgeon) & Dr. Dick Gerrits (Interventional Radiologist), Medisch Spectrum Twente, Enschede, the Netherlands

Patient history
An 89-year old female patient was admitted to the vascular department because of a necrotic fifth toe of the left foot accompanied with untenable rest pain. Computed Tomography Angiography (CTA) of the aorto-iliac and femoral vessels showed severe atherosclerotic disease (Fig. 1 and 2). Furthermore, the right hepatic artery originated from the Superior Mesenteric Artery (SMA) and a large gastro-duodenal collateral between the Celiac Artery (CA) and the SMA was observed. Two diagnosis were established: critical ischemia of the left leg (Fontaine stage IV, Rutherford class 5) and two-vessels chronic mesenteric ischemia (Fig. 1 and 2).

Clinical Challenge
Based on the recommendations in the European guideline1 and a recent publication2, it was decided to perform an antegrade endovascular revascularization of the mesenteric vessels. MST Enschede is equipped with a Discovery IGS 740 with Vessel ASSIST®. The gantry was positioned at the patient’s left side to enable imaging of the lower limbs and the lateral mesenteric vessels. CT fusion on top of fluoroscopy was used as a navigation tool and in order to reduce the radiation dose and contrast agent.

Intervention
Surgical part
The procedure was performed under general anesthesia. An infragenual and groin incision were performed at the left side of the patient (Fig. 3). An externally supported heparin coated ePTFE bypass was tunneled. After arteriotomy in the PA (P3 segment), a side to end anastomosis was made with continuous sutures. Next, the CFA was clamped and an arteriotomy and partial re-endarterectomy were performed. Subsequently, a side to end anastomosis was made with continuous sutures. After releasing of the clamps, Doppler demonstrated a good flow in the Femoral-Popliteal (Fem-Pop) bypass and peroneal artery.

Endovascular part
Thereafter, a retrograde puncture of the ePTFE bypass, at the level of the groin, with introduction of a 6 French sheath was performed. DSA of the Fem-Pop bypass (Fig. 4) showed an intact anastomosis without leakage and a single vessel outflow over the peroneal artery, filling the distal posterior tibial artery (PTA) and subsequently the foot arch. It was assessed that there was no possibility for successful antegrade endovascular revascularization of the PTA or anterior tibial artery (ATA). Subsequently, an amputation of the tip of the necrotic fifth toe was performed. Retrograde DSA of the left iliac arteries demonstrated severe calcifications, however the previous placed stent in CIA and the external iliac artery were patent.

3. Vessel ASSIST solution includes Vessel 2, VesselIQ Express and Autobone Express, and requires AW workstation with Volume Viewer and Volume Viewer Innova. These applications are sold separately. Not available for sale in all regions.
Hybrid and collaborative approaches

Using lateral fluoroscopy with CT-fusion thanks to Vessel ASSIST, a steerable guiding catheter was positioned at the origin of the SMA and a 0.014" guidewire was positioned in the SMA. Next, a 7x30mm self-expandable bare metal stent was placed in the extended SMA stenosis over the guidewire. Selective DSA demonstrated a restored inflow of the SMA, but also a severe steal towards the CA outflow. The CA inflow was restored with a 6x14mm self-expandable bare metal stent over a 0.018" guidewire. Completion DSA showed an uncompromised inflow to the CA and SMA. The right renal artery showed a pre-existing occlusion.

Conclusion
A femoral-popliteal infragenual bypass (prosthetic) for critical limb ischemia stage V, amputation of the fifth toe and endovascular antegrade revascularization of the CA and SMA for severe 2-vessels chronic mesenteric ischemia was successfully performed in a single procedure with support of the Discovery IGS 740 with Vessel ASSIST.

The patient visited the outpatient clinic four months after this hybrid procedure. She was doing well, had a good appetite, gained weight and the left foot was completely healed. Duplex of the mesenteric stents and Ankle-Brachial Index showed good flow, underlining the successful clinical course.

Dose levels

<table>
<thead>
<tr>
<th>Dose Level</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total OR time</td>
<td>196 minutes</td>
</tr>
<tr>
<td>Blood loss</td>
<td>200mL</td>
</tr>
<tr>
<td>DAP</td>
<td>107.8 Gy.cm²</td>
</tr>
<tr>
<td>Fluoroscopy time</td>
<td>13.35 minutes</td>
</tr>
<tr>
<td>Contrast Medium</td>
<td>20mL for leg, 100mL for bowel</td>
</tr>
</tbody>
</table>

This case report is being made available to assist medical professionals’ awareness and understanding of the current state of research related to the device, technology, and application categories at issue in this material and at the date of this case report. The statements by GE customers described here are based on their own opinions and on results that were achieved in the customers’ specific setting. Since there is no “typical” hospital and many variables exist, i.e. hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results. GE customers are solely responsible for the analyses and conclusions in the referenced material. GE does not endorse the conclusions or recommendations contained in the material.

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SHARE
Share your experience, publish content and stay up to date with the latest clinical trends shared by your peers.

LEARN
Learn new techniques and increase your skills in your daily practice. Access online trainings, educational contents, clinical webinars built by experts for experts.
Survival of lung cancer patients remains limited, between 10 and 17.4%\(^1,2\), mainly due to late diagnosis. Recent screening programs developed have led to an increasing number of detected pulmonary nodules for which firm histopathological diagnosis is complex, given the size, nature or location of the lesion. Video-Assisted Thoracic Surgery (VATS) is able to provide histological diagnosis, but localization of such lesions during surgery is a challenge. The CHU de Rennes Cardio-Thoracic Surgery department has implemented a new approach to combine localization and resection in a single procedure in their Discovery Hybrid Operating Room (HOR).
Dr. Simon Rouzé is a cardio-thoracic surgeon, with a mixed activity of conventional cardiac surgery, coronary cardiac surgery and thoracic surgery. Passionate about new technologies and innovative approaches, Dr. Rouzé quickly performed his lobectomy cases using video-assisted thoracoscopic surgical access (VATS), and developed an innovative approach combining imaging and VATS in a hybrid operating room.

Dr. Rouzé explains to us his approach and the challenges for pulmonary nodules surgery.

Dr. Rouzé, what are the main clinical challenges to treat pulmonary nodules?

The biggest challenge today is that we are facing an increasing number of indeterminate pulmonary nodules. Indeed, the patient population at risk is increasing, and in addition to that, recent Northern-American studies have shown that screening programs using CT instead of X-ray radiography could improve the survival of lung cancer patients by detecting more pulmonary nodules and in earlier stages. The exact etiology of those detected nodules needs to be determined in order to decide upon the best course of action. Such nodules are often small, scarcely visible on X-ray, or very deep in the lung, so that it is difficult to localize them during surgery. Conventional localization techniques are invasive. We can for instance put a hook-wire under CT guidance with local anesthesia before surgery, or inject micro-coils or lipiodol. But these options are not comfortable for the patients and they carry high risks of pneumothorax, not to mention that they might not be efficient if the marker moves between the pre-op localization procedure and the actual surgery. Some teams have also used ultrasonography using intraoperative ultrasound probes inserted through trocars, but it is very operator dependent, and you need a perfect pneumothorax, because any presence of air will prevent you from seeing correctly lung density and thus localize the nodule.

How is your approach different?

The main benefit of our approach is to skip the pre-op procedure and do everything directly in the operating room, eliminating therefore the invasive localization procedure. We localize the nodule directly in the operating room by performing an initial cone-beam CT acquisition with our Discovery IGS 7 robotic system. We locate and segment the nodule on this 3D volume and use this as a fusion mask on top of fluoroscopy to guide the positioning of our instruments for resection.

What are the benefits for the patient?

When we were doing the hook-wire localization, we were inserting them the morning or even sometimes the day before the surgery, as it was logistically complicated to do the CT scan the same day as the surgery. But it was painful for the patient to have this hook-wire in place. Sometimes, the patient would develop a pneumothorax and need to spend the night with it after drainage with a pigtail, so it was not really ideal and quite stressful for the patient. Now, everything is performed in one place in one session by a single operator. There is no learning curve really, as we are not changing the way we perform the surgery, and don’t need to learn how to insert a hook-wire. So, the benefit is obvious for the patient, but also for the surgeon and the department organization overall.

Can you describe the procedure?

The patient is lying on the side on the operating table, under general anesthesia, with a selective intubation probe in order to ventilate unilaterally the operated side. At the beginning of the procedure, we put a trocar in place, and then insufflate oxygen in the non-ventilated pulmonary side, so as to limit the pneumothorax compared to a standard resection and increase the lung volume a little bit. Otherwise, if the lung is completely collapsed, it is hard to even find the nodule, since the nodule density becomes similar to healthy lung.

We then perform a CBCT, locate and segment the nodule on the axial, coronal and sagittal views, and we fuse this in 3D with fluoroscopy. From that moment on, we use the fluoroscopic fused view in order to place our instruments with regards to the nodule position, switching from the VATS camera view to the augmented fluoroscopic view using different C-arm angulations.

Now that we have the Discovery IGS 7 HOR, we also use Stereo 3D (Needle ASSIST, GE Healthcare) in order to locate the tip of our instruments and compare it to the nodule location with image fusion. Once we are confident...
that we are at the right location, we electro-cause-ulate the lung surface where the nodule is supposed to be and do a wedge resection with conventional stitches. Then we wait for frozen section of the nodule to come back in order to verify that localization was successful.

How long is the procedure?

It all depends on the duration of the frozen section. If the analysis comes back indicating that there is no need for a frozen section, we can count between 7 and 20min for the location and about 1h-1h30 for the whole surgical resection. If lobectomy needs to be performed, it usually lasts for 2h in total.

What are the clinical challenges of your approach?

I think that the main challenge is the induced pneumothorax for surgery. Indeed, we need to create a pneumothorax in order to deflate the lungs and do the resection. But this causes the position of the nodule to change compared to the pre-op CT. So, we cannot simply register the pre-op CT to the fluoroscopy image in the hybrid OR, we need intra-operative CBCT.

Secondly, installation of the patient is important. We need to remove sternal and gluteal supports in order to avoid collisions during CBCT. The wide bore C-arm of the Discovery IGS 7i is of great help to limit collisions and facilitate 3D acquisitions. Lastly, we need to constantly switch between the VATS view and the augmented fluoroscopy view.

How does your approach compare to conventional techniques in terms of success?

Conventional localization techniques, such as hook-wire implantation or tattooing, have between 94–96% success rates. In our limited series of 34 procedures so far, we are slightly better than these conventional techniques, with only one patient (i.e. 3%) for which localization failed due to a failed centering of the lesion. But the true benefit is that we are less invasive with no hemothorax or pneumothorax complication compared to pre-op localization.

What about radiation dose?

CBCT does bring some radiation during surgery, but sparing the patient the pre-op procedure for coils, lipiodol or hook-wire placement guided by CT actually represents a reduction in total radiation.

What are the benefits of the Discovery IGS 7i for thoracic surgery?

Initially in our series, before acquiring the Discovery, we were working in a hybrid OR from another manufacturer, and we have seen several areas of improvement when we switched to the Discovery IGS 7i for image-guided procedures. Thanks to the Stereo 3D solution, which is more cumbersome, we found it challenging to position the anesthesia and other equipment at head side without conflicts, and smoothly position the gantry for 2D/3D imaging. The Discovery has a predefined trajectory, and moves at a steady pace allowing us to adapt patient or staff positioning along the way. With the wide bore C-arm, collisions are quite rare, and we also like the fact that we have a cleared volume around the patient’s head thanks to the offset C-arm design.

Lastly, the Discovery is very reassuring for the staff, thanks to its design for intuitive use and its small footprint. With our previous HOR, which is more cumbersome, we found it challenging to position the anesthesia and other equipment at head side without conflicts, and smoothly position the gantry for 2D/3D imaging. The Discovery has a predefined trajectory, and moves at a steady pace allowing us to adapt patient or staff positioning along the way. With the wide bore C-arm, collisions are quite rare, and we also like the fact that we have a cleared volume around the patient’s head thanks to the offset C-arm design.

In the future, do you envision another approach to diagnose and treat lung nodules, such as endobronchial interventions?

Navigation bronchoscopy is now more commonly used in order to access and tattoo lung nodules by injecting a dye such as methylene blue, so as to guide subsequent surgical resection. If you can avoid surgery to have a diagnosis, it is ideal. But not all nodules can be diagnosed through an endobronchial approach. For instance, ground glass opacities are usually at the periphery of the lungs, and you need a large piece of the nodule in order to have a firm diagnosis. But deep, small and dense nodules, which represent about 50% of my cases, preferentially could be accessed and treated through bronchoscopic access. I would like to develop such an endobronchial activity, which would be a very interesting and less invasive alternative to thoracic surgery.
Wedge Resection of a Left Lower Lobe Nodule with Video-Assisted Thoracic Surgery (VATS) under CBCT and Image Fusion Guidance

Patient History
A 68-year-old female patient was admitted for surgical resection of a left lower lobe nodule located in segment VI. The nodule was found incidentally two years earlier during a thoracic CT exam for a cough episode. Lately, a repeated thoracic CT revealed extension of the nodule and PET-CT did not show any abnormality of the lesion. The patient was asymptomatic, pulmonary functional test and lesion. The patient was asymptomatic, cardiopulmonary auscultation were normal, pulmonary functional test and episode. Lately, a repeated thoracic CT during a thoracic CT exam for a cough was found incidentally two years earlier nodule located in segment VI. The nodule for surgical resection of a left lower lobe A 68-year-old female patient was admitted for surgical resection of a left lower lobe nodule located in segment VI. The nodule was found incidentally two years earlier during a thoracic CT exam for a cough episode. Lately, a repeated thoracic CT revealed extension of the nodule and PET-CT did not show any abnormality of the lesion. The patient was asymptomatic, cardiopulmonary auscultation were normal, pulmonary functional test and episode. Lately, a repeated thoracic CT during a thoracic CT exam for a cough was found incidentally two years earlier nodule located in segment VI. The nodule for surgical resection of a left lower lobe

Clinical Challenge
The nodule is a densified ground-glass opacity of about 15mm in size and located 1cm below the parenchyma. Its size, position and low-density make it a challenging lesion to locate during surgery.

Procedure
Plan
The patient was placed in lateral decubitus under general anesthesia, with a selective intubation probe to ventilate the patient on single-lung ventilation. For optimal centering without X-ray acquisition, the patient’s preoperative CT was automatically segmented using Thoracic VCAR. The Volume Rendering of bone and nodule were extracted and fused with real-time fluoroscopy, using Vision 2. Registration of the pre-operative CT to fluoroscopy was performed with the bi-view mode using two fluoroscopy shots. Volumes were then fully recorded for later recall during the procedure for image guidance.

The Discovery IGS 7° was moved into the parking position. At the beginning of surgery, the lung was excluded and the trocar put in place. Immediately, oxygen was blown into the non-ventilated lung in order to increase the lung volume and reduce the pneumothorax, for better visibility of the lung nodule. The position of the C-arm and table were automatically recalled from table-side, to have an optimal centering of the lesion. A Cone-Beam CT (CBCT) acquisition was performed at 28°/s, under apnea.

Guide
The multi-oblique views of the CBCT were automatically reconstructed on the AW workstation. The identification of the nodule was done on the multi-oblique views and its volume rendering was extracted in order to fuse it with live fluoroscopy. The positioning of surgical instruments was guided using the image fusion showing the nodule fused on fluoroscopy, as well as the video-thoracoscopic view. In order to validate the optimal positioning of surgical instrument versus the nodule location, the Stereo 3D solution (part of Needle ASSIST, GE Healthcare) was used. Two fluoroscopic shots were performed at different angulations, the position of the instrument was automatically detected and projected in the multi-oblique views of the initial CBCT, without the need to perform an additional CBCT.

Conclusion
The patient had her drain removed one day after surgery, suffered no respiratory or infectious complication and was discharged at day 2. In this VATS procedure, Stereo 3D allowed the surgeon to understand the relative position of the surgical forceps with regards to the nodule in 3D and guide the resection more precisely, whereas the video-thoracoscopic guidance alone only provided the view of the surface of the lung.

Dose levels

<table>
<thead>
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<th>Fluoroscopy Time</th>
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<tr>
<td>Dose</td>
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<tr>
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11. Thoracic VCAR solution requires AW workstation with Volume Viewer. This application is sold separately. Not available for sale in all regions.
Interventional Oncology (IO) is one of the youngest and most rapidly growing branches of Interventional Radiology. Driven by rapid technological innovation and implementation, IO is a continually evolving specialty on the cutting edge of clinical oncology. Consequently, in recent years, IO has joined Medical, Surgical, and Radiation Oncology to become widely recognized as the fourth pillar of cancer therapy.

Wake Forest Baptist Medical Center is an academic medical center located in Winston-Salem, North Carolina. It is a preeminent, internationally recognized academic medical center of the highest quality with balanced excellence in patient care, research and education. Wake Forest Baptist Medical Center was awarded the designation of “Comprehensive Cancer Center” in 1990 by the National Cancer Institute. It is one of the few cancer centers in the United States to continuously hold that official designation since that time. In 2018, U.S. News & World Report ranked the Comprehensive Cancer Center highest in North Carolina for cancer care and 19th in the United States.
Practice. First and foremost is having a successful development of an IO factors which contribute to a Forest, I have identified several key “Based on my experience at Wake of his clinical practice.

represents the overwhelming majority chemoembolization and trans-arterial therapies such as liver-directed therapy in the form of liver radiofrequency ablation to his conventional chemoembolization and in 2011 with the addition of Dr. Kouri began offering IO treatments

practice. From that beginning, his interest in liver-directed therapy as well as the scope of his practice have grown exponentially. Currently, liver-directed therapy in the form of trans-arterial therapies such as chemoembolization and radioembolization as well as image-guided microwave liver ablation represents the overwhelming majority of his clinical practice.

Tips to building an Interventional Oncology Practice

“Based on my experience at Wake Forest, I have identified several key factors which contribute to a successful development of an IO practice. First and foremost is having a dedicated Interventional Radiology (IR) Clinic:

• The clinic provides a professional environment in which you are able to build a productive relationship with your oncology patients.
• The clinic makes the referral process simple and seamless for referring physicians.
• Having a clinic coordinator is a tremendous asset. My coordinator is intimately involved in the management of patients at all levels including scheduling procedures and imaging, obtaining insurance approvals and facilitating the patient’s entire experience with the IR department by providing traditional patient navigator services.

A second one contributing factor is being an active tumor board participant. I regularly participate in my institution’s hepatobiliary oncology tumor board and often present my own patients for review. In addition to discussing how IO treatments may or may not be appropriate for patients, I also often suggest how IO treatments may be integrated with treatments offered by other specialists from the traditional ‘pillars of oncology’.

Lastly, it is key to have strong communication with referring physicians. Consistent, timely and comprehensive communication with referring physicians improves the care of patients, provides comfort to the referring physicians that the patient is being well attended, and maintains awareness among the referring base of the services you provide”.

Combining conventional chemoembolization with microwave ablation

“In recent years, the practice of combining chemoembolization with microwave ablation has grown in favor within the IO field to treat liver tumors which are larger than the traditionally accepted upper size threshold for successful ablation. Many experts in the field, as reflected in the National Comprehensive Cancer Network (NCCN) guidelines, believe that ablation is suitable as a standalone, potentially curative option for tumors that are less than 3 cm in diameter. However, for tumors between 3 and 5 cm in diameter, trans-arterial therapies such as chemoembolization or radioembolization significantly improve the likelihood of achieving a complete response from treatment. Tumors greater than 5 cm in diameter are typically only treated with trans-arterial therapies with palliative intent. However, in some cases, even these larger tumors are able to be downstaged for treatment with curative intent with microwave ablation. At Wake Forest Medical Center, I have incorporated this philosophy into my practice and now regularly combine conventional chemoembolization with microwave ablation in a single setting to treat tumors within the intermediate 3-5 cm size range.

In addition to being able to successfully reduce post-ablation margin recurrences through the use of pre-ablation conventional chemoembolization, I have found lipiodol in many cases to be invaluable merely for improving the visualization of target lesions during the subsequent ablation portion of the procedure. This facilitates accurate placement of the ablation probe as well as enabling more precise and aggressive ablation of lesions near sensitive structures since the margins are more easily identified once they have been stained with lipiodol”.

The value of Discovery™ IGS 7 in trans-arterial liver-directed therapy

“For me, the largest incremental value that the GE Discovery™ IGS 7 provides is its 3D capabilities. Its unique value with 3D imaging begins with the simple fact that acquiring a CBCT is very easy due to the wide bore and offset C-arm. Due to the size and position of the C-arm, a CBCT acquisition can be obtained without having to position the patient in any particular manner and without any significant delay in the workflow. This is especially advantageous for cases done under general anesthesia, as I do with all microwave ablations. Having the patient under general anesthesia allows for precise, reproducible breath holds during CBCT acquisition. The resulting consistency between CBCT acquisitions throughout the case...
provides the opportunity to fuse multiple images sets together4 to greatly improve the confidence I have in targeting lesions for ablation. Subsequent CBCT acquisitions during a case are also simplified because the tableside auto-positioner controls allows me to quickly and automatically reposition the table and C-arm at any point later in the case to do another CBCT. Because the acquisition process is so effortless, I am able to truly exploit the technology to its fullest extent.

Once the CBCT is acquired, I also find the 3D software to be intuitive. One of my favorite solutions is the 2-click Vessel ASSIST® in which I can quickly determine which specific subsegmental hepatic artery is supplying the tumor of interest. I am then able to create and overlay a 3D roadmap onto live fluoroscopy to aid in cannulating the vessel of interest. Most importantly, I am able to perform all 3D post-processing functions at the timeside with a sterilely prepped mouse. This provides tremendous benefits with respect to convenience and efficiency.

Because of the advantages provided by the advanced 3D imaging capability of the GE Discovery, my practice has changed. Now, I acquire a CBCT at the beginning of almost every hepatic trans-arterial case in order to have a 3D roadmap to use for the remainder of the case. I find that the 3D roadmap5 often allows for the remainder of the case to proceed more smoothly and efficiently. This ultimately results in less total radiation dose, contrast usage and overall procedural time.

Exploiting the benefits of CBCT to change practice patterns

“Prior to purchasing the Discovery® IGS 7, my practice when combining conventional TACE with microwave ablation was to perform these procedures on sequential days with the patient staying in the hospital between the two days. This was necessitated by the fact that the TACE procedure was done in an angio suite and the microwave ablation required a dedicated procedural CT suite and general anesthesia. Logistically, it was not feasible to start the procedure in the angio suite and then move the patient under general anesthesia to a CT room. This would have required tying up two rooms and for the patient to undergo prolonged general anesthesia.

Given the advantages provided by the GE Discovery CBCT capabilities, I have now changed my practice so that I perform the entire TACE and microwave ablation procedure in a single setting in the angio suite under general anesthesia. This saves a tremendous amount of time and cost, as well as makes the experience vastly more convenient for my patients.

In addition, the trajectory planning solution provided by Needle ASSIST® allows me to successfully and safely target lesions for ablation in locations which are difficult to reach with traditional axial CT imaging. Specifically, lesions in the hepatic dome which require a steep oblique trajectory to avoid traversing the pleural space can be ablated much more safely and accurately with CBCT using Needle ASSIST. In these cases, I perform a conventional lipiodol TACE first to maximize tumor visibility. I then acquire a CBCT and reformat the images at table side with the steriley prepped mouse. I can then move immediately to placing the microwave ablation antenna under CBCT guidance with Needle ASSIST. By combining these techniques and technologies I can accurately place the ablation antenna with confidence along very steep oblique trajectories in a manner of minutes”.

Place of Interventional Oncology at Wake Forest Baptist Medical Center:

“At Wake Forest, IO is now commonly perceived as an equal pillar in oncology treatment. Unlike some institutions in which IO is still relied upon only in salvage situations, I am often included in patient treatment decisions throughout the entire spectrum of disease severity. This ranges from using ablation as a curative option in appropriately selected patients to utilizing trans-arterial therapies in conjunction with earlier lines of systemic treatment. As a consequence, I have been able to consistently demonstrate the value of IO treatments to oncology patients at different stages of the disease process and not just in the salvage setting”.

1. IGS 740 configuration.
2. Needle ASSIST solution includes TrackVision 2, stereo 3D and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately.
3. Using ASSIST image fusion. ASSIST solutions require AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately. https://www.gehealthcare.com/assist
4. VESSEL ASSIST solution includes Vision 3, VesselIQ Xpress, Autobone Xpress and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately.

This article is being made available to assist medical professionals’ awareness and understanding of the current state of research related to the device, technology, and application categories at issue in this material and as of the date of this article. The statements by GE customers described here are based on their own opinions and on results that were achieved in the customer’s unique setting. Since there are “typical” hospitals and many variables exist, i.e. hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results. GE customers are solely responsible for the analyses and conclusions in the referenced material. GE does not endorse the conclusions or recommendations contained in the material.
When Augmented Reality helps Salvage Limbs at the Franciscaine Private Hospital, Nimes, France

When Nicolas Louis, Vascular Surgeon in Nimes first worked in his Hybrid Room he could not imagine how far he could push the boundaries in endovascular treatments... A story of how a vascular surgeon leveraged image fusion to improve patient outcomes.
After ten years at AP-HP public hospitals in Paris, doing his fellowship in prestigious institutions in Pr. Becquemin’s team, Dr. Louis decided to move to Nimes, in the south of France. His passion for cutting-edge treatments urged him to use new technologies to push the boundaries of current indications for endovascular treatments.

What changes have you noticed since you have been working in your hybrid room?
Since the installation of our hybrid room with Innova™ IGS 530 (GE Healthcare), we have improved significantly our working conditions. We have pushed the boundaries of endovascular treatments thanks to new imaging techniques such as image fusion with all the ASSIST packages1 which are available in our room. Now, we can treat patients we were not able to treat in the past.

The first thing I noticed when I started to work in the hybrid room was the drop in radiation dose. Indeed, being able to plan the case in advance and fuse the planning images on top of fluoroscopy allowed us to save several minutes of fluoroscopy for each case we perform in the room. It represents between 5 to 10 minutes for a standard EVAR, compared to using a mobile C-arm without fusion. For complex EVAR, studies showed that the radiation dose can be very low as well2, compared to data published in the past for the same procedures.

Then, the ease of use of the system was also a great change for me. The ergonomy of the gantry with its offset C-arm allows better patient access for the anesthesiologist, and the ease of use of the Cone-Beam CT increases my level of confidence during my procedures.

Last but not least, the hybrid room is very convenient if there is surgical conversion (which happened once since I have it). The room is big, and the table and gantry rotation capabilities enable a full access around the patient; the imaging system does not get in our way. We regularly do cases with extra corporeal circulation in aortic arch surgery procedures without any issue.

In which cases do you use CBCT, and why?
I use CBCT to control the endograft position after an EVAR procedure. Being able to control the outcome of the procedure while the patient is still in the Operating Room (OR), is one of the great advantages of our Innova IGS 530, because it allows us to re-intervene immediately if there is a stent kink or an endoleak suspicion.

DSA does not usually give us enough information, especially in fenestrated cases where stents are overlapping in 2D projections, making it difficult to understand if each of them is well deployed.

Then, for the percutaneous treatment of type II endoleaks, we use CBCT to guide us during the translumbar puncture to reach the aneurysm sac. Thanks to Needle ASSIST3, we are able to reach the sac at the location of the leak with...
When Augmented Reality helps Salvage Limbs at the Franciscaine Private Hospital, Nimes, France

ASSIST

Fig. 1. A: 3D reconstruction of the needle trajectory on top of the CBCT. B: Fusion between the arterial CT and the CBCT with needle trajectory superimposed. C: Needle trajectory on top of fluoroscopy. (Right view). D: 3D reconstruction of the needle position obtained from two views on top of the pre-operative CT showing that the needle tip is inside the leak.

In aortic procedures, I see real benefits for dissection cases in particular. Indeed, the ability to split the false and true lumen and display them on top of fluoroscopy allows us to save a lot of contrast injections, and to go from the false to the true lumen with more confidence (Fig. 2). Of course, image fusion has also proven to be very efficient for standard and advanced aortic aneurysm procedures1, in terms of dose reduction and contrast media saving.

What is valuable with the ASSIST image fusion solutions1 (GE Healthcare), is that they are flexible and can be adapted to the physician’s specific clinical needs. This is why we have been able to use the power of ASSIST for complex lower limbs recanalization.

How did Vessel ASSIST image fusion help you perform lower limbs recanalization?

The flexibility of Vessel ASSIST1 enabled me to apply all concepts we were using for EVAR (vessel segmentation and quantification, planning lines, contours...) to peripheral artery obstructive diseases in a very intuitive way. However, we had to work hand in hand with our radiology department, as we needed to (a) have a CT available for all patients coming to the OR for Peripheral Artery Occlusive Disease (PAOD). We then decided together with the radiologists upon the right acquisition protocol in order to optimize the fusion during the case (including adapting the patient position amongst other parameters). Thanks to this, we are now able, during the case, to fuse the pre-operative CT with segmented iliac arteries, calcifications and re-entry areas on top of fluoroscopy. In a lot of cases, it replaces the use of Intra/Venous UltraSound (IVUS), thus saving a lot of time during the intervention. A recent abstract published in 2018 showed that in 65 chronic total occlusions, we were able to have a technical success rate of recanalization of 96.9%6.

What are the benefits of this treatment for PAOD patients?

These patients are generally not eligible for bypass grafting as they are old and would not support a heavy surgery. They will clearly benefit from an endovascular approach.

I remember a 100 years old patient who suffered from a severe PAOD. We prepared the treatment strategy with the radiologist, looking at the pre-operative CT to determine which arteries we would manage to recanalize. Once we were in the hybrid OR, we could leverage the planning done on the CT, fuse the vessel volume on top of fluoroscopy and advance the guide through the occlusion following the fusion mask displayed by our machine. The blood flow was restored 45 minutes after the beginning of the procedure. When the patient woke up, she told me: “Doctor, you cut my leg out, I don’t feel pain anymore!”.

What would you advise to a surgeon willing to start image fusion-based treatments in a hybrid room?

I would advise him or her to perform a maximum number of cases with image fusion, even the simplest ones. Fusion has proven very effective in terms of clinical outcomes, even for simple cases1. The more you use fusion, the more you get familiar with the concept, and the more you are prone to use it for more complex cases, and even for other types of procedures than the one initially planned. With the advent of Artificial Intelligence (AI), 3D navigation and image fusion technologies, it is a safe bet to say that endovascular treatments will improve a lot in the years to come! 

1. Y. Kusumoto, et al., “Comparison of the Circles of Planning under 3D Fusion of images in Treat Chronic Arterial Occlusions, Atrial fibrillation surgery, November 2018, Volume 63, Pages 27–30. The recoarctation was closed transcutaneously in 63%, subintimal in 36% and required the use of a patch in two cases. Mortality in 7%.
2. Radiation Dose Reduction During EVAR: Results From a Prospective Multicenter Study (The REVAR Study) Hartono B, et al. J Vasc Interv Radiol. 2011; 22(8):1188-1196. https://doi.org/10.1016/j.jvir.2011.05.011. This article and the associated case report are being made available to assist medical professional’s awareness and understanding of the current state of research related to device technology and application categories at issue in this material and as of the date of this article. The statements by GE customers described here are based on their own opinions and on results that were achieved in the customer’s unique setting. Since there is no “typical” hospital and many variables exist, i.e. hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results. GE customers are solely responsible for the analyses and conclusions in the referenced material. GE does not endorse the conclusions or recommendations contained in the material.
Treatment of Chronic Total Occlusion (CTO) of Femoro-Popliteal Arteries using Vessel ASSIST

Courtesy of Dr. Nicolas Louis, Vascular Surgeon, Les Franciscaines Private Hospital, Nîmes, France

Patient history
A 62-year-old male patient was admitted for invalidating claudication of the left lower limb. He had pain with cramps in his calf with a walking distance limited to 50m. Doppler ultrasound highlighted a short occlusion. CT angiography confirmed the same lesion with an external iliac lesion next to the hypogastric artery. An endovascular recanalization of the superficial femoral and popliteal arteries was proposed to the patient.

Clinical Challenge
The CTO of the superficial femoral artery was very calcified, leading to a high risk of dissection while crossing the lesion.

Procedure

Plan
It was possible to locate the calcifications on the pre-operative CT, to identify their density and the lumen of the vessel thanks to the “perfusion” visualization mode. Bone volume was automatically extracted thanks to Vessel ASSIST® and the centerline of the vessels was automatically tracked down to the occlusion, and manual tracking was performed at the level of the occlusion. The calcification volume was extracted to be used as a landmark during guidance. Contour lines (circles) were planned at the level of the occlusion to give the best angulation for the recanalization during the guidance. Best angulation found was 24°RAO, 3°CAU. The patient was installed in a supine position on the Innova IGS 530 system. The procedure was performed under local anesthesia.

Guide
The volumes extracted from the pre-operative CT were fused with live fluoroscopy thanks to Vessel ASSIST. A registration was performed with the “Bi-View” mode based on the bone structures close to the area of the interest. Heparin was administered to the patient. Puncture of the right common femoral artery was performed under ultrasound guidance. A 5F introducer was used for the catheterization and a right-left crossover was performed with a dedicated probe.

Active balloon angioplasty and stenting of the popliteal artery
Once the catheter was placed at the level of the popliteal artery, the initial registration was finetuned based on the first arteriography. (Fig.2)

Digital zoom was used for a better visibility without changing the size of the field of view and thus without increasing the radiation dose. Vessels, calcification and contour lines were fused with live fluoroscopy. The 24°RAO, 3°CAU working incidence was automatically recalled from table side. A 0.18mm guide was used for the procedure. Collateral vessels seemed to interfere with the guide during catheterization and, relying on fusion imaging, the guidewire seemed to dissect the occluded vessel. (Fig.3)

The guide was then re-positioned relying on the CT fusion. Initial catheter and guide were replaced with dedicated ones for an optimal crossing of the lesion. The probe was advanced through the lesion, and no dissection was observed while crossing the lesion, which avoided the use of a reentry system. (Fig.4)

A 4x60 balloon was used and inflated during 3 minutes. A 5x100 active balloon was then inflated for 2 minutes. A small proximal dissection was identified. A Supera® 5.5x60 stent (Abbott Vascular, USA) with the same size balloon was positioned. The results on the injected acquisition were very satisfying. (Fig. 5)
Case Report

Endovascular Recanalization of the Crural Artery using CO2 with Discovery IGS 730

Courtesy of Dr. Eva-Line Decoster, Vascular Surgeon, AZ Sint-Jan Bruges, Belgium

Patient History

An 86-year old female patient was admitted to the vascular department because of decubitus ulcers of both heels accompanied by unbearable rest pain. Standard imaging protocol should have been Computed Tomography Angiography (CTA) of the aortoiliac and femoral vessels (arterial phase with 1 mm slices), however due to the patient’s contra-indication for iodine-based contrast media, a Magnetic Resonance Angiogram (MRA) was performed. MRA confirmed diagnosis of critical ischemia of both legs (Fontaine stage IV, Rutherford class 5), with multiple stenosis at both left and right sides (Fig. 1).

Clinical Challenge

Due to normal flow of all arterial vessels up to the popliteal arteries at both sides, open surgery i.e. bypass was not a possibility. The only treatment option remaining was endovascular revascularization of the crural arteries. Given the patient’s age and comorbidities, it was decided that the best treatment strategy was to perform revascularization in two procedures, one foot at a time. To prevent complete kidney failure of the patient, CO2 angiography was proposed, instead of iodine-contrast angiography. After shared decision making, the patient granted permission for this treatment plan.

Solution

The Hybrid Operating Theater of AZ Sint-Jan Bruges is equipped with the Discovery IGS 730 mobile robotic gantry. The gantry was positioned on the patient’s left side to enable imaging of the lower limbs. For CO2 angiography, the Angiodroid CO2 Injector (Angiodroid SRL, Bologne, Italy) was used.

Procedure

The procedure was performed under general anesthesia. A 6 French introducer was placed percutaneously in the right common femoral artery and subsequently placed in the superficial common artery. CO2 angiography showed no signs of stenosis in the femoral and proximal popliteal artery, which was in accordance with the MRA (Fig. 2a and 2b).

Conclusion

Complete re-opening of left lower limb was performed in the hybrid room with Vessel ASSIST. Immediate assessment with DSA showed good restoration of the blood flow in the SFA and popliteal artery. Image fusion helped detect dissections during the procedure, and thus use an appropriate catheter/guide to cross the lesion, avoiding to use a re-entry system.

Patient was discharged one day after the procedure.

Dose levels

<table>
<thead>
<tr>
<th>Procedure Time</th>
<th>Dose</th>
<th>Air Kerma</th>
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<tbody>
<tr>
<td>17’21 min</td>
<td>4.35 Gy.cm²</td>
<td>64 mGy</td>
</tr>
</tbody>
</table>

Fig. 1. For the right leg, no stenoses nor calcifications are seen on the MRA in the aorto-femoral trajectory (left image). The first stenosis is seen at the distal popliteal artery (middle image). Both the peroneal artery and the tibial anterior artery show significant stenosis (right image).

Fig. 6. Balloon angioplasty and stent deployment with Vessel ASSIST image fusion in the left superficial femoral artery.
New imaging workflows

CO2 angiography below the knee showed a significant stenosis at the tibial-fibular trunk, as shown in Fig. 3. Furthermore, almost all outflow was over the peroneal artery and the Anterior Tibial Artery (ATA) was occluded just after the ostium.

Percutaneous Transluminal Angioplasty (PTA) of the tibial-fibular trunk was performed with a 3×40 mm balloon. After recanalization of the ATA with a 0.018” wire, subsequently a 2×120 mm balloon was used to perform a PTA of the ATA. The distal part of the ATA was too narrow, which led to a switch to a 0.014” wire. Full recanalization of the ATA was done with a 2×20 mm and 2×40 mm PTA, however the full-foot arcade was not successfully recanalized. CO2 angiography showed outflow of the ATA comparable with the peroneal artery. After removing the sheath, manual compression was used to close the puncture site. Postoperative lab showed (6 days later) a renal clearance of 18 ml/min, which was the same renal clearance as at the day of surgery.

**Conclusion**

CO2 angiography was successfully used with Discovery IGS 730 to perform an endovascular recanalization of the ATA and the tibial-fibular trunk in a patient with critical limb ischemia stage IV, without impairing the limited renal function of the patient.

**Dose levels**

<table>
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<td>Dose</td>
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<td>Fluoroscopy time</td>
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<tr>
<td>Contrast Medium</td>
<td>5 mL iodine to check quality of CO2 angiography against iodine.</td>
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</table>

This case report is being made available to assist medical professional’s awareness and understanding of the current state of research related to the device, technology, and application categories at issue in this material and as of the date of this case report. The statements by GE customers described here are based on their own opinions and on results that were achieved in the customer’s unique setting. Since there is no “typical” hospital and many variables exist, i.e. hospital size, case mix, etc., there can be no guarantee that other customers will achieve the same results. GE customers are solely responsible for the analyses and conclusions in the referenced material. GE does not endorse the conclusions or recommendations contained in the material.
Reducing Radiation Dose during EVAR in the Hybrid Operating Room: the REVAR study

Since the introduction of endovascular aneurysm repair (EVAR) in the 1990s, the numbers of open aneurysm repairs has significantly declined, with 60-70% of all abdominal aortic aneurysms (AAAs) repairs being performed through an endovascular approach1,2. With the minimally invasive endovascular procedure trend comes the need for an X-ray system to guide devices. Though EVAR decreases perioperative mortality, procedure and ICU time as well as hospital stay compared to the former open surgical approach3, it poses however the challenge of radiation dose, and therefore the need to reduce radiation dose both for patients, but also for the staff involved. Keeping dose to a minimum has become a goal for image-guided therapies as well as a research topic for many experts in minimally invasive vascular surgery, as exemplified by the REVAR study (Radiation Dose Reduction During EVAR: Results from a Prospective Multicentre Study) published in 2018 in the European Journal of Endovascular Surgery4.

The objective of the multicentric REVAR study was to evaluate radiation exposure in standard EVAR using intra-operative guidance with pre-operative computed tomographic angiography (CTA) fusion and strict adherence to ALARA guidelines in a modern hybrid room. Six centers prospectively enrolled 85 patients undergoing standard EVAR and recorded their dose levels. These centers were all equipped with a Discovery IGS 7 Hybrid OR (GE Healthcare), as well as EVAR ASSIST 2® image fusion (GE Healthcare). Before enrolment, all centers were trained through a webinar by the principal investigator, Stéphan Haulon, on the ALARA principles, as well as the golden rules to reduce dose with image fusion in the Hybrid OR.

Results showed a median DAP of 14.7 Gy.cm² achieved across all 6 centers of the study (ranging from 10.3 to 28.1 Gy.cm²), highlighting the fact that very low dose could be achieved by all centers, thanks to a quick learning curve with easy-to-use solutions. These results are 12 times lower than the mean DAP of 181 Gy.cm² reported in a meta-analysis published in 2016 by de Ruiter et al5 in the non-complex EVAR subset with fixed C-arms. The infographics presented at the end of the article summarizes the REVAR study design and main outcomes.

Principal investigator of the REVAR study, Pr. Stéphan Haulon shares why he initiated the REVAR study.

“Radiation dose exposure during endovascular procedures has always been a major concern for me. When we installed our Discovery IGS 730 hybrid OR, we initiated a study to compare our radiation dose results versus mobile C-arm and published literature. We achieved an extremely low median DAP of 12.2 Gy.cm² for standard EVAR. Many of my peers questioned whether this very low radiation dose levels were achievable elsewhere, not just in expert aortic centers. So, we launched the multicentric REVAR study including centers performing mid-to-low volume EVAR, equipped and trained to use GE hybrid OR and fusion imaging in accordance with ALARA principles. The goal was to demonstrate that any center could achieve low dose results, with radiation dose monitoring and awareness, as well as a systematic use of the advanced tools in a modern hybrid room, all without compromising procedural success.”

5. EVAR ASSIST 2® solution includes FlightPlan for EVAR CT, EVARVision and requires AW workstation with Volume Viewer, Volume Viewer Innova, VesselIQ Xpress, Autobone Xpress. These applications are sold separately.
6. The sites in the REVAR study used Discovery IGS 730 and Discovery IGS 740, previous product versions of Discovery IGS 7 with GE OR table. They also used EVAR ASSIST image fusion, a precursor version of EVAR ASSIST 2.

Focus on new clinical evidence

Snapshot on the REVAR study results
“How do we reduce radiation dose today in our interventions? It’s a mix of several factors. Fusion will allow us to position the C-arm and the table without shooting X-rays, so when you press the pedal, you know exactly what you’re going to see. Then dose reduction is achieved through the control of all dose parameters at tableside very easily. It means using collimation, but also starting the case with very low-dose protocols by default, and then increase dose only if needed. The absence of magnification is something very important because

since we use EVAR ASSIST 2 fusion every day, we will use digital zoom as well as collimation, and then fusion for the positioning, so all of this put together has a big impact on the dose level in the end.

Another important point to reduce radiation exposure is to be able to bring the detector as close as possible to the patient, and that’s what Innova Sense® (GE Healthcare) does automatically. In practice, it saves us a lot of time, because while moving the table or the C-arm, the detector positions itself automatically close to the patient, helping to minimize the radiation.

When you move from a mobile C-arm to a hybrid room with a fixed system, and you compare both in terms of radiation, the Discovery has a huge advantage and you can see it in publications, you can reduce radiation exposure by 4 to 15 folds. That’s not negligible.

Our hybrid OR has become something essential for the endovascular practice. I cannot envision today doing all these complex aortic repairs but also peripheral surgeries without the Discovery IGS 7 hybrid OR, because we need image fusion, cone-beam CT, and all these tools which allow us to work efficiently and quickly every day to achieve technical success, while reducing X-ray exposure for patients but also for the surgical and paramedical team. It has become a must, one cannot imagine how it changes completely your practice once you are equipped with a hybrid room of that quality.”

“Reduction in patient dose and operator dose in our daily practice. Among the factors decreasing dose, an example is the pre-operative CTA registration, thanks to which you can position the table and the C-arm without shooting additional X-rays since you have a permanent mask of the aorta on the screen. What is also interesting is that you can adjust collimation as well as position the C-arm working angles for catheterization and navigation without X-ray. So, all of this represents a huge benefit in terms of radioprotection. Regarding the final control, we changed our practice since the installation of this hybrid room. Before, we used to do a 2D antero-posterior angiography at the end of the case, and then complete this control with a CTA before the patient was sent home. Now we do a CBCT acquisition in the room at the end of the case and a post-operative ultrasound. The control CBCT allows us to verify the endograft architecture and to ensure that there is no issue that we could solve during the same intervention. We have noticed with this new control strategy, that we can not only reduce re-intervention rates, but also patient radiation dose and contrast media levels.”

8 Applicable to Discovery IGS 730 and Discovery IGS 7160 (IGS 7160 configuration)
"Regarding the evolution of patient management, we had conventional flat panel angiography systems up until 2016, and then we switched to the Discovery IGS 7 hybrid OR, and we saw immediately an important decrease in radiation dose levels.

Thanks to EVAR ASSIST 2, you can visualize the connecting visceral arteries arising from the region that you want to treat, without the need to do additional injections, so you can reduce the amount of contrast and radiation dramatically. This is a major advantage. Then you can position your tube depending on the angles defined on the fusion mask, so we save a lot of time for the deployment of the endograft, and it makes it easier. In my practice, we saw huge benefits of fusion imaging to treat dissections. It enables to visualize the true and false lumen, position landmarks for stent graft insertion, false lumen embolization and identify visceral branches from the false lumen."

"In my hospital, I was using a hybrid OR from another vendor for my endovascular procedures. When the Discovery IGS 7 hybrid OR was installed in 2014, I observed a significant drop in radiation dose for my procedures and was very satisfied with the result. However, when Stephan Haulon initiated the REVAR study in 2016 and we did the initial baseline, I realized that our radiation dose levels were still very high compared to his practice. We followed the training on "Golden rules to reduce radiation for EVAR" and more importantly on the steps and the tools to use in everyday practice. With the REVAR study experience, I adopted a new way of working during EVAR procedures, minimizing the use of DSA to the strict necessary, and increasing the use of larger Field Of View (FOV) with collimation, since the digital zoom enables me to work comfortably with a larger fusion image, with aorta and ostia contours. The radiology technicians had a quick learning curve with EVAR ASSIST 2 as it is intuitive and easy to use, and when I enter the hybrid OR to start a case, the fusion mask is already prepared and registered and all set to go! I'm very proud of the low dose results from my center and performing low dose procedures is now part of our DNA!"

"Switching from mobile C-arms to the hybrid OR."

Interview with Hervé Rousseau
Head of Radiology, CHU Toulouse, France

Interview with Robert Rhee
Director of Vascular Surgery, Maimonides Medical Center, USA

Focus on new clinical evidence

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Focus on new clinical evidence
Evaluate radiation exposure in standard EVAR using image fusion & ALARA guidelines in a hybrid OR

** RESULTS **

Median DAP of 14.7 Gy.cm²
Achieved across all 6 centers of the prospective multicentre observational study¹

<table>
<thead>
<tr>
<th>Median DAP (Gy.cm²)</th>
<th>Center 1</th>
<th>Center 2</th>
<th>Center 3</th>
<th>Center 4</th>
<th>Center 5</th>
<th>Center 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10.3</td>
<td>14.2</td>
<td>20.2</td>
<td>12</td>
<td>16</td>
<td>14.2</td>
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</table>
| Mean DAP of 181 Gy.cm²
Reported in the meta-analysis by de Ruiter et al. in the non-complex EVAR subset with fixed C-arms²

<table>
<thead>
<tr>
<th>Mean DAP (Gy.cm²)</th>
<th>Philips</th>
<th>Siemens</th>
<th>GE Healthcare</th>
<th>Not reported</th>
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</thead>
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<td>16</td>
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</tr>
</tbody>
</table>

12X lower median DAP compared to literature²

** PROSPECTIVE MULTICENTER STUDY¹ **

Evaluate radiation exposure in standard EVAR using image fusion & ALARA guidelines in a hybrid OR

<table>
<thead>
<tr>
<th>6 centers</th>
<th>85 patients undergoing standard EVAR</th>
</tr>
</thead>
</table>

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³ Data points were extracted from the meta-analysis by De Ruiter et al. (2016). The differences between DAP levels reported in the graph account for several parameters, such as the fusion, the equipment used, the patients characteristics, the operators, the use of ALARA principles, the institution, etc. Therefore, results may vary from one site to another. The results described here were obtained in the customer’s unique setting. Since there is no “typical” hospital and many variables exist (e.g. hospital size, case mix), there can be no guarantee that other customers will achieve the same results.

¹ EVAR ASSIST 2 solution includes FlightPlan for EVAR CT, EVARVision and requires AW workstation with Volume Viewer, Volume Viewer Innova, VesselIQ Xpress, Autobone Xpress. These applications are sold separately.
² EVAR ASSIST image fusion, a previous version of EVAR ASSIST 2.
³ EVAR ASSIST 2 solution includes FlightPlan for EVAR CT, EVARVision and requires AW workstation with Volume Viewer, Volume Viewer Innova, VesselIQ Xpress, Autobone Xpress. These applications are sold separately.

By following the ALARA principle in a modern hybrid room with routine use of fusion imaging guidance for EVAR, low radiation exposure compared with the published literature can be achieved in a real world setting.
GE Healthcare

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