ASSIST MAGAZINE

Innovative Interventional Treatments

The hybrid OR of the future

VIDEO-ASSISTED THORACIC SURGERY OF LUNG NODULES

UROLOGY & INTERVENTIONAL RADIOLOGY COLLABORATION

DOSE REDUCTION RESULTS FROM THE REVAR STUDY

Magazine#6

Jean-François Drouet
Image Guided Therapy
Director Europe

France Schwarz
Interventional & Hybrid OR
Marketing Manager Europe

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.

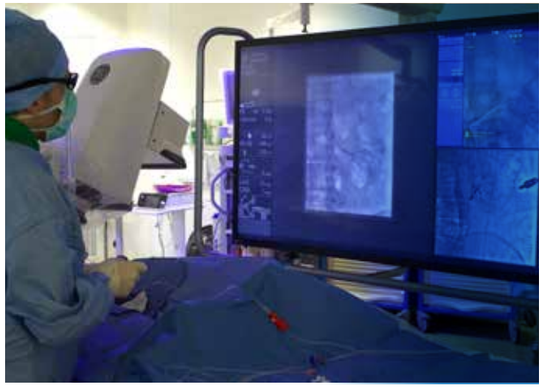
Key considerations for building an HOR, such as having a flexible imaging solution to enable diverse clinical setups, meet stringent OR hygiene standards, maximize OR utilization, and improve clinical outcomes through intra-operative 3D imaging and augmented reality 3D guidance are driving hospitals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

ASSIST MAGAZINE



Local Contact Information:

GE Healthcare Buc
283, rue de la Miniere
78533, Buc Cedex, France

Chief Editor: France Schwarz

Editorial Team: Dustin Boutboul, Mathilde Dauchez, Jean-François Drouet, Paul Ayestaran, Thijs ter Mors, Aïcha Zammouri, Cecilia Félix.

Design: Nathalie Ollivier

Printer: Groupe Lecaux Imprimeries HandiPRINT

Many thanks to our contributors :

Pr. Pierre Bigot, France
Dr. Antoine Bouvier, France
Pr. Bob Geelkerken, The Netherlands
Dr. Dick Gerrits, The Netherlands
Dr. Simon Rouzé, France
Dr. Brian Kouri, USA
Dr. Nicolas Louis, France
Dr. Eva-Line Decoster, Belgium
Pr. Stéphan Haulon, France*
Dr. Adrien Hertault, France
Pr. Hervé Rousseau, France
Dr. Robert Rhee, USA*

* These contributors are paid consultant for GE Healthcare, but they have not been paid for the interviews here and did not receive orientations for them.

ASSIST Solutions

www.gehealthcare.com/assist

POWER UP PATIENT CARE

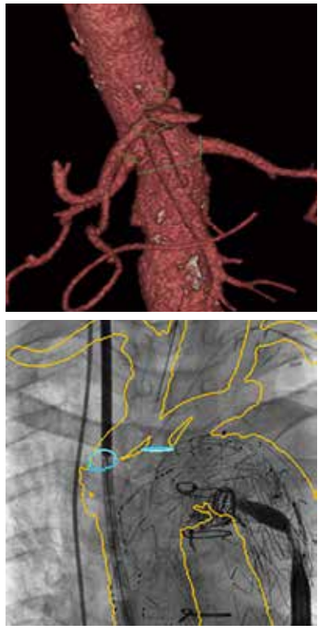
Your patients benefit from greater diagnostic accuracy and therapeutic effectiveness with minimal exposure.

POWER UP YOUR CLINICAL CAPABILITIES AND SERVICE LINE

ASSIST gives you the clinical information to let you plan, guide and assess interventional procedures.

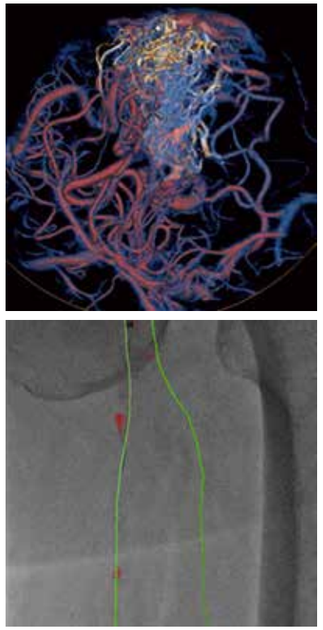
POWER UP PRODUCTIVITY

The ASSIST portfolio provides intuitive planning, designed to make your procedures easier and more efficient.



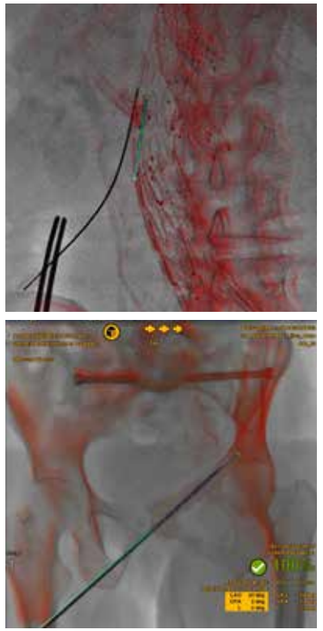
EVAR ASSIST 2 *

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.



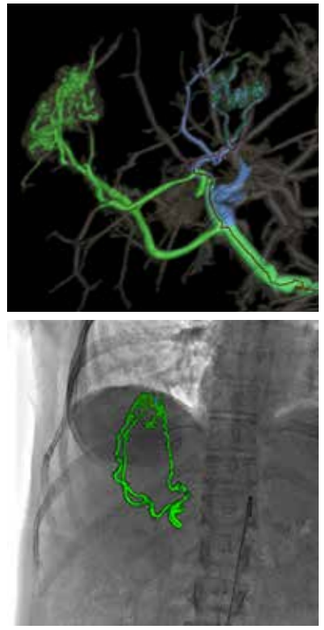
Vessel ASSIST **

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.



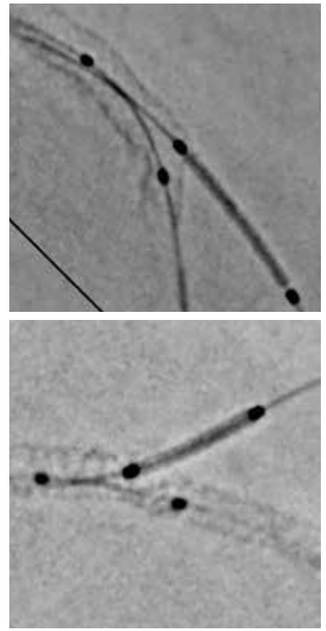
Needle ASSIST ***

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[1]. With the guided-workflow instructions, you can reconstruct a needle in 3D with only two fluoroscopic images in less than 1 minute.[2]



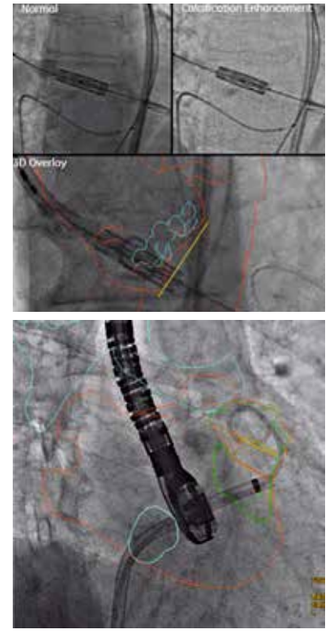
Liver ASSIST V.I.****

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[3]. 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.



PCI ASSIST *****

Now you can perform long, complex PCI procedures with the same precision and confidence as routine cases – without increasing dose[4]. PCI ASSIST significantly helps to improve contrast and visibility. You can clearly see even small details to accurately position and deploy stents thanks to advanced stent visualization softwares. It all adds up to more efficient PCI procedures.



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[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. ** Vessel ASSIST solution includes Vision 2, VesselIQ Xpress, Autobone Xpress and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately. *** Needle ASSIST solution includes TrackVision 2, Stereo 3D and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately. (1) Measurement conditions: system with Innova-IQ table or Omega V table, rigid geometric phantom, CBCT data, frontal plane, L-arm at 0 degree, region of interest of 10cm. (2) Time to reconstruct the object may vary depending on user experience and case complexity.**** Liver ASSIST V.I. solution which includes Hepatic VCAR and FlightPlan For Liver that can be used independently. It also requires an AW workstation with Volume Viewer and Volume Viewer Innova. These applications are sold separately. May not be available in all markets. (3) The above Liver ASSIST V.I. performances aspects reflect the results of published journal articles conducted by using previous version of FlightPlan for Liver software (b) or its prototypes (a) for the validation and they do not necessarily represent individual performance of FlightPlan for Liver: a. Computed Analysis of Three-Dimensional Cone-Beam Computed Tomography Angiography for Determination of Tumor-Feeding Vessels During Chemoembolisation of Liver Tumor: A Pilot Study – Deschamps et al. Cardiovasc Intervent Radiol. 2010. b. Tracking Navigation Imaging of Transcatheter Arterial Chemoembolisation for Hepatocellular Carcinoma Using Three-Dimensional Cone-Beam CT Angiography –Minami et al. Liver Cancer. 2014. c. Clinical utility and limitations of tumor-feeder detection software for liver cancer embolisation. Iwazawa et al. European Journal of Radiology. 2013. ***** PCI ASSIST solution includes StentViz and StentVesselViz. (4) IQ improvement is measured on Innova IGS530 with phantoms using various PlexiglasThicknesses, acquisition parameters and the NEMA spoke wheel tool (ref 1), calculating the ratio of the contrast of the moving wires to the background noise level. The amount of IQ improvement related to HCF depends on the acquisition parameters, clinical task, patient size, amount of motion in the image, anatomical location, and clinical practice. Ref1: A new tool for benchmarking cardiovascular fluoroscopes; S. Balter, Radiation Protection Dosimetry, Vol. 94, No. 1–2 pp. 161–166 (2001). Applicable to Innova IGS 5 (IGS 520, IGS 530 configurations), Innova IGS 6 and Discovery IGS 7 (IGS 730 configuration). ****** Valve ASSIST 2 solution includes TAVI Analysis, HeartVision 2 and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately. (5) Compared to a workflow which does not involve image fusion.

Hybrid and collaborative approaches

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[1,2,3,4]. 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).

1 Bigot, P., Bouvier, A., Panayotopoulos, P., Aubé, C., Azzouzi, A.R. Partial nephrectomy after selective embolization of tumor vessels in a hybrid operating room: a new approach of zero ischemia in renal surgery.

2 Panayotopoulos, P., Bouvier, A., Besnier, L. et al, Laparoscopic partial nephrectomy following tumor embolization in a hybrid room. Feasibility and clinical outcomes. Surg Oncol. 2017;26:377–381

3 Borojeni S. et al. Study of Renal and Kidney Tumor Vascularization Using Data from Preoperative Three-dimensional Arteriography Prior to Partial Nephrectomy. Eur Urol Focus. 2018 Aug 2. pii: S2405-4569(18)30212-8. doi: 10.1016/j.euf.2018.07.028

4 Benoit M. et al. Laparoscopic Partial Nephrectomy After Selective Embolization and Robot-Assisted Partial Nephrectomy: A Comparison of Short-Term Oncological and Functional Outcomes.2018. Clinical Genitourinary Cancer.

Hybrid and collaborative approaches

Dr. Antoine Bouvier is Interventional Radiologist at the CHU d'Angers, where he has been working for seventeen years. His main focus is on interventional oncology, in particular the endovascular treatment of liver tumors, as well as pre-operative embolization of renal tumors.

Pr. Pierre Bigot is Professor of Urology and Chief of the Urology department at the CHU d'Angers. His main specialty is renal cancer, which he studied during his PhD, and at the National Cancer Institute in Washington. Before developing the renal cancer activity at the CHU d'Angers, he learned the open surgical technique with Pr. Jean Jacques Patard, who pioneered the partial nephrectomy open surgical approach.

Selective renal artery embolization using Vessel ASSIST image fusion.

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 (eg. 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[7], 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*

...

5 Ljungberg B, Hanbury DC, Kuczyk MA, et al. Guidelines on Renal Cell Carcinoma.
6 Safety and efficacy of partial nephrectomy for all T1 tumors based on an international multicenter experience. Patard JJ. Et al. J Urol. 2004 Jun;171(6 Pt 1):2181-5
7 Chronic kidney disease after nephrectomy in patients with renal cortical tumours: a retrospective cohort study. Huang WC. et al. The Lancet Oncology, 2006

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[9]. *"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.

Instead of clamping the renal artery, we decided to embolize selectively the artery going to the tumor to avoid bleeding during subsequent resection

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."*

This combined approach has the benefit of avoiding risks of renal ischemia

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[4]. *"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[10], 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[4]. 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."*

•••

8 Zero Ischemia Laparoscopic Partial Nephrectomy After Superselective Transarterial Tumor Embolization for Tumors with Moderate Nephrometry Score: Long-Term Results of a Single-Center Experience. Simone G. et al. J. of Endourology, 2011, Vol. 25, No. 9

9 Benefits and shortcomings of superselective transarterial embolization of renal tumors before zero ischemia laparoscopic partial nephrectomy. D'urso L. et al EJSO, 2014

10 Comparison of 1800 Robotic and Open Partial Nephrectomies for Renal Tumors. Peyronnet B. at al. 2016. Ann Surg Oncol. 2016 Dec;23(13):4277-4283.

"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 thermoablations 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.

The hybrid room enables us to perform a combination of surgical and endovascular approaches in one room and in one setting.

At a glance

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 [11] 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.

HOR room set-up for embolization

The Discovery system is at head position during the entire endovascular procedure, allowing to image the groin and kidney without any L-arm movements or interference with anesthesia thanks to the offset C-arm.

HOR room set up for partial nephrectomy

The Discovery system is parked in a corner of the operating room, allowing for total patient access for the surgical part of the procedure.

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=0.32)

Key operational outcomes:

- Decreased operating time: mean operating time of 150 min for LPN (46 min of embolization plus 84 min of laparoscopy) compared to 195 min for RPN (p<0.001)
- Decreased hospital stay: median hospital stay duration of 3 days

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.

11 Vessel ASSIST solution includes Vision 2, VesselIQ Xpress, Autobone Xpress and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately.

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.

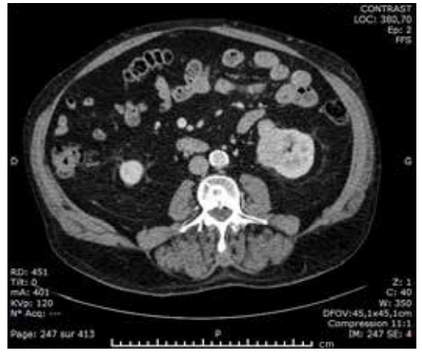


Fig. 1 Axial view of the pre-operative CT showing a lesion of the inferior pole on the left kidney

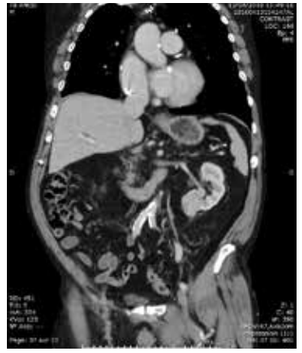


Fig. 2 Coronal view of the pre-operative CT showing a lesion of the inferior pole on the left kidney

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 (Fig3). 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.

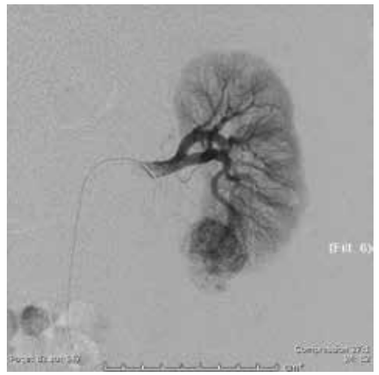


Fig. 3 Native acquisition of subtracted CBCT

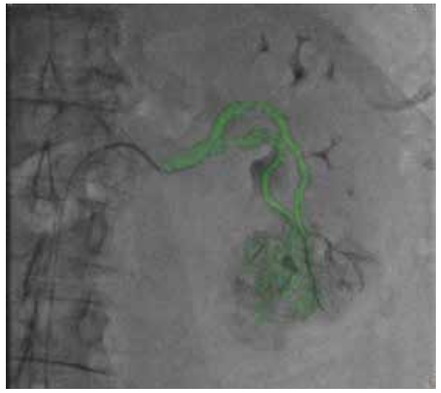


Fig. 4 Identification of the feeders and guidance with Vessel ASSIST

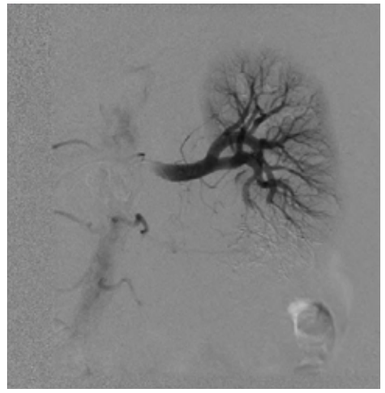


Fig. 5 Final arteriography after embolization showing complete devascularization of the tumor

Guide
The 3D volume of the feeders was fused with live fluoroscopy to optimize the guidance, using Vessel ASSIST[11] (Fig. 4). The 3D volume was fully synchronized with the gantry and the table, which allowed to reduce contrast media and dose.
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).

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.

Dose levels

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

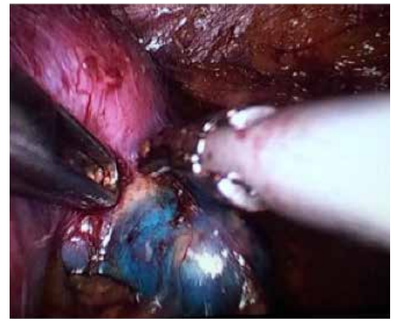


Fig. 6 Tumor enhanced with patent blue

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 guideline[1] and a recent publication[2], 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[3]. 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.

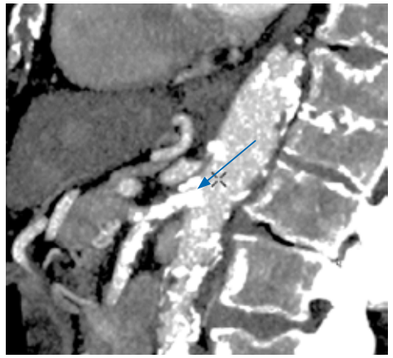


Fig. 1. Pre-operative CT (sagittal view of the aorta) showing a calcified 90% stenosis at the origin of the CA and an elongated calcified 70% stenosis at the origin of the SMA (blue arrow).

Fig. 2. Pre-operative CT (Volume Rendering). Perfusion of the left leg was severely compromised due to multiple significant stenosis in the left external iliac artery, a re-occlusion of the SFA up to the infragenual popliteal artery (P3 segment) with only a crural run off via the peroneal artery.

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 arcade. 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.

Fig. 3. Arteriotomy & bypass. Discovery IGS 740 is parked in a corner of the OR outside the operation field.

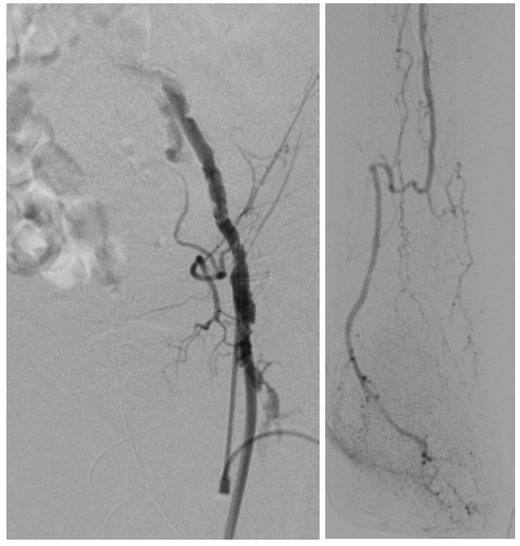


Fig. 4. Left - DSA of the EIA showing a sufficient inflow in the bypass. Right - Crural DSA of the left foot demonstrating single vessel peroneal artery outflow with collateral filling of the distal ATP.

1 Management of the Diseases of Mesenteric Arteries and Veins. Clinical Practice Guidelines of the European Society of Vascular Surgery (ESVS). Björck M, et al, EJVES April 2017. https://doi.org/10.1016/j.ejvs.2017.01.010

2 Chronic mesenteric ischemia: when and how to intervene on patients with celiac/SMA stenosis. Blauw et al. J Cardiovasc Surg (Torino), 2017. DOI:10.23736/S0021-9509.16.09829-3

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

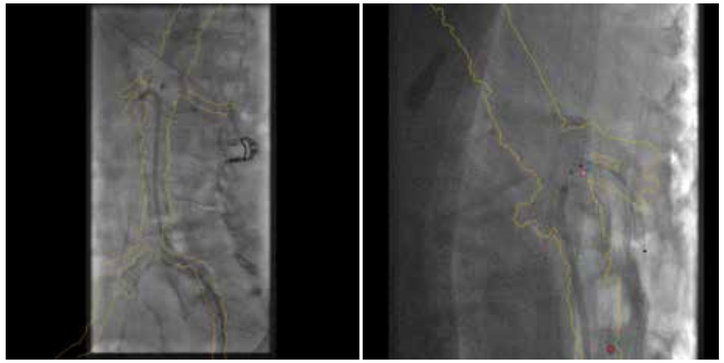


Fig. 5. Catheterization of the SMA and stent deployment performed using 3D-CT-fusion with Vessel ASSIST.

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 in- and outflow of 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

Total OR time	195 minutes
Blood loss	200mL
DAP	107.8 Gy.cm2
Fluoroscopy time	13.35 minutes
Contrast Medium	20mL for leg, 100mL for bowel

Fig. 6. Post-operative CT demonstrating a patent left Fem-Pop bypass.

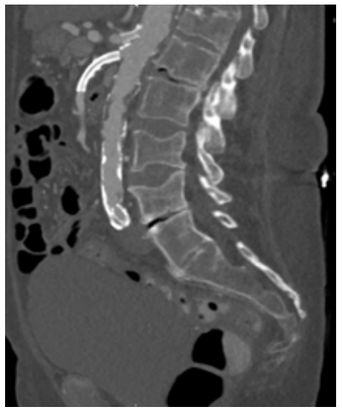


Fig. 7. Post-operative CT demonstrating good flow through both stents and a patent CA and SMA.

Focus on a new specialty in the hybrid OR

Video-Assisted Thoracic Surgery in the Hybrid Operating Room for Lung Nodule Resection

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).

1 Berrino F, Capocaccia R, Estève J, Gatta G, Hakulinen T, Micheli A et al. Survival of cancer patients in Europe: the EUROCARE-2 study. IARC Sci Publ 1999;151:1–572

2 National Cancer Institute. SEER Cancer Statistics Review 1975–2012 [Internet]. Available from http://seer.cancer.gov.

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[4]. 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 hookwire 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 though trocars[4], 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[5]. We locate and segment the nodule on this 3D volume and use this as a fusion mask[6] 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 it 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 fluoroscopy view using different C-arm angulations.

Now that we have the Discovery IGS 7 HOR, we also use Stereo 3D (Needle ASSIST[7], 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

"We have gained precision thanks to the Stereo 3D solution, which provides live feedback about our position compared to the nodule, with only two fluoroscopy shots"

Side by side display of the VATS view[8] and the fluoroscopic view with 3D fused nodule on top

3 Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening. The National Lung Screening Trial Research Team. N Engl J Med. 2011 August 4; 365(5): 395–409. doi:10.1056/NEJMoa1102873.
4 Matsumoto S, Hirata T, Ogawa E, Fukuse T, Ueda H, Koyama T, et al. Ultrasonographic evaluation of small nodules in the peripheral lung during video-assisted thoracic surgery (VATS) Eur J Cardiothorac Surg. 2004;26:469–73
5. IGS 730 configuration
6 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.
7 Needle ASSIST solution includes TrackVision 2, Stereo 3D and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately. Not available for sale in all regions.
8 The VATS video input has not been validated as such. The availability of this input on the large display monitor cannot be guaranteed. Contact your sales representative.

that we are at the right location, we electro-coagulate 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 lobectomy, then 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 HOR, we need intra-operative CBCT. Second, 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 7 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.

Patient positioning for initial intra-operative CBCT acquisition

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[9]. 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 7 HOR 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 7 HOR. I would say that the three main benefits of the Discovery are lower radiation dose, better precision, and improved workflow.

Dose levels in our Discovery IGS 7 hybrid OR are two to three times lower than in our other hybrid operating room. The difference is quite significant and surprising.

Secondly, we have gained precision thanks to the Stereo 3D solution, which provides live feedback about our position compared to the nodule, with only two fluoroscopy shots. We do not need to take an extra margin anymore, we know that are very precise. Stereo 3D gives me a lot of confidence.

Lastly, the Discovery is very re-assuring 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.

VATS surgical set up

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[10]. 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.

Surgical set-up and observation of the wedge resected tissue

9 Zaman M, Bilal H, Woo CY, Tang A. In patients undergoing video-assisted thoracoscopic surgery excision, what is the best way to locate a subcentimetre solitary pulmonary nodule in order to achieve successful excision? Interact CardioVasc Thorac Surg 2012;15:266–72

10 Sun J, Mao X, Xie F, et al. Electromagnetic navigation bronchoscopy guided injection of methylene blue combined with hookwire for preoperative localization of small pulmonary lesions in thoracoscopic surgery. J Thorac Dis 2015;7:E652-6

Wedge Resection of a Left Lower Lobe Nodule with Video-Assisted Thoracic Surgery (VATS) under CBCT and Image Fusion Guidance

Courtesy of Dr. Simon Rouzé, Thoracic Surgeon, Rennes University Hospital, France

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 cardiopulmonary auscultation were normal, without thoracic deformity.

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[11]. 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 synchronized with the Discovery IGS 7[5] and the lesion could be centered on the imaging area without performing X-Rays. The position of the C-arm and table were recorded for later recall during the intervention for image guidance.

Fig 1. Biview registration of pre-op CT and fluoroscopy.

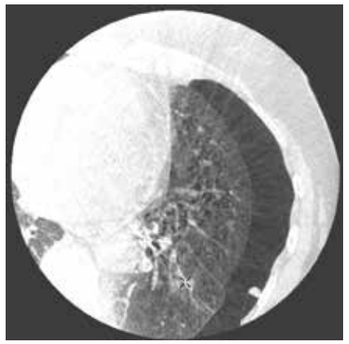


Fig 2. Axial view of the initial CBCT with induced pneumothorax. The collapsed lung makes the nodules harder to identify.

The Discovery IGS 7[5] 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.

Assess

In order to validate the optimal positioning of surgical instrument versus the nodule location, the Stereo 3D solution (part of Needle ASSIST, GE Healthcare)[7] 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.

Once the location was validated by Stereo 3D, the Discovery IGS 7[5] was moved to its parking position, electro-coagulation of the pulmonary surface was initiated and the wedge resection performed with conventional automatic stapler. After wedge resection, frozen section of the nodule was carried out in order to analyze the nature and margins of the tumor, and decide upon the surgical strategy to come. The result came back positive for adenocarcinoma, and the resection was extended to the lobe.

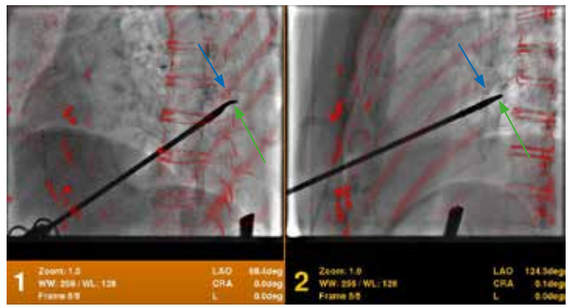


Fig 4. Two fluoro shots to automatically detect the surgical instrument, and allow to subsequently position its tip (green arrow) with regards to the nodule (blue arrow) in the initial CBCT thanks to Stereo 3D

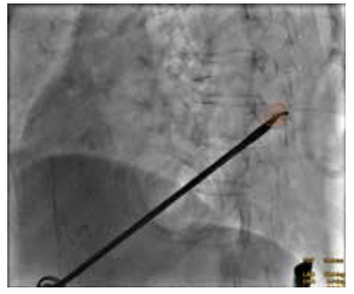


Fig 3. Lateral view of the surgical instrument in relationship to the nodule overlaid on top of fluoroscopy.

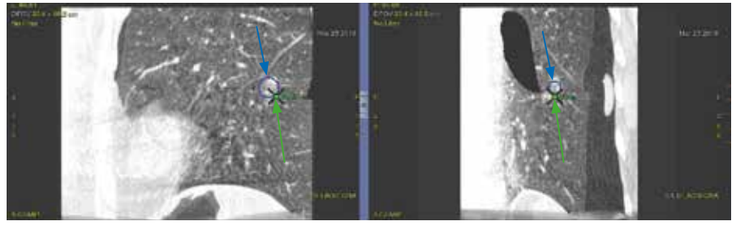


Fig 5. Stereo 3D result showing the location of the surgical instrument's tip (2A, green arrow) close to the nodule (1, blue arrow) in the initial CBCT cross sections and volume rendering.

Conclusion

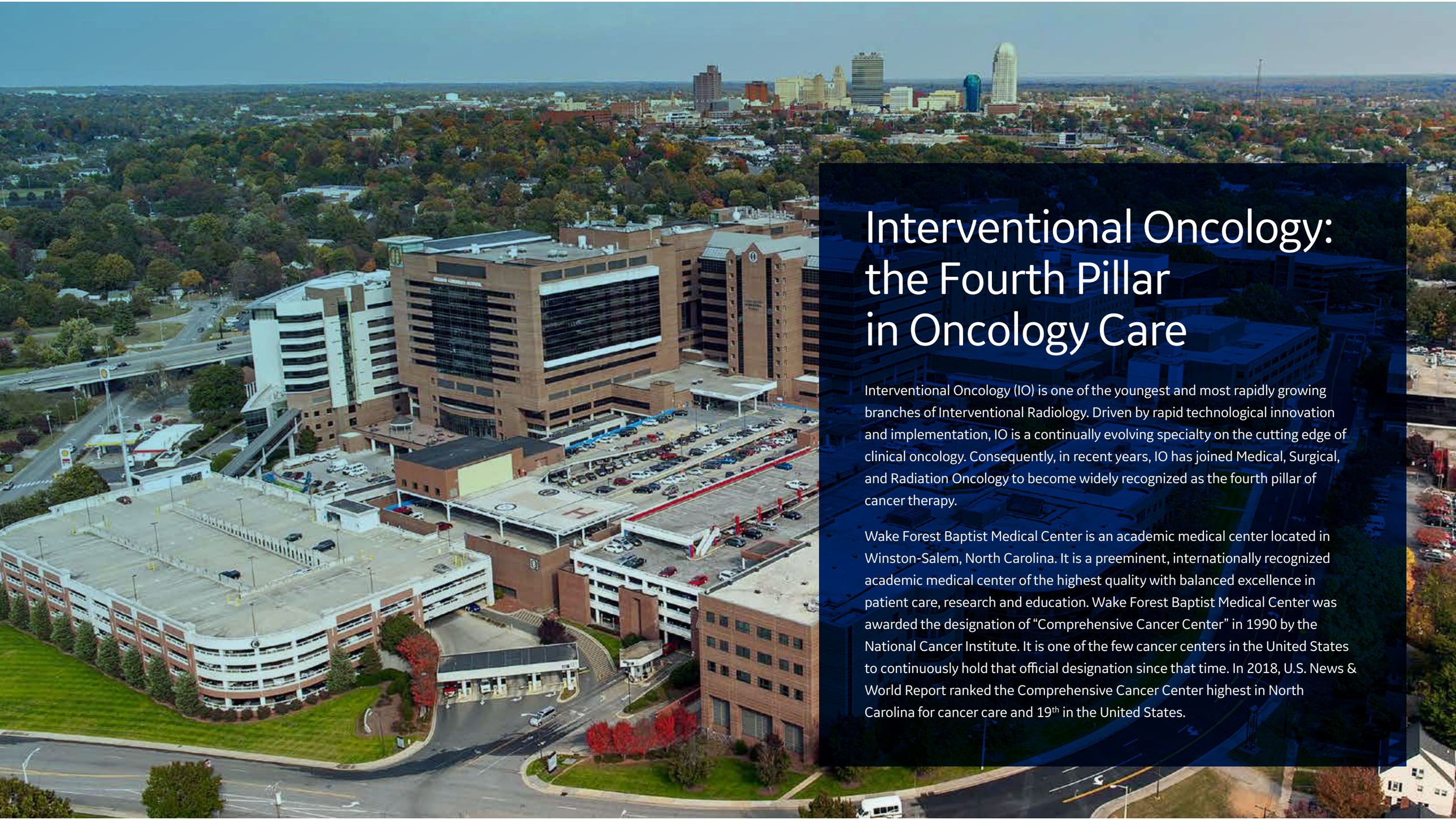
The patient had her drain removed one day after surgery, suffered no respiratory or infectious complication and was discharged at day 2. In this VATS procedure, Stereo 3D allowed the surgeon to understand the relative position of the surgical forceps with regards to the nodule in 3D and guide the resection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

Dose levels

Fluoroscopy Time	1'33 min
Dose	13.9 Gy.cm^2
Air Kerma	71.5 mGy

11 Thoracic VCAR solution requires AW workstation with Volume Viewer. This application is sold separately. Not available for sale in all regions.

New imaging workflows



Interventional Oncology: the Fourth Pillar in Oncology Care

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.

New imaging workflows

Dr. Brian Kouri received his medical degree from the University of North Carolina School of Medicine in 2002. He then completed a transitional year internship at Mayo Clinic Jacksonville. He has been at Wake Forest since 2003 where he did his residency and fellowship. He has been a member of the faculty since 2008. During that time he has served as Section Chief and Medical Director of Interventional Radiology.

Dr Kouri using the in-room mouse to control the AW and assess the CBCT from table-side.

Dr. Kouri began offering IO treatments in 2011 with the addition of conventional chemoembolization and liver radiofrequency ablation to his 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 referral base of the services you provide".

Combining conventional chemoembolization with microwave ablation

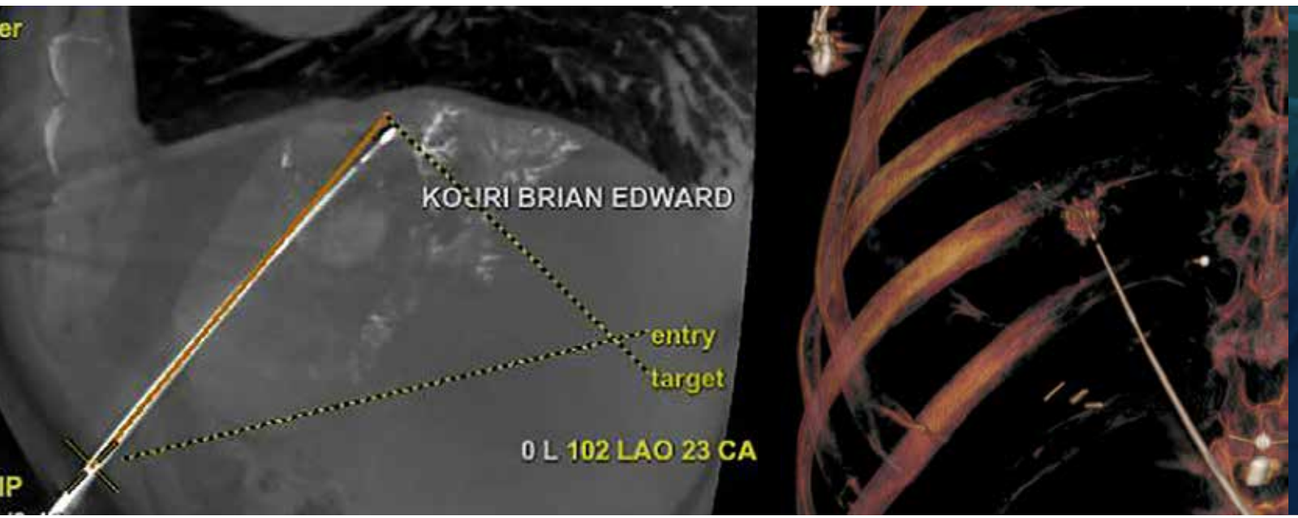
"In recent years, the practice of combining chemoembolization with microwave ablation has grown in favor within the IO field to treat liver tumors which are larger than the traditionally accepted upper size threshold for successful ablation. Many experts in the field, as reflected in the National Comprehensive 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 chemoembolizaton with microwave ablation in a single setting to treat tumors within the intermediate 3-5 cm size range.

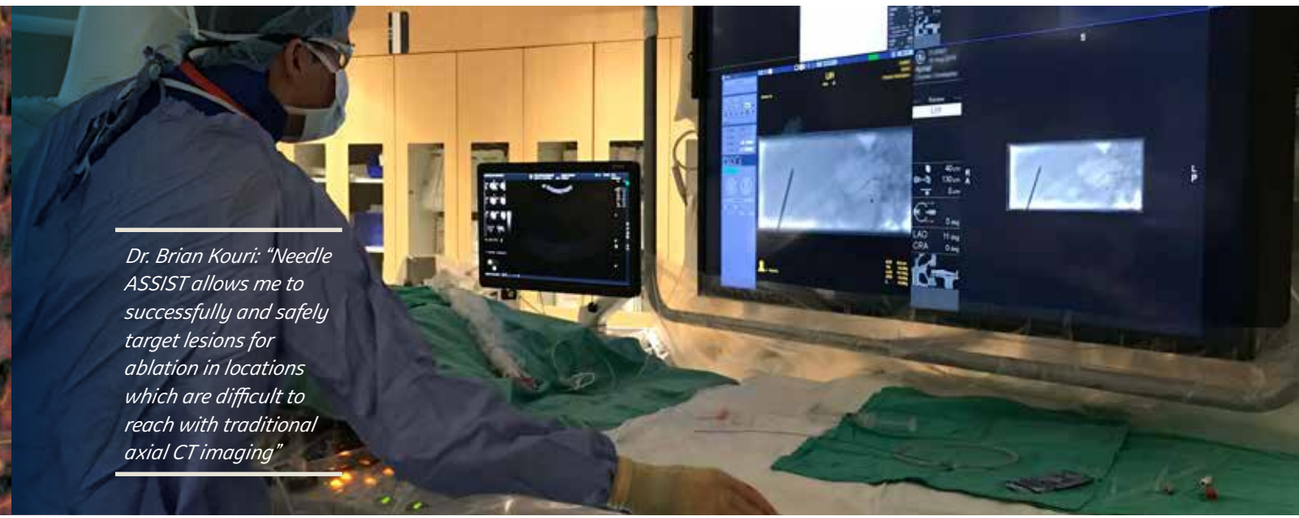
In addition to being able to successfully reduce post-ablation margin recurrences through the use of pre-ablation conventional chemoembolization, I have found lipiodol in many cases to be invaluable merely for improving the visualization of target lesions during the subsequent ablation portion of the 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[1] 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

New imaging workflows





Dr. Brian Kouri: "Needle ASSIST allows me to successfully and safely target lesions for ablation in locations which are difficult to reach with traditional axial CT imaging"

Dr Kouri utilizing Needle ASSIST[2] in a combined TACE/ablation procedure to treat a tumor high in the right hepatic lobe.

provides the opportunity to fuse multiple image sets together[3] 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[4] 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 tableside 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 roadmap[3] 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[2] 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 sterilely 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 2, VesselIQ Xpress, Autobone Xpress and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately.

New imaging workflows

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 is valuable with the ASSIST image fusion solutions, is that they are flexible and can be adapted to the physician's specific clinical needs"

Dr. Louis, can you describe your current practice, procedure mix, and the type of interventions that you perform?

I am a vascular surgeon, doing all types of open and endovascular procedures, from aortic procedures such as standard and complex EVARs (branched, fenestrated) to lower limbs treatments (peripheral arterial obstructive disease, iliac or femoral dilatations), and other vascular procedures (carotids...). I perform around 80 endovascular aortic procedures per year, and more than 80% of my practice is endovascular.

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 packages[1] 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 well[2], 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 ASSIST[3], we are able to reach the sac at the location of the leak with •••

1 ASSIST solutions require AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately. https://www.gehealthcare.com/assist

2 Impact of hybrid rooms with image fusion on radiation exposure during endovascular aortic repair. Hertault A. et al. Eur J Vasc Endovasc Surg. 2014. 48(4):382-90. doi: 10.1016/j.ejvs.2014.05.026.

3 Needle ASSIST solution includes TrackVision 2, stereo 3D and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately. Not available for sale in all regions.

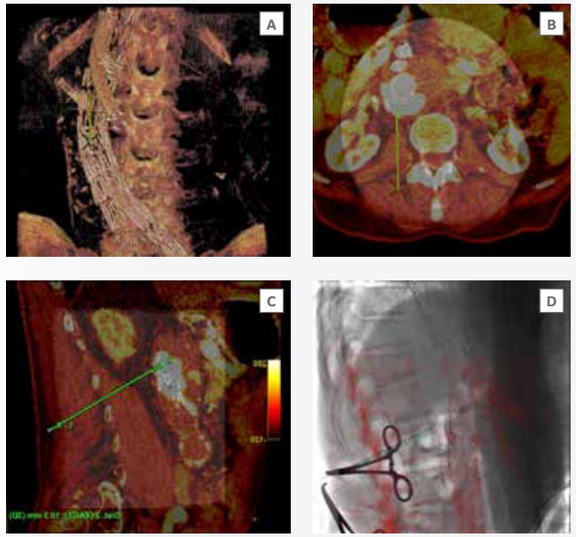


Fig. 1. A: 3D reconstruction of the needle trajectory on top of the CBCT. B: Fusion between the arterial CT and the CBCT with needle trajectory superimposed. C: Needle trajectory on top of fluoroscopy (progression view). D: 3D reconstruction of the needle position obtained from two views on top of the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

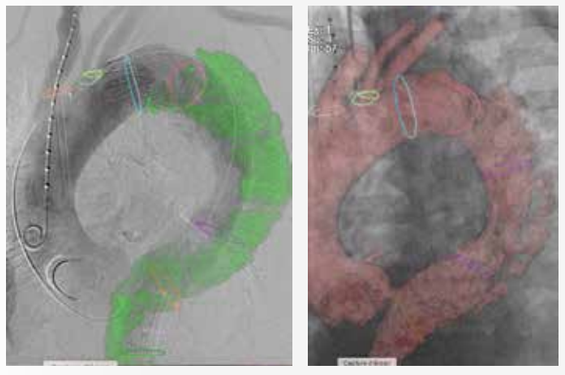


Fig. 2. In this aortic dissection case of the descending aorta, CT is fused over fluoroscopy. False lumen appears in green in the left side image, and true lumen appears in red in the right side image. Coloured contours symbolize the true lumen aorta, and helped the physician to remain in the true lumen while advancing the catheter, without the need to inject iodine (except for registration phase)

a millimetric accuracy. Moreover, for those challenging cases, we fuse the CBCT with another pre-operative modality (CT, MR) using Integrated Registration[4] in order to limit contrast injection during the case (Fig. 1).

How often do you use image fusion, and which outcomes does it bring?

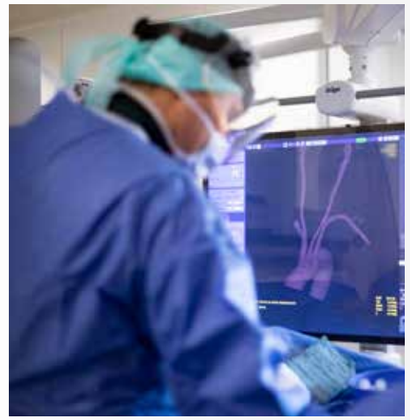
I use image fusion on a daily basis. For aortic procedures, I see real benefits for dissection cases in particular. Indeed, the ability to split the false and true lumen and display them on top of fluoroscopy allows us to save a lot of contrast injections, and to go from the true to the false lumen with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

What is valuable with the ASSIST image fusion solutions[1] (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 ASSIST[5] 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 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 IntraVenous 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]



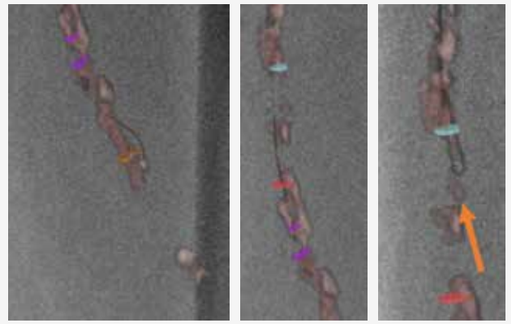


Fig. 3. Lower limbs recanalization with Vessel ASSIST Fusion
Circles symbolize re-entry zones to avoid artery dissection while calcifications overlay ensure a good registration between CT and fluoroscopy

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 cases[7]. 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!

4 Integrated Registration requires the AW Workstation or AW Server platforms, and Volume Viewer. These applications are sold separately. Not available for sale in all regions. Integrated Registration currently supports only 3D X-Ray Angiography images (stored as CT Image Storage DICOM objects) acquired with GE interventional equipment and reconstructed with the Innova3DXR application.
5 Vessel ASSIST solution includes Vision 2, VesselIQ Xpress and Autobone Xpress, and requires AW workstation with Volume Viewer and Volume Viewer Innova. These applications are sold separately. Not available for sale in all regions.

6 N Louis et al., Contribution of the Circles of Planning under 3D Fusion of Images to Treat Chronic Arterial Occlusions, Annals of Vascular surgery, November 2018, Volume 53, Pages 27–28. The recanalization was direct transluminal in 58.5%, subintimal in 30.8% and required the use of an echo-guided system of reentry in 7.6%.
7 Radiation Dose Reduction During EVAR: Results from a Prospective Multicentre Study (The REVAR Study). Hertault A. et al. Eur J Vasc Endovasc Surg (2018). https://doi.org/10.1016/jejvs.2018.05.001

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

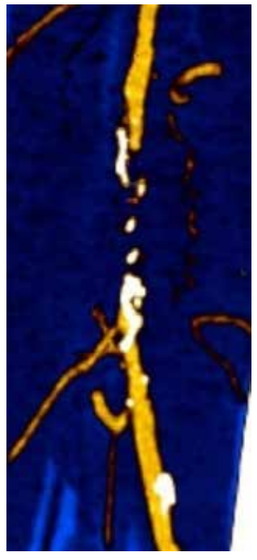


Fig. 1. "Perfusion" mode on the pre-operative CT. Calcifications are identified in white, in black we can identify the intima and in yellow the lumen of the vessel

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 calficications 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[5] 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.

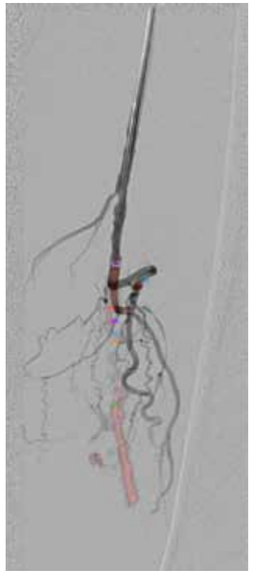


Fig. 2. Finetuning of the initial registration using DSA.

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[7] 5.5x60 stent (Abbott Vascular, USA) with the same size balloon was positioned. The results on the injected acquisition were very satisfying. (Fig. 5)

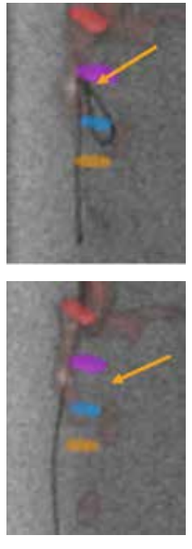


Fig. 3. Guidewire navigation inside the occlusion, the guidewire seems to go outside of the vessel.

Fig. 4a. Guidewire going in dissection.

Fig. 4b. Crossing the lesion using a dedicated catheter and guide.

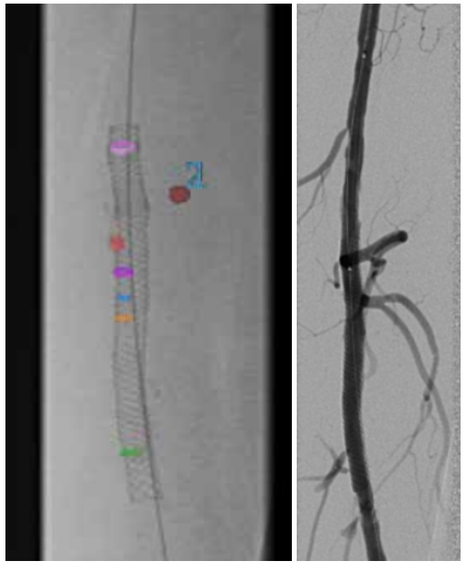


Fig. 5. Fluoroscopy image showing full deployment of the stent across the lesion, and DSA of the artery showing restored blood flow.

7 Supera is a registered or unregistrered trademark of Abbott Vascular or its affiliates.

Angioplasty of the left superficial femoral and external iliac arteries:

The same balloon was positioned at the level of the left superficial femoral artery with long inflation times. A stent mounted on an 8 X 25 balloon was positioned on the external iliac lesion relying on contour lines and imaging fusion.

A closure system was put in place with a manual compression of 10 minutes.

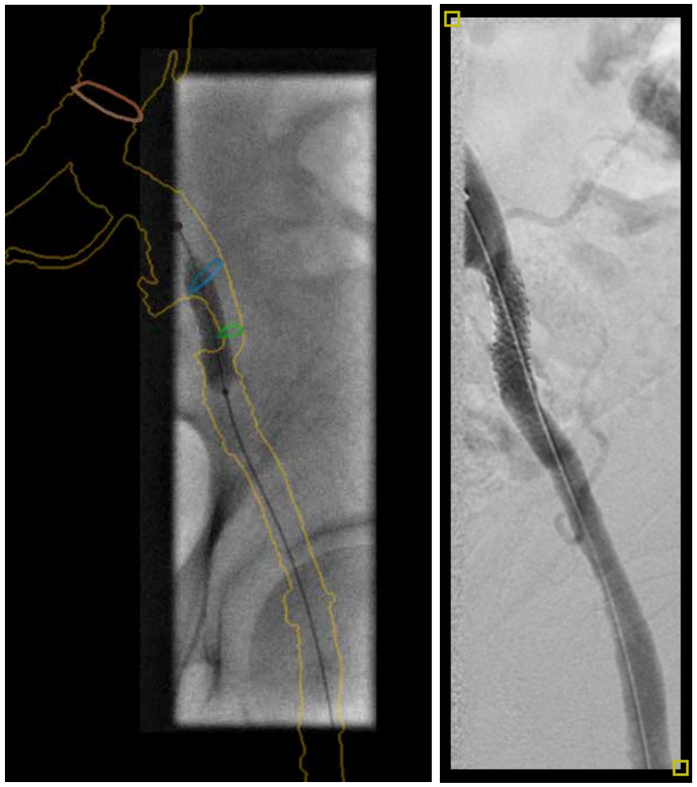


Fig. 6. Balloon angioplasty and stent deployment with Vessel ASSIST image fusion in the left superficial femoral artery.

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

Fluoroscopy Time	17'21 min
Dose	4.35 Gy.cm²
Air Kerma	64 mGy

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).

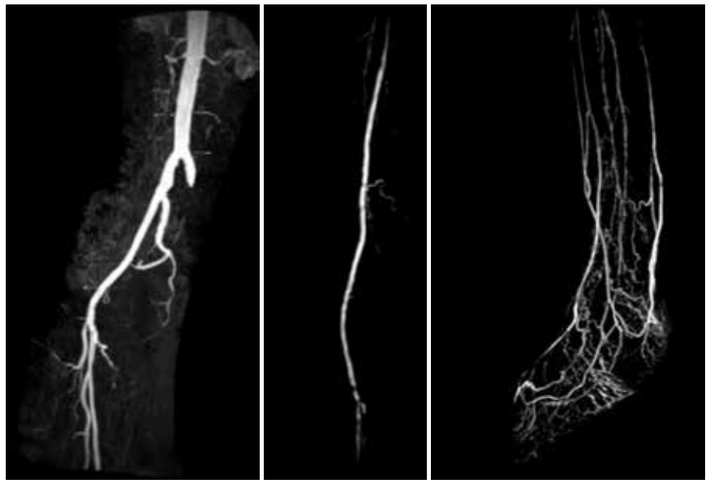
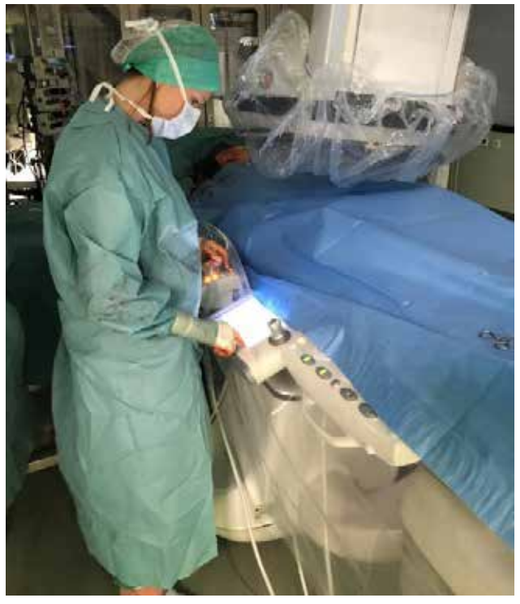


Fig. 1. For the right leg, no stenoses nor calcifications are seen on the MRA in the aorto-femoral trajectory (left image). The first stenosis is seen is at the distal popliteal artery (middle image). Both the peroneal artery and the tibial anterior artery show significant stenosis (right image).

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 3x40 mm balloon. After recanalization of the ATA with a 0.018' wire, subsequently a 2x120 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 2x20 mm and 2x40 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.



Dr. Decoster changing imaging settings with tableside controls. Discovery IGS 730 gantry panning on left side of patient for imaging coverage of the feet.

Dr. Decoster performing manual compression after the procedure with the Discovery IGS 730 parked away.

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

DAP	23.52 Gy.cm^2
Dose	170 mGy
Fluoroscopy time	27:35 min
Contrast Medium	5 mL iodine to check quality of CO2 angiography against iodine.

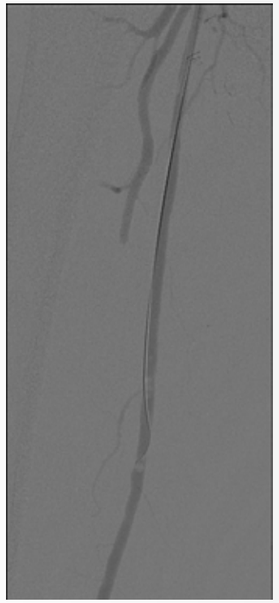


Fig. 2a. CO2 DSA of the superficial femoral artery.

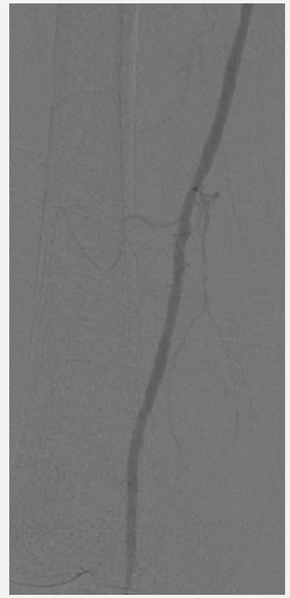


Fig. 2b. CO2 DSA of the femoral artery.

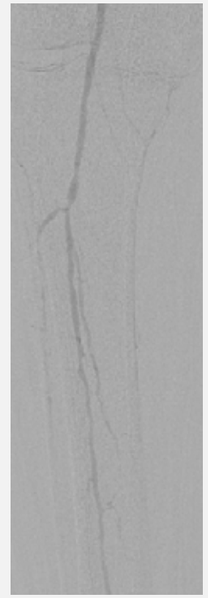


Fig. 3. CO2 DSA of the tibial fibular trunk.

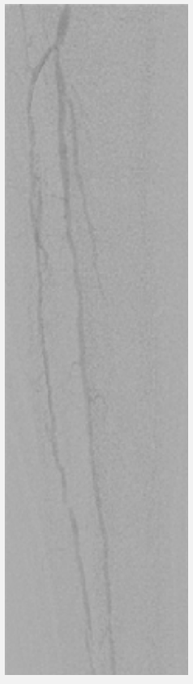


Fig. 7. Flow of the tibial-fibular trunk after PTA of the ostium of the ATA and the peroneal artery.

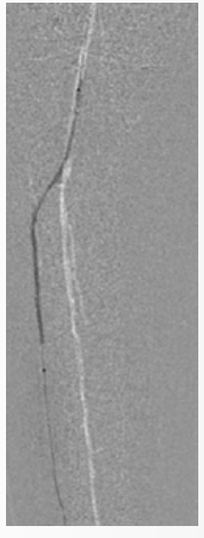


Fig. 4. PTA of the ATA using 2D roadmapping

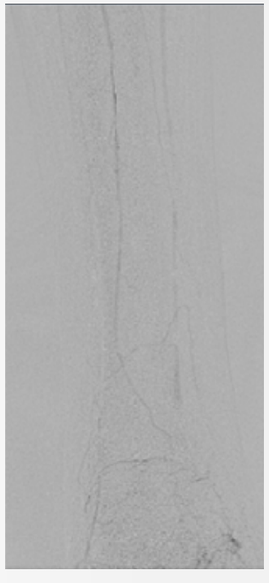


Fig. 5. CO2 DSA of the ankle.

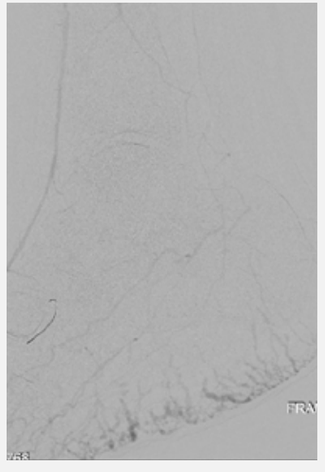
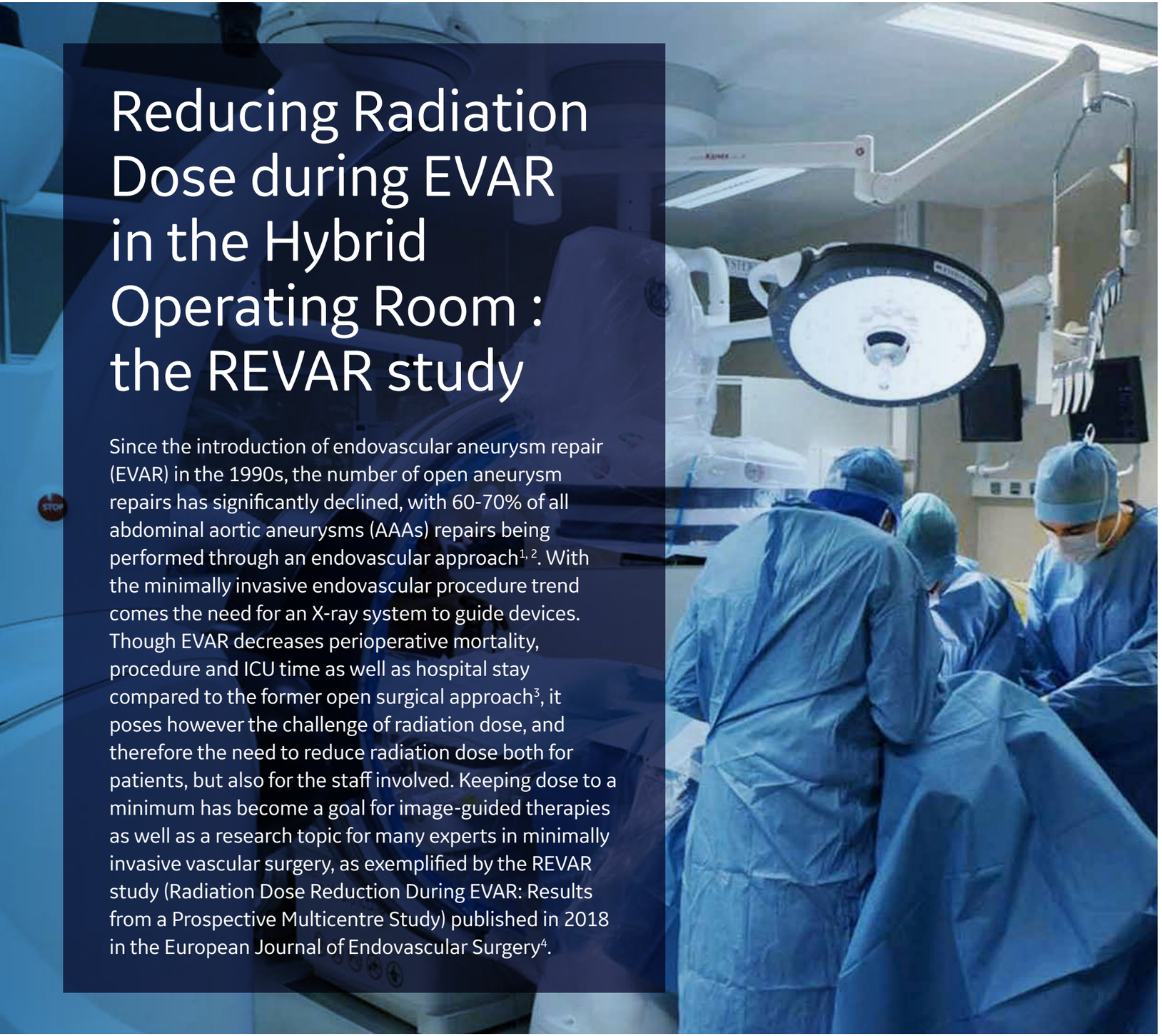


Fig. 6. CO2 DSA of the right foot after successful endovascular revascularization.



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 number of open aneurysm repairs has significantly declined, with 60-70% of all abdominal aortic aneurysms (AAAs) repairs being performed through an endovascular approach[1, 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 approach[3], 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 Surgery[4].

Snapshot on the REVAR study results

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[5] image fusion (GE Healthcare)[6]. 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.cm^2 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.cm^2 reported in a meta-analysis published in 2016 by de Ruiter et al[7]. 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.cm^2 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."

1 Levin DC et al. Endovascular repair vs open surgical repair of abdominal aortic aneurysms: comparative utilization trends from 2001 to 2006. J Am Coll Radiol. 2009;6:506–9. doi: 10.1016/j.jacr.2009.02.003.

2 Schwarze ML et al. Age-related trends in utilization and outcome of open and endovascular repair for abdominal aortic aneurysm in the United States, 2001–2006. J Vasc Surg. 2009;50:722–9. doi: 10.1016/j.jvs.2009.05.010.

3 OVER Trial : Lederle FA et al. Outcomes following endovascular vs open repair of abdominal aortic aneurysm: a randomized trial. JAMA 2009;302:1535–42.

4 Hertault et al. Radiation Dose Reduction During EVAR: Results from a Prospective Multicentre Study (The REVAR Study). Eur J Vasc Endovasc Surg (2018). https://doi.org/10.1016/jejvs.2018.05.001

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 previous version of EVAR ASSIST 2.

7 de Ruiter et al. Meta-analysis of cumulative radiation duration and dose during EVAR using mobile, fixed, or Fixed/3D fusion C-Arms. J Endovasc Ther (2016). https://doi.org/10.1177/1526602816668305

My golden rules to reduce radiation dose in the OR.

Interview with Stéphan Haulon
Head of Vascular & Aortic Surgery,
Marie Lannelongue Hospital, France

"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[8] (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[9]. 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[6], 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."

Using EVAR ASSIST 2 image fusion to position table and gantry without shooting X-ray

8 Applicable to Discovery IGS 730 and Discovery IGS 7 (IGS 730 configuration)

Tips & tricks to reduce dose in the hybrid OR.

Interview with Adrien Hertault
Vascular Surgeon,
CH Valenciennes, France

"In my mind, the main benefit of the hybrid room, which has been largely demonstrated in our experience but also in the literature, is clearly an improvement in terms of radioprotection. We have been able to observe a significant decrease in patient dose and operator dose in our daily practice[9].

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[10]."

Image fusion with EVAR ASSIST 2 to guide endograft deployment

9 Hertault A. et al. Impact of Hybrid Rooms with Image Fusion on Radiation Exposure during Endovascular Aortic Repair, Eur J Vasc Endovasc Surg 2014;48(4):382-90.

10 Hertault A. et al., Benefits of Completion 3D Angiography Associated with Contrast Enhanced Ultrasound to Assess Technical Success after EVAR, European Journal of Vascular and Endovascular Surgery (2015), http://dx.doi.org/10.1016/j.ejvs.2015.01.010.

Switching from mobile C-arms to the hybrid OR.

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

"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[6], 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."

The path towards low-dose procedures.

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

"In my hospital, I was using a hybrid OR from another vendor for my endovascular procedures. When the Discovery IGS 7 hybrid OR[6] 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!"

This article 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 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.

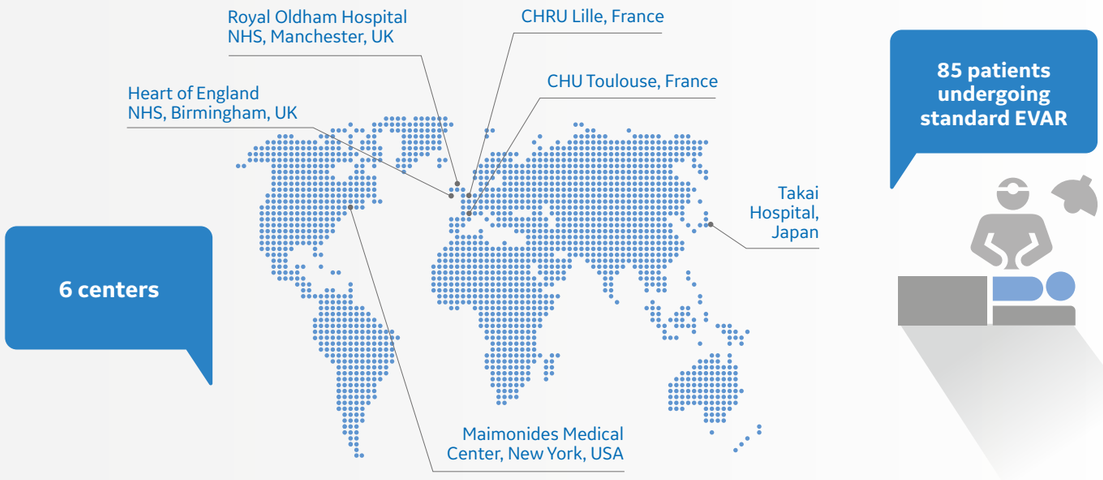
Stéphan Haulon, Adrien Hertault and Robert Rhee are paid consultants for GE Healthcare.

THE REVAR STUDY[1]

RADIATION DOSE REDUCTION DURING EVAR

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

PROSPECTIVE MULTICENTER STUDY[1]

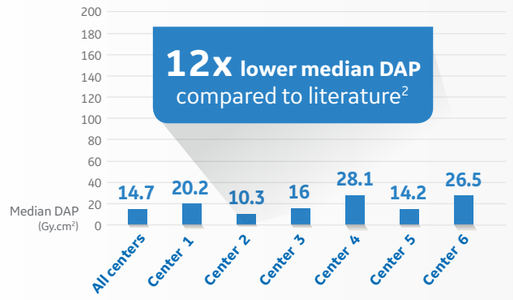


* EVAR ASSIST 2 solution includes FlightPlan for EVAR CT, EVARVision and requires AW workstation with Volume Viewer, Volume Viewer Innova, VesselIQ Xpress, Autobone Xpress. These applications are sold separately.

RESULTS

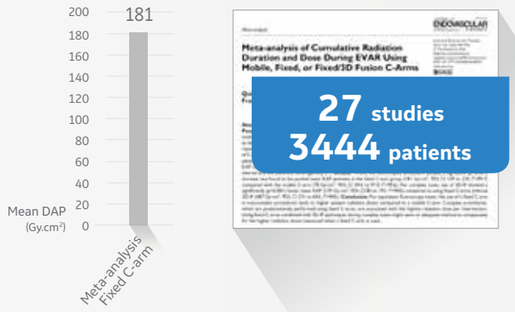
Median DAP of 14.7 Gy.cm²

Achieved across all 6 centers of the prospective multicentre observational study[1]



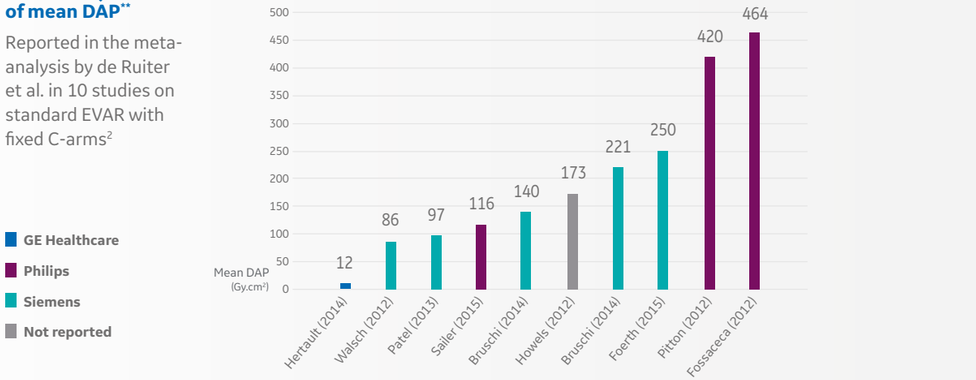
Mean DAP of 181 Gy.cm²

Reported in the meta-analysis by de Ruiter et al. in the non-complex EVAR subset with fixed C-arms[2]



Meta-analysis of mean DAP**

Reported in the meta-analysis by de Ruiter et al. in 10 studies on standard EVAR with fixed C-arms[2]



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.

** Data points were extracted from the meta-analysis by De Ruiter at 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. Hertault et al. Radiation Dose Reduction During EVAR: Results from a Prospective Multicentre Study (The REVAR Study). Eur J Vasc Endovasc Surg (2018). https://doi.org/10.1016/j ejvs.2018.05.001 | 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 previous version of EVAR ASSIST 2.
2. de Ruiter et al. Meta-analysis of cumulative radiation duration and dose during EVAR using mobile, fixed, or Fixed/3D fusion C-Arms. J Endovasc Ther (2016). https://doi.org/10.1177/1526602816668305

GE Healthcare

GE Healthcare provides medical technologies and services to help solve the challenges facing healthcare providers around the world. From medical imaging, software, patient monitoring and diagnostics, to biopharmaceutical manufacturing technologies, GE Healthcare solutions are designed to help healthcare professionals deliver better, more efficient and more effective outcomes for more patients.
GE Healthcare is betting big on digital; not just connecting hospital departments and physicians more effectively, but utilizing the masses of data from its equipment and the collaboration between hardware and software –"digital industrial" – to help clinicians make better care decisions. Sensors, software and smart data analytics are converging to enhance GE Healthcare's offerings not just in diagnostics, but also pathology, gene sequencing and even hospital asset tracking.

GE interventional imaging systems help you plan, guide and assess your wide range of interventional procedures precisely and efficiently. The new generation of ASSIST advanced applications allow you to extend your clinical capabilities and help simplify and streamline your procedural workflow.

Gehealthcare.com/ASSISTInterventional

The statements by GE's customers reported here are based 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.

Product may not be available in all countries and regions and cannot be placed on the market or put into service until it has been made to comply with all required regulatory authorizations. Refer to your sales representative for more information.

JB68548XE