ASSIST MAGAZINE

Innovative Interventional Treatments

Cardiovascular procedures

RADIAL APPROACH IN OUTPATIENT SERVICE

CHALLENGES IN THE CORONARY AND AORTIC FIELDS

INNOVATIVE CARDIO CENTER

Magazine #5 | European edition

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Dear reader,

From simple diagnostic exams to more complex procedures, our goal is to ASSIST you with equipment and clinical tools, providing simple workflows to ultimately help you improve your patients' outcomes.

This special edition dedicated to cardiovascular procedures will feature different departments across Europe, all deeply involved in both routine and complex clinical procedures in percutaneous coronary & aortic interventions.

You will thus find exclusive testimonials of several of our clients who have recently implemented innovative platforms in their daily practice: These expert teams will share their activities, challenges, and the solutions they've put in place.

We warmly thank our partners and wish you a pleasant read.

Jean-François Drouet and Erika Saillant

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ASSIST MAGAZINE

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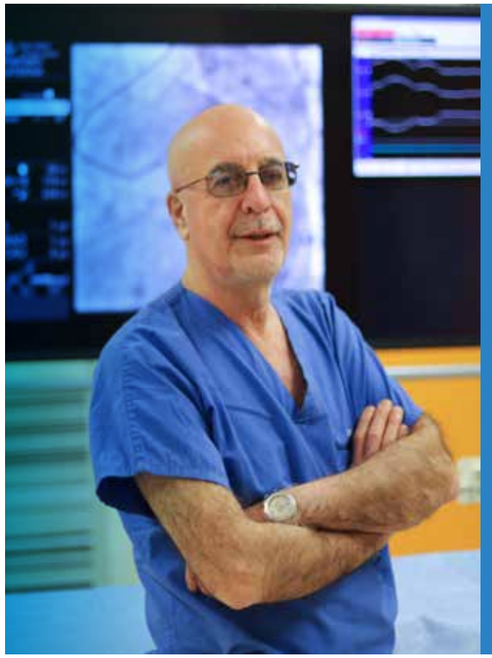
Innovative Cardio Center

Innovative & high standard cardiac department in south of Italy

@ Magna Graecia University, Catanzaro (Italy)

Focused on routine clinical efficiency, as well as being capable of innovation and research, the Cardiology Department at the Magna Graecia University in Catanzaro offers a comprehensive service to the region of Calabria in the south of Italy.
We met with Pr. Indolfi and his team and could feel an incredible energy and pride in their achievements.
The main achievement was to build this department from scratch in 2000 since there was no cardiology department nor even this hospital.
In the south of Italy, few industries are supporting local economic environment, and there was a real need to build this center to support the local population.

Innovative Cardio center



Legacy of a cardiology department created in 2000

Pr. Ciro Indolfi
Head of cardiac department

Legacy of a cardiology department created in 2000

Originally from Naples, Pr. Ciro Indolfi came by chance working in the region of Calabria : Indeed there was an open position of associate professor, which he took right after his studies at the University of California San Diego in the United States.

"I had 2 big mentors: John Ross Junior and Massimo Chiariello and they pushed me to accept this position, I was ready to make a lot of sacrifices."

Pr. Indolfi met at this time the hospital director Pr. Venuta and convinced him to purchase GE solutions, which he considered to be the best equipment. *"We have a long-standing cooperation with GE, our local representative Vincenzo is near to us and is always supporting, being the interface with our department and GE organization."*

The cathlabs activity was then getting started in 2000, knowing what it means in terms of organization to set up such an activity. One of the main lessons learnt from his years in the US is that the patient should always be at the center, and this was the driver for the organization in this department.

Later on, 3 additional cathlabs were opened, the CCU, and the EPlab.

Project leaders in the different specialties have been assigned and Pr. Indolfi continued the coordination of the team developing this activity further, including the training of physicians.

In 2008 the Cardiology Department was a pioneer in this region in the development of transcatheter aortic valve implantation (TAVI), a minimally invasive option for patients too diseased to undergo open heart surgery. "*For me, the main milestone in the last 15 years is TAVI. I was skeptical that this would be feasible, at the time I was myself implanting the first coronary stents.*"

Pr. Alain Cribier came to Catanzaro to assist the first cases, and since then they have worked as a Heart Team, before the term officially existed. Pr. Indolfi strongly believes that TAVI will be the future gold standard technique, since it is a very established and successful therapeutically strategy for aortic stenosis.

"Interventional cardiology is such an exciting field, there can be surprises beyond imagination. This is what we've seen in the past! I would have never thought that TAVI would be feasible as it is today."

The team is now implanting MitraClip® (Abbott) devices and performing PFO and ASD closures. PTCA on STEMI, NSTEMI and CAD patients are routinely addressed.

Pr. Indolfi has indeed been lucky enough to witness of all these evolutions, starting with the femoral approach while now the center has moved to 100% radial approach for PCI.

High standard of care

The Cardiology Department at the Magna Graecia University offers comprehensive services provided by a highly skilled medical team. *"Our Cardiology Department's reputation is impeccable. High standards of care is the cornerstone of our success"* comments Pr. Indolfi.

The Cardiology Department is a 40-bed facility. Of those, 12 beds are dedicated to the coronary care unit (CCU) on the first floor. The CCU was built to meet the increasingly complex needs of patients from all over the region of Calabria.

General Cardiology, Cardiac Diagnostic Investigations, Cath Lab, Arrhythmia Management, Pacemaker Clinic, Paediatric Echolab, and CCU are all part of the cardiology department activities, and the main

Innovative Cardio center

axis of development of this hospital in cardiology is certainly the Cath Lab.

"My physicians have a record of nationally ranked excellence. They are known for their research and innovation that advances heart care, ensuring that the latest treatment options are available for our patients. Our physicians specialize in treating a wide range of heart and coronary conditions, and they have extensive experience diagnosing and treating advanced and complex cases."

In recent years, the percentage of patients with multivessel disease and multiple complex stenosis have significantly increased. Mostly, the complexity of these patients is characterized not only by their comorbidities but also by multivessel disease, bifurcation disease, left main disease, or stenoses of calcified or tortuous vessels, degenerated saphenous vein graft lesions, and thrombotic lesions. These specific lesion types are typically associated with lower rates of procedural success and higher rates of recurrence or major adverse cardiac events.

Equipped with the latest generation of IGS system

Pr. Indolfi believes that one of the more significant advancements for interventional X-ray in the past few years has been an increased focus on core and supporting technologies to provide high-quality, high-resolution images without a corresponding increase in radiation dose.

"I really wanted to keep the ergonomic design of the IGS, which I find helpful as it is very intuitive and really easy to handle in daily practice."

The team routinely exploits the imaging capabilities with PCI ASSIST[1]

StentViz is providing helpful information in many use cases, helping to assess stent deployment, position stents more precisely with respect to existing stents, accurately evaluate stent overlap in cases, long lesions or bifurcation stenting, and finally increasing clinical confidence with immediate and routine control of stent deployment.

"This is saving time and money by choosing the right stenting strategy to avoid additional procedures and patient re-treatment. My level of confidence about StentViz is high and it is clearly easy, cheap, and fast; it is helping me to clearly visualize stent borders and details from images in which the stent is barely visible and is providing critical clinical information" adds Pr. Indolfi. As a complement, the team uses coronary intracardiac imaging for diagnostic purposes to assess plaque characteristics, and after stent deployment also when required.

Pr. De Rosa, working closely with Pr. Indolfi, believes that the intra procedural tools should always be very simple and provide useful information such as PCI ASSIST (including StentViz and Stentvesselviz). *"In case of stent restenosis, we want to differentiate if the stent is hypo expanded or understand what is behind the restenosis. When there is a restenosis, there is a complex interplay between the flow and the angiogram and the resistance from the stent itself, and usually it magnifies"* says Pr. De Rosa. They also routinely use PCI ASSIST[1] during stent release and optimization.

A center oriented towards Research and development

Pr. Salvatore De Rosa
Head of the research activity

Research is an important side of the activity here, divided in 3 main areas: Clinical research, basic research in laboratory dedicated to cardiovascular science, and research and development applied to cardiology applications. Below three examples among the rich scope of projects the team is leading:

Radial complication prevention

The main access route used in the cathlabs in the Cardiology Department at the Magna Graecia University in Catanzaro is the radial artery. *"An issue that we're not enough aware of is post-procedural radial artery occlusion, which can range from to 6 % to 20% of patients depending on the studies"*, explains Pr. De Rosa.

Since it is mostly asymptomatic, the patient is not aware that the complication arises. When it happens, only one artery remains. The direct consequence if the remaining artery becomes occluded, the patient can lose his arm. Furthermore, if another PCI needs to be performed, the radial artery can't be reused. And for fragile patients, in case of kidney injury, no fistula can be performed.

It can simply be checked using bidimensional and doppler echo, which nevertheless requires an operator ; which in the reality is not done systematically.

"In our preliminary reference[2], we were able to identify 8% of totally asymptomatic radial artery occlusions when we check 24 to 74 hours after the PCI has been performed. This can occur despite the occlusive bandage which is applied after the procedure, and the event can indeed happen later", comments Pr. De Rosa.

One of the requirements of the study was to avoid patients having to return to the hospital, and this is the reason why we perform this on the patient's discharge.

We have about 2500 patients a year and we will involve other centers since we wish to include the pre-care of the patient, before he comes here and also the rehabilitation of the patient. This will be a regional approach.

Coronary robotization and beyond

A very specific initiative is to move toward robotization in the cathlab: the Catanzaro team has designed a robotic system to perform transcatheter angioplasty, in partnership with the university of Calabria in Cozensa, and Pr. Dianele, professor in mechatronics.

It is based on a very simple system, including both a measuring unit, called Master, used by the physician to lead the operations, and an actuation device, called Slave, located near the patient, that actively reproduces the movements commanded by the operator at the passive Master unit. Both systems require a small additional element that makes direct contact with guides and catheters and needs therefore to be sterile on the Slave unit. The system has been designed with the possibility of adding an alternative Master station equipped with two joysticks and a series of knobs and can drive up to three different Slaves, one dedicated to the guiding catheter, the second and third to balloon catheters and relative guide wires, that may be used also in coupled mode. Two patents applications have already been submitted on this topic.

"My experience with the first case was extremely positive, since it allowed the separation of the physician from the patient, ensuring the physician could keep the patient under continuous radiographic control, without being affected by ionizing radiation, while operating in the way in which he has been already trained." Comments Pr. Indolfi.

The team is not far from their final experimentation and starting pre-clinical trials. *"We believe that this system will indeed be suitable not only for angioplasty, but for a number of other procedures thanks to the ability to drive the initial catheter in situations that can be much more complex than simply reaching the coronaries."* says Pr. Indolfi. The system is potentially not very expensive, even the investment for its development was substantial.

Applications in patient workflow

Patient workflow is definitely a field that the team of Catanzaro University hospital is looking at streamlining for the benefit of the patient's comfort.

A patient tracking system based on a bracelet tagged to each patient has been developed. The patient journey can then be analyzed, since the patient is automatically scanned by panels located in the different parts of the department including at the entrance of the waiting area and in the cathlabs. "We use this to analyze the efficiency of our patient pathway and propose improvements", comments Pr. De Rosa.

"Our next project relates to heart failure patients to understand the detailed picture of this patient's management. We will use process mining which is a novel way of analyzing retrospectively data connected to patients and the process itself", concludes Pr. De Rosa.

Linking clinical routine and research in electrophysiology

Pr. Antonio Curcio
Head of cardiac electrophysiology activity

The main fields of clinical activity in the EPlab of Catanzaro university are AF ablation using cryoballoon, EP studies, RF ablation of supra ventricular and ventricular tachyarrhythmias, and cardiac rhythm management through device implantation, beyond simply intravascular devices and subcutaneous cardiac defibrillators.

The daily activity of the outpatient clinic is split into inherited congenital disease followed with noninvasive assessment in an ambulatory setting in the next building, and the activity of the EP lab described previously.

At the same time, critical patients in CCU sometimes with cardiogenic shock due to arrhythmia or persistent tachyarrhythmia, are stabilized to further be treated in the EP lab.

Looking specifically at the outpatient activity, the site is the first department in the country for the evaluation of sub-clinical AF for patients implanted with devices for cardiac rhythm.

Pr. Curcio comments two ongoing clinical studies, one from the US (ARTISIA[3]) and one from Europe (NOAC[4]):
"Both studies randomize patients with sub-clinical AF and sometimes AF but the patient is not aware that he has this arrythmia. The main question is whether or not to treat these patients."
The center belongs to the five European centers involved in the NOAC trial that are randomizing patients between placebo and anticoagulants, which is currently the recommended guideline.

Cryo and Radiofrequency ablation

Both techniques are used here. Cryoablation is used as a first approach. If an ablation has to be redone, the team prefers then carto-mapping ablation to visualize the scared tissues within the left atrium and pulmonary veins.

Pr. Curcio comments the recent Fire and Ice Clinical Trial[5], published in 2016 on The New England Journal of Medicine, comparing radiofrequency current and cryoballoon catheter ablation for the treatment of patients with drug/refractory symptomatic paroxysmal atrial fibrillation: *"It showed that the two procedures are basically similar, but the patients treated with cryoenergy required less antiarrhythmic drug therapy as compared to radiofrequency ablation patients. This study demonstrated that, as long as the cardiac electrophysiologist can see clearly the anatomy under radiation exposure, there are several clinical benefits for the patients undergoing cryo-ablation."*

In both ablation technics, electrophysioly signals remains key: *"The signal is now of very good quality. This allows us to reach the right position and place the electrode exactly where you want to study or ablate"*, comments Pr. Curcio.

On his current EP lab setting, Pr. Curcio develops: CardioLab/Mac-Lab and Carto®3* Biosense Webster[6] are integrated in this cathlab. *"When the 3D mapping engineers support us, this really enhances the communication with the physician, we then see and speak about the same thing, certainly we are more efficient. It makes us more comfortable"*. And finally, CARTOUNIVU™ Module* is available in our practice too, we use it mainly in AF ablation to reduce X-rays."

Advice to next gen

Pr. Indolfi was lucky enough to find great mentors at an early stage. He greatly recommends research fellows to choose a good mentor. *"Research fellows are not sufficiently aware that this represents a real opportunity, or do not dare ask. This is critical to get some perspective, and in this sense mentorship is of paramount importance"*.

Pr. Indolfi enjoys mentoring colleagues, supporting trainees and research fellows to initiate careers in interventional cardiology by encouraging them to perform practical training and clinical research. He also organizes weekly meetings and web-seminars.

He sees an evolution in physicians' profiles: *"I see them taking less risks and aiming to strike a balance between their private and professional lives. They want things to move faster. That's a significant change"*.

1. PCI ASSIST refers to features of Innova IGS 5, Innova IGS 6, Discovery IGS 7 and Discovery IGS 7 OR. PCI ASSIST refers to features of Interventional X-ray system: StentViz and StentVesselViz.
2. Indolfi C, Passafaro F, Mongiardo A, Spaccarotella C, Torella D, Sorrentino S, Polimeni A, Emanuele V, Curcio A, De Rosa S. HYPERLINK "http://www.ncbi.nlm.nih.gov/pubmed/25761194" Delayed sudden radial artery rupture after left transradial coronary catheterization: a case report. Medicine (Baltimore). 2015 Mar;94(10):e634. doi: 10.1097/MD.0000000000000634.
   De Rosa S, Passafaro F, Polimeni A, Sorrentino S, Indolfi C. A novel quick and easy test for Radial Artery Occlusion with the Laser Doppler Scan. JACC Cardiovasc Interv. 2014;7(8):e89-90. doi: 10.1016/j.jcin.2013.11.028.
   De Rosa S, Torella D, Caiazzo G, Giampa S, Indolfi C. Left radial access for percutaneous coronary procedures: from neglected to performer? A meta-analysis of 14 studies including 7603 procedures. Int J Cardiol. 2014 Jan 15;171(1):66-72.
3. Indolfi C, Passafaro F, Sorrentino S, Spaccarotella C, Mongiardo A, Torella D, Polimeni A, Sabatino J, Curcio A, De Rosa S. HYPERLINK "https://www.ncbi.nlm.nih.gov/pubmed/30279350" Hand Laser Perfusion Imaging to Assess Radial Artery Patency: A Pilot Study. J Clin Med. 2018 Oct 2;7(10). pii: E319. doi: 10.3390/jcm7100319.
4. New Oral Anticoagulants (NOAC) in Stroke Patients (NOACISP), NCT03826927.
5. Cryoballoon or Radiofrequency Ablation for Paroxysmal Atrial Fibrillation, N Engl J Med 2016; 374:2235-2245
6. CARTO is a trademark of Biosense Webster, Inc.

*Product availability may differ in each country. Please contact Biosense Webster to find out further information.

The statements by GE's 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.

Reduction of patient radiation dose with Innova IGS 5* and PCI ASSIST during a Cardiac CTO procedure

Courtesy of Dr. V. Decalf, Pontoise Hospital Center (France)

Clinical Challenge

CTO procedures involve two parameters that must be taken into account: radiation exposure and volume of contrast media used.
The complexity of traversing the lesion, the use of dual-approach techniques increase the X-Ray exposure and contrast media volume.

Solution

The procedure was performed using the Innova IGS 5 (configuration 520) system and the PCI ASSIST[1] Solution. PCI ASSIST helps improve visibility in larger patients without increasing the radiation dose. StentViz helps enhance stent visibility and visualization to assess stent deployment. Several features helped during this procedure: Firstly, InnovaSense[2], which automatically reduces the patient/detector distance to optimize overall procedure dose. Secondly, DoseMap[3], which enables to visualise the estimated local cumulative dose during the exam dose with a map. Finally, a low-dose protocol, collimation and a frame rate of 7.5 fps were used throughout this procedure despite the patient's high BMI.

Clinical case

A 58-year-old man with a BMI of 31.8 (180 cm - 103 kg) suffered from stable angina with myocardial ischemia authenticated by scintigraphy. The coronary angiogram shows a multivessel complex coronary artery disease with double CTO (circumflex and RCA), LAD and obtuse marginal significant stenosis. The SYNTAX score (Syntax Score Working Group)[4] was 28.5.

After discussion in medico-surgical staff, a complete percutaneous revascularization strategy was planned. Firstly, the patient had a successful RCA CTO PCI. Then, this circumflex CTO PCI procedure. An additional LAD and obtuse marginal PCI will be scheduled after the circumflex CTO PCI.

Procedure

ANGIO

Dynamic images (Fig. 1) showed a long (over 20 mm in length) mid circumflex CTO including the origin of the marginal branch (bifurcation lesion). The proximal cap is clear but the entry shape is blunt. There is no calcification. The bending isn't superior to 45°. It's a first attempt. We calculated that the JTO Score was 2 points that means a difficult CTO.
There is only homolateral epicardial collaterals from the LAD (Rentrop classification, grade 2), none from RCA. The quality of the distal vessel is good with a 3 mm diameter at this level.
So we planned an antegrade approach with wire escalation.

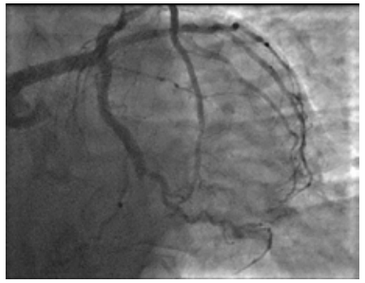


Fig. 1 Mid Circumflex CTO, Dynamic Acquisition

PROCEDURE

The procedure was performed under local anesthesia with a right radial approach and 6 french sheet. The angulation used during the procedure was LAO11°, CAU38° (Fig. 2).

- A guiding catheter was positioned in the left main coronary artery.
- Then, a coronary micro-guide catheter was used to support the guidewire during crossing attempts, to enhance the penetrating capacity of the guidewire, and to allow for easy guidewire reshaping and exchanges.
- After two attempts with two different guidewires (a polymer-jacketed guidewire and a stiff guidewire), increasing stiffness, a last one crossed the lesion and was positioned into the distal true lumen of the circumflex (Fig. 3)
- Then the microcatheter was advanced over the crossing guidewire which was exchanged for a floppy guidewire. Another guidewire was positioned distal to the marginal branch (Fig. 4).
- A predilatation of the circumflex lesion was achieved with two balloons (1.5 x 10 mm and 2.5 x 20 mm).
- A 2.75 x 33 mm DES was implanted in the mid circumflex (Fig. 5).
- A POT (Proximal Optimization Technique) is performed to optimize the deployment of the proximal part of the DES with a 3.50 x 12 mm balloon catheter.
- A StentViz acquisition was performed to assess the right position of the balloon (Fig. 6).
- After the guidewires exchange, a "kissing balloon" was realized with an 2.75 x 12 mm balloon catheter positioned at the marginal branch ostium and a 3.50 x 12 mm balloon catheter positioned in the mid circumflex (Fig. 7).

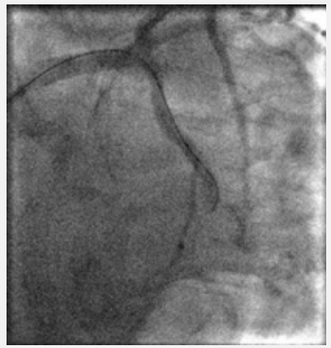


Fig. 2 Mid Circumflex CTO, Fluoroscopy - LAO 11°CAU38°

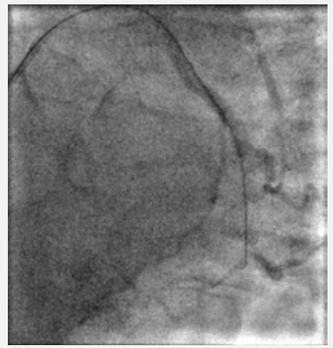


Fig. 3 CTO guidewire crossed the lesion and positioned into the distal true lumen of the circumflex

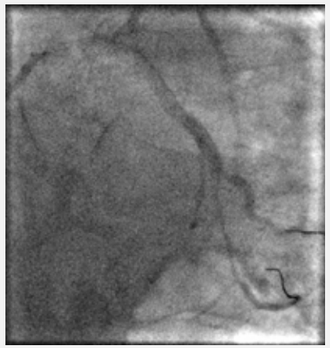


Fig. 4 Guidewires positioned distal to the circumflex and the marginal branch

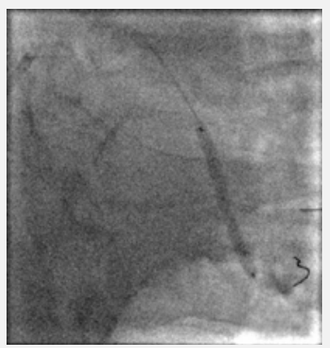


Fig. 5 DES deployment

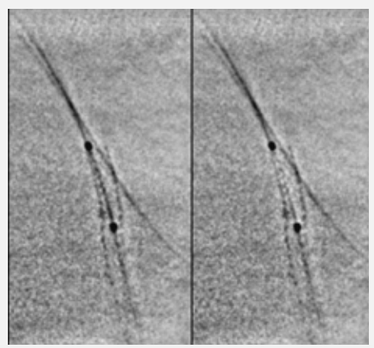


Fig. 6 StentViz

DoseMap

Result

The circumflex has been successfully recanalized (Fig.8). The circumflex/marginal bifurcation was treated with the provisional T stenting technique, one long DES in the main circumflex branch and a final “kissing-balloon” procedure to open the strut for the side marginal branch.

Conclusion

« InnovaSense allows patient contouring at the optimal distance. We use it routinely, it reduces the irradiation of the patient. Now we don’t need to think of moving the detector at optimal distance of the patient, it is done automatically. There is a clear dose reduction in routine activity and a preserved or even optimized image quality compared with previous generation systems. The image quality allows us to visualize anatomical details, unlike other imaging brands, that are too smooth and less contrasted. »

Total DAP (Gy.cm²)	40.03
Total AK (mGy)	1233
Fluoro Time (min)	17:66
Contrast media (ml)	154

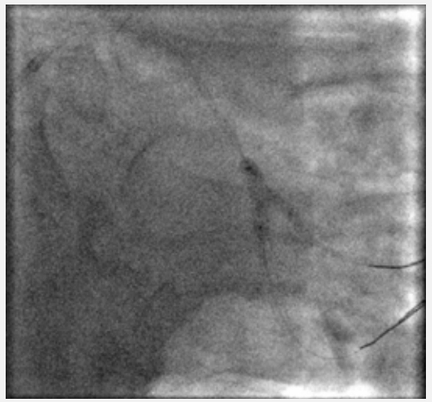


Fig. 7 Kissing balloon, Fluoroscopy

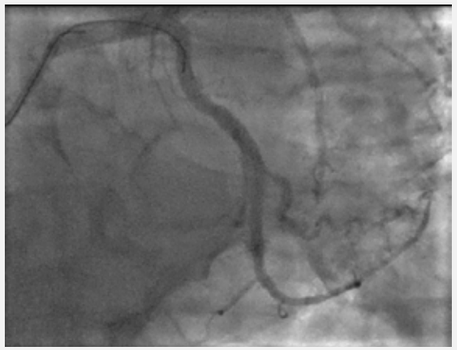


Fig. 8 Final result.

1. PCI ASSIST refers to PCI ASSIST refers to features of Innova IGS 5, Innova IGS 6, Discovery IGS 7 an1. PCI ASSIST refers to PCI ASSIST refers to features of Innova IGS 5, Innova IGS 6, Discovery IGS 7 and Discovery IGS 7 OR.
   PCI ASSIST refers to features of Interventional X-ray system: StentViz and StentVesselViz.
2. Applicable to Innova IGS 5 (IGS 520 and IGS 530 configurations), Innova IGS 6 and Discovery IGS 7 (IGS 730 configuration).
3. Applicable to Innova IGS 5, Innova IGS 6 and Discovery IGS 7.

The statements by GE’s 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.

4. The SYNTAX Score is a tool developed in connection with the SYNTAX Trial, a trial comparing PCI and Cardiac Surgery in complex, high-risk LM and/or 3VD patients. It is important to note that the safety and effectiveness of drug-eluting stents have not been established in these high risk patients, and physicians are strongly encouraged to review the indications, contraindications, warnings and instructions included in the products’ Directions for Use.

The SYNTAX Score and related materials are not intended to provide medical advice or guidance as to appropriate treatment strategies for individual patients. Risks and benefits should be carefully considered for each patient taking into account all available data and treatment options and physicians and other healthcare providers should always exercise their own clinical judgment for any given situation. In cases where SYNTAX Score and related materials are relevant to the diagnosis, prevention or treatment of medical conditions which can also be diagnosed, prevented or treated by any products, physicians and other healthcare providers must take care to always follow individual product instructions for use in order to ensure safe use and that the products intended performance(s) is/are achieved. Physicians and other healthcare providers are therefore cautioned that such tools are not intended to supersede individual product instructions for use in any way.

The Syntax Score and related materials were developed under the direction of the SYNTAX Steering Committee, and was made possible by support from Boston Scientific Corporation and Cardialysis BV.

*IGS 5 (configuration 520)

Case report Coronary Interventions

Radial approach in a new outpatient coronary center in Switzerland

@ Centre de Cardiologie du Valais, Switzerland

The canton of Valais is one of the 26 cantons of Switzerland, located in the southwestern part of the country, around the Rhône valley from its headwaters to Lake Geneva, separating the Pennine Alps from the Bernese Alps. The canton is both one of the driest regions of Switzerland in its central Rhône valley and among the wettest, having large amounts of snow and rain up on the highest peaks found in Switzerland.

It is in the heart of "*Le Valais*" that a team of experienced and passionate healthcare professionals opened an outpatient service for invasive cardiology, the "*Centre de Cardiologie du Valais*."

An activity centered on the patient journey:

The team of physicians in the Cardiocenter is made up of three interventional cardiologists and one electrophysiologist.

All four have international experience and have been either Head of Clinic in a university hospital or head of a regional public institution in Switzerland.

This team has been performing invasive cardiology in an outpatient service within a private institution in Sion for ten years now. The team recently opened this new independent service, which aims to place the patient journey at the heart of the process.

Four main pillars drive the decisions and activities in this new center:

Quality and professionalism, patient safety, patient comfort, and, last but not least, personalized care.

The team's objective is to support the patient from the first diagnostic exam in outpatient care, through to the follow-up of post-invasive treatment once this takes place.

The center is split in two parts: one dedicated to non-invasive exams with private rooms for cardiologists who run their private consultations and one dedicated to invasive procedures with an activity that requires more personal investment to maintain the patient's safety with a team of experienced professionals either in intensive or continuous care.

The team of physicians and nurses worked as a team to physically set-up the center, analyzing patient flow with the help of an architect, decide on the acquisition of the heavy equipment, including the Innova IGS 5 (configuration 520) and Mac-Lab, and organize all device sourcing, from stents to sterile drapes.

"The nurse's role is key", comments P. Hildbrand: The patient has a scheduled arrival in the morning, when the nurse personally welcomes and installs the patient. The nurse then accompanies the patient to the cathlab and assists the physicians there. The nurse then returns with the patient, who is able to stand right after the procedure, to his bed.

The nurse is then in charge of the continuous care of the patient, until he is discharged to return home with all the information for the follow-up.

This has three main benefits: Firstly, the patient always has a reference nurse to speak with and does not need to repeat information many times to different people. Secondly, the nurse has optimized interaction and follow-up with the patient. And, last but not least, there is less need to transfer information between nurses.

Focus on radial access

Almost all coronary interventions are made using radial access at the Centre de Cardiologie du Valais.

"Ten years ago, we knew that performing coronary interventions with a radial access could drastically reduce risks and complications. This technique was developed mainly in France at the time.

"We were able to develop radial approach in 2006/2007. I was myself trained in France in ICPS Massy and saw that thanks to this technique, we could reduce complications" explains Dr. Christophe Imsand.

The cardiology community in our region was generally reluctant to use the radial procedure, and we were told it would increase risks compared to femoral access, including subclavian artery dissection, though it was mainly a question of pushing senior colleagues beyond their comfort zone.

"The method is not really more difficult, even though the learning curve is a little longer. Finally, we lowered the complication rate compared to femoral access: The ongoing complications occurred at the early stage in the learning curve for radial access and we were still performing femoral-access procedures in parallel. So we decided to move to radial access only."

Over these ten years, the complication rates were carefully analyzed and compared with femoral access, and they were indeed found to be much lower. "*Not because we are any better than other physicians, it is more a question of the techniques and devices*" comments P. Hildbrand.

"*The only complications we encountered, which were nevertheless significant, were a few cases of limited strokes (TIAs). So we performed a careful analysis to understand the root causes, and how to reduce these complications*", adds C. Imsand. "*We realized that strokes appeared mainly when we were aggressively rotating guiding catheters to find the coronary artery. We now very quickly change catheters when we can't easily find the coronaries, and do not keep trying with the same one. This has improved results almost achieving no strokes.*

Out of 1000 patients a year, we might have one transfer of a stabilized patient to the hospital, who is then taken into intensive care.

We keep the patients six to eight hours. The studies have shown that complications occur within 6 hours of angioplasty. During the intervention, we can quickly identify the patients that already show ECG modifications, experience pain.

It is rare that a patient who seemed fine during the intervention develops complications later on."
P. Hildbrand continues, "*We also need to be fair. There might be a patient selection that is not initiated by our services. We accept everyone, and it is more the primary-care physicians that direct the patients to a university hospital or to our center.*

While we were far from this 10 years ago, our district in Switzerland is now the 3rd in the country to require all centers to perform these interventions in an outpatient setting." explains C. Imsand. "*It is indeed a trend now in Switzerland for all pathology treatments, not only coronary interventions, to be dealt with in an outpatient setting.*"

No sedation in most cases

Commentary from Dr. Kathrin Flückiger

"Since we perform this outpatient activity in a dedicated center, it is important to have anesthetist capabilities available. For the EP activity, drug delivery is required to decrease pain. A continuous monitoring of the patient is key.

We perform MAC (Monitor Anesthesia Care), and do not use a laryngeal mask by default.

In the coronary activity, we are present only in case complications arise. This is mainly a safety issue.

There is no sedation, and as soon as the patient has finished the exam, he can stand and is directly mobilized. A few patients may receive some sedation, but only if they experience anxiety, which is the case for less than 5% of the patients. In this case, they stay in bed a little longer."

A high tech platform equipped with Innova IGS 5 (configuration 520)

Interview with Dr. Patrick Hildbrand and Dr. Christophe Imsand

What is your cathlab equipped with?

Dr. P. Hildbrand: *"Our cathlab is equipped with our Innova IGS 5 (configuration 520), recently installed, with which we are very satisfied. We have Optical Computed Tomography and FFR too of course for decision support. We have equipment dedicated to electrophysiology in the same lab.*

In my opinion, we will obtain much more OCT (Optical Computed Tomography) information in the next 5 years.

We do a kind of artery biopsy with OCT and we do not know exactly what to do with this information.

For now, what we know well is how to utilize the stent, ensuring there is good apposition, good expansion, no edge-dissection."

Dr. Christophe Imsand

There is a great deal of information that OCT could provide us with, such as the presence of a fibrotic or lipidous plaque and if so to what extent.

Should we put the patient on statins or not? I think that based on all this information, we will be able to propose much more personalized care and treatment."

How did you adapt?

Dr. P. Hildbrand: *"We've been using many other brands over the past few years. This Innova IGS 5 (configuration 520) is very easy to get trained on. After just two patients we were comfortable to work on it."*

Dr. C. Imsand: *"The x-ray images are of great quality, we see the difference in terms of contrast, it's been improved. We also have patients with a high BMI with no issues.*

I personally found it very simple. I know GE from the sonography side, and always found it to be robust, fast, and easy to handle, so I was not disappointed with our Innova IGS 5 (configuration 520)!

We adapted fast to this new installation. Thanks to stent enhancement tools, when we have a restenosis we can see if there is proliferation around the stent.

We can combine this with OCT that shows over the length of the stent that the diameter has decreased by a certain percentage. We know then that we need to post-dilate. We then use StentViz to understand where we need to place the balloon to be right at the stent border.

We foresee the more extensive use of PCI ASSIST[1] and to check our final result with OCT."

Dr. P. Hildbrand: *"After safety, the speed of the procedure is also a key point, I find this also very convenient to take the best image of the diagnostic and recall the angle during the procedure."*

Dr. C. Imsand: *"The more autonomy we have, the better it is for the speed of the procedure. We can perform pressure zeroing from table side. Here we have an excellent staff who is following the procedure. Though this is a step where we do not need to wait."*

What do you think is of fundamental importance in a cathlab, what makes this organization successful?

Dr. C. Imsand : *"I think that experience is key. The more cases you've handled, the more errors you've made, and the more you bring safety to the procedures.*

The fact that there is always two

experienced physicians during a procedure allows us to discuss the best decisions, including clinical ones.

Our nurses are also very experienced and have all worked in cardiology before. It has now been 10 years that we have all been working together. I fully trust them, they take initiatives. To me, this is critical to ensuring safe and smooth operations.

The technology should then support us by providing reliable systems. I think we will increase the quality and speed with this Innova IGS 5 (configuration 520)"

Are there already areas of development for your center?

P. hildbrand : *"It depends on the medical advances in themselves.*

With the Innova IGS 5 (configuration 520), we are fully equipped to do percutaneous valves. It is true that it is not yet the right time to do this in an outpatient setting, but we are convinced that in five to ten years from now it will be possible.

I have recently spent some time at the University hospital in Bern. Enormous progress has been made over the last 5 years in terms of devices, complication rates have drastically decreased, and whilst previously I thought that TAVI would be for the next generation of young cardiologists, I am now convinced that we could provide a patient service in the near future. This would be the next step.

In EP, we observe technical improvements such as cryoablation for AF ablation treatment that we can also perform in an outpatient setting right now. This has only become possible since the cryo technique has been developed and is less aggressive than radiofrequency with less complications."

Dr. Patrick Hildbrand

Dr. P. Hildbrand: *"Our cathlab is equipped with our Innova IGS 5 (configuration 520), just installed, with which we are very satisfied. We have Optical Computed Tomography and FFR too of course for decision support. We have equipment dedicated to electrophysiology in the same lab."*

The role of the nurse is key.

Interview with Alexandra Deluca

Please let us know more about your role in the center:

"In our organization, one nurse is dedicated to the control room for a full day, about once a month. The other nurses take care of the patients in the outpatient setting, which means from welcoming the patient to discharge, including care during the angioplasty and assisting the doctors in the cathlab.

When I am working on the intervention side of the cathlab. I'm in charge of installing the patient on the table, monitoring and covering him, preparing the sterile material needed to have the room ready for the physicians to start the procedure. Then I put on a lead apron and assist the physician throughout the procedure, injecting drugs to the patient, providing any additional devices that may be needed, and taking care of the patient until the procedure is completed.

I remain in charge until the patient is discharged, and make sure he has all information and safety recommendations when he leaves the center.

We find that this is reassuring for the patient. We keep the need to transmit information between nurses to a minimum.

We see the patient when he arrives, in his bed, during and after the intervention. We know the patient much better and can assess his reaction in a much more effective way.

When I am in the cathlab's control room, my role consists of taking care of the IT side, tracing the intervention, medication, devices, start and end times of the procedure, hemodynamics, lesions that are diagnosed and treated. And we issue a comprehensive report at the end of the procedure.

I observe that the overall administrative burden has increased over the last few years. I aim to keep as much time as possible to care for our patients, we need to go through all for reasons of traceability but I find the overall balance to be acceptable.

Spending that day in the control room allows me to take a breather and recharge to be fully available for the patients the rest of the time.

Lastly, I'm in charge of making sure the room is cleaned and disinfected and provides an optimal sanitary setting for the next patient.

The circuit here is as short as possible, and from my point of view this is essentially centered on the patient."

What is your experience in cardiology?

"The whole team comes from a hospital cardiology department. They are used to patients with serious heart conditions.

I am the only one with a different background. I was trained as a nurse in the German-speaking part of Switzerland. Then I wanted to get trained in emergency medicine, so I took 2 additional training years post

diploma. This is the equivalent of intensive care and anesthesia, but without the respiratory aspects (intubation).

I then came back to Valais. I worked in dialysis & emergency at the Sierre hospital. After that, I came to the private clinic in Sion in the cardiology department, where I learned about the outpatient and cathlab side.

I enjoyed this very much, since there is a technical side with emergency, and also what I like is taking care of the patient, reassuring, explaining, de-stressing the patient. We intervene on the heart, so there is probably also an emotional aspect to it.

I enjoy working both on clinical aspects and patient care. There is also an immediate reaction when you inject a drug.

I have now been working in cathlabs for 8 years. I also speak both German and French, which is quite useful since some days we speak only in German to adapt to our patients.

I can see that the team is always seeking to improve and find how we could make things simpler whilst at the same time improving the quality of care."

As part of this team, you were in charge of organizing this entire new set-up. Could you please tell us more?

"It was both exciting and nerve-racking as we changed from a classic hospital organization, where we have a pharmacy and backups, to a fully private activity.

We had to organize everything, order all components to start the activity. Finally, it took up a lot of space.
As I like emergencies, new things are also stimulating.

We have a certain comfort zone based on our experience and are now adapting to this new environment. It is by overcoming challenges that we can move forward, and this why we learn and why I enjoy this job. I learned the technical and GE room aspects quickly. When I look at the Mac-Lab, the pressure pullback for example is very simple to handle.

The statements by GE's 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.
1. PCI refers to features of Interventional X-ray system: StentViz and StentVesselViz

Alexandra Deluca:
"The team is always seeking to improve and find how we could make things simpler whilst at the same time improving the quality of care"

JB66633XX

Heart Care

Dedicated to Interventional Cardiology

A comprehensive set of solutions for the cardiac care pathway. From diagnostic to PCI to structural heart interventions, GE's portfolio provides a comprehensive set of solutions to the Heart Teams, enabling them to make the appropriate decisions for the optimal patient care pathway, in an accurate and timely manner, at very low dose.

Treatment of Abdominal aortic aneurysm (AAA) with Endovascular stent grafts using EVAR ASSIST 2[1]

Courtesy of Dr. Sauguet, Clinique Pasteur, Toulouse (France)

Case Background

A 66-year-old patient (BMI 25, 1.90 m for 91 kg) arrived at the Clinic for abdominal aortic aneurysm management. He is a dyslipidemic patient and an active smoker.

Presentation

A CT scan showed a 60 mm intra renal aortic aneurysm diameter. The decision was to implant bifurcated aortic prosthesis: 34 mm aortic stage and 20 mm primitive iliac.

Solution Used

The procedure was guided using image fusion (CT and X-Ray) with EVAR ASSIST solution and Innova IGS 5 (configuration 530).

Intervention

The procedure was performed under general anesthesia by the transcutaneous route with a bilateral femoral approach.

Preparation on EVAR ASSIST 2

Fig. 1 Rapid segmentation of the ascending aorta. Creation of 3D bone, venous and calcifications volumes for image fusion.

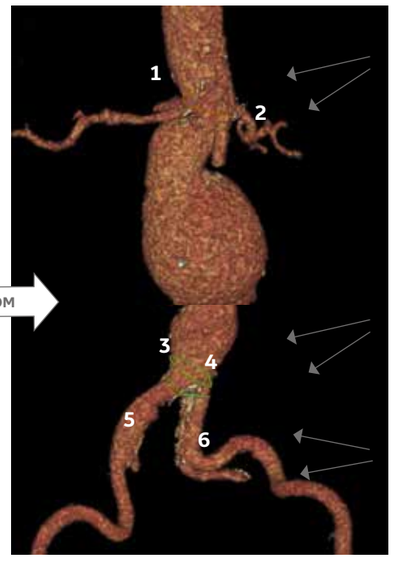


Fig. 2 Creation of planning lines and markers to facilitate the Ostia location on images from scanner.

Creation planning line and two markers at the ostia of the renal

Creation of planning lines at the ostia of the femoral.

Creation of two markers at the ostia of the hypogastric.

Performing measurements to define the prosthesis size.

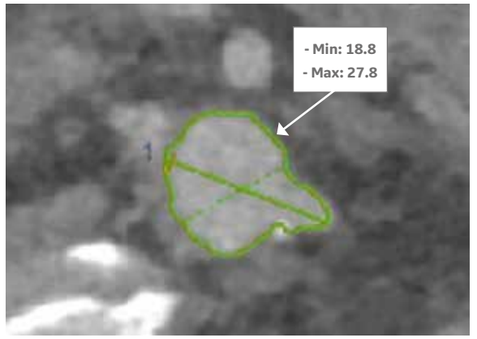


Fig. 3 The right common iliac artery diameter.

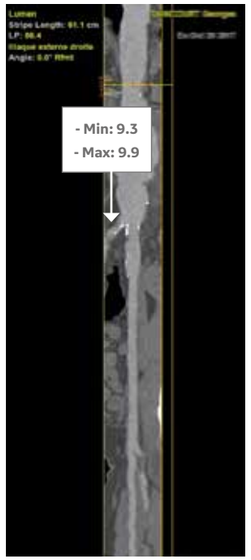


Fig. 4 The left common iliac artery.

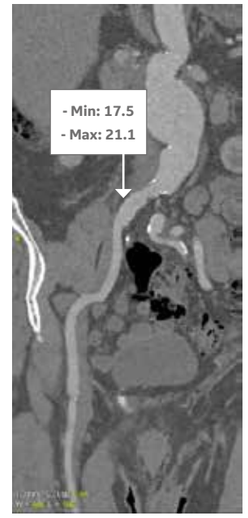
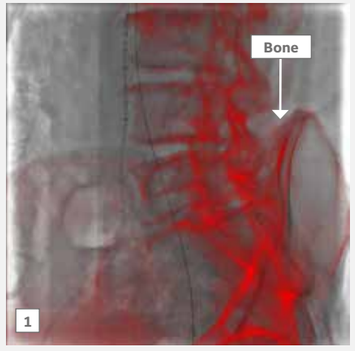
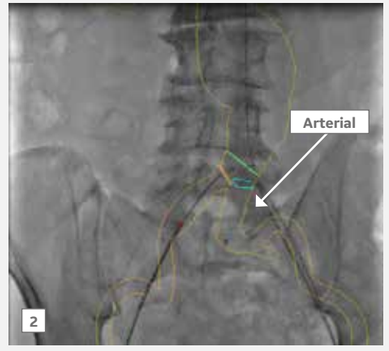
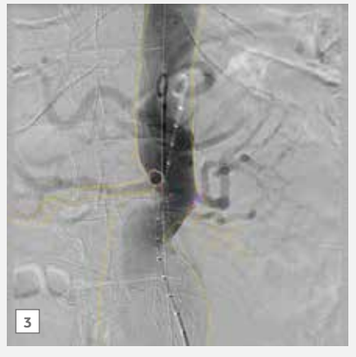


Fig. 5 Sub-renal aorta.

Step 1
Registration of volumes with the live fluoroscopy





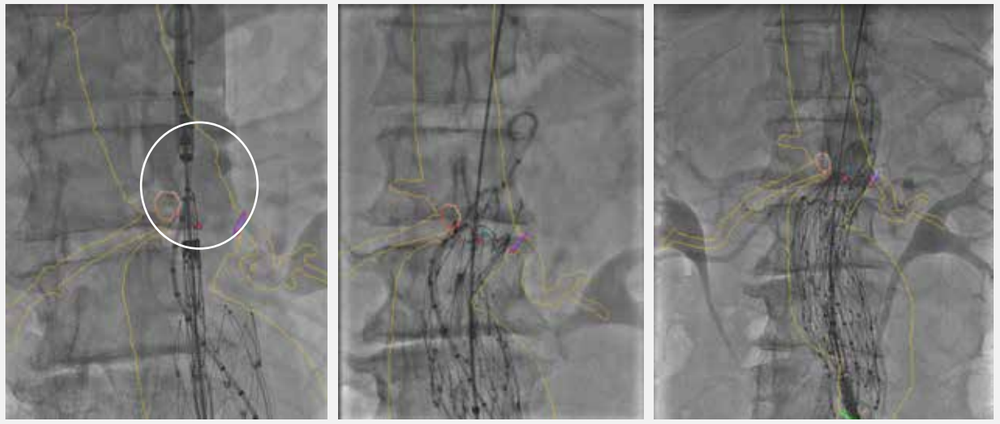


1. ***Registration on two angulations by using the bone volume (at the level of the pelvis and the first vertebrae).***
2. ***Vessels and markers display.***
3. ***Additional registration by angiography to match the arterial volume on the live fluoroscopy.***

Step 2

Orientation, positioning and stent deployment

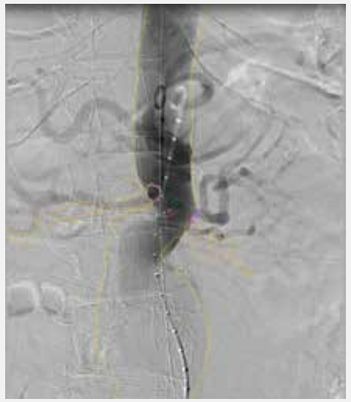
The operator used markers in order to position the top of endoprosthesis (28x110 / 120x30) and did not obstruct renals.



- ***Stent deployment.***
- ***Proximal Endoprosthesis system***
- ***Endoprosthesis system 34x34 / 100x20***
- ***Post dilation with an aortic modeling balloon***
- ***Distal segment positioning of the stent at the bifurcation level to the common iliacs.***
- ***2 proximal extensions positioning (34x34 / 100x20).***
- ***The proximal extremity of the last implanted segment has been just below the renal arteries.***

Step 3

Assess with help of imagery



The angiographic result is excellent and shows absence of endoleaks and the exclusion of the aneurysm sac. Conclusion : The time of the procedure was 1:40. After checking the Endoprosthesis with a CT scan and a control ultrasound, the patient returned home 3 days later. Image fusion minimized contrast volume, fluoroscopy time, and patient dose.

DAP	58.35 Gy.cm²
Air Kerma	367.24 mGy
Procedure time	19.92 mn
Contrast media	120 cc

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.

The statements by GE's 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.

FOCUS ON YOUR PATIENTS

Our systems are low dose by design

GE IS A LEADING PLAYER IN DOSE REDUCTION

Automated radiation dose reduction
Without any manual intervention

- 46% DAP reduction for CA[1]
- 56% DAP reduction for PCI[1]
- 54% DAP reduction for CA + PCI[1]

CTO-PCI USING DOSEMAP

- -31% CAK reduction[2]
- -33% DAP reduction[2]

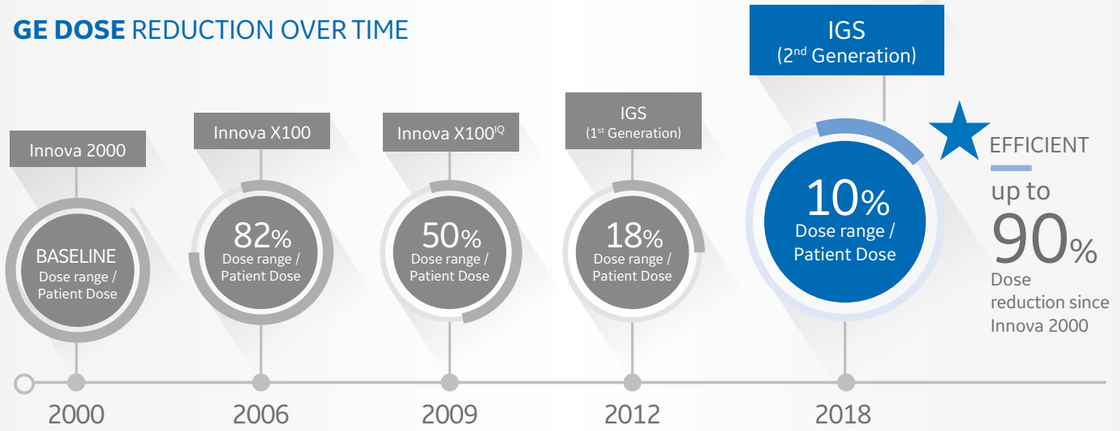
TAVI WITH VALVE ASSIST 2*

- -30% dose[3]
- -38% contrast media volume[4]

LAAC WITH VALVE ASSIST 2*

- -28% procedure time[5]
- -25% fluoro time[5]
- -78% contrast media[5]

GE DOSE REDUCTION OVER TIME



Introduction of a new detector and new processing

- New generation of automatic dose exposure
- Dynamic 7,5 fps
- Improved tube performance
- Image noise reduction

Image quality improvement, with the same dose

- PCI ASSIST**

* Valve ASSIST 2 solution includes TAVI Analysis, HeartVision 2 and requires AW workstation with Volume Viewer, Volume Viewer Innova. These applications are sold separately.

* * PCI ASSIST refers to features of Innova IGS 5, Innova IGS 6, Discovery IGS 7 and Discovery IGS 7 OR. PCI ASSIST refers to features of Interventional X-ray system: StentViz and StentVesselViz.

1. Didier, R., et al., The utilisation of the cardiovascular automated radiation reduction X-ray system (CARS) in the cardiac catheterisation laboratory aids in the reduction of the patient radiation dose. EuroIntervention, 2016. 12(8): p. e948-e956
2. Euro17A-POS0652 Intra-procedural characterisation of estimated peak skin dose during PCI of CTO using a new patient dose mapping technology: the Dosemap studyMANGIAMELI A.(1), LEFEVRE T.(1), HOVASSE T.(1)(1) ICPS, Massy France
3. Overtchouk P, Sudre A, Delhaye C et al. Advanced image processing with fusion and calcification enhancement in transcatheter aortic valve implantation: impact on radiation exposure. Interact Cardiovasc Thorac Surg 2018.
4. Shafiq A, O'Hair DP, Allaqaband SQ, Ullah R, Nfor T, Bajwa T. TCT-353 Effect of a New Enhanced Fluoroscopy Technology (Valve ASSIST2) on Contrast and Radiation Use in Patients Undergoing Transcatheter Aortic Valve Replacement. Journal of the American College of Cardiology 2017;70:B145-B146.
5. Novel Integrated 3D Multi-Detector Computed Tomography and Fluoroscopy Fusion for Left Atrial Appendage Occlusion Procedures. Catheter Cardiovasc Interv 2017; Mar 17, DOI:10.1002/ccd.26998

Guidelines on Myocardial Revascularization - 2018 ESC/EACTS Guidelines (Extract)

Sources

2018 ESC/EACTS Guidelines on myocardial revascularization
European Heart Journal, Volume 40, Issue 2, 07 January 2019, Pages 87–165,
https://doi.org/10.1093/eurheartj/ehy394 - Published: 25 August 2018

Official guidelines, section preamble

Classes of recommendations	Definition	Suggested wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective	Is recommended/Is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure	
Class IIa	Weight of evidence/opinion is in favour of usefulness/ efficacy	Should be considered
Class IIb	Usefulness/efficacy is less well established by evidence/ opinion	May be considered
Class III	Evidence or general agreement that the given treatment pr procedure is not usefull/effective, and in some cases may be harmful	Is not recommended

Level of evidence

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from multiple randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

Guidelines planned in

2019

- Diabetes, Pre-diabetes & Cardiovascular Diseases
- Acute Pulmonary Embolism, Supraventricular Tachycardia
- Chronic Coronary Syndromes (previously Stable Coronary Artery Disease)
- Dyslipidaemias

Guidelines planned in

2020

- Non-St-Segment Elevation Acute Coronary Syndromes
- Atrial Fibrillation
- Grown-Up Congenital Heart Disease (GUCH)
- Sports Cardiology & Physical Activity in Patients with Cardiovascular Disease (Position Paper)

What's new

- Calculation of the Syntax Score, if left main or multivessel revascularization is considered
- Radial access as standard approach for coronary angiography and PCI
- DES for any PCI
- Systematic re-evaluation of patients after myocardial revascularization
- Stabilised NSTE-ACS patients: revascularization strategy according to principles for SCAD
- Use of the radial artery grafts over saphenous vein grafts in patients with high-degree stenosis
- Myocardial revascularization in patients with CAD, heart failure, and LVEF <= 35%
- CABG preferred
- PCI as alternatives to CABG
- Completness of revascularization prioritized, when considering CABG vs PCI
- NOAC preferred over VKA in patients with non-valvular AF requiring anticoagulation and antiplatelet treatement
- No-touch vein technique, if open vein harvesting for CABG
- Annual operator volume ofr left main PCI of at least 25 cases per year
- Pre-and post-hydration with isotonic saline in patients with moderate or severe CKD if the expected contrast volume is >100mL
- Routine non-invasive imaging surveillance in high-risk patients 6 months after revascularization
- Double-kissing crush technique preferred over provisional T-stenting in true left main bifurcations.
- Cangrelor in P2Y12-inhibitor naïve patients undergoing PCI
- GP IIb/IIIa inhibitors for PCI in P2Y12-inhibitor naïve patients with ACS undergoing PCI
- Dabigatran 150-mg dose preferred over 110-mg dose when combined with single antiplatelet therapy after PCI
- De-escalation of P2Y12 inhibitor guided by platelet function testing in ACS patients
- Routine revascularization of non-IRA lesions in myocardial infarcion with cardiogenic shock
- Current generation BRS for clinical use outside clinical studies

Recommendation changes in the guidelines

UPGRADES

- For PCI of bifurcation lesions, stent implantation in the main vessel only, followed by provisional balloon angioplasty with or without stenting of the side branch
- Immediate coronary angiography and revascularization, if appropriate, in survivors of out-of-hospital cardiac arrest and an ECG consistent with STEMI
- Assess all patients for the risk of contrast-induced nephropathy
- OCT for stent optimization

DOWNGRADES

- Distal protection devices for PCI of SVG lesions
- Bivalirudin for PCI in NSTE-ACS
- Bivalirudin for PCI in STEMI
- PCI for MVD with diabetes and SYNTAX score <23
- Platelet function testing to guide antiplatelet therapy interruption in patients undergoing cardiac surgery
- EuroSCORE II to assess in-hospital mortality after CABG

The figure does not show changes compared with the 2014 version of Myocardial Revascularization Guidelines that were due toupdates for consistency with other ESC Guidelines published since 2014.

Class I | Class IIa | Class IIb | Class III

ACS = acute coronary syndromes ; AF = atrial fibrillation; BRS = bioresorbable scaffolds; CABG = coronary artery bypass grafting; CAD = coronary artery disease; CKD = chronic kidney disease; DES = drug-eluting stents; FFR = fractional flow reserve; GP = glycoprotein; IRA = infarct-related artery; LVEF = left ventricular ejection fraction; NOAC = non-vitamin K oral anticoagulants; NSTEMI = non-ST-elevation; PCI = percutaneous coronary intervention; SCAD = stable coronary artery disease; VKA = vitamin K antagonists.

CABG = coronary artery bypass grafting; MVD = multivessel coronary artery disease; NSTE-ACS = no-ST-elevation acute coronary syndromes; OCT = optical coherence tomography; PCI = percutaneous coronary interventions; STEMI = ST-elevation myocardial infarction; SVG = saphenous vein grafts.

Source: 2018 ESC/EACTS Guidelines on myocardial revascularization European Heart Journal, Volume 40, Issue 2, 07 January 2019, Pages 87–165, https://doi.org/10.1093/eurheartj/ehy394 - Published: 25 August 2018

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.

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