

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.

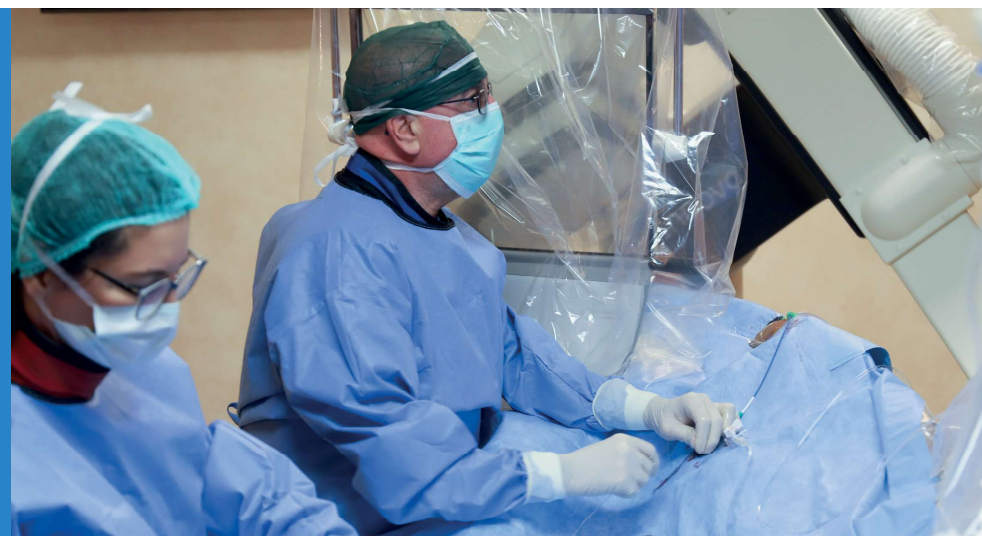
In the south of Italy, few industries are supporting local economic environment, and there was a real need to build this center to support the local population.





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



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 ASSIST¹

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 ASSIST¹ 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 reference², 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. Daniele, 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 (ARTISIA³) and one from Europe (NOAC⁴):

"Both studies randomize patients with sub-clinical AF and sometimes AF but the patient is not aware that he has this arrhythmia. 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 Trial⁵, 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 techniques, electrophysiology 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[®] 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(18):e89-90. doi: 10.1016/j.jcin.2013.11.028.
De Rosa S, Torella D, Calazzo 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 27(10). pii: E319. doi: 10.3390/jcm7100319.

4. New Oral Anticoagulants (NOAC) in Stroke Patients (NOACISPI), 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.