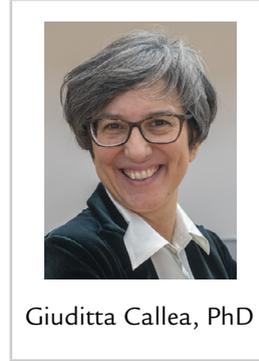


Conversations With the Editor: Optimizing Patient Pathways Through the Activation of an Aortic Valve Outpatient Day Service



Sergio Berti, MD



Giuditta Callea, PhD

Featured Guest Biography: Sergio Berti, MD, is the Director of the Diagnostic and Interventional Cardiology at Ospedale del Cuore G. Pasquinucci Massa, and Area della Ricerca C.N.R. Pisa Italy. He is also the President of the Italian Society of Interventional Cardiology (GISE) Foundation and a member of several Scientific Medical Societies. He is specialized in Radiology, Cardiology and Nuclear Medicine. He has served as a principal investigator for profit and not for profit clinical trials for over 10 years in the field of Cardiology (pharmaceutical as well as device-specific), predominantly for Phase III trials. He is the Scientific Coordinator of the II level Master Programme in Percutaneous interventional treatment of structural heart diseases at Scuola Superiore Sant'Anna in Pisa, Italy.

EDITOR'S NOTE

Throughout a medical technology's life cycle, stakeholders may play different roles of varying significance. National agencies (eg, the US Food and Drug Administration, European Union Competent Authorities) are the key actors in regulatory approval (eg, US Food and Drug Administration approval, CE Mark), whereas national/regional policy makers determine coverage and reimbursement of innovative technologies. For mature, already adopted technologies, the hospital level has a pivotal role in the rational and appropriate use of resources. Dr. Sergio Berti has implemented a pilot project for TAVI patient pathway optimization at the Ospedale del Cuore G. Pasquinucci–G. Monasterio Foundation, Massa, Italy, based on the activation of a dedicated day service ambulatory program to perform advance imaging tests and examinations. This project has resulted in facilitating patient referrals to the most appropriate therapeutic option, faster patient recovery due to earlier patient mobilization and shorter length of stay, and better capacity to plan operating room activity. This experience shows how organizational innovations might help hospitals improve patient care and gain efficiency.

INTERVIEW

Giuditta Callea, PhD: Dr. Sergio Berti, thank you for joining us, it's really a pleasure. We're here today to talk about a pilot project for optimization of the transcatheter aortic valve implantation (TAVI) patient pathway that you recently implemented in collaboration with hospital management. In recent years, your hospital has experienced a huge increase in the number of patients treated and is currently among the 10 hospitals with the highest volume of

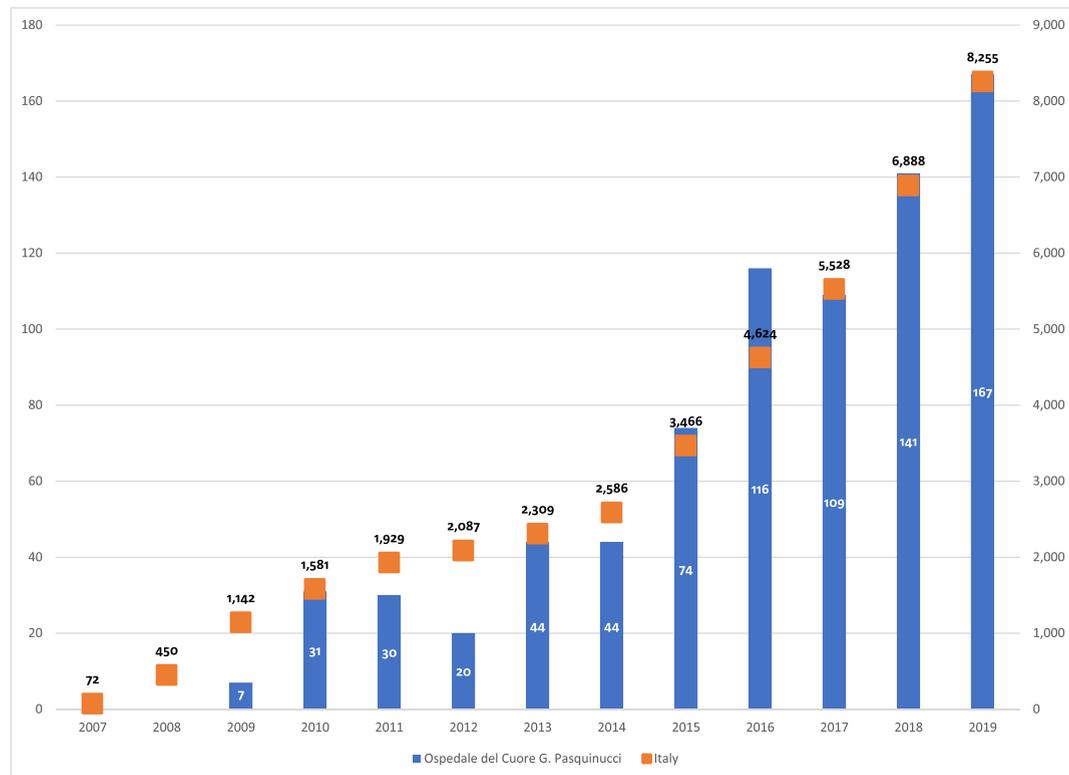


Figure 1. Yearly number of transcatheter aortic valve implants at Ospedale del Cuore G. Pasquinucci and in Italy, 2009 to 2019. (Source: Italian Society of Interventional Cardiology.)²

implants in Italy. Can you talk about the state-of-the art and the challenges in treating patients with severe aortic stenosis before starting the pilot project?

Sergio Berti, MD: Good morning, and thank you, Professor Callea, for inviting me to this very interesting Conversation With the Editor. Ospedale del Cuore is a public hospital and a special institute, the result of an agreement between the national health care system and the Italian Council of Research. The aim of the founder was to create a hospital that could facilitate research at the bed of the patient. In particular, I want to emphasize the strong level of cooperation among all the teams that work in the hospital, including cardiologists, cardiac surgeons, anesthesiologists, and computer scientists. This is a very special situation that allows us to do a lot of things and is part of the history and philosophy of my institution. Just a comment on the trend of TAVI implants. TAVI procedures in my hospital have grown at a rate of ~20% per year (Figure 1). This figure reflects Italian and European trends and highlights the impressive and constant diffusion of TAVI as a treatment of preference for patients affected by symptomatic severe aortic stenosis who are older than 75 years. Many aspects influenced these phenomena. First, there is the impressive improvement in device technologies that increased procedural success, with a sizeable reduction in patient discomfort. Just think that now we perform the procedure without general anesthesia and without intubation. So, the patient has great acceptance of the procedure. The second main reason is the high number of published trials that have shown excellent results for TAVI compared with open heart surgery in patients at high and intermediate risk and, more recently, also in low-risk patients. Despite the results, we have a lot more to do to provide the appropriate number of TAVI treatments needed on the basis of current indications. Just think that treatment needs are estimated to be 290 TAVI per million inhabitants, but in 2019, in Italy we were able to treat only 137 patients per million inhabitants.¹ Now, we are waiting for the 2020 data from the National Registry

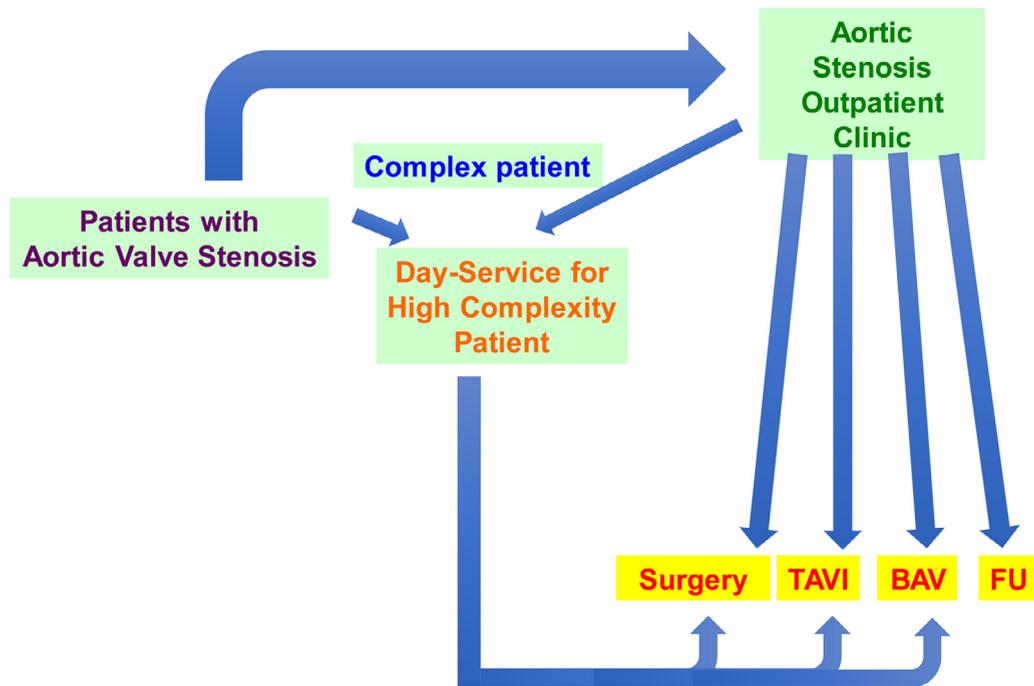
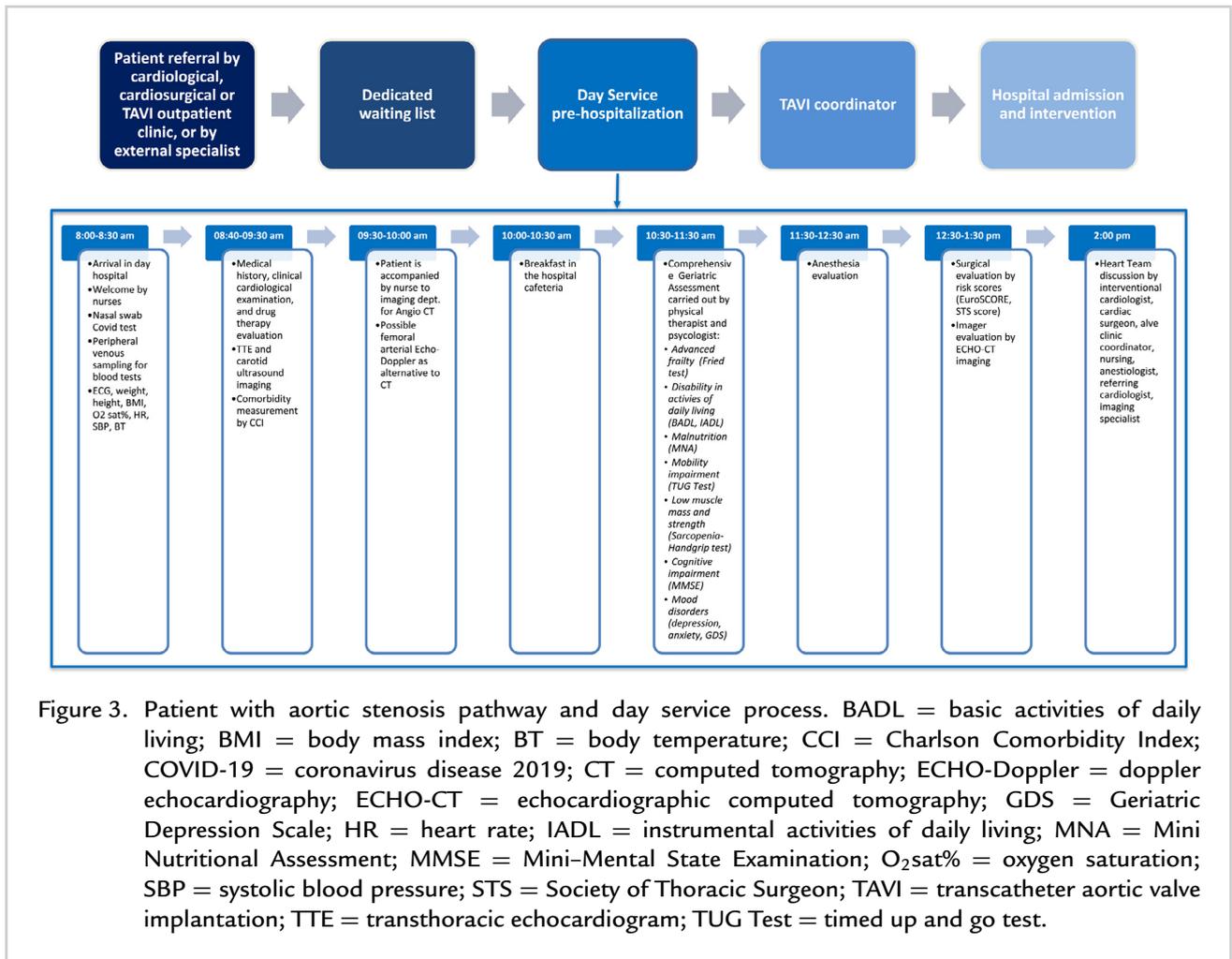


Figure 2. Severe aortic stenosis patient pathway implemented at Ospedale del Cuore G. Pasquinucci. BAV = balloon aortic valvuloplasty; FU = follow-up; TAVI = transcatheter aortic valve implantation.

of the Italian Society of Interventional Cardiology, but I presume that the data have been affected by coronavirus disease 2019 (COVID-19). To that end, we have to improve the link between the TAVI centers and peripheral referral hospitals and the territorial care services. We have to improve the information and awareness of aortic stenosis with patients and among general practitioners. Another critical step for the diffusion of TAVI is to establish dedicated patient pathways, from referral to TAVI centers, to facilitate patient access to the most appropriate procedure and the most appropriate care. This is the state-of-the-art today.

Giuditta Callea, PhD: To improve the overall pathway of patients with severe aortic stenosis, you designed and implemented an Aortic Valve Outpatient Day Service. Can you give our readers an overview of the characteristics of the pilot project and how you have changed your practices?

Sergio Berti, MD: The project was conceived more or less 5 years ago and has been gradually implemented since then. Our aim was to optimize the procedural pathway, select the appropriate candidate for the TAVI procedure, and reduce the risk of inappropriate hospital admission and last-minute cancellation of interventions. Basically, we plan 2 sessions of Aortic Valve Outpatient Day Service per week. In each session, 2 to 3 patients are evaluated. From March 1, we will have increased the number of patients to 3 per session. Let me give you some details for a better understanding of the Aortic Valve Outpatient Day Service organization. When a patient affected by aortic valve stenosis is referred to our hospital, he or she is sent to an Aortic Stenosis Outpatient Clinic, where a cardiac surgeon and an interventional cardiologist cooperate to evaluate the patient (Figure 2). At the end of the evaluation, the team makes a decision on whether the patient is a good candidate for surgery, TAVI, or follow-up. In some cases, when the patient is really complex—and this situation is frequent because we are talking about an elderly patient with a lot of comorbidities—we send him or her to the Day Service for High Complexity Patients that you mentioned before, where more in-depth and multidimensional evaluation is performed. At the end of the evaluation, with all



the information, the team makes a decision regarding the most appropriate treatment for the patient. In addition, we provide a dedicated telephone number and e-mail address to facilitate the patient's access to our center.

The Day Service has a dedicated waiting list in which cardiologic outpatient clinics, cardiosurgical outpatient clinics, TAVI outpatient clinics, and external specialists can insert appointments for patients to be evaluated in the day service (Figure 3). The patient arrives in the morning at 8:00 AM. After a welcome by the day service nurses, he or she undergoes a nasal swab COVID-19 test (introduced in February 2020), peripheral venous sampling for blood tests, an ECG, and other general evaluations by the nursing team. Immediately after, a dedicated cardiologist takes charge of the patient for medical history, cardiologic examination, and evaluation of drug therapy, and performs the first transthoracic echocardiography and the first comorbidity evaluation using the Charlson Comorbidity Index. At 9:30 AM, the patient is accompanied by the nurse to the imaging department, where we have a dedicated slot for the angio CT scan, which is a critical step in evaluating patients for TAVI. After a short break in the hospital cafeteria, the patient undergoes a comprehensive geriatric assessment conducted by physical therapists and psychologists to control for advanced frailty, disability, malnutrition, mobility impairment, low muscle mass and strength, cognitive impairment, and mood disorder. Geriatric evaluations are extremely important because we have to know the patient's condition beyond the aortic stenosis. The question is: can this patient benefit from a surgical or transcatheter aortic valve replacement? Afterwards, the anesthesiology team evaluates the patient and, finally, the surgical team evaluates the risk score profile using the EuroSCORE and the STS scores, and an expert in imaging evaluates the ECHO computed tomography scan imaging. With all this information, the heart team, which has a

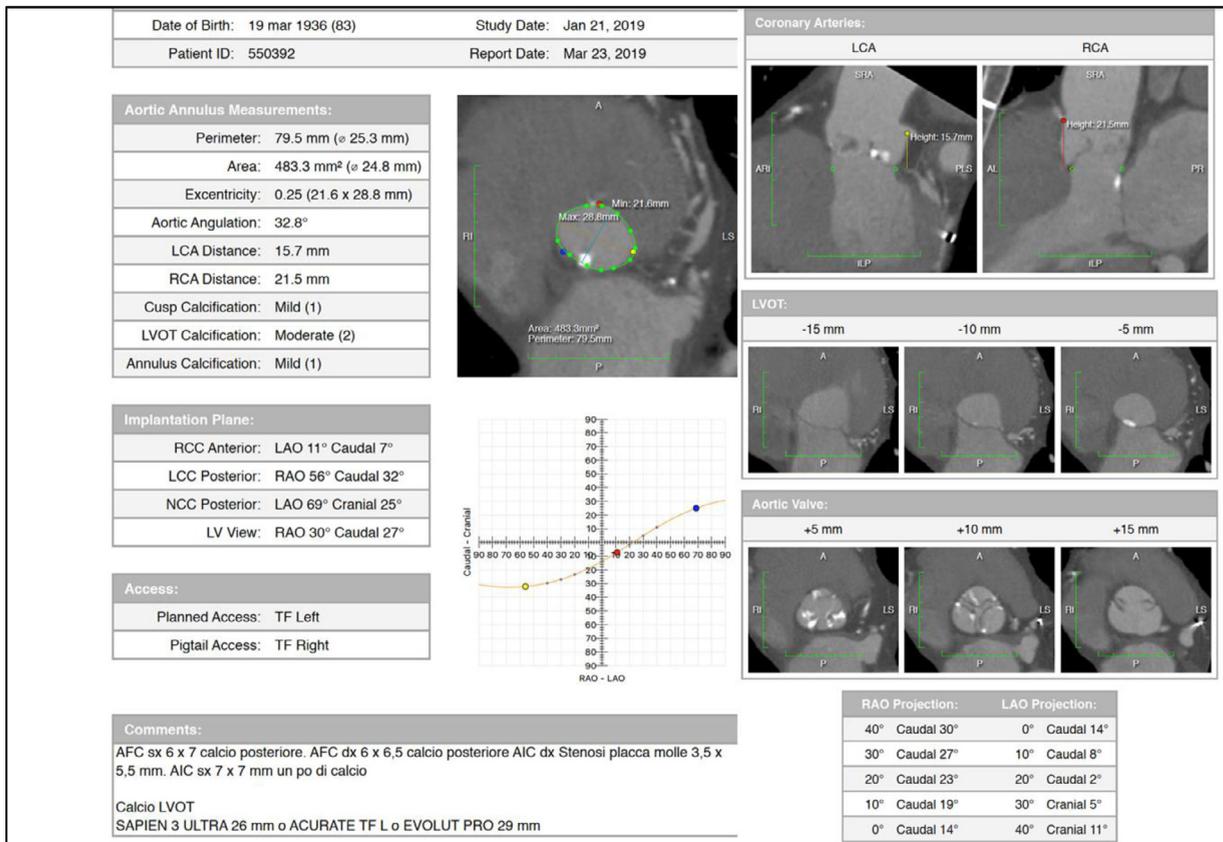


Figure 4. Example of patient procedural planning for transcatheter aortic valve implantation. LAO = left anterior oblique; LCA = left coronary artery; LCC = left coronary cusp; LV = left ventricular; LVOT = left ventricular outflow tract; NCC = noncoronary cusp; RAO = right anterior oblique; RCA = right coronary artery; RCC = right coronary cusp; TF = transfemoral.

meeting at ~2:00 PM, evaluates the patient and decides on the most appropriate treatment. If the patient is a good candidate for TAVI, the team prepares a surgical plan like the one shown in Figure 4, where we include all the main parameters needed for the operation (eg, type of valve to be used, radiologic projection, some information about the calcium distribution, or possible difficulties that we might have during the procedure). This form is sent to an iPad placed in the operating room so that on the day of the intervention, the team has all aspects related to the planning of the procedure. At this point, the TAVI coordinator takes charge of the patient and goes through the following steps: checks the availability of the anesthesiology team; checks with the head nurse of the catheterization laboratory regarding the availability of devices, materials, and operators; checks with the ward head nurse regarding the number of available beds; and checks the availability of specialists in case the interventional team needs specialists from manufacturers or if the patient needs to do an additional procedure (eg, to place an endograft). If everything is fine, the TAVI coordinator gives the green light for the hospital admission and schedules the intervention for the following week. Upon discharge from the day service, the patient receives a summary of the procedure, which is collected in an electronic folder that will be available at the time of the hospital admission. This way, all the work done is available for all colleagues at hospital admission.

Giuditta Callea, PhD: What are the direct and indirect benefits of optimizing the TAVI patient pathway?

Sergio Berti, MD: The benefit for the patient is, first, a shorter length of stay due to the reduction of the time between admission and the day and time of the operation. This aspect is achieved with a parallel program of easy (or minimalist) TAVI, which consists of avoiding general anesthesia, no intubation, and no intensive care. After the procedure, the patient is transferred directly from the catheterization laboratory to his or her bed in the ward. An additional parallel program of early mobilization and early discharge completes the pathway. The latter have been implemented because there is evidence that such activities can lower the risk of disorientation in elderly patients. In the end, the total hospital stay is relatively shorter compared with before implementation of the project. There is an additional benefit for the hospital organization that we can summarize in a higher availability of beds because of the reduction in length of stay. In other words, we gain the capacity to treat more patients and optimize operating room activity, with a shorter waiting list for TAVI. In the end, this means saving resources for the hospital.

Giuditta Callea, PhD: That's very interesting. How costly was it for your hospital to implement the pilot project and what type of investment, in terms of both human resources and capital equipment, was required?

Sergio Berti, MD: The incremental cost should be evaluated in terms of balance of the optimization of resources. Basically, the pivotal professional figure I mentioned before is the TAVI coordinator, a very critical figure. She is not a clinician, but she has great experience and know-how regarding hospital organization. She carefully arranges every week the catheterization laboratory schedule on the basis of the availability of the interventional cardiologist, the anesthesiology team, beds, and materials. She readjusts operating room scheduling in case of a cancellation by any patient and provides for replacement. The project needs 2 or 3 dedicated beds for the day service 2 days a week, one dedicated cardiologist for 2 days a week, one physiotherapist, and one psychologist. It is not mandatory to have a physiotherapist and a psychologist, but they are extremely helpful for patient support. In addition, an electronic clinical folder adapted for the day service activity is helpful.

Giuditta Callea, PhD: At the beginning of the interview, you mentioned that your hospital has some special features. It is relatively small, specialized in cardiovascular diseases, open to innovation and experimentation, and has a consolidated tradition of collaboration between clinicians and computer scientists. Do you think that these characteristics functioned as facilitating factors and what pre-conditions must be met by a hospital interested in adapting this pilot project to its context?

Sergio Berti, MD: This is a correct observation. My hospital is really a very special reality because in our tradition we enjoy close collaboration between physicians and computer scientists, as you correctly mentioned. Our organization is extremely flexible and, of course, this facilitates the introduction of innovative models of hospital organization. In my opinion, our role is to be forerunners. I think that our model of aortic valve outpatient day service is an excellent pilot project. Of course, it needs to be adapted to the hospital organization considering implementation because my hospital's organization is different from that of a general hospital.

Giuditta Callea, PhD: Let's talk about the effects and impact of the experience that you have implemented. Let's start from the patients. How successful has the program been for patients in terms of satisfaction with the program and improvement in outcomes, particularly in the context of noninvasive procedures such as TAVI?

Sergio Berti, MD: The program was well received by patients, mainly for the reduction of in-hospital length of stay and for the opportunity to concentrate all the diagnostic and decisional steps in only 1 day of outpatient evaluation. Furthermore, the integration into the team of 2 innovative professional figures, 1 physiotherapist and 1 psychologist, who coordinated with the general practitioner and the family to ensure adequate support after discharge, contributed to increase the grade of acceptance of the project. More in general, I think that the TAVI procedure is well accepted by the patient because its low invasivity, high rate of procedural success, and low rate of discomfort are all pivotal steps of the procedure.

Giuditta Callea, PhD: In general, we tend to emphasize clinical benefits generated by technological innovation in health care. Your experience shows that organizational innovation might help hospitals to fully benefit from new medical technologies, improving the level of care, gaining efficiency, and even reducing costs without cutting the use of resources. Often organizational innovation generates resistance to change. I would like your advice on this.

Sergio Berti, MD: This is an extremely important question. In my opinion, when we pronounce the word innovation, our mind immediately goes to new and innovative technologies, devices, materials, and so on. But there is another way to innovate that is not less strategic, and that is by introducing new and more efficient organizational models. The introduction of innovative organizational models in the health care system plays a strategic role in improving the quality of care, improving efficiency, and reducing costs without cutting the use of resources, as you correctly stated. The main difficulty when you introduce an organizational innovation, or more in general, a change, is to pronounce a sentence and convince all the members of the organization to pronounce it. This sentence is “Today we change.” This is the main difficulty to overcome in making a system change.

Giuditta Callea, PhD: Was it hard to introduce this organizational innovation in your hospital?

Sergio Berti, MD: In my hospital, the sentence “Today we change” is pronounced every day. But of course, in general, we find some resistance to change. The main resistance to the project was the natural passive resistance to change within each of us, in particular, the concern of discharging the patient too early, concern regarding early mobilization, and so on. But when the project started, we slowly observed a change in the minds of the cardiologists, and we had very good feedback from the nursing team, who are extremely reactive.

Giuditta Callea, PhD: Sometimes it seems that people might be scared by the adoption of a new model, that they are not convinced. But then applying the model and measuring the impact and the effects might convince them that it's a good model, and it's good to go on with the experience.

Sergio Berti, MD: Yes, to give feedback is probably the best strategy to convince colleagues that the change is fine.

Giuditta Callea, PhD: Dr. Berti, I have a last question for you. How did the COVID-19 pandemic affect your everyday work? Did you interrupt or cancel the day service or was it helpful to keep treating the patients?

Sergio Berti, MD: Yes, of course the pandemic affected and affects our daily work. In March and April 2020, during the lockdown, the activity was greatly reduced. We slowly restarted in June 2020. The main difficulty was to treat non-COVID-19 patients due to the resource consumption by COVID-19 patients, the use of intensive care, and the necessity to separate COVID-19 from non-COVID-19 patients. Our aims are not to delay urgent interventions but rather to maintain a high quality of treatment and at the same time save health resources and minimize COVID-19 exposure for patients and staff. A very interesting phenomenon we observed during the lockdown in my hospital, which is the referral hospital for the STEMI network and for acute coronary syndrome, was a reduction in the assessment of patients with ST-elevation myocardial infarction of ~50%.³ Because of patient concern about calling the emergency team in case of chest pain and going to the hospital, a lot of patients remained with the infarction at home. And it's terrible to observe that we had an increase in mortality of ~40% during that period. So, the effect of the COVID-19 pandemic was often not only patient death from COVID-19 but also patients indirectly dying for fear of the COVID-19 pandemic. I mean, the patients died of other pathologies, too.

Giuditta Callea, PhD: Dr. Berti, I would like to thank you so much for sharing your experience, and I hope that this experience will be inspiring for other colleagues of yours around the world, as it was for me. So, really, thank you so much.

Sergio Berti, MD: Thank you so much. It's been a great pleasure to talk with you.

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