

Round Table
CARDIOVASCULAR DISEASE IN PEOPLE LIVING WITH DIABETES IN ITALY

MARCH 27, 2023 – MILAN – ITALY
Hybrid Format (in presence and online)

Introduction

The "cardio-metabolic" syndrome is the definition that best represents the clinical condition involving 70% of people with diabetes (2.5 million out of a total of 3.8 million) for whom cardiovascular events are the main cause of death. Another worrying fact to underline is the lack of awareness of one's own condition in over half of people suffering from diabetes.

Analyzing the Italian scenario, the Italian Heart Foundation (IHF) organized on 27 March 2023 in Milan the Round Table "CARDIOVASCULAR DISEASE IN PEOPLE LIVING WITH DIABETES IN ITALY" by gathering thirteen Key Opinion Leaders (KOLs) to stimulate discussion and collect indications on therapeutic pathways for a better management of the people suffering from diabetes and its cardiovascular complications. The Round Table is as part of the World Heart Federation (WHF) project "A Roadmap on the Prevention of CVD Among People Living with Diabetes". Among the many topics discussed, special attention was paid to the existing barriers in the therapeutic and care pathway, in addition to some examples of best practices and the importance of adherence to therapy with the final goal to achieve a shared action with stakeholders to improve on patient care.

Discussion

THE SITUATION IN ITALY: NATIONAL SCENARIO

Dan Gaita – (World Heart Federation Representative; Vice President Romanian Society of Cardiology; Board Member, European Heart Network) – presented the WHF Roadmap <https://world-heart-federation.org/cvd-roadmaps/whf-global-roadmaps/cvd-diabetes/> explaining how it has to be considered as a fundamental reference document for anyone involved in the management of cardiovascular diseases starting from the planning, organization, implementation, monitoring and evaluation of approaches.

The Italian "Cardiovascular Disease Scorecard" (drafted in 2022) presented by **Roberto Volpe** (National Research Council-CNR; Italian Society for Cardiovascular Prevention-SIPREC) and **Paolo Magni** (Scientific Committee Coordinator Italian Heart Foundation; Department of Pharmacological and Biomolecular Sciences - DiSFeB University of Milan), showed that the Italian scenario is generally good considering that the situation is reassuring from the point of view of premature and mortality rate in addition to the general life expectancy. However, it emerged also that there is room for improvement concerning:

- the prevalence and control of the main modifiable cardiovascular risk factors such as, for example, diabetes mellitus, hypercholesterolemia, arterial hypertension, smoking, sedentary lifestyle (factors linked to a detectable unhealthy lifestyle that unfortunately shows to be increasing even among teenagers);

- the premature mortality rate which is not so high but still detectable (mainly in males);
- the availability of excellent diagnostic and therapeutic pathways but with a very low percentage of therapeutic adherence;
- the availability of updated prevention guidelines but not still very known and/or not fully followed by HCPs;

More specifically, regarding the cardio-metabolic syndrome, the Italian scenario was analyzed by comparing the different landscapes seen by the main players involved in taking charge of the diabetic patient with cardiovascular complications, that are the cardiologist, the diabetologist, the general practitioner and, last but not least, the citizen/patient's voice.

Massimo Volpe (President of the Italian Society for Cardiovascular Prevention-SIPREC; Department of Clinical and Molecular Medicine, La Sapienza University, Rome) presented the point of view of the cardiologist on the management of people living with diabetes and cardiovascular complications. His presentation "Diabetes at the heart of contemporary healthcare agenda" illustrated how the data related to the significant increase of cardiovascular pathologies in diabetic patients, in particular type 2, are now well known and established. A global assessment of the prevalence of CV pathologies in people with diabetes was collected by the CAPTURE study, a prospective non-interventional study performed on over 10,000 adult patients in 13 different countries in 5 continents: the study shows the need for integration not only between the different health professionals involved in the management of the patient with diabetes but also a better collaboration among the scientific societies involved, including the GPs. Other data collected from a cohort study on 34,200 British patients underline that about 1 in 5 people with type 2 diabetes experiences the first CV event 5 and a half years after the diagnosis and among the CV comorbidities experienced in those patients, atherosclerotic disease is the most frequent (60%). The possible scope of action in this scenario regards the integration of the activity of the diabetologist/endocrinologist with the cardiologist, who, together, should provide the right indications to the general practitioner in the field.

Prof. Volpe, illustrating the UNITE project developed at the Sant'Andrea University Hospital in Rome, remarked how a shared intra-hospital diagnostic/therapeutic pathway through the collaboration among endocrinologists/diabetologists, cardiologists, internists and nephrologists is truly doable and necessary, and how this can offer real integrated care pathways to the diabetic patient starting from admission to the emergency room, to discharge up to intra and/or extra-hospital follow-up. The feasible solution, proposed by Prof. Volpe, is the implementation of multidisciplinary approach by creating cardio-metabolic clinics where the patient could be visited together by specialists with integrated skills, ensuring a holistic view of the patient and syndrome.

Paolo Di Bartolo (President of the Italian Association of Diabetologists; Director of the Diabetology Clinical Network - AUSL of Romagna Ravenna) presented the point of view of Italian diabetologists based on the analysis of cardiovascular disease in people living with diabetes (*Annals of the Association of Diabetologists-AMD, 2021*).

From the data collected in the Scorecard on cardiovascular diseases in Italy, it emerges that there are approximately 3.8 million people with type 1 and 2 diabetes, of which 70% are treated with antihypertensives and 60.8% with lipid-lowering drugs. As a further demonstration of the importance of the relationship between diabetes and cardiovascular diseases, there is the alarming data concerning the percentage of people with diabetes who die from cardiovascular diseases: the percentage varies between 60% and 80%, according to which a further data is represented by 20.9% of patients with a high cardiovascular risk, followed by 15% who have already had a heart attack, stroke or vascular complications in the lower limbs, in addition to 40% of patients with kidney disease.

All these data underline how diabetes, if not diagnosed, misdiagnosed or untreated, can cause severe complications that can negatively affect a person's well-being, heavily influencing the QoL (quality of life). Therefore, the management of the risk of cardio-renal disease in people with diabetes is of great importance in the prevention of complications associated with diabetes. Fortunately, today there are effective treatment opportunities for the reduction of cardio-renal risk but due to the complexity of the pathology and the difficulty in guaranteeing sustainability and access to treatment, it is more necessary than ever to guarantee assistance to the person with diabetes through a multi-professional approach and a real collaboration between the hospital and medicine in the field. The diabetologists, therefore, underlined the need for an integration of skills ensuring a holistic approach to the treatment of the cardio-metabolic syndrome.

The SID-AMD guidelines have been recently updated (July 2021) and **Angelo Avogaro** (President of the Italian Society of Diabetology-SID; Department of Endocrinology and Metabolic Diseases, University of Padua) remarked how these guidelines represent an important turning point in the management of diabetes and cardio-metabolic syndrome. Today the treatment of diabetes is experiencing a very positive moment because some innovative drugs are available and their efficacy is not only in reducing the blood sugar, but also in reducing the cardiovascular risk, and also the risk of chronic kidney disease and therefore the correlated cardiovascular risk, and ultimately the risk of dialysis. The new guidelines capture the new treatment paradigm of the cardio-metabolic syndrome by showing how the new therapies (GLP1 receptor agonists and glycozines) have been included in the new document, effectively modifying the previous recommendations, and completely replacing, for example, the sulphonylureas, the most used drugs in the treatment of diabetes so far.

However, there are two relevant issues that act as barriers still hindering the achievement of the goals: 1. the non-adherence to therapy by the patient and 2. the therapeutic inertia by the HCP. Non-adherence is a clear consequence of therapeutic inertia, which is the resistance by clinicians to use innovative, more effective and at the same time safer drugs, which would make it possible to reach the set targets in a simpler and safer way. The low level of therapeutic adherence by patients is strictly related to the lack of self-motivation that physicians are unable to inspire and transfer to their patients.

Prof. Avogaro's final recommendation is a call to action to support the multi-specialist approach in the management of the diabetic patient and also the empowerment of all stakeholders involved in order to build a more fruitful HCP-patient communication as the real added value able to promote a concrete therapeutic alliance.

Ovidio Brignoli (Vice President, Italian Society of General Medicine and Primary Care-SIMG, Brescia) brings the point of view of the general practitioners underlining as they have always been called upon to deal with the management of cardio-metabolic pathology in its complexity. He pointed out that about an average of 10% of the patients that an Italian GP follows is represented by people with type 2 diabetes with related cardiovascular pathologies. Dr. Brignoli underlined how the therapeutic inertia issue experienced by GPs, is attributable on the one hand to the fact that, unfortunately, the GPs were allowed to prescribe the new pharmacological categories just only a couple of years ago, and on the other hand to the habit of using a therapeutic approach more focused on the treatment of the pathology and less on the personalization of the approach, thus circumventing the implementation of a personalized therapy which should gradually become the standard approach to follow.

Another barrier identified by Dr. Brignoli was the complexity of the development of PDTAs shared and agreed upon by all the stakeholders as well as the long-standing historical lack of culture of performance's evaluation that is the measure of the outcome of the work of GPs (issue applicable not only in the field but also to physicians working in hospital).

Therefore, his proposed suggestions were:

- ensuring training courses for GPs focused not only on the pathology itself but rather on the process of taking charge of the person with diabetes; from a logistic point of view it would also be useful to guarantee operational support to the GPs through the collaboration of a nurse who could help with the management of the daily working in the ambulatory. This could help to reduce the flow of patient referring to the hospital;
- changing the method of managing chronicity on the territory by defining it by indicators and by processes to offer a better quality of taking charge of the management of non-complex diabetic patients;
- involving the General Medicine in performing clinical research in the field gathering useful and interesting data to forward to specialists.

Annalisa Mandorino (Secretary General of Cittadinazattiva-Active Citizens Association, Rome) brought the point of view of the citizen/patient agreeing with what has been stated by all the previous speakers. She remarked that the very low level of collaboration between the general practitioner and the specialist in the hospital and the lack of integration of the specialists among each other, in particular between the two main stakeholders such as diabetologists and cardiologists, is the main gap to fill in to achieve an effective approach for people living with diabetes. A practical example of this situation is the lack of a developed PDTA where the two components "diabetologist-cardiologist" are properly represented ensuring a pragmatic and successful patient management.

This scenario seems to be confirmed by a recent survey to diabetic patients conducted by Cittadinanzattiva which reveals that 53% of the responders stated that they are not (or they have never been in the past) included in tailored PDTA.

Furthermore, the survey shows that vast majority of patients interviewed declare that they are paying out of their own pocket for medical devices or visits and clinical tests necessary for the management of their disease.

It was also underlined by Annalisa Mandorino that the issue of ineffective communication between healthcare professionals and patients is one of the crucial elements that still contributes to keeping very low the percentage of therapeutic adherence in diabetic patients that is around 50 %, an average value already evaluated in other chronic pathologies.

BEST PRACTICE IN ITALY: VIRTUOUS EXAMPLES

At the end of the round table, three examples of successful best practices to improve the management of diabetic patients with cardiovascular risk have been presented as concrete examples of collaboration between hospitals and general medicine in the field in three different Italian regions, through the synergy between diabetologists and cardiologists:

1. in Lombardy: at the IRCCS Galeazzi-Sant'Ambrogio Hospital (Milano);
2. in Piedmont: the Regional Diabetic Register at the University Hospital "Maggiore della Carità" (Novara);
3. in Latium: the initiative implemented by ASL Roma 2, the Italian largest ASL (Local Health Authority).

1) **Isabella Bosi** (Director, Internal Medicine Department, IRCCS Ospedale Galeazzi-Sant'Ambrogio, Milan) explained how the Diabetology-Cardiology Project, started in 2022, is an excellent example of collaboration that can be implemented in practice. The project consists in the standardized sharing between diabetologists and cardiologists of the management of the patient during the hospitalization but also during the follow up and during outpatient visits. The sharing practice is about of both organizational and therapeutic-pharmacological aspects. This constant knowledge exchange among HCPs allows the reduction of cardiovascular complications and of the related associated costs as well as the improvement the QoL of the person with diabetes.

2) **Gianluca Aimaretti** (President-Elect Italian Society of Endocrinology-SIE, Director of SCU Endocrinology, Maggiore della Carità University Hospital, Novara) presented the experience of the Regional Diabetic Registry in Piedmont in people with diabetes and CVD that started working in 2016 by the need to address type 2 diabetes mellitus in terms of complexity and multidisciplinary. The Piedmont Territorial Network provides assistance to diabetic or endocrinological patients by promoting integration between local specialists, hospitals and general practitioners, both in the therapeutic diagnostic approach and in counseling and therapeutic education. The Network is therefore able to identify specific pathways for diabetes and its complications, for endocrine and metabolic diseases and for pregnant women by involving the professional figures in charge, as well as all the necessary specialists.

3) **Giorgio Casati** (General Director, ASL Roma 2 - the largest Local Health Authority in Italy assisting more than 2 million patients), presented the health database of information available on 1.300,000 people containing all the diagnostic-therapeutic pathways of patients suffering from diabetes, heart failure and dyslipidemia. This sizeable database also represents a way to monitor the therapeutic pathways of patients. Among the many initiatives promoted and organized by ASL Roma 2, a project that involves the use of an experimental platform for the digital management of people affected by

chronic pathologies ensuring a multi-skills approach is running. This is a “pilot project” involving 33 general practitioners with the aim to define and monitor the personalized path for the individual patient directly through the platform. Indeed, the GPs can directly plan and book specialist consultations and diagnostic procedures thus being constantly informed about results and involved in setting up the patient journey by collaborating directly through the platform with all specialists involved.

Furthermore, a particular mention was also made to the “Curare@casa - Care@Home” project, an initiative focused on fragile patients who can be constantly monitored remotely via home device, ensuring the preventing from hospitalization. The monitoring of patient's status is guaranteed twice a day through a telemedicine system which transmits the parameters established by hospital specialists who are able to arrange any appropriate diagnostic-therapeutic interventions, in case of need.

Conclusions

The take home message strongly shared by all the KOLs underlines how the strengthening of collaboration between General Practitioners and physicians working in hospital, firstly cardiologists and nephrologists, is not yet a widespread working practice on a national scale but, where instead it is a consolidated practice, as documented by the concrete examples illustrated during the round table, it is able to offer an excellent service to the diabetic patient who can be successfully followed throughout the entire patient journey, from diagnosis to follow-up.

The diabetic patient with cardiovascular complications is a person who needs the activation and monitoring of an integrated care pathway where a holistic approach of the patient is achieved by the synergistic alliance of different competencies, between specialists within hospitals and, above all, between specialists in hospital and general practitioners working locally in the field.

Another aspect stressed out and shared among KOLs was related to the need of strengthening the doctor-patient communication. A good communication between the two actors involved favors the establishment of a virtuous relationship which can be considered propaedeutic to the establishment of a therapeutic alliance between patient and his/her physician. This can have as a direct consequence an improvement in adherence to therapy, unfortunately still dramatically low (50%) in chronic patients including people suffering from diabetes with cardiovascular complications.

The mutual exchange of information and the creation of a relationship of trust between the healthcare professional and the citizen/patient is fundamental indeed in promoting both the patient's ability to correctly understand the instructions received and the doctor's ability to correctly motivate the patient to adhere to the prescribed therapy properly.

All KOLs agreed on the need to organize another round table to concretely formulate a joint action plan that could fill the emerged gaps by trying to expand, for example, some of the best practices shared during the discussion.

Finally, the Italian Heart Foundation underlined the importance that the virtuous collaboration with the global network may continue, also thanking the companies that support the WHF's activity such as Ely Lilly and Novo Nordisk who contributed to the drafting of the roadmap with the hope that they still continue to collaborate and support the necessary next steps.