

Clinical inertia in Italy and clinical practice

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The AMD Annals initiative has been using for a long time a series of indicators of clinical inertia, focusing on the late initiation of insulin treatment, lipid lowering treatment, and blood pressure lowering treatment, as well as on the failure to achieve at least acceptable targets for major indicators of diabetes care, which are metabolic control, lipid control, and blood pressure control.

Having used these indicators for long time allowed us to look at their improvements overtime: there was a substantial improvement in anticipating the intensification of therapy and in reaching specific therapeutic targets, even if much more needs to be done for many patients. Even in terms of major intermediate outcomes, there has been an improvement in the last few years in terms of the number of patients with poor outcomes, such as HbA1c >9%, or LDL cholesterol \geq 130 mg/dL, or blood pressure \geq 140/90 mmHg. Of course, the situation is not the same for all the indicators, and much more has to be done for blood pressure: we need to focus not only on metabolic control, but also on the overall cardiovascular risk.

Another way of looking at the problem of clinical inertia is to evaluate the average HbA1c level at the time of add-on of a second drug to metformin monotherapy, or add-on to dual oral therapy with a third drug. From 2005 to 2019, not too much has changed in terms of HbA1c at the moment of add-on to metformin, and the HbA1c at the moment of addition of a third drug has improved a little bit over time⁽¹⁾. On the other hand, one year after the add-on, the HbA1c level has decreased progressively over the time, which is an indirect indication of therapy intensification after the adding-on of a second drug or a third drug to the ongoing therapy. A new project is now ongoing, that is based on artificial intelligence and it will give us much more information on which are the major determinants of clinical inertia, and which patients are more likely to be at risk of clinical inertia.

Now, let's look at the impact of the Covid-19 pandemic on the overall care provided by Diabetes Clinics. In 2020, the pandemics brought to a dramatic decrease in the total number of prescriptions of glucose lowering drugs, particularly during the phase of lockdown from March to June 2020, with a relative decrease of more than 60% overall. The decrease in the number of visits during the whole year has been around



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30%, which means that there is the potential risk for clinical inertia related to the reduction in the number of encounters between the patients and the health care system, particularly Diabetes Centers.

In 2019, there were more than 531,000 patients with at least one visit at a Diabetes Clinic, while in 2020 the patients who had at least one visit at a Diabetes Center were 383,441, plus about 140,000 patients who had at least one prescription following a remote contact. In other words, there was a reduction of about 28% in the number of patients who had at least one diabetes visit in 2020 compared to 2019, but summing up the number of patients with at least one visit and those with at least one prescription, the overall number is nearly the same in 2019 and 2020, which means that Diabetes Clinics were able to reach almost all patients with type 2 diabetes during 2020. Not all the patients were seen at a Diabetes Clinic: many of them were likely contacted by phone, messages, or emails. Nevertheless, these data show that Italian diabetes care services were able to ensure continuity of care for most of the patients during the pandemics.

However, some data are matter of concern: the number of the patients at their first visit at a Diabetes Clinic was 60% lower in 2020 as compared to 2019. This implies that many patients were not able to access for the first time a diabetes clinic, and they were probably precluded the possibility to be prescribed new drugs, considering that new classes of glucose lowering drugs can only be prescribed by specialists at Diabetes Centers.

The same figures emerge for patients with newly diagnosed diabetes, who were 23% less in 2020 than in 2019, suggesting a possible delay in diagnosis and effective treatment. These data can be used to make a projection at the national level. Considering that in Italy there are more than 3.7 million people with diabetes, 50% of whom are seen by Diabetes Clinics, we can estimate that during 2020 about 100,000 first visits and about 30,000 new diagnoses of diabetes were lost because of the problems caused by the Covid pandemics.

When comparing the characteristics of patients attending Diabetes Centers during 2020 to those of patients with remote contact, it emerged that individuals who did not attend Diabetes Centers were more likely to be older and with longer diabetes duration, but without major differences in terms of insulin treatment or major cardiovascular disease. On the other hand, they were less likely to

be treated with new drugs as compared to patients attending the clinics.

In terms of process measures, there has been a reduction in the rate of performance of different procedures in patients who were not attending Diabetes Clinics; however, this reduction has not been as substantial as we could expect, considering that these patients were not seen in diabetes centers. In fact, for many of these patients we still have information about lipid profile, albuminuria, and other parameters.

In terms of intermediate outcome measures, the most important message emerging from the data is that the level of metabolic control was exactly the same in those patients who attended the Diabetes Clinics and in those who were contacted by phone, by email, or by other methods. For all the intermediate outcome measures, no particular problem was observed for those patients who were not attending diabetes centers; the higher prevalence of individuals with eGFR below 60 mL/min is likely to be related to the older age of patients who did not attend the diabetes center.

As for the clinical inertia indicators used in the AMD Annals initiative, the percentages are only slightly higher for those patients who did not attend Diabetes Clinics than for those who attended the centers. These findings suggest that diabetes centers were able to efficiently manage these patients from remote. The same is true for the major intermediate outcome indicators: the proportion of patients with HbA1c >9% was slightly higher for those patients not attending the diabetes centers overall in 2020 compared to 2019, but differences were very small, showing that the healthcare system was successful in ensuring adequate care to almost all patients with type 2 diabetes.

In summary, these data suggest that Italian diabetes centers have been able to respond to the Covid-19 emergency very efficiently, by combining site visits with remote contacts. However, a large number of patients were precluded the possibility of a first visit to a diabetes center, and for many patients the diagnosis of diabetes will be postponed. The traditional AMD Annals indicators suggest only a slight worsening of the quality of care in 2020 as compared to 2019, and remote contacts, mainly by telephone or email/message, allowed to maintain the continuity of specialist care and ensured adequate metabolic control, even if monitoring of diabetes complications would require a more

structured telemedicine approach. It is likely that this type of approach will be very useful even once the emergency related to Covid-19 is overcome; the combination of outpatient visits and remote monitoring through telemedicine will represent the new paradigm for the management chronic diseases in general, not only diabetes.

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