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Annals of Medical Research and Practice

Original Article

Comparative analyses of type 2 diabetes mellitus care at primary and tertiary healthcare settings in Malta: A cross-sectional study

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Received: 31 March 2023
Accepted: 09 December 2024
Published: 21 April 2025

DOI
10.25259/ANMRP_8_2023

Quick Response Code:

Supplement material available on:
https://dx.doi.org/ 10.25259/ANMRP_8_2023

ABSTRACT

Objectives: Diabetes mellitus (DM) is a global epidemic, with 537 million adults living with DM in 2021, out of which 90% suffer from type 2 DM (T2DM). Malta, a European country, is no exception. Different global organizations have set forward DM care guidelines. The study aims to explore whether DM guidelines are utilized as part of the standard care practice in Malta across both primary and tertiary settings.

Material and Methods: An anonymous literature-based questionnaire was developed by the authors and disseminated among doctors working at the only state's hospital endocrinology department and primary healthcare. Descriptive analyses were performed.

Results: Discrepancies in guideline usage were observed between participants, with the National Institute for Health and Care Excellence guidelines being mostly favored by participants irrespective of their place of work.

Conclusion: Management of T2DM patients in Malta appears to be following different care plans, resulting in potentially different investigations and treatments. It is, therefore, advisable that a local guideline is created to ensure a standardized care plan among all T2DM in Malta. This will enable homogenous treatment between primary and tertiary care.

Keywords: Diabetes mellitus, Guidelines, Healthcare center, Mater Dei hospital

INTRODUCTION

Diabetes mellitus (DM) is a global epidemic, with the International Diabetes Federation (IDF) reporting that by the end of the year 2021, 537 million adults were living with DM (IDF Diabetes Atlas 10th Edition, 2021).[1] When compared with the year 2019, a 16% (74 million) raise in newly diagnosed DM has been noted (IDF Diabetes Atlas 10th Edition, 2021).[1] DM is also a cause of morbidity and mortality in Malta. Malta is a small European country in the middle of the Mediterranean Sea with a total population of 0.54 million for the year 2022 (Trading Economics 2022).[2] In 2018, it was reported that in Malta, DM contributed to 5.6% of total deaths in males and 5.7% of deaths in females [National statistics office (NSO) annual report 2018].[3]

Diabetes has a significant impact on the quality of life of persons with diabetes and their families, especially when complications arise (IDF Diabetes Atlas 10th Edition, 2021).[1] The rise in Type 2 DM (T2DM) is driven by a complex interplay of socio-economic, demographic, environmental, and

genetic factors (Cuschieri, 2020).[4] The key contributors to this epidemic in Malta have been noted to include urbanization, an aging population, decreasing levels of physical activity, and increasing prevalence of overweight and obesity (Ministry of Health Malta. Diabetes: A National Public Health Priority A National Strategy for Diabetes, 2016–2020).[3]

Aim and objectives

Numerous guidelines, including those by the National Institute for Health and Care Excellence (NICE), American Diabetes Association (ADA), World Health Organization (WHO), and IDF, have been established using evidence-based data targeting the care and management for adults (aged 18 years and over) with T2DM. These guidelines focus on patient education, dietary advice, health risk factors, and blood glucose monitoring, among other aspects. The main aim of this study is to explore whether any of these guidelines are being used on a local level as part of the standard caring practice and, if so, which guidelines are being used. This is being done to evaluate if there are any discrepancies between primary health and tertiary healthcare settings in T2DM care and the use of guideline. Such information will determine whether a standardized national guideline for T2DM care is recommended.

MATERIAL AND METHODS

Malta has both a public healthcare system, known as the government healthcare service and a private healthcare system. On the island of Malta, there is one government tertiary hospital Mater Dei Hospital (MDH), while another smaller tertiary hospital (Gozo General Hospital) is situated on the smaller sister island of Gozo. Across the islands, there are 10 government primary health centers (HCs) situated in different localities. These medical facilities offer primary care service for free to all tax paying citizens as well as European Union (EU) citizens on presentation of a valid European health insurance card (Cuschieri, *et al*., 2019).[5] On the other hand, there are numerous private hospitals and clinics where people can attend healthcare services against an out-of-pocket fee. In Malta and Gozo, patients with T2DM are either diagnosed incidentally at our tertiary hospital or during routine follow-ups at primary HCs or through private clinics. Patients with T2DM can then be followed up at the endocrinology department at the tertiary hospital or also at HCs' diabetic clinic which is manned by general practitioners with special interest in diabetes. The latter service has been set up in partnership with the tertiary hospital to increase the accessibility and enhance the management care of T2DM.

An anonymous questionnaire was created by the authors. The questionnaire gathered data including the demographics of the responder, which T2DM guidelines are used by the doctor, which investigations are booked for T2DM patients, what treatment is started on diagnosis, and what is done in situations of uncontrolled T2DM. Quantitative analyses were performed on the free text, with different themes being identified and reported. A copy of the questionnaire is found as part of the Supplement material. In addition, a comparative analysis of the different T2DM guidelines considered as part of this study can also be found as part of the Supplement material.

Study population

For this study, only doctors working on the island of Malta were considered due to accessibility issues. Considering Malta is the main island, this study still provides an adequate snapshot of the guideline/s practice followed by doctors. The questionnaire was distributed through email with the aid of the head of departments (endocrinology department at MDH and healthcare centers). The target study population was doctors working at the diabetes clinic at the tertiary hospital and the HCs.

Data collection

The data collection period was from the end of May 2022 till the end of June 2022. Considering the General data protection regulation (GPDR) regulations and the nature of this study, it was not possible to identify doctors working in the private sector. Therefore, the study was carried out only among doctors working within the Government of Malta healthcare setting.

Ethical approval for this study was obtained from the local ethics committee of the University of Malta [Malta Medical Journal (MED)-2022-00081]. Permission for dissemination was also obtained from the Department of Endocrinology at MDH and the local HCs General Practitioners' Committee.

Study design and analysis

The study was a questionnaire-based observational study. Data collection was through Google Forms, that was later translated into a spreadsheet for analysis purposes. The analysis of data was carried out by the three authors. The data were grouped into appropriate themes, and statistical analysis was done using Microsoft Excel®. For categorical data, comparative analysis was performed using Chi-squared. Follow-up care plans were compared between doctors working in the state hospital as opposed to those working at primary health care using the Chi-squared test.

RESULTS

A total of 101 participated, with a male predominance (55.4%). The participant demographic characteristics are shown in Table 1. Most of the responders (29.7%) were between the ages of 31 and 40 years.

Table 1: Demographic characteristics of the study participants.

Characteristics	*n*=101	%
Gender		
Female	45	44.6
Male	56	55.4
Prefer not to say	0	0
Age groups		
30 or younger	17	16.8
31–40 years	30	29.7
41–50 years	24	23.8
51–60 years	26	25.7
61 or over	4	4
Location		
Mater Dei Hospital	40	39.6
HealthCare Center	61	60.4
Location of healthcare center		
Paola	13	21.3
Kirkop	0	0
Cospicua	4	6.6
Floriana	13	21.3
Gzira	3	4.9
Birkirkara	4	6.6
Rabat	4	6.6
Mosta	12	19.7
Victoria Gozo	4	6.6
Qormi	3	4.9
Telemedicine for the past 2 years	1	1.6

T2DM follow-ups and care plans

Most of the doctors (68.3%) follow up with their patients every 6 months, while 19.8% follow up with their patients yearly and 11.9% follow up with patients as required, based on the patient's symptoms, diabetes control, hemoglobin A1c (HbA1c) control, change in treatment, pregnancy, perioperative patients, and any recent hypoglycemic episodes ($P = 0.004$).

HbA1c is ordered following every visit by most of the doctors (68.3%). While 19.8% order HbA1c yearly, 1% every 6 months and 10.9% order the test based on their patients' requirements ($P = 0.173$). The importance of exercise and the patient's goals is discussed regularly during the consultation by 83.2% of the doctors, while nutritional goals are discussed by 87.1% during a typical consultation ($P = 0.076$ and $P = 0.083$, respectively). In addition, during a normal consultation, most doctors (97%) encourage their patients to keep a record of their blood glucose levels ($P = 0.154$).

76.2% of doctors reported discussing long-term complications with their patient, and 82.2% actively look out for complications ($P = 0.009$), 87% of which work at the healthcare center. All participating doctors reported to monitor their patient's blood pressure for hypertension. Even though more than 70% of patients monitor their weight patients should still undergo capillary blood glucose to monitor diabetes control. Urine dipstick should also be performed to check for nephropathy.

99% of the participants start their patients on metformin as first-line treatment of type 2 DM, whereas only 1% start their patients on sodium-glucose cotransporter-2 inhibitor or Glucagon like peptide-1 agonists. Sulfonylureas are the most common second-line treatment prescribed by doctors (73%), although 8% prefer insulin while 19% had other preferences.

The initiation of pharmacologic therapy is mostly based on the HbA1C level ($P = 0.001$). At the HCs, most initiate treatment at an HbA1C level of 7.5, whilst at MDH, most initiate at HbA1C level of <7. Out of the 101 participants, 84.2% actively monitor for side effects of medications, such as diarrhea in metformin and hypoglycemia in gliclazide. 15.8% do not monitor actively for side effects.

Investigations performed

A consensus was observed between responders working in Mater Dei and in Primary Healthcare centers on when patients are referred to nephrology, i.e., when the GFR declines <25 mL/min/1.73 m^2 or when the albumin-to-creatinine ratio is elevated. Of note, the urea and electrolyte investigation was the most common blood investigation ordered (95%) for T2DM, whereas more than 88% of doctors order liver function tests, complete blood count, HbA1c, and lipid profile. Fasting and random blood glucose are ordered by <50% of the doctors who answered the questionnaire.

Referral to other healthcare professionals

The typical scenarios when individuals with T2DM are referred to a nutritionist by doctors (both working in Mater Dei and in Healthcare centers) include (i) on the diagnosis of T2DM, (ii) when the patient is obese, (iii) if the patient is struggling to lose weight despite eating "healthy," (iv) when the patient is finding it difficult to plan meals, (v) when the patient has little insight into carbohydrate counting and a correct diet to follow, (vi) if reexperiencing recent episodes of hypoglycemia, and (vii) all insulin-dependent patients.

74% of the participants refer their patients to ophthalmology yearly ($P = 0.001$), with 89% of participants in healthcare centers making up the majority of those who prefer. It was noted that doctors referring their patients less frequently to ophthalmology are the result of performing an ophthalmic examination themselves. While 65% refer to podiatry yearly ($P = 0.001$), with the majority of 85%, being doctors situated at healthcare centers. Referral to the cardiology

department was noted to occur for various reasons, such as in the presence of cardiac signs, ECG changes, and so on. The different reasons for referral can be found as part of the supplement material. Of note, 90.3% of participants working in the primary healthcare setting refer their patients to a diabetologist for various reasons, as shown in Table 2.

DISCUSSION

T2DM poses a major threat to health and our economy not only on an individual and population level but also on a global level (IDF Diabetes Atlas 10th Edition, 2021).[1] T2DM pathophysiology, diagnostic criteria, and treatment modalities have been established throughout the centuries (Cuschieri, 2019).[5] Even though across the years, numerous medical advancements for T2DM have been established, T2DM prevalence is on the rise worldwide.

Most diabetic patients in the western world are diagnosed in the primary HCs. Overall, primary health care is associated with lower costs of care, higher satisfaction of the population with its health services, better health levels, and lower medication use (Starfield, 1994).[6] In Malta, a Maltese Transition Project was carried out in HCs between 2001 and 2004, and it has shown that from 12,227 patients encountered by general practitioners, 398 (88%) of those patients had T2DM (Soler and Okkes, 2005).[7] In Malta, newly diagnosed patients with DM are typically diagnosed by their general practitioner at the HC during regular health check-ups (Soler and Okkes, 2005).[7]

Table 2: The various reasons doctors at primary health care refer to tertiary health care.

Reasons for referral to diabetologist in Tertiary health care	*n*	%
Poor control	25	43.86
Need for schedule 5*	6	10.53
Complex case	3	5.26
Persistently high HbA1c	3	5.26
Maximum oral treatment	2	3.51
When a patient requires insulin	3	5.26
Need for schedule 5*, new cases, poor control	1	1.75
On diagnosis	5	8.77
Non-compliance to medication	1	1.75
Depending on BMI	1	1.75
On diagnosis, poor control	1	1.75
Poor control when patient requires insulin	2	3.51
Depends on case	1	1.75
All patients	1	1.75
new diagnosis	1	1.75
Total	56	98.25

*Schedule 5: Entitlement to free Medicinal. BMI: Body mass index, HbA1c: Hemoglobin A1c

In fact, general practitioners (GPs) have an active role in the management of diabetic patients as they provide routine medical care, including ordering laboratory investigations, undergoing physical examinations, and providing medicine prescriptions. GPs also act as a bridge of care for T2DM patients and the rest of the multi-disciplinary team, including endocrinologists, ophthalmologist podiatrists, pharmacists, registered nurses, registered dietician nutritionists, certified diabetes care and education specialists, mental health professionals, fitness professionals (Bonner *et al*., 2016).[8] On the other hand, endocrinologists who specialize in DM can provide the patient with their expertise, tools, and resources specific to their individual symptoms and condition (Soler and Okkes, 2005).[7] In fact, a study performed by Healy *et al*. (2018)[9] concluded that even though general practitioners are fundamental for caring for patients with T2DM, it is beneficial for patients with T2DM to be seen at least once by endocrinologists, particularly when diabetes is poorly controlled. Indeed, this echoes the findings of our study.

It is fundamental for doctors who are working in primary HCs and those working in tertiary centers to keep up to date with continuous advancements in research and technology to fight the T2DM epidemic (Healy *et al*., 2018).[9] This has resulted in the development of multiple guidelines to standardize appropriate therapy and to disseminate the information (Grol *et al*., 1998).[10] The Institute of Medicine (IOM) defines clinical practice guidelines as "statements that include recommendations intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" (Shekelle, 2022).[11] Guidelines highlight current literature and new evidence, and they create an easy stepwise approach to the management of diseases, the targets for disease control, and the standards of care. In fact, the use of guidelines in clinical practice improved the quality of care received by patients (Shekelle, 2022).[11] When doctors use different guidelines as part of their care treatment plan, they expose their patients to different investigations, treatments, and continuity of care (Grol *et al*., 1998).[10]

In our study, both doctors working in primary HC and those at MDH mainly made use of NICE guidelines. Different reasons may be contributing to the doctors' preference toward the NICE guidelines, which may vary between the ease of guideline accessibility, to the guideline recommendations that are more acceptable to Maltese patient, among others. It is recommended that further research targeting the reasons behind the doctors' preference toward guidelines is carried out.

Patients with T2DM (especially the elderly) should undertake resistance training at least 2–3 times/week (Sato, 2020).[12] Only NICE and IDF guidelines give recommendations on prescribing exercise regimens in T2DM. Given that most participants, locally follow the NICE guidelines, the majority

of T2DM individuals are being prescribed regular exercise (NICE guidelines, 2015 and IDF, Recommendations For Managing Type 2 Diabetes In Primary Care, 2017).[13]

T2DM patients should be referred to the ophthalmic department yearly as DM may result in diabetic retinopathy (Turbert, 2021). NICE, WHO, and ADA guidelines suggest that the doctor should refer to an ophthalmologist upon diagnosis, whereas IDF suggests screening every 1–2 years. This is reflected in the results, more so in those working in HCs, as most clinicians in Malta refer to ophthalmology as per NICE guidelines. Doctors in HCs could be referring their patients to ophthalmology more due to various reasons, such as different level of expertise in ophthalmic examination. Doctors practicing at the HC may also be choosing to refer their patients to focus on other aspects of the diabetic consultation whilst leaving the specialist to focus on any eye pathology (Turbert *et al*., 2021).[14]

All drugs, including metformin, have their side effects. It is important for prescribers to monitor drug side effects as these side effects may show ineffective drug treatment, non-compliance, and adverse drug reactions (Dighriri *et al.,* 2021).[15] NICE guidelines discuss the importance of up-titrating metformin slowly to reduce the risk of gastrointestinal side effects, as well as stresses the importance of monitoring side effects and the effect this has on drug compliance. A good number of participants (over 80%) do, in fact, discuss this with their patients (NICE guidelines, Dec 2015).

Considering that the NICE guidelines were the preferred T2DM management guide for the participating doctors, it was expected that all management care pathways for T2DM would be similar. Yet, some differences could be observed.

Dietary factors are of paramount importance in the management and prevention of type 2 diabetes (Sami *et al*., 2017),[16] yet different guidelines provide different recommendations. The WHO and NICE guidelines agree on their dietary recommendations, while IDF has its own recommendations. Even though most doctors in our study claim to follow the NICE guidelines, not every doctor tackles dietary habits during consultations. (NICE guidelines, Dec 2015. IDF. Recommendations for Managing Type 2 Diabetes in Primary Care, 2017. WHO; 2020).

Patients should be referred to podiatry to prevent peripheral vascular disease and peripheral diabetic neuropathy (Bonner *et al*., 2016).[8] NICE guidelines suggest that only if a limb or life-threatening foot problem occurs should the clinician immediately refer otherwise, patients require education as part of the management. However, almost three-fourths of our study's doctors refer their patients to podiatry even though this is not recommended by NICE guidelines.[17] This can be due to various contributing factors such as the physician's gender, own expertise, as well as doing what other physicians are doing within the HCs (IDF. Recommendations For Managing Type 2 Diabetes In Primary Care, 2017.[18] WHO; 2020). (Turbert *et al*., 2021).[14]

The initiation of T2DM pharmacologic therapy is mostly based on the HbA1c level (Dighriri *et al*., 2021).[15] Different guidelines recommend different HbA1c levels for initiation of treatment, yet all agree that metformin is the initial drug of choice. NICE guidelines provide different target ranges; however suggests that for those controlling their diabetes with lifestyle and a single drug of choice, the target should be 6.5. This is a much lower threshold than those reported by this study and might suggest that the local doctors follow different guidelines than the NICE when it comes to initiation of treatment based on HbA1c. It may also be reflective that the Malta patients carry different characteristics that merit a higher HbA1c threshold for initiation of treatment. However, this merits further research.

Although it was observed that doctors in Malta prefer to follow the NICE guidelines in managing T2DM, differences were still evident in their practices. Yet, some practicing doctors opt to follow other guidelines rather than the NICE guidelines. Considering that other guidelines provide different recommendations; with caution, one would speculate that patients with T2DM are not receiving the same care, with potentially different management plans. It is evident that doctors need a standardized local guideline. Such guideline needs to be constructed by considering the different practices and local patients' characteristics as well as the availability of medicines and healthcare services to ensure that the best standardized care management plan is offered to the local T2DM population.

Implementations to practice

As part of the study, participants shared their opinions of how the system could be improved. A consensus was reached that the health system has shortcomings, with limited time allocated for consultations being center stage, along with the need for continuity of care for these patients, ideally in the primary healthcare setting. In addition, it was noted that the lack of local guidelines presents challenges when dealing with patients. Therefore, it is evident that a health system reform in dealing with T2DM should be considered as well as equipping the primary health care with tools to deliver a continuity of care for these patients. It is also recommended that local guidelines are developed to ensure a standardized care plan for T2DM in Malta and Gozo.

Study limitations

Validation of the questionnaire was not done, and this might have affected the results of this study. Due to GPDR constraints, private clinics, and hospitals could not be

included in this study. The questionnaire was distributed electronically only, thus automatically excluding those doctors who may not be technology-friendly. Due to the anonymity distribution process of this questionnaire, it was not possible to calculate the response rate.

CONCLUSION

Different guidelines are being followed by caring T2DM doctors in Malta, resulting in the delivery of different management plans. A standardized local guideline is recommended to be developed to ensure that optimal management is provided to patients with diabetes living in Malta.

Ethical approval: The research/study complied with the Helsinki Declaration of 1964.
Declaration of patient consent: Patient's consent is not required as there are no patients in this study.
Financial support and sponsorship: Nil.
Conflicts of interest: There are no conflicts of interest.
Use of artificial intelligence (AI)-assisted technology for manuscript preparation: The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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How to cite this article: Caruana R. Comparative analyses of type 2 diabetes mellitus care at primary and tertiary healthcare settings in Malta: A cross-sectional study. Ann Med Res Pract. 2025;6:1. doi: 10.25259/ANMRP_8_2023