Acta Biomed 2023; Vol. 94, Supplement 3: e2023189 DOI: 10.23750/abm.v94iS3.14406

Original article

Mediterranean Diet (MedDiet) and Lifestyle Medicine (LM) for support and care of patients with type II diabetes in the COVID-19 era: a cross-observational study

Giovanni Cangelosi[1], Iolanda Grappasonni[2], Cuc Thi Thu Nguyen[3], Mattia Acito[4], Paola Pantanetti[1], Andrea Benni[1], Fabio Petrelli[2]

[1]Units of Diabetology, ASUR Marche, Fermo, Italy; [2]School of Medicinal and Health Products Sciences, University of Camerino, Camerino, Italy; [3]Department of Pharmaceutical Administration and Economics, Hanoi University of Pharmacy, Hanoi, Vietnam; [4]Department of Pharmaceutical Sciences, University of Perugia, Perugia, Italy

Abstract. *Introduction:* Diabetes affects 425 million people worldwide (range 20-79 years). Of these, between 87% and 91% are affected by type 2 diabetes mellitus (DM2), and 79% live in medium/low income countries. *Objectives:* the main objective of the study was to observe, through the administration of specific questionnaires, the relationship existing between metabolic clinical parameters, quality of life of patients with DM2 and adherence to the MedDiet at first access to Diabetes Center in the period after the COVID-19 pandemic. The secondary objective was to observe the results obtained both qualitatively and quantitatively. *Materials and Methods:* the study was a cross-sectional study. Two types of questionnaires were administered; the first (Medi-Lite) that expresses with specific score the level of "Mediterraneanness" diet while the second concerns the assessment of the SF-36 quality of life. Quantitative data such as biochemical and anthropometric parameters were collected and, through multiple regression, based on the method of least squares (OLS Model) and through the Gretl open source software were analyzed. *Results:* fifty-two of the 90 patients at first access to the recruiting center in the period considered, met the inclusion criteria and and written consent. None of the estimated coefficients was statistically significant except Diastolic Blood Pressure (DBP), with a p-value < 0.0466. With an improvement in the level of "Mediterraneanness" there is a favorable relationship regarding creatinine, High-Density Lipoprotein (HDL), DBP and glycemia. *Conclusions:* The necessary post-COVID-19 territorial management cannot fail to take into consideration this new method of care which puts the patient and the community to which they belong at the center of the complex process of assistance. (www.actabiomedica.it)

Key words: COVID-19, Type II diabetes (DM2), Lifestyle Medicine (LM), Mediterranean Diet (MedDiet)

Introduction

Diabetes affects 425 million people worldwide (range 20-79 years). Of these, between 87% and 91% are affected by type 2 diabetes mellitus (DM2) and 79% live in medium/low income countries. With this dizzying rate of growth, in 2045 the figure will increase to 629 million individuals, with an overall cost for health institutions of approximately 727 billion US dollars (1). In Italy, in 2016 (ISTAT data), over 3 million and 200 thousand people were declared to be affected by diabetes, a figure corresponding to approximately 5.3% of the entire population (16.5% among the over-65's). From a precise analysis of these data, it can be observed that diabetics are obese and sedentary in 28.9% of cases among males and in 32.8%

among women in the age group ranging from 45 to 64 years (2). Lifestyle Medicine (LM) is a modern scientific discipline, with a multi-disciplinary approach, which mainly deals with prevention, treatment and research on the main chronic pathologies linked to modifiable environmental factors such as incorrect diet, physical inactivity, stress and excessive alcohol and smoking from an early age (3-5). Adherence to the Mediterranean Diet (MedDiet) can prevent the onset of DM2 and improve the quality of life of those affected (6). In this connection, numerous benefits have been observed for people with DM2 who decide to adhere to the MedDiet, including improvement of general glycemic control and reduction of overall mortality and cardiovascular diseases (CVC) (7,8).

Objectives

The main objective of the study was to observe, through the administration of specific questionnaires, the relationship between metabolic clinical parameters, quality of life of patients with DM2 and adherence to the MedDiet at first access to the Asur Marche – Area Vasta 4 Fermo Diabetes Center in the post-COVID-19 pandemic period. The secondary objective was to observe both qualitatively and quantitatively the results obtained.

Materials and methods

The study was a cross-sectional study. All subjects with the following inclusion criteria took part in the observation:

- patients of the U.O.S.D Asur Marche - Area Vasta 4 Fermo Diabetes Center;
- subjects at first access to the recruiting center;
- subjects who gave written consent subject to specific information;
- adults of both sexes;
- subjects able to participate in the study independently or with the support of specifically trained personnel.

The study was carried out after the first wave of the COVID-19 pandemic, specifically from June 2020 to August 2020. Two types of questionnaires were administered and considered for convenience as dependent variables. One (Medi-Lite) relates to the patient's adherence to the MedDiet (9) (Annex 1), through a specific score, it expresses the level of "Mediterraneanness" of the subject's diet. The other, in its validated version in Italian, concerns evaluation of the SF-36 quality of life (10) (Annex 2), it expresses the level of well-being of the patient (and, taken altogether,) according to a specific score which provides for a subdivision into eight specific domains (physical activity, role limitations due to physical health, role limitations due to emotional state, physical pain, perception of general health, vitality, social activities, mental health). The assessment can be carried out for single domain. Quantitative data were collected such as biochemical parameters [Fasting Glucose (FG), Glycosylated Hemoglobin (HbA1c), Creatinine, Total Cholesterol (TC), High-Density Lipoprotein (HDL), Low-Density Lipoprotein (LDL), Systolic (Arterial) Blood Pressure (SBP) and Diastolic (Arterial) Blood Pressure (DBP)] and anthropometric ones [Body Mass Index (BMI)]. Through multiple regression based on the least squares method (OLS Model) applied using based standard equation:

$$y_i = \alpha + \beta_i x_i' + \varepsilon_i$$

Specific Econometrics for Regression Gretl open source (11) software were analyzed, the relationship and the possible trend of the functional link between the quality of life and degree of adherence to the MedDiet of the subjects taking part in the study and their respective blood and anthropometric parameters were evaluated. The study was carried out according to the ethical principles of the Declaration of Helsinki and consent was obtained in written form from all the participants after they received the necessary information on the objectives of the observation. The analysis of the results was carried out in such a way that, according to the reference legislation, the privacy of all patients was guaranteed.

Results

Fifty-two of the 90 patients at first access to the recruiting center in the period considered, met the inclusion criteria and gave written consent was given to participate in the study (response rate 65%) equally distributed between males and females (summary in Table 1).

From the estimation output of Model 1 (summarized Table 2), the positive values of the estimated regression coefficients relating to the blood parameters of the i-th patient, such as LDL (+0.0013), HDL (+0.0055), TC (+0.0046), SBP (+0.0082) and HbA1c% (+0.0053), represent the constant absolute variation achieved on average by the state of health of the i-th subject. The unitary increase of the characteristics

Table 1. Population characteristics.

No. PATIENTS	52								
MALE	26								
FEMALE	26								
PARAMETERS OBSERVED	**BMI**	**FG (mg/dl)**	**HbA1c (%)**	**HbA1c (mmol/mol)**	**LDL (mg/dl)**	**HDL (mg/dl)**	**TC (mg/dl)**	**CREATININE (mg/dl)**	**SBP (mm/hg)**	**DBP (mm/hg)**
Avarege	30.46	174.83	8.60	71.37	135.19	51.35	201.58	0.93	138.85	82.88
SD	5.64	73.93	2.32	25.91	43.12	20.29	49.42	0.32	17.08	14.19
Min	19.6	76	5.54	37	48	21	86	0.51	110	60
Max	50	368	15.23	143	292	146	314	2.12	190	140

Table 2. General Health Variable Regression.

Model 1: OLS, observations 1-52 **Dependent variable: General Health**				
	Coefficient	*St. Error*	*T ratio*	*p-value*	
Const.	0.926279	1.04143	0.8894	0.3788	
BMI	-0.0127238	0.0184892	-0.6882	0.4951	
LDL	0.00132195	0.00287527	0.4598	0.6481	
HDL	0.00555767	0.00500294	1.111	0.2729	
TC	0.00459668	0.00270485	1.699	0.0966	*
Creatinine	-0.0955751	0.305252	-0.3131	0.7558	
SBP	0.00815430	0.00631863	1.291	0.2039	
DBP	-0.00821730	0.00837682	-0.9810	0.3322	
FG	-0.00085245	0.00206875	-0.4121	0.6824	
HbA1c (%)	0.00528034	0.00577309	0.9146	0.3656	
Dependent var. average	2.519231		Dependent var. SQM	0.699871	
Residual sum squares	17.80504		Regression E.S.	0.651099	
R-squared	0.287250		R-squared corrected	0.134518	
F (9, 42)	1.880745		P-value (F)	0.081757	
Log-Likelihood	-45.91899		Akaike's criterion	111.8380	
Schwarz's criterion	131.3504		Hannan-Quinn	119.3186	

Table 3. Mediterranean Diet Variable Regression.

Model 2: OLS, observations 1-52 Dependent variable: Mediterranean diet					
	Coefficient	*St. Error Std.*	*t ratio*	*p–value*	
Const.	9.64315	3.77463	2.555	0.0143	**
BMI	0.0676762	0.0670138	1.010	0.3183	
FG	-0.00409266	0.00749814	-0.5458	0.5881	
LDL	0.00690064	0.0104214	0.6622	0.5115	
HbA1c (%)	0.0170734	0.0209245	0.8160	0.4191	
HDL	-0.00161954	0.0181331	-0.08931	0.9293	
TC	0.00591176	0.00980370	0.6030	0.5497	
Creatinine	-0.842843	1.10638	-0.7618	0.4504	
SBP	0.00973550	0.0229018	0.4251	0.6729	
DBP	-0.0622656	0.0303616	-2.051	0.0466	**
Dependent var. average	9.653846		Dependent var. SQM	2.299911	
Residual sum squares	233.9026		Regression E.S.	2.359896	
R-squared	0.132953		R-squared corrected	-0.052843	
F (9, 42)	0.715586		P-value (F)	0.691585	
Log-Likelihood	-112.8800		Akaike's criterion	245.7600	
Schwarz's criterion	265.2724		Hannan-Quinn	253.2406	

considered indicates that the relationship between the variables is positive; as one grows, so does the other. The negative values of the estimated regression coefficients relating to the blood and anthropometric parameters of the i-th patient, such as BMI (-0.013), creatinine (-0.095), DBP (-0.008) and FG (-0.00085), represent the constant absolute variation achieved on average by the state of health of the i-th subject. None of the estimated coefficients appear to be statistically significant with respect to the improvement in general health. However, a favorable relationship can be observed between general health and levels of creatinine, DBP and glycemia.

From the estimation output of Model 2 (summarized Table 3), positive values of the estimated regression coefficients relating to the blood parameters of the i-th subject, such as BMI (+0.007), LDL (+0.007), TC (+0.0006), SBP (+0.009), and HBA1c% (+0.02), represent the constant absolute change achieved on average with adherence to the MedDiet of the i-th subject. The unitary increase of the characteristics considered indicates that the relationship between the variables is positive; as one grows, so does the other. The negative values of the estimated regression coefficients relating to the blood parameters of the i-th subject, such as FG (-0.004), HDL (-0.0016), creatinine (-0.843) and DBP (-0.0062), represent the constant absolute variation experienced on average with the adherence of the i-th subject to the MedDiet. None of the estimated coefficients is statistically significant except DBP, with a p-value < 0.0466. With an improvement in the level of "Mediterraneanness" there is a favorable relationship regarding creatinine, HDL, DBP and glycemia.

Conclusions

The present study, albeit with obvious limitations in terms of sample size, highlights the fact that targeted education actions in the field of nutrition and disease management can positively influence some blood and anthropometric parameters related to DM2. This preliminary investigation has highlighted the importance of educating the patient to opt for correct

lifestyles, which also include conscious choices in the food sector. The study is the first step in a broader investigation that will be conducted with a view to promoting patient training aimed at verifying, over time, the positive effects on the general health of the subjects involved. In this context, actions aimed at educating healthier eating habits and lifestyles are to be considered an integral part of the prevention and/or treatment of various chronic diseases such as diabetes but also obesity, hypertension and chronic diseases in general (12-14). The COVID-19 pandemic, caused by Severe Acute Respiratory Syndrome Coronavirus 2 (Sars-Cov-2), immediately appeared to be the most tragic global pandemic event of the twentieth century, with almost half a billion infections (data from 5 April 2022) and over six million dead. About two years after its worldwide diffusion, it reached dimensions that were difficult to control and above all highlighted the difficulties of territorial management of chronic pathologies (15,16). From the first moments of the pandemic it immediately appeared evident that the presence of severe comorbidities such as arterial hypertension, chronic obstructive bronchitis, immunosuppression and above all DM2, were an unfavorable prognostic element for the evolution of COVID-19 (17,18). On DM2 management, the ability to actively involve the patient in the articulated treatment process could be decisive, in both the short and medium term, for the purposes of the necessary post-COVID-19 health reorganization (19-24). The necessary post-COVID-19 territorial management cannot fail to take into consideration this new method of care which puts the patient and the community at the center of the complex assistance process (25-31).

Conflicts of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

Ethics Approval and Consent to Participate: Not applicable

Availability of Data and Materials: The data that support the findings of this study are available on request from the corresponding author, IG upon reasonable request.

Authors' Contributions: FP and GC designed and conducted research, analyzed data and wrote the paper. All authors approved the final manuscript.

References

1. International Diabetes Federation. IDF Diabetes Atlas. 8th Ed. 2017. Available online: https://www.diabetesatlas.org /en/resources/ [Last accessed: 2022 December 1].
2. Istituto Nazionale di Statistica (ISTAT). Il diabete in Italia. Available online: https://www.istat.it/it/archivio/202600 [Last accessed: 2022 December 1].
3. Hivert MF, Arena R, Forman DE, et al. Medical Training to Achieve Competency in Lifestyle Counseling: An Essential Foundation for Prevention and Treatment of Cardiovascular Diseases and Other Chronic Medical Conditions: A Scientific Statement From the American Heart Association. Circulation. 2016;134: e308–e327. doi: 10.1161 /CIR.0000000000000442
4. Sagner M, Kats D, Egger G, et al. Lifestyle medicine potential for reversing a world of chronic disease epidemics: from cell to community. Int J Clin Pract. 2014; 68(11): 1289–1292. doi: 10.1111/ijcp.12509
5. Petrelli F, Scuri S, Tanzi E, et al. Lifestyles and discomfort in a sample of young Romanian students. J Prev Med Hyg. 2018; 59(3): E230-E235. doi: 10.15167/2421-4248 /jpmh2018.59.3.985.
6. Vitale M, Masulli M, Calabrese I, et al. On behalf of the TOSCA.IT Study Group. Impact of a Mediterranean Dietary Pattern and Its Components on Cardiovascular Risk Factors, Glucose Control, and Body Weight in People with Type 2 Diabetes: A Real-Life Study. Nutrients. 2018; 10: 1067. doi.org/10.3390/nu10081067
7. American Diabetes Association. Standards of Medical Care in Diabetes 2017 Abridged for Primary Care Providers. Diabetes Care. 2017; 40(Suppl 1): S1-135. doi: 10.2337 /cd16-0067
8. Associazione Medici Diabetologi (AMD) – Società Italiana di Diabetologia (SID). Standard italiani per la cura del diabete mellito 2018. Available online: https://www.siditalia.it /pdf/ Standard%20di%20Cura%20AMD%20-%20SID% 202018_protetto2.pdf [Last accessed: 2022 December 1]
9. The Medi-Lite project. Available online: https://medi-lite. com/index.php/medi-lite [Last accessed: 2022 December 1]
10. Apolone G, Mosconi P. The Italian SF-36 Health Survey: translation, validation and norming. J Clin Epidemiol. 1998; 51 (11): 1025-1036. doi: 10.1016/s0895-4356(98)00094-8.
11. Cottrell A, Lucchetti R. Gretl User's Guide. Gnu Regression, Econometrics and Time-series Library. March, 2023

12. Ricci G, Tomassoni D, Pirillo I, et al. Obesity in the European region: social aspects, epidemiology and preventive strategies. Eur Rev Med Pharmacol Sci. 2018;22(20):6930-6939. doi:10.26355/eurrev_201810_16163.
13. Nittari G, Scuri S, Petrelli F, Pirillo I, di Luca NM, Grappasonni I. Fighting obesity in children from European World Health Organization member states. Epidemiological data, medical-social aspects, and prevention programs. Clin Ter. 2019;170(3):e223-e230. doi:10.7417/CT.2019.2137.
14. Grappasonni I, Petrelli F, Scuri S, Mahdi SS, Sibilio F, Amenta F. Knowledge and Attitudes on Food Hygiene among Food Services Staff on Board Ships. Ann Ig. 2018;30(2):162-172. doi:10.7416/ai.2018.2207.
15. World Health Organization (WHO). Coronavirus. Available online: https://www.who.int/ health topics/coronavirus [Last accessed: 2022 November 1]
16. Covid-19 Coronavirus Pandemic COVID-19 Coronavirus Pandemic. Available online: https://www. worldometers. info/coronavirus/?utm_campaign=homeAdvegas1? [Last Accessed: 2022 April 5]
17. Kumar A, Arora A, Sharma P, et al. Is diabetes mellitus associated with mortality and severity of COVID-19? A meta-analysis. Diabetes Metab Syndr. 2020;14(4):535-545. doi: 10.1016/j.dsx.2020.04.044.
18. Puig-Domingo M, Marazuela M, Giustina A. COVID-19 and endocrine diseases. A statement from the European Society of Endocrinology. Endocrine. 2020; 68 (1): 2–5. doi: 10.1007/s12020-020-02294-5
19. Petrelli F, Cangelosi G, Nittari G, et al. Chronic Care Model in Italy: a narrative review of the literature. Prim Health Care Res Dev. 2021: 22(e32): 1–7. doi: 10.1017/S1463423621000268
20. Petrelli F, Cangelosi G, Scuri S, et al. Conoscenze alimentari in pazienti afferenti ad un centro di diabetologia. Acta Biomed. 2020; 91(S3): 160-164 doi: 10.23750/abm.v91i3-S.9418
21. Petrelli F, Cangelosi G, Scuri S, et al. Diabetes and technology: A pilot study on the management of patients with insulin pumps during the COVID-19 pandemic. Diabetes Res Clin Pract. 2020 Nov;169:108481. doi: 10.1016/j.diabres.2020.108481.
22. Natalucci V, Villarini M, Emili R, et al. Special Attention to Physical Activity in Breast Cancer Patients during the First Wave of COVID-19 Pandemic in Italy: The DianaWeb Cohort. J Pers Med. 2021;11:381. doi.org/10.3390/jpm1105038.
23. Acito M, Rondini T, Gargano G, et al. How the COVID-19 pandemic has afected eating habits and physical activity in breast cancer survivors: the DianaWeb study. J Cancer Surviv. 2023; 17: 974–985. https://doi.org/10.1007/s11764-022-01294-w
24. Lazzeroni P, Motta M, Monaco S, et al. Improvement in glycaemic control in paediatric and young adult type 1 diabetes patients during COVID-19 pandemic: role of telemedicine and lifestyle changes. Acta Biomed. 2021; 92(5): e2021399. doi: 10.23750/abm.v92i5.11911
25. Scuri S, Tesauro M, Petrelli F, et al. Use of an Online Platform to Evaluate the Impact of Social Distancing Measures on Psycho-Physical Well-Being in the COVID-19 Era. Int J Environ Res Public Health. 2022; 19: 6805. doi.org/10.3390/ijerph19116805
26. WHO. Diabetes. Available online: https://www.who.int/health-topics/diabetes. [Last Accessed: 2023 August 28]
27. Ministero della Salute. Linee di indirizzo sull'attivita fisica per le differenti fasce d'eta e con riferimento a situazioni fisiologiche e fisiopatologiche e a sottogruppi specifici di popolazione. Available online: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2828_ allegato.pdf [Last Accessed: 2022 April 5]
28. International Diabetes Federation. The global impact of Diabetes. Available online: https://www.idf.org/ [Last Accessed: 2022 April 5]
29. Cangelosi G, Grappasonni I, Pantanetti P, et al. Nurse Case Manager Lifestyle Medicine (NCMLM) in the Type Two Diabetes patient concerning post COVID-19 Pandemic management: Integrated-Scoping literature review. Ann Ig. 2022;34(6):585-602. doi: 10.7416/ai.2022.2500
30. D'Alleva A, Leigheb F, Rinaldi C, et al. Achieving quadruple aim goals through clinical networks: A systematic review. J Healthc Qual Res. 2019; 34(1): 29-39. doi: 10.1016/j.jhqr.2018.10.010
31. Standard italiani per la cura del diabete mellito 2018. Available online: https://aemmedi.it/wp-content/uploads/2009/06/AMDStandard-unico1.pdf [Last Accessed: 2022 April 5]

Correspondence:
Received: 06 March 2023
Accepted: 10 June 2023
Dr. Paola Pantanetti
Units of Diabetology, ASUR Marche
Area Vasta 4, 63900 Fermo, Italy
E-mail: paola.pantanetti@sanita.marche.it