

The household financial burden of Diabetes Mellitus and its effect on adherence and beliefs about medicines among patients followed in primary care settings in a Sousse governorate, Tunisia

Le fardeau financier des ménages lié au diabète sucré et son impact sur l'adhérence et les croyances concernant les médicaments chez l'échantillon de la population tunisienne

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ABSTRACT

Background: Diabetes Mellitus (DM) represents a significant public health challenge on a global scale, with rising prevalence rates and substantial economic burdens. The current study aimed to measure DM related Out-of-Pocket Costs among Tunisian patients and its effect on adherence to treatment and beliefs about medicines.

Methods: A cross-sectional study was conducted from May to July 2023 in basic health facilities in Sousse governorate, Tunisia. For data collection, we used the Arabic version of self-report scale "The Cost for Patients Questionnaire" in order to measure Health-Related Out-of-Pocket Costs. Assessment of patients' adherence to diabetes medications was made using the eight-item Morisky Medication Adherence Scale (MMAS-8). The third part included a self-reported questionnaire to measure patients' perceptions of medication; the Beliefs about Medicines Questionnaire (BMQ-specific).

Results: A total of 273 patients responded to the questionnaire from 8 Basic Health Center (BHC) in Sousse. The mean age of the patients was $60 \pm 11,3$ years, with extremes ranging from 28 to 86 years and Females predominance, with a sex ratio equal to 0.73. The study revealed that the median duration of diabetes among patients was 6 years, with (IQR) of [3-15] years. Among the respondents, 39.3% reported having paid employment, with a median salary equal to 600 Tunisian Dinars and (IQR) of [250-900]. Patients had a median direct medical cost of 75 TND (IQR: [20-170]). The median indirect medical cost for patients was 8 TND (IQR: [2.7-19.75]). Which gives a total of annual cost of 94.59 USD. The study found that the median total cost per month was significantly lower for non-adherent patients at 17.2 [5.84-36] ($p=0.001$) compared to adherent patients, who had reported a higher median total cost per month at 26 [11-26.32] ($p=0.001$). The Beliefs about Medicines Questionnaire (BMQ) revealed moderate to high perceived necessity of medications (mean score of 3.99 ± 0.74) and a moderate level of concern (mean score of 3.28 ± 0.7). BMQ Necessity was significantly higher among adherent patients while BMQ concern was lower among them.

Conclusion: Diabetes is a significant economic burden that has a direct impact on patients and healthcare systems. Addressing the issue of out-of-pocket costs and providing support to alleviate concerns about diabetes treatment could improve adherence rates and overall health outcomes for patients with diabetes in Tunisia.

Keywords: Diabetes; Cost, Out-Of-Pocket; Treatment; Adherence; Beliefs

RÉSUMÉ

Contexte : Le diabète sucré (DM) représente un défi important de santé publique à l'échelle mondiale, avec des taux de prévalence croissants et des charges économiques importantes. La présente étude vise à mesurer les coûts de charge liés aux DM chez les patients tunisiens et leur impact sur l'adhésion au traitement et les croyances concernant les médicaments.

Méthodes : Une étude transversale a été menée de mai à juillet 2023 dans des établissements de santé de base du gouvernorat de Sousse, en Tunisie.

Résultats : L'âge moyen des patients était de $60 \pm 11,3$ ans, avec des extrêmes allant de 28 à 86 ans et une prédominance féminine, avec un ratio hommes-femmes égal à 0,73. Les patients avaient un coût médical direct médian de 75 TND (IQR : [20-170]). Le coût médical indirect médian pour les patients était de 8 TND (IQR : [2,7-19,75]). Ce qui donne un coût annuel total de 94,59 USD. L'étude a révélé que le coût total médian par mois était significativement plus faible chez les patients non adhérents à 17,2 [5,84-36] ($p=0,001$) comparé aux patients adhérents, qui avaient rapporté un coût total médian par mois plus élevé à 26 [11-26,32] ($p=0,001$). Le questionnaire Beliefs about Medicines Questionnaire (BMQ) a révélé une nécessité perçue modérée à élevée des médicaments (score moyen de $3,99 \pm 0,74$) et un niveau modéré d'inquiétude (score moyen de $3,28 \pm 0,7$). La nécessité en QM était significativement plus élevée chez les patients adhérents tandis que la préoccupation du QB était plus faible chez eux.

Conclusion : S'attaquer au problème des coûts à la charge et apporter un soutien pour atténuer les préoccupations concernant le traitement du diabète pourrait améliorer les taux d'adhésion et les résultats globaux de santé des patients diabétiques en Tunisie.

Mots clés : Diabète; Coût, à la charge ; Traitement ; Adhésion ; Croyances

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INTRODUCTION

Diabetes Mellitus (DM) is a metabolic disease resulting in an inappropriately elevated blood glucose level. It represents a global public health problem and is responsible for significant morbidity and mortality. Type 1 diabetes and type 2 diabetes (T2D) are the main subtypes, each of which involves either a defective insulin secretion and/or insulin action respectively (1). The prevalence of DM has been rising exponentially over the last few decades as the International Diabetes Federation (IDF) has estimated that as of 2021, 10.5% (536.6 million people) of individuals between 20 and 79 years old had DM (2). This figure is expected to rise to 12.2% (783.2 million people) by 2045 (3).

DM is a growing health concern in Tunisia, where the prevalence of the disease is increasing at an alarming rate. A 2015 study projected a continued rise in type 2 diabetes prevalence in Tunisia through 2027, using a validated forecasting model. While the study does not provide specific estimates for 2021, it underscores the growing burden of the disease in the country. (4).

Overall, DM is an important public health issue in Tunisia, and it is clear that more must be done to address both the growing prevalence of the disease and its associated economic burden (5).

The financial burden of diabetes on individuals is substantial, encompassing both direct and indirect costs. Direct medical costs include routine doctor visits, prescription medications, insulin, glucose monitoring, and other necessary treatments. In addition to these, individuals often incur out-of-pocket expenses such as transportation to medical appointments, medical supplies, specialized diets, and health insurance premiums (6).

Indirect costs—though less visible—can be equally significant. These include lost wages and reduced productivity, as individuals with diabetes may need to take time off work or may be unable to perform at full capacity due to the physical and psychological demands of the disease (7).

Beyond individual cases, the overall economic impact of diabetes also includes the costs associated with disease complications such as eye and foot care, and the emotional toll of managing a chronic illness. A systematic review found that the average annual direct medical cost incurred by patients/households in both lower-middle income countries (LMICs) and upper-middle income countries (UMICs) was similar—\$546.93 and \$505.02, respectively—with an overall average of \$536.46. The average annual indirect cost was estimated at \$78.94. Notably, Sudan, a LMIC, reported the highest direct medical cost, with patients incurring an average of \$1367.67 annually (8).

The economic burden of DM is significant in Tunisia, with patients spending an important part of their total household income on medical care related to diabetes. This expenditure is often greater than what is spent on food or other essential items, leading to an increased risk of poverty and deprivation (6,7). Out-of-pocket health expenditures include they can represent the payment of cash or goods for direct health care services, such as medicines, consultation fees, and laboratory diagnostic

tests. Thus, they can represent constitute a substantial portion of household expenditure. The incidence of catastrophic out-of-pocket health payments, defined by the World Health Organization (WHO) as exceeding 40% capacity to pay for health care (8), is linked to a vicious cycle of impoverishment because households have to scale back spending on other necessities such as food and children's education (9). Few studies have explored out-of-pocket health expenditures, and many have focused on catastrophic health expenditures (10,11). Documenting levels and determinants of out-of-pocket health expenditures can help inform public policies aimed at achieving universal health coverage.

To our knowledge, the only study that has examined this issues in Tunisia was dealing with direct cost of the ambulatory management of diabetes (12).

→ The aim of this study is to measure DM related Out-of-Pocket Costs among Tunisian patients followed in primary care settings in Sousse Governorate, Tunisia ; and its effect on treatment adherence and beliefs about medicines.

METHODS

Study setting

A cross-sectional study was conducted from May to July 2023 (data collection) in basic health facilities in Sousse governorate, Tunisia.

Population and data collection

Inclusion and exclusion criteria

Inclusion Criteria

Participants were eligible for inclusion if they met the following conditions :

- Adults diagnosed with type 2 diabetes mellitus.
- Followed up in primary health care settings in the region of Sousse.
- Receiving treatment with one or more oral hypoglycemic agents (OHA), with or without insulin therapy.
- Patients with or without common comorbidities such as hypertension, dyslipidemia, or diabetic nephropathy were also included.

Exclusion Criteria

Type 1 diabetes, gestational diabetes, cognitive impairment, secondary diabetes and patients who refused to participate

Sample size and sampling method

A convenient sample was selected and all patients accessible at the time of data collection were asked to participate. The minimum required sample size was calculated using Cochran's formula for estimating sample size in cross-sectional studies:

$$n = \frac{Z^2 \cdot p \cdot (1-p)}{i^2}$$

The minimum sample size has been calculated based on a precision of 5%, a confidence level of 95%, and an expected prevalence of diabetes of 23%, as reported in the literature (13). Therefore, a sample of 273 patients was required.

Study instrument

We used the Arabic version of self-report scale “The Cost for Patients Questionnaire” in order to measure Health-Related Out-of-Pocket Costs (14). The Arabic version of the questionnaire was developed through a rigorous forward-backward translation process, following international guidelines for the cross-cultural adaptation of health-related instruments (15). Authorization for the translation and use of the instrument was obtained from the original authors (Table 1). Assessment of patients’ adherence to diabetes medications was made using medication adherence report scale (MARS 5). The MARS 5 is a self-report scale that has been used to measure medication adherence behavior in many chronic diseases including diabetes. The Arabic version has demonstrated good reliability and predictive validity. It has been previously validated in a population with chronic illnesses, demonstrating good internal consistency (Cronbach’s $\alpha > 0.70$) and predictive validity (16). The third part included a self-reported questionnaire; the Beliefs about Medicines Questionnaire (BMQ-specific). This well-validated tool is used to measure patients’ perceptions and insights of a particular medication in more definite situations such as chronic illnesses (16).

Authorization for the use of the validated Arabic version was obtained from the authors.

The study was conducted over a period of 5 months (Data collection and analysis)

We extracted the unit costs in Tunisian Dinars then converted the costs to United States dollars (US\$) using a yearly average conversion rate of 3.08 Tunisian Dinars per US\$ in 2023 (17).

Table 1. step of cross-cultural adaptation process

STEP	DESCRIPTION
1. AUTHORIZATION	Permission to translate the questionnaire was obtained from the original authors.
2. FORWARD TRANSLATION	Two independent bilingual translators (Arabic-native, fluent in English) translated the original version.
3. RECONCILIATION	The research team compared the two forward translations and produced a reconciled Arabic version.
4. BACKWARD TRANSLATION	A third independent translator (English-native, unaware of the original scale) translated it back to English.
5. EXPERT COMMITTEE REVIEW	A panel of experts (including public health researchers and primary care professionals) reviewed all versions.
6. PRE-TESTING / PILOT	The pre-final Arabic version was tested on a sample of 15 patients to assess clarity and cultural relevance.
7. FINALIZATION	Minor modifications were made based on pre-test feedback to produce the final Arabic version.

Data analyses

Statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS) for Windows version 21. For qualitative data, variables were expressed as frequencies and percentages. For quantitative data, the normality of the distribution was tested by the Kolmogorov-Smirnov test. Quantitative variables with a normal distribution were expressed as means $\pm$ standard deviation; those without a normal distribution were expressed as medians with inter-quartile range (IQR). The Chi-square test was used to compare percentages; the student t test was used to compare means. We set the statistical significance threshold p value at 0.05.

RESULTS

Socio-demographic and clinical characteristics of patients

A total of 273 patients responded to the questionnaire from 8 Basic Health Center (BHC) in Sousse. The mean age of the patients was 60 ± 11.3 years, ranging from 28 to 86 years. There was a female predominance, with a sex ratio of 0.73. Most participants had primary school education level (42.6%).

More than half of the patients (52.4%) reported having children residing in the same household. The children's median age was 12 months (IQR: 6.25–17 months; range: 1–192 months).

The study revealed that the median duration of diabetes among patients was 6 years, with (IQR) of [3–15] years. The range of diabetes duration varied from 0 to 35 years.

Among the respondents, 39.3% reported having paid employment, with a median salary TND 600 (IQR: TND 250–900; range: TND 0–2 000). For further details about demographics and clinical characteristics of the study population see Table 2.

Direct and indirect costs of diabetes

The analysis indicated that patients had a median direct medical cost of 75 TND (IQR: [20–170 TND]), with costs ranging from 0 to 1210 TND. The median indirect medical cost for patients was 8 TND (IQR: [2.7–19.75]; range: 0–189.6TND). The median total monthly cost was 24.28 TND (IQR: [8.93–48.86]), with a maximum total cost of 453.33 TND (Table III).

Diabetes costs and salary

The study demonstrated a statistically significant positive correlation between the direct medical costs of diabetes and monthly salary ($r = 0.278$, $p < 0.05$), as well as between the direct non-medical costs of diabetes and monthly salary ($r = 0.252$, $p < 0.05$). A significant correlation was also found between total costs monthly of diabetes-related costs and monthly salary ($r = 0.339$, $p < 0.05$) (Table 3 and Table 4).

Table 2. Socio-demographic and clinical characteristics distribution of patients with diabetes in Sousse, Tunisia (N=273)

Socio-demographic characteristics of patients	n (%)
Gender (264)	
Male	112(42.4)
Female	152(57.6)
Geographical origin(264)	
Urban	68(74.2)
Rural	196(25.8)
School level (272)	
Primary	116(42.6)
Secondary	43(15.8)
Certificate of professional competence	15(5.5)
Baccalaureate	24(5.9)
University degree	16(8.8)
Master	4(1.5)
Other	54(19.9)
Paid employment (270)	
Yes	106(39.3)
No	164(60.7)
If not, why? (110)	
Housewife	9(8.2)
Health problems	11(8.2)
Unpaid work	2(1.8)
Looking for work	15(13.6)
Retirement	41(37.3)
Other	32(29.1)
Family situation (273)	
Married	196 (71.8)
Separated	8(2.9)
In relation	1(0.4)
Divorced	12(4.4)
Widowed	45(16.5)
Single	11(4.0)
person living with him (273)	
Only	41(15.0)
with another person	232(85.0)
Child at home (250)	
Yes	131(52.4)
No	119(47.6)
Salary according to minimum wage (250)	
<SMIG	108(43.2)
≥ SMIG	142(56.8)
Name of BHC (273)	
Chat mariem	15 (5.5)
Laouina city	41(15.0)
Hammam Sousse	14(5.1)
Kalaa kbiraâ	79(28.9)
Kondar	7(2.6)
Msaken	20(7.3)
Nfidha	81(29.7)
South BHC	16(5.9)
Health insurance (273)	
Yes	264(96.7)
No	9(3.3)
Apci (162)	
Yes	94(58.0)
No	68(42.0)

Table 2. (continued) Socio-demographic and clinical characteristics distribution of patients with diabetes in Sousse, Tunisia (N=273)

Socio-demographic characteristics of patients	n (%)
Type of insurance (266)	
CNAM public sector	142 (53.38)
CNAM private sector	21(7.9)
CNAM reimbursement of expenses	25(9.4)
free care scheme	64(24.06)
reduced rate scheme	14(5.3)
Do you have any Co-morbidity? (273)	
Yes	162(59.3)
No	111(40.7)
If so, name it (149)	
Hypertension	99 (66.4)
Coronary	13(8.7)
Lung neoplasia	3(2.0)
Gout	6(4.0)
Osteoarthritis	12(8.1)
Rheumatoid arthritis	1(0.7)
Dyslipidemia	7(4.7)
Hypothyroidism	3(2.0)
COPD	3(2.0)
Allergy	1(0.7)
BPH	1(0.7)

* BHC : basic health center

*CNAM : National Health Insurance Fund

*APCI :fully covered medical conditions

*COPD : Chronic obstructive pulmonary disease

*BPH : Benign prostatic hyperplasia

Table 3. Direct and indirect costs in TND of patients with diabetes in Sousse, Tunisia

		Median medical cost (Q1-Q3) TND*	Annual costs		USD*
			Min	Max	
Direct costs	Direct medical costs				
(over 5months)	For the patient	75 [20- 170]	0	1210	58.44
	For family caregivers	0	-	-	-
	Direct non-medical costs				
	For the patient	4 [0-12,54]	0	1803.52	
	For family caregivers	0 [0-2,19]	0	92	
Indirect costs	Indirect medical costs				
(over 5months)	For the patient	8 [2,7-19,75]	0	189.6	6.23
	For family caregivers	0 [0-12]	0	58.8	-
Total Cost per month		24,28 [8,93- 48,86]	0	453.33	94.59

*TND: Tunisian Dinars

*USD: United States Dollar

Table 4. Correlation between diabetes costs and patients' salary

Costs	Monthly Salary	
	r	p
Direct medical costs		
For the patient	0.278	<10 ⁻³
For family caregivers	-	-
Direct non-medical costs		
For the patient	0.252	<10 ⁻³
For family caregivers	0.001	0.993
Indirect medical costs		
For the patient	-0.017	0.786
For family caregivers	-0.030	0.642
Total Cost per month	0.339	<10 ⁻³

*TND: Tunisian Dinars

*USD: United States Dollar

Diabetes costs and treatment adherence

The study found that the median total cost per month was significantly lower for non-adherent patients at 17.2 TND [5.84-36] ($p=0.001$) compared to adherent patients, who reported a higher median total cost per month at 26 TND [11-26.32] ($p<0.001$). Non-adherent patients reported a lower median monthly salary of 300 TND [200-685] ($p<10^{-3}$), while adherent patients had a higher median monthly salary of 700TND [427-1000] ($p<10^{-3}$) (Table 5).

Table 5. The Impact of Diabetes Costs and Monthly Salary on Treatment Adherence

Costs	Adherence	Median (IQR)	p
Direct medical costS			
For the patient	No	50 [0-120]	0.001
	Yes	100 [38.5-186.5]	
For family caregivers	No	-	-
	Yes	-	-
Direct non-medical costs			
For the patient	No	7 [0-8]	<10-3
	Yes	6 [0-15.04]	
For family caregivers	No	0 [0-0.44]	0.171
	Yes	0 [0-3.47]	
Indirect medical costs			
For the patient	No	6 [0.15-18]	0.172
	Yes	8. 4[3.5-20.28]	
For family caregivers	No	0[0-0]	0.37
	Yes	0[0-0]	
Total Cost per month	No	17.2[5.84-36]	0.001
	Yes	26 [11-26.32]	
Monthly salary	No	300[200-685]	<10-3
	Yes	700[427-1000]	

Concerns about treatment

In our study, the Beliefs about Medicines Questionnaire (BMQ) was used to assess participants' beliefs about their diabetes medications. Analysis revealed a mean score of 3.99 ± 0.74 on the BMQ Necessity subscale, indicating moderate to high perceived necessity of the medications. Scores ranged from a minimum of 1.6 to a maximum of 5. On the BMQ Concerns subscale, the mean score was 3.28 ± 0.7 , indicating a moderate level of concern about their diabetes medication, with scores ranging from 1.5 to 5. The analysis showed no statistically significant negative correlation between BMQ Necessity scores and monthly costs ($r = -0.024$, $p = 0.693$). However, a statistically significant negative correlation was found between BMQ Concerns scores and monthly costs ($r = -0.161$, $p = 0.008$) (Table VI).

Patients who were more adherent to their treatment have a significantly higher BMQ Necessity score than those who adhere less (4.10 vs. 3.82, $p = 0.002$). Conversely, individuals who adhere less demonstrate a significantly higher BMQ Concerns score compared to their more adherent counterparts (3.47 vs. 3.17, $p = 0.001$) (Table 6).

Table 6. The associations between BMQ Necessity and BMQ Concerns about adherence and monthly treatment costs.

Treatment	BMQ Necessity: Beliefs about the personal need for medicines to maintain health	
	Score Mean (SD)	p
Adherence		
No	3.82(0.78)	0.002
Yes	4.10(0.69)	
	r	p
Monthly costs	-0.024	0.693
Treatment	BMQ Concerns: Concerns about the potential adverse effects of medicines	
	Score Mean (SD)	p
Adherence		
No	3.47(0.77)	0.001
Yes	3.17(0.63)	
	r	p
Monthly costs	-0.161	0.008

DISCUSSION

This is a pilot study assessing the out-of-pocket (OOP) expenditure of patients with type 2 diabetes attending a Basic Health Center in Sousse, Tunisia. It also examined their level of medication adherence and concerns.

In Tunisia, where the majority of the population falls within a low or middle-income groups, diabetes-related expenses represent a growing burden for individuals and society (18). Both direct and indirect household expenditures associated with diagnosed diabetes in Tunisia have not

been studied before.

The findings provide valuable insights into the demographic and socioeconomic characteristics of Tunisian diabetes patients. We have reported a predominance of females in the sample, with a sex ratio of 0.73. While globally men tend to have a higher age-standardized prevalence of diabetes, this pattern is not always consistent across regions. In particular, studies from North Africa, including Tunisia, have sometimes reported smaller sex differences or even a reversed pattern, with women showing equal or higher prevalence rates. (19). This highlights the importance of considering regional and population-specific epidemiological data when interpreting sex disparities in diabetes prevalence (20). This highlights the importance of gender-specific considerations in diabetes management. As noted by Ciarambino et al., biological differences between men and women—such as variations in hormone levels, fat distribution, and insulin sensitivity—can influence disease progression and response to treatment. Moreover, gender roles and socio-cultural factors often impact health behaviors, access to care, and adherence to therapy. In regions like North Africa, including Tunisia, these factors may contribute to observed variations in diabetes prevalence and outcomes between men and women. Therefore, tailoring diabetes prevention and management strategies to account for gender-specific needs is crucial to improving health outcomes and reducing disparities. (21). The average age of participants in the study was 60 ± 11.3 years, suggesting a notable prevalence of diabetes among older individuals in the Tunisian population. This finding aligns with the prevalence global consensus that diabetes tends to increase with age, as reported by the International Diabetes Federation. Additionally, 42.6% of the participants had only completed primary education, indicating a need for targeted health education interventions aimed at improving diabetes awareness and self-management skills among individuals with basic literacy levels (22). Participants reported a median diabetes duration of 6 years, with a wide range from 0 to 35 years. This underscores the chronic nature of the disease and emphasizes the need for long-term management strategies to prevent complications and improve outcomes (23). Employment and income are important factors in determining access to healthcare and the affordability of diabetes management. In this study, 39.3% of respondents reported having paid employment, with a median salary of 600 TND. The wide income range (0 to 2000 TND) reflected significant economic heterogeneity within the sample. This economic diversity can significantly affect individuals' ability to afford diabetes-related expenses. Healthcare policymakers must consider socioeconomic disparities when designing interventions and support programs, as lower-income individuals face greater challenges affording medications and may be at a higher risk of non-adherence due to financial constraints.

The OOP costs incurred by individuals living with diabetes represent a matter of serious concern.

The cost analysis provides valuable insights into the economic challenges of managing diabetes for both individuals with the condition and their caregivers. The median direct OOP medical cost for patients was 75

TND (approximately USD 24), with a wide range of costs ranging from 0 to 1,210 TND (approximately USD 389). This observation aligns with existing literature, highlighting the significant heterogeneity in medical expenses associated with diabetes care. Various factors contribute, this variability including treatment modalities, complications, and disparities in healthcare access (24).

Notably, family caregivers reported a median direct medical cost of 0 TND, underlining that the primary financial responsibility lies on the patients themselves. This is consistent with the general understanding that caregivers typically incur indirect costs associated with their caregiving highlights the distinct and substantial financial challenges borne directly by patients (25).

Accurate estimation and understanding of diabetes-related costs have become increasingly important in light of the global rise in diabetes prevalence of this condition worldwide. Our study reported an annual direct OOP medical cost for diabetes at approximately USD 58.44.

Studies conducted in various regions have revealed the multifactorial nature of medical costs associated with diabetes. For example, Butt et al. conducted a study in Pakistan and reported annual direct medical costs for diabetes at approximately USD 639.45 (26). International comparisons have also highlighted geographical variations in healthcare expenditures for diabetes, with annual direct costs ranging from approximately USD 242 in Mexico to as low as USD 11917 in a cost study conducted in the United States (27). The observed cost differences across regions highlight the importance of adopting a nuanced approach when interpreting and generalizing findings. Factors such as local healthcare policies, access to medical services, and economic conditions play a crucial role in shaping the economic landscape of diabetes care (28). The interpretation of differences in OOP costs should be considered in the context of underlying healthcare financing mechanisms, such as insurance coverage and government subsidization, which were not assessed in detail in this study and may influence both the magnitude and distribution of patient expenditures. In addition, Our findings should be interpreted in light of regional variations in healthcare financing models, availability and accessibility of diabetes care services, and the broader economic context, all of which can fundamentally shape the magnitude and patterns of patients' out-of-pocket costs.

The annual direct OOP non-medical cost for patients with diabetes was USD 3.14. In this context, non-medical costs can include expenses such as transportation, special dietary needs, and other lifestyle-related modifications (29). The modest annual direct OOP non-medical cost reported in the study may suggest effective financial protection measures, comprehensive insurance coverage, or potentially low utilization of non-medical services.

To improve the holistic management of diabetes and enhance the quality of life for affected individuals, it is crucial to tailor interventions and support mechanisms that address both medical and non-medical aspects.

The annual indirect medical cost for individuals with diabetes was found to be USD 6.17, highlighting the wider economic impact of direct medical expenses. This cost

includes productivity losses, absenteeism, and caregiving-related expenses(30). In Tunisia, the median monthly wage in 2023 was approximately 850–1,000 TND ($\approx$ 275–325 USD), with a labor market characterized by a high proportion of public-sector employment and informal work in certain regions. Many people with chronic illnesses, including diabetes, are retired, unemployed, or engaged in informal work with limited income variability. In addition, partial subsidization of public transport for elderly and low-income individuals, as well as strong reliance on family support networks (31–33), may contribute to the relatively low indirect OOP costs observed in our sample. Comparable studies, have reported indirect costs ranging from USD45 in Pakistan to USD16,914 in the Bahamas(28). Our findings align with existing evidence that diabetes management imposes not only direct healthcare expenses, such as medications, consultations, and diagnostic tests, but also indirect costs that affect patients and their caregivers, including transportation, time lost from work, and informal caregiving. In the Tunisian context, these indirect costs appear relatively low, likely reflecting a combination of partial public subsidies, strong family support networks, and the local labor market characteristics, which shape both the financial and opportunity burdens of diabetes care. Zhang et al emphasized the importance of incorporating indirect costs into the overall economic burden of diabetes(34). This is crucial for developing comprehensive strategies and policies to support individuals managing diabetes.

Our study found a positive correlation between direct medical costs for patients and their monthly salary ($r = 0.278$, $p < 10^{-3}$), which is consistent with previous research indicating that individuals with higher incomes have greater financial resources to allocate towards healthcare expenses. This implies that as patients' income levels increase, so does their ability to afford and access medical services, medications and potentially more advanced and expensive treatment modalities for diabetes.

These findings must also be interpreted in light of Tunisia's health-financing framework. The Tunisian healthcare system is characterized by a combination of public and private providers, with the public sector offering a basic package of services through a network of primary health care centers. It is estimated that approximately 46% of the population is covered by the National Health Insurance Fund (CNAM), which provides partial reimbursement for outpatient and inpatient care, including medications for chronic conditions such as diabetes(35). However, essential antidiabetic medications are not always available in public pharmacies, often resulting in patients purchasing them at full price from private pharmacies. This inconsistency in supply undermines the protective effect of insurance and exposing patients to significant out-of-pocket (OOP) costs, particularly those with limited financial means (6).

Likewise, the positive correlation between direct non-medical costs for patients and monthly salary ($r = 0.252$, $p < 10^{-3}$) highlights the financial impact of lifestyle changes and non-medical aspects of diabetes care. While higher income levels may allow for healthier lifestyle choices, they may also result in increased expenses for specialized dietary needs and other non-medical aspects of diabetes

management (36).

These correlations support the findings of previous studies that have investigated the link between income and healthcare costs. For example, Dang et al demonstrated that higher income levels are associated with increased healthcare expenditures for individuals with type 2 diabetes(37). This suggests a complex interplay between financial capacity and health-related costs. However, given the cross-sectional nature of our study, causality cannot be inferred. Temporality remains unknown, and reverse causation is possible—for instance, higher healthcare costs might also influence income through work absenteeism or reduced productivity. Moreover, income is closely linked to other sociodemographic and clinical variables (such as education, insurance status, and disease severity) that were not fully accounted for and may confound the observed associations. Future studies employing multivariable modeling or stratified analyses would be valuable to better disentangle these complex relationships and clarify the independent effect of income on healthcare expenditures.

The observed patterns in healthcare costs and treatment adherence among diabetic patients offer insights into the dynamics of diabetes management. Patients who did not adhere to treatment exhibited a significantly lower costs, both in terms of direct medical and non-medical expenses, compared to those who did adhere. This finding suggests financial implications associated with adherence behavior, and indicates that those who invest the most are the most likely to adhere to treatment.

In addition, the extant literature suggests that coverage under such schemes is partial, with many services and medications still requiring out-of-pocket payments. This has been shown to contribute to healthcare inequity (38). This context may help explain observed higher level of adherence to treatment among patients with higher incomes in our study. It is hypothesized that these patients have greater access to private healthcare providers and out-of-stock medications. Conversely, patients with lower incomes may not fully benefit from existing subsidies or insurance schemes, leading to cost-related non-adherence. This finding is consistent with the conclusions of earlier research, which has underscored the economic implications of non-adherence in chronic conditions and highlights importance of interventions designed to enhance patient compliance.

Furthermore, the observed association between monthly salary and treatment adherence highlights the socio-economic dimension of diabetes management. Patients who adhered to treatment reported a significantly higher median monthly salary, which may suggest that greater economic resources facilitate better access to healthcare services, medications, and follow-up. However, this relationship should be interpreted with caution, as correlation does not imply causation. Other factors—such as disease severity, health literacy, or insurance coverage—may simultaneously influence both adherence and income. Nonetheless, this finding is consistent with existing literature emphasizing the complex interplay between socioeconomic status and health outcomes. It also underscores the need for targeted interventions

and supportive policies in Tunisia to reduce economic disparities, ensure equitable access to care, and strengthen adherence among vulnerable populations. (39).

The Beliefs about Medicines Questionnaire (BMQ) was used in our study to assess participants' perceptions of their diabetes medications. The analysis showed that the mean BMQ Necessity subscale score was 3.99 ± 0.74 , indicating a moderate to high perceived necessity of the medications, while the mean BMQ Concerns subscale score was 3.28 ± 0.70 , signifying a moderate level of concern. These findings suggest that patients recognize the importance of their treatments but remain cautious about potential risks. The results are consistent with a similar study conducted in China, where the mean BMQ Necessity and Concerns scores were 3.75 ± 0.40 and 3.15 ± 0.58 , respectively (40). Addressing beliefs is crucial when developing interventions to improve medication adherence and diabetes management.

The observed association between medication adherence and BMQ scores in our study further highlights the role of beliefs in shaping treatment behaviors. Patients with higher adherence had significantly stronger perceptions of necessity (4.10 vs. 3.82 , $p = 0.002$), whereas those with lower adherence expressed greater concerns (3.47 vs. 3.17 , $p = 0.001$). This aligns with evidence from a meta-analysis showing a positive correlation between perceived necessity and adherence (41). Conversely, individuals with lower adherence demonstrated a significantly higher BMQ Concerns score (3.47 vs. 3.17 , $p = 0.001$), reflecting heightened concerns about their medications. Improving patient communication and tailoring interventions to enhance medication adherence in diabetes management is crucial for healthcare providers to address these concerns. Beyond these descriptive results, several contextual factors in Tunisia may help explain these findings. Limited health literacy, cultural perceptions about chronic disease treatment, mistrust in generic drugs, and financial pressures may amplify patients' concerns about long-term medication use. Conversely, individuals with greater access to healthcare services and consistent medical follow-up may be more likely to internalize the necessity of treatment. These dynamics underscore the importance of targeted interventions to strengthen trust and improve adherence (42,43).

For healthcare providers, this means not only educating patients on the clinical benefits of diabetes medications but also directly addressing concerns such as fear of side effects, long-term dependence, and financial burden. Structured patient-provider communication, culturally sensitive counseling, and community-based education initiatives could help bridge the gap between perceived necessity and concerns. At the policy level, improving access to affordable and high-quality medications, as well as supporting pharmacists and diabetes educators in patient counseling, may further reduce barriers to adherence (42,43).

Strength and Limitations:

To the best of our knowledge, this study is a pilot one represents the initial investigation into the out-of-pocket (OOP) burden among Tunisian diabetes patients.

Nevertheless, we acknowledge certain limitations. Firstly, it is crucial to highlight that this study is conducted in a single region, and its findings may not be generalizable to other regions of Tunisia. We did use convenience sample even that may limit generalizability for feasibility reasons, because it is fast and simple, practical for pilot study and allow a quick access to available people which is very hard in our context. For a more comprehensive insight, future studies should encompass a broader, nationwide scope. Furthermore, a key limitation of this study is the absence of randomization, which may affect the external validity of the conclusions drawn from its implementation.

CONCLUSION

Diabetes is not only a public health challenge but also a significant economic burden. Our study reinforces the need for comprehensive policies to reduce out-of-pocket expenditures and improve diabetes care and outcomes, particularly in resource-constrained settings. To alleviate the financial burden on low-income patients with type 2 diabetes, policymakers should consider measures such as subsidies for essential medications and healthcare services. In parallel, educational programs promoting regular physical activity, balanced nutrition, and awareness of diabetes management—including strategies to improve medication adherence and address patient concerns—are essential. Strengthening the healthcare system through investments in infrastructure, healthcare professional training, and patient-centered care is also crucial. Finally, future research should evaluate the long-term impact of adherence on health outcomes and explore interventions designed to reduce out-of-pocket costs, thereby informing more equitable and sustainable diabetes management policies. While our findings provide valuable insights, they should be interpreted in light of the study's limitations, including its cross-sectional design, potential unmeasured confounders, and reliance on self-reported data.

Consent to Participate: Authorization was obtained from the Regional Directorate of health and informed consent from participants.

Ethical clearance to conduct this study was obtained from the Ethics Committee of Sahloul University Hospital, Sousse, Tunisia (number HS 22-2023) Written informed consent was obtained from all participants

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