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Original Article

A Cross-Sectional Analysis of Health Status, Economic Burden, and Lifestyle Factors among Patients with Type 2 Diabetes at a Tertiary Care Hospital

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ABSTRACT

Background: Type 2 Diabetes Mellitus is one of the most prevalent non communicable chronic disease globally. Early detection and modification of lifestyle including diet and physical activity, are crucial to prevent the progression and economic burden experienced by the patient in developing countries like India. **Objectives:** This study aimed to assess the health and economic outcomes associated with diabetes in consideration of lifestyle of patients with T2DM. **Materials and Methods:** A 6-months cross-sectional was conducted in tertiary care hospital. The study included 196 participants diagnosed with T2DM and based on the study criteria. Data collected from patient records and questionnaires were analysed by chi-square, correlation, and linear regression statistical methods. **Results:** Lifestyle habits, diet, and diabetes management were significantly associated with *p*-values <0.05, 95% CI for Chi-square and Pearson correlation. The average monthly cost of managing diabetes was found to be INR 7,197 (85.71 USD), exceeding the national minimum wage per month. **Conclusion:** Thus, the lifestyle factors such as diet, physical activity and healthy habits are effective adjuvants in managing health and economic constituents significantly there by reducing the complications and economic consequences of diabetic patients.

Keywords: Economic evaluation, Health care outcomes, Healthy lifestyle, Type 2 diabetes mellitus.

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INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is one of the Non-Communicable Chronic Diseases (NCCD) largely influenced by genetics, lifestyle, diet, habits, and environmental factors (Boutayeb, 2010; Budreviciute *et al*., 2020; Derman *et al*., 2008; *India - International Diabetes Federation*, n.d.; Ranieri *et al*., 2022). T2DM is characterized by impaired insulin secretion and insulin resistance affecting 90% of individuals worldwide, particularly in low- to middle-income countries, posing an increased mortality rate and reduced quality of life for the patients. The ICMR-INDIAB study reports that about 62.4 million people have diabetes, while 77.2 million are prediabetic in India (Anjana *et al*., 2011; Lambrinou *et al*., 2019). Whereas the global prevalence of diabetes stands at 9.3%, impacting 473 million people, it is predicted to increase to 10.2% i.e.,700 million individuals, by 2045, primarily in high-income countries and urban settings compared to rural (Saeedi *et al*., 2019). Developing countries like India and Nepal face an increased risk of diabetes due to sedentary lifestyles and dietary habits, such as high-carbohydrate consumption, obesity, and insulin resistance for which preventive measures such as lifestyle and dietary changes to lower glycaemic index by including high-protein diets and physical activity play a crucial role (Fitipaldi *et al*., 2018; Shrestha and Ghimire, 2012; Stephenson *et al*., 2014).

Numerous clinical trials have demonstrated that targeted weight reduction, increased physical activity, and the adoption of diets low in saturated fat, fibre and protein rich diets are effective as primary treatments or adjuvants with pharmacological therapy to prevent the progression of the T2DM (*Diabetes Prevention Program (DPP) - NIDDK*, n.d.; Espinosa-Salas and Gonzalez-Arias, 2023; Haase *et al*., 2021; Hill-Briggs *et al*., 2020; Mohamed, 2014; Uusitupa *et al*., 2019). The expenditure for managing diabetes is estimated at $414 billion (Yang *et al*., 2018). By 2030, the global prevalence of diabetes may rise to

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10%, leading to economic costs between $2.12 trillion and $2.48 trillion (Bommer *et al.*, 2018). In India, the annual economic cost for managing diabetes is approximately INR Rs. 10,969.6 ($132.83), where the majority of the expense is related to drug prescriptions, increased with hospitalization and mortality worsens the condition socioeconomically (Fano *et al.*, 2013; L *et al.*, 2024; Shah *et al.*, 2013). Cost-effectiveness analysis conducted by the Diabetes Prevention Program found that interventions applied in clinical practices, particularly lifestyle interventions, were effective across all age groups (Herman *et al.*, 2005). These interventions significantly improve glycaemic control and reduce glycosylated haemoglobin (HbA_{1c}) levels, contributing to better health and improved economic outcomes through cost-effective treatments (García-Molina *et al.*, 2020). Thus, this study aimed to assess the health and economic outcomes associated with diabetes in consideration of the lifestyle of the T2DM patients.

MATERIALS AND METHODS

Study design and study settings

This was a cross-sectional study conducted in tertiary care hospital and research centre in rural settings for a period of 6 months (February 2024 to July 2024). The hospital settings provide multi-speciality facilities for various health issues and diabetic related issues as well and the hospital is accessible to more than three cities. The study was conducted in accordance with the Ethical guidelines for biomedical research on human participants and Declaration of Helsinki; after obtaining approval from the Institution Ethics Committee (IEC/AH&RC/AC/10/2024) and we reported this article as per the STROBE Checklist (Elm *et al.*, 2007). And after explanation of specific of the study informed consent was obtained from the study participants as provided in supplementary file S3 and S4.

Study participants inclusion and exclusion criteria

The T2DM patients aged 18 or above, increased $HbA_{1c} \geq 6.5\%$, RBS ≥ 200mg/dl, FBS ≥ 120 mg/dl and PPBS ≥ 140 mg/dL were considered for this study. After the explanation of all the specific methods, those who were willing to give written consent were included in the study.

Participants less than age 18, T1 DM patients, gestational diabetes patients and those who were not willing to give informed consent were excluded from the study. And patients had right to withdraw from study at any point of the study without any explanation.

Sampling techniques and sample size calculation

Random sampling technique was used to calculate the sample size in this study. We estimated a minimum sample size of 196 participants with a margin of error of 5%, population proportion of 50%, precision of 0.05, at 95% of confidence interval with a prevalence of 8.3% in India according to Indian diabetic federation (*India - International Diabetes Federation*, n.d.). Sample size was calculated by using random sampling method, the desired sample size was calculated by using the formula for infinite sample size (n_0) and was found to be 384. The actual sample size was calculated by using finite sample size (n) formula and was found to be 196.

Formula used to calculate infinite sample size (n_0) was:

$$n_0 = \frac{z^2 P(1-P)}{E^2}$$

Where:

- Z = 1.96 (Z score for a 95% confidence interval)
- P = 50% (population proportion)
- E = 5% (margin of error)

And the finite sample size (n) was Calculated by using following formula,

$$n = \frac{n_0}{1 + \left(\frac{n_0}{N}\right)}$$

Where:

- n_0 = 384 (desired sample size for an infinite population)
- N = 400 (assumed population size)

Thus, the final sample size for the study was found to be 196 participants.

Data collection

Patients demographics details and clinical data such as patient history, age, diabetic status, presence of comorbidities and laboratory reports were obtained from the patients, using a pre-designed data collection form (Supplementary file S1). The pilot study of 30 participants with questionaries resulted 0.870 Cronbach value and reliability analysis interpreting good internal consistency of the questionnaire.

The questionnaire was composed of three parts, Diabetic status of the patient (Part 1) to determine the patient diabetic status and control over the diabetes and was made to scales with score such as 1-10 Indicates Under control, 11-20 Indicates Average control, 21-30 Indicates Poor control. Lifestyle, diet and habits related (Part 2) data of the patient, the pattern of diet, lifestyle and habit among diabetes patients was assessed in this section mainly to know the attitude, perception and knowledge of the diabetic patients where, 1-10 is Modified control on diabetes, 11-20 is Average control on diabetes and 21-30 is Non modified control on diabetes. And Pharmacoeconomic (Part 3) related information of the patient which includes, the economic burden which includes the scales with scores as 1-10 as Acceptable economic status, 11-20 is Average economic status and 21-30 as provided in supplementary file S2.

Statistical analysis

All the collected data were entered into Microsoft Excel sheets, thoroughly verified, and analysed Statistical Package for the Social Sciences (SPSS) free version 25.0 developed by IBM (Armonk, 2017). The categorical and continuous data were presented as frequency with percentages and mean with standard deviation respectively. Chi square and Cor-relation statistical methods were used to check the association between the variables of Parts of the questionnaire i.e., Diabetic status (Part1) and lifestyle, diet and habits parameters (Part 2) with pharmacoeconomic status (Part 3). Linear regression was analysed for the demographics with direct and indirect cost of cost of illness of diabetes.

The indirect cost was calculated based on the human capital approach and India's national floor level minimum wage is INR 5,340 monthly, the Minimum Wages Act provided specific powers to the Central and State Government in 2023 in India (*Official Website of Labour Department, Government of Puducherry, India*, n.d.).

RESULTS

Demographic characteristics of the patients

A total of 196 patients with T2DM were included of which 121 (61.7%) were male and 75 (38.2%) were female; most of the patients 90(45.9%) belongs to 41-60 years of age group, and also, median age of 86 (43.88%) belongs to 61-80 years of age group. It was observed that more than half, 127 (64.8%) of the patients were not had any habits and 97 (49.49%) were unemployed. The median income per month in Indian rupees were found to be 21000-30000 (17.35%), most of the patients were farmers 48 (24.5%) by occupation.

Also, 70 (35.5%) had T2DM only and more than 60% were had T2DM with comorbidities such as hypertension 67 (34.18%), hypothyroidism 13 (6.63%), chronic obstructive lung disease 7 (3.57%) and others. And most of the patients were on medication metformin 100 (39.84%) described in Table 1.

Association between Diabetic status, lifestyle factors and Pharmacoeconomics parts

The association between the total score obtained from the Diabetic status part and the lifestyle part of the questionnaire of the individual patient compared by using Chi square and correlation statistical methos resulted with *p* value *of <0.05*, CI of 95% *(p* value *<0.001*, 95% CI) and *p* value *of <0.001*, under 99% of confidence interval. Similarly, the association between the total score of the patient's diabetic status and pharmacoeconomic parts of the questionnaire were resulted with *p* value *of <0.05*, CI of 95% (*p* value *<0.003*, 95% CI) and *p* value of <0.001, under 99% of confidence interval as provided in Table 2.

Table 1: Distribution of demographic details and clinical parameters.

Variables	Frequency	Percentage
Age		
20-40	15	7.6%
41-60	90	45.9%
61-80	86	43.8%
81-100	5	2.5%
Gender		
Male	121	61.7%
Female	75	38.2%
Occupation		
Farmer	48	24.5%
House wife	41	20.9%
Welder	3	1.5%
Attender	3	1.5%
Lab attender	2	1.0%
Hotel	2	1.0%
Teacher	2	1.0%
Watchman	1	0.5%
Driver	11	5.6%
General store	3	1.5%
Zomato worker	1	0.5%
Garments worker	3	1.5%
Bus conductor	3	1.5%
Market vendor	1	0.5%
Tailor	2	1.0%
Mechanic	2	1.0%
Factory employee	2	1.0%
Carpenter	1	0.5%
Unknown	65	33.2%
Anti-diabetic medication		
Metformin	100	39.8%
Glimepiride	81	32.2%
Dapagliflozin	5	1.9%
Sitagliptin	3	1.2%
Vildagliptin	15	5.9%
Pioglitazone	2	0.8%
Glipizide	2	0.8%
Voglibose	7	2.7%
Glargine	1	0.4%
Mixtard	28	11.1%
Actrapid	7	2.7%
Range of income		
≤10000	2	1.0%

Variables	Frequency	Percentage
11000-20000	33	16.8%
21000-30000	34	17.3%
31000-40000	17	8.6%
41000-50000	8	4.0%
≥51000	5	2.5%
Unemployed	97	49.4%
Habits		
Nil	127	64.8%
Smoker	33	16.8%
Alcoholic	31	15.8%
Tobacco chewer	3	1.5%
Beetle nut chewer	2	1.0%
Diagnosis		
T2DM and HTN	67	34.1%
T2DM and Htn and Hypothyroidism	13	6.6%
T2DM and Htn Hyperthyroidism	6	3.0%
T2DM and COPD	7	3.5%
T2DM and CLD	5	2.5%
T2DM and IHD	6	3.0%
T2DM and AKI	4	2.0%
T2DM CKD	3	1.5%
T2DM Anaemia	4	2.0%
T2DM HF	2	1.0%
T2DM Pyelonephritis	1	0.5%
T2DM and TB	3	1.5%
T2DM and epilepsy	2	1.0%
T2DM Glaucoma	1	0.5%
Newley diagnosed with T2DM	2	1.0%
T2DM only	70	35.7%
Diabetic status		
T2DM with complications	16	8.1%
T2DM without complications	180	91.84%
Diet, lifestyle and habits status		
8.1 Diet pattern of the patients		
Mixed, but with moderate carbohydrate and dietary fibres	34	17.3%
Mixed with high carbohydrate.	137	69.9%
Mixed with high fat.	25	12.8%
8.2 Physical activities or exercises		
Walking 30-40 minutes daily	28	14.3%
Walking 30 minutes 2 times in week	122	62.2%
Rarely	46	23.5%
Habits observed among patients		
No	157	80.1%
Daily 1-2 puffs or 1-2 drinks (60ml)	17	8.7%
1 pack daily or more than 2 drinks (>60 mL)	22	11.2%

Cost of illness

The mean of the total direct cost found to be $ 29.04. While the mean of total indirect cost found to be $56.67. The mean of total cost (direct cost + indirect cost) was observed to be 85.71 USD (29.04+56.67), which is Rs. 7,197 Indian rupees as described in Table 3.

Factors affecting the direct and indirect cost

Various demographic factors assessed for linear regression with direct and indirect cost and the significant association observed for Inj. glargine and indirect cost with a *p* value *of <0.05*, 95% of confidence interval. While, duration of hospital stays, glaucoma, chronic liver disease and Injection Mixtard were resulted in significant *p* value *of* <0.05, 95% of confidence interval with direct cost as provided in Table 4.

DISCUSSION

T2DM is still a global concern affecting nearly 90% of individuals worldwide particularly in low to middle income countries resulting in increased mortality and cost associated for the long-term treatment of the same (Anjana *et al.*, 2011; Bommer *et al.*, 2018; Fano *et al.*, 2013; *India - International Diabetes Federation*, n.d.; L *et al.*, 2024; Shah *et al.*, 2013). Thus, the findings of this study emphasize the critical role of lifestyle, diet, and habits in the effective management of diabetes, these factors not only improve the quality of life of diabetic patients but also reduce the associated economic burden. It was observed that major proportion of included participants were aged between 41 and 60 years. A similar study by Khowaja LA *et al.*, found mean age of population to be (38%) 51 and 60 years (Khowaja *et al.*, 2007). However, remaining were 35.9% and 26.1% of 41 to 50 and 20 to 40. Also, in our study 61.7% were males and 38.2% were females respectively. Where the study from Pakistan by Butt M D *et al.*, found the female population with more proportion 52.2% than male 47.5% (Butt *et al.*, 2022).

The increasing global economic burden of diabetes, especially in countries like India, the United States, and China, address the lifestyle factors effective in management of type 2 diabetes relies heavily on lifestyle modifications targeting obesity and physical inactivity mitigates the diabetes risk and overall burden of the disease (Alfaifi, 2023; Campbell *et al.*, 2011; Cobden *et al.*, 2007; Foreyt and Poston, 1999; Galaviz *et al.*, 2018; Ratner, 1997; Sagarra

Table 2: Statistical analysis of Diabetic status, lifestyle and Economic status.

Chi square test for association of Diabetic status, lifestyle and Economic status			
Variables	**Chi square**	**d_f**	***p* value**
Diabetic status (Part 1) Vs Diet and lifestyle (Part 2)	552	255	0.001**
Diet and lifestyle (Part 2) Vs Pharmacoeconomic status (Part 3)	640	187	0.002*
Diabetic status (Part 1) Vs Pharmacoeconomic status (Part 3)	327	165	0.003*
Corelation for association of Diabetic status, lifestyle and Economic status			
Variables	Pearson co-efficient		*p* value
Diabetic status (Part 1) Vs Diet and lifestyle (Part 2)	0.585		0.001**
Diet and lifestyle (Part 2) Vs Pharmacoeconomic status (Part 3)	0.728		0.001**
Diabetic status (Part 1) Vs Pharmacoeconomic status (Part 3)	0.53		0.001**

(*) Indicates Significant correlation at 95% CI and (**) Indicates Significant correlation at 99% CI.

Table 3: The mean of direct and indirect cost of diabetes of hospitalized patients (*n*=196).

Cost component	Mean cost in USD	Percentage of mean cost
Direct medical cost		
Doctor visit	11.8	13.7%
Antidiabetic medication cost	5.8	6.7%
Lab investigation cost	11.8	13.7%
Overall cost of hospitalization	23.8	27.7%
Direct non-medical cost		
Travelling cost	2.4	2.7%
Total direct cost	29.04	33.8%
Indirect cost		
Productivity loss	44.0	45.4%
Other loss	68.7	80.1%
Total Indirect cost	56.7	66.1%
Total cost (a+b)	85.74	

Note: Here the mean of total direct and indirect cost of 196 patients was taken. And the other loss refers to intangible cost (non-measurable cost).

et al., 2014). In terms of economic outcomes, this study found the total cost for diabetic patients, including direct and indirect expenses, was approximately ₹7,197 (85.71 USD). Which exceeds the Indian National minimum wage of ₹5,340 per month. This financial burden suggests that many diabetic patients may struggle to afford necessary treatments, posing a challenge for government and healthcare policymakers. Similar study by M. Laxy *et al.* found that the Lifestyle Change Intervention significantly reduced type 2 diabetes risk and proved more cost-effective than routine care, with an Incremental Cost-Effectiveness Ratio (ICER) of US$34,000 per Quality-Adjusted Life Year (QALY) (Laxy *et al.*, 2020).

Other studies support the idea that lifestyle changes that can significantly increase the economic burden of diabetes. Similar studies carried out by L. A. Khowaja *et al.* found that medication constituted the largest cost component (46%), followed by laboratory costs (32%), with direct costs averaging Rs. 1,930 per visit. Also, the study by Raghuram N. *et al.* reported that the mean monthly health cost stood at 1,098.25 INR, representing approximately 17% of household expenses, with variations observed between gender and urban and rural environments (Nagarathna *et al.*, 2020).

The smaller population was a limitation of study, and further studies with a larger population shall be planned to strengthen our findings. This study was conducted among the rural population and hence future comparative studies are needed to understand the effect of lifestyle status, economic status and health status in diabetic patients to provide a support for diabetic patients in managing their disease and economic status as well.

CONCLUSION

The findings of the study highlight the significant role of lifestyle factors diet, physical activity and habits in managing diabetes, which not only improves health outcomes but also reduces the economic burden associated with the disease. In developing countries like India many patients struggle to afford costly antidiabetic medications and longer hospital stays. Thus, promoting of accessible healthcare and preventive measures by government health programmes and policy makers is essential to reducing the economic impact of diabetes. Further adequately powered prospective studies are needed to strengthen these findings.

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Table 4: Linear regression of direct and indirect cost with sociodemographic (To identify the association of variables).

Variable	Direct cost		Indirect cost	
	Adjusted R value	*p* value	Adjusted R value	*p* value
Over all result of Diabetic status	-0.0202	0.119	-2.33	0.195
Over all result of Lifestyle and diet	1.10E-04	0.993	5.05	0.006*
Over all result of Pharmacoeconomics	0.0279	0.15	-5.62	0.037*
Overall cost of hospitalization	0.0992	.099**	-1.6	0.577
Antidiabetic medication cost	0.9772	.001**	3.87	0.189
Metformin	-0.045	0.673	0.042	0.658
Glimepiride	-0.033	0.741	0.07	0.433
Mixtard	0.264	0.002*	-0.03	0.697
Actrapid	0.07	0.422	-0.041	0.6
vildagliptin	0.011	0.888	-0.009	0.898
pioglitazone	-0.073	0.304	-0.005	0.94
voglibose	0.064	0.504	0.158	0.066
Glargine	0.162	0.087	0.168	0.049*
Glycomet	-0.026	0.777	-0.063	0.448
T2DM	-0.05	0.479	0.118	0.067
HTN	0.151	0.096	0.122	0.13
Hypothyroidism	-0.063	0.39	-0.004	0.953
Hyperthyroidism	-0.095	0.224	-0.108	0.125
COPD	-0.022	0.768	-0.001	0.988
CLD	-0.221	0.004*	0.019	0.78
IHD	0.139	0.066	0.049	0.471
AKI	-0.045	0.542	-0.017	0.793
CKD	0.071	0.358	-0.022	0.746
Anaemia	-0.078	0.645	-0.029	0.847
Hypertension	0.017	0.844	0.03	0.704
HF	0.004	0.951	-0.097	0.104
Pyelonephritis	0.025	0.705	-0.044	0.455
TB	-0.046	0.642	0.042	0.637
Epilepsy	0.043	0.6	0.01	0.893
T2DM and HTN	-0.061	0.494	-0.152	0.058
Glaucoma	-0.256	0.003*	-0.04	0.596
Newley diagnosed	-0.051	0.512	0.008	0.906
Nil	-0.104	0.383	-0.001	0.991
Smoker	0.232	0.049	-0.078	0.462
Alcoholic	0.207	0.061	-0.03	0.758
Tobacco chewer	-0.045	0.655	-0.05	0.578
Beetle nut chewer	-0.093	0.209	-0.076	0.253
21-40	-0.094	0.36	0.091	0.322
41-60	-0.17	0.041	0.029	0.695
81-100	-0.072	0.331	0.043	0.514
HbA_{1c}%	0.068	0.479	0.135	0.116

Variable	Direct cost		Indirect cost	
	Adjusted R value	*p* value	Adjusted R value	*p* value
T2DM Without complications	0.028	0.762	0.026	0.756
Duration of hospital stay	0.252	0.003*	-0.044	0.557

(*) Indicates Significant correlation at 95% CI and (**) Indicates Significant correlation at 99% CI.

study. Also, we thank the patient participated in the study for their support.

ABBREVIATIONS

ICER: Incremental Cost-Effectiveness Ratio; **ICMR:** Indian council for medical research; **IFG:** Impaired fasting glucose; **NCCD:** Non communicable chronic disorders; **OGTT:** Oral glucose tolerance test; **OHA:** Oral hypoglycaemic agents; **T2DM:** Type 2 diabetes mellitus; **QALY:** Quality adjusted life years.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICAL APPROVALS

The study was conducted in accordance with the Ethical guidelines for biomedical research on human participants and Declaration of Helsinki, after obtaining approval from the Institution Ethics Committee (IEC) with IEC no: IEC/AH&RC/AC/10/2024.

INFORMED CONSENT STATEMENT

Informed consent was obtained from all subjects involved in the study.

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