Section: Community Medicine

Original Research Article

EXPLORING THE CONTRIBUTION OF FACTORS RELATED TO COMPLIANCE STATUS OF PATIENTS WITH TYPE 2 DIABETES MELLITUS USING STRUCTURE EQUATION MODELLING

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ABSTRACT

Background: Medication adherence is essential for achieving glycaemic control and preventing complications among people with type 2 diabetes mellitus. This study assessed factors associated with medication adherence and explored their interrelationships using the Health Belief Model and structural equation modelling. **Materials and Methods:** An analytical cross-sectional study was conducted from October 2023 to March 2024 among 132 adults with type 2 diabetes attending Killai Primary Health Centre, Cuddalore district, Tamil Nadu. Participants aged over 30 years, diagnosed for at least one year and receiving treatment were recruited by convenience sampling. Data were collected using a semi-structured questionnaire, the eight-item Morisky Medication Adherence Scale and a Health Belief Model questionnaire assessing perceived susceptibility, severity, benefits, barriers, self-efficacy and cues to action. Recent fasting and postprandial blood glucose values were obtained from medical records. Stepwise multiple linear regression and structural equation modelling were performed. **Results:** The mean medication adherence score was 6.54±1.49. Mean scores for perceived barriers and self-efficacy were 27.50±6.48 and 18.33±3.60, respectively. Perceived self-efficacy was positively associated with adherence (standardised $\beta=0.328$, $p<0.001$), while perceived barriers ($\beta=-0.299$, $p<0.001$) and postprandial blood glucose ($\beta=-0.286$, $p<0.001$) were negatively associated. Age showed a weaker positive association ($\beta=0.136$, $p=0.032$). The regression model explained 52.3% of the variation in adherence. Structural equation modelling suggested both direct and indirect relationships among self-efficacy, perceived barriers, postprandial blood glucose and adherence. **Conclusion:** Medication adherence was associated with self-efficacy, perceived barriers, age and postprandial blood glucose. Routine assessment of barriers and self-efficacy during clinical visits may help identify patients needing adherence support.

INTRODUCTION

Diabetes is a serious condition with potentially devastating complications that affects all age groups worldwide.[1] And thus, the successful management of diabetes mellitus depends to a great extent upon strict compliance with treatment regimens.[2]

The term therapeutic compliance (or adherence), is defined as "the extent to which a patient acts in accordance with the prescribed interval, dose, and dosing regimen".[3] Non-compliance to treatment regimen possesses a great threat to patient's recovery as well as maintenance of good health.[2]

A WHO report has shown that only approximately 50% of patients in developed countries are compliant and adhere to treatment in chronic diseases and this is even lower in developing countries.[4]

The Health Belief Model (HBM) has continued to be a major organizing framework for explaining and predicting acceptance of health and medical care recommendations.[5]

According to the HBM, a subject is more likely to take a "health action" if he perceives, he is at risk, the disease is severe, health action is beneficial, understands limited barriers to the health action, confident enough to follow the health action and receives a cue to get the health action. So people with diabetes will adhere to treatment plans if they worried

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about their health and believe that they are susceptible to problems/complications, diabetes could have serious consequences, and following medical recommendations will reduce threats, and believe that the benefits outweigh the costs of not adhering.[6]

The present study is to find out the significant factors related to compliance status and to explore them using Structure Equation Modelling.

Structure equation modelling

The main purpose of structural equation modelling (SEM) is to find out the interrelationship between the dependent variables and the selected independent variables. Secondly it is used to find out how much effect each independent variable contributes directly and indirectly to the dependent variable.

MATERIALS AND METHODS

This was a descriptive study done from October 2023 to March 2024 in Killai, a primary health centre in Cuddalore district, Tamilnadu after getting approval from institutional ethics committee, patients of age more than 30 years, already diagnosed to have type II diabetes mellitus and on treatment for at least one year of duration, attending primary health centre, were selected for the study. Patients who cannot give response like critically ill patients, those who cannot hear/communicate; patients with mental health problems were excluded from the study. Sample size was calculated using the results of a similar study done by Tayebe Pourghaznein was taken into consideration for sample size calculation.[7] In that study, the lowest correlation co-efficient was found to be 0.035 between medication adherence and perceived benefits. Keeping this as prior information, sample size was determined using nmaster sample size software, with sample correlation co-efficient as 0.035, population correlation co-efficient as 0.25, power of the study as 80%, level of significance as 5% and sample size required was found to be 130. However, a sample of 132 subjects has been selected for this study. The data collection was done using convenient sampling method among the patients attending the primary health care.

The study tool consists of pre validated and semi structured interview questionnaire which included five sections which are as follows:

Section 1 - Consists of questions on participants socio-demographic details, such as, name, age, sex, marital status, education, occupation and income status of the participants,

Section 2 - Clinical details of diabetes mellitus, the duration of diabetes mellitus, duration of treatment for diabetes, type of medication, number of doses, number of tablets per dose, side effects of drugs, presence of associated chronic disease, complications of diabetes mellitus, details about lifestyle factor such as diet and physical activity.

Section 3 - This section included documentation of patient's blood pressure measurement and the lab findings of recent fasting and post-prandial sugar from their available medical records.

Section 4 - Eight Item Morisky medication adherence questionnaire. This questionnaire consisted of eight questions which was used to measure the drug compliance status of the patients. The total score was 8. Patients were then classified according to their compliance score. Those who scored 8 were classified as compliant, 6-7.75 as partially compliant and <6 as non-compliant to the treatment regimen.

Section 5 - Questionnaire to assess participants' perceived health belief with the application of Health Belief Model. This section consisted of questions on 6 components of Health Belief Model namely perceived susceptibility, perceived severity, perceived benefits, perceived barriers, perceived self-efficacy and cues to action which assessed the beliefs of patients about their disease and medication. Questions were asked for each of the components separately and the individual responses for each component were recorded with the help of 5 point Likert scale of strongly agree, agree, neutral, disagree and strongly disagree. The participants were then categorized to have low, medium and high perceived susceptibility, perceived severity, perceived benefits, perceived barriers, perceived self-efficacy and cues to action based on their scores.

Data Analysis

The data obtained was compiled and entered in excel sheet and then analyzed using SPSS version 22. Stepwise regression model and Structure Equation modelling were used to find out the relationship between compliance level and other selected independent variables.

RESULTS

Regarding the socio-demographic characteristics of the participants, majority (44.7%) of the participants are in the age group of 46-60 years. Most of the participants (64.4%) were females. Majority (72%) of the respondents were married.

Table 1 shows the descriptive statistics of compliance status and HBM constructs. The mean compliance level of the patients was 6.537. Thus, majority of the participants were partially compliant. Among the HBM constructs, the mean score of the participants for perceived susceptibility was 19.54, mean perceived severity score was 19.87, for perceived benefits it was 14.97, for perceived barriers it was 27.50, and the mean score for perceived self-efficacy and cues to action were 18.33 and 10.97 respectively.

It was found in the step wise regression analysis that variables such as age, PPBS status, perceived barriers and perceived self-efficacy are the most significant variables which influences on the compliance level. The other variables have been excluded from the model. The r^2 value of 0.523 indicates that the model is adequate for prediction. (table 2)

Standardized co-efficient indicates that perceived self-efficacy is the foremost variable which

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influences the compliance status among all the abovesaid four predictor variables. Perceived barrier is the next significant variable which influences compliance level.

Based on the results of regression analysis, the structure equation modelling for this study has been developed. (fig.1)

SEM explored the interrelationship between independent variables like age of the diabetes patients, their perceived self-efficacy, perceived barriers, recent PPBS level and the dependent variable, compliance status of the diabetic patients. It has been observed that the independent variables' direct contribution was higher than their indirect contribution towards the patients' compliance status.(table 3 & 4)

It was found that age of the patient has directly influenced the compliance status whereas age of the patient has no significant association with other independent variables. This finding infers that when a diabetic patient for whom perceived barriers, perceived self-efficacy, his/her PPBS status were not known/assessed and if age of the patient is known, we can predict his/her compliance level.

If the perceived self-efficacy score of a diabetic patient is known, and if it is found to increase, we can predict that compliance level of the patient will also increase.

By knowing the perceived barrier score of a diabetic patient and it can be predicted that if perceived barriers is found to increase, compliance level of the patient will decrease.

PPBS status has been found to directly influence the compliance status of the diabetic patient. If the PPBS level of the patient is uncontrolled, it can be predicted that compliance level will be lower.

Hence, it is concluded that compliance status of a diabetic patient can be predicted if we concentrate on these four variables.

Table 1: Descriptive statistics of compliance status and HBM constructs

	N	Minimum	Maximum	Mean	SD
Compliance	132	2.50	8.00	6.537	1.49
Perceived susceptibility	132	12.00	28.00	19.545	3.23
Perceived severity	132	10.00	30.00	19.87	3.90
Perceived benefits	132	4.00	20.00	14.97	3.07
Perceived barriers	132	16.00	40.00	27.50	6.48
Perceived self- efficacy	132	5.00	25.00	18.33	3.60
Cues to action	132	5.00	20.00	10.97	2.99

Table 2: Stepwise regression model of Compliance based on Health belief model constructs and other variables

Model	Unstandardized Coefficients		Standardized Coefficients	T	Sig.
	B	Std. Error	Beta		
Constant	5.888	1.134		5.190	0.000
Perceived Barriers	-0.069	0.018	-0.299	-3.802	0.000
Perceived self-efficacy	0.136	0.032	0.328	4.276	0.000
PPBS status	-0.006	0.002	-0.286	-4.256	0.000
Age	0.020	0.009	0.136	2.163	0.032

r^2=0.523

Table 3: Regression weight analysis of compliance status with HBM constructs, age and PPBS status

Relationship between variables			Unstandardized Estimate	Stan-dard Error	Critical Ratio	P	Standardized estimate
Age	--->	Perceived self-efficacy	-.057	.031	-1.831	.067	-.158
Perceived self-efficacy	--->	Perceived barrier	-1.060	.129	-8.201	***	-.590
Age	--->	Perceived barrier	-.057	.047	-1.212	.225	-.087
Perceived barrier	--->	PPBS status	3.373	.995	3.389	***	.332
Age	--->	PPBS status	-.601	.538	-1.117	.264	-.091
Perceived self-efficacy	--->	PPBS status	-2.054	1.811	-1.134	.257	-.112
Perceived self-efficacy	--->	Compliancestatus	.136	.031	4.343	***	.328
Perceived barrier	--->	Compliance status	-.069	.018	-3.862	***	-.299
PPBS status	--->	Compliance status	-.006	.002	-4.323	***	-.286
Age	--->	Compliance status	.020	.009	2.197	**.028**	.136

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Table 4: Standardized Total, Direct, Indirect effects of SEM

Variables	Total effects of SEM				Direct effects of SEM				Indirect effects of SEM			
	Age	Perceived self-efficacy	Perceived barrier	PPBS status	Age	Perceived self-efficacy	Perceived barrier	PPBS status	Age	Perceived self-efficacy	Perceived barrier	PPBS status
Perceived self-efficacy	-.158	.000	.000	.000	-.158	.000	.000	.000	.000	.000	.000	.000
Perceived barrier	.006	-.590	.000	.000	-.087	-.590	.000	.000	.093	.000	.000	.000
PPBS status	-.071	-.308	.332	.000	-.091	-.112	.332	.000	.020	-.196	.000	.000
Compliance status	.102	.593	-.394	-.286	.136	.328 (55.3%)	-.299 (75%)	-.286	-.033	.264 (44.7%)	-.095 (25%)	.000

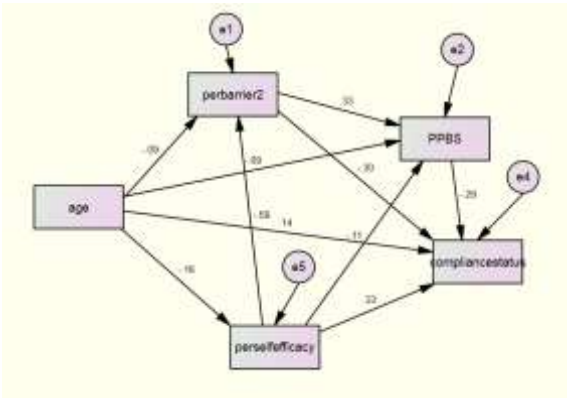

Figure 1: Structure Equation Modelling

DISCUSSION

The compliance level of the participants has been predicted based on the participants' socio-demographic characteristics, clinical characteristics, life style factors and HBM constructs using step-wise regression analysis. The analysis showed that variables such as age, post prandial blood sugar status, perceived self-efficacy and perceived barriers significantly influences the compliance level.

This was similar to the results found by Kavita S et al which revealed that elderly patients showed good adherence when compared to young patients.[8] Similarly, Mahmoud Radwan in his study found that old age (>60 years) as one of the predictors of adherence rate.[9] Increase in awareness regarding disease and its complication might be probable reasons for increased adherence in elderly patients.

PPBS status of the patients was found negatively correlated with compliance level in this model. It infers that when PPBS status of the patients is less than 200 mg/dl (controlled blood sugar), we can predict that compliance level of the patient will be high.

In the regression model, it was found that perceived barriers was negatively correlated with compliance level which denotes that the compliance level of patients decreases when perceived barriers increases. This finding was supported by Tayebe Pourgaznein's study which found that patients with lesser barriers had higher scores for medication adherence.[7] This shows that level of therapeutic compliance among the diabetic patients will decrease if they perceive any hindrance or inconvenience in following the treatment regimen.

Among the all four predictor variables, it was found that the perceived self-efficacy was the foremost variable which influences the compliance status. This finding was supported by a study in Myanmar which revealed that, though all the constructs of HBM were significantly associated with compliance level of diabetic patients, perceived severity and perceived self-efficacy as the strongest predictors of compliance level of diabetic patients.[10] This infers that diabetic patients are more likely to follow their treatment if they have self-confidence and believe on their ability to comply with their anti-diabetic regimen.

Structure Equation Modelling Discussion

SEM reveals that there was a significant and negative relationship found between perceived barrier and perceived self-efficacy. This denotes that whenever patients' perceived self-efficacy increases, patients' perceived barriers to follow anti-diabetic regimen decreases and vice-versa. When a patient perceives few barriers, he/she will be more confident to follow the anti-diabetic regimen. This was similar to the results found by Zahra Hosseini et al in their studies among osteoporosis patients, which revealed that perceived self-efficacy had significant and negative relationship with perceived barriers.[11] Lyutha Al Subhi et al also supported this finding in their study done among diabetic patients in Oman.[12]

In the model, it was found that compliance status was influenced by perceived barriers, perceived self-efficacy, age and PPBS status.

Perceived self-efficacy

Compliance status was significantly correlated with perceived sel-efficacy. This means that compliance level of the diabetic patients increases with increase in the level of their perceived self-efficacy. Perceived self-efficacy influences compliance level directly and also indirectly through perceived barriers.

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Perceived barriers

Participants' level of perceived barriers was significant and negatively correlated with compliance status. This indicates that when level of perceived barriers increases, patients' compliance level decreases. It contributes to compliance level directly and also indirectly through other variables.

Age

In the SEM, it was found that age was significantly associated with compliance status. It was also found that age as the predominant contributor towards compliance level which overcomes the effect of other variables.

PPBS status

PPBS status was found to be negatively correlated with compliance status.

CONCLUSION

Age and post prandial blood sugar status of the patients were the significant predictors of their compliance level. Of the HBM constructs, perceived self-efficacy and perceived barriers were significant predictors.

The study highlights that the above said four variables had direct influence on the compliance level. Also it explored the interrelationship between them. SEM helps to split the relationship into direct and indirect contribution towards the compliance status of the Type 2 Diabetes mellitus patients.

It is recommended to assess the perceived barriers and self-efficacy of the diabetic patients during every physician visit.

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