Assessment the Influential Factors Associated with Medication-Non-Adherence and Self-Care Practices among Diabetes Mellitus Patients in Saudi Arabia 2023

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Abstract:

Background:

Diabetes Mellitus is considered a key public health problem globally due to its incidence and prevalence and the complications therein. Globally, diabetes affects 425 million people at a prevalence of 8.8% and will rise to approximately 700 million people by the year 2040.

Diabetes Mellitus is one of the most common metabolic problems in Saudi Arabia and its chronic progressive disease is characterized by numerous health complications. Diabetes is a growing medical problem and the costs to society are great and rising. The recent report formed by International Diabetes Federation Diabetes Atlas values that there are presently 387 million people alive with diabetes globally in 2014, a 105% rise from its last report in 2011 with the highest number of people living in the western pacific. Influential factors causing poor adherence to antidiuretic medications and self-care practices among diabetes mellitus (DM) patients have not been reported before in Saudi Arabia. Currently, one in every 11 adults worldwide is living with the condition with 90% of these being type II diabetes patients. The past three decades have recorded a distressing rise in the cases of diabetes mellitus, resulting in quadrupling of the cases.

Aim of the study: To assessment the influential factors associated with medication-non adherence and self-care practices among diabetes mellitus patients in Saudi Arabia 2023.

Method: cross sectional study conducted at outpatient clinics in diabetes mellitus centers in Saudi Arabia in Sample population consists of Saudi out patients aged 30 <60 years attending. Our total participants were (200).

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Results: Show age majority of the study groups from the 30-39 years were (52.0%) gender many of the respondents were male (58.0 %) regarding the work status the most of the participants answer I am in formal employment were (45.0%) regarding the nationality the majority of the respondents Saudi were (87.0%) regarding the salary satisfaction the most of participant sufficient were (62.0%) while partly sufficient were (21.0%) while the insufficient were (10.0%) while quite Insufficient were (7.0%)

Conclusion: In previous research's it was found that the majority of participants were not adherent to anti-diabetes medication. Non-adherence to medication was associated with younger age and low level of education. Interventions to improve adherence should target younger and newly diagnosed patients through aggressive counseling to address healthy self-management behavior's.

Keywords: Assessment, influential, factors, associated, medication-non, adherence, self-care, practices, diabetes mellitus, Saudi Arabia.

Introduction

Background

Diabetes mellitus (DM) is an emerging lifestyle disease and is now an important global public problem and a silent killer [1]. Diabetes often coexists with other medical conditions and is a contributing cause of death in 88% of people who have it [2]. The ravages of diabetes mellitus are estimated to affect about 625 million people by 2045 [3]. Globally, type 2 diabetes mellitus (T2DM) is the most common form of DM accounting for more than 90% of cases [4]. Its escalating incidence in combination with high rates of morbidity and mortality imposes a significant burden on the healthcare system and reduces the quality of life of those affected [5].

Although adherence to medication therapy is a well-known issue in clinical practice, medication adherence of DM patients reportedly varies, and non-adherence is a significant obstacle in providing diabetic care and treatment delivery [6]. Over \$100 billion is estimated to be spent yearly on managing the consequences of inadequate medication adherence [7]. Patients who do not adhere to their drug therapy might do so on purpose or accidentally (i.e., intentional or unintentional non-adherence [8]. However, a medicine should be taken as directed to attain its intended effectiveness [9]

Poor medication adherence is a significant contributor to uncontrolled hyperglycemia [10]. Acute and chronic DM complications can result from inadequate and poorly controlled hyperglycemia. Several of these complications are permanent and can cause impairment and failure to many body organs, particularly the nerves, eyes, and kidneys, if they are not managed [11]. Chronic diabetes complications are the main reason for the high hospitalization rate of DM patients in Saudi Arabia, despite the fact that effective treatments and medications that lower glycaemia levels are available nationwide [12].

Diabetes knowledge is crucial in enhancing patients' adherence to treatment [10]. Evidence from previous studies has indicated that having adequate knowledge about DM influences good self-care practices and attenuate diabetes complications tremendously [13]. The patients' knowledge about diabetes does not only promote self-management but provides them the ability to effectively adhere to treatment. It is very necessary to continue to assess adherence level to medication and self-care behavior's in patients with type 2 diabetes

mellitus. This will enhance health care providers' identification of patients with poor medication adherence and assist in planning appropriate strategies to promote medication and self-care adherence.[14]

It seems evident from the review of relevant literature that similar studies have been conducted in Europe [15], Middle East [16], South Africa [17], East Africa [18] with limited studies in the West African sub-region [19]. The studies done in Saudi Arabia had shown low adherence to medication [20] and poor self-care behavior's [21]. The Saudi Arabia studies focused on only medication adherence [22] and factors that influence participants' adherence to four self-care activities (diet, exercise, self-monitoring of blood glucose, and foot care [23] without assessing adherent factors to diabetic medications. Moreover, missing in the prior studies is the link between medication adherence, self-care behaviors, and diabetes knowledge. To address this deficiency in knowledge, the present study aimed at evaluating medication adherence and self-care behavior's among patients with type 2 diabetes mellitus in Saudi Arabia.

Review of literatures

A recent systematic analysis study on global load disease analyzed data from health examination surveys and epidemiological studies involving data from 2.7 million participants and 370 country-years reports that a total of 347 million adults are alive with diabetes worldwide[24]

Few studies on adherence to anti-diabetic medication among T2DM patients in Saudi Arabia were identified [25]. Two of these studies took place in Riyadh Diabetes Centre and targeted both T1 and 2 DM patients at different periods. The first aimed to assess patients' practices and knowledge [26]. The other study also assessed patients' ability in addition to factors that improve adherence to the condition's treatment and management [27]. A most recent study, which took place in Saudi Arabia at the NCDE, assessed the influence of illness perceptions on medication adherence among T2DM patients [28]. Each of this research utilized a different adherence measure. Still, none of these studies have focused on the influential factors causing poor adherence to diabetic medication and self-care practices in the country. The status of adherence to anti-diabetic medication reported by this study was unsatisfactory 67.1% but reasonable when compared to other developing African countries such as Egypt (38.9%), Sudan (45%), Ethiopia (95.7%) and Nigeria (86.8%) [29].

In 2015, it was estimated that diabetes caused an approximate 1.6 million deaths globally while in 2017 an approximate 2.2 million fatalities are linked to high blood glucose. In 2018, it was ranked the 7th leading causes of death globally [30].

Lemay, et al. study Medication adherence in chronic illness: do beliefs about medications play a role? Investigated the relationship between patients' beliefs about medications with self-reported adherence to treatment among a chronically ill multicultural patient population. The study was conducted by a prospective cross- sectional study was conducted among patients treated for chronic illnesses in the Ministry of Health primary care clinics in Kuwait. Patients completed a questionnaire that consisted of questions to collect information about their health status and demographics using validated instruments: the Beliefs about Medication, Sensitive Soma Assessment Scale, and Medication Adherence Report Scale-5 items. The main outcome measures were self-reported adherence to medications, beliefs, and

perceived sensitivity toward medications. The study concluded that Medication adherence is a complex, multifaceted issue and patient beliefs about medications contribute significantly, although partially, to adherence among a multicultural Middle Eastern patient population [31]

A recent systematic review and meta-analysis indicated that Ghana has a prevalence rate of 6.4% in adults [32]. If measures are not taken to improve diabetes management, the prevalence of the disease will continue to rise.

Medication adherence is a critical element in treating chronic diseases especially diabetes among elderly and non-adherence among elderly patients is an issue facing health care providers. Previous studies report that measuring adherence and patient compliance is quite difficult and is patient-dependent most of the time.[33]

Study in Saudi Arabia Risk Factors of Treatment Non-compliance we found that 64.9% of participants had a high level of medication adherence, 21.3% had a good level of adherence, 13.3% had a partial level of adherence, and 0.5% had a low level of adherence [34]

These findings rates are higher than those in previous studies that used different medication adherence assessment tools.[23] One similar study in Saudi Arabia used the same tool to assess diabetic patients, reporting that a third of patients were (highly adherent 35.8%), (22.6% were good), (34.9% were partial), and (4.7% of patients had low medication adherence).[26] The high level of adherence in this study might have been related to populations' age (69.7±6.8); another study in Saudi Arabia founds a positive correlation between the level of adherence and age, high rates of adherence in patients aged 60 years and above.[27] Furthermore, one factor that might have contributed to this finding was that we used validated Arabic translation questionnaires to ensure participants clearly understood the questions.[24]

Rationale

Non-adherence to recommended medication and self-care practices exists among T2DM patients in Saudi Arabia revealed a high prevalence of non-adherence. The factors associated with non-adherence were age, education, and practice of self-care activities. Knowledge also had a significant influence on self-care practice. We recommend consistency in education to deal with issues related to self-care behaviors and medication adherence as this is necessary to enhance self-management and minimize complications. Non-adherence was associated with younger age. Interventions to improve adherence should target younger and newly diagnosed patients through aggressive counseling to address healthy self-management behaviors. Other approaches that have been used to study adherence measure validity could be future research, monitoring T2DM individuals' medication adherence levels and self-care practices through regular follow-up and providing these patients with the necessary education is vital. This will make it easier for medical practitioners to recognize patients who don't take their medications as prescribed, aid in creating effective programs, and facilitate the establishment of successful measures to encourage medication adherence and self-care practices and eventually prevent diabetic complications.

Aim of the study

To assessment the influential factors associated with medication-non adherence and self-care practices among diabetes mellitus patients in Saudi Arabia 2023.

Specific objective

To assessment the influential factors associated with medication-non adherence and self-care practices among diabetes mellitus patients in Saudi Arabia 2023.

Methodology

Study setting:

This study has been conducted among diabetes mellitus in the outpatient clinics in diabetes mellitus centers .

Study Population

The study population consists of diabetes mellitus in the outpatient clinics in diabetes mellitus centers aged 30 to more than 60 years attending to outpatient Saudi Arabia .

Study Design

Cross-sectional, analytic study, systematic random sampling technique

Inclusion criteria:

- Patients attending outpatient clinics in diabetes mellitus centers
- Aged 30-60 years
- Able and willing to participate in the study.
- Take some sort of prescribed medications.

Exclusion Criteria

- Out patients less than 30 years
- Not able and refuses to participate in the study.

Sample size:

Using EPI info version 24, the study sample size has been determined based on the following assumptions :

Since there is not an official release, e.g., by the "Central Department of Statistics and Information" in Saudi, of the exact census of Saudi Arabia residents falling within the study's age category, a source population size of the same of has be assumed. (Definitely, the true population of such category is greater, also to be most conservative, the least number needed for a reasonably large sample size that allows generalizability of the study result. Knowingly, sample sizes obtained from source population sizes above are not significantly different).

Accordingly, a sample size (n) would be 200. In order to account for non-response and achieve more generalizable results, the investigator has be increase the sample size up to 200.

Sampling Technique:

Regarding outpatient clinics in diabetes mellitus centers selection, by using simple random sample technique (by using randomizer.org), regarding patients' selection, the total number visiting is 3391 per month and the sample size is 200. The data collection period is 30 days

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(four weeks minus weekends). Every day there are nearly 80 patients attending in outpatient clinics in diabetes mellitus centers in both sections (male and female sections). To collect data from sample size, the researcher needs nearly 20 patients per day to collect desired sample size. The researcher has been selecting every 4th patient to cover the sample size during data collection period.)

Sampling method:

The total number of patients attending outpatient clinics in diabetes mellitus centers in one month is 3391. Based on this information sample size was calculated using a website (raosoft.com). The resulted estimated sample size is 200 elderly patients. The confidence interval is 95% and margin of error is 5%. The estimated prevalence used is 50% to calculate maximum sample size.

Data collection method:

Self-administered questionnaire has been given to all participants. Those who have trouble reading or writing the questionnaire, has be filled by the interviewer

Questionnaire:

An Arabic self-administered questionnaire has been used. It consisted of three sections. **The first** section is on the socio-demographic and presence of chronic disease, and present medication history (e.g., age and education level). **The second** sections cover common reasons of drug noncompliance (patient, medication, health care related factors). **The third** section addresses the part the possible suggestion to increase the patient level of adherence and compliance with medications.

Data Collection Technique

The researcher has visit the outpatient clinics in diabetes mellitus centers, the researcher has filled the questionnaires through the interview with patients who are attending patients in outpatient clinics in diabetes mellitus centers met the inclusion criteria after taking their verbal consent. After obtaining necessary approvals, the researcher and one trained nurse used a since all centers work on walk-in basis, i.e., using "systematic random sampling" technique.

Data Entry and Analysis

Data has been collected and coded and then entered to a MS program with adequate backup. Descriptive statistics, e.g., number, proportions, cumulative proportions, mean and standard deviation, etc. has been displayed, as appropriate. Analytically, a parametric technique, e.g., t-test, has been attempted, as applicable, especially analyzing normally distributed variables. Otherwise, a non-parametric alternative, e.g., Man Whitney U test or χ^2 test of independence, has been used, as necessary. The Statistical Package for Social Sciences (SPSS) software for MS- version-24 will be used for the analysis. All tests has been conducted at level of significance a=0.05; results with p-values<0.05 has been considered "statistically significant".

Pilot Study

A pilot study has been done on 10 Saudi patients who meet the study's eligibility criteria. The pilot study has been mainly help examine both the instrument's content validity and construct validity issues, alongside with other needed information.

Ethical Considerations

Necessary approval has been the Research Ethics Committee of the PHC, shall be obtained prior to the study .

A written consent has been obtained both from PHC administration. The aim of the study has been explained to them. Feedback about the results has been sent to these organizations. Data has been treated confidentially and has been used only for the purpose of research.

Budget: Self-funded.

Result

Table 1: Distribution of the Socio-demographic characteristics of the respondents included (n=200)

included (n=200)				
	N	%		
Age	•			
30-39	104	52		
40-49	64	32		
50-59	20	10		
More than 60	12	6		
Gender	•			
Female	84	42		
Male	116	58		
Education	•			
Informal Education	24	12		
Primary	22	11		
Secondary	30	15		
Tertiary	124	62		
Work status	<u>,</u>			
I am a small-scale farmer	38	19		
I am self-employed	64	32		
I am in formal employment	90	45		
I am retired or a pensioner	8	4		
Residence	<u>,</u>			
Urban	130	65		
Rural	70	35		
Distance to health facility	1			
Less than 10 km	42	21		
10-19 km	56	28		

20-29 km	34	17		
≥ 30 km	68	34		
Nationality				
Saudi	174	87		
Non-Saudi	26	13		
Marital status				
Married	130	65		
Single	44	22		
Divorced	26	13		
Salary satisfaction				
Sufficient	124	62		
Partly Sufficient	42	21		
Insufficient	20	10		
Quite Insufficient	14	7		

Regarding the distribution of the socio-demographic details among the patients regarding age majority of the study groups from the 30-39 years were (52.0%) followed by 40 to 49 years were (32.0%) but 50-59 years were (10.0%) while more than 60 were (6.0%), regarding the gender many of the respondents were male (58.0 %) while female were (42.0%), regarding the education status the majority of the respondents tertiary were (62.0%) but secondary were (15.0%), while informal education were (12.0%) but the primary were (11.0%), regarding the work status the most of the participants answer I am in formal employment were (45.0%) while I am self-employed were (32.0%) but I am a small-scale farmer were (19.0%) while I am retired or a pensioner were (4.0%), regarding the residence the majority of the respondents urban were (65.0%) while rural were (35.0%), regarding the distance to health facility the majority of the respondents ≥ 30 km were (34.0%) while 10-19 km were (28.0%) while 20-29 km were (17.0%), while less than 10 km were (21.0%), regarding the nationality the majority of the respondents Saudi were (87.0%) while Non-Saudi were (13.0%), regarding the marital status the majority of them married were (65.0%) while single were (22.0%) but divorced were (13.0%), regarding the salary satisfaction the most of participant sufficient were (62.0%) while partly sufficient were (21.0%) while the insufficient were (10.0%) while quite Insufficient were (7.0%).

Table 2: Distribution of the History of Diabetes among the patients

	N	%	
Duration with diabetes	·		
Below one year	36	18	
1-5 years	44	22	
6-10 years	28	14	
More than 10 years	92	46	
Co-morbidities			
None	38	19	
Hypertension	68	34	

Tuberculosis	58	29
Arthritis	16	8
CVD	20	10
Patient on medication	<u>.</u>	
Yes	68	34
No	132	66
Initial treatment and advice give	n	
None	8	4
Insulin injection	46	23
Tablets	64	32
Change of Diet	70	35
Exercise and weight loss	12	6
Number of tablets		
None	136	68
One	20	10
Two	32	16
three	12	6
Time for medication		
Morning	64	32
Afternoon	24	12
Evening	84	42
Morning & Evening	28	14

Regarding the table 2 distribution of the History of Diabetes among the patients regarding duration with diabetes majority of the study more than 10 years were (46.0%) followed by 1-5 years were (22.0%) but below one year were (18.0%) while 6-10 years were (14.0%), regarding the Co-morbidities most of participant Hypertension were (34.0%) while Tuberculosis were (29.0%) while none were (19.0%) but the CVD were (10.0%) but the arthritis were (8.0%), regarding the patient on medication the majority of the respondents answer No were (66.0%) but answer Yes were (34.0%), regarding initial treatment and advice given the most of the participants Change of Diet were (35.0%) while tablets were(32.0%) insulin injection were (23.0%) while exercise and weight loss were (6.0%) while none were (4.0%), regarding Number of tablets the majority of the respondents none were (68.0%) while two were (16.0%) but one were (10.0%) while three were (6.0%), regarding the time for medication the majority of the respondents evening were (42.0%) while morning were (32.0%) while morning and evening were (14.0%) while after noon were (12.0%).

Table 3 Distribution of Reasons for Missing Ant diabetics

Reasons	N	%
Lack of money	30	15
Lack of drugs in the hospital	64	32
Distance to the hospital	48	24
I forget	60	30
I don't like taking drugs	54	27
Pain when administering insulin	38	19

Regarding the table 3 distribution of Reasons for Missing Ant diabetics the majority of the participants Lack of drugs in the hospital were (32.0%) followed by were (46.0%) followed by I forget were (30.0%) but I don't like taking drugs were (27.0%) while Distance to the hospital were (24.0%), regarding the Pain when administering insulin were (19.0%).

Table 4: Distribution of the Knowledge on Management of Diabetes

Variables	High Adherence		low adherence		Chi-square	
	N	%	N	%	\mathbf{X}^2	P-value
DM can be cured	42	21	158	79	67.280	<0.001*
Stop taking drugs when sugar is controlled	96	48	104	52	0.320	0.572
Detect low blood sugar levels through signs and symptoms and manage	132	66	68	34	20.480	<0.001*
Beneficial to stop smoking	144	72	56	28	38.720	<0.001*
Checking blood pressure while being DM	130	65	70	35	18.000	<0.001*
Shaking and fast heart rate	130	65	70	35	18.000	<0.001*
Low blood sugar	144	72	56	28	38.720	<0.001*
High blood sugar	166	83	34	17	87.120	<0.001*

Regarding Table 4 distribution of the Knowledge on Management of Diabetes regarding diabetes mellitus patients can be cured a statistical significant relation were P=value 0.001 and X^2 67.280, the majority of the Participants in low adherent were (79.0%) followed by high adherent were (21.0%), regarding stop taking drugs when sugar is controlled no statistical significant relation were P=value 0.572 and X^2 0.320, the majority of the

participants in low adherent were (52.0%) followed by high adherent were (48.0%), regarding detect low blood sugar levels through signs and symptoms and manage a statistical significant relation were P=value 0.001 and X² 20.480, the majority of the participants in high adherent were (66.0%) followed by low adherent were (34.0%), regarding beneficial to stop smoking a statistical significant relation were P=value 0.001 and X² 38.720, the majority of the participants in high adherent were (72.0%) followed by low adherent were (28.0%), regarding Checking blood pressure while being diabetes mellitus patients a statistical significant relation were P=value 0.001 and X² 18.000, the majority of the participants in high adherent were (65.0%) followed by low adherent were (35.0%), regarding Shaking and fast heart rate a statistical significant relation were P=value 0.001 and X² 18.000, the majority of the participants in high adherent were (65.0%) followed by low adherent were (35.0%), regarding Low blood sugar a statistical significant relation were P=value 0.001 and X² 38.720, the majority of the participants in high adherent were (72.0%) followed by low adherent were (28.0%), regarding High blood sugar a statistical significant relation were P=value 0.001 and X^2 87.120, the majority of the participants in high adherent were (83.0%) followed by low adherent were (17.0%)

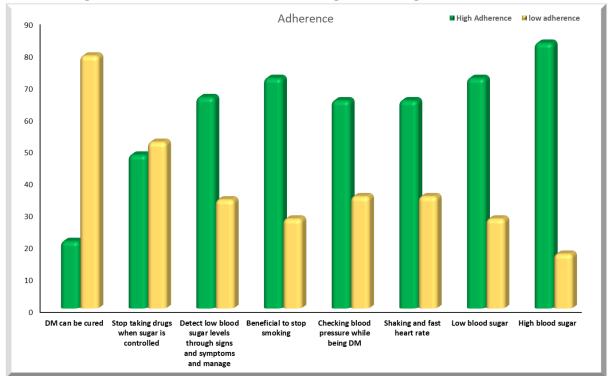


Figure (1) Distribution of the Knowledge on Management of Diabetes

Discussion

Many researchers and health professionals have acknowledged that diabetes is a self-management disease with the onus on the patients to take care of themselves [17]. Two of the most essential facets of diabetes management are medication adherence and self-care behavior's. Adherence to these aspects of care is very challenging for most patients with diabetes [19]. Previous studies have established that adherence to medication has a positive influence on glycaemic control in patients with type 2 diabetes mellitus [16]. The present

study assessed the influential factors associated with medication-non adherence and self-care practices among diabetes mellitus patients . In our study show age majority of the study groups from the 30-39 years were (52.0%), gender many of the respondents were male (58.0%), regarding the education status the majority of the respondents tertiary were (62.0%), the residence the majority of the respondents urban were (65.0%), regarding the distance to health facility the majority of the respondents \geq 30 km were (34.0%). (See table 1).

in this study the influential distribution of the History of Diabetes among the patients factors associated with medication-non adherence and self-care practices among diabetes mellitus patients (patient, medication, health care related factors).(Insufficient knowledge about medications, no progress, depression sense of unusualness. Medication adherence is a critical element in treating among diabetic patients, and non-adherence among patients is an issue facing health care providers. Previous studies report that measuring adherence and patient compliance is quite difficult and is patient-dependent most of the time.[35] Hence, this study aimed to assess prevalence and risk factors of treatment Non-compliance among Diabetic Patients in Saudi Arabia 2023, in our study show duration with diabetes majority of the study more than 10 years were (46.0%), regarding the Co-morbidities most of participant Hypertension were (34.0 %), the patient on medication the majority of the respondents answer No were (66.0%), regarding Number of tablets the majority of the respondents none were (68.0%) (See table 2). In line with prior studies [32], an overwhelming percentage of the participants were adherent to medication. This study found no statistically significant association between knowledge and medication adherence. We therefore argue that participants might have had the perception that medication is more important than other selfcare behavior's for example diet and exercise to control diabetes [34] Regarding the distribution of Reasons for Missing Ant diabetics the majority of the participants Lack of drugs in the hospital were (32.0%) followed by were (46.0%) followed by I forget were (30.0%) but I don't like taking drugs were (27.0%) while Distance to the hospital were (24.0%), regarding the Pain when administering insulin were (19.0%) (See table 3)

It could be assumed that clinicians probably focused more on the importance of adherence to therapeutic regimen than other self-car behavior's. Contrasting findings were reported in Cameroon [19] and Malaysia [27] whereby the majority of patients were non-adherent to medication. The study in Cameroon cited financial challenges as a reason for the low adherence with patients having to purchase expensive drugs out of pocket. Though the National Health Insurance status of participants was not assessed, its coverage on antidiabetes medications in Ghana might have contributed to the high adherence rate of the present study population as most of the patients were not affluent, in our study found regarding diabetes mellitus patients can be cured a statistical significant relation were P=value 0.001 and X2 67.280, the majority of the Participants in low adherent were (79.0%) followed by high adherent were (21.0%), regarding stop taking drugs when sugar is controlled no statistical significant relation were P=value 0.572 and X2 0.320, the majority of the participants in low adherent were (52.0%) followed by high adherent were (48.0%), regarding detect low blood sugar levels through signs and symptoms and manage a statistical significant relation the majority of the participants in high adherent were (66.0%), regarding beneficial to stop smoking a statistical significant relation the majority of the participants in high adherent were (72.0%), regarding Checking blood pressure while being diabetes

mellitus patients a statistical significant relation were P=value 0.001, the majority of the participants in high adherent were (65.0%) followed by low adherent were (35.0%) (See table 4)

Conclusion

The present study findings revealed a low prevalence of medication adherence. The factors associated with adherence were age, education, and practice of self-care activities. Knowledge also had a significant influence on self-care practice. We recommend consistency in education to deal with issues related to self-care behavior's and medication adherence as this is necessary to enhance self-management and minimize complications. Non-adherence was associated with younger age. Interventions to improve adherence should target younger and newly diagnosed patients through aggressive counseling to address healthy self-management behavior's. Other approaches that have been used to study adherence measure validity, could be future research. Medical practitioners need to be aware of it and address this problem because compliance is directly related to the prognosis of the illness. A high prevalence of non – compliance is still a problem in the treatment of patients, particularly those who had positive risk factors future studies should investigate potential strategies to identify at-risk patients and develop new methods to increase persistence and adherence by addressing the modifiable risk factors.

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