

Original

Variables affecting compliance of diabetic patients with their respective Management Protocol at Ribat University Hospital, Khartoum – Sudan 2021

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Abstract

Background: This study attempts to investigate the variants affecting diabetic patients compliance to their diabetic management protocols, such as their level of awareness towards their treatment being much more than just medications to be taken, but rather an overall package of medication and life-style changing, and their level of willingness to change in order to decrease morbidity and mortality associated with diabetes.

Objectives: To determine the level of compliance of diabetic patients to their respective treatment protocol at Ribat University Hospital in Khartoum, Sudan 2021, and the variants affecting such compliance.

Materials & Tools: This is meant to be a Cross sectional facility based study with total sample size is 101, random systemic sampling was used to select the participants for this research, data was collected using self-made questionnaires, and the data was analyzed using an SPSS based cross tabulation analysis.

Results: The overall compliance rate in this study was 63%. Females were found to be more significantly compliant (P value <0.05) in comparison to males. Married individuals also had a

better compliance (P value <0.05) in comparison to single, widowed, or divorced individuals. There was also, a statistically significant relationship between higher educational levels and compliance rate, p value of (<0.001) the higher education level was linked with a better compliance level.

Middle and higher socio-economic statuses (SES) diabetic patients had higher compliance rates. Middle SES had a p value of <0.04 , and wealthier classes had a p value of 0.05 respectively, while lower socio-economic groups had significantly lower compliance levels.

Age groups >66 years was shown to be statistically significant in regards compliance (p value 0.05) in comparison to younger age groups. No significant relationship was found between compliance and co-morbidities.

Conclusion: This study highlights the importance of conduction of awareness raising campaign regarding the importance of patient's compliance to these protocols.

Key Words: Compliance, adherence, maladherence, non-compliance, type 1 diabetes, type 2 diabetes, adherence, and treatment protocol.

Introduction

Diabetes mellitus (DM) keeps on expanding internationally, with the subsequent weight resting more forcefully on tropical, developing countries (1,2)

Compliance to therapy is the degree of the person's behavior in refining their overall lifestyle to control diabetes. This includes taking medication, regularly following a diet, and/or executing lifestyle changes, as well as adhering with the agreed recommendations from their healthcare provider. (3)

Maintaining adequate treatment compliance necessitates constantly monitoring blood glucose, being aware of the signs and symptoms of hypoglycemia, and following a healthy diet. Effective completion of these steps is not as easy as it may seem and requires effort and organization, encouragement, and a good mindset (4) that encompasses a broad cognitive domain of skills. (5)

Studies have been able to identify the factors affecting patient's overall compliance rate (6) which are support from friends and family, the mental status of the patient, age,

socio- economic status, and the patients' health beliefs have been proven to be associated with the overall compliance. (7)

Other factors that are believed to play a major role in adjusting to chronic diseases include the patient's complexity of the treatment regimen, and duration of the disease. (8)

As there are not enough studies made in Sudan, this study will compare the factors stated above and in addition, the marital status, gender, as well as the educational level with the compliance levels.

As stated by the International Diabetes Federation (IDF), 387 million people are living with diabetes in the world and of which more than 22 million are in the African region. (3)

Sustainable treatments are accessible requiring achieving balanced insulin dosing, diet and exercise alongside regular monitoring from blood glucose observing outcomes. Along these lines, execution of a steady adherence to such a challenging

treatment routine difficulties even the most motivated juvenile. (9)

Close compliance to sugar admission is simultaneously associated with a better glycemic control. It is worth mentioning that a healthy diet is encouraged for all the patients with type 1 diabetes (even for patients not having a disease-specific diet); diabetic patients are more prone to develop dyslipidemia and cardiovascular diseases. Multiple researches have proven that patients with Type 1 Diabetes Mellitus were found to have abnormal lipid levels increasing the risk factor for cardiovascular diseases. According to the 2005 Dietary Guidelines for Americans, it is important to include fruits and vegetables, whole-grain foods, and foods that have a lesser percentage of fats. (10)

With this in mind, studies unfortunately found that patients diagnosed with Type 1 Diabetes Mellitus were found to be consuming more fat than the recommended level for them and even more than the non-diabetic people. According to the Healthy People 2010 recommendation, the limit of energy from saturated fat should not exceed 7, but their range was a great deal higher. (between 11 to 15 %). (10)

A relationship between symptoms and higher HbA1c levels has been found and is mediated by declined compliance to blood glucose recording in a study of 276 teens with T1D. (9)

This shows the importance of testing HbA1c levels regularly, as individuals with better adherence rates were the group that checked their HbA1c levels every 3 months and were shown to have better glycemic control and lower risk of developing CKD. (11) Rapid uncontrolled urbanization and major changes in lifestyle are most likely driving this epidemic. This puts a great demand on the health care system and on society to keep up and work against this rapid increase. (12)

Appropriate diabetes programs in Sub-Saharan African countries are particularly needed to have in order to ensure the right treatment, to lower the risk of diabetes-related morbidity and mortality. (12)

The World Health Organization (WHO) has shown that compliance to long-term therapy for chronic illnesses in developed countries averages only around 50%. (13)

Compliance rates are usually reduced for patients with chronic conditions than those with acute conditions; this is associated with the long-term nature of chronic diseases

because the decline in compliance is most rapid after the first 6 months of therapy. Such reduced compliance not only results in poor health outcomes but it also has a significant impact on healthcare costs. Thus, the overall management of type 2 diabetes should address compliance as well as appropriate medications. (3)

A literature search conducted in the years (1966–2003) was fulfilled to single-out reports on compliance with oral hypoglycemic agents (OHAs) and insulin and interrelationship between compliance rates and glycemic control. Retrospective studies indicated that compliance to oral hypoglycemic agent's therapy ranged from 36 to 93% in patients remaining on treatment for 6–24 months.

Prospective electronic monitoring studies showed that patients took 67–85% of oral hypoglycemic agent's doses as prescribed. Electronic monitoring identified poor compliers for interventions that improved compliance (61–79%; $P < 0.05$). Patients in the age of youth filled prescriptions for one-third of prescribed insulin doses. Insulin compliance among patients with type 2 diabetes was 62–64%. This study validates that many patients for whom diabetes medication was prescribed were poor

compliers with treatment, including both oral hypoglycemic agents and insulin. Despite that though, electronic monitoring systems were proven helpful in improving compliance for individual patients. (8)

Research based on large claims databases have identified other key demographic factors, which include young age, lower educational level, and lower socio-economic status. These are associated with poor medication compliance in Type 2 Diabetes. Cost of treatment, medication beliefs, and how much trust they put onto the physician, there's other factors (e.g. depression, forgetfulness, and limited diabetes knowledge) but the factors mentioned above are the most amenable to change.(14)

One way in which patients will be better able to manage their illnesses is by adhering to their medication regimens. Many patients, especially patients with a chronic illness, experience complications in following treatment recommendations. (13)

As a result of poor compliance, patients do not receive optimal benefit from their drug therapy. Suboptimal treatment can lead to increased use of health care services (acute care and hospitalizations), drop in patient's quality of life, and amplified burden on health care costs (drug costs and medical

costs). The reports of World Health Organization have emphasized that “increasing the effectiveness of compliance interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments. (13)

The data demonstrates that health beliefs, the quality of doctor/patient communication, and the quality of the information patients received are important factors for patient compliance to treatment. Conceivable explanatory models for compliance emerged, relating to knowledge of the illness, body awareness and the doctor/patient relationship (15)

With appropriate life-style changes and commitment to medication as well as an overall positive outlook these factors contribute positively to the life of the patient. (15)

Better regimen compliance may close the gap between the possible treatment benefits, and the benefits patients actually receive. (16)

Possible ways to intervene and support in improving compliance of diabetic patients to their treatment regimen include the recall

and comprehension method in which the physician inquires the patient to repeat the instructions being told, this should not make the patient feel as if he/she is being tested but instead to make sure that the patient has fully seized the information and that a proper doctor- patient communication has been established. (16)

Additionally, ensuring that the patient’s awareness to the rewards of being adherent in the entire regimen in the short and long run, including the importance of exercise and diet, and asking the patient which medication they see themselves mostly forgetting and resolving that by creating a system that would help them remember all their medications, and informing the patient about the consequences of not being adherent. (16)

Statement of the Problem

It has been established that diabetes carries with it a plethora of probable complications, especially when patients do not adhere to the treatment plan set forth by their healthcare providers. For this reason, as well as for the rather grey insight by the IDF stating that these numbers are assured to double by 2035. Mal- adherence will present a myriad of issues related to the healthcare of these

patients including an unnecessary economic burden that affects the patients as well as society in general. This study aims to assess the issue at hand so that recommendations regarding the necessity for immediate action (or possible lack thereof) are taken into account. It is also necessary that the more effective educational programs receive the support they need.

In Africa, diabetes mellitus is estimated to affect around 14 million individuals and this is expected to rise to about 28 million by 2030. (35) In Sudan, the national prevalence of diabetes in adults is 7.7% and is expected to reach 10.8% in 2035. (35)

The incidence of Type 2 Diabetes Mellitus and pre-diabetes in north Sudan has had a significant increase since 1996. (36)

Rationale / Justification

An evaluation of patient self-care behavior can show how successful the education and counseling has been achieved.

In spite of the importance of self-care activities in the management of DM, only few studies have been conducted in the country regarding the compliance of diabetic's patients and its related to quality of life. Studying and identifying the level of

compliance is essential for developing more effective means to reduce complications related to poor control.

Research hypothesis

This study is expecting the compliance rate to be sub-optimal, and a direct relationship in regards to the level of compliance of diabetic patients with gender, with females being more compliant as they seem to be more adherent to guidelines, married couples to be more adherent due to the presence of a motivational partner, and a direct relationship between better educational level, higher socio-economic statuses, and presence of co-morbidities.

Methods

Study Population

Inclusion:

- 1) Any adult with Diabetes Mellitus

Exclusion:

1. Cognitively impaired

The calculation formula of Taro Yamane is presented as follows.

$$n = \frac{N}{1 + N(e)^2}$$

2. Gestational Diabetes

Sampling Technique

Data collection tool:

Questionnaires were self-built in an MCQ format, and were filled by the researchers.

The questionnaire had 24 questions in total.

A compliance scale was built from the questionnaire itself, by all the members in this research and approved by the referee, using 3 Point Likert scale, where "Yes" had 2 points, while "Sometimes" had 1, and "No" had 0 points in the interval scale.

Technique:

Random systemic sampling in Ribat University Hospital in the referral clinic, the hospital admission list would be taken and the group would pick one and skip three, and for every ward one would decide on a new number to skip from.

Sample size:

Yamane's Formula

Where :

n=samplesizerequired

N=number of people inthepopulation

e=allowableerror(%)

n =

$$\frac{480}{1+480 (0.04)^2}$$

$$= 267 \text{ patients}$$

Study variables

Dependent	Independent
Compliance level	Age
	Gender
	Known co-morbidities
	Marital status
	Socio-economic status
	Educational level

Data collection

Permission was granted from the hospital to collect the data; Google form was used for the creation of questionnaires; data was collected using SPSS.

Results

The overall compliance rate in this study was found to be sub-optimal with a percentage of 63%.

Females were found to be significantly compliant (P value <0.05) in comparison to males. Married individuals also had a better compliance rate (P value <0.05) in comparison to single, widowed, and divorced individuals, there was a statistically significant relationship between higher educational levels and compliance rate, as higher educational levels college education and above had a p value of (<0.001), vice versa. (Table 1)

Individuals with higher socio-economic statuses were also better adherent, middle and higher classes had higher compliance rates. Middle classes had a p value of <0.04 and wealthier classes had a p value of 0.05 respectively, while lower socio-economic groups had lower adherence rates. (Table 2)

Age groups >66 years showed statistically significant in regards to compliance rates (p value 0.05) in comparison to younger age groups.

No significant relationship was found between better compliance and co-morbidities. (Table 1)

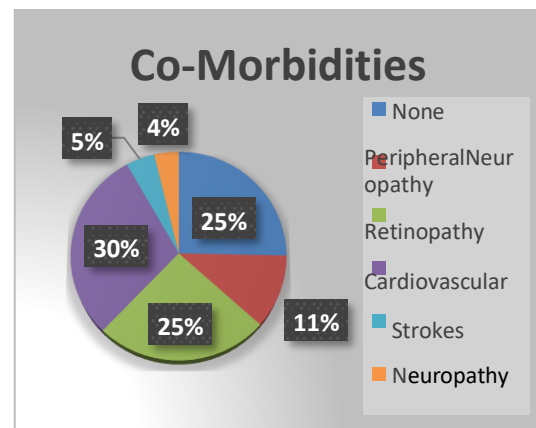


Figure 1: Percentages of co- morbidities in Ribat University Hospital in Khartoum-Sudan 2021

75% of the patients had diabetes-related co-morbidities, while 25% of the patients stated that they did not have any complications related to diabetes.

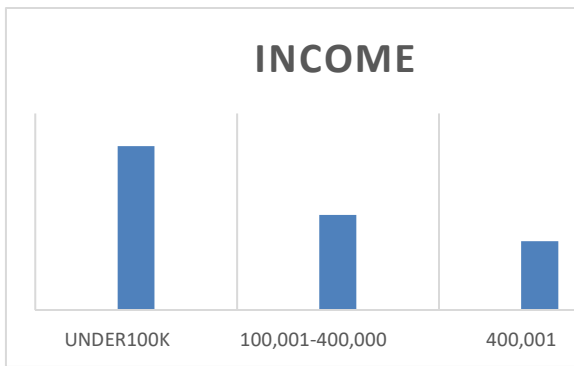


Figure 2: Socio-economic status of the participants in Ribat University Hospital in Khartoum- Sudan 2021

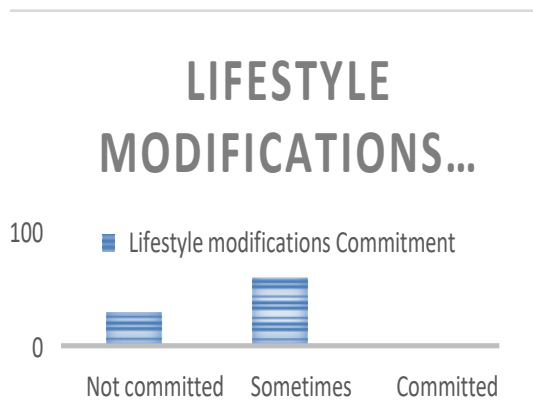


Figure 3: Commitment towards life- style modifications in Ribat University Hospital in Khartoum- Sudan 2021

50% of the participants had a ‘low’ socio-economic status 59% stated that they “try” committing to life-style modifications every now and then.



Figure 4: Commitment towards maintaining a healthy weight in Ribat University Hospital in Khartoum- Sudan 2021

40% of the patients try exercising every once in a while.

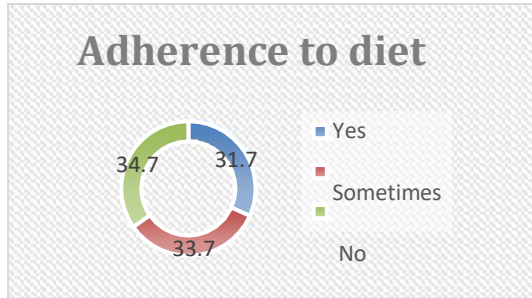


Figure 5: Commitment towards diet in Ribat University Hospital in Khartoum-Sudan 2021
34.7% are not committed to diet while 31.7% are committed to diet

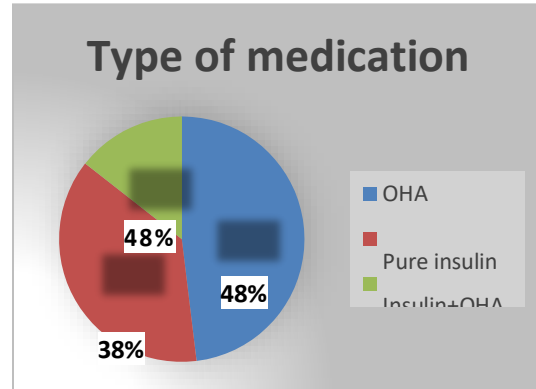


Figure 7: Type of medication used in Ribat University Hospital in Khartoum- Sudan 2021

48% of the participants are using oral hypoglycemic agents while 38% are using insulin as a medication, and 14% are using both.

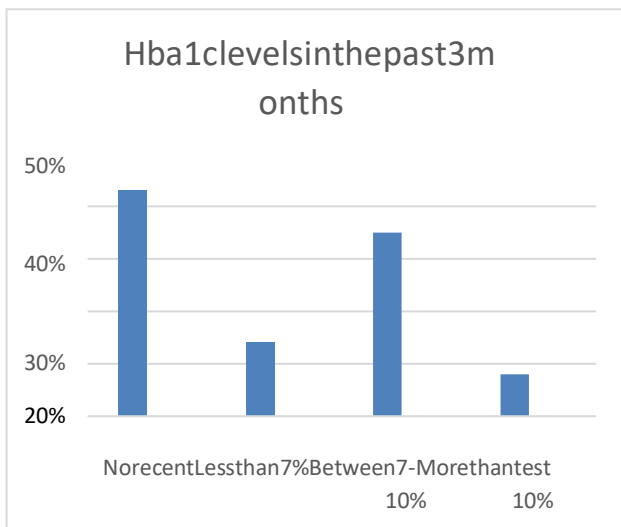


Figure 6: Hba1c testing results in the last 3 months of the participants in Ribat University Hospital in Khartoum- Sudan 2021

43% of the participants did not test their Hba1C levels in the past 3 months.

Table 1 – List of relationshipsfor adherents – Gender, age,andmarital status

Variables affecting compliance of diabetic patients		Osman <i>et al</i>							
Compliance level		Compliance level	Std .Error	Wald	Df	Pvalue	Odd ratio	Lower Bound	UpperBound
Adherent	Intercept	-1.612	4539 .576	.000	1	1.000			
	Male	1.152	.565	4.159	1	.083	3.165	1.046	9.575
	Female	1.152	.564	4.161	1	.043	3.164	1.044	9.577
	Age: < 40 years	1.810	1.29 8	1.947	1	.163	6.113	.481	77.760
	40- 55years	1.513	.847	3.193	1	.074	4.541	.864	23.875
	56-65 years	.679	.675	1.012	1	.314	1.972	.525	7.405
	66+ years	.626	.589	1.021	1	.049	1.965	.497	.
	Marital Statu : Married	18.337	4539 .576	1.032	1	.043	4.251	1.294	9.689
	Widow	1.445	4539 .576	1.022	1	.081	4.362	1.157	9.568
	Singl e	1.301	4539 .576	1.040	1	.093	4.147	.926	9.598
	Divorc ed	1.810	4539 .576	1.032	1 209	.122	1.200	.259	5.553

Table 2 – List of relationship of adherence in comparison to Socio-economic statuses

Compliancelevel	Compliance level	Wald	Df	P value	Odd Ratio	95% Confidence Interval for Exp(B)	
						Lower Bound	Upper Bound
Socio-economic status: Lowincome	.183	.055	1	.065	1.200	.259	5.553
Middleclass	.077	.010	1	.039	2.073	.243	4.797
Wealthy	.077	.010	1	.049	2.080	.243	4.797

**Table 3 – List of relationship
between adherence and
educational level**

College/ University	18.572	345.177	1	.001	116312550 .08 3	1639 65 64.67 5	825088033.702
Uneducated	19.481	125.640	1	.069	288785394 .82 0	95759 5 9.860	8708996850.575
Post-graduate	20.153	193.679	1	.001	565344553 .74 8	3308 95 68.15 0	9659070284.632
Secondary	18.652	353.408	1	.065	126035134 .99 7	1802 80 99.80 4	881116447.463
Literate	18.260	.	1	.092 211	85121580. 971	8512 15 80.97 1	85121580.971
Quranicstudies	0b	.	0	.096	.	.	.

Discussion

Female gender was found to be statistically significant in regards to compliance levels, as females were found to be more adherent (P value 0.043/Table 1) in comparison to males. Individuals that were married were also more adherent (P value 0.043) in comparison to other marital statuses, there was a statistically significant relationship between the socio-economic status and educational level, as those that had a lower socio-economic status or lower educational levels were found to be less adherent in comparison to the individuals that had a higher socio-economic status or higher educational levels, as individuals that had an educational level of university and above had a p value of .001, and those of a higher socio- economic status were found to be more adherent as well, middle classes had a p value of .039, and wealthier classes had a p value of .049 respectively. (Table 2 and 3)

Older age groups above the age 66 years were found to also be statistically significant in regards to overall compliance rates. (P value .049)

No significant relationship was found when comparing compliance levels to the presence of co-morbidities.

In this present study, women were found to be more adherent towards medication and life-style modification 71% (figure 4.13), supporting studies in China (17), Saudi Arabia (18) Bangladesh (19), and India (20).

In this present study, married individuals were found to be more adherent (P value .043) in comparison to individuals that were single, windowed, or divorced. A study in Ghana concluded a similar finding in which the compliance in married people were (62.4%) more than the single persons (42.4%), (21) a similar study in Egypt found that 56.8% of the adherent patients were married.(22)

The link between marital status and compliance level is still not clear but implies the possibility of having a supportive partner could play a motivational role to the patient.

Several studies concluded that older age groups had better compliance rates in China (17), due to this finding in China they encouraged more intensive medication compliance monitoring among younger, male diabetic patients who are newly prescribed antidiabetic medications.

Physicians should spend more time and effort in explaining the importance of optimal medication compliance to these patients during their consultations, a finding opposing this current study was how adherent they found their participants to be with a compliance level of 89.6%. (17)

Similar studies were found in Saudi Arabia (18), as well as in Ghana. (21).

These findings in regards to age are similar to this study as older age groups were found to be more adherent than younger groups (Table 1) while more researches should be made in trying to understand why older age groups are more adherent, it is safe to assume that older age groups receive better care and can be constantly reminded by people in their households, which is a hypothesis supported by a study in Kenya, where the majority of participants in their study were over fifty-five years of age and would likely be living with children or relatives; the protective effect of family noted above is likely to facilitate compliance with medication. In contrast younger patients who are professionally active have been shown to be more likely to skip or forget their medication (23) hence poorer compliance. (24)

These findings oppose a study in Egypt where patients who were younger than the age of 40 were found to be adherent by 66.7% and the age group of 40-60 were adherent by 53% while patients older than the age of 60 had an adherent rate of 20.8%. (22)

This present study has found a significant relationship between socio-economic status and compliance levels, as a lower socio-economic status has been linked with a decreased compliance level. (Table 2) This supports other studies that have found a significant relation between poor compliance and financial problems. A study in USA showed that 34% of patients stated that paying for medications was a reason for the lack of compliance (25). Yusuff et al. study in Nigeria (26) and Nasir et al. study in Ethiopia (27) specified lack of finance as major barrier for anti-diabetic drug compliance; which institute 51.9% and 37.1% respectively. (28)

In China, they also stated that there was a relationship between district of residence and the odds of better medication compliance, as patients living in Taipo (a region more urbanized than the North district but less urbanized than Shatin) were found to be more adherent. (17) as well as Saudi Arabia, which linked those of a higher

socioeconomic class, to be more adherent to their medications by (45.5%). (18)

Similar statement was made in Ghana, the socioeconomic status that had the highest compliance rate to their medications where of a high socio- economic status (21), as well as India which stated that upper socio-economic classes were more adherent. (20)

This could be due to the fact that higher socio-economic status is able to afford better health-care facilities, even if they are living in a developing country, they have the privilege of travelling to countries that could provide a better healthcare to them, while those of a lower socio-economic status or those living in countries of poor economy will not be able to afford medication, this statement has been supported in a study in Kenya which states that “Cost of treatment has been implicated as a barrier in achieving medication compliance and glycemic control among Type 2 diabetes mellitus patients (29) Almost half of diabetic patients recruited reported cost as their main challenge to medication access. In Kenya, where the bulk of health care costs are paid out of pocket (OOP); this increased expenditure can result in impoverisation of individuals and their families especially if the breadwinner is affected (30).

At the public or national health level; increased resources need to be invested” (24)

A similar finding has been found in Sudan, the country in which this research is currently being made which has highlighted the impact of economic burdens among patients with diabetes in regards to affording medication. (31)

Another study also done in Sudan had very similar findings to our research finding when discussing gender and economic status, and the overall adherence was considered poor in their study, as little as 15% of the participants had high adherence rates. (34)

In this present study, a significant relationship (Pvalue .001/Table3) between higher education and higher compliance levels, 89.5% of this study’s participant’s responses had an educational level of complete school education or above, In South Sudan 58% of the responses showed poor knowledge. This was associated with a low level of education among participants (32) while compared to India which they were illiterate by 30% it was found that a strong association between compliance to medications and literacy levels. (20)

This implies the importance of education among all age groups to have a better understanding about the disease complications, and importance of compliance.

In this current study when asked about commitment to life-style changes, exercise and diet ,59% stated that they “sometimes” commit to their life-style modifications, and only 29% are always committed, in regards to weight and exercise 33% are fully committed in incorporating exercise to their everyday routine, while 40% sometimes try to commit. When finally asked about their diet 31.7% are committed fully in adjusting their diet to being diabetic while 33.7% stated that they sometimes adjust their eating habits, but it is usually on and off.

In South Sudan, when they were asked about diet almost 50% of respondents were not following diet recommendations (32) stating that physical activity has the greatest effect to minimize diabetes complications and reducing weight They suggested some barriers to exercise compliance such as lack of motivation and convenience and weather, which the participants stated is why they aren't able to commit as well.

A finding in this current study was that 43% of the diabetic patients did not test their

Hba1C levels in the past 3 months (figure 6), which is a similar finding to a study in South Sudan.

A study in Sudan stated that only (44.3%) patients had been tested for HbA1C within the last four months. (32)

Although it isn't the scope of this research, this society as a whole need to find ways to help patients to get encouraged to test their HbA1C levels every 3-4 months.

This current study has found that a good doctor-patient relationship in which a doctor properly educates the patient about the side-effects of medication and the importance of compliance is linked with an increased motivation to adhere which has been stated by 61% of the participants.

This supports a study in Saudi Arabia which states that “Medication therapy management and better communication of the patients and healthcare providers are highly relevant for therapy optimization and reducing non-compliance and approaching the glycated hemoglobin targets” (33)

Although this research has not found a significant link between co-morbidities and the level of compliance of diabetics towards their management protocol, the presence of co-morbidities is common in diabetics, this

current study has found that 30% of patients with diabetes have cardiovascular complications, 25% have retinopathy, 11% have peripheral neuropathy, 4% of the participants had strokes and nephropathy, while 25% stated that they do not have complications.

The results of the present study can be interpreted as an indicative of uniformity among other countries; this implies the need of counseling among diabetic patients, emphasizing the need of counseling among patients that are males, of lower socio-economic statuses, and lower educational levels, which was also recommended by a study made in Bangladesh, which had similar results to this study. (19)

The study recommends that further studies should be made with a larger sample size, and the importance of conducting awareness raising campaigns, among diabetic patients in regard of importance of compliance to management protocol.

Limitations

Due to the political instabilities that were taking place in Sudan, and the limited time allocated to the conduction of this project, this study was unable to reach the requested sample size.

Conclusion

Among the studied variables, the variables that were found to be statistically significant and linked with better compliance and adherence rates were the female gender, older age groups (above the age of 66), married couples, middle and higher socio-economic statuses, and educational level of college and above.

The overall compliance rate in Ribat University Hospital was 63% and is considered sub-optimal.

More researches with larger sample sizes need to be made, and awareness about the factors linked with poor adherence should be implemented, as well as awareness of the complications related to diabetes.

Ethical Considerations

Ethically approved by the ethical committee department at Napata College, and verbal consent was taken from all the participants. All the data collected from the participants remained confidential, and participation in this study was voluntary.

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