

Research Article

Clinical Inertia and Barriers to Insulin Injection among Sudanese Patients with Type 2 Diabetes Mellitus

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Keywords

- Clinical inertia; Insulin; Attitude; Type 2 diabetes; Sudan

Abstract

Objectives: The study aimed to assess the clinical inertia and patients attitude towards insulin among patients with type 2 diabetes.

Methods: This cross-sectional study conducted at a diabetes clinic in Omdurman, Sudan during the period from June to December 2017. One hundred and two patients with the diagnosis of type 2 diabetes were interviewed using a structured questionnaire to collect: Demographic data, the medication used, and attitude towards insulin injection. The clinical inertia was then estimated. The Statistical Package for Social Sciences (SPSS) was used for data analysis, and the ethical committee of Omdurman Teaching Hospital approved the research.

Results: Participants (70.6% females), their age was (59.62±9.91) years, the glycated hemoglobin (HbA1c) was (10.16±3.14), clinical inertia to insulin was reported in 47.1%, the commonest negative attitude towards insulin was keeping insulin as a last resort for treatment. A highly significant statistical difference was evident between patients with clinical inertia and those without (P-value<0.001) regarding HbA1c, no significant differences were found regarding age, sex, diabetes duration, neck circumference, neuropathy, and retinopathy.

Conclusion: Clinical inertia to insulin was found in nearly half of Sudanese patients with type 2 diabetes. Patients with clinical inertia had higher HbA1c compared to their counterparts, but no differences were evident regarding other patient characteristics. The commonest negative attitude towards insulin was keeping insulin as a last resort.

ABBREVIATIONS

SPSS: The Statistical Package for Social Sciences; HbA1c: The glycated hemoglobin; NC: Neck circumference; GLP-1: Glucagon-like peptide-1; DPP-4: Dipeptidyl peptidase-4 inhibitors; NSAID: Non-Steroidal Anti-Inflammatory Drugs

INTRODUCTION

Diabetes mellitus is a global health burden causing a lot of mortality and morbidity; the disease has attained an epidemic proportion. Currently, 285 million are affected, and this number is projected to reach 438 million by the year 2030 [1]. Despite the dramatic improvement in the management of the disease, still nearly half of patients with diabetes are not approaching the American Diabetes Association HbA1c target of 7.0% (53mmol/mol) even in the developed countries [2].

The glycated hemoglobin (HbA1c) provide information about glycemic control over long period of time (two to three months). There are upper and lower security zones for the glycated hemoglobin, the relationship between HbA1c and mortality is J-shaped [3,4].

The delay of the treatment intensification (clinical inertia) is a principal cause of inadequate glycemic control in patients with

type 2 diabetes mellitus. Clinical inertia is defined as failure to intensify or initiate treatment when glycemic targets are not met for two to three months [5]. Clinical inertia may contribute to patient with type 2 diabetes living with the glycated hemoglobin >7 with deleterious consequences in terms of diabetes microvascular complications [6] (nephropathy, neuropathy, and retinopathy). Higher morbidity and mortality, lower quality of life, and enormous public health costs are also associated with uncontrolled diabetes mellitus.

Recommendation on basal insulin initiation and intensification has been developed. The key recommendation is to use insulin in symptomatic patients with entry HbA1c >10 and patients on two or three oral hypoglycemic agents who fail to achieve optimal glycemic control [7]. In spite of these recommendations, many patients with type 2 diabetes are not receiving timely and appropriate insulin treatment.

The sufficient understanding of the goal of therapy, proper communication of physician with the patients, and trusting the healthcare provider have been shown to alleviate patients discomfort and increase their adherence to treatment [8,9].

Failure to initiate and intensify the treatment is common especially in chronic asymptomatic diseases with great

implications on the patients' health and overall health costs [10,11]. Clinical inertia has been implicated in the suboptimal management of diabetes mellitus contributing to higher rates of chronic kidney disease, peripheral neuropathy, and blindness. There is an increasing awareness about clinical inertia and drug intensification in type 2 diabetes. Therefore, it is possible that pattern and trends in the existence of inertia have changed [12], updated information about this significant health problem to help the healthcare providers to avoid clinical inertia are highly needed. To our best of knowledge, no researchers have studied clinical inertia to insulin in Sudan. Thus we conducted this research to investigate the clinical inertia to insulin and the patient's attitude towards insulin therapy in Sudan.

MATERIALS AND METHODS

Study design

This cross-sectional study conducted at a diabetes clinic randomly chosen from seven clinics in Omdurman, Sudan during the period from June to September 2017.

Subjects

One hundred and two consecutive patients with the diagnosis of type 2 diabetes (according to American Diabetes Association Guidelines [13] were asked to sign a written informed consent, then interviewed using a structured questionnaire. Pregnant ladies, severely ill patients, and patients with type 1 diabetes were not included.

Sample size and data collection tools

The sample size was calculated using the formula: $n = Z^2 P \cdot Q / d^2$ and was found to be 102, where $Z = 95\%$ confidence (1.96), $P =$ Prevalence of diabetes mellitus in Sudan [1,14], $Q = 100 -$ prevalence, and $d =$ tolerated error. The following information were collected: demographic data, time since the diagnosis of diabetes, number and type of medications taken by the patients, microvascular and macrovascular complications of diabetes, financial issues with drugs, medication side effects, education about insulin, attitude and barriers towards taking insulin including needle phobia, fear of hypoglycemia and weight gain. An open question was left for the patients to report their attitude towards insulin. The patient's knowledge about Glucagon-Like Peptides was reported.

For the purpose of this survey the following measures were adopted:

Neck circumference (NC)

Neck circumference was measured as a marker of upper body subcutaneous adipose tissue distribution, it is a relatively new method of differentiating between normal and abnormal fat distribution. Previous studies have shown that the (NC) >37 cm and 34 cm in men and women respectively are probably the best cutoff points to determine subjects with central obesity [15,16]. Neck circumference is measured below the laryngeal prominence and perpendicular to the long axis of the neck, and the minimal circumference is recorded to the nearest 0.1 cm. The patients should look forward and the shoulders not elevated.

The glycated hemoglobin

A blood sample was taken for HbA1c measurement to assess the degree of diabetes control using a glycol hemoglobin reagent set from HB1C Siemens Healthcare Diagnostics Newark, DE 19714, USA.

Inertia to insulin

Patients on two or three oral hypoglycemic medications and not achieving optimal diabetes control were considered as having insulin inertia [7].

Statistical analysis

The Statistical Package for Social Sciences (SPSS, version 20, Chicago) was used for data analysis. The Chi-square, independent t-test, and one-way ANOVA tests were used to verify the statistical significance when appropriate.

The data were presented as percentages and mean \pm SD, a P-value of <0.05 was considered significant.

Ethical consideration

The ethical committee of Omdurman Teaching Hospital, Omdurman, Sudan approved the research. All the participants signed a written informed consent.

RESULTS AND DISCUSSION

Results

Out of 102 patients with type 2 diabetes, females dominance was apparent (70.6%), their ages ranged from 28-82 years with a mean of 59.62 ± 9.91 years, the majority had primary education (64.6%), 60.8% were housewives, 17.6% were laborers, 15.7% were employed, while 5.9% were teachers. Table 1 illustrated other patient's characteristics.

The mean glycated hemoglobin was 10.16 ± 3.14 , the average time since diabetes diagnosis was 11.90 ± 8.72 years, and the neck circumference was 34.27 ± 9.26 cm Table 2.

In the current study, metformin was the commonest prescribed drug (88.2%), followed by sulfonylureas (78.4%), and insulin in 9.8% of patients. Table 3. Illustrated the pattern of prescription among the study group.

In the present study, 63.6% of diabetic patients were receiving five or more drugs, table 4, depicted the number of medication taken by type 2 diabetic patients.

Table 5 showed the attitudes and barriers towards insulin, the commonest barrier to insulin was viewing insulin as the last resort in the management of type 2 diabetes, followed by fear of hypoglycemia, insulin storage issues, and needle phobia. Furthermore, nearly two thirds had poor knowledge regarding insulin, more than one third were concerned about medications side effects and reported financial difficulties. It is interested to not that only one in four patients received education regarding insulin and a minority have heard about glucagon-like peptides-1 agonists.

In the present study, a high significant statistical difference was evident (P-value <0.001) between diabetic patients with

Table 1: Basic characteristics among the study group.

Character	No%
Sex	
Males	30 (29.4%)
Females	72 (70.6%)
Education	
Illiterate	26 (25.5%)
Primary	30 (29.4%)
Intermediate	10 (9.8%)
High secondary	22 (21.6%)
University	14 (13.7%)
Occupation	
Housewives	62 (60.8%)
Laborer	18 (17.6%)
Employee	16 (15.7%)
Teachers	6 (5.9%)
Diabetes retinopathy	30 (29.4%)
Peripheral neuropathy	36 (35.3%)
Ischemic heart disease	4 (3.9%)
Good glycemic control	24 (23.5%)
Clinical inertia to insulin	48 (47.1%)

Table 2: Patient's characteristics mean ±SD.

Character	Mean ±SD
Age	59.62±9.91
HbA1c%	10.16±3.14
Meantime since diabetes diagnosis	11.90±8.72
Neck circumference (cm)	34.27±9.26
HbA1c: The glycated hemoglobin	
SD: Standard deviation	

Table 3: Prescription pattern among patients with type 2 diabetes.

Medication	No%
Metformin	90 (88.2%)
Sulphonylureas	80 (78.4%)
Pioglitazone	2 (2%)
Insulin	10 (9.8%)
Antihypertensive	58 (56.9%)
Statins	62 (60.8%)
Gabapentin	4 (3.9%)
Aspirin (low dose)	56 (54.9%)
Proton pump inhibitors	36 (35.3%)
Vitamins	94 (92.2%)
No steroidal anti-inflammatory drugs	6 (11.8%)

inertia to insulin and those without regarding the glycemic control, no significant differences were detected regarding age, (P-value > 0.05, CI=-12.20-0.26), the duration since diabetes diagnosis, (P-value > 0.05, CI=-8.25-3.03) and neck circumference, (P-value > 0.05, CI=-10.59-1.18) Table 6.

No significant statistical difference between diabetic patients with inertia and those without the character regarding neuropathy, neuropathy, and gender, P-values > 0.05 Table 7.

Table 8 depicted the result of One-Way ANOVA in which: No difference was evident between those with inertia to insulin and those without inertia regarding education and occupation (P-values=>0.5, F=1.08 and 0.536) respectively.

Discussion

Clinical inertia is one of the main causes of inadequate glycemic control. In the present study, clinical inertia to insulin was found in 47.1% of patients with type 2 diabetes mellitus, similarly to researchers from Spain [17] who concluded inertia

Table 4: Medications number among patients with type 2 diabetes.

Medications number	No%
Eight	2 (2%)
Seven	8 (7.8%)
Six	30 (29.4%)
Five	24 (23.5%)
Four	26 (25.5)
Three	6 (5.9%)
Two	6 (5.9%)

Table 5: Clinical inertia and attitude towards insulin among patients with type 2 diabetes mellitus¹.

Character	No%
Insulin is the last resort	42 (41.2%)
Insulin storage problems	22 (21.6%)
Needle phobia	18 (17.6%)
Hypoglycemia risk	28 (27.5%)
Weight gain	10 (9.8%)
Don't know to inject insulin	4 (3.9%)
Fear of retinopathy	2 (2%)
Insulin is from pigs	2 (2%)
Lack of knowledge about insulin	64 (62.7%)
Financial issues	40 (39.2%)
Medications side effects	38 (37.3%)
Did your treating doctor give education about insulin?	24 (23.5%)
Have you heard about injectable drugs other than insulin (GLP-1 receptors agonists)?	1 (2%)
¹ Some patients had more than one factor	
GLP-1 receptors agonists: Glucagon-like peptide-1 receptors agonists	

Table 6: Inertia to insulin and patients characteristics^{*}.

Character mean± SD	Inertia	No inertia	P-value	95% CI
Age	58.10±9.78	64.07±9.22	0.060	-12.20-0.26
HbA1c%	11.15±2.97	7.29±1.45	<0.001	2.12-5.58
Duration of diabetes	11.23±8.03	13.84±10.06	0.357	-8.25-3.03
Neck circumference	33.07±10.22	37.78±4.21	0.115	-10.59-1.18
T-test				
HbA1c%: The glycated hemoglobin				
CI: Confidence Interval				

Table 7: Inertia to insulin relation to retinopathy, neuropathy, and sex*

Character	Inertia (n=38)	No inertia (n=13)	P-value
Neuropathy	13 (34.2%)	5 (38.4%)	1.000
Retinopathy	11 (28.9%)	4 (30.7%)	1.000
Sex	10 (26.3%)	5 (38.4%)	0.487
Chi-square test			

Table 8: Relation of inertia to insulin, education, and occupation*

Character	F	P-value
Level of education	1.08	0.383
Occupation	0.536	0.660
*One-Way ANOVA		

in 52% of non-insulin treated patients with type 2 diabetes. The present findings are similar to Mahabaleshwarkar et al. [18], who conducted a survey at a large integrated health care system in the United States and found clinical inertia in 48.9%.

The American diabetes association recommended metformin mono-therapy as the first line for patients with type 2 diabetes if not contraindicated and to add another drug if glycemic targets are not met within three to six months [8]. In the present study, 88.2% of patients were taking metformin followed by sulphonylureas (78.4%) and insulin in 9.8%. The current findings were similar to a study published in Colombia [19] in which metformin was used in 84.0%, followed by sulphonylureas in 23.4%, and insulin in 20.7%. In the current study, glucagon-like peptide-1 (GLP-1) receptor agonists, and dipeptidyl peptidase-4 (DPP-4) inhibitors were not prescribed to the patients despite the lower risk of hypoglycemia, previous researcher from the United State [20] reported glucagon-like peptide-1 (GLP-1) receptor agonists, and dipeptidyl peptidase-4 in 3.4% and 12% respectively, the lack of prescription in the present sample could be due to cost and availability of these medications. In the present study, 92.2% of patients were taking Vitamins regularly, 11.8% were on regular Non-Steroidal Anti-Inflammatory Drugs (NSAID), 35.3% were on regular Proton Pump Inhibitors (PPI), while only 23.5% were educated about insulin. Furthermore, nearly two-thirds of patients were on five medications or more (polypharmacy), and some were on eight medications which may lead to non-compliance with medications and harmful side effects. The physician's adherence to the current guidelines is highly needed. The current data showed that, the belief that insulin is the last resort in the treatment of type 2 diabetes is the most common negative attitude towards insulin use (42.1%), followed by hypoglycemia risk (27.5%), the present findings are in accordance with previous studies in Saudi Arabia [21], another study conducted in five countries [22] (Germany, Sweden, Netherland, UK, and USA) reported similar results and the patients were concerned that insulin is the end of the road. In the present study, needle phobia was reported in 17.6% in contradiction to studies in China [23] in which the majority of patients reported needle phobia, the differences across countries could be explained by social and healthcare factors, furthermore only a minority of patients have adequate health education, therefore the misconception regarding diabetes therapy is expected. The

fear of diabetes complications such as hypoglycemia and weight gain, although rare with modern insulin (Degludec, Fiasp, and the smart insulin) could be acceptable, but retinopathy concerns and the fact that insulin is from Pigs is wrong belief reflecting a big gap in the knowledge regarding diabetes management. The link of blindness to insulin and not to poor diabetes control which was commonly reported in Singapore [24] (72.2%) and Malaysia [25] (54.5%) could lead to poor glycemic control with deleterious consequences.

The current data showed that, clinical inertia was commoner among patients with poor glycemic control in accordance with Mata-Cases et al. [26] who reported similar results. Previous literature indicated the absence of correlation of ophthalmic disorder to treatment addition similar to the present finding in which no significant difference was observed between patients with and without clinical inertia regarding retinopathy. In the current study, no significant statistical differences were evident between patients with clinical inertia to insulin and their counterparts regarding age, sex, occupation, level of education, peripheral neuropathy, the time since the diagnosis of diabetes, and neck circumference similar to Batais et al. [21] and Yu et al. [27]. The contradicting results reported regarding clinical inertia relation to retinopathy to duration of diabetes could be explained by the fact that type 2 diabetes may be present for years before the diagnosis. The lack of the association of the glycated hemoglobin with retinopathy and peripheral neuropathy may be to the fact that, these information were collected from the patients records and we did not conduct a recent clinical assessment. The small size of the study sample could be a plausible explanation.

The study limitations

The current study had many limitations, first the small size of the survey population, second is the cross-sectional type of the survey, and the fact that the survey was conducted at a single diabetes clinic, so generalization cannot be insured. Further larger multi-center studies are highly recommended.

CONCLUSION

The present study presents a study of Sudanese population with higher rates of clinical inertia to insulin, polypharmacy, and negative misconception and emotions towards commencing insulin like keeping insulin as a last form of treatment, storage problems, wrong believe regarding insulin source and side effects. Poor glycemic control is prevalent among the study group and associated with clinical inertia to insulin. Target intervention targeting their fears and misconception are highly needed.

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