

Original Research Article

MULTICENTRE EVALUATION OF TYPE 2 DIABETES MELLITUS OUTPATIENTS ON INSULIN THERAPY IN NIGERIA (METOIN STUDY).

ABSTRACT

Background: Insulin use in type 2 diabetes mellitus (T2DM) outpatients remains largely not well accepted in Nigeria. Both the physicians and the patients tread with caution whenever insulin is suggested as an outpatient treatment option. However, some patients are on insulin therapy despite the misgivings against insulin. This study on the type 2 diabetes mellitus outpatients on insulin therapy in Nigeria, is, therefore, compelling and at best overdue.

Methodology: This was a cross sectional study in which consenting T2DM outpatients who meet the inclusion criteria for the study in five tertiary health facilities were recruited and relevant data obtained via investigator-administered questionnaire between January 1, 2020 and December 31, 2021. Data obtained were analyzed using Statistical Package for Social Sciences (SPSS) version 23.0 software.

Results: A total of 268 T2DM outpatients were recruited into the study, made up of 116 (43.3%) men and 152 (56.7%) women. Out of this, 212 (79.1%) patients did not start insulin from onset of the illness. About 203 (75.7%) patients had their insulin first prescribed for them by endocrinologists in teaching and specialist hospitals. A total of 161 (69.1%) patients used insulin pen as against 107 (39.9%) patients that used insulin syringes and needles. Insulin was self-administered by 189 (70.5%) of the patients while intermediate acting insulin was the predominant insulin used by 127 (47.4%) of the patients. No insulin side effects was reported by 191 (71.3%) of the patients and 252 (94.0%) of patients reported that insulin injection pain was not enough reason not to be on insulin. Of the total number of patients, 110 (41.0%) patients reported hypoglycaemia which was treated at home by 90 (81.8%) of the patients. A total of 225 (84%) patients had personal glucometers of which 182 (80.9%) patients had glucose strips at the time of being recruited into the study.

Conclusion/recommendation: this study has shown that insulin is initiated for majority of patients several years after the onset of the illness and that insulin is prescribed mainly at teaching and specialist hospitals. Insulin pens were predominantly used and most of the patients administered themselves insulin which had no side effects in majority of them. Self glucose monitoring of blood glucose was done by a majority of the patient. It is recommended that continuous diabetes education and improvement in insulin technology be done to increase insulin acceptance and usage.

Keywords: insulin use, multicentre, outpatients, type 2 diabetes mellitus, Nigeria

INTRODUCTION:

Diabetes mellitus (DM) is a metabolic disease characterized by chronic hyperglycaemia due to reduced insulin secretion by the beta cells of the pancreas, decreased glucose utilization by the target tissues and increased hepatic glucose production [1]. The prevalence of DM is on the increase [2], more so, in sub Saharan African countries [3] due to ageing of the population, improving survival of people living with diabetes, obesity, increased urbanization and westernization of their diets, dietary changes and physical inactivity. It is projected by the WHO that by 2030, the number of persons living with type 2 diabetes mellitus (T2DM) will have risen to 552 million people world-wide but it currently affects 371 million people in the world [4].

In sub-Saharan Africa (SSA), the estimated prevalence of DM in the general population ranges from as low as 0.6% in rural Uganda to 12% in urban Kenya [5, 6]. In Nigeria, the reported prevalence of DM ranges from 4.4% to 11.0% [7-11]. Out of this number, between 14.2% and 20.8% of persons with type 2 DM are on insulin therapy either alone or in combination with oral or non-insulin anti-diabetic agents [12-14]. In Nigeria and other SSA countries, type 2 DM accounts for 85-99% of all the diabetic populations [15,16]. Therefore, T2DM patients constitute a considerable proportion of diabetic patients in our diabetes clinics. Oral anti-diabetic drugs (OAD), diets and lifestyle modifications alone or in combination with insulin are effective in lowering the blood glucose of persons living with T2DM while T1DM patients are dependent on insulin only for their blood glucose control. Type 2 diabetes mellitus is a chronic progressive disease in which, as beta cell dysfunction progresses, many patients will eventually need insulin treatment [17].

At the time of diagnosis of T2DM, the patient's pancreatic reserve remains about 35-40% and with a progressive pancreatic islet beta cell loss over time, the patient will, eventually, have absolute insulin deficiency just like the T1DM patients [1]. At this point, the T2DM patients will require insulin alone or in combination with diets, OAD and lifestyle changes for glucose control. Therefore, most persons living with T2DM who survive for long with the disease will eventually need insulin for blood glucose control. It is reported that insulin has benefits in achieving good glycaemic control and reduce the risks of long term diabetes complications [18,19]. Despite this obvious need for insulin therapy, it is documented that there are misconceptions and barriers to insulin initiation in T2DM outpatients by the primary care physicians who attend to most of these patients [20,21]. There are, also, patients' factors and barriers [22] to initiation and adherence to insulin therapy in T2DM outpatients which influence their non-acceptance of insulin therapy except in emergency and co morbid conditions.

A good number of T2DM outpatients are currently on insulin therapy in Nigeria. Most of the insulin therapies were initiated by non-specialists and primary care physicians. At what point were the insulin therapy started? Which regimen and how are they administered? Is diabetes care and practice as regards insulin therapy in T2DM outpatients associated with unfavorable outcome and side effects? Which side effects? Finally, some practitioners believe in initiating insulin therapy when there is secondary treatment failure with the OAD. Some specialists, however, are of the opinion that insulin should be started much earlier before the patients reach the point of secondary treatment failure with OAD. How do these schools of thought reflect on the T2DM outpatients on insulin therapy? These are the research questions of this study, answers to which are expected at the end of the study.

Physicians' factors in insulin initiation issues have been documented [20]. Published literature on the socio-demographic profile, insulin use practices, complications encountered by the patients and the self management of blood glucose (SMBG) practices of T2DM outpatients are scanty. This study, therefore, is aimed to fill this gap in knowledge; the findings would eventually influence diabetes care and practice in Nigeria.

MATERIALS AND METHODS:

Study design and Setting

This was a cross sectional observational study which took place simultaneously in five tertiary health facilities in Nigeria between January 1st 2020 and December 31st 2021. The centres were Federal Medical Centre, Umuahia, Nnamdi Azikiwe University Teaching hospital, Nnewi, Obafemi Awolowo University, Ile Ife, University of Port Harcourt Teaching hospital and Federal Medical centre, Yenogua, Bayelsa state. The principal investigator in each of the health institution was an endocrinologist assisted by residents. It was a tertiary hospital based study in which consecutive consenting T2DM outpatients on insulin therapy who meet the inclusion criteria for the study were recruited. An investigator administered questionnaire was used to generate data for the study; data collection was concluded within 24 months. Baseline demographic and insulin therapy information were obtained.

Inclusion criteria

All T2DM outpatients on insulin therapy including all women of child-bearing ages who were on insulin therapy to achieve a better control in an effort to achieve pregnancy were included in the study.

Exclusion criteria

All type 1 diabetes mellitus (T1DM) patients, pregnant women/gestational diabetes mellitus (GDM) patients, post operative T2DM patients or patients recovering from diabetic foot ulcer were excluded from the study.

Recruitment and Data Collection

From January 1, 2020 to December 31, 2021, all consenting T2DM outpatients who met the inclusion criteria for the study were consecutively recruited. Data for the study were extracted from patients using the investigator-administered questionnaire which consisted of the socio-demographic characteristics of the subjects, their insulin use patterns, insulin complications, challenges to insulin use and glucose monitoring data

Ethical consideration

Ethical approval was obtained from the Institution's Health Research Ethics Committee of each health facility participating in the study before commencing the study.

Statistical Analysis

The Statistical Package for Social Sciences (SPSS Inc. Chicago IL. USA) version 23.0 statistical software was used for data analysis. For continuous variables such as the ages of the study subjects, mean values and standard deviations (SD) were calculated and the means compared using independent two samples t-test. Categorical variables such as the gender, number of patients on insulin pen or syringes, etc were summarized using proportions expressed in percentages. The categorical variables were compared using the non-parametric test, chi square test. Level of statistical significance was set at $p < 0.05$.

RESULTS

A total of 268 T2DM outpatients participated in the study; made up of 116 (43.3%) men and 152 (56.7%) women; mean age of the participants was 56.90 ± 13.28 ; mean age of the men was 59.16 ± 14.16 years and women was 55.18 ± 12.35 years, age range of the participants was 23 – 85 years. The difference in the mean ages of the men and women were statistically significant ($t=2.446$, $p=0.015$). The socio-demographic characteristics of the study participants are shown in Table 1.

Characteristics		Frequency	(n = 268) (%)
Gender:	Male	116	43.3
	Female	152	56.7
Marital status:	Married	197	73.5
	Single	23	8.6
	Widow/widower	47	17.6
	Separated	1	0.4
Highest level of education:	No formal education	5	1.9
	Primary education	57	21.3
	Secondary education	60	22.4
	University education	113	42.2
	Postgraduate education	24	9.0
Occupation:	Civil servant	71	26.5
	Trader	61	22.8
	Self employed	43	16.0
	Unemployed	16	6.0
	Retired	68	25.4
	Clergy	9	3.4

A total of 56 (20.9%) T2DM outpatients were on insulin from onset of DM diagnosis while 212 (79.1%) patients did not for various reasons ranging from family GP's claim that insulin should be a last resort to prior misinformation about insulin, ignorance about which of insulin or oral anti-diabetic drugs to use and fear of insulin injection pain. About 44 (16.4%) and 122 (45.5%) patients started insulin when they had lived with diabetes for 5-10 years and >10 years respectively (Table 2).

Table 2: Duration of participant's DM prior to insulin initiation

	F r e q u e n c y		P e r c e n t a g e (%)		
Less than 6 months	2	3 8	.	.	6
6 months to 12 months	1	8 6	.	.	7
1 to 2 years	2	0 7	.	.	5
>2 years to 5 years	4	1 1	5	.	3
>5 years to 10 years	4	4 1	6	.	4
> 1 0 y e a r s	1	2 4	5	.	5

Insulin was first prescribed for 203 (75.7%) diabetic patients by endocrinologist in Federal Medical Centres (FMC) and teaching hospitals but started for 33 (12.3%) patients by endocrinologists in private hospitals. It is noteworthy that 19 (7.1%) of the patients had their insulin initiation by General Practitioners (GPs) in private health facilities. Insulin pens were used by 161 (69.1%) patients as against 107 (39.9%) patients that used insulin syringes and needles. Insulin was self-administered by 189 (70.5%) patients and by first degree relatives in 85 (24.3%) of the patients (Table 3).

Table 3: who administers the insulin to the participants

W h o a d m i n i s t e r s i n s u l i n	F r e q u e n c y	P e r c e n t a g e s (%)		
S e l f	1 8 9	7 0	.	5
First degree relatives eg spouse or child	6	5 2	4	3
Caregiver not related to patient	8	3	.	0
Neighbourhood nurse or other paramedical	6	2	.	2

Intermediate acting insulin was the predominant insulin used by 127 (47.4%) patients, followed by long acting insulin once daily and basal insulin once or twice daily by 81 (30.2%) and 45 (16.8%) of the patients respectively. No side effects was reported by 191 (71.3%) patients while weight gain and lumps/scars were reported by 30 (11.2%) and 26 (9.7%) of the patients respectively. Only about 16 (6.0%) patients reported that insulin injection pain was such that they could stop insulin injection while 252 (94%) did not care about the injection pain. A total of 110 (41.0%) patients reported hypoglycaemia of which 90 (81.8%) of the patients were treated by self at home while the hypoglycaemia was so severe in 20 (18.2%) patients that they needed treatment at hospital. Hypoglycaemia was not reported by 158 (59.0%) of the patients. A total of 225 (84%) patients had personal glucometers of which 182 (67.9%) patients had glucose strips and practiced self monitoring of blood glucose at the time of being recruited into the study.

DISCUSSION

More women living with type 2 diabetes mellitus used insulin therapy and this is similar to the reports by Ogbera et al [23] and Olamoyegun et al [24]. Reasons for this higher acceptance and use of insulin by women living with type 2 DM cannot be readily found except that it could be due to a better health seeking behavior among females [25] as reported by Omemu et al.

Insulin pens were the predominant device used in the index study at 69.1% and this was higher than the 55.4% reported by Olamoyegun et al [24], 18% by Ogbera et al [26] in 2008, 33% reported in Mexico [27], 29% by Ogbera et al [23] in 2012 but similar to the 65.6% reported in the Diabcare Indian Study [28]. It was, however, lower than the findings from the multinational MOSAIC study [27] where it was reported that majority of patients used pen devices over syringes in countries like China (100%), Germany (95%), Russia (93%) and Saudi Arabia (63%). It was, also, lower than the findings in a recent large worldwide survey in which it was shown that insulin pen alone was used by 85.6% of patients while 9.6% used a syringe device [29]. This finding is, however, a sharp contrast to the 98.5% of patients who used insulin syringes in a Nigerian local report [30]. Explanation for this could be from the high literacy level where about 73.6% of the participants had a secondary and university education. Insulin pens have become the choice device despite not being readily available to patients because they are convenient to use, more accurate, take less time to teach patients and its needle is less painful. It is important to note that none of the study participants was using insulin pump.

Premixed insulin was the commonest insulin preparation used in this study at 47.4% and this is similar to the reports by Ogbera et al [23] and that by Olamoyegun et al [24]. This is probably because of the convenience of taking it twice per day and still achieving good glycaemic control. Insulin was self administered by 70.5% of the patients in this study which was very similar to the reported 71.8% of self injection in the Olamoyegun et al [24] study. However, this figure is at variance with the reported 33% self injection in the Ezeani et al [30] study. This high percentage of self injection can be traced to their level of education as 51.1% of them attained university and postgraduate education. Insulin analogues was used by 16.8% of the participants in the index study unlike in the Ogbera [23] and Olamoyegun [24] studies where the percentages of insulin analogues use was 29% and 19.2% respectively.

A total of 67.9% of the participants practised self monitoring of blood glucose despite that 84% of them had glucometer. This is comparable to the 69.0% of the study participants who practiced SMBG in the Olamoyegun et al [24] study. This is, however, lower than the 70-80% reported by researchers in developed countries [31,32] but much higher than the 40% reported by Iwuala et al [33], 50.8% by Ezeani et al [30] and in Kenya [34]. Reason why 16.1% of the study participants in the index study had glucometer but did not practice SMBG is not known but may have to do with the cost of the glucose strips which are sourced out of pocket.

Insulin use by T2DM is usually initiated after the patients must have been on diets, oral anti-diabetic agents and or lifestyles modifications for sometimes until they reach secondary treatment failure with the aforementioned regimen. But, in the index study, it is noteworthy that 20.9% of the participants started insulin therapy with onset of DM diagnosis. This is despite the myths about insulin use in the Nigerian setting. On the hand, 79.1% of the participants started insulin use after several years of living with DM. These are the participants who believe insulin therapy should be the last resort or were fed with wrong information about insulin therapy or were afraid of insulin injection pain or a combination of the above reasons.

Insulin was initiated for 75.7% of the patients by endocrinologists in teaching hospitals and federal medical centres probably because that is where the bulk of the specialists practice and most of the patients enrolled in the study were primarily from those centres. The myths and misconceptions were easily doused. It is heartwarming that insulin initiation was done for 7.1% of the patients by GPs in private health facilities. A total of 71.3% of the patients reported no side effects as at the time of enrollment in the study irrespective of duration of use of insulin. This is probably because most insulin vials in use today are human insulin or are bioengineered and not porcine or bovine derived. The increased absence of side effects makes for increasing acceptance of insulin as a treatment modality. The commonest side effects were weight gain and lumps/scars; weight gain can be an advantage in cases of severe weight loss and the lumps/scars are just of cosmetic consequences.

One major drawback to insulin therapy is hypoglycaemia which was reported in 41.0% of the patients of which home self management was all that was needed in 81.8% of these patients. Hypoglycaemia was, however, reported in 31.9% of the patients in the study by Olamoyegun et al [24]. Management of hypoglycaemia underscores the place of diabetes self management education in the overall care of patients on insulin therapy. Diabetic patients, whether on insulin therapy or not, need continuous diabetes education to increase acceptance of insulin therapy and other novel treatment techniques.

In conclusion, about 94% of the patients in the index study felt that the insulin injection pain was not such as to stop insulin therapy. This is good for insulin acceptance and arises from improvements in insulin injection techniques and insulin pen technology. Patient's education will play a critical role in this respect.

CONCLUSION/RECOMMENDATIONS

In conclusion, more women participated in the study in which most of the patients used insulin pen and premix insulin which were mostly self administered. Insulin initiation was mostly at the specialist and teaching hospitals several years after disease onset. Self blood glucose monitoring, a critical part of insulin therapy, was done by a significant number of the participants. It is recommended that diabetes self management education be stressed to increase acceptance and usage of insulin therapy.

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