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Research Article

Insulin initiation in Type 2 diabetes mellitus outpatients – data from the multicentre evaluation of type 2 diabetes mellitus outpatients on insulin therapy in Nigeria (METOIN study)

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Abstract

People living with type 2 diabetes mellitus (T2DM) have relative insulin deficiency and, therefore, have options to insulin therapy. To be on insulin alone or in combination with other therapies in type 2 DM outpatients is a choice made personalized for each patient. Published literature on the insulin initiation patterns among T2DM outpatients in Nigeria is scanty. The objective of this study, therefore, is to bridge this gap in knowledge. This was a prospective cross sectional study conducted in five tertiary health facilities in Nigeria in which consenting type 2 DM outpatients on insulin therapy alone or in combination with other therapies and who meet the inclusion criteria for the study were recruited. Relevant data relating to insulin use initiation by the patients were analyzed using Statistical Package for Social Sciences (SPSS) version 23.0 software. A total of 268 outpatients living with type 2 DM on insulin therapy, made up of 116 (43.3%) male and 152 (56.7%) females participated in the study. Only 55 (20.5%) of the patients started insulin at onset of diagnosis of T2DM while 46 (17.2%) of the patients started insulin therapy after 5 years of living with T2DM. The duration of living with DM before insulin initiation and the patient's highest level of education were not statistically significant. Insulin initiation was delayed several months to years after diagnosis of T2DM by predominantly endocrinologists in tertiary health facilities but it was initiated in 19 (7.1%) of the T2DM outpatients by primary care physicians (GPs) in peripheral hospitals. It is recommended that diabetes education be intensified for T2DM patients to appreciate the key role of insulin therapy in diabetes care.

Keywords: insulin initiation, type 2 diabetes mellitus outpatients, Nigeria.

INTRODUCTION:

Good glycaemic control is central to reduction in risks of microvascular (affecting the eyes, kidneys and the nerves) and macrovascular complications of diabetes mellitus and the associated mortality and morbidity [1]. It is documented that insulin has benefits in achieving good glycaemic control and reducing the risks of long term diabetes complications [1,2]. It is recommended by the American Diabetes Association, the European Association for the Study of Diabetes [3] and the British National Institute of Clinical Excellence (NICE) guidelines on type 2 diabetes mellitus [4] that insulin be initiated for people with poorly controlled type 2 diabetes mellitus who are on maximum tolerated doses of metformin and sulphonylurea.

Type 2 diabetes mellitus is characterized by insulin resistance and progressive decline in pancreatic islet beta cell function [5] leading to a reduction in endogenous insulin production with time till the insulin reserve is completely depleted. Physicians and patients, therefore, need to appreciate this progressive nature of type 2 diabetes mellitus and understand the need for insulin therapy at some points while living with T2DM [6]. At this point, there is an indication for insulin therapy. Despite this obvious need for insulin therapy in type 2 diabetes mellitus patients, healthcare professionals exhibit some clinical inertia [7,8] to initiation and intensification of insulin therapy.

For many general practitioners (GPs), initiating insulin therapy in people living with type 2 DM can be anxiety provoking and time consuming Often, it is the physicians lack

of confidence in starting insulin, not the patients fear of insulin injection needles [9] that delays optimizing glycaemic control. Again, there are patient's barriers [10] to insulin initiation in T2DM outpatients except when deployed in emergency and co-morbid conditions. Fear of hypoglycaemia, concerns about isulin injection needle pain, concerns about the socioeconomic factors including concerns about affordability of insulin, cost of glucose monitoring and availability of insulin storage facilities constitute some of the patient's barriers to insulin initiation [10].

At what points while living with DM were the type 2 diabetes mellitus outpatients initiated to insulin, who initiated the insulin, where and what are the profiles of patients who start insulin therapy? These are the research questions this study attempted to answer, answers of which would influence endocrine practice in the sub-region.

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 Portharcourt Teaching hospital and Federal Medical centre, Yenogua, Bayelsa state. The principal investigator in each of the health institution was a Consultant endocrinologist assisted by medical 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 socio-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, who initiated insulin and where insulin was started.

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, 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. While 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 and the difference in the mean ages of the men and women were statistically significant (t=2.446, p=0.015).

Table 1: The socio-demographic characteristics of the study participants

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	15.3
	Separated	1	2.6
Highest level of education:	**No formal education**	14	5.2
	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

Only 55 (20.5%) of the patients started insulin at onset of diagnosis of T2DM. Insulin initiation in the rest patients are shown in Table 2 below.

Table 2: Diabetes mellitus duration before insulin initiation

Duration of DM	No. of diabetic outpatients
Started insulin from onset of diagnosis of DM	55 (20.5%)
< 6 months	80 (29.8%)
6-12 months	35 (13.1%)
13-24 months	30 (11.2%)
25-60 months	22 (8.2%)
> 5 years	46 (17.2%)

Insulin initiation in 203 (75.7%) of the diabetic patients was by endocrinologists in teaching hospitals and similar institutions while 7 (2.6%) of the diabetic outpatients had insulin initiated by nurses, pharmacists, lab technicians and other paramedicals (Table 3).

Table 3: Who and where insulin initiation was done

Who initiated the insulin?	No. of diabetic patients
Primary care physicians in private hospitals	19 (7.1%)
Nurses, pharmacists, laboratory technicians and scientists	7 (2.6%)
Specialists (Endocrinologists) in private hospitals	33 (12.3%)
Specialists (Endocrinologists) in teaching and similar institution	203 (75.7%)
Medical facilities abroad	3 (1.1%)

More T2DM outpatients who had university and postgraduate education were on insulin therapy (Figure 1) but the duration of living with DM before insulin initiation and the patient's highest level of education were not statistically significant (X^2 = 26.38, p = 0.38).
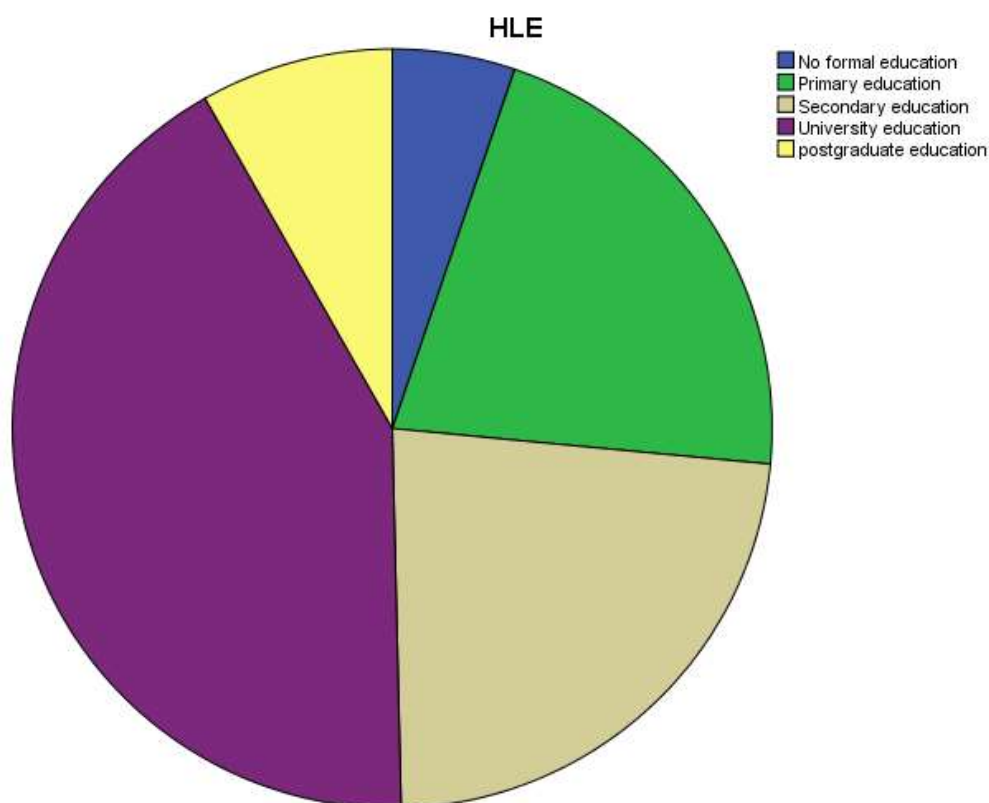
Key: HLE = highest level of education

Figure 1: Distribution of the T2DM outpatients according to their highest level of education

DISCUSSION

The main findings of this study included the fact that 20.5% of the T2DM outpatients commenced insulin use as soon as the diagnosis of diabetes mellitus was made in them, majority of the outpatients on insulin therapy had university and postgraduate education and insulin initiation in 203 (75.7%) of the diabetic patients was by endocrinologists in teaching hospitals and similar institution.

In this report, the finding that 20.5% of the T2DM outpatients commenced insulin at onset of diagnosis of DM would lead to preservation of their insulin reserve. This means that with proper guidance and good education, T2DM outpatients can reason that insulin should not be a last resort medication. As a result, the waiting until the pancreatic beta cell reserve is completely depleted before commencing insulin is avoided. However, a greater percentage of the patients (29.8%) still waited for more than 6 months before initiating insulin suggesting a probable population of T2DM outpatients who were not convinced why they should start insulin at diagnosis. It is a welcome development that the percentage of the patients who started insulin more than 5 years after diagnosis onset was just 17.2%.

More than half of the participants in this study (51.2%) had university and postgraduate education and this, has probably, rubbed off on their acceptance of insulin as treatment modality. The implication of this is that general and health education have a great role to play in behavior change and acceptance of novel treatment options. The finding that 5.2% of the participants in this study had no formal education but still keyed into insulin therapy underscores the place of diabetes self management education in the care of diabetes and its complications.

Insulin initiation in 203 (75.7%) of the T2DM outpatients was effected by endocrinologists in teaching hospitals and similar health institutions because they understood insulin use and are confident of starting their patients on it. Clinical inertia (6) which stood the way of most physicians was not an issue with endocrinologists. This is, also, probably, why a further 12.3% of the patients on insulin therapy had their insulin initiated by endocrinologists in private health facilities. It is important to note that in this report, insulin was initiated in 7.1% of the patients by primary care physicians in private health facilities and the trend is encouraging for glycaemic control. It is worrisome to note that 2.6% of the patients had their insulin therapy initiated by nurses, medical laboratory technicians and other paramedicals whose competence to prescribe insulin is questionable.

Finally, duration of living with DM prior to insulin initiation and highest level of education was not statistically significant in this report. One would have expected that with higher level of education, the sooner the initiation of insulin. The implication of this is that diabetes education should be targeted to all T2DM patients irrespective of levels of education.

CONCLUSION/RECOMMENDATIONS

This study has shown that a significant number of T2DM out-patients commenced insulin at diagnosis and most patients on insulin had university education. Again, majority of the patients were, first, initiated to insulin by endocrinologists in teaching hospitals and federal medical centres. This calls for improved literacy and diabetes education of the T2DM patients and capacity building of the healthcare professionals

CONFLICTS OF INTEREST – Nil

AUTHOR'S CONTRIBUTIONS:

1. Dr Marcellinus O. Nkpozi - Conception and design of the research with drafting of the manuscript. He, also, takes overall responsibility for the study.

2. Dr Gesiye E Bozimo, Dr Blessing C. Ubani, Dr Funmilayo A. Owolabi, Dr Kariba Akhidue, Dr Chidiebere M Ezeude - Collection of the data; analysis, interpretation of the data and statistical analysis

3. Dr Stanley U.Ogbonna - Final approval and critical revision of the manuscript

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