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Evaluation of Prescription Pattern and Glycaemic Control Among Diabetes Patients in an Ambulatory Tertiary Care Setting in Southwestern Nigeria

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of article.

Abstract

Background: Drug prescription in diabetes is complex, thereby making diabetes patients a high-risk group. Thus, treating the patient with diabetes remains a practice that entails constant re-evaluation and assessment of patient's therapy and response.

Objective: To evaluate pattern of antidiabetes and adjunctive medications prescribed for patients as well as extent of glycaemic control.

Method: A cross-sectional concurrent review of case-notes of diabetes patients attending the endocrinology out-patient clinic of the University College Hospital, Ibadan, for 4-consecutive weeks. In-patient case-notes, newly diagnosed, and those with incomplete data were excluded. Data were summarised using descriptive statistics. Chi-square was used to investigate categorical variables at $p<0.05$.

Results: Mean age and duration of diagnosis were 60.6±13.0 and 10.2±7.9 years, respectively. Type-1-diabetes accounted for 4 (6.9%) and type-2-diabetes (54; 93.1%). Co-administered combination of metformin and glimepiride (15; 25.9%) was most commonly prescribed. Mean glycosilated haemoglobin was 6.9±1.8%. Nineteen (59.4%) were adjudged to have good glycaemic control (HbA1c<7%). Calcium-channel-blockers (23; 19.5%), statins (23; 19.5%), angiotension-converting-enzyme inhibitors (22; 18.6%) and low-dose aspirin (20; 17.0%) were the commonly prescribed adjuncts. Of the 16 (27.6%) patients whose adherence status was documented, 8 (50.0%) who were regular on medication were subjectively adjudged adherent.

Conclusion: Metformin-based regimen, specifically, the co-administered combination of metformin and glimepiride is mostly prescribed. Overall blood glucose profile indicates fair glycaemic control. There is a greater likelihood of evidence-based prescriptions for the patients. However, there is a need for concerted efforts by providers in ensuring improved medication adherence, in order to ensure better therapeutic outcomes.

Key words: Antidiabetes medication, glycaemic control, diabetes patients, ambulatory.

INTRODUCTION

Diabetes mellitus is a chronic disease with increasing prevalence and socioeconomic burden (ADA, 2013; Ward *et al*., 2014; WHO, 2017, ADA, 2018). It has been projected that the number of individuals with diabetes mellitus will continue to increase in the near future, and by 2030, it is expected to affect 380 million (Shaw *et al*., 2010; IDF, 2015; WHO, 2015; CDC, 2017). The global statistics indicate that the burden of type 2 diabetes is not restricted to the developed nations but also a problem for developing countries (WHO, 2015; CDC, 2017; IDF, 2017). The World Health Organization estimates that about 1.7 million people are living with diabetes in Nigeria, which is expected to increase to 4.8 million by the year 2030 (Wild *et al*., 2004; Ogbera *et al*., 2014; Oteikewebia *et al*., 2015; WHO, 2017). Type 1 diabetes typically develops in childhood or adolescence and accounts for 5% to 10% of all cases of diabetes, whereas type 2 diabetes generally develops in adults and becomes more common with age, and it accounts for as much as 90% (ADA, 2013; ADA, 2017, ADA, 2018). The rising scourge of type 2 diabetes has been largely attributed to population growth and aging, as well as changes in lifestyle and urbanisation resulting in greater levels of obesity and physical inactivity (Amos *et al.*, 2010; Mayer-Davis *et al*., 2017; WHO, 2017). Factors such as uncontrolled diet, sedentary lifestyle, inappropriate therapeutic regimens and medication nonadherence have been known to have significant impact on glycaemic control and outcome of diabetes treatment (IDF, 2012; WHO, 2015; WHO, 2017).

The demonstrated morbidity and mortality as well as the economic cost associated with management of chronic diseases have demanded for increased research in rational use of medicines among patients with long-term and complex regimen (Zoungas *et al*., 2012; WHO, 2015; ADA, 2018). Antidiabetes pharmacotherapy is of particular importance in this respect in view of the fact that significant number of new agents have been developed in the last two decades, making treatment increasingly complex (Kumar *et al*., 2011; Qaseem *et al*., 2017). Also, in the management of diabetes, preference is given to the use of multiple antidiabetes drugs to achieve optimal glycaemic control, while drugs for other comorbid conditions are also put into consideration (Rodbard *et al*., 2009; ADA, 2013; WHO, 2015). There is therefore the need for periodic review of prescription pattern among diabetes patients and ascertain the relationship with glycaemic control. This study aimed to comprehensively evaluate pattern of antidiabetes and adjunctive medications, as well as glycaemic control among patients attending the out-patient endocrinology clinic of the University College Hospital, Ibadan, southwestern Nigeria.

METHODOLOGY

Study population/Description

The study population comprised of diabetes patients attending the endocrinology outpatient clinic of the University College Hospital (UCH), Ibadan. The UCH is a 900-bed teaching hospital and affiliated with University of Ibadan. The tertiary teaching hospital has established endocrinologist-managed clinic where different categories of ambulatory and institutionalised patients within and outside the region receive treatment and care

Study design

This study was a cross-sectional concurrent review of case-notes of ambulatory diabetes patients attending the endocrinology medical out-patient clinic of UCH for four consecutive weeks.

Inclusion/exclusion criteria

Case-notes of ambulatory patients with primary diagnosis of diabetes mellitus and who have been on therapy for more than three months were selected for review, while case-notes of patients who were booked for admission and the newly diagnosed diabetes patients, as well as case notes with incomplete data were excluded. Patient's hospital number was used as identification code in order to assure that patients were not repeated within clinic visits

Sample size and sampling techniques

Available information from the medical record department of the hospital indicated that average of 35 to 40 diabetes patients were regularly attended to by physicians on the weekly Monday clinic. Of this, 28 to 30 case-notes that completely met the study eligibility/inclusion criteria per clinic day were chronologically arranged, with every other case-note consecutively selected for review. On average, 15 case-notes were subsequently reviewed on every clinic day for the 4-weeks study period.

Data collection procedure

A pre-piloted data collection form guided information retrieval from the case-notes. Socio-demographic characteristics including age, sex, occupation; duration of diabetes, physician's documentation of medication adherence or non-adherence, as well as presence or absence of complication(s) and comorbities were collected. Other information retrieved include prescribed medications, disease-specific clinical parameters such as fasting blood

glucose (FBG), two-hour postprandial glucose (2HPPG), glycosilated haemoglobin (HbA1c) and blood pressure for two most recent contacts.

DATA ANALYSIS

Data were analysed using the Statistical Package for Social Sciences (SPSS) version 20. Descriptive statistics including frequency, percentage and mean ± standard deviation were used to summarise the data. Chi-square was used to investigate the categorical variables at $p < 0.05$ considered significant.

RESULTS

Out of the 60 diabetes case-notes reviewed within the study period, 58 (96.7%) have complete documentation. Type 1 diabetes patients were 4 (6.9%), while type 2 diabetes were 54 (93.1%). The mean age for patients was 60.6 ± 13.0 years. Majority (26; 44.8%) were within the age range of 41 - 60 years. Female constituted the highest proportion, 42 (72.2%). Mean duration of diagnosis as diabetes was 10.2 ± 7.9 years with majority diagnosed within <1 – 10 years. Details of socio-demographic and other clinical characteristics are shown in Table 1.

Table 1: Socio-demographic and clinical characteristics of patients (n = 58)

Variables	Frequency	Percent
Age (year)		
≤ 20	1	1.7
21 – 40	2	3.4
41 – 60	26	44.8
61 – 80	25	43.1
>80	4	6.9
Gender		
Male	16	27.6
Female	42	72.4
Occupation		
Trader	28	48.3
Retired	20	34.5
Civil servant	5	8.6
Artisan	5	8.6
Educational qualification		
No formal education	9	15.5
Primary	14	24.1
Secondary	16	27.6
Tertiary	19	32.8
Marital status		
Single	0	0.0
Married	58	100.0
Duration of diagnosis (year)		
<1 – 10	34	58.6
>10	24	41.4
Types of diabetes		
Type 1	4	6.9
Type 2	54	93.1

Pattern of prescribed antidiabetes medications showed that co-administered combination of metformin and glimepiride (15; 25.9%) was the most commonly prescribed dual therapy for patients. Metformin monotherapy was prescribed for 12 (20.7%) and only few patients 5 (8.6%) were on triple antidiabetes regimen. Details are shown in Table 2.

Table 2: Pattern of antidiabetes medications for patients (n = 58)

Medication pattern	Frequency	Percent
Monotherapy		
Metformin alone	12	20.7
Insulin alone	7	12.1
Vildagliptin alone	2	3.4
Glibenclamide	1	1.7
Dual therapy		
Metformin + Glimepiride	15	25.9
Metformin + Insulin premixed	6	10.3
Metformin + Glibenclamide	4	6.9
Metformin + Sitagliptin	3	5.2
Metformin + NPH insulin	2	3.4
Metformin + Glipizide	1	1,7
Triple therapy		
Metformin + Liraglutide + Insulin detemir	3	5.2
Metformin + Pioglitazone + Insulin glargine	1	1.7
Metformin + Pioglitazone + Glimepiride	1	1.7

NPH = Neutral Protamine Hagedon

Summary of adjunct medicines prescribed alongside antidiabetes medications were in the order of calcium channel blockers (23; 19.5%) = statins (23; 19.5%) > angiotension converting enzyme inhibitors (22; 18.6%) > low dose aspirin (20; 17.0%) > angiotensin receptor blockers (10; 8.5%) > diuretics (9; 7.6%) > anticonvulsants (7; 5.9%) > beta blockers (4; 3.4%). Other categories of adjunctive medicines constituted (14; 10.7%), while 6 (10.3%) patients had no adjunct prescribed.

The mean glycosilated haemoglobin was 6.9 ± 1.8%. Mean fasting blood glucose (FBG) was 124.2 ± 42.1 mg/dL. There was about 5% reduction in mean FBG

values from 125.0 ± 56.5 to 119.8 ± 42.6 mg/dL between the first and second contacts. Also, mean systolic (SBP) and diastolic blood pressure (DBP) for first contact were 127.7 ± 24.2 and 73.5 ± 11.1 mmHg, respectively, while the second blood pressure readings were SBP (130.1 ± 20.3) and DBP (74.3 ± 11.1) mmHg. There was about 2% increase in SBP and 1% increase in DBP values between the first and second contacts. Details of patients' clinical parameters are shown in Table 3.

Table 3: Patients' descriptive parameters

Variables	Frequency	Mean ± SD
Age (year)	58	60.6 ± 13.0
Duration of diagnosis (year)	58	10.2 ± 7.9
First systolic blood pressure (mmHg)	57	127.7 ± 24.2
First diastolic blood pressure (mmHg)	57	73.5 ± 11.1
Second systolic blood pressure (mmHg)	52	130.1 ± 20.3
Second diastolic blood pressure (mmHg)	52	74.3 ± 11.1
First fasting blood glucose (mg/dL)	55	125.0 ± 56.5
Second fasting blood glucose (mg/dL)	42	118.8 ± 42.6
Average fasting blood glucose for the two contacts (mg/dL)	42	124.2 ± 42.1
Two-hour postprandial glucose (mg/dL)	39	169.7 ± 77.3
Glycosilated haemoglobin (%)	32	6.9 ± 1.8

SD=standard deviation

Table 4: Clinical outcome indicator for patients

Clinical outcome indicator	Frequency	Percent
Glycaemic control based on HbA1c (n = 32)		
Good (HbA1c < 7%)	19	59.4
Poor (HbA1c ≥ 7%)	13	40.6
Glycaemic control based on FBG (n = 42)		
Good (FBG = 70 - 110 mg/dL)	11	26.2
Fair (FBG ≥ 110 – 140 mg/dL)	11	26.2
Poor (FBG > 140 mg/dL)	20	47.6
Physician's documentation of medication adherence status in the case note (n = 58)		
Yes, regular on medication (adherence)	8	13.8
Yes, not regular on medication (non-adherence)	8	13.8
Not documented	42	72.4
Self-monitoring of blood glucose (n = 58)		
Yes	15	25.9
No	43	74.1

n = number, FBG = Fasting blood glucose, HbA1c = Glycosilated haemoglobin

A total of 19 (59.4%) were adjudged to have good glycaemic control with HbA1c < 7%, but 22 (52.4%) had FBG between 70 and 140 mg/dL. Of the 16 (27.6%) patients whose medication adherence status was documented in the case notes by physician, 8 (50.0%) were regular on medication and were subjectively adjudged adherent. A larger proportion (43; 74.1%) did not engage in self-monitoring of blood glucose (SMBG). Details of these outcome parameters are shown in Table 4. Out of the case notes reviewed, 29 (50.0%) of the patients had complication(s), and of this, peripheral neuropathy recorded the highest proportion (6; 20.7%). Also, hypertension (35; 62.5%) was documented as the most common comorbid disease among patients. Details of complications and comorbidities for patients are shown in Table 5.

Table 5: Complications and comorbities among patients

Variables	Frequency	Percent
Complication	**Yes, n (%)**	**No, n (%)**
	29 (50.0)	29 (50.0)
If yes, specific complication (n = 29)		
Peripheral Neuropathy	6	20.7
Bilateral immature cataract	5	17.2
Retinopathy	4	13.8
Erectile dysfunction	3	10.3
Kidney disease/nephropathy	2	6.9
Hypoglycaemia	2	6.9
Hoarseness of voice	2	6.9
Diabetes ketoacidosis	1	3.4
Left hemispheric stroke	1	3.4
Lumbar spondylosis	1	3.4
Foot ulcer/lower leg amputation	1	3.4
Peripheral arterial disease	1	3.4
Comorbidity (n = 56)		
Hypertension	35	62.5
Hyperlipidemia	4	7.1
Thyrotoxicosis	2	3.6
Osteomyelitis	1	1.8
Erectile dysfunction	1	1.8
None	13	23.2

There was no statistically significant difference between some relevant parameters and glycaemic control as well as engagement in SMBG (Table 6). Though, patients without complication and whose duration of diagnosis was between < 1 and 10 years appeared to have better glycaemic control compared with those who had complication and whose duration of diagnosis was > 10 years ($p > 0.05$) Table 6.

DISCUSSION

From this study, female constitutes the majority of patients with diabetes. This further corroborate the findings of previous studies that obesity and insulin resistance which are important risk factors for development of type 2 diabetes are more common in women (Yekeen *et al*., 2003; Flegal *et al*., 2010; Garber, 2012). However, there may also be the possibility of female diabetes patients patronizing the hospital for clinic appointment more than their male counterparts. The reason for the disparity in clinic attendance between male and female diabetes patients may need to be further explored.

Less than one-tenth of the diabetes case-notes reviewed belong to the type 1 diabetes category, and the rest were type 2 diabetes patients. This corroborates the literature report that more than 90% of all cases of diabetes in both developed and developing nations belong to type 2 diabetes mellitus (ADA, 2013; Treister-Goltzman & Peleg, 2015). The rising scourge of type 2 diabetes has been linked to westernisation and urbanisation which has led to unhealthy lifestyle habits and increased physical inactivity (Amos *et al*., 2010; IDF, 2012; Ismail-Beigi *et al*., 2017; ADA, 2018). It is therefore essential to constantly creating awareness on the need for every individual to embrace healthy living habits, while those who are already living with diabetes should be continuously educated on the importance of adherence

Table 6: Association between relevant categorical variables

Variables	Responses, n (%)		Chi-square	p-value
	Glycaemic control			
Gender	**Good (HbA1c < 7%)**	**Poor (HbA1c≥7%)**		
Male	7 (36.9)	5 (38.5)		
Female	12 (63.2)	8 (61.5)	0.009	0.926
Duration of diagnosis (year)				
< 1 – 10	10 (52.6)	8 (61.5)		
>10	9 (47.4)	5 (38.5)	0.249	0.818
Presence of complication				
Yes	8 (42.1)	5 (38.5)		
No	11 (57.9)	8 (61.5)	0.042	0.837
	Practice of SMBG			
Gender	Yes	No		
Male	5 (33.3)	11 (27.5)		
Female	10 (66.7)	29 (72.5)	0.180	0.671
Duration of diagnosis (year)				
< 1 – 10	10 (66.7)	23 (56.1)		
>10	5 (33.3)	18 (43.9)	0.507	0.476
Presence of complication				
Yes	5 (33.3)	24 (58.5)		
No	10 (66.7)	17 (41.5)	2.794	0.095

n = number. SMBG = Self-monitoring of blood glucose, HbA1c = Glycosilated haemoglobin, Level of significance p < 0.05

to prescribed medications and other recommended management options including diet.

It is worthy of note to mention that metformin-based regimen mostly as a dual therapy was the commonly prescribed regimen for patients. This further substantiates the literature report that metformin, a biguanide, is the first-line drug of choice (UKPDS 34, 1998; Rodbard *et al*., 2009; ADA, 2011; Beatriz *et al*., 2013; Boussageon *et al*., 2016) and the most widely prescribed drug in the management of type 2 diabetes (Adisa *et al*., 2009; Inzucchi *et al*., 2015; Sanchez-Rangel & Inzucchi, 2017) either as monotherapy in mildly elevated blood glucose or as dual and triple therapy with other oral agents or insulin regimen in moderately elevated blood glucose levels. Co-administered combination of metformin and glimepiride as the highest proportion of dual therapy medication for patients could be explained from the patients' mean blood glucose profile, where a substantial number had HbA1c > 7% and FBG > 140mg/dL, an indication of suboptimal glycaemic control. Thus, the necessity of dual therapy antidiabetes medications, especially with different mechanisms of action, such as a secretagogue (e.g. glimepiride) and a sensitizer (e.g. metformin). The recent insurgence in the prescription for glimepiride by physicians may possibly be linked to its relatively fewer tendencies to cause hypoglycaemia compared to glibenclamide (AbdulBasit *et al*., 2012; Ismail-Beigi *et al*., 2017). However, patients on this combination should be appropriately counseled on signs and symptoms of hypoglycaemia which is likely the major disturbing side effect with the combination.

It is observed that prescriptions containing newer agents such as dipeptidyl peptidase-4- inhibitors (DPP4-I) and incretins were scanty. The low prescription for these agents may probably be linked to the relatively high costs of these groups of antidiabetes medication which may not be affordable by many diabetes patients who usually make out-of-pocket payments for their treatment. In addition, insulin regimen either alone or in combination with other oral agents was prescribed for a few patients. Although, insulin should be exclusively reserved for management of type 1 diabetes, some type 2 diabetes patients may be candidate for insulin regimen perhaps as a low dose bed time administration. Insulin administration in type 2 diabetes is most desirable when the oral antidiabetes medications are no longer adequately controlling the blood glucose, possibly due to weaning effect of beta cell functions with long term duration of diabetes (Garber, 2003)

Calcium channel blockers, statins, angiotensin-converting enzyme inhibitors and low dose aspirin were the most highly prescribed adjunctive medications for patients in this study. The treatment guidelines by the American Diabetes Association (ADA) and American Association of Clinical Endocrinologist stated that inclusion of low dose statin and aspirin should be encouraged in the regimen of

patients with diabetes so as to ensure prevention of any occurrence of cardiovascular events (UKPDS 38, 1998; Rodbard *et al*., 2009; ADA, 2013; Inzucchi *et al*., 2015; Ismail-Beigi *et al*., 2017). However, caution should be exercised among patients with contraindication. Also, ADA recommends the use of angiotensin-converting enzyme inhibitors (ACEIs) for diabetes patients with or without high blood pressure on account of the renoprotective and cardioprotective advantages of ACEIs (UKPDS 38, 1998; Rodbard *et al*., 2009; ADA, 2013; WHO, 2017; Ismail-Beigi *et al*., 2017). Therefore, the evidence highlighted in the above mentioned guidelines might perhaps buttress the rationale of adjunctive medicine prescriptions for the patients. In this study, hypertension was the most common comorbid disease reported for patients, and calcium channel blocker was the commonly prescribed antihypertensive medication.

Summarily, the overall blood glucose profile for patients could be adjudged as fair glycaemic control, with mean glycosilated haemoglobin of 6.9 ± 1.8% and average FBG ≥ 124.2 mg/dL. The reduction in blood glucose levels between the two contacts might probably implied that the dual therapy of secretagogue and sensitizer as the most prescribed oral antidiabetes medication is largely achieving the desired blood glucose lowering goals. Although, a slight increase in systolic and diastolic blood pressure readings was noted between the first and second contacts, the overall blood pressure value is within the recommended blood pressure target of 130/85 mmHg for diabetes patients (Chobanian *et al*., 2003; IDF, 2012; ADA, 2017). This seems encouraging and further underscore the need for evidence-based prescribing for patients, so as to ensure better and improved therapeutic outcomes.

In this study, medication adherence status was documented by physician in less than one-third of patients whose case-notes were reviewed, of which, one-half who were regular on medication were subjectively adjudged adherent. Adherence to medication and other lifestyle measures is key to achieving optimal glycaemic control, in order to ensure reduction in the risk of developing diabetes complication. One-half of the patients have one form of complication or the other documented in their case-notes, with peripheral neuropathy, a micro-vascular complication, constituting the highest proportion. Studies have reiterated that intensive glycaemic control is necessary for prevention of microvascular complications of diabetes (UKPDS 34, 1998; UKPDS 35, 2000; IDF, 2012; ADA, 2017). Therefore, in the course of prescribing antidiabetes medications for patients, diabetes primary care provider should always strive to ensure evidence-based medicine prescriptions that will ensure achievement of intensive glycaemic control. However, in ensuring optimal glycaemic control, patient's involvement in the management is essential. Over two-third of patients do not engage in self-monitoring of blood glucose (SMBG), this is in spite of its inherent advantages. Healthcare provider at every patient-provider encounter may therefore need to redouble their efforts in this regard, by educating and encouraging diabetes patients to imbibe this self-monitoring practice. Although, none of the evaluated categorical variables seem to significantly influence glycaemic control and SMBG practice. However, patients without complication were those who largely engaged in SMBG, as well as constituting the higher proportion of those who were adjudged to have good glycaemic control. These findings may further buttress the importance of patient's involvement in self-monitoring practices to ensure better therapeutic outcomes.

Despite useful information from this study, it is limited by the small sample size and short period of review, this coupled with inadequate documentation of some relevant parameters in the case-notes, especially the glycosilated haemoglobin (HbA1c). Thus, the need for caution in generalising the study findings to the entire patients' population. However, the 4-week snapshot review of patients' medical records for prescribed medications may still be considered as a replica of the long-period medication profile, since patients with chronic diseases are likely to be on a particular regimen or combination for a long-term provided the medication(s) is/are tolerable and effective in achieving the target therapeutic goals. In addition, availability of HbA1c values for every patient might have been an objective assessment of glycaemic control. The relatively high cost of between N2000 (US$ 5.6) and N3000 (US$ 8.6) for the HbA1c test in the studied facility may be a limiting factor, thereby necessitating for physician's dependence/reliance on fasting blood glucose as a routine measure of glycaemic control for most patients. Nevertheless, there might be a need for future study to consider incorporation of these identified gaps in order to ensure far-reaching conclusions.

CONCLUSION

It can be concluded from this study that metformin-based antidiabetes regimen, specifically, the co-administered combination of metformin and glimepiride is mostly prescribed for type 2 diabetes patients, which is the most common in the studied facility. The overall blood glucose profile among patients indicates fair glycaemic control. Calcium channel blockers, statins, angiotensin-converting enzyme inhibitors and low dose aspirin were the most commonly prescribed adjunctive medicines, with hypertension representing the most common comorbid

disease among patients. Patients without complication were those who largely engage in self-monitoring of blood glucose, as well as constituting the higher proportion of those who were adjudged to have good glycaemic control. In general, there is a greater likelihood of evidence-based prescriptions in the medication patterns for diabetes patients in the studied facility. However, there is a need for continuing and concerted efforts by providers in ensuring improved medication adherence among patients, as well as encouraging patient's consistent engagement in self-monitoring practices in order to ensure better therapeutic outcomes.

Ethical approval

The study protocol was approved by the joint University of Ibadan/University College Hospital (UI/UCH) Health Research and Ethics Committee with approval number UI/EC/18/0161, while permission for access into the patients' medical records was granted by the Chairman Medical Advisory Committee of UCH.

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