Assessment of the Rational Use of Anti Diabetics in Type 2 Diabetes Mellitus using Case Notes of Patients at a Tertiary Health Care Centre in South West Nigeria

Moses Kayode[1]

[1] University of Ibadan.

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Abstract

This study was a prospective study of cases at the University College Hospital, Ibadan. A total of four in-patients comprising of two male and two female adults of the Endocrinology unit were monitored for the study. Patients? case notes and drug administration charts were used to obtain necessary drug information in addition to information obtained directly from the patients. The age group distribution of the patients was found to be between 34-64 years. The mean age was 47.5 years. The drug regimen showed that Patients A, B, C and D received a total of 8, 10, 11 and 7 drugs respectively. These included Metformin, Insulin, Glibenclamide and Glimepiride as antidiabetic agents. Other drugs prescribed for coexisting diseases included: Nifedipine, Lisinopril, Alpha-methyldopa and Hydrochlorothiazide as Antihypertensives, Atorvastatin as Lipid-Lowering agents and Ceftriaxone, Lxime, Metronidazole, Ciprofloxacin as Antibiotics. Analgesics such as paracetamol and Hematinics such as ferrous sulphate were also prescribed as needed. Co-morbidities studied include hyperglycemic coma, peripheral neuropathy, Diabetic foot disease, Diabetic ketoacidosis, Hypertension and Hyperlipidemia. The results were documented and analysed using charts and tables.

Index terms— Patients, Type 2 Diabetes Mellitus, Endocrinology, Antidiabetics.

1 INTRODUCTION

he aim of drug therapy for Diabetes mellitus is to reduce morbidity, mortality, control symptoms, delay progression, and improve patients' wellbeing. These can only be achieved with the right drugs and dosages used at the right intervals. It is estimated that more than 50% of all medicines are prescribed, dispensed or sold inappropriately, and that 50% of all patients fail to comply or adhere. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards **??**WHO, 2003). Rational drug use includes correct prescribing, dispensing and patient adherence. Hence, promoting rational use of drugs requires that the behaviors of all persons involved in each process of prescribing, dispensing and patient use be addressed. **??**WHO, 1985) Diabetes mellitus is a metabolic disorder with widespread prevalence. Its actual epidemiology in Africa is unknown because many of the cases are unreported, undiagnosed and untreated. (Aguwa and Omole, 2004). Studies reveal that it affects over 150 million people worldwide. A doubling of this figure is expected in the near future especially in the African and Asian continents due to inadequate research funding and technical expertise. **??**Ogbera et al, 2007). Its widespread prevalence is due to various factors which include: aging, obesity, sedentary lifestyle, genetic or ethnicity factors and unhealthy diet. Morbidity and mortality of diabetes mellitus are associated with retinopathy, nephropathy, and neuropathy which are complications of diabetes mellitus. However, cardiovascular disease remains the leading cause of death in Type 2 DM. The treatment of risk factors such as obesity, hypertension, and hyperlipidemia is very important in achieving good glycemic control.

The morbidity and mortality rates with Type 2 DM have been found to be very high as shown by reports of several studies conducted in Nigeria. Out of 502 subjects, 20 were previously diagnosed to have Type 2 diabetes mellitus, 14 were diagnosed with diabetes during the study. 34 were, therefore, found to have diabetes, giving a crude prevalence rate of 6.8%. Other cities in Nigeria showed prevalence rates of 1.5% in Ibadan, 6.8% in Port-Harcourt and 3.1% in Jos. The study also revealed the presence of risk factors such as obesity, sedentary lifestyle, alcohol; age, genetics ethnicity, smoking and social class (Nyenwe et al, 2003 **??** Stephen M. Setter 2004). Other studies also reveal that diabetes is a leading cause of blindness, visual impairment, kidney failure and non-traumatic limb amputations. (Khodabandehlou et al, 2004).

The goal of treatment of diabetes mellitus is to control blood glucose and ultimately prevent long-term complications, as shown by the United Kingdom Prospective Diabetes Study group and Diabetes **??**ontrol and Complications Trial (British Medical Journal, 1998). The objective of this study is to assess factors that influence the rational use of antidiabetics among inpatients admitted with type 2 diabetes mellitus (DM) at the University College Hospital, Ibadan with the goal of providing and promoting pharmaceutical care.

2 II.

3 PATIENTS AND METHODS

A total of four in-patients comprising of two male and two female adults of the Endocrinology unit were randomly selected for the study. Patients' case notes and drug administration charts were used to obtain necessary information.

The patients were randomly selected based on the following inclusion criteria: (1.) Patients diagnosed with Diabetes mellitus Type 2, (2.) Patients between the ages of 18 years and above. (3.) Type 2 diabetes who are on insulin. Patients with type 1 DM were excluded from the study.

Information obtained from the case notes include: medication histories, prescribed dosage regimen, duration of illness, patients' bio-data, chief complaints, co-morbidities (compelling indications), signs and symptoms, physical examinations, laboratory findings as related to the chief complaints, the past medical histories, family and social histories and drug allergies.

The fasting and postprandial blood glucose records were used to assess the patients' glucose level.

Interaction with the patients helped to ascertain their level of knowledge about the disease, their attitude and the extent to which they were involved in the management. The overall results were then discussed.

Ethical approval for this study was obtained along with an online ethical training certificate from UI/UCH ethical committee.

4 III.

5 RESULTS

6 a) Patient presentation

Patient was admitted unconscious sequel to high fever, headache, weakness and seizures. He had rashes which receded on application of palm oil. At presentation, his random blood sugar was 264mg/dl and blood pressure was 180/94mm/Hg. Laboratory Tests And Results:Na = 142 mmol/L, K = 2.9 mmol/L, HCO3 = 23mmol/L, Urea = 63mg/dL , HDL= 33mg/dL ,LDL= 172mg/Dl, Creatinine=1.5mg/dL, Total cholesterol=215mg/dL, PCV = 32%, Bilirubin = negative, Ketone = negative, Nitrite = negative, Glucose = positive , Leucocycte = negative, Protein = positive, Blood = positive, pH = 6.0, SG=1.025, I/O= 600mls (oral) + 300mls (intravenous infusions)/ 650mls urine.

Therapeutic Plan:Foot X-RAY, HbA1C IV.

7 Discussion

The purpose of anti-diabetic therapy is to reduce morbidity, mortality and to improve patient's wellbeing. It involves taking measures that result in adequate control of plasma glucose while taking into consideration co-morbid conditions and individual needs of patients such as financial constraints, gender and age **??**Enovare et al 2006, Priscilla et al, 2010). In this study, the patients were admitted on account of deranged blood glucose levels precipitated by stress, infections and non-compliance with prescribed therapy.

The connection between infections and hyperglycemia follows a vicious cycle in which hyperglycemia increases susceptibility to infections which deteriorates metabolic conditions within the body leading to difficulty in control of hyperglycemia **??**Rang, 2008). This is evident in the fluctuations which occurred during Insulin therapy. Patients A and C (Tables 1&3).

Patients C and D (Tables 3&4) had low response to Insulin even on addition of Oral Hypoglycemic Agents (OHAs) to their insulin therapy. For patient D (table **??**), there was no established microbial infection therefore; the poor response might have been due to presence of risk factors such as hyperlipidemia, obesity with Body Mass Index (BMI) values being 38.1kg/m 2 and uncontrolled hypertension.

Blood pressure goals are generally more difficult to achieve in diabetic patients especially in the presence of risk factors such as obesity which aggravate the metabolic syndrome (Diabetic control and complication trial

1998). Other factors that result in suboptimal glycemic control include hypersecretion of glucagon, presence of insulin antibodies, poor absorption at injection site and physical inactivity which impairs insulin absorption (American Diabetes **??**ssociation 2003 **??**ssociation , 2004)).

Patient B (Table 2) responded positively to insulin therapy. This underscores the fact that no two diabetics are the same and there is need for individualized treatment. Patient A (Table 1) was administered Glucose:Potassium:Insulin in order to restore potassium ion balance. The combination is useful because hypokalemia could lead to cardiac arrhythmias. **??**Rang et al, 2008). Potassium was given with insulin and glucose in order to maintain intracellular concentration of potassium (The National high blood pressure working group 1994, **??**trev C.T et al 1998) During insulin therapy, patient A tended towards hypoglycemia, hence, the dosage was reduced. For the four patients, there were no adverse reactions documented during insulin therapy.

The four patients were administered Metformin, a biguanide which is known to consistently reduce fasting plasma glucose levels significantly. It also provides the advantage of modest weight reduction and an inhibitory effect on glucagon, an antagonist of insulin. **??**Curtis et al, 2005).

The results of the United Kingdom Prospective Diabetes Study reveals that Biguanides and Sulphonylureas are useful as first and second-line therapy alone or in combination with added advantages of cost and efficacy.

Patients A, B and C (Tables 1,2 &3) were discharged with prescriptions of these combination drugs while patient D (Table **??**) was discharged on insulin and Metformin alone. No adverse reactions or contraindications were encountered.

Risk factor reduction focuses on management of co-morbidities such as hyperlipidemia. (Omole and Bello, 2011) in order to reduce morbidity and mortality associated with DM. Patient B (Table 2) was placed on lipid-lowering therapy with Atorvastatin and this seemed appropriate due to her high total cholesterol and obesity **??**Erickson J. et al 1995) In the management of hypertensive Type 2 DM patients, Angiotensin Converting Enzyme Inhibitors (ACEIs) and Angiotensin II Receptor Blockers (ARBs) are generally recommended as drugs of choice (Standard treatment guideline for Nigeria 2008). This is due to their well-documented reno-protective effects. **??**Curtis et al, 2005.) The four patients were prescribed Lisinopril. The America Diabetic Association (ADA), and the 7 th report of the Joint National Committee for Evaluation, Prevention and Treatment of Hypertension (JNC VII) recommend currently, the use of any class of antihypertensives as long as they show benefits in prevention of poor cardiovascular outcomes and show no contraindications or poor tolerance. It seems appropriate that patient C (table **??**) was prescribed a combination of Lisinopril and Nifedipine while Patient D (table **??**) was prescribed Lisinopril, Alpha-methyldopa and hydrochlorothiazide. These combinations yielded better results as patients were monitored to prevent electrolyte imbalance and other adverse effects(UK Prospective Diabetic Study Group 1998)

The metabolic syndrome is associated with a clustering of cardiovascular risk factors including coagulation abnormalities. **??**Reaven, 1988) which necessitates the use of low-dose Aspirin at 75mg daily. It is recommended especially in patients who have a history of macrovascular disease, coronary heart disease, hypertension, cigarette smoking, hyperlipidemia and obesity.

Only patient A (Table 1) was prescribed Aspirin. It is likely that it was contraindicated in the other patients. Patient C had severe epigastric pain for which chronic use of low-dose Aspirin was contraindicated. The pain was managed with Omeprazole. In patients B and D, it is likely that Aspirin was simply omitted.

The control and prevention of microbial infections has been found to have significant positive effects on glycemic control **??**British Medical Journal, 2010). The four patients A, B, C & D (Tables 1, 2 ,3 & 4) received antibiotic therapy which was aimed at treatment of existing microbial infections and prophylaxis of Hospital-acquired sepsis. Ceftriaxone, Metronidazole, Ciprofloxacin and Ixime were prescribed. They act against Gram positive and Gram negative micro-organisms as well as protozoal and anerobic organisms. Anti-tetanus toxoid was administered to patient B (Table 2) to prevent sepsis of her foot ulcer. Analgesics were also administered as needed to the patients.

The patients received non-pharmacologic therapy as an adjunct to pharmacotherapy. The patients also benefited from our (Clinical Pharmacists) educating them on hygiene, diet and lifestyle modifications as well as attitude to disease.

Patients A, B and D (Tables 1, 2 & 4) were discharged accordingly except Patient C (Table **??**) who began to refuse treatment during his admission period. He asked to be discharged against medical advice. This presented another factor militating against rational management of disease conditions. Rational use of drugs depends not only on members of the healthcare team but also on the patient who is required to cooperate with healthcare providers in order to achieve success in therapy.

V.

8 Conclusion

This study has shown that rational use of medicines lies with the patient as well as healthcare providers. It also revealed problems militating against the rational use of medications. These include: drug availability, financial constraints, socio-cultural backgrounds of patients, co-morbidities, age, gender, drug allergies and personal preferences. The roles of Clinical Pharmacists in counseling and monitoring the diabetic patient during drug dispensation cannot be underestimated as these roles helps in the provision and promotion of pharmaceutical care.

9 VI.

[1] [2]

Family/Social History: Mother Diabetic, Husband is diabetic, no alcohol, not smoking.
Past Medication History: Oral hypoglycemic agents (metformin and chlorpropamide) but not regular on medications. Takes herbal medications (bitterleaf and oranges)
Assessment: Grade III diabetic foot, Diabetes mellitus Type 2, Present risk factors of family history and obesity. Diabetes mellitus complications with peripheral vascular disease, autonomic neuropathy and senile cataract.

b) physical examination:
Chest: Acidotic breathing, Respiratory Rate: 56 cycles/min, Intranasal Oxygen: in-situ,Percussion Node: resonant, Breast sounds: widespread transmitted sounds
Cns: Unconscious, Neck is supple, slowly reactive to light
Reflexes: normal. Cvs: Pulse: 98 beats/min, normal volume, regular, No arterial wall thickening, Heart Sounds: 1 and 2 only, Bp: 180/94mmHg. Abdomen: Flat, moves with respiration, Soft,Liver span 10 ascites.
Medical History: Patient has been diabetic for 3 years, Not regular on medications Family Histor Monogamous family, has one child, Parents had DM and hypertension. Social History: Not a sm alcoholic
Past Medication History: Metformin and Glibenclamide. Dosage regimen -not stated
Laboratory Tests And Results: Pcv 38%,Na + 146, K + 3.2, Urea 27mg/dl, HCO 3

Urinalysis: Glucose +++,Ketone ++,Protein + 5.0. Other Investigations: UrineM/C/S, Cranial
Assessment: Viral Encephalitis, Background Diabetes mellitus with Hyperglycemia, Aspirati pneumonitis, Hypertension.
Therapeutic Plan: Continue intranasal oxygen delivery 4-5L/min, Monitor RPG 5-hourly, IV c 1g 12-hourly, IV normal saline 0.9% 1L 6-hourly Mannitol 250ml 8-hourly for 48 hours, G: K: I at 100ml/hour, Run neurological and viral studi Monitor blood pressure.
08/07/11: Plan: Commence oral hypoglycemic agents, Monitor RPG, Monitor BP, Tab. Metfo 500mg 12-hourly, Tab. ASA 75mg daily, Diabet 200kCal/day.
09/07/11: FPG: 204mg/dl, BP: 130/90mm/Hg. Plan: Continue with current treatment. Tab. Lisinopril 7.5mg daily 13/07/11:RPG: 153mg/dl, BP: 140/70mm/Hg Patient feels w improved state of health.
Case 2 (Patient B)
Patient Biodata: Age: 64, Religion: Christian Tribe: Yoruba, Sex: Female
Occupation: Trader, Marital Status: Married

Figure 1:

years,Religion:
Islam,Tribe: Yoruba, Sex: Female
Marital Status: Married, Date of Admission:
15/07/11
Patient Presentation:Patient recently had a new
baby. She had Nocturia (4-5 times at night), dizziness
and headache earlier in pregnancy. She complained of
muscle cramps in both legs, occasional numbness,
frothy urine and blurred vision. She was diagnosed with
Hypertension in the 3 rd trimester of pregnancy and was
referred from a private hospital to the University College
Hospital on account of a deranged glucose profile of
FPG 387mg/dl and RPG of 551mg/dl.
Physical Examination: Patient is obese, not
pale. She is mildly dehydrated and has pedal oedema
up to the ankles bilaterally. Weight 92kg, Height
155.4cm, BMI 38.1kg/m2, Waist 118cm, Hip 110cm
CVS: Pulse 120/min, Thickened arterial wall, BP:
160/90mmHg, Jugular Vein Pressure technically difficult
to check.
Heart Sounds: 1 and 2 only Chest: Respiratory
rate: 20 cycles/min, Trachea central, Vesicular breast
sounds
Abdomen: Obese, soft, Surgical scar noted
midline infraumbilically, No areas of tenderness, Liver 0
Spleen 0 Kidney 0 , Liver span 11cm CNS: Conscious,
, Wound biopsy, ECG/ECHO Sc. Soluble Insulin 4IU 30mins before breakfast, lunch and dinner, Sc. Soluble NPH 4IU at bedtime, Sc. Anti-tetanus toxoid 1500IU after test dose, IV ceftriaxone 1g 12-hourly, IV Flagyl 500mg 8-hourly, Tab. Vitamin C 200mg 8-hourly, Tab. PCM 1000mg 8-hourly, Fluid input and output monitoring, Ophthalmology review, Elevate right lower limb, Carry out pus aspirate test Case 3 (Patient C) Patient Biodata: Age: 48, Religion: Christianity, Sex: Male, Occupation: civil servant (Soldier), Marital Status: Married, Tribe: Efik, Date of admission: 28/06/11. Patient Presentation: Patient presented alert, Power and reflexes normal, Sensation normal to light touch, vibration and pain. Past medical history: Hypertension, DM 2, Had ectopic pregnancy and surgery in 2002 History of infertility for 16 years. Had a baby 3 weeks prior to admission. Assessment: Hyperglycemic state in newly diagnosed Diabetes mellitus Type 2. Systemic hypertension. Stage 2 obesity. Laboratory Tests And Results: Na + 131, K + 4.4,Urea 18mg/dl HCO 3 -20mmol/L, Creatinine 0.8mg/dl, Cl 103mEq/L Urinalysis :Nitrogen +,Protein +,Glucose +,Ketone -,Bilirubin -, Blood -, pH 5.0 PCV 42% Therapeutic Plan:Commence Pre-mixed insulin 20IU in the morning, Premixed insulin 20IU in the evening, IV Normal saline 1L 6-hourly for 24 hours, Diet unconscious sequel to Assessment: Hyperglycemic state in a known diabetic, Hyperglycemic hyperosmolar state precipitated by sepsis (likely urinary tract infection), Intestinal obstruction, Stress-induced gastritis Laboratory Tests And Results: Na + 138,K + 4.9, Urea 27mg/dl HCO 3 -23mmol/L, Glucose +,Ketone +, Urobilinogen +, Bilirubin negative Protein negative, Leucocyte, Nitrogen negative, Weight 55kg Height 1.75m, BMI 18kg/m2 Therapeutic Plan:Deep IM soluble Insulin 10IU stat, IV soluble Insulin 10IU stat, IVF 0.9% Normal saline 1L 4-hourly, IV Metronidazole 500mg 8-hourly, IV Ciprofloxacin 200mg 12-hourly. Invite general surgeons to review on account of intestinal obstruction features observed. 28/06/11:Patient complains of epigastric pain. He is given:, IV Omeprazole 40mg daily for 3days Requests to be discharged against medical advice, Social workers invited to counsel patient. 10/07/11: HbA1C investigations were hindered by financial

1

Figure 3: Table 1 :

1B

/N	Name of Drug	Class of Drug	Dosage Regimen
1	Metformin	Biguamide	Tab. 500mg 12-hourly
2	Glibenclamide	Sulforyl urea	Tab. 5mg daily
3	Lisinopril	ACEI-Antihypertensive	Tab. 10mg daily
4	ASA	Anti-platelet	Tab. 75mg daily

Figure 4: Table 1B :

2

Date	Insulin dosage	FPG mg/dl	BP mm/Hg	Remarks
12/07/15	Sc. Soluble Insulin 4IU 30mins before breakfast, lunch and dinner Sc. Soluble NPH 4IU at bedtime	370	144/70	
13/07/15	Sc. Soluble Insulin 4IU 30mins pre-breakfast, lunch and dinner. Sc. Soluble NPH 4IU at bedtime.	235	130/90	Ceftriaxone not available
14/07/15	Sc. Soluble Insulin 4IU 30mins before breakfast, lunch and dinner Sc. Soluble NPH 4IU at bedtime	222	180/90	Poor glycemic control with elevated BP
16/07/15	Sc. Soluble NPH 8IU at bedtime	135	120/70	Improved

Figure 5: Table 2 :

2B

Date	Insulin Dosage G: K: I	RPG (mg/dl) before insulin administration	BP (mm/Hg)	Remark
At presentation	-	264	180/94	
01/07/11	5: 5: 5	252		Patient responding
04/07/11	5: 5: 25	156		Patient hypoglycemic?
06/07/11 at 8.00 a.m.	5: 5: 10	172		Insulin dosage reduced
06/07/11 at 11 p.m.	5: 5: 15	259		Poor control
07/07/11		142	120/70	Good response. Patient is alert
S/N	Name of Drug	Class of Drug		Dosage Regimen
1	Candesartan	Neurologic analgesic		Tab. 16mg daily
2	Atorvastatin	Anti-hyperlipidemis		Tab. 20mg daily
3	Metformin		Biguanide	Tab. 500mg 8-hourly
4	Glibenclamide		Sulforyl urea	Tab. 5mg daily

Figure 6: Table 2B :

3A

Date	Insulin dosage	RPG mg/dl	FPG mg/dl	BP mmHg	Remarks
28/06/11(at presentation in the morning)	IV Insulin 10IU stat. Deep IM Insulin 10IU stat	600		120/74	First dosage
28/06/11 (evening)	Deep IM Insulin 10IU 2-hourly	406		140/90	Patient conscious. Complains of epigastric pain which worsens after food.
29/06/11 (1.30 a.m.)	Deep IM Insulin 8IU 2-hourly	331			Gradual decrease.
29/06/11 (8.00a.m.)	Deep IM Insulin 8IU 2-hourly	287		160/110	
29/06/11 (2.00p.m.)	Deep IM Insulin 8IU 2-hourly	339			Poor control, gradual derangement
29/06/11 (6.50p.m.)	Deep IM Insulin 8IU 2-hourly	291			
30/06/11 (12.30a.m.)	Deep IM Insulin 8IU 2-hourly	149		160/90	RPG now normal. Patient feels better.
30/06/11 (9.00a.m.)	Deep IM Insulin 8IU 2-hourly	310			
30/06/11 (6.00p.m.)	Deep IM soluble Insulin 8IU 2-hourly Sc. Soluble Insulin 8IU 8-hourly pre-meals	359		160/120	
01/07/11	Deep IM soluble Insulin 8IU pre-meal and 14IU bedtime		150/100	203	
05/07/11			130/110	120	
06/07/11			130/120	151	Patient started on oral hypoglycemic agents
07/07/11 (8.30 a.m.)	OHA+insulin		110/70	157	
07/07/11 (11.30a.m.)	OHA+insulin	238	100/90		
08/07/11 (8.00a.m.)	OHA+insulin		110/90	307	
10/07/11 (8.00a.m.)	OHA+insulin			362	
10/07/11 (11.30a.m.)	OHA+insulin	465			
11/07/11 (08.00a.m.)	OHA+insulin			369	Bedtime insulin was missed
11/07/11 (10.00a.m.)		247			Patient asks to be discharged.

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