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Full Length Research Paper

Clinical pharmacists education and counselling in patients with co-morbid hypertension and diabetes in a Municipal hospital in Ghana

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Hypertension and diabetes co-morbidity are very common chronic diseases in today's world. Patients with such conditions may have medication related problems. Assessment was made on the impact of clinical pharmacists' led education and counselling in patients with co-morbid hypertension and diabetes in a hospital setting. This study was done at the medical outpatient department (OPD) of a Municipal Hospital in Tema in the Greater Accra Region of Ghana. This was an intervention study conducted in patients with co-morbid hypertension and diabetes (n=338). Patients were randomized to the case group (n=144) and the control group (n=194). Patients in the case group received the education and counselling from the clinical pharmacists', whilst patients in the control group had the usual care. Patients in the case group had a better knowledge (p<0.0001) and adhered (p<0.0001) to their medication than those in the control group. The case group had a significant reduction in body mass index (p=0.005), systolic blood pressure (p<0.0001), diastolic blood pressure (p<0.0001) and fasting plasma blood glucose (p<0.0001). The clinical pharmacists' led counselling and education to support the management of co-morbid hypertension and diabetes at the hospital helped improved patient outcomes.

Key words: Co-morbid, diabetes, hypertension, intervention, counselling, education.

INTRODUCTION

The cumulative burden of non-communicable diseases (NCDs) demands for health care personnel to address its management comprehensively. These diseases are known to be a principal cause of mortality and morbidity globally (Gouda et al., 2019; WHO, 2018). Patients with co-morbid hypertension and diabetes face a myriad of challenges to their health. Management of these conditions are multifaceted, and patients need accurate information about their condition and medications among other things, to maximize the full benefit of treatment and

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prevent complications. These conditions are managed primarily with multiple drug therapy or dual therapy depending on patient characteristics and risk factors such as age, sex, past medical history, and social history among others (Alomar, 2014). Furthermore, these diseases affect different organ systems whereby patients are required to receive prescriptions with two or more medicines (Whitson et al., 2016). Universally, patients being on multiple drug therapy have been found to experience increased risk of medication error, undesirable side effects, adverse reactions, or increased medical expenditure (Alomar, 2014). To bridge this gap, pharmaceutical care, that is the delivery of medication-related care to improve the quality of life of the patient, is very essential (da Costa et al., 2019). Pharmacists have a key role in the prevention, identification, and correction of drug-related problems because of their pharmacotherapeutic training (da Costa et al., 2019). The process involves retrieving patient and medication data, recording the objectives, assessing the therapeutic plan, recognizing drug related adverse events or any drug related problem, responding to the problems, designing a monitoring plan, proposing the intervention to the doctor or patient, executing the intervention and implementing a monitoring plan that will continuously improve the quality of life of the patient (Chemello et al., 2014; Cipolle et al., 2012). It also involves the provision of essential services before, during, and after treatment to ensure effective and safe drug therapy (Chemello et al., 2014). Counselling, which is pivotal to pharmaceutical care, helps clients become more empowered to make informed decisions concerning the appropriate treatment with prescription and non-prescription medicines. This includes suitable actions to be taken in the event of side effects and adverse drug reactions. Furthermore, it helps patients comprehend the importance of their medicines and their storage conditions, which will help maintain and promote their well-being, as well as contribute to patient participation in their own care. This adds to the patient's health literacy (Hickey et al., 2018).

In Ghana, although there is a higher burden of communicable diseases, there has been an upsurge in the number of patients with NCDs (Agyei-Mensah and Aikins, 2010; Dosoo et al., 2019; Gatimu et al., 2016). Many studies around the world in recent times have reported the importance of pharmaceutical care in the management of patients with hypertension (Robinson et al., 2010; Skowron et al., 2011) and diabetes (Nogueira et al., 2020; Sriram et al., 2011). All these reinforce the fact that the normalization of blood glucose, systolic and diastolic blood pressure significantly prevent complications and improve the quality of life of patients. Therefore, pharmaceutical care provided by clinical pharmacists', can have a positive impact on patient care since they can provide education on medicines, disease condition, and therapeutic life style modifications such as diet, exercise, self-monitoring of blood pressure, and blood glucose. Furthermore, most studies are carried out in patients with single conditions rather than those with co-morbid conditions. Patients with co-morbidities are likely to be on multiple drug therapy and need more education and counselling. Therefore, the aim of this study was to assess the impact of counselling and education led by clinical pharmacists in patients with co-morbid hypertension and type -2-diabetes mellitus.

MATERIALS AND METHODS

Study setting

The study participants were recruited from the medical outpatient clinic, situated at the main outpatient department (OPD) of the Tema Municipal Hospital (TMH). TMH is the biggest government funded public health institution in the Tema Metropolitan Area, which is a Harbour City. The area of operation of the hospital includes the Tema Metropolis, towns and villages around it. The peculiar location of the hospital makes it one of the busiest in the Greater Accra Region of Ghana. TMH which has a bed capacity of about 399 is the chief referral point for other clinics and hospital in the metropolis. It has a medical OPD which operates a clinic for hypertension and diabetic patients.

Study design

This was an intervention study conducted at the medical out-patient clinic of TMH from August, 2018 to June, 2019. Three hundred and thirty-eight patients were recruited voluntarily on clinic days.

Inclusion and exclusion criteria

Co-morbid hypertension and type-2-diabetes patients who were at least 18 years and above. They should have had both conditions for at least six months. They were required to consent to regularly visit the hospital for the period of the study. Patients who were pregnant, had mental challenges or any other forms of diabetes were excluded from the study.

Sampling procedure

Participants were enrolled using a simple random technique. Participants were clients visiting the diabetes clinic. This clinic runs three days in a week (Wednesday, Thursday, and Friday) and attends to eighty-five patients per day on an average. Ten patients were selected for participation each day using a computer-generated sequence of random numbers. A person with no involvement in the study randomly allocated participants into the case and control groups.

The clinical pharmacists and nurses were not aware of the allocation, whereas the pharmacy interns, other pharmacy staff, and the patients were. The sampling frame was the number of patients who were booked for a clinic day. Each patient was given a unique number on each clinic day and patients who had been previously sampled were excluded from subsequent sampling using the dates of their previous clinic attendance. A total of thirty-six clinic days were used for the recruitment of participants at baseline. In all, three hundred and eighty-nine patients were recruited but fifty-one declined to participate in the study. This reduced the number of participants by 13% to 338. They were then grouped into the case (n=144) and control (n=194) groups by computer-generated numbers. At months 3 and 6, there were 187 participants in the control group and 141 in the case group.

Data collection methods

Data collection forms and questionnaires were used for this study. Experts on the subject matter reviewed the developed questionnaire to validate the content for comprehensiveness, clarity and readability. A consent form was thumb printed or signed by all prospective participants. Participants, who were unable to read, write or sign nominated an independent witness to attest to the consent process. A case report form was also generated to document data on their age, weight, height, body mass index, fasting plasma glucose, systolic blood pressure, diastolic blood pressure, adherence, patient knowledge and follow-up visits at months 3 and 6. Bloom's cut off point was used to categorize the level of knowledge into high, moderate, and low levels. Low and moderate knowledge levels were categorized as inadequate knowledge, while high knowledge levels were categorized as adequate knowledge. For adherence the MARS-10 was used to categorize the level of medication adherence into adherent and non-adherent. The blood pressure was measured by well-trained nurses who were blinded to the study. The body mass index was measured by well-trained pharmacist interns.

Intervention program

The case group was subjected to an intervention program provided by the clinical pharmacists which included a face to face interview which lasted for 10-20 min for the first session. The second session lasted for approximately 10 min which was based on the baseline data. The intervention centered mainly on educating patients on their disease condition, medication, therapeutic lifestyle, and individualized support systems. For educating the patients regarding their conditions, flyers and verbal communication were used by the clinical pharmacists. Aspects of the education included: The meaning of both hypertension and diabetes mellitus, the common signs and symptoms, risk factors, meaning of hypoglycemia and hyperglycemia, the common signs and symptoms of hyperglycemia and hypoglycemia, and common complications.

For educating the patients on their medications, emphasis was made on knowing the name of their medicines, identifying their medicines and what each is being used for, the importance of the medicine on their blood pressure and blood glucose, the common side effects and adverse effects of each medication, the dose to be taken daily, the dosing frequency, the duration of therapy, how to administer their medicines (especially insulin), how to store their medicines, common drug-drug interactions, common drug-food interactions, the importance of adhering to their medicines and refill dates, not sharing their medicines with other people, and keeping the medicines away from children.

In the area of therapeutic lifestyle, the clinical pharmacists used pictorial flyers and verbal communication to emphasize the importance of increasing physical activity (e.g., 30 min daily walks), eating diet rich in vegetables (e.g., green beans, cauliflower, lettuce), fruits (e.g., oranges, apples), fish, lean meat, avoiding adding salt and sugar to meals, avoiding foods such as salted tilapia and sugar-coated biscuits. Participants' ideas and preferences were discussed before any inputs were made on their diet. In addition, the importance of quitting smoking or the use of nicotine gums, the importance of rest and taking short breaks during working hours, reducing intake of alcohol, inspecting feet daily, cutting nails carefully, keeping feet warm and dry, not walking bare footed, self-monitoring of blood pressure (normal and abnormal ranges) daily, self-monitoring of blood sugar daily, and regular hospital checkups were emphasized.

The individualized supportive care was tailored to the personal needs of each participant. There was variation among the participants in terms of background, social and cultural beliefs, knowledge, among other factors. Participants had the opportunity to ask the clinical pharmacist any question concerning their health outcomes. The control group had no clinical pharmacist involved in counselling and education. They received the usual services provided by the hospital in which patients come for their medication and are counselled for some few minutes due to the heavy patient burden and the lack of health personnel. However, there were continuous telephone follow-up calls for both the case and the control groups.

Monitoring parameters and outcome measures

The parameters listed in Table 1 and related outcome measures were observed at baseline and months 3 and 6 in the case and control groups.

Data analysis

Prior to data entry and analysis, a unique identification number (ID) was assigned to every completed questionnaire. The coded data forms (questionnaires) were entered into the Epi info 7 data base. Data were processed using Microsoft Excel 2016. Categorical data were presented as frequencies (percentages). Bloom's cut off point and MARS-10 were used to assess the overall knowledge and adherence respectively. Chi-squared test was used to test the significance of associations. Normality of continuous data was assessed with Shapiro Wilk's test and was found not to be normally distributed. All continuous data were non-parametric and presented as median (interquartile ranges). The Mann-Whitney U test was used to evaluate the significance of the differences in anthropometric, hemodynamic, and biochemical parameters between the case and control groups. Non-parametric repeated-measures analysis of variance was used to determine the significance of the differences between systolic and diastolic blood pressure and fasting blood glucose across times of visit. p-values < 0.05 were considered statistically significant.

Ethics approval

Ethical clearance for research involving human subjects was obtained from the Committee on Human Research Publication and Ethics (CHRPE) Kwame Nkrumah University of Science and Technology (KNUST). The research protocol, questionnaire, participant information leaflet, and patient consent forms were reviewed and approved by the committee. The ethical approval code and date were CHRPE/AP/409/18 and July 18, 2018, respectively. Additionally, authorization was obtained from the hospital management before the commencement of the study.

RESULTS

Socio-demographic and lifestyle characteristics of the case and control groups

Participants in the case and control group had similar characteristics. There were no statistically significant differences in socio-demographic and lifestyle characteristics (Table 2).

Comparison of the clinical characteristics of the case and control groups

There were no statistically significant differences between

Table 1. Description of outcomes and measures.

	Outcome	Measure
A	Blood pressure monitoring	A manual mercury sphygmomanometer was used to measure the blood pressure of patients. Patients were made to rest 3 to 5minutes before the blood pressure measurement was taken. They sat comfortably in a chair with their back supported. The nurses ensured that the right cuff size was used for the measurement of the blood pressure according to the patients arm circumference. The readings were performed three times and the average recorded. Well trained nurses performed this task who were blinded to the study.
B	Fasting blood glucose monitoring	A validated automatic glucometer (Yasee blood glucometer GLM-77) was used for the measuring of the blood sugar. Patients were told to fast before the reading is done. Well trained nurses who were blinded to the study performed this task.
C	Body Mass Index measuring	The body mass index was measured with a scale that measured client's weight and height. In computing the Body mass index formula, weight in kilogram/height in m^2 was used. The World Health Organization classification of body mass index was used to categorize patients into underweight (below18.5kg/m^2), Normal weight (18.5kg/m^2to24.9kg/m^2), overweight (25.0kg/m^2 to29.0kg/m^2) and Obese (30.0kg/$m^2$and above) A well-trained pharmacy intern performed this task.
D	Level of adherence	Patient self-reporting using the medication adherence reasoning scale (MARS-10). Patients who scored 6≤ was considered adherent and <6 non-adherent.
E	Level of knowledge	Patient knowledge was assessed based on the name, dosage, duration of therapy, common side effects, purpose of anti-hypertensive medicine and purpose of anti-diabetic medicine. Blooms cut off point was used to assess the overall knowledge, patients with a score above 80% had adequate knowledge whilst patient with scores below 80% had inadequate knowledge.

the case and control groups with respect to clinical characteristics (Table 3).

Biochemical, anthropometric and hemodynamic profiles of the case and control group stratified by visit type

There were no statistically significant differences between the parameters for the case and control groups at baseline. After intervention, the case group had improved outcomes (Table 4).

Level of knowledge of the case and control groups stratified by visit type

There was no statistically significant difference in the level of knowledge on medication use between the case and control groups at baseline. However, after intervention, the case group recorded a significantly higher knowledge on medication than the control group at both 3 and 6 month of follow up (Table 5).

Level of adherence of the case and control groups stratified by visit type

There was no statistically significant difference in the level of adherence on medication use between the case and control groups at baseline. However, after intervention, the case group recorded a significantly higher adherence to medication than the control group at both 3 and 6 month of follow up (Table 6).

DISCUSSION

Pharmaceutical care interventions which focused on patient education and counselling have resulted in the improvement of the quality of life of patients worldwide (da Costa et al., 2019; De La Monte and Wands, 2008; Nogueira et al., 2020; Saleem et al., 2015; Shao et al., 2017; Skowron et al., 2011; Tommelein et al., 2014). The results of the present study support the fact that pharmaceutical interventions have positive effects on patients' health even in co-morbid conditions. In this study, the baseline median body mass index of the case group decreased from 27.85 to 27.3 kg/m2 as compared to the control group where there was an increase from 29.4 to 29.6 kg/m^2 ($p = 0.005$). In a randomized controlled trial in patients with diabetes mellitus, there was a reduction in the median body mass index of the case group from 34.10 to 32.40 kg/m^2 ($p < 0.001$) (Korcegez et al., 2017). This reiterates the fact that pharmacist involvement in the healthcare of patients can help in the reduction of body mass index and improve health outcomes. Additionally, the median fasting blood glucose of the case group decreased from 8.1 to 6.2 mmol/L compared to the control group where there was an increase from 7.5 to 8.8 mmol/L ($p < 0.0001$). In a systematical review involving 2,997 patients in 25 studies, pharmaceutical care intervention programs helped in reducing the plasma glucose of patients (Iqbal et al., 2019). Poor glycemic control is associated with many complications which can result in disabilities and even death (Haghighatpanah and Nejad, 2018). Pharmacist involvement in counselling and other supportive care has a positive outcome on the fasting plasma glucose of patients. Additionally, the median

Table 2. Comparison of socio-demographic and lifestyle characteristics between the case and control groups of the study population.

Variable	Case	Control	p-value
Age (years)	62.0 (56.0-69.0)	61.0 (54.0-69.0)	0.194
Sex			0.317
Female	122 (44.0)	155 (56.0)	
Male	22 (36.1)	39 (63.9)	
Religion			1.000
Christianity	135 (42.7)	181 (57.3)	
Islamic	9 (40.9)	13 (59.1)	
Marital status			0.076
Married	80 (39.6)	122 (60.4)	
Widowed	35 (42.7)	47 (57.3)	
Divorced	21 (63.6)	12 (36.4)	
Single	8 (38.1)	13 (61.9)	
Education			0.834
Secondary	49 (40.2)	73 (59.8)	
Primary	47 (44.8)	58 (55.2)	
None	32 (45.1)	39 (54.9)	
Tertiary	12 (44.4)	9 (55.6)	
Vocational	4 (30.8)	9 (69.2)	
Residential status			0.602
Urban	101 (43.2)	133 (56.8)	
Peri-urban	22 (37.3)	37 (62.7)	
Rural	21 (46.7)	24 (53.3)	
Employment status			0.659
Unemployed	80 (44.0)	102 (56.0)	
Employed	64 (41.0)	92 (59.0)	
Lifestyle characteristics			
Practice vigorous physical activities besides usual activities	90 (40.0)	135 (60.0)	0.200
Consume salty food	79 (46.7)	90 (53.3)	0.153
Consume high lipid diet	44 (43.6)	57 (56.4)	0.904
Consume alcohol beverage	21 (45.7)	25 (54.3)	0.078
Smoked in the past	7 (50.0)	7 (50.0)	0.591
Currently smoking	2 (50.0)	2 (50.0)	1.000
Health Financing Scheme			0.426
Insured	143 (42.4)	194 (57.6)	
Non-insured	1 (100.0)	0 (0.0)	

Significant when variables are in bold print with p value<0.05.

systolic blood pressure improved for both the case (from 130 to 120 mmHg) and control group (140 to 130 mmHg) after the 6-month study period with $p < 0.0001$. However, the case group had a better outcome. In a cluster, randomized, controlled trial in patients with hypertension, the case group had a significant reduction in systolic blood pressure compared to the control group ($p < 0.001$) (Anderegg et al., 2018). The median diastolic blood

Table 3. Comparison of clinical characteristics between the case and control groups of the study population.

Variable	Case	Control	p-value
Family history of disease			
Hypertension	75 (41.0)	108 (59.0)	0.795
Diabetes	74 (40.4)	109 (59.6)	0.613
Personal history of disease			
Hypertension	144 (42.6)	194 (57.4)	1.000
Diabetes	144 (42.6)	194 (57.4)	1.000
Duration of hypertension (years)			0.433
< 5	23 (39.0)	36 (61.0)	
5 – 10	54 (40.6)	79 (59.4)	
> 10	67 (46.2)	79 (53.8)	
Duration of diabetes (years)			0.156
< 5	26 (36.6)	45 (63.4)	
5 – 10	49 (39.2)	76 (60.8)	
> 10	69 (48.6)	73 (51.4)	
Complications			
Hypertension-related	2 (66.7)	1 (33.3)	0.577
Diabetes-related	15 (48.4)	16 (51.6)	0.569

Significant when variables are in bold print with p value<0.05.

Table 4. Evaluation of the differences in the biochemical, anthropometric, and hemodynamic profiles of the case and control groups stratified by visit type.

Variable	Baseline			Month 3			Month 6		
	Case	Control	p-value	Case	Control	p-value	Case	Control	p-value
Fasting blood glucose (mmol/L)	8.1 (6.5-10.1)	7.5 (6.1-9.8)	0.153	6.6 (5.8-7.9)	8.5 (7.2-10.9)	<0.0001	6.2(5.5-7.0)	8.8 (7.3-10.7)	<0.0001
Systolic blood pressure (mmHg)	130.0(120-150)	140.0(120.0-150.0)	0.540	125.0(120-130)	130.0(120.0140.0)	<0.0001	120.0(120-130)	130.0(120.0-14.0)	<0.0001
Diastolic blood pressure (mmHg)	80.0 (80.0-90.0)	80.0 (80.0-90.0)	0.764	80.0 (80.0-80.0)	80.0 (80.0-90.0)	0.007	80.0 (80.0-80.0)	80.0 (80.0-90.0)	<0.0001
Weight (kg)	75.0(64.3-86.0)	77.0(70.0-89.0)	0.132	73.1(63.0-84.0)	77.6(68.7-91.0)	0.006	73.0(63.0-84.0)	77.5(68.4-91.0)	0.006
Body mass index (kg/m^2)	27.85(24.2-32.0)	29.4(24.8-33.8)	0.057	27.3(23.9-31.2)	29.1(24.61-33.96)	0.005	27.3(23.9-31.2)	29.6(24.6-33.9)	0.005

Significant when variables are in bold print with p value < 0.05.

Table 5. Comparison of proportional differences in knowledge on medication use between the case and control groups stratified by visit type.

Visits	Case (%)	Control (%)	p-value
Baseline	20.4	24.3	0.302
Month 3	44.0	23.9	<0.0001
Month 6	44.0	23.9	<0.0001
p-value	0.0002	0.999	

Significant when variables are in bold print with p value < 0.05.

Table 6. Comparison of proportional differences in adherence on medication use between the case and control groups stratified by visit type.

Visits	Case (%)	Control (%)	p-value
Baseline	20.7	24.26	0.460
Month 3	30.47	19.23	<0.0001
Month 6	39.64	22.19	<0.0001
p-value	**0.0003**	**<0.0001**	

Significant when variables are in bold print with p value <0.05.

pressure of both the case and control group was normal (80 mmHg). However, most patients in the case group had an improved diastolic pressure compared to those in the control group. In an exploratory study in Ghana, in a community setting, pharmaceutical care intervention improved the diastolic blood pressure of patients with hypertension (p = 0.01) (Marfo and Owusu-Daaku, 2017). With respect to patients' knowledge, there was no statistically significant difference between the case and control groups at baseline. However, after intervention, the case group recorded a significantly higher knowledge on medication compared to the control group at both month 3 (44.0 vs 23.9%, p < 0.0001) and month 6 (44.0 vs 23.9%, p < 0.0001). In a randomized control study in hypertension patients where educational intervention was provided by a pharmacist to the case group, there was an increase in the median knowledge score from 12 to 20 (p<0.001) (Muhammad et al., 2018). Lack of knowledge on medicines can lead to over dose or under dose of medication, which can further lead to treatment failure and put the health of the patient at risk (Saqib et al., 2019). Although in public hospitals, pharmacists are overburdened with the number of patients or prescriptions they attend to, nevertheless there is a need for pharmacists to encourage drug-therapy information awareness, counselling on medicines etc. which will improve on patient outcomes and also prevent any untoward effects. In respect to adherence to medication, there was no statistically significant difference in the proportion of patients who were adherent to their medication between the case and control, however after the intervention, the case group had a higher adherence level compared to the control group at both month 3(30.47 vs 19.23%, p < 0.0001) and month 6(39.64 vs 22.19%, p < 0.0001). Adherence to medication is important when it comes to the management of patients with hypertension and diabetes. Non- adherence to prescribed medicines, sub-optimal utilization of pharmacotherapy and lack of monitoring contribute to the poor control of blood sugar and blood pressure in hypertension and diabetes patients (Bajorek et al., 2016). Improvement in medication adherence has been found to be linked to the patient knowledge and understanding, their beliefs about their treatment and health condition (Kardas et al., 2013). Hence the need for pharmacists and other health care team members to educate and counsel their patients about their medication and health condition.

Strength of the study

To our knowledge, studies have been conducted on the impact of education and counselling provided by pharmacists in chronic disease in Sub-Saharan Africa, however there appears to be paucity of research information in patients with co-morbid hypertension and diabetes.

Limitations of the study

This study was conducted in a municipal hospital with a study population of three hundred and thirty- eight patients, which though adequate for this specific study, may not fully represent the general outcome of education and counselling provided by pharmacists in the

management of patients with co-morbid hypertension and diabetes.

Conclusion

The counselling and education led by clinical pharmacists improved the health outcomes of patients with hypertension and diabetes seeking care at the hospital. Thus, the clinical pharmacy services instituted at the hospital were efficient in supporting therapy and improving patient outcomes.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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