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Impact of Structured Medication Review Services on Hypertension Treatment Outcomes in Two Nigerian Teaching Hospitals: An Interventional Study

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ABSTRACT

Background: The prevalence of hypertension has dramatically increased in Sub-Saharan Africa due to poor treatment outcomes. Inappropriate interventions are a major cause of poor blood pressure control among hypertensive patients. The development of an appropriate development intervention would significantly reduce blood pressure in the adult population. **Objective:** To assess the impact of structured medication review services on hypertension treatment outcomes in hypertensive patients. **Methods:** This was a 6-months prospective, randomized controlled study of 378 hypertensive patients in two tertiary hospitals where the impact of structured medication review services as compared to patients that received usual care by assessing treatment outcomes. The interventions comprised monthly tailored verbal education and counseling, medication adherence and blood pressure assessments, telephone calls and SMS interventions and reminders, and monthly follow-up. Primary outcomes were medication adherence and change in blood pressure. To determine the mean change in continuous variables such as blood pressure, a paired t-test was applied to compare blood pressure at baseline and endpoints. A chi-square analysis was used to determine the impact of the intervention on medication adherence and mean blood pressure change between groups from baseline to endpoint. **Results:** More than half (n = 220, 58.5%) of the participants were female with a mean (SD) age of 50.36 (±10.186) years. Most (n = 213, 56.3%) participants lacked home blood pressure monitoring devices. At baseline to endpoint, there was large improvement in adherence within the Intervention group (73.1% to 96.2%) when compared to the Usual-care group (84.2% to 82.1%). Systolic blood pressure between Intervention and Usual-care groups at endpoint were 126.2 mmHg and 143.0 mmHg respectively. The mean change in systolic blood pressure between groups was -11.5 mmHg [95% CI: -11.53 to -19.90; p = 0.001]. **Conclusion:** Medication adherence and blood pressure of patients were significantly improved when pharmacist-led structured medication review services are employed in the management of hypertensive patients. This study may provide a framework for practice and policy for future development of studies in pharmacist-led interventions in hypertension treatment outcomes.

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INTRODUCTION

The rate of hypertension has dramatically increased in Sub-Saharan Africa. This increase is due to poor treatment outcomes. Treatment outcomes in this study were medication adherence and blood pressure control.[1] Lack of adequate clinical interventions are associated with an increasing healthcare cost that adversely affects the health system.[2,3] Poor medication adherence can lead to greater risks for coronary disease, cerebrovascular disease, and chronic heart failure.[4] Poor medication adherence also increases relapse and recurrent hospitalization. Hence, the climax of poor medication adherence is the disability, poor health-related quality of life and mortality.[4]

Achieving optimal hypertension treatment outcomes remain a major challenge to both patients and health practitioners. This is due to multiple reasons, such as, intentional medication non-adherence due to unpleasant side-effects, worries about specific medications, forgetting to take medications, poor treatment-related knowledge, quality of life, and difficulty in achieving recommended blood pressure targets.[5,6] In an observational cross-sectional study, poor medication adherence and blood pressure control were noted in 92.5% [95% CI 89.3–95.8] hypertensive patients in Nigeria whereas 93.3% [95% CI 90.9–95.8] were observed in Ghana.[7] Another data reported that patients missed their treatment due to forgetfulness (34.3%), high cost of medications (26.0%), side effects (16.8%) and not feeling well (11.8%) as the main reasons for not adhering to their medications, thus resulting in poor blood pressure control.[2]

Structured Medication Review Services

Structured Medication Review Services are a critical examination of a patient's medication (s) by a clinical pharmacist in collaboration with other health professionals, with the objectives of reaching an agreement with the patient about their treatment, improving adherence and quality of life, minimizing the number of medication-related problems and avoiding wastage.[8]

Structured Medication Review Services are a distinct group of services that improve treatment outcomes for individual patient with chronic medical conditions, and are a care model built on team-based care principles that are effective in optimizing hypertension treatment outcomes.[9,10] The SMR Services emphasize planned face-to-face pharmacist-

patient meetings, education and counseling, review of current medications, encourages active patient's participation in his/her medication therapy, and follow-up. It is important to note that Structured medication review services are the same as medication therapy management (MTM) or comprehensive medication management (CMM) in the United States of America.

Understanding obstacles to, and determinants of adherence among hypertensives are crucial in developing interventions that improve treatment outcomes.[11] Interventions aimed at promoting treatment outcomes among hypertensive patients are therefore important to eliminate or reduce hypertension-induced complications.

In Jos, Northern Nigeria, pharmacy practice is mostly by the traditional medication dispensing and management of antihypertensives and other medications are performed by pharmacists. In this traditional role, pharmacists are restricted to medication dispensing and have limited time and interactions with patients. Moreover, in Sub-Saharan Africa, the traditional role of medication dispensing is the very common and is the accepted mode of pharmacy practice among pharmacists and the healthcare systems. Moving away from this type of practice and into a more patient-oriented care has often been resisted by many Sub-Saharan health systems.

The SMR is a new intervention in the health systems of Sub-Saharan Africa especially in Jos, Plateau State, Nigeria. This form of intervention allows pharmacists to interact with patients and to educate them on the proper use of their medications.

This study aimed at assessing the impact of a pharmacist-led structured medication review services on treatment outcomes in hypertensive patients in two teaching hospitals in Jos, Plateau State, northern Nigeria.

The specific objectives of the study were:

1. To compare medication adherence between structured medication review services group/Intervention group (IG) and Usual-Care group (UG).

2. To compare mean blood pressure, change between Intervention and Usual-care groups.

METHODS

Study Design and Settings

The design was a 6-month, prospective study among hypertensive patients. The outcomes of the interventions were assessed and compared between the IG and UG patients in the General Outpatient Departments (GOPDs) of two teaching hospitals from June 2019 until December 2019. The two hospitals were Plateau State Specialist Hospital (PSSH) and the Bingham University Teaching Hospital (BhUTH) all located in Jos, Plateau State, northern Nigeria. The two facilities were divided into the IG and the UG. PSSH was the IG while BhUTH was the UG. Patients were randomized to the IG and UG. The research facilities were not staffed by the same people but by different health professionals of equal qualification and competence.

In the IG group, the services were provided by the lead researcher, a certified clinical pharmacist, who spent 10 – 15 minutes with every patient discussing their blood pressure and current medications.

The study protocol was approved by the Health Research Ethics Committees of the Bingham University Teaching Hospital (REF NHREC/21/05/2005/00635) and the Plateau State Specialist Hospital (REF PSSH/ADM/ETH.CO/2019/005).

Study Population

The target population was hypertensive patients that were followed-up monthly in the General Outpatient Departments of PSSH and BhUTH Hospitals. Inclusion criteria included patients ≥ 18 years, known hypertensive patients and can clearly communicate either in English or in their dialect through an interpreter. Patients with cognitive impairment and terminally ill were excluded from the study. Hypertension was defined as systolic blood pressure ≥ 140 mmHg while diastolic blood pressure was ≥ 90 mmHg.

Sample size was derived by calculating the difference between two - independent means based on the followings: detecting a 5 mmHg difference in systolic blood pressure (SBP) between the IG and UG at endpoint by using an effect size Δ (0.3), a power [1-β (0.90)], a 5% chance of type 1 error (α = 0.05, 2 - sided) and a standard deviation of 10 mmHg in SBP with a ratio of 1:1.[12] Inserting these figures in an online sample size calculator, power analysis

produced a sample size of 388 with 194 in each arm.[13] Accounting for an estimated 10% patient dropout rate,[14,15] the sample size was adjusted upward to 427.

Randomization and blinding

Patients were randomly recruited based on the inclusion criteria as listed in the study and were provided a unique patient's number in their recruitment booklet. The IG was assigned to one arm, while the UG was assigned to another. Participants were individually interviewed by the lead researcher, but they were not informed as to who would receive the intervention. They were given general information about the nature of the study to obtain their consent and cooperation for the course of the study. Nevertheless, due to the nature of the study, blinding was not possible.

Study Instruments

The Structured Medication Review Services instrument comprised four sections. The sections were 1) demographic characteristics, 2) medication adherence, 3) health-related quality of life (Physical and Mental Composite Scores), and 4) blood pressure monitoring. Demographic characteristics were assessed at baseline. They included age (years), gender, weight (Kg), systolic and diastolic BP levels, educational status, occupational status and area of residence.

Medication adherence was measured using a modified 4-Item Morisky Medication Adherence Scale,[16] a validated 4-item questionnaire with 4 yes/no questions with a scoring scheme of "Yes" = 0 and "No" = 1. The 4-Items Medication Adherence Questionnaire was the quickest to administer and score and easily used to discover barriers to adherence.[16] Adherence was rated as high adherence (4), medium adherence (3), poor adherence (< 2). For the current study, mean higher adherence score denoted better adherence.[17] All patients who had adherence score (≤ 2) were considered poorly adherent.

Hypertension referred to systolic BP ≥ 140 mmHg and diastolic BP ≥ 90 mmHg at the time of the study or antihypertensive therapy for at least 1 month prior to the study.[18] Clinical significance in systolic blood pressure was set at SBP ≤ 5 mm Hg. Clinical significance in the current study refers to minimal reduction in SBP ≤ 5 mm Hg between groups. The clinical significance also indicates a point in which the intervention made an impact in BP reduction and control. Blood pressure was considered reduced in all treated hypertensive patients who had SBP < 140 mmHg and DBP < 90 mmHg at the time of the study. Blood pressure was

measured in participants in a sitting position with feet flat on the floor after at least ≥ 3 minutes of rest[19] and measured using the validated electronic blood pressure device OMRON® HEM – 720 – E. The mean BP change was obtained by calculating the difference between mean BP baselines to endpoint between groups. Body weight was measured in kilogram (Kg) to the nearest 0.1 kg using a PH – 2015A brand electronic weight scale.[19]

Primary outcome was any change in medication adherence. Change in mean SB and DBP were the secondary outcomes.

Descriptions of Interventions

Participants were randomized into the IG, and the UG. Participants were assessed for their level of literacy during the screening process. The IG arm received a 10–15-minute face-to-face interview and education session per clinic visit or follow-up. The lead researcher, a certified clinical pharmacist, had regular monthly structured education sessions with the patients from baseline to endpoint in a private spot in the hospital pharmacy.

Participants in the structured medication review group were provided with

- Hypertension-information leaflets (provided in English) on risk factors, complications, the importance of lifestyle modifications and medication adherence. Education on lifestyle modifications included encouraging patients on physical activities, moderate alcohol consumption, discouraging high salt intake, smoking or secondhand smoking, weight management and benefits of consuming diets that are required for their health such as vegetables and fruits.

- Hypertension diaries in order to monitor patients' blood pressure, weight, and diet.

- Monthly tailored and targeted verbal education directed at patients in order to improve patients' knowledge about hypertension, current medications, adherence, and lifestyle changes in order to achieve target blood pressure change

- Monthly medication adherence assessments

- Monthly blood pressure measurements.

- Monthly telephone calls and SMS interventions and reminders.

- Monthly follow-up assessments and Documentation.

Standard Medication Dispensing/Usual-care Group

Participants in the Usual-care group did not receive any interventions, but they however received monthly assessments on medication adherence and blood pressure measurements, telephone call reminders, and monthly follow-up visits by the lead researcher. All of these were not for therapeutic purposes.

In this group, the participants received care from physicians, nurses and their scheduled medication refill from pharmacy personnel in the department of pharmacy.

Data collection

At baseline, the patient's socio-demographic (age, sex, highest level of education, marital status, employment status, living alone) and clinical characteristics (adherence level, BP measurements, weight, waistline, home BP monitoring) were recorded using a pre-designed data collection form through a face-to-face interview session. Patients were assessed for alcohol consumption which was designated by "never/at least once a week", smoking status (never/at least once a week), caffeine or intake of caffeinated products (never/at least once a week), and regular exercise (never/at least 30 minutes once a week). Family history of hypertension referred to patients whose father, mother, siblings, uncle, or aunt were diagnosed with hypertension.

After the collection of baseline data, patients were follow-up monthly for 6 months. At every follow-up visit, patient's medication adherence and standard blood pressure measurements were assessed. Medication adherence was assessed by patients' self-reported questionnaires such as modified MMAS-4. Blood pressure was measured in participants in a sitting position with feet flat on the floor after at least ≥ 3 minutes of rest and measured using a validated electronic blood pressure device OMRON® HEM – 720 – E.

Statistical analysis

Statistical Package for Social Sciences (SPSS) version 25.0 (IBM Corp, Armonk, NY, USA) was used to analyze baseline and endpoint data. Descriptive statistics was used to report age, weight and waistline in Mean and Standard deviation. Categorical variables such as gender, marital status, caffeine intake and family history of hypertension were reported in

frequencies/proportions. To determine the mean change in continuous variables such as blood pressure, a paired t-test was applied. A chi-square analysis was used to determine the impact of the intervention on medication adherence, health-related quality of life, and mean blood pressure change between groups from baseline to endpoint. Data on adherence and blood pressure were analyzed at three-point time: baseline, 3rd month follow-up and endpoint at 6th month. Missing values as a result of a participant's not responding to certain items or withdrawal from the study were analyzed by performing missing value analysis (chi-square = 8.649, df = 22, p = 0.995). All missing values were purely by chance and excluded from the data analyses. Significance was set at $p < 0.05$.

RESULTS

Of the 378 participants that completed the study, more than half (n = 220, 58.5%) were female with a mean (SD) age of 50.36 (10.186) years. The majority (n = 348, 92.3%) were married. More than half (n = 212, 56.2%) of the participants had tertiary education and most (n = 261, 67.8%) were civil servants. Most (n = 213, 56.4%) participants lacked home blood pressure monitoring devices. The demographic characteristics of the patients are illustrated (**Table 1**).

Medication adherence between IG and UG at baseline to endpoint is illustrated in **Table 2**. The proportion of adherent participants in the Intervention group improved (73.1% to 96.2%) when compared to the Usual-care group (84.2% to 82.1%) (**Table 2**). Systolic BP between Intervention and Usual-care groups at the endpoint was 126.2 mmHg and 143.0 mmHg respectively. The mean SBP change between groups was -11.5 mmHg [95% CI: -11.53 to -19.90; p = 0.001] (**Table 2**).

Table 3 illustrates the medications that were commonly prescribed among the participants. The most prescribed were Amlodipine and Lisinopril (43.6% vs. 31.2%). The most prescribed combination medication was Moduretic (11.4%).

Table 1: Demographic characteristics of study participants

Characteristics	Total Subjects		Intervention Group		Control Group	
	N	%	N	%	N	%
Sex of Participants						
Males	156	41.5	96	61.5	60	38.5
Females	222	58.5	140	63.6	82	36.4
Marital status						
Married	348	92.3	225	64.7	123	35.3
Single	29	37.7	11	37.9	18	62.1
Educational status						
Primary and others	69	18.7	38	55.1	31	44.9
Secondary	88	23.9	59	67.0	29	33.0
Tertiary	212	57.4	135	63.7	77	36.3
Occupational status						
Housewife	39	10.1	35	89.7	13	10.3
Traders	85	22.1	37	43.5	48	56.5
Civil servants	261	67.8	166	63.6	95	35.4
Family history of hypertension						
Present	212	56.4	143	67.5	69	32.5
Purposeful exercise						
Never	128	34.4	76	59.4	52	40.6
At least once a week	244	65.6	158	64.8	86	35.2
Caffeine intake						
Never	166	44.4	111	66.9	55	33.1
At least once a week	208	55.6	123	59.1	85	40.9
Home Blood Pressure Measurements						
Never	213	56.4	139	62.3	74	34.7
At least once a week	165	43.6	93	56.4	72	45.6
Medications regimen						
Taking a single antihypertensive	127	27.1	67	52.8	60	47.2
Taking multiple antihypertensives	344	72.9	125	36.3	219	63.7

Table 2: **Treatment Outcomes of Participants**

SN	Treatment outcomes	Intervention (n=236)	Usual-care (n=142)
1	**Medication Adherence at Baseline**		
	Mean Adherence (Self-Report) Score	2.96	3.45
	Range	1 - 4	1 - 4
	Proportion of Adherent Patients (%)	73.1	84.2
2	**Medication Adherence at Endpoint**		
	Mean Adherence (Self-Report) Score	3.66	3.27
	Range	1 - 4	1 - 4
	Proportion of Adherent Patients (%)	96.2	82.1
	Mean Difference from Baseline (%)	23.1	- 2.1
	p< 0.05	0.001	0.009
3	**Systolic BP (mm Hg) at Baseline**		
	Mean (±SD)	139.7 (±18.32)	141.0 (±16.23)
4	**Systolic BP (mm Hg) at Endpoint (6th month)**		
	Mean (±SD)	126.2 (±11.80)	143.0 (±24.79)
	Difference from Baseline	-13.5	2.0
	Mean Difference in SBP between Groups	11.5	--
	P < 0.05	0.001	0.059
5	**Diastolic BP (mm Hg) at Baseline**		
	Mean (±SD)	86.2 (±12.44)	90.3 (±14.10)
6	**Diastolic BP (mm Hg) at Baseline**		
	Mean (±SD)	82.8 (±6.88)	87.1 (±14.68)
	Mean Difference from Baseline	-3.70	-3.3
	P < 0.05	0.001	0.095

*BP – Blood Pressure, BP - Blood Pressure, SD – Standard Deviation, mm Hg – millimeter mercury,

Table 3: Medications Commonly Prescribed to Both Groups in the Study

SN	Medications	n	%
1	Amlodipine	602	43.6
2	Lisinopril	431	31.2
3	Hydrochlorothiazide	87	7.0
4	Moduretic	157	11.4
5	Vasoprin	71	5.1
6	Glimepiride	23	1.7
7	**Total**	**1381**	**100%**

DISCUSSION

Adherence to medication

Patients in the intervention group reported a higher proportion in adherence to antihypertensive medication therapy from baseline to endpoint, while the Usual-care group patients reported a 2.1% decrease. The difference in adherence between groups was 21.1%. The overall improvement between the IG and UG was substantial (23.1% vs 2.2%, p = 0.001). The improvement in adherence of the IG was visibly due to the services provided by the research pharmacists to patients. The interventions/services were structured and maintained in order to improve treatment outcomes among hypertensive patients.

From data obtained in the current study, most of the patients in the intervention group had higher levels of education and were civil servants in the employ of national government. The level of education could have greatly impacted the understanding and adherence of the IG in conforming to lifestyle changes. With the issuance of the hypertension diaries to patients, it was observed that that the IG responded favorably to patient-centered education and adherence counseling.

A prospective randomized controlled trial of 278 hypertensive patients reported low adherence in an IG that was followed up for 6 months.[20] Poor adherence was reportedly due to lack of medication counseling and poor communication by healthcare professionals that resulted in patient factors for low medication adherence.[21,22] Two systematic reviews showed significantly greater improvements in adherence and other health outcomes in the intervention groups compared to the Usual-care groups.[12,23] Other studies have indicated a

strong relationship between medication adherence and overall treatment outcomes. A systematic review identified a positive association, that is, it was expected that as adherence improved, so would treatment outcomes as well.[24] Therefore, it was expected that the 23.1% improvement of the IG would yield better long-term treatment outcomes. To avoid low adherence, the current study maximized and enforced the intervention employing phone calls and SMS text to follow up its participants for a 6-month period.

Blood Pressure

The Structured Medication Review/Intervention group experienced a significant reduction ($p = 0.001$) in systolic blood pressure from baseline to endpoint, while the Usual-care group had an elevation in blood pressure from baseline to endpoint (Table 2). Blood pressure reduction in the Intervention Group was significantly greater than the Usual-Care Group (13.5 mmHg vs 2.0 mmHg, $p<0.001$). A mean blood pressure difference of -11.5 mm Hg was obtained between groups. These findings differ with findings in a meta-analysis of pharmacist intervention in hypertension management which revealed a mean BP of 6.9 mm Hg greater improvement in the intervention group and consistent with findings of an interventional study which presented a mean BP change of -10.9 mm Hg improvement in the intervention group.[12,25]

Studies have shown that clinically detecting a 5-10 mmHg systolic BP reduction decreases the chances of cardiovascular events and stroke by 50%.[14-26] The present study reported a clinical detection of -11.5 mmHg decline in systolic blood pressure. This clinical detection produced a significant positive impact on treatment outcomes in the study and was expected to lower the chances of developing cardiovascular disease. This is clinical detection of -11.5 mm Hg systolic BP reduction was possible due to the structured medication review services/interventions which were continuously maintained, as demonstrated in the current study. It is also probable that when there is a cessation or the absence of pharmacist interventions, there could be an increased in patients relapse towards an unhealthy lifestyle and poor blood pressure control. Consequently, hypertension management in the healthcare system should be structured in a manner to include active pharmacist's structured medication review services to ensure that patients are given the care and support they need to maintain adequate lifestyle adjustments and blood pressure control.

The current study reported reductions in diastolic BP that were slightly greater for the Intervention group than the Usual-care group. From baseline report, the intervention group had better controlled diastolic BP than the Usual-care group. Therefore, the impact that the intervention could have on patients' diastolic BP was narrow. However, the results from the study indicate that patients who received comprehensive structured medication review services from pharmacists are significantly more likely to reach blood pressure targets than patients who only receive care from physicians.

LIMITATIONS

Response to medication adherence questionnaires may not reflect the actual adherence level of patients who may have responded in the affirmative to please the researchers. This factor the researchers had no control over.

CONCLUSIONS

Based on the outcomes of this 6-months prospective randomized study, medication adherence and blood pressure reduction rates of patients were significantly improved by pharmacist-led structured medication review services. We recommend that the role of the pharmacist be expanded on the healthcare team to effectively improve hypertension treatment outcomes. This study may therefore provide a framework for practice and policy for future development of studies in pharmacist-led interventions in hypertension treatment outcomes.

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CONFLICT OF INTEREST

The authors declare no conflict of interest associated with this study.

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