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IMPACT OF PHARMACIST-LED EDUCATIONAL INTERVENTIONS IN ASTHMA ON INHALER TECHNIQUES

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ABSTRACT

The correct use of inhalers allows for optimal safety and efficacy. This study assessed the impact of pharmacist-led educational interventions in asthma on inhaler techniques. This was a single-blinded, three-arm, prospective, randomized, controlled intervention study conducted in the Respiratory Units of the University of Nigeria Teaching Hospital (UNTH), Enugu State and the Lagos University Teaching Hospital (LUTH), Lagos State between March 2016 to September 2017. The three arms were: Usual Care, Individual Intervention, Caregiver-assisted Intervention. The intervention arms received education for 6 months while the usual care arm received no education. Using a validated checklist, inhaler techniques were assessed at baseline, 3 months, and 6 months after baseline. Data were analyzed using the IBM SPSS Version 25.0 with statistical significance set as $P < 0.05$. Seventy-eight (78) asthma patients participated; 39 patients per hospital; 13 patients in each arm. There was significant improvement ($P < 0.05$) in PMDI scores for the Individual Intervention compared to Usual Care arm at 3 months (11.00 vs. 9.38; $P = 0.005$, $t = 3.086$, $df = 25$) and 6 months (11.00 vs. 9.54; $P = 0.013$, $t = 2.658$, $df = 25$) but at 3 months only (10.54 vs. 9.38; $P = 0.044$, $t = 2.126$, $df = 25$) for the Caregiver-assisted Intervention arm. Furthermore, there was significant improvement ($P < 0.05$) in accuhaler scores for the Individual Intervention compared to Usual Care arm at 3 months (11.00 vs. 9.35; $P = 0.028$, $t = 2.421$, $df = 16$) and 6 months (11.00 vs. 9.18; $P = 0.016$, $t = 2.696$, $df = 16$) but at 3 months only (10.77 vs. 8.85; $P = 0.045$, $t = 2.241$, $df = 12$) for the Caregiver-assisted Intervention arm. The individualized educational intervention produced better improvements in inhaler techniques than the caregiver-assisted intervention.

KEYWORDS: **Asthma; Inhalers; Interventions; Pharmacist.**

INTRODUCTION

Respiratory diseases such as asthma or chronic obstructive pulmonary disease (COPD) are frequently managed by administering drugs through the inhalation route [1]. Drugs administered by the inhalation route include beta-sympathomimetics, corticosteroids, muscarinic antagonists, and antibiotics [1]. The direct delivery of drugs to the lungs makes the inhaled therapy the cornerstone of asthma treatment as it ensures reduced dose, reduced side effects, and increased efficacy [2]. More than 90% of patients with asthma and COPD do not use their inhaler devices appropriately [3 – 7]. The correct use of inhalers allows for optimal safety and efficacy.

In Nigeria, the pressurized metered dose inhalers (PMDIs) and dry powder inhalers (DPIs) are prescribed for patients with asthma. The commonly prescribed DPI devices are the accuhaler and the

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turbuhaler devices. The techniques for the use of the devices differ [8]. Patients need to shake their PMDIs before use but this is not required for the DPIs. The PMDIs require slow inhalation with simultaneous activation of the canister which varies from the DPIs that require forceful and deep inhalation with no concurrent process. There are also differences in the handling of the accuhaler and turbuhaler. To use the accuhaler, the device should be held horizontally with the lever pushed away from the mouthpiece until a click is heard. Contrarily, the turbuhaler device should be held upright with the grip rotated anti-clockwise, then back, until a click is heard [8, 9].

The most frequently prescribed inhaler devices are the PMDIs [10]. The correct use of inhalers is a challenge for many patients and it is worse when patients are using more than one inhaler [11]. Health professionals have also been found to be deficient in the knowledge of correct inhaler techniques [12, 13]. Pharmacists who might be the last port of call amongst the health professionals before patients take their medications have also demonstrated poor knowledge of correct inhaler techniques [14, 15].

In the management of asthma, educating patients about the disease and its management could improve health outcomes [16, 17]. Although health professionals are most responsible for educating patients, caregivers can also assist patients to achieve the desired outcomes [18, 19]. Evidence for pharmacist-led interventions to improve asthma outcomes in Nigeria are needed. Correct inhaler techniques would not only ensure well-controlled asthma but also be life-saving during asthma attacks. Pharmacists are well-positioned to identify patients with poorly controlled asthma due to poor inhaler techniques [20, 21]. This study assessed the impact of pharmacist-led educational interventions in asthma on inhaler techniques.

METHODS

Study design

This was a single-blinded, three-arm, prospective, randomized, controlled intervention conducted in the Respiratory Units of the Department of Medicine, University of Nigeria Teaching Hospital (UNTH), Ituku-Ozalla, Enugu State and the Lagos University Teaching Hospital (LUTH), Idi-Araba, Lagos State between March 2016 to September 2017.

Within the specified timeline, eligible participants were recruited into one of the three arms: Usual Care, Individual Intervention and Caregiver-assisted Intervention. The Random Allocation Software developed by Saghaei was utilized for the randomization process into arms [22]. The patients were oblivious of the arms they fell into. However, the health professionals were informed.

The principal investigator trained the pharmacists involved in the research on the study protocol. They were called “pharmacist researchers” in order to differentiate them from the pharmacists who worked in the hospitals but were not involved with the study.

The Usual Care arm entailed that the patients received the standard care of the hospitals, with no active participation by the pharmacist researchers.

Patients in the intervention arms (Individual and Caregiver-assisted) received education about asthma and its management, inhaler techniques, peak flow meter use and other self-management measures. Patient education was on individual basis for the Individual Intervention arm. For the Caregiver-assisted Intervention arm, the caregivers were educated and informed to educate the asthma patients receiving their care. These caregivers were followed-up to encourage their patients to adhere to the interventions. The patients suggested their choice caregivers. The contact details of the caregivers were provided by the patients, after receiving consent. Patients in the Intervention arms (Individual and Caregiver-assisted) received education on different asthma topics via phone calls and text-messages outside clinic visits.

At baseline, there was an initial assessment interview for all study participants where patient-specific data were collected. All patient data were maintained with confidentiality. A validated checklist for optimum inhaler technique was utilized to assess the proficiency in the use of inhalers at baseline and during the follow-up interviews at three and six months after baseline [9].

The patients were taught how to assess their peak expiratory flow rate (PEFR) and document in the Symptom/Peak Flow Diary developed by Juniper and colleagues [23]. The diaries were requested for, and assessed, during each follow-up interview. Peak flow meters were provided to all the study participants, free-of-charge. The provision of peak flow meters to all participants, and education on the use of the device, was a highlight of this research. It served to prevent interactions between patients in the Usual Care and Intervention arms since the patients believed they were receiving similar services. The peak flow meter measures peak expiratory flow (PEF) and detects airflow limitation [24].

Patients were encouraged to participate but duly informed that they could withdraw from the study at any time. Other participants were recruited to fill the

void of dropouts (within the specified recruitment time frame).

Study setting

The University of Nigeria Teaching Hospital (UNTH) Ituku-Ozalla, Enugu State and the Lagos University Teaching Hospital (LUTH), Idi-Araba, Lagos State are federal tertiary hospitals. They serve as major referral centres. As of 2010, UNTH had bed capacity exceeding 500 beds [25]. In 2018, it was reported that LUTH had a 600-bed capacity [26]. Enugu is the capital of Enugu State located in South Eastern Nigeria while Lagos is the commercial capital of Nigeria.

The Respiratory Clinic of UNTH holds every Tuesday. In LUTH, the Respiratory Clinic holds on Mondays. However, LUTH also runs an Asthma Clinic on Wednesdays.

Eligibility criteria

The eligibility criteria for the asthma patients comprised confirmed diagnosis of asthma by a physician, no concurrent respiratory medical condition, adults not less than 16 years old, ability to communicate in English (oral and written), able/willing to complete follow-up questionnaires, telephone access, non-pregnant females, non-lactating females, no psychiatric barrier.

Sample size and selection

All asthma patients that met the eligibility criteria within a year of recruitment, and gave consent for participation, were included in the study. The researchers utilized start and stop dates that were specific to each of the asthma patients. Although the baseline date was not the same, all the participants received the same interventions specific to their groups at the specified timelines.

Data collection

A pro forma was utilized to collect patient-specific data. In addition, a validated checklist for optimum inhaler technique was utilized to assess the proficiency in the use of inhalers [9]. The patients' techniques were actively checked against the appropriate checklist for the specific inhaler type. One point was assigned for each correct step demonstrated, except for the essential steps which were assigned two points, resulting in a maximum score of eleven. Three steps were designated essential. Even if the overall score was high, if one of these essential steps was incorrect, then inhaler technique was classified as poor. Good technique was defined as having at least five of the eight steps correct, including all essential steps of the checklist.

The Symptom/Peak Flow Diary provided a means for the patients to document their symptoms and peak expiratory flow rate [23]. Permission was received to utilize the Symptom/Peak Flow Diary.

Data analysis

Data were analyzed using the IBM SPSS Version 25.0. Descriptive statistics were used to summarize data. Inferential statistics such as Pearson's Chi-Square test, independent t-test and paired t-test were used, where applicable, with statistical significance set as $P < 0.05$.

Ethical considerations

Ethical approval was obtained from the Health Research and Ethics Committee (HREC) of the University of Nigeria Teaching Hospital (UNTH), Ituku-Ozalla, Enugu State (NHREC/05/01/2008B-FWA00002458-1RB00002323) and the Lagos University Teaching Hospital (LUTH), Idi-Araba, Lagos State (ADM/DCST/HREC/APP/431). The patients provided both written and oral consents, prior to participation. Confidentiality was maintained.

RESULTS

Seventy-eight (78) asthma patients were involved in the study with thirty-nine (39) asthma patients recruited from each hospital. There were 13 patients per arm (Usual Care, Individual Intervention, Caregiver-assisted Intervention) in each hospital.

More than half of the participating asthma patients were female (61.5%). In UNTH, females were twice the number of males. Most of the patients (79.5%) utilized domestic fuel. Domestic fuel was described as the use of kerosene stove, kerosene lantern or generator set. About a tenth of the patients (10.3%) reported prior peak flow meter training. There was a statistically significant association between age and hospital site ($\chi^2 = 27.106$, df = 6, $P < 0.001$), to the extent that more asthma patients in UNTH were between 20 to 29 years old (17.9%), compared to their LUTH counterparts (5.1%) (Table 1).

At baseline, less than half (UNTH – 43.6%; LUTH – 46.2%) of the asthma patients exhaled to residual volume while demonstrating PMDI use (Table 2).

None of the asthmatic patients on the DPIs (accuhaler or turbuhaler) correctly demonstrated any of the three essential steps at baseline (Tables 3 and 4).

There was no significant difference ($P > 0.05$) in the baseline characteristics for the Individual Intervention arm, Caregiver-assisted Intervention arm and Usual Care arm for LUTH and UNTH.

There was significant improvement (P < 0.05) in PMDI scores for the Individual Intervention compared to Usual Care arm at 3 months (11.00 vs. 9.38; P = 0.005, t = 3.086, df = 25) and 6 months (11.00 vs. 9.54; P = 0.013, t = 2.658, df = 25). In addition, there was significant improvement in PMDI scores for the Caregiver-assisted Intervention compared to Usual Care arm at 3 months (10.54 vs. 9.38; P = 0.044, t = 2.126, df = 25) but none at 6 months (10.65 vs. 9.54; P = 0.089, t = 1.768, df = 25) (Table 5).

There was significant improvement (P < 0.05) in accuhaler scores for the Individual Intervention compared to Usual Care arm at 3 months (11.00 vs. 9.35; P = 0.028, t = 2.421, df = 16) and 6 months (11.00 vs. 9.18; P = 0.016, t = 2.696, df = 16). In addition, there was significant improvement (P < 0.05) in accuhaler scores for the Caregiver-assisted Intervention compared to Usual Care arm at 3 months (10.77 vs. 8.85; P = 0.045, t = 2.241, df = 12) but none at 6 months (10.77 vs. 9.08; P = 0.094, t = 1.821, df = 12) (Table 6).

There was no significant difference (P > 0.05) in turbuhaler scores between the Individual Intervention/Caregiver-assisted Intervention at 3 months and 6 months. Few patients (UNTH – 4; LUTH – 8) utilized the turbuhaler.

DISCUSSION

This study revealed that the Individualized Interventions produced better improvements in inhaler techniques than the Caregiver-assisted Interventions. Asthmatic patients in the Individual and Caregiver-assisted Intervention arms demonstrated significantly better PMDI and accuhaler techniques compared to Usual Care arm at 3 months but only the Individual Intervention arm improved the PMDI and accuhaler techniques at 6 months.

More than half of the participating asthma patients were females. Asthma prevalence differs by gender with changes through the reproductive phases of life. As children, more boys are asthmatic compared to girls. The frequency of asthma and allergic diseases begins to change from being higher in males to higher in females around puberty suggesting sex hormones and other factors alter pathways important in asthma pathogenesis. By adulthood, more women have asthma compared to men [27, 28].

Domestic fuel was utilized by most of the patients. The standard of living in Nigeria and erratic power supply encourage the use of kerosene stove, kerosene lantern and generator sets. Generator sets are commonplace in Nigerian homes. The symptoms of asthma could worsen with exposure to both indoor and outdoor allergens [29].

At baseline, poor inhaler techniques were evident in both hospitals. Less than half of the asthmatic patients exhaled to residual volume while demonstrating PMDI use. None of the asthmatic patients on the DPIs (accuhaler or turbuhaler) correctly demonstrated any of the three essential steps. Improper asthma inhaler device use is associated with poor asthma control and more frequent emergency department visits [30]. The pressurized metered dose inhalers are the most common inhaler devices and this may be responsible for better handling by the patients compared to the dry powder inhalers [10, 30]. As of the time of conducting this research, the Global Initiative for Asthma (GINA) Report recommended the use of an inhaled short-acting beta-2 agonist (SABA) with no controller for the management of chronic asthma in adults and children over 5 years in Step 1 [31]. In Nigeria, inhaled SABA is available as PMDI. Since patients with asthma are advised to always have their rescue inhalers, all the patients utilized the PMDI. The controller inhalers are available as PMDI, accuhaler or turbuhaler. Dependent on the Step in the management of chronic asthma, patients could utilize the PMDI alone or in combination with other inhaler devices [31].

The turbuhaler was rarely utilized by participants in this study. The major reason provided by the Pulmonologists/patients was the cost of the drug available as turbuhalers. Patients found it difficult to make refills since payments were made out-of-pocket. This led to poor adherence and discouraged the prescribers from making similar prescriptions during asthma reviews. Interestingly, a study conducted in Canada revealed that treatment with a turbuhaler was more cost-effective than a PMDI in asthmatic patients [32]. Numerous studies have analyzed patients' preference for and satisfaction with inhaler devices [33 - 35].

There was significant improvement in the PMDI/accuhaler scores for the Individual and Caregiver-assisted Intervention arms compared to the Usual Care arm at 3 months but only the Individual Intervention showed significant improvement at 6 months. A study in Egypt also showed significant improvement in inhalation techniques in the intervention arm compared to the usual care arm after two months follow-up [36]. Similarly, other studies have indicated that pharmacist intervention improved inhaler techniques in asthma patients who were followed-up for 12 months [37, 38]. Another study in Spain showed

Table 1: Demographic details of the asthma patients, N (number of physical contacts) = 234

Independent Variables	LUTH	UNTH	Total	P-value
Gender		**χ^2 (1, N = 234) = 2.600**		**0.107**
Male	51 (43.6)	39 (33.3)	90 (38.5)	
Female	66 (56.4)	78 (66.7)	144 (61.5)	
Age (in years)		**χ^2 (6, N = 234) = 27.106**		*** < 0.001**
16-20	9 (7.7)	15 (12.8)	24 (10.3)	
20-29	6 (5.1)	21 (17.9)	27 (11.5)	
30-39	15 (12.8)	18 (15.4)	33 (14.1)	
40-49	15 (12.8)	15 (12.8)	30 (12.8)	
50-59	42 (35.9)	30 (25.6)	72 (30.8)	
60-69	9 (7.7)	15 (12.8)	24 (10.3)	
≥ 70	21 (17.9)	3 (2.6)	24 (10.3)	
Home Domestic Fuel Use		**χ^2 (1, N = 234) = 0.944**		**0.331**
Yes	96 (82.1)	90 (76.9)	186 (79.5)	
No	21 (17.9)	27 (23.1)	48 (20.5)	
Economic Status		**χ^2 (3, N = 234) = 23.194**		*** < 0.001**
Low Class	3 (2.6)	3 (2.6)	6 (2.6)	
Middle Class	111 (94.9)	90 (76.9)	201 (85.9)	
Upper Class	3 (2.6)	3 (2.6)	6 (2.6)	
I won't say	0 (0.0)	21 (17.9)	21 (9.0)	
Prior Peak Flow Meter Training		**χ^2 (1, N = 234) = 1.671**		**0.196**
Yes	9 (7.7)	15 (12.8)	24 (10.3)	
No	108 (92.3)	102 (87.2)	210 (89.7)	
Cigarette Smoking History		**χ^2 (1, N = 234) = 3.162**		**0.075**
Yes	3 (2.6)	9 (7.7)	12 (5.1)	
No	114 (97.4)	108 (92.3)	222 (94.9)	
Highest Education Received		**χ^2 (3, N = 234) = 12.689**		*** 0.005**
Post-SSCE	72 (61.5)	66 (56.4)	138 (59.0)	
SSCE	45 (38.5)	39 (33.3)	84 (35.9)	
FSLC	0 (0.0)	9 (7.7)	9 (3.8)	
No Formal Education	0 (0.0)	3 (2.6)	3 (1.3)	
Occupation		**χ^2 (7, N = 234) = 43.649**		*** < 0.001**
Civil Servant	12 (10.3)	39 (33.3)	51 (21.8)	
Health Worker	6 (5.1)	3 (2.6)	9 (3.8)	
Self-employed	39 (33.3)	18 (15.4)	57 (24.4)	
Unemployed	6 (5.1)	3 (2.6)	9 (3.8)	
Private Company	9 (7.7)	9 (7.7)	18 (7.7)	
Retiree	24 (20.5)	9 (7.7)	33 (14.1)	
Student	12 (10.3)	33 (28.2)	45 (19.2)	
Engineer	9 (7.7)	3 (2.6)	12 (5.1)	

* $P < 0.05$

Table 2: Patients' demonstration of PMDI use assessed against the eight steps for correct use in the validated checklist

QUESTIONS	BASELINE	
	LUTH Yes (%)	UNTH Yes (%)
1. Remove the cap from the inhaler	33 (84.6)	38 (97.4)
2.* Shake the inhaler	34 (87.2)	28 (71.8)
3. Hold the inhaler upright	36 (92.3)	31 (79.5)
4. Exhale to residual volume	18 (46.2)	17 (43.6)
5. Place the mouthpiece between lips and teeth to seal the mouthpiece	35 (89.7)	35 (89.7)
6.* Inhale slowly and simultaneously activate the canister	32 (82.1)	23 (59.0)
7.* Continue slow and deep inhalation	30 (76.9)	26 (66.7)
8. Take inhaler out of mouth and hold breath for 5-10 seconds	24 (61.5)	27 (69.2)

***** Essential steps for optimal PMDI (pressurized metered dose inhaler) technique

Table 3: Patients' demonstration of accuhaler use assessed against the eight steps for correct use in the validated checklist

QUESTIONS	BASELINE	
	LUTH Yes (%)	UNTH Yes (%)
1.* Hold accuhaler horizontally	0 (0.0)	0 (0.0)
2.* Push the lever away from the mouthpiece until you hear the 'click'	0 (0.0)	0 (0.0)
3. Exhale as much as you can	16 (61.5)	13 (41.9)
4. Exhale away from the mouthpiece	14 (53.8)	11 (41.5)
5. Place the mouthpiece between lips and teeth to seal the mouthpiece	24 (92.3)	29 (93.5)
6.* Inhale forcefully and deeply	0 (0.0)	0 (0.0)
7. Remove accuhaler from the mouth	23 (88.5)	27 (87.1)
8. Hold breath for 5-10 seconds	16 (61.5)	20 (64.5)

* Essential steps for optimal accuhaler technique
Patients on accuhaler: LUTH – 26; UNTH – 31

Table 4: Patients' demonstration of turbuhaler use assessed against the eight steps for correct use in the validated checklist

QUESTIONS	BASELINE	
	LUTH Yes (%)	UNTH Yes (%)
1. Remove the cap from the inhaler	8 (100.0)	4 (100.0)
2.* Keep the inhaler upright	0 (0.0)	0 (0.0)
3.* Rotate grip anti-clockwise then back until a click is heard	0 (0.0)	0 (0.0)
4. Exhale to residual volume	2 (25.0)	0 (0.0)
5. Exhale away from mouthpiece	5 (62.5)	0 (0.0)
6. Place mouthpiece between teeth and lips	8 (100.0)	4 (100.0)
7.* Inhale forcefully and deeply	0 (0.0)	0 (0.0)
8. Hold breath for 5-10 seconds	5 (62.5)	1 (25.0)

* Essential steps for optimal turbuhaler technique
Patients on turbuhaler: LUTH – 8; UNTH – 4

Table 5: Effect of pharmacist-led educational interventions on PMDI scores, n = 26

Variables	Mean (SD)	Correlation		Mean Difference	t	df	P-value
		r	p				
Individual Intervention vs. Usual Care at 3 months	11.00 (0.00) vs. 9.38 (2.67)	-	-	1.62	3.086	25	0.005*
Caregiver-assisted Intervention vs. Usual Care at 3 months	10.54 (1.50) vs. 9.38 (2.67)	0.216	0.290	1.15	2.126	25	0.044*
Individual Intervention vs. Usual Care at 6 months	11.00 (0.00) vs. 9.54 (2.80)	-	-	1.46	2.658	25	0.013*
Caregiver-assisted Intervention vs. Usual Care at 6 months	10.65 (1.41) vs. 9.54 (2.80)	-0.062	0.763	1.12	1.768	25	0.089

* $P < 0.05$

Table 6: Effect of pharmacist-led educational interventions on accuhaler scores

Variables	Mean (SD)	Correlation r	Correlation p	Mean Difference	t	df	P-value
Individual Intervention vs. Usual Care at 3 months	11.00 (0.00) vs. 9.35 (2.80)	-	-	1.65	2.421	16	0.028
Caregiver-assisted Intervention vs. Usual Care at 3 months	10.77 (0.83) vs. 8.85 (3.05)	0.083	0.787	1.92	2.241	12	0.045
Individual Intervention vs. Usual Care at 6 months	11.00 (0.00) vs. 9.18 (2.79)	-	-	1.82	2.696	16	0.016
Caregiver-assisted Intervention vs. Usual care at 6 months	10.77 (0.83) vs. 9.08 (3.09)	-0.187	0.541	1.69	1.821	12	0.094

* $P < 0.05$

significant improvement in inhaler technique after a pharmacist intervention [39]. These studies reveal the critical role pharmacists can play to achieve definite health outcomes.

Poor inhaler technique is a substantial and avoidable contributor to the burden of asthma [40]. Asthma patients with poor inhaler techniques have poorer symptom control compared to those with good inhaler techniques [9]. Thus, providing education on proper inhaler techniques would improve symptoms, self-management and adherence to therapy [9, 41]. Training of asthma patients on the inhaler techniques have been found to increase the rate of correct usage for DPIs and PMDIs [42]. Multimedia and medication information leaflets can be used to supplement the education provided by health professionals. The reinforcement of inhaler education should be through an interdisciplinary approach [9]. Inhaler techniques should always be evaluated and adequate education provided to patients, especially before changing dosage [16]. Higher patient satisfaction with their inhaler device is a significant predictor of more favourable clinical outcomes [35]. Physical demonstration of inhaler techniques is better in improving accuracy of the technique than use of instructional pictorial leaflets [43]. Adherence to correct inhaler techniques is one of the key factors of successful asthma management [44]. Inhaler reminders offer an effective strategy for improving adherence with controller treatment in primary care patients [45].

CONCLUSION

The individualized interventions produced better improvements in inhaler techniques than the caregiver-assisted interventions. Asthmatic patients in the Individual and Caregiver-assisted Intervention arms demonstrated significantly better PMDI and accuhaler techniques compared to Usual Care at 3 months but only the Individual Intervention arm improved the PMDI and accuhaler techniques at 6 months.

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