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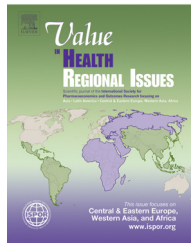

The Impact of Pharmaceutical Care Intervention on the Quality of Life of Nigerian Patients Receiving Treatment for Type 2 Diabetes

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ABSTRACT

Objectives: To evaluate the impact of pharmaceutical care (PC) intervention on health-related quality of life (HRQOL) of patients with type 2 diabetes. **Methods:** This study was a randomized, controlled study with a 12-month patient follow-up. The study protocol was approved by the Research Ethical Committees of the institutions in which this study was conducted. A total of 110 patients were randomly assigned to each of the "intervention" (PC) and "control" (usual care [UC]) groups. Patients in the UC group received the usual/conventional care offered by the hospitals. Patients in the PC group received UC and additional PC for 12 months. The HUI23S4EN.40Q (developed by HUInc - Mark index 2&3) questionnaire was used to assess the HRQOL of the patients at baseline, 6 months, and 12 months. Two-sample comparisons were made by using Student's *t* tests for normally distributed variables or Mann-Whitney *U* tests for nonnormally distributed data at baseline, 6 months, and 12 months. Comparisons of proportions were done by using the chi-square test. **Results:** The overall HRQOL (0.86 ± 0.12 vs. 0.64 ± 0.10; $P < 0.0001$) and single attributes except "hearing" functioning of the patients were significantly improved at 12 months in the PC intervention arm when compared with the UC arm. The HRQOL utility score was highly negatively (deficit ≥10%) associated with increasing age (≥52 years), diabetes duration (>4 years), emergency room visits, comorbidity of hypertension, and stroke in both PC and UC groups. **Conclusion:** Addition of PC to UC improved the quality of life in patients with type 2 diabetes.

Keywords: HRQOL, patients with diabetes, pharmaceutical care intervention, quality of life, usual care.

Introduction

Chronic medical conditions can impact multiple dimensions of health-related quality of life (HRQOL) [1]. Given that diabetes is part of a metabolic syndrome that increases the risk of heart disease and stroke [2], it is not uncommon for these conditions to occur as comorbidities in individuals with diabetes. Because comorbidities are prevalent in diabetes, it is unlikely that the HRQOL deficits associated with diabetes would be limited to the condition itself. Indeed, the presence and severity of complications or comorbidities have been associated with depression, anxiety, and impairment on multiple dimensions of HRQOL in diabetes [3]. The presence of cardiovascular complications as comorbidity with diabetes also leads to deficit in HRQOL [4].

The national standardized prevalence rate of diabetes mellitus in Nigeria is 2.2%, while the crude prevalence rate is 74% in those aged 45 years and above who live in urban areas [5]. Global estimates of the prevalence of diabetes for 2010 and 2030 showed that the prevalence of diabetes in Nigeria in 2010 was 4.7% and that it would be 5.5% in 2030 when compared with world population [6]. The complex nature of diabetes management prompted the Nigerian Ministry of Health to come up with a standard treatment guideline to streamline the process of diabetes management and what service the patients should receive [7].

Several research studies have been carried out on health deficit associated with diabetes comorbidities. For instance, the work done by Maddigan et al. [8] to assess the impact of comorbid heart disease, stroke, and arthritis on HRQOL in people with diabetes in the general Canadian population concluded that "The illness burden experienced by individuals with diabetes is not only associated with diabetes itself, but largely with co-morbid medical conditions." Also, Westaway [9] reported that chronic disease status and comorbidities were more important determinants of health and well-being than were ethnicity, age, language, gender, and marital status. Quality of life (QOL) is also increasingly recognized as an important health outcome in its own right, representing the ultimate goal of all health interventions [10].

The health utilities index Mark 3 (HUI3) classification system comprises eight attributes: vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain—each with five or six levels of ability/disability. Most of these attributes can be negatively affected by diabetes and its complications.

Pharmaceutical care (PC) is the direct, responsible provision of medication-related care with the purpose of achieving definite

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outcomes that improve a patient's QOL [10]. The principal elements of PC are that it is medication related; it is care that is directly provided to the patient; it is provided to produce definite outcomes; these outcomes are intended to improve the patient's QOL; and the provider accepts personal responsibility for the outcomes [10]. It is also the determination of the drug needs for a given individual and the provision of not only the required drug but also the necessary services (before, during, or after treatment) to ensure the optimally safe and effective drug therapy [11].

Diabetes is a disease that desperately needs more pharmacist involvement. Pharmacists who are specialized in this growing chronic condition can make a significant, positive impact on the patient, the health care system, and themselves [12]. Health care professionals are becoming increasingly aware of the need to assess and monitor the QOL as an important outcome of diabetes care. The QOL is an important outcome in its own right and because it may influence the patient's self-care activities, which may consequently have an impact on the diabetes control [13]. Many PC programs have been established in various countries to enhance clinical outcomes and the HRQOL. These programs were implemented by pharmacists, with the cooperation of physicians and other health care professionals. PC and the expanded role of pharmacists are associated with many positive diabetes-related outcomes, including improved clinical measures [14], improved patient and provider satisfaction [15,16], and improved cost of management [15,17]. The pharmacist can, therefore, in collaboration with physicians and other health care professionals, contribute to an improvement in the QOL of patients with diabetes by informing and educating patients, answering their questions, and, at the same time, monitoring the outcomes of their treatment [18]. Such interventions, however, are not very common in Nigeria. Therefore, this research was aimed at evaluating the impact of the PC intervention on the QOL of patients with type 2 diabetes mellitus in a tertiary hospital setting in Nigeria.

Methods

Research Design

This study was a randomized, controlled, and longitudinal prospective study with a 12-month patient follow-up. The study protocol was approved by the Research Ethical Committees of the University of Nigeria Teaching Hospital, ItukuOzalla, and Nnamdi Azikiwe University Teaching Hospital, Nnewi, in which this study was conducted. These hospitals are tertiary hospitals that serve as referral centers to most of the hospitals in Nigeria.

Patients with type 2 diabetes mellitus who fulfilled the entrance criteria were identified and included in the study. The inclusion criteria were as follows:

1. patients who were diagnosed with type 2 diabetes mellitus,
2. patients with type 2 diabetes who were receiving oral hypoglycemic and/or insulin therapy,
3. patients who provided written informed consent,
4. patients who expressed willingness to abide by the rules of the study, and
5. patients who were certified fit for the study by their consulting doctors.

Exclusion criteria were as follows:

1. patients who were diagnosed with type 1 diabetes (to avoid complexity in the study scope),
2. patients who were younger than 18 years (they are legally regarded as dependents and consequently they cannot take decisions of their own),
3. patients who were pregnant (they are generally not allowed to participate in a study of this nature by the institutions used for the study), and
4. patients who expressed willingness to withdraw from the study (participation is voluntary).

These criteria were according to the guiding principles of the institutional review boards of the hospitals used in this study. Following sample size determination, a sample size of at least 104 patients in each of the control and intervention groups was required. Based on these data, to ensure sufficient statistical power and to account for "dropouts" during the study, a target sample size of 220 patients was recruited (110 patients from each of the hospitals). The folders of the 110 selected patients in each hospital were assigned numbers 1 to 110, which represented an individual patient, and patients were randomly assigned to one of two groups (intervention group or control group) on the basis of the number on their folders by using online "random sequence generator" [19] with sequence boundaries of 1 to 110 (boundaries inclusive) set in a two-column format: the first column was priori designated to the intervention group (55 patients) and the second column to the control group (55 patients).

Patients in the usual care (UC) group received the usual/conventional care offered by the hospitals, which included hospital visits on appointment or on a sick day, consultations with doctors, prescription of drugs and routine laboratory tests, review of diagnosis and medications, refilling of prescriptions by patients, and referral. This UC was offered with no education/training of the patients on their diseases and drugs and without empowerment of the patients to be fully involved in the self-management of their illnesses. Patients in the PC group received UC and PC for 12 months. This additional PC included a stepwise approach: setting priorities for patient care, assessing patients' specific educational needs and identification of drug-related problems, development of a comprehensive and achievable PC plan in collaboration with the patient and the doctor, implementation of this plan, and monitoring and review of the plan from time to time [10]. The nurses collaborated with the pharmacist in terms of organizing the patients and patients' folders, taking point-of-care testing, counseling the patients, and reinforcing the information given to the patients during training sections. The physicians provided the visitation/appointment schedule for the patients, and prescription of laboratory tests. They were also involved in the implementation of consensus strategies in managing drug-related problems in areas of changing, substitution, and withdrawal of medications.

The educational/training program for the patients consisted of four sessions of 90 to 120 minutes. The program covered the following areas: diabetes overview and its complications, self-monitoring blood glucose techniques and interpretation of diabetes-related tests, medications and their side effects, lifestyle modification, counseling, and effective interaction with health providers. PC provided ground for the patients to monitor and react to changes in their blood glucose levels, allowing them to integrate their diabetes into the lifestyle they preferred.

Data Collection

The HUI23S4EN.40Q (developed by HUInc - Mark index 2&3) questionnaire was used to assess the HRQOL of the patients. HUI23S4EN.40Q questionnaires were interviewer-administered to the patients in the intervention group and the control group at baseline, 6 months, and 12 months.

The HUI3 classification system comprises eight attributes. It defines 972,000 unique health states. Single-attribute scores of morbidity are defined on a scale such that the worst level has a score of 0.00 and the best level has a score of 1.00. Multiattribute