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Original Article

Impact of pharmaceutical care interventions on glycemic control and other health-related clinical outcomes in patients with type 2 diabetes: Randomized controlled trial

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ABSTRACT

Aims: The primary aim of this study was to evaluate the impact of pharmaceutical care interventions on glycemic control and other health-related clinical outcomes in patients with type 2 diabetes patients in Jordan.
Methods: A randomized controlled clinical trial was conducted on 106 patients with uncontrolled type 2 diabetes seeking care in the diabetes clinics at Jordan University Hospital. Patients were randomly allocated into control and intervention group. The intervention group patients received pharmaceutical care interventions developed by the clinical pharmacist in collaboration with the physician while the control group patients received usual care without clinical pharmacist's input. Fasting blood glucose and HbA1c were measured at the baseline, at three months, and six months intervals for both intervention and control groups.
Results: After the six months follow-up, mean of HbA1c and FBS of the patients in the intervention group decreased significantly compared to the control group patients ($P < 0.05$). Also, the results indicated that mean scores of patients' knowledge about medications, knowledge about diabetes and adherence to medications and diabetes self-care activities of the patients in the intervention group increased significantly compared to the control group ($P < 0.05$).
Conclusions: This study demonstrated an improvement in HbA1c, FBS, and lipid profile, in addition to self-reported medication adherence, diabetes knowledge, and diabetes self-care activities in patients with type 2 diabetes who received pharmaceutical care interventions. The results suggest the benefits of integrating clinical pharmacist services in multidisciplinary healthcare team and diabetes management in Jordan.

1. Introduction

Diabetes mellitus is a chronic disease that requires ongoing medical care and ongoing patient self-management education and support to prevent acute complications and to reduce the risk of chronic complications of diabetes [1]. Globally it is estimated that 382 million people suffer from diabetes for a prevalence of 8.3% among adults and this number expected to rise beyond 592 million by 2035 [2]. Moreover, the International Diabetes Federation estimated that global healthcare expenditures for diabetes management totaled at least US dollars (USD) 465 billion in 2011 and this number is projected to exceed USD 595 billion by the year 2030 [3]. In Jordan, the age standardized prevalence rate of diabetes and impaired fasting blood glucose was 17.1% and 7.8%, respectively [4]. The high prevalence of diabetes point to the need for immediate implementation of educational programs and other interventions to prevent and control the burden of diabetes in Jordan [5]. Therefore, because of high prevalence of diabetes and its complications, control of diabetes is one of the important

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components of diabetes management in healthcare programs [6]. Glycemic control as measured by glycosylated hemoglobin (HbA1C) is fundamental to the management of diabetes and it is an important predictor of several chronic complications of diabetes [1]. Both ADA [1] and the American Association of Clinical Endocrinologists [7] guidelines emphasized the importance of achieving and maintaining glycemic levels as near to the normal non-diabetic range as possible to prevent or delay diabetes-related complications. Several observational studies have shown that intensive glycemic control leads to improved cardiovascular and microvascular outcomes [8–10]. The ADA guidelines recommended a multidisciplinary, collaborative, and integrated team approach to the management of diabetes, that individuals with diabetes play an active role in their care [1]. The role of the pharmacist as part of the healthcare team is expanding and includes more direct patient care and clinical activities [11]. Several randomized clinical trials have reported that clinical pharmacist diabetes care programs improved glycemic control and other clinical outcomes in patients with diabetes [12–19]. In Jordan, the clinical pharmaceutical services are at an early stage of development and have recently been introduced to healthcare facilities and the implementation of such services is still limited [20]. Moreover, in Jordan there are several barriers for clinical pharmaceutical care includes physicians' negative attitudes toward expanding the pharmacist's role in the process of patient care [21] and the lack of effective pharmaceutical care training [22]. Therefore, there is a need to investigate the impact of implementing pharmaceutical care program on reaching glycemic control goals and other clinical outcomes because of the increasing prevalence of diabetes and the limited implementation of effective clinical pharmaceutical services for patients with type 2 diabetes in Jordan. The information obtained may help in developing interventions and techniques for effective diabetes management. The primary aim of the present study was to investigate, via a randomized controlled clinical trial, the impact of pharmaceutical care interventions on glycemic control and other health-related clinical outcomes in patients with type 2 diabetes patients in Jordan. Specific objectives of the study were:

1. To measure the impact of initiation and/or dose titrations of oral hypoglycemic agents by the clinical pharmacist with collaboration with physician on glycemic control as measured by HbA1c and fasting blood sugar (FBS) levels at 6 months' follow-up period.
2. To examine the impact of the pharmaceutical care interventions on the glycemic control as measured by HbA1c, FBS levels, lipid profile, and body mass index (BMI) at 6 months' follow-up period.
3. To evaluate the impact of pharmaceutical care interventions on adherence to prescribed diabetes medications, diabetes knowledge and diabetes self-care activities at 6 months' follow-up period.

2. Subjects, materials and methods

2.1. Study design, setting, and sample

The study was a randomized, controlled, prospective clinical trial with a 6-month follow-up period. This study was approved by the Institutional Review Board at Jordan University Hospital (JUH). The study site was the outpatient diabetes clinic at JUH, a major teaching hospital in Amman, capital of Jordan. The diabetes clinic at JUH provides usual care services to more than 90 patients daily with regular follow-up clinic visits every 1–3 months, depending on the glycemic control for each patient. Patients were included in the study if they were $\geq$18 years, have been diagnosed with type 2 diabetes, with HbA1c $\geq$6.5% for initial diagnosis or HbA1c $>$7 for uncontrolled diabetes, managed with diet and exercise only and/or use oral hypoglycemic agents. Patients were excluded if they were diagnosed with serious renal or hepatic diseases, patients on insulin treatment, pregnant women, patients with dementia or cognitive impairment, and patients who were unable to provide consent form.

2.2. Patient recruitment and randomization

After recruitment, written informed consent was obtained from each participant in both study groups. During the process of obtaining the consent, participants were informed that they would be assigned to either the intervention group (pharmacist–physician collaborative practice) or the control group (usual care, physician-only team). At the time of recruitment, patients were randomized into the intervention group (n = 52) and the control group (n = 54) using a coin-toss method. The anonymity of the participants and confidentiality of the data were ensured. The participants were informed that their participation in the study was voluntary, that they could withdraw from the study at any time, and that their refusal to participate in the study would have no negative impacts on the medical care they received.

2.3. Outcome measurements

According to ADA guidelines [1], HbA1c is considered the primary clinical target for diabetes control management, and for this reason, HbA1c was set as the primary outcome in this study. Three readings of HbA1c were taken and were performed in the same day of the interviews. The first was the baseline reading at the initial interview and the second was after 3 months, and the third was after six months of follow up. Current guidelines for glycemic control recommends HbA1c $<$7% as a treatment goal for most patients [1]. Other clinical outcomes that were obtained during the course of the study were FBS, serum low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), serum triglycerides, serum total cholesterol, weight, height, and blood pressure. Patient's knowledge about diabetes, patients' adherence to prescribed medications and diabetes self-care activities were also measured for both groups.

2.4. Description of pharmacist intervention versus usual care

According to participants HbA1c levels and their clinical status, patients who were not controlled by their usual diabetes treatment management and were on diet only were initiated on metformin therapy, and those who were already on metformin monotherapy were initiated on a second hypoglycemic agent. Oral hypoglycemic agent doses were titrated according to results of HbA1c and FBS levels. The drug therapy initiation and/or drug dose titration was done according to the most current clinical guideline for type 2 diabetes management [1] in collaboration with the physician. In the intervention group, patient condition was assessed and managed collaboratively by focused care plans designed by the clinical pharmacist and approved by the physician. Efficacy of medications was monitored through laboratory results. In this study the clinical pharmacist recommendations with respect to drug therapy included initiation of oral hypoglycemic agents, titration of drug therapeutic dosage, and changing the current medication due to ineffectiveness. The pharmacists' interventions and the proposed patient care plans were discussed with the physicians, who specified whether to accept or reject them as part of each patient's individualized treatment plan. At each clinic visit, participants in the intervention group met with the clinical pharmacist in a private room at the outpatient clinic for 30 min