“Impact of a Physician - Clinical Pharmacist Collaborative Approach on Improving the Clinical Outcomes in Type 2 Diabetic Patients”

Thesis

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By

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DEDICATION

To my inspirer, my wife, for her support and encouragement

To my beloved mother

To all people who contributed to the success of this work

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Abbreviation	Description
AACE	American Association of Clinical Endocrinologists
ACEI	Angiotensin Converting Enzyme Inhibitor
ADA	American Diabetes Association
ADR	Adverse drug reaction
ARB	Angiotensin Receptor Blocker
CVD	Cardiovascular disease
DCCT	Diabetes Control and Complications Trial
DKA	Diabetic Ketoacidosis
DM	Diabetes Mellitus
DPP-4	Dipeptidyl Peptidase-4
DRPs	Drug related problems
EASD	European Association for the Study of Diabetes
ESRD	End-Stage Renal Disease
FBG	Fasting Blood Glucose
FDA	Food and Drug Administration
GDM	Gestational diabetes mellitus
GLP-1	Glucagon-Like Peptide-1
HbA1c	Glycosylated hemoglobin
HDL	High density lipoprotein
HHS	Hyperglycemic Hyperosmolar non-ketotic Syndrome

IFG	Impaired Fasting Glucose
IGT	Impaired glucose tolerance
LDL	Low density lipoprotein
MAS	Medications Adherence Score
MNT	Medical Nutrition Therapy
OGTT	Oral Glucose Tolerance Test
PAD	Peripheral Artery Disease
PCP	Pharmaceutical Care Practice
PVD	Peripheral Vascular Disease
RPG	Random Plasma Glucose
SFUs	Sulfonylureas
SGLT2	Sodium-glucose cotransporter 2
SMBG	Self-Monitored Blood Glucose
SOAP	Subjectives, Objectives, Assessment, Plan
TZDs	Thiazolidinedione
UKPDS	United Kingdom Prospective Diabetes Study
WHO	World Health Organization

Abstract

Background: Glycemic goals (HbA1c < 7%) are often not achieved in patients with type 2 diabetes despite the availability of many effective treatments. Several studies have established the important positive effects of pharmacist-led management on achieving glycemic control and other clinical outcomes in patients with diabetes. In most countries of Middle East region, the Pharmaceutical Care practice is not well established. Also the role of the clinical pharmacists in monitoring and educating diabetic patients is not well defined. The primary aim of this study was to evaluate the effect of a clinical pharmacist-physician collaborative practice compared with usual care on improving outcomes in patients with type 2 diabetes mellitus.

Patients and Methods: A randomized controlled clinical trial was conducted on 80 patients with uncontrolled type 2 diabetes (HbA1c > 7%) at a teaching hospital in Yemen. 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.

Results: After the nine months follow-up, there was statically significant in a mean reduction of HbA1c between groups of this study (2.8 % in the intervention group versus 1.8 % in the control; P = 0.009). In addition, the clinical pharmacist intervention led to a significant improvement in patients' health outcomes such adherence to medications and life style modifications.

Conclusion: The results suggested the benefits of integrating clinical pharmacist services in multidisciplinary healthcare team of diabetes management.

Key Words: Pharmaceutical care, Clinical pharmacy, Type 2 diabetes, HbA1c, Drug-related problems (DRPs).

INTRODUCTION

1. Introduction:

Diabetes mellitus is a chronic metabolic disease that directly affects well-being and has a high morbidity risk (Al Mazroui, *et al.*, 2009). Patients with Type 2 diabetes are predisposed to a clustering of cardiovascular risk factors, including hypertension and dyslipidemia. Cardiovascular disease (CVD) is the major cause of death and disability in these patients and contributes to a high increase in management costs (Simpson, *et al.*, 2011).

Diabetes is worldwide in distribution. It is the fourth leading cause of death in developed countries, affecting 3% of the population and 5–10% of those over 65 years old (Venkatesan, *et al.,* 2012).

Diabetes mellitus is an increasingly common condition among adults in the United States and is associated with substantial morbidity and mortality. In United States, national data indicate that almost 30% of patients with diabetes have uncontrolled hemoglobin A1C values; 51% do not meet lipid management goals; and about 40% have uncontrolled blood pressure (Kirwin, *et al.,* 2010).

Diabetes mellitus with its accompanying complications such as cardiovascular diseases, retinopathy, nephropathy, and neuropathy is a serious health problem (Matzer, *et al.,* 1998). The complication risk is directly related to high blood glucose levels (American Diabetes Association, Implications of the diabetes control and complications trial, 2002). The result of the Diabetes Control and Complication Trails (The Diabetes Control and Complications Trial Research Group, 1993) and the United Kingdom Prospective Diabetes study (United Kingdom Prospective Diabetes Study Group, 1998) demonstrated that the near- normalization of blood glucose level in patients with diabetes could

significantly slow the progression of microvascular complications. The essential issues for managing of diabetes are patient's compliance to strict dietary, exercise, self-care behavior, and medication regimens. Diabetic patients usually use more than one drug, so the greater the number of medications, the more drug related problems (Irons, *et al.,* 2008). Poor medication adherence seems to be a significant obstacle to the attainment of positive clinical outcomes among patients with type 2 diabetes in both developed and developing countries (Diehl*, et al.,* 1985).

Pharmacists are essential health-care team who can help build a safe medication environment and prevent medication errors (Vessal*,* 2010).

Recently, the role of pharmacists in improving treatment outcomes in many chronic diseases, such as hypertension, diabetes mellitus, heart failure, and dyslipidemia, has been demonstrated by many studies through pharmaceutical care (PC) practice using different designs (Hammad, *et al.,* 2011).

The PC program has been found useful in improving the quality of care of patients with various diseases (Brooks, et al., 2007). The PC is defined by Hepler and Strand (1990) as "the responsible provision of drug therapy for the purpose of achieving the definite outcomes that improve the patients' quality of life". According to Helper and Strand definition, PC is a philosophy of practice where the pharmacist interacts directly with patients for the purpose of identifying, resolving, and preventing drug related problems (Hepler and Strand, 1990). The role of pharmacists in diabetes management is essential for identifying patients, assessment, education, referral and continuous follow up. Pharmacists can help identify diabetic patients through regular screening procedures

(Venkatesan, *et al.,* 2012). Pharmaceutical care services have been reported to reduce not only costs of therapy, but also morbidity and mortality (Vessal, 2010).

A cornerstone of PC practice is identification, solving and prevention of drug-related problems. A drug related problem is defined as "an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes". Drug related problems have been categorized by different research groups into different classification systems. In short, these problems deal with choice of drug, drug dosages, adverse drug reactions, drug interactions, adherence problems, and lack of monitoring of drug effects and toxicity (Viktil and Blix, 2008).

For patients with diabetes, the application of pharmaceutical care practice can benefit from a comprehensive understanding of current clinical guidelines such as the American diabetes association (ADA), the European association for the study of diabetes (EASD), the American association of clinical endocrinologists (AACE), the clinical trials that provide the evidence that supports the guidelines, and recommendations provided by groups of experts in order to become active members of the health care providers managing patients with type 2 diabetes (Liday, 2011).