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A SYSTEMATIC REVIEW ON CLINICAL PHARMACIST INTERVENTION IN IMPROVING CLINICAL OUTCOMES IN TYPE 2 DIABETES MELLITUS AND HYPERTENSION AND OBESITY

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ABSTRACT

Background: The global burden of type 2 diabetes mellitus is rapidly increasing, affecting individuals of all ages. The global burden of T2DM in people 20–79 years is further projected to increase to 629 mil- lion in 2045 compared to 425 million in 2017. **Methods:** A review of various published literatures was identified to evaluate the effectiveness of clinical pharmacist services reporting educational and/or psychological interventions for people with T2DM were implemented. We conducted searches using MEDLINE, EMBASE, CINAHL, PubMed and ASSIA databases between January 2007–2015. The Studies published in English were included. Two reviewers independently extracted data on participant and intervention characteristics. The quality of evidence was rated on predetermined criteria. Main outcomes included glycaemic control, blood pressure control and reduction in obesity levels. **Conclusion:** It has been concluded that the diabetes prevention programmes can significantly reduce the progression to type 2 diabetes mellitus, hypertension and obesity with usual care. Those developing prevention programmes should adhere to the standard NICE guidelines to increase efficacy.

KEYWORDS: Diabetes mellitus, of clinical pharmacist services, hypertension, obesity, NICE guidelines.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a common endocrine disorder characterized by variable degrees of insulin resistance and deficiency, resulting in hyperglycemia. The complications of T2DM include cardiovascular disease, neuropathy, nephropathy, retinopathy, and increased mortality. *e worldwide prevalence rates of T2DM were was 9% in men and 7.9% in women in 2014. Hypertension is a sustained elevation of the systemic arterial blood pressure, commonly defined as systolic blood pressure (SBP) ≥140mmHg and/or diastolic blood pressure (DBP) ≥90 mm Hg. Risk factors for hypertension include weight gain and obesity, alcohol use (particularly in men), and hyperinsulinemia. Untreated or uncontrolled hypertension is associated with an increased risk of cardiovascular events and mortality. About 50% of patients with T2DM also have hypertension; meanwhile, 20%–80% of hypertensive patients suffer from T2DM, a rate that can even be as high as 40–80%. Hypertension and T2DM are chronic conditions that require lifelong therapy.[1-6] The prevention of diabetes with other risk factors treatment involves the combined use of many drugs, leading to poor adherence, low treatment and control rates, and high morbidity and mortality. A previous study showed a control rate for hypertension of 15% in patients with hypertension and T2 DM.

Hypertension (HTN) is considered a silent killer with major risk factors such as chronic heart failure, chronic kidney failure, stroke, and coronary heart disease. The overall world population having HTN with ethnic variation is about 28–44% at a cutoff of 140/90 mmHg. The estimated pervasiveness of HTN in Indian population is approximately 25% among urban adults and 10% in the rural zones.[2] The uncertainty of HTN in one's lifetime is estimated to be 90%. As per the Eighth Report of the Joint National Committee (JNC) on prevention, detection, and treatment of high BP, the targeted BP should reach within a month of drug therapy in either ways by doubling the dose of the first drug or by combing it with other antihypertensive to increase the effect. In present days, the patients aged less than 60

years are not only initiating the pharmacotherapy at a BP of 140/90 mmHg but are also adopting nonpharmacological methods such as lifestyle modifications with increasing prominence. Nonpharmacological methods that are dramatically tapering the BP are limited alcohol consumption, augmented exercise, entertainment, weight loss, recreational activities, cut salt intake, and the dietary approaches to stop hypertension (DASH) diet. Eventually, the target of anti‑HTN therapy is to cut down cardiovascular and renal morbidity and mortality rates. Despite the availability of several guidelines and pharmacological and nondrug therapies, it is hard for most of the hypertensive patients to reach an adequate BP. Such unsatisfactory low‑lying control rates may be because of insufficiency of information, failure to augment the treatment, noncompliance of the patient's with treatments, and the need of giving importance to supportive and nonpharmacological approaches.[7-10]

Diabetes mellitus (DM) is a chronic condition that can lead to complications and is increasing worldwide.1 In addition; more than one-third of patients with T2D have a higher risk of mortality from CVD compared to those without diabetes. Therefore, controlling the major risks for CVD, such as hypertension, dyslipidaemia and obesity, reduces long-term diabetes progression. Hypertension and T2D are commonly associated with diabetes because they share severe risk factors, such as insulin resistance, obesity and stress. According to the International Diabetes Federation (IDF), diabetes is a major expense for individuals, society and healthcare providers. In 2017, the accounted cost was USD 850 billion globally and the expenditure is estimated to increase by 12.7% in 2045.8 Even worse, the incidence of medication adherence ranged from 38% to 93%.9 However, intensive complex interventions and effective models of diabetes care are required to maintain tight clinical parameters, improve quality of life and decrease healthcare costs. Several studies have highlighted the value-added by the pharmacist in chronic disease management for instance, improving diabetes care, CVD, hypertension and hyperlipidaemia.[11-15]

The role of pharmacists is more than dispensing medications; it has shifted from a product-centered approach to patient-centered care. Pharmaceutical care is defined as 'the responsible provision of drug therapy to achieve definite outcomes which improve a patients' quality of life',15 and the care provided by the pharmacist is an essential element for patient health. Moreover, pharmacists' knowledge of diabetes therapy and the relationship between pharmacists and patients during prescription refills build trust, promote good healthcare and help patients attain the required outcome. Extensive international studies have assessed the effectiveness of pharmacist-led interventions in supporting individuals with T2D and CVD.

The components of the pharmacist interventions varied between the studies and are divided into 4 categories including

Educational interventions: educate patients about their condition and the medications offered by a pharmacist, nurse or other healthcare professional. The information is delivered to patients via phone, email, video and/or through individual or group sessions.

Behavioural interventions: assist patients in changing their lifestyle and attitude, including advice on smoking, diet and exercise.

Psychological interventions: work directly on mood states such as anxiety, depression and stress. They aim to increase problem-solving using cognitive approaches to change their behaviors. Clinical interventions: work directly towards improving the use of medications by solving drug-related problems, such as drug interactions, side effects and drug duplication issues. Diabetes self-management education considers the pharmacist an integral part of designing curricula, delivering diabetes care and teaching self-management practices.[16-18]

While CVD is the principal cause to death, lowering HbA1c alone is not enough to prevent or delay diabetes progression. Therefore, complex interventions are in high demand and include complex therapy regimens comprising diet, physical activity, smoking cessation. Treating T2D is complicated and a challenge for healthcare providers. Nevertheless, such treatment is crucial in reducing diabetes complications and cardiovascular risk factors and improving clinical outcomes and quality of life. The effectiveness of self-management education and techniques are well documented by pharmacists. Increasing patients' awareness and through education that focused on their illness, complications related to diabetes and medications adherence; they also need to be encouraged to promote lifestyle modification such as exercise and diet plan, which are keys to disease management. In addition, self monitoring of blood glucose is a crucial tool in controlling T2D.

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drug interactions, side effects and drug duplication issues. Diabetes self-management education considers the pharmacist an integral part of designing curricula, delivering diabetes care and teaching self-management practices[19-23].

The International Diabetes Federation (IDF) estimates that metabolic syndrome affects one-quarter of the world's population, doubling the risk of coronary heart disease, increasing the risk of mortality secondary to coronary heart disease by three-fold and increasing the risk of developing Type 2 diabetes mellitus (DM risk. As a result, a number of international organizations including the IDF, the American Heart Association, the National Heart, Lung and Blood Institutes (NHLBI), the World Heart Federation, the International Atherosclerosis Society and the International Association for the Study of Obesity harmonized the criteria for metabolic syndrome (MetS). The health consequences associated with MetS are significant,[2,3] as are the direct and indirect burdens on the healthcare system and society more generally, It is estimated that more than 80% of cardiovascular disease (CVD) complications secondary to MetS can be prevented by optimizing blood pressure and lipid profiles, with the most effective, evidence-based measures being lifestyle interventions usually increased physical activity and adopting a healthier diet. Pharmacological treatment is considered in cases of failure of nonpharmacological interventions in achieving modifiable risk factor reduction.

Diabetes is highly prevalent in the US, affecting at least 30.3 million people or around 9.4% of the population. Many medications for diabetes are effective at controlling blood glucose and HbA1c levels but their effect can be inadequate if not taken correctly. Pharmacists have a role in helping patients who take diabetes medications achieve their target goals, typically defined by the American Diabetic Association (ADA) as maintaining blood glucose levels between 70-130 mg/dL and HbA1c less than 7%. Hypertension is defined as blood pressure _130/80 mmHg and affects almost half of US adults (116 million), of which a majority do not have their blood pressure under control (92.1 million). Hypertension also adversely affects the kidneys, brain, and arterial blood vessels leading to major comorbidities and complications. Lifestyle changes can help lower blood pressure to an extent before pharmacological treatment has to be utilized. Dyslipidemia is considered an imbalance in total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides.[24] Dyslipidemia is more prevalent in adults over the age of 20, with 11.5% of US adults having a high serum total cholesterol (240 mg/dL) in 2018.

Pharmacists are experts in medications and therefore have an important role helping patients to optimize their medication regimens for these three common conditions through MTM services. Pharmacists are also trained to assess and determine the appropriateness of medications, alleviate barriers to adherence, and provide education regarding the medications, such as common adverse drug events (ADEs) and guidance on correct administration. Pharmacists therefore have an important role in MTM to identify and find solutions for various medication-related problems, including drug-drug and drug disease interactions and monitoring for adjustments that need to be made such as renal and hepatic impairment.

Aim of the review

The aim of this systematic review was to synthesise, and present the evidence on A systemic review on clinical pharmacist intervention on diabetes mellitus and hypertension and obesity and to identify the facilitators and barriers to the effective implementation of pharmacist important.

METHOD

Protocol development

The systematic review protocol was developed based on the Preferred Reporting Items for Systematic Review and Meta- Analysis Protocols (PRISMA-P) 2015 guidance (Online Appendix A) and registered in the International Prospective Register of Systematic Reviews (PROSPERO).

Type of studies

All research studies related to selected title.

Type of interventions

All pharmacist activities in the screening, prevention or management of diabetes mellitus and hypertension and obesity were included.

Type of outcomes

All studies were assessing the pharmacists' input in the screening, management and prevention of diabetes mellitus and hypertension and obesity. The outcomes were diverse and included the following: comparisons of different models of pharmacist input in management of diabetes mellitus and hypertension and obesity and the clinical outcomes of such interventions.[25]

Types of studies to be included

The initial search indicated that the first relevant article was published in 2008; hence, all studies published between 2007 and March 2015, in the English language was included.

Exclusion Criteria

Grey literature was excluded due to the potentially limited quality and difficulties in searching and retrieval.

Search strategy and data sources

This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria. A focused systematic literature search strategy was developed by the research team to identify relevant articles. The search strategy used a combination of medical subject headings (MeSH) and

title and abstract keywords. The search strategy was adapted for use in seven electronic databases: PubMed/Medline (NLM), Embase, Cochrane Library, Scopus, Psyc INFO (Ebsco), Cumulative Index to Nursing and Allied Health Literature (CINAHL) and the International Pharmaceutical Abstracts (IPA). The following keywords were used to search the databases which include medication therapy management, pharmacists, diabetes mellitus, hypertension, dyslipidemia, and treatment outcome.

Risk of Bias Assessment

The risk of bias in randomized controlled trials was assessed using the Cochrane Risk of Bias tool for RCTs (RoB 2). This tool assessed six bias domains: (1) selection; (2) performance; (3) detection; (4) attrition; (5) reporting; and (6) other bias, which could be reported as having low risk, some concerns, or high risk of bias.

LITERATURE REVIEW

Author & Year	Study design	Study/ intervention name	Definition of highrisk of T2DM	Focus of Intervention(s)	No recruited overall (& by group)	No study groups	Follow-up (months)	Setting	Country
Costa 2012	Prospective cohort	DE-PLAN Spain	FINDRISC score ≥14 or 2hr OGTT(≥7.8 and <11.1mmol/l)	Lifestyle (Diet &exercise)	552 (219+333)	2	Median 4.2yrs	Primary care	Spain
Davis-Smith 2007	Before & after	DPP in rural church basedsetting	ADA diabetes riskscore ≥10; CBG fasting (100 — 125mg/dl)	Lifestyle (Diet &exercise)	11	1	12	Community (Church)	US
Author & Year	Study design	Study/ intervention name	Definition of highrisk of T2DM	Focus of Intervention(s)	No recruited overall (& by group)	No study groups	Follow-up (months)	Setting	Country
Faridi 2010	Non-randomised controlled trial	PREDICT	1 or more risk factor from BMI ≥25, FH diabetes, gestational diabetes	Lifestyle (Diet &exercise)	146	2	12	Community (Church)	US
Gilis-Januszewska 2011	Before & after	DE-PLAN Poland	FINDRISC score ≥14	Lifestyle (Diet &exercise, optional supervised sessions)	175	1	12	Primary care	Poland
Janus 2012	RCT	pMDPS	Aged 50–75 years; AUSDRISK score ≥15,	Lifestyle (Diet &exercise)	92 (49 + 43)	2	12	Community /primary care	Australia

uthor & Year	Study design	Study/ intervention name	Definition of highrisk of T2DM	Focus of Intervention(s)	No recruited overall (& by group)	No study groups	Follow-up (months)	Setting	Country
Kramer 2012	Before &after	GLB 2009	Fasting glucose100 – 125mg/dl	Lifestyle (Diet & exercise)	60 (31+29)	2	12	Community (YMCA) and university	US
Kulzer 2009	RCT	PREDIAS	FINDRISC score ≥10 or assessedas ↑risk diabetes	Lifestyle (Diet & exercise)	182 (91 + 91)	2	12	Outpatient setting	Germany

			by primary care physician						
Laatikainen 2007 (& 2012)	Before &after	GGT study	FINDRISC score ≥12	Lifestyle (Diet & exercise)	311	1	12	Primary care	Australia
Ma 2013 (Ma 2009 & Xiao 2013)	RCT	E-LITE	BMI ≥25 & fastingplasma glucose 100 – 125mg/dl or metabolic syndrome	Lifestyle (Diet & exercise, supervised exercise for 1 group) ‡	241 (79 + 81 + 81)	3	15 & 24	Primary care	US
Author & Year	**Study design**	**Study/ intervention name**	**Definition of highrisk of T2DM**	**Focus of Intervention(s)**	**No recruited overall (& by group)**	**No study groups**	**Follow-up (months)**	**Setting**	**Country**
Makrilakis 2010	Before &after	DE-PLAN Greece	FINDRISC score ≥15	Lifestyle (Diet & exercise)	191	1	12	Primary care, workplace	Greece
Marrero 2015	RCT	Weight Watchers	ADA risk score ≥5, HbA1c % > 5.7 and < 6.4 and CCBG of 110–199 mg/dl (100–109 iffasting ≥8 hours)	Lifestyle (Diet & exercise)	225 (113 + 112)	2	6, 12	Private	US
Nilsen 2011	RCT	APHRODITE study	FINDRISC score ≥9	Lifestyle (Diet & exercise, minimal supervised exercise)	213 (104+109)	2	18	Primary care	Norway
Ockene 2012	RCT	Lawrence Latino DPP	BMI≥24, >30% increased likelihood of diabetes over next 7.5 from validatedrisk algorithm	Lifestyle (Diet & exercise, supervised exercise)	312 (150+162)	2	12	Community, family health centre	US
Parikh 2010	RCT	Project HEED	BMI ≥25 & pre- diabetes; CBG fasting <126mg/dl& 2hr CBG following 75g	Lifestyle (Diet & exercise)	99 (50 + 49)	2	12	Community various venues	US

DISCUSSION

This review adhered to best practice in conducting and reporting a systematic review, as described in "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" (PRISMA) (Online Appendix A). The main review limitation was restricting the review to papers published in English, resulting in four studies not being included. While the quality of the studies was generally good, reporting could be enhanced by encouraging the authors to adopt robust reporting criteria such as those recommended by the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) network. pharmacist-based intervention around MetS could be argued to be a complex intervention as defined by the UK Medical Research Council (MRC) which defines a 'complex intervention' as one with several interacting components, involving different behaviours and variability in outcomes. Ideally, the interventions should be developed and informed by evidence base in the literature (e.g. a systematic review), consider the theoretical basis for the intervention (e.g. behaviour

change theory) and involve all stakeholders in development. Interventions developed according to this system are more likely to be successful compared to those developed pragmatically. There is also a lack of consideration of the MRC framework in the primary studies included in previous systematic reviews describing pharmacists input to managing Mets elements such DM, HTN, obesity and cardiovascular risk factors. Obese adults with chronic comorbid conditions and paediatrics with risk factors were identified in this review to be among the beneficiary populations.[26-27] These findings concur with at-risk populations highlighted by international organizations. A multidisciplinary approach with engaging patients and their families was recommended to increase the readiness of the staff and patients to accept the pharmacist service. Emphasizing the potential long-term healthcare cost reduction secondary to the pharmacist collaboration and having more than one source of funding and cutting unnecessary expenses were suggested to overcome the financial barrier.

Diabetes

In the four studies that showed improved biomarkers of diabetes, different objective measurements were used. Two studies reported significant mean HbA1c improvement during the study period while the other two focused on measuring the percentage of patients achieving the HbA1c goal of <7% or 8% in a year study period. The therapeutic goals were based on the clinical practice guidelines that were set in studies such as D5 diabetic measure by Minnesota Community Measurement (MNCM) and 2013 ACC/AHA guideline, respectively. The D5 diabetic measure consists of five treatment goals set by MNCM for diabetic patients; blood pressure control, lowering bad cholesterol, blood sugar maintenance, avoid tobacco and as take aspirin as recommended. One further study that looked at the percentage of diabetic patients having HbA1c <7% showed a positive trend towards better diabetic outcomes among those who declined MTM intervention. This change was not statistically significant and was based on 6-months outcome analysis. One reason to explain this finding could be that patients who declined MTM may have had this chronic disease for many years and are actively engaged in the self management of their diabetes.

Hypertension

Four of the six studies in our review showed a statistically significant improvement in objectively measured reduction in blood pressure, and they varied in the measurement parameters. Two studies used mean change in SBP and DBP values while one looked at the percentage change in patients achieving hypertensive goal of <130/80 mmHg and another looked at the percentage who achieved <140/90 mm Hg.

Dyslipidemia

Pharmacist provided medication therapy management services increased the percentage of patients attaining the LDL goal of <100 mg/dL and found a significant change in the statin prescription between patients seen by the pharmacist in MTM setup and the usual care.

Clinical Implications

The results of this systematic review provide evidence that pharmacist provided medication therapy management services have a role in improving clinical outcomes in the outpatient setting. Pharmacists are uniquely and ideally positioned to provide various services such as patient education, quality follow-up, monitoring and encouraging health-promoting behavior needed for improved clinical outcomes. This systematic review article highlighted the gap in the literature and provided evidence about the more effective model-of care for the pharmacist to intervention in diabetes associated complications as well comorbid conditions. Future research is directed to define the potential patient-centred model of care that should be systematically developed, evaluated, implemented in the clinical settings.

CONCLUSIONS

The findings of the present systematic review indicate that pharmacist delivered intervention services can improve clinical outcomes for patients with diabetes, hypertension, and dyslipidemia. These findings lend further evidence to the value of pharmacist provided services for patients with common chronic conditions. Future research could be conducted to help provide more targeted and definitive evidence for the value of clinical pharmacist services[28-30]. The prevalence of hypertension and obesity in patients with T2DM are high throughout the world. Controlling hypertension and reducing obesity in these patients is important to limit the morbidity and costs for the health care systems derived from diabetic complications. Better understating of diabetic complications and comorbidities is important for determining the right treatment strategies to reduce diabetes mellitus, blood pressure and obesity levels in the patients.

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