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REVIEW

An evolving role of clinical pharmacists in managing diabetes: Evidence from the literature

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Abstract *Background:* Diabetes mellitus is a rapidly growing disease world-wide that is estimated to be present in 6.6% of the international population and projected to be increased by 7.8% in 2030. Treating diabetic patients is multifaceted in all aspects and they require objectives and optimum information in order to obtain the maximum benefits of their treatment and avoid complications. Pharmacists are increasingly considered as a part of the health care system. Hence, the aim of this review is to address and summarize the effectiveness of clinical pharmacists in managing diabetic patients.

Method: This is a narrative review of the evidence from the literature in order to answer the present question of what is the evidence of the role of clinical pharmacists in managing diabetic patients. We searched five databases including: the Cochrane library, MEDLINE, EMBASE, TRIP, and Science Direct. We will also try to look for other potentially eligible trials or ancillary publications by searching the reference lists of retrieved included trials, (systematic) reviews, meta-analyses and health technology assessment reports. Outcomes included short-term and long-term measures.

Results: Final search revealed nine studies. They were heterogeneous in terms of interventions, participants, settings and outcomes. Studies varied in their quality and/or reporting of their findings conducted in several settings. Majority of the studies were conducted in Western countries, one in Hong Kong and one in South India. In majority of the studies, pharmacists' role was mainly to specify all drug-related problems including poor drug compliance and side effects and communicating these to the physician. We found that those who received the pharmacist care had a statistically significant reduction in coronary heart disease, blood pressure, HA1c, quality of life and lipid profile.

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Conclusion: Our review demonstrated the important role of clinical pharmacists in managing diabetic patients at diverse settings worldwide. There is an urgent need to recognize and change regulations to allow shared practice agreements among physicians, pharmacists, and other allied health professionals. These mutual agreements would allow more streamlined provision of health care delivery from non-physician health professionals to participants with common health conditions.

Contents

1. Introduction

Diabetes mellitus is a rapidly growing disease world-wide that is estimated to be present in 6.6% of the international population and projected to increase by 7.8% in 2030 (Wild et al., 2004). It is considered of clinical and public health significance, as it adversely affects personal health, health-related quality of life, life expectancy and has significant implications on the health care system. Epidemiological evidence shows that diabetes frequently results in severe complications, such as cardiovascular disease, cerebro-vascular disease, micro-vascular disorders (e.g. nephropathy, retinopathy, neuropathy, sexual dysfunction) and diabetic foot disorders (ADA, 2009).

Treating diabetic patients is multifaceted in all aspects and they require objectives and optimum information in order to obtain the maximum benefits of their treatment and avoid complications. This is a collaborative process involving the patient, physician, pharmacist and other health care professionals. Pharmacists are increasingly considered as a part of the healthcare system whether in community pharmacies, primary care centers, or hospitals (Ghani et al., 2010). The role of pharmacists in several countries has expanded beyond medication dispensing to a more active involvement of patient management and follow up. The contribution of pharmacists in the detection of drug complications, interactions or treatment failures is of valuable information for physicians, who may then, if they judge it convenient, introduce some changes in the prescribed medication (Berenguer et al., 2004).

Recent and comprehensive evidence on levels and trends of the effectiveness of clinical pharmacists in managing diabetes is a critical input to more informed priority setting. It provides an opportunity to quantify process of care against explicit health targets whether local, national or global and to evaluate whether programs are working or not. Quantification across populations and overtime using diverse or even comparable process and methods can also facilitate meaningful benchmarking efforts. Regular and comprehensive updating of the evidence or the role of clinical pharmacists in the control of diabetes can also help in identifying new challenges as they emerge. Hence, the aim of this review is to address and summarize the effectiveness of clinical pharmacists in managing diabetic patients.

2. Method

This is a narrative review of the evidence from the literature in order to answer the present question of what is the evidence of the role of clinical pharmacists in managing diabetic patients. We searched five databases including: the Cochrane library, MEDLINE, EMBASE, TRIP, and Science Direct. We also searched databases of ongoing trials (clinicalTrials.gov/ and controlled-trials.com). We will also try to look for other potentially eligible trials or ancillary publications by searching the reference lists of retrieved included trials, (systematic) reviews, meta-analyses and health technology assessment reports.

Search terms used were MeSH and keywords with different combinations of Boolean operators according to the database but were comparable (see Appendix A for search terms). Outcome measures included: glycemic control (HA1c), body mass index (BMI), lipid profiles, medications adherence, quality of life, mental health outcomes, utilization of health services, adverse effects, and economic outcomes. Search was conducted on April 2013 and updated on March 2014. Studies included were: randomized controlled trials, cohort and case-controlled studies, health technology report, meta-analysis and systematic reviews. Types of participants included in this review were pharmacist delivering services other than or in addition to medications dispensed in different health settings.

3. Results

Search revealed 67 hits. Of these, 57 studies were excluded and nine were retrieved as they fulfilled the inclusion criteria. They were heterogeneous in terms of interventions, participants, settings and outcomes (Table 1). Studies varied in their quality and/or reporting of their findings conducted in several settings including: primary care in the UK, managed care, family practice in the US and Canada or elsewhere in the world (Chan et al., 2012; Clifford et al., 2005; Cohen et al., 2011; Pinto et al., 2012; Richmond et al., 2010; Sriram et al., 2011; Li et al., 2010; Smith et al., 2013; Pande et al., 2013). They also differed in the methods and instruments used to assess the effectiveness and impacts of pharmaceutical care and/or clinical pharmacists on the health outcomes of patients with diabetes mellitus and/or multiple chronic diseases. Majority of the studies were conducted in Western countries, one in Hong Kong and one in South India. All the studies compared the clinical pharmacist/pharmaceutical care (intervention) with the usual care (control) diabetic patients received in the correspondent health settings. In all the studies, follow-up of patients ranged from 12 weeks to 2 years.

Chan and colleagues in Hong Kong conducted a randomized controlled trial (RCT) comparing regular drug-counseling sessions performed by pharmacist in addition to routine medical care compared to routine medical care in diabetic II patients (Chan et al., 2012). They found that those who received the pharmacist care had a statistically significant reduction in the coronary heart disease (CHD) risk compared to those in the control group ($-1.64 \pm 3.56\%$; $n = 51$ vs. $0.01 \pm 3.08\%$; $= 54$, $P = .013$), reduction in stroke ($-1.06 \pm 1.82\%$ vs. $0.31 \pm 2.51\%$, $P = .002$), decreased hemoglobin A1c ($-1.57 \pm 1.50\%$ vs. $-0.40 \pm 1.19\%$, $P = < .001$), and lowering of low-density-lipoprotein (LDL) (-0.36 ± 0.76 vs. 0.03 ± 0.74, $P = .026$). Although the diastolic blood pressure was 4 times greater in the intervention group, there was no significant difference in blood pressure between the intervention and control groups.

In Australia, the Fremantle diabetes study investigated the effect of a pharmaceutical care (PC) program on vascular risk factors in type II DM (Clifford et al., 2005). PC patients had face-to-face goal-directed medication and lifestyle counseling at baseline and at 6 and 12 months plus 6-weekly telephone assessments and provision of other educational material. The study revealed a significant improvement in r HbA1c (-0.5% [95% CI -0.7 to -0.3] vs. 0 [-0.2 to -0.2]) and systolic (-14 mmHg [-19 to -9] vs. -7 [-11 to -2]) and diastolic (-5 mmHg [-8 to -3] vs. -2 [-4 to -1]) blood pressure ($P = 0.043$). Authors also showed that the improvement in HbA1c persisted after adjustment for baseline value and demographic and treatment-specific variables. Additionally, there was a significant reduction in 10-year estimated risk of a first CHD event in the intervention group ($p = < 0.01$).

Moreover, in a randomized controlled trial in the US (Rhode Island), researchers found that a pharmacist-led shared medical management program significantly improved hypertension, hyperglycemia and lipidemia in patients with diabetes than those followed up by the usual standard primary care physicians (Cohen et al., 2011).

In a longitudinal prospective study conducted in the US, pharmacist led care resulted in significant improvement in mean HA1C concentration at 12 months, a decrease in mean systolic and diastolic blood pressure, and a decrease in alcohol and smoking consumption and an increase in exercise (Pinto et al., 2012). However, Richmond and colleagues in the UK also conducted a study at primary care centers to estimate the effectiveness of pharmaceutical care for older people, shared between GPs and community pharmacists in the UK, relative to usual care (Richmond et al., 2010). The results did not significantly change the appropriateness of prescribing or quality of life (QOL) in older patients.

QOL is another measure that interested researchers to examine in diabetic patients. Sriram et al. in India, conducted a prospective study to evaluate the impact of pharmaceutical care on QOL in patients with type 2 diabetes mellitus (Sriram et al., 2011). They showed a significant improvement in the intervention group ($p < 0.01$) using Bradley's questionnaire, the Audit of Diabetes Dependent Quality of Life (ADDQOL). Patients were satisfied with their treatment, felt slightly affected due to their disease, and rarely worried about the negative consequences of their diabetes. Furthermore, several clinical measures correlated well with the quality of life. Patients who were more satisfied with their current treatment tend to have better glycemic and blood pressure control.

Also, in a meta-analysis, pharmaceutical care (PC) programs delivered separately or in combination by pharmacists and other health professionals can lead to an improvement in glycemic control compared to the usual care. The researchers also recommended that the incorporation of PC programs into disease management should be strongly considered (Li et al., 2010).

Nichols-English emphasized that a major role of pharmacists in collaborative care is to assist patients to adhere to their self-care and therapeutic regimens (Nichols-English et al., 2002). An optimal role in assisting other primary care providers is to simplify, clarify and reinforce the prescribed therapeutic and self management regimens.

In a recent Cochrane systematic review, authors found that in the care of elderly with poly-pharmacy, pharmaceutical care appears beneficial in terms of reducing inappropriate prescribing and medication-related problems (Patterson et al., 2012). Additionally, a review showed that pharmacist intervention in type 2 Diabetes Mellitus patients was successful in leading to reductions in mortality, morbidity and cost of treatment (O'Donovan et al., 2011).

4. Discussion

This review highlighted the value of the clinical pharmacist/pharmacist care program that targeted immediate and long-term risk factors associated with DM. This extended across multiple health care settings and cultures worldwide. In the majority of the studies, pharmacists' role was mainly to specify all drug-related problems including poor drug compliance and side effects and communicating these to the physician. Such communication (verbal and/or written) is crucial in building professional working relationships necessary to ensure optimal patient care. However, pharmacists' involvement is not meant to replace the formal DM education or physician direct care, nevertheless, the program provides a useful supplement or enhancement to the care of diabetic patients. This is especially important to be emphasized, where there might be a culture of

Table 1 Summary of included studies.

Study	Country	Intervention	Control	Results
Chan et al. (20120: A pharmacist care program: Positive impact on cardiac risk in patients with type 2 diabetes	Hong Kong	RCT: regular drug-counseling sessions with pharmacists in addition to routine medical care	Routine medical care	Intervention group had a statistically significant reduction in CHD risk compared to those in the control group, $P = 0.013$ ↓stroke ($p = 0.002$), ↓HA1c ($p < 0.001$), ↓ LDL ($p = 0.03$)
Clifford et al. (2005): effect of a pharmaceutical care program on vascular risk factors in type 2 diabetes	Australia	RCT: had face-to-face goal-directed medication and lifestyle counseling at baseline and at 6 and 12 months plus 6-weekly telephone assessments and provision of other educational material	Regular care	Significant improvement in BMI, FBS, HA1C, BP, Lipid profiles ($p = 0.001$–0.04)
Cohen et al. (2011): Pharmacist-led shared medical appointments for multiple cardiovascular risk reductions in patients with type 2 diabetes	US	RCT: 1 h session every month for 6 months, led by Pharmacist; multidisciplinary diabetes specific healthy lifestyle education + pharmacotherapeutic interventions performed by a clinical pharmacist	Standard primary care	↓Total cholesterol, ↓ BP, ↓ HA1C ($p = 0.015$). However, no change in smoking rate and QOL
Pinto et al. (2012): Evaluation of outcomes of a medication therapy management program for patients with diabetes	US	Prospective longitudinal study: counseling sessions	No control	↓HA1C, ↓ BP ($p = 0.02$)
Richmond et al. (2010): Effectiveness of shared pharmaceutical care for older patients: RESPECT trial findings	UK	Prospective follow up: shared between GPs and community pharmacists	Patients acted as heir own controls	Did not significantly change the appropriateness of prescribing or quality of life in older patients
Sriram et al. (2011): Impact of pharmaceutical care on quality of life in patients with type 2 diabetes mellitus	South India	RCT: diabetes education, medication counseling, instructions on lifestyle that needed modifications (necessary for better drug function) and dietary regulations regarding their prescribed drugs	Usual care	Improvement in the quality of life score, $p < 0.01$
Li et al. (2010): Effect of pharmaceutical care programs on glycemic control in patients with diabetes mellitus: a meta-analysis of randomized controlled trials	Multi-countries	Meta-analysis: 14 RCT; Drug counseling, drug therapy management, lifestyle education, self-monitoring, and recommendations of drug therapy changes	Usual care	PC intervention groups had significant ↓ in HA1C levels ($p < 0.01$, 95% CI −1.03 to −0.34)
Smith et al. (2013): Interventions for improving outcomes in patients with multimorbidity in primary care and community settings	Cochrane review	Ten studies, low risk of bias, complex interventions; multiple elements, multidisciplinary team work, involving pharmacist in many	Usual care	Mixed effects; improve prescribing, medication adherence, predominant change to the organization of care delivery, potential significant cost saving
Pande et al. (2013): The effect of pharmacist-provided non-dispensing services on patient outcomes, health service utilization and costs in low- and middle-income countries	Cochrane review	12 studies, pharmacist-provided services	Usual care	Reduction in health service utilization, small improvement in clinical outcomes, improvement in quality of life

sensitivity from other health professionals (e.g. physicians) and the fear of taking over responsibilities by the pharmacists (personal view).

Pharmacist contributed to beneficial reductions in modifiable vascular risk factors, most notably glycemic control and blood pressure. In the case of glycemic control, the improvement continued after adjustment for key demographic variables and intensification of pharmacotherapy, suggesting that the participation of the pharmacists had a positive impact on medication adherence and other factors that are important in diabetes self-care. Furthermore, the PC program was associated with a significant reduction in the estimated 10-year risk of CHD in a primary prevention setting.

Another study that was conducted in Australia, a 12 month program in type 2 diabetes that was managed by pharmaceutical care reduced HA1C and blood pressure significantly compared to those who were managed by clinicians only (Clifford et al., 2005). However, the patients in the intervention group had longer diabetes duration than the control which might explain the observed benefits.

There are differences between studies and this might compromise the generalizability of the findings. For example, the equation used for the CHD risk score in one study was tailored for a specific population (Hong Kong); therefore, findings of their study may not apply to other ethnic groups as they are correctly highlighted. In addition, such a program might be considered a success as every 0.5% reduction in HbA1c might lead to a 7% decrease in myocardial infarction and a 12% decrease in the risk of stroke (Stratton et al., 2000). The reduction in systolic blood pressure might explain the significant reduction in the rate of stroke. This is very essential to address as cardiovascular disease is the main cause of death in patients with diabetes mellitus and is largely preventable by simultaneous control of cardiovascular risk factors (Leonard, 2003; Gæde et al., 2008). Moreover, this is consistent with the current guidelines for comprehensive diabetes management that ensures intensive pharmacologic and behavioral interventions for the treatment of hypertension, hyperlipidemia, hyperglycemia, and tobacco cessation (Association, 2010).

Although all the studies included showed some benefits of the clinical pharmacists, only one that was conducted in the UK showed no evidence of effectiveness. The researchers explained that the lack of positive evidence stems from researchers' experience that pharmaceutical care is difficult to implement fully in the community. Furthermore, they addressed that self-selection of the included practices may have excluded those practices associated with poorer standards of prescribing, which could have affected the results of their study. However, taken together, these results suggest that the success of PC depends on the combination of patient characteristics, context, settings, and duration.

This review has some limitations. Some studies might be missed and not included as the search terms and/or database search was not meant to be conducted for a systematic review rather for the purpose of a narrative review. Additionally, search was limited to studies published in English and, hence, studies conducted in other languages might be overlooked. Furthermore, some of the results were based on patient self-reporting, which might likely overestimate, for example, the adherence. Therefore, we tried to limit these probable biases by focusing on objective measures as endpoints. Also, blinding in these studies was not possible and this might impact the level of care and education provided to patients under the usual care arm as a control. Moreover, generalizability of our findings might not be extrapolated to different settings and context. This is due to variations in health system set-up and cost implications in different countries.

The strengths of this review lie in its comprehensive search and summarization of results from different countries in different health care settings and various cultures. This review motivated the effort to conduct a more systematic review with focus on subgroup analysis to address different benefits and level of evidence in terms of settings, culture, health care system arrangement, gender, and age groups.

5. Conclusion

Our review demonstrated the important role of clinical pharmacists in managing diabetic patients at diverse settings in many countries worldwide. This was established for both the immediate care of such patients and their associated risk factors targeting holistically their care in partnership with the physician and other health care professional team. Furthermore, pharmacist contributed to medication adherence, knowledge and understanding of diabetic patients at multiple levels. Therefore, they are very valuable to the care of such patients and should be considered and involved in other health care problem management especially in patients with chronic diseases.

Moreover, our review revealed that the pharmacist-led group intervention program was an efficacious and sustainable collaborative care approach to manage diabetes, educate patients to improve self-care behaviors, and reduce associated cardiovascular risk.

6. Implications

This review has several implications for the practice and future research efforts. Economic analysis was not performed in the studies included in this review. Therefore, the need for such analysis is imperative. This is because we think that the standard model of diabetes care may not be practical in the future with the continued increase in diabetes diagnoses, decrease in primary care physicians, and decreasing funds for medical treatment, especially in developing countries. This is evidenced by all the aforementioned studies, that pharmacists are crucial members of inter-professional teams and will continue to be in the light of the need for changes and innovations we need in the current health care services.

Furthermore, there is an urgent need to recognize and change regulations to allow shared practice agreements among physicians, pharmacists, and other allied health professionals with pharmaco-therapeutic co-management. These mutual agreements would allow more streamlined provision of health care delivery from non-physician health professionals to participants with common health conditions, such as diabetes and cardiovascular risks.

Additionally, it would be interesting to explore the gender differences in diabetic patients. Studies have shown that men may not have as much progress in self-care behavior as women due to differences in the social cognitive determinants between sexes (Hankonen et al., 2010). Therefore, we encourage investigating such differences in future research as this might help in focusing the management and resource distribution to the most needed population.

Moreover, there is a need to extend the duration of future studies into longer period in order to evaluate the effectiveness of clinical pharmacists not only on short morbidity outcome, but also on mortality in the long-term scale.

Clinicians' perceptions and views about the role of clinical pharmacists need also to be explored in future research efforts in order to obtain various role perceptions that are likely to result in barriers to pharmacists expanding their roles in different health care settings.

Appendix A. Search strategy

1. Pharmaceutical Care.mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (1231).

2. Clinical pharmacists.mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (686).
3. Pharmacist.mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (7889).
4. 1 or 2 or 3 (8717).
5. Family physician.mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (3395).
6. Primary care.mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (65516).
7. General practitioner.mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (13469).
8. 5 or 6 or 7 (80143).
9. Diabetes.mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (385066).
10. Diabetic patients.mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (41614).
11. 9 or 10 (390626).
12. Control.mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (1864991).
13. Effectiveness.mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (248213).
14. Impact.mp. [mp = title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (448593).
15. 12 or 13 or 14 (2430258).
16. 4 and 8 and 11 and 15 (49).

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