

Role of Pharmaceutical Care in Type 2 Diabetic Patients in Kirkuk City

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Abstract:

Background and objectives. Diabetes Mellitus is a chronic metabolic disorder that negatively affects patient's quality of life and creates a huge burden on both patients and health care system. Effective pharmaceutical intervention could result in a tighter disease control,

reducing long term complications and improving the quality of life.

Methods: In this study, a prospective clinical trial was performed to evaluate the role of pharmaceutical care in reducing complications and in improving the quality of life among patients with T2DM. A total of 189 patients were included and divided into two groups; the first group: consisted of 95 patients, comprised the intervention group who received regular pharmaceutical care on monthly basis. The rest 94 patients were allocated to the non-intervention group who only received usual medical care. Patient selection was carried out according to certain inclusion and exclusion criteria. Two categories of data were recorded from each participant at 6 time points during the study period. The first category was assessment of risk factors of complication such as hypertension, hyperlipidemia, uncontrolled hyperglycemia, physical inactivity and smoking. The second category was current status of diet and quality of life.

Results: The number of drug therapy problems non-adherence to medication and HBA1c were significantly reduced and quality of life was significantly improved among intervention group. Other Clinical and blood parameters were not affected.

Conclusion: Pharmacist collaboration with physicians regarding management of type II diabetes patients have yielded a better patient management outcome, reduced risk factors and improved the quality of life in those patients.

Key words: Clinical pharmacist, pharmaceutical care, diabetes mellitus and Drug therapy problems.

دور الرعاية الصيدلانية في مرضى السكري من النوع الثاني في مدينة كركوك

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الخلاصة:

الخلفية والاهداف:

داء السكري هو اضطراب أيضي مزمن يؤثر سلبيًا على نوعية حياة المريض ويخلق عبئًا كبيرًا على كل من المرضى ونظام الرعاية الصحية. يمكن أن يؤدي التدخل الصيدلاني الفعال إلى تشديد السيطرة على المرض ، والحد من المضاعفات طويلة الأجل وتحسين نوعية الحياة.

طريقة العمل:

في هذه الدراسة ، تم إجراء تجربة سريرية مستقبلية لتقييم دور الرعاية الصيدلانية في الحد من المضاعفات وتحسين نوعية الحياة بين مرضى T2DM. تم إدراج ما مجموعه 189 مريضاً وتم تقسيمهم إلى مجموعتين. المجموعة الأولى: تتكون من 95 مريضاً ، وتتكون من مجموعة التدخل التي تلقي رعاية صيدلانية منتظمة على أساس شهري. تم تخصيص 94 مريضاً الباقين إلى مجموعة عدم التدخل الذين تلقوا فقط الرعاية الطبية المعتادة. تم اختيار المريض وفقاً لمعايير إدراج واستبعاد معينة. تم تسجيل فنتين من البيانات من كل مشارك في 6 نقاط زمنية خلال فترة الدراسة. الفئة الأولى كانت تقييم عوامل خطر المضاعفات مثل ارتفاع ضغط الدم ، زيادة الدهون الدم ، ارتفاع السكر في الدم غير المنضبط ، الخمول البدني والتدخين. الفئة الثانية كانت الوضع الحالي للنظام الغذائي والتدخين (عدد السجائر / اليوم) والنشاط البدني ونوعية الحياة.

النتائج:

انخفض عدد مشاكل العلاج الدوائي (DTP) ، وعدم الالتزام بالأدوية و HbA1c بشكل كبير وتحسنت نوعية الحياة بشكل ملحوظ بين مجموعة التدخل. لم يتم تقليل تأثيرات السريرية والدم الأخرى بشكل كبير.

الاستنتاج:

أدى التعاون الصيدلاني مع الأطباء المسؤولين عن إدارة مرضى السكري من النوع الثاني إلى نتائج أفضل لإدارة المرضى ، وتقليل عوامل الخطر وتحسين نوعية الحياة لدى هؤلاء المرضى.

الكلمات المفتاحية: الصيدلاني السريري ، الرعاية الصيدلانية ، داء السكري ، مشاكل العلاج الدوائي (DTP)

Introduction

Diabetes Mellitus is a chronic metabolic disorder that negatively affects patient's quality of life and creates a huge burden on both patients and health care system. Iraq is one of the nineteen countries of the International Diabetes Federation Middle East and North Africa (IDF MENA) region. Four hundred and twenty-five million people have diabetes in the world and more than thirty-nine million people in the MENA Region; it is predicted that, by the year of 2045, this number will rise to sixty-seven million. Total adult population of Iraq is 18,738,000 and the prevalence of diabetes in adults in Iraq is 7.5% (1,411,500 cases) (1). Type 2 diabetes mellitus accounts for majority of diabetes cases. It occurs when an unhealthy lifestyle such as excessive calories, inadequate exercise, and obesity is superimposed upon a susceptible genotype (2).

Physicians are the only responsible health care provider in such health care centers all over Iraq including Kirkuk Diabetes Center. Having a large number of already diagnosed patients visiting the center to receive treatment on monthly basis, plus

newly diagnosed and recruited patients create a huge burden on the center which in turn affects the quality of healthcare provision. Moreover, the health system in Iraq allows the pharmacist to dispense prescribed drugs at both community and hospital pharmacy levels. The role of pharmacist is very restricted to product focused pharmacy while in most of the cases, the clinical role of pharmacists is marginalized or unrecognized. Universally speaking, the value of team-based care to patients has long been recognized as a cornerstone in the management of chronic diseases (3). Additionally, the WHO and International Pharmaceutical Federation (FIP) stated that "Pharmacists have an important role to play in health care, which is much more than selling medicines". (4) In the current research, it has been proposed that integration of qualified pharmacists into the health care team in chronic disease centers has the potentiality to yield a significant positive clinical outcome. Effective pharmaceutical intervention could result in a tighter disease control, reducing long term complications and improving the quality of

life. In this study, a prospective clinical trial was performed to evaluate the role of pharmaceutical care in reducing complications and in improving the quality of life among patients with T2DM.

Methods

Study settings

An Interventional prospective study was carried out at Diabetic Center of Azadi Teaching Hospital between 2nd of Feb 2019 to 13th of Sept 2019. The study population was recruited by simple randomization process. A total of 189 patients were included and divided into two groups; the first group: consisted of 95 patients, comprised the intervention group who received regular pharmaceutical care on monthly basis. The rest 94 patients were allocated to the non-intervention group who only received usual medical care.

Inclusion criteria

Patients in both groups were selected according to certain inclusion and exclusion criteria. Inclusion criteria were: patients with type -2 diabetes mellitus, there age were ranged from 47 – 73 years old, patient should have at least 2 risk factors out of 5 risk factors to develop diabetic complication (Hypertension, hyperlipidemia, uncontrolled hyperglycemia, physical inactivity and smoking).

Exclusion criteria

Patients with type -1 diabetes mellitus, end stage diseases such as renal and heart

failure, current pregnancy and psychiatric disorders were excluded from the study.

Assessment of risk factors

Two categories of data were recorded from each participant at 6 time points during the study with regular monthly intervals. The first category was assessment of risk factors for complication documenting their numbers and severity. The 5 risk factors were hypertension, hyperlipidemia, uncontrolled hyperglycemia, physical inactivity and smoking. For assessing hypertension, systolic and diastolic blood pressures were recorded from each participant. Lipid profiles including LDL, HDL, serum cholesterol and TG were used to assess hyperlipidemia and fasting plasma glucose plus HBA1c were used to assess glycemic status. The second category of patient's sociodemographic current status of diet, smoking (number of cigarettes / day), physical activity and quality of life. They were assessed at baseline and advisements about each of the above problems were given to the patients in the intervention group.

Assessment of quality of life

The revised version of Diabetes quality of life (DQoL) instrument published by the Diabetes Control and Complications Trial (DCCT) Research Group was used as a tool for assessment of quality of life in both groups as shown in table 1 (5). The tool is classified into 3 domains; Satisfaction, Impact, and Worry.

Table (1): Diabetes quality of life (DQoL)

Domain: Satisfaction (1 = very satisfied, 2 = moderately satisfied, 3 = neither, 4 = moderately dissatisfied, 5 = very dissatisfied)	Domain: Impact (1 = never, 2 = very seldom, 3 = sometimes, 4 = often, 5 = all the time)	Domain: Worry (0 = does not apply ,1 = never, 2 = very seldom, 3 = sometime 4 = often, 5 = all the time)
How satisfied are you: - With the flexibility you have in your diet? - With your sleep? - With your social relationships and friendships? - With your work, school, and household activities? - With the time you spend exercising?	How often do: - You have low blood sugar? - your diabetes interferes with sex life? - your diabetes keeps you from driving a car or using a machine? - you tell others about your diabetes? - you find that you eat something you should not rather than tell someone that you have diabetes?	How often do you worry about whether you? - Will get married? - Will have children? - Will not get a job you want? - Will miss work? - Will be able to take a vacation or trip?

Pharmaceutical interventions

Proper pharmaceutical advices were given to the patients in the intervention group in cooperation with physician responsible for disease management. Pharmaceutical intervention was carried out according to Pharmaceutical society of Australia – standard and Guidelines for pharmacists performing clinical intervention, March - 2011 (6).

Drug therapy problems were identified in the intervention group during the study period. They were listed as one or more of the DTPs:

- 1- Additional drug therapy needed.
- 2- Unnecessary drug therapy being used.
- 3- Ineffective drug therapy.
- 4- Dosage too high.
- 5- Adverse drug reaction.
- 6- Dosage too low.
- 7- Adherence to medication.

Interprofessional relationships were developed with the physicians responsible for the management of patients at different levels:

At drug level

- Changing the dose of drug / administration / frequency.
- Enhancing medication adherence.
- Use the drug by correct instruction.
- Adding drug therapy.

- Changing the drug.
- Changing the Formulation.

At patient / career level

- Patient (medication) counseling.
- Providing written information to the patients.
- Speaking to the family members / caregivers.

Patient follow-up

A face to face pharmaceutical care was performed with both patients and the physicians responsible for patient’s management on monthly basis for 6 months. HBA1c was also measured at baseline, 3 months and 6 months. The quality of life was only assessed at two time points; baseline and after 6 months (end of the data collection period). The researcher used a special instruction template to give pharmacist advises to the interventional group only. For the non-intervention group, the Lab parameters were recorded at the usual monthly checkups for a total 6 months, but no advice were provided regarding DTP or advised related to diet, smoking and exercise.

Data analysis:

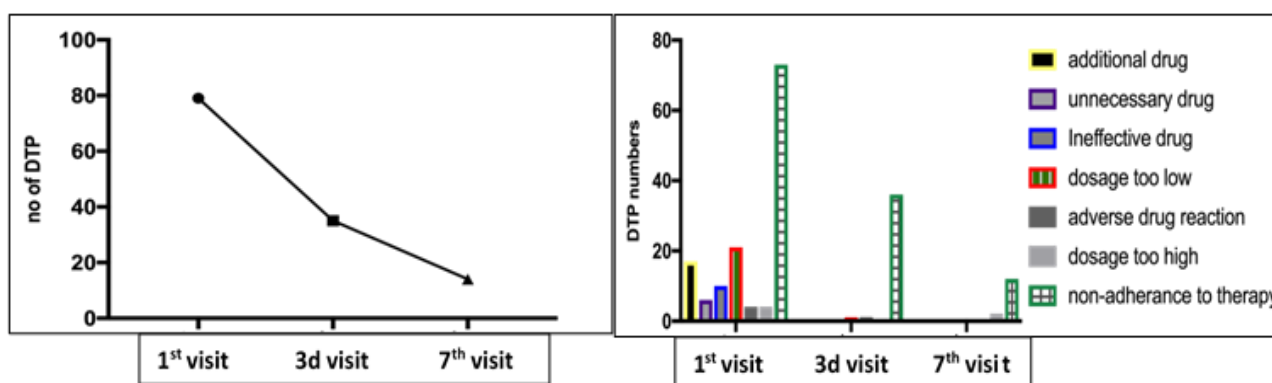
Data analysis was performed using GraphPad Prism version 7. Chi-square test, Student t-test and One-way ANOVA test were used. p Value of less/equals to 0.05 was considered as significant.

Results

Drug therapy problems (DTP)

The figure below (fig.1) shows the prevalence of DTP in diabetic patients in the intervention group, comparing the number of DTPs between first (baseline),

second (month 3) and third (month 6) visits. It was observed that number of DTPs was significantly reduced (p Value= 0.0006) by the end of pharmaceutical intervention. Among DTPs, non-adherence to therapy found to be the most common problem at first visit and it has been reduced markedly in the seventh visit (73 patients in first visit vs 12 patients) (Fig.2). The other common DTP was low drug dose given to the diabetic patient in the first visit and this has been corrected in subsequent visits.



Figure(1):Prevalence of DTP in the intervention group at successive

Figure (2): DTPs categories

Causes of Non-adherence to therapy

Figure 3.3 (A, B and C) shows causes of non-adherence to therapy at baseline and successive visits among the intervention

group. The most common cause of non-adherence was that the patients forget to take drug. This problem was reduced by the end of the study period after monthly interventions.

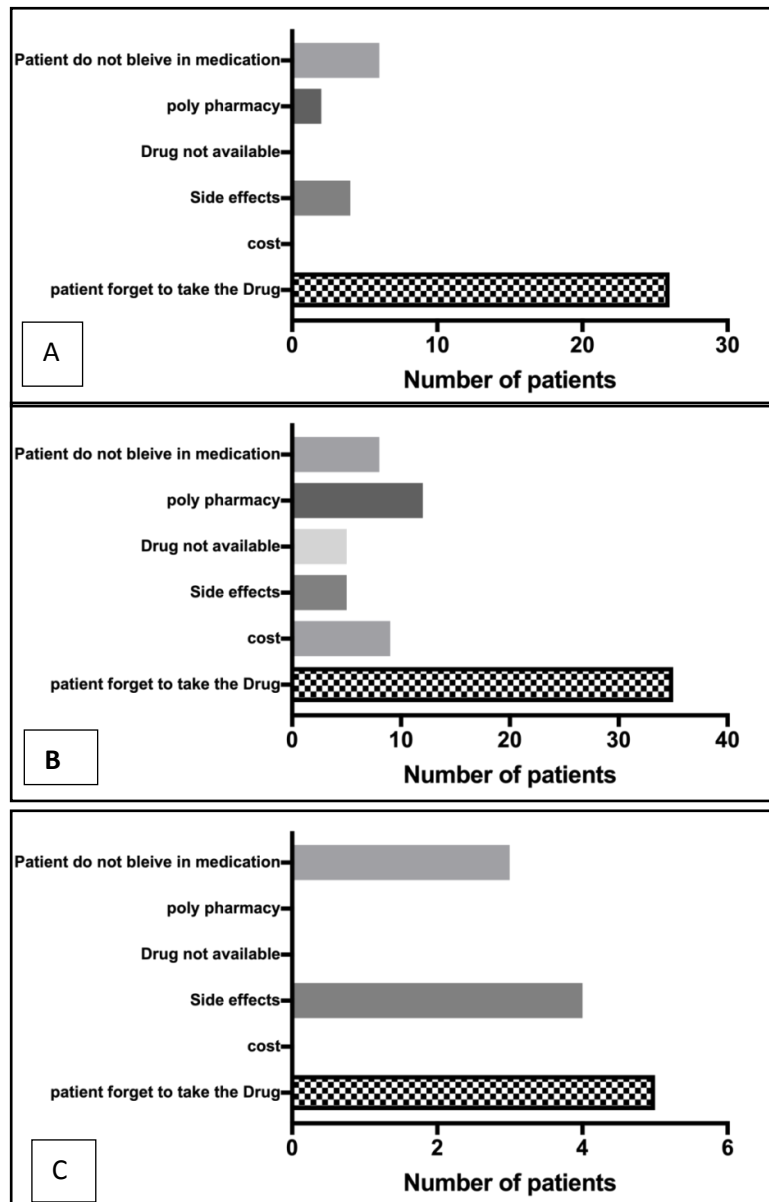


Figure (3): Number and causes of non-adherence to therapy at baseline and successive visits. A=visit 1, B=visit 3, C=visit 7

BMI

The data of body mass index throughout the study also reveals that there are no significant differences between

intervention and non-intervention groups following pharmacist intervention via 7 consecutive visits (p Value=0.99).

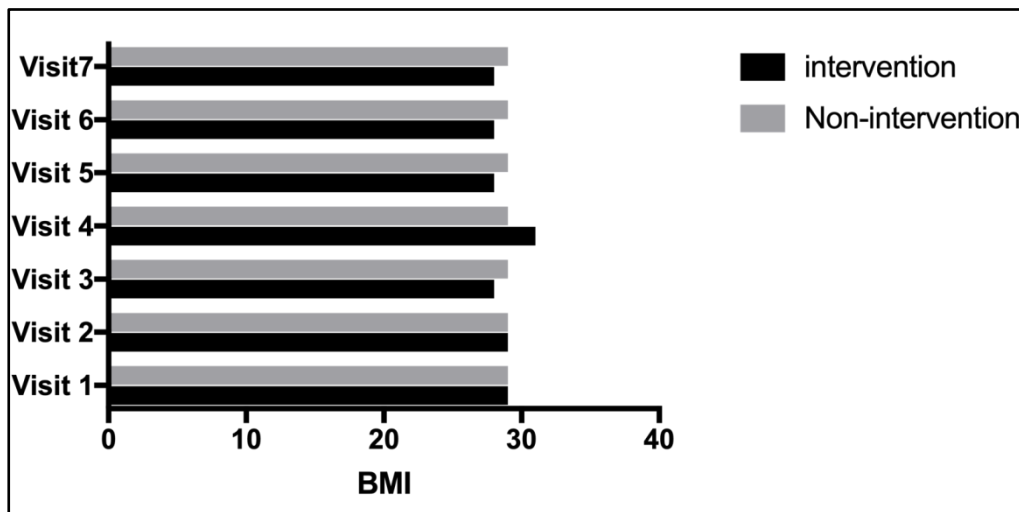


Figure (4): BMI in both intervention and non-intervention group throughout successive visits.

Blood pressure:

Systolic and diastolic blood pressures were recorded for both groups at baseline (visit 1) and after 6 successive visits. As shown

in figure 6, there were no significant differences in the reduction of systolic and diastolic pressures between the two groups (pValue: >0.99).

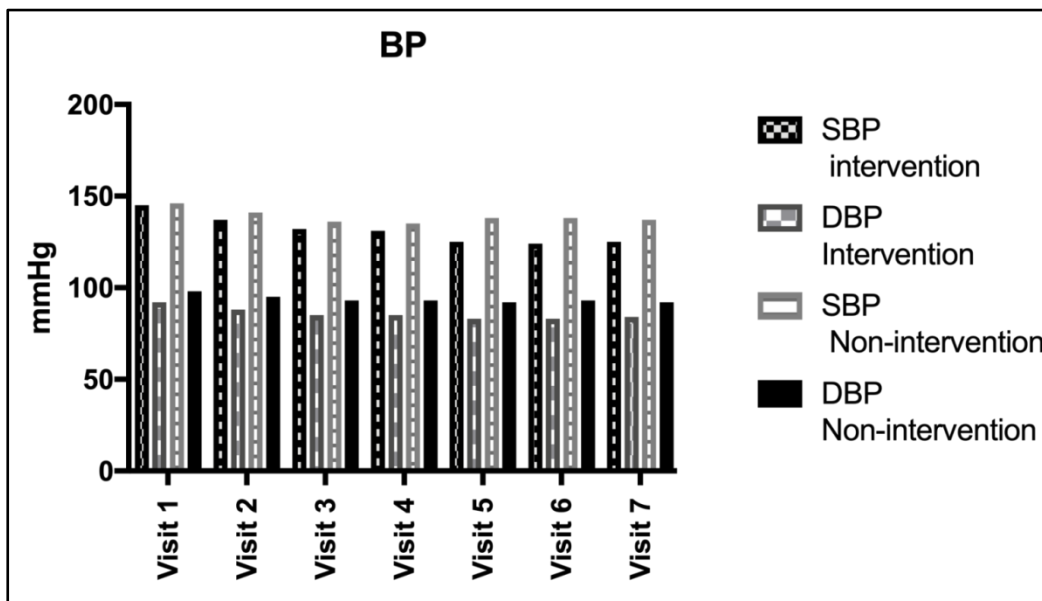


Figure (5): systolic and diastolic blood pressure of both intervention and non-intervention groups at different visits

Fasting plasma glucose:

Monthly FPG of both interventional and control groups were demonstrated in figure 7 (A, B and C). There was significant

reduction in the level of FPG among the intervention group throughout study period in comparison to the control group (p Value= 0.009)

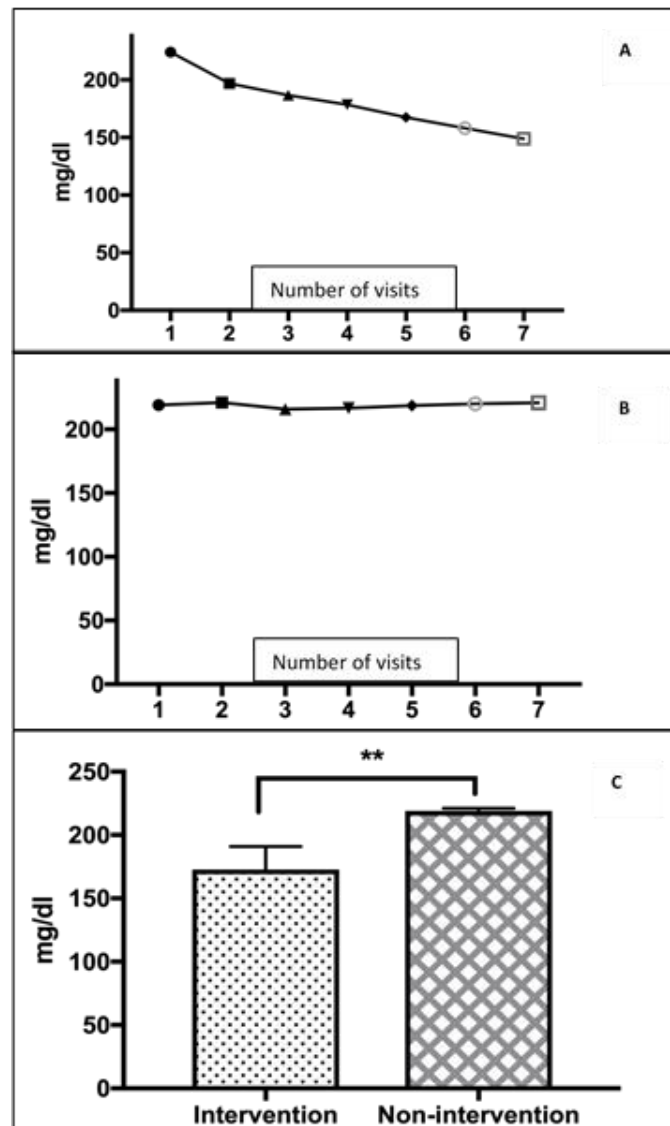


Figure (6): fasting plasma glucose level among control and intervention groups. **A=**monthly changes in the FPG level among the intervention group, **B=** monthly changes in the FPG level among the control group, **C=** Level of significance in the FPG level between intervention and control groups. **** highly significant**

HbA1c

HbA1c levels of intervention and control groups throughout the study were shown in the figure 8. A significant reduction in the

HbA1c level was observed among the intervention group in comparison to the control one (p value=0.012).

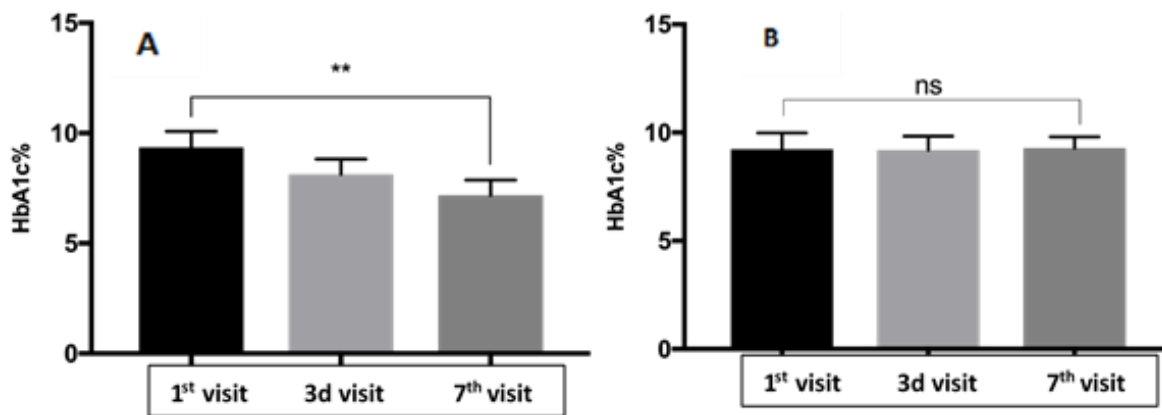


Figure (7): HbA1c levels among intervention and control groups in three visits. A: The intervention group B: the control group

lipid profile

Lipid profile for both groups were closely monitored. Following six months pharmacist intervention, no significant

difference between intervention group and control group was observed as shown in figure 9.

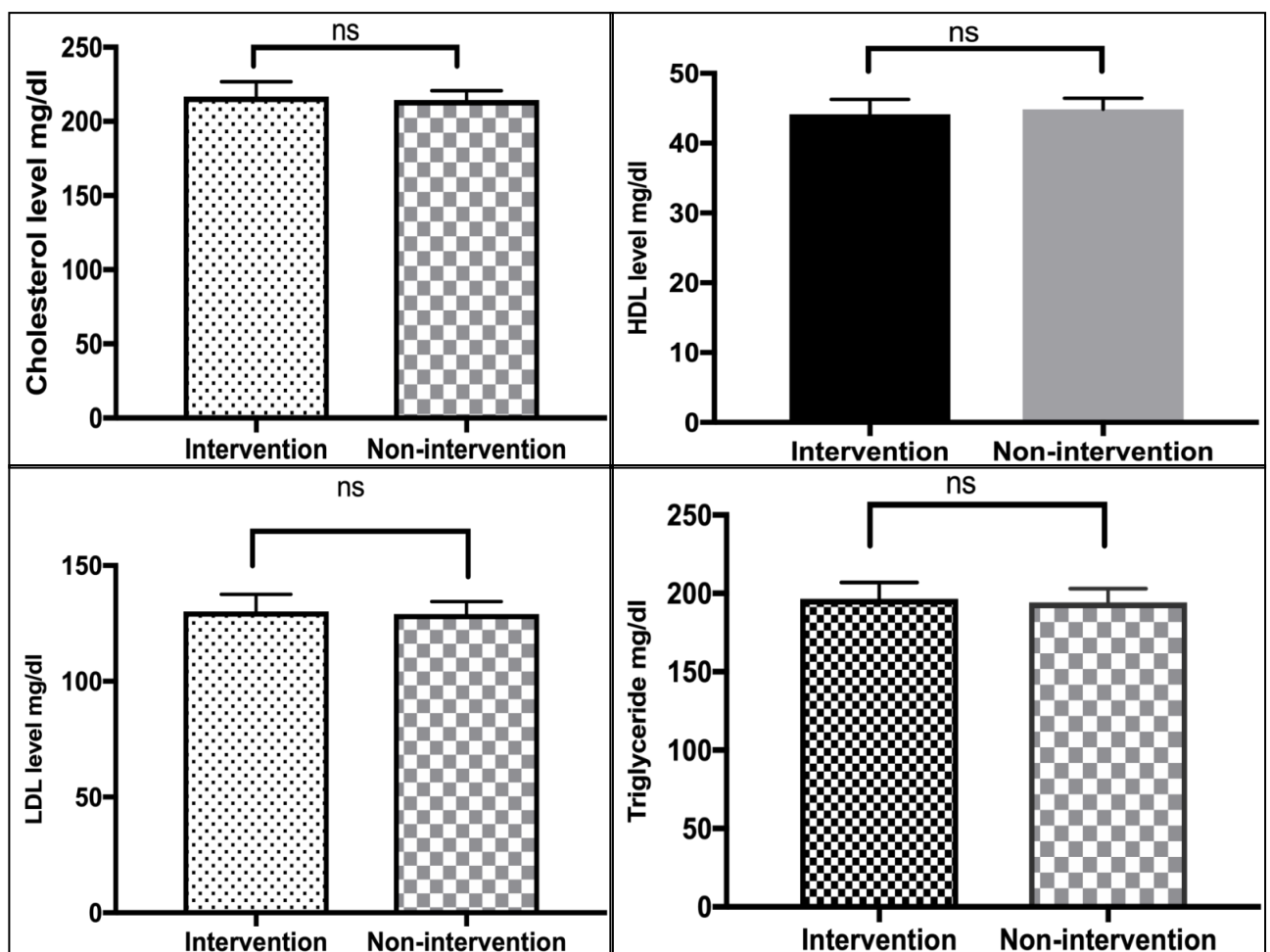


Figure 8: serum cholesterol, HDL, LDL and triglyceride between intervention and non-intervention groups.

Risk factors for complications

The five risk factors that may lead to complications in type 2 DM were assessed at baseline and at visit 7 for both non-intervention and intervention groups. The baseline comparison of the number of these risk factors showed no significant differences (fig. 10). While the number of all the risk factors was reduced in intervention group at visit 7 compared to the first visit. This observation was not seen in the non-intervention group. As it is clear from the figure 10, the most important risk factors that reduced after

pharmaceutical intervention were physical inactivity and hyperglycemia (p value = 0.008) The other risk factors like hyperlipidemia, hypertension and smoking were also improved to some extent at visit 7 compared to non-intervention group (fig. 11).

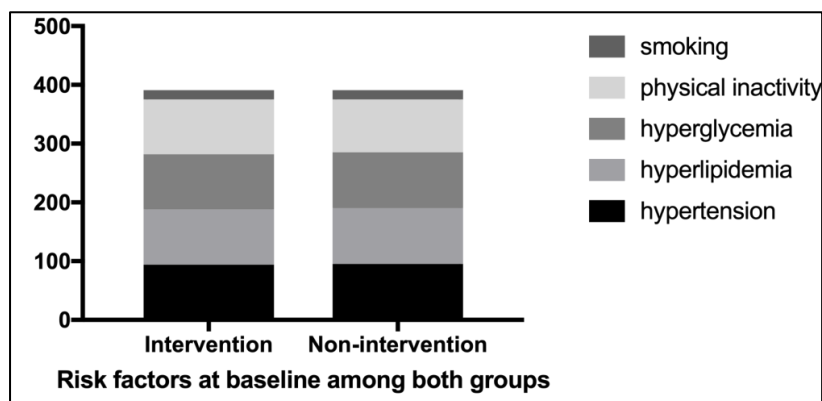


Figure (9): Risk factors among both groups at baseline

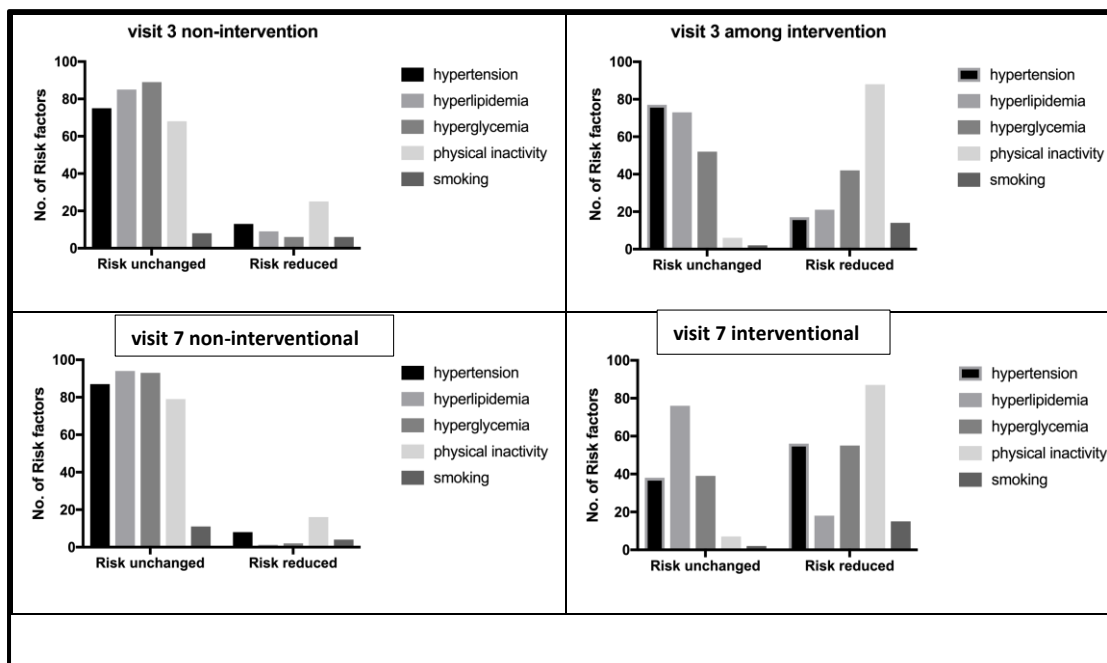


Figure (10): Comparison of the number of risk factors between visit 3 and visit 7 of both groups. The numbers from 0-100 indicate number of patients having those particular risk factors

Discussion

Studies of pharmacist interventions in developed health care systems among patients with chronic diseases show that pharmaceutical interventions improve medication adherence, treatment outcomes and/or quality of life (7,8). This study was designed to examine the impact of pharmaceutical care in reducing disease complications of type 2 diabetic patients in Kirkuk city/Iraq. In the setting of a team work, chronic diseases such as diabetes mellitus are not managed by a team of health care professionals which, based on medical care standards, consists of pharmacist, physician, nurse, technician and nutritionist. Thus pharmacists are still not part of an overall team in chronic disease management in Iraq. Studies in this region start to focus on this issue in the aim of integration of pharmacists in management strategies.

Drug therapy problems

According to the present study, many drug therapy problems were diagnosed as the patients were first enrolled to the pharmaceutical intervention group. The different categories of DTPs were non-adherence to therapy, low dosage and ineffective drugs, unnecessary drug prescribed, additional drug needed and adverse drug interactions. Many studies globally highlighted and assessed magnitude and pattern of DTP in patients with type 2 DM and in other chronic diseases (9,10).

Studies about DTP in patients with chronic diseases have found different sequences of DTP in terms of the most common problem encountered. Yohaneset. al. has found that the drug is not optimal in 49.2% of patients and 77% of patients did not get drug therapy for a clear indications and symptoms. Another study found that the most frequent types of DTP were drug-drug interaction (18.0%), drug not taken (14.3%) and insufficient awareness of health and diseases (11.8%) (11). In this

study, it was found that non-adherence to therapy is the most prevalent DTP. The most common cause is turned out to be forgetfulness to take medication. The other frequent cause of non-adherence was that the patients do not believe in medication. In a study conducted in Baghdad/Iraq, the researchers found similar common causes of non-adherence to therapy, which was closely associated with the age of the patients (12).

Forgetfulness to take medication was the first common cause of non-adherence throughout the successive visits to the diabetic center in the Kirkuk city. However, after pharmaceutical intervention this problem was dramatically reduced, the number being 5 patients in the last visit compared to 25 patients initially.

Fasting plasma glucose

Fasting plasma glucose was noted to be significantly reduced after pharmaceutical intervention. This observation is closely related to the fact that the overall number of DTP were reduced as the pharmaceutical care was given to the interventional group which, through better adherence to medication and disease control, has resulted in significant reduction in fasting plasma control over time. Studies found that control of plasma glucose is directly related to reduction of long-term diabetic complications (13,14). More importantly, not only the FPG level, but also HbA1c was reduced significantly. And according to prior studies, HbA1c predicts the risk for the development of diabetic complications in diabetes patients. Therefore, controlling this factor is closely related to reducing diabetic complications.

Lipid profile

Lipid profile was not significantly reduced in intervention group compared to control group. This possibly arises because much more time may be required than the study period for lipid profile correction or dietary regimen correction might not be appropriate.

Overall risk factors:

The overall risk factors were better controlled in intervention group. Among them, hyperglycemia (reflected in HbA1C) and physical inactivity were reduced to a significant level (p value=0.018). Since the primary pathology in patients with type 2 diabetes is a high plasma glucose, then the primary focus in the view of patients is blood sugar control, therefore they put a lot of effort, throughout adherence to anti-diabetic medication and doing regular exercise, to control their blood sugar.

Quality of life assessment

The collaboration between physicians and pharmacists addresses undesirable and ineffective consequences of medication use. Pharmacists working in collaboration with physicians through a redesigned approach to medication use can prevent errors and reduce drug costs (15). In the present study, it was found that this pharmaceutical intervention has worked and there was a statistically significant improvement in the three domains assessed for the quality of life in the intervention group.

Conclusion:

Pharmacist collaboration with physicians in charge of management of type II diabetes patients have yielded a better patient management outcome, reduced risk factor to some extent and improved the quality of life in those patients. Through better adherence to medication, plasma glucose monitoring, advises related to diet and physical exercise, these positive outcomes have been achieved.

Recommendation:

Based on achievement of positive outcomes regarding type II diabetic patients, the present study recommends enrolment of pharmacists into the management team for chronic diseases such as type II diabetes mellitus. Also, monthly regular checks of complication

risk factors, medication adherence, plasma glucose control and encouraging healthy diet and physical activity may be very useful to be provided by chronic disease health centers such as Kirkuk diabetic center.

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