Clinical pharmacy in medical practice: the impact of detection, prevention and resolution of Drug Therapy Problems (DTPs) on patients with chronic diseases

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Abstract:

(i). Background & objective: Recently, the role of pharmacists in the healthcare settings has dramatically evolved through the application of pharmaceutical care process. However, this new role has not been fully elucidated and reflected in the Iraqi healthcare system. Therefore, the aim of this study was to evaluate the impact of clinical pharmacist intervention on the management of patients with common chronic diseases.

(ii) Methods: a randomised controlled trial study was performed with 125 patients with one or more of these conditions: hypertension, hyperlipidaemia and Diabetes mellitus. They have divided into two groups i.e. intervention and non-intervention groups.

(iii) Results: The results revealed that pharmacist intervention played a significantly role in the management of chronic diseases given that a significant reduction in the various clinical parameters such as blood pressure, lipid profile, HbA1c and FPG were observed among the intervention group. Apart from development of a therapeutic relationship with the patients, these results are largely amounted to the detection, prevention and resolution of a massive number of DTPs among the patients in the intervention group.

(iv) interpretation & Conclusion: Clinical pharmacist intervention can play a pivotal role in the management of patients with chronic diseases. This could be extended to the other healthcare settings as well. Moreover, clinical pharmacist plays a key role in the achievement of therapeutical goals and avoiding Drug Therapy Problems (DTPs).

Key words: Clinical pharmacy, DTPs and health care setting, Pharmaceutical care and Pharmacist.

تأثير الكشف والوقاية وحل مشاكل العلاج الدوائي على المرضى الذين يعانون من الأمراض المزمنة

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الخلاصة:

المعالجة الدوائية

هي عملية اتخاذ القرار الرشيد ليستتخدم في ممارسة الرعاية الصيدلانية.القرارات السريرية للصيدلاني المختص تتضمن تقييم متطلبات المريض المتعلقة بالدواء،تحديد مشاكل الجرعة الدوائية،وضع اهداف العلاج،اختيار التدخلات و تقييم النتائج.

بيان لطريقة التفكير،الفرضيات، إنشاء العلاقات، واتخاذ القرارات، وحل المشاكل في مجال توفير الرعاية الصيدلية.

الهدف من الدراسة:

العمل الحالي هو دراسة الآثار المفيدة المحتملة لبرنامج المعالجة الدوائية هادفا تنظيم نسبة السكر في الدم والعناصر الدهنية وضغط الدم في المرضى الذين يعانون من ارتفاع ضغط الدم، اختلال الدهون و مرض السكري (نوع الثاني). وثمة هدف آخر هو تخفيض الأعباء على ميزانيات الصحة.

مواد وطرق البحث:

هذه الدراسة أجريت في كانون الثاني/يناير 2019 إلى حزيران/يونيه 2019 في قسم الأمراض المزمنة في مستشفى "كلار العام" في مدينة كلار في العراق. تم اختيار مائة وثلاثون مريضا للمشاركة في هذه الدراسة والتي تم تشخيصهم سابقا أما كمرضى السكري (النوع الثاني)، ارتفاع ضغط الدم، اختلال العناصر الدهنية ,اللذين عندهم اثنين أو أكثر من هذه الأمراض. تم تقسيم المرضى إلى مجموعتين من مجموعة التدخل العلاجي ومجموعة عدم التدخل العلاجي. لمجموعة التدخل تم أجراء عملية المعالجة الدوائية والتي تضمنت الرعاية الصيدلانية وتغيير نمط الحياة بما في ذلك التعديلات الغذائية وممارسة الرياضة البدنية.أما أثناء متابعة فريق عدم التدخل مجرد تسجيل بيانات والمتابعة الشهرية أجريت دون أي تدخلات لمشاكل العلاج. التقييم والمتابعة أجريت لكلا الفريقين في البداية مع الفحص المختبري لمستويات السكر في الدم في حالة الصيام،مستوى المصل لكل من الكولستيرول الكلي، (LDL) البروتين الدهني منخفض الكثافة ،(HDL) البروتين الدهني عالي الكثافة، الدهون الثلاثية، ضغط الدم ومعدل ضربات القلب ومن ثم يكرر شهريا بأستثناء الهيموغلوبين السكري(HbA1c) الذي تم قياسه كل ثلاثة أشهر.

نتائج البحث:

أظهرت الفحص الأولي ضمن نتائج هذا العمل في فريق التدخل وفريق عدم التدخل للمرضى الذين يعانون من ارتفاع ضغط الدم أختلال العناصر الدهنية ومرض السكري (النوع الثاني) أن هناك أعدادا كبيرة من مشاكل العلاج الدوائي، ومستويات مرتفعة لنسبة الكلكوز في المصل في حالة الصيام، ، الهيموغلوبين السكري (HbA1c %) الكولستيرول الكلي، الدهون الثلاثية، البروتين الدهني منخفض الكثافة(LDL) و ضغط الدم مع مستويات منخفظة البروتين الدهني عالي الكثافة (HDL). كنتيجة المعالجة الدوائية في مجموعة التدخل أعداد مشاكل العلاج الدوائي انخفض بشكل كبير أيضا كان هناك انخفاض كبير لنسبة الكلكوز في المصل في حالة الصيام، الهيموغلوبين السكري (HbA1c %) الكولستيرول الكلي، الدهون الثلاثية, البروتين الدهني منخفض الكثافة(LDL) و ضغط الدم مع ارتفاع البروتين الدهني عالي الكثافة (HDL). وأظهرت النتائج في مجموعة عدم التدخل أن غياب دور الصيدلي الاكلينيكي خلال عملية المعالجة الدوائية ازدادت مشاكل العلاج الدوائي بنسبة كبيرة بالمقارنة ببيانات خط الأساس ومستويات الكلكوز في المصل في حالة الصيام، ، الهيموغلوبين السكري (HbA1c %) الكولستيرول الكلي، الدهون الثلاثية، البروتين الدهني منخفض الكثافة(LDL)و ضغط الدم أبقت عالية مع انخفاض في مستوى البروتين الدهني عالي الكثافة (HDL).

الأستنتاج:

أظهرت نتائج هذه الدراسة أن استخدام برنامج المعالجة الدوائية لمرضى ارتفاع ضغط الدم، اختلال العناصر الدهنية، والنوع الثاني من مرض السكري يحسن من نسبة مستوى السكر في الدم والعناصر الدهنية، وضغط الدم، ويمنع المضاعفات المرتبطة بهذه الأمراض. وبالإضافة إلى ذلك قد تساعد في الحد من ميزانية الصحة

Introduction

Traditionally, pharmacist is perceived a person who prepares and dispenses medications. Clinical pharmacy, as a form of medical practice, is relatively a new field in the world of medical sciences generally, and pharmacy, specifically. It is a patient centered service implemented via embracing the strategy of safe, proper and cost-effectiveness use of medications (1). It is proposed that clinical pharmacists can play a pivotal role in healthcare setting with their in-depth knowledge, skills and experience in rationalizing drug therapies and avoiding problems related to medication uses (2). Drug therapy problem (DTP) is defined as unwanted results of medications experienced by a patient that avoids patients from obtaining the optimal results of the therapy which can be categorised into four main problems namely indication, effectiveness, safety and compliance (3). Through a reasonable medical teamwork, clinical pharmacists can contribute in creating a robust care plan in order to detect and resolve these categories of drug therapy problems maximising the opportunity to obtain the therapy aims and goals (4).

In Iraq, over the past few decades, a significant increase in the incident rate of non-communicable diseases was observed,

including the diabetes mellitus, hypertension and dyslipidaemia (5), (6) and (7). This dramatic elevation in the prevalence of above-mentioned diseases poses a serious health threat to the Iraqi population, alongside with an ever-increasing pressure on the health burden of Iraqi economy. Studies performed on variety of health setting are suggesting that that pharmacists' intervention might play a key role in the management of chronic diseases which eventually contribute to the significant reduction in the complications of these chronic diseases with a dramatic decreasing in health care cost (8). However, more robust studies are need in variety of health settings to further elucidate the role of pharmacist intervention on the management of chronic diseases.

Although, globally speaking, many attempts have done to elucidate the role of clinical pharmacist on the overall disease management via implementing pharmaceutical care process and resolution of drug therapy problems. Although, It is believed that Pharmacists in Iraq could face several barriers upon application of the concept of pharmaceutical care (9), further studies are need in Iraqi society to eliminate controversies regarding how crucial the role of pharmacist is, therefore, the main aims and objectives of the current study was to evaluate the role of clinical pharmacist's intervention on the management of diabetes mellitus, hypertension and hyperlipidemia via detection and resolution of DTPs.

Material & Methods

Ethical Approval:

This study was approved by the Ethical Committee of Faculty of Medical Science University of Sulaimani, number # 8. The consent was also achieved from the participants to publish the results of this study.

Study setting:

The study design is a selective control trial. It was conducted during the period of January 2019 to June 2019 at the department of chronic diseases at Public Kalar hospital in Kalar /Sulaimani city in Iraq. Five physicians are working in this medical center. There is one lab, a pharmacy and a special section for blood pressure checking, electrocardiograph and echocardiograph. The physicians have referred those patients willing to attend this study to the researcher.

Patient recruitment:

Patients with one or more of these conditions (type 2 diabetes, hypertension, and dyslipidemia) were recruited to the study. One hundred thirty patients randomly allocated into two groups, i.e. intervention group and non-intervention group using simple randomization process. One hundred twenty-five patients completed the study, 64 and 61 patients in the intervention and non-intervention groups, respectively.

Baseline evaluations:

The baseline evaluations of patients have been performed in which the demographic data, past medical history, current medications, patients' general attitude towards medications and organ assessment's data were gathered among the intervention and non-intervention groups.

Research procedure:

Patients in the intervention group have received pharmacotherapy work up and pharmaceutical care process via a monthly face to face meeting with the pharmacist. Upon the meetings, the pharmacist has attempted to detect and resolve any kind of drug therapy problems including problems related to the indication, safety, effectiveness of medications and patient's compliance toward drugs, and also, patients were adequately advised on life style modifications. While, those of non-intervention groups only received the

conventional health care and the researcher has collected the same parameters from them without attempting at resolving drug therapy problems.

Data collection:

Information regarding the demographic characteristics, disease record, past medication history and laboratory data (FPG, HbA1c, Cholesterol, TG, LDL and HDL) were gathered from patients and then, six months pharmacist intervention were performed (the intervention sheet presented in the in the index) and DTPs were identified in both groups using British National Formulary (BNF), American Diabetes Association (ADA) clinical guideline for the treatment of DM, the American College of Cardiology and American Heart Association (ACC/AHA 2018) guideline for the treatment of hypertension and American College of Cardiology (ACC 2018) guideline for the treatment of hyperlipidaemia. Robust DTPs resolution was performed for the intervention group via implementing pharmaceutical care process described by (3) to show the impact of DTP resolution on the above mentioned parameters.

Results

Baseline characteristics:

Basic characteristics of the participants were gathered and presented in table 1. No significant differences were found intervention and non-intervention groups.

Table (1): Baseline characteristics of the participants

Data	Intervention Group	Non-intervention Group	p-Values
No. of subjects	64	61	ns=0.64
No. of males	41	37	ns=0.90
No. of females	23	24	
Age (year)			ns=0.76
31-40	3	3	
41-50	12	12	
51-60	23	22	
61-77	26	24	
BMI (kg/m^2)			ns=0.92
Normal	12	8	
Overweight	32	35	
Obese	20	18	
Smokers	8	5	ns=0.96
Non-smoker	56	56	

Drug therapy problems:

The results of six consequent monthly interventions and follow-up in the intervention and non-intervention groups have shown the fluctuations in the monthly number of DTPs among both groups *(Figure 1)*. In the intervention group, following pharmacist intervention, a significant reduction in the number of DTPs incidents were observed. The total number of DTPs of the first and last visit were 134 and 32, respectively. In contrast, in the non-intervention group the DTPs numbers remained significantly high throughout the course of the study. The total number of DTPs of the first and last visit were 146 and 190, respectively.

Furthermore, the individual main categories of DTPs were further analysed via given their sub-categories and presented in the Figure 2&3 and Table 1&2

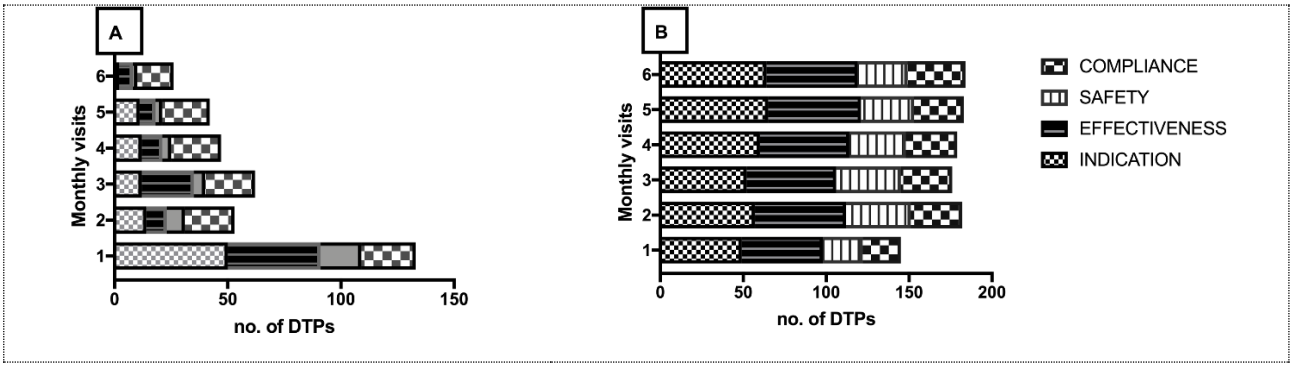


Figure (1): Monthly DTPs categories among the both groups A. intervention group B. non-intervention group.

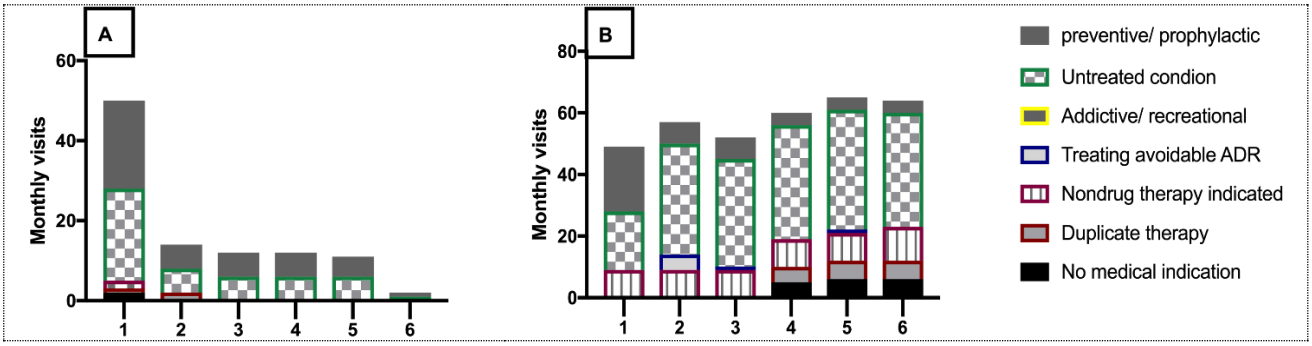


Figure (2): Monthly problems in indication categories among the both groups A. intervention group B. non-intervention group.

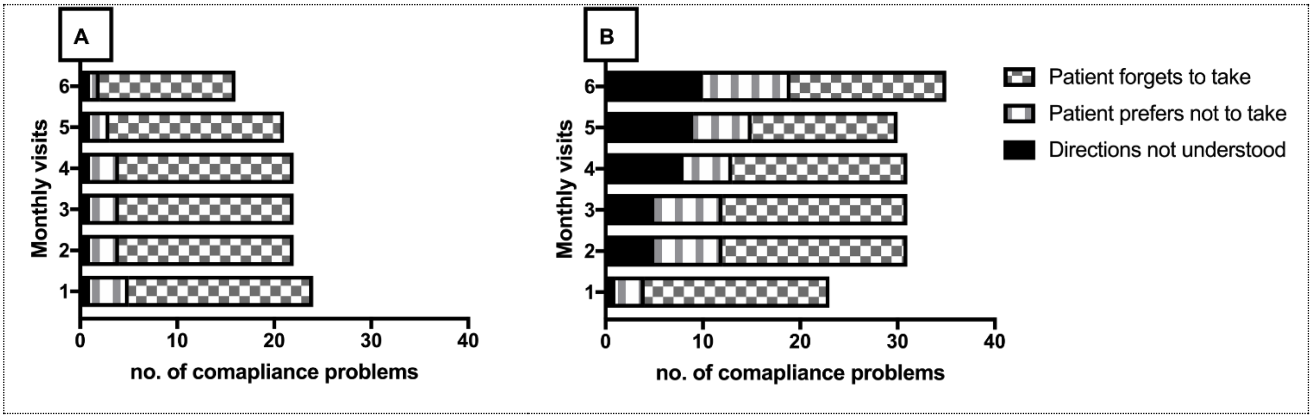


Figure (3): Monthly problems in compliance categories among the both groups A. intervention group B. non-intervention group

Table 2 DTPs related to the effectiveness categories among intervention group

Visits	More effective drug available	Condition refractory to drug	Dosage form inappropriate	Not effective for condition	Wrong dose	Frequency inappropriate	Drug interaction	Duration inappropriate
1	15	3	0	3	4	9	7	1
2	3	1	0	1	1	2	1	0
3	4	1	0	2	1	12	3	0
4	2	1	0	1	1	2	2	0
5	0	1	0	1	1	2	2	0
6	0	1	0	1	0	2	1	1

Table (3): DTPs related to the effectiveness categories among non-intervention group

Visits	More effective drug available	Condition refractory to drug	Dosage form inappropriate	Not effective for condition	Wrong dose	Frequency inappropriate	Drug interaction	Duration inappropriate
1	15	3	0	1	6	10	12	1
2	14	3	0	6	5	13	12	2
3	13	3	0	6	5	12	11	2
4	13	3	0	6	5	12	11	2
5	13	4	1	6	6	11	12	3
6	12	3	1	5	8	10	12	4

Table (4): DTPs related to the safety categories among intervention group

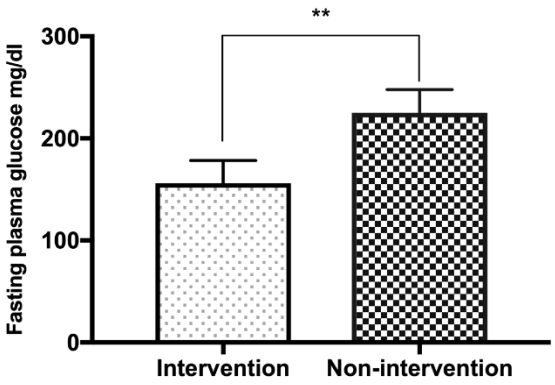
Visits	Undesirable effect	Unsafe drug for patient	Drug interaction	Dosage administered or changed too rapidly	Allergic Reaction	Contraindication present
1	9	0	7	0	1	1
2	3	0	4	0	0	1
3	2	0	2	0	0	0
4	2	0	2	0	0	0
5	1	0	1	0	0	0
6	1	0	1	0	0	0

Table (5): DTPs related to the safety categories among non-intervention group

Visits	Undesirable effect	Unsafe drug for patient	Drug interaction	Dosage administered or changed too rapidly	Allergic Reaction	Contraindication present
1	8	0	12	0	2	2
2	14	0	19	1	3	2
3	14	0	19	1	3	2
4	11	0	15	2	3	2
5	10	0	14	2	3	2
6	11	0	12	2	3	2

Clinical parameters:

Regarding the patients with DM, in addition to DTPs detection and resolution, pharmacist intervention has led to a significant reduction in the mean FPG level among the intervention (156.2±02 mg/dl) in comparison to the non-intervention group (225±22.90 mg/dl) as it is shown in figure 4. The monthly fluctuation of FPG in both groups also presented in Figure 5 which reflects a monthly sustain decline in the mean FPG among the intervention group



Figure(4): Mean fasting plasma glucose level of six months among intervention and non-intervention groups, **pValue= 0.0013

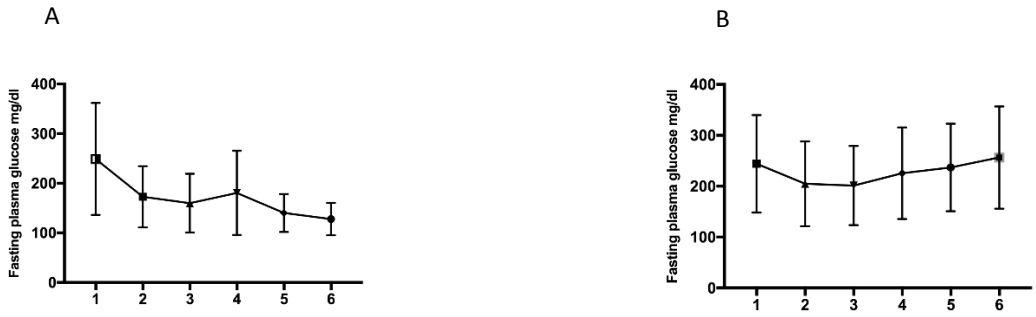


Figure (5): Monthly changes in the mean FPG A. intervention group B. non-intervention group.

In accordance with the data presented above, The results presented in the figure no.6 and 7 shows that pharmacist intervention over the course of six months has also led to a significant reduction in the mean value of glycated haemoglobin (HbA1c) among the intervention group (7.5±1.0) in comparison to the control one (9.1±0.13).

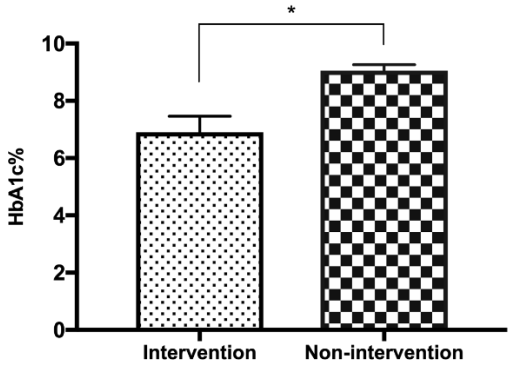


Figure (6): Mean HbA1c% among intervention and non-intervention groups,* pValue= 0.0373

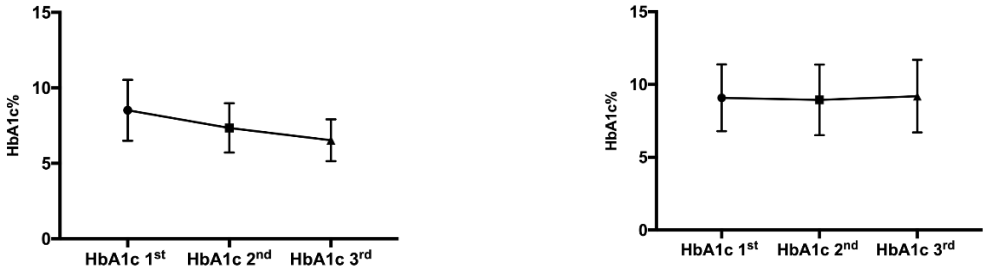
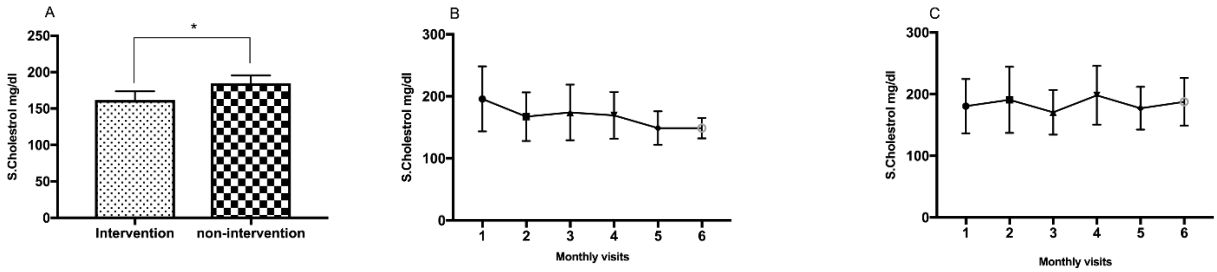


Figure (7): A. Monthly changes in the HbA1c level among the intervention (pValue=0.0001). B. Monthly changes in the HbA1c level among non-intervention group (pValue= 0.8242)

The lipid profile data, presented Figure 8, 9, 10 and 11 are also show that pharmacist intervention plays a key role in the control of plasma lipid level among the intervention group. A significant reduction of total cholesterol (161±12.02 mg/dl), LDL (90.3±4.09 mg/dl), and TG (144.7±11.96 mg/dl),were observed in the intervention group in comparison to the non-intervention one, where the results of cholesterol, LDL and TG were 184.9±10.97, 109.3±7.54, and 220.5±20.75, respectively. The HLD result was in line with the above data which indicates a significant elevation of its value in the intervention group (48.9±3.10) in comparison to the non-intervention one (44.4±2.91)



Figure(8): A. Mean Cholesterol level among intervention and non-intervention group pValue 0.0128 B. Monthly changes in the mean cholesterol level among the intervention group pValue 0.0073 C. Monthly changes in the mean cholesterol level among the non-intervention group pValue 0.99.

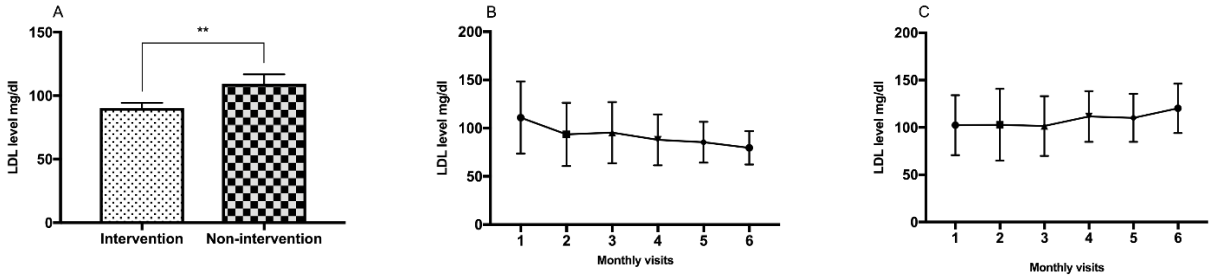


Figure (9): Mean LDL level among intervention and non-intervention group pValue 0.0011 B. Monthly changes in the mean LDL level among the intervention group pValue 0.024 C. Monthly changes in the mean LDL level among the non-intervention pValue 0.019

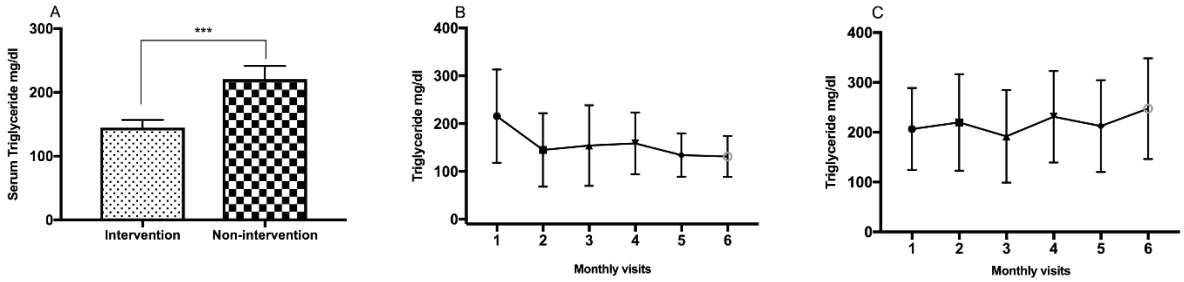


Figure (10): Mean TG level among intervention and non-intervention group pValue 0.0001 B. Monthly changes in the mean TG level among the intervention group pValue 0.0001 C. Monthly changes in the mean TG level among the non-intervention pValue 0.15.

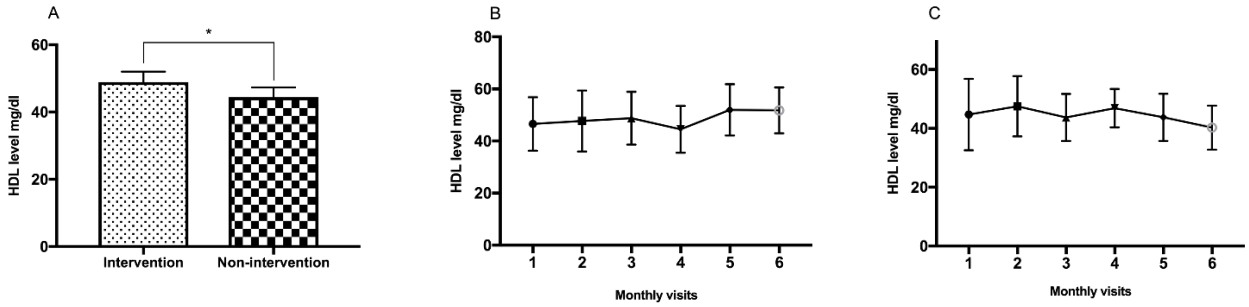


Figure (11): Mean HDL level among intervention and non-intervention group pValue 0.044 B. Monthly changes in the mean HDL level among the intervention group pValue 0.039 C. Monthly changes in the mean HDL level among the non-intervention pValue 0.70

In terms of hypertension, the results presented in figure 12 and 13, are also aligned with other parameters. A significant reduction in the mean systolic and diastolic pressure were observed among patients in the intervention group in comparison to the control ones. The mean systolic and diastolic pressure among intervention group were (129.3±5.24 mmHg), (83.30±1.76 mmHg), while in the control group these values were (144.60±3.84 mmHg) and (92.70±1.8 6mmHg), respectively.

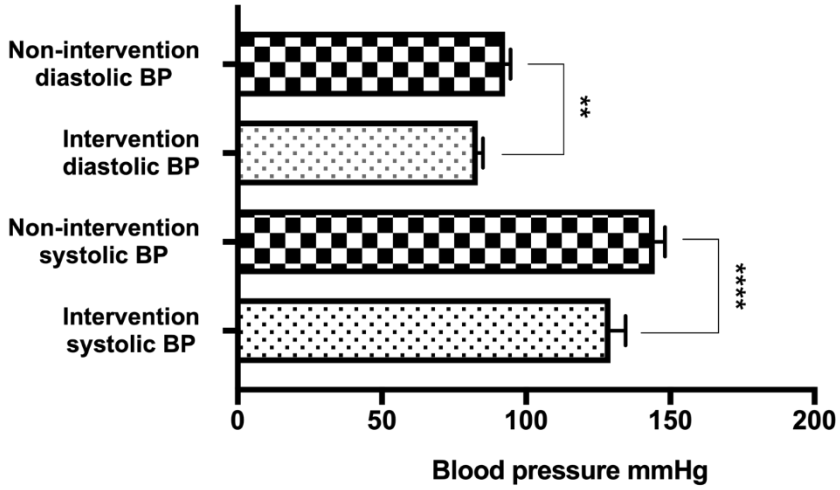


Figure (12): Mean BP measurement among intervention and non-intervention groups pValue **0.0023 ** <0.0001**

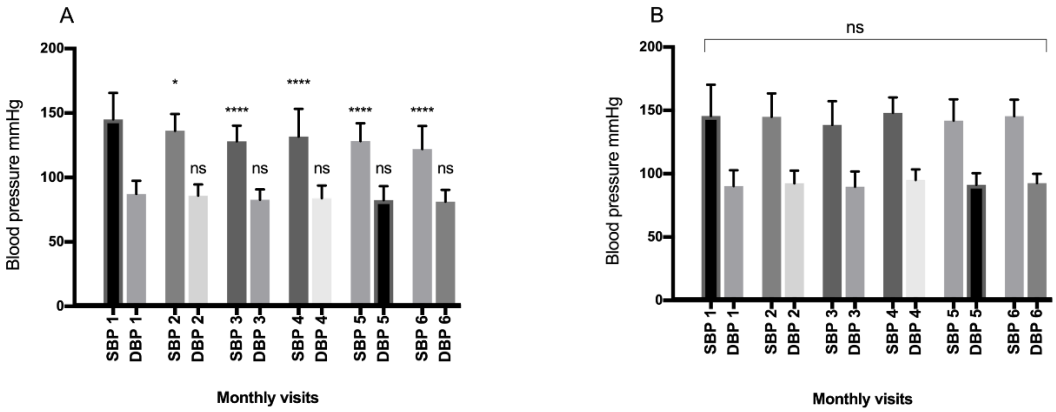


Figure (13): A. Monthly changes in the mean BP among intervention group pValue * 0.0144 **<0.00001 B. Monthly changes in the mean BP among non-intervention group pValue ns> 0.05.**

Discussion

The role of clinical pharmacists as healthcare provider in Iraq is a controversial issue among Iraqi health community. Recently, in accordance with universal developments in their practice as a medical team leader, pharmacists in Iraq have tried to evolve their roles via the application of the concept of clinical pharmacy. To support this attempt, extensive research is needed to elucidate the role of clinical pharmacist through the application of pharmaceutical care process. This is a patient- centered process to meet the drug related needs via a reasonable decision making practice aimed in recognising, resolving and preventing drug therapy problems (3). Our study is one of the few researches in the field of clinical pharmacy conducted in different settings in Iraq to unravel the role of pharmacist as a healthcare provider. During the study time, the researchers have optimised the pharmacotherapy work-up via close work with the physicians, nurses and patients. In this process, the drug therapy was

optimised, individuated, and discussed with the patients in the intervention group. The patient was received adequate education regarding self-management, medication compliance and achieving the therapeutical targets. We have performed an intensive six months follow-up of the patients and any drug related needs were documented and discussed with the physicians. Additionally, for the intervention group, any documented drug related needs were resolved accordingly.

In the current study, we observed a significant reduction in the mean values FBG (156.2±02 mg/dl) and HbA1c (7.5±1.0) among the intervention group in comparison to the control one. The proportion of patient who have reached to FPG <120mg/dl and HbA1c <7% were 33, 45, respectively. However, the same values at the base line were 10 and 12 patients, respectively. These overall reduction in mean FPG and HbA1c play a significant role in reduction of long term complications of diabetes mellitus. Studies have shown that 1% reduction in the HbA1c value, can minimise the risk of macrovascular and microvascular complications by 21% and 37%, respectively (10). Our results are in accordance with the other pharmaceutical care studies carried out at different settings. A study conducted by Mazroui et al (2009) showed that a 12 months intervention and follow up of 240 patients resulted in a significant reduction (by 1.66%) in the mean HbA1c among intervention group (11). Our results are also in agreement with a systematic review conducted by Pousinho et al (2016) in which it was revealed that pharmacist intervention can play a key role in glycaemic control among diabetic patients (8). Another study performed by Mourao et al (2013) in Brazil with 129 patients revealed that clinical pharmacists' intervention resulted in a significant reduction in both HbA1c (0.7%) and FPG (21.4mg/dl) levels among the intervention group (12)(11).

In terms of the impact of clinical pharmacist intervention on the lipid profile of the participants, our study results indicate that pharmacist intervention plays a pivotal role in the tight control of lipid profiles. Results showed a significant reduction in the values of total cholesterol (161±12.02 mg/dl), LDL (90.3±4.09 mg/dl), and TG (144.7±11.96 mg/dl) among the intervention group in comparison to the control group, where the values were 184.9±10.97, 109.3±7.54, and 220.5±20.75, respectively. The results also indicate an elevation in the mean HDL level (48.9±3.10 mg/dl) among the intervention group. These results are in consistent with other studies performed in different settings. A study conducted by Villa et al., 2009, over the course of 32 weeks period with 142 patients indicated a significant improvement in total cholesterol (230 ± 40, pValue<0.0001) , LDL (136 ± 42, pValue<0.0001), and triglycerides (253 ± 19 pValue 0.009) in the intervention group as compared with the control one. On the other hand, our results are also consistent with a systematic review conducted by Charrois et al (2012), revealing that Patients in the pharmacist intervention groups were almost twice as likely as patients in the standard care groups to achieve targets via lipid-lowering therapy.

Our study results also indicated a significant decrease in the SBP (129.3±5.24 mmHg) and DBP (83.30±1.76 mmHg) compared with the same values among the non-intervention group, (144.60±3.84 mmHg) and (92.70±1.86mmHg), respectively. The results also indicated that 72% of patients achieved the targeted blood pressure of < 140/90 mmHg versus 20% in the non-intervention one. The present study is in line with a six year retrospective data collection performed by (13). the results of this study showed that pharmacist intervention plays a pivotal role in the management of blood pressure. Another study conducted by Vivian et al (2002)

chiya with 56 patients over the course of 6 months. Twenty-one (81%, p < 0.0001) patients in the intervention group obtained their blood pressure goal of below 140/90 mmHg at the completion of the study versus only eight (30%) in the control group. Another study has shown that a 12-month pharmaceutical care practice significantly reduced the (P<0.001) in SBP and DBP (11).

These clinical achievements among the intervention group can be largely amounted to the detection, prevention and resolution of DTPs. Our results have shown that clinical pharmacist intervention contributed in detecting of a significant number of DTPs among both groups, i.e. intervention (134 on first visit) and non-intervention (146 on first visit) groups. In the intervention group, this number has reduced into 32 via six months continuous intervention. However, in the non-intervention group, the number of DTPs have reached to 190 by the end of our study. Figure 1 indicated that majority of the DTPs are related to the non-compliance and ineffectiveness of the medications. Continuous pharmacist engagement with the patients resulted in the development of a strong relationship with the patients which in turn it has participated in a significant improvement in the compliances towards medications. In contrast to the non-intervention group, number of non-compliant patients in the intervention group have reduced from 24 to 16 while the same values in the non-intervention group were 23 and 35, respectively. These results are consistent with a minireview performed by (14) who showed evidences that clinical pharmacist can detect and resolve a significant number of DTPs, which in turn maximize the positive clinical outcomes. Another study conducted by (15) with a group of patients on statin medications showed that the pharmacist intervention resulted in a significant increase in the medication accordance in the intervention group compared to the non-intervention one. Further, another study performed by Jabri et al (2019) revealed that pharmacist play a key role in increasing medication compliances in patients with acute coronary syndrome (16).

Conclusion

In conclusion, pharmacist intervention and providing pharmaceutical care process can play a pivotal role alongside with other medical care processes in maximizing positive clinical outcomes. In the current study, clinical pharmacist intervention has contributed to the detection, prevention and resolution of an enormous number of DTPs which in turn it has led to a significant improvement of patients' clinical outcomes. The result of our study has the potentiality to be extended to the other medical settings in Iraq and across the globe.

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Conflict of interest

We confirm that there is no conflict of interest

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