Incidence of stroke with uncontrolled DM: effect of pharmaceutical care intervention to DM type-2 patients in Iraqi hospitals.

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Abstract: Diabetes is a chronic disease that is associated with high morbidity and mortality from its complications. The aim of this study was to describe the role of the pharmacist as a health care provider and the implementation of a pharmaceutical care model to improve blood sugar level, lipid profile, medications adherence and knowledge in a sample of Iraqi patients suffering from DM and evaluate the incidence of stroke with uncontrolled DM patient. A total of 70 patients, whether their blood sugar was controlled or not, were enrolled in the study and randomly classified into either control group (CG) or intervention group (IG); both received the usual hospital care and kept on their antihypertensive. Patients in the IG, beside the usual hospital care, received a pharmaceutical care program described in the methods. All patients visited the clinic monthly up to three months for check and evaluation. Significant improvements were observed in the studied parameters for the IG compared with the CG, at the end of the study, although there was no significant difference (P > 0.05) between them in demographics and characteristics at the baseline. evaluated the studied parameters at the baseline and at the end of the study for both groups. For control group regarding FBG, HbA1C, TG and cholesterol at baseline and the end of study results revealed non-significant difference in each of FBG(P=0.497), HbA1C (P= 0.11), TG (p=0.177) and cholesterol (p=0.36). While in response to the pharmaceutical care intervention, results at the end of the study for the intervention group, compared with the base line, revealed a statistically significant reduction (P < 0.05) in all FBG, HbA1C, TG and cholesterol. Regarding medications adherence findings showed that 10 of 35 patients (28.57%) had low adherence, 19 of 35 patients (54.29%) had intermediate adherence and 6 of 35 patients (17.14%) had high adherence for control group at baseline and that not be changed at the end of the study. Regarding the intervention group was at a baseline 13 of 35 patients (37.14%) had low adherence, 15 of 35 (42.86%) had intermediate adherence and 7 of 35 (20%) had high adherence, at the end of study results highly improved, that 2 only of 35 patients (5.17%) had low adherence, 6 of 35 patients (17.14%) had intermediate adherence and all 27 of 35 patients (77.14%) had high adherence. Also for control group the result revealed that the patient which developed to have a stroke increased to 8 of 35 patients (22.8) after was 4of 35 patient (11.42). Respecting that in intervention group that the patients had stroke was 5 of 35 patients (14.28%) at a baseline and in the end of the study developed to 7of 35 patients (20%) with a stroke. At the end of study the patients knowledge for control group not significant improved (p=0.638) while there...
was a significant improved (p= <0.001) for intervention group. Conclusion: Pharmacist intervention can significantly improve Blood sugar level, lipid profile, medication adherence and patients’ knowledge.

Key words: DM, Stroke, Medication, adherence, Pharmaceutical care, Pharmacist intervention


Introduction:

Diabetes is a chronic disease that is associated with high morbidity and mortality from its complications. In 2014, diabetes caused 4.9 million deaths globally. The International Diabetes Federation estimates that 246 million adults worldwide have diabetes mellitus and will increase to 439 million adults by 2030 in developed countries (1).

Diabetes mellitus (DM) describes a metabolic disorder of multiple etiologies characterized by chronic hyperglycemia with disturbances of carbohydrate fat and protein metabolism resulting from defects in insulin secretion, insulin action or both. Hyperglycemia leads to spillage of glucose into urine, hence the term diabetes-sweet urine. DM involves not only a deficiency of insulin but also an excess of certain other hormones such as growth hormones, glucocorticoids and glucagon (2).

Untreated diabetes can cause many complications. Acute complications include diabetic ketoacidosis and nonketotic hyperosmolar coma. Serious long-term complications include heart disease, stroke, kidney failure, foot ulcers and damage to the eyes.

There are three main types of diabetes mellitus:

• Type 1 DM results from the body's failure to produce enough insulin. This form was previously referred to as "insulin-dependent diabetes mellitus" (IDDM) or "juvenile diabetes". The cause is unknown
• Type 2 DM begins with insulin resistance, a condition in which cells fail to respond to insulin properly and referred to as "non insulin-dependent diabetes mellitus" (NIDDM) or "adult-onset diabetes". The primary cause is excessive body weight and not enough exercise.
• Gestational diabetes is the third main form and occurs when pregnant women without a previous history of diabetes develop a high blood glucose level.

Prevention and treatment involves a healthy diet, physical exercise, not using tobacco, and being a normal body weight. Blood pressure control and proper foot care are also important for people with the disease. Type 1 diabetes must be managed with insulin injections. Type 2 diabetes may be treated with medications with or without insulin. Insulin and some oral medications can cause low blood sugar. Gestational diabetes usually resolves after the birth of the baby (3).

People with diabetes should receive DSME (Diabetes self management educations) and diabetes self-management support (DSMS) which are depend on support informed decision making, self-care behaviors, problem solving, and active collaboration with the health care team to improve clinical outcomes, health status, and quality of life in a cost-effective manner.
Education helps people with diabetes initiate effective self-management and cope with diabetes when they are first diagnosed (4).

The essential issues for managing of diabetes are patient's compliance to strict dietary, exercise, self care behavior, and medication regimens (5). And Poor compliance seems to be a significant barrier to the attainment of positive clinical outcomes among diabetes patients in both developed and developing countries (6).

Also having concomitant disease, diabetes patients usually use poly pharmacy, the greater the number of medications, the more drug related problems such as adverse drug reaction, drug interaction, medication non-compliance, no valid medical indication, and so on (5).

Increased pharmaceutical compliance was associated with fewer emergency department visit and patient admissions. Increased medication adherence was associated with decreased medical care cost (7). In recent years, pharmacists in many practice settings have begun providing patient centered services with the goal of improving drug therapy outcomes through practices such as pharmaceutical care (PC). These PC programs have been found useful in improving the quality of care of patients with various diseases. Pharmacist's interventions in diabetes have also resulted in beneficial outcomes (8).

Aim of the study:

To evaluate the incidence of stroke with uncontrolled DM and the effect of pharmaceutical care for DM type-2 patients in Iraqi hospitals.

Patients and Methods:

Patients:

The study was carried on 70 type 2 diabetes patients from those attending the Specialized Center for Endocrinology and Diabetes for routine follow up, during the period from May (2018) to March (2019) in Al-muthann town/Iraq.

Included patients:

1. Patients were diagnosed with type 2 diabetes mellitus and/or patients that were receiving oral hypoglycemic therapy.
2. Patients aged between 20 to 80 years old and having ability to communicate verbally.

Excluded patients

1. Patients who were diagnosed of Type 1 diabetes (to avoid complexity in the study scope).
2. Patients unable verbally to communicate ex: (deaf, senile dementia, or Alzheimer's disease).
3. They were unable to undertake self-care or do not receive medications by themselves.
4. Patients who were pregnant (they are generally not allowed to participate in the study of this nature by the institutions used for the study).
5. Patients who expressed willingness to withdraw from the study (participation is voluntary).
Method

Study design:

The study was a prospective, randomized, controlled trial in which patients were selected to have non-significant variation in terms of demographics and pre-treatment clinical presentation. It was conducted with 70 type 2 diabetes patients, they divided randomly into two groups: (i) pharmaceutical care (intervention) group (n=35), and (ii) the control group (n=35). Both received the usual hospital care. The intervention group beside the usual hospital care, patients received the proposed pharmaceutical care that included general and individual education. Face to face interviews (for approximately 25 min) at baseline were conducted for selection, evaluation, grouping and education. Patients in the pharmaceutical care group (intervention group) were asked to visit the clinic monthly up to three months in a regular manner with continuous weekly telephone calling for check, evaluation, continual education, blood sugar measurement, lipid profile measurement and ensuring compliance.

Patients in the control group, who were receiving the usual hospital care only, were asked to visit the clinic monthly as usual for check and evaluation (blood sugar level and lipid profile).

Patients in both groups, after enrolled the study were kept on the same or a modified antidiabetic therapy, according to physician recommendations, the two groups became similar in terms of demographics and the provided treatments.

Study Tools:

Data collection:

General Demographic Data:

At baseline, patient’s details were collected by making patients’ interviews and suitably designed data collection sheet contained: (Name, age, gender, body mass index, education status, telephone number). Medical Data (Family history of diabetes, duration of diabetes, type of treatment, having hypertension, hyperlipidemia or other complications).

Sources of Data:

All necessary data was collected from the following sources:

1. Patient data collection form.
2. Patient case history.
3. Patient prescriptions.
3. Laboratory data.

Questionnaires:

1. Patient’s medication adherence.
2. Patient’s knowledge
Blood Sugar measurements:

Blood sugar testing requires the use of a small electronic device called a glucometer. The meter reads the amount of sugar in a small sample of blood, usually from the fingertip, that you place on a disposable test strip.

In general the following points follow when blood sugar measure (9):

1. Wash and dry the hands well.
2. Insert a test strip into the meter.
3. Prick the side of the fingertip with the needle (lancet) provided with the test kit.
4. Gently squeeze or massage the finger until a drop of blood forms.
5. Touch and hold the edge of the test strip to the drop of blood.
6. The meter will display the blood glucose level on a screen after a few seconds.

The American Diabetes Association generally recommends the following target blood sugar levels:

• Between 80 and 130 mg/dl (4.4 and 7.2 mmol/L) before meals at least 6 hours.
• Less than 180 mg/dl (10.0 mmol/L) two hours after meals.

Measurements of body mass index (BMI): weight, height

The weight was measured in kilogram without shoes using a standing weighing machine. Checks on the scale were made routinely before recording the weight of each patient and the pointer was adjusted to zero using the screw provided, reading was taken to the nearest 1 kg. The height was taken barefooted in centimetre using standard measuring tape; reading was taken to the nearest 1 cm. Then by equation: \( \text{BMI} = \frac{\text{weight}}{\text{height}^2} \text{ (kg/m}^2) \) (10).

Blood sampling:

Blood samples were withdrawn from all patients enrolled in study by the nurse working in Specialized Center for Endocrinology and Diabetes, and the blood samples were used for determination of Fasting plasma glucose (FPG), glycated hemoglobin (HbA1c) and lipid profile.

Patients’ education for the intervention group:

1. General instructions (verbal and written).
   - The educational/training program for verbal education for the patients consisted of 3 sessions of 30 to 45 min each session consists of (3-7) patients. The program covered the following areas:
     diabetes overview and its complications, self-monitoring blood glucose techniques and interpretation of diabetes related tests, medications and their side-effects, life style modification, effect of obesity, exercises and meal plan.
   - Written education by patients’ leaflet information and pictures in Arabic language that were distributed to the patients to take them home. The leaflet containing information about diabetes, its complications, signs, symptoms of hyperglycemia and hypoglycemia, importance of exercise and lifestyle modification and treatment.
2- Individual instructions.

Individual interview with the patient by using open-ended questions. Each patient received a 15-20 minutes in the interview for teaching patients to take their prescribed medications correctly may be as important as the medication itself because, without a good understanding, patients may take it incorrectly, with poor outcomes. Also to resolving problems associated with patient’s medication.

Measured parameters:

Primary parameters were measured for both (control and intervention) groups at the baseline and monthly up to three months which are (Fasting plasma glucose (FPG), glycated hemoglobin (HbA1c), lipid profile, medication adherence, knowledge).

For the intervention group, monthly follow-up and measurements were important for early detection of problems that are related to poor DM control.

For the control group, monthly follow-up only for receiving the traditional services provided by the hospital clinic.

1. Blood test:

To investigate the fasting plasma glucose (FPG), HbA1c, and lipid profile were measured and recorded routinely every month for 3 months.

2. Patient’s medication adherence:

Patients adherence was evaluated by specific questionnaire contained 9 questions (11) and evaluation based on: Six or more answers with “yes” mean high adherence, four or five answers with “yes” mean intermediate adherence and three or less answers with “yes”=low adherence.

3. Patient’s knowledge:

Patients’ knowledge were assessed by using a standardized and structured questionnaire (12), which contained 30 questions. If patient’s answered to each question was positive take 1 score and if negative take 0 score.

Results:

All of 70 patients who completed the study (35 patients in the intervention group and 35 patients in the control group). At baseline, the intervention and control group were comparable and there was no significant difference (p > 0.05) between values of the two groups with respect to age, gender, education status, family history with DM, duration of DM, complications and type of therapy, body mass index. The both groups showed equal characters (Table -1).
(Table -1): Baseline demographics and clinical characteristics of patients enrolled in the study.

<table>
<thead>
<tr>
<th>variables</th>
<th>status</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control N= (35) (%)</td>
<td>Intervention N=(35) (%)</td>
</tr>
<tr>
<td>Sex</td>
<td>19(54.3)</td>
<td>18(51.4)</td>
</tr>
<tr>
<td>female</td>
<td>16(45.7)</td>
<td>17(48.6)</td>
</tr>
<tr>
<td>Age</td>
<td>0.728</td>
<td></td>
</tr>
<tr>
<td>18-40</td>
<td>4(11.4)</td>
<td>4(11.4)</td>
</tr>
<tr>
<td>41-60</td>
<td>20(57)</td>
<td>21(60)</td>
</tr>
<tr>
<td>661-80</td>
<td>11(31.4)</td>
<td>10(28.5)</td>
</tr>
<tr>
<td>BMI</td>
<td>24.29+/- 3.53</td>
<td>26.47+/- 4.48</td>
</tr>
<tr>
<td>Education status</td>
<td></td>
<td>0.284</td>
</tr>
<tr>
<td>illiterate</td>
<td>14(40)</td>
<td>17(48.6)</td>
</tr>
<tr>
<td>Primary education</td>
<td>10(28.6)</td>
<td>11(31.4)</td>
</tr>
<tr>
<td>Secondary education</td>
<td>7(20)</td>
<td>5(14.3)</td>
</tr>
<tr>
<td>University education</td>
<td>4(11.4)</td>
<td>2(5.7)</td>
</tr>
<tr>
<td>Duration of DM(year)</td>
<td></td>
<td>0.78</td>
</tr>
<tr>
<td>0-5</td>
<td>17(48.6)</td>
<td>22(62.7)</td>
</tr>
<tr>
<td>6-10</td>
<td>9(25.7)</td>
<td>7(20)</td>
</tr>
<tr>
<td>11-15</td>
<td>6(17.1)</td>
<td>1(14.3)</td>
</tr>
<tr>
<td>16-20</td>
<td>3(8.6)</td>
<td>1(2.9)</td>
</tr>
<tr>
<td>Family history of DM</td>
<td></td>
<td>0.115</td>
</tr>
<tr>
<td>negative</td>
<td>16(45.7)</td>
<td>18(51.4)</td>
</tr>
<tr>
<td>positive</td>
<td>19(54.3)</td>
<td>17(48.6)</td>
</tr>
<tr>
<td>Complication</td>
<td></td>
<td>0.151</td>
</tr>
<tr>
<td>Without complication</td>
<td>9(35.71)</td>
<td>10(28.57)</td>
</tr>
<tr>
<td>Hypertension with or without stroke</td>
<td>4(11.42)</td>
<td>5(14.29)</td>
</tr>
<tr>
<td></td>
<td>12(24.3)</td>
<td>10(28.57)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>10(28.57)</td>
<td>10(28.57)</td>
</tr>
<tr>
<td>Type of DM therapy</td>
<td></td>
<td>0.76</td>
</tr>
<tr>
<td>Mono -therapy</td>
<td>7(20)</td>
<td>7(20)</td>
</tr>
<tr>
<td>di- therapy</td>
<td>14(40)</td>
<td>13(37.14)</td>
</tr>
<tr>
<td>Tri-therapy</td>
<td>10(28.57)</td>
<td>10(28.57)</td>
</tr>
<tr>
<td>With insulin</td>
<td>4(11.42)</td>
<td>5(14.29)</td>
</tr>
</tbody>
</table>

N: number of patients; %: percentage, BMI: body mass index, DM: diabetes mellitus.

Comparisons of patients’ clinical characteristics were tested by Chi-square test except the age; BMI and duration of antihypertensive were tested by student “t”

(Table-2) evaluated the studied parameters at the baseline and at the end of the study for both groups. For control group regarding FBG, HbA1C, TG and cholesterol at baseline and the end of study results revealed non-significant difference in each
of FBG (P=0.497), HbA1C (P= 0.11), TG (p=0.177) and cholesterol (p=0.36). While in response to the pharmaceutical care intervention, results at the end of the study for the intervention group, compared with the base line, revealed a statistically significant reduction (P < 0.05) in all FBG, HbA1C, TG and cholesterol.

the result also revealed that the patient in control group which developed to have a stroke increased to 8 of 35 patients (22.8%) after was 4 of 35 patient (11.42%). respecting that in intervention group that the patients had stroke was 5 of 35 patients (14.28%) at a baseline and in the end of the study developed to 7 of 35 patients (20%) with a stroke.

Patients knowledge evaluated for control group which found that not significant improved (p=0.638) while there was a significant improved (p= <0.001) for intervention group.

Regarding medications adherence findings showed that 10 of 35 patients (28.57%) had low adherence, 19 of 35 patients (54.29%) had intermediate adherence and 6 of 35 patients (17.14%) had high adherence for control group at baseline and that not be changed at the end of the study. Respecting the intervention group was at a baseline 13 of 35 patients (37.14%) had low adherence, 15 of 35 (42.86%) had intermediate adherence and 7 of 35 (20%) had high adherence. At the end of study results highly improved, that 2 only of 35 patient (5.17%) had low adherence, 6 of 35 patients (17.14%) had intermediate adherence and all 27 of 35 patients (77.14%) had high adherence.

**Table -2:** Comparison between baseline and the end of the study results for intervention and control groups regarding the studied parameters.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control group (N=35)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(At baseline)</td>
<td>(At the end of study)</td>
</tr>
<tr>
<td>FBG mean(SD)</td>
<td>245.14(88.48)</td>
<td>254.40(50.74)</td>
</tr>
<tr>
<td>HbA1C mean(SD)</td>
<td>10.76(1.708)</td>
<td>10.1(1.55)</td>
</tr>
<tr>
<td>TG mean(SD)</td>
<td>231.43(94.03)</td>
<td>220.34(60.84)</td>
</tr>
<tr>
<td>Cholesterol mean(SD)</td>
<td>25.386(37.33)</td>
<td>251.60(38.29)</td>
</tr>
<tr>
<td>Patient have stroke N (%)</td>
<td>4(11.42)</td>
<td>8(22.8)</td>
</tr>
<tr>
<td>Knowledge (30 mark)</td>
<td>13.11</td>
<td>13.54</td>
</tr>
<tr>
<td>Medications adherence N (%)</td>
<td>Low</td>
<td>10(28.57)</td>
</tr>
<tr>
<td></td>
<td>intermediate</td>
<td>19(54.29)</td>
</tr>
<tr>
<td></td>
<td>high</td>
<td>6(17.14)</td>
</tr>
<tr>
<td>Intervention group (N=35)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(At baseline)</td>
<td>(At the end of study)</td>
</tr>
<tr>
<td>FBG mean(SD)</td>
<td>246 (70.96)</td>
<td>198.30(65.83)</td>
</tr>
<tr>
<td>HbA1C mean(SD)</td>
<td>11.08 (1.737)</td>
<td>8.77(2.102)</td>
</tr>
<tr>
<td>TG mean(SD)</td>
<td>239.6(65.7)</td>
<td>175.20(38.28)</td>
</tr>
<tr>
<td>Cholesterol mean(SD)</td>
<td>233.90(28.96)</td>
<td>179.50(14.71)</td>
</tr>
<tr>
<td>Patient have stroke N (%)</td>
<td>5(14.28)</td>
<td>7(20)</td>
</tr>
<tr>
<td>Knowledge (30 mark)</td>
<td>12.54</td>
<td>25.9</td>
</tr>
<tr>
<td>Medications adherence N (%)</td>
<td>Low</td>
<td>13(37.14)</td>
</tr>
<tr>
<td></td>
<td>intermediate</td>
<td>15(42.86)</td>
</tr>
<tr>
<td></td>
<td>high</td>
<td>7(20)</td>
</tr>
</tbody>
</table>

N: number of patients; SD: standard deviation, %: percentage; FBG: fasting blood glucose; TG: triglyceride; HbA1C: hemoglobin A1C; “t” test was used to evaluate each of FBG, HbA1C, TG, Cholesterol, patients’ knowledge., Chi-square test was used to evaluate Medications adherence. Bolded p-values means that there is a statistically significant difference (P-value < 0.05).
Discussion:

Pharmacist is part of a multi-disciplinary team. This team normally consists of pharmacist, physician, nurse, technician, nutritionist, and other health care professions. All of the members in multidisciplinary team have important roles in diabetes management in achieving the goal of treatment, improving quality of life, controlling disease and its complications, delaying complication, and decreasing mortality and morbidity. Pharmacists’ interventions are an important factor to improve glycemic control in diabetic patients and that include diabetes education and counseling on drug, disease, diet, exercise, life style modification, and self-management, assessment and adjustment of anti-diabetic medications, identifying and solving drug-related problems, co-operation with physician and other diabetes health care team, providing materials that reinforce patients to achieve a target goal. All of these interventions aimed at improving glycemic control (13).

In this study, There were 70 patients who all completed the study (35 patients in the intervention group and 35 patients in the control group) and the data for them analysis showed there were significant reductions in FPG and HbA1c was (246 mg/dl - 198.3 mg/dl) (11.08% – 8.2%) respectively in the intervention group at the end of the study period. But there is no significant glycemic reduction in the control group (245.14 mg/dl - 254.40 mg/dl) (10.76% – 10.1%) respectively.

The lipid profile for both groups also showed there were significant reductions in Cholesterol and TG (233 mg/dl – 179 mg/dl, 239.60 mg/dl – 175.2 mg/dl, respectively) obtained in the intervention group at the end of the study. But there is no significant Cholesterol and TG reduction in the control group.

Improvement of these values seen in the intervention group was probably due to the fact that the patients in this group implemented the recommended to life style modification such as increase exercise and reducing weight, restricted unhealthy food intake as advisable by pharmacist and patients become more knowledge about disease and that lead to increase medication adherence.

Medications adherence of the enrolled patients was assessed by using nine questions which showed non-significant difference between both groups at the baseline.

At the end of the study, results of medications adherence revealed a statistically significant reduction in the number of patients with low adherence (2 of 35 patients: 5.71%) when compared with those at the baseline (13 of 35 patients: 37.14%) for the intervention group. In the other hand, findings at the end of the study revealed a statistically significant increase in the number of patients with respect to both intermediate adherence (6 of 35 patients: 17.14%) and with high adherence (27 of 35 patients: 77.14%) when compared with those at the baseline (15 of 35 patients: 42.86%) and (7 of 35 patients: 20.00%) for intermediate and high adherence, respectively. these results statistically show a significant difference from results of the control group.

Increase in medication adherence obtained could be attributed to the DM and drug education given to patients. Lack of knowledge about blood glucose targets, DM complications and the benefits of antidiabetic medication have been recognized as a barrier to adherence.

Increase knowledge of patients was one of main target in our study by making complete educational system as explained in the methods section, patients’ knowledge measured by 30 questions, the results showed that there was no significant difference between control and intervention groups in almost dimensions of questionnaire at the baseline but after pharmaceutical care the intervention group highly improved. The mean patients' knowledge
statistically was significant increased to (25.910), when compared with mean patients' knowledge (13.540) at the baseline for intervention group and was significantly different (p=0.001) from results of the control group.

Because that the cardiovascular disease including stroke is a major complication that tremendously increases the morbidity and mortality in patients with diabetes mellitus (14).

So in the present study we assessed the relation of stroke with DM and the results revealed that the incidence of stroke in the end of study in controlled group more than with intervention group. in control group was 8 in the end of study after was 4 in the baseline of study while in intervention group was 7 in the end of study after was 5. and this result may due to we get improving in all FBG, HbA1c, TG and cholesterol in intervention group.

**Conclusion:**

Study demonstrates that pharmacist’s interventions achieved significant reduction in mean blood sugar level, HbA1c and lipid profile. Based on these findings, this study concludes that pharmacist’s interventions can be effective in reducing blood sugar level, improving medications adherence, knowledge of DM patients. This study may provide a practice framework for the future development of other studies in pharmaceutical care to DM patients.

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