Role of Clinical Pharmacist in the Management of Type II Diabetes Mellitus and its Outcomes

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Research Article

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Abstract

In India the prevalence of diabetes has grown over the past decade. Diabetic patients develop complications due to poor awareness regarding the disease and inadequate glycemic control. Patient education is the cornerstone of diabetes care and is the most effective way to lessen the complications of diabetes and its management. A total of 91(66 males and 25 females) type 2 diabetes mellitus patients were enrolled and randomized in to test and control groups. Patients in the test group received counselling at each visit whereas control group were not provided with a counselling session. A modified knowledge, attitude and practice (KAP) questionnaire was administered to both test and control group patients at baseline to assess their current knowledge, attitude and practice with respect to their condition. On the basis of KAP analysis a diabetic foot care questionnaire was administered to both test and control group patients at baseline and at follow-up to assess awareness regarding disease management. Blood glucose parameters were also evaluated at baseline and follow-up in both the groups. At the end of the study, the diabetic foot care score of test group patients improved significantly (P<0.05), whereas no significant changes were observed in control group patients. The FBS and PPBS levels decreased significantly in the test group. Whilst a small reduction, which is statistically not significant, was detected in the control group. HbA1C also showed a decrease in the test group. The pharmacist, although not the health care professional to diagnose diabetes, can monitor the patient's blood glucose levels and keep a track of it. Thus our study reveals that pharmacist counselling might be an important element in diabetes management programs.

Introduction

WHO has defined diabetes mellitus as a chronic disease caused by inherited and/or acquired deficiency in production of insulin by the pancreas, or by the ineffectiveness of the insulin produced. Such a deficiency results in increased concentrations of glucose in the blood, which in turn damage many of the body's systems, in particular the blood vessels and nerves [1]. Mr. Keith Vaz, the UK Member of Parliament said that India is the diabetic capital of the world with around 70 million people currently suffering from diabetes. In his talk he explains that people should be made aware of the dangers of the disease and how it affects all the major organs of the body, if untreated (March 2013).

The prevalence of diabetes is rapidly rising all over the globe at an alarming rate. According to the Diabetes Atlas published by the International Diabetes Federation, in India the number of people with diabetes currently around 40.9 million is expected to rise to 69.9 million by 2025, if urgent preventive steps were not taken. IDF released on 2012 says that India stays just next to China that is 60 million in the race to capture first place. According to IDF Atlas data, over 371 million people are diabetics and nearly 90% of the cases are of type 2. New data released by IDF showed that out of the world's 285 million population , India contains 60 million diabetics , and most of them affecting in the employed age group and provides to be an economic burden to the society[2].

The epidemic is gone out of control. "In every country and in every community worldwide, we are losing the battle against this cruel and deadly disease" warned IDF President Jean Claude Mbanya, in his talk on world diabetes day 2011. In India the first national study on the prevalence of type 2 diabetes was done between 1972 and 1975 by the Indian Council Medical Research (ICMR, New Delhi). Subsequent studies showed a rising trend in the prevalence of diabetes across different parts of India[3] .

Diabetes-related complications include micro-vascular diseases (for example, retinopathy, blindness, nephropathy, and kidney failure) and macro-vascular diseases (coronary heart disease, stroke, peripheral vascular disease, and lower-extremity amputation) results indisability [4].

Four major trials were conducted in China, Finland, Sweden, and the United States. These studies demonstrated that intensive lifestyle interventions involving a combination of diet and physical activity can delay or prevent diabetes among people at high risk.[5] In such Diabetes Prevention Program, the goals of the intensive lifestyle intervention were weight loss of 7 percent of baseline bodyweight through a low-calorie diet and moderate physical activity for at least 150 minutes per week. After 2.8 years of follow-up, the average weight loss was 4.5 kilograms for those in the lifestyle intervention group and less than 0.3 kilograms for those in the placebo group[6].

To this end, diabetes education is of critical importance and should be considered an integral part of diabetes prevention and care[7]. Education training is important since people with diabetes and their families provide 95% of their care themselves. Without appropriate education people cannot make the complex daily medical decisions required for good health, quality of life and survival.

Material and Method

A prospective interventional study on role of clinical pharmacist in the management of type 2 diabetes mellitus and its outcomes was conducted in Kovai Medical Centre and Hospital, Coimbatore.

Objective:
Primary Objectives -
- Assessment of patient knowledge about diabetes, attitude towards the condition and practice with respect to the condition (KAP).
- Assessment of patient knowledge about diabetic foot care and provide a diabetic foot care education .

Secondary Objectives
- To study the pattern of drug prescribing among study population.
- To provide general education about diabetes and improves patients ability to cope with their disease.

Study Period:
The study was carried over a period from the month of January 2014 to July 2014.

Study Population:
 Inclusion Criteria:
- Type 2 DM patients visiting the OPD during the study period.
- Patients above 20 years who have the ability to communicate verbally.
- Patient from whom oral consent is received.

Exclusion Criteria:
- People with type I and gestational diabetes; psychiatric illness patients
- patients unable verbally to communicate

Study Materials:

1) Modified Knowledge, Attitude, Practice (KAP) Questionnaire (Adopted from Stanford Patient Education Research Centre) prior to starting any educational program it is appropriate to gauge the awareness level of the community under study by conducting a KAP study.

Part I - Patient's diabetes knowledge questionnaire. Among the total 25 questions in KAP questionnaire 15 questions related to knowledge about diabetes. A system of point allocation was employed with 1 point being awarded for each correct response and none for incorrect answer.

Part II: Attitude Questions
 There are 5 questions to assess the attitude of the patient towards the disease on a 5 point likert scale.

Part III: Practice Questions : questionnaire has been used in previous KAP studies among diabetics and has proven to be reliable. There are 5 questions regarding practices which reflect how the patients put their knowledge and attitude in to action.

2) Diabetic Foot Care Questionnaire
The section on diabetic foot care knowledge consists of 15 questions. A scoring system was developed, in which each correct answer was given a 1 point.

3) Data Collection Form
This is the diabetes initial evaluation form used to collect individual details like socio demographic details; lab investigations; glucose testing; current activity & exercise; meal plan etc.

Study Procedure:
Out of 120 patients there were 91 patients who completed the study. That is 46 patients in intervention group and 45 patients in control group came for their next review.
The whole study consists of 6 phases:

Phase I: includes the preparation of data collection form, KAP questionnaires and diabetic foot care questionnaires. This phase also includes the preparation of various supportive materials for patient education.

Phase II: includes random selection of patients and divided in to 2 groups.

Control Group:
- Random selection of type 2 diabetic patients from general population.
- Patient receives treatment in the hospital from the department of diabetology.

Intervention (Test) Group:
- Random selection of type 2 diabetic patients from general population.
- Along with general care setup in hospital, they were provided with a counseling session.

Phase III: once the patients were categorized in to 2 groups then the KAP and diabetic foot care knowledge were assessed in both groups.

Phase 1V: since there are no specific standards for diabetic counselling, the KAP and diabetic foot care questionnaire responses were analysed and used to develop an appropriate counselling program. In our study, counselling is given only for test group.

Phase V: the effect of pharmacist counselling is assessed in this phase by means of diabetic foot care questionnaire and by comparing the changes in parameters like FBS, PPBS and HbA1C between intervention (test) and control groups.

Phase VI: this phase includes statistical analysis.
The data were entered in to a Microsoft Excel Spreadsheet, after data cleaning, SPSS (Statistical Package for the Social Sciences-Version 20) package software program were used for statistical analysis. In total study population the relationship between knowledge and attitude &knowledge and practice responses were analysed by using Chi-square.
The improvement in diabetic foot care knowledge during each visit was analysed by means of Wilcoxon Sign test and Mann Whitney U- test in test and control group.
Blood glucose parameters in both test and control groups were compared by means of two-tailed unpaired t test. p< 0.05 was considered significant

Results
Out of 91 patients in the total study population, control group consists of 45 patients and intervention group consists of 46 patients
Response to Knowledge, Attitude and Practice Questionnaires
In our study it is encouraging to note that the majority of respondents had average basic knowledge regarding DM. Even though respondents knowledge of diabetes was an acceptable level but there were areas of deficiency.
About 86% of the total study population had a positive attitude towards their condition and had the desire to control DM but lacked the will to do so.
It was found that our respondents performed a worst practice in foot care and eye care. In our study we observed that only 15 (16%) went for a yearly visits to ophthalmologist while 25(27%) were of the opinion that they should do consultation

only when a problem arises. Only 16(18%) recognised the importance of foot care and only 2(2%) had a proper foot care practice among our study population.

Table 1: Demographic Details of Both Groups

Variables	Control N (%)	Test N (%)
Age groups		
Below 30	1 (2.22)	1(2.17)
30 - 49	15(33.33)	10 (21.73)
50 - 69	26(57.77)	30 (65.21)
Above 69	3(6.66)	5 (10.86)
Mean ± SD	54.32 ± 11.77	56.39 ± 10.20
Gender		
Male	35 (77.77)	31 (67.39)
Female	10 (22.22)	15 (32.60)
Duration of diabetes		
Below 5 years	22 (48.88)	23 (50)
5 - 10 years	14 (31.11)	17 (36.95)
11 - 20 years	6 (13.33)	5 (10.86)
Above 20 years	3 (6.66)	1 (2.17)
Mean ±SD	6.65 ± 5.78	6.97 ± 15
Family history of DM		
Positive	12 (26.66)	19 (41.30)
Negative	33 (73.33)	27 (58.69)
Occupation		
Employed	31 (68.88)	26 (56.52)
Unemployed	14 (31.11)	20 (43.47)
Level of Education		
Illiterate	4 (8.88)	4 (8.69)
School	26 (57.77)	29 (63.04)
College	15 (33.33)	13 (28.26)

Relationship between Knowledge and Attitude And Knowledge And Practice
In our study there was a positive relationship between the knowledge and attitude (P = 0.00) . But there was no relation between the knowledge and practice responses (P=0.434) . A poor practice response was found among our study population which reflects in their actual control of diabetes mellitus. (Table 2).
Foot care knowledge assessment among study population
It was observed that among the total study population 73 (80.21%) patients had a poor knowledge regarding diabetic foot care. The level of knowledge was found to be similar in both groups. It means that 39 (86.66%) patients in control group and 34 (73.91%) patients in intervention group had poor knowledge regarding diabetic foot care.
Based on the above results it is necessary to provide a foot care counselling. In our study we provided a foot care counselling for intervention group. It was observed that in intervention group, there was an improvement in mean foot care knowledge scores from 5.63 ± 2.27 to 12.32 ± 1.82 after counselling

Table2. Relationship Between Knowledge, Attitude And Knowledge, Practice

Changes In Blood Glucose Parameters

At baseline, FBS value were 191.10 ± 81.90 Vs

		Attitude Range Scores				Practice Range Scores			
		neutral	agree	strongly agree	Total	poor	satisfactory	good	Total
Knowledge Range scores	Poor (<7)	6	23	1	30	17	9	4	30
	Average (7-10)	7	42	3	52	18	23	11	52
	Good (11-15)	0	8	1	9	2	2	5	9
Total no: of patients		13	73	5	91	37	34	20	91
P-value			0.00*				0.434'		

Table3. FBS changes during the study period

FBS Readings	Control (n = 45)	Test (n = 46)
FBS1 (mg/dl)		
Mean	191.10	154.52
SD	81.90	59.13
FBS2 (mg/dl)		
Mean	189.71	131.34
SD	87.77	45.43
P Value	0.870 '	0.046 *

P value < 0.05 is significant

and was found to be statistically significant (P = 0.000). Whereas in control group, there was a slight improvement in mean foot care knowledge scores from 5.04 ± 2.01 to 5.66 ± 2.14 during their first and second visit. But it was found to be statistically not significant (P = 0.181).

Table4. PPBS changes during the study period

PPBS Readings	Control (n = 45)	Test (n = 46)
PPBS1 (mg/dl)		
Mean	284.58	247.97
SD	98.96	92.79
PPBS2 (mg/dl)		
Mean	273.20	208.08
SD	74.93	68.56
P Value	0.630 '	0.021*

P value < 0.05 is significant

154.52 ± 59.13 and PPBS value were 284.58 ± 101.86 Vs 247.97 ± 92.79 in the control and intervention groups respectively. (Table 3 & 4). It was observed that the mean FBS and PPBS shows a trend continuous improvement in the intervention group, but for the control group there is a fluctuations in the second visit, and at the end of the study the improvement of mean FBS and PPBS were observed that reaches statistical significant differences in reduction in FBS and PPBS for intervention group (P= 0.046 and P= 0.020), but statistical significant differences in reduction in FBS and PPBS for the control group were not obtained (P = 0.870 and P =0.630).

Table5. HbA1C changes during the study period

HbA1C Reading	Control (n = 45)	Test (n =46)
HbA1C1		
Mean	8.86	8.82
SD	2.33	2.09
HbA1C2		
Mean	10.87	8.05
SD	2.73	1.67
P Value	0.261'	0.064'

P value < 0.05 is significant

During this study, there are changes in the HbA1C value for both control and intervention groups. In intervention group, it was observed that the mean HbA1C value at the end of the study shows tendency toward lower value than the first visit, but

was not statistically significant (P = 0.064). Whereas the mean HbA1C level in control group during their 2nd visit was found to be increased from 8.86 to 10.87% was not statistically significant   (P = 0.26). (Table. 5)

Our study had provided a baseline data regarding the prescribing pattern in diabetes patients, who were enrolled in our study population. The average number of drugs per prescription was found to be 3.45. Biguanide-sulfonylurea combinations (37%) were the most commonly prescribed anti diabetics. Anti-diabetic medications accounted for more than half of the total prescription. (Table. 6 & 7)

Table 6. Therapeutic category of drugs prescribed   (n = 91)

Therapeutic Classification	No: of drugs	Percentage
Anti diabetics	154	48.73
Cardiovascular drugs	94	29.74
Vitamins, minerals and Dietary supplements	32	10.12
Anticonvulsants	11	3.48
Antidepressants	5	1.58
Anti asthmatics	3	0.94
Gastrointestinal system drugs	5	1.58
Antimicrobials	5	1.58
Analgesics and anti-inflammatory	7	2.22

Prescribing pattern in diabetic patients mainly related to their current co-existing illness. Among the various complications, cardiovascular complications pose a major threat. In our study it was observed that hypertension accounted for 31% of the total complications followed by peripheral neuropathy (26%). (Table. 8)

Discussion

Our study has two important findings in KAP analysis:

- Diabetic patients possess an acceptable level of knowledge even though there were areas of deficiency and had a positive attitude towards their condition.
- There was a positive relationship between the knowledge and attitude. But there was no relation between the knowledge and practice responses. A poor practice response was found among our study population which reflects in their actual control of diabetes mellitus.

Table 7. Class of anti-diabetics prescribed   (n = 91)

Anti-diabetic class	Number of drugs	Percentage (%)
Sulfonylurea + Biguanide	57	37.01
Insulin	35	22.72
Biguanides	17	11.03
DPP4 inhibitors	14	9.09
DPP4 + Biguanides	12	7.79
Sulfonylureas	9	5.84
Alphaglucosidase inhibitors	8	5.19
Alphaglucosidase inhibitor + Biguanide	2	1.29

Table 8.Coexisting illness in study population (n = 9)

Coexisting Illness	Number of Patients	Percentage (%)
Hypertension	49	31
Peripheral neuropathy	41	26
Hyperlipidemia	28	18
Heart failure	19	11
UTI	13	8
Renal failure	3	2
Stroke	3	2
Others	4	3

A study conducted by Ranjini *et al*; (2003) in Malaysia reported that diabetic patients in a primary care centre had good knowledge and better attitude towards the care of their own disease. But they were not reported whether the knowledge and attitude translated in to practices as recommended by the management guidelines. They also did not measure the actual control of DM in their study population[8] .Our study explored the relation between knowledge and attitude and knowledge and practices as reported by the respondents and compare it with actual glycaemic control of diabetics. In our study 62% of the subjects were between 50-69 years of age and being closer to retirement or already retired, they may have different priorities or lack of self-interest. Older

patients may need frequent follow-ups and closer monitoring along with motivation and counselling stressing the importance of life style modifications and self-management.

Since our study population had a poor foot care knowledge and practice we provided a foot care counselling session for patients in intervention group. It is also observed that among our study population about 41 (26%) patients had peripheral neuropathy as a coexisting illness. So the need for foot care counselling is essential for our study population. Similarly, Ekore RI *et al* ; conducted a study to determine the level of awareness and attitude to foot care among adult diabetic patients attending a university health centre. Finally they concluded that awareness of foot care measures is very poor among known diabetic patients and this is largely due to a lack of education of the patients by their health care providers [9] .

Our study shows that better glycemic control was obtained in the intervention group and that the pharmacist education session and follow up calls proved beneficial in reducing mean FBS and PPBS significantly (P = 0.046; P = 0.021) and the mean HbA1C value at the end of the study shows tendency toward lower value than the first visit after counselling, but was not statistically significant (P= 0.064). A study conducted by Mahwi *et al* 2013; in Iraq during the period from 18 Sep 2010 to Jan 2011 observed that a statistically significant reduction was observed in the glycemic levels of patients in the intervention group whilst a small reduction, which is statistically not significant, was detected in the control group.[10]

A study conducted by Ebbesen *et al*;(2001) and Good CB;(2002) found out that poly pharmacy is associated with a higher cost, increased risk of side-effects, drug interactions and non-compliance[11] .So one should be especially aware of the drug interactions between anti diabetics and anti-hypertensive drugs. In our study population about 29.74% of the total prescription was contributed by cardiovascular drugs. Drugs like beta blockers and ACE inhibitors can interact with anti-diabetic drugs. Beta blockers are known to mask the symptoms of hypoglycemia if taken with insulin. Similarly, ACE inhibitors are known to have a hypoglycemic effect.

Conclusion

In conclusion, although overall knowledge about diabetes among our patients was acceptable, there were critical gaps in knowledge. This study has helped identify areas where there were gaps in patient knowledge. Our results suggest that there may not be a direct relation between knowledge and practice. Various issues need to be addressed in order to close the gaps between knowledge and practice. It was also observed that there were a lot of factors beyond knowledge and attitude contribute to disease management. Possible factors could be poor self-management, lack of motivation, inadequate social support or lack of resources that are necessary for sustained lifestyle modification.

The result of this study encourage a positive outlook: all that is required is that a diabetes educator preferably a clinical pharmacist trained in diabetes management counsel patients during every visit and we believed that such counselling program could definitely have immense impact on the

profession of pharmacy, giving it an even greater place in the medical management of patients.

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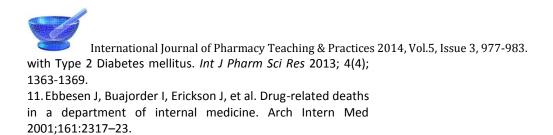
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AUTHORS' CONTRIBUTIONS

Authors contributed equally to all aspects of the study.

PEER REVIEW

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests.