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Abstract

Role of community pharmacists in improving knowledge and glycemic control of type 2 diabetes

Objective: To study the role of the community pharmacists in improving knowledge and glycemic control in patients with type 2 diabetes residing in villages of Coimbatore district, Tamil Nadu. Materials and Methods: Fifty patients were interviewed, of whom 39 subjects were included in the study. The literate and chronic diabetic patients were included in the study and illiterate, children below 12 years of age, pregnant women, nursing mothers and subjects with any other chronic disorders were excluded from the study. The subjects were interviewed and divided randomly into two groups. There were 20 subjects in the control group and 19 in the intervention group. The study protocol was explained to all the participants, and written informed consent was obtained from them. Before the initiation of the study, the subjects were interviewed for 20-40 min to educate them about diabetes. Subjects in the intervention group received continuous counselling and medical advice to improve their awareness about the disease and drugs. During the study period, the Diabetes Care Profile (a questionnaire developed by J.J. Fitzgerald of the Michigan Diabetes Research and Training Center, University of Michigan Medical School, Michigan) was performed to each subject. The interval between visits was 2 months. All the values are expressed in mean \pm standard deviation. **Results:** The intervention group showed better progress in the recovery of diabetics because of the continuous counselling and monitoring. There were significant changes in Diabetes Care Profile subscale scores in both the control and the intervention groups at the end of the study, viz. 1.8 ± 4.52 to 2.75 ± 6.62 and 3.10 ± 3.23 to 1.53 ± 2.66 . Similarly, the knowledge test score was found to be increased in the intervention group compared with the baseline values $(8.53 \pm 1.81 \text{ to } 12.16 \pm 1.34)$. **Conclusions:** At the end of the study period, the patients of the intervention group had very good glycemic control. Their health status and understanding of diabetes and its management were better, and they had fewer problems such as episodes of hyperglycemia or hypoglycemia.

Key words: Community pharmacist, Diabetes Care Profile, type 2 diabetes patients

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INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic disorders characterized by hyperglycemia associated with abnormalities in carbohydrate, fat and protein metabolism and resulting in chronic complications including microvascular, macrovascular and neuropathic complications.^[1] Diabetes is worldwide in distribution, and the prevalence of type 1 and type 2 diabetes varies considerably in different parts of the world. This is probably due to differences in genetic and environmental factors.^[2] It is the fourth leading cause of death in developed countries, affecting 3% of the population and 5-10% of those over 65 years old.^[3] Diabetes can be managed by drug therapy and non-pharmacological therapy. The cornerstone of nonpharmacologic therapy is lifestyle modifications, including nutritional therapy, physical activity and avoidance of smoking.^[4] Education of the patient in diabetes self-care, including self-monitoring of blood glucose levels, is also vital.^[5] The role of pharmacists in diabetes management is essential for identifying patients, assessment, education, referral and continuous monitoring. Pharmacists can help identify patients with diabetes through regular screening procedures.^[6] Patient education should be provided immediately after a diagnosis of diabetes or any other diseases. Later on, patient assessment can be performed, and the patient can be educated to reinforce concepts and provide a motivational boost.^[6] The role of the community pharmacists in monitoring and educating diabetic patients is not well defined. The present study was undertaken to evaluate the role of the community pharmacists in improving knowledge and glycemic control of type 2 diabetes in patients in villages of Coimbatore district, Tamil Nadu.

MATERIALS AND METHODS

The study design involved a repeated intervention versus control design. Two community pharmacies in a rural area of Coimbatore district in the state of Tamil Nadu were selected for the study. The study was carried out for 8 months, from May to December 2005. The study design and protocol were accepted by the proprietors of the community pharmacies. The study protocol and informed consent form were approved by the Institute Human Ethics Committee of Sri Ramakrishna Institute of Paramedical Sciences. Written informed consent was obtained from each participant.

Fifty patients were interviewed, of whom 39 participants met the inclusion criteria and were enrolled in the study. The literate (more than higher secondary level) and chronic diabetic patients (history of type 2 DM of more than 3 years) were included in the study and illiterate, children below 12 years of age, pregnant women, nursing mothers, type 1 DM patients and subjects with any other chronic disorders were excluded from the study. Twenty of these participants were allocated randomly to the control group and 19 were allocated to the intervention group. Pharmacists had a discussion about the study with the eligible patients or their caregivers when prescriptions for diabetes medications were issued. Subjects were included if they had type 2 DM and gave informed consent.

Patient background questionnaire

The study participants completed a seven-item demographic questionnaire, providing information about their sex, age, marital status, education, income level, type of diabetes, length of time since diagnosis of diabetes and presence of other specific health problems.

Diabetes Care Profile: An instrument of the study

The data were collected using Diabetes Care Profile (DCP)-a questionnaire developed by J.J. Fitzgerald of the Michigan Diabetes Research and Training Center (MDRTC), University of Michigan Medical School, Michigan. DCP was developed as an instrument to assess social and psychological factors related to diabetes and treatment.^[7,8] The questionnaire was translated into the local language, as is frequently done. The questionnaire was self-administered. It consists of 234 items including information on demography and self-care practices and 116 questions divided into 16 profile scales, including health status understanding, control problem and social and personal factors scales. The items were scored using a variable five-point Likert scale, in which 1 = goodand 5 = poor,^[9] and item scores were summed to gain a total score. Each scale was scored by summing certain item scores and dividing the sum by the appropriate number of items. The interval between two visits was 2 months, and all the study subjects in the intervention group were interviewed a minimum of four times. DCP was performed in the 2nd and 8th months, and the results were compared. The study subjects were interviewed for a duration of 20-40 min.

Patients' knowledge about diabetes and its management were tested at the baseline and final visits using the MDRTC Brief Diabetes Knowledge Test Questionnaire. The questionnaire tests knowledge of 15 test items. Correct answers scored one point and wrong answers scored zero points. It took approximately 10 min to complete this questionnaire.

Biochemical analysis

Fasting blood glucose levels were measured for all patients initially and 4 and 8 months after the initial meeting of the patient and the pharmacist. The demographic characteristics of the study subjects were collected at every visit. A capillary blood sample was collected by pricking the skin of the finger, and the fasting blood glucose level was measured using a one-touch blood glucose monitor (Accusure, MicroGene Diagnostic Systems [P.] Ltd., New Delhi, India).

Patient counseling

Patients in the intervention group received diabetic medication counseling, printed educational material and instructions on dietary regulation, exercise and lifestyle modifications from the community pharmacist, while the control group patients did not receive any counseling till the end of the study. Through dietary modifications, type 2 DM patients had to attain and maintain their ideal body weights. The modifications included reducing the intake of fats, increasing the intake of high-fiber carbohydrates, reducing the intake of refined sugars and salts, restricting alcohol consumption, spacing meals evenly (4-5 h apart), maintaining regular eating habits and eating fruits in moderate amounts (preferably raw and partially ripe fruits). In the intervention group, the study subjects were advised to perform any one exercise regularly to improve blood sugar control and body weight control and to increase the body's sensitivity to insulin. This regular exercise included walking, jogging, aerobics, dancing and swimming for 30-45 min at least three times a day.^[10]

The patients in the intervention group were also advised to consult a physician before starting any exercise and modifying the diet; patients with poorly controlled blood glucose levels, patients with specific complications such as diabetic retinopathy, sensitive feet or hypertension and those with an increased risk of diabetic complications were excluded. All the study subjects were advised to keep sugar or something sweet handy to avoid low blood sugar levels, and were advised to always have someone around who can detect symptoms of hypoglycemia.

Diabetic eye disease silently robs adults between the ages of 27 and 74 years of their sight, making diabetes a leading cause of blindness. Uncontrolled diabetes can cause permanent damage to the eyes (retinopathy). In the intervention group, the subjects were advised to (a) undergo scheduled yearly eye exams to ensure that diabetic eye diseases are detected before causing permanent loss of vision, (b) control the blood pressure within normal limits and (c) avoid risk factors that induce high blood pressures, such as smoking and alcoholism.^[11,12]

The subjects in the intervention group were educated on protecting their feet to avoid gangrene, and counseling on drugs was given. Counseling on drugs includes general instructions on the importance of the following: (a) following the prescribed diet, exercise and medical regimen, (b) taking a dose immediately if it has been missed, unless it is almost time to take the next dose, (c) avoiding doubling the doses, (d) avoiding alcohol and products containing alcohol, (e) learning to recognize and manage hyperglycemia, (f) avoiding smoking, (g) understanding that therapy relieves symptoms but does not cure the disease, (h) wearing or carrying medical identification regarding diabetic status and (i) avoiding other medications, including over-the-counter drugs, without medical approval.^[13-15] Flow diagram of requirement, allocation and follow-up of participants are given in Figure 1.

Statistical analysis

All the values in the following are the mean \pm standard deviation (SD). Significant differences between groups were determined using the paired t-test. A *P*-value less than 0.05 was considered to be significant.

RESULTS

The control group consisted of 10 males and 10 females, while the intervention group consisted of eight males and 11 females. They ranged in age from 33 to 80 years. The control group had a mean age of 57.05 ± 12.06 years, and the intervention group had a mean age of 51.47 ± 9.99 years. The duration over which these patients had suffered diabetes ranged from 1 to 25 years, with the mean duration of the control group being 5.80 \pm 5.34 years and that of the intervention group being 5.21 ± 4.88 years. All patients with type 2 diabetes take an average of two oral drugs to treat their diabetes. Of the 39 patients, 38 were on only oral hypoglycemic agents. One patient was on insulin alone, and none of the patients were on both oral hypoglycemic agents and insulin. In addition to the medications for treatment of diabetes, 12 patients were taking drugs for co-morbidities, including hyperlipidemia, hypertension and asthma. The demographic data of the study subjects are provided in Table 1.

All the patients completed DCP at their first visit to the pharmacist, prior to any counseling. The four subscale scores of DCP were health status, understanding, control problem and social and personal factors scales (scales I, II, III and IV) for both the control and the intervention group patients at the baseline interview. The average pre-study fasting blood glucose levels in the control and intervention groups were $150.30 \pm 40.82 \text{ mg/dL}$ and $155.58 \pm 27.55 \text{ mg/dL}$, respectively.

There was a slight difference between the results of the two groups during the second interview. The average fasting blood glucose of the control group during the second interview was $155.65 \pm 35.76 \text{ mg/dL}$, and during the final interview was $169.70 \pm 42.16 \text{ mg/dL}$. For the intervention group, the corresponding values were $127.63 \pm 19.07 \text{ mg/dL}$ and $108.10 \pm 12.53 \text{ mg/dL}$, respectively. The service was able to achieve a mean reduction in the blood glucose level of 47.47 mg/dL in patients who





Table 1: Demographic details of study participants				
Characteristic	Control group (<i>n</i> = 20)	Intervention group (<i>n</i> = 19)		
Age (years)	57.05 ± 12.05	51.47 ± 9.99		
Body mass index (kg/m ²)	25.81 ± 5.83	25.09 ± 2.49		
Duration of diabetes (years)	5.80 ± 5.34	5.21 ± 4.88		
Fasting blood glucose (mg/dL)	150.30 ± 40.82	155.58 ± 27.55		
Values are the mean + SD. Significant differences deterr	nined using the paired t-test			

received pharmaceutical care, while the mean blood glucose values in the control patients increased by 19.4 mg/dL at the end of the study.

The average body mass index of the control group during the second interview was $24.50 \pm 4.70 \text{ kg/m}^2$, and it was

 $24.38 \pm 4.75 \text{ kg/m}^2$ during the final interview. For the intervention group, the values were $24.31 \pm 1.84 \text{ kg/m}^2$ and $22.99 \pm 0.87 \text{ kg/m}^2$ during the second and final interviews, respectively. The mean weight reduction at the end of the study was 2.10 kg/m^2 in the intervention group and 1.43 kg/m^2 in the control group.

DCP was answered by patients again during the two later visits. During the second interview, the mean scores obtained for the DCP subscales I, II, III and IV for the control group were 4.0 ± 3.53 , $3.04 \pm .15$, 2.67 ± 4.47 and 2.15 \pm 4.43, and for the intervention group were 3.05 \pm $2.70, 3.04 \pm 2.75, 2.05 \pm 2.27$ and 2.32 ± 4.14 , respectively. At the final interview, the mean subscale scores obtained were 4.55 \pm 2.68, 2.16 \pm 2.33, 3.28 \pm 4.25 and 2.75 \pm 6.62 for the control group and 2.26 \pm 1.96, 4.01 \pm 2.22, 1.76 ± 2.31 and 1.53 ± 2.66 for the intervention group. Table 2 presents the four DCP subscale scores of the control and intervention group patients at the second and final interviews. The pharmacists' counselling produced significant improvement in the knowledge of the patients about DM and its management. The mean diabetes knowledge test score obtained during the final interview was 8.90 \pm 7.24 and 12.16 \pm 5.84 for the control and intervention groups, respectively [Table 2].

DISCUSSION

Implementation of the pharmaceutical care model for management of diabetes in a rural community pharmacy has resulted in better diabetes control and substantial healthcare improvements for patients. The blood glucose levels dropped and the patients' quality of life and knowledge about diabetes management improved. This is one of the few studies that have used a controlled research design and documented the clinical and humanistic outcomes in the pharmaceutical care intervention delivered in a community pharmacy in a rural area of Tamil Nadu.

Intensive interventions were undertaken, especially with respect to blood glucose monitoring, education about the disease and about medications and lifestyle (diet and exercise). Interventions were tailored according to individual patients' needs. All interventions were documented to measure the effectiveness. Strict control of diabetes can result in significant risk reduction in terms of the onset of complications. Intensive blood glucose control in patients with type 2 diabetes has also been shown to be cost-effective in terms of managing these complications.^[16]

In this study, it was possible to achieve clinically important and statistically significant drops in the mean blood glucose level in the intervention group over the duration of the study compared with control patients. The service was able to achieve a mean reduction in the blood glucose level of 47.47 mg/dL in patients who received pharmaceutical care, while the mean blood glucose values in the control patients increased by 19.4 mg/dL at the end of the study. This reduction in blood glucose level in the intervention group is an excellent achievement given that the service was provided for such a short period of time. A similar study conducted by Berringer et al. in two community pharmacies in the USA showed that blood glucose levels decreased in the intervention group by 19.3 mg/dL in 6 months.^[17] The frequency of symptomatic episodes of hyperglycemia and hypoglycemia was significantly reduced in the intervention group.

From the study, it is evident that the rural population knew very little about diabetes and lifestyle modifications. The pharmacists' intervention produced statistically significant improvements in the intervention group. The improved diabetes knowledge scores among the patients in the intervention group show that the participants successfully retained the information delivered over the duration of the study.

A lack of knowledge about the disease and its management can be considered as an important reason for improper control of DM. Another study conducted in Bangalore in 2005 showed that patient counselling by pharmacists on diabetes significantly increased patients' knowledge about all aspects of DM and its management.^[17,18]

The pharmacist is an integral member of a healthcare team and assumes varied functional roles including the procurement and supply of medicines to pharmaceutical care services and helping ensure that patients receive the best treatment. Involvement of pharmacists in patient care

Table 2: Outcome measures at baseline and final interview of patients					
DCP subscale scoring stage	Group	Baseline interview	Final interview		
Subscale I (health status)	Control group	3.60 ± 3.04	4.55 ± 2.68***		
	Intervention group	3.73 ± 4.32	2.26 ± 1.96***		
Subscale II (understanding)	Control group	2.03 ± 2.55	2.16 ± 2.33		
	Intervention group	2.36 ± 3.40	4.01 ± 2.22***		
Subscale III (control problems)	Control group	2.02 ± 4.70	3.28 ± 4.25***		
	Intervention group	2.52 ± 3.66	1.76 ± 2.31**		
Subscale IV (social and personal factors scale)	Control group	1.80 ± 4.52	2.75 ± 6.62*		
	Intervention group	3.10 ± 3.23	1.53 ± 2.66***		
Diabetes knowledge test score	Control group	8.60 ± 11.27	8.90 ± 7.24		
	Intervention group	8.53 ± 5.14	12.16 ± 5.84***		

All the values are means ± SD, DCP, Diabetes Care Profile, n = 20 in control group and 19 in intervention group, *P < 0.05; **P < 0.01; ***P < 0.001, paired t-test

has reduced the number of hospital admissions and patient visits for medical emergencies. As Dr. Hans V. Hogerzeil, WHO Director of Medicines Policy and Standards, said, "Pharmacists have an important role to play in health care, which is much more than selling medicines."^[19,20]

At the end of the study, the intervention group showed a noticeable improvement in the mean of DCP subscale score. All the four subscales (health status [subscale I], understanding [subscale II], control problems [subscale III] and social and personal factors [subscale IV]) showed statistically significant improvements in the intervention group compared with the control group.

CONCLUSIONS

Community pharmacists are in a unique position to monitor and counsel rural patients with DM. The need for increased diabetes care presents an excellent opportunity for community pharmacists to become more involved in the management and follow-up of people with diabetes. This study demonstrates the positive impact that the community pharmacist can have in achieving the primary therapeutic goal in diabetes patients of overall diabetes control. The data analysis indicated that at the end of the study period, the intervention group patients had very good glycemic control, good health, a good understanding of diabetes and its management and the fewest control problems, such as incidences of symptomatic episodes of hyperglycemia or hypoglycemia.

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