



INFLUENCE OF STRUCTURED PATIENT EDUCATION ON THERAPEUTIC OUTCOMES IN DIABETES AND HYPERTENSIVE PATIENTS

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ABSTRACT

Background: Poor control of diabetes and hypertension may result in end organ damage and affect the patient's quality of life. Studies have corroborated the positive influence of patient counseling on improved therapeutic outcomes and enhanced quality of life in patients suffering from chronic disorders. **Objective:** To assess the influence of structured patient education on therapeutic outcomes in patients with type-2 diabetes and hypertension. **Methodology:** This is a prospective, randomized study conducted at a South Indian tertiary care teaching hospital after receiving the ethical committee approval. Eligible patients were randomized in to test and control using simple randomization technique. Test group patients received structured patient education and the control group patients received education at the end of the study. At each follow up, blood pressure (BP) and capillary blood glucose (CBG) of all enrolled patients were recorded. At baseline and final follow-up, adherence behavior and Knowledge Attitude and Practice (KAP) of patients towards their disease were assessed using suitable Questionnaires. **Results:** A significant ($p < 0.05$) improvement in KAP, mean scores of regimen, belief and access screens of BMQ and was observed in all test group patients. Statistically significant ($p < 0.05$) change in BP and CBG score was observed in test group patients. **Conclusion:** Pharmacist provided structured education in patients with type-2 diabetes and hypertension regarding their disease, medications and lifestyle modifications improved Knowledge Attitude and Practice towards their disease, therapeutic outcomes, and adherence behavior in test group patients compared the patients in control group.

Key words: Diabetes, Hypertension, Education, Therapeutic outcome, Adherence.

INTRODUCTION

Diabetes and hypertension are the chronic disorders causes several complications leading to end organ damage, Poor control of the disease, and impaired health related quality of life and augmented health care expenditures¹. Successful management of these disorders requires both pharmacological and non-pharmacological interventions. Desired therapeutic outcomes are achieved only when the patients adhere to the prescribed medications and practice the non-pharmacological strategies².

The prevalence of hypertension in western population increases with age and degree of obesity and it is 1.5 times higher in diabetic groups than the non diabetic patients. Approximately 20–60% of patients with type 2 diabetes may develop hypertension depending upon their age, ethnicity, and obesity. Epidemiological studies indicate that patients with both the diseases are more prone to develop cardiovascular complications and about 86% of deaths in diabetic individuals are due to cardiovascular complications³.

About 5 to 15% of health care budget is consumed by the diabetes in developed countries and major share goes for treatment of diabetic complications. The prevalence of diabetes in south Asian population with more than 40 years of age is 20 to 30%. The prevalence of the disease in adult population is 3-5 % and an increase of 10% can be seen in people above 65 years⁵. Over 972 million adult populations were estimated to have hypertension in 2000 and this number is expected to increase to 1.56 billion by the year 2025. In India 66 million hypertensive patients are present and among these 25% adults are from urban area and 10% of adults from rural areas⁶.

Optimal blood glucose control and blood pressure in diabetes and hypertension can be achieved through strict adherence to the medications, diet and exercise. This in turn will minimize the long-term complications⁷.

Collaborative approach between patient and health care professional is required to improve medication adherence and outcomes in these chronic illnesses⁹. According to National Institute for Clinical Excellence (NICE) Health Technology appraisal, the structured patient education is defined as "a planned and graded program that is comprehensive in scope, flexible in content, responsive to an individual's clinical and psychological needs, and adaptable to his or her educational and cultural background"¹¹. Patient education is a process that improves patient's ability to cope

up and make informed decisions regarding their disease, medications, and motivate the patients to introduce changes in diet and life style medications⁷.

The present study was designed to assess the influence of structured patient education by the pharmacist in order to improve patients' medication adherence behavior, knowledge, attitude, skills, and confidence towards their disease management, and in turn to improve therapeutic outcomes.

METHODOLOGY

The present study was a prospective, randomized and interventional study conducted in the Medicine Outpatient Department (OPD) of a South Indian Tertiary care teaching hospital and the study was approved by Institutional Ethics Committee.

Patients of either sex, suffering from type 2 Diabetes Mellitus, or hypertension or both knowing working Kannada or English language and willing to give their written Informed Consent to participate in the study. Pregnant women with gestational diabetes or pre eclampsia or patients with uncontrolled and complicated diabetes and hypertension or patients who had any significant cardiac complications in the last six months were excluded from the study.

Patients' demographic and educational details, social habits, socio economic conditions, past medical history and patients' known allergies to foods and drugs were collected using suitable data collection form which was designed for the study.

At baseline, patients' demographics, history of social habits, educational level, socio economic status, past medical and medication history were collected. All enrolled patients were followed for a period of 3 months from baseline with an interval of 30 days between the follow-ups. At every follow-up visit, Blood Pressure (BP) and Capillary Blood Glucose (CBG) were recorded. The test group patients received the education regarding disease, medication, diet, and lifestyle modification at baseline and at each follow-up and the control group patients received detailed education only at final follow-up visit.

All enrolled patients were assessed for Knowledge, Attitude and Practices (KAP) towards their disease using suitable KAP questionnaire. This questionnaire was administered to both test and control groups at baseline and final follow-up. Diabetes KAP

questionnaire contains 25 scored questions. The maximum score is 25 and a higher score indicates the greater knowledge. This questionnaire was applied to patients having diabetes and both diabetes and hypertension. Hypertension KAP questionnaire contains 26 scored questions and 2 unscored questions. The maximum score is 26 and higher the score indicates the greater knowledge. This questionnaire was applied to patients having hypertension and both hypertension and diabetes.

Medication adherence behavior was assessed using standardized questionnaire called Brief Medication Questionnaire (BMQ) at baseline and final follow up to both control and test groups. This questionnaire consist of 4 screens namely, regimen screen, belief screen, recall screen and access screen. Regimen screen contains 0-9 score range and other screen contains 0-2 score range. The regimen screen assesses self reported adherence behavior. Subtotal of each screen is called as Adherence Risk Scale (ARS). This ARS contains of 0 to 4 scores. 0 score indicates the self reported non adherence where as 4 indicated self reported adherence.

Patients were randomized in to DM-Control, DM-Test, HTN-Control, HTN-Test, DM+HTN-Control and DM+HTN-Test. Their respective percentage proportion for all patients was calculated. Patients were classified according to their demography and socio economic status. The average number of medication and average duration of the disease in study population was also estimated.

Results were analyzed using Statistical Package for the Social Sciences (SPSS) for windows Version 17.0. Significance of change in BP and CBG at each follow-up visit compared to baseline was assessed using paired t-test. Significance of change in KAP and BMQ scores from baseline to final follow-up were also assessed using paired t-test. P value of < 0.05 is considered as significant.

RESULTS

A total of 240 patients were enrolled into in to the study. Out of them 227 (94.5%) patients completed all the study follow ups and 13 patients were considered as drop out because of the missed follow-ups. The average age of patients enrolled into the study was 57 years. No significant difference was observed between the number of enrolled male and female patients. ($p > 0.05$). However a significant difference was found in the social habits and employment status of the enrolled patients. The demographic details of the 227 patients are presented in Table 1.

Comparison of mean changes in the blood pressure values: Control versus Test Group

Although when compared to baseline, a reduction in the mean systolic and diastolic blood pressure was observed in patients having either hypertension or both diabetes and hypertension at each follow up. However these changes were statistically significant in test group patients. ($p < 0.05$). Details of change in BP of control and test group patients are presented in the Tables 2.

Comparison of mean changes in the capillary blood glucose values: Control versus Test Group

A non significant decrease in CBG was observed in control group patients from baseline to final follow up. When compared to baseline decrease in the CBG at each follow up of test group patients having both diabetes and hypertension was significant. But change in the CBG from baseline to first follow up in diabetes patients was not significant. However decrease in CBG from first to second and second to final follow up was significant in diabetes patients. (Table 3)

Medication adherence of the study patients

Significant improvement in all screen scores was seen from the baseline to final follow up in test group patients having DM and Hypertension. But no significant improvement was seen in the access screen of test group patients having both DM and Hypertension. In control group patients having both Hypertension and DM, changes in adherence risk scale, access barrier and recall barriers were significantly improved from the baseline to final follow up. However there was no significant improvement was observed in the regimen and belief barriers. In controlled diabetic

patients, a non significant improvement was observed in the regimen, belief and access barriers. However the change in the recall barriers was significant. Similarly in controlled hypertensive patients' change in all screen scores were not significant. Details of change in BMQ scores are presented in the Table 4.

Knowledge, Attitude and Practices of the study patients

A significant change in the scores of KAP Diabetes questionnaire was observed in control and test group patients having both diabetes and hypertension. However there was no significant change observed in the diabetes control group. Significant improvement in scores of KAP Hypertension was observed in both the groups (HTN-T, HTN+DM-T) from the baseline to final follow up. Details of the mean scores and significance are given Table 5.

DISCUSSION

In many countries health care providers accept the importance of education to patients in order to improve the therapeutic outcomes. Many studies have shown that the education to patients improves their understanding about the disease, importance of medication and life style modifications with necessary dietary changes decreases the morbidity rate and mortality rate¹². Many studies have corroborated the active role of pharmacists in improving the health and quality of life in patients with chronic diseases¹³⁻²¹.

Influence of education on Knowledge, Attitude and Practice of the study patients

Patients' knowledge, attitude and practices have an effect on the medication adherence behavior. Medication adherence is essential to achieve better therapeutic outcomes in chronic diseases such as diabetes and hypertension. An understanding of the cause of the disease, importance of regular intake of medicines and necessary life style modifications in controlling the disease will help to improve the therapeutic outcomes.

KAP – Diabetes: At baseline only few patients were aware of the cause of disease, signs and symptoms, complications and management of the diabetes. Patients' knowledge about the signs, symptoms and life style modifications of diabetes was good, but their attitude towards practicing the self management of disease was poor. Most of the patients were aware of how to recognize and control the hypoglycemic symptoms but was not carrying sugar or sugar candy with them. This observation shows that patients had good knowledge, but their attitude towards the practice was poor.

In a study conducted by *Ranjini A et al.* observed a significant correlation between the knowledge and attitude, but a non significant correlation observed between the attitude and practice of patients towards their disease¹⁸. The similar findings were observed in our study suggest that, though most of the patients know well about the disease, patients may not practice the same due to negligence.

KAP – Hypertension: At baseline most of the patients knew about the cause and signs of hypertension. However they were unaware of asymptomatic hypertension and complications associated with it. Most of the patients were on strict diet but they were not practicing the exercise. *Ranjini A et al* and *Palain S et al.* observed a lack of attitude in patients, towards the disease and hence the poor practice. In both the studies after the education the researchers found an improvement in the attitude towards the disease in study patients and concluded that results may be confounding due to less sample size. In the present study, the sample size ($n=227$) was good as per the sample size calculation (n required is 222). We also observed that, lack of attitude and practice among the enrolled patients which was improved by the pharmacist intervention and the same was reflected in their KAP.^{22, 18}

Influence of education on Medication Adherence

Structured patient education has a major role in patient medication adherence behavior. Medication adherence has direct influence on the blood glucose and blood pressure control. The study had highlighted the need for continuous education to the patients to improve knowledge, attitude and practices towards disease management. In the present study, regular interaction between the

Table 1: Demographic details of the enrolled patients

	Female (54.54)	112	49.3
	Male (59.81)	115	50.7
	Total (57.21)	227	100.0
Education		N	Percentage
	Illiterate	64	28.2
	Primary School	86	37.9
	Secondary School	41	18.1
	PUC	14	6.2
	Degree	22	9.7
Employment Status			
	Employed	54	23.8
	House wife	85	37.4
	Retired	72	31.7
	Unemployed	16	7.0
Alcohol history			
	Alcoholic	3	1.3
	Non-alcoholic	207	91.2
	Past-alcoholic	13	5.7
	Social Alcoholic	4	1.8
Smoking history			
	Non smoker	215	94.7
	Past smoker	2	0.2
	Smoker	10	4.4
Diet			
	Mixed diet	105	46.3%
	Vegetarian	122	53.7%

pharmacist and patients influenced a lot in improving the patient medication adherence behavior.

It was observed that the male patients were time bound and found to be more adherent in their routine life. Female patients tend to skip the doses due to unscheduled life style as most of the patients enrolled were house wives. The common reasons for the non adherence in the enrolled patients were forgetfulness (regimen screen) and financial (access screen) problems.

At the final follow up, statistically significant improvement was observed in all screens in the test group patients. The regimen screen deals with how well patients know about their medication regimen. After education, patients were able to recall the name and/or were able to identify their medicines, what dose they were receiving and why they were on these medications. Reductions in the number of times skipped in medication schedules in the patients were also observed.

Patients also showed an improvement in their belief and recall screen scores. This implies that during the study, as a result of increased adherence they saw their blood pressure was reaching goal blood pressure and this has improved their belief and perception of the effect of medications. During the study period, test group patients were made aware of consequences of non adherence on disease, as a result they made a conscious effort to remember to take medications and this resulted in improved scores in recall screen.

Table 2: Significance of change in Blood pressure in control group

Group		Systolic			Diastolic		
		First follow up	Second follow up	Final Follow up	First follow up	Second follow up	Final Follow up
HTN -C	Change in BP	23.49	22.53	24.57	10.6	10.15	12.49
	Significance	0.79	0.23	0.14	0.009	0.75	0.58
HTN -T	Change in BP	18.53	17.4	6.78	9.25	6.93	2.4
	Significance	0.033	0.064	0.001	0.001	2.4	0.001
HTN+DM-C	Change in BP	22.8	27.47	27.49	11.58	10.34	8.507
	Significance	0.09	0.3	0.4	0.91	0.02	0.47
HTN+DM-T	Change in BP	20.79	6.68	7.25	9.93	7.06	7.59
	Significance	0.03	0.001	0.005	0.63	0.11	0.035

Table 3: Significance of CBG in control group

Significance of Change in CBG		Change in CBG	Significance	Change in CBG	Significance
Control Group	First follow up	88.4069	0.782	37.9967	0.268
	Second follow up	96.7456	0.686	116.105	0.883
	Final Follow up	99.4249	0.525	109.093	0.798
Test Group	First follow up	13.5351	0.001	68.7168	0.258
	Second follow up	21.0556	0.001	16.3235	0.001
	Final Follow up	20.6434	0.002	25.352	0.001

Table 4: Change in BMQ scores in control group

BMQ		Control						Test					
		DM+HTN		DM		HTN		DM+HTN		HTN		DM	
		Change in Score	p value	Change in Score	p value	Change in Score	p value	Change in Score	p value	Change in Score	p value	Change in Score	p value
ARS	Baseline	± 1.11	0.003	± 1.11	0.021	± 1.04	0.009	± 0.91	0.000	± 0.93	0.000	± 0.73	0.000
	Final	± 0.62		± 0.67		± 0.70		± 1.06		± 0.98		± 0.88	
Regimen	Baseline	± 1.20	1.000	± 1.04	0.270	± 1.10	0.644	± 0.90	0.000	± 0.73	0.000	± 0.88	0.000
	Final	± 0.79		± 0.83		± 0.84		± 0.9		± 0.75		± 0.87	
Belief	Baseline	± 0.55	0.303	± 0.50	0.110	± 0.52	0.109	± 0.54	0.031	± 0.53	0.009	± 0.50	0.012
	Final	± 0.54		± 0.55		± 0.50		± 0.40		± 0.34		± 0.31	
Recall	Baseline	± 0.54	0.031	± 0.60	0.030	± 0.54	0.831	± 0.58	0.000	± 0.67	0.009	± 0.55	0.057
	Final	± 0.45		± 0.47		± 0.54		± 0.49		± 0.57		± 0.50	
Access	Baseline	± 0.49	0.001	± 0.49	0.201	± 0.60	0.071	± 0.49	0.096	± 0.64	0.001	± 0.58	0.000
	Final	± 0.47		± 0.64		± 0.51		± 0.44		± 0.49		± 0.48	
	Final	± 0.47		± 0.64		± 0.51		± 0.44		± 0.49		± 0.48	

Table 5: KAP Scores in control groups

KAP		Control						Test					
		DM+HTN-C		HTN		DM		DM+HTN		HTN		DM	
		Change in Score	p value	Change in Score	p value	Change in Score	p value	Change in Score	p value	Change in Score	p value	Change in Score	p value
DM	Baseline	± 4.36	0.068	NA		± 2.64	0.003	± 2.61	< 0.001	NA		± 2.98	< 0.001
	Final	± 3.67		± 3.48	± 2.99	± 2.41							
HTN	Baseline	± 2.73	< 0.001	± 3.90	0.101	NA		± 3.07	< 0.001	± 3.42	< 0.001	NA	
	Final	± 2.49		± 2.97		± 2.63	± 3.44						

It was also observed that patients were not able to refill their medications on time. The main reason for this was lack of time and unavailability of medicines in pharmacy. Hence study pharmacist asked patients to call up pharmacy well in advance to their visit to the pharmacy and order the medicines they require. This strategy helped the patients to have their refills in time and ultimately improved the access screen in the test group patients.

Over all in the present study, non adherence was mainly due to forgetfulness (regimen screen) and lack of time and financial problems (access screen). Similar results were found in the study conducted by Carvalho S et al. the forgetfulness among the patients was mainly due to lack of knowledge and awareness about the consequences of the uncontrolled disease. Similarly Carvalho S et al found that patients were not able to refill their medication in time because of lack of time. These barriers (forgetfulness and refill) were improved when patients were provided with education¹⁴.

These findings suggest that educating patients about their medications and their role in the management of disease helped them to improve the adherence. The greater control of blood glucose and blood pressure levels seen in the test group patients suggests the improved adherence levels, which improved the therapeutic outcomes.

Influence of education on blood pressure and capillary blood glucose

During the study period, patients were asked to visit their physician regularly, in order to achieve goal blood pressure and goal blood glucose levels. As patients of both groups continued to see their physician regularly, both groups showed an improvement in the treatment outcomes. However patients in the test group showed a significant decrease in the blood pressure and blood glucose levels. This is due to regular pharmaceutical care apart from their regular medical care. The significant improvement seen in the test group was due to the practice of the recommended lifestyle modifications and self management strategies. Similar results were found in the studies conducted by Adepu *et al* and Carvalho S et al in diabetic and hypertensive patients respectively.^{23,14}

Studies conducted by, Vivian EM et al¹⁰, Hennessey S et al²⁴, Chobot I et al¹³ assessed the improvement in the BP and CBG levels after the patient education. In these studies a significant improvement in BP and CBG values were observed in patients who received education by both physician and pharmacist than the education provided by physician alone.

Several parameters are gaining importance as therapeutic outcomes are important than the clinical and psychological outcomes. In case of diabetes and hypertension, definite cure cannot be provided by medicines alone. Thus decreased symptoms and slowing down the progression of the disease and improvement in the function becomes important in the management of the disease.

In order to get these outcomes, patients must be educated regularly to improve their knowledge, attitude and practices. They must be made to understand the need for treatment, benefits and risk associated with the prescribed medicines and impact of non adherence to their medications. The present study has shown the pharmacist's education role improved the therapeutic outcomes in patients by improving their medication adherence behavior and practice of healthy life styles.

CONCLUSION

Our study concludes that improving the patients' knowledge, attitude and practice about their disease can improve the medication adherence behavior, which in turn improves the therapeutic outcomes. Thus this study emphasizes the potential role of the pharmacist as patient educator in the management of diabetes and hypertension.

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