

Asian Journal of Pharmaceutical and Clinical Research

1, Issue 3, 2011 ISSN - 0974-24

Research Article

INFLUENCE OF POST DISCHARGE COUNSELLING ON HEALTH OUTCOMES IN DIABETIC AND HYPERTENSIVE PATIENTS

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ABSTRACT

Hypertension and Diabetes mellitus are the chronic disorders that affect the patients' quality of life. Diseases and medication related information empowers patients to adopt positive lifestyles that help in improving health outcomes and the quality of life. A prospective, randomised study was conducted to assess the impact of post discharge counselling on health outcomes in diabetic and hypertensive patients. A total of 158 patients meeting the inclusion criteria were enrolled and randomized into control and test groups. Test group patients received counseling at discharge and in the subsequent follow ups. At each follow up, blood pressure (BP) and capillary blood glucose (CBG) were recorded. Health related quality of life was assessed using suitable questionnaires at baseline and every follow up. A statistically significant (p<0.05) improvement in HRQoL was observed in hypertension (HTN), diabetes (DM) and HTN+DM test group patients. Also a better improvement in goal blood pressure and goal capillary blood glucose (p>0.05) was observed in test group patients compared to the control group patients. Pharmacist provided post discharge counselling has shown positive impact on therapeutic outcomes and health related quality of life.

Key words: Diabetes; Hypertension; Health Related Quality of Life, Counselling, Therapeutic Outcomes.

INTRODUCTION

Diabetes and Hypertension are the chronic disorders emerging as major health problems which increase the rate of morbidity and mortality. Poor management of these two disorders leads to several complications and end organ damage that ultimately impairs the health related quality of life (HRQoL) in the individuals. For the optimal therapeutic outcomes, adherence to the prescribed medications and adopting required lifestyle modifications is very much essential¹. According to World Health Organisation (W.H.O) estimation, the global prevalence of diabetes is increasing at a rate of more than 120%. In 1995 there were 135 million people affected with DM, in 2000 the number rose to 171 million. World wide the projected estimate of the people likely to get affected with diabetes by 2025 will be 300 million and by 2030 will be 366 million² and in India with 31.7 million in 2000 is projected to increase to 79.4 million by 2030 5. Diabetes is prevailed in similar proportion in both men and women.

However, it is found slightly more in men with age < 60 years and in women at older age ³. In developing countries, majority diabetics are in the age range of 45 to 64 years where as in developed countries the age range is >64 years4. International Diabetic Federation (IDF) estimates that diabetes represents the fourth leading cause of global deaths 2. In India, direct expenditure related to diabetes care is presently 10,000 crores which is likely to scale up to Rs. 1, 25,000 crores by 2025. The mean direct annual cost for management of a diabetic out patient is estimated as Rs. 5000 and is likely to increase by 50% more, if diabetic complications also exist 6. The incidence rate of hypertension depending on the age, ethnicity, gender and body size lies between 3% and 18%7. Despite advances in hypertension treatment, control rates still remain sub optimal. In India, deaths caused due to cardiovascular disorders will be around 1.5 million annually. Hypertension is directly responsible for 57% of stroke deaths and 24% of coronary heart disease deaths8. W.H.O estimates that countries like India, China, and Russia are likely to lose \$200 billion to \$550 billion in their gross domestic product during the next 10 years because of heart diseases 9.

Type 2 diabetes mellitus and hypertension will carry an increased risk of cardiovascular and renal disorders. Prevalence of hypertension in type 2 diabetes mellitus is higher than in the general population¹⁰. At the age of 45 years, approximately 40% of patients with type 2 diabetes mellitus are hypertensive, with the proportion increasing to 60% by the age of 75 years¹¹.

Many studies have proven that diabetic patients have poor knowledge about their disease, long term complications and its

management ¹¹. Management of Diabetes involves optimal glucose control which can be achieved through strict adherence to the medications, diet and exercise which in turn minimizes long-term complications. Management of hypertension is a special situation. It involves long term management plans, ensuring adherence and efficient management of drug related problems ¹². Though pharmacological treatment reduces the morbidity and mortality rate, they have been associated with various degrees of side effects. Often, side effects of the drugs will affect the adherence behavior among the patient population, which in turn affects the therapeutic outcomes and the ultimate HRQoL.

World Health Organization defines Health as being not only the absence of disease and infirmity but also presence of physical, mental and social well being¹³. In health care practice, therapeutic outcomes are very important and influences directly the physical, psychological and social domains of health, which in turn affects the overall HRQoL. Medication adherence, dietary and life style modifications contribute significantly the therapeutic outcomes. Structured education regarding the disease, medication usage and life style modifications will greatly influence on therapeutic outcomes and ultimately the health related quality of life.

Despite the considerable technological and scientific progress in the disease management, Patient education is considered as the most noticeable innovation in the patient care¹⁴. It is necessary to encourage an understanding of their condition and how the prescribed treatment will work and affect their daily life. Specific advice should reinforce the timing of doses and how each medication should be taken. Patients also need to be advised about potentially troublesome symptoms that occur with their medication and whether the effects are avoidable, self- limiting or a cause for concern¹⁵. Many studies have corroborated the counseling role of pharmacists' in assisting the patients through a structured education and monitor the medication adherence behaviour and life style modifications to achieve the therapeutic outcomes and health related quality of life ^{11,12,16}.

MATERIALS AND METHODS

This study was carried out over a period of 7 months from July 2009 to Jan 2010 in a tertiary care teaching hospital in Mysore. Ethical clearance to conduct this study was obtained from the Institutional Human Ethical Committee of JSS College of Pharmacy, Mysore and strict confidentiality was assured for all the collected information. Patients admitted to the medicine inpatient department with a clinical diagnosis of type 2 diabetes mellitus (DM), hypertension

(HTN) or patients having both clinical disorders (HTN +DM) were enrolled in to the study after getting their written informed consent.

Demographic details of the patients, social habits, educational details and employment details were collected in a suitably designed form. All enrolled patients were followed for a period of 2 months from the discharge with an interval of 15 days between follow-ups. BP and CBG were recorded at every follow up. Education regarding disease, medication, diet, and lifestyle modification was provided at discharge and at each follow-up to the test group patients. The control group patients received detailed education only at the final follow-up visit. Health related quality of life of the diabetic patients was assessed by using Ferrans and Power Quality of Life questionnaire^{17, 18}. Disease induced hospitalization was assessed in each follow up by patient interview.

RESULTS

A total of 158 patients were enrolled into in to the study. Out of them 154 patients completed all the study follow ups and 04 patients were considered as drop out because of the missed followups. The mean age of the enrolled patients was 53.04 years. No significant difference was found between the age and gender among the enrolled patients. Demographic details of the enrolled patients, treatment details are presented in table 1. Reduction in both systolic and diastolic blood pressure from baseline and in three successive follow ups was comparatively improved in test group patients compared to the control group patients. However, these changes were found statistically non significant. Influence of post discharge counselling on blood pressure in Hypertension (HTN) group patients is shown in figure No.1.

Influence of post discharge counselling on Quality of Life in HTN Patients and HTN+DM patients

Quality of life scores in hypertensive patients was assessed using a generic questionnaire the Psychological General Well Being Index (PGWBI). At the first follow up, the anxiety subscale mean scores of the hypertension control group were higher than the test group patients. Whereas at final follow up, the mean scores of the test group patients were significantly increased than the control group patients. In patients with hypertension and type 2 diabetes mellitus, the test group patients showed better improvement than the control group in both the follow ups.

The test group patients with hypertension alone and with both hypertension and type 2 diabetes mellitus showed better improvement in the mean scores of depressed mood subscale, positive well being subscale, self control subscale, general health subscale, vitality subscale when compared to the control group patients. Hence, the overall quality of life of the test group patients was better than the control group patients in both the follow ups. The changes in mean scores between test and control were found to be statistically significant in both the follow ups. The mean scores of all the subscales are presented in table 2 and 3.

Influence of post discharge counselling on CBG values in DM patients

Changes in the CBG values were significant between the DM test and the control group. In test group, the baseline mean values of CBG were found to be 165.23, which were reduced to 143.69 at first follow up, 133.38 and 121.54 in second and in third follow ups respectively. Whereas in control group, the reduction in mean CBG values was observed from baseline to second follow up. But the elevation was found from second follow up to final follow up. This is shown in figure 2.

Influence of post discharge counselling on Blood Pressure in DM+HTN patients

The reduction in the mean blood pressure was found to be comparatively better in test group patients in all the three follow ups from the baseline when compared to the control group patients. However, the changes between the test and control group were statistically non significant during all the follow ups. The changes are presented in figure 3

Influence of post discharge counselling on CBG levels in DM+HTN patients

A non significant decrease in the capillary blood glucose levels of test group patients was observed when compared to the control group patients. Changes in the CBG values at each follow up were recorded and the mean CBG values at each follow up are shown in fig. 4.

Influence of Education on Quality of life in DM patients and DM+ HTN patients

The mean scores of the health and functional subscale, social and economic subscale, psychological and spiritual subscale and family subscale revealed better improvement in the HRQoL of the test group patients when compared to control group patients. The mean scores of overall quality of life were also improved in test group patients than control group patients from first follow up to the final follow up. The mean scores are presented in tables 4 and 5.

Table 1: Demographic details of the study subjects

Age	1	Number		Percentage
30-40	12		7.59	
41-50	44		27.84	
51-60	80		50.63	
>60	22		13.92	2
Gen	der DM-C		16	10.12
Male	DM-C DM-T		15	09.49
	DM+HTN-C		13	09.49
	DM+HTN-T		16	10.12
	HTN-C		11	06.96
	HTN-T		16	10.12
	DM-C		09	05.69
Female	DM-T		14	08.86
	DM+HTN-C		12	07.59
	DM+HTN-T		12	07.59
	HTN-C		13	08.22
	HTN-T		11	06.96
	cation			
University	7	13		08.22
PUC		21		13.29
Secondary		28		17.72
Primary S	chool	54		34.17
Illiterates		42	2	26.58
	loyment Status			
Employed		37		23.41
Unemploy		29		18.35
Housewife		58		36.70
Retired		11		06.96
Business		23		14.55
Alcoholic	ol History	12		07.59
	1.			
Non Alcoh		136		36.07
Past Alcoh		07		04.43
Social Alco		03		01.89
	ing History			
Non Smok	er	156		98.74
Smoker		02	(01.26

Table 2: HTN Quality of Life Scores- HTN group

	Anxi	Anxiety Depressed		_		Positive well Self control			Gene		Vitality		Overall quality		
			mo	ood being		ng			Health				of life		
1st Follow up	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Test	13.18	2.18	9.59	2.29	10.22	2.81	8.85	2.03	9.40	2.69	12.62	3.06	64.22	5.28	
Control	16.39	23.1	7.34	2.05	08.34	2.34	6.95	2.34	7.69	2.38	10.43	2.19	52.47	6.12	
Significance	P<0.05		P<0.05		P<0.05		P<0.05		P<0.05		P<0.05		P<0.05		
Final Follow	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
up															
Test	15.81	2.33	11.88	1.36	13.44	2.80	11.74	2.03	11.59	2.17	15.40	2.39	79.25	6.78	
Control	14.17	2.46	07.39	1.90	8.60	2.51	7.17	2.42	8.00	2.50	10.43	2.35	52.78	6.16	
Significance	P<0.05		P<0	P<0.05		P<0.05		P<0.05		P<0.05		P<0.05		P<0.05	

(Significance p≤ 0.05) Legends: SD- Standard Deviation, QOL-Quality of life, HTN-Hypertension

Table 3: HTN Quality of Life Scores- HTN+DM group

	Anxi	ety	Depre mo	_	Positiv bei		Self co	ntrol	Gene Hea		Vitality		Overall quality of life		
1st Follow up	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Test	12.57	1.64	8.95	1.60	9.56	2.04	8.47	1.34	9.04	1.52	11.17	1.4	57.67	11.58	
Control	11.34	2.08	8.67	1.80	9.46	2.74	7.85	2.49	8.53	2.47	11.03	2.97	58.57	5.87	
Significance	P<0.	05	P<0	.05	P<0.05		P<0.05		P<0.05		P<0.05		P<0.05		
Final Follow	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
up															
Test	15.35	1.68	11.25	1.29	12.71	1.94	10.64	1.85	11.53	1.85	14.35	1.78	75.07	6.7	
Control	11.13	1.91	8.69	1.45	9.47	2.10	8.43	1.44	9.04	1.77	10.78	1.24	57.13	6.68	
Significance	P<0.	P<0.05		P<0.05		P<0.05		P<0.05		P<0.05		P<0.05		P<0.05	

Legends: DM-Diabetes Mellitus, HTN-Hypertension, C-Control, T-Test, SD-Standard Deviation

Table 4: DM Quality of Life scores-DM group

	Health and Functioning subscale		Social and Economic subscale		Psychological/ Spiritual subscale		Family s	ubscale	Overall quality of Life		
First Follow up	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Test	17.84	0.93	17.94	0.89	18.00	0.84	17.97	0.79	18.01	0.83	
Control	16.79	0.81	16.90	0.90	16.79	0.86	17.01	0.73	16.99	0.79	
Significance	P<0.05	P<0.05		P<0.05		P<0.05		P<0.05		P<0.05	
Final Follow up	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Test	20.47	0.83	20.54	0.81	20.56	0.85	20.51	0.91	20.35	1.75	
Control Significance	15.76 P<0.05	1.17	15.84 P<0.0	1.13)5	15.93 P<0.0	1.2 5	15.85 P<0.	1.20 05	15.95 P<0.05	1.11	

Table 5: DM Quality of Life Scores- DM+HTN group:

	Health and Functioning subscale		Social and Economic subscale		Psycholog Spiritual		Family s	ubscale	Overall quality of Life		
First Follow up	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Test	17.52	0.93	17.28	0.84	17.34	0.90	17.37	0.88	17.47	0.85	
Control	16.71	0.81	16.78	0.67	16.81	0.69	16.80	0.69	16.95	0.66	
Significance	P<0.05		P<0.05		P<0.05		P<0.05		P<0.05		
Final Follow up	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Test	19.84	0.76	19.83	0.72	19.88	0.73	19.82	0.72	19.95	0.76	
Control	15.89	0.82	15.94	0.83	15.96	0.84	16.06	0.86	16.05	0.82	
Significance	P<0.05		P<0.	05	P<0.05		P<0.0	P<0.05			

Legends: DM-Diabetes Mellitus, HTN-Hypertension, SD-Standard Deviation

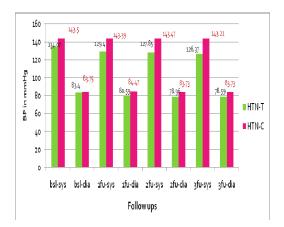


Fig. 1: Comparison of changes in the blood pressure in HTN patients

HTN=Hypertension, T=Test, C=Control, BSL= Baseline, 1FU= Follow up 1, 2FU= Follow up 2, 3FU= Follow up3, Sys=Systolic blood pressure, Dia=Diastolic blood pressure

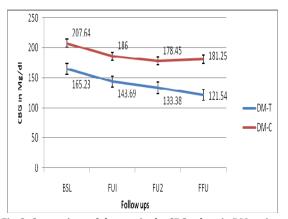


Fig. 2: Comparison of changes in the CBG values in DM patients. Legends: DM=Diabetes Mellitus=Test, C=Control, BSL= Baseline, FU1= Follow up 1, FU2= Follow up 2, FFU= Final Follow up

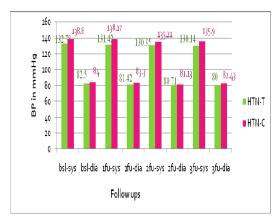


Fig. 3: Comparison of changes in blood pressure in DM+HTN patients

Legends: HTN=Hypertension, T=Test, C=Control, BSL= Baseline, 1FU= Follow up 1, 2FU= Follow up 2, 3FU= Follow up3, Sys=Systolic blood pressure, Dia=Diastolic blood pressure

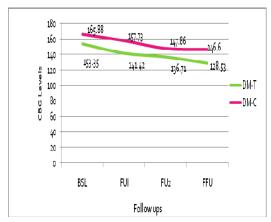


Fig. 4: Comparison of changes in CBG in DM+HTN patients Legends: DM-T=Diabetes Mellitus-Test, DM-C= Diabetes Mellitus-Control, BSL= Baseline, FU1= Follow up 1, FU2= Follow up 2, FFU= Final Follow up

DISCUSSION

Many studies suggest that, pharmacists can play an important role by providing the counselling, which has shown a positive impact on health care and decreases the mortality and morbidity 19. Hypertension and Diabetes are the common chronic disorders where the patient reports lower quality of life than the patients with acute conditions. This study evaluated the impact of post discharge counselling on health outcomes in patients with diabetes, hypertension or both diabetes and hypertension.

Influence of Education on Blood Pressure and capillary blood glucose in study patients

One of the main objectives of the study was to measure the impact of post discharge counselling on blood pressure in the hypertensive patients and glycemic control in type 2 diabetes mellitus patients. The mean blood pressure values and mean CBG values suggests that the blood pressure and glycemic control was better controlled in the test group compared to control group from baseline to final follow up.

However, the changes in blood pressure and CBG values between both the groups were statistically non significant. This decrease demonstrates that influence of education on the medication adherence behaviour, adoption of recommended dietary changes and life style modifications, which in turn has shown an influence on the blood pressure and capillary blood glucose values. Many interventional studies have shown similar results.

In a study conducted by Tankova T, Dakovska G, Koev D in Bulgaria in 2002, influence of education has shown a significant improvement in glycosylated hemoglobin in test group patients compared to the control group patients²⁰.

In a meta analysis of the studies conducted by Machado M, Bajkar J, Guzzo GC, Einarson TR to assess the influence of education on therapeutic outcomes has shown a significant improvement in the glycosylated hemoglobin in test group patients than the control group patients²¹.

In an another study conducted by Adepu R, Rasheed A, Nagavi BG in community pharmacies in Kerala, patient counselling has shown a significant decrease in the mean capillary blood glucose values in test group patients compared to the control group patients²².

In the studies conducted by Chabot I *et al* and Vivian EM to assess the influence of pharmaceutical care on blood pressure control has shown better blood pressure improvement among the patients with pharmacist provided care 23,24 .

Similarly post discharge counselling has shown a positive impact on blood pressure control. In plain hypertensive group and patients with hypertension and diabetes mellitus, achieving goal blood pressure is the important clinical outcome.

Influence of Education on quality of life in study patients with Hypertension.

The psychological General Well Being Index (PGWBI), a generic QoL questionnaire was administered to the hypertensive patients in order to measure their quality of life in previous month. This questionnaire contains 22 questions and composed of six separate subscales: anxiety subscale (five questions), depressed mood subscale (three questions), positive well being sub scale (four questions), self control subscale (three questions), general health subscale (three questions) and vitality subscale (four questions). It has a 6- point likert scale from 0 to 5 points.

An increase in the quality of life score indicates an improvement in the quality of life. Scores of various subscales of the PGWBI such as anxiety, depressed mood, positive well being, self control, general health, vitality.

Overall Quality of Life: Overall quality of life is the combination of scores in all the subscales. The test group patients showed significant improvement in all the six subscales, which in turn has influenced constructively on the overall quality of life in the hypertensive test group patients.

In a review conducted by Coyne KS *et al* to assess the impact of antihypertensive therapy on the HRQoL in hypertensive patients suggested that proper education found very much useful to improve the HRQoL in the hypertensive patients²⁵.

In an another study conducted by Vivian EM to assess the treatment outcomes in hypertensive patients showed the improvement in the health related quality of life in the patients with pharmacist provided education²⁴.

In a study conducted by Carvalho S and Nagavi B.G. in 2006, to study the influence of pharmacist provided education on health related quality of life has shown a significant improvement in the overall QoL scores. This improvement can be attributed to the improved medication adherence behaviour in test group patients²⁶.

These studies demonstrated the influence of pharmacist provided patient counselling on therapeutic outcomes and overall quality of life.

Assessment of quality of life in study patients with DM

Ferrans and Powers diabetic specific questionnaire was used to assess the health related quality of life in the diabetic patients. The questionnaire contains satisfaction part and importance part. Four different subscales are present in both parts. Health and functioning subscale contains 14 questions, social and economic subscale contains 8 questions psychological and spiritual subscale contains 7 questions and family subscale contains 5 questions. All the subscales of the quality of life instrument were affected in diabetes patients of both the study groups.

Overall Quality of Life:

The overall improvement was seen in quality of life score, which is a subtotal of the four subscales of the QLI instrument. Continuous education and better medication and life style adherence has improved the patients' health, functioning capacity, their family and social relationship, psychological and spiritual aspects, and ultimately their overall quality of life in test group.

The similar study was conducted by R Adepu *et al* to evaluate the health related quality of life in type 2 diabetes mellitus patients, which showed the pharmacist provided counselling improved the overall quality of life in diabetic patients in test group²².

In a study conducted by Arun KP *et al* to evaluate the impact of pharmaceutical care on the clinical outcomes in diabetes mellitus patients, the influence of pharmaceutical care showed significant improvement in HRQoL in diabetes patients in rural India²⁷.

Hence, in order to improve the therapeutic outcomes and the HRQL of HTN and DM patients, the proper education about the disease, medication usage and life style modifications are very essential. The present study has shown that the pharmacist provided education can improve the patients' therapeutic outcomes such as achieving goal blood pressure and goal blood glucose levels, also the overall HROoL.

CONCLUSION

The study findings conclude that the structured post discharge counselling showed a positive impact on health outcomes such as glycemic control and blood pressure control and health related quality of life in test group patients in both the disorders compared to control group patients.

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