

# Impact of pharmacist's intervention on improving quality of life in patients with diabetes mellitus

## Abstract

**Introduction:** Diabetes mellitus is a chronic disease affecting multiple organ systems leading to significant morbidity and mortality.

**Objectives:** To assess the impact of pharmacist led interventions in the quality of life in patients with type 2 diabetes mellitus.

**Methods:** A prospective, interventional study carried over a period of 12 months from October 2014 – September 2015 in general medicine outpatient department of a tertiary care teaching hospital. A total of 106 Patients who fulfilled the study criteria were randomized into intervention group (55 patients) and usual care groups (51 patients) and completed the study. Patient information leaflet and medication counselling was provided to intervention group by the clinical pharmacist. Quality of life scores were collected by using Audit of diabetes dependent quality of life questionnaire to both the groups at the beginning and at the end of the study. In a group of 30 patients in the intervention group glycosylated haemoglobin was recorded at baseline and final follow up. These quality of life scores and glycaemic levels (fasting plasma glucose and post prandial plasma glucose) were obtained and compared between both groups at the end of the study.

**Results:** The intervention group showed an improvement in the quality of life score from  $-2.69 \pm 1.53$  at the baseline to  $-1.92 \pm 0.59$  at the final visit ( $p < 0.05$ ). The average HbA1c values decreased from  $9.15 \pm 1.37$  to  $7.21 \pm 0.844$  in the intervention group ( $p < 0.05$ ). There was a significant decrease in the post prandial blood glucose from  $260.30 \pm 93.43$  to  $165.19 \pm 33.44$  and fasting blood glucose from  $163.45 \pm 56.03$  to  $114.45 \pm 18.87$  from the baseline value to the final follow up in the intervention group ( $p < 0.05$ ).

**Conclusion:** The study shows that clinical pharmacist guided appropriate interventions were found to be effective in achieving better glycaemic control and better quality of life in patients with diabetes mellitus.

**Keywords:** diabetes mellitus, quality of life, pharmacist interventions, audit of diabetes dependent quality of life (ADDQoL)

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## Introduction

Diabetes mellitus is a chronic disease that requires a continuous medical care along with patient education, self care, lifestyle modifications and support by the individual to prevent the risk of complications and associated co-morbidities. It has considerable impact on health status and quality of life and limit's patient's routine activities in terms of physical, social and psychological well-being.<sup>1</sup> The increase in number of people with diabetes mellitus is mainly because of population growth, aging, sedentary lifestyle, obesity and lack of physical activity.<sup>2</sup> Uncontrolled glucose levels result in the development of acute and chronic complications and are associated with disease progression, hospitalization, premature disability and mortality. Several observational studies have shown that intensive glycaemic control will lead to improved outcomes in cardiovascular, cerebrovascular and peripheral vascular diseases.<sup>3-5</sup> The challenges in optimally managing the individuals with diabetes mellitus are aimed at preventing or reducing complications, improving life expectancy and quality of life. Quality of life represents the effects of an illness on a patient as perceived by the patient and yields complementary information to medical or epidemiological data. It can powerfully predict an individual's capacity to manage his disease and maintain

long term health and well being. Diabetes mellitus is associated with a major burden of physical and psychological disability and these are likely to substantially impair quality of life. Quality of life has been increasingly used as an important outcome measure to assess efficacy of diabetes care.<sup>6</sup>

A multidisciplinary, collaborative and integrated team based approach with the involvement of all healthcare professionals along with the support of the individual with diabetes mellitus playing an active role in their care is needed in the management of diabetes mellitus. The role of pharmacist within the healthcare system has evolved from a product-centered approach to patient centered care and clinical activities.<sup>7</sup> Several randomised clinical trials have reported that clinical pharmacist interventions in diabetes mellitus care programmes through patient education and medication counseling improved glycaemic control, health related quality of life and other clinical outcomes in patients with diabetes mellitus.<sup>8-10</sup> However, most of the studies in the literature were carried out in countries such as United States, United Kingdom, Canada and Australia. Such service is deemed too have a greater effect in India than in the developed countries where the roles of pharmacist in patient care is not well established and prevalence of diabetes continue to rise

rapidly. Therefore, the present study is aimed to assess the impact of pharmacist interventions in the quality of life in patients with type 2 diabetes mellitus.

## Materials and methods

It was a prospective, randomised interventional study conducted at a multi specialty tertiary care teaching hospital at Dakshina Kannada district, Mangalore, Karnataka. The study was carried out for a period of 12 months (October 2014 to September 2015). Ethical committee clearance was obtained from the institutional ethical committee. The main outcome of this study was improvement in the quality of life assessed by using ADDQOL questionnaire in patients with diabetes mellitus and in their clinical parameters such as fasting blood sugar, post prandial blood sugar and glycosylated haemoglobin level. Patients with diabetes mellitus visiting the outpatient general medicine department were included in the study. Informed written consent was obtained from all participants in the study. Pregnant women, mentally challenged patients and critically ill patients were excluded from the study.

Patients who met the study criteria were randomly allocated to the intervention group or to the usual care group using simple randomization method. Patient details including demographic data, laboratory data and treatment details from patient case records were documented in the data collection form designed as per need of the study. Patients in the intervention group apart from the clinical care also received pharmaceutical care which included counseling on knowledge about the disease, signs and symptoms, instructions on dietary regulation, exercise and other life style modifications while the usual care group patients received clinical care only. The patient information leaflet including diabetic diet chart (prepared in three languages: English, Malayalam and Kannada in discussion with the chief dietician of the study hospital) were also provided to the intervention group in order to provide better counseling. The baseline score was obtained during the first visit for both intervention and usual care groups by using the ADDQOL questionnaire to access the quality of life of patients with diabetes mellitus before the pharmacist intervention.

The pharmacist followed the patient's progress with follow up visits and phone calls and the patient progress was recorded during each visits. On the first follow up visit, after two months from baseline, the intervention group was provided with patient information leaflet and medication counselling by the pharmacist. The medication counselling and education was continued during their second follow up, after four months from baseline. On the final interview, after eight months from baseline, both intervention and usual care groups were again provided the ADDQOL questionnaire and the final scores were collected and documented. The patient's fasting and post prandial blood sugar levels of both intervention and usual care groups were recorded during the baseline and various follow ups of the study. Glycosylated haemoglobin (HbA1c), a measure of the average control of the blood glucose over the previous three months was also assessed in 30 patients from intervention group at baseline and final follow up. The data was analyzed by using SPSS software version 17.0. Descriptive statistics were used to describe demographic characteristics of the sample. Paired t-test was used for inter group analysis to compare follow up values with the baseline values and for categorical variables chi-square test was used. P-values of less than 0.05 were considered statistically significant.

## Audit of diabetes dependent quality of life questionnaire

Bradley's questionnaire was used; Audit of Diabetes dependent Quality of Life (ADDQOL) was utilized to measure an individual perception of the impact of diabetes on their quality of life. The questionnaire was content and cultural validated and tested for reliability for the new language (cronbach's  $\alpha=0.836$ ) by using standard methods. Written permission was obtained from the developer of questionnaire (Dr. Claire Bradley) prior to the study. The questionnaire includes 19 life domain specific items and 2 overview items to be scored between -9 to +9, which is affected by diabetes. The ADDQOL allows the respondent to indicate the aspects of life rate the amount of impact of diabetes and rate the perceived importance of each applicable aspect of life for the quality of life. The impact rating is multiplied by the importance rating for each applicable aspect of life to provide weighted impact scores, which can be averaged across all applicable domains to form a single, average weighted impact (AWI) score. The questionnaire took approximately 15-20 minutes to complete by each individual.

## Results

A total of 147 patients who met the study criteria were enrolled into the study. Out of them 106 patients completed the study (three follow ups of three month interval each) with 55 patients in the intervention group and 51 patients in the usual care group. Forty one patients had lost follow up due to unknown reasons. Among the 106 patients, 58 were males (49.07%) and 48 were females (50.92%). The age range of the participants was between 33 to 79 years in both the groups. The mean age of the study population in both intervention and usual care groups was found to be  $58.38 \pm 10.43$  and  $55.37 \pm 9.88$  (Mean  $\pm$  SD) years respectively. The following Table 1 show the characteristics of the groups studied in relation to the sociodemographic variables. The results of the glycaemic control parameters which have been monitored at baseline and final visits shows that there is a wide variation between usual care and interventions group. In the case of intervention group, a statistically significant difference ( $p < 0.005$ ) was observed from the baseline to the final follow up in the fasting blood glucose from  $163.45 \pm 56.03$  mg/dL to  $114.45 \pm 18.87$  mg/dL and for post prandial from  $260.30 \pm 93.43$  mg/dL to  $165.19 \pm 33.44$  mg/dL. The average fasting blood glucose for the usual care group at the baseline and the final follow up was found to be  $146.48 \pm 45.73$  mg/dL and  $162.52 \pm 28.27$  mg/dL and the average post prandial blood glucose for the usual care group at the baseline and final visits was found to be  $264.88 \pm 104.05$  and  $262.92 \pm 57.31$  respectively. Statistical tests revealed that these values were not statistically significant. The following Tables 3 & 4 shows the comparison of both fasting and post prandial blood glycaemic levels among patient with diabetes mellitus between the groups.

Glycosylated haemoglobin (HbA1c) values for 30 patients in the intervention group were recorded at the baseline and final follow up. Small number was taken due to financial constraints. A significant reduction in the HbA1c level in the intervention group was observed from the baseline value when compared to the final follow up. The comparison of HbA1c values from the baseline to final follow up in the intervention group is shown in the Table 5.

All the patients completed the ADDQOL questionnaire at their first visit with the pharmacist, before any educational activity (baseline)

and at their final follow up visit. The average baseline score was found to be  $-2.98 \pm 1.68$  for the usual care group and  $-2.69 \pm 1.53$  for the intervention group. In the final interview the usual care group score was found to be  $-3.62 \pm 0.54$  which was not statistically significant from the baseline scores ( $p > 0.05$ ). However, in the intervention group the score was found to be  $-1.92 \pm 0.59$  which was found to be statistically significant from the baseline values ( $p < 0.001$ ). The comparison of quality of life scores within groups at the baseline and final follow up is shown in the following Table 6.

**Table 1** Baseline demographic details of the study populations

SI no	Demographic details	Intervention group(N)	Usual care group(N)
1	<b>Gender</b>		
	Male	31(56.4%)	27(52.9%)
	Female	24(43.6%)	24(47.1%)
2	<b>Age (in years)</b>		
	31 - 40	3(5.45%)	5(9.80%)
	41 - 50	8(14.54%)	9(17.64%)
	51 - 60	20(36.36%)	22(43.13%)
	61 - 70	16(29.09%)	13(25.48%)
	71 - 80	8(14.54%)	2(3.92%)
3	<b>Duration of diabetes mellitus (in years)</b>		
	≤1	5(5.05%)	5(9.80%)
	5-Jan	6(6.06%)	19(37.25%)
	10-Jun	31(31.31%)	19(37.25%)
	15-Nov	33(33.33%)	3(5.88%)
	16 - 20	21(21.21%)	3(5.88%)
	≥ 21	3(3.03%)	2(3.92%)
4	<b>Family history of diabetes mellitus</b>		
	Yes	24(43.6%)	19(37.3%)
	No	31(56.4%)	32(62.7%)
5	<b>Co-morbidities</b>		
	0	5(9.1%)	18(35.3%)
	1	30(54.5%)	16(31.4%)
	2	13(23.6%)	12(23.5%)
	3	4(7.3%)	4(7.8%)
	4	2(3.6%)	1(2.0%)
6	<b>Marital status</b>		
	Married	54(98.2%)	50(98.0%)
	Unmarried	1(1.8%)	1(2.0%)
7	<b>Mother tongue</b>		
	Malayalam	25(45.5%)	29(56.9%)
	Kannada	30(54.5%)	22(43.1%)
8	<b>Educational qualifications</b>		
	Illiterate	16(29.1%)	7(13.7%)
	Primary school	30(54.5%)	36(70.6%)
	Secondary school	7(12.7%)	5(9.8%)
	Graduate & above	2(3.6%)	3(5.9%)

**Table 2** Individual life domains in Intervention groups

Domains	Intervention			t	p
		Baseline	Final follow up		
Leisure activities	mean	-2.63	-2.16	1.03	0.305
	std deviation	3.18	1.37		
Working life	mean	-2.8	-2.02	1.07	0.292
	std deviation	2.16	1.92		
Travel	mean	-2.94	-2.27	1.51	0.136
	std deviation	3.29	1.78		
Holidays	mean	-2.86	-2.27	1.24	0.219
	std deviation	3.41	1.94		
Do physically	mean	-3.09	-2.47	1.66	0.102
	std deviation	2.43	1.65		
Family life	mean	-3.12	-1.98	4.09	<0.001
	std deviation	1.66	1.56		
Social life	mean	-2.63	-1.54	2.55	0.014
	std deviation	3.39	1.28		
Personal relationship	mean	-2.59	-1.21	2.41	0.021
	std deviation	3.01	1.19		
Sex life	mean	-1.96	-1.55	0.37	0.71
	std deviation	2.49	1.54		
Physical appearance	mean	-3.07	-1.7	3.28	0.002
	std deviation	2.59	1.28		
Self confidence	mean	-3.12	-1.92	3.32	0.002
	std deviation	2.7	1.18		
Motivation	mean	-2.81	-1.81	2.33	0.023
	std deviation	2.62	1.26		
Society reaction	mean	-1.98	-2.12	0.32	0.744
	std deviation	3.17	1.7		
Future	mean	-2.69	-2.14	1.38	0.17
	std deviation	2.8	1.41		
Finances	mean	-3.01	-2.14	2.17	0.03
	std deviation	2.79	1.35		
Living conditions	mean	-3.12	-3.12	1.01	0.319
	std deviation	1.66	2.91		
Depend on others	mean	-3.12	-1.83	3.5	0.001
	std deviation	2.41	1.22		
Freedom to eat	mean	-3.2	-1.87	3.52	0.001
	std deviation	2.34	1.29		
Freedom to drink	mean	-3.18	-2	3.15	0.003
	Std deviation	2.39	1.41		

**Table 3** Comparison of fasting blood sugar levels among patients with diabetes mellitus between the groups by using repeated measures of ANOVA

Group	Evaluation	Mean	Std. deviation	p
Intervention group	Baseline	163.45	56.03	<0.001 Greenhouse Geisser
	1st follow up	149.04	41.96	
	2nd follow up	127.57	33.26	
	Final follow up	114.45	18.87	
Usual care group	Baseline	146.48	45.73	0.28 Greenhouse Geisser
	1st follow up	153.12	43.82	
	2nd follow up	147.24	43.54	
	Final follow up	162.52	28.27	

**Table 4** Comparison of post prandial blood sugar levels among patients with diabetes mellitus between the groups by using repeated measures of ANOVA

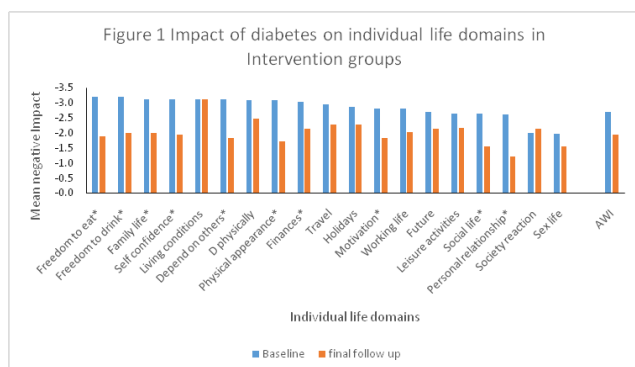
Group	Evaluation	Mean	Std. deviation	p
Intervention group	Baseline	260.3	93.43	<0.001 Greenhouse Geisser
	1st follow up	230.89	74.04	
	2nd follow up	207.57	57.26	
	Final follow up	165.19	33.44	
Usual care group	Baseline	264.88	104.05	0.408 Greenhouse Geisser
	1st follow up	250.04	89.31	
	2nd follow up	238.2	79.97	
	Final follow up	262.92	57.31	

**Table 5** Comparison of HbA1c values among the groups in the intervention group by using paired 't' test

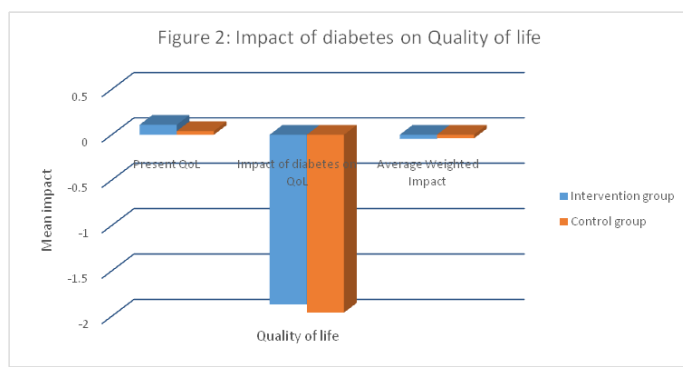
Group	Evaluation	N	Mean	Std. deviation	p
Intervention group	Baseline	30	9.15	1.37	<0.001
	Final follow up	30	7.21	0.844	

**Table 6** Comparison of quality of life within groups by using paired 't' test

Groups	Evaluation	N	Mean	Std. deviation	t	p
Intervention group	Baseline	55	-2.69	1.53	-3.74	<0.001
	Final follow up	55	-1.92	0.59		
Usual care group	Baseline	51	-2.98	1.68	2.69	0.01
	Final follow up	51	-3.62	0.54		



**Figure 1** Impact of diabetes on individual life domains in Intervention groups.



**Figure 2** Impact of diabetes on Quality of life.



## Discussion

Diabetes mellitus is a growing public health concern all over the world. It imposes a personal burden on individuals, negatively affects the health related quality of life and consumes a significant portion of society's scarce health care resources. This negative impact affects multiple aspects of a person's life, including the social, psychological part of one's life being chronically ill, dietary restrictions, symptoms of inadequate metabolic control, chronic complications and lifelong disabilities.<sup>11</sup> The present study evaluated the impact of pharmacist interventions on the quality of life in patients with type 2 diabetes mellitus showed that intervention group who received pharmacist interventions reported overall improvement in diabetes-specific health related quality of life using ADDQOL questionnaire ( $p < 0.05$ ). Pharmacist interventions are considered an important factor in improving glycaemic control and there by achieving better quality of life. Pharmacist's interventions include a printed educational leaflet containing information about diabetes and medication counselling on drug, disease, diet, exercise, lifestyle modification and self-care management which will reinforce patients to achieve target goal. Evidence is clear that improving glycaemic control and preventing complications result in significant cost saving and improved quality of life.<sup>12</sup> From the study, it was found that all the domains mentioned in the questionnaire were affected by the patients with diabetes mellitus. The changes in the average scores of both the groups (intervention and usual care) were observed. In the intervention group the changes in the quality of life score was found to be more significant ( $p < 0.005$ ) as compared to the usual care group. In the study, it was found that the most commonly affected domains of quality of life questionnaire in the study participants were freedom to eat, freedom to drink, family life, self confidence, depend on others, physical appearance, finances, motivation, social life and personal relationship domain of the patients. The improvement in the ADDQoL may in part be attributed to the increased contact of patients with diabetes mellitus with the clinical pharmacist, but it is also likely to be associated with improved adherence to life style modification and self care activities. This study results was consistent with the study carried out by various authors who showed that better glycaemic control in patient with diabetes mellitus is associated with few physical symptoms, better mood and well being which ultimately impacts better quality of life and may helps in health expenditure.<sup>13-17</sup>

## Blood glucose levels

Statistically significant differences in blood glucose levels were observed in the intervention group during their first follow up after intervention and sustained until the end of the study period. The blood glucose levels (both fasting blood glucose and post prandial levels) showed a statistically significant reduction from baseline visit until the final follow up of the study period for the intervention group as compared to the usual care group. Tables 4 & 5 shows the comparison of both fasting and post prandial blood glycaemic levels amongst patient with diabetes mellitus between the groups. Glycosylated haemoglobin (HbA1c) is the internationally accepted test for glycaemic control. Small number was taken due to financial constraints. A significant reduction in the HbA1c level in the intervention group was observed from the baseline value when compared to the final follow up. The comparison of HbA1c values from the baseline to final follow up in the intervention group is shown in the Table 6.

## Conclusion

The results emphasizes the positive impact of clinical pharmacist

mediated interventions on drug, disease, diet, exercise, life style modifications and self care practices in achieving better management of diabetes with significant reduction in glycaemic levels and improved quality of life in patients with type 2 diabetes mellitus. The improved quality of life scores in various domains clearly indicates the benefits of integrating clinical pharmacist services in a multidisciplinary team for a comprehensive management of diabetes mellitus in a hospital care settings.

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## Conflict of interest

Author declares that there is no conflict of interest.

## References

1. Kumaran R, Sudha S, Jayaveera KN. Can a pharmacist improve life of diabetes patient? An overview. *RJPBCS*. 2010;1(3):5-11.
2. Eva T, Valentina PR, Alojz T, et al. An audit of Diabetes-dependent quality of life (ADDQOL) in older patients with diabetes mellitus type 2 in Solvenia. *Value Health Reg Issues*. 2013;2(2):248-253.
3. Mahesh G, Mohideen AKM, Arunmozhy BS, et al. Role of clinical pharmacist in the management of diabetic patients. *Pharmacie Globale*. 2011;2(4).
4. Adibe MO, Ukwe CV, Aguwa CN. The impact of pharmaceutical care intervention on the quality of life of Nigerian patients receiving treatment for type 2 diabetes. 2013;2(2):240-247.
5. Mahvash Iram, Rani Shobha Rani RH, Nalini Pais. Impact of patient counselling and education of diabetic patients in improving their quality of life. *Archives of Pharmacy Practice*. 2010;1(2):18-22.
6. Ramanath KV, Santhosh YL. Impact of clinical pharmacist provided patient education on quality of life outcome in type II diabetes mellitus in rural population. *Asian J Pharm Clin Res*. 2011;4(4):15-20.
7. Ghosh S, Rajvanshi AK, Kishun S. Assessment the influence of patient counselling on quality of life in type II diabetes mellitus patients. *International Journal of Pharma & Bio sciences*. 2010;1(3).
8. Farsaei S, Sabzghabae AM, Zargarzadeh AH, et al. Effect of pharmacist-led patient education on glycaemic control of type 2 diabetes: a randomized controlled trial. *J Res Med Sci*. 2011;16(1):43-49.
9. Balaiah S, Tirupa M, Narayana G, et al. Assessment of pharmaceutical care services on health related quality of life in patients with type II diabetes mellitus-A prospective interventional study. *Int J Pharm sci*. 2014;6(7).
10. Chidambaram D, Sumy S, Kumaran KSGA. Role of clinical pharmacist in the management of type 2 diabetes mellitus and its outcomes. *IJPTP*. 2014;5(3):977-983.
11. Seema M. Evaluating the impact of counselling on quality of life in type 2 diabetes mellitus patients. *IJPA*. 2013;2(6):137-141.

12. Wishah RA, Omar AA, Abla MA. Impact of pharmaceutical care interventions on glycaemic control and other health-related clinical outcomes in patients with type 2 diabetes: randomized controlled trial. *Diabetes Metab Syndr*. 2015;9(4):271–276
13. Modh KM, Patel KM, Anand IS, et al. Impact of clinical pharmacist intervention on quality of life in type 2 diabetes mellitus. *J Res Med Sci*. 2011;2(8):451–460.
14. Gillani SW, Sulaiman SAS, Victor SC, et al. Applicability of pharmaceutical care in endocrine clinic of hospital Penang, Malaysia. *Journal of diabetes research & clinical metabolism*. 2012.
15. Adepu R, Rasheed A, Nagavi BG. Effect of patient counselling on quality of life in type-2 diabetes mellitus patients in two selected south Indian community pharmacies: A study. *Indian J Pharm Sci*. 2007;69(4):519–524.
16. Shivashankar V, Sriram S, Rajalingam B, et al. Study on impact of pharmacist intervention with type II diabetic patients. *Pharmacie Globale*. 2012;3(11):1–3.
17. Sriram S, Chack LE, Ramasamy R, et al. Impact of pharmaceutical care on quality of life in patients with type 2 diabetes mellitus. *J Res Med Sci*. 2011;16(supply 1):S412–S418.