



JOURNAL OF PHARMACEUTICAL SCIENCE AND BIOSCIENTIFIC RESEARCH (JPSBR)

(An International Peer Reviewed Pharmaceutical Journal that Encourages Innovation and Creativities)

Achieving Glycemic Control of Diabetic Patients through Clinical Pharmacist provided Counseling

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ABSTRACT:

Pharmaceutical care programs developed and implemented by the pharmacists are useful in improving quality of care of both ambulatory as well as hospitalized patients with diabetes and also with other chronic diseases such as, hypertension, asthma, dyslipidemia, heart failure and tuberculosis. In recent years, pharmacists in many practice settings have begun providing patient-centered services with the goal of improving drug therapy outcomes through practices such as pharmaceutical care.

30 patients of both the genders who were diagnosed with Diabetes Mellitus (either type 1 or type 2) and taking anti-diabetic agents were recruited for the study. Baseline HbA1c was performed. Patient counseling was provided regarding their disease, drugs and life-style modifications (including exercise, self-care activities, etc). Follow-up was taken every 4-5 weeks Post-counseling HbA1c was performed after 12 weeks to assess the impact of patient counseling on glycemic control.

Mean Baseline HbA1c value of 30 patients was observed to be 8.37% having the standard deviation of 1.76. The lowest HbA1c of patient that was observed was 5.8% and the highest one was > 14%. Post-counseling HbA1c was performed after the end of 12 weeks of each patient, starting from date of enrollment. The mean HbA1c found at the endpoint was 7.96% ± 1.58%. At the endpoint the lowest test result was noted to be 5.60% and highest was 13.30%. The paired T-test result showed that there was significant difference existed in the pre-counseling HbA1c and post-counseling HbA1c after 12 weeks. Thus patient counseling showed significant reduction in HbA1c.

Our study concluded that clinical pharmacist provided patient counseling in community settings has a positive impact on glycemic indices.

KEY WORDS: Glycemic control, HbA1c, Clinical Pharmacist, Patient Counseling, Pharmaceutical Care, Diabetic Patients

Article history:

Received 18 March 2015

Accepted 23 March 2015

Available online 01 May 2015

Citation: Shah J V, Patni K N, Deshpande S S. Achieving Glycemic Control of Diabetic Patients through Clinical Pharmacist provided Counseling. *J Pharm Sci Bioscientific Res.* 2015 5(3):322-327

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INTRODUCTION:

Diabetes Mellitus (DM), a disease of endocrine and metabolism. It is not a single disease; rather it is a syndrome consisting of various subtypes of diabetes with hyperglycemia. ^[1] One of the definitions suggests that diabetes is a chronic condition caused by relative or absolute lack of insulin. Its hallmark clinical characteristic is symptomatic glucose intolerance resulting in hyperglycemia and alterations in lipid and protein metabolism. ^[2] Today, India is the country which leads the world with its largest diabetic population of 32 million in the year of 2000. This number is predicted to rise to 80 million by year of 2030. It has also been observed that the prevalence is higher and rapid in urban areas from 2% in 1970s to 12% in 2000, as well in rural areas; this is now also beginning to increase. ^[3]

Thus pharmaceutical care plays an important role in chronic conditions like DM. 'Pharmaceutical care' is a practice in which the practitioner takes responsibility for a patient's drug-related needs and is held accountable for this commitment.

In the course of this practice, responsible drug therapy is provided for the purpose of achieving positive patient outcomes.^[4] It is the 'heart' of pharmaceutical care practice and is the combination of everyday activities that pharmacists perform when interacting with patients in pharmaceutical care practice. The purpose of patient care process are to attain the most effective, appropriate, safe and convenient drug therapy for the patient; to identify, resolve and prevent any drug therapy problems that could hinder in this attainment; and to ensure positive patient outcomes. The patient care process involves three steps: assessment, pharmaceutical care plan and follow-up evaluation. This process is comprehensive and systemic problem solving process.^[5] The interpersonal communication plays a major role to achieve the goal of pharmaceutical care process.

Patient counseling on disease, drugs and life-style modifications including self-care activities, exercise, etc., plays a vital role. The effect of patient counseling provided by clinical pharmacists can be assessed by the improvement in glycemic control. This can be seen by obtaining the baseline glycemic indices and post-counseling glycemic indices. According to WHO HbA1c is the gold standard for analyzing the glycemic control.^[6]

Need of present study:

The rapidly increasing number of patients with Type-2 Diabetes Mellitus is making type – 2DM a serious healthcare problem worldwide.^[7] Education plays an important role in DM treatment, as it enables patients to manage their disease.^[8] Meta-analysis of randomized control trials have shown that lifestyle interventions reduced progression from impaired glucose tolerance to type 2 diabetes and that glycaemic control improved postprandial plasma glucose levels after meals.^[7] Numerous negative health outcomes related to diabetes, including macro-vascular and micro-vascular complications, cause higher rates of morbidity and mortality in these patients. The Canadian Diabetes Association has stated that people with diabetes are twice as likely to die prematurely as those without diabetes.^[9] Since this is primarily a lifestyle disease, the professional bodies and professional community must accept the challenge of creating awareness so that appropriate changes are made in the pre-natal, natal, post natal, childhood and specifically in the Middle Ages.^[10]

It is found that the pharmaceutical care programs developed and implemented by the pharmacists are useful in improving quality of care of both ambulatory as well as hospitalized patients with diabetes and also with other chronic diseases

such as, hypertension, asthma, dyslipidemia, heart failure and tuberculosis.^[11] In recent years, pharmacists in many practice settings have begun providing patient-centered services with the goal of improving drug therapy outcomes through practices such as pharmaceutical care.

Moreover, diabetes is a chronic condition in which medications are to be taken life-long. Thus along with patient counseling, cost minimization also plays an important role. This becomes helpful in reducing the economic burden on the patients. As a result, the treatment can be made affordable and adherence to the therapy can be increased.

Methodology:

For the conduct of this study, permission from Human Ethics Committee (KBIEC) was obtained. The total duration of the study was of 16 weeks and for each patient's study, it was of 12 weeks. Patient with either type 1 or type 2 DM, patient taking anti-diabetic agents, patients' Age: 18 year or above and patients of either of gender were included. Patients who did not wish to participate and who did not provide the information were excluded. Once patients were enrolled and afterwards they did not provide information were considered withdrawn patients. Patients lost to follow-up or who did not wish to continue with the study were dropped-out. Sample size was as per convenient sampling method for this pilot study.

Patient counseling:

After recruitment of patients according to inclusion and exclusion criteria, studied the patient profile/case notes [Demographic details; present complains (if any); detailed medical, medication, family and social history; current therapy]. Baseline HbA1c test was performed and thereafter, counseling regarding disease, drugs and life-style modifications to improve their glycemic control was provided. Follow-up of patients was done every 4-5 weeks. A post-counseling HbA1c was performed after 12 weeks to evaluate the effect of counseling.

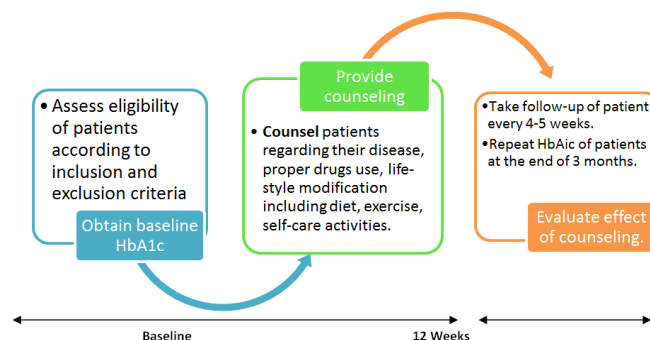


Figure 1: Methodology for study

Results:

During the study period, patients were recruited from three different community settings of Ahmedabad city namely: Nirnaynagar, Maninagar and Sardar Patel Stadium. From these three areas, total of 30 patients were enrolled in the study in accordance with the inclusion and exclusion criteria, after giving the written consents. During the study period, patients case files and medical records were reviewed and noted in the case record form.

Out of 30 patients, there were 40% (12) females and 60% (18) males enrolled in the study. The mean age of the recruited patients was 57.8 years with standard deviation (\pm) of 10.18 years. The minimum age of patient was 42 years and maximum age of patient was 88 years. Majority of the patients were in the age group of 41-50 years (10 patients) followed by 51-60 and 61-70 years (9 patients in each group). The BMI of patients was also obtained. The mean BMI was found to be $24.98 \text{ kg/m}^2 \pm 3.22 \text{ kg/m}^2$. Out of the recruited 30 patients, majority of patients (16) were having the BMI ranging from $24.1-30.0 \text{ kg/m}^2$. This shows majority of patients were overweight. 12 of the patients were having normal weight, whereas 2 patients had BMI ranging from $30.1 - 35.0 \text{ kg/m}^2$.

The mean Baseline HbA1c value of 30 patients was observed to be 8.37% having the standard deviation of 1.76. The lowest HbA1c of patient that was observed was 5.8% and the highest one was $> 14\%$ (undetected in the diagnostic machine). The overall HbA1c of patients were considered as not too much out of the limits.

Table 2: HbA1c Baseline and Endpoint

Baseline and Endpoint comparison of Hemoglobin A1c (HbA1c)		
(n = 30)	Baseline HbA1c of patient	Endpoint HbA1c
Mean	8.37%	7.96%
Std. Deviation	1.76%	1.58%
Minimum	5.80%	5.60%
Maximum	14.00%	13.30%

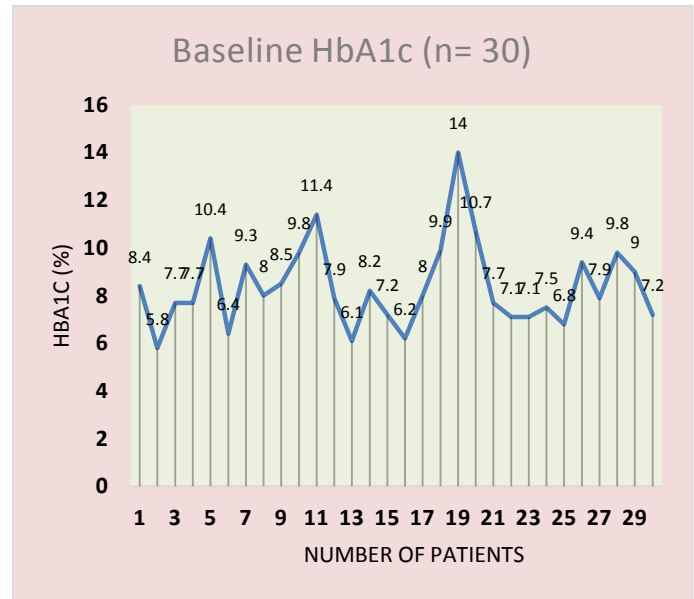


Figure 2: Baseline HbA1c

The endpoint of patients, also referred as post-counseling HbA1c was performed after the end of 12 weeks of each patients, starting from date of enrolment. The mean HbA1c found at the endpoint was $7.96\% \pm 1.58\%$. At the endpoint the lowest test result was noted to be 5.60% and highest was 13.30%.

Out of 30 patients, the HbA1c of total of 5 patients were increased and of the two patients, it was same at the start and end of the study. There are various factors that may have contributed to this scenario.

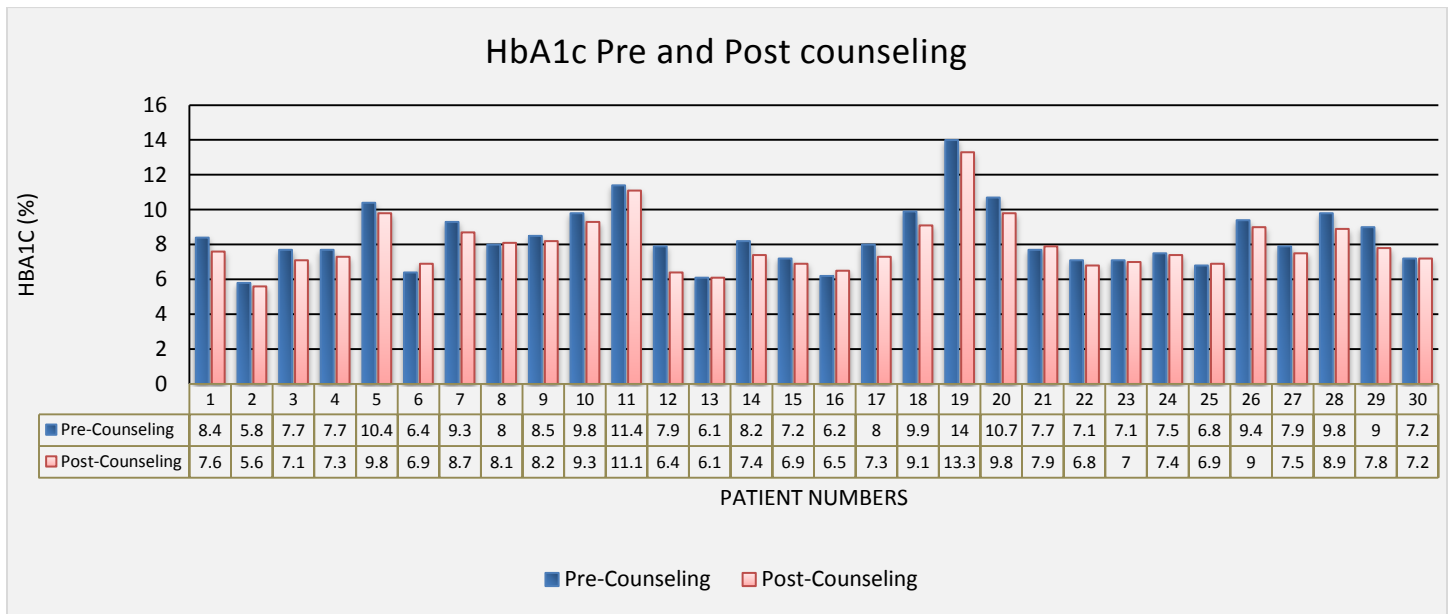
The paired T-test result showed that there was significant difference existed in the pre-counseling HbA1c and post-counseling HbA1c after 12 weeks.

Table 1: Paired T-Test

Paired Samples Test							
Paired Differences							
95% Confidence Interval of the Difference							
Mean	Std. Deviation	Lower	Upper	t	df	Sig. (2-tailed)	
Baseline - Endpoint	0.41	0.45	0.24	0.57	4.95	29	.000

t: T calculated value, df: Degree of Freedom.

Figure 3: Pre and Post-counseling HbA1c



It is observed that at 29 degree of freedom and 95% confidence interval, the T- calculated (4.95) is much higher than the T-tabled (2.04) value. The *p*- value of <0.5 is considered significant. This shows that there is significant statistical difference exists in both the condition.

Discussion:

The Paired sample T- test of the first 30 patients showed significant differences in the baseline and endpoint HbA1c ($T_{Cal} > T_{Tab}$). This proves that there is a positive impact of patient counseling on the glycemetic control of patient. The similar results are also observed in other published literatures. Although out of 30 patients 4 patients’ HbA1c was increased compared to baseline and of 2 patients’ it was same for baseline and endpoint. There could be multiple factors for it. The possible factors are: these patients may require larger time to follow, or the instructions given during the counseling were not properly followed. These patients may require more/frequent counseling to achieve their personalized goal of therapy.

Satpute DA et al, in their study found significant reduction in HbA1c (1% in group 1, 1.3% in group 2 and 1.2% in group 3). He has concluded that significant reduction was observed in the patient counseling group after 3 months. He notes that glycemetic control of type – 2 DM patients can be improved through patient counseling regarding the disease, medication, personal hygiene, diet and exercise.^[12]

Compared to our study results, **average reduction of 0.41% HbA1c** of 30 patients, the Diabetes Control and Complications Trial Research group (DCCT) study reported a 1.6% (8.5% baseline v/s 6.9% at 12 months) reduction in HbA1c levels.^[11] Another study performed in India by Ramanath KV et al, on 113 patients, a significant increase QOL, KAP and adherence score was noted in their intervention group. Also the blood glucose level (FBS & PPBS) was significantly changed in the intervention group. Thus, they have concluded that the pharmacist can play an important role in giving education to patients to maintain and control their disease condition.^[13]

Mazroui NR et al, in his study found that the pharmacist provided extensive diabetes care results in more healthy behaviors of patients specifically relating to diet and diabetes self-care. Although in his study, statistical significant improvement was not observed; the study results showed that pharmacists were effective in improving patient’s self-care behavior.^[11] Doucette WR et al. concluded significant reduction (0.27%) at 4, 8 and 12 months post-counseling in HbA1c.^[14]

One more study from India, by Adepu R et al, concluded in their study that the structured post discharge counseling shows a positive impact on glycemetic control and blood pressure control and health related quality of life. Similarly in our study, it was observed that the counseling shows reduction in the glycemetic control of the patients.^[15] Similarly to our study, counseling regarding life-style modifications including self-care activities was also provided,

in a randomized, controlled, parallel group trial of six months conducted in 66 community pharmacies of Belgium by Mehuys E, et al., a significant reduction in HbA1c (0.5%) was recorded in the group of patients provided counseling. They have found that diabetes education program resulted in better glycemic control. Along with that the study also showed improvement in patients' practical knowledge about diabetes, as well as their self-care activities (foot care, eye care etc.)^[16]

They have noted that treatment of hyperglycemia in DM is the main priority due to the reasons of, tight glycemic control reduces the risk of complications of DM. According to UKPDS, each 1% HbA1c reduction over 10 years is related to risk reduction of 21% for reduction in diabetes related endpoints, 14% myocardial infarction, 21% diabetes related mortality, 12% stroke and 37% microvascular complications (retinopathy, nephropathy and neuropathy).^[16, 17]

Here in our study majority of patients are having diabetic complications such as hypertension, IHD, stroke and hyperlipidemia. Of the 30 completed patients, 10 patients are having hypertension; reduction of minimum 0.1% and maximum of 1.5% in HbA1c and two patients are having hypertension along with IHD (reduction of 0.9% HbA1c is observed in one patient) as a co-morbid condition. One of the patients is having hypertension along with hyperlipidemia in which reduction of 0.3% HbA1c is observed. Reduction in HbA1c in such patients would reduce the risk of further aggravation of their co-morbidities.

While performing literature review, it was observed that none of the study performed on the effect of counseling on glycemic control, took the follow-up of HbA1c. All the studies, including the present work performed the HbA1c only after 3 months and not repeated the test after another 3, 6 and so on months (excluding one study). If it was done, it would produce much more effective data of evidences.

Conclusion:

Our study concluded that clinical pharmacist provided patient counseling in community settings has a positive impact on glycemic indices. Similar studies published in past, also have the similar conclusions. It means that it is concluded that counseling improved glycemic control of patients. Providing a short course of counseling on disease, drugs and life-style changes in controlling of DM, has a positive impact on the glycemic control of patients with DM. This counseling also helps in better adherence to their therapy and results in achieving the personalized therapeutic goal in more efficient way.

Limitation and future recommendations of study(s):

There were few limitations in the study which can be taken care in future research. In our study for evaluation of effect of counseling only HbA1c test was taken into consideration, the co-morbid conditions parameters (such as blood pressure, lipid levels, etc.) should be added for assessment. Patient follow-up was taken at 4-5 weeks which can be increase for every 2 weeks. Diet chart and diary for record can be given to patients. As per our pilot study we had the study for 4 months but study must be plan for minimum of 6-12 months so patients not showing decrease in HbA1C can be given more counseling and better effect can be observed.

Acknowledgment:

We are grateful to **Dr. Rajesh R. Shah**, M.D.; Consulting Physician and Cardiologist (Siddhi Heart and Medical Hospital, Nirnaynagar, Ahmedabad) and to, **Dr. Jitendra B. Patel**; M.D., F.R.S.H., Consulting Physician, Cardiologist and Diabetologist (Pruthvi Medical Nursing Home and Heart Centre, Naranpura, Ahmedabad), for providing us a site for research and recruitment of patients. Their continuous support in this research is heartily appreciated. Thank you for believing in the work of Clinical Pharmacists.

Conflict of Interest:

There are no conflicts of interests.

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