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IMPACT OF PATIENT COUNSELLING IN IMPROVING MEDICATION COMPLIANCE AMONG DIABETIC PATIENTS

Dr. Sabyata Gautam[1*], Rojina Basnet[2] and Dr. Balmukunda Regmi[3]

[1*]Associate Prof., Department of Pharmacy, National Model College for Advance Learning (Affiliated to IOM, TU), Khusibhu, Kathmandu, Nepal.
[2]Research Officer, Ethical Review Board, National Health Research Council, Nepal
[3]Professor and Former HOD, Institute of Medicine (IOM),TU and Director, Confucius Institute, TU, Nepal.

***Corresponding Author: Dr. Sabyata Gautam**
Associate Prof., Department of Pharmacy, National Model College for Advance Learning (Affiliated to IOM, TU), Khusibhu, Kathmandu, Nepal.

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ABSTRACT
The main aim of the study was to find the impact of pharmacist's counselling in improving medication adherence among diabetic patients in Kathmandu valley. Data collection was done from Jan 2017 till June 2018. In our descriptive cum exploratory study, of total 321 diabetic patients, the mean age was 57.5 ± 12.47years. MARS and MARS-5 scoring models were used to measure compliance before and after counselling. MARS had ten questions with total score of 10 and MARS-5 contained five questions with total score of 25. MARS-5 scoring after counseling had mean value of 24.06 ± 1.54, which was 23.17 ± 2.40 before counselling ($P \leq 0.000$). Similarly, the study found the mean values of 8.21 ± 1.24, before counselling and 9.03 ± 0.89, after counselling, while using MARS questionnaire ($P \leq 0.000$). Notable improvement in patient's blood sugar levels (F, PP and Hb1Ac) too were also observed after counselling. Thus, counselling from pharmacist is effective in improving the compliance among diabetic patients. Since most of the patients, with reference to the self, admitted that lack of knowledge regarding disease management is the major reason for non-adherence, counselling or awareness programs are much in need.

KEYWORDS: Diabetic, Counselling, Compliance, MARS.

INTRODUCTION
Diabetes prevalence has been increasing daily due to urbanization, obesity and physical inactivity. According to the article published by Wild et al. "the prevalence of diabetes for all age groups worldwide was estimated to be 2.8% in 2000 and is projected to reach 4.4% in 2030. The total number of people with diabetes is projected to rise from 171 million in 2000 to 366 million in 2030".[1]

Non-compliance to anti-diabetic medication has been one of the main reasons for poor glycemic control. It has been a universal problem. According to the study done in Dhulikhel Hospital, Kavre, Nepal, commonly suggested factors for non-adherence to OHA's includes "forgetfulness, lack of self-discipline and limited knowledge or fearless attitude towards the consequences of diabetes" and only "37.7% of the patients prescribed with OHA's had HbA1c value less than 7%" i.e. controlled glucose level.[2] Poor-adherence to anti-diabetic medication has been found to be related with uncontrolled blood glucose level and then, development of further complications, premature disability and death. So, this matter must be taken seriously and disease must be treated properly on time.

Patient counselling can motivate them for better quality of life. Patients' motivated behavior helps them to follow better way for better health. Counselling can motivate patient to comply with advices on disease management and lead to fit life in remaining days.

The incidence associated with uncontrolled diabetes are number of serious complications, including large and medium muscle arteries (macrovascular disease) and capillary dysfunction (microvascular disease) in target organs like retina, kidney and peripheral nerves. "Macrovascular complication leads to accelerated atherosclerosis causing serious risk of MI, stroke and gangrene in the lower extremities".[3] Thus, proper disease management is very necessary for patients in order to delay the onset of complications. Pharmacist is important member of health care team who can perform counselling for proper glycemic control among diabetics.

The objectives of the research work were
1. To study demographic profile of diabetic patients.
2. To analyze improvement in compliance before and after counselling (after three months) through MARS scoring; to examine impact of pharmacist's

counseling, and relate medication adherence pattern (MARS scoring) with demographic data.
3. To analyze the causative factors for medication non-adherence in diabetic patients.

METHODOLOGY

Study design: Explorative cum descriptive.

Research method: Mix-method (using both quantitative and qualitative method).

Study site and sampling technique: The research site will be Kathmandu Valley including Kathmandu and Lalitpur districts.

Patient inclusion criteria: 1. Patients having glycosylated hemoglobin (Hb1Ac) value > 6.5% despite being treated with anti-diabetic medication for over a month.

Patient exclusion criteria: 1. Patient seriously ill to participate or hospitalized patients. 2. Newly diagnosed (less than 1 month) patients.

Sample size: The total number of patients was 321.

Data collection: The key informants were the diabetes patients of out-patient department. The people were asked to fill their demographic information on the semi-structured questionnaire and remaining check-list was filled by researcher by self. The informants in their in-depth interview declared the reasons for patient non-compliance and proper counselling was done orally and by providing leaflets.

Ethical Principles: The formal research protocol will be agreed by Department of Pharmacy, Shri JJT University, Rajasthan, India. A questionnaire or information sheet was given to respondents, in Nepali and then request to make contact with researcher after their consent.

Before beginning this study, permission was taken from Ms. Kulkarni for taking data by using MARS (Medication Adherence Rating Scale) questionnaire. Data collection has been started only after taking permission from respective centers. Approval had been taken from **National Health Research Council** (NHRC), GoN, Ramshah path, Kathmandu, Nepal also (Ref no. 1856).

Data analysis technique: All prospective data were analyzed with the help of statistics (paired t-test), using MS-Excel and SPSS 20.0.

RESULT AND DISCUSSIONS

DEMOGRAPHIC PROFILE: The demographic profile of total 321 patients like address, gender, education were noted.

Address: Regarding address, 68.2% of the patients were residing in urban Kathmandu valley and 31.8% of the diabetics were from outside Kathmandu valley.

Gender: 172 patients were male and 149 patients were female in current study.

Education Level: Most of the patient (n= 91) had education till primary level only, 44 patients had education till secondary level, 29 patients had education till higher secondary, 28 patients had education till diploma level, 49 were graduate, 10 were educated upto masters and above, but 70 patients were illiterate in our study.

Age-wise distribution: In this study, age group of 51-60 years was found to contain 98 patients (30.5%), which was highest. In our study, the "mean age of patients" was found to be 57.5 ± 12.47years in our study.

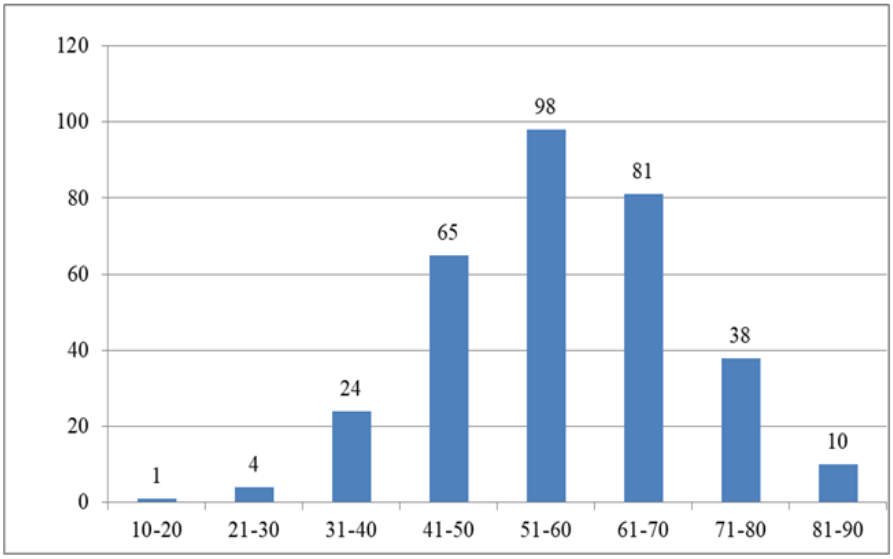

Figure 1.1: Age-wise distribution of patients.

Years with Diabetes Mellitus: 34 years was maximum year with disease and 7.88 years ±6.92 was "mean" years lived with diabetes.

Family history: Regarding family history, 128 patients had someone suffering from diabetes in their family, 184 patients had no family history and whereas 9 patients were unknown that if someone suffered from diabetes in their family. Among those who had diabetics in family, mostly answered relationship was Brother and Mother, followed by Father. Parents and siblings have strong genetic relation in case of DM.

BMI: 36.3% diabetic patients were found to be overweight (BMI 25-29.9 Kg/m^2) and 21.2% patients were found to be obese (≥30 Kg/m^2) in our study. Problem of Type 2 DM has increased with increasing cases of obesity, which is assumed due to increased amount of adipose tissue and insulin resistivity. In fact, over 80% of individuals with Type 2 DM are obese. The over-expression of Tumor Necrosis Factor α (TNF-α) in adipose tissue in obese patients, would inhibit the transport of glucose by hindering formation of GLUT-4. Thus, during obesity, disturbances in the TNF-α metabolism may affect the onset of Type 2 diabetes mellitus. However, the exact role of TNF-α in the duration and progression of the disease is not clear. Study also suggests that, along with "its effect on the pancreatic islet cells, TNF-α also has a regulatory effect on the immune system"[4] and also may lead to Type 1 DM.

COMPLIANCE ASSESSMEMT BEFORE AND AFTER COUNSELLING

Questionnaires were filled after taking consent from patients and then they were counseled. They were told to come for follow-up after three months with laboratory reports.

Counselling points or patient instructions for different diabetic medications:

Patient's instructions for different drugs provided by pharmacist's to improve compliance and awareness were as follows.

Insulin

1. Insulins must be injected at proper time. They should be administered 15-30 mins before meal. Patient should not to miss the meal after taking insulin.
2. Patient must carry a source of sugar such as candy at all times, so that it could be used in case of hypoglycemia. Hunger, sweating, palpitations and tremor are autonomic hypoglycemic symptoms are observed at plasma sugar level of 60-80 mg/dl.
3. When long acting insulins are given twice day, they show steady state plasma profile and decreased chance of hypoglycemia than other types of insulin like "NPH insulin". T2 diabetic patients also may require intermediate acting insulin or long acting insulin, to be used at bedtime for controlling basal blood glucose.
4. Storage: Insulin should be stored in "a refrigerator at cold temperature of 2-8^{0}C". If refrigerator is unavailable it should be stored in the coldest place of the house.
5. Route: Subcutaneous administration is preferred. Injection should be given with maintaining angle of 45°. Patients must rotate the site of injection to prevent the problem of lipo-hypertrophy.

Sulfonylureas

1. Hypoglycaemia is prominent side-effect and related to the potency and duration of the drug, and to the physiological status of liver and kidney. So, patients must check their liver and kidney once a year.
2. Glibenclamide may be more sensitive to hypoglycaemia, especially in elderly patients. They must carry sugar containing products all the time.
3. Patients must check their plasma glucose level often (once a week). Acute neurological problem along with cerebrovascular accident may occur in elderly patients due to severe hypoglycemia.
4. Patients must know that dose adjustment is necessary as some patients may develop resistance and require high dose.

Metformin

1. The common side-effects are abdominal discomfort, diarrhea, nausea, anorexia and metallic taste (in 20% of cases). These effects can be reduced by decreasing dose. The dose of the drug must be increased slowly and drug must be taken with meals.
2. Patient's renal function should be assessed before using metformin and then-after annually. In cases of hepatic disease, it may lead to lactic acidosis, cardiac failure requiring drug therapy, or chronic hypoxic lung disease. So, if patient develops a condition associated with hypoxemia or dehydration, he/she must visit clinic, because, then the drug should be discontinued immediately.
3. Metformin must be discontinued for a certain time before any surgical process or before administrating any i.v contrast media. The drug should not be taken before 2 days of such surgeries.
4. Intestinal absorption of vitamin B12 and folate may be decreased during metformin therapy. So, patients were advised to consume food containing Vit. B12 in regular basis.
5. Metformin doesn't increase weight and it decreases triglycerides level by 15 to 20%. Thus metformin is the only drug that is proved for preventing macro-vascular complications in T2 diabetes. Thus patient should take it regularly without any misses.

α-Glucosidase Inhibitors

1. α-glucosidase inhibitors may results in flatulence, diarrhea and mal-absorption since they baffle carbohydrate digestion, but do not cause hypoglycaemia.

2. Antacids should not be taken with this drug to overcome the side-effects of acarbose/ voglibose.
3. In case of hypoglycaemia, when used with insulin, glucose (rather than sucrose or starch) must be provided.
4. Insulin therapy must be started if combinations of four drugs are insufficient to control BG. Yoga and morning walk (life-style modifications) has become popular and was advised to patient.

Meglitinides

1. Their primary therapeutic effect is to reduce postprandial blood glucose elevation (causing insulin release by closing ATP-dependent K^+ channels in pancreatic β-cells), but they can cause hypoglycaemia.
2. It is mandatory to discontinue them in emergency cases of myocardial infarction or sepsis.
3. Patients suffering from nephropathy needs precaution. Dose adjustments are needed in those patients.

Thiazolidinediones

1. It is found to decrease HbA1c value by 1 to 1.5%. They must be taken once daily at proper time.
2. They are metabolized in liver so they must not be given to the patient with hepatic impairment or in cases of significant hepatic transaminases (AST and ALT) elevations. Patient must check liver function before taking this drug.
3. Thiazolidinediones may cause increased weight, edema and sometimes anemia. Plasma volume rise or the edema problem is increased if thiazolidinedione is used along with insulin. Heart condition must be monitored regularly.

Glucagon-like Peptide 1 (DPP 4 inhibitors)

1. If taken regularly, they (Teneligliptin, Sitagliptin etc.) are effective in lowering HB1Ac upto 1-1.3%, so it must be taken regularly.
2. Hypoglycemia may be seen when DPP-4 inhibitors are used in combination with other insulin secretagogues. Patient must take candy or sugar in case of hypoglycaemia.
3. Self-limiting nausea may be present in 15-30% patients.

Thus while dispensing these drugs, pharmacist must be well-versed with all key information of these drugs and counseled it to patients taking enough time. Different textbooks on pharmacology from writers like B. Katzung[5] and F. S. K Barar[6] were used to gather information on medications used in DM.

Compliance measurement through MARS-5 scale

Self-reporting monitoring rating scale was used in our study. MARS-5 had five questions with likert scoring with total score of 25 was used in our current study. Patient who obtained MARS score ≥ 23 were categorized as "adherent" and those with a score ≤ 22 as "non-adherent" as per Cottrell N.[7] Before proper counseling, out of 25, mean score was 22.98 with standard deviation of 2.49. The MARS 5 consist of five questions including "forgetting", "changing of dosages", "stopping", "skipping" and "decreasing dose". Likert scale consisting five options were "always", "often", "sometimes", "rarely" or "never" for each question; with increasing order from "always" (1 score) to "never" (5 score). This scale has been used as many public health professional. The individual score for "each of the five questions are cumulated to give total score of five to twenty-five points". Medication informations were recovered from subject's medical records and laboratory data.

As per MARS-5 questionnaire contains five questions with total score of 25.[7] The minimum score was 12 and the maximum was 25. MARS-5 scoring after counseling, had mean of 24.04 ±1.54. In our study, the minimum score was 14 and the maximum was 25.

Table 1.2: Comparison of Means of MARS-5 scoring.

	Mean	Std. Dev. (S. E)	Significance (2-tailed)
Mars-5 Score (before counselling)	23.17	2.403 (S. E = 0.182)	0.000 (Paired sample T-test, t = -5.142, CI: -1.225 to -0.545)
Mars-5 Score (after counselling)	24.06	1.538 (S. E = 0.117)	

Source: Field Study, 2018

Paired t-test was done for MARS-5 counselling before and after counselling, there was significant difference with P = 0.000. (with confidence interval of -1.225 to -5.545, t = -5.142). Paired-T test is used in this study as same patients are used before and after for measuring compliance. Thus, MARS-5 scoring was 23.17 ± 2.40 before counselling, but, 24.06 ±2.40 after counselling, which was statistically significant (P=0.000). MARS-5 questions was used similarly in the study done by Lee C. S. et al., in which similar result was found. Upon the total score of 25, the "median MARS-5 score was 24" in their study conducted in Malaysia.[8]

Compliance measurement through MARS scale

Medication compliance has been one of the foremost problems in chronic diseases. In our study, it we use Thomson's MARS questionnaire (Thomson, 2000) for measuring compliance. "Development of the new MARS (Medication Adherence Rating Scale)" was based on the MaQ and DAI questions, which uses "individual responses" on each item. The MARS questionnaire for

adherence had ten questions. Score of "1" was given for complaint attitude or behavior and "0" for non-compliance. The minimum value was O and maximum was 10. In our study, the mean value was 8.06 ± 1.37 before counselling, which was increased to 9.03 ± 0.89 after counselling.

Table 1.3: Comparison of means of MARS Scoring.

	Mean	Std. Dev	S. E	Significance
MARS Scoring (before)	8.06	1.37	0.094	.000 (t = -9.478, CI: -0.994 to -0.652)
MARS Scoring (after)	9.03	0.89	0.068	

Source: Field Study, 2018

Impact of counselling on increasing compliance was main target of this study. The mean MARS scorings before and after counselling were calculated and there was significant difference with P = .000. (CI was -0.994 to -0.652, t = -9.478). The data had been analyzed using MS-excel and SPSS. Since, both MARS-5 and MARS are significant after counselling, we can say that there is strong impact of counseling in improving compliance in diabetic patients were statistically significant (P< 0.05) in both the cases. This implicated that pharmacist counselling can provide significant improvement in MARS score. Along with MARS scorings; FBG, PPBG and Hb1Ac laboratory values was also observed during first visit and during follow-up. The average fasting, PP and Hb1Ac level in patients showed significant reduction (P = 0.000) after counselling corroborating with MARS result.

As per Johnson A. B.'s (2016) article, categorization model for patient compliance was as: MARS score having "0-3" was considered Non-adherent, "4-6" was considered partially adherent and "7-10" was considered as Adherent patients.[9] Similarly, in our data, using above modality, we had 86.7% complaint or adherent, 12.6% partially adherent and only 0.7% non-adherent patients in our study (before counselling).

Table 1.4 Categorization of population as per Adherence score.

Adherence category	No. of patients (Before counselling)	No. of patients (After counselling)
Non-adherent	2 (0.7%)	0 (0.0%)
Partially adherent	35 (12.3%)	3 (1.7%)
Adherent	248 (87.0%)	173 (98.3%)
Total	285	176

Source: Field Study, 2018

After counselling, there had been no any non-adherent patient, 1.7% patients felled in partially adherent group, whereas 98.3% patient felled in adherent group. Thus, it was clearly noted that compliant percentage of diabetic patient after counseling was increased. But, during the research period, patient follow up had been a great baffle, as reponse rate after three months was only 63.7%.

Blood Glucose level

The blood glucose level was measured before and after counseling from pharmacist. Before counseling the mean fasting, post prandial and HB1Ac level in patients were 147.60 ±50.67mg/dl, 213.34 ±75.50mg/dl and 7.86% ±1.57% respectively. Whereas, after three months of counseling the mean fasting level was 129.08 ± 32.30mg/dl, post prandial level was 186.83 ± 57.68 and HB1Ac level was 7.50% ± 1.15% in diabetic patients. Significant decrement (P = 0.000) was found in all the fasting, PP and Hb1Ac values.

The similar observational study regarding significance of patient counseling in diabetes mellitus done by Y. H. Reddy in Rajiv Gandhi Institute of Medical Sciences (RIMS), 2015, showed a significant reductions [p = 0.0004] in FBS values, in group-I (mono-therapy) i.e. from 220 ± 8 to 203 ± 11 after 3 months, followed by reduction to 180 ± 3 and 172 ± 7 after 6 and 9 months respectively; similar reductions were also observed in group-II (double combination therapy) and group-III patients (triple combination therapy). A notable reduction [p = 0.0012] were also found in PPBS values too.[10]

Thus, notable improvement in patient's Quality of life (QOL) was notice in previous research articles after interventions. These studies has "concluded that chronic diseases like DM affect the QOL of patients", so, the pharmacist providing proper counseling has a major impact in improving the health-care outcomes like blood glucose levels and quality of life.

Table 1.5 Blood sugar level (Before and after counselling).

	Before counselling	After counselling	Significance (before and after)
FBS	147.60 ± 50.67	129.08 ± 32.30	0.000
PPBS	213.34 ± 75.50	186.83 ± 57.68	0.000
HB1Ac	7.86% ± 1.57%	7.50% ± 1.15%	0.000

Source: Field Study, 2018

All FBS, PPBS, and HB1Ac values are significant before and after counselling, when done paired T-test. So, this shows the effect of counselling in diabetic patients.

REASONS FOR NON-COMPLIANCE (with reference to self)

The various reasons for non-compliance answered (with response to self) in our study are given below.

Table 1.6: Reasons for non-compliance.

S. No.	Reasons	No. of respondents
1	Inadequate knowledge about therapy/ complexities of dosage regimen	127 (36.39%)
2	Financial problem	80 (22.92%)
3	Patient feeling better	42 (12.03%)
4	Patient feeling worse	22 (6.31%)
5	Side-effects	37 (10.61%)
6	Service dissatisfaction with health professionals/ Switch to traditional system	29 (8.31%)
7	Transportation problem/ Access problem	12 (3.43%)
	Total frequency of reasons given	**349**

According to the WHO, "factors which affect adherence are in five dimensions i.e. social and economic factors, disease and therapy-related factors, health-system and clinician factors, patient factors, and patient-provider relationship factors". Besides therapy-related factors, healthcare system problems were found to be significantly related to compliance. Accessibility and satisfaction with the healthcare facilities are important contributors to compliance because patient's satisfaction with healthcare is crucial for their compliance. Long waiting time for clinic visits and unhappy experience during clinic visits was indicated by many studies.[11] In this study with reference to the self, most of the patients told that lack of knowledge regarding disease and treatment complications, is the major problem for compliance. Thus, lack of knowledge was commonest answer i.e. 36.39% patients answered that point. Then second frequently answered point was "financial problem" i.e. 22.92%, followed by "patients feeling better" or over-confidence in self (12.03%), side-effects of medications (10.61%), service dis-satisfaction (8.31%), patient feeling worse or disease being uncontrolled (6.31%) and least answered reason was transportation difficulties (3.43%). Thus, in our study, mostly answered cause for medication non-compliance was "inadequate knowledge or carelessness" which was followed by financial problem. It was very peculiar that one of the patient 29B told that her sugar level was 500 and told that she had not been doing diet control and now she will start diet control. One of the patient "E22" left medicines and switched to Ayurvedic medicines and strict diet control. Amazingly she resists visiting clinic then and says all is "ok". One of the patient (G3) left diabetes medicine after taking thyroid medicine. In this patient it was notice that thyroid disturbance is increasing blood sugar level and when thyroxine is started the problem of diabetes disappeared.

CONCLUSION

Patient counselling on timely intake of medicine, knowledge on their side-effects and controlling weight and other life-style modifications are the key points for diabetic patients for managing disease. Patient themselves had admitted that counseling motivate them to increase medication on time, as well as make them serious on regular blood glucose monitoring. So, family and peer members of diabetic need them to motivate them for regular checking and monitoring of blood glucose. Care and concern can become important asset to them to have controlled glucose level. Hence, these types of study regarding management of diabetes and the impact of counseling are of great asset and more research works is to be done in future in developing countries. Both MARS-5 and MARS scoring techniques were used in our study. The paired t-test was done on MARS scoring, before counselling and after counselling, which showed significant difference with P=0.000. (CI: -0.994 to -0.652, t = -9.478 and S.D = ±2.27). Thus, the fact has been well established that counselling helps in increasing compliance. Involving of family members in facilitating medication accessibility and awareness on timely intake helps to increase adherence. Lastly, researcher wants to tell that physician must also be involved more in counselling and compliance studies and get regular feed-backs, for monitoring the success of overall treatment strategy. Thus, Physician, Pharmacist and Patient (3 P's)

must all work in collaboration for implementing health programs effectively.

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Competing interests

The authors declare that they have no competing interests.

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