

A COMMUNITY BASED STUDY TO ASSESS THE MEDICATION ADHERENCE IN PATIENTS WITH DIABETES MELLITUS IN ERODE

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ABSTRACT

Diabetes mellitus is the chronic metabolic disorder with the condition where there is abnormal high blood glucose level. Home medication review (HMR) is patient centered process which provides the effective and quality use of medication at patient's home. According to a study, nearly 50% of Type II diabetes fail to recite adequate glycemic control due to poor management of anti-diabetic medications. So, a community based interventional study was conducted in 150 subjects residing in various parts of Erode, with the aim to assess the knowledge, attitude and practices on management of anti-diabetic medications at home in diabetes patient through HMR after obtaining ethical committee approval. Information regarding medication adherence, medication errors and drug related problems was collected through systematically designed data collection form and patient information leaflet through home medication review. Questionnaires was prepared and given to patients before and after intervention. The low adherent patients were given with PIL and also counselled before the post interventional study. Among 150 subjects 85(56.6%) subjects in medication adherence, 135(90%) subjects in modification of dose, 115(76.7%) of subjects in time modification, 115(76.7%) subjects in knowledge of storage had shown improvement after the interventions (PIL and counselling). So, it was concluded that the pharmacist intervention was helpful in improving the overall diabetes management through HMR, thereby leading to a better health care outcome.

Key words: Home medication review (HMR), Medication adherence, Diabetes mellitus, Drug related problems (DRPs)

INTRODUCTION:

Medication adherence is an important service in assisting the consumers living at home in preventing the problems related to medication and in maximizing the benefits of their medication regimen. Medication adherence study includes the consumer, their clinicians, their pharmacy and their general practitioner with other relevant members of the health care team in the home setting of the medications.¹ Medication adherence study is considered as important due to the medication error, drug-food interactions which takes place due to the patients' irresponsibility of not taking the medications as prescribed and which could lead to the termination of the medication itself or causes the alteration of dose frequency².

The inappropriate medication use by the consumer causes those ADRs which are the major burden to the patients. Therefore, HMR programs and several studies have been conducted in minimizing and preventing the drug related problems³.

The goal of home medication review program is to enhance the patients' medication adherence by reducing the drug related problems (DRPs) that are caused due to the inappropriate use of medications⁴.

Diabetes mellitus is a chronic metabolic disorder which is probably one of the oldest diseases known to man. Diabetes mellitus is the group of metabolic disease, a condition where there is abnormal high blood glucose level. Normally the food gets digested and the glucose is produced as one of the end products of carbohydrates. As a result, production of the insulin hormones takes place from the pancreas due to the increase in the blood glucose level. It converts the glucose to glycogen thereby it reduces the blood glucose level to a normal range. There are many types of diabetes mellitus due to various reasons like, insulin is not all produced in the body, insulin is not sufficiently produced or not effective as it should be. Most common form of diabetes are, type 1 diabetes (5%), which is an autoimmune disorder, type 2 diabetes (95%), which is associated with obesity. The life style of a person is the main factor that results in diabetes including physical activities and balanced diet and genetic factor (heredity). 1 Department of Pharmacy Practice JKKMMRF's College of pharmacy

Home medication review (HMR) is patient-centred process which provides the effective and quality use of medication at patients' home. It includes a systematic and detailed assessment of the patient's medication towards to identify and the medication related needs with the aim to identify and prevent medication errors⁵.

HMR service helps in identifying various potential DRPs which is ultimately beneficial for the patients. Adverse drug reactions (ADR), drug interaction, untreated indication, sub therapeutic dose, improper drug selection, alternative dosage forms, drug duplication are the DRPs which are addressed in HMR. This will help to improve medication adherence behaviour and health related quality of life of the patients. Proper home medication administration plays a role in retaining drug efficacy and assure safe medication practices, which is a key to establish positive treatment outcomes⁶.

According to International Diabetes Federation, India secures second position in having highest number of individuals with diabetes with 77 million individuals as of 2019. It is estimated that the number might increase to 134 million by 2045. It was also found that, since 2000, there was a drastic increase in the number of individuals having diabetes ⁷.

According to World Health Organization (WHO), diabetes is the ninth most leading cause of death. It was found that 74% of deaths were due to non-communicable diseases out of which 1.6 million death was due to diabetes. It is estimated that by 2035, nearly 592 million deaths may occur due to diabetes ⁸.

Current statistics show that 463 million people have diabetes and 374 million have impaired glucose tolerance (IGT) which is a pre-diabetic condition. There is an estimation that, by 2045, these number may increase to 700 million and 548 million in numbers respectively which implies a 51% increase when compared to 2019 ⁹.

Statically data showed that nearly 50% of type 2 diabetics failed to achieve adequate glycemic control. It was due to various reasons but was largely due to poor adherence. A study showed that many discontinue the medication due to poor medication adherence ¹⁰.

Poor adherence to medication led to increased mortality, increased costs of outpatient care, emergency room (ER) visits, hospitalization and also management of complications of diabetes. Hence it has become a necessity to approach the issue. A community-based home medication review is required to assess the medication adherence, to identify and resolve the drug related problems and thereby reducing the complications of diabetes and managing it ¹¹.

AIM & OBJECTIVE

To assess the medication adherence on management of Anti-diabetic medications at home in diabetic patient through home medication review.

SPECIFIC OBJECTIVES OF THE PRESENT INVESTIGATION ARE:

To assess and improve medication adherence in patients with diabetes mellitus using Morisky Medication Adherence scale-8 (MMAS-8).

To identify and resolve drug related problems in diabetic patients using Hepler-Strand classification.

To identify and prevent medication errors in diabetic patients.

To review the patient's method of storage of anti- diabetic medication at home.

METHODOLOGY

MATERIALS AND METHODS

Study design: Interventional Study.

Study site: The study was conducted at community level within Erode.

Study duration: The study was conducted for the duration of 9 months

Sample size: The study was limited for a sample of 150 based on the criteria included in the study. Sample size was calculated by using RAO Software by keeping 5% margin error 90% of confidence interval and 50% response distribution the sample was found to be 150.

Study criteria Inclusion criteria:

Patients who are admitted to the ward and have type II diabetes mellitus and are no less than 18 years old will be included in the study. The study includes patients who have been treated with insulin or at least one hypoglycemic medication, gestational diabetes.

. Exclusion criteria:

The study will exclude the patient with incomplete data and records, those who have undergone any major surgical intervention in the previous three months, pregnant and lactating women, patient who are not willing to participate the study and individual who are not diabetic.

Source of data

Questionnaire was used to collect the data from the subjects of the community.

Study method

Preparation of subject information sheet: Subject information sheet was prepared in both Tamil and English language. Both were used in the study.

Preparation of informed consent form: Informed consent form was prepared in Tamil and English and the same was used in the study.

Before the selection of subjects, the subject information sheet was explained orally. Later consent form was orally explained to the participants before filling it taking their signature. Only the willing participants were used for the study Data collection: Data were collected in the form of data collection form and questionnaires.

Data collected included demographic details like age, gender, blood glucose level, comorbidity, treatment including drug name, its dose and frequency. It also included information regarding the medication management and medication adherence of the subjects. After the collection of the data, the study subjects were counseled using PIL. Later post interventional study was conducted.

Data analysis: The collected data were analyzed using Microsoft excel and paired t test.

Morisky Medication Adherence Scale-8 (MMAS-8)

The Morisky Medication Adherence Scale-8 (MMAS-8) is a validated tool designed to assess medication adherence in patients:

Questionnaire Structure MMAS-8 consists of eight items, with the first seven having dichotomous (yes/no) responses and the last item employing a 5-point Likert scale. Each affirmative response receives a score of 1, while negative responses score 0, except for the

final item, which ranges from 1 to 5. The total score ranges from 0 to 8, with higher scores indicating better adherence. High Adherence (Score 8) indicates excellent medication adherence. Medium Adherence (Score 6-7) suggests moderate adherence but with room for improvement. Low Adherence (Score ≤ 5) indicates poor adherence and the need for intervention or support.

Hepler-Strand classification:

The Hepler-Strand classification will be used to identify drug-related problems (DRPs), which include adverse medication responses, poor drug therapy, and drug interactions. These problems are frequently encountered by diabetes patients. The Hepler-Strand framework, which covers criteria like needless medication therapy, too-low dosage, and adverse effects, will next be used to classify the detected DRPs. After categorisation, intervention plans will be created and customised for each unique issue. These plans may include patient education, medication dosage adjustments, or drug switches. Multidisciplinary cooperation with medical specialists, such as doctors, nurses, and chemists, will be implemented to handle DRPs thoroughly, guaranteeing improved results and holistic patient care. Furthermore, because diabetes therapy is dynamic and necessitates frequent follow-ups and medication reviews to obtain optimal therapeutic outcomes, diabetic patients will be continuously monitored to identify any new or ongoing DRPs.

RESULT:

DEMOGRAPHIC DETAILS OF THE STUDY POPULATION

The study was carried out in about 150 diabetic patients in the community level acquiring information from the patients. Among them 76 (51%) were male and 74 (49%) were female subjects. Here the figure 1 gives the percentage of male and female participants in the study. Among the diabetic patients participated in the study 10(6.6%) subjects were between the age group years of age. Among the 150 patients who participated in the study, 2 were alcoholic, 9 were smokers and 3 consumed tobacco.

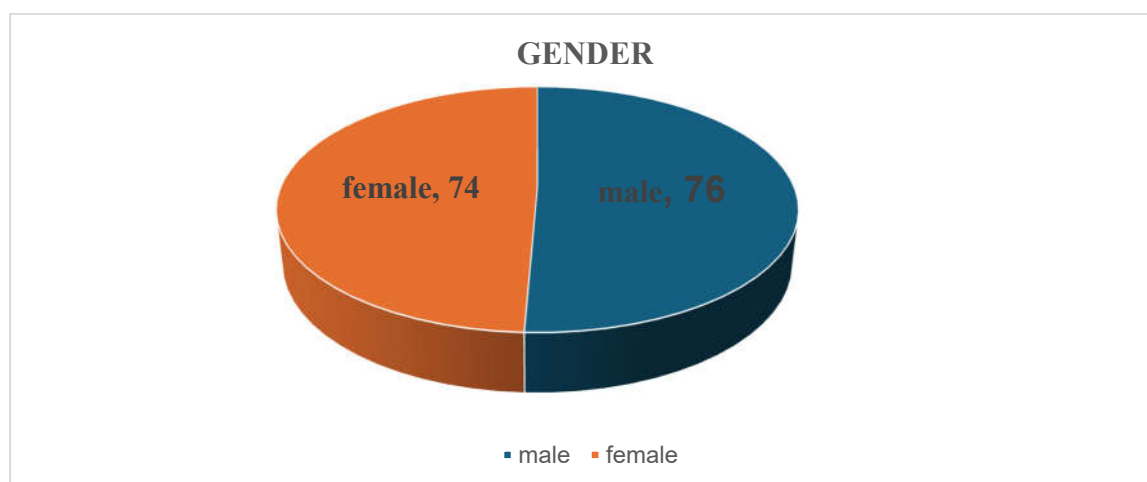


Figure no. 1: Gender distribution of the study participants

Table 1.1 Demographic features of the patients

Variables	Category	Frequency N=150	Percentage (%)
Age	< 40 years	10	6.6%
	41-60 years	79	52.66%
	age 61 and above	61	40.66%

**Table 1.2
Demographic
features
of the
patients**

Variables	Category	Frequency N=150	Percentage (%)
Social history	Alcoholic	2	1.4%
	Smoking	9	6%
	Tobacco	3	2%
	None	136	90.6%

Table 1.2 shows that majority 52.66% patients belongs to age group of 41-60 years of age followed by ≥ 60 years 40.66% and least among

NUMBER OF PARTICIPANTS FROM EACH AREA

The total number of participants in the study were 150 among which they are distributed in different areas of Erode.

Table 2. Number of study participants from each area

PLACE	NUMBER OF PARTICIPANTS
Pallipalayam	10
Bhavani	28
Kumarapalayam	12
Perundurai	20
Gobichettipalayam	30
Kodumudi	24
Chithode	26

The table shows number of participants each area there is different participant in different places, that is among 150 participants taken in different areas

ADHERENCE OF THERAPY AMONG DIABETIC PATIENTS

Medication adherence of each study subject was recorded using Morisky medication adherence scale -8(MMAS-8) with the information obtained from the patients. Morisky medication adherence scale is a validated assessment tool which is used to check the adherence in the population. It consists of 8 questions with respective scores and as the score increases adherence and the maximum score that can be acquired is 8. It is divided into high adherence (≥ 8), medium adherence ($6 < 8$) and low adherence (< 6). It was found that 97(64.7%) of the population had low adherence, 30(20%) of the population had medium adherence and 23(15.3%) of the population were highly adherent. Hence, it was seen that more than half of the population had poor adherence during the pre-intervention study. Those who were low adherent to anti-diabetic medication were given PILs and patient counselling, patients who were medium and high adherent to anti-diabetic medication were given only PILs. After the intervention it was seen that 40(26.7%) of the population had low adherence, 25(16.7%) of the population had medium adherence and 85(56.6%) of the population were highly adherent. This observation was found significant with the help of paired t-test where p value was less than 0.05. The medication adherence of study subject was assessed with Morisky scale -8 and is described in table number 3.

Table 3. Morisky scale-8

Sl.no	Question	Yes		No	
		Pre	Post	Pre	Post
1.	Do you sometimes forget to take your medications?	81(54%)	40(26.6%)	69(46%)	110(73.3%)
2.	In the past 2 weeks, were there any days when you did not take your medications?	95(63.3%)	44(29.3%)	55(36.6%)	106(70.6%)
3.	Have you ever stopped your medications without telling your doctor, because you felt worse when you took it?	38(25.3%)	20(13.3%)	112(74.6%)	130(86.6%)

4.	When you travel or leave home, do you sometimes forget to bring along your medication?	67(44.6%)	38(25.3%)	83(55.3%)	112(74.6%)
5.	Did you take your medication yesterday?	140(93.3%)	148(98.6%)	10(6.66%)	2(1.33%)
6.	When your health condition is under control, do you sometimes stop taking your medications?	50(33.3%)	21(14%)	100(66.6%)	129(86%)
7.	Do you feel hassled about sticking to your treatment plan?	62(41.3%)	28(18.6%)	88(58.6%)	122(81.3%)
8.	How often do you have difficulty in remembering to take all your medication?	Pre-intervention		Post-intervention	
	a) Never/Rarely (1)	59(39.3%)		80(53.3%)	
	b) Once in a while (0.75)	36(24%)		60(40%)	
	c) Sometimes (0.75)	49(32.6%)		10(6.66%)	
	d) usually (0.25)	5(3.3%)		0	
	e) All the time (0)	1(0.66%)		0	

Table 4. Medication adherence level

Medication adherence level	Pre intervention	Post intervention	P Value
Low adherence <6	97(64.7%)	40(26.7%)	< 0.05
Medium adherence 6-8	30(20%)	25(16.7%)	< 0.05
High adherence ≥8	23(15.3%)	85(56.6%)	<0.05

N Value-150

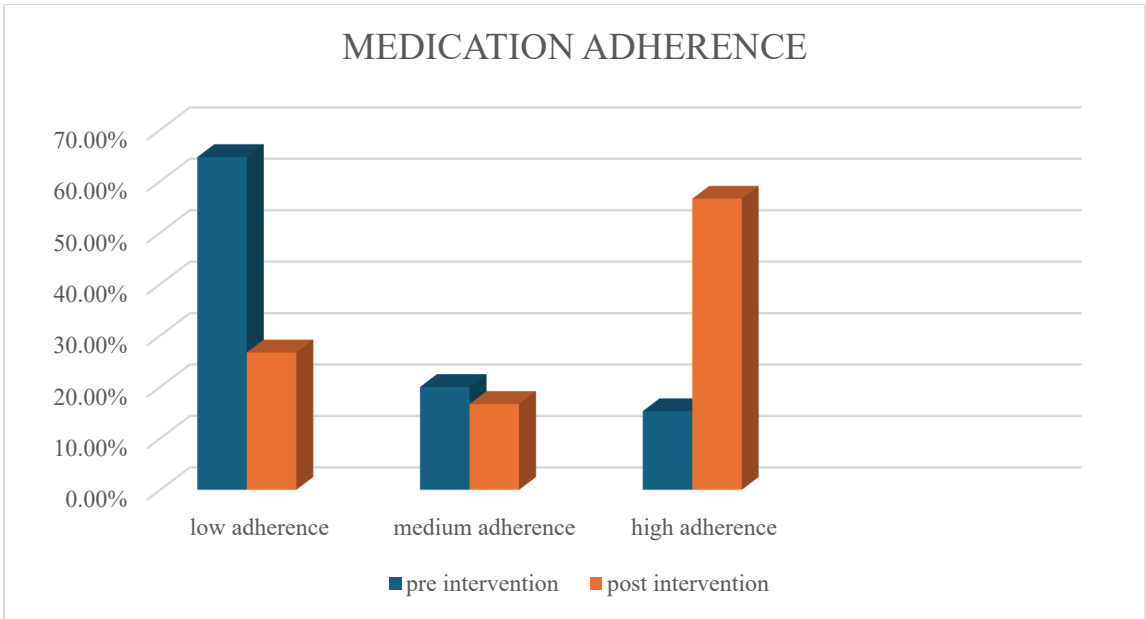


Figure no. 2: Medication adherence in pre and post intervention.

Table 4.1:

Age	Pre intervention study %	Post intervention study %	P value
< 40 years	18%	10%	<0.05
41-60 years	25%	20%	<0.05
age 61 and above	57%	50%	<0.05

Table shows: During pre-interventional study age category as less than 40 age the medication adheres as found to be a 18% and after post interventional study was found to be a 10 %. The 41-60 age was found to be a medication adherence as 25% after post interventional study 20 %. And the age as above 60 year the medication adherence as found to be pre interventional study in 57% and post interventional study as 50%

IDENTIFIED DRUG RELATED PROBLEMS(DRPs) AMONG THE STUDY PARTICIPANTS

In the present study, ADRs were assessed with the help of Naranjo Scale. Out of 30 identified ADRs, 4 were definite, 17 were probable, 8 were possible and 1 was unlikely ADRs. The present study also identified 25 drug interactions. Among them 5 were major, 12 were moderate and 8 were minor interactions based on Medscape. The identified DRPs among the study participants were described in the

table 6. Table 5. Identified drug related problems among the study participants:

SI No.	Types of DRPs	Pre-intervention	Post-intervention	P value
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1	Untreated indication	5	1	< 0.05
2	Improper drug selection	2	0	< 0.05
3	Sub-therapeutic dosage	4	1	< 0.05
4	Failure to receive drugs	121	65	< 0.05
5	Over dosage	8	2	< 0.05
6	Adverse reactions	30	12	< 0.05
7	Drug interactions	25	10	< 0.05
8	Drug use without indications	0	0	< 0.05

DISCUSSION:

Home medication review (HMR) is an important service in assisting the consumers living at home in preventing the problems related to medication and in maximizing the benefits of their medication regimen in patients having diabetes mellitus. Diabetes mellitus is the chronic metabolic disorder with the condition where there is abnormal high blood glucose level. Home medication review (HMR) is patient centred process which provides the effective and quality use of medication at patient's home. According to a study, nearly 50% of Type II diabetes fail to recite adequate glycaemic control due to poor management of anti-diabetic medications. A community based interventional study was conducted with the objectives of assessing and improving medication adherence in patients with diabetes mellitus using Morisky scale-8. This study also had few more objective that include identification and resolution of drug related problems (DRP) in diabetic patients using Hepler-strand classification, prevention of medication errors and reviewing of patient's method of storing of anti- diabetic medication at home. A total of 150 of subjects who were suffering from diabetes mellitus were included in the study. Out of which 76 (51%) were male and 74 (49%) were female. While assessing medication adherence using Morisky scale-8, 97 people with low adherence (8) were found in pre interventional study. The reasons for low adherence found during the study was forgetfulness to take anti diabetic drugs, cost of the drug, multiple medication/ complex regimen, and unavailability of particular brand which may lead to hyperglycaemia. As a part of the study, subjects with low adherence were given with PIL and patient counselling, whereas people with medium and high adherence were given with PIL only. The study showed a significant change in intervention in improving medication adherence i.e 40 people in low adherence, 25 people in medium adherence and 85 people in high adherence.

This study identified total of 195 DRPs in diabetic patients like untreated indication which included 5(7.5%) subjects. Here the patients were found to be in initial stage and the subjects used to modify their lifestyle without the medication. Improper drug selection was

also identified here Metformin was given to diabetic patient who are lean in nature which shows the improper drug selection in study group of 2(3%) patients. sub therapeutic doses in the study was found to be 4 (2.6%) which may lead to therapeutic failure. In the present study it was found that 8 study subjects were overdosed with anti-diabetic medication which can lead to hypoglycaemia and other adverse effects. Among 150 study participants, 121(80.6%) showed failure to receive drugs which was caused due to non-adherence by the study subject. The study also showed Adverse drug reaction in 30(12%%) of study subjects which included unexplained weight gain in patient using glimepiride. The ADRs was classified based on Naranjo scale. Lipo hypertrophy in patient administrating insulin. 25(10%) had experienced drug interactions mainly due to multiple drug therapy and co-morbid condition. No drug without indication was found during the study. In the Post interventional study, it was found that there was a significant reduction in the number of DRPs i.e., untreated indication was reduced to 1 (0.6%), improper drug selection was absent in the post interventional study, sub therapeutic dosage was reduced to 1(0.6%), failure to receive the drug was declined to 65(43.3%), overdosed in post interventional was found to be 2(1.33%), ADR was reduced to 12(8%), drug interaction was declined to 10(6.6%) in post interventional study. According to this study shows that failure to receive the drug was found to be the major type of drug related problem.

CONCLUSION:

This study was conducted in Erode, TamilNadu , to evaluate the pharmacist-led home medication review for diabetes mellitus. The Morisky scale -8 was used to calculate medication adherence. Hepler's Strand was used to examine drug-related issues. grouping. Medication error was assessed. A questionnaire was used to examine the anti-diabetic medicine storage method. The research participants were educated about managing anti-diabetic medications through the use of a questionnaire, PILs, and counselling. The study employed the paired t test using Microsoft Excel 2017 to assess and determine the significant value. Following the intervention, it was discovered that the study's findings had significantly improved. Therefore, it was determined that the study contributed to bettering the overall treatment of diabetes with HMR, which in turn improved health care outcomes.

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