

## COMPARISON OF EFFECTIVENESS OF METFORMIN WITH NUTRITIONAL COUNSELLING ON GLYCEMIC CONTROL IN PRE-DIABETICS

Namrah Fatima Mujeeb<sup>\*1</sup>, Sadaf Nawaz<sup>2</sup>, Ayesha Nudrat<sup>3</sup>, Sadia Azam Khan<sup>4</sup>,  
Marwa Ansar Kazmi<sup>5</sup>, Rafia Latif<sup>6</sup>

<sup>\*1</sup>MBBS, PGD Family Medicine, Certified Clinical Nutritionist Family Medicine Department/ PEMH, RWP

<sup>2</sup>MBBS, FRCGP Family Medicine Family Medicine Department/ PEMH, RWP

<sup>3</sup>MBBS Family Medicine Department/ PEMH, RWP

<sup>4</sup>MBBS, MRCGP Family Medicine Department of Family Medicine/ RMU, Rwp

<sup>5</sup>BS Nutrition Nutrition Department/ RWP

<sup>6</sup>BS Nutrition Nutrition Department/ PEMH, RWP

<sup>\*1</sup>namrahfatimamujeeb@gmail.com, <sup>2</sup>sadafnawaz990@gmail.com, <sup>3</sup>ayesha.nudrat7@gmail.com,

<sup>4</sup>dr.skhan2022@gmail.com, <sup>5</sup>marwa.kazmi1@gmail.com, <sup>6</sup>rafialatifemail@gmail.com

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Corresponding Author: \*

Namrah Fatima Mujeeb

### Abstract

*Background: Prediabetes, a condition where blood glucose levels are higher than normal but not yet in the diabetic range, affects many individuals worldwide. This condition arises when the body fails to produce enough insulin, causing glucose to stay in the blood. Objective: The main objective of the study is to find the comparison of effectiveness of metformin with nutritional counselling on glycemic control in pre-diabetics. Methodology: A six-month cohort study was conducted at Pak Emirate Military Hospital (PEMH) in Pakistan from June to November 2023 to compare the effectiveness of Metformin and nutritional counseling in controlling glycemic levels. The study included 120 participants with prediabetes, divided into two groups: 60 received Metformin and 60 received nutritional counseling. Results: It evident from study that Metformin significantly improved glycemic control, with a 15% reduction in fasting blood glucose levels and an average decrease of 1.9% in HbA1c levels. The nutritional counseling group also demonstrated substantial benefits, with a 12% reduction in fasting blood glucose levels and an average decrease of 1% in HbA1c levels. Conclusion: Both Metformin and nutritional counseling effectively reduced blood glucose levels in individuals with prediabetes. Metformin was more effective, but nutritional counseling also had a significant impact.*

### INTRODUCTION

Prediabetes is a health condition that affects massive number of individuals worldwide, this condition occurs when the body fails to make enough insulin eventually body fails to get reasonable portion of glucose into cells to get energy despite of that the

glucose stays in the blood which causes higher level of blood glucose than normal range but not too to fall in type 2 category. To manage prediabetes the Metformin is considered as the first line medication as compared to insulin and other drugs available in

the market but it is noted that the effectiveness of nutritional counselling is also significant in treating prediabetes. So, this study particularly aims at the comparison of effectiveness of Metformin and on the other side the effectiveness of nutritional counseling will be assessed. The RCTs (Randomized Controlled Trials) has defined the efficacy of Metformin in controlling the glycemic levels in prediabetes<sup>1</sup>. The DPP (Diabetes Prevention Program) demonstrated through their research that Metformin has capability of reducing the chances of developing Type 2 diabetes by 58% as compared to another drug placebo<sup>2</sup>. Research has found that the function of Metformin in body is to reduce the production of hepatic glucose<sup>3</sup>. Another study by DPS (Finnish Diabetes Prevention Study) has reported that there is a bright chance of delaying or even reducing the risk of developing Type 2 diabetes with intensive nutritional intervention<sup>4</sup>. Some of the studies has stated that the effectiveness of Metformin is short-termed as compared to the nutritional interventions because maintaining a healthy lifestyle is easier as compared to taking medications for long time period<sup>5</sup>. Some of the researchers also believes that if these both interventions are combined for the treatment then the result are remarkable because both modalities have benefits on their users. Significance expected from this study is that it will add valuable insights in managing prediabetes through Metformin and nutritional counselling, the results will help the medical professionals to make prompt and beneficial decision regarding their prediabetic patients according the needs and the preferences of the individual<sup>6</sup>. In addition to that, health care professionals can develop a strategic plan to deal this disease with more appropriate method because in today's era this problem has increased to crucial level and people are unaware of methods or procedures of controlling the levels at initial stage and delay the progression to Type 2 diabetes<sup>7</sup>.

## Objectives:

The main objectives of this study is to find the:

- comparison of effectiveness of metformin with nutritional counselling on glycemic control in pre-diabetics.

## Methodology

This prospective study was conducted at Pak Emirates Military Hospital, PEMH in Pakistan from June 2023 to November, 2023. 120 cases of prediabetes, out of the 60 were included for Metformin intervention and 60 for nutritional counselling. Adults who have been diagnosed with prediabetes with age group 30-75 having HbA1c level between 5.7% to 6.4% with BMI of 25kg or greater and they have given consent to provide their personal data and adhere to protocols of the study were included. Pregnant Women, individuals who are already taking medications that can affect blood glucose levels, patient having any severe medical condition, nursing mothers, individuals allergic to Metformin were excluded. Data were collected on the basis of demographics, anthropometric ratios, medical history, Lab reports (HbA1c), assessment of dietary intake through interviews. Data were collected into two groups:

**Group A: Metformin:** In this group participants received metformin tablets considering the standard protocols, initially giving them low dose with gradual increase in dose up to their maximum dose tolerance level.

**Group B: Nutritional Counselling:** This group of participants received personalized nutritional counselling sessions given by registered appointed nutritionist or dietitian.

The basic protocol for the Metformin group was to take medication on time, the dosage should be accordance to the prescribed one. Afterwards the process was repeated during intervals of 3 and 6 months after the start of intervention while considering the compliance of both groups with the intervention protocols. Data were analyzed using SPSS v21. The chi-square test was conducted to evaluate the comparison of effectiveness of Metformin and Nutritional Counselling in Prediabetics.

## Results

Total sample size was 120 out of which 60 samples were taken for Metformin group and 60 were taken for Nutritional Counselling group. Self-administered interview questionnaire was used for study with 5 sections. Study shows that there is significant improvement in patients who have been given

Metformin with dosage of ranging from 250mg/once daily to 850 mg/once daily, their blood glucose level in fasting has reduced to almost 15% which demonstrates the effectiveness of the Metformin in controlling glycemic level, the Hb1Ac was reduced by 1.9% on average in 60 cases taken for study. So, results suggest that Metformin is an effective method to manage the glycemic level and prevents the progression towards Type 2 diabetes. But along with that the medication always has some side effects so Metformin has caused gastrointestinal problems like diarrhea or nausea. On the other hand, the

Nutritional Counselling group also validates a substantial impact in controlling glycemic level by an average reduction of 12% in blood glucose level fasting and average decrease of 1% in Hb1Ac level. This shows that nutritional counselling also has potential to reduce the risk of onset of Type 2 diabetes. When the outcomes are compared it is noted that both groups of intervention show significant results in improving the glycemic levels of prediabetics so it depends on the patient that which intervention he would like to choose whether the adherence to medication or giving preference to dietary plans.

**Table 1:** Demographic Characteristics (N = 120)

Variable	Metformin Group (n=60)	Nutritional Counselling Group (n=60)
<b>Age groups</b>		
30-39	20	15
40-49	15	23
50-59	12	11
60-69	8	7
70-75	5	4
<b>Gender</b>		
- Male	35	30
- Female	25	30
HbA1c (%)	6.39 (SD 0.2)	6.35(SD 0.1)
Hypertension (Yes/No)	15/45	10/50

The table 1 shows the age groups taken for the study and the gender and mean and SD of HbA1c levels of participants of both interventions.

**Table 2:** Fasting Glucose blood levels of participants of both interventions (N = 120).

Intervention Group	Frequency	Percent
<b>Metformin Intervention</b>	<70	5.0
	70-84	1.7
	85-99	18.3
	100-109	35.0
	110-125	21.7
	126-139	3.3
	>140	15.0
	Total	100.0
<b>Nutrition Counseling Intervention</b>	<70	1.7
	85-99	23.3
	100-109	28.3
	110-125	25.0
	126-139	21.7
	Total	100.0

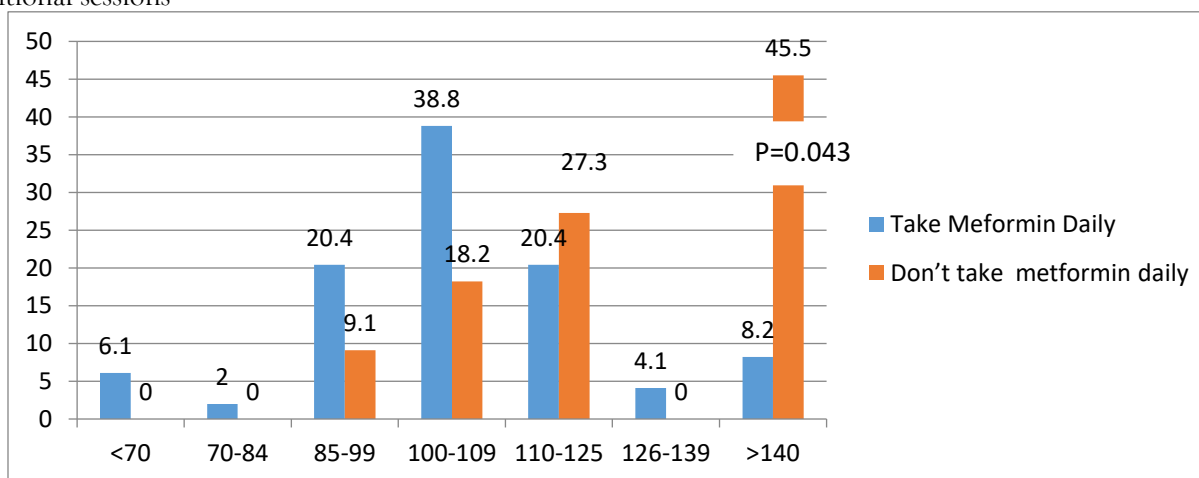
Table 2 shows the fasting plasma glucose values of participants in two groups of intervention. Metformin users had more with high glucose ( $\geq 110$  mg/dL) and Nutrition Counseling users more in the normal range (85–109 mg/dL), indicative of better glycemic control among the latter intervention.

**Table 3:** Frequency of participants who have taken Metformin daily and any changes made in their dosage (N = 120).

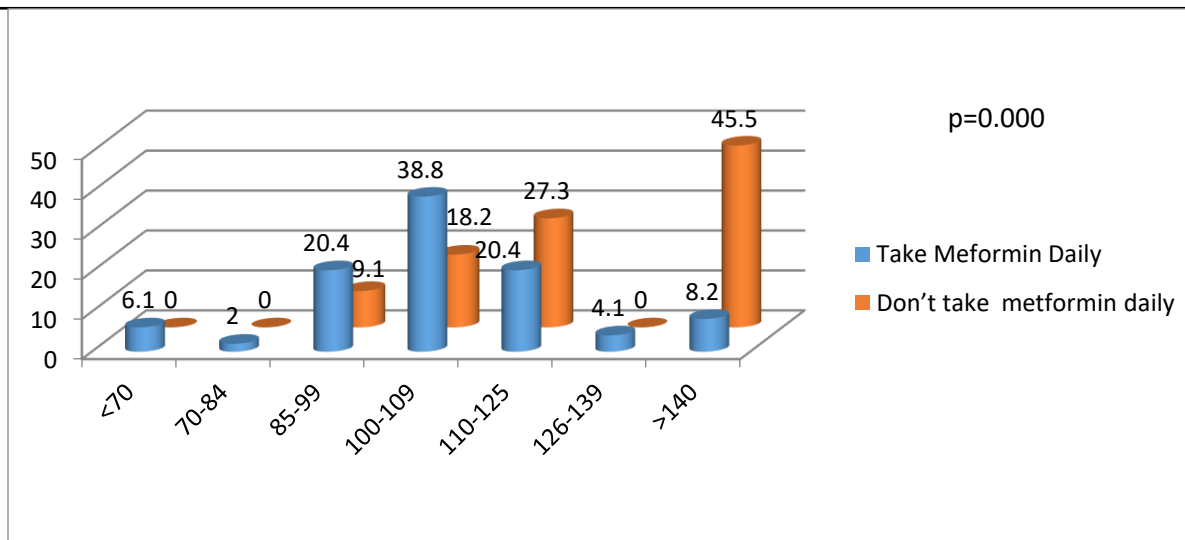
	<i>f</i>	%
<b>Metformin group</b>		
Participants who took Metformin daily	49	(81.7%)
Any changes in the dosage?	15	(25%)
<b>Nutritional Counseling group</b>		
Participants who took nutritional counselling.	48	(80%)
Any changes in number of sessions?	10	(16.7%)

The table shows the frequency of participants who have taken Metformin daily and any changes made in their dosage according to their medical condition and the participants who have take the nutritional counselling session on regular basis and if there were made any changes in the frequency of sessions.

Association of Blood glucose levels fasting and those who attended nutritional sessions is illustrated in **Figure 1 below**. Non-significant association is found ( $p > 0.05$ ) between Blood glucose levels fasting and those who attended nutritional sessions



Association of Blood glucose level fasting and those who take metformin is illustrated in **Figure 2 below**. Highly Significant association ( $p < 0.05$ ) between Blood glucose level fasting and those who take metformin is found using chi-square test.



### Discussion

The discussion part mainly defines three main domains: interpretation of results, comparing this study with the previous ones and limitations faced during the process. The outcomes of the cohort study states that the effectiveness of metformin with nutritional counselling reveals notable findings, the results clearly shows that the Metformin has been more effective than the nutritional counselling in bringing down the glycemic levels in prediabetics, study also explicates that participants of both interventions have experienced improvements in their metabolic reports like blood glucose level, resistance to insulin and body weight<sup>8,9</sup>. Considering the previous research relevant to this study it was evident that the American Diabetes Association ADA has published article how people with prediabetes can be early treated with the moderate change in their life style and dietary habits, and the nutritional counselling can bring their Hb1Ac levels to normal range and can delay the risk of developing Type 2 diabetes in them. In another article ADA described the Diabetes Prevention Program conducted by them to educate the individuals regarding the positive impact of Metformin and nutritional counselling to control glycemic levels and they have come up with the results that nutritional counselling alone can bring 30-40% decline in the prediabetic ratio<sup>10</sup>. Moreover, study conducted by the ACP American College of Physicians also states that the Metformin and the Medical Nutrition Therapy can give significant impact on the Hb1Ac levels of patients and prevents them from other cardiovascular disease for

which sometimes the metabolic syndrome is the root cause<sup>11,12</sup>.

### Limitations

Further study should be done at massive level to gain more accurate findings because right now the study was conducted with a limited number of participants and the data acquired from them was self-reported so there are chances that the data does not actually reflects the behavior of them, secondly the most important part was long term follow up which may give accurate situation of the glycemic levels of the patients over a period of time, and we have only focused on the data of 6 months which is definitely not sufficient to evaluate the enduring effectiveness of interventions. The study also missed the important factor of our society that is the availability of the resources to the selected participants and their socioeconomic position, that can influence the outcomes obtained from them.

### Recommendations

In future the research should be done with a more participants with prediabetes to get more accurate results and as cost-effective method of nutritional counselling should be designed to cater the socioeconomic factor of individuals, the optimal frequency should be investigated form improving the nutritional counselling sessions. Most importantly the arranging awareness programs regarding the control of glycemic level at initial levels is necessary because in our society the routine lab tests isn't normally done unless and until patient is diagnosed with some

serious symptoms so people should get awareness regarding checking their glycemic levels on at least 6 months intervals to diagnose the problem at initial stage.

## Ethical considerations

Consent form was signed by the individuals who agreed to share their data. Participants were given surety that the data provided them will be kept confidential and only a specific part of the interview will be used in the study paper.

## Conclusion

It is evident from the study that Metformin and the nutritional counselling both have positive impact over reducing the blood glucose levels, Metformin has proved to be more effective as compared to nutritional counselling but lifestyle also seems have significant impact over the study. The outcomes of this study are consistent with the previously conducted studies that demonstrated the benefit of both interventions.

## Conflict of interest

Authors declares no conflict of interest.

## Contribution

(See above S.No.7)

Conception, STUDY DESIGN, DATA COLLECTION, STATISTICAL ANALYSIS, writing and editing of manuscript

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Nutritional Counselling

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- How often do you attend nutritional counselling sessions?

- Rate your adherence to nutritional Counselling intervention on scale of 1 to 5?

Rate overall satisfaction level from nutritional Counselling intervention on scale of 1 to 5?

## Questionnaire for interview

### ID Number:

### Section:1: Demographic Information

- Age
- Gender

### Section:2: Medical History

- Date Prediabetes Diagnosis
- Any other medical condition

### Section:3: Baseline Assessment

- Glucose Level Fasting
- Anthropometric measurements:
  1. Height
  2. Weight
  3. BMI



### Section: 4: Dietary Habits and Physical Activity

- Number of meals per day
- Types of food
- Average physical activity per week.

### Section: 5: Intervention details

#### Metformin Group:

- How often do you take Metformin and any changes in the dosage?
- Rate your adherence to metformin intervention on scale of 1 to 5?
- Rate overall satisfaction level from metformin intervention on scale of 1 to 5?

#### Nutritional Group: