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Comparative study of Metformin mono-therapy and combination therapy in Diabetes Mellitus patients.

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ABSTRACT: Diabetes mellitus is a group of metabolic disorder characterized by hyperglycemia and abnormalities in carbohydrates, fats and protein metabolism. Type - 2 DM is mono-insulin dependent. Metformin mono therapy is the first choice for type 2 DM. The objective of is to comparatively study of metformin mono-therapy and combination therapy in DM patients. This Prospective and Observational study in which 79 subjects were enrolled based on the criteria and Descriptive statistical methods were used. Total of 79 patients were included for the study and the mean age of the study participants were 59.5 years. Among them 46(58.2%) female and 33(41.7%) male participants. In our study 58(73.4%) were diabetic without comorbidities and 21(26.5%) were diabetic with hypertension and 53(67%) patients were prescribed with metformin in which 32.9% participants were prescribed mono-therapy. Glimepiride is the most acceptable combination drug with metformin (55%). On 6th follow-up, normal blood glucose levels were reported at 40%(FBS), 27.8%(PPBS) and 45%(RBS) on gender wise analysis female 25%(FBS) 1%(PPBS) 30%(RBS) male 15%(FBS), and 24%(RBS) shown normal blood glucose levels. Our study revealed that patients above the age of 50 years had better glycemic control with the metformin mono therapy as well as combination therapy our data also found out that most of the diabetic patients with comorbidities were prescribed with combination therapy. We also conclude that female patients had better response for metformin mono therapy as well as combination drug therapy than male patients.

KEYWORDS: Diabetes, Metformin, Mono-therapy, Combination therapy.

I. INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic disorders characterized by hyperglycemia and abnormalities in carbohydrates, fat, and protein metabolism. The number of people with diabetes is increasing due to population growth, aging, urbanization, and increasing prevalence of obesity and physical inactivity. According to the statistics from the International Diabetes Federation (IDF), India has more diabetics than any other nation of the world.

Type-1 DM accounts for 5% to 10% of all diabetes cases. It is generally develop in childhood or adulthood and results from immune mediated destruction of pancreatic beta cells, resulting in an absolute deficiency of insulin. Type-2 DM accounts for as many as 90% of DM cases and is usually characterized by the presence of both insulin resistance and relative insulin deficiency.

Criteria for the diagnosis of diabetes 1.A1C -6.5%. The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay. *OR 2.FPG -126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h.*OR 3. 2-h plasma glucose -200 mg/dl (11.1 mmol/l) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water. *OR 4. In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose -200 mg/dl (11.1 mmol/l)10 .

Metformin is an anti-diabetic medication manufactured from galegine, a naturally occurring substance obtained from the plant Galega officinalis. It has been discovered that it inhibits gluconeogenesis in the liver and mitochondrial respiratory complex I, resulting in an increase in the cellular ratio of adenosine monophosphate (AMP) to adenosine triphosphate (ATP) and activation of AMP-activated protein kinase (AMPK). It also reduces glucose levels by inhibiting the activity of adenylate cyclase, an essential mediator of glucagon action. Metformin increases pancreatic -cell function while decreasing compensatory -cell hyperplasia, both of which are symptoms of T2D. It can directly reduce

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cell proliferation generated by HFD and excessive glucose, and it may cause metformin buildup in individuals with renal impairment.

Metformin has a reduced chance of developing lactic acidosis than Phenformin. Urinary tract infection has been recorded in 8 or 1.1% of patients on metformin alone or in fixed combination with glipizide, respectively, and severe acute hepatitis has been described in association with significant increases in blood hepatic aminotransferase levels and cholestasis. Metformin is the first-line therapy for individuals with type 2 diabetes because of its great blood glucose-lowering impact, low side effects, long-term safety, low risk of hypoglycemia, and low weight gain. Combination medication treatment should employ the fewest drugs possible to address the greatest number of pathophysiologic pathways producing hyperglycemia. FDCs can increase treatment adherence and optimise glycemic goal accomplishment and maintenance, but economic aspects must also be considered.

The choice of diabetes therapies must be individualized based on attributes specific to both patients and the medications themselves.

II. OBJECTIVE

General Objectives:

- A comparative study of metformin mono-therapy and combination therapy in DM patients

Specific Objectives:

- To assess the patient characteristics in DM patients
- To assess the variables in DM patients
- To assess and evaluate the outcome in DM patients

III. METHODOLOGY

The study was conducted on patients with Diabetes mellitus and who were admitted in the Medicine and Endocrinology department of Sagar Hospitals in Bengaluru during the study period and screened based on the inclusion and exclusion criteria.

Inclusion Criteria includes patients with type 2 Diabetes mellitus, previously diagnosed and newly diagnosed diabetes patients, patients of all age groups and both the genders. Exclusion Criteria excludes pregnant and lactating women, patients who have no recorded diagnosis of DM.

This Prospective study was conducted to assess the characteristics of the patient, the baseline information such as demographic details like age, sex, weight, occupation was obtained. To assess the outcome resources like social history Past medical and Past medication history, family history of diabetes was recorded. To assess the variables, parameters like Fasting Blood Sugar, Random Blood Sugar, Post Prandial Blood Sugar, HbA1c were recorded. A follow up for parameters such as FBS, RBS, PPBS, HbA1c was done for every one month. Data was evaluated by using suitable statistical tools such as mean standard deviation are applied. Demographic data, mono-therapy and combination therapy data is presented in frequencies and percentages. Charts and tables are developed based on frequencies and percentages and were used to represent the consolidated data for inferential statistics. Statistical software - IBM SPSS version 20.00 used for the analysis of the data and drawn charts and graphs etc.

IV. OBSERVATIONS

Table.no 01: Distribution of subjects according to age group

Age group	Frequency	Percent
21 to 30	2	2.5
31 to 40	9	11.4
41 to 50	10	12.7
51 to 60	23	29.1
61 to 70	17	21.5
71 to 80	13	16.5
81 to 90	5	6.3
Total	**79**	**100.0**

Mean age: 59.58 Std. dev: 14.81

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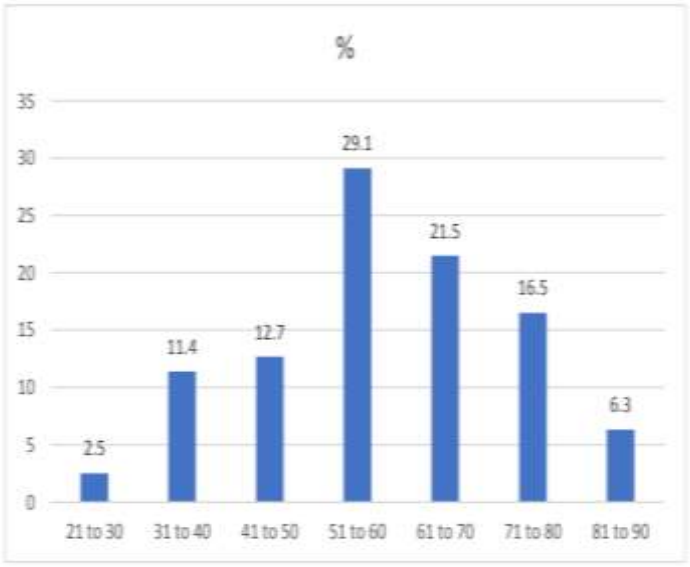

Figure no 01: Distribution of subjects according to age group

Our study observed that, majority of patients were identified at the age group of 51 to 60 years old followed by 61 to 70 years old. Mean age of the patients is 59.58.

Table no 02: Distribution of subjects according to gender

Gender	Frequency	Percent
Female	46	58.2
Male	33	41.8
Total	**79**	**100.0**

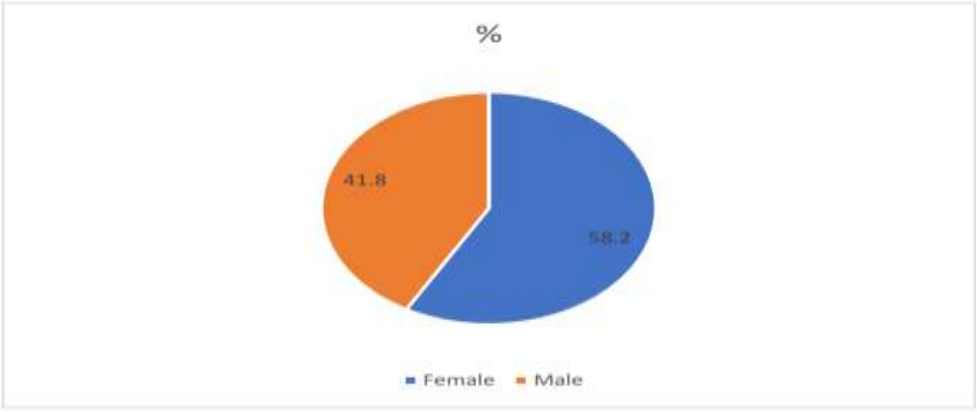

Figure no 02: Distribution of subjects according to gender

In our findings, we have observed that majority of subjects were female gender at 58.2%.

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Table no 03: Fasting blood sugar levels of patients at 06 follow up periods

FBS	1	2	3	4	5	6
<70	3	2	4	11	7	9
	3.8	2.5	5.1	13.9	8.9	11.4
>100	49	56	51	50	45	38
	62.0	70.9	64.6	63.3	57.0	48.1
70 to 100	27	21	24	18	27	32
	34.2	26.6	30.4	22.8	34.2	40.5
Total	**79**	**79**	**79**	**79**	**79**	**79**
	100.0	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**

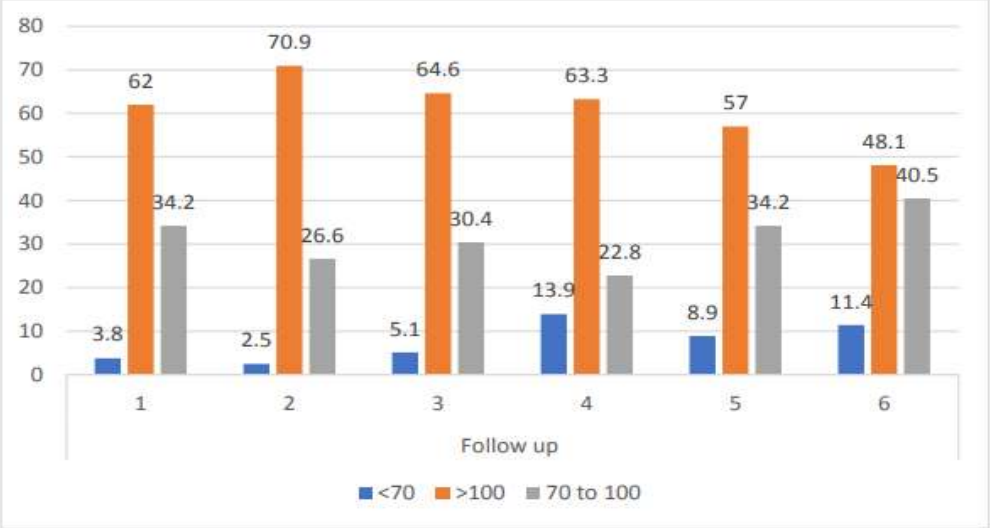

Figure no 03: Fasting blood sugar levels of patients at 06 follow up periods

We have observed that almost 70% of patients were hyperglycemic at second follow up, it has reduced to 48% by 6th follow up. Normal FBS levels were increased from second follow up (26.6%) to 6th follow up (40.5%)

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Table no 04: Postprandial blood sugar levels of patients at 06 follow up periods

PPBS	1	2	3	4	5	6
<120	0	0	1	0	0	1
	0	0	1.3	0	0	1.3
120-140	0	0	0	0	0	0
	0	0	0	0	0	0
140-200	16	12	14	19	22	22
	20.3	15.2	17.7	24.1	27.8	27.8
>200	63	67	64	60	57	56
	79.7	84.8	81.0	75.9	72.2	70.9
Total	**79**	**79**	**79**	**79**	**79**	**79**
	100.0	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**

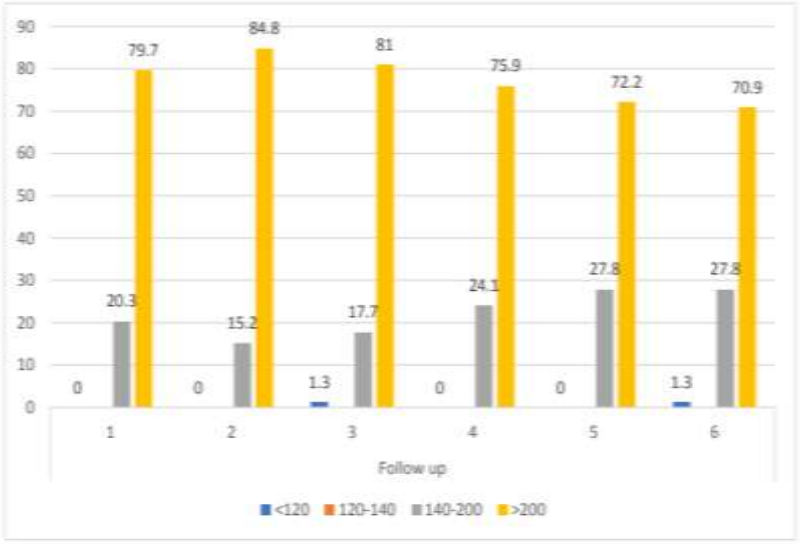

Figure no 04: Postprandial blood sugar levels of patients at 06 follow up periods

We have observed that majority of patients were identified with post prandial blood sugar levels at >200mg/dl, followed by 140 to 200 mg/dl.

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Table no 05: Random blood sugar levels of patients at 06 follow up periods

RBS	1	2	3	4	5	6
<180	35	32	36	41	43	43
	44.3	40.5	45.6	51.9	54.4	54.4
>200	44	47	43	38	36	36
	55.7	59.5	54.4	48.1	45.6	45.6
Total	**79**	**79**	**79**	**79**	**79**	**79**
	100.0	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**

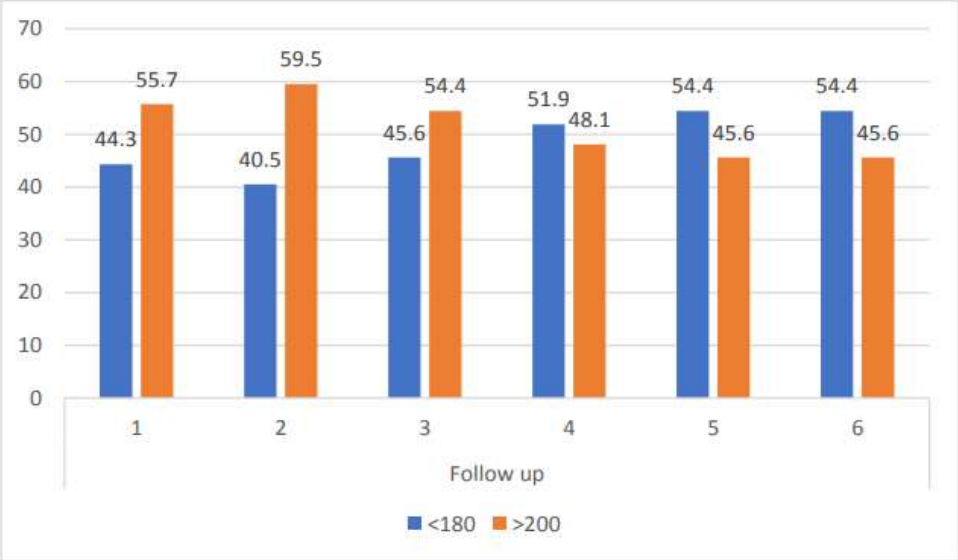

Figure no 05: Random blood sugar levels of patients at 06 follow up periods

In the first three followup periods, we have observed that almost 59% of patients had >200 mg /dl of glucose, then in the 4th to 6th followup almost 55% of patients were identified with <180 mg/ dL of glucose.

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Table no 06: Distribution of subjects according to monotherapy

Monotherapy	Frequency	Percent
Metformin	26	32.9
Nil	53	67.1
Total	**79**	**100.0**

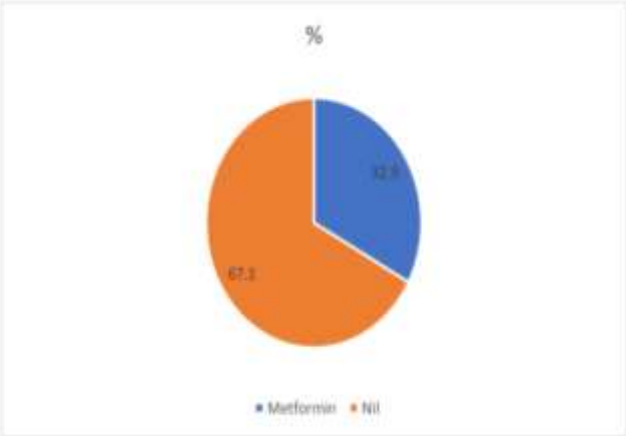

Figure no 06: Distribution of subjects according to monotherapy

We have observed that 67.1% of patients were prescribed with mono-therapy metfomin.

Table no 07: Distribution of subjects according to combination therapy

Combination Therapy	Frequency	Percent
Glibenclamide+Metformin	1	1.3
Gliclazide+Metformin	1	1.3
Glimepiride+Metformin	6	7.6
Glipizide+Metformin	1	1.3
Glipizide+voglilbose+Metformin	1	1.3
Metformin+Glimepiride	38	48.1
Metformin+Vildaglipti	1	1.3
Nil	23	29.1
Pioglitazone+Metformin	1	1.3
Pioglitazone+Metformin+Glimepiride	2	2.5
Teneligliptin+Metformin	2	2.5
Voglibose+Glimepiride+Metformin	1	1.3
Voglibose+Metformin	1	1.3
Total	**79**	**100.0**

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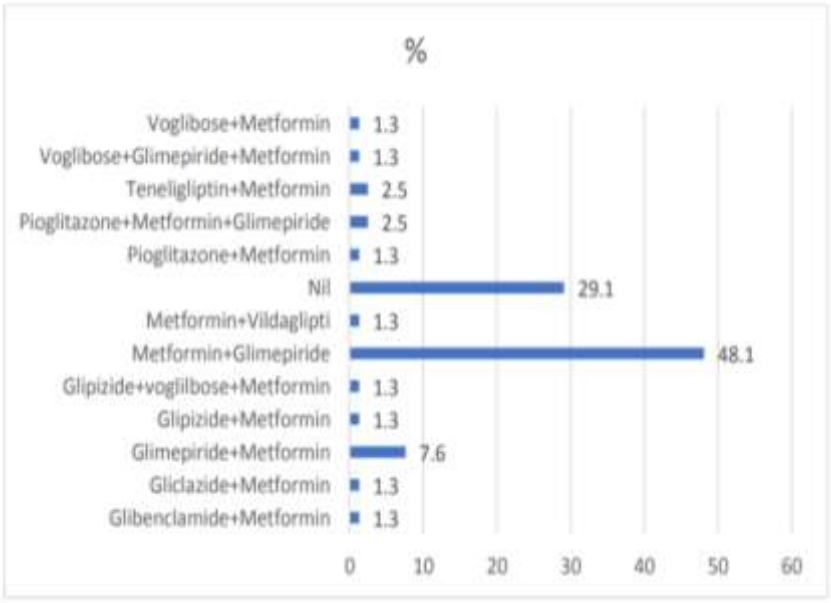

We have observed that almost 48.1% of patients were prescribed with combination drugs metformin and glimepiride.

Table no 08: Distribution of subjects according to final diagnosis

Final Diagnosis	Frequency	Percent
Diabetes mellitus	58	73.4
DM with HTN	21	26.6
Total	**79**	**100.0**

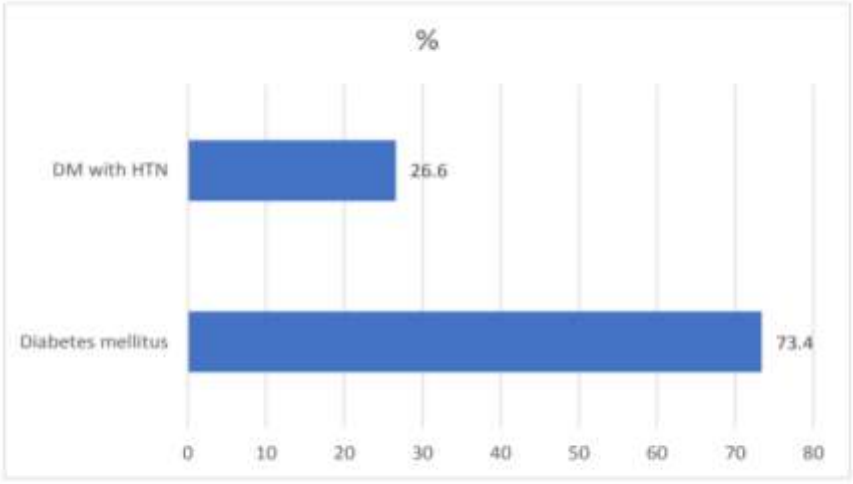

Figure no 08: Distribution of subjects according to final diagnosis

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We have observed that almost 73.4% of patients were diagnosed with diabetes mellitus only.

Table no 09: Distribution of subjects according to outcome

Outcome	Frequency	Percent
Improved	53	67.1
Not improved	26	32.9
Total	**79**	**100.0**

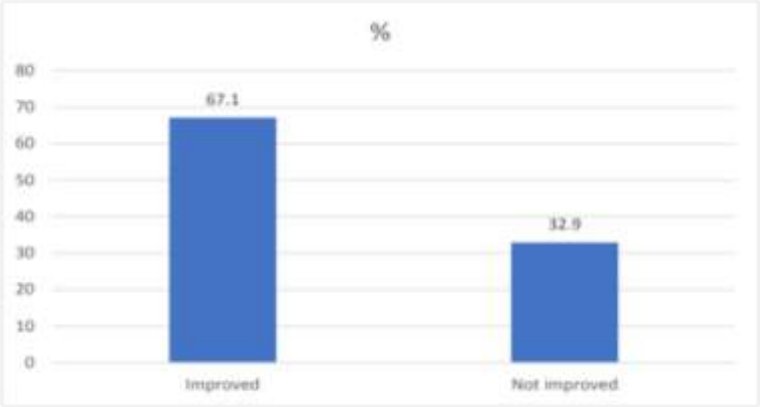

Figure no09: Distribution of subjects according to outcome

Our research findings has shown that almost 67.1% of patients were improved followed by post treatment.

Table no 10: Monotherapy Vs outcome of patients

Monotherapy	Outcome		Total
	Improved	Not improved	
Metformin	18	8	26
	22.8%	10.1%	32.9%
Nil	35	18	53
	44.3%	22.8%	67.1%
Total	**53**	**26**	**79**
	67.1%	**32.9%**	**100.0%**

Chi-Square: .081, df: 1, p-value: .777

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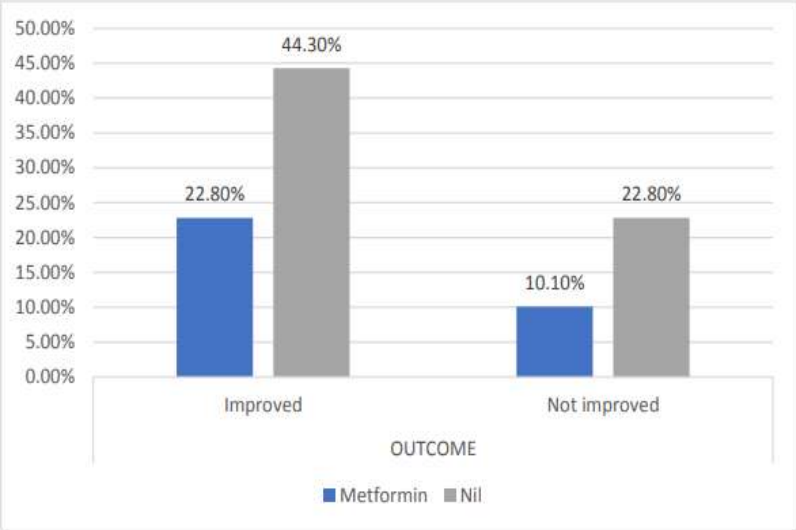

Figure no 10: Monotherapy Vs outcome of patients

Patients who were prescribed with metformin had shown 22.8% of improvement than patients without metformin, but statistically not significant, at CI 95%, α 0.05.

Table no 11: Combination therapy Vs outcome pf patients

Combination Therapy	Outcome		Total
	Improved	Not improved	
Glibenclamide+Metformin	1	0	1
	1.3%	0.0%	1.3%
Glielazide+Metformin	1	0	1
	1.3%	0.0%	1.3%
Glimepiride+Metformin	6	0	6
	7.6%	0.0%	7.6%
Glipizide+Metformin	1	0	1
	1.3%	0.0%	1.3%
Glipizide+voglilbose+Metformin	1	0	1
	1.3%	0.0%	1.3%
Metformin+Glimepiride	24	14	38
	30.4%	17.7%	48.1%
Metformin+Vildaglipti	0	1	1
	0.0%	1.3%	1.3%
Nil	15	8	23
	19.0%	10.1%	29.1%
Pioglitazone+Metformin	1	0	1
	1.3%	0.0%	1.3%
Pioglitazone+Metformin+Glimepiride	1	1	2
	1.3%	1.3%	2.5%
Teneligliptin+Metformin	1	1	2
	1.3%	1.3%	2.5%

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Voglibose+Glimepiride+ Metformin	1	0	1
	1.3%	0.0%	1.3%
Voglibose+Metformin	0	1	1
	0.0%	1.3%	1.3%
Total	**53**	**26**	**79**
	67.1%	**32.9%**	**100.0%**

Chi-Square: 10.795, df: 12, p-value: .547

Patients with Metformin + Glimepiride had shown 30.4% improvement, but statistically not significant, at CI 95%, α 0.05

Table no 12: Monotherapy Vs diagnosis

Monotherapy	**Final Diagnosis**		**Total**
	Diabetes mellitus	**DM with HTN**	
Metformin	17	9	26
	21.5%	11.4%	32.9%
Nil	41	12	53
	51.9%	15.2%	67.1%
Total	**58**	**21**	**79**
	73.4%	**26.6%**	**100.0%**

Chi-Square: 1.281, df: 1, p-value: .258

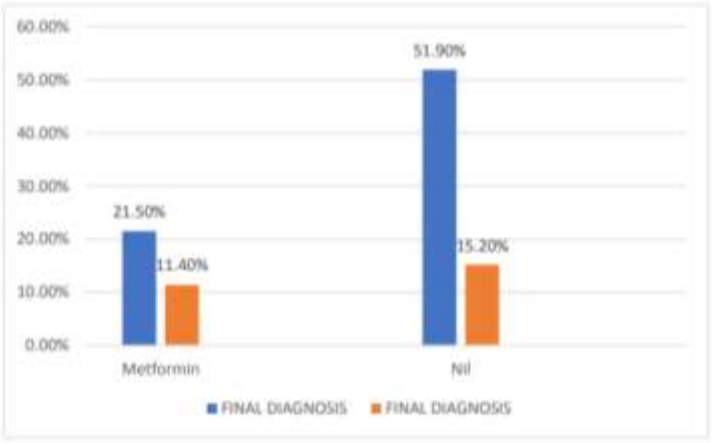

Figure no 12: Monotherapy Vs diagnosis

Metformin is prescribed in 21.5% of patients who were diagnosed with diabetes only, followed by patients with diabetes mellitus and hypertension.

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Table no 13: Combination therapy Vs diagnosis

Combination Therapy	Final Diagnosis		Total
	Diabetes mellitus	DM with HTN	
Glibenclamide+Metformin	0	1	1
	0.0%	1.3%	1.3%
Gliclazide+Metformin	1	0	1
	1.3%	0.0%	1.3%
Glimepiride+Metformin	3	3	6
	3.8%	3.8%	7.6%
Glipizide+Metformin	1	0	1
	1.3%	0.0%	1.3%
Glipizide+voglilbose+Metformin	1	0	1
	1.3%	0.0%	1.3%
Metformin+Glimepiride	30	8	38
	38.0%	10.1%	48.1%
Metformin+Vildaglipti	1	0	1
	1.3%	0.0%	1.3%
Nil	16	7	23
	20.3%	8.9%	29.1%
Pioglitazone+Metformin	0	1	1
	0.0%	1.3%	1.3%
Pioglitazone+Metformin+Glimepiride	2	0	2
	2.5%	0.0%	2.5%
Teneligliptin+Metformin	1	1	2
	1.3%	1.3%	2.5%
Voglibose+Glimepiride+Metformin	1	0	1
	1.3%	0.0%	1.3%
Voglibose+Metformin	1	0	1
	1.3%	0.0%	1.3%
Total	**58**		**79**
	73.4%		**100.0%**

Chi-Square: 11.439, df: 12, p-value: .492

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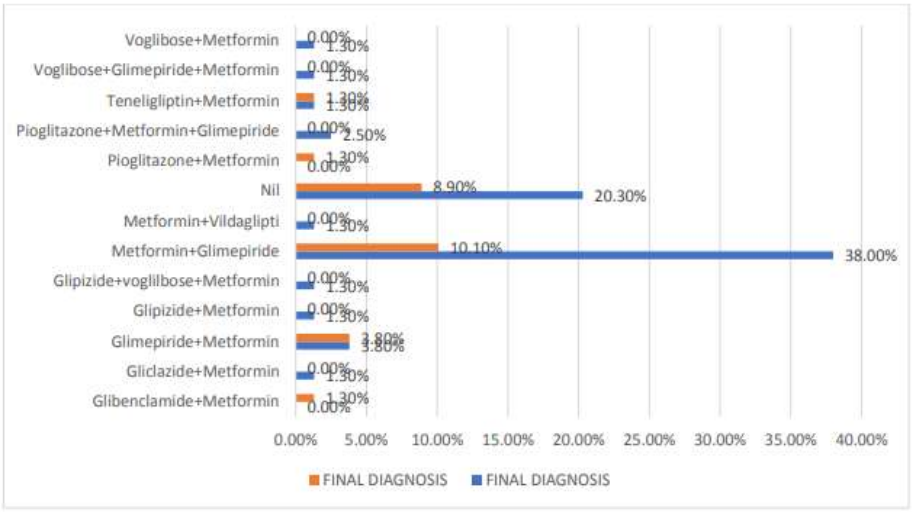

Figure no 13: Combination therapy Vs diagnosis

Metformin + Glimepiride is prescribed in 38% of patients with diabetes mellitus only.

Table no 14: Age group Vs FBS at 1st follow up

Age group	FBS-1			Total
	<70	>100	70 to 100	
21 to 30	0	1	1	2
	0.0%	1.3%	1.3%	2.5%
31 to 40	0	8	1	9
	0.0%	10.1%	1.3%	11.4%
41 to 50	0	8	2	10
	0.0%	10.1%	2.5%	12.7%
51 to 60	0	16	7	23
	0.0%	20.3%	8.9%	29.1%
61 to 70	2	8	7	17
	2.5%	10.1%	8.9%	21.5%
71 to 80	1	5	7	13
	1.3%	6.3%	8.9%	16.5%
81 to 90	0	3	2	5
	0.0%	3.8%	2.5%	6.3%
Total	**3**	**49**	**27**	**79**
	3.8%	**62.0%**	**34.2%**	**100.0%**

20.3% of patients at the age group 51 to 60 years were identified as hyperglycaemic

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Table no 15: Age group Vs FBS at 2nd follow up

Age group	FBS-2			Total
	<70	>100	70 to 100	
21 to 30	0	1	1	2
	0.0%	1.3%	1.3%	2.5%
31 to 40	0	8	1	9
	0.0%	10.1%	1.3%	11.4%
41 to 50	0	8	2	10
	0.0%	10.1%	2.5%	12.7%
51 to 60	0	18	5	23
	0.0%	22.8%	6.3%	29.1%
61 to 70	2	11	4	17
	2.5%	13.9%	5.1%	21.5%
71 to 80	0	6	7	13
	0.0%	7.6%	8.9%	16.5%
81 to 90	0	4	1	5
	0.0%	5.1%	1.3%	6.3%
Total	**2**	**56**	**21**	**79**
	2.5%	**70.9%**	**26.6%**	**100.0%**

22.8% of patients at the age group 51 to 60 years were identified as hyperglycemic, followed by 13.9% of patients at the age group of 61 to 70 years

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Table no 16: Age group Vs FBS at 3rd follow up

Age group	FBS-3			Total
	<70	>100	70 to 100	
21 to 30	0	1	1	2
	0.0%	1.3%	1.3%	2.5%
31 to 40	0	9	0	9
	0.0%	11.4%	0.0%	11.4%
41 to 50	0	7	3	10
	0.0%	8.9%	3.8%	12.7%
51 to 60	1	16	6	23
	1.3%	20.3%	7.6%	29.1%
61 to 70	2	8	7	17
	2.5%	10.1%	8.9%	21.5%
71 to 80	1	6	6	13
	1.3%	7.6%	7.6%	16.5%
81 to 90	0	4	1	5
	0.0%	5.1%	1.3%	6.3%
Total	**4**	**51**	**24**	**79**
	5.1%	**64.6%**	**30.4%**	**100.0%**

In the 3rd follow-up we have observed that, hyperglycemic levels are reduced comparatively than 2 nd follow-up

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Table no 17: Age group Vs FBS at 4th follow up

Age group	FBS-4 Range			Total
	<70	>100	70 to 100	
21 to 30	0	1	1	2
	0.0%	1.3%	1.3%	2.5%
31 to 40	0	8	1	9
	0.0%	10.1%	1.3%	11.4%
41 to 50	1	8	1	10
	1.3%	10.1%	1.3%	12.7%
51 to 60	1	17	5	23
	1.3%	21.5%	6.3%	29.1%
61 to 70	4	9	4	17
	5.1%	11.4%	5.1%	21.5%
71 to 80	4	5	4	13
	5.1%	6.3%	5.1%	16.5%
81 to 90	1	2	2	5
	1.3%	2.5%	2.5%	6.3%
Total	**11**	**50**	**18**	**79**
	13.9%	**63.3%**	**22.8%**	**100.0%**

In the 4th follow up we have observed that little fluctuation in the FBS levels of patients.

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Table no 18: Age group Vs FBS levels at 5th follow up

Age group	FBS-5 Range			Total
	<70	>100	70 to 100	
21 to 30	0	1	1	2
	0.0%	1.3%	1.3%	2.5%
31 to 40	0	7	2	9
	0.0%	8.9%	2.5%	11.4%
41 to 50	1	8	1	10
	1.3%	10.1%	1.3%	12.7%
51 to 60	1	15	7	23
	1.3%	19.0%	8.9%	29.1%
61 to 70	3	6	8	17
	3.8%	7.6%	10.1%	21.5%
71 to 80	2	5	6	13
	2.5%	6.3%	7.6%	16.5%
81 to 90	0	3	2	5
	0.0%	3.8%	2.5%	6.3%
Total	**7**	**45**	**27**	**79**
	8.9%	**57.0%**	**34.2%**	**100.0%**

In the follow up we have observed that almost 34.2% of patients were identified with normal levels of glucose.

Table no 19: Age group Vs FBS levels at 6th follow up

Age group	FBS-6 Range			Total
	<70	>100	70 to 100	
21 to 30	0	0	2	2
	0.0%	0.0%	2.5%	2.5%
31 to 40	0	7	2	9
	0.0%	8.9%	2.5%	11.4%
41 to 50	0	7	3	10
	0.0%	8.9%	3.8%	12.7%
51 to 60	2	12	9	23
	2.5%	15.2%	11.4%	29.1%
61 to 70	2	5	10	17
	2.5%	6.3%	12.7%	21.5%
71 to 80	5	5	3	13
	6.3%	6.3%	3.8%	16.5%
81 to 90	0	2	3	5
	0.0%	2.5%	3.8%	6.3%
Total	**9**	**38**	**32**	**79**
	11.4%	**48.1%**	**40.5%**	**100.0%**

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It has good improvement in the 6th follow up. Almost 40.5% of patients were identified normal blood glucose levels and hyperglycemic patients rate also reduced to 48% compared to previous follow ups.

Table no 20: Age group Vs PPBS

Age group	PPBS-1 Range		Total
	>200	140-200	
21 to 30	2	0	2
	2.5%	0.0%	2.5%
31 to 40	9	0	9
	11.4%	0.0%	11.4%
41 to 50	9	1	10
	11.4%	1.3%	12.7%
51 to 60	19	4	23
	24.1%	5.1%	29.1%
61 to 70	11	6	17
	13.9%	7.6%	21.5%
71 to 80	8	5	13
	10.1%	6.3%	16.5%
81 to 90	5	0	5
	6.3%	0.0%	6.3%
Total	**63**	**16**	**79**
	79.7%	**20.3%**	**100.0%**

24.1% of patients at the age group of 51 to 60 years were identified with hyperglycemia with Post prandial blood sugar test at follow up-1

Table no 21: Age group Vs PPBS at 2nd follow up

Age group	PPBS-2		Total
	>200	140-200	
21 to 30	2	0	2
	2.5%	0.0%	2.5%
31 to 40	9	0	9
	11.4%	0.0%	11.4%
41 to 50	10	0	10
	12.7%	0.0%	12.7%
51 to 60	22	1	23
	27.8%	1.3%	29.1%
61 to 70	11	6	17
	13.9%	7.6%	21.5%
71 to 80	8	5	13
	10.1%	6.3%	16.5%
81 to 90	5	0	5
	6.3%	0.0%	6.3%
Total	**67**	**12**	**79**
	84.8%	**15.2%**	**100.0%**

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In our study we have observe that, almost 84.8% of patients were had abnormal blood glucose levels at 2nd follow up for PPBS

Table no 22: Age group Vs PPBS at 3rd follow up

Age group	PPBS-3			Total
	<120	>200	140-200	
21 to 30	0	2	0	2
	0.0%	2.5%	0.0%	2.5%
31 to 40	0	9	0	9
	0.0%	11.4%	0.0%	11.4%
41 to 50	0	10	0	10
	0.0%	12.7%	0.0%	12.7%
51 to 60	1	20	2	23
	1.3%	25.3%	2.5%	29.1%
61 to 70	0	10	7	17
	0.0%	12.7%	8.9%	21.5%
71 to 80	0	8	5	13
	0.0%	10.1%	6.3%	16.5%
81 to 90	0	5	0	5
	0.0%	6.3%	0.0%	6.3%
Total	**1**	**64**	**14**	**79**
	1.3%	**81.0%**	**17.7%**	**100.0%**

To the third follow up of patients, almost 17% of patients maintains the blood glucose levels at normal level than 2nd follow up

Table no 23: Age group Vs PPBS at 4th follow up

Age group	PPBS-4		Total
	>200	140-200	
21 to 30	2	0	2
	2.5%	0.0%	2.5%
31 to 40	9	0	9
	11.4%	0.0%	11.4%
41 to 50	9	1	10
	11.4%	1.3%	12.7%
51 to 60	17	6	23
	21.5%	7.6%	29.1%
61 to 70	12	5	17
	15.2%	6.3%	21.5%
71 to 80	6	7	13
	7.6%	8.9%	16.5%
81 to 90	5	0	5
	6.3%	0.0%	6.3%
Total	**60**	**19**	**79**
	75.9%	**24.1%**	**100.0%**

In the fourth follow up, we have observed that, normal levels of PPBS is increased to 24% of patients

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Table no 24: Age group Vs PPBS at 5th follow up

Age group	PPBS-5		Total
	>200	140-200	
21 to 30	2	0	2
	2.5%	0.0%	2.5%
31 to 40	9	0	9
	11.4%	0.0%	11.4%
41 to 50	9	1	10
	11.4%	1.3%	12.7%
51 to 60	18	5	23
	22.8%	6.3%	29.1%
61 to 70	9	8	17
	11.4%	10.1%	21.5%
71 to 80	6	7	13
	7.6%	8.9%	16.5%
81 to 90	4	1	5
	5.1%	1.3%	6.3%
Total	**57**	**22**	**79**
	72.2%	**27.8%**	**100.0%**

To the 5th follow up, it was observed that rate of abnormal PPBS levels were reduced than previous follow-ups

Table no 25: Age group Vs PPBS at 6th follow up

Age group	PPBS-6 Range			Total
	>200	120-140	140-200	
21 to 30	2	0	0	2
	2.5%	0.0%	0.0%	2.5%
31 to 40	9	0	0	9
	11.4%	0.0%	0.0%	11.4%
41 to 50	7	0	3	10
	8.9%	0.0%	3.8%	12.7%
51 to 60	17	0	6	23
	21.5%	0.0%	7.6%	29.1%
61 to 70	10	0	7	17
	12.7%	0.0%	8.9%	21.5%
71 to 80	7	1	5	13
	8.9%	1.3%	6.3%	16.5%
81 to 90	4	0	1	5
	5.1%	0.0%	1.3%	6.3%
Total	**56**	**1**	**22**	**79**
	70.9%	**1.3%**	**27.8%**	**100.0%**

To the 6th follow up, not much differences identified in patients with respect to normal levels of PPBS

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Table no 26: Age group Vs RBS at 1st follow up

Age group	RBS-1		Total
	<180	>200	
21 to 30	1	1	2
	1.3%	1.3%	2.5%
31 to 40	0	9	9
	0.0%	11.4%	11.4%
41 to 50	2	8	10
	2.5%	10.1%	12.7%
51 to 60	8	15	23
	10.1%	19.0%	29.1%
61 to 70	12	5	17
	15.2%	6.3%	21.5%
71 to 80	9	4	13
	11.4%	5.1%	16.5%
81 to 90	3	2	5
	3.8%	2.5%	6.3%
Total	**35**	**44**	**79**
	44.3%	**55.7%**	**100.0%**

Patients were observed for RBS for 6 follow-ups, in the first follow up we have observed that only 44.3% of patients had <180 of RBS

Table no 27: Age group Vs RBS at 2nd follow up

Age group	RBS-2		Total
	<180	>180	
21 to 30	1	1	2
	1.3%	1.3%	2.5%
31 to 40	2	7	9
	2.5%	8.9%	11.4%
41 to 50	3	7	10
	3.8%	8.9%	12.7%
51 to 60	8	15	23
	10.1%	19.0%	29.1%
61 to 70	9	8	17
	11.4%	10.1%	21.5%
71 to 80	8	5	13
	10.1%	6.3%	16.5%
81 to 90	1	4	5
	1.3%	5.1%	6.3%
Total	**32**	**47**	**79**
	40.5%	**59.5%**	**100.0%**

In the 2nd follow up, rate of RBS levels >200 is increased to 59.5% than first follow up

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Table no 28: Age group Vs RBS at 3rd follow up

Age group	RBS-3		Total
	<180	>180	
21 to 30	1	1	2
	1.3%	1.3%	2.5%
31 to 40	1	8	9
	1.3%	10.1%	11.4%
41 to 50	3	7	10
	3.8%	8.9%	12.7%
51 to 60	11	12	23
	13.9%	15.2%	29.1%
61 to 70	11	6	17
	13.9%	7.6%	21.5%
71 to 80	8	5	13
	10.1%	6.3%	16.5%
81 to 90	1	4	5
	1.3%	5.1%	6.3%
Total	**36**	**43**	**79**
	45.6%	**54.4%**	**100.0%**

In the third follow up, patients with >200 RBS levels are reduced to 54.4%

Table no 29: Age group Vs RBS at 4th follow up

Age group	RBS-4		Total
	<180	>180	
21 to 30	2	0	2
	2.5%	0.0%	2.5%
31 to 40	1	8	9
	1.3%	10.1%	11.4%
41 to 50	4	6	10
	5.1%	7.6%	12.7%
51 to 60	12	11	23
	15.2%	13.9%	29.1%
61 to 70	11	6	17
	13.9%	7.6%	21.5%
71 to 80	9	4	13
	11.4%	5.1%	16.5%
81 to 90	2	3	5
	2.5%	3.8%	6.3%
Total	**41**	**38**	**79**
	51.9%	**48.1%**	**100.0%**

In the fourth follow up, we have observed that patients with <180 RBS levels rate increased to 51.9%

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Table no 30: Age group Vs RBS at 5th follow up

Age group	RBS-5		Total
	<180	>180	
21 to 30	2	0	2
	2.5%	0.0%	2.5%
31 to 40	4	5	9
	5.1%	6.3%	11.4%
41 to 50	4	6	10
	5.1%	7.6%	12.7%
51 to 60	9	14	23
	11.4%	17.7%	29.1%
61 to 70	13	4	17
	16.5%	5.1%	21.5%
71 to 80	10	3	13
	12.7%	3.8%	16.5%
81 to 90	1	4	5
	1.3%	5.1%	6.3%
Total	**43**	**36**	**79**
	54.4%	**45.6%**	**100.0%**

To the fifth follow up, patients with <180 RBS levels rate further increased to 51.4% and >200 is reduced to 45.6%

Table no 31: Age group Vs RBS at 6th follow up

Age group	RBS-6		Total
	<180	>180	
21 to 30	2	0	2
	2.5%	0.0%	2.5%
31 to 40	2	7	9
	2.5%	8.9%	11.4%
41 to 50	5	5	10
	6.3%	6.3%	12.7%
51 to 60	10	13	23
	12.7%	16.5%	29.1%
61 to 70	14	3	17
	17.7%	3.8%	21.5%
71 to 80	9	4	13
	11.4%	5.1%	16.5%
81 to 90	1	4	5
	1.3%	5.1%	6.3%
Total	**43**	**36**	**79**
	54.4%	**45.6%**	**100.0%**

To the 5th and 6th follow ups, no much difference was observed in the patients with respect to RBS levels

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Table no 32: Gender Vs FBS at 1st follow up

Gender	FBS-1			Total
	<70	>100	70 to 100	
Female	1	27	18	46
	1.3%	34.2%	22.8%	58.2%
Male	2	22	9	33
	2.5%	27.8%	11.4%	41.8%
Total	**3**	**49**	**27**	**79**
	3.8%	**62.0%**	**34.2%**	**100.0%**

In our study, we have observed that, majority females maintained normal levels of fasting blood glucose levels than male patients In the first follow up

Table no 33: Gender Vs FBS at 2nd follow up

Gender	FBS-2			Total
	<70	>100	70 to 100	
Female	1	32	13	46
	1.3%	40.5%	16.5%	58.2%
Male	1	24	8	33
	1.3%	30.4%	10.1%	41.8%
Total	2	56	21	79
	2.5%	70.9%	26.6%	100.0%

In the second follow up, we have observe that rate of hyperglycemia is increased in both the gender

Table no 34: Gender Vs FBS at 3rd follow up

Gender	FBS-3			Total
	<70	>100	70 to 100	
Female	3	30	13	46
	3.8%	38.0%	16.5%	58.2%
Male	1	21	11	33
	1.3%	26.6%	13.9%	41.8%
Total	**4**	**51**	**24**	**79**
	5.1%	**64.6%**	**30.4%**	**100.0%**

In third follow up, we have observed that female patients had more abnormality of FBS levels than male patients

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Table no 35: Gender Vs FBS at 4th follow up

Gender	FBS-4			Total
	<70	>100	70 to 100	
Female	5	29	12	46
	6.3%	36.7%	15.2%	58.2%
Male	6	21	6	33
	7.6%	26.6%	7.6%	41.8%
Total	**11**	**50**	**18**	**79**
	13.9%	**63.3%**	**22.8%**	**100.0%**

In the fourth follow up, we have observed that rate of hypoglycemia is increased in both the gender

Table no 36: Gender Vs FBS at 5th follow up

Gender	FBS-5			Total
	<70	>100	70 to 100	
Female	3	25	18	46
	3.8%	31.6%	22.8%	58.2%
Male	4	20	9	33
	5.1%	25.3%	11.4%	41.8%
Total	**7**	**45**	**27**	**79**
	8.9%	**57.0%**	**34.2%**	**100.0%**

In the fifth follow up, female patients had shown good improvement and maintains normal levels of blood glucose levels than male patients

Table no 37: Gender Vs FBS at 6th follow up

Gender	FBS-6			Total
	<70	>100	70 to 100	
Female	6	20	20	46
	7.6%	25.3%	25.3%	58.2%
Male	3	18	12	33
	3.8%	22.8%	15.2%	41.8%
Total	**9**	**38**	**32**	**79**
	11.4%	**48.1%**	**40.5%**	**100.0%**

In the sixth follow up, we have observed that rate of normal levels of fasting blood glucose were increased in the both gender

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Table no 38: Gender Vs PPBS at 1st follow up

Gender	PPBS-1		Total
	>200	140-200	
Female	38	8	46
	48.1%	10.1%	58.2%
Male	25	8	33
	31.6%	10.1%	41.8%
Total	**63**	**16**	**79**
	79.7%	**20.3%**	**100.0%**

We have observed that almost 79% of patients were identified with abnormal post prandial blood glucose levels, among these female gender had higher rate than male gender

Table no 39: Gender Vs PPBS at 2nd follow up

Gender	PPBS-2		Total
	>200	140-200	
Female	40	6	46
	50.6%	7.6%	58.2%
Male	27	6	33
	34.2%	7.6%	41.8%
Total	**67**	**12**	**79**
	84.8%	**15.2%**	**100.0%**

In the second follow up, rate of abnormal PPBS was increased to 84.5%

Table no 40: Gender Vs PPBS at 3rd follow up

Gender	PPBS-3			Total
	<120	>200	140-200	
Female	1	37	8	46
	1.3%	46.8%	10.1%	58.2%
Male	0	27	6	33
	0.0%	34.2%	7.6%	41.8%
Total	**1**	**64**	**14**	**79**
	1.3%	**81.0%**	**17.7%**	**100.0%**

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In the third follow up, we have observed that, rate of normal PPBS levels are increased in female gender up to 10.1%

Table no 41: Gender Vs PPBS at 4th follow up

Gender	PPBS-4		Total
	>200	140-200	
Female	34	12	46
	43.0%	15.2%	58.2%
Male	26	7	33
	32.9%	8.9%	41.8%
Total	60	19	79
	75.9%	24.1%	100.0%

In the fourth follow up, rate of normal PPBS levels are increased in both the gender

Table no 42: Gender Vs PPBS at 5th follow up

Gender	PPBS-5		Total
	>200	140-200	
Female	33	13	46
	41.8%	16.5%	58.2%
Male	24	9	33
	30.4%	11.4%	41.8%
Total	**57**	**22**	**79**
	72.2%	**27.8%**	**100.0%**

In the fifth follow up, rate of normal PPBS values are further increased to 27.8% in both gender

Table no 43: Gender Vs PPBS at 6th follow up

Gender	PPBS-6			Total
	>200	120-140	140-200	
Female	33	1	12	46
	41.8%	1.3%	15.2%	58.2%
Male	23	0	10	33
	29.1%	0.0%	12.7%	41.8%
Total	**56**	**1**	**22**	**79**
	70.9%	**1.3%**	**27.8%**	**100.0%**

In the sixth follow up, not much difference was identified with respect to normal level of PPBS

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Table no 44: Gender Vs RBS at 1st follow up

Gender	RBS-1		Total
	<180	>180	
Female	19	27	46
	24.1%	34.2%	58.2%
Male	16	17	33
	20.3%	21.5%	41.8%
Total	**35**	**44**	**79**
	44.3%	**55.7%**	**100.0%**

We have observed that, almost 55.7% of patients were identified with >180 RBS levels, out of this female gender rate is high

Table no 45: Gender Vs RBS at 2nd follow up

Gender	RBS-2		Total
	<180	>180	
Female	16	30	46
	20.3%	38.0%	58.2%
Male	16	17	33
	20.3%	21.5%	41.8%
Total	**32**	**47**	**79**
	40.5%	**59.5%**	**100.0%**

In the second follow up, rate of hyper glycemia is increased, specifically it was increased female gender patients

Table no 46: Gender Vs RBS at 3rd follow up

Gender	RBS-3		Total
	<180	>180	
Female	21	25	46
	26.6%	31.6%	58.2%
Male	15	18	33
	19.0%	22.8%	41.8%
Total	**36**	**43**	**79**
	45.6%	**54.4%**	**100.0%**

In third follow up, rate of hyperglycemia levels are reduced in female patients and increased in male patients

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Table no 47: Gender Vs RBS at 4th follow up

Gender	RBS-4		Total
	<180	>180	
Female	22	24	46
	27.8%	30.4%	58.2%
Male	19	14	33
	24.1%	17.7%	41.8%
Total	**41**	**38**	**79**
	51.9%	**48.1%**	**100.0%**

In the fourth follow up, normal levels of RBS was increased in both gender

Table no 48: Gender Vs RBS at 5th follow up

Gender	RBS-5		Total
	<180	>180	
Female	24	22	46
	30.4%	27.8%	58.2%
Male	19	14	33
	24.1%	17.7%	41.8%
Total	**43**	**36**	**79**
	54.4%	**45.6%**	**100.0%**

In the fifth follow up, normal levels of RBS was increased in both the gender to 54.4%

Table no 49: Gender Vs RBS at 6th follow up

Gender	RBS-6		Total
	<180	>180	
Female	24	22	46
	30.4%	27.8%	58.2%
Male	19	14	33
	24.1%	17.7%	41.8%
Total	**43**	**36**	**79**
	54.4%	**45.6%**	**100.0%**

In the sixth follow up, we haven't observed any difference in RBS levels of both gender patients

V. DISCUSSION

A Hospital based prospective observational was carried out in the Department of Medicine and Endocrinology, Sagar hospital, Bengaluru. A total of 84 patients had enrolled in the study as per the study inclusion and exclusion criteria and in which 5 patients had withdrawn from the study due to lack of follow up data then finally data of 79 patients were taken for statistical analysis. Comparative study of metformin mono-

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therapy and combination therapy was conducted among the diabetic patients to evaluate the efficacy of the drug. Blood sugar level of the patients on metformin monotherapy was compared with the blood sugar level of the patients taking metformin in combination at every month for the duration of six months.

Age: Table no 01 and figure no 01 depicts the age wise distribution of the study participants, out of 79 patients 2.5% of them falls in 21 to 30 years age group, 11.4% in 31 to 40 years age group, 12.7% in 41 to 50years age group, 29.1% in 51 to 60 years age group, 21.5% were in 61 to 70 years age group, 16.5% in 71 to 80 age group and 6.5% are in 71 to 80 years age group. The mean age of the study participants were found to be 59.58. Further data analysis also showed that more than 80% of the study participants are above the age of 50 years which reported that older adults are more prone to get diabetes compared to young adults. Same kind of observations was found in the study conducted by Asiimwe D et al., where the study found that the age group of 61 to 65 years are more highly diagnosed with diabetes mellitus.

Gender: Data from table no 02 and figure no 02, A grand total of 79 patients were included in the study and out of which 58.2% were male gender and 41.8% were female gender. This revealed that male genders showed more risk than female gender towards diabetes mellitus among our study population.Our findings are similar to Chris E Ekpenyong et.al in which 43.8% were males and 56.2% were females indicating that females predominated over males.

FBS distribution: Fasting blood glucose data of the study participants during the 6 follow ups had represented in the table 03 and figure 03, the data showed that the low fasting blood glucose level was reported for the 3.8% in the baseline follow up and followed by gradual increased to 11.4% in sixth follow up. Rate of patients with high fasting blood glucose level data showed uncertain decline among study participants from 62% in baseline follow up to 48.1% in the sixth follow up. Number of study participants with controlled fasting blood sugar level had reported with increased from baseline follow up to sixth follow up as 34.2% to 40.5%. This data revealed that fasting blood sugar level was reduced with proper drug therapy. Results findings are identical with the study conducted by M Freemark et al., in which there was a marked reduction in fasting blood sugar was noted from mean of 84.9 to 75.1 mg after metformin therapy.

Post prandial distribution: Among the 79 study participants, a negligible number of participants (1) only reported with less than 120 mg/dl of post prandial blood glucose level in third and sixth follow ups and none of the study participants had reported with 120-140 mg/dl among all follow ups. 20.3% of the study participants were found with the post prandial blood sugar level of 140-200 mg/dl in the baseline and which increased in unsettled manner in the further follow ups as 15.5% in second follow up, 17.7% in third follow up, 24.1% in fourth follow up, 27.8% in fifth follow up and 27.8% in sixth follow up. Most of the study participants have reported with post prandial blood sugar level of >200 mg/dl in almost all the follow ups but a overall decline have been noted from baseline followup levels to sixth follow up levels in ambiguous manner from 63 participants(79.7%) to 56 participants(70.9%) respectively. These data have clearly represented in the table no 04 and illustrated in figure no 04.

Random blood sugar distribution: From the data represented in the table no 05 and figure no 05, out of 79 participants 35(44.3%) participants had reported their random blood sugar level as <180 mg/dl in the baseline follow up which increased gradually to 43 (54.4%) in the sixth follow up. The percentage of study population noted with random blood glucose level >200 mg/dl was also decreased in the study state from 55.7%(44 participants) to 45.6%(36 participants). This shows the better efficacy of the treatment in the random blood sugar control.

Distribution of subjects according to monotherapy: Table no 06 and figure no 06 illustrates the distribution of the study subjects based on their antidiabetic monotherapy, Among the total of 79 study population 26(32.9%) were treated with metformin as monotherapy and 53 participants(67.1%) were treated with other antidiabetic as monotherapy for the blood glucose management. Our study data found out that the usage of metformin as monotherapy was not on a regular basis. This finding was against the systematic review carried out by Maruthur et al,. where the metformin used in most of participants than other combinations.

Distribution of subjects according to combination therapy: Study participants were distributed based on their antidiabetic combinational drug therapy which is clear elicited in table no 07 and figure no 07 as 38 participants(48.1%) were managed with Metformin

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+ Glimepiride combination, 23 participants(29.1%) were managed with other antidiabetic combination agents without metformin, 6 participants(7.6%) were managed with Glimepiride + Metformin 2 participants(2.5%) each were managed with Teneligliptin + Metformin and Pioglitazone + Metformin and 1 participants(1.3%) were managed with any of each combinations of Glibenclamide + Metformin, Gliclazide + Metformin, Glipizide + Metformin, Metformin + Vildagliptin, Pioglitazone + Metformin, Voglibose + Metformin,Voglibose + Glimepiride + Metformin and Glipizide + Voglibose + Metformin. Data showed that Metformin + Glimipride is the most utilised combination for the antidiabetic management in the study samples.Our results are similar with study conducted by Sushruth VS et al., where the combination antidiabetic drug therapy(66.8%) was used more frequently than monotherapy(34.8%).

Distribution of subjects according to final diagnosis: In the table no 08 and figure no 08 the data of distribution of study participants based on diagnosis were represented, out of 79 participants 73.4%(58 participants) were diagnosed with diabetes mellitus and 26.6%(21 participants) were diagnosed with diabetes mellitus with hypertension. Our study found out that the diabetes mellitus without hypertension patients have admitted in the hospital in large number than the diabetic patients with hypertension Our findings are supported by the study conducted by Chen H et al, showed that hypertension is the major comorbidity with diabetes.

Distribution of subjects according to outcome: Outcome of the study population were reported and used to distribute the subjects which had demonstrated in the table no 09 and also in figure no 09 as 53 participants (67.1%) were showed improvement in their glycemic control during the study period and 26 participants (32.9%) were failed to show the improvement in their glycemic control. Majority of the study population showed better control over the glucose level in antidiabetic therapy.

Monotherapy Vs outcome of Patients: Table no 10 and figure no 10 was used to illustrate the data comparison of antidiabetic agent monotherapy with the outcome of the study participants. Among 26 metformin users 18(22.8%) were shown improvement and 08 participants (8%) had failed to show improvement. Out of 53 participants using other antidiabetic agents as monotherapy, 35 participants (44.3%) had been reported with better improvement and 18 participants(22.8%) were reported with no improvement. Data revealed less effectiveness of metformin in monotherapy compared with other classes of antidiabetic agents. Statistical evaluation of the study data for the difference in the improvement among the metformin and other antidiabetic agents have shown no significance at 95% confidence interval.

Combination therapy Vs outcome of patients: Effectiveness of the combination therapy in diabetic management have reported in the table no 11 and figure no 11 as 100% outcome in the combination therapy were reported for Glibenclamide + Metformin, Gliclazide + Metformin, Glimepiride + Metformin, Glipizide + Metformin, Pioglitazone + Metformin, Glipizide + Voglibose + Metformin and Voglibose + Glimepiride + Metformin combinations. Further data analysis had revealed that more than 98% effective outcome were reported with Teneligliptin + Metformin, Voglibose + Metformin, more than 70% effectiveness with Metformin + Glimepiride and 50% effectiveness with Pioglitazone + Metformin + Glimepiride. Also the other antidiabetic drugs combination without metformin also showed more than 65% among study participants. Statistical analysis of the above data were done and results are chi-square t value was found to be 10.795 and p-value was found to be 0.547 which revealed that the difference in the antidiabetic management outcome among the different combination was not statistically significant at 95% Confidence Interval. Results are similar with study conducted by Fleury F et al, in which the glimepiride with metformin combination gives effective outcome in glycemic control.

Monotherapy Vs diagnosis: Table no 12 and figure no 12 are used to elicit the data to evaluate the correlation between diagnosis and the selection of agent for monotherapy and the interpretations are as follows 17 participants (21.5%) with diabetic mellitus alone were managed with metformin as monotherapy and 41 participants(51.9%) with diabetic mellitus only were managed with other antidiabetic agents as monotherapy. 09 patients (11.4%) with diabetes mellitus and hypertension were managed with metformin and 12 patients (15.2%) were managed with other antidiabetic agents as monotherapy. Further analysis showed that the 32.9% of the study population had managed with metformin as monotherapy and 67.1% of the study population had managed with other antidiabetic agents as monotherapy. Statistical analysis was done for the

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data which showed that t value of 1.281 and p value of 0.258 which emphasizes that there is no significant correlation between the selection antidiabetic agent and the final diagnosis. Our study report contradict with the study conducted by Diethelm T et al,. where the metformin was usually preferred over other antidiabetic agents as first line treatment of type 1 diabetes.

Combination therapy Vs diagnosis: Comparison of drug therapy with combination of antidiabetic drugs with the diagnosis of the patient was carried out and the data are expressed in the table no 13 and figure no 13 and interpreted as patient with only diabetes mellitus have managed with the combination of antidiabetic medications like 30 participant(38%) were managed with Metformin + Glimepiride, 16 participants (20.3%) were managed with Other than metformin combinations, 3 Participants(3.8%) were managed with Glimepiride + Metformin, 2 participants(2.5%) were managed with Pioglitazone + Metformin + Glimepiride and then the combination of Gliclazide + Metformin, Glipizide + Metformin, Metformin + Vildagliptin, Teneligliptin + Metformin, Voglibose + Metformin, Voglibose + Glimepiride + Metformin and Glipizide + Voglibose + Metformin had used in 1 participant(1.3%) for managed of their blood glucose level. Both the combination of Glibenclamide + Metformin and Pioglitazone + Metformin have not been used in the management of blood glucose levels in the patients who had only diabetes mellitus in the study population. Data also showed that the patients with Diabetes mellitus with hypertension had prescribed with the combination of antidiabetic drug therapy such as Metformin + Glimepiride in 08 patients (10.1%), Combinations without Metformin in 7 patients (8.9%), Glimepiride + Metformin in patients (3.8%) and each of the following combinations had been prescribed for 1 patient (1.3%) Glibenclamide + Metformin, Pioglitazone + Metformin, Teneligliptin + Metformin. The comparison had undergone statistical analysis which results shown that comparatively there is no significant difference in the drug utilization between the patients with diabetes mellitus alone and diabetes mellitus with hypertension. Our study results counter the observation found in the study conducted by Rakesh KS et al, where the metformin and glimepiride combination used diabetic patients with comorbidities in India.

Age group vs FBS at first follow up Table no 14 illustrates the comparison of the age group with the fasting blood glucose level in the first follow up. The data showed that 02 participants (2.5%) from the age group of 61 to 70 and 01 participants (1.3%) from 71 to 80 age group had reported with 100 mg/dl of fasting blood glucose level. 08 participants (10.1%) from each of the 31 to 40 years age group, 41to 50 years age group and 61 to 70 years age group had reported with fasting blood glucose level >100 mg/dl. Optimum range of fasting blood glucose level of 70 to 100 was reported by the participants from the age group 51 to 60(23 participants) followed by 61 to 70 (17 participants), 71 to 80 (13 participants). Our study data revealed that the age group of 50 to 70 had very good control of their fasting blood glucose level in the baseline follow up.

Age group Vs FBS at second follow up: In the second follow up data which had been represented in table no 15 showed that only 2 participants (2.5%) from the age group of 61 to 70 years had fasting blood glucose level 100 mg/dl. The number of participants with the optimum range of fasting blood glucose levels were reported from 51 to 06 years of age group (23 participants) followed by 61 to 70 years of age group (17 participants) and 70 to 80 years of age (13 participants). Hence these comparisons also suggested that the age group of above 51 years have better glycemic control than younger adults.

Age group vs FBS at third follow up: Comparison of fasting blood glucose level of third follow up with age group was elicited with the table no 16 as 100 mg/dl of fasting blood glucose levels have been reported in the age group of 51 to 60 years (16 patients), 31 to 40 years (09 participants) and 61 to 70 years (08 participants). 07 participants (8.9%) from the 61 to 70 years of age group had reported the fasting blood sugar level within the range of 70 to 100 mg/dl. 06 participants (7.6%) from both 51 to 60 and 71 to 80 years of age group were reported with 70 to 100 mg/dl. This follow up data also proves that diabetic patients of the age group above 50 have better glycemic control.

Age group Vs FBS of fourth follow up: Table no 17 represents the data of comparison of age group with fast blood glucose level in fourth follow up, out of 79 participants 11 participants had reported fasting blood glucose level of with 100 mg/dl which mainly from the age groups of 51 to 60(21.5%), 61 to 70(11.4%), both 31 to 40 and 41 to 50(10.1% each), 71 to 80(6.3%), 81 to 90 and 21 to 30(1.3% each). study data also showed that from the age group of 51 to 60 years had reported with

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70 to 100 mg/dl of fasting glucose level (05 participants) followed by 61 to 70 and 71 to 80 years age group (04 participants each) 81 to 90 (02 participants) and 21 to 30 (01 participants). This data analysis showed that the older adults had better glycemic control.

Age group Vs FBS of fifth follow up: comparison of the age group with fasting blood glucose level in the fifth follow up, 7 participants had reported with 100 mg/dl of fasti.ng blood sugar level from the age group of 51 to 60(15 participants), 41 to 5(8 participants), 31 to 40(07 participants) 61 to 70(6 participants, 71 to 80(5 participants), 81 to 90(03 participants) and 21 to 30(01 participant). out of 79 participants 27 had reported with fasting blood sugar level in the range of 70 to 100 from various age groups such as 61 to 70(08 participants), 51 to 60(07 participants), 71 to 80(06 participants), 81 to 90(02 participants), 31 to 40(02 participants) and 41 to 50(01 participant). data analysis suggested that old adults have better glycemic control than the youngster and the data were presented in table no 18 and figure no 18.

Age group Vs FBS of sixth follow up: Comparison of age group with fasting blood sugar level in sixth follow up was done and the data were represented in the table no 19, 2 participants from the 51 to 60 years of age group, 2 participants from 61 to 70 years of age group, 5 participants from 71 to 80 years of age group were reported with fasting blood sugar level

up. 07 participants form 31 to 40 years of age group, 07 participants from 41 to 50 year of age group, 12 participants from 51 to 60 years of age group, 05 participants from both 61 to 70 and 71 to 80 years of age groups, and 2 participants from 81 to 90 years of age group were reported with fasting blood sugar level of >100 mg/dl. out of 79 patients 32 patients were found to had fasting blood sugar level in the range of 70 to 100 mg/dl in sixth follow up in which the age group distribution had found to be 02 participants from 21 to 30 years of age group, 02 participants from 31 to 40 years of age group, 03 participants from 41 to 50 years of age group, 09 participants from 51 to 60 years of age group, 10 participants from 61 to 70 years of age group, 03 participants from 71 to 80 years of age group, 03 participants from 71 to 80 years of age group and 03 participants from 81 to 90 years of age group. From the above data analysis it is clear that more than 78% of the participants who had better control in fasting glucose levels are found to be above the age of 51 which implies that the elder population has better glycemic control among the study population.

Age group Vs PPBS at first follow up: Post prandial blood sugar was analyzed with age group to find out any significance between these two variables which had been illustrated in the table no 20 the data were showed that 63 participants out of 79 were found to be hyperglycemic which means their postprandial blood glucose level reported with >200 mg/dl the age group distribution revealed that 19 participants are from the 51 to 60 years of age group followed by 11 participants from 51 to 60 years age group, 09 participants for each of 31 to 40 years of age group and 41 to 50 years of age group, 8 participants from 71 to 80 years of age group, 05 participants from 81 to 90 years of age group and 02 participants from 21 to 30 years of age group. Out of 16 participants with the post prandial blood sugar levels within the range of 140 to 200 mg/dl 6 participants are from 61 to 70 years of age group, 05 participants are from 71 to 80 years of age group, 4 participants are from the age group of 51 to 60 and 01 participant from 41 to 51 years of age group. These results showed that hyperglycemia was more in the age group of 51 to 60 in the baseline data among the study population.

Age group Vs PPBS at second follow up Table no 21 were depicts the data of comparison between age group and postprandial blood sugar level in second follow up among the study population(79 participants) 67 participants(84.8%) were found to be hyperglycemic and the further analysis revealed that 22 participants are from 51 to 60 years of age group, 11 participants from 61 to 70 years of age, 10 participants from 41 to 50 years of age group, 09 participants from 31 to 40 years of age group, 08 participants from 71 to 80 years of age, 05 participants from 81 to 90 years of age group and 02 participants from 21 to 30 years of age group. Participants with 140 to 200 mg/dl of post prandial blood sugar level were found in 06 participants from 61 to 70 years of age group, 05 participants from 71 to 80 years of age group and 01 patient from 51 to 60 years of age group. Results showed that postprandial blood sugar level was at optimum control in the elderly population compared to younger age participants.

Age group Vs PPBS at fourth follow up: Table 23 was used to illicit the data which compares the age group of the study participants with their postprandial blood glucose level at fourth follow up. And the data revealed that 75.9% of the study participants had sugar level >200 mg/dl and the they were distributed among 51 to 60 year of

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age group (21.5%), 61 to 70 years of age group(15.2%), 31 to 40 and 41 to 50 years of age group(11.4% each), 71 to 80 years of age group(7.6%), 81 to 90 years of age group(6.3%) and 21 to 30(2.5%). Among 79 participants 19 were reported with postprandial blood sugar of 140 to 200 mg/dl were 7 participants from the age group of 71 to 80, 06 participants from 51 to 60 years of age group, 05 participants from 61 to 70 years of age group and 01 participant from age group of 21 to 30. Data revealed that postprandial hyperglycemia was not reduced even in fourth follow up and less no of participants who showed glycemic control also belongs to older adults age group.

Age group Vs PPBS at fifth follow up: From the table no 24 the postprandial blood sugar level at fifth follow up was found to very high in 72.2% of the study participants and the age wise distributions showed as 22.8% of the participants belongs to 51 to 60 years of age group, 11% of the participants belongs to 61 to 70 years of age, 61 to 70 years of age and 31 to 40 years of age each, 5.1% of the participants belongs to 81 to 90 years of age and 2.5% of them are belongs to 21 to 30 years of age. Further analysis depicts that 27.8% of the study participants are having postprandial blood sugar level in the range of 140 to 200 and they are distributed as 10.1% from 61 to 70 years of age group, 8.9% from 71 to 80 years of age group, 8% from 61 to 70 years of age group, 6.3% from 51 to 60 years of age and 13% from 41 to 50 years of age and 81 to 90 years of age each. This data reveals that even in the fifth follow up the study population has hyperglycemia in postprandial blood sugar analysis and also only little glycemic control had reported only with the elderly population.

Age group Vs PPBS at sixth follow up 56 participants (70.9%) in the study population had reported with posting blood sugar level >200 mg/dl which was represented in table no 25. The age group comparison at sixth follow up postprandial blood sugar level showed that 17 participants(21.5%) are from the age group of 51 to 60 years, 10 participants(12.7%) are from 61 to 70 year of age group, 9 participants(11.4%) are from age group of 31 to 40 years, 7 participants(8.9%) from each of 31 to 40 years of age group and 71 to 80 years of age group, 4 participants(5.1%) from 81 to 90 years of age group and 02 participants(2.5%) from 21 to 30 years of age which showed that high sugar level in the postprandial evaluation is not related with age group. Postprandial blood sugar level within range of 120 to 140 mg/dl was reported in only 01 participant from 71 to 80 years of age group. And the 140 to 200 mg/dl range of postprandial blood sugar level was reported in 22 participants at sixth follow up and their age group distribution was found to be 7 participants (8.9%) from 61 to 70 years of age, 6 participants (7.6%) from 51 to 60 years of age, 05 participants(6.3%) from 71 to 80 years of age, 3 participants(3.8%) from 41 to 50 years of age and 01 participant(1.3%) from 81 to 90 years of age. Data analysis depicts that postprandial blood sugar level management does not had proper outcome and a few appropriate levels of postprandial sugar levels had noted only in elderly population.

Age VS RBS at first follow up: Table no 26 was used to illustrate the data of comparison between the age group of the study population with their random blood sugar level at first follow up. out of 79 study participants 35 had 180 mg/dl at baseline follow up with distributed among the age groups as 15 participants(19%) are from the age group of 51 to 60, 9(11.4%) participants are from the age group of 31 to 40 years, 8 participants(10.1%) are from the age group of 41 to 50, 5 participants(10.1%) are from 61 to 70 years of age group, 4 participants(5.1%) are from the age group of 71 to 80 years of , 02 participants(2.5%) are from 81 to 90 years of age group and 01 participant(1.3%) was from the 21 to 30 years of age group. Results are shown in the baseline follow up, more than half of the study participants reported with hyperglycemia but better control in the random blood sugar level was highly reported in the age group above 50 years of age.

Age group Vs RBS at second follow up: Data about the comparison of age group with random blood sugar level at second follow up were documented in the table no 27 and illustrated in table no 27, from the study participants 11.4% participants from 61 to 70 years of age group, 10.1% participants from both 51 to 60 years of age group and 71 to 80 years of age group, 3.8% participants from 41 to 50 years of age group, 2.5% participants of 31 to 40 years of age group and 1.3% participants from 21 to 30 and 81 to 90 years of a group are reported with random blood sugar level of 180 mg/dl at second follow up and the age group categorization among the participant represented as 15 participants(19%) are from the age group of 51 to 60 years, 8 participants(10.1%) are from 61 to 70 years of age group, 07 participants(8.9%) are from each age group of 31 to 40 years and 41 t0 50 years, 5 participants(6.3%)

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are from 71 to 80 years of age group, 04 participants(5.1%) are from 81 to 90 years of age group and 01 participant(1.3%) was form 21 to 30 years of age group. This analysis showed that the random blood sugar level was reported in optimum range by less than half of the participants and in that also most of them were belonging to the age group of above 50 years.

Age Group Vs RBS at third follow up: From the data in table no 28 it is clear that 45.6% of the study participants are had random blood sugar level >180 mg/dl at third follow up and they had age group distribution as 11 participants (1.9%) are in each age group of 51 to 60 years and 61 to 70 years, 08 participants (10.1%) are in 71 to 80 years, 3 participants(3.8%) are in 41 to 50 years and 1 participants(1.3%) in each age group 21 to 30 years, 31 to 40 years and 81 to 90 years. >180 mg/dl of random blood sugar level was reported by 12 participants (8.9%) in 51 to 60 years of age group, 07 participants (8.9%) in 41 to 50 years of age group, 6 participants(7.6%) in 61 to 70 years of age group, 5 participants(6.3%) in 71 to 80 years of age group, 04 participants(5.1%) in 81 to 90 years of age group and 01 participant(1.3%) from 21 to 30 years of age group. This reveals that most of the younger adults are reported with random blood sugar levels of >180 mg/dl and the majority of the participants with sugar levels is above in the above 50 years of age group than compared to the younger age groups.

Age group Vs RBS at fifth follow up: Table 30 is used to illustrate the data of comparing the age group of the participants and the random blood sugar level of the participants at fifth follow up and 81 to 90 years of age group (1 participants). Out of 79 participants 36 had reported with random blood sugar levels >180 mg/dl among them 14 participants (17.7%) are belongs to the age group of 51 to 60 years, 6 participants(7.6%) are belongs to 41 to 50 years of age group, 5 participants belongs to 31 to 40 years of age group, 4 participants belongs to each of 61 to 70 years of age group and 81 to 90 years of age group and 03 participants belongs to 71 to 80 years of age group. Results found out that glycemic control was shown only among the participants belonging to the age group of 50 years.

Age group Vs RBS at sixth follow up: From the table no 31 the 43 participants were reported with random blood sugar levels 180 mg/dl 13(16.5%) are from 51 to 60 years of age group, 7(8.9%) are from 31 to 40 years of age group, 5(6.3%) are from 41 to 50 years of age group, 04 from each 71 to 80 years of age group and 81 to 90 years of age group and 3(3.8%) from 61 to 70 years of age group. Results showed that most of participants with random blood sugar < 49 the above 50 age group were less likely to report poor glycemic control.

Gender Vs FBS at first follow up: Table no 32 depicts the data comparing the gender of the study participants with their fasting blood glucose at first follow up. In the study fasting blood glucose level of 100 mg/dl 18 female and 27 male had reported 70 to100 mg/dl of fasting blood glucose level at first follow up. Results depicts that female gender had optimum fasting blood sugar level than male gender in the study.

Gender Vs FBS at second follow up: Out of 46 female participants in the study 32(40.5%) were reported with fasting blood sugar of >100 mg/dl, 13(16.5%) were reported within 70 to 100 mg/dl and 3(3.8%) were reported with 100 mg/dl of blood sugar level, 8(10.1%) were reported within range of 70 to 100 mg/dl and 1 participant (1.3%) was reported with <70 mg/dl at seconf follow up which is represented in Table 03.

Data reveals female gender reports more hyperglycemia than the male gender.

Gender Vs FBS at third follow up: Comparison of gender with fasting blood sugar of the participants at third follow up were represented in the table no 34. There are 51(64.6%) participants who reported their fasting blood glucose level >100 mg/dl in which 30(38%) were female participants and 21(26.6%) were male participants. 24 participants (30.4%) were reported with fasting blood glucose level 70 to 100 mg/dl in that 13(16.5%) were female and 11(13.9%) were male and also out of 4 participants (5.1%) with fasting blood glucose level <70, 3 were female and 1 was male.

Results showed that 75% of the hypoglycemia during fasting state was reported by the female gender in the study during third follow up.

Gender Vs FBS at fourth follow up: Comparative analysis of data from the gender of the study participants with fasting blood sugar level of them at fourth follow up was elicited in the table no 35 and figure no 35. Among 46(58.2%) female participants 29(36.7%) had fasting blood glucose level >100 mg/dl, 12(15.2%) had 70 to 100 mg/dl and 5(6.3%) had Out of 33 male participants (41.8%) 21(26.6%) had fasting blood glucose level >100 mg/dl, 6(7.6%) had 70 to 100 mg/dl and 6(67.6%) had <70 mg/dl during the fourth follow

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up. Results revealed that the percentage of participants with a normal range of fasting glucose value is double compared to male participants.

Gender vs FBS at fifth follow up: In the fifth follow up 27 participants (34.2%) were reported with fasting blood glucose level 70 to 100 mg/dl in that 18(22.8%) were female and 9(11.4%) were male participant and 7(8.9%) participants were reported with <70 mg/dl in that 3(3.8%) were female and 4(5.1%) were male and these data are presented with table no. 36. Results depict that in the fifth follow up male gender reported more hypoglycemia than the female gender in the study.

Gender vs FBS at six follow up: Table 37 represented the comparative data of gender and the fasting blood glucose level of the study participants at six follow up. Among 46 female participants (58.2%) 20(25.3%) were reported with >100 mg/dl of fasting blood sugar level, 20(25.3%) were reported with 70 to100 mg/dl and 6(7.6%) were reported with <70mg/dl of the fasting blood sugar level. Data analysis reveals that glycemic control among female genders was comparatively higher than the male genders among study participants.

Gender Vs PPBS at first follow up: As per the table no 38 out of 46(58.2%) female study participants 38(48.1%) had postprandial blood sugar level >200 mg/dl and 8(10.1%) had 140 to 200 mg/dl in the first follow up. And also out of 33(41.8%) male participants 25(31.6%) were reported with >200 mg/dl and 8(10.1%) were reported with postprandial blood sugar levels between 140 to 200 mg/dl. Results depict that glycemic control was very bad among both genders in the study.

Gender Vs PPBS at second follow up: Table no 39 showed that 67(84.8%) participants were reported with >200 mg/dl of postprandial blood sugar levels in the second follow up in which 40(50.6%) were female and 27(34.2%) were male participants. 12 Participants reported their postprandial blood sugar level within the range of 140 to 200 mg/dl among them 6(7.6%) were female and 6(7.6%) were male participants. Results reveal that the hyperglycemia was reported in a larger portion of female gender than male gender of the study population in the second follow up.

Gender Vs PPBS at third follow up: Out of 46(58.2%) female study participants 37(46.8%) were reported with >200 mg/dl of fasting blood sugar level, 8(10.1%) were reported with 140 to 200 mg/dl and 1(1.3%) was reported with 200 mg/dl, 6 had 140 to 200 mg/dl of postprandial blood sugar level and the data was represented in table no 40. Results showed that glycemic control was comparatively better in female patients than male patients among the study population.

Gender Vs PPBS at fourth follow up: Table no 41 describes that among the 60(75.9%) participants with postprandial blood sugar level >200 mg/dl 34(43%) were female and 26(32.9%) were male and among 19(24.1%) participants with 140 to 200 mg/dl 12(15.2%) were female and 7(8.9%) were male. Data showed that high postprandial sugar level was noted in female gender in larger proportion than male gender in the study sample.

Gender Vs PPBS at fifth follow up: In the study table no 42 explained that 33(41.8%) of female participants had postprandial sugar level >200 which is higher than the male participants which is 24(30.4%) and also 13(16.5%) female participants had postprandial blood sugar level in 140 to 200 mg/dl range which is also higher than male participants of 9(11.4%). Analysis of data revealed that female gender is more in hyperglycemia as well as glycemic control than male gender in the fifth follow up.

Gender Vs PPBS at sixth follow up: Out of 56(70.9%) participants with >200 mg/dl of postprandial blood sugar level 33(41.8%) are female and 23(29.1%) were male, only 1 female participant had reported with the postprandial blood sugar level between 120 to 140 mg/dl and 22(27.8%) are reported with 140-200 mg/dl of postprandial sugar level in which 12(15.2%) are female and 10(12.7%) were male participants. These data are represented in the table no 43. Results depicts that in the sixth follow up no significant difference among the study participant genders in postprandial blood sugar level were not found.

Gender Vs RBS at first follow up: From the table no 44 the data showed that among 46(58.2%) female participants 19(24.1%) had random blood sugar levels 180. in male gender (33 participants) 16(20.3%) had 16(20.3%) had <180mg/dl and 17(21.5%) had >180 mg/dl. Results reveal that female participants had high blood sugar levels than male participants among the study population.

Gender Vs RBS at second follow up: In the study out of 32(40.5%) participants with random blood sugar level 180 mg/dl, 30(38%) were female and 17(21.5%) were male. These data were represented in table no 45. Data showed that random blood sugar level <180 mg/dl was noted in both the genders in the same percentage at second

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follow up.

Gender Vs RBS at third follow up: Among 46(58.2%) female participants 21(26.6%) were reported with the random blood sugar level 180 mg/dl. Among 33(41.8%) male participants 15(19%) were reported with 180 and the data were represented in table no. 46. Results showed that more female participants are reporting hyperglycemia than the male participants.

Gender Vs RBS at fourth follow up: Table no 47 depicts that 22(27.8%) female participants showed random blood sugar levels of 180 mg/dl which was also higher than 14(17.7%) male participants. Results reveal that female genders are showing better glycemic control than male participants in the study.

Gender Vs RBS at fifth follow up: Out of 46(58.2%) female participants 24(30.4%) were reported with random blood sugar 180 mg/dl. Out of 33(41.8%) male participants, 19(24.1%) were reported with 180 mg/dl and these data are illustrated in table 48. Data showed that women gender had better glycemic control over male gender among the study population.

Gender Vs RBS at sixth follow up: From the table no 49 among 43(54.4%) participants with the random blood sugar level 180 mg/dl 22(27.8%) were female and 14(17.7%) were male participants. Data depicts that female participants are showing better random blood glucose level than male participants. Our results counters the observation shown form the study conducted by Choe SA. found that no difference between gender in diabetic control after 1 year treatment male (40.6%) and female (38.9%).

VI. CONCLUSION

Diabetes mellitus is a group of metabolic disorder characterized by hyperglycemia. It is the most commonly suffered disease in most of the population hence efficient maintenance of the blood sugar level is very much important in the patients. Our study was conducted to compare the effectiveness of metformin mono-therapy and combination therapy in Diabetes mellitus patients and we found out that diabetes mellitus was seen in all age categories but after 50 years of age its occurrence was increasing. We also found that prevalence of disease was more in female gender than the male gender and fluctuations in blood glucose levels have been seen in study duration and it was witnessed with the help of continuous follow up data of fasting, postprandial and random sugar values. In our study we were exposed that metformin is not familiarly used in monotherapy but as a combination metformin was captured a very important place in the prescriptions and Glimepiride with metformin was the drug combination commonly used in the antidiabetic combination therapy and also the most effective one. our study described that in endocrinology department most of the diabetic patients doesn't had comorbidities and few had hypertension Data rooted out that both monotherapy and combination therapy showed almost less than 70% improvement in the patient's glycemic control and there is not much difference among the monotherapy and the combination therapy efficacy. Our study analysis discovered that metformin usage was slightly less in the patient with comorbidities as monotherapy and also as in combination therapy. Follow up data pointed out that a good improvement was seen in the fasting glycemic control whereas no significant difference had been found in the postprandial and random blood sugar level. Comparative analysis of age with blood sugar values of six follow ups and the results showed that uncontrolled diabetes had been reported in all age categories at the same time good improvement had been seen in the above 50 years age category in fasting blood sugar, postprandial blood sugar and random blood sugar. Further analysis of our data to identify the correlation between the gender and blood sugar level revealed that female participants had better response for the drug therapy than male participants. As controlling the blood glucose level with an appropriate therapy one can prevent further complications which cause economic burden to the patients as well as challenging task for the for the physicians to treat. Hence, this study will also be helpful forus in improving the knowledge.

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