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ORGINAL REASEARCH

THE VITAMIN B12 IN TYPE 2DIABETES MELLITUS PATIENTS USING METFORMIN OR NOT ON METFORMIN-A CROSS SECTIONAL STUDY.

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ABSTRACT

Background. The vitamin b12 in type 2diabetes mellitus.Patients using metformin or not on metformin-a cross sectional study.

Methods: Data was collected from T2DM patients attending Department of General medicine of Sree Mookambika Institute of Medical Sciences,Kanyakumari, TamilNadu from march 2022 to September 2023 .data collected from 110 patients with type 2 diabetes mellitus on metformin and patients not on metformin(dose and duration) Age group (18to 80 years).

Results: The age group didn't shows significant p value. The Pearson chi square for age is 8.057,p=0.089.The sex also shows no significant p value(Pearson chi square=0.131,p=0.717) Mathew c pflipse et al,shows high prevalence of vitamin b12 deficiency among 22% of diabetes with metformin therapy.In our study also had almost same percentage of the metformin group patients affected.Ting et al, noticed that the metformin duration are main factors for Vitamin B12 deficiency .This is similar to our study and shows association between duration of metformin and with B12 levels.

Conclusion: In the study, metformin therapy for >2 years had shows significant vitamin B12 deficiency and less than 6 months has no significant vitamin B12 deficiency.

Keywords: Type 2 Diabetes Mellitus.

INTRODUCTION:

Metformin as a first-line oral treatment for hyperglycemia in diabetes is generally regarded as having few side effects.[1] However, since Berchtold et al first reported in 1969 that metformin could cause vitamin B12 deficiency by reducing vitamin B12 absorption in the gastrointestinal tract, such findings have been

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constantly published.[2] It has been reported that an average of 6% to 30% of patients could show vitamin B12 deficiency due to metformin use.[3,4]

In addition, some studies have reported that serum vitamin B12 levels were inversely related to the duration and dose of metformin use.[5–8] Since large prospective studies have clarified this relationship recently,[9,10] the 2017 American Diabetes Association treatment guidelines now recommend regular monitoring of vitamin B12 levels in patients with diabetes taking metformin.[11]

As metformin been prescribed worldwide and the duration of treatment period increases,the prevalence of the metformin induced vitamin b12 deficiency is also increased. Although clinical entity of vitamin b12 deficiency related to metformin is a debate one vitamin b12 monitoring is important In a patient with type 2 diabetic mellitus patients on metformin therapy.

OBJECTIVE

•To assess the vitaminB12 levels in type 2 diabetes mellitus patients on metformin and not on metformin.•To assess relationship between metformin therapy and development of vitamin B12 deficiency.

METERIALS AND METHEDOLOGY:

Data was collected from diabetic patients attending Department of General medicine of Sree Mookambika Institute of Medical Sciences,Kanyakumari, TamilNadu from march 2022 to September 2023 . All 110 patients were explained in detail about the procedure and informed consent was obtained.The inclusion criteria were All patients with type 2 diabetes mellitus on metformin and patients not on metformin(dose and duration) Age group (18to 80 years).Type-II DM who on metformin more than 6 months. Type-II DM who on metformin more than 2 year.Patients who are giving consent to participate in the study.The exclusion criteria Patients who or on irregular treatment. Anemia, pancytopenia, lactating mothers, All Patients of age group less than 18 andgreater than 80 years of age with diabetes mellitus .Patients not giving consent to .participate in the study. patients of gastritis.immune disorders, vegetarian diet, chronic ill nourished patients, Chronic alcohol. All diabetic patients will be selected for the study. A detailed case history of each patient with reference to Name, Age, Sex, Address, Contact number, OP number occupation ,Presenting complaints with duration,treatment history , associated comorbid illness, history of any drug intake forother conditions ,Any similar complaints in the family members ,will be recorded. General , Systemic examination and vitals will be Done and recorded. Blood investigations such as Complete Blood Count, FBS,PPBS, VITAMIN B12. After obtaining a Proper Informed Written Consent from the patient ,blood vitamin b12 was taken and sent to laboratory... All patients participating in the study will be given Appropriate treatment and follow up will be made.The collected data will be analysed using SPSS 20.0 trial version. Study parameter entered in the Microsoft office EXCEL 2019

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TABLE 1: DISTRIBUTION BASED ON AGE

			ON METFORMIN		Total
			No	Yes	
age group	30-40 Years	Count	10	1	11
		% within ON METFORMIN	13.2%	2.9%	10.0%
	41-50 Years	Count	25	10	35
		% within ON METFORMIN	32.9%	29.4%	31.8%
	51-60 Years	Count	20	16	36
		% within ON METFORMIN	26.3%	47.1%	32.7%
	61-70 Years	Count	8	5	13
		% within ON METFORMIN	10.5%	14.7%	11.8%
	Above 70 Years	Count	13	2	15
		% within ON METFORMIN	17.1%	5.9%	13.6%
Total			76	34	110
			100.0%	100.0%	100.0%

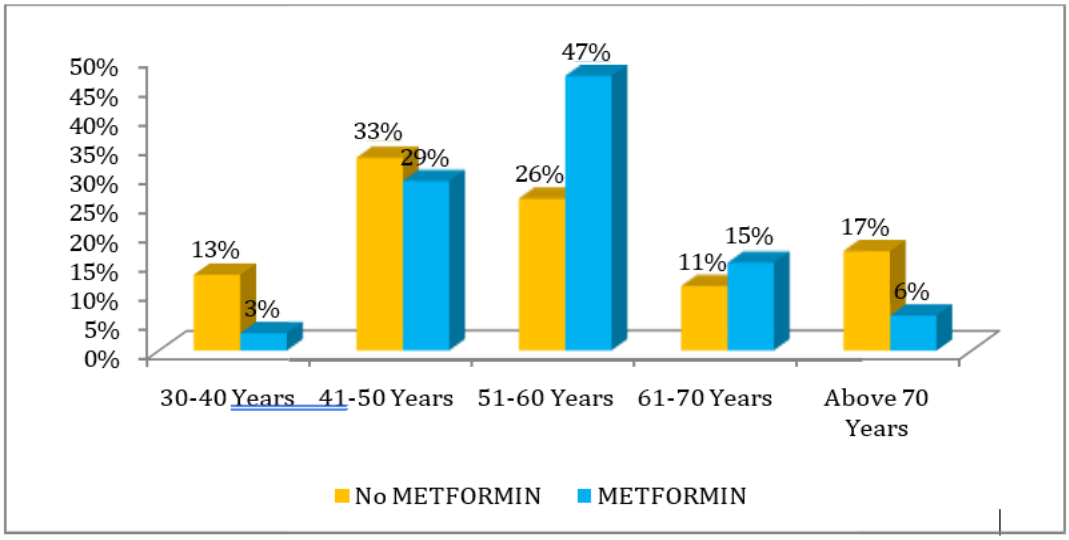

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TABLE 2: DISTRIBUTION BASED ON SEX

			ON METFORMIN		Total
			No	Ye s	
SEX	Male	Count	51	24	75
		% within ON METFORMIN	67.1%	70.6%	68.2%
	Female	Count	25	10	35
		% within ON METFORMIN	32.9%	29.4%	31.8%
Total		Count	76	34	110
		% within ON METFORMIN	100.0%	100.0%	100.0%

ChiSquare=0.131 p=0.717

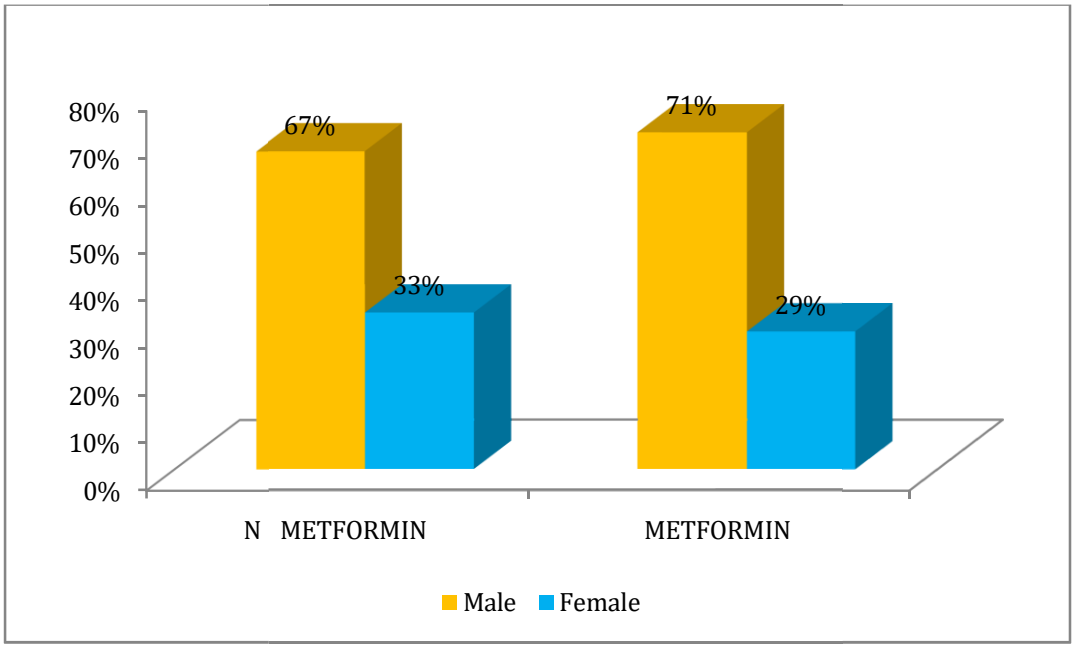

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TABLE 3: DISTRIBUTION BASED ON DURATION<6 MONTHS

Crosstab					
			ON METFORMIN		Total
			No	Yes	
DM <6mon	No	Count	66	2	90
		% within ON METFORMIN	86.8%	70.4%	81.8%
	Yes	Count	10	1	20
		% within ON METFORMIN	13.2%	29.6%	18.2%
Total		Count	76	3	110
		% within ON METFORMIN	100.0%	100.0%	100.0%

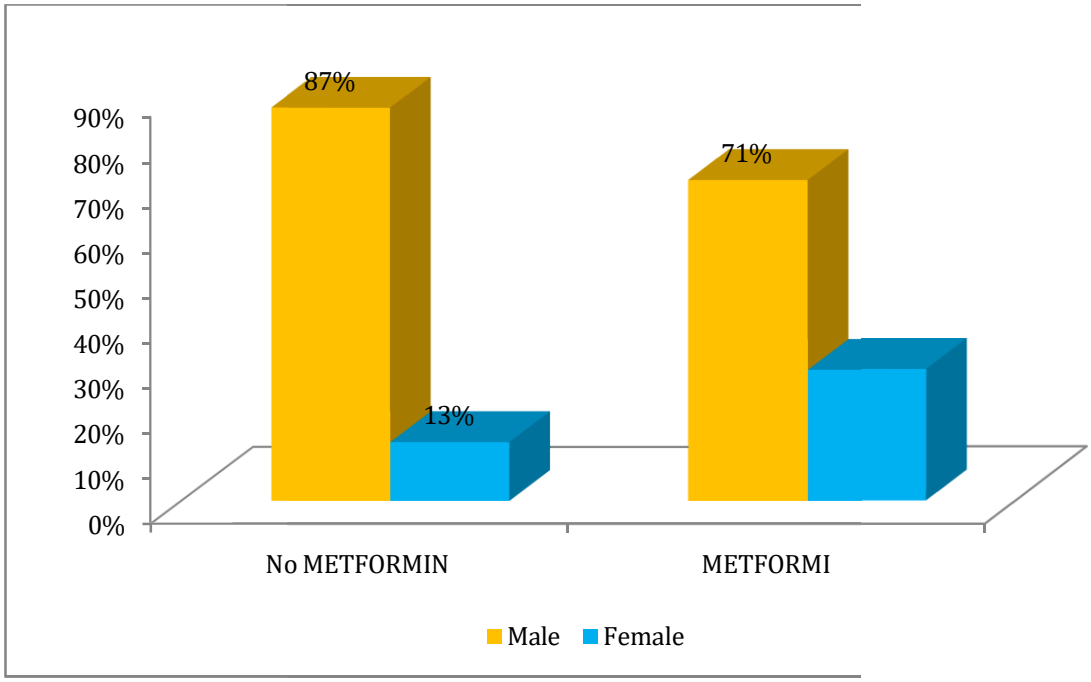

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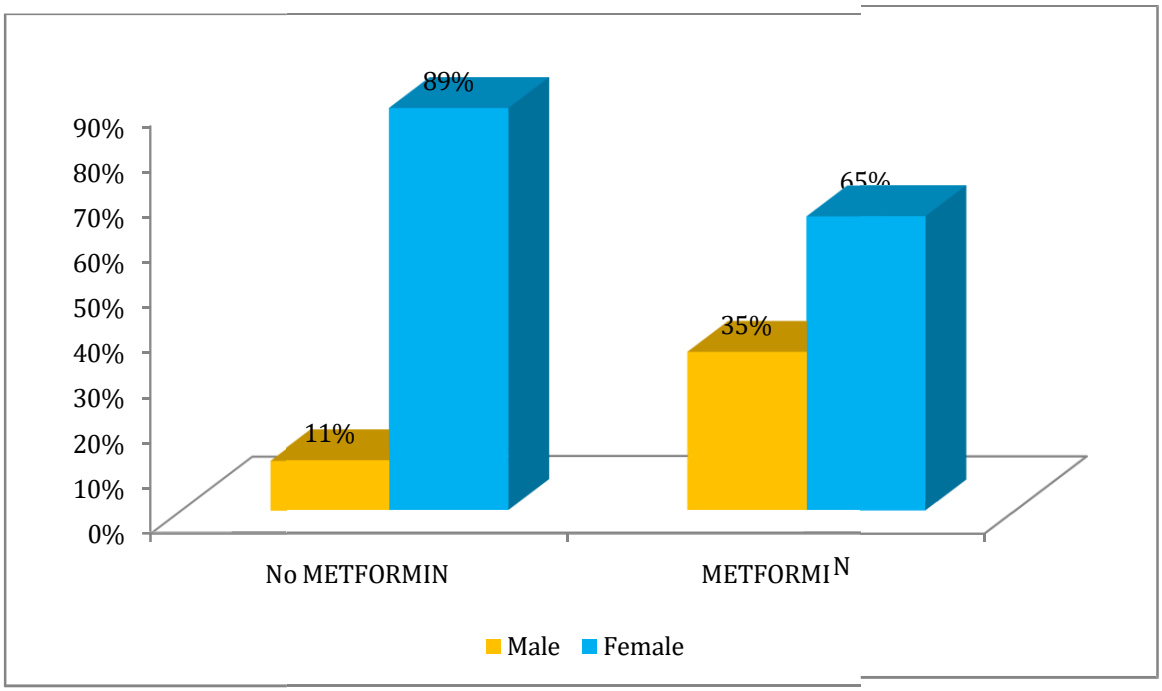
TABLE 4: DISTRIBUTION BASED ON DURATION >2YEARS

Crosstab					
			ON METFORMIN		Total
			No	Yes	
DM >2yr	No	Count	8	12	20
		% within ON METFORMIN	10.5%	35.3%	18.2%
	Yes	Count	68	22	90
		% within ON METFORMIN	89.5%	64.7%	81.8%
Total		Count	76	34	110
		% within ON METFORMIN	100.0%	100.0%	100.0%

Pearson Chi-Square=9.687** p=0.001



DISTRIBUTION BASED ON VITAMIN B12

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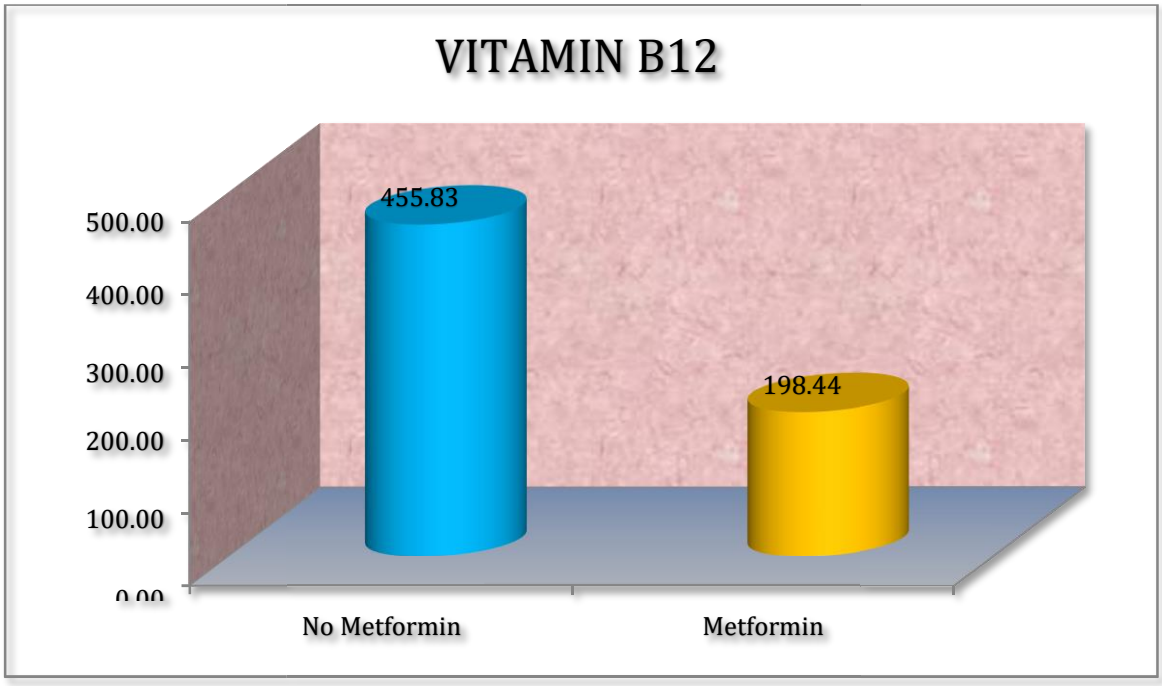
On metformin		N	Mean	SD	Std.error Mean	t value	p value
VIT B12	No	76	455.828	69.90	8.018	19.225	p<0.001
	Yes	34	198.441	51.71	8.868		



The mean vitamin B12 in metformin group is 198 and in non metformin group is 455.this shows vitamin B12 is moderately reduced in metformin group the p value is <0.001 and it shows significant between metformin and vitamin B12 deficiency.

DISCUSSION:

This is a single centre observational cross sectional study carried out in the Institute of Internal Medicine Sree mookambika institute of medical sciences between march 2022 to September 2023. 110 patients attending our out patient department with Type 2 Diabetic mellitus were selected based on the inclusion and exclusion criteria as mentioned above.

Our study had 110 patients,of which 75 male and 35 female.All the patients recruited under the inclusion criteria.The patients separated into metformin group with duration and non-metformin group and in metformin group they further separated to <6months and >2years duration.The age groups are 10% in 30-40 years,31% in 41-50 years,36% in51-60 years,11% in 61-70 years,10% in 71-80 years. Of 75 males 51 in metformin and 24 were not in metformin.Of 35 females 25 on metformin and 10 are not in metformin.Based on duration of metformin ,71% are in metformin,29% are not on metformin in <6 months,in >2 years 65% are in metformin and 35% are not on metformin.

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The age group didn't shows significant p value. The Pearson chi square for age is 8.057,p=0.089.The sex also shows no significant p value(Pearson chi square=0.131,p=0.717)

The mean value for total count for metformin is 4957,those on non metformin found to be 7373.7. The p values shows significant (p<0.001).

The mean MCV value in metformin group was 104.75 and not on metformin is 80.68.There is significant p value(<0.001) in between vitamin b12 and metformin group.

The p values calculated for finding the significance between the sex and vitamin b12 deficiency is not established. The number of males and females were not equal in our study .similarly based on age,patients are divided into subgroups and p value calculated and shows no significance.yet this may be differences among these populations in various other parameters like dosage calculation of metformin etc.

The p value calculated for the duration of diabetes is calculated and it shows significant p values for > 2 years(Pearson chi-square=9.687;p<0.001) and no significance for <6 months(Pearson chi square 4.172,p=0.041). The more the mean duration of metformin therapy shows more development of vitamin b12 deficiency.

The peripheral smears shows in metformin group 65%(22) had macrocytosis,15% microcytic normochromic,18% had normal,3% had microcytic hypochromic. The peripheral smear had shown significant p value.Those who are not on metformin 74% had normal,13% had microcytic hypochromic,12 had microcytic normochromic,1% had normocytic normochromic,the non metformin group shows No significant p values.

Similarly the correlation between LDH,FBS,PPBS,URIC ACID, TB, DB, SGOT, SGPT, ALP, CREATININE shows almost equal percentage distributions between the metformin based on duration and non metformin group. The above said values had shows no significant p values.

The national health and nutritional survey done in US from 1999-2006 had document vitamin b12 deficiency is more in patients on metformin than non metformin group. The biochemical vitamin b12 deficiency is high in metformin group,and it is well corellated in our study and we found significant relation with duration of metformin >2 years had more deficiency by significant p values.

Mathew c pflipse et al,shows high prevalence of vitamin b12 deficiency among 22% of diabetes with metformin therapy.In our study also had almost same percentage of the metformin group patients affected.

Ting et al, noticed that the metformin duration are main factors for Vitamin B12 deficiency .This is similar to our study and shows association between duration of metformin and with B12 levels.

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CONCLUSION:

In the study, metformin therapy for >2 years had shows significant vitamin B12 deficiency and less than 6 months has no significant vitamin B12 deficiency.

Vitamin B12 deficiency in metformin group is associated with macrocytosis and longer the duration of metformin therapy has significant deficiency status.The vitamin B12 is not much affected those who are not on metformin therapy.The serum vitamin B12 assay helps the patient on metformin therapy helps to asses the early vitamin B12 deficiency.

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