Original research article

Comparison of Efficacy and Safety of Metformin with Teneligliptin Versus Metformin with Glimepiride in Patients of Type 2 Diabetes Mellitus: A Open-Label Randomized Trial

Insha E Rab[1], Pramod Kumar Manjhi [1], Divendu Bhushan [2], Shruti Singh[3], Sunil Kumar Singh [4], Rajesh Kumar [5]

[1]Department of Pharmacology, All India Institute of Medical Sciences, Patna, Bihar, India.
[2] Department of General Medicine, All India Institute of Medical Sciences, Patna, Bihar, India.
[3] Department of Pharmacology, All India Institute of Medical Sciences, Patna, Bihar, India.
[4] Department of Pharmacology, All India Institute of Medical Sciences, Patna, Bihar, India.
[5]Department of Pharmacology, All India Institute of Medical Sciences, Patna, Bihar, India.

Corresponding Author: Dr. Pramod Kumar Manjhi

Abstract

Background: Teneligliptin, a new DPP4 inhibitor, was approved in India in 2019 and has been shown to improve blood glucose and lipid profile. The purpose of this study was to compare the efficacy and safety metformin with teneligliptin combination versus metformin with glimepiride which is the most common combination prescribed in diabetes. **Material and Method:** This was an interventional, open-label, randomized trial on T2DM patients presenting to the OPD of the general medicine department at AIIMS Patna**.** A total of 326 patients were enrolled with a 10% dropout rate then they were randomly assigned to one of two groups: Group A (163) received metformin (500 mg) with teneligliptin (20 mg), while Group B (163) received metformin (500 mg) with glimepiride (1 mg). Both combinations were once daily and were evaluated to improve glucose and lipids at regular intervals. ADRs of both groups were also recorded. **Result:** The comparison of blood glucose indices between the two groups was significant at the end of the six-month treatment period. HbA1c (p=0.02), FBG (p=0.02), and PPBG (p=0.03). When the group's lipid profiles were examined at the end of treatment, there was a significant difference seen in HDL (p=0.001), LDL (p=0.12), and TG (p=0.01). The common ADRs were nausea in both groups while gastritis and weight loss were most common in Group A and hypoglycemia and diarrhea were mostly seen in Group B**. Conclusion:** In this study, both combinations were well tolerated, but patients who received metformin and teneligliptin showed better control of their lipid profile and glycemic index. **Keywords:** Type2 Diabetes Mellitus(T2DM), efficacy, safety, Metformin with Teneligliptin, Metformin with Glimepiride..

Introduction

Type 2 DM (T2DM) is growing more common throughout the world, notably in Southeast Asia. There were 537 million individuals having diabetes in 2021 globally, with 88 million in Southeast Asia.[1] T2DM is caused by either insufficient insulin production from beta cells or insulin resistance.[2] Managing Diabetes Mellitus (DM) is not always effective and safe. Both

the effects of medical treatment and the consequences of the condition still have an impact on the patients The most annoying ADRs associated with the administration of antidiabetic medications are hypoglycemia, GIT upset, allergic reactions, etc. According to the American Diabetes Association (ADA), the management of T2DM starts with lifestyle modification, exercise if not controlled then oral-antidiabetic drugs.[3] Metformin is the first choice of drug as it prevents the micro and macrovascular complications of diabetes as well as it has a low impact on body weight, and does not raise the risk of fracture.[4] If metformin monotherapy fails to manage hyperglycemia, another oral antidiabetic drug with a different mechanism of action should be given.[3] Among the combinations of Anti-diabetic drugs clinicians usually prefer metformin with glimepiride because of its low cost although hypoglycemia and weight gain are the most common adverse effects of this combination.[5] Similarly, various other combinations are also available in the market having drawbacks like poor medication adherence, hypoglycemia, weight gain, and treatment refractoriness. Due to this, a search for new types of antihyperglycemic medications started, in which dipeptidyl peptidase (DPP)-4 inhibitors came into market. Teneligliptin is a novel DPP-4 inhibitor as it lower fasting and postprandial blood glucose levels by blocking the DPP-4 enzyme, which degrades GLP-1 (glucagon-like peptide1).[6] These drugs do not promote weight gain and hypoglycemia since DPP4 releases insulin in a glucose-dependent way.[7] It can be used in hepatic/ renal impairment due to its multiple pathways of elimination.[8] Additionally, its single daily dose increases compliance.

This study compared the efficacy and safety of two antidiabetic drug combinations metformin withglimepiride versus metformin with teneligliptin.

Novelty: The most frequently recommended T2DM medication combination is metformin and glimepiride; however, only a few trials have demonstrated that metformin and teneligliptin are superior on metformin and glimepiride. As a result, this research may contribute to what is previously known regarding the combination of metformin and teneligliptin.

MATERIAL AND METHODS

1.1 Study Participants and sample size calculation: T2DM patients aged 18-75 years who attended the general medicine OPD with uncontrolled blood glucose levels on metformin alone were included. Patients with a variety of comorbidities, pregnant and nursing women, and those who had not given consent were all barred from participating. The trial enrolled 326 patients in total, with 10% dropping out. Based on previously provided data, the sample size was estimated using mean with standard division at 95% CI and power were set at 80%. **Trial design**: Interventional, open-label randomized trial. Because of the lack of human interaction owing to the Covid 19 pandemic, this trial fails to get blinded. Randomization is done by chit technique.

Patient recruitment and trial completion: After taking informed consent 326 patients in total were included, who were divided into two groups: Group A (metformin 500 mg plus teneligliptin 20 mg) and Group B (metformin 500mg with glimepiride 1mg). In each group, 163 patients were enrolled, of which 62 patients were lost to follow-up. Following the loss to follow-up, the number of patients remaining in group A was 152, and group B was 149. Both combinations were administered once daily for six months, with patients being monitored at baseline, three and six months. The CONSORT flow diagram is presented in fig:1

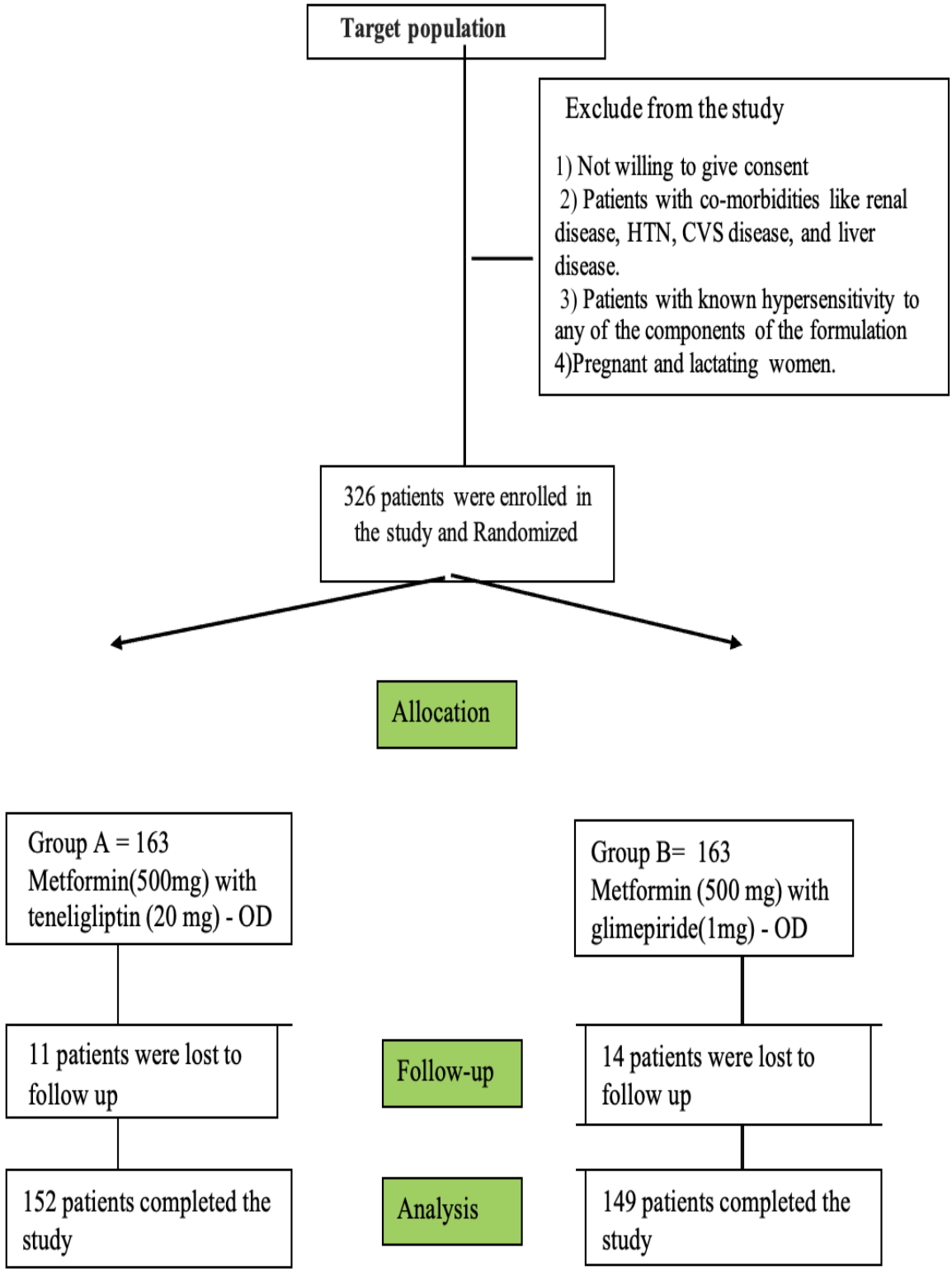

Figure: 1 CONSORT FLOW diagram

Primary and secondary objectives: The primary objective was to compare the efficacy and safety characteristics of the two combinations. The efficacy parameters were assessed by

measuring FBG, PPBG, and HbA1C, and the safety profile was determined by examining the lipid profile of the two combinations.

The secondary objective was to assess the adverse events that patients experienced while on medication **Data entry and Statistical analysis:** Data was gathered and entered into Microsoft Excel spreadsheet. SPSS software was used to import data from the excel sheet.The descriptive analysis was carried out by calculating the mean and standard deviation for quantitative variables, frequency, and proportion for categorical variables. The categorical outcome was compared between the study groups using the chi-square test. All quantitative variables were checked for assumptions that needed to perform before the conduction of the independent sample t-test and dependent sample t-test.

The normal distribution of quantitative data was checked through visual inspection of Q-Q plots. Boxplot was used to look for any significant outliers in the data. For normally distributed quantitative data, intra-group change in the mean values was compared using dependent sample t-test and repeated measure ANOVA while inter-group change was compared by independent sample t-test. The homogeneity of variance was tested using Levene's test. For all statistical evaluations, the significance level was taken at 95% ($p<0.05$ was taken to indicate statistical significance) and the power of the study was 80% for each time interval.

RESULT

Patient socio-demographic characteristics

In **Table 1**, the age distribution was summarized. The mean age of the patients in groups A and B was 50.72 and 50.47, respectively.

Table 1: Mean Age Differences Across Treatment Groups (N=301)

Variable	Groups	Mean± S. D	t- value	p-value
Age (yrs)	A (n= 152) B (n=149)	50.72± 5.5 50.47 ± 5.4	0.391	0.696

(Group A =Metformin with Teneligliptin, Group B =Metformin with Glimepiride)

Table 2 showed Patients' socioeconomic status, it was classified according to the modified Kuppuswamy Scale in which, out of 152 patients in group A, 28 belonged to class I (upper class), 60 to class II (upper middle class), 40 to class III (lower middle), 13 to class IV (upper-lower), and 11 to class V. (lower).

Similarly, out of the 149 patients in Group B, 18 were in class I, 59 were in class II, 55 were in class III, 11 were in class IV, and 6 were in class V. **Table 2** showed the dietary habits of patients which were divided into three categories: vegetarian, eggetarian, and non-vegetarian. In Group A, 31 patients were vegetarian, 38 were eggetarian, and 83 were nonvegetarian, whereas, in Group B, 31 patients were vegetarian, 40 were eggetarian, and 78 were nonvegetarian.

Table -2 showed the relationship between the presence and absence of family history in which out of 152 patients in Group A, 86 had a family history while 66 had none, and out of 149 patients in Group B, 77 had a family history while 72 had none. **Table -2** showed that

males had a higher prevalence of DM (53.48%) than females (46.30%)

Table 2: Distribution of patients based on Socio-demographic Profile (N=301)

Variables	Group A		Group B	Total (%)	chi-Square	p-value
	I	28				
Socio-economic	60		18	46(15.28%)	6.159	0.188
status	40					
	13		59	119(39.53%)		
	V	11				
			55	95(31.56%)		
			11	24(7.97%)		
			6	17(5.6%)		
Diet pattern	Vegetarian	31	31	62(20.59%)	0.177	0.915
	Eggetarian	38	40	78(24.91%)		
	Non-vegan	83	78	161(54.48%)		
	Yes	86				
Familyhistory	No	66	77	163(54.15%)	0.728	0.394
			72	138(45.84%)		
Gender	Male	81 (53.3%)	80 (53.70%)	161(53.48%)	0.005	0 .944
	Female	71(46.60%)	69(46.3%)	140(46.30%)		

(Group A =Metformin with Teneligliptin, Group B =Metformin with Glimepiride)

3.2 Efficacy outcome: In our study efficacy parameters were assessed by FBG, PPBG, and HbA1C.

Table -3 showed an inter and intragroup comparison of various glucose monitoring metrics. The baseline FBG levels in Groups A and B were 193.25±38.91 mg/dl and 192.22±38.49 mg/dl,
respectively. An independent-sample t-test was used to detect the significant differences in mean FBG levels between the two groups at different time points, and it was found to be non-significant at the baseline and the end of three months, but significant (p=0.02) at the end of six months. The baseline PPBG level of Group A and Group B were 310.06±56.84 and 307.86±58.84 respectively. An independent sample t-test was used to compare the mean PPBG levels in groups A and B at different time points. There was no significant difference in mean at the beginning and end of three months, but at the end of six months, the mele became significant (p=0.038).

Table 3: Inter and intra- group comparison of glucose parameters over a period of 24 weeks

Parameters	Follow-up	Group A	Group B	p-value
FBG	0 Day	193.25±38.91	192.22±38.49	0.817
	3 month	163.86±41.14	172.29±39.51	0.071
	6 month	146.41±42.04	157.39±40.36	0.022*
	P-value	0.00	0.00	
PPBG	0 Day	310.06±56.84	307.86±58.84	0.741
	3 month	271.28 ± 33.11	278.35±30.68	0.251
	6 month	247.42±29.13	260.55±25.20	0.038*
	p-value	0.01	0.00	
HbA1c	0 Day	10.22±1.10	10.20±1.13	0.827
	3 month	9.06±1.10	9.38±1.09	0.014*
	6 month	8.62±1.05	9.06±1.109	0.00*
	p-value	0.00	0.00	

(Group A =Metformin with Teneligliptin, Group B =Metformin with Glimepiride)

At baseline, an independent sample t-test was used to compare the mean HbA1c of Group A (10.22 1.10%) and Group B (10.20 1.13%); the difference was nonsignificant (p=0.827). At three months, the difference became significant (p=0.014), and at six months, the difference became extremely significant(p=0.00).

The intra- group comparison of various parameters at different time points was done by repeated measureANOVA which was found to be significant ($p<0.05$).

3.2 Safety outcome

The lipid profile was used to analyze the safety criteria in our investigation (HDL, LDL, and TG levels).

Table 4 depicts the inter and intra-group comparison of the lipid profiles of different groups during 24weeks.

At baseline, group A mean HDL was 33.49±4.8, while group B was 32.99±4.2. After six months, the HDL levels in groups A and B were 45.41±4.68 and 39.28±4.75 respectively. An independent sample t- test was conducted to determine the significant difference between the two groups, and it was discovered to be non-significant at the beginning (p=0.347) but significant after six months (p=0.001).

Table 4: Inter and intra-group comparison of lipid profile over a period of 24 weeks

Parameters	Follow -up	Group A	Group B	p-value

HDL	0 day	33.49±4.8	32.99±4.2	0.347
	24 Weeksp-value			
		45.41±4.68	39.28±4.75	0.001*
		0.00	0.00	
LDL	0 day	145.63±8.66	145.12±7.99	0.591
	24 weeksp-value			
		130.54±9.13	135.72±8.47	0.012*
		0.00	0.00	
TG	0 day	198.89±23.96	199.90±22.50	0.708
	24 weeksp-value			
		180.90±28.55	194.12±22.77	0.001*
		0.00	0.00	

(Group A =Metformin with Teneligliptin, Group B =Metformin with Glimepiride)

The mean LDL of groups A and B at baseline was 145.63±8.66 and 145.12±7.99, respectively. After six months, the mean LDL levels in groups A and B were 130.54±9.13 and 135.72±8.47, respectively. an independent sample t-test was done to see the significant difference between the two groups, and it was nonsignificant at the baseline (p=0.591), but after six months of treatment the difference in mean becamesignificant (p=0.012).

The mean TG before treatment began in groups A and B was 198.89±23.96 and 199.90±22.50, respectively. The mean TG of groups A and B at the end of treatment was 180.90±28.50 and 194.12±22.77, respectively. The comparison was made using an independent sample t-test, which was nonsignificant at the start (p=0.708) but significant at the end (p=0.001).

The intra-group comparison was done by dependent sample t-test, which was found to be significant in allthe parameters($p<0.05$)

3.2 Secondary outcome

The assessment of reported ADR between the two groups was done by a percentage. Apart from nausea in both groups, the most common ADR in group A was gastritis while in group B was hypoglycemia. The other most peculiar ADR in group A was weight loss while in group B was diarrhea. As shown in **Table 5.**

Table 5: ***Adverse Effects of Treatment Groups (Group A and Group B)***

	Group A	Group B	Percentage
Constipation	4	0	1.3
Diarrhea	0	2	0.6
Fatigue	3	1	1.3
Gastritis	6	4	3.3
Hypoglycemia	0	10	3.3
Metallic taste	1	2	0.9
Nausea	6	14	6.6
Pallor	0	3	1.3
Vomiting	2	0	0.6
Weight gain	0	6	1.9
Weight loss	2	0	0.6
Total	24	42	
NA	128	107	
Total	152	149	

DISCUSSION:

The mean age of patients in both groups was 50.72 and 50.47 respectively. A similar mean age of the participants was observed in a study conducted by Hans N et al.[9] and Nishanth et al.[10] were 51.03 and 52.66 respectively.

Males were found to have a higher prevalence of diabetes (53.48%) than females (46.03%) in this study. The gender distribution is consistent with the findings of the study conducted by Takashi Kadowaki et al.[11]

The current investigation found a greater incidence of T2DM in patients with a familial history (54%). Donny et al found a similar demographic frequency. [12] When socioeconomic status was compared, it was shown that most patients (39.53%) belonged to the upper-middle class. Skar et al[13] discovered a similar finding in their investigation. In our study, we observed that non-vegetarian patients (54%) have a higher chance of acquiring T2DM than vegetarians (46%), a comparable conclusion is seen in a systemic review and meta-analysis done in 2016 by Schwingshakl et al.[14] In our study efficacy parameters were assessed by FBG, PPBG, and HbA1C in Group A (metformin with teneligliptin) and Group B (metformin with glimepiride). The FBG levels in Groups A and B were 193.25±38.91 mg/dl and 192.22±38.49 mg/dl, respectively. The mean FBG exhibited a statistically significant reduction at 3 and 6 months of follow-up. The mean FBG. levels in Groups A and B decreased by 46.84 mg/dl and 34.86 mg/dl, respectively. A similar decrease in the mean FBG (45.3 mg/dl) level of metformin with teneligliptin combination had shown in the study conducted by Raghuveer et al.[15] and a similar result of fall in mean FBG (35.4 mg/dl) level with metformin with glimepiride combination had been observed by Hyesoon Kim et al.[16] This study found that PPBG in Group A decreased by 62.64 24.09 mg/dl, a similar result in a drop in mean PPBG (70.6 mg/dl) was found by Konru et al. [17] and Group B decreased by 47.30 mg/dl. Raghuveer et al. 15 reported a similar outcome of a decrease in mean PPBG at 78.46 mg/dl. After three months of treatment, HbA1c reductions in Group A and Group B were

1.16% and 0.81%, respectively, and after six months, HbA1c reductions in Group A and Group B were 1.60% and 1.13%, respectively. Nitika Hans. [9] and Kim et al. [7] both saw a reduction in HbA1c of 1.39% and 1.2% in their respective investigations. In our study safety parameters had been assessed by lipid profile (HDL, LDL, TG). After six months of treatment, the mean HDL in groups A and B increased by 11.92 mg/dl and 6.29 mg/dl, respectively.

A comparable increase in HDL (13.93 mg/dl) level was observed in group A in research conducted by Hans et al. [18] Nishanth et al.[10] discovered a 4 mg/dl increase in HDL in group B. The current study found that from baseline, LDL levels in groups A and B fell by 15.09 mg/dl and 9.39 mg/dl, respectively, while Nishanth et al .[10] found a nearly same decrease in LDL levels (17.58 mg/dl). After 24 weeks of treatment in the current trial, the TG levels in groups A and B decreased by 17.98 mg/dl and 5.77 mg/dl, respectively. Hans et al.[9]comparing metformin with teneligliptin and metformin with glimepiride showed a similar decline in TG levels (22.70 mg/dl). There were numerous ADRs discovered by both groups, the most common of which were a metallic taste, tiredness, and gastritis. The most unusual ADRs in Group A were nausea, constipation, and weight loss, while the most unusual ADRs in Group B were hypoglycemia and weight gain. Similar ADRs were seen in the study of Pravin Kumar et al.[18], Hans et al.[9], Gupta et al.[19], Konru et al.[17], and Mahapatra et al.[20]

LIMITATIONS OF THE STUDY

This study included diabetes patients without complications, the results for diabetic patients with complications may vary with the use of combination drugs. This study fails to get blinded, so, there is a risk of selection bias. Due to a limited study period and less sample size, chronic adverse effects were not ascertained. Because of all these results cannot be generalized

CONCLUSION:

The most popular medication combination for T2DM patients, metformin-glimepiride, effectively lowers glycemic indices. Teneligliptin is a novel DPP-4 inhibitor that is more effective than other drugs in the same family. In this experiment, glimepiride and teneligliptin were both well tolerated in combination with metformin, and those taking metformin-teneligliptin had better control over their lipid profiles and glycemic indices.

RECOMMENDATION: Based on the findings of this study, we can say that diabetic patients taking metformin plus teneligliptin can benefit out of its effective glucose control, reduced side effects, and improved lipid profile.

ETHICAL APPROVAL: This research was approved by IEC and IRC of AIIMS, Patna, having clearance number AIIMS/Pat/IEC/PGTh/Jan19/29. The trial was also registered on CTRI with the registry number CTRI/2020/04/024425

AUTHOR CONTRIBUTIONS.

Conceptualization: P.P.Gupta, Pramod Kumar Manjhi, Divendu Bhushan, Formal analysis: Pramod Kumar Manjhi, Shruti Singh, Sunil Kumar Singh, Rajesh Kumar Meena, Methodology: Pragya Kumar, Shamshad Ahmad,Writing –review & editing: Pramod Kumar Manjhi , Shruti Singh, Aakanksha Priya, Dharani Lenin.

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CONFLICT OF INTEREST: No any

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