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Combination of Topiramate and Empagliflozin is Considered a Good Option for the Treatment of Obesity

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Abstract

Introduction: The incidence of obesity has raised very much in the latest decades in which more than 30% of peoples are considered obese. It is evidenced that genetics has a great impact on obesity occurrence; all in all, the risk of getting obesity in the future is linked to many factors like sedentary lifestyle, type of diet. Aside from decreasing blood glucose, empagliflozin can lead to a reduction of weight due to the loss of calories by excretion of glucose. Research papers also discuss the weight reducing effect of topiramate and demonstrated that this effect is dependent on the dose of the drug and duration of treatment.

Materials and Methods: 4 groups of patients with obesity had been monitored in a private clinic, each group 50 patients' number, with 35 females and 15 males after written consent from all patients. The results show that both topiramate and empagliflozine have weight loss effect if used alone with significant p value which iss0.0480with topiramate and 0.0048 in empagliflozine and the greatest weight loss effect if used in combination with p value less than 0.0001.

Keywords: Obesity; Empagliflozine; Topiramine; Combination therapy; Overweight; Hypothalamus

Introduction

The incidence of obesity has raised very much in the latest decades in which more than 30% of peoples are considered obese [1]. Obesity is defined as exaggerated fat that is deposited abnormally in tissues and make health hazards, promoting adipose tissue dysfunction. Guidelines state that the normal body mass index is from 18.5 to 24.9,BMI from =25kg/m2 to 29.9kg/m2 is known to be overweight, BMI=30kg/m2 known to be obese. The body mass index (BMI) is a value extracted from (weight) and height of a person [2]. Obesity is considered a disease that is generated from many factors affecting energy balance, as input is more than the output, which is transformed into triglycerides making fat cells larger in size causing an increase in weight [3]. It is evidenced that genetics has a great impact on obesity occurrence; all in all, the risk of getting obesity in the future is linked to many factors like sedentary lifestyle, type of diet [4]. One of the most important factors determining obesity risk is genetics [5]. It's is now known that body mass index is hereditable in 25–40%. But there must be environmental factors with genetics for obesity to occur [6]. Researchers consider Basal metabolic rate (which is energy loss during rest) as a possible cause of obesity, as it is considered that obese persons have a low basal metabolic rate [5]. It is a great target to act to treat obesity and to decrease the occurrence of diseases related to obesity like cardiovascular diseases, type 2 diabetes, and fatty liver. and it is considered a priority of WHO to control obesity prevalence.

It is well known that obesity due to an imbalance between calories input and output [7]. And current obesity treatment based on decreasing calorie input and increasing calorie output which is unsuccessful in most cases [8]. Many research papers discussing obesity causes and ways of treatment, discussing the role of the brain in determining the desire for food, and the role of git, liver and fat cells hormones in appetite regulation by affecting the hypothalamus [9]. In fact, due to the nature of obesity which leads to impairment of homeostatic mechanisms leading to an inability to maintain a normal weight, obesity is considered as a chronic disease. And so, obesity cannot be managed by short term therapy [10]. Due to the complex nature and overlapping factors in obesity pathogenesis, treatment available now is non-compatible with most causes of obesity which result often by the interaction between the environmental factors and the person genetics [11]. Until this moment, the drugs approved by the FDA for treating obesity act to reduce appetite by affecting satiety centers like phentermine / topiramate and lorcaserin, and by decreasing fat absorption like orlistat. we must put in mind

that the efficiency of most of these drugs are 3-7% weight loss [12]. Now there are a group of new antidiabetic drugs known as sodium-glucose co transporter 2 inhibitors, which lead to reasonable control of blood glucose, and blood pressure and a great decrease in body weight. This group has an unparalleled feature in which it leads to a great decrease in visceral fat than subcutaneous fat [13].

Normally, the kidney can filter about 180g/day of glucose which occurs in the proximal convoluted tubule. SGLT2 is responsible for about 90% reabsorbed glucose [14]. Empagliflozin is the most selective sglt2 inhibitor, which leads to urinary glucose excretion depending on the dose, urinary glucose excretion may reach 90gram per day [15]. Empagliflozin is approved for managing adults with T2D [16]. Aside from decreasing blood glucose, empagliflozin can lead to a reduction of weight due to the loss of calories by excretion of glucose [17]. Empagliflozin inhibit urinary glucose reabsorption, in which 10mg of empagliflozin can prevent absorption of about 40% of glucose increasing with dose to 90g of glucose. With the use of empagliflozin in non-diabetic persons, no decrease in blood glucose level, because of the liver increase glucose production [15]. Empagliflozin is a well-tolerated drug but with an inconsiderable occurrence of genital infections, and no increase in frequency in urinary tract infections [18]. Topiramate is a drug used for the treatment of convulsions and migraine. topiramate is known to decrease appetite and so used off-label for obesity [19]. Topiramate is used for migraine by a dose of 100mg and by a dose up to 400mg for epilepsy and in combination with pheniramine for obesity by a dose from 23 to 90mg [20]. Topiramate is a drug that is detected in 1979 as an anticonvulsant with t half of about 30hours and leads to debates and disputes and is used for the treatment of obesity [21]. There are many types of research discussing the role of topiramate in the treatment of many diseases like binge eating disorder [22] and post-traumatic stress disorder [23]. Research papers also discuss the weight reducing effect of topiramate and demonstrated that this effect is dependent on the dose of the drug and duration of treatment [24]. Topiramate is a drug that is known to have anti impulsive behavior effect [25]. In one study topiramate given to mouse's led to a decrease in body fat and decreased food intake with the increasing metabolic rate [26], with decreasing lipoprotein lipase activity [27]. And in a clinical trial in patients with epilepsy taking topiramate, the patient's weights decrease in the early period of treatment with 2 to 5% decrease in weight, weight loss increase by 18months of treatment [28].

Materials and Methods

4 groups of patients with obesity had been monitored in a private clinic, each group 50 patients' number, with 35 females and 15 males after written consent from all patients. The ages of all patients were between 30 and 55 years. weights of all patients were between 90 to 160kg. All patients participating in this trial are asked to have a diet regimen all the time of the trial.

Inclusion criteria

a. Stable weight in the previous 6 months.

b. A sedentary lifestyle.

c. No history of diabetes mellitus.

d. Taking medication that affects appetite, or weight within the past 6 months

Exclusion criteria

1. Severe anemia
2. Hypothyroidism and hyperthyroidism
3. Diabetes mellitus
4. Moderate to severe liver or kidney disease
5. Body mass index less than 30

The first group patients received topiramate 25mg twice daily for 6moths, the second group received empagliflozin 10mg once daily, the third group patients received topiramate 25mg twice daily and empagliflozin 10mg once daily, the fourth group received placebo for 6months. During the period of treatment, we followed the patients and if there were side effects of the drugs used. No side effects were monitored during the period of treatment.

Results

Table 1: All Patients Data.

Table format Grouped		Group A		Group B		Group C		Group D	
	Topiramate		Empagliflozine		Both drugs		placebo		
		Before	After	Before	After	Before	After	Before	After
1	Title	90	79	89	74	88	67	90	89
2	Title	92	80	90	76	90	69	92	92
3	Title	93	75	92	78	91	70	93	90
4	Title	96	81	93	78	92	70	96	95
5	Title	98	85	94	79	94	71	90	89

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6	Title	100	81	96	81	95	72	92	93
7	Title	101	83	97	81	96	72	94	94
8	Title	103	78	98	83	97	74	96	95
9	Title	104	82	100	84	99	77	98	99
10	Title	105	86	102	86	100	78	100	102
11	Title	108	90	103	88	101	78	101	103
12	Title	109	94	104	89	102	79	103	102
13	Title	111	93	106	91	104	80	105	106
14	Title	112	88	108	93	105	81	107	108
15	Title	114	97	109	93	107	83	109	108
16	Title	115	99	110	96	108	83	111	110
17	Title	117	97	113	100	109	85	113	115
18	Title	118	100	114	100	111	85	115	116
19	Title	119	101	115	99	112	87	117	119
20	Title	120	98	117	102	114	88	119	120
21	Title	122	103	118	101	116	90	120	122
22	Title	123	108	119	104	117	94	122	121
23	Title	125	111	121	6	119	94	123	124
24	Title	126	109	122	106	121	96	125	126
25	Title	127	115	123	105	123	96	127	127
26	Title	129	113	124	107	125	98	129	126
27	Title	130	108	125	109	126	99	130	128
28	Title	131	110	127	110	128	100	131	130
29	Title	133	117	129	110	129	100	133	133
30	Title	135	120	130	116	130	102	135	136
31	Title	136	115	131	115	131	104	136	135
32	Title	137	106	132	117	132	103	137	139
33	Title	139	121	133	115	134	107	139	138
34	Title	140	115	136	120	135	105	140	140
35	Title	141	121	138	123	137	108	141	140
36	Title	142	119	139	121	138	108	142	138
37	Title	144	119	140	120	140	110	144	140
38	Title	146	123	141	125	141	110	146	144
39	Title	147	126	142	122	143	112	147	148
40	Title	149	119	143	125	144	113	149	149
41	Title	150	126	145	127	145	113	150	152
42	Title	153	124	147	127	146	116	153	153
43	Title	155	128	148	125	148	115	155	154
44	Title	156	127	152	130	149	119	156	157
45	Title	157	124	153	131	150	120	157	156
46	Title	159	128	156	129	152	120	158	156
47	Title	160	130	157	32	153	121	160	157
48	Title	161	131	159	135	156	123	161	160
49	Title	163	132	160	137	157	123	162	163
50	Title	165	136	163	136	160	125	162	160

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Table 2: Topiramate vs Placebo Shows that Topiramate has Considerable weight loss effect in comparison to Placebo with P Value 0.0480.

	Unpaired t test	
1	Table Analyzed	Data 1
2		
3	Column B	placebo
4	vs.	vs.
5	Column A	topiramate
6		
7	**Unpaired t test**	
8	P value	0.0480
9	P value summary	*
10	Significantly different (P < 0.05)?	Yes
11	One- or two-tailed P value?	Two-tailed
12	t, df	t=2.003, df=98
13		
14	**How big is the difference?**	
15	Mean of column A	117.6
16	Mean of column B	126.1
17	Difference between means (B - A) ± SEM	8.510 ± 4.249
18	95% confidence interval	0.07748 to 16.94
19	R squared (eta squared)	0.03932
20		
21	**F test to compare variances**	
22	F, DFn, Dfd	1.401, 49, 49
23	P value	0.2415
24	P value summary	ns
25	Significantly different (P < 0.05)?	No
26		
27	**Data analyzed**	
28	Sample size, column A	50
29	Sample size, column B	50

Table 3: Empagliflozine vs Placebo shows that Empagliflozine has considerable weight loss effect in comparison to Placebo with P value 0.0048.

	Unpaired t test	
1	Table Analyzed	Data 1
2		
3	Column B	empagliflozine
4	vs.	vs.
5	Column A	placebo
6		
7	**Unpaired t test**	
8	P value	0.0048
9	P value summary	**
10	Significantly different (P < 0.05)?	Yes
11	One- or two-tailed P value?	Two-tailed
12	t, df	t=2.888, df=98
13		
14	**How big is the difference?**	
15	Mean of column A	126.1
16	Mean of column B	113.4
17	Difference between means (B - A) ± SEM	-12.69 ± 4.394
18	95% confidence interval	-21.41 to -3.970
19	R squared (eta squared)	0.07843
20		
21	**F test to compare variances**	
22	F, DFn, Dfd	1.201, 49, 49
23	P value	0.5237
24	P value summary	ns
25	Significantly different (P < 0.05)?	No
26		
27	**Data analyzed**	
28	Sample size, column A	50
29	Sample size, column B	50

Group 2 of Patients on Empagliflozine vs Placebo

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Table 4: All Patients vs Placebo shows that Empagliflozine+Topiramate have the Greatest weight loss effect in comparison to Placebo with P Value less than 0.0001.

	Unpaired t test	
1	Table Analyzed	Data 1
2		
3	Column B	empa + topiramate
4	vs.	vs.
5	Column A	placebo
6		
7	**Unpaired t test**	
8	P value	<0.0001
9	P value summary	****
10	Significantly different (P < 0.05)?	Yes
11	One- or two-tailed P value?	Two-tailed
12	t, df	t=4.244, df=98
13		
14	**How big is the difference?**	
15	Mean of column A	126.1
16	Mean of column B	108.1
17	Difference between means (B - A) ± SEM	-17.96 ± 4.232
18	95% confidence interval	-26.36 to -9.562
19	R squared (eta squared)	0.1553
20		
21	**F test to compare variances**	
22	F, DFn, Dfd	1.429, 49, 49
23	P value	0.2152
24	P value summary	ns
25	Significantly different (P < 0.05)?	No
26		
27	**Data analyzed**	
28	Sample size, column A	50
29	Sample size, column B	50

Group 3 vs Placebo

We compared each group with the placebo group after 6 months of treatment. For analysis of data, we used the unpaired T-test [Table 1-4]. The results show that both topiramate and empagliflozine have weight loss effect if used alone with significant p value which iss0.0480with topiramate and 0.0048 in empagliflozine and the greatest weight loss effect if used in combination with p value less than 0.0001 [Figures 1-11].

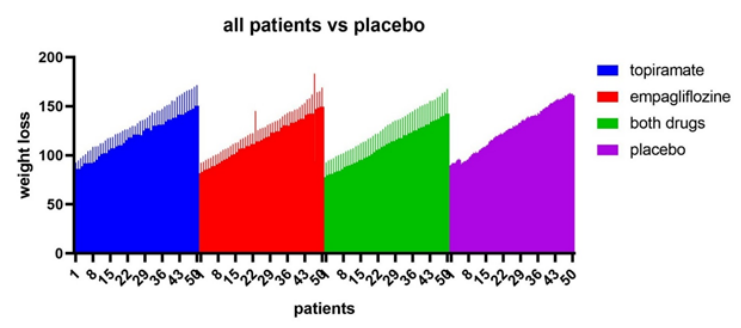

Figure 1: All Patients vs Placebo shows that Empagliflozine +Topiramate have the Greatest weight loss effect.

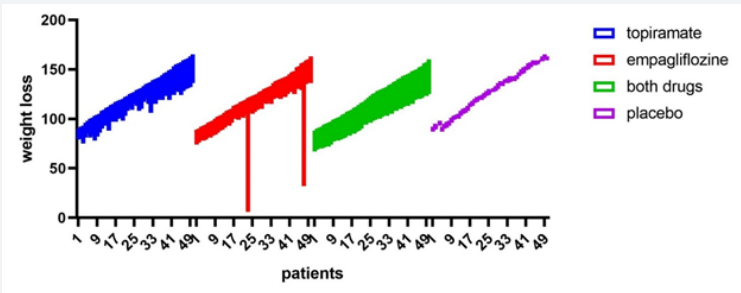

Figure 2: All Patients vs Placebo shows that Empagliflozine +Topiramate have the Greatest weight loss effect.

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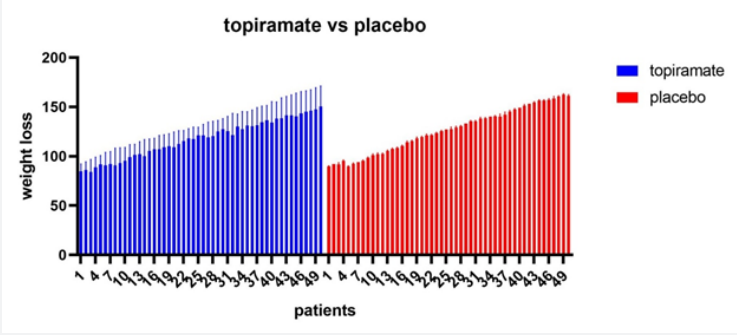


Figure 3: Topiramate vs Placebo shows that Topiramate has Considerable weight loss effect in Comparison to Placebo with P value 0.0480.

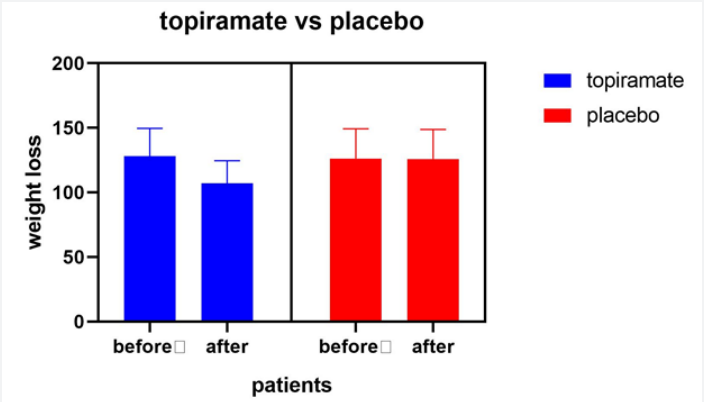


Figure 4: Topiramate vs Placebo shows that Topiramate has Considerable weight loss effect in Comparison to Placebo with P value0.0480.

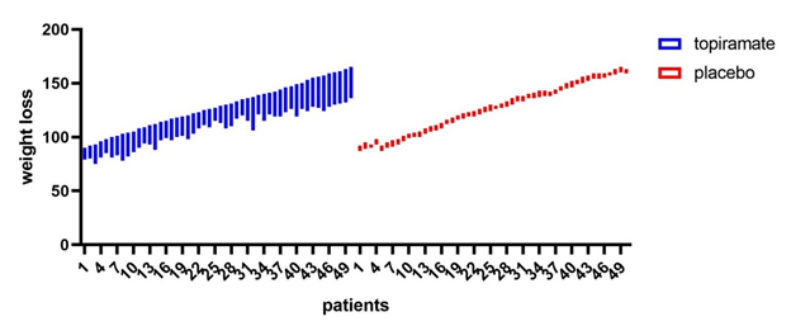
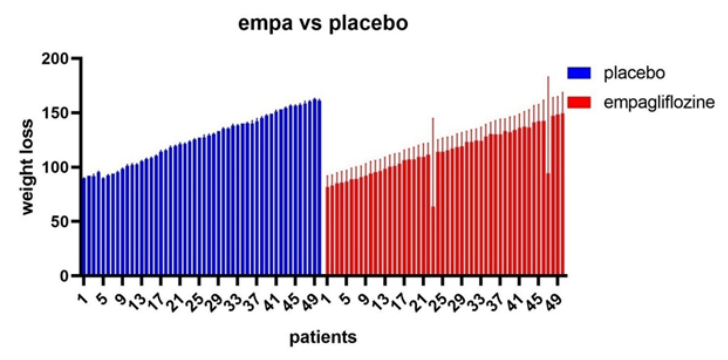


Figure 5: Topiramate vs Placebo shows that Topiramate has Considerable weight loss effect in Comparison to Placebo with P Value0.0480.



Empagliflozine vs Placebo

Figure 6: Empagliflozine vs Placebo Shows that Empagliflozine has Considerable weight loss effect in Comparison to Placebo.

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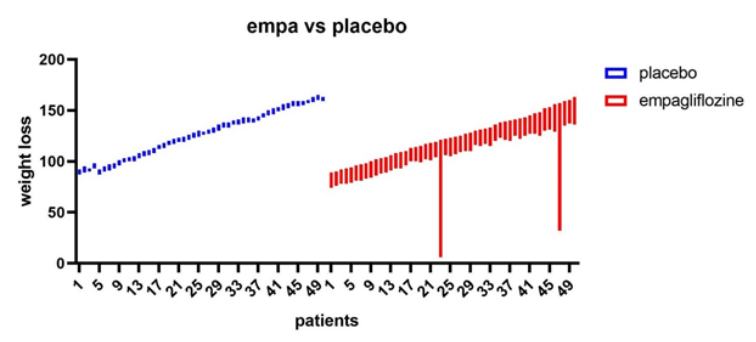

Figure 7: Empagliflozine vs Placebo Shows that Empagliflozine has Considerable weight loss effect in Comparison to Placebo.

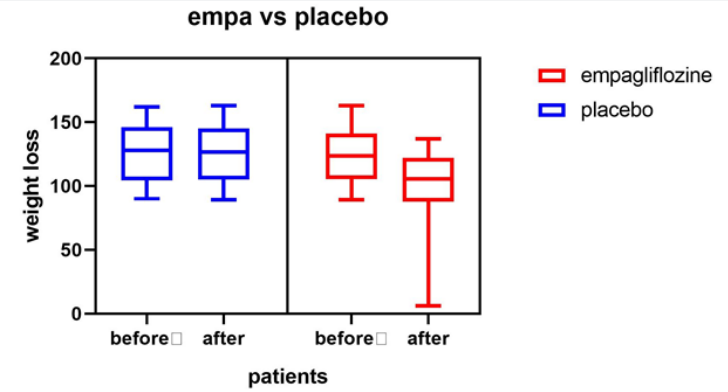

Figure 8: Empagliflozine vs Placebo shows that Empagliflozine has Considerable weight loss effect in Comparison to Placebo.

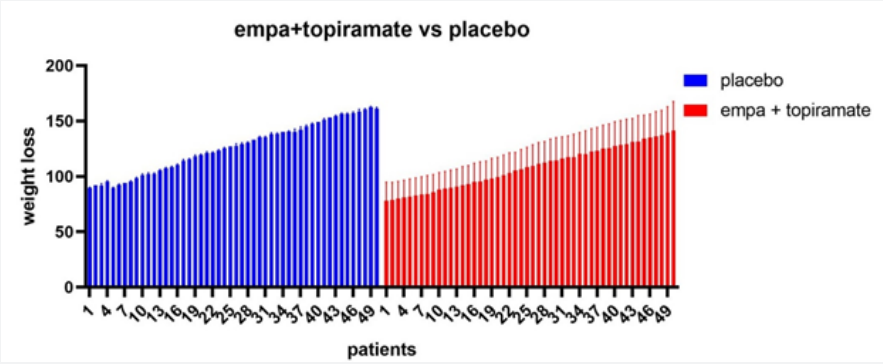

Figure 9: All Patients vs Placebo shows that Empagliflozine +Topiramate E have the Greatest weight loss effect in Comparison to Placebo.

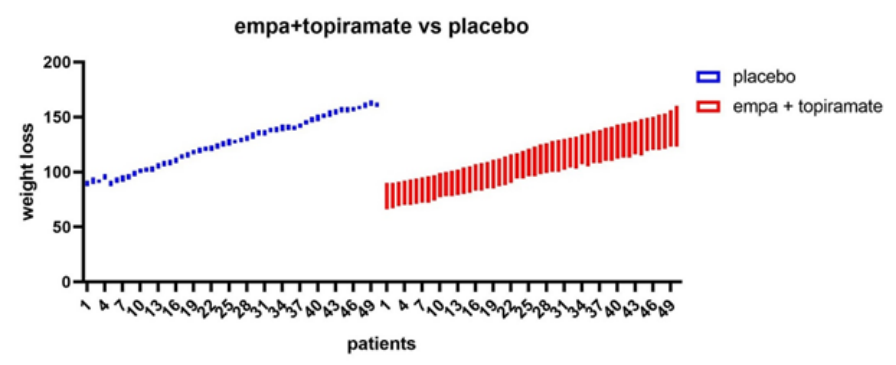

Figure 10: All Patients Vs Placebo shows that Empagliflozine +Topiramate have the Greatest weight loss effect in Comparison to Placebo.

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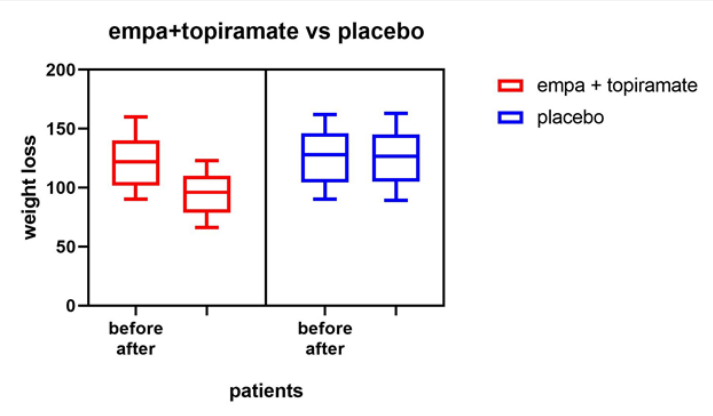

Figure 11: All Patients Vs Placebo Shows that Empagliflozine +Topiramate have the Greatest weight loss effect in Comparison to Placebo.

Discussion

There is a great risk of developing diseases and early mortality in patients with obesity, also obesity has a bad effect on the quality of life, by affecting mental and physical health [29]. Wide use of 'Western diet' with high energy all over the world explains the high prevalence of obesity worldwide, not only diet is the culprit also there is a great rule for genetic and epigenetic factors for the occurrence of weight gain [30]. The occurrence of obesity and changes in body weight could be caused by genetic factors, environmental factors or interaction between the 2 factors. also, diet in pregnancy has a considerable effect on DNA methylation that impacts its effect for a long time and inherited by upcoming generations [31]. As obesity prevalence increases very much in the last years all over the world and increased health problems related to it, itis a must to develop new ways for the treatment of obesity [32]. Empagliflozin which is the most selective sglt2 inhibitor when compared with placebo leads to great bodyweight reduction with decreasing visceral fat in patients with obesity [33]. Topiramate is a drug which is approved for use in the treatment of epilepsy and migraine, it had a considerable effect on decreasing body weight by reducing calorie input and change in taste [34].And by comparing topiramate with placebo, there were considerable improvement in blood pressure and in lipid profile with an increase in HDL and a decrease in triglyceride levels [35]. In my trial, combination of topiramate and empagliflozine results in considerable decrease in weight compared to each drug alone and compared to placebo.

The restriction of my study is the few patients sample size. While the inclusion of a small number of patients limits and restricts the extrapolation of our findings to the general population, obesity is a serious health problem, and my study aims to find a new treatment option for obesity. My findings in this study indicate that combination of topiramate and empagliflozine is a potential treatment for obesity by decreasing body weight, visceral obesity and improving lipid profile. Further large-scale studies and clinical trials are required to confirm our results.

Conflicts of Interest

There is no conflict of interest to declare.

Conclusion

As obesity prevalence increases very much worldwide, there is an urgent need to discover a new treatment option for diabetes to control this epidemic. Now, there are many approved drugs for obesity, but maximal body weight reduction is about 5%. Combination of drugs is considered as an optimal option for the treatment of diabetes. Combination of topiramate and empagliflozin show a considerable reduction of body weight and so is considered as an option for treatment of obesity.

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