A PROJECT REPORT ON

TRANSFORMING WEIGHT LOSS: SEMAGLUTIDE'S MARKET POTENTIAL

AND

ROLE IN OBESITY MANAGEMENT

PREPARED BY

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MBA- PHARMACEUTICAL MANAGEMENT

IIHMR-UNIVERSITY, JAIPUR.

UNDER THE SUPERVISION AND GUIDANCE OF

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CEO AT BLUE BERRY PHARMA ADVISORY

2024

Blue Berry Pharma Advisory

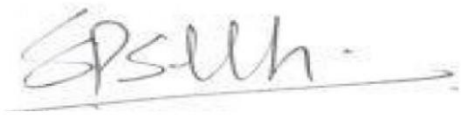
1st July 2024

TO WHOMSOEVER IT MAY CONCERN

This is to certify that MR. YASH GOYAL student of MBA PHARMACEUTICAL MANAGEMENT AT IIHMR, JAIPUR has undergone summer internship project from 1ST April-3oth June 2024

The candidate has successfully carried out the study designated during dissertation and his approach to the study has been good.

I wish him all the success in his future endeavor.



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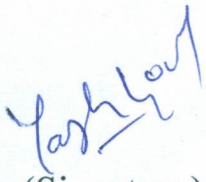
DECLARATION BY STUDENT

I hereby declare that this dissertation titled TRANSFORMING WEIGHT LOSS: SEMAGLUTIDE'S MARKET POTENTIAL AND ROLE IN OBESITY MANAGEMENT is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.



(Signature)

Yash Goyal

05/July/2024

IIHMR UNIVERSITY

CERTIFICATE

This is to certify that dissertation titled **TRANSFORMING WEIGHT LOSS : SEMAGLUTIDE'S MARKET POTENTIAL AND ROLE IN OBESITY MANAGEMENT** is a record of the research work undertaken by **YASH GOYAL** in partial fulfilment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

DR. ASHOK PEEPLIWAL
Faculty Guide
IIHMR University, Jaipur

Date 05/07/2024

DR. MANTHAN D. JANODIA
School Dean
IIHMR University, Jaipur

Date 05/07/2024

EXECUTIVE SUMMARY

The obesity is global health crisis with significant health and economic consequences. Both WHO and AMA recognise obesity as a serious disease in worldwide. Traditional method for weight loss yields less or limited result. A semaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist, has emerging as promising new treatment option for the weight loss / weight management.

This project investigates the market size of obesity and market potential of semaglutide for weight loss. It analyses factors such as patient population size, patient demographic, current treatment landscape, FDA approve drugs for obesity and competitor landscape.

The project explores the effectiveness of semaglutide in promoting weight loss. It examines the clinical data on weight loss efficacy, safety profile, potential improvements in obesity-related health conditions and although weight regain after withdrawing of semaglutide.

Key findings of the study are:

- Semaglutide demonstrated the significant effect on weight loss in comparision of placebo in clinical trials.
- The market of obesity is significantly growing than expected, so that the market of semaglutide also rapidly growing.
- Semaglutide have additional benefits to the obesity patient those are suffering from diabetes.
- Semaglutide may improve cardio metabolic risk factors associated with obesity.

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Abbreviations

BMI	Body Mass Index
PAHO	Region of ways the Americas
EURO	European region
EMRO	Eastern Mediterranean region
WPRO	Western Pacific region
AFRO	African region
SEARO	South-East Asia region
FDA	Food and Drug Administration
GLP-1	Glucagon Like Peptide-1
DPP-4	Dipeptidyl-Peptidase 4
CI	Confidential Interval
LDL	Low-Density Lipoproteins
HDL	High-Density Lipoproteins

Obesity?

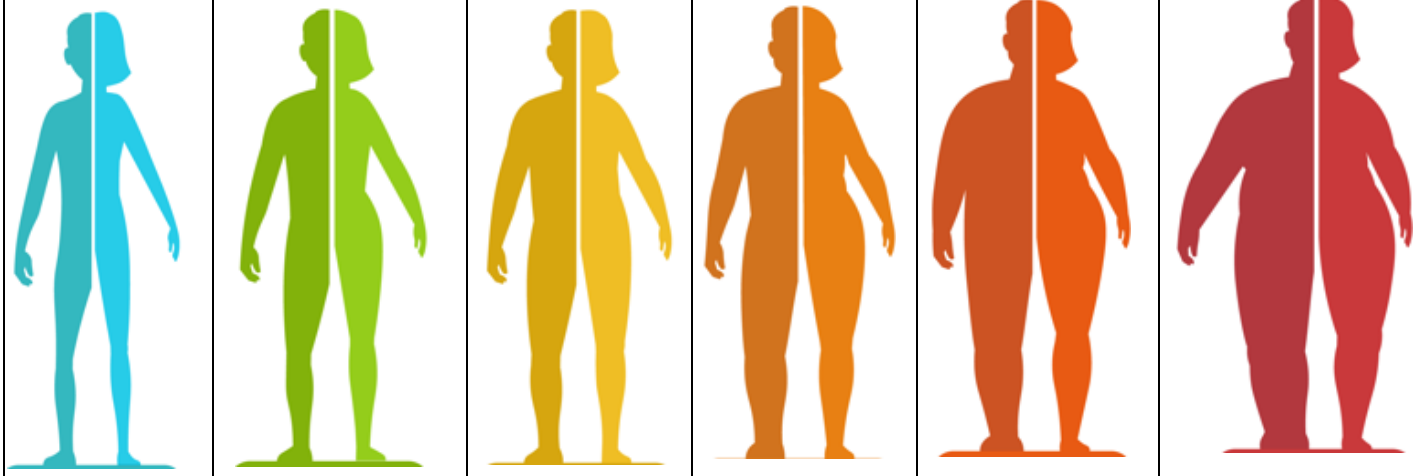
The body's excessive fat buildup and distribution have an impact on metabolic risk.

There are two types of body fat display, depending on where in the body the fat accumulates:

Gynecoid or pear-shape	Fat stored in the thighs and hips of the lower body	Peripheral is a chronic illness that primarily affects women.
Android or apple-shape	Fat stored in the abdomen or visceral areas of the upper body	Central obesity is regarded as the most dangerous type of distribution of body fat.

How to KNOW you are Obese?

We can know that we are obese by calculating BMI

Under Weight	Normal weight	Over Weight	Obesity (class I)	Obesity (class II)	Obesity (class III)
					
<18.5	18.5 - 24.5	25 – 29.9	30 – 34.9	35 – 39.9	>40

$$BMI = \frac{\text{Weight in kilogram}}{\left(\text{Height in meter}\right)^2}$$

Different kinds of obesity (Global)–

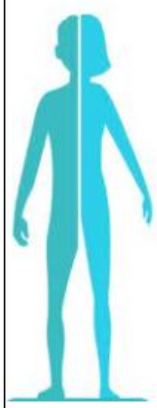
Based on Fat Distribution:

Gynecoid or pear-shape	Fat stored in the thighs and hips of the lower body	Peripheral is a chronic illness that primarily affects women.
Android or apple-shape	Fat stored in the abdomen or visceral areas of the upper body	Central obesity is regarded as the most dangerous type of distribution of body fat.

Based on Diseases:

Type 1 Obesity	Caused by a diet that is heavy in calories and low in physical activity.
Type 2 Obesity	Brought on by illnesses like hypothyroidism, insulinoma, Cushing's syndrome, and polycystic ovarian syndrome.

Based on BMI:

Under Weight	Normal weight	Over Weight	Obesity (class I)	Obesity (class II)	Obesity (class III)
					
<18.5	18.5 - 24.5	25 – 29.9	30 – 34.9	35 – 39.9	>40

Based on Fat Cells:

Hypertrophic Obesity	A typical adult increase in fat cell size.
Hyperplastic Obesity	An increase in fat cells, usually in young people.

Different of segmentation of obesity market (Global).

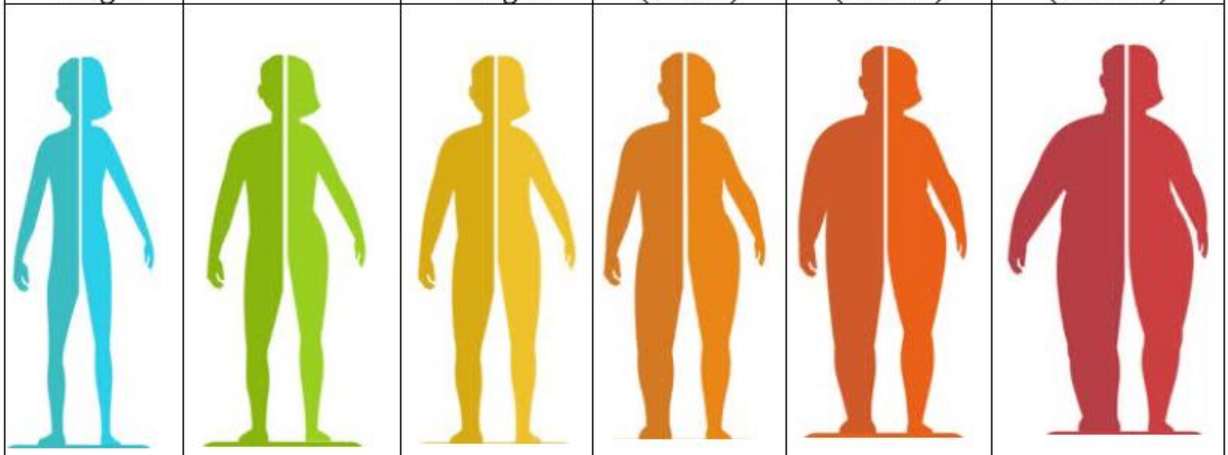
Regions wise

Regions	Adults with overweight (millions)	Adults with obesity (millions)	Prevalence of overweight and obesity (high BMI)
PAHO	245.4	292.55	71%
EURO	255.11	212.73	66%
EMRO	123.25	133.68	54%
WPRO	449.3	160.25	41%
AFRO	143.51	94.72	39%
SEARO	305.86	110.28	30%

Income groups wise (Global)

Income Group	Adults with overweight (millions)	Adults with obesity (millions)	Prevalence of overweight and obesity
Low	57.76	41.23	29%
Lower-Middle	479.29	254.82	36%
Upper-Middle	669.3	392.2	51%
High	316.07	312.85	64%

BMI wise

Under Weight	Normal weight	Over Weight	Obesity (class I)	Obesity (class II)	Obesity (class III)
					
<18.5	18.5 - 24.5	25 – 29.9	30 – 34.9	35 – 39.9	>40

According to adult men and women wise

	men with high BMI		women with high BMI
Tonga	80%	**Tonga**	87%
Samoa	79%	**Samoa**	86%
United States	79%	**Kuwait**	79%
Malta	78%	**Jordan**	78%
Kuwait	77%	**Saudi Arabia**	78%
New Zealand	76%	**Qatar**	77%
Australia	76%	**Türkiye**	76%
Israel	76%	**Libya**	75%
Qatar	76%	**Lebanon**	75%
Canada	76%	**Oman**	74%
Saudi Arabia	75%	**United Arab Emirates**	74%
Spain	74%	**Egypt**	74%
United Kingdom	74%	**Bahamas**	73%
Jordan	74%	**Fiji**	73%
Czechia	74%	**Iraq**	73%
Greece	74%	**Algeria**	73%
Bulgaria	73%	**Tunisia**	72%
Lebanon	73%	**Bahrain**	72%
Iceland	73%	**Iran**	72%
Montenegro	73%	**Mexico**	71%

According to Age wise

Age	Prevalence rate of obesity
0-5	5%
5-9	22%
9-11	15%
11-15	16%
15-18	23%
18-84	24%

According to Prevalence of child and adult obesity

	Prevalence rate in world
Child	24%
Adult	22%

What drugs are approved for weight loss?

The U.S. Food and Drug Administration (FDA) has approved six medications for weight loss for long-term use:

MKT. Status	Application No.	Drugs	Proprietary Name	Dosage form	Strength	**Applicant Holder**	**Patent No.**	**Patent Expiration**
Rx	N200063	Bupropion-Naltrexone	Contrave	Tablet, Extended Release; Oral	90mg; 8mg	Nalpropion Pharmaceuticals Inc	7375111	Mar/26/2025
Rx	N022341	Liraglutide Recombinant	Victoza	Solution; Subcutaneous	18mg/3ml (6mg/Ml)	Novo Nordisk Inc	7762994	May/23/2024
			Saxenda					
Rx	N020766	Orlistat	Xenical	Capsule; Oral	120mg	Cheplapharm Arzneimittel Gmbh	5447953	Jun/14/2013
OTC	N021887		Alli		60mg	Haleon Us Holdings Inc		
Rx	N022580	Phentermine Hydrochloride; Topiramate	Qsymia	Capsule, Extended Release; Oral	Eq 15mg Base;92mg	Vivus Inc	8895058	Jun/09/2028
					Eq 11.25mg Base;69mg			
					Eq 7.5mg Base;46mg			
					Eq 3.75mg Base;23mg			
Rx	N215256	Semaglutide	Wegovy	Solution; Subcutaneous	0.25mg/0.5ml	Novo Nordisk Inc	7762994	Mar/20/2026
					0.5mg/0.5ml			
					1mg/0.5ml			
					1.7mg/0.75ml			
					2.4mg/0.75ml			
Rx	N213793	Setmelanotide Acetate	Imcivree	Solution; Subcutaneous	Eq 10mg Base/Ml	Rhythm Pharmaceuticals Inc	9458195	Nov/25/2025

Brands of semaglutide?

There are three brands of semaglutide are:

Ozempic (injection, prefilled, single-dose pen) for Diabetes.

- 2 mg/1.5 mL (1.34 mg/mL); provides injections of 0.25 mg or 0.5 mg.
- 4 mg/3 mL (1.34 mg/mL); provides 1 mg shot.
- 8 mg/3 mL (2.68 mg/mL); provides 2 mg shot by shot.

Wegovy (Injection, Prefilled, Single-Dose Pen) for Obesity.

- 0.25mg/0.5ml
- 0.5mg/0.5ml
- 1mg/0.5ml
- 1.7mg/0.75ml
- 2.4mg/0.75ml

Rybelsus (Oral Tablet) for Obesity.

- 3mg
- 7mg
- 14mg

What is semaglutide?

Semaglutide is a GLP-1 antagonist that work by decreases glucagon release, delays stomach emptying, increases insulin release, and decreases appetite.

Wegovy is only one of the brand of semaglutide which is approved by FDA.

Dosage form is injection which is prescribes as ones in a week

Semaglutide injection is in a class of medications called incretin mimetic.

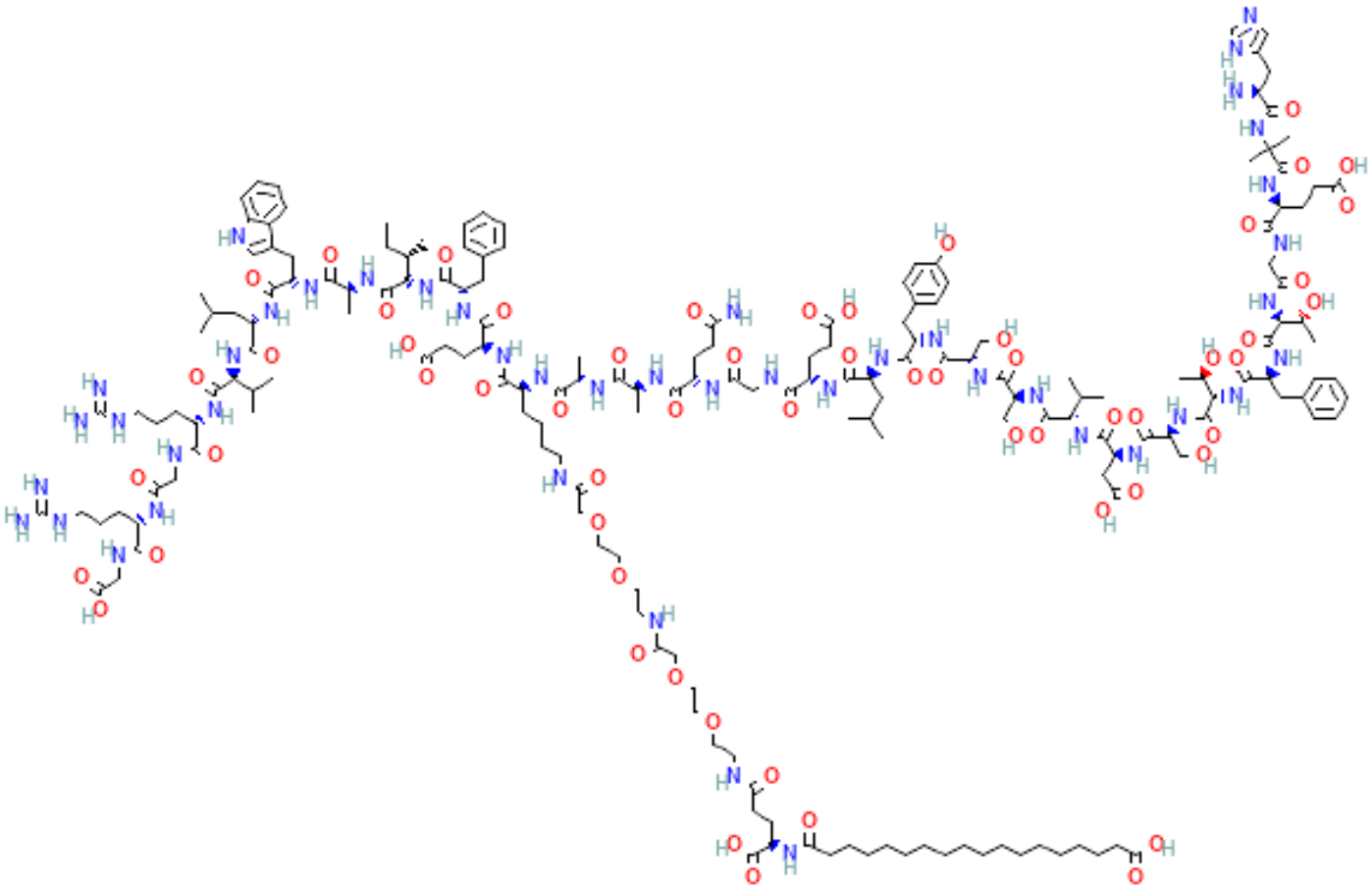


Fig. 0.1 The molecular formula is $C_{187}H_{291}N_{45}O_{59}$ and the molecular weight is 4113.58 g/mol.

The prevalence rate of obesity in India is about 22% and launching price in india is ₹7800/- for a four-week supply according to Bloomberg report. India's 32% of population belong to higher and upper-middle income groups. So total market size of semaglutide/month is about 7,91,4Cr.

We launch our brand is **GO-FAT.**

Introduction of Other drugs for obesity

Weight Management Medication	**Orlistat**
Approved For	Adults and kids (≥12)
How It Works	Reduce the absorption quantity of fat from meal.
Common Side Effects	· Diarrhea
	· Gas
	· Stomach pain
Warnings	· Do not combine with cyclosporine.
	· Multivitamin supplement every day.

Weight Management Medication	**Phentermine-topiramate**
Approved For	Adults and kids (≥12)
How It Works	Reduce Hunger
Common Side Effects	· Constipation
	· Dizziness
	· Dry mouth
Warnings	· Experienced a heart attack, stroke, irregular heart rhythm, kidney illness, or mood disorders.

Weight Management Medication	**Naltrexone-bupropion**
Approved For	Adults
How It Works	Reduce Hunger
Common Side Effects	· Constipation
	· Dizziness
	· Dry mouth
Warnings	· Avoid using narcotics or alcohol

Weight Management Medication	**Liraglutide**
Approved For	Adults and kids (>12)
How It Works	Control hunger and food intake by imitating the hormone glucagon-like peptide-1 (GLP-1).
Common Side Effects	· Diarrhea
	· Gas
	· Leakage of oily stools
	· Stomach pain
Warnings	• May raise the risk of pancreatitis.

Weight Management Medication	**Setmelanotide**
Approved For	kids (>6)
How It Works	Reduce Hunger
Common Side Effects	· Constipation
	· Dizziness
	· Dry mouth
Warnings	Deficiency in proopiomelanocortin

Difference between Semaglutide and other drugs.

Drug (Brand Name)	Mechanism of Action	Dosage Form	How it Works	Potential Advantages
Semaglutide (Wegovy, Ozempic)	An agonist of the GLP-1 (glucagon-like peptide-1) receptor	Injection (weekly or daily)	Slows stomach emptying, raises satiety, decreases glucagon secretion, and increases insulin secretion.	Among these drugs, the one with the highest average weight reduction can help regulate blood sugar.
Bupropion-naltrexone (Contrave)	Bupropion, an inhibitor of dopamine and norepinephrine reuptake, combined with naltrexone, an opioid receptor antagonist.	Tablet	May improve sensations of fullness and reduce cravings.	Has the ability to lessen alcohol cravings and may be more tolerable than stimulants.
Liraglutide (Saxenda)	An agonist of the GLP-1 (glucagon-like peptide-1) receptor	Injection (daily)	slows stomach emptying, raises satiety, decreases glucagon secretion, and increases insulin secretion	Like semaglutide, but possibly less effective in reducing body weight
Orlistat (Xenical, Alli)	Lipase inhibitor	Capsule	prevents some dietary fat from being absorbed	Possibly a decent choice for those who have trouble eating meals high in fat.

Phentermine-topiramate (Qsymia)	Stimulant (phentermine) + anticonvulsant (topiramate)	Capsule	suppresses hunger and could speed up metabolism	perhaps beneficial for temporary weight loss
Setmelanotide (Imcivree)	Melanocortin-4 receptor (MC4R) agonist	Injection (monthly)	stimulates brain receptors that control hunger and energy expenditure	For those with genetic abnormalities impacting appetite regulation, it might be a possibility.

5C Analysis

Company	Highly qualified field force. Convert plan in action. Pan India operation. Active culture.
Competitors	Daily routine exercise. Other FDA approve drug for obesity
Customer	Obese population (Adult) which comes under higher and upper-middle income group.
Collaborator	Logistic transportation company. Doctors, Stockist, Hospitals, Manufacturing company & Stack holder.
Climate	It is approved by FDA. Advance technology to advertise our brand only to doctors. Higher population wants to loss fat. India become a high potential country for semaglutide. Increasing obesity population in India.

SWOT Analysis of Semaglutide Injection

Strength • Well-tolerated side effect profile. • High effectiveness for weight loss. • Multifaceted mechanism of action (slow digestion, suppress appetite, and manage blood sugar). • Synergistic effect on blood sugar control	Weakness • Injection Requirement • High Cost
Opportunity • Growing Obesity Market • Dosage Flexibility • Increased Patient Awareness	Threat • Competition from Existing and New Drugs • Public Perception and Stigma • Stringent Regulatory Landscape

STP

Segmentation:-

- Obesity

Target

- Endocrinologists
- Primary Care Physicians (PCPs)
- Bariatric Specialists (specialize in weight loss)

Positioning

We position our brand as obesity remedy

To the Bariatric specialist / Endocrinologists whose goal is to treat obesity and is concerned about the obesity patient those face society discrimination and facing difficulties in doing day to day work. GO-FAT a brand of to treat obesity and provides freedom from obesity and helps to enjoy fat free life.

Measurable Goals

MRP	6000		Total Population suffering from obesity in india	101470268
PTR	4285.71			
PTS	3857.14		Total Population suffering from obesity in india (Tire 1 cities)	6,08,82,161

Target Plan Based on addressing number of Obese Patient

Cities Tire1	1 Month	2 Month	3 Month	4 Month	5 Month	6 Month	7 Month	8 Month	9 Month	10 Month	11 Month	12 Month
Chennai	3,55,500	3,91,050	4,30,155	4,73,171	5,20,488	5,72,536	6,29,790	6,92,769	7,62,046	8,38,250	9,22,075	10,14,283
Delhi	3,55,500	3,91,050	4,30,155	4,73,171	5,20,488	5,72,536	6,29,790	6,92,769	7,62,046	8,38,250	9,22,075	10,14,283
Hyderabad	3,55,500	3,91,050	4,30,155	4,73,171	5,20,488	5,72,536	6,29,790	6,92,769	7,62,046	8,38,250	9,22,075	10,14,283
Bangalore	3,55,500	3,91,050	4,30,155	4,73,171	5,20,488	5,72,536	6,29,790	6,92,769	7,62,046	8,38,250	9,22,075	10,14,283
Kolkata	3,55,500	3,91,050	4,30,155	4,73,171	5,20,488	5,72,536	6,29,790	6,92,769	7,62,046	8,38,250	9,22,075	10,14,283
Mumbai	3,55,500	3,91,050	4,30,155	4,73,171	5,20,488	5,72,536	6,29,790	6,92,769	7,62,046	8,38,250	9,22,075	10,14,283
Ahmedabad	3,55,500	3,91,050	4,30,155	4,73,171	5,20,488	5,72,536	6,29,790	6,92,769	7,62,046	8,38,250	9,22,075	10,14,283
Pune	3,55,500	3,91,050	4,30,155	4,73,171	5,20,488	5,72,536	6,29,790	6,92,769	7,62,046	8,38,250	9,22,075	10,14,283
Total to Acchive	28,44,000	31,28,400	34,41,240	37,85,364	41,63,900	45,80,290	50,38,319	55,42,151	60,96,367	67,06,003	73,76,604	81,14,264

6,08,16,903

Cities Tire2		7 Month	8 Month	9 Month	10 Month	11 Month	12 Month	
Amritsar		263000	289300	318230	350053	385058	423564	
Bhopal		263000	289300	318230	350053	385058	423564	
Bhubaneswar		263000	289300	318230	350053	385058	423564	
Chandigarh		263000	289300	318230	350053	385058	423564	
Faridabad		263000	289300	318230	350053	385058	423564	
Ghaziabad		263000	289300	318230	350053	385058	423564	
Jamshedpur		263000	289300	318230	350053	385058	423564	
Jaipur		263000	289300	318230	350053	385058	423564	
Kochi		263000	289300	318230	350053	385058	423564	
Lucknow		263000	289300	318230	350053	385058	423564	
Nagpur		263000	289300	318230	350053	385058	423564	
Patna		263000	289300	318230	350053	385058	423564	
Raipur		263000	289300	318230	350053	385058	423564	
Surat		263000	289300	318230	350053	385058	423564	
Visakhapatnam		263000	289300	318230	350053	385058	423564	
Agra		263000	289300	318230	350053	385058	423564	
Ajmer		263000	289300	318230	350053	385058	423564	
Kanpur		263000	289300	318230	350053	385058	423564	
Mysuru		263000	289300	318230	350053	385058	423564	
Srinagar		263000	289300	318230	350053	385058	423564	
Total to Acchive		5260000	5786000	6364600	7001060	7701166	8471283	40584109

Budgeting

Incentive for Dr. on ₹25/patient												
Cities Tire1	1 Month	2 Month	3 Month	4 Month	5 Month	6 Month	7 Month	8 Month	9 Month	10 Month	11 Month	12 Month
Chennai	8887500	9776250	10753875	11829262.5	13012188.75	14313407.63	15744748.39	17319223.23	19051145.55	20956260.1	23051886.11	25357074.73
Delhi	8887500	9776250	10753875	11829262.5	13012188.75	14313407.63	15744748.39	17319223.23	19051145.55	20956260.1	23051886.11	25357074.73
Hyderabad	8887500	9776250	10753875	11829262.5	13012188.75	14313407.63	15744748.39	17319223.23	19051145.55	20956260.1	23051886.11	25357074.73
Bangalore	8887500	9776250	10753875	11829262.5	13012188.75	14313407.63	15744748.39	17319223.23	19051145.55	20956260.1	23051886.11	25357074.73
Kolkata	8887500	9776250	10753875	11829262.5	13012188.75	14313407.63	15744748.39	17319223.23	19051145.55	20956260.1	23051886.11	25357074.73
Mumbai	8887500	9776250	10753875	11829262.5	13012188.75	14313407.63	15744748.39	17319223.23	19051145.55	20956260.1	23051886.11	25357074.73
Ahmedabad	8887500	9776250	10753875	11829262.5	13012188.75	14313407.63	15744748.39	17319223.23	19051145.55	20956260.1	23051886.11	25357074.73
Pune	8887500	9776250	10753875	11829262.5	13012188.75	14313407.63	15744748.39	17319223.23	19051145.55	20956260.1	23051886.11	25357074.73

Cities Tire2	1 Month	2 Month	3 Month	4 Month	5 Month	6 Month	7 Month	8 Month	9 Month	10 Month	11 Month	12 Month
Amritsar							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Bhopal							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Bhubaneswar							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Chandigarh							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Faridabad							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Ghaziabad							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Jamshedpur							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Jaipur							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Kochi							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Lucknow							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Nagpur							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Patna							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Raipur							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Surat							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Visakhapatnam							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Agra							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Ajmer							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Kanpur							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Mysuru							6575000	7232500	7955750	8751325	9626457.5	10589103.25
Srinagar							6575000	7232500	7955750	8751325	9626457.5	10589103.25

Cities Tire1	MR	Visual Aid	LBL	Poster	CME	Online marketing
Chennai	1	2000	1440000	144000	120000	10000
Delhi	1	2000	1440000	144000	120000	
Hyderabad	1	2000	1440000	144000	120000	
Bangalore	1	2000	1440000	144000	120000	
Kolkata	1	2000	1440000	144000	120000	
Mumbai	1	2000	1440000	144000	120000	
Ahmedabad	1	2000	1440000	144000	120000	
Pune	1	2000	1440000	144000	120000	
	8	16000	11520000	1152000	960000	10000
Final Expenditure Excl. MR		13658000				

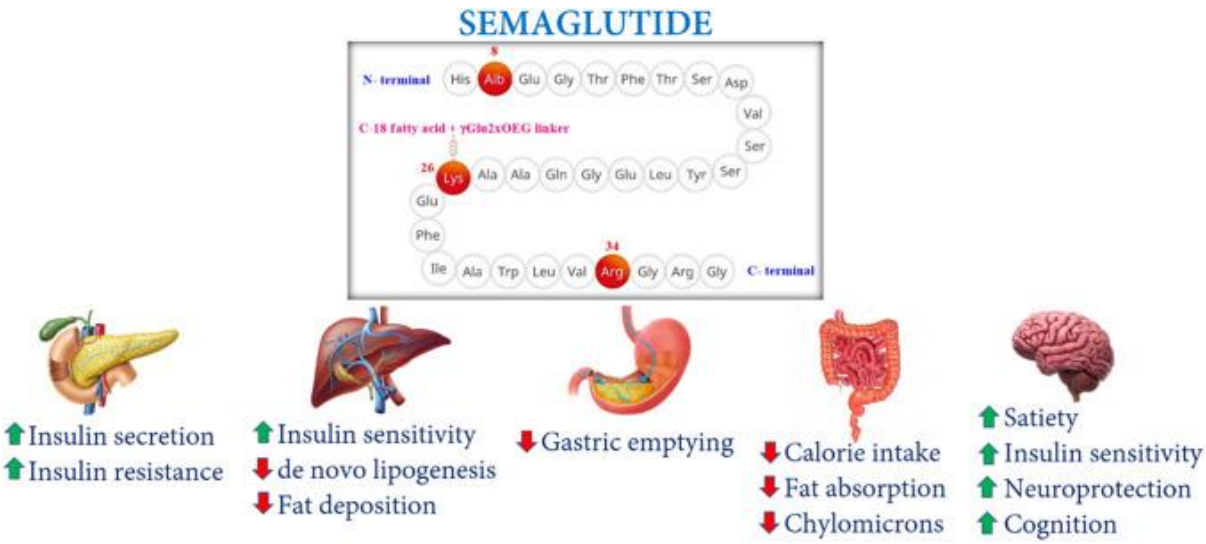
Cities Tire2	MR	Visual Aid	LBL	Poster	CME	Online marketing
Amritsar	1	2000	1440000	144000	120000	20000
Bhopal	1	2000	1440000	144000	120000	
Bhubaneswar	1	2000	1440000	144000	120000	
Chandigarh	1	2000	1440000	144000	120000	
Faridabad	1	2000	1440000	144000	120000	
Ghaziabad	1	2000	1440000	144000	120000	
Jamshedpur	1	2000	1440000	144000	120000	
Jaipur	1	2000	1440000	144000	120000	
Kochi	1	2000	1440000	144000	120000	
Lucknow	1	2000	1440000	144000	120000	
Nagpur	1	2000	1440000	144000	120000	
Patna	1	2000	1440000	144000	120000	
Raipur	1	2000	1440000	144000	120000	
Surat	1	2000	1440000	144000	120000	
Visakhapatnam	1	2000	1440000	144000	120000	
Agra	1	2000	1440000	144000	120000	
Ajmer	1	2000	1440000	144000	120000	
Kanpur	1	2000	1440000	144000	120000	
Mysuru	1	2000	1440000	144000	120000	
Srinagar	1	2000	1440000	144000	120000	
	20	40000	28800000	2880000	2400000	20000
Final Expenditure Excl. MR		34140000				

4 P's

Product	GO-FAT (Semaglutide) inj. Free exercise guidance. Emboss brand name with UV. Pack of 4 one-month therapy.
Price	MRP = 6000 PTR = 4285.71 PTS = 3857.14 Competitor Pricing = ₹7000/- to ₹7800/- 15 days credit to stockist
Place	Presence on both online and offline Pan-India First inventory = 11376000/- By temperature control truck with distribution partners
Promotion	Creating awareness about diabetes. Creating buzz that only exercise and diet are not effective for weight loss. Promotion by Omni-channel. CME. Those buy 6-month therapy they got 20% discount for consumer.

MOA of Semaglutide: -

Position 26 lysine is modified with a C18 fatty di-acid and a hydrophilic spacer to facilitate albumin binding, the main mechanism of semaglutide's protraction. Furthermore, semaglutide's position 8 modification offers stability against the enzyme DPP-4 degradation. Ensure that there was only one fatty di-acid attached, position 34 was slightly changed. Fig. 0.2



Pharmacodynamics

Semaglutide reduces body weight by reducing fat mass, reduce calories consumption.

Stomach emptying

Gastric emptying is delayed with semaglutide.

Pharmacokinetics

Absorption

89% bioavailability. Reaches maximum concentration within 1 – 3 days.

Distribution

Since 99% of semaglutide is bound to plasma albumin, renal clearance is decreased, and it is shielded from degradation.

Elimination

Semaglutide has a roughly one-week elimination half-life and a bloodstream half-life of five to seven weeks.

Metabolism

Proteases break down the peptide and subsequently beta oxidize the fatty acid sidechain.

Excretion

The body rids itself of semaglutide-related material primarily through urine and feces. In the urine, about 3% of the dosage is excreted as intact semaglutide.

CLINICAL STUDIES

CT-1-Adults with Obesity or Overweight and Cardiovascular Disease: Cardiovascular Outcomes Trial

In this study, 17,604 participants were randomized at random to receive semaglutide or a placebo. 84% White, 4% Black or African American, 8% Asian, and 10% Hispanic or Latino made up the baseline demographics, which included 72% of men. The age range was 45-93 years, with a mean of 62. The mean body weight was 97 kg, and the average baseline BMI was 33 kg/m^2.

Table 1.1	Patients with events n (%)		
	Placebo N=8,801	Semaglutide N=8,803	Hazard Ratio (95% CI)
Primary composite endpoint			
Combination of non-fatal myocardial infarction, non-fatal stroke, and cardiovascular death	701 (8.0%)	569 (6.5%)	0.80 (0.72; 0.90)
Key secondary endpoints			
Cardiovascular death	262 (3.0%)	223 (2.5%)	0.85 (0.71; 1.01)
All-cause death	458 (5.2%)	375 (4.3%)	0.81 (0.71; 0.93)
Other secondary endpoints			
Fatal or non-fatal myocardial infarction	334 (3.8%)	243 (2.8%)	0.72 (0.61; 0.85)
Fatal or non-fatal stroke	178 (2.0%)	160 (1.8%)	0.89 (0.72; 1.11)

Table 1.2	Placebo		Semaglutide		
	Baseline	Change from Baseline (LSMean)	Baseline	Change from Baseline (LSMean)	Difference from Placebo (LSMean)
Body Weight (kg)	96.8	-0.9	96.5	-9.4	-8.5
Waist Circumference (cm)	111.4	-1.0	111.3	-7.6	-6.5
Systolic Blood Pressure (mmHg)	131	-0.5	131	-3.8	-3.3
Diastolic Blood Pressure (mmHg)	79	-0.5	79	-1.0	-0.5
Heart Rate	69	0.7	69	3.8	3.1
HbA1c (%)	5.8	0.0	5.8	-0.3	-0.3
	Baseline	% Change from Baseline (LSMean)	Baseline	% Change from Baseline (LSMean)	Relative difference from placebo (%) (LSMean)
Total Cholesterol (mg/dL)	156.0	-1.9	155.5	-4.6	-2.8
LDL Cholesterol (mg/dL)	78.5	-3.1	78.5	-5.3	-2.2
HDL Cholesterol (mg/dL)	44.2	0.6	44.1	4.9	4.2
Triglycerides (mg/dL)	139.5	-3.2	138.6	-18.3	-15.6

CT-2: Studies on Weight Loss and Long-Term Maintenance in Obese or Overweight Adults

To investigate the safety and efficacy of Semaglutide for weight loss and long-term maintenance of body weight in conjunction with a reduced calorie diet and increased physical activity, three 68-week randomized, double-blind, placebo-controlled trials, one 68-week randomized, double-blind, placebo withdrawal trial, and a second 68-week randomized, double-blind trial comparing two different doses of Semaglutide to placebo were carried out.

Result

In Studies 2, 3, and 4, the proportion of patients who discontinued their study medication was 16.0% for the semaglutide group and 19.1% for the placebo group. 3.2% of discontinuations of placebo treatment and 6.8% of discontinuations of semaglutide treatment were due to adverse reactions. 5.8% of patients in Research 5 stopped taking the semaglutide trial medication, while 11.6% of patients stopped taking the placebo. In Study 6, the discontinuation rates of semaglutide 1.7 mg, semaglutide 2.4 mg, and placebo were 7.9%, 6.5%, and 3.0%, respectively, among the patients.

The mean percent change in body weight and the percentage of patients who lost more than or equal to 5% of their baseline body weight by week 68. After 68 weeks, semaglutide therapy produced a statistically significant reduction in body weight when compared to placebo. A greater proportion of patients treated with semaglutide lost 5%, 10%, and 15% of their body weight in comparison to those who received a placebo.

Study 5 was the mean percent change in body weight from the randomization week (20) to week 68. Between the time of randomization (week 20) and week 68, there was a statistically significant reduction in body weight with semaglutide treatment. The results might not accurately reflect people beginning semaglutide in the general population because patients who discontinued during titration and those who were unable to reach the weekly dosage of 2.4 mg were not included in the randomized treatment period.

	Study 2 (Obesity or overweight with comorbidity)		Study 3 (Type 2 diabetes with obesity or overweight)		Study 4 (Obesity or overweight With comorbidity undergoing intensive lifestyle therapy)	
Intention-to-Treat	Placebo N=655	Semaglutide N=1306	Placebo N=403	Semaglutide N=404	Placebo N=204	Semaglutide N=407
Body Weight						
Baseline mean (kg)	105.2	105.4	100.5	99.9	103.7	106.9
% change from Baseline (LSMean)	-2.4	-14.9	-3.4	-9.6	-5.7	-16.0
% difference from placebo (LSMean) (95% CI)		-12.4 (-13.3; -11.6)*		-6.2 (-7.3; -5.2)*		-10.3 (-11.8; -8.7)*
% of Patients losing greater than or equal to 5% body weight	31.1	83.5	30.2	67.4	47.8	84.8
% difference from placebo (LSMean) (95% CI)		52.4 (48.1; 56.7)*		37.2 (30.7; 43.8)*		37.2 (30.7; 43.8)*
% of Patients losing greater than or equal to 10% body weight	12.0	66.1	10.2	44.5	27.1	73.0
% difference from placebo (LSMean) (95% CI)		54.1 (50.4; 57.9)*		34.3 (28.4; 40.2)*		45.9 (38.0; 53.7)*
% of Patients losing greater than or equal to 15% body weight	4.8	47.9	4.3	25.1	13.2	53.4
% difference from placebo (LSMean) (95% CI)		43.1 (39.8; 46.3)*		20.7 (15.7; 25.8)*		40.2 (33.1; 47.3)*

Changes in Body Weight at Week 68 in Studies 2, 3, and 4 - Table 2.1

Changes in Body Weight at Week 68 in Study 5 (Obesity or overweight with comorbidity after 20-week run-in) - Table 2.2

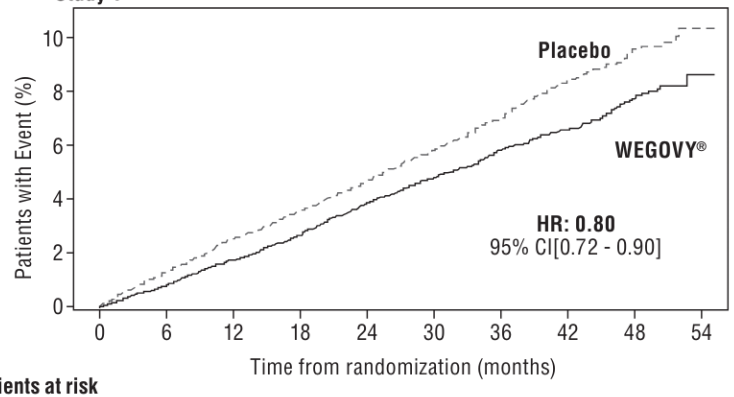
	Semaglutide N=803	
Body Weight (only randomized patients)		
Mean at week 0 (kg)	107.2	
	Placebo N=268	Semaglutide N=535
Body Weight		
Mean at week 20 (SD) (kg)	95.4 (22.7)	96.5 (22.5)
% change from week 20 at week 68 (LSMean)	6.9	-7.9
% difference from placebo (LSMean) (95% CI)		-14.8 (-16.0; -13.5) *

Changes in Body Weight at Week 68 in Study 6 in East-Asian Patients (Semaglutide 1.7 mg) - Table 2.3

	Study 6 (BMI ≥35 kg/m2 with at least one comorbidity or BMI 27-34.9 kg/m2 with at least two comorbidities)		
Intention-to-treat	Placebo N=101	Semaglutide 1.7 mg N=101	Semaglutide 2.4 mg N=199
Body Weight			
Baseline mean (kg)	90.2	86.1	86.9
% change from baseline (LSMean)	-2.1	-9.6	-13.2
% difference from placebo (LSMean) (95% CI)		-7.5 (-9.6; -5.4)*	-11.1 (-12.9; -9.2)*
% of patients losing greater than or equal to 5% body weight	19.4	72.8	84.0
% difference from placebo (LSMean) (95% CI)		53.3 (41.0; 65.6)*	64.5 (54.8; 74.3)*
% of patients losing greater than or equal to 10% body weight	4.5	39.1	59.9
% difference from placebo (LSMean) (95% CI)		34.5 (23.9; 45.1)*	55.4 (47.3; 63.6)*
% of patients losing greater than or equal to 15% body weight	2.6	20.8	38.2
% difference from placebo (LSMean) (95% CI)		18.2 (9.8; 26.7)*	35.6 (27.9; 43.3)*

Placebo	Semaglutide 1.7 mg	Semaglutide 2.4 mg

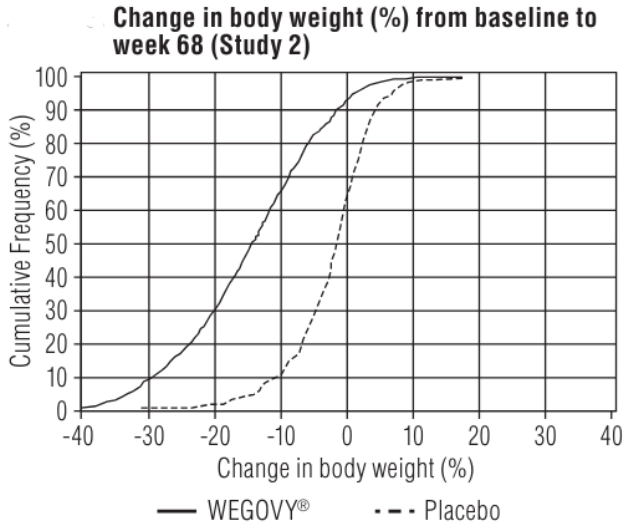
Figure 4. Cumulative Incidence Function: Time to First Occurrence of MACE in Study 1



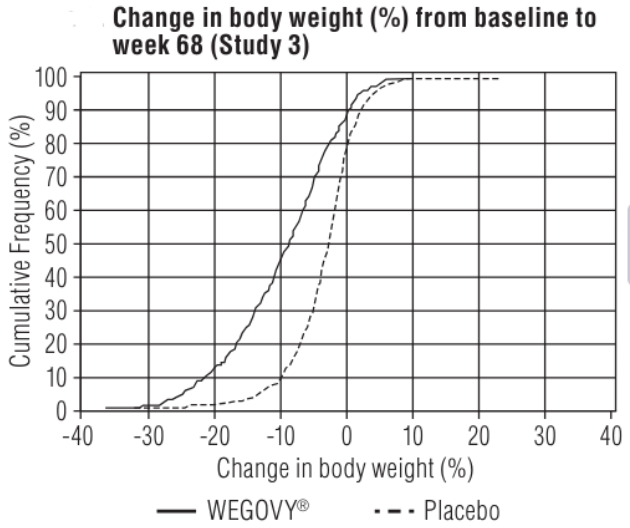
Patients at risk

WEGOVY®	**8803**	**8695**	**8561**	**8427**	**8254**	**7229**	**5777**	**4126**	**1734**	**71**
Placebo	**8801**	**8652**	**8487**	**8326**	**8164**	**7101**	**5660**	**4015**	**1672**	**59**

Fig. 1

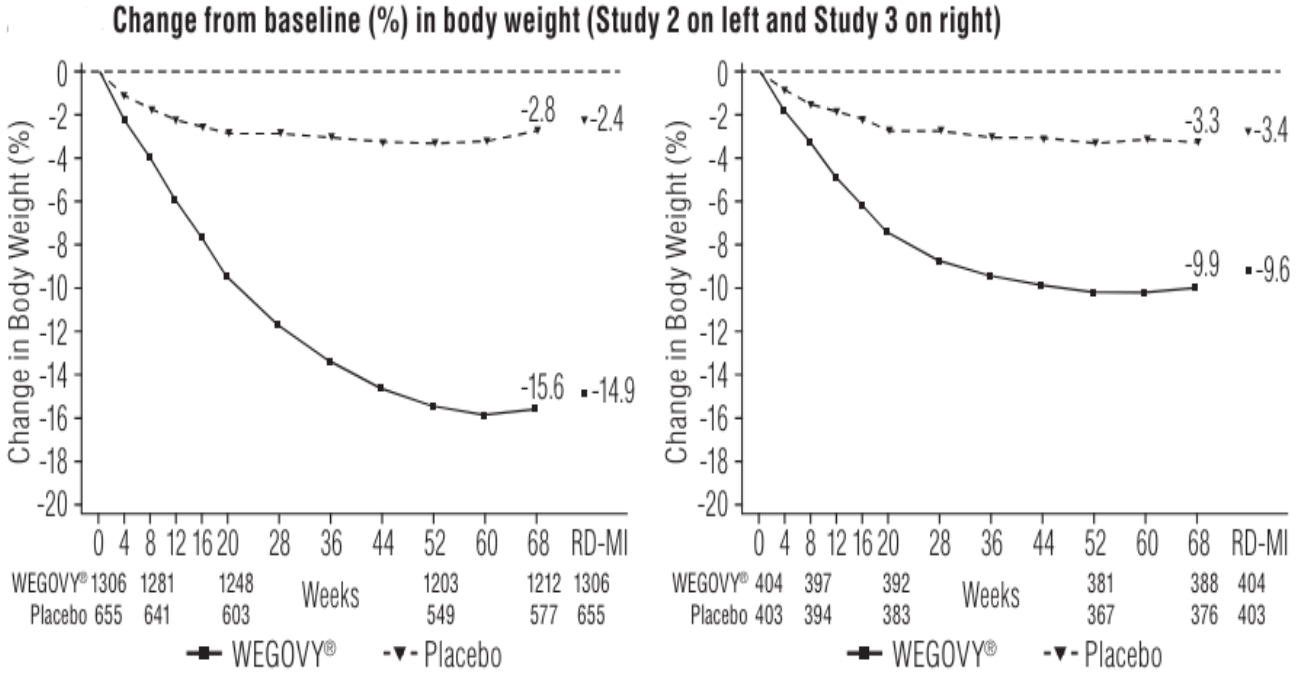


Observed data from in-trial period including imputed data for missing observations (RD-MI).

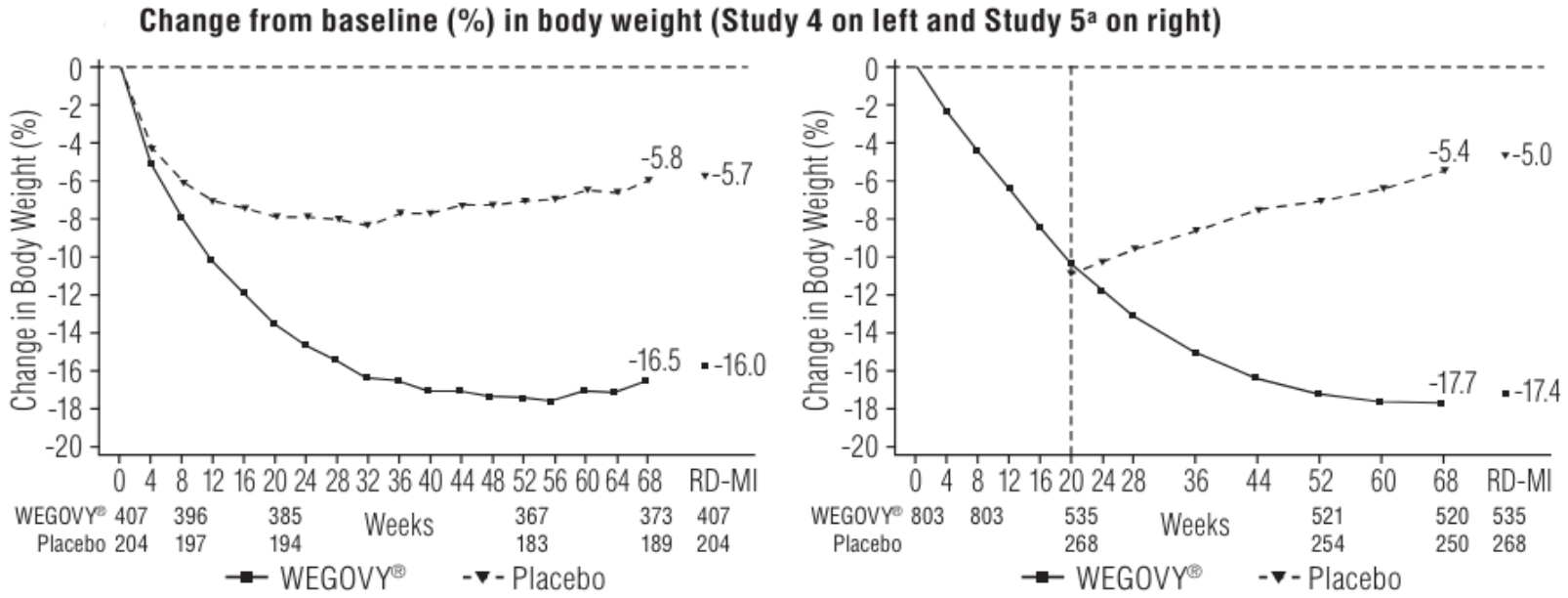


Observed data from in-trial period including imputed data for missing observations (RD-MI).

Fig. 2.1



Observed values for patients completing each scheduled visit, and estimates with multiple imputations from retrieved dropouts (RD-MI)



Observed values for patients completing each scheduled visit, and estimates with multiple imputations from retrieved dropouts (RD-MI)
[a]Change from week 0 was not a primary endpoint in study 4. Dotted line indicates time of randomization. Randomized patients (shown) do not include 99 patients that discontinued during the 20-week run-in period.

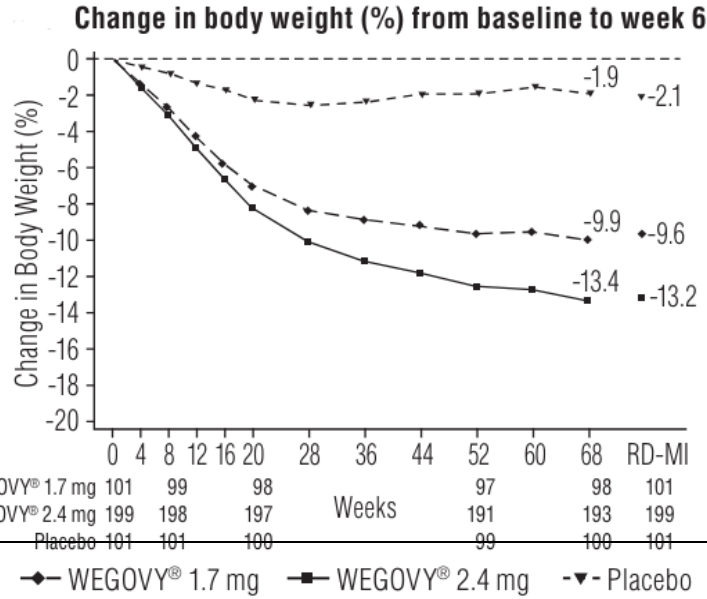


Fig. 2.3

Fig. 2.4

	Study 2 (Obesity or overweight with comorbidity)		Study 3 (Type 2 diabetes with obesity or overweight)		Study 4 (Obesity or overweight with comorbidity undergoing intensive lifestyle therapy)	
Intention-to-Treat	PLACEBO N=655	WEGOVY N=1306	PLACEBO N=403	WEGOVY N=404	PLACEBO N=204	WEGOVY N=407
Waist Circumference (cm)						
Baseline	114.8	114.6	115.5	114.5	111.8	113.6
Changes from baseline (LSMean)	-4.1	-13.5	-4.5	-9.4	-6.3	-14.6
Difference from placebo (LSMean)		-9.4		-4.9		-8.3
Systolic Blood Pressure (mmHg)						
Baseline	127	126	130	130	124	124
Changes from baseline (LSMean)	-1.1	-6.2	-0.5	-3.9	-1.6	-5.6
Difference from placebo (LSMean)		-5.1		-3.4		-3.9
Diastolic Blood Pressure (mmHg)						
Baseline	80	80	80	80	81	80
Changes from baseline (LSMean)	-0.4	-2.8	-0.9	-1.6	-0.8	-3.0
Difference from placebo (LSMean)		-2.4		-0.7		-2.2
Heart Rate						
Baseline	72	72	76	75	71	71
Changes from baseline (LSMean)	-0.7	3.5	-0.2	2.5	2.1	3.1
Difference from placebo (LSMean)		4.3		2.7		1.0
HbA1c (%)						
Baseline	5.7	5.7	8.1	8.1	5.8	5.7
Changes from baseline (LSMean)	-0.2	-0.4	-0.4	-1.6	-0.3	-0.5
Difference from placebo (LSMean)		-0.3		-1.2		-0.2
Total Cholesterol (mg/dL)						
Baseline	192.1	189.6	170.8	170.8	188.7	185.4
Percent Change from baseline (LSMean)	0.1	-3.3	-0.5	-1.4	2.1	-3.9
Relative difference from placebo (LSMean)		-3.3		-0.9		-5.8
LDL Cholesterol (mg/dL)						
Baseline	112.5	110.3	90.1	90.1	111.8	107.7
Percent Change from baseline (LSMean)	1.3	-2.5	0.1	0.5	2.6	-4.7
Relative difference from placebo (LSMean)		-3.8		0.4		-7.1
HDL (mg/dL)						
Baseline	49.5	49.4	43.8	44.7	50.9	51.6
Percent Change from baseline (LSMean)	1.4	5.2	4.1	6.9	5.0	6.5
Relative difference from placebo (LSMean)		3.8		2.7		1.5
Triglycerides (mg/dL)						
Baseline	127.9	126.2	159.5	154.9	110.9	107.9
Percent Change from baseline (LSMean)	-7.3	-21.9	-9.4	-22.0	-6.5	-22.5
Relative difference from placebo (LSMean)		-15.8		-13.9		-17.0

Changes in Anthropometry and Cardio metabolic Parameters at Week 68 in Studies 2, 3, and 4. – Table-2.4

Mean Changes in Anthropometry and Cardio metabolic Parameters in Study 5 (Obesity or overweight with comorbidity after 20-week run-in). - Table-2.5

	PLACEBO N=268		WEGOVY N=535		
	Randomization (week 20)	Change from Randomization (week 20) to week 68 (LSMean)	Randomization (week 20)	Change from Randomization (week 20) to week 68 (LSMean)	Difference from placebo (LSMean)
Waist Circumference (cm)	104.7	3.3	105.5	-6.4	-9.7
Systolic Blood Pressure (mmHg)	121	4.4	121	0.5	-3.9
Diastolic Blood Pressure (mmHg)	78	0.9	78	0.3	-0.5
Heart Rate	76	-5.3	76	-2.0	3.3
HbA1c (%)	5.4	0.1	5.4	-0.1	-0.2
	Randomization (week 20)	% Change from Randomization (week 20) (LSMean)	Randomization (week 20)	% Change from Randomization (week 20) (LSMean)	Relative difference from placebo (LSMean)
Total Cholesterol (mg/dL)	175.1	11.4	175.9	4.9	-5.8
LDL Cholesterol (mg/dL)	109.1	7.6	108.7	1.1	-6.1
HDL Cholesterol (mg/dL)	43.6	17.8	44.5	18.2	0.3
Triglycerides (mg/dL)	95.3	14.8	98.1	-5.6	-17.8

Mean Changes in Anthropometry and Cardio metabolic Parameters at Week 68 in Study 6 in East-Asian Patients (WEGOVY® 1.7 mg). - Table-2.6

	Study 6 (BMI ≥35 kg/m2 with at least one comorbidity or BMI 27-34.9 kg/m2 with at least two comorbidities)		
Intention-to-treat	PLACEBO N=101	WEGOVY 1.7 mg N=101	WEGOVY 2.4 mg N=199
Waist circumference (cm)			
Baseline	103.8	101.4	103.8
Change from baseline (LSMean)	-1.8	-7.7	-11
Difference from placebo (LSMean)		-5.9	-9.3
Systolic blood pressure (mmHg)2			
Baseline	133	135	133
Change from baseline (LSMean)	-5.3	-10.8	-10.8
Difference from placebo (LSMean)		-5.4	-5.5
Diastolic blood pressure (mmHg)2			
Baseline	86	85	83
Change from baseline (LSMean)	-2.2	-4.6	-5.3
Difference from placebo (LSMean)		-2.4	-3.1
Heart Rate			
Baseline	73	73	73
Change from baseline (LSMean)	2.4	4.4	6.3
Difference from placebo (LSMean)		2	3.9
HbA1c (%)			
Baseline	6.4	6.4	6.4
Change from baseline (LSMean)	0.0	-0.9	-0.9
Difference from placebo (LSMean)		-0.9	-0.9
Total Cholesterol (mg/dL)			
Baseline	203.1	203.3	197.2

Percent change from baseline (LSMean)	0.8	-6.6	-8.7
Relative difference from placebo (LSMean)		-7.3	-9.4
LDL Cholesterol (mg/dL)			
Baseline	123.3	120.1	116.5
Percent change from baseline (LSMean)	-3.8	-10.1	-14.6
Relative difference from placebo (LSMean)		-6.5	-11.2
HDL Cholesterol (mg/dL)			
Baseline	48.7	50.2	50.8
Percent change from baseline (LSMean)	5.9	6.7	9.2
Relative difference from placebo (LSMean)		0.7	3.1
Triglyceride (mg/dL)			
Baseline	134.2	138.8	127.1
Percent change from baseline (LSMean)	5.5	-19.5	-21.2
Relative difference from placebo (LSMean)		-23.7	-25.3

CT-3- Weight Loss and Long-Term Maintenance Research in Pediatric Obesity Patients 12 Years of Age and Up

201 Pediatric patients in their pubertal years, aged 12 and older, whose BMI fell within the ≥95th percentile normalized for age and sex, participated in a multi-centre, 68-week, double-blind, randomized, parallel group, placebo-controlled study.
The patients' racial or ethnic backgrounds were as follows: 79% were White, 8% were Black or African American, 2% were Asian, and 11% were of other or unknown race. The patients' average age was fifteen years, and 38% of them were male. The average baseline body weight was 108 kg, and the mean BMI was 37 kg/m2.

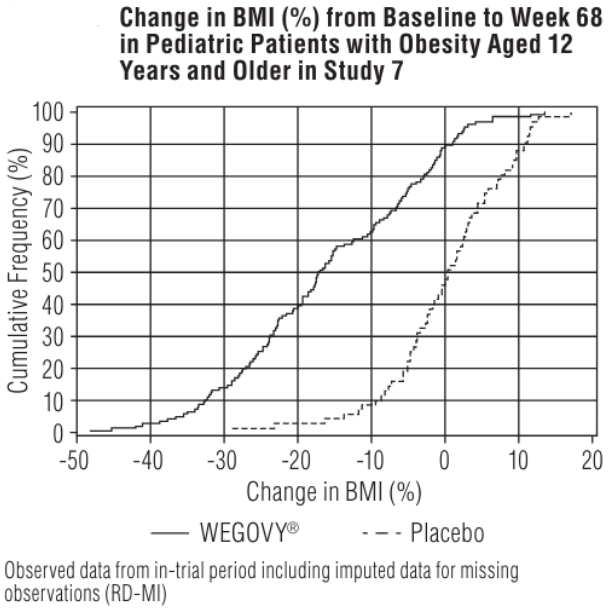
Result

Ten percent of patients receiving WEGOVY® treatment and ten percent of patients receiving a placebo quit taking the study drug.

The primary result was the percentage change in BMI from baseline to week 68. After 68 weeks, WEGOVY® treatment resulted in a statistically significant reduction in percentage BMI when compared to a placebo. A greater proportion of patients treated with WEGOVY® saw a ≥5% reduction in their initial BMI compared to patients treated with placebo.

Changes in Weight and BMI at Week 68 in Pediatric Patients with Obesity Aged 12 Years and Older – Table-3.1

Intention-to-Treat	Placebo N=67	Wegovy N=134
BMI		
Baseline mean (kg/m)	35.7	37.7
% change from baseline in BMI (LSMean)	0.6	-16.1
% difference from placebo (LSMean) (95% CI)		-16.7 (-20.3; -13.2)
% of patients with greater than or equal to 5% reduction in baseline BMI	19.7	77.1
% difference from placebo (LSMean)		57.4
% of patients with greater than or equal to 10% reduction in baseline BMI	7.7	65.1
% difference from placebo (LSMean)		57.5
% of patients with greater than or equal to 15% reduction in baseline BMI	4	57.8
% difference from placebo (LSMean)		53.9
Body Weight		
Baseline mean (kg)	102.6	109.9
% change from baseline (LSMean)	2.7	-14.7
% difference from placebo (LSMean)		-17.4



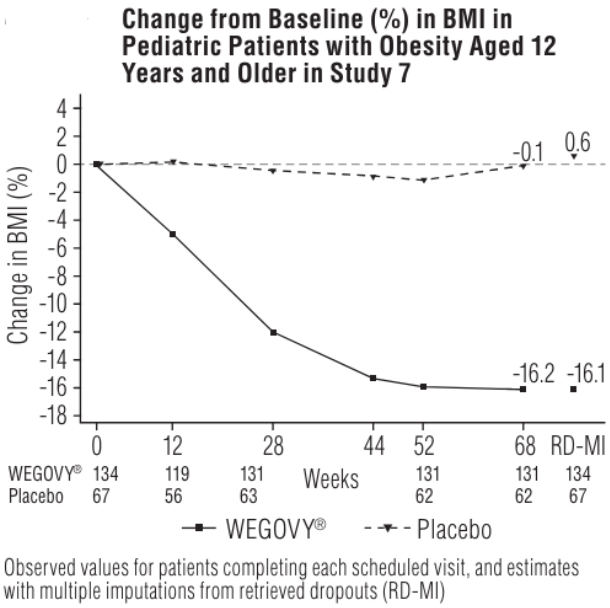


Fig. 3.1

Fig. 3.2

Mean Changes in Anthropometry and Cardio metabolic Parameters in Pediatric Patients with Obesity Aged 12 Years and Older Table-3.2

	PLACEBO N = 67		WEGOVY N = 134		
	Baseline	Change from Baseline (LSMean)	Baseline	Change from Baseline (LSMean)	Difference from placebo (LSMean)
Waist Circumference (cm)	107.3	-0.6	111.9	-12.7	-12.1
Systolic Blood Pressure (mmHg)	120	-0.8	120	-2.7	-1.9
Diastolic Blood Pressure (mmHg)	73	-0.8	73	-1.4	-0.6
Heart Rate	76	-2.3	79	1.2	3.5
HbA1c (%)	5.4	-0.1	5.5	-0.4	-0.2
	Baseline	% Change from Baseline (LSMean)	Baseline	% Change from Baseline (LSMean)	Relative difference from placebo (LSMean)
Total Cholesterol (mg/dL)	160.1	-1.3	159.4	-8.3	-7.1
LDL Cholesterol (mg/dL)	91.7	-3.6	89.8	-9.9	-6.6
HDL Cholesterol (mg/dL)	43.3	3.2	43.7	8.0	4.7
Triglycerides (mg/dL)	108.0	2.6	111.3	-28.4	-30.2

METHODOLOGY

Research Question:

- To know about various US FDA, approve medication for obesity.
- To find solutions to obesity patients.
- To know about limitations of semaglutide.
- To know about the effectiveness of semaglutide.

Research Objective:

- In-depth learning of Obesity.
- To learn about treatments for obesity.
- Semaglutide as an effective drug in treatment of obesity.
- Efficacy & Safety of semaglutide in obesity patients.
- Wegovy Trial

Study Area: Field knowledge about obesity and potency of Semaglutide.

Study Design: Observational study.

Study Tool: Review articles, Research articles, field understanding.

Study Duration: 90 days

Analysis: Population of obesity patients is both child and adult. Various treatment regimens are available in the market but those are effective but hard and time taken. Potency of semaglutide more efficient in OAB category, where other have less potency with more side-effect. I met multiple bariatric surgeons in Agra and Delhi, surprisingly they gave positive responses about semaglutide. Which drug come under US FDA. Semaglutide is the highly effective drug in the category of obesity by Novo Nordisk, so this is trusted molecule for the obesity Patients in India. And that's why doctors don't hesitated to prescribe semaglutide molecules.

Discussion

Obesity the most common disease in the world. The prevalence rate of obesity is 40%. The obesity measure according to region wise like PAHO, EURO, EMRO, WPRO, AFRO & SEARO.

Obesity is measure by BMI. Fat of obesity is display on body in two types like Gynecoid or pear-shape, Android, or apple-shape.

Semaglutide is a GLP-1 antagonist that work by decreases glucagon release, delays stomach emptying, increases insulin release, and decreases appetite. Wegovy is only a of the brand of semaglutide which is approved by FDA. Dosage of semaglutide is Injection (weekly or daily). Semaglutide work by Slows stomach emptying, raises satiety, decreases glucagon secretion, and increases insulin secretion. Semaglutide have the highest average weight reduction can help regulate blood sugar.

Multiple studies were conducted on semaglutide brand Wegovy which show high reduction in weight in both adult and children with some workout and diet control. And with placebo which show less reduction in weight with some workout and diet control.

Most of Doctors prescribe semaglutide drug for weight loss to obesity patients and to those obesity patients which are suffering from diabetes because the semaglutide give a synergistic effect in controlling hyperglycaemia, semaglutide have lower does frequency and have less side-affect than other drug.

In few cases, weight regain shows after stop taking semaglutide this is done because patients do not follow diet plan and routine exercise after stop taking semaglutide.

Conclusion

Semaglutide is best and most effective drug for treating obesity. Semaglutide show higher reduction in weight than other drugs. Semaglutide also have lower does frequency and have less side-affect than other drug.

Semaglutide is best for obesity patient those are suffer from diabetes because it has a synergistic effect in controlling hyperglycaemia.

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