Comprehensive Weight Control Center


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1165 York Avenue, New York, NY weillcornell.org/weight

2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults:

A Report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines and The Obesity Society

July 1, 2014

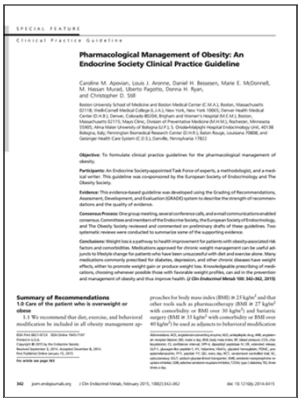

2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults

J Am Coll Cardiol. 2014 Jul 1;63(25 Pt B):2985-3023.

PHARMACOLOGICAL MANAGEMENT of OBESITY:

An Endocrine Society Clinical Practice Guideline

January 15, 2015


Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline

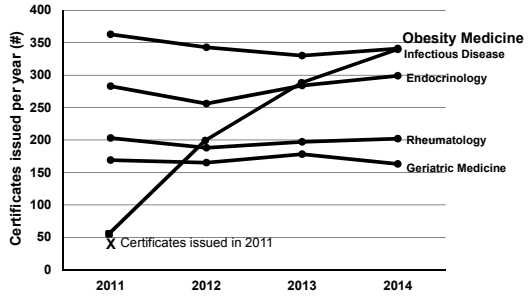
Apovian CM, Aronne LJ, Bessesen D et al. J Clin Endocrinol Metab. 2015;100:342-362.

Obesity Medicine:
The Newest Specialty in Medicine

ABOM Partner Organizations

American Board of Medical Specialties (ABMS) Fields of Medicine Partners	Partner Organizations
• American College of Physicians • The Endocrine Society • American Gastroenterological Association • American Congress of Obstetricians and Gynecologists • American College of Preventive Medicine	• The Obesity Society • American Society of Bariatric Physicians • American Society of Metabolic and Bariatric Surgery

Number of Certificates Issued in Various Medical Specialties



The Endocrine Society Guidelines Task Force agrees with the opinion of prominent medical societies that current scientific evidence supports the view that obesity is a disease.

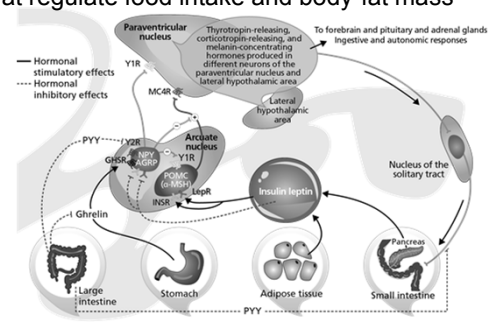
A disease is a disorder of structure or function that affects all or part of an organism.

It is a medical condition associated with symptoms and signs.

It has a pathology.

What is the disease?

Interactions among hormonal and neural pathways that regulate food intake and body-fat mass



AGRP: agouti-related peptide; α-MSH: α-melanocyte-stimulating hormone; GHSR: growth hormone secretagogue receptor; INSR: insulin receptor; LepR: leptin receptor; MC4R: melanocortin-4 receptor; NPY: neuropeptide Y; POMC: proopiomelanocortin; PYY: peptide YY; Y1R; neuropeptide Y1 receptor; Y2R: neuropeptide Y2 receptor.

Apovian CM, Aronne LJ, Bessesen D et al. *J Clin Endocrinol Metab*. 2015;100:342-362.

Related Commentary, page 22 Research article

Obesity is associated with hypothalamic injury in rodents and humans

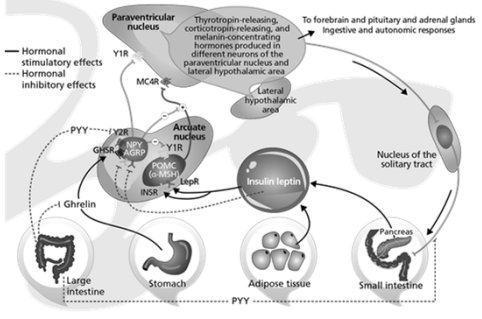
Joshua P. Thaler,[1,2] Chun-Xia Yi,[3] Ellen A. Schur,[2] Stephan J. Guyenet,[1,2] Bang H. Hwang,[1,2,4] Marcelo O. Dietrich,[5] Xiaolin Zhao,[1,2,6] David A. Sarruf,[1,2] Vitaly Izgur,[7] Kenneth R. Maravilla,[7] Hong T. Nguyen,[1,2] Jonathan D. Fischer,[1,2] Miles E. Matsen,[1,2] Brent E. Wisse,[1,2] Gregory J. Morton,[1,2] Tamas L. Horvath,[5,8] Denis G. Baskin,[1,2,4] Matthias H. Tschöp,[3] and Michael W. Schwartz[1,2]

[1]Division of Metabolism, Endocrinology and Nutrition, Diabetes and Obesity Center of Excellence, and [2]Department of Medicine, University of Washington, Seattle, Washington, USA. [3]Metabolic Diseases Institute, Division of Endocrinology, Department of Medicine, University of Cincinnati, Cincinnati, Ohio, USA. [4]Research and Development Service, Department of Veterans Affairs Puget Sound Health Care System, Seattle, Washington, USA. [5]Program in Integrative Cell Signaling and Neurobiology of Metabolism, Section of Comparative Medicine, Yale University School of Medicine, New Haven, Connecticut, USA. [6]Department of Physiology and Pathophysiology, School of Medicine at Xi'an Jiaotong University, Xi'an, China. [7]Department of Radiology, University of Washington, Seattle, Washington, USA. [8]Department of Obstetrics/Gynecology and Reproductive Sciences, Yale University School of Medicine, New Haven, Connecticut, USA.

Rodent models of obesity induced by consuming high-fat diet (HFD) are characterized by inflammation both in peripheral tissues and in hypothalamic areas critical for energy homeostasis. Here we report that unlike inflammation in peripheral tissues, which develops as a consequence of obesity, hypothalamic inflammatory signaling was evident in both rats and mice within 1 to 3 days of HFD onset, prior to substantial weight gain. Furthermore, both reactive gliosis and markers suggestive of neuron injury were evident in the hypothalamic arcuate nucleus of rats and mice within the first week of HFD feeding. Although these responses temporarily subsided, suggesting that neuroprotective mechanisms may initially limit the damage, with continued HFD feeding, inflammation and gliosis returned permanently to the mediobasal hypothalamus. Consistent with these data in rodents, we found evidence of increased gliosis in the mediobasal hypothalamus of obese humans, as assessed by MRI. These findings collectively suggest that, in both humans and rodent models, obesity is associated with neuronal injury in a brain area crucial for body weight control.

Thaler PT, et al. *J Clin Invest*. 2012 Jan 3;122(1):153-62. doi: 10.1172/JCI59660. Epub 2011

Hypothalamic Injury Diminishes Signaling to Cortex and NTS, Leading to Greater Weight Gain



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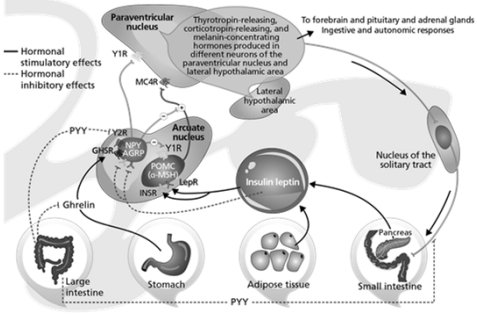
Apovian CM, Aronne LJ, Bessesen D et al. *J Clin Endocrinol Metab*. 2015;100:342-362.

Bad Habits Damage Hypothalamic Pathways

if Hypothalamus is Damaged, Leptin Resistance is a Result



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Apovian CM, Aronne LJ, Bessesen D et al. *J Clin Endocrinol Metab*. 2015;100:342-362.

If resistance to leptin is the problem, can we increase sensitivity to leptin?

Article

Cell

Treatment of Obesity with Celastrol

Junli Liu,[1,4] Jaemin Lee,[1,4] Mario Andres Salazar Hernandez,[1] Ralph Mazitschek,[2,3] and Umut Ozcan[1,*]
[1]Division of Endocrinology, Boston Children's Hospital, Harvard Medical School, Boston, MA 02130, USA
[2]Massachusetts General Hospital, Center for Systems Biology, Boston, MA 02114, USA
[3]The Broad Institute of Harvard and Massachusetts Institute of Technology, Cambridge, MA 02142, USA
[4]Co-first author

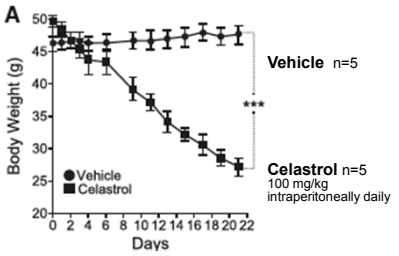
Highlights

- Celastrol is a natural compound extracted from thunder god vine
- Celastrol creates similar expression profile to those of reduced ER stress conditions
- Celastrol is a powerful leptin sensitizer
- Celastrol has potential as an anti-obesity therapeutic agent

Liu J, et al. Cell. 2015 May 21;161(5):999-1011.

Treatment with Celastrol produced 45% total body weight loss in mice with diet induced obesity

It's in development as a drug…



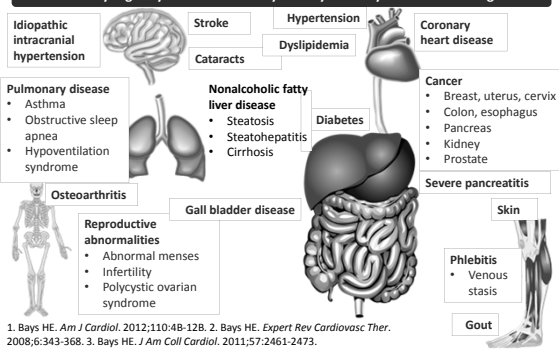
Liu J, et al. Cell. 2015 May 21;161(5):999-1011.

OK, Great, Now What?

- What do I do for my patients until we have better treatments!

Medical Complications of Obesity[1-3]

Almost every organ system is affected by obesity and may benefit from weight loss

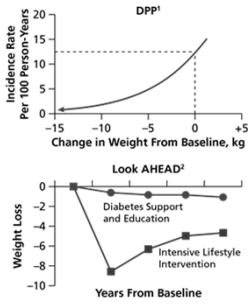


1. Bays HE. *Am J Cardiol*. 2012;110:4B-12B. 2. Bays HE. *Expert Rev Cardiovasc Ther*. 2008;6:343-368. 3. Bays HE. *J Am Coll Cardiol*. 2011;57:2461-2473.

Why Is 5%-10% Weight Loss the Goal of Treatment?

Modest weight loss (5%-10%) can:

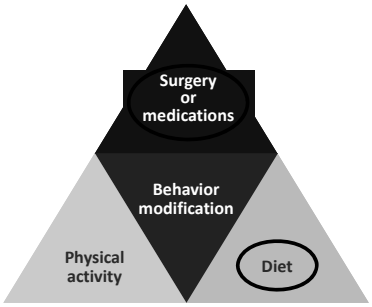
- Prevent T2DM[1]
- Improve glycemic control in T2DM
- Reduce need for antidiabetic agents
- Reduce blood pressure
- Reduce triglycerides
- Increase HDL-C
- Reduce CRP
- Improve symptoms of sleep apnea
- Improve markers of NAFLD



CRP: C-reactive protein; DPP: Diabetes Prevention Program; HDL-C: high-density lipoprotein cholesterol; NAFLD: nonalcoholic fatty liver disease.

1. Hamman RF et al. *Diabetes Care*. 2006;29:2102-2107.
2. http://www.lookaheadtrial.org/public/bibliography.pdf. Accessed September 17, 2014.

Components of an Effective Obesity Management Program[1,2]



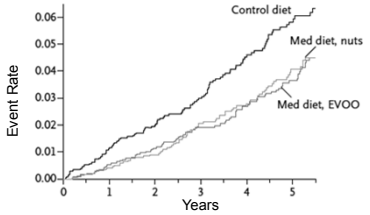
1. Wadden TA, Foster GD. *Med Clin North Am*. 2000;84:441-461.
2. Stumbo PH et al. *Surg Clin N Am*. 2005;85703-85723.

What's the best diet for my patients?

- No diet is "The Best"
- We favor low glycemic, Mediterranean diet
  - Appears to improve compliance
  - Reduces CV risk

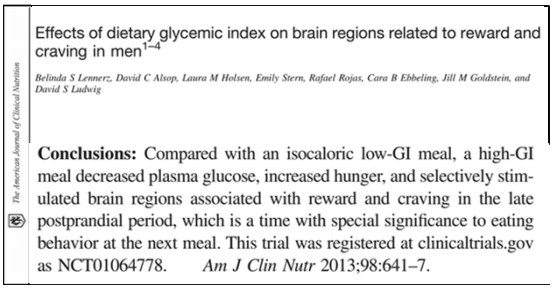
Primary Prevention of Cardiovascular Disease with a Mediterranean Diet

- 7447 persons were enrolled (55-80 years); 57% were women.
- Med Diet /Extra Virgin Olive oil – l L/week
- Med Diet /Nuts – 1 oz/day
- Control Diet - Low Fat



Among persons at high cardiovascular risk, a Mediterranean diet supplemented with extra-virgin olive oil or nuts reduced the incidence of major cardiovascular events.

Estruch R, et al, N Engl J Med. 2013 Apr 4;368(14):1279-90.



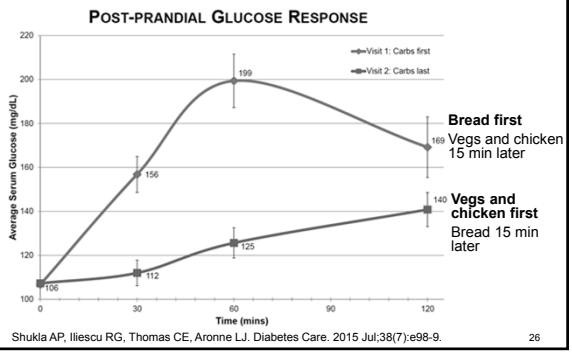
Effects of dietary glycemic index on brain regions related to reward and craving in men[1–4]

Belinda S Lennerz, David C Alsop, Laura M Holsen, Emily Stern, Rafael Rojas, Cara B Ebbeling, Jill M Goldstein, and David S Ludwig

Conclusions: Compared with an isocaloric low-GI meal, a high-GI meal decreased plasma glucose, increased hunger, and selectively stimulated brain regions associated with reward and craving in the late postprandial period, which is a time with special significance to eating behavior at the next meal. This trial was registered at clinicaltrials.gov as NCT01064778. *Am J Clin Nutr* 2013;98:641–7.

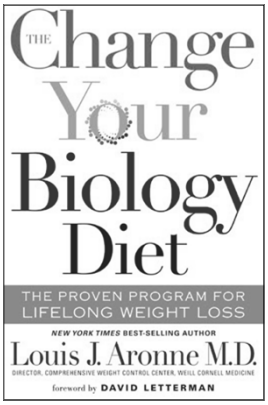
This finding and many others fit with our clinical experience. A low glycemic diet reduces food intake in many people by reducing the urge to eat later in the day. A high glycemic breakfast may make some people hungrier.

Eat Vegetables and Protein Before Carbs
The Order in Which Food is Consumed Impacts Post-prandial Glycemia



Shukla AP, Iliescu RG, Thomas CE, Aronne LJ. Diabetes Care. 2015 Jul;38(7):e98-9.

RESOURCES:
Everything your patients need is in here



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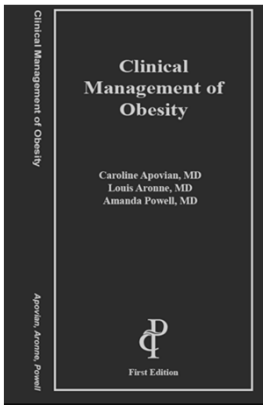


How Do You Deliver a Weight Management Program in a Practice Setting?

RESOURCES:

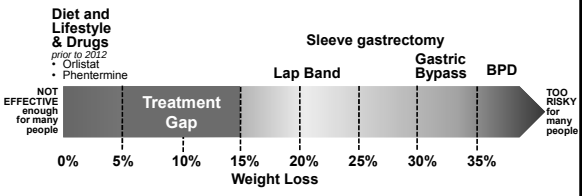
SOON FOR FREE

BMIQ.COM

- Comprehensive delivery system for large scale implementation of a weight management intervention
- Easy to implement, flexible to use, and supports patients outside of the office setting
- Complete program and educational materials for both professionals and patients, including session guides, patient lessons, patient videos, tutorial videos, references, and more

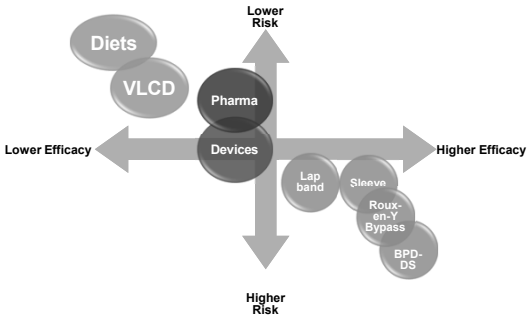
Treatment Gap in Mid-BMI Range

New drugs and devices can reduce weight and weight-related comorbidities



After Aronne L. FDA VI-0521 EMDAC 2010.

Current Treatments: Efficacy and Risks



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PHARMACOLOGICAL MANAGEMENT of OBESITY:

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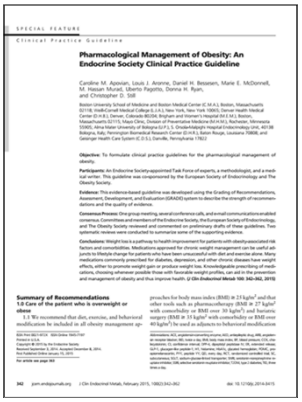
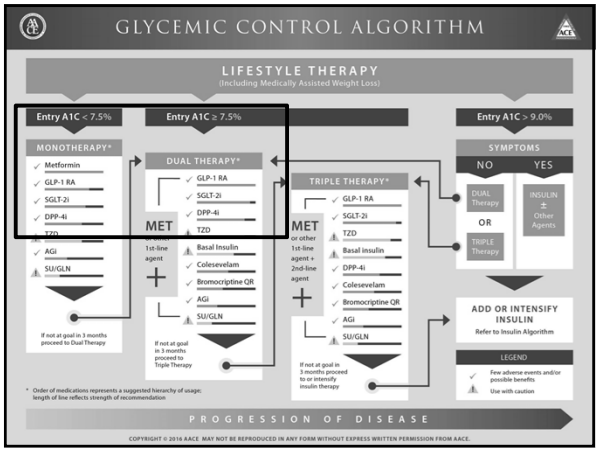


Apovian CM, Aronne LJ, Bessesen D et al. J Clin Endocrinol Metab. 2015;100:342-362.

Medications Can Cause Weight Gain

Before You Prescribe:

- Psychotropic medications
  - Tricyclic antidepressants
  - Monoamine oxidase inhibitors
  - Specific SSRIs
  - Lithium
- Atypical antipsychotics
- Specific anticonvulsants
- Highly active antiretroviral therapy
- Antihistamines
- Diabetes medications
  - Insulin
  - Sulfonylureas
  - Thiazolidinediones
- β-adrenergic receptor blockers
- Metabolic syndrome meds
- Steroid Hormones
  - Glucocorticoids
  - Progestational steroids



Presentation

Case Study

Patient AC
Weight Regain
s/p Lap Band

- 69-year-old M with:
  - Obesity (BMI 35.7 kg/m^2)
  - DM2 (HA1c 6.2)
  - HTN
- S/p lap band 10 years ago
  - Regained all weight
  - Poor dietary compliance
- Medications:
  - Actos 45 mg daily
  - Metformin 500 mg daily
  - Lisinopril 40 mg daily
  - Tricor 145 mg daily
  - Vytorin 10-10 mg daily

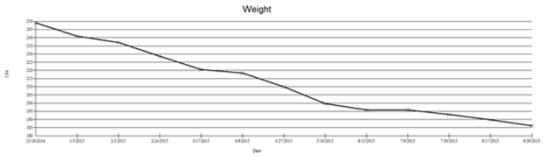
Prescription

Case Study

Patient AC
Weight Regain
s/p Lap Band

- Low glycemic index diet
- D/c'd Actos
- Increased metformin
  - 500 mg BID
  - Titrated up to 1000 mg BID
- Added liraglutide
  - 0.6 mg daily
  - Titrated up to 1.8 mg daily

Patient AC



12/2014
249 lbs

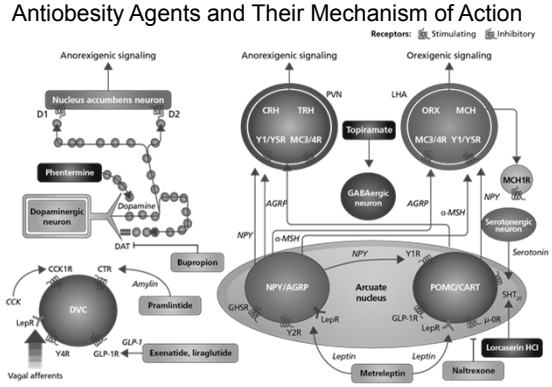
Actos 45 mg
Metformin 500 mg

9/2015
186 lbs

Metformin 2000 mg
Victoza 1.8 mg

63 lb wt loss
over 9 months

Antiobesity Agents and Their Mechanism of Action



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Pharmacotherapy for Obesity: ENDO Society Guidelines[1]

Drug	Mechanism of Action	Mean Weight Loss[a]	Study Duration
Phentermine	Norepinephrine-releasing agent	3.6 kg	2 to 24 weeks
Diethylpropion	Norepinephrine-releasing agents	3.0 kg	6 to 52 weeks
Orlistat	Pancreatic and gastric lipase inhibitor	2.9 to 3.4 kg, 2.9% to 3.4%	1 year
Lorcaserin	$5HT_{2C}$ receptor agonist	3.6 kg, 3.6%	1 year
Phentermine/ topiramate	GABA receptor modulation (topiramate) plus norepinephrine-releasing agent (phentermine)	6.6 kg *(recommended dose)* 6.6%; 8.6 kg *(high dose)*, 8.6%	1 year
Naltrexone bupropion	Reuptake inhibitor of dopamine and norepinephrine (bupropion) and opioid antagonist (naltrexone)	4.8%	1 year
Liraglutide	GLP-1 agonist	5.8 kg	1 year

[a] Mean weight loss in excess of placebo as percentage of initial body weight or mean kg weight loss over placebo.
GABA: gamma-aminobutyric acid; GLP-1: glucagon-like peptide-1.

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Advantages and Disadvantages Associated With Weight-Loss Medications

Key Point: At present, prescribing is often based on cost and side effect profile

Drug	Advantages	Disadvantages
Phentermine	Inexpensive, greater weight loss[a]	Side-effect profile, no long-term data[b]
Topiramate/phentermine	Robust weight loss[a], long-term data	Expensive, teratogen
Lorcaserin	Side-effect profile, long-term data[b]	Expensive
Orlistat, prescription	Nonsystemic, long-term data[b]	Less weight loss[a], side-effect profile
Orlistat, over the counter	Inexpensive	Less weight loss[a], side-effect profile
Natrexone/bupropion	Greater weight loss[a], food addiction, long-term data[b]	Side-effect profile, mid-level price range
Liraglutide	Side-effect profile, long-term data[b]	Expensive, injectable

[a] Less weight loss = 2%-3%; greater weight loss = >3%-5%; robust weight loss = >5%. [b] Long-term data is 1-2 years.

Apovian CM, Aronne LJ, Bessesen D et al. *J Clin Endocrinol Metab*. 2015;100:342-362.

ENDO Society Guidelines: common side effects

Key Point: Side Effects Guide Treatment

Drug	Common Side Effects
Phentermine resin	Headache, elevated BP, elevated heart rate, insomnia, dry mouth, constipation, anxiety; palpitation, tachycardia,
Diethylpropion	
Orlistat	Decreased absorption of fat-soluble vitamins, steatorrhea, oily spotting, fecal urgency, oily evacuation, increased defecation
Lorcaserin	Headache, nausea, dry mouth, dizziness, fatigue, constipation
Phentermine/ topiramate	Insomnia, dry mouth, constipation, paresthesia, dizziness, dysgeusia
Naltrexone bupropion	Nausea, constipation, headache, vomiting, dizziness
Liraglutide	Nausea, vomiting

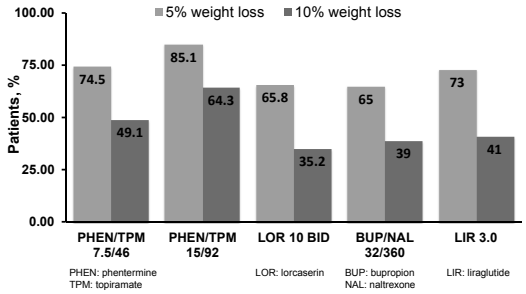
1. Apovian CM et al. *J Clin Endocrinol Metab*. 2015;100:342-362.

ENDO Society Guidelines: common side effects
Key Point: Side Effects Guide Treatment

Drug	Common Side Effects
Phentermine resin	Avoid CV risk, HTN, DM
Diethylpropion	
Orlistat	Avoid diarrhea, bowel disorders, malabsorption, and kidney stones
Lorcaserin	Avoid valvular dz, headaches
Phentermine/ topiramate	Avoid insomnia, kidney stones, CV?
Naltrexone bupropion	Avoid Headaches, pain sensitivity
Liraglutide	Avoid in Pancreatitis, thyroid Ca

1. Apovian CM et al. *J Clin Endocrinol Metab*. 2015;100:342-362.

Odds of Reducing Body Weight by % Categories at 1 Year With Adjunctive Medication Among Those Who Complete Treatment
Combined with lifestyle modification



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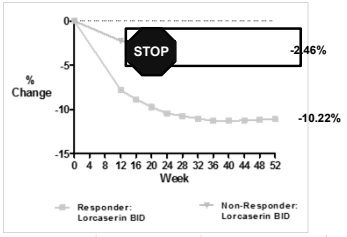
If It Does Work, Don't Bother!
Those Who Lost ≥ 4.5% Total Body Weight by Week 12 Lost 10.2% at 1 year
Lorcaserin



MITT Lorcaserin BID	Week 12	Completed Week 12	Completed Week 52
N = 3097	≥4.5% wt loss	1369/3097 (44.2%)	1083/1369 (79.1%)
	<4.5% wt loss	1168/3097 (37.7%)	680/1168 (58.2%)

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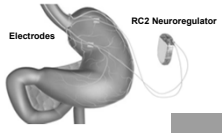
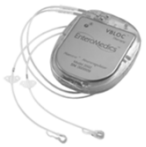
Devices

FDA Approval January 14, 2015

Vagal Blocking Therapy





- Pacemaker-like device designed to control hunger and fullness by blocking the vagus nerve to affect the perception of hunger and fullness
- Satiation by delaying food processing and gastric emptying

%EWL achieved	VBLOC 12 months (N=147)	VBLOC 24 months (N=103)
≥5.0%	67%	58%
≥7.5%	56%	45%
≥10.0%	39%	34%
≥12.5%	32%	27%
≥15.0%	22%	21%

Ikramuddin S, et al. *JAMA* 2014;312(9):915-922

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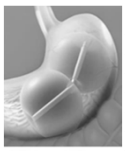
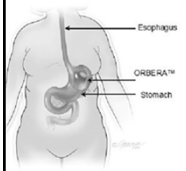
Two Balloon Devices Approved in 2015


ReShape Dual Balloon

ReShape™ Integrated Dual Balloon System
- 25.44% EWL and 11.27% TBWL at 12 months (n=1683)[1]
- Two attached balloons placed into stomach through mouth
- Filled with ~2 cups of saline and a blue dye (methylene blue)
- If a balloon breaks, blue dye will appear in the patient's urine
- Balloons are deflated at removal in 6 months
- FDA approved July 28, 2015
- BMI of 30-40 kg/m^2



ORBERA™ Intragastric Balloon System
- Lost 10.2% of body weight at 6 months
- Placed endoscopically in the stomach through mouth
- Filled with varying amounts of saline (400-700 ml) to best match the patient's body structure
- Maximum use of 6 months before removal
- FDA approved August 6, 2015
- BMI of 30-40 kg/m^2

1. ASGE Bariatric Endoscopy Task Force, et al. Gastrointest Endosc. 2015 Sep;82(3):425-38.e5.
2. www.fda.gov/MedicalDevices

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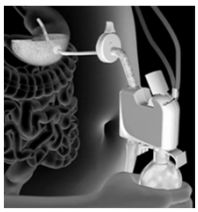
Devices in Trial: Aspire Assist

- Removable device
- 20 minute procedure is performed under conscious sedation – no general anesthesia is required
- Removes ~30% of food from stomach before calories are absorbed, causing weight loss
- Thin tube connects inside of stomach directly to a discreet Skin-Port on outside of abdomen. Valve on port valve controls flow of stomach contents
- Aspiration process is performed ~20 minutes after entire meal is consumed and takes 5 to 10 minutes to complete, 3x/day

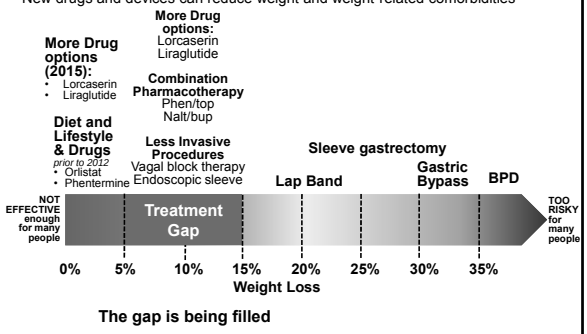


16 weeks mean weight reduction:
– 12.4 kg, 32.2% Excess Weight Loss

http://aspirebariatrics.com/about-the-aspireassist/

Treatment Gap in Mid-BMI Range

New drugs and devices can reduce weight and weight-related comorbidities



The gap is being filled

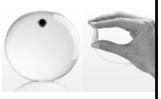
After Aronne L. FDA VI-0521 EMDAC 2010.

Questions you may have???

- Q: What medicine should I use for which patient?
  - A: Based on side effect profile and coverage
- Q: What about metformin?
  - A: It works
- Q: What do you use for drug-induced weight gain?
  - A: Depends on the drug, how critical, what the MD prescribing it says

Balloon Devices Under Review

Name	Procedure	Time	Weight Loss
Obalon Balloon Pill Obalon	Attached to lightweight catheter; swallow with water; dissolves in stomach	3 mos	**50.2% Excess Weight Loss** 8.3% Total Body Weight Loss and 2.8 point reduction in BMI in 3 months (n=110)
The Elipse Allurion Technologies	**"Procedure-less"** Swallowed and excreted without surgery, endoscopy, or anesthesia	3 mos	**13% Excess Weight Loss** at 6 weeks 3.0 kg total body weight loss 6 weeks

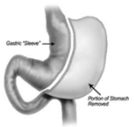


http://www.obalon.com/hcp/en/
http://allurion.com/the-elipse-gastric-balloon/

Endoscopic Sleeve Gastroplasty

Minimally invasive, safe and cost-effective

- N = 25 obese patients
- Reduced excess body weight by 54% at one year
- Outpatient treatment, requiring less than two hours of procedure time
- Patients resumed normal lifestyle in 1-3 days
- Performed using standard "off-the-shelf" endoscopic tools
- Cost roughly 1/3 that of bariatric surgery



- Gastric emptying significantly delayed
- Satiation increased
- Caloric intake decreased
- Serum ghrelin levels decreased by 29%
- Insulin resistance decreased
- Postprandial glucose levels decreased

Abu Dayyeh BK, et al. Clin Gastroenterol Hepatol 2015 Dec 31; [e-pub]. In press.

Endoscopic Sleeve Gastroplasty

Minimally invasive, safe and cost-effective

BACKGROUND AND AIMS:

- Our aim was to evaluate the safety, technical feasibility, and clinical outcomes for endoscopic sleeve gastroplasty

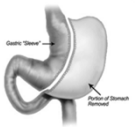
PATIENT AND METHODS:

- ESG was performed on 10 patients using an endoscopic suturing device August 2013 and May 2014. Weight loss, waist circumference, and clinical outcomes were assessed.

RESULTS:

- Differences in mean BMI and waist circumference were 4.9 kg/m^2 (P=0.0004) and 21.7 cm (P=0.003), respectively.
- There were no significant adverse events noted.

Results	1 month	3 Months	6 Months
Excess wt loss	18%	26%	30%
Mean wt loss	11.5 kg	19.4 kg	33 kg

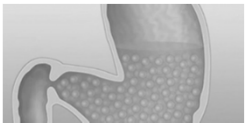


N=10
43.7 years mean age
45.2 kg/m^2 mean BMI

Sharaiha RZ, et al. Endoscopy. 2015 Feb;47(2):164-6.

Devices in Trial: GELESIS100 Polymer

- Superabsorbent hydrogel capsules taken orally prior to a meal
- Contain small particles that expand ~100 times when hydrated in the stomach and small intestine, triggering several important satiety and glycemic control mechanisms
- Mean ± SD body weight percent change from baseline to the end of 12 week treatment were -6.1 ± 5.1% (P=0.026) with Gelesis100 2.25 g



www.gelesis.com/press-releases/06232014.php