



CARDI•OH

Ohio Cardiovascular Health Collaborative



In partnership with:



Cardi-OH ECHO Weight Management A Patient-Centered Approach

Thursday, December 12, 2019

Disclosure Statements



The following planners, speakers, moderators, and/or panelists of the CME activity have financial relationships with commercial interests to disclose:

- Adam T. Perzynski, PhD reports being co-founder of Global Health Metrics LLC, a Cleveland-based software company and royalty agreements for forthcoming books with Springer publishing and Taylor Francis publishing.
- Siran M. Koroukian, PhD received funds for her role as a site PI on a subcontract with the Cleveland Clinic.
- Christopher A. Taylor, PhD, RDN, LD, FAND reports grant funding and travel support for his role as a consultant, researcher, and presenter for Abbott Nutrition, and is also a member of the Scientific Advisory Council of Viocare, Inc.
- These financial relationships are outside the presented work.

All other planners, speakers, moderators, and/or panelists of the CME activity have no financial relationships with commercial interests to disclose.

The Future & Wrap-up



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Objectives



After attending this brief didactic session, you should be able to accomplish the following:

- 1) List and describe a minimum of 2 emerging pharmacotherapies for obesity care.
- 2) List and describe a minimum of 3 endoscopic balloon treatments for obesity care.
- 3) Summarize changes in the relative use of bariatric surgery procedures over the past decade.



Deborah A. Cohen
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**Senior Physician
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by [Deborah A. Cohen](#)

Two years ago, much ado was made about what appeared to be a decline in obesity rates among 2- to 5-year-olds, a finding based on a national study of fewer than 1,000 children that age. However, subsequent analyses have shown the decline to be transient at best. The number of overweight, obese and severely obese children in that age group—as well as older children, adolescents and adults—has only continued to climb.

Significant efforts to address obesity have been made, but they have not been effective at a national level. They include improving the quality of food available at public schools and encouraging more school-based physical activity, but they have not addressed the larger food environment at the community level.

It has been a mistake to treat childhood obesity as a separate subcategory of obesity. A school's food environment can be fixed, but as soon as children leave campus, they are exposed to the underlying cause of the epidemic—"food swamps" filled with fast-food places and convenience stores that aggressively market low-nutrient foods or offer excessive portions of food that set up people to eat more calories than they can burn.

Topics

[Diet and Nutrition](#)
[Obesity](#)
[United States](#)

Deb Cohen, PhD



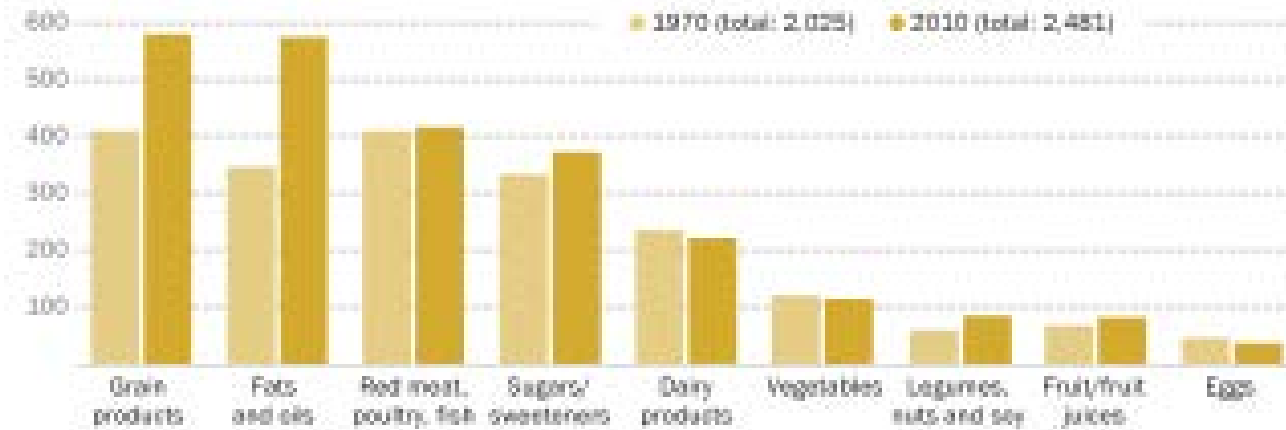
The largest barrier to taking effective action is the mistaken belief that each individual has the capacity to ignore or transcend the food environment.

Reducing the salience, convenience, and ubiquity of junk food may be politically difficult, but ultimately will be necessary.



Modern American diet has gotten bigger, heavier on grains and fat

Average daily per capita calories

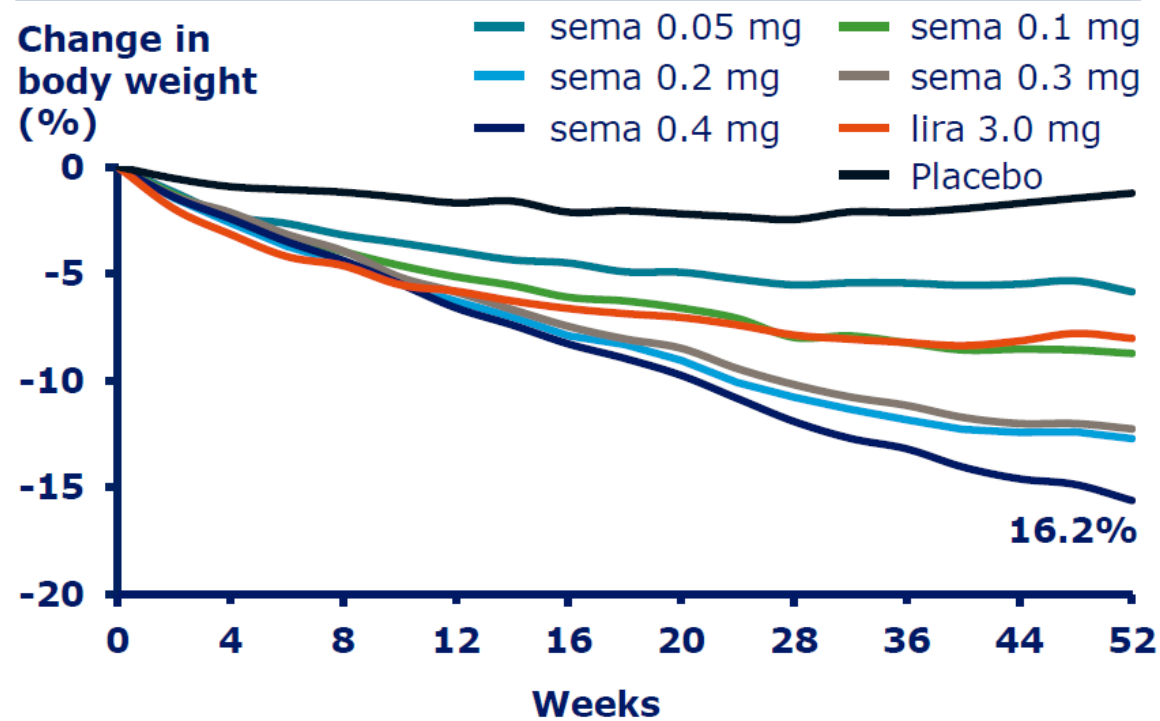


Note: "Fats and oils" includes butter, margarine and other dairy fats. Figures adjusted for leakage and other losses.
Source: USDA Economic Research Service; Pew Research Center analysis.

PEW RESEARCH CENTER

Pharmacotherapy - Semaglutide

16.2% weight reduction with the highest semaglutide dose in phase 2 obesity trial



Note: All treatment arms are adjunct to diet and exercise
QD: Once-daily; sema: Semaglutide; lira: Liraglutide

Source: Novo Nordisk investor presentations

Other emerging GLP-1 agonists

- Codatutide



Setmelanotide

An investigational, melanocortin-4 receptor (MC4R) agonist in clinical development for the treatment of rare genetic disorders of obesity



	Proof of Concept	Phase 1	Phase 2	Phase 3
Setmelanotide				
POMC Deficiency Obesity	✓	█	█	█
LEPR Deficiency Obesity	✓	█	█	█
Bardet-Biedl Syndrome	✓	█	█	█
Alström Syndrome	✓	█	█	█
MC4R Pathway Heterozygous Obesity	✗	█	█	█
POMC Epigenetic Disorders	✗	█	█	█

The rise of sleeve gastrectomy in bariatric surgery

- Changes in types of operations in adults:
- 2008 – RYGB 75.4%; AGB 23.8%; Sleeve gastrectomy 0.9%
- 2012 – RYGB 59.6%; AGB 4.1%; Sleeve gastrectomy 36.3%

The beginnings...

- Garren-Edwards Gastric Bubble (GEGB) – approved in December 1984
- Placed endoscopically in the stomach
- Filled with 200-220mL of air
- Free floating
- Removed at 4 months
- 7-10kg weight loss; gradually regained
- Complications: spontaneous deflation; ulcers
- Withdrawn completely in 1992
- No FDA approved intra-gastric balloons until 2015



Tarpon Springs Workshop - 1987



- “Obesity and the Gastric Balloon: A Comprehensive Workshop”
 - 1) construction with high-quality silicone elastomer
 - 2) saline-fluid filled
 - 3) spherical with a smooth surface
 - 4) radiopaque marker
 - 5) volume to be adjustable between 400 – 500mL
 - 6) BMI $\geq 30\text{kg/m}^2$; No prior gastric surgery

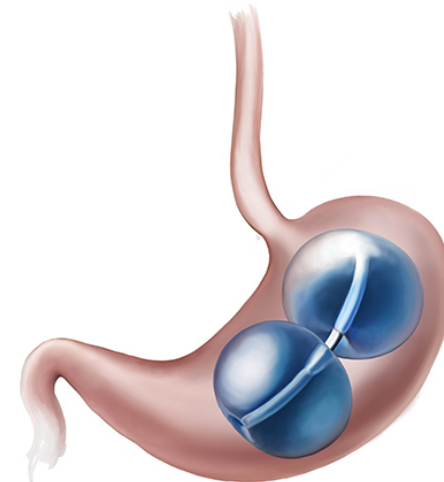
Bioenterics Intragastric Balloon (Orbera)

- 1991
- FDA Approval 2015
- Endoscopic placement and removal (6 months)
- Effectiveness:
 - ASGE Meta-Analysis (2015):
 - At 12 months post-placement
 - 11.3% absolute weight loss;
 - 25.4% EWL
 - At 5 years, average BMI loss is 2.5kg/m²
 - 23% of patients maintain > 20% EWL at 5 years
 - Early removal, 7.5%; migration 1.4%; gastrointestinal perforation, 0.1%.
- Genco et al – European multi-center study:
 - 55.6% EWL at 6 months; 29.1% at 3 years
 - Hypertension prevalence ↓ 29% to 16%
 - Diabetes prevalence ↓ 15% to 10%
 - Hyperlipidemia ↓ 32% to 21%
- FDA revised labeling



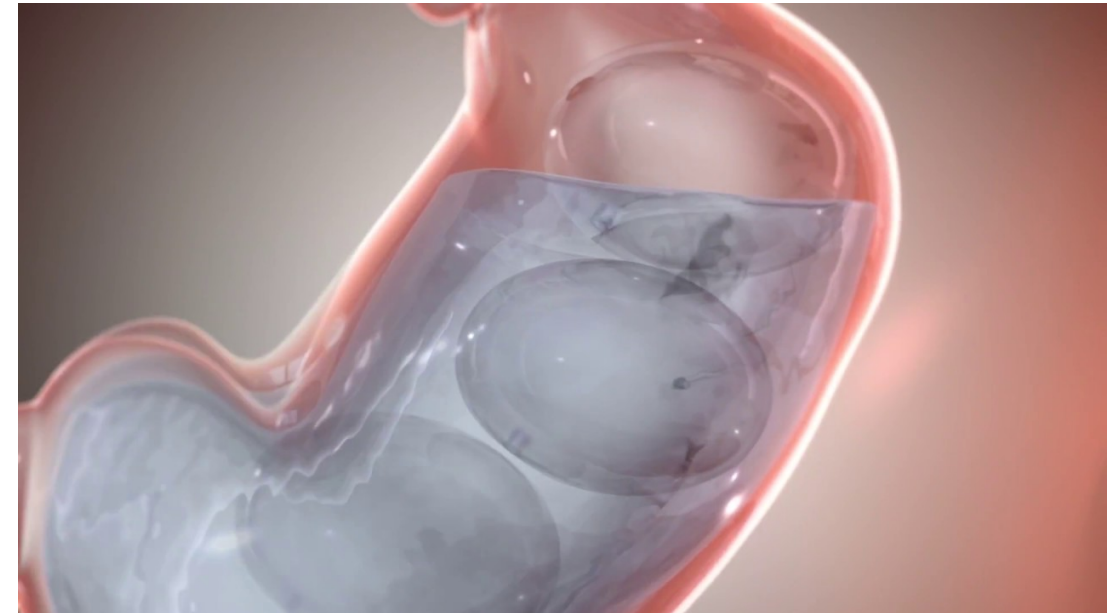
ReShape Integrated Dual Balloon System

- Approved in 2015
- Endoscopic placement and removal
- Saline-filled (750 – 900mL)
- REDUCE sham controlled trial:
 - AT 6 months, EWL was 25.1% vs 11.3% after sham endoscopy
 - Systolic BP fell by 8.3mmHg; HbA1C% fell by 0.2%; LDL fell by 4.1mg/dL
 - 9% of devices removed for intolerance



Obalon

- Approved in 2016
- 3 balloons, placed one month apart.
- Swallowed placement; endoscopic removal
- RCT Results: EWL of 24.1%
- More recent data (cohort)
 - 1300+ dataset
 - Average weight loss of 21.7lbs; 9.9% reduction in body weight
 - Top quartile lost 39lbs on average (16.8% of body weight)



Mechanism of Action

Primary: Delayed gastric emptying

Table 2. Summary of Major Gut Hormones Involved in Appetite Regulation and Their Changes After Bariatric Surgery

Hormones	Site of secretion	Stimulus for secretion	Major actions	Changes after bariatric surgery		
				LAGB	LSG	RYGB
Ghrelin	Gastric fundus (A cells)	Empty stomach	Stimulates appetite and hunger Increases gastric emptying and motility Induces growth hormone release	↑	↓	↓
GIP	Duodenum and jejunum (K cells)	Nutrients in the gut lumen	Incretin effect (release of insulin after ingestion of oral glucose) Promotes satiety	Unclear	Unclear	↓
GLP-1	Ileum and colon (L cells)	Nutrients in the gut lumen	Incretin effect (release of insulin after ingestion of oral glucose) Promotes satiety Delays gastric emptying	↑	↑	↑
PYY	Ileum and colon (L cells)	Nutrients in the gut lumen	Promotes satiety Delays gastric emptying Ileal break	↑	↑	↑
Oxyntomodulin	Ileum and colon (L cells)	Nutrients in the gut lumen	Promotes satiety Delays gastric emptying Agonist of GLP-1 receptors	Unclear	Unclear	↑

Business

New Plenity™ Pivotal Safety and Efficacy Data to be Presented at ObesityWeek 2019

October 29, 2019 7:00 AM

...The bottom line

- Policy changes to promote a healthier built environment are our only long-term hope.
- Consider obesity a chronic, relapsing condition, for which a number of treatments are available.

Thank you!

Questions/Discussion

Reminders

- A Post-Clinic Survey will be emailed to you. Please complete this survey as soon as possible.
- *The MetroHealth System is accredited by the Ohio State Medical Association to provide continuing medical education for physicians.*
- *The MetroHealth System designates this educational activity for a maximum of 1 AMA PRA Category 1 Credit(s)TM. Physicians should only claim credit commensurate with the extent of their participation in the activity.*



Final ECHO Evaluations



- You will receive two surveys at the completion of today's clinic:
 1. Week 12 Post-Clinic Survey (please complete by Friday, 12/13/19 at 5:00 PM)
 2. Exit Survey (please complete this series evaluation by Friday, 1/10/20 at 5:00 PM)
- To those who wish to claim CME credits:
 - You will receive a survey from the CME office through MyEvaluations.com on Tuesday, 12/17/19. You will need to register with MyEvaluations.com to begin this process.

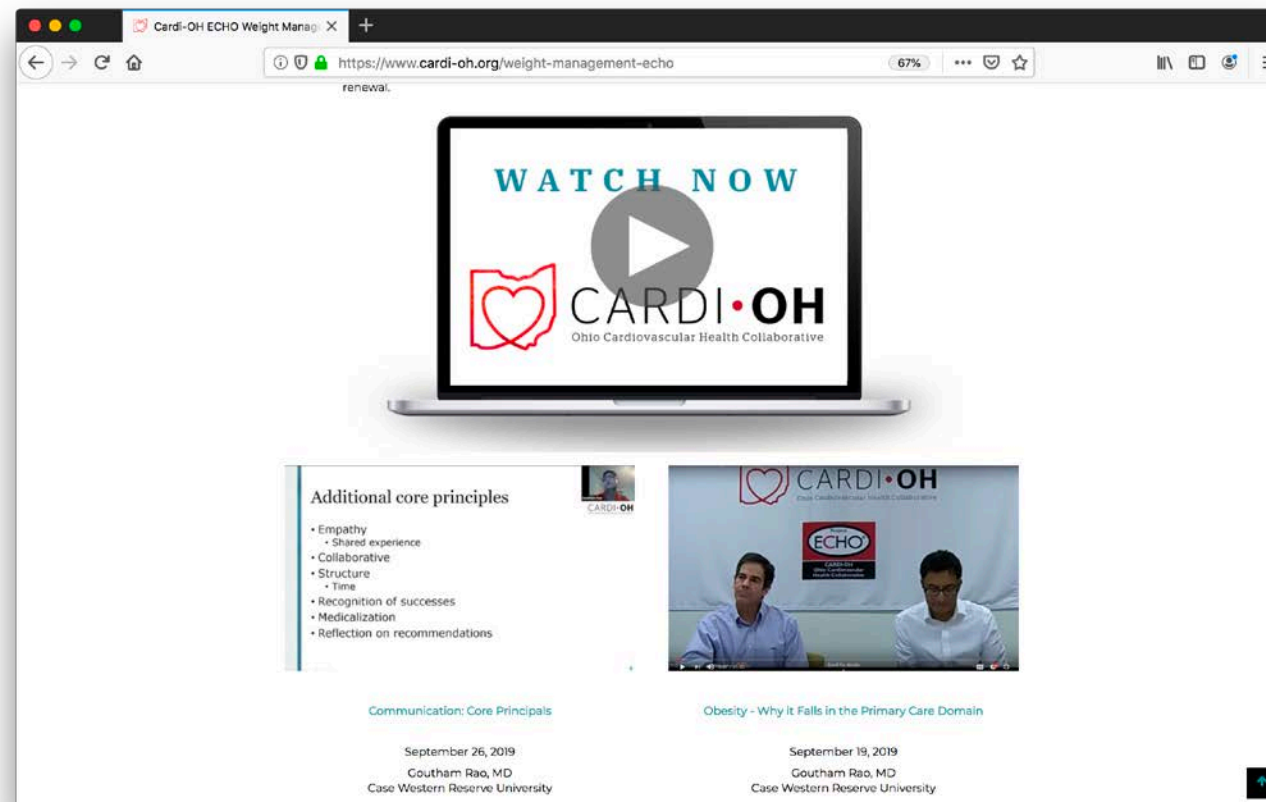
Watch Previous ECHO Clinics



Register with Cardi-OH and watch all ECHO Weight Management Clinics

<https://www.cardi-oh.org/user/register>

<https://www.cardi-oh.org/echo/weight-management-fall-2019>





Registration is Open!



Spring 2020 teleECHO Clinic: **Reducing the Burden of Hypertension**

Thursdays, 8-9 AM, January 16 – April 2, 2020

<https://www.cardi-oh.org/echo/hypertension-spring-2020>