New Guidelines for Obesity Clarity or Confusion?

Donna Ryan, MD
Professor Emerita
Pennington Biomedical Research Center
Baton Rouge, LA

Disclosures

- Dr. Ryan has received financial remuneration for services rendered to Eisai, Novo Nordisk, Takeda, Vivus and Real Appeal and has ownership interest in Scientific Intake.

Objectives

- describe the different methodologies behind
  - 2013 Obesity Guidelines (AHA/ACC/TOS)
  - AACE 2014 Advanced Framework for Obesity Management
  - ASBP 2013 Algorithm for Obesity Management
  - ENDO 2015 Guideline for Pharmacologic Management of Obesity
- relate the major recommendations for patient management from these guidelines targeted to primary care providers
- recognize the differences in guidances based on methodologies and describe the limitations of each in formulating patient care decisions.

New Guidelines for Obesity – Clarity or Confusion?

- AHA/ACC/TOS Guidelines (2013)
  - Based on systematic evidence review of 5 topics
- AACE Advanced Framework (2014)
  - Expert opinion on framing obesity as chronic disease
- ASBP Algorithm (2014)
  - Expert opinion, broad and holistic in annual slide set
- ENDO Guidelines Pharmacologic Management of Obesity (2015)
  - Systematic evidence review of 2 topics

Where to find them…

- Jensen MD, Ryan DH, Donato KA, et al. Guidelines (2013) for managing overweight and obesity in adults. Obesity 2014;22(S2):S1-S410.
- AACE Advanced framework for a new diagnosis of obesity as a chronic disease. Available at https://www.aace.com/files/2014-advanced-framework-for-a-new-diagnosis-of-obesity-as-a-chronic-disease.pdf
- Seger JC, Horn DB, Westman EC, Primack C, et al. Obesity Algorithm, presented by the American Society of Bariatric Physicians, 2014-2015. www.obesityalgorithm.org
- Apovian CM, Aronne LJ, Bessesen DH et al. Pharmacologic Management of obesity: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2015;100(2):342–362.

All may be downloaded free of charge.

Too much information?

Not when you consider the burden of disease….

- Overweight and obesity affect ~ 69% of US adults

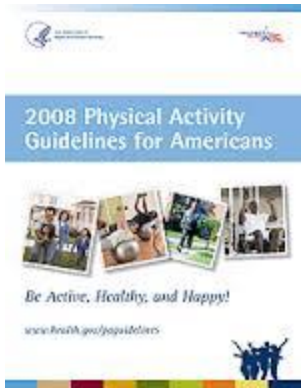
  35% are obese
- Obesity affects ~ 17% of US children ages 2-19
- Minorities, women, and people of lower socioeconomic status have higher obesity rates - but *everyone* is at risk
- The estimated economic costs of obesity in the US is over $215 billion annually
- People with obesity pay on average of $1,429 more each year for health care than non-obese people

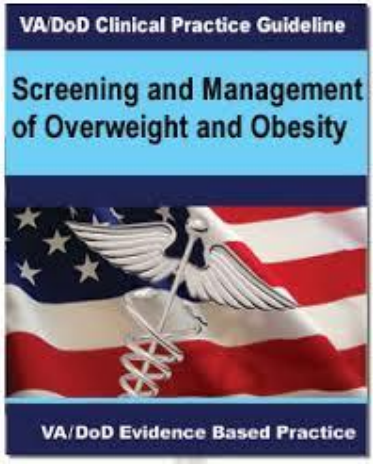
http://www.nhlbi.nih.gov/health/public/heart/obesity/wecan/healthy-weight-basics/obesity.htm. Accessed April 30, 2014; Go AS, et al. Circulation. 2014;129(3):e28-e292; Hammond RA, et al. Diabetes Metab Syndr Obes. 2010;3:285-95.

And that's not all…

- > 44 countries have published obesity guidelines
  - NICE Guidelines -National Institute for Health and Clinical Excellence. (UK). 2014 Nov.6.
- US Lifestyle Guidelines overlap in dietary and physical activity recommendations
  - ACC/AHA Lifestyle Guidelines (2014)
  - Dietary Guidelines for Americans (2015)
  - Physical Activity Guidelines for Americans (2008)

NICE National Institute for Health and Care Excellence





… and although the target is primary care, there is a need for training of health care providers.

BECOMING A PHYSICIAN

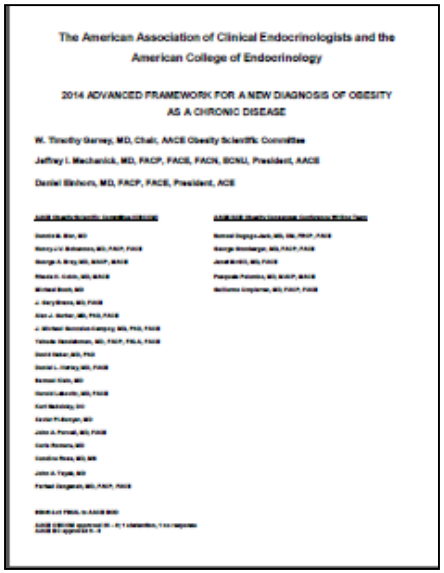
Training Physicians to Manage Obesity — Back to the Drawing Board

James A. Colbert, M.D., and Sushrut Jangi, M.D.

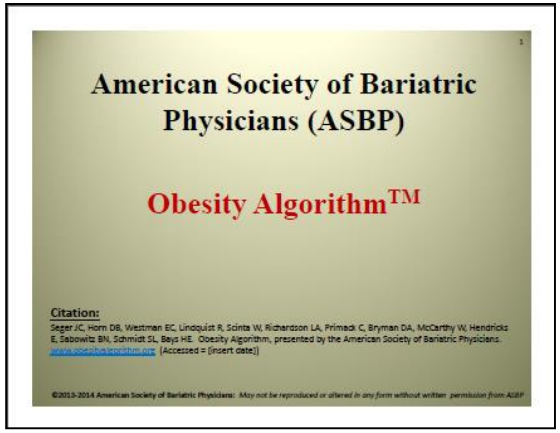
According to the Centers for Disease Control and Prevention, nearly one third of U.S. children and about two thirds of U.S. adults are overweight or obese (see map) and therefore at increased risk for hypertension, diabetes, and musculoskeletal disease. If the trend continues unchecked, half the adults in the United States may be obese by 2030. Although a few clinics specializing in weight

Primary Sources (Guidelines) in this talk….

Obesity 2
ACC/AHA/TOS



AACE
Advance Framework



ASBP
Obesity Algorithm™

ENDO
Pharma Management

The Good News… These Guidelines

- Are not contradictory – they are additive
- Achieve different objectives, relevant to the target audience and goals
- (despite using different methodologies)

Obesity 2	AACE obesity as chronic disease	ASBP	ENDO Pharmacotherapy
Most stringent Systematic Evidence Review	Consensus opinion	Consensus opinion	Systematic Evidence Review
Trustworthy, authoritative with focus on 5 questions	Focus on specialty approach to obesity as disease	Detailed approach to weight management	Focus on prescribing in patients with obesity

The Good News… These Guidelines are additive

Obesity 2	AACE obesity as chronic disease	ASBP	ENDO Pharmacotherapy
Narrow: 5 critical questions • Benefits of weight loss • Risks of excess weight • Best diet for weight loss • Efficacy of lifestyle intervention approaches • Efficacy and safety of bariatric surgery	Complications-centric; risk drives treatment intensity • Conceptual: anthropometric and complications-related evaluation. • Actionable: complications-centric approach to treatment decisions.	Holistic approach • Expert opinion of obesity specialists • covers etiology, pathogenesis, all forms of therapy (counseling, medications, drugs, devices) • presented in PowerPoint format	Targets prescribing patterns Narrow: 2 topical areas • Medications approved for weight loss • Weight effects of medications used for chronic disease management

Let's look at some office scenarios; systematic reviews will be emphasized but we will expand to recommendations aided by expert opinion…

How Do You Decide Who Needs Medical Help to Lose Weight?

1. I use ideal body weight criteria (from life insurance tables).
2. I use BMI criteria.
3. I use BMI and waist circumference.
4. I use BMI and health risk.
5. I wait for the patient to ask for help.

First Major Message from 2013 Obesity Guidelines

- It is imperative that PCPs engage in weight management as a pathway to better health for their patients.
- Screen with BMI at every visit. But BMI is only a screening tool.
- Waist circumference is a risk factor. Use the conventional cutpoints >35 inches for women and > 40 inches for men to identify patients that are high risk.
- Patients that are overweight and obese should be screened for CVD risk factors and comorbidities.
- Who needs to lose weight? BMI $\geq$30 kg/m^2 or BMI $\geq$25 kg/m^2 with a risk factor, like elevated waist circumference.

Obesity Guidelines: Recommendation 1 Grade A (Strong)

To identify patients who might be at risk for CVD, diabetes, all-cause mortality:

- Use BMI as an easily performed first-screening step
- Use waist circumference as an indicator of risk for CVD, type 2 diabetes, and all-cause mortality
- Continue to use current BMI and WC cut points in common use

How Much Weight Does the Patient Need to Lose?

1. 5% is enough
2. 10% is enough
3. The goal is the patient's decision. I say, 'Go for it.'
4. It does not matter, because it will all be regained.
5. They must reach BMI <25.

Second Major Message from 2013 Obesity Guidelines

- You do not need to get your patients to an ideal weight. Modest weight loss has major health benefits.

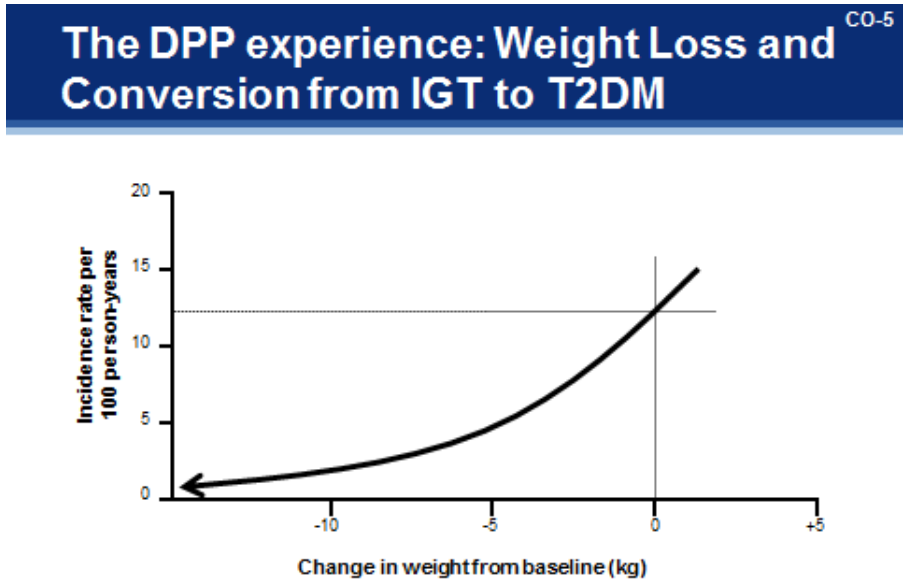
- Patients may do very well with lifestyle changes (diet and exercise). But if they struggle, we need to intensify approaches.

Obesity Guidelines: Recommendation 2 Grade A (Strong)

Counsel patients about the benefits of weight loss:

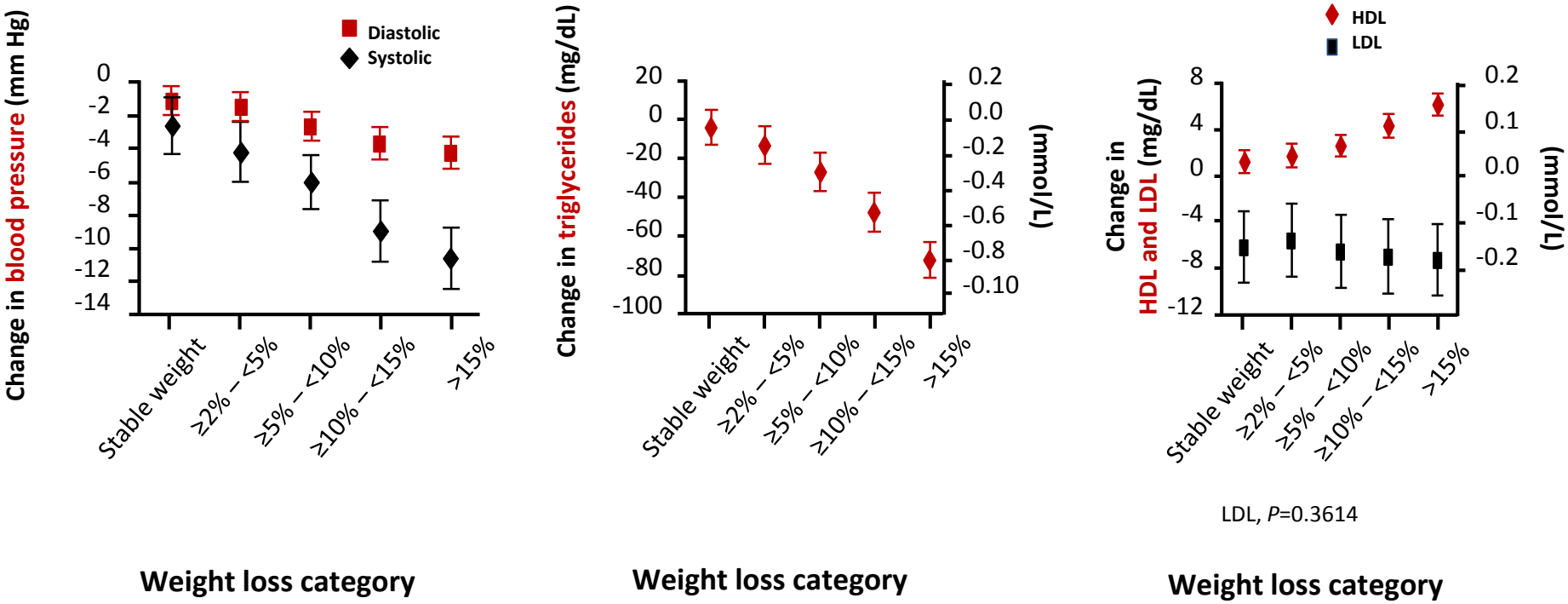
- Lifestyle changes that produce modest (3% to 5%) sustained weight loss result in clinically meaningful health benefits - improvements in TG, glucose, HbA1c, and diabetes risk.
- Greater amounts of weight loss improve blood pressure, LDL-C, HDL-C, and reduce the need for medications to control blood glucose, blood pressure, and lipids, as well as further reduce TG and glucose.

Note: most studies recommended a goal of 5% to 10% weight loss



Hamman, et al Diabetes Care 29:2102-2107,2006.

Look AHEAD 1-year Data: Modest Weight Loss (5% to 10%) Improved CVD Markers



Data presented as adjusted least square means and 95% CIs. Stable weight defined as ±2% of baseline weight. $P<0.0001$ vs baseline for all weight categories,unless specified otherwise.

Wing RR, et al. *Diabetes Care*. 2011;34(7):1481-1486.

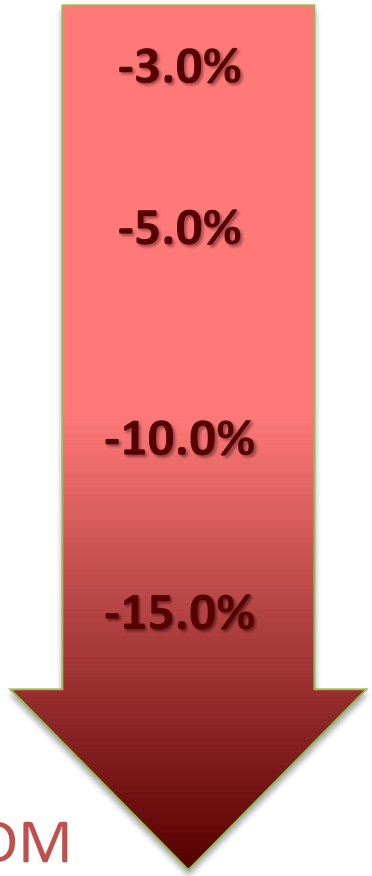
Does this mean that we only need to target modest weight loss?

AACE: Obesity with a serious complication warrants aggressive initial therapy: lifestyle + meds and consider bariatric surgery.
ASBP: Goals are multiple – improve health, improve quality of life, improve body weight and body composition

The principle: the goal is improving targeted health goals through weight reduction

Modest Weight Loss Has Benefits, with Greater Weight Loss Associated with Greater Benefit

- Measures of glycemia[1]
- Triglycerides[1] and HDL cholesterol[1]
- Systolic and diastolic blood pressure
- Hepatic steatosis measured by MRS[2]
- Measures of feeling and function:
  - Symptoms of urinary stress incontinence[5]
  - Measures of sexual function[6,7]
  - Quality of life measures (IWQOL)[8]
- NASH Activity Score measured on biopsy[3]
- Apnea-hypopnea index[4]
- Reduction in CV events, mortality, remission of T2DM



1. Wing *et al. Diabetes Care* 2011;34:1481-1486
2. Lazo *et al. Diabetes Care* 2010;33:2156–2163
3. Promrat *et al. Hepatology* 2010;51:121–129
4. Foster *et al. Arch Intern Med* 2009;169:1619–1626
5. Phelan *et al. Urol*. 2012;187:939-944
6. Wing *et al. Diab Care* 2013;36:2937-2944
7. Wing *et al. Journal of Sexual Medicine* 2010 ; 7:156-65
8. Crosby, *Manual for the IWQOL-LITE Measure* www.qualityoflifeconsulting.com
9. Sjostrom,*et al*

How do we handle patients who have unrealistic goals?

Your patient asks, "My husband lost 20 pounds on the Wheat Belly Diet. Will this work for me?" Your response is:

1. Yes, you should try it.
2. Yes, it will work as long as you follow it.
3. No. You must count calories.
4. Let's schedule some time to talk about weight loss?
5. I do not know. I have not read the book.

Copyright © 2011 by The New York Times

THE NEW YORK TIMES BOOK REVIEW

Best Sellers Advice, How-To and Misc

THIS WEEK	HARDCOVER	WEEKS ON LIST
1	**THE 17 DAY DIET,** by Mike Moreno. (Free Press, $25.) Four cycles to help you burn fat every day. (†)	29
2	**GO THE _ TO SLEEP,** by Adam Mansbach. Illustrated by Ricardo Cortés. (Akashic Books, $14.95.) A children's book parody for tired parents.	14
3	**THE DUKAN DIET,** by Pierre Dukan. (Crown Archetype, $26.) A program that rejects calorie counting and assigns protein a major role.	20
4	**PRIME** [illegible] $27.) The actress [illegible] out pioneer offers suggestions on exercise, [illegible] meditation and "successful aging."	4
5	**WHEAT BELLY,** by William Davis. (Rodale, $25.99.) An examination of wheat in modern diets and an argument for its elimination.	
6	**THE 4-HOUR BODY,** by Timothy Ferriss. (Crown Arche[illegible]) [illegible] your Workweek."	38
7	**ONE THOUSAND GIFTS,** by Ann Voskamp. (Zondervan, $16.99.) On living a life of joy.	5
8	**SWITCH,** by Chip Heath and Dan Heath. (Broadway, $26.) How everyday people can effect transformative change at work and in life. (†)	32

THIS WEEK	PAPERBACK
1	**CRAZY LOVE,** by Francis Ch[illegible] Cook, $14.99.) A pastor on br[illegible] quo. (†)
2	**WHAT TO EXPECT WHEN Y[illegible]** and Sharon Mazel. (Workm[illegible]
3	**THE FIVE LOVE LANGUAGE[illegible]** $14.99.) How to communicat[illegible] understand.
4	**EAT TO LIVE,** by Joel Fuhrm[illegible] rich program that offers help[illegible] loss.
5	**FORKS OVER KNIVES,** edit[illegible] $13.95.) A guide to adopting [illegible]
6	**CLARK HOWARD'S LIVING [illegible]** Howard. (Avery, $18.) Small [illegible] debt. (†)
7	**RADICAL,** by David Plat[illegible] challenges Christians to con[illegible] teachings of Jesus. (†)
8	**THE POWER OF NOW,** by E[illegible] A guide to personal growth [illegible]

Third Major Message from 2013 Obesity Guidelines

- There is no magic diet for weight loss. It is about a calorie deficit. Choose the diet composition based on the patient's health status and personal preference.

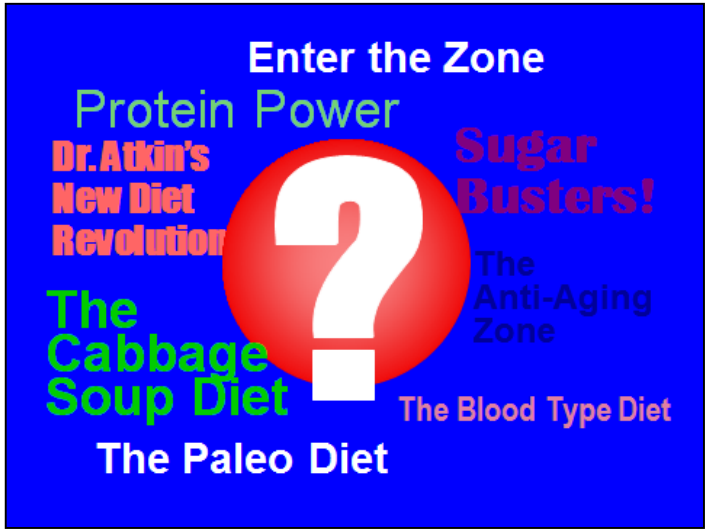
Obesity Guidelines: Recommendation 3 Grade A (Strong)

Prescribe a diet to achieve reduced calorie intake, as part of a comprehensive lifestyle intervention. Use any one of the following methods:

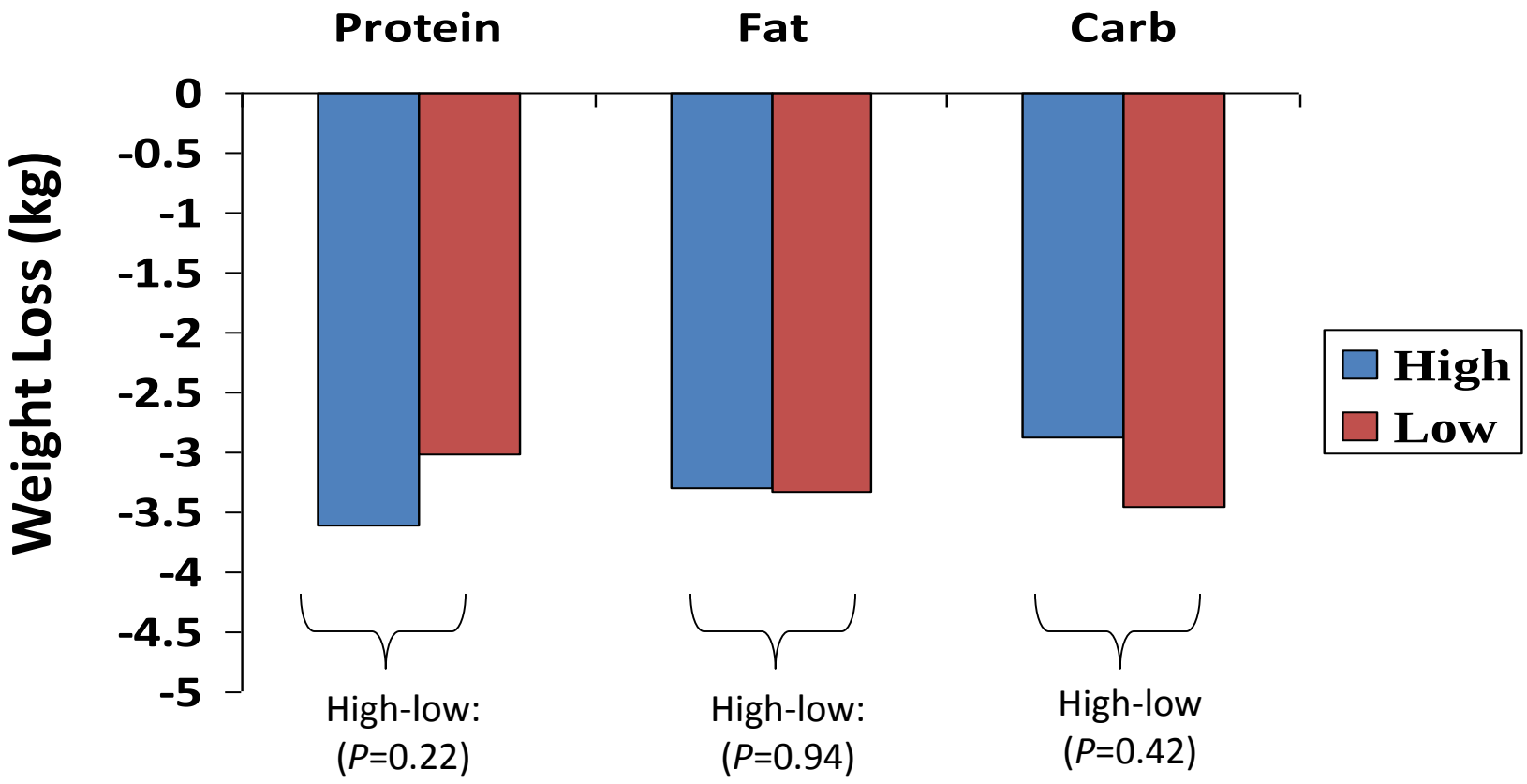
A. 1200 to 1500 kcal/day for women and 1500 to 1800 kcal/day for men;

B. Calculate energy requirements & subtract 500 to 750 kcal/day; or

C. Prescribe one of the evidence-based diets that restricts certain food types (such as, high-carbohydrate foods, low-fiber foods, or high-fat foods)

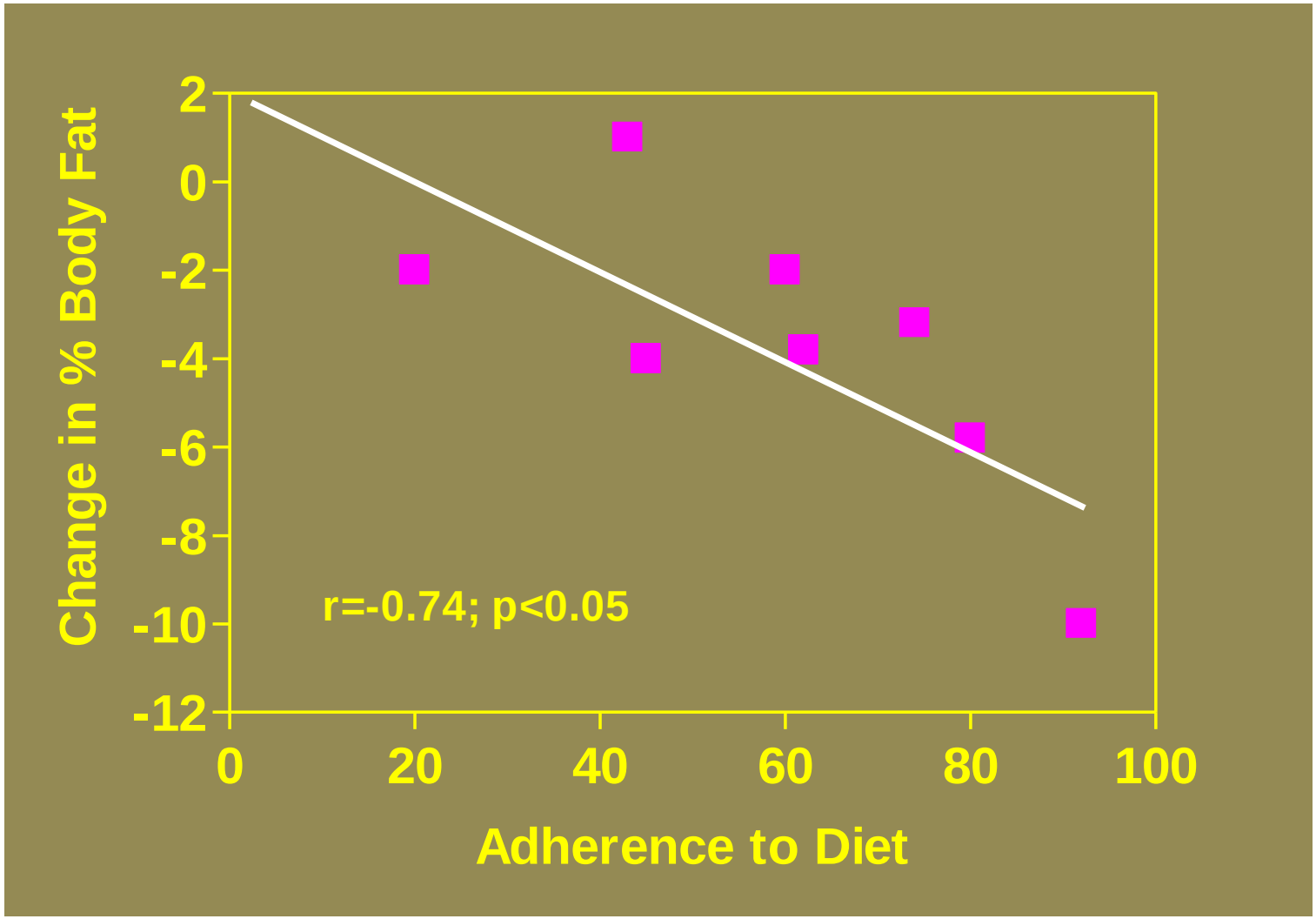


POUNDS LOST: Weight Change from Baseline to 2 years: N=811



Sacks, et al. *NEJM.* 2009;360(9):859-873.

Adherence Predicts Loss of Body Fat During Dieting



Lyon XH, et al. *Int J Obes Relat Metab Disord*. 1995;19(4):260-269.

Does this mean that ANY diet is ok for weight loss, as long as its calorie reduced?

Diet Pattern Recommendations for LDL-C and BP Lowering

Advise adults who would benefit from LDL-C or BP lowering to:

- Consume a dietary pattern that emphasizes intake of vegetables, fruits, and whole grains; includes low-fat dairy products, poultry, fish, legumes, non-tropical vegetable oils and nuts; and limits intake of sweets, sugar-sweetened beverages and red meats.

Strength of evidence: Strong IA

Diet Pattern Recommendations for LDL-C and BP Lowering

Advise adults who would benefit from LDL-C or BP lowering to:

- Adapt this dietary pattern to appropriate calorie requirements, personal and cultural food preferences, and nutrition therapy for other medical conditions (including diabetes mellitus).
- Achieve this pattern by following plans such as the DASH dietary pattern, the USDA Food Pattern, or the AHA Diet.

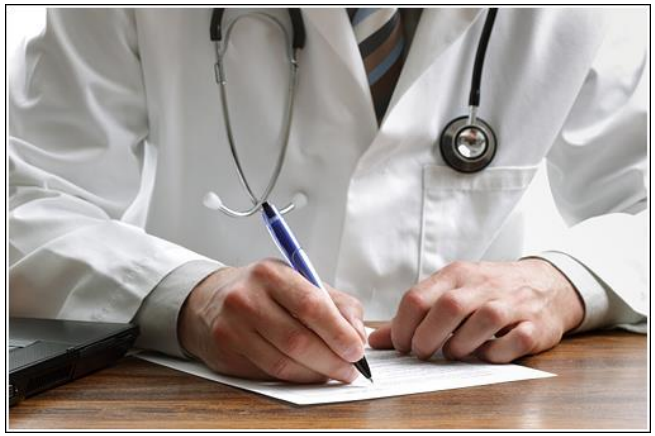
Strength of evidence: Strong IA

Heart Healthy Nutrition and Physical Activity Behaviors for All

- Consume a dietary pattern that emphasizes intake of vegetables, fruits, and whole grains; includes low-fat dairy products, poultry, fish, legumes, non-tropical vegetable oils and nuts; and limits intake of sodium, sweets, sugar- sweetened beverages and red meats.
  - Adapt this dietary pattern to appropriate calorie requirements, personal and cultural food preferences, and nutrition therapy for other medical conditions, e.g. DM. mellitus).
  - Adapt this dietary pattern to appropriate calorie requirements, personal and cultural food preferences, and nutrition therapy for other medical conditions, e.g. DM.

If I give my patient a diet sheet and exercise prescription, what are the odds that the patient will achieve 5% weight loss?

1) 1 in 5
2) 2 in 5
3) 3 in 5
4) 4 in 5
5) 100%, because my patients always take my advice



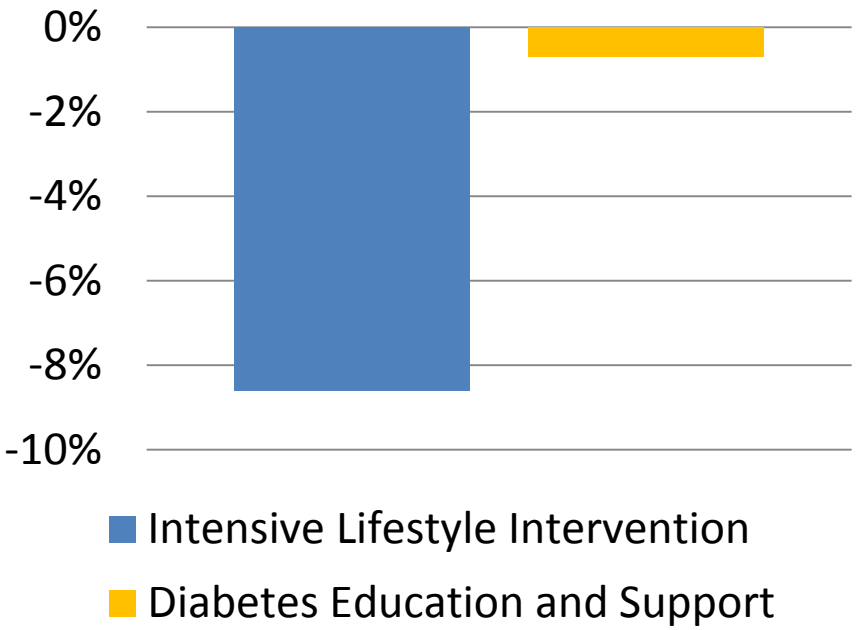
Fourth Major Message from 2013 Obesity Guidelines

- Losing weight requires honing a skill set of behaviors around diet and physical activity.
- Everyone who needs to lose weight should have access to a comprehensive lifestyle intervention program with 14 sessions in 6 months and follow-up for a year.
- If your patient does not have access to a comprehensive program in a medical or community setting, a commercial program with an evidence base to recommend it is acceptable.

Obesity Guidelines: Recommendation 4 Grade A (Strong)

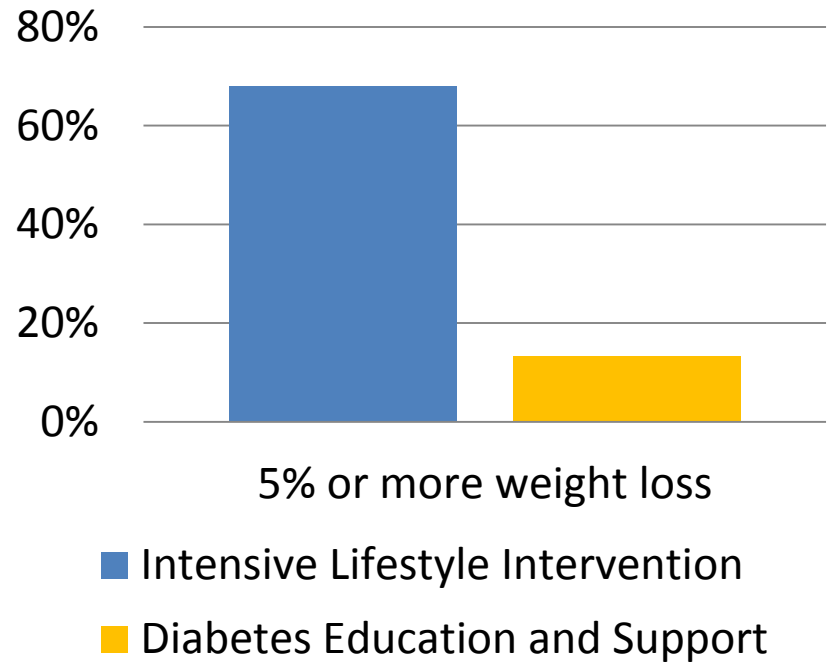
- Patients who need to lose weight should receive a comprehensive program (diet, physical activity, and behavior modification) of 6 months or longer.
- The gold standard is on-site, high intensity (>14 sessions in 6 months) comprehensive intervention delivered in group or individual sessions by a trained interventionist and persisting for a year or more.
- Other approaches (ie, web-based, telephonic) may be used when patients cannot access the gold standard, albeit though the amount of weight loss on average may be less.

Weight Loss at One Year With Intensive Lifestyle Intervention or Support and Education – the Look AHEAD Study



Mean weight loss at one year 8.6% vs. 0.7%

The Look AHEAD Research Group. *Diabetes Care*. 2007 Jun;30(6):1374-1383.



Proportion achieving ≥5% weight loss 68% vs. 13.6%

32% of lifestyle participants did not achieve 5% weight loss

Wadden TA, et al. *Obesity*. 2009;17(4):713-722.

I have a patient who really needs to lose weight – she has obesity, pre-diabetes and she is only 33 years of age. What should the PCP require before prescribing medications along with her lifestyle program?

1. The PCP should see her try to lose weight with a program and if she fails, then prescribe.
2. She needs to show she can lose at least 3% before the PCP should prescribe.
3. She needs to have a history of trying in the past, *and succeeding,* before the PCP should prescribe for this weight loss effort.
4. She needs a history of trying in the past *with or without* success.
5. Past attempts don't matter; she just needs to know she needs help, and share in the decision to choose a medication and lifestyle program.

Messages from Obesity Guidelines on Pharmacotherapy

- Obesity 2: For patients who struggle, intensification is appropriate. Medications as adjuncts to lifestyle intervention are appropriate for patients with BMI $\geq$30 kg/m^2 or $\geq$27 kg/m^2 with a comorbidity, who have a *history* of lack of success.
  - This was based on expert opinion, and is not supported by a systematic evidence review.
  - An algorithm for chronic obesity management is provided in addition to the recommendations from the 5 critical questions.
- ENDO Guidelines on Pharmacotherapy are concordant with Obesity 2 on indications.
  - Based on SER
- AACE: patients with grade 2 obesity (obesity with a serious comorbidity, lifestyle + meds are appropriate initial therapy.

Medications Approved for Chronic Weight Managment and How They Work

http://www.accessdata.fda.gov/scripts/cder/drugsatfda/http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.

Agent	Action	Approval	Scheduled Drug
Orlistat	• Peripheral pancreatic lipase inhibitor; blocks ingested fat absorption	Approved 1997	No
Lorcaserin	• Sympathomimetic • Anticonvulsant (GABA receptor modulator carbonic anhydrase inhibitor, glutamate antagonist)	Approved 2012	• YES
Phentermine/ Topiramate ER	• 5-HT_{2C} serotonin agonist • Little affinity for other serotonergic receptors	Approved 2012	• YES
Naltrexone SR/ Bupropion SR	• Opioid receptor antagonist • Dopamine/noradrenaline reuptake inhibitor	Approved 2014	• NO
Liraglutide 3.0 mg	• GLP-1 receptor agonist	Approved 2014	• No

ER: extended release; GABA: gamma-aminobutyric acid; SR: sustained release.

Principles of Using Medications for Chronic Weight Management

- All drugs rigorously studied; must approximate 5% greater weight loss than placebo, but response is variable.
- Any medication should be assessed at 12 to 16 weeks and stopped if weight loss is not >4% or 5%.
- All drugs have different safety and tolerability profiles; no one drug is right for every patient.
- Choosing a medication is a shared decision between prescriber and patient.

ENDO Obesity Pharmacotherapy Guidelines:
Drugs that Cause Weight Gain and Alternative Approaches for Overweight and Obese Patients

Medications for Diabetes and Weight

WEIGHT GAIN ASSOCIATED WITH USE	ALTERNATIVES (WEIGHT REDUCING IN PARENTHESES)*
Insulin (weight gain differs with type and regimen used) Sulfonylureas Thiazolidinediones Sitagliptin? Metiglinide	(Metformin) (Acarbose) (Miglitol) (Pramlintide) (Exenatide) (Liraglutide)* (SGLT2 inhibitors)

* Only liraglutide 3.0 is FDA-approved for chronic weight management in patients with BMI 30+ kg/m^2 or BMI 27 <30 kg/m^2 with one or more comorbidities.

Apovian CM, Aronne LJ, Bessesen DH et al. Pharmacologic Management of obesity: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2015 doi:10.1210/jc.2014-3415

Cardiologic Medications and Weight

	WEIGHT GAIN ASSOCIATED WITH USE	ALTERNATIVES (WEIGHT REDUCTING IN PARENTHESES)
Hypertension medications	α-blocker? β-blocker?	ACE inhibitors? Calcium channel Blockers? Angiotensin-2 receptor antagonists

Apovian CM, Aronne LJ, Bessesen DH et al. Pharmacologic Management of obesity: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2015 doi:10.1210/jc.2014-3415

Antidepressant Medications and Weight

	WEIGHT GAIN ASSOCIATED WITH USE	ALTERNATIVES (WEIGHT REDUCTING IN PARENTHESES)*
Antidepressants/mood stabilizers: tricyclic antidepressants	Amytriptyline Doxepin Imipramine Nortriptyline Trimipramine Mirtazapine	(Bupropion) Nefazodone Fluoxetine (short term) Sertraline (< 1 yr) * Only naltrexone SR/ bupropion SR combination is FDA-approved for chronic weight management in patients with BMI 30+ kg/m^2 or BMI 27 <30 kg/m^2 with one or more comorbidities
Antidepressants/mood stabilizers: SSRIs	Fluoxetine? Sertraline? Paroxetine Fluvoxamine	
Antidepressants/mood stabilizers: MAO Inhibitors	Phenylzine Tranylcypromine	
Lithium		

Apovian CM, Aronne LJ, Bessesen DH et al. Pharmacologic Management of obesity: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2015 doi:10.1210/jc.2014-3415

Antipsychotic and Anticonvulsant Medications and Weight

	WEIGHT GAIN ASSOCIATED WITH USE	ALTERNATIVES (WEIGHT REDUCTING IN PARENTHESES)*
Antipsychotics	Clozapine Risperidone Olanzapine Quetiapine Haloperidol Perphenazine Quetiapine	Ziprasidone Aripiprizole
Anticonvulsants	Carbamazepine Gabapentin Valproate	Lamotrigine? (Topiramate) (Zonisamide)

* Only phentermine/topiramate ER is FDA-approved for chronic weight management in patients with BMI 30+ kg/m^2 or BMI 27 <30 kg/m^2 with one or more comorbidities

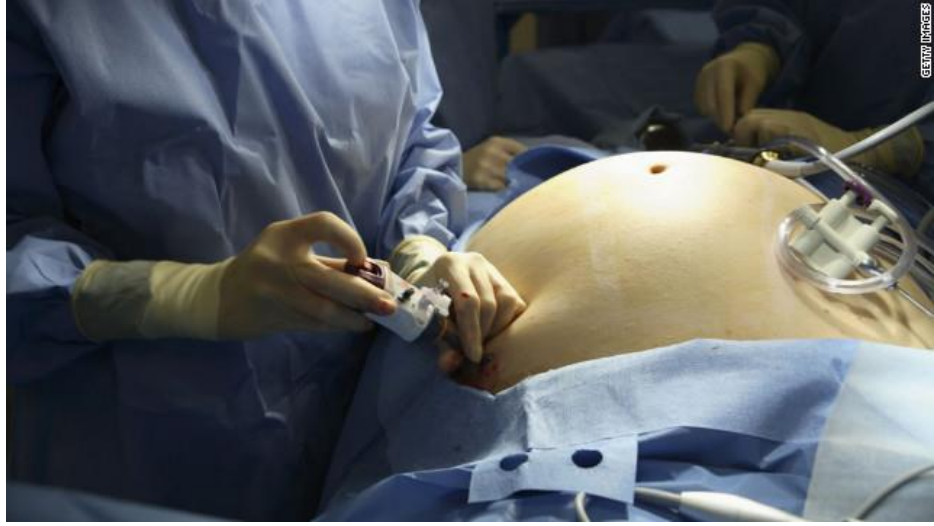
Apovian CM, Aronne LJ, Bessesen DH et al. Pharmacologic Management of obesity: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2015 doi:10.1210/jc.2014-3415

Gynecologic Medications and Weight

	WEIGHT GAIN ASSOCIATED WITH USE	ALTERNATIVES (WEIGHT REDUCTING IN PARENTHESES)
Oral contraceptives	Progestational steroids Hormonal contraceptives containing progestational steroids	Barrier methods IUDs
Endometriosis treatment	Depot leuprolide acetate	Surgical treatment

Apovian CM, Aronne LJ, Bessesen DH et al. Pharmacologic Management of obesity: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2015 doi:10.1210/jc.2014-3415

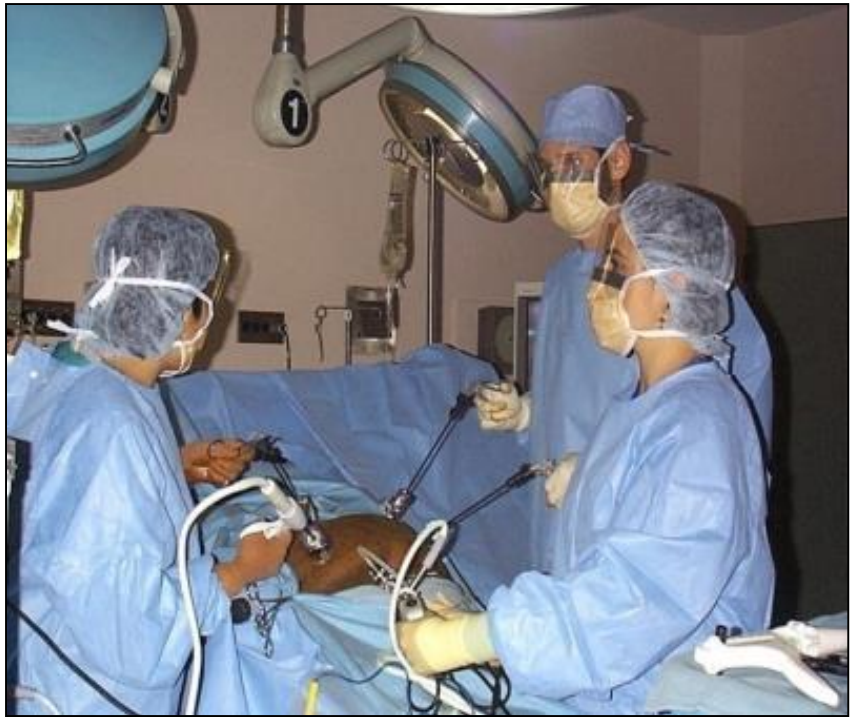
Which Best Describes the PCP Role in Advising Patients About Bariatric Surgery?



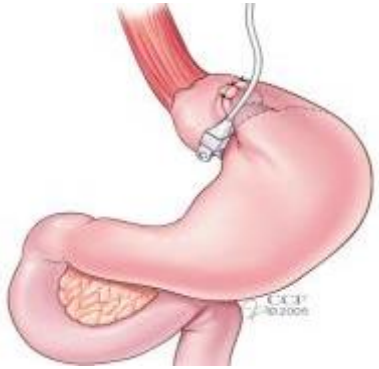
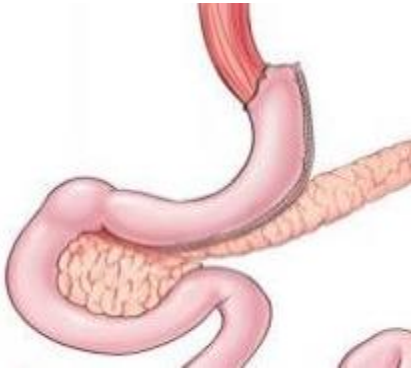
1. They don't advise or refer. Patients choose (or not) to seek bariatric surgery on their own.
2. The PCP should refer if the patient asks for a recommendation.
3. The PCP should ask the patients if they have thought about it and if they are interested, refer. If not, let it go.
4. The PCP should identify patients who meet criteria and who are at serious risk and advise those patients that this should be something they should seriously consider.

Obesity Guidelines: Recommendation 5 Grade A (Strong)

- Advise your patients with a BMI $\geq$35 kg/m^2 and a co-morbidity or $\geq$40 kg/m^2 that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation.



Common Bariatric Surgery Procedures

	Adjustable Gastric Banding 	Sleeve Gastrectomy 	Gastric Bypass 
Pouch Size	Small	Small	Small
Hormone Effects	None	Ghrelin ↓	GLP-1 ↑ PYY ↑
Cost	+	++	++
Weight Loss	+	+++	++++
Peri-operative Risk	+	++	+++

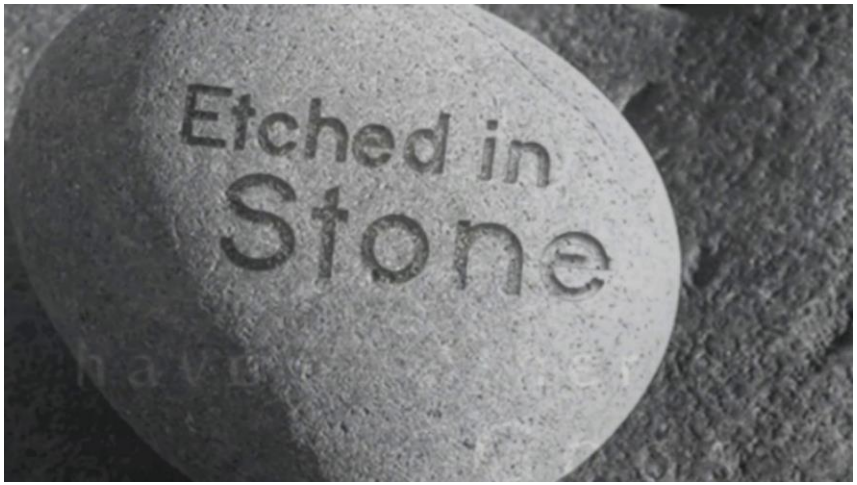
Jensen MD, et al. *J Am Coll Cardiol*. 2013;pii:S0735-1097(13)06030-0. Vincent RP, et al. *Clin Endocrinol* (Oxf). 2008;69(2):173-179.

Take-away Messages

- All primary care physicians must engage in addressing obesity as a pathway to health improvement.
- The systematic evidence reviews are needed for authoritative statements. Our professional societies provide broad guidance on best practices.
- Together, the different Guidelines provide a comprehensive approach to weight management.
- Two spheres of knowledge are needed:
  - Intensive medical efforts at weight loss
  - Chronic weight management over the life course

The Last Words…

The Guidelines are not …



We have a lot to learn about the biologic and behavioral basis of weight loss and weight loss maintenance.

The Guidelines are not…

They are meant to advise clinical practitioners. They are not laws.

Thank You