Battle of the Bulge: A Review of Weight Loss

Medications and Supplements

Disclosure

- · Andrea Chase does not have any actual or potential conflicts of interest to disclose
- No discussion of off-label use of prescription medications, but will discuss a variety of non-prescription agents for weight loss

Presentation Overview

- Introduction
- Discontinued Medications
- Current FDA Approved Medications
- Dietary Supplements
- Herbal Medicine
- Counseling Patients
- Summary

Learning Objectives for Pharmacists

- · Understand the varying definitions and metrics of obesity
- Evaluate the most common side effects of weight loss medications
- Summarize contraindications and precautions of each FDA approved medication
- · Given a patient case, select the most appropriate initial weight loss medication
- Formulate 3 counseling points for patients interested in herbal supplements for weight loss

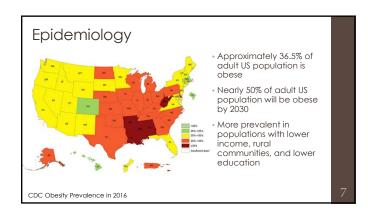
Learning Objectives for Pharmacy **Technicians**

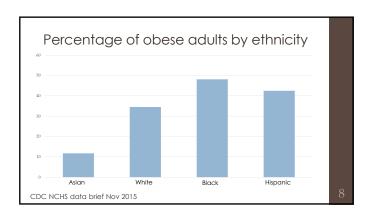
- · Recall the 6 FDA approved medications used for weight loss
- · Identify which FDA medication is also approved for OTC use
- Learn about the regulatory differences between dietary supplements and medications
- · List 2 supplements commonly used for weight loss

What Is Obesity?

- · Excess adipose tissue increases health risks
- Range of biological responses
- · Reduction in energy expenditure
- · Changes in hunger and satiety favoring increased food intake
- · Decreased insulin sensitivity

Am J Clin Nutr. 2006;83:4615-55.





Defining Obesity

- Body Mass Index (BMI)
- Devised in the 1830s by a Belgian astronomer, statistician and sociologist
- · Divide weight (kg) by height squared (m²)
- Coined in 1972 in the Journal of Chronic Diseases
- Explicitly cited as appropriate for **population** studies
- · Inappropriate for individual evaluation

Arch Dis Child. 2006;91(4):283-286.

ВМІ		
Weight Classification	BMI (kg/m²)	
Underweight	< 18.5	
Normal	18.5 to 25	
Overweight	25 to < 30	
Obesity (Class I)	30 to < 35	
Obesity (Class 2)	35 to < 40	
Obesity (Class 3)	40 or higher	
CDC: Defining Adult Overweight and C	Dbesity	10

Oversimplification of BMI

- In 2013 the American Medical Association classified obesity as a disease with the definition of BMI ≥ 30
- Healthcare work force, insurance companies, and general public started using BMI cut-offs as diagnostic
- Individuals can have weight-associated health problems at BMI < 25, others can have no identifiable health problems at BMI ≥ 30

Circulation. 2014;129:\$102-38.

BMI Limitations

- BMI cannot assess **body fat** percentage or regional fat distribution
- Generally accepted cut-offs may not be appropriate for different ethnic populations



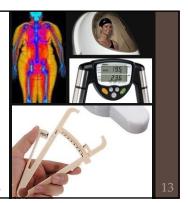
Endocr Pract. 2016;22(3):1-203.

2

Other Methods of Measurement

- Waist circumference
- Percentage above ideal body weight
- Body fat percentage
 - Calipers
- Tape Measurements
- Bioimpedence Bod Pods
- · DEXA Scan

c.ccsu.edu/bdtac/images/BodPod.png c.bodyandbone.com/wp-content/uploads/ 2015/11/BB_de



Contributing Factors to Obesity

- Nutrition
- Genetics
- Physical activity
- Secondary causes

Medication side effects

- Sleep
- Workplace
- Commuting
- Leisure activities
- Community planning

Endocr Pract. 2016;22(3):1-203. J Clin Endocrinol Metab. 2015;100(2):342-62.

Medications with Weight Gain Side Effects

Class	More Weight Gain Potential	Less Weight Gain Potential
Anti-depressants	mirtazapine, paroxetine, amitriptyline	bupropion, fluoxetine
Anti-hypertensives	beta-blockers	ACEIs, ARBs, CCBs
Anti-psychotics	Second generation	First generation
Contraceptives	Depo Provera	oral contraceptives
Corticosteroids	Long-term use, higher doses, systemic, inhaled	Short-term, lower doses, topical
Hypoglycemics	insulin, sulfonylureas	metformin, GLP-1 analogs, SGLT-2 inhibitors

Health Risks Associated with Obesity

- Cardiovascular disease
- Osteoarthritis
- Gallstones
- · Sleep apnea • Some forms of cancer
- Gout Hyperlipidemia
- Type 2 diabetes
- Hypertension
- Non-alcoholic fatty liver
- disease

Endocr Pract. 2016;22(3):1-203. J Clin Endocrinol Metab. 2015;100(2):342-62.

The Cost of Obesity

- Estimated at \$149.4 \$215 billion dollars annually
- Health care costs are approximately 42% higher for obese patients compared to normal-weight patients
- CDC estimates 112,000 excess deaths per year associated
- Individuals with obesity are often excluded from clinical trials, creating paucity of data guiding treatment

WHO Obesity and overweight fact sheet no 311, 2017. TFAH & RWJF, 2016.

Patient Case

JG is a 32-year-old Hispanic female. She is 62" tall and currently weighs 236 lb, her BMI is 43. She also has pre-diabetes and takes metformin. Latest A1c 6.2%. She works 2 jobs and only gets 5-6 hours of sleep most nights.

She decided a year ago ago to change her eating habits and joined a local gym. After losing 10 lb her weight loss has stalled and hasn't budged for the last 6 months.

She feels "doomed to be fat" because her whole family is overweight. You ask if she has considered pharmacotherapy to assist with her weight loss efforts, and she replies, "Aren't those drugs dangerous?"



Patient Case Continued

- Which of the following obesity risk factors apply to JG?
- A. Ethnicity (Hispanic/Latina)
- B. Family history of obesity
- c. Reduced sleep
- D. All of the above
- 2. What weight classification
- (Weight 236 lb, BMI 43)
- A. Overweight
- B. Obesity (Class 1)
- c. Obesity (Class 2)
- D. Obesity (Class 3)

Discontinu	ed W	eight l	oss Agents	
Agent	Introduced	Withdrawn	Concerns	
Thyroid Extract	Late 1800s	1960s	Increased BP, chest pain, arrhythmia	
Dinitrophenol	1930s	1938	Organ failure	
Amphetamines	1950	1973	Addictive properties	
Phenmetrazine	1956	1965	Addictive properties	
Aminorex furarate	1965	1968	Pulmonary hypertension	
Fenfluramine	1973			
Phen-Fen	1992	1997	Pulmonary hypertension Valvular heart disease	
Dexfenfluramine	1996		valvoidi fiedif disease	
Sibutramine	1997	2010	Increased HR, BP Cardiovascular complications	
Phenylpropanolamine	1982	2005	Increased risk of stroke	_
			Dis Model Mech. 2012; 5(5):621-	626.

Current FDA Approved Medications for Obesity

FDA Approved Medications

- · Phentermine (Adipex, Lomaira)
- Orlistat (Xenical, Alli)
- · Lorcaserin (Belviq)
- Phentermine/topiramate ER (Qsymia)
- Naltrexone/bupropion (Contrave)
- · Liraglutide (Saxenda)

Class Characteristics

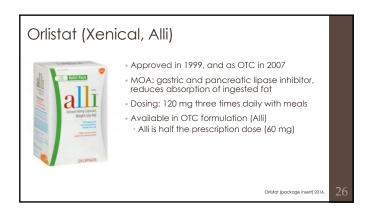
- · Indication for all anti-obesity medications
 - BMI ≥ 30 kg/m²
 - BMI \geq 27 kg/m² in the presence of other risk factors
- · Pharmacotherapy is recommended only as an adjunct to lifestyle modifications
- Contraindication for entire class: pregnancy or lactation

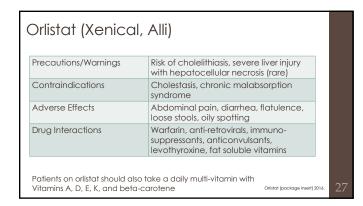


Phentermine (Adipex, Lomaira)

- Approved in 1959 for short-term use only (12 weeks)
- MOA: indirect sympathomimetic,
- Dosing: 15 to 37.5 mg once daily
- Lomaira approved in 2016
- 8 mg tablet three times daily
- Schedule IV Drug

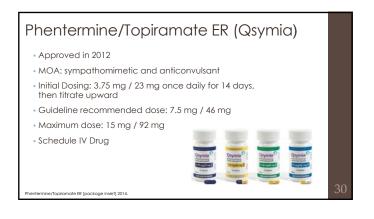
Phentermine (Adipex, Lomaira)	
Precautions/Warnings	Hypertension, heart failure, abuse potential	
Contraindications	History of CV disease, hyperthyroidism, MAOI use (within 14 days), glaucoma	
Adverse Effects	Increased HR and BP, restlessness, insomnia, dry mouth, arrhythmia, pulmonary hypertension (extended use)	
Drug Interactions	Anti-hypertensives, CNS stimulants	
	Phentermine (package insert) 201:	2. 25







Lorcaserin (Belvio	۵)	
Precautions/Warnings	CNS depression, diabetes, psychiatric disorders, priapism	
Contraindications	Severe hepatic impairment ESRD	
Adverse Effects	Headache, hypoglycemia, constipation, bradycardia, serotonin syndrome	
Drug Interactions	Serotonergic agents	
		20
	Larcaserin/Lorcaserin XR [package insert] 2017	29

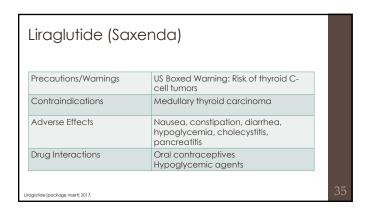


Phentermine/To	opiramate ER (Qsymia)	ı
Precautions/Warnings	Fetal toxicity (REMS program), cognitive impairment	1
Contraindications	Glaucoma, hyperthyroidism, MAOI use (within 14 days), ESRD	
Adverse Effects	Constipation, headache, paresthesia, dizziness, dry mouth, hypokalemia	
Drug Interactions	CNS depressants, anti-hypertensives	
Phentermine/Topiramate ER [package insert] 2014.		3

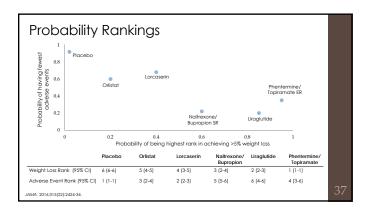


ramozono, bol	oropion SR (Contrave)
Precautions/Warnings	US Boxed Warning: Suicidality and Antidepressant Drugs
Contraindications	Opioid use, history of seizures, MAOI use (within 14 days), ESRD, severe hepatic impairment
Adverse Effects	Increased HR and BP, headache, insomnia, nausea, hepatotoxicity
Drug Interactions	Psychotropic medications





3 y 31 Ci i i Gi	ic keview di	nd Meta-An	alysis	
Drug	Mean weight loss in kg (95% CI)	OR > 5% weight loss (95% CI)	OR of d/c due to Adverse Event (95% CI)	
Orlistat (Xenical)	-2.63 (-2.94, -2.32)	2.69 (2.36, 3.07)	1.84 (1.55, 2.18)	
orcaserin.	-3.35 (-3.55, -2.95)	3.09 (2.49, 3.83)	1.40 (0.96, 2.03)	
Phentermine/ opiramate	-8.80 (-9.62, -7.98)	9.10 (7.68, 10.78)	2.32 (1.86, 3.89)	
Naltrexone/ oupropion	-4.95 (-5.54, -4.36)	3.90 (2.91, 5.22)	2.60 (2.15, 3.14)	
iraglutide	-5.24. (-5.6, -4.87)	5.09 (4.07, 6.37)	2.82 (2.10, 3.77)	



Summary of Anti-Obesity Medications

- · Optimal duration of use has not been established
- · Long-term outcomes beyond 2 to 4 years has not been studied
- Medication selection should be based on efficacy, tolerability, and patient's comorbidities
- Use of more than one weight loss medication concurrently has not been studied
- · No clinical trials to date evaluating mortality

38

Endocrine Society Recommendations

- Pharmacotherapy should be considered for obesity management for BMI ≥ 30 (Or BMI ≥ 27 with comorbidity)
- Assess for efficacy monthly for first 3 months, and at least every 3 months thereafter
- Discontinue if patient does not achieve weight loss ≥ 5% at 3 months
- Suggest against off-label use of medications approved for other disease states for sole purpose of weight loss

Endocr Pract. 2016;22(3):1-203. J Clin Endocrinol Metab. 2015;100(2):342-62.

Patient Case Continued

After describing all the FDA approved anti-obesity medications to JG, she asks "Which drug has demonstrated the greatest weight loss effects?"

- A. Liraglutide
- B. Lorcaserin
- c. Naltrexone/Bupropion SR
- D. Orlistat
- E. Phentermine/Topiramate ER

40

Agent	MOA	Year	Intended Duration	Dosing	AWP (30 day supply)	
Phentermine (Adipex, Lomaira)	indirect sympathomimetic	1959	12 weeks	Adipex: 15-37.5 mg daily Lomaira: 8 mg 3x/day	\$52	
Orlistat (Xenical, Alli)	lipase inhibitor, ↓ absorption of fat	Rx: 1999 OTC: 2007	Chronic use	Rx: 120 mg 3x/day OCT: 60 mg 3x/day	\$703 OTC \$53	
Lorcaserin (Belviq)	selective serotonin 5HT-2C receptor agonist	2012	Chronic use	IR: 10 mg 2x/day ER: 20 mg daily	\$239	
Phentermine/ Topiramate ER (Qsymia)	sympathomimetic with anticonvulsant	2012	Chronic use	Initial: 3.75/23 mg daily Max: 15/92 mg daily	\$318	
Naltrexone/ Bupropion SR (Contrave)	dopamine & NE reuptake inhibitor with opioid receptor antagonist	2014	Chronic use	Weekly titration over 4 weeks up to 2 tabs 2x/day	\$290	
Liraglutide (Saxenda)	glucagon-like peptide 1 receptor agonist	2014, 2017	Chronic use	Daily SubQ inj 0.6 mg \rightarrow 3 mg	\$1,385	41

Barriers to Use

- Less than 2% of eligible patients in the US are prescribed antiobesity medications
- Why are anti-obesity drugs prescribed so infrequently?
 Safety concerns
- · Lack of guideline recommendations
- Relatively modest benefits
- Insurance coverage
- · Cost-effectiveness

Perceptions of obesity

Clev J Med. 2017;84(1):539-546.

42

Dietary Supplements

Dietary Supplements

- Approximately 15% of US adults used at least one supplement for weight loss within the last year
- Americans spend almost \$2.1 billion a year on weight-loss supplements in pill form
- May contain up to 90 separate ingredients

Prim Care. 2017;44(2):217-227.

Dietary Supplement Health and Education Act (DSHEA)

- Legislation passed in 1994
- Allows supplements to be marketed without evidence to support efficacy or safety
- Definition of dietary supplement
- "Product (other than tobacco) intended to supplement the diet that bears one more ingredients including a vitamin, mineral, herb or other botanical, amino acid... or combination of any of the aforementioned ingredients"

Am J Clin Nutr. 2004;79:529-36.

Lack of Regulation

- Claims must be limited to "general structure function" and may not assert that a product prevents or treats
- No system in place for FDA to inspect supplements for purity or quality prior to marketing
- FDA maintains adverse event reporting reported by

Am J Clin Nutr. 2004;79:529-36.

Ephedra (ephedrine)

- Derived from Ephedra sinica (Ma Huana)
- Many supplements started adding extracts of ephedra alkaloids in high quantities
- Adverse reactions:
- Arrythmia, palpitations, increased heart rate Stroke, MI
- · Sudden death from cardiomyopathy
- Not banned as a supplement until 2004



Phytother Res. 2016;30(5):732-40.

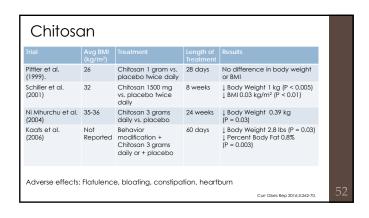
Weight Loss Supplements Recently Removed from Market

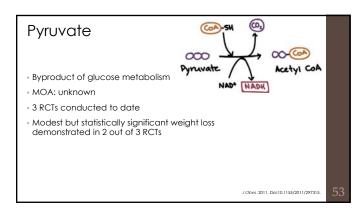
- QuickTrim
- Xendarine
- One a Day Weight Smart
- CortiSlim
- TrimSpa
- Fastin
- Stimerex-ES Lipodrene
- Ultimate Lean
- A1 Slim
- Physic Candy
- Slimming Plus Advanced
- Platinum Weight Loss Solution
- · Lean Extreme ABX Weight Loss
- Skinny Bee Diet
- Accelerator Boost
- Slim Fit X
- X-celerated Weight Loss Ultra
- Dream Body
- Advanced Extra Slim Plus
- ZlimXter Capsules Eradicate
- Ultimate Body Tox Jenesis Lipo Escultra Perfect Slim



Con	nmon Ingredi	ents in Weight-Loss Su	upplements
Ingredient	Proposed MOA	Evidence of Efficacy	Reported Adverse Effects
Bitter orange (Citrus aurantium L.)	Increased lipolysis, mild appetite suppressant	Small trials, poor methodologic quality Inconclusive effects	Chest pain, anxiety, headache, increased BP and HR
Caffeine	CNS stimulant	Short term trials Possible modest weight reduction	Generally safe <400 mg/day Nervousness, increased HR
Capsaicin	Increased satiety and lipid oxidation	Several trials, no effect on body weight	GI distress, increased insulin levels, decreased HDL
Garcinia cambogia	Inhibits lipogenesis	Several short-term trials, varying methodology Little to no effect on body weight	Headache, nausea, GI distress, liver damage
Green tea extract	Increased energy expenditure and lipid oxidation	Several trials, good quality Possible modest effects	Constipation, abdominal pain, nausea, liver damage (rare)
Raspberry ketones	Lipid metabolism	Several clinical trials No effect on body weight	Tolerable upper intake 4,000 IU/day Polyuria, increased calcium levels, arrhythmia
White kidney bean	Interferes with carbohydrate absorption	Several clinical trials, varying methodological quality Possible modest effects	Few safety concerns up to 3,000 mg/day for up to 12 weeks Headache, soft stools, flatulence
			NIH Dietary Supplements for Weight Loss, Nov 2017







Pyruv	ate				
Trial	Avg BMI (kg/m²)	Treatment	Length of Treatment	Results	
Stanko et al. (1992)	27.8- 52.7	Pyruvate 30 grams/ day and calcium pyruvate 16 grams/ day or placebo	21 days	Pyruvate vs placebo ↓ Body Weight 0.22 kg vs. 0.17 kg (P < 0.05) ↓ BMI 2.2 kg/m² vs.1.5 kg/m² (P <0.05) ↓ Fat 7.3% vs. 5.4% (P < 0.05)	
Kalman et al. (1998)	>25	Pyruvate 6 grams/ day; placebo or nothing (control)	6 weeks	↑ LBM 2.4% (P = 0.001) ↓ Fat Mass 12.2% (P < 0.001) ↓ Body Fat 12.4% (P < 0.001)	
Kalman et al. (1999)	>25	Pyruvate 6 grams/ day vs placebo	6 weeks	↓ Body Weight 1.6% (P < 0.001) ↓ Body Fat 14% (P < 0.001) ↓ Percent Body Fat 11.7% (P < 0.001)	
Adverse eff	ects: Diar	rhea, gas, bloating			_
Adverse em	ocis. Diai	mea, gas, bleamig		J Obes. 2011. Doi:10.1155/2011/297315.	3



Irvingia gabonesis

- Mango-like fruit native to western and centra Africa
- Proposed MOA: down regulation of PPAR-
- Proprietary extract IGOB131 formulated as 150 mg dáily

Trial	Avg BMI (kg/m²)	Treatment	Length of Treatment (weeks)	Results	
Ngondi et al. (2005)	Not Reported	Irvingia gabonensis 350 mg/day vs. placebo	4	↓ Body Weight 5.6% (P < 0.001) ↓ Hip Circumference 3.42% (P < 0.001)	
Ngondi et al. (2009)	26-40	Irvingia gabonensis 150 mg/day vs. placebo	10	12.8 kg vs 0.7 kg placebo(P < 0.01) ↓ Percent Body Fat 6.3% (P < 0.05)	
Adverse effec	cts: Headac	the, insomnia, flatulence,	gas	J Diet Suppl. 2013;10(1):29-38.	-

Herbal Medicine

What is herbal medicine?

- Also known as botanical medicine
- · System based on the use of plants or plant extracts that may be ingested or applied topically
- Many different cultural systems
- Traditional Chinese Medicine
- · Traditional Indian Medicine (Ayurveda)
- Western herbalism
- In many of these systems the line between food and medicine is blurred

Forms of herbal medicine

- Extracts
- Tinctures
- Elixers
- Capsules
- Tablets
- Teas
- Pastes/Salves
- Infused Oils

Prim Care. 2017;44(2):217-227.



Who regulates herbal medicine?

- Practice of herbal medicine is not a licensed profession in
- Herbs can be prepared and sold as "dietary supplements"
- Organizations attempting to solidify best practices and promote self-regulation
- Association of Naturopathic Physicians
- American Herbalist Guild

Prim Care. 2017;44(2):217-227.

If your patient has decided to use herbal medicine...

- Share reputable resources the patient can read for further education
- Encourage use of brands adhering to good manufacturing practices
- Recommend sharing list of ALL supplements and herbs taken with their providers
- Reinforce that plants and plant parts may contain ACTIVE INGREDIENTS and therefore can have side effects and interactions

61

Herbal Medicine Resources for Providers

- American Botanical Council (http://abc.herbalgram.org)
 - Monographs
 - · Adulterant monitoring program
 - Commission E Monographs
- Natural Medicines Database (formerly Natural Standard)
- PubMed "Dietary Supplement Subset" filter

62

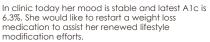
Free Herbal Medicine Resources for Patients

- University of Maryland Medical Center http://www.umm.edu/health/medical/altmed
- NIH Dietary Supplement Label Database https://dsld.nlm.nih.gov/dsld/index.jsp
- Examine.com
 Links to evidence and summary tables

63

Patient Case Continued

JG was prescribed Qsymia (after proper enrollment in REMS) for one year and had good results. She stopped taking the medication when her insurance changed and no longer covered it. She soon regained the weight, developed depression, and started taking sertraline 150 mg daily.



Is Qsymia still a good option?

If not what would you recommend next?



Patient Case Continued

JG is now 34 years old, she stopped taking the medication previously prescribed due to unpleasant side effects.

While dutifully performing medication reconciliation, she mentions recently starting an herbal tea her Aunt suggested that is "an old family recipe."

What would be the best counseling advice for her?

- A. Discontinue using herbal tea immediately.
- B. Great idea! See if her aunt can also provide something for her prediabetes.
- C. Encourage her to find out the ingredients of the tea. Offer to help her look up more information if she can provide names of the plants

65

Summary

- BMI is a screening tool that should be utilized in context of other factors
- Six current FDA approved weight loss medications in use
- Multiple barriers to use
- Select dietary supplements and herbs have growing clinical evidence
- · Dietary supplements and herbs are not regulated

66

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69

Questions?

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