

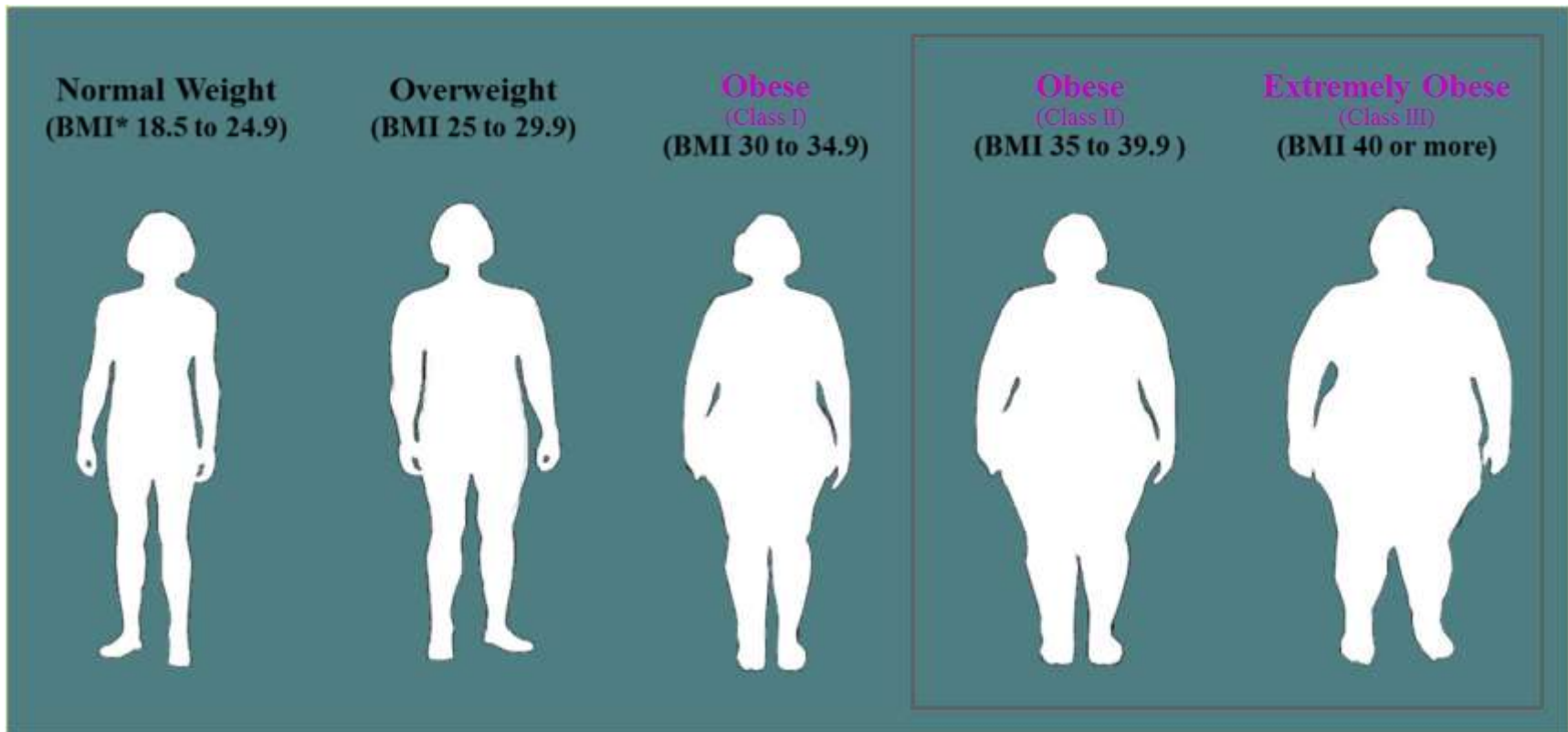
# Step Up Treatment for Obesity: The way forward or delaying the inevitable?

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# Disclosures

- ValenTx- medical advisory board
- BaroNova- Research DSMB

# Body Mass Index (BMI)



- Being significantly overweight can lead to comorbidity and premature death

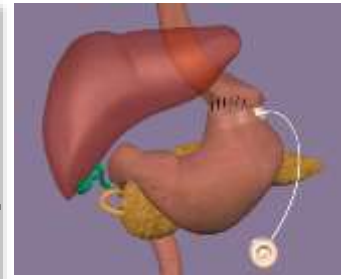
# Obesity in the U.S.

- Over 35 million obese adults
- 12 million morbidly obese
- 170k bariatric procedures
- Most others get no effective long term therapy
- Why???
  - Blame / Can do it Themselves
  - Don't believe treatment works
  - Fear of side effects, complications

# Obesity Care Continuum



ENDOLUMENAL



Less Invasive

Unmet Needs

More Invasive

**Diet and  
Exercise**

**Drugs**

**Gastric  
Banding**

**Gastric  
Bypass**

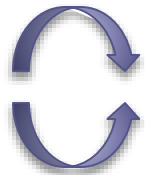
**What are the  
Goals?**

# Rationale for Step Up Treatment

- “Lower the bar” for entry into treatment
- Low risk treatment likely effective for some
- High risk patients can be improved before next step
  - Fewer complications will lead to lower mortality for higher risk interventions

# Patient Perspective

- Stress / Discomfort
- Fear / Disbelief
- Excitement
  - Reach/Maintain Goal
- Disappointment
  - Next Step



- Defeat



# Potential Problems with Step Up

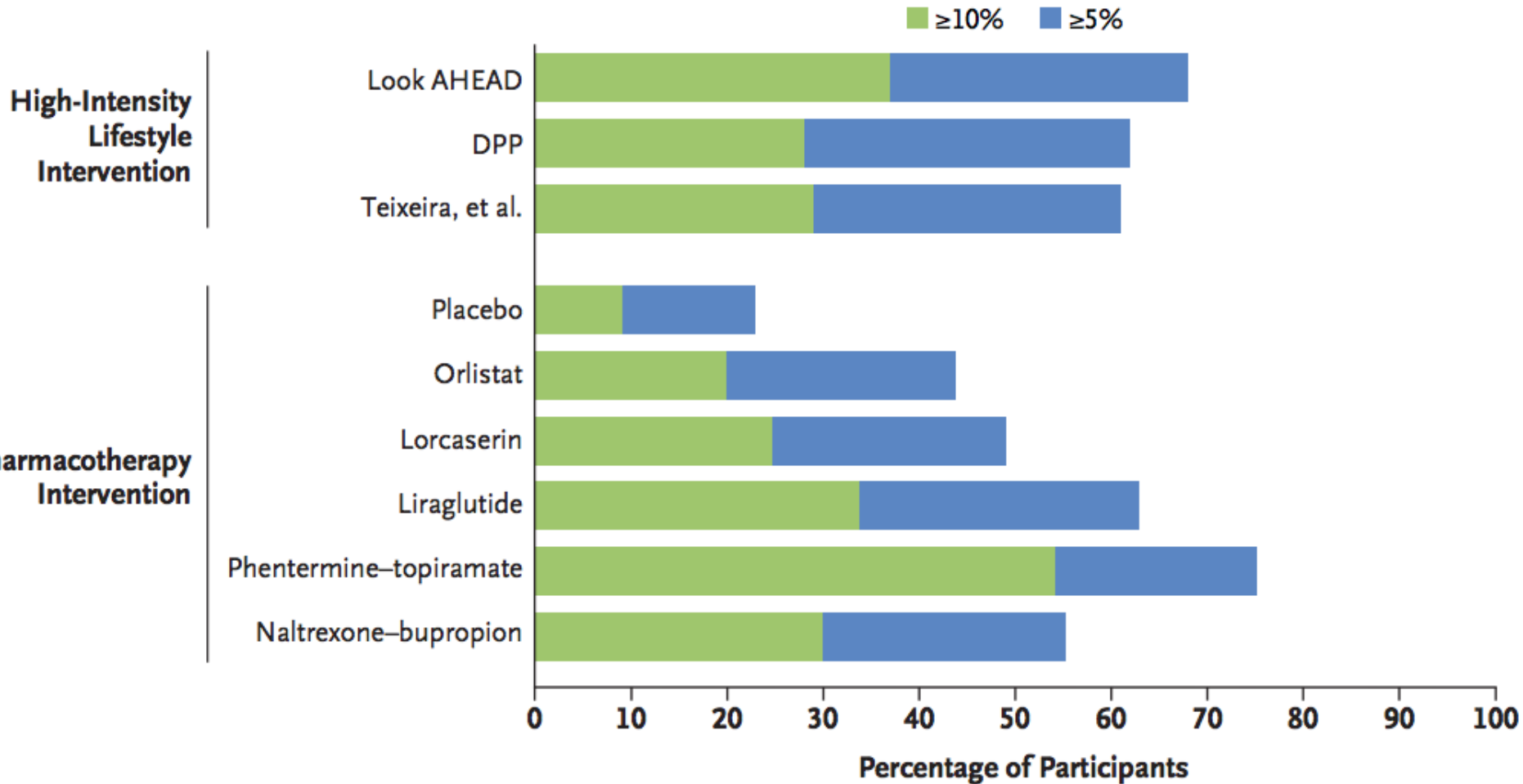
- Patient frustration with “failure”, lost chance for effective treatment
- Delay in getting effective treatment
  - complications
- Increased overall cost?
- Worse overall outcomes?



<b>OBESITY COMPLICATION</b>	<b>% wt loss for Rx benefit</b>	<b>Notes</b>	<b>References</b>
T2DM Prevention	3-10%	Maximum benefit at 10%	DPP (Lancet, 2009) SEQUEL (Garvey et al, 2013)
T2DM (HbA1c)	3-15%	HA1c still decreasing at >15%	Look AHEAD (Wing, 2011)
Dyslipidemia (TG/HDL)	3-15%	TG still decreasing at >15%	Look AHEAD (Wing, 2011)
HTN	5-15%	BP still decreasing at >15%	Look AHEAD (Wing, 2011)
NAFLD	10%	Improved steatosis, inflammation, mild fibrosis	Assy et al, 2007; Dixon et al, 2004; Anish et al, 2009
Sleep Apnea	10%	Little benefit at ≤ 5%	Sleep AHEAD (Foster, 2009) Winslow et al, 2012
Osteoarthritis	5-10%	Improved symptoms and joint stress mechanics	Christensen et al, 2007 Felson et al, 1992; Aaboe et al, 2011
Stress Incontinence	5-10%		Burgio et al, 2007 Leslee et al, 2009
GERD	5-10% (F) 10% (M)		Singh et al, 2013 Tutujian R, 2011
PCOS	10-15%	Lower androgens, improved ovulation, increased insulin sensitivity	Panidis D et al, 2008 Norman et al, 2002 Moran et al, 2013

Paused

# Efficacy of non-invasive treatments

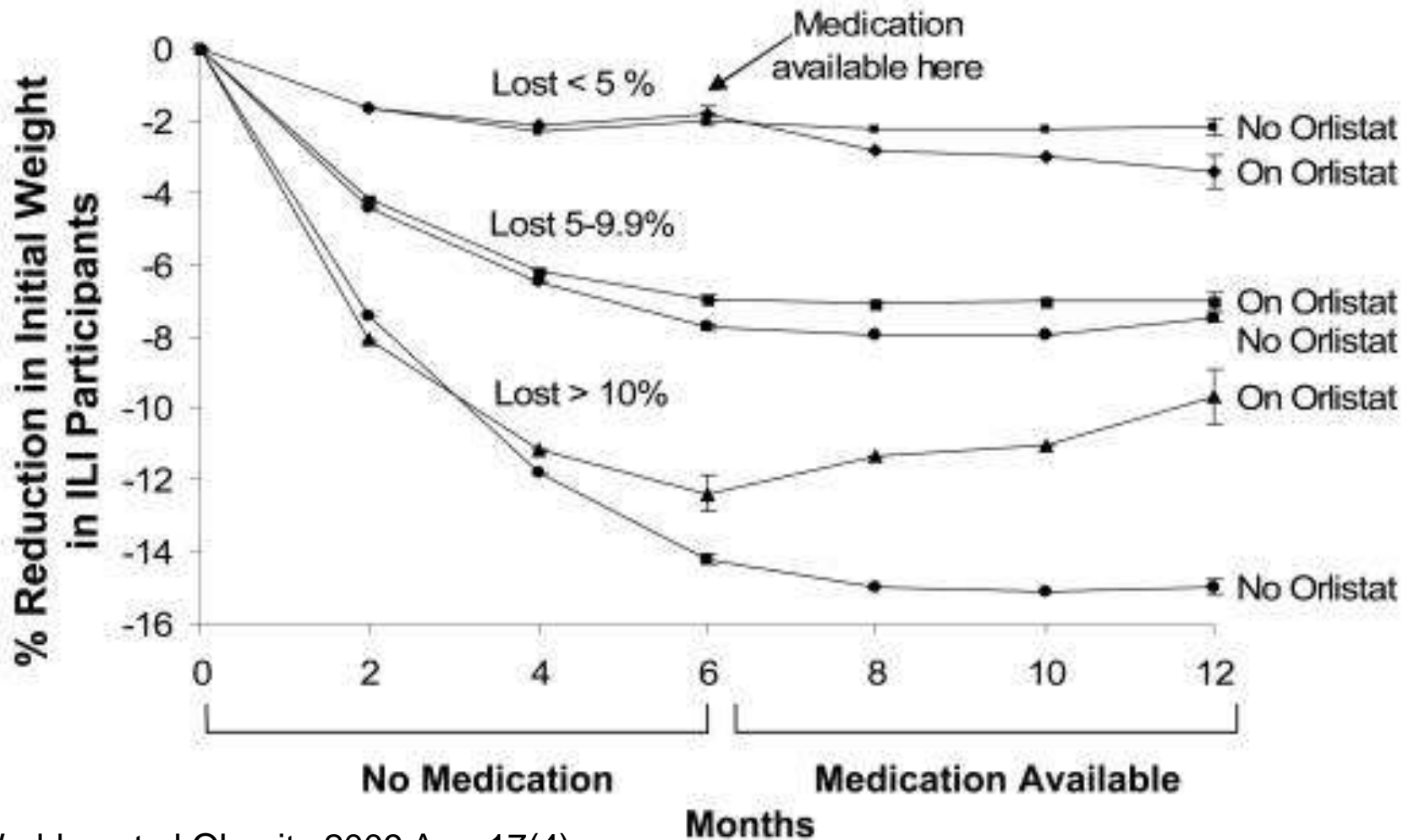


Heymsfield SB NEJM 2017

# Medical therapy

Drug	BMI	Length of observation/ study	Results
Phentermine	>27	Many	
Orlistat	>27; >30	RCT 1- 4 years	With Behavioral therapy 5-10 kg vs 3-6 kg in pacebo
Lorcaserin (Belvicq)	>27; >30	RCT 52 weeks	5.8 kg vs 2.2 kg (47% vs 20% lost >5% body weight
Phentermine/Topiramate (Qsymia)	>25	RCT 52 wks	21% vs 60-70% lost >5 % body weight

# Look AHEAD Poor Responders +/- Orlistat



# Weight Management is Often Patient Driven

- Willingness / Ability to change diet and exercise
- Acceptance of specific treatments
- Insurance Coverage
- Risk Tolerance
  
- We Must Educate Patients About ALL Options
  - Not just availability but reasonably expected outcomes
  - Extent of weight loss
  - Durability
  - Comorbidity improvement / resolution

# Modifiable Risk Factors

- Co-Morbidity
  - Diabetes control
  - HTN management
  - Treatment of OSAS
- BMI
- Liver Size
  - Length of Surgery



# VLCD

- Widely studied
  - Safe in majority of patients
    - Renal failure
    - CHF
  - Medical supervision



***Slim-Fast***



# Intragastric Balloon Pre Surgery

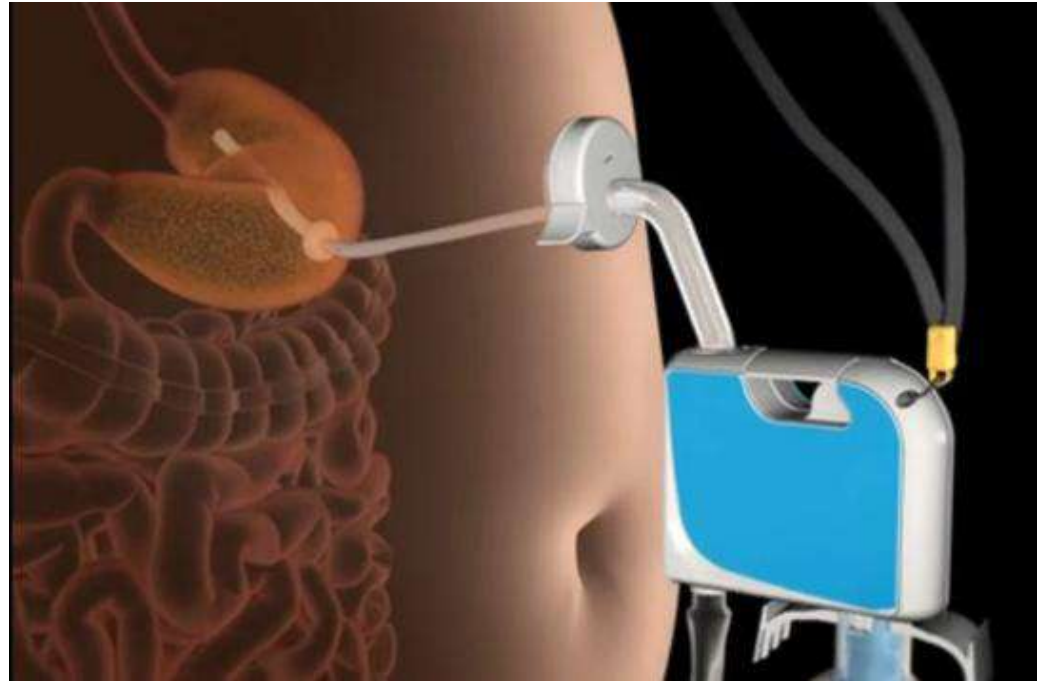
- Pre-op weight loss without surgery or GA
- Busetto et. al. Obesity Surgery 2004
  - Case control pre-op balloon v. none
  - Placed without general anesthesia
  - Left in place 6 months
    - 7% complication rate with balloon
  - 26.4% EWL
    - Less operative time
    - Shorter hospital stay
    - Fewer conversions





# Aspire Assist

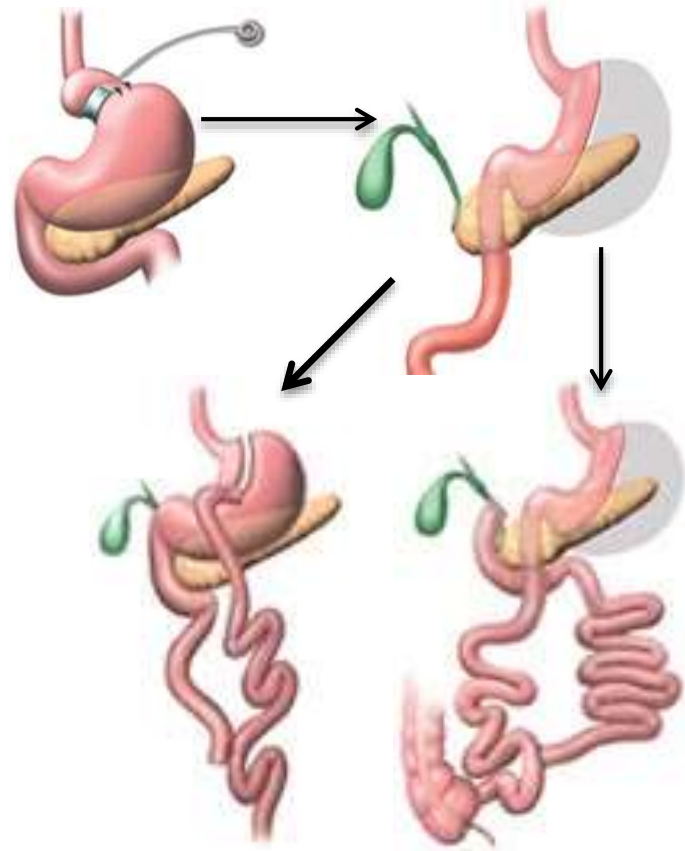
40% EWL 6mo



- Source: Sullivan S, Stein R, Jonnalagadda S, Mullady D, Edmundowicz S. Aspiration Therapy Leads to Weight Loss in Obese Subjects: A Pilot Study. *Gastroenterology* 2013;145:1245–1252.

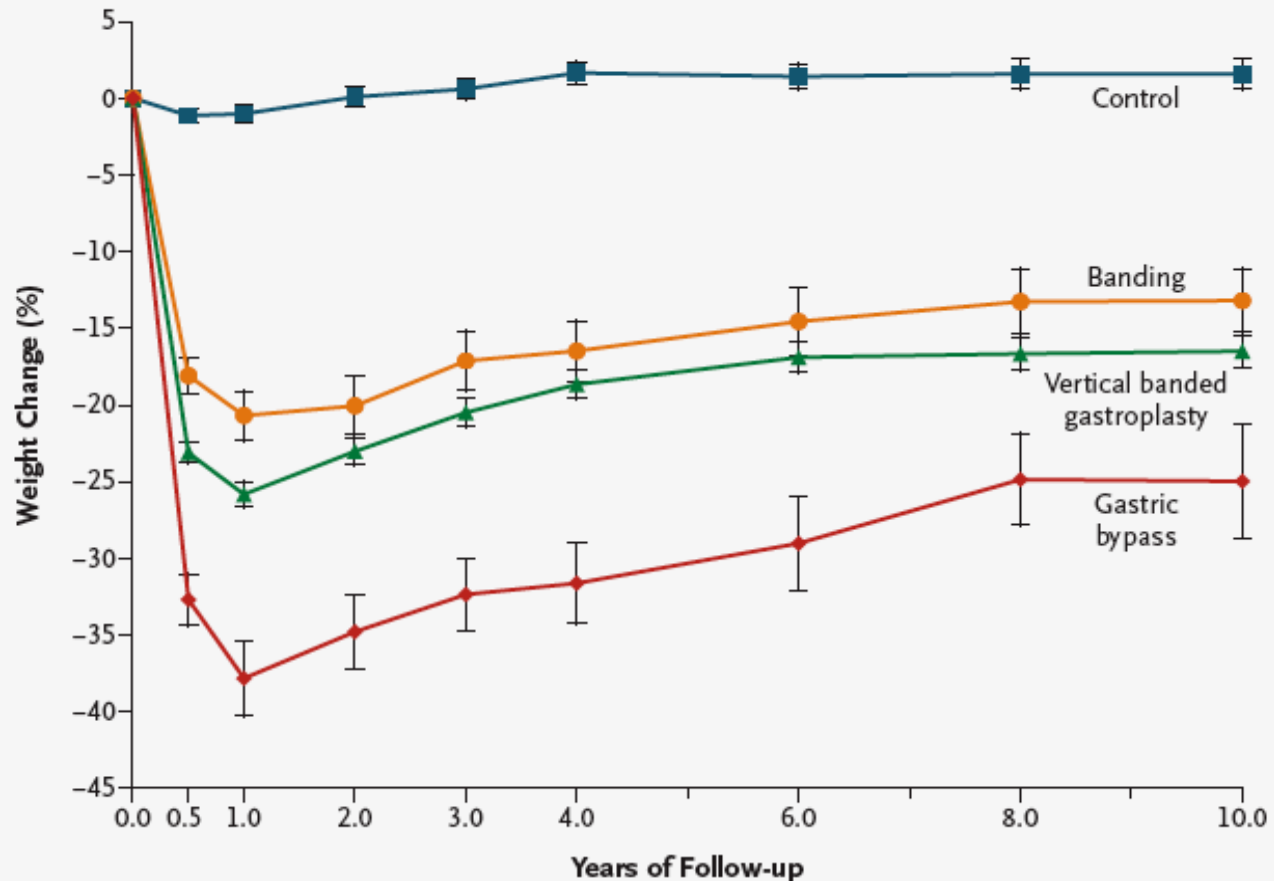
# Step Up Surgery

- **Banding**
  - Least risk, no anastomosis
  - Least weight loss
  - Less predictable
- **Sleeve Gastrectomy**
  - ? Less risk than bypass
- **Proximal Gastric Bypass**
  - Diabetes or Reflux Control
- **Biliopancreatic Diversion**
  - Diabetes and Weight Loss



# Lifestyle, Diabetes, and Cardiovascular Risk Factors 10 Years after Bariatric Surgery “SOS STUDY”

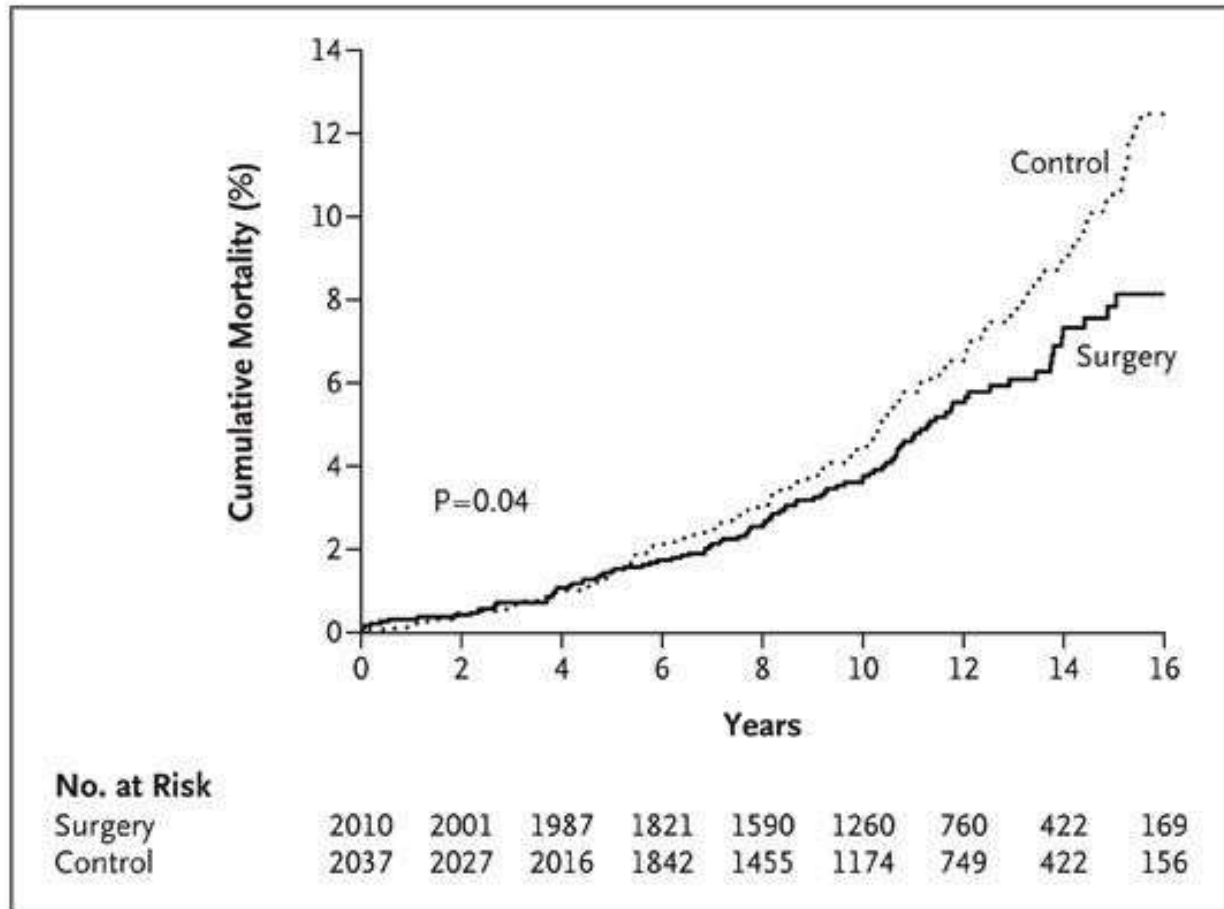
Sjostrom L et al. N Engl J Med 2004;351:2683-93



## No. of Subjects

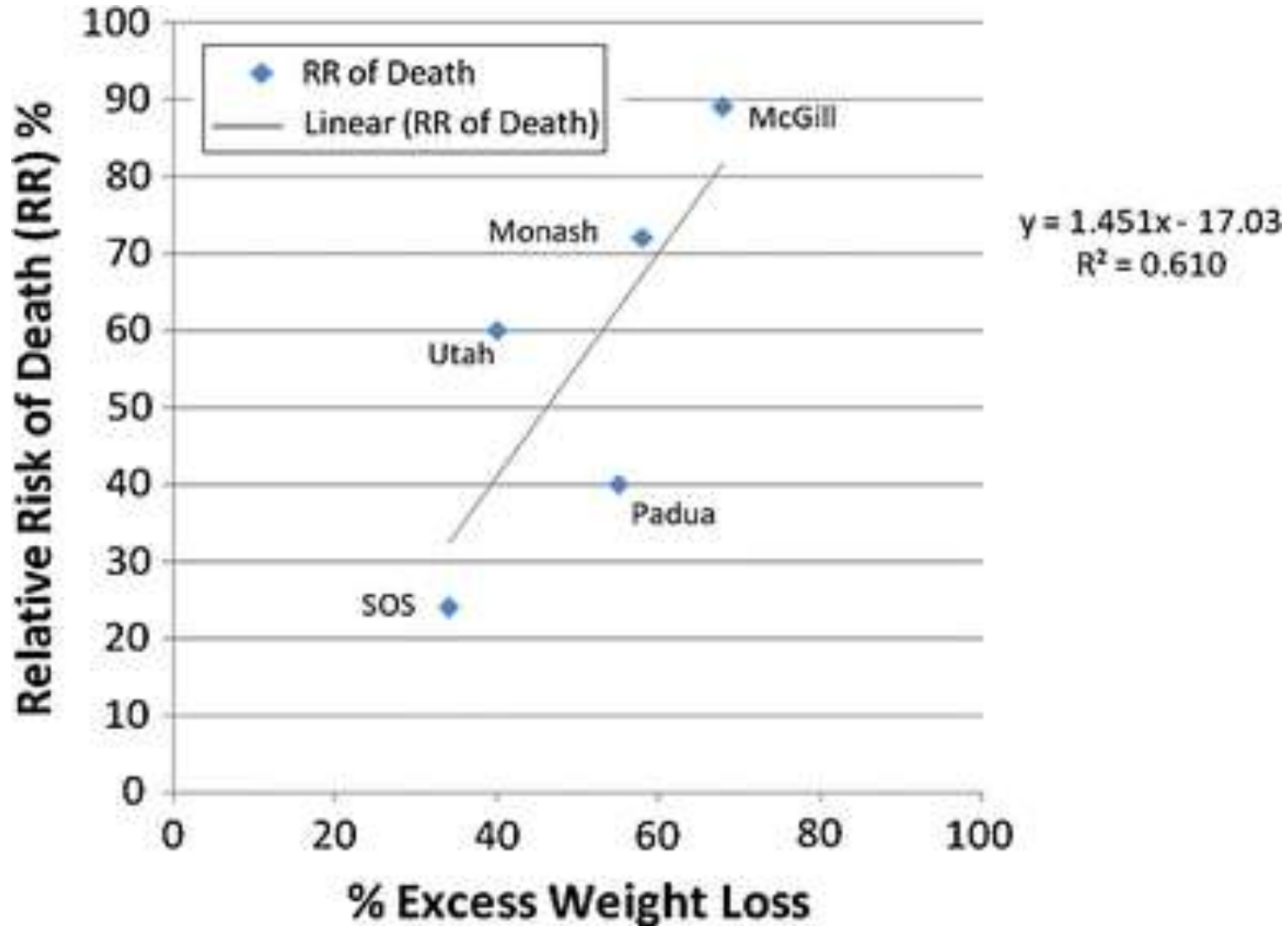
Control	627	585	594	587	577	563	542	535	627
Banding	156	150	154	153	149	150	147	144	156
Vertical banded gastroplasty	451	438	438	438	429	417	412	401	451
Gastric bypass	34	34	34	34	33	32	32	29	34

# SOS Study Survival



24%  
Mortality  
Reduction

# Survival Dose Response



# Endoluminal Bariatrics

- Procedures may be:
  - Revisional
    - Reduce stoma or pouch size
    - Repair fistulas
  - Short-term devices for weight loss
    - Preparation for a definitive procedure
    - For a specific event, transplant...
    - Cosmetic??
  - Primary providing durable weight loss??
- All except perhaps balloon are of *unproven efficacy/safety!*

# Summary

- Most Obese individuals do not get effective therapy
- Endolumenal therapy holds promise to fill a void between medication and surgery but none have the data to advocate for wide application
- Many new approaches are being developed and evaluated
- The safety and degree as well as duration of weight loss will determine the role of these therapies
- Durability will be required to achieve insurance coverage and wider application