COLUMBIA UNIVERSITY
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Current Trends in Bariatric Surgery

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Outline

- Why consider surgery
- Bariatric surgery as metabolic surgery
- Considering surgery at lower BMIs
- Change in the types of cases being performed
- Emergence of robotic bariatric surgery

Why consider surgery?

Surgery shown to improve survival

Sjostrom et al. Effects of Bariatric Surgery on Mortality in Swedish Obese Subjects. (NEJM, 2007)

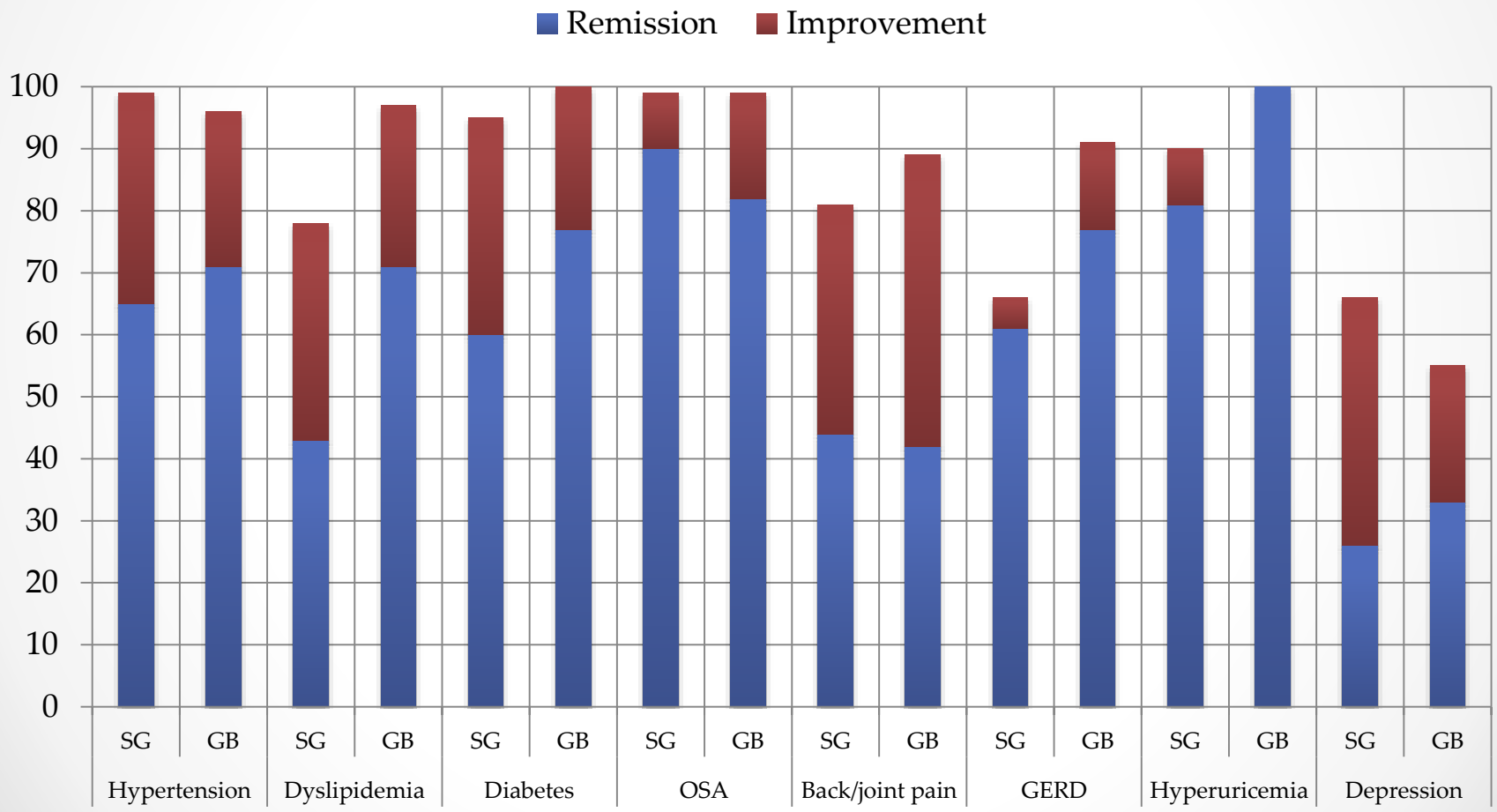
- Prospective cohort study
- SOS Study 4047 pts.
  - 2010 patients in surgery group (68% VBG, 19% Band, 13% GBP)
- 10.9Y avg. f/u
- weight loss 25% GBP, 16% VBG, 14% Band
- Overall mortality reduced 24% in surgery group
- 40% fewer cancer deaths, 50% fewer MI deaths

Surgery shown to improve survival

Adams et al. Long-Term Mortality after Gastric Bypass Surgery. (NEJM, 2007)

- 7925 GBP and 7925 Matched Controls
  - Age, sex, BMI from DMV records, year
- All cause and disease specific mortality
  - Avg. f/u 7.1Y
- Overall Mortality 40% less in GBP group
  - 59% fewer deaths due to MI, 92% fewer due to diabetes, and 60% to cancer

Remission of comorbid conditions



1. Peterli et al. Laparoscopic sleeve gastrectomy versus roux-y-gastric bypass for morbid obesity – 3-year outcomes of the prospective randomized Swiss multicenter bypass or sleeve study (SM-BOSS). (Ann Surg, 2017)

Bariatric surgery increasingly seen as **metabolic surgery**

- The GI tract is more than just plumbing.
- The alterations in anatomy lead to hormonal changes in the gut-brain hormonal axis that lead to weight loss and changes in glucose homeostasis

45 medical societies support surgery to treat diabetes

- Diabetes Surgery Summit II (2015)
- Recommend metabolic surgery to treat T2DM BMI > 40 and BMI 35-39.9 hyperglycemia inadequately controlled.
- Consider for patients with T2DM and BMI 30-34.9 if inadequately controlled despite optimal medical treatment with either oral meds or injectables
- Endorsed by 45 worldwide medical and surgical societies

1. Rubino et al. Metabolic surgery in the treatment algorithm for type 2 diabetes: a joint statement by International Diabetes Organizations (SOARD, 2016)

Multiple RCTs have shown effectiveness of surgery

Table 1—Metabolic surgery RCTs for T2D (n = 794)

Study	BMI (kg/m^2), % of patients	Design	No. of patients randomized	Follow-up (months)	Remission criteria*	Outcome (remission or change in HbA_{1c})
Dixon (8)	<35, 22%	LAGB vs. control	60	24	HbA_{1c} <6.2%	73% vs. 13%, $P < 0.001$
Schauer (30,31)	<35, 36%	RYGB vs. SG vs. control	150	36	HbA_{1c} ≤6.0%	35% vs. 20% vs. 0, $P = 0.002$
Mingrone (32,33)	>35, 100%	RYGB vs. BPD vs. control	60	60	HbA_{1c} ≤6.5%	42% vs. 68% vs. 0, $P = 0.003$
Ikramuddin (34,35)	<35, 59%	RYGB vs. control	120	24	HbA_{1c} <6%	44% vs. 9%, $P < 0.001$
Liang (36)	<35, 100%	RYGB vs. control	101	12	HbA_{1c} <6.5%**	90% vs. 0 vs. 0, $P < 0.0001$
Halperin (37)	<35, 34%	RYGB vs. control	38	12	HbA_{1c} <6.5%	58% vs. 16%, $P = 0.03$
Courcoulas (38,39)	<35, 43%	RYGB vs. LAGB vs. control	69	36	HbA_{1c} <6.5%	40% vs. 29% vs. 0, $P = 0.004$
Wentworth (40)	≤30, 100%	LAGB vs. control	51	24	Fasting blood glucose <7.0 mmol/L	52% vs. 8%, $P = 0.001$
Parikh (41)	<35, 100%	Bariatric surgery (RYGB, LAGB, SG) vs. control	57	6	HbA_{1c} <6.5%	65% vs. 0, $P = 0.0001$
Ding (42)	<35, 34%	LAGB vs. control	45	12	HbA_{1c} <6.5%***	33% vs. 23%, $P = 0.46$
Cummings (43)	<35, 25%	RYGB vs. control	43	12	HbA_{1c} <6.0%	60% vs. 5.9%, $P = 0.002$

*Remission was a primary or secondary end point. Reaching HbA_{1c} value without diabetes medication, unless otherwise specified. **Remission not precisely defined, HbA_{1c} <6.5% by extrapolation. ***On or off diabetes medications.

- No mortalities
- major complication rates < 5%
- Surgery effective against diabetes and reduced medications taken, weight, and dyslipidemia

1. Schauer et al. Clinical outcomes of metabolic surgery: Efficacy of glycemic control, weight loss, and remission of diabetes (Diabetes Care, 2016)

Ikramuddin et al. Roux-en-Y gastric bypass for diabetes (the **Diabetes Surgery Study**): 2-year outcomes of a 5-year, randomized, controlled trial. (Lancet, 2015)

Randomized groups:

intensive medical therapy (n=60) vs RYGB + intensive medical therapy (n=60)

Inclusion: A1C > 8%, BMI 30-39.9, T2DM for >6 months

avg BMI 34, avg A1C 9.6%

Primary endpoint:

Triple control - A1C < 7%, LDL < 2.59 mmol/L, SBP < 130mmHg

24 months:

Meeting triple control endpoint: RYGB+IMT 43% vs IMT 14%

A1C < 7: RYGB+IMT 75% vs IMT 24%

Gastric bypass group had a greater number of adverse events including falls, fractures, infections and nutritional deficiencies despite use of nutritional supplements

Mingrone et al. Bariatric Surgery versus Conventional Medical Therapy for Type 2 Diabetes

- RCT
- RYGB vs BPD vs MT (lifestyle, exercise, nutrition)
- n= 60 (inclusion: BMI > 35, A1C > 7, DM > 5 years)
- Primary endpoint: HbA1C < 6.5 + fasting glucose < 5.6, without meds x1 year

	EWL		DM remission	
	2 yrs	5 yrs	2yrs	5yrs
RYGB	68%	67%	75%	37%
BPD	69%	73%	95%	63%
Medical	9%	16%	0%	0%

- Patients who relapsed diabetes at 5 years able to maintain A1C 6.7% with diet +- metformin alone

1. Mingrone et al. Bariatric Surgery versus Conventional Medical Therapy for Type 2 Diabetes. (NEJM, 2012)
2. Mingrone et al. Bariatric-metabolic surgery versus conventional medical treatment in obese patients with type II diabetes: five-year follow-up of an open-label, single-center, randomized controlled trial. (Lancet, 2015)

Schauer et al. Bariatric Surgery versus Intensive Medical Therapy in Obese Patients with Diabetes

- RCT
- RYGB vs SG vs MT (lifestyle, exercise, nutrition)
- n = 150 (avg preop A1C 9.3, BMI 36)
- Primary endpoint: A1C < 6% +- DM medications

	%EWL		Primary endopoint		HgA1C	
	3 yrs	5 yrs	3yrs	5yrs	base	5yrs
RYGB	73%	68%	38%	29%	9.3	7.3
SG	72%	61%	24%	23%	9.5	7.4
Medical	14%	8%	5%	5%	8.8	8.5

1. Schauer et al. Bariatric Surgery versus Intensive Medical Therapy in Obese Patients with Diabetes. (NEJM, 2012)
2. Schauer et al. Bariatric surgery versus intensive medical therapy for diabetes - five-year outcomes. (NEJM, 2017)

Who Qualifies?

- BMI > 40
- BMI > 35 with comorbidity

- Medically fit and optimized to undergo surgery
- No psychiatric contraindications
- Needs to be able to **understand** and be **committed** to behavior changes necessary to ensure safety and success
- No strict age limits (adolescents and elderly have special considerations)

Should surgery be considered at lower BMIs?

- Most insurances currently still require BMI > 35 for diabetics to qualify for surgery
- Data suggests that BMI is not a good predictor of effectiveness of surgery
- Recent meta-analysis showed no difference in remission of diabetes if BMI < 35 vs BMI > 35 (Panunzi, 2015)
- Strong support of DSS-II consensus statement aiming to get change in insurance policies for lower BMI

1. Panunzi et al. Predictors of remission of diabetes mellitus in severely obese individuals undergoing bariatric surgery: do BMI or procedure choice matter? A meta-analysis (Ann Surg, 2015)
2. Rubino et al. Metabolic surgery in the treatment algorithm for type 2 diabetes: a joint statement by International Diabetes Organizations (SOARD, 2016)

How safe is it?

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Minimally Invasive Bariatric Surgery is Safe

Use and Outcomes of Laparoscopic Sleeve Gastrectomy vs Laparoscopic Gastric Bypass: Analysis of the American College of Surgeons NSQIP

Monica T Young, MD, Alana Gebhart, BA, Michael J Phelan, PhD, Ninh T Nguyen, MD, FACS

(JACS, 2015)

- Analysis of ACS NSQIP database
- 24,117 patients (20% SG, 80% GB)

(Young et al, JACS 2015)

Table 3. Intraoperative and Postoperative Outcomes of Patients Undergoing Laparoscopic Gastric Bypass vs Laparoscopic Sleeve Gastrectomy, 2010 to 2011

Variable	Laparoscopic gastric bypass (n = 19,172)	Laparoscopic sleeve gastrectomy (n = 4,945)	p Value
Operative time, min, mean (SD)	133 (56)	101 (50)*	<0.01
Anesthesia time, min, mean (SD)	187 (70)	147 (65)*	<0.01
Complications, %			
Urinary tract infection	0.91	0.71	0.21
Wound infection	0.2	0.06*	0.05
Abscess	0.63	0.69	0.73
Pneumonia	0.5	0.38	0.37
Pulmonary embolism	0.21	0.18	0.79
Deep venous thrombosis	0.21	0.47*	<0.01
Acute renal failure	0.11	0.14	0.72
Bleeding requiring transfusion	1.5	0.65*	<0.01
Stroke/CVA	0.03	0.02	0.82
Myocardial infarction	0.1	0.06	0.53
Sepsis	0.58	0.34*	0.05
Cardiac arrest	0.08	0.04	0.55
Serious morbidity, %	5.8	3.8*	<0.01
Length of stay, d, mean (SD)	2 (6)	2 (11)	0.99
30-day readmission, %†	6.08	4.05*	<0.01
30-day reoperation, %	2.46	1.6*	<0.01
30-day mortality, %	0.15	0.1	0.58

*$p \leq 0.05$, compared to laparoscopic gastric bypass.
†Based on 2011 data only.
CVA, cerebrovascular accident.

Estimate of Bariatric Surgery Numbers, 2011-2015

Published July 2016

	2011	2012	2013	2014	2015
Total	**158,000**	**173,000**	**179,000**	**193,000**	**196,000**
RNY	36.7%	37.5%	34.2%	26.8%	23.1%
Band	35.4%	20.2%	14%	9.5%	5.7%
Sleeve	17.8%	33%	42.1%	51.7%	53.8%
BPD/DS	0.9%	1%	1%	0.4%	0.6%
Revisions	6%	6%	6%	11.5%	13.6%
Other	3.2%	2.3%	2.7%	0.1%	3.2%
Balloons					~700 cases
V-Bloc					18 cases

ASMBS total bariatric procedures numbers from 2011, 2012, 2013, 2014 and 2015 are based on the best estimation from available data (BOLD, ASC/MBSAQIP, National Inpatient Sample data and outpatient estimations).

Robotic Bariatric Surgery

Pros and Cons

Pros

- great visualization (high resolution, 3D, stable camera position, great magnification)
- more stable retraction
- more dexterity and precision
- increased autonomy
- better ergonomics for the surgeon
- Stapler can assess thickness of the tissue
- potential of future development on the platform

Cons

- increased cost
- increased OR time
- learning curve (both surgeon and staff)
- can't feel the tissue (haptics)
- less global experience with the robotic stapler and instruments relative to the lap equivalents – is the technology reliable?

Utilization and outcome of laparoscopic versus robotic general and bariatric surgical procedures at Academic Medical Centers

Nguyen N, Surg Endosc (2015)

- HealthSystem Consortium clinical database from 10/2010 to 2/2014
- Shorter LOS for heller myotomy
- Costs were significantly higher for all procedures
- For SG and GB - no increase in hospital mortality, major complications and 30-day readmissions with robotic surgery

Robotic versus laparoscopic sleeve gastrectomy for morbid obesity: systematic review and meta-analysis

Magouliotis (Obes Surg, 2017)

- Included 16 studies and 29,787 patients
- Majority of studies found increased costs and OR times associated with robotic sleeve gastrectomy
- No differences in rates of leaks or bleeding

Laparoscopic versus robotic roux-en-y gastric bypass: lessons and long-term follow-up learned from a large prospective monocentric study.

Buchs et al. (Obesity Surgery, 2014)

- 2003-2013
- 389 lap GB, 388 robotic GB
- robotic bypass had lower conversion rate (0.8% vs 4.9%), fewer complications (11% v 16%), fewer leaks (0.3% v 3.6%), shorter hospital stay
- handsewn GJ for robotic, circular stapled GJ for lap

Current studies are limited

- Are early studies just capturing the results and costs of the learning curve?
- Older generation robot
- Unclear on technique used during the surgery
- Lack of uniformity on technique

Future for robotic bariatric surgery

- Once people get over the learning curve, will we see an improvement in outcomes, OR efficiency, and costs?
- Will better visualization and precision translate into better results?
- Increased competition (Google/J&J, medtronic, others)over next few years
- Decreased costs
- Innovations in technology (single-site, embedded imaging, haptics)
- Decreased size of the platform – system to become more mobile

Summary

- Metabolic surgery is the most effective treatment currently available for morbid obesity and diabetes
- Minimally invasive bariatric surgery is safe
- Push towards offering metabolic surgery to lower BMIs
- Mix of cases continues to evolve
- May see an increased role for robotics with greater surgeon experience, increased industry competition and lower cost.

Thank you

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