The one anastomosis gastric bypass (OAGB)

The ASMBS position

Eric J. DeMaria, MD, FACS, FASMBS

Past-President, ASMBS 2019

Professor and Chair, General and Bariatric Surgery, East Carolina University

My disclosures for this talk

- I have never done this operation
- I have published exactly 1 paper on this topic
- I worked for 5 years at the hospital in NC where this procedure was performed after its originator left UNC-CH

Overview

1. U.S. experience with OAGB complications
2. The ASMBS review of this procedure in 2018
3. Concerns about OAGB in long-term follow up
4. Why the USA can not take any chances with new procedures

ELSEVIER

Surgery for Obesity and Related Diseases 3 (2007) 37–41

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

Surgical revision of loop ("mini") gastric bypass procedure: multicenter review of complications and conversions to Roux-en-Y gastric bypass

William H. Johnson, M.D.[a], Adolfo Z. Fernanadez, M.D.[b], Timothy M. Farrell, M.D.[c], Kenneth G. MacDonald, M.D.[d], John P. Grant, M.D.[a], Ross L. McMahon, M.D.[a], Aurora D. Pryor, M.D.[a], Luke G. Wolfe, M.S.[e], Eric J. DeMaria, M.D.[a,e,*]

Our motivation: Report of 2,410 patients, only 3 patients reported who required revisional surgery [1]

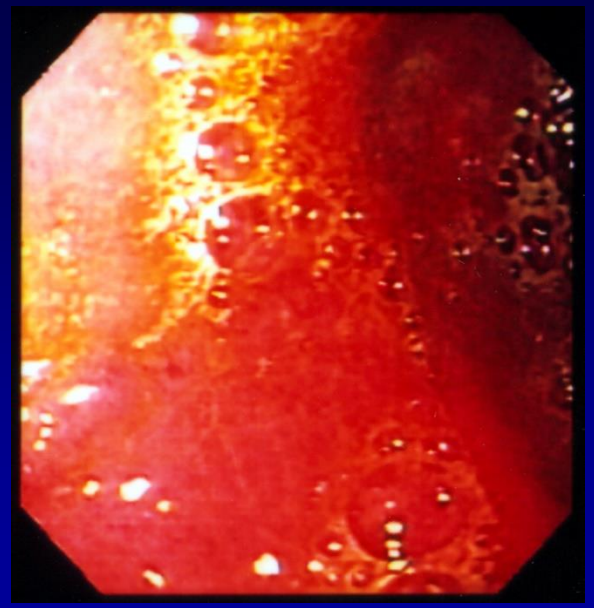
1 – Rutledge R, Walsh T. Obesity Surgery (2005) 15:1304-1308

Surgical Revision of the Loop “Mini” Gastric Bypass

- 32 patients identified by query of 5 referral centers

- Bile Reflux Gastritis– 20
- Intractable Marginal Ulcers – 5
-Gastrojejunostomy leak – 3
-Malabsorption/Malnutrition – 8
-Weight gain – 2

Bile Reflux Gastritis

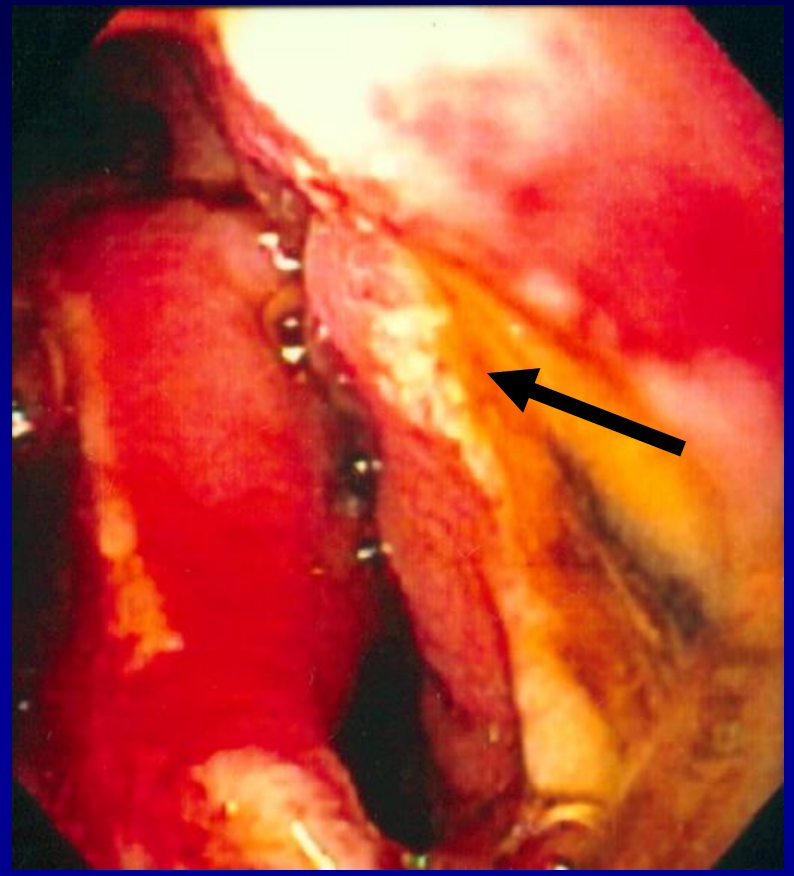


- 20 patients unresponsive to medical management
- 14 - conversion to roux
- 4 - planned roux
- 2 - Braun entero-enterostomy

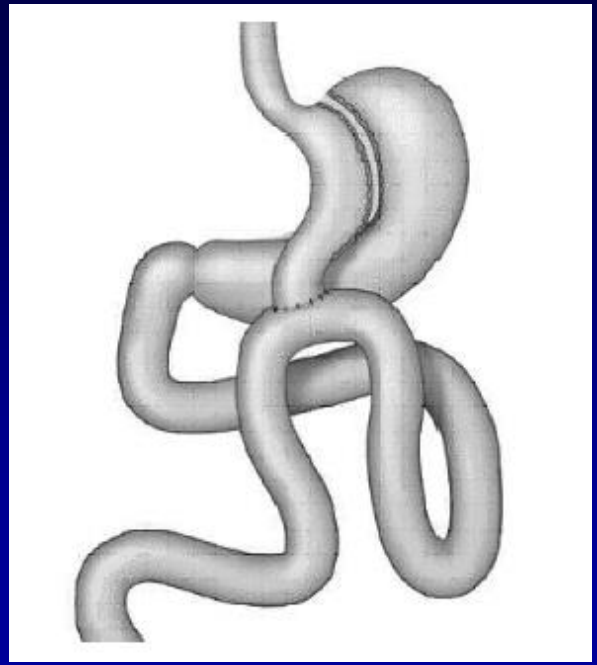
- Failure of medical therapy does occur and is the most common complication requiring revisional surgery

Intractable Marginal Ulcer

- 5 patients identified who required revisional surgery
- 4 - conversion to roux
- 1 - planned roux



Anastomotic leak



- 3 patients referred with acute leaks from gastrojejunostomy
- All required multiple procedures to control sepsis
- 2 patients- conversion to roux
- biliary-pancreatic secretions - high output fistula

Surgical Revision of the Loop “Mini” Gastric Bypass

- Weight gain
  - 2 patients – both converted to a RYGB

- Malabsorption/ malnutrition
  - 8 patients
  - 5 have undergone conversion to RYGB
  - 2 have planned conversions to RYGB
  - **1 had a short common channel**

Surgical Revision of the Loop “Mini” Gastric Bypass

32 patients who require/required revision

- 21 patients have undergone conversion to a RYGB
- 2 patients underwent a Braun entero-enterosotmy
- 4 required multiple explorations
- 5 patients have a RYGB conversion planned
  -highlights difficulties in getting these patients to surgery

Surgical Revision of the Loop “Mini” Gastric Bypass
Update on the same region / centers

Initial series-32 patients who require/required revision

Past 10 years – estimated additional 30 cases
Vast majority related to bile reflux symptoms / ulcers / gastritis

ASMBS literature review of OAGB

ELSEVIER

Surgery for Obesity and Related Diseases 14 (2018) 1088–1092

Review article

American Society for Metabolic and Bariatric Surgery review of the literature on one-anastomosis gastric bypass

Manish Parikh, M.D.[a,*], Dan Eisenberg, M.D.[b,c], Jason Johnson, M.D.[d], Maher El-Chaar, M.D.[e], for the American Society for Metabolic and Bariatric Surgery Clinical Issues Committee

Summary and conclusions

In conclusion, our review has found that (1) OAGB has a relatively short operative time, low complication rate, and excellent weight loss outcomes; and (2) the retrospective nature of most series and lack of long-term (>5 year) follow-up limits the current evidence regarding OAGB, particularly in regard to concerns about long-term nutritional deficiencies due to the hypoabsorptive nature of the OAGB procedure, as well as issues specific to the loop gastroenterostomy configuration, such as bile reflux and its potential long-term carcinogenic effects. Only prospective studies with long-term follow-up can alleviate these concerns.

Malabsorptive procedures

1. Currently a very small number are done in the United States- less than 1% of all bariatric ops
2. Complexity of patient management is much greater than with restrictive procedures
3. We are already not doing a great job longterm with managing our current, less malabsorptive procedure population
4. Need to solve problems of access and professionalism in bariatric surgery
5. How many black eyes can our field sustain?

Bile Reflux / Duodenogastric reflux

Loop gastrojejunostomy provides for an experimental Model of esophageal Ca

Human studies

Post gastrectomy with B1 or B2 reconstruction

- 5% of esophageal adenocarcinoma series patients have history of previous gastrectomy
- Interval between Ca and gastrectomy ?

The OAGB has been around for 20 years- isn’t that enough time to see cancers if they were going to occur?

Ref.	Primary disease	No. of patients	Initial reconstruction (B-Ⅰ/B-Ⅱ/R-Y)	Interval (yr)	L
Tanigawa *et al*[8] 2002	Benign	20	7/13	25.8	
	Cancer	27	18/9	10.6	
An *et al*[22] 2007	Benign	25	-	28.6	
	Cancer	13	-	18.8	
Ohashi *et al*[23] 2007	Cancer	108	71/28[1]	7.5	
Schaefer *et al*[24] 2007	Benign	19	1/18	34.0	
Ahn *et al*[25] 2008	Benign	13	0/13	32.4	
	Cancer	45	6/38[1]	6.8	
Firat *et al*[26] 2009	Benign	26	0/26	32.0	
Ojima *et al*[27] 2010	Benign	17	12/5	22.0	
	Cancer	21	16/5	9.0	
Mezhir *et al*[3] 2011	Benign	105	B-Ⅱ: 97	32.0	
Komatsu *et al*[28] 2012	Benign	19	4/15	30.0	
	Cancer	14	12/1[1]	12.0	
Li *et al*[29] 2013	Benign	88	28/60	32.1	
	Cancer	24	14/10	16.8	
Tokunaga *et al*[30] 2013	Benign	89	23/66	31.0	
	Cancer	78	59/17[1]	9.4	
Leo *et al*[31] 2014	Benign	176	10/167	34.6	

USA :

Bariatric surgery subjected to tremendous scrutiny

More so due to tremendous growth

We need to be cautious with our endorsements
"Black eye" events in bariatric surgery

1970's	JI Bypass
1990's	Vertical banded gastroplasty
2000's	laparoscopic learning curve adverse events
	gastric plication "the sleeve killer"?
	Adjustable gastric banding

ASMBS new procedure endorsement process

Search Resources

Enter a name, topic or any other keyword and press **Search**.

Search

Resource Categories

All Resources

Approved Procedures and Devices

Published October 2016

Obesity has been recognized as a disease by the American Medical Association in 2013. Bariatric and metabolic surgery is a proven, effective and enduring treatment for obese patients in need. Bariatric and metabolic surgery strives to provide the most innovative therapies for obese patients. As new devices and procedures emerge, the ASMBS leads the way in creating, evaluating and implementing devices and procedures for obesity. At this time, the society supports the following procedures:

- Roux-en-Y Gastric Bypass
- Duodenal Switch
- Intragastric Balloon
- Sleeve Gastrectomy
- Adjustable Gastric Banding
- Bariatric Reoperative Procedures
- Open procedures as deemed appropriate by the surgeon

*Vertically Banded Gastroplasty under review by the Pathway for Approval of New Devices and Procedures Committee

With the advent of new obesity devices and procedures entering our field, ASMBS developed an official pathway for the approval and sanction of new procedures and decides. Any ASMBS member can submit an application for a new procedure or removal of an approved procedure by following the below link.

http://asmbs.org/pathway-for-approval-for-new-devices-and-procedures

Pathway for endorsement of new devices and procedures

Process

1. **Application by an ASMBS Member Sponsor in active practice** for a new procedure or removal of an approved procedure. Multiple ASMBS Member Co-Sponsors are allowed and encouraged.
2. **Primary ECEC Review:** 75% Approval Required to Next Stage. This review will be inclusive and mainly to ensure plausibility of new procedure and device before invoking full review.
3. **Application Assessed by the ASMBS Pathway for Approval of New Devices and Procedures Committee.** The Pathway for Approval of New Devices and Procedures Committee will include the Chairs of Clinical Issues, Insurance, Quality Improvement & Patient Safety, Emerging Technology and Integrated Health President or their designee. In the course of their review, a Clinical Issues Position Statement may be produced concurrently.
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6. **ASMBS Member Comment** of New Procedure/Device Application with Pathway for Approval of New Devices and Procedures Committee Summary.
7. **Final EC Vote:** 75% Approval Required for final affirmation
8. **Outcome of approval** sent to major insurers and Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program once application approved

https://asmbs.org/pathway-for-approval-for-new-devices-and-procedures

ELSEVIER

Check for updates

Surgery for Obesity and Related Diseases 14 (2018) 1088–1092

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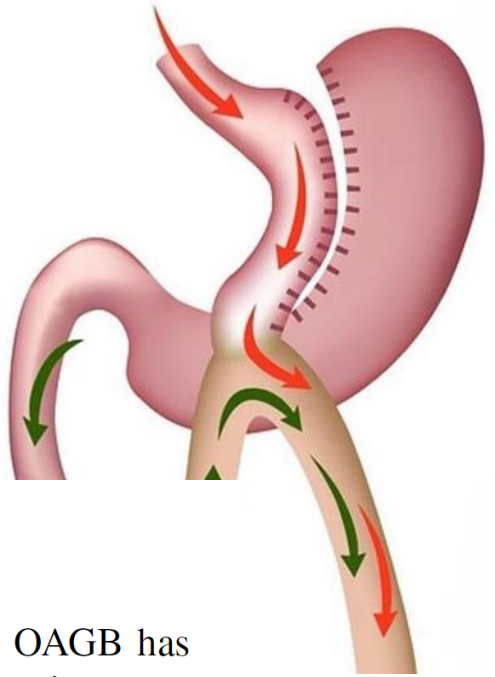
Review of Literature.

Not a position statement.



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In conclusion, our review has found that (1) OAGB has a relatively short operative time, low complication rate, and excellent weight loss outcomes; and (2) the retrospective nature of most series and lack of long-term (>5 year) follow-up limits the current evidence regarding OAGB, particularly in regard to concerns about long-term nutritional deficiencies due to the hypoabsorptive nature of the OAGB procedure, as well as issues specific to the loop gastroenterostomy configuration, such as bile reflux and its potential long-term carcinogenic effects. Only prospective studies with long-term follow-up can alleviate these concerns.

Strongest argument

When considering a novel treatment approach the strongest argument is relative to

PATIENT SAFETY

“Bariatric surgery still does not have sufficient data from enough patients with any procedure to say which operation is best.

I am concerned about the goals of surgeons and patients and their level of interest in what really goes on inside the body after alterations of the anatomy.

I am concerned about the focus on the superficial and results from the first year with a lack of concern about how life will be affected when patients are 10 and 20 years older.”

FDA analogy

- If the FDA were to consider approving a new medication that demonstrated an increased risk of cancer in pre-clinical animal models, they would require the labeling to include a warning about potential long-term risk of malignancy

FDA analogy

- If the FDA were to consider approving a new medication that demonstrated an increased risk of cancer in pre-clinical animal models, they would require the labeling to include a warning about potential long-term risk of malignancy
- At this point in time, the OAGB should come with a warning on its label regarding potential long-term risks based on both pre-clinical animal data and retrospective human data in similar anastomotic procedures.
- More long-term human data is needed to alleviate this concern.

ASMBS update 2022

- Began re-review as part of the endorsement pathway in 2020, slowed by pandemic
- In Jan 2022, EC held an in-person review with pro and con presentations. EC then voted to move the procedure forward in the pathway by requesting comments by ASMBS membership
- Member comments returned and were supportive with more than half of membership agreeing with endorsement

May 5, 2022 Announcement by Dr. Shanu Kothari, President of ASMBS

Thank you

Published Mortality Rates

January 21, 2005

CBS NEWS

"Gastric Bypass Surgery Gone Bad:
1 In 50 People Die Within A Month Of Surgery"

Impact of Gastric Bypass Operation on Survival: A Population-Based Analysis

David R Flum, MD, MPH, E Patchen Dellinger, MD

30-day mortality:

1.9%

J Am Coll Surg 2004; 199: 543-51

ORIGINAL CONTRIBUTION

Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures

2.0%

JAMA 2005; 294: 1903-8

ORIGINAL ARTICLE

The Impact of Age and Medicare Status on Bariatric Surgical Outcomes

Edward H. Livingston, MD; Joshua Langert, BA

3.2%

Arch Surg 2006; 141: 1115-20

U.S. Department of Health & Human Services

CMS Centers for Medicare & Medicaid Services

- MCAC. *November 4, 2004.*

JAMA The Journal of the American Medical Association

Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures

David R. Flum, MD, MPH
Leon Salem, M
Jo A
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Context Case series demonstrate that bariatric surgery can be performed with a low rate of perioperative mortality (0.5%), but the rate among high-risk patients and the
mmunity at large is unknown.

"Mortality rates were greater for those aged 65 years or older compared with younger patients (4.8% VS 1.7% at 90 days, and 11.1% vs 3.9% at 1 year, P<0.001)."

- **Non-coverage Proposal.** *November 23, 2005.*

For patients 65 years or older

“Centers of Excellence” or Accreditation Programs in the USA

AMERICAN COLLEGE OF SURGEONS
FOUNDED IN 1913
OMNIBVS PER ARTEM FIDEMQVE PRODESSE

ACS BSCN
AMERICAN COLLEGE OF SURGEONS
BARIATRIC SURGERY CENTER NETWORK
ACCREDITATION PROGRAM

+

MBSAQIP
METABOLIC AND BARIATRIC SURGERY
ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

ASMBS

BOLD
Bariatric Outcomes Longitudinal Database
SRC SURGICAL REVIEW CORPORATION

March 1, 2012

U.S. Department of Health & Human Services

CMS Centers for Medicare & Medicaid Services

- **Period for Discussion (30 days)**

- **National Coverage Determination February 15, 2006.**

  Cover for age greater than 65.
  Cover Bypass and LapBand.
  Cover BMI 35 and over, with comorbidity.
  Cover if accredited by ASBS or ACS.

ACS BSCN
AMERICAN COLLEGE OF SURGEONS
BARIATRIC SURGERY CENTER NETWORK
ACCREDITATION PROGRAM

ASMBS American Society for Metabolic & Bariatric Surgery

Bariatric Surgery CENTER OF EXCELLENCE
AMERICAN SOCIETY FOR METABOLIC & BARIATRIC SURGERY
SURGICAL REVIEW CORPORATION

Lessons Learned: ACCREDITATION

- **Accreditation has led to a dramatic improvement in the quality of care provided.**

30-day mortality:

1.9%

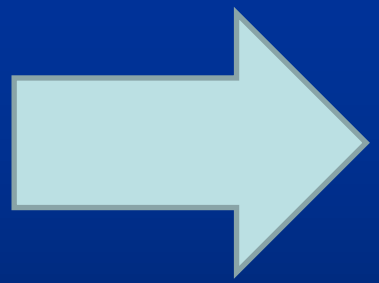
J Am Coll Surg 2004; 199: 543-51

2.0%

JAMA 2005; 294: 1903-8

3.2%

Arch Surg 2006; 141: 1115-20



0.08%

Safer than a Lap Chole…….

ACS NSQIP

3 yrs (2106-2018)

	Sleeve	vs	Lap Chole
	n=36,972		n=113,730
Mortality:	0.06%		0.2%
Complication:	4.9%		6.8%

→ Laparoscopic Sleeve Gastrectomy has 1/3 the 30 day mortality of Laparoscopic Cholecystectomy.

MGH 1811

Pathway for endorsement of new devices and procedures

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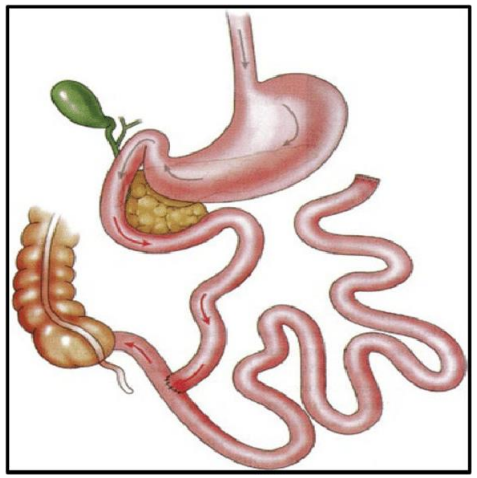
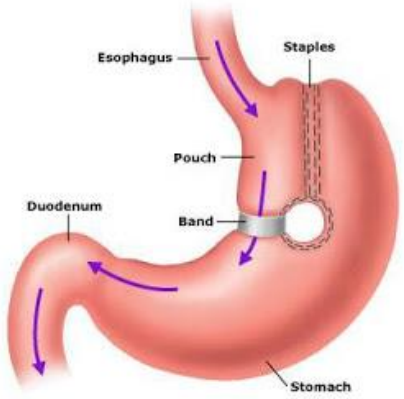
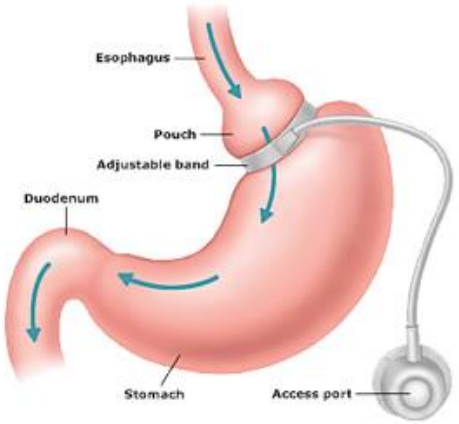
Our History of Bariatric Operations in the USA….



Jejunoileal Bypass



Vertical Banded Gastroplasty



Laparoscopic Adjustable Gastric Band

Gastric Plication

Increased Number of Bariatric Surgery operations

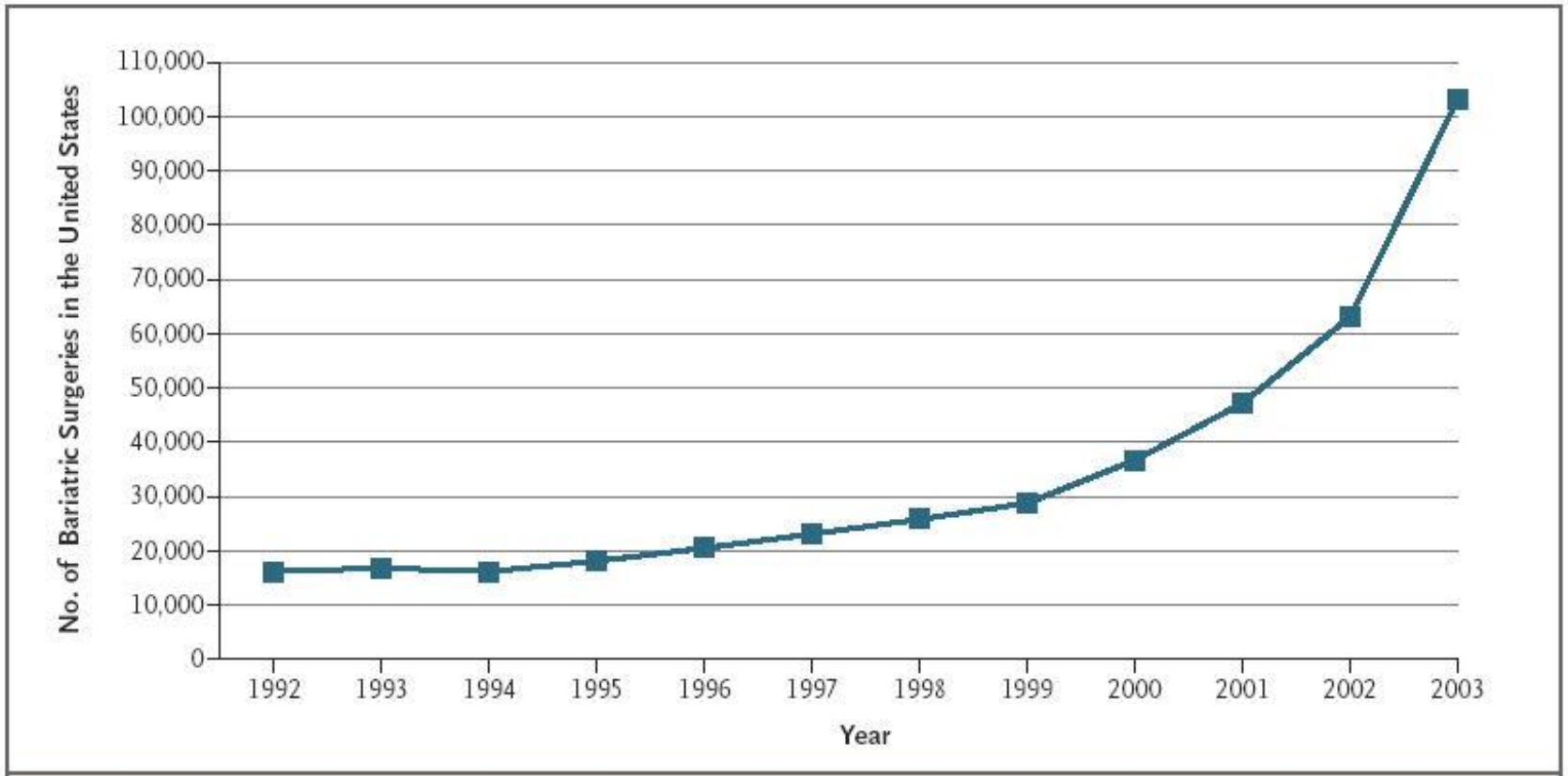


Figure 1. **Estimated Number of Bariatric Operations Performed in the United States, 1992–2003.**
Data are from the American Society for Bariatric Surgery.

NEJM 2004; 350:1076

New Bariatric Techniques

Obesity Surgery (2018) 28:1188–1206
https://doi.org/10.1007/s11695-018-3182-3

ORIGINAL CONTRIBUTIONS

Mini Gastric Bypass-One Anastomosis Gastric Bypass (MGB-OAGB)-IFSO Position Statement

Maurizio De Luca [1] · Tiffany Tie [1] · Geraldine Ooi [1] · Kelvin Higa [1] · Jacques Himpens [1] · Miguel-A Carbajo [1] · Kamal Mahawar [1] · Scott Shikora [1] · Wendy A. Brown [1]

Published online: 29 March 2018

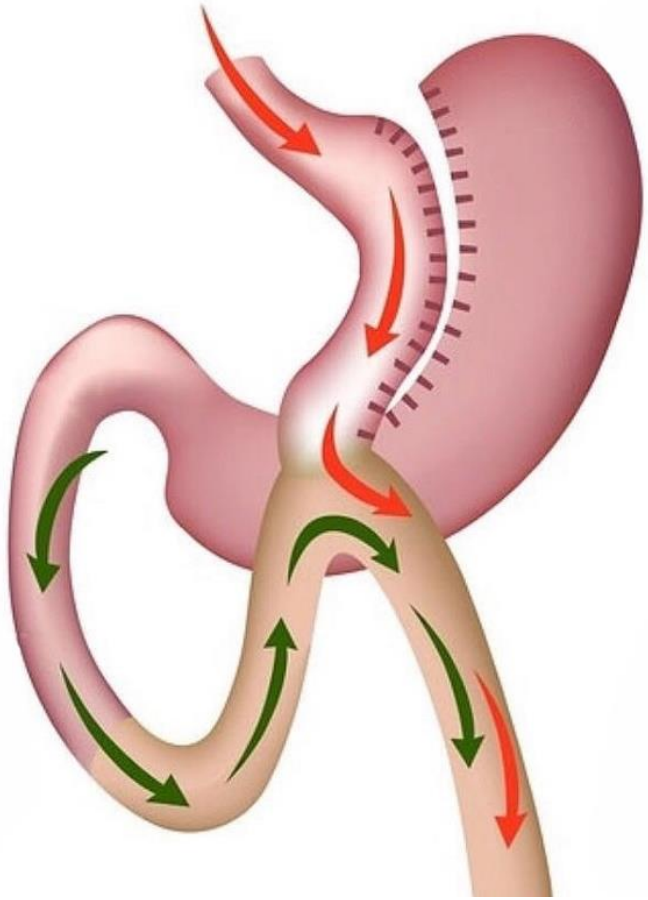
New Bariatric Techniques

Recommendation of the IFSO MGB-OAGB Taskforce

Based on the existing data, we recommend the following:

1. OAGB should be the identifier for this procedure in future publications.
2. Whilst early results are promising in terms of weight and T2DM management, there is a lack of long-term evidence for durability of effect as well as long-term nutritional complications. Bile reflux is either under reported or does not seem to be a major issue, but remains a theoretical risk. Patients should be encouraged to remain in long-term multidisciplinary care.
3. Patients undergoing OAGB in the revisional setting have less weight loss and more complications than with primary procedures.
4. Surgeons performing this, as well as any other bariatric/metabolic procedure, are encouraged to participate in a national or international registry so that long-term data may be more effectively identified.
5. OAGB is a recognised bariatric/metabolic procedure and should not be considered investigational.

One Anastomosis Gastric Bypass



Obesity Surgery (2018) 28:1207–1216
https://doi.org/10.1007/s11695-018-3201-4

ORIGINAL CONTRIBUTIONS

Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS) IFSO Position Statement

Wendy A. Brown [1] · Geraldine Ooi [1] · Kelvin Higa [1] · Jacques Himpens [1] · Antonio Torres [1] · on behalf of the IFSO-appointed task force reviewing the literature on SADI-S/OADS

Published online: 23 March 2018

New Bariatric Techniques

Recommendation of the IFSO SADI-S/OADS Taskforce

Based on the existing data, we recommend the following:

1. SADI-S/OADS should be the standard identifier for this classification of modified DS.
2. There is insufficient data to comment on the long-term safety and efficacy of SADI-S/OADS and patients undergoing this procedure need to be aware of this, and counselled to stay in long-term multidisciplinary care.
3. Surgeons performing this, as well as any other bariatric/metabolic procedure, are encouraged to participate in a national or international registry so that data may be more effectively identified.
4. IFSO supports the SADI-S/OADS as a recognised bariatric/metabolic procedure, but highly encourages RCT's in the near future.

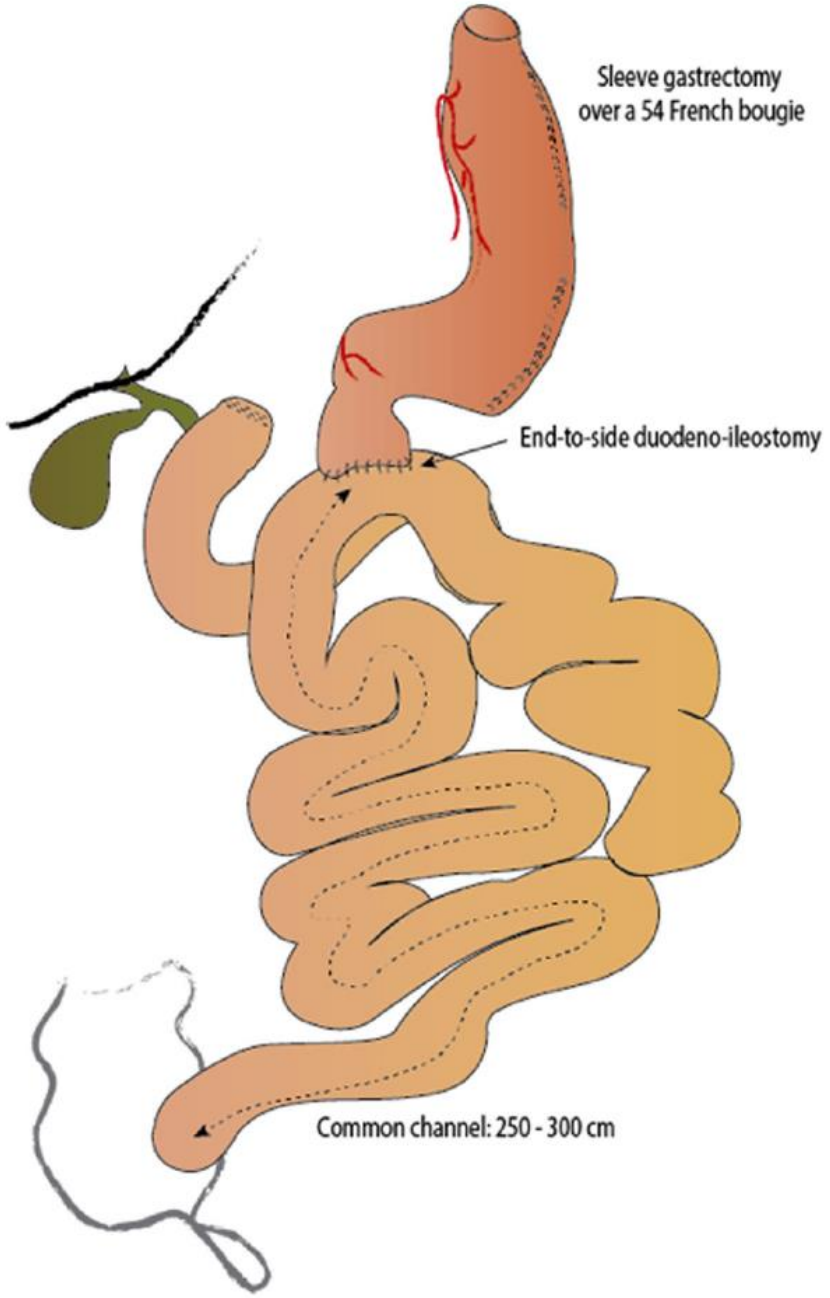


Fig. 1 Diagramme of a typical SADI-S/OADS

Brown WA et al. Obesity Surgery (2018) 28:1207-1216.

ELSEVIER

CrossMark

SURGERY FOR OBESITY AND RELATED DISEASES

Surgery for Obesity and Related Diseases 12 (2016) 944–945

ASMBS Guidelines/Statements

American Society for Metabolic and Bariatric Surgery statement on single-anastomosis duodenal switch

Julie Kim, M.D., F.A.C.S., F.A.S.M.B.S.,* on behalf of the American Society for Metabolic and Bariatric Surgery Clinical Issues Committee

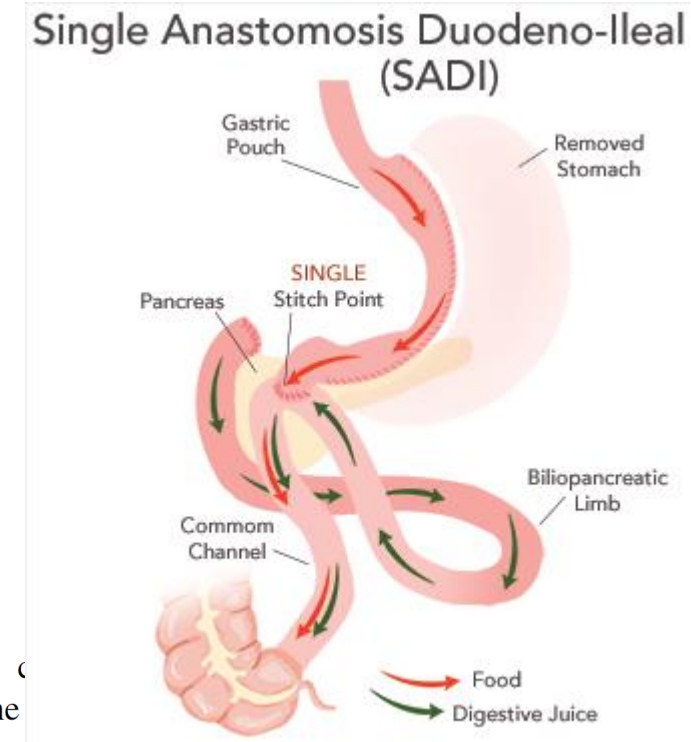
Department of General Surgery, Tufts Medical Center, Boston, Massachusetts

Received May 3, 2016; accepted May 3, 2016

The following recommendations are endorsed by the ASMBS regarding SADS for the treatment of obesity or metabolic disease:

1. Single-anastomosis duodenal switch procedures are considered investigational at present. The procedure should be performed under a study protocol with third-party oversight (local or regional ethics committee, institutional review board, data monitoring and safety board, clinicaltrials.gov, or equivalent authority) to ensure continuous evaluation of patient safety and to review adverse events and outcomes.
2. Publication of short- and long-term safety and efficacy outcomes is strongly encouraged.
3. Data for these procedures from accredited centers should be reported to the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program

Position Statement "Investigational"



Search Resources

Enter a name, topic or any other keyword and press **Search**.

Search

Resource Categories

All Resources

Approved Procedures and Devices

Published October 2016

Obesity has been recognized as a disease by the American Medical Association in 2013. Bariatric and metabolic surgery is a proven, effective and enduring treatment for obese patients in need. Bariatric and metabolic surgery strives to provide the most innovative therapies for obese patients. As new devices and procedures emerge, the ASMBS leads the way in creating, evaluating and implementing devices and procedures for obesity. At this time, the society supports the following procedures:

- Roux-en-Y Gastric Bypass
- Duodenal Switch
- Intragastric Balloon
- Sleeve Gastrectomy
- Adjustable Gastric Banding
- Bariatric Reoperative Procedures
- Open procedures as deemed appropriate by the surgeon

*Vertically Banded Gastroplasty under review by the Pathway for Approval of New Devices and Procedures Committee

With the advent of new obesity devices and procedures entering our field, ASMBS developed an official pathway for the approval and sanction of new procedures and decides. Any ASMBS member can submit an application for a new procedure or removal of an approved procedure by following the below link.

http://asmbs.org/pathway-for-approval-for-new-devices-and-procedures

Pathway for approval for new devices and procedures

Process

1. **Application by an ASMBS Member Sponsor in active practice** for a new procedure or removal of an approved procedure. Multiple ASMBS Member Co-Sponsors are allowed and encouraged.

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3. **Application Assessed by the ASMBS Pathway for Approval of New Devices and Procedures Committee.** The Pathway for Approval of New Devices and Procedures Committee will include the Chairs of Clinical Issues, Insurance, Quality Improvement & Patient Safety, Emerging Technology and Integrated Health President or their designee. In the course of their review, a Clinical Issues Position Statement may be produced concurrently.

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5. **Executive Council Review and Open Vote:** 75% Approval Required to Next Stage.

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5. **Executive Council Review and Open Vote:** 75% Approval Required to Next Stage.
6. **ASMBS Member Comment** of New Procedure/Device Application with Pathway for Approval of New Devices and Procedures Committee Summary.

https://asmbs.org/pathway-for-approval-for-new-devices-and-procedures

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6. **ASMBS Member Comment** of New Procedure/Device Application with Pathway for Approval of New Devices and Procedures Committee Summary.
7. **Final EC Vote:** 75% Approval Required for final affirmation

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6. **ASMBS Member Comment** of New Procedure/Device Application with Pathway for Approval of New Devices and Procedures Committee Summary.
7. **Final EC Vote:** 75% Approval Required for final affirmation
8. **Outcome of approval** sent to major insurers and Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program once application approved

https://asmbs.org/pathway-for-approval-for-new-devices-and-procedures

ELSEVIER

Check for updates

Surgery for Obesity and Related Diseases 14 (2018) 1088–1092

SURGERY FOR OBESITY AND RELATED DISEASES

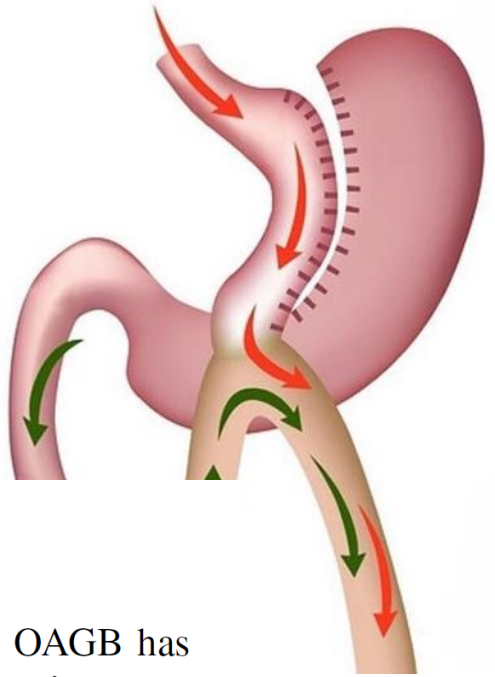
Review article

American Society for Metabolic and Bariatric Surgery review of the literature on one-anastomosis gastric bypass

Manish Parikh, M.D.[a,*], Dan Eisenberg, M.D.[b,c], Jason John[illegible] M.D.[d], Maher El-Chaar, M.D.[e], for the American Society for Metabolic[illegible] Bariatric [illegible] Clinical Issues Committee

Review of Literature.

Not a position statement.



Summary and conclusions

In conclusion, our review has found that (1) OAGB has a relatively short operative time, low complication rate, and excellent weight loss outcomes; and (2) the retrospective nature of most series and lack of long-term (>5 year) follow-up limits the current evidence regarding OAGB, particularly in regard to concerns about long-term nutritional deficiencies due to the hypoabsorptive nature of the OAGB procedure, as well as issues specific to the loop gastroenterostomy configuration, such as bile reflux and its potential long-term carcinogenic effects. Only prospective studies with long-term follow-up can alleviate these concerns.

Relevant issues regarding medical investigation and The current situation regarding OAGB/SADS

- Necessity? **Elective**
- Risk to the individual? **“Should be less”**
- Benefit to the individual? **“May be less”**
- Availability of alternative “accepted” treatments
- Vulnerability of population- Vigilance is most essential when vulnerable populations are involved.
- Conflicts of interest?
- Coercion?

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- Vulnerability of population- Vigilance is most essential when vulnerable populations are involved.
- Conflicts of interest?
- Coercion?

How does one reconcile this last concern with the issue of surgeon / investigators receiving $ payment for performing these procedures?

What about the issue of surgeon investigators earning notoriety, celebrity, speaking engagements ($), increased referrals ($), etc from getting more patients to consent to a novel procedure they are “studying” but also actively promoting?

IRB

- Human research subjects protection

Conclusion

- IFSO just recently published position statements that
  - the OAGB is NOT investigational and
  - The SADIS-S/ OADS is recognized as a bariatric procedure

- The ASMBS has a process for approval or endorsement of new techniques.
  - The OAGB is not an approved procedure in the USA.
  - All investigational procedures can be done under IRB guidance.

“A burning platform
makes people move their feet”…

New Bariatric Techniques

6.1 Data Entry of All Metabolic and Bariatric Procedures and Interventions

Any primary, revision, or conversion procedure, whether surgical or nonsurgical, performed for metabolic or bariatric diagnoses requires entry into the data registry. FDA preapproval trials are the only exception to this rule.

ASMBS publishes an approved list of metabolic and bariatric surgery procedures on the ASMBS website, *asmbs.org*. Accredited centers may not perform nonapproved primary or conversional procedures unless approved by an Institutional Review Board (IRB).

The MBS Committee is responsible for overseeing the process in which emerging technologies, new procedures, and variation of existing approved techniques may be safely introduced into the center with adequate patient protection, oversight (including IRB approval when indicated), and outcomes reporting.

New Bariatric Techniques

6.1 Data Entry of All Metabolic and Bariatric Procedures and Interventions

- The center provides a copy of IRB approval to perform an investigational metabolic and bariatric procedure, if any investigational procedures or procedures not approved by the ASMBS are performed at the center.

MBSAQIP Current Enrollment

- 897 Participating MBSAQIP centers
  - 810 Fully Accredited
- 16 Data Collection Centers
  - 5 International Centers
    - American University of Beirut-Medical Center, *Beirut, Lebanon*
    - GBMC-Jordan Hospital, *Amman, Jordan*
    - Hamad General Hospital, *Doha, Qatar*
    - International Medical Center Hospital, *Jeddah, Saudi Arabia*
    - Sheikh Khalifa Medical City, *Abu Dhabi, United Arab Emirates*

Where are MBSAQIP-Accredited Centers?

ALL 50 states

✚

Puerto Rico

✚

Canada

MBSAQIP®
METABOLIC AND BARIATRIC SURGERY ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

MBSAQIP Current Enrollment

Accredited Centers by Designation Level	
Comprehensive	696
Comprehensive with Adolescent	86
Low Acuity	23
Ambulatory Surgery Centers	12
Adolescent Centers	5
Data Collection Centers	16

MBSAQIP®
METABOLIC AND BARIATRIC SURGERY ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

US Trend:

Bariatric Surgery Numbers, 2011-2017

Published June 2018

	2011	2012	2013	2014	2015	2016	2017
Total	**158,000**	**173,000**	**179,000**	**193,000**	**196,000**	**216,000**	**228,000**
Sleeve	17.80%	33.00%	42.10%	51.70%	53.61%	58.11%	**59.39%**
RYGB	36.70%	37.50%	34.20%	26.80%	23.02%	18.69%	**17.80%**
Band	35.40%	20.20%	14.00%	9.50%	5.68%	3.39%	**2.77%**
BPD-DS	0.90%	1.00%	1.00%	0.40%	0.60%	0.57%	**0.70%**
Revision	6.00%	6.00%	6.00%	11.50%	13.55%	13.95%	**14.14%**
Other	3.20%	2.30%	2.70%	0.10%	3.19%	2.63%	**2.46%**
Balloons	—	—	—	—	0.36%	2.66%	**2.75%**

RYGB = Roux-en-Y gastric bypass;
LAGB = laparoscopic adjustable gastric band;
SG = sleeve gastrectomy;
BPD/DS = biliopancreatic diversion/duodenal switch.

Sleeve is 3 times more common than bypass

Bariatric Surgery

MBSAQIP
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- 100% of cases. Not a sample.
- Bariatric specific data points:
  - Leaks, strictures, internal hernias etc.
- Clinical Effectiveness
  - (not just "death and destruction")
    - Weight.
    - Weight related illnesses.
      - Diabetes, HTN, High Chol, GERD, OSA
- Long term follow-up.
  - 30 days, 6 months, one-year……..Annually…

- Accreditation program.
- CMS PQRS QCDR (Qualified Clinical Data Registry)

Data Collection System – Overview

The Key is **High Quality Data**

that is

- objective
- reliable
- accurate
- complete
- risk-adjusted

and

- captures clinical effectiveness that we and our patients care about.

Morbidity and Mortality Report

MBSAQIP
METABOLIC AND BARIATRIC SURGERY ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

30-Day Morbidity and Mortality Report

Reports case counts and percentages of morbidities and mortalities. Displays surgeon specific, site specific, and comparison data by procedure type.

Start Date: 01/01/2016
End Date: 12/31/2018
CPT® Group: All Operations
Total # of Cases: Site = 958 / Comparison = 571,949

All

Deaths: 0.1%

Complications: 3.1%

	ALL OPERATIONS				LAPAROSCOPIC SLEEVE GASTRECTOMY (LSG)				LAPAROSCOPIC ROUX-EN-Y GASTRIC BYPASS (LRYGBP)			
	SITE		COMPARISON		SITE		COMPARISON		SITE		COMPARISON	
Total Number of Cases[1]	958		571,947		696		334,566		157		118,686	
Mortality												
Mortalities			645	0.1%	0	0%	232	0.1%	0	0%	166	0.1%
Morbidity												
Cases with one or more occurrence			17566	3.1%	8	1.1%	6530	2%	1	0.6%	5049	4.3%
GENERAL POSTOPERATIVE OCCURRENCES												
Cases With W												
			3060	0.5%	0	0%	784	0.2%	0	0%	1021	0.9%
			532	0.1%	0	0%	81	0%	0	0%	158	0.1%
			1777	0.3%	0	0%	463	0.1%	1	0.6%	416	0.4%
Wound Dis		0%	466	0.1%	0	0%	137	0%	0	0%	102	0.1%
Cases With Respiratory Occurrences												
Pneumonia	0	0%	1370	0.2%	0	0%	406	0.1%	0	0%	415	0.3%
Intraoperative OR Postoperative Unplanned Intubation	0	0%	914	0.2%	0	0%	336	0.1%	0	0%	254	0.2%
Pulmonary Embolism	0	0%	675	0.1%	0	0%	275	0.1%	0	0%	209	0.2%
On Ventilator > 48 hours	0	0%	560	0.1%	0	0%	136	0%	0	0%	162	0.1%
Cases With Urinary Tract Occurrences												
Progressive Renal Insufficiency	1	0.1%	326	0.1%	1	0.1%	120	0%	0	0%	103	0.1%
Acute Renal Failure	0	0%	369	0.1%	0	0%	133	0%	0	0%	117	0.1%
Urinary Tract Infection	2	0.2%	1899	0.3%	1	0.1%	900	0.3%	0	0%	559	0.5%
Cases With CNS Occurrences												
CVA	0	0%	78	0%	0	0%	47	0%	0	0%	8	0%
Cases With Cardiac Occurrences												
Intraoperative OR Postoperative Cardiac Arrest Requiring CPR	0	0%	269	0%	0	0%	115	0%	0	0%	67	0.1%
Intraoperative OR Postoperative Myocardial Infarction	0	0%	178	0%	0	0%	78	0%	0	0%	51	0%
Cases With Other Occurrences												
Transfusion Intraop/ Postop (72h of surgery start time)	8	0.8%	4344	0.8%	6	0.9%	1625	0.5%	1	0.6%	1297	1.1%
Vein Thrombosis Requiring Therapy	0	0%	1027	0.2%	0	0%	602	0.2%	0	0%	205	0.2%
C. diff	0	0%	755	0.1%	0	0%	312	0.1%	0	0%	243	0.2%
Sepsis	0	0%	853	0.1%	0	0%	221	0.1%	0	0%	202	0.2%
Septic Shock	0	0%	464	0.1%	0	0%	101	0%	0	0%	140	0.1%
Cases With Metabolic/Bariatric Occurrences												
Coma > 24 hours	0	0%	19	0%	0	0%	8	0%	0	0%	3	0%
Peripheral Nerve Injury	0	0%	36	0%	0	0%	12	0%	0	0%	15	0%
Unplanned Admission to ICU within 30 days	2	0.2%	4610	0.8%	2	0.3%	1705	0.5%	0	0%	1287	1.1%
CASES WITH MBSAQIP-SPECIFIC EVENTS[2]												

Morbidity and Mortality Report

MBSAQIP
METABOLIC AND BARIATRIC SURGERY ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

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End Date: 12/31/2018
CPT® Group: All Operations
Total # of Cases: Site = 958 / Comparison = 571,949

Sleeve

Deaths: 0.07%

Complications: 2.0%

	ALL OPERATIONS				LAPAROSCOPIC SLEEVE GASTRECTOMY (LSG)				LAPAROSCOPIC ROUX-EN-Y GASTRIC BYPASS (LRYGBP)			
	SITE		COMPARISON		SITE		COMPARISON		SITE		COMPARISON	
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Bypass

Deaths: 0.14%

Complications: 4.3%

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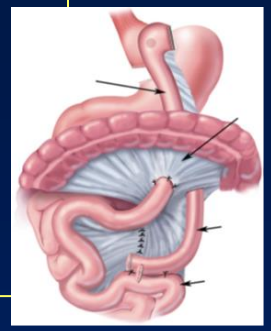
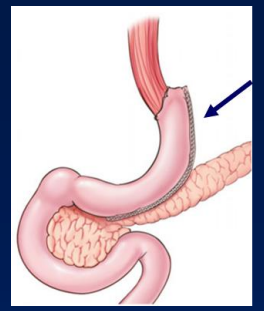
GENERAL POSTOPERATIVE OCCURRENCES												
Cases With W												
				0.5%	0	0%	784	0.2%	0	0%	1021	0.9%
			532	0.1%	0	0%	81	0%	0	0%	158	0.1%
			1777	0.3%	0	0%	463	0.1%	1	0.6%	416	0.4%
Wound Disr		0%	466	0.1%	0	0%	137	0%	0	0%	102	0.1%
Cases With Respiratory Occurrences												
Pneumonia	0	0%	1370	0.2%	0	0%	406	0.1%	0	0%	415	0.3%
Intraoperative OR Postoperative Unplanned Intubation	0	0%	914	0.2%	0	0%	336	0.1%	0	0%	254	0.2%
Pulmonary Embolism	0	0%	675	0.1%	0	0%	275	0.1%	0	0%	209	0.2%
On Ventilator > 48 hours	0	0%	560	0.1%	0	0%	136	0%	0	0%	162	0.1%
Cases With Urinary Tract Occurrences												
Progressive Renal Insufficiency	1	0.1%	326	0.1%	1	0.1%	120	0%	0	0%	103	0.1%
Acute Renal Failure	0	0%	369	0.1%	0	0%	133	0%	0	0%	117	0.1%
Urinary Tract Infection	2	0.2%	1899	0.3%	1	0.1%	900	0.3%	0	0%	559	0.5%
Cases With CNS Occurrences												
CVA	0	0%	78	0%	0	0%	47	0%	0	0%	8	0%
Cases With Cardiac Occurrences												
Intraoperative OR Postoperative Cardiac Arrest Requiring CPR	0	0%	269	0%	0	0%	115	0%	0	0%	67	0.1%
Intraoperative OR Postoperative Myocardial Infarction	0	0%	178	0%	0	0%	78	0%	0	0%	51	0%
Cases With Other Occurrences												
Transfusion Intraop/ Postop (72h of surgery start time)	8	0.8%	4344	0.8%	6	0.9%	1625	0.5%	1	0.6%	1297	1.1%
Vein Thrombosis Requiring Therapy	0	0%	1027	0.2%	0	0%	602	0.2%	0	0%	205	0.2%
C. diff	0	0%	755	0.1%	0	0%	312	0.1%	0	0%	243	0.2%
Sepsis	0	0%	853	0.1%	0	0%	221	0.1%	0	0%	202	0.2%
Septic Shock	0	0%	464	0.1%	0	0%	101	0%	0	0%	140	0.1%
Cases With Metabolic/Bariatric Occurrences												
Coma > 24 hours	0	0%	19	0%	0	0%	8	0%	0	0%	3	0%
Peripheral Nerve Injury	0	0%	36	0%	0	0%	12	0%	0	0%	15	0%
Unplanned Admission to ICU within 30 days	2	0.2%	4610	0.8%	2	0.3%	1705	0.5%	0	0%	1287	1.1%
CASES WITH MBSAQIP-SPECIFIC EVENTS[2]												

Morbidity and Mortality
30 days





		LRYGB	Sleeve
	n=	*80,574*	*223,267*
Mortality Rate		0.15%	0.06%
Complication Rate		4.3%	1.9%
Anastomotic Leak		0.3%	0.2%
Bleeding		0.9%	0.3%
PE		0.2%	0.1%
Wound infection		1.3%	0.3%
Pneumonia		0.4%	0.1%
Stomal stenosis		0.6%	0.1%
Internal hernia		0.9%	NA
Nausea/Vomiting Dehydration		1.9%	1.1%

MBSAQIP. 1/1/16 to 12/31/2017.

MBSAQIP 01/01/2016 - 12/31/2016 Semiannual Report: Site Summary

Mass General Hospital

Site Number: 14

Laparoscopic Sleeve Gastrectomy

	Total	Observed		Pred**	Expected	Odds	C.I.***		Outlier	Decile	Performance*
	Cases	Events	Rate	Obs. Rate	Rate	Ratio	Lower	Upper			Assessment
LSG Morbidity	260	1	0.38%	0.78%	1.29%	0.60	0.22	1.60	No	1	Exemplary
LSG All Occurrences Morbidity	260	3	1.15%	2.23%	3.57%	0.61	0.34	1.10	No	1	Exemplary
LSG Leak	260	0	0.00%	0.11%	0.15%	0.76	0.14	4.08	No	1	Exemplary
LSG Bleeding	260	1	0.38%	0.43%	0.46%	0.93	0.30	2.93	No	6	As Expected
LSG SSI	260	0	0.00%	0.21%	0.33%	0.65	0.15	2.75	No	1	Exemplary
LSG All Cause Reoperation	260	0	0.00%	0.47%	0.70%	0.68	0.26	1.73	No	1	Exemplary
LSG Related Reoperation	260	0	0.00%	0.32%	0.45%	0.70	0.23	2.13	No	1	Exemplary
LSG All Cause Intervention	260	0	0.00%	0.30%	0.60%	0.51	0.12	2.07	No	1	Exemplary
LSG Related Intervention	260	0	0.00%	0.26%	0.46%	0.57	0.14	2.36	No	1	Exemplary
LSG All Cause Readmission	260	2	0.77%	1.76%	2.66%	0.66	0.36	1.20	No	1	Exemplary
LSG Related Readmission	260	2	0.77%	1.33%	1.84%	0.72	0.36	1.45	No	1	Exemplary

Laparoscopic Roux-en-Y Gastric Bypass

	Total	Observed		Pred**	Expected	Odds	C.I.***		Outlier	Decile	Performance*
	Cases	Events	Rate	Obs. Rate	Rate	Ratio	Lower	Upper			Assessment
LRYGB Morbidity	66	0	0.00%	1.56%	2.97%	0.52	0.15	1.76	No	1	Exemplary
LRYGB All Occurrences Morbidity	66	0	0.00%	4.40%	8.74%	0.48	0.22	1.03	No	1	Exemplary
LRYGB Leak	66	0	0.00%	0.28%	0.30%	0.94	0.32	2.80	No	2	None
LRYGB Bleeding	66	0	0.00%	1.31%	1.83%	0.71	0.25	2.07	No	1	Exemplary
LRYGB SSI	66	0	0.00%	0.39%	0.62%	0.62	0.07	5.65	No	2	As Expected
LRYGB All Cause Reoperation	66	0	0.00%	1.46%	1.94%	0.75	0.29	1.93	No	1	Exemplary
LRYGB Related Reoperation	66	0	0.00%	1.21%	1.59%	0.76	0.27	2.11	No	1	Exemplary
LRYGB All Cause Intervention	66	0	0.00%	1.20%	1.96%	0.61	0.17	2.18	No	1	Exemplary
LRYGB Related Intervention	66	0	0.00%	1.03%	1.61%	0.63	0.17	2.41	No	1	Exemplary
LRYGB All Cause Readmission	66	1	1.52%	4.28%	5.68%	0.74	0.38	1.44	No	1	Exemplary
LRYGB Related Readmission	66	1	1.52%	3.46%	4.45%	0.77	0.37	1.61	No	1	Exemplary

These are Effective Procedures

BMI Reduction over Time Report

MBSAQIP
METABOLIC AND BARIATRIC SURGERY ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

BMI Reduction Over Time

Summary analysis of comorbidity data at baseline and at follow-up periods. Provides reduction in comorbidity percentage at each fo

Start Date: 01/01/2007
End Date: 12/31/2018

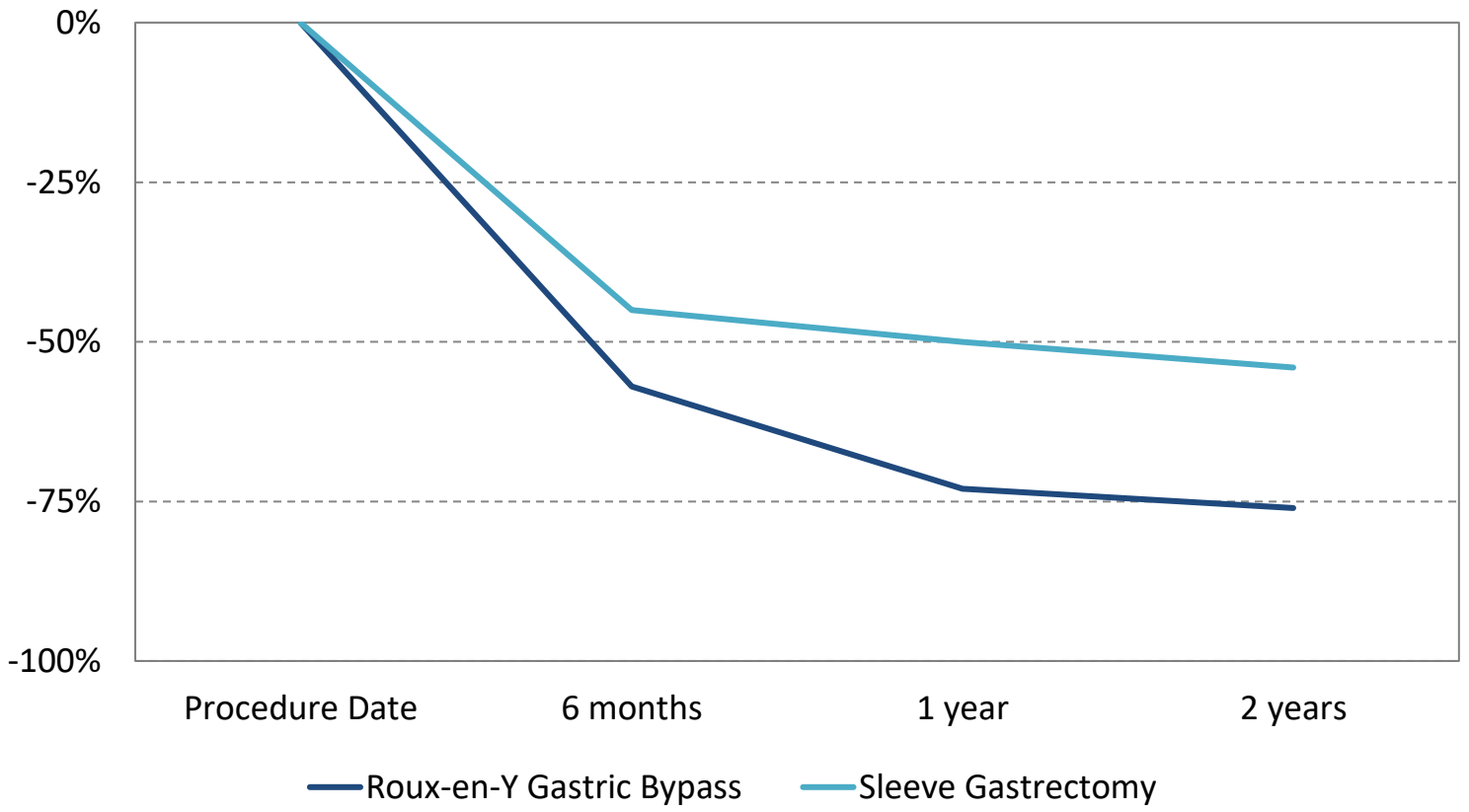
	30 DAYS		6 MONTHS		1 YEAR		2 YEARS	
	SITE	COMPARISON	SITE	COMPARISON	SITE	COMPARISON	SITE	COMPARISON
Lap Roux-en-Y								
Cases Successfully Followed Up [1]	1029	122057	1092	262837	895	166711	675	93649
Baseline BMI Mean	47.02	46.51	46.46	46.15	46.11	46.18	46.22	46.17
Followup BMI Mean	41.46	42.92	35.11	35.85	31.01	31.64	31.02	
Mean % Weight Loss Towards Ideal BMI [2]	0.25	0.17	0.53	0.49	0.72	0.69	0.72	0.7
Sleeve Gastrectomy								
Cases Successfully Followed Up [1]	389	106337	1031	441197	625	227923	343	103430
Baseline BMI Mean	45.75	45.31	45.29	45.1	44.98	45.25	44.57	45.29
Followup BMI Mean	40.47	42.07	36.4	36.52	34.22	33.42	34.66	
Mean % Weight Loss Towards Ideal BMI [2]	0.25	0.16	0.44	0.43	0.54	0.58	0.51	0.55

Bypass:
69%
EWL at 1 year

Sleeve:
58%
EWL at 1 year

69% EWL (%Excess Weight Loss): a patient who is 100 lbs overweight, would expect to lose 69 lbs.

Reduction in Body Mass Index (BMI) by Type of Surgery



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Mass General data: Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSA-QIP) Data period: Jan 2012 –Dec 2016

MASSACHUSETTS GENERAL HOSPITAL
WEIGHT CENTER

Reduction in Comorbidities Over Time Report

Reduction in Comorbidities Over Time

Summary analysis of comorbidity data at baseline and at follow-up periods. Provides reduction in comorbidity percentage at each follow-up period. Report displays surgeon specific, site specific, and comparison data.

Start Date: 01/01/2007
End Date: 12/31/2018
CPT® Group: Lap Roux-en-Y
Display 3 follow up periods beginning with: 1 Year

Bypass

	LAP ROUX-EN-Y							
	BASELINE		1 YEAR		2 YEARS		3 YEARS	
	SITE	COMPARISON	SITE	COMPARISON	SITE	COMPARISON	SITE	COMPARISON
Number of Cases	1456	364461						
Cases Eligible for Follow-Up[1]			1388	312566	1300	271271	1182	218461
Cases Successfully Followed Up[2]			887	154064	608	76982	416	38352
Comorbidity Analysis in Cases Successfully Followed Up								
Sleep Apnea								
Collected (Yes/No) at Baseline & Followup	100%					.5% (76615)	99.8% (415)	99.7% (38235)
Present at Baseline	43.8% (637)					(34140)	50.8% (211)	44.7% (17095)
Present at Followup Period			16.5% (146)	17.4% (26622)	12.7% (77)	14.7% (11254)	(44)	13.5% (5158)
Reduction from Baseline			64.4% (264)	60.1% (40019)	72.3% (201)	67% (22886)	79.1% (167)	69.8% (11937)
GERD								
Collected (Yes/No) at Baseline & Followup	100%					.5% (76604)	100% (416)	99.7% (38225)
Present at Baseline	40.5%					.1% (29942)	43.5% (181)	39% (14907)
Present at Followup Period						21.9% (16783)	29.1% (121)	23.6% (9023)
Reduction from Baseline					37% (94)		33.1% (60)	39.5% (5884)
Hyperlipidemia								
Collected (Yes/No) at Baseline & Followup	100%					99.5% (76585)	100% (416)	99.6% (38216)
Present at Baseline	37.6%					7% (26596)	40.9% (170)	36.2% (13834)
Present at Followup Period							23.8% (99)	13.8% (5286)
Reduction from Baseline					(96)	61.6% (16394)	41.8% (71)	61.8% (8548)
Hypertension								
Collected (Yes/No) at Baseline & Followup	100%					99.5% (76566)	99.5% (414)	99.6% (38214)
Present at Baseline	53.9%					8% (44242)	62.6% (259)	58.9% (22524)
Present at Followup Period							34.1% (141)	27.5% (10496)
Reduction from Baseline					(166)	54.6% (24164)	45.6% (118)	53.4% (12028)
Diabetes								
Collected (Yes/No) at Baseline & Followup	100%					99.4% (76541)	100% (416)	99.6% (38214)
Present at Baseline	39.					5.1% (27630)	41.6% (173)	36.7% (14039)
Present at Followup Period							13.5% (56)	11.2% (4272)
Reduction from Baseline					(174)	71.4% (19718)	67.6% (117)	69.6% (9767)
Comorbidity Summary								
One or more Comorbidites Present at Baseline			87.9% (780)	83.8% (129157)	87.5% (532)	84.7% (65206)	90.4% (376)	85.4% (32746)
Reduction of one or more Comorbidites			88.6% (691)	84.4% (109049)	91.5% (487)	87% (56741)	94.4% (355)	87.7% (28710)

Sleep apnea: 70% 3 yrs

GERD: 40% 3 yrs

Hyperlipidemia: 62% 3 yrs

Hypertension: 53% 3 yrs

Diabetes: 70% 3 yrs

Reduction in Comorbidities Over Time Report

Summary analysis of comorbidity data at baseline and at follow-up periods. Provides reduction in comorbidity percentage at each follow-up period. Report displays surgeon specific, site specific, and comparison data.

Start Date: 01/01/2007
End Date: 12/31/2018
CPT® Group: Sleeve Gastrectomy
Display 3 follow up periods beginning with: 1 Year

Sleeve

	SLEEVE GASTRECTOMY							
	BASELINE		1 YEAR		2 YEARS		3 YEARS	
	SITE	COMPARISON	SITE	COMPARISON	SITE	COMPARISON	SITE	COMPARISON
Number of Cases	1722	663941						
Cases Eligible for Follow-Up[1]			1554	551366	1366	447604	1074	318247
Cases Successfully Followed Up[2]			441	205036	169	77872	70	30411
Comorbidity Analysis in Cases Successfully Followed Up								
Sleep Apnea								
Collected (Yes/No) at Baseline & Followup	100% (1722)					99.9% (77764)	100% (70)	100% (30398)
Present at Baseline	39.8% (686)	34.8% (231)			44.4% (75)		50% (35)	39.8% (12095)
Present at Followup Period			15.7% (69)	17.3% (35375)	17.8% (30)	16.2% (12579)	25.7% (18)	15.4% (4689)
Reduction from Baseline			62.3% (114)	54.7% (42635)	60% (45)	59% (18122)	48.6% (17)	61.2% (7406)
GERD								
Collected (Yes/No) at Baseline & Followup	100%					9% (77760)	100% (70)	100% (30398)
Present at Baseline	33.6%					2.1% (24930)	37.1% (26)	32.1% (9767)
Present at Followup Period					(64)	20.4% (2352)	37.1% (26)	28.5% (8662)
Reduction from Baseline			6.9% (12)	18% (11162)	-4.9% (-3)	17.7% (4403)	0% (0)	11.3% (1105)
Hyperlipidemia								
Collected (Yes/No) at Baseline & Followup	100%					9.9% (77756)	100% (70)	100% (30397)
Present at Baseline	28.5%					.3% (21246)	41.4% (29)	28.2% (8566)
Present at Followup Period							31.4% (22)	16.4% (4993)
Reduction from Baseline					16.4% (9)	43.8% (9306)	24.1% (7)	41.7% (3573)
Hypertension								
Collected (Yes/No) at Baseline & Followup	100%					9.8% (77745)	100% (70)	100% (30397)
Present at Baseline	44.9%					.7% (40178)	60% (42)	52.2% (15853)
Present at Followup Period							44.3% (31)	28.3% (8605)
Reduction from Baseline					34.5% (29)	47.8% (19211)	26.2% (11)	45.7% (7248)
Diabetes								
Collected (Yes/No) at Baseline & Followup	100%					99.8% (77743)	100% (70)	99.9% (30395)
Present at Baseline	28.6					4.6% (19161)	27.1% (19)	25.2% (7673)
Present at Followup Period							14.3% (10)	10% (3041)
Reduction from Baseline					45.8% (22)	64.2% (12295)	47.4% (9)	60.4% (4632)

Sleep apnea: 61% 3 yrs

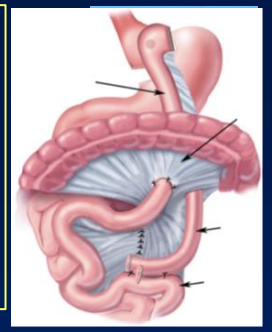
GERD: 11% 3 yrs

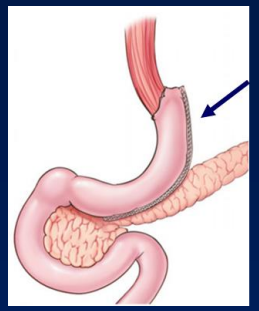
Hyperlipidemia: 42% 3 yrs

Hypertension: 46% 3 yrs

Diabetes: 60% 3 yrs

Reduction in Weight and Weight Related Diseases

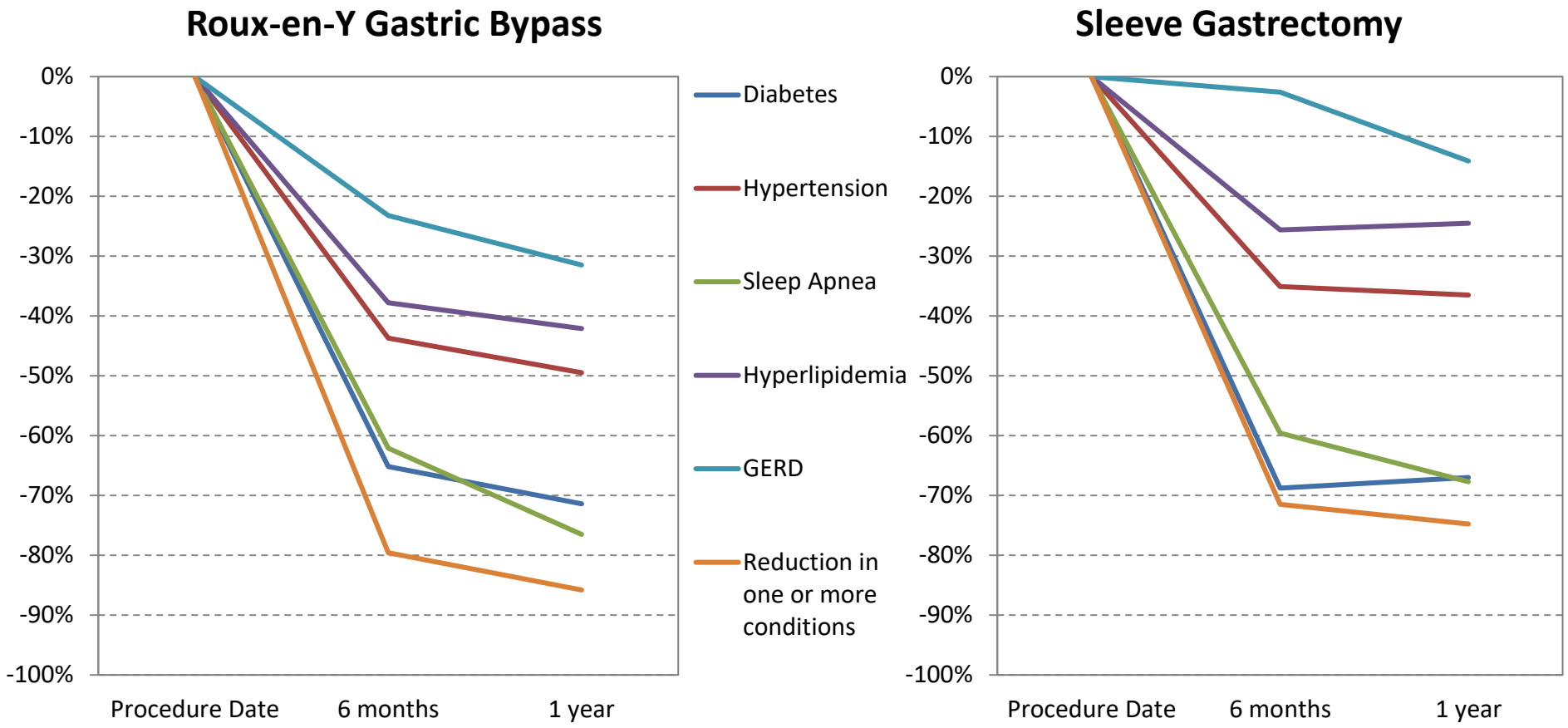




		LRYGB	Sleeve
	n=	*102,337*	*249,648*
% Excess Weight Loss (1 yr)		67%	58%
Diabetes		70.9%	66.3%
Hypertension		52.1%	47.4%
High Cholesterol		57.3%	43.9%
GERD		44.4%	19.3%
Obstructive Sleep Apnea		58.8%	54.3%

MBSAQIP. 1/1/15 to 12/31/2017.

Improvement in Obesity-Related Diseases



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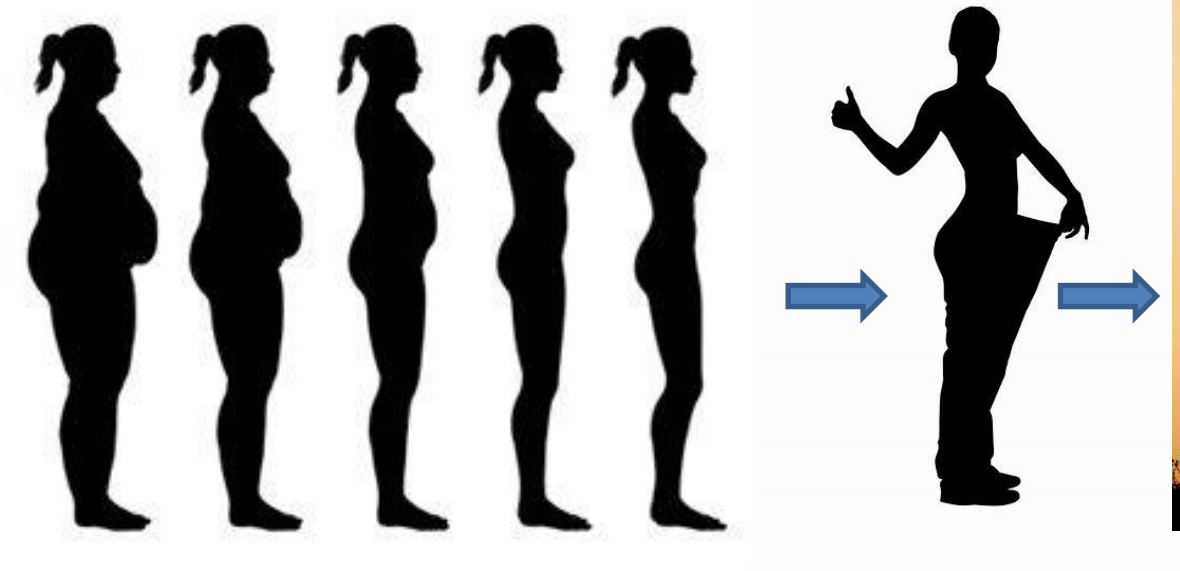
Mass General data: Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSA-QIP) Data period: Jan 2012 –Dec 2016

MASSACHUSETTS GENERAL HOSPITAL
WEIGHT CENTER

Putting the Patient First: Measuring PROs

MBSAQIP
METABOLIC AND BARIATRIC SURGERY
ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM



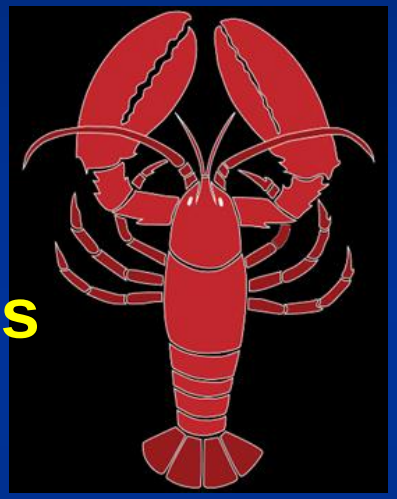
- I can play with my kids!
- I can go on a plane!
- I can shop in stores!
- I have so much more energy!

Patient Centered Outcomes Research Institute

5 year project

MBSAQIP
METABOLIC AND BARIATRIC SURGERY ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

"LOBSTER PROMs"



Long-term Outcomes of Bariatric Surgical Techniques and their Effect on Related Patient Reported Outcome Metrics

Assessed Preop and annually postop.

ASMBS
American Society for Metabolic & Bariatric Surgery

“MBSAQIP PROMs”

Milestones

Milestones	Goals
Focus Groups	Identification of outcomes and validated PROMS
Alpha Pilot	PROM implementation at 5 Partners Hospitals
Beta Pilot	PROM implementation in a national sample
National Rollout	PROM implementation at all MBSAQIP centers
Analysis	Comparative effectiveness of bariatric procedures
Data Dissemination Tool	Web-based tool to aid in shared decision making

Importance of Quality of Life Domains Ranked by Focus Groups

- 20 focus groups
- Facilitated by quantitative experts from Harvard School of Public Health and Brown University.

Rank	Caregivers	Preop Patients	Preop Family	Postop Patients	Postop Family
1	Health	Health	Health	Health	Self-confidence
2	Self-confidence	Self-confidence	Self-confidence	Mobility	Health
3	Social/Interpersonal	Relationship with Food	Relationship with Food	Everyday Activities	Everyday Activities
4	Mobility	Mobility	Everyday Activities	Self-confidence	Relationship with Food
5	Everyday Activities	Everyday Activities	Mobility	Social/Interpersonal	Social/Interpersonal
6	Relationship with Food	Work/School	Social/Interpersonal	Relationship with Food	Mobility
7	Intimate Relationships	Intimate Relationships	Work/School	Intimate Relationships	Work/School
8	Work/School	Social/Interpersonal		Work/School	

Focus Group 2 – Identify PROMs

	BODY-Q Physical Symptoms n = 11	WRSM n = 20	BODY-Q Physical Function n = 7	OWLQOL n = 17	BODY-Q Body Image n = 7	BODY-Q Social Function n = 10	OP n = 8	BODY-Q Psychological Function n = 10	BODY-Q Sexual Function n = 5
Health	IIIIIIIIIII	IIIIIIIIIIIIIII		IIIII					
Self-confidence		I		IIII	IIIIIII			IIIIIIIII	
Social/Interpersonal				III		IIIIIIIII	IIIII		
Mobility			IIIIIII						
Everyday Activities				III			II		
Relationship with Food		II		II					
Sexual Life		I					I		IIIII
Work/School									

PROMs Chosen

General Health:

PROMIS 10 was selected as the general health measure

Disease Specific:

1. ***Obesity-related Problem Scale*** and
2. the ***Obesity and Weight-Loss Quality of Life*** survey were selected as the obesity specific surveys

Obesity-Related Problem Scale

Does your body weight or body shape bother you in the following situations?
Read each statement and mark the alternative that best applies to you.

	Definitely bothered	*Mostly bothered*	*Not so bothered*	*Definitely not bothered*
1. Private gatherings in my own home	1☐	2☐	3☐	4☐
2. Private gatherings in a friend's or relative's home	1☐	2☐	3☐	4☐
3. Going to a restaurant	1☐	2☐	3☐	4☐
4. Going to community activities, courses etc.	1☐	2☐	3☐	4☐
5. Vacations away from home	1☐	2☐	3☐	4☐
6. Trying on and buying clothes	1☐	2☐	3☐	4☐
7. Bathing in public places (beach, public pool, etc.)	1☐	2☐	3☐	4☐

Obesity and Weight-Loss Quality of Life Instrument

Your Feelings About Your Weight

Below is a list of statements about your quality of life in relation to being overweight and trying to lose weight.

For each of the following statements, please mark an ☒ in the one box that best describes your answer <u>at this time</u>.

	Not at all	Hardly	Some-what	Moder-ately	A good deal	A great deal	A very great deal
1. Because of my weight, I try to wear clothes that hide my shape.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
2. I feel frustrated that I have less energy because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
3. I feel guilty when I eat because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
4. I am bothered about what other people say about my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6

(Please turn the page)

Obesity and Weight-Loss Quality of Life Instrument

	Not at all	Hardly	Some-what	Moder-ately	A good deal	A great deal	A very great deal
5. Because of my weight, I try to avoid having my photograph taken.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
6. Because of my weight, I have to pay close attention to personal hygiene.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
7. My weight prevents me from doing what I want to do.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
8. I worry about the physical stress that my weight puts on my body.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
9. I feel frustrated that I am not able to eat what others do because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
10. I feel depressed because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6

(Please turn the page)

Obesity and Weight-Loss Quality of Life Instrument

	Not at all	Hardly	Some-what	Moder-ately	A good deal	A great deal	A very great deal
11. I feel ugly because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
12. I worry about the future because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
13. I envy people who are thin.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
14. I feel that people stare at me because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
15. I have difficulty accepting my body because of my weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
16. I am afraid that I will gain back any weight that I lose.	☐0	☐1	☐2	☐3	☐4	☐5	☐6
17. I get discouraged when I try to lose weight.	☐0	☐1	☐2	☐3	☐4	☐5	☐6

Please go back to the questions you just answered to make sure you did not miss any items

Thank you for completing these questions!

Patient Email

Dear [PATIENT FIRST NAME],

As your surgeon, the most important information to me is how you feel about your health and quality of life. Until now, we did not systematically collect this information. To improve care for you and others like you, we want to hear about your health and quality of life as they relate to your weight and decision to have bariatric surgery. Not only will your responses be used by your bariatric clinical team to provide you with the best care possible, but they will also be part of a national quality improvement program for all bariatric surgery patients. Please click on the link below and answer the questions about your current health and quality of life. The survey should take less than 10 minutes to complete.

https://nationalbariatric.co1.qualtrics.com/SE/?SID=SV_ero5C5HjJmo5s6V

Sincerely,

Dr. [SURGEON]

ASMBS American Society for Metabolic & Bariatric Surgery

MBSAQIP ACCREDITED CENTER QUALITY PROGRAM

American College of Surgeons
Inspiring Quality:
Highest Standards, Better Outcomes
100+years

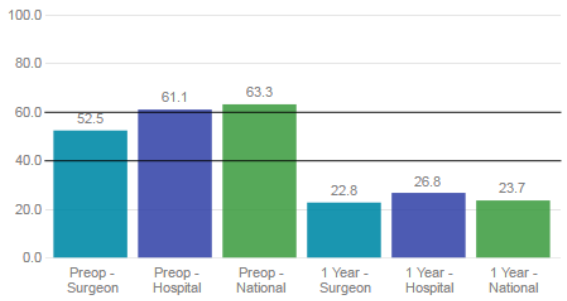
Surgeon Dashboards

Patient Tab | Surgeon Tab - Sleeve vs. Bypass | Surgeon Tab - Band vs. Other Primary | Surgeon Tab - Conversion vs. Other Revision, Reoperation, Other Non-primary | **Surgeon Tab - All Procedures**

Filtering by: Surgeon: Matthew Hutter | Location: Massachusetts General Hospital | Operation Date: All Time | Follow-up Interval: All | Hide Filters | Reset to Default | Page Options | Edit Page

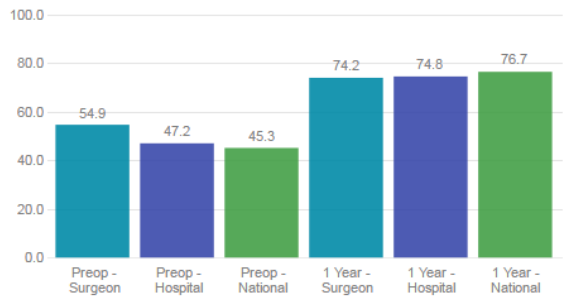
Average Patient-Reported Outcome Measure Scores

Average Obesity-Related Problem Scale



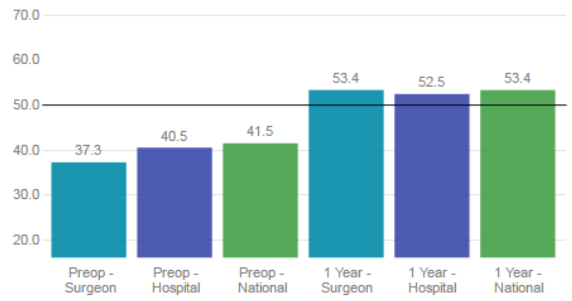
Scores indicate the level of mental and/or social impairment due to obesity-related problems. Individuals with scores less than 40 have few problems, scores from 40 to 59 have moderate problems, and scores of 60 or higher have severe problems.

Average Obesity and Weight-Loss Quality of Life

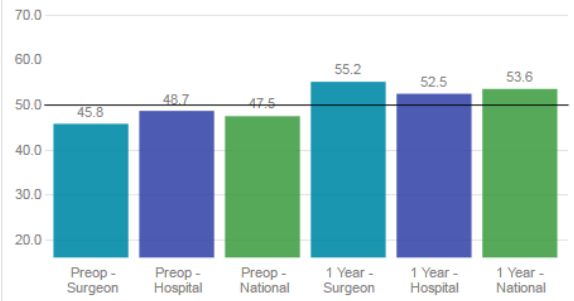


Scores indicate the obesity and weight-loss quality of life on a scale from 0 to 100. The higher the score is, the better the obesity and weight-loss quality of life is reported to be.

Average Overall Physical Health

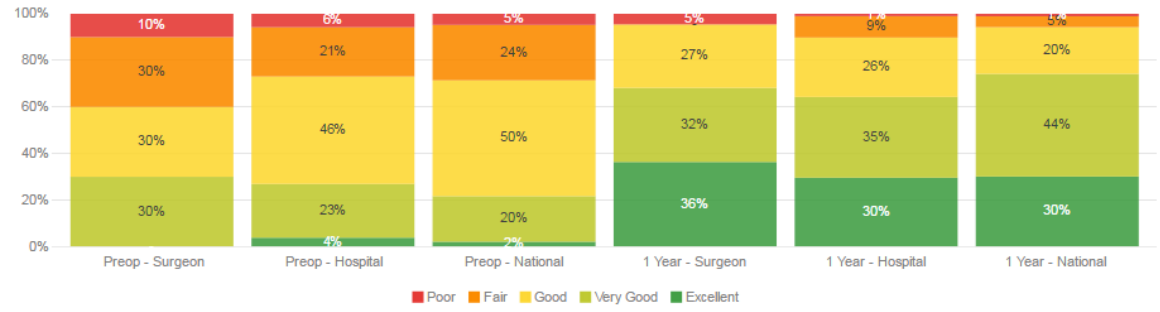


Average Overall Mental Health

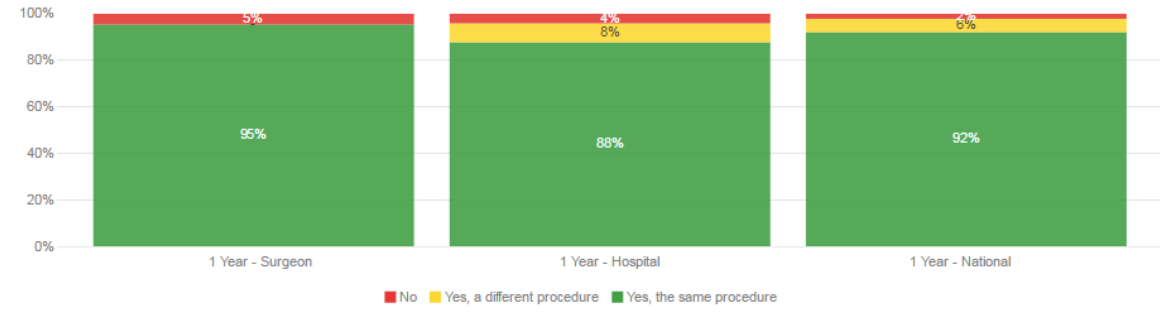


The average general US population score is 50 with a standard deviation of 10 for both the Overall Physical and Mental Health subscales. For example, someone with a score of 60 is one standard deviation better (more healthy) than the general population.

Patient-Reported General Health



Would you have surgery again?



The Right Operation for the Right Patient Tool

Options | Legend | Feedback | Help

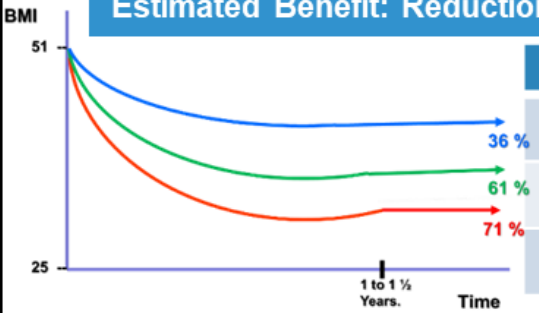
Long, Alvan (0000002) 107/M Visit Date: 2012-11-12 Selected Intervention: CEA - Left Assessment completed.

Intervention | Clinical Summary | Guidelines | Risks | **Assessment** | Consent | Schedule

Assessment

Estimated Risk:	Bypass	Sleeve	Band
Mortality 30 days 1 year	 0.15% 0.19%	 0.08% 0.10%	 0.5% 0.08%
Morbidity 30 days	 12.3%	 6.2%	 3.1%
Surgical Complications: Superficial Infection Leaking Bleeding	 1% 0.5% 0.8%	 0.3% 0.5% 0.3%	 0.4% 0.0% 0.1%
Readmission	6.9%	3.8%	2.0%
Reoperation or Intervention	4.9%	1.9%	1.2%

Estimated Benefit: Reduction in Weight



	6 Months	12 Months
Bypass	EWL:50 %	EWL: 70%
Sleeve	EWL: 43%	EWL: 60 %
Band	EWL: 27%	EWL: 36%

EWL = your extra weight that is lost

Estimated Benefit: Resolution of Diseases (1 Year):

	Bypass	Sleeve	Band
Diabetes	70%	63%	43%
Hypertension	54%	49%	33%
Hyperlipidemia	62%	49%	37%
Sleep Apnea	65%	59%	53%
GERD	47%	15%	55%

Patient Reported Outcomes:

Obesity Problem | OWL-QOL | Physical Health | Mental Health | Overall QOL

Sleeve Bypass | Sleeve Bypass | Sleeve Bypass | Sleeve Bypass | Sleeve Bypass

MBSAQIP

METABOLIC AND BARIATRIC SURGERY
ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

- International Sites- Data Collection

mbsaqip.org

2019 MBSAQIP Standards
Highlights

New Standard:

↳ Ambulatory Surgery Center Patient and Procedure Selection

- Patient Selection remains the same (low acuity guidelines)
- Procedure selection
  - — Approved to perform all revisional cases
    - ✓ Elective and Emergent
    - ✓ Band → Sleeve
    - ✓ Band → Bypass
    - ✓ Anastomotic revisions

MBSAQIP®
METABOLIC AND BARIATRIC SURGERY ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

2019 MBSAQIP Standards
Highlights

New Standard:

- Obesity Medicine Qualifications
  - Optional qualification
  - Only available for facilities with a Comprehensive Center designation
  - Led by Obesity Medicine Director
  - Integration of surgical and medical weight loss services
  - Focus on obesity medicine care pathways and data collection

MBSAQIP®
METABOLIC AND BARIATRIC SURGERY ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

MBSAQIP Journey…

Where we are

MBSAQIP®
METABOLIC AND BARIATRIC SURGERY
ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

2018

01

SAR released using data
07/01/2016-06/30/2017

02

Revision for MBSAQIP
Standard version 3.0
begins

03

Surgeon consent due
03/01/2018 to MBSAQIP
to participate in QCDR

05

Clinical Support
developed an Online
interactive Case
Inclusion Decision Trees
& Online Searchable
Clinical Definitions
Manual

2018

06

Concluded E. N. E. R. G. Y.
National Collaborative Project

07

ACS Quality and Safety Conference – presenting 20+ abstracts utilizing MBSAQIP data

SAR released using data 01/01/2017-12/31/2017

10

2017 Participant Use
Data File (PUF) released

11

Obesity Week in Nashville, TN - presenting 20+ abstracts utilizing MBSAQIP data

Dr. Stacy Brethauer's paper selected as a Top 10 paper for E. N. E. R. G. Y.

2019

01

New modules released for MBSCR training

Spring

MBSAQIP Standards V 3.0 Released

06

ASMBS Weekend

07

ACS Quality and Safety Conference

Patient Reported Outcomes project launch at ASCQSC

2019

Summer

Bariatric Surgery Targeting Opioid Prescriptions – Opioid reduction project launch

Fall

Risk and Efficacy Calculator

11

Obesity Week

Winter

New Data Registry Platform

What's next for MBSAQIP?

- Continued work on Bariatric Risk & Efficacy Calculator
- Continued work on the release of new and refined data registry platform
- Develop educational opportunities for surgeons (i.e. ? CMEs to meet surgeon verification requirements)
- Launch opioid-sparing surgery national collaborative project
- Patient – Reported Outcomes (PROs)
- MBSAQIP Standards version 3.0 release

Questions ?

Contact MBSAQIP:

312-202-5565

mbsaqip@facs.org