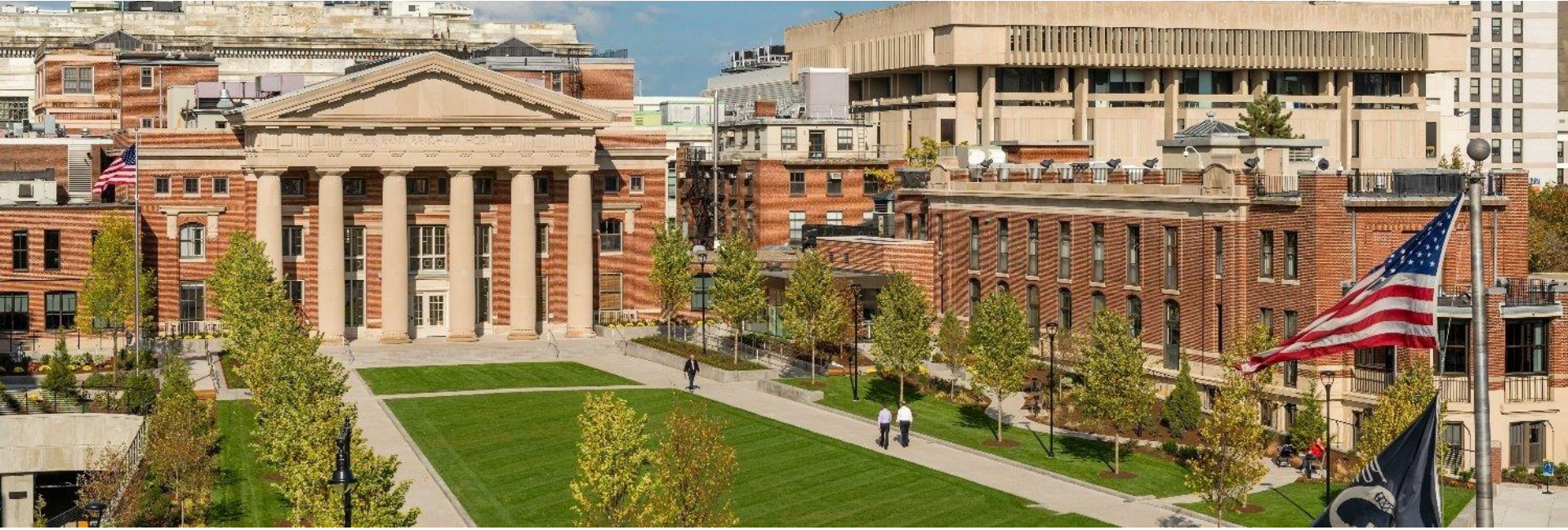


# Medicolegal aspects of MBS in the US: what crisis?

**Abdelrahman A. Nimeri, MD, FACS, FASMBS Dipl ABOM**

**Director, Bariatric Surgery Brigham & Women's Hospital**

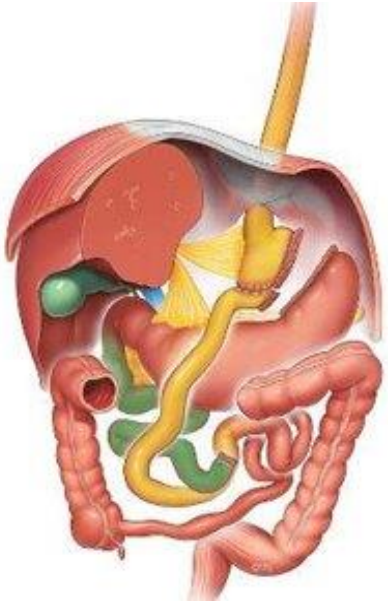
**Secretary/Treasurer, IFSO**

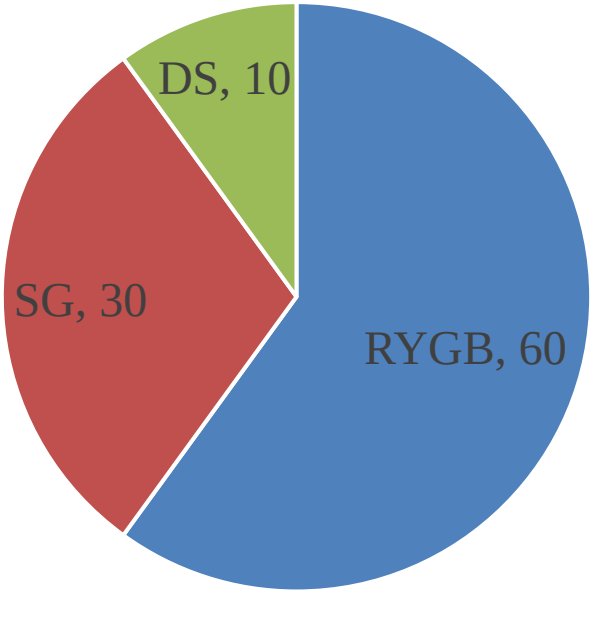
HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

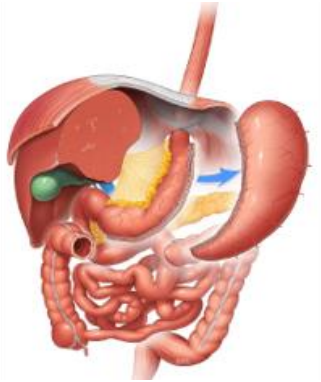
Brigham and Women's Hospital
Founding Member, Mass General Brigham

# Speaker/Advisory board, Medtronic, Intuitive & Ethicon

## Procedure disclosure





# Presentation outline

- *Status of medicolegal practice in the US.*
- **Why MBS surgeons get sued & how to prevent them.**
- *Early detection, prevention and management.*

# Changes in Utilization of Bariatric Surgery in the United States From 1993 to 2016

Guilherme M. Ca



MD,

**Any complication**

**Mortality**

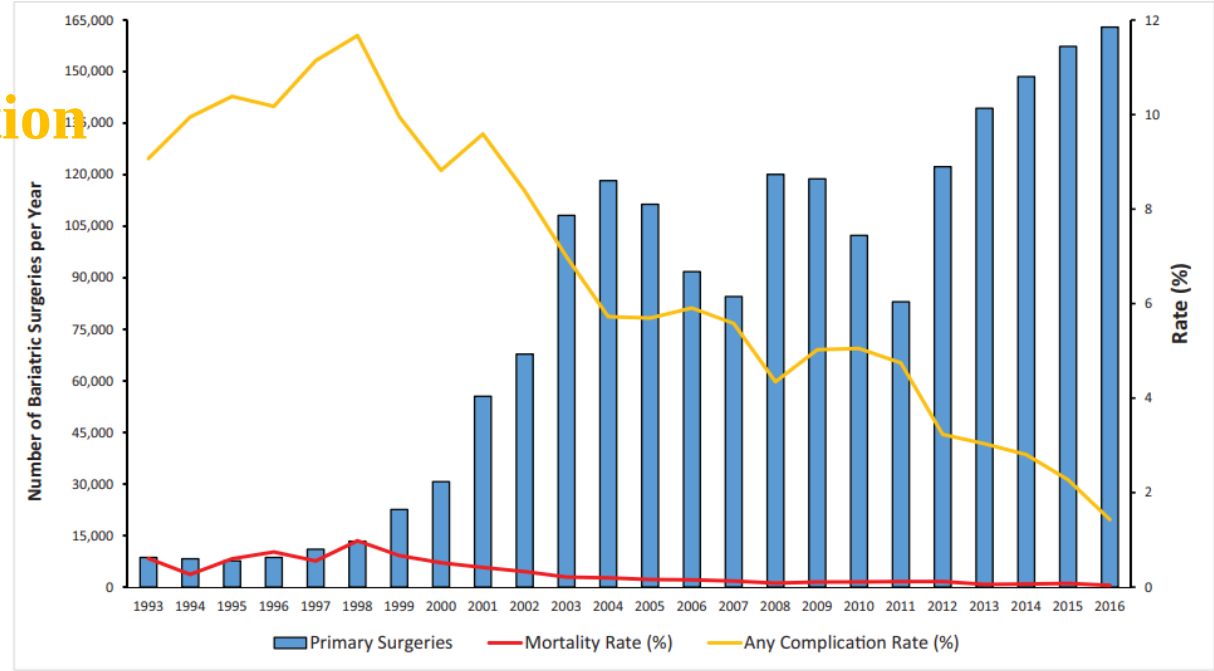
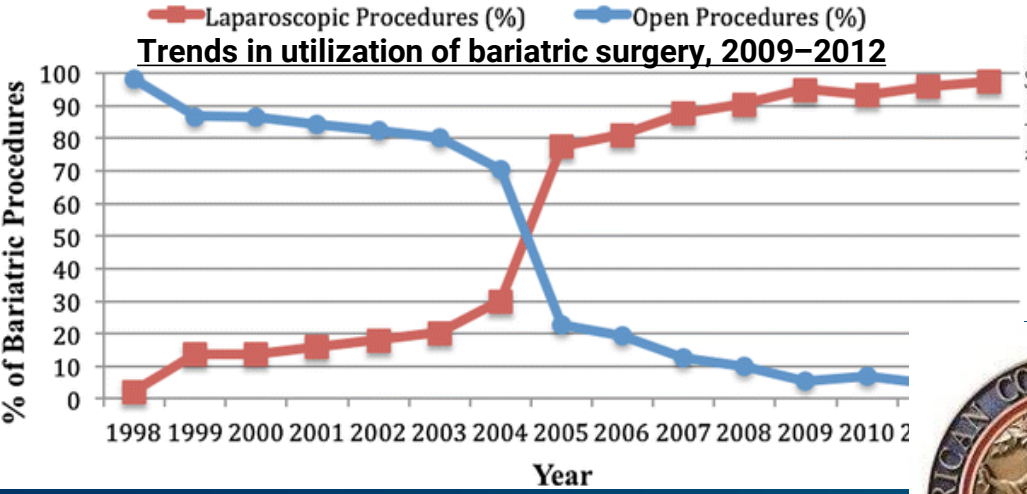
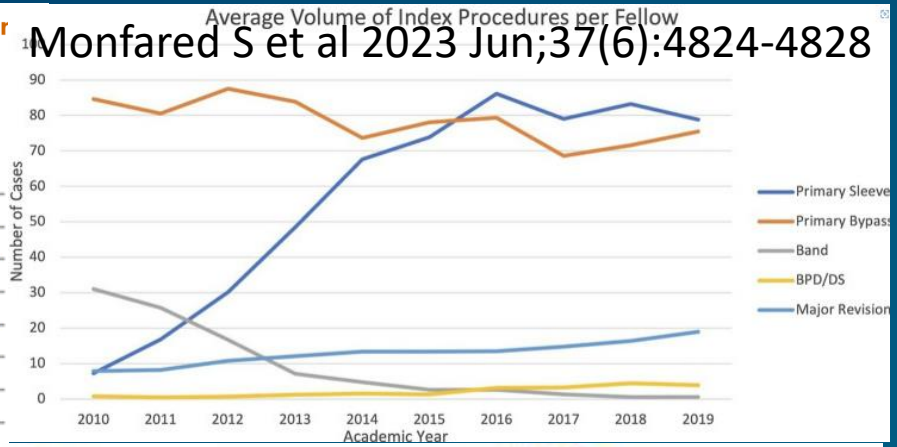



**FIGURE 2.** Number of inpatient primary bariatric surgery procedures and initial admission complication and mortality rates in the United States from 1993 to 2016.

# Laparoscopic revolution in bariatric surgery




MBSAQIP
METABOLIC AND BARIATRIC SURGERY
ACCREDITATION AND QUALITY IMPROVEMENT PR
ACCREDITED CENTER

AMERICAN COLLEGE OF SURGEONS
FOUNDED IN 1913
OMNIBVS PER ARTEM
FIDEMQVE

ASMBS

AMERICAN COLLEGE OF SURGEONS
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QUALITY PROGRAM
AMERICAN SOCIETY FOR METABOLIC AND BARIATRIC SURGERY

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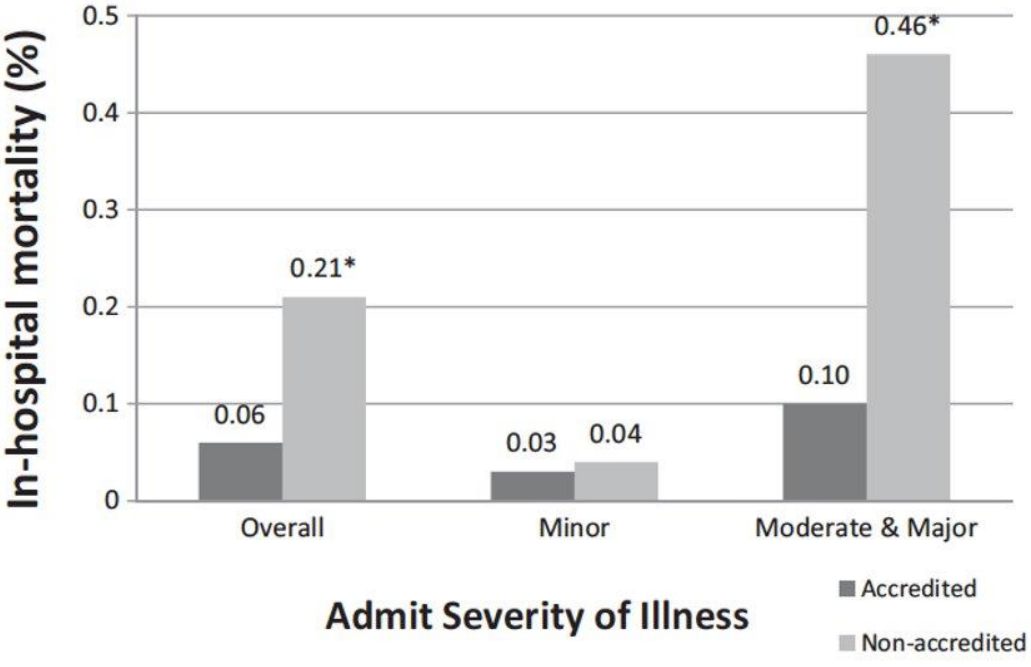
Founding Member, Mass General Brigham

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

# Outcomes of Bariatric Surgery Performed at Accredited vs Nonaccredited Centers




Ninh T Nguyen, MD, FACS, Brian Nguyen, BS, Vinh Q Nguyen, PhD, Argyrios Ziogas, PhD, Samuel Hohmann, PhD, Michael J Stamos, MD, FACS

# Bariatric Surgery and Malpractice: an Extensive Review of Demographics, Complications, Litigation, and Proactive Mitigation Strategies

Obesity Surgery (2023) 33:3611–3620

Salman AlSabah[1] · Eliana Al Haddad[2]

- Systematic review of **19 papers** from 1999-2023.
- The increase in **MBS from 2002 to 2013** was accompanied by a concurrent rise in malpractice claims & **25% of all visceral surgery** complaints linked to MBS [most claims from **young female patients**].
- **History of abdominal surgery** (26.6%), **depression or psychiatric illness** (24.8%) **Smoking** (17.8%).
- **To reduce complications**: **effective risk management**, **comprehensive preoperative assessment**, & **postoperative FU**.

# Bariatric Surgery and Malpractice: an Extensive Review of Demographics, Complications, Litigation, and Proactive Mitigation Strategies

Obesity Surgery (2023) 33:3611–3620

## Primary prevention:

Salman AlSabah[1] · Eliana Al Haddad[2]

**(a) Communication and informed consent:** clear communication about the potential risks, benefits, and alternative options associated with MBS.

**(b) Proper selection of surgical technique:** surgeons should adhere to established, evidence-based surgical procedures. Nonstandard weight loss operations, especially in high BMI patients, were overrepresented in malpractice claims. Procedures should be selected according to patient suitability and the surgeon's competency.

**(c) Surgical skill and competence:** surgeons should ensure their technical skills are continually updated through ongoing training.

**(d) Accreditation and board certification:** hospitals should strive to obtain accreditation for MBS. Surgeons should also attain board certifcation, as there is a higher risk of malpractice claims against non-board-certifed surgeons.

**Bariatric Surgery and Malpractice: an Extensive Review of Demographics, Complications, Litigation, and Proactive Mitigation Strategies**

Obesity Surgery (2023) 33:3611–3620

Salman AlSabah[1] · Eliana Al Haddad[2]

## Secondary prevention:

**(a) early detection and management of complications:** this involves prompt identification and appropriate management of common postoperative complications.(
(b) **Effective postoperative care:** postoperative care plans should be personalized to patient needs and should involve MDT teams to prevent nutrient deficiencies.
**(c) Communication in postoperative period:** consistent communication between medical providers and patients is vital during the postoperative.
**(d) Responsiveness to changes in patient status:** high vigilance and responsiveness are necessary when managing postoperative patients.
**(e) Referral to specialists:** in case of complex complications, immediate referral to specialists for further evaluation and management is recommended.

Bariatric Surgery and Malpractice: an Extensive Review of Demographics, Complications, Litigation, and Proactive Mitigation Strategies

Obesity Surgery (2023) 33:3611–3620

# Risk factors for lawsuits

Salman AlSabah[1] · Eliana Al Haddad[2]

- **Inadequate patient communication & preoperative evaluation.**
- **Improper or delayed diagnosis and treatment.**
- **Surgical errors:** an ASMBS expert panel concluded that **58.1**% of all complications could have been prevented by the surgeon.
- **Inadequate postoperative care**: improved postoperative care could have prevented complications in 45.1% of cases.
- **Inadequate supervision in teaching hospitals.**
- **Performing nonstandard weight loss operations.**

# Presentation outline

- *Status of medicolegal practice in the US.*
- **Why MBS surgeons get sued & how to prevent them.**
- *Early detection, prevention and management.*

# First report from the American Society of Metabolic and Bariatric Surgery closed-claims registry: prevalence, causes, and lessons learned from bariatric surgery medical malpractice claims

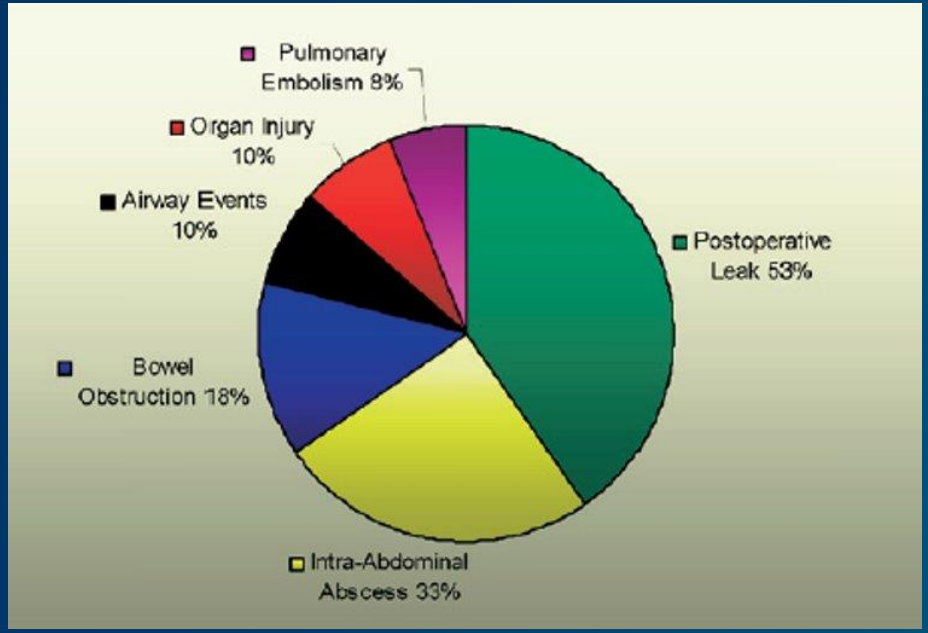
- A total of 175 closed claims were collected from 4 national malpractice insurers for index MBS from 2006–2014.
- **Of these, 75.9% of surgeons were board certified & 43.3% of the hospitals were accredited for MBS.**
- Most clinical complications after MBS that led to malpractice lawsuits were **mortality (35.1%) & leaks (17.5%), Tech error (6.9%), bleeding (5.3%), retained foreign body (5.3%), & vascular injury (4.4%)** occurred at higher rates than national averages.

John M. Morton, M.D., M.P.H.[a,*], Habib Khoury, B.S.[b], Stacy A. Brethauer, M.D.[c], John W. Baker, M.D.[d], William A. Sweet, M.D.[e], Samer Mattar, M.D.[f], Jaime Ponce, M.D.[g], Ninh T. Nguyen, M.D.[h], Raul J. Rosenthal, M.D.[i], Eric J. DeMaria, M.D.[j]

Surgery for Obesity and Related Diseases 18 (2022) 943–947

## Medicolegal analysis of 100 malpractice claims against bariatric surgeons

Daniel Cottam, M.D.[a], Jeffrey Lord, M.D.[b,*], Ramsey M. Dallal, M.D.[c], Bruce Wolfe, M.D.[d], Kelvin Higa, M.D.[e], Kathleen McCauley, J.D.[f], Philip Schauer, M.D.[g]




**The prevention of leaks, their timely diagnosis** & treatment is the **single most important strategy** to **improve patient outcomes and prevent malpractice lawsuits related to bariatric surgery.**

Cottam D Surg Obes Relat Dis. 2007 Jan-Feb;3(1):60-6; discussion 66-7. Epub 2006 Dec 27.

Medicolegal analysis of 100 malpractice claims against bariatric surgeons

Daniel Cottam, M.D.[a], Jeffrey Lord, M.D.[b,*], Ramsey M. Dallal, M.D.[c], Bruce Wolfe, M.D.[d], Kelvin Higa, M.D.[e], Kathleen McCauley, J.D.[f], Philip Schauer, M.D.[g]

- ***Leak or collection in 86% of patients.***
- ***In 15% of the cases, it was noted that the primarysurgeon had left town or transferred coverage immediately before the occurrence of a complication.***

Cottam D Surg Obes Relat Dis. 2007 Jan-Feb;3(1):60-6; discussion 66-7. Epub 2006 Dec 27.

Bariatric-related medical malpractice experience: survey results among ASMBS members

Ramsey M. Dallal, M.D.[a,*], John Pang, M.D.[a], Ian Soriano, M.D.[a], Daniel Cottam, M.D.[b], Jeffrey Lord, M.D.[c], Susan Cox[d]

The probability of a medical malpractice lawsuit correlates positively to the ***number of procedures performed and the number of years the surgeon has been in practice.***

Surgery for Obesity and Related Diseases 10 (2014) 121–124

There's an old Chinese proverb that goes: 上得山多终遇虎 (pinyin: shàng de děi shān duō zhōng yù hǔ). "If you go to the mountain often enough, you will meet the tiger."

*Surgeons don't get in trouble because a patient had a leak or complication*

*"It is rather because there was delay in diagnosis, lack of adequate surgical coverage, or the possibility of a leak/complication was never discussed with the patient and their family"*

# *You cannot plan on NOT having complications*

- **Follow guidelines like those established by IFSO or ASMBS to help reduce the risk of liability.**
- ***Establishing and maintain a solid physician-patient relationship*** ***by*** **using appropriate interpersonal skills.**
- ***Your relationship with the patient and family*** **remains the most effective way of reducing the risk of being sued when there is an unfortunate complication, as well as increasing the chances of a successful defense in the event of suit.**

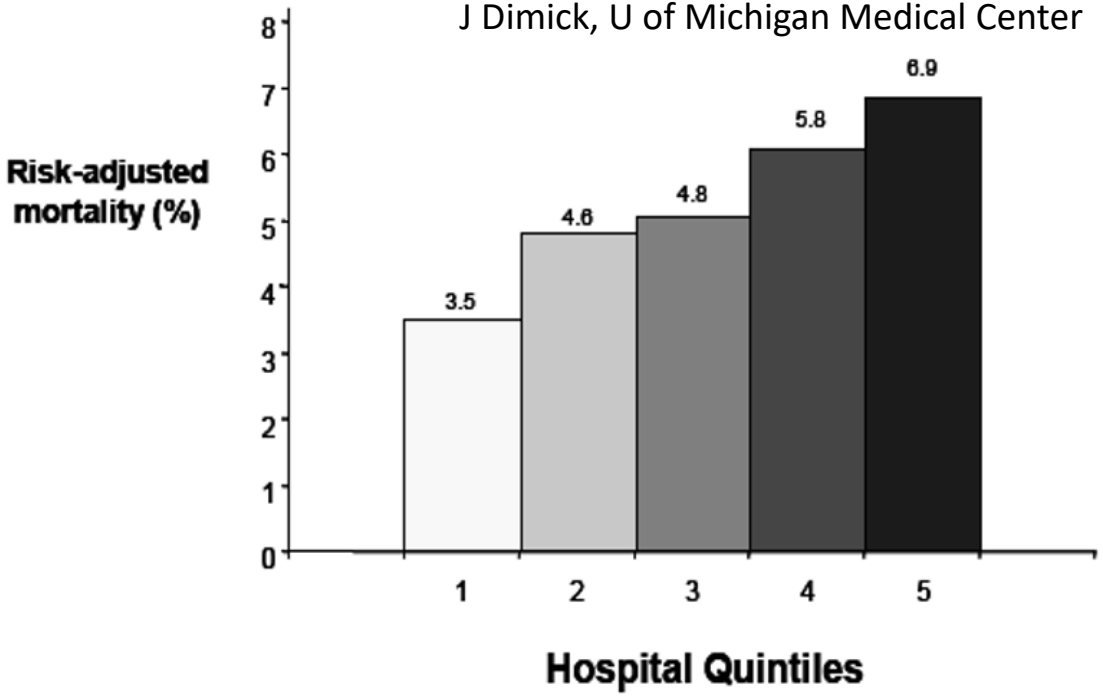
Eagan MC et al Am Surg. 2005 May;71(5):369-75.

# Presentation outline

- *Status of medicolegal practice in the US.*
- **Why MBS surgeons get sued & how to prevent them.**
- ***Early detection, prevention and management.***

# Are Variations in Hospital Mortality Rates with Inpatient Surgery Related to Differences in Complication Rates or Failure to Rescue?

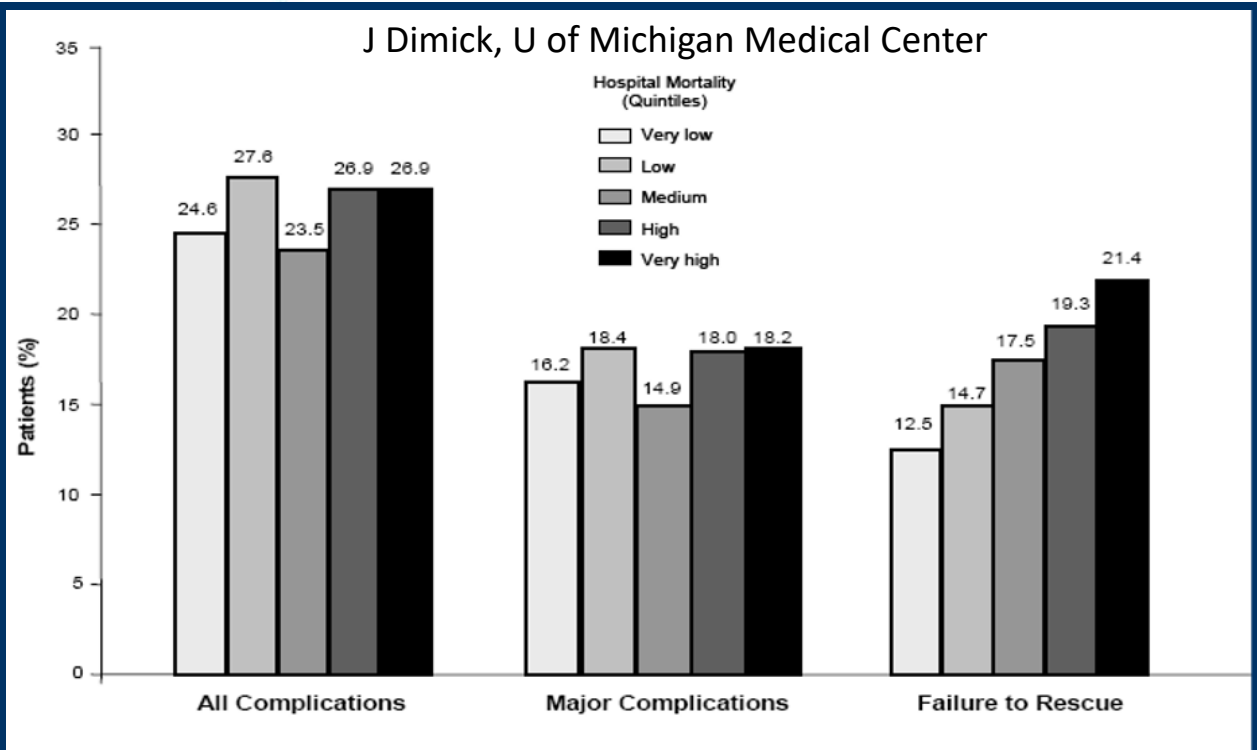
J Dimick, U of Michigan Medical Center




***Does early detection matter?***

# Are Variations in Hospital Mortality Rates with Inpatient Surgery Related to Differences in Complication Rates or Failure to Rescue?

J Dimick, U of Michigan Medical Center



Metabolic & Bariatric Surgery

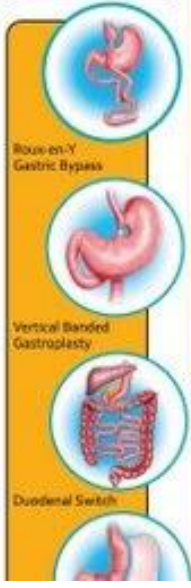
## EMERGENCY PRESENTATIONS:

1. Unstable Vital Signs
   - *Fever > 101° F*
   - *Hypotension*
   - *Tachycardia > 120 bpm x 4 hours*
   - *Tachypnea*
   - *Hypoxia*
   - *Decreased urine output*
2. Bright Red Blood by Mouth or Rectum, Melena, Bloody Drainage
3. Abdominal Pain or Colic > 4 hours
4. Nausea ± Vomiting > 4 hours
5. Vomiting ± Abdominal Pain

## BARIATRIC COMPLICATIONS:

- Intra-Abdominal Bleeding
- Leaks and Sepsis
- Obstruction
- Pulmonary Embolism
- Vomiting ± Abdominal Pain
- Abdominal Compartment Syndrome

IMPORTANT: KNOW THE ANATOMY! IT CAN BE VERY CONFUSING! Patients often don't know which procedure they have had, and surgeons vary the procedure dramatically. If you're not the primary surgeon, call the surgeon who performed the procedure.




## Principles to Guide Management of Bariatric Emergencies

### I. Critical Time Frame

- Diagnose within 6 hours
- Tx OR within 12-24 hours

### II. Critical Warnings

- Call bariatric surgeon early, if not available, call general surgeon on call
- These are not typical abdominal surgery patients, they do not exhibit expected or typical signs and symptoms, and they have no physiological reserve to weather complications
- NG-tube:
  - Avoid "blind placement" due to risk of perforation
  - Will not decompress the distal stomach
- Avoid NSAIDs, ASA, Plavix, Ibuprofen
  - Greater risk of ulcer, bleed/erosion and perforation
  - Place on PPI for gastric erosion safeguard
- Thiamine deficiency:
  - Initially avoid glucose in IV fluids (unless hypoglycemia is confirmed)
  - Use 1L or NS w/ 100 cc/hr ampule of multivitamin
  - Can result in Wernicke's syndrome, characterized by ataxia, confusion, blurred vision. IV dextrose will increase the risk of permanent neurologic impairment.
- Avoid overloading the gastric pouch with oral fluids or contrast - should only take a sip.

### Initial Assessments

1. Physical exam and vital signs - may need to be serial.
2. Labs:
   - CBC
   - Comprehensive Chemistry Profile
   - Amylase
3. Imaging:
   - Chest X-Ray
   - CT of Abdomen with oral contrast
   - CT of Chest with IV contrast

## INTRA-ABDOMINAL BLEEDING

### I. Emergency Presentation

Bright Red Blood Oral or Rectal, Melena, Bloody Drainage, Tachycardia, Hypotension, Fainting

- < 48 hrs postop indicates potential bleed from staple line
- > 48 hrs postop indicates potential marginal ulcer hemorrhage
- Bleeding via oral route indicates potential pouch source
- Melena or bleeding via rectal route indicates potential duodenal ulcer or distal stomach or bowel source.

### II. Emergency Assessment and Treatment

- Give 1 piece IVS fluid bolus
- Stop Anticoagulants, ASA or Plavix
- Type/Crossmatch PRBCs, may need FFP or platelets
- Serial Hct/Hgb
- Frequent Vital Signs
- Monitor Urine Output
- Check Renal Profile
- Good IV access, may need central line

### III. To Surgery if:

- Hypotension
- Drop in Hct of 10%
- Falling Hct despite transfusion
- Tachycardia > 120 x 4 hrs despite fluid bolus or blood transfusion

*NOTE: Consider ECG in OR under general anesthesia to control airway. Supervised by CRNA. Check for perforation, high BMI? Intubation difficult if head down.

## PULMONARY EMBOLISM

### I. Emergency Presentation

- Unstable vital signs with tachypnea ± chest pain

### II. Emergency Assessment

- IV contrast enhanced chest CT

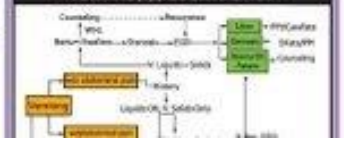
*Presentation of an intra-abdominal complication such as leak or closed loop obstruction is often similar to that of PE

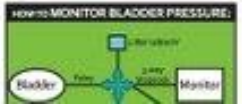
## VOMITING ± ABDOMINAL PAIN

### I. Emergency Presentation

Vomiting associated with abdominal pain needs prompt surgical evaluation and observation until resolved or surgical exploration.

### I. Emergency Assessment and Treatment




## LEAKS AND SEPSIS

### I. Emergency Presentation

- Unstable vital signs within 72 hours of bariatric surgery
- Persistent and progressive tachycardia (>120 bpm > 4 hrs) is the most sensitive indicator of potential surgical emergency.
- Signs of sepsis/leak may be subtle at first and may need to rule out hypovolemia, atelectasis, bleeding, pulmonary embolism (PE), obstruction and/or leak.
- Unstable vital signs or presentation are all signs of sepsis/leak, especially within 72 hours of bariatric surgery: Fever > 101° F, Hypotension, tachycardia, tachypnea, hypoxia, decreased urine output.
- Presentation of an intra-abdominal complication, such as leak, is often similar to that of PE. Once PE is ruled out (with ventilation enhanced chest CT), consider immediate surgical exploration.
- A negative abdominal CT does not definitively rule out a complication such as a leak. Abdominal series and gastrografin swallow can be negative even when there is a leak.

### II. Emergency Treatment

- Conservative, nonoperative management of leaks may be considered if contained (walled/sealed) is well drained internally or externally with communication to drain documented by imaging and GI/Dr. If the patient is stable clinically (T < 101° F, pulse < 120 bpm, WBC < 15,000, normal renal and respiratory function).

CONSIDER:

- Surgical exploration

## OBSTRUCTION

### I. Emergency Presentation

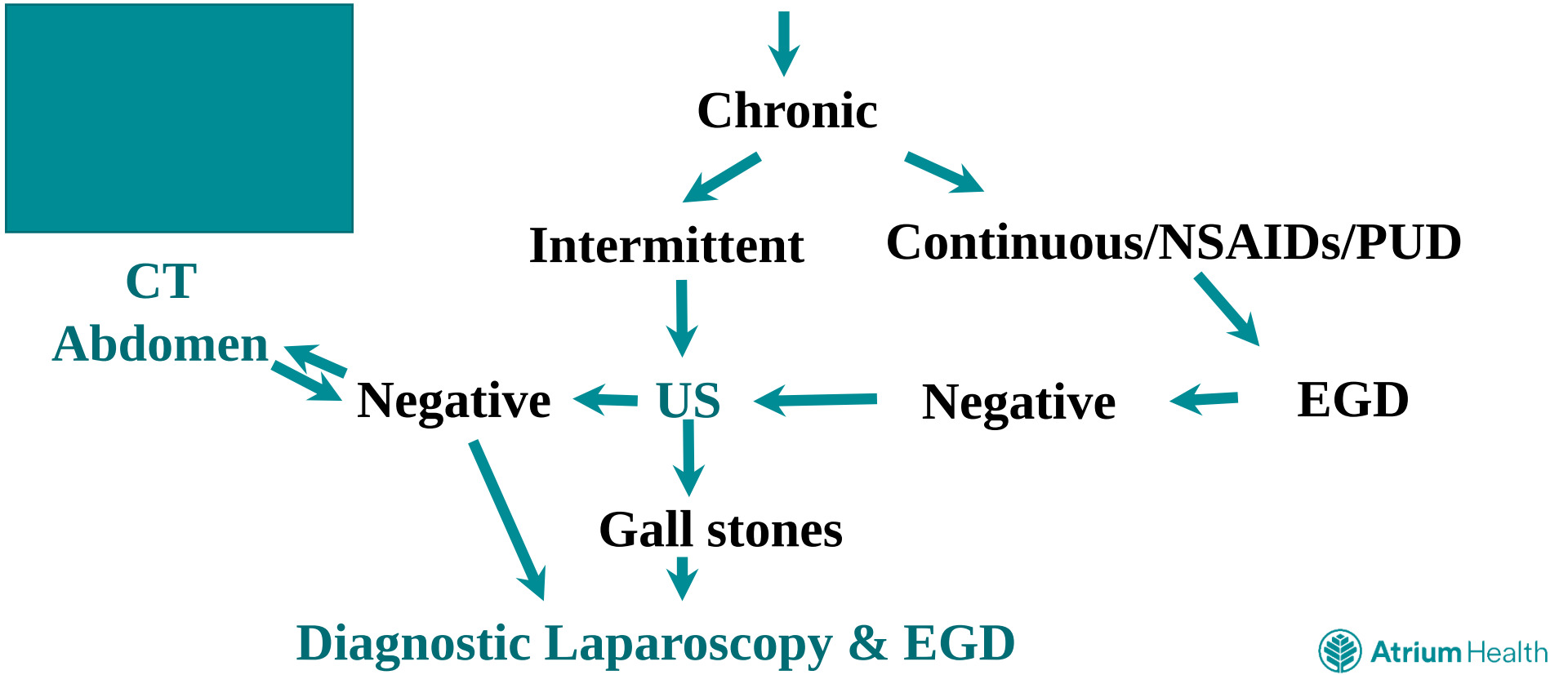
- Abdominal Pain or Colic > 4 hours
- Common presentation complaint. Duration of more than 4 hours, or associated with vomiting, requires surgical evaluation and observation until resolved or treated. CT/UGI diagnostic in most cases, but not all.
- No place for NG-tube or conservative management.
- Acute bowel obstruction potential obstruction due to Sx is a true emergency that may cause perforation.
- Consider CT of abdomen with oral contrast or barium UGI with small bowel follow through to the colon with contrast to assess for possible obstruction.
- Consider ERCP for GB/CBD duct stones, stricture or IBD stricture (gastrografin contrast prior to anesthesia to prevent aspiration).
- X-rays, labs and physical exam often negative in patients with obstruction.
- Closed loop obstructions and internal hernias are a risk after gastric bypass and

## Adjustable Gastric Band

- If nausea and vomiting is present, obtain flat plate of abdomen, with band tilted up compared to spine, and barium swallow to assess for possible stenosis or obstruction.
- Fully seen on x-ray → urgent deflate, possibly operate
- To deflate the band, ask patient where their port is located and should be able to palpate on abdominal wall or use fluoroscopy. Can also see it on flat plate x-ray. Use sterile prep under local. Insert non-coring huber needle similar to that used for port-a-cath, as the system is under pressure and will leak. Remove as much fluid as possible, then re-evaluate symptoms and findings.
- Maximum band volume is 9-10 mL depending on model.

## Adjustable Gastric Band Obstructions

# Abdominal pain after any gastric bypass




Atrium Health

# Probability of reoperation due to SBO due to internal hernia

## Closure of mesenteric defects in laparoscopic gastric bypass: a multicentre, randomised, parallel, open-label trial

Erik Stenberg, Anders Thorell, Ingmar Näslund

www.thelancet.com Vol 387 April 2, 2016

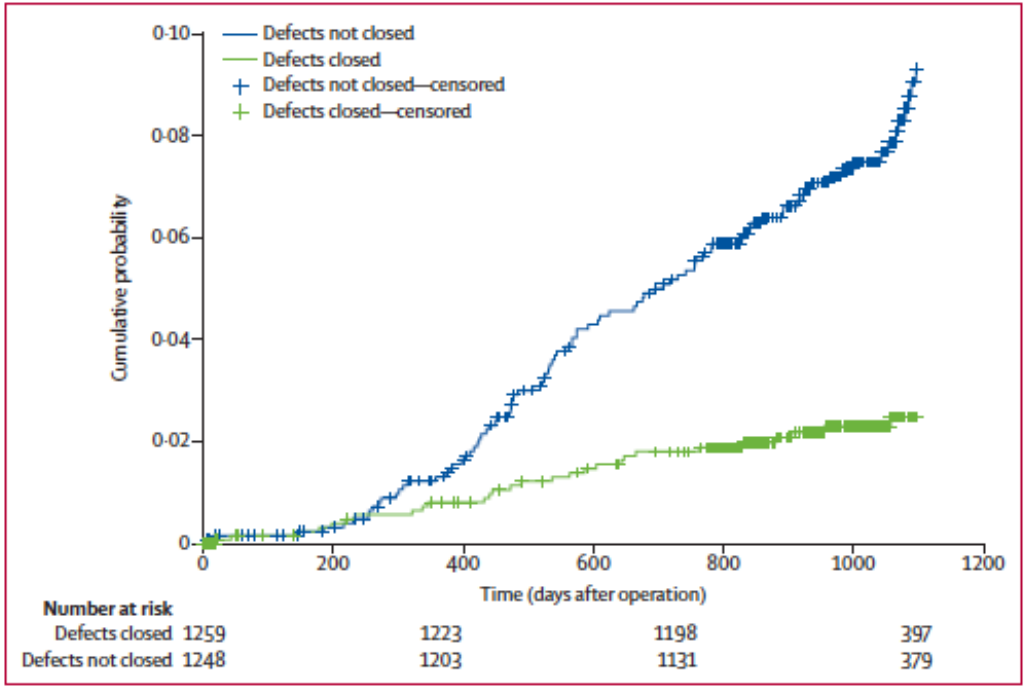
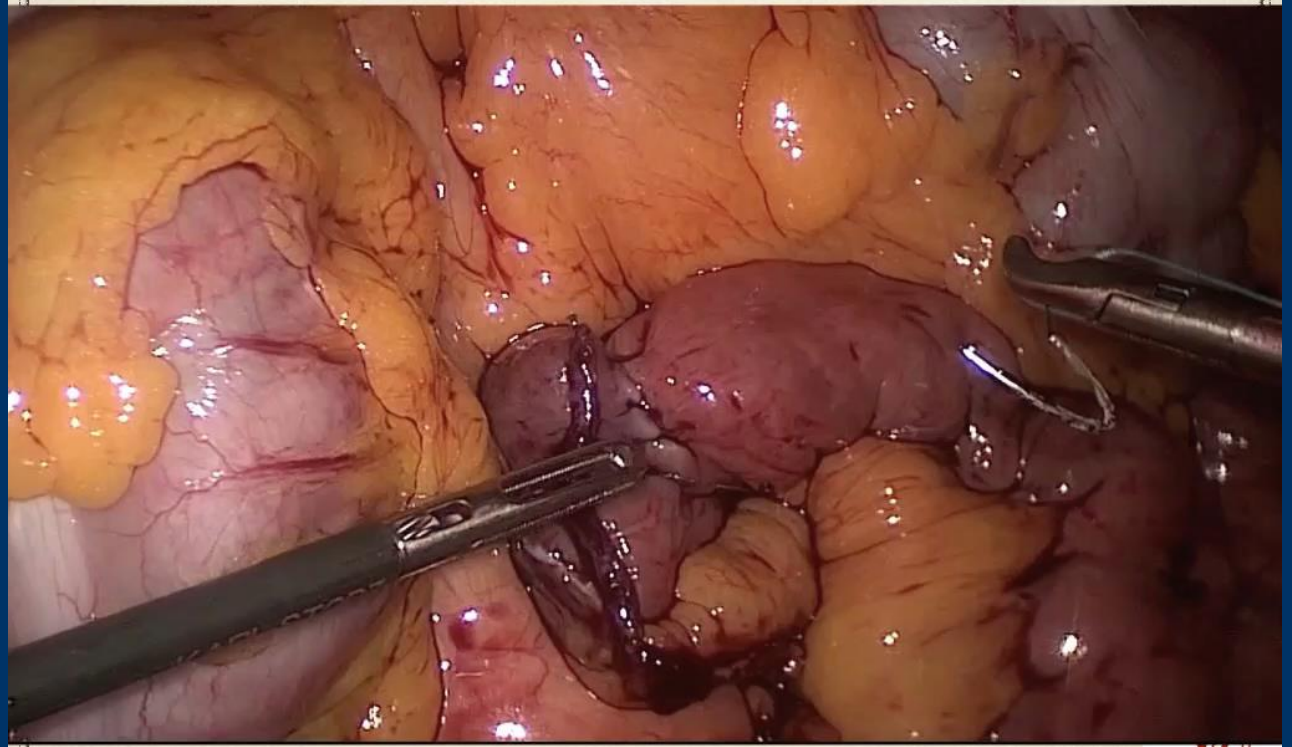



*Figure 3:* Cumulative probability of reoperation because of small bowel obstruction due to internal hernia

Atrium Health

# Closure of the jejuno-jejunostoy mesenteric defect



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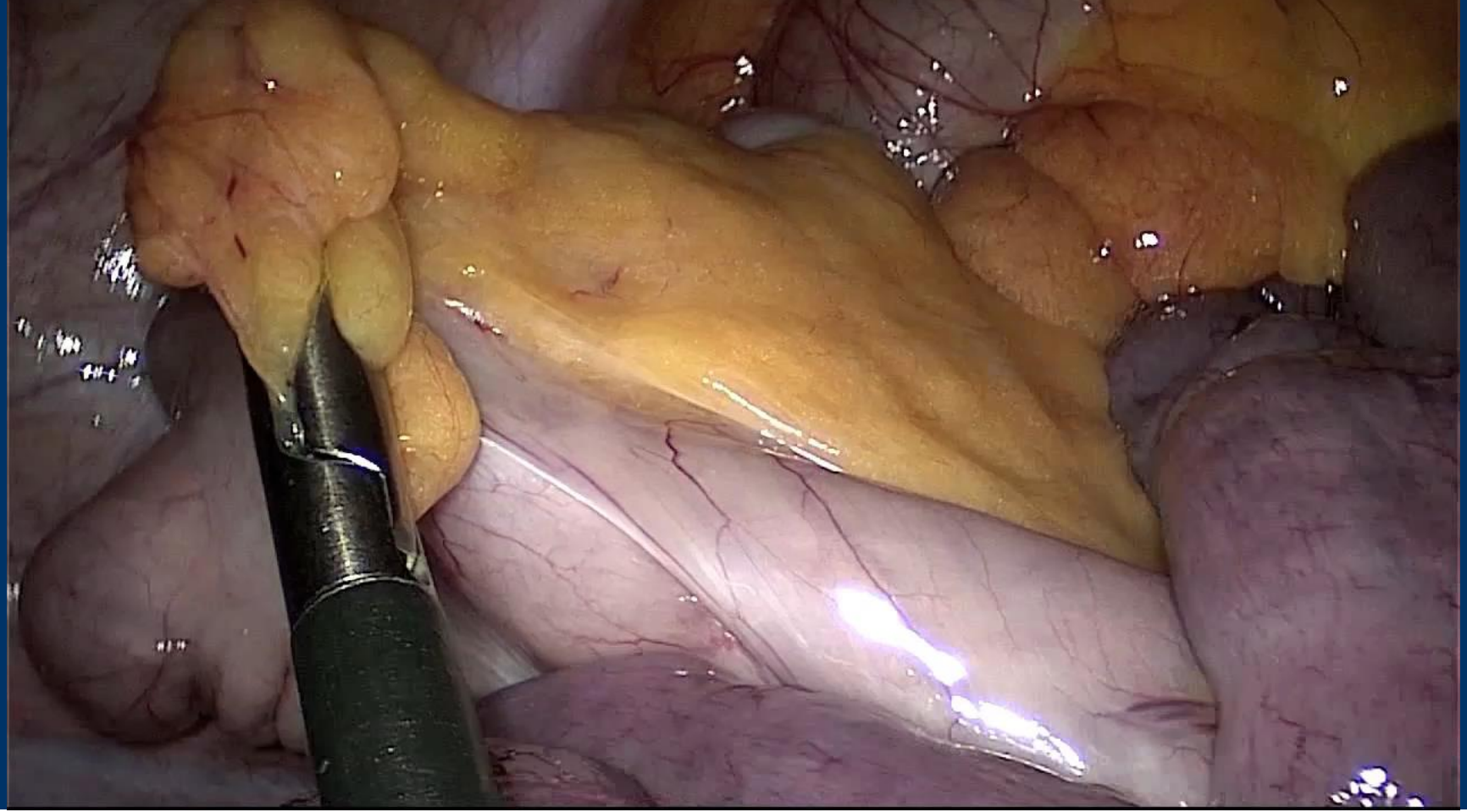

# *Take home messages*

- ***MBS is as safe as gall bladder surgery.***
- **Patient education, communication and informed consent.**
- ***Proper selection of surgical technique, Surgical skill & competence.***
- **COE accreditation & surgeon certification [FPD MBS & ABOM].**
- ***Early detection and management of complications.***
- **Effective postoperative care**
- ***Communication in postoperative period.***
- **Responsiveness to changes in patient status.**
- ***Referral to specialists.***