Reducing Errors in Surgery

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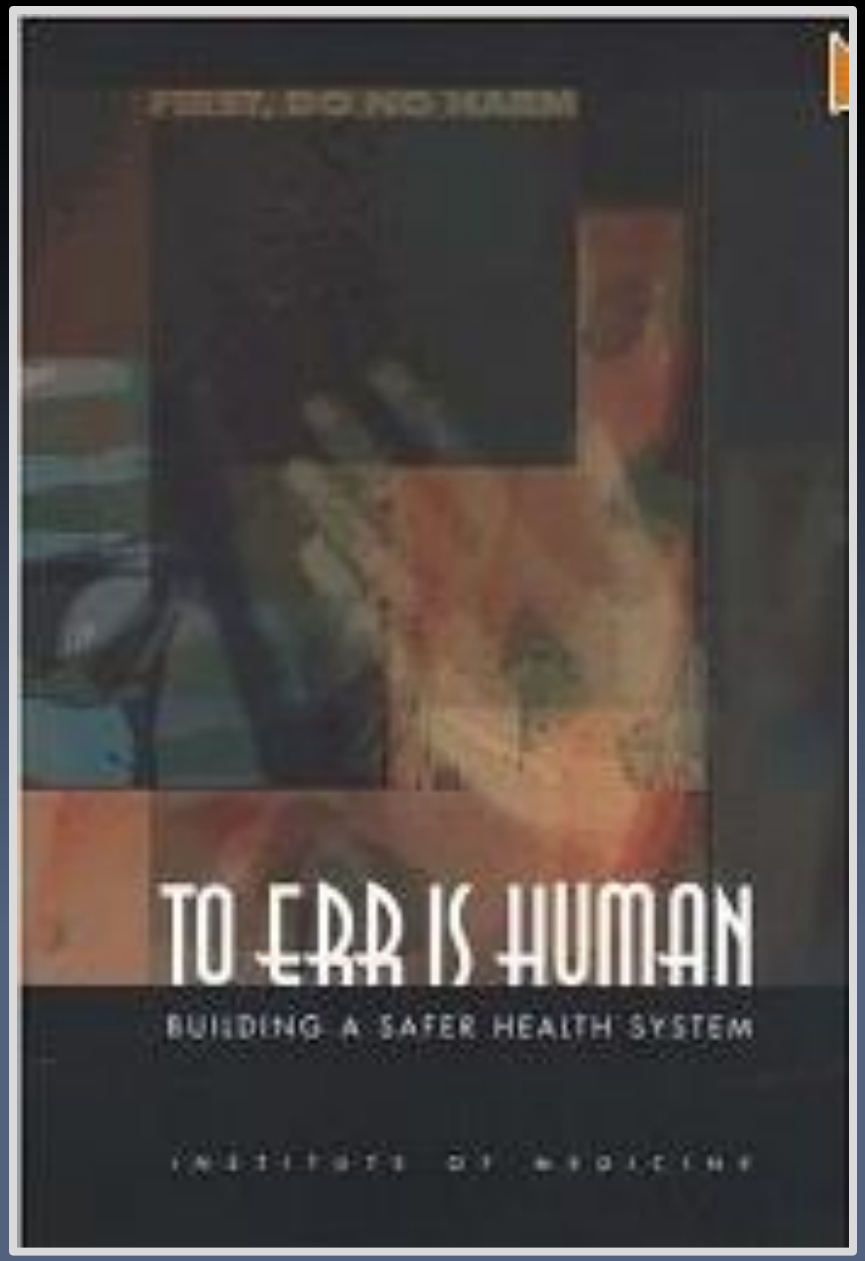
SCHOOL OF MEDICINE

Disclosures

- Institutional research support:
  - Gore
  - Karl Storz Endoscopy

Reducing Errors in Surgery

- Surgical checklists and culture of safety
- Surgical energy safety
- Reducing biliary injuries during cholecystectomy

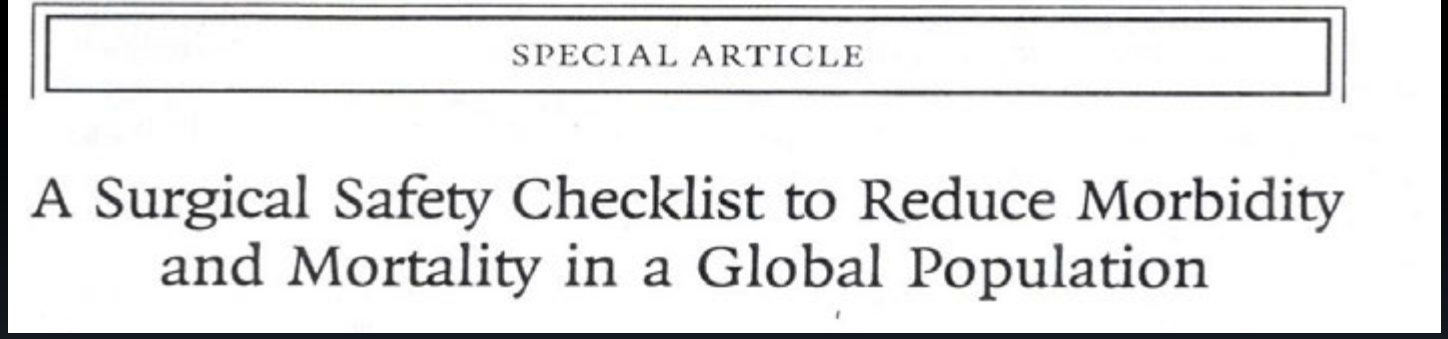

TO ERR IS HUMAN
BUILDING A SAFER HEALTH SYSTEM

Wrong-Site Surgery, Retained Surgical Items, and Surgical Fires
A Systematic Review of Surgical Never Events

Susanne Hempel, PhD; Melinda Maggard-Gibbons, MD; David K. Nguyen, MD; Aaron J. Dawes, MD; Isomi Miake-Lye, BA; Jessica M. Beroes, BS; Marika J. Booth, MS; Jeremy N. V. Miles, PhD; Roberta Shanman, MLS; Paul G. Shekelle, MD, PhD

- Review of 138 studies
  - Wrong site surgery: 1:100,000
  - Retained surgical items: 1.32:10,000
- Cause analysis: need for improved communication

JAMA Surg 2015;150:796-805.


SPECIAL ARTICLE

A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

Haynes A et al NEJM 2009;360:491-499

- Studied pre vs post checklist intervention in 3733 pts from 8 hospitals from diverse populations undergoing noncardiac surgery

	Pre-Checklist	Post-Checklist	p value
Death rate	1.5%	0.8%	0.003
Inpatient Complications	11.0%	7.0%	<0.0001

Aviation Industry/Cockpit Checklists

Committed or Perfunctory?

Patient Safety Oriented Approaches: OR Time Out

Committed or Perfunctory?

Patient Safety Oriented Approaches: OR Time Out

Committed or Perfunctory?

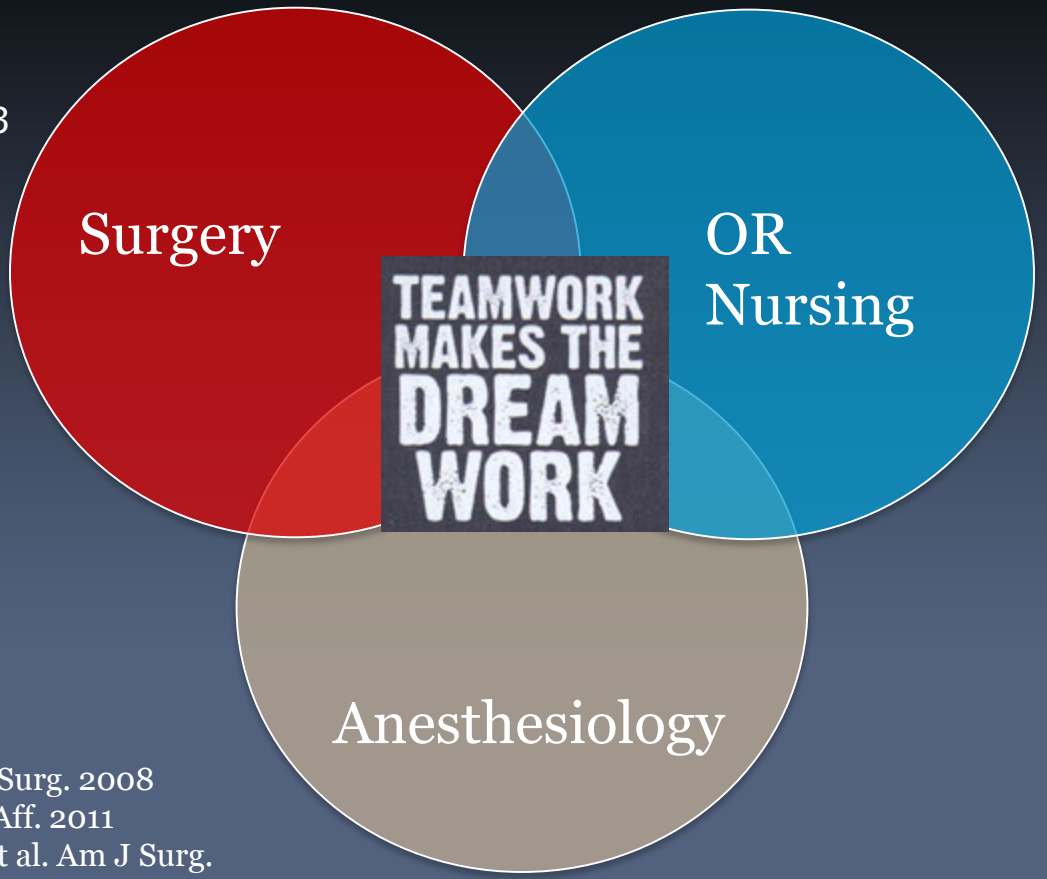
Wrong Site Surgery

- Joint Commission Center for Transforming Health
- Factors contributing to increased risk of wrong site surgery:
  - Scheduling and preop/holding processes
  - Ineffective communication in the OR
  - Distraction in the OR
  - Time out without full participation by all key people in OR

Culture of Safety

Surgical Safety Checklist Implementation

- Decreases mortality[1-3]
- Decreases complications[1-3]
- Improves self-perceptions of communication and teamwork[4]
- Reduces communication failures[5]
- Decreases cost[6,7]
- Does not increase OR time[7]



Source: Jennifer Yu, WUDOS

1. Haynes, et al. NEJM. 2009
2. Kwaan, et al. Arch Surg. 2006
3. Loftus, et al. JACS. 2015
4. Russ, et al. Ann Surg. 2013
5. Lingard, et al. Arch Surg. 2008
6. Semel, et al. Health Aff. 2011
7. Papaconstantinou, et al. Am J Surg. 2006

Surgical Checklist and Compliance Protocol Project Evaluation

- Baseline assessment of current surgical checklist implementation
- Study Population
  - BJH operating rooms
- Procedure Audit Process
  - Goal: 100 randomly selected procedures
  - Observation of time out component
  - Elective cases
  - Diverse case complexity and specialty/attending

Acute and Critical Care

Cardiothoracic

Colorectal

Endocrine/Oncologic

Hepatobiliary

Minimally Invasive

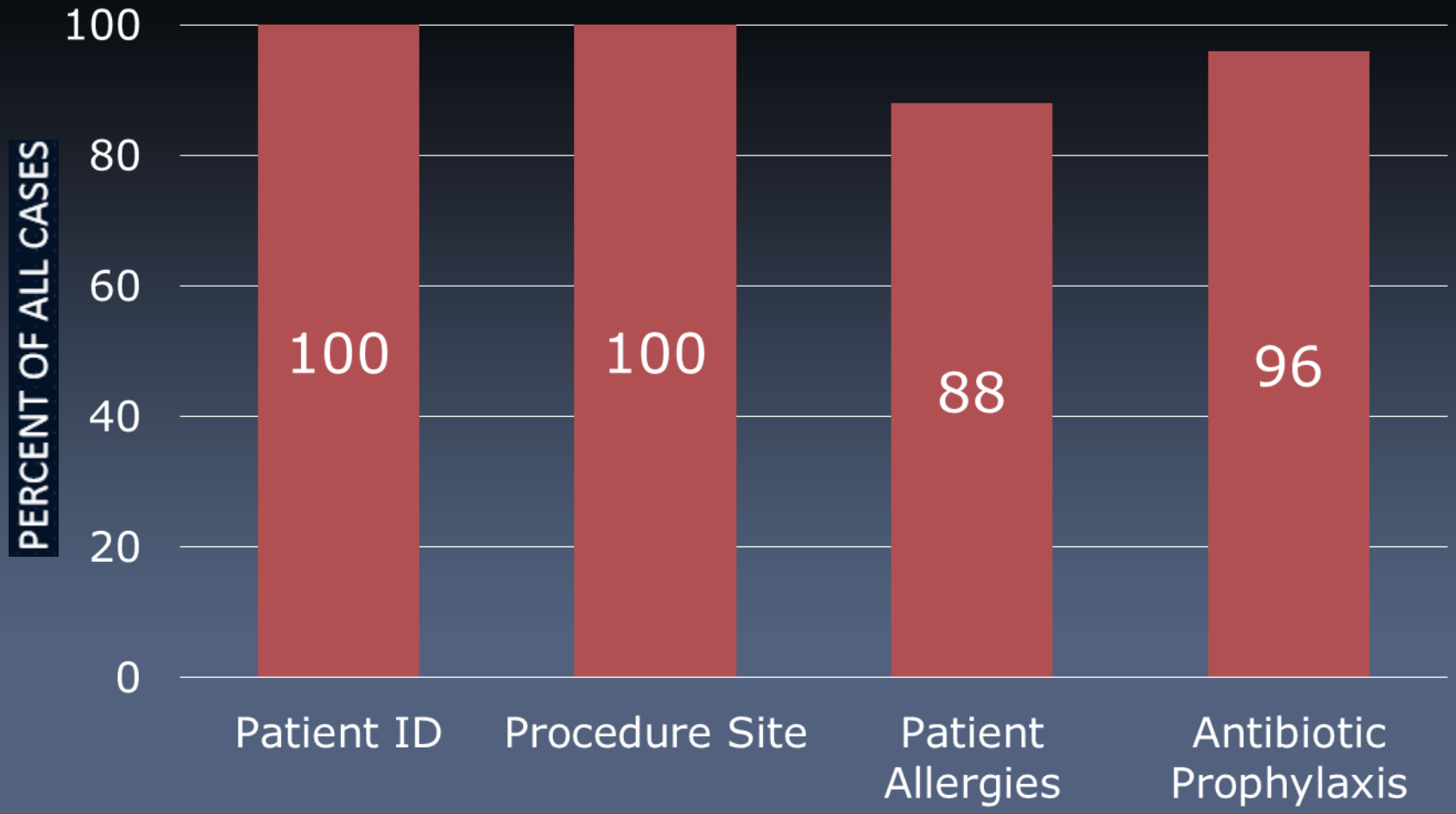
Plastic/Reconstructive

Transplant

Urology

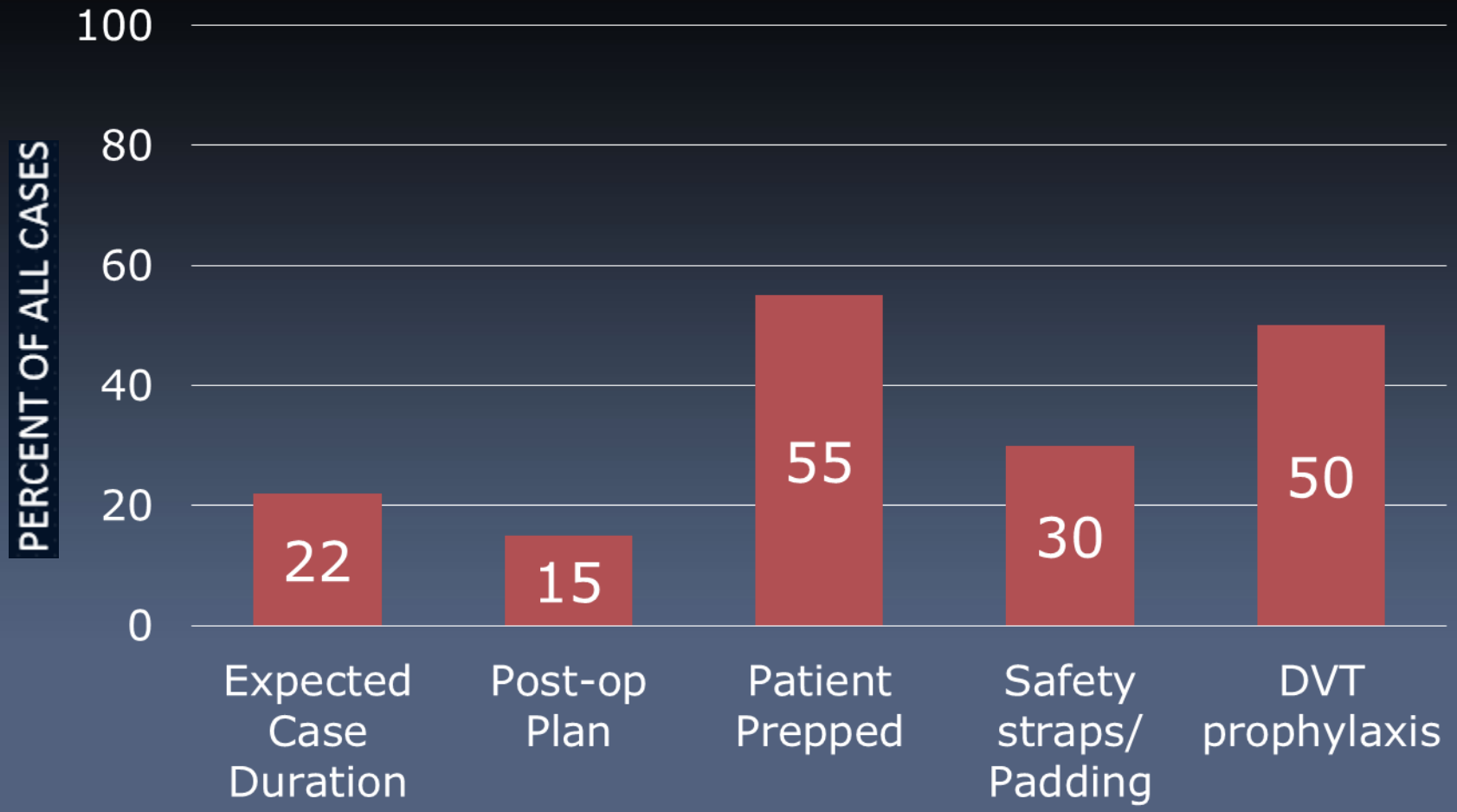
Vascular

Checklist Item Completion

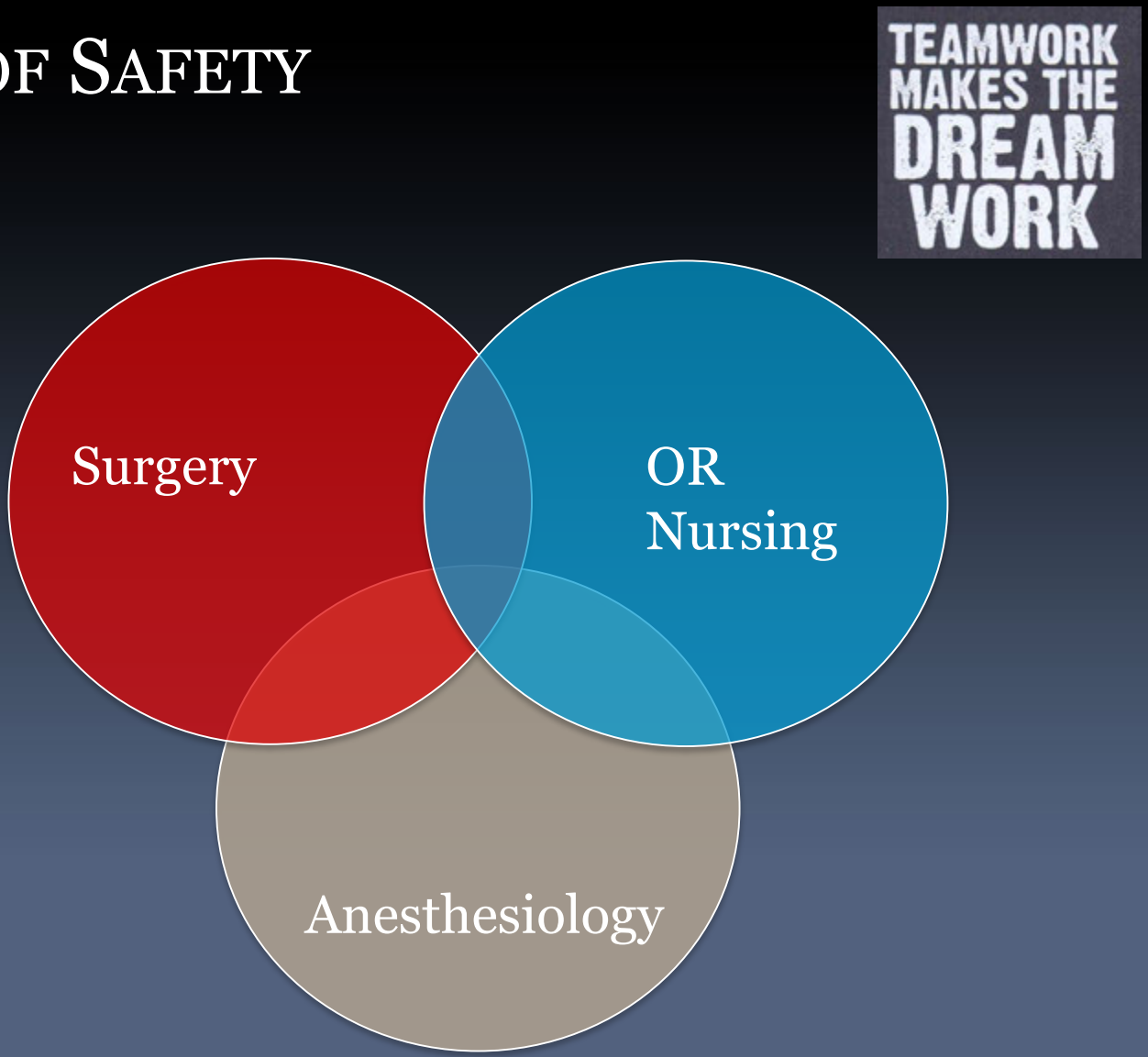


Checklist Item Completion

Checklist Item Completion



Culture of Safety



Source: Jennifer Yu, WUDOS

Iatrogenic Injuries

- Current measures are inadequate for quality improvement
- 24% of all surgical adverse events involved some technique related problem
- Malpractice claims analysis:
  - 49% of pt injuries are attributable to a manual error
  - 34% of manual errors were injuries to viscera or other anatomy
    - Regenbogen SE et al Ann Surg 2007;p 246:705-711.

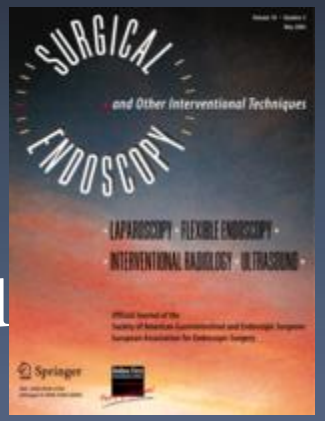
Electrosurgical Injuries

- Association of Operating Room Nurses (AORN) estimates c. 40,000 patients burned by faulty ES devices per year
- Up to 70% of ES burns in laparoscopic surgery may be undetected at the time of injury
- ACS survey: 18% of surgeons had experienced insulation failure or capacitive coupling injury, 54% knew a colleague who had a stray electrical burn

Surgeons don't know what they don't know about the safe use of energy in surgery

Liane S. Feldman · Pascal Fuchshuber · Daniel B. Jones · Jessica Mischna · Steven D. Schwaitzberg · the FUSE (Fundamental Use of Surgical Energy™) Task Force

- 48 Leading surgeons took pilot exam: average score = 59 %
- 31% did not know how to correctly handle a fire
- 31 % could not identify the device least likely to interfere with a pacemaker;
- 13 % did not know that thermal injury can extend beyond the jaws of a bipolar instrument;
- 10 % thought a dispersive pad should be cut to fit a child



Surg Endosc 2012;26:2735-39.

OR Fires

- 200-240 fires per year
- Most are minor
  - (20-30 are serious, disfiguring)

Clarke JR, Bruley ME. Surgical fires: Trends associated with prevention efforts. Pennsylvania Patient Safety Advisory 2012 Dec; 9(2): 130-5. [cited 2012 Dec 12].

OR Fires: Fire Triangle

- Fire triangle:
  - Heat source (ESU, lasers)
  - Fuel (drapes, prep)
  - Oxidizer (O2, N2O)

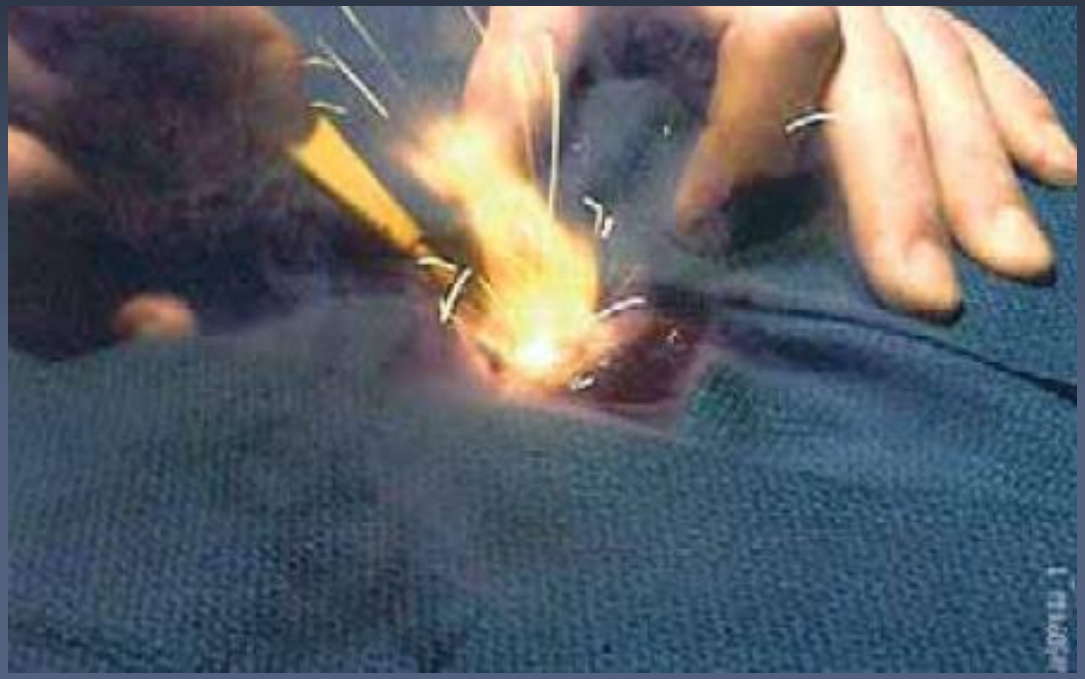
- Prevention requires coordination by providers

OR Fire Scenario

- Patient undergoing excision of face/scalp lesion under local anesthesia with sedation
- Alcohol-based prep, O2 by nasal cannula
- An incision was made and the electrosurgical unit (Bovie) was applied and there was a spark

OR Fire Scenario

- And a flash beneath the drapes

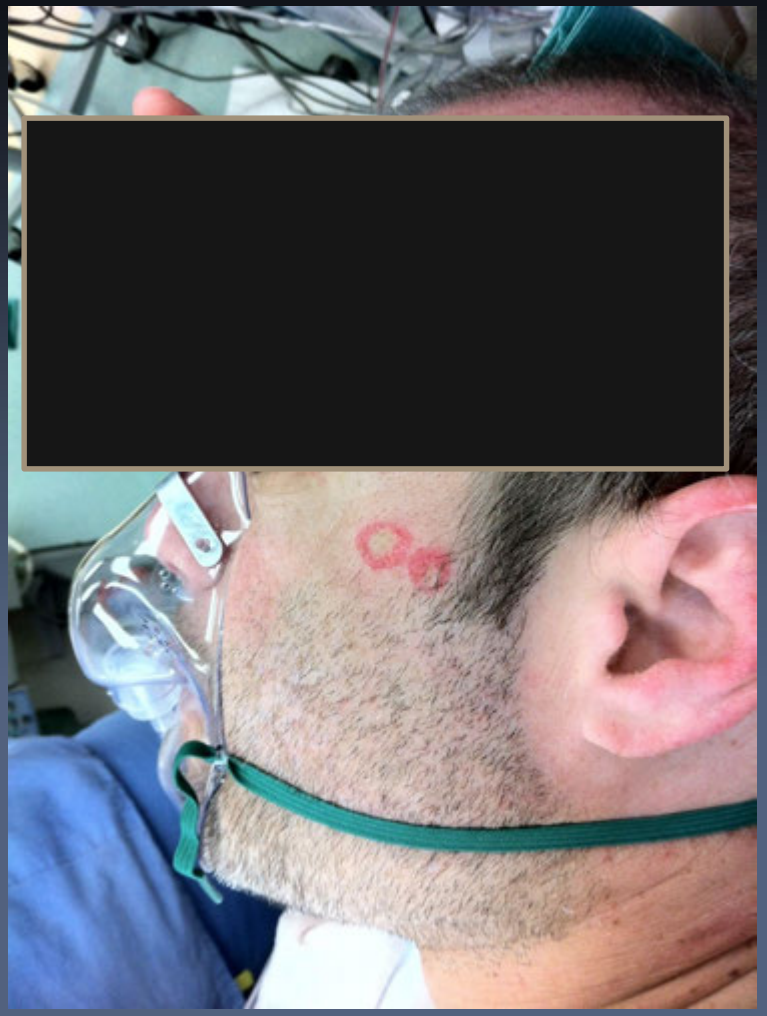


OR Fire Case

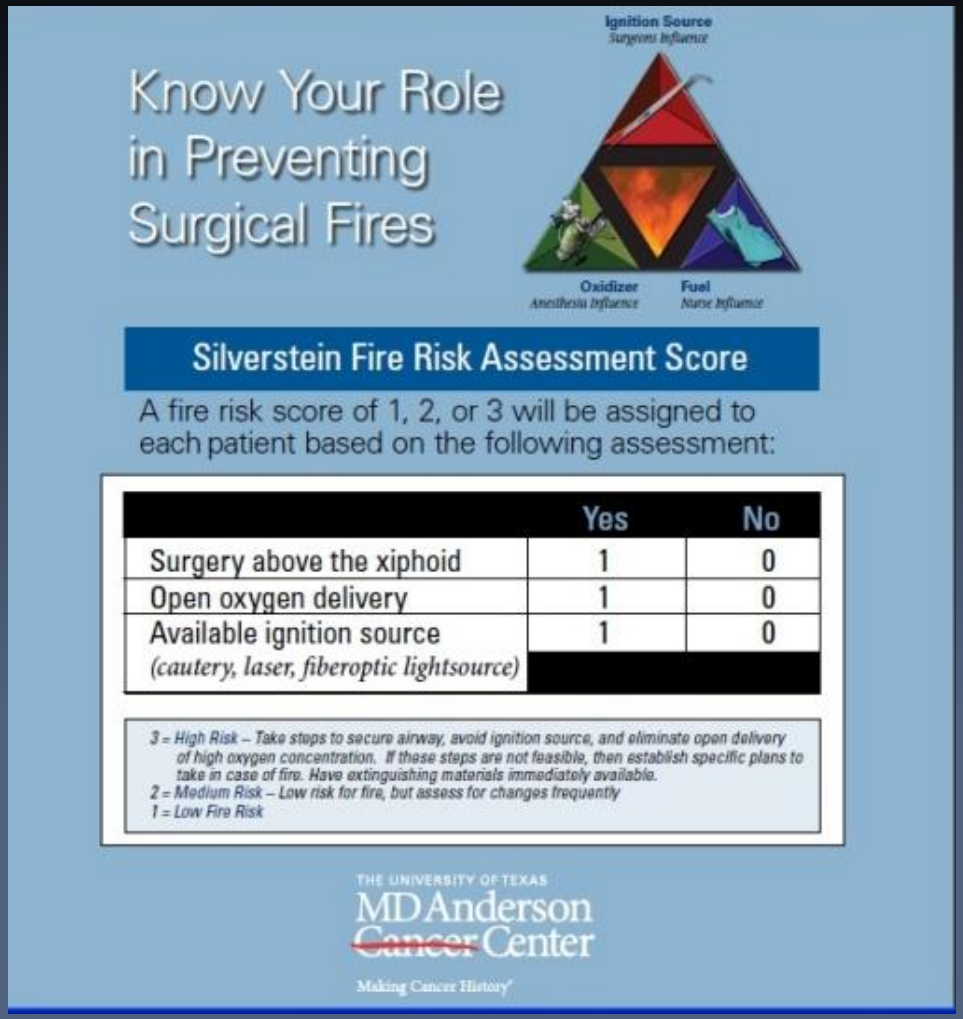
NBC Today Show: Nov 2011

Light Cord Burns

High Intensity Light Source



OR Fire Risk Assessment

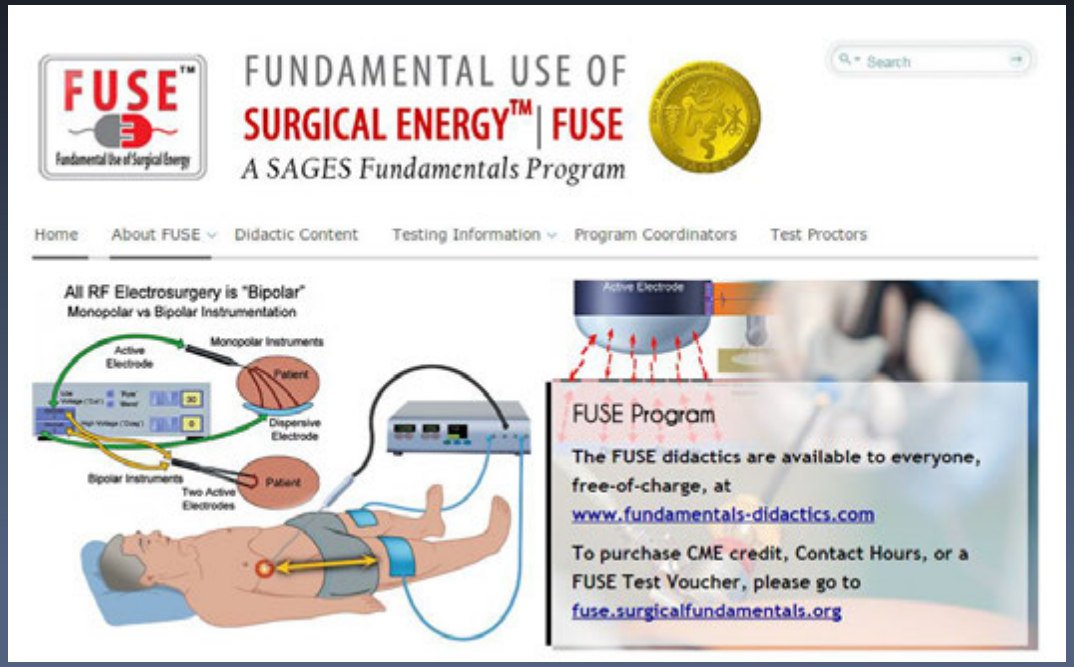


FDA: National Fire Protection Week

- Find out how to prevent fires
- Incorporate fire risk assessment into your intraoperative time out
- Tell your colleagues and staff about the importance of using surgical fire risk assessment
- Give a talk to your OR personnel on this topic

Fundamental Use of Surgical Energy (FUSE)

- Web based didactic modules – access free
- Fundamental Use of Surgical Energy Manual – Springer
- Certification exam



www.fuseprogram.org

Background

- 750,000 LC's performed in US/year
- CBD injury rate still in 0.3-0.6% range
- Translates to ≥3000 injuries/year in US
  - >$1 billion in associated costs
    - ½ medicolegal, ½ patient care
- More likely in early experience, and with more advanced pathology

Berci G et al, Surg Endosc 2013;27:1051-1054

Background

- Issues with prevention and treatment of CBD injury amongst most important demographic issues in contemporary general surgical practice

Predictors of Major Complications after Laparoscopic Cholecystectomy: Surgeon, Hospital, or Patient?

Melissa M Murphy, MD, MPH, Sing-Chau Ng, MS, Jessica P Simons, MD, MPH, Nicholas G Csikesz, MD, Shimul A Shah, MD, FACS, Jennifer F Tseng, MD, MPH, FACS

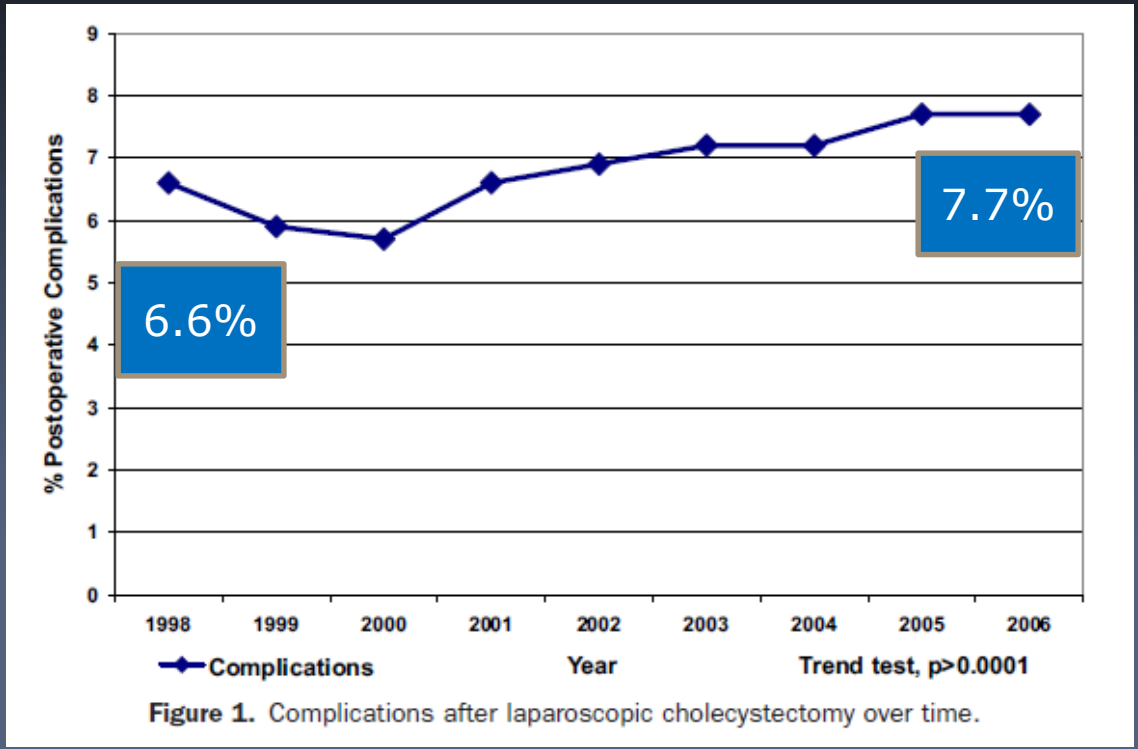


Figure 1. Complications after laparoscopic cholecystectomy over time.

JACS 2010;21:73-80.

Prioritizing Quality Improvement in General Surgery

Peter L Schilling, MD, Justin B Dimick, MD, MPH, John D Birkmeyer, MD, FACS

- All pts undergoing Gen Surg procedure reported in NSQIP 2005-2006
- Grouped into 36 categories by CPT code

Table 1. Relative Contribution of 36 Procedures to Adverse Events and Excess Length of Stay in General Surgery, American College of Surgeons – National Surgery Quality Improvement Program, 2005–2006

Procedure	Procedures		Adverse event rate, %	Proportion of all adverse events, %	Average excess length of stay for adverse event, d	Proportion of all excess length of stay, %
	n	% of total				
1. Colectomy ± colostomy	12,767	9.9	28.9	24.3	9.8	23.5
2. Small intestine resection	3,576	2.8	32.9	7.7	13.9	10.6
3. Cholecystectomy/inpatient	11,718	9.1	7.5	5.7	8.7	4.9
4. Ventral hernia repair	7,477	5.8	10.1	4.9	6.3	3.1
5. Pancreatectomy	1,927	1.5	34.9	4.4	6.8	3.0
6. Appendectomy	9,016	7.0	7.2	4.3	4.4	1.9
7. Bariatric procedures	6,167	4.8	8.3	3.4	3.7	1.2
8. Proctectomy ± colectomy ± anastomosis	1,402	1.1	31.5	2.9	6.2	1.8
9. Lysis of adhesions	1,323	1.0	23.1	2.0	10.5	2.1
10. Liver resection	1,045	0.8	27.0	1.9	8.8	1.6

JACS 2008;207:698-704.

Surgical management of acute cholecystitis: results of a 2-year prospective multicenter survey in Belgium

Navez B et al Surg Endosc 2012;26:2436-45.

- Prospective study of 1089 pts with acute cholecystitis from 53 surgeons
- Operative approach:
  - Laparoscopic: 93.2% Open – 6.8%
- Conversion to open: 11.4%
  - 7.5% in females and 14.9% in males
- Incidence of biliary injury: 1.2%

Surgical management of acute cholecystitis: results of a 2-year prospective multicenter survey in Belgium

Navez B et al Surg Endosc 2012;26:2436-45.

	Successful Lap N=899 (82.5%)	**Lap Converted to Open N=116 (11.4%)**	**Open Group N=74 (6.8%)**
Bile duct injury	4 (0.4%)	**7 (6.0%)***	2 (2.7%)
Biliary fistula	13 (1.4%)	**9 (7.7%)**	3 (4.1%)
Total Biliary Complications	17 (1.9%)	**16 (13.7%)**	5 (6.8%)

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*4 injuries occurred before and 3 after conversion

The SAGES Safe Cholecystectomy Program

Strategies for Minimizing Bile Duct Injuries: Adopting a Universal Culture of Safety in Cholecystectomy

Stop Bile Duct Injuries

The Mission

To enhance a universal culture of safety for cholecystectomy to minimize the risk of bile duct injury

6 Step Program

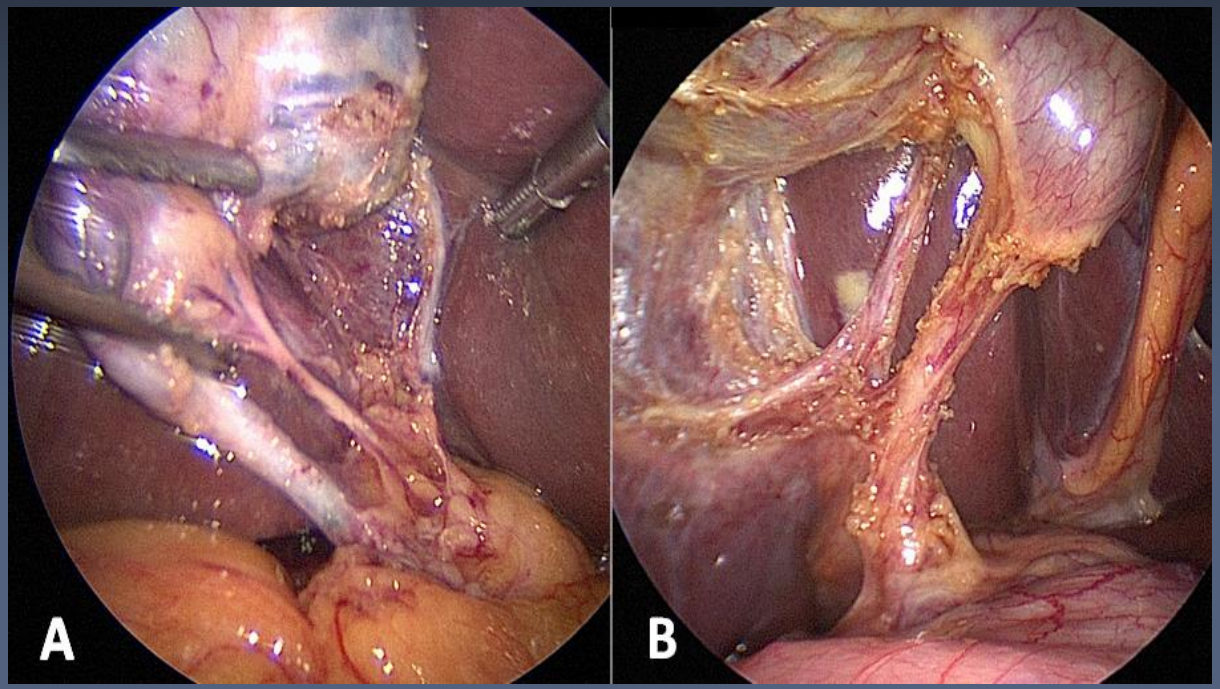
1. Understand and apply the critical view of safety
2. Intraop time out before clipping/cutting any ductal structures
3. Understand and recognize aberrant anatomy
4. Liberal use of cholangiography or other imaging modalities
5. Recognize difficult chole and how to manage
6. Get help for difficult cases

1. Understand and Apply the Critical View of Safety

Rationale and Use of the Critical View of Safety in Laparoscopic Cholecystectomy

Steven M Strasberg, MD, FACS, L Michael Brunt, MD, FACS

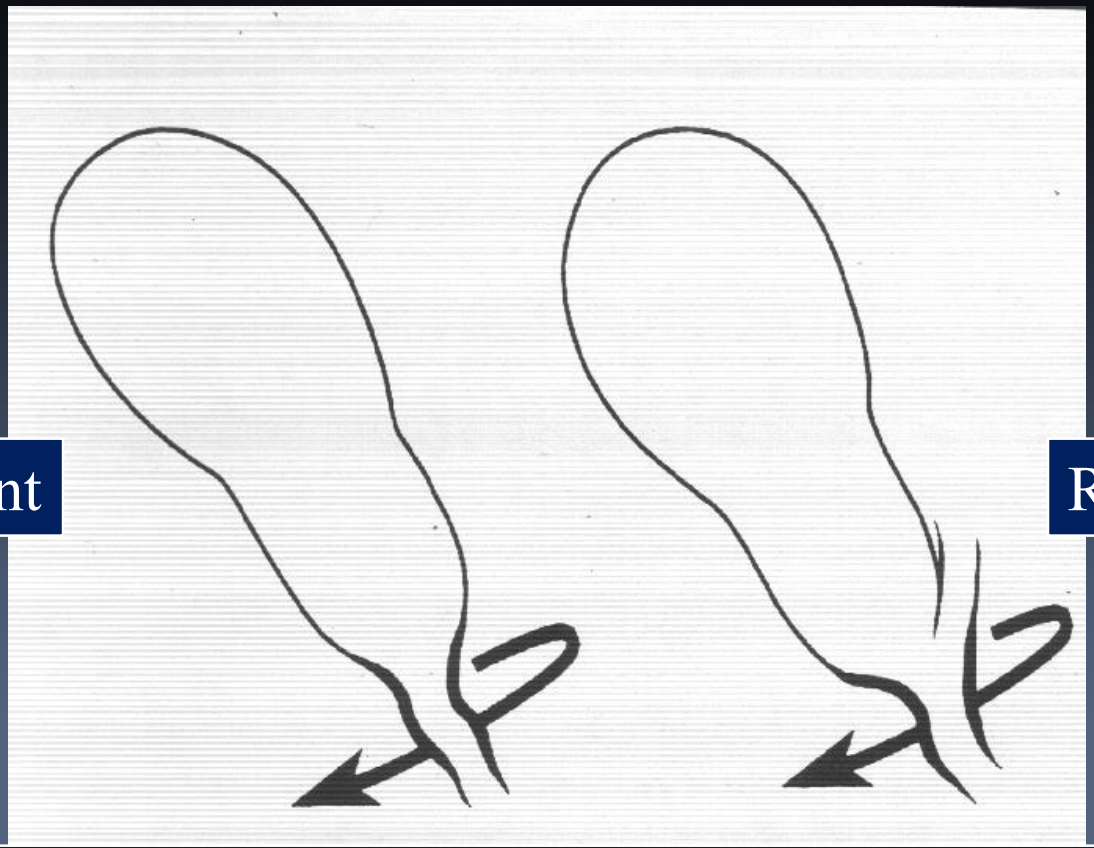
JACS 2010;211:132-38.



The Infundibular Technique

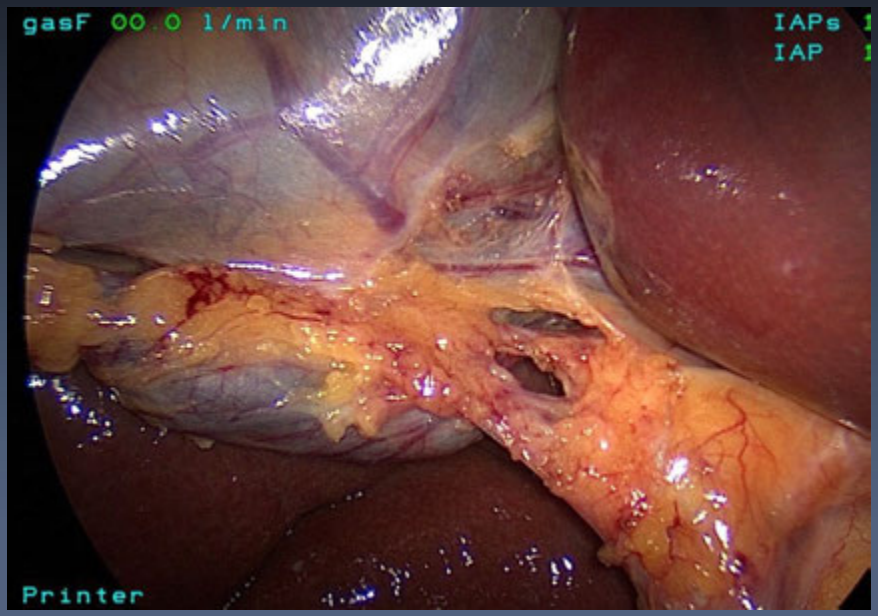
"If you see the flare,
You're there"

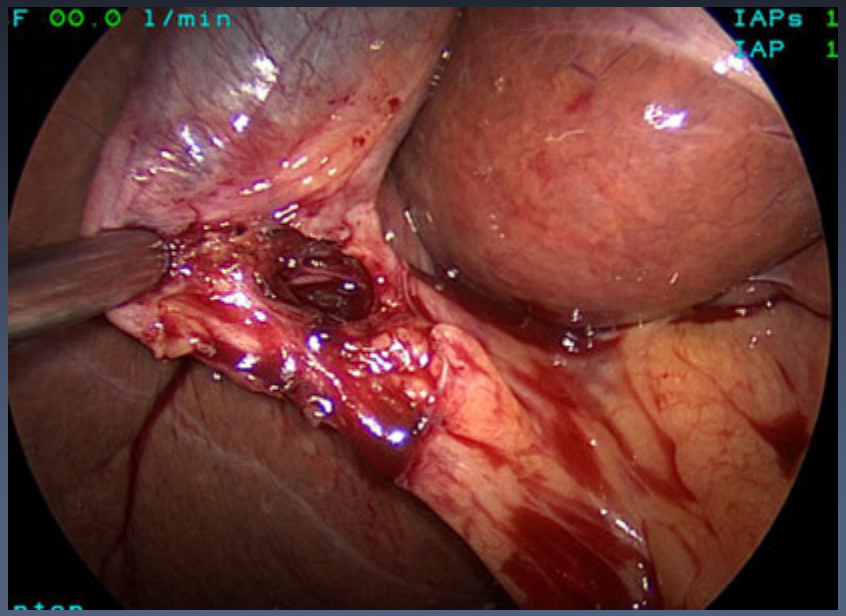
The Fallacy of the Infundibular Technique



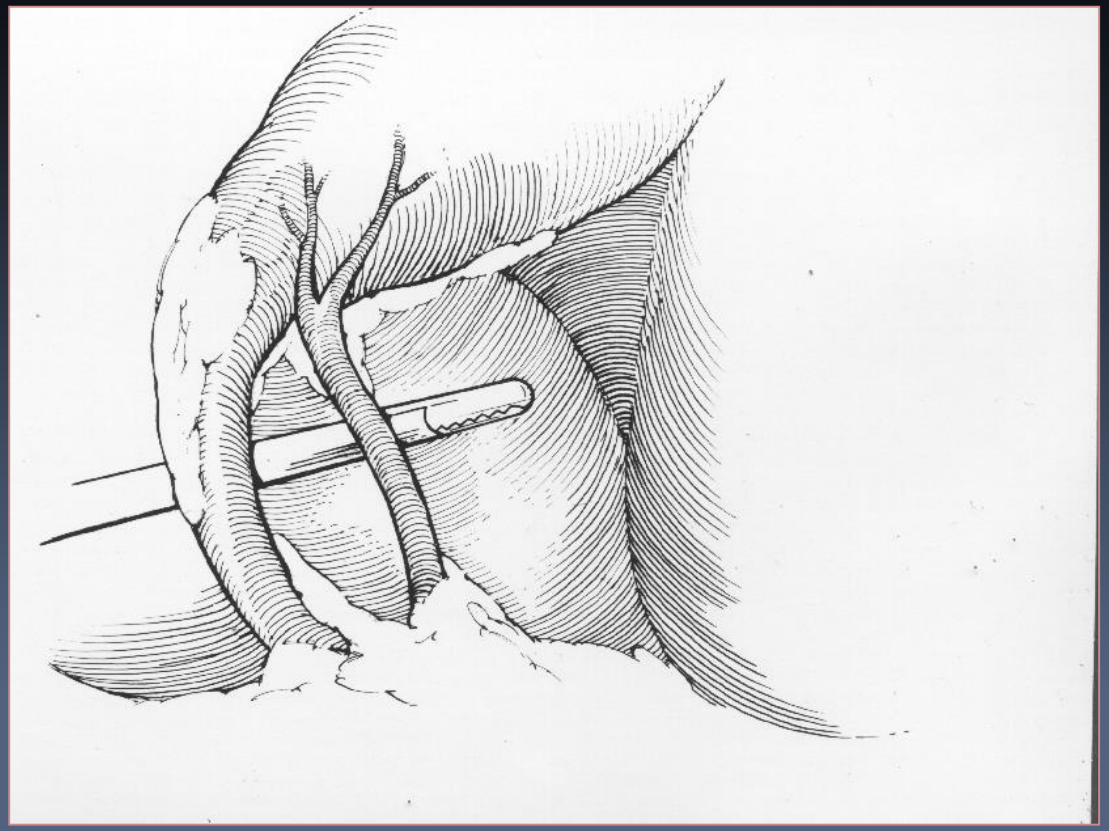
A visual deception inherent in the technique makes the surgeon think he is around the CD when in reality he is around the CBD. "If you see the flare, BEWARE"

Do These Photographs Meet CVS Criteria?



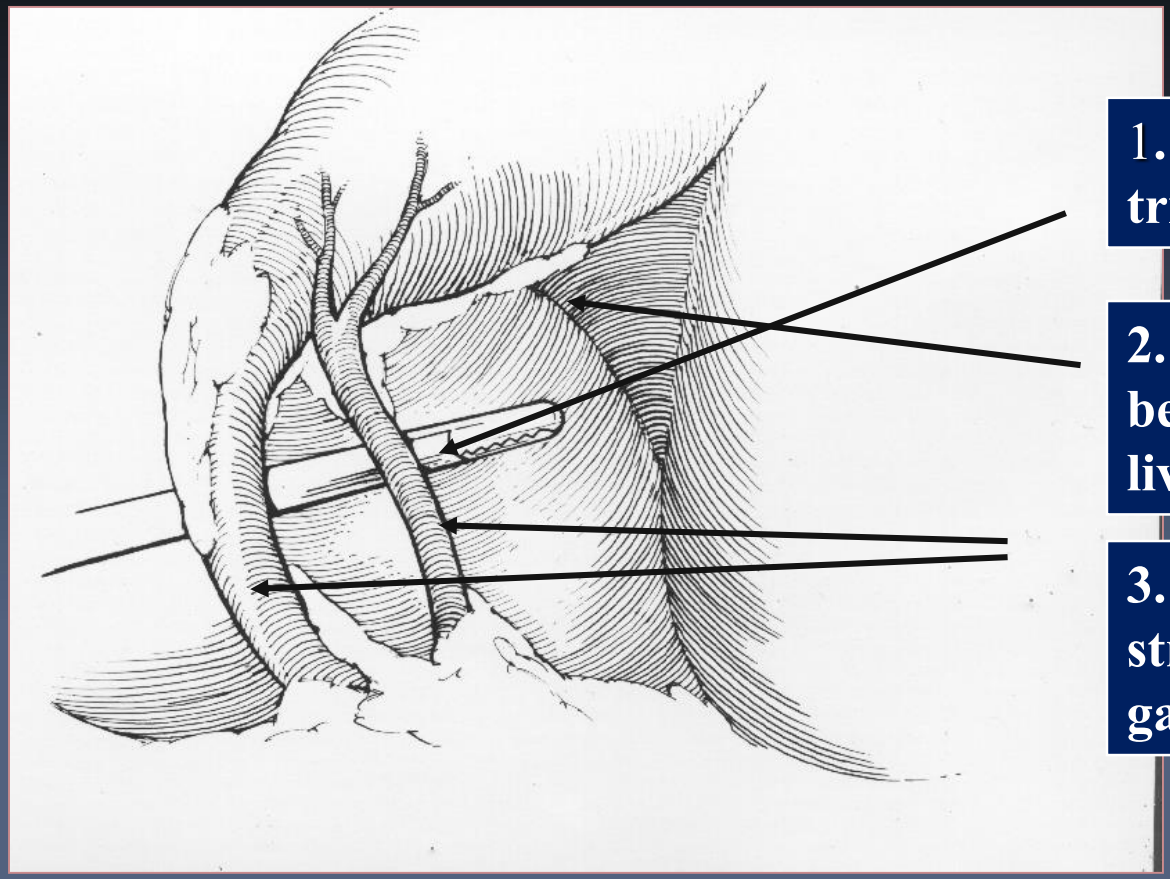


The “Critical View” Method



Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. J Am Coll Surg 180:101-25, 1995.

The "Critical View" Technique



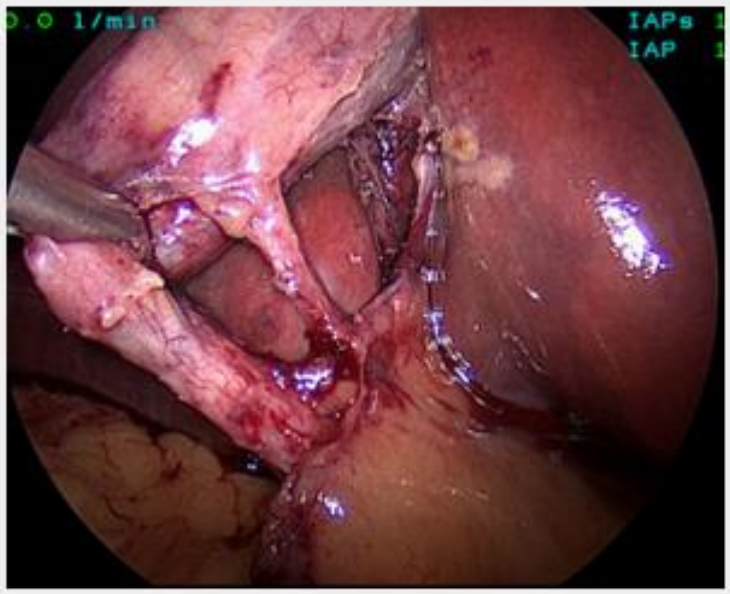
1. **Hepatocystic triangle cleared**

2. **Lower gallbladder bed separated from liver bed to cystic plate**

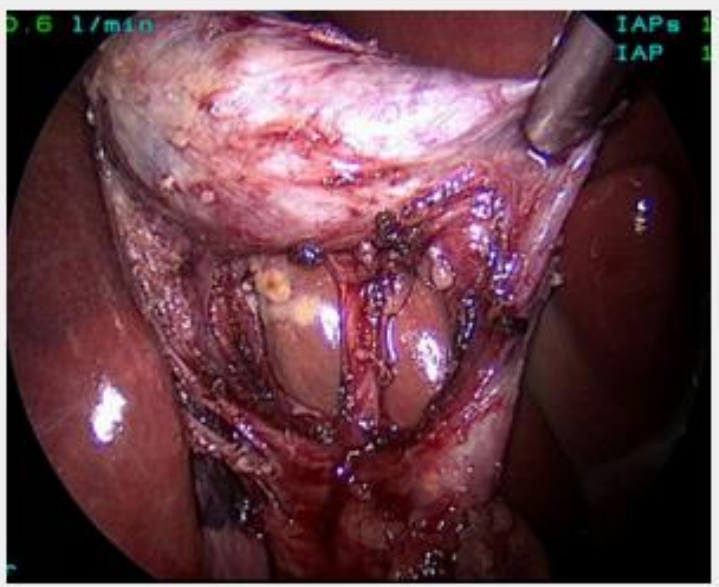
3. **Two and only two structures entering gallbladder**

Strasberg SM, Hertl M, Soper NJ. J Am Coll Surg 180:101-25, 1995.

Strategies for Minimizing Bile Duct Injuries: Adopting a Universal Culture of Safety in Cholecystectomy



Visualization of the doublet view (anterior)

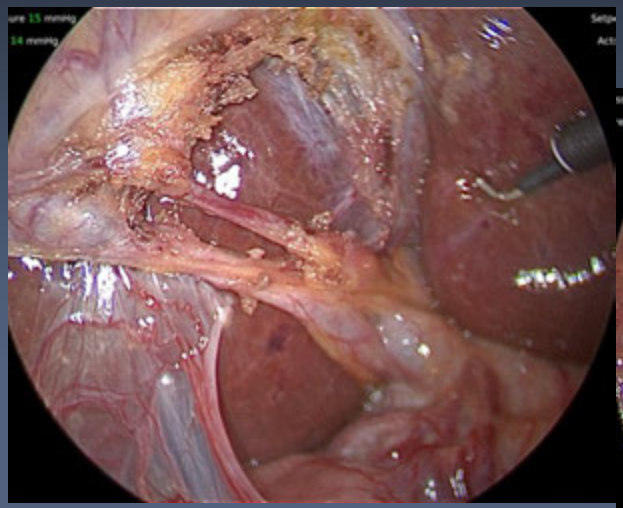


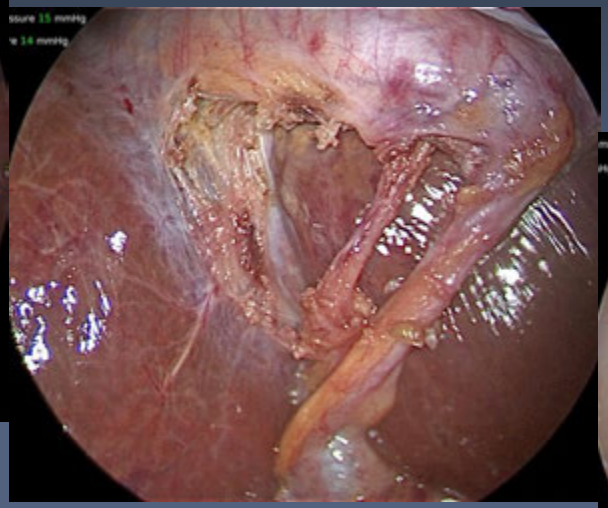
Visualization of the doublet view (posterior)

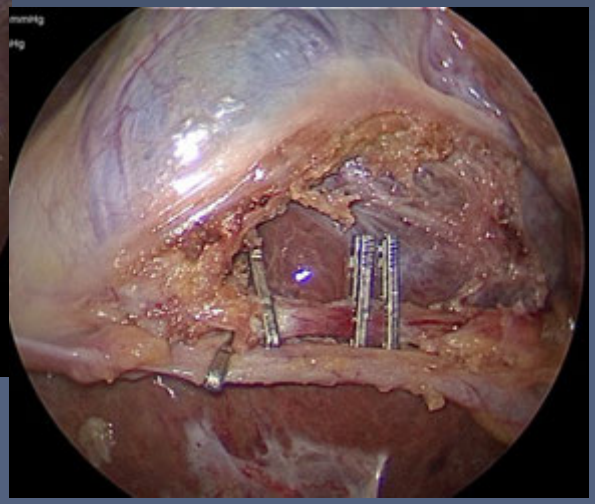
Doublet Photo Critical View of Safety

Step 2: Perform an Intra-operative Time-Out (prior to clipping, cutting or transecting any ductal structures)

- The intraoperative time out is a stop point before clipping or cutting any structures

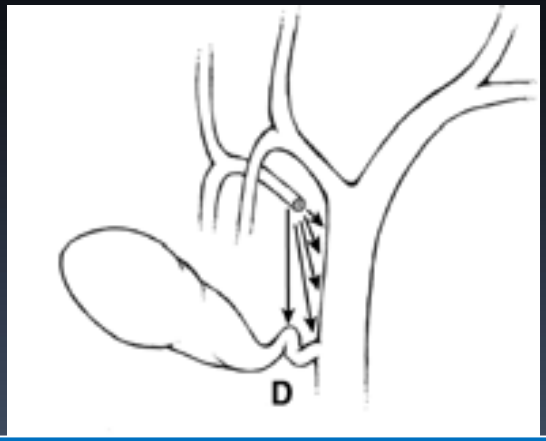




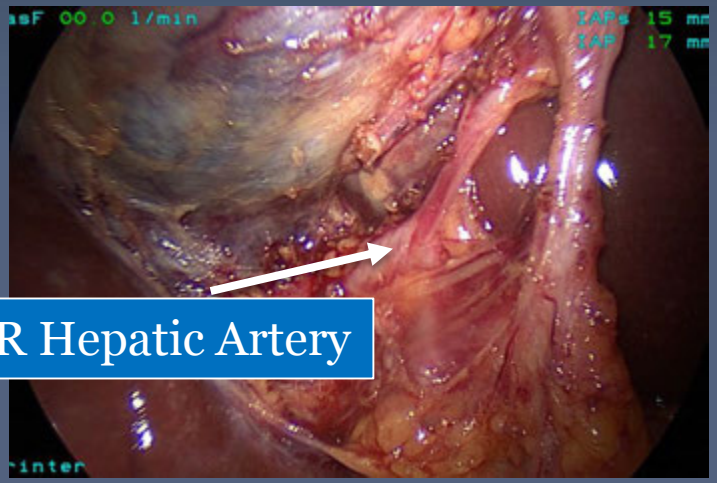


3. Understand Aberrant Anatomy

- Aberrant anatomy may include
  - short cystic duct
  - aberrant hepatic ducts
  - right hepatic artery that crosses anterior to the common bile duct.



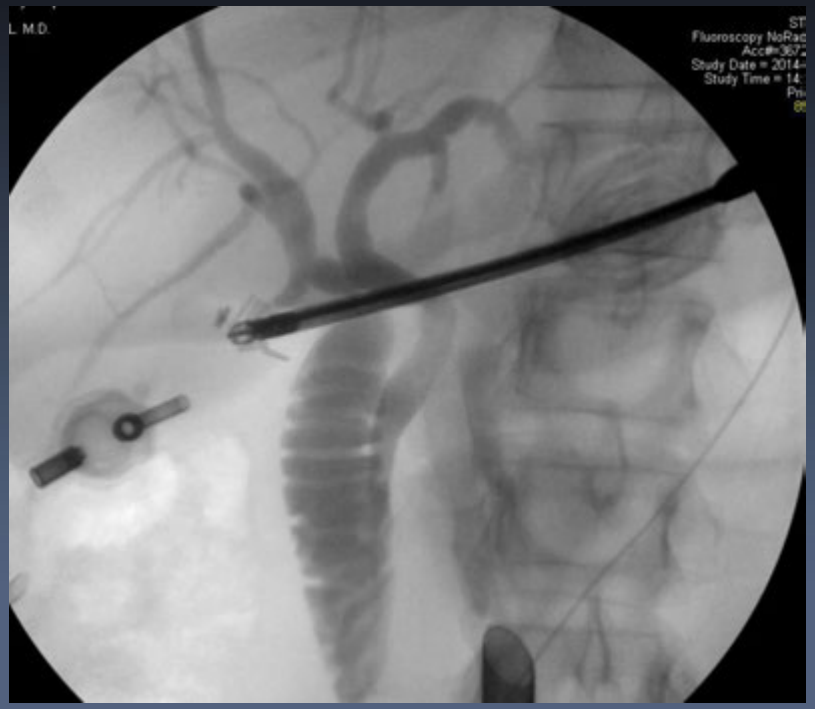
R Hepatic Duct anomalies



R Hepatic Artery

4. Make Liberal Use of Cholangiography or other means (US, infrared)of intraoperative biliary imaging

- Cholangiography may be especially important in difficult cases or unclear anatomy
- Several studies have found that routine cholangiography reduces the incidence of biliary injury but controversy on this issue exists

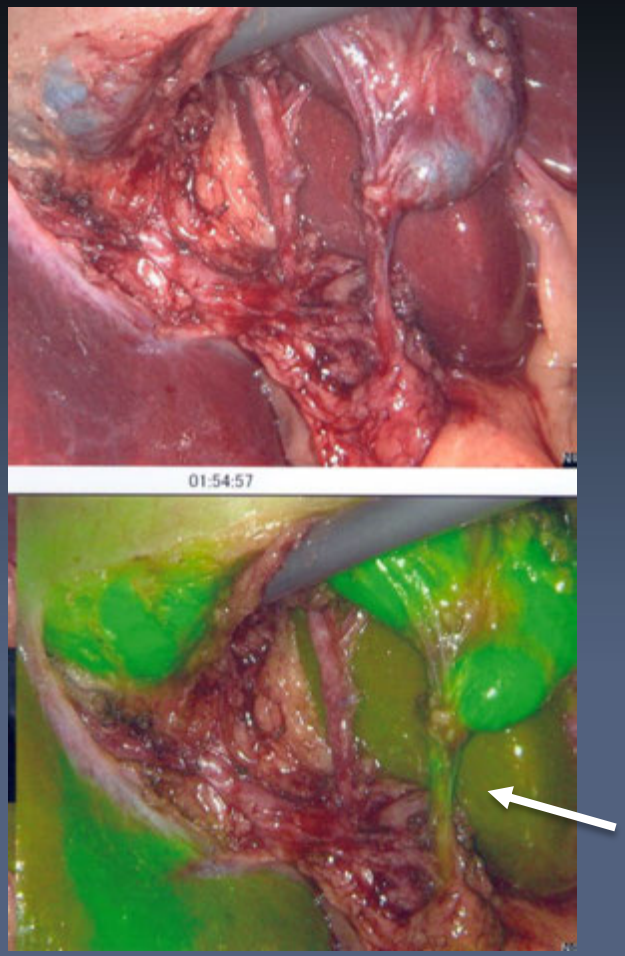


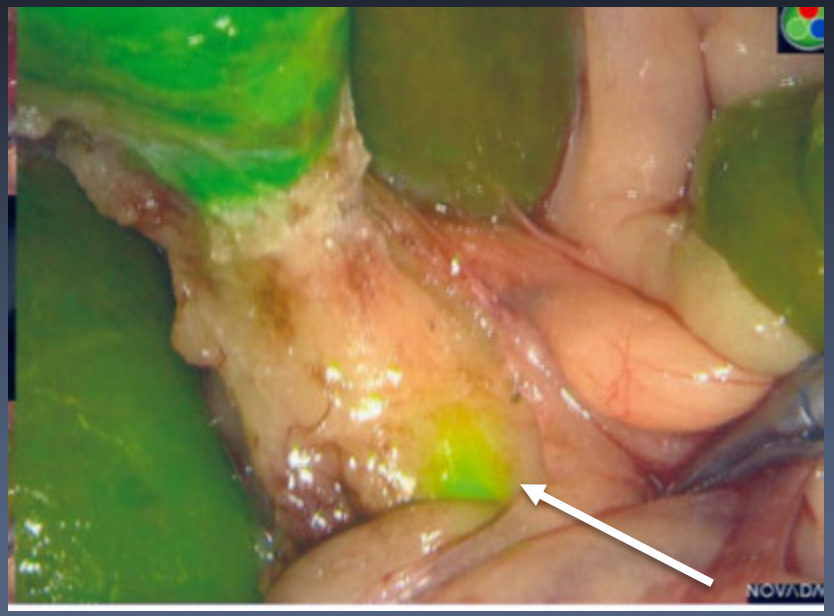
Cystic Duct Enters Right Hepatic Duct

5 Reasons to Do Cholangiography

1. It is an essential and unique skill component of cholecystectomy
2. Enables accurate interpretation of cholangiogram findings
3. May help identify aberrant biliary anatomy
4. Is a prerequisite to performing lap CBD exploration
5. May reduce the incidence of biliary injury and/or reduce the severity of biliary injury if one occurs

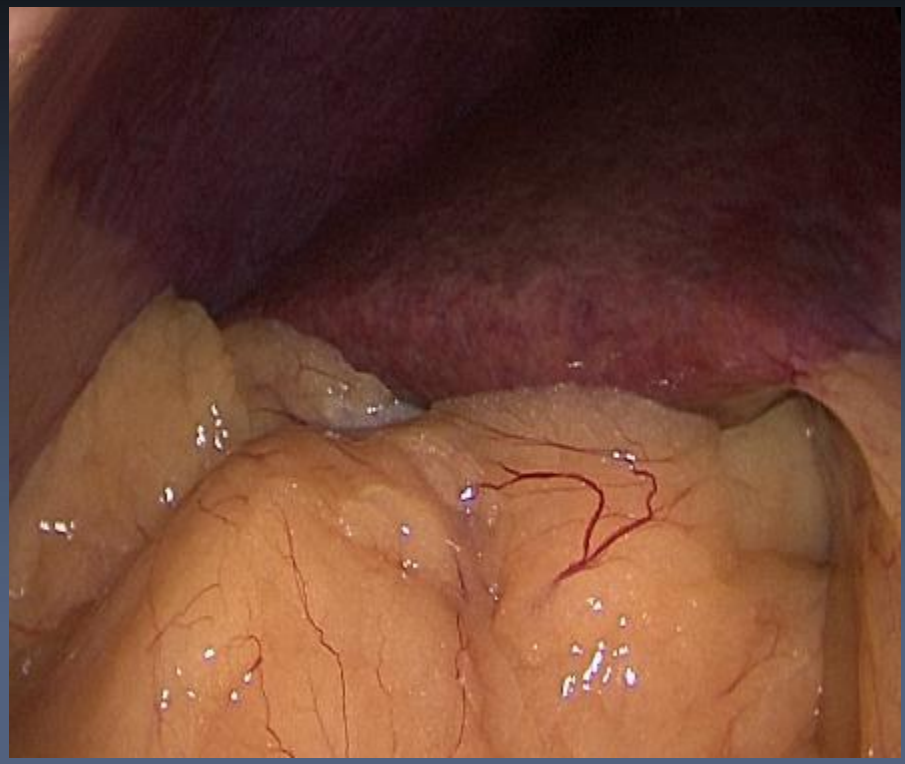
Infrared Fluorescent Cholangiography





Step 5: The Difficult Cholecystectomy

- Conditions assoc w Difficult Cholecystectomy
  - Morbid obesity
  - Severe chronic cholecystitis (contracted GB)
  - Acute cholecystitis
  - Mirizzi's syndrome
  - Cirrhosis

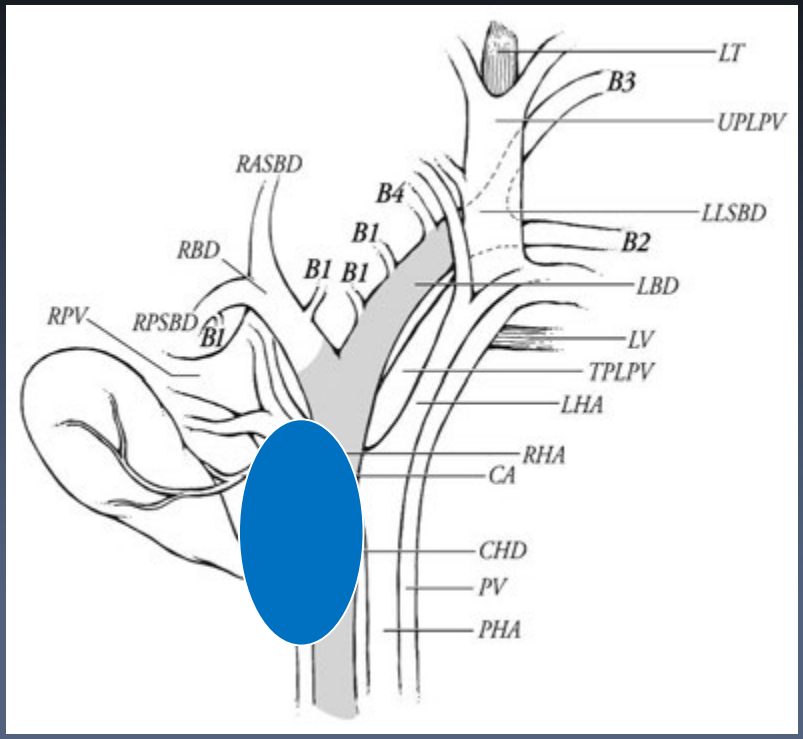


Morbidly Obese Pt with
Bulky Fatty Liver and Omentum

Step 5: The Difficult Gallbladder

- Recognize when the dissection is approaching a zone of significant risk and halt the dissection before entering the zone (biliary inflammatory fusion)

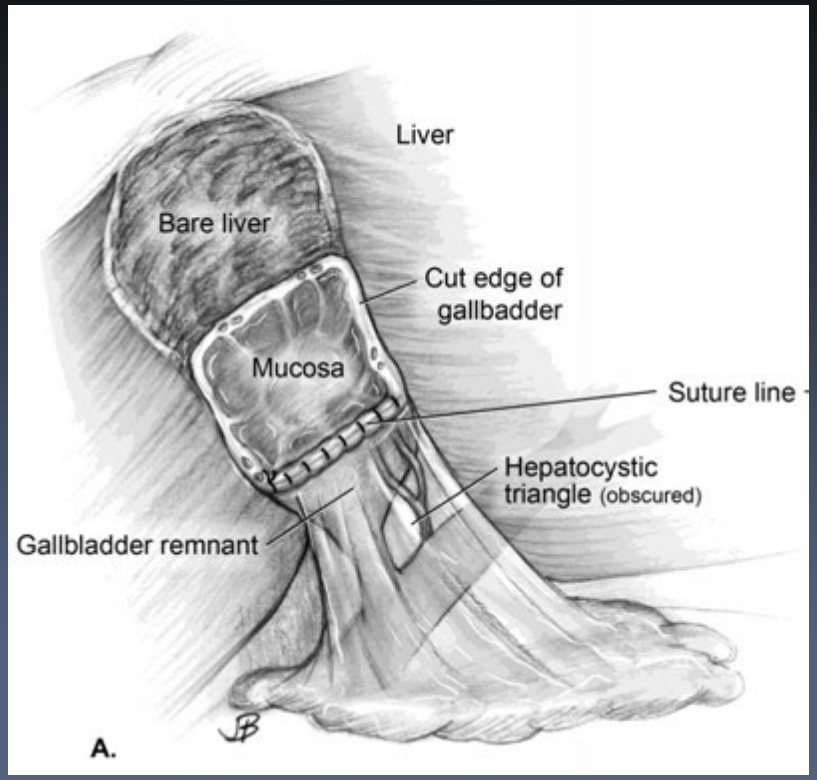
- Finish the operation by a safe method other than cholecystectomy if conditions around the gallbladder are too dangerous.
  - Subtotal CCX
  - Percutaneous cholecystostomy tube
  - Abort



Zone of Danger
Difficult Lap Chole

Subtotal Cholecystectomy

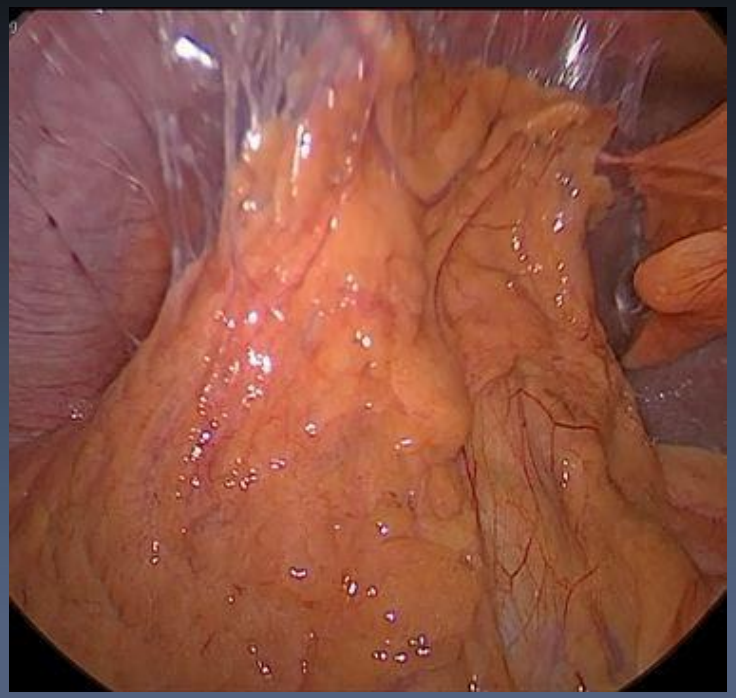
- Leave posterior wall on liver
- Leave 2 cm of GB neck
  - Can remove impacted calculi
  - Oversew neck
- Coagulate GB bed
- Drain the GB fossa



Strasberg SM et al JACS (2015)

Step 6: Consider Help from Another Surgeon

- When it is practical to obtain, the advice of a second surgeon is often very helpful under conditions in which
  - the dissection is stalled
  - anatomy is unclear
  - under other conditions deemed "difficult" by the surgeon.



Omental Pack over GB

The SAGES Safe Cholecystectomy Program

Strategies for Minimizing Bile Duct Injuries: Adopting a Universal Culture of Safety in Cholecystectomy

http://www.sages.org/safe-cholecystectomy-program/

Trocar-associated injuries and fatalities: An analysis of 1399 reports to the FDA

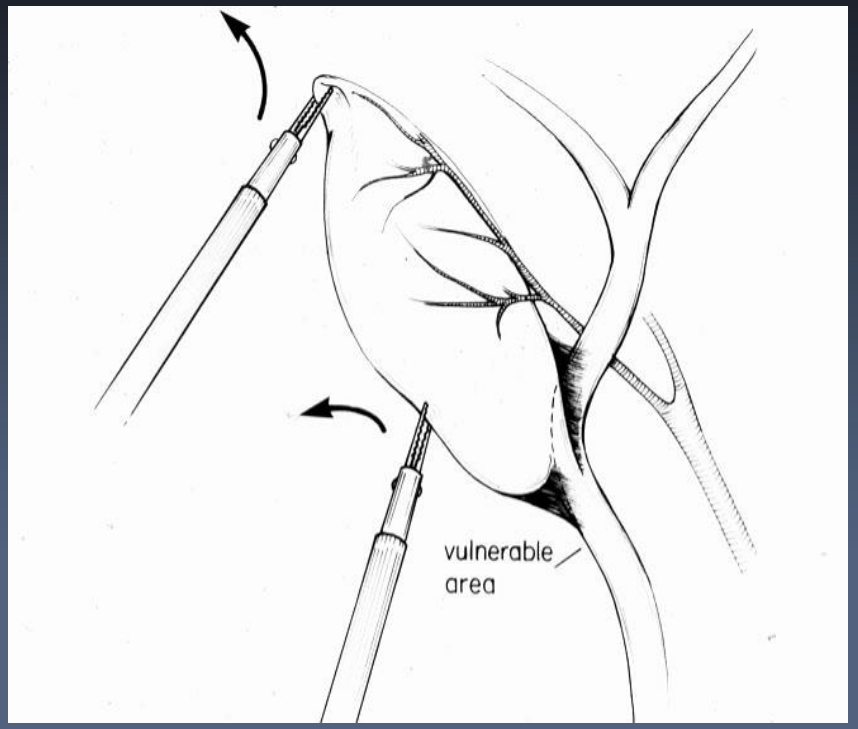
Janie Fuller, DDS, MPH, Binita S. Ashar, MD, and Julia Carey-Corrado, MD

- Trocars are the most common device named in malpractice injury claims assoc. with laparoscopic procedures
- Cholecystectomy most frequent procedure assoc with both fatal and non-fatal trocar injuries
- All fatality reports involved shielded or optical type trocars
- Distribution of injuries in 31 fatal cases
  - Aorta: 10
  - Iliac artery/vein: 5
  - Vena cava: 3
  - Bleeding NOS: 5
  - Gastric vessel: 1
  - Bowel: 7

J Min Inv Gynecol 2005;12:302-7.

Factors Associated with Failure of the Infundibular Technique

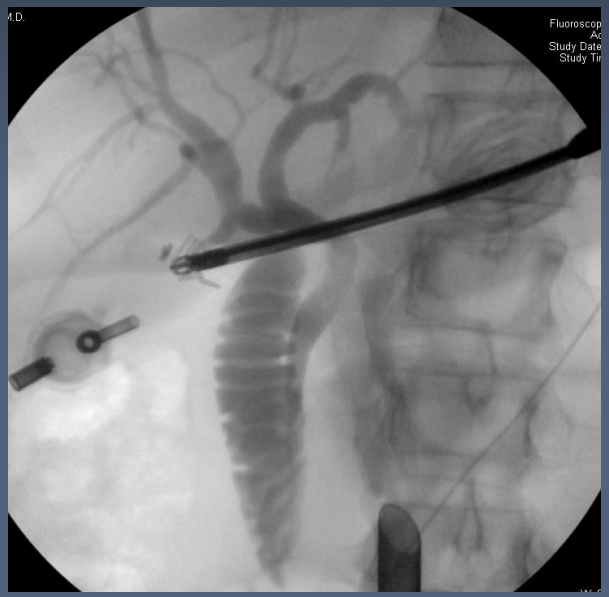
- Acute Inflammation
  - Thick GB wall
  - GB distension
  - Impacted stone
- Severe Chronic Inflammation
  - Thick GB wall
  - Severely contracted GB or impacted stone
- Intrahepatic GB
- Aberrant ducts

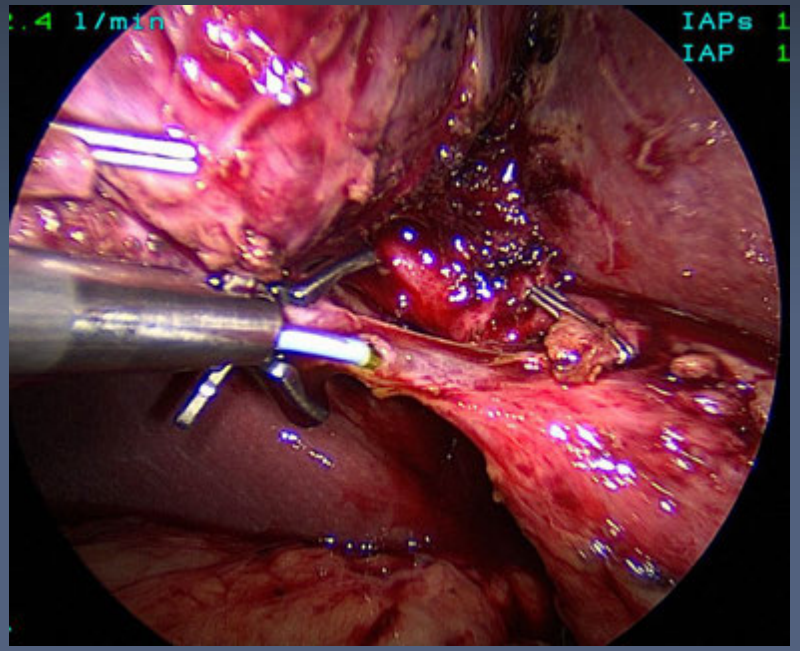


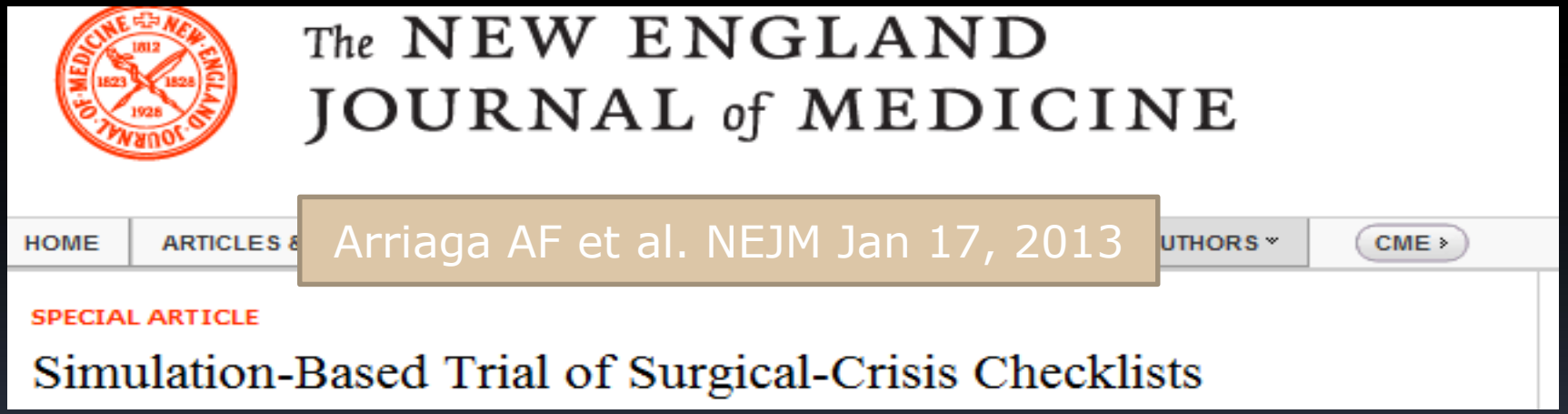
From Brunt & Soper
Complications in Surg 1993

Imaging in the Difficult Cholecystectomy

- Cholangiography or other imaging should be used liberally in the difficult GB
- Should not be a substitute for good dissection technique







- OR teams from 3 institutions took part in a series of surgical crisis videos
- Randomized to manage scenarios either from memory or with set of crisis checklists
- Failure to adhere to life-saving processes was less common when checklists were available (6% vs 23%)
- Every team performed better when the crisis checklist was available

Cystic Duct Stump Leaks

After the Learning Curve

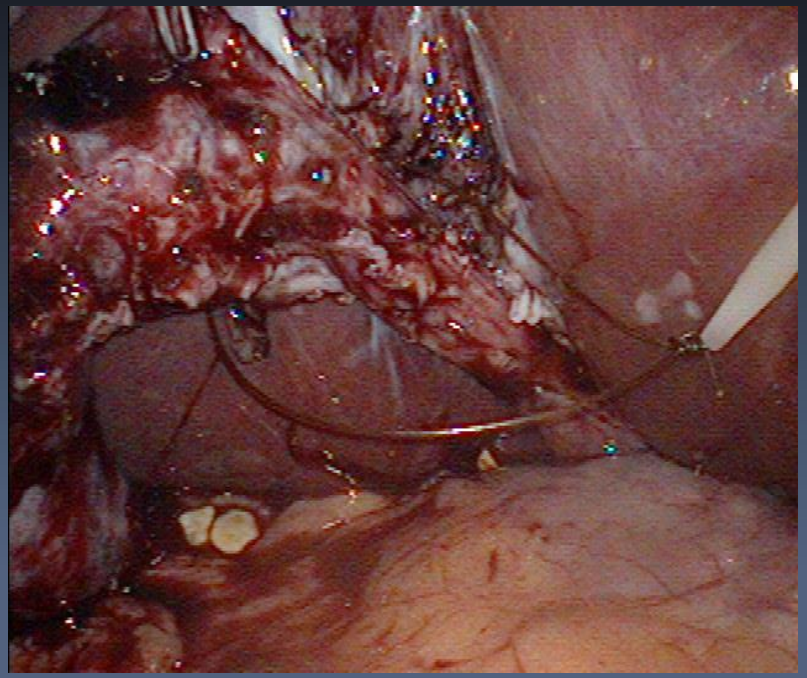
Samuel Eisenstein, MD; Alexander J. Greenstein, MD; Unsup Kim, MD; Celia M. Divino, MD

- 12 pts w cystic duct stump leaks (12/5751 LC's: 0.2%)
- Presentation mean 2.3 d postop
  - 5 pts had "abnormal" cystic ducts
  - Abdominal pain most common symptom (58%)
- Treatment:
  - ERCP and stenting alone – 8 (67%)
  - Additional CT drainage – 2 (17%)
  - One patient died

Arch Surg 2008;143:1178-1183

Avoiding Cystic Duct Stump Leaks

- Risk factors for cystic duct leak
  - thickened cystic duct (difficult GB)
  - distal obstruction (CBD stone)
  - transcystic exploration
- Use a loop suture (Endoloop) to secure the cystic duct

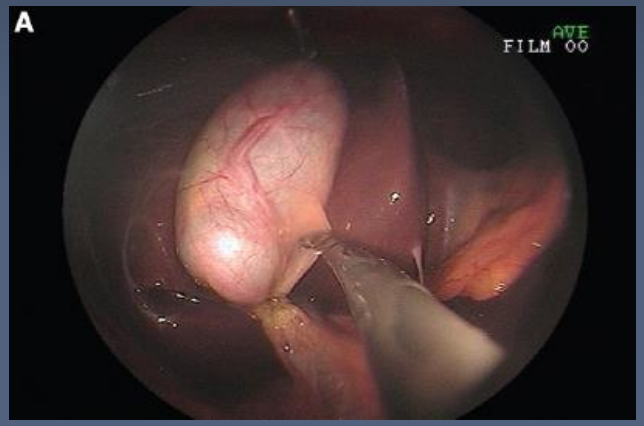


New Approaches: A Word of Caution

- Single incision
- NOTES
- Robotic (single incision)

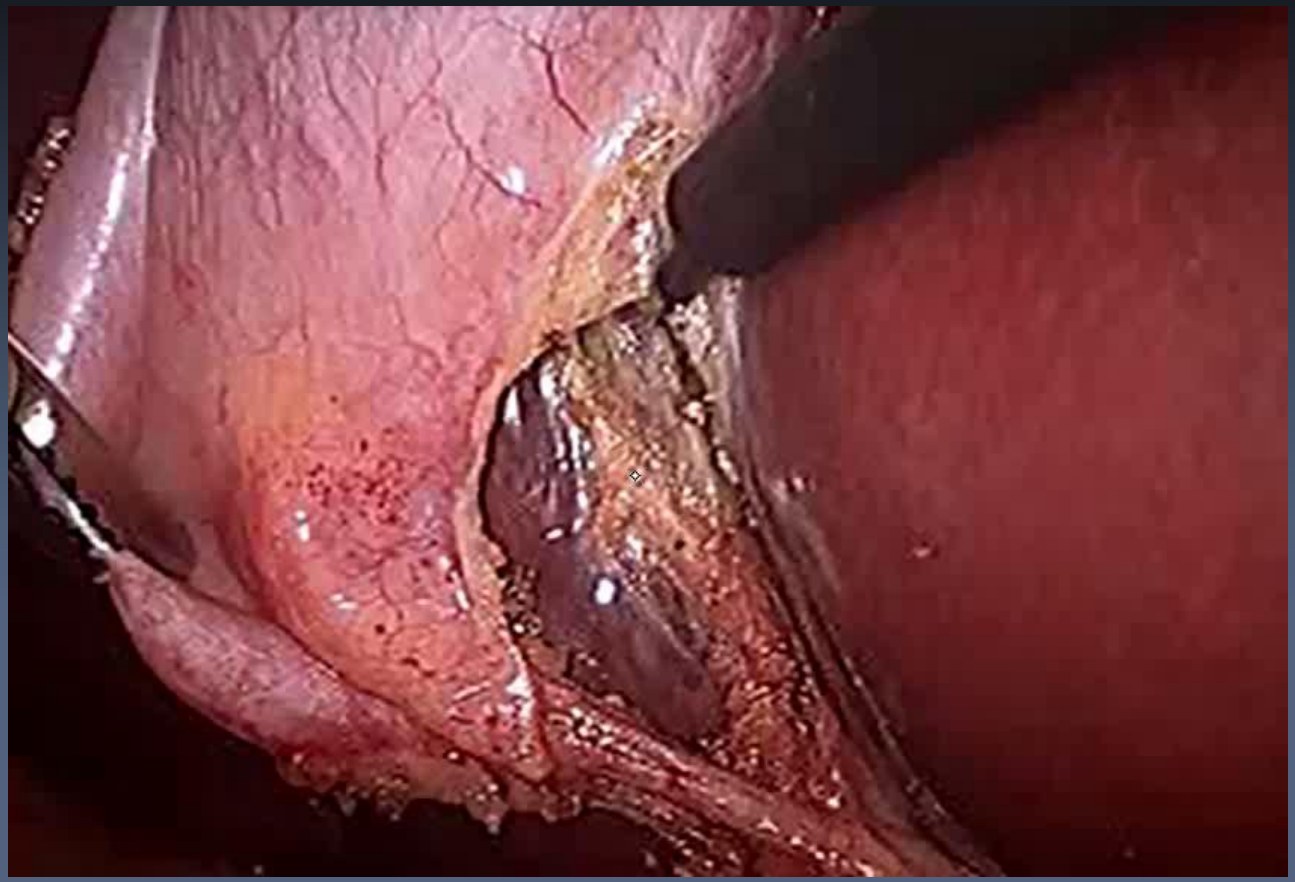
Robotic

SILS



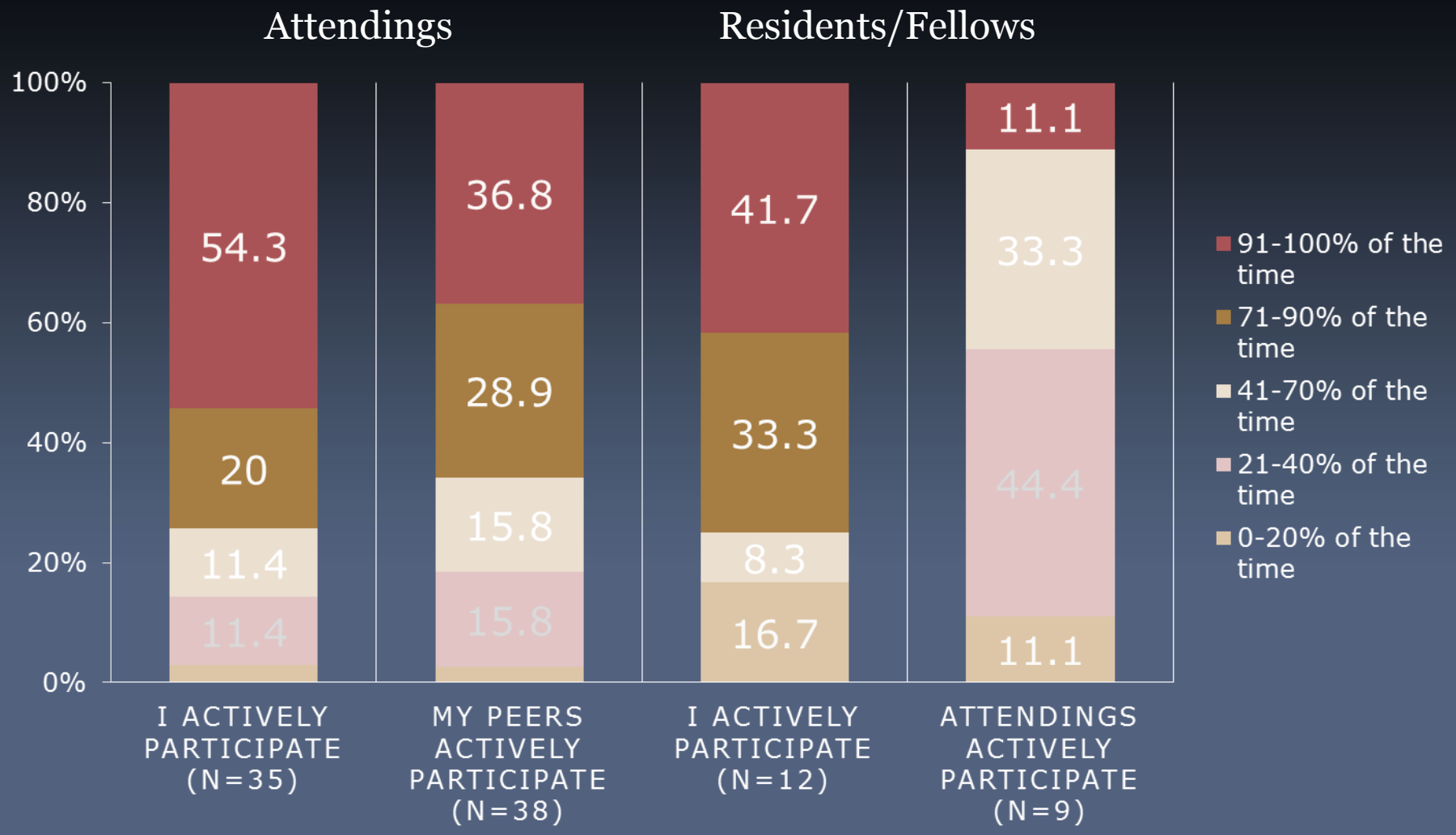
Transvaginal

Dissection of GB Off Liver Bed to Cystic Plate



AUDIENCE SURVEY RESULTS

DURING TIME OUTS FOR ELECTIVE CASES…



Effect of A 19-Item Surgical Safety Checklist During Urgent Operations in A Global Patient Population

Thomas G. Weiser, MD,† Alex B. Haynes, MD,*‡ Gerald Dziekan, MD,§ William R. Berry, MD,*¶ Stuart R. Lipsitz, ScD,¶ and Atul A. Gawande, MD,*†¶ for the Safe Surgery Saves Lives Investigators and Study Group*

Weiser TG et al Ann Surg 2010;251:976-980

- 1750 pts undergoing urgent non-cardiac surgery at 8 hospitals around the world
- Studied pre and post implementation of WHO Checklist

	Pre-Checklist	Post-Checklist	p value
Complications	18.4%	11.7%	0.0001
Death rates	3.7%	1.4%	0.0067
Adherence to 6 safety steps	18.6%	50.7%	<0.0001

Wrong-Site Surgery, Retained Surgical Items, and Surgical Fires
A Systematic Review of Surgical Never Events

Susanne Hempel, PhD; Melinda Maggard-Gibbons, MD; David K. Nguyen, MD; Aaron J. Dawes, MD; Isomi Miake-Lye, BA; Jessica M. Beroes, BS; Marika J. Booth, MS; Jeremy N. V. Miles, PhD; Roberta Shanman, MLS; Paul G. Shekelle, MD, PhD

- OR Fires
  - 103 cases – electrosurgical unit ignition source in 90%
  - Risk increased w head and neck procedures
  - Lack of staff awareness and failure to communicate were primary root causes

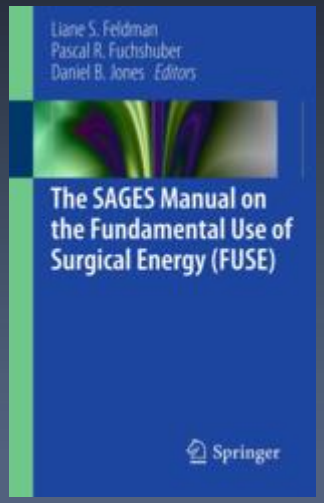
JAMA Surg 2015;150:796-805.

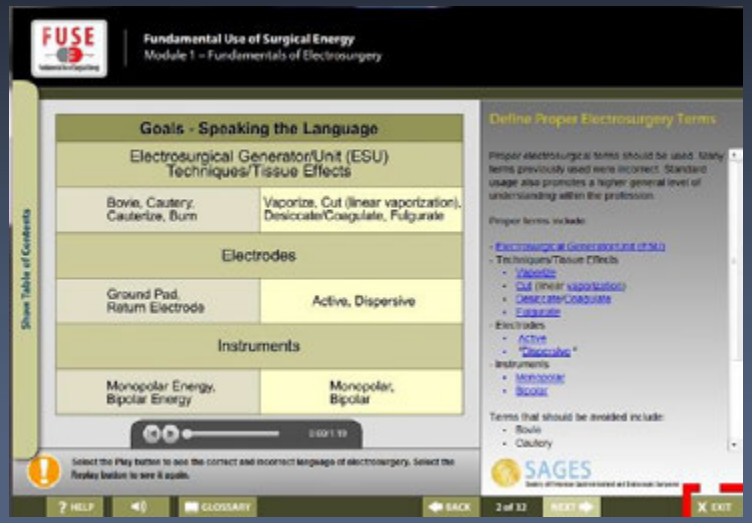
Basic curriculum in the science and safety of surgical energy

FUSE

Fundamental Use of Surgical Energy

Web based and book formats





Developed in multidisciplinary collaborative fashion

High stakes
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