Multi-society State-of-the-Art Consensus Conference on Prevention of Bile Duct Injury During Cholecystectomy

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State of the Art Consensus Conference on Prevention of Bile Duct Injury During Cholecystectomy

Saturday, October 20, 2018 • Boston, MA

L. Michael Brunt, MD

Disclosures:

- Institutional research support: Gore
- Chair, SAGES Safe Cholecystectomy Task Force

NIH Consensus Conference

Gallstones and Laparoscopic Cholecystectomy

NIH Consensus Development Panel on Gallstones and Laparoscopic Cholecystectomy

JAMA 1993; 269: 1018-1024

Journal of the American College of Surgeons
January, 1995, Vol. 180, 101-125

AN ANALYSIS OF THE PROBLEM OF BILIARY INJURY DURING LAPAROSCOPIC CHOLECYSTECTOMY

Steven M. Strasberg, M.D., F.R.C.S.(C), F.A.C.S., Martin Hertl, M.D., *and* Nathaniel J. Soper, M.D., F.A.C.S.

Causes and Prevention of Laparoscopic Bile Duct Injuries

Analysis of 252 Cases From a Human Factors and Cognitive Psychology Perspective

Lawrence W. Way, MD,* Lygia Stewart, MD,* Walter Gantert, MD,* Kingsway Liu, MD,* Crystine M. Lee, MD,* Karen Whang, MD,* and John G. Hunter, MD†

Common Bile Duct Injury During Laparoscopic Cholecystectomy and the Use of Intraoperative Cholangiography

Adverse Outcome or Preventable Error?

David R. Flum, MD; Thomas Koepsell, MD; Patrick Heagerty, PhD; Mika Sinanan, MD; E. Patchen Dellinger, MD

Conference Background/Goals

1. To identify optimal strategies for BDI prevention during cholecystectomy.

2. To develop and disseminate evidence-based practice guidelines for safe cholecystectomy.

3. The information from this conference should help inform efforts by surgical training programs, hospitals, and professional associations to create and disseminate interventions that enhance patient safety in cholecystectomy and improve patient outcomes.

Consensus Conference Timeline

- 2014 SAGES Safe Cholecystectomy Task Force formed
- 2016 joint session (SAGES, AHPBA, IHPBA) on safety in cholecystectomy at 13th International HPB Association Meeting, Sao Paulo, Brazil
- Multi-society Task Force and Steering Committee formed 2016
- Process for consensus meeting
  - Development of key questions for conference
  - Formulation of work groups/leads
  - Literature search and data extraction
  - GRADE evidence development and formulation of recommendations
  - Voting by group leads on consensus recommendations
  - Oct 20 consensus meeting and presentation of recommendations and voting by panel of experts

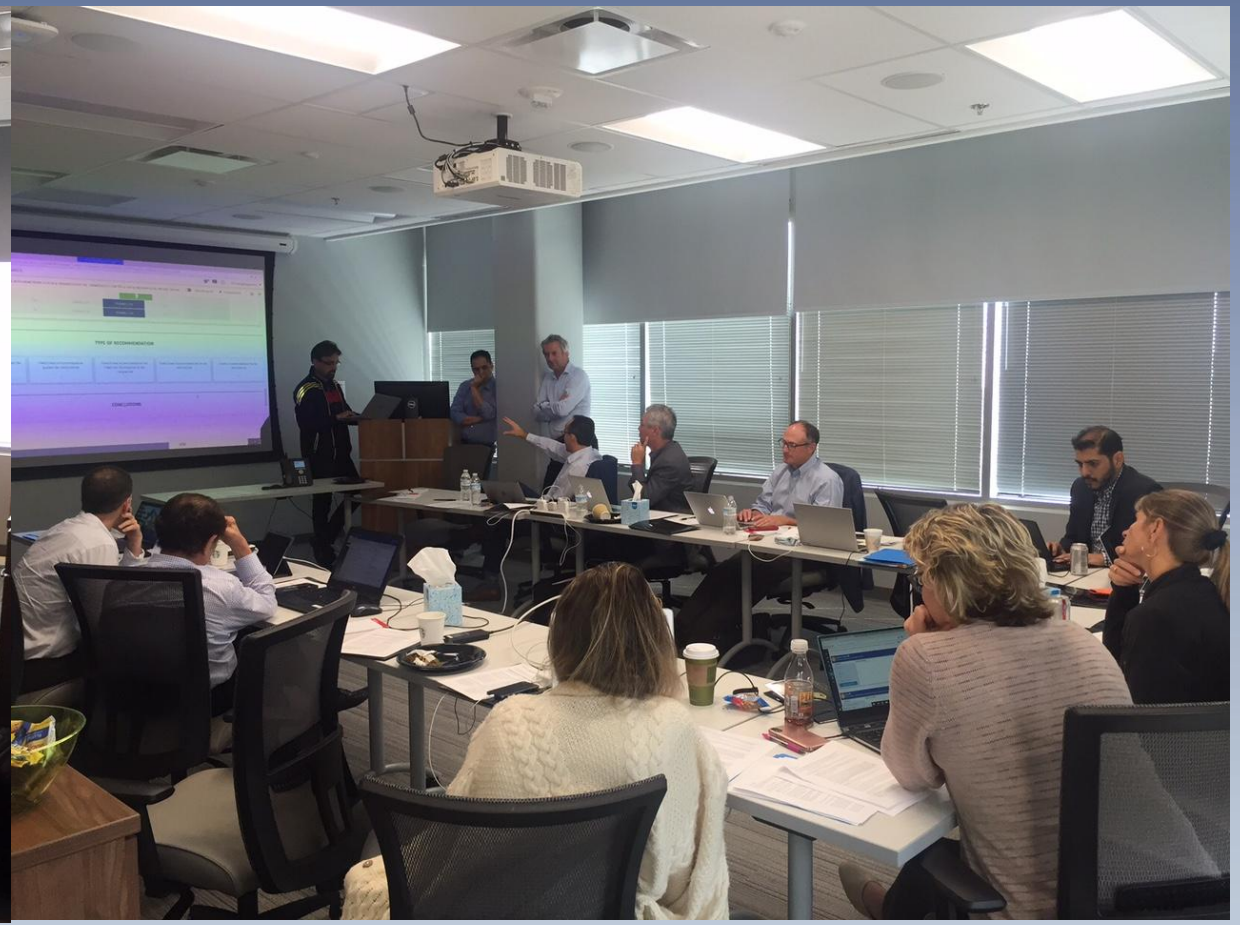
Consensus Conference Steering Committee

Society	Representative
SAGES	Michael Brunt, Horacio Asbun
AHPBA	Rebecca Minter, Charles Vollmer
IHPBA	Oscar Imventarza
SSAT	Nat Soper
EAES	Jaap Bonjer

Consensus Work Groups

Work Groups	PICO Questions	Leads	Members
1	1,2,3	Daniel Deziel, Marian McDonald	Maria Altieri, Ben Veenstra, Justin Gerard, Ismael Domiguez-Rosado, MacKenzie Landin
2	4,5	Michael Brunt, Adnan Alseidi, Mike Ujiki	Tim Schaffner, Eugene Ceppa, Sadiq Sikora, Sara Holden, Shanley Deal, Alessandro Paganini, Bailey Su
3	6,7,9	Dana Telem, Taylor Riall	Daniel Hashimoto, Chris Davis, Marie Crandall, Ryan Campagna, Chantal den Bakker, Leonie van Gastel, Charles Lawrence
4	8,11	Steven Strasberg, Saxon Connor, Chet Hammill	Blaire Anderson, Megan Thomas, Scott Dojels, Waala Abdelmoaty
5	10, 12-17	Raj Aggarwal, Carol-Anne Moulton	Phil Pucher, Fernando Santos, Nate Stoikes, Romeo Ignacio, Ryan Campagna, Sara Monafred
6	18	Horacio Asbun, Rowan Parks, Jaap Bonjer	Ewen Harrison, Luigi Boni, Oscar Imventarza, Rohan Jeyarajah, Marc Mesleh, Domenech Asbun, Levan Tsalamaidze, Eline Zwart

Conference Planning:



Expert Voting Panel

Society Representation:

- Americas Hepato-Pancreato-Biliary Association
- European Association of Endoscopic Surgeons
- International HPB Association
- Society for Surgery of the Alimentary Tract
- Society American Gastrointestinal and Endoscopic Surgeons
- American Association for the Surgery of Trauma
- Rural/Community surgeons group
- Endoscopic and Laparoscopic Society of Asia

Experts Panelists

- AHPBA: Chuck Vollmer, Keith Lillemoe, Attila Nakeeb, Wright Pinson, Emily Winslow, Major Kenneth Lee
- SSAT: Nat Soper, Henry Pitt, Jeff Barkun, Mark Callery
- IHPBA: Oscar Imventarza, Miguel Mercado
- SAGES: Steve Schwaitzberg, Ken Murayama, Gary Vitale, Kevin Wasco
- EAES: Andrea Pietrabissa, Abe Fingerhut
- AAST: Jose Diaz, Stephen Barnes
- Rural/Community surgeons: Randy Zuckerman, Patrick Molt, Tyler Hughes
- ELSA: Alfred Buenafe, Davide Lomanto
- At Large: Go Wakabayashi

Acknowledgements

- Dimitrios Stefanidis, MD, PhD– Chair SAGES Guideline Committee
- Stephen Haggerty, MD, Co-Chair, SAGES Guideline Committee

- Mohammed Ansari, MD, MMedSci, MPhil – Research Methodologist, Univ Ottawa

- Valerie Langberg, Sc.M - Biostatistician, Brown University

- Brenda Castaneda – SAGES Staff
- Shelley Ginsburg – SAGES Staff

Conference Grant Support

- National Institutes of Diabetes and Digestive and Kidney Diseases: This conference is supported by an R13 conference grant NIDDK 1 R13 DK 120271-01.
  The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies and of the Department of Health and Human Services; nor does mention by trade names, commercial practices, or organizations imply endorsement by the US government.

- SAGES Education and Research Foundation

We gratefully acknowledge educational grant support for this conference from the following:

- Boston Scientific
- Ethicon, Inc
- Intuitive Surgical
- Karl Storz Endoscopy
- Medtronic
- Stryker Endoscopy

Consensus Schedule:

8:00-9:00 Introductory session

9:00-10:00am PICOs 1-3

10:00-10:15am Break

10:15-12:15 PICOs 4-7, 9

12:10-1:00pm Buffet Lunch

1:00-1:50pm PICOs 8,11

1:50-3:00pm PICOs 10, 12-14, 18

3:00-3:15pm Break

3:15-4:00pm PICOs 15-17

4:00-4:30pm Open Panel Discussion

4:30-4:40pm Closing Remarks

State of the Art Consensus Conference on Prevention of Bile Duct Injury During Cholecystectomy

Saturday, October 20, 2018 - Boston, MA

#PreventBDI

Help Us Share Live Updates from the Conference!

Use this hashtag on your social media sites during the meeting.

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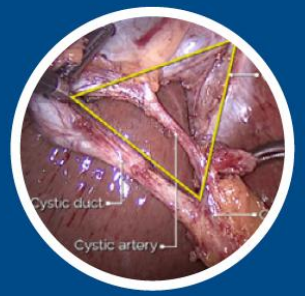

The Safe Cholecystectomy Didactic Modules are live!

Tailored to:

- Enhance safety
- Reduce bile duct injuries
- Lower complication rates

Access the modules at **http://fesdidactic.org**

Brought to you by the SAGES Safe Cholecystectomy Task Force

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Impact of Bile Duct Injury on the Patient and Society

Dana A. Telem MD MPH

Associate Professor of Surgery

Associate Chair for Clinical Affairs

Director, Comprehensive Hernia Program

University of Michigan

Tweet: #PreventBDI

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

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Disclosures

- Agency for Healthcare Research and Quality (AHRQ) KHS025778A
- Medtronic

- *** None relevant to the subject matter of this talk*

Cholecystectomy (LC)

- ~750,000 laparoscopic cholecystectomies/year
- Complications occur in up to 6-7% of patients*
  - Bleeding
  - Abscess
  - Bile leak
  - Bowel/vascular injury
  - Wound complications
  - ***Common bile duct injury (BDI)***
- Impact on health resource utilization – perioperative ER utilization 10%, readmission 5-7%

Murphy et al. JACS 2010;21:73-80

Complications of LC over time

- Trends in complications of LC over time (NIS)
- Data until 2006 – still relevant

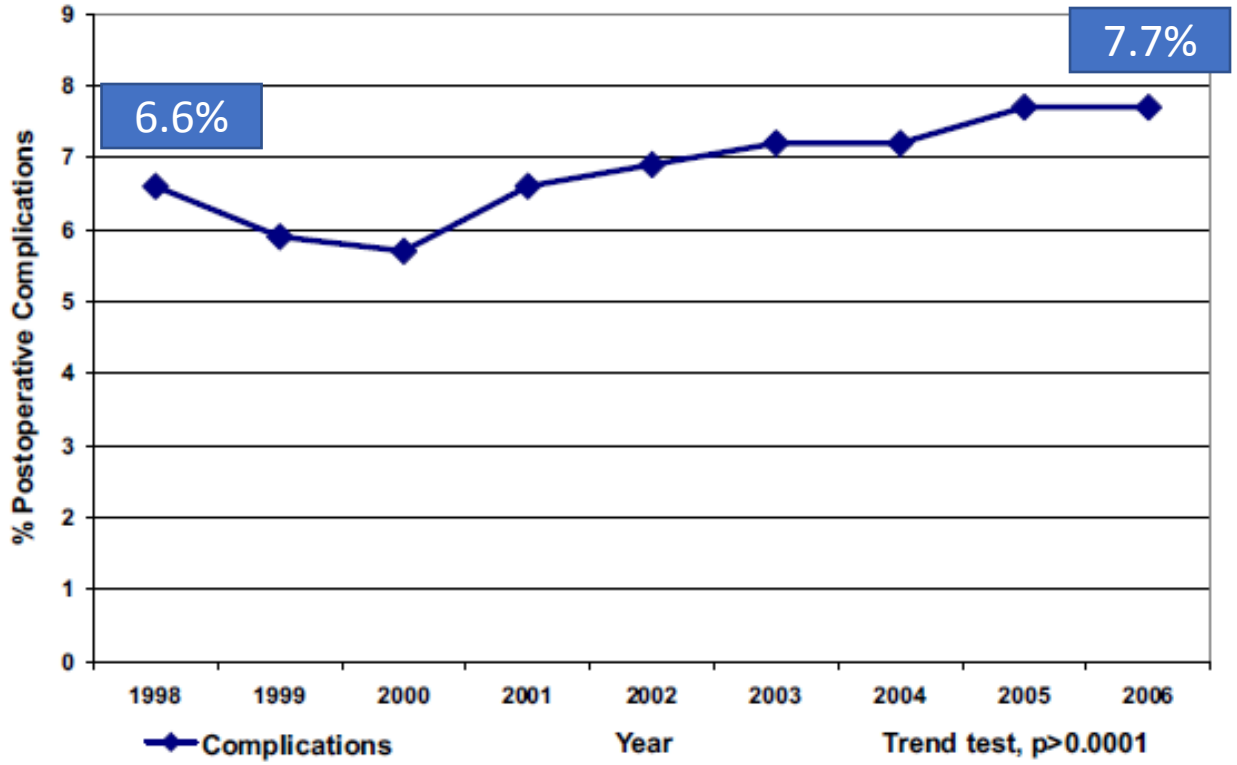


Figure 1. Complications after laparoscopic cholecystectomy over time.

Murphy et al. JACS 2010;21:73-80

BDI

- BDI is the most dreaded complication

- Incidence is variable
  - Depends on whether inclusive of bile leaks
  - Up to 4 per 1000

- Data indicating incidence may be decreasing
  - NY State (2005-2010): Major BDI 0.08%
  - Buenos Aires (1991-2010): Major BDI 0.2%

Surg Endosc. 2016
J Am Coll Surg. 2013;216(5):894-901

BDI: Contemporary Studies

Study	Source	N	Total BDI
Schwaitzberg 2014	Payor admin data	53,632	82 (0.15%)
Tornqvist 2015	Swedish national registry	51,041	747 (1.5%; 0.36% major BDI)
Barrett 2017	Truven database	319,184	741 (0.23%) major BDI
Lilley 2017	Medicare Admin data	472,367	0.3%
Pucher 2018	Systematic review	505,292	0.32-0.52%
Fong 2018	CA State Admin data	711,454	0.22% major BDI 0.50% bile leaks

BDI

- Data derived from GallRiks.
  - Founded in 2005
  - National Swedish Registry for Surgery and ERCP
  - Captures ~90 per cent of all cholecystectomies
  - Aims to provide current information regarding indications, treatment methods and complications.
- 1.5% of patients had BDI (including bile leaks)
- Incidence of major BDI requiring reconstruction was 0.4%

Br J Surg. 2015;102(8):952-8
Arch Surg. 2006;141(12):1207-13.

Distribution of BDI

- Distribution of 747 bile duct injuries among 51,041 cholecystectomies in GallRiks (2005-10)

Type of Injury (n=747)	Hannover Grade	N (%)
Cystic duct leak	A1	265 (35.5)
Peripheral duct injury gallbladder bed	A2	106 (14.2)
Tangential lesion common bile duct	C1, C2, C3	130 (17.4)
Transected bile duct (below hepatic bifurcation)	D1, D2, D3	16 (2.1)
Obstructive injuries	B1, B2	7 (0.9)
Lesions above the hepatic bifurcation	C4, D4	32 (4.3)
Injuries with insufficient information		191 (25.6)

Br J Surg. 2015;102(8):952-8

Self-reported Incidence of BDI

- Survey administered to practicing surgeons across US (2001)
- Anonymous questionnaire mailed to 3,657 who completed an ACGME accredited residency.
- 45% (n=1,661) completed and returned the survey
- 565 self–reported bile duct injuries

**** 34% of surgeons self-reported a BDI ****

Ann Surg. 2001;234(4):549-58.

Societal Impact OF BDI

- Significant economic healthcare burden
  - **ONE BILLION** in associated health care costs
- A key source of medical malpractice claims against surgeons
- BDI malpractice claims represent 20% of money paid to plaintiffs

Surg Endosc 2013;27:1051-1054; HPB. 2009;11(2):130-4

Impact on Patients: Clinical

- Numerous reinterventions/hospitalizations
- Early/late complications
- Mortality (short-term)

Table 5 Reports rates of mortality following CBD injury

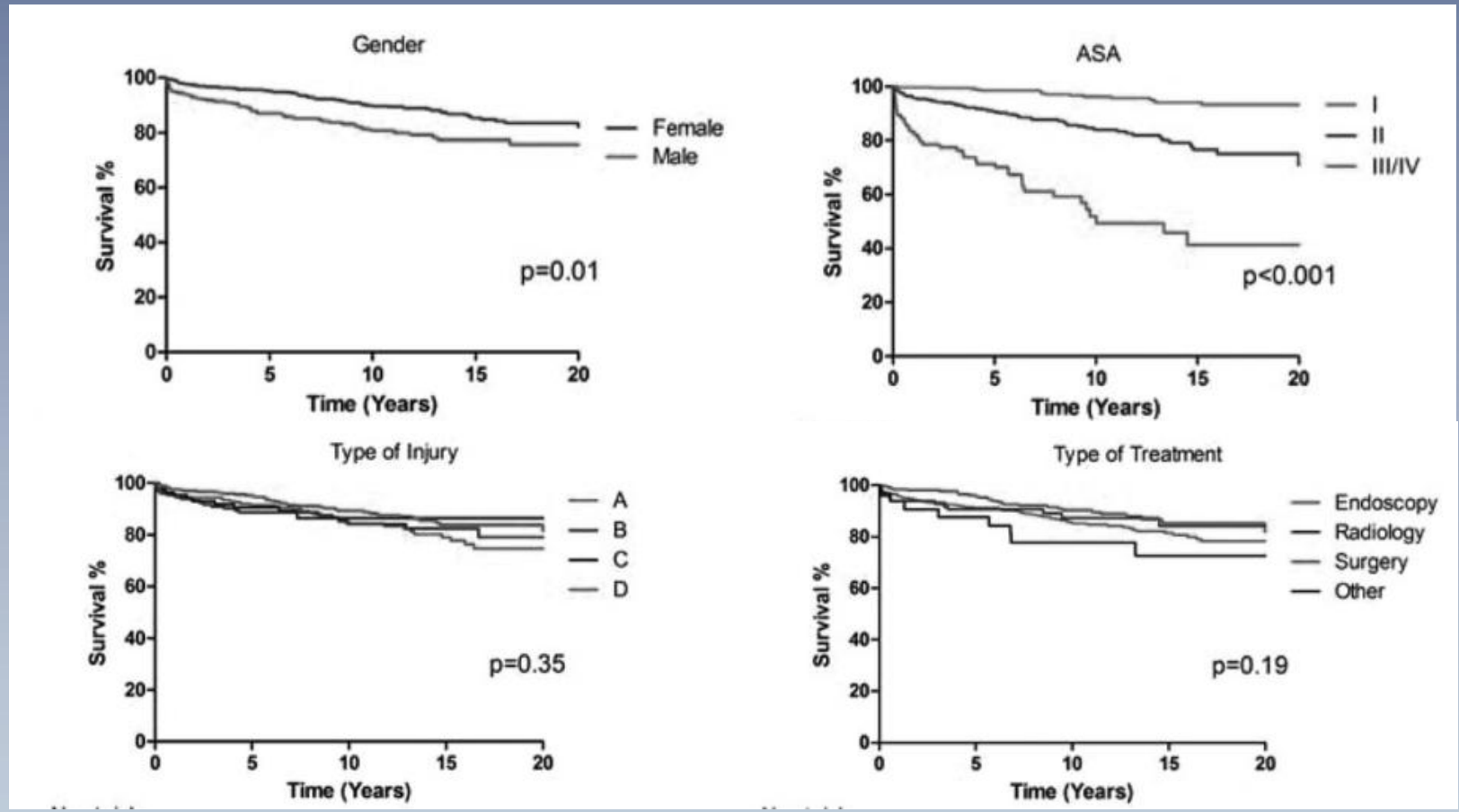
References	Total patients	CBD injury rate	All-cause mortality	Attributable mortality
MacFadyen et al. [4]	114,005	0.50 %	0.06 %	0.03 %
Savassi-Rocha et al. [5]	91,232	0.18 %	4.2 %	–
Pitt et al. [11]	–	–	2.4 %	–
Udekwu and Sullivan [6]	1083	0.10 %	0.80 %	0.20 %

- Mortality (long-term) – 20.8%
  - 8.8% above the cohort's expected age-adjusted rate of death

Surg Endosc. 2016

Long term Mortality

- N=800
- Mean Survival: 17.6 years
- BDI related mortality: 3.5%



Booij K, Ann Surg. 2018

Quality of Life (QOL)

- Evaluation of QOL after surgical repair of major bile duct injuries (n=89).
- Significant difference as evaluated from a **psychological** dimension.
- Physical and social domains comparable to control patients.
- Presence of a lawsuit was associated with a poorer QOL assessment

Ann Surg. 2002 Jun;235(6):888-95

Quality of Life (QOL)

- N=62 BDI
- Statistically similar:
  - Physical functioning
  - Bodily pain
  - General health perceptions
  - Vitality and social functioning
  - Mental health index
- Mean emotional scores were worse

Ann Surg. 2009 Feb;249(2):292-5

Quality of Life (QOL) – Long Term

- Longitudinal QOL study (n=403, response 68%)
- Changes in outcome at a mean of 5.5 and 11 yrs
- At 5-years, QOL significantly worse as compared to chole and non-operative controls
- No improvement at 11 years
- 19% filed a malpractice claim
  - ➢ QOL improved if claim resolved in their favor vs. if claim rejected

Endoscopy. 2008 Aug;40(8):637-43.

Quality of Life (QOL) – Long Term

- Long-term study of 800 BDI pts (compared to 175 controls) in Amsterdam

- Patients with BDI
  - Significantly worse physical QoL
  - Significantly worse disease specific QoL
  - Increased loss of work productivity
  - Increase rate of receiving daily benefits

Booij K, Ann Surg. 2018

Quality of Life (QOL) – Long Term

TABLE 3. Work Related Quality of Life (WLQ) of Patients With BDI Referred to A Tertiary Center (n = 399) and Control Patients Who Underwent An Uncomplicated LC in A Tertiary Center (n = 93)

	BDI patients	Controls	*P*
Work related quality of life (WLQ)	n = 149 median (IQR)	n = 42 median (IQR)	
Time management scale	10.0 (0–25.0)	0 (0–21.3)	0.01
Physical scale	10.0 (0–25.0)	0 (0–19.1)	0.08
Mental-interpersonal scale	12.5 (0–25.0)	8.3 (0–20.1)	0.07
Output scale	15.0 (0–30.0)	2.5 (0–25.0)	0.05
WLQ Productivity Loss Score	4.1 (0.8–7.7)	2.3 (0–5.6)	0.03
Absence from work	n = 391 n (%)	n = 93 n (%)	
Paid work during LC	207 (52.9)	67 (72.0)	0.004
Decreased working after LC	106 (27.7)	6 (6.6)	0.000
Currently receiving disability benefits	135 (34.9)	18 (19.6)	0.004
Health and Labor Questionnaire	n = 399	n = 94	
Hindrance domestic work	161 (41.7%)	24 (26.1%)	0.01
Hindrance buying grocery	159 (41.1%)	24 (26.1%)	0.01
Hindrance routine tasks	151 (38.9%)	26 (28.3%)	0.07
Hindrance activities with children	n = 161 49 (30.4%)	n = 43 12 (27.9%)	0.85

HLQ indicates Health and Labor Questionnaire; LC, laparoscopic cholecystectomy; WLQ, Work Limitation Questionnaire.

Booij K, Ann Surg. 2018

Patient Accounts

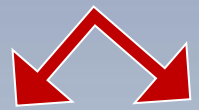
susanp

I went in for a lap-gallbladder removal in October 2003, was toldi could go home that day after the surgery i was put in a room, very sick, the doctor told my husband, that he had nicked the bile duct, they kept me on pain meds and fluids, i kept getting worse, also on moriphine for pain,on the 8th day in the hospital my husband confronted the doctor and told him he had better do something or else, he sent me to another hospital, upon arrival, after an x-ray,i was put into icu, they could not do any surgery, because i was so swollen, all they could do was put drainage tubes (4)in my abdomen to drain the bile. (I was 136lbs when i went into the er the first time) on this 8th day i weighed 198, and had not had a bite to eat. I stayed in this hospital for 30 days untili was stable enough to go home, and was told i would have to have more surgery to repair what the first doctor did, which by the way was not a nick, my bile duct was cut completely in half. 4 months later i had the surgery after becoming very sick, and almost scratched my skin off, brome the bile in my blood. To this day i still have good days and bad, and it all ended up costing us 300,000.00 in medical bills, with no insurance we lost our home and 10 acres of land. Yes I have a law suit,it's been building going on 7 years, just heard the other day we will have our day in court Sept. 2010

http://www.curezone.org/forums/am.asp?i=1501569

Take Home

- Major BDI injury rate still in 0.4% range
- Translates to 3000 injuries/year in US
- >$1 billion in associated costs



½ medicolegal ½ patient care

- Key contributor to healthcare costs and adverse patient and surgeon outcomes

Thank you!

Questions?

@DanaTelem

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Introduction to The PICO Questions

Steven M. Strasberg, M.D.
Section of Hepatobiliary and Pancreatic Surgery

Washington University in St. Louis
School of Medicine

3 Topics in 10 Minutes

1. Definition: Major/Minor Bile duct Injury
2. Incidence of BDI and Effect on Studies of BDI
3. The PICO Questions

HPB 2018, 20: 370–378

ORIGINAL ARTICLE

Proposed standards for reporting outcomes of treating biliary injuries

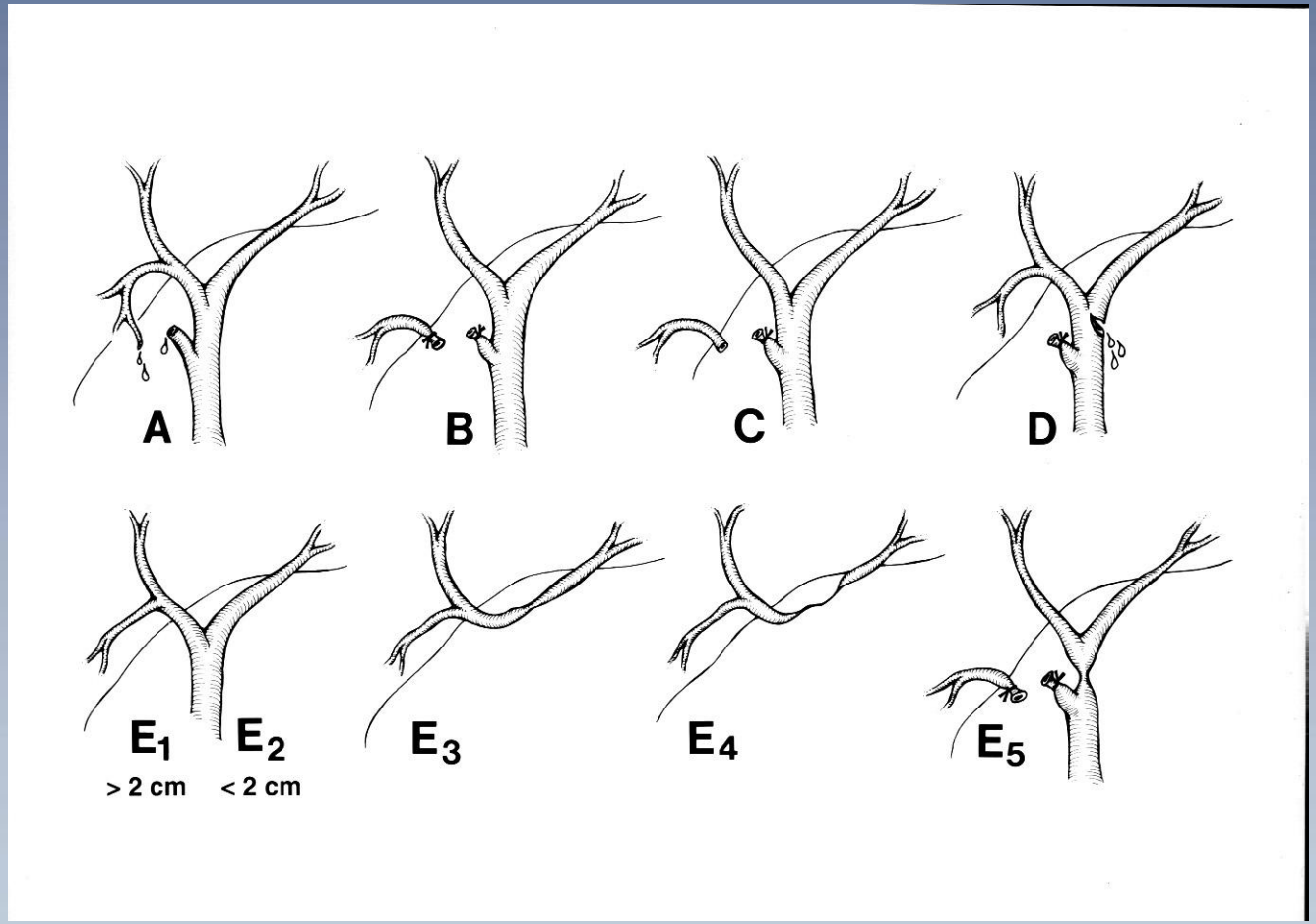
Jai Young Cho[1], Todd H. Baron[2], David L. Carr-Locke[3], William C. Chapman[4], Guido Costamagna[5], Eduardo de Santibanes[6], Ismael Dominguez Rosado[7], O. James Garden[8], Dirk Gouma[9], Keith D. Lillemoe[10], Miguel Angel Mercado[7], Daniel K. Mullady[11], Robert Padbury[12], Daniel Picus[13], Henry A. Pitt[14], Stuart Sherman[15], Richard Shlansky-Goldberg[16], Bjorn Tornqvist[17] & Steven M. Strasberg[18]

Surgery
- Cho
- Chapman
- deSantibanes
- Domingues
- Garden
- Gouma
- Lillemoe
- Mercado
- Padbury
- Pitt
- Tornqvist
- Strasberg

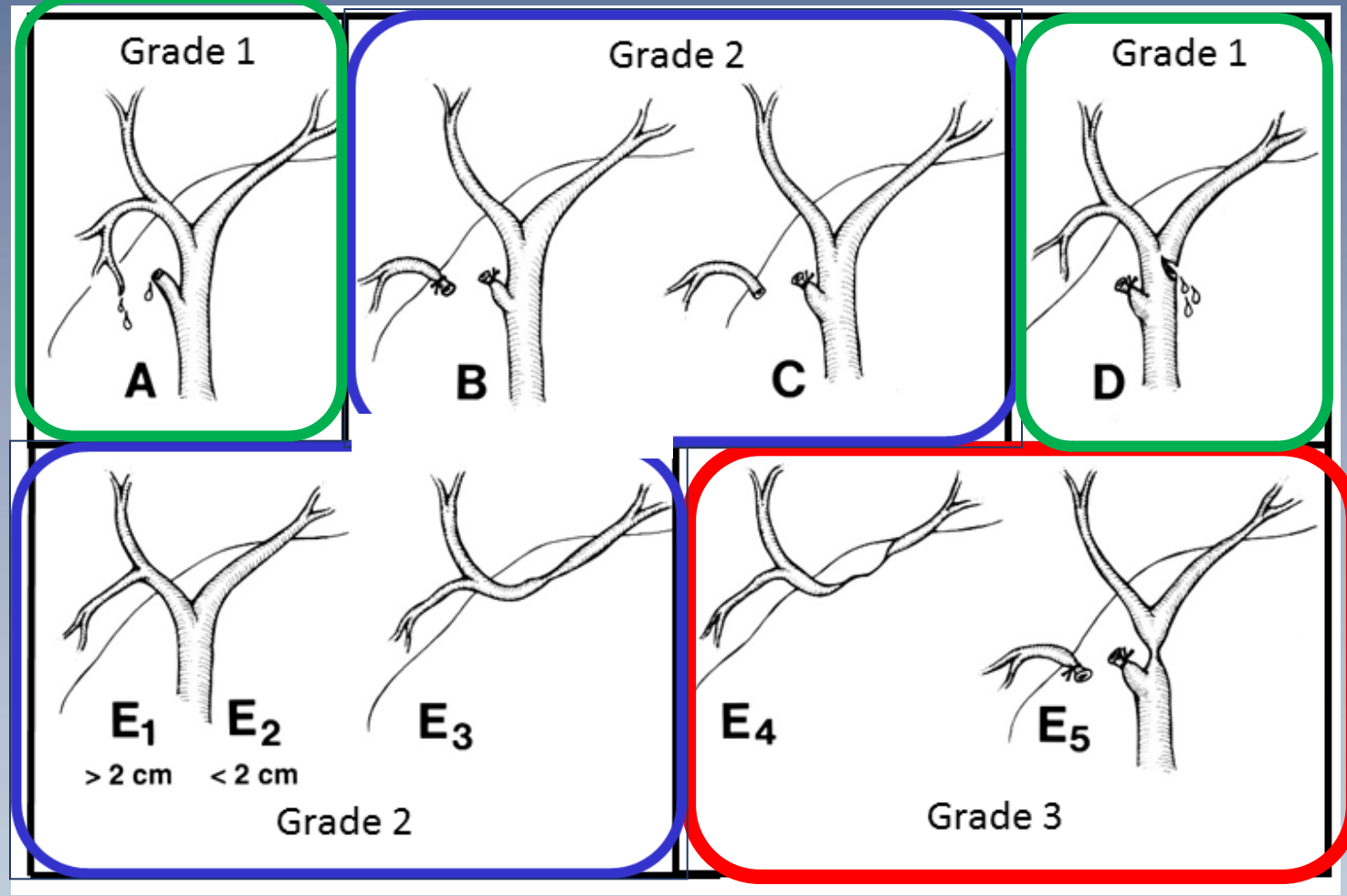
Biliary Endoscopy
- Baron
- Carr-Locke
- Costamagna
- Mullady
- Sherman

Interventional Radiology
- Picus
- Schlansky- Goldberg

Washington University Classification of Biliary Injuries



International Severity Grading of Biliary Injury



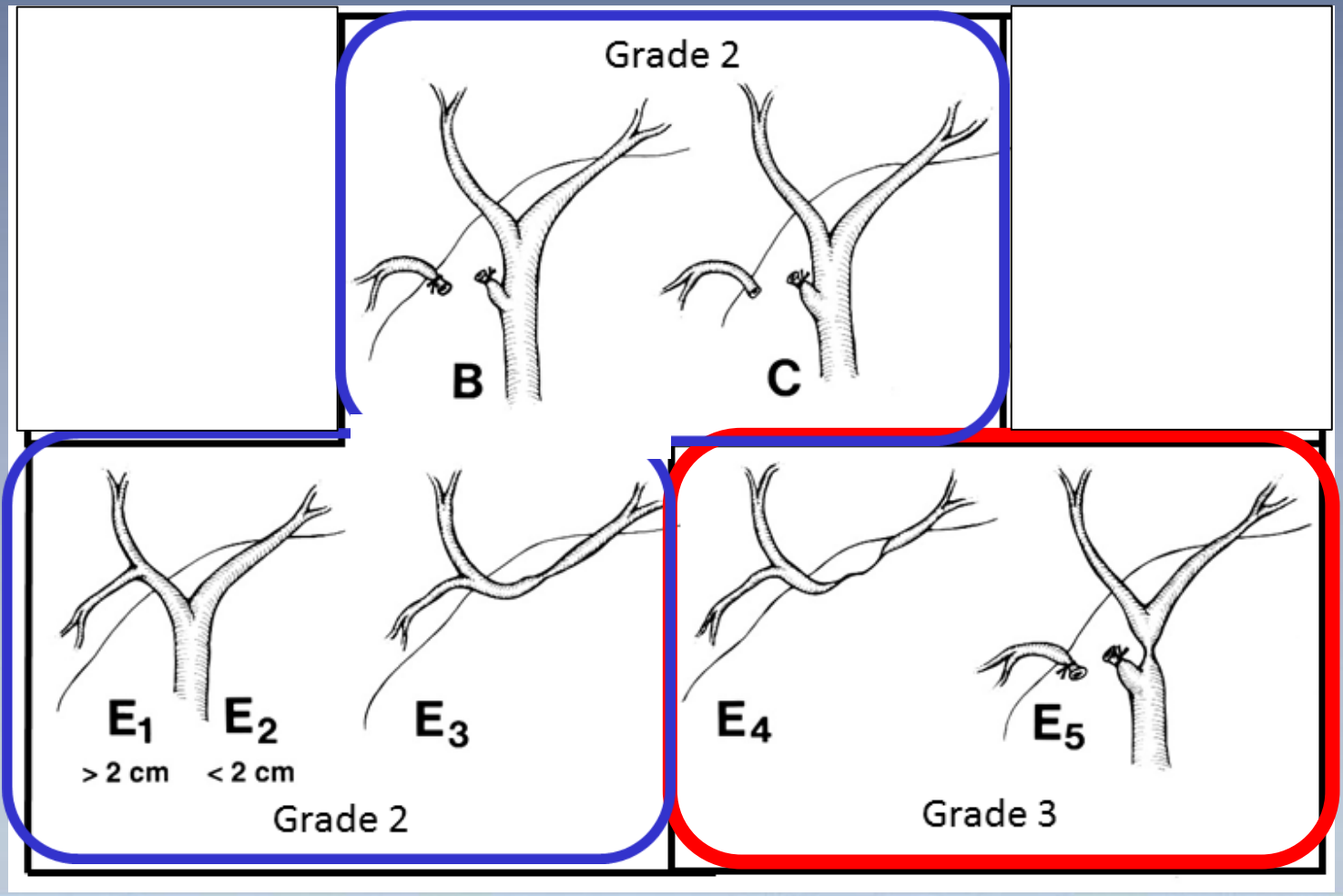
Grade 1: Stent or Suture

Grade 2: One duct for anastomosis or stenting

Grade 3: More than one duct for anastomosis or stenting

International Severity Grading of Biliary Injury

Major Bile Duct Injuries



Grade 2: One duct for anastomosis or stenting

Grade 3: More than one duct for anastomosis or stenting

MAJOR = Grade 2 and Grade 3

Incidence of BDI and Studies of BDI

- Major BDI in open era **1 in 1000**
- Major BDI in lap era **3 in 1000**
- 1 million LC /yr = 3000 major BDIs in the USA
- Major BDIs have aspects of **rare and common** problems,
- To have sufficient events for studies thousands of patients are needed.
- Drawing conclusions from fewer patients may give an illusion of safety "500 LCs with only 1 BDI"
- Probably need at least 5000-10,000 in comparative study
- Studies of BDIs themselves are probably rewarding

  20 BDIs happen in 6000 patients

Types of Studies on BDI

1. Observational studies of patients <u>with bile duct injuries</u>	10-500 patients. Small number of patients but large number of events
2. Single or Multicenter Studies of Laparoscopic Cholecystectomy including RCTs and MAs	100-2000 patients. Larger number of patients but relatively few events
3. Population Studies of Laparoscopic Cholecystectomies	3000-50,000+ patients. Largest number of patients with large number of events

Theoretical Study of BDI in Open vs Lap Chole with 2000 Patients

- **Open Chole**
- **1000 patients**

- **Lap Chole**
- **1000 patients**

Theoretical Study of Open vs Lap Chole with 2000 Patients

- Open Chole
- 1000 patients

- Projected BDI rate 0.1%

- Events?

- Lap Chole
- 1000 patients

- Projected BDI rate 0.3%

- Events?

Theoretical Study of Open vs Lap Chole with 2000 Patients

- Open Chole
- 1000 patients

- Projected BDI rate 0.1%

- Events = 1

- Lap Chole
- 1000 patients

- Projected BDI rate 0.3%

- Events = 3

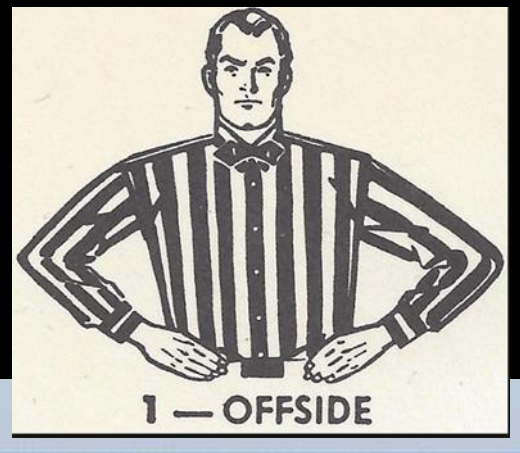
Theoretical Study of Open vs Lap Chole with 2000 Patients

- Open Chole
- 1000 patients

- Lap Chole
- 1000 patients

4 events in 2000 patients.
Too few BDIs to draw conclusions

Underpowered fault



Types of Studies on BDI

1. **Observational studies of patients with bile duct injuries** ✓ **10-500 patients. Small number of patients but large number of events**

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2. **Single or Multicenter Studies of Laparoscopic Cholecystectomy including RCTs and MAs** X **100-2000 patients. Larger number of patients but relatively few events**

---

3. **Population Studies of Laparoscopic Cholecystectomies** ✓ **3000-50,000+ patients. Largest number of patients with large number of events**

The Questions

Prevention of Bile Duct Injury Consensus Conference

Questions Draft

October 30, 2016

The SAGES Prevention of Bile Duct Injury Consensus Conference work group has identified the following 10 questions that should be considered for the consensus conference

1.What is the incidence of bile duct injury (BDI) during cholecystectomy and how should these injuries be classified?
What is the incidence of major BDI?
What are the types of BDI (nature and classification)?

2.What is the impact of bile duct injuries on patient outcomes and associated health care costs?
What is the effect of BDI on the quality of life and longevity of the patient?
What are the costs to the health care system associated with BDI?
What are the medical-legal implications of BDI and what are the primary factors that impact outcomes of litigation?

Mother elephant delivering a baby elephant - Period of gestation twenty-two months

Prevention of Bile Duct Injury Consensus Conference

- Decision to concentrate on Guideline Development
- Use of GRADE method of guideline development

McMaster University
Inspiring Innovation and Discovery

Formulate question

Select outcomes

Rate importance

P
I
C
O

Outcome Critical
Outcome Critical
Outcome Important
Outcome Not important

Outcomes across studies

Create evidence profile with GRADEpro

Summary of findings & estimate of effect for each outcome

Rate quality of evidence for each outcome

RCT start high, obs. data start low

High
Moderate
Low
Very low

Grade down
1. Risk of bias
2. Inconsistency
3. Indirectness
4. Imprecision
5. Publication bias

Grade up
1. Large effect
2. Dose response
3. Confounders

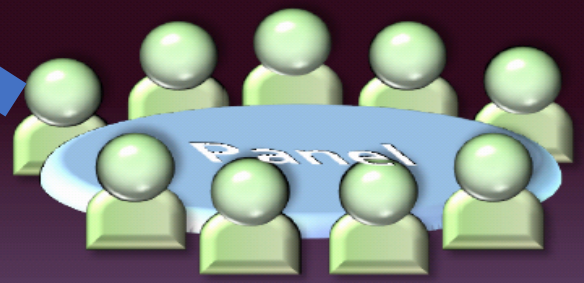
Systematic review

Guideline development

Formulate recommendations:
- For or against (direction)
- Strong or weak (strength)

By considering:
- ❑ Quality of evidence
- ❑ Balance benefits/harms
- ❑ Values and preferences

Revise if necessary by considering:
- ❑ Resource use (cost)



Rate
overall quality of evidence
across outcomes based on lowest quality of *critical* outcomes

- "We recommend using…"
- "We suggest using…"
- "We recommend against using…"
- "We suggest against using…"

McMaster University
Inspiring Innovation and Discovery

Formulate question

Select outcomes

Rate importance

Outcomes across studies

Create evidence profile with GRADEpro

Rate quality of evidence for each outcome

P
I
C
O

Outcome Critical

Outcome Critical

Outcome Important

Outcome Not important

Summary of findings & estimate of effect for each outcome

High
Moderate
Low
Very low

RCT start high, obs. data start low

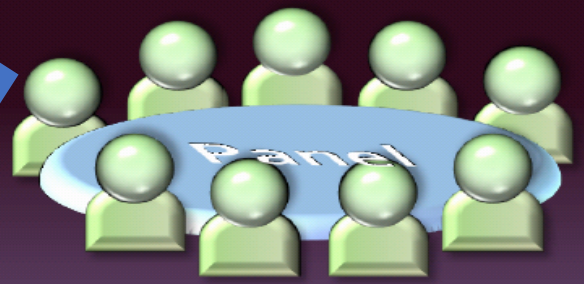
Grade down
1. Risk of bias
2. Inconsistency
3. Indirectness
4. Imprecision
5. Publication bias

Grade up
1. Large effect
2. Dose response
3. Confounders

Systematic review

Guideline development

Rate
overall quality of evidence
across outcomes based on
lowest quality
of ***critical*** outcomes



Formulate recommendations:
- For or against (direction)
- Strong or weak (strength)

By considering:
- ❑ Quality of evidence
- ❑ Balance benefits/harms
- ❑ Values and preferences

Revise if necessary by considering:
- ❑ Resource use (cost)

- "We recommend using…"
- "We suggest using…"
- "We recommend against using…"
- "We suggest against using…"

PICO Format Questions

PICO formatting frames the question

- P=population
- I=intervention
- C=comparator
- O=outcome(s)

GRADE Guideline question template: Should **X** versus **Y** be used for/in [health problem or population]

PICO Question 8

Should **immediate cholecystectomy (WITHIN 72 HOURS From SYMPTOM ONSET)** versus **cholecystectomy delayed beyond 72 hours (BUT < 10 days AFTER SYMPTOM ONSET)** versus **cholecystectomy delayed beyond 6 weeks** versus **cholecystectomy delayed beyond 12 weeks** be used for patients with acute cholecystitis?

P I C O 8

In patients with acute cholecystitis how effective is early cholecystectomy versus delayed cholecystectomy in limiting the risk and severity of bile duct injury?

Condensed PICO Question List: State of the Art Consensus Conference on Prevention of Bile Duct Injury*

1. Should one anatomic technique (CVS) vs another (infundibular, top down, IOC) be used to reduce or limit risk of BDI during cholecystectomy (CCX)?
2. Should the top down technique vs subtotal cholecystectomy be used when the CVS cannot be achieved?
3. How should the CVS be documented during laparoscopic cholecystectomy (still doublet photos vs operative notes vs video vs no documentation)?
4. Should intraoperative biliary imaging (e.g. intraoperative cholangiography, US) vs no intraoperative biliary imaging be used for limiting the risk of bile duct injury during laparoscopic cholecystectomy?
5. Should near infrared vs IOC or white light be used in avoiding /limiting BDI?
6. Should surgical (complexity) risk stratification vs alternative or no risk stratification be used for limiting/preventing BDI?
7. Should risk stratification that accounts for cholecystolithiasis vs no/alternate risk stratification be used for limiting/preventing BDI?
8. Should immediate cholecystectomy (within 72 hrs from symptom onset) vs CCX delayed beyond 72 hours (< 6 weeks vs >6-12 weeks) be used for acute cholecystitis?
9. Should subtotal CCX vs total laparoscopic or open CCX be used for limiting/avoiding BDI in marked acute inflammation or chronic biliary inflammatory fusion (BIF)?
10. Should 4-port lap cholecystectomy vs reduced port/single incision vs robotic CCX be used for limiting/avoiding BDI?
11. Should interval/delayed lap chole vs no additional treatment be used for patients previously treated by percutaneous cholecystostomy?
12. Should conversion of laparoscopic to open cholecystectomy vs no conversion be used for limiting/avoiding BDI in the difficult laparoscopic cholecystectomy?
13. Should a time out to verify the CVS vs no time out be used for limiting/avoiding BDI?
14. Should two vs one surgeon(s) be used for limiting/avoiding BDI?
15. Should CVS coaching of surgeon vs no coaching be used for limiting/avoiding BDI?
16. Should training by simulation or video-based education vs alternative surgeon training be used for limiting/avoiding BDI?
17. Should more vs less surgeon experience be used for limiting/avoiding the risk of BDI?
18. Should immediate reconstruction by the operating surgeon vs referral to a specialty center be used for patients with BDI during cholecystectomy?

18 PICO Questions: Focussed Mainly on Prevention of Bile Duct Injury

- PICO 1-5: Anatomic identification in CCX
- PICO 6-8: Role of disease and patient factors
- PICO 9-12: Place of surgical techniques other than laparoscopic total cholecystectomy
- PICO 13-17: Role of the surgeon and education of the surgeon
- PICO 18: Management of bile duct injury

18 PICO Questions Focussed Mainly on Prevention of Bile Duct Injury

- It was expected that much data would be available for some question while little data would be available for others.

- Therefore some data rich questions will result in recommendations coming directly from the GRADE review (when to operate in AC) while other data poor ones will act as stimuli and pathways for studies which experts consider most important for future development the field of biliary injury prevention (does coaching/simulation reduce BDI)

Recommendations PICO 8: Can be Type A or B

- Type A recommendations flow from the data in the GRADE process. Currently available evidence supports the recommendations.

- Type B recommendations flow from recognition of deficiencies in our knowledge which were also identified during the GRADE review and these recommendations relate to studies to be done or study methodology in the future.

The PICO Questions

Steven M. Strasberg, M.D.
Section of Hepatobiliary and Pancreatic Surgery

Washington University in St. Louis
School of Medicine

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Formulating and Answering a Guideline Question

Mohammed T. Ansari (MD, MMedSc, MPhil)
Consultant Guideline Methodologist
Adjunct Professor, University of Ottawa
Scientific Evaluator, Health Canada

Disclosure of Conflicts of Interest

- Financial – none
- Intellectual – none

The GRADE Approach

- GRADE: The Grading of Recommendations Assessment, Development and Evaluation
- Methods approach developed collaboratively by many international organizations
- Adopted by more than 100 organizations (e.g. the World Health Organization, the UK National Institute for Health and Care Excellence, etc)
- Now considered the standard in guideline development

Guideline Question

- A Guideline question addresses variability and uncertainty in clinical practice
- The question may be about etiology, therapy, diagnosis, or prognosis
- Guideline questions are phrased in a language that reflects the relevant decision-making equipoise
- The usual presentation of the Q is:

*Should **option A** vs. **option B** be used for a condition, a state of health, health purpose, or population*

Question Specific PICO

- Population, intervention, comparator and outcome(s)
- Potential challenges:
  - how broadly the patients and intervention should be defined (mild or severe disease, low or higher dose, class effect or specific drugs?)
  - multiple comparators (no treatment, alternative therapy or therapies)
  - specification of patient-oriented outcomes (usually: morbid and mortal events, hospitalization, QOL, disability, inconvenience, resource use, and unintended harms)

Outcome Prioritization

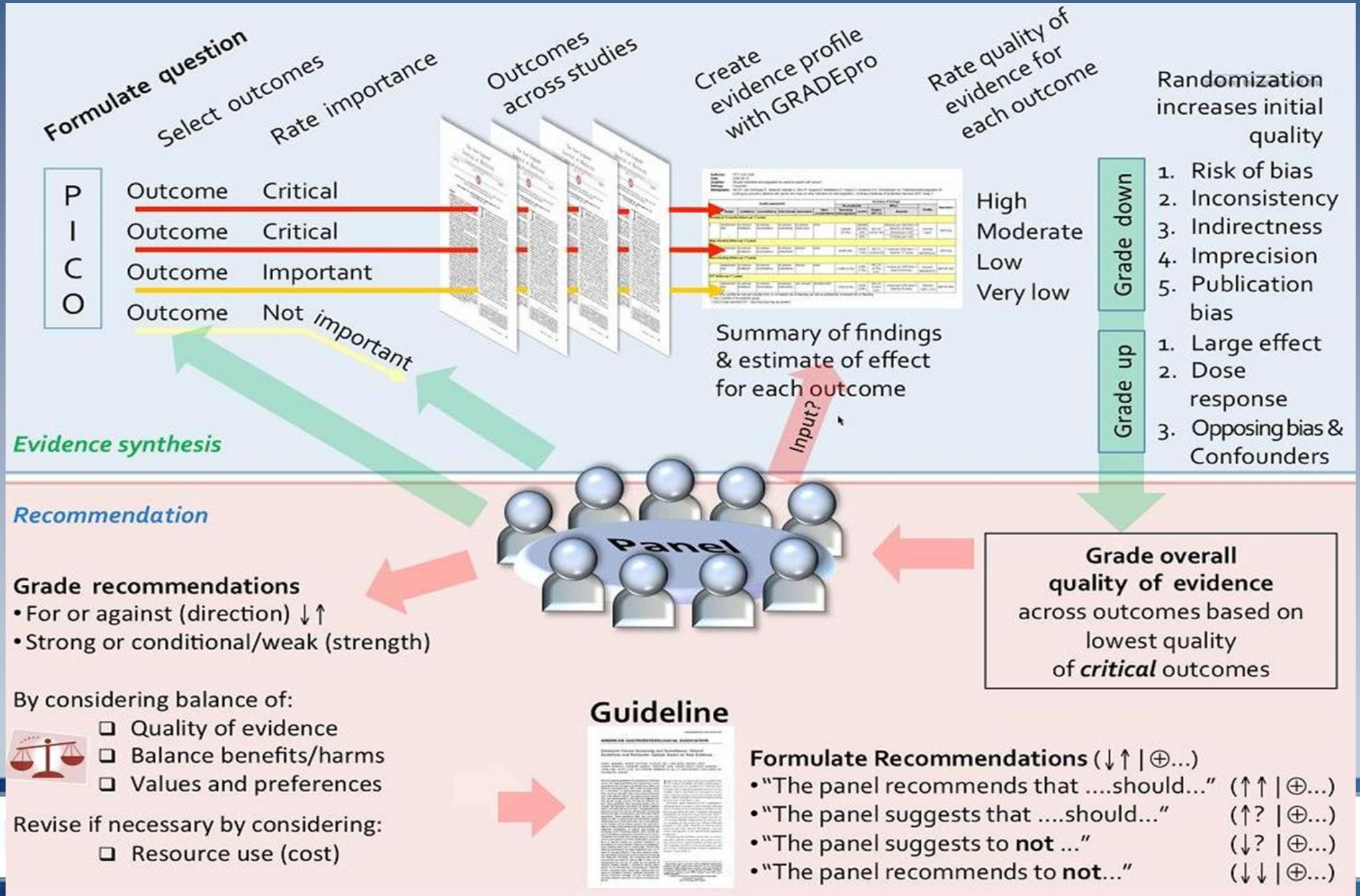
- Categories: **critical**, **important**, and limited importance on a 1-9 scale
- Importance varies by perspective – for CPGs, the perspective would generally be that of the patient
- Evidence of patient values and preferences and associated variability should be sought
- 3 Steps – preliminary classification, reassessment in light of evidence, and judging the balance between the desirable and undesirable effects

Outcome Proxies (contingency!)

- Surrogate outcome must be in the causal pathway of the disease process.
- Surrogate end point must capture the net effect of the treatment on the patient-important outcome.
- Examples – narcotic consumption for postop pain, Hb for blood loss, CVS for BDI…..

Example Q: *Should fewer than four ports vs. four ports be used for laparoscopic cholecystectomy?*

- **Population** – patients undergoing laparoscopic cholecystectomy (elective or emergency) for any reason
- **Intervention** – Single-port, single-incision LCCX
- **Comparator** – Standard four-port LCCX
- **Outcomes** – BDI, readmission, total analgesic consumption, total serious or major complications, duration of surgery, and failure to complete cholecystectomy
- Proxy outcomes: CVS, conversion, intraoperative blood loss


Formulate question
Select outcomes
Rate importance
Outcomes across studies
Create evidence profile with GRADEpro
Rate quality of evidence for each outcome
Randomization increases initial quality
P
I
C
O
Outcome Critical
Outcome Critical
Outcome Important
Outcome Not important
High
Moderate
Low
Very low
Grade down
1. Risk of bias
2. Inconsistency
3. Indirectness
4. Imprecision
5. Publication bias
Grade up
1. Large effect
2. Dose response
3. Opposing bias & Confounders
Summary of findings & estimate of effect for each outcome
Input?
Evidence synthesis
Recommendation
Panel
Grade overall quality of evidence across outcomes based on lowest quality of critical outcomes
Grade recommendations
• For or against (direction) ↓↑
• Strong or conditional/weak (strength)
By considering balance of:
❑ Quality of evidence
❑ Balance benefits/harms
❑ Values and preferences
Revise if necessary by considering:
❑ Resource use (cost)
Guideline
Formulate Recommendations (↓↑ | ⊕...)
• "The panel recommends that ....should..." (↑↑ | ⊕...)
• "The panel suggests that ....should..." (↑? | ⊕...)
• "The panel suggests to not ..." (↓? | ⊕...)
• "The panel recommends to not..." (↓↓ | ⊕...)

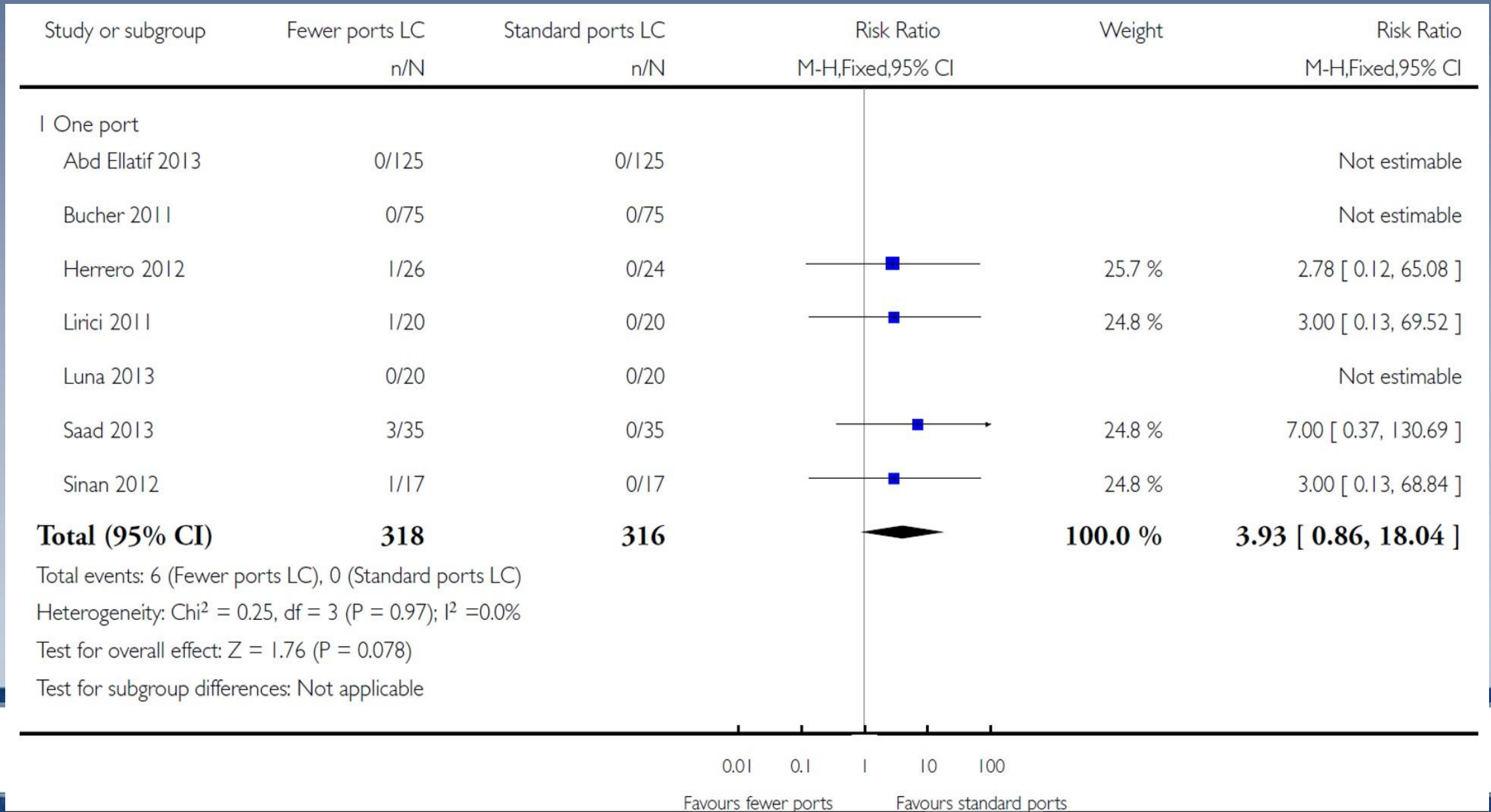
Introduction to GRADE Approach for Rating Certainty of Evidence

Grading Certainty of Evidence

Definition of CoE: *the extent of our confidence that the estimates of the effect are correct or are adequate to support a particular decision or recommendation*

- Outcome specific
- Applies to the *Body* of contributing evidence (a meta-analysis or a narrative synthesis)
- Rated as High, moderate, low or very low

Fewer-than-four ports versus four ports for laparoscopic cholecystectomy: serious adverse events, CDSR 2014



Example of an Evidence Profile (< 4 ports vs. 4 ports for Lap Chole)

Certainty assessment							№ of patients		Effect		Certainty
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	fewer than four ports	four ports	Relative (95% CI)	Absolute (95% CI)	
SERIOUS ADVERSE EVENTS											
7	randomised trials	very serious	not serious	not serious	very serious	none	6/318 (1.9%)	0.0%	**RR 3.93** (0.86 to 18.04)	**1 more per 1,000** (from 0 fewer to 5 more)	⊕◯◯◯ VERY LOW
CONVERSION TO OPEN CHOLECYSTECTOMY											
5	randomised trials	very serious	not serious	not serious	very serious	none	3/289 (1.0%)	5/292 (1.7%)	**RR 0.68** (0.19 to 2.35)	**5 fewer per 1,000** (from 14 fewer to 23 more)	⊕◯◯◯ VERY LOW

Quality of Evidence Domains

G. Guyatt et al. / Journal of Clinical Epidemiology 64 (2011) 383–394

Study Design	Quality of Evidence	Lower if	Higher if
Randomized trial →	High	Risk of bias -1 Serious -2 Very serious	Large effect +1 Large +2 Very large
	Moderate	Inconsistency -1 Serious -2 Very serious	Dose response +1 Evidence of a gradient
Observational study →	Low	Indirectness -1 Serious -2 Very serious	All plausible confounding +1 Would reduce a demonstrated effect or
	Very low	Imprecision -1 Serious -2 Very serious	+1 Would suggest a spurious effect when results show no effect
		Publication bias -1 Likely -2 Very likely	

THANK YOU!

…….Questions?

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SAGES Guideline Development Process

Dimitrios Stefanidis, MD, PhD
Chair, SAGES guidelines committee
Vice Chair of Education
Chief, MIS/ Bariatric Surgery
Indiana University School of Medicine

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Disclosures

- **Nothing to disclose**

Evidence-based Medicine (EBM)

Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients

Guidelines

- Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances

Institute of Medicine

- Guidelines provide the framework of EBM
- Clinicians, policy makers, and payers see guidelines as a tool for making care more consistent and efficient and for closing the gap between what clinicians do and what scientific evidence support

Why are Guidelines Needed?

- **Rising healthcare costs** fueled by increased demand for care, more expensive technologies, and an ageing population
- **Variations in service delivery** among providers, hospitals, and geographical regions and the presumption that at least some of this variation stems from inappropriate care, either overuse or underuse of services
- The intrinsic desire of healthcare professionals **to offer**, and of patients to receive, **the best care possible**

Results of Non-Adherence to EBM: Quality Gaps

Preventive care deficiencies
- **Child immunizations 76%**
- **Influenza vaccine 52%**
- **Pap smear 82%**

Acute care deficiencies
- **Antibiotic misuse 30-70%**
- **Prenatal care 74%**

Health Services…
Safe
Effective
Patient-centered
Timely
Efficient
Equitable

Surgery care deficiencies
- **Inappropriate hysterectomy 16%**
- **Inappropriate CABG surgeries 14%**

Chronic care deficiencies
- **Beta blockers 50%**
- **Diabetes eye exam 53%**

Hospital care deficiencies
- **Proper CHF care 50%**
- **Preventable deaths 14%**
- **Preventable ADEs 1.8/100 admits**
  - **Life threatening 20%**
  - **Serious 43%**

Benefits of Guidelines

Patients

- Improve health outcomes
- Improve the consistency of care
- Inform patients about what their clinicians should be doing
- Empower patients to make more informed healthcare choices and to consider their personal needs and preferences in selecting the best option
- Can help patients by influencing public policy

Physicians

- Improve the quality of clinical decisions
  - call attention to ineffective, dangerous, and wasteful practices
- Support quality improvement activities
  - Development of standing orders, care pathways, algorithms, etc
- Identify gaps in the evidence and research needed
- May offer medicolegal protection
- Prompt government or private payers to provide coverage or to reimburse doctors for services

Potential Limitations & Harms

Patients

- Flawed guidelines can result in suboptimal, ineffective, or harmful practices
- Inflexible guidelines can harm by leaving insufficient room for clinicians to tailor care to patients needs
- Imprudent recommendations for costly interventions may displace limited resources that are needed for other services of greater value to patients

Physicians

- Flawed guidelines harm practitioners by providing inaccurate scientific information and clinical advice, thereby compromising the quality of care
- A negative (or neutral) recommendation may prompt providers to withdraw availability or coverage
- Auditors and managers may unfairly judge the quality of care based on criteria from invalid guidelines
- Citable evidence for malpractice litigation

SAGES Guidelines Development Process

1. Working groups determined by steering committee
2. Definition of Key Questions (PICO methodology)
3. Systematic Literature Search
4. Abstract Review
5. Full Paper Review
6. Data Extraction and Analysis
7. Guidelines Panel Recommendation Formulation & Voting
8. Consensus Conference with Expert Voting (validation)
9. Public comment period and Publication

Work Groups	PICO Questions	Leads	Members
1	1,2,3	Daniel Deziel, Marian McDonald	Maria Altieri, Ben Veenstra, Justin Gerard, Ismael Domiguez-Rosado, MacKenzie Landin
2	4,5	Michael Brunt, Adnan Alseidi, Mike Ujiki	Tim Schaffner, Eugene Ceppa, Sadiq Sikora, Sara Holden, Shanley Deal, Alessandro Paganini, Bailey Su
3	6,7,9	Dana Telem, Taylor Riall	Daniel Hashimoto, Chris Davis, Marie Crandall, Ryan Campagna, Chantal den Bakker, Leonie van Gastel, Charles Lawrence
4	8,11	Steven Strasberg, Saxon Connor, Chet Hammill	Blaire Anderson, Megan Thomas, Scott Dojels, Waala Abdelmoaty
5	10, 12-17	Raj Aggarwal, Carol-Anne Moulton	Phil Pucher, Fernando Santos, Nate Stoikes, Romeo Ignacio, Ryan Campagna, Sara Monafred
6	18	Horacio Asbun, Rowan Parks, Jaap Bonjer	Ewen Harrison, Luigi Boni, Oscar Imventarza, Rohan Jeyarajah, Marc Mesleh, Domenech Asbun, Levan Tsalamaidze, Eline Zwart

Literature Search

	Concept A	Concept B	Concept C
MESH terms	Cholecystectomy OR cholecystectomy, laparoscopic AND robotics OR robotic surgical procedures AND bile ducts or common bile duct OR bile ducts, extrahepatic OR bile ducts, intrahepatic	Cholecystectomy OR cholecystectomy, laparoscopic AND robotics OR robotic surgical procedures AND bile ducts or common bile duct OR bile ducts, extrahepatic OR bile ducts, intrahepatic	Cholecystectomy OR cholecystectomy, laparoscopic AND robotics OR robotic surgical procedures AND bile ducts or common bile duct OR bile ducts, extrahepatic OR bile ducts, intrahepatic
Textwords	infundibular technique AND bile duct injury	Top-down technique AND bile duct injury	Critical view of safety AND bile duct injury///// cholangiogram AND bile duct injury

Concept	A	B	C
MESH terms	MT1 MT2	MT3	MT4 MT5
Textwords	TW1 TW2*	TW3 TW4	TX5 TX6

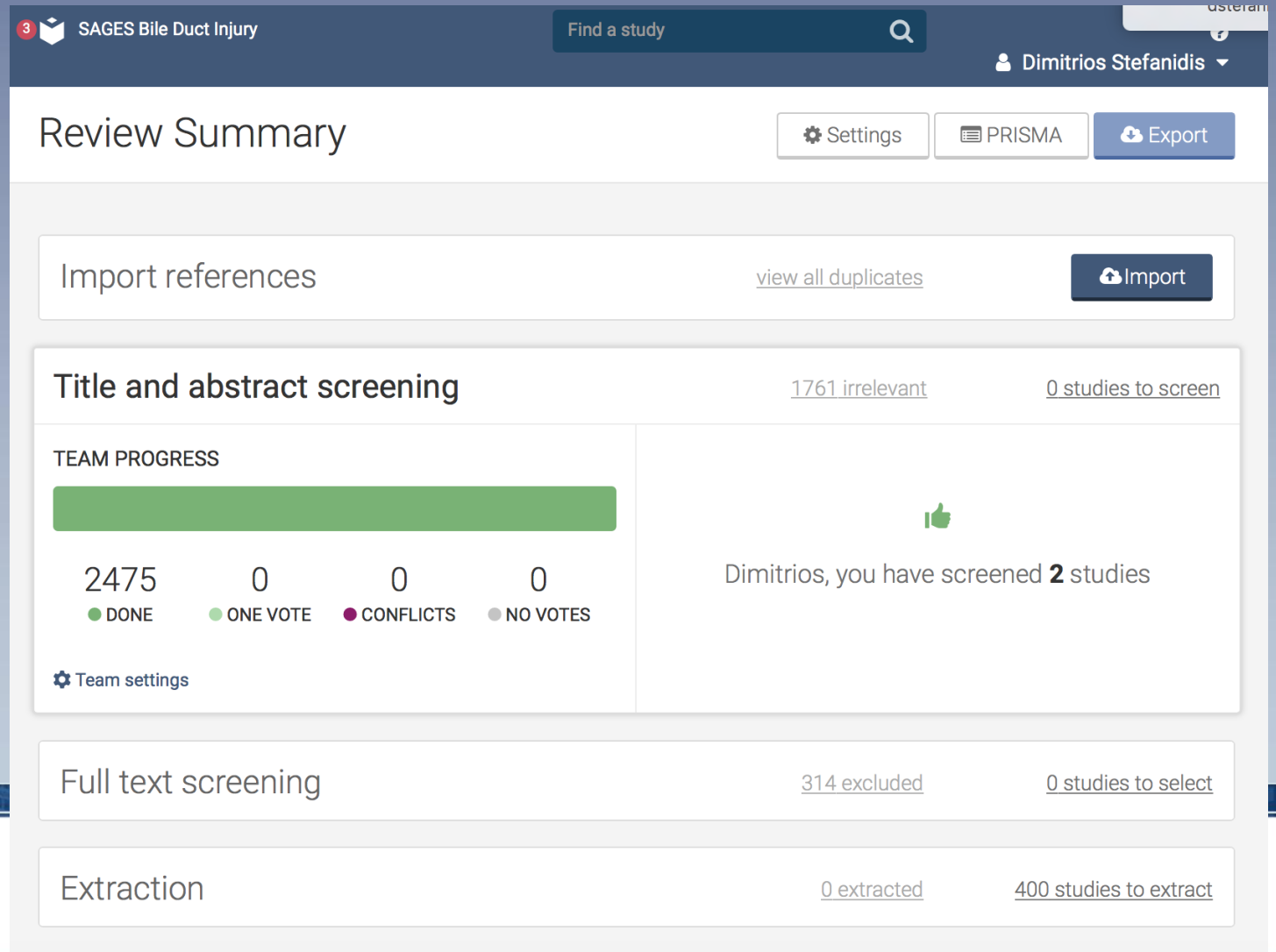
SEARCH STRATEGY:

1. MT1 or MT2 or TW1 or TW2
2. MT3 or TW3 or TW4
3. MT4 or MT5 or TW5 or TW6
4. 1 and 2 and 3

Abstract Review – Reviewer Calibration

Abstract and Full Paper Review

- 2,475 abstracts screened
  - 714 included
  - 1761 excluded
- 714 full papers reviewed
  - **400 extracted**
  - 314 excluded



Data Extraction

GENERAL STUDY DATA

EXTRACTOR (YOUR NAME)	PAPER REF ID	LAST NAME 1st AUTHOR	PUB. YEAR	RELEVANT PICO/ KEY Question	STUDY DESIGN (use the other excel workbook for nested case-control study, case-control study or a study with defined group(s) by outcome of interest, not exposure/intervention)	DESIGN-OTHER (specify)	CENTER(s)	TOTAL SAMPLE SIZE (numbers only)	FUNDING	REGION OF STUDY	MULTI-REGION (If applicable insert countries)

PICO DATA

OUTCOME DOMAIN	OUTCOME DEFINITION/DETAILS	SUMMARY POPULATION DESCRIPTION [study level (SL) disorder subtype; key comorbidity (or score); symptom duration; past procedure history]	KEY ELIGIBILITY CRITERIA IMPACTING GENERALISABILITY OF FINDINGS (add any concenrs you have)	INTERVENTION	INTERVENTION DETAILS TEXT BOX	COMPARATOR	COMPARATOR DETAILS TEXT BOX	Outcome duration with time unit if data numerical (e.g. intraop, 1 week post op, 30-days posto-op, etc)	OUTCOME UNIT IF APPLICABLE (e.g. days, ml, etc.)	Currency for cost data (USD, CAD, GBP, EURO, etc)	OUTCOME CHARACTERISTIC	OUTCOME METRIC	N analyzed relevant to outcome of interest	Data of Interest	Type of Analysis

RESULTS INTERVENTION ARM (numbers only)

N Events or Cases - intervention group	Mean/median Intervention group	Standard Deviation for Mean for Intervention Group	Standard Error for Mean for Intervention group	Interquartile range (IQR) for median for Intervention group	Range for median for Intervention group	Total number of patients - Intervention group

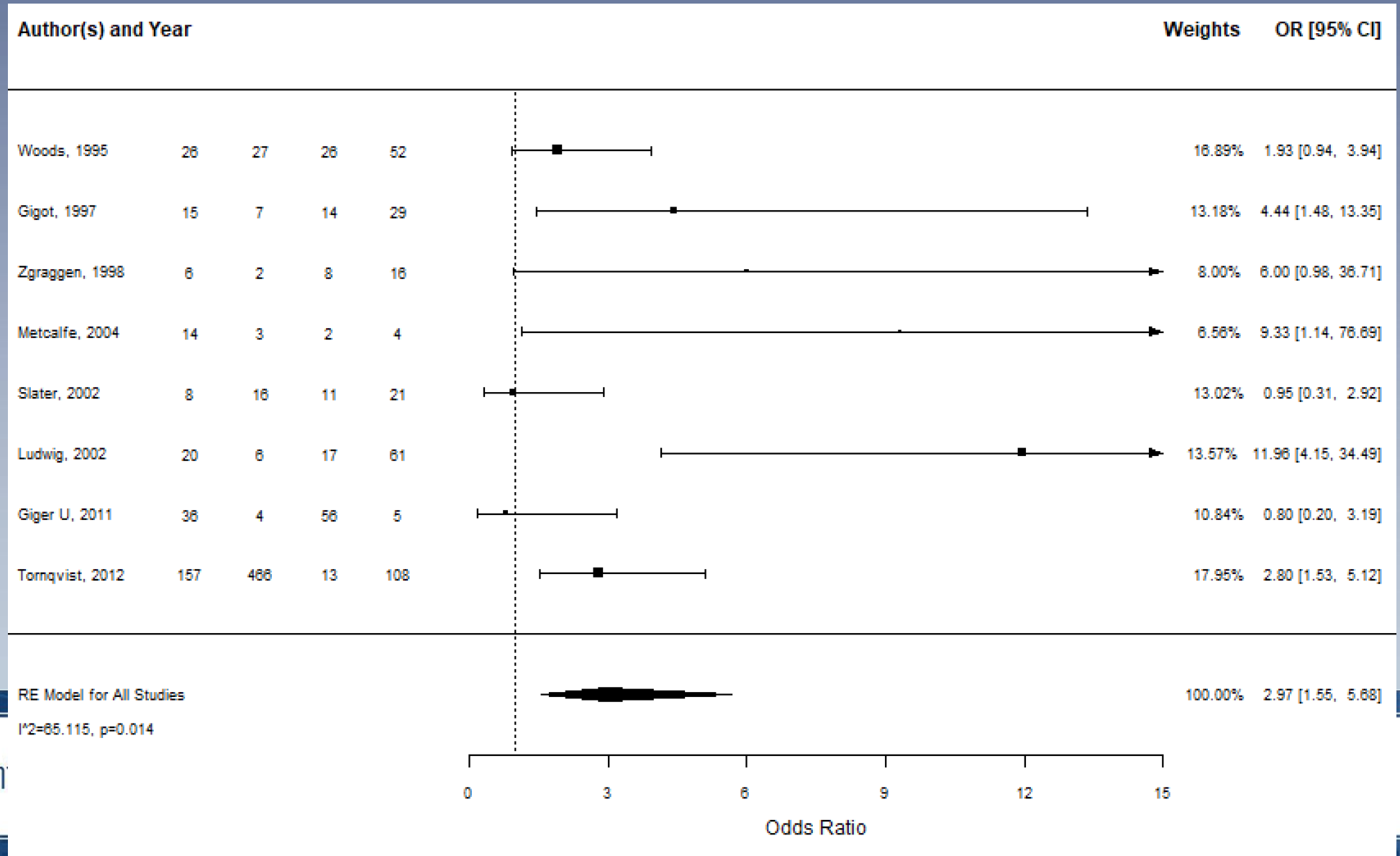
RESULTS COMPARATOR ARM (numbers only)

Events or Cases - Comparator group	Mean/median Comparator group	Standard Deviation for Mean for Comparator Group	Standard Error for Mean for Comparator group	Interquartile range (IQR) for median for Comparator group	Range for median for Comparator group	Total number of patients - Comparator group

RISK OF BIAS ASSESSMENT

...ons (SQ)		Domain judgment (DJ)	SQ					DJ	SQ	DJ	SQ		DJ	SQ		DJ	Other biases not accounted fo		OVERALL BIAS JUDGMENT	
...cerns about ...baseline ...mbalance ...veen groups ...ch was not ...dressed or ...completely ...dressed in ...alysis (for	Additionally for cluster trials: Were all the individual participants identified before randomization of cluster or baseline	Judgment about bias due to imbalanced groups	Concerns about the level of care (other than the intervention or comparator) being different between groups because patients or providers were	Concerns about adherence to or implementation of the intended intervention	Concerns that deviation from intended interventions (e.g. crossover or switching) were not addressed in analysis (e.g. inverse	Concerns that co-interventions different in both groups may have influenced the results.	For non-randomized comparative studies, please indicate whether potential confounders were properly accounted for. If	Judgment about bias due to deviations from intended intervention	Are missing patient/cluster outcome data similar in number across intervention & comparator and reasons for missingness	Judgment about bias due to missing data	Were outcome assessors/reporters aware of the intervention received by study participants?	Was the assessment of the outcome likely to be influenced by knowledge of intervention received?	Judgment about bias due to measurement of outcome	Are the reported outcome data likely to represent a select of multiple analyses undertaken on the basis of the results – i.e.	Are the reported data clear with no discrepancies, and the intervention and eligibility criteria adequately described?	Judgment about biased reporting of results	Other biases not accounted in previous columns	Specify Other biases	Overall Outcome specific risk of bias	Support for judgment of bias (Text box)

Data Analysis



Preven

CRITERIA	SUMMARY OF JUDGEMENTS						IMPORTANCE FOR DECISION
DESIRABLE EFFECTS	Trivial	Small	**Moderate**	Large	Varies	Don't know	**HIGH**
UNDESIRABLE EFFECTS	Large	Moderate	**Small**	Trivial	Varies	Don't know	**LOW**
CERTAINTY OF EVIDENCE	Very low	**Low**	Moderate	High	No included studies		**LOW**
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			**MODERATE**
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know	**MODERATE**
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes	Varies	Don't know	**MODERATE**
FEASIBILITY	No	Probably no	**Probably yes**	Yes	Varies	Don't know	**MODERATE**

Recommendation Formulation

GRADEpro GDT

- **Recommendation**
- Justification
- Subgroup considerations
- Implementation considerations
- Monitoring and Evaluation
- Research Priorities

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	**Conditional recommendation for the intervention**	Strong recommendation for the intervention
○	○	○	◉	○

Recommendations

- GRADE recommendations
- Type B recommendations
  - Other non GRADE recommendations often related to future research
- Did not consider cost
  - Focus on patients
  - Severely limited available evidence
- Panel voting – social aspect/ stakeholder agreement
  - Low quality of evidence
  - >80% panel agreement in all recommendations

Expert Validation of Recommendations

State of the Art Consensus Conference on Prevention of Bile Duct Injury During Cholecystectomy

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Prevent Bile Duct Injury Consensus Conference

Prevent BDI Consensus Conference

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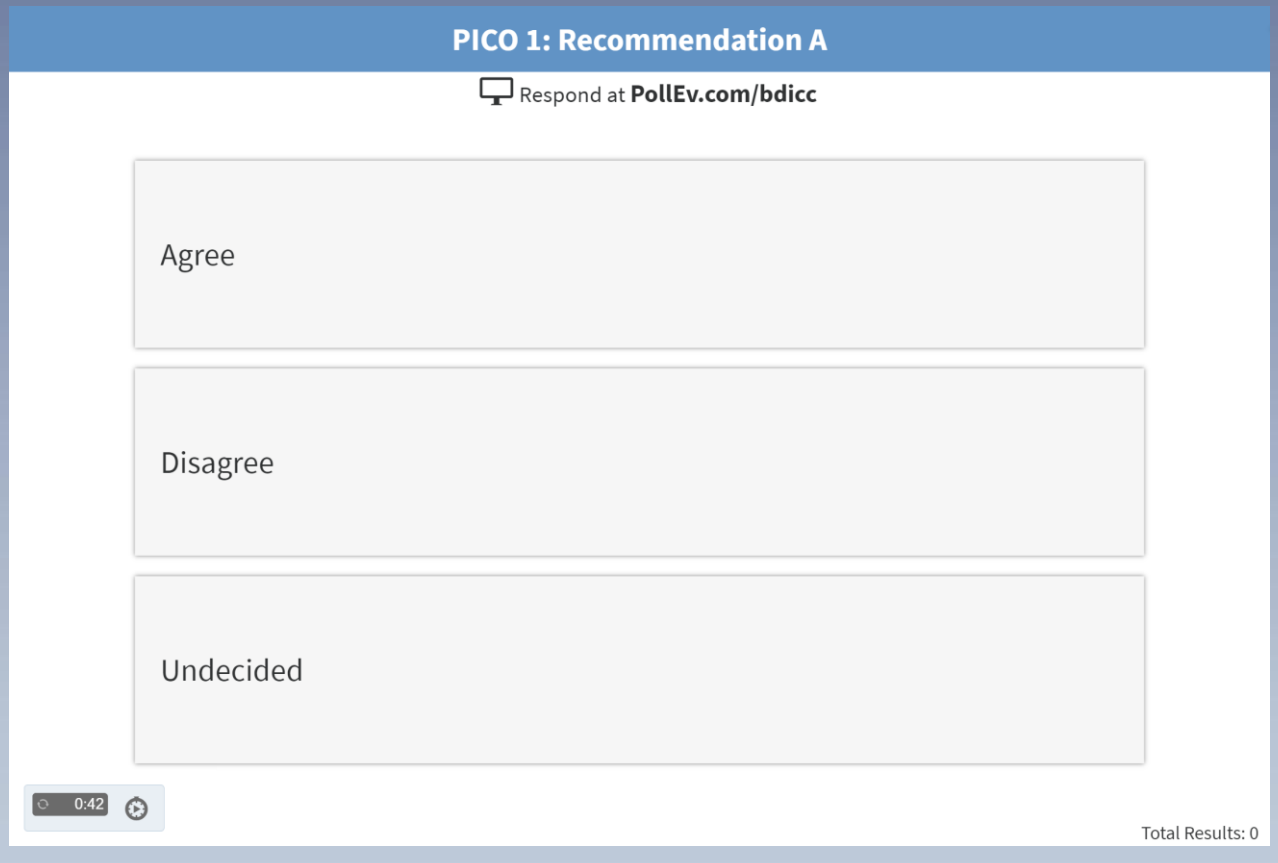

Meeting and Voting Process

Presentation of PICO question/recommendation/justification and evidence

↓

Voting by expert panel

Voting by audience (MD's only)

↓

If > 80% agreement by **expert panel**, recommendation is approved

If < 80% agreement by **expert panel,** discussion by expert panel

(open audience discussion after expert panel)

↓

Revote or reconsider/revise for later consideration

Consensus Recommendations (from GRADE Handbook)

- Two types of recommendations:
  - Strong - confident that the desirable effects of an intervention outweigh its undesirable effects (strong recommendation for an intervention) or that the undesirable effects of an intervention outweigh its desirable effects (strong recommendation against an intervention)

    Implies that most or all individuals will be best served by the recommended course of action.

  - Conditional – desirable effects probably outweigh undesirable effects or undesirable effects probably outweigh the desirable effects (weak recommendation against an intervention) but appreciable uncertainty exists

    Depending on patient values, resources available or setting

- Panel should consider both the content and strength of the recommendation in voting

Consensus Recommendations for Future Studies: Type B Recommendations

- Criteria:
  - There is insufficient evidence to support a decision for or against an intervention
  - Further research has large potential for reducing uncertainty about the effects of the intervention
  - Further research is thought to be of good value for the anticipated costs
- Panel voting to help establish prioritization for the proposed studies

From GRADE Handbook
https://gdt.gradepro.org/app/handbook/handbook.html#h.w29yp7vuyzwo

Consensus Post Meeting

- Recommendations posted for one month for public comment
- https://www.preventbdi.org/

https://pollev.com/bdicc

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Prevent BDI Consensus Conference

State of the Art Consensus Conference on Prevention of Bile Duct Injury During Cholecystectomy

Saturday, October 20, 2018 • Boston, MA

Workgroup I : PICOs #1 - 3

- Co-leads: Marian McDonald, Daniel Deziel
- Maria Altieri
- Benjamin Veenstra
- Justin Gerard
- MacKenzie Landin
- Ismael Dominguez-Rosado

State of the Art Consensus Conference on Prevention of Bile Duct Injury During Cholecystectomy

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PICO # 1

Should the critical view of safety (CVS) vs. other methods (e.g. infundibular, top down, or intraoperative cholangiography) be used to mitigate the risk of bile duct injury during laparoscopic cholecystectomy?

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PICO #1: Method Anatomic Identification Recommendation

In patients undergoing laparoscopic cholecystectomy,
we suggest that surgeons use the critical view of safety
for anatomic identification of the cystic duct and cystic artery.

Conditional recommendation
Very low certainty of evidence

PICO # 1: Method Anatomic Identification: Summary of Literature Reviewed

- 3 Systematic Reviews (2002-2011)
- 1 Prospective RCT (2011)
- 1 Retrospective Comparative Study (2011)
- 12 Single Arm Cohort Studies (1991-2017)
- 4 Case Series (2000-2014)
- 6 Survey Studies (1997-2018)
- 7 Expert Opinion Papers (2002-2018)

Insufficient for meta analysis

PICO # 1: Indirect evidence for CVS

1. Using CVS, large institutional studies demonstrate lower than expected rates of bile duct injury.

Observed rate : 0 – 0.07%
Expected rate : 0.2 – 0.4%
O/E = 0.125 – 0.25

Palanivelu,	2007	N = 9,864	0.07% BDI
Yegiyants,	2008	N = 3,042	0 BDI
Avgerinos,	2009	N = 998	0 BDI
Tsalis,	2015	N = 873	0 BDI

PICO # 1: Indirect evidence for CVS

2. Combined cohort studies using CVS demonstrate a lower rate of BDI compared to combined cohort studies using infundibular approach.

CVS: 1 BDI/5,421 cases **(0.018%)**
Infundibular: 5 BDIs/6,810 cases **(0.07%)**

PICO # 1: Indirect evidence for CVS

3. Case series of bile duct injuries with analysis of mechanism of injury (videos, OR reports) do not document use of critical view of safety

Booij,	2014	528 BDIs: CVS documented in 33 (6.3%)
Nijssen,	2015	11 BDIs with video: No CVS
Strasberg,	2000	21 BDIs: No CVS

PICO # 1: Undesirable effects of CVS

Little evidence that CVS, or attempt to achieve CVS, is associated with undesirable effects

One report of 600 selected LCs with 7 BDIs:
1 BDI occurred while dissecting CVS
Kohn, 2017

PICO #1: Data Summary Laparoscopic Top Down (Fundus-First) Method

1. Combined 13 cohort studies/ 1,181 cases : Deemed “safe & effective” in difficult cases based on conversion rate and complications (BDI rate not specified).
2. Prospective randomized trial “contracted” GB:

	33 fundus-first	vs.	**31 standard LC**
BDI	0		2
Complications	1		10
Conversion	0		7

(*Huang, 2011)*

PICO #1: Data Summary Laparoscopic Top Down (Fundus First) Method

3. Case series 30 laparoscopic BDIs (plus 152 open chole BDIs) found all occurred with hilar first (vs. fundus-first)dissection. *Yang, 2002*

4. Case series 8 “extreme” vasculobiliary injuries found all occurred with fundus-first dissection after lap converted to open. *Strasberg, 2012*

PICO #1: Data Summary Intraoperative Imaging Methods for Anatomic Identification

1. IOC use associated with fewer BDIs, lower severity BDI, more frequent intraoperative detection of BDI.
   Causal relationship not conclusive.

2. Laparoscopic ultrasonography may prevent BDI in difficult cases.
   12 studies/7,905 cases.

Note: Additional data on intraoperative imaging addressed in PICO # 4

PICO #1: Use of CVS

CRITERIA	SUMMARY OF JUDGEMENTS						IMPORTANCE FOR DECISION
DESIRABLE EFFECTS	Trivial	Small	Moderate	**Large**	Varies	Don't know	
UNDESIRABLE EFFECTS	Large	Moderate	Small	**Trivial**	Varies	Don't know	
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High	No included studies		
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	**No important uncertainty or variability**			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes	Varies	Don't know	
FEASIBILITY	No	Probably no	**Probably yes**	Yes	Varies	Don't know	

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	**Conditional recommendation for the intervention**	Strong recommendation for the intervention
○	○	○	◉	○

PICO #1: Recommendation

In patients undergoing laparoscopic cholecystectomy,
we suggest that surgeons use the critical view of safety
for anatomic identification of the cystic duct and cystic artery.

Conditional recommendation

Very low certainty of evidence

Additional consideration : When the CVS cannot be achieved safely (e.g. due to pathologic alterations of, or native variations in, biliary anatomy,
we suggest that surgeons consider intraoperative imaging for anatomic identification.

Vote on PICO 1 Recommendation

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PICO # 2

Should the **top down technique** of total cholecystectomy versus **subtotal cholecystectomy** be used to mitigate the risk of bile duct injury when critical view of safety cannot be achieved during laparoscopic cholecystectomy?

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PICO #2: Top Down vs. Subtotal Recommendation

When the critical view of safety cannot be achieved and the biliary anatomy cannot be clearly defined by other methods (e.g. imaging) during laparoscopic cholecystectomy, we suggest that surgeons consider subtotal cholecystectomy over total cholecystectomy by the top down approach.

Conditional recommendation
Very low certainty of evidence

PICO #2: Subtotal vs. Top down
Summary of Literature Reviewed

2 Systematic Reviews (2011, 2015): 30 unique studies
10 additional cohort studies (1993- 2017)
1 Prospective RCT (2011)
2 Administrative database studies (2012, 2017)
2 case series (2002, 2011)

Insufficient for meta analysis

Note: Additional data on subtotal cholecystectomy addressed in PICO #9

PICO # 2: Data Summary Laparoscopic Top Down (Fundus First) Method

1. Combined 13 cohort studies/ 1,181 cases : Deemed “safe & effective” in difficult cases based on conversion rate and complications (BDI rate not specified).
2. Prospective randomized trial “contracted” GB:

	33 fundus-first	vs.	**31 standard LC**
BDI	0		2
Complications	1		10
Conversion	0		7

(*Huang, 2011)*

PICO # 2: Data Summary Laparoscopic Top Down (Fundus-First) Method

3. Case series 30 laparoscopic BDIs (plus 152 open chole BDIs) found all occurred with hilar first (vs. fundus-first)dissection. *Yang, 2002*

4. Case series 8 “extreme” vasculobiliary injuries found all occurred with fundus-first dissection after lap converted to open. *Strasberg, 2012*

PICO # 2: Data Summary Laparoscopic Subtotal Cholecystectomy

1. 1,868 lap subtotals from 39 studies
   BDI: 2/1,460 cases (0.14%)
   Conversion: 202/1,850 cases (10.9%)
2. Administrative database studies
   a) UHS Consortium: Lap Subtotal (N = 487) vs. Lap Total (N = 131,082)
      1:1 propensity score match: no difference mortality, LOS, readmits (*Kim, 2017)*
   b) NIS: 3.3% BDI (360/10,872) cases lap subtotal, open subtotal & "trocar" cholecystostomy. No difference in BDI between laparoscopic vs. converted subtotal cholecystectomy *(Lee, 2012)*

PICO # 2: Literature Summary

1. No direct comparative studies of laparoscopic subtotal vs. laparoscopic top down total cholecystectomy.
2. Each has been safely performed in selected cases.
3. Each has been associated with morbidity in some cases.
4. There are no standardized selection criteria as to when these methods are best applied.

PICO #2: Top down vs. subtotal

CRITERIA	SUMMARY OF JUDGEMENTS						IMPORTANCE FOR DECISION
DESIRABLE EFFECTS	Trivial	Small	Moderate	**Large**	Varies	Don't know	
UNDESIRABLE EFFECTS	Large	**Moderate**	Small	Trivial	Varies	Don't know	
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High	No included studies		
VALUES	Important uncertainty or variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes	Varies	Don't know	
FEASIBILITY	No	Probably no	**Probably yes**	Yes	Varies	Don't know	

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	**Conditional recommendation for the intervention**	Strong recommendation for the intervention
○	○	○	◉	○

PICO #2: Top Down vs. Subtotal Recommendation

When the critical view of safety cannot be achieved and the biliary anatomy cannot be clearly defined by other methods (e.g. imaging) during laparoscopic cholecystectomy, we suggest that surgeons consider subtotal cholecystectomy over total cholecystectomy by the top down approach.

Conditional recommendation
Very low certainty of evidence

Vote on PICO 2 Recommendation

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PICO # 3

How should the critical view of safety be documented during laparoscopic cholecystectomy (still doublet photos vs. operative notes vs. video vs. no documentation) ?

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PICO # 3: Documentation of CVS Recommendation

When performing laparoscopic cholecystectomy, we suggest that surgeons incorporate documentation of the critical view of safety by doublet photography or video in addition to written documentation.

Conditional recommendation
Very low certainty of evidence

PICO #3: Documentation of CVS Summary of Literature Reviewed

5 Cohort Studies
1 Survey Study

Insufficient for meta analysis

PICO # 3: Documentation of CVS : Data Summary

5 cohort studies/368 cases: No BDIs.

- Description of CVS in OR dictations is poor compared to photos or video.
- Videos superior to OR notes *(Wauben 2011, Plaisier 2001)* and to CVS photos with 2 views *(Emous 2010).*
- CVS photos with 2 views were superior to photos with one view *(Sanford 2014).*
- IOC superior to CVS photos with one view *(Buddingh 2012).*

Survey study: surgeons using CVS. 80% document in OR report, 43% by photo, 30% by video *(Buddingh 2011).*

PICO # 3: Documentation CVS

CRITERIA	SUMMARY OF JUDGEMENTS						IMPORTANCE FOR DECISION
DESIRABLE EFFECTS	Trivial	Small	**Moderate**	Large	Varies	Don't know	
UNDESIRABLE EFFECTS	Large	**Moderate**	Small	Trivial	Varies	Don't know	
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High	No included studies		
VALUES	Important uncertainty or variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies / Don't know	
ACCEPTABILITY	No	Probably no	Probably yes	Yes	Varies	Don't know	
FEASIBILITY	No	Probably no	**Probably yes**	Yes	Varies	Don't know	

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	**Conditional recommendation for the intervention**	Strong recommendation for the intervention
○	○	○	◉	○

PICO # 3: Documentation of CVS Recommendation

When performing laparoscopic cholecystectomy, we suggest that surgeons incorporate documentation of the critical view of safety by doublet photography or video in addition to written documentation.

Conditional recommendation
Very low certainty of evidence

Vote on PICO 3 Recommendation

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