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Guideline

Delphi consensus on bile duct injuries during laparoscopic cholecystectomy: An evolutionary cul-de-sac or the birth pangs of a new technical framework?

Yukio Iwashita, Taizo Hibi, Tetsuji Ohyama, Akiko Umezawa, Tadahiro Takada, Steven M. Strasberg, Horacio J. Asbun, Henry A. Pitt, Ho-Seong Han, Tsann-Long Hwang, Kenji Suzuki, Yoo-Seok Yoon, In-Seok Choi, Dong-Sup Yoon, Wayne Shih-Wei Huang, Masahiro Yoshida, Go Wakabayashi, Fumihiko Miura, Kohji Okamoto, Itaru Endo, Eduardo de Santibanes, Mariano Eduardo Giménez, John A. Windsor, James Garden, Dirk J. Gouma, Daniel Cherqui, Giulio Belli, Christos Dervenis, Daniel J. Deziel, Eduard C. Jonas, Palepu Jagannath, Avinash Nivritti Supe, Harjit Singh, Kui-Hin Liau, Xiao-Ping Chen, Angus C.W. Chan, Wan Yee Lau, Sheung Tat Fan, Miin-Fu Chen, Myung-Hwan Kim, Goro Honda, Atsushi Sugioka, Koji Asai, Keita Wada, Yasuhisa Mori, Ryota Higuchi, Takeshi Misawa, Manabu Watanabe, Naoki Matsumura, Toshiki Rikiyama, Naohiro Sata, Nobuyasu Kano, Hiromi Tokumura, Taizo Kimura, Seigo Kitano, Masafumi Inomata, Koichi Hirata, Yoshinobu Sumiyama, Kazuo Inui, Masakazu Yamamoto

The author's affiliations are listed in the Appendix.

Corresponding author:

Tadahiro Takada, M.D., Ph.D. Department of Surgery, Teikyo University School of Medicine 2-11-1, Kaga, Itabashi-ku, Tokyo, Japan 173-8605 Phone: +812 3964 1211 ext. 1424 Fax: +813 3961 6944

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Keywords: Laparoscopic cholecystectomy, bile duct injury, Delphi consensus, Critical view of safety, surgical difficulty

Abstract

Background

Bile duct injury (BDI) during laparoscopic cholecystectomy remains a serious iatrogenic surgical complication. BDI most often occurs as a result of misidentification of the anatomy; however, clinical evidence on its precise mechanism and surgeons' perceptions is scarce.

Methods

Surgeons from Japan, Korea, Taiwan, and the U.S., etc. (n = 614) participated in a questionnaire regarding their BDI experience and near-misses; and perceptions on landmarks, intraoperative findings, and surgical techniques. Respondents voted for a Delphi process and graded each item on a five-point scale. The consensus was built when \geq 80% of overall responses were 4 or 5.

Results

Response rates for the first- and the second-round Delphi were 60.6% and 74.9%, respectively. Misidentification of local anatomy accounted for 76.2% of BDI. Final consensus was reached on: 1) Effective retraction of the gallbladder, 2) Always obtaining critical view of safety, and 3) Avoiding excessive use of electrocautery/clipping as vital procedures; and 4) Calot's triangle area and 5) Critical view of safety as important landmarks. For 6) Impacted gallstone and 7) Severe fibrosis/scarring in Calot's triangle, bail-out procedures may be indicated.

Conclusions

A consensus was reached among expert surgeons on relevant landmarks and intraoperative findings and appropriate surgical techniques to avoid BDI.

Introduction

Laparoscopic cholecystectomy (LC) is a widely accepted standard procedure that is performed across the globe; however, its safety has yet to be established. The incidence of bile duct injury (BDI) during LC ranges between 0.2 and 1.1%, is reported to be higher than an open cholecystectomy, and remains an uncommon but one of the most serious iatrogenic surgical complications (1–3). In extreme BDI cases, a liver resection or even liver transplantation is required (4, 5). BDI is not only associated with increased medical costs but also an increased mortality rate, which can be as high as 21% (6, 7).

BDI during LC most often occurs as a result of misidentification of the common hepatic/bile duct as the cystic duct (8–10). The technique to establish a critical view of safety (CVS) (11) has been adopted worldwide to prevent misidentification. Disappointingly, the number of BDI cases does not seem to have gone down over the years, despite the introduction of other safety measures such as intraoperative cholangiography (12), use of landmarks other than CVS (13, 14), and efforts to facilitate surgical education (15, 16). BDI may also occur in difficult situations, particularly in acute cholecystitis (AC) (17, 18). A recent study demonstrated an increased risk of BDI according to the severity grade of AC per Tokyo Guidelines 13 (19, 20). In addition, Strasberg and Gouma (21) reviewed eight cases of extreme vasculobiliary injury in details, the most severe type of BDI, and concluded that the fundus-down technique should be strictly avoided for AC cases with severe inflammation.

Our group has been vigorously working on the establishment of best practice for cholecystitis and it is our fervent desire to prevent and eradicate BDI (22, 23). Heinrich (24) claimed that for every major injury, there were 29 minor injuries and 300 no-injury accidents or near-misses, this is well known as Heinrich's safety pyramid. Therefore, investigations on near-miss events are of paramount importance to avoid serious complications during an operation and they also provide a rich source of learning (25, 26).

In LC, clinical evidence is currently scarce on when, where, and why surgeons experience BDI or a near-miss, how can we avoid or reduce the risk of BDI, and what are the alternative bail-out procedures when BDI is likely to occur. In the present study, we conducted an international survey

among expert LC surgeons in Japan, Korea, Taiwan, the U.S, and other nations on BDI during LC and aimed to reach a consensus on risk management strategies by using the Delphi method.

Methods

A total of 614 expert LC surgeons in Japan, Korea, Taiwan, the U.S, and other nations were invited to participate in the first- and second-round Delphi process in a web-based, English questionnaire survey. The questionnaire consisted of eight questions regarding their BDI experience and its risk management strategies and was created by 12 expert LC surgeons in Japan working at tertiary hepatobiliary and pancreatic surgical institutions, using the nominal group technique. The first round was conducted in April 2017. Questions 1 and 2 consisted of workplace (by nation) and lifetime experience in LC and open cholecystectomies (total caseloads were categorized into four different levels: 1–199, 200–499, 500–999, and \geq 1,000). Questions 3 and 4 focused on their personal experience of BDI and near-misses. Questions 5–8 were designed to establish a consensus on the situations and landmarks or intraoperative findings that were likely to be associated with BDI and on the surgical techniques that could be used to avoid, or reduce the risk of, BDI. Respondents were asked to grade each factor according to its importance on a five-point scale (Likert scale) of 1 (not at all important) to 5 (very important). The second round took place in May 2017 and questions 1, 2, and 5-8 were repeated. To build a consensus among expert LC surgeons on perceptions of BDI, an anonymous summary of the first-round Delphi was provided together with the questions. The results from the first round were expressed as percentage of respondents for each answer option (from 1 to 5) and the median (interquartile range) for each factor. Each respondent had the option to either retain or change his/her initial opinion in the first round with reference to the response of the entire group. A complete version of the questionnaire is depicted in supplementary Figure 1. Delphi consensus was reached when at least 80% of respondents ranked an item as 4 or 5 on a Likert scale of 1 to 5, in accordance with the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Delphi consensus (27). Data from the second-round Delphi were further stratified by workplace and LC experience level. All data were collected using Microsoft Office Excel 2010.

Results

Respondent characteristics

A link to the web-based questionnaire was sent via email to a total of 614 surgeons for the first- and second-round Delphi. The response rates were 60.6 % (Japan, n = 279; Korea, n = 39, Taiwan, n = 34; the U.S. and others, n = 20) and 74.9% (Japan, n = 287; Korea, n = 60, Taiwan, n = 92; the U.S. and others, n = 21) for the first and second rounds, respectively. Table 1 shows the distribution of lifetime cases among nations. In Korea and the U.S. and others, >60% of surgeons experienced >1,000 cases and this ratio was higher than that of Japan and Taiwan.

Field study

Overall, the number of respondents who experienced BDI or near-misses was 267/372 (72.3%) and the ratio increased as experience accumulated, reaching >80% among surgeons who had performed >1,000 cases during their career (Table 2). Of these, 205 recalled that misidentification of local anatomy was the main reason for BDI and near-misses. One hundred forty surgeons recognized misidentification after BDI, corresponding to 37.6% of the entire group. BDI and near-misses most often occurred during the dissection of the Calot's triangle area (42.4%) and around the cystic duct (42.4%) (Table 3). Misidentification of the common bile/hepatic duct instead of the cystic duct was the most common reason of BDI (65.4%), followed by the hepatic artery instead of the cystic artery (10.4%) (Table 4). Misrecognition was revealed by the identification of a landmark (40.5%), followed by intraoperative cholangiography (20.5%) and advice from a member of the surgical team other than the operator (18.0%).

Delphi study

In the first-round Delphi, the five items for which \geq 80% of the respondents had graded either a 4 or 5 on a five-point scale (1, not at all important; 5, very important) were: A) Impacted gallstone in the confluence of the cystic, common hepatic, and common bile duct and B) Severe fibrosis and scarring in Calot's triangle due to inflammation in the "When to stop" category (high-risk intraoperative situations that are likely to be associated with BDI); C) Calot's triangle area and D) CVS in the This article is protected by copyright. All rights reserved.

"Where to stop" category (landmarks or intraoperative findings that might be helpful in avoiding BDI); and E) Effective retraction of the gallbladder to develop a plane in the Calot's triangle area and identify its boundaries (countertraction) in the "How to prevent" category (surgical techniques that can be used to avoid, or reduce the risk of BDI) (Table 5).

In the second-round Delphi, two more items reached a consensus where \geq 80% of the responses were either grade 4 or 5: F) Always obtaining the CVS (i.e., maximum effort should be made to achieve CVS as long as it is safe to do so; however, surgeons should be prepared to switch to other bail-out procedures in cases where attainment of CVS itself appears dangerous because of severe inflammation, adhesion, disorientation, etc.) and G) For persistent hemorrhage, achieving hemostasis primarily by compression and avoiding excessive use of electrocautery or clipping in the "How to prevent" category, in addition to the five items that emerged in the first round. Furthermore, there were eight other items in which 50–80% of the respondents had graded either a 4 or 5 and were thus considered to be relatively important: a) Anomalous bile duct and b) Extensive blood loss in the "When to stop" category; c) Starting dissection from the posterior leaf of the peritoneum covering the neck of the gallbladder and exposing the subserosal (SS) inner layer above Rouvière's sulcus, d) Maintaining the plane of dissection within the SS layer (i.e., exposing the SS inner layer) throughout LC, and e) Dissecting the lower part of the gallbladder bed (at least one-third) to obtain the CVS in the "Where to stop" category; and f) Open conversion, g) Fundus-first (dome-down), and h) Subtotal (partial) cholecystectomy in the "What are the alternatives" category.

We conducted further subgroup analyses for the above 15 items (seven items that reached a consensus plus the eight items that were graded either a 4 or 5 by 50–80% of the respondents). When the responses were stratified by workplace, Rouvière's sulcus was considered as an important landmark in >80% of Japanese surgeons. This ratio was higher compared to those in Korea, Taiwan, and the U.S. and others, which were in the 50–60% range. Likewise, for a bail-out procedure, while >80% of Japanese surgeons responded that they would convert to an open cholecystectomy, <80% of those in other nations would do the same. The number of surgeons who chose Fundus-first (domedown) was in the 60% range in all three Asian nations, but it fell below 50% in the U.S. and others. On the contrary, >90% of surgeons in the U.S. and others believed that a partial cholecystectomy is an This article is protected by copyright. All rights reserved.

effective alternative, but this ratio was <80% in Asian nations (Figure 1). Stratified analyses by lifetime experience of cholecystectomies revealed that the importance among surgeons decreased with an accumulation of cases in the following eight items: 1) Severe fibrosis and scarring in Calot's triangle due to inflammation, 2) Anomalous bile duct, and 3) Extensive blood loss in the "When to stop" category; 4) CVS and 5) Calot's triangle area in the "Where to stop" category; 6) Always obtaining the CVS in the "How to prevent" category; and 7) Open conversion and 8) Subtotal (partial) cholecystectomy in the "What are the alternatives" category (supplementary Figure 2).

Discussion

To decrease the incidence of BDI during LC, finding a common ground among surgeons in order to establish an effective surgical education system is imperative (16). Previous population-based studies listed male gender, elderly patients, delayed surgery, severity of acute cholecystitis, surgeons' experience, and academic hospital setting etc. as risk factors of BDI (28–33). Several large-scale questionnaire surveys have also been conducted to date (27, 34, 35) (Table 6); however, very few specifically looked at the surgical techniques or the landmarks that have been reported as important in preventing BDI. In the present study, we shed light on the mechanisms of BDI as well as perception of surgeons on risk management. We further attempted to elucidate the significance of various safety measures and landmarks.

In the field study component of this analysis, we found that >75% of respondents have experienced BDI and/or near-misses at some point during their surgical career. Moreover, the ratio was dependent on the number of lifetime cases of cholecystectomies and it reached >80% among surgeons who had performed >1,000 cases, which was similar to the observation by Massarweh et al (34). The question we should ask to ourselves is: Is BDI an inherent complication associated with LC and is it inevitable regardless of a surgeon's experience? In our study, the vast majority of the misidentification occurred by mistaking the common bile/hepatic duct or the right hepatic duct for the cystic duct. This is called the "classic laparoscopic injury" and many investigators have analyzed its mechanism (8–10). Operators appear to interpret their deficit in visual information based on what they "like to" see (i.e., cystic duct) rather than what they "don't like to" see (i.e., common bile/hepatic duct This article is protected by copyright. All rights reserved. or the right hepatic duct). A fixed mindset is difficult to correct and it is believed to occur even in cases without severe inflammation and among expert LC surgeons. Therefore, the answer to the aforementioned question might be "Yes" for the time being, disappointingly, but we hold the responsibility to consolidate a global effort to launch a novel technical framework and solve this problem. Massarweh et al. (34) also mentioned in their study that the risk of BDI was lower in hospitals that had a surgical residency program, underscoring the paramount importance of constantly raising awareness of BDI through surgical education.

Otto Von Bismarck once said "Fools say they learn from experience; I prefer to learn from the experience of others." So, to avoid BDI, what lessons can we learn from the past? CVS proposed by Strasberg et al. (36) is one of the most important LC concepts accepted worldwide. In this study, we reached a consensus among >600 expert international LC surgeons in the following seven technical aspects: A) Effective retraction of the gallbladder to develop a plane in the Calot's triangle area, B) Always obtaining CVS (as long as it is safe and secure to do so), and C) Avoiding excessive use of electrocautery or clipping for persistent hemorrhage and achieving hemostasis primarily by compression are vital procedures; recognition of the D) Calot's triangle area and E) CVS as landmarks is required to avoid BDI. In cases with F) Impacted gallstone in the confluence of the cystic, common hepatic, and common bile duct and G) Severe fibrosis and scarring in Calot's triangle due to inflammation (i.e., when CVS cannot be obtained), bail-out procedures may be the treatment of choice. CVS and appropriate surgical techniques are the key components, which are in line with the expert Delphi consensus reported by SAGES (27). In the SAGES survey, CVS was listed as one of the top five items in all three key domains (training, assessment, and research). Meanwhile, a misunderstanding of CVS may lead to BDI (36). Chen et al. (37) recently reported that the CVS training course for residents not only significantly improved the CVS score, but also enabled the trainees to appropriately choose bail-out procedures. As Onoe et al. (38) has described, creating CVS is difficult when severe cholecystitis exists, and it can even become a harmful procedure. In such instances, mobilization of the gallbladder off the cystic plate from the posterior aspect of the gallbladder neck might be important in securing safety during LC. Honda et al. (39-41) proposed that the dissection of the gallbladder wall should always expose the "SS-Inner" layer to prevent BDI, This article is protected by copyright. All rights reserved.

based on anatomical and histological investigations. Although their concept was built upon a discussion between surgeons and pathologists, there are criticisms that the gallbladder serosa cannot be separated anatomically and hence the term "SS-Inner" layer is inappropriate. In addition to the controversial terminology, whether this SS-Inner layer theory contributes to a reduction of BDI awaits clinical validation.

Only 20% of all respondents considered intraoperative cholangiography (IOC) to be important in our survey. The ratio of surgeons that routinely perform IOC is reportedly highly variable, ranging from <5% in the Netherlands, 25% in the U.S. and U.K., to as high as >60% in Australia (42–45). Several authors claimed that IOC cannot prevent BDI and its implication has yet to be defined (46, 47). However, IOC is a definitive procedure to confirm BDI and may preclude further damage to the biliary system and surrounding vital vessels (48). In the aforementioned SAGES survey, almost 90% of respondents agreed that "Surgeons should be able to perform and interpret IOC" (27). LC surgeons should at least be able to judge the need for IOC.

For the past few years, we have been striving to define surgical difficulty during LC based on objective, intraoperative findings (17, 18, 49). Although a universal grading system has yet to be defined, we have set a difficulty score per expert consensus (49). Not surprisingly, the factors with a high difficulty score corresponded with those identified in the present study. For example, the item "Severe fibrosis and scarring in Calot's triangle due to inflammation" in the "When to stop" category had the highest response rate of 94.3% in the present study, which also was identified as one of the most difficult intraoperative findings in our surgical difficulty study (49). A universal grading system on surgical difficulty is expected to identify patients at high risk of BDI, thereby enabling appropriate surgical decisions to be made before a catastrophe occurs.

In our survey, four types of bail-out procedures were presented. Both open conversion and fundus-first technique are controversial as to whether they are useful in avoiding or reducing the risk of BDI. Lengyel et al. (50) did not find a significant difference in the complication rate between laparoscopic and open conversion groups and concluded that open conversion should be determined only after surgeons make a genuine effort at a laparoscopic approach. All extreme vasculobiliary injuries reported by Strasberg and Gouma (51) occurred during conversion to an open This article is protected by copyright. All rights reserved.

cholecystectomy and fundus-first technique, raising a red flag to rely on these procedures without knowing their disadvantages. A subtotal (partial) cholecystectomy is another useful alternative to avoid/reduce the risk of BDI in difficult situations; however, the procedure remains ill-defined and new terms "fenestrating" and "reconstituting" have been proposed recently (51). Clinical evidence is insufficient to date to support one specific bail-out procedure over the other; however, surgeons should recognize the pros and cons of each technique and be prepared to use it judiciously.

In conclusion, our large-scale international survey clarified the mechanisms of BDI during LC and reached a consensus among expert surgeons on relevant landmarks and intraoperative findings and appropriate surgical techniques. This consensus should be the beacon of light to establish a new technical framework to eradicate BDI.

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Conflict of Interest

Goro Honda has received honoraria from Johnson and Johnson and Medtronics.

Appendix

Yukio Iwashita, Department of Gastroenterological and Pediatric Surgery, Oita University Faculty of Medicine, Oita, Japan; Taizo Hibi, Department of Surgery, Keio University School of Medicine, Tokyo, Japan; Tetsuji Ohyama, Biostatistics Center, Kurume University, Fukuoka, Japan; Tadahiro Takada, Fumihiko Miura, and Keita Wada, Department of Surgery, Teikyo University School of This article is protected by copyright. All rights reserved. Saint Louis, Washington, USA; Horacio J. Asbun, Department of Surgery, Mayo Clinic College of Medicine, Florida, USA; Henry A. Pitt, Lewis Katz School of Medicine at Temple University, Philadelphia, Pennsylvania, USA; Ho-Seong Han and Yoo-Seok Yoon, Department of Surgery, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Seoul, Korea; Tsann-Long Hwang and Miin-Fu Chen, Division of General Surgery, Lin-Kou Chang Gung Memorial Hospital, Tauyuan, Taiwan; Kenji Suzuki and Taizo Kimura, Department of Surgery, Fujinomiya City General Hospital, Shizuoka, Japan; Akiko Umezawa, Minimally Invasive Surgery Center, Yotsuya Medical Cube, Tokyo, Japan; In-Seok Choi, Department of Surgery, Konyang University Hospital, Daejeon, Korea; Dong-Sup Yoon, Department of Surgery, Yonsei University Gangnam Severance Hospital, Seoul, Korea; Wayne Shih-Wei Huang, Department of Surgery, Show Chwan Memorial Hospital, Changhua, Taiwan; Masahiro Yoshida, Department of Hemodialysis and Surgery, Chemotherapy Research Institute, International University of Health and Welfare, Chiba, Japan; Go Wakabayashi, Department of Surgery, Ageo Central General Hospital, Saitama, Japan; Kohji Okamoto, Department of Surgery, Center for Gastroenterology and Liver Disease, Kitakyushu City Yahata Hospital, Fukuoka, Japan; Itaru Endo, Department of Gastroenterological Surgery, Yokohama City University Graduate School of Medicine, Kanagawa, Japan; Eduardo de Santibanes, Department of Surgery, Hospital Italianio, University of Buenos Aires, Buenos Aires, Argentina; Mariano Eduardo Giménez, Chair of General Surgery and Minimal Invasive Surgery "Taquini" University of Buenos Aires. Argentina DAICIM Foundation, Argentina; Mariano Eduardo Gimenez, Chair of General Surgery and Minimal Invasive Surgery "Taquini" University of Buenos Aires. Argentina, DAICIM Foundation, Argentina; John A. Windsor, Department of Surgery, The University of Auckland, Auckland, New Zealand; James Garden, Clinical Surgery, The University of Edinburgh, Edinburgh, UK; Dirk J. Gouma, Department of Surgery, Academic Medical Center, Amsterdam, The Netherlands; Daniel Cherqui, Hepatobiliary Center, Paul Brousse Hospital, Villejuif, France; Giulio Belli, Department of General and HPB Surgery, Loreto Nuovo Hospital, Naples Italy; Christos Dervenis, First Department of Surgery, Agia Olga Hospital, Athens, Greece; Daniel J. Deziel, Department of Surgery, Rush University Medical Center, Chicago, USA; Eduard C. Jonas, Surgical This article is protected by copyright. All rights reserved.

Medicine, Tokyo, Japan; Steven M. Strasberg, Section of HPB Surgery, Washington University in

Gastroenterology/Hepatopancreatobiliary Unit University of Cape Town and Groote Schuur Hospital, Cape Town, South Africa; Palepu Jagannath, Department of Surgical Oncology, Lilavati Hospital and Research Centre, Mumbai, India; Avinash Nivritti Supe, Department of Surgical gastroenterology, Seth G S Medical College and K E M Hospital, Mumbai, India; Harjit Singh, Kui-Hin Liau, Xiao-Ping Chen, Hepatic Surgery Centre, Department of Surgery, Tongji Hospital, Tongi Medical College, Huazhong University of Science and Technology, Wuhan, China; Angus C.W. Chan, Surgery Centre, Department of Surgery, Hong Kong Sanatorium and Hospital, Hong Kong, Hong Kong; Wan Yee Lau, Faculty of Medicine, The Chinese University of Hong Kong, Shatin, Hong Kong; Sheung Tat Fan, Department of Surgery, The University of Hong Kong, Queen Mary Hospital, Hong Kong, Hong Kong; Myung-Hwan Kim, Department of Gastroenterology, University of Ulsan College of Medicine, Seoul, Korea; Goro Honda, Department of Surgery, Tokyo Metropolitan Komagome Hospital, Tokyo, Japan; Atsushi Sugioka, Department of Surgery, Fujita Health University School of Medicine, Aichi, Japan; Koji Asai and Manabu Watanabe, Department of Surgery, Toho University Ohashi Medical Center, Tokyo, Japan; Yasuhisa Mori, Department of Surgery I, Kyushu University, Faculty of Medicine, Fukuoka, Japan; Ryota Higuchi and Masakazu Yamamoto, Department of Surgery, Institute of Gastroenterology, Tokyo Women's Medical University, Tokyo, Japan; Takeshi Misawa, Department of Surgery, The Jikei University Kashiwa Hospital, Chiba, Japan; Naoki Matsumura and Hiromi Tokumura, Department of Surgery, Tohoku Rosai Hospital, Miyagi, Japan; Toshiki Rikiyama, Department of Surgery, Saitama Medical Center, Jichi Medical University, Saitama, Japan; Naohiro Sata, Department of Surgery, Jichi Medical University, Tochigi, Japan; Nobuyasu Kano, Director, Chiba Tokushukai Hospital, Chiba, Japan; Seigo Kitano, President, Oita University, Oita, Japan; Masafumi Inomata, Department of Gastroenterolgical and Pediatric Surgery, Oita University Faculty of Medicine, Koichi Hirata, Department of Surgery, JR Sapporo Hospital, Hokkaido, Japan; Yoshinobu Sumiyama, Director, Toho University, Tokyo, Japan; Kazuo Inui, Department of Gastroenterology, Second Teaching Hospital, Fujita Health University, Aichi, Japan; Masakazu Yamamoto, Department of Surgery, Institute of Gastroenterology, Tokyo Women's Medical University, Tokyo, Japan

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Figure Legends

Figure 1. Subgroup analyses of factors contributing to bile duct injury stratified by nation.

Supplementary Figure 1. A complete version of the web-based questionnaire.

Supplementary Figure 2.

| - | | | | | 1 ^s | t rour | nd | | | | | |
|---|-----------------------|-------------|---------|--------|----------------|-----------------|---------|-------|------------|---------|---------|--|
| | | J | lapan |] | Korea | Γ | Taiwan | U.S. | and others | r | Total | |
| | | Ν | = 279 | N = 39 | | 1 | N = 34 | | N = 20 | N = 372 | | |
| | 1-199 | 21 | (7.5%) | 2 | (5.1%) | 6 | (17.6%) | 1 | (5.0%) | 30 | (8.1%) | |
| | 200-499 | 106 | (38.0%) | 11 | (28.2%) | 6 | (17.6%) | 0 | (0.0%) | 123 | (33.1%) | |
| 7 | 500-999 | 93 | (33.3%) | 3 | (7.7%) | 13 | (38.2%) | 7 | (35.0%) | 116 | (31.2%) | |
| | ≥1000 | 59 | (21.1%) | 23 | (59.0%) | 9 | (26.5%) | 12 | (60.0%) | 103 | (27.7%) | |
| | 2 nd round | | | | | | | | | | | |
| | | Japan Korea | | Taiwan | | U.S. and others | | Total | | | | |
| | | Ν | = 287 | N | N = 60 | 1 | N = 92 |] | N = 21 | Ν | = 460 | |
| | 1-199 | 24 | (8.4%) | 2 | (3.3%) | 11 | (12.0%) | 1 | (4.8%) | 38 | (8.3%) | |
| | 200-499 | 96 | (33.4%) | 10 | (16.7%) | 29 | (31.5%) | 2 | (9.5%) | 137 | (29.8%) | |
| | 500-999 | 105 | (36.6%) | 8 | (13.3%) | 28 | (30.4%) | 5 | (23.8%) | 146 | (31.7%) | |
| | ≥1000 | 62 | (21.6%) | 40 | (66.7%) | 24 | (26.1%) | 13 | (61.9%) | 139 | (30.2%) | |
| | | | | | | | | | | | | |

Table 1. Respondent demographics.

| Stratification | | Ν | (%) |
|--------------------|-----------------|---------|---------|
| Workplace | Japan | 203/279 | (72.8%) |
| | Korea | 29/39 | (74.4%) |
| | Taiwan | 27/34 | (79.4%) |
| | U.S. and others | 10/20 | (50.0%) |
| Lifetime caseloads | 1-199 | 19/30 | (63.3%) |
| | 200-499 | 82/123 | (66.7%) |
| | 500-999 | 83/116 | (71.6%) |
| | ≥1000 | 85/103 | (82.5%) |
| Total | | 269/372 | (72.3%) |

Table 2. Experience of bile duct injury and near-misses during laparoscopic cholecystectomy

Accepted

Table 3. Situation of bile duct injury

| Surgical Step | Ν | (%) | BDI including near-misses related to | Ν | (%) | Misidentific | ation noted |
|---|-----|---------|---|----|---------|--------------|---------------|
| | | | misidentification of local anatomy, Yes/No | | | Before BDI | After BDI |
| Dissection of Hartmann's pouch (at the | 21 | (7.8%) | Yes | 14 | (66.7%) | 5 (35.7%) | 9 (64.3%) |
| right side of the gallbladder) | | | No | 7 | (33.3%) | | |
| Dissection of the Calot's triangle area (at the left side of the gallbladder) | 114 | (42.4%) | Yes | 94 | (82.5%) | 32 (34.0%) | 61 (64.9%) |
| | | | No | 19 | (16.7%) | | |
| | | | Unknown | 1 | (0.9%) | | |
| Dissection around the cystic duct | 114 | (42.4%) | Yes | 87 | (76.3%) | 23 (26.4%) | 63 (72.4%) |
| | | | No | 26 | (22.8%) | | |
| | | | Unknown | 1 | (0.9%) | | |
| Fundus-first technique (retrograde dissection to remove the fundus and body | 11 | (4.1%) | Yes | 7 | (63.6%) | 3 (42.9%) | 4 (57.1%) |
| of the gallbladder before approaching the Calot's triangle area) | | | No | 4 | (36.4%) | | |
| Other | 9 | (3.3%) | Yes | 3 | (33.3%) | 0 (0.0%) | 3 (100%) |

| | | No | 6 | (66.7%) | | |
|-----------------------------------|-----------------------------|---------|-----|---------|------------|------------|
| Total | 269 (100%) | Yes | 205 | (76.2%) | 63 (30.7%) | 140 (68.3) |
| | | No | 62 | (23.0%) | | |
| | | Unknown | 2 | (0.7%) | | |
| BDI, bile duct injury. | | | | | | |
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Table 4. Top 5 patterns of misidentification: "Structure 1 was misrecognized as Structure 2"

| Structure 1 | Structure 2 | Ν | (%) | Misrecognition was revealed by | Ν | (%) |
|---------------------|------------------|----|---------|---|----|---------|
| Common bile duct | Cystic duct | 83 | (40.5%) | Advice from a member of the surgical team other than the operator | 16 | (19.3%) |
| | | | | Identification of a landmark | 39 | (47.0%) |
| | | | | Intraoperative cholangiography | 18 | (21.7%) |
| (| | | | Other | 10 | (12.0%) |
| Common hepatic duct | Cystic duct | 34 | (16.6%) | Advice from a member of the surgical team other than the operator | 4 | (11.8%) |
| | | | | Identification of a landmark | 10 | (29.4%) |
| | | | | Intraoperative cholangiography | 11 | (32.4%) |
| | | | | Other | 9 | (26.5%) |
| Right hepatic duct | Cystic duct | 16 | (7.8%) | Advice from a member of the surgical team other than the operator | 4 | (25.0%) |
| | | | | Identification of a landmark | 4 | (25.0%) |
| | | | | Intraoperative cholangiography | 2 | (12.5%) |
| | | | | Other | 5 | (31.3%) |
| | | | | Unknown | 1 | (6.3%) |
| Cystic duct | Common bile duct | 13 | (6.3%) | Advice from a member of the surgical team other than the operator | 0 | (0.0%) |

| | | | | | Identification of a landmark | 7 | (53.8%) |
|---|-------------------------|------------------------|------------|--------|---|----|---------|
| | | | | | Intraoperative cholangiography | 3 | (23.1%) |
| | | | | | Other | 3 | (23.1%) |
| | Hepatic artery | Cystic artery | 8 | (3.9%) | Advice from a member of the surgical team other than the operator | 3 | (37.5%) |
| | | | | | Identification of a landmark | 4 | (50.0%) |
| | | | | | Intraoperative cholangiography | 0 | (0.0%) |
| | | | | | Other | 1 | (12.5%) |
| | Total | | 205 | (100%) | Advice from a member of the surgical team other than the operator | 37 | (18.0%) |
| | | | | | Identification of a landmark | 83 | (40.5%) |
| | | | | | Intraoperative cholangiography | 42 | (20.5%) |
| | | | | | Other | 42 | (20.5%) |
| 4 | | | | | Unknown | 1 | (0.5%) |
| | | | | | | | |
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Table 5. Summarized results of the first- and second-round Delphi.

| | 1 st | round | | 2 nd round | | | |
|--|-----------------|----------------|-----|-----------------------|-----------------|-----|--|
| When to stop: | % rating 4 or | Mean ± | Ran | % rating 4 or | Mean \pm SD | Ran | |
| | 5 | SD | k | 5 | | k | |
| i. Extensive and dense adhesion to surrounding organs and/or greater omentum | 28.6% | 2.87 ± 1.11 | 6 | 23.3% | 2.90 ± 0.86 | 5 | |
| ii. Impacted gallstone in the confluence of the cystic, common hepatic, and common bile duct (included in the expanded classification of Mirizzi syndrome) | 80.6% | 4.15 ± 0.86 | 2 | 88.7% | 4.22 ± 0.73 | 2 | |
| iii. Severe fibrosis and scarring in Calot's triangle due to inflammation | 88.7% | 4.41 ± 0.77 | 1 | 94.3% | 4.60 ± 0.61 | 1 | |
| iv. Severe fibrosis and scarring in gallbladder bed due to inflammation (includes sclero-atrophic gallbladder) | 28.8% | 2.94 ± 1.01 | 5 | 17.4% | 2.79 ± 0.84 | 6 | |
| v. Anomalous bile duct | 65.5% | 3.75 ± 1.01 | 3 | 64.8% | 3.73 ± 0.83 | 3 | |
| vi. Extensive operative time | 22.4% | 2.67 ± 1.03 | 7 | 15.0% | 2.72 ± 0.82 | 7 | |
| vii. Extensive blood loss | 50.9% | 3.45 ± 1.04 | 4 | 59.1% | 3.62 ± 0.79 | 4 | |

| Where to stop: | % rating 4 or 5 | Mean ± SD | Ran k | % rating 4 or 5 | Mean \pm SD | |
|--|--------------------|-------------|----------|--------------------|-----------------|-----|
| | 5 | SD | К | 3 | | k |
| i. Rouvière's sulcus | 69.5% | 3.92 ± 1.07 | 3 | 74.1% | 3.95 ± 0.86 | 3 |
| ii. Sentinel lymph node (cystic lymph node of Lund) | 23.2% | 2.72 ± 1.02 | 8 | 13.7% | 2.75 ± 0.83 | 8 |
| iii. Base of segment IV (hilar plate) | 29.4% | 3.00 ± 0.97 | 7 | 16.3% | 2.91 ± 0.75 | 7 |
| iv. Calot's triangle area | 83.0% | 4.24 ± 0.82 | 2 | 91.5% | 4.39 ± 0.68 | 2 |
| v. Infundibulum-cystic duct junction (so-called elephant trunk sign) | 49.9% | 3.45 ± 0.97 | 4 | 48.5% | 3.44 ± 0.76 | 4 |
| vi. Sclero-atrophic gallbladder (so-called double hump sign) | 37.7% | 3.21 ± 0.92 | 6 | 19.3% | 3.03 ± 0.69 | 6 |
| vii. Critical View of Safety | 85.4% | 4.37 ± 0.86 | 1 | 91.5% | 4.56 ± 0.73 | 1 |
| viii. SS inner layer | 46.6% | 3.35 ± 1.01 | 5 | 38.7% | 3.25 ± 0.84 | 5 |
| How to prevent: | % rating 4 or | Mean ± | Ran | % rating 4 or | Mean \pm SD | Ran |
| | 5 | SD | k | 5 | - | k |
| i. Decompression of a distended gallbladder with needle aspiration | 43.9% | 3.33 ± | 7 | 44.1% | 3.38 ± 0.75 | 7 |

| | | 0.04 | | | | |
|---|---------------|---|-----|---------------|-----------------|-----|
| | | 0.96 | | | | |
| ii. Effective retraction of the gallbladder to develop a plane in the Calot's triangle area and identify its boundaries (countertraction) | 82.5% | $\begin{array}{c} 4.19 \pm \\ 0.80 \end{array}$ | 1 | 93.5% | 4.25 ± 0.60 | 1 |
| iii. Starting dissection from the posterior leaf of the peritoneum covering the neck of the gallbladder and exposing the SS inner layer above Rouvière's sulcus | 67.7% | 3.83 ± 0.94 | 5 | 74.1% | 3.80 ± 0.73 | 5 |
| iv. Maintaining the plane of dissection within the SS layer (i.e. exposing the SS inner layer) throughout laparoscopic cholecystectomy | 52.3% | 3.45 ± 0.97 | 6 | 54.1% | 3.50 ± 0.72 | 6 |
| v. Dissecting the lower part of the gallbladder bed (at least one-third) to obtain the critical view of safety | 71.4% | 3.91 ± 0.86 | 3 | 78.0% | 3.87 ± 0.68 | 4 |
| vi. Always obtaining the critical view of safety | 76.0% | 4.01 ± 1.02 | 2 | 83.5% | 4.08 ± 0.85 | 2 |
| vii. For persistent hemorrhage, achieving hemostasis primarily by compression and avoiding excessive use of electrocautery or clipping | 69.0% | 3.87 ± 0.91 | 4 | 82.4% | 3.98 ± 0.67 | 3 |
| viii. Intraoperative cholangiography | 32.6% | 2.93 ± 1.13 | 8 | 19.6% | 2.71 ± 0.91 | 8 |
| ix. Intraoperative ultrasound | 6.2% | 1.94 ± 0.91 | 10 | 3.7% | 1.78 ± 0.77 | 9 |
| x. Intraoperative indocyanine green fluorescent imaging | 8.9% | 2.03 ± 1.10 | 9 | 5.0% | 1.73 ± 0.88 | 10 |
| What are the alternatives: | % rating 4 or | Mean ± | Ran | % rating 4 or | Mean \pm SD | Ran |

2

| | 5 | SD | k | 5 | | k |
|---|-------|-------------|---|-------|---------------|---|
| i. Open conversion | 69.4% | 3.87 ± 1.17 | 1 | 79.8% | 4.07 ± 0.95 | 1 |
| ii. Fundus-first (dome-down) | 56.5% | 3.54 ± 1.07 | 3 | 65.4% | 3.63 ± 0.88 | 3 |
| iii. Subtotal (partial) cholecystectomy | 69.1% | 3.80 ± 1.00 | 2 | 75.0% | 3.81 ± 0.80 | 2 |
| iv. Cholecystostomy (drainage only) | 21.2% | 2.46 ± 1.17 | 4 | 9.6% | 2.15 ± 0.94 | 4 |

Table 6. Large-scale questionnaire survey on bile duct injury during laparoscopic cholecystectomy

| Author/Journal (Year) | Participants | Ν | Response rate, % | Nation | Summary |
|--|---|-------|---|-------------|--|
| Massarweh/J Am Coll Surg (2009) 29) | General surgeons randomly selected from ACS members | 4,100 | 44% | U.S. | Surgeons that were slightly older and in practice longer were associated with an increased rate of BDI. Surgeons in academic practice or who work with residents had lower reported rates of BDI. |
| Buddingh/World J Surg (2011) 30) | All members of the Dutch Society of Surgery | 1,206 | 40.40% | Netherlands | • If the CVS is not obtained, 50.9% of surgeons convert to open approach, 39.1% continue laparoscopically, and 10.0% perform IOC. |
| Pucher/Surg Endosc (2015) 22) | SAGES committee members | 407 | 1 st round: 40.2%, 2 nd round: 34.0% | U.S., U.K. | Establishing the CVS Understanding of relevant anatomy Appropriate intraoperative retraction and exposure Start dissection of Calot's triangle high on gallbladder Knowing when to call for help Surgeon able to perform and interpret IOC Appropriate use of energy devices by surgeon Timing of operation with reference to disease history Recognize need for conversion or alternate procedure |

| ✓ CVS How to prevent ✓ Effective retraction of the gallbladder to develop a plane in the Calot's triangle area and identify its boundaries (countertraction) ✓ Always obtaining the CVS ✓ For persistent hemorrhage, achieving hemostasis primarily by compression and avoiding excessive use of electrocautery or clipping | Present study | Expert surgeons, international | 614 | 1 st round: 60.6%, 2 nd round: 74.9% | Japan, Korea, Taiwan, U.S. and others | <u>How to prevent</u> ✓ Effective retraction of the gallbladder to develop a plane in the Calot's triangle area and identify its boundaries (countertraction) ✓ Always obtaining the CVS ✓ For persistent hemorrhage, achieving hemostasis primarily by compression | n |
|---|---------------|-----------------------------------|-----|---|---|--|---|
|---|---------------|-----------------------------------|-----|---|---|--|---|

ACS, American College of Surgeons; BDI, bile duct injury; CVS, critical view of safety; IOC, intraoperative cholangiography; SAGES, Society of American Gastrointestinal and Endoscopic Surgeons.

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