



# Prevention and acute management of biliary injuries during laparoscopic cholecystectomy: Expert consensus statement

## Laparoskopik kolesistektomi sırasında olan safra yolları yaralanmalarının önlenmesi ve erken yönetimi: Konsensus raporu

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### ABSTRACT

Gallstone disease is very common and laparoscopic cholecystectomy is one of the most common surgical procedures all over the world. Parallel to the increase in the number of laparoscopic cholecystectomies, bile duct injuries also increased. The reported incidence of bile duct injuries ranges from 0.3% to 1.4%. Many of the bile duct injuries during laparoscopic cholecystectomy are not due to inexperience, but are the result of basic technical failures and misinterpretations. A working group of expert hepatopancreatobiliary surgeons, an endoscopist, and a specialist of forensic medicine study searched and analyzed the publications on safe cholecystectomy and biliary injuries complicating laparoscopic cholecystectomy under the organization of Turkish Hepatopancreatobiliary Surgery Association. After a series of e-mail communications and two conferences, the expert panel developed consensus statements for safe cholecystectomy, management of biliary injuries and medicolegal issues. The panel concluded that iatrogenic biliary injury is an overwhelming complication of laparoscopic cholecystectomy and an important issue in malpractice claims. Misidentification of the biliary system is the major cause of biliary injuries. To avoid this, the "critical view of safety" technique should be employed in all the cases. If biliary injury is identified intraoperatively, reconstruction should only be performed by experienced hepatobiliary surgeons. In the postoperative period, any deviation from the expected clinical course of recovery should alert the surgeon about the possibility of biliary injury.

**Keywords:** Bile duct, bile duct injury, laparoscopic cholecystectomy

### ÖZ

Safra kesesi taş hastalığı çok sık görülür ve laparoskopik kolesistektomi en sık yapılan ameliyatlardandır. Laparoskopik kolesistektomi sayısındaki artışa paralel olarak safra yolları yaralanmaları da artmıştır. Safra yolları yaralanma sıklığı %0,3 ile %1,4 arasında bildirilmektedir. Laparoskopik kolesistektomi sırasında olan safra yolları yaralanmalarının çoğu deneyimsizlikten değil, temel teknik hatalardan ve yanlış yorumlamalardan kaynaklanmaktadır. Türk Hepatopankreatobiliyer Cerrahi Derneği tarafından düzenlenen ve genel cerrahi uzmanları, bir endoskopist ve adli tıp uzmanından oluşan uzman hepatopankreatobiliyer cerrahi çalışma grubu, güvenli kolesistektomi ve laparoskopik kolesistektomi sonrası safra yolları yaralanmaları konusundaki yayınları taramış ve değerlendirmişlerdir. E-posta yolu ile grup üyelerinin görüşlerinin alınması sonrası farklı tarihlerde iki kez toplantı yapılarak, güvenli kolesistektomi, safra yolları yaralanmalarının erken yönetimi ve medikolegal konular üzerinde bir uzlaşi metni hazırlanmıştır. Çalışma grubu, safra yolları yaralanmalarının, laparoskopik kolesistektominin çok önemli bir komplikasyonu ve malpraktis davalarının önemli bir konusu olduğunu vurgulamıştır. Bu komplikasyonu önlemek için tüm ameliyatlarda mutlaka "güvenlik için kritik görüş" tekniğinin kullanılması gereklidir. Ameliyat sırasında biliyer yaralanma olduğu farkedilirse, onarım mutlaka hepatobiliyer cerrahi konusunda deneyimli bir uzman tarafından yapılmalıdır. Ameliyat sonrası dönemde ise, beklenen seyirden farklı bir klinik tablonun ortaya çıkmasının, safra yolları yaralanmasının belirtisi olabileceği akılda tutulmalıdır.

**Anahtar Kelimeler:** Safra yolu, safra yolu yaralanması, laparoskopik kolesistektomi

### INTRODUCTION

Gallstone disease is common all over the world. Gallstones are frequently seen in European and North American populations, whereas it is rare in most of the African populations. Using autopsy series findings, Brett and Parker reported that the prevalence of gallstones in European populations was 15.7% in 1976 (1). The prevalence of gallstones in sonographically based epidemiologic studies is reported to be between 3.1% and 24.5% depending on geographical location (2).

Laparoscopic cholecystectomy is the most common surgical procedure in many countries. In 2014, 96.700 cholecystectomies (84500 laparoscopic and 12 200 open) have been performed in the state hospitals of Turkey. If university and private hospitals are included, the estimated total number of cholecystectomies in 2014 rises to about 200 000. The population of Turkey is 78 million and accordingly about 0.26% of the population in Turkey undergo cholecystectomy each year (3).

Many reports have cited increased use of cholecystectomy after the popularization of laparoscopic cholecystectomy (4). Concomitantly, parallel to the increase in the number of laparoscopic cholecystectomies, bile duct injuries increased dramatically (5). It was shown that laparoscopic approach is associated with two-fold increase in the risk of bile duct injuries compared to open cholecystectomy, and addition-

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ally these injuries were comparatively more severe (6). The reported incidence of bile duct injuries show variations depending on the patient population as well as the definition criterias used, and ranges from 0.3% to 1.4% (7). Many of the bile duct injuries during laparoscopic cholecystectomy are not due to inexperience, but are the result of basic technical failures and misinterpretations (8).

Bile duct injuries are severe complications which may lead to bile leaks and peritonitis, bile duct strictures, recurrent cholangitis, sepsis, secondary biliary cirrhosis, liver failure and finally may result in mortality (9). Even if adequately managed and repaired, these patients usually require life-long follow-up to recognize possible recurrences and further complications.

In this country, about 90% of the 200 000 cholecystectomies performed annually are performed laparoscopically. As an estimation, 600 to 2400 patients will suffer from bile duct injuries per year (3). Some of these injuries are minor and conservative treatment is sufficient, but many patients eventually require reconstructive surgery. Besides medical problems, these injuries also have the potential of being subject to medicolegal claims. Bile duct injuries are among the leading reasons of medicolegal claims not only in the field of general surgery, but overall.

In 2012, the European Association for Endoscopic Surgery published clinical practice guidelines on the prevention and treatment of bile duct injuries during laparoscopic cholecystectomy (10). These evidence based recommendations form the basis of contemporary clinical practice standards in terms of proper surgical technique and approach to management of biliary injury. On the other hand, circumstances may vary according to populations and geographical locations. Taking this into account and adding the issues of laparoscopic repair, approach to vascular injury, and medicolegal considerations, a study group was formed by the Turkish Association of Hepatopancreatobiliary Surgery to re-evaluate the prevention and management of biliary injuries in the early postoperative period. Consensus statements were prepared to provide recommendations for practicing surgeons.

#### STUDY GROUP, METHODOLOGY

The study was conducted by the Turkish Association of Hepatopancreatobiliary Surgery and prepared by a group of expert hepatopancreatobiliary surgeons, an endoscopist, and a specialist of forensic medicine. Experts were chosen according to their clinical experience and scientific standing. A brief explanatory report and a questionnaire including the principal and critical issues regarding the mechanisms, prevention and management of bile duct injuries during laparoscopic cholecystectomy were e-mailed to these experts in February 2014. Two months later, the panel joined at a consensus development meeting that was organized by the Association in Ankara. The purpose of the study, comments of the panel regarding the questions, and controversial aspects of bile duct injuries were discussed in a one-day meeting. The total number of participants was 17. A modified Delphi procedure was used for consensus development. After the first round, opinions were grouped under specified headings and sent back to the experts by e-mail. Participants ranked their agreement with each heading in the questionnaire. Agreement or disagreement was indicated on a 7-point Likert scale (1 indicates strong disagreement, 7 indicates complete agreement) (11).

The rankings were then collected, analyzed, reviewed and a repeat version of the questionnaire was e-mailed to the panel for a third round. Experts had the opportunity to change their scores and re-rank their agreement according to the feedback from the group. Results were re-analyzed and re-rankings were evaluated to define consensus level.

After the third round the panel was joined in a half-day meeting in January 2016 and the consensus statements were finalized.

The strength of consensus was given in two categories. Strong consensus implies that more than 80% of the participants completely agree or agree. Weak consensus indicates that the level of agreement was between 60% to 79%.

#### CONSENSUS STATEMENTS

The questions and answers of the consensus meeting are discussed in detail and the following results were reached:

##### 1. Safe Cholecystectomy

###### a) What are the essentials of safe laparoscopic cholecystectomy?

Technical quality of the laparoscope, instruments and operating theatre equipment is very important for safe surgery. If these equipment are not adequate, safety of the operation may be at risk. Strict adherence to principles of safe cholecystectomy prevents majority of the complications. Rationale of the "critical view of safety" is to preclude misidentification of the bile ducts. Cephalic traction of the gallbladder fundus inferiorly and laterally will decrease the redundancy of the infundibulum. Additionally, lateral retraction of the infundibulum will expose the Calot's triangle and the cystic duct and artery can be seen lying perpendicular to the common bile duct. Dissection should start close to the gallbladder infundibulum and not on the tubular structures joining the gallbladder. Peritoneum on the infundibulum is divided on both medial and lateral aspects. Lateral dissection is usually safe and facilitates medial dissection. Distal one third of the gallbladder bed should be completely lifted off the liver bed before dividing any tubular structure. No tubular structure should be clipped or cut unless completely (360-degree) encircled. There should be two and only two tubular structures joining the gallbladder. Either the cystic duct or artery can be clipped first, depending on the anatomy and ease of the procedure. Electrocautery must be used very cautiously to avoid thermal damage. If critical view of safety cannot be achieved by any reason, laparoscopic cholecystectomy should not be performed (10, 12). In this situation, further approach depends on the anatomy of the patient and the preference and experience of the surgeon. In case of unclear anatomy, conversion to open surgery is advocated. If anatomy is clear, but dissection cannot proceed mainly because of inflammation, partial (subtotal) cholecystectomy can be considered, although the safety of this approach is questionable (13). In partial laparoscopic cholecystectomy, either the cystic duct or the remnant gallbladder may be sutured and closed (14-16). Dissection can be done by scissors, dissector, hook etc. depending on the preference of the surgeon.

**Statement:** Critical view of safety should be obtained in all cases. If the critical view of safety cannot be achieved, either subtotal cholecystectomy or conversion to open cholecystectomy may be considered depending on the experience of the surgeon.

**Consensus:** Strong.

**b) What is the preferred way of achieving pneumoperitoneum and entering the abdominal cavity? Veress needle method, direct trocar insertion or open entry technique?**

The way of achieving pneumoperitoneum has no role in the development of biliary injuries but may be associated with bowel perforation and major vascular injuries. In one randomized study with limited number of patients, the open technique was shown to have significantly less complications compared to the blind approach (17). In patients with previous abdominopelvic surgery, especially with midline incisions, complications may be increased with the Veress needle method. In gynecologic laparoscopic surgery, the Veress needle puncture method was found to increase minor complications compared with both the open and direct trocar insertion techniques (18). Direct trocar insertion may be a safe technique in thin patients (19-21).

**Statement:** Current evidence in laparoscopic cholecystectomy is not sufficient to recommend a preferable way for achieving pneumoperitoneum and entering the abdominal cavity. In patients with prior abdominopelvic surgery, open entry with direct vision may decrease intestinal and vascular injuries.

**Consensus:** Weak.

**c) Is there a difference between 30-degree and 0-degree laparoscopes on the development of biliary injuries?**

A thirty-degree laparoscope may be helpful to minimize biliary injuries by increasing the exposure, but there are no clinical studies about the effect of laparoscope angle on the development of biliary complications (22-25).

**Statement:** Laparoscopic cholecystectomy can be safely performed with either a 30-degree or 0-degree laparoscope. Using a 30-degree laparoscope may improve exposure.

**Consensus:** Weak.

**d) What is the role of intraoperative cholangiography in laparoscopic cholecystectomy?**

Selective use of intraoperative cholangiography is recommended, rather than its routine use. Although there are controversial studies, the evidence in the literature do not support routine use of intra-operative cholangiography. Hundreds of intra-operative cholangiographies need to be performed to diagnose one bile duct injury. Intraoperative cholangiography also lengthens the operation time (26). On the other hand, performance and interpretation of intra-operative cholangiography should be taught to residents during their general surgery training (27-30).

**Statement:** Routine intraoperative cholangiography is not necessary in laparoscopic cholecystectomy, but should be considered under the following conditions: uncertain biliary anatomy, planned laparoscopic common bile duct exploration, suspicious or evident injury of the bile ducts. The skill and knowledge of intraoperative cholangiography should be incorporated into the curriculum of general surgery residency.

**Consensus:** Strong.

**e) Is the risk of biliary injury increased in single-incision laparoscopic cholecystectomy?**

Single-incision laparoscopic cholecystectomy is largely operator and instrument dependent, and skills of the surgeon may have an influence on the complication rates and outcome (31-33).

Most of the studies report the results of experienced centers and it may not be suitable to extrapolate these findings. In these studies, postoperative pain, duration of the operation, cosmetic results and incisional hernia development were rather studied in more detail (34-36). Additionally, long term results are lacking in many reports (37-39).

**Statement:** Single-incision cholecystectomy does not increase the risk of biliary injury in the hands of experienced surgeons.

**Consensus:** Weak.

## 2. Biliary Injury

**a) What are the risk factors for bile duct injury?**

There is no consensus in clinical studies about patient-related risk factors on the development of biliary injuries. In most studies, patient age greater than 70, male sex, acute cholecystitis, bleeding during surgery, impacted stone in Hartmann's pouch, severe thickening of the gallbladder wall, cirrhosis, previous upper abdominal surgery and anatomical variations are considered as predictors of difficult laparoscopic surgery. Whether the risk of biliary injury is increased in these difficult cases is unclear. Misidentification of biliary structures is the leading cause of biliary injury and patient related factors may contribute to this error. Although the latter point is controversial, these injuries are more often seen in difficult cases (40-48). Lack of experience is a risk factor, but injuries may also occur in the hands of experienced surgeons (49, 50).

**Statement:** Surgeons, especially inexperienced, should be more alert for the possibility of biliary injury during laparoscopic surgery in difficult cases.

**Consensus:** Weak.

**b) What are the symptoms and signs of biliary injury?**

Most biliary injuries are diagnosed in the postoperative period and about 30% of these are diagnosed after discharge (51). Major symptoms and signs depend on the type of injury. Biliary leak presents mainly with abdominal pain, tenderness, fever and signs of sepsis. Biliary strictures usually have a more indolent course and jaundice may be the presenting symptom. Nausea and vomiting, tachycardia, weakness, anorexia are common symptoms in both type of injuries. Liver function tests, mainly cholestatic enzymes are elevated. Usually, there is delay in diagnosis. In these patients, cholangitis is the leading symptom of presentation (52, 53).

**Statement:** The possibility of biliary injury should be considered whenever the general condition of the patient is poor after surgery and not improving.

**Consensus:** Strong.

**c) What is the management of biliary injuries diagnosed intra-operatively?**

Whenever biliary injury is suspected intraoperatively, laparoscopic intra-operative cholangiography should be performed. If this confirms the diagnosis, immediate repair may be performed in specialist hepatobiliary centers 1 See comment in PubMed Commons below (54). Strasberg type E injuries should be treated with hepaticojejunostomy (55-59).

When the surgeon is not experienced in biliary reconstructive surgery, referral to an experienced hepatobiliary center will better serve the interest of the patient. Laparotomy should be avoided as this may further complicate the injury (60). Placing a subhepatic drain and constituting contact with the center before referral is beneficial. Any delay may worsen prognosis.

An alternative intervention is inviting an experienced surgeon for definitive on-table repair if the regulations of the center and the country permit this approach (61).

**Statement:** Immediate biliary reconstruction should only be attempted by experienced hepatobiliary surgeons. Otherwise, the patient should be referred to an experienced center with a subhepatic drain without attempting a laparotomy.

**Consensus:** Strong.

#### d) Can biliary injuries be repaired laparoscopically?

There are no clinical studies on the results of immediate laparoscopic repair of biliary injuries. In experienced centers, laparoscopic repair of minor leaks can be performed after obtaining an intra-operative cholangiography (62). Bile duct transection should not be repaired laparoscopically as this procedure requires advanced laparoscopic skills and fine instruments. Similarly, evidence on late repair of biliary strictures by laparoscopic hepaticojejunostomy is scarce. Long term follow-up of these patients is not known (63, 64). Laparoscopic repair of biliary strictures should only be considered in research protocols in highly specialized centers.

**Statement:** On-table immediate laparoscopic repair of biliary injuries is not recommended except for minor leaks from the cystic duct or liver bed. Current evidence also does not permit to advise any late laparoscopic repair.

**Consensus:** Strong.

#### e) How is right hepatic artery injury handled?

Associated right hepatic artery injury in patients with biliary injury during laparoscopic cholecystectomy is not rare. Despite this fact, a correlation between right hepatic artery injury and success of biliary reconstruction has not been demonstrated (65). Furthermore, right hepatic artery repair is a demanding procedure with low success rates (66). Liver necrosis or ischemia of the hepatic ducts occur in about 10% of the cases and may necessitate intervention (67, 68).

Right hepatic artery injury alone usually does not lead to liver necrosis because of preformed arterial hilar shunts at the level of hilar plate (69). In the presence of combined arterial and biliary injury, the possibility of biliary ischemic damage and liver necrosis is increased. The distortion of hilar plate further increases this risk (70).

In case of proper hepatic artery or portal vein injury, the patient should be referred to a hepatobiliary center emergently.

**Statement:** Right hepatic artery repair is usually difficult and benefit of this repair is uncertain.

**Consensus:** Weak.

### 3. Medicolegal Issues

#### a) What are the medicolegal perspectives of laparoscopic biliary injuries?

Laparoscopic cholecystectomy is among the leading subjects of medicolegal claims (71, 72). The first step in dealing with medicolegal issues is the indication for cholecystectomy. The indication should be objective and the patient complaints, physical examination findings and imaging studies should be clearly documented in the patient chart. If the indication of surgery is not straightforward or the documentation is doubtful, this may be a reflection of substandard care (73). The signed informed consent form should be obtained and placed in the patient's file prior to surgery. This form should include detailed information about the procedure and potential risks and complications. Before the operation, the patient should be aware of the potential to undergo major surgery.

Operative notes should be written as soon as possible after the operation, explaining the critical steps of the procedure. If injury was encountered during surgery, the extent and type of intra-operative approach should be described in detail. The patient and the family must be informed in detail following the operation. It is wise to discuss the referral of the patient to a specialized hepatobiliary unit (74). The perception of the patient and family of negligent behavior of the surgical team is usually more noteworthy than the injury itself. Delay in diagnosis or negligence of appropriate interventions should be avoided by all costs and a proactive approach should be instituted. Delay in diagnosis is usually the key issue in medicolegal claims. Injuries may occur despite employing safe cholecystectomy techniques and many of these injuries are regarded as surgical complications. On the other hand, delay in diagnosis despite warning signs and symptoms and laboratory and imaging studies, thus inappropriate management of the patients may be the subject of malpractice.

**Statement:** It is the surgeon's responsibility to document the indication, obtain consent, and perform a proper surgical procedure and post-operative follow-up. In the event of an inadvertent biliary injury, any delay in diagnosis and mismanagement should be avoided.

**Consensus:** Strong.

#### CONCLUSION

Iatrogenic biliary injury is a devastating complication of laparoscopic cholecystectomy and a growing issue in malpractice claims. Misidentification of the bile ducts is the leading cause of biliary injury. To avoid this, the "critical view of safety" technique should be employed with utmost care. Inexperienced surgeons should be cautious about using the single-incision technique, as this may increase the risk of biliary injury in difficult cases. If biliary injury is identified intraoperatively, reconstruction should only be undertaken by experienced hepatobiliary surgeons following an operative cholangiogram. In the postoperative period, any deviation from the expected clinical course of recovery should alert the surgeon to suspect biliary injury and take a proactive approach to diagnosis and proper management

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