System Approach to Prevent Common Bile Duct Injury and Enhance Performance of Laparoscopic Cholecystectomy

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Abstract: Experience collected from 5200 cases of laparoscopic cholecystectomy (LC) and 29 patients (6 ours, 23 referred) with major common bile duct (CBD) injury during LC in our institute between December 1990 and July 2004 was reported to demonstrate that the system approach we applied in performing LC prevents CBD injury and enhances surgical performance. Each case of CBD injury was meticulously analyzed to identify causative factors. We developed preventive strategies focusing on 4 dimensions: patient, environment, procedure, and operator. Surgical performance was then evaluated to demonstrate improvements. Incidence of CBD injury was calculated for early and latter halves of the series to compare 5 parameters of surgical performance: patient selection, operation time, indwelling drainage tube, surgeon, and conversion rate. Results of accident analysis demonstrated that CBD injury followed definite mechanisms; several warning signs appearing before and during injury were identified and classified. According to these results, we designed strategies to prevent injury, including: setting up patient-selection program, controlling surgical environment, developing error-proof procedures, and constructing training programs. Incidence of CBD injury in the whole series was 0.12% (6/5200), 0.27% in early half (6/2224), and zero (0/2967) in latter half. Attending doctors had significantly shorter operation times in latter period for both elective and emergent LC. Rate of using drainage tubes for elective surgery by attending doctors was significantly decreased in latter period. Operation time for elective surgery by residents was similar in both early and latter periods. However, residents in latter period had longer operation times (around 23 min long, $P < 0.001$) for emergent LC. Steps of our system approach include: (1) detailed accident analysis focusing on patient, environment, procedure, and surgeon; (2) developing 4 strategies directly responding to accident analysis results, including proper patient selection, control of environment, error-proof procedures, and a well-designed training program; and (3) demonstrating improved patient safety and surgical performance. Consistent use of systems approach promises continuing quality improvement. We believe our working model will help perform safer LC and also benefit other medical disciplines.

Key Words: bile duct injury, laparoscopic cholecystectomy, system approach

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Laparoscopic cholecystectomy (LC) has become standard management of gallstone disease.[1,2] However, adaptation of LC is associated with an increased incidence of common bile duct (CBD) injury.[3,4] Occurrence of CBD injury always results in difficult reconstruction, prolonged hospitalization, and high risk of long-term complications.[5,6] Many studies have focused on the classification and management of CBD injury.[7,8] Nevertheless, global incidence of CBD injury has remained fairly constant around 0.5%, as reported by various meta-analyses studies over a 15-year period (1993: 0.47%,[9] 365/77,604; 1998: 0.50%,[10] 561/114,005; 2003: 0.5%,[11] 7911/1,570,361).[9–11] These studies have shown that traditional surgical strategies have not reduced the incidence of CBD injury. This situation resembles the report titled "Cross the Quality Chasm" published by The American Institute of Medicine 2001, which stated, "Trying harder will not work; poor designs set the workforce to fail. If we want safer, higher-quality of care, current care systems cannot do the job; changing systems of care will."[12] The information transferred from this statement is exactly what we want to present in this article: focus on a special working system and its major problem, thoroughly analyze system details and problem, develop and adapt strategies for problem solving, and deliberately evaluate results to form a continuous cycle of improvement. We summarized this cycle as a system approach and initiated as the first step of the approach: to focus on the accident itself! "Accidents are a form of information about a system; they represent places in which the system failed and the breakdown resulted in harm."[13] We must first determine where the problem lies before we can make improvements.

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Another important idea occurred to us from multi-etiologies of a single accident addressed in Reason's Swiss cheese model, which represents how defenses, barriers, and safeguards are penetrated by an accident.[14] Essentially, we must understand and classify what type of factors contribute (hole in the cheese in Reason's model) to these accidents and whether it is possible to develop strategies toward preventing them from happening again. Attention has increasingly been given to issues related to accidents and safety, and to learning from other systems that demand high security (commercial aviation, nuclear energy), to quantify medical quality, and to explore relationships to human errors in surgery.[15–20]

In this study, we first performed a detailed analysis to determine how and why injuries occurred in LC and to categorize potential causative factors. We then tried to find strategies that might prevent these injuries from happening again. Finally, we documented the effectiveness of our strategies through indicator analysis.

MATERIALS AND METHODS

Patients

Five thousand two hundred LC cases were performed in Cathay General Hospital between December 1990 and July 2004. Twenty-nine cases of major CBD injury were managed surgically during the same period, including 6 that happened in our own hospital and 23 referred from other hospitals for surgical management. Videotapes of CBD injury were collected and analyzed. Our own 6 major CBD injury cases all happened before case No. 2224 (September 1997); case serial numbers for each injury were: No.63, 386, 526, 800, 1049, and 2224.

System Approach

The goal of our system approach is to reform the tentative working system, making it more effective and safer. It includes 3 steps: accident analysis, strategy development, and database evaluation to verify these strategies. Each step involves specific details. Accident analyses were performed through detailed review of all operation tapes of major injury. Strategies for preventing CBD injury were developed according to the results of accident analyses. Our database on the incidence of CBD injury in different stages was examined and surgical performance was measured using 5 indicators: operation time, indwelling drainage tube or not, attending doctor or resident as surgeon, and conversion rates to find any difference before and after introducing new strategies.

The incidence of CBD injury was determined for the whole study period (1990 to 2004), and for the early half (1990 to 1997) and latter half (1997 to 2004) of our series to find improvements. Two additional identical sample periods representing early and latter halves of our series were selected to compare surgical performance. Because improvement of surgical performance is a continuous process, and no definite point was determined as to when we started implementing these strategies, a 4-year interval is shown between the 2 selected sample periods (1995 to 1997; 2002 to 2004).

The early period was from July 1995 to June 1997(cases 1373 to 2080; total 672 cases, 28 cases/mo) and the latter period from July 2002 to June 2004 (cases 4338 to 5203; 866 cases, 36 cases/mo).

RESULTS

Accident Analyses

After accident analyses, we found that CBD injury always followed a definite sequence (Fig. 1). Severity of injury depended on the step in which the error was identified and the surgeon stopped the procedure. In patients with the most severe injuries, CBD had been cut and divided twice and the site of injury was always very close to the liver hilum, making repair difficult and resulting in poor long-term prognosis (last picture in Fig. 1). The root cause of injury was misidentifying the distal CBD as the cystic duct, which the surgeon tried to dissect for clip and division. The surgeon performed the procedure as smoothly as in a routine LC and did not notice that the CBD was being clipped and cut.

Warning Signs

We recognized several warning signs associated with injury, including:

1. Most common warning sign was status of acute inflammation, adding difficulty to procedures.
2. Unsuspected bleeding or appearance of unpredicted vessels or ducts: in these situations, possibility of anatomic variation does exist but possibility of a deviated operating target is more customary.
3. Acute inflamed tissue always appears different from normal tissue; it may be hard, dense, severely adhesive, and/or edematous. Dissection area should always be within area of acute inflammation, which may complicate dissection, but is nevertheless safe. By contrast, if the dissection areas become soft or loose during surgery, it indicates that the dissecting target has shifted toward the noninflamed area and therefore away from the safe zone. This shifting may result in inappropriate and dangerous dissection close to the CBD.
4. Paradoxical bile color: white bile or turbid bile is common when the gallbladder is acutely inflamed. If clear bile is observed during dissection, or clear bile

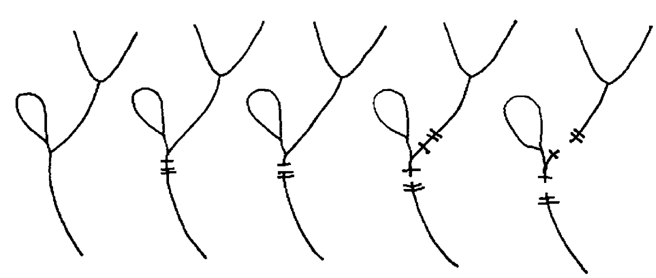

FIGURE 1. Mechanism of CBD injury.

appears after dirty bile, the surgeon must immediately consider bile origin—gallbladder or CBD. To the best of our knowledge, this important manifestation has not been reported elsewhere.

5. Different mucosal pattern of CBD and cystic duct. The mucosal patterns of CBD and cystic duct are different; the former is smooth and thin, and the latter villous and thick. If an inconsistent mucosal pattern is found during cutting of cystic duct, the possibility of CBD injury should be considered.
6. Surgeons' feelings of hesitation during surgery should be taken as a sign that something unusual has happened and that the situation must be reevaluated. Encountering these situations typically means that the surgeon's experience has been exceeded.

Types of Error

Besides the warning signs we identified, our analyses also identified 4 types of factors that lead to injury: patient, environmental, procedural, and human factors (Fig. 2). Any of these factors, as in Reason's cheese model, could contribute to the injury.

1. Patient factors include severe inflammation or surrounding adhesions owing to acute cholecystitis or previous operation, increasing difficulty of dissection and risk of injury. Other patient factors include old age and concomitant diseases, such as diabetes or cardiovascular disease, which can increase surgical risk.
2. Environmental factors were defined as preventable factors that could increase difficulty of performing the operation, including blurred visual field, inadequate lightening, trouble maintaining proper intra-abdominal pressure, poorly fitted instruments, and insufficient training or experience of assistants. Every operator should be very sensitive to the presence of these factors, which must be addressed immediately to avoid injury.
3. Procedural factors were defined as omission of surgical steps that might have prevented injury, or potential harmful actions such as failure to identify anatomy before cutting, or failure to adequately expose Calot's triangle, including cephalic and lateral traction of gallbladder. Another procedural factor is failure to include a proper checking protocol for early identification of warning signs of injury.
4. Human factors were defined as behavioral characteristics contributing to injury, including
   a. Failure to stop and reassess performance when operator feels hesitant during the operation, as evidenced by slowing movement or delaying clipping and cutting actions. Usually adequate effort was not taken to determine proper action in these situations.
   b. Panic often followed discovery of some accident (bleeding) and resulted in further incorrect action (eg, clipping without precise identification of anatomy).
   c. Inability to tolerate the "environment of uncertainty" created by near-injury or difficult situations that create a feeling of necessity to proceed rapidly with the "regular procedure" rather than to stop and observe the whole event or to take a different perspective, perhaps even to call for help through a peer opinion.
   d. Limited knowledge and experience with CBD injury, which may lead to lack of quick and appropriate response and development of advanced complications.

Safe Working System

Our review of these accidents led to the development of 4 strategies for constructing a safe working system, including: patient selection, control of environment, formulated error-proof procedures, and a detailed training program for young surgeons (Fig. 3). The 4 strategies are:

1. Identify patients with high risk factors that could increase risk of injury, such as acute cholecystitis, severe adhesions due to previous surgery, inflammation, and concomitant CBD stone.

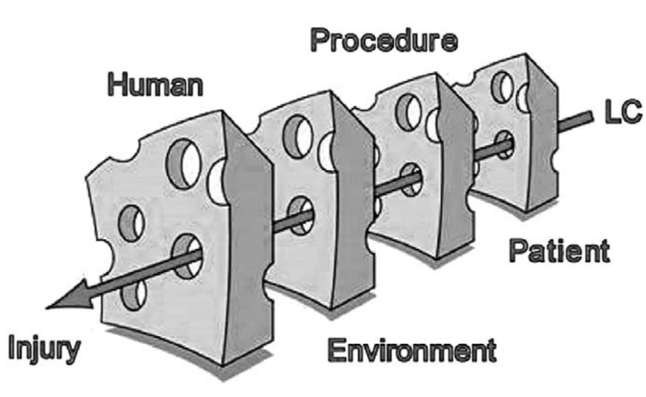

FIGURE 2. Factors of CBD injury based on Reason's Swiss cheese model of accident happening.

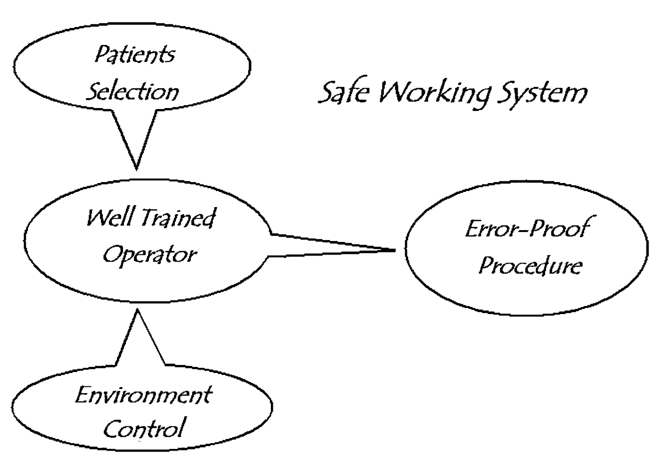

FIGURE 3. Elements of a safe working system.

2. Appropriate response to the operational environment so that problems encountered during the course of surgery can be dealt with adequately before they compromise safety. For example, sometimes the scopeman was not especially well trained and the operation was interrupted frequently due to blurred vision. At this moment, much effort must be paid to correcting vision and increasing safety of the operation. Surgeons should not operate in environments that they cannot totally control.
3. Adoption of an error-proof procedure: We developed a formulated error-proof procedure for LC, the key elements was described below.

Error-Proof Procedure

a. Identify: "If you don't want injury, find it first!" Although identification could be considered the most important step in LC, this step was frequently ignored because identification itself is not a dynamic action, but a state of close inspection. Before dissection, surgeons should make a concerted effort to identify the CBD location. Labeling of danger and safe zones can also facilitate a safe start to subsequent procedures.
b. Recognize landmarks: maintaining awareness of CBD location is essential. CBD landmarks include the round ligament (located at the left portal branch), duodenum (CBD is always found vertical to it), cystic lymph node (cystic artery is always found behind it), cystic artery (always parallel with cystic duct), and Hartmann's pouch (upper most part of cystic duct).
c. Maintain proper traction: appropriate traction of the fundus cephalic and Hartmann's pouch right lateral traction for extending the angle of the cystic duct and CBD is necessary for safe dissection and identification of the cystic duct and artery. Incomplete traction is a common mistake made by beginners.
d. Adequate dissection of the serosa from both anterior medial and posterior lateral sides of Hartmann's pouch is needed to expose the cystic duct and artery gradually and safely.
e. Proper check points: we set up 4 check points for LC and before crossing these check points, we performed an extra rechecking action, including adding photographs of these points to the surgical record. The 4 "check points" are: (1) before the operation an image is taken of the gallbladder fundus pushed cephalic and Hartmann's pouch pushed right lateral, and also include visible CBD; (2) an image of cystic duct is taken before it is clipped and cut and also CBD and liver hilum; (3): an image of liver bed is taken after removing gallbladder; (4): an image of the removed specimen is taken with visible orifice of cystic duct.

4. Well-designed training program: our training program focuses on 4 elements: knowledge base of LC, technique-related skills, standard error-proof procedure, and non–technique-related skills. In our training program we emphasize the non–technique-related skills, including ability to control environment, leadership of surgical team, proper personal behavior, appropriate response to difficult situations, avoidance of dangerous actions, alertness to warning signs, and willingness to call for help. Calling for available help should be considered an important action for all surgeons. Actually, in 3 cases of the latter period, peer consultation prevented CBD transections.

Our training program starts with students in the role of second assistant observing how to perform LC. It is important for surgeons to clearly demonstrate technique-related skills, steps of the error-proof procedure and non–technique-related skills. After the observation stage, trainees can start to use the laparoscope as scopeman, and trainees should then be required to demonstrate adequate vision throughout the operation without any guidance from the operator. This requires a thorough understanding of the procedure and also the ability to help control the environment so that it is conducive to injury prevention. Once these skills have been demonstrated, trainees may be authorized to start hands-on surgery. It is very important that the instructor stands by and provides thorough surveillance of the first few LCs performed by trainees. During this period, instructors should provide direct feedback to trainees about pitfalls and technique nuances that may make the operation go more smoothly. This surveillance period should also be used to highlight potentially dangerous behaviors and how to avoid them.

Data Analysis

Our database was checked to compare results before and after introduction of these strategies. In this series, no CBD injury occurred after patient number 2224 (September 1997). Overall incidence of CBD injury throughout the entire study period was 0.12% (6/5203; December 1990 to June 2004). Incidence was 0.27% (6/2203) in the early half of the series (December 1990 to September 1997; 2203 cases/82 mo), while no cases of CBD injury occurred in the latter half of the study period (October 1997 to June 2004; 3000 cases/81 mo).

Differences in surgical performance were analyzed in 2 identical periods, early and latter, before and after implementation of our error-proof strategies, with a 4-year gap between. Results are summarized as follows:

1. Operation time for attending doctors to perform both elective and acute surgery was significantly shorter in the latter period compared to the early period (elective: later; 38.5 ± 13.6 vs. early; 60.8 ± 28.2 min, $P < 0.001$; 2 sample t test, acute: latter; 68.9 ± 28.2 vs. early; 80.0 ± 43.0 min, $P = 0.043$; 2 sample t test) (Table 1).
2. Operation time for residents to perform elective surgery in the 2 periods was similar (latter: 62.3 ± 24.9 min vs. early: 64.6 ± 29.9 min, $P = 0.404$; 2 sample t test). However, residents had a significantly longer operation time for acute surgery performed in the latter period (latter; 103.4 ± 46.3 min

TABLE 1. Comparison of the Operation Time for Attending Doctors and Residents to Perform Both Elective and Acute Surgery in Recent and Early Period With 2 Sample *t* Test

	Attending Doctors			Residents		
	Elective	**Acute**	***P***	**Elective %**	**Acute %**	***P***
Operation time						
Later period	38.5 ± 13.6 min	68.9 ± 28.2 min	< 0.001	62.3 ± 24.9 min	103.4 ± 46.3 min	< 0.001
Residents	60.8 ± 28.2 min	80.0 ± 43.0 min	0.015	64.6 ± 29.9 min	79.8 ± 30.9 min	0.001
P	< 0.001	0.043		0.404	0.003	

Two sample *t* test.

vs. early; 79.8 ± 30.9 min, $P = 0.003$; 2 sample *t* test) (Table 1).

3. In elective surgery, attending doctors used a drainage tube less frequently in latter period than in early period (latter: 6.5%; 27/415, vs. early: 15.3%; 41/268, $P < 0.001$; χ^2 test). By contrast, the rate of indwelling drainage tubes used by attending physicians in acute surgery did not differ significantly between early and latter periods (latter: 57.7%; 75/130, vs. early: 55.1%; 43/78, $P = 0.946$; χ^2 test) (Table 2).
4. For residents, rate of using a drainage tube in elective surgery was similar in both periods (latter: 24.3%; 56/236, early: 21.8%; 54/248, $P = 0.577$; χ^2 test), whereas the rate of using indwelling drainage tubes in acute surgery showed no significant increase in latter period (latter: 70.6%; 36/51, early: 57.6%; 34/59, $P = 0.269$; χ^2 test) (Table 2).
5. Percentage of residents as operators decreased in the latter period (early period: 47%; 307/655, latter period: 34%; 281/826).
6. No conversion of LC happened in the latter elective surgery group for either attending doctors or residents compared with 2 and 3 conversions by attending doctors and residents in the early elective surgery group. One conversion occurred in each attending doctors and residents groups in latter-period acute surgery group compared with 2 and 3 conversions in each attending doctors and residents groups in the early acute surgery group.

TABLE 2. The Difference in the Rate of Drainage Tube Indwelling Between Attending Doctors and Residents; Recent and Early Periods

Factor	Attending Doctors	Residents	*P*
Rate of drainage tube indwell			
Elective			
Recent	6.5%; 27/415	24.3%; 56/236	< 0.001
Early	15.3%; 41/268	21.8%; 54/248	0.083
P (χ^2 test)	< 0/001	0.577	
Acute			
Recent	57.7%; 75/130	70.6%; 36/51	0.097
Early	55.1%; 43/78	57.6%; 34/59	0.218
P	0.946	0.269	

With χ^2 test.

DISCUSSION

Investigation of causes of medical errors has led to better understanding that the everyday surgical environment is not as safe as may be expected, and that surgeons as human beings will inevitably make mistakes. Considering accidents as information about a failed system is an effective strategy for improving the safety and quality of our medical care systems.[10,19]

The accident analysis process provides understanding of the background, causative factors, and causative mechanisms of accidents, and also indicates that most injuries are preventable. Our accident analysis process was especially concerned about human, environmental, and procedural factors and we expected to gain critical information to improve safety.

Mature surgeons should not only be familiar with *how* to do things right but should also realize how wrong things happen. In our study of accidents, signs characteristic of near-injury or injury were frequently either ignored or responded to in an inappropriate manner. We asked what we could do if we wanted to teach young surgeons to react properly in an unfamiliar situation. We brought up the warning signs of injury as an important result of accident analysis; to the best of our knowledge there have been no similar reports in the literature that summarize these warning signs. In our study, we wanted to be clearly aware of surgeons' actions in a case of near or existing injury.

Error-proof Procedure

The idea of creating an error-proof procedure originated from the automatic teller machine model, which prevents users from forgetting to take back their bank card simply by requiring users to taking back the card before withdrawing money.[21] If this procedure were to be reversed, the incidence of forgetting the card would increase dramatically. This is an excellent example of how a procedure can be designed to prevent potential errors. It inspired our desire to develop an error-proof procedure for LC. To construct a safety network, our error-proof procedure had to have multiple components focusing on each potential risk of injury (Fig. 4). We believed that no single step alone could reach this goal. It has long been debated about using an intraoperative cholangiogram (IOC) to prevent CBD injury.[21] Although we doubted that IOC itself could prevent injury, we believed that

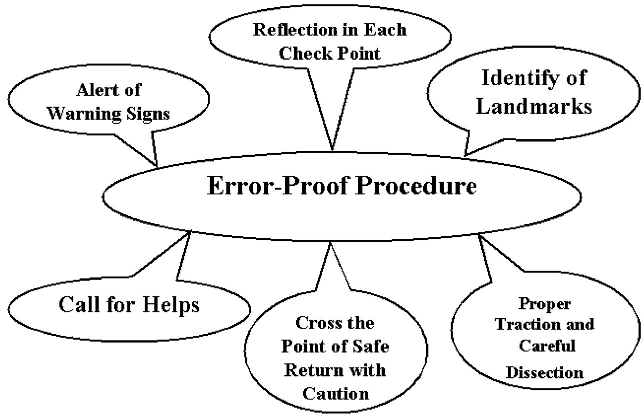

FIGURE 4. Elements of an error-proof procedure.

identifying the cystic duct for IOC could prevent injury. No study had been conducted to compare the incidence of CBD injury between IOC groups and groups without IOC but with performance of the same dissecting steps as in IOC group. In our institute, IOC was not performed as a procedure for preventing CBD injury during LC, but as an alternative procedure for endoscopic retrograde cholangiography to survey the existence of choledocholithiasis. Actually, after the introduction of magnetic resonance cholangiopancreatography, application of both IOC and endoscopic retrograde cholangiography were dramatically decreased in our institute.

Check Points

We designed 4 check points in our error-proof procedure, taking the idea from aviation terminology, "point of safe return." In aviation, before crossing specific points, a pilot can go back to the departure point safely without any sacrifice or injury. In LC, the most obvious example is the step of clip and divide, which must be performed very carefully to avoid crossing the "point of safe return" with resulting injury. Another important check point is to identify CBD before dissection, although this is not always possible due to inflammation or obesity. If CBD can be identified, the surgeon will know exactly where the danger zone is; (if not, the surgeon is alerted at the beginning that an important danger zone was not identified and more attention should paid throughout the next procedural steps) if not, the surgeon should aware that in such an environment of uncertainty more attention should paid throughout the next procedural steps. The 4 check points in our procedure have been shown previously. The use of different check points could be debated, but the primary intent of using these check points is to add a protective mechanism in the procedure to prevent injury.

A well-trained surgeon is essential for safe, successful surgery. In this series, almost all injuries were singular events that had not been previously encountered by the surgeon. Our strategies for preparing surgeons to respond properly to difficult situations in which they have no previous experience is to develop a detailed training program with special emphasis on non–technique-related surgical skills, which have previously been underrecognized. Technique-related surgical skills can be standardized and taught through various learning models,[22,23] whereas non–technique-related skills are not so easily transferred to students, in part because they cannot be easily quantified or enumerated. It is easier to transmit the knowledge base and formulated procedure, and to coach technique-related skills for performing LC, than it is to demonstrate competence with non technique-related skills as described in results section. Traditional apprenticeship-style surgical training is the optimal training model and adequate implementation requires 2 prerequisites: well-qualified teachers and teaching programs; and a highly structured authorization process by which new surgeons start to perform operations on patients.

It is reasonable to find that residents had spent similar time to complete elective surgery during the selected early and latter periods, while they spent more time to complete acute surgery in the latter period. It is unlikely that prolonged operation time was due to decreased chance of practice (similar case number; latter: 51 cases vs. early: 59 cases) or due to decreased ability of recent residents. The most likely explanation seems to be that more complete awareness of injury risk by these young operators resulted in more time being applied to carefully proceed with the surgery.

We all accept that high-volume institutions have good results, whereas more effort is still needed to extend these excellent experiences. We intended for our study to clearly list all experiences we collected and demonstrate the evolution of our clinical practice. It is never easy to evaluate each human or behavior factor that influences surgical results. Further studies should be designed to analyze these factors and focus more attention on them. Overall, we summarized all these efforts we had made as a system approach, having the intention of emphasizing a global view of our working system and reconstruction of the currently practiced system. We believe that our system approach not only increases safety and effectiveness for LC, but is also worth adopting in any other fields of medical practice.

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