

# Adopting “Culture of Safety for Laparoscopic Cholecystectomy” in a Rural Hospital: A Prospective Observational Study

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## ABSTRACT

**Background:** The most feared complication of laparoscopic cholecystectomy is injury to bile duct. Different strategies have been proposed to avoid this serious complication. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) “Culture of Safe Cholecystectomy” is one such strategy.

**Aim:** This study was done to evaluate and validate SAGES “Culture of Safe Cholecystectomy” components modified and tailored to the setting of a rural hospital with emphasis on a bystander surgeon.

**Materials and methods:** This was a prospective study of 382 patients with gallstone disease who underwent surgery at District Hospital, Anantnag, a rural hospital from September 2016 to September 2018.

**Results:** Mean age of patients was 43 years. Two-hundred and ninety-eight (78%) patients were females, and 84 (22%) were male with male female ratio of 1:3.54. Most common indication was chronic cholecystitis in 213 patients (55.7%). Bystander surgeon was present in all cases. Critical view of safety (CVS) was achieved in 256 patients (67%). Rouviere’s sulcus was present in 242 patients (63.3%). Bailout option was adopted in 19 patients (4.97%). Conversion to open cholecystectomy was done in 11 of the 382 patients (2.87%). Most common indication for conversion was inability to achieve CVS. Mean duration of surgery was 45 minutes. None of the patients in our study had bile duct injury.

**Conclusion:** SAGES culture of safe cholecystectomy can be modified to make it applicable to rural hospitals in developing countries where more reliance can be put on a detached bystander surgeon who is likely available in the vicinity.

**Keywords:** Bile duct injury, Calot’s triangle, Common bile duct, Cholangiography, Cholelithiasis, Laparoscopic cholecystectomy.

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## INTRODUCTION

In modern surgical practice, laparoscopic cholecystectomy (LC) is the most frequent surgical procedure performed on digestive tract worldwide.<sup>1</sup> It is considered to be the procedure of choice for the treatment of symptomatic gallstone disease.<sup>2</sup> Iatrogenic bile duct injury (BDI) is the most concerning complication after LC. The incidence of this complication is variable but usually approaches 0.5%.<sup>3,4</sup> BDI continues to happen, and despite advances in technology, there has been no decline in rate of injury.<sup>5</sup> About 97% of iatrogenic biliary ductal injury are attributed to visual misinterpretation of biliary anatomy during the procedure.<sup>6</sup> Many strategies have been proposed to avoid this serious complication. Society of American Gastrointestinal and Endoscopic Surgeons’ (SAGES) culture of safe cholecystectomy is a strategy directed to decrease this complication. It consists of six components.<sup>7</sup> This study was done to evaluate and validate these components, modified and tailored to the setting of a rural hospital with emphasis on a bystander surgeon.

## MATERIALS AND METHODS

This was a prospective study conducted at District Hospital Anantnag, a rural health care center located in the Indian valley of Kashmir, from September 2016 to September 2018. Three-hundred and eighty-two patients admitted for LC were enrolled. Clinical history, physical examination, blood counts, biochemistry, and abdominal ultrasound were routine in all patients. Preanesthetic check-up was done in all. The operations were done in elective

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setting under general anesthesia with four-port technique. We excluded patients with body mass index >30 (as our rural hospital was not equipped with facilities to operate on obese patients) and patients with acute cholecystitis who presented beyond 72 hours of symptom development from our study. We adopted components of safe cholecystectomy tailored to our settings of a rural hospital with emphasis on bystander surgeon as detailed below.

- Operating surgeon dissected Calot’s triangle and ensured that critical view of safety (CVS) was achieved.
- Starting dissection from a fixed extra biliary point, i.e., Rouviere’s sulcus.
- Intraoperative time-out before transecting cystic duct and artery.

- Availability of a detached observer in all cases. The bystander surgeon would stand by monitor to watch and observe the procedure with a keen intent and would alert the operating surgeon if any wrong space of dissection was entered or incorrect duct was being dissected. To ascertain this, the bystander surgeon would always ensure that the operating surgeon is ventral to Rouviere’s sulcus when present and has achieved CVS before clipping and dividing any structure. Minute-to-minute feedback was provided by the detached observer in difficult situations, so that the surgeon can accept the need for plan modification if by a given hypothesis placement of cognitive map is a misfit.
- Adopting bailout options as merited by the situation early in course of procedure.

For logistic reasons, intraoperative cholangiography (IOC) was not done in our hospital. All patients were advised to attend outpatient clinics at regular intervals of 1 week, 1 month, and 6 months. Telephonic communication was kept for any patient who defaulted to visit outpatient clinics.

**RESULTS**

Mean age of patients was 43 years (range 16–82 years). Two-hundred and ninety-eight (78%) patients were females, and 84 (22%) were male, with a male female ratio of 1:3.54. Indication of surgery is detailed in Table 1. Most common indication was chronic cholecystitis in 213 patients (55.7%). Adaptation of components of safe cholecystectomy is detailed in Table 2. CVS was achieved in 256 patients (67%). Rouviere’s sulcus was present in 242 patients (63.3%). Intraoperative time-out was done in all patients. Bystander surgeon (independent second observer) was present in all cases. Bailout option as shown in Table 3 was adopted in 19 patients (4.97%). Conversation to open cholecystectomy was done in 11 of the 382 patients (2.87%). Subtotal cholecystectomy was done in 7 of the 382 (1.83%) patients. In two patients, it was possible to do a laparoscopic subtotal cholecystectomy. Tube cholecystostomy was done in one patient (1.3%). Reason for adopting bailout options are discussed in Table 4. Most common indication was inability to achieve CVS. Mean duration of surgery was 48 minutes. Mean duration of

**Table 1:** Indications of cholecystectomy

Indications	No.	Percentage
Chronic cholecystitis	213	55.7%
Acute cholecystitis	81	18.84%
Biliary colic	72	21.20%
Asymptomatic gallstone disease	13	3.4%
Biliary pancreatitis	7	1.83%
Gb polyp	4	1.047%
Empyema	3	0.78%

**Table 2:** SAGES safe cholecystectomy components (tailored to rural setting)

Components	Numbers	Percentage
(a) Use of CVS	256	67.01%
(b) Starting dissection from fixed point	242	63.35%
(c) Use of intraoperative timeout	382	100%
(d) Availability of a bystander surgeon	382	100%

**Table 3:** Bailout options adopted

Options	Numbers	Percentage
(i) Open cholecystectomy	11	2.87%
(ii) Subtotal cholecystectomy	7	1.83%
(a) Open	5	1.30%
(b) Lap	2	0.52%
(iii) Tube cholecystectomy	1	0.26%

**Table 4:** Indications for bailout

1. Inability to achieve CVS	7/19	36.84%
(a) Tissue inflammation	6/19	31.57%
(b) Fibrosis of Calot triangle	5/19	26.3%
(c) Severe adhesion	4/19	21.05%
(d) Unclear anatomy	3/19	15.79%
2. Inability to proceed at expected pace	2/19	10.52%
3. Technical difficulties in handling GB	2/19	10.52%
4. Contracted/shrilled GB	2/19	10.52%
5. Bleed in surgical field (from GB bed)	1/19	10.52%
6. Cirrhotic liver with varices in hepatocystic triangle	1/19	5.26%
7. Hidden GB	1/19	5.26%
8. Mirzzi syndrome	1/19	5.26%
9. Hemodynamic instability secondary to pneumoperitoneum	1/19	5.26%
10. Suspected GB malignancy	1/19	5.26%

hospital stay was 24 hours in laparoscopic group and 72 hours in open cholecystectomy subset of patients. No patient was lost to follow up. In our study, there was no instance of BDI. We report a low conversion rate of 2.5% and is probably because of exclusion criteria adopted by us (Table 4).

**DISCUSSION**

Gallstone disease is a common disease affecting general adult population.<sup>8,9</sup> LC has evolved as the standard of care treatment for management of this disease due to its various advantages.<sup>10–12</sup> Although it is invariably accepted as a safe procedure, complications still happen in approximately 5% of patient.<sup>13</sup> Of these, BDI remains the most feared and dreadful complication of LC that at times can be life-threatening. The etiology is multifactorial, but misidentification of anatomy is perhaps the most important factor responsible for BDI mishap.<sup>14</sup> Way et al. concluded that primary cause of BDI was a visual perceptual illusion in which the surgeon misidentifies common bile duct (CBD) as cystic duct. Erroneous technical skills were identified as the primary mechanism of injury in only 3% of cases.<sup>6</sup> To minimize the risk of BDI, SAGES, in 2014, formed the Safe Cholecystectomy Task Force, with the aim of propagating a culture of safety around LC.<sup>7</sup> Following six steps were described to create a culture of safe cholecystectomy and minimize the risk of BDI: (a) identification of the cystic duct and artery by using CVS, (b) awareness of the potential for aberrant anatomy, (c) identification of anatomy using IOC or any other relevant method, (d) intraoperative time-out or pause during surgery before clipping and dividing the structures in Calot’s triangle for verification of anatomy, (e) early adaptation of the bailout options, (f) call for help from another surgeon whenever required.



The CVS has been adapted for clear identification of structures in Calot's triangle to reduce the risk of BDI.<sup>15</sup> The requirements are as follows: The hepatocystic triangle must be cleared of all the fatty and fibrous tissue. Second, the lowest one-third of the gallbladder must be separated from the liver bed. The third requirement is to ensure that only two structures are seen to be entering the gallbladder. Once these three criteria have been fulfilled, CVS is said to be attained. Most surgeons around the world acknowledge the importance of CVS during LC for prevention of biliary injury.<sup>16,17</sup> There has been indirect evidence from literature to suggest that the use of the CVS is helpful in preventing BDI. None of the patients in the study conducted by Yegiyants and Collins had an injury to biliary ducts because of visual misidentification when CVS was achieved.<sup>16</sup> CVS was achieved in 998 of the 1,046 patients in the study conducted by Avgerinas et al. who reported a conversion rate of 2.7%. Five patients had minor bile leak that resolved spontaneously. They didn't report any major BDI.<sup>18</sup> Heistermann et al. evaluated 100 patients who had LC in whom CVS was achieved. Only one patient in their study had postoperative cystic duct stump leak.<sup>19</sup>

Variations in biliary anatomy are common.<sup>14</sup> Variable biliary anatomy can predispose to BDI. Awareness to variation in biliary anatomy can be enhanced by starting from a fixed point a concept borrowed by Huges from maritime and aviation industries.<sup>20</sup> Rouviere's sulcus is one such extra biliary fixed point.<sup>20</sup> The right portal pedicle runs in this fissure and thus demarcates the plane of the porta hepatis. The dissection during the procedure should always stay anterior to this sulcus. Minimal incidence of BDI has been reported in a large series of LC by Huges et al.<sup>21</sup> and Singh and Ohri<sup>22</sup> when dissection is done ventral to this sulcus.

As per SAGES recommendations, it is advised to keep IOC available as an integral tool while performing LC. Selective use, however, has been practiced more commonly.<sup>23</sup> Utility of IOC is, however, controversial as many authors report it to be time-consuming and complex procedure. It is also considered to be inefficient with few authors suggest that many surgeons may not be able to read it correctly.<sup>24,25</sup> As per the current literature, there is no level evidence to suggest the use of IOC.<sup>26</sup> An alternative is laparoscopic ultrasonography, but it is subject to significant interoperator variability.<sup>27,28</sup> Another method to identify and continuously map the biliary anatomy is near-infrared fluorescent cholangiography, which is technically easy but the data as of now are insufficient to suggest its role in minimizing biliary injury.<sup>14</sup> Due to the lack of expertise or for logistic reasons, these methods of mapping biliary anatomy are not available in most rural hospitals in India.

Intraoperative time-out should be considered by operating surgeon always in the process of dissection of Calot's triangle. This step helps to confirm that the CVS has been achieved. The proposed disadvantage of this step is that this step is adopted by the operating surgeon who may still suffer from the heuristic error.<sup>29</sup> As already discussed, injuries stem principally from misidentification secondary to visual misperception rather than error of skill, knowledge, or judgement.<sup>6</sup> This visual misperception is a result of misplaced cognitive map,<sup>30</sup> and sometimes this illusion is so compelling as to end into an error. A detached observer can be helpful in this situation.<sup>31</sup> The detached observer present should agree with the surgeon that CVS has been achieved. Hori et al. have also advised to take the opinion of an independent detached surgeon while demonstrating CVS as he is unbiased and free from the any heuristic impression of the primary surgeon.<sup>32</sup> Surgical colleague can act as an unbiased observer free from heuristic impression of operating surgeon. He or she can ascertain whether

the CVS is achieved or not, whether it is safe to continue dissection in the assumed plane, and when to apply stopping rules. Kapoor also suggests that the primary surgeon should always call another surgical colleague for opinion and assessment of the biliary ductal anatomy, if in doubt, before the structures of Calot's triangle are divided.<sup>29</sup> The new and unbiased input of the detached observer can avoid the visual perception error of the primary surgeon. He calls this "in vicinity colleagueography."

Bystander surgeon for the reason that he is detached is more likely to seek information from surgical field and more likely to recognize misplacement of cognitive map by the operating surgeon that can result in spatial disorientation.<sup>31</sup> He is more alert for cues from surgical environment if demanded by the situation. He can refute the working hypothesis which the operator has entertained. Significance of unexpected observation may go unrecognized by the operating surgeon due to conformation bias.<sup>6</sup> Since detached observer is not committed to a judgment and is free from confirmation bias, he may be able to attach significance to some unexpected observation.<sup>31</sup> As mentioned by Way et al. in their seminal paper, "human performance cannot be pushed to perfection and that most fruitful correction strategy often lies outside the individual."<sup>6</sup> Bystander surgeon can be considered as one such outside correction strategy.<sup>31</sup>

Alternative or bailout options should be considered in those cases where achievement of CVS remains elusive due to dense adhesions, uncertain anatomy, or severe inflammation.<sup>14</sup> Conversion to open cholecystectomy is the most practical option in this situation. The decision to convert to open should take into consideration the experience of surgeon since difficult LC usually suggests a difficult open cholecystectomy with chances of biliary injuries remaining higher.<sup>14</sup> Subtotal cholecystectomy may also be considered in select situations. It can be done by laparoscopic or open method. Surgical cholecystostomy tube drainage is a safe alternative in difficult situations. In case of inexperience, the best possible method to prevent BDI may be to abort the procedure and referral to the higher center.

## CONCLUSION

SAGES culture of safe cholecystectomy can be modified to make it applicable to rural hospitals in developing countries, where due to logistic and other reasons, IOC is not available. More reliance can be put on a detached bystander surgeon who is likely available in the vicinity.

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