

Intraoperative Cholangiography during Cholecystectomy Using a Biliary-nose Tube: Routinely Used in Patients with Main Bile Duct Stones

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ABSTRACT

Background: Nowadays, the “gold standard” treatment for gallbladder stones is laparoscopic cholecystectomy but the risk of iatrogenic biliary duct injuries is increased compared to “open” surgery. Intraoperative cholangiography (IOC) can be useful to avoid biliary injuries but it can also be a no-safe procedure in center in which it is not routinely performed.

Aim and objective: The aim of our study is to trust the efficacy of IOC in a patient with common bile duct (CBD) and gallbladder stones using a biliary-nose tube.

Materials and methods: 135 patients with gallbladder and CBD stones were treated with sequential therapy and randomly divided into two groups. Laparoscopic cholecystectomy was performed within 24/48 h. During endoscopic retrograde cholangiopancreatography, a biliary-nose catheter was left to perform cholangiography during the following surgical procedure. Group A had also a cholangiography at the beginning of the surgical procedure in order to evidence biliary duct structure.

Results: Cholangiography avoided a lesion of the biliary ducts in nine patients. Only a patient had a residual stone in the CBD. The dissection at Calot’s triangle was faster in group A patients without differences between the surgeons involved.

Conclusion: The biliary-nose tube can be useful in patients with gallbladder and CBD who underwent cholecystectomy for different reasons: it lets the surgeon performing IOC faster and without risk linked to the technique used; it reduces the risk of biliary injuries; and surgeons feel more safe and calm during the surgical procedure.

Keywords: Endoscopic sphincterotomy, endoscopic retrograde cholangiopancreatography, Gallbladder stones, Laparoscopy, Video laparoscopic cholecystectomy.

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BACKGROUND

Today the “gold standard” treatment of gallbladder stones is laparoscopic cholecystectomy. Nevertheless, the risk of an iatrogenic injury of the biliary ducts has increased from two to four times compared to “open” surgery.^{1,2} The incorrect visualization of the cystic duct, the common bile duct (CBD), and the cystic artery is often responsible for lots of injuries in both techniques.^{3,4}

Anatomical changes can involve the hepato-cystic triangle, due to acute or chronic inflammatory phenomena, as well as frequent anatomical variations.^{5,6} They have always been an important element of operative outcome and they can reduce long-term survival and patient’s quality of life.^{7,8}

In 1932, Mirizzi developed intraoperative cholangiography (IOC), an imaging technique to evidence biliary ducts intraoperatively.⁹

This method has been widely applied in North American clinical practice in association with open cholecystectomy since the early 1950s.¹⁰

At the beginning of the technique, surgeons explored the CBD biliary tract during the cholecystectomy in 30–65% of cases.¹⁰ However, surgical exploration of CBD was associated with a significant increase in mortality and morbidity. Based on these observations, a routine use of the IOC associated with cholecystectomy has been proposed.^{11,12} The IOC associated with open cholecystectomy decreased the incidence of misrecognition of asymptomatic lithiasis of the CBD that is 7%.¹³ The routine use of IOC reduces the requirement of CBD surgical exploration from 66% to <5%.¹⁴

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The introduction in 1974 of endoscopic retrograde cholangiopancreatography (ERCP) with the endoscopic sphincterotomy, offered for the first time an alternative to reoperation for the treatment of residual CBD stones.¹⁵

Video laparoscopic cholecystectomy (VLC) in 1988, opened again the debate around the routine or selective use of IOC for the increased CBD iatrogenic lesions associated with VLC.^{16,17} Different factors can be involved: the incorrect identification of the anatomical structures; a large number of anatomical biliary duct variations and vascular abnormalities; the anatomical changes due to prolonged and repeated inflammatory processes involving the gallbladder and the adjacent tissues; and surgeons learning curve.^{18–20}

Nowadays, IOC has a marginal role in lots of surgical centers because few surgeons use it routinely, most of them use it occasionally or do not use it.^{21,22}

Nowadays, ultrasound (US) technology, the ERCP, and MRI allow a higher diagnostic accuracy on the stones' presence.^{23,24}

On the other hand, lots of studies showed that the IOC associated with the VLC decreases the incidence of misrecognition of asymptomatic CBD stones that is usually around 7%.^{13,25} It can also avoid possible complications linked to the surgical procedure.²⁶⁻²⁸ In addition, ERCP stones removal with the "inverse sequential" treatment may not be always successful and this situation requires to carry out a new surgical procedure.^{29,30}

Moreover the surgical centers in which IOC is not routinely used, reported a higher risk of biliary injuries performing IOC than in centers in which IOC is routinely performed.³¹⁻³³

For these reasons, we designed a prospective randomized study to verify the usefulness of routinely IOC during laparoscopic cholecystectomy, using a biliary-nose tube, inserted in a patient having main bile duct stones, previously treated by ERCP.

AIMS AND OBJECTIVES

This prospective randomized study aim is to verify the importance of IOC during laparoscopic cholecystectomy, testing its features in avoiding biliary injuries especially in difficult anatomical conditions. We also tried to propose a form taking into account patients' features to hypothesize the surgical complexity of the procedure.

MATERIALS AND METHODS

We enrolled in our study patients with gallbladder and CBD stones diagnosed at US and MRI, undergoing endoscopic sphincterotomy before laparoscopic cholecystectomy. In all patients, a biliary-nose tube had been left inside the bile duct during ERCP and cholecystectomy had been performed in 24/48 hours after endoscopic sphincterotomy.

In the period from January 1, 2011 to December 31, 2015, 135 patients with inclusion criteria were recruited. Patients' age ranged from 41 to 84 years, 43 were male (31.8%) and 92 female (68.1%).

Anamnestic data were collected for each patient, as well as all the diagnostic data obtainable from the instrumental exams used to do the diagnosis.

Some features taken from clinical history and imaging data were taken into account to develop an evaluation form that could allow to preview surgical dissection difficulties. In the form, we attributed the number 1 with a negative sign (-) when the predictivity of difficulties was negative and with a positive sign (+) if it was positive (Table 1).

In patients with a positive-sum (risk group), we expected to find altered locoregional anatomical conditions, while in the negative-sum (no-risk group), these conditions were not expected. In cases of a sum equal to 0, the patient was attributed to the subgroup of those with probable alterations.

We divided all the patients randomly into two groups (Table 2) and we valued:

- The real correspondence with the prediction of anatomical findings;
- The time needed in surgical dissection;
- The biliary duct integrity;
- IOC time;
- The presence of residual stones in CBD.

Table 1: Form used to divide patients into two subgroups

Age	<40 years	-1
	>40 years	+1
Sex	Male	+1
	Female	-1
Murphy's sign	Negative	-1
	Positive	+1
Symptoms time-frame	Recent/accidental reporting/asymptomatic	-1
	<2 years	-1
	>2 years	+1
Previous episodes of jaundice or subicterus		+1
No previous episodes of jaundice or subicterus		-1
Jaundice at first diagnosis		+1
Previous episodes of cholangitis		+1
Previous episodes of cholecystitis		+1
Previous recurrent biliary pain		+1
Previous biliary pain sporadic and infrequent		-1
US abdominal findings	Non complicated	-1
	Complicated	+1
MRI valuation	Normal anatomy	-1
	Possible alterations	+1

If the sum was ≥ 0 , the patient belonged in the risk group of complicated surgical dissection

Table 2: Study parameters considering the applied form of Table 1

Study parameters	Group A	Group B
Number of patients	68	67
Male	22	21
Female	46	46
Risk group expected (≥ 0)	45 (66.2%)	42 (62.7%)
No-risk group expected (< 0)	23 (33.8%)	25 (37.3%)
IOC before dissection	Yes	No
IOC before cutting	Yes	Yes
Positioning time radiological equipment (minutes)	5'12"	4'40"

In group A, the ICO was performed through the biliary-nose tube at the beginning of the surgical procedure and once isolated the cystic duct and artery. In group B, the ICO was performed after dissection, before cystic duct and artery section.

According to the preoperative study form, we hypothesized 87 patients (64.4%) who have had unfavorable local anatomical conditions (risk group) and 48 (35.5%) in which unfavorable locoregional conditions were not expected (no-risk group).

In group A, after random division, 68 patients were included with 45 patients (66.1%) of risk group. In group B were enrolled 67 patients, including 25 (37.3%) of no-risk group and 42 (62.6%) of risk group.

All the procedures were performed by three different surgeons: two seniors, who had done 382 and 259 open cholecystectomies, respectively, with an IOC percentage of 83% and 87%, 150 and 167 VLC with an IOC percentage of 6 and 7.2%; a junior surgeon, younger and not expertise, who had done 29 open cholecystectomies performing an IOC in 12 cases (41.4%) and 47 VLC with an IOC in 6 cases (12.7%).

At the beginning of surgical procedures, surgeons had to declare their perception of the degree of safety owned, expressing it through a numerical score from 1 to 5 and giving the value of 5 to a mood of peaceful safety. Surgeons knew in which of risk or no-risk group the patient belonged.

Once the trocars were positioned and the surgeons evaluated the surgical field, they had to do a survey attributing the following values:

- 5 if he was sure of being able to complete the procedure laparoscopically;
- 4 if he was sure to complete the laparoscopic procedure with longer time;
- 3 if he thought he needed to perform an IOC;
- 2 if there was the possibility to convert the procedure to open surgery;
- 1 if he wanted to convert immediately.

At the end of the procedures, surgeons had to express their opinion on the usefulness of cholangiography, with also the subjective influence that it has had on the procedure.

In both groups, there were no significant differences in the positioning time of the radiological equipment that was about 5 minutes and cholangiography time that was between 3 minutes and 6 minutes.

RESULTS

In group A, "difficult" anatomical conditions were found in 9 of the 23 patients (39.1%) of no-risk group and in 27 (60%) among the 45 of the risk group (Table 3). When locoregional anatomy was not significantly changed, the dissection time after cholangiography was between 10 minutes and 20 minutes. In those patients with locoregional alterations, the dissection time was between 10 minutes and 35 minutes. Transcatheter cholangiography allowed the safe recognition of anatomical structures in all patients without complications. Surgeons avoided injuries in the patients in which difficult conditions were not expected thanks to IOC. The second cholangiography avoided a lesion of the biliary duct in two patients of this group.

In group B, we performed cholangiography after the isolation of the anatomical structures at Calot's triangle. In the 42 patients of the risk group, we found 31 (73.8%) difficult surgical dissections and 9 among the 25 in which anatomical alterations were not hypothesized (26%) (Table 3).

Table 3: Results. There were no significant differences in IOC time. The form applied showed low sensitivity and specificity

Results	Group A	Group B
Patients without surgical complications	68	67
Risk group results	27 of 45 (39.7%)	31 of 42 (46.3%)
No-risk group results	14 of 23 (20.6%)	16 of 25 (23.9%)
Surgical dissection time (minutes)	24'17"	32'38"
No-biliary duct integrity before cutting	2 (2.9%)	7 (10.4%)
IOC time (minutes)	5 ± 1	4 ± 1
Residual stones in CBD	0	1
Bile duct injuries	0	0

In patients without altered locoregional anatomical conditions, dissection time was between 10 minutes and 35 minutes and between 20 minutes and 45 minutes when difficult anatomy had been found. IOC avoided a lesion of the biliary duct in 7 patients (10.4%) of which 2 (6.6%) with normal anatomical conditions.

Only 1 patient (0.7% of all) had a small stone in CBD. The surgeon eliminated it during the procedure, washing it through the catheter.

All surgeons evaluated their approach to surgery with a score of 5 before the surgical procedure, also in patients where difficult anatomical conditions were expected by the form applied. The rating given by the surgeons after the inspection of the operating field was 3 in 21 cases (13 by the junior surgeon).

Maybe, the IOC previously performed in group A patients provided a first picture of the biliary duct map and this had influenced the rapidity in the dissection that was shorter than group B without significant difference between senior and junior surgeons. It seems that a preventive view of the biliary ducts can contribute to a faster dissection but it is the IOC performed before the section that had a real meaning in avoiding biliary injuries. In fact, in nine cases surgeons avoid biliary damages thanks to IOC.

The form used to hypothesize the anatomical conditions, based on the elements we have taken into, has shown poor specificity (67%) and sensitivity (76%).

DISCUSSION

Laparoscopic cholecystectomy is the gold standard for gallbladder cholelithiasis but is linked to an increased rate of biliary injuries.³⁴ The incorrect visualization of the cystic duct, the CBD, and the cystic artery is often responsible for surgical injuries.¹¹ The European Association for Endoscopic Surgery's guideline shows the importance of dissection and the relevance of the critical view of safety (CVS).³⁵ CVS is not only a dissection method but also the final picture that is obtained through a careful and prudent dissection of the Calot's triangle to highlight the duct and the cystic artery.^{36,37}

Despite its adoption, however, the percentage of biliary injuries has not decreased even in centers where it is routinely adopted.

Laparoscopic surgeons lack three-dimensional (3D) view and tactile sensitivity causing iatrogenic bile duct injuries.⁵ These problems are on the focus of scientific discussion. 3D laparoscopy helps surgeons, especially in difficult surgical procedures, but this technology is still not present in most of the surgical departments.³⁸

Since 1932, IOC can help to avoid biliary injuries but its routine use is controversial: it is very useful to find anatomical biliary alterations or to find residual/unknown stones in the CBD,^{39,40} however, it is expensive in terms of time and costs and it can also cause biliary damages by itself.^{41,42}

The ERCP changed the choledocholithiasis therapy and it let to avoid complications linked to the surgical exploration of CBD. Lots of patients need ERCP because it immediately solves their choledocholithiasis pathology with a short time of hospitalization. Nowadays, ERCP is routinely performed and lots of centers follow the sequential treatment in gallbladder/choledocholithiasis. Leaving a biliary-nose tube during ERCP is a simple and safe procedure. It can be useful in sequential therapy in patients who should undergo cholecystectomy. In this way, we can avoid the problems linked to loss of time and biliary injury due to tube insertion procedure. It can also be avoided that a stone could pass through the cystic duct to the CBD during intraoperative anterograde cholangiography.

Surgeons feel more comfortable knowing to have a biliary-nose catheter to perform an IOC and this is well expressed in our

study according to the surgeon's answers. It seems to reduce the open conversion rate but there will be further necessary studies to underline it. In our experience, a predictive form of anatomical alterations finding seems not to be useful before a surgical procedure because all the surgeons give an answer of five independently of the surgical difficulties hypothesized.¹⁷ IOC costs are not excessive when compared to human and economic costs after iatrogenic biliary injuries.^{16,43} The costs for a lesion that required a biliodigestive anastomosis over a lifetime are estimated at around €300,000 that is like the cost of 3000 VLC.⁴⁴

As also shown by a study on over 300,000 laparoscopic cholecystectomies, the percentage of lesions was 0.21% when routinely IOC was performed, compared to 0.43% in cases of selective cholangiography. If the technique does not eliminate iatrogenic injuries, it certainly minimizes the incidence.^{45,46}

CONCLUSION

A primitive evaluation of the possible difficult anatomy findings seems to have no influence on the surgeon's mood. Prior knowledge of the "biliary tree" map may help to speed up dissection time in difficult cases, but it is the cholangiography performed before cutting the cystic artery and duct that can avoid biliary injuries.

IOC should be used more frequently especially in patients with gallbladder and CBD stones. The use of a previously positioned biliary-nose tube lets surgeons doing IOC faster and without risks linked to the technique.

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