

## Safety of Elective Laparoscopic Cholecystectomy in the Hands of Postgraduate Trainees

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### ABSTRACT:

#### BACKGROUND:

From the start of era of laparoscopic surgery the debate starts regarding the best time for laparoscopic training and in most developed countries the training is part of residency program nowadays; the safety of surgeons performing laparoscopic cholecystectomy assessed by results of surgery in addition to different scoring systems( like GOALS and Thomas R Eubanks).

#### OBJECTIVE:

The purpose of this study is to evaluate the safety of elective laparoscopic cholecystectomy done by postgraduate trainees under supervision and the introduction of proper training program of laparoscopic surgery in postgraduate residency programs in Iraq. The safety of the procedure performed was determined using The Global Operative Assessment of Laparoscopic Skills (GOALS) and Thomas R. Eubank scoring systems which were designed for evaluation of resident and surgeon in training laparoscopic performance .

#### PATIENTS AND METHODS:

This prospective study includes 200 consecutive cases underwent laparoscopic cholecystectomy for symptomatic cholelithiasis, conducted in AL-Jumhoori Teaching Hospital in Mosul city - Iraq during the period from (October 2010 to October 2011). These laparoscopic cholecystectomies were performed by(5<sup>th</sup>&4<sup>th</sup> year) postgraduate trainees under supervision of senior laparoscopic surgeons.

#### RESULTS:

Among 200 cases, there were 45 (22.5 %) males and 155 (77.5 %) females. The age of patients ranged from 18-65 years. All cases were done by 4<sup>th</sup> and 5<sup>th</sup> post graduate trainees with minimal complications. The results and observations were made for the operating time, difficulty in dissection, open conversion rate and early complications, The mean operating time was 40 minutes. The open conversion was 3%. and gut injury was 0.5% with no mortality.

#### CONCLUSION:

laparoscopic cholecystectomy can be performed safely by resident postgraduate trainees according to the outcome data , "Global Operative Assessment of Laparoscopic Skills" (GOALS) and Thomas R Eubanks scoring system and this proves the effectiveness of the suggested training program.

**KEYWORDS:** laparoscopy, postgraduate trainee, cholecystectomy, cholelithiasis.

### INTRODUCTION:

Minimal access surgery is a marriage of modern technology and surgical innovation that aims to accomplish surgical therapeutic goal with minimal somatic and psychological trauma <sup>(1)</sup>. Laparoscopic cholecystectomy is a minimally invasive procedure in which the gallbladder is removed <sup>(2)</sup>.

For more than a century, classical cholecystectomy has been the method of choice in the surgical management of gall bladder diseases. At the end of the eighties and the

beginning of the nineties of the 20<sup>th</sup> Century, laparoscopic cholecystectomy (LC) was introduced, gained more and more acceptance, and now appears to have taken over the position of open cholecystectomy for both chronic and acute cholecystitis <sup>(2,3,4)</sup>.

Factors driving this rapid advancement in laparoscopic surgery are rapid recovery and discharged of the patient from hospital. In LC, there appear to be fewer wound problems, especially with infection and dehiscence, as the small portals of entry result in far less tissue devascularization. There is also considerable drive from the patients to have their procedures

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performed laparoscopically because of the decreased post operative pain, an earlier return to work and better cosmetic results<sup>(5, 6, 7, 8)</sup>.

The first Laparoscopic Cholecystectomy was performed by Mouret in Lyons France in 1987. Then laparoscopic cholecystectomy became the "gold standard" treatment for patients with symptomatic cholelithiasis. It is now one of the most common operations performed by general surgeons<sup>(9)</sup>.

Now a days most surgeons performing laparoscopic cholecystectomy today are trained outside of a structured residency program. Much debate regarding appropriate postgraduate training and credentialing has surfaced. Little attention has been given, however, to the impact of the new technique on resident training<sup>(10)</sup>.

The young surgical post graduates must be trained in the craft and skills of laparoscopic surgery in their formative years<sup>(11)</sup>.

Residency education in the United States is the most rigorous in the world and is regulated by the Accreditation Council for Graduate Medical Education (ACGME) through Residency Review Committees (RRC) for each recognized medical and surgical specialty and subspecialty<sup>(12)</sup>.

In keeping with the principle published by the ACS, only those surgeons privileged to perform open abdominal surgical procedures were permitted to apply for privileges in laparoscopic general surgery<sup>(13, 14)</sup>.

Laparoscopic surgery incorporated into most general surgery residency curricula since 1991-1993, and residents are being trained as in other surgical procedures by assisting an experienced surgeon and then performing the procedure under gradually decreasing supervision<sup>(15, 16, 17, 18, 19)</sup>.

Reports showed that residents can perform LC with equivalent safety and in equal time as their attendings, and often in patients who are less healthy than were previously operated on laparoscopically<sup>(20, 21)</sup>.

### **AIM OF STUDY:**

This study is performed to assess the safety of elective laparoscopic cholecystectomy performed by fourth and fifth post graduate trainees (who follow our suggested training program in Al-Jumhoori Teaching Hospital) depending on the "Global Operative Assessment of Laparoscopic Skills" GOALS and Thomas R Eubanks scoring system as an evaluation system in addition to the outcome data and finally the study can assess the effectiveness of the this training program.

### **MATERIALS AND METHODS:**

This prospective study was conducted at AL-Jumhoori Teaching Hospital in Mosul city- Iraq during the period from (October 2010 to October 2011). It Includes 200 consecutive patients who underwent laparoscopic cholecystectomies for symptomatic gall stones performed by postgraduate trainees (4<sup>th</sup> and 5<sup>th</sup> year) under supervision of senior laparoscopic surgeon.

All trainees followed our suggested program which includes, in order:

1- Videos about the procedure.

2- Pelvitrainer and hands-on training (using the manikin simulator).

3- Software (Simi Praxis): which offers an easy, cost effective, and engaging way to deliver cognitive training on new and existing medical procedures quickly and directly to those who need it, when and where they need it. SimPraxis can be installed from a DVD onto a personal computer, and requires only a mouse for interaction. It provides a realistic, interactive experience for learning and rehearsing the steps of a medical procedure. Automated skill indicators provide instant, objective user progress. The new SimPraxis Laparoscopic Cholecystectomy Trainer was authored by Dr Mika Sinanan PhD, Professor of Surgery University of Washington and it was reviewed and edited by leading medical clinicians and educators at the University of Washington, University of Minnesota, Columbia University, Northwestern University and University of British Columbia<sup>(22)</sup>.

4- Assisting in 50 cases at first then performing the procedure under supervision of laparoscopic surgeon.

Clinical data were recorded and pre-operative investigations according to the guidelines along with abdominal ultrasound were carried out. All patient were admitted a day before surgery. The nature of the procedure was explained and consent for open conversion was also taken. Difficulty in dissection of the gall-bladder with dense adhesions of omentum all around and dense adhesions at Calot's triangle were the main difficulties found; so help was sought by senior surgeon to manage. Sixteen cases were excluded from our study as they were performed by senior surgeon.

The safety of the procedure performed by post graduate trainees was determined depending on:

1- The Global Operative Assessment of Laparoscopic Skills (GOALS), this scoring system designed for evaluation of resident

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laparoscopic performance which is mentioned in detail in Appendix 1<sup>(23, 24)</sup>.

2-The post graduate trainees record 1 L.C. operation performed (randomly) and the procedure was reviewed by the laparoscopic committee of Al-Jumhoori Teaching Hospital and scored according to the system used by Thomas R Eubanks to track the learning curve of surgeons in training, evaluate efficacy of alternative training and provide a means of self

assessments for the trainees and this system mentioned in details in Appendix 2<sup>(25)</sup>.

3-All operative findings, operative difficulties, operating time, outcome data and early postoperative complications (specific to the procedure) were recorded. The data were compiled and results were analyzed.

### RESULTS:

Among 200 cases, there are 45 (22.5 %) males and 155 (77.5 %) females. The age of patients ranged from 18-65years with a mean of (44). The results and observations are as follows:

1.**Age:** The table below shows the age distribution of the patients with gall stones.

Table 1: The age distribution of the patients with gall stones.

Age	Number
<20	15
20-29	27
30-39	40
40-49	63
50-59	47
60-69	8

2.**Operative Time:** In early cases, the total operating time was one hour in simple cases and 70 minutes in difficult cases; operative difficulties were assessed in terms of duration of surgery from insertion of port to create CO2 pneumoperitoneum till the removal of last port, access to peritoneal cavity, intraoperative bleeding, bile leak, unclear Calot's triangle anatomy following adhesions and conversion to open cholecystectomy.

Later the operating time was decreased to 20-30 minutes in simple cases and 40-60 minutes in difficult cases. Twenty one case (10.5%) were regarded as lengthy procedure (more than 70 minutes); six of these cases were converted to open procedure while the remaining 15 cases were completed laparoscopically. The causes of prolongation are shown in table (2)

Table 2: Shows the causes of prolongation.

Causes of prolongation	Number	Percent
Uncontrolled bleeding	7	33%
Acute inflammation with dense adhesion	7	33%
Spillage of stones during LC	6	28.5
Mirrizi syndrome and duodenal perforation	1	6%

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**3. Open Conversion:** Only six cases (3 %) were mentioned in table 1 and managed accordingly. converted to open procedure for the reasons

**Table 3: Reasons for conversion to open procedure.**

Causes of open conversion	Number of cases	percent
Acute inflammation with dense adhesion	2	1%
Uncontrolled bleeding	2	1%
Spillage of stones during LC	1	0.5%
Mirrizi syndrome and duodenal perforation	1	0.5%

**4. Difficulties and Complications:** Intra-operative difficulties and post-operative complications found in this series are summarized in Table 4 and 5.

**Table 4: Shows Intra-operative difficulties (that were treated laparoscopically except the duodenal perforation).**

Difficulties	numbers	percent
1-Bleeding	21	(10.5%)
Liver bed	10	
Omentum	8	
Cystic artery	3	
2-Spillage	26	(13%)
Bile	19	
Stone	7	
3-Intestinal injury(duodenum)	1	(0.5%)

Regarding postoperative complications five cases (2.5%); 3 cases (1.5%) were treated by open surgery while the remaining 2 cases (1%) were treated conservatively.

We have 1 case (0.5%) (Duodenal injury) and that complication was diagnosed during the operation which was converted to open

procedure and the perforation sutured; the patient discharged well after 5 days.

**5. The performance of post graduate trainees:** this was assessed using Thomas R Eubanks scoring system and (Excluding 4 steps related to cholangiography) and the minimum score obtained was 14 out of 19.

**Table 5: Shows the post operative complications (which failed to be recognized during the procedure.**

Complications	numbers	percent
1-Bile collection	2	(1%)
Slipped clips of cystic duct	1	
Cystic duct stump (missed injury)	1	
2-Post operative jaundice	1	(0.5%)
Missed CBD stone	1	

**6. The laparoscopic skill** of post graduate trainees assessed by the GOAL scoring system and the table below shows the comparison

between the two groups (post graduates trainees versus laparoscopic senior) ; eight surgeons in each group and the five domains assessed).

**Table 6: Two-Sample t-Test for Laparoscopic Cholecystectomy, post graduates trainees versus laparoscopic senior.**

Domain	Mean (PGTY4,5)	SD	Mean (senior)	SD	t-test	P value
Depth perception	3.75	1.49	4.50	0.93	1.2104	0.2462
Bimanual dexterity	2.25	1.49	4.00	1.51	2.3333	0.0351
Efficiency	3.25	1.67	4.25	1.04	1.4402	0.1718
Tissue handling	3.25	1.28	4.25	1.04	1.7168	0.1080
Autonomy	3.75	1.04	4.50	0.93	1.5275	0.1489
Degree of difficulty	2.75	1.39	3.63	1.06	1.4163	0.1786

**Table 7: Two-Sample t-Test for Laparoscopic Cholecystectomy, post graduates trainees versus laparoscopic seniors using Thomas R.Eubank scoring system.**

	Mean (PGTY4,5)	SD	Mean (senior)	SD	t-test	P value
Score	62.50	6.82	70.30	5.81	2.7528	0.0131

**DISCUSSION:**

**1- Operative time :**

In our study the mean operating time was 40 minutes which is comparable with a study performed by Waseemmemon<sup>(26)</sup> in which the mean operating time was 45 minutes and the lengthy procedure takes more than 70 minutes according to the study done by G.Welty, E.Schippers<sup>(27)</sup>; We have a total of 21 cases (10.5%) prolonged operation due to difficulty and complication and these results are better than the results obtained by M.Rafiquememon and Wang WN.<sup>(28, 29)</sup>

We have to mention that when operative time prolonged more than 90 minutes; ten penalty points accounted for each extra fifteen minutes according to Thomas R.Eubank scoring system.

**2- Conversion rate:**

Conversion to open cholecystectomy is neither a failure nor a complication but an attempt to avoid complication; yet generally the conversion of LC to open technique is regarded as a major morbidity as it loses the supremacy over open technique once the conversion takes place<sup>(30)</sup>.

In our study the conversion rate was (3%) while the study done by Waseemmemon reported a conversion rate (4%)<sup>(26)</sup> and other literatures mentioned a conversion rate between (3.6%-13.9%)<sup>(31,32,33,34,35)</sup>; While Rafiquememon<sup>(28)</sup> reported a conversion rate (1.5%).The largest

study in USA noted that the conversion rate to an open procedure was 2.16%<sup>(36)</sup>.

The most common cause of conversion(in our study) are dense adhesions and uncontrolled bleeding which is similar to the above studies while Jaffary et al<sup>(37)</sup> found conversion rate( 7.53%)due to instrumental failure only(insufflators ,camera, monitor, clip applicator ).

**3- Intra-operative difficulties:**

**-Biliary Spillage:** occurred in 26 cases (13%) including both bile and stone, because of perforation of the gallbladder. According to literatures the rate of bile leak and loss of gallstones into the peritoneum has been reported to be between 3% and 33%<sup>(38, 39)</sup>.

The spillage was dealt in our series by irrigation and suction with removal of stones and in all cases we put a tube drain.

**-Bleeding:** The reported incidence varies from 0.04% to 0.5% of all laparoscopies<sup>(40,41)</sup>.Bleeding has been reported to occur with an incidence of up to nearly 10% in various series<sup>(42)</sup>; in our study it occurs in 21 cases (10.5%) of cases (from liver bed , omentum, cystic artery )and this results is comparable with the study done by crolla<sup>(43)</sup>who found that the bleeding occur in 8% if surgery is performed by senior surgeon while his results for surgeries done by resident surgeon is 21% which is much

higher than ours.(Souba ACS 2004)<sup>(44)</sup>.In our patients the bleeding was controlled by diathermy and clips ,only 2 cases converted to open surgery to control the bleeding ; our results are higher than the study done by Kanyari Z. et al (0.18%) which is significant bleeding<sup>(45)</sup>.

**-Intestinal injury:** there is a risk of perforation of the duodenum as a result of the inflammatory process and the fact that the duodenum adheres to the inflamed gall bladder<sup>(11)</sup>. In our study we have one case (0.5%) of intestinal injury (duodenum) and this patient explored and the perforation was sutured; while the result obtained by M.Rafiq (0.12%)<sup>(28)</sup> and Kanyari Z. et al (0.12%)<sup>(45)</sup> ,while other study mentioned that intra-operative non-biliary injuries (duodenal perforation, diaphragmatic injury, small bowel injury, portal vein injury, liver laceration) during laparoscopic cholecystectomy occur as frequently as biliary injuries and can be life-threatening and difficult to manage<sup>(46)</sup>. Duodenal injury is a rare complication of LC. In a series of 22 patients treated for severe complications of LC there was a single (fatal) case of duodenal injury<sup>(47)</sup>. Indeed this rare complication appears to be highly lethal. In a series of 12 patients sustaining intestinal injuries during laparoscopic procedures, three out of the four patients with duodenal perforation died<sup>(48)</sup>. Nevertheless the incidence of bowel injury is 0 to 5% in different series<sup>(49)</sup>.

#### **4. Post Operative Complication:**

**-Common bile duct injury and bile collection :** CBD injury has clearly been the Achilles' heel of the laparoscopic method<sup>[38]</sup> , but this complication was not recorded in this series ; while post operative bile leak is a less catastrophic and more common complication ; in our study we have two cases of bile collection (1%), both of them were explored for proper drainage .The literature stated that bile leak and injury to biliary tree increased after the introduction of laparoscopic cholecystectomy<sup>(50)</sup> ; In a study by Deziel DJ, et al<sup>(51)</sup> he reported an incidence of bile leak 0.3% which is better than our results probably because they use intraoperative cholangiogram also bragheto mentioned an incidence of leak 0.6%.<sup>(52)</sup> .One meta-analysis of more than 40 published series found that the mean incidence of major bile duct injury was 0.5%, two to four times the rate cited for open cholecystectomy (0.1–0.25%)<sup>(53)</sup> . The incidence of Post-operative biliary collection by post graduate trainees is 0.87 %

according to M. Rafique Memon<sup>(28)</sup> .

There are two large studies about bile duct injury; the first included forty series reporting experience with laparoscopic cholecystectomy in the United States from 1989 to 1995 was reviewed. A total of 114,005 cases were analyzed and 561 major bile duct injuries (0.50%)and 401 bile leaks from the cystic duct or liver bed (0.38%) were recorded; the second study occurred during a 3-year period (1995-1997) 130 items of all LC data were collected on a central computer system from 84 surgical institutions in Switzerland by the Swiss Association of Laparoscopic and Thoracoscopic Surgery and evaluated for major BDIs mention that the overall BDI incidence was 0.3%. In 47% BDIs were caused by experienced laparoscopic surgeons, perhaps because they tend to operate on more difficult patients, these results are also better than ours but we did not record a major bile duct injury and also they perform intra operative cholangiogram.<sup>(36,54)</sup> .

We have to mention that there is an elegant study comparing two groups of surgeons performing LC the first trained during residency while the second trained after residency. It was found that residency training decreases the likelihood of injuring a bile duct, but only by decreasing the frequency of early "learning curve" injuries. If one accepts a liberal definition of the learning curve (200 cases), it appears that at least one third of injuries are not related to inexperience but may reflect fundamental errors in the technique of laparoscopic cholecystectomy as practiced by a broad population of surgeons in the United States.<sup>(55)</sup>

**-Jaundice :**We have 3cases (1.5%) of post operative jaundice; 1 case is due to retained stone in the CBD and managed by ERCP; the other two cases are caused by bile collection and this results is better than the accepted percentage mentioned by textbook(NMS)<sup>(56)</sup> which is 10% probably because they operate during an acute attack.

**5. Mortality:** We have no mortality in our study; the mortality rate after LC is low and according to the study done in USA<sup>[42]</sup> it is mentioned that the overall mortality was 0.06%; while the mortality rate by the hand of post graduate trainees is 0.25% because of hepatic failure in patients with decompensated cirrhosis<sup>(28)</sup> .

**6. Assessment of post graduate trainees:** All post graduate trainees complete more than 14 steps out of 19 and according to Thomas Eubank this result means that the post graduate trainees can perform LC safely. When the scoring system applied and calculated the results shows statistical significant difference and this was used to provide a means of self assessments for the trainees but still this means that the postgraduate trainees performed the procedure safely.

**7. Laparoscopic skills:** There is no significant statistical difference between post graduate trainees and seniors regarding 4 parts of the domain while there is a significant statistical difference in bimanual dexterity.

**CONCLUSION:**

laparoscopic cholecystectomy can be performed safely by resident postgraduate trainees according to the outcome data, "Global Operative Assessment of Laparoscopic Skills" (GOALS) and Thomas R Eubanks scoring system and this proves the effectiveness of the suggested training program.

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