

## Systematic Review

# Laparoscopic versus open surgical approach of cholecystectomy in patients with symptomatic cholelithiasis: a systematic review of comparative trials

Omer A. Marzoug\*

The Research Unit, Faculty of Medicine, University of Khartoum, Khartoum State, Sudan

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### \*Correspondence:

Dr. Omer A. Marzoug,

E-mail: [omerabdalla777@yahoo.com](mailto:omerabdalla777@yahoo.com)

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## ABSTRACT

Symptomatic cholelithiasis (gallstone disease) is the most common biliary pathology that affects women predominantly around the world. Earlier open cholecystectomy was the gold standard of treatment of this disease before introduction of laparoscopic cholecystectomy. The aim of this study is to systematically review the most recent published data that compared laparoscopic with open cholecystectomy in symptomatic cholelithiasis in terms of operative and post-operative morbidity, mortality, operative time, length of hospital stay, and conversion rates. The Medline, Cochrane library, Embase, and PubMed databases were vigorously searched for trials that compared laparoscopic with open cholecystectomy in patients with symptomatic cholelithiasis, a systematic review of these comparative trials was performed. No mortality was detected in both groups; the conversion rate was 6.75%. The laparoscopic approach associated with significantly shorter hospital stay (2.31 versus 4.42 days,  $p$  value $>0.001$ ), lower post-operative pain duration (30.5 versus 66.9 hours,  $p$  value $>0.001$ ) and lower rate of post-operative wound infection (2.8% versus 10.5%,  $p$  value $>0.001$ ). Regarding operative time it was significantly longer in laparoscopic approach (77.3 versus 67.1 min,  $p$  value $>0.001$ ), there were no significant differences in the rates of bile duct injury (0.84% versus 0.25%,  $p$  value=0.08) and intra-operative bleeding (4.2% versus 3.5%,  $p$  value=0.81) between the two procedures. Post-operative wound infection and pain duration in addition to length of hospital stay in patients with symptomatic cholelithiasis were reduced with laparoscopic cholecystectomy. However, the laparoscopic approach associated with longer duration of surgery. No significant differences between the two procedures in the rates of bile duct injury and intra-operative bleeding.

**Keywords:** Symptomatic cholelithiasis, Laparoscopic cholecystectomy, Open cholecystectomy

## INTRODUCTION

Symptomatic cholelithiasis (gallstone disease) is the most common biliary pathology that affects women predominantly around the world.<sup>1</sup> It is considered as one of the main causes of morbidity and mortality, the frequent appearance and serious complications of this disease have made it one of the most important diseases to be corrected surgically.

Many studies indicate that most gallstones are asymptomatic; surgical intervention is rarely required in these cases. The German surgeon Carl August Langenbuch famously quoted in 1882 - "The gallbladder should be removed, not because it contains stones, but because it forms them".<sup>2</sup> The main purpose of cholecystectomy is to give relief to the patients by removing the diseased gallbladder by performing safe surgery with little morbidity and early recovery.

Earlier before introduction of laparoscopic approach open cholecystectomy was the gold standard of treatment of

patients with symptomatic cholelithiasis, it was first performed in 1882 by Carl Langenbuch.<sup>3</sup> Laparoscopic cholecystectomy was first introduced into practice in the late 1980s, Philippe Mouret performed the first procedure in Lyon, France and has now become the most common performed laparoscopic procedure all over the world.<sup>4,5</sup> Many alternative methods of treating symptomatic gallstone diseases have been developed including oral bile acid and extracorporeal shock wave lithotripsy (ESWL), but none of them was satisfactory.

With the advent of laparoscopic technique of cholecystectomy, the scenario of surgical treatment for symptomatic cholelithiasis has changed dramatically. A number of trials have compared the two approaches and showed the superiority of one approach over the other one by reporting the advantages and drawbacks of each one. It has been well demonstrated that the laparoscopic approach compared to open surgical approach, leads to fewer post-operative complications and earlier recovery.<sup>6</sup> Now about 70-80% of cholecystectomies are performed by laparoscopic approach,<sup>7</sup> and 20-30% are still performed by open surgical approach.<sup>8</sup> The high costs of instruments, the need for specialized training, and the long learning curve of the procedure are strong factors that limit the use of the laparoscopic approach.<sup>10</sup>

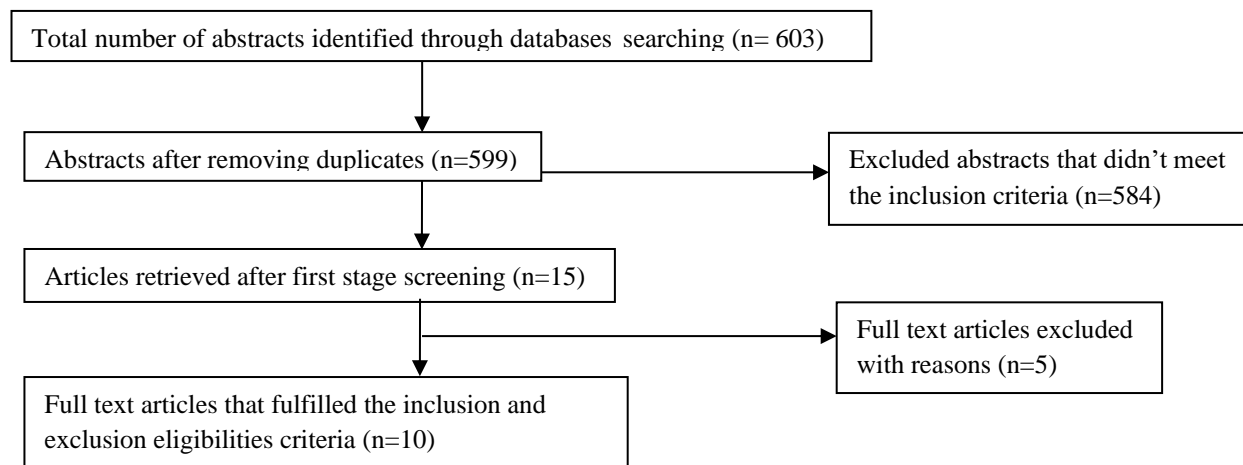
It is important to remember that the post-operative morbidity and the impact of hospital stay are not only influenced by the choice of surgical approach, peri-operative care is also an important contributing factor, it has changed substantially in recent years, with trends towards better care. Thus, comparisons between

laparoscopic and open approaches can be made only if both groups of patients are offered a similar peri-operative care program that is designed to optimize recovery.<sup>9</sup> To our knowledge there are no recent systematic reviews from the past ten years comparing recent data for these two techniques in patients with symptomatic cholelithiasis, and we believe that the systematic review of this subject will add recent updated data to literature. The aim of this study is to systematically review the published data comparing laparoscopic and open cholecystectomy in patients with symptomatic cholelithiasis in terms of operative and post-operative morbidity, mortality, operative time, length of hospital stay, and conversion rates.

## METHODS

### Search strategy

A vigorous, maximal sensitive literature review with using electronic data bases was performed including: PubMed (2000 – June 2020), Embase (2000 – June 2020), Cochrane library, and Medline. The search terms used were: “cholelithiasis”, “laparoscopic”, “open”, “minimally invasive”, no other search restrictions were applied. This search strategy yielded 603 hits and the studies were collected in a screening sheet. Duplicates were removed using Endnote to ensure a valid and reliable pool of studies, and a first stage screening was performed on the titles and abstracts identified with our inclusion criteria. Full text screening was performed for the articles that met the previously designed criteria. The data from the final articles were extracted onto standard forms after satisfying the inclusion and exclusion criteria (Figure 1).



**Figure 1: Flow diagram outlining the review process of the studies comparing laparoscopic with open cholecystectomy in symptomatic cholelithiasis.**

### Outcome measures

The clinical outcomes that were compared between the laparoscopic and open approaches to cholecystectomy included: operative time, length of hospital stay, mortality, conversion rate, post-operative pain duration, bile duct

injury, intra-operative bleeding, and post-operative wound infection.

### Selection criteria

Inclusion criteria published randomized and non-randomized trials that compared laparoscopic

cholecystectomy with open cholecystectomy in patients with symptomatic cholelithiasis in addition to cases of the disease that complicated with acute calculus cholecystitis and chronic calculus cholecystitis that were confirmed by ultrasonography and published from 2000 and on.

Exclusion criteria included studies published before 2000, studies compared laparoscopic and open cholecystectomy in patients with gall bladder cancer, choledocholithiasis, gangrenous and perforated gall bladder, and patients underwent cholecystectomy for acute or chronic cholecystitis without cholelithiasis. To achieve valid, high quality comparisons in this study we ensured that the studies that compared the two groups have similar demographic data and clinical presentations, studies that included patients who were not feasible to laparoscopic procedure for any reason were excluded.

### Quality assessment

This systematic review included ten studies, 4 randomized controlled trials, 3 prospective non-randomized trials, and 3 retrospective trials (Table 1).<sup>6,9-17</sup> The data quality of the four randomized controlled trials was assessed according to Cochrane collaboration guidelines six items were considered: allocation concealment, loss to follow up and

drop out described, eligibility criteria, homogeneous baseline characteristic, intention to treat analysis, and randomization.<sup>18</sup> The evaluation process was performed as follows: a positive answer to at least six questions was needed to consider the study of high quality. A positive answer to five or four questions was needed to consider the study of fair quality. A positive answer to three or less questions the study quality was considered to be low (Table 2).

Data quality assessment of the six non-randomized trials was performed using the methodological index for non-randomized studies (MINORS), twelve items were considered in the assessment (eight for non-comparative plus four for comparative trials), the total score was calculated as follows: 0 (not reported), 1 (reported but inadequate), 2 (reported and adequate).<sup>19</sup> The global ideal score to assess non-comparative studies is 16 and for comparative studies is 24 (Table 3). The level of evidence was also determined for each study by indicating the methodological quality of their design. Levels of evidence were defined using commonly accepted standards in the literature as follows: randomized controlled trials (level 1), prospective comparative studies (level 2), and retrospective comparative studies (level 3) (Table 1).

**Table 1: Details of the included studies and patients' data.**

Study	No. of patients Total=1703		Study characteristics	Level of evidence	Sex: male, female		Age (year)*		P value
	Lap (n=895)	Open (n=808)			Lap	Open	Lap	Open	
Kumar <sup>10</sup>	140	160	Randomized controlled trial	1	NA	NA	NA	NA	NA
Rubert <sup>15</sup>	70	43	Retrospective comparative	3	NA	NA	70 (NA)	70.2 (NA)	0.873
Majbar <sup>16</sup>	53	42	Retrospective comparative	3	04, 49	06, 36	50.3 (NA)	52.6 (NA)	0.42
Ahmed <sup>11</sup>	50	50	Randomized controlled trial	1	11, 39	12, 38	45.32 ±9.76	49.00±14.28	0.04
Singh <sup>12</sup>	50	50	Prospective non randomized	2	12, 38	09, 41	NA	NA	NA
Doke <sup>6</sup>	25	25	Randomized controlled trial	1	9, 16	10, 15	NA	NA	NA
Johansson <sup>9</sup>	35	35	Randomized controlled trial	1	19, 16	16, 19	53 (23-84)	56 (31-80)	0.171
Talpur <sup>13</sup>	200	200	Prospective non randomized	2	22, 178	27, 173	37.64 ±9.08	45.56±12.18	0.01
Bosch <sup>17</sup>	222	153	Retrospective comparative	3	47, 175	46, 107	49.2 (10-84)	52.0 (14-87)	0.474
Shakula <sup>14</sup>	50	50	Prospective non randomized	2	11,39	7, 43	39.16 ±11.43	43.44±12.31	0.075

NA: not available , \*data shown represent mean±SD or median (range)

**Table 2: Quality assessment of randomized controlled trials.**

Study	Eligibility criteria	Allocation concealment	Homogeneous baseline characteristic	Intention to treat analysis	Loss to follow up and drop out described	Randomization	Study quality
Kumar <sup>10</sup>	Yes	Yes	Yes	Yes	Yes	Yes	High
Ahmed <sup>11</sup>	Yes	Yes	Yes	Yes	Yes	Yes	High
Doke <sup>6</sup>	Yes	Yes	Yes	Yes	Yes	Yes	High
Johansson <sup>9</sup>	Yes	Yes	Yes	Yes	Yes	Yes	High

**Table 3: Quality assessment of non-randomized controlled trials.**

Study	Quality evaluation criteria						Additional criteria in comparative studies						Total
	Clear stated aim	Inclusion of consecutive patients	Prospective data collection	End-points appropriate to the study aim	Unbiased assessment of study endpoint	Appropriate follow up period	Loss to follow up less than 5%	Prospective calculation of the study size	Adequate control group	Contemporary groups	Base-line equivalence	Adequate statistical analysis	
Rubert <sup>15</sup>	2	2	0	2	2	2	2	0	2	1	2	2	19
Majbar <sup>16</sup>	2	2	0	2	2	2	2	0	2	1	2	2	19
Singh <sup>12</sup>	2	2	2	2	2	2	1	0	2	1	2	2	20
Talpur <sup>13</sup>	2	2	2	2	2	2	2	0	2	2	2	2	22
Bosch <sup>17</sup>	2	2	0	2	2	2	2	0	2	1	2	2	19
Shakula <sup>14</sup>	2	2	2	2	2	2	2	0	2	2	2	2	22

## RESULTS

This study systematically reviewed ten comparative trials that satisfied the inclusion and exclusion criteria. Of these ten comparisons, there were six randomized controlled trials that showed high quality in the assessment (Table 2), in addition to three prospective non-randomized trials and three retrospective trials that showed good scores in the assessment (Table 3); all studies were found to have an accepted level of bias. These studies were published between 2002 and 2017; they were the most recent evidence of this topic. The two groups were similar in the demographic data and the clinical presentation. The study found that the main sufferers of symptomatic cholelithiasis were females in both groups and this is supporting the fact that gallstone disease is affecting women predominantly.<sup>1</sup> A summary of the included studies can be found in (Table 1). The outcome measures used in this systematic review were:

### Mortality

Eight studies reported operative mortality (Table 4), none of them reported a mortality rate other than zero.<sup>6, 9-13,15,17</sup>

### Conversion

Six studies reported the conversion to open surgery (Table 4), the overall mean conversion rate was found to be 6.75% ranged from 0% to 23% (Table 6).<sup>9-11,13,15,16</sup> The most common reasons for conversion stated by the studies were: common bile duct injury, intra-operative bleeding, and inadequate visualization of calots' triangle.

### Operative time

The operative time was reported in eight studies (Table 5).<sup>6,9,10,12-15,17</sup>

It is defined by Shakula et al as the time taken from skin incision to skin closure.<sup>14</sup> Overall, the mean operative time was found to be significantly higher in laparoscopic surgery compared with open surgery [77.3 versus 67.1 min, p value<0.001] (Table 6).

### Post-operative pain duration

The post-operative pain duration in this systematic review corresponded to four studies (Table 5).<sup>6,10,12,14</sup> Overall, the

mean duration of pain was found to be significantly higher in open surgery compared with laparoscopic surgery [30.5 versus 66.9 hours,  $p$  value<0.001] (Table 6).

### Bile duct injury

Bile duct injury was reported in eight studies (Table 4), we found slightly higher rates associated with the laparoscopic approach, but the overall difference between laparoscopic and open approaches was statistically insignificant [0.84% versus 0.25%,  $p$  value=0.08].<sup>6,9-11,13,15-17</sup>

### Length of hospital stay

The length of hospital stay was stated by Ahmed et al as the period from the time of surgery to the time of discharge, studies reported shorter post-operative length of hospital stay with laparoscopic surgery compared with open surgery (Table 5), and this was reflected in the overall

mean of length of hospital stay [2.31 versus 4.42 days,  $p$  value<0.001] (Table 6).<sup>11</sup>

### Wound infection

All the studies reported data on post-operative wound infection (Table 4). Overall, it was found to be significantly less in laparoscopic surgery compared with open surgery [2.8% versus 10.5%,  $p$  value<0.001] (Table 6).

### Intra-operative bleeding

Seven studies reported intra-operative bleeding (Table 5).<sup>6,9,10,12-14,17</sup> The estimated amount of blood loss was reported in only two studies (Table 5).<sup>6,9</sup> Overall, no significant difference in the intra-operative blood loss between laparoscopic and open surgical approaches [4.2% versus 3.5%,  $p$  value=0.81] (Table 6).

**Table 4: Operative and post-operative outcomes of laparoscopic versus open cholecystectomy in symptomatic cholelithiasis.**

Study	Conversion : No. (%)	Mortality: No. (%)			Bile duct injury: No. (%)			Wound infection: No. (%)		
		Lap	Open	P value	Lap	Open	P value	Lap	Open	P value
Kumar <sup>10</sup>	11 (8)	0 (0)	0 (0)	NS	2 (1.4)	0 (0)	0.1	2 (1.4)	7 (4.3)	0.13
Rubert <sup>15</sup>	2 (2.9)	0 (0)	0 (0)	NS	1 (1.4)	0 (0)	0.43	1 (1.4)	1 (2.3)	0.72
Majbar <sup>16</sup>	3 (5.6)	NA	NA	NA	1 (1.9)	0 (0)	0.184	1 (1.8)	4 (9.3)	0.04
Ahmed <sup>11</sup>	0 (0)	0 (0)	0 (0)	NS	0 (0)	0 (0)	NS	3 (6)	11 (22)	0.02
Singh <sup>12</sup>	NA	0 (0)	0 (0)	NS	NA	NA	NS	2 (3)	3 (6.5)	0.64
Doke <sup>6</sup>	NA	0 (0)	0 (0)	NS	0 (0)	0 (0)	NS	1 (4)	4 (16)	0.15
Johansson <sup>9</sup>	8 (23)	0 (0)	0 (0)	NS	0 (0)	0 (0)	NS	1 (2.9)	2 (5.7)	0.5
Talpur <sup>13</sup>	2 (1)	0 (0)	0 (0)	NS	3 (1.5)	2 (1)	0.32	13 (6.5)	27 (13.5)	0.01
Bosch <sup>17</sup>	NA	0 (0)	0 (0)	NS	1 (0.5)	0 (0)	0.4	2 (0.9)	2 (1.3)	0.7
Shakula <sup>14</sup>	NA	NA	NA	NA	NA	NA	NS	0 (0)	12 (24)	0.0002

**Table 5: Operative and post-operative outcomes of laparoscopic versus open cholecystectomy in symptomatic cholelithiasis.**

Study	Operative time (min)*			Post-operative pain duration <sup>1</sup> (hours)			Hospital stay (days)*			Intra -operative bleeding No. (%)		
	Lap	Open	P value	Lap	Open	P value	Lap	Open	P value	Lap	Open	P value
Kumar <sup>10</sup>	105 <sup>1</sup> (50-170)	70 <sup>1</sup> (38-92)	<0.001	40.8	88.8	<0.001	2.7 <sup>1</sup> (NA)	4.4 <sup>1</sup> (NA)	<0.001	5 (3.6)	0 (0)	0.01
Rubert <sup>15</sup>	88±31	76±27	0.582	NA	NA	NA	2.01±0.9	2.95±1.5	0.001	NA	NA	NA
Majbar <sup>16</sup>	NA	NA	NA	NA	NA	NA	2.9 (1-4)	4.1 (2-8)	<0.0001	NA	NA	NA
Ahmed <sup>11</sup>	NA	NA	NA	NA	NA	NA	2.49±1.49	6.66±1.72	0.001	NA	NA	NA

Continued.

Study	Operative time (min)*			Post-operative pain duration <sup>1</sup> (hours)			Hospital stay (days)*			Intra-operative bleeding No. (%)		
	Lap	Open	P value	Lap	Open	P value	Lap	Open	P value	Lap	Open	P value
<b>Singh<sup>12</sup></b>	44.7 <sup>1</sup> (40-55)	72.7 <sup>1</sup> (55-80)	0.001	18.3	30.7	0.002	1.8 <sup>1</sup> (NA)	4.8 <sup>1</sup> (NA)	<0.001	0 (0)	0 (0)	NS
<b>Doke<sup>16</sup></b>	100 <sup>1</sup> (NA)	80 <sup>1</sup> (NA)	<0.05	48	120	<0.001	2 <sup>1</sup> (NA)	5 <sup>1</sup> (NA)	<0.001	3 (12) 20-200 ml	2 (8) 20-200 ml	0.6
<b>Johanson<sup>9</sup></b>	90 (30-155)	80 (50-170)	0.040	NA	NA	NA	2 (1-10)	2 (1-8)	0.011	3 (8.6) <500 ml	3 (8.6) <500 ml	1.00
<b>Talpur<sup>13</sup></b>	46.89±14.83	54.16±11.94	<0.001	NA	NA	NA	3.02±1.75	5.56±2.98	<0.001	11 (5.5)	17 (8.5)	0.2
<b>Bosch<sup>17</sup></b>	92±36	66±19	<0.001	NA	NA	NA	3±1	8±1	<0.001	0 (0)	0 (0)	NS
<b>Shakula<sup>14</sup></b>	52.32±13.33	37.66±4.94	0.001	14.68	27.92	0.001	1.18±0.52	4.78±1.42	0.001	0 (0)	0 (0)	NS

NA: not available, NS: not significant, \*data shown represent mean±SD or median (range) unless otherwise indicated, <sup>1</sup>mean

**Table 6: Summary of results of the comparative studies of laparoscopic versus open cholecystectomy in symptomatic cholelithiasis.**

Parameters	Lap		Open		P value
	No. of patients available for analysis	Results	No. of patients available for analysis	Results	
<b>Total no. of patients</b>	895		808		
<b>Mortality</b>	792	0 (0)	716	0 (0)	NS
<b>Conversion</b>	548	26 (6.75)			
<b>Operative time, mean (min)</b>	792	77.3	716	67.1	<0.001
<b>Post-operative pain duration, mean (hours)</b>	265	30.5	285	66.9	<0.001
<b>Bile duct injury</b>	795	8 (0.84)	708	2 (0.25)	0.08
<b>Hospital stay, mean (days)</b>	895	2.31	808	4.42	<0.001
<b>Wound infection</b>	895	25 (2.8)	808	48 (10.5)	<0.001
<b>Intra-operative bleeding</b>	722	22 (4.2)	673	22 (3.6)	0.81

Data are numbers with percentages unless otherwise indicated.

## DISCUSSION

In the history of surgery, there are very few operations that have changed the way of thinking and operating habits of surgeons as quickly and as extensively as laparoscopic surgery; it is vitally important area that needs careful assessments.<sup>21</sup> In the recent years, various comparative trials studied the laparoscopic and open cholecystectomy techniques in patients with symptomatic cholelithiasis.

Now about 70-80% of cholecystectomies are performed by laparoscopic approach, and 20-30% are still performed by open surgical approach.<sup>7,8</sup> The high costs of instruments, the need for specialized training, and the long learning curve of the procedure are strong factors that limit the use of the laparoscopic approach.<sup>10</sup> The indications for surgery

are similar for both procedures, however, the choice of the surgical technique depends mainly on the patients' preference, in addition to the costs of the procedure and hospital stay, and surgeons' expertise.<sup>12</sup> Earlier, people with advanced age were a relative contra-indication to the laparoscopic approach, despite recent evidence demonstrating that it is feasible in elderly patients.<sup>15</sup> Now, the absolute contra-indications for laparoscopic cholecystectomy include patients who are incapable to tolerate uncontrolled coagulopathy and general anesthesia, also the patients with congestive heart failure or severe obstructive pulmonary disease because carbon dioxide insufflations can lead to cardiac arrhythmia.<sup>14,22</sup>

This review attempted to make recent, valid, and quality comparisons by emphasizing various parameters, we



ensured that the two groups were similar in the demographic data and clinical presentation; studies that included patients with contra-indications to the laparoscopic technique were not included in this review. The superiority of laparoscopic over open cholecystectomy was well demonstrated in these comparative trials with lower post-operative wound infection rates, shorter duration of hospital stay and shorter post-operative pain duration. The lower rates of post-operative wound infection in laparoscopic surgery compared with open surgery can be explained by the fact that the larger incision of open surgery can act as a breeding place for the infectious agents leading to wound infection and its associated complications, correspondingly, the shorter duration of post-operative pain in laparoscopic surgery can be explained by the fact that laparoscopic technique affects only limited area and results in lesser tissue destruction compared to open technique resulting in shorter post-operative pain duration.<sup>14</sup> The duration of post-operative hospital stay is the period from the time of surgery to the time of discharge, as it would be expected laparoscopic approach was associated with shorter duration of hospital stay.<sup>11</sup>

This review didn't detect mortality in either the laparoscopic or the open group, and this can be explained by the best practice of peri-operative care program provided to the patients. The conversion rates ranged from 0% to 23%, the overall mean was 6.75 %, it is acceptable rate since the conversion rates in laparoscopic cholecystectomy normally ranges from 3% - 15% in well trained hands, the most common reasons for conversion to open surgery in this review were: common bile duct injury, intra-operative bleeding, and inadequate visualization of calots' triangle.<sup>9-11,13,15,16</sup> In symptomatic cholelithiasis there is no specific factor that reliably predict conversion to open surgical approach, but both patient and surgeon factors that predict the conversion, The decision of conversion should be considered as surgical maturity sign rather than a failure, it is mature and safe choice and considered as sound surgical judgment.<sup>10</sup> Thus, it is considered mandatory to explain to the patients about possibility of conversion to open surgical approach when we are taking the consent for the laparoscopic approach.<sup>23,24</sup> With regard to the operative time which is the time from skin incision to skin closure, the review showed considerably longer operative time in laparoscopic approach as compared to open surgical approach.<sup>14</sup> The rates of bile duct injury were slightly higher in the laparoscopic technique, it was one of the most common reasons for conversion to open surgery as stated previously, but the overall difference was statistically insignificant between the two procedures, it is important to mention the fact that in the laparoscopic surgical technique the depth perception is limited, thus the proper visualization of the internal structures may be difficult to some extents, this can be a strong contributing factor to the higher rates of bile duct injury associated with the laparoscopic surgery.<sup>20</sup> Similarly, intra-operative bleeding wasn't statistically significant between the laparoscopic

and open procedures; it was also one of the most common reasons for conversion to open surgical approach as mentioned previously for better access to manage the bleeding. It is important to mention that this systematic review included comparative trials for patients with symptomatic cholelithiasis considering specific and strict criteria, thus it does not represent the full spectrum of gallstone disease.

## CONCLUSION

Post-operative wound infection and pain duration in addition to length of hospital stay in patients with symptomatic cholelithiasis were reduced with laparoscopic cholecystectomy. However the laparoscopic approach associated with longer duration of surgery. No significant difference between the two procedures in the rates of bile duct injury and intra-operative bleeding.

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