



## COMPARISON OF GALL BLADDER REMOVAL WITH AND WITHOUT ENDOBAG DURING LAPAROSCOPIC CHOLECYSTECTOMY IN TERM OF PORT SITE INFECTION

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### ABSTRACT:

#### INTRODUCTION:

Laparoscopy has become the gold standard approach to cholecystectomy since its introduction 30 years ago, and is one of the most commonly performed general surgical procedures<sup>1</sup>. LC compared to open approach is the treatment of choice for symptomatic cholelithiasis with the proven benefits of less postoperative pain, shorter hospital stay, improved cosmesis, and increased patient satisfaction<sup>2</sup>. The present study will compare the port site infection (PSI) in patients whose gallbladder is removed using an endobag compared to no use of endobag. As mentioned above, the retrieval of GB during LC remains a permanent challenge despite huge advances in its operative procedures and perforation of GB during LC can lead to significant morbidity particularly in term of PSI. The results of this study will be compared with other local surgeons and on the basis of results of this study, we will be able to draw conclusions for future research and policy recommendations.

#### OBJECTIVE:

To compare the port site infection between endobag versus no endobag for gallbladder removal during laparoscopic cholecystectomy.

#### METHODOLOGY:

This study was carried out at the department of Surgery, Lady Reading hospital, Peshawar. Study Design was randomized controlled trial and the period of study was one year from 10<sup>th</sup> September 2019 to 9<sup>th</sup> September 2020. The sample size was 448 (224 in each group). All the patients undergoing single port LC for chronic cholecystitis with ASA class 1 and 2, age between 20 – 60 years and either gender were included. All the patients were randomly allocated in two groups by blocked randomization. Patients in group A were subjected to LC with use of endobag for retrieval of GB while patients in group B was subjected to LC with no endobag use for GB retrieval. Once the surgery is completed, standard post-operative protocols was maintained for all patients which includes triple antibiotic regime for all patients, analgesics and daily wound dressings. All the

patients were followed up for the next 30 days to detect port site infection. The data collected was analyzed in SPSS version 22.

### **RESULTS:**

In this current study patients in group A were subjected to LC with use of endobag for retrieval of GB while patients in group B was subjected to LC with no endobag use for GB retrieval. Mean age in Group A was 44 years with SD  $\pm$  15.71 while mean age in Group B was 45 years with SD  $\pm$  14.39. In Group A 87(39%) patients were male and 137(61%) patients were female while in Group B 83(37%) patients were male and 141(63%) patients were female. In Group A 4(2%) patients had port site infection and 220(98%) patients didn't had port site infection while in Group B 13(6%) patients had port site infection and 211(94%) patients didn't had port site infection.

### **CONCLUSION:**

Our study concludes that port site infection was low in endobag as compare to no endobag for gallbladder removal during laparoscopic cholecystectomy.

**KEYWORDS:** port site infection, endobag versus, endobag, gallbladder removal, laparoscopic cholecystectomy.

### **INTRODUCTION:**

Laparoscopy has become the gold standard approach to cholecystectomy since its introduction 30 years ago, and is one of the most commonly performed general surgical procedures<sup>1</sup>. LC compared to open approach is the treatment of choice for symptomatic cholelithiasis with the proven benefits of less postoperative pain, shorter hospital stay, improved cosmesis, and increased patient satisfaction<sup>2</sup>.

However, despite its advantages, single incisions LC (SILC) has not yet overruled LC as the leading method for gallbladder removal. This is mainly because of a lack of validated data from large multicenter randomized controlled trials (RCT) which could attest SILC a safety profile that is equal to that of LC<sup>3</sup>. Recently, Garg et al<sup>4</sup> recapitulated the results from 9 small RCTs in a review article. The authors concluded that patients who underwent SILC profited from better cosmesis, whereas no differences could be observed in regard of postoperative complications.

During laparoscopic cholecystectomy, gallbladder perforation is a common problem, which results in lost gallbladder stones and spillage of its contents. Complications may range from intra-abdominal and subcutaneous abscesses and fistulas to liver abscess, staphylococcal bacteraemia. Broncholithiasis, empyema, granulomas, bowel obstruction and hernia have been also reported<sup>5</sup>. Port site infections, sometimes seen in laparoscopic cholecystectomy, are usually superficial and respond to local measures. This is mostly seen at the trocar site of gallbladder extraction due to surgical site infection<sup>6</sup>.

In order to prevent above complications, gall-bladder specimen is retrieved in an endobag. Acutely inflamed or distended gall-bladder packed with stones always creates a problem during its retrieval. Gall-bladder removal in these cases requires a needle decompression, stone fragmentation and stone removal from the gall-bladder near the port site or extension of one of the fascial incisions to facilitate gall-bladder retrieval, which causes more post-operative port site pain<sup>7</sup>.

Any surgical procedure conducted has some risks and complications. Large series documented a reduced incidence of port site infection and other wound-related complications following laparoscopic surgeries but spillage of bile is more common with laparoscopy as compared to open procedures.<sup>8-11</sup> Certain situations lead to higher risk of gallbladder perforation during laparoscopic cholecystectomy like acutely inflamed gallbladders having friable tissue and distended gallbladder that has not been decompressed.<sup>12,13,14</sup> Spilled stones are also caused by the slipping of the cystic duct clip or the tearing of the gallbladder while it is retrieved from the port site.<sup>215,16,17</sup>

The present study will compare the port site infection (PSI) in patients whose gallbladder is removed using an endobag compared to no use of endobag. As mentioned above, the retrieval of GB during LC remains a permanent challenge despite huge advances in its operative procedures and

perforation of GB during LC can lead to significant morbidity particularly in term of PSI. The results of this study will be compared with other local surgeons and on the basis of results of this study, we will be able to draw conclusions for future research and policy recommendations.

**OBJECTIVE:**

To compare the port site infection between endobag versus no endobag for gallbladder removal during laparoscopic cholecystectomy.

**METHODOLOGY:**

This study was carried out at the department of Surgery, Lady Reading hospital, Peshawar. Study Design was randomized controlled trial and the period of study was one year from 10<sup>th</sup> September 2019 to 9<sup>th</sup> September 2020. The sample size was 448 (224 in each group) which was calculated on WHO formula for sample size calculator by taking 1.11% proportion of PSI in endobag group and 5.2%9PSI in no endobag group during LC, 95% confidence level and 80% power of the test. Non probability consecutive sampling technique was used for sample collection. More over all patients undergoing single port LC for chronic cholecystitis with ASA class 1 and 2, age between 20 – 60 years and either gender were included while patients presenting with serum urea of > 65mg/dl, Obesity, chronic diabetes mellitus were excluded from the study. All patients were randomly allocated in two groups by blocked randomization. Patients in group A were subjected to LC with use of endobag for retrieval of GB while patients in group B was subjected to LC with no endobag use for GB retrieval. Once the surgery is completed, standard post-operative protocols was maintained for all patients which includes triple antibiotic regime for all patients, analgesics and daily wound dressings. All the patients were followed up for the next 30 days to detect port site infection. The data collected was analyzed in SPSS version 22. Mean ± SD was calculated for continuous variable like age and BMI. Frequencies and percentages were calculated for categorical variable like gender and PSI. PSI in both the groups was compared by applying chi square test at < 0.05% significance level. Chi-Square test was applied on post stratification of age, gender and BMI in which p value <0.05 was considered as significant value to identify effect modification.

**RESULTS:**

Our study shows that in Group A 128(57%) patients were in age range 20-40 years, 96(43%) patients were in age range 41-60 years. Mean age was 44 years with SD ± 15.71. Where as in Group B 123(55%) patients were in age range 20-40 years, 101(45%) patients were in age range 41-60 years. Mean age was 45 years with SD ± 14.39. (Table no 1) In Group A 87(39%) patients were male and 137(61%) patients were female. Where as in Group B 83(37%) patients were male and 141(63%) patients were female. ( table no 2) In Group A 125(56%) patients had BMI ≤ 25 Kg/m<sup>2</sup> while 99(44%) patients had BMI >25 Kg/m<sup>2</sup>. Where as in Group B 114(51%) patients had BMI ≤ 25 Kg/m<sup>2</sup> while 110(49%) patients had BMI >25 Kg/m<sup>2</sup> (table no 3) More over in Group A 4(2%) patients had port site infection and 220(98%) patients didn't had port site infection. Where as in Group B 13(6%) patients had port site infection and 211(94%) patients didn't had port site infection. (table no 4)

**TABLE NO 1. AGE DISTRIBUTION**

AGE	GROUP A	GROUP B
<b>20-40 years</b>	128(57%)	123(55%)
<b>41-60 years</b>	96(43%)	101(45%)
<b>Total</b>	224(100%)	224(100%)
<b>Mean and SD</b>	44 year ± 15.71	45 year ± 14.39

**Group A:** LC with endobag

**Group B:** LC with no endobag

T Test was applied in which P value was 0.4827

**TABLE NO 2. GENDER DISTRIBUTION**

GENDER	GROUP A	GROUP B
Male	87(39%)	83(37%)
Female	137(61%)	141(63%)
Total	224(100%)	224(100%)

**Group A:** LC with endobag

**Group B:** LC with no endobag

Chi Square test was applied in which P value was 0.6969

**TABLE NO 3. BMI**

BMI	GROUP A	GROUP B
≤ 25 Kg/m <sup>2</sup>	125(56%)	114(51%)
>25 Kg/m <sup>2</sup>	99(44%)	110(49%)
Total	224(100%)	224(100%)
Mean and SD	25 ± 3.11	26 ± 2.09

**Group A:** LC with endobag

**Group B:** LC with no endobag

T Test was applied in which P value was 0.0001

**TABLE NO 4. PORT SITE INFECTION**

PORT SITE INFECTION	GROUP A	GROUP B
Yes	4(2%)	13(6%)
No	220(98%)	211(94%)
Total	224(100%)	224(100%)

**Group A:** LC with endobag

**Group B:** LC with no endobag

Chi Square test was applied in which P value was 0.0260

**TABLE NO 5. STRATIFICATION OF PORT SITE INFECTION W.R.T AGE**

AGE	PORT SITE INFECTION	GROUP A	GROUP B	P value
20-30 years	Yes	2	7	0.0786
	No	126	116	
Total		128	123	
31-40 years	Yes	2	6	0.1703
	No	94	95	
Total		96	101	

**Group A:** LC with endobag

**Group B:** LC with no endobag

**TABLE NO 6. STRATIFICATION OF PORT SITE INFECTION W.R.T GENDER**

GENDER	PORT SITE INFECTION	GROUP A	GROUP B	P value
Male	Yes	1	5	0.0851
	No	86	78	
Total		87	83	
Female	Yes	3	8	0.1362
	No	134	133	
Total		137	141	

**Group A:** LC with endobag

**Group B:** LC with no endobag

**TABLE NO 7. STRATIFICATION OF PORT SITE INFECTION W.R.T BMI**

BMI	PORT SITE INFECTION	GROUP A	GROUP B	P value
≤ 25 Kg/m <sup>2</sup>	Yes	2	7	0.0655
	No	123	107	
<b>Total</b>		125	114	
>25 Kg/m <sup>2</sup>	Yes	2	6	0.1963
	No	97	104	
<b>Total</b>		99	110	

**Group A:** LC with endobag

**Group B:** LC with no endobag

### DISCUSSION:

Laparoscopy has become the gold standard approach to cholecystectomy since its introduction 30 years ago, and is one of the most commonly performed general surgical procedures<sup>1</sup>. LC compared to open approach is the treatment of choice for symptomatic cholelithiasis with the proven benefits of less postoperative pain, shorter hospital stay, improved cosmesis, and increased patient satisfaction<sup>2</sup>. However, despite its advantages, single incisions LC (SILC) has not yet overruled LC as the leading method for gallbladder removal. This is mainly because of a lack of validated data from large multicenter randomized controlled trials (RCT) which could attest SILC a safety profile that is equal to that of LC<sup>3</sup>. Recently, Garg et al<sup>4</sup> recapitulated the results from 9 small RCTs in a review article. The authors concluded that patients who underwent SILC profited from better cosmesis, whereas no differences could be observed in regard of postoperative complications. Our study shows that mean age in Group A was 44 years with SD ± 15.71 while mean age in Group B was 45 years with SD ± 14.39. In Group A 87(39%) patients were male and 137(61%) patients were female while in Group B 83(37%) patients were male and 141(63%) patients were female. In Group A 4(2%) patients had port site infection and 220(98%) patients didn't had port site infection while in Group B 13(6%) patients had port site infection and 211(94%) patients didn't had port site infection.

Similar results were observed in another study carried out by Singh K et al<sup>84</sup> in which mean age of the patients was 44.5 years with 94 (94%) females. The minimum hospital stay was one day and maximum stay was three days in Group A patients with a mean hospital stay of 2.52 days. The minimum hospital stay in Group B patient was two days and max stay was four days with a mean hospital stay of 2.94 days. No patients presented with the port site malignancy in both the groups. In Group A 1 (2%) of the patient had port site infection and 4 (8%) patients had port site infection in Group B. It was related to the port site spillage as 4 (8%) patient in Group B had port site spillage. The statistical analysis showed that difference between two groups was insignificant (p-value 0.169). Similar results were observed in another study carried out by Narayanswamy T et al<sup>85</sup> in which there were 270 histologically proven cholecystitis during the study period. A bag was not used to retrieve the gallbladder [Group A] in 39.6% (n = 104) patients. A retrieval bag was used in the majority of patients [Group B] (62.6%). Overall wound infection rate was 7.2%, with 80% (n = 16) of those being in patients where no retrieval bag was used. more over they had concluded that epigastric port retrieval without endobag resulted in more port site wound infection and use of endobag was associated with less port site infections but has its own disadvantages like increase need for extension of facial incision and longer operating time.

Similar results were observed in another study carried out by Regina DL et al<sup>86</sup> in which wound infections were documented in 14 on 334 (4,2%) patients operated using a retrieval bag versus 16 on 271 (5,9%) patients operated without the use of a retrieval bag. The statistical analysis revealed a risk ratio (RR) of 0.82 (0.41–1.63 95% CI). Concerning sensitivity analysis the estimated pooled RR ranged from 0.72 to 0.96, both not statistically significant. Harbord test did not reveal the occurrence of small-study effect (p = 0.892) and the funnel-plot showed no noteworthy pattern.

Similar results were observed in another study carried out by Rehman H et al<sup>87</sup> in which mean age of patients was  $40.77 \pm 10.95$  years. Out of 254 patients, 98 (38.58%) were males and 156 (61.42%) were females with male to female ratio of 1:2.5. Patients were divided in two groups A and B and the frequency of patients having port site wound infection in group A was 1(0.4%) whereas in group B was 14(5.5%). more over they had concluded that the use of retrieval bag to remove gallbladder in laparoscopic cholecystectomy resulted in decreased frequency of port site wound infection. The insignificant association of port site wound infection with different age groups, gender categories and with duration of cholelithiasis was revealed. Moreover wound infection proved significantly associated with both categories with operating time.

### CONCLUSION:

Our study concludes that port site infection was low in endobag as compare to no endobag for gallbladder removal during laparoscopic cholecystectomy.

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