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**INCIDENCE OF PORT-SITE INFECTIONS IN RELATION TO THE NON-BAG VERSUS BAG EXTRACTION OF GALL BLADDER STONES VIA LAPAROSCOPY**

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**ABSTRACT**

**Introduction:** For biliary tract and gall bladder surgeries, laparoscopic cholecystectomy (LC) is the gold standard surgical procedure that is taken into consideration.

**Aim:** to assess the incidence of port-site infections in relation to the non-bag versus bag extraction of gall bladder stones via laparoscopy.

**Methods:** 164 subjects were randomly divided into two groups of the bag and non-bag extraction of the gall bladder. Post op-surgery, the port site utilized for the extraction of the gall bladder was attentively assessed for 7 days for any incidence of infection at the wound site.

**Results:** In the non-bag extraction group, HbA1c and diabetes were likewise statistically significant with a p-value of less than 0.01; however, in the bag extraction group, these results were statistically non-significant with p-values of 0.732 and 0.116, respectively.

**Conclusion:** The current study suggests that bag extraction reduces infection rates; thus, bag extraction need to be used routinely in all laparoscopic cholecystectomy procedures, particularly in patients who are at higher risk due to conditions like diabetes mellitus and immunocompromised states.

**Keywords:** Laparoscopic Cholecystectomy, End Glove, Port Site Infections, Bag Extraction.

**INTRODUCTION**

Since cholecystectomy was discovered to be the best surgical procedure for cholecystectomy patients, there have been many advances in surgical techniques. For biliary tract and gall bladder surgeries, laparoscopic cholecystectomy (LC) is the gold standard surgical procedure that is taken into consideration. The great dependability of laparoscopic cholecystectomy can be attributed to the much lower rates of complications (1%–5%) associated with the procedure.<sup>1</sup>

In most cases, laparoscopic cholecystectomy has taken the place of open cholecystectomy, with the exception of patients who had malignancies, were contraindicated for general anaesthesia, or experienced intraoperative difficulties that required them to change their course of therapy during the procedure.

However, because of advances in surgical equipment and methods, careful patient selection, and enhanced surgeon abilities, the number of LC conversions to open cholecystectomy due to intra-operative problems has significantly decreased recently. Data from recent literature indicate that conversion rates may be as high as 7%.<sup>2</sup>

Although there is less evidence and fewer problems in terms of mortality and morbidity, these aspects nonetheless present a challenge to the treating surgeon. These include the potential intraoperative complications that can arise at any point during the procedure, such as anaesthesia induction, trocar insertion injury, bile leak, gall bladder perforation, liver trauma during gall bladder dissection, injury to the common bile duct, compromised respiration during carbon dioxide insufflations, and so on.

Postoperative problems with LC include port site metastases, port site hernias, and/or port site infections (PSI), which are frequently observed after intraoperative difficulties. According to recent literature statistics, umbilical PSI, which occurs between 8% and 89% of the time, is the most frequent complication observed in cholecystectomy patients.<sup>3</sup>

Even though the number of complications related to laparoscopic cholecystectomy has significantly decreased recently, understanding the various complications and risk factors that can be targeted to lower the chances of complications related to the cholecystectomy is essential to further reducing the incidence of these complications and improving patient care.<sup>4</sup> In order to compare the incidence of port-site infections between bag and non-bag gall bladder stone extraction techniques using laparoscopy, the current study was carried out.

PSI incidence was assessed based on various factors including immunocompromised state, hypoalbuminemia, BMI, and/or diabetes mellitus.

## **MATERIALS AND METHODS**

The current randomized-controlled trial was carried out to assess the incidence of port-site infections in relation to the non-bag versus bag extraction of gall bladder stones via laparoscopy. After receiving approval from the relevant ethical council, the study was carried out in the department of general surgery. Adult patients having cholecystectomy who were at least 18 years old were included in the research. People with gall bladder empyema, LC converted to open cholecystectomy, and people unwilling to participate in the trial were the exclusion criteria for the research.

The study included a total of 164 subjects from both genders. 164 subjects were randomly divided into two groups of the bag and non-bag extraction of the gall bladder. After explaining the detailed study design, informed consent was taken from all the subjects in both written and verbal form. This was followed by a recording of detailed history and general examination. A pre-anesthetic assessment was done for all the study subjects. Surgery was then done for all the subjects for extracting gall bladder via the epigastric port.

For the groups where bag extraction was done, a sterile and aseptic endo bag was made which was introduced from gall bladder fossa after gall bladder resection through the 10mm port. Roeder's knot was tied to close the mouth of the bag after maneuvering the gall bladder. This was followed by extraction of the specimen via the epigastric port. After the procedure, standard antibiotic therapy was given for five days for all the study subjects.

Post op-surgery, the port site utilized for the extraction of the gall bladder was attentively assessed for 7 days for any incidence of infection at the wound site. In cases where infection sign was noticed including discharge, swelling, erythema, or pain, a swab was taken and sent to the laboratory for the culture where a positive growth indicated the infection of the port site. For further management, antibiotics were given to all the study subjects.

The demographics, history, and clinical characteristics including immunocompromised state, BMI, and diabetes were recorded on a structured proforma for all the subjects. The venous blood was collected for all the study subjects under sterile and aseptic conditions which were sent to the laboratory for assessing serum creatinine, serum albumin, and HbA1c (glycosylated hemoglobin). Non-infective or infective pathology of the gall bladder was also assessed and documented.

The collected data were subjected to the statistical evaluation using SPSS software version 21 (Chicago, IL, USA) and one-way ANOVA and t-test for results formulation. The data were expressed in percentage and number, and mean and standard deviation. The level of significance was kept at  $p < 0.05$ .

## **RESULTS**

The present randomized-controlled study was conducted to comparatively evaluate the non-bag to bag extraction of gall bladder stones via laparoscopy concerning the incidence of port-site infections. The study included a total of

164 subjects from both genders within the age range of 26-58 years and the mean age of  $38.4 \pm 6.26$  years. The demographic characteristics of the study subjects are listed in Table 1. There were 57.44% (n=54) females and 42.55% (n=40) males in non-bag extraction and 57.14% (n=40) females and 42.85% (n=30) males in the bag extraction group. There were 12.76% (n=12) immunocompromised subjects in non-bag extraction and 8.57% (n=6) in bag extraction group. Diabetes was present in 32.97% (n=31) and 31.42% (n=22) subjects from non-bag extraction and bag extraction groups respectively. Infective pathology was seen in 23.40% (n=22) and 28.57% (n=20) subjects respectively from non-bag and bag extraction subjects respectively (Table 1).

On assessing the laboratory parameters in the study subjects, serum creatinine was  $1.2 \pm 0.3$  in non-bag and  $1.1 \pm 0.3$  for bag extraction group, serum albumin was  $3.6 \pm 0.5$  and  $3.4 \pm 0.7$  for non-bag and bag extraction group, BMI for non-bag and bag extraction group was  $24.9 \pm 4.4$  and  $26.4 \pm 3.4$  respectively, and HbA1c values were  $5.4 \pm 1.2$  and  $5.7 \pm 1.2$  respectively for non-bag and bag extraction groups. All these values were statistically non-significant with respective p-values of 0.3, 0.3, 0.12, and 0.11. In the non-bag extraction group, infection was seen in 1.06% (n=1) study subjects, whereas, for the bag extraction group, infection was seen in 8.57% (n=6) study subjects as depicted in Table 2.

For the factors depicting risk of infection in the study subjects, age was non-significant with p-values of 0.575 and 0.982 for the non-bag and bag extraction group, and gender was also non-significant with p-values of 0.942 and 0.133 respectively. Infective pathology was significant in the non-bag extraction group with  $p < 0.01$ . The immunocompromised state was significant for non-bag extraction with  $p = 0.002$ . HbA1c and diabetes were also statistically significant in the non-bag extraction group with the p-value of  $< 0.01$ , whereas, for bag extraction, these values were statistically non-significant with respective p-values of 0.732 and 0.116 respectively (Table 3).

## DISCUSSION

The present randomized-controlled study was conducted to comparatively evaluate the non-bag to bag extraction of gall bladder stones via laparoscopy concerning the incidence of port-site infections. The study included a total of 164 subjects from both genders within the age range of 26-58 years and the mean age of  $38.4 \pm 6.26$  years. There were 57.44% (n=54) females and 42.55% (n=40) males in non-bag extraction and 57.14% (n=40) females and 42.85% (n=30) males in the bag extraction group. There were 12.76% (n=12) immunocompromised subjects in non-bag extraction and 8.57% (n=6) in bag extraction group. Diabetes was present in 32.97% (n=31) and 31.42% (n=22) subjects from non-bag extraction and bag extraction groups respectively. Infective pathology was seen in 23.40% (n=22) and 28.57% (n=20) subjects respectively from non-bag and bag extraction subjects respectively. These demographics were comparable to the studies of Satheshkumar T et al in 2004 and Saud JD et al in 2010 where authors assessed subjects with demographics comparable to the present study.

Concerning the laboratory parameters in the study subjects, serum creatinine was  $1.2 \pm 0.3$  in non-bag and  $1.1 \pm 0.3$  for the bag extraction group, serum albumin was  $3.6 \pm 0.5$  and  $3.4 \pm 0.7$  for non-bag and bag extraction group, BMI for non-bag and bag extraction group was  $24.9 \pm 4.4$  and  $26.4 \pm 3.4$  respectively, and HbA1c values were  $5.4 \pm 1.2$  and  $5.7 \pm 1.2$  respectively for non-bag and bag extraction groups. All these values were statistically non-significant with respective p-values of 0.3, 0.3, 0.12, and 0.11. In non-bag extraction group, infection was seen in 1.06% (n=1) study subject, whereas, for bag extraction group, infection was seen in 8.57% (n=6) study subjects. These results were consistent with the studies of Brockmann JG et al in 2002 and Taj MN et al in 2012 where authors reported similar laboratory parameters and infection rates in subjects with bag and non-bag extraction.

On assessing the factors depicting risk of infection in the study subjects, age was non-significant with p-values of 0.575 and 0.982 for the non-bag and bag extraction group, and gender was also non-significant with p-values of 0.942 and 0.133 respectively. Infective pathology was significant in the non-bag extraction group with  $p < 0.01$ . The immunocompromised state was significant for non-bag extraction with  $p = 0.002$ . HbA1c and diabetes were also statistically significant in the non-bag extraction group with the p-value of  $< 0.01$ , whereas, for bag extraction, these values were statistically non-significant with respective p-values of 0.732 and 0.116 respectively. These results were in agreement with the studies of Mir IS in 2003 and Sasmal PK et al in 2015 where authors suggested similar factors to be responsible for infection as in the present study.

## CONCLUSION

Within its limitations, the present study concludes that lower rates of infection are associated with bag extraction, and hence, bag extraction should be routinely employed in all laparoscopic cholecystectomy surgeries, especially in

subjects with higher risks as immunocompromised state and diabetes mellitus. However, the present study had a few limitations including small sample size and geographical area biases. Hence, more longitudinal studies with a larger sample size will help reach a definitive conclusion.

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**TABLES**

Characteristics	Non-bag extraction (n=94)		Bag extraction (n=70)	
	%	N	%	N
<b>Mean age (years)</b>				
<b>Gender</b>				
Females	57.44	54	57.14	40
Males	42.55	40	42.85	30
<b>Immunocompromised state</b>				
Present	12.76	12	8.57	6
Not present	87.23	82	91.42	64
<b>Diabetes</b>				
Present	32.97	31	31.42	22
Not present	67.02	63	68.57	48
<b>Infective Pathology</b>				
Present	23.40	22	28.57	20
Not present	76.59	72	71.42	50

**Table 1: Demographic and disease characteristics of the study subjects**

Characteristics	Non-bag extraction	Bag Extraction	p-value
<b>Laboratory Parameters</b>			
Serum creatinine	1.2±0.3	1.1±0.3	0.3
Serum albumin	3.6±0.5	3.4±0.7	0.3
BMI	24.9±4.4	26.4±3.4	0.12
HbA1c	5.4±1.2	5.7±1.2	0.11
	<b>No infection % (n)</b>	<b>Infection % (n)</b>	<b>p-value</b>
<b>Non-bag extraction (n=94)</b>	98.93 (93)	1.06 (1)	<b>&lt;0.01</b>

<b>Bag Extraction (n=70)</b>	91.42 (64)	8.57 (6)	
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**Table 2: Laboratory parameters and infection rates in the study subjects after non-bag and bag extraction of gall stones**

<b>Characteristics</b>	<b>Non-Bag Extraction (P-Value)</b>	<b>Bag Extraction (P-Value)</b>
<b>Age</b>	0.575	0.982
<b>Gender</b>	0.942	0.133
<b>Infective Pathology</b>	<0.01	0.424
<b>Immunocompromised State</b>	0.002	0.163
<b>Serum Creatinine</b>	0.316	0.977
<b>Serum Albumin</b>	0.734	0.144
<b>BMI</b>	0.464	0.496
<b>Hba1c</b>	<0.01	0.732
<b>Diabetes</b>	<0.01	0.116

**Table 3: Factors affecting the infection risks in the study subjects**