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COMPARATIVE EVALUATION OF NON-BAG TO BAG EXTRACTION OF GALL BLADDER STONES VIA LAPAROSCOPY: A CLINICAL STUDY

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ABSTRACT

Introduction: For the surgeries of the biliary tract and gall bladder region, the gold standard surgical procedure considered is LC (Laparoscopic cholecystectomy). However, various complications are seen associated with these procedures of LC where significantly high mortality and morbidity are seen associated with PSIs (port site infections).

Aims: The present 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.

Methods: The present randomized controlled trial was conducted on 164 study subjects having a history of Laparoscopic cholecystectomy for 2 years, and was randomly divided into two groups of bag extraction and non-bag extraction. All the subjects were postoperatively followed for 1 week to assess the incidence of PSI.

Results: Serum creatinine was 1.2±0.3 in non-bag and 1.1±0.3 for bag extraction group, serum albumin was 3.6±0.5 and 3.4±0.7 for non-bag and bag extraction group, BMI for non-bag and bag extraction group was 24.9±4.4 and 26.4±3.4 respectively, and HbA1c values were 5.4±1.2 and 5.7±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.. 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 was 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

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Conclusion: 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.

Key Words: Bag Extraction, Gall Bladder Diseases, End Glove, Port Site Infections, Laparoscopic Cholecystectomy

INTRODUCTION

Since the identification of cholecystectomy as the choice of surgical procedure in subjects with cholecystectomy, various advancements have been seen in surgical techniques, where for the surgeries of the biliary tract and gall bladder region, the gold standard surgical procedure considered is LC (Laparoscopic cholecystectomy). Owing to the significantly lesser rates of complications associated with Laparoscopic cholecystectomy seen in the range of 1%-5%, the reliability of Laparoscopic cholecystectomy is high.[1]

Open cholecystectomy has been largely replaced with Laparoscopic cholecystectomy in the majority of subjects except for subjects with intraoperative complications changing the course of treatment during the surgery itself, malignancies, and subjects with contraindications to general anesthesia. However, conversion of LC to open cholecystectomy due to intra-surgical complications has largely reduced recently owing to advancements in surgical techniques and instruments, wise patient selection, and improved surgeon skills. Recent literature data suggest conversion rates of approximately 7%.[2]

Concerning mortality and morbidity, these factors challenge the surgeon despite having less evidence and few, these complications still challenge the treating surgeon. These include the intraoperative complications that may come into play at any time from anesthesia induction to trocar insertion injury, bladder stone spillage during retrieval, bile leak, gall bladder perforation, liver trauma during gall bladder dissection, injury to the common bile duct, adjacent structure injury while dissection compromised respiration during insufflations of carbon dioxide. Followed by intraoperative complications, postoperative complications are also seen with LC including port site metastases, port-site hernias, and/or port-site infections (PSI). Recent literature data showed that the most common complication seen in cholecystectomy subjects is umbilical PSI having an incidence of 8%-89%.[3]

Despite the large reduction in complications associated with laparoscopic cholecystectomy in the recent past, to further reduce the incidence of these complications and to provide better care to the subjects, it is vital to have the knowledge of various complications and risk factors that can be focused to decrease the complication chances related to the cholecystectomy.[4] Hence, the present 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. PSI incidence was assessed based on various factors including immunocompromised state, hypoalbuminemia, BMI, and/or diabetes mellitus.

MATERIALS AND METHODS

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

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infections. The study was conducted at Department of General Surgery, Rama Medical college Hospital and Research Center, Kanpur, Uttar Pradesh after obtaining clearance from the concerned Ethical committee. The study population was comprised of the subjects visiting the Department of General Surgery of the Institute. The study included adult subjects of age 18 years or older undergoing cholecystectomy. The exclusion criteria for the study were subjects where LC was converted to open cholecystectomy, gall bladder empyema, and the subjects who were not willing to participate in the study were excluded. The study included a total of 164 subjects from both genders.

164 subjects were randomly divided into two groups of the bag and non-bad 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.

After the 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±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)

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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±0.3 in non-bag and 1.1±0.3 for bag extraction group, serum albumin was 3.6±0.5 and 3.4±0.7 for non-bag and bag extraction group, BMI for non-bag and bag extraction group was 24.9±4.4 and 26.4±3.4 respectively, and HbA1c values were 5.4±1.2 and 5.7±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±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±0.3 in non-bag and 1.1±0.3 for the bag extraction group, serum albumin was 3.6±0.5 and 3.4±0.7 for non-bag and bag extraction group, BMI for non-bag and bag extraction group was 24.9±4.4 and 26.4±3.4 respectively, and HbA1c values were 5.4±1.2 and 5.7±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

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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
Mean age (years)				
Gender				
Females	57.44	54	57.14	40
Males	42.55	40	42.85	30
Immunocompromised state				
Present	12.76	12	8.57	6
Not present	87.23	82	91.42	64
Diabetes				
Present	32.97	31	31.42	22
Not present	67.02	63	68.57	48
Infective Pathology				
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
Laboratory Parameters			
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
	No infection % (n)	**Infection % (n)**	**p-value**
Non-bag extraction (n=94)	98.93 (93)	1.06 (1)	**<0.01**
Bag Extraction (n=70)	91.42 (64)	8.57 (6)	

Table 2: Laboratory parameters and infection rates in the study subjects after non-bag and bag extraction of gall stones

Characteristics	Non-bag extraction (p-value)	Bag Extraction (p-value
Age	0.575	0.982
Gender	0.942	0.133
Infective Pathology	<0.01	0.424
Immunocompromised state	0.002	0.163
Serum creatinine	0.316	0.977
Serum albumin	0.734	0.144
BMI	0.464	0.496
HbA1c	<0.01	0.732
Diabetes	<0.01	0.116

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