

A PROSPECTIVE COMPARATIVE STUDY OF PORT SITE (EPIGASTRIC VS UMBILICAL) PAIN AND INFECTION FOLLOWING GALL BLADDER EXTRACTION IN PATIENTS OF LAPAROSCOPIC CHOLECYSTECTOMY

Surgery

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KEYWORDS

INTRODUCTION

Laparoscopic cholecystectomy, is now the preferred method for cholecystectomy. Laparoscopic cholecystectomy has advantage over open cholecystectomy due to shorter hospital stay, easy return to work and low cost.

Post operative pain is most frequent complaint after laparoscopic cholecystectomy, it depends on multiple factors (distension due to pneumoperitoneum, traumatic traction on nerves, abdominal trauma due to port and gallbladder retrieval. Incisional pain is more severe in initial 48 hrs.

Retrieval of gallbladder is an important event of laparoscopic cholecystectomy, and is thought to be one of the factors affecting postoperative port site pain and infection. Retrieval of gallbladder can be done either via epigastric port or via umbilical port. Advantage of gallbladder retrieval via either of port over other is not established till date.

This study was undertaken to establish whether retrieval of gallbladder via umbilical port is associated with more pain and infection at port site in comparison to epigastric port.

MATERIAL AND METHODS

Setting: Department of Surgery, LLRM Medical college & SVBP Hospital and MSY Medical College, Meerut from Sep 2018 to Sep 2019.

Type of study: Double blinded –Prospective randomised control trial.
Group A: Patients undergoing extraction of gall bladder via epigastric port.(43 patients)

Group B: Patients undergoing extraction of gall bladder via umbilical port.(38 patients)

Inclusion criteria: All patients >18 years with symptomatic cholelithiasis consenting for inclusion in study and undergoing laparoscopic cholecystectomy in department of surgery.

Exclusion criteria: Spillage/Perforation of gall bladder during dissection /extraction. Those patients in whom laparoscopy is converted to open cholecystectomy. Portal hypertension.

Process of randomisation and blinding: All 80 patients were randomly allocated to extraction of gall bladder through either epigastric or umbilical port. The randomisation scheme will be computer generated.

Methods: Informed consent was taken from all eligible patients.

All patients were randomised as mentioned above.

The patients were not informed, through which group they will undergo the surgery and the randomisation will be generated and maintained by a third person who is not involved in the study.

Intra operative post dissection gallbladder extraction time in minutes were noted. Post operative port site pain was assessed at 8,16 & 24 hours just before analgesic dose. Dressing was done after 24 hours and epigastric and umbilical port site were clinically examined for local port site signs of soiling/staining of dressing, redness, induration, pus discharge, blackening of skin.

Outcome Measures:

Primary outcome measures:

Port site pain in epigastric and umbilical port by VAS.
Gall bladder extraction time in minutes.
Presence or absence of local port site signs of infection.

Secondary outcome measures:

Surgeon perception on ease of gallbladder extraction.

STATISTICS:

The data was tabulated in MS-Excel. It was analysed with IBM-SPSS version 21. For parametric quantitative data the results are depicted as mean and standard deviation, comparisons were made by independent sample "T" for comparing data between two groups, p-value considered as significant for $p < 0.05$. Mann whitney U test was used to compare non parametric data between two groups, level of significance defined at value < 0.05 .

OBSERVATIONS

This study was conducted in the Department of Surgery, SVBP Hospital, LLRM Medical College, Meerut. 123 patients of cholelithiasis were admitted and evaluated in the department, from 01 august 2017 to 31 July 2018. Out of total 123 patients, 22 patients were declared unfit for laparoscopic cholecystectomy because of various pre-operative morbid conditions.

Total 101 patients were taken for laparoscopic cholecystectomy and were included in this study. Out of 101 patients, in 18 cases gallbladder got perforated due to intra-operative difficulties and 2 got converted to open, therefore they were excluded from the study. Finally total 81 patients were included in this study and divided in two groups, **Group A**, in this group gallbladder was extracted via **epigastric port** and had **43 patients**.

Group B, in this group gallbladder was extracted via **umbilical port** and had **38 patients**.

TABLE 1: Port site pain as per Visual Analogue Scale(VAS) score at post op 8th hour:

Group	VAS Score at 8th hour	P value
A	6.20 ± 1.16	0.001
B	5.03 ± 1.31	

In Group B, patients experienced significantly less pain than group A at 8th hour and it was statistically significant (p value **0.001**)

Graphical representation of VAS score at 8th hour:

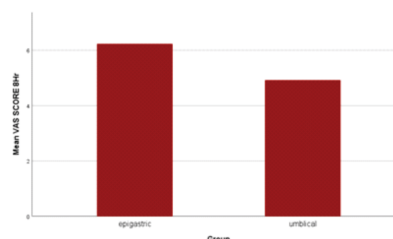
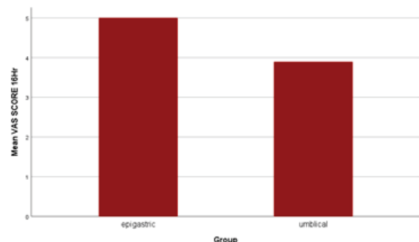


TABLE 2: Port site pain as per Visual Analogue Scale (VAS) Score at post op 16th hour:

Group	VAS Score at 16 th hour	P value
A	5 ± 0.72	0.001
B	3.89 ± 0.92	

In group B, patients experienced less pain than in group A and it was statistically significant (p value **0.001**)

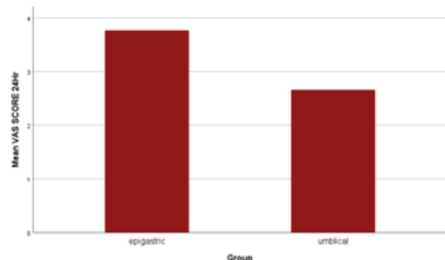
Graphical representation of VAS score at 16th hour:

**TABLE 3: Port site pain as per Visual Analogue Scale (VAS) score at post op 24th hour:**

Group	VAS Score at 24 th hour	P value
A	3.63 ± 1.35	0.008
B	2.80 ± 1.36	

In group B, patients experienced less pain than in group A and it was statistically significant (p value **0.008**)

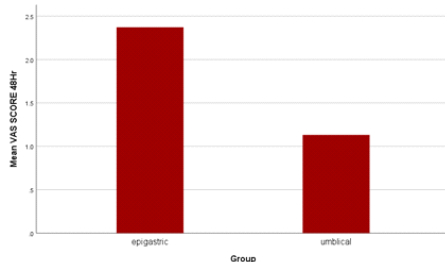
Graphical representation of VAS score at 24th hour:

**TABLE 4: Port site pain as per Visual Analogue Scale (VAS) score at post op 48th hour:**

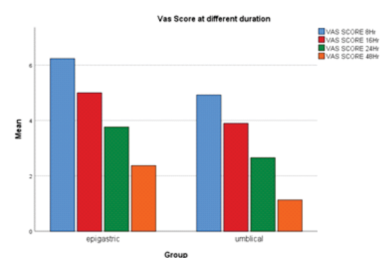
Group	VAS Score at 48 th hour	P value
A	2.20 ± 1.22	0.002
B	2.80 ± 1.36	

In group B, patients experienced less pain than in group A and it was statistically significant (p value **0.002**)

Graphical representation of VAS score at 48th hour:



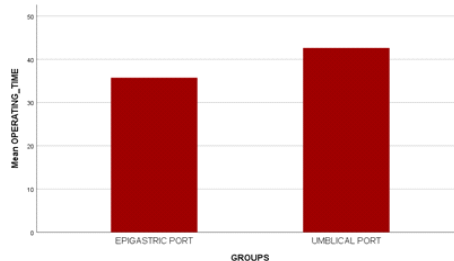
Graphical representation of combined VAS score at 8th, 16th, 24th and 48th hour:

**TABLE 5: COMPARISON OF OPERATIVE TIME IN BOTH GROUPS:**

S.NO.	Group	Extraction Time	P value
1	A	35.74 ± 8.24	0.01
2	B	42.63 ± 6.24	

Operating time in Group A (35.74 ± 8.24) was less (about 7 minutes) than in Group B (42.63 ± 6.24) and it was statistically significant (P value 0.01).

Depiction of operating time in both the groups.

**TABLE 6: INCIDENCE OF PORT SITE INFECTION IN BOTH THE GROUPS:**

	GROUP A	GROUP B	P value
No. Of Patients infected	1	1	0.8

Considering the above table only one patient in each group got infected and p value for comparison was 0.08, which was statistically insignificant.

DISCUSSIONS

Total 123 patients were diagnosed with cholelithiasis in department, out of which **22** were declared unfit because of various preoperative comorbid conditions and **101** patients were included in this study. Total 101 patients underwent laparoscopic cholecystectomy, out of which, in **18** cases gallbladder got **perforated** and **2** got converted to **open** cholecystectomy.

Based on the inclusion and exclusion criteria, **81** patients were included in this study, we had 43 patients in Group A and 38 in Group B.

Group A had patients in whom gallbladder was extracted by epigastric port and,

Group B included patients, in which gallbladder was extracted by umbilical port.

In this study, what we concluded was that severity of port site pain following gallbladder extraction via **umbilical port** was **less** at **8th, 16th, 24th and 48th hour** following laparoscopic cholecystectomy as compared to epigastric port.

P value for this was **0.001** at **8th hour**, **0.001** at **16th hour**, **0.008** at **24th hour** & **0.002** at **48th hour**. All these were <0.05, hence statistically significant.

In previous studies:

By **Nadeem Ahmed Siddiqui et al**, in March 2012, they concluded that incidence of port site pain following laparoscopic cholecystectomy was **more** in patients in whom gallbladder was extracted **via epigastric port** than in whom it was extracted via umbilical port. There P value for the comparison was **0.01**.

By **Bashir Azhar et al**, in June 2015, they concluded that incidence of port site pain following laparoscopic cholecystectomy was **similar** in both the groups when compared. P value was **0.089**.

By **Cemal Kaya et al**, Oct 2017, they concluded that port site pain was **lower** in patients in whom gallbladder was extracted **via umbilical port**.

Table for pain comparison at 24th hour using VAS Score for different studies.

	Nadeem Ahmed Siddiqui et al	Bashir Azhar et al	Cemal Kaya et al	Our study
Group A	3.05 ± 0.87	3.54 ± 1.03	4.7 ± 1.2	2.2 ± 1.22

Group B	2.15 ± 0.87	3.11 ± 1.37	5.2 ± 1.5	1.33 ± 1.27
P Value	0.01	0.089	0.081	0.002

We have also compared the operating time in both **Group A & Group B**.

In our study we have concluded that operating time was more when gallbladder was extracted via umbilical port in comparison to epigastric port.

P value for operating time in two groups was **0.01**, which was less than 0.05, hence statistically significant.

In Previous studies:

By **Bashir Azhar et al**, in June 2015, they concluded that extraction time was **more** when gallbladder was extracted **via umbilical** port, with **P value of 0.032**. Our findings were also similar to this study.

By **Cemal Kaya et al**, Oct 2017, they concluded that operating time in both groups were **comparable** and there was no significant difference in gallbladder extraction time in both the groups.

By **Prem Chand, Ashok Kumar et al**, they also concluded that operating time was **comparable** in both the groups and there was **no significant difference** between the two groups.

	Bashir Azhar et al	Cemal Kaya et al	Prem Chand et al	Our Study
Op Time Grp A	10.62 ± 4.61	-	33.33 ± 7.23	35.74 ± 8.24
Op Time Grp B	8.64 ± 4.18	-	33.16 ± 7.25	42.63 ± 6.24
P value	0.032	No Statistical Difference	0.92	0.01

However in our study the operating time was 7 minutes more in Group B (42.63 ± 6.24) patients than Group A (35.74 ± 8.24) patients and it was statistically significant (P value 0.01)

While comparing the port site infection in two groups, we have come to the conclusion that only one patient in each group developed port site infection and hence incidence of port site infection was comparable in both groups according to **MANN WHITNEY U** non parametric test, and was statistically insignificant, showing that gallbladder extraction from epigastric port or umbilical port had no effect over port site infection.

In previous studies:

By **Bashir Azhar et al**, June 2015, they concluded that port site infection is comparable in both groups and there is no statistically significant difference between two groups.

By **Cemal Kaya et al**, Oct 2017, they also concluded that port site infection rates were similar in both the groups.

By **Prem Chand, Ashok Kumar et al**, their study came to the conclusion that port site infection rates were similar between the two groups and there is no statistically significant difference of port site infection between two groups.

Table for depiction of port site infection:

	Bashir Azhar et al	Cemal Kaya et al	Prem Chand et al	Our Study
Inf in Grp A	-	0	1	1
Inf in Grp B	-	2	1	1
P Value	No Statistical difference	0.063	1	0.8

In above mentioned studies, incidence of port site infection were similar in both the study groups, we also attained similar results as only 1 patient in each group got discharge from port site and it was managed conservatively. This was statistically insignificant (0.08).

CONCLUSION

Traditionally it is the usual practice to extract gall bladder via epigastric port following laparoscopic cholecystectomy. The aim of this study was to observe any change in term of port site infection and pain if we extract gallbladder from other 10mm working port, i.e. umbilical port.

In this double blinded randomised control study, we concluded that extraction of gallbladder through umbilical port was an effective

alternate method and was found to be more effective in terms of less port site pain as per visual analogue scale (VAS) score. Although a little more time (5-8 minutes) was expended in changing laparoscope position from umbilical to epigastric, incidence of port site infection remained same in extraction from either port.

This was a single centre study with inclusion of 81 patients, for further confirmation, its required to do multiple studies from different centres and to meta-analyse the collected data in order to finally recommend that gallbladder extraction from umbilical port is **safe & more effective** in terms of port site pain incidence.