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Original Research Article

Role of a modified epigastric port in reducing post operative pain and causing early ambulation in a patient undergoing laparoscopic cholecystectomy as compared to a standard four port procedure, a randomized controlled study

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ABSTRACT

Background: Standard four port laparoscopic cholecystectomy is the gold standard in the treatment of gall stones. Modified epigastric port laparoscopic cholecystectomy may be considered an alternative, as this procedure maintains the advantages of four ports and does not require any special set of instruments. In this study we aimed to see whether this procedure is comparable to the standard four port laparoscopic cholecystectomy based on the primary objectives of postoperative pain score, degree of ambulation, time to return to normal activities.
Methods: Consecutive patients due to undergo laparoscopic cholecystectomy, meeting all the predefined criteria were recruited into the study. The group A was assigned to receive intervention in the form of modified epigastric port laparoscopic cholecystectomy. The group B was assigned to receive intervention in the form of standard four port laparoscopic cholecystectomy. Patients in group A were compared with patients in group B based on multiple pre-defined parameters.
Results: Pain scores were significantly better in group A. Degree of ambulation at was significantly better in group A. In respect to the time to resumption of normal activities there was no significant difference between the two groups. When comparing the quality life at 1 month following surgery with SF-36 health survey, the patients in group A did better than patients in group B with respect to the six scales.
Conclusions: Modified epigastric port laparoscopic cholecystectomy appears to be significantly better than the standard four port cholecystectomy in terms of postoperative recovery.

Keywords: Laparoscopic cholecystectomy, Post operative pain, Early ambulation, Modified epigastric port

INTRODUCTION

Work done by surgeons like Prof. Dr. Med Erich Muhe, having performed the first ever laparoscopic cholecystectomy stressed on the need to reduce the surgical stress in patients, the need for early recovery and the need for offering patients with significantly improved quality of life, following a surgical procedure.[1]

Thus, laparoscopic cholecystectomy along with its many other technical benefits, has become the standard of care in the treatment of gall stone disease. Over the years, minimally invasive procedures have gained greater acceptance among patients, as a result of obviously greater pain benefits, early recovery and better cosmesis.

An effort towards further improvement from the standard four port laparoscopic cholecystectomy, has led to an increasing trend towards reduction in number of ports, while performing a laparoscopic cholecystectomy. However, this sacrifice has made reduced port laparoscopic cholecystectomies technically more challenging with greater learning curve, more operative time, compromised triangulation with increased risks of complications and a more expensive procedure.

Laparoscopic cholecystectomy with a smaller epigastric (5 mm) port and rest of the ports as in a standard four port laparoscopic cholecystectomy may prove beneficial. This procedure does not require any special set of instruments and it maintains the advantages of four ports, as in the standard procedure. The procedure should have a better pain profile and earlier post-operative recovery than following a standard four port laparoscopic cholecystectomy.

It needs to be seen whether this reciprocates to an early discharge in our setting. Although, there are number of studies, comparing quality of life after single incision laparoscopic cholecystectomy with standard four port (conventional) laparoscopic cholecystectomy, not many studies to compare the same between reduced (number/size) cholecystectomies with standard four port laparoscopic cholecystectomy.[2,3]

Aim and objectives

The aim of the current study was to assess early recovery following modified epigastric port laparoscopic cholecystectomy as compared to the standard four port laparoscopic cholecystectomy.

Objectives of the current study were to assess; post-operative pain scores at 6 hours and 24 hours, degree of ambulation postoperatively at 6 hours and 24 hours, time to resumption of normal activities (pre-surgery work) following surgery and quality of life at 1month following surgery.

METHODS

The prospective randomised controlled trial was conducted on adult patients (>18 years); undergoing laparoscopic cholecystectomy at the department of surgery, KPC medical college and hospital, Kolkata. The study period was between 01 March 2018 to 28 February 2019.

The sample size was calculated taking into consideration the mean postoperative pain scores for conventional laparoscopic cholecystectomy (2.78) and the modified procedure (1.43). A total number of 101 patients were enrolled for this study.[4,5]

Patients with physical deformities interfering with early ambulation, chronic analgesic use other than gall bladder pathology and those with psychiatric illness were excluded from the study.

Patients meeting the inclusion criteria and who gave consent, were randomized to either group A or B group based on a pre-generated random number sequence by the principal investigator just before the incision. Therefore, patients were not aware of their group at the time of allocation and until 48 hours after surgery, when the dressings were removed. The group A was assigned to receive intervention in the form of modified epigastric port laparoscopic cholecystectomy. The group B was assigned to receive intervention in the form of standard four port laparoscopic cholecystectomy.

Operative procedure

Pneumoperitoneum was created by open technique through a 10mm infraumbilical/supraumbilical incision and insertion of 10 mm port followed by CO2 insufflation to a pressure of 12 mmHg. Patients were placed in reverse trendelenburg's position with a left tilt. This was required for both the procedures. In both the procedures 5 ml of 0.25% injection. Bupivacaine was infiltrated at 10mm port sites and 2.5 ml of 0.25% injection bupivacaine at 5 mm port sites, in the subcutaneous plane, before their creation.

One of the two following procedures were performed in a patients: standard four port laparoscopic cholecystectomy; it required a 10 mm epigastric port, a 5 mm port at right mid-clavicular line about 2 finger breadth below the costal margin, a 5 mm port in the right anterior axillary line, about 5-8 cms below the costal margin, apart from the 10 mm infraumbilical or supraumbilical telescope port. In the standard procedure, a 10 mm 30 degree telescope was used throughout the procedure or modified epigastric port laparoscopic cholecystectomy; this technique involved the placement of four ports at the sites as followed for the standard four port laparoscopic cholecystectomy. However, the epigastric port was 5 mm in size and not 10 mm, as in standard four port laparoscopic cholecystectomy. Other ports were of same size as the standard procedure. With this modification, the cystic artery was occluded through the 10 mm infraumbilical or supraumbilical port (using 5 mm, 30 degree telescope through the epigastric port for viewing). Cystic duct was also occluded through the 10 mm infraumbilical or supraumbilical port (using 5 mm, 30 degree telescope through the epigastric port for viewing). Both cystic artery and duct were divided through the epigastric port as in the standard four port laparoscopic cholecystectomy (however using 5 mm 30 degree telescope through infraumbilical or supraumbilical port for viewing). During dissection of gall bladder from its fossa in the liver and hemostasis, in most cases, 5mm 30 degree telescope was used for viewing through infraumbilical/supraumbilical port. Only sometimes the telescope was changed to 10 mm 30 degrees, for the same if the vision seemed unsatisfactory. However, 5 mm, 30

degree telescope was used during specimen extraction through the infraumbilical/supraumbilical port.

Both the procedures followed the sequence of creation of pneumoperitoneum ≥ separation of all adhesions to the gall bladder and the surrounding liver ≥ exposure of the peritoneal fold in which the cystic artery and duct were situated ≥ dissection and skeletonisation of the cystic artery and duct (demonstration of critical view of safety) ≥ occlusion of cystic artery with clips and division of cystic artery, followed by occlusion of cystic duct with clips and division of the cystic duct ≥ dissection of gall bladder from its fossa in the liver and extraction of the gall bladder from the infraumbilical/supraumbilical port.

A 20 Fr. abdominal drainage kit, drain was placed in the Morrison's pouch. This was followed by intraperitoneal instillation of 10ml of 0.25% injection. Bupivacaine in the right subdiaphragmatic space. When the drain was placed, it was clamped for ten minutes and then kept open. After deflation of pneumoperitoneum, closure of infraumbilical/supraumbilical port sheath was done using no.1 braided coated polyglactin 910 violet. Skin over all the port sites were apposed using 3-0 monofilament poliglecaprone 25, undyed with subcuticular sutures.

Postoperative analgesia was provided to all patients with intravenous injection. Paracetamol 1 gm SOS. Patients were prescribed oral analgesic tab. Paracetamol 650 mg tablets, 1tablet, thrice daily, starting 6 hours post-surgery for 2 days then SOS. Severity of pain was recorded at 6 and 24 hours post-operatively using numeric rating scale (NRS). The scores were provided by the patients themselves after the numeric rating scale of pain was explained to them.

Degree of ambulation was assessed at 6 and 24 hours post-operatively in terms of ability to sit up unassisted or ability to get out of bed unassisted or ability to perform routine activity (i.e., going to toilet).

Patients were called to the hospital 1 week and 1month from the day of surgery for review. All patients in the study, came to the hospital for review at 1 week. Most patients were unable to attend the outpatient department for review at 1 month. So, these patients were enquired telephonically. At 1 month, patients were assessed for quality of life following surgery using the RAND 36-item short form (SF-36) survey (version 1.0) questionnaire.

During this time, they were also enquired about the time taken to resume normal activities (pre-surgery work) from the day of surgery. SF-36 scores were calculated using online RAND 36 score calculator. Scores were calculated over 8 health concept scales to determine quality of life, which includes: physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain and general health. Besides these, SF-36 health survey, also includes a scale that provides an indication of the perceived changed in health (called health change) compared to one year ago and this score was also calculated alongwith the eight health concept scales as enumerated above. The scores ranged from 0-100. Zero was the least possible score and 100 was the highest possible score. Higher scores defined a more favourable health state.

Statistical analysis

Categorical variables (i.e., sex distribution) have been expressed as number of patients and percentage of patients and compared across the two groups using Pearson's Chi Square test for independence of attributes. Continuous variables (i.e., age) have been expressed as mean +/- standard deviation and compared across the 2 groups using Mann-Whitney U test as the data does not follow normal distribution.

The statistical software SPSS version 20 was used for the analysis. An alpha level of 5% has been taken, i.e. if p value is less than 0.05 it has been considered as significant.

RESULTS

The study was conducted at department of general surgery, KPC medical college and hospital from 01 March 2018 to 28 February 2019. After obtaining approval from institutional ethics committee, 101 patients planned for laparoscopic cholecystectomy, satisfying the inclusion criteria were selected for the study. The patients were randomized into 2 groups, group a and group B. The data of 101 patients (n=50 in group A and n=51 in group B) was analysed. The following parameters for each patient in a group were analysed; age, gender, diagnosis, operating time, pain scores at 6 and 24 hours, ambulation at 6 and 24 hours, SOS dose of paracetamol, fit for discharge, SF36 survey, return to normal life.

Table 1: Age distribution.

	Groups		P value
	A	**B**	
Age (years)	**Mean±SD**	**Mean±SD**	
	43.3±15.12	47.29±13.94	0.115 Not significant

Age distribution of patients in group A was 43.3±15.12 years (mean±SD). Age distribution of patients in group B was 47.29±13.94 years. There was no significant difference between the two groups in terms of age distribution (p=0.115) (Table 1). In group A, 34 out of 50 (68%) were female. In group B, 39 out of 51 (76.47%) were female. There was no significant difference in sex distribution in between the two groups (p=0.342). (Table 2).

Table 2: Gender distribution.

Gender	Groups, N (%)		Total	P value	
	A	B			
	N (%)	N (%)	N (%)		
Female	34 (68)	39 (76.47)	73 (72.28)		
Male	16 (32)	12 (23.53)	28 (27.72)	0.342	Not Significant
Total	50 (100)	51 (100)	101 (100)		

Table 3: Pain score at 6 hours and 24 hours following surgery.

Pain score	Groups		P value	
	A	B		
	Mean±SD	Mean±SD		
6 hours following surgery	3.04±1.5	4.14±1.33	<0.001	Significant
24 hours following surgery	1.56±0.76	2.12±0.99	0.003	Significant

Table 4: Degree of ambulation at 6 and 24 hours following surgery.

Degree of ambulation		Groups, N (%)		Total	P value	Significance
		Group A	Group B			
		N (%)	N (%)	N (%)		
6 hours following surgery	Able to sit up unassisted	0 (0)	6 (11.76)	6 (5.94)	0.020	Significant
	Able to get out of bed unassisted	11 (22)	15 (29.41)	26 (25.74)		
	Able to perform routine activity	39 (78)	30 (58.82)	69 (68.32)		
Total		50 (100)	51 (100)	101 (100)		
24 hours following surgery	Able to get out of bed unassisted	1(2)	2 (3.92)	3 (2.92)	0.570	Significant
	Able to perform routine activity	49 (98)	49 (96.08)	98 (97.03)		
Total		50 (100)	51 (100)	101 (100)		

In both groups A and B, biliary colic due to cholelithiasis was the most frequent diagnosis 23 out of 50 (46%) in group A and 23 out of 51 (45.1%) in group B. Chronic calculous cholecystitis was the next most common indication for cholecystectomy, 12 out of 50 (24%) in group A and 7 out of 51 (13.73%) in group B. Acute calculous cholecystitis was the diagnosis in 5 out of 50 (10%) and 6 out of 51 (11.76%) cases in groups A and B respectively. Asymptomatic cholelithiasis (incidental cholelithiasis) constituted 5 out of 50 (10%) and 6 out of 51 (11.76%) cases in groups A and B respectively. Cholelithiasis and status post-acute biliary pancreatitis and cholelithiasis and status post ERCP and stone extraction constituted 2 (4%) cases each in group A. One patient in group A, presented with acute calculous cholecystitis about 2 weeks post ERCP and stone extraction. Cholelithiasis and status post acute biliary pancreatitis and cholelithiasis and status post ERCP and stone extraction constituted 3 (5.88%) and 4 (7.84%) cases respectively in group B. Chronic calculous cholecystitis and status post acute biliary pancreatitis constituted 2 (3.92%) cases in group B. There was statistically no significant difference between the two groups (p=0.617) in terms of the distribution of cases with different diagnoses.

The operation time in group A was 85.66±27.04 minutes. The operation time taken in group B was 87.96±36.54 minutes. There was statistically no significant difference between the two groups A and B with respect to the procedure time (p=0.762).

At 6 hours, the pain score in group A was 3.04±1.5 which was less than in group B, which was 4.14±1.33. At 24 hours, the pain score in group A was 1.56±0.76 which was less than in group B, which was 2.12±0.99. There was statistically significant less pain perceived among patients in group A versus those in group B, at 6 hours following surgery (p<0.001). Similarly, there was statistically significant less pain perceived among patients in group A versus those in group B, at 24 hours following surgery (p=0.003) (Table 3). Statistically there was significant difference between the two groups A and B with respect to degree of ambulation at 6 hours following

surgery (p=0.020). Thirty nine out of 50 (78%) patients in group A were able to perform routine activities (i.e., going to toilet) as compared to 30 out of 51 (58.82%) patients in group B at 6 hours following surgery. Therefore, less number of patients in group A, 11 out of 50 (22%) patients as compared to 15 out of 51 (29.41%) patients in group B had some limitation in ambulation and were able to get out of bed unassisted but not able to perform routine activities. Six out of 51 (11.76%) patients only in group B had significant limitation in ambulation and were only able to get up in bed unassisted. Overall, the degree of ambulation among patients in group A was better than in patients in group B at 6 hours following surgery. There was no significant difference in degree of ambulation between patients in groups A and B at 24 hours following surgery (p=0.570) (Table 4).

In group A, 11 out of 50 (22%) received SOS doses of injection paracetamol. In group B, 17 out of 51 received SOS doses of injection paracetamol. There was statistically no significant difference between the two groups A and B with respect to SOS doses of injection paracetamol received or not (p=0.203) (Table 5).

Table 5: Whether received SOS doses of injection paracetamol?

		Groups, N(%)		Total	P value	Significance
		A	B			
Received SOS doses of injection paracetamol	No	39 (78)	34 (66.67)	73 (72.28)	0.203	Not significant
	Yes	11 (22)	17 (33.33)	28 (27.72)		
Total		50 (100)	51 (100)	101 (100)		

Table 6: Fit for discharge.

		Group A N (%)	Group B N (%)	Total	P value	
Fit for discharge	Postoperative day 1	43 (86)	40 (78.43)	83 (82.18)		Significance
	Postoperative day 2	7 (14)	9 (17.65)	16 (15.84)	0.309	Not significant
	Postoperative day 3	0 (0)	2 (3.92)	2 (1.98)		
Total		50 (100)	51 (100)	101 (100)		

Table 7: SF-36 health survey.

Scale	Groups		P value	
	A	B		
	Mean±SD	Mean±SD		
Physical functioning	73.54±16.76	70.59±15.26	0.217	Not significant
Role limitations due to physical health	75.84±33.51	57.84±36.91	0.014	Significant
Role limitations due to emotional problems	90.66±23.41	84.96±28.58	0.244	Not significant
Energy/fatigue	73.7±11.69	69.55±9.75	0.008	Significant
Emotional well-being	83.44±9.31	78.41±9.96	0.001	Significant
Social functioning	98.3±88.2	78.55±18.39	0.026	Significant
Pain	79.22±11.95	71.63±12.5	0.002	Significant
General health	78.9±14.75	67.55±15.82	<0.001	Significant

Table 8: Time to return to normal activities (pre-surgery work).

	Groups		P value	
	A	B		
	Mean±SD	Mean±SD		
Time to return to pre-surgery work from day of surgery (days)	10.09±6.3	11.47±6.8	0.311	Not Significant

Eighty three out of 101 (82.18%) patients were fit for discharge in the first postoperative day. Forty three out of 50 (86%) patients in group A and 40 out of 51 (78.43%) patients in group B were fit for discharge in the first postoperative day. Seven out of 50 (14%) patients in group A and 9 out of 51 (17.65%) patients in group B

were fit for discharge by second postoperative day. Two out of 51 patients, in group B, who had delayed recovery, were fit for discharge by third postoperative day. There was statistically no significant difference between the two groups A and B in terms for postoperative recovery (p=0.309). All the patients, once fit were discharged the same day. In six out of eight healths concept scales of the SF-36 survey, there was statistically significant difference between the two groups A and B (Table 6). Time to return to normal activities (pre-surgery work) was 10.09±6.3 days in group A and 11.47±6.8 days in group B. In this regard, there was statistically no significant difference between the two groups (Table 7).

DISCUSSION

In this study, our aim was to see whether the postoperative recovery of patients who underwent modified epigastric port laparoscopic cholecystectomy (group A) was better than in patients who underwent standard four port laparoscopic cholecystectomy (group B). The pain scores at 6 hours (p<0.001) and 24 hours (p=0.003) following surgery were significantly better among patients in group A, compared to patients in group B. In terms of the degree of ambulation at 6 hours, patients in group A did better than in group B (p=0.020). However, when the degree of ambulation was assessed at 24 hours following surgery, there was no significant difference between the two groups (p=0.570). There was no significant difference between the two groups, with respect to time to resumption of normal activities (pre-surgery work) following surgery (p=0.311). When comparing the quality life at 1 month following surgery with SF-36 health survey, the patients in group A did better than patients in group B with respect to the six scales namely: role limitations due to physical health, energy/fatigue, emotional well-being, social functioning, pain and general health (p values significant). There was statistically no significant difference between the two groups (p values not significant) with respect to physical functioning, role limitations due to emotional problems and health change scales.

Strengths of the study

This was a randomized controlled study. The pain scores were given by the patients themselves, after they were explained about the numeric rating scale for pain. The number of patients in group A (N=50) and B (N=51) appears well-matched for comparison. There was statistically no significant difference (p value not significant) between the two groups with respect to age and sex distribution, diagnoses, surgeons who performed the procedures, peroperative complications, usage of drain, operation time, difficulty, patients who received SOS doses of inj. Paracetamol. This was an interventional study, where the performance of the procedures did not require any special set of instruments. Therefore, there was no difference in costs, in the performance of the two procedures.

Limitations of the study

Pain is a subjective parameter and perception may vary from person to person. In our study, requirement of stretching of infraumbilical/supraumbilical port was not noted during gall bladder extraction. This factor may have had an impact on the postoperative pain score. The difficulty, felt by the surgeons in performance of these procedures, is again a subjective parameter, assessed in this study. The assessment of this parameter seems to be confounded by factors like level of training and skill of the individual who performed it. This also means that, the operation time could have been lesser, if all the procedures were performed by surgeons with similar skills in laparoscopy. We feel that fitness for discharge also could have been assessed at 6 hours following the surgery, as considerable number of patients had acceptable pain scores and were able to perform routine activity at 6 hours following surgery. The SF-36 health survey consists of many questions which took 15-25 minutes to record, interviewing the patients. Making this a laborious task for the patients to think and answer the questions. Although all patients were advised to start normal activities (pre-surgery work) soon after discharge, many did not resume normal activities early, due to local beliefs. This may have had an impact on the results.

There are number of studies comparing postoperative pain scores, between single incision laparoscopic cholecystectomy and standard four port laparoscopic cholecystectomy.[6,7] Comparison of minilaparoscopic cholecystectomy and four port laparoscopic cholecystectomy with respect to postoperative pain and other parameters exists in the literature.[8] Similarly, there is a study comparing two port versus conventional four port laparoscopic cholecystectomy with respect to this parameter.[9] There is one study comparing three port versus four port laparoscopic cholecystectomy, which includes assessment of postoperative pain.[10] Another study comparing single-port versus needlescopic versus conventional laparoscopic cholecystectomy is there.[11] Study comparing needlescopic versus conventional laparoscopic cholecystectomy (authors in this study considered modified epigastric port laparoscopic cholecystectomy as conventional laparoscopic cholecystectomy) exists.[5] However, comparison of postoperative pain scores after modified epigastric port versus standard four port laparoscopic cholecystectomy has not been done before.

Majority of the studies have used visual analog scale to assess pain scores. Numeric rating scale for pain has been used, only in few studies.[12,13] In this study, we used the numeric rating scale, as it has the advantage of being self administered and can be even recorded verbally, over a telephone call.

Number of studies are there, to assess determining factors as well as feasibility of early discharge following day case laparoscopic cholecystectomy.[14-16] Ambulatory

capacity remains one of the key factors for early discharge of patients.[17,18] When degree of ambulation was assessed, in our study, it revealed that 39 patients in group A compared to 30 patients in group B were able to perform routine activities (i.e., going to toilet) at 6 hours following surgery. In comparison, this result was statistically significant and better in the group of patients who underwent modified epigastric port laparoscopic cholecystectomy (group A). There was no difference in the degree of ambulation between the two groups at 24 hours following surgery. Thus, more number of patients who underwent modified epigastric port laparoscopic cholecystectomy could have been discharged earlier than patients who underwent standard four port laparoscopic cholecystectomy and on the day of surgery.

The time taken to return to normal activities (pre surgery work) by patients who underwent modified epigastric port laparoscopic cholecystectomy was 10.09 days (mean) versus 11.47 days (mean) in patients who underwent standard four port laparoscopic cholecystectomy. This result was not statistically significant in our study. Wasowicz-Kemps et al assessed resumption of daily physical activity (or postoperative activity resumption) to preoperative level after day-case laparoscopic cholecystectomy.[19] The recovery of daily physical activity in this study took more than one week in most patients, similar to the results in our study.

There are studies comparing quality of life after single incision laparoscopic cholecystectomy versus conventional laparoscopic cholecystectomy.[20,21] In terms of comparison of quality of life after modified epigastric port versus standard four port laparoscopic cholecystectomy, this is an unique study. More studies are required in this regard to support or refute our results.

CONCLUSION

This study was undertaken to compare the postoperative recovery following modified epigastric port laparoscopic cholecystectomy with standard four port laparoscopic cholecystectomy. In this study, patients who underwent modified epigastric port laparoscopic cholecystectomy, had better postoperative pain scores, had significantly better ambulatory capacity at 6 hours following surgery. Although there was no difference in time to resumption of normal activities (pre surgery work) between the two groups, the quality of life scores were significantly better with respect to role limitations due to physical health, energy/fatigue, emotional well-being, social functioning, pain and general health, in patients who underwent modified epigastric port laparoscopic cholecystectomy. Thus, modified epigastric port laparoscopic cholecystectomy appears to be significantly better than the standard four port cholecystectomy in terms of postoperative recovery. It is comparable to standard four port laparoscopic cholecystectomy in terms of complication rate and operating time. In addition, there is no need for special set of instruments and the advantages of four ports are maintained. Moreover, this is a good option for patients undergoing laparoscopic cholecystectomy, as there is no extra cost of this procedure. Further studies are required to compare the rates of same day discharge after the two procedures. Studies are required to investigate the factors/ local beliefs/ myths, which result in delay in resuming normal activities (pre-surgery work) in an Indian scenario. Also, the difference in cosmesis between the two procedures needs to be studied. More studies needed in different study population to validate our results.

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