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RESEARCH ARTICLE

POSTOPERATIVE PORT-SITE PAIN AFTER GALL BLADDER RETRIEVAL FROM EPIGASTRIC VS UMBILICAL PORT IN LAPAROSCOPIC CHOLECYSTECTOMY: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Objective: To determine whether gall bladder (GB) retrieval from umbilical port is associated with more pain at port site as compared to GB retrieval from epigastric port in adult patients undergoing four port elective laparoscopic cholecystectomy at a tertiary care hospital. **Methods:** Adult patients, who were undergoing elective laparoscopic cholecystectomy during a six-month period in 2010 at our institute, were randomized to either group A (n = 60, GB retrieval through epigastric port) or group B (n = 60, GB retrieval through umbilical port). VAS for pain was assessed by a registered nurse at 1, 6, 12, 24 and 36 h after surgery. Results: The VAS for pain at umbilical port was less than epigastric port at 1, 6, 12, 24 and 36 h after surgery (5.9 ±1.1 vs. 4.1± 1.5, 4.6± 0.94 vs. 3.5± 1.05, 3.9± 0.85 vs. 2.4± 0.79, 3.05± 0.87 vs. 2.15± 0.87, respectively) and the difference was statistically significant (p-value < 0.001). Multiple linear regression was done for port site pain at 24 h and the VAS at umblical port was less than epigastric port with VAS difference of 0.9 after adjusting for age, sex, duration of surgery and additional analgesia use (r 2 =0.253, p-value < 0.001).
Conclusion: Gall bladder retrieval from umbilical port is associated with lower port site pain than GB retrieval from epigastric port in patients undergoing elective laparoscopic cholecystectomy. We recommend umbilical port for gall bladder retrieval.

Introduction:-

Laparoscopic cholecystectomy, introduced in 1987, is now the preferred method of cholecystectomy.[1] Laparoscopic cholecystectomy has revolutionized the surgical management of gall bladder (GB) diseases by reducing postoperative pain,[2,3]risk of surgical site infection and incisional hernia. Laparoscopic cholecystectomy is also reported to have an edge over open cholecystectomy due to shorter hospital stay, early return to work and overall low cost.[4]

Pain is the most frequent complaint after laparoscopic cholecystectomy and the main reason for staying overnight at hospital on the day of operation.[5] Pain after laparoscopic cholecystectomy depends on multiple factors including rupture of blood vessels caused by rapid distension of the peritoneum, traumatic traction on the nerves, trauma to the abdominal wall during port insertion and GB retrieval and pneumoperitoneum created by use of CO2 to maintain high abdominal pressure.[6]

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It is reported that incisional pain is more intense than visceral pain and is dominant during the first 48 h after laparoscopic cholecystectomy.[7] Apart from this, response to different pain-relieving measures is variable in different individuals.

Many trials have assessed different methods of reducing pain after laparoscopic cholecystectomy including use of non-steroidal anti-inflammatory drugs, pre-emptive analgesia (incisional or intraperitoneal infiltration of local anaestheticagentanaesthetic), intraperitoneal saline, a gas drain, heated gas, low-pressure gas and nitrous oxide pneumoperitoneum. Effectiveness of some of these methods has been reported, but none of them has been recommended as standard of care.[8]

Retrieval of GB is an important terminal event of laparoscopic cholecystectomy and is reported as one of the factors affecting postoperative port site pain. GB is extracted commonly either from the epigastric or umbilical port. Both the ports have been recommended for retrieval of GB in laparoscopic cholecystectomy,[9-11] and are always selected as per surgeon's preference. To date, there is no evidence to support any one port being superior to other for GB extraction while considering the postoperative-port site pain.Our aim is to determine whether gall bladder (GB) retrieval from umbilical port is associated with more pain at respective port site as compared to GB retrieval from epigastric port in adult patients undergoing four port elective laparoscopic cholecystectomy at a tertiary care hospital.

Methods:-

A randomized controlled trial was conducted on patient between age group 18-75 yrs. operated in operation theater of Indra Gandhi institute of medical science, Patna between July 2020 to July 2021 who were admitted under general surgery

Inclusion criteria

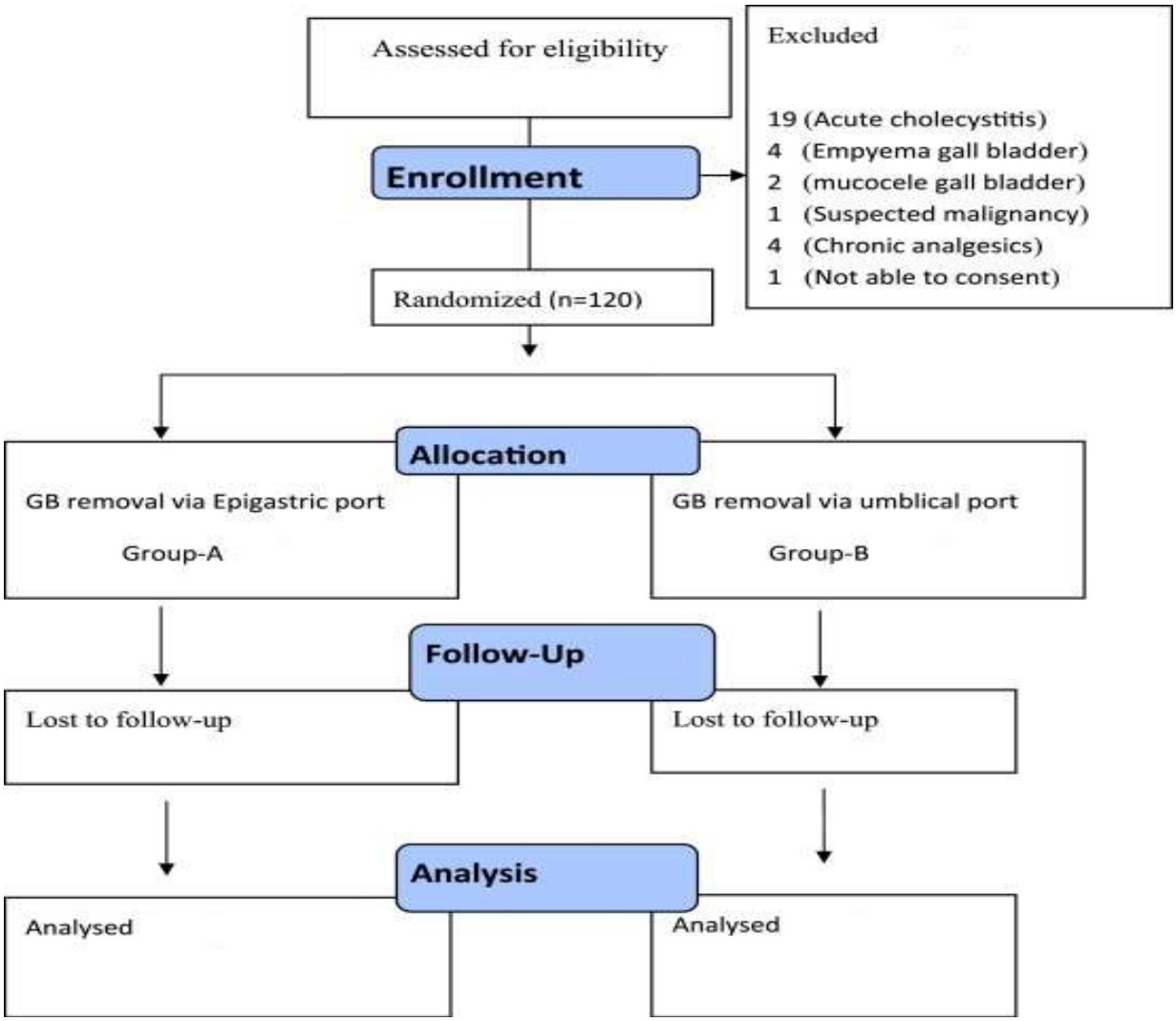
1) Patients who underwent elective laparoscopic cholecystectomy for benign GB diseases (symptomatic gallstones, GB polyps) between age group 18 – 75.
2) Patients in whom informed consent could be obtained.

Exclusion criteria

1) Acute cholecystitis, empyema GB, mucocele of GB,
2) Suspected/proven malignancy of GB,
3) Patients in whom laparoscopic cholecystectomy had to be converted in open procedure,
4) Patients who were chronic users of analgesic medicines and steroids.

Patients, who fulfilled the inclusion criteria, were randomized by drawing lottery slips by a third person i.e. OR technician not related to the study just before retrieval of gall bladder, from a box containing 150 sealed opaque envelops (75 slips for each group) and were assigned to one of the two groups i.e. (Group A) GB retrieved from epigastric port and (Group B) GB retrieved from umbilical port. An informed consent was taken before procedure from each participant in a language understood by patient. Data were recorded on Proforma that included sociodemographic, clinical and outcome variables. Surgery was done by consultant general surgeon or the seniorresident under general anaesthesia with four ports technique. 10 mm ports were inserted at infraumbilical (open technique) and epigastric regions (closed technique). After completion of dissection, GB was extracted in a bag (selfmade from latex glove) either through epigastric or umbilical port. If epigastric port wereused for GB retrieval, it was dilated with a metallic dilator to facilitate GB extraction. On the other hand, retrieved through umbilical port, telescope was shifted to epigastric port to facilitate GB retrieval through umbilical wound. In both the groups, if GB was found distended or contained large stone, it was opened at the time of retrieval and bile was sucked (and/or stone is retrieved) under vision. If GB could still not be retrieved, then the sheath was incised over a metallic groove dilator. Fascial sheath of umbilical wound was closed with absorbable suture (Vicryl) and skin with non-absorbable sutures (nylon) without infiltration of local anaesthetic agent at wound margins. Postoperative analgesia were standardized in both the groups. Intramuscular pethidine 0.5 mg/kg body weight every 6 hourly were given in initial 24 h of surgery only. Oral analgesics (paracetamol in dose of 1000 mg every 6 h or diclofenac, 50 mg every 12 h) were started postoperatively once diet has been started. The patients with significant pain (as assessed by registered nurse looking after the patient and not involved in the study) i.e. who have VAS of 7 or more, despite being on standard analgesia, required additional analgesia (intravenous pethidine in dose of 0.5 mg/kg body weight or intravenous ketorolac as 0.3 mg/kg every 8 hourly) to alleviate pain at an acceptable level i.e. VAS of 3 or less. Outcome i.e. postoperative port site pain were assessed with Visual Analog Scale (VAS) ranging from 0 to 10.

Patients were educated about use of VAS preoperatively (either in clinic or in ward before surgery). Pain was assessed in every patient at both port sites at 1, 6, 12, 24 and 36 h postoperatively by a trained nurse who were blinded to the intervention.



Results:-

During the study period, 151 patients were evaluated to select 120 patients fulfilling the inclusion criteria and 31 patients were excluded because of above mentioned exclusion criteria. The flow diagram of patients' enrollment, allocation, follows up and analysis is shown in Fig. 1. Both the groups were comparable for the baseline variables (as summarized in Table 1) with mean SD age of 42.5 10 vs. 40.6 12.6 years in group-A and group-B, respectively. All the patients were followed up till 36 h for pain assessment and there were no dropouts. The VAS for pain at umbilical port was less than epigastric port at 1, 6, 12, 24 and 36 h after surgery and the difference was statistically significant (Table 2). Multiple linear regression was done for port site pain at 24 h and the VAS at umbilical port was less than epigastric port by the factor of 0.9 after adjusting for age, sex, duration of surgery, retrieval difficulty and additional analgesia use (r^2=0.253, p-value=<0.01). The difference between the groups for operative time, difficulty in retrieval of gall bladder as perceived by operative surgeons and the additional analgesia requirement was statistically insignificant (Table 1).

Table 1:- Showing comparision of different variables between the group.

Variables	Group A	Group B	p value
Age	42.5±10.7	40.6±12.6	0.38
Sex			

Female	47	45	
Indication			
Symptomatic gallbladder	57	58	
Gallbladder polyp	3	2	
Duration of surgery in minutes	52.5±12.1	56.7±13.8	0.078
Retrieval difficulty	4.4±1.2	42±1.1	0.393
Number of patients required	9	17	0.42
Additional analgesia			
Pethidine required in mg	10±16.7	8±15.4	0.49
Ketorolac required in mg	6.5±14.7	3.7±9.8	0.23

Table 2:- Showing comparision of VAS for pain at specified port site at different post operative periods between the group.

Pain score	**Group AGroup B**	**p value**	
Epigastric port	Umblical port		
At 1hr	5.9±1.1	4.1± 1.5<0.01	
At 6hr	4.6±0.94	3.5±1.05	<0.01
At 12hr	3.9±0.85	2.4±0.79	<0.01
At 24hr	3.05±0.87	2.15±0.87	<0.01
At 36hr	1.9±0.8	1.2±0.49	<0.01

Discussion:-

Based on the results of this RCT, we failed to reject the null hypothesis and we found that GB retrieval from umbilical port was less painful than epigastric port. This is the first randomized trial comparing the pain score between two ports used for gall bladder retrieval. The pain was assessed by a registered nurse unaware of the site of the retrieval as well as study hypothesis, thus excluding the information bias. Higher intensity of pain observed in epigastric group may be attributed to use of metallic dilator; forcibly stretching the sheath and muscles, and at time tearing apart the skin to deliver the gall bladder. As compared to epigastric port, umbilical port was inserted by open technique, where by a 5 mm stab incision in the sheath to facilitate the entry of port, which might have resulted in port site wider enough to deliver gall bladder without much stretch. Pain reaches a peak within the first few hours following LC, but diminishes during the next 2 or 3 days. Some patients experience a rather painful early post-operative period, and some dynamic conditions such as coughing and mobilization can further aggravate the pain. Three types of pain have been proposed i.e. visceral, parietal and shoulder tip pain, with different intensity and time courses; visceral and parietal pain being the most important during first 24e48 h after surgery. The main sources of pain are: incision sites within the abdominal wall; the pneumoperitoneum in association with both local (peritoneal and diaphragmatic stretching, acidosis and ischemia) and systemic (hypercarbia causing sympathetic nervous system excitation with an amplification of local tissue inflammatory response) changes; and the ‘‘post cholecystectomy wound’’ within the liver (visceral pain). The largest component (50-70%) arises from incisional sites, followed by the pneumoperitoneum (20-30%) and ‘‘cholecystectomy wound’’ (10-20%). Several measures have been utilized/ investigated at reducing the pain from one or more mechanisms explained above. One common measure is pre-emptive local anaesthesia at port sites, which has been almost now standard of care13; which we didn’t use in order to determine the actual pain at port sites after gall bladder removal. We must also remember that pain is a subjective sensation and its measurement is difficult. Apart from sensory stimulus; Pain has motivational and affective components which might be related to cultural and previous pain experiences. Different factors affect the perception of pain. Several factors were excluded at the subject selection phase i.e. empyema, mucocele, acute cholecystitis, tumor, chronic use of steroids or analgesics. Other factors i.e. sex, age, duration of surgery and additional analgesia were also controlled at analysis phase by running multivariate linear regression.

Although the difference of pain score was statistically significant, however, this finding needs to be put in the clinical contextwhether the difference of 0.9 is clinically significant or not. To answer this, we also need to consider other aspects of procedure apart from pain i.e. difficulty in removal of GB from both the ports, comfort in training the residents, ergonomics & safety of the equipment. The difficulty in retrieval of gall bladder from port site is an important determinant of post operative pain in laparoscopic cholecystectomy. In our study groups, as per surgeon’s assessment, mean difficulty level in gall bladder retrieval were comparable i.e. 4.25 and 4.43 in group A and B, respectively. In a study done by Poon CM et al.,12 mean difficulty level in gall bladder retrieval was 3.6 3.0. Relatively higher difficulty in gall bladder retrieval in our study may be explained by difference in length of

incision, technique of gall bladder retrieval and difference in surgeon's perception of rating difficulty in retrieval of gall bladder.

Patients in both groups did require additional analgesia besides the standard analgesic regimen provided to every patient included

Conclusion:-

Gall bladder retrieval from umbilical port is associated with lower pain than epigastric port in patients undergoing elective laparoscopic cholecystectomy. We recommend umbilical port for gall bladder retrieval.

Ethical approval

Ethical Review Committee of Indira Gandhi Institute of Medical Science. 1914/IEC/IGIMS/2020.

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Conflicts of interest

None.

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