GENERAL SURGERY AND TRAUMA

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Effect of intra-abdominal pressure on post-laparoscopic cholecystectomy shoulder tip pain: A randomized control trial

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Abstract

Objective: To compare the effect of intra-abdominal pressure on postoperative shoulder-tip pain in laparoscopic cholecystectomy.

Methods: This was a randomized control study, conducted at Lady Reading Hospital Peshawar from January to August 2013 on160 patients, randomized to two groups i.e. the low pressure (LPLC) and the standard pressure group (SPLC) where the intra abdominal pressures were kept 10mmHg and above 10mmHg during surgery respectively. The age, gender, weight, duration of surgery, postoperative pain and frequency of analgesic administration in first 24 hours recorded and analyzed using Statistical Package for Social Sciences v20.0. Frequency and percentages were calculated for categorical while mean ± SD was calculated for continuous variables. P-value of <0.05 was considered significant.

Results: The mean operative times in group A and B were 27.84±6.078 vs. 28.51±7.45 minutes (p-value=0.625) respectively. Overall, the shoulder tip pain was reported in 25 (15%) patients. The frequencies in group A and B were 6 (7.5%) vs. 19 (23.8%) respectively (p-value = 0.005). The mean intensity of pain on VAS was 0.28±0.90 vs. 1.31±2.38 in the two groups respectively (p-value of 0.001). The mean number of analgesic administration in the first 24 hours was 2.24±0.48 in Group A vs.2.41±0.52 in Group B (p-value = 0.02) respectively.

Conclusion: Our study shows that low intra-abdominal pressure results in reduced frequency of post-operative shoulder tip pain without any prolongation of duration of surgery.

Keywords: Laparoscopic Cholecystectomy, Shoulder-tip pain, pneumoperitoneum. (JPMA 66: S-45; 2016)

Introduction

In 1882, Carl Langebuch of Germany performed the first cholecystectomy and in 1985, Prof Dr Erich Mühe of Germany performed the first laparoscopic cholecystectomy (LC).[1] In less than three decades no other operation has been so profoundly affected by the advent of laparoscopy as cholecystectomy. LC has now become the gold standard for routine gallbladder removal.[1,2]

Minimal invasiveness is one of the most important properties of laparoscopic surgery. It renders the patient a speedy recovery.[3] However unlike the open procedure some patients experience an unpleasant post-surgical symptom, ie, shoulder pain, seemingly specific to laparoscopic surgery.[4] About one third of the patients of LC develop this complaint postoperatively.[5] The origin of shoulder pain is only partly understood, but it is commonly assumed that the cause is overstretching of the diaphragmatic muscle fibers owing to a high rate of insufflations.[6] Other causes like peritoneal stretching and diaphragmatic irritation have also been considered and different institutions have accordingly postulated different solutions.[7-10]

The creation of pneumoperitoneum to get a working space is a crucial step in carrying any laparoscopic surgery. Standard pressure pneumoperitoneum for laparoscopic cholecystectomy employs a pressure range of 12-14 mm Hg.[10] Many researchers have directly related the pressure of the pneumoperitoneum to the postoperative shoulder tip pain and trials have been conducted where LC could be carried out safely, without prolongation of operative time and lower incidence of postoperative shoulder tip pain at pressures lower than those considered as standard. A study conducted by Yasir M et al, the frequency of pain was 28% vs. 10% in standard vs. low-pressure cholecystectomy respectively.[11] A recent systematic review also supported that low pressure cholecystectomy appears to reduce postoperative shoulder tip pain.[12]

No study has been conducted in our country on this aspect of laparoscopic surgery. We therefore conducted

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this study to analyze if LC at lower pressures can reduce the shoulder tip pain without compromising on patient safety and duration of surgery. This would not only improve patient satisfaction and well-being but also facilitate the establishment the emergent idea of LC as a day case procedure curtailing the expense both in the terms of personnel and monetarily.

Objective

To compare the effect of intra-abdominal pressure during laparoscopic cholecystectomy on post operative shoulder tip pain.

Material and Methods

This was a randomized control study conducted in the Department of Surgery of Lady Reading Hospital Peshawar from January 30th to August 27th 2013 after approval from Institutional Research and Ethical Board. The sample size was a total of 160 patients, allocated randomly to two groups of 80 patients using the reference value of 28% pain in standard while 10% pain in low intra-abdominal pressure group with a 95% confidence as calculated by the WHO software for sample size determination.[12] A consecutive non-probability sampling technique was used. All patients admitted through outpatients department for elective LC after being diagnosed to have cholelithiasis and a normal CBD and liver on ultrasound were included in this study. Cases of technically difficult LC or those converted to open, patients with history of co-morbid conditions and patients complaining of shoulder pain before surgery were excluded.

All patients meeting the inclusion criteria were admitted and after taking informed consent for surgery and randomized into two groups. Group A was the low-pressure LC group (LPLC) in which the intra abdominal pressure was to be kept 10 mmHg. Group B was the standard pressure LC group (SPLC) where theintra abdominal pressure was kept above 10 mmHg during the entire duration of surgery.

The same surgeon using the same technique operated all patients. Apart from the intra abdominal pressure, all parameters of surgery were kept similar between the two groups. An intravenous injection of Tramadol 50mg and Ketorolac 30 mg was given at the end of the procedure. The age, gender, weight, duration of surgery and postoperative pain at 8 hours, and the numbers of times analgesic (Ketorolac) administered for pain in 24 hours after the surgery in both the groups was entered on a structured proforma. Since majority of our patients were illiterate, the 10 mm line used in the standard visual analogue scale (VAS) was marked from 1 to 10 to quantify their pain from1 to 10 on the basis of severity.[13]

Data Analysis

Data were recorded and analyzed using Statistical Package for Social Sciences v 20.0 (SPSS, Inc., Chicago, IL, USA). Frequency and percentages were calculated for categorical variables whereas mean ± SD was calculated for numerical variables. Chi square test was applied to compare the frequency of pain in both the groups. Student T- test was applied to compare the duration of surgery, number of times the analgesia was administered and the intensity of pain. P-value of <0.05 was be considered as significant in all cases.

Results

A total number of 160 patients were randomly allocated to Group A or B (i.e. 80 patients in each group). In group A, the LPLC group, a pneumoperitoneum pressure of ≤ 10 mm Hg whereas in group B i.e. SPLC a pressure of >10 mm Hg was maintained during laparoscopic cholecystectomy.

Out of total patients 160 patients, 20 were male and 140 were female patients. In the group A, 7 (8.8%) were male and 73 (91.2%) were female patients. On the other hand in group B 13(16.2%) patients were male and 67(83.8%) were female. This difference in gender between the two groups was statistically insignificant (p-value= 0.151).

The mean age of the patients of our entire sample was 40.92±12.01 years. The mean age of patients in the group A it was 40.74 years ±12.32 SD while in the group B it was 41.10 years ±11.96 SD. The age distribution between the two groups did not have statistically significant difference

Table-1: Operative time in both the groups.

	Duration (in minutes)	Groups		Total
		Group A	Group B	
	≤ 25	35 (43.8%)	34 (42.5%)	69 (43.1%)
	26-35	37 (46.2%)	34 (42.5%)	71 (44.4%)
	≥ 36	8 (10%)	12 (15%)	20 (12.5%)
Mean±SD		27.84±6.078	28.51±7.45	

P-value=0.625(Student t-test).

Table-2: Comparison of shoulder tip pain in between the groups.

Pain	Group		Total
	Group A	Group B	
Yes	6 (7.5%)	19 (23.8%)	25 (15.6%)
No	74 (92.5%)	61 (76.2%)	135 (84.4%)
	80 (100%)	80 (100%)	160 (100%)

P-value=0.005 (Chi-Square Test).

Table-3: Analgesic requirement for pain in first 24 hours in both the groups.

	Number of Injections	Group		Total
		Low Pressure	Standard Pressure	
	1	0 (0%)	1 (1.2%)	1 (0.6%)
	2	61 (76.2%)	45 (56.2%)	106 (66.2%)
	3	19 (23.8%)	34 (42.5%)	53 (33.1%)
Mean±SD		2.24±0.48	2.41±0.52	

P-value=0.022 (Student T-test).

(p-value= 0.397). Likewise, the mean body weight of the patients undergoing low pressure LC was 63.15 ± 10.98 kg as compared to 59.61±12.979 kg of the patients undergoing SPLC and was also statistically insignificant (p-value of 0.057).

The mean operative time in 160 patients was 28.18±6.787 minutes. In Group A it was 27.84±6.078 minutes where as the mean operative time in the Group B of 28.51±7.45 minutes as shown in Table-1. T-test was applied and this difference between two groups was found to be statistically with p-value= 0.625.

The shoulder tip was reported in 15% i.e. 25 of the total 160 patients. The difference of frequency between the two groups as shown in table 2 was statistically significant i.e. 0.005 on applying Chi-square test. The mean intensity of pain on VAS in the group A 0.28±0.90 was whereas in Group B it was 1.31±2.38 with a p-value of 0.001 which is again statistically significant.

Analgesic requirements for shoulder tip pain as shown in table 3 were less in group A as compared to group B. The mean number of analgesic injections administered in the first 24 hours was 2.24±0.48 in Group A and 2.41±0.52 in Group B. The difference between the two was subjected to Student T- test and was statistically significant with a p-value = 0.02.

Discussion

The success laparoscopic cholecystectomy is a milestone achieved in the evolution of minimal access surgery as a whole.[14,15] An adequate working field is traditionally achieved by creating a pneumoperitoneum of up to 14-15 mm Hg.[4] The cliché "higher the pressure, better the view" is quite tempting to achieve the desired effect of raising the abdominal wall away from the viscera. This gives room to visualize the gall bladder and surrounding organs, allowing manipulation of instruments and also allows the intestine to fall away from the sub-hepatic space. Nonetheless higher pneumoperitoneum pressures are now being linked with the post-operative referred shoulder-tip pain; an early post-operative problem seemingly exclusive to all the laparoscopic procedures. As a matter of fact, the gynaecologists originally noticed it.[4,11,15-17]

In our study, the overall frequency of shoulder tip pain was much lower in LPLC than in the SPLC group. The difference was statistically significant. It is important to mention here that the demographic data i.e. the age distribution, gender distribution and the body weight were statistically similar between our two groups. Interestingly our overall frequency of shoulder tip pain is much lower than that reported by Bisgaard and his colleagues. They reported that 30-50% patients suffer from it in the first 24 hours of surgery.[18] Likewise, another study by Kandil TS published in October 2010 has mentioned an even greater frequency of 62% within first 12 hours of surgery. However, the authors of this particular study did mention that despite the high over all frequency, there was significant difference between those operated at lower pressures and those operated with a standard pressure pneumoperitoneum. They conducted a 4-arm study with pressure cut-offs being 8, 10, 12, 14 mmHg amongst the groups respectively. The frequency of pain was 11% in the lowest pressure group, while was 20% in the highest of pressure (14mmHg) group.[16] Although our study was a two arm study with a cut-off value for pressure being >10mmHg, our results of frequency of pain in the two groups are quite comparable with those of Kandil TS. In our study STP was present in 6 (7.5%) vs. 19 (23.8%) patients in low vs. standard pressure group, which is significantly lower. Yasir et al have brought similar findings forward. According to their study the incidence of shoulder tip pain was 2.8 times lower after LPLC. The cut off they used for the two groups was 8mmHg vs. 14mmHg, which is a bit sharper than ours. Their results were 10% vs. 28% that again is quite significant with a p value (of <0.05). The reduction in STP in low pressure LC has also been confirmed by Esmat et al, Sarli et al, Jorgensen JO and Barczynski and Herman in their respective studies.[19-22] Likewise Ibraheim et al reported higher incidence of shoulder tip pain when LC was done at higher pressures (i.e. 12-14mmHg).[23] One Cochrane review based on 4 Randomized control trails (RCTs) evaluated the effect of low-pressure pneumoperitoneum and found it to result in significant reduction in the shoulder tip pain (STP).[12] The only issue with all these studies confirming the effectiveness of reducing intra-abdominal pressure on STP is the heterogeneity that is noticed in the cut-offs for low and standard or high pressure which makes the comparison slightly difficult. Nonetheless they do undoubtedly indicate the association between the two phenomena. Interestingly according to Kanwar et al, even though their

study showed low incidence of shoulder pain in both groups the difference was not statistical significant.[10]

The pain being a very subjective feeling is difficult to measure and analyze. We measured the intensity of pain only once at 8 hours after the procedure in our study using a combination of visual analogue scale (VAS) and Visual Rating scale (VRS). Despite the difference in values of the intensity of pain between the two groups, it was not proven to be statistically significant (i.e. p value = 0.28). Our findings are consistent with those of Yasir et al taken at 8 hours post-operatively.[11] They however measured the intensity of pain thrice in 24 hours i.e. at 4 hours, 12hours and 24 hours post-operatively and reported that the difference in the mean intensity of STP between two groups was significant at 4 hours from surgery with pain being less severe in the LPLC group. Nonetheless it became insignificant for the latter two readings. Sarli et al's findings are however in contradiction to ours whereby in their study the shoulder-tip pain scores at 12 and 24 h and postoperative analgesia requirements were significantly lower in the low-pressure laparoscopic cholecystectomy group ($P<0.001$).[20] The same findings have been reinforced by those of Esmat et al.[19] A recently published systematic review based on 11 studies, evaluating the severity of STP found a significant reduction associated to low-pressure pneumoperitoneum and also mentioned that the reduction was mostly evident during the first 24 hours of surgery.[11,16-20]

Another effective way of assessing pain is through the analgesic requirements of the patient. Reduced analgesic requirements not only signify improved patient wellbeing but also indicate a reduction of workload on the nursing staff. In our study the difference in the number of times the analgesic had to be administered between the two groups was statistically significant with the requirement being low in the LPLC group. Reduction in analgesic demand has also been confirmed by the Cochrane review by Gurusamy in 2009.[12] Our findings were also in concordance with those of Yasir et al who concluded their study with the remarks that the analgesic requirement is reduced significantly in LPLC and thus recuperates the quality of life in the early stage of postoperative rehabilitation which is an ultimate and much desirable attribute of any procedure.[11] However, Kanwer DB and Sandhu et al did not find a statistically significant difference in analgesic requirements between the two groups of their respective studies.[6,10] Likewise, similar analgesic requirement with equal patient satisfaction has been reported in both groups in a comparative study by Chok et al.[15]

Working in lower intra-abdominal pressures logically seems to result in an inadequate exposure of the operating field, rendering the procedure difficult and result in longer than usual operating time and higher rate of intraoperative complications,[20,21,24-28] Comparison of the duration of surgery between the two groups was another important outcome measure of our study and the difference was found to be statistically insignificant. Our study clearly indicates that performing LC at lower intra-abdominal pressures does not have any effect of the duration of surgery that an adequate exposure can still be achieved without creating undue intra-abdominal pressure. An important factor in determining the duration of surgery is the experience of the surgeon and his or her acquaintance with the procedure. We avoided this bias in our study by getting all procedures done by surgeons of the same level and well versed with the procedure. Our results are comparable with those of Kanwer DB et al in terms of the difference between the two groups being insignificant. Their mean operative time was in generally longer than ours in both the groups. According to their study LC with low-pressure pneumoperitoneum took an average of 49.1±5.7 minutes vs. 46.4±6.9 minutes in the LC with standard pressure pneumoperitoneum and as in our case, the difference was not statistically significant ($p = 0.1$).[10] Likewise a Cochrane review, the operating time was similar between the groups (MD 2.30 minutes; 95% CI 0.42 to 4.18); however the risk of bias due to incomplete outcome data in seven of the trials kept them from commenting on the safety of LPLC.

Conclusion

The results of this study clearly show that there is less shoulder tip pain in low intra-abdominal pressure laparoscopic cholecystectomy as compared to standard pressure laparoscopic cholecystectomy without causing any effect on the duration of surgery.

Disclaimer: This study was originally conducted and accepted as a dissertation for the fellowship exam of the College of Physician & Surgeons of Pakistan in the subject of General Surgery.

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