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To evaluate of severity of post-operative pain in right sub-diaphragmatic region, shoulder tip, port site and its comparison with controls and the amount of analgesic usage post operatively laparoscopic cholecystectomy

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Abstract
Background & Method: 90 cases of symptomatic cholelithiasis admitted and operated upon during the period of two years from August 2014 to August 2016 at Bharati Hospital, Pune. The study will be conducted using a pre-tested proforma meeting the objectives and the postoperative pain will be evaluated using visual analog scale (VAS) and verbal rating score(VRS) for a period of 48 hours post operatively. The analysis of the results will be done statistically with relevant tests.
Result: The mean ± standard deviation of age of the patients from Group A, Group B and Group C is 40.2 ± 12.1 years, 43.7 ± 13.6 years and 49.4 ± 17.3 years respectively. The age range for patients enrolled in the study was between 16 – 80, mean age being 42.78 years. 1) Values are Mean and standard deviation (SD). P-values by One-way analysis of variance (ANOVA) with Post-Hoc Boferroni's test for multiple group comparisons. P-value <0.05 is considered to be statistically significant. *P-value<0.05, **P-value<0.01, ***P-value<0.001, NS: Statistically Non-Significant.
Postoperative shoulder tip pain was present in all three groups, 4 patients group A, 3 patients in group B & 4 patients in the control group complained of shoulder tip pain postoperatively. However chi square test yielded that the results were insignificant with a p value = 0.392
Conclusion: The present study was conducted on a group of 90 patients diagnosed to have symptomatic cholelithiasis and who underwent elective laparoscopic cholecystectomy under General Anaesthesia at the department of surgery. Majority of patients were females (73.4%).
To conclude, Instillation of bupivacaine intra-peritoneally and at port sites in laparoscopic cholecystectomy irrespective of the timing of instillation is an effective method of achieving pain control in the post-operative period as long as 12 hours after surgery.

Keywords: severity, diaphragmatic, analgesic & post operatively

Introduction
Langenbach performed the first Cholecystectomy on July 15, 1882 in Berlin [1]. One hundred and four year later in 1985, Muhe performed the first laparoscopic cholecystectomy and the following year he presented to the German Surgical Congress but was greeted with hostility.
The first laparoscopic cholecystectomy recorded in the medical literature was performed in March 1987 by Mouret, in Lyon, France [2]. Subsequently the technique was done by Dubois, Perrisat and Reddick and in a very short period it became the gold standard operation for conditions of the gall bladder.
Laparoscopic procedures are associated with rapid post operative recovery, low post operative complication rates and early discharge home, so these advantages have made laparoscopic procedures very popular [1, 2]. Various studies have shown that laparoscopy is associated with less pain than laparotomy, though it is not completely pain free [3].
A recent randomized controlled trial has shown that there may be more intense pain and greater analgesic requirement in the immediate post operative period after laparoscopic surgery than open laparotomy.
The pain in the conventional cholecystectomy is a parietal pain. In laparoscopic cholecystectomy, pain is derived from multiple situations: incision pain (somatic), deep intra abdominal pain (visceral), and shoulder pain (visceral pain due to phrenic nerve irritation) [4]. The improved understanding of origin of abdominal and shoulder pain after laparoscopic

procedures has lead to the use of intra-peritoneal instillation of local anesthetic to reduce post operative pain [5]. Port site instillation of local anesthetic in combination with general anesthesia has been investigated in several interventional studies during laparoscopic cholecystectomy [6]. Approximately half of these studies showed reduction in the postoperative pain significantly [7]. Bupivacaine is a local anesthetic that has a good safety profile, is long acting and relatively free of side effects.

Material & Method

90cases of symptomatic cholelithiasis admitted and operated upon during the period of two years from August 2014 to August 2016 at Bharati Hospital, Pune.

Mode of Selection of Cases and Method of Analysis: It is a randomized controlled study of patients undergoing laparoscopic cholecystectomy for symptomatic gallstones, where the patients will be allocated into three study groups:

(A) To receive intra-peritoneal instillation of Inj. Bupivacaine on gall bladder fossa after the procedure.

(B) To receive intra-peritoneal instillation of Inj. Bupivacaine on gall bladder fossa and at the port site after the procedure.

(C) Control group will not be given instillation of Inj. Bupivacaine after the procedure.

The study will be conducted using a pre-tested proforma meeting the objectives and the postoperative pain will be evaluated using visual analog scale (VAS) and verbal rating score (VRS) for a period of 48 hours post operatively. The analysis of the results will be done statistically with relevant tests.

Inclusion Criteria

All patients undergoing laparoscopic cholecystectomy in Bharati Hospital, Department of Surgery.

Exclusion Criteria

Open cholecystectomy

Results

Table 1: The distribution of the patients studied between three intervention groups (n=90)

Group	Group Description	No. of patients	% of patients
Group A	Intra-peritoneal instillation of Inj. Bupivacaine on gall bladder fossa post procedure	30	33.3
Group B	Intra-peritoneal instillation of Inj. Bupivacaine on gall bladder fossa and at the port site post procedure	30	33.3
Group C	No instillation of Inj. Bupivacaine post procedure	30	33.3
Total	--	90	100.0

Values are n (% of patients)

Table 2: The age distribution of the patients studied between three intervention groups (n=90)

Age Group (years)	Group A [n=30]		Group B [n=30]		Group C [n=30]		P-value [Inter-Group]		
							Group A v Group B	Group A v Group C	Group B v Group C
	n	%	n	%	n	%			
<30.0	6	20.0	4	13.3	3	10.0	0.999^{NS}	0.375^{NS}	0.999^{NS}
30.0 – 39.0	10	33.3	9	30.0	9	30.0			
40.0 – 49.0	5	16.7	7	23.3	3	10.0			
50.0 – 59.0	7	23.3	6	20.0	5	16.7			
>60.0	2	6.7	4	13.3	10	33.3			
Total	30	100.0	30	100.0	30	100.0			

Values are n (% of cases). P-value by Chi-Square test. P-value <0.05 is considered to be statistically significant. *P-value<0.05, **P-value<0.01, ***P-value<0.001, NS: Statistically Non-Significant.

1) The mean ± standard deviation of age of the patients from Group A, Group B and Group C is 40.2 ± 12.1 years, 43.7 ± 13.6 years and 49.4 ± 17.3 years respectively.
2) The age range for patients enrolled in the study was between 16 – 80, mean age being 42.78 years.

Table 3: The inter-group comparison of pain score (VAS) (n=90)

Pain Score (VAS)	Group A [n=30]		Group B [n=30]		Group C [n=30]		P-value [Inter-Group]		
							Group A v Group B	Group A v Group C	Group B v Group C
	Mean	SD	Mean	SD	Mean	SD			
2-Hours	5.87	0.78	5.03	1.35	5.90	1.06	0.012^{*}	0.999^{NS}	0.008^{**}
4-Hours	5.23	0.73	4.67	1.03	5.20	0.85	0.042^{*}	0.999^{NS}	0.062^{NS}
8-Hours	4.93	0.79	4.73	0.94	4.47	0.90	0.999^{NS}	0.128^{NS}	0.729^{NS}
12-Hours	4.93	0.83	4.97	1.07	4.90	0.89	0.999^{NS}	0.999^{NS}	0.999^{NS}
24-Hours	4.60	0.86	4.40	1.30	4.47	1.38	0.999^{NS}	0.999^{NS}	0.999^{NS}
% Change at 24-Hours	20.9%	--	6.6%	--	21.2%	--	0.180^{NS}	0.999^{NS}	0.167^{NS}

1) Values are Mean and standard deviation (SD). P-values by One-way analysis of variance (ANOVA) with Post-Hoc Boferroni's test for multiple group comparisons. P-value <0.05 is considered to be statistically significant. *P-value<0.05, **P-value<0.01, ***P-value<0.001, NS: Statistically Non-Significant.

Table 4: The inter-group comparison of incidence of shoulder tip pain (n=90)

Shoulder Tip Pain	Group A [n=30]		Group B [n=30]		Group C [n=30]		P-value [Inter-Group]		
							Group A v Group B	Group A v Group C	Group B v Group C
	n	%	n	%	n	%			
Yes	4	13.3	3	10.0	4	13.3	0.999^{NS}	0.999^{NS}	0.999^{NS}
No	26	86.7	27	90.0	26	86.7			
Total	30	100.0	30	100.0	30	100.0			

Values are n (% of cases). P-value by Chi-Square test. P-value <0.05 is considered to be statistically significant. *P-value<0.05, **P-value<0.01, ***P-value<0.001, NS: Statistically Non-Significant.

1) Postoperative shoulder tip pain was present in all three groups, 4 patients group A, 3 patients in group B & 4 patients in the control group complained of shoulder tip pain postoperatively.
2) However chi square test yielded that the results were insignificant with a p value = 0.392

Discussion

In the present study, we compared intra-peritoneal instillation (grp-A) and combination of intra-peritoneal and intra-incisional infiltration (grp-B) of bupivacaine with control group (grp-C) for post-operative parietal, visceral and shoulder pain relief after laparoscopic cholecystectomy for 24 hrs.

We observed a statistically significant reduction in overall pain scores in the study groups A and B compared to control group C for up to 4 hours (p value-), which is consistent with a previous randomized control trial by Pavlinal [8] in which post-operative pain scores were significantly lower in group receiving port sites peritoneal bupivacaine for pain relief after laparoscopic cholecystectomy, as compared to controls.

We found that combination of intra-incisional and intra-peritoneal use of local anesthetic is more effective than only IPLA in controlling post-operative pain upto 4hrs, (p value-0.042% vs 0.99%) which is consistent with the study done by Murrat Sarac *et al*. [9] and the meta-analysis done by Maharjan SK *et al.* [10].

IPLA did not significantly reduce parietal pain. This result may be explained by the different origins of parietal and visceral pain. The analgesic effect of IPLA is favorable to visceral pain because IPLA is aimed at the injured viscera in the peritoneal cavity, not the abdominal wall. Parietal pain is a lesser component of the pain that is somatic origin and induced by the surgical incision in the abdominal wall for trocar insertion [11]. The origin of parietal pain supports the application of local anesthetics to trocar insertion sites, i.e., wound infiltration with local anesthetics would be beneficial. Several studies investigated the effect of wound infiltration on pain after LC [12, 14] and demonstrated favorable results in regard to pain control.

Postoperative shoulder tip pain was observed equally in all the three groups. There was no overall statistically significant difference in the occurrence of shoulder tip pain which is inconsistent with study of Pavlidis *et al.* [13], this may be explained by duration of surgery and age related co-morbidities. Pavlidis *et al.* [13] found an unchanged incidence of shoulder tip pain but there study was only on local anesthetics at trocar site.

Conclusion

The present study was conducted on a group of 90 patients diagnosed to have symptomatic cholelithiasis and who underwent elective laparoscopic cholecystectomy under General Anaesthesia at the department of surgery. Majority of patients were females (73.4%). Mean pain scores at 2 hr, 4 hr, 8hrs postoperatively were significantly lower in the Group-A and group-B as compared to the control group, which received no local anesthesia to the port sites.

To conclude, Instillation of bupivacaine intra-peritoneally and at port sites in laparoscopic cholecystectomy irrespective of the timing of instillation is an effective method of achieving pain control in the post-operative period as long as 12 hours after surgery.

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