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Original Research Article

Intraperitoneal local anesthetic instillation as a method to attenuate pneumoperitoneum induced hemodynamic response during laparoscopic surgeries: A randomized placebo controlled study

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ABSTRACT

Background: Laparoscopy is associated with significant hemodynamic changes due to pneumoperitoneum creation. We sought to study the effectiveness of intraperitoneal local anesthetic instillation in attenuating pneumoperitoneum-mediated hemodynamic response in patients undergoing laparoscopic cholecystectomy.

Materials and Methods: This randomized study was conducted after approval from the institutional ethics committee, and 100 patients were randomly assigned to either group R (40 mL of 0.2% Ropivacaine intraperitoneally) or group N (40 mL of 0.9% normal saline intraperitoneally). Data analysis was performed using SPSS version 23. Independent Samples T test was used to compare hemodynamic variables between groups at regular intervals. Statistical significance was set less than 0.05.

Results: Heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial blood pressure were significantly lower in Group R than in Group N at 15,30, 45,60,75, and 90 min (P<0.05).

Conclusion: Intra peritoneal instillation of 0.2% Ropivacaine in laparoscopic cholecystectomy attenuates intra operative hemodynamic changes associated with pneumoperitoneum.

1. Introduction

Laparoscopic surgery has gained widespread popularity as the definitive treatment for several significant abdominal conditions. Advantages of laparoscopic surgery include shorter hospital stay, early ambulation, smaller scarring, and less compromised postoperative respiratory function. However, laparoscopy is associated with significant hemodynamic changes owing to the creation of a pneumoperitoneum. Laparoscopic surgery begins with intra-abdominal placement of the insufflation needle or trocar, followed by gas insufflation (commonly CO_2) of the abdominal cavity to an intra-abdominal pressure (IAP) of 12–15 mmHg.[1,2] The peritoneum and abdominal viscera are highly innervated by autonomic nerve fibers. Stimulation of these autonomic pathways during pneumoperitoneum, typically results in sympathetic nervous system activation, catecholamine release, activation of the renin–angiotensin system, and release of the neurohypophysial hormones. These potent endogenous hormone can cause intense vasoconstriction, an increase in SVR, MAP, BP and increases in left ventricular afterload.

Effective pain control, which is also affected by high levels of CO_2, is essential for maintaining stable hemodynamics during surgery. When patients experience pain, there are increased stress responses[3] (e.g., increased heart rate and blood pressure) that can negatively

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affect hemodynamics. The use of systemic opioids is associated with complications, such as nausea, vomiting, pruritus, dizziness, and respiratory depression.[4] Local anestheticsprevent and relieve pain by interrupting nerve excitation and conduction in a reversible, direct interaction with voltage-gated sodium (Na) channels that block membrane electrical excitability. Local anesthetics mitigate inflammation by their effects on granulocytes which include inhibiting the release of inflammatory mediators, lysosomal enzymes, and free radicals. Ropivacaine is an amino amide local anaesthetic drug which has lower risk of systemic and cardiac toxicity and thus a larger and more potent dose can be safely administered. The rationale for intraperitoneal administration of Ropivacaine in attenuating hemodynamic response to pneumoperitoneum and also perioperative analgesia is that a) the peritoneum is exposed to block of free afferent nerve endings[5] and visceral nociceptive conduction from area of damaged tissues, thereby providing an additional mechanism of analgesia there by reducing the need for systemic opioids, b) systemic absorption from the large peritoneal surface may also occur, and provide analgesia, c) its anti-inflammatory action.Most studies have focused on intraperitoneal instillation of local anesthetics for laparoscopic surgeries aimed at observing its effectiveness in post-operative analgesia; however, few studies have examined its effectiveness in attenuating the hemodynamic response to pneumoperitoneum. Thus, we sought to study the effectiveness of intraperitoneal local anesthetics in attenuating the pneumoperitoneum-mediated hemodynamic response.

2. Materials and Methods

This prospective randomized study was conducted after getting approval from Institutional Ethics Committee and registered in Clinical Trials Registry of India (CTRI/2023/06/053899).

A total of 100 patients aged between 18 and 58 years, with ASA physical status I and II, undergoing laparoscopic cholecystectomy not lasting beyond 90 min were selected and randomized into two groups by a computer-generated randomization table with 50 patients in each group. Informed written consent was obtained from the patients before they were included in the study. Patient refusal, known allergy to local anesthetics, surgery duration > 90 min, and surgeries that were converted to open procedures were excluded from the study.

On the day of surgery, after counseling and checking for informed and written consent, the patients were transferred to the operation theatre. Standard ASA monitoring (ECG, SPO2, NIBP, and ETCO2) was established. Intravenous access was achieved using an 18 gauge IV cannula. The patients received standard general anesthesia with endotracheal intubation, according to institutional protocols. Fentanyl 2mcg/kg, Propofol (2 mg/kg and Vecuronium 0.1 mg/kg were administered, and the patients were intubated with an appropriately sized endotracheal tube.

Surgery was commenced, and after confirmation of the peritoneum by closed method using Veress needle, 40 ml of the drug was instilled into the peritoneal space via the same needle. Group R received 40 ml of 0.2% Ropivacaine and Group N received 40 ml of 0.9% normal saline (placebo). After instillation procedure, in order to obtain thorough diffusion 5 minutes of trendelenburg position was maintained. Gas insufflation was performed and a pneumoperitoneum was created to maintain an IAP of 10-12 mm Hg. Ports were placed and positioned for surgery, if any was allowed.

The patients' intraoperative heart rate and Systolic, Diastolic and Mean arterial pressures were recorded at regular intervals of 0, 5, 15, 30, 45, 60, 75, and 90 minutes or until the end of the surgery, whichever was earlier. Anesthesia was maintained with 50% oxygen and 50% air, and the expired concentration of Sevoflurane (1 MAC and Vecuronium 0.08 mg /kg was used intermittently for muscle relaxation. Intraoperatively, all patients received Paracetamol 1 gm intravenously. After the surgery, residual neuromuscular block was reversed and the patients were extubated after return of adequate airway reflexes.

2.1. Statistical analysis

The calculation of the sample size for this research was determined through the application of formula: total sample size (N) = $4pq/d^2$, Where P=prevalence, Q=100-p, d=allowable error.

As this is new study with very less past data, we choose prevalence as 50% and allowable error as 10% of prevalence. On calculation using above formula, total sample size is 100 with 50 participants in each group.

Data were tabulated into spread sheet for analysis using Microsoft Excel version 2007 and analyzed using SPSS (Statistical Package for Social Sciences) version 17 (IBM Corp, USA).Categorical data were expressed as absolute number. Quantitative data were presented as mean, standard deviation and standard error mean. An independent Samples t-test was performed to compare the mean systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate at regular intervals from the onset of pneumoperitoneum (zero min) to 90 min. Any adverse events during perioperative period were presented as percentages. P value <0.05 was considered statistically significant.

3. Results

A total of 100 patients were randomized into 50 groups, and no patients were excluded from the study.

3.1. Demographic data

The demographic data (age, sex) and distribution of ASA physical status class I and II were comparable between the two groups (Table 1).

Table 1: Demographic data

Demographic variables	Group R	Group N
Mean age (years)	35	35.5
Sex(male/female)	33/17	30/20
ASA (I/II)	27/23	26/24

3.2. Hemodynamics

3.2.1. Systolic blood pressure (SBP)

Differences in SBP were compared between the groups at regular intervals. The difference was not significant at 0 and 5 min, but was statistically significant in Group R when compared to Group N at 15,30,45,60, 75, and 90 min (Table 2).

3.3. Diastolic blood pressure (DBP)

Differences in DBP were compared between the groups at regular intervals. The difference was not significant at 0 and 5 min, but was statistically significant in Group R when compared to Group N at 15,30,45,60, 75, and 90 min (Table 3).

3.4. Mean arterial pressure (MAP)

Differences in MAP were compared between the groups at regular intervals. The difference was not significant at 0 and 5 min, but was statistically significant in Group R when compared to Group N at 15,30,45,60, 75, and 90 min (Table 4)

3.5. Heart rate (HR)

Differences in HR were compared between the groups at regular intervals. The difference was not significant at 0 and 5 min, but was statistically significant in Group R when compared to Group N at 15,30,45,60, 75, and 90 min (Table 5).

4. Discussion

Pneumoperitoneum during laparoscopic surgery causes physiological effects mainly due to three mechanisms: a) mechanical effects due to intraperitoneal pressure, b) chemical effect of CO2 used for insufflation, and c) desiccation effects due to cool and dry gas. Pneumoperitoneum causes hemodynamic changes due to an increase in intra-abdominal pressure, leading to increases in mean arterial pressure, heart rate, systemic vascular resistance, pulmonary vascular resistance, venous return, and cardiac output due to mechanical and humoral factors.[6]

Pneumoperitoneum causes transient hypercapnia and respiratory acidosis, leading to cardiac arrhythmias, sympathetic stimulation, and catecholamine release. Several studies have been conducted to minimize postoperative pain and attenuate the hemodynamic responses to pneumoperitoneum.

Joris et al. have shown that administration of clonidine (8mcg/kg) one hour before induction and increasing cardiac filling pressures by fluid loading with 500ml RL before pneumoperitoneum attenuated these hemodynamic changes.[6]

Local anesthetics prevent and relieve pain by interrupting nerve excitation and conduction in a reversible, direct interaction with voltage-gated sodium (Na) channels that block membrane electrical excitability. Local anesthetics have anti-inflammatory properties, and their mechanisms could be prostaglandin antagonism, inhibiting release of lysosomal enzymes, inflammatory mediators, free radicles and leukocyte migration. By using intraperitoneal local anesthetics (IPLA) before pneumoperitoneum, we hypothesized that it may be possible to modulate peritoneal and visceral signalling to the brain, thereby attenuating hemodynamic and metabolic changes during laparoscopic surgeries.

A. Ng et al[7] mentioned that the peritoneum is exposed to block the visceral nociceptive conduction from the area of tissue damage and the peritoneum, thereby providing an additional mechanism of analgesia. However, absorption from the large peritoneal surface may be a further mechanism of analgesia.

For postoperative analgesia, Bupivacaine by M. Barczynski et al[8] and Ropivacaine by Maestroni et al[9] used for intraperitoneal instillation and have shown that there was effective analgesia when administered before creation of pneumoperitoneum rather than after creation of pneumoperitoneum. Putta et al[10] studied that intra peritoneal local anaesthetic instillation immediately after creation of capnoperitoneum reduces the magnitude of postoperative pain, prolongs the duration of first analgesic request, reduces analgesic consumption, reduces incidence of shoulder pain in the postoperative period and facilitates early resumption of normal activity.

Das NT et al[11] have used port site infiltration and intraperitoneal instillation in the gallbladder fossa and sub-diaphragmatic hepatic surface in two groups of patients with 35 ml of 0.375% Ropivacaine in one group and 35 ml of 0.25% Bupivacaine in the other as part of multimodal analgesia in patients undergoing laparoscopic cholecystectomy and concluded that Ropivacaine provided more profound and prolonged analgesia when compared to Bupivacaine.

Indira et al[12] showed that intraperitoneal instillation of 20 ml of 0.5% lignocaine was superior in maintaining

Table 2: Systolic blood pressure between two groups

Time	Group	Mean (mmhg)	Standard Deviation (mmhg)	Standard Error Mean	Mean Difference (mmhg)	T value	P value
0 Min	Group R	123.97	16.88	1.68	5.37	2.516	0.130
	Group N	129.34	13.05	1.30			
5 Min	Group R	113.81	16.08	1.60	10.11	4.48	0.05
	Group N	123.92	15.80	1.58			
15 Min	Group R	104.96	7.52	0.75	21.53	15.33	0.001
	Group N	126.49	11.85	1.18			
30 Min	Group R	109.36	11.18	1.11	18.10	11.31	0.001
	Group N	127.36	11.43	1.14			
45 Min	Group R	106.12	8.82	0.88	21.23	14.03	0.001
	Group N	127.35	12.28	1.22			
60 Min	Group R	110.37	5.56	0.55	18.31	15.35	0.001
	Group N	128.68	10.54	1.05			
75 Min	Group R	110.98	9.17	0.91	18.41	14.37	0.001
	Group N	129.39	10.83	1.08			
90 Min	Group R	108.90	9.33	0.93	21.92	16.64	0.001
	Group N	130.82	9.29	0.92			

Table 3: Diastolic blood pressure between two groups

Time	Group	Mean (mmhg)	Standard Deviation (mmhg)	Standard Error Mean	Mean Difference (mmhg)	T Value	P Value
0 Min	Group R	79.79	12.39	1.23	2.8	1.83	0.07
	Group N	82.28	8.83	0.88			
5 Min	Group R	78.01	12.16	1.21	2.09	1.31	0.19
	Group N	80.10	10.28	1.02			
15 Min	Group R	70.71	10.06	1.00	11.44	9.36	0.001
	Group N	82.15	6.92	0.69			
30 Min	Group R	73.42	9.66	0.96	8.33	7.22	0.001
	Group N	81.75	6.30	0.63			
45 Min	Group R	72.74	8.34	0.83	8.54	7.30	0.001
	Group N	81.28	8.18	0.81			
60 Min	Group R	74.30	8.42	0.84	7.49	5.67	0.001
	Group N	81.79	10.15	1.01			
75 Min	Group R	70.64	8.88	0.88	10.69	9.1	0.001
	Group N	81.33	7.68	0.76			
90 Min	Group R	71.65	8.33	0.83	11.25	10.83	0.001
	Group N	82.90	6.18	0.61			

stable hemodynamics when compared to 20 ml of 0.125% Bupivacaine and 20 ml of 0.2% Ropivacaine in the initial period following pneumoperitoneum.

The In our study, we instilled 40 ml of 0.2% Ropivacaine in Group R and 40 ml of normal saline in Group N and found that there was no significant difference in SBP, DBP, and MAP in both groups at 0 and 5 min, but there was a significant reduction at 15, 30, 45, 60, 75, and 90 min. HR was significantly reduced at 5, 15, 30, 45, 60, 75, and 90 min in Group R than in Group N. Therefore, Ropivacaine peritoneal instillation before pneumoperitoneum was effective in minimizing hemodynamic changes compared with placebo.

Karaaslan et al[13] studied that preemptive analgesia by intra peritoneal instillation of local anaesthetic prevents the formation of central sensitization to painful stimuli by decreasing response from pain sensation.

Kahokehr et al[14] conducted A systematic review that summarized the available literature on serum local anesthetic levels reached after intraperitoneal administration of lignocaine, Bupivacaine and Ropivacaine, and estimated their peak serum level (C-max) and time-to-peak serum level (T-max) based on the reported literature. Importantly, there were no cases of clinical toxicity reported in any of these trials, and the addition of adrenaline to the solution to prolong T-max and lower C-max increases the safety profile.

Table 4: Mean arterial blood pressure between two groups

Time	Group	Mean (mmhg)	Standard Deviation (mmhg)	Standard Error Mean	Mean Difference (mmhg)	T Value	P Value
0 Min	Group R	93.03	13.35	1.33	5.07	3.1	0.07
	Group N	98.1	9.43	0.94			
5 Min	Group R	88.38	11.90	1.19	6.78	4.11	0.06
	Group N	95.16	11.39	1.13			
15 Min	Group R	80.71	6.10	0.61	17.47	17.56	0.001
	Group N	98.18	7.85	0.78			
30 Min	Group R	84.10	9.10	0.91	13.36	11.80	0.001
	Group N	97.36	6.58	0.65			
45 Min	Group R	81.96	7.67	0.76	14.39	10.33	0.001
	Group N	96.35	11.62	1.16			
60 Min	Group R	84.01	5.98	0.59	13.98	15.15	0.001
	Group N	97.99	7.01	0.70			
75 Min	Group R	82.35	7.37	0.73	16.03	17.13	0.001
	Group N	98.38	5.75	0.57			
90 Min	Group R	83.06	7.06	0.70	15.62	16.38	0.001
	Group N	98.68	6.39	0.36			

Table 5: Heart rate between two groups

Time	Group	Mean (bpm)	Standard Deviation (bpm)	Standard Error Mean	Mean Difference (bpm)	T value	P value
0 Min	Group R	85.23	11.84	1.18	3.20	1.75	0.08
	Group N	88.43	13.83	1.38			
5 Min	Group R	81.12	11.87	1.18	6.41	3.57	0.001
	Group N	87.53	13.43	1.34			
15 Min	Group R	79.76	10.99	1.09	9.57	6.16	0.001
	Group N	89.33	10.95	1.09			
30 Min	Group R	80.29	12.94	1.29	10.26	6.05	0.001
	Group N	90.35	10.41	1.04			
45 Min	Group R	79.13	11.03	1.10	10.63	7.10	0.001
	Group N	89.76	10.11	1.01			
60 Min	Group R	79.38	10.99	1.09	11.26	7.63	0.001
	Group N	90.64	9.83	0.98			
75 Min	Group R	79.10	11.36	1.13	12.0	8.04	0.001
	Group N	91.30	9.65	0.96			
90 Min	Group R	79.10	11.79	1.17	12.29	7.98	0.001
	Group N	91.39	9.89	0.98			

Hernández-Palazón et al. and Narchi et al[15,16] showed that the mean plasma concentration after intraperitoneal instillation of Bupivacaine 100-150 mg is well below the toxic concentration of 3μg/ml.

Labaille et al[17] defined that systemic toxicity of serum level more than four μg/ml, based on a previous study on healthy adult volunteers who received intravenous infusions of Ropivacaine. Indira et al[12] also states that Ropivacaine, in view of its better cardiovascular safety profile, can be an alternative to bupivacaine.

Therefore, in our study, we used 40 ml of 0.2% Ropivacaine (80 mg), which was within the plasma toxic limits, and none of the cases reported adverse effects associated with the use of Ropivacaine, such as allergic reactions and local tissue, cardiovascular, central nervous system, or systemic toxicity. Loizides S et al.[18] studied that Intraperitoneal administration of local anaesthetic has also been shown to reduce nausea and vomiting.

There are many methods for attenuating hemodynamic responses in laparoscopic surgeries using clonidine, magnesium, dexmedetomidine, propofol, labetalol, and opioids, such as fentanyl. In our study we used Ropivacaine a local anesthetic instilled intra-peritoneally before creating pneumoperitoneum has resulted in minimal hemodynamic changes intraoperatively. So we can use local anesthetics by intraperitoneal instillation before creating pneumoperitoneum to attenuate hemodynamic responses and also provides peri-operative analgesia.

5. Conclusion

We conclude that intraperitoneal instillation of 40ml of 0.2% Ropivacaine before creating pneumoperitoneum will attenuate hemodynamic changes, reduce peritonitis and also provide perioperative analgesia without any adverse effects. This concept of IPLA can minimize the perioperative opioids and NSAID's usage and their side effects like opioids related nausea, vomiting, pruritus, urinary retention, delayed recovery and NSAIDS related gastritis, platelet dysfunction, AKI and provides ambulatory analgesia, early discharge for day care surgeries.

6. Limitations

The study did not measure the serum concentration of ropivacaine, and surgical procedures lasting more than 90 minutes were excluded from the analysis. Postoperative analgesia and hemodynamics were not assessed. The study only involved patients classified as ASA 1 and 2; therefore, further investigation is needed to explore the effects in ASA 3 and 4 patient groups.

7. Conflict of Interest

None.

8. Source of Funding

None.

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