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Original Article

Comparison of intraperitoneal nebulisation of ropivacaine and morphine versus intraperitoneal nebulisation of ropivacaine and fentanyl for post operative analgesia in pediatric patients undergoing laparoscopic upper abdominal surgeries

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ABSTRACT

Background: Intraperitoneal nebulisation of local anaesthetic in laparoscopic abdominal surgeries has been reported to provide a homogeneous spread of local anaesthetics and provide better analgesia. In our study, we hypothesized that Intraperitoneal nebulisation of Ropivacaine with adjuvants as Fentanyl and Morphine will alleviate postoperative pain after laparoscopic upper abdominal surgery in paediatric patients aged between 6 and 16 years.

Methodology: This prospective, randomized, interventional clinical study was conducted in paediatric patients undergoing Laparoscopic upper abdominal surgeries for a duration of 1 year**.** 50 patients were randomized into two equal groups to receive allocated intervention. 25 patients were analysed in each group.

Results: The mean VAS score at 6 hours in Group A was 3.56 and in Group B was 5.36 which was statistically significant (p=0.001). Mean duration of analgesia, when first dose of rescue analgesia was required was 6.84 hours in Group A and 5.00 hours in Group B which was statistically significant (p=0.002).

Conclusion: Intraperitoneal nebulization of Ropivacaine with Morphine as adjuvant in elective laparoscopic upper abdominal surgeries in paediatric population significantly increases the duration of postoperative analgesia as compared to Intraperitoneal nebulization of Ropivacaine with Fentanyl as adjuvant with stable haemodynamics and comparable side effects.

Keywords: Intraperitoneal, Nebulisation, Ropivacaine, Morphine, Fentanyl, Analgesia, Pediatric, Laparoscopic.

INTRODUCTION

Postoperative pain management is a key to a patient's early recovery in laparoscopic surgeries. Paediatric patients undergoing laparoscopic abdominal surgeries experience moderate to severe pain, especially on the first and second postoperative days.[1]The laparoscopic surgical approach is associated with pain due to intraperitoneal insufflation of carbon dioxide, which results in peritoneal stretching, diaphragmatic irritation, a change in intra-abdominal pH, and retention of the insufflated gas in the abdominal cavity after surgery.[2] These factors may lead to visceral and shoulder pain due to the irritation of the peritoneal nerves among paediatric patients. Previous studies [3,4] have reported that as many as 80% of paediatric patients required opioid analgesia after abdominal laparoscopic surgery, which also may increase postoperative morbidity and hospital stay.

Intraperitoneal nebulization of local anaesthetics through microvibration-based aerosol humidification devices combines the analgesic benefits of gas conditioning (humidification) and local anaesthetic instillation, thereby allowing uniform

dispersion of the solution throughout the peritoneum.[5] This method has shown great efficacy in the control of postoperative pain. The main principles of enhanced recovery after surgery are to reduce the physiologic derangement and stress response in paediatric patients, thereby improving recovery, reducing complication rates, and shortening inpatient hospital stays.[6] This also aims to avoid opioid use altogether, or at least reduce opioid doses required, and thereby reduce the risk of side effects from opioids that are common and cause delays in recovery.

With this background, the present study was planned to compare the efficacy of intraperitoneal nebulization of Ropivacaine and Morphine vs Ropivacaine and Fentanyl for post-operative analgesia in paediatric patients aged 6-16 years undergoing laparoscopic upper abdominal surgeries.

Aims And Objectives

The aim of the study is to compare the efficacy of intraperitoneal nebulization of Ropivacaine and Fentanyl vs Ropivacaine and Morphine for postoperative analgesia in paediatric patients undergoing laparoscopic upper abdominal surgeries.

MATERIAL AND METHODS

This prospective, randomised, interventional clinical study was conducted in the Department of Anaesthesia and the Department of Paediatric Surgery of a research institute for a duration of one year. The study protocol was approved by the Institutional Ethical Committee (Dean/2019/EC/1792 date: 18.11.2019), and informed written consent was obtained from the parents of all patients. Children were explained how to report the VAS score in the post-operative period.

Inclusion Criteria: Patients aged between 6 and 16 years, belonging to the American Society of Anaesthesiologists physical status 1 and 2; undergoing laparoscopic upper abdominal surgeries.

Exclusion Criteria: Refusal to participate by parents/guardians or by patient; Allergy to study drugs**;** ASA Grade 3,4; Patients with a history of cardiopulmonary, renal, neurological and psychiatric disorders; Those in whom the laparoscopic procedure was converted to an open procedure; Presence of communicative or cognitive limitations interfering with pain measurements; History of developmental delays or mental retardation.

In this study, 60 patients were assessed for eligibility, out of which 10 were excluded for not meeting inclusion criteria, and the remaining 50 patients were randomly allocated by a computer-generated table into one of the 2 groups; the randomisation sequence was concealed in sealed envelopes.

The sample size was calculated using a minimum detectable difference of 30 mins in duration of analgesia with a standard deviation of 30 mins, alpha = 0.05 and power of 0.8. 25 patients per group were needed for the study. We recruited 60 patients to compensate for patient /data loss.

A thorough Preanaesthetic evaluation was done a day prior to surgery.

Preparation: All patients were examined in the evening before surgery to confirm pre-anaesthetic findings, and informed consent was taken. Fasting status for solids and clear liquids was explained. The type of surgery, along with baseline blood pressure, heart rate and oxygen saturation, was noted.

Study Procedure and Technique: All patients received pre-medication in the form of Inj. Midazolam 0.1 mg/kg intravenously (iv) 15 minutes prior to Anaesthesia and fentanyl (2µg/kg) iv just before induction. Surgery was carried out under general anaesthesia with propofol (2–2.5 mg/kg) for induction and vecuronium (0.1 mg/kg) as muscle relaxant to facilitate tracheal intubation. Anaesthesia was maintained at 50% oxygen and 50% Air with titrated isoflurane. Adequate muscle relaxation was maintained with intermittent vecuronium (0.01 mg/kg). Ventilation (tidal volume 6-8 ml/kg) was adjusted to maintain end tidal CO2 between 30 and 35 mmHg. During laparoscopy, intra-abdominal pressure was maintained at 6 to 12 mmHg. Inj. Paracetamol was given at a dose of 15 mg/kg IV. After removal of the gall bladder and irrigation of the peritoneal cavity, the nebulization device was connected to one of the laparoscopic ports. The nebulization device consisted of a compressor nebuliser connected to a T-piece nebuliser chamber. One end of the nebuliser was closed with sterile tape, and the other end connected via an endotracheal tube connector (6mm internal diameter ET tube) to one of the laparoscopic ports (Figure 1). Nebulization was then started, and the spread of the nebulised solution was observed via the laparoscope. Nebulization was stopped when no residual solution could be appreciated in the nebuliser. At the end of the surgery, port sites were infiltrated with 2 ml of 0.75% ropivacaine each.

The two study groups are as follows:

- **GROUP A:** Ropivacaine and Morphine group (n=25): Patients received Intraperitoneal nebulization of Ropivacaine 0.75% 2mg/kg and Morphine 10mcg/kg
- **GROUP B:** Ropivacaine and Fentanyl group (n=25): Patients received Intraperitoneal nebulization of Ropivacaine 0.75% 2mg/kg and Fentanyl 3mcg/kg

After completion of the surgical procedure, patients were awakened and extubated after the neuromuscular block was reversed with Inj. Glycopyrrolate 8mcg/kg and Inj. Neostigmine 0.05mg/kg. Extubation was done after oral and endotracheal suction. Pulse, blood pressure, SPO2, and respiratory rate were recorded and transferred to the post anaesthesia care unit (PACU) for 24 hrs.

Patients were monitored for haemodynamic parameters: heart rate, blood pressure and saturation at baseline, after extubation and then at 30 mins, 1 hour, 2 hours, 4 hours, 6 hours, 12 hours, and 24 hours post extubation. In PACU, patients were observed for postoperative need of rescue analgesia and its time and dose, complications (nausea, vomiting, shoulder tip pain, haemodynamic changes).

Analgesia was assessed using the VAS (Visual Analogue Score) scale. Rescue analgesia was administered at VAS score >= 4. First line rescue analgesia was given Inj. Paracetamol 15mg/kg, if adequate pain relief was not present even after 1 hour of paracetamol administration, 2nd line rescue analgesic - Inj. Diclofenac- 0.1mg/kg was administered.
The time when the first rescue analgesia was given was defined as duration of analgesia. Duration of analgesia provided was compared between the two groups.

Primary outcome – The quality and duration of analgesia assessed by VAS. VAS Score >=4 was considered significant pain

Secondary outcome-

- Haemodynamic effects- heart rate, blood pressure and respiratory rate at various intervals,
- Side effects like nausea, vomiting, shoulder tip pain, hypotension, bradycardia, respiratory depression, if any.

Statistical Analysis
The data was entered into a computer through Microsoft(MS) Office Excel Software to create a database of the study, and was analysed using a post hoc analysis method to assess the outcome of the study. Statistical analysis was performed using IBM SPSS version 20.0 software. Categorical variables are expressed using frequency and percentage. Continuous variables are presented using mean and standard deviation. To test the statistical significance of the comparison of categorical variables between groups, the chi-square test was used. To test the statistically significant difference in the mean values of continuous variables, Student's *t*-test was used. $P < 0.05$ was considered statistically significant. Measurement data were expressed as mean standard deviation (SD) and were analysed by Student's t-test.

RESULTS
In the present study, 60 patients were assessed for eligibility criteria. 10 patients were excluded from the study who did not meet the inclusion criteria. 50 patients were randomised into two equal groups to receive the allocated intervention. 25 patients were analysed in each group. The consort diagram is given in Figure 2.

Figure 1. Nebulisation device used in study

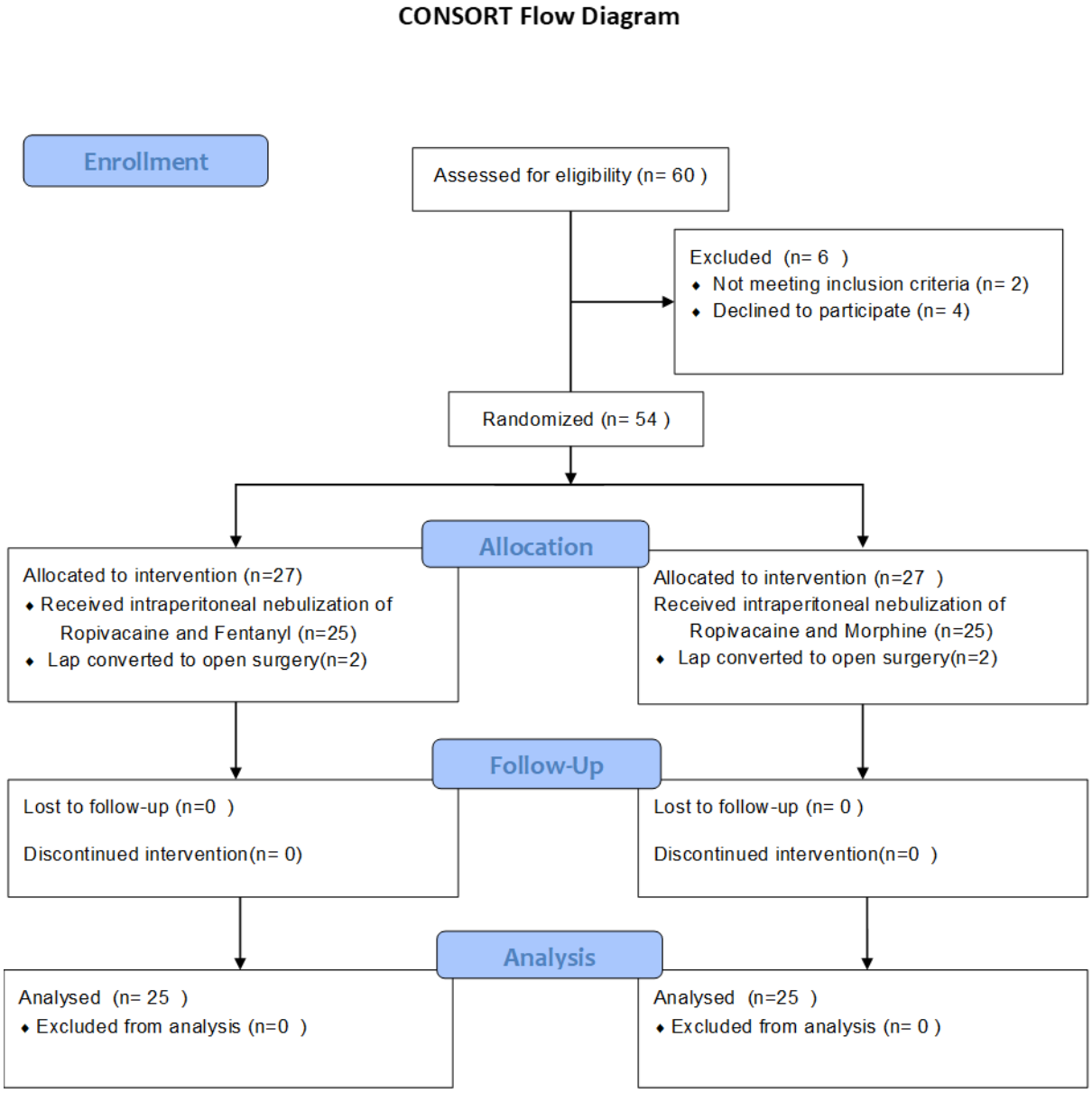

Figure 1. Consort flow diagram of the study

Demographic data showed that **the maximum** number of patients in group A (80%) & group B (84%) were aged between 5-10 yrs and the results were statistically insignificant (p-value>0.05) (Table 1). In Group A, there were 56% females and 44% males, whereas in Group B, there were 28% females and 72% males, and the results were statistically significant (p-value<0.05) (Table 1). In group A, the mean weight is 28.56 kg, whereas in group B, it is 26.32 kg, which was statistically insignificant (p-value>0.05) (Table 2). The maximum number of patients in group A (68%) were ASA grade 1, and the maximum number of patients in group B (64%) were ASA grade 1; the results were statistically insignificant (p-value>0.05) (Table 1). According to the type of surgery, the maximum number of patients in both group A (44%) and group B (48%) underwent Laparoscopic Cholecystectomy, which was statistically insignificant (p-value>0.05) (Table 1).

Table 1 Table showing Demographic details, ASA grade, Type of surgery among 2 groups

		Group A		Group B		Chi square	p-value
		Number	percentage	Number	percentage		
Age groups	5-10	20	80.0%	21	84.0%	**0.136**	**0.713**
	11-16	5	20.0%	4	16.0%		
Gender	Female	14	56.0%	7	28.0%	4.023	**0.045**
	Male	11	44.0%	18	72.0%		

ASA grade	1	17	68.0%	16	64.0%	**0.00**	**1.00**
	2	8	32.0%	9	36.0%		
Type of surgery	Lap Appendicectomy	1	4.0%	3	12.0%	6.155	0.291
	Lap Cholecystectomy	11	44.0%	12	48.0%		
	Lap Duhamel Procedure	0	0.0%	1	4.0%		
	Lap Gastrostomy	4	16.0%	5	20.0%		
	Lap Nephrectomy	9	36.0%	3	12.0%		
	Lap Splenectomy	0	0.0%	1	4.0%		

The difference in baseline mean heart rate in the two groups was statistically insignificant (p=0.278). The Mean heart rate at 30 min post extubation was 106 in Group A and 99 in Group B, which was statistically significant (p<0.05). Mean heart rate at other various intervals in the postoperative period was statistically insignificant (Fig. 3). There was a decrease in MAP at 30 min after extubation in Group A (73mm Hg) compared to Group B (77 mm Hg), which was statistically significant (p=0.020). Compared to Group B there was more decrease in MAP in group A at 2, 4 and 6 hours post extubation but results were not statistically significant (Fig. 4). There was no statistically significant difference in respiratory rate between the two groups (p>0.05) (Fig. 5). The mean VAS score at 6 hours in Group A was 3.56 and in Group B was 5.36 which was statistically significant (p=0.001). After it, the VAS score was not statistically significant (Table 2).

Table 2. Table showing Weight, Baseline vitals, VAS Score at induction and in postoperative periods & Postoperative analgesia details

Variables			GROUP				t-test for Equality of Means		
			A		B		T	df	p-value
			Mean	SD	Mean	SD			
Weight(kg)			28.56	5.08	26.32	5.60	1.482	48	.145
Baeline mean BP	SBP		96.16	7.81	105.04	7.77	-4.029	48	.000
	DBP		62.72	5.33	64.48	5.98	-1.099	48	.277
VAS Score at induction and in postop periods	VAS At Induction		0.64	0.70	0.56	0.51	-.463	48	.646
	VAS 30 Min		2.28	1.06	2.48	0.96	0.698	48	.489
	VAS 1hr		2.32	1.25	2.60	1.08	0.848	48	.401
	VAS 2hr		2.80	1.55	3.08	1.12	0.732	48	.468
	VAS 4hr		3.08	1.41	3.56	1.53	1.824	48	.074
	VAS 6hrs		3.56	1.92	5.36	1.47	3.727	48	**.001**
	VAS 12hr		5.44	1.87	6.28	1.24	1.869	48	.068
	VAS 24hr		5.32	1.55	6.12	1.56	1.819	48	.075
Duration of Analgesia (hours)			6.84	2.48	5.00	1.32	2.48	48	**.002**
Adverse events	Nausea/ Vomiting	No	17	68.0%	20	80.0%	.936[a]	1	.333
		Yes	8	32.0%	5	20.0%			
	Shoulder Tip Pain	No	21	84.0%	18	72.0%	1.049[a]	1	.306
		Yes	4	16.0%	7	28.0%			

Mean duration of analgesia was 6.84 hours in Group A and 5.00 hours in Group B, which was statistically significant (p=0.002) (Table 2). Among side effects, there was no statistically significant difference in the incidence of nausea/vomiting in patients in both groups (p>0.05). 16% patients in Group A and 28% patients in Group B had shoulder tip pain with no statistically significant difference (p>0.05) (Table 2). There was no incidence of hypotension and bradycardia, respiratory depression in any of the groups.

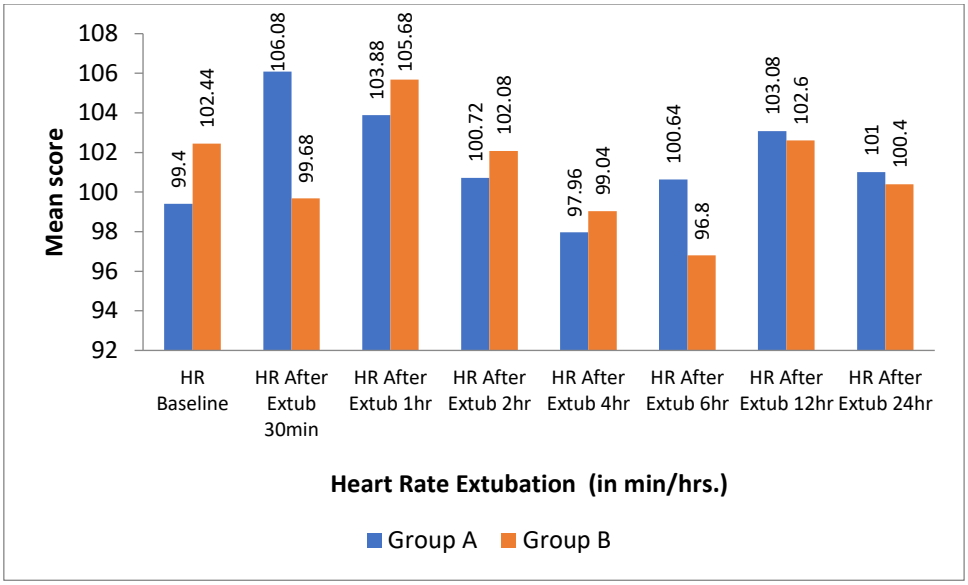

Figure 2. Comparison of Heart rate after extubation at various times

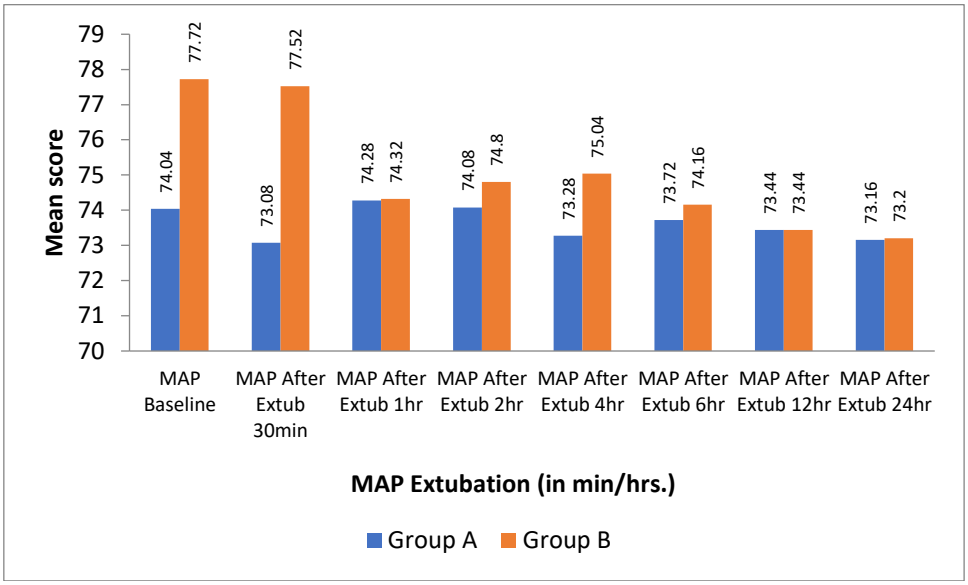

Figure 3. Comparison of Mean arterial pressure (MAP) after extubation

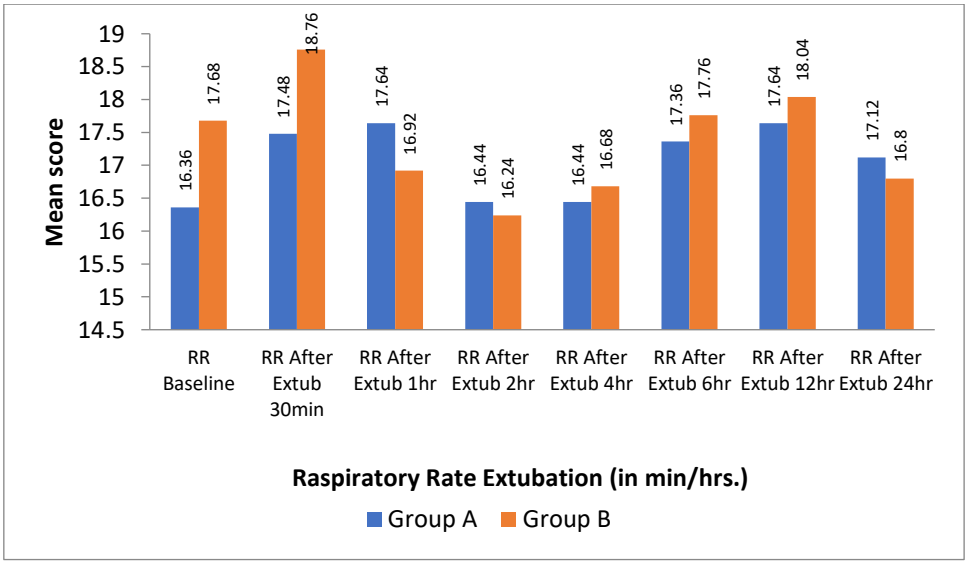

Figure 4. Comparison of Respiratory rate after extubation

DISCUSSION

The anaesthetic management in paediatric laparoscopic surgeries requires special attention due to the pneumoperitoneum created and extremes of position adopted, in addition to the fact that paediatric anaesthesia itself is a challenge.

Visceral and shoulder pain after laparoscopic cholecystectomy is caused by surgical manipulations, disruption of the peritoneum, and dissection of viscera, which result in irritation of peritoneal nerves.[7] Studies have shown that instillation and nebulization of local anaesthetic into the peritoneal cavity can also be used to relieve pain after laparoscopic surgery. It produces analgesia by blocking the visceral nociceptor.[7]

The reduced shoulder pain observed in our study was also reported by Bucciero et al [8], who compared the effects of ropivacaine nebulization using the Aeroneb Pro® device before and after surgery with intraperitoneal instillation of ropivacaine in laparoscopic cholecystectomy and found that ropivacaine nebulization significantly reduced the incidence of shoulder pain and the time to unassisted walking. The use of humidified insufflation gas, resulting in a more uniform spread of ropivacaine throughout the peritoneum, including the area under the diaphragm, may explain the lower incidence of shoulder pain in the nebulization group.

Due to the lack of availability of the Aeroneb Pro device in our hospital, we used the conventional compressor nebuliser for nebulization of ropivacaine. The compressor nebuliser creates a significant gas flow and flushes the peritoneal cavity with air, and removes residual CO2. This can additionally benefit in achieving better pain control as compared to the mesh nebuliser used by Ingelmo and colleagues. Their device worked effectively, but the availability of the Aeroneb Pro device is limited owing to the significantly high cost. The device used in our study was cost effective, components were easily available and simple to assemble and worked efficiently. The components used were disposable (except the compressor nebuliser) and therefore would not affect the aseptic conditions required during surgery. Both groups in our study received nebulisation, and significant analgesia was reported by both groups, which emphasises the fact that pain after a laparoscopic procedure is multifactorial in origin.

One of the limitations of the nebulization technique is that the small droplet size creates a “foggy” environment, which might interfere with the surgeon's vision. Thus, local anaesthetic nebulization may not be feasible throughout the surgical procedure. Therefore, we performed the nebulisation after the surgery, and it was completed just prior to exsufflation of the pneumoperitoneum.

Porika et al [9] compared intraperitoneal nebulizations of ropivacaine and bupivacaine and observed that both were equally efficacious in reducing pain. Das *et al* [10] used intraperitoneal nebulization of ropivacaine and found that it reduced pain scores in the early postoperative period, making laparoscopic cholecystectomy more amenable to day care surgery. Our study was also consistent with their findings, with a significant reduction in postoperative pain following Ropivacaine nebulization.

In our study, it was found that the duration of analgesia (VAS ≥4) was at a mean of 5.00 +/-1.32 hours in the Ropivacaine plus Fentanyl group, while in the Ropivacaine plus Morphine nebulization group it was at 6.84 +/- 2.48 hours, which was statistically significant (p value= 0.002). Solankhi Rekha et al [11] in their study compared intra-peritoneal instillation versus nebulization for laparoscopic surgeries for postoperative pain relief using Ropivacaine plus morphine in both groups and found that the requirement for first rescue analgesic was 17.57+/- 0.02 hours.

In our study, 4 out of 25 patients in group A and 7 out of 25 patients in group B experienced shoulder tip pain, which was not statistically significant. Therefore, there was better control of shoulder tip pain in the Ropivacaine plus Morphine nebulization group because of the pharmacokinetic and pharmacodynamic properties of the drug used. Ingelmo et al [12] observed that there was no incidence of shoulder tip pain in the Ropivacaine nebulization group as compared to the Normal Saline control. Solanki Rekha et al [11] found that the incidence of shoulder tip pain was zero in the Ropivacaine nebulization group. Instillation of local anaesthetics in the supine position might prevent their flow over the celiac plexus and phrenic nerve endings, whereas nebulization provides uniform distribution, giving better results. We did not observe any incidence of hypotension, bradycardia or respiratory depression in any of the cases.

In our study, patients had adequate pain relief, with a smaller dose of 2mg/kg of 0.75% Ropivacaine with adjuvant as Fentanyl or Morphine. In a study by Allegri *et al* [13], 50 mg of nebulised ropivacaine was found to be effective in providing adequate analgesia in patients undergoing laparoscopic cholecystectomy. Further increase in the dose of ropivacaine did not provide any additional benefit.

In our study, mean VAS scores were below 4 cm in the Ropivacaine plus fentanyl group till 4 hours post extubation, while it was below 4 cm till 6 hours in the Ropivacaine plus morphine group. Therefore, we found that both groups were effective in controlling postoperative pain significantly. A study by Bhatia N, et al [14] found that following laparoscopic cholecystectomy surgeries, ropivacaine nebulization of the intraperitoneal cavity, with or without fentanyl, provides highly

effective postoperative analgesia, with decreased incidence of shoulder pain. Furthermore, the addition of fentanyl to ropivacaine prolongs the duration of analgesia.
Mean arterial pressures and heart rate were comparable and statistically insignificant in both the study groups, the reason being the rescue analgesia given on demand whenever VAS scores reached 4 cm. Moreover, none of the agents used intraperitoneally was described as causing a rise in blood pressure.

Adverse effects associated with the use of local anaesthesia, such as allergic reactions and local tissue, cardiovascular, central nervous system and systemic toxicity, were not observed in our study with the use of local anaesthesia.

CONCLUSION

The present study showed that in terms of VAS score, the Ropivacaine plus Morphine nebulization group showed greater reduction in intensity of postoperative pain. In terms of duration of analgesia, those in the Ropivacaine plus Morphine group showed longer duration of analgesia with both groups showing stable haemodynamics and statistically comparable side effects. Hence, the study concluded that Intraperitoneal nebulization of Ropivacaine with Morphine as adjuvant in elective laparoscopic upper abdominal surgeries in paediatric population significantly increases the duration of postoperative analgesia as compared to Intraperitoneal nebulization of Ropivacaine with Fentanyl as adjuvant.

Limitations Of the Study: Our results should be interpreted with caution because of some limitations: Firstly, the relatively limited number of paediatric patients in the present study could be one of the reasons why no complications or adverse reactions to ropivacaine occurred. Secondly, the power of the study is less, and therefore, the sample size is small. A larger sample size will establish further conclusive evidence.

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