Original Article

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Epidural Ropivacaine versus Ropivacaine with Fentanyl for Analgesia in Paediatric Laparoscopic Surgeries: A Double-Blind Randomized Comparative Study

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Abstract

Background: Laparoscopic surgery in children has beneficial outcomes like decreased pain and less tissue manipulation. That is why we get better outcomes and better healing. In abdominal surgeries, local anaesthesia and opioid by epidural route prove to have a significant analgesic effect. The aims is to compare the hemodynamic effects, use of rescue analgesia after adding fentanyl to ropivacaine in single bolus epidurals in laparoscopic surgeries of paediatric patients. Settings and Design is Randomized double-blind study. **Subjects and Methods:** We conducted a study in 1 to 5 years age group patients undergoing laparoscopic procedures under general anaesthesia, divided into two groups after randomization, Group I has been given single bolus dose epidural ropivacaine (0.2%) and Group II has been given single bolus dose epidural ropivacaine (0.2%) with fentanyl (1mg ml^{-1}). Hemodynamic stability, Intra and postoperative analgesic needs were compared. Statistical analysis used: We have used paired "t" test for comparison of continuous data at different time intervals in a group and unpaired "t" test for comparison between two groups. We have used chi-square (χ^2) for comparison of discrete (categorical) variables. **Results:** We have found a significant rise in heart rate and mean arterial pressure at all-time intervals ($p<0.001$) except just after induction (5 min), but the rise was more significant in Group I. Intraoperative fentanyl requirement was significantly higher ($15.54\pm3.77\mu g$ vs $0.74\pm1.91\mu g$) in Group I. Similarly in the postoperative period the rescue analgesic was also required early (2.27 ± 0.50hrs vs 7.13 ± 0.81 hrs) and more (412 ± 32mg vs 284 ± 27 mg) in Group I. **Conclusions:** It was concluded that single-dose epidural ropivacaine with fentanyl provides more hemodynamic stability with less need of intra and postoperative rescue analgesics.

Keywords: Laparoscopy, Epidural, Fentanyl, Ropivacaine, Modified Objective Pain Score

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Introduction

Paediatric laparoscopy is very popular nowadays. It has been first described by Kelling in 1923. The laparoscopic approach provides various benefits above an open procedure; major reduction in the surgery-related stress, postoperative analgesia, respiratory and wound complications; reduces fluid shifts, fastens postoperative recovery, early ambulation, resuming normal diet with shortening of hospital stay.[1] In children, a number of surgeries can be done and the anaesthetic technique in these patients should be with the consideration of hemodynamic and respiratory changes due to carbon dioxide (CO_2) insufflation and the pneumoperitoneum.[2] Tracheal intubation during general anaesthesia may lead to hypertension, tachycardia, and sometimes arrhythmias due to a reflex increase in sympathetic activity.[3,4] In laparoscopy, the pain is mainly due to over-stretching of the peritoneum, traction and irritation of phrenic nerves, visceral manipulation, presence of gases and produced inflammatory mediators.[5] This pain can be managed by a variety of methods such as instilling local anaesthetic with a laparoscope, use of bilateral rectus sheath block, caudal/epidural block with local anaesthetics, opioids and adjuncts or intravenous/intramuscular opioids and NSAIDS.[6]

Fentanyl is used as an adjuvant to general anaesthesia in the iv and epidural route. The epidural route is found to be better for attenuation of hemodynamic alterations.[7] Ropivacaine is found effective in the epidural route for the management of pain in abdominal surgeries. It has the same epidural analgesic potency as bupivacaine but less cardiac and motor involvement. Ropivacaine is used safely in children of 1-12 years for local infiltration, nerve blocks, epidural and intrathecal anaesthesia to relieve surgical pain. To date, no study has been found which compares epidural ropivacaine and epidural ropivacaine with fentanyl for analgesia in paediatric laparoscopic surgeries on reviewing the literature.[8–10]

Subjects and Methods

This study was a prospective randomized, double-blind, study conducted in the operation theatre of our tertiary care institute and research center over a period of one year. We had recruited 60 paediatric patients of either sex, ASA I and II, between 1 to 5 years of age, undergoing different laparoscopic supraumbilical surgeries under general anaesthesia (GA). Before the start of the study, we have taken approval from the Institutional Ethical Committee. The exclusion criteria were any contraindication to neuraxial block, central nervous system disorder and known allergy to used medications. We had divided patients into two groups by computer-generated random number table and allocation concealment was done using sequentially numbered opaque envelopes (SNOPES) with 30 patients each in both the groups in a double-blind manner.

We had secured a cannula of 22G or 24G and intravenous fluid started. Every child received inj. atropine 0.02mg/kg, inj. midazolam .08 mg/kg and inj. ondansetron 0.1mg/kg as premedication. All basic monitors like pulse oximeter (SPO2), Non-invasive blood pressure (NIBP), Electrocardiography (ECG) and precordial stethoscope were attached. The induction of general anaesthesia was done with inj. fentanyl 1mg/kg, inj. thiopentone 5-7 mg/kg and endotracheal intubation was done with succinyl choline 1.5 mg/kg. Maintenance was done with 50 % 0_2, 50% air, isoflurane 0.8-1% and boluses of inj. Cis-atracurium. A paediatric epidural set 19G 5cm Tuohy Needle with 21 G catheter was used and placed in lateral position in T 11-12 or L 1-2 interspace under strict aseptic conditions. Group I received a single epidural bolus of 1ml/kgropivacaine 0.2% only and group II received a single epidural bolus .75 ml/kg ropivacaine 0.2% with fentanyl 1mg/ml respectively. After 10 min of epidural dose, surgery was started. We had checked intraabdominal pressure up to 10 mm hg during CO_2 insufflation.[8] Intraoperatively, we have monitored ECG, Heart Rate (HR), Mean Arterial Pressure (MAP), SPO_2 and $EtCO_2$. $EtCO_2$ value was maintained from 30-35. Inj. fentanyl 0.5 mg/ kg was given i.v. for any increase in HR or MAP of $\geq$ 20% from the baseline, and the total dose required was noted. Inj. atropine 0.02 mg/kgi.v. was given to treat bradycardia (20% below baseline HR) and fluid bolus and inj. mephentermine i.v. used to treat hypotension (20% below baseline MAP). We reversed the patient using neostigmine 0.05 mg/kg and atropine 0.02 mg/kg. Extubation was done after assessing the criteria. "Modified Objective Pain Score" (MOPS) [Table 1] was used for 24 hours postoperatively to assess pain.[9] Oral paracetamol syrup 10mg/kg was given as a rescue analgesic and for MOPS score $\geq$ 4. The time to first postoperative analgesic requirement and total dose given was also recorded.

Adverse effects like pruritus, nausea-vomiting, hypotension, bradycardia, sedation, respiratory depression and urinary retention were recorded and treated accordingly.

Statistical analysis

For continuous variables and for categorical variables the chi-square test was used for analysis. The parametric data were expressed as mean $\pm$ standard deviation. A P-value of <0.05 was considered statistically significant and a $P > 0.05$ was not considered statistically significant. We had used an unpaired 't' test for comparison between groups for parametric data.

SPSS 16 version software was used for all the statistical analyses.

Results

As shown in [Table 2], we have not found any significant difference between groups in terms of age, sex, weight, ASA status or duration of surgery. We have found that heart rate and MAP was significantly high at all-time intervals ($p<0.001$) as compared to baseline in both the groups. We found a significantly lower heart rate and MAP as compared to baseline in both the groups after 5 minutes of induction. We have found a maximum rise in HR and MAP at 90 min in Group I while at 10 min in Group II, and on comparison it was found that the rise in HR and MAP was more significant in Group I [Table 3 & 4]. Oxygen saturation (SPO_2) of both groups remained above 99% throughout the procedure and did not show a statistical significance between the groups ($P>0.05$). Similarly we have not found any significant difference in $EtCO_2$ ($P>0.05$). [Figure 1] shows that Intraoperative fentanyl requirement was significantly higher (15.54 ± 3.77 μg vs $0.74\pm1.91\mu$g, $P<0.001$) in Group I. In the postoperative period the rescue analgesic was required early (2.27 ± 0.50 hrs vs 7.13 ± 0.81 hrs, $P=0.0001$) and more (412 ± 32 mg vs 284 ± 27 mg, $P=0.0001$) in Group I as shown in [Figure 2]. We have also found a statistically significant difference between the two groups when compared the number of times fentanyl given intraoperatively (2.13 ± 0.43 vs 0.1 ± 0.31, $P<0.001$) and the number of times rescue analgesic

Table 1: Modified Objective Pain Score (MOPS). [9]

Criteria	Points		
	0	1	2
Crying	None	Consolable	Not consolable
Movement	None	Restless	Thrashing
Agitation	Asleep/Calm	Mild	Hysterical
Posture	Normal	Flexed	Holds injury site
Verbal	Asleep/no complain	Complain but cannot localize	Complain and can localize

Table 2: Demographic Profile of patients

SN	Variables	Group I (n=30)	Group II (n=30)	"p" value
1	Age (months) (Mean±SD)	35.63±17.14	36.17±17.52	0.904
2	Weight (in kg) (Mean±SD)	15.60±2.61	14.80±3.12	0.285
3	Gender (M: F)	17:13	16:14	0.931
4	ASA Grade (I: II)	25:5	24:6	0.739
5	Duration of surgery (Minutes)	73.68±5.51	75.32±4.32	0.203

Data are Mean±SD and Proportion. No significant difference is P> .05. SD- Standard Deviation.

Table 3: Comparison of Heart Rate within and in between the groups

SN	Parameter	Group I (n=30)			Group II (n=30)		"P" value
		Mean	SD		Mean	SD	
1.	At baseline	110.30	16.35		112.73	18.75	0.594
2.	5 min after induction	103.60	15.93		107.40	18.62	0.399
After CO_2 insufflation							
3.	5 min	119.87	16.81	119.53		19.15	0.943
4.	10 min	128.17	17.76	126.27		19.62	0.696
5.	15 min	123.20	17.99	122.73		19.63	0.924
6.	20 min	120.63	17.57	120.20		19.38	0.928
7.	25 min	121.73	18.53	118.80		19.19	0.549
8.	30 min	123.53	18.91	118.87		19.49	0.351
9.	45 min	127.20	19.93	119.20		19.92	0.125
10.	60 min	127.27	19.89	119.07		19.94	0.116
11.	75 min	125.87	18.94	118.60		20.32	0.157
12.	90 min	130.67	21.88	118.73		19.67	0.030
"p" Value (paired "t" test)		< 0.001		< 0.001			———

Data are Mean±SD. The significant difference was found in inter and intragroup analysis if P < .05. SD- Standard Deviation.

given in 24 hours postoperatively (3.77±0.32 vs 2.58±0.18, P=0.0001). As shown in table 5, no significant difference was found in terms of different complications between groups 1 and 2.

Discussion

The laparoscopic approach is always advantageous over an open procedure as it reduces surgical stress, fluid shift and post-operative complications. It fastens postoperative recovery, early ambulation, resuming normal diet with shortening of hospital stay. We also get superior postoperative management of pain.[1] This pain can be managed by a variety of

Table 4: Comparison of MAP within and in between the groups

SN	Parameter	Group I (n=30)			Group II (n=30)		"P" value
		Mean	SD		Mean	SD	
1.	At baseline	81.07	10.04		81.97	9.05	0.717
2.	5 min after induction	78.20	10.16		79.60	8.97	0.574
After CO_2 insufflation							
3.	5 min	85.87	10.38	85.33		9.16	0.834
4.	10 min	90.53	9.63	89.47		9.29	0.664
5.	15 min	87.80	9.72	87.40		9.04	0.869
6.	20 min	87.27	11.57	85.93		9.18	0.623
7.	25 min	88.13	11.74	84.97		9.11	0.248
8.	30 min	88.87	11.87	84.60		8.76	0.119
9.	45 min	92.53	12.44	85.47		8.88	0.014
10.	60 min	92.90	11.76	85.47		9.70	0.010
11.	75 min	93.13	13.15	85.60		9.59	0.014
12.	90 min	95.50	10.87	85.47		10.30	0.001
P-value		< 0.001		< 0.001			———

Data are Mean±SD. A significant difference was found in inter and intragroup analysis if P < .05. SD- Standard Deviation.

Table 5: Adverse effects/ Complications

SN	Variables	Group I (n=30)		Group II (n=30)		"P" value
		No.	%	No.	%	
1.	Nausea-vomiting	8	26.7	7	23.3	0.76
2.	Pruritus	4	13.3	6	20.0	0.48
3.	Sedation	0	0.0	1	3.3	0.31
4.	Urinary retention	2	6.7	1	3.3	0.54

No significant difference found if P>.05.

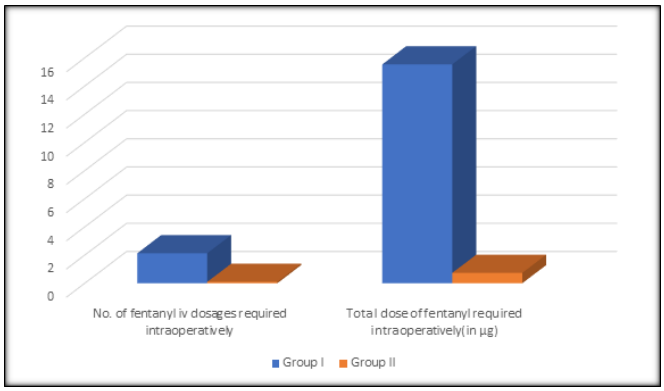

Figure 1: Comparison of intraoperative analgesic need

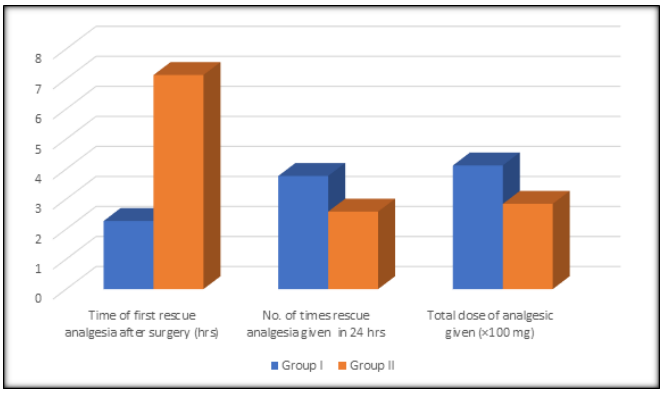

Figure 2: Comparison of post-operative analgesic need

methods such as instilling local anaesthetic with a laparoscope, use of bilateral rectus sheath block, caudal/epidural block with local anaesthetics, opioids and adjuncts or intravenous/intramuscular opioids and NSAIDS.[6] Caudal epidu-

ral block has been very effective in children for inguinal herniorrhaphy with laparoscopy. [10]

We have divided 60 paediatric patients into two groups. In Group I, ropivacaine was given epidurally and in group II ropivacaine was given with fentanyl by epidural route. We have found a reduced dose of intraoperative fentanyl and decreased postoperative analgesic requirements in group II. This is similar to a study done by Carr et al, [11] they found that in both groups having fentanyl or fentanyl with bupivacaine .125% by epidural route, MOPS was found 0. The pain was almost nil. They also complained of some motor weakness in the 2^{nd} group, which was not found in our study because we have used ropivacaine in place of bupivacaine. De Negri et al, [12] concluded in his study that with the addition of clonidine with ropivacaine by epidural route, stable hemodynamics with perfect analgesia and nominal side effects was found in our study with the addition of fentanyl. Kokinsky et al, [13] compared intravenous fentanyl to placebo for analgesic effect and PONV in paediatric boys during the first 24 hrs after daycare penile surgery with both groups administered ropivacaine in the caudal block immediately after surgery. In this study they found that iv fentanyl has a very insignificant effect on postoperative pain relief and is associated with PONV. In our study, we have seen less incidence of nausea and vomiting due to the use of inj ondansetron as premedication in both groups. Bai S et al, [14] also concluded the same results as we have found in our study.

Conclusion-

In this study, it is concluded that ropivacaine with fentanyl by epidural route in a single bolus dose can be used safely in paediatric laparoscopic supraumbilical surgeries with stable hemodynamic.

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