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INTRAVENOUS VERSUS EPIDURAL ANALGESIA WITH FENTANYL IN PAEDIATRIC LAPAROSCOPIC SURGERIES

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ABSTRACT

Laparoscopic surgery offers children and newborns a significant number of advantages, including a reduction in pain and cosmetic injury that facilitates early ambulation and a rapid return to normal activities. Although the surgery is of a minimally invasive nature, there are a number of specific physiological alterations occurring as a result of creating the pneumoperitoneum and the postural changes involved in optimizing patient position. Cardiovascular an hemodynamic changes associated with laparoscopic procedure is most significant in infant and child. A study was conucted in patients between 6 month to 6 years age group devided in two group, one group received intravenous fentanyl and other group received epidural fentanyl along with ropivacaine and intraoperative and postoperative hemodynamic stability was compared. It was concluded that epidural analgesia group was more hemodynamically stable and less requirement of rescue analgesia.

KEYWORDS : Laparoscopic, Fentanyl, Ropivacaine, Epidural, Modified Objective Pain Score (MOPS)

Laparoscopic surgery compared to conventional surgery has many advantages for the patient, including smaller incisions, lesser postoperative pain, earlier oral intake, quicker mobilization, faster discharge and a better cosmetic effect (Bannister et al., 2003, Holocomb et al., 1991). In recent years, there has been a considerable improvement in laparoscopic surgical techniques and equipments and this has led to an increasing number of diagnostic and surgical procedures being done laparoscopically not only in adults but also in paediatric patients.

In addition to the routine anaesthetic considerations for the individual patient, the choice of the anaesthetic technique in these patients should consider changes in haemodynamic and respiratory functions induced by the pneumoperitoneum and carbon dioxide (CO_2) insufflation (Bergesio et al., 1999).

Induction of general anaesthesia is known to induce clinically relevant changes in hemodynamic variables probably generated by direct laryngoscopy and endotracheal intubation. Tracheal intubation causes a reflex increase in sympathetic activity that may result in hypertension, tachycardia, and arrhythmia (Stoelting et al., 1978, Robert et al., 1971).

The overall cardiovascular changes associated with laparoscopic surgery depend upon the intra-abdominal pressure attained, the amount of CO_2 absorbed, the patient's intravascular volume status, the ventilatory technique, surgical conditions and the anaesthetic agents used (Davenport, 2003).

Patient positioning, hypercarbia, and the use of positive pressure ventilation can further compromise the cardiovascular function. The anaesthesiologist should also be aware of the fact that vagally mediated reflex bradycardia or even asystole can occur during insufflation, especially in infants and small children, (Tobias, 1998), and should be well prepared for any such event.

Fentanyl is used widely as an adjunct to general anaesthesia for attenuating hemodynamic responses to nociceptive stimuli induced by tracheal intubation and surgical procedures. Epidural administration of fentanyl can offer better attenuation of hemodynamic and hormonal responses to nociceptive stimuli during surgery than intravenous (IV) administration although one report found no significant differences in such benefits during surgery between epidural and IV administrations of fentanyl (Guinard and Carpenter, 1995).

Epidural analgesia has many beneficial effects in the pediatric patient population. In clinical practice, it is commonly used to augment general anaesthesia and to manage postoperative pain. A combination of local anesthetic with opioid provides good analgesic property in abdominal surgeries. Ropivacaine, a local anesthetic, has epidural analgesic potency same as bupivacaine but it has

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less of cardiac and motor involvement as compared to bupivacaine. Ropivacaine is indicated for local anaesthesia including infiltration, nerve block, epidural and intrathecal anaesthesia. It is also indicated for peripheral nerve block and caudal epidural in children 112 years for surgical pain. It is also sometimes used for infiltration anaesthesia for surgical pain in children.

On reviewing the literature, there has been no study on comparing intravenous and epidural analgesia in paediatric laparoscopic surgeries till date.

MATERIALS AND METHODS

A prospective randomized, double blind, carried out on admitted patients in paediatric surgery department of Gandhi Memorial & Associated Hospitals, K G medical university , Lucknow,(former CSSMU) undergoing various laparoscopic procedures under general anaesthesia (GA) after getting approval from Ethical Committee and obtaining a written consent from the patient relative.

For this purpose a total of 60 patients of either sex of age group between 06 month 06 yrs and ASA grade I&II were submitted. Patients having contraindication to neurexial block, known allergy to used medication central nervous system disorder were excluded from study.

A general physical and detailed clinical examination supported by routine blood, urine and biochemical test as per need was carried out. After taking the patient in the operating room, an intravenous line with 24G/22G cannula was secured and i.v. fluid (isolyte P) was started at standardized rate. All patients received inj. atropine 0.02mg/kg and inj. ondensetron 0.1mg/kg as premedication. None of the patients was given any sedative or analgesic premedication in the pre operative room.

All the monitors i.e. pulse oximeter, NIBP, ECG and precordial stethoscope were attached. The anaesthesia was induced with thiopentone sodium 5-7 mg/kg and endotracheal intubation was facilitated with succinylcholine 2.0 mg/kg. The endotracheal tube was secured after confirming bilateral equal breath sounds and end tidal CO_2 probe was attached. Anaesthesia was maintained with 50% N_2O in oxygen, isoflurane 0.2% and atracurium besylate as non-depolarising muscle relaxant.

The patients were devided into two group, one group received fentanyl 2 ug/kg intravenously as analgesia placed in group I and another group for analgesia received epidural bolus 1ml/kg ropivacaine 0.2% with fentanyl 1 ug/kg placed in group II. Epidural needle was placed in lateral decubitus position in T_{12} L_1 or L_1-L_2 interspace with pediatric epidural set 19 G 5cm Tuohy Needle with 21 G catheter under strict aseptic technique and loss of resistance was assessed with saline. A test dose of lignocaine with adrenaline (1:200,000) (0.1ml/kg) was given and after 10 min the epidural bolus was administered slowly. Surgical intervention was allowed after 10 min of epidural bolus in group II patients. Intraabdominal pressure upto 10mm Hg was maintained during CO_2 insufflation (Huettemann et al; 2003).

Intraoperatively, HR, MAP, SPO_2, Et CO_2 and ECG were monitored in all patients. Et CO_2 value (30-32 mmHg) was maintained by increasing minute volume. For increase in HR or MAP of ≥ 20% from the baseline, iv fentanyl 0.5 μg/kg was supplemented and total dose required was noted. Bradycardia (20% below baseline HR) was treated with i.v. atropine 0.02 mg/kg and hypotension (20% below baseline MAP) was treated with fluid bolus and i.v. mephentermine. After completion of the surgery, the patients were reversed with neostigmine 0.05 mg/kg and atropine 0.02 mg/kg and then patients were extubated.

Postoperatively, patients were assessed for pain using "Modified Objective Pain Score" (MOPS) (Martindale et al., 2004) for 24 hrs and for score ≥ 4, rescue analgesia in form of oral paracetamol syrup (10mg/kg) was given and time to first postoperative analgesic requirement and total dose given was recorded. Adverse effects like hypotension, bradycardia, sedation, pruritus, nausea, vomiting, respiratory depression, urinary retention were recorded and treated accordingly.

Continuous data is being summarized as Mean ± SD while discrete (categorical) in percentage. To compare the change in a parameter at two different time intervals paired "t" test was used. The discrete (categorical) variables were compared by chi-square (χ^2) test. Significance was determined at $p<0.05$. All statistical analysis was done using SPSS 16 Version. Continuous data is being summarized as

Modified Objective Pain Score (MOPS)

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 can not localize	Complain and can localize

Mean ± SD while discrete (categorical) in percentage. To compare the change in a parameter at two different time intervals paired "t" test was used. The discrete (categorical) variables were compared by chi-square (χ^2) test. Significance was determined at $p<0.05$. All statistical analysis was done using SPSS 16 Version.

RESULTS

60 patient of pediatric age group were studied and devided into two group. The demographic variables such as age, weight, sex and ASA grade were comparable and found statistically insignificant between two group.

Table 1 shows Mean age of patients in group I and II was 25.83±17.18 and 26.07±17.55. On comparing the data statistically, no significant intergroup difference was observed (p=0.959).

Table 1 also shows mean weight of patients in group I and II was 11.70±2.71 kg and 11.60±2.77 kg. On comparing the data statistically, no significant intergroup difference was observed (p=0.888).

Table 1, shows distribution of subjects according to their gender and on comparing data statistically no significant difference was observed (p=1).

Table 1 : Demographic Profile of Patients in Two Groups

S. N.	Variable	Group I (N=30)		Group II (N=30)		Significance of Difference	
		Mean	SD	Mean	SD	"t"	"p"
1.	Age (in months)	25.83	17.18	26.07	17.55	-0.052	0.959
2.	Weight (kg)	11.70	2.71	11.60	2.77	0.141	0.888
		No.	%	No.	%	χ^2	p
3.	Gender						
	Male	17	56.7	17	56.7		
	Female	13	43.3	13	43.3	0	1
4.	ASA Grade						
	I	25	83.3	24	80.0		
	II	5	16.7	6	20.0	0.111	0.739

Table 2 : Baseline Hemodynamic Parameters

	Parameter	Group I (n=30)		Group II (n=30)		Significance of Difference	
		Mean	SD	Mean	SD	"t"	"p"
1.	Heart rate (bpm)	110.30	16.35	112.73	18.75	-0.536	0.594
2.	Mean Arterial Pressure (mm Hg)	81.07	10.04	81.97	9.05	-0.365	0.717
3.	Oxygen Saturation (%)	99.40	0.68	99.47	16.35	0.982	0.330

Table 3 : Within Group Change in Heart Rate (as Compared to Baseline) at Different Intervals (Paired "t"-test)

SN	Parameter	Group I (n=30)				Group II (n=30)			
		Mean change	SD	"t"	"p"	Mean change	SD	"t"	"p"
1.	5 min after induction	-6.70	1.99	18.48	<0.001	-5.33	1.60	18.21	<0.001
After CO_2 insufflation									
2.	5 min	9.57	4.31	-12.15	<0.001	6.80	1.85	-20.18	<0.001
3.	10 min	17.87	5.11	-19.15	<0.001	13.53	2.49	-29.80	<0.001
4.	15 min	12.90	4.22	-16.74	<0.001	10.00	2.21	-24.75	<0.001
5.	20 min	10.33	5.01	-11.31	<0.001	7.47	2.08	-19.66	<0.001
6.	25 min	11.43	7.95	-7.88	<0.001	6.07	1.98	-16.77	<0.001
7.	30 min	13.23	7.77	-9.33	<0.001	6.13	2.79	-12.05	<0.001
8.	45 min	16.90	6.84	-13.52	<0.001	6.47	3.32	-10.67	<0.001
9.	60 min	16.97	7.09	-13.11	<0.001	6.33	3.76	-9.22	<0.001
10.	75 min	15.57	9.26	-9.21	<0.001	5.87	4.13	-7.79	<0.001
11.	90 min	20.37	9.27	-12.03	<0.001	6.00	3.80	-8.66	<0.001

Table 4 : Within Group Change in MAP (as Compared to Baseline) at Different Intervals (Paired "t"-test)

SN	Parameter	Group I (n=30)				Group II (n=30)			
		Mean change	SD	"t"	"p"	Mean change	SD	"t"	"p"
1.	5 min after induction	-2.87	1.11	14.20	<0.001	-2.37	0.85	15.25	<0.001
After CO_2 insufflation									
2.	5 min	4.80	2.12	-12.38	<0.001	3.37	1.00	-18.45	<0.001
3.	10 min	9.47	2.50	-20.73	<0.001	7.50	1.46	-28.21	<0.001
4.	15 min	6.73	2.72	-13.58	<0.001	5.43	1.74	-17.15	<0.001
5.	20 min	6.20	4.00	-8.48	<0.001	3.97	1.54	-14.09	<0.001
6.	25 min	7.07	5.04	-7.68	<0.001	3.00	1.55	-10.58	<0.001
7.	30 min	7.80	5.15	-8.30	<0.001	2.63	2.08	-6.95	<0.001
8.	45 min	11.47	5.99	-10.49	<0.001	3.50	2.42	-7.93	<0.001
9.	60 min	11.83	4.53	-14.29	<0.001	3.50	3.68	-5.20	<0.001
10.	75 min	12.07	6.59	-10.04	<0.001	3.63	3.86	-5.15	<0.001
11.	90 min	14.43	6.93	-11.40	<0.001	3.50	3.83	-5.00	<0.001

Table 1, shows the ASA grade of subjects in all groups and majority of subjects in all the groups were in ASA Grade I. On comparing the data statistically, no significant intergroup difference was observed (p=0.739).

Table 2 shows, comparison of hemodynamic and other vital parameters in different groups. At baseline all the groups were matched for MAP, heart rate and % oxygen saturation showing no statistically significant difference among groups (p>0.05).

Table 3 shows in both the groups, as compared to baseline a significant difference in heart rate was observed at all the perioperative intervals (p<0.001). At 5 min after induction both the groups had significantly lower heart rate as compared to baseline. However, at all subsequent intervals, heart rate was higher as compared to baseline. In Group I maximum change from baseline was observed at 90 min interval while in Group II, maximum change from baseline was observed at 10 min interval. By comparing it

Table 5 : Comparison of Analgesic Need Between Two Groups

S. N.	Parameter	Group I (n=30)		Group II (n=30)		Significance of difference	
		Mean	SD	Mean	SD	"t"	"p"
1.	No. of fentanyl iv dosages required intraoperatively	2.13	0.43	0.10	0.31	20.987	<0.001
2.	Total dose of fentanyl required intraoperatively	11.52	3.77	0.62	1.91	14.132	<0.001
3.	Time of first rescue analgesia after surgery (hrs)	2.27	0.58	7.30	2.20	12.115	<0.001
4.	No. of times rescue analgesia given in 24 hrs	3.77	0.57	2.60	0.68	7.244	<0.001
5.	Total dose of analgesic given	412.67	116.68	301.00	111.09	3.797	<0.001

Table 6 : Comparison of Adverse Effects/ Complications Between Two Groups

S. N.	Variable	Group I (n=30)		Group II (n=30)	
		No.	%	No.	%
1.	None	19	63.3	16	53.3
2.	Nausea	8	26.7	7	23.3
3.	Pruritus	1	3.3	6	20.0
4.	Sedation	0	0.0	1	3.3
5.	Urinary Retention	2	6.7	0	0.0
6.	Respiratory Depression	0	0.0	0	0.0
7.	Motor Weakness	0	0	0	0.0

χ^2=6.895 (df=4); p=0.142

was found that change was more significant in group I (maximum mean 20.37 compared to 13.53)

Table 4 shows in both the groups, as compared to baseline a significant change in MAP was observed at all the perioperative intervals (p<0.001). At 5min after induction both the groups had significantly lower MAP as compared to baseline. However, at all subsequent intervals, MAP was higher as compared to baseline. In Group I maximum change from baseline was observed at 90 min interval while in Group II, maximum change from baseline was observed at 10 min interval. By comparing it was found that change was more significant in group I(maximum mean 14.43 compared to 7.50)

Table 5 shows Intraoperative fentanyl requirement was significantly higher as well as postoperative rescue analgesic was required early and more in Group I.

Table 6 shows Majority of patients in both the groups did not have any complication. Statistically, there was no significant difference with respect to any complication encountered.

DISCUSSION

A laparoscopic approach offers several advantages over an open procedures; potentially reduces the surgical stress and fluid shifts that may accompany it; in addition there is less need for postoperative analgesia, reduction of postoperative respiratory and wound complications; shortens postoperative convalescence, including an intensive care unit stay; rapid return to normal diet and decreased overall hospital stay.

Perioperative analgesia is best provided with a multimodal approach using a combination of local infiltration of the trocar insertion site, opioids and nonsteroidal anti-inflammatory drugs. Caudal epidural block has been demonstrated to be effective following inguinal herniorrhaphy with laparoscopy in children (Tobias et al., 1994).

Epidural local anaesthetic drugs administered alone has never become widely used for routine postoperative analgesia because of the significant failure rate resulting from regression of the sensory block and the unacceptable incidence of motor blockade and hypotension. The use of epidural analgesia for pain relief is revolutionized by the use of epidural opioids after the discovery of opioid receptors in the dorsal horn of the spinal cord. Opioids have both presynaptic and postsynaptic effects in the dorsal horn and affect the modulation of nociceptive input but do not cause motor or sympathetic blockade.

Carr et al. (1998) compared epidural infusions of fentanyl (2μg/ml) alone or combined with bupivacaine 0.125% for perioperative analgesia, motor block and other side-effects in children who underwent urological surgery in 42 children, ASA I-II, 1-16 yr.Both infusion regimens provided excellent analgesia (median objective pain scores=0). Three children in the F group and all children in the F-B group developed lower limb weakness ($P < 0.05$).

In contrast to author's study, we compared intravenous fentanyl with epidural fentanyl ropivacaine bolus (single dose) in paediatric patients undergoing laparoscopic surgeries and found less requirement of postoperative analgesics in epidural group. In above mentioned study, lower limb weakness was reported with use of bupivacaine (0.125%) infusion but since we used ropivacaine (0.2%) bolus, no postoperative motor weakness was observed.

Wolf et al., 1998 studied various measures to modify infant stress in twenty-six infants who underwent major abdominal or thoracic surgery under general anaesthesia and showed that Spinal analgesia followed by epidural analgesia might result in more complete control of cardiovascular or stress responses than the using only epidural analgesia or only intravenous fentanyl group.

Similarly, in our study opioid analgesia with intravenous fentanyl provided less hemodynamic stability as compared to epidural fentanyl ropivacaine bolus.

De Negri et al. (2001) studied in 55 pediatric patients(1-4 yr old) who were randomly given a postoperative epidural infusion of plain ropivacaine 0.1% or ropivacaine 0.08% with varying doses of clonidine. Analgesia was improved without any signs of increased sedation or other side effects with addition of clonidine.

In place of clonidine we have used single dose of fentanyl with ropivacaine (0.2%) bolus preoperatively and this combination provided stable hemodynamics intraoperatively, improvement in postoperative pain and no clinically significant side effects…

Kokinsky et al., 2003 compared the analgesic effect and PONV of intravenous fentanyl to placebo in pediatric boys during the first 24 hrs after day care penile surgery. Both group were administred caudal block with ropivacaine immediately afer surgery. The median time to first administration of analgesics after the caudal block was approximately 6 h. Intraoperative use of i.v. fentanyl 1μg/kg combined with a regional anaesthetic block is associated with an increased incidence of PONV without any significant contribution to the postoperative pain relief.

Similar with author's study, the median time to first administration of analgesics postoperatively in group of epidural fentanyl ropivacaine was approximately 6 h. But, unlike in above study there was less incidence of nausea vomiting in either group of our study. This may be attributed to the use of inj. Ondensetron in premedication.

Bai et al., 2004 also practiced same concept by using epidural lidocaine and fentanyl in two group accompanied with general anaesthesia in pediatric patient undergoing lower extremity surgery Compared to IV fentanyl group, epidural lidocaine group had significantly lower Objective Pain Score (OPSs) at 6 hours after arrival. Epidural lidocaine group had significantly lower Parent Visual Analog Scale (PVAS) immediately, 6 hrs and 24 hours after arrival. There was no significant difference in the incidence of postoperative nausea and vomiting.

Similar to above study, we used MOPS pain score postoperatively and found that MOPS score remained lower in epidural ropivacaine-fentanyl group than in iv fentanyl group till average 6 hr postoperatively and also there was no significant difference in incidences of postoperative nausea -vomiting between the groups.

On reviewing the literature till date, we did not find any study comparing the different analgesic regimens either intravenous opioids or use of epidural analgesia in pediatric patients undergoing laparoscopic surgeries. The results of above mentioned study was a base to conduct the present study.

CONCLUSION

It was concluded from our study after discussion that epidural ropivacaine fentanyl bolus with general anaesthesia is effective and safe in paediatric laparoscopic surgeries. It provides stable intraoperative hemodynamics without residual motor weakness in the postoperative period as well reduced need for postoperative analgesics.

There are certain limitataion of our study like relatively small sample size in our study, and age related physiological and pharmacological differences were not considered separately. So it is recommended that further case control study can be conducted regarding establishing role of epidural analgesia with different dose, concentration in different pediatric age group.

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