Section: Anaesthesia

Original Research Article

CLINICAL STUDY OF INJECTION FENTANYL AS AN ADJUVANT TO INJECTION ROPIVACAINE IN CAUDAL EPIDURAL FOR POST-OPERATIVE PAIN RELIEF IN PAEDIATRIC INFRA- UMBILICAL SURGERIES

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Abstract

Background: Among the various techniques of regional analgesia, caudal-epidural analgesia is one of the most popular one, providing both intra- and post-operative analgesia in paediatric age group. Fentanyl has been widely used as analgesic adjuvant to epidural analgesia and it acts on substantia gelatinosa on the dorsal horn of spinal cord by blocking fibers carrying nociceptive impulses both pre- and post-synaptically. The study was conducted to see the efficacy of Fentanyl used as an adjuvant to Ropivacaine in Caudal epidural anaesthesia to provide postoperative analgesia in pediatric patients undergoing infra-umbilical surgeries. **Materials and Methods:** Present observational study was conducted in 40 patients at LG hospital, Maninagar, Ahmedabad for the duration of 2 years. Total 40 patients (ASA I-II) aged 2- 8 years of either sex undergoing elective infra umbilical surgeries included in this study. Patients received injection Ropivacaine 0.2% 1ml/kg with injection Fentanyl 1mcg/kg. All patients were observed for following parameters: Duration of post-operative analgesia, Peri operative vitals and Adverse effects. **Result:** Majority of surgeries were herniotomy (40%), circumcision (22.5%), orchidopexy (7.5%). Patients remained hemodynamically stable throughout the surgery and post-operative period. Mean duration of analgesia of patients was 14.937±2.81. There were no significant complications noted in post-operative period. **Conclusion:** Ropivacaine and Fentanyl in caudal anaesthesia appears to provides prolonged and more intense post-operative analgesia in children undergoing infra umbilical surgeries without any hemodynamic instability and any significant side effects.

INTRODUCTION

Pain is defined by the international association for study of pain as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage". Postoperative pain management in children has been a challenging issue since long past owing to various obstacles and misbelieves. However, this concept is gradually gaining importance as it has become clear with time that children not only feel pain of same intensity as adults but also, pain is associated with serious consequences, including harmful neuroendocrine responses, disrupted eating and sleep cycle and increased pain perception in subsequent painful experiences. In addition, the invention of different pain scales has improved pain assessment in paediatric patients and thereby, aiding in better paediatric pain management. The most preferred paediatric regional anaesthesia techniques for infra umbilical surgeries are caudal and lumbar epidural blocks and ilioinguinal, iliohypogastric, and penile

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nerve blocks.[1-3] When compared with adults, lower concentrations of local anaesthetics are sufficient in children; have a rapid onset but the duration is usually less.1 The search for the ideal adjuvant and a local anaesthetic with a wide margin of safety, limited motor blockade, and prolonged period of analgesia continues till date.[2-4] Caudal analgesia is a good, reliable and easy method to provide intra operative and postoperative analgesia in the infra umbilical surgery in paediatrics. But the single shot caudal analgesia is short in duration so the use of catheter injection may be used to prolong the analgesia time but it is technically challenging associated with infection.[5,6] Among the various techniques of regional analgesia, caudal-epidural analgesia is one of the most popular one, providing both intra- and post-operative analgesia in paediatric age group. Earlier racemic Bupivacaine was routinely used for caudal block, to minimize the risk of unwanted motor blockade; anesthesiologist is favoring one of the two new long-acting single enantiomeric local anaesthesia drugs, Ropivacaine or Levobupivacaine.[7,8]Ropivacaine is less lipophilic; hence, it is less likely to penetrate large myelinated motor fibers, resulting in a relatively reduced motor blockade and longer postoperative analgesia and has a greater degree of motor sensory differentiation, which could be useful when motor blockade is not desired.[5]Ropivacaine, the S(−) enantiomer of Bupivacaine analogue, is known to have lesser cardiotoxicity and less motor blockade with similar pain relief at equivalent analgesic dose. The main reason for increasing popularity of choosing Ropivacaine, as having a lesser motor blocking potency with similar analgesic effect is that it selectively blocks nerve fibers involved in pain transmission (A-delta and C fibers) to a greater degree than those controlling motor function (A-beta fibers). Many additives were used in combination with local anesthetics in caudal block to prolong the postoperative analgesia.[6] Fentanyl has been widely used as analgesic adjuvant to epidural analgesia and it acts on substantia gelatinosa on the dorsal horn of spinal cord by blocking fibers carrying nociceptive impulses both pre- and post-synaptically. But it has undesirable side effects as respiratory depression, itching and vomiting.[1,8] The addition of an adjuvant, like Fentanyl prolongs and intensifies the sensory blockade produced by local anaesthetics with reduction in dose of the latter, thereby reducing the adverse effects.The study was conducted to see the efficacy of Fentanyl used as an adjuvant to Ropivacaine in Caudal epidural anaesthesia to provide postoperative analgesia in pediatric patients undergoing infra-umbilical surgeries.

MATERIALS AND METHODS

Study Design – Observational prospective study
Study time- June 2019- June 2021
Study area- LG hospital, Maninagar,Ahmedabad.
Sampling size - Study included total 40 patients.
All Patients receiving Ropivacaine 0.25% 1 ml/kg with Fentanyl in a Dose of 1mcg/kg.Ethical approval was taken from the institutional ethical committee and written informed consent was taken from all the participants.

Inclusion Criteria

- 40 Patients aged between 2 to 8 years
- Either sex
- Having ASA grade I and II
- Weight 10 -25 kg
- Infra umbilical Planned surgeries

Exclusion Criteria

- History of mental retardation or delayed development that may interfere with pain intensity assessment.
- Known or suspected coagulopathy
- Patients with known hypersensitivity to the study drugs.
- Congenital anomalies of sacrum
- Infection at site of block.
- Parents refusal
- ASA grade III, IV and V

All patients underwent thorough pre- anaesthetic check-up including history taking and examination. Routine investigations like Haemoglobin, blood sugar, serum creatinine and X ray chest were done. All patients were kept nil by mouth for at least 4 hours before surgery.In operation theatre, routine monitors like SpO2, ECG and NIBP were attached.
After securing i.v. Access, i.v. Fluid was started. Premedication was given with inj. Glycopyrrolate 0.004 mg/kg, inj. Ondansetron 0.08mg/kg and inj. Midazolam 0.05 mg/kg. Patient was preoxygenated with 100% O2. Patient was induced with inj. Propofol 2mg/kg iv and appropriate sized I-Gel was inserted. Proper position of I-Gel was confirmed with bilateral symmetrical chest expansion and equal air entry. Anaesthesia was maintained with O 2 and Sevoflurane to maintain vitals within 20% of baseline. The child was put in left lateral position and under aseptic precautions the sacral hiatus was identified. Caudal epidural space was identified by using loss of resistance technique. With 23 G hypodermic needle, Injection Ropivacaine 0.2 % 1 ml/kg with Injection Fentanyl 1 mcg /kg drug was deposited after confirming negative aspiration for blood and CSF. Child was turned supine immediately after the injection.
Surgeon was allowed to start the surgery and patient was observed for

- Perioperative vitals
- After the end of surgery, I-Gel was removed in deeper plane of anaesthesia.

After emergence from anaesthesia, effect of caudal block was assessed by
FLACC score

- Duration of post-operative analgesia was assessed by FLACC score.

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- Patient was given rescue analgesia when FLACC score >4 in the form of oral syrup Paracetamol 15mg/kg body weight and this was considered as duration of postoperative analgesia.
- Patients were monitored for complication like post-operative nausea, vomiting, respiratory depression, urinary retention.

Statistical Analysis

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables.

RESULTS

Table 1: Demographic Data

Variable	Mean±SD (n=40)
Gender Male Female	36(90%) 04(10%)
Age(years)	4.40±1.91
Weight(kg)	16.725±5.237
Duration of surgery(min)	57.75±11.76

In our study,27 (67.5%) patients were 2-5 years of age and 13(32.5%) patients were 6-8 years of age The above table showed that mean age of patients was 4.400±1.91, mean weight was 16.725±5.237 and mean duration of surgery was 57.75±11.76.

Table 2: Distribution of Surgery

Surgery	Frequency	Percent
B/L Herniotomy	1	2.5%
B/L Orchidopexy	2	5.0%
Circumcision	9	22.5%
Femur-Ender'snailing	1	2.5%
Herniotomy	16	40.0%
Herniotomy + circumcision	2	5.0%
Herniotomy + eversion of sac	2	5.0%
Herniotomy + excision of lipoma of cord	1	2.5%
Orchidopexy	3	7.5%
Sinus tract exploration + biopsy	1	2.5%
Urethroplasty	2	5.0%
Total	40	100.0%

There were 40 {40%} farmers, 16{16%} construction workers, 24 labourers, 10 {10%} were coolies. Remaining twenty percent patients were doing sedentary jobs like being housewife, students and office work. This clearly indicates that individuals involved in hard physical work are more prone to get varicose vein disease and its complicationsThe above table showed that majority of surgeries were herniotomy (40%), circumcision (22.5%), orchidopexy(7.5%).

Table 3: Distribution of mean Pulse (per min)

Time	Mean±SD (n=40)
0min	111.2000±12.041
5min	115.200±12.015
10min	117.350±11.479
15min	117.800±11.184
20min	113.25±11.155
30min	110.50±10.570
40min	107.875±10.253
60min	107.95±10.342
90min	111.250±9.189
2hr	110.250±7.74
3hr	110.050±7.558
4hr	109.50±7.53
5hr	108.45±7.009
6hr	109.150±6.25
9hr	108.45±6.33
12hr	110.575±7.10
18hr	109.30±6.99
24hr	109.10±7.39

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The above table showed that after 20minutes of caudal block pulse rate starts to return normal to baseline or below and remain within 20% of baseline throughout rest of the intra operative and post-operative period

Table 4: Distribution of mean MBP (mmHg)

Time	Mean±SD (n=40)
0min	78.3750±3.52
5min	77.6750±5.27
10min	77.4750±4.24
15min	77.3750±4.45
20min	77.90±4.211
30min	77.2250±3.59
40min	78.050±3.999
60min	77.550±4.06
90min	77.2250±4.41
2hr	76.550±3.94
3hr	77.2750±4.69
4hr	76.6250±3.998
5hr	76.7750±3.83
6hr	77.9750±4.34
9hr	78.3250±3.65
12hr	79.3500±3.44
18hr	79.8750±4.398
24hr	79.9500±3.86

The above table showed that MBP remain within 20% of baseline throughout intra operative and post-operative period.

Table 5: Distribution of mean FLACC Score

Time	Mean±SD (n=40)
15min	0.8750±0.722
30min	1.025±0.53
1hr	1.25±0.49
2hrs	1.625±0.49
3hrs	1.90±0.44
4hrs	2.175±0.500
5hrs	2.425±0.500
6hrs	2.70±0.46
9hrs	2.850±0.36
12hrs	3.10±0.30
18hrs	3.95±0.45
24hrs	3.625±0.63

The above table shows, FLACC score (mean ± SD) during postoperative period. FLACC Score was analyzed at various interval of time at 15 min, 30 min, 1 hr, 2 hr, 3 hr, 4 hr, 5 hr, 6 hr, 9 hr, 12 hr, 18 hr, 24 hr post operatively. The FLACC Score of less than 4 was assumed as effective analgesia and score 4 or more was assumed as pain. In this study, the mean FLACC Score reached 4 or more than 4 at 15 hrs.

Table 6: Distribution of mean Duration 0f analgesia (hr)

	Mean±SD (n=40)
Duration 0f analgesia (hr)	14.937±2.81

In above table showed that the mean Duration 0f analgesia (hr) (mean±s.d.) of patients was 14.9375± 2.8198.

Table 7: Distribution of complication

Complication	Frequency
Nausea & vomiting	3
Respiratory depression	0
Urinary retention	0

Previous DVT	Number of patients	Percentage
No	97	97%
Yes	3	3%
Total	100	100%

In our study, 3 patients (7.5%) patients had nausea and vomiting.

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DISCUSSION

Caudal epidural blockade is one of the most popular regional block used in paediatric anaesthesia. This reliable and safe technique is used widely for many surgical procedures in combination with general anaesthesia. It allows rapid recovery from anaesthesia with effective post-operative analgesia. Kawaraguchi Y et al.[5](2006) in their study showed that Ropivacaine is less cardio toxic and there is a greater separation of sensory and motor effects than with Bupivacaine. ThereforeRopivacaine is increasingly used for caudal block in children. Fentanyl is synthetic, highly selective opioid agonist that works mainly at mu- opioid receptor with some activity at delta and kappa receptor and it prolongs and intensifies the sensory blockage produced by local anesthetic with reduction in dose of the letter, thereby reducing the adverse effects Sengupta S et al.[9](2015).Total 40 pediatric patients with physical status ASA I-II aged 2-8 years undergoing infra umbilical surgeries were selected for studies. This study was planned to observe the effect of Fentanyl (1mcg/kg) and 0.2%Ropivacaine for caudal epidural block in pediatrics patients undergoing infra umbilical surgeries. All patients induced with injection Propofol and maintained with O2 and Sevoflurane to maintain vitals within 20% of baselines and then caudal blocks was given. HR, MBP, SPO2 were recorded intra operatively and postoperatively for 24 hrs. Postoperative analgesia was assessed by FLACC score for 24 hrs post-operatively and if FLACC ≥ 4, First rescue analgesia was given with Paracetamol syrup 15 mg/kg. Duration of analgesia was defined as Time of drug injection in caudal space to FLACC ≥4 or time of first rescue analgesia. Postoperatively all the patients were monitored for any complications like Nausea, Vomiting, Respiratory depression.In the present study, mean age was 4.400+1.91, mean weight (kg) was 16.725+5.23 and mean duration of surgery (min) was 57.75+11.7642. 90% patients were males in the study. This could be due to the fact that common pediatric infra umbilical surgeries like herniotomy, orchidopexy are male specific surgeries or more common in males. Cook et al studied the effect of Adrenaline, ketamine and clonidine on duration of caudal analgesia in paediatric patients in age group of 1-10 years, undergoing only orchidopexy, hence all the cases were male(100%)In the present study, heart rate, mean blood pressure and spo2 of all the patients were monitored intra-operative and post – operatively up to 24 hrs. Hemodynamic data in the study might be influenced by the pre-medication with Glycopyrrolate, intraoperative use of inhalational agent and postoperative arousal reactions that might have changed the extent of the hemodynamic responses. Intraoperatively there was no fall in saturation. Post operatively SpO2 was above 98% in all patients in room air none of them required oxygen supplementation. And hence there was no incidence of respiratory depression. Gupta at el.[3] in 2014 compared Ropivacaine alone and Ropivacaine with Fentanyl in subumbilical surgeries and concluded that there was no significant hemodynamic instability observed in either group throughout the study period. Saini S et al.[8] (2016)compare caudal Ropivacaine with Clonidine and Fentanyl for paediatric post operative analgesia in children posted for infra umbilical surgeries and found that there was no significant differences in hemodynamic parameters between two group.The FLACC score of less than 4 was assumed as effective analgesia and score 4 or more was assumed as pain, so rescue analgesia was given to maintain score below 4. At the 18th hr postoperatively, the mean FLACC score was 3.95±0.45. Gupta et al3 in 2014 conducted a study to compare Fentanyl with Ropivacaine and Ropivacaine alone for caudal analgesia in pediatric patients and observed that pain score (FLACC score) was >4 at 16hrs in Ropivacaine group and it was >4 at 36hrs in Ropivacaine fentanyl group.In present study, duration of analgesia was defined as Time of drug injection in caudal space to FLACC ≥4. Mean Duration of analgesia (hr) of patients was 14.9375± 2.8198. Shukla et al.[7] in 2016 compared caudal Fentanyl and Clonidine as an additive to Ropivacaine in infra-umbilical abdominal surgeries and observed that addition of Fentanyl to Ropivacaine provides prolonged postoperative analgesia in children. In the study of caudal epidural block by Tejendra Kaur et al observed that only 3 patients out of 25 patients who received Ropivacaine along with Fentanyl in caudal epidural block.Khatvakar et al10 in 2014 compared Fentanyl with Ropivacaine and Ropivacaine alone for caudal epidural block in paediatric patients and reported that 1 patient in Ropivacaine group and 4 patients in Ropivacaine Fentanyl group had vomiting. No patient developed respiratory depression, bradycardia and hypotension. In our study 3 children had nausea and vomiting which was treated with injection Ondansetron 0.1 mg/kg. No other side effects like respiratory depression and urinary retention was observed in any child.The limitation of our study is that type of surgical procedure is varied in the study. The intensity of post-operative pain may vary depending on the type of surgical procedure. Moreover, the study population was aged from 2-8 years, age may affect on the behaviour and response to pain.

CONCLUSION

Ropivacaine and Fentanyl in caudal anaesthesia appears to provides prolonged and more intense post operative analgesia in children undergoing infra umbilical surgeries without any hemodynamic instability and any significant side effects. Due to limitations like small sample size, further more

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studies and RCT required to observe the effect of Ropivacaine and Fentanyl in caudal epidural block in paediatric patients.

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