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Original Research Paper

Postoperative analgesia in pediatric inguinal surgeries: comparison of caudal block, wound infiltration, and paracetamol suppositories

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ABSTRACT:
Background: In pediatrics, acute postoperative pain is commonly treated with simple analgesics that often are not very effective and frequently are used at doses lower than would be optimal. Effective pain therapies to block or modify the physiologic responses to pain and stress have become an essential component of modern pediatric anesthesia and surgical practice. **Aim of study**: to compare the analgesic efficacy and to evaluate complications of caudal block, local infiltration, with paracetamol suppository in children undergoing inguinal surgeries. **Patients and Methods**: A prospective, randomized, controlled study of 120 children with one of the inguinal surgical conditions (inguinal hernia, hydrocele, or undescended testis) scheduled for elective surgical repair over a period of 13 months from January 2017 to February 2018 in Baghdad. Preoperatively the patients were randomized in to three groups according to the operation waiting lists. Group 1; caudal block with bupivacaine, group 2; local infiltration with bupivacaine. group 3; paracetamol suppository. For all the patients included in this study, a standardized anesthetic protocol was used. **Results**: A total of 120 patients were divided into three groups according to the type of analgesia received, Group 1 were (38 patients 31.7%), Group 2 were (42 patients 35%), and Group 3 were (40 patients 33.3%), the mean age was (3.6years), mean time of anesthesia was (36.5min) and the mean time of surgery was (28.7min), no major complication was reported. Pain score was low in the first two groups in the 1% and 2™ hours postoperatively compared to the 3™ group. Time for walking was significantly delayed in patients receiving caudal block. **Conclusion**: Caudal block and Local wound infiltration, for postoperative pain management are highly effective and safe for surgical procedures in the inguinoscrotal region.

Keywords: local infiltration, paracetamol suppository, caudal block, inguinal surgeries

INTRODUCTION:

The inguinoscrotal region is the most common site for surgical conditions in childhood" A Certain patient populations are at risk of inadequate pain control and require special attention, including pediatric patients, geriatric patients, and patients with difficulty in communication. Children suffer from postoperative pain at least to the same extent as their adult counterparts, yet they often receive less analgesia (1). Pain may trigger biochemical and physiologic stress responses and leads to impairments in pulmonary, cardiovascular, neuroendocrinal, gastrointestinal, immunological, and metabolic function even in children and newborns (2). Optimal postoperative pain relief minimizes the metabolic rate for oxygen, reduces cardiorespiratory demands, promotes early ambulation, and speeds recovery. In addition, postoperative emotional disturbance is reduced if pain is well controlled (3). In pediatrics, acute postoperative pain is commonly treated with simple analgesics that often are not very effective and frequently are used at doses lower than would be optimal. Effective pain therapies to block or modify the physiologic responses to pain and stress have become an essential component of modern pediatric anesthesia and surgical practice. Pain is a complex interaction that involves sensory, emotional and behavioral factors, and so its definition and treatment must include all of these aspects (4).

AIM OF THE STUDY:

to compare the analgesic efficacy and to evaluate complications of caudal block, local infiltration, with paracetamol suppository in children undergoing inguinal surgeries.

PATIENTS AND METHOD:

A prospective, randomized, controlled study of 120 children with (inguinal hernia, hydrocele, or undescended testis) scheduled for elective day case unilateral inguinal surgery over a period of thirteen months from January 2017 to February 2018 in Baghdad. The study was performed after obtaining a written informed consent from the participants parents. Age, weight, gender, type of surgery, anesthesia and surgery periods, severity of pain, and complications for the patients were recorded in a special data form.

Exclusion criteria were:

Refusal by parent, cutaneous infections, anatomical malformation at the puncture site, hypersensitivity to local anesthetics or paracetamol, history of seizures, neurological or neuromuscular disorders, age <l year. For all the patients included in this study, a standardized anesthetic protocol was used, induction with Ketamine (1-1.5mg/kg), Propofol (1.5-2mg/kg), and maintenance with Halothane (2-2.5%) in O_2. Preoperatively the patients were randomized in to three groups according to the operation waiting lists .group 1 included patients who received single -shot caudal block with bupivacaine preoperatively after induction of anesthesia by the anesthetist, group 2 included patients who received local infiltration with bupivacaine, group 3 included patients who received paracetamol suppository.

Protocol for pain management: -

For group 1:-

The child placed in the lateral decubitus position and after identifying the sacral cornua and hiatus 23G needle is inserted into the sacral epidural space and by loss of resistance technique with saline ,children received bupivacaine 0.25% (1ml/kg).

For group 2:-

The surgeon infiltrate the wound at the end of surgery with bupivacaine 0.25% in a dose (1.25mg/kg=0.25ml/kg) using 23G needle subcutaneously.

For group 3:-

Paracetamol suppository was given to the patients in a dose (15-20mg/kg) after induction of anesthesia (adol® 125,250mg/Julfar).

The pain was measured by using FLACC scale at 30 minutes after discharge from the theater and then every hour during the next 3 hours of postoperative period by senior house officer. The FLACC scale is scored in a range of 0-10, with 0 representing no pain Relaxed and comfortable ,1-3 mild discomfort ,4-6 moderate pain ,7-10 severe discomfort or pain. All the patients were observed in the surgical ward for development of any adverse effects or complications.

The patient considered for home discharge when: conscious., hemodynamically stable, tolerating oral intake, Absence of vomiting and other side effect. 24 hours after surgery, reports on delayed side-effects and demands for rescue paracetamol suppository and time of first urination and walking were gathered.

Statistical Analysis:

Data were first entered in an excel file, transported later into statistical SPSS —software (package for social sciences file version 24) (SPSS v24) for data analysis. Continuous variables presented as means and discrete variables presented as numbers and percentages. Chi-square test for independence used to test the significance of association between discrete variables. ANOVA test used to test the significance of difference in means between independent samples. Level of significance was set at P value equal or less than 0.05.

Data Collecting Form

Central child's teaching hospital

Pediatric surgery center

Name: *Age:* *Gender:* *wt:*

Record No.: *Mob No.:*

Type of Surgery:-

Inguinal hernia ☐ *Hydrocele* ☐ *Undescended testis* ☐

Duration of anesthesia ( )min *Duration of surgery :( )min*

Pain free for the 1st 3hrs ☐

Time to the 1st analgesic administration :

No. of paracetamol supp. demand in 24hrs :

Time to 1st walking :

Time to 1st micturation:

(FLACC scale)

	Score 0	Score 1	Score 2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
½h	1h	2h	3h
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
½h	1h	2h	3h
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
½h	1h	2h	3h
Cry	No cry (awake or asleep)	Moans, or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
½h	1h	2h	3h
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to, distractible	Difficult to console or comfort
½h	1h	2h	3h
½h Score:	1h Score:	2h Score:	3h Score:

Complications:- *vomiting* ☐ *agitation* ☐ *urinary retention* ☐

Others:-

RESULTS:

A total of 124 patients were enrolled in this study and four patients from caudal group were excluded because of failure of caudal block (passive reflux of blood), so data from 120 patients were analyzed . number of patients in caudal group were (38 patients 31.7%), number of patients in infiltration group were (42 patients 35%), and number of patients in suppository group were (40 patients 33.3%) figure.12.

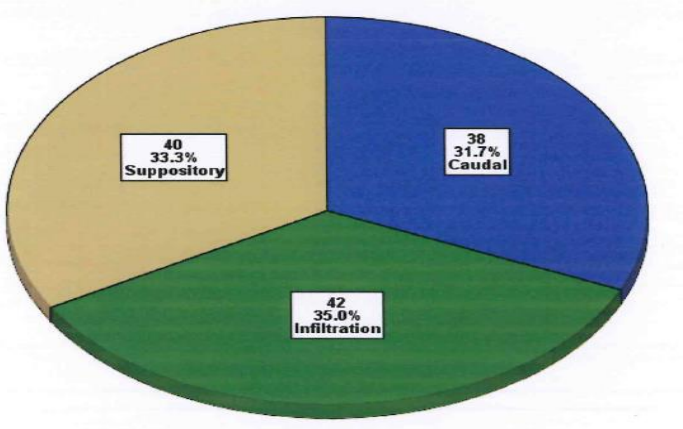

Figure. 1 Distribution of sampled patients according to type of given analgesia.

Minimum age in this study was (1.5year) while the maximum age was (7years) ,also the minimum weight was (8.5 kg) and the maximum weight was (29 kg).(table.1). in respect to age and weight there were no significant variation in mean age and weight between analgesia groups (p >0.05).

Table. 1: Distribution of age and weight according to groups .

Variables	group	N	Min	Max	Mean	SD
	• Caudal	38	1.6	7.0	3.9	1.7
Age (y)	• Infiltration	42	1.5	7.0	3.6	1.6
P=0.103	• Suppository	40	1.6	7.0	3.2	1.5
	Total	***120***	***1.5***	***7.0***	***3.6***	***1.6***
	• Caudal	38	8.5	27.0	15.1	4.8
Weight (Kg)	• Infiltration	42	8.5	20.0	15.0	3.3
P=0.940	• Suppository	40	10.0	29.0	14.8	5.4
	Total	***120***	***8.5***	***29.0***	***14.9***	***4.5***

In this study there were 98 male (81.7%) and 22 female (18.3) patients in all analgesic groups, male to female ratio was 4.5:1 . Regarding type of surgery the total number of patients with inguinal hernia were 70 (58.3%), total number of patients with hydrocele were 14 (11.7%), and total number of patients with undescended testis were 36 (30%) in all analgesia groups . so the majority of patients in this study were male sex and patients with inguinal hernia (table.2) . There was no significant association between type of analgesia and any of patient gender or type of surgery (p >0.05).

Table.2: Distribution of sex, type of surgery among groups.

	Analgesia Group								
	Caudal		Infiltration		Suppository		Total		P
Variables	N	%	N	%	N	%	N	%	value
Gender									0.305
• Male	28	73.7%	36	85.7%	34	85.0%	98	81.7%	
• Female	10	26.3%	6	14.3%	6	15.0%	22	18.3%	
Type of Surgery									0.239
• Inguinal Hernia	22	57.9%	20	47.6%	28	70.0%	70	58.3%	
• Hydrocele	6	15.8%	6	14.3%	2	5.0%	14	11.7%	
• Undescended Testis	10	26.3%	16	38.1%	10	25.0%	36	30.0%	

The minimum time for anesthesia was (20minutes) while the maximum time was (60 minutes) and the mean was (36.5 minutes). Regarding the operative time the minimum time was (15 minutes) while the maximum time was (50 minutes) and the mean was (28.7 minutes) (table.3). There was no significant variation in mean time of anesthesia and surgery between analgesia groups (p>0.05).

Table.3: Distribution of patient regarding duration of anesthesia and surgery in allocated groups.

Variables	Category	N	Min	Max	Mean	SD
	• Caudal	38	25.0	60.0	38.5	11.0
Duration of Anesthesia (min)	• Infiltration	42	25.0	60.0	35.2	9.2
P=0.318	• Suppository	40	20.0	60.0	36.0	9.9
	Total	***120***	***20.0***	***60.0***	***36.5***	***10.0***
	• Caudal	38	15.0	50.0	28.1	11.1
Duration of Surgery (min)	• Infiltration	42	20.0	50.0	28.6	7.7
P=0.792	• Suppository	40	15.0	50.0	29.5	8.6
	Total	***120***	***15.0***	***50.0***	***28.7***	***9.1***

Regarding patients with pain free in the first 3hours postoperatively (FLACC scale was zero) there were 12 patients out of 38 in caudal group,4 patients out of 42 in infiltrative group and 4 patients out of 40 in suppository group . There was significant variation between analgesic groups (p< 0.05). Those Patients needed another dose of analgesia after

discharge and up to (24 hours) were recorded and analyzed the results were (14 patients) (36.8%) from caudal group (12 patients) (28.6%) from local infiltration group and (10 patients) (25%) from paracetamol suppository group. Postoperative complications also recorded there were only two patients (5.3%) from caudal group complains from repeated vomiting and another two patients (5.3%) also from caudal group complains from temporary muscle weakness. (Table.4).

Table 4: Distribution of sampled patients according to post operative findings:

Variables	Analgesia Group						Total		P value
	Caudal		Infiltration		Suppository				
	N	%	N	%	N	%	N	%	
Pain Free 1st 3 hours									*0.011
• Yes	12	31.6%	4	9.5%	4	10%	20	16.7%	
• No	26	68.4%	38	90.5%	36	90%	100	83.3%	
Added analgesia									0.506
• Yes	14	36.8%	12	28.6%	10	25.0%	36	30.0%	
• No	24	63.2%	30	71.4%	30	75.0%	84	70.0%	
Vomiting									0.111
• Yes	2	5.3%%	0	0.0%	0	0.0%	2	1.7%	
• No	36	94.7%	42	100.0%	40	100.0%	0	98.3%	
Muscle Weakness									0.111
• Yes	2	5.3%%	0	0.0%	0	0.0%	2	1.7%	
• No	36	94.7%	0	0.0%	0	0.0%	0	98.3%	

Pain measured after recovery by FLACC scale (2 hour ,1 hour ,2 hours and 3 hours) (table.12). Minimum FLACC scale was (0) and the maximum FLACC scale was (10). Mean FLACC scale postoperatively was (0.5,1.6,0.5,0.4) in caudal group in the (1/2,1 ,2 ,3 hours) while in the infiltration group the mean was (4.8,1.6,2.1,0.3) in (1/2,1,2,3 hours), in the suppository group the mean was (5.1 ,3.5,14,0.7) in (1/2 ,1 ,2 ,3 hours) respectively (Figure.5). The scale was significant at (1/2 ,1 ,2 hours) and not significant at (3 hours) postoperatively.

Table 5: postoperative pain measurement by FLACC scale in the analgesia groups

FLACC Score after	Category	N	Min	Max	Mean	SD
	• Caudal	38	0	9	0.5	2.0
1/2 h	• Infiltration	42	0	9	4.8	3.5
P<0.001	• Suppository	40	0	10	5.1	3.9
	Total	***120***	***0***	***10***	***3.5***	***3.8***
	• Caudal	38	0	5	1.6	1.7
1 h	• Infiltration	42	0	5	1.6	1.5
P<0.001	• Suppository	40	0	10	3.5	2.7
	Total	***120***	***0***	***10***	***2.2***	***2.2***
	• Caudal	38	0	3	0.5	0.9
2 h	• Infiltration	42	0	9	2.1	2.1
P<0.001	• Suppository	40	0	5	1.4	1.8
	Total	***120***	***0***	***9***	***1.4***	***1.8***
	• Caudal	38	0	3	0.4	0.9
3 h	• Infiltration	42	0	2	0.3	0.6
P=0.178	• Suppository	40	0	4	0.7	1.2
	Total	***120***	***0***	***4***	***0.4***	***0.9***

In this study the mean time for postoperative analgesia duration were (8.4,9.9,8.4) hours in caudal, infiltration, and suppository groups while the mean number of paracetamol suppository that administered during 24 hours were (1.9,1.3,1.6) in caudal, infiltration, and suppository groups. also, the mean time for walking were reported (10.3,5.6,8.7) hours in caudal, infiltration, and suppository groups respectively. The mean time for micturition were (6.6,6.0,5.1) hours in caudal, infiltration, and suppository groups respectively (table.6). There is significant difference in the mean time for walking between these groups ($p < 0.05$).

Table 6: distribution of sampled patient according to need for extra-analgesia, time for walking, time for micturition.

Variables	Category	N	Min	Max	Mean	SD
Time for paracetamol supp. Administration (h) P=0.143	• Caudal	14	6.5	12.0	8.4	1.9
	• Infiltration	12	8.5	11.0	9.9	1.1
	• Suppository	10	5.0	13.0	8.4	3.1
	Total	***36***	***5.0***	***13.0***	***8.9***	***2.2***
No. of Paracetamol Suppositories Administered within 24h P=0.379	• Caudal	14	1.0	4.0	1.9	1.2
	• Infiltration	12	1.0	3.0	1.3	0.8
	• Suppository	10	1.0	3.0	1.6	0.8
	Total	***36***	***1.0***	***4.0***	***1.6***	***1.0***
Time for Walking ***P=0.015****	• Caudal	38	2.0	26.0	10.3	9.0
	• Infiltration	42	1.5	20.0	5.6	5.0
	• Suppository	40	1.3	24.0	8.7	7.3
	Total	***120***	***1.3***	***26.0***	***8.1***	***7.5***
Time to Micturition P=0.545	• Caudal	38	2.0	23.0	6.6	4.3
	• Infiltration	42	2.0	24.0	6.0	5.1
	• Suppository	40	1.3	9.5	5.6	2.3
	Total	***120***	***1.3***	***24.0***	***6.1***	***4.1***

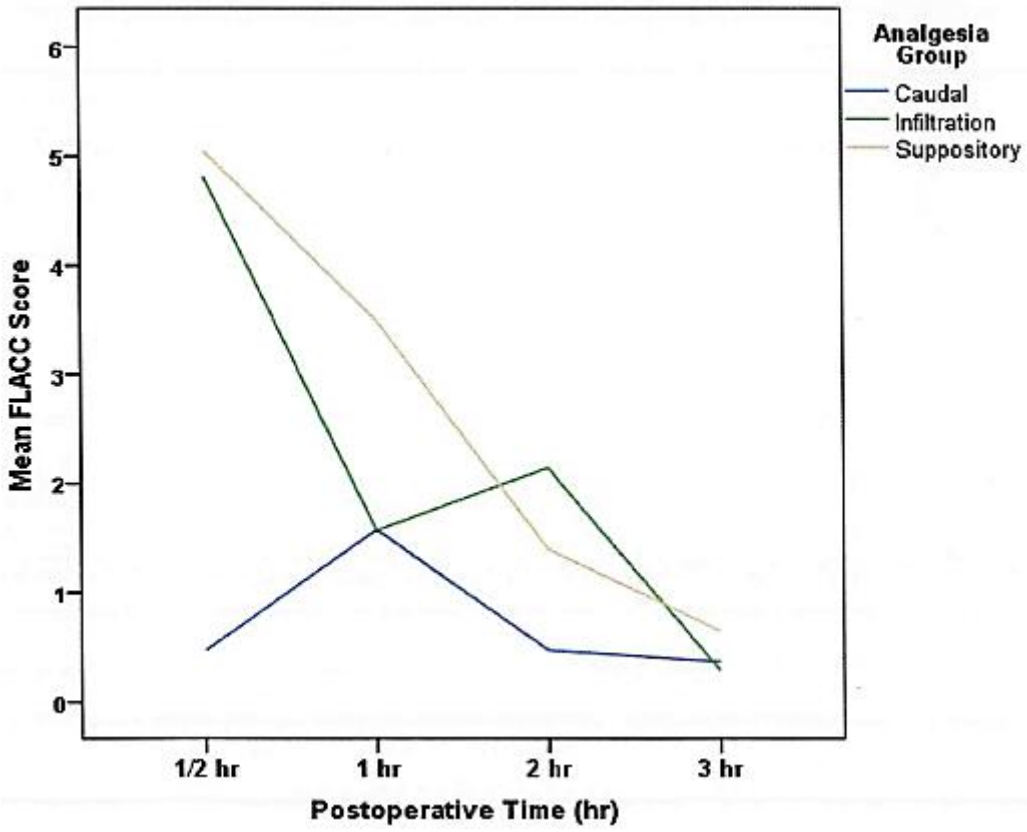

Figure 13: Mean FLACC score according to postoperative time and to type of given analgesia.

DISCUSSION:

The inguinoscrotal region is the most common site for surgical conditions in childhood (5). effective pain therapies to block or modify the physiologic responses to pain and stress have become an essential component of modern pediatric anesthesia and surgical practice). Acute postoperative pain is commonly treated with simple analgesics that often are ineffective and frequently used at doses lower than would be optimal. Systemic analgesics and regional anesthetic techniques with various efficacies have been used for pain relief after inguinal surgeries (6). In our study the efficacy of caudal block, local infiltration with bupivacaine and paracetamol suppository was compared in cases of inguinal surgeries cases. Because the total spinal blockade sometimes having potential serious complication, awareness of the anatomy in different age groups is important to prevent this from occurring.

Anatomical features that contribute to these incidents are the caudal position of the dural sac in infants less than layer at the level of S3, only a few millimeters from the puncture site (7). That is why in this study we select patients with ages older than 1,5 year, while the reason behind restricting the study to maximum age of 7 years is that the sacral fat is usually start to develop at school age children making caudal somewhat difficult and better to be limited to children less than 7 years (1). Because infants and children are usually uncooperative and unlikely to remain calm while awake, caudal blocks and local infiltration are typically performed under general anesthesia. In this study there was no significant variation among the analgesia groups regarding the mean age, mean weight, mean time of anesthesia and mean operative time also there was no significant association between type of analgesia given to patients and each of patient gender and type of surgery. The current study reveals that there is statistically significant difference between analgesia groups caudal group and other groups regarding pain free patients (FLACC score zero) in the first three hours after recovery. patients who received caudal block or local infiltration exhibit excellent and reliable postoperative pain relief when compared to paracetamol group. The same thing was reported by Hong et al. (8). The pain intensity at the 1st and 2nd hour post recovery was low in both caudal block and local infiltration groups while it remains high in the paracetamol suppository group, then at the 3rd hour post recovery, the pain score was not significant among the three groups and intensity of pain was low. This can be attributed to the fact that paracetamol have delayed absorption (The time to peak effect after rectal administration is 60—180 min and rectal bioavailability can be poor) (9). Rectal paracetamol in a dose of 30 to 40 mg/kg may take up to 2 hours to achieve a therapeutic level and so is not effective for treating acute pain (10). There are several studies highlighted the comparative efficacy of different analgesic agents for postoperative pain relief, Jahromi et al. (11) found that there is no significant difference between caudal and local infiltration but there were significant statistical differences between these two groups and paracetamol suppository group. Razavi and colleagues compared paracetamol suppository and caudal block in relieving pain after pediatric surgery and concluded that caudal block was more effective than paracetamol suppository (12). In this study, the mean analgesic duration of caudal block, bupivacaine infiltration, and paracetamol suppository groups was 8.4, 9.9, and 8.4 hours respectively and it was not significant, while other studies like Jahromi et al. ® and Razavi, et al. "? founded that caudal group and infiltration group have longer analgesic effect duration than paracetamol suppository group. The variation in determining the maximum duration of analgesia among studies may be due to the fact that we depend on the parents for following & assessing their patient at home and then they inform us about the time for additional analgesia needed. On comparing the efficacy of caudal block to local infiltration, we found that some authors stated that single dose of local wound infiltration with bupivacaine does not provide superior postoperative pain relief when compared to caudal block (13). While in this study we found a significant difference between caudal block group and local infiltration group in the first assessment of pain at 2-hour post recovery and this is may be related to the time of application. after that there is no significant difference between these two groups. Also, we found that there was no significant variation among the three analgesia groups regarding the number of patients who needs extra paracetamol suppository, time for first suppository needed, and number of suppositories required during 24 hours after discharging home. Our finding is agreed with Machotta, Andreas, et al. who reported that there is no significant difference between (caudal group and infiltration group) regarding need for acetaminophen administration (14). But disagreed with Conroy et al. who reported that caudal analgesia group need less supplementation with systemic analgesics compared to local infiltration group (15). Major complication rates of caudal block or local infiltration were found very low in previous studies. Similarly, no technical difficulties, major complications, or neurological sequelae during local infiltration or caudal block was observed in our study. However minor complications rates were seen in previous studies. In this study, although we reported two cases with repeated vomiting and two cases with temporary muscle weakness following caudal block, and statistically was not significant. This is similar to what stated by Taenzer et al. in 2014% (16). While Gauntlet ®® reported statistically significant motor blocks in caudal block with bupivacaine and no difference in the incidence of nausea and vomiting (17). Here in this study, we found that there is significant difference in the mean time for walking between the caudal group and the other two groups, those patients received caudal block took a longer time to walk which is similar to what is reported by Bengisun et al. (18), but we did not find an effect on the time of micturition. which is also similar to what is reported by Haliloglu et al. (19).

CONCLUSION:

1. Caudal block and local wound infiltration with bupivacaine are highly effective in relieving pain in the postoperative period.
2. When comparing caudal block with local wound infiltration, caudal block had better analgesic effect (fewer pain related behavior).
3. Wound infiltration is easy to administer without significant side effect and analgesia extend into the postoperative period, while Caudal block is relatively easy to perform with no major complications were observed and minor complications were acceptable.

4. Both caudal block and local wound infiltration reducing the need for other analgesics in the postoperative period when the oral route is not available.
5. Paracetamol suppository was insufficient to achieve good analgesia at the early postoperative period.

RECOMMENDATION:

1. Caudal block and local wound infiltration is recommended in children with inguinal surgery to achieve good postoperative analgesia.
2. Concerning local wound infiltration, subcutaneous injection of local anesthetic it is better to be given just when operative incision is made to reach the maximum analgesic efficacy.
3. If we decide to use paracetamol suppository as postoperative analgesic, we recommend using it preoperatively in operations taking long time and with double dose to achieve analgesic plasma concentration.

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