

EFFICACY OF COMBINED LOCAL ANESTHETIC WOUND INFILTRATION AND PARACETAMOL SUPPOSITORIES IN RELIEVING POSTOPERATIVE PAIN IN CHILDREN

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ABSTRACT

Objective: To evaluate the efficacy of combined incisional infiltration with Bupivacaine and Paracetamol suppositories with Paracetamol suppositories alone in relieving the postoperative pain associated with surgery of inguinal pathologies.

Methods: Prospectively, one hundred and ten children whom underwent groin surgery at Prince Rashed Ben Al-Hassan hospital from April 1, 2008 to December 1, 2008 were included in the study. Their ages ranged from six months to 13 years. Surgery was performed under general anesthesia. Patients were randomized into two groups; group A (55patients) received Paracetamol rectally 30 mg/kg immediately preoperatively, while group B (55 patients) had Paracetamol rectally 30 mg/kg and incisional wound infiltration with Bupivacaine 1mg/kg. Postoperative pain was managed by giving Paracetamol. The duration of the postoperative analgesia was estimated based on the time when rescue analgesia was first given. Assessment of the quality of postoperative analgesia was based on the children's behavior.

Results: In our study, both parents and older children were willing to cooperate. None of the children in the study groups suffered from local anesthetic toxicity such as arrhythmias, seizures, allergy and hematoma or tissue edema. In group A, 15 children suffered pain in the recovery room and received further analgesia in the form of Paracetamol suppositories, 18 had pain and received analgesia at home within four to six hours after discharge. The remaining 22 suffered pain during the next five days after surgery. In group B, two patients had pain in the recovery room, eight had pain with early mobilization at home and had their first analgesic dose after five to eight hours. The other 45 children had no significant post-operative pain. Group B showed an increased duration of postoperative analgesia with early mobilization. Rescue mean time at which children had their first post-operative dose of analgesia was two to four hours in group A and it was five to eight hours in group B. No patient in group B needed analgesia after day three post-operatively.

Conclusion: Wound infiltration with Bupivacaine 1mg/kg combined with rectal Paracetamol 30 mg/kg has a better and valuable efficacy compared to the rectal Paracetamol 30 mg/kg alone with respect to providing pain relief following inguinal herniotomy, hydrocelectomy and orchidopexy in children, with a longer duration of pain relief and earlier mobilization.

Key words: Analgesic, Bupivacaine, Groin pathologies, Local anesthetic, Paracetamol

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Introduction

Surgery for groin pathologies such as inguinal herniotomy, hydrocelectomy and orchidopexy in children is usually a day case procedure frequently associated with considerable postoperative pain and it remains a challenge to provide adequate analgesia with minimal side effects.⁽¹⁾ Opioids administration is among the oldest and most commonly used medication for postoperative analgesia. Unfortunately, pain relief with opioids is often unsatisfactory and can lead to a delay in recovery and hospital discharge due to associated adverse events.⁽²⁻⁵⁾ Paracetamol is widely accepted as a standard pain treatment for postoperative children in many countries and commonly used for outpatient management of pain in pediatrics.^(4,6,7) Various regional anesthetic techniques are widely used to provide postoperative analgesia in infants and children following inguinal hernia repair, circumcision, hypospadias repair, orchidopexy, lower limb, perineal or lower abdominal surgery.⁽⁸⁻¹²⁾ Based on the fact that multimodal analgesia decreases postoperative pain and improves patient comfort,⁽¹¹⁾ we hypothesized that the addition of pre- and post-surgical Bupivacaine wound infiltration would enhance Paracetamol suppositories' induced postoperative analgesia. Therefore, to verify this hypothesis, we performed a prospective, double blind, placebo controlled study designed to assess the analgesic effect of pre- and post-surgical Bupivacaine wound infiltration when administered as an adjuvant to using preoperative Paracetamol suppositories.

Methods

After human research ethics committee approval and obtaining informed consent from the parents, 110 children underwent surgery for different groin pathologies with ages ranging from six months to 13 years and body weight ranges from 5kg to 49kg were enrolled in this study. Anesthesia was induced via a facemask with 8% sevoflurane in a mixture of 50% nitrous oxide in oxygen. After induction and establishment of intravenous access, Fentanyl (2µg/kg) and Atracurium (0.5mg/kg) was administered intravenously to facilitate laryngeal mask airway insertion. Anesthesia for both groups was maintained with 1–3% sevoflurane in a mixture of 50% nitrous oxide in oxygen. Mechanical ventilation was adjusted to maintain the end-tidal carbon dioxide between 35–45 mmHg. Monitoring during anesthesia included electrocardiogram, pulse

oximeter and noninvasive blood pressure. Patients were randomized by means of sealed envelopes into two groups (55 each). The anesthetist was aware of the randomization and ensured that the correct drugs and doses were administered. The anesthetist was not part of the assessment of patients.

Group A (55 children) after anesthesia and before scrubbing the patient, Paracetamol 30mg/kg given rectally. As a control group, half the dose of normal saline 0.4ml/kg (0.2ml/kg for those above 20kg) was infiltrated after patient's preparation immediately prior to wound incision, surgery then carried out according to the specific groin pathology which was inguinal hernia, hydrocele or orchidopexy. Before skin closure the remaining half of the normal saline was infiltrated through the wound. At the completion of the surgery, muscle relaxation was reversed by a combination of 0.02 mg/kg Atropine Sulphate and 0.05 mg/kg Neostigmine. The laryngeal mask airway was removed when the patient was awake; patients were sent to the recovery room and observed for two hours.

Group B (55 children) after anesthesia and before scrubbing the patient, received Paracetamol 30mg/kg rectally. As a study group, half the dose of the local anesthetic drug Bupivacaine 1mg/kg of the 0.25% solution (0.5% solution for those above 20kg) was infiltrated after patient's preparation immediately prior to wound incision, then carried out according to the specific groin pathology. Before skin closure the remaining half of the local anesthetic drug was infiltrated through the wound, with 1-2ml infiltrated in the scrotal wound in cases of orchidopexy. The analgesic status of the patient was evaluated by an attending nurse in the recovery room for two hours and by the parents at home using an objective pain score as described by Wolf *et al.*⁽¹³⁾ (Table I). This involved assessing pain by five criteria; crying, movement, agitation, posture and localization to pain. The minimum score is zero and the maximum score is 10 (maximum score if too young to complain of pain is 8). A pain score of four or more signified pain. Parents were taught the use of this pain scale and were advised that if the child scored four or more, Paracetamol 30 mg/kg should be given but they should not exceed four doses in a day for the next five days.

A follow-up appointment was scheduled within two weeks after surgery. Statistical analysis of the results was performed using SPSS for window program, Mann Whitney U and T-tests. P-value <0.05 was considered statistically significant.

Table I. Wolf objective pain scale

No	Parameter	Findings	Points
1	Crying	no crying	0
		crying respond to tender loving care	1
		crying not responding to tender loving care	2
2	Movements	no movements	0
		restless moving about in bed constantly	1
		thrashing (moving wildly)	2
3	Agitation	asleep or calm	0
		can be comforted to lessen the agitation (mild)	1
		cannot be comforted (hysterical)	2
4	Posture	normal	0
		flexing legs and thighs	1
		holding groin	2
5	Complains of pain	asleep or states no pain	0
		cannot localized	1
		can localizes pain	2

Table II. Demographic data, duration of operation and time of rescue analgesia

	Group A (control) N = 55	Group B (Study) N = 55	P-value
M/F	41/14	48/7	0.089*
Age (Years)	0.5-13 (4.91±2.11)	0.5-13 (5.39±2.48)	0.272*
Weight (Kg)	5-49 (19.21± 7.16)	5-49 (18.17± 5.59)	0.398*
Duration of operation (Minutes)	20-45 (37.20±5.09)	25-50 (38.64±6.11)	0.183*
Rescue analgesia (Hours)	2-4 (3.36±0.68)	5-8 (6.51±1.15)	<0.001**

*No statistical significant differences were found between groups.

**Statistical significant differences were found between groups.

Table III. Number of patients requiring postoperative analgesia

	Group A (control) N = 55	Group B (Study) N = 55	P-value
1 st day	33	10	<0.001
2 nd day	22	8	0.002
3 rd day	10	3	0.038
4 th day	5	0	0.022
5 th day	4	0	0.041

Statistically significant differences were found between groups.

Results

In our study, both parents and older children were willing to cooperate and no patient dropped out. No statistically significant difference was noticed between the two groups with respect to age, weight or duration of the operation (Table II). None of the children in the study group suffered from local anesthetic toxicity, arrhythmia, seizure, allergy, hematoma or tissue edema. In group A, 15 children suffered pain in the recovery room and received further analgesia in the form of Paracetamol suppositories, 18 had pain and received analgesia at home within four to six hours after discharge, 22 suffered pain during the few days after surgery and had occasional analgesia.

In group B, two patients had pain in the recovery room, eight had pain with early mobilization at home and had their first analgesic dose after five to eight hours. The other 45 children had no significant post-operative pain (Table III). Group B showed a significant increase in the duration of postoperative analgesia with early mobilization. The efficacy of postoperative analgesia tended to be more adequate in group B. The mean duration and standard deviation of the postoperative analgesia in group B was 6.51±1.15 hours, while in group A it was 3.36±0.68 hours. From the beginning of the observation period, group B tended to have a better quality of postoperative analgesia. Nine children in group B were mobilized earlier, during the first two hours postoperatively, compared to only two

children in group A who were mobilized, while the rest were mobilized later

Discussion

Pediatric patients with groin pathologies such as inguinal hernia, hydrocele and undescended palpable testes are good candidates for day-case surgery. Effective postoperative analgesia and early mobilization of children are considered important in order to shorten the duration of the postoperative stay. Local and regional techniques performed under general anesthesia are well-established in postoperative pain control following inguinal surgery in children such as caudal block, ilioinguinal/iliohypogastric nerve block, paravertebral block and wound infiltration.^(3,9,12,14)

Studies comparing postoperative pain relief for inguinal surgery in children using wound infiltration with that provided by other regional techniques have been reported, only a few are comparing wound infiltration with Paracetamol, which is a routine method for pain relief after herniotomy in children.⁽³⁾ In the present study, the efficacy, duration and quality of postoperative analgesia provided by wound infiltration with 0.25% (0.5% for those above 20kg) Bupivacaine 1mg/kg, combined with rectal Paracetamol 30mg/kg were compared to that of Paracetamol 30mg/kg alone. Previous studies in children and infants have shown that wound infiltration with Bupivacaine at the end of inguinal herniotomy produces analgesia comparable to that rendered by caudal block or by ilioinguinal/iliohypogastric nerve block.^(9,12) Wound infiltration is easy to perform and small doses of Bupivacaine are effective for wound infiltration and are half the dose required for caudal or field block. Mobley *et al.* measured serum Bupivacaine concentrations in 12 children who underwent elective herniotomy or who received analgesia in the form of wound infiltration with Bupivacaine 1.25mg/kg. They found that the peak serum concentrations were lower than those associated with other local anesthetic blocks and well below potentially toxic levels.⁽¹⁵⁾ In our study, none of the children in the wound infiltration group suffered from local anesthetic toxicity, Bupivacaine was injected just before wound incision and before wound closure. Although most patients in group B had adequate postoperative analgesia, six children in group A and two in group B suffered severe pain. In our study, the presence of 15 children in group A who complained of pain in the recovery room

indicates that in 27% of children who received rectal Paracetamol, the analgesia was inadequate. Matsota *et al.*, they compared the efficacy of post-incisional wound infiltration with levobupivacaine 1.25mg/kg with Paracetamol 30mg/kg administered rectally and found that post-incisional wound infiltration with levobupivacaine 1.25mg/kg has a similar efficacy to rectal Paracetamol 30mg/kg with respect to providing pain relief following inguinal hernia repair in children, but with a longer duration and earlier mobilization of the children.⁽³⁾

Prevention of pain whenever possible, using multimodal analgesia, has been shown to work well for nearly all cases and can be adapted for day cases, major cases, the critically ill child, or the very young.⁽¹¹⁾ In the present study, group B had prolonged analgesia with a better quality. The mean duration of postoperative analgesia in the post-incisional wound infiltration group was 6.51 ± 1.15 hours, while in group A it was 3.36 ± 0.68 hours, respectively.

The statistical analysis showed a significant difference between the two groups, taking into account that even a short lasting pain is important for children's postoperative discomfort and that these children may develop increased anxiety about any future medical intervention. Early mobilization is another important factor that affects both the quality of postoperative analgesia and the discharge from hospital after day-case surgery. In our study, the assessment of the quality of postoperative analgesia based on children's mobilization revealed a significant difference between the two groups during the early postoperative period.

Conclusion

Wound infiltration with Bupivacaine 1mg/kg combined with rectal Paracetamol 30mg/kg has better and more valuable efficacy compared to rectal Paracetamol 30mg/kg alone with respect to providing pain relief following inguinal herniotomy, hydrocelectomy and orchidopexy in children. Furthermore it is associated with a longer duration of pain relief and earlier mobilization.

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