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Efficacy of three doses of tramadol with bupivacaine for caudal analgesia in paediatric inguinal herniotomy

S. Prakash[1]*, R. Tyagi[1], A. R. Gogia[1], R. Singh[2] and S. Prakash[3]

[1]Department of Anaesthesia and Intensive Care, Vardhman Mahavir Medical College and Safdarjang Hospital, New Delhi, India [2]Department of Biostatistics, AIIMS, New Delhi, India [3]Central Hospital, New Delhi, India

**Corresponding author. E-mail: drsunilprakash@rediffmail.com*

Background. This study was designed to evaluate the analgesic efficacy of three doses of tramadol, administered caudally with bupivacaine, in providing postoperative pain relief in children.

Methods. Eighty children, aged between 2 and 8 yr, undergoing inguinal herniotomy were randomly allocated to receive bupivacaine 0.25% 0.75 ml kg^{-1} (Group B; n=20), bupivacaine 0.25% 0.75 ml kg^{-1} with tramadol 1 mg kg^{-1} (Group BT1; n=20), bupivacaine 0.25% 0.75 ml kg^{-1} with tramadol 1.5 mg kg^{-1} (Group BT1.5; n=20), or bupivacaine 0.25% 0.75 ml kg^{-1} with tramadol 2 mg kg^{-1} (Group BT2; n=20) by the caudal route immediately after induction of general anaesthesia. Heart rate, arterial pressure and oxygen saturation were monitored. Postoperative pain was assessed at regular intervals for 24 h using All India Institute of Medical Sciences pain score. Analgesia was supplemented whenever pain score was $\geqslant$4. Duration of analgesia and requirement for additional analgesics was noted.

Results. Duration of analgesia was longer in Group BT2 [(mean (SD) 12 (0.9) h] compared with Group B [4 (1) h], Group BT1 [8 (0.9) h], or Group BT1.5 [11 (1) h]; all P<0.001. Total consumption of rescue analgesic was significantly lower in group BT2 compared with other groups (P<0.001). There were no significant changes in heart rate, arterial pressure and oxygen saturation between groups. Adverse effects were not observed.

Conclusions. Caudal tramadol 2 mg kg^{-1}, combined with bupivacaine 0.25% 0.75 ml kg^{-1}, provided longer duration of postoperative analgesia and reduced requirement for rescue analgesic compared with tramadol 1 mg kg^{-1} or 1.5 mg kg^{-1} in children undergoing inguinal herniotomy.

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Caudal epidural block with bupivacaine is a common local anaesthetic technique in paediatric anaesthesia. However, a single caudal injection of bupivacaine provides analgesia for only 2–4 h. The administration of opioids into the epidural space significantly prolongs the duration of caudal analgesia but is associated with a number of unpleasant side-effects including the potentially serious risk of respiratory depression. Tramadol, a synthetic analogue of codeine, is a racemic mixture of two enantiomers: (+)-tramadol and (−)-tramadol. The (+)-enantiomer has a moderate affinity for the opioid μ-receptor and also inhibits serotonin uptake, while the (−)-enantiomer is a potent norepinephrine inhibitor.[1] These complementary properties result in an opioid with an analgesic potency approximately equal to that of meperidine, but without any respiratory depressant effect.[2 3]

It has previously been demonstrated that the addition of tramadol to bupivacaine for caudal epidural block in children significantly prolongs the duration of postoperative analgesia.[4–8] The dose of tramadol used for caudal epidural block has ranged between 1 and 2 mg kg^{-1} in these studies. The purpose of this prospective, randomized, double-blind study was to identify the dose of tramadol, as adjunct to bupivacaine caudal epidural block, that would produce maximum duration of caudal analgesia with minimal adverse effects in children undergoing inguinal herniotomy.

Methods

After approval by the hospital ethics committee and written informed parental consent, we studied 80 children, ASA I

or II, aged between 2 and 8 yr, who were undergoing unilateral inguinal herniotomy. Children in whom caudal block was contraindicated (infection at the site of block, bleeding diathesis, pre-existing neurological or spinal disease, or abnormalities of the sacrum) were excluded from the study. Patients were fasted for 6 h before the procedure. Clear fluids (10 ml kg^{-1} body weight) were allowed up to 3 h before the procedure. No premedication was administered.

After cannulation of a suitable vein, anaesthesia was induced with thiopental 4–6 mg kg^{-1} or with inhalation of halothane and nitrous oxide in oxygen. Anaesthesia was maintained via a facemask with the same volatile agents. No sedatives or opioids were administered during operation.

Patients were allocated randomly (sealed envelope, random number table) to receive one of four solutions, the volume injected into the caudal epidural space being 0.75 ml kg^{-1}. Group B received plain bupivacaine 0.25% 0.75 ml kg^{-1}; Group BT1 received plain bupivacaine 0.25% 0.75 ml kg^{-1} combined with tramadol 1 mg kg^{-1}; Group BT1.5 received plain bupivacaine 0.25% 0.75 ml kg^{-1} combined with tramadol 1.5 mg kg^{-1}; Group BT2 received plain bupivacaine 0.25% 0.75 ml kg^{-1} combined with tramadol 2 mg kg^{-1}. Preservative free tramadol was used (Supridol, Neon Laboratories Limited, India). After induction of anaesthesia and before surgery, patients were placed in the lateral position, and a 23-gauge needle was inserted into the caudal epidural space. After negative aspiration for blood or cerebrospinal fluid, the study solution was administered.

Patients were monitored during operation for heart rate, ECG, ventilatory frequency, end-tidal carbon dioxide and arterial oxygen saturation continuously and non-invasive blood pressure every 5 min (Cardiocap II, Datex-Ohmeda, Finland). Adequate intraoperative analgesia was defined by haemodynamic stability, as indicated by the absence of an increase in heart rate or systolic arterial pressure greater than 15% compared with baseline values obtained just before surgical incision.

Anaesthesia was discontinued at the completion of skin closure. After the operation, time from discontinuation of anaesthesia to spontaneous eye opening and the duration of surgery were noted. Pain in the postoperative period was assessed by using All India Institute of Medical Sciences (AIIMS) pain discomfort scale.[9] The scale uses five criteria: ventilatory frequency, heart rate, discomfort, cry and pain at site of operation. Each criterion scores from 0 to 2 to give a possible total score of 0–10. Assessments were made by an investigator (who was blinded to the mixture used for caudal injection) at 1, 2, 3, 4, 6, 8, 12 and 24 h after recovery from anaesthesia. AIIMS score was evaluated by the nursing staff (who were unaware of the treatment given) during the remaining period. Patients received acetaminophen 10 mg kg^{-1} orally as rescue analgesic when AIIMS score was $\geqslant 4$.

Time for first analgesic (time between caudal injection and first administration of rescue analgesic) and the total consumption of analgesic in the first 24 h were recorded. Assessment of sedation was done at 1 and 4 h by using an objective score based on eye opening (eyes open spontaneously=0, eyes open in response to verbal stimulation=1, eyes open in response to physical stimulation=2).[10]

Duration of motor block (by determining when the child began to move his legs), time to first void and side-effects (emesis, urinary retention, facial flushing or pruritus), if any, were recorded.

To assess the difference among the groups for continuous variables, one-way ANOVA was used with *post hoc* analysis. For finding association among the categorical variables, two-way ANOVA was used. $P< 0.05$ was regarded as statistically significant. Statistical software SAS 8.0 (SAS Institute Inc., Cary, NC, USA) was used for statistical analysis.

Results

The four groups of patients were comparable with respect to age, weight, gender distribution and duration of surgery (Table 1). No statistically significant differences were observed in intraoperative and postoperative heart rate, arterial pressure, ventilatory frequency and oxygen saturation between the four groups.

The results are given as mean (SD). The time to first administration of rescue analgesia was 4 (1) h in Group B, 8 (0.9) h in Group BT1, 11 (1) h in Group BT1.5 and 12 (0.9) h in Group BT2 (Table 2). The duration of analgesia in Group B was significantly shorter than that in the other three groups (all $P<0.001$). The difference in mean time to first analgesia between groups BT1, BT1.5 and BT2 was also significant (all $P<0.001$).

Total consumption of analgesic was significantly higher in Group B [450.3 (93.2) mg] compared with that in Group BT1 [297.8 (90.7) mg], Group BT1.5 [294.1 (99.1) mg], and Group BT2 [189.0 (68.6) mg]; all $P<0.001$. Fifteen patients

Table 1 Patient characteristics and duration of surgery. Data are mean (range or SD)

	Group B	Group BT1	Group BT1.5	Group BT2	*P*-value
Age (yr)	5.52 (2–8)	4.62 (2–8)	4.62 (2–8)	4.75 (2.5–7)	0.435
Weight (kg)	15.80 (3.94)	14.18 (5.50)	15.48 (4.45)	14.00 (2.99)	0.454
Gender ratio (M : F)	19 : 1	18 : 2	16 : 4	18 : 2	
Duration of surgery (min)	33.9 (4.76)	35.95 (9.43)	35.10 (7.89)	35.15 (13.97)	0.926