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 >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.

Keywords: anaesthetic techniques, epidural; analgesia, postoperative; analgesics opioid, tramadol; surgery, paediatric

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or II, aged between 2 and 8 yr, who were undergoing uni-
ilateral 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, ran-
dom 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 tra-
madol 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
noted. The postoperative period was assessed by using All
India Institute of Medical Sciences (AIIMS) pain discomfort
scale. 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 ≥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 catego-
rical 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 satura-
tion 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           |

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Sedation scores confirmed the efficacy of tramadol in paediatric postoperative analgesia. Dose of 2 mg kg\(^{-1}\) of tramadol was significantly more effective than 1 mg kg\(^{-1}\) and 1.5 mg kg\(^{-1}\). There was no difference in postoperative analgesia between the groups as evident by the time to spontaneous eye opening and sedation scores at 1 and 4 h after operation.

Senel and colleagues\(^5\) examined the analgesic efficacy of bupivacaine 0.25\% 1 ml kg\(^{-1}\), tramadol 1.5 mg kg\(^{-1}\) in normal saline, or bupivacaine 0.25\% 1 ml kg\(^{-1}\) mixed with tramadol 1.5 mg kg\(^{-1}\) in children undergoing herniorrhaphy. Their results showed that patients who received bupivacaine and tramadol had a significantly longer time period to administration of first analgesic [13 (2) h] than either the bupivacaine group [10 (2) h] or the tramadol alone group [5 (1) h]. This is comparable with the duration of postoperative analgesia of 11 (1) h observed in the group receiving bupivacaine 0.75 ml kg\(^{-1}\) combined with tramadol 1.5 mg kg\(^{-1}\) in our study.

Caudal tramadol (2 mg kg\(^{-1}\)) provided reliable postoperative analgesia similar to caudal morphine (0.03 mg kg\(^{-1}\)) in quality and duration of pain relief in children undergoing herniorrhaphy.\(^6\) Batra and colleagues\(^7\) concluded that caudal tramadol 1 mg kg\(^{-1}\) can be safely used for postoperative analgesia with a longer duration as compared with caudal bupivacaine.

Prosser and colleagues\(^8\) reported that the addition of tramadol (2 mg kg\(^{-1}\)) to caudal bupivacaine (2 mg kg\(^{-1}\)) provided a mean duration of analgesia of 10 (2) h. The addition of tramadol did not prolong significantly the action of caudal bupivacaine. This is because the mean duration of action of caudal bupivacaine in their study [9 (3) h] was much longer than that reported in other studies.\(^9\) Differences in the type of surgery, method of pain scoring, dosage and volume of administered medication, and calculation of analgesia time probably account for this discrepancy. Also, postoperative pain was assessed for only 12 h after caudal injection.

It is not clear whether the prolonged duration of action of caudal tramadol is caused by slow absorption across the dura or slow-uptake of tramadol from the epidural space into the systemic circulation. Our institution lacks the facilities to estimate serum tramadol concentrations, hence it was not possible to do so in our study. However, lower plasma levels after epidural administration of tramadol have been reported in most clinical studies. Chrubasik and colleagues,\(^10\) in their study of 21 patients given epidural tramadol infusion, found mean plateau serum concentrations of around 300 \(\mu\)g ml\(^{-1}\) that were far lower than those seen with i.v. tramadol treatment.\(^11\)

The data from Murthy and colleagues\(^7\) study suggest that injection of tramadol in the epidural space appears to act only as a depot for immediate and delayed systemic absorption. It is of interest to note that tramadol is one of the few drugs that is administered in the same dose both epidurally and i.v. Gunes and colleagues\(^12\) concluded that caudal tramadol (2 mg kg\(^{-1}\)) provided better and long-lasting postoperative analgesia (>24 h) than i.v. tramadol 2 mg kg\(^{-1}\) [2 (0.6) h]. Majority of patients (30 of 34 patients), receiving tramadol i.v., needed supplementary analgesia compared with 5, 3 and 0 patients in groups BT1, BT1.5 and BT2, respectively (Table 3).

There was no significant difference in duration of time from discontinuation of anaesthesia to spontaneous eye opening between the four groups; \(P=0.91\) (Table 2). Sedation scores at 1 and 4 h after surgery were comparable in the four groups (Table 4). None of the patients had motor block on emergence from anaesthesia. Time to first void was significantly longer in Group BT2 compared with that in Group B; \(P<0.001\) (Table 2). No child required bladder catheterization.

The incidence of emesis was not statistically different between the groups; \(P=0.498\) (Table 2). Facial flushing or pruritus was not observed.

### Discussion

This study has supported the findings of previous work and confirmed the efficacy of tramadol in paediatric postoperative pain control.\(^4\)\(^6\)\(^8\) Addition of tramadol to bupivacaine administered caudally provided a dose-related increase in postoperative analgesia. Dose of 2 mg kg\(^{-1}\) of tramadol was significantly more effective than 1 mg kg\(^{-1}\) and 1.5 mg kg\(^{-1}\). There was no difference in postoperative sedation scores at 1 and 4 h after operation.

### Table 2

<table>
<thead>
<tr>
<th>Group</th>
<th>Group BT1</th>
<th>Group BT1.5</th>
<th>Group BT2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of analgesia (h)</td>
<td>4 (1.0)</td>
<td>8 (0.9)*</td>
<td>11 (1.0)*</td>
</tr>
<tr>
<td>Duration of motor block (h)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Time to first void (h)</td>
<td>3 (1.2)</td>
<td>3 (1.3)</td>
<td>2 (1.0)</td>
</tr>
<tr>
<td>Time to spontaneous eye opening (min)</td>
<td>5 (1.8)</td>
<td>5 (2.4)</td>
<td>5 (1.7)</td>
</tr>
<tr>
<td>Emetic events [n (%)]</td>
<td>1 (5)</td>
<td>2 (10)</td>
<td>2 (10)</td>
</tr>
</tbody>
</table>

### Table 3

<table>
<thead>
<tr>
<th>Number of doses of acetaminophen received</th>
<th>Group B</th>
<th>Group BT1</th>
<th>Group BT1.5</th>
<th>Group BT2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0 (0)</td>
<td>3 (15)</td>
<td>5 (25)</td>
<td>13 (65)</td>
</tr>
<tr>
<td>2</td>
<td>5 (25)</td>
<td>12 (60)</td>
<td>12 (60)</td>
<td>7 (35)</td>
</tr>
<tr>
<td>3</td>
<td>13 (65)</td>
<td>5 (25)</td>
<td>3 (15)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>4</td>
<td>2 (10)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

### Table 4

<table>
<thead>
<tr>
<th>Sedation score at 1 h</th>
<th>Group B</th>
<th>Group BT1</th>
<th>Group BT1.5</th>
<th>Group BT2</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (0–1)</td>
<td>1 (0–1)</td>
<td>1 (0–1)</td>
<td>1 (0–1)</td>
<td>1 (0–1)</td>
</tr>
<tr>
<td>Sedation score at 4 h</td>
<td>0 (0–1)</td>
<td>0 (0–1)</td>
<td>0 (0–1)</td>
<td>0 (0–1)</td>
</tr>
</tbody>
</table>
analgesia, whereas no boys given caudal tramadol required postoperative analgesia during the 24 h study period. Tramadol has been reported to depress the spinal nociceptive receptors in the rat, indicating that, similarly to morphine, it acts at the spinal level.16

The most frequently reported side-effect of epidural tramadol is nausea. We found a low incidence of emesis with all three doses of tramadol compared with previous reports.68 Similar results were reported by Senel and colleagues4 who found that the addition of tramadol 1.5 mg kg$^{-1}$ to bupivacaine did not result in any significant increase in the incidence of emesis. The longer time to first void in patients receiving tramadol 2 mg kg$^{-1}$, though statistically significant, appears clinically acceptable. No child required bladder catheterization.

We used the AIIMS discomfort scale for assessment of pain because it provides allowance for thirst and hunger, avoids duplication of behaviour, and includes physiological changes such as heart rate and respiration, which can be measured without causing discomfort to the patient. For this reason, it is a clinically relevant scoring system and has been validated for use in children.9

In summary, when tramadol 2 mg kg$^{-1}$ is used to prolong the duration of caudal epidural analgesia with bupivacaine in children, the duration of analgesia is longer and the requirement for postoperative analgesia less than that seen with tramadol 1 or 1.5 mg kg$^{-1}$, without an increase in adverse effects.

References