INTRODUCTION

Caudal block is the most common regional anaesthetic technique performed in children.\(^1\) It is very reliable, safe and has a low failure rate. It can be used in children with general anaesthesia for intra- and postoperative analgesia in all procedures below the umbilicus including herniotomy, orchidopexy and penile surgeries.\(^2\)

Administration of a single agent for caudal block with a high dose may provide a satisfactory analgesia but may cause side effects i.e. hypotension, respiratory depression etc.\(^3\) To overcome this problem, two agents with low doses may prove superior in achieving effects i.e. prolonged effect and minimal side effects. Ketamine, clonidine and various opioids have been combined with bupivacaine with varied degrees of success.

Tramadol is a synthetic analogue of codeine that has an analgesic potency approximately equal to that of pethidine but without respiratory depressant effect.\(^4\) It has been shown to be as effective as bupivacaine in providing postoperative analgesia when administered caudally in children.\(^5\)

Different studies have been done to compare caudal bupivacaine and tramadol for postoperative analgesia in children. Khan and Hussain observed that caudal tramadol as a single dose was as effective as bupivacaine in relieving pain in children.\(^6\) Similarly, Ozkan and colleagues using either 0.25% bupivacaine (2 mg/kg) or 5% tramadol (2 mg/kg) or both as a caudal block, observed that caudal tramadol was superior to bupivacaine in analgesic efficacy and reducing the need for postoperative additional analgesia.\(^7\) Similar results were found by Senel et al.\(^8\)

Adding tramadol to bupivacaine not only increases the duration of analgesia but markedly decreases the dose of both agents thereby decreasing the incidence of side effects i.e. respiratory depression, vomiting, pruritus and flushing in young children.

The aim of this study was to compare the combination of 0.125% (1 ml/kg) bupivacaine and tramadol (1 mg/kg) with bupivacaine 0.25% (1 ml/kg) administered caudally in young children with hypospadias repair for reduction in dose of both agents and extension of the duration of analgesia.

ABSTRACT

Objective: To compare the effects after caudal bupivacaine alone and bupivacaine-tramadol in young children with hypospadias repair.

Study Design: Randomized controlled trial.

Place and Duration of Study: The Department of Paediatric Anaesthesia, Children Hospital, Pakistan Institute of Medical Sciences, Islamabad, from April to September 2006.

Methodology: Sixty children aged between 13-53 months coming for hypospadias repair were divided randomly into two groups A and B. A caudal block was performed immediately after induction of general anaesthesia. The patients in group A received 0.125% bupivacaine 1 ml/kg with tramadol 1 mg/kg body weight caudally. Group B patients received 0.25% bupivacaine 1 ml/kg body weight caudally. Anaesthesia was discontinued after completion of surgery. In the recovery area, ventilatory frequency and pain scores were recorded at 1 hourly interval for first 6 hours and then every 2 hours for next 6 hours postoperatively. A modified TPPPS (Toddler-Preschool Postoperative Pain Scale) was used to assess the pain. Episodes of vomiting, facial flush and pruritus were noted, if present.

Results: The duration of analgesia was significantly prolonged in group A patients (p-value=0.001). A low frequency of postoperative vomiting was observed in both groups i.e. 10% in group A and 6.66% in group B (p-value=0.64). No respiratory depression, flushing and pruritus were observed.

Conclusion: Low dose combination of bupivacaine and tramadol, when administered caudally, had an additive effect and provided prolonged and effective postoperative analgesia with minimal side effects. The risk of toxicity from bupivacaine decreased when combined with tramadol in low doses.

Key words: Bupivacaine. Hypospadias. Penile surgery. Tramadol. Analgesia.

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METHODOLOGY

The study was conducted after informed consent from parents and approval by the Hospital Ethics Committee at the Department of Paediatric Anaesthesia, Children Hospital, Pakistan Institute of Medical Sciences, Islamabad, from April to September 2006. Sixty children admitted for hypospadias repair, aged between 13-53 months, were divided into two groups, A and B. Sequential randomization was used to allocate patients in the two groups. The first patient was selected by toss of coin. It was a single-blinded study. Standard monitoring including electrocardiogram (ECG), non-invasive blood pressure (NIBP), heart rate (HR) and oxygen saturation was conducted perioperatively. Anaesthesia was induced either with intravenous thiopentone 3-5 mg/kg or by inhalation of nitrous oxide and sevoflurane in oxygen. Tracheal intubation was done by using atracurium 0.5 mg/kg body weight. Anaesthesia was maintained with 1-1.5% isoflurane and 70% nitrous oxide in oxygen.

A caudal epidural block was performed immediately after induction of anaesthesia. Group A received 0.125% bupivacaine 1 ml/kg with tramadol 1 mg/kg body weight. Group B patients received a 0.25% bupivacaine 1 ml/kg. Total volume of solution injected caudally in both groups remained constant i.e. 1 ml/kg body weight. No other peroperative analgesia was given. Anaesthesia was discontinued when the wound dressing had been applied; residual neuromuscular block was antagonized with neostigmine 50 µg/kg. The infant's trachea was extubated after return of spontaneous breathing.

In the recovery area, ventilatory frequency and pain scores were recorded on the proforma at 1, 2, 3, 4, 5, 6, 8, 10 and 12 hours postoperatively, initially in the recovery room and then in the surgical ward. A modified Toddler-Preschool Postoperative Pain Scale (TPPPS) (Table I), is a behavioural pain scale used to assess pain in infants and pre-school children between 13-53 months of age. A score of more than 3 requires rescue analgesia to be given. Pain score of 10 was used to stop caudal when the infant was awake, by ward nurses as a protocol.

Data was entered and analyzed by using SPSS version 10.0 data base programme. Mean hourly pain scores, ventilatory frequency and duration of analgesia was calculated and analyzed. In order to observe statistical significance, patient data including mean age and weight, mean duration of analgesia and ventilatory frequency in each group were compared using Student's t-test. The incidence of side effects in percentage of patients in each group were analyzed using chi-square test. A p-value less than 0.05 was considered statistically significant.

RESULTS

During the study period, 60 boys were enrolled, 30 in each group. The demographic features i.e. ages and weights of children in both groups are shown in Table II.

The mean duration of analgesia in both groups was compared using modified Toddler-Preschool Postoperative Pain Scale (TPPPS). It was 10.4±1.69 hours in group A and 7.93±1.52 hours in group B. Group A patients had significantly longer duration of analgesia as compared to group B (p-value < 0.001, Table III).

Mean hourly pain scores were similar upto 5 hours in both groups, but the scores were higher in group B from 6 to 10 hours after surgery (p=0.05, Figure 1). In group A, 56.66% patients didn't require rescue analgesia for upto 12 hours postoperatively, while in group B, all patients required rescue analgesia within 12 hours. After 12 hours, oral paracetamol was given to all patients who were awake, by ward nurses as a protocol.

There were no significant differences between the groups in mean hourly respiratory rate. Emeis occurred in the two groups in mean hourly respiratory rate. Emeis occurred in the two groups.

Table I: Modified TPPPS* pain score.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Score 0</th>
<th>Score 1</th>
<th>Score 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verbal complaint/cry</td>
<td>None</td>
<td>Once</td>
<td>&gt; Once</td>
</tr>
<tr>
<td>Groan/moan/grunt</td>
<td>None</td>
<td>Once</td>
<td>&gt; Once</td>
</tr>
<tr>
<td>Facial expression</td>
<td>Neutral</td>
<td>One</td>
<td>&gt; One</td>
</tr>
<tr>
<td>Restless motor behaviour</td>
<td>None</td>
<td>One</td>
<td>&gt; One</td>
</tr>
<tr>
<td>Rub/touch painful area</td>
<td>None</td>
<td>Once</td>
<td>&gt; Once</td>
</tr>
</tbody>
</table>

*Toddler-Preschool Postoperative Pain Scale

Table II: Mean age and weight – all patients (n=60) and comparison between two groups.

<table>
<thead>
<tr>
<th>Demographic features</th>
<th>All patients</th>
<th>Group A</th>
<th>Group B</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (months)</td>
<td>27.72±11.67</td>
<td>28.57±12.762</td>
<td>26.87±10.61</td>
<td>0.577</td>
</tr>
<tr>
<td>Weight (kgs)</td>
<td>14.38±2.38</td>
<td>14.3167±2.62</td>
<td>14.45±12.15</td>
<td>0.831</td>
</tr>
</tbody>
</table>

Table III: Comparison of mean duration of analgesia and mean breaths/minute in two groups (n=60).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A</th>
<th>Group B</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of analgesia (hours)</td>
<td>10.40±1.69</td>
<td>7.93±1.52</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Respiratory rate (breaths/min)</td>
<td>20.30±1.83</td>
<td>21.22±1.80</td>
<td>0.057</td>
</tr>
</tbody>
</table>
in 3 patients in group A and 2 patients in group B with no statistically significant difference (p=0.064). No pruritus and flushing were observed in both groups.

Three patients were excluded from the study. In one patient, we failed to perform caudal block, while in other two, subcutaneous injection led to failure of the block.

**DISCUSSION**

Ease of performance and reliability makes caudal block the most commonly performed block in children. Caudal administration of bupivacaine is a widespread regional anaesthetic technique for intra- and postoperative analgesia during lower limb, anoperineal, penoscrotal and abdominal surgical procedures in children.\(^{10,11}\) Unintentional intravascular injection of bupivacaine during caudal block placement may cause life threatening cardiovascular and central nervous system complications.\(^{12,13}\) There have been reports of death attributable to bupivacaine-induced cardiotoxicity in adults after accidental i.v. injection.\(^{14}\) Even an epidural test dose containing epinephrine does not reliably produce hemodynamic responses in children during inhalation anaesthesia.\(^{15,16}\)

To overcome this problem as well as to increase the duration of analgesia, combining local anaesthetic agents with other drugs such as adrenaline, clonidine, ketamine or various opioids have met with varying degrees of success.\(^{3,17-20}\)

In this study, caudal block was performed in 60 children, 13-53 months of age, to compare the effects of bupivacaine alone with a low dose combination of bupivacaine with tramadol for hypospadias repair. The incidence of failed block is 2.8% in a study done by McGown and 23.2% in the first paediatric series.\(^{21,22}\)

The effectiveness of the block was 100% in both groups. In one study, the effectiveness of caudal bupivacaine 0.25% (1 ml/kg) was 94% in patients undergoing sub-umbilical surgery.\(^{23}\) As we have used a volume of 1 ml/kg for penile surgery, this much of volume is sufficient to block all the sacral, lumbar and lower thoracic segments\(^{24}\) and the block regresses slowly.

The duration of analgesia was longer and statistically significant in group A patients. In a comparative study done by Senel and colleagues,\(^{8}\) caudal bupivacaine 0.25% (1 ml/kg (-1)) with the addition of tramadol 1.5 mg/kg (-1) resulted in significantly longer postoperative analgesia duration of 13 ± 2.2 hours.\(^{8}\) The difference in their duration of analgesia as compared to the present study is due to the low concentration of both agents. The combination of bupivacaine and tramadol was chosen for caudal block because caudal bupivacaine provides analgesia in the immediate postoperative period, whereas caudal tramadol provides analgesia in the late postoperative period thereby increasing the total duration of analgesia (additive effect).\(^{9}\)

The mean duration of action of caudal bupivacaine in this study is longer than that found in previous studies.\(^{25,26}\) Differences in the operations performed, method of pain scoring, bupivacaine dose and volume, and calculation of analgesia time probably account for this discrepancy.

The overall frequency of vomiting seen in this study is 8.33% in both groups, 10% in group A and 6.66% in group B. The reason is unclear and may depend more upon other factors, such as the selection of sedatives or anaesthetic agents, rather than upon the agents used in caudal block.

If by 12 hours no additional analgesia had been required, it was assumed for the sake of comparison that the duration of analgesia was 12 hours, although it is possible that useful analgesia may have continued for longer time in group A patients. However, logistic problems dictated that further observations were impracticable and after 12 hours observations were completed, there was a tendency for prophylactic paracetamol analgesia to be given by the ward nurses to any patient who was still awake. All patients were managed successfully with paracetamol alone after this time.

All patients were catheterized during surgery, so urinary retention was not seen in both groups. No flushing and pruritus were observed in any patient in either group. The reason could be the low dose of tramadol.

**CONCLUSION**

Low dose combination of 0.125% bupivacaine and tramadol 1 mg/kg body weight injected caudally for hypospadias repair in young children had an additive effect and provided effective postoperative analgesia with minimal side effects. The duration of postoperative analgesia was significantly prolonged as compared to
0.25% bupivacaine. The toxicity from bupivacaine was decreased when combined with tramadol in low doses. Tramadol as an adjunct to bupivacaine may prove more useful in young children and infants than other opioids because of its lack of respiratory depressant effect.

REFERENCES


