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Reducing Pain after Inguinal Hernia Repair in Children

Caudal Anesthesia versus *Ketorolac Tromethamine*

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Background: **The optimal method to achieve analgesia after inguinal hernia repair in children is unknown. This study compared the analgesic efficacy, adverse events, and the costs associated with supplementation of local anesthesia (infiltration of the wound) with either intravenous ketorolac or caudal analgesia in children having inguinal hernia repair.**

Methods: **With parental consent and institutional review board approval, children aged 2–6 yr having elective, outpatient inguinal hernia repair were studied in this randomized, single-blinded investigation. Anesthesia was induced by inhalation with nitrous oxide and halothane or intravenously with propofol. Anesthesia was maintained with nitrous oxide and halothane. Patients were randomly assigned to receive caudal analgesia (1 ml/kg 0.20% bupivacaine with 1/200,000 epinephrine) or intravenous ketorolac (1 mg/kg) immediately after induction of anesthesia. Both groups received field blocks with 0.25% bupivacaine administered by the surgeon under direct vision during operation. Patients were assessed for 24 h. In-hospital pain was assessed using a behavior-based pain score. Parents assessed pain with a visual linear analog pain scale with anchors of 0 (no pain) and 100 (worst pain imaginable).**

Results: **The authors studied 164 children, with 84 patients in the ketorolac group. The groups had similar demographic data. In-hospital analgesic requirements and pain scores were almost identical in both groups. Pain at home was significantly less in the ketorolac group, with visual linear analog pain scale scores of 10 (0–80) compared with 20 (0–80) (median [range]) for ketorolac *versus* caudal ($P = 0.002$ by the Mann-Whitney U test). The ketorolac group also had a lower incidence of vomiting, ambulated more rapidly, and micturated earlier ($P < 0.05$).**

Conclusion: **The use of intravenous ketorolac to supplement local anesthesia infiltrated by the surgeon during pediatric inguinal hernia repair is superior to supplementation with caudal analgesia. (Key words: Anesthesia, pediatric. Anesthetic techniques: general; regional; caudal; local. Pain: postoperative. Drugs: ketorolac.)**

ADEQUATE analgesia after inguinal hernia repair in children is essential and may be obtained through various techniques. These methods include the administration of opioids, such as codeine; the administration of nonsteroidal anti-inflammatory drugs, such as ketorolac; and the use of regional anesthetic techniques, such as local anesthesia and caudal anesthesia and analgesia. Each of these techniques has their advantages and disadvantages, and they have proved efficacy when compared with placebo.[1] Some of these methods have been compared to determine if one is superior with respect to pain control or adverse effects.[2–6] When an inguinal field block was compared with caudal anesthesia, the investigators concluded that they had similar effects on postoperative care.[2,3] In practice, field block appears to be the technique of choice in many pediatric institutions because it is usually effective and has low cost and minimal risks. Local anesthesia is typically effective, but studies have shown that supplementation with either a nonsteroidal anti-inflammatory drug or caudal block further improves analgesia.[7,8] The purpose of our study was to assess the efficacy and adverse effects of supplementation of local anesthesia with either caudal anesthesia or ketorolac.

Methods

With approval of the ethics committee of Children's Hospital of Eastern Ontario and parental consent, we studied children aged 2–6 yr who were having elective

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repair of unilateral inguinal hernias in this single-blinded, randomized investigation. Patients were excluded from the study if they had allergies to any of the drugs that were to be administered during this study, they had a symptomatic systemic illness, they had a history of chronic, therapeutic administration of analgesics, or if they required premedication. The parents were given a copy of and instructed in the use of a horizontal linear analog pain scale with anchors of 0 (no pain) and 100 (worst pain imaginable) after consent was obtained. The parents were also instructed that they would be contacted the day after surgery.

Standard patient monitoring included electrocardiograph, noninvasive blood pressure, pulse oximetry, capnography, and inhalation agents. General anesthesia was induced by inhalation of nitrous oxide and halothane in oxygen or intravenously with 2.5–3.5 mg/kg propofol. A laryngeal mask airway was inserted after induction of anesthesia. All patients were administered 50 μg/kg midazolam immediately after induction of anesthesia and 68% nitrous oxide, 30% oxygen, and halothane during their operation. The halothane concentration (0.75–2.0%) was adjusted to achieve stable intraoperative hemodynamic measurements. The administration of intravenous fluids in the operating room followed standard guidelines (Ringer's lactate solution at maintenance rates, plus replacement of fluid deficits, third-space fluid loss, and blood loss).

Patients were randomly assigned to a caudal group or ketorolac group using a computer-generated random-number table. A caudal epidural regional anesthetic was performed immediately after anesthesia was induced in the caudal group without the presence of the surgical team in the operating room. The patients in the caudal group received 1 ml/kg 0.20% bupivacaine with 1/200,000 epinephrine to a maximum dose of 25 ml. After the caudal block, the anesthesiologist placed an adhesive strip over the needle puncture. (The patients in the ketorolac group had an adhesive strip placed on the skin superficial to the caudal space to "blind" the observers.) Patients in the ketorolac group received 1 mg/kg ketorolac tromethamine intravenously immediately after induction of anesthesia, and the caudal group received placebo intravenously. Near the end of the surgery, the local infiltration block was performed by the surgeon with up to 0.2 ml/kg 0.25% bupivacaine injected into the subcutaneous tissue of the surgical incision (about 0.1 ml/kg) and next to the ilioinguinal and iliohypogastric nerves under direct vision (about 0.1 ml/kg).

Score	0	1	2
CRY	no cry	crying, moaning	scream
FACIAL	smiling	composed	grimace
VERBAL	positive	none or other complaint	pain complaint
TORSO	neutral	shifting, tense, upright	restrained
LEGS	neutral	kick, squirm, drawn-up	restrained

Fig. 1. Modified Children's Hospital of Eastern Ontario Pain Scale.

Patients had their pain assessed in the postanesthetic recovery room (PARR) every 5 min with a modified Children's Hospital of Eastern Ontario Pain Scale (mCHEOPS)‡ (fig. 1) by recovery room nurses who were unaware of group assignment. Patients with a pain score greater than 5 were treated with 50 μg/kg morphine. Patients were discharged from the PARR and into the Day Care Surgical Unit (DCSU) when they achieved an Aldrete score of ten.[9] The minimum length of stay in the DCSU after inguinal hernia repair is 1 h. Pain was assessed in the DCSU with mCHEOPS. If the attending DCSU nurse rated the mCHEOPS greater than 5, the child received 15 mg/kg acetaminophen orally or rectally for pain. If the child's pain did not respond to acetaminophen and the mCHEOPS remained greater than 5, the child received 1 mg/kg codeine orally or rectally. After discharge from the hospital, the children received 10–15 mg/kg acetaminophen from their parents for pain. The following were recorded: the time to recovery to an Aldrete score of 10, the incidence of vomiting, analgesic use (codeine, acetaminophen, or both), the length of stay in the recovery room, and the time to first micturition and to first ambulation. For the purpose of this study, ambulation was defined as the ability to walk with or without assistance, and we de-

‡ Splinter WM, Semelhago L, Chou S: The reliability and validity of a modified CHEOPS pain score [Abstract]. Anesth Analg 1994; 78:S413.

fined micturition as the purposeful emptying of bladder contents. Parents were contacted the day after surgery and were asked to report the following: their child's pain since discharge from the hospital, vomiting, time to first micturition, and time to first ambulation.

Age, weight, length of procedure, and anesthetic recovery times were compared using one-way analysis of variance. The average mCHEOPS scores in the PARR were compared using Mann-Whitney U tests. Requirements for analgesia in the PARR and DCSU were compared with chi-squared analysis and Fisher's exact tests. The incidences of vomiting were compared using chi-squared analysis. Visual linear analog pain scale scores were compared with results of the Mann-Whitney U test. An acceptable alpha error was set at 0.05. We expected the incidence of pain requiring treatment in the PARR to be 5% in the two groups. For the purpose of this study, a 10% difference in pain scores was considered clinically significant, so the projected sample size for an alpha error of 0.05 and beta error of 0.20 was 80 children per group.

Table 1. Demographic Data, Pain Scores, and Adverse Events

Group	Ketorolac	Caudal
n	81	78
Age (yr)	4.3 ± 1.4	4.0 ± 1.5
Weight (kg)	18 ± 4	17 ± 4
Inhalation induction (n)	61	61
Anesthetic time (min)	38 ± 11	41 ± 11
PARR time (min)	43 ± 16	46 ± 22
DCSU time (min)	113 ± 22	120 ± 39*
mCHEOPS ≥ 6 in PARR (n)	4	5
Acetaminophen use in DCSU (n)	59	61
Codeine use in DCSU (n)	56	50
Parental pain score (VAS)	10 (0–80)	20 (0–80)†
Vomiting (%)	15	29‡
Time to first ambulation (min)	130 ± 35	143 ± 49*
Time to first micturition (min)	150 (0–1,380)	291 (0–1,135)§

Values are n, mean ± SD, or median (range).

PARR = postanesthetic recovery room; DSCU = day care surgical unit.

* $P = 0.05$ (ANOVA).

† $P = 0.002$, Mann-Whitney U test.

‡ $P = 0.05$, chi-square analysis.

§ $P = 0.004$, Mann-Whitney U test.

Results

We enrolled 164 patients into this study. One patient was subsequently eliminated because of major protocol violations, and four patients were eliminated because they received premedication. The groups were similar with respect to demographic data, except the caudal group spent more time in the DCSU (table 1). The ketorolac group received on average 17.6 mg (0.99 ± 0.01 mg/kg [mean ± SEM]) ketorolac, and the caudal group was administered on average 16.3 ml (0.96 ± 0.01 ml/kg [mean ± SEM]) of 0.2% bupivacaine with 1/200,000 adrenaline.

Pain scores in the PARR and analgesic requirements in the PARR and DCSU were similar (table 1). The ketorolac group had lower pain scores based on parental assessment of pain (table 1). The incidence of in-hospital vomiting was less in the ketorolac group. Patients in the ketorolac group could ambulate earlier and micturated earlier (table 1).

Discussion

Supplementation of local anesthesia with either intravenous ketorolac or caudal analgesia resulted in only 6% of the children experiencing moderate to severe pain during the immediate recovery period in the PARR. This incidence of inadequate pain relief is comparable to the 4–12% previously reported.[3,10,11]

Only the attending anesthesiologist was aware of patient assignment. Our ethics committee requested that the attending anesthesiologist not be blinded and considered the administration of placebo (normal saline) into the caudal space of the patients in the ketorolac group unethical. In theory, one or more of the 12 attending anesthesiologists involved in this study could be biased and have altered their anesthetic technique according to the patient's assignment. We could argue that noncompliance with the study protocol would be highly unlikely, given the serious repercussions of such a decision, but bias is possible and, if present, potentially subtle. The large number of anesthesiologists and many anesthesia residents involved in the study lessens the chance of systematic bias. Such bias may lead to small but "significant" differences, such as the trivial difference in ambulation noted in this study. Other differences, such as time to micturition and pain scores, are greater and have probability values less than 0.01 and are unlikely to be altered by subtle biases.

Of all the nonsteroidal anti-inflammatory drugs available, we chose ketorolac because it can be administered intravenously and is a potent analgesic. Ketorolac is not

a benign medication. Adverse effects associated with nonsteroidal anti-inflammatory drugs include bleeding,[12] acute renal failure,[13] and bronchospasm. During the current study, none of these adverse effects became apparent.

Pain assessment in children is difficult, especially in children unwilling or unable to verbalize.[14] Each of the methods of rating pain used in this study has their own merits. All of the methods are valid and reliable and were applied similarly in a blinded manner to a narrow age range. The mCHEOPS is a valid and reliable method of assessing pain in children and has been used by others under similar conditions.[2,3] Unfortunately, the rated behaviors are children's cry; verbal responses; facial, limb, and torso movements, which are not limited to pain. In addition, mCHEOPS was developed for children aged 1 to 7 yr.

After hospital discharge, continuous estimation of pain by a single, objective observer was not possible. We did not use the mCHEOPS because it was designed for use in the immediate postoperative period and becomes imprecise after discharge from hospital because pain behaviors habituate with time.[15] We could have used the Faces scale developed by Bieri *et al.*,[16] but we considered this self-reported measure impractical. Thus we asked parents to assess pain with a simple and reliable tool (a linear analog scale, with anchors of no pain and worst pain imaginable).

Most of the patients in the current study initially had adequate postoperative analgesia, with only nine patients requiring analgesics in the PARR. Thus, although neither of the study regimens was ideal, they often achieved acceptable analgesia. The reasons for clinically important pain in the PARR may be multifactorial. First, our method of pain assessment, mCHEOPS, is a behavior-based method. High pain scores may be the result of pain or other causes, such as parental separation, which may lead to pain-related behaviors such as crying. Alternatively, technical errors in the administration of the regional anesthetic by the surgical team could result in inadequate analgesia and high pain scores. This was unlikely to be a major contributor in the current study, because children in the ketorolac group behaved almost identically to the caudal group.

The lower incidence of vomiting observed in ketorolac group was not surprising. Previous investigations have also noted a decreased incidence of vomiting among the groups treated with ketorolac.[17] We do not know why ketorolac is associated with a lower incidence of vomiting. A possible mechanism of action is an opiate-sparing effect. This is unlikely to be the case in the current study because the use of opioids before hospital discharge was almost identical among the two groups studied.

In conclusion, among children undergoing elective inguinal hernia repair, supplementation of intraoperatively administered local anesthesia with ketorolac results in a small improvement in pain (as assessed by parents), a lower incidence in vomiting, a slight decrease in the time to ambulation, and a more notable decrease in the time to micturition than does caudal anesthesia. Whether similar benefits might be achieved with other nonsteroidal anti-inflammatory drugs is unknown.

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