Brief Report

Ropivacaine *vs* bupivacaine in major surgery in infants

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Purpose: To assess and compare the onset time and duration of neuroblockade obtained after ropivacaine or bupivacaine in infants undergoing major abdominal surgery. We also evaluated the efficacy and safety of employing ropivacaine instead of bupivacaine to provide operative anesthesia and postoperative analgesia.

Methods: In a prospective double blind study 28 infants, aged 1-12 months, undergoing elective major abdominal surgery, were randomly allocated to receive, after induction of general anesthesia, either 0.7 ml·kg^{-1} bupivacaine 0.25% (group B) or ropivacaine 0.2% (group R) via lumbar epidural block. The onset time, total surgical time and duration of analgesia were recorded.

Results: No differences were noted in demographic data, hemodynamic variables or duration of surgery. The onset time for sensory blockade was 13.1 min ± 2.1 (group B) and 11.7 ± 2.4 min (group R). The duration of analgesia was 491 ± 291 (group R) and 456 min ± 247 (group B). Eight patients in group B and six in group R needed codeine and acetaminophen rescue on at least one occasion during the 24 hr study period. No major side effects were noted in either groups.

Conclusions: In infants undergoing major abdominal surgery under combined epidural/light general anesthesia, ropivacaine 0.2% produces sensory and motor blockade similar in onset, duration of action and efficacy to that obtained from an equal volume, 0.7 ml·kg^{-1}, of bupivacaine 0.25%.

Objectif : Évaluer et comparer la rapidité d'action et la durée du blocage neuromusculaire obtenues après l'administration de ropivacaïne ou de bupivacaïne chez des enfants qui subissent une intervention abdominale majeure. Évaluer aussi l'efficacité et l'innocuité de la ropivacaïne employée à la place de la bupivacaïne pour l'anesthésie opératoire et l'analgésie postopératoire.

Méthode : Dans une étude prospective, à double insu, 28 enfants de 1-12 mois, devant subir une intervention abdominale majeure élective, ont été répartis de façon aléatoire et ont reçu, après l'induction de l'anesthésie générale, soit-0,7 ml·kg^{-1} de bupivacaïne 0,25 % (groupe B), soit de la ropivacaïne 0,2 % (groupe R) au moyen d'un blocage péridural lombaire. La rapidité d'action, le temps de l'opération et la durée de l'analgésie ont été enregistrés.

Résultats : On n'a noté aucune différence dans les données démographiques, les variables hémodynamiques ou la durée de l'intervention. Le début d'action du blocage sensitif a été de 13 1 min ± 2 1 (groupe B) et de 11 7 ± 2,4 min (groupe R). La durée de l'analgésie a été de 491 ± 291 (groupe R) et de 456 min ± 247 (groupe B). Huit patients du groupe B et six du groupe R ont eu besoin de codéine et d'acétaminophène de rattrapage au moins une fois pendant les 24 h de l'étude. Aucun effet secondaire important n'a été signalé dans les deux groupes.

Conclusion : Chez les enfants qui subissent une intervention abdominale majeure sous une anesthésie péridurale et générale légère combinée, la ropivacaïne 0,2 % produit un blocage sensitif et moteur de début d'action, de durée et d'efficacité similaires à ceux qu'on obtient en utilisant un volume égal, 0,7 ml·kg^{-1}, de bupivacaïne 0,25 %.

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ROPIVACAINE is a new aminoamide local anesthestic. Previous studies in animals and in adult patients suggested that ropivacaine produces sensory blockade similar in duration to that obtained with equipotent doses of bupivacaine but with less motor blockade. Also, it has been reported that ropivacaine provides a better safety profile than bupivacaine regarding CNS and cardiac toxicity. Moreover, ropivacaine causes less motor block than bupivacaine.[1-3] Few data are available on its use in children via caudal or lumbar epidural block.[4-6] The aim of this study was to assess and compare the onset time and duration of neuroblockade obtained from equipotent concentrations of either ropivacaine or bupivacaine in infants undergoing major abdominal surgery. We also evaluated the efficacy and safety of employing ropivacaine instead of bupivacaine to provide adequate operative anesthesia and postoperative analgesia in infants undergoing major abdominal surgery.

Methods

After obtaining Ethics Committee approval and parental written informed consent, 28 infants, ASA status 1-2, aged from 1-12 months of age and undergoing elective major abdominal surgery (urological procedures or colonic surgery) were studied. General anesthesia was induced with 3-5 $mg \cdot kg^{-1}$ thiopental and tracheal intubation was facilitated with 0.5 $mg \cdot kg^{-1}$ atracurium. Mechanical ventilation was planned for all patients and a light plane of general anesthesia was maintained with sevoflurane 1.5%, in O_2/air mixture throughout surgery. After induction of general anesthesia a lumbar epidural block was performed at the L_{3-4} level using a loss-of-resistance technique via a 19G Tuohy needle. Infants were randomly allocated, by sealed envelope, to group R (ropivacaine) or group B (bupivacaine). In a double-blind, prospective manner group B patients received 0.7 $ml \cdot kg^{-1}$ bupivacaine 0.25% (2 $mg \cdot kg^{-1}$) and group R patients received a similar volume of ropivacaine 0.2% (1.4 $mg \cdot kg^{-1}$). Standard monitors, NIBP, HR, SpO_2, were applied and measurements recorded at five minute intervals throughout surgery. The onset to satisfactory block was assessed according to the method of Dalens[7] and duration of postoperative analgesia (time to first administration of rescue analgesia) by hourly observations of a modified objective pain scale (OPS),[8] were monitored. Infants scoring ≥ six points on the OPS were given codeine/paracetamol rescue analgesia. Motor block was assessed by Bromage scale on awakening. Statistical analysis was with ANOVA, Chi-square test and Mann-Whitney test correction and $P < 0.05$ was considered significant.

Results

All blocks were successful; no differences were evidenced in demographic data or hemodynamic parameters. The duration of surgery was similar for both groups: 101.5 ± 27.8 min (58 – 150 min) for group R and 112 ± 15.7 min (75 – 140 min) for group B (*P*: NS) (Table I). There were no differences in onset, duration or time to analgesia between groups. The time to achieve neuroblockade was 11 ± 2.4 and 13.1 ± 2.1 min, and the duration of analgesia was 491.2 ± 291.9 and 456.6 ± 247.6 min for ropivacaine and bupivacaine respectively. Six patients (43%) in group R and eight patients (57%) in group B required paracetamol and codeine on at least one occasion (Table II). No major adverse side effects were noted in either group.

Discussion

Recently, a new aminoamide local anesthetic L-ropivacaine, a pure enantiomere has been introduced in adults for orthopedic and general surgery, labour and postoperative pain control. Sensory block is equivalent to that of bupivacaine but with a less intense motor block, shorter duration of action and reduced cardiac toxicity have been observed.[9-10] These features suggest that ropivacaine might be of potential benefit in pediatric patients

In a previous study of caudal ropivacaine in children undergoing minor surgery[4] we compared 2 $mg \cdot kg^{-1}$ ropivacaine 0.2% with 2 $mg \cdot kg^{-1}$ bupivacaine 0.25% and demonstrated earlier onset and longer duration of postoperative analgesia with ropivacaine. In a second multicentre study[5] we established that, for caudal analgesia, 1 $ml \cdot kg^{-1}$ ropivacaine 0.2% and bupivacaine 0.25% were equipotent and had similar onset

TABLE I Clinical data with no statistical significant differences, expressed as mean ± SD (range)

	age (months)	*Weight (kg)*	*Duration of surgery (min)*
Group B	7.3 ± 3.1 (2-12)	8.0 ± 1.8 (5-10)	112.3 ± 15.7 (75-140)
Group R	7.7 ± 2.9 (3-12)	8.2 ± 1.6 (5-10)	101.5 ± 27.8 (58-150)

TABLE II Duration of analgesia and onset time with no statistical significant differences, expressed as mean + SD; patients who required rescue analgesia

	Onset (min)	*Duration of analgesia (min)*	*Pts who needed analgesics*
Group B	13.1 ± 2.1 (9-17)	491.2 ± 291.9 (120-930)	8
Group R	11.7 ± 2.4 (7-15)	456.6 ± 247.6 (75-850)	6

and in duration. No differences were observed in the duration of postoperative analgesia. There was no motor block present at the end of surgery, probably due to the low concentration of the drugs.

In the present study we used a single injection of lumbar epidural anesthetic with either bupivacaine or ropivacaine, in concentrations, 0.25% and 0.2%, and found them to be equipotent for caudal analgesia. The onset time, duration of sensory blockade and time to first analgesic were compared in infants undergoing abdominal surgery. The complication rate was monitored to evaluate the safety of both drugs. When used at the caudal level for minor surgery, 1 $ml \cdot kg^{-1}$ bupivacaine 0.25% and ropivacaine 0.2% were equipotent.[5] Thus, the similar onset and duration in the present study of 0.7 $ml \cdot kg^{-1}$ ropivacaine 0.2% and bupivacaine 0.25% suggest that these doses are equipotent when given for lumbar epidural analgesia. Together with the previous results, which showed that in children ropivacaine seemed to be more potent than bupivacaine, the absence of major side effects and the minor toxicity of ropivacaine, we conclude that ropivacaine is effective and safe for pediatric regional anesthesia.

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