Ropivacaine 0.2% versus Bupivacaine 0.25% in para-umbilical block in children

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Comparaison de la Ropivacaïne 0,2 % à la Bupivacaïne 0,25 % dans le bloc para-ombilicale chez l'enfant

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RÉSUMÉ

Prérequis : Le bloc paraombilical, associé à une sédation représente actuellement la technique anesthésique de choix pour la cure de la hernie ombilicale chez l'enfant. La Ropivacaïne, malgré sa moindre toxicité cardiaque et neurologique, n'a pas été utilisée dans ce type de bloc.
But : Comparer la Ropivacaïne 0,2% à la Bupivacaïne 0,25% en matière d'analgésie pour herniorraphie ombilicale.
Méthodes : Etude prospective randomisée en double aveugle qui a inclus des enfants âgés de un à six ans, programmés pour herniorraphie ombilicale: paraombilical par côté : Ropivacaïne 0,2%: 0,2 ml.kg-1 (groupe GR), versus Bupivacaïne 0,25% : 0,2 ml.kg-1 (groupe GB).
Résultats : Soixante-quinze enfants ont été inclus dans cette étude (GR= 38; GB= 37). Les groupes étaient comparables de point de vue caractères démographiques et concernant les scores de « Children's Hospital of Eastern Ontario Pain Scale ». Nous n'avons pas noté de différence concernant le délai de la première demande analgésique. Les deux groupes étaient comparables de point de vue analgésie peropératoire. Aucune complication n'a été relevée dans cette étude.
Conclusion : La Ropivacaïne 0,2% est équivalente à la Bupivacaïne 0,25% en matière d'analgésie postopératoire et peropératoire à la dose de 0,2 ml.kg-1 de chaque côté dans le bloc paraombilical pour herniorraphie ombilicale.

Mots-clés
Hernie ombilicale, bloc paraombilical, Ropivacaïne, Bupivacaïne, tirage au sort

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SUMMARY

Background: Para-umbilical block was an old block that regains a new interest. No study was available using Ropivacaine in this block.
Aim: To compare quality of analgesia after using Ropivacaine 0.2% to Bupivacaine 0.25% in para-umbilical blocks.
Methods: In a prospective randomized double blind study we included one to six years old children, scheduled for umbilical herniorrhaphy. The children were randomized in two groups to receive in para-umbilical block by side: Ropivacaine 0.2%: 0.2 ml.kg-1 (group GR) or Bupivacaine 0.25%: 0.2 ml.kg-1 (group GB).
Results: The data of 75 children (GR= 38; GB= 37) were analyzed. The groups were comparable regarding the demographics' characters. The scores of Children's Hospital of Eastern Ontario Pain Scale in different postoperative times were comparable between the two groups. No difference was noted in the time of the first analgesic request. The two groups were comparable regarding the peroperative analgesia. No complication was recorded in this study.
Conclusion: Ropivacaine 0.2% is equivalent to the Bupivacaine 0.25% concerning postoperative and peroperative analgesia in the para-umbilical block for umbilical herniorrhaphy.

Key-words
Umbilical hernia; Para-umbilical block; Ropivacaine; Bupivacaine, randomized clinical trial

The techniques of loco regional anaesthesia are very used in paediatrics and are integrated in the control of per and postoperative pain (1). The practice of peripheral blocks is more used relatively to the central blocks (2, 3).
Since its efficiency, security and simplicity of realization, the para-umbilical block (PUB) associated with sedation represent the anaesthesic technique preferred for the repair of umbilical hernia in the child (4-6). Many anaesthesic solutions were used in this block, such the Bupivacaine (5, 7, 8).
The Ropivacaine, dated 10 years ago, has interesting properties that provide its enantiometric form S and its low liposolubility. Those properties which are a less cardio and neurotoxicity (9), associated to an ability to create a differential block with less motor block, and to its own vasoconstrictor effect, have motivated the authors to recommend its use on the first intention in children. No study in the literature that has used the Ropivacaine in the PUB in children was available.
The aim of our study was to compare the Ropivacaine 0.2% with the Bupivacaine 0.25 % in PUB under general anaesthesia concerning analgesia for the cure of umbilical hernia in the child.

MATERIAL AND METHODS

After the approval of the local ethics committee and a clear consent of the parents, we conducted a double blind, randomized prospective study in during 2008. We have included one to six years old children, ASA I or II, scheduled for elective surgery of umbilical hernia. Non-inclusion criteria were "full stomach" children; personal or family history of malignant hyperthermia; seizures; or epilepsy.
A pre anaesthesic consultation was performed to all the children at least 48 hours before the programming of the surgical act. During this consultation, the children and their parents were clearly informed of the nature and the course of the considered protocol.
The way and the timetable of the premedication's administration and also preoperative fasts' rules were explained to them.
The course of the general anaesthesia was standardized. The monitoring consists on the electro cardioscope, the measure of non invasive arterial pressure, the use oximeter of pulse, capnographe and gaz analysor. Induction was inhalatory using Sevoflurane at 6% concentrated added in an equimolar mixture of oxygen and nitrous oxide.
As soon as there is a loss of eyelash's reflex, we performed a venous tract followed by the administration of hydro-electrolytic inputs calculated according to the child's weight. The maintenance of anaesthesia was assured by the Sevoflurane 1MAC in an equimolar mixture of oxygen and nitrous oxide. No opioid analgesic was systematically administered during the surgery.
The PUB was carried out according to the technique described by Courreges [5]. The dose of the local anaesthesic is 0.2 ml.kg-1 by side. The regional anaesthesia was performed in sterile condition. The injection of the local anaesthesic was carried out by the following way: in each puncture point, needle was inserted in caudal direction with an incline of 60° relatively to the skin until a clear click indicated the crossing of the aponevrose of the big right muscle of the abdomen.
We inject the 3/4 of the anaesthesic solution fan-shaped under the aponevrose. The injection should be done without any resistance. We removed carefully the needle until the click indicates that it crossed again above the aponevrose.
We injected a fan-shaped of the last quarter of the anaesthesic solution. All the injections were carried out after an aspiration's test.
The children were randomized with a hazard table in two groups to receive in the PUB: Ropivacaine concentrated to 0.2%: 0.2 ml.kg-1 by side (group GR) or Bupivacaine concentrated to 0.25%: 0.2 ml.kg-1 by side (group GB). The syringe was prepared by anaesthesiologist different from who will perform the block and collect the data.
A painful stimulation was carried out in the operative site ten minutes after carrying out of PUB. In the absence of hemodynamic answer (increase of heart rate (HR) and/or of systolic arterial pressure (SAP) by more than 20% relatively to basic value collected after performing the PUB and before the incision), we authorize the surgeon to continue. In an opposite case, the surgeon was in demand to temporize again for five minutes. If this increase persists more than the supplementary five minutes, analgesia was carried out by the Fentanyl 2 micg.kg-1 for block's failure.
At the end of surgery, all children were brought to the post-anesthesia care unit (PACU). The children didn't systematically receive any analgesic. The quality of analgesia was assessed by the score of Children's Hospital of Eastern Ontario Pain Scale (CHEOPS). If the score was superior or equal to 7, the child receives 15 mg.kg-1 of paracetamol. If the pain persists during an hour, we administered 0.2 mg.kg-1 of nalbuphine.
From the sixth postoperative hour and out of any incident or complication, the exit authorization was delivered to parents.
Our principal criterion of judgment was the quality of postoperative analgesia. It was assessed by the time of the first analgesic request, total analgesic consumption and CHEOPS's score during the first six postoperative hours.
The quality of peroperative analgesia (judged by the values of HR and of SAP in different peroperative times), the quality of operative conditions, the incidence of undesirable effects and the complications were considered as secondary criterions of judgment.
The sample size was determined assuming that the probability of the efficiency of analgesia provided by the PUB at the second postoperative hour was 80% or more. We wanted to find a significant difference ($p< 0.05$) ($\alpha= 0.05$, one-tailed) with a power of 80% (, error= 0.2) to detect a difference of 19%. The sample size was calculated to be 37 children in each group. Were excluded children who failed regional anesthesia or received intravenous opioid analgesia (Fentanyl) during surgery. A number of excluded children less than 5% of the total study population were tolerated for the analysis of our results.
The statistical analysis was carried out with SPSS 15.0 software. Continuous variables were expressed as means and

standard deviations. The qualitative variables were expressed as a percentage (%). the Gaussian's distribution of quantitative variables was checked by the test of normality of Kolmogorov-Smirnov. We used the test t of student to compare the quantitative variables and the test Chi2 of Pearson and if it's appropriate, the test of Fisher to compare the qualitative variables. The threshold of signification was 0.05.

RESULTS

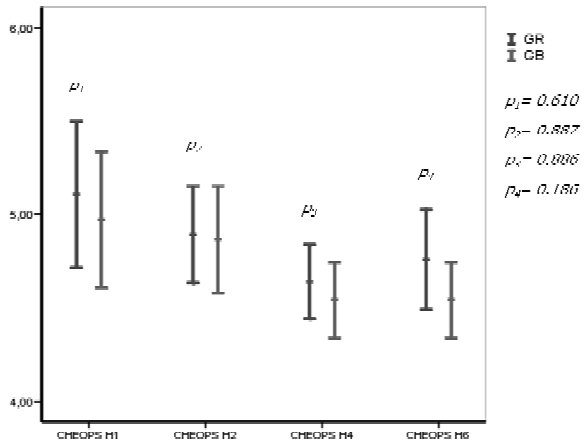
Seventy five children were included in this study (GR= 38; GB= 37). We haven't noted any case of block failure or opioid adjunction during surgery. The two groups were comparable according to demographic parameters, surgery duration and hemodynamic parameters collected in pre-induction and before the carrying out of PUB (Table 1).

Table 1 : Comparison of the two groups according to demographic parameters, surgery duration and hemodynamic parameters

	GR (n= 38)	GB (n= 37)	p
Age (months)	44 ± 14	46 ± 13	0.506
Sex-ratio	19/19	13/24	0.193
Weight (kg)	16.4 ± 3.4	17.9 ± 4.2	0.078
Average SAP (mmHg)			
Before induction	96 ± 13	98 ± 13	0.545
Before PUB	91 ± 12	90 ± 12	0.706
Average HR (min-1) Before induction	106 ± 26	114 ± 17	0.155
Before PUB	106 ± 18	104 ± 15	0.658
Surgical duration (min)	26 ± 16.7	23.3 ± 11.8	0.429

The scores of CHEOPS noted in different postoperative times were comparable between the two groups (Figure 1). 89.2% of children in two groups haven't necessities additional analgesic at the second postoperative hour.

Figure 1: Scores of CHEOPS according to groups



Nine children (12.2%) required the administration of paracetamol in the six postoperative hours, five children in the GR and four in the GB. The difference wasn't significant between groups. The mean time of the first analgesic request was comparable between the two groups (132 ± 130.1 min for the GR vs 75 ± 30 min for GB with p= 0.425). No child required the addition of nalbuphine in the two groups.

In the peroperative period, the SAP and the HR collected in different time were comparable between the two groups and we didn't notice a significant difference in their evolutions.

The rate of efficiency of the PUB was 94.7% in the GR and was 94.6% in the GB (p= 1) after ten minutes of carrying it out and it was 97.4% in the GR and was 100% in the GB after fifteen minutes. A child of GR had block's failure. The quality of muscular relaxation was judged good in 94.6% and there was no significant difference between the two groups.

During our study, we didn't notice any incident in relation with the PUB technique (hematoma, puncture of peritoneum...) and any cardiac or neurological complication in relation with the local anaesthesic used.

DISCUSSION

In our study, we compared the quality of analgesia after using Ropivacaine 0.2% to Bupivacaine 0.25% in the dose of 0.2 ml.kg-1 by each side in the PUB for the umbilical hernia repair. The efficiency of the analgesia provided by the PUB was comparable between the two groups in different postoperative times.

Many studies have compared the effects of the Ropivacaine 0.2% and of the Bupivacaine 0.25% in the central and peripheral blocks in children (10-16). They concluded Ropivacaine at that concentration of 0.2% procure analgesia and motor block comparable to Bupivacaine at 0.25% concentration. No study was found, comparing Ropivacaine 0.2% to Bupivacaine 0.25% in the PUB.

The analgesia provided by the PUB on the second postoperative hour was satisfying in 89.2% of children in the two groups. This rate is comparable in the literature's data. Clarke and Cassey (8), by comparing the effects of the PUB relatively to a local infiltration in 40 children scheduled for an umbilical hernia repair, demonstrated that in the PUB group, carried out with the Bupivacaine 0.25% at the dose of 0.4 ml.kg-1 by each side, 80% of children haven't necessities supplement analgesia at the second postoperative hour.

The scores of CHEOPS noted in different postoperative times were comparable between the two groups. During the first six postoperative hours, five children of GR and four of GB had a score of CHEOPS superior or equal to 7 and required the administration of paracetamol without addition of nalbuphine. The mean time of the first analgesic request of the five children for GR was 132 ± 130 min whereas it was 75 ± 30 min in the four children for GB. These differences were not significant. This time of the first analgesic request is comparable to those found in the studies taking an interest to the trunk's block. In the study of Dalens (17), the time of the first analgesic request of

the Ropivacaine 0.5% on the dose of 0.6 ml.kg-1 after ilio-inguinal ilio-hypogastric block was 90 minutes.

However, the mean time of the first analgesic request could be longer with increase doses. Thus, Pettersson and al. (18) have compared two doses (300 and 375 mg) of Ropivacaine 0.75% for a postoperative analgesia by an infiltration in the surgical site after inguinal hernia repair in the adult. The average time of the first analgesic request was 336 minutes in the group 300 mg and 456 minutes in the group 375 mg. Those doses, related to the weight of children, are very high and they cannot be used.

Few studies compared the Ropivacaine with the Bupivacaine according to peroperative analgesia and the results are contradictory (11, 13). In our study, the anaesthesia protocol was respected in the two groups, the maintenance was provided by Sevoflurane 1MAC in an equimolar mixture of oxygen and nitrous oxide without need to increase the inspired fraction of Sevoflurane in one of the two groups. The hemodynamic parameters chosen as indicator of the quality of peroperative analgesia were comparable between the two groups. According to our results, the Ropivacaine 0.2% is equivalent to the Bupivacaine 0.25% concerning peroperative analgesia on the dose 0.2 ml.kg-1 by each side in the PUB for umbilical hernia repair.

However, the disadvantage of the PUB is that it requires many injections with a risk of failure in some cases in relation with an unavoidable anatomic variation. In our study, a child had a PUB's failure. Knowing that the echo-guidance allowed to reduce the number of punctures and the time of carrying out of peripheral blocks in adults (19), the carrying out of the echo-guidance of the PUB could make up for this failure. It allows ameliorating the performance of this block with the decrease of the total dose of the local injected anaesthesic. It also allows the decrease of the incidence of complications knowing that the loco regional anaesthesia was done under sedation in children (20).

CONCLUSION

The results of our study demonstrate the equivalence of the Ropivacaine 0.2% to the Bupivacaine 0.25% concerning postoperative and peroperative analgesia in the dose of 0.2 ml.kg-1 by each side in the PUB for the umbilical hernia repair.

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