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Extradural ropivacaine and bupivacaine in hip surgery

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Summary

We studied 126 patients undergoing elective hip surgery; they received 20 ml of 0.5%, 0.75%, 1.0% ropivacaine or 0.5% bupivacaine extradurally in a double-blind design. Sensory block (pinprick), motor block (modified Bromage scale), quality of analgesia and neuromuscular block were assessed intermittently. Heart rate and arterial pressure were measured at regular intervals. A total of 115 patients were evaluated for efficacy. Onset of analgesia, onset of motor block and maximum cephalad spread (T4) did not differ between the groups. Duration and quality of analgesia and motor block increased with the concentration of ropivacaine. Ropivacaine 1.0% provided a longer duration of analgesia and motor block, more intense motor block and more patients with satisfactory analgesia than 0.5% bupivacaine. More patients treated with the higher concentrations of ropivacaine required treatment for hypotension and bradycardia. (*Br. J. Anaesth.* 1995; 74: 458–460)

Key words

Anaesthetic techniques, extradural. Anaesthetics local, bupivacaine. Anaesthetics local, ropivacaine. Surgery, orthopaedic.

Ropivacaine is an amide-type local anaesthetic agent with a structure similar to that of bupivacaine and mepivacaine. It is prepared as the pure *s*-enantiomer of 1-propyl-2',6'-piperidino-xylylidide. It has been shown in animals [1] and humans [2] that the effects of ropivacaine on the central nervous system and heart are less toxic than those of bupivacaine. Previous clinical studies have indicated that the anaesthetic properties of ropivacaine and bupivacaine are similar, although ropivacaine produces less intense motor block [3]. The intensity of motor block varies with the concentration of ropivacaine [4–6].

Until now there have been no data on the clinical efficacy of extradural ropivacaine in patients undergoing elective hip surgery. Most of these patients are elderly with physiological responses that affect responses to extradural anaesthesia. The present study is a dose-finding study and was undertaken to establish the dose-response relationship for the duration of analgesia and motor block, and to assess the clinical efficacy of ropivacaine when used in extradural anaesthesia for hip surgery in 0.5%, 0.75% and 1.0% solutions. Bupivacaine 0.5% served as a control.

Methods and results

This randomized, double-blind, prospective, multi-centre study was performed in accordance with the principles of the Declaration of Helsinki. It was approved by the Ethics Committees of all participating centres. ASA I and II patients undergoing elective total hip replacement or hip arthroplasty gave informed consent to participate. The inclusion criteria were age between 18 and 80 yr, weight between 50 and 100 kg and height at least 1.50 m. Patients were allocated randomly to four parallel treatment groups to receive either 20 ml of 0.5%, 0.75%, 1% ropivacaine or 0.5% bupivacaine. The solutions were manufactured by Astra Pain Control AB (Södertälje, Sweden).

Premedication comprised diazepam 5–15 mg orally. All patients had an extradural catheter inserted at the L2–3 or L3–4 interspace. Three minutes after the test dose (4 ml of the study drug) the main dose of 16 ml was administered in incremental doses over 3 min. All assessments were made at 5, 10, 15, 20 and 30 min after the end of injection. Thereafter sensory (pinprick) and motor block (modified Bromage scale) were assessed at 30-min intervals, where possible, and then hourly until they disappeared. Quality of analgesia and neuromuscular block were assessed by the anaesthetist and surgeon at the end of operation as satisfactory, satisfactory until a specified time, unsatisfactory or not applicable. Heart rate, systolic and diastolic arterial pressures and ECG were recorded throughout surgery. Treatment for hypotension and bradycardia consisted of ephedrine 5 mg and atropine 0.5 mg i.v., repeated if necessary.

The results were analysed by analysis of covariance and the hypothesis of equal treatment effects in the three ropivacaine groups was tested against the hypothesis of a monotonous dose-response relationship by the Mantel-Haenszel test. Pairwise comparisons were performed between the three ropivacaine groups and the 0.5% bupivacaine group.

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Table 1 Sensory block and motor block in the four groups (mean (SD) or number). Dose-dependent for ropivacaine: ¹ $P = 0.0030$; ² $P = 0.0014$; ³ $P = 0.0001$; ⁴ $P < 0.05$; ⁵ $P = 0.0006$; ⁶ $P = 0.0167$; ⁷ $P = 0.0465$.
* Statistically significant difference (see P values). † Satisfactory until a specified time

	Ropivacaine			Bupivacaine	P
	0.5 % ($n = 29$)	0.75 % ($n = 29$)	1.0 % ($n = 29$)	0.5 % ($n = 28$)	
Duration of analgesia (h)					
S3 ¹	4.6 (1.5)	5.2 (1.9)	6.5 (2.4)	5.2 (2.2)	
L1 ²	4.5 (1.8)	5.7 (2.5)	6.9 (2.6)*	5.0 (2.7)*	0.00975
T10 ³	3.5 (1.7)	4.5 (1.9)	5.9 (2.3)*	4.3 (1.9)*	0.01598
Regression time to T12 ⁴	4.3 (1.7)	5.3 (2.2)	6.9 (2.4)*	4.8 (2.4)*	0.00381
Quality of analgesia (No.)					
Satisfactory	19/29	22/29	25/29*	19/28*	0.0023
Satisfactory until†	4/29	4/29	1/29	3/28	
Frequency of motor block (No.)					
Degree 1	21/28	24/29	25/29	22/28	
Degree 2	7/26	13/28	21/29	14/27	
Degree 3	3/25	7/28	16/28	8/27	
Duration of motor block (h)					
Degree 1 ⁵	3.0 (1.4)	3.1 (1.3)	4.6 (1.5)*	3.3 (1.4)*	0.00844
Degree 2 ⁶	2.7 (1.2)	2.6 (1.2)	3.7 (1.4)*	2.8 (1.0)*	0.03821
Degree 3 ⁷	1.7 (0.5)	2.7 (1.2)	3.4 (1.5)*	2.1 (0.9)*	0.04955
Quality of block (No.)					
Satisfactory	22/29	23/29	25/29	19/28	
Satisfactory until†	0/29	3/29	1/29	3/28	

$P = 0.05$ was considered statistically significant. All data are expressed as mean (SD) unless indicated otherwise.

A total of 115 out of 126 patients were evaluated for efficacy. Apart from an overall predominance of females, patient characteristics did not differ between the four groups. Mean age was 60–65 yr for all groups.

The onset times of analgesia appropriate for surgery (T10–S3) were largely less than 30 min and were not statistically different. The median cephalad dermatomal level of analgesia was T4 for all groups. Extradural 0.5 % ropivacaine and 0.5 % bupivacaine were indistinguishable. Increasing the concentration of ropivacaine gave a longer duration of anaesthesia, a greater degree and longer duration of motor block and also more patients with satisfactory analgesia. Ropivacaine 1.0 % provided a longer duration of analgesia and motor block, a more intense motor block and more patients with satisfactory analgesia and neuromuscular block than 0.5 % bupivacaine.

The number of patients who required additional anaesthesia was highest in the 0.5 % ropivacaine and 0.5 % bupivacaine groups (five patients each), compared with two patients each in the 0.75 % and 1.0 % ropivacaine groups. In 11 patients analgesia was adequate until a specified time (table 1). In most of these patients pain occurred when the surgeon started hammering the shaft of the femur to enlarge it for the hip prosthesis. In some patients, this was also the moment when satisfactory neuromuscular block changed to unsatisfactory. I.v. opioids were effective in providing analgesia in these patients. The use of concomitant opioids and sedatives was similar in all treatment groups.

Systolic and diastolic arterial pressures decreased in all groups. Treatment with ephedrine or atropine was required more often in the 0.75 % ropivacaine

group (21 of 30 and 14 of 30 patients, respectively) and in the 1 % ropivacaine group (29 of 29 and 9 of 29 patients) compared with the 0.5 % ropivacaine group (14 of 29 and 8 of 29 patients) and the 0.5 % bupivacaine group (17 of 28 and 7 of 28 patients).

Adverse events were mostly of mild or moderate intensity and almost equally distributed between the groups. The most common adverse events were paraesthesiae in one of the legs when the extradural catheter was inserted (14 patients) and nausea (10 patients). All patients recovered without sequelae.

Comment

The concentration dependent efficacy of ropivacaine noted in this study is in agreement with results reported elsewhere [3, 4–6]. However, this is the first study to test ropivacaine in a large patient group with a mean age greater than 60 yr undergoing hip surgery. In our study 1.0 % ropivacaine provided satisfactory anaesthesia most often without unacceptable side effects. The high concentration is responsible for the superior clinical efficacy; the use of this concentration is feasible because of the relative low toxicity of ropivacaine [1, 2]. Taking into consideration the high median cephalad level of analgesia (T4) and the frequent requirement for vasopressors and anticholinergics, a smaller volume than 20 ml would probably result in adequate analgesia and less hypotension and bradycardia. Further studies are needed to evaluate volume–concentration relationships in older patients undergoing hip surgery in order to define the optimum dose.

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