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Short communication

Local infiltration anaesthesia with ropivacaine 0.5% for excision of benign naevi

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Abstract

Ropivacaine is a new type of long-acting local anaesthetic of less systemic toxicity than bupivacaine. The objective of this double-blind study was to compare the efficacy and safety of ropivacaine 0.5% and mepivacaine 1% for infiltration anaesthesia in dermatologic surgery. Sixty out-patients aged 18–65 years, scheduled for excision of a benign naevus on the back, were randomly assigned to infiltration anaesthesia with either ropivacaine or mepivacaine. Both agents had a fast onset, and provided reliable anaesthesia and painfree surgery which could be carried out without the use of vasoconstrictive adjuncts or diathermy. Ropivacaine resulted in a longer duration of analgesia than mepivacaine, and both treatments were well tolerated.

Keywords: Ambulatory surgery; Local anaesthetic; Infiltration; Mepivacaine; Ropivacaine

1. Introduction

Ropivacaine, a new long-acting amide local anaesthetic (LA), is a homologue to the already clinically used local anaesthetics, mepivacaine and bupivacaine. Ropivacaine is unique in being the first LA to be introduced as the pure S-enantiomer, whereas its homologues are racemates. Both preclinical and clinical studies have shown that ropivacaine is similar to bupivacaine in onset and duration of sensory block, while its motor blockade is less pronounced and of shorter duration [1]. It has also been shown that ropivacaine has a lower CNS and cardiac toxicity than bupivacaine [2]. Several clinical studies have demonstrated ropivacaine's suitability for epidural and peripheral nerve blockade in surgery [3,4], as well as for per- and postoperative infiltration in postoperative pain management after various abdominal surgical procedures [5].

Ropivacaine has previously not been used for infiltration anaesthesia in minor dermatologic surgery. In the present study, ropivacaine's suitability as a dermal infiltration anaesthetic agent for minor skin surgery was evaluated.

2. Material and methods

Sixty patients (29 males and 31 females, aged between 18–65 years) were scheduled for ambulatory excision of a single, benign naevus (5–15 mm in diameter) located on the back. Each patient's medical history was obtained and standard physical examination was carried out prior to inclusion in the study. The patients were randomly assigned to either of two parallel groups of 30 patients each for a double-blind comparison of ropivacaine 0.5% and mepivacaine 1.0% when used for intra- and subcutaneous infiltration anaesthesia. 1–5 ml of the study solution were infiltrated before surgery, which started when adequate analgesia was established according to pin-prick testing, performed every 10 s after the end of the infiltration. Additional injection of

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local anaesthetic could be given as needed during surgery.

Time of onset of analgesia was recorded, and the patients were asked to note the time for début of discomfort or pain in the wound area after surgery in order to assess the duration of analgesia.

Pain during the injection of the study drugs and during surgery was estimated by the patients with the aid of a visual analogue scale (VAS) where 0 = no pain, and 100 = worst imaginable pain. The skin colour of the injected area was also assessed, as was the need for haemostatic action during surgery. The overall quality of treatment was judged by the investigator at the end of the surgery. At the follow-up visit approximately 2 weeks after surgery, wound healing was checked and the wounds inspected for signs of complications.

Before discharge from the hospital and at the follow-up visit, the patients were interviewed for adverse events in a standardized way.

Wilcoxon's rank sum test and Fisher's exact test were used as statistical methods. Each test was two-tailed and performed at a significance level of 0.05.

3. Results

The mean dose of ropivacaine 0,5% administered was 2.1 ml (11 mg) (range 1–4 ml) and mepivacaine 1%, 1.8 ml (18 mg) (range 1–3 ml). Onset of analgesia was immediate in all patients but two: one patient in the ropivacaine group had a time to onset of 35 s, the other, anaesthetized with mepivacaine, had a time to onset of 5 s.

The pain scores during the injections were low in both groups. Median VAS score during the injection was 14.5 (range 1–61) mm in the ropivacaine group and 6 (range 0–56) mm in the mepivacaine group; this difference was not significantly different. Four patients (13%) in the ropivacaine group and five patients (17%) in the mepivacaine group had VAS scores above 30. After injection, the local skin colour changed in two ropivacaine-treated (pale and red, respectively) and three mepivacaine-treated patients (pale, pink and red, respectively).

The duration of surgery was short, 2–8 min, and no additional infiltration was needed during surgery. There was no pain at all (VAS score = 0) during the surgical procedure in 56 out of 60 patients. Two patients had a VAS scores of 11 mm and 24 mm, respectively, both in the ropivacaine group. In the mepivacaine group, VAS measured 1 mm and 4 mm, respectively, for two patients. There was no difference in peroperative bleeding between the groups. One patient in each treatment group needed diathermy for haemostasis. The mean duration of analgesia was 3.1 ± S.D. 2.8 h in the ropivacaine group, compared to 2.2 ± S.D. 1.9 h in the mepivacaine group; this difference was not statistically significant.

Wound healing was normal in all patients and the quality of treatment was considered as excellent in all patients.

Five patients in the ropivacaine group and three in the mepivacaine group reported mild adverse events mostly of short duration, e.g. vertigo, nausea, or postoperative burning and itching in the wound area. None of these was considered to be related to the tested local anaesthetics. There were no serious adverse events.

4. Discussion

Excision of a benign naevus is one of the most frequent surgical procedures performed on adult outpatients where solely a local anaesthetic is used. Mepivacaine 10 mg/ml is a drug commonly used for dermal infiltration for this type of surgery. Addition of epinephrine 5 μg/ml is often used to prolong the duration of action and for haemostatic reasons [6]. However, this combination is often more painful at injection than when the plain solution is used, partly due to its lower pH [7].

Ropivacaine is a new long-acting local anaesthetic belonging to the same homologue series of compounds as bupivacaine and mepivacaine. Ropivacaine has a pH of 4.0–6.0 and pharmacodynamic and pharmacokinetic properties resembling those of bupivacaine but with less central nervous and cardiovascular toxicity [1,2]. No data has previously been available concerning the efficacy of ropivacaine for infiltration anaesthesia for minor surgery.

This study of infiltration anaesthesia showed that the overall quality of treatment was excellent with both ropivacaine and mepivacaine. The time of onset of analgesia was immediate in all patients. Pain was minimal during injection and surgery as assessed using a visual analogue scale. There were no haemostatic problems during surgery and diathermy equipment had to be used only once in each group. The duration of analgesia was longer for ropivacaine, although the difference was not statistically significant, probably due to the relatively large variation in duration and the limited number of patients.

In conclusion, for excision of cutaneous naevi, infiltration with ropivacaine 0,5% provided excellent and reliable analgesia with rapid onset and a clinically longer duration of anaesthesia than that of mepivacaine 1%. Ropivacaine seems to be an interesting alternative for minor surgery of longer duration where a local anaesthetic without epinephrine is preferred.

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