

Postoperative pain relief and recovery with ropivacaine infiltration after inguinal hernia repair

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Abstract

The purpose of this study was to assess the analgesic effects of wound infiltration with 300 mg ropivacaine. A total of 77 inpatients scheduled for inguinal hernia repair were randomized, to receive postoperative local infiltration with 40 ml ropivacaine 7.5 mg/ml or placebo. Wound pain, consumption of analgesics and time when patients were fit for discharge were assessed. Pain scores upon mobilization and coughing were significantly lower in the ropivacaine group over 0–24 h. At rest, this difference was noted until 12 h. The mean time to the first request for analgesics was significantly longer in the ropivacaine group. The consumption of analgesics was comparable. The median time when patients were fit for discharge occurred significantly earlier in the ropivacaine group. Wound infiltration with ropivacaine after inguinal hernia repair results in lower postoperative pain scores, delays the requirement for additional analgesics, and allows earlier patient discharge. © 1998 Published by Elsevier Science B.V. All rights reserved.

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1. Introduction

Wound infiltration with local anaesthetics has been shown to be a simple and effective procedure for postoperative pain relief after inguinal hernia repair [1,2]. However, the need for the use of large volumes and the constraint of a 150 mg bupivacaine maximum dose, allow a relatively short lasting effect [3,4].

Ropivacaine is a new long acting local anaesthetic, structurally closely related to bupivacaine. It is the first enantiomerically pure local anaesthetic, and exists as the *S*-enantiomer [5]. Ropivacaine exhibits less central nervous system and cardiovascular toxicity than bupivacaine in healthy volunteers [6,7].

Because the duration of action of local anaesthetics is dose dependent, ropivacaine may provide long-acting analgesia following wound infiltration as a higher dose can be used. Until now, doses up to 200 mg ropivacaine infiltration have been evaluated for pain relief after

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inguinal hernia repair [8–10]. These studies demonstrated a dose-related analgesic efficacy and significant pain relief for 6 h with 200 mg.

This study investigated the analgesic efficacy obtained after infiltration with 300 mg ropivacaine for inpatients undergoing inguinal hernia repair under general anaesthesia. Furthermore, postoperative recovery and criteria for discharge from hospital were assessed in order to investigate if infiltration with ropivacaine could reduce postoperative morbidity and the length of hospital stay.

2. Methods

This study was designed as a parallel, randomized, double blind, controlled, eight centres trial with two treatment groups.

After Ethical Committee approval and written informed consent, 77 adult, male inpatients, ASA group I–III, scheduled for open primary elective inguinal hernia repair under general anaesthesia were included in the study.

Patients received hydroxyzine or a benzodiazepine as premedication. Surgery was performed under general anaesthesia: propofol, fentanyl (3 µg/kg), and muscle relaxant were given for the induction; for maintenance, nitrous oxide–oxygen, inhaled anaesthetic agent, and muscle relaxant were administered. Reinjections of fentanyl were not allowed during maintenance. Patients were randomized to receive either 40 ml ropivacaine 7.5 mg/ml (300 mg) or 40 ml placebo (sodium chloride solution). At the conclusion of surgery, the solution was infiltrated as follows: before wound closure, 2 ml in the region of the ilioinguinal nerve, 6 ml around the neck of the hernia sac and 12 ml into the muscular layers; before or after wound closure, 20 ml into the subcutis and cutis. The surgical procedure was a MacVay or a Shouldice repair. For postoperative analgesic therapy, propacetamol IV (8 g/24 h) and/or oral paracetamol 500 mg–codeine 30 mg (6 tablets/24 h) were administered at the request of the patient.

Postoperative wound pain was assessed during the first 24 h after infiltration, on a visual analogue scale (VAS: 0 = no pain, 10 = worst pain) at rest, upon coughing, and during mobilization from supine to sitting position. The time when patients were fit for discharge from hospital was assessed using five criteria: ((1) vital signs; (2) activity and mental status; (3) pain, nausea and vomiting; (4) surgical bleeding; (5) per os fluids and defecation) quoted 0, 1 or 2. Patients scoring ³ 9 were considered fit for discharge. A questionnaire using a seven-item score (none, minor, mild, moderate, quite severe, severe, very severe), evaluated postoperative recovery in terms of the degree to which patients were bothered by difficulty in concentrating, difficulty in urinating, by pain when moving around, by a poor appetite and by nausea.

Table 1
Patients characteristics

	Ropivacaine <i>n</i> = 37	Placebo <i>n</i> = 40
Age (years)	55.7 ± 2.7	51.1 ± 2.6
ASA group I/II/III	21/15/1	26/12/2
Weight (kg)	73.6 ± 1.6	72.9 ± 1.6
Duration of surgery (min)	49.5 ± 3.2	52.4 ± 3.2

Values shown are means ± S.E.M.

Adverse events observed by the staff or reported spontaneously by the patient were recorded during hospitalization. For statistical analysis, stratified Wilcoxon rank sum test was used for pain scores, time to the first request and total consumption of additional analgesics. Pain scores were expressed as area under the curve (AUC) divided by time period. A survival analysis was used for time when patients were fit for discharge from hospital. *p* < 0.05 was considered significant. The last value carried forward to missing principle was utilized.

3. Results

A total of 77 patients were randomized (ropivacaine *n* = 37, placebo *n* = 40). There were no significant differences between groups with respect to demographic characteristics and duration of surgery (Table 1).

Pain scores over time upon coughing, during mobilization and at rest were lower in the ropivacaine group compared to the placebo group (Figs. 1–3). The area under the curve (AUC) divided by time for pain scores was significantly lower in the ropivacaine group over 0–24 h upon coughing and during mobilization, and over 0–12 h at rest (Table 2).

Table 2
Median AUC divided by time for pain scores (cm)

	Ropivacaine	Placebo
Mobilization		
0–4 H	1.37*	3.91
0–8 H	1.78*	4.46
0–12 H	1.92*	4.07
0–24 H	2.07*	3.82
Coughing		
0–4 H	1.69*	4.26
0–8 H	1.91*	4.83
0–12 H	2.06*	4.87
0–24 H	2.45*	4.25
Rest		
0–4 H	0.75*	2.66
0–8 H	0.94*	2.29
0–12 H	1.10*	2.12
0–24 H	1.16	1.62

* *p* < 0.05 compared with placebo.

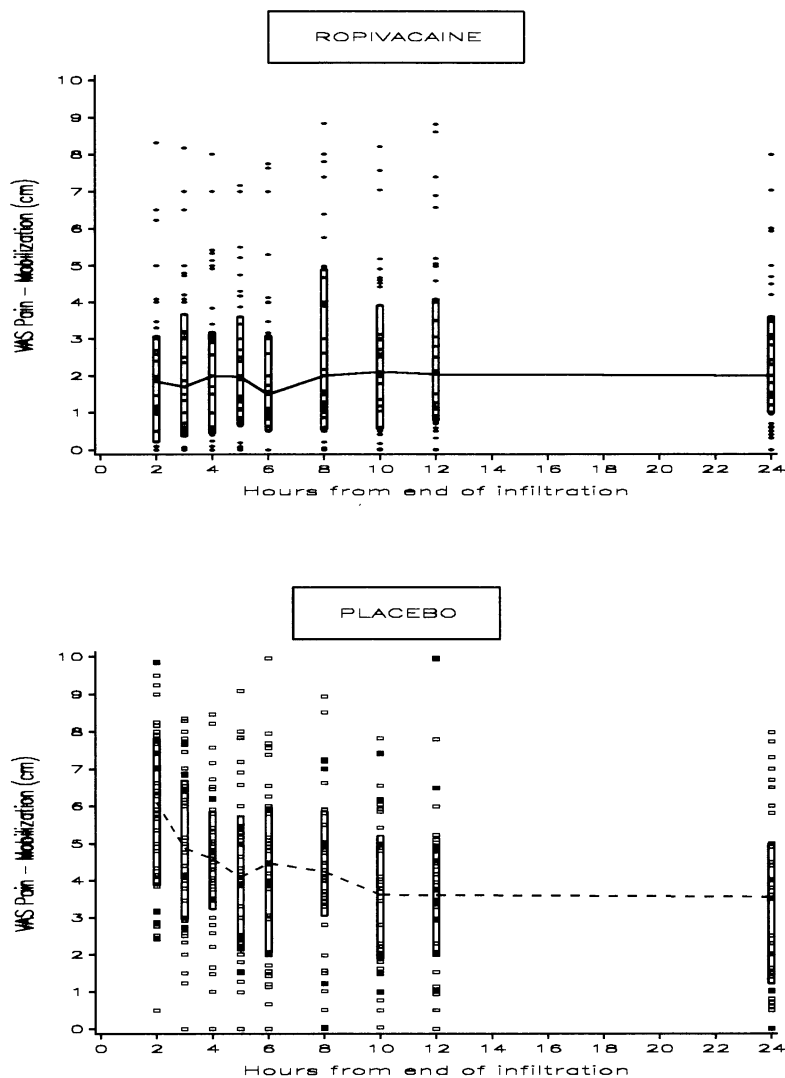


Fig. 1. Pain scores during mobilization over the 24-h postoperative period. Individual values and box plots (Q1, median, Q3), median scores connected.

A total of 31 patients in the ropivacaine group and 36 patients in the placebo group received postoperative analgesics with propacetamol and/or paracetamol-codeine, without significant difference between the two groups regarding the amount of analgesics. The mean time to the first request for analgesics was significantly longer in the ropivacaine group (7.7 h) compared to the placebo group (1.8 h) ($p < 0.05$). Four patients in the ropivacaine group and 13 patients in the placebo group required at least once an analgesic other than propacetamol or paracetamol-codeine due to insufficient pain relief.

A total of 31 patients in the ropivacaine group and 30 patients in the placebo group reached the criteria for discharge (score ≤ 9) at 24 h. The median time when patients were deemed ready for discharge occurred significantly earlier in the ropivacaine group (10 h) compared to the placebo group (24 h) ($p < 0.05$) (Fig. 4). The actual mean duration of stay in hospital was

similar between the two groups: 3.76 days in the ropivacaine patients and 3.25 days in the placebo patients.

The postoperative questionnaire did not show major differences for patients' distress due to difficulty in concentrating and urinating, poor appetite and nausea. Pain when moving around was found to bother more patients in the placebo group, especially during the first six postoperative hours; 16, 18, 11% of the ropivacaine patients experienced moderate to very severe discomfort due to pain when moving around, compared to 74, 55, 50% of the placebo patients at 2, 4, 6 h postoperatively.

From 8 h, the proportion of the ropivacaine patients bothered by moderate to very severe discomfort increased slightly (26–36%), but was still less than in the placebo group (36–45%).

The frequency of adverse events was similar in the two treatments groups. The most common adverse event was bradycardia at the time of induction of general anaesthesia or during surgery. Three postopera-

tive wound haematomas of mild intensity were reported in the ropivacaine group, and none in the placebo group.

4. Discussion

The results of this study confirm the efficacy of ropivacaine infiltration in preventing postoperative pain after inguinal hernia repair. At a dosage of 300 mg, a significant effect on pain during mobilization and coughing was observed during the 24 h postoperative study period. Previous studies using lower amounts of ropivacaine failed to demonstrate such a long period of postoperative analgesia. Johansson et al. [9] using 200 mg of ropivacaine preoperatively demonstrated a dose-dependent analgesia limited to 6 h postoperatively, regarding pain during mobilization. Mulroy et al. [10]

showed a significant dose-related reduction in postoperative pain after inguinal hernia repair when comparing 37.5, 75 and 150 mg of ropivacaine. The longer postoperative analgesia found in our study is probably due to the higher dose of ropivacaine infiltrated (300 mg). Potency of bupivacaine and ropivacaine is similar. Indeed, Erichsen et al. [8] showed that wound infiltration after hernia repair using 100 mg of either ropivacaine or bupivacaine yielded similar pain scores at rest, upon coughing or during mobilization. However, the greater safety of ropivacaine regarding cardiac toxicity, enables the physician to prolong postoperative analgesia by increasing the dose without jeopardizing the patient. This represents the major advantage of preferring ropivacaine to the older bupivacaine drug during wound infiltration.

Many studies have indicated a beneficial effect of adding local anaesthetics, either as topical [11] or as

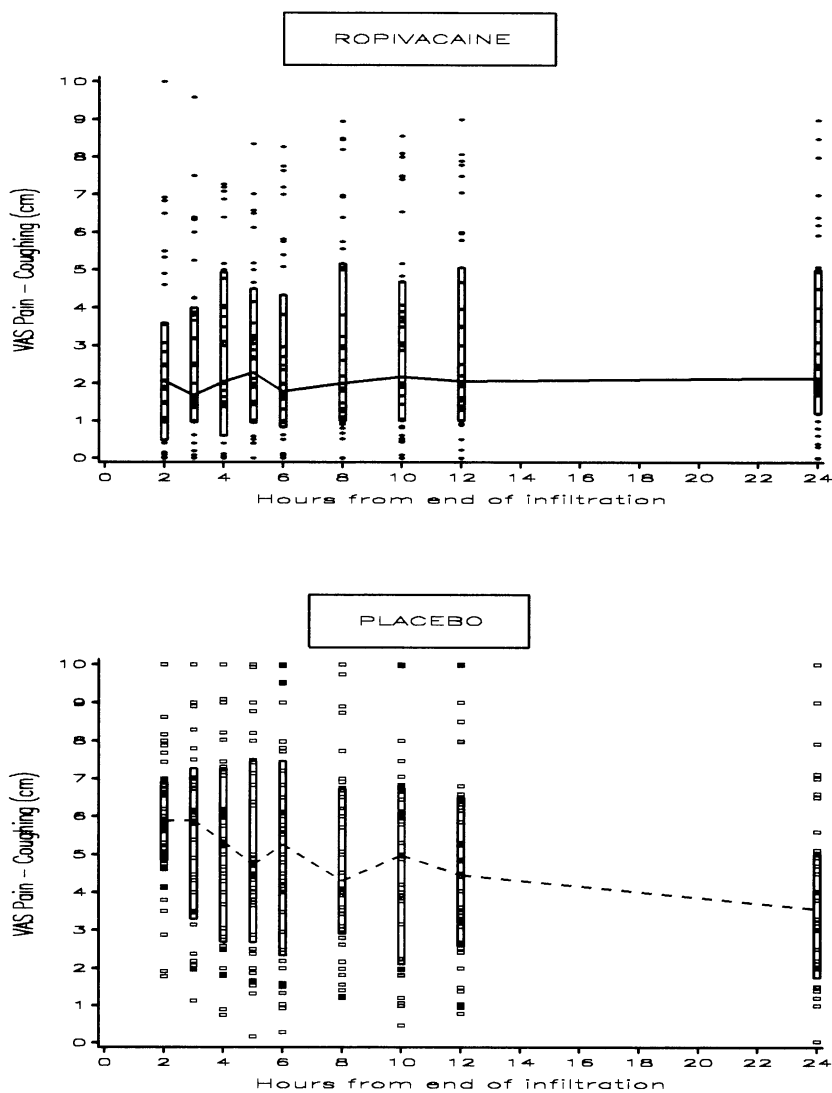


Fig. 2. Evolution of pain scores at rest (VAS) over the 24-h postoperative period. Individual values and box plots (Q1, median, Q3), median scores connected.

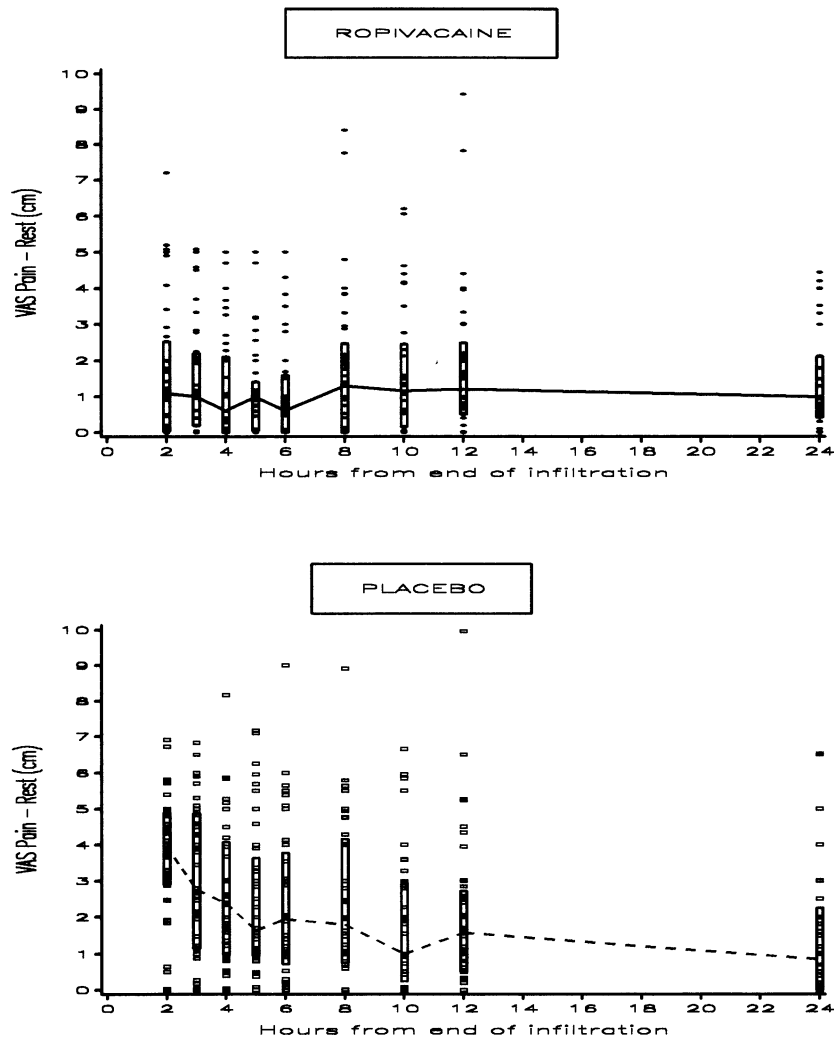


Fig. 3. Evolution of pain scores at rest (VAS) over the 24-h postoperative period. Individual values and box plots (Q1, median, Q3), median scores connected.

infiltration in the surgical layers [12], in reducing postoperative pain after inguinal hernia repair. Furthermore, Johansson et al. [13] showed that preoperative wound infiltration with ropivacaine before open cholecystectomy was followed by a significant dose-related decrease in wound pain during mobilization lasting only 6 h. This short lasting analgesia after cholecystectomy is probably due to the longer and stronger postoperative pain patterns after open cholecystectomy when compared to inguinal hernia repair.

The influence of ropivacaine on postoperative recovery is difficult to assess. It seems that ropivacaine infiltration had no influence on nausea, poor appetite, difficulty in concentrating and urinating. This may be due to the fact that all patients received comparable depths of general anaesthesia i.e., amounts of hypnotics and opioids, because infiltration was done at the end of surgery. We speculate that if the infiltration was performed before the surgical incision, patients in the ropivacaine group may have required less general

anaesthetic, than patients in the placebo group, and in this setting, patients in the former group would probably have less discomfort during postoperative recovery. Another alternative would be to operate on these patients under spinal anaesthesia followed by infiltration at the end of the procedure.

Ambulatory surgery represents nearly 30% of all procedures in France which is obviously insufficient when compared to other European countries or to the United States. The French legislation as well as the absence of an optimal incentive system to encourage ambulatory surgery in this country explain the relative lack of enthusiasm for ambulatory surgery. Although our study population consisted of only inpatients, this surgical procedure is performed on an outpatient basis in many institutions. Indeed, such an orientation toward outpatient surgery should be encouraged since advantages clearly outweigh risks: less separation from home, reduced health care costs, limited postoperative nursing. However, pain control as well as nausea and

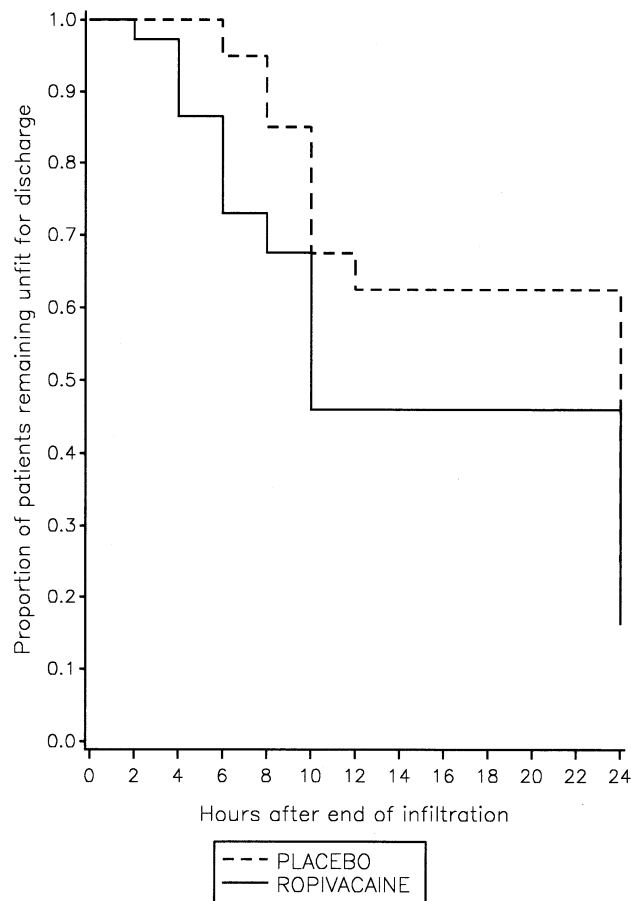


Fig. 4. Time when patients are fit for discharge.

vomiting control should be prompt and reliable, otherwise unplanned postoperative admissions to the hospital should be expected. Despite an identical duration of stay in hospital between both groups, the theoretical time when patients were fit for discharge occurred significantly earlier in the ropivacaine group (10 h) compared to the placebo group (24 h).

Thus, patients given ropivacaine wound infiltration experienced significantly less postoperative pain, were less bothered by pain when moving around postoperatively and finally met criteria for discharge earlier. If we intended to discharge patients fulfilling these criteria at the 8-h hour postoperatively, we would find that 32% of patients in the ropivacaine group and only 15% in the placebo group would have been discharged. This difference of 17% in patient discharge, when correlated to the number of these procedures performed annually and to the cost of an extra day stay at the ward, represents a

significant economical benefit for institutions. All these clinical, humanistic and economical benefits of ropivacaine infiltration outweigh the cost of the drug and the limited extra-time required to perform this simple technique.

In conclusion, wound infiltration with 300 mg of ropivacaine after inguinal hernia repair is safe and effective in reducing postoperative pain scores at mobilization, coughing and rest. This reduction is observed during the 24-h postoperative period, delaying the need for additional analgesics and allowing early patient discharge from hospital.

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