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A comparison of patient-controlled subacromial and i.v. analgesia after open acromioplasty surgery

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Background. The aim of this study was to compare three patient-controlled analgesia (PCA) techniques for pain relief after acromioplasty. These techniques included use of subacromial ropivacaine, subacromial fentanyl or i.v. fentanyl.

Methods. Forty-eight patients scheduled for open acromioplasty surgery were prospectively randomized to receive ropivacaine 0.2% (Group R) or fentanyl 4 $\mu g\ ml^{-1}$ (Group F) for subacromial analgesia, or fentanyl 4 $\mu g\ ml^{-1}$ (Group C) for i.v. analgesia. All patients received background infusion at a rate of 5 ml h^{-1} plus a PCA bolus dose of 3 ml with a lockout time of 20 min. In addition, rescue analgesia with tramadol 50–100 mg i.v. was available on demand. Pain relief was regularly assessed using a visual analogue scale (0–10 cm) and side-effects were noted.

Results. The postoperative pain scores at 2, 4, 6 and 12 h after the start of PCA were higher in Group F compared with Group R and Group C ($P<0.001$), However, the pain scores at the other time points were similar between the three groups. Pain scores, incremental dose requested and received, total volume of analgesic solution infused and rescue tramadol were similar between Group R and Group C. Specific side-effects were similar in the three groups.

Conclusion. The PCA techniques using subacromial ropivacaine or fentanyl i.v. provided similar and adequate pain relief and minimal side-effects after open acromioplasty surgery. The PCA using subacromial fentanyl was not as effective as either subacromial ropivacaine or i.v. fentanyl.

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Adequate pain relief after shoulder surgery is necessary both for the comfort of the patients and for an early use of rehabilitation exercise. The management of acute postoperative pain after shoulder surgery has been performed using local injection of analgesics into the subacromial bursa,[1 2] i.v. patient-controlled analgesia (PCA),[3] patient-controlled interscalene analgesia[4 5] and the continuous intrabursal infusion of analgesics.[6] However, the number of studies investigating the analgesic efficacy of patient-controlled subacromial analgesia remains limited.

Opioids such as oxycodone,[1 2] morphine[6] and local anaesthetics such as bupivacaine,[1 2 6] lidocaine[7] or ropivacaine,[8–10] given into subacromial bursa, have been used for pain relief after shoulder surgery. In order to get acceptable pain relief after operation, use of high doses of opioids may cause respiratory depression, nausea, vomiting, pruritus and drowsiness.[3] On the other hand, local anaesthetics may produce motor block, which can delay motion exercises.[11] The continuous subacromial infusion of these analgesics for postoperative analgesia is controversial. Boss and colleagues[12] reported that bupivacaine 0.25% at a rate of 6 ml h^{-1} given as infusion in the subacromial space after open acromioplasty and rotator cuff repair surgery was ineffective for postoperative pain relief. Harvey and colleagues[13] reported that the use of subacromial ropivacaine 0.25% as PCA provided effective control of postoperative pain. However, a comparison of patient-controlled subacromial analgesia with ropivacaine and i.v. PCA with fentanyl has not been reported.

The aim of this prospective, randomized study was to compare the analgesic efficacy, the rescue analgesic consumption and side-effects of patient-controlled subacromial analgesia with ropivacaine or fentanyl, or i.v. PCA with fentanyl after open acromioplasty surgery.

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Materials and methods

The approval of Karadeniz Technical University Ethic Committee and written informed consent from patients were obtained. Forty-eight patients, ASA I or II, aged between 25 and 63 yr, undergoing elective open acromioplasty surgery under general anaesthesia were enrolled in this prospective, randomized study. Patients with severe pulmonary, cardiovascular, liver, renal or psychiatric diseases and those with chronic pain, known allergy to trial drugs and inability to understand the instructions concerning the study or the use of the PCA pump (Abbott Pain Management Provider, Abbott Laboratories, North Chicago, IL, USA) were excluded.

Patients were randomly assigned by sealed envelope method to receive patient-controlled subacromial analgesia with ropivacaine (Group R, n=16), patient-controlled subacromial analgesia with fentanyl (Group F, n=16), or patient-controlled i.v. analgesia with fentanyl (Group Control, n=16). One of the physicians, not involved in the care or monitoring of the patient, prepared the analgesic solutions. The analgesic solutions contained 2 mg ml^{-1} of ropivacaine or 4 $\mu g\ ml^{-1}$ of fentanyl. The patients and attending anaesthesiologists, as well as physicians and nurses of the acute pain service, were blinded to the study drug used.

Midazolam 0.1 mg kg^{-1} was given orally to the patients 1 h before anaesthesia. All the patients in the three study groups received general anaesthesia with propofol 2–3 mg kg^{-1} and remifentanil 1–2 $\mu g\ kg^{-1}$ i.v. for induction and vecuronium 0.1 mg kg^{-1} for tracheal intubation. Anaesthesia was maintained with 66% nitrous oxide in oxygen and isoflurane (1–2%) and continuous infusion of remifentanil (0.1–0.2 $\mu g\ kg^{-1}\ min^{-1}$). During the operation ECG, non-invasive blood pressure, peripheral arterial oxygen saturation (Sa_{O_2}) and end-tidal carbon dioxide were monitored using a Datex S/5 monitor (Datex-Ohmeda, Helsinki, Finland).

All procedures were performed by the same orthopaedic surgeon using conventional open technique. The surgical procedures included acromioplasty for impingement syndrome (rotator cuff tendonitis) with possible repair of the rotator cuff rupture. In Group R and Group F, the surgeon placed a 20 G epidural catheter (Perifix® Soft, B Braun, Melsungen, Germany) into the subacromial space under direct vision at the end of the surgery. The catheter was fixed to the skin with an adhesive tape. After the catheter was connected to the pump, a loading dose of 5 ml of the analgesic solution was administered in the operating room. At the same time, Group C received 5 ml of the fentanyl solution i.v.

Postoperative analgesia was provided by patient-controlled subacromial or i.v. analgesia in three groups. Groups R and F received continuous subacromial infusion of ropivacaine 0.2% or fentanyl 4 $\mu g\ ml^{-1}$ respectively and Group C received i.v. fentanyl 4 $\mu g\ ml^{-1}$. Patients in Group C also received a dummy subacromial catheter injection. The PCA was started at a background infusion rate of 5 ml h^{-1} plus a bolus dose of 3 ml with a lockout time of 20 min in the three groups. In addition, rescue analgesia with tramadol 50–100 mg i.v. was available on demand or visual analogue scale (VAS) $\geqslant$3.

An observer physician, not involved in the intraoperative part of the study, was responsible for asking the patient about pain scores, appearance of side-effects, patient satisfaction and recording technical problems associated with PCA pumps. Patients were asked to mark their pain by using a 10 cm VAS, which divides a length of 10 cm into 10 parts (0 cm= no pain; 10 cm=worst pain imaginable). Pain was evaluated during passive abduction movement of shoulder by the orthopaedic surgeon or the observer physician in charge on each patient in the recovery room and in the surgical ward. The degree of pain was recorded at the beginning of PCA in the recovery room (T0) and then at the following time points: 2 h (T2), 4 h (T4), 6 h (T6), 12 h (T12), 18 h (T18), 24 h (T24), 32 h (T32), 40 h (T40) and 48 h (T48) after the beginning of PCA in the surgical ward. The incidence of nausea, vomiting, pruritus or other side-effects was noted. Nausea and vomiting were treated with ondansetron 4 mg i.v. Total consumption of analgesic solution, the number of requested and received doses by the patients, the time to the first administration and the amount of rescue tramadol during the 48 h were recorded. Patients' satisfaction was evaluated 48 h after surgery with a 10-point score (0=not satisfied, 10=entirely satisfied). At the end of the 48 h study period, the catheters were carefully removed and the tips sent for bacterial culture, and then the patients were discharged from the hospital with oral analgesic. The presence of persistent neurologic symptoms was evaluated 2–4 weeks after surgery by the orthopaedic surgeon.

A power analysis was performed on the basis of the difference of the pain scores (VAS) between the subacromial and i.v. groups at 2 h after the beginning of PCA (T2). Based on previous clinical experience, assuming a two-tailed type 1 error 0.05 and a β error of 0.1, approximately 16 patients in each group were required to detect a difference of 1.5 (SD 1.3) in the pain score (VAS) between the groups. I studied 16 patients in each group; thus, the study reached a power of 90%.[14]

The Kolmogorov–Smirnov test was used for normality and homogeneity of data distribution. Parametric data (age, weight, height, duration of surgery, pain scores, total volume infused, number of requested and received doses, total tramadol per patient and satisfaction score) were compared with one-way ANOVA. *Post hoc* comparisons were performed with Dunnett two-tailed t-test by using control as the reference control group. Discrete variables (sex, side-effects and technical problems) were compared by using χ^2-test. All data are presented as means (SD) or number. A P value <0.05 was considered as statistically significant.

Table 1 Patients characteristics of study groups. Data are given as mean (range) or mean (SD)

	Group F (n=16)	Group R (n=16)	Group C (n=16)
Age (yr)	49 (25–61)	52 (26–63)	50 (26–60)
Weight (kg)	70 (5)	74 (7)	72 (6)
Height (cm)	167 (6)	169 (8)	167 (7)
Sex (male/female)	10/6	11/5	10/6
Duration of surgery (min)	46 (8)	48 (9)	48 (8)

Table 2 Pain scores (VAS, 0–10 cm) and PCA variables. Values are given as mean (SD). *P<0.001

	Group F (n=16)	Group R (n=16)	Group C (n=16)
VAS T0	2 (1)	2 (1)	2 (1)
VAS T2	6 (2)*	2 (1)	2 (1)
VAS T4	5 (2)*	2 (1)	2 (1)
VAS T6	4 (1)*	1 (1)	1 (1)
VAS T12	4 (2)*	2 (1)	1 (1)
VAS T18	3 (2)	1 (1)	1 (1)
VAS T24	3 (2)	1 (1)	1 (1)
VAS T32	2 (1)	2 (1)	1 (1)
VAS T40	1 (1)	1 (1)	1 (1)
VAS T48	1 (1)	1 (0)	1 (0)
No. of requested doses	52 (12)*	16 (3)	15 (3)
No. of received doses	40 (11)*	14 (2)	13 (2)
Total volume infused (ml)	402 (64)*	296 (30)	288 (28)
Total tramadol (mg per patient)	159 (62)*	30 (66)	28 (64)
Patient satisfaction score	7 (3)	9 (1)	9 (1)

Results

There were no differences in age, weight, height, sex and duration of surgery between the three groups (Table 1). The postoperative pain scores at T2, T4, T6 and T12 were higher in the Group F compared with Groups R and C (P<0.001). However, the pain scores at the other time points were similar between the three groups. Total volume of analgesic solution infused, the number of requested and received doses were lower in Groups R and C compared with those of Group F (P<0.001). Ten patients in Group F, 5 in Group R and 4 in Group C received rescue tramadol. The median (range) times to first dose of tramadol times were 73 (32–114) min in Group F, 147 (126–168) min in Group C and 162 (134–196) min in Group R. There was a significant difference in the amount of rescue tramadol per patient between Group F and the other two groups at the end of the study (P<0.001). Pain scores, the number of requested and received doses, total volume of analgesic solution infused and rescue tramadol per patient were similar between Groups R and C (Table 2).

No clinically relevant difference was observed between the three groups in terms of respiratory rate, pulse rate, blood pressure and oxygen saturation throughout the study. No symptoms of systemic toxicity were reported in any patient. Specific side-effects and technical problems were comparable in the three groups (Table 3). The patient satisfaction scores [7 (3) in Group F and 9 (1) in Groups R and C] were high and similar between the three groups (Table 2). No case of persistent neurologic dysfunction was reported at the routine postoperative visit 2–4 weeks after surgery.

Table 3 Incidence of side-effects and technical problems in the groups

	Group F (n=16)	Group R (n=16)	Group C (n=16)
Nausea	4	3	4
Vomiting	2	2	2
Pruritus	1	0	1
Drowsiness	1	1	1
Catheter removed	0	0	0
Neurologic dysfunction	0	0	0

All catheter tips were cultured. Two patients in Group F and one in Group R had an isolated growth of coagulase negative staphylococcus. Clinically, these patients had no evidence of infection.

Discussion

The present study shows that patient-controlled subacromial analgesia with ropivacaine 0.2% and patient-controlled i.v. analgesia with fentanyl 4 μg ml^{-1} at a rate of 5 ml h^{-1} provided similar and acceptable pain relief (VAS⩽3) after open acromioplasty surgery. But, patient-controlled subacromial analgesia with fentanyl was less effective in controlling postoperative pain up to 12 h after surgery.

In order to get acceptable pain relief after acromioplasty, Muittari and colleagues[1 2] reported that administration of oxycodone 5 mg alone or in combination with bupivacaine 0.5% intrabursally may offer an effective, simple and safe method. However, Laurila and colleagues[8] reported that subacromial bursa block with ropivacaine 0.5%15 ml had a minor effect only, whereas an interscalene brachial plexus block with ropivacaine 0.5% effectively relieved early postoperative pain and reduced the need for opioids after arthroscopic shoulder surgery. However, in these studies, only a single dose of analgesics was administered in the subacromial bursa. Therefore, the analgesic effectiveness was limited by the duration of action of the analgesics.

Continuous infusion of analgesics is an alternative technique that can provide prolonged postoperative analgesia. Park and colleagues[6] reported that the continuous intrabursal infusion of bupivacaine 2.5 mg h^{-1} combined with morphine compared with saline resulted in a decreased perception of rest pain and reduced supplemental analgesic requirement for 2 days after subacromial arthroscopy. Mallon and Thomas[7] reported that PCA using lidocaine 2% in the subacromial space appeared to be a safe method for achieving high levels of pain control in patients undergoing an acromioplasty. Harvey and colleagues[13] reported that PCA infusion of subacromial ropivacaine 0.25% provided effective postoperative pain control after arthroscopic shoulder surgery. In another study, Axelsson and

colleagues[9] evaluated postoperative analgesia and safety of wound instillation of ropivacaine 250 mg either by a single dose or a patient-controlled regional anaesthesia technique after arthroscopic subacromial decompression; they reported that the combination of prilocaine 1% 20 ml and epinephrine injected preoperatively in the subacromial bursa and postoperative subacromial administration of ropivacaine 0.5% in the elastomeric balloon pump for postoperative pain relief provided the most effective analgesia with no major side-effects. However, some studies[1 12] demonstrated that the effect of both bolus and continuous infusion of subacromial bupivacaine alone remained ineffective after shoulder surgery.

In this study, I firstly compared patient-controlled subacromial analgesia with ropivacaine or fentanyl and patient-controlled i.v. analgesia with fentanyl after open acromioplasty surgery. It is known that the advantage of the PCA is to permit the patients not only to correct for individual variation in pain intensity, but also for the duration of analgesia after single-dose administration. The subacromial bursa offers a suitable compartment for the administration of local anaesthetics and opioids, and for the spread of these analgesics to the injured area after open acromioplasty surgery. However, continuous interscalene block was found to be more efficient than the subacromial continuous infusion of ropivacaine for pain control after arthroscopic shoulder surgery.[8 10] Nevertheless, the technique of subacromial catheter is simple and has no serious adverse effects compared with interscalene plexus block anaesthesia and analgesia.[5 10 15] However, adverse events (necrosis, surgical wound infection, cellulites and infection) after continuous direct infusion of bupivacaine into surgical wounds have been reported.[16]

This study demonstrated that PCA with subacromial ropivacaine or i.v. fentanyl provided similar pain relief and high patient satisfaction after operation. However, subacromial fentanyl group showed higher VAS values and rescue tramadol requirement than the subacromial ropivacaine groups after the procedure. And, the mean first time of tramadol requested was shorter in subacromial fentanyl group than ropivacaine group. This may be due to shorter duration of effect of fentanyl than ropivacaine. The analgesic effect of opioids on subacromial bursa has not been clearly demonstrated yet. Lawrence and colleagues[17] theorized that there was evidence for analgesia mediated by peripheral opioid receptors in inflamed synovial tissue. Considering the results of this study, there was no evidence that peripheral antinociceptive effects of fentanyl were as effective as that of ropivacaine. The opioids, which have been tested in previous studies, are oxycodene[1 2] and morphine,[6] which are both hydrophilic drugs. By contrast, fentanyl is a lipophilic drug, which might be absorbed easily from a local injection. This is important as patients in the subacromial fentanyl group received higher amount of analgesic solution, and were allowed to receive an additional tramadol when using their PCA pump.

There are some shortcomings of this study as I could not measure plasma concentrations of trial drugs, and whether the dosages of two drugs were appropriate in the PCAs. Continuous infusions of ropivacaine 0.2% were successfully used to control postoperative pain after major shoulder surgery.[8 10 18 19] PCA with fentanyl was assessed using different dosages in orthopaedic and other procedures.[20–22] In this study, continuous infusions of ropivacaine 0.2%, and fentanyl 4 μg ml^{-1} were selected at a rate which had been previously shown to be effective.[18–21] Also at the rate used in this study, unbound plasma concentrations of ropivacaine or fentanyl would be far below the threshold levels for systemic toxicity.[18 20] I observed no symptoms of systemic toxicity related to ropivacaine or fentanyl in this study. Side-effects of two drugs in this study were similar.

In conclusion, the use of the PCA techniques with subacromial ropivacaine 0.2% and with i.v. fentanyl 4 μg ml^{-1} at a rate of 5 ml h^{-1} plus a bolus dose of 3 ml with a lockout time of 20 min provide similar and adequate pain relief, minimal side-effects and high patient satisfaction after open acromioplasty surgery. Whereas the PCA with subacromial fentanyl is not as effective as subacromial ropivacaine or i.v. fentanyl.

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