Infiltration with ropivacaine plus lornoxicam reduces postoperative pain and opioid consumption

[L'infiltration avec de la ropivacaïne, plus du lornoxicam, réduit la douleur postopératoire et la consommation d'opioïdes]

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Purpose: To compare efficacy and patient outcome of wound infiltration with ropivacaine, lornoxicam, or their combination for control of pain following thyroid surgery.

Methods: Eighty patients underwent thyroid surgery were randomly assigned to one of four groups. Before skin closure, local tissues were infiltrated with 12 mL saline in Group S, with 10 mL of ropivacaine 0.75% plus 2 mL saline in Group R, with 2 mL of lornoxicam (8 mg) plus 10 mL saline in Group L, and with 10 mL ropivacaine 0.75% plus 2 mL lornoxicam (8 mg) in Group RL. Pain scores, total and incremental meperidine consumption were recorded at 30 min, one, two, three, four, six, eight, 12, 18, and 24 hr postoperatively. Time to first analgesic requirement, patient satisfaction, and duration of hospital stay were also compared after surgery.

Results: The pain scores in Group RL were significantly lower in the first 12 hr than in Group S, and in the first four hours than in Groups R and L ($P < 0.01$). The time to first analgesic requirement was significantly longer (14.8 ± 8.4 hr *vs* 5.9 ± 5.2 hr; $P < 0.01$), the total pethidine consumption was significantly less than Group S (34.0 ± 33.0 mg *vs* 78.0 ± 29.8 mg; $P<0.001$), return of gastrointestinal function, ambulation time, length of hospital stay ($P < 0.05$) were significantly shorter, and patient satisfaction ($P < 0.01$) was significantly better in Group RL than in Group S ($P < 0.05$).

Conclusion: Wound infiltration with ropivacaine 0.75% plus lornoxicam 8 mg combination improved postoperative pain control and patient comfort, and decreased the need for opioids than the use of either drug alone.

***Objectif** : Comparer l'efficacité d'une infiltration avec de la ropivacaïne, du lornoxicam ou leur combinaison après une opération de la thyroïde et comparer l'évolution des patients.*

***Méthode** : Des patients devant être opérés à la thyroïde (80) ont été répartis en quatre groupes. Avant la fermeture cutanée, les tissus locaux ont été infiltrés avec 12 mL de solution saline dans le groupe S, 10 mL de ropivacaïne à 0,75 % plus 2 mL de solution saline dans le groupe R, 2 mL de lornoxicam (8 mg) plus 10 mL de solution saline dans le groupe L et 10 mL de ropivacaïne à 0,75 % plus 2 mL de lornoxicam (8 mg) dans le groupe RL. Les scores de douleur et la consommation totale et incrémentielle de mépéridine ont été notés à 30 min, puis à une, deux, trois, quatre, six huit, 12, 18 et 24 h après l'opération. Le moment de la première demande d'analgésique, la satisfaction du patient et la longueur du séjour ont été comparés.*

***Résultats** : Les scores de douleurs ont été significativement plus bas chez les patients du groupe RL que chez ceux du groupe S pendant les 12 premières heures et que chez ceux des groupes R et L pendant les quatre premières heures ($P < 0,01$). Le moment de la première demande d'analgésique a été plus tardif (14,8 ± 8,4 h vs 5,9 ± 5,2 h ; $P < 0,01$), la consommation totale de péthidine a été plus basse que dans le groupe S (34,0 ± 33,0 mg vs 78,0 ± 29,8 mg ; $P < 0,001$), le retour de la fonction gastro-intestinale et de la marche a été plus précoce, la longueur du séjour hospitalier ($P < 0,05$) plus courte et la satisfaction des patients ($P < 0,01$) meilleure dans le groupe RL que dans le groupe S ($P < 0,05$).*

***Conclusion** : L'infiltration dans le site d'incision avec une combinaison de ropivacaïne à 0,75 % et de 8 mg de lornoxicam a amélioré le contrôle postopératoire de la douleur et le confort des patients et a diminué les besoins d'opioïdes par rapport à l'usage d'un seul médicament.*

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THYROID surgery induces brief postoperative pain, requiring analgesia/therapy during the first day after thyroid surgery. Post-thyroidectomy pain has frequently been treated with nonsteroidal anti-inflammatory drugs (NSAIDs) or opioids.[1,2] Lornoxicam is a potent new NSAID of the oxicam class that has been shown to be effective and well tolerated in the treatment of postoperative pain.[3–5] The short plasma half-life (three to five hours) of lornoxicam may provide advantages over other NSAIDs.[4]

Wound infiltration with local anesthetics is an alternative and acceptable method for the management of postoperative pain.[6,7] The main limitation of wound infiltration is that only long-acting local anesthetics produce effective and sufficient duration of analgesia. Bupivacaine is the most preferred long-acting local anesthetic and has been used successfully for local infiltration after surgery.[8,9] However, large doses of bupivacaine are relatively toxic, and moderate plasma concentrations can cause catastrophic cardiotoxicity.[10] Ropivacaine, a long-acting amide local anesthetic, is chemically related to bupivacaine but it has less cardiac and central nervous system toxicity.[11] It produces cutaneous vasoconstriction that restricts systemic absorption of the drug and increases its local duration of action.[12] Moreover, ropivacaine possesses anti-inflammatory activity that may further reduce pain when administered locally.[13]

The analgesic synergy of NSAID-local anesthetic-opioid combination was demonstrated by Visalyaputra *et al.*[14] In a recent study, postoperative wound infiltration with levobupivacaine plus lornoxicam provided better postoperative pain relief than levobupivacaine alone after cholecystectomy.[15] Further studies are needed to evaluate the analgesic efficacy of wound infiltration with another regimen of ropivacaine enriched with the NSAID lornoxicam alone on acute pain with different postoperative pain models. We therefore designed, a prospective, randomized, double-blinded, placebo-controlled study, to compare the effect of ropivacaine, lornoxicam or their combination on analgesia efficacy and patient outcome after thyroid surgery.

Methods

After obtaining the approval of the Institutional Ethics Committee (Trakya University, Edirne, Turkey) and written informed consent from the patients, we studied 80 patients, American Society of Anesthesiologists physical status I and II, undergoing elective partial or total thyroidectomy, in a prospective, randomized, double-blinded, placebo-controlled protocol. All patients were physiologically euthyroid. Exclusion criteria included a known allergy, sensitivity, or contraindication to opioids, local anesthetic or any NSAID, renal or liver failure, a history of peptic ulcer, a history of asthma, clotting disorder, an intrathoracic goiter, and pregnancy. In addition, patients who had previously suffered from a difficult endotracheal intubation (more than two attempts at tracheal intubation) at the induction of anesthesia were also excluded.

Patients were randomly divided into four groups of 20 patients each. For premedication, midazolam 0.07 $mg \cdot kg^{-1}$ was administered *im* 45 min before the surgical procedure. In the operating room, a crystalloid infusion was started, and mean arterial blood pressure (MAP), heart rate (HR), and peripheral oxygen saturation were monitored (Cato PM 8040; Dräger, Lübeck, Germany). After the administration of oxygen, anesthesia was induced with propofol (2 $mg \cdot kg^{-1}$ *iv*) and fentanyl (2 $\mu g \cdot kg^{-1}$ *iv*). Tracheal intubation was facilitated with atracurium (0.6 $mg \cdot kg^{-1}$ *iv*). Anesthesia was maintained with 1 to 2.5% (inspired concentration) sevoflurane and 66% nitrous oxide in oxygen. Additional fentanyl boluses up to 0.2 mg *iv* were allowed during surgery. Ventilation was controlled mechanically (Cato; Dräger, Lübeck, Germany), and adjusted to maintain end-expiratory carbon dioxide between 34 to 36 mmHg. Muscle relaxation was maintained with atracurium (0.1 $mg \cdot kg^{-1}$ *iv*) boluses as required.

At the end of surgery and before skin closure, would infiltration was performed by the surgeon, who was blinded to the applied drug solution. The patients were allocated by computer randomization to receive: (Group S) 12 mL of normal saline; (Group R) 10 mL of ropivacaine 0.75% (Naropin®; AstraZeneca, Milano, Italy) with 2 mL of normal saline; (Group L) 2 mL (8 mg) of lornoxicam (4 $mg \cdot mL^{-1}$), (Xefo®; Nycomed Pharma AS, Roskilde, Denmark) with 10 mL of normal saline; (Group RL) 10 mL of ropivacaine 0.75% with 2 mL (8 mg) of lornoxicam. The thyroid surgery was performed with patients in the supine position, with the head slightly hyperextended. At the completion of the surgery, neostigmine (1.5 mg *iv*) and atropine (0.5 mg *iv*) were administered for reversal of the residual paralysis, and the trachea was extubated.

After tracheal extubation, patients were transferred to the postanesthesia care unit. Assessment of postoperative pain was made on the basis of the visual analogue scale (VAS) where 0 = 'no pain' and 10 = 'worst pain imaginable'. Degree of sedation was determined according to a sedation score ranging from 0 to 2 (0 = alert, 1 = drowsy but rousable to

TABLE I Demographic characteristics, and surgical data of patients

Variable	*Group S (n = 20)*	*Group R (n = 20)*	*Group L (n = 20)*	*Group RL (n = 20)*
Age (yr)	48 ± 15	51 ± 16	49 ±15	46 ± 14
Weight (kg)	79 ± 21	76 ± 17	78 ± 19	75 ± 16
ASA physical status (I/II/III)	7/11/2	7/12/1	8/11/1	8/11/1
Gender (female/male)	15/5	14/6	15/5	13/7
Duration of anesthesia (min)	170 ± 35	163 ± 33	166 ± 34	168 ± 35
Duration of operation (min)	153 ± 29	148 ± 30	150 ± 30	152 ± 31
Unilateral/bilateral lobectomy	4/16	5/15	4/16	3/17

Group S = 12 mL saline; Group R = 10 mL of ropivacaine 0.75% plus 2 mL saline; Group L = 2 mL of lornoxicam (8 mg) plus 10 mL saline; Group RL = 10 mL ropivacaine 0.75% plus 2 mL lornoxicam (8 mg). ASA = American Society of Anesthesiologists. Values are number (n) or mean ± standard deviation. No statistical difference was found among the groups.

voice, 2 = very drowsy, rousable to shaking). The VAS scores, MAP, HR, respiratory rate, and sedation scores were assessed at one, two, three, four, six, eight, 12, and 24 hr after surgery. The total and incremental meperidine requirement at these times, and the time to first analgesic need were determined according to VAS; when VAS > 4, pethidine 1 $mg \cdot kg^{-1}$ *im* was administered and noted. The first analgesic need was regarded as the time elapsed between the administration of the study drugs and the administration of an analgesic. On patient request or if postoperative nausea and vomiting (PONV) occurred, ondansetron 8 mg *iv* was given. The number of patients receiving antiemetics and doses in patients receiving antiemetics were recorded. Patients were assessed for return of gastrointestinal function twice daily by a physician who systematically questioned the patients and consulted nurse observations for the time until return of bowel sounds, time of the first flatus and time of the oral intake. Time of being able to walk unassisted (ambulation) was also assessed after surgery. After 24 hr, satisfaction with the analgesia was evaluated using a four-point scale (0 = poor; 1 = satisfactory; 2 = good; 3 = excellent). In addition, patients were questioned about the occurrence of any adverse effects during the first 24 hr, and adverse effects were recorded. All data were recorded by the same anesthesia resident who was blinded to the study drugs administered.

Every 24 hr after the operation, patients were assessed as ready or not ready for discharge from hospital, by four discharge criteria: 1) normal defecation and no urinary retention: yes/no; 2) able to mobilize and dress: yes/no; 3) need for opioid: yes/no; 4) surgical complication requiring patient hospitalization: yes/no. When the patient scored yes on the two former, and no on the latter questions, they were considered ready for discharge from hospital.[16] Then, the length of stay (LOS) in hospital was recorded.

Statistical analysis

Descriptive statistics are expressed as mean ± standard deviation (SD) unless otherwise stated. All continuous variables were tested for normal distribution by the Kolmogorov-Smirnov test. One way ANOVA was used for normally distributed variables. The Bonferroni post-hoc tests were applied to determine the significance of differences in means. Kruskal-Wallis ANOVA was used for non-normally distributed data. If a significant result was obtained, Kruskal-Wallis Z test was performed for multiple comparisons. Categorical data were analyzed using Chi-square or Fisher's exact test, as appropriate. A value of $P < 0.05$ was considered statistically significant. Data were analyzed using NCSS 2001 for Windows (NCSS, Kaysville, UT, USA). According to a power analysis for VAS scores in patients, we calculated that 20 patients in each group would be required to demonstrate a maximum difference = 1.6 (SD = 1.7) among groups ($\alpha = 0.05$, ß = 0.2).

Results

Eighty patients were enrolled in the study, 20 in each group. The four groups were comparable with respect to demographic and surgery data (Table I). There were no differences in the HR, MAP, respiratory rate, and sedation scores (data not shown) between the groups at any time during the first 24 hr after surgery.

As shown in Figure 1, pain scores during the first 12 hr postoperatively were significantly lower in the Group RL compared with the Group S ($P < 0.01$). Additionally, pain scores were significantly lower in the Group RL compared with the Groups R and L during the first four hours postoperatively ($P < 0.01$). Pain scores were significantly lower in the Groups R and L compared with the Group S during the first six and eight hours ($P < 0.01$, $P < 0.01$; $P < 0.05$, $P < 0.05$, respectively). The incremental meperidine

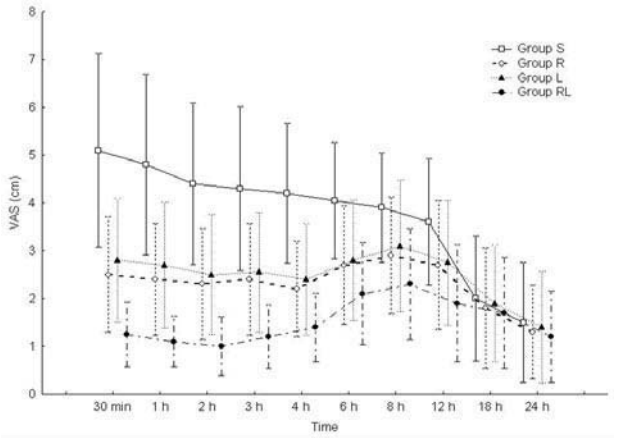

FIGURE 1 Visual analogue scale (VAS) pain scores during the first 24 hr after surgery. Values are mean ± standard deviation. Pain scores during the first 12 hr postoperatively were significantly ($P < 0.01$) lower in Group ropivacaine plus lornoxicam (RL) when compared with Group saline (S). Pain scores were significantly lower in Group ropivacaine plus lornoxicam (RL) when compared with Group ropivacaine (R) and lornoxicam (L) during the first four hours postoperatively ($P < 0.01$). Pain scores were significantly lower in Groups ropivacaine (R) and lornoxicam (L) when compared with Group saline (S) during the first six and eight hours ($P < 0.01$, $P < 0.01$; $P < 0.05$, $P < 0.05$, respectively).

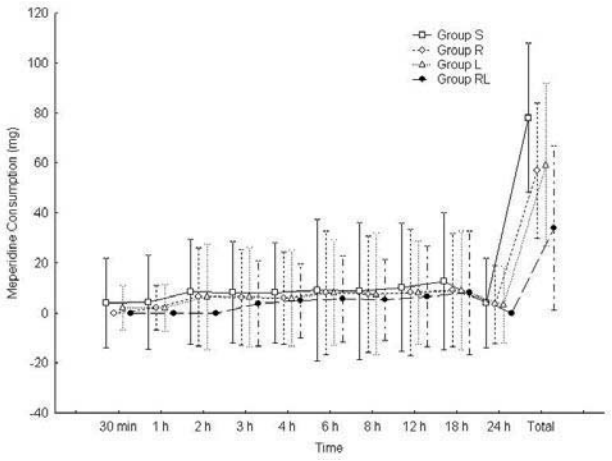

FIGURE 2 Meperidine consumption during the first 24 hr after surgery. Values are mean ± standard deviation. The incremental meperidine consumption did not differ significantly among the four study groups. Total meperidine consumption was significantly less in Group ropivacaine plus lornoxicam (RL) when compared with Group saline (S), ($P < 0.001$).

consumption did not differ significantly among the four study groups. However, the total meperidine consumption was significantly less in the Group RL compared with the Group S (34.0 ± 33.0 mg *vs* 78.0 ± 29.8 mg; $P < 0.001$), (Figure 2). The time to first analgesic was also significantly longer in the Group RL compared with the Group S (14.8 ± 8.4 hr *vs* 5.9 ± 5.2 hr, $P < 0.01$), (Table II). The return of bowel sounds, time of the first flatus and oral intake, and ambulation time were significantly faster in the Group RL compared with the Group S ($P < 0.05$; Table II).

The most common adverse effect observed during the study were nausea, vomiting, abdominal discomfort, and dizziness (Table III). Incidence of PONV (Table III), and number of patients receiving antiemetics, and number of doses for patients receiving antiemetics were significantly ($P < 0.05$) less in Groups RL and S compared with Groups R and L; there was no difference in the incidence of other adverse effects among the groups (Table III). As shown in Table IV, more patients described their analgesia as good or excellent in Group RL than other groups ($P < 0.01$). The LOS was significantly shorter in Group RL (2 ± 1 days) compared with the other groups (3 ± 1 days), ($P < 0.05$). The LOS was not significantly different among Groups R, L, and S (Table II). No patient experienced wound infection or delayed wound healing during their stay in hospital.

Discussion

Thyroid surgery induces postoperative discomfort caused by several mechanisms. Post-thyroidectomy pain perception likely includes components linked to the deep and superficial layers of the wound, intraoperative neck position and wound drainage. This pain may be treated with NSAIDs or opioids.[1,2]

Nonsteroidal anti-inflammatory drugs are commonly used analgesics for minor surgery and are useful adjunctive analgesics in patients undergoing major surgery, decreasing pain and opioid requirements.[17] However, their use in some patients may be limited by adverse renal, gastrointestinal, and hematological effects.[18] Opioids, although highly effective in managing pain, have a range of side effects such as respiratory depression, sedation, nausea, and vomiting.[19]

Lornoxicam is a potent new NSAID of the oxicam class.[3,4] Previous studies with lornoxicam 8 mg have shown it to be as effective as meperidine 50 mg[5] or

TABLE II Postoperative outcome

Variable	*Group S (n = 20)*	*Group R (n = 20)*	*Group L (n = 20)*	*Group RL (n = 20)*
Time to first analgesic (hr)	5.9 ± 5.2	10.7 ± 8.3	11.1 ± 7.7	14.8 ± 8.4†
Return of bowel sounds (hr)	9.6 ± 2.5	8.8 ± 2.2	9.0 ± 2.2	7.8 ± 1.7*
Time of the first flatus (hr)	14.7 ± 3.1	13.9 ± 2.9	14.1 ± 2.8	2.2 ± 2.7*
Oral intake (hr)	10.3 ± 2.2	9.4 ± 2.2	9.6 ± 2.1	8.5 ± 1.9*
Ambulation (hr)	13.0 ± 2.2	12.0 ± 2.0	12.2 ± 2.1	11.2 ± 2.0*
Duration of hospital stay (days)	3 ± 1	3 ± 1	3 ± 1	2 ± 1‡

Group S = 12 mL saline; Group R = 10 mL of ropivacaine 0.75% plus 2 mL saline; Group L = 2 mL of lornoxicam (8 mg) plus 10 mL saline; Group RL = 10 mL ropivacaine 0.75% plus 2 mL lornoxicam (8 mg). Values are mean ± SD. *$P < 0.05$, †$P < 0.01$ vs Group S; ‡$P < 0.05$ *vs* the other groups.

TABLE III Adverse effects

Variable	*Group S (n = 20)*	*Group R (n = 20)*	*Group L (n = 20)*	*Group RL (n = 20)*
Nausea	7 (35%)	11 (55%)	11 (55%)	8 (40%)
Vomiting	4 (20%)	8 (40%)	8 (40%)	5 (25%)
Abdominal discomfort	2 (10%)	2 (10%)	2 (10%)	2 (10%)
Dizziness	1 (5%)	1 (5%)	1 (5%)	2 (10%)
Headache	0 (0%)	1 (5%)	1 (5%)	1 (5%)
Urinary retention	1 (5%)	0 (0%)	1 (5%)	0 (0%)

Group S = 12 mL saline; Group R = 10 mL of ropivacaine 0.75% plus 2 mL saline; Group L = 2 mL of lornoxicam (8 mg) plus 10 mL saline; Group RL = 10 mL ropivacaine 0.75% plus 2 mL lornoxicam (8 mg). Values are number (n) and percentages (%). The incidence of postoperative nausea and vomiting (PONV) was significantly different in the Group ropivacaine plus lornoxicam (RL) and, saline (S) when compared with Groups R and L (*$P < 0.05$).

TABLE IV Patient satisfaction

	Group S (n = 20)	*Group R (n = 20)*	*Group L (n = 20)*	*Group RL (n = 20)*
Excellent	3 (15%)	5 (25%)	4 (20%)	8 (40%)
Good	4 (20%)	6 (30%)	7 (35%)	9 (45%)
Satisfactory	10 (50%)	8 (40%)	8 (40%)	3 (15%)
Poor	3 (15%)	1 (5%)	1 (5%)	0 (0%)

Group S = 12 mL saline; Group R = 10 mL of ropivacaine 0.75% plus 2 mL saline; Group L = 2 mL of lornoxicam (8 mg) plus 10 mL saline; Group RL = 10 mL ropivacaine 0.75% plus 2 mL lornoxicam (8 mg). Values are number (n) and percentages (%). $P < 0.01$ ropivacaine plus lornoxicam (RL) Group vs the other groups (comparing excellent and good vs satisfactory and poor).

tramadol 50 mg[20] after various surgical procedures. In another study, Trampitsch *et al.*[21] determined that lornoxicam administered preemptively appears to improve the quality of postoperative analgesia, and leads to reduced consumption of opioid analgesics postoperatively in patients undergoing gynecological operations.

Studies have demonstrated that wound infiltration with local anesthetics are effective for the management of postoperative pain.[6,7] Infiltration with local anesthetic at operative sites can improve postoperative analgesia and reduce opioid requirements after different surgical procedures.[6,7,22]

Previous studies determined that postoperative analgesia using wound infiltration with ropivacaine 3.75%[23] or 7.5%,[7] leads to a significant reduction of VAS values and opioid consumption in patients undergoing major shoulder surgery. However, studies related with abdominal hysterectomy demonstrated that local anesthetic wound infiltration does not decrease postoperative opioid requirements or improve patient comfort.[24,25]

Local anesthetic wound infiltration may reduce post-thyroidectomy pain. Gozal *et al.*[26] reported that bupivacaine infiltration in thyroid surgery markedly reduced opioid requirements. In another study, bupivacaine wound infiltration effectiveness was considered disappointing when compared with two opioid regimens.[27]

The analgesic efficacy of the lornoxicam-ropivacaine combination infiltrated into wound for thyroid surgery has not been assessed previously. Georgiadou *et al.*[15] determined that wound infiltration with levobupivacaine 0.5% plus lornoxicam 8 mg provided better postoperative pain relief and reduced analgesic

requirement more than levobupivacaine alone after cholecystectomy. In another study, Visalyaputra *et al.*[14] reported that time to first analgesic requirement and morphine requirement during the first six hours was significantly lower in the group using local infiltration with lornoxicam and ropivacaine combination when compared with *iv* morphine alone after abdominal hysterectomy.

Our study demonstrated that postoperative wound infiltration with ropivacaine 0.75% plus lornoxicam 8 mg effectively reduced postoperative pain scores during the first 12 hr postoperatively ($P < 0.01$), compared with saline. Our data further indicate that ropivacaine 0.75% or lornoxicam alone are less effective than their combination. Patients infiltrated with ropivacaine 0.75% plus lornoxicam required less total opioid consumption in the first 24 hr postoperatively compared to placebo. Additionally, we found that the time to first analgesic was significantly longer in the combination group than in the control group.

The short plasma half-life (three to five hours) of lornoxicam may provide advantages over other NSAIDs.[4,28] In the postoperative setting, lornoxicam has been well tolerated, with a tolerability profile similar to diclofenac[29] but superior to that of indomethacin.[5] The most frequent adverse effects were dizziness, abdominal pain, headache, and vomiting.[3–5]

Postoperative nausea and vomiting after thyroid surgery is especially common, with previous studies reporting a rate of 51% to 76%.[30–32] Similarly in our study, the most common adverse effect in the study groups were PONV, and we determined a decrease in adverse effects associated with opioid consumption in the combination group, demonstrating that a multimodal analgesic approach using adjunctive drugs reduces the need for opioid analgesic and decreases adverse effects. The incidence of PONV (65% *vs* 95%, respectively) and antiemetic requirements were less in the combination group and Group S than in the R and L Groups ($P < 0.05$). We have no idea why the placebo group had a lower PONV incidence. Since sex and age were similar, other confounding factors such as history of PONV may be included. Unfortunately, we did not control for other factors. However, there were no significant differences among groups with respect to other adverse effects. A possible concern about this technique may be the potential risk of delayed wound healing and infection.[31] Our study revealed no signs of local inflammation in any of the patients.

In our study, the return of gastrointestinal function and times to ambulation were significantly faster in Group RL compared with Group S ($P < 0.05$). We conclude that higher patient satisfaction in the combination group is a reflection of shortened time of return of gastrointestinal function and ambulation time. This is also clinically significant. Hospital LOS ($P < 0.05$) was shorter, and patient satisfaction was better in the combination group when compared with the other groups, without increasing the bleeding risk in Group RL compared with Group S. Patients treated with ropivacaine plus lornoxicam experience a more rapid return of gastrointestinal function, probably because of reductions in meperidine consumption.

The higher degree of patient satisfaction ($P < 0.01$) in the combination group compared with the other groups is further evidence in favour of the use of this technique for postoperative pain management. Early mobilization of patients after thyroid surgery is one of the most important surgical determinants for hospital discharge.[22]

In conclusion, wound infiltration with ropivacaine 0.75% plus lornoxicam 8 mg administered postoperatively, provides better postoperative pain relief and patient comfort, and decreased opioid consumption compared with saline in patients undergoing thyroid surgery. When wound infiltration is planned in thyroid surgery a local anesthetic/NSAID combination provides a more favourable outcome than either drug alone.

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