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# A study to evaluate the efficacy of instillation of ropivacaine with fentanyl, dexmedetomidine, or morphine through surgical drain for post-operative analgesia in patients undergoing modified radical mastectomy

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## ABSTRACT

**Background:** Local anesthetics have become vital part of multimodal analgesia approach. Instillation of local anesthetics through surgical drain is easier and safer method than conventional nerve blocks. Various local anesthetic drugs and adjuvants have been used for post-operative pain management through surgical drains. **Aims and Objectives:** This study was conducted to evaluate the efficacy of instillation of ropivacaine with fentanyl, dexmedetomidine or morphine through surgical drain for post-operative analgesia and patient satisfaction in patients undergoing modified radical mastectomy. **Materials and Methods:** A prospective, randomized, and double-blind study was conducted dividing 75 female patients aged 30–70 years who underwent modified radical mastectomy into three groups: Group (RM) received 40 ml 0.25% ropivacaine with 4.5 mg morphine, group (RD) 40 ml 0.25% ropivacaine with 1 mg/kg dexmedetomidine and group (RF) 40 ml 0.25% ropivacaine with 50 microgram fentanyl, instilled through surgical drains. **Results:** Visual analog score for pain at rest and movement was significantly lower in group RM as compared to group RD and RF with no significant difference among group RD and RF at different time intervals postoperatively. Patient satisfaction at 24-h postoperatively was significantly better in group RM as compared to group RD and RF (P = 0.01) with no significant difference among group RD and group RF. **Conclusion:** Instillation of ropivacaine with morphine provides good pain relief, prolonged duration of analgesia, and good patient satisfaction in the post-operative period as compared to ropivacaine with dexmedetomidine or fentanyl.

**Key words:** Wound instillation; VAS; Ropivacaine; Morphine; Dexmedetomidine; Surgical drain; Mastectomy; Post-operative analgesia

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## INTRODUCTION

Number of patients undergoing modified radical mastectomy is very large due to high prevalence of breast cancer among females and surgery being the mainstay of treatment in operable cases of breast malignancy.[1,2] Modified radical mastectomy is frequently complicated by post-mastectomy pain due to extensive tissue dissection causing more post-operative pain which often last for several days.[2] Post-operative pain is a nightmare for its wide ranging adverse effects on clinical outcome of patients. Uncontrolled post-operative pain has multiple adverse effects including

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delayed resumption of normal pulmonary function and increase in the systemic vascular resistance, cardiac work, and myocardial oxygen consumption through an increase in the catecholamine release induced by the stress response.[3] Post-operative pain may also lead to restriction of mobility contributing to thromboembolic complications along with increased nausea and vomiting episodes. Inadequate post-operative pain management negatively affects patient satisfaction and potentially can have long lasting psychological sequelae specially in cancer patients who are already going through traumatic experience.[4] Successful management of post-operative pain increases patient satisfaction, leads to earlier recovery, shortens hospital stay, and consequently reduces treatment costs.[5]

Post-operative pain management is becoming more vital than ever to anesthesiologists and surgeons with increasing scope of ambulatory surgery. Multimodal analgesic approaches with non-steroidal anti-inflammatory drugs, opioids, peripheral nerve blocks, and wound infiltration with local anesthetics are preferred practice for postoperative pain relief.[6] Opioid sparing approaches are being increasingly adopted to avoid variety of side effects, such as ventilatory depression, drowsiness and sedation, post-operative nausea and vomiting, pruritus, urinary retention, ileus, and constipation, which can delay hospital discharge and leads to decreased patient satisfaction.[7,8] However, wound infiltration of local anesthetic along surgical incision may cause seeding and cutaneous spread of malignancies.[9] Other techniques such as field block, intercostal block, brachial plexus block, and paravertebral are difficult to perform, require specialist experience and can cause adverse effects such as bleeding, permanent nerve damage, and hypotension. Wound instillation with local anesthetics through surgical drain is a simple and more convenient alternative technique, used widely to manage postoperative pain.[10] Ropivacaine is one such local anesthetic agent which has a good safety profile with long duration of action that can be used with many adjuvants.[11]

### Aims and objectives

This study was aimed to evaluate the efficacy of instillation of ropivacaine with fentanyl or dexmedetomidine or morphine through surgical drains for post-operative analgesia and patient satisfaction in patients undergoing mastectomy.

## MATERIALS AND METHODS

The present prospective, randomized, and double-blind study was conducted at a tertiary care center after obtaining approval from institutional ethics committee between February 2019 and March 2020.

### Inclusion criteria

Seventy-five female patients, aged between 30 and 70 years belonging to ASA Physical Status Class I and II, who underwent mastectomy with axillary clearance were enrolled in the study.

### Exclusion criteria

Patients with uncontrolled cardiovascular, pulmonary, hepatic, renal, neurologic, psychiatric or diabetes mellitus, major blood loss during surgery, continued excessive blood collection in the drains, allergy to the study drugs, and patients refusing to participate were excluded from the study.

Sample Size was determined based on the visual analog score (VAS) in three groups. With 21 patients in each group, there was 90% power at an alpha 0.05 to detect a difference of 1 in VAS postoperatively between any two groups with an effect size of 1.0.[5] Factoring a dropout rate of approximately 20%, we calculated that 25 patients would be required in each group. All the patients were subjected to a detailed clinical history and a complete general physical examination. Routine investigations such as hemoglobin, bleeding time, clotting time, blood sugar, blood urea, serum sodium and potassium, complete urine examination, chest X-ray, and electrocardiography (ECG) were done. Other investigations were obtained as per requirements. The purpose and protocol of study were explained to the patients and informed written consent was obtained. VAS 0–10 for assessment of pain was explained to each patient during pre-operative visit. In operating room, monitoring comprising of ECG, pulse oximeter ($SpO_2$), and non-invasive blood pressure (NIBP) was initiated and continuously monitored. Intravenous line was secured with 18G venous cannula. Ringer lactate was used as maintenance fluid. Anesthesia was induced with standard anesthesia protocol. Pre-oxygenation was done with 100% oxygen for 3 min followed by injection thiopentone (3–5 mg/kg iv). Injection vecuronium 0.1 mg/kg iv was given to facilitate orotracheal intubation. Intraoperative analgesia was achieved with fentanyl 2 μg/kg iv. Maintenance of anesthesia was done with sevoflurane and 66% nitrous oxide in oxygen. At the end of the surgical procedure, drains were placed by the surgeon before closing the surgical incision. Patients were divided in to three groups of 25 each using computer generated randomization number table:

- Group I (RM) (n=25): 40 mL 0.25 % ropivacaine with 4.5 mg morphine was instilled through the surgical drains
- Group II (RD) (n=25):40 mL 0.25 % ropivacaine with 1 microgram/kg dexmedetomidine was instilled through the surgical drains
- Group III (RF) (n=25): 40 mL 0.25 % ropivacaine with 50 microgram fentanyl was instilled through the surgical

drains. The surgical drains were clamped for a period of twenty minutes after instillation of the study drug.

After a dwell time of 20 min, the clamp was released to allow the drug solution (if any) in to the negative pressure suction drain. If two drains were placed by the surgeon, then 20 mL of drug solution was instilled through each drain and total volume did not exceed 40 mL in any case. The drug solution was prepared by the anesthesiologist not involved in the study. Four 10 mL syringes containing colorless drug solution (40 mL) was used. The candidate observing patients postoperatively was not aware of the type of drug solution administered. The patients were not aware of the type of drug solution administered as it was injected before extubation. At the end of the procedure, the residual neuromuscular block was reversed using intravenous neostigmine 0.05 mg/kg and intravenous glycopyrrolate 0.01 mg/kg before extubation.

Pain was assessed using VAS 0–10 on rest and movement. It was recorded immediately after surgery, hourly for up to 4 h and then four hourly till 24 h. Pulse rate, NIBP, and respiratory rate were recorded immediately after surgery, hourly for up to 4 h and then four hourly till 24 h. All patients were administered injection diclofenac 75 mg im whenever VAS was more than 3 on rest or more than 4 on movement at any time during the study period. The time to requirement of first rescue analgesia and duration of analgesia was recorded. The total requirement of analgesia in 24 h was recorded. However, injection diclofenac was not administered more than eight hourly. If after giving inj. diclofenac 75 mg im, VAS was more than 3 on rest or more than 4 on movement then inj. tramadol 100 mg slow intravenously was given as additional analgesia. The time of administration and total requirement of analgesia was recorded. Patient satisfaction regarding pain relief was subjectively assessed at 24 h postoperatively as excellent, good, satisfactory or poor. Side effects such as nausea, vomiting, pruritus, and others, if any, were recorded and managed accordingly.

### Statistical analysis

Statistical testing was conducted with the Statistical Package for the Social Science system version SPSS 17.0. Continuous variables were presented as mean±SD or median (IQR) for non-normally distributed data. Categorical variables were expressed as frequencies and percentages. The comparison of normally distributed continuous variables between the groups was performed using ANOVA. If the F value was significant, Tukey or Tamhane's T2 multiple comparison test was used to assess the differences between the individual groups. Nominal categorical data between the groups were compared using Chi-squared test or Fisher's exact test as appropriate. Non-normal distribution continuous variables were compared using Kruskal–Wallis test and further paired comparisons were done using Mann–Whitney U test. For all statistical tests, $P<0.05$ was taken to indicate a significant difference.

## RESULTS

All the three groups were comparable in mean age, side of surgery, and duration of surgery (Table 1).

The mean heart rate and $SpO_2$ in the three groups at different time intervals intraoperatively and postoperatively were comparable among the three groups (one-way Analysis of variance [ANOVA], $P>0.05$) at different time intervals with no significant difference. Mean systolic blood pressure in the three groups at different time intervals intraoperatively and postoperatively was comparable among the three groups (One-way ANOVA, $P>0.05$) at different time intervals, except at 90 min intraoperative period where Group I recorded significantly lower blood pressure compared to group II and III ($P=0.01$). The mean diastolic blood pressure in the three groups at different time intervals intraoperatively was comparable amongst the three groups (One-way ANOVA, $P>0.05$) but it was significantly lower in Group I compared to Group II and III (One-way ANOVA, $P>0.05$) at 1 h, 4 h, and 8 h postoperatively.

In this study, VAS 0–10 at rest was significantly lower in Group I as compared to Group II and III at 2, 8, 12, 20, and 24 h postoperatively ($P<0.05$). However, VAS at rest was comparable between Group II and III at different time intervals postoperatively (Table 2 and Figure 1).

### ANOVA test

VAS 0–10 on movement was significantly lower in Group I as compared to Group II and III at 2, 4, 20, and 24 h

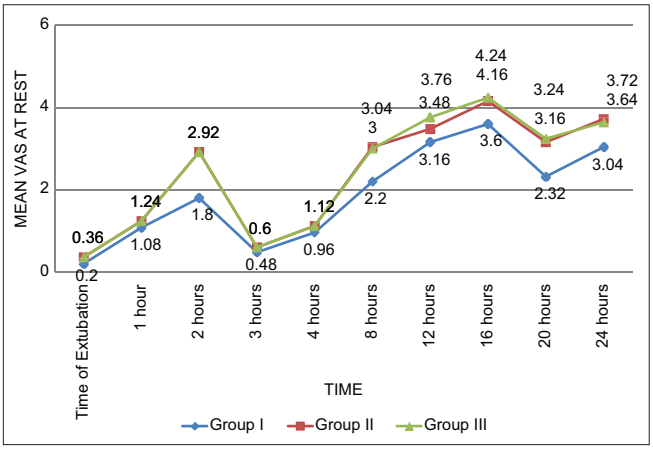


**Figure 1:** Comparison of VAS at rest in three groups

**Table 1: Comparison of baseline characteristics of three groups**

| Baseline characteristics | Group I | Group II | Group III | P-value |
|---|---|---|---|---|
| Age (Years) | 50.04±11.33 | 52.56±10.62 | 55.00±7.46 | 0.21 |
| Duration of surgery (Min.) | 118.40±17 | 120.40±17.13 | 120.80±14.33 | 0.85 |
| Baseline HR | 86.56±11.11 | 82.56±10.46 | 85.60±6.48 | 0.31 |
| Baseline SBP | 116.88±12.21 | 118.16±15.57 | 124.48±10.75 | 0.09 |
| Baseline DBP | 72.96±9.72 | 75.48±12.75 | 79.76±7.04 | 0.06 |

**Table 2: Comparison of VAS at rest in three groups**

| VAS at rest | Mean±SD | Minimum | Maximum | P-value |
|---|---|---|---|---|
| Time of Extubation | | | | |
| Group I | 0.20±0.40 | 0 | 1 | 0.37 |
| Group II | 0.36±0.49 | 0 | 1 | |
| Group III | 0.36±0.49 | 0 | 1 | |
| 1 h | | | | |
| Group I | 1.08±0.27 | 1 | 2 | 0.25 |
| Group II | 1.24±0.43 | 1 | 2 | |
| Group III | 1.24±0.43 | 1 | 2 | |
| 2 h | | | | |
| Group I | 1.80±0.50 | 1 | 3 | 0.001 (S) |
| Group II | 2.92±0.27 | 2 | 3 | |
| Group III | 2.92±0.27 | 2 | 3 | |
| 3 h | | | | |
| Group I | 0.48±0.51 | 0 | 1 | 0.62 |
| Group II | 0.60±0.50 | 0 | 1 | |
| Group III | 0.60±0.50 | 0 | 1 | |
| 4 h | | | | |
| Group I | 0.96±0.20 | 0 | 1 | 0.23 |
| Group II | 1.12±0.44 | 0 | 2 | |
| Group III | 1.12±0.44 | 0 | 2 | |
| 8 h | | | | |
| Group I | 2.20±0.57 | 1 | 3 | 0.001 (S) |
| Group II | 3.04±0.61 | 2 | 4 | |
| Group III | 3.00±0.64 | 2 | 4 | |
| 12 h | | | | |
| Group I | 3.16±0.37 | 3 | 4 | 0.02 (S) |
| Group II | 3.48±0.91 | 2 | 5 | |
| Group III | 3.76±0.87 | 2 | 5 | |
| 16 h | | | | |
| Group I | 3.60±1.08 | 1 | 5 | 0.11 |
| Group II | 4.16±0.21 | 3 | 7 | |
| Group III | 4.24±1.23 | 3 | 7 | |
| 20 h | | | | |
| Group I | 2.32±0.47 | 2 | 3 | 0.001 (S) |
| Group II | 3.16±0.47 | 3 | 5 | |
| Group III | 3.24±0.59 | 3 | 5 | |
| 24 h | | | | |
| Group I | 3.04±0.35 | 2 | 4 | 0.001 (S) |
| Group II | 3.72±0.79 | 2 | 5 | |
| Group III | 3.64±0.81 | 2 | 5 | |

**Table 3: Comparison of VAS at movement in three groups**

| VAS at movements | Mean±SD | Minimum | Maximum | P-value |
|---|---|---|---|---|
| Time of Extubation | | | | |
| Group I | 0.88±0.44 | 0 | 2 | 0.35 |
| Group II | 1.04±0.45 | 0 | 2 | |
| Group III | 1.04±0.45 | 0 | 2 | |
| 1 h | | | | |
| Group I | 2.04±0.67 | 1 | 3 | 0.37 |
| Group II | 2.24±0.52 | 1 | 3 | |
| Group III | 2.24±0.52 | 1 | 3 | |
| 2 h | | | | |
| Group I | 2.36±0.56 | 1 | 3 | 0.001 |
| Group II | 3.92±0.27 | 3 | 4 | (S) |
| Group III | 3.92±0.27 | 3 | 4 | |
| 3 h | | | | |
| Group I | 1.16±0.62 | 0 | 2 | 0.81 |
| Group II | 1.24±0.43 | 1 | 2 | |
| Group III | 1.24±0.43 | 1 | 2 | |
| 4 h | | | | |
| Group I | 1.68±0.47 | 1 | 2 | 0.09 |
| Group II | 1.96±0.53 | 1 | 3 | |
| Group III | 1.96±0.53 | 1 | 3 | |
| 8 h | | | | |
| Group I | 2.72±0.45 | 2 | 3 | 0.001 |
| Group II | 3.96±0.67 | 3 | 5 | (S) |
| Group III | 3.96±0.67 | 3 | 5 | |
| 12 h | | | | |
| Group I | 4.28±0.61 | 4 | 6 | 0.07 |
| Group II | 4.40±1.00 | 3 | 6 | |
| Group III | 4.84±1.02 | 3 | 6 | |
| 16 h | | | | |
| Group I | 4.76±0.97 | 3 | 6 | 0.39 |
| Group II | 5.08±1.11 | 4 | 7 | |
| Group III | 5.16±1.17 | 4 | 7 | |
| 20 h | | | | |
| Group I | 3.28±0.67 | 2 | 4 | 0.001 |
| Group II | 4.16±0.47 | 4 | 6 | (S) |
| Group III | 4.24±0.59 | 4 | 6 | |
| 24 h | | | | |
| Group I | 3.84±0.62 | 2 | 5 | 0.001 |
| Group II | 4.68±0.74 | 3 | 6 | (S) |
| Group III | 4.60±0.76 | 3 | 6 | |

postoperatively (P<0.05). However, VAS at movement was comparable between Group II and III at different time intervals postoperatively (Table 3 and Figure 2).

In this study, analgesia (inj. Diclofenac sodium 75mg slow intravenously) was administered whenever VAS was more than three at rest and more than four at movement. The duration of analgesia, that is, Administration of first dose of analgesia was significantly longer in Group I as compared to Group II and Group III (P=0.001). However, it was comparable between Group II and Group III (Figure 3).

The total number of doses of analgesic administered was 1.08±0.27, 1.92±0.64, and 1.92±0.64 in the Group I, II, and III, respectively. Total number of doses of analgesic administered were significantly lower in Group I as compared to Group II and III (P=0.001). However, it was comparable between Group II and Group III. After

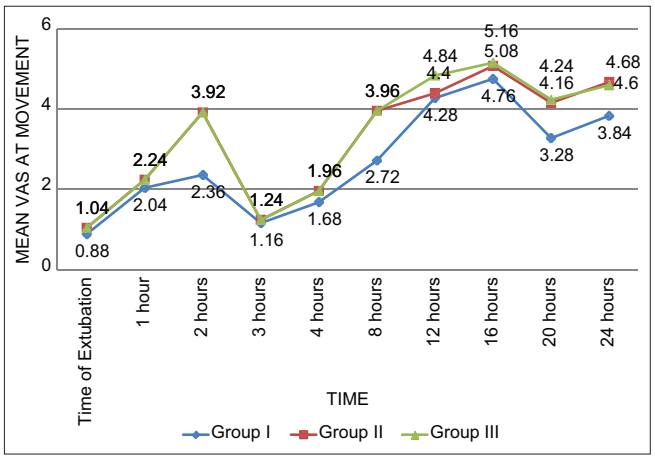


**Figure 2:** Comparison of VAS at movement in three groups

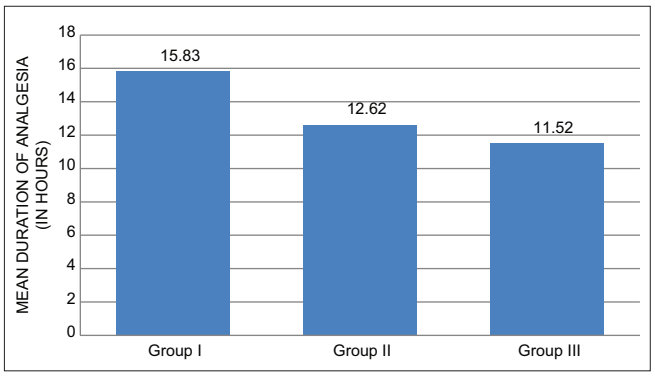


**Figure 3:** Comparison of duration of analgesia (hours) in three groups

giving inj. diclofenac 75 mg im. whenever VAS was more than 3 on rest or more than 4 on movement then inj. tramadol 100 mg slow intravenously was given as additional analgesia. Patients in Group I did not require any additional analgesia whereas three patients in Group II and 10 patients in Group III required additional analgesia (Figure 4). Therefore, Group I required significantly lower additional analgesia compared to Group II and Group III (P=0.0001).

Patient satisfaction at 24 h postoperatively was observed to be significantly better in Group I as compared to Group II and III (P=0.01). However, it was comparable in between Group II and Group III (Table 4). No other side effects such as nausea, vomiting, or pruritus were observed in any of the patient in the three groups.

## DISCUSSION

Post-operative pain management is a crucial component of patient care and its importance is much emphasized in cancer patients undergoing modified radical mastectomy to minimize emotional and physical sufferings of patients. Post-operative pain management is multifaceted involving psychoeducational care, optimal surgical care, and proper

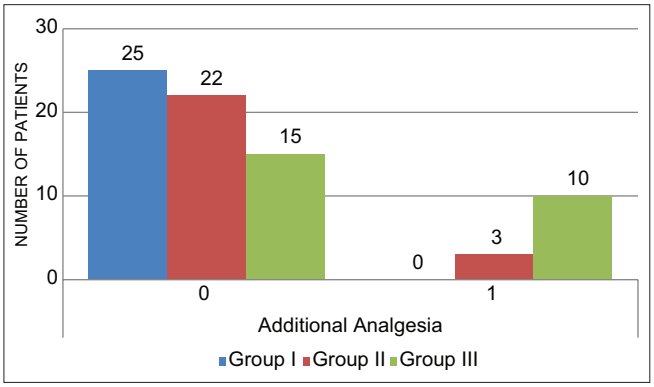


**Figure 4:** Comparison of number of additional analgesia required in three groups

**Table 4: Comparison of patient satisfaction score in three groups**

| Patient satisfaction | Score | | | Total |
|---|---|---|---|---|
| | 1 | 2 | 3 | |
| Groups | | | | |
| Group I (RM) | | | | |
| Number | 19 | 6 | 0 | 25 |
| % | 76.0 | 24.0 | 0.0 | 100.0 |
| Group II (RD) | | | | |
| Number | 12 | 11 | 2 | 25 |
| % | 48.0 | 44.0 | 8.0 | 100.0 |
| Group III (RF) | | | | |
| Number | 7 | 16 | 2 | 25 |
| % | 28.0 | 64.0 | 8.0 | 100.0 |
| Total | | | | |
| Number | 38 | 33 | 4 | 75 |
| % | 50.7 | 44.0 | 5.3 | 100.0 |

Chi-square test, P-*value* =0.01 (S)

post-operative care with active measures of multimodal analgesic therapy. Psychoeducational care includes health-care information, skills teaching (coughing, breathing and bed exercises, relaxation, and hypnosis), and psychosocial support (identifying and alleviating concerns, reassurance, problems solving, and encouraging questions).[12] Optimal surgical care is skilled and gentle handling of tissues, carrying out the operation with dispatch and observance of other surgical principles to minimize trauma. Proper post-operative care involves continuing psychological support, multimodal analgesia, proper care of wounds, early ambulation, and good nursing care.[13]

Multimodal analgesia components are systemic analgesics and adjuvant drugs, local infiltration and field block, regional nerve blocks with local anesthetics, epidural or intrathecal opioids, combined local anesthetics and opioids, and electrical analgesia achieved with transcutaneous electrical stimulation or electroacupuncture. It has been suggested that simple technique of instillation of local anesthetic through the surgical drain may avoid some of the difficulties and provide superior post-operative

analgesia to a standard general anesthetic/opioid based technique.[14,15] Ropivacaine is a preferred local anesthetic for such use due to its better safety profile and long duration of action. Multiple adjuvants are used with ropivacaine to potentiate analgesia while limiting concerns due to dose sparing effect. In our study, we aimed to compare efficacy of instillation of ropivacaine with different adjuvants (fentanyl, dexmedetomidine, or morphine) through surgical drain for post-operative pain in modified radical mastectomy patients and found better analgesia and patient satisfaction in ropivacaine with morphine group as compared to instillation of ropivacaine with dexmedetomidine or fentanyl.

Patel et al., demonstrated that that patients receiving ropivacaine 0.2% (0.5 mL/kg)) instillation through axillary and chest drains placed post surgically in modified radical mastectomy patients experienced better analgesia and less incidence of post-operative nausea and vomiting as compared to patients who received normal saline 0.9% (0.5 mL/kg) through axillary and chest drains.[2]

Chhatrapati et al., while comparing bupivacaine and ropivacaine wound instillation through surgical drain for post-operative analgesia in modified radical mastectomy found near similar pharmacological effects with both drugs; however, duration of analgesia was longer with bupivacaine. In their study, systolic and diastolic blood pressures were significantly higher in bupivacaine group than in ropivacaine group.[16]

In a prospective study, Prieto et al., concluded the same efficacy of preventive treatment of pain for instillation or infiltration with 7.5% (20 mL) ropivacaine in patients after modified radical mastectomy and little need for rescue medication after surgery.[17]

Many authors have evaluated combination of local anesthetics with different adjuvants for purpose of postoperative analgesia. While comparing postsurgical wound infiltration with ropivacaine 0.375%, ropivacaine 0.375% combined with fentanyl 0.5 microgram/kg and intravenous (i.v.) fentanyl 0.5 microgram/kg before skin incision without wound infiltration, Johansson et al., found comparable frequencies of post-operative pain at rest, and nausea and vomiting in all the groups in patients of breast surgery.[18]

Similarly Yadav et al., found instillation of ropivacaine or ropivacaine with tramadol through surgical drain to be safe, effective, and inexpensive technique for post-operative analgesia in providing good relief of pain, prolonged analgesia, decreased analgesic requirement, and increased patient's satisfaction in modified radical mastectomy patients. However, addition of tramadol to ropivacaine did not add advantage when compared to ropivacaine alone in their study.[19]

In contrast to above findings, addition of opioids to local anesthetics resulted in better post-operative analgesia and reduced opioid requirement in post-operative period in a prospective and randomized study by Chander et al., who evaluated wound infiltration with bupivacaine alone and with fentanyl for analgesia after abdominal surgery.[20]

### Limitations of the study

Effect on the incidence and severity of chronic post-surgical pain was not studied as patients were followed up for 24 h postoperatively only.

## CONCLUSION

Wound instillation with ropivacaine has emerged as a frequently used technique due to its safer profile and efficacious combination with different adjuvants. Instillation of wound with ropivacaine and morphine as adjuvant through surgical drain provides good pain relief, prolonged duration of analgesia, decreased analgesic requirement, and good patient satisfaction in the post-operative period of modified radical mastectomy as compared to instillation with ropivacaine with dexmedetomidine or fentanyl.

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