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Original Research Article

Efficacy of dexamethasone as an adjuvant to ropivacaine versus ropivacaine alone in ultrasound-guided erector spinae plane block for post-operative analgesia in modified radical mastectomy: A randomized controlled trial

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Abstract

Background and Aims: Effective postoperative pain management is crucial for improving recovery and patient satisfaction, particularly following Modified Radical Mastectomy (MRM) surgery. Traditional opioid analgesia often results in side effects like nausea and sedation, prompting the need for alternative strategies. The ultrasound-guided Erector Spinae Plane Block (ESPB) has emerged as a promising technique for providing reliable analgesia for thoracic and abdominal surgeries, including MRM, with minimal complications. Ropivacaine, a long-acting local anesthetic, is commonly used in ESPB but may benefit from the addition of adjuvants such as Dexamethasone, known for its anti-inflammatory and analgesic properties. This study aimed to compare the efficacy of Dexamethasone as an adjuvant to Ropivacaine versus Ropivacaine alone in providing postoperative analgesia for MRM surgery.

Materials and Methods: This randomized controlled trial was conducted at a tertiary care hospital involving 64 patients scheduled for Modified Radical Mastectomy (MRM) surgery. After obtaining ethical approval and informed consent, participants were randomly assigned into two groups: Group RD (Ropivacaine with Dexamethasone) and Group RS (Ropivacaine alone). In Group RD, patients received a combination of 0.5% Ropivacaine and 8 mg of Dexamethasone, while Group RS received only 0.5% Ropivacaine. The primary outcomes measured were the time to first rescue analgesia and the total analgesia required within the first 24 hours following surgery. Secondary outcomes included pain scores assessed using the Visual Analog Scale (VAS) at 4, 6, 12, and 24 hours post-surgery, as well as the incidence of any adverse events. Data was analysed using appropriate statistical methods, including t-tests and chi-square tests, with a significance level set at $P<0.05$.

Results: Group RD (Ropivacaine with Dexamethasone) demonstrated a significantly longer time to first rescue analgesia compared to Group RS (Ropivacaine alone). Additionally, Group RD required less total analgesia within the first 24 hours post-surgery than Group RS. Pain scores, assessed using the Visual Analog Scale (VAS), were significantly lower in Group RD at 4, 6, 12, and 24 hours post-surgery ($P<0.05$ at all time points). No significant adverse events or complications related to the ultrasound-guided Erector Spinae Plane Block (ESPB) were observed in either group.

Conclusion: The addition of Dexamethasone to Ropivacaine in ultrasound-guided Erector Spinae Plane Block (ESPB) significantly improves postoperative analgesia in patients undergoing Modified Radical Mastectomy (MRM) surgery. This combination results in prolonged analgesic effects, less total analgesic consumption, and lower pain scores compared to Ropivacaine alone.

Keywords: Erector spinae plane block, Ropivacaine, Dexamethasone, Ultrasound guided.

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1. Introduction

Postoperative pain management, especially early postoperative pain following Modified Radical Mastectomy (MRM) surgery, remains a significant challenge for anesthesiologists. Immediately after surgery, patients often experience acute pain due to the incision and tissue manipulation.[1] This pain typically diminishes over days to weeks as the healing process progresses. Effective pain management is critical, as inadequate control of acute postoperative pain can lead to chronic pain disorders. Some patients may experience phantom breast pain, characterized by sensations of discomfort in the area where the breast tissue was removed, despite the absence of physical tissue.[1] Phantom breast pain, a form of neuropathic pain, results from nerve damage during surgery. Postmastectomy Pain Syndrome (PMPS) is a chronic pain condition that affects the

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chest wall, armpit, and/or arm, often arising in conjunction with nerve injury during the procedure.

Despite advancements in pain relief strategies, postoperative analgesia remains insufficient for some patients, which leads to poor recovery and decreased satisfaction. Postoperative pain management following MRM surgery often involves a multidisciplinary approach. This includes the use of opioids and non-opioid analgesics, local anesthetic infiltration at the surgical site, and adjuvant medications like gabapentin/pregabalin for neuropathic pain and corticosteroids to address inflammation.[1,2] The ESPB, an interfascial plane block, is employed to provide pain relief by delivering local anesthetic deep into the erector spinae muscle adjacent to the transverse processes.

Multidisciplinary approaches, utilizing various modalities to ensure effective pain relief have been implicated for pain management after Modified Radical Mastectomy Surgery, which include opioids & non-opioid analgesics, local anaesthetic infiltration at the surgical site, adjuvant medications like gabapentin/pregabalin for neuropathic pain, corticosteroids for inflammation.[1,2] The ultrasound-guided erector spinae plane block (ESPB) has gained increasing popularity due to its accuracy and low risk of complications.[3] ESPB, a type of interfascial plane block, provides effective pain relief by depositing a local anaesthetic deep into the erector spinae muscle, which lies adjacent to the transverse processes.

Given the limited research on the use of adjuvants in ESPB, this study was designed to explore the effects of dexamethasone as an adjuvant to ropivacaine in the context of postoperative analgesia for MRM surgery. Dexamethasone when used as an additive to ESPB aids in pain management through anti-inflammatory effects and suppression of potassium channel-mediated discharge of nociceptive C-fibers. Ropivacaine was Chosen as the local anaesthetic due to its long duration of action, favourable safety profile, and effectiveness, establishing it as the preferred choice in our research. A distinctive feature of Ropivacaine is its differential blockade property. Additionally, its lower potential for cardiotoxicity and central nervous system toxicity makes it particularly suitable for patients with multiple comorbidities.

The primary objective of the study was to compare dexamethasone as an adjuvant to ropivacaine versus ropivacaine alone in ultrasound-guided ESPB for postoperative pain management. The effectiveness of analgesia was assessed by measuring the time to first rescue analgesia, total rescue analgesia required within the first 24 hours, and postoperative pain scores using the numerical rating scale.

2. Materials and Methods

The study was designed as a randomized controlled trial conducted at the Department of Anaesthesiology in a Tertiary Care centre, with approval obtained from the Institutional Ethics Committee (IEC/14/9/2022). Informed consent was acquired from all participating patients, and convenience sampling was used to select those who met the eligibility criteria.

The sample size was determined based on effect sizes from a previously published study by Gao et al., with the primary outcome being the time to first rescue analgesia between the two groups.[4]

The following formula was used:

$$N \text{ (Per Group)} = 2[(Z_{\alpha/2}+Z_{\beta})\,\sigma]/\Delta)^2$$

Where:

1. n = Sample size (per group)
2. $Z_{\alpha/2}$=1.96 for 95% confidence (i.e., α=0.05)
3. Z_{β}=0.8416 for 80% power
4. Δ = Mean difference to be detected = 4.5 hours (time to first rescue analgesia)
5. σ = Standard deviation

Effect size ($\frac{\Delta}{s}$) was calculated as 0.70, meaning the group means were expected to differ by 0.70 standard deviations (SD) as per the literature evidence, so s (σ) =4.50/0.70=6.4286.

The calculated sample size was 32.04, which was rounded to 32 patients per group, yielding a total of 64 participants.

Patients were randomly assigned to either the RD (Ropivacaine with Dexamethasone) or RS (Ropivacaine alone) intervention groups using the computer-generated RALLOC program by Minitab Corporation. Randomization was concealed through the use of sequentially numbered, opaque, sealed envelopes. One anaesthesiologist administered the block, while another anaesthesiologist, who was blinded to the treatment allocation, assessed postoperative analgesia. Additionally, participants were also blinded to the treatment they received.

Eligible participants included those scheduled for Modified Radical Mastectomy Surgeries, aged 30-70 years, with an American Society of Anesthesiologists (ASA) physical status of I, II, or III. Exclusion criteria included coagulopathy or bleeding disorders, local infection at the injection site, hypersensitivity to the study drug, BMI >30 kg/m², or a history of chronic pain medication use. Patients who chose to withdraw from the study at any stage were excluded. (**Figure 1**)

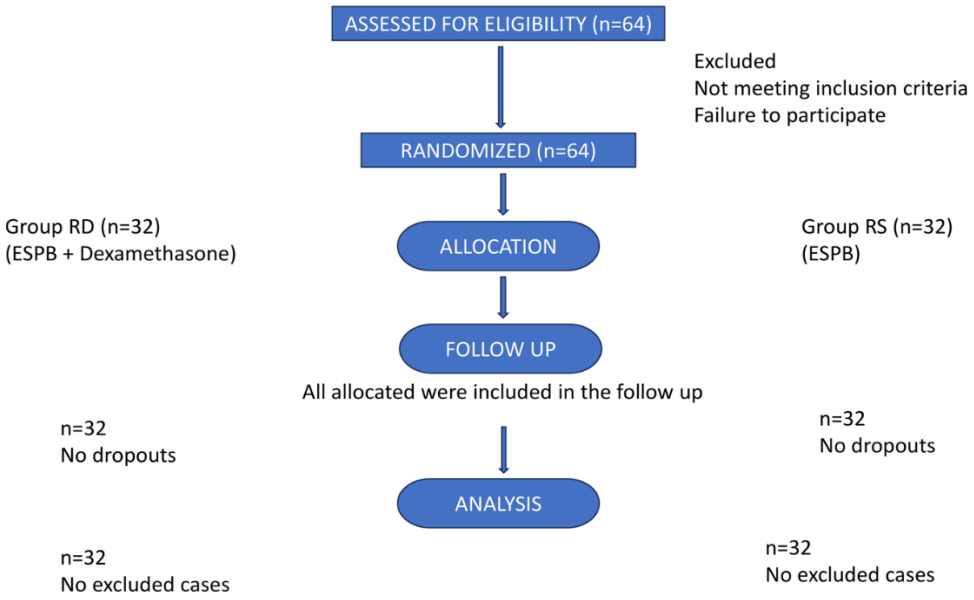

Figure 1: Consort diagram

The pre-anesthetic check-up was conducted prior to surgery, during which patients were instructed on how to use the Numerical Rating Scale (NRS) for pain assessment throughout the study. Patients were advised to remain nil per oral (NPO) for at least 8 hours before the procedure.

Following administration of General anaesthesia as per standard protocol, the Erector Spinae Plane (ESP) block was performed. For the ultrasound-guided ESP block, a SONOSITE USG MACHINE (MODEL- M Turbo) with a 6-13MHz linear transducer was utilized. Patients were positioned laterally on the affected side for the ESP block. The linear transducer probe was placed longitudinally at the T3 level of the spine, 2-3 cm from the midline. The block was performed by injecting the local anesthetic into the fascial plane, targeting the depth of the erector spinae muscles and the space between the transverse processes. Correct needle tip placement was confirmed by injecting 1 mL of 0.9% normal saline. The study group received 30 mL of 0.375% Ropivacaine combined with 8 mg of Dexamethasone, while the control group received the same volume of 0.375% Ropivacaine with 2 cc of normal saline. Following the block, patients were repositioned supine for the surgical procedure. Throughout the surgery, heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen saturation were recorded every 5 minutes for the first 30 minutes, then every 15 minutes until the completion of surgery. Intraoperative episodes of tachycardia and hypertension were managed with a bolus dose of 0.5 µg/kg of Injection Fentanyl.

Pain was assessed using both the Numerical Rating Scale (NRS) and the Visual Analog Scale (VAS). Pain scores using the VAS were specifically recorded at 4, 6, 12, and 24 hours post-surgery. In the post-operative period, ff the NRS score exceeded 4, the first rescue analgesic administered was 100 mg of intravenous Tramadol, followed by 1000 mg of intravenous Paracetamol for the second rescue analgesia if necessary.

For statistical analysis, data collected during the study was coded and analysed using STATA statistical software version 10.1. Descriptive statistics were used to summarize patient demographics and baseline characteristics. Continuous variables were presented as mean ± standard deviation. For comparing continuous variables between the two groups, independent t-tests were used for normally distributed data, while Mann-Whitney U tests were employed for non-normally distributed data. Categorical variables were compared using Chi-square tests or Fisher's exact tests as appropriate. Repeated measures ANOVA or mixed-effects models were utilized to analyse pain scores and hemodynamic parameters over time. A p-value < 0.05 was considered statistically significant for all analyses.

3. Observation and Results

Table 1: Demographic variables of two groups

Variable	Group RS (n=32)	Group RD (n=32)	p-value
Age (years) **(Mean ± SD)**	51.19±11.39	49.47 ± 9.45	0.514^{NS}
BMI (kg/m²) **(Mean ± SD)**	22.15 ± 2.32	21.64 ± 2.24	0.375^{NS}
ASA I	21 (65.6%)	21 (65.6%)	0.836^{NS}
ASA II	10 (31.3%)	10 (31.3%)	
ASA III	1 (3.1%)	1 (3.1%)	

The study included 64 patients divided equally into two groups: Group RS (Ropivacaine with Saline) and Group RD (Ropivacaine with Dexamethasone). Demographic and

clinical characteristics were comparable between the two groups, with no statistically significant differences in age, BMI, or ASA grade ($p > 0.05$). The mean age was 51.19 ± 11.39 years for Group RS and 49.47 ± 9.45 years for Group RD, while the mean BMI was 22.15 ± 2.32 for Group RS and 21.64 ± 2.24 for Group RD. The ASA grade distribution was similar in both groups, with 21 patients in ASA I, 10 in ASA II, and 1 in ASA III for each group (p-value = 0.836). This baseline similarity ensured a reliable comparison of outcomes between the groups.

3.1. Physiological parameters

The physiological parameters, including pulse rate, systolic BP, diastolic BP, mean arterial pressure, and oxygen saturation levels, were monitored at multiple intervals post-procedure. No significant differences were observed across these parameters between the two groups (p-value > 0.05), suggesting that the addition of Dexamethasone to Ropivacaine did not adversely affect hemodynamic stability during the study period.

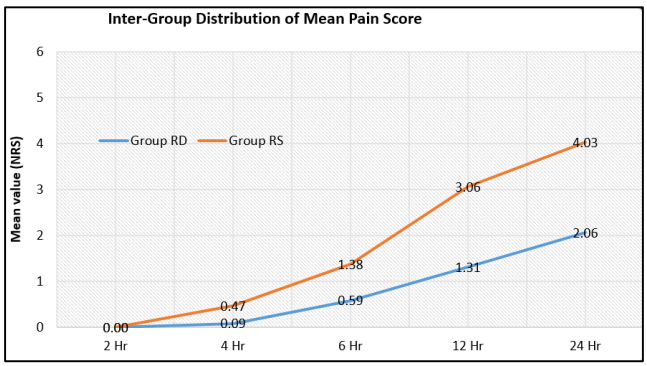

Figure 2: Inter-group distribution of mean pain score

3.2. Pain scores

Pain scores, assessed using a numerical rating scale, showed no significant difference between the groups at 2 hours post-surgery ($p > 0.05$). However, at 4, 6, 12, and 24 hours, Group RD consistently demonstrated lower pain scores compared to Group RS ($p < 0.05$ for all time points). This finding suggests that Dexamethasone as an adjuvant to Ropivacaine effectively enhanced postoperative analgesia (**Figure 2**).

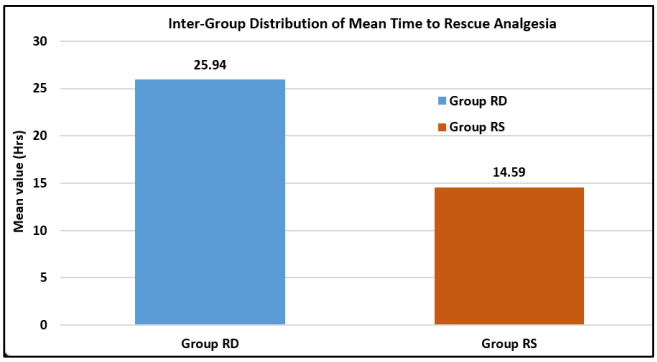

Figure 3: Mean time to first rescue analgesia

3.3. Time to rescue analgesia

The mean time to the first instance of rescue analgesia was significantly longer in Group RD (25.94 ± 5.63 hours) compared to Group RS (14.59 ± 3.88 hours). The range of time to rescue analgesia varied, with Group RD having a range of 15 to 37 hours, while Group RS ranged from 9 to 25 hours. This suggests that patients receiving the Dexamethasone-Ropivacaine combination experienced longer durations of analgesia before additional pain relief was necessary ($p < 0.05$) (Figure-3).

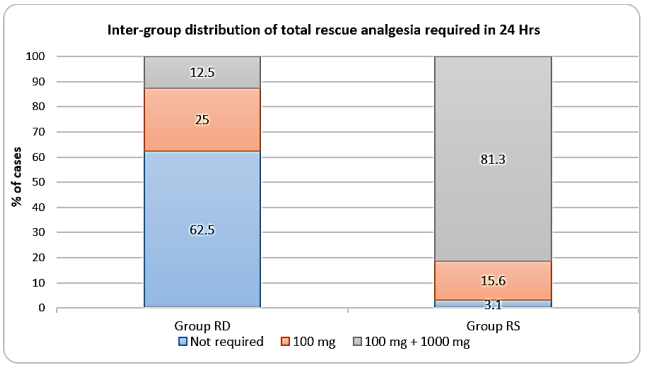

Figure 4: Inter-group distribution of total rescue analgesia required in 24 Hrs

3.4. Rescue analgesia requirements

Rescue analgesia requirements within the 24-hour postoperative period further highlighted the efficacy of the Dexamethasone-Ropivacaine combination. In Group RD, 62.5% of patients required no rescue analgesia, compared to only 3.1% in Group RS. Additionally, 25% of Group RD patients needed 100 mg of rescue analgesia, and 12.5% required both 100 mg and 1000 mg. In contrast, 15.6% of Group RS patients needed 100 mg, while a substantial 81.3% required higher doses (100 mg + 1000 mg). These differences were statistically significant ($p < 0.05$) (**Figure 4**).

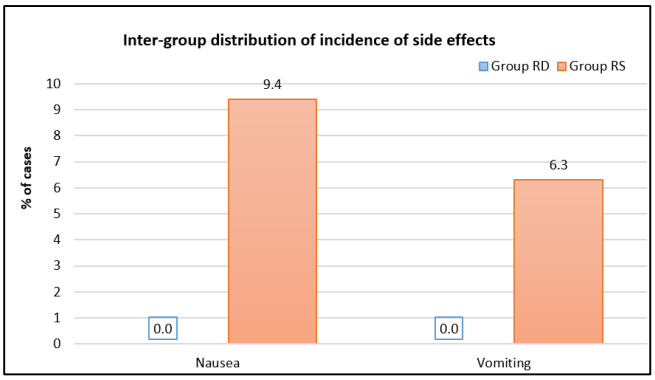

Figure 5: Inter-group incidence of side effects

3.5. Incidence of nausea and vomiting

In terms of side effects, none of the patients in Group RD reported nausea, while 9.4% of patients in Group RS did. The difference in the incidence of nausea was not statistically significant (p-value > 0.05). Similarly, no patients in Group RD experienced vomiting, whereas 6.3% in Group RS did. This suggests that the combination of Dexamethasone and Ropivacaine may also contribute to a better side effect profile compared to Ropivacaine alone, although these findings were not statistically significant.(**Figure 5**)

4. Discussion

The Erector Spinae Plane Block (ESPB) has emerged as an effective technique for pain relief, particularly in surgeries involving the chest wall and breast. By targeting the dorsal and ventral rami of the spinal nerves, ESPB provides comprehensive analgesia to these regions. Its straightforward nature and strong safety profile, especially when performed under ultrasound guidance, make it a reliable and simple procedure for postoperative pain management.[5] The use of ultrasound ensures precise needle placement, reducing the risk of complications and enhancing the block's effectiveness.

Several factors influence the outcomes of studies evaluating postoperative analgesia with Dexamethasone and Ropivacaine in ultrasound-guided ESPB. Patient characteristics, such as age, BMI, ASA physical status, and the presence of comorbidities, play a significant role in determining the analgesic response and recovery patterns. For instance, older patients or those with higher BMIs may experience variations in drug metabolism and distribution, affecting the duration and intensity of pain relief. Additionally, the type, dosage, and method of drug administration are critical factors. Dexamethasone, when used as an adjuvant to Ropivacaine, has been shown to prolong the duration of analgesia and reduce inflammation, thereby enhancing postoperative comfort.[1] The use of ultrasound ensures accurate delivery of the local anesthetic, minimizing variability and improving safety, which contributes to more consistent outcomes across patients.

Pain assessment is a crucial component of evaluating the efficacy of ESPB. In this study, pain was monitored using a Numerical Rating Scale (NRS) at various intervals post-surgery. While the NRS is a widely accepted tool for pain assessment, the choice of assessment scale can influence study outcomes. For example, alternative scales like the Visual Analog Scale (VAS) or Verbal Rating Scale (VRS) might yield slightly different results due to variations in patient interpretation and reporting. Side effects, such as nausea and vomiting, were also monitored, as these could affect patient comfort and the overall effectiveness of the analgesic strategy. Managing these side effects is essential to ensure patient satisfaction and recovery.

The use of Ropivacaine in peripheral nerve blocks, including ESPB, offers several advantages. As a long-acting local anesthetic, Ropivacaine provides an extended duration of both sensory and motor blockade, making it particularly suitable for prolonged surgical procedures and postoperative pain management.[6] Its favourable safety profile, with a lower risk of cardiotoxicity compared to other local anesthetics, further enhances its acceptance in clinical practice. When combined with adjuvants like Dexamethasone, Ropivacaine's efficacy is further amplified, offering patients sustained pain relief and reducing the need for additional opioid analgesics.

One key benefit of Ropivacaine is its differential blockade effect, which enables sensory block at lower concentrations while minimizing motor block. This characteristic is especially advantageous in procedures where maintaining motor function is crucial. Additionally, when compared to Bupivacaine, Ropivacaine offers a superior safety profile, as it carries a lower risk of cardiotoxicity and central nervous system toxicity. As a result, Ropivacaine is considered a safer option, especially for higher doses or for patients with elevated risk factors.

In our study, we selected 0.375% Ropivacaine for peripheral nerve blocks, as this concentration effectively balances analgesia and motor blockade. This concentration has been shown to provide effective pain relief while minimizing motor dysfunction, making it suitable for a wide range of surgical procedures and postoperative pain management. Research supports that 0.375% Ropivacaine is associated with a lower incidence of adverse effects, particularly in terms of cardiovascular and central nervous system toxicity, compared to higher concentrations of local anesthetics.[4] Moreover, Ropivacaine at this concentration results in less motor blockade than higher concentrations or other local anesthetics, such as Bupivacaine, which can be beneficial for specific procedures.[7]

Incorporating dexamethasone as an additive in peripheral nerve blocks has been shown to significantly enhance the quality and duration of analgesia. Due to its potent anti-inflammatory properties, dexamethasone reduces local inflammation and pain at the surgical site, thus improving overall pain management.[5,8] The addition of dexamethasone can prolong the duration of analgesia, reduce

the need for rescue analgesics, and potentially reduce opioid consumption, which enhances patient outcomes post-surgery.

Ensuring that baseline characteristics are comparable between study groups is essential for the validity of clinical trials. In our study, 64 patients were randomly assigned to two equal groups: Study Group RD and Control Group RS. The demographic characteristics, including age, BMI, and ASA grades, were well-matched and comparable between the two groups, ensuring the reliability of the results. These findings are consistent with the study by Gao et al. which also found no significant differences in age, BMI, and ASA grades between the study groups, further supporting the comparability and validity of the outcomes.

Various physiological parameters, including pulse rate, systolic and diastolic blood pressure, mean arterial pressure (MAP), and oxygen saturation (SpO2) were carefully monitored at multiple time points. The results revealed no significant differences between the two groups, indicating that the inclusion of Dexamethasone did not affect the patients' hemodynamic stability. These findings align with the observations of Gao et al., who also reported no notable hemodynamic changes associated with the use of adjuvants in ESPB. Similarly, studies by Yang et al. and Ahmed et al. demonstrated stable hemodynamic parameters, further confirming the safety and reliability of Dexamethasone as an adjunct in regional anesthesia.[9,10]

The stability of hemodynamic parameters in our study reinforces the conclusion that combining Ropivacaine with Dexamethasone does not disrupt cardiovascular or respiratory functions, making it a safer option compared to conventional opioid-based pain management.[11] This is particularly important, as maintaining stable physiological parameters is crucial for minimizing complications during and after surgical procedures. Thus, the addition of Dexamethasone not only improves analgesia but also ensures a secure and consistent hemodynamic profile for patients.

While opioids have long been the primary method for managing acute postoperative pain, recent studies have raised concerns about their safety. A study examining clinical and administrative data from adult patients who received opioids following hospital-based surgeries or endoscopic procedures found that 10.6% of patients experienced opioid-related adverse events. These events were associated with worse outcomes, including increased inpatient mortality, longer hospital stays, and higher rates of readmission within 30 days.[12,13] These findings emphasize the need for alternative pain management strategies, such as the combination of Dexamethasone and Ropivacaine, which may offer safer and more effective options, particularly as a response to the risks associated with opioid use.

Pain scores, as measured by the Numerical Rating Scale (NRS), were significantly lower in Study Group RD at all postoperative time points beyond 2 hours. At 4, 6, 12, and 24 hours post-surgery, Study Group RD consistently reported lower pain scores compared to Control Group RS ($P<0.05$). These findings are consistent with those of Yang et al., who also observed that groups receiving adjuvants, like Dexamethasone, experienced lower postoperative pain scores and a longer duration before requiring rescue analgesia.[9]

Other studies have similarly demonstrated the effectiveness of combining Ropivacaine and Dexamethasone in peripheral nerve blocks. For instance, Choi et al. found that the combination of Ropivacaine and Dexamethasone in an ESPB resulted in superior postoperative analgesia compared to Ropivacaine alone, leading to a significant reduction in opioid consumption and pain scores.[5] Likewise, Tulgar et al. reported that Ropivacaine at a concentration of 0.375% provided effective analgesia with minimal motor blockade, supporting its use in a range of surgical procedures.[14] A study by Garg et al. examined the use of Ropivacaine with Dexamethasone in pectoral nerve blocks for breast cancer surgeries. They found that patients receiving the combination experienced significantly lower pain scores and reduced opioid consumption in the first 24 hours post-surgery compared to those receiving Ropivacaine alone.[15] These studies further validate the benefits of using Ropivacaine and Dexamethasone together, offering improved postoperative pain management while maintaining a favourable safety profile.

The need for rescue analgesia within 24 hours post-surgery was significantly lower in Study Group RD. Specifically, 62.5% of patients in Study Group RD did not require any rescue analgesia, compared to just 3.1% in Control Group RS. Additionally, fewer patients in Study Group RD needed higher doses of analgesics, further emphasizing the effectiveness of Dexamethasone as an adjunct to Ropivacaine.

The safety profile of the interventions was closely monitored by assessing the incidence of side effects and complications. The absence of significant adverse effects in Study Group RD, in contrast to the higher incidence of complications in Control Group RS, further validate the safety and efficacy of the combination therapy. These results highlight the potential benefits of incorporating Dexamethasone into regional anesthesia for enhanced postoperative pain management with minimal side effects.

This study acknowledges several limitations that could impact the generalizability of its findings. Firstly, a multi-centre approach could have provided more diverse data by capturing variations across different healthcare settings and patient populations. This would enhance the representativeness of the results and reduce potential biases inherent in a single-centre study. Additionally, increasing the sample size would have improved the statistical power, allowing for more precise and reliable conclusions.

Another limitation is the restriction of the study to patients with specific BMI criteria. This exclusion limits the applicability of the findings to a broader population, particularly those with higher BMI or more complex comorbidities, who may respond differently to the analgesic combination. Expanding the inclusion criteria to include a wider range of patients would make the findings more universally applicable.

Addressing these limitations in future research would enhance the applicability and validity of the findings, contributing to more comprehensive and effective perioperative pain management practices.

5. Conclusion

The addition of Dexamethasone to Ropivacaine in Ultrasound-Guided Erector Spinae Plane Block significantly improves postoperative pain management for Modified Radical Mastectomy patients. This combination extends the duration of analgesia, decreases rescue analgesic requirements, and minimizes side effects. By enhancing pain control and reducing opioid needs, this approach may lead to improved recovery experiences and potentially shorter hospital stays for patients undergoing breast cancer surgery.

6. Source of Funding

None.

7. Conflict of Interest

None.

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