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Original Research Article

A comparative evaluation of dexamethasone and MgSO₄ as an adjuvant to ropivacaine in transversus abdominis plane block for post operative analgesia in patients undergoing elective cesarean section, a triple blinded randomised controlled trial

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ABSTRACT

Background: In regional blocks, dexamethasone and magnesium sulphate (MgSO₄) have been used as an adjunct to local anesthesia. But more research needs to be done on each one's effectiveness. This study aims to assess the efficacy of dexamethasone 4mg and MgSO₄ 150mg as an adjunct to ropivacaine 0.375% in transversus abdominis plane (TAP) block for postoperative analgesia in patients undergoing cesarean section under subarachnoid block (SAB).

Materials and Methods: Ninety patients undergoing cesarean section under SAB belonging to American Society of Anesthesiologists physical status I or II, were recruited and randomised in three groups. Each group comprised of 30 patients. Group RS received 20ml 0.375% ropivacaine with 2 ml normal saline, Group RD received 20ml 0.375% ropivacaine with 4 mg dexamethasone and Group RM received 20ml 0.375% ropivacaine with 150 mg MgSO₄. Time to first analgesic request, VAS score at rest and movement, patient satisfaction score, hemodynamic parameters and side effects were recorded in each group post-TAP block for 24 hours.

Results: Time to first analgesic request was significantly longer in group RD (814.0 ± 277.3 min) compared to group RM (606.5 ± 279.9 min) and group RS (545.5 ± 254.3 min) (p = 0.001). The mean value of tramadol requirement was statistically higher in Group RS compared to Group RD and Group RM (p < 0.001). The mean differences in VAS score at rest and movement at 6 & 8 h was significantly lower in dexamethasone and MgSO₄ compared to control group p = 0.001.

Conclusion: The addition of dexamethasone to ropivacaine in TAP block significantly prolonged the duration of analgesia, reducing the need for systemic analgesia with minimal side effects.

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1. Introduction

The most undesirable clinical outcome associated with the lower segment cesarean section (LSCS) is pain.¹ Inadequate pain management following surgery can negatively impact

ambulation thereby increasing the risk of thromboembolic episodes, breastfeeding, maternal-child bonding and potentially lead to chronic pain.² An ideal analgesic regimen should aim to minimize drug transfer through breast milk and maternal side effects.

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Transversus abdominis plane (TAP) block, as a part of multi-modal analgesia, has enhanced the recovery of patients from abdominal surgery.³ Ultrasound-guided (USG) TAP block described by Hebbard et al. has significantly improved this technique's performance resulting in accurate placement of block needle and deposition of drugs with increased margin of safety, and success rate.⁴

Various local anesthetics (LA) have been used in TAP block.⁵ Ropivacaine is used for nerve block in various concentrations 0.75%, 0.5%, 0.375%, and 0.2%.⁶ However, LA alone has a limited window of action, hence adjuvants are added to enhance the quality and prolong the duration of regional anesthesia.⁷

Dexamethasone, a long-acting glucocorticoid, has been proven safe and effective as an adjuvant to LA when given intraneurally at doses of 4 mg to 8 mg.⁸ Perineural dexamethasone inhibits nociceptive C-fibre signal transmission and locally induced vasoconstriction, prolonging the local anaesthetic effect.^{8,9}

Magnesium sulphate (MgSO₄) provides antinociceptive and analgesic effects by inhibiting the N-methyl-D-aspartate (NMDA) receptor ion channels and activating the nitric oxide pathway. Peripheral NMDA receptors have recently been found to be involved in the sensory transmission of noxious stimuli in the skin, muscles, and knee joints.¹⁰

Considering the above facts, we hypothesized that addition of adjuvants to ropivacaine will prolong the duration of analgesia of TAP block. There are very limited studies comparing the efficacy of dexamethasone and MgSO₄ with LA in TAP block and the results are contradictory.^{11,12} Hence, this study was designed to determine the post operative analgesic efficacy of MgSO₄ and dexamethasone when added to ropivacaine in TAP block in patients undergoing LSCS under subarachnoid block (SAB). The primary objective is the duration of analgesia which is defined as the time to the first request for additional analgesics after administering TAP block.

2. Materials and Methods

This triple-blind, randomized, controlled study was conducted out after obtaining approval from the Institutional Ethical Committee: Human Research (SMIMS/IEC/2021-01) and was registered in the Clinical Trial Registry of India (CTRI/2021/04/033211). All the procedures were done according to the Helsinki Declaration of 1975 (revised in 2013). Written informed consent was sought from all the participating patients.

Ninety pregnant women who underwent elective cesarean section under spinal anesthesia belonging to American Society of Anesthesiologists (ASA) physical status I or II, were included. Patients nonconsenting to block, BMI >35kg/m² and pregnancy weight <50kg, history of hypersensitivity with any drugs used in this

study, contraindication to regional anaesthesia, eclampsia, gestational diabetes, intraoperative complications like postpartum haemorrhage were excluded from study.

A computer-generated random number table was used for randomization. The random assignment of groups was concealed in identical opaque envelopes that were sealed. Each group comprising of 30 patients after random allocation received either of the following drug. Group RS 20ml 0.375% ropivacaine + 2ml Normal saline, Group RD 20 ml 0.375% ropivacaine + 4 mg dexamethasone in 2ml Normal saline, Group RM 20 ml 0.375% ropivacaine + 150 mg MgSO₄ in 2ml Normal saline.

Triple blinding was ensured in a manner that participants, outcome assessors, the anesthetist who performed the block and the statistician analysing the data were unaware of allocation. The drugs were prepared by an independent anesthesiologist not involved in the study, and the drug-filled transparent syringes were handed out to the anesthetist performing the block.

The confidentiality regarding allocation and blinding were guaranteed till the completion of data collection. The group assignments were coded during statistical analysis and were revealed after completion of the analysis.

Preoperatively, a routine pre anesthetic assessment was done. Written informed consent was obtained. Patients were introduced to the 10 cm visual analogue scale (VAS) for assessing the pain. Patients were kept fasting overnight. In the operating room, Intravenous (IV) access was secured with 18G cannula and baseline heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and oxygen saturation were recorded. Patients were co-loaded with 10 ml/kg of IV crystalloid (ringer lactate). The SAB was performed under all aseptic measures, with 25 G Quincke's needle at L3-L4 intervertebral space. Intrathecal anesthetic drug 0.5% hyperbaric bupivacaine 10 mg solution was injected after free flow of CSF was confirmed. Surgery was started only after an adequate block has reached till T4 dermatome. Bilateral TAP block was performed after the surgical wound was closed. Under aseptic precaution, a linear ultrasound probe (5-13 megahertz, Mindray) was placed in the anterolateral abdominal wall between iliac crest and costal margin in the anterior axillary line. A 23-gauge, 89-mm spinal needle was introduced through the skin anteriorly in the plane to USG beam till it reached the fascial plane between the internal oblique and transversus abdominis muscles. Once the exact location of needle tip was seen, a hydro dissection was done with 2ml normal saline to separate the fascial layers and confirmed the position of needle tip. Then 22 ml of study drug was injected slowly after careful aspiration to exclude vascular puncture, while signs of neurotoxicity such as perioral numbness, metallic taste in mouth, tinnitus, slurring of speech and mental status changes were closely monitored. Vital signs (HR, MAP) before and after the procedure was

recorded. At the end of the block, all the groups received inj. Paracetamol 1gm IV as a part of multimodal analgesia. Time to first analgesic request was recorded from the time of giving TAP block to the time when patient requested for additional analgesia or VAS score ≥ 3 . Inj Tramadol 50 mg IV was administered as a rescue analgesia. Hemodynamic parameters (HR, MAP), pain score and nausea score were assessed in all the groups at 2, 4, 6, 8, 10, 12, 18 and 24 hours after the TAP block. Pain score at rest and on movement was quantified using 0–10 cm VAS (visual analogue scale) where 0 signified no pain and 10 signified the worst imaginable pain.¹³

A 4-point rating score was used to measure the severity of nausea.¹⁴ 0-absent, 1-mild, 2- moderate and 3- severe and vomiting. Rescue antiemetics (Inj Ondansetron 4mg IV) was offered to patients who complained of nausea with vomiting.

At the end of study period after 24 hours, patient satisfaction score with the management of pain was rated on 3-point scale.¹⁴ 1- Dissatisfied, 2- satisfied, and 3- highly satisfied.

The primary outcome measure was time to first analgesic request and secondary outcomes measures include VAS score at rest and movement, Tramadol consumption over 24 h after the block, hemodynamic changes, patient satisfaction score, post-operative nausea score and any side-effects.

Sample size and statistical analysis

Sample size was calculated using the formula $[N = 2 \times (Z_{\alpha/2} + Z_{\beta})^2 \sigma^2 / D^2]$, where

N = sample size per group

σ^2 = population variance

$Z_{\alpha/2} = 1.96$ (the critical value at $\alpha/2$, confidence level of 95%, $\alpha = 0.05$)

$Z_{\beta} = 0.84$ (the critical value at β , power of 80%, $\beta = 0.2$)

D = difference of means

Based on previous literature, with an aim to find 25% prolongation in the time to first analgesic request (mean 11.62 h, standard deviation 3.80 h).¹⁵ A sample size of 24 subjects per group were required to achieve these differences at 80% power and clinical significance of 95%. Considering a 10% attrition rate, each group consisted of a minimum thirty patients.

Statistical analysis was done using SPSS, software version 26.0. The quantitative parameters were compared using analysis of variance (ANOVA) test. Categorical data were analysed using the Chi-square test. Post hoc Tukey honestly significant difference (HSD) test was applied for multiple comparisons. A p-value <0.05 was considered significant.

3. Results

In this trial, 95 patients who underwent cesarean section under SAB were evaluated for eligibility (Diagram 1). Out of these, five patients were not meeting the inclusion

criteria. The remaining ninety patients were assigned to one of the three study groups using random number table. The patients belonging to each group received the study drug following USG guided TAP block at the end of surgery.

In the end, 90 patients were evaluated. The demographic characteristics and surgical duration were comparable in all three groups. (Table 1)

3.1. Primary outcome

Time to first analgesic request was significantly longer in group RD (814.0 ± 277.3 min) compared to group RM (606.5 ± 279.9 min) and group RS (545.5 ± 254.3 min) ($p = 0.001$). Further, tukeys HSD multiple group comparison test was applied to find out the statistical difference between the groups. Group RD provided longer duration of analgesia compared to group RM and group RS, $p < 0.05$. However, duration of analgesia provided by group RS and group RM were comparable ($p = 0.673$). (Table 2)

Kaplan Meier graph of survival shows the number of patients not requiring supplemental analgesia at every point of time in the study was proportionally higher in group RD compared to group RS and group RM ($p = 0.001$). The groups were compared using log rank (Mantel-Cox test). (Figure 1)

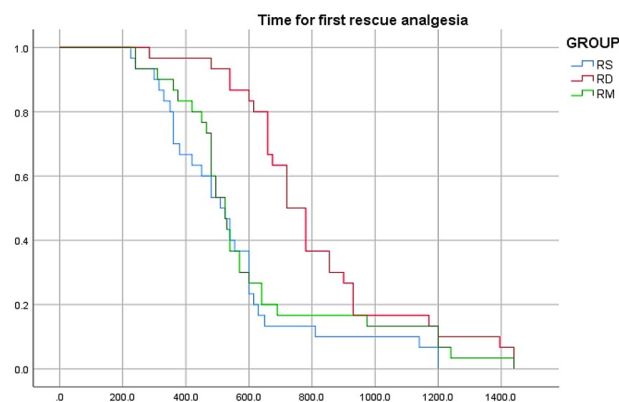


Figure 1: Kaplan Meier graph for effective analgesia period. ($p = 0.001$, log rank mantel-cox test, RS = Ropivacaine & normalsaline, RD = ropivacaine & dexamethasone, RM = Ropivacaine & MgSO₄)

3.2. Secondary outcome

VAS score at rest and movement: The mean differences in VAS score at rest at 6 & 8 h was significantly lower in dexamethasone and MgSO₄ compared to control group ($p = 0.001$). On intergroup comparison VAS score at 6 h was least in dexamethasone group. At 10 to 12 h, VAS score recorded at rest and movement in group RD was higher whereas in group RM the VAS score at rest and movement was higher around 8 -10 h and the score in both the group reduced further after receiving supplemental analgesia. At

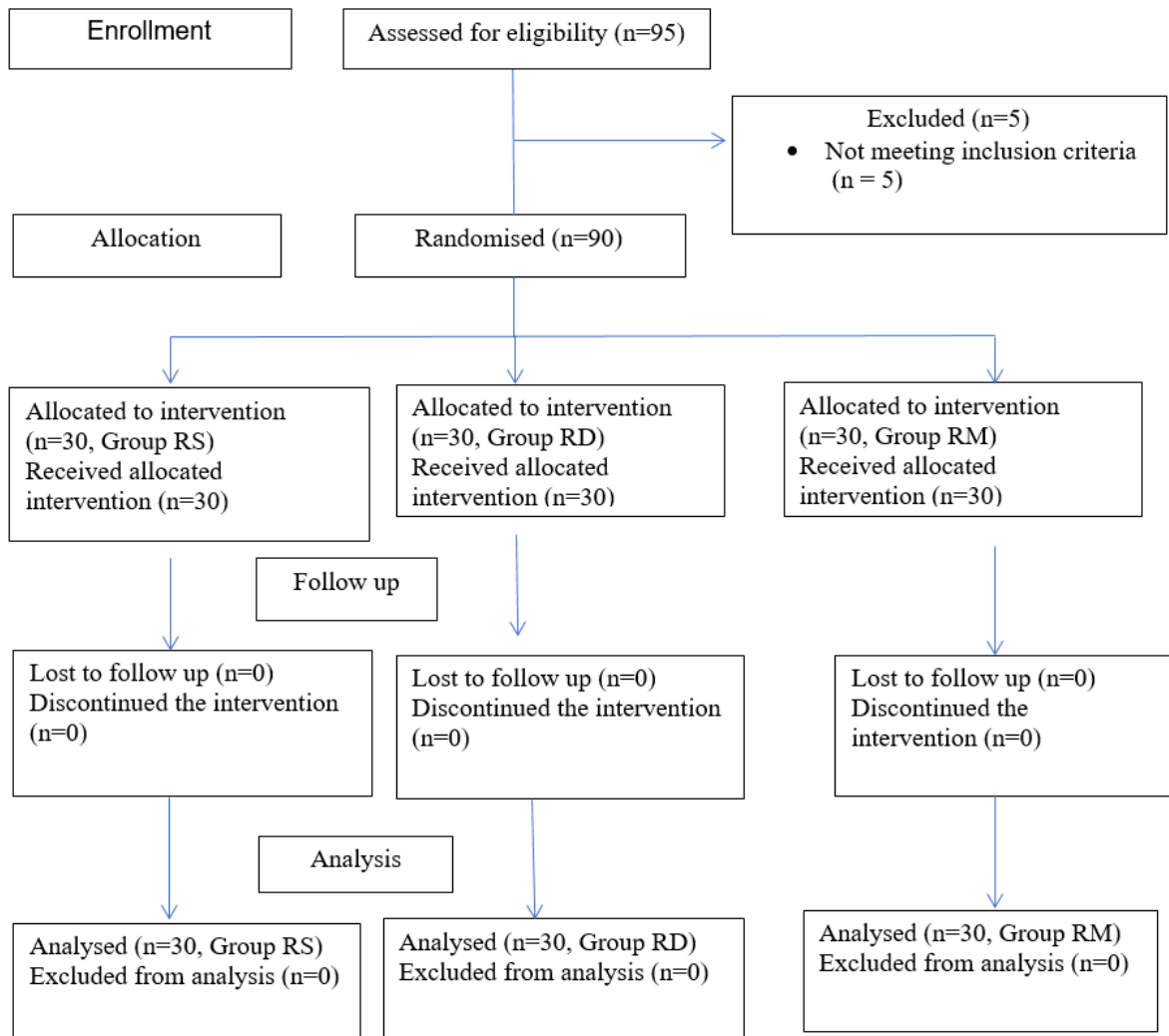


Diagram 1: Consort flow diagram

18 and 24h VAS score recorded in group RD was less compared to group RM and group RS. Additionally, VAS score recorded at 24 h was significantly low in both the group RD and group RM as compared to the control group. ($p < 0.05$). (Figures 2 and 3)

Tramadol consumption over 24 h: The mean value of tramadol requirement was statistically higher in group RS compared to group RD and group RM ($p < 0.001$). (Table 2)

Hemodynamic: The mean HR rise at 4, 6, 8 h was seen more in control group compared to group RM and group RD and was statistically significant ($p < 0.05$). However, MAP recorded after TAP block at all time intervals were comparable in all three groups. (Figures 4 and 5)

Highest patient satisfaction score at end of 24 hours was reported in group RD and was statistically significant ($p < 0.001$). (Figure 6)

Side effects, such as nausea was reported highest in group RS and least in group RD.

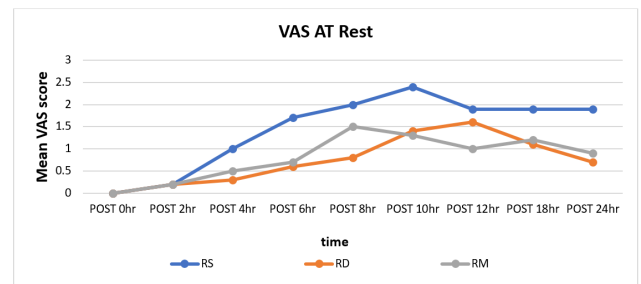


Figure 2: Comparison of VAS score at rest between three groups (RS = ropivacaine & normal saline, RD = Ropivacaine & dexamethasone, RM = Ropivacaine & MgSO₄)

4. Discussion

TAP block as an element of multi-model analgesia in abdominal surgeries has been proved beneficial. Compared

Table 1: Demographic profile

Variables	Group						ANOVA P value
	RS (n=30)		RD (n=30)		RM (n=30)		
	Mean	SD	Mean	SD	Mean	SD	
Age* (years)	31.3	6.0	30.3	5.6	31.8	3.3	0.531
Height* (cm)	154.3	3.2	153.7	2.8	153.7	2.3	0.625
Weight* (kg)	66.6	7.5	65.5	8.5	66.1	6.8	0.855
Gestational Age* (weeks)	38.6	.8	38.5	.7	38.6	.9	0.852
Duration of Surgery* (min)	62.2	6.4	60.0	.0	61.0	4.0	0.143

*Values are expressed as Mean±SD, SD = Standard deviation, n= number of cases, RS = ropivacaine & normal saline, RD= ropivacaine & dexamethasone, RM = ropivacaine & MgSO4, P<0.05 significant

Table 2: Time to first rescue analgesia (TFA) and total amount of rescue drug

Variables	Group						ANOVA P value
	RS		RD		RM		
	Mean	SD	Mean	SD	Mean	SD	
Duration of analgesia (min)	545.5	254.3	814.0	277.3	606.5	279.78	0.001
Doses of tramadol	2.0	.8	1.1	.6	1.5	.7	<0.001

*Values are expressed as Mean±SD, SD = Standard deviation, RS = Ropivacaine & normal saline, RD = ropivacaine & dexamethasone, RM = Ropivacaine & MgSO4, P<0.05 significant

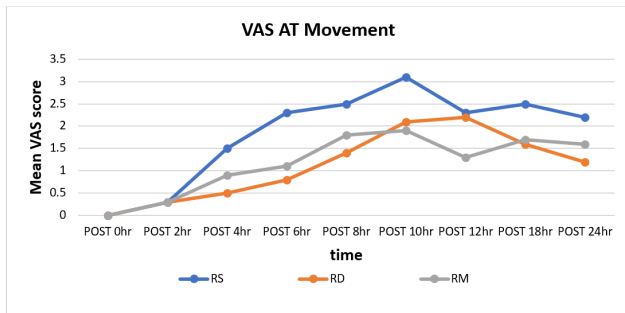


Figure 3: Comparison of VAS score at movement between three groups (RS = ropivacaine & normal saline, RD = ropivacaine & dexamethasone, RM = ropivacaine & MgSO4)

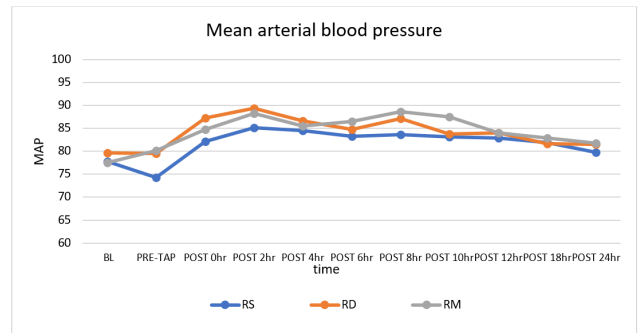


Figure 5: Comparison of mean arterial blood pressure between three groups (RS= ropivacaine & normal saline, RD = ropivacaine & dexamethasone, RM = ropivacaine & MgSO4, BL= baseline)

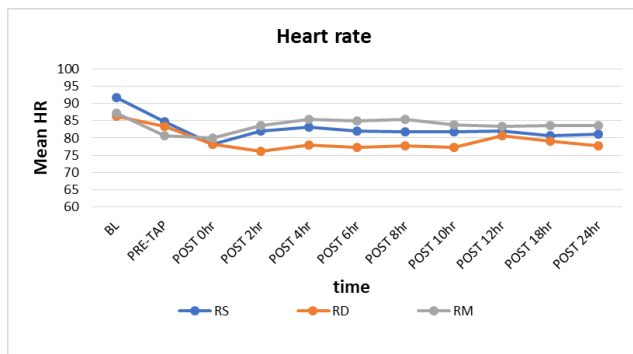


Figure 4: Comparison of heart rate between three groups (RS= ropivacaine & normal saline, RD = Ropivacaine & dexamethasone, RM = Ropivacaine & MgSO4, HR = Heart rate, BL= baseline)

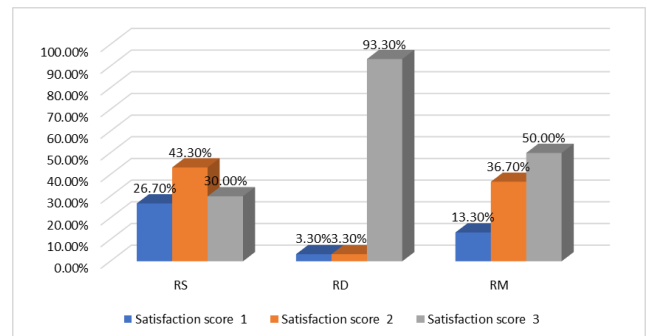


Figure 6: Patient satisfaction score (RS = Ropivacaine & normal saline, RD = Ropivacaine & dexamethasone, RM = Ropivacaine & MgSO4)

to MgSO₄ and ropivacaine alone, USG Bilateral TAP block using dexamethasone as an adjuvant to ropivacaine offered greater analgesic efficacy in this study.

We used ropivacaine as LA in our study because it is less cardiotoxic and neurotoxic and has proven analgesic efficacy in TAP block. Ropivacaine in TAP block has been studied using different concentration 0.5%, 0.25% and 0.375%. A meta-analysis study by Sun et al¹⁶ compared various concentration of ropivacaine in TAP block in abdominal surgery and reported ropivacaine 0.375% safe and effective in providing greater degree of analgesia in 24 hours. In the current study ropivacaine 0.375% provided a mean analgesic duration of 5 - 8 h, which was found similar to the study done by Qian et al.¹⁷ LA alone has limited duration of analgesia and if used in maximum dose can result in systemic toxicity. Hence, the addition of adjuvant has beneficial role in prolonging the duration as well as improving the quality of analgesia.

Perineural dexamethasone and MgSO₄ with LA have proven to be beneficial in extending the duration of analgesia.^{18,19} There are, however only handfuls of studies comparing their analgesic efficacy in TAP block. As a result, we sought to test the analgesic efficacy of dexamethasone and MgSO₄ when used as an adjuvant to ropivacaine. Additionally, we compared the results with the control group, which was not done in the earlier trial.

In accordance with EI Shamouby et al²⁰ 4 mg of dexamethasone was as effective as 8 mg dexamethasone when added to LA for TAP block. Based on the aforementioned results, we have chosen dexamethasone 4mg in our study. Addition of dexamethasone 4mg to 0.375% ropivacaine 20ml has significantly prolonged the duration of analgesia (13.56 h ± 4.6) (p<0.001). Supplemental analgesic requirement was significantly less, and patient has reported higher satisfaction score. Incidences of nausea, vomiting were significantly reduced. Dexamethasone showed significant reduction in VAS score at 4, 6, 8, 24 h both in rest and movement (p<0.05).

Gupta et al¹⁵ employed a similar dose of dexamethasone 4 mg with ropivacaine 0.375% 25 ml in TAP block in patients undergoing LSCS. The time taken to administer first rescue analgesia (19.04± 4.13 h) was longer than in our study. This could be due to higher volume of drug used in their study as the clinical effect of TAP block is a volume dependent. The VAS score at 8,12,24 h was less and consistent with our findings.

MgSO₄ dose used in this study was derived from a data given by Gunduz et al²¹ where in MgSO₄150mg in comparison to 100mg when added to prilocaine provided a pronounced prolongation in duration axillary block without any systemic or neurotoxicity. Additionally, Rana et al²² had reported 150 mg MgSO₄ as safe and effective dose in providing better analgesia in TAP block. However, in the current study MgSO₄ 150 mg as adjuvant to ropivacaine

did not show any significant prolongation in duration of analgesia in comparison to ropivacaine alone.

Furthermore, dexamethasone (4mg) with 0.375% ropivacaine provided a significantly longer duration of analgesia compared to MgSO₄ (150 mg) in TAP block. Shambhavi et al¹² reported similar outcomes of prolonged analgesia with dexamethasone in TAP block. Few other studies have compared dexamethasone and MgSO₄ as an adjuvant to LA in other regional blocks and have reported dexamethasone as superior to MgSO₄ in terms of duration of analgesia.^{23,24}

In contrary, Gad et al¹¹ reported MgSO₄ as superior to dexamethasone in prolonging the duration of analgesia when used as an adjuvant to bupivacaine in TAP block for total abdominal hysterectomy. These variances could be due to difference in the form of surgery and the conduct of general anesthesia for total abdominal hysterectomy.

Mah et al²⁵ reported no significant differences in postoperative analgesia between dexamethasone and MgSO₄ when added to levobupivacaine in supraclavicular nerve block. This discrepancy could be due to levobupivacaine being a long acting hence it could have masked the effects of the two adjuvants. This could also be due to the different type of block under which the effect of drug was studied.

The post-operative pain was measured using VAS score at rest and movement. VAS score for both rest and movement in all three groups were insignificant at time points of 0 h and 2 h postoperatively. Because of the effect of spinal anesthesia, which is anticipated to relieve pain for up to 2 hours with hyperbaric bupivacaine alone, this occurred. At 6, 8,10 and 24 h VAS score in rest and movement were significantly lower in dexamethasone group in comparison to control group. At 10 to 12 h, VAS score recorded in group RD was higher as majority of patient complained of pain after 10 h which was reflected with higher VAS score whereas in group RM the VAS score was higher around 8 -10h and the score reduced further after receiving supplemental analgesia. Additionally, VAS score recorded at 24 h was significantly lower in both the group RD and group RM as compared to the control group. Similarly, shambhavi et al¹² reported significantly lower postoperative pain scores with dexamethasone with higher score at 10h in comparison to MgSO₄ with LA in TAP block for inguinal hernia repair. Whereas Sharma et al²⁴ employed the same adjuvant and reported lower VAS score at 12 h and 24h in dexamethasone group.

The rescue analgesia consumption was highest in control group followed by MgSO₄ and least in dexamethasone group. Claiming that dexamethasone offers better pain relief and over an extended period. Thus, reduces the need for rescue analgesia. In contrary, Gad et al¹¹ reported lesser requirements of rescue analgesics in the magnesium group compared to the dexamethasone group when used in TAP

block for total abdominal hysterectomy. This could be due to temporal variation in administration of TAP block after GA versus after SAB in this study and variation in the nature of the surgery.

Patient satisfaction score at the end of 24 h was significantly high in dexamethasone group ($p < 0.001$). Incidences of postoperative nausea & vomiting were least in dexamethasone compared to MgSO₄. This could also be due to the systemic effect of dexamethasone in reducing nausea & vomiting.

The strength of our study was the comparison of adjuvants with the control group improved the validity of our findings. In addition, pain score was assessed both in rest and movement to ascertain the analgesic effectiveness. Our study had certain limitations as we did not study the adjuvants serum levels to determine whether their analgesic effects were due to local or systemic effects. Additionally, we could have investigated the effect of perineural dexamethasone on pre and post TAP serum glucose levels.

5. Conclusion

Dexamethasone as an adjuvant to ropivacaine in TAP block significantly prolonged the duration of analgesia, reduced the need for systemic analgesia, and resulted in fewer side effects and higher patient satisfaction scores compared to MgSO₄ in patients undergoing cesarean section under SAB.

6. Conflict of Interest

None.

7. Sources of Funding

None.

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