International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

A Randomized Double Blinded Study of Ultrasound Guided Tap Block for Post Operative Analgesia for Cesarean Section with Bupivacaine Vs Bupivacaine with Dexamethasone (Perineural Vs Intravenous)

Dr S Ramya[1], Dr G Shanmugapriya[2], Dr S Dinesh Kumar[3]

[1]Senior Resident, Government Kallakurichi Medical College, Kallakurichi
[2]Senior Assistant Professor, Institute of Anaesthesiology and Critical Care, Madras Medical College, Chennai.
[3]Assistant Professor, Government Kallakurichi Medical College, Kallakurichi

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Corresponding Author:

DR S RAMYA
Senior Resident, Government Kallakurichi Medical College, Kallakurichi

Received: 11-12-2025
Accepted: 24-01-2026
Available online: 03-03-2026

ABSTRACT

BACKGROUND AND GOAL OF THE STUDY: The aim and objective of the study is to compare the duration of Postoperative Analgesia with Bupivacaine Vs Bupivacaine with Dexamethasone (perineurally or intravenously) in patients undergoing caesarean section using Ultrasound guided Transverse Abdominis Plane Block.

METHODS: We studied sixty antenatal patients those who meet inclusion criteria were randomized and allocated into three groups. After caesarean section under spinal anaesthesia , all the sixty patients received bilateral ultrasound guided transverse abdominis plane block when the spinal level regressed to T8 level, for post operative analgesia .Bupivacaine group (B) patients received 20 ml of 0.25 % Bupivacaine +2 ml of normal saline + 2 ml distilled water IV, Perineural Dexamethasone group (D1) patients received 20 ml of 0.25 % Bupivacaine +2 ml (8 mg) Dexamethasone + 2 ml distilled water IV and Intravenous Dexamethasone group (D2) patients received 20 ml of 0.25 % Bupivacaine +2 ml of normal saline + 2 ml (8 mg) Dexamethasone IV. Patients were evalauated for Demographic datas like Age, Weight, block grade, numerical pain scale for 24 hrs postoperatively, duration of analgesia, total dosage of tramadol used and Complications.

RESULTS: The duration of analgesia is prolonged in perineural Dexamethasone group (795 +/- 374.89 min) when compared to Bupivacaine group (513 +/-259.33 min) with a p value of 0.03 and also duration of analgesia is prolonged in intravenous Dexamethasone group (774 +/- 369.81 min) when compared to Bupivacaine group with a p value of 0.04 with no statistical significant difference between perineural and intravenous group (p 1.00) .

Total dose of rescue tramadol used is higher in Bupivacaine group (72.50+/- 30.24 mg) when compared to perineural Dexamethasone group (45 +/- 27.62 mg) in first 24 hours which is statistically significant with a p value of 0.01 and similarly total rescue tramadol dose used is lower in intravenous Dexamethasone group (47.50 +/- 30.24 mg) compared to plain bupivacaine group with a p value of 0.03 with no statistical significance between perineural and intravenous Dexamethasone group (p value 1.00).No complications like nausea, vomiting, dizziness, femoral nerve palsy, pelvic hematoma, liver trauma etc. during first 24 hour study period.

CONCLUSION: The Dexamethasone in the dose of 8 mg added either Perineurally or Intravenously to 0.25 % Bupivacaine in Transverse abdominis plane block in cesaerean patients prolongs the duration of the block significantly and also reduces postoperative rescue analgesic requirement in the first 24 hours compared to plain Bupivacaine group.

Keywords: *Tap block, Dexamethasone, post lscs*

INTRODUCTION

Pain is the 5th vital sign that has to be monitored in the postoperative period. Pain is defined as a sensory or emotional unpleasant experience associated with actual or related tissue damage. [6]

It is one's fundamental right to be pain free. In women who undergoes lower segment caesarean section the postoperative pain is felt as moderate to severe. It is challenging for the anaesthesiologist to make their patients pain free. Postoperatively, for women undergoing caesarean section, pain has to be addressed effectively with minimal interruptions and complications in order to make these women alert and comfortable to take care of their newborn.

The use of peripheral nerve blockade has grown in popularity because it decreases pain as assessed by visual analogue scores postoperatively, decreases the need for postoperative analgesics, decreases the incidence of nausea, shortens postanesthesia care unit time, and increases patient satisfaction. [1]

An ultrasound-guided approach of the Transverse abdominis plane block was first described in 2007 by Hebbard et al. [5] The ultrasound technique was induced to improve the success rate of the TAP block. This ultrasound procedure is performed with ultrasound high frequency (5–13 MHz) probe which is placed on the lateral abdominal wall between the costal margin and the iliac crest at the anterior axillary line. The technique involves injection of local anesthetic solution into a plane between internal oblique muscle and transversus abdominis muscle. This plane contains the thoracolumbar nerves originating from T6 to L1, ilioinguinal and iliohypogastric nerves. They supply sensory blockade to the skin, muscles and parietal peritoneum of the anterolateral abdominal wall. Real-time ultrasonography facilitates easy needle visualization and visualization of the local anesthetic spread in to the target "fascial plane" which is parallel to the ultrasound probe.

There is a new strategy to prolong analgesia beyond the pharmacological duration of the local anesthetics. They include introduction of perineural catheters to allow prolonged infusion of the Local anesthetics or co-administration of adjuvants such as Epinephrine, α2 agonists (i.e. Clonidine), Midazolam or Corticosteroides – Dexamethasone . The perineural catheter techniques can be very effective and can provide analgesia for several days, but this technique is limited with difficulties in placement and removal of the catheter, or rarely, with infection . It is believed that dexamethasone as a supplement improves the quality and duration of the local anesthetics. This is thought to be mediated by attenuating the release of inflammatory mediators, reducing ectopic neuronal discharge, and inhibiting potassium channel-mediated discharge of nociceptive C-fibres.

Transverse abdominis plane block in post-cesarean patients has revolutionised the acute pain management avoiding the side effects of opioids and NSAIDS. Dexamethasone added to local anaesthetics have been proved to prolong the duration of analgesia.

The mechanism of action of dexamethasone on peripheral nerve during perineural injection is unknown. Desmet et al. [4] concluded that systemic (intravenous) injection of Dexamethasone is equivalent to perineural Dexamethasone injection about the prolonging the analgesic duration of single-shot interscalene block with Ropivacaine. Kawanishi et al.[7] have come to an opposite conclusion that perineural but not systemic Dexamethasone prolongs the duration of interscalene block .This study is designed to compare the duration of post operative analgesia provided by ultrasound guided bilateral transverse abdominis plane block with bupivacaine vs bupivacaine with dexamethasone (perineural vs intravenous) for cesarean section.

AIM OF THE STUDY

To compare the duration of Postoperative Analgesia with Bupivacaine Vs Bupivacaine with Dexamethasone (perineurally or intravenously) in patients undergoing caesarean section using Ultrasound guided Transverse Abdominis Plane Block.

MATERIALS AND METHOD

This study was conducted in the Obstetrics theatre, Kanyakumari government medical college after obtaining ethical committee approval and approval from Obstetrics & Gynecology department.

STUDY DESIGN

This was a Prospective Randomized double blinded study. This study was conducted in our department of Anaesthesiology after receiving,

1. Institutional Ethical Committee approval
2. Department of obstetrics and gynecology approval and
3. Informed written consent from all the patients.

RANDOMISATION

Sample was randomized by closed envelope method. 60 plain covers each with a single sheet written B in 20 sheets, D1 in 20 sheets and D2 in 20 sheets were prepared and kept in the operation theatre. The covers were mixed thoroughly.

Before the start of the surgery , theatre staff picked up a cover of his/her choice.If that cover contains a sheet written B in it, then the case was included in Bupivacaine Group (B) and vice versa.,This procedure were continued till all the 60 covers were exhausted , thereby enrolling 20 cases in each group.

SAMPLE SIZE

Sample size is calculated using the formula $\mathbf{n = \frac{2 \times \{Z_{(1-a/2)} + Z_{(1-b)}\}^2}{D^2}}$

The number of participants required in each intervention group was calculated as 14 for a Significance level of 99.9% and power of 95%.

Based on the figures for duration of anaesthesia by Amany S. Ammar et al in their study , "Effect of adding dexamethasone to bupivacaine on transversus abdominis plane block for abdominal hysterectomy: A prospective randomized controlled trial" published in Saudi Journal of Anaesthesia, July – Sept. 2012 6(3) : 229 -233. [9] 60 Antenatal patients were studied.

GROUP ALLOCATION

Randomised into three groups –

GROUP (B, D1 and D2) - 20 patients each. In group B – 20 ml of 0.25 % bupivacaine +2 ml of normal saline + 2 ml distilled water IV. In group D 1 – 20 ml of 0.25 % bupivacaine +2 ml (8 mg) dexamethasone + 2 ml distilled water IV. In group D 2 – 20 ml of 0.25 % bupivacaine +2 ml of normal saline + 2 ml (8 mg) dexamethasone IV.

BLINDING

The anaesthesiologist who administered the drug and the observer were blinded to the study. Local anaesthetic, study drug mixture was prepared by duty anaethesiologist not participating in the study. Postoperative observation was done by the same anaesthesiologist who administered the drug, who was unaware of the group allocation.

INCLUSION CRITERIA Age 20-35 years , ASA II , Posted for LSCS .

EXCLUSION CRITERIA

Patient refusal , ASA grade III & IV , Height <140 cms,BMI>30, Known allergy to study drug, Patient with coagulopathies and Patient with diabetic, renal, liver diseases, pre eclampsia, eclampsia.

MATERIALS

Ultrasound machine with a high frequency probe (10-5 MHz) ,Ultrasound probe cover , Antiseptic solution for skin disinfection ,Ultrasound gel , 25 gauge quinke spinal needle , 20ml needle and injection tubing , Drug mixture for the block and Equipments & drugs for resuscitation.

INTERVENTION

All patients received premedication with Inj. Metoclopromide & Inj.Ranitidine intravenously before shifing the patient into operating room. Under strict aseptic precautions **Spinal Anaesthesia** was administered in Right Lateral position in L3 -L4 space using 10 mg 0.5% Bupivacaine using 25G Quinke's needle. At the end of surgery, when the spinal anaesthesia level regressed to T8 , TAP block was given using **ultrasound guidance (sonoray)** by Curvilinear probe. The Transverse abdominis plane was approached through mid-axillary approach - **In Plane Technique** using a 23 Gauge quincke's spinal needle .Drug was given and the correct spread of local anesthetic mixture was visualized through ultrasound. The same procedure was repeated on the other side of the abdomen.

ASSESSMENT OF BLOCK

After spinal regression below L2,checked for cold sensation at L1 dermatome.

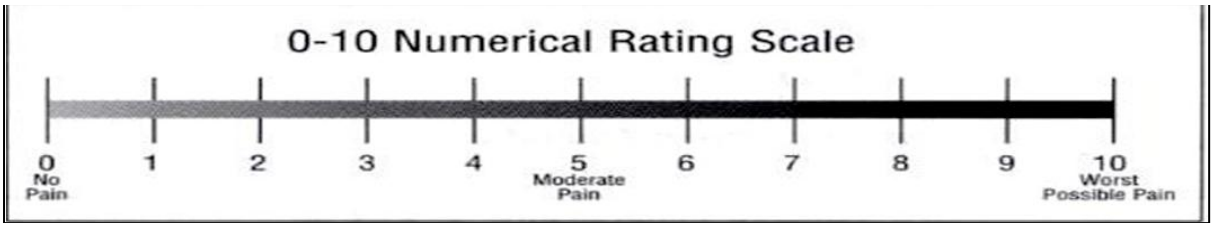
SUCCESS	Grade 2	Not able to perceive cold sensation at L1 on both sides .
PARTIAL	Grade 1	Able to perceive cold sensation at L1 on any one side .
FAILED	Grade 0	Able to perceive cold sensation at L1 on both sides .

OBSERVATION

The following parameters were observed.

1. Demographic data - Age, Weight.
2. Block grade
3. Numerical pain scale for 24 hrs postoperatively
4. Duration of analgesia
5. Total dosage of tramadol used
6. Complications if any

The Numerical rating pain scale was compared at the time intervals 0,1,2,3,4,5,6,8,12,24 hrs during rest as well as movement



Inj. TRAMADOL 50 mg was given intramuscularly when Numerical rating scale score =/> 5 and the time was noted as time of first analgesic dose.

OUTCOME

PRIMARY OUTCOME - DURATION OF ANALGESIA

Time interval between the block time and the time of first analgesic dose.

COMPLICATIONS - Nausea, vomiting, transient femoral nerve palsy.

STATISTICAL TOOL

Data analysis was performed using IBM-SPSS version 20.0 (IBM-SPSS Science Inc., Chicago, IL).The above said datas were collected and tabulated. Data are presented as mean, standard deviation, percentages, or number of cases. Continuous data were compared by One way Anova. Significance was defined by P values less than 0.05. Non-parametric data were compared by Kruskal–Wallis one-way analysis of variance .

OBSERVATION AND RESULTS

The data's are tabulated and analyzed statistically using SPSS version 20.0 .

DISTRIBUTION OF AGE

The age of all patients were comparable in all groups. Statistically analysed results for age were GROUP B 25.05 +/- 3.59 GROUP D1 24.75+/-2.86 and GROUP D2 24.25 +/- 5.23 and are not statistically significant with a p value 0.817.

DISTRIBUTION OF WEIGHT

The statistically analysed results for weight were GROUP B 53.25 +/- 4.37, GROUP D1 53.2+/-3.18 and GROUP D2 55.1 +/- 4.35 which was not statistically significant with a p value 0.241.

BLOCK SUCCESS GRADE

GROUP	GRADE 2 -SUCCESS	GRADE 1 -PARTIAL	GRADE 0 - FAIL
GROUP B	100 %	NIL	NIL
GROUP D1	100 %	NIL	NIL
GROUP D2	100 %	NIL	NIL

Transverse abdominis plane block were 100 % successful in all the three groups.

DURATION OF ANALGESIA

GROUP	MEAN	STANDARD DEVIATION	P VALUE
GROUP B	513.00	259.33	
GROUP D1	795.00	374.89	0.018 (significant)
GROUP D2	774.00	369.81	

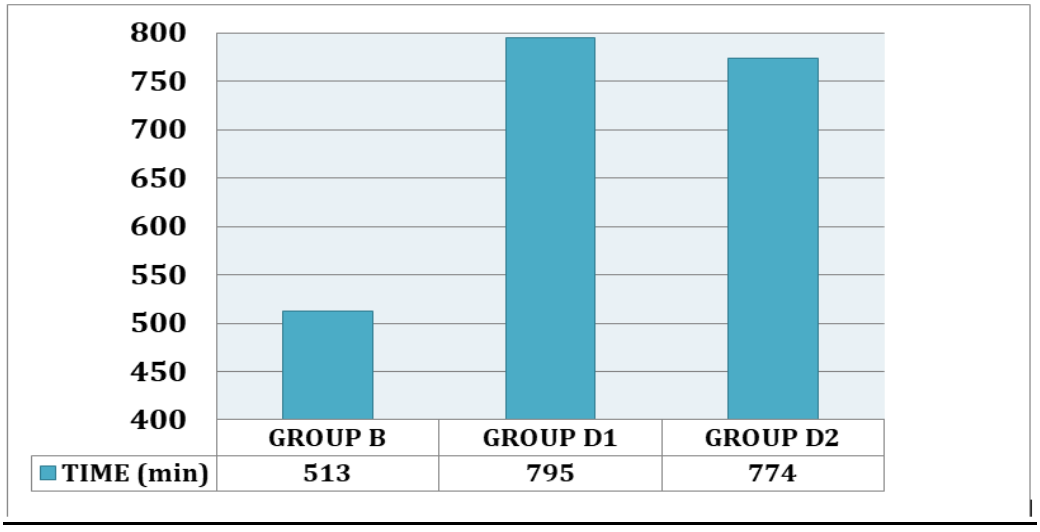
The duration of analgesia in GROUP B was 513 minutes +/- 259.33 compared to 795 +/-374.89 minutes in GROUP D1 and GROUP D2 was 774 +/- 369.81 minutes with a significant p value of 0.018.

BLOCK SUCCESS GRADE

	GROUP B	GROUP D1	GROUP D2
PERCENTAGE	100	100	100

DURATION OF ANALGESIA

	COMPARISON		MEAN DIFFERENCE	P VALUE
TRAMADOL USED	B	D1	27.5	0.01
	B	D2	25	0.03
	D1	B	-27.5	0.01
	D1	D2	-2.5	1.00
	D2	B	-25	0.03
	D2	D1	2.5	1.00



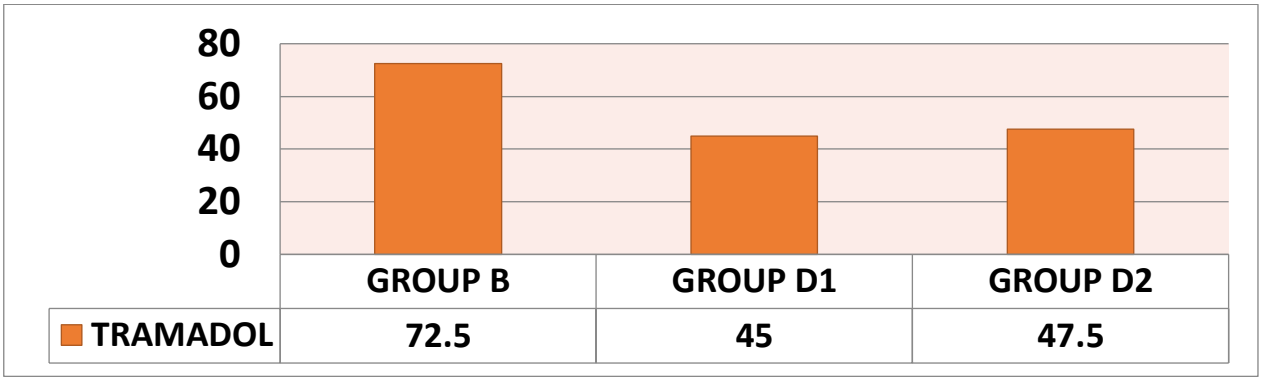
MULTIPLE COMPARISONS OF DURATION OF ANALGESIA

	COMPARISON BETWEEN GROUPS		MEAN DIFFERENCE	P VALUE
DURATION OF ANALGESIA	B	D1	-282	0.03
	B	D2	-261	0.04
	D1	B	282	0.03
	D1	D2	21	1.00
	D2	B	261	0.04
	D2	D1	-21	1.00

Comparison of duration of analgesia between three groups proved that the mean difference between GROUP B and GROUP D1 , GROUP B and GROUP D2 was statistically significant with a p value of <0.05.

TOTAL DOSE OF TRAMADOL USED

The total dose of tramadol used were with a mean of 72.50 mg in GROUP B compared to 45 mg in GROUP D1 and 47.5 mg in GROUP D2 with a significant p value of 0.007.



MULTIPLE COMPARISONS OF TOTAL DOSE OF TRAMADOL USED

Comparison of Total dose of tramadol used between three groups proved that the mean difference between GROUP B and GROUP D1 , GROUP B and GROUP D2 was statistically significant with a p value of <0.05.

COMPLICATION

None of the patients registered complications like nausea, vomiting, dizziness, femoral nerve palsy, pelvic hematoma, liver trauma etc. during first 24 hour study period.

DISCUSSION

Several researches have revealed that addition of Dexamethasone to local anaesthetics proved to prolong the duration of analgesia and reduces rescue analgesic requirements. Several mechanism have been hypothesized to explain that addition of Dexamethasone reduces pain transmission in C fibres, vasoconstriction ,and also has anti inflammatory effect. This study is designed to find out wheather there is any difference in action of Dexamethasone given via perineurally or systemically when added to local anaesthetics.

Abdallah et al in 2015[7] conducted a study comparing Intravenous dexamethasone and perineural dexamethasone for supraclavicular brachial plexus block using 30-mL bupivacaine 0.5% alone (Control), with concomitant intravenous dexamethasone 8 mg , or with perineural dexamethasone 8 mg . The duration of analgesia was prolonged in the intravenous Dexamethasone group (25 hours) and perineural Dexamethasone group (25 hours) when compared to Control group (13.2 hours) with a p value of < 0.001 .

Consistent with this study , in my study Duration of analgesia is prolonged in perineural Dexamethasone group (795 +/- 374.89 min) and in intravenous Dexamethasone group (774 +/- 369.81 min) when compared to Bupivacaine group (513 +/-259.33 min) and is statistically significant with a p value 0.018 with no statistical significance difference between perineural and intravenous group (p 1.00).

Similar results have been obtained by Desmet et al in 2013 who Performed a study on intravenous Dexamethasone and its equivalency to perineural Dexamethasone in prolonging the analgesic duration of single-shot interscalene block with Ropivacaine where the median time of a sensory block was equivalent for perineural and i.v. dexamethasone: 1405 min and 1275 min respectively. There was a significant difference between the Ropivacaine group (757 min) and the Dexamethasone groups (P<0.0001) and Rahangdale et al in 2014[11] who conducted a study to assess the effects of perineural versus intravenous dexamethasone on sciatic nerve blockade by using 0.5% bupivacaine with epinephrine 1:300,000 (0.45 mL/kg) and he concluded that there is no significant difference in the time to first toe movement or analgesic duration between the perineural (P < 0.001) and IV dexamethasone groups (P = 0.008) .

Conflicting results have been reported by KAWANISHI et al in 2014 [8]conducted a study to compare perineural Dexamethasone vs systemic low-dose dexamethasone 4mg in interscalene block with Ropivacaine 0.75% , The median times of sensory block in Ropivacaine group was 11.2 hours , in perineural dexamethasone group was 18.0 hours, and in intravenous dexamethasone group was 14.0 hours and he concluded that Perineural but not intravenous administration of 4 mg of dexamethasone significantly prolongs the duration of postoperative analgesia.

In my study, total dose of rescue tramadol used is higher in Bupivacaine group (72.50 +/- 30.24 mg) when compared to perineural Dexamethasone group (45 +/- 27.62 mg) which is statistically significant with a p value <0.01 and similarly total rescue tramadol dose used is lower in intravenous Dexamethasone group (47.50 +/-30.24 mg) compared to plain bupivacaine group with a p value of 0.03.This observation correlates well with the study conducted by Deshpande et al in 2017[10] to check the Analgesic Efficacy of Dexamethasone Added to Ropivacaine in Transversus Abdominis Plane Block for Transabdominal Hysterectomy under Subarachnoid Block and concluded that lesser Tramadol requirement in first 24 h in Ropivacaine dexamethasone group (50.2 ± 34 vs. 94 ± 35 mg, $P < 0.001$) as compared to Ropivacaine group.

No studies were available to compare the rescue analgesic requirement between intravenous and perineural dexamethasone goup but in my study there is no significant difference in the requirement of tramadol between perineural and intravenous group with a p value 1.00.

No complication such as nausea, vomiting, dizziness, femoral nerve palsy, pelvic hematoma, liver trauma were recorded during the study period.

SUMMARY

To summarise, All the demographic data like age and weight are comparable. In this study either Perineurally or Intravenously Dexamethasone added to Bupivacaine in Transverse abdominis plane block prolongs the duration of analgesia (260 -280 minutes)compared to plain bupivacaine group.Comparison of rescue analgesic tramadol is reduced (25 -30 mg) in the both groups (GROUP D1 and D2) compared to plain Bupivacaine group.No complication was noted.

CONCLUSION

Addition of Dexamethasone 8 mg either Perineurally or Intravenously to 0.25 % Bupivacaine in Transverse abdominis plane block in cesaerean patients prolongs the duration of the block and reduces postoperative rescue analgesic requirements compared to plain Bupivacaine group.

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