Original Article

Comparative evaluation of bupivacaine with magnesium sulphate and dexamethasone as adjuvants in ultrasound-guided transversus abdominis plane block for open unilateral inguinal hernia surgeries: A randomised controlled trial

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ABSTRACT

Background and Aims: Inguinal hernia repair is associated with moderate to severe pain that is most extreme in the first 24 hours. The aim of this study was to compare the efficacy of dexamethasone versus magnesium sulphate ($MgSO_4$) with bupivacaine in ultrasound-guided transversus abdominis plane (TAP) block for patients undergoing unilateral inguinal hernioplasty. **Methods:** Eighty patients were randomly allocated to two groups to receive ultrasound-guided TAP block postoperatively with either 20 ml of 0.25% bupivacaine with 8 mg of dexamethasone (Group BD) or 20 ml of 0.25% bupivacaine with 250 mg of $MgSO_4$ (Group BM). Patients were assessed for the first 24 hours after surgery for pain at rest and movement using a numerical rating scale (NRS). Two mg/kg of tramadol was administered as rescue analgesia. The time to first demand tramadol, total consumption of tramadol, patient satisfaction score and side effects were evaluated. **Results:** The time to the first dose of rescue analgesia was significantly longer in BD group (596.13 ± 57.93 min) than in the BM group (422.50 ± 51.95 min). The NRS scores in the BD group were significantly lower compared to the BM group both at rest and on movement. The total requirement of tramadol was significantly less in the BD group (154.55 ± 59.11 mg) compared to the BM group (270.25 ± 105.72 mg). The incidence of side effects was lower and patient satisfaction was higher in BD group compared to BM group. **Conclusion:** Bupivacaine with dexamethasone in TAP block after unilateral open inguinal hernioplasty provides increased duration of analgesia and decreased requirement for rescue analgesics compared to magnesium sulphate, with lesser side effects and better patient satisfaction.

Key words: Analgesia, dexamethasone, inguinal hernia, magnesium, ultrasonography, surgery

INTRODUCTION

Inguinal hernia surgery is one of the most commonly performed surgical procedures which is associated with moderate to severe intensity of pain that is at its most extreme in the first 24 hours postsurgery.[1,2] Inadequate pain relief in these patients can lead to delayed recovery, extended duration of hospital stay and also lead to persistent pain after surgery.[2]

The transversus abdominis plane (TAP) block is a fascial plane block where local anaesthetic is deposited in the plane between the internal oblique and the transversus abdominis muscle containing T10–L1 thoracolumbar nerves.[3] Although only the somatic component of pain is blocked, a consistent benefit in

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terms of prolonged duration of postoperative analgesia and decreased consumption of opioids in the first 24–48 hours has been shown in many studies.

A number of adjuvants have been used with local anaesthetics, like dexamethasone, magnesium sulphate ($MgSO_4$), adenosine, buprenorphine and dexmedetomidine in TAP block to prolong the analgesic action in lower abdominal surgeries with varying results.[2-4]

$MgSO_4$ is an N-methyl-D-aspartate (NMDA) receptor antagonist. It acts by non-competitive antagonism blocking the voltage-dependent ion channels. This receptor is found in many parts of the body, including the nerve endings, and plays a role in modulating inflammatory responses and pain responses by preventing central sensitisation caused by peripheral nociceptive stimulation.[5]

Dexamethasone is a highly potent, long-acting glucocorticoid. It inhibits potassium conductance by binding to glucocorticoid receptors which decrease the activity of nociceptive C-fibres and may also prolong the analgesia duration through systemic anti-inflammatory effects and local vasoconstrictive action.

There are very few studies which have compared the efficacy of TAP block using different adjuvants in cases of open inguinal hernia repair;[2,3,6] however, none of them have compared the effect of $MgSO_4$ versus dexamethasone as adjuvants in TAP block for inguinal hernia surgeries. Therefore, we conducted this study with the aim of comparing the duration of analgesia obtained by addition of dexamethasone and $MgSO_4$ as adjuvants to bupivacaine in TAP block in patients undergoing unilateral open inguinal hernia repair and to evaluate postoperative analgesic requirements, side effects and level of patient satisfaction. Our primary objective was to compare the duration of analgesia conferred by bupivacaine plus dexamethasone and bupivacaine plus $MgSO_4$ in ultrasonogram-guided TAP block in unilateral open inguinal hernia surgeries. Our secondary objectives included the comparison of the NRS scores, the need for the total amount of rescue analgesics, to assess the incidence of nausea and vomiting and to assess the level of patient satisfaction between the two groups.

METHODS

The randomised, double-blind interventional study was conducted in the Department of Anaesthesiology at a tertiary care hospital in India. After obtaining approval from Institutional Ethics Committee, this study was conducted between September 2019 and September 2021 in 80 American Society of Anesthesiologists (ASA) physical status I and II patients in the age group of 18–60 years posted for elective unilateral open inguinal hernia surgeries. We excluded patients with a history of allergy to drugs used in the study, a history of substance abuse, with a body mass index (BMI) ≥35 and patients with psychosis/gross neurological disorders. All the patients who met the inclusion criteria were enrolled in the study and written informed consent was obtained for the participation in the study and use of the patient data for research and educational purposes. The study was conducted following the ethical guidelines of the Declaration of Helsinki. The trial was registered with the Clinical Trials Registry of India with registration number CTRI/2019/10/021563.

A detailed pre-anaesthetic checkup was done during the pre-operative visit. The anaesthesia procedure and the numerical rating scale (NRS) for pain were explained to the patients in detail. NRS is a commonly used scale to assess pain. The numerical scale is most commonly 0–10, with 0 being 'no pain' and 10 being 'the worst pain imaginable'. All patients were made to fast according to the standard nil per oral guidelines. The patients were randomised into two groups by a computer-generated randomisation list to receive either of the two regimens. [Figure 1] For the BD group, 20 ml of 0.25% bupivacaine with 8 mg of dexamethasone and for the BM group 20 ml of 0.25% bupivacaine mixed with 250 mg of $MgSO_4$ was prepared to keep the total volume the same in both groups.

A double-blinding technique was followed, where an anaesthesiologist who was not part of the study prepared the solution according to the allocated group. The solution was then handed over to the investigator who administered the TAP block after the surgery was completed under spinal anaesthesia. The investigator was unaware of the group allocation.

On arrival in the theatre, an intravenous (IV) access was secured and IV fluids started. Standard ASA monitoring was instituted which included pulse oximetry (SpO_2), electrocardiogram and non-invasive blood pressure (NIBP), and the baseline parameters was recorded. Spinal anaesthesia was administered under aseptic precautions using 3 ml of 0.5% bupivacaine heavy in the sitting position at the L3–L4 or L4–L5

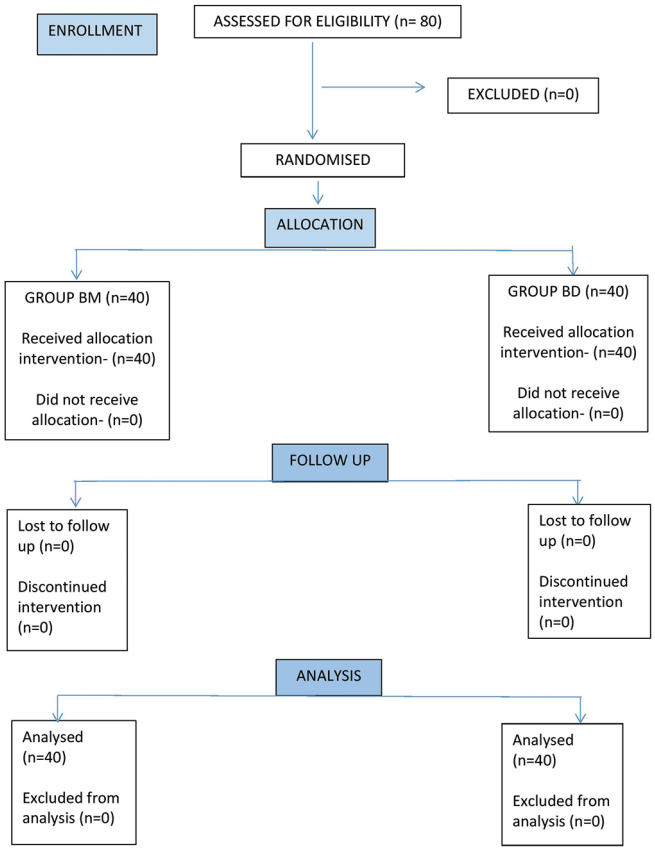

Figure 1: Consort flow chart

intervertebral space using a 25-G 'Quincke' tip spinal needle. A sensory level of T6 was achieved.

Intra-operatively, continuous monitoring of vitals with NIBP recording every 5 min was done. After the surgical procedure was complete, an USG-guided unilateral TAP block via the posterior approach was performed on the side of the surgery, under aseptic precautions using an 80 mm 22 G stimuplex needle. The given solution was deposited in the desired plane.

The study data were recorded by an independent observer who was blinded to the patient groups. Each patient was assessed at 2, 4, 6, 8, 10, 12, 16, 20 and 24 hours after surgery for pain at rest and on movement (coughing) using NRS.

All the patients received paracetamol 15 mg/kg 8 hourly IV and tramadol 2 mg/kg IV was administered as rescue analgesia on the patient's demand or when NRS ≥4. The duration of analgesia was defined as the time interval between the end of local anaesthetic administration and the first administration of tramadol. The time of first demand for tramadol, total consumption for tramadol in the 24-hour period post-surgery, patient satisfaction with pain management (a three-point score was used, 0: not satisfied, 1: somewhat satisfied, 2: Fully satisfied) and side effects were observed. Rescue antiemetics (injection ondansetron 4 mg IV) was given to any patient who had nausea and/or vomiting.

Our primary outcome was to compare the duration of analgesia with $MgSO_4$ and dexamethasone as adjuvants to bupivacaine. Based on the results of our pilot study on 20 patients, taking 10 patients in each group using the doses mentioned in our study, we found BM group had a mean analgesia duration of 389 ± 31 min compared to 422 ± 44 min in the BD group. Considering a 95% confidence interval and 95% power, a sample size of 35 in each group was calculated. To adjust for any dropouts, 40 patients were recruited in each group. STATA 11.2 (College Station TX USA) was used to perform the statistical analysis. Continuous variables were analysed using the independent samples Student's *t*-test for normally distributed data, and the Chi-square test was used to analyse discrete variables. Data are presented as the mean standard deviation or as a number (percentage). Shapiro–Wilk test was used to check normality. The time to first analgesic administration was analysed by Kaplan–Meier survival analysis and log-rank test. $P < 0.05$ was considered statistically significant.

RESULTS

Baseline characteristics like age, sex distribution, height, weight and duration of surgery were comparable in both groups [Table 1]. The time to the first dose of rescue analgesia was significantly longer in the BD group (596.13 ± 57.93 min) than in the BM group (422.50 ± 51.95 min) (*P* value < 0.001*)*. Kaplan–Meier curve for the first analgesic request is depicted in Figure 2. The log-rank test revealed a statistically significant difference in the survival distribution for the two groups, $\chi^2 = 82.105$, *P* value < 0.0001. The total amount of rescue analgesia administered was significantly less in the BD group (154.55 ±59.11 mg) compared to the BM group (270.25 ± 105.72 mg) (*P* value < 0.001*)* [Table 2]. The NRS scores in the BD group were significantly lower compared to BM group, in the first 24 hours following administration of the block (*P* value < 0.05*)*, except at the 10th hour where the NRS score at rest and on movement was higher in BD group than BM group [Figure 3]. There was no significant difference between the incidence of nausea in both groups. The incidence of vomiting was significantly lower in the BD group (0%) compared to the BM group (10%),

P = 0.04. Patient satisfaction was significantly better in the BD group as compared to the BM group (85 % vs 25%) [Table 3].

DISCUSSION

The results of our study show that the addition of 8 mg dexamethasone to bupivacaine in ultrasound-guided TAP block results in significantly prolonged duration of analgesia, reduced consumption of rescue analgesics, lower NRS scores and better patient satisfaction compared to the addition of 250 mg $MgSO_4$ to bupivacaine for open unilateral inguinal hernia surgeries.

Adequate postoperative analgesia leads to a reduction in postoperative morbidity, reduced postoperative stress response and improved surgical outcomes. Other benefits include a decrease in the intensity of pain, a low incidence of adverse effects from analgesics, better patient comfort and early recovery.

Beneficial effects of the addition of adjuvants to local anaesthetics in TAP block include prolonged analgesia, decreased consumption of rescue analgesics and minimal side effects. A number of studies conducted show the beneficial effects of the addition of adjuvants like dexmedetomidine, clonidine, dexamethasone, magnesium sulphate and adenosine;[2-4,7-10]

$MgSO_4$ as an adjuvant to local anaesthetics has been shown to prolong the duration of sensory and motor blockade without any significant side effects. The duration and intensity of postoperative analgesia are dependent on the degree of inhibition of NMDA receptor signal transmission. $MgSO_4$ as an adjuvant has been used intrathecally and in peripheral nerve blocks. It has been used in different doses for peripheral nerve blocks ranging from 100mg to 500 mg with varying results.[5,11-13] Since the total number of studies using $MgSO_4$ in a dose greater than 250 mg in TAP block was very few,[8,10,14] we chose a dose of

Table 1: Demographic characteristics

Characteristics	Group BD	Group BM
Age (in years)*	51.32±9.49	46.6±11.60
Height (cm)*	164.02±5.64	162.82±7.82
Weight (cm)*	65.35±8.67	62.90±9.44
BMI*	24.25±2.67	23.68±2.82
Male/Female†	40 (100%)/0	38 (95%)/2 (5%)
Duration of surgery*	69±9.82	74±12.81

*Data presented as mean±SD and analysed using Students Independent sample *t*-test. †Data presented as number (percent) and analysed using Chi-square test for goodness of fit

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

	Group BD	Group BM	*P*
TFA (minutes)	596.13±57.93	422.50±51.95	<0.001
Rescue drug (mg)	154.55±59.11	270.25±105.72	<0.001

Data presented as mean±SD and analysed using Students Independent sample *t*-test

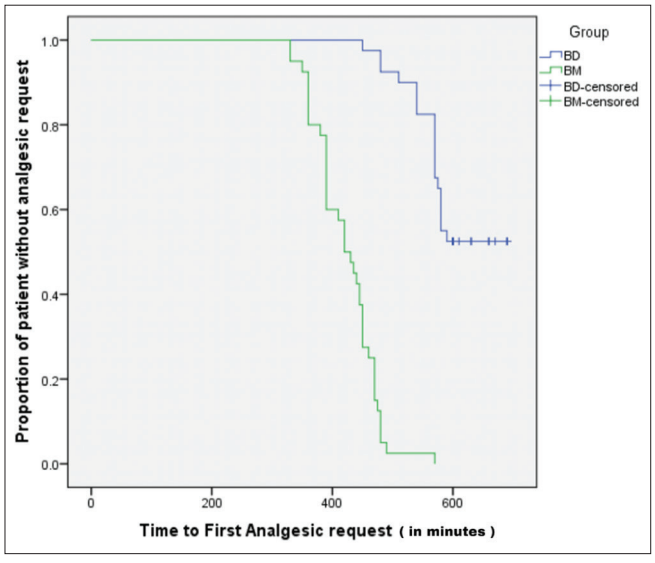

Figure 2: Kaplan–Meier survival analysis for time to first analgesic request

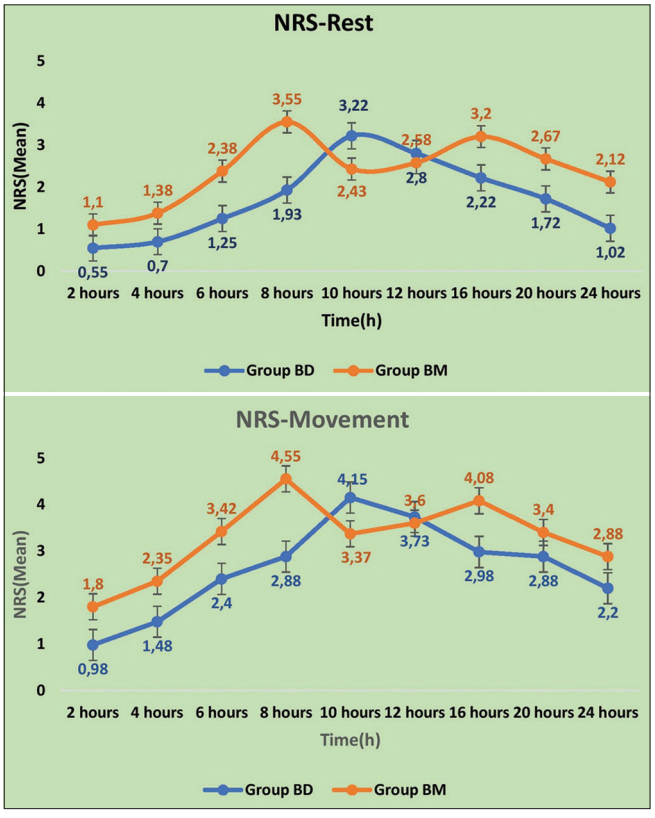

Figure 3: Comparison of mean numerical rating scale (NRS) scores at rest and on movement

Table 3: Patient satisfaction scores				
Score	**Group BD**	**Group BM**	**Total**	***P***
0	0	14	14	<0.001
1	6	18	24	
2	34	8	42	

Data presented as number (percent) and analysed using Chi square test for goodness of fit

250 mg for our study taking into account the safety profile of the drug. $MgSO_4$ was used in 250 mg based on the data from a study[15] where $MgSO_4$ was used in the dose of 125 mg and 250 mg along with bupivacaine in the supraclavicular brachial plexus block.

The exact mechanism for the analgesic effect of dexamethasone is unknown. Various mechanisms have been suggested which include the anti-inflammatory action or immune-suppressive action of dexamethasone, modulation of potassium channels, perineural vasoconstriction delaying the absorption of local anaesthetics and direct inhibition of ectopic neural discharge.

In our study, we found that dexamethasone (8 mg) provides a significantly longer duration of analgesia compared to $MgSO_4$ (250 mg) when added to bupivacaine as an adjuvant to 0.25% of bupivacaine in TAP block for inguinal hernia surgeries. Similar results of prolonged analgesia with dexamethasone compared to magnesium as adjuvants to local anaesthetics were shown by previous studies, though in different regional blocks.[16,17] However, a study conducted by Gad *et al*.[18] using the same adjuvants in a TAP block for total abdominal hysterectomy showed that $MgSO_4$ provides prolonged analgesia compared to dexamethasone. This discrepancy could be due to different types of surgery and also they carried out the study under general anaesthesia. Adel A.N. Mahgoub[19] compared the same adjuvants with levobupivacaine in USG-guided supraclavicular brachial plexus block for upper-limb surgery and found no difference in postoperative analgesia between the two drugs. This could be due to the different doses of $MgSO_4$ and different types of blocks used in the studies. Another reason for this could be because of the use of levobupivacaine which may cause prolonged nerve block compared to bupivacaine which could have masked the difference between the two adjuvants.

The total amount of rescue analgesics consumed by the patients in the BM group was significantly higher than that of patients of the BD group. Dexamethasone conferred a longer duration of analgesia and better pain control, resulting in lesser demand for rescue analgesics by the patients. However, Gad *et al*.[18] found lesser use of rescue analgesics in the magnesium group compared to the dexamethasone group in a study where they used TAP block for total abdominal hysterectomy. They administered block after general anaesthesia, while patients in our study received spinal anaesthesia. The nature of the surgery and the difference in anaesthetic technique could possibly be the reason for the difference.

The incidence of vomiting was significantly higher in the BM group compared to the BD group. This observation could be due to the anti-emetic property of dexamethasone. Also, more requirements of tramadol, an opioid, in the BM group, could have contributed to emesis compared to the BD group. There was no significant difference in the incidence of nausea in both groups.

Patient satisfaction was significantly higher in the BD group as compared to the BM group. This can be attributed to the longer duration of analgesia, less tramadol consumption and lesser incidence of side effects in the BD group.

The limitation of this study was that serum drug levels were not measured, hence we could not comment on whether the analgesic effect is through the local effect or systemic absorption of drugs. Also, the dose of $MgSO_4$ used could have been increased to 500 mg which could have provided prolonged analgesia.

CONCLUSION

In conclusion, we state that bupivacaine with 8 mg dexamethasone in TAP block provides an extended duration of analgesia and decreased requirement for rescue analgesics compared to 250 mg $MgSO_4$, with lesser side effects and better patient satisfaction in patients undergoing unilateral open inguinal hernia surgery.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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