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Comparison of analgesic efficacy of perineural dexamethasone in rectus sheath block and intravenous dexamethasone with levobupivacaine in bilateral rectus sheath block for patients undergoing midline abdominal surgery: a randomized controlled trial

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Abstract

Background Dexamethasone is used in regional analgesia to prolong the duration of analgesia and anaesthesia. The perineural and intravenous (IV) dexamethasone in fascial plane block have conflicting results. The study aimed to compare analgesic efficacy of perineurally and intravenously dexamethasone in rectus sheath block (RSB). This prospective, double-blinded, randomized control study was conducted in 105 patients, equally divided in three groups. All the patients received ultrasound-guided RSB block with 20 ml of 0.25% levobupivacaine on each side. Additionally, in group A, 1-ml normal saline (NS) on each side in RSB block and 2-ml NS IV; in group B, 4-mg dexamethasone on each side in RSB block and 2-ml NS IV; and in group C, 1-ml NS on each side in RSB block and 8-mg dexamethasone IV.

The primary objective of the study was the duration of analgesia, and secondary objectives were total morphine consumption in the first 24 h, numeric rating scale (NRS) scores at rest and on cough, complications and patient's satisfaction score.

Results The duration of analgesia was maximum in group B (935.91 ± 121.82 min) and then in group C (730.31 ± 129.64 min) and group A (418.34 ± 29.22 min) ($P < 0.0001$). The morphine consumption and mean NRS score (at rest and cough) were lowest in group B and then group C and group A ($P < 0.0001$).

Conclusions The perineural dexamethasone as an adjuvant to levobupivacaine prolongs the duration of analgesia with decreased analgesic requirements compared to intravenous dexamethasone in bilateral RSB in patients undergoing midline laparotomy surgery.

Keywords Dexamethasone, Levobupivacaine, Laparotomies, Analgesia, Rectus sheath block

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Background

The patients undergoing midline laparotomy incision have experienced excruciating pain, which may compromise postoperative pulmonary functions, early mobilization and recovery. Alleviating postoperative pain is an integral component of successful implementation of enhanced recovery after surgery (ERAS) protocol (Gelman et al. 2018). The central neuraxial blocks are the main analgesic modality for postoperative pain in abdominal surgeries, but the haemodynamic instability and systemic infection, sepsis and coagulation disorders preclude its use (Novak-Jankovic and Markovic-Bozic 2019). The multimodal analgesic approach using regional nerve blocks reduces the opioid requirement in postoperative period, thus reducing the undesired adverse effects of opioids such as sedation, respiratory depression, postoperative ileus and postoperative nausea vomiting (PONV) (Ramirez et al. 2020).

The rectus sheath block (RSB) was used initially for umbilical hernia repair and laparoscopic gynaecologic surgical procedures (Gurnaney et al. 2011). However, with advent of ultrasound (US) imaging and experience of anaesthesiologists, the RSB is performed more precisely in major open urological pelvic surgeries (Dutton et al. 2014).

Local anaesthetic (LA) agents having cardio-stable profile, such as levobupivacaine and ropivacaine, are commonly used in regional nerve block nowadays, but limited duration of LA restricted its use in single-shot blocks (Desai et al. 2019). Some studies are reported efficacy of dexamethasone in perineural route, while other studies are reported efficacy of intravenous administration of dexamethasone as an adjuvant to LA agent in terms of prolongation of duration of analgesia (Bailard et al. 2014; Zorrlla-Vaca and Li 2018). The prolongation of analgesic effect of LA with dexamethasone was reported in fascial plane blocks such as quadratus lumborum block, (Singariya et al. 2020), but studies are lacking in rectus sheath block. The hypothesis of our study was that the dexamethasone in RSB block and intravenous administration was equally effective. This study was planned to evaluate the analgesic efficacy of perineurally dexamethasone and intravenous dexamethasone as adjuvant to 0.25% levobupivacaine in US-guided bilateral RSB in patients undergoing midline laparotomy surgery.

Methods

Ethics statement

This prospective, double-blinded, randomized control trial (RCT) was conducted in a medical college hospital after approval from institutional ethical committee Dr. S. N. Medical College Jodhpur (IEC no. F.1/Acad/MC/JU/18/14022, dated 07/08/2018) and registered under Clinical Trial Registry-India (Ref. number: CTRI/2018/11/016455). The study was carried between December 2018 and November 2019 after written informed consent from the patients. This study adheres to CONSORT guidelines.

Study protocol

Inclusion criteria

The American Society of Anesthesiologists (ASA) physical grade I/II patients, aged 18–60 years, scheduled to undergone laparotomy with midline infraumbilical incision under general anaesthesia were included in the study.

Exclusion criteria

The patients who refuse to participate, allergic to LA, local infection at the block site, coagulopathy or patients on anticoagulants, body mass index (BMI) > 30 kg/m^2, patients on steroid treatment, pre-existing diabetes or peripheral neuropathy and patients undergoing psychiatric treatment were excluded from the study.

Preoperative assessment (history, general examination and systemic examination with all baseline investigations) of all the patients was done before operation. The patients were explained in detail about the procedure, advantages, disadvantages and numerical rating scale (NRS) for pain. The patients were educated about the reporting of pain on 11 points NRS (ranging from 0 to 10 cm: where 0 = no pain, 10 = worst pain imaginable) in pre-anaesthesia check-up pain clinic. All the patients were kept fasting as per guidelines.

Patients' recruitment and randomization

The one-hundred five (105) patients were randomized into three equal groups (35 in each group) by computer-generated random number table, and group allocation was kept in a sealed opaque envelope. The envelope was opened just before the induction of anaesthesia by the attending anaesthesiologists, who was not aware of group assigned. The standard ASA monitors such as the electrocardiogram (ECG), noninvasive blood pressure (NIBP) and pulse oximeter were attached. The heart rate (HR), mean blood pressure (MBP) and peripheral oxygen saturation (SpO_2) were recorded at baseline and then every 15 min throughout the surgical procedure. The anaesthesia was administered with fentanyl 2 μg/kg and propofol 2 mg/kg. The airway was secured with an appropriate size endotracheal tube after adequate muscle relaxation 3 min of atracurium besylate 0.5 mg/kg administration. Patients were ventilated with volume control mode aiming to keep an end-tidal carbon dioxide ($EtCO_2$) 30–35 mmHg by using 50:50 O_2/air mixture. The

anaesthesia was maintained with isoflurane (end-tidal concentration of 0.9–1.2) and supplemental boluses of atracurium and fentanyl.

Study intervention

After completion of the surgery, bilateral RSB block was performed in supine position, with the help of ultrasound machine (Sonosite, M-Turbo Inc., Bothell, WA, USA) and a high-frequency linear ultrasound probe (6–13 MHz; 38-mm footprint). Under aseptic condition, RSB was performed using an insulated 22-G, 100-mm and blunt tip sonoplex needle (Pajunk), with the in-plane technique at a point 2–4 cm lateral to umbilicus on either side. The needle was introduced in the long axis up and down as possible. Visualization of fascial split during injection ensures accurate RSB. Following negative aspiration, drugs were injected (according to the allocated group) between the rectus abdominis muscle and the posterior rectus sheath on either side.

The group A patients received RSB block with 20 ml of 0.25% levobupivacaine + 1-ml normal saline on each side (total 42 ml) and 2-ml normal saline IV, group B patients received RSB block with 20-ml 0.25% levobupivacaine + 1 ml (4 mg) dexamethasone on each side (total 42 ml) and 2-ml normal saline IV and group C patients received RSB block with 20-ml 0.25% levobupivacaine + 1-ml normal saline on each side (total 42 ml) and 2 ml (8 mg) dexamethasone IV. The study drugs were prepared by the anaesthesiologist, who was not involved in performance of block and collection of data. The patients, attending anaesthesiologists and the staff collecting the data were unaware of group allocation and identity of the drugs used.

After the adequate neuromuscular reversal, patients were extubated and observed in the post-anaesthesia care unit (PACU). All patients were received paracetamol 1-g IV every 6 h until 24 h. Postoperative pain was assessed at rest and coughing using NRS at 0 (immediately postoperative) and at 2, 4, 6, 8, 10, 12, 16, 20 and 24 h postoperatively, and total morphine consumption (mg) per 24 h was recorded. If $NRS \geq 4$ in first 24 h of post-operative period, the morphine 3-mg IV was given. The next dose of morphine 3 mg was repeated after at least 15 min of previous dose. The maximum three doses of morphine 3 mg were allowed in 1 h.

Also, postoperative adverse effects or complications such as hypotension (which was defined as mean blood pressure less than 20% of the basal value), nausea or vomiting, pruritus or any signs or symptoms of local anaesthetic toxicity (drowsiness, convulsions) were noted and treated. The patient's satisfaction score was recorded after 24 h of surgery, on 4-point Likert scale, 4 = excellent, 3 = good, 2 = fair and 1 = poor.

Measured outcome

The primary objective of the study was the duration of analgesia defined from administration of RSB to the need for the first rescue analgesic agent. The secondary objectives were total morphine consumption in the first 24 h; NRS scores at rest and on cough at 0, 2, 4, 6, 8, 10, 12, 16, 20 and 24 h postoperatively; and complications like nausea, vomiting, hypotension, pruritus, drowsiness, convulsions and patient's satisfaction score.

Statistical analyses

Sample size

The sample size was calculated using a difference of 6.1 h between ropivacaine and ropivacaine with dexamethasone in time to first rescue analgesia, with a standard deviation of 4.6 h and 7.6 h, which was obtained from the result of previous study (Deshpande et al. 2017). With the alpha error 0.05 and power of the study 95%, the sample size was calculated to be 28 in each group. To compensate for possible dropouts, we enhanced the estimated sample size of 35 in each group. The OpenEpi software was used for sample size calculation.

Statistical method

The data were arranged in a Microsoft spreadsheet and were analysed with a Statistical Package for Social Science (SPSS) version 22.0. Descriptive statistics was done for quantitative data as mean ± SD (standard deviation) for quantitative normally distributed data, median and 1st and 3rd interquartile range for quantitative nonnormally distributed data, while it was done for qualitative data as number and percentage. Inferential analyses were done for quantitative variables using Shapiro–Wilk test for normality testing, Student's unpaired *t*-test, with normally distributed data and were compared for significance by using one-way ANOVA with post hoc Turkey test. In qualitative data, inferential analyses for independent variables were done using chi-square test for differences between proportions. Kruskal–Wallis test used for nonparametric data. A $P < 0.05$ was considered statistically significant.

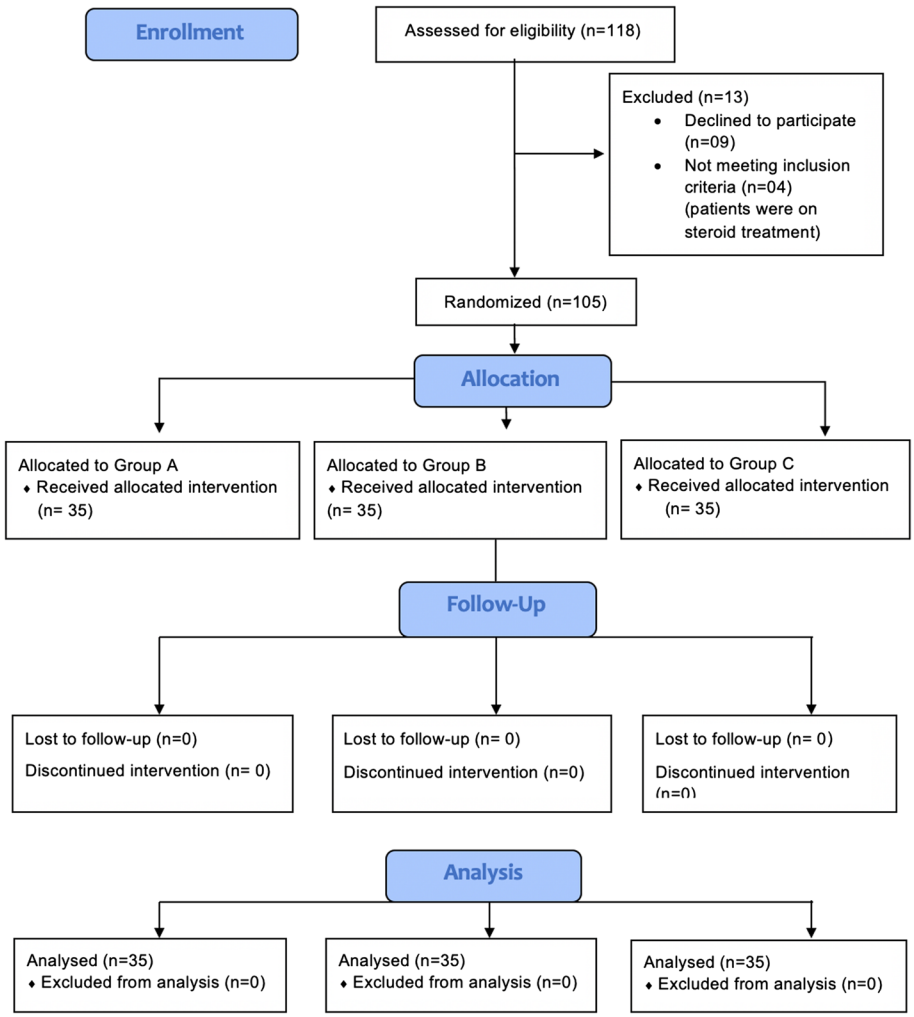

Fig. 1 Consort flow diagram

Table 1 Demographic characteristics

	Group A ($n=35$)	Group B ($n=35$)	Group C ($n=35$)	*p*-value
Age (years)	36.65 ± 14.58	37.65 ± 13.89	38.68 ± 12.08	0.742[α]
Weight (kg)	57.62 ± 9.74	57.8 ± 10.67	58.25 ± 6.18	0.844[α]
Height (cm)	160.65 ± 6.93	160.31 ± 6.28	160.37 ± 6.12	0.837[α]
Sex (M/F)	28 (80%)/7 (20%)	25 (71.43%)/10 (28.57%)	26 (74.29%)/9 (25.71%)	0.699[β]
ASA-PS (I/II)	13 (37.14%)/22 (62.86%)	14 (40%)/21 (60%)	13 (37.14%)/22 (62.86%)	0.674[β]
Duration of surgery (min)	132 ± 11.05	134 ± 10.46	134.34 ± 13.02	0.634[α]

M male, *F* female, *ASA-PS* American Society of Anesthesiologist physical status, *min* minutes. Data are presented as mean ± standard deviation or number (*n*) (%).
[α]$P > 0.05$, one-way ANOVA test between groups. [β]$P > 0.05$ chi-square test between groups

Results

A total of 118 patients were enrolled for the study. The nine patients were denied to participate in the trial, and four patients were on steroid treatment, hence excluded from the trial. The remaining 105 patients were divided into 3 groups of 35 each (Fig. 1).

The demographic characteristics, baseline clinical profile and surgical duration were comparable in all

Table 2 Duration of analgesia and total morphine consumption during the 24 postoperative hours

	Group A ($n=35$)	Group B ($n=35$)	Group C ($n=35$)	*p*-value
Duration of analgesia (min)	418.34 ± 29.22	935.91 ± 121.82	730.31 ± 129.64	< 0.0001
Total morphine consumption (mg)	13.37 ± 1.68	6.68 ± 2.42	10.2 ± 2.54	< 0.0001

The duration of analgesia and total morphine consumption were presented in mean ± SD and compared with one-way ANOVA with post hoc Turkey test. $P<0.05$ is statistically significant

Table 3 Postoperative NRS scores among the study groups

Variable	Time	Group A ($n=35$)	Group B ($n=35$)	Group C ($n=35$)	*p*-value
NRS at rest median (1st–3rd IQR)	0 h	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	NA
	2nd h	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	NA
	4th h	0.0 (1.0–2.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	**< 0.001^***
	6th h	3.0 (3.0–3.0)	1.0 (0.0–1.0)	1.0 (1.0–2.0)	**< 0.001^***
	8th h	4.0 (3.0–4.0)	1.0 (1.0–2.0)	2.0 (2.0–2.0)	**< 0.001^***
	10th h	3.0 (2.0–3.0)	2.0 (1.0–2.0)	3.0 (3.0–3.0)	**< 0.001^***
	12th h	3.0 (3.0–4.0)	2.0 (2.0–3.0)	4.0 (4.0–4.0)	**< 0.001^***
	16th h	3.0 (3.0–4.0)	4.0 (4.0–4.0)	3.0 (3.0–4.0)	0.056^
	20th h	3.0 (3.0–4.0)	4.0 (3.0–4.0)	4.0 (3.0–4.0)	0.132^
	24th h	4.0 (4.0–5.0)	4.0 (4.0–5.0)	5.0 (4.0–5.0)	0.431^
NRS at cough median (1st–3rd IQR)	0 h	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	NA
	2nd h	1.0 (0.0–1.0)	0.0 (0.0–0.0)	0.0 (0.0–1.0)	**< 0.001^***
	4th h	3.0 (2.0–3.0)	1.0 (0.0–2.0)	2.0 (1.0–2.0)	**< 0.001^***
	6th h	4.0 (4.0–5.0)	2.0 (1.0–2.0)	2.0 (2.0–3.0)	**< 0.001^***
	8th h	5.0 (4.0–5.0)	2.0 (2.0–3.0)	3.0 (3.0–4.0)	**< 0.001^***
	10th h	4.0 (4.0–4.0)	3.0 (3.0–4.0)	4.0 (4.0–5.0)	**< 0.001^***
	12th h	4.0 (4.0–5.0)	4.0 (3.0–4.0)	4.0 (3.0–4.0)	**< 0.001^***
	16th h	4.0 (4.0–5.0)	4.0 (3.0–5.0)	5.0 (4.0–5.0)	0.066^
	20th h	4.0 (4.0–6.0)	4.0 (4.0–5.0)	4.0 (3.0–5.0)	0.207^
	24th h	5.0 (4.0–6.0)	4.0 (4.0–5.0)	4.0 (4.0–6.0)	0.316^

NRS, numerical rating scale; *IQR* interquartile range. Data presented as median (1st–3rd IQR). *NRS* numerical rate scale. ^Kruskal–Wallis test. *$P<0.05$ is statistically significant

Table 4 Comparison of side effects among the study groups

Side effects	Group A		Group B		Group C		*p*-value
	N	%	*N*	%	*N*	%	
Nausea & vomiting	04	11.43	03	8.57	02	5.71	0.694
Drowsiness	01	2.86	00	0.00	02	5.71	0.357
Hypotension	02	5.71	01	2.86	01	2.86	0.771
Pruritis	01	2.86	01	2.86	00	0.00	0.661
Respiratory depression	01	2.86	00	0.00	00	0.00	0.364
Convulsion	00	0.00	00	0.00	00	0.00	-

Chi-square test was used

three groups (Table 1). The mean duration of analgesia was highest in group B (935.91 ± 121.82 min) compared to group A (418.34 ± 29.22 min) and group C patients (730.31 ± 129.64 min) ($P<0.0001$) (Table 2). Total morphine consumption in the first 24 h postoperatively was in group B (6.68 ± 2.42 mg) compared to group A

Table 5 Comparison of patient's satisfaction score among the study groups

Patient satisfaction score	Group A		Group B		Group C		*p*-value
	N	%	*N*	%	*N*	%	
1	02	5.71	0	0.00	0	0.00	0.364
2	03	8.57	0	0.00	6	17.14	0.356
3	20	57.14	20	57.14	17	48.57	0.834
4	10	28.57	15	42.86	12	34.29	0.691

Chi-square test was used

(13.37 ± 1.68 mg) and C (10.2. ± 2.54 mg), which was statistically significantly ($P < 0.0001$) (Table 2). Mean NRS scores at rest and on cough were significantly lowest in group B compared to group A and C during the first 12 h postoperatively ($P < 0.0001$) (Table 3). Postoperative side effects like nausea, vomiting and hypotension were lower in group B than groups A and C, but the difference was statistically not significant (Table 4). The patient satisfaction score was comparable in all three groups (Table 5).

Discussion

The results of our study showed that perineural dexamethasone as an adjuvant to levobupivacaine in US-guided bilateral RSB prolongs the duration of analgesia, significant reduction in pain score and total consumption of morphine compared to systemic administration of dexamethasone or control group.

The less popularity of central neuraxial blocks is due to more invasiveness, and the fascial plane blocks are more frequently administered nowadays as a part of the ERAS programme. The fascial plane blocks are an integral component of the multimodal analgesia technique. The ERAS protocol boosts the outcome and decreases perioperative morbidity after major surgeries (Gelman et al. 2018).

The RBS anaesthetizes the ventral rami of the 7th to 12th intercostal nerves by deposition of LA in the space between the posterior wall of the rectus abdominis muscle and its sheath. Among fascial plane blocks, bilateral RSB proved to provide good patient analgesia which in turn reduced postoperative opioid consumption, PONV, postoperative ileus and early mobilization allowing fast track discharge. The continuous delivery has an inherited risk of catheter dislodgement or infection, and surgeons may also not be willing of the catheter in the rectus sheath plane (Nicolotti et al. 2016). Therefore, there has been a continuous quest for an adjuvant to LA to prolong the duration of analgesia after single-shot administration of peripheral nerve block (PNB) (Desai et al. 2019). The preservative-free dexamethasone has been studied extensively as an adjuvant to augment and prolong the local anaesthetics in PNB and may decrease requirement of perineural catheter insertion (Zhao et al. 2017; Baeriswyl et al. 2017).

Levobupivacaine is the latest LA having a better cardiovascular safety profile compared to bupivacaine. The pharmacodynamic interaction of adjuvants such as alpha-2 agonists, NMDA antagonists, opioids, vasoconstrictors or steroids with LA has been studied regarding their potency and efficacy to increase the sensory and motor block of LA (Bailard et al. 2014).

Dexamethasone is a synthetic glucocorticoid which inhibits the release of inflammatory mediators such as interleukins and cytokines. The perineural dexamethasone acts additionally on local glucocorticoid receptors to cause local vasoconstriction and thereby decreases the systemic absorption of LA. Other potential mechanisms may be suppression of C-fibre-mediated pain signal transmission and upregulation of neuronal potassium channels (Zhao et al. 2017).

Dexamethasone added to the local anaesthetic agent reduces postoperative pain and improves the quality of analgesia (Pehora et al. 2017). The meta-analysis by Heesen et al. and Tan et al. established that perineural dexamethasone prolongs the duration of analgesia compared with IV dexamethasone, while meta-analysis by Hussain et al. shows equivalent analgesic efficacy benefit and similar safety profile (Heesen et al. 2018; Tan et al. 2022; Hussain et al. 2018). Zemedkun et al. established that the efficacy of dexamethasone both intravenously and perineurally as an adjuvant to bupivacaine on bilateral TAP block prolonged potent analgesia and reduced analgesic consumption in patients with caesarean section (Zemedkun et al. 2020). Martinez et al. study showed no clear benefit of perineural administration of dexamethasone over intravenous administration, and perineural route is not licenced until now (Martinez and Fletcher 2014). The systematic review by Zhang et al. recommended the routine use of dexamethasone and LA in TAP block as a part of multimodal regime in abdominal surgeries or inguinal hernia repair surgeries to enhance the recovery process (Zhang et al. 2019). This discrepancy could be due to a difference in study design, variability in the population, surgical procedures, timing of the block (preoperative or postoperative), variation in the

anaesthetic strategies used (i.v. sedation vs general anaesthesia vs spinal anaesthesia), drugs and doses of LA alone or with adjuvants.

Total morphine consumption in the first 24 h postoperatively was minimum in group B compared to groups A and C. The similar effect of adding dexamethasone to bupivacaine on TAP block showed that the total postoperative 24-h morphine consumption was significantly reduced in dexamethasone group 19.2 (8.1–24.2) vs 4.1 (1.7–6.2), $P=0.01$ (Ammar and Mahmoud 2012). Zhao et al. showed the two routes of administration (intravenous and perineural) did not show any significant difference in post-op analgesic consumption (Zhao et al. 2017).

The mean NRS score at rest or cough was found to be lowest in perineural dexamethasone administration compared to the placebo group or IV administration, and similar results were found in the study by Hewson et al. (Hewson et al. 2019). The statistically significant differences were found in NRS scores between TAP-PD and TAP alone ($P<0.05$) and TAP-IVD and TAP alone ($P<0.05$) groups at 6th and 24th h at rest and on coughing, but there was no statistically significant difference in NRS score between TAP-PD and TAP-IVD group at all times during 24 h except at 24th h with adjusted *P*-value of < 0.0001 (Zemedkun et al. 2020). The dexamethasone did not seem to significantly prolong the analgesia time, independent of mode of administration, but it improved the quality of analgesia as depicted by the VAS in the first 24 h which is < 3 (Vetriselvan et al. 2019).

The addition of dexamethasone in fascial plane block is still a topic of debate. Dexamethasone has shown its effectiveness as a neuroprotective steroid in the peripheral or central nervous system so perineural administration of dexamethasone in a dose range of 8 mg or lower has no clinical evidence of human neurotoxicity compared to LA alone (Tan et al. 2022). Although there was no statistically significant difference between the groups in terms of adverse effects in the study by Ma et al., 2019 the increase in the number of nausea and vomiting can be attributed to general anaesthesia, type of surgery, opioid consumption, etc. While IV administration of dexamethasone may also be associated with some adverse effects like hyperglycaemia, postoperative wound infection, perineal irritation and delayed wound healing, but these adverse events have not been reported with the perineural administration of dexamethasone (Hewson et al. 2019).

There are a few limitations to our study. First, the RCT was conducted in relatively healthy subjects who are non-diabetic, not on prolonged steroid use and not having chronic pain or with existing neuropathy, so the data cannot be extrapolated to these subgroups of the population. Second, we did not have patients-controlled analgesia, which can be an alternative method to supplement morphine according to pain score assessments.

Conclusions

This study concluded that perineural dexamethasone as an adjuvant to levobupivacaine prolongs the duration of analgesia with decreased analgesic requirements compared to intravenous dexamethasone in bilateral RSB in patients undergoing midline infraumbilical laparotomy surgery.

Abbreviations

IV	Intravenous
RSB	Rectus sheath block
NS	Normal saline
NRS	Numeric rating scale
ERAS	Enhanced recovery after surgery
PONV	Postoperative nausea vomiting
US	Ultrasound
LA	Local anaesthetic
RCT	Randomized control trial
ASA	American Society of Anesthesiologists
BMI	Body mass index
ECG	Electrocardiogram
NIBP	Noninvasive blood pressure
HR	Heart rate
MBP	Mean blood pressure
SpO_2	Peripheral oxygen saturation
$EtCO_2$	End-tidal carbon dioxide
PACU	Post-anaesthesia care unit
SPSS	Statistical Package for Social Science
PNB	Peripheral nerve block
TAP	Transversus abdominis plane
TAP-PD	Transversus abdominis plane-perineural dexamethasone
TAP-IVD	Transversus abdominis plane-intravenous dexamethasone

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Nil

Authors' contributions

The idea of the research belongs to GS, PKS and UC. The GS, PKS, MK and PB designed the study and also participated in clinical data collection and shared in writing the manuscript. GS and PKS performed the statistical analysis and also participated in clinical data collection and shared in writing the manuscript. GS, PKS, MK, PB and CK searched literature and also participated in clinical data collection and shared in writing the manuscript in addition to provision of patients. KC performed literature search and manuscript preparation, editing and final approval. All authors have read and approved the manuscript.

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Availability of data and materials

The datasets generated during and/or analysed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Name of ethics committee: Dr SN Medical College Jodhpur (IEC no. F.1/Acad/MC/JU/18/14022, dated 07/08/2018) and registered under Clinical Trial Registry-India (Ref. number: CTRI/2018/11/016455). Informed written consent to participate in the study was provided by all the participants.

Consent for publication
Written informed consent for publication was obtained from all the participants.

Competing interests
The authors declare that they have no competing interests.

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