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Original article

Effect of Dexamethasone as an Adjunct to Epidural Bupivacaine for Postoperative Analgesia Following Major Lower Abdominal Surgery

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Keywords.
Epidural Analgesia, Postoperative Pain, Analgesia, Dexamethasone, Lower Abdominal Surgeries.

ABSTRACT

Epidural analgesia is effective for postoperative pain. However, the unacceptable incidences of side effects such as hypotension and motor blockade have limited its use. This study aims to evaluate the effect of epidural dexamethasone as an adjunct to epidural bupivacaine for postoperative analgesia in major lower abdominal surgeries. This was a prospective, double-blinded, randomised controlled study where participants received either epidural bupivacaine alone or bupivacaine with one of two doses of dexamethasone. Participants were given either a bolus dose of 8 ml of 0.125% plain bupivacaine (group A), 8 ml of 0.125% plain bupivacaine + 4mg dexamethasone (group B), or 8 ml of 0.125% plain bupivacaine + 8 mg dexamethasone as an initial postoperative epidural analgesia. The main outcome measures are the VAS pain scores, time to first analgesic request, and analgesic consumption. VAS pain scores were significantly lower, and time to first analgesic request was significantly higher in the dexamethasone groups when compared to the control group, with a p-value of 0.000. Tramadol and bupivacaine consumption were significantly reduced in group C (p=0.000) but not in group B (p=1.000) compared to the control group. Both doses of epidural dexamethasone as an adjunct to plain bupivacaine reduced VAS pain scores. The 8 mg dose was more effective in increasing the duration of analgesia, as well as reducing tramadol and plain bupivacaine consumption.

Introduction

Pain is a frequent complication of surgery. A study conducted in our hospital in 2003 showed that the percentage of patients admitted into the recovery room with moderate to severe pain was 75.2% [1]. Inadequate postoperative analgesia has been found to be a cause of anxiety in 56.8% of surgical patients [2]. Systemic opioids such as morphine have been used in different doses to control moderate to severe pain with good results. They, however, have side effects such as a significantly high incidence of nausea, vomiting, pruritus, respiratory depression, and constipation [3]. Therefore, the use of agents with opioid sparing effects has gained increasing popularity, and there has been an increasing drive towards tailoring multimodal analgesia to reduce overreliance on opioids [4].

Epidural analgesia has been found to be effective with a significant opioid sparing effect [5]. However, the unacceptable incidence of side effects such as local anaesthetic toxicity, hypotension, and motor blockade has limited its use [3]. In an effort to enhance the effect of epidural analgesia while minimizing the side effects, several adjuncts such as low-dose opioids, steroids, clonidine, and dexmedetomidine have been added to local anaesthetic agents. Dexamethasone is a non-particulate steroid with glucocorticoid properties. The addition of dexamethasone as a single bolus of 8 mg to an epidural plain bupivacaine-fentanyl combination significantly prolonged the duration of analgesia and reduced VAS pain scores [5].

A meta-analysis reviewing the use of dexamethasone for postoperative epidural analgesia found that the appropriate dose has not yet been determined, as a variety of doses have been used, ranging from a low dose of 0.1 mg/kg to 12 mg; the most common dose used was 8 mg [6]. Doses above 12 mg were rarely used for the management of acute pain [6]. The aim of this study was to evaluate the effect of epidural dexamethasone as an adjunct to epidural plain bupivacaine for postoperative analgesia in major lower abdominal surgeries, including urological, gynaecological, and pelvic surgeries.

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Methods

Study setting/design

This study was carried out at the main theatre of our hospital. About three hundred lower abdominal surgeries take place in the main theatre of the hospital annually. This was a prospective, double-blind, randomised controlled study on patients scheduled for elective, major, lower abdominal surgeries under epidural anaesthesia.

Ethical consideration

Ethical approval was obtained from the University of Ilorin Teaching Hospital Ethical Review Committee with approval number ERC PAN/2023/10/0432 before the commencement of the study. Also, in accordance with the Declaration of Helsinki, written informed consent, signed and dated, was obtained from all participants after the investigator provided them with a detailed explanation of the procedure. All information obtained from the patients was treated with strict confidentiality. No funding was received for this research, and the authors have no conflicts of interest to declare.

Study population

The study participants were patients between the ages of 18 and 65 years who were ASA physical status classes I and II, scheduled for elective major lower abdominal surgeries. Exclusion criteria included patients' refusal, allergy to any of the study drugs (e.g., dexamethasone, plain bupivacaine), patients with diabetes mellitus, hypertension, renal or hepatic failure, and those with a body mass index over 40 kg/m2. Also, patients on chronic steroid therapy or contraindications to epidural anaesthesia, like coagulopathy, deformity of the spine, and sepsis at the site of catheter insertion, were excluded.

Sample size determination

Sample size was calculated using the St. George's University of London formula for comparing means [7]. In a previous study [8], the difference in mean of visual analogue scale (VAS) pain scores 6 hours postoperatively was 0.75, and the standard deviation for the VAS pain score for postoperative epidural analgesia with dexamethasone as an additive was found to be 1.11. Therefore, the total number per group is 34 + 3 = 37. A total of 111 patients were recruited for the study.

Sampling technique

All consecutive consenting patients who met the inclusion criteria were recruited into the study. Patients were allocated into three groups (A, B, and C) using simple randomisation.

Preparation of the study drug

A research assistant (resident doctor) who was not involved in the data collection prepared the drugs aseptically for epidural administration, and the drug was administered by one of the investigators. The patient and the investigators were blinded to the constituent drugs in the syringe.

Preoperative assessment and preparation

The patient's weight and height were measured and documented during the pre-anaesthetic review, and the body mass index was calculated. Patients were educated on the use of the VAS for pain. All patients were fasted for 8 hours from solid food before surgery and informed to request analgesics when they feel pain after surgery.

Intraoperative patient management

On arrival at the operating suite, the patient's baseline vital signs (pulse rate, non-invasive systolic, diastolic and mean arterial blood pressure, temperature), ECG and peripheral arterial oxygen saturation {SPO2} were obtained and documented using a DASH 4000 multi-parameter monitor, GE Medical Systems Information Technologies Inc., 8200W, TOWER AVE MILWAUKEE, WISCONSIN, USA. Subsequently, pulse rate, ECG, and SPO2 were monitored continuously, while non-invasive blood pressures (SBP, DBP, MAP) were monitored every 2 minutes for the first 20 minutes after induction of epidural anaesthesia or epidural top-up, then subsequently every 5 minutes till the end of surgery. A wide-bore intravenous cannula size 16G was used to secure venous access for drug and fluid administration. An epidural catheter was sited before surgery by the managing anaesthetist under aseptic conditions at the L3/L4 interspace. The patient was then positioned supine with a pillow under the shoulder to elevate the head before epidural activation with 20ml of 0.5% (100 mg) plain bupivacaine. The sensory level was assessed every minute for the first 5 minutes and every 5 minutes until a block height of T6 was achieved. Intermittent boluses of 5 ml of 0.5% plain bupivacaine were given for maintenance of epidural anaesthesia hourly via the epidural catheter till the end of surgery.

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Postoperative patient management
In the recovery room, the investigator assessed the pain score every 10 minutes till the VAS pain score at rest was> 3 cm (time 0), at which point postoperative epidural analgesia administration began.

Analgesia and pain scoring
Patients who complained of pain or had a reported VAS pain score at rest > 3 cm were given either the study or the control drug according to randomization. Group A (the control) received a bolus dose of 8 ml of 0.125% plain bupivacaine, group B received a bolus dose of 8 ml of 0.125% plain bupivacaine + 4mg dexamethasone, and group C received a bolus dose of 8 ml of 0.125% plain bupivacaine + 8 mg dexamethasone as an initial postoperative epidural analgesia bolus. The study period commenced at the time of injection of the first postoperative epidural bolus dose and lasted for the next 24 hours. Pain (at rest and on movement) was assessed every 10 minutes in the first 30 minutes after commencement of the study (time 0), then at 1 hour, 2 hours, 4 hours, and every 4 hours subsequently till 24 hours. The duration of analgesia was measured from the time of the first epidural bolus drug administration (Time 0) to the next complaint of pain or VAS pain score at rest > 3 cm. The patients were given intermittent top-up bolus doses of 6 ml of 0.125% plain bupivacaine whenever they complained of pain or VAS pain score at rest > 3 cm throughout the study period. Persistent VAS of > 3 cm up to 15 minutes after a bolus dose was considered ineffective analgesia and treated with a repeat bolus supplemental top-up dose of 6 ml 0.125% plain bupivacaine. Intravenous tramadol 50mg, with antiemetic prophylaxis, ondansetron 4 mg, was given as rescue analgesia for pain that did not respond to the supplemental bolus top-up dose of epidural bupivacaine. The patient was transferred to the ward when epidural analgesia was established, and the VAS pain score was ≤ 3 cm. The total epidural plain bupivacaine dose requirement and tramadol dose required in the study period were calculated and documented. The epidural catheter was removed at the end of the study.

Patient satisfaction
Patient satisfaction was assessed at the end of the study using a five-point Likert scale graded as totally unsatisfied, unsatisfied, neither dissatisfied nor satisfied, satisfied, and totally satisfied

Statistical analysis
Data were analysed using the statistical package for the social sciences (IBM SPSS) software version 20. Qualitative variables such as gender were presented as proportions and percentages and analysed using the chi-square test. Quantitative variables such as age, weight, body mass index, total dose of opioid analgesics, and VAS pain scores were presented as mean with standard deviation and analysed using the ANOVA. A p-value of < 0.05 was considered statistically significant.

Results
A total of 111 patients met the inclusion criteria; they were divided into three groups of 37 patients each. Three patients were excluded (two from group A and one from group B) after randomization on account of a change in anaesthetic technique to general anaesthesia. Therefore, only 108 out of the total of 111 patients recruited completed the study.

Demographic data
Participants in group A had a mean age of 52.66±11.97, group B 54.14±16.63, and group C 46.73±13.80; the difference was not statistically significant (p = 0.068). Also, there was no statistically significant difference in BMI (p = 0.108), with participants in group A having a mean BMI of 25.11±4.07, group B of 27.60±5.07, and group C of 26.16±5.52. However, the difference in gender distribution was statistically significant (p = 0.032), with the male/female distribution of group A being 18 (51.4%)/17 (48.6), group B 8 (22.2%)/28 (77.8), and group C 14 (37.8%)/23 (62.2%).

VAS pain scores
The resting and dynamic VAS scores were significantly lower in groups B and C when compared to the control group at most time periods (p values between 0.000 and 0.026) except at 0 mins, 30 mins, and 4 hours. However, when Groups B and C were compared against each other, the static VAS scores were only significant in six out of twelve time periods but not significant at 0, 30mins, 1hr, 2hrs, 4hrs, 12 hrs, and the dynamic VAS scores were significant in seven out of twelve time periods but not significant at 0, 30mins, 2hrs, 4hrs, 12hrs. The values are stated in (Tables 1 and 2).

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Table 1. Comparison of the mean VAS scores at rest (static)

Time	Group A	Group B	Group C	p value α	A vs B p value μ	A vs C p-value μ	B vs C p-value μ
0 minute	3.72±0.43	3.85±0.34	3.86±0.72	0.462	0.2021	0.3771	0.9459
10 minutes	3.09±3.35	0.75±1.49	3.12±1.08	0.000	0.0009	0.9647	0.0001
20 minutes	3.47±3.30	0.83±1.23	1.92±1.06	0.000	0.0001	0.0236	0.0008
30 minutes	0.94±1.01	1.00±1.43	0.99±0.83	0.974	0.8534	0.8410	0.9747
1 hour	1.71±1.81	0.57±1.29	0.56±0.52	0.000	0.0071	0.0024	0.9701
2 hours	2.51±1.82	0.68±0.98	1.25±1.59	0.000	0.0001	0.0081	0.1052
4 hours	3.03±2.77	2.10±2.53	3.23±1.57	0.095	0.1832	0.7434	0.0505
8 hours	3.60±3.10	0.52±1.17	1.78±1.70	0.000	0.0001	0.0094	0.0018
12 hours	2.57±2.73	1.92±1.74	1.36±0.70	0.029	0.2784	0.0296	0.1242
16 hours	1.10±2.00	0.17±0.38	0.89±1.06	0.000	0.0153	0.6292	0.0010
20 hours	1.59±1.11	0.00±0.00	1.23±0.92	0.000	0.0001	0.1937	0.0001
24 hours	1.26±0.77	0.18±0.42	0.72±0.51	0.000	0.0001	0.0033	0.0001

α ANOVA, μ t test.

Table 2. Comparison of the mean dynamic VAS scores

Time	Group A	Group B	Group C	p value α	A vs B p value μ	A vs C p-value μ	B vs C p-value μ
0 minute	4.96±1.72	5.68±1.30	5.22±2.01	0.196	0.0743	0.6043	0.3047
10 minutes	3.65±2.98	1.10±2.07	3.55±1.30	0.000	0.0003	0.8730	0.0001
20 minutes	4.44±2.97	1.13±1.63	2.49±1.21	0.000	0.0001	0.0025	0.0008
30 minutes	1.09±1.16	1.35±2.01	1.48±1.05	0.525	0.5471	0.1938	0.7646
1 hour	2.34±2.43	0.67±1.51	0.78±0.80	0.000	0.0024	0.4368	0.0125
2 hours	3.33±1.51	1.00±1.25	1.79±1.76	0.000	0.0001	0.0009	0.0540
4 hours	4.20±2.42	2.98±2.85	4.23±2.43	0.068	0.0822	0.9633	0.0820
8 hours	4.45±2.90	1.27±1.88	3.09±3.27	0.000	0.0001	0.0056	0.0117
12 hours	3.38±2.39	1.52±1.54	1.58±0.54	0.000	0.0007	0.0012	0.8485
16 hours	1.45±1.23	0.17±0.38	1.35±0.71	0.000	0.0001	0.7136	0.0001
20 hours	2.07±1.24	0.17±0.38	1.49±0.74	0.000	0.0001	0.0399	0.0001
24 hours	1.44±0.85	0.37±0.83	1.14±0.14	0.000	0.0001	0.0758	0.0001

α ANOVA, μ t test.

Time to first analgesic request / total dose of analgesics

The mean time to 1st analgesic request was significantly longer in groups B (3.02± 0.96 hours) and C (4.11± 2.01 hours) compared to the control group (1.51± 0.91 hours), with a p value of 0.000. Group C also had a significantly longer time to first analgesic request than group B (p = 0.004), as shown in (Table 3). Patients in group A consumed more tramadol (217.14 ± 48.42 mg) than those in groups B (208.19±88.60 mg) and C (116.67 ± 37.80 mg), with a p-value of 0.000. Also, group B tramadol consumption was statistically higher than group C, with a p-value of 0.000, as shown in (Table 3). The mean dose of epidural plain bupivacaine given as top-up doses for analgesia in group A was 169.24 ± 18.55 mg. There was no statistically significant difference between this and group B, with a mean dose of 166.25 ± 32.82 mg (p = 1.000). However, the mean top-up dose of bupivacaine in group C (143.96 ± 23.70 mg) was significantly lower than that of groups A (p = 0.000) and B (p = 0.001), as shown in Table III.

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Table 3. Mean time to first analgesic request, tramadol dose, and dose of plain bupivacaine.

Variable	Group A n=35	Group B n=36	Group C n=37	p value	Group A vs B (p value)	Group A vs C (p value)	Group B vs C (p value)
Time to first analgesic request (hours)	1.51±0.91	3.02±0.96	4.11±2.01	0.000	0.000	0.000	0.004
Dose of tramadol (mg)	217.14±48.42	208.19±88.60	116.67±37.80	0.000	1.000	0.000	0.000
Dose of bupivacaine (mg)	169.24±18.55	166.25±32.82	143.96±23.70	0.000	1.000	0.000	0.001

Analysed using ANOVA

Patient satisfaction

Group A had a median satisfaction score and range of 4(2-4), group B 4(4-5) and group C 4(2-4). No patient reported that they were totally unsatisfied with their management. All patients in group B were either satisfied or totally satisfied. The levels of satisfaction were higher in the groups that were administered epidural dexamethasone than in those that were not (p = 0.00005, Table 4).

Table 4. Patient satisfaction

	Totally Unsatisfied	Unsatisfied	Neither Dissatisfied Nor Satisfied	Satisfied	Totally Satisfied	Kruskal-Wallis Test	P Value
Group A	0 (0%)	10 (28.6%)	6 (17.1%)	19 (54.3%)	0 (0%)	19.7428	0.00005
Group B	0 (0%)	0 (0%)	0 (0%)	30 (83.3%)	6 (16.7%)		
Group C	0 (0%)	2 (5.4%)	12 (32.4)	23 (62.2%)	0 (0%)		

Discussion

This study found that the addition of either 4 or 8 mg of dexamethasone resulted in a reduction in resting and dynamic VAS pain scores. However, patients who received 8mg of epidural dexamethasone had a longer time to first analgesic request and consumed less postoperative tramadol and epidural bupivacaine than those who received 4 mg.

In the management of acute pain, it is also important to assess pain on movement, as the dynamic pain score will show if patients will be able to cough, clear secretions without excess pain, take deep breaths when needed, and ambulate to prevent deep vein thrombosis. The difference in dynamic pain scores largely followed the same pattern as the mean resting VAS scores. Groups B and C had lower VAS pain scores than group A at most of the study time periods, demonstrating that the addition of dexamethasone to epidural bupivacaine was effective in reducing pain scores. The analgesic efficacy of epidural dexamethasone has also been established by other studies [5,9] that found a reduction in both resting and dynamic VAS pain scores when dexamethasone was added to epidural bupivacaine.

The mechanism of the analgesic effect of epidural steroids may be associated with the anti-inflammatory action, oedema reduction, and shrinkage of connective tissue [9]. It has been reported that corticosteroid application locally blocks transmission by suppressing nerve conduction in nociceptive C-fibers and might have a local anaesthetic effect on nerves due to direct membrane action [9]. However, the pain scores in group B (4 mg dexamethasone) were, at most assessment times of the study, lower than those in group C (8 mg dexamethasone). This may be because of the proportion of males to females. Group B had 8 males and 28 females (females were almost 4 times the number of males), while group C had 14 males and 23 females (females were almost twice the number of males).

Some authors[10,11] have demonstrated different pain perception and reporting between males and females; the reason for this remains unclear. The review article by Pieretti et al. [12] concluded that it may largely be due to differences in sex hormones. Another reason the VAS pain scores in group B may have been lower than those in group C at most times of the study might be due to the unequal distribution of surgeries. Gerbershagen et al. [13] demonstrated that postoperative pain scores varied among different lower abdominal procedures. The index study found that epidural dexamethasone had a beneficial effect on the duration of action of bupivacaine, as it increased the time to first analgesic request when compared with the control group. It also found that the 8 mg dexamethasone group had an increased time to first analgesic request when compared to the 4 mg dexamethasone group, and this difference was statistically significant (4.11 ± 2.01 hours vs 3.02 ± 0.96 hours, p-value 0.004). The exact mechanism by which dexamethasone exerts all of its effects is not known, but it is assumed that its anti-inflammatory properties play a major role. This effect of an increase in duration of action was also demonstrated by the study done by Naghipour et al. [5]. Dexamethasone was shown to have

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reduced analgesic consumption of epidural plain bupivacaine and tramadol in this study. This is similar to another study [9], where it was also found that the total opioid consumption was lower in the groups that received dexamethasone compared to the control. Thomas and colleagues [14] found that epidural dexamethasone was better than intravenous dexamethasone at reducing VAS pain scores and opioid consumption. Group B patients were administered a higher mean dose of tramadol and bupivacaine. This suggests that the ability of epidural dexamethasone to reduce analgesic requirements was dose-related.

The patients' satisfaction was better in the dexamethasone groups than in the control group. This may be due to the improvement in analgesia, as other studies have found that improved patient satisfaction is an outcome of better pain management [15,16]. Hefni et al. [17] also found improved patient satisfaction with the use of dexamethasone when compared to that of the control. Effective postoperative analgesia is an important part of the management of surgical patients. Ineffective postoperative analgesia results in delayed recovery and increased risk of chronic pain syndromes [18]. With multimodal analgesia, various pain pathways are targeted with different classes of analgesics, resulting in better analgesia and a reduction in opioid use [19]. This results in reduced postoperative opioid consumption, reduced length of hospital stay, and decreased sedative medication requests [20]. Epidural dexamethasone increases the options available for multimodal analgesia in the postoperative period. The increasing application of the principles of Enhanced Recovery After Surgery (ERAS) has highlighted the importance of postoperative analgesia as a key component of postoperative surgical care. The effectiveness of epidural dexamethasone in reducing tramadol consumption and prolonging the time to first analgesic request would likely lead to better patient recovery after surgery.

Limitation of the study

This study did not look at the type of surgical incisions used or the lengths of these incisions, as this may have impacted the level of pain. Also, the different types of surgical procedures, despite the fact that they were all lower abdominal surgeries, may have affected the results.

Conclusion

This study showed that epidural dexamethasone at a dose of 4 – 8 mg was an effective adjunct to bupivacaine in reducing VAS pain scores. However, dexamethasone at a dose of 8mg clearly demonstrated greater efficacy than the dose of 4mg in increasing time to first analgesic request and reducing bupivacaine and tramadol consumption without any additional side effects.

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