Original Article

Evaluation of segmental epidural blockade following standard test dose versus test dose with addition of saline in abdominal surgeries

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Submitted: 23-Apr-2020
Revised: 12-May-2020
Accepted: 16-Aug-2020
Published: 01-Sep-2020

Access this article online

Website: www.ijaweb.org

DOI: 10.4103/ija.IJA_310_20

Quick response code

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ABSTRACT

Background and Aims: Epidural analgesia is widely used for pain relief but confirmation of accurate epidural placement is poorly understood. We proposed that sensory blockade to cold sensation would predict the accurate placement of epidural. The primary outcome was the assessment of sensory blockade at 5 and 10 min with a standard epidural test dose versus test dose with additional saline. We looked at haemodynamic changes following administration as secondary outcomes. **Methods:** Following Ethics Committee approval, 161 patients presenting for elective abdominal surgery needing epidural analgesia with general anaesthesia were randomly allocated into Group 1 receiving standard test dose (3 ml of 2% lignocaine with 1:2,00,000 adrenaline) or Group 2 (standard test dose with 6 ml of saline) epidurally. The blockade to cold sensation was assessed at 5 and 10 min. The heart rate (HR), systolic blood pressure (SBP), and mean arterial pressure (MAP) were recorded at baseline, 1, 5, and 10 min following epidural dosing. Statistical analysis was performed with Chi-square test for categorical and Student's *t*-test for continuous variables. **Results:** The sensory blockade at 5 min was 69.5% versus 82.3% ($P = 0.059$), and at 10 min 85.4% versus 97.5% ($P = 0.01$) in Groups 1 and 2, respectively. The MAP at 5 min ($P = 0.032$) and the HR and MAP at 10 min ($P = 0.015$, 0.04) were significantly lower in Group 2. **Conclusion:** An epidural test dose of 3 ml followed by additional 6 ml saline accurately predicted sensory blockade to cold at 10 min in comparison to the standard dose of 3 ml but was associated with a decrease in the HR and MAP.

Key words: Adrenaline, analgesia, epidural, lidocaine, saline

INTRODUCTION

Epidural analgesia through an indwelling catheter decreases intra and postoperative opioid usage and is a part of enhanced recovery programmes in abdominal surgery.[1,2] Accidental intravascular or intrathecal placement is ruled out by confirming negative aspiration of cerebrospinal fluid (CSF) or blood and by observing haemodynamic changes or motor blockade on injecting small volume of test dose containing epinephrine and lignocaine.

The failure rate for epidurals can range from 32% for thoracic and 27% in lumbar with an overall failure rate of 30%.[3,4] Novel techniques such as thermographic scans have lower sensitivity and positive predictive values in comparison to cold sensation assessment for confirmation of correct epidural placement.[5] We hypothesised that blockade to cold sensation following test dose could predict correct placement of epidural catheter preoperatively.

How to cite this article: Joseph N, Kumar L, Shyamsundar P, Balakrishnan S, Kesavan R, Rajan S. Evaluation of segmental epidural blockade following standard test dose versus test dose with addition of saline in abdominal surgeries. Indian J Anaesth 2020;64:790-5.

We compared detection of segmental blockade with additional volumes of saline added to the standard epidural test dose.

The primary objective of the study was to assess onset of segmental blockade to cold following administration of standard epidural test dose versus test dose with additional saline in abdominal surgery. The secondary objective was to assess hemodynamic changes with two different volumes of epidural test dose.

METHODS

After obtaining Institutional Ethical Committee clearance on 17th April 2017 and informed consent from patients, this prospective randomised study was conducted during the period from April 2017 to November 2017. (CTRI/2017/10/010170)

161 adult patients belonging to American Society of Anesthesiologists Physical Status (ASAPS) 1, 2, or 3 undergoing elective abdominal surgeries requiring general anaesthesia with epidural analgesia were included. Exclusion criteria included patients with spinal deformities, patients on anticoagulants, psychiatric disorders, impaired hearing, language problems and pregnant patients.

Patients were randomly allocated into Group 1 or Group 2 based on computer-generated random sequence of numbers and concealment of allocation ensured using sequentially numbered envelopes. Of 161 patients allocated to the study, 82 were allocated to Group 1 and 79 to Group 2. The epidural catheter was sited in patients using standard aseptic technique under local anaesthesia at lower thoracic or upper lumbar space by loss of resistance (LOR) to air technique with an 18 G Tuohy needle using midline approach in left lateral position. After confirmation of space, 18 G multiport closed end catheter (Smith Medical, Portex) was threaded into the space and fixed at 5 cm depth from skin. If technical difficulty was encountered, paramedian approach was attempted. The absence of intrathecal or intravascular placement was assessed by negative aspiration to blood and CSF. At the end of 1 min, the epidural test dose was administered to the patient in the same position through the bacterial filter as per randomisation.

Group 1 received a standard test dose of 3 ml of 2% lignocaine and 1:2,00,000 adrenaline, followed immediately by 1 ml of normal saline for dead space of the filter.

Group 2 received a test dose of 3 ml of 2% lignocaine and 1:2,00,000 adrenaline, followed immediately by 6 ml of normal saline and additional 1 ml for dead space of the filter.

The heart rate (HR), systolic blood pressure (SBP), and mean arterial blood pressure (MAP) were recorded at baseline, 1 min, 5 min, and 10 min following administration. An increase in HR or SBP of more than 20% from the baseline was considered as an intravascular placement. The patients were also evaluated for motor blockade at 5 min and 10 min to rule out accidental intrathecal injection.

At 5th min, segmental blockade to cold sensation using ice packs was measured and repeated at 10 min after test dose. The assessment was completed in 1 min. An anaesthesiologist with minimum experience of 2 years after training sited the epidural and administered test dose as per group allocated. The evaluation of epidural blockade to cold sensation was performed by a postgraduate student blinded to test dose administered. At the end of 10 min, general anaesthesia was administered as per protocol using intravenous (IV) midazolam 1–2 mg, IV fentanyl 2 μg/kg, and IV propofol titrated to loss of verbal response. Intubation was performed after administration of IV atracurium 0.5 mg/kg or IV rocuronium 0.9 mg/kg. Anaesthesia was maintained using air, oxygen, and isoflurane to maintain a 0.8–1.0 MAC (minimum alveolar concentration) of inhalational agent.

Intraoperatively patients received epidural infusion of 0.25% bupivacaine with 2 μg/ml of fentanyl after patient positioning at 4-8– ml/h at the discretion of the consultant anesthetist. When MAP was <65 mmHg, crystalloid fluid bolus of 250 ml was given and checked for fluid responsiveness. If no change was noted, IV noradrenaline infusion was started at 0.02 μg/kg/min and titrated to maintain MAP >65 mmHg. Epidural infusion was stopped if noradrenaline infusion requirement was more than 0.1 μg/kg/min.

The epidural infusion of 0.125% bupivacaine with 2 μg/ml fentanyl at 4–8 ml/h was continued in the postoperative period after evaluating motor power at extubation and assessment of haemodynamic stability. Segmental blockade to cold and pain was re assessed at 6 h and 12 h post-extubation. Pain was assessed using the numeric rating scale (NRS). An NRS score ≤ 3 was considered as adequate pain relief and no additional analgesics were administered.

To compare the mean of continuous variables between groups, independent sample *t*-test was applied. To study statistical significance of association between two categorical variables, the Chi-square test was applied. A *P* value <0.05 was considered as statistically significant. Statistical analysis was done using International Business Machines Corporation, Statistical Package for the Social Sciences (IBM SPSS) version 20 (ARMONK, NY, USA). As no similar study was published, we conducted a pilot study in 20 patients to calculate sample size. The loss to cold sensation at 10 min was our primary end point (Group 1-90% and Group 2-100%). With 95% confidence interval and power of 80%, sample size estimated was 71 in each group. However, we were able to recruit 82 patients to Group 1 and 79 patients to Group 2.

RESULTS

The consort flow diagram is shown in Figure 1. Demographic details age, gender, and weight were comparable in the two groups [Table 1]. The study was performed in patients undergoing a range of surgeries from abdominal, urological, and minimally invasive [Figure 2]. The site of placement of epidural catheter was found to be comparable in both groups (Group 1: 65 lower thoracic, 17 upper lumbar; Group 2: 66 lower thoracic, 13 upper lumbar).

At 5 min, 57 (69.5%) patients in Group 1 and 65 (82.3%) patients in Group 2 had sensory loss to cold and this was comparable. At 10 min 70 (85.4%) patients in Group 1 and 77 (97.5%) patients in Group 2 documented loss of sensation to cold stimulus and this difference was significant statistically [Table 2]. The HR, SBP, and MAP were comparable between the two groups at baseline. The MAP was significantly lower in Group 2 as compared to Group 1 at the end of 5 min and 10 min. The HR was also found to be significantly lower in Group 2 versus Group 1 at 10 min [Table 3]. None of the patients needed vasopressors after the test dose (MAP at 10 min 90.2 ± 13.5 mm Hg vs. 85.4 ± 15.5 mm Hg in Group 1 vs. 2). Intravascular or intrathecal placement was not detected in any of the patients. Intraoperatively, 45 patients in Group 1 and 50 patients in Group 2 needed noradrenaline infusions to maintain MAP as per standard protocols ($P = 0.278$). The HR, SBP, and MAP when compared as difference from baseline in both groups (Δ-delta) were not found to be statistically significant except for Δ MAP (delta mean arterial pressure) at 5 min. This was lower in Group 2 as compared to Group 1 ($P = 0.042$).

All patients received intraoperative epidural infusions in our study as we did not identify intravascular or intrathecal placement. Postoperative epidural infusion was continued in 159 patients in the ICU. Two patients who had no sensory block in the preoperative or the

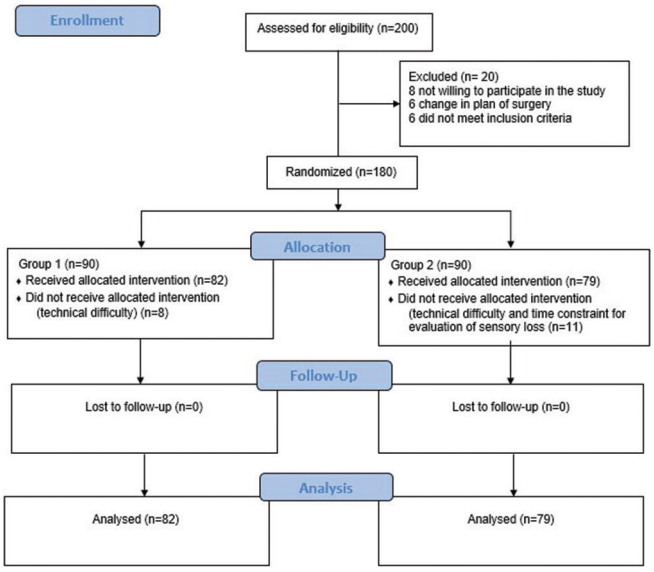

Figure 1: Consort Flow diagram

Table 1: Comparison of gender, age and weight between two groups

	Mean±SD		*P*
	Group 1 (*n*=82)	Group 2 (*n*=79)	
Age (Years)	57.5±12.8	52.3±15.1	0.021
Weight (Kg)	58.8±10.2	60.6±10.7	0.267
Gender	Male 53 (64.6%)	Male 46 (58.2%)	0.404
	Female 29 (35.4%)	Female 33 (41.8%)	

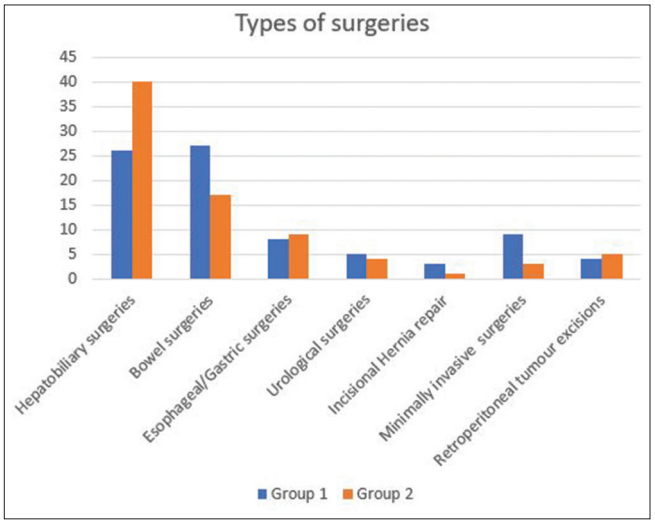

Figure 2: Types of surgeries in both groups

postoperative period and had NRS score >3 were classified as non-working epidurals. They were supplemented with fentanyl infusion as alternative analgesia. Among the 13 patients who did not have sensory block preoperatively, six continued to have no sensory blockade in postoperative period but adequate analgesia [Table 4]. None of the patients had any motor blockade or serious adverse events relating to epidural in the postoperative period.

DISCUSSION

We sought to evaluate the usefulness of epidural test dose with addition of saline versus the standard volume in confirming accurate placement of epidural before start of surgery. The additional saline group had higher prediction of successful placement at 5 min and significantly so at end of 10 min.

Although test dose picks up intravascular or intrathecal placement accurately, misplaced catheters in subcutaneous tissue,[6] pleural space, intrathecal migration[7] and placement in intermuscular space have been reported.[3]

There is limited current literature on the utility and effectiveness of the standard epidural test dose in surgical patients. A test dose should consist of 45 mg of lignocaine that produces motor blockade if intrathecal and 15 μg of adrenaline that can identify intravascular placement by an increase in HR, T wave amplitude or rise in SBP. Guay[4] recommends a SBP rise >15 mmHg or HR rise >10 bpm as indicative of intravascular placement. Contrarily Pong *et al*.[8] state that 15 μg of adrenaline does not cause a recommended 20/min increase in HR in non-sedated beta blocked patients and recommends revised tests. We used 3 ml of 2% lignocaine with 1:2,00,000 adrenaline that is commercially available for test dose as per institutional protocol.

Literature states that intrathecal spread of a drug is determined by dose or concentration of the drug rather than volume.[9] We kept the administered drug dose constant and added 6 ml of normal saline to the standard test dose.

Loss of resistance to saline is an accepted method of identification of the epidural space even in parturients and the volumes that can enter the epidural space is variable.[10] The practice of avoiding test dose and administering the first dose of labor analgesia is practised in obstetrics.[11] Saline pre-distension of epidural space with 2 ml versus 10 ml prior to test dose has reported wider dermatomal block in parturients.[12] However, our study population included only non-pregnant patients. A time period of 6 min is required to detect motor blockade due to accidental intrathecal placement with 60 mg lignocaine.[13] We had evaluated motor blockade at 10 min prior to induction of anaesthesia.

An additional epidural bolus after administration of a standard test dose to confirm accurate epidural placement may take excessive time for patient readiness, although offering more safety. The Tsui test uses an electric current through metal conducting catheters for confirming epidural placement.[14] A

Table 2: Comparison of sensory block among two groups at 5 min and 10 min

Sensory Blockade	Group 1	Group 2	*P*
At 5 min			
Yes	57 (69.5%)	65 (82.3%)	0.059
No	25 (30.5%)	14 (17.7%)	
At 10 min			
Yes	70 (85.4%)	77 (97.5%)	0.010
No	12 (14.6%)	2 (2.5%)	

P<0.05 statistically significant

Table 3: Comparison of haemodynamic parameters at different time intervals between two groups

Variable	Mean±SD		*P*
	Group 1 (*n*=82)	Group 2 (*n*=79)	
HR (beats/minute)			
$HR_{baseline}$	80.9±18.1	76.3±15.7	0.086
$HR_{1\ min}$	82.1±19.1	78.7±19.9	0.260
$HR_{5\ min}$	81.6±19.7	77.6±14.9	0.154
$HR_{10\ min}$	82.6±17.3	76.2±15.3	0.015
SBP (mm Hg)			
$SBP_{baseline}$	133.4±19.9	131.8±21.1	0.618
$SBP_{1\ min}$	130.6±19.7	127.4±20.7	0.326
$SBP_{5\ min}$	126.6±22.9	122.5±21.5	0.253
$SBP_{10\ min}$	124.3±21.6	121.0±22.6	0.341
MAP (mm Hg)			
$MAP_{baseline}$	99.3±16.5	97.1±15.7	0.394
$MAP_{1\ min}$	97.0±16.3	94.3±15.4	0.294
$MAP_{5\ min}$	92.9±15.1	87.9±14.1	0.032
$MAP_{10\ min}$	90.2±13.5	85.4±15.5	0.040

HR - Heart rate, SBP - Systolic blood pressure, MAP - Mean arterial pressure.
•*P*<0.05 statistically significant

Table 4: Number of patients without segmental blockade and pain relief in Groups 1 and 2

Group	Pre-op no block (*n*=13)	Post op no block (*n*=8)	No pain relief (*n*=2)	Alternative analgesia required (*n*=2)
Group 1	11	7	2	2
Group 2	2	1	0	0

current between 1 mA and 10 mA will produce muscle twitches in the intercostal and abdominal muscles with accurate epidural placement while twitches are elicited with lesser current <1 mA with subdural or intrathecal catheter placement. However, these catheters are not available easily and may carry an increase in cost with use.

We believe that careful aspiration and administration of epidural test dose after 1 min may be safe as evidenced consistently amongst our patients.

The spread of drug in the epidural space is variable[15] In epidural blocks, increasing the volume of local anaesthetic while holding the dose constant will result in cephalad spread of the drug with wider segmental distribution.[16]

A pre-induction knowledge of a working epidural will allow the anaesthesiologist to understand dermatomes blocked and plan analgesic management. As we had practised the restrictive fluid policy with a low threshold for initiating noradrenaline,[17] a large number of patients in both our groups received noradrenaline infusions, (54.9% vs. 63.3% in Groups 1 and 2) but this was not significant. None of our patients needed cessation of epidural infusion intraoperatively.

Although patients in Group 2 had reduction in MAP at 5 and 10 min and HR at 10 min, these were in the acceptable range and the lowest MAP recorded was 90.2 ± 13.5 mm Hg vs. 85.4 ± 15.5 mm Hg in Group 1 vs. Group 2. In 13 patients, there was no detection of sensory loss at 10 min. A paramedian approach had been used in these patients. Five patients among them reported loss of cold sensation in postoperative period which could indicate a delayed onset as well as individual patient variability and cooperation. Studies done in parturients posted for caesarean section demonstrated an onset time between 2-22 minutes for lignocaine with adrenaline with a mean of 5 min using a volume of 13 ml.[18] Epidural fat, CSF volume, sub arachnoid space diameter and length are few factors that could explain this variability.[15]

Among eight patients who did not have any loss of cold sensation in the postoperative period, two needed alternative modes of analgesia. The six patients who failed to appreciate any loss of cold sensation but were pain free could be explained by the individual variability in perception of cold sensation, patient cooperation and differential nerve block.

The dermatomal testing of cold sensation can predict accurate epidural placement. The success rate of prediction increased to 97.5% with a larger volume test dose as compared to 85.4% with standard test dose volume at 10 min. Although fall in MAP from baseline at 5 min was greater in Group 2, this was in the normal range and did not need additional vasopressors and sympathomimetics.

A certainty of epidural placement will allow to plan for effective analgesia[19] and avoid multiple local anaesthetic boluses. The occurrence of intrathecal placement with an epidural is rare (incidence 0.53%[6]) and can be avoided by our technique of aspiration with reasonable safety as has been consistently seen in our patients.

Our study had some limitations. In an attempt to document dermatomal blockade effectively we had chosen 6 ml additional saline in our patients. A reduction in this volume in prospective studies may overcome some haemodynamic changes that we had encountered. An inadvertent intrathecal placement could result in a high spinal in the larger volume group and a subdural placement of such large volumes could be dangerous.[20,21] We had used a commercial preparation of 2% lignocaine with adrenaline that is higher than the recommended test dose. The large volume of saline that was used was based on the saline volumes with LOR to saline technique[9] or the pre-distension of epidural space in the obstetric population.[10,11] Perhaps, pre-distension or use of smaller volumes of saline of 3–4 ml may provide early sensory loss without undesirable haemodynamic side effects. This would be beneficial in elderly and frail population where haemodynamic changes are exaggerated. The use of beta blockers could have negated an increase in HR among our patients. We did not factor the correlation between patient's height and epidural spread of drug, and did not identify patients on beta blockers during assessment. The dermatomal block by the test dose was not consistent and highly subjective. Hence, we did not include this in our analysis. As this study was conducted in a large volume center, the operator variability could have contributed to some variations in the results.

We believe that our study can provide insight on a working epidural preoperatively. Future studies could include refinement in saline dosing and administration and incorporation of a larger number of patients to document its use and safety.

CONCLUSION

An epidural test dose of 3 ml followed by additional 6 ml saline accurately predicted sensory blockade to cold at 10 min in comparison to the standard dose of 3 ml but was associated with a decrease in HR and MAP.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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