**INTRODUCTION**

 The regional nerve blocks serve dual purpose of anaesthesia for operation as well as analgesia for post-operative pain for considerable amount of time. Among the various regional blocks, epidural block with local anaesthetic with or without various additives is being used for intraoperative and post operative analgesia.

Epidural technique involves blocking of the nerve routes emerging from the spinal cord with a local anaesthetic and/or painkilling medication. It provides better quality of postoperative analgesia in comparison with systemic opioids and it has been observed that conducting surgery under epidural anaesthesia is associated with lower perioperative morbidity and mortality as compared to general anaesthesia alone**1** . Lower incidence of perioperative arrhythmias and postoperative backache are additional advantages of epidural anaesthesiaover general anaesthesia.2.

Various additives have been used to enhance the effect of regional blocks including epidural blocks. The use of clonidine, neostigmine, adrenaline and corticosteroids ( dexamethasone) as additive to local anaesthetics have been widely reported.Addition of dexamethasone has been reported to result in quicker onset of action and prolonged duration of analgesia when used as additive in brachial plexus block. This prospective, randomized, double blind study was been designed to find out analgesic effect and duration of action of single shot epidural bupivacaine with or without dexamethasone in patients undergoing lower abdominal surgeries.

Methods

This was prospective, randomized, double blind study conducted in 90 patients of ASA PS I and II of age group 16-70 years of age undergoing routine elective lower abdominal surgeries of duration more than one hour. Ethical approval obtained from the institutional ethical committee, written and informed consent was obtained from the patients. The patients were divided randomly into two equal groups using computers generated sequence maintained in sequentially numbered opaque envelopes and the study medication was given according to following distribution.

Group 1 received :- 9ml of 0.5% bupivacaine plain with 1 ml of NS

Group 2 received:- 9ml of 0.5% bupivacaine plain 9 ml with 1 ml of dexamethasone(4mg)

Allergy or any contraindication to study medication, ASA 3 and above, any contraindication to steroid- diabetes mellitus, hypertension, immunocompromised patient, morbidly obese patient and contraindication to epidural block- anticoagulant therapy, spine pathology and deformities were used as exclusion criteria. Medications used in the study involved 0.5% isobaric bupivacaine and dexameathasone.

**Anesthetic technique**

All recruited patients and their relatives were informed regarding the study, medication being used and expected co-operation from them for the study during pre-anesthetic check up in the ward, the evening before the surgery. Informed written consent was obtained from each patient for accepting participation in the study. During the visit, the patient was familiarized and explained about the use of visual analogue scale (VAS) for pain assessment (0 as “ no pain at all” to 10 as “worst imaginable pain”). All the patients were premedicated with diazepam 0.2mg/kg given orally at night and morning before surgery.

On the day of operation, intravenous cannulation was established and patient monitor was attached for monitoring vital parameters ( heart rate, NIBP, SpO2). Epidural catheter was inserted in sitting or lateral position under all aseptic conditions. Skin was infiltrated with 3ml of 2% lignocaine prior to insertion of an 18 G Touhy needle at the L1-L2 intervertebral space. Catheter was fixed after administrating the test dose of 3ml of lignocaine with adrenaline 1:200000 (15 microgram adrenaline and 15 mg lignocaine) . Heart rate and BP after injection were monitored and noted. Then the patient was positioned for general anesthesia. Anesthesia was induced using propofol (2ml/kg) and vecuronium was used for facilitation of endotracheal intubation and muscle relaxation, injection pethidine (1mg/kg) was used for analgesia. Patients were mechanically ventilated with oxygen and isoflurane. Parameters monitored intraoperatively included BP, heart rate, pulse oximetry. The cumulative dose of pethidine and time of last pethidine supplement were recorded. All the patients received epidural block ( bupivacaine with or without dexamethasone) 15 mins prior to completion of surgery. The study medication was prepared by anesthesia assistant not involved in the study. The residual neuromuscular blockade was reversed using neostigmine and glycopyrrolate. VAS score for pain, level of consciousness, systolic BP, SpO2 were recorded starting at 30 min postoperatively, and then at six hours intervals for 24 hours. After each VAS score patient was asked if he/she required additional analgesics regardless of his /her VAS score. Every patient was also instructed to request analgesics from the nurse whenever he/she required pain relief, and not to wait for their next scheduled pain assessment. Tramadol 50 mg iv was given as rescue analgesic. No other analgesics or sedative was given for 24hrs after surgery. Time to first analgesia after surgery, hemodynamic variables (MAP,HR, SpO2) and occurrence of intra or post operative adverse events, including, if any were noted.

**Assessment and management of pain**

The pain intensity was measured regularly at intervals mentioned above by using 10 cm Visual Analogue Scale (VAS). VAS ruler consisted of a 10 cm horizontal line with ‘no pain’ at one end and worst imaginable pain at other end.

Then the intensity of pain was assessed by asking the patient to grade the severity of pain they felt by pointing on the scale. The distance from patient’s mark in cm from no pain (end 0) in whole number was taken as numerical index of the severity of pain.

If the severity of pain (VAS score ) was more than 4 then inj tramadol 50 mg iv was given slowly to the patient as a rescue analgesic and repeated if required. Time of administration of rescue analgesic and the total analgesic requirement in the post operative period for 24 hours were noted. Time of administration of first dose of rescue analgesic was considered as the time of termination of post operative analgesic effect of epidural block. The comparison of this duration of analgesia attained in the study groups is the primary objective of the study along with the quality of post operative analgesia experienced by the patient receiving epidural block.

**Statical analysis**

Data were entered into the master sheet in Microsoft Excel, Statistical Package for Social Science (SPSS version 15) was used for data analysis.

Results were compared using independent t-test for continuous variables and chi square test for discrete variables. Level of significance was set at p<0.05 **RESULTS**

All together 90 patients belonging to ASA physical status 1 and 2 undergoing lower abdominal surgery under general anaesthesia were studied. The patient’s age ranged from 16 to 65 years.

**1 DEMOGRAPHIC PARAMETERS**

The demographic parameters of the patients of both the groups are given in table

Table 1: Comparison of age, sex and weight

|  |  |  |
| --- | --- | --- |
| Variable | Group | p- value |
| 1 (n=45) | 2 (n=45) |
| Age (years) | 39.3 ±11.2  | 37±10.6 | 0.219 |
| Sex  | Female | 31(68.9%) | 28 (62.2%) | 0.651 |
| Male | 13 (31.1%) | 16 (37.8%) |
| Weight (Kg) |  |  |  |
| 53.1±11.97 | 54.7±11.4 | 0.522 |

 The values are in mean±SD, number(percentage)

**3. POSTOPERATIVE DATA**

 3.1 DURATION OF ANALGESIA

Duration of analgesia following the administration of epidural block and analgesic consumption in 24 hours are given in table 3.1

Table 3.1 Comparison of duration of analgesia

|  |  |  |
| --- | --- | --- |
| Variable | Group | p-value |
| 1(n=44) |  2(n=44) |
| Duration of analgesia (min)  | Mean ±SD | 271.13±121.7 | 478.40±147.5  | <0.001 |
| Median (IQR) | 242.50(183.75-323.75) | 477.50(371.25-611.25) |
| Mean tramadol consumption in 24 hours in mg ±SD | 169.31±50.82 | 114.77±60.59 | <0.001 |

 Values are in mean±SD, median(interquartlie range)

Fig 3. Comparison of duration of analgesia following epidural block

The mean duration ±SD of analgesia in group 2 (478.40±147.5) minutes was signigicantly longer than that in group 1 (271.13±121.7) minutes with p-value <0.001.

3.2 PAIN VAS SCORE

The pain VAS score and vital hemodynamic parameters documented at 0 minutes, 30 minutes, 360 minutes, 720 minutes, 1440 minutes after single shot epidural block administration are given in table 3.2 and 3.3

Table 3.2 Comparison of VAS Score for pain following administration of block

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| --- | --- | --- |
| Time interval after the block | Group | p value |
| 1 (n=44) | 2 (n=44) |  |
| 30 minutes  | Mean±SD | 1.63±0.86 | 1.27±0.81 | 0.046 |
| Median(IQR) | 2.00 (1.00-2.00) | 1.00 (1.00-2.00) |  |
| 360 minutes  | Mean±SD | 3.09±0.67 | 2.34±1.11 | <0.001 |
| Medaian(IQR) | 3.00 (3.00-4.00) | 3.00 (1.25-3.00) |  |
| 720 minutes  | Mean±SD | 2.09±0.60 | 2.36±0.60 | 0.064 |
| Median(IQR) | 2.00 (2.00-2.75) | 2.00 (2.00-3.00) |  |
| 1440 minutes  | Mean±SD | 1.56±0.81 | 1.61±0.68 | 0.779 |
| Median(IQR) | 1.00 (1.00-2.00) | 1.50 (1.00-2.00) |  |
| The values are in mean±SD , median (interquartile range) |

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Fig 4.1 : Comparison of VAS Score

After 30 minutes of block administration ( end of surgery) the mean pain VAS scores (±SD) was comparable between the groups, 1.63 (±0.86) vs 1.27±0.81,

 At 360 minutes, mean VAS score ±SD for pain in group 1 was more than that of group 2 and the difference was statistically highly significant (3.09 ±0.67 vs 2.34 ±1.11 with p value <0.001).

3.3 HAEMODYNAMIC DATA

Table 3.3.1 Comparison of changes in Heart rate

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| Time interval after the block | Group | P value |
| 1 (n=44) | 2 (n=44) |
| 0 min | 76.15±13.4 | 79.25±12.8 | 0.263 |
| 30 mins | 73.18±14.14 | 76.79±13.7 | 0.228 |
| 360 mins | 90.61±10.60 | 86.97±10.67 | 0.113 |
| 720 mins | 81.20±7.48 | 85.34±9.01 | 0.022 |
| 1440 mins | 79.318±6.89 | 82.18±9.76 | 0.116 |

 The values are in mean±SD

In both the groups the lowest pulse rate was observed at 30 minutes following the block and highest at 360 minutes. While comparing the two groups at 720 minutes the pulse rate in group 1 (81.20±7.48) was significantly less than that in group 2 (85.34±9.01) (p-value 0.022). No significant difference was observed at 30 minutes,360 minutes and 1440 minutes after the block .

Fig 3.2: Comparison of Heart rate following block

Table 3.3.2 Comparison of post operative systolic blood pressure

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| --- | --- | --- |
| Time interval  | Group | P value |
| 1 (n=44) | 2 (n=44) |
| 0 min | 115.4(8.67) | 115.09 (9.49) | 0.870 |
| 30 min | 113.52 (8.73) | 112.61 (7.66) | 0.605 |
| 360 min | 125.90 (9.54) | 120.56 ( 12.06) | 0.024 |
| 720 min | 120.56 (6.39) | 120.00 (5.54) | 0.675 |
| 1440 min | 122.1 5(5.54) | 121.2 5(4.59) | 0.404 |

 The values are in mean(SD),

In both the groups the lowest blood pressure was observed at 30 minutes following the block and highest at 360 minutes. While comparing the two groups at 360 minutes the blood pressure in group 2 (120.56±12.06) was significantly less than that in group 1 (125.90±9.54) (p=0.024). No significant difference was observed at 30 minutes, 720 minutes and 1440 minutes after the block.

Fig 3.3.2 Comparison of systolic blood pressure following between two groups

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Table 3.3.3 Comparison of changes in diastolic blood pressure between two groups

|  |  |  |
| --- | --- | --- |
| Time interval  | Group  | P value |
| 1 (n=45) | 2 (n=45) |
| 0 min | 69.32(11.9) | 71.7 (8.8) | 0.273 |
| 30 mins | 70.6 (9.7) | 66.8 (6.4) | 0.035 |
| 360 mins | 80.3(7.8) | 75.13 (9.4) | <0.001 |
| 720 mins | 74.8 (6.1) | 75.5 (6.8) | 0.613 |
| 1440 mins | 75.5 (6.22) | 74.8 (5.4) | 0.560 |

 The values are in mean(SD),

The minimum diastolic blood pressure mean (±SD) in group 1 was observed at 0 min 69.2 (±11.9) as compared to 66.89 (±6.42) mm Hg observed at 30 mins in group 2. Similarly, the maximum mean diastolic blood pressure mean (±SD) in group 1 was observed at 360 mins after the block, 80.2 (±7.83) mm of Hg as compared to 75.5 (±6.8) mm of Hg at 720 mins after block in group 2. The variation was statistically comparable.

Fig 3.4: Comparison of diastolic blood pressure following between two groups.

Discussion

Due to its unpleasant nature and associated adverse consequences, post operative pain has still remained a concern to practicing clinicians despite development and advances in various newer techniques and modalities for its management.2,3

Epidural techniques are particularly effective at providingdynamic analgesia, allowing the patient to mobilize and resumenormal activities unlimited by pain.4

Epidural analgesia has been shown to have benefits over conventional intramuscular opioid analgesia and patient controlled analgesia using opioids.5,6,7,8 It provides excellent pain relief associated with minimal side effects9 and better patient satisfaction10 in comparison to other methods of analgesia. Epidural analgesia with local anaesthetics combined with opioids has been shown not only to provide better analgesia but also to improve post operative outcome.11,12

We chose bupivacaine as the local anaesthetic for both arms of our study as it has the best pharmacological profile for post operative analgesia when used as single shot. Since dexamethasone, a steroid additive has been shown to hasten the onset and prolong the duration of regional blocks when used with local anaesthetic 13,14 we chose it as the study medication in our study.

In order to give adequate time for onset and longest possible duration of analgesia we injected the study medication approximately 15 mins prior to the end of surgery.

There was no significant difference between the two groups in respect to demographic characteristics including age, sex and weight of the subjects in the present study. Similarly no significant difference was observed between the groups in respect to type of surgical procedures, duration of anaesthesia and surgery, intra operative fluid administered, urine output and intraoperative analgesia requirement.

Since we injected our study medication through the epidural catheter at the end of the surgical procedure we could not assess the onset time of analgesia in our case and it was not the objective of the present study.

Our study showed significantly longer duration of analgesia of 468 mins (almost 8 hours) when dexamethasone was added to bupivacaine for single shot epidural injection compared to 271 mins (approximately 4 and half hours) when bupivacaine alone was used. In other words, addition of dexamethasone to bupivacaine for single shot epidural block almost doubled the duration of analgesia.

We could not compare our findings on duration of single shot epidural technique with similar other studies as we could not find one in the literature search

When dexamethasone 4-8mg was added as adjuvant to 2% lignocaine with adrenaline and 0.5% bupivacaine mixture for brachial plexus block in patients undergoing upper limb surgeries Shrestha et al15 observed almost 4 times longer ( 12.75 hours Vs 3.11 hours) duration of analgesia as compared to the mixture without dexamethasone. Thus the findings in their study compares with our study quite well though they had much longer duration of analgesia with combination arm of their study. The difference can be considered quite expected and can be attributed to the difference in the study design, type of regional block and the local anaesthetic drugs and adjuvant used in the study.

Addition of small amount of dexamethasone to bupivacaine incorporated in microcapsules has been shown to prolong local analgesia through subcutaneous route in the study by Holte and colleague.16 Similar prolongation of the effect has been observed by Kopacz et al17 when dexamethasone added to bupivacaine was used for intercostal blockade in healthy volunteers.

To substantiate pain relief during post operative period we monitored VAS for pain, total analgesic requirement, pulse rate and blood pressure for up to 24 hours afer the block. While comparing the pain VAS we found significantly higher VAS at 360 minutes in the group receiving bupivacaine alone as compared to the combination group mean ±SD, (3.09±0.67 vs 2.43±1.11, p-value <0.001) , median (IQR) [3.00(3.00-4.00) vs 3.00(1.25-3.00)]. This point of time corresponds closely with the time of termination of the duration of analgesia in that group. Significantly higher VAS for pain at 720 minutes in combination group similarly corresponds to the termination of effect of block and need of rescue analgesic in that group. At this point of time, the group receiving bupivacaine alone expectedly had lower VAS owing to the effect of the rescue analgesic already received. Thereafter, the VAS for pain was lower in both the groups.

Post operative analgesic (tramadol) requirement in our study has clearly demonstrated analgesic sparing effect of single shot dexamethasone added to bupivacaine for epidural analgesia. We observed almost 33% reduction in analgesic requirement in the group receiving combination of dexamethasone and bupivacaine for epidural analgesia.

Thomas and collegues18 also observed significantly lower VAS in the postoperative period up to 24 hours in the groups receiving epidural dexamethasone added to bupivacaine as compared to those receiving saline. Their study showed more than 50% reduction in post operative morphine consumption. Although there are major differences in the design and primary objective of their and our studies, both the studies have clearly demonstrated significant analgesic effect of epidural dexamethasone evidenced by reduction in VAS score and analgesic consumption.

Similar to the observation of VAS for pain, the maximum pulse rate was observed at 360 minutes after the block in both the groups. Significantly higher blood pressure (systolic) was observed in group receiving bupivacaine alone in comparison to bupivacaine and dexamethasone at 360 min (125±9.5 vs 120±12 mm of Hg, p-value 0.024). This also corresponds closely with the time of termination of duration of analgesia in that group.

The limitation of this study is that we included surgical procedures producing different postoperative pain intensities in order to complete the study in the stipulated time period. This has contributed to some extent to heterogeneity of the observations despite our randomization.

 **CONCLUSION**

Clinicians and researcher’s interest in epidural analgesic techniques has never declined due to the quality of analgesia it offers not only in post operative pain but also in labour analgesia and chronic pain management.

In the present study, 90 patients of age group 16-65 years, belonging to ASA physical status 1 or 2, who were undergoing lower abdominal surgery under general anaesthesia were enrolled and randomly divided into two groups. The patient in group 1 received single shot epidural bupivacaine 0.25% 8ml +2ml NS and patients in group 2 received 0.25% bupivacaine 8ml+2ml dexamethasone(8 mg). The block was administered 15 minutes prior to end of surgery by anaesthesiologist. The main outcome variable was duration of analgesia ( defined as the time to the requirement of first rescue analgesic). As a rescue analgesic, tramadol 50 mg was administered whenever patient complained of pain and or had VAS score more than 4.

The total duration of analgesia achieved in group 2 (468.4±147.5 min) was significantly longer than group 1 (271.13±121.7 min) with p-value <0.001. All other parameters like demographic parameters clinical parameters were comparable between groups. The VAS score, post operative analgesic requirement and physiological parameters observed were correlating to and substantiating the findings of our main outcome.

In conclusion, our study has shown that single shot epidural block using bupivacaine alone provides effective post operative analgesia for almost 4 hours and 51 minutes which can be further prolonged to around 7hours by addition of dexamethasone while significantly reducing the postoperative analgesic requirement. Based on one finding we recommend the use of dexamethasone as additive to local anaesthetics for single shot epidural analgesia wherever appropriate.

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