

Comparing efficacy of epidural dexamethasone versus fentanyl on post operative analgesia – a double blinded randomized study

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Abstract

Introduction: Various techniques and drugs have been adopted to prolong postoperative analgesia. Epidural steroids have been used successfully for long time for chronic pain syndrome. The safety of epidural steroids is well established. Based on the above evidences and concepts we used dexamethasone and opioid as adjuvant to local anesthetic agent in our study.

Aim and Objective: To compare the efficacy of epidural dexamethasone versus fentanyl on post operative analgesia.

Materials and Method: After getting Ethical committee approval and written informed consent the study was conducted in 60 adult male patients aged between 25 –45 years belonging to ASA Physical status I and II undergoing elective hernioplasty under epidural anesthesia were randomly allocated into one of the three groups (20 patients per group) by lotting method.

Method of blinding: Patients and the person performing the epidural technique was unaware of the epidural drug composition. The drug solution was prepared by an anaesthesiologist assistant in the operating room and was labelled accordingly.

Study period: From onset of epidural blockade to onset of postoperative pain with VAS > 5.

Group 1: Patients receiving 11 cc of 0.5% bupivacaine plus normal saline 1 cc epidurally.

Group 2: Patients receiving 11 cc of 0.5% bupivacaine plus 50 µg fentanyl epidurally.

Group 3: Patients receiving 11 cc of 0.5% bupivacaine plus 4 mg preservative free dexamethasone epidurally.

All patients received a total volume of 15 ml of study drug including 3 ml of test dose plus 1 ml of adjuvant. All patients were monitored for 24hrs postoperative period for complications, hemodynamics and pain.

Results: Group 2 patients with fentanyl as adjuvants showed early onset of anesthesia 5.075 min when compared with their two groups (group 1 -5.3min and group 3 6.252 min) v but group 3 patients with dexamethasone showed prolonged duration 373 min (group 1 -256.05 min and group 2- 347.25min).

Conclusion: We conclude that epidural dexamethasone resulted in prolonged postoperative analgesia without any side effects like nausea, vomiting, pruritus, sedation except hypotension in few patients. Dexamethasone can be used as adjuvant in single dose epidural techniques with adequate monitoring.

Keywords: Fentanyl, Dexamethasone, Local anesthetics, Epidural analgesia, Duration of analgesia

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Introduction

Various techniques and drugs have been adopted for postoperative analgesia. These include regional techniques like epidural analgesia with local anesthetics alone or opioid alone or combination of both, peripheral blocks, NSAIDs, parenteral opioids, non epidural analgesia like intrapleural analgesia, paravertebral block, intra articular analgesia etc. Opioid receptors are located in the areas of brain (periaqueductal gray matter of brainstem, amygdala, corpus striatum, hypothalamus) and spinal cord (substantia gelatinosa) that are involved in pain perception, integration of pain impulses and responses to pain. Epidural steroids have been used successfully for long time for chronic pain syndrome. The safety of epidural steroids is well established. Based on the above evidences and concepts we used dexamethasone and opioid as adjuvant to local anesthetic agent in our study.

Materials and Method

After getting Ethical committee approval from Government Kilpauk Medical College Hospital. Chennai

10, we conducted the study in our hospital in 60 adult male patients aged between 25 –45 years belonging to ASA Physical status I and II undergoing elective hernioplasty under epidural anesthesia after obtaining written informed consent. Patients were randomly allocated into one of the three groups (20 patients per group) by lotting method.

Method of blinding: Patients and the person performing the epidural technique was unaware of the epidural drug composition. The drug solution was prepared by an anaesthesiologist assistant in the operating room and was labelled accordingly.

Study period: From onset of epidural blockade to onset of postoperative pain with VAS > 5.

Inclusion Criteria:

- Adult male patients aged 25 – 45 years
- ASA physical status I & II
- For uncomplicated inguinal hernia surgery

Exclusion Criteria:

- Patient unwilling for the procedure
- Obese

- Systemic illness
- History of peptic ulcer disease

Those received corticosteroids or immune suppressive drugs in the last 6 months those with contraindications to steroids Patients on anticoagulants Patchy or inadequate blockade which required supplemental narcotics or general anesthesia monitoring done with t five lead ECG, Non Invasive Blood Pressure, Pulse Oximeter and baseline parameters were recorded. An intravenous line was established with 18 gauge venflon and preloaded with 15 ml / kg of ringer lactate. Under strict aseptic precautions with the patient in right lateral position local anaesthetic infiltration was given with 1% lignocaine. Epidural space was identified at L2 – L3 space through 16 gauge Tuohy needle by loss of resistance technique. An 18 gauge epidural catheter was inserted in L2 – L3 space and 5 cm of catheter kept inside epidural space. Test dose was given with 3 ml of 0.5% bupivacaine with epinephrine 1:2,00,000 dilution via catheter before it is fixed to rule out intravascular or intrathecal placement. After confirming the epidural placement of the catheter, 12 ml of blinded study solution was given and level of blockade was noted at 5 min interval till 20 minutes. Oxygen at 4L/min via venturi mask was provided. If there was any hypotension (systolic blood pressure < 80 mm hg or mean arterial pressure < 60 mm hg) Inj. Ephedrine 6mg IV was given along with intravenous fluid. If the heart rate fell below 50 / minute, Inj. Atropine 0.6 mg IV was given. The respiratory rate and type of respiration was also monitored.

Group 1: Patients receiving 11 cc of 0.5% bupivacaine plus normal saline 1 cc epidurally.

Group 2: Patients receiving 11 cc of 0.5% bupivacaine plus 50 µg fentanyl epidurally.

Group 3: Patients receiving 11 cc of 0.5% bupivacaine plus 4 mg preservative free dexamethasone epidurally.

All patients received a total volume of 15 ml of study drug including 3 ml of test dose plus 1 ml of adjuvant.

After the administration of study medication, the onset of analgesia and the level achieved was noted at 5

min interval. Surgery was allowed to proceed when the level of blockade was T8. Throughout the intraoperative period vitals like heart rate, systolic blood pressure, mean arterial pressure, oxygen saturation and respiratory rate were monitored. At the end of surgery the level of sensory blockade was assessed. The patient was shifted to recovery room and observed for 2 hour and vitals were recorded and shifted to Post Anesthesia Care Unit. In the PACU, pain score was observed at 30 min intervals upto 10hrs on a 10cm Visual analogue scale and for occurrence of side effects like nausea, vomiting, pruritus, respiratory depression, sedation and changes in hemodynamic variables.

The time since injection of drug into epidural space to the time required to obtain sensory blockade upto T8 (loss of pin prick to 22 gauge needle) noted as onset of analgesia. The time between the onset of analgesia and return to baseline VAS of 5 was noted as the duration of analgesia.

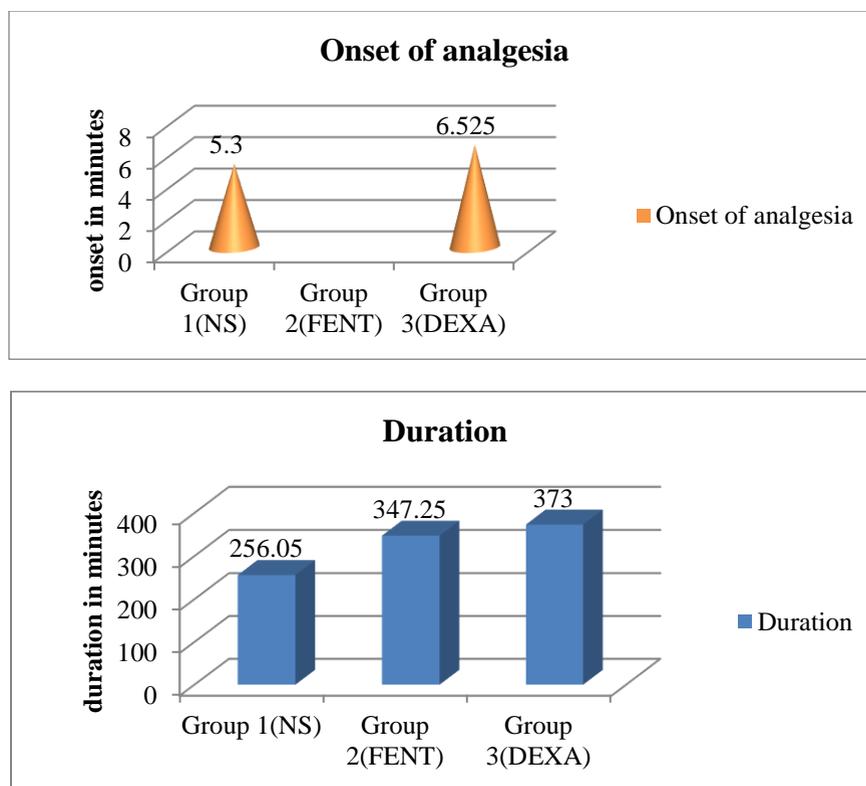
Rescue Analgesia in the Postoperative Period: When the VAS score was more than 5 or when the patients complained of pain, since the study was concluded Inj. Diclofenac 50mg was given intramuscularly and epidural catheter was removed. The patients were followed for a period of 24 hours in PACU for any occurrence of nausea, vomiting, sedation, pruritus, respiratory depression (RR<10/min), and parameters like duration of analgesia, hemodynamic variables etc. were noted.

Statistical analysis was done on collected data. Analysis of variances (ANOVA) was used for comparison of mean values between more than two groups. Posthoc test was used to find any significance between the individual groups.

Observations and Results

The demographic data was analysed and it was found to have statistically no significant difference in parameters such as age, height, weight, ASA status. On comparing the mean onset of analgesia between three groups, the group 2 patients receiving fentanyl (5.075 minutes) had shorter onset of time than other two groups.

S. No	Parameter (min)	Group 1(ns)	Group 2(FENT)	Group 3(DEXA)	p value
1	Onset of analgesia	5.300	5.075	6.525	0.003
2	Duration	256.05	347.25	373.00	0.000



On comparing the mean duration of analgesia among the three groups, group 3 patients receiving dexamethasone (373 minutes) had prolonged duration of analgesia than the group 2 (347.25 minutes) and group 1 patients (256.05 minutes). There was no significant changes in the hemodynamics between the groups during the study period. The two segment regression time in group 1 and 2 was 120 min and 131.5 minutes respectively. The regression time was 122 min in group 3 patients. This was comparable with the three groups.

S. No	Parameter	Group 1 (NS)	Group 2 (FENT)	Group 3 (DEXA)	p value
1.	Nausea	3.55%	20%	-	0.000
2.	pruritus	-	15%	-	0.033
3.	Sedation	-	25%	-	0.000
4.	hypotension	10%	15%	20%	0.070

Discussion

The onset of analgesia was earlier in the fentanyl group when compared to the control group. This finding correlates with the study done by Manpreet Kaur et al who studied the effect of intrathecal bupivacaine alone and intrathecal bupivacaine along with opioids like butorphanol and sufentanil. Khafagy et al. In his study he concluded that epidural dexamethasone resulted in low post operative pain score and analgesic requirements and prolonged analgesic duration similar to our study which showed that steroid adjuvant prolonged duration of epidural analgesia compared to the opioid or local anesthetic alone. Results of our study also correlate with the study of Thomas & Beevi et al who concluded that patients receiving epidural dexamethasone had less post-operative VAS scores and analgesic consumption. Dexamethasone had action at spinal cord level in addition to its action on the peripheral tissues after

systemic absorption from epidural space. There was statistically significant decrease in the incidence of nausea, sedation, and pruritus in group 3 patients receiving dexamethasone compared with group 2 patients receiving fentanyl and group 1 patients receiving normal saline. This correlated with the study done by Bisgaard et al who concluded that less incidence of nausea, pruritus, fatigue, overall pain following IV administration of dexamethasone 8 mg. There was no long term neurological complications in group 3 patients receiving dexamethasone.

Conclusion

We conclude that epidural administration of dexamethasone –bupivacaine admixture resulted in better postoperative analgesia in terms of lower postoperative pain score, prolonged postoperative analgesia and patient comfort with fewer side effects

when compared with the other two groups. We also conclude that this epidural dexamethasone resulted in prolonged postoperative analgesia without any side effects like nausea, vomiting, pruritus, sedation except hypotension in few patients. Dexamethasone can be used as adjuvant in single dose epidural techniques with adequate monitoring.

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