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Original Research Article

A COMPARATIVE STUDY OF FENTANYL, CLONIDINE AND DEXMEDETOMIDINE WITH BUPIVACAINE FOR PERIOPERATIVE ANALGESIA IN PEDIATRICS UNDERGOING LOWER ABDOMINAL, PERINEAL AND LOWER LIMB SURGERIES UNDER CAUDAL BLOCK.

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Abstract

Introduction- Caudal epidural anaesthesia is one of the common of all regional anaesthetic techniques in children and is recommended for surgical procedures lasting for less than 90 minutes. Several adjuncts such as opioids, ketamine, midazolam, neostigmine and Clonidine have been studied with bupivacaine to prolong its duration of action allowing single shot caudal anaesthesia to be used for surgery lasting 90 - 150 minutes.In light of the above facts this clinical study is designed to compare the analgesic efficacy and side effects of a bupivacaine-fentanyl, bupivacaine-clonidine and bupivacaine-dexmedetomidine mixture for caudal analgesia in children in lower limb/ lower abdominal surgery.

Aims and objective- This study is aimed at evaluating the efficacy of fentanyl, clonidine and dexmedetomidine as additives with 0.25% bupivacaine for caudal analgesia and observe the side effects if any and compare it among the three groups.

Material and methods- A total 90 children age 2-8 years of either sex, undergoing general anaesthesia for below the umbilicus surgery, were randomly allocated into 3 groups of 30 patients each for this study. Group 1 received Bupivacaine 0.25% 1ml/kg with fentanyl 2ug/kg, group 2 received bupivacaine 0.25% with clonidine 2ug/kg and group 3 received bupivacaine 0.25% 1ml/kg with dexmedetomidine 2ug/kg through caudal epidural block. Baseline Heart rate, Systolic Blood Pressure, Diastolic Blood Pressure, oxygensaturation, respiratory rate were recorded, before & after caudal block, then every 5 min interval for next 15 minutes, then at 10 min interval till the surgery ends. These readings were recorded from Operation Theatre monitors. Sedation score, duration of analgesia and incidence of side effects were recorded in post operative period.

Results- The age and sex distribution were comparable in all the three groups and there was no significant difference. The duration of analgesia was maximum with bupivacaine-dexmedetomidine group (11.65 hours), lesser with bupivacaine-clonidine group (9.616 hours)

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and least (6.77 hours) with bupivacaine fentanyl group. The children who were given clonidine along with bupivacaine in caudal epidural block were more drowsy or sedated in post operative period than the children who were given bupivacaine dexmedetomidine or bupivacaine fentanyl mixture. Heart rate showed a comparable declining pattern in dexmedetomidine and clonidine groups as compared to fentanyl group during intraoperative period.

However, the clonidine and dexmedetomidine groups showed a significant decrease in heart rate than fentanyl group in post operative period. There was significant drop in blood pressure in dexmedetomidine and clonidine group than fentanyl group in both intraoperative and post operative period. There was no respiratory depression seen in all the three groups and oxygen saturation was maintained. The incidence of post operative nausea and vomiting, and pruritus was noted in all the three groups and it was found to be more in fentanyl-bupivacaine group (30%) than in clonidine-bupivacaine group (33%) and dexmedetomidine-bupivacaine group (33%).

Conclusions- We conclude that addition of fentanyl, clonidine and dexmedetomidine as adjuvants to bupivacaine prolonged the duration of surgical analgesia after single shot caudal injection, thus allowing the caudal analgesia to be recommended for surgeries lasting up to or more than 150 mins.

Categories: Pediatrics, Pediatric Surgery, Anesthesiology

Keywords: perioperative analgesia, clonidine, dexmedetomidine, fentanyl, caudal epidural block

1. Background

The International association for study of pain has described pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage [1]. It may be registered at subconscious level, whether the patient responds physically to noxious stimuli or not, be it a child or a grown up. It is now well established that even newborns respond to noxious stimuli by behavioural, physiological and psychological changes as adults, however it is a complex phenomenon in paediatric age as it is difficult to differentiate pain from restlessness or stranger anxiety [2].

In 1987, Anand et al [3] demonstrated significant reduction in morbidity and mortality of children with adequate perioperative pain relief. Since then, effective perioperative analgesia has become an integral component of paediatric anaesthesia and surgery. Advantages cited of providing post operative pain relief in children include reduction in nausea and vomiting, early return of normal appetite, early ambulation, improved wound healing and rapid return of patient to full activity [4-6]. Over the years, a large number of options for analgesia have been emerged out ranging from traditionally used intramuscular opioids to regional techniques with newer drugs like Clonidine, dexmedetomidine, NMDA(n-methyl d-aspartate) antagonists etc. Regional anaesthesia, having advantages in terms of profound analgesia with minimal physiologic disturbances, safe and easy to perform and gained popularity over parental drugs in paediatric age groups.

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Caudal epidural anaesthesia which accounts for 60% of all regional anaesthetic techniques in children, was first described at the turn of last century by two French physicians, Fernand Cathelin and Jean Anthanase Sicard [7]. Bupivacaine is the most commonly used local anaesthetic in caudal anaesthesia with the limitation of short duration of action, when given as single shot technique. Thus, caudal anaesthesia is recommended for surgical procedures lasting for less than 90 minutes. Several adjuncts such as opioids, ketamine, midazolam, neostigmine and Clonidine have been studied with bupivacaine to prolong its duration of action allowing single shot caudal anaesthesia to be used for surgery lasting 90-150 minutes [8]. Fentanyl, a lipophilic opioid, is usually added to local anaesthetic has been demonstrated to improve caudal analgesia in children but also has been associated with side effects like nausea and vomiting, pruritus, urinary retention and potentially life-threatening respiratory depression [9-12]. Clonidine, an alpha 2 agonist, has advantage over fentanyl that it lacks side effects associated with use of systemic and spinal opioids. The analgesic action of epidurally administered Clonidine is due to stimulation of noradrenergic pathways inhibiting the release of nociceptive neurotransmitters in the dorsal horn of spinal cord. It has been shown to provide analgesia of variable efficacy and duration [13,14] to potentiate postoperative analgesia when used in combination with local anaesthetic [15] or opioids [16] via the extra dural and intrathecal routes. In doses more than 5g/kg, it can produce significant hypotension, bradycardia and sedation [17]. Dexmedetomidine is another selective alpha 2 agonist having sedative properties. It has eight times greater affinity for alpha 2 adrenergic receptors than clonidine and much less alpha-I effects. A major advantage of dexmedetomidine is its higher selectivity compared with clonidine for alpha- 2a adrenergic receptors, which is responsible for the hypotensive and analgesic effects of such drugs. Dexmedetomidine causes dose dependent sedation, anxiolysis, analgesia and blunt the sympathetic responses to surgery and other stress. It has opioid-sparing effects and does not significantly depress the respiratory drive. The common side effects are bradycardia, hypotension and heart block. In light of the above facts this clinical study is designed to compare the analgesic efficacy and side effects of a bupivacaine-fentanyl, bupivacaine-clonidine and bupivacaine-dexmedetomidine mixture for caudal analgesia in children in lower limb/ lower abdominal surgery.

2. Materials and Methods

With the approval of research and ethical committee of the hospital, this study was carried out on 90 children of either sex, their age ranging from 2-8 years and weight under 25 kgs, and belonging to ASA class I and Il. This study is intended to evaluate, perioperative analgesia in caudal block with 0.25% bupivacaine and its combination with three other agents namely fentanyl, dexmedetomidine and clonidine in children undergoing lower limb/lower abdominal surgery. After approval from ethical committee of the institution (St Stephens Ethics committee, 132069/2013), 90 patients were selected using preset inclusion and exclusion criteria.

Inclusion criteria: Patients of either sex aged between 2-8 years, Weight less than 25 kg. Belonging to ASA class I and Il , Scheduled for elective surgery below umbilicus.

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Exclusion criteria: 2 of 10 Children with following disorders were excluded from the study; Lack of parental consent, those with hypersensitivity to local anaesthetic, those having focus of infection around the site of block, Coagulation disorders, septicaemia, spinal deformities, those operated for lumbar meningo-myelocoele &Sensory loss below the girdle. These 90 patients were allocated into three groups of 30 children each by computer generated randomization.

Group I - This group of 30 children received Bupivacaine 0.25% in a dose of 1ml/kg along with fentanyl 2 ug/kg by single shot caudal epidural block (B+F).

Group II - This group of 30 children received Bupivacaine 0.25% in a dose of 1ml/kg along with clonidine 2 ug/kg by single shot caudal epidural block(B+C).

Group III- This group of 30 children received Bupivacaine 0.25% in a dose of 1ml/kg along with dexmedetomidine 2 ug/kg by single shot caudal epidural block(B+D).

All the above children underwent a pre-anaesthetic evaluation at least a day before the surgery. Informed consent was taken from their guardians. All the children were kept nil per orally for 2 hrs for clear fluids, 4 hrs for milk and 6 hrs for solids. The children were premedicated with oral midazolam in a dose of 0.5mg/kg, half an hour prior to the proposed anaesthetic induction time. Baseline vital parameters were recorded on arrival in the OT. To alleviate the pain of injection and to keep the child immobile, general anesthesia was administered with halothane 1-2% and nitrous oxide in oxygen (2:1) by face mask through a Jackson Rees modification of Ayres T piece. Once the child was asleep an intravenous access was established using a 22G or 24G PVC cannula, monitors were attached, baseline vitals were recorded and paediatric electrolyte solution was set on flow. The child was completely anaesthetized by increasing halothane concentration and airway was secured with Laryngeal Mask Airway connected to Jackson Rees circuit. Then the child was placed in left lateral position and sacral hiatus was located. Using Betadine and spirit the area was thoroughly cleaned and draped. Then a 23G needle was inserted at an angle of 45 degree to the skin. A "Giving in" feel was appreciated as the needle pierces the sacrococcygeal membrane, and then the needle was slanted further to an angle of 30 degree to the skin and advanced further 1-2mm in line with sacral canal. After ensuring that no CSF or blood is aspirated into the syringe one of the three drug combinations prepared by another anaesthetist was injected into the caudal space gradually (after a test dose of 0.5ml) and child was made supine. The contents of the syringe were blinded to the investigators. Surgical incision will be allowed 15-20 min after instituting the caudal block. No further analgesic or sedative was given intraoperatively. Halothane was switched off at the beginning of closure of wound and nitrous at last skin suture, LMA was removed and when child was stable, transferred awake to the recovery room for further evaluation. No analgesic was given post operatively till the child complained of pain.

The parameters which were monitored intraoperatively are Heart rate, NIBP, ECG, Respiratory Rate and oxygen saturation (pulse oximetry), Temp -On arrival of child in the operation thereafter inducing sleep and just prior to caudal block, immediately after the caudal block, Every 5 mins after the block until incision is given and Every 10 mins thereafter till the end of surgery.

Any sign of pain response such as grimace, sweating, excessive increase in heart rate or involuntary movements or withdrawal of limbs on the start of surgery was noted. If there was

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an increase in HR or Systolic arterial pressure by> 15% of baseline within 15 min of skin incision it was considered as failure of caudal anaesthesia. If more than 45 min after skin incision HR or systolic arterial pressure increases by >15% analgesia was considered inadequate and child was given rescue opioid (fentanyl 1ug/kg). The need for opioid was considered as the first end point of the study and subsequent data obtained from those children were not considered. Any adverse event such as catatonia, respiratory depression, apnoea, vomiting, laryngospasm was also recorded. Postoperatively- Following parameters were observed and recorded.

Duration of caudal analgesia-the time from administration of caudal block to the time child first complained of pain. FACES Pain Score was monitored every 30mins by Wong-Baker FACES Pain Rating scale (0 no pain-5 severe pain) 3 of 10 Sedation was assessed every 30 min using a three point sedation score; Awake (0),Drowsy (l), Asleep(2). Heart Rate, NIBP. Respiratory Rate and Temp, every half an hour for 2 hrs and then every 2 hrs up to 6hrs in the recovery room.

Side Effects: Spells of apnoea, respiratory depression, chest wall rigidity, nausea & vomiting, pruritus, urine retention or any other untoward incidence was noted. Degree of recovery from general anaesthesia was done using modified Aldrete score. Behavioural and physiologic changes are graded according to CRIES Scale. Thus on the basis of above parameters (both intraoperative and postoperative), the three groups of drugs were analyzed and compared.

Study type: Computer generated randomized controlled double blind clinical trial.

Sample size calculation:- Total Sample Size: 90.Significance 0.05, power of study= 85%. Hence, we decided to take 30 patients in each group with a total of 90 patients comprising of 30 patients in each group. OPENEPI software was used for predicting adequate sample size

Statistical methods: Chi-square test was applied for the cross tabulation between the groups, age and sex. Student 't' test was applied to compare the data in each group with respect to other groups for all the parameters. Analysis of variance (ANOVA) was applied to compare the data between the groups for each event.

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3. Result

Demography	Gr I	GrII	GrIII	P value
Age(2-4)yrs	7	10	10	
(5-7)yrs	15	16	16	0.608
(8-9)yrs	8	4	4	
Sex (male)	23	26	24	0.602
(female)	7	4	6	
Weight (mean)	15.87	17.10	17.10	0.326

TABLE 1: Table 1 shows demographic details of the patients in the study which was not significant (p>0.05)

p-value >0.05 is considered significant.

Figure *1* shows intraoperative change in heart rate .

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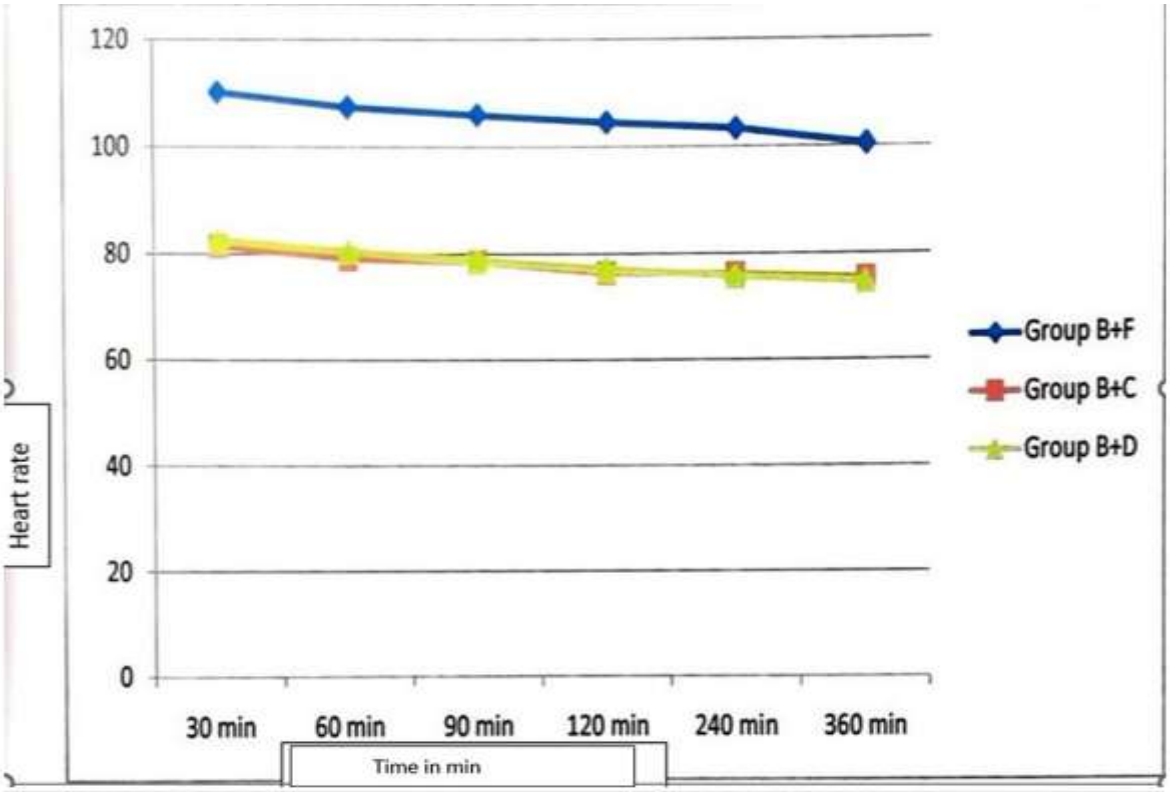

FIGURE 1: shows intraoperative heart rate at different time intervals(b+f=bupivacaine+fentanyl; b+c=bupivacaine+clonidine;b+d=bupivacaine+dexmedetomidine)

Initially the heart rate was comparable among all the three groups and the difference in heart rate in three groups was not statistically significant up to 30 min as the 'p' value > 0.05 in intraoperative period, after that there was significant drop in heart rate in group II and III in comparison to group I and the difference in heart rate was significant, as the p value <0.016 at 40 min and subsequently 0.001

figure 2 shows post-operative change in heart rate.

Initially the heart rate was comparable among all the three groups and the difference in heart rate in three groups was not statistically significant up to 30 min as the 'p' value > 0.05 in intraoperative period as shown in figure 1 after that there was significant drop in heart rate in group Il and Ill in comparison to group I and the difference in heart rate was significant, as the p value 0.235 but it became significant at 60 min due to drop in blood pressure in clonidine and dexmedetomidine group.

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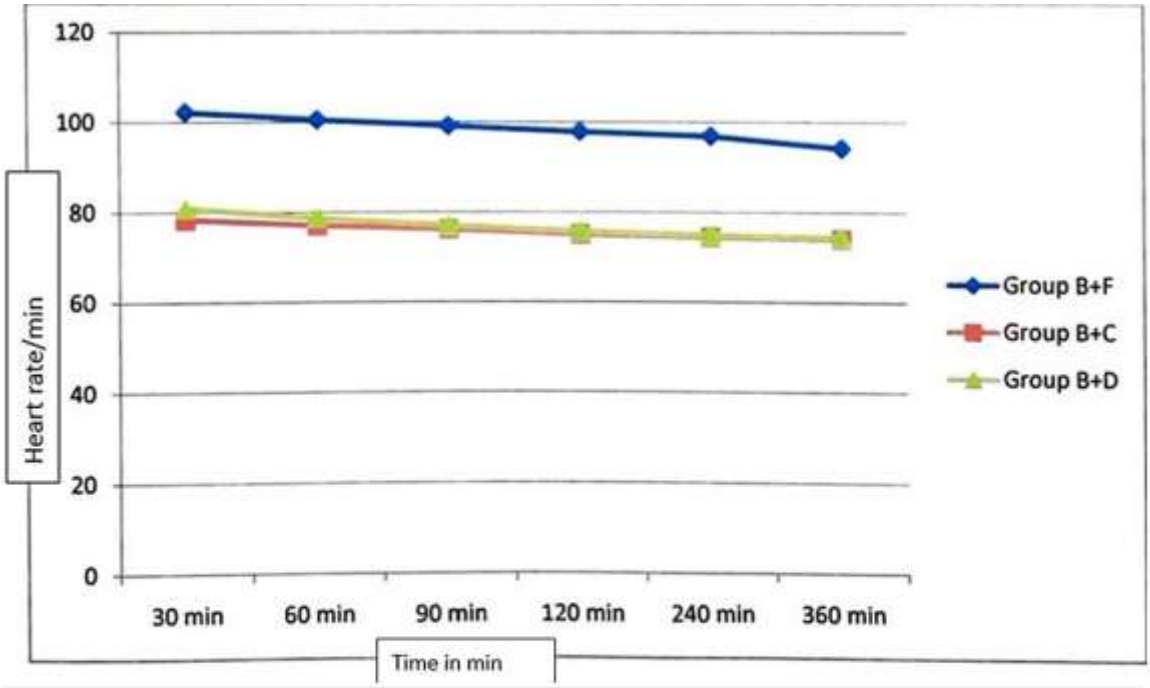

FIGURE 2: shows post operative changes in heart rate

The difference in heart rate changes is statistically significant between all groups throughout the postoperative periods as the p value is 0.001. The heart rate in group II (clonidine) &group III(dexmedetomidine) was significantly lower than group I (fentanyl) may be because of sedative effect.

Figure 2 shows difference in heart rate changes is statistically significant between all groups throughout the postoperative periods as the p value is 0.001. The heart rate in group Il (clonidine) &group Ill(dexmedetomidine) was significantly lower than group I (fentanyl) may be because of sedative effect.

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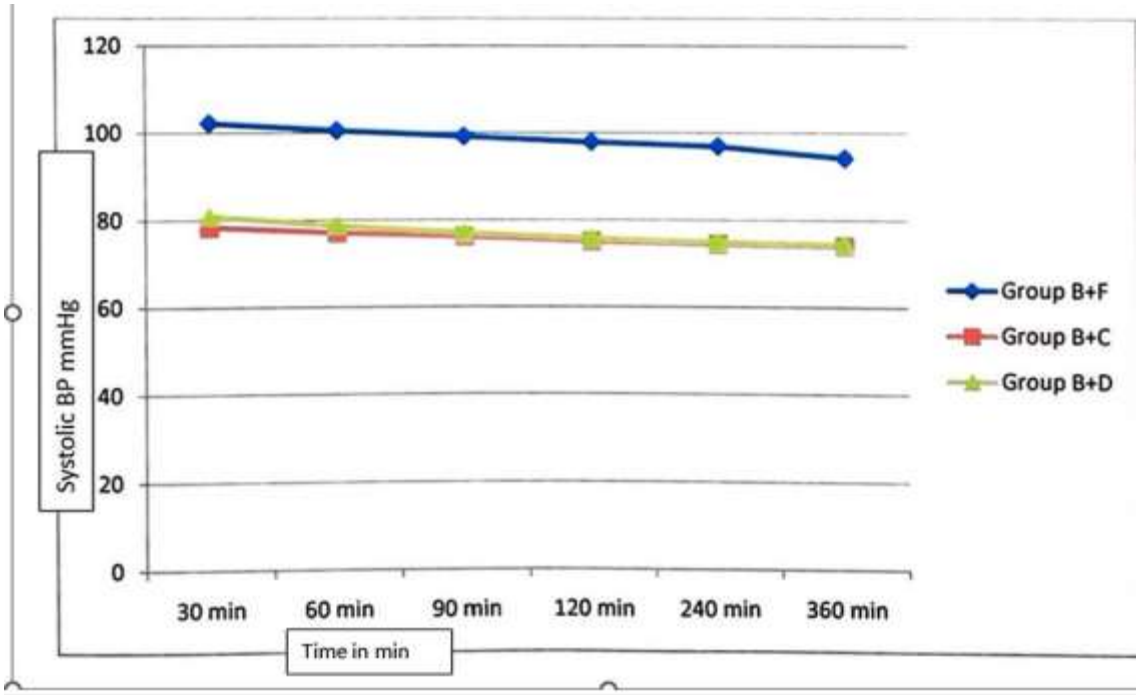

FIGURE 3: shows intraoperative systolic blood pressure changes

Inter group comparison of systolic blood pressure revealed comparable baseline systolic blood pressure in all the three groups and difference in SBP was statistically not significant as p value > 0.235 but it became significant at 60 min due to drop in blood pressure in clonidine and dexmedetomidine group.

Figure 3 shows that inter group comparison of systolic blood pressure revealed comparable baseline systolic blood pressure in all the three groups and difference in SBP was statistically not significant as p value > 0.235 but it became significant at 60 min due to drop in blood pressure in clonidine and dexmedetomidine group.

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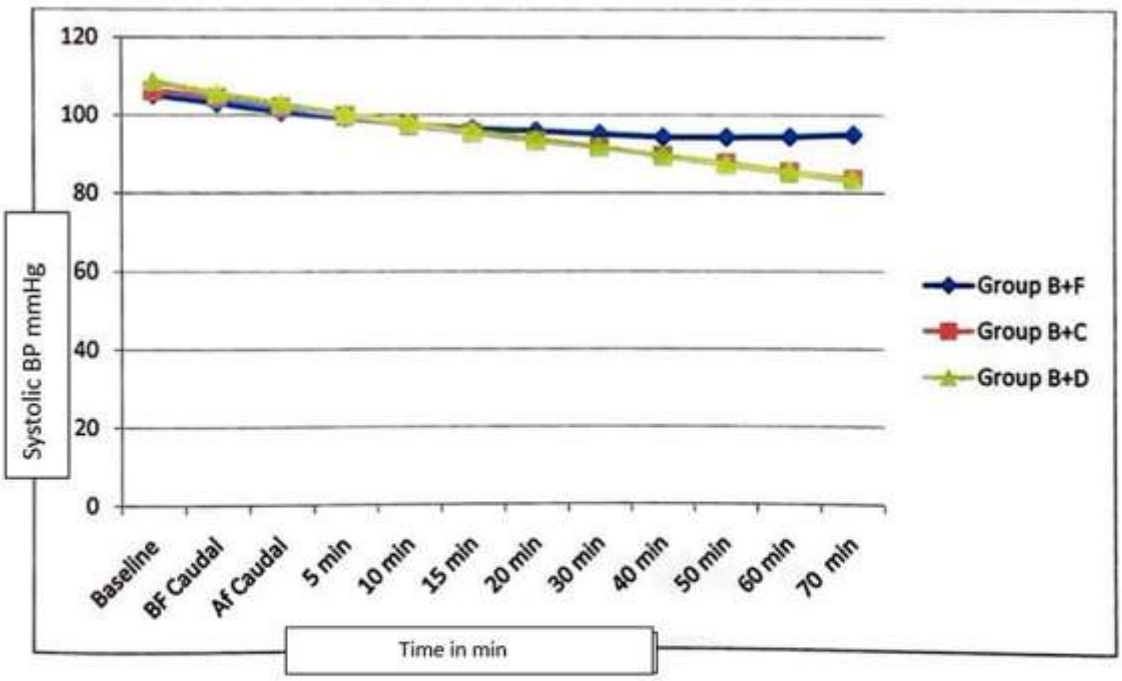

FIGURE 4: shows postoperative BP at different time intervals

The systolic blood pressure in fentanyl group return to baseline at 102 mm Hg at 30 min in post operative period. However, in clonidine and dexmedetomidine group the systolic blood pressure remains low, suggestive of prolonged action of clonidine. The difference in systolic blood pressure among the groups was statistically significant as $p < 0.05$.

FIGURE 4: shows postoperative BP at different time intervals The systolic blood pressure in fentanyl group return to baseline at 102 mm Hg at 30 min in post operative period. However, in clonidine and dexmedetomidine group the systolic blood pressure remains low, suggestive of prolonged action of clonidine. The difference in systolic blood pressure among the groups was statistically significant as $p < 0.01$. FIGURE 4: shows postoperative BP at different time intervals The systolic blood pressure in fentanyl group return to baseline at 102 mm Hg at 30 min in post operative period. However, in clonidine and dexmedetomidine group the systolic blood pressure remains low, suggestive of prolonged action of clonidine. The difference in systolic blood pressure among the groups was statistically significant as $p < 0.05$. There was

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significant changes in postoperative systolic BP among groups(figure 4). 6 of 10

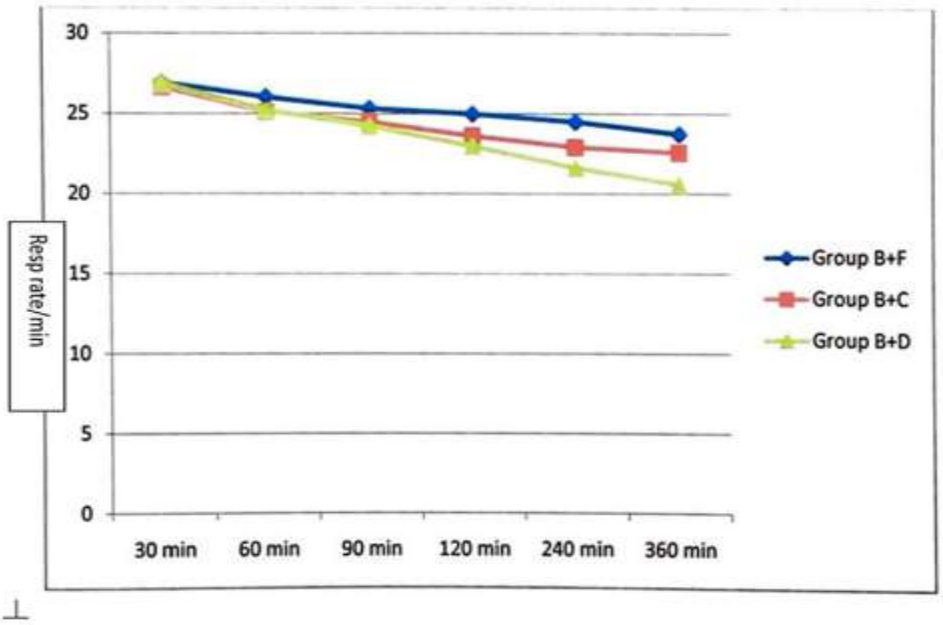

FIGURE 5: shows postoperative changes in respiratory rate

There was no significant difference in respiratory rate among three groups in intra operative as well as post operative period ($p > 0.05$).

FIGURE 5: shows postoperative changes in respiratory rate There was no significant difference in respiratory rate among three groups in intra operative as well as post operative period ($p > 0.05$). FIGURE 6: shows duration of analgesia amongst all the three groups. The mean duration of analgesia in Group I was 6.77 ±0.683 hours, 9.616 ±0.995 hours in clonidine Group II and 11.65 ±1.287 hours in dexmedetomidine group III.

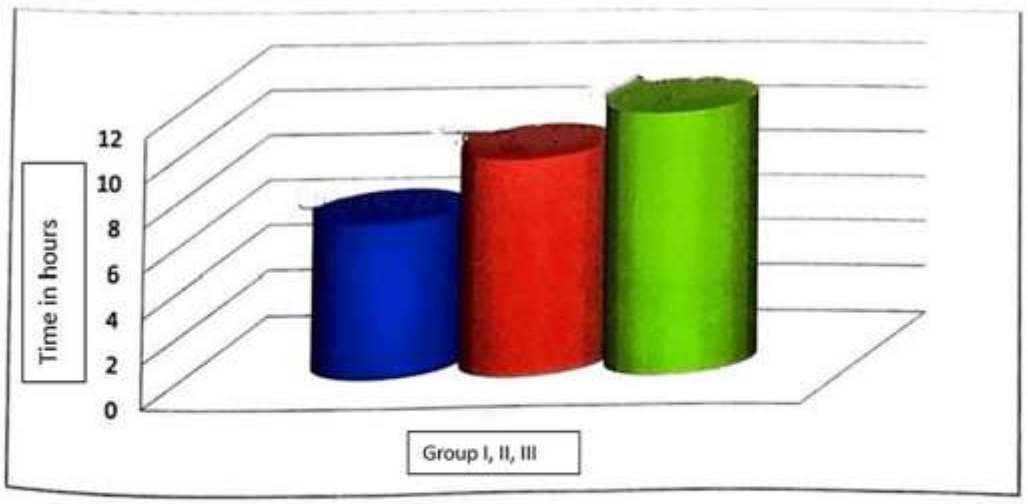

FIGURE 6: shows duration of analgesia amongst all the three groups.

The mean duration of analgesia in Group I was 6.77 ±0.683 hours, 9.616 ±0.995 hours in clonidine Group II and 11.65 ±1.287 hours in dexmedetomidine group III.

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The duration of analgesia was significantly higher in dexmedetomidine group (Figure 6). Incidence of side effectsThe comparison of sedation in three groups were compared and it showed more number of sedated children in clonidine group who got awake at 2hours and the result was not significant. In Group I, six children complained of nausea while 24 children had uneventful post operative period, which was clinically significant (p=0.03). In Group Il, I out of thirty children had nausea and vomiting in post operative period. In group Ill, only one child complained of vomiting suggesting the stable post operative period in rest of 29 children.

In Group II and III, none of the children complained of pruritus after caudal administration of drug while in

Group I (fentanyl) 3 out of 30 children (10%) complained of pruritus (itching) in post operative period.

Discussion

In this study, we have made an attempt to compare the analgesic efficacy of Bupivacaine with fentanyl, bupivacaine with clonidine and bupivacaine with dexmedetomidine in caudal block in children 2 - 8 years of age undergoing lower abdominal and lower limb surgeries. Administration of nitrous oxide with halothane and airway management with LMA has been a common denominator in all patients in order to quieten them for caudal block, or for insertion of an intravenous line.

The analgesic efficacy was analysed in terms of hemodynamic stability, duration of analgesia and incidence of side effects in each of the three groups.

The mean age, sex, weight and heart rate of each group was comparable and difference was not

significant(table1). However, there was significant difference seen in the blood pressure among the three groups noted before and after 60 min of corresponding drug administration. The average baseline blood pressure in group I was 105/69 mm Hg which dropped down to 94/63 mm Hg at 60 min, while in group Il, the baseline blood pressure was 106/63 mm Hg which dropped down to 85/48 mm Hg after 60 min of drug administration. In group Ill, the baseline blood pressure was 109/65 mm Hg which declined to 85/46 mm Hg after 60 min of drug administration. This difference seems to be significant as p value was less than 0.05.

There was 15% drop in blood pressure in Group II (clonidine-bupivacaine) and Group Ill(dexmedetomidine-bupivacaine) as compared to Group I(fentanyl-bupivacaine)[figure1,2]

These observations are consistent with study conducted by Jarraya et al [18] who compared the effect of bupivacaine-clonidine mixture with bupivacaine alone on duration of caudal block in children aged between 2-7 years. He observed significant difference in the mean systolic pressure ($p<0.01$), diastolic blood pressure ($p< 0.013$) and heart rate ($p< 0.001$).

Our study was in agreement with a 2009 study conducted by A.M El-Hennawy, A.M.Abd-ElwahabL and S.R.Bouis [19] on addition of clonidine or dexmedetomidine to bupivacaine for caudal analgesia in 60 children and concluded that there was no significant change in heart rate and blood Pressure in between the two groups(figure 3,4,5). The changes were not statistically significant.

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On the other hand, there are studies which disagree with our study like I. Constant et al, who conducted a double- blind study comparing clonidine or fentanyl as adjuvant to bupivacaine for caudal analgesia in children undergoing infraumbilical surgeries. He found that there was drop in blood pressure and heart rate among clonidine group, but the difference was not significant. The duration of analgesia in our study was calculated from the time of administration of caudal block to the time when child first complained of pain or showed any evidence of pain. It was the difference in duration of analgesia between the three groups that stands out prominently. In fentanyl group the mean duration of analgesia was 6.77 hours which was significantly less as compared to 9.616 hours in clonidine group to 11.65 hours in dexmedetomidine group. This difference came out to be significant as p value being 0.001(figure6)

Our study is consistent with Yao Y et al [20] who conducted a double-blind study comparing the efficacy of dexmedetomidine, clonidine, tramadol and fentanyl as adjuvant to local anesthetic for caudal analgesia in paediatric surgery. They concluded that duration of analgesia was significantly longer in the four groups who received additives. In dexmedetomidine and clonidine, the mean duration of analgesia was significantly longer than tramadol and fentanyl group (p value < 0.05), but no significant differences were observed between dexmedetomidine and clonidine.

A similar study was conducted by Upadhyay P and Handa [21] in 2005 on fifty children aged between 6 months to 6 years divided into two groups, one with 0.25% bupivacaine alone and the other with 0.25% bupivacaine with clonidine 1ug/kg in caudal block, undergoing elective lower limb and lower abdominal surgeries. They found that the mean duration of analgesia in clonidine group was 10.33 hours which is consistent with our finding of 9.616 hours.

Similarly, in the study conducted by Parmeshwari et al [22] in 2010 where she compared efficacy of clonidine as adjuvant to bupivacaine in single shot caudal analgesia in 100 children and found that the mean duration of analgesia in clonidine group was 593 min (9.88 hours) as compared to bupivacaine group 288 min (4.8 hours) and the difference was statistically significant, the period of sedation was significantly longer in clonidine group than in dexmedetomidine and fentanyl group.

Our findings were similar to the study conducted by J. J. Lee et al [23] comparing bupivacaine clonidine mixture and plain bupivacaine for caudal analgesia in forty-six children aged 1-10 years undergoing elective orthopaedic surgery. The sedation score (I-awake, 2=drowsy and 3=asleep) was recorded for 24 hours after 8 of 10 operation. They found that mean duration of sedation in clonidine was 9.1 hours and the difference was clinically significant. In our study, the incidence of nausea and vomiting is more in fentanyl (20%) group than in clonidine or dexmedetomidine group (3.3%). The incidence of pruritus in fentanyl group was 3 out 30 while no such case was reported in clonidine or dexmedetomidine group and the difference was found to be significant as p value was <0.05 for both conditions. Our study was consistent with findings seen in the study conducted by I.Constant et al who compared the incidence of side effects in four groups (plain bupivacaine, fentanyl, clonidine and fentanyl plus clonidine) and concluded that there was significant increase in the incidence of vomiting in the groups in whom fentanyl was added to local anaesthetic for caudal administration.

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Limitations- To reach to a more conclusive result, large sample size is required and sometimes caudal block may be difficult in children.

4. Conclusions

We conclude that addition of fentanyl, clonidine and dexmedetomidine as adjuvants to bupivacaine
prolonged the duration of surgical analgesia after single shot caudal injection, thus allowing the caudal analgesia to be recommended for surgeries lasting up to or more than 150 mins. This could be a safe and cheap alternative to extradural catheter placement for surgical procedures of intermediate duration.

Dexmedetomidine has some advantages that it prolongs duration of analgesia more than fentanyl and clonidine but does not produce clinically significant side effects like nausea, vomiting, pruritus and sedation associated with fentanyl and clonidine. Therefore, dexmedetomidine may be the drug of choice to prolong the duration of caudal analgesia provided by single injection in children. However, to get some conclusive result, more studies with a large sample size are required. Our study favors dexmedetomidine and clonidine over fentanyl as adjuvant to local anesthetic to prolong the duration of analgesia after a single shot caudal injection.

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