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A Comparative Study of Bupivacaine and Bupivacaine plus Midazolam for Caudal Analgesia in Paediatric Patients

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I. Introduction

Pain is the most common and most distressing effect of disease and surgery. Pain is an un measurable entity and any scheme for its assessment in man must be open to both subjects and observer error.

Fast and effective relief of pain is gratifying. Studies over the past fifteen years found that inadequate pain management is common in children (Mc caffery and Hart, 1976). Children receive fewer, less frequent and smaller doses of potent opioid analgesics compared with adults.

The reason for this includes overriding concern regarding respiratory depression in children. The drugs used as post operative analgesics should be potent and should not produce side effects such as emesis respiratory depression or addiction when used for long periods. Local infiltration of operative incision sites with local anesthetics, oral administration of opioids, acetaminophen, NSAID's, IM and IV routes of analgesics administration, patient controlled analgesia(PCA), continuous IV infusion of analgesics, continuous intra pleural analgesia, inter costal block, brachial plexus block for continuous analgesia, trans cutaneous electrical nerve stimulation (TENS) and cryo analgesia are some of the techniques for pain relief with some disadvantages and limitations.

Epidural analgesia in children is probably the most versatile regional analgesic technique (Desparmet et al, 1987, Mc chain, 1990, Valley et al, 1991). Epidural analgesia is also associated with good respiratory function after thoracotamy and upper abdominal procedures (Spence and smith, 1971; Meignier et al, 1983; Simanneu et al 1983; Bonnet et al, 1984). Caudal analgesia is the most useful and popular pediatric regional block technique useful today.

The ease of performance, reliabilities and safety (Dolers and Hasnoul, 1989; Veyckemans et al, 1992) are important features of caudal block, particularly for infra umbilical surgery (Dalens and Hasnaoul, 1989). This technique reduces the intra operative requirements for potant inhaled agents and also an excellent post op pain relief (Hannallah et al, 1987; Rice et al, 1990).

Local anesthetic agents like bupivacaine, opioids have all been tried with success via the epidural route. Epidural opioids should be reserved for inpatients because of the risk of respiratory depression and urinary retention. Hence this clinical study was undertaken in children to provide an observative evaluation of equality of pain relief, duration of analgesia and the incidence of undesirable side effects after single dose of 1 mg/kg body wt and a mixture of bupivacaine and midazolam (50 mcg/kg).

II. Aims And Objectives

The aim is evaluating relative efficacy and duration of caudal analgesia in children with bupivacaine (0.25%) and a combination of bupivacaine and midozolam for intra or post operative analgesia.

Combination of bupivacaine and midazolam for intra or post operative analgesia. It is also intended to study the incidence of side effects with caudal epidural bupivacaine and bupivacaine plus midozolam for intra and post operative analgesia in children.

III. Methods And Material

The study was undertaken in 50 patients between the age group of 2 months to 11 years and weighing between 5 kg to 26 kg undergoing the elective surgeries performed below the umbilical area. A & A class I & II are included.

Inclusion criteria: Patients with any systemic diseases particularly neurological diseases and bleeding diathesis patients with a history of NSAID intake are excluded. All children were submitted to routine investigations like CBP to complete urine analysis. Written and informed consent was obtained from all the children undergoing surgery. Children taken up for the study were not pre medicated with analgesic drugs and

were fasted for 6 hours for solids and 2 hours for clear fluids Pre anesthetic record of BP, PR and respiratory rate was recorded.

All the children were anaesthetized with thiopentone @ 6mg/kg as an inducing agent preceded by 20 mg/kg of inj. atropine. Intubation was performed with succinyl cholin 1.5 mg/kg, a depolarizing muscle relaxant. General anesthesia maintained using nitrous oxide (66.66%) and oxygen (33.33%) and non depolarizing muscle relaxant vecuronium at .1 mg/kg(loading dose).

After induction of anesthesia all children were turned to left lateral position. Inj. Bupivacaine (0.25%) preservative free at 1 mg/kg or inj. Bupivacaine (0.25%) with midozolam 50 µg/kg preservative free was injected into the caudal epidural space under strict aseptic conditions.

Equipment for the procedure of caudal epidural include:

1. Sterile gown.
2. Centrally fenestrated drope
3. Disposable 23 g needle (hypodermic)
4. 2 ml glass syringe
5. Disposable 10 ml syringe.
6. 2 sponge holders

One ampule midozolam (preservative free and one bupivacaine (0.25% preservative free).
Golli pot.
Intra operative BP, PR and respiration rate were recorded at every 5 min interval. At the end of surgery, children were allowed to recover completely from GA and were transferred to recovery room. IV infusion of crystalloid DNS or RL was administered at the rate of 10 ml/kg/hour. After full recovery in recovery room children were shifted to post operative ward.
Post operation assessment for pain and side effects were undertaken at 15 min, 30 min, 1 h, 11/2 h, 2 h, 3 h and 6 h, 24 hrs following the surgery.
Assessment for pain was recorded using the following objective score.
Assessment to the extent of pain was recorded using the following objective score.
PAIN SCORE
Grade 1: Pain free (Pain none/Insignificant)
Happy, contended, playful, calm. Or sleep
Grade 2: Moderate pain.
Grimacing, restlessness, can distract with toys, food and parents.
Grade 3: Severe pain.
Crying, tense, screaming, inconsolable tearful.
Side effects such as motor weakness, vomiting and retention of urine, and respiratory depression were also recorded, during the 24 hours post operative period.

IV. Results:

The variables recorded are compared within the group and in between the groups for any statistical significance by analyzing the analysis of variance. The "P" value obtained is significant if "P" is less than 0.05.

To evaluate the efficacy of Bupivacaine and Bupivacaine with midazolam which were caudally for intra operative and postoperative analgesia, 50 children were studied in the age group ranging from 2 months to 11 years belonging to ASA grade 1, all those undergoing surgeries performed below the umbilicus and lower extremity,. Average duration of surgery was 30 minutes.
The patients were studied under the following demographic data, depicted in table-1.
Demographic data showing age, weight and sex distribution of children in 2 groups.

Table-1

Group	Age (mean ±S.D)	Weight (in kgs) (mean ± S.D)	Sex ratio (M:F)
BUPIVACAINE	6.12±2.6975	15.32±3.8157	24:1
BUPIVACAINE + MIDAZOLAM	5.68±2.4617	16.16±3.4361	24:1

The demographic data were comparable without any statistical significance (p value>0.05).
Intraoperative

TIME(MIN)	5	10	15	20	25	30
PULSE RATE						
RESPIRATORY RATE						

BLOOD PRESSURE						
SPO2						

ASSESSMENT

Post-operative pain score

	15 min	30 min	45 min	1 hr	1 1/2 hr	2 hours	3 hours	6 hours	24 hours
Grade									

Analgesic supplement.

15 min	30 min	45 min	1 hr	1 1/2 hr	2 hours	3 hours	6 hours	24 hours

Side effects

Nausea — Urinary retention

Vomiting — Motor blockage

Table-2

Group	Pulse rate (mean±S.D.)	Blood pressure Systolic (mean±S.D.)	Blood pressure Diastolic (mean±S.D.)	Respiratory rate (bpm) (mean±S.D.)
B	119.36±12.379	90.8±7.287	61.6±6.68799	21.84±4.56
B+M	11824±13.283	92.0±8.165	62.6±7.3485	22.48±4.48

All preoperative vital parameters were comparable without any statistical significance ($p>0.05$)

The vital data recorded were PR,BP and RR at the interval of 5 minutes for 30 min duration which depicted in table below

Group	Pulse rate (mean±S.D.)	Blood pressure Systolic (mean±S.D.)	Blood pressure Diastolic (mean±S.D.)	Respiratory rate (bpm) (mean±S.D.)
B	117.333±13.5939	86.2667±6.733	60.4±7.6122	20.92±4.0993
B+M	115.32±10.4237	88±6.576	62.2±6.36	21.92±3.4216

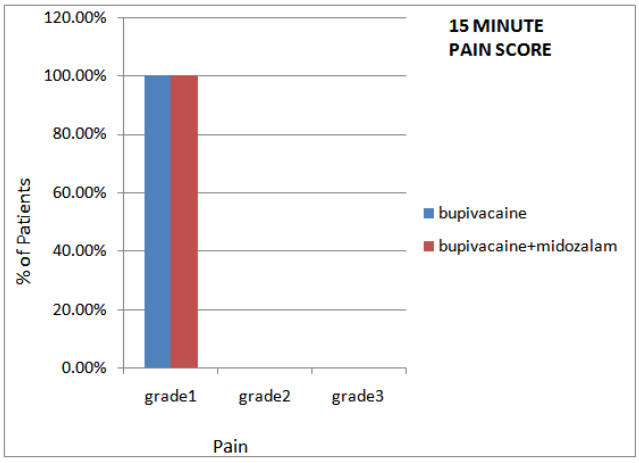
Intra operative vital parameters in all groups excluding the time did not show any statistical significance.

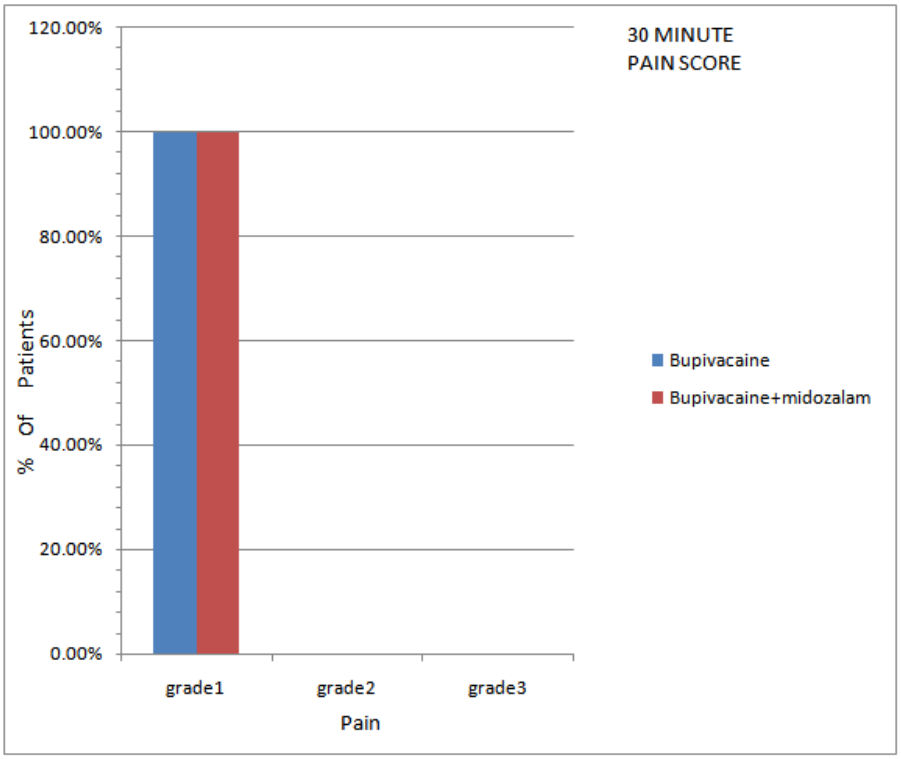
Objective score of pain gradings were recorded as follows..

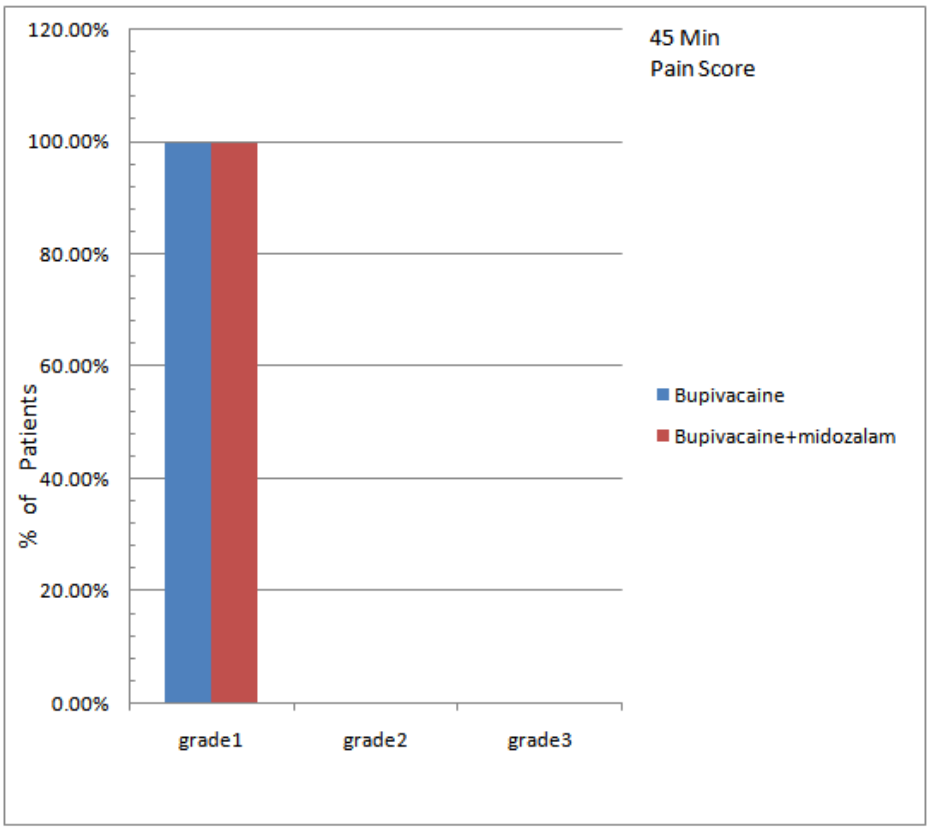
Pain grade	Child behavior
GRADE—1	Pain free(None/Insignificant Pain)
	Happy, contended, playful, calm or sleep
GRADE-2	Moderate pain
	Grimacing, restlessness can distract with toys food and parents
GRADE-3	Severe pain
	Crying, tense, screaming, inconsolable tearful

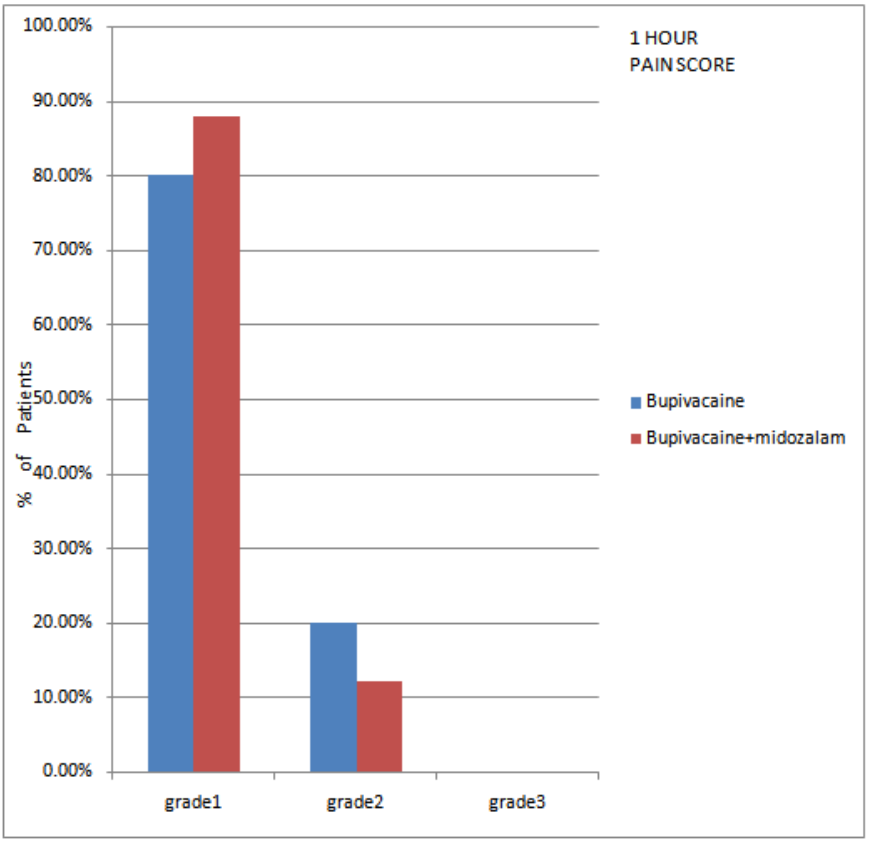
Pain intensity was calculated at each time in comparison to basal level. Pain intensity alone when compared among the group was found to have no statistical significance. However when time is taken into consideration the pain intensity in all groups showed statistical significance. ($P<0.05$)

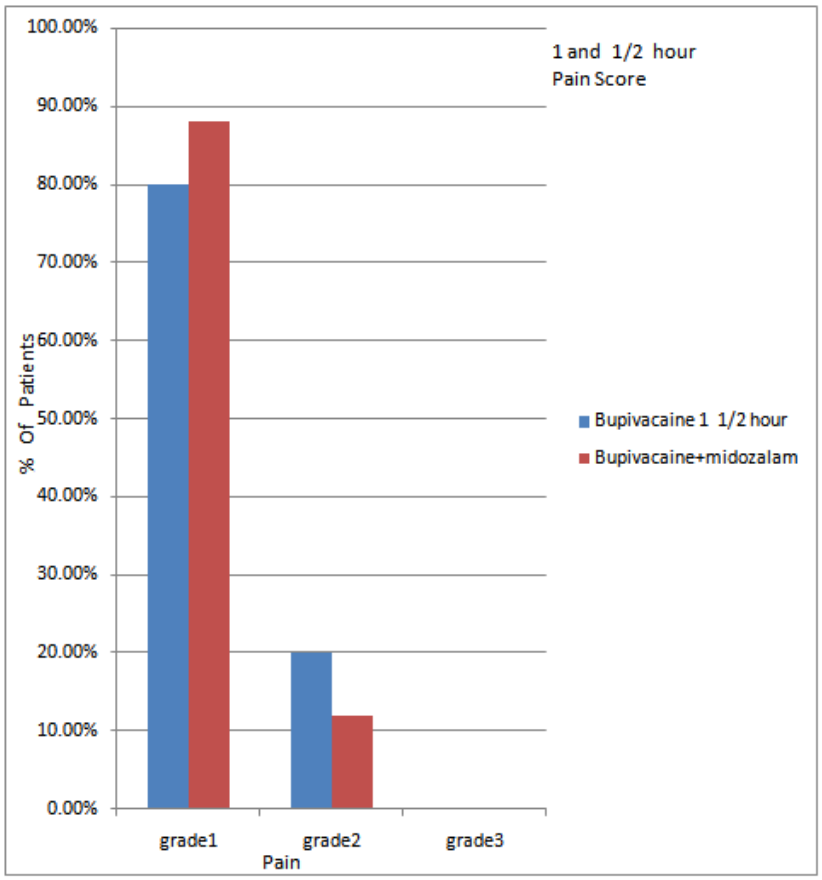
In bupivacaine group the pain intensity was significantly more after 3 hours. The intensity of pain was significant after 6 hours in the group of bupivacaine+midazolam group. ($p<0.05$)

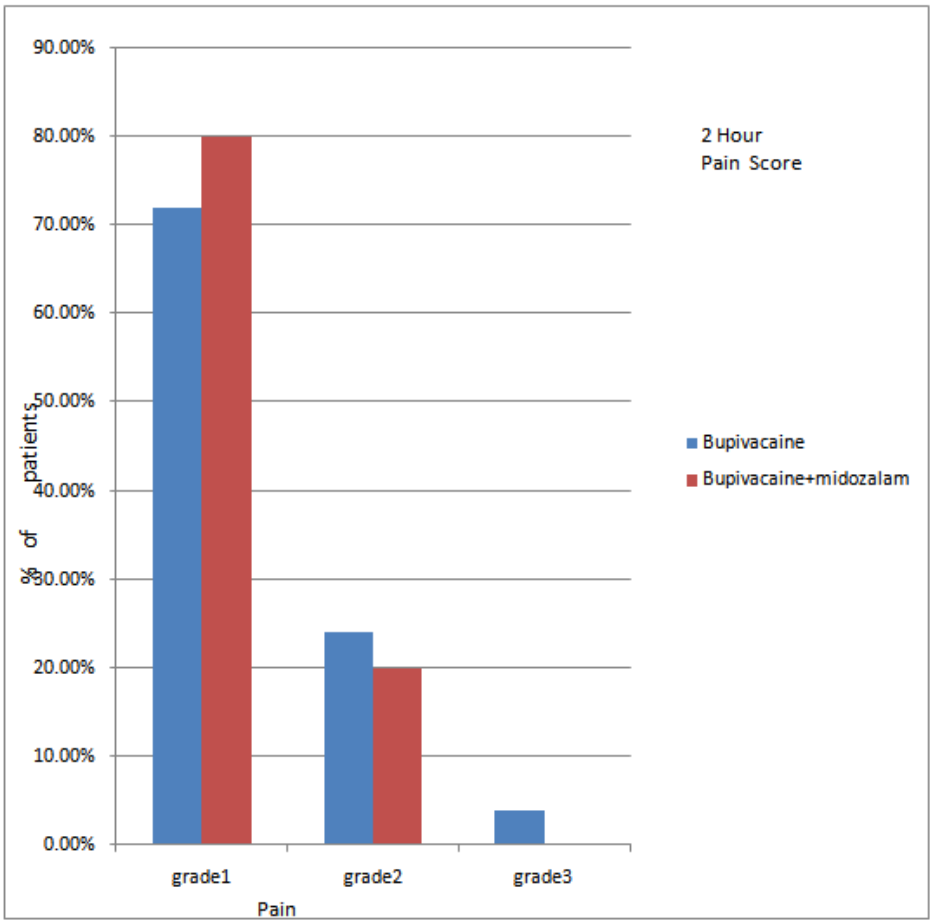


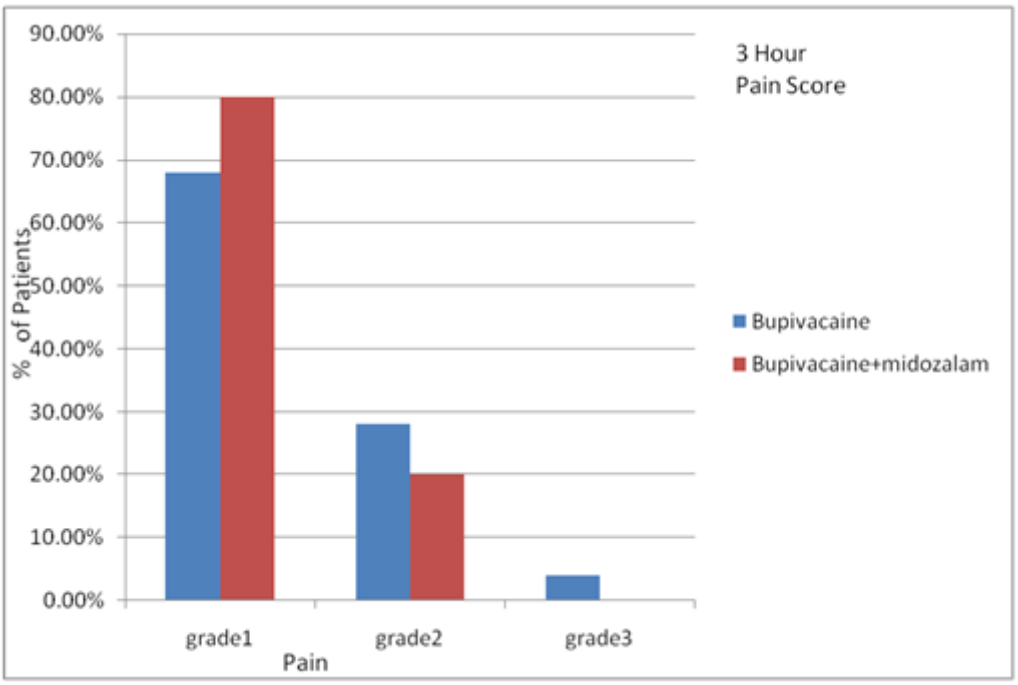

30 MINUTE
PAIN SCORE
120.00%
100.00%
80.00%
60.00%
40.00%
20.00%
0.00%
% Of Patients
grade1
grade2
grade3
Pain
Bupivacaine
Bupivacaine+midozalam

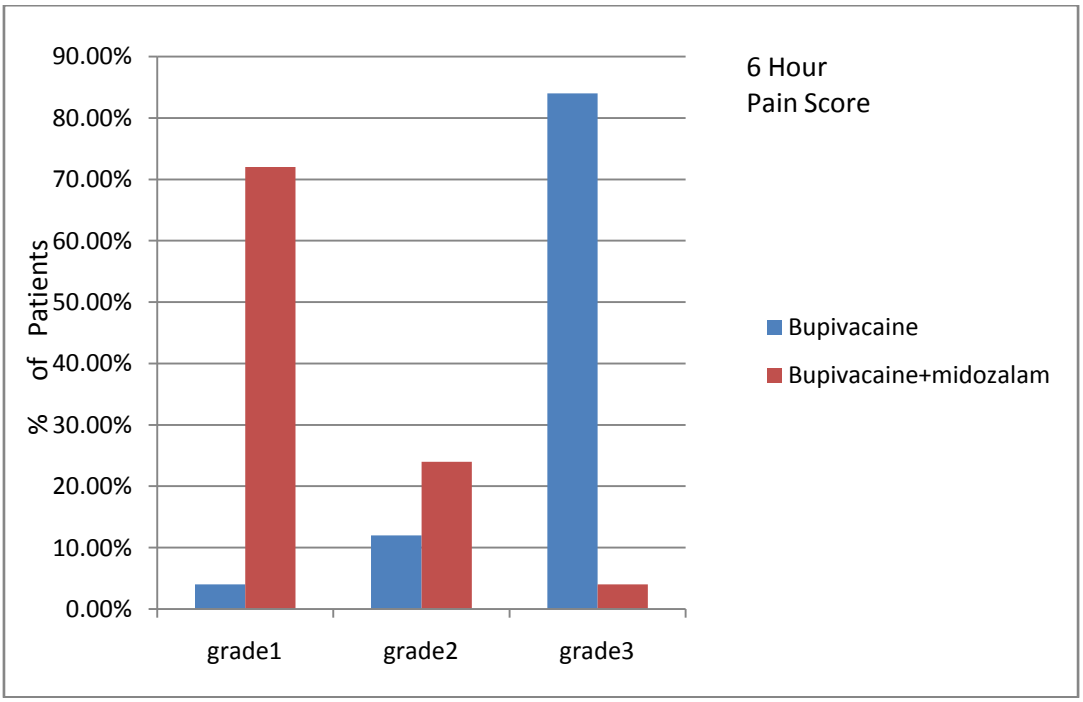

45 Min
Pain Score
120.00%
100.00%
80.00%
60.00%
40.00%
20.00%
0.00%
% of Patients
grade1
grade2
grade3
Bupivacaine
Bupivacaine+midozalam

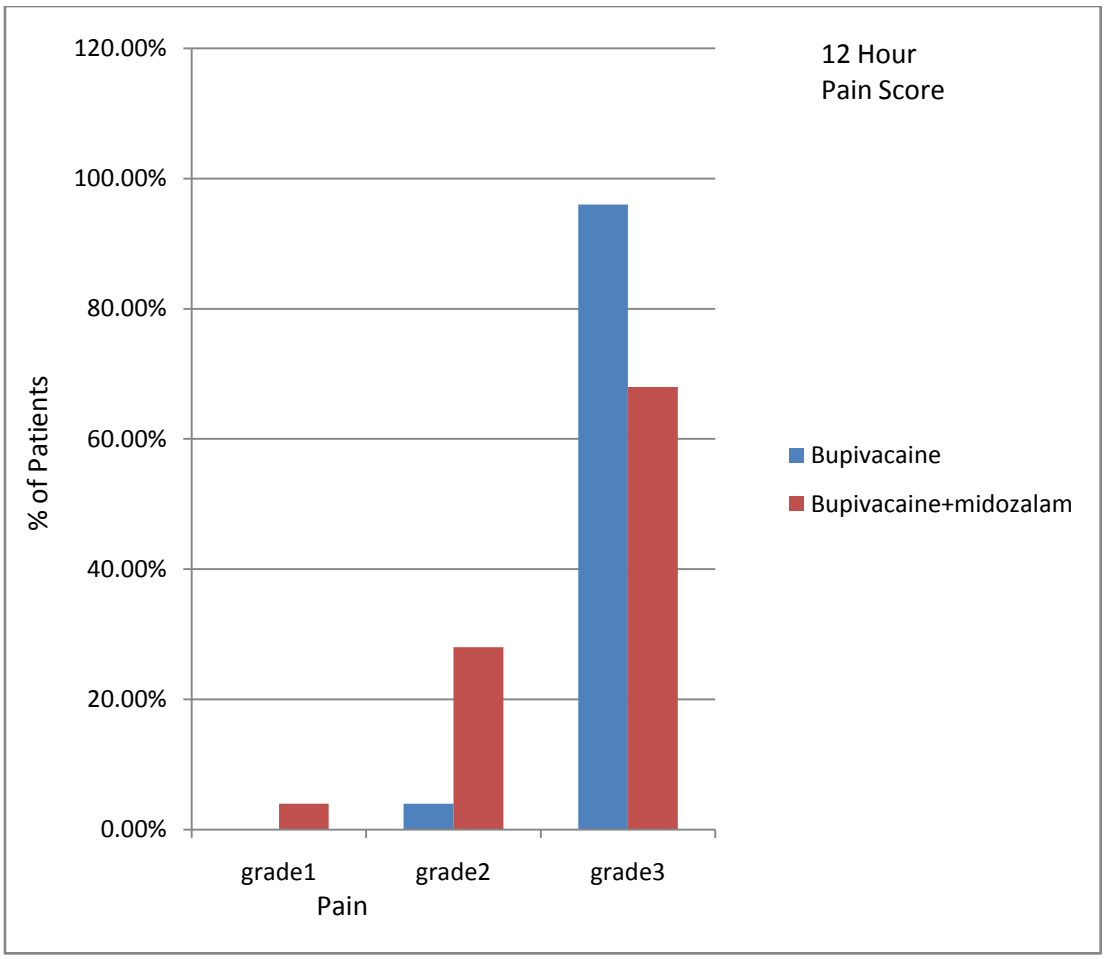

100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
% of Patients
1 HOUR
PAIN SCORE
Bupivacaine
Bupivacaine+midozalam
grade1
grade2
grade3

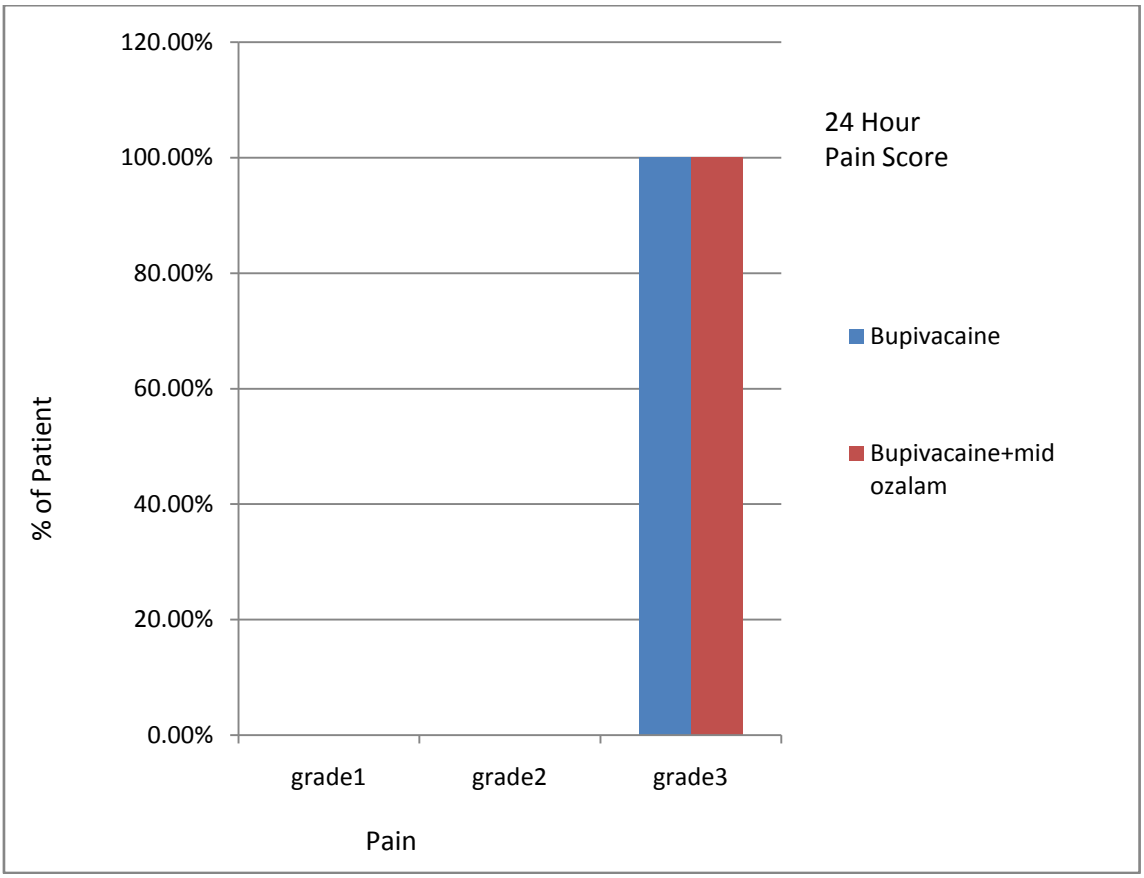

100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
% Of Patients
1 and 1/2 hour
Pain Score
Bupivacaine 1 1/2 hour
Bupivacaine+midozalam
grade1
grade2
grade3
Pain


90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
% of patients
grade1
grade2
grade3
Pain
2 Hour
Pain Score
Bupivacaine
Bupivacaine+midozalam

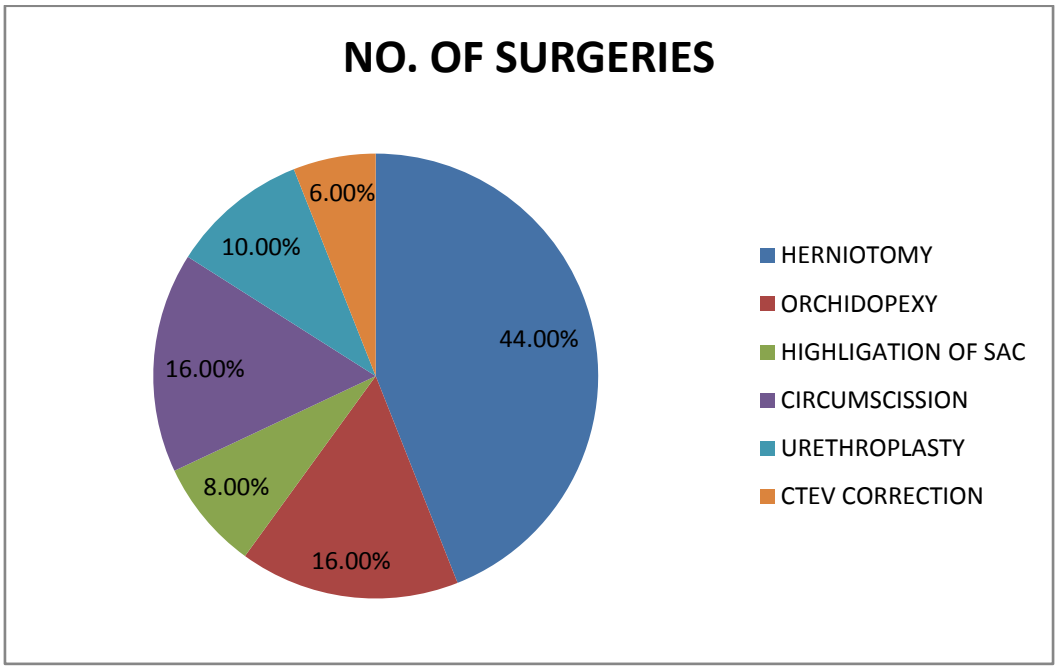

90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
% of Patients
grade1
grade2
grade3
Pain
3 Hour
Pain Score
Bupivacaine
Bupivacaine+midozalam


6 Hour
Pain Score
% of Patients
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
grade1
grade2
grade3
Bupivacaine
Bupivacaine+midozalam


12 Hour
Pain Score
% of Patients
120.00%
100.00%
80.00%
60.00%
40.00%
20.00%
0.00%
grade1
grade2
grade3
Pain
Bupivacaine
Bupivacaine+midozalam



When the time is taken into consideration the pain intensity in all groups showed statistical significance($p<0.05$). In bupivacaine group the pain intensity was significantly more after 3 hours. The intensity of pain was significant after 6 hours in the bupivacaine with midazolam group ($p<0.05$).



Post operatively all children were observed for adverse effects like nausea, vomiting, retention of urine, motor weakness for 24 hours which were shown in table below

Table

INCIDENCEOF POST-OPERATIVE SIDE EFFECTS.

Group Adverse effects(number of patients)

	Nausea	Vomiting	Retention of urine	Motor weakness
B	--	5	2	2
B+M	--	4	3	--

Patients received injection paracetamol >0.5mg/kg i.m. as analgesic supplement during the post operative period as and when required.

V. Discussion

Post operative discomfort that arises from pain is annoying for the child and parents. Some genital and perineal surgical procedures such as anoplasty and hypospadiasis correction are followed by moderate to severe post operative pain. Feeling the pain after the surgical procedures may cause the child to manipulate the operative site, which in turn may lead to post operative bleeding, infection, or other surgical complications, and also result in long term psychological problems.

Assessing pain in children poses more problems than in adults. The developmental stage of young children does not permit them to express their suffering verbally, in all age groups of children regress when they are hospitalized and confronted with severe postoperative pain. They refuse to speak, they only cry until a reasonable pain relief has been given. Presently there are no valid and universally accepted tools for accurately measuring pain in small children. Paediatric pain scores are innumerable. Lack of verb al communication by the child, defective and prejudiced interpretation of pain signals by the attending staff makes it very difficult to evolve comprehensive pain scores.

Pain score for the study was taken from the scoring pattern utilized by Naguid M et al (1991), who studied caudal Bupivacaine and Bupivacaine + midazolam in 50 cases for intra operative analgesia in pediatric age group.

In recent years under treatment of pain in children, including post operative pain has been reported in several centers.Children do not approve the same kind of analgesic therapy as do adults. On the other hand we have very less pharmacological preparations to offer the children. Tablets, suppositories designed for the use in adults, make it difficult to give accurate doses in small children. One of the major difficulties is the reluctance of the children to accept injections. The short duration of the effect of narcotics demands to multiple intramuscular injections per day to control severe post operative pain. Thus an analgesic with longer duration of action would be advantageous in children.

A needle may be placed with in the caudal space more easily than in the epidural space in children. The non availability of appropriate sized epidural needles for paediatric use makes caudal injection or caudal catheters a preferred route for administration of epidural drugs such as local anaesthetics, Midazolam in young children.

In this study caudal Bupivacaine (preservative free) (0.25%) with a dose of 1 ml/kg weight and midazolam (preservative free) with dose of 50 microgram/kg body weight were used.

The patients were between 2 months to 11 years of age were almost statistically close by i.e., group B – 6.12 years, Group B+ M 5.68 years.

The average weights in all the two groups were also adjusted to be uniforms.

Apart from recording the severity of pain, degree and duration of pain relief with various agents used in the study. The vital parameters viz. pulse rate, blood pressure, and respiratory rate and side effects were noted in each group.

Though the number of cases studies were only fifty, they were reasonably distributed between the age group of 2 months to 11 years so as to give good idea of the usefulness of the procedure, technique and its acceptance. Seevers(1936), Ruston(1954 &1957), Spigel (1962) Frotina (1967), touloukian (1971) et al, studied more than 750 cases and contributed their experiences with the technique in the paediatric age group 0-14 years.

All the children in this study underwent procedure such as inguinal hernia repairs, orchidopexies, urological procedures, which are very painful in the postoperative period hence children tend to be less cooperative. It was found that intra operatively there was no raise in pulse rate, respiratory rate, and blood pressure to surgical stimulus in both the groups indicating adequacy of analgesia.

Up to 68% of children in the bupivacaine group were pain free, (laughing, happy, contended, cheerful, playful, and asleep. Until 3 hours after surgery. 80% of children were pain free in Bupivacaine+Midazolam group up to 3 hours following surgery. The observation in our study shows that caudal Bupivacaine + Midazolam prolonged postoperative pain relief which correlated well with the earlier studies of Jose-adlofo isles et al (1985) and Naguib M et al (1995).

Only 4% of children in Bupivacaine group were pain free until 6 hours after surgery. 72% of children Bupivacaine + Midazolam were pain free up to 6 hours following the surgery, indicating that duration of analgesia was prolonged in bupivacaine + Midazolam group. These results are in correlation with the study of Naguib M et al (1995).

Post operative pain relief was provided with inj. Paracetamol when the child was Grade 3. By hours 84% of children received first dose of analgesia in Bupivacaine group, but only 4% of children received first dose of analgesia in bupivacaine + midazolam group indicating that duration of analgesia was prolonged in bupivacaine + midazolam group.

Naguid et al (1991) reported an incidence of 21.66% of vomiting in their studies which is higher when compared to only 18% found in the present study which could be attributed to a good postoperative pain relief and all the precautions were taken for the cardiopulmonary stability during anesthesia and in postoperative period. General anesthesia was administered in all the cases using inhalational agents; hence nausea and vomiting can be attributed to general anesthesia.

The study indicates mixture of bupivacaine + midazolam has least side effects and prolonged effect of postoperative pain relief than bupivacaine. However the quality of pain relief was comparable.

The incidence of motor weakness was observed in 2 children who received caudal bupivacaine, however the complete motor recovery was observed, 2 hours following surgery.

The effects of bupivacaine and midazolam in two groups on hemodynamics were also noted in the post operative period. It was observed that there were no significant changes pulse rate and blood pressure in both groups.

The recording of the respiratory rate was observed to be almost similar in both the groups of our study.

The caudal block is more reliable and produced a longer duration of postoperative pain relief in children with low incidence of adverse effects. This observation in our study correlates well with the study of Irwin. M>G>Chang.W. (1996)

VI. Summary

A Clinical study for intraoperative and postoperative analgesia was undertaken in fifty ASA grade I children undergroing elective surgical procedures. 25 children received caudal epidural bupivacaine (0.25%) with the dose of 1 ml/kg body weight. 25 children received a mixture of bupivacaine + midazolam (50 micro gram/kg bdy weight) through the caudal epidural route after a standard general surgical procedure.

30% of children were of 2 months-4 years range, 50% belonged to 5-8 years range and 20% belonged 9-11 years range.

44% of the children underwent herniotomy, 8% of patients underwent high ligation, 8% children underwent orchidopexy, 10% underwent urethroplasty, 16% underwent circumscion, 8% underwent orchdopexy and 6% underwent CTEV correction surgery.

18% of children were in the range of 5-10 kg weight 60% children in the range of 11-19 kg and 22% of children were 21-26 kg range.

Baseline heart rate, respiratory rate, systolic and diastolic blood pressure were comparable in the two groups and they did not differ significantly during the study period.

The duration of post operative analgesia was 3 hours in 68% of children who received caudal Bupivacaine while it was 6 hrs in 72% of children who received caudal Bupivacain + Midazolam.

No side effects were observed in the 70% of cases in this study.

VII. Conclusion

From this study it was concluded that

1. Caudal extra dural route has been preferred in children for its higher predictability, as regards to technical aspects of location of space and efficacy of pain relief with drugs administered by this route.
2. Epidural bupivacaine and midazolam mixture definitely prolonged the duration of post operative pain relief in children.
3. It drastically cuts down the use of parenteral analgesics in the post operative period.
4. There were a minimal incidence of side effects like vomiting and retention of urine which responded to conservative treatment.

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