

Comparing Local Infiltration of Wounds with Bupivacaine and Intravenous Paracetamol in Paediatric Inguinal Surgeries

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ABSTRACT

Background: Bupivacaine is quite effective in reducing post-operative pain in children and it helps to reduce the dosage of analgesia after operation. It contributes significantly to early mobilization and discharge from hospital thus reducing cost incurred by the patient.

Aim: To evaluate and compare the efficacy of local infiltration of Bupivacaine in surgical clean wounds with I/V Paracetamol (acetaminophen) among children in early post-operative pain management in inguinal surgeries.

Study design: It was double blind randomized clinical trial.

Place & duration of study: This study was conducted in the Department of Paediatric Surgery, Shaikh Zayed Hospital, Lahore from July 2016 to July 2017.

Methods: 140 patients were enrolled and divided in two groups. All relevant surgical steps were followed and in one group before closing skin 0.5% Bupivacaine (1 mg/kg) diluted in distal water and infiltrated in the incision, while in second group Paracetamol infusion was given intravenously during surgery. The pain score was measured in both groups of patients by applying the Face, Leg, Activity, Cry and Consolability scale (FLACC) 30 minutes after operation as base line and then after every 1 hour for the next 06 hours. Comparison at each hour interval for FLACC and duration without requirement of additional analgesia was performed between two groups by using independent sample T-test. Data for requirement of additional analgesia was described by using frequency and percentages for two groups and comparison was made by using Chi-Square test.

Results: Age range in this study was from 2 to 60 months with mean age of 27.32±16.29 months. The mean age of patients in group A was 26.48±19.70 months and in group B was 28.51±19.18 months. In Group-A, 62(88.6%) were males and 8(11.4%) were female. In Group-B, 58(82.9%) were male and 12(17.1%). It was also recorded that, there was a significant difference between groups according to additional analgesia given ($p>0.001$).

Conclusion: Local infiltration of wound with Bupivacaine provides better and prolong analgesia than IV paracetamol in post-operative pain management.

Keywords: Bupivacaine, Paracetamol, Pain management, FLACC Score.

INTRODUCTION

Post-operative pain management in children is crucial and if inadequate can be distressful both for the child and the parents¹. Infants undergoing surgery with no or minimal analgesia show a significant rise in catecholamines, growth hormone, glucagon, corticosteroids levels while insulin level is suppressed leading to hyperglycemia. In contrast to the infants who receive potent analgesia, have significantly fewer post-operative bio-chemical changes². Local infiltration with Bupivacaine is 95% effective in providing analgesia⁴ and is preferable due to its simplicity, low incidence of complications and failure rate¹. Currently various techniques, including opioids, non-steroidal anti-inflammatory drugs, caudal and peripheral nerve blocks, sublingual or transmucosal, per rectal drug administration and wound infiltration with local anesthetics are being used in order to get maximum relief of pain. Regional anesthesia significantly decreases pain and need for intravenous narcotics, facilitating rapid recovery and early discharge from the hospital¹⁻³.

Postoperative pain delays the return to a normal level of activity and prolongs hospital stay. The use of narcotic analgesics increases the incidence of nausea, vomiting, respiratory depression and also causes undesired sedation. They are less safe in paediatric age group^{1,4}. Psychological disturbance was significantly less in children undergoing day case surgery compared with children admitted on the day before and discharged on the day after surgery⁷.

Bupivacaine is quite effective in reducing post-operative pain in children and it helps to reduce the dosage of analgesia after operation. It contributes significantly to early mobilization and discharge from hospital thus reducing cost incurred by the patient⁸.

In a study reported by Jahromi SAH et al, there was a significant difference in effectiveness of Bupivacaine infiltration and Acetaminophen group. Patients in acetaminophen group had less average pain free interval than in Bupivacaine group without additional analgesia requirement¹.

While in the study by Dahi Taleghani et al, on "rectal acetaminophen versus peritonsillar infiltration of bupivacaine for postoperative analgesia after tonsillectomy in children", there was no difference between the two

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groups and concluded that when considering feasibility of rectal acetaminophen, it is superior due to minimal risks in children⁹.

Regarding pain management in children undergoing inguinal herniotomy, there is no statistical significant difference between intravenous acetaminophen and caudal block with levobupivacaine as reported by Serbüent Gökhan Beyaz¹⁰.

Different drugs are used in post operative pain management especially opioids in intravenous form. It increases the incidence of nausea, vomiting, respiratory depression and also causes undesired sedation. Use of opioids require the maintenance of IV line which is sometimes difficult in small children.

Local infiltration of Bupivacaine does not require the maintenance of IV line and requires less material resources, expertise and time. It is being used to get maximum relief of pain, also facilitate rapid recovery and early discharge from hospital. It provides good analgesia while avoiding complications of narcotic analgesics and is therefore encouraged in children¹⁻⁶

This study was conducted to evaluate and compare the efficacy of local infiltration of Bupivacaine in surgical clean wounds with Intravenous Paracetamol among children in early post-operative pain management in inguinal surgeries.

PATIENTS AND METHODS

This study was conducted in the Department of Paediatric Surgery, Shaikh Zayed Hospital, Lahore from July 2016 to July 2017 after the approval from Institutional Review Board. It was double blind randomized clinical trial. The estimated sample size of 70 in each group was calculated by using 95% confidence level, 90% power of test with expected ratio of additional analgesia requirement for Bupivacaine group and Paracetamol group 13.33% and 36.7% respectively¹.

Patients undergoing surgery for inguinal hernia of both genders, hydrocele and undescended testis in male patients from age 2 months to 5 years admitted through Out Patient Department were included.

Children allergic to Bupivacaine and Paracetamol (confirmed by history and test dose prior to infiltration and IV administration), obstructed Hernia in both genders and testicular torsion among male patients and children with Cerebral Palsy were excluded from the study.

Treatment was allocated to patient at random by lottery method in group A and group B. Researcher and patient were unaware of treatment allocated to the patient. Groups were decided by the supervisor.

All the patients who underwent surgery were thoroughly examined, investigated and written informed consent was taken. After general anaesthesia, all relevant surgical steps were followed and in one group before closing skin 0.5% Bupivacaine (1 mg/kg) diluted in distal water in equal amount to make 0.25% were infiltrated in the incision, while in second group Paracetamol infusion was given intravenously during surgery. Data collections were performed on given proforma by researcher. The pain score was measured in both groups of patients by applying the Face, Leg, Activity, Cry and Consolability scale

(FLACC) 30 minutes after operation as base line and then after every 1 hour for the next 6 hours.

Additional analgesia was administered to the patients with FLACC \geq 4.

Data were entered and analyzed by using SPSS v23.0. Data for age, FLACC score and duration without requirement of additional analgesia was described by using Mean \pm SD. Comparison at each hour interval for FLACC and duration without requirement of additional analgesia was performed between two groups by using independent sample T-test if normally distributed and Mann Whitney U test otherwise. Data for requirement of additional analgesia were described by using frequencies and percentages for two groups and comparison was made by using Chi-Square test. P-value \leq 0.05 was considered significant.

RESULTS

During the study period, 140 patients underwent inguinal surgeries. There were total 120 male patients, 62 in Group-A and 58 in Group-B. Total female were 20, 8 in Group-A and 12 in Group-B, percentages shown in table 1. There were 103 patients of inguinal hernia, 54 patients in Group-A and 49 patients in Group-B, 20 patients of hydrocele, 7 patients in Group-A and 8 patients in Group-B and 17 patients of undescended testes, 9 patients in Group-A and 8 patients in Group-B, percentages shown in table 2. The mean age of patients was 27.32 \pm 16.29 months with minimum age of 2 months and maximum 60 months, 26.48 \pm 19.70 months in Group-A and 28.51 \pm 19.18 months in Group-B and difference was not statistically significant (p = 0.538).

In Group-A, Mean FLACC score was 0.63 \pm 0.64 after 30 minutes and in Group-B, Mean FLACC score was 0.80 \pm 0.69. There was no significant difference of pain score between groups after 30 minutes (p=0.131) and no patient required additional analgesia. Mean FLACC score was 1.19 \pm 0.77 in Group-A at the end of 1 hour while it was 1.49 \pm 0.85 in Group-B, the difference in the mean score was statistically significant with p-value of 0.030 and no patient required additional analgesia.

Mean FLACC score was 1.53 \pm 0.77 in Group A at the end of 2 hours while in Group-B it was 2.01 \pm 0.83 and the difference in the mean score was statistically significant with p-value of 0.0001 and no patient required additional analgesia.

At the end of 3 hours, In Group-A, Mean FLACC score was 1.79 \pm 0.95 and it was 1.74 \pm 0.76 in Group-B. There was no significant difference of pain score between groups p-value of 0.768 and no patient required additional analgesia. Mean FLACC score was 1.91 \pm 0.76 in Group-A at the end of 4 hours, and it was 2.20 \pm 0.71 in Group-B, and the difference in the mean score was statistically significant with p-value of 0.023 and no patient required additional analgesia.

At the end of 5 hours, in Group-A, Mean FLACC score was 2.26 \pm 0.79 and in Group-B, it was 2.71 \pm 0.73 and the difference in the mean score was statistically significant with p-value of 0.001. Total 11 patients who had mean FLACC score of 4.27 \pm 0.46 required additional analgesia, 4 (36.4%) patients in Group-A and 7 (63.6%) in Group-B.

Mean FLACC score at the end of 6 hours, it was 2.80 ± 0.61 In Group-A while in Group-B it was 3.44 ± 0.76 and the difference in the mean score was statistically significant with p-value of 0.0001. Total 25 patients who had mean FLACC score of 4.40 ± 0.5 required additional analgesia, 5 (20%) patients in Group-A and 20 (80%) in Group-B. Total 36(25.75%) patients required additional analgesia in both groups with mean FLACC score 4.33 ± 0.48 . Detailed comparison shown in table 3 and figure 1.

When comparing overall group wise distribution of requirement of additional analgesia in group A 9(12.9%) patients required additional analgesia and in group B 27(38.6%). There was a significant difference between groups according to additional analgesia given with p value of 0.001. In Group-B more patients required additional analgesia as compared to Group-A.

Table-1: Frequency of distribution of Gender in both groups

Groups	Gender	Frequency	Percent
Group-A	Male	62	88.6
	Female	8	11.4
	Total	70	100.0
Group-B	Male	58	82.9
	Female	12	17.1
	Total	70	100.0

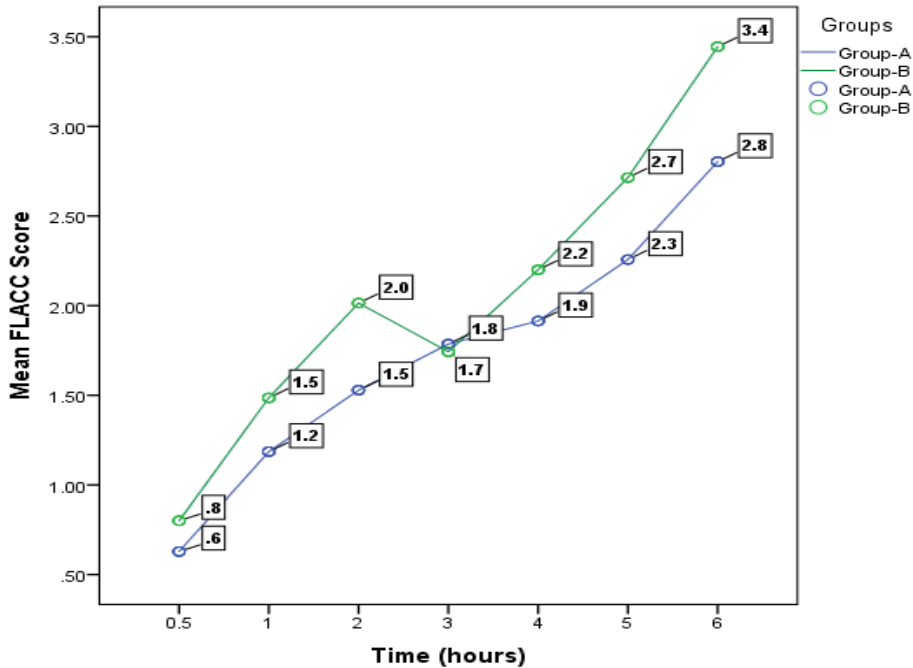
Table 2: Frequency of diagnosis in both groups

Groups	Diagnosis	Frequency	Percent
Group-A	Inguinal Hernia	54	77.1
	Hydrocele	7	10.0
	Undescended Testis	9	12.9
	Total	70	100.0
Group-B	Inguinal Hernia	49	70.0
	Hydrocele	13	18.6
	Undescended Testis	8	11.4
	Total	70	100.0

Table 3: Comparison of Mean FLACC score at different intervals in both groups

FLACC Score	Groups	n	Mean	Std. Deviation	Std. Error Mean	p-value
FLACC score after 30 minutes	Group-A	70	0.63	0.64	.077	0.131
	Group-B	70	0.80	0.69	.083	
FLACC score after 1 hour	Group-A	70	1.19	0.77	.092	0.030
	Group-B	70	1.49	0.85	.101	
FLACC score after 2 hours	Group-A	70	1.53	0.77	.093	0.0001
	Group-B	70	2.01	0.83	.099	
FLACC score after 3 hours	Group-A	70	1.79	0.95	.113	0.768
	Group-B	70	1.74	0.76	.090	
FLACC score after 4 hours	Group-A	70	1.91	0.76	.090	0.023
	Group-B	70	2.20	0.71	.085	
FLACC score after 5 hours	Group-A	70	2.26	0.79	.095	0.001
	Group-B	70	2.71	0.73	.087	
FLACC score after 6 hours	Group-A	66	2.80	0.61	.075	0.0001
	Group-B	63	3.44	0.76	.095	

Fig.-1: Comparison of Mean FLACC Score in both groups at different times



DISCUSSION

In our study, our hypothesis was found to be true on comparing local infiltration of bupivacaine in the wound with intravenous paracetamol using FLACC score, it was observed that patients with local infiltration of wound with bupivacaine required less additional analgesia and the FLACC score was significantly low in this group. This observation shows that local infiltration of bupivacaine was more effective in relieving the pain post operatively in children. Studies comparing post operative pain relief in children using bupivacaine wound infiltration with other regional techniques have been reported.³⁻⁶ Only few studies were found where wound infiltration with bupivacaine was compared with rectal acetaminophen suppository^{1,9,15}.

In a study by Jahromi et al effects of acetaminophen suppository with bupivacaine wound infiltration and caudal block using FLACC score for inguinal surgeries in children were compared. They concluded that wound infiltration and caudal block were more effective relieving post operative pain than paracetamol.¹ In our study age children ranged from 2 months to 5 years and were divided in 2 groups and in their study age ranged from 2 months to 7 years and were divided in 3 groups. The mean age of patients in our study was 27.32 ± 16.29 months and in their study it was 38.58 ± 20.51 months. In our study 85.71% were male patients and 14.29% were female, where as in their study 96.7% were male and 3.33% were female¹. The male to female ration in our study is 4:1, similar ratio reported in international literature¹¹. In their study 36.7% in acetaminophen group and 13.3% in bupivacaine wound infiltration group required additional analgesia.¹ Similar findings were observed in our study where 36.37% patients in paracetamol group and 12.9% in bupivacaine wound infiltration group required additional analgesia, although paracetamol was used through intravenous route.

In this study all the patients in first 4 hours of post operative period did not required additional analgesia, although FLACC score in bupivacaine group was 1.91 and paracetamol group it was 2.20 at the end of 4 hours with significant P value of 0.023. Similar effect of paracetamol was noted by Khalili GR et al in their study. It was also noted in their study intravenous paracetamol had greater sedative effects in comparison with acetaminophen suppository¹² but this effect was not observed in our study. In patients undergoing surgeries where long term analgesia is not required intravenous paracetamol can be used.

In this study it was observed that, the FLACC score at the end of 2 hours increased in intravenous paracetamol group to 2.01 and at the end of 3 hours it came to 1.74 without any additional analgesia, as this type of change was not noted the bupivacaine wound infiltration group. As a routine all patients were kept in the recovery room after surgery for observation. This was the shifting time from the recovery room to the ward. Once the patients were settled in the ward, the FLACC score decreased without any additional analgesia at the end of 3 hours. This change in the wound infiltration with bupivacaine group in FLACC score was not noted. This observation could be due to better analgesic effect of wound infiltration with bupivacaine than intravenous form of paracetamol. The analgesia effect

results in the wound infiltration with bupivacaine group as compared to paracetamol group was more satisfactory. Even at the end of 6 hours, 25 patients required additional analgesia and 80% were in Paracetamol group. This observation shows that local infiltration of Bupivacaine was more effective in relieving the pain post operatively.

Matsota et al. compared the efficacy of wound infiltration with levobupivacaine with rectal suppository of paracetamol and concluded that, the wound infiltration had an increased duration of postoperative analgesia and early mobilization and the efficacy of postoperative analgesia was more adequate, but the requirement for additional analgesia was the same in both groups.¹³ In another study by Ahmad M. et al, the postoperative analgesic effect of suppository paracetamol was compared with the bupivacaine wound infiltration for inguinal herniorrhaphy. The bupivacaine method produced better analgesia than suppository paracetamol alone¹⁴.

Another study by Khasawneh M. et al, compared efficacy of combined incisional infiltration with bupivacaine and paracetamol suppositories with paracetamol suppository alone in relieving the postoperative pain in groin surgery in children was compared. Their patient population were similar with our patient population in terms of diagnosis. They concluded that, the patients in a combined group had better pain relief and earlier mobilization¹⁵.

Baird R et al did a systemic review and meta-analysis of thirteen articles comparing caudal blockade with alternative pain management including wound infiltration with Bupivacaine. In five studies wound infiltration was compared with caudal analgesia and observed that, the pain score was similar in wound infiltration and caudal block with bupivacaine and no significant differences in complication rates were reported between groups.⁶

In the other study by Tahir M et al, found that bupivacaine infiltration in post operative pain relief in children is quite effective, reduces the dosage of analgesia after surgery, early mobilization and discharge from hospital⁸.

The analgesic effect was much longer and better in the Bupivacaine group which was confirmed by low pain scores. These results comparable with the several studies done previously where bupivacaine was used as local anaesthetic. Senel et al. observed prolonged analgesic effect by bupivacaine in children undergoing herniotomy¹⁶. There are some studies tried to prove that Alpha² Adrenergic receptor agonists could extend the time period of action of bupivacaine and improve the quality of analgesia. This effect is due to vasoconstriction and increasing the potassium conductance in A and C fibres¹⁷.

FLACC scale has been used to assess the pain in children from 2 months to 7 years of age in different studies. The results have shown that, the FLACC scale was a valid and reliable tool for pain assessment in children^{18,19}.

Wound infiltration is a simple technique and have negligible side effects. It is quick and less expensive technique and has been proven to be adequate in post operative pain management.^{20,21} Theoretical risk of systemic toxicity is there with this technique, although evidence supporting the true importance of the complication is lacking. In addition,

some concerns of wound healing after wound infiltration have been reported,²² however these observations have not been widely disseminated and wound infiltration continues to be an extremely popular practice for a variety of operative procedures.

In most of the studies bupivacaine was used as caudal or epidural block. The results in relieving the pain in post-operative period were good and are comparable with this study. Administration of caudal or epidural blocks is technically demanding and it is not always easy in children, well trained anaesthetist is needed. There are often chances of failure and even side effects. The local infiltration of bupivacaine does not require any special expertise. Operating surgeon can do it easily without any complication. This can be done easily in all hospital setups where children are being operated without any difficulty. No complications were observed in the both studied groups.

Limitations of the study: It was single center study and no monitoring of the patients in terms of FLACC score after 6 hours.

CONCLUSION

Local infiltration of wound with Bupivacaine provides better and prolong analgesia than IV paracetamol in post-operative pain management and is recommended in all children undergoing inguinal surgeries in future.

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