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RANDOMISED PROSPECTIVE TRIAL COMPARING INTRANASAL FENTANYL TO INTRAVENOUS MORPHINE FOR MANAGING ACUTE PAIN IN CHILDREN IN THE EMERGENCY DEPARTMENT.

Pediatrics

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ABSTRACT

Objectives: To compare the efficacy of intranasal fentanyl versus I/V morphine in pediatric population presenting with long bone fractures.

Methods : We conducteda prospective randomised comparative study from September 2017 to August 2018 on 80 patients of pediatric age group (7-12 Years) presenting in emergency department Patients were divided into two groups of 40 each. One group received intranasal fentanyl (0.2 µg/kg) and second group received I/V morphine (0.1mg/kg). Pain scores were obtained at baseline ,5,10,20 and 30 minutes. Vital signs and adverse effects were noted.

Results : The pain scores in both the groups were comparable at all times during observation. But, intranasal fentanyl is superior with regard to easy administration and not requiring specialized skills.

Conclusions: Intranasal fentanyl delivered at 0.2µg/kg were shown to be an equally effective analgesic in children aged 7 – 12 years presenting to an ED with acute long bone fractures when compared to I/V morphine

KEYWORDS

Intranasal fentanyl, Intravenous Morphine, Emergency Department (ED).

INTRODUCTION

Pain is a common complaint for patients presenting to a pediatric emergency department. However, pain in children is often undertreated (1). Children are most susceptible to fear, anxiety and stress due to their limited cognitive capabilities and dependencies (2). As recognition of this problem grows, several guidelines have been developed to assess pain assessment and management for children treated in ED (3, 4)

Analgesia for orthopedic trauma pain is often provided through administration of opiate medications. When given via an I/V route, opioids have a rapid onset of action and maybe titrated to effect . However placement of an I/V cannula is difficult in pediatric population and also produces additional pain and anxiety. Another alternative, oral pain medications, may be with held to protect the patients NPO status[1]. In addition, the delayed onset of oral medication &I/M injections makes these routes suboptimal for timely pain control Intranasal dosing of opiates can produce rapid treatment of pain without the pain, risk or delay of alternative administration options. Recognition of this rapid opiate analgesic effect has resulted in numerous studies evaluating the treatment of acute pain via fentanyl or diamorphine administration across the nasal mucosa (5 - 9).

We conducted a study to compare the efficacy of intranasal fentanyl with I/V morphine for acute pain management in orthopedic trauma in pediatric patients presenting with long bone fractures.

MATERIALAND METHODS

The present study was conducted on 80 patients of ASA I-II category in the age group of 7-12 years who presented in the orthopedic ED of either sex in the Govt. Medical college Jammu for the period of one year from September 2017 to August 2018.Written informed consent was obtained from the parents of the child.

Exclusion criteria was patients who had received narcotic analgesic with in 4 hours of arrival, sustained head injury, allergic to opiate analgesics, had a blocked or traumatised nose and weight more than 50 kg.

Every patient was weighed on the same weighing scale. Routine observations were noted (pulse rate, respiratory rate, blood pressure and O2 saturation).The patients were then shown a 100mm unmarked visual analog scale with 'no pain' at the left end and 'worst pain' at the right end and invited to mark the level of pain & this number was noted for each patient.

Now the patients were divided into two groups

Group I (n=40) : Received 2µg/kg of intranasal fentanyl half dose in each nostril

Group II (n=40) : Received 0.1mg/kg of I/V morphine. In this group I/V cannula was established for administration of drug .

Routine observations were carried out every five minutes including blood pressure, pulse rate, respiratory rate and oxygen saturation. Adverse effects were also looked for in particular sedation, respiratory or cardiovascular signs, nausea, vomiting and discomfort related to nasal spray.

The patient provided a pain score with the visual analog scale at 0,5,10,20 and 30 minutes after the administration of analgesic. They also compared the current pain with previous pain rating verbally as ' much better' 'little better' 'same' 'little worse' or 'much worse'

The study periods finished after 30 mins and the patients whose pain relief was inadequate were given I/V morphine additional dose.

The study hypothesis was to test equivalence of the two analgesic agents. Means, medians were calculated for all continous data with propotions was determined for all categorical variables. Differences in pre and post analgesic pain scores were assessed with ANOVA (analysis of varience) test which allowed simultaneous testing of repeated measures during the study intervals (visual analog scale scores) in addition to assessment of differences between the two treatment arms.

RESULTS

We enrolled 80 patients between September 2017 to august 2018. Demographic profile was similar in both the groups

Table 1 : Demographic Profile

	Group I	Group II
Mean Age	9.5(7-12)	9.7 (7-12)
Mean Weight	36.8 (20-50)	35.9(20-50)
Diagnosis		
Fracturehumerus	7	
Fracture Radius or ulna	24	25
Fractured femur	3	2
Fractured Tibia/fibula	6	5
Total No. Of patients	40	40

The visual analog score during 5 periods at which pain was assessed between fentanyl and I/V morphine are illustrated below. Overall no statistically significant differences in visual analog scale scores between the two treatments were observed.

Table 2 : Mean Visual Analog Scale

Time	Group I Fentanyl	Group II Morphine	P Value
0 min	70	72	>0.05
5 min	57	47	>0.05
10 min	48	43	>0.05
20 min	37	37	>0.05
30 min	37	35	>0.05

P value ≥0.05 is insignificant

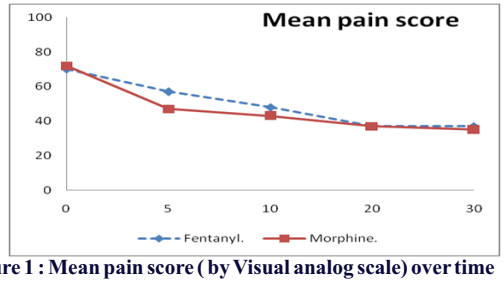

Figure 1 : Mean pain score (by Visual analog scale) over time

- X axis - Time (min)
- Y axis - VAS score (mm)

Five Children in fentanyl group had bad taste in mouth, but they were not excluded from the study. The patients in Group I (Fentanyl) had an average decrease in VAS score of about 13mn at 5 mins and further 9 mn at 10mins and20 minutes. Thereafter, there was no decrease in VAS score. The patients in Group II (Morphine) had an average decrease in VAS at 5 minutes of 25mm, further 4mm at 10minutes, 6mm at 20 minutes &2mm at 30 minutes. The difference in VAS score in both the groups at all time intervals was statistically insignificant. No patients had Vomiting, Hypoxia or Hypotension. No patients had Rhinorrhea, epistaxis or nasal complaints after medication administration.

DISCUSSION

Although intravenous morphine traditionally has been considered the 'gold standard' analgesic for moderate to serve pain, the skills required to establish vascular access in children are not universally available. Furthermore, the insertion of an intravenous line invariably adds to the distress of most children (10). Intranasal dosing of opiates can produce rapid treatment of pain without the pain risk or delay of alternative pain medication (1).The ideal analgesic for children should be available in preparation that is readily accepted by them, have a rapid onset, provide anxiolysis with mild sedative effects and be free of side effects (2). Fentanyl is a potent synthetic opioid analgesic with a rapid onsent and short duration of action (11). It is strong agonits of μ receptors.

Daniel et al did a study in comparing I/M fentanyl vs I/V morphine for abscess incision & drainage. In this study there was less self reported pain in patients who received intranasal fentanyl as compared to I/V morphine (12). In our study, there was no statistically significant difference found among both the groups. Borland in 2017 conducted a study to compare the efficacy of intranasal fentanyl with I/V morphine in pediatric population presenting to an emergency department with long bone fractures and they found that visual analog score showed significant reduction in both the groups at all intervals which is very similar to our results (13).

Theoretically, an I/V narcotic would be likely to be superior to an intranasal narcotic at 5 minutes because of the slight delay in absorption of intranasal fentanyl in comparison to I/V administration of morphine. However our results showed no significant difference in I/V morphine in comparison to intranasal fentanyl at any period, which correlates with the rapid bio availability of the intranasal fentanyl. Intranasal fentanyl has been shown to have therapeutic serum levels in two minutes, reflecting the good venous outflow of nasal mucosa and the bypassing of the liver avoiding first pass hepatic metabolism(13). Similar results were seen by Boland at al. Intranasal drug can be administrated before the I/V insertion, resulting in effective earlier analgesia. Having achieved initial improvement in pain, the child may not have any further need for I/V access in the ED for analgesia.(13).Also, if I/V line is needed for other medications it will make the child calm and pain free so that he cooperates for I/V canullation . In practice, Intranasal administration was simple (13)

Since very small volume of drug intranasally was used, it minimises difficulties such as sneezing and swallowing the solution and may be the reason for early onset due to increased bio availability. There was no adverse effects of either active drug in our study. Our results were similar to the study done by Younge et al(14).Mary Saunders et al conducted a study to evaluate the use of 2μg/kg of intranasal fentanyl as analgesia for painful orthopedic injuries in children and found it providing rapid analgesia that was sustained for 30 mins. Our results were also very similar with their study. They also observed that there was no adverse effects in their patients. Similar results were seen in our study.

The adverse effect profile for the intranasal administration of fentanyl is superior to that of oral transmucosal administration of fentanyl. Prior studies with oral transmucosalfentany demonstrated vomiting, pruritus and hypoxia. Schutzman et al reported a 5% to 7% incidence of facial pruritus and a 3% to 4% vomiting rate in children receiving low dose (10-15 μg/kg) or high dose (15-20μg/kg) oral transmucosal fentanyl for laceration repair(15). Klein et al reported an 11% rate of oxygen desaturation when oral transmucosal fentanyl was combined with oral midazolam for sedation during laceration repair (16). So, intranasal route is better than transmucosal oral route with regard to onset ease and adverse effects. That is why probably none of our patients had any side effects.

To conclude, though both I/V morphine and intranasal fentanyl had similar onset of action of analgesia & pain scores the ease of putting the nasal drops & the avoidance of I/V cannulation makes intranasal fentanyl equally effective technically easy alternative to I/V morphines.

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