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# ASSESSMENT OF PAIN AND ADEQUACY OF POST-OPERATIVE AND POST PROCEDURAL PHARMACOLOGICAL ANALGESIA IN CHILDREN IN A TERTIARY CARE PEDIATRIC CENTER

**Vijaya Surya Kiran KM[1], Niveditha HV[1], Shruthi Siddalingappa[1], Rahul M. Adsul[2]**

[1]Assistant Professor, Department of Paediatrics, Subbaiah Institute of Medical Sciences and Research Centre, Shivamogga, India
[3]Nanavati Super Specialty Hospital, Mumbai

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Corresponding Author:
**Dr. Vijaya Surya Kiran KM,**
Email: dr.jayman22@gmail.com

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## Abstract

**Background:** Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage". Perception of pain in pediatrics is complex, and entails physiological, psychological, behavioral, and developmental factors. The objective is to assess post-operative and post procedural pain in children using various age specific pain scales. **Materials and Methods:** This prospective and observational study was conducted in Department of Pediatrics, Dr. Balabhai Nanavati Super-Specialty Hospital, Mumbai. **Result:** Our study enrolled 150 children of pediatric age group who had undergone operative procedures under general anesthesia. Duration of surgery had no effect on pain score in children. Pain scales used according to age group has significant association with pain score. Out of 150 patients, 131 patients received intraoperative analgesia (87.3%) in the form of Drug Fentanyl (with mean dose of 1.55mcg/kg/dose), remaining 19 (12.7%) patients did not receive any type of intraoperative analgesia. 119 patients (79.3%) received intraoperative sedation in the form of drug Midazolam (with mean dose of 0.1mg/kg/dose) and 31 patients (20.7%) did not receive any form intraoperative sedation. **Conclusion:** Whether male and female have different pain threshold or pain tolerance could not be concluded. Association between intraoperative analgesia and pain score was statistically significant. (P=<0.001). Out of 150 patients. Association between intraoperative sedation and pain score is statistically significant. (P= <0.02).

## INTRODUCTION

According to the International Association for the Study of Pain, "Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage". Perception of pain in pediatrics is complex, and entails physiological, psychological, behavioral, and developmental factors.[1] However, in spite of its frequency, pain in infants, children, and adolescent is often underestimated and under treated. It has also been shown that infants and children, who experience pain in early life, show long-term changes in terms of pain perception and related behaviors. Health care professionals in this setting have a responsibility to reduce pain and anxiety as much as possible while maintaining patient safety.[1]

Infants perceive pain in the same way as adults. The receptors of nociceptive stimuli are free nerve endings that are widely distributed all over the body. They are maximally present in the superficial layers of the skin and internal tissues such as periosteum, arterial walls, and joint surfaces. Mechanical, chemical, or thermal stimuli excite the nociceptors and electrical impulses are transmitted to the dorsal horn of the spinal cord through two sets of nerve fibres— namely, large myelinated A-delta (A-δ) fibers and slower conducting, non-myelinated C fibers. The spinothalamic pathway transmits the impulses to the thalamus where pain is perceived. Third order neurons terminating in the sensory cortex and basal areas of the brain probably influence the appreciation of the quality of pain and the affective component. The neurotransmitters involved in the suppression of pain are endogenous opiates that include β- endorphin, met and leu encephalins, and dynorphin.[2] Other neurotransmitters such as serotonin and gamma-amino butyric acid (GABA) also decrease the sensation of pain. The anatomical, physiological, and biochemical prerequisites for pain perception are present by the early part of intrauterine life.

Therefore, even preterm infants can perceive pain comparable to older children. In addition, newborn babies have a well-developed endocrine system that is able to release cortisol and catecholamines in response to painful stresses, resulting biochemical and physiological alterations that make it possible to objectively assess response to pain.[2]

Pain can be assessed using self-report, behavioral observation, or physiologic measures, depending on the age of the child and his or her communication capabilities. Specific measures vary in their validity and usefulness. Accurate acute pain assessment requires consideration of the plasticity and complexity of children's pain perception, the influence of psychologic and developmental factors, and the appreciation of the potential severity and specific types of pain experienced.[3] Because pain is a subjective experience, individual self-report is often favored; however, it is important to be sure that children, particularly those between 3 and 7 years of age, are competent to provide information before their report of location, quality, intensity, and tolerability are accepted.[3] Children's capability to describe pain increases with age and experience, and changes throughout their developmental stages. Although, observed reports of pain and distress provide helpful information, particularly for younger children, they are reliant on the individuals completing the report. Behavioral measures consist of assessment of crying, facial expressions, body postures, and movements. They are more frequently used with neonates, infants, and younger children where communication is difficult. Physiological measures include assessment of heart rate, blood pressure, respiration, oxygen saturation, palmer sweating, and sometimes neuroendocrine responses. They are however generally used in combination with behavioral and self-report measures, as they are usually valid for short duration acute pain and differ with the general health and maturational age of the infant or child.[1]

The greatest advance in pediatric pain medicine is the recognition that untreated pain is a significant cause of morbidity and even mortality after surgical trauma. Accurate assessment of pain in different age groups and the effective treatment of postoperative pain are constantly being refined; with newer drugs being used alone or in combination with other drugs continues to be explored. Systemic opioids, nonsteroidal anti-inflammatory agents and regional analgesics alone or combined with additives are currently used to provide effective postoperative analgesia. These modalities are best utilized when combined as a multimodal approach to treat acute pain in the perioperative setting. The development of receptor specific drugs that can produce pain relief without the untoward side effects of respiratory depression will hasten the recovery and discharge of children after surgery.[4]

An individualized pain management plan can be made for each child based on a cycle of assessment and documentation of the child's pain using appropriate tools and self-reporting, with interventions linked to the assessments. A safety net is needed for rapid control of breakthrough pain, to monitor the efficacy of analgesia, to identify and treat adverse effects, and to ensure equipment is functioning correctly.[1]

## MATERIALS AND METHODS

**Study Design**

This prospective and observational study was conducted in Department of Pediatrics, Dr. Balabhai Nanavati Super-Specialty Hospital, Mumbai.

**Study Population**

Children aged day 1 of life to 18 years, undergone operations and invasive procedures under general anesthesia in Pediatric ward and ICU in Dr. Balabhai Nanavati Super- specialty hospital

**Study duration**

12 months (July 2018 to June 2019)

**Sample Size:**

Perceived pain score=5.32±1.32

1.96= z value for 5% confidence level e= Margin of error =0.50

Cochran formula for descriptive analysis Minimum sample size = N = $\frac{Z^2 * SD^2}{e2}$

1.962∗$SD$2

Minimum Sample Size=N = = (3.8416*1.32 )/(0.5)

$e$2

Minimum sample size=27

Where n is sample size, Z is the z-statistics for the desired level of confidence of 1.96, e is margin of error, and Standard deviation (SD) of 1.32. Using above mention formula, sample size calculated was 27.

To increase the power of study as well as considering high loss of follow up rate, looking at the resources available, including time, patient, tool it is planned to recruit 150 cases for present study.

**Inclusion Criteria**

- Children undergoing operative procedures under General anesthesia aged day 1 to 18 years in Pediatric ward and ICU.
- Children undergoing invasive procedures under general anesthesia aged day 1 to 18 years in Pediatric ward and ICU.

**Exclusion Criteria**

- Patients going DAMA/LAMA before the completion of post-operative treatment
- Post-Operative Fatality
- Patients undergoing minimally invasive procedures under Local Anesthesia
- Children with intellectual disability and/or cerebral palsy who cannot interpret pain scale

**Pre-anesthetic evaluation**

**Selection of Subjects**

A written informed consent of the parents was obtained prior to participation. The participants were informed about the nature of the study, voluntarily, right to withdrawal and their right to access health care facility irrespective of the fact whether they agree to participate in the study or not. All children satisfying the predetermined inclusion and exclusion criteria were enrolled for the study.

**Assessment of Pain**

Below is the different pain scales used for different age groups.

1. Neonatal/Infant Pain Scale (NIPS) for children less than 1-year-oldIt is interpreted as 0-2 No pain/Mild Pain, 3-4 moderate pain, >5 severe pain.
2. Faces, Legs, Activity, Cry, Consolability (FLACC) for 1-3 years' old
3. Pain score is divided as Score 1-3 = mild pain, score 4-6= moderate pain, score 7-10 = severe pain.
4. Faces Pain Scale- Revised (FACE-Revised) 3 to 7 years old: Pain score is divided as 0-2= no/mild pain, 4-6= moderate pain, 7-10= severe pain
5. Numeric rating scale (NRS) > 7 years old:
6. The numeric rating scale may be categorized into no pain (0), mild pain (1-3), moderate pain (4-6), and severe pain, (7-10).

The data will be collected by using various pain scales. Data will be collected using proforma including age in months, gender, nature of surgery/interventional procedure and pain medication history will be obtained. Surgical procedures will be grouped as category of surgery and duration of surgery. Pre-operative analgesia and post-operative anesthesia details will be obtained. Post-operative pain will be monitored using pain scales designed according to the age groups. Pain will be monitored by medical professional who will be either 1st year resident/2nd year resident/ 3rd year resident/registered nurse three times a day starting from post- operative / post procedure till mild or no pain is recorded on the pain scale.

**Statistical Analysis**

Data entry was done in MS Excel 2010. Data was analyzed using professional statistics package EPI Info 7.0 version for windows. Descriptive data was represented as mean ± SD for numeric variables, by percentage, Chi square test, fisher exact test and proportions for categorical variables. Appropriate tests of significance were used depending on nature & distribution of variables. One way ANOVA was applied.

## RESULTS

In this study total 150 children were included among which 63% were male (n=93) and 38% were female (n=57).

In this study, chi square test was applied for association between pain score and gender and found that P value was not statistically significant. (P= 0.24)

In our study, the children ranged in age from 0 days to 18 years. Mean age of study population was 90.66 (SD = 65.43) and median age was 84 months. It is seen that maximum number was between 1 year to 5 years (12 months to 60 months).

In our study, out of 150 patients, maximum surgeries were ENT surgeries, n=40 (26.70%) And least number was spine surgery n=1 (0.70%). Out of 150 patients, none of the patient received any pre-operative sedation or pre-operative analgesia. Out of 150 patients, 131 patients received intraoperative analgesia (87.3%) in the form of Drug Fentanyl (with mean dose of 1.55mcg/kg/dose), remaining 19 (12.7%) patients did not receive any type of intraoperative analgesia. [Table 1]

91.74% (n=100) of patients who had moderate pain score had received intraoperative analgesia and with Chi square test applied, Association between intraoperative analgesia and pain score was found statistically significant. (P=<0.001)

Out of 150 patients, 119 patients (79.3%) received intraoperative sedation in the form of drug Midazolam (with mean dose of 0.1mg/kg/dose) and 31 patients (20.7%) did not receive any form of intraoperative sedation. Out of 119 (79.3%) patients who had received intraoperative sedation in form of Midazolam, 74.31% (n= 81) patients had moderate pain score and with chi square test applied Association between intraoperative sedation and pain score is statistically significant. (P= <0.02). [Table 2]

Out of 150 patients, 48 patients (32%) had less than 60 minutes' duration of surgery, 64 patients (42.67%) had 60-120 minutes duration of surgery, 26 patients (17.33%) had 120- 180 minutes duration of surgery and 12 patients (8%) had more than 180 minutes duration of surgery. Association between duration of surgery and Pain score was statistically not significant. [Table 4]

Pain Scales were used according to age of the child and reliability and validity of pain scale. Out of 150 study population, according to age groups, NIPS was used for 17 children (11.3%), FLACC was used for 34 children (22.7%), FACES was used for 33 children (22.0%) and NRS was used for 66 (44.0%) children. [Table 5]

For NIPS, mean highest pain score was 3.88, for FLACC mean highest pain score was 3.65, for FACES mean highest pain score was 4.97, for NRS mean highest pain score was 4.85.

With one ANOVA applied it was found that Association between Highest Pain Score and age wise pain scales was statistically significant (P value < 0.0001). [Table 6]

**Table 1: Association between gender and pain score**

| Pain score | Gender | | P value | Association |
|---|---|---|---|---|
| | Male | Female | | |
| Mild (N=21) | 11(11.83%) | 10(17.54%) | 0.24 | Not significant |


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| | | | | |
|---|---|---|---|---|
| Moderate(N=109) | 72(77.42%) | 37(64.91%) | | |
| Severe(N=20) | 10(10.75%) | 10(17.54%) | | |
| Total | 93(100%) | 57(100%) | | |

**Table 2: Association between Intraoperative analgesia and pain score**

| Intraoperative Analgesia | Mild | Moderate | Severe | P value | Association |
|---|---|---|---|---|---|
| Yes | 12(57.14%) | 100(91.74%) | 19(95%) | <0.001 | Significant |
| No | 9(42.86%) | 9(8.26%) | 1(5%) | | |

**Table 3: Duration of Surgery Wise Distribution**

| Duration of Surgery Minutes | Total N | N% |
|---|---|---|
| < 60 | 48 | 32% |
| 60 - 120 | 64 | 42.67 |
| 120 - 180 | 26 | 17.33 |
| > 180 | 12 | 8 |
| Total | 150 | 100 |

**Table 4: Association between Duration of Surgery and Pain Score**

| Pain score | N (100%) | Duration of surgery (min) | | P value | Association |
|---|---|---|---|---|---|
| | | Mean | SD | | |
| MILD | 21(14%) | 117.62 | 56.82 | 0.23 | Not Significant |
| Moderate | 107(71.33%) | 96.59 | 54.93 | | |
| Severe | 20(13.33%) | 103.75 | 64.62 | | |

**Table 5: Number of Children according to Pain Scales**

| | | Count | Column N % |
|---|---|---|---|
| Pain Scale | FACES | 33 | 22.0% |
| | FLACC | 34 | 22.7% |
| | NIPS | 17 | 11.3% |
| | NRS | 66 | 44.0% |
| | Total | 150 | 100.0% |

**Table 6: Association of Pain Scale and Highest Pain Score**

| | N | Mean | Std. Deviation | P value | Association |
|---|---|---|---|---|---|
| FACES | 33 | 4.97 | 1.237 | 0.0001 | Significant |
| FLACC | 34 | 3.65 | 1.152 | | |
| NIPS | 17 | 3.88 | 1.409 | | |
| NRS | 66 | 4.85 | 1.231 | | |
| Total | 150 | 4.49 | 1.345 | | |

**Table 7: Association of Lowest pain score and Pain Scale**

| Pain Score Lowest | N | Mean | Std. Deviation | P value |
|---|---|---|---|---|
| FACES | 33 | 0.79 | 0.96 | 0.005 |
| FLACC | 34 | 0.62 | 0.604 | |
| NIPS | 17 | 0.12 | 0.332 | |
| NRS | 66 | 0.71 | 0.548 | |
| Total | 150 | 0.64 | 0.678 | |

**Table 8: Association of average Pain score and Pain scales**

| Pain Score Average | N | Mean | Std. Deviation | P value |
|---|---|---|---|---|
| FACES | 33 | 2.79 | 1.053 | 0.0001 |
| FLACC | 34 | 1.85 | 0.958 | |
| NIPS | 17 | 1.71 | 1.16 | |
| NRS | 66 | 2.41 | 0.701 | |
| Total | 150 | 2.29 | 0.972 | |

For lowest pain score, For NIPS, mean lowest pain score was 0.12, for FLACC mean lowest pain score was 0.62, for FACES mean lowest pain score was 0.79, for NRS mean lowest pain score was 0.71. With one ANOVA applied it was found that Association between lowest Pain Score and age wise pain scales was statistically significant (P value = 0.005). [Table 7]

For average pain score, For NIPS, mean average pain score was 1.71, for FLACC mean average pain score was 1.85, for FACES mean average pain score was 2.79, for NRS mean average pain score was 2.41. With one ANOVA applied it was found that Association between average Pain Score and age wise pain scales was statistically significant (P value = 0.0001).

Out of 150 patients in our study, 129 (86%) patients received post-operative analgesia, 21 patients (14%) did not. Only 7 (4.70%) patients received Bolus of Analgesia post operatively.

## DISCUSSION

Our study sample size was similar to a study conducted by Keck et al. whose sample consisted of 118 children aged 3 to 18 years undergoing painful procedures.[6] In our study, the children ranged in age from 0 days to 18 years. Mean age of study population was 90.66 (SD = 65.43) and median age was 84 months with maximum number was between 1 year to 5 years (12 months to 60 months). Out of 150 patients, maximum surgeries were ENT surgeries, n=40 (26.70%) And least number was spine surgery n=1 (0.70%). Out of 150 patients, none of the patients received any preoperative analgesia or preoperative sedation.

**Preoperative and Intraoperative**

Out of 150 patients, 131 patients received intraoperative analgesia (87.3%) in the form of Drug Fentanyl (with mean dose of 1.55mcg/kg/dose), remaining 19 (12.7%) patients did not receive any type of intraoperative analgesia. 91.74% (n=100) of patients who had moderate pain score had received intraoperative analgesia and with Chi square test applied, Association between intraoperative analgesia and pain score was found statistically significant. (P=<0.001)

Similar study using drug Ketamine was conducted by S. Dahmani et al 2011 where ketamine was used as a perioperative analgesic compound in children and infants and meta-analysis found that administration of ketamine was associated with decreased PACU postoperative pain intensity and nonopioid analgesic requirement.[7] Another study conducted by Upton H.D et al, Patients receiving intraoperative ANI-guided fentanyl administration during sevoflurane anesthesia demonstrated decreased pain in the recovery room, likely as a result of more objective intraoperative fentanyl administration.[8]

Out of 150 patients, 119 patients (79.3%) received intraoperative sedation in the form of drug Midazolam (with mean dose of 0.1mg/kg/dose) and 31 patients (20.7%) did not receive any form intraoperative sedation. Out of 119 (79.3%) patients who had received intraoperative sedation in form of Midazolam, 74.31% (n= 81) patients had moderate pain score and with chi square test applied Association between intraoperative sedation and pain score is statistically significant. (P= <0.02). Similar study was conducted by A.P. Schmidt Et Al 2007, which enrolled 60 school children and premedication with oral midazolam, oral clonidine, or trans mucosal dexmedetomidine was given and it was found that Dexmedetomidine and clonidine were related to lower scores of pain than midazolam.[9]

According to duration of surgery patients were categorized. Out of 150 patients, 48 patients (32%) had less than 60 minutes duration of surgery, 64 patients (42.67%) had 60-120 minutes duration of surgery, 26 patients (17.33%) had 120- 180 minutes duration of surgery and 12 patients (8%) had more than 180 minutes duration of surgery but Association between duration of surgery and Pain score was statistically not significant and no study was found which studied relation between duration of surgery and post-operative pain score in children.

**Pain scales**

Different pain scales were used according to age distribution. NIPS were used for 17 children (11.3%), FLACC was used for 34 children (22.7%), FACES was used for 33 children (22.0%) and NRS was used for 66 (44.0%) children. Pain score was measured from post- operative period till discharge of the patient. Pain scores were categorised as highest, lowest and average. For NIPS, mean highest pain score was 3.88, for FLACC mean highest pain score was 3.65, for FACES mean highest pain score was 4.97, for NRS mean highest pain score was 4.85. With one ANOVA applied it was found that Association between Highest Pain Score and age wise pain scales was statistically significant (P value < 0.0001).

For lowest pain score, For NIPS, mean lowest pain score was 0.12, for FLACC mean lowest pain score was 0.62, for FACES mean lowest pain score was 0.79, for NRS mean lowest pain score was 0.71. With one ANOVA applied it was found that Association between lowest Pain Score and age wise pain scales was statistically significant (P value = 0.005).

For average pain score, For NIPS, mean average pain score was 1.71, for FLACC mean average pain score was 1.85, for FACES mean average pain score was 2.79, for NRS mean average pain score was 2.41. With one ANOVA applied it was found that Association between average Pain Score and age wise pain scales was statistically significant (P value = 0.0001). From this we can probably say that pain scales used according to age of the child and cognitive capability are valid and reliable to use in children to analyze pain in children.

Similar study was done by Tsze et al. 2017 for NRS, where 760 children were enrolled between age group of 4 to 17 years. Pearson correlations were strong to very strong (0.62 to 0.96) in all years of age except 4 and 5 years, and agreement was strong for children aged 8 and older, concluding that numerical rating scale (NRS) is reliable to be used in 7 years and above.[10] Another study done by Keck et al. who studied FACES and word descriptor scale, enrolled 118 children between 3 to 18 years showed that The Faces and Word Descriptor Scales are valid and reliable instruments to measure procedural pain intensity with P value=0.001.[6] Another study done by Forough Sarhangi et al proving reliability and validity of neonatal infant pain scale ( NIPS) enrolled 68 infants. Validity tests showed a high correlation between NIPS and visual analog scale (r = 0.949; p < 0.001) confirming validity and reliability use of NIPS as for newborns and infants.[11] Study done by L. Subhashini *et al*

showed that FACES pain scale was reliable and valid pain scale to be used in children.[12]
Study done by S. NILSSON ET AL included 80 children and FLACC scale was used which showed Construct validity by the increase in FLACC with P value < 0.001 supporting the use of FLACC as a valid and reliable tool for assessing procedural pain in children aged 5–16 years. (37) Another study by Malviya S et al. enrolled 89 children aged 2 months to 7 years concluded that FLACC is valid and reliable.[13]

## CONCLUSION

Our study enrolled 150 children of pediatric age group who had undergone operative procedures under general anesthesia. Whether male and female have different pain threshold or pain tolerance could not be concluded. Duration of surgery had no effect on pain score in children. Pain scales used according to age group has significant association with pain score. Out of 150 patients, 131 patients received intraoperative analgesia (87.3%) in the form of Drug Fentanyl (with mean dose of 1.55mcg/kg/dose), remaining 19 (12.7%) patients did not receive any type of intraoperative analgesia. Association between intraoperative analgesia and pain score was statistically significant. (P=<0.001) Out of 150 patients, 119 patients (79.3%) received intraoperative sedation in the form of drug Midazolam (with mean dose of 0.1mg/kg/dose) and 31 patients (20.7%) did not receive any form intraoperative sedation. Association between intraoperative sedation and pain score is statistically significant. (P= <0.02).

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