TITLE:

Distraction techniques for post-operative pediatric patients in post anaesthesia care unit (PACU); a randomized control trial

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Distraction techniques for post-operative pediatric patients in post anaesthesia care unit (PACU); a randomized control trial

INTRODUCTION:

Pediatric pain is complex involving physiological, behavioral and developmental factors. In spite of different assessment tools, the pediatric pain is mostly underestimated and under treated. Many at times physicians do not want to treat pain because of fear of side effects or sedations which hinders discharge from Post Anaesthesia Care Unit **(**PACU). Another problem in our part of the world is availability of the medications like short acting narcotics and lack of regional anaesthesia practices. In addition to the standard pharmacological treatment non-pharmacological therapies like distraction can be used to treat the affective, cognitive, behavioral and socio-cultural dimensions of pain.[1] Distraction has been used effectively in the emergency department to guide children's attention away from the painful stimuli and reduce pain[2]. But use of this method in the postoperative anesthesia care unit is still limited.

The aim of this study is to compare the distraction method with the conventional pharmacological method in pediatric postoperative pain management, as this method is simple, economical and is devoid of any adverse effects.

OBJECTIVE:

The aim of this study is to compare the post operative analgesia between two groups (Group C and Group CD) receiving conventional analgesia with or without distraction technique. Group C will only receive conventional analgesia while group CD will receive conventional analgesia as well as distraction technique.

Operational definition:

- **Distraction technique** is a non-pharmacological method of pain relief for post-operative paediatric patients in post anesthesia care unit. (games on tablets, listening poems, watching cartoons)

- **Conventional analgesia** is the standardize rescue analgesia of intravenous administration of analgesics in post anesthesia care unit (PACU) prescribed. The analgesia will include I/V Tramadol 0.5 to 1mg/kg and Paracetamol 10mg/kg).

Primary outcome:

1. Pain scores using Wong-Baker FACES® pain rating scale [3]
2. Use of rescue analgesia

Secondary outcome: Parent's satisfaction.

MATERIALS & METHODS:

SETTING: This study will be conducted at post anaesthesia care unit of Department of Anesthesiology, Aga Khan University Hospital Karachi.

DURATION OF STUDY: Six to twelve months after approval of synopsis.

STUDY DESIGN: Randomized control trial

SAMPLING TECHNIQUE: Consecutive sampling methods

SAMPLE SELECTION:

Inclusion Criteria:

- All elective cases on paediatric list (orthopaedics, plastic surgery, paediatrics surgery)
- ASA I and II
- Children 3 to 7 years of age.

Exclusion Criteria:

- Parent's refusal for participation.
- CP child/ neurologically challenged pediatric patients
- Paediatric patients undergoing head, neck, ENT and Neurosurgery.
- Emergency surgery
- Language barrier (failure to understand Urdu and English)
- Difficult airway.

Sample Size: Sample size calculation is performed by using software PASS version 11.04 and based on previous study [4] .Post-operative mean pain score was reported 3.95(SD=1) in conventional groups. Assuming 25% difference in reduction and aiming for a power 80% and a risk of 0.05 for a type-I error, 14 patients will be required for each group. We will include 20 patients per group to anticipate a 30% dropout rate.

Ethics: Written informed consent will be taken from patient's parents/guardian participating in the study in ward. A copy of the informed consent will be given to the parents/ guardian. The confidentiality of the patient and data will be maintained by assigning a number for each patient data, electronic data will be password protected and data on hard copies will be kept in a lock and key.

Data Collection: The study will be conducted after approval from Hospital Ethical Review committee of Aga Khan University Hospital, Karachi. All pediatric patients fulfilling the inclusion criteria will be enrolled in the study. The purpose along with procedure of the study will be explained to the parents/guardian and informed consent will be taken in the ward. The information and the demographics of the patients will be entered in the proforma attached as annexure. Data will be collected in the pre designed form. For the purpose of data collection the form is divided into two sections:

SECTION I: - This section will be filled by the primary investigator in operation room.

SECTION II: - This section will be completed by the data collector in PACU.

Randomization: Patients will be divided into two equal groups (group C) and (group CD) by computer generated random number and the information will be provided to the investigator in the form of sealed envelopes which will not be opened until patient consent is obtained.

Procedure: When the patient received in PACU, the data collector will be informed about the allocated group (C or CD). Patients in group C will receive their routine rescue analgesics. While patients in group CD will be engaged in distraction methods once the child is awake and his/her response will be noted in form II at given intervals. Heart Rate (H/R), Blood pressure (BP), oxygen saturation and respiratory rate (R/R) will be noted from the monitors. The pain scale will be noted with the help of given Wong Baker faces pain scale on proforma. Routine rescue analgesia will be used if patient still experiences pain.

Distraction Method: These children will be given tablets/smart phone to choose one of the following options:

- To play games.
- To listen poems.
- To watch cartoons.

Data Handling and Record Keeping: It will be the responsibility of primary investigator with assistance of data collector. Study monitoring regarding protocol compliance will be done by the primary investigator. A copy of the consent form taken will be attached with proforma. The confidentiality of the patient and data will be maintained by assigning a number for each patient data. The electronic data will be password protected and hard copies will be kept in research cell.

At the completion of the study, results will be shared with the parents upon their request. Public disclosure includes publication of an abstract or full paper in a scientific journal and presentation at a scientific meeting.

Data Analysis: Data will be analyzed by Statistical packages for social science version 19 (SPSS Inc., Chicago, IL). Endpoint of the study will be patient's sign out from recovery room. Frequency, percentage, mean and standard deviation will be reported for different variables.

References:

1. Yavuz, M (2006). Ağrıda Kullanılan Nonfarmakolojik Yöntemler, In: Ağrı Doğası ve Kontrolü, 1st edition, F.E. Aslan (Editor), Vol.42, pp.135-147. Avrupa Tıp Kitapçılık Ltd. Şti. Bilim Yayınları, ISBN: 975-6257-17-2
2. Vessey JA, Carlson KL, McGill J. Use of distraction with children during an acute pain experience. *Nursing Research*. 1994; 43(6):369–372. [PubMed]
3. Whaley LF, Wong DL. Nursing care of infants and children, 3rd ed. St. Louise: Mosby; 1987
4. He H.-G., Jahja R., Lee T.-L., Ang E.N.K, Sinnappan R, Vehvilainen H. -T. -L, Vehvila Inenjulkunen K. & Chan M.F. (2010) Nurses' use of non-pharmacological methods in children's postoperative pain management: educational intervention study. *Journal of Advanced Nursing* 2010; 66(11), 2398–2409.doi: 10.1111/j.1365-2648.