

**EFFECT OF DURATION OF PREOPERATIVE FASTING ON THE
INCIDENCE OF EMERGENCE DELIRIUM IN PAEDIATRIC
PATIENTS DURING RECOVERY FROM GENERAL ANAESTHESIA:
A RANDOMIZED CONTROLLED TRIAL**



THESIS

Submitted to

**All India Institute of Medical Sciences, Jodhpur
In partial fulfillment of the requirement for the degree of**

DOCTOR OF MEDICINE (MD)

(ANAESTHESIOLOGY AND CRITICAL CARE)

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DECLARATION



I here declare that thesis titled **“EFFECT OF DURATION OF PREOPERATIVE FASTING ON THE INCIDENCE OF EMERGENCE DELIRIUM IN PAEDIATRIC PATIENTS DURING RECOVERY FROM GENERAL ANESTHESIA: A RANDOMIZED CONTROLLED TRIAL”** embodies the original work carried out by the undersigned in All India Institute of Medical Sciences, Jodhpur.

The submitted thesis **“EFFECT OF DURATION OF PREOPERATIVE FASTING ON THE INCIDENCE OF EMERGENCE DELIRIUM IN PAEDIATRIC PATIENTS DURING RECOVERY FROM GENERAL ANESTHESIA: A RANDOMIZED CONTROLLED TRIAL”** has been evaluated on Duplichecker software platform and the report reads that the submitted thesis has no similarity in discussion and introduction section.

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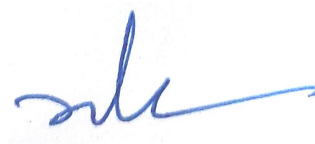


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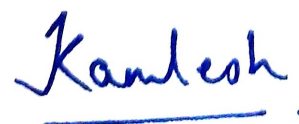


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Enclose:

1. Annexure 1


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“An investment in knowledge pays the best interest”

-Benjamin Franklin

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- **DR. ANAS V P**

ABBREVIATIONS

IV	Intra Venous
PAED	Pediatric Anaesthesia Emergence Delirium
GABA	Gamma Amino-Butyric Acid
CNS	Central Nervous System
ED	Emergence Delirium
FLACC	Face Legs Activity Cry Consolability
BIS	Bispectral Index
Mins	Minutes
GA	General Anaesthesia
EA	Emergence Agitation
MAC	Minimum Alveolar Concentration
mYPAS	Modified Yale Preoperative Anxiety Score
PONV	Postoperative nausea and vomiting
PACU	Post Anaesthetic Care Unit
TIVA	Total Intravenous Anaesthesia
IQR	Interquartile Range
OT	Operation Theatre
ASA	America Society Anaesthesiologist

SUMMARY

BACKGROUND

Emergence delirium is one of the adverse effects of general anesthesia, especially common in pediatric age group, which may lead to unwanted effects. It is thus essential to avoid possible risk factors which might increase its incidence. There are multiple studies to ascertain its risk factors and prolonged fasting is one of the proposed risk factors for post-operative emergence delirium. Hence, we planned this study to ascertain this association. We also compared relationship of prolonged fasting with postoperative pain and postoperative nausea and vomiting (PONV).

METHOD

In this single-blinded, prospective randomized controlled trial, paediatric patients aged 2 to 8 years, who were to undergo surgeries for 1-4 hours duration, under general anaesthesia were enrolled. Patients were randomly assigned into two groups based on the duration of preoperative fasting for clear fluids into 1 hour and 2 hours group. Emergence delirium was assessed by PAED score and pain was assessed by FLACC score for 30 minutes postoperatively, in post anaesthesia care unit (PACU).

RESULTS

The two study groups were comparable with age, gender, preoperative anxiety. There was no significant difference in PAED score for ED denoting no difference in duration of preoperative fasting with emergence delirium, at any point of time in the first 30 minutes after extubation between the two groups (p-value 0.288). There was no statistically significant relationship of duration of preoperative fasting with pain or PONV between the 2 groups with a p value of 0.405 and 0.616 respectively. Occurrence of ED has statistically significant relation with prolonged PACU stay (p value-0.002).

CONCLUSION

There was no difference in the emergence delirium in children undergoing surgeries under general anaesthesia depending on whether they fasted for one or two hours prior to surgery. Similarly, there was no difference between the two groups in terms of postoperative pain and PONV. Patients with ED, on the other hand, had a longer stay in the PACU.

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INTRODUCTION

INTRODUCTION

Emergence Delirium is an altered state of consciousness, which may begin with emergence from anesthesia and may continue through the early recovery period¹. It manifests as disorientation, hyperactive behavior, and hypersensitivity in the immediate period after anesthesia². Emergence agitation (EA) is the umbrella term that includes Emergence Delirium, pain, hypothermia, and hypoxia, etc. Emergence Delirium may last 20 to 30 minutes after general anesthesia and it may not respond to usual comforting measures³. It can present even in the operation room at the time of extubation but mainly in PACU.

The incidence of ED in children ranges from 2% to 80%⁴. ED can cause disruption of surgical dressing, surgical dehiscence, increased bleeding from the surgical site, removal of iv lines, foleys catheters, and drains, and can lead to difficulties in the monitoring of patients and nursing care⁵. ED may prolong stay in a post-anesthesia care unit (PACU) stay, even after short surgical procedures⁶.

There are some theories to explain the pathophysiology of ED like awakening from GA in a strange environment, variable recovery of CNS function, precipitous withdrawal from GABA receptor, rapid emergence from anesthesia, and rate of emergence from different parts of the brain may not be the same in case of sevoflurane anesthesia, thereby creating a confusional state in children^{7,8}.

Certain factors like prolonged fasting, use of volatile anesthetic agents⁹, prolonged duration of surgery, pain, dehydration, and rapid emergence are proven to increase the incidence of emergence delirium. Inhalational agents cause more ED compared to TIVA^{9,10}. Among inhalational agents, sevoflurane causes maximum ED explained by rapid emergence from surgery. Many scales like PAED, Cravero, ChiPPS, and Watcha have been proposed and used to evaluate the incidence and severity of ED but the PAED scale is a validated tool to use in clinical practice and has a higher overall sensitivity and specificity than any other scale¹¹.

Prophylactic administration of fentanyl^{10,12}, clonidine, ketamine, Dexmedetomidine, and propofol were found to reduce ED^{10,12,13}.

Preoperative fasting is being done as a protocol in all elective cases to avoid pulmonary aspiration of gastric content due to regurgitation of a full stomach and blunting of airway reflexes by the anesthetic agents. Gastric volume and Gastric pH are the two main determinants of aspiration pneumonia⁶. Studies show that there is no difference in gastric volume and pH between 1 hr fasting and 2 hrs fasting for clear fluid, hence we can follow 1 hr fasting for clear fluids⁶. Prolonged preoperative fasting especially in the pediatric population leads to thirst, hunger, noncompliance, hypoglycemia, dehydration, and increased anxiety of child as well as parents¹⁴. Anxiety may lead to crying, irritability, and inconsolability in the preoperative period and have an impact on ED postoperatively. A Cochrane database systematic review has reported that clear fluids permitted to drink till 2 hours before surgery had a more comfortable preoperative experience in children. Shortening the fasting times in pediatric patients improve hydration, patient comfort, and cooperation at the time of induction of anesthesia and thus improving the perioperative experience of children and parents¹⁵. Reduced fasting duration will reduce preoperative anxiety thereby indirectly reducing the ED. European Society of Anesthesiology and intensive care (ESAIC) 2021, have recommended children clear fluid fasting for only 1 hour¹⁶. In our study, we followed ESAIC 2021 recommendations of fasting by giving dextrose water one hour before induction to reduce the side effects of emergence delirium¹⁶. The present study was planned to compare the incidence of emergence delirium between preoperative fasting of 1 hour and 2 hours duration for clear fluids in pediatric patients of age 2 to 8 years posted for surgeries of 1 to 4 hours duration under general anesthesia.

AIMS & OBJECTIVES

AIMS AND OBJECTIVES

AIM:

To compare the effect of duration of preoperative fasting on the incidence of emergence delirium in paediatric patients of age group 2 to 8 years posted for surgeries of 1 – 4 hours duration under general Anesthesia.

OBJECTIVES:

PRIMARY OBJECTIVE: To compare the effect of duration of preoperative fasting on the incidence of emergence delirium between two groups

SECONDARY OBJECTIVE: To compare the effect of duration of preoperative fasting on the incidence of postoperative pain and nausea and vomiting between two groups.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

1. **Eckenhoff et al (1960)**¹⁷ first described Emergence Delirium (ED). It is a post-surgical phenomenon often leading to an increase in morbidity, mortality, and resource utilization. The condition is a dissociative state of consciousness characterized by confusion, hallucination, and delusions featured by moaning, restlessness, involuntary physical activities like moving to and fro, headbanging, thrashing about in the bed. Amongst the 14000 patients studied by **Eckenhoff et al**, 5.3% had signs of hyperexcitation in patients recovering from the ether, cyclopropane, or ketamine anesthesia. The incidence of ED in the general population ranges from 5-30%. However, most often, ED is seen in the pediatric population, especially in age below 5years. The rapid recovery from anesthesia in combination with the psychological immaturity in these populations has been postulated for ED
2. **Leila G et al (1996)**¹⁸. published a study of Comparison of Emergence and Recovery Characteristics of Sevoflurane, Desflurane, and Halothane in Pediatric Ambulatory Patients in 1-7 years of age. Patients were randomly assigned to one of 4 groups with sevoflurane induction and maintenance halothane induction and sevoflurane maintenance, halothane induction and maintenance, and halothane induction and desflurane maintenance. They found that significantly greater incidence of postoperative agitation who received desflurane (55%) and sevoflurane (10%) and halothane (25%).
3. **Aono et al (1997)**¹⁹ Conducted a study to compare the difference between Halothane and Sevoflurane anesthesia, as it was previously shown that the age of the patient is often associated with the ED. In contrast, they found an increase in ED in the Sevoflurane group than Halothane in pre-school children aged 3-5years (40% vs. 10%). Thus, they thought the psychological immaturity of pre-school children might be a cause of ED. There are speculations that ED could be associated with genetic polymorphism, but at present, there are not many studies to thoroughly explain the basis for genetic predisposition to ED.
4. **Cc Apfel et (2002)**²⁰ all conducted a study to know the incidence of PONV in 1184 patients postoperatively. They found that 355 patients had PONV within 24hr postoperatively. They found that early PONV (0 to 2 hrs.) is related to the use of inhalational agents. They suggested avoiding inhalational agents in people who are already having risk for PONV.

5. A Prospective Cohort Study of Emergence Agitation in the Pediatric Post anesthesia Care Unit conducted by **Terri Voepel-Lewis et al (2003)**³ evaluated 521 children of age 3 to 7 years who underwent elective surgeries under GA. parents completed a behavioral style questionnaire. 96 number (18%) of this exhibited ED. agitation lasted up to 45 min postoperatively. 52% of children required pharmacologic intervention and was associated with a prolonged post anesthesia care unit stay. Ten factors were found to be associated with EA, including age, previous surgery, adaptability, ophthalmology and otorhinolaryngology procedures, sevoflurane, isoflurane, sevoflurane/isoflurane, analgesics, and time to awakening. they concluded that this data may help in planning post-anesthesia care in children.
6. **Sikich N, Lerman J, (2004)**¹¹, developed and evaluated the Pediatric Anesthesia Emergence Delirium (PAED) scale to measure emergence delirium in children >2 yr of age. The internal consistency of the PAED scale was 0.89, and the reliability was 0.84 (95% confidence interval, 0.76-0.90). The sensitivity was 0.64. Their results supported the reliability and validity of the PAED scale. Many scales have been proposed to identify ED but they have not been psychometrically tested and they follow emotional distress and psychomotor agitation as surrogate markers of delirium. PAED scale has been psychometrically evaluated and is used most commonly.
7. **Shukry et al (2005)**²¹ studied the effects of a continuous perioperative infusion of 0.2µg/kg/h dexmedetomidine on the incidence of ED in 50 children aged 1–10 years scheduled for sevoflurane-based GA. Results showed that the incidence of ED was statistically significantly less in the dexmedetomidine group compared to the saline group (26% in Group D Vs 60.8% in Group S) (P =0.036). Additionally, the number of episodes of ED was lower in Group D (P < 0.017). They concluded that the perioperative infusion of dexmedetomidine decreases the incidence and frequency of ED in children after sevoflurane-based GA without prolonging the time to extubate or discharge.
8. **Gordana P. et al (2007)**²² in their review article emphasizes the importance of identifying the risk factors and taking preventive measures like reducing preoperative anxiety, postoperative pain, and providing a quiet, stress-free environment in reducing ED. They suggested that there is often a requirement for additional nursing care and the use of

pharmacological treatment for the management of ED. These measures increase the duration of PACU stay and economic burden.

9. **Seija klemetti et al (2008)**²³ studied the effect of duration of fasting on postoperative pain and PONV in children undergoing adenotonsillectomy. They counseled parents well and gave clear juices without pulp for 2 hrs. before induction as many children want at the max of 10ml/kg and study group and control group kept as fasting instruction as per institute. They found that children who were given clear juices had less postoperative pain in the initial hours and were better tolerable to PONV also.
10. **Bong and Ng et al (2009)**²⁴ conducted a study to evaluate the emergence behavior in 316 children who underwent GA for elective surgeries using the PAED Scale .no premedication was given. The result was One hundred and thirty-six children (43%) had PAED Scores >0 and 33 (10.4%) had PAED Scores of ≥ 10 . Only 28 children (8.9%) had clinical agitation consistent with ED, the rest were agitated for other reasons. A score of ≥ 10 on the PAED Scale was the best discriminator between the presence and absence of clinical agitation. they concluded that the ideal cut-off for PAED Score is more than or equal to 10 and which are clinically correlated well.
11. **Bajwa and colleagues (2010)**²⁵ conducted a study to compare the sensitivity and specificity of different scales to measure the emergence of delirium. Pediatric anesthesia emergence delirium (PAED), watcha, and cravero scales were used to detect the presence of ed in 117 of 118 consecutive children <18 years recovering from general anesthesia by an experienced anesthesiologist. The result shows that a PAED score of ≥ 10 detected ed in 37 children (32%), while the watcha detected 30 (26%) and cravero 41 (35%). Twenty-five patients (21%) fulfilled the criteria for ed in all three scales as did all eight patients assessed by the experienced pediatric anesthetist observer. They concluded that all three scales correlated reasonably well with each other but have individual limitations. They also mention that a PAED score >12 appears to provide greater sensitivity and specificity than a PAED score ≥ 10 .
12. **B. J. Pieters et al (2010)**²⁶ used ≥ 10 PAED scores as a cut-off to diagnose ED. It appeared to be overestimating the actual incidence of ED whereas when the cut-off of ≥ 16 was used the incidence of ED appeared to be very less than the reality which is why we in our study have

considered a cut-off of ≥ 12 as a diagnostic tool. Only a few recent studies have highlighted the importance of choosing a cut-off of ≥ 12 . As pain is one of the causes of ED, it was necessary to assess the pain intensity. It is again a difficult task to evaluate the pain in children as they cannot quantify pain. The studies confirm inter-rater reliability and suggest preliminary validation of the FLACC assessment tool. It is easy to use and incorporate into documentation which may provide an advantage over other behavioral pain assessment tools. Thus, we used the FLACC scale to assess the severity of pain and provide adequate treatment whenever needed.

13. **Vikas Sharma et al (2011)**²⁷ conducted a study with 100 children of age 6 months to 6 years age who were undergone elective surgeries. they made 2 groups, one group they had given 5 % dextrose solution orally of 10ml/kg 3 to 4 hours before surgery and other groups with midnight fasting, they found that hypotension after induction is more common in the midnight fasting group and there was no incidence of hypoglycemia in both groups.
14. **Thomas Engelhard et al (2011)**²⁸ conducted a prospective study to assess the effect of duration of preoperative fasting on thirst and hunger before elective surgeries. they took 1350 children of age less than 16 years and there were asked about the timing of the last food and drink. They assessed the severity of hunger and thirst preoperatively. the result shows median (range) fasting times were 12:05 (00:45-21:50) hours and 07:57 (00:05-20:50) hours for solids and fluids, respectively. The majority of children were very hungry or starving (756/1350=56%), but less than a third of all children were very thirsty (361/1350=27%). Duration of solid food fast and severity of hunger correlated for patients fasted from before midnight ($r=0.92$) but not for food after midnight. No correlation was found between fluid intake and perception of thirst. so, they concluded that children were suffered considerable discomfort before elective surgery because of prolonged fasting.
15. **Yilmaz N et al (2013)**²⁹ conducted a study on carbohydrate drinks before surgery to PONV. they recruited adult patients posted for laparoscopic cholecystectomy, divided into two groups randomly, and one group was given 400 ml of sucrose drinks 2hour before elective surgery and the control group was kept fasting for 8 hours. they found that better patient comfort and lesser PONV were found in the group which had been given sucrose juice. they concluded that preoperative carbohydrate drinks reduce PONV and increase patient comfort compared to prolonged fasting.

16. **Zhang et al (2013)**³⁰, who has done a meta-analysis that includes 12 papers with 447 children, found that prophylactic administration of midazolam decreased the incidence of ED. Later on, this was supported by the study by Cho et al. in 2019(36), which concluded that intravenous midazolam at the dose of 0.03mg/kg reduced the incidence of ED and without delay in emergence time in children having strabismus surgery. Many older studies had shown no or increased incidence of ED when preoperative Benzodiazepines were administered.
17. **Sameer Sethi et al (2013)**³¹ conducted an RCT to compare the effect of desflurane and sevoflurane on the postoperative ED in children undergoing cataract surgery under general anesthesia. They recruited 88 children of ASA 1 and 2, aged 2 to 6 years, in which general anesthesia was induced with sevoflurane and maintained with sevoflurane and desflurane to achieve MAC of 1 to 1.2. They measured post-operative ED using PAED score. They found that ED using the cutoff of >12 in PAED scale was 8 of 44 (18.18%) in the sevoflurane group and 9 of 44 (20.45%) in the desflurane group. They concluded that ED was comparable after desflurane and sevoflurane anesthesia using a validated PAED scale in pediatric cataract surgery and there was no correlation between preoperative anxiety and ED in these children.
18. **R. Schmidt et al (2014)**⁶ published a study regarding the effect of duration of fasting on the gastric PH and volume. they took 131 children with age group 1 to 16 years of ASA 1 OR 2 for the studies, given clear fluid 1 hr and 2 hrs. before induction. they aspirated gastric volume with help of an orogastric tube in a different position (supine, left lateral, and right lateral) and measured the ph and volume. they found that no significant difference in gastric pH [1.43 (1.30–1.56)/1.44 (1.29–1.68), P=0.66] or residual volume [0.43 (0.21–0.84)/0.46 (0.19–0.78) ml kg⁻¹, P=0.47. They concluded that there is no alteration of gastric ph and residual volume with 1 hr fasting hence there is no alteration with risk of aspiration.
19. **Kain et al (2014)**³² conducted a study to know the relation between preoperative anxiety with post-operative maladaptive behavior in children. They took children who had undergone surgery under general anesthesia. they measured preoperative anxiety score with mYPAS score and compared with postoperative emergence delirium. They found that emergence delirium is increased by 10 % for each increase in score of 10 in the mYPAS score.

20. **Bong et al (2015)**³³ compared the effect of a single dose of dexmedetomidine and propofol on emergence delirium in children undergone MRI. they categorized 120 children into 3 groups. one group was given dexmedetomidine 0.3 mcg/kg and the second group with propofol 1 mg/kg and 3rd group with 0.9 % saline just before extubation. they estimated emergence delirium with PAED scores of more than 10. The result obtained was Administration of neither dexmedetomidine nor propofol significantly reduced the incidence, or severity, of emergence delirium. instead, they found that the time taken to awaken a child from GA is a significant predictor. they also added that every minute increase in wake-up time reduced the odds of emergence delirium by 7%.
21. **M. Somaini et (2016)**³⁴ all have done an observational study to differentiate between emergence delirium and pain. they recruited 512 children who underwent surgeries like adenotonsillectomy, sub umbilical surgeries, and MRI. They assessed postoperative emergence delirium with PAED score and pain by FLACC score with the help of 2 untrained observers. they found that delirium is characterized by ‘No eye contact’ and ‘no awareness of surroundings and pain is characterized by ‘Abnormal facial expression’, ‘crying’, and ‘inconsolability.
22. **Chauvin et al (2017)**³⁵ conducted a study on 231 children, where postoperatively they were grouped under Control and Liberal group. The Liberal group received apple juice when the FLACC score was more than 4 whereas the Control group was given opioids in the PACU. The incidence of POV was 11.40 and 23.93% in the LG and the CG, respectively. An opioid was needed in 14.04% (mean total dose: 0.18 mg kg⁻¹) and 35.89% (mean total dose: 0.20 mg kg⁻¹) of the patients in the LG and the CG. The PACU stay was significantly shorter in the LG group (53.45 vs 65.05 min, p = 0.002) so they concluded that early postoperative oral fluid intake was associated with a reduction in opioid use and POV incidence.
23. **Khanna et al (2018)**¹ conducted an observational study to identify any correlation between the duration of preoperative fasting and emergence delirium in children undergoing ophthalmic examination under anesthesia. 100 children were recruited and their preoperative fasting was recorded and the presence of emergence delirium was assessed by the PAED scale at 5-minute interval till 30 minutes from the time of leaving the operation theater. Results showed that the mean (standard deviation) duration of fasting to clear liquid was 6.3 (1.7) hrs. 24 children (24%) had at least 1 recorded PAED score >10 at any time point in the

postoperative period. PAED scores at 15 and 25 minutes were significantly correlated with the duration of fasting. They concluded that Increased duration of preoperative fasting may be a risk factor for postoperative emergence delirium in children undergoing ophthalmic examination under general anesthesia.

24. **Anderson et al (2018)**³⁶ conducted a cohort study for 1 year in children with a new fasting regimen of 6-4-0 and compared it with the existing 6-4-2 regimen. They found that patients fasting according to the 6-4-2 fasting regimen (n = 66) had a median fasting time for clear fluids of 4.0 h and a 33.3% incidence of fasting more than 6 h. After transitioning to the 6-4-0 fasting regimen (n = 64), the median duration of fasting for clear fluids decreased to 1.0 h, and the incidence of fasting more than 6 h decreased to 6.3%. They concluded that the introduction and implementation of a 6-4-0 regimen of preoperative fasting reduces the median fluid fasting duration and the number of children subjected to extended fasting.
25. **Byung et al (2018)**³⁷ conducted a prospective, double-blind, randomized study to see the effect of a mother's recorded voice on the incidence of postoperative ED in 2- to 8-yr-old patients who had undergone surgery under general anesthesia. Their result showed that the mother's voice reduced the initial PAED score compared with a stranger's voice [mean (standard deviation), 9.8 (2.5) vs 12.5 (4.1); P=0.002]. They concluded that the mother's voice reduced emergence delirium scores and the incidence of emergence delirium in pediatric patients compared with a stranger's voice after general anesthesia.
26. **Rosen D et al (2019)**³⁸ Current pediatric anesthetic guidelines for the management of preoperative fasting of clear fluids is 2 hours. The literature suggests that the 2-hour clear fasting policy translates into 6-7 hours of the actual duration of fasting. With a 1-hour clear fluid policy, there is no increased risk of pulmonary aspiration and there is less nausea and vomiting, thirst, hunger, and anxiety. The Association of Paediatric Anesthetists of Great Britain and Ireland, the European Society for Paediatric Anesthesiology agree that, based on the current convincing evidence base, unless there is a clear contraindication, it is safe and recommended for all children able to take clear fluids, to be allowed and encouraged to have them up to 1 hour before elective general anesthesia.

27. **Al-Robeye et al (2019)**³⁹ conducted a study to detect prolonged fasting in children undergoing surgeries. survey forms are distributed to parents 2 weeks before and a particular special survey is made for children over 6 years to know how much discomfort child is facing, the result shows that Seventy-one parent surveys and 48 child surveys were completed, with a mean patient age of 8.3 years (SD 4.1). The mean preoperative fasting time for food was 11.7 hours (SD 4.4) and 6.9 hours (SD 5.0) for fluids. they concluded that most of the children are faced much more prolonged fasting apart from recommended duration and thereby children underwent emotional disturbance, thirst, and hunger.
28. **Hajian et al (2020)**⁴⁰ have done a cross-sectional study to know the effect of preoperative fasting on blood sugar values and hemodynamic stability. they conducted a study in 50 children of age 3 to 12 years duration of fasting for solids and liquids were found from history from parents and blood sugar were checked at operation room and 20 min after induction, similarly blood pressure was monitored. the result shows the mean age of the children was 6.63 (SD 1.85) years. Mean blood glucose 20 minutes after the surgery was 101.17 (SD 92) mg/dl, which was significantly higher than the baseline values (87.66 (SD 11.84) mg/dl) ($p < 0.001$). they concluded that prolonged fasting cant affect blood glucose levels but it has a significant impact on systolic blood pressure
29. **Suleyman Yalcin et al (2021)**⁴¹ compared the effect of preoperative duration of fasting with postoperative pain and nausea vomiting. they took 124 children who had undergone tonsillectomy. mean duration of fasting was 11.03 ± 1.17 hours, the duration of thirst was 10.17 ± 1.00 hours. The mean behavior scores of the children were 1.28 ± 0.27 points, the mean vomiting score of the children was 0.01 ± 0.07 points, 56.9% of the children in the postoperative unit were not experiencing nausea. they concluded that pre-operative fasting time did not affect postoperative agitation and vomiting, but it affected nausea.
30. **Thomasseau et al (2021)**⁴² compared different modes of fasting counseling in children undergoing surgeries. they took 152 children under 15 years of age and they counseled the parents' days before surgery and one group they reminded with text messages apart from usual counseling. they observed that There was a difference in observance of clear fluid fasting instructions (bet in favor of the text message group 33% versus 92% OR 29.2 (10.9–95.2) $p < 0.001$, the average fasting duration for clear fluids was $8.7 \text{ h} \pm 4.8 \text{ h}$ vs.

4.3 h \pm 2.4 h ($p < 0.001$). they concluded that text reminder just a day before surgery was one method to strictly follow the fasting guidelines.

31. **Dobson GR (2021)**⁴³ et al announced the guideline for practice of anesthesia revised on 2021, it states that fasting for clear fluid to infants and children is 1 hour and for adults is for 2hours.
32. **Karasu et al (2021)**⁴⁴ studied the effect of a different combination of anesthetic sedation among children posted for MRI. they took 140 children of 2 to 10 years of age posted for MRI under sedation and divided them into 4 groups, Group MP (midazolam-propofol), Group MK (midazolam-ketofol). Group DP (dexmedetomidine-propofol) Group DK (dexmedetomidine-ketofol). They found that Delirium developed in 1.42% of all the patients, and in 5.7% of Group MP.so they concluded that delirium is very low at group MP.
33. **Torabikhah et al (2021)**⁴⁵ studied the effect of reducing fasting hours on postoperative pain among orthopedic patients. They recruited 64 patients randomly and made it to 2 groups (group 1 entire midnight fasting and group 2, 2 hrs. fasting for carbohydrate drinks. They found that postoperative pain was reduced in less fasting hour group.
34. **Li et al (2021)**⁴⁶ conducted a cross-sectional study to check the preoperative fasting guidelines and practically followed are matching or not. They took 211 children to shanghai hospital China and assessed the fasting status by records and found that children fasted more than the recommended duration. There is a big gap between the recommended ASA fasting guideline and actual practice

JUSTIFICATION OF THE STUDY

Literature suggest that prolonged fasting is one of the possible avoidable risk factors for adverse reactions like emergence delirium, postoperative pain and PONV after general anesthesia. We compared the effect of 1hour and 2-hour duration as per the fasting guidelines, of preoperative fasting for clear fluid to postoperative emergence delirium, pain and nausea and vomiting.

RESEARCH QUESTION

Does the different duration of preoperative fasting for clear fluids have any effect on postoperative emergence delirium, pain and PONV in pediatric age group of 2 to 8 years undergoing surgery under general anaesthesia?

MATERIALS & METHODS

MATERIAL AND METHODS

STUDY SETTING:

This single-blinded, prospective randomized controlled trial was conducted in the Department of Anesthesiology and Critical Care, AIIMS, Jodhpur after getting approval from Institutional Ethical Committee (IEC **Ref.No. AIIMS/IEC/2019-20/994**) and registration in CTRI (CTRI Reg No.**2020/03/024375**). Patients included in the study group were intervened in the preoperative period and were observed and monitored for 30 minutes postoperatively, in post anaesthesia care unit (PACU).

STUDY DESIGN:

Single blinded randomized controlled trial

INCLUSION CRITERIA:

Paediatric patients of age 2-8 years belonging to ASA I or ASA II posted for surgery of duration 1-4 hours under general anaesthesia.

EXCLUSION CRITERIA:

1. Refusal of assent of child or consent of parents
2. Patients posted for elective surgery under regional anaesthesia.
3. The child with congenital disorder and developmental abnormalities.
4. Patients with gastroesophageal reflux, hiatus hernia
5. GI surgeries with delayed gastric emptying and increased risk of nausea and vomiting.
6. Non-adherence to the fasting guidelines, and refusal to drink prescribed fluid according to the protocol.

METHODOLOGY

Paediatric patients of age 2 to 8 years who were planned for surgeries of duration 1-4 hours, under general anaesthesia were taken as participants. A pre-anaesthetic check-up was done for these patients, one day before surgery. Informed and written consent was taken from parents of the participants and assent for children > 7 years of age, before surgery after properly explaining about the study, the anaesthesia procedure and probable stay in the PACU. All children were kept fasting for 6 hours for solid foods following the standard protocol as per the guidelines.

Patients were randomly assigned into two groups based on the duration of preoperative fasting for clear fluids by using the block randomization technique.

1. Group 1- 1hour
2. Group 2- 2 hours

A randomization sequence was kept in an opaque sealed envelope. On the morning of the surgery in the preoperative area, the assistant, not involved in the study opened the sealed envelope and allocated the child into either Group 1 or Group 2. The child was given dextrose containing clear fluid, 1 hour (Group 1) or 2 hours (Group 2) before induction time for a maximum of 3ml/kg. Preoperative anxiety was assessed using the mYPAS scale just before shifting the child to operation theatre (OT). Premedication was given to all patients as per the Institute's protocol - with i.v midazolam (0.025 to 0.05 mg/kg), and i.v ketamine (0.5 mg/kg). After shifting the patient to OT, standard ASA monitoring -including pulse oximetry (SpO₂), Non-invasive arterial blood pressure (NIBP), electrocardiography (ECG) and temperature probe was applied. After recording baseline vital parameters, Inj. Fentanyl 2 µg/kg i.v and Inj. Lidocaine 0.25 mg/kg i.v was given to all patients before induction. General anaesthesia was induced with injection Propofol (1%) 3 mg/kg and after confirmation of mask ventilation, neuromuscular blockade was achieved with Inj Atracurium besylate 0.5 mg/kg. The patient was then intubated with an appropriate size cuffed endotracheal tube. Anaesthesia was maintained with sevoflurane (1-1.2 MAC), Oxygen (FiO₂ 0.50) and air. Depth of anaesthesia was maintained by adjusting the concentration of sevoflurane to achieve a Bispectral Index Score of 40–60. At the end of the surgery, all the patients received i.v paracetamol 15 mg/ kg and ondansetron 0.1 mg/ kg to reduce pain and PONV respectively. The surgeon also administered a surgical site infiltration by Inj. Bupivacaine 0.5% at dose of 2 mg/kg. After the completion of the surgery, anaesthesia

was discontinued and residual neuromuscular blockade was antagonized with Inj. Neostigmine methyl sulfate 0.05 mg/ kg and Inj. Glycopyrrolate 0.01 mg/kg. Once awake, and on return of adequate muscle power, the patient was extubated and shifted to post anaesthesia care unit (PACU). Emergence delirium just after extubation and every 5 min till 30 min postoperatively in PACU were recorded as per PAED scale. FLACC scale was used to assess the severity of pain, if any, which is an important contributing factor for the emergence of delirium. Both ED and pain were monitored at intervals as mentioned in Proforma. The presence or absence of postoperative nausea and vomiting during PACU stay was also noted.

SAMPLE SIZE AND STATISTICAL ANALYSIS PLAN:

The sample size was calculated based on our primary outcome measure i.e, the incidence of emergence delirium. Based on the previous studies Khanna et al¹ and Leila G et al¹⁸ total sample sizes were calculated as 100. Fifty patients in each group would be required at a 5% significance level (α error) and 80% power (1- β). Considering a 10% contingency, the final sample size was 50 participants in each group.

Data were entered into Microsoft Excel and analyzed using SPSS version 21 (IBM Corp. Ltd, Newark, USA). Descriptive statistics were presented in numbers and percentages for categorical variables, mean and standard deviation for continuous variables, and median and inter-quartile range for the ordinal variables. Two independent group variables were compared using the unpaired T-test. Categorical data were analyzed using the Chi-square test or Fischer exact $P < 0.05$ was considered statistically significant.

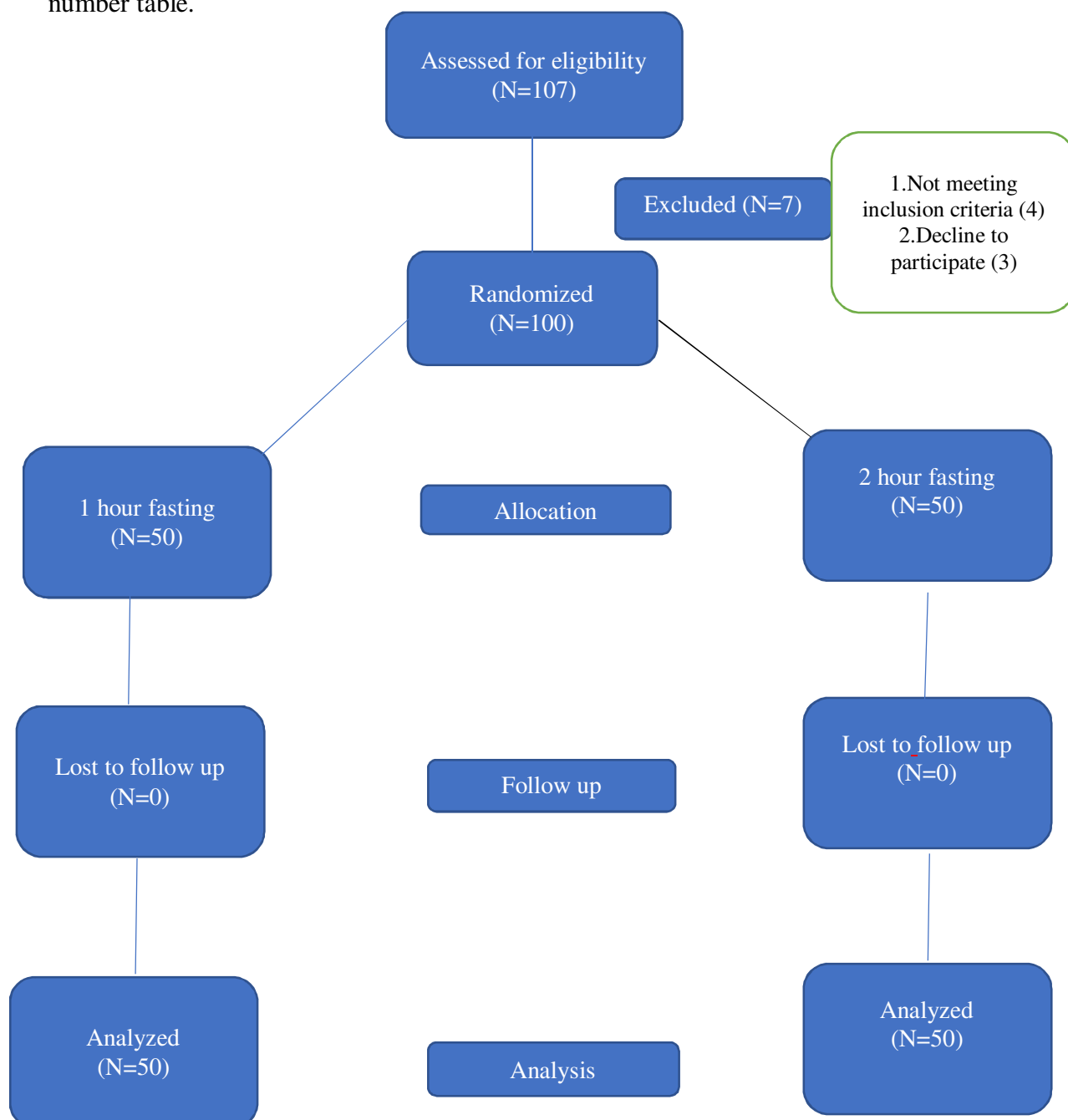
ETHICAL CONSIDERATIONS

- The study is ethical as fasting of 1-2 hours for clear fluids is standard, safe, and widely used.
- Patient comfort will be ensured as
 - i. Clear fluids were given to the child as per his demand irrespective of this protocol.
 - ii. Any incidence of ED as assessed by the PAED scale was treated with dexmedetomidine
 - iii. Pain, as assessed by the FLACC scale was be treated with fentanyl
- Informed written consent was taken from parents and assent from children >7 years in their own language & English.
- They were given full information about the study including the benefits and risks associated with its conduct
- Strict confidentiality about the patient information was maintained.

OBSERVATION & RESULTS

OBSERVATION AND RESULTS

This single-blinded, prospective randomized controlled trial was conducted in the Department of Anesthesiology and Critical Care, AIIMS, Jodhpur on 100 children of age group 2 to 8 years with ASA physical status I or II of either sex. They were randomly divided into two groups, Group 1 of 1-hour fasting for clear fluids and Group 2 of 2 hours fasting for clear fluids, using a computer-generated random number table.



CONSORT FLOW DIAGRAM

TABLE 1: COMPARISON OF GENDER DISTRIBUTION BETWEEN TWO GROUPS

SOCIODEMOGRAPHIC PARAMETER		RANDOM GROUPS				TOTAL NUMBER
		GROUP 1 (N=50)		GROUP 2 (N=50)		
		NUMBER	PERCENT	NUMBER	PERCENT	
GENDER	FEMALE	18	36%	17	34%	35
	MALE	32	64%	33	66%	65

(P-value = 0.833)

In this study, the number of females in Group 1 was 18 (36%) and in Group 2 were 17 (34%). The number of males in -Group1 was 32 (64%) and in group 2 were 33 (66%).

TABLE 2: COMPARISON OF AGE DISTRIBUTION BETWEEN TWO GROUPS

SOCIO- DEMOGRAPHIC PARAMETER	RANDOM GROUP				P-VALUE
	GROUP 1 (N=50)		GROUP 2 (N=50)		
	Median	IQR	Median	IQR	0.143
AGE IN YEARS	2	2.38 – 7.00	3	2.00-6.00	

(P-value by Mann Whitney u test, P =0.143)

In this study, the median age of children in Group 1 was 2 years (2.38-7.00) and for Group 2 was 3 years (2.00-6.00). The distribution of children in each group based on age is **not** statistically significant (**P=0.143**).

TABLE 3: COMPARISON OF PREOPERATIVE ANXIETY BETWEEN THE GROUPS

		GROUPS						P VALUE
		GROUP 1 (N=50)		GROUP 2 (N=50)		TOTAL		
		NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT	
PREOPERATIVE ANXIETY	PRESENT	40	80 %	34	68%	74	74%	0.171
	ABSENT	10	20 %	16	32%	26	26 %	

(Chi-square value 1.87)

Preoperative anxiety is defined as an mYPAS score of more than 30⁴⁷ and was present in 80 % of children who were fasted for 1 hour and 68% of children who were fasted for 2 hours and there is **no** statistically significant difference between the two groups in terms on the presence of anxiety (p-0.171)

TABLE 4: COMPARISON OF ED AT ANY POINT OF TIME BETWEEN TWO GROUPS

		GROUPS						P- VALU E
		GROUP 1 (N=50)		GROUP 2 (N=50)		TOTAL		
		NUMBE R	PERCEN T	NUMBE R	PERCEN T	NUMBE R	PERCEN T	
E D	PRESEN T	14	28%	19	38%	33	33%	0.288
	ABSEN T	36	72%	31	62%	67	67%	

(chi-square value- 1.13), Reative risk-0.737 (0.417-1.30)

In our study, 33 % of children developed emergence delirium of the score more than ≥ 12) at least at any point of time till 30 min after extubation and 67 % did not develop within this particular period.

Out of the total of 33 children who developed ED, 14 children were of Group 1 who fasted for 1 hour, which comprised 42.42% of total children having ED and 19 children of Group 2 which comprises 57.5%

There is **no** statistically significant difference between the two groups in terms of duration of preoperative fasting and incidence of emergence delirium, with **p-value of 0.288**.

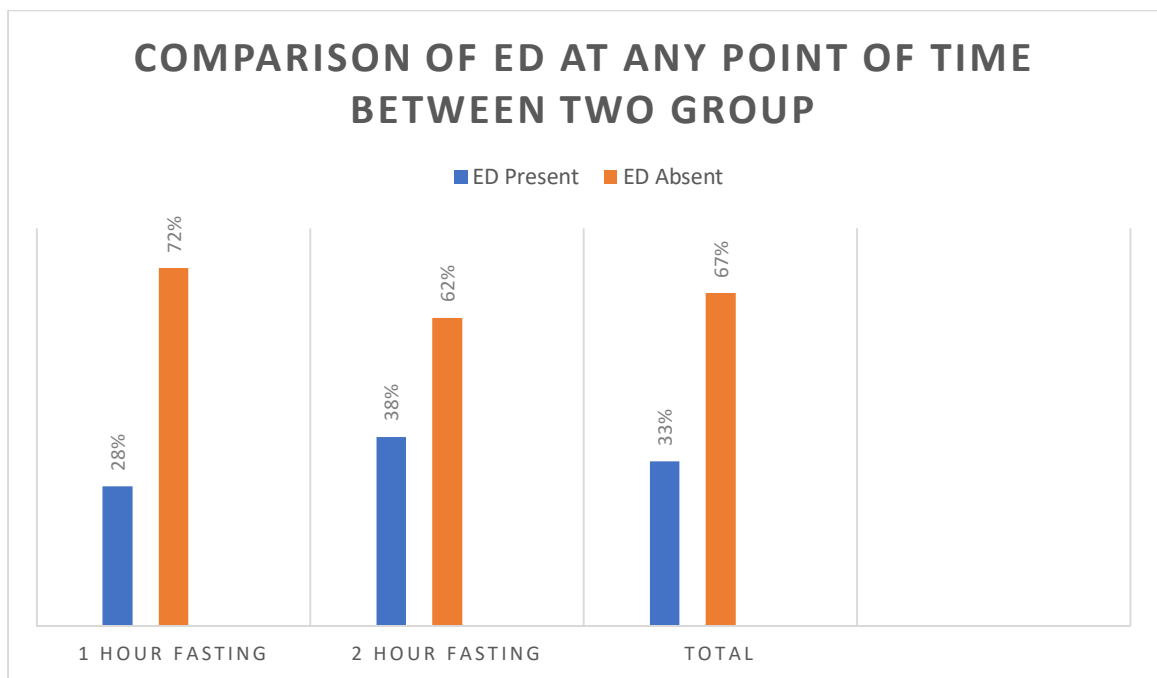


Figure 1

ED was found in 28% of children who had fasted for one hour and 38% of children who had fasted for two hours. ED was found in 33 percent of the children in the study, regardless of how long they had fasted.

TABLE 5: COMPARISON OF TIME OF OCCURRENCE OF ED BETWEEN TWO GROUPS AFTER EXTUBATION AT DIFFERENT TIME INTERVALS

		GROUPS						P-VALUE
		GROUP 1 (N=50)		GROUP 2 (N=50)		TOTAL		
		NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT	
ED AT 0 MIN	ABSENT	39	78%	32	64%	71	71%	0.123
	PRESENT	11	22%	18	36%	29	29%	
ED AT 5 MIN	ABSENT	39	78%	35	70%	74	74%	0.362
	PRESENT	11	22%	15	30%	26	26%	
ED AT 10 MIN	ABSENT	44	88%	40	80%	84	84%	0.275
	PRESENT	6	12%	10	20%	16	16%	
ED AT 15 MIN	ABSENT	44	88%	6	12%	89	89%	0.749
	PRESENT	6	12%	5	10%	11	11%	
ED AT 20 MIN	ABSENT	46	92%	45	90%	91	91%	0.727
	PRESENT	4	8%	5	10%	9	9%	
ED AT 30 MIN	ABSENT	45	90%	45	90%	90	90%	1.00
	PRESENT	5	10%	5	10%	10	10%	

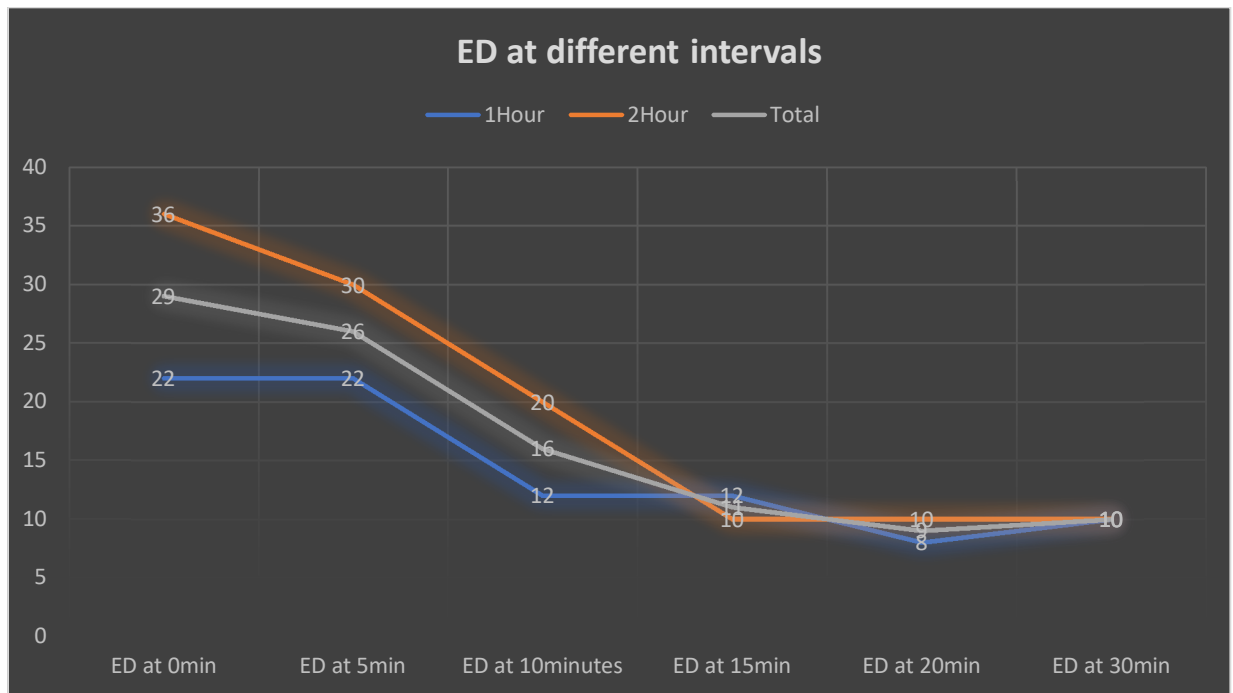


Figure 2

As the time increased after extubation the incidence of emergence delirium was decreased in both the groups and the distribution of Emergence Delirium at variable intervals up to 30 minutes shows **no** statistical relationship between the groups (p-value > 0.05 at all time intervals)

TABLE 6: COMPARISON OF POSTOPERATIVE PAIN BETWEEN TWO GROUPS AFTER EXTUBATION AT ANY POINT OF TIME UP TO 30 MIN

		GROUPS						P- VALU E
		GROUP 1 (N=50)		GROUP 2 (N=50)		TOTAL		
		NUMBE R	PERCEN T	NUMBE R	PERCEN T	NUMBE R	PERCEN T	0.405
POSTO P PAIN	YE S	30	60%	34	68%	64	64%	
	NO	20	40%	16	32%	36	36%	

(P-value is calculated by chi-square with value 0.694)

Post-op pain is defined as FLACC score ≥ 4 . In group 1 60% of children had post-op pain while in Group 2 was 68%. Postoperative pain was higher in group 2 but there is **no** statistically significant difference in incidence of postoperative pain due to of preoperative duration of fasting for clear fluids in two groups as the **p-value was (0.405)** calculated by chi-square.

TABLE 7:COMPARISON OF PONV BETWEEN 2 GROUPS

		GROUPS					
		GROUP 1 (N=50)		GROUP 2 (N=50)		TOTAL	
		NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT
PONV	YES	9	18%	11	22%	20	20%
	NO	41	82%	39	78%	80	80%

(P value (0.616) by chi square test value 0.250)

In our study, 22% of children who fasted for 2 hours developed PONV as compared to 18 % of children who fasted for 1 hour but there is **no** statistically significant difference in the incidence of PONV between the two groups.

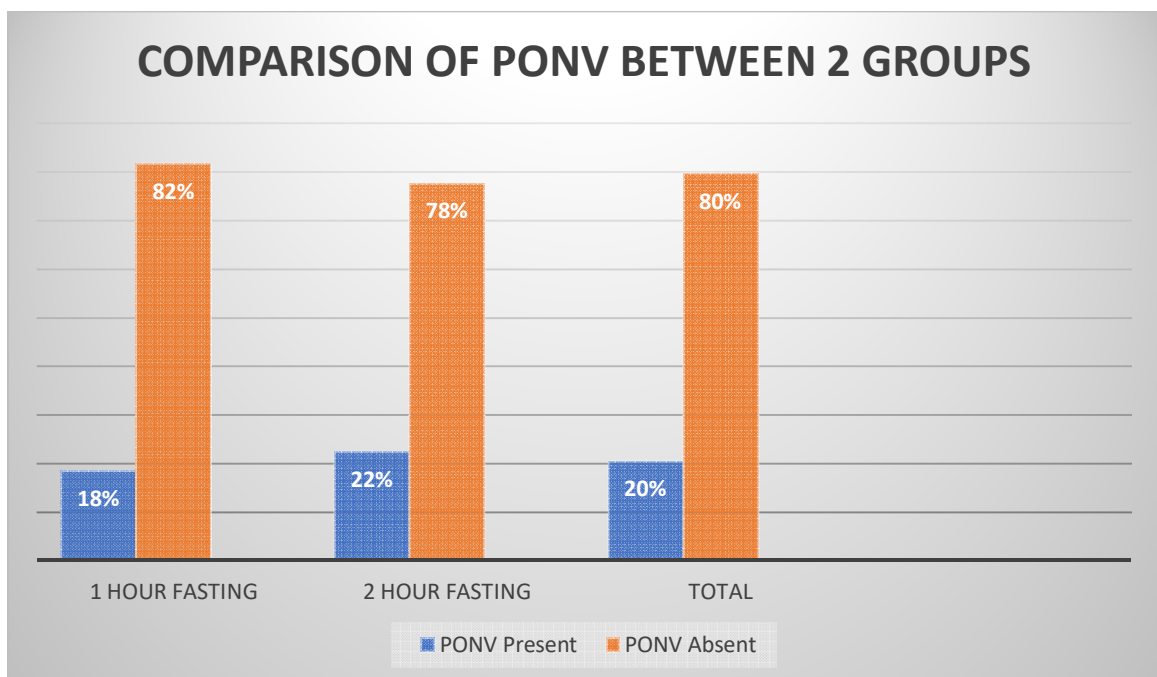


Figure 3

TABLE 8: COMPARISON OF USE OF INJ FENTANYL BETWEEN 2 GROUPS

		GROUPS					
		GROUP 1 (N=50)		GROUP 2 (N=50)		TOTAL	
		NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT
INJ FENTANYL	GIVEN	7	14%	6	12%	13	13%
	NOT GIVEN	43	86%	44	88%	87	87%

(chi-square value-(0.0884), P-VALUE 0.766)

In our study 14% of children who fasted for 1 hour preoperatively received fentanyl of 0.5 mcg/kg within 30 minutes post-extubation and 12 % of children of fasted for 2 hours received the same dose. There were no statistically significant differences between fentanyl requirement between 2 groups with a p-value of 0.766 obtained via chi-square test.

TABLE 9: COMPARISON OF DURATION OF PACU STAY WITH ED AT ANY POINT OF TIME AFTER EXTUBATION UP TO 30 MINUTES

	ED				
	Absent		Present		p-value
	Median	IQR	Median	IQR	
Duration of PACU stay	45	40-60	60	52.5-80	0.002

(p-value calculated using Mann Whitney U test)

There was a statistically significant relation of incidence of emergence delirium with the prolonged duration of PACU stay with a **p-value of 0.002**.

**TABLE 10: COMPARISON OF AGE VARIATION WITH EMERGENCE
DELIRIUM**

	ED				
	Absent		Present		P-value
	Median	IQR	Median	IQR	
Age of the patients	4	2-6	4	2-7	0.621

(P-value calculated using Mann Whitney U test)

Emergence delirium was present in children with a median age of 4 (2-7) and was absent in median age of 4 (2-6). There was no relation between age distribution and incidence of ED with a P-value of 0.621.

TABLE 11: COMPARISON OF ED ACCORDING TO POST-OPERATIVE PAIN

		GROUPS						P- VAL UE
		ED PRESENT		ED ABSENT		TOTAL		
		NUMB ER	PERCE NT	NUMB ER	PERCE NT	NUMB ER	PERCE NT	0.086
POSTOPERA TIVE PAIN	YE S	25	75.8%	39	41.8%	64	%64	
	NO	8	24.2%	28	58.2%	36	%36	

(p-value is calculated by chi-square test,)

Emergence delirium was present in 75.8 %of the patient who was having postoperative pain at any point of time up to 30 min post-extubation. The relation of pain and ED was not statistically significant with a p-value of (0.086)

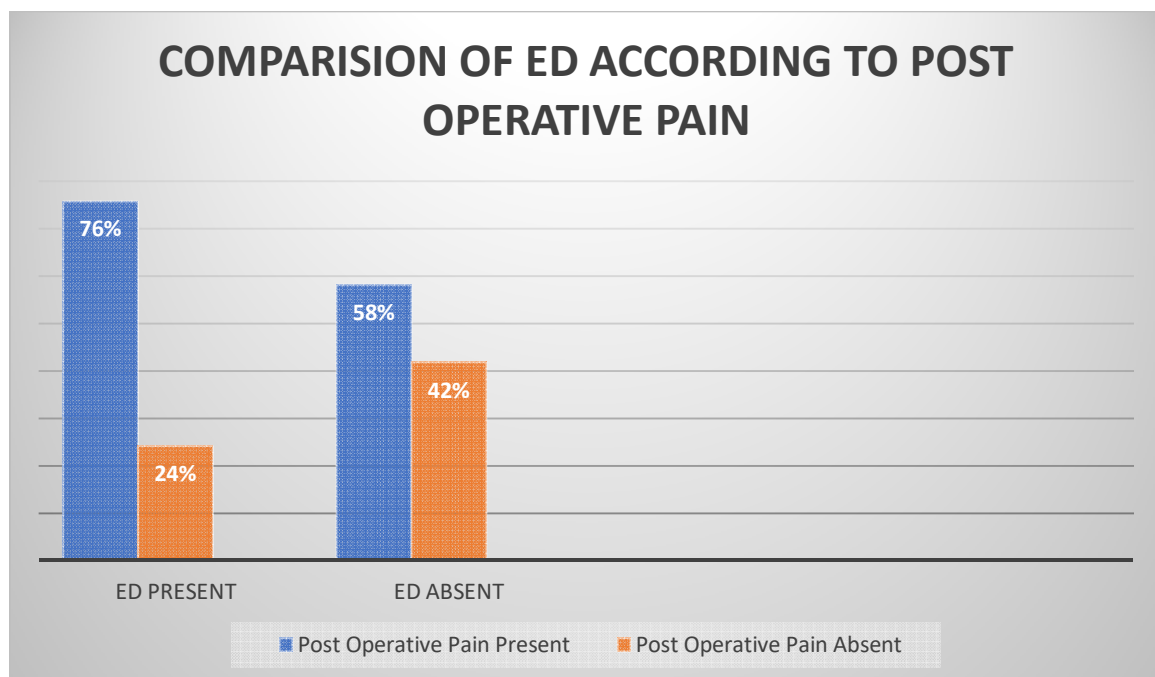


Figure 4

DISCUSSION

DISCUSSION

Preoperative fasting should be adequate in patients who are undergoing surgery to avoid pulmonary aspiration. However, prolonged fasting has adverse effects as well, especially in the pediatric age group. In practice, children posted for routine surgeries are suffering from prolonged fasting because for many reasons like parents are afraid of getting cancellation of the elective surgery or the sequence of the list is altered. Hence, it becomes important to avoid prolonged fasting to prevent its postoperative complications.

According to previous literature, prolonged preoperative fasting has an unfavorable effect. (**Thomas Engelhard et al**⁴⁸. and **Torabikhah et al**⁴⁵.). The European preoperative fasting guidelines endorsed these studies, stating that preoperative fasting for clear fluids in children should be limited to one hour. **Rosen et al**³⁸ also suggested keeping preoperative fasting for clear fluids up to 1 hour. In our study, the results have revealed that there was no difference in the emergence delirium as seen in the study by **Suleyman Yalcin et al**. The two research groups in our study agree well with the study groups in **Schmidt et al's**⁶ research comparing stomach pH and volume. In paediatric patients aged 1 to 16 years, they observed that there was no statistically significant change in gastric pH and gastric volume between the 1-hour and 2-hour fasting groups for clear fluids.

There are multiple studies conducted to find out risk factors of emergence delirium and compared different risk factors with ED. But, as per best of our knowledge, there was no study to compare the duration of preoperative fasting of 1 hour and 2 hours with ED in children undergoing General anesthesia. Only one research **Khanna P et al**. investigated the effect of preoperative fasting duration on the emergence of delirium in patients undergoing ophthalmic examination under GA. It was a prospective observational study, 24 % of the children developed ED as evident by PAED score of more than 10 at any point of time and there was a significant correlation of preoperative fasting duration with incidence of ED. However, in our study, there was no statistically significant relation between different duration of fasting and Emergence delirium at any point in time. Our study revealed a statistically significant difference between the occurrence of ED with prolonged PACU stay which corroborates with the findings of the study done by **Voepel-Lewis et al**³. In our study, we had given clear fluid 1 hour before surgery in one group similarly there was a study conducted by **Andersson et al**³⁶ in which they introduced the 6-4-0 rule instead of 6-4-2 so

that the median duration of fasting decreased from 4 hours to 1 hour thereby they could avoid extended fasting in children. We administered midazolam in both groups to avoid confounding factors as midazolam will decrease the emergence of delirium similar to a meta-analysis conducted by **Zhang et al**³⁸ concluded that prophylactic administration of midazolam or clonidine could significantly decrease the incidence of sevoflurane-induced EA in pediatric patients which includes 12 papers with 447 children. We also compared preoperative anxiety using the Modified Yale preoperative anxiety Scores between 2 groups. a score of more than 30 was considered as the presence of anxiety⁴⁷. In our study, 80 % of children had anxiety in the 1-hour group instead of 68% in the 2-hour group which was not statistically significant and is contradictory to the study conducted by **Rosen D et al**³⁸ in which they observed less anxiety with less duration of fasting.

Post-operative pain is one of the common sufferings in children in the post-operative care unit which children are not able to express. There are many risk factors like preoperative anxiety, prolonged fasting, etc. proposed in the literature and their correlation pain was available.

In our study, we compared preoperative fasting duration with postoperative pain after extubation up to 30 minutes as pain and emergence delirium present similarly. So validated scales were used to differentiate between the two. We used the PAED scale for ED and FLACC scale for postoperative pain. We found that postoperative pain was higher in group 2 compared to group 1 but it was not statistically significant, which is contradictory to the study conducted by **Klemetti et al**²³. who conducted a study to see the effect of preoperative fasting duration on postoperative pain and PONV. They found that there was a decreased incidence of postoperative pain in the group that were given liberal fluids preoperatively by counseling and was statistically significant.

CONCLUSION & RECOMMENDATION

CONCLUSION

There was no difference in the incidence of emergence delirium in children undergoing surgeries under general anaesthesia depending on whether they fasted for one or two hours before surgery. Similarly, there was no difference between the two groups in terms of postoperative pain and PONV. However, patients having ED had a prolonged PACU stay.

RECOMMENDATION

One-hour and 2-hour preoperative fasting for clear fluids is equally effective.

LIMITATION

1. We did not correlate one- and two-hour of preoperative fasting with a greater duration of fasting, with ED.
2. We have generalized our study population and have not categorized patients according to the type of surgery.
3. It is difficult to distinguish the immediate post-operative irritability in children due to pain or ED.

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BIBLIOGRAPHY

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ANNEXURES

ANNEXURE 10
MASTER CHART

ANNEXURE 1

INFORMED CONSENT FROM

Title of Thesis/Dissertation :

EFFECT OF DURATION OF PREOPERATIVE FASTING ON THE INCIDENCE OF EMERGENCE DELIRIUM IN PAEDIATRIC PATIENTS DURING RECOVERY FROM GENERAL ANESTHESIA: A RANDOMIZED CONTROLLED TRIAL.

Name of PG Student : Dr. Anas V P MOB No. 9995004968

Patient/Volunteer Identification No. : _____

I, _____ S/o or D/o _____

R/o _____

Give my full, free, voluntary consent to be a part of the study "EFFECT OF DURATION OF PREOPERATIVE FASTING ON THE INCIDENCE OF EMERGENCE DELIRIUM IN PAEDIATRIC PATIENTS DURING RECOVERY FROM GENERAL ANESTHESIA: A RANDOMIZED CONTROLLED TRIAL" the procedure and nature of which has been explained to me in my own language to my satisfaction. I confirm that I have had the opportunity to ask questions.

I understand that my participation is voluntary and am aware of my right to opt-out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individual from _____ (Company Name) or from regulatory authorities. I permit these individuals to have access to my records.

Date : _____

Place : _____ Signature/Left thumb impression

This is to certify that the above consent has been obtained in my presence.

Date : _____

Place : _____ Signature of PG Student

Witness 1

Signature

Name: _____

Address : _____

Witness 2

Signature

Name: _____

Address : _____

ANNEXURE 2

All India Institute of Medical Sciences

Jodhpur, Rajasthan

ऑल इंडिया इंस्टिट्यूट ऑफ मेडिकल साइंसेस

जोधपुर, राजस्थान

सूचित सहमति प्रपत्र

थीसिस/निबंध का शीर्षक: "EFFECT OF DURATION OF PREOPERATIVE FASTING ON THE INCIDENCE OF EMERGENCE DELIRIUM IN PAEDIATRIC PATIENTS DURING RECOVERY FROM GENERAL ANESTHESIA: A RANDOMIZED CONTROLLED TRIAL" पीजी छात्र का नाम: डॉ. अनस वी पी No 9995004968 रोगी/स्वयं सेवक पहचान संख्या: _____

मैं, _____ एस / ओयाडी / ओ _____
आर / ओ _____

अध्ययन के एक भाग होने के लिए मेरी पूर्ण, स्वतंत्र, स्वेच्छिक सहमति दें सामान्य संज्ञाहरण से प्राप्त होने वाले "EFFECT OF DURATION OF PREOPERATIVE FASTING ON THE INCIDENCE OF EMERGENCE DELIRIUM IN PAEDIATRIC PATIENTS DURING RECOVERY FROM GENERAL ANESTHESIA: A RANDOMIZED CONTROLLED TRIAL" प्रक्रिया और प्रकृति जिसकी मुझे स्वयं में समझाया गया है मेरी पूरी संतुष्टि के लिए भाषा में पुष्टि करता हूं कि मुझे प्रश्न पूछने का अवसर मिला है। मैं समझता हूं कि मेरी भागीदारी स्वेच्छिक है और मुझे किसी भी कारण दिए बिना किसी भी समय अध्ययन से बाहर निकलने के मेरे अधिकार की जानकारी है।

मैं समझता हूं कि मेरे और मेरे मेडिकल रिकॉर्ड के बारे में एकत्रित की गई जानकारी को (कंपनी नाम) या विनियामक प्राधिकरणों से जिम्मेदार व्यक्ति द्वारा देखा जा सकता है। मैं इन लोगों के लिए मेरे रिकॉर्डों तक पहुंच की अनुमति देता हूं

तारीख : _____

जगह: _____ हस्ताक्षर / बाएं अंगूठे का छाप

यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त की गई है

तारीख : _____

जगह: _____ पीजी छात्र के हस्ताक्षर

गवाह 1

गवाह 2

हस्ताक्षर

नाम:

पता:

हस्ताक्षर

नाम:

पता

ANNEXURE 3
PATIENT INFORMATION SHEET

Patient name:

Patient id:

Title of study:

EFFECT OF DURATION OF PREOPERATIVE FASTING ON THE INCIDENCE OF EMERGENCE DELIRIUM IN PAEDIATRIC PATIENTS DURING RECOVERY FROM GENERAL ANESTHESIA: A RANDOMIZED CONTROLLED TRIAL.

Purpose of study: To find the incidence of emergence delirium in the PAEDIATRIC patient

Study design: SINGLE BLINDED RCT

Benefits of the study to the patients: reduced HDU stay and avoiding unnecessary fasting

Any potential risks to the participants: none

Details of the candidate with phone number: Dr. Anas V P

9995004968

Junior resident in Anesthesiology & Critical Care

AIIMS Jodhpur

ANNEXURE 4

रोगी सूचना पत्रक

रोगी का नाम:

रोगी आईडी:

अध्ययन का शीर्षक “EFFECT OF DURATION OF PREOPERATIVE FASTING ON THE INCIDENCE OF EMERGENCE DELIRIUM IN PAEDIATRIC PATIENTS DURING RECOVERY FROM GENERAL ANESTHESIA: A RANDOMIZED CONTROLLED TRIAL”

अध्ययन का उद्देश्य: बालरोगी रोगी में उभरता भ्रूण की घटनाओं को खोजने के लिए

अध्ययन डिजाइन: आरसीटी

मरीजों के अध्ययन के लाभ: एचडीयू को कम करें और अनावश्यक उपवास से बचें

प्रतिभागियों को कोई भी संभावित जोखिम: कोई नहीं

फोन नंबर वाले उम्मीदवार का विवरण: डॉ अनस वी पी

पीजी अनैथीसिओलॉजी और क्रिटिकल केयर

एम्स जोधपुर

No 9995004968

ANNEXURE 5
PATIENT INFORMATION SHEET

1. Risks to the patients: No interventions or life-threatening procedures will be done.
2. Confidentiality: Your participation will be kept confidential. Your medical records will be treated with confidentiality and will be revealed only to doctors/ scientists involved in this study. The results of this study may be published in a scientific journal, but you will not be identified by name.
3. Provision of free treatment for research-related injury. Not applicable.
4. Compensation of subjects for disability or death resulting from such injury: Not Applicable
5. Freedom of the individual to participate and to withdraw from the research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
6. You have complete freedom to participate and to withdraw from the research at any time without penalty or loss of benefits to which you would otherwise be entitled.
7. Your participation in the study is optional and voluntary.
8. The copy of the results of the investigations performed will be provided to you for your record.
9. You can withdraw from the project at any time, and this will not affect your subsequent medical treatment or relationship with the treating physician.
10. Any additional expense for the project, other than your regular expenses, will not be charged from you.

ANNEXURE 6

रोगीसूचनापत्रक

1. रोगियों के लिए जोखिम: कोई हस्तक्षेप या जीवन-धमकी प्रक्रिया नहीं की जाएगी।
2. गोपनीयता: आपकी भागीदारी को गोपनीय रखा जाएगा। आपके मेडिकल रिकॉर्ड को गोपनीयता के साथ इलाज किया जाएगा और केवल इस अध्ययन में शामिल डॉक्टरों / वैज्ञानिकों को पता चलेगा। इस अध्ययन के परिणाम एक वैज्ञानिक पत्रिका में प्रकाशित हो सकते हैं, लेकिन आपको नाम से पहचाना नहीं जाएगा।
3. अनुसंधान संबंधी चोट के लिए निःशुल्क उपचार की व्यवस्था लागू नहीं।
4. ऐसी चोट से उत्पन्न विकलांगता या मृत्यु के लिए विषयों का मुआवजा: लागू नहीं है
5. किसी भी समय दंड या लाभों के नुकसान के बिना किसी भी समय भाग लेने के लिए व्यक्ति को स्वतंत्रता लेने और अनुसंधान से वापस लेने के लिए स्वतंत्रता, जिस के तहत विषय अन्यथा हकदार होगा
6. आपको जुर्माना या लाभ के नुकसान के बिना किसी भी समय भाग लेने और अनुसंधान से वापस लेने की पूरी आजादी है, जिस पर आप अन्यथा हकदार होंगे।
7. अध्ययन में आपकी भागीदारी वैकल्पिक और स्वैच्छिक है।
8. प्रदर्शन की जांच की परिणामों की प्रति आपके रिकॉर्ड के लिए आपको उपलब्ध कराई जाएगी।
9. आप किसी भी समय परियोजना से वापस ले सकते हैं, और यह आपके बाद के चिकित्सा उपचार या उपचार चिकित्सक के साथ संबंध को प्रभावित नहीं करेगा।
10. परियोजनाकेलिएकोईभीअतिरिक्तव्यय, आपकेनियमितखर्चोंकेअलावा, आपसे शुल्क नहीं लिया जाएगा।

ANNEXURE 7

MODIFIED YALE PREOPERATIVE ANXIETY scale

A. Activity

- 1 = Looking around, curious, playing with toys, reading (or other age-appropriate behavior); moves around holding area/treatment room to get toys or go to parent; may move toward OR equipment
- 2 = Not exploring or playing, may look down, may fidget with hands or suck thumb (blanket); may sit close to the parent while waiting, or play has a definite manic quality
- 3 = Moving from toy to parent in an unfocused manner, nonactivity-derived movements; frenetic/frenzied movement or play; squirming, moving on table, may push mask away or cling to the parent
- 4 = Actively trying to get away, pushes with feet and arms may move the whole body; in the waiting room, running around unfocused, not looking at toys, or will not separate from the parent, desperate clinging

B. Vocalizations

- 1 = Reading (nonvocalizing appropriate to activity), asking questions, making comments, babbling, laughing, readily answers questions but maybe generally quiet; child too young to talk in social situations or too engrossed in play to respond
- 2 = Responding to adults but whispers, “baby talk,” only head nodding
- 3 = Quiet, no sounds or responses to adults
- 4 = Whimpering, moaning, groaning, silently crying
- 5 = Crying or maybe screaming “no”
- 6 = Crying, screaming, sustained (audible through mask)

C. Emotional expressivity

- 1 = Manifestly happy, smiling, or concentrating on the play
- 2 = Neutral, no visible expression on the face
- 3 = Worried (sad) too frightened, sad, worried, or tearful eyes
- 4 = Distressed, crying, extreme upset, may have wide eyes

D. State of apparent arousal

- 1 = Alert, looks around occasionally, notices/watches what anesthesiologist does with him/her (could be relaxed)
- 2 = Withdrawn, child sitting still and quiet maybe sucking
on thumb or face turned into an adult
- 3 = Vigilant, looking quickly all around, may startle to sounds, eyes wide, body tense
- 4 = Panicked whimpering, maybe crying or pushing others away turn away

Scoring: Divide each item rating by the highest possible rating (i.e., 6 for the “vocalizations” item and 4 for all other items), add all of the produced values, divide by 4 and multiply by 100.

More than 30: anxiety present

Less than or equal to 30: anxiety absent

ANNEXURE 8

PAEDIATRIC ANAESTHESIA EMERGENCE DELIRIUM SCORE (PAEDS)

Behavior	Not all	at Just a bit	Quite a bit	Very much	Extremely
Makes eye contact with care giver	4	3	2	1	0
Purposeful actions	4	3	2	1	0
Aware of surroundings	4	3	2	1	0
Restless	0	1	2	3	4
Inconsolable	0	1	2	3	4

Scores above or equal to 12 will be considered ED

FLACC BEHAVIOURAL SCALE

	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Unease, restless, tense	Kicking or legs were drawn up
Activity	Lying quietly, normal position moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, the occasional complaint	Crying steadily, screams or sobs, frequent complaints
Controllability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to, distractable	Difficult

0-3: minimal/no pain

>_4 : pain present

ANNEXURE 9

PROFORMA

S.No.

Date:

±

THESIS TITLE: EFFECT OF DURATION OF PREOPERATIVE FASTING ON THE INCIDENCE OF EMERGENCE DELIRIUM IN PAEDIATRIC PATIENTS DURING RECOVERY FROM GENERAL ANESTHESIA: A RANDOMIZED CONTROLLED TRIAL.

IPD Serial no:

Sticker:

Age/Sex:

Weight :

ASA1/II:

Type of Surgery:

Duration of Surgery:

Preoperative anxiety score:

Postoperative nausea and vomiting: Yes/No

After extubation	0 mins	5 mins	10 mins	15 mins	20 mins	30mins
PAED Score						
FLACC score						

Modified Yale Preoperative anxiety scale

A. Activity

1 = Looking around, curious, playing with toys, reading

(or other age-appropriate behavior); moves around

holding area/treatment room to get toys or go to parent;

may move toward OR equipment

2 = Not exploring or playing, may look down, may fidget

with hands or suck thumb (blanket); may sit close to the parent

while waiting, or play has a definite manic quality

3 = Moving from toy to parent in an unfocused manner,

nonactivity-derived movements; frenetic/frenzied movement or play; squirming, moving on table, may push mask away or cling to the parent

4 = Actively trying to get away, pushes with feet and arms may move the whole body; in the waiting room, running around unfocused, not looking at toys, or will not separate from the parent, desperate clinging

B. Vocalizations

1 = Reading (nonvocalizing appropriate to activity), asking questions, making comments, babbling, laughing, readily answers questions but maybe generally quiet; child too young to talk in social situations or too engrossed in play to respond

2 = Responding to adults but whispers, “baby talk,” only head nodding

3 = Quiet, no sounds or responses to adults

4 = Whimpering, moaning, groaning, silently crying

5 = Crying or maybe screaming “no”

6 = Crying, screaming, sustained (audible through mask)

C. Emotional expressivity

1 = Manifestly happy, smiling, or concentrating on the play

2 = Neutral, no visible expression on the face

3 = Worried (sad) too frightened, sad, worried, or tearful eyes

4 = Distressed, crying, extreme upset, may have wide eyes

D. State of apparent arousal

1 = Alert, looks around occasionally, notices/watches what anesthesiologist does with him/her (could be relaxed)

2 = Withdrawn, child sitting still and quiet maybe sucking on thumb or face turned into an adult

3 = Vigilant, looking quickly all around, may startle to sounds, eyes wide, body tense

4 = Panicked whimpering, maybe crying or pushing others away turn away

Scoring: Divide each item rating by the highest possible rating (i.e., 6 for the “vocalizations” item and 4 for all other items), add all of the produced values, divide by 4 and multiply by 100.

Paediatric Anaesthesia Emergence Delirium Score (PAEDS)

<i>Behavior</i>	<i>Not at all</i>	<i>Just a bit</i>	<i>Quite a bit</i>	<i>Very much</i>	<i>Extremely</i>
<i>Makes eye contact with care giver</i>	4	3	2	1	0
<i>Purposeful actions</i>	4	3	2	1	0
<i>Aware of surroundings</i>	4	3	2	1	0
<i>Restless</i>	0	1	2	3	4
<i>Inconsolable</i>	0	1	2	3	4

FLACC behavioural scale

	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, clenched, jaw, quivering chin
Legs	Normal position or relaxed	Unease, restless, tense	Kicking or legs were drawn up
Activity	Lying quietly, normal position moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Activity	Lying quietly, normal position moves	Squirming, shifting back and forth, tense	Arched, rigid, or jerking

	easily		
Cry	No cry (awake or asleep)	Moans or whimpers, the occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to, distractable	Difficult

0-3: minimal/no pain

>_4 : pain present

Vitals at the time of recovery from Anaesthesia:

Inj. Fentanyl at the time of Recovery (0.5mcg/kg) if FLACC Scale is >4:

PONV: Yes / No

Pain at emergence: Yes / No

Recall of events: Yes / No

Duration of HDU stay:

Dr. ANAS V P

Dr. SHILPA GOYAL

(candidate)

(guide)

ANNEXURE 10

MASTER CHART

S.NO	DATE	NAME	AGE	SEX	HOSPITAL ID	WEIGHT (KG)	ASA GRADE	TYPE OF SURGERY	DURATION OF SURGERY (MIN)	PREOPERATIVE ANXIETY SCORE (mYPAS)	PONV (YES/NO)	HOURS OF FASTING	PAED SCORE AFTER EXTUBATION						FLACC SCORE AFTER EXTUBATION						VITALS AT THE TIME OF RECOVERY FROM GA			INI FENTANYL AT THE TIME OF RECOVERY IF FLACC >4				DURATION OF HDU STAY (MIN)		
													0 MIN	5 MIN	10 MIN	15 MIN	20 MIN	30 MIN	0 MIN	5 MIN	10 MIN	15 MIN	20 MIN	30 MIN	PR	BP(MMHG)	SPO2(%)	YES/NO						
1	08/06/2020	SAKSHI	4 YEAR	F	AIIMS/DH/2020/02/013488	14		1 LAPAROSCOPIC ABDOMINAL HYSTERECTOMY+VAGINECTOMY	180	33.3	YES		2	10	8	8	8	4	4	4	4	4	3	3	4	118/98/68	98		NO				45	
2	08/11/2020	SUBHASH RAM	3 YEAR	M	AIIMS/DH/2017/08/007630	12		1/B/L URETERESTOMY	120	22.75	NO		2	8	8	6	7	7	7	3	3	2	2	0	0	108/100/60	99		NO				30	
3	08/11/2020	YUKTI	7 YEAR	F	AIIMS/DH/2020/07/004473	20		1 LAPAROSCOPIC LEFT PNELOPLASTY	120	22.75	NO		2	12	10	10	8	8	8	4	4	4	3	2	2	124/110/78	99		NO				60	
4	14/08/2020	HEMI	6 YEAR	F	AIIMS/DH/2020/08/002972	18		1 LAPAROSCOPIC VESICULITHOMY	90	29	NO		1	10	10	8	8	8	6	5	3	3	3	2	1	112/106/60	99		NO				30	
5	26/08/2020	DIVYANSHI	5 YEAR	F	AIIMS/DH/2020/03/009708	16		2 LEFT THORACOSCOPIC GANGLIONEUROMA EXCISION	120	35.25	NO		2	14	12	12	12	10	10	4	4	4	4	4	4	138/124/64	94		NO				90	
6	14/09/2020	MANJEET	6 YEAR	M	AIIMS/DH/2020/09/004998	16.5		1 LAPAROSCOPIC APPENDICECTOMY	60	22.75	YES		2	12	12	10	8	8	8	3	2	2	1	1	1	98/100/70	97		NO				30	
7	22/09/2020	BHUPENDRA	7 YEARS	M	AIIMS/DH/2018/11/008253	20		1 LAPAROSCOPIC APPENDICECTOMY	60	29	YES		2	10	10	8	8	8	7	3	2	2	0	0	0	86/120/86	97		NO				30	
8	10/06/2020	IMRAN	3 YEARS	M	AIIMS/DH/2020/06/004415	12		1 OPEN PNET EXCISION	180	35.25	YES		2	14	12	12	10	8	8	4	4	4	3	3	3	134/110/56	97		NO				30	
9	10/07/2020	ADIRAJ	5 YEARS	M	AIIMS/DH/2020/09/010173	17.5		2 CYSTOSCOPY FOR B/L VUR	60	29	NO		1	10	8	8	6	6	6	3	3	2	1	1	1	84/100/60	99		NO				30	
10	10/09/2020	KULDEEP	8 YEARS	M	AIIMS/DH/2020/10/000440	22.5		1 CRIF WITH K WIRE OF # DER	60	35.25	YES		1	14	12	10	8	8	8	5	4	4	3	3	3	126/124/68	99		YES				60	
11	13/10/2020	SAKSHI	4 YEARS	F	AIIMS/DH/2020/02/013488	10		2 O/C/O VAGINAL RMS WITH HDUN FOR DJ STENTING	60	35.25	YES		2	14	12	12	10	10	10	8	4	4	3	3	2	2	116/110/64	98		NO				60
12	13/10/2020	B/O NAZIYA	2 YEARS	F	AIIMS/DH/2018/12/002811	9.5		1 GASTRIC PULL UP FOR ESOPHAGEAL ATRESIA	240	33.3	YES		1	12	12	10	10	10	8	5	5	4	4	4	4	136/132/82	97		YES				40	
13	13/10/2020	NISANT	2 YEARS	M	AIIMS/DH/2020/08/009954	11		1 RIGHT RADICAL NEPHRECTOMY FOR WILMS TUMOUR	120	35.25	YES		1	10	10	10	10	8	8	4	4	4	3	3	2	120/138/67	98		NO				60	
14	13/10/2020	VIKRAM	8 YEARS	M	AIIMS/DH/2020/10/002016	22		1 POST ELECTRIC BURN OF UL -DEBRIDMENT AND SSG	120	35.25	YES		1	14	12	12	12	10	10	5	5	5	4	4	3	140/136/56	98		YES				60	
15	14/10/2020	BHAVESH KAUR	6 YEAR	M	AIIMS/DH/2017/09/002734	20		1 O/C/O RMS WITH HDUN FOR DJ STENTING	60	29	NO		1	8	6	6	6	6	6	3	3	2	2	2	0	100/110/54	99		NO				30	
16	14/10/2020	BABY OF SANJU	2 YEARS	M	AIIMS/DH/2019/08/018013	8		1 EPISPADIAS REPAIR	60	33.3	NO		1	10	8	8	6	6	6	4	3	3	2	2	1	130/118/48	99		NO				30	
17	21/10/2020	HARSHITA	5 YEARS	F	AIIMS/DH/2020/10/001644	18		1 LAPAROSCOPIC CHOLEDOCHAL CYST REPAIR	180	33.3	NO		1	10	8	10	8	8	8	3	2	2	2	2	1	112/126/74	98		NO				45	
18	21/10/2020	VIVEK NAYAK	8 YEARS	M	AIIMS/DH/2020/09/000656	21		1 RESECTION AND ANASTOMOSIS OF ESOPHAGEAL STRICTURES	240	77.3	YES		2	12	12	12	12	12	12	4	4	4	3	3	3	124/100/64	94		NO				60	
19	22/10/2020	DHAPU	5 YEARS	M	AIIMS/DH/2020/10/002293	16		1 OPEN RIGHT NEPHRECTOMY	180	89.5	YES		2	12	12	10	10	10	10	12	3	3	3	3	3	138/110/68	97		NO				60	
20	23/10/2020	TARUSH	5 YEARS	M	AIIMS/DH/2010/06/002051	15		1 MODIFIED SISTRUNG OPERATION	60	72.9	NO		2	12	12	10	10	10	12	12	4	3	4	4	4	112/100/74	96		NO				60	
21	29/10/2020	TANUSHREE	8 YEARS	F	AIIMS/DH/2020/09/002177	19.5		1 LAP CHOLEDOCHAL CYST EXCISION	60	35.25	NO		2	12	12	12	12	12	12	3	3	2	1	1	1	100/96/65	95		NO				45	
22	29/10/2020	SARITA	8 YEARS	F	AIIMS/DH/2020/09/005656	20		1 LAP OVARIAN CYSTECTOMY	60	35.25	NO		1	10	10	10	10	10	10	3	2	2	2	2	1	86/105/68	98		NO				30	
23	11/05/2020	DRASHTI	2.5 YEARS	F	AIIMS/DH/2020/06/001734	20		1 CHEMOPORT INSERTION	60	77.3	NO		1	14	12	12	12	12	12	4	3	3	3	3	3	114/116/76	97		NO				30	
24	11/05/2020	DINESH KUMAR	8 YEARS	M	AIIMS/DH/2020/10/006560	22		1 LAPPYLOPLASTY	120	77.3	NO		1	12	12	12	12	12	12	3	3	3	3	3	3	98/108/54	96		NO				30	
25	11/10/2020	SONU	5 YEARS	M	AIIMS/DH/2020/07/002950	17.5		1 CYSTOSCOPY FOR OPERATED CASE OF BLADDER EXTROTROPH	60	89.5	NO		1	12	12	12	12	12	12	3	3	3	3	3	3	96/118/45	96		NO				30	
26	11/11/2020	KALI BANO	3 YEARS	F	AIIMS/DH/2020/08/001613	12		1 RIGHT NEPHROURETERCTOMY	120	95	NO		2	0	12	12	10	8	8	0	8	6	6	6	6	4	96/104/57	96		YES				90
27	11/10/2020	SARASWATI	2 YEARS	F	AIIMS/DH/2019/05/002479	8.5		1 REDO PSARP	120	35.2	NO		1	12	12	12	12	10	12	3	3	3	2	1	1	126/90/60	96		NO				40	
28	17/11/2020	RAKSHITA	4 YEARS	F	AIIMS/DH/2019/06/015225	14.5		1 STOMA CLOSURE OF GRADE 4 PERINEAL INJURY	90	95.83	NO		1	12	12	12	12	12	12	4	3	2	0	0	0	78/87/54	97		NO				40	
29	17/11/2020	DEEPAK	5 YEARS	M	AIIMS/DH/2020/11/003455	15.5		1 LAP HERNIOTOMY OF LEFT SIDE	100	77.3	NO		1	10	8	8	8	8	8	2	2	2	2	2	2	84/92/44	96		NO				45	
30	11/12/2020	MUBARAK	4 YEARS	M	AIIMS/DH/2020/05/000549	18.5		1 LEFT STAG HORN CALCULUS DJ STENT REMOVAL	60	35.25	NO		1	8	6	6	6	6	6	5	3	2	2	2	0	86/80/42	99		NO				45	
31	24/11/2020	NAVEEN SEWADA	6 YEARS	M	AIIMS/DH/2020/10/004279	29.8		1 B/L NON PALPABLE UDT LAPAROSCOPY AND PROCEED	120	22.9	NO		2	4	3	2	1	0	0	0	0	0	0	0	0	83/112/78	99		NO				120	
32	24/11/2020	TUSHAR	6 YEARS	M	AIIMS/DH/2020/03/006279	22.9		1 O/C/O ARM WITH MUCOSAL HYPERTROPHY FOR ANAL TRIMM	60	22.9	NO		2	3	2	1	0	0	0	1	0	0	0	0	0	78/98/68	98		NO				120	
33	26/11/2020	PHALAK BHATI	12 YEARS	F	AIIMS/DH/2020/09/004635	11		1 B/L HAND SYNDACTYLY RELEASE	120	68.75	NO																							