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Original Article

Anaesthesia Section

Effect of Oral 12% Carbohydrate Containing Clear Fluid in Children on Post-anaesthesia Recovery Profile- A Randomised Clinical Trial

ARCHANA ANILKUMAR BHARADWAJ[1], ISHWAR BHUKAL[2], PREETHY JOSEPH MATHEW[3]

ABSTRACT

Introduction: The perioperative fast is an unpleasant experience, especially for children, as prolonged fasting leads to dehydration, hunger and anxiety. American Society of Anaesthesiology (ASA) recommends the 6-4-2 regimen for preoperative fasting. Preoperative carbohydrate containing clear fluids have been included in the Enhanced Recovery After Surgery (ERAS) protocol due to benefits in adult surgical patients, but very little has been studied about postanaesthesia recovery, especially in children.

Aim: To study the effect of oral 12% clear carbohydrate fluid on postanaesthesia recovery profile in children.

Materials and Methods: The randomised clincial trial was done on 101 children belonging to ASA physical status I and II, aged 2 to 8 years, scheduled for elective procedures, who were randomly allocated to two groups. The study children received 5 mL/Kg of body weight of clear apple juice two hours prior to anaesthetic induction, and those in the control group were advised to follow the standard 6-4-2 fasting regimen (solid, breast milk, clear fluid). A Random Blood Sugar (RBS) value was measured intraoperatively. The time taken to achieve a Modified Aldrete Score (MAS) of >9 was noted from the time of extubation. The time taken for the children to ask for oral intake and the time taken to attain the recommended discharge criteria were noted in the recovery room. Independent t-test and Mann-Whitney U-test were applied for comparing the various parameters assessed, with a significance level of α=0.05.

Results: Mean age of the population in the study group and the control group were 4.520±1.9 years and 4.775±2.02 years (p-value=0.548), respectively. It was found that the children in the study group took a longer time to attain MAS of >9 (study group 18.70±10.19 minutes and control group 16.86±6.85 minutes, p-value=0.007) and had lower intraoperative blood sugar levels compared to the control group {the median (IQR) values of study group 70 (60-79) mg/dL and control group 90 (85-98) mg/dL, p-value=0.005}. Time to ask for oral intake was longer in the study group indicating decreased thirst (study group 49.40±31.08 (minutes) and control group 25.88±16.93 (minutes), p-value=0.0001). None of the children had complications like vomiting or pulmonary aspiration in the perioperative period.

Conclusion: Oral clear 12% carbohydrate fluid as part of preoperative fasting regime is safe for post-anaesthesia recovery.

Keywords: Apple juice, Children, Fasting, Modified aldrete score, Thirst

INTRODUCTION

Pulmonary aspiration is an inherent risk with anaesthesia and by planned fasting of patients this risk can be reduced. Therefore, the practitioner should evaluate fasting and ensure that recommended preoperative fasting guidelines are followed which, as per American Society of Anaesthesiology (ASA) 6-4-2 fasting regimen, allow solids up to six hours, non clear liquids up to six hours, breast milk up to four hours and clear liquids up to two hours before anaesthetic induction [1-3].

Prolonged preoperative fasting leads to thirst, hunger and anxiety in children, which are important factors contributing to perioperative discomfort adversely affecting the postanaesthesia recovery profile making optimal fasting times an integral part of perioperative care [4,5]. In spite of established fasting guidelines, there are many factors which lead to unnecessarily prolonged fasting times [6].

A couple of studies [7,8] that evaluated the effect of preoperative oral clear apple juice have found that the children in the study group had decreased gastric volume, decreased thirst and hunger, and were less irritable preoperatively. However, in the current study the effect of clear apple juice on postoperative recovery was evaluated which is unique to this study. The present study also investigated the average fasting times in the children who were advised to follow standard fasting guidelines (control group).

The present study was designed to study the effects of oral intake of clear 12% carbohydrate fluid (clear apple juice) given two hours before the anaesthetic induction on the child's postoperative recovery profile. The primary objective was to assess the time taken to achieve Modified Aldrete Score (MAS) of >9 and assessment of perioperative anxiety levels, sedation levels and incidence of hypoglycaemia were the secondary objectives.

MATERIALS AND METHODS

The single-centre, randomised, single-blind trial was done over a period of 15 months from August 2014 to October 2015 at Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, India. The Institutional Ethical committee approval (NK/1752/MD/10837-38) was obtained. The trial has been registered at Clinical Trial Registry of India (CTRI/2017/10/010110).

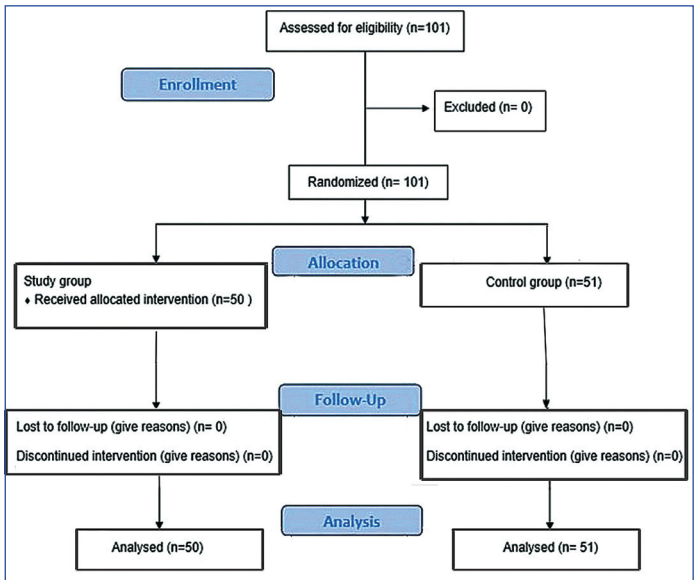
Inclusion criteria: Children with ASA physical status I and II, belonging to the age group of 2 to 8 years, scheduled for surgeries requiring general anaesthesia for two hours or less were enrolled in the trial with a written informed consent from the parents/guardians were included in the study.

Exclusion criteria: Children with active vomiting, inadequate fasting status or with active upper respiratory tract infection and whose parents refused to participate were excluded from the study.

Sample size calculation: The sample size was estimated based on previous similar studies [5,8-11]. Assuming the mean difference for achieving a MAS of >9 between the two groups to be 5 with a Standard Deviation (SD) of 10, the sample size was calculated to be a minimum of 48 subjects per group at a power of 80% and confidence interval of 95%.

The children were randomly allocated into two groups with the use of a computer-generated random number table and the numbers

were kept in opaque sealed envelopes, numbered sequentially. Each envelope was opened, in confidentiality, by a resident in the preoperative room to assign the participants to the two groups to which the principal investigator was blinded until the assessment of all the cases was complete. The study was designed as per CONSORT guidelines [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram.

Procedure

Children were allocated into one of the two groups: The study group or the control group. Children allocated to the study group received 5 mL/kg Body Weight (BW) of pulp-free clear apple juice (Tropicana (100 mL pack)-containing 12% sugar, Tropicana Products, Inc., division of PepsiCo, Inc., Chicago, USA), 2 hours prior to induction of anaesthesia. Children allocated to the control group were advised to follow the standard ASA fasting guidelines (6-4-2 regimen) [3] and the number of fasting hours noted. All children were premedicated with oral midazolam 0.5 mg/kg BW 30 minutes prior to anaesthetic induction., the following parameters were noted before transferring into the operating room: sedation score using the University of Michigan Sedation Scale (UMSS), behaviour score for assessment of anxiety level, Child parent separation score [Table/Fig-2] [12,13].

Score	University of Michigan Sedation score	Behaviour score	Child parent separation score	Mask acceptance score
0	Awake and alert	-	-	-
1	Minimally sedated: tired/ sleepy; appropriate response to verbal conversation/sound	Crying/ resisting	Unafraid, cooperative or asleep	Combative, crying
2	Moderately sedated: somnolent/sleepy; easily aroused with light tactile stimuli or simple verbal command	Anxious and not reassurable	Slightly fearful and/ crying, quieted with reassurance	Moderate fear of the mask, not easily calmed
3	Deeply sedated: deep sleep; arousable only with significant physical stimulation	Anxious, but reassurable	Fearful and crying, not quieted with reassurance;	Coperative with reassurance
4	Unarousable	Calm and cooperative	-	Calm, cooperative or asleep

[Table/Fig-2]: Scoring systems used to assess sedation and anxiety levels in children [12,13].

Anaesthesia was induced using a controlled oxygen-sevoflurane technique via facemask. Mask acceptance was noted based on a four-point scale [Table/Fig-2] [15]. Baseline vitals were recorded. Intravenous (i.v.) access was secured when a Minimum Alveolar Concentration (MAC) of 2.0 was attained and a venous blood sample for blood glucose was taken from the tip of the cannula used to secure I.v. access and Random Blood Sugar (RBS) level was measured using a glucometer (FreeStyle Optium, Abbott Laboratories Limited, Abbott Park, Illinois, USA) and the value noted. After securing the I.v. access, I.v. fentanyl 2 µg/kg BW + I.v. atracurium 0.5 mg/kg BW were given and after 3 minutes, airway was secured with an endotracheal tube of appropriate size. Adequate depth of anaesthesia was maintained with oxygen + nitrous oxide 60% + isoflurane at a MAC of 0.8 to 1.0. All the children were given I.v. Ringer's lactate intraoperatively as per Holliday and Segar formula [16]. All children were given paracetamol 15 mg/kg BW I.v. for analgesia, ondansetron 0.1 mg/kg BW I.v. for antiemesis towards the end of the procedure. On completion of the surgery, neuromuscular blockade was reversed with neostigmine 50 µg/kg BW + glycopyrrolate 10 µg/kg BW after the beginning of spontaneous respiratory efforts and tracheal extubation was performed in the appropriate plane of anaesthesia with full return of respiratory efforts and the child was adequately oxygenated. The MAS was noted from the time of extubation till a score of >9 was attained [Table/Fig-3] [17,18]. The total procedure time, which was defined as the time from the start of anaesthesia to the time of tracheal extubation, was noted. Children were then transferred to the recovery room. Children were shifted to a step-down ward in case of inpatients or discharged home in case of out patients, when the recommended discharge criteria were met, with clear instructions to the parents [Table/Fig-4] [18,19].

Criteria	Condition	Points
Activity, able to move voluntarily or on command	4 extremities	2
	2 extremities	1
	No	0
Respiration	Able to breathe deeply and cough freely	2
	Dyspnoea, hypoventilation	1
	Apnoea	0
Circulation: Blood Pressure (BP)	BP ±20% of preanaesthesia level	2
	BP >20-49% of preanaesthesia level	1
	BP >50% of preanaesthesia level	0
Consciousness	Fully awake	2
	Arousable	1
	Unresponsive	0
SpO_2*	Maintain SpO_2 >92% in ambient air	2
	Maintain SpO_2 >90% with O_2	1
	Maintain SpO_2 <90% with O_2	0

[Table/Fig-3]: Modified Aldrete Score (MAS) [17].
*Oxygen saturation as measured by a pulse oximeter

1.	Vital signs are stable.
2.	Intact gag reflex, swallowing, and cough, allowing for oral intake.
3.	Ambulation or movements are appropriate for developmental level.
4.	Nausea and vomiting should be minimal, allowing for retention of ingested fluids.
5.	No signs of respiratory distress, such as stridor, retractions, nasal flaring, "barking" cough, wheezing, cyanosis, or dyspnoea.
6.	Patient is oriented to person, place, and time as appropriate for age.

[Table/Fig-4]: Discharge criteria [18,19].

STATISTICAL ANALYSIS

The collected data was tabulated in Microsoft Excel and analysed using Statistical Package for the Social Sciences (SPSS) for Windows (version 17.0; SPSS Inc., Chicago, IL, USA). Independent t-test was applied for univariate variables. Mann-Whitney U-test was applied to compare behaviour scores and UMSS preoperatively and postoperatively. Multivariate tests were applied for intergroup comparison. A p-value <0.05 was considered statistically significant.

RESULTS

A 101 children, who met the inclusion criteria, were enrolled in the trial. The two groups were comparable in terms of demographic characteristics and procedure time, however the mean fasting duration was more than advised in the control group [Table/Fig-5].

Demographic characteristics	Study group Mean±SD* (Range)	Control group Mean±SD (Range)	t-test p-value
Number (N)	50	51	-
Age (years)	4.520±1.9 (2-8)	4.775±2.02 (2-8)	0.548
Weight (Kilograms)	16.03±5.1	15.8±5.7	0.947
Gender (Male/Female)	35/15	35/16	-
Fasting duration (Hours)	2	12.5±2.92 (6-18)	-

[Table/Fig-5]: Demographic data and fasting duration.
*SD: Standard deviation

A statistically significant difference (p-value=0.001) was observed between the preoperative UMSS of the study and the control groups, with the median of the study group being lower than the control group. No statistically significant difference was observed in the intergroup comparison of postoperative UMSS. No significant difference was observed in the Behaviour Scores, preoperative or postoperative, in the intergroup comparison. No significant difference was observed between the study and the control groups in terms of Child-Parent Separation score and Mask Acceptance score [Table/Fig-6].

Variables	Study group	Control group	Z score (Mann-Whitney U-test)	p-value
Preoperative UMSS Median (Range)	0 (0-2)	1 (0-3)	3.229	0.001†
Postoperative UMSS Median (Range)	2 (0-3)	2 (0-3)	0.509	0.305
Preoperative behaviour score Median (Range)	3 (1-4)	3 (1-4)	0.434	0.667
Postoperative behaviour score Median (Range)	3.5 (1-4)	3 (1-4)	-0.815	0.412
Child-parent separation score	2 (1-3)	2 (1-3)	0.051	0.960
Mask acceptance score	3 (1-4)	3 (1-4)	0.445	0.659

[Table/Fig-6]: Comparison of University of Michigan Sedation Score (UMSS), behaviour score, child-parent separation score and mask acceptance score.
†p-value <0.05 was considered statistically significant

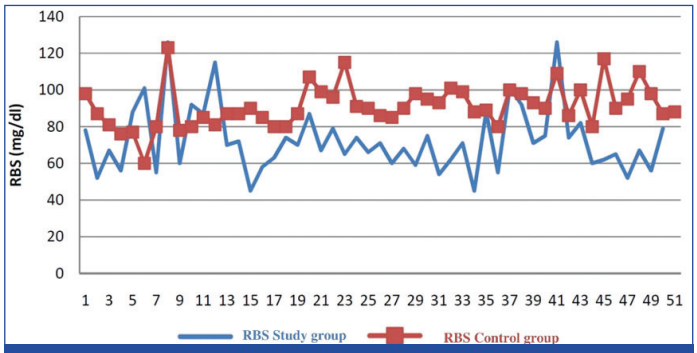
No significant difference was observed between the study and the control groups with the same scores in terms of Child-Parent Separation score {median (range), 2 (1-3)} and Mask Acceptance score {median (range), 3 (1-4)}.

Statistically significant differences were observed between the study and the control groups in the time taken to attain MAS of >9 and time to ask for oral intake [Table/Fig-7]. The values of the time to attain MAS >9 in the study group seem to be trending higher in comparison to the control group. It can also be observed that the children in the control group experienced thirst earlier than children in the study group.

Parameters	Group	Mean±SD (Range)	p-value
Time to attain MAS† >9 (minutes)	Study group	18.70±10.19 (5-40)	0.007‡
	Control group	16.86±6.85 (0-30)	
Time to ask for oral intake (minutes)	Study group	49.40±31.8 (10-120)	0.0001‡
	Control group	25.88±16.93 (5-90)	
Time for attaining the discharge criteria (minutes)	Study group	35.5±14.11 (15-60)	0.841
	Control group	38.04±13.71 (20-60)	

[Table/Fig-7]: Analysis of recovery parameters.
†Modified aldrete score; ‡p-value of <0.05 was considered statistically significant

The median {Inter Quartile Range (IQR)} RBS levels of the study and control groups were 70 (60-79) mg/dL and 90 (85-98) mg/dL, respectively and the difference between them was statistically significant (p-value=0.005). The RBS values in the control group were trending towards a higher range than the study group [Table/Fig-8]. Only one child in the study group had an RBS value of 45 mg/dL (RBS <50 mg/dL: hypoglycaemia).



[Table/Fig-8]: Comparision of Random Blood Sugar (RBS) trend between the two groups.

DISCUSSION

To reduce the risk of regurgitation and pulmonary aspiration, preoperative fasting is routinely followed. Research findings document that pulmonary aspiration is a rare complication in children (incidence 3 to 10/10,000), and the reported mortality is extremely low [20].

Various professional associations for both anaesthesiology {Indian Society of Anaesthesiologists, Canadian, American, European, and South African (SA) society guidelines} and surgery (ERAS) support the Nil per os 6-4-2 regimen [1,21]. Actual fasting time in children is often longer than recommended and many children suffer from a considerable amount of perioperative discomfort [5].

In this study, children in the control group were instructed to follow the standard 6-4-2 fasting regimen. Despite clear instructions, most children in the control group did not follow the regimen and the number of fasting hours on an average was 12.5±2.92 hours (range 6-18 hours). Where the loophole lies needs to be known. There might be many reasons for this as investigated by Buller Y and Sims C ineffective communication, rescheduling of the procedure, delays in transport to the operation theatre, lack of coordination between the anaesthesiologists, surgeons and the preoperative care-givers [6].

Children in the study group had lower preoperative sedation scores compared to those in the control group (p-value=0.001). This indicates that children in the study group were alert and less drowsy, whereas there was no significant difference in the postoperative sedation scores between the groups [Table/Fig-6]. There was no significant difference in the Behaviour Scores, Child-Parent Separation scores, and Mask acceptance scores between the groups, with most children being slightly anxious, but reassurable [Table/Fig-6].

Schreiner MS et al., reported that ingestion of clear fluids before surgery may provide psychological benefit as evidenced by decreased irritability prior to anaesthetic induction, based on a questionnaire filled by the parents, where the parents from the study group rated their children less irritable than the parents from the control group, with a mean±SD score for disposition of 8.7±1.7 in study children compared with 6.6±3.0 in controls (p-value <0.01), which is comparable to the results of the present study [22].

Castillo-Zamora C et al., reported that children were irritable (Odds Ratio, OR 4.5, 95% CI: 1.9-10.8) and dehydrated (OR 21.6; 95% CI 5.9-79.0) in overnight fasting group at the time they arrived in the operating room, compared to the study group which received clear apple juice (10-15 mL/kg, max. 250 mL) at 6:00-6:30 AM on the day of surgery, which is comparable to the present study [8].

In the present study, the recovery profile was assessed in terms of time taken to attain a MAS of >9, time to ask for oral intake of fluid

(thirst), and the time taken to meet the discharge criteria [Table/Fig-7]. There was a significant difference between the groups in terms of time to attain MAS >9 (p-value=0.007) and time to ask for oral intake (p-value <0.001). The mean time to attain MAS >9 was longer in the study group compared to the control group, probably indicating that children in the study group were more comfortable postoperatively in contrast to children in the control group who were restless and attained a MAS of >9 earlier. The children in the control group were thirsty earlier compared to the study group [Table/Fig-7]. There was no significant difference between the groups in the time taken to meet the discharge criteria (p-value=0.8). Splinter WM et al., found that children who received clear apple juice (3 mL per kg) 2.5 hours prior to anaesthesia were not as hungry and thirsty as the controls [7].

In paediatric practice, hypoglycaemia is a perioperative complication resulting in irritability, lethargy, metabolic acidosis and seizures. During surgery, there is a rise in the plasma glucose level in a normal adult, but it has been shown that children do not respond with a hyperglycaemic reaction to the same degree. Controversies still exist regarding the influence of preoperative starvation on blood glucose concentration in paediatric patients, despite various studies [5,8,10]. In this study, a significant difference in the RBS values between the groups (p-value=0.005) was observed. The RBS values in the control group seemed to be trending towards a higher range than the study group [Table/Fig-8], probably indicating higher preoperative stress in the control group leading to increase in fasting blood sugar.

In a study by Sharma V et al., the blood glucose levels were higher in group II (oral 5% dextrose group) as compared to group I (fasted group), 20 minutes after induction of anaesthesia with a statistically significant difference (p-value=0.001) [10]. The blood glucose levels (mg/dL) 20 minutes after induction of anaesthesia in group I and II were 85.52±11.73 and 93.28±8.89, respectively. However, the difference in the mean blood glucose levels before induction between the groups (I and II) was not significant statistically.

Castillo-Zamora C et al., did not find any significant difference in the average preoperative blood glucose levels between the overnight-fasting group (86.3±12.4 mg/dL) and oral clear apple juice group (86.1±15.2 mg/dL) [8]. None of the children enrolled in our study had complications like vomiting or pulmonary aspiration.

Limitation(s)

There were few limitations to the present study. The assessment of the recovery profile requires qualitative components in the scoring system, which was not covered by MAS, which was assessment of physical recovery parameters. Future studies are necessary to formulate a new scoring system with both qualitative and quantitative recovery parameters.

CONCLUSION(S)

It can be concluded that administering oral clear 12% carbohydrate fluid to children as part of a preoperative fasting regimen is safe and also beneficial for postanaesthesia recovery and perioperative experience. Also, the take home message is that it is imperative to properly instruct the patients/their guardians about the fasting regimen, creating awareness regarding the benefits of short liberal fasting regimen as well as the harmful effects of prolonged fasting.

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PARTICULARS OF CONTRIBUTORS:
1. Assistant Professor, Department of Anaesthesiology, SDM Medical College and Hospital, Shri Dharmasthala Manjunatheshwara University, Dharwad, Karnataka, India.
2. Professor, Department of Anaesthesia and Intensive Care, Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, India.
3. Professor, Department of Anaesthesia and Intensive Care, Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Archana Anilkumar Bharadwaj,
Plot No. 4, Shakambari, 2nd Main, 2nd Cross, Vidyagiri,
Dharwad-580004, Karnataka, India.
E-mail: archana.a.b16@gmail.com

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