

Evaluation of Effect of Preoperative Oral Carbohydrate on the Perioperative Agitation in Pediatrics Undergoing Elective Herniorrhaphy; A Doubl-Blind Randomized Clinical Trial

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Abstract

Background

The aim of this study was to evaluate the effect of preoperative oral carbohydrate on the perioperative agitation in pediatrics with elective herniorrhaphy.

Materials and Methods

In this randomized clinical trial study, 120 pediatrics, 6 months to 10 years-old who underwent elective herniorrhaphy were admitted. Sixty pediatrics in the intervention group received 5 ml/kg of 20% dextrose solution manufactured by Samen Company as carbohydrate beverage exactly 2 hours before surgery and the control group (n=60) received distilled water. The perioperative agitation score was calculated as follows. Score 1: quiet, silent child, score 2: mild but agitated, score 3: medium aggression, and score 4: severe agitation measured before surgery, at recovery, 5, 15 and 30 minutes after intervention. Also, the incidence of nausea and vomiting was recorded in each group.

Results

Of the 60 pediatrics in the intervention group, 54 patients were quiet and silent at the time of entry into the operating room, and 6 patients had mild agitation; in the control group, 7 patients were quiet and silent, 41 patients were mild but agitated, and 12 were moderate. There was a significant difference in agitation between the two groups ($P = 0.001$). Five minutes after surgery, 54 patients scored 1, 6 patients scored 2 in the control group, 27 patients scored 1 and 33 patients scored 2. There was a significant difference between agitations of children 5 minutes after intervention in the two groups.

Conclusion

Five ml/kg of 20% dextrose solution as carbohydrate beverage exactly 2 hours before anesthesia may lead to parental satisfaction and improvement in positive behavior of pediatrics at anesthesia induction and wake up from anesthesia.

Key Words: Carbohydrates, Children, Herniorrhaphy, Preoperative fasting, Perioperative agitation.

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1- INTRODUCTION

Nowadays, more than 6 million patients in the world undergo surgery annually. Surgery is a stress that causes physiological reactions (endocrine) and psychological stress (fear and anxiety) (1). One of the main causes of stress and discomfort in patients before surgery is the need for preoperative fasting, which is taken worldwide as a precautionary measure to minimize the risk of aspiration and regurgitation during induction of general anesthesia (2). About 10% of people develop a type of hernia in their lifetime (3), and inguinal hernia repair is one of the most common surgeries performed worldwide (4). At present, the exact number of surgeries performed in Iran is not known, but, for example, it is reported that in the Netherlands, which is a small country with a small population, about 30,000 cases of inguinal hernia repair are performed annually and also inguinal hernia repair is reported to be 10 per 100,000 in the United Kingdom and 28 per 100,000 in the United States (5).

Between 2001 and 2002, about 70,000 cases of inguinal hernia repair were performed in the UK resulting in a total of more than 100,000 days of hospitalization (6). Fear of aspiration of stomach contents and its deadly consequences has led anesthesiologists to strictly follow the rules of fasting. The day of surgery is generally spent in a state of anger, hunger, thirst, and possibly dizziness (7). According to recommendations published by anesthesia communities, the current guidelines for not consuming food before surgery in children are: 6 hours for solid foods, 6 hours before surgery for cow's milk, 4 hours before surgery for breast milk, and 2 hours before surgery for fluids (8-11). Preoperative fasting strategy can have a significant impact on nausea and vomiting, pain, dizziness, drowsiness (12). A study by Singh et al. found that concomitant consumption of carbohydrate-

rich beverages could reduce nausea, vomiting, and postoperative pain in patients undergoing outpatient cholecystectomy, as well as the consumption of carbohydrate-containing beverages 2 hours before surgery is not associated with additional complications (13). Another study by Perrone et al. in 2011 concluded that co-consumption of preoperative protein and carbohydrate beverages was safe and reduced insulin resistance and the acute postoperative phase response (14). In a systematic study of 17 different studies, it has been reported that preoperative carbohydrate intake can reduce postoperative hunger, thirst, weakness, anxiety and nausea (15). In a study, Song et al. examined the effect of preoperative carbohydrate intake on gastric volume using ultrasound in children and concluded that consuming carbohydrates 2 hours before surgery reduced gastric volume and did not cause serious complications in children (16). With these interpretations, the results of preoperative oral carbohydrate intake in postoperative agitation in children candidates for elective hernioraphy in the form of a study to determine the effectiveness of this method in controlling agitation and determine the appropriate treatment plan for this group of patients. So, we decided to study the effect of preoperative oral carbohydrates on postoperative agitation in children candidates for elective herniauraphy.

2- MATERIALS AND METHODS

2-1. Study design and population

In this study, a double-blind randomized clinical trial, sample size was calculated 120 pediatrics according to the study by Tudor et al. (17) who were randomly divided into two groups of 60 pediatrics. In this study, 120 pediatrics were randomly divided into intervention and control groups using random allocation software (**Figure.1**).

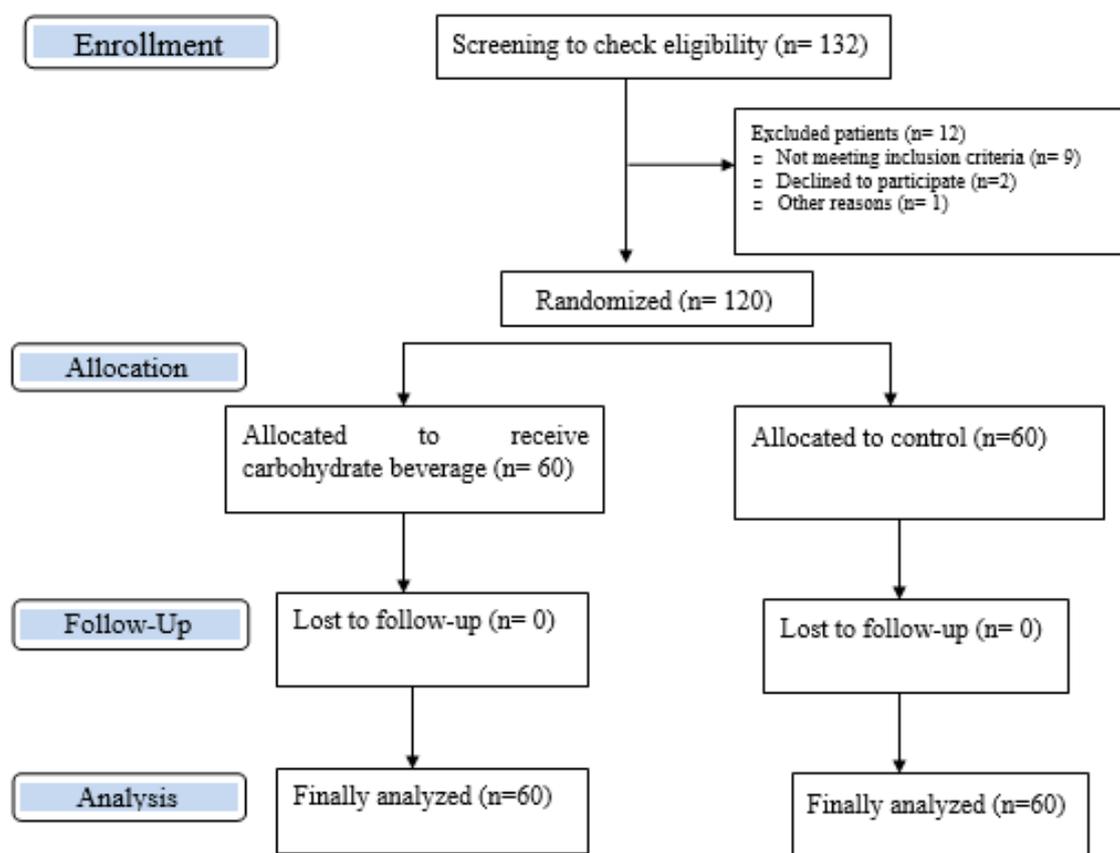


Fig.1: CONSORT diagram.

2-2. Methods

Random allocation was conducted based on a permutation block by a statistical consultant using random allocation software and the output sequences A and B were available to the researcher. Accordingly, 6 blocks were allocated to patients, in each block, 2 from A treatment group, 2 from the B control group were placed. Eventually, after completing the blocks group A received oral carbohydrate and group B did not receive any special treatment (control). The double-blind procedure was performed in such a way that the patients and the outcome assessor were unaware of the random allocation to groups and the carbohydrate-containing fluids were prescribed to the patients by the ward nurse. The parameters of nausea and vomiting at the time of induction of anesthesia and after waking up from anesthesia, agitation around the operation,

5 minutes, 15 minutes and 30 minutes after waking up from anesthesia were collected and recorded in the data collection form.

2-3. Measuring

The perioperative agitation score was calculated as follows. Score 1: quiet, silent child, score 2: mild but agitated, score 3: medium aggression, and score 4: severe agitation (18). Also, nausea and vomiting at the time of induction of anesthesia and after waking up from anesthesia. The perioperative agitation score was recorded around the operation, 5 minutes, 15 minutes and 30 minutes after waking up from anesthesia.

2-4. Intervention

Sixty pediatrics in the intervention group consumed 5 ml/kg of 20% dextrose solution manufactured by Samen Company as carbohydrate beverage exactly 2 hours before the operation and 60 pediatrics were

included in the study as a control group who received 5 ml distilled water. Patients took 3 mg/kg propofol, 0.05 mg/kg midazolam and fentanyl 2 µg / kg for general anesthesia. Maintenance of anesthesia was performed with 1.2% isoflurane, 50% nitrous oxide and 50% oxygen.

2.5-Ethical consideration

The research followed the tenets of the Declaration of Helsinki. The Ethics Committee of Urmia University of Medical Sciences with code of IR.UMSU.REC.1398.145. Accordingly, written informed consent was taken from all participants' parent before any intervention. This trial was registered in Iran Registry of Clinical Trials (IRCT) with code of IRCT20170516033992N1.

2-6. Inclusion and exclusion criteria

Inclusion criteria were peditrics with American Society of Anesthesiologists (ASA) I and II who were candidates for elective inguinal hernia repair admitted to Motahhari hospital in Urmia, Iran, during the first half of 2019 and were between 6 months and 10 years old. Exclusion criteria were peditrics with ASA III and more, and patients who were candidates for emergency inguinal hernia repair surgery. ASA was checked by an anesthesiologist.

2-7. Data Analyses

The data were analyzed using SPSS software version 21.0, descriptive statistics including frequency and percentage, mean and standard deviation (SD). Chi-square and Fisher exact tests were used for qualitative variables. $P < 0.05$ was considered statistically significant. The outcome of the study was binary variable, and then quantitative tests such as t-test or Mann-Whitney were not used.

3- RESULTS

In this study, there were 39 boys (65%) and 21 girls (35%) in the intervention group and 36 boys (60%) and 24 girls (40%) in the control groups. According to Chi-square statistical test, there was no significant difference between the genders of peditrics in the two groups ($P = 0.57$). The mean age was 42.98 ± 4.33 months in the intervention group and 38.58 ± 3.77 months in the control group. According to t-test, there was no significant difference between the mean age of peditrics in the two groups ($P = 0.44$). The mean weight in the intervention and control groups was 14.59 ± 0.81 kg and 14.30 ± 5.33 kg, respectively. According to t-test, there was no significant difference between peditrics' weight in the two groups ($P=0.78$) (**Table. 1**).

Table-1: Demographic characteristics of children in the two groups.

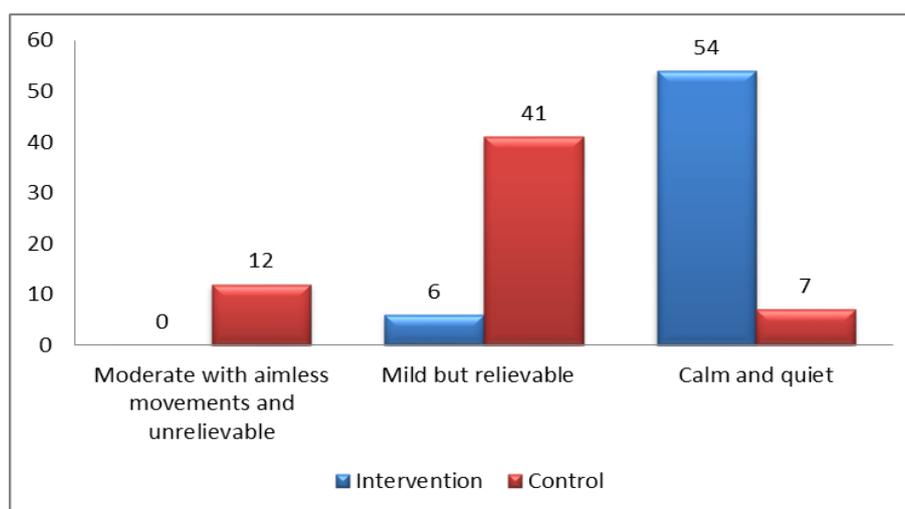
Variables		Intervention group	Control group	P-value
Gender Number (%)	Boy	39 (65)	36 (60)	0.57
	Girl	21 (35)	24 (40)	
Age (month)		42.98 ± 4.33	38.58 ± 3.77	0.44
Weight (year)		14.59 ± 0.81	14.30 ± 5.33	0.78

Regarding agitation, 54 peditrics (90%) were calm and quiet, 6 peditrics (10%) had mild but relieved agitation in the intervention group. In the control group, 7 peditrics (11.7%) were calm and quiet, 41 peditrics (68.3%) had mild but relievable agitation, and 12 peditrics (20%) had

moderate agitation with aimless movements and unrelievable. According to Chi-square test, there was a significant difference between perioperative agitation of peditrics in the two groups ($P = 0.001$) (**Table. 2 and Figure. 2**).

Table-2: Frequency of perioperative agitation in the two study groups, n=120.

Group	Perioperative agitation			P- value (Chi-square)
	Calm and quiet	Mild but relievable	Moderate with aimless movements and unbelievable	
Intervention Number (%)	54 (90)	6 (10)	0 (0)	0.001
Control Number (%)	7 (11.7)	41 (68.3)	12 (20)	
Total Number (%)	61 (50.8)	47 (39.2)	12 (10)	

**Fig.2:** Frequency of perioperative agitation in the two study groups.

Five minutes after waking up from anesthesia in the intervention group, the level of agitation for 54 patients (90%) was calm and quiet, 6 patients (10%) were mild but relievable and in the control group, 27 patients (45%) were calm and quiet and 33 patients (55%) had mild but

relievable agitation. According to the Chi-square test, there was a significant difference between the agitation of children 5 minutes after waking up from anesthesia in the two groups ($P = 0.001$) (**Table. 3**).

Table-3: Frequency of agitation 5 minutes after waking up from anesthesia in the two study groups, n=120.

Groups	Agitation 5 minutes after wake up from anesthesia		P value (Chi square)
	Calm and quiet	Mild but relievable	
Intervention Number (%)	54 (90)	6 (10)	0.001
Control Number (%)	27 (45)	33 (55)	
Total Number (%)	81 (67.5)	39 (32.5)	

Agitation after anesthesia at 15 and 30 minutes was not significantly different between the two groups ($P=0.25$ and $P=0.24$, respectively) (**Tables 4 and 5**). In

this study, no case of vomiting before and after waking up from anesthesia was reported in the studied children (intervention and control groups).

Table-4: Frequency of agitation 15 minutes after waking up from anesthesia in the two study groups, n=120.

Groups	Agitation 15 minutes after waking up from anesthesia		P- value (Chi square)
	Calm and quiet	Mild but relievable	
Intervention Number (%)	57 (95)	3 (5)	0.25
Control Number (%)	54 (90)	6 (10)	
Total Number (%)	11 (92.5)	9 (7.5)	

Table-5: Frequency of agitation 30 minutes after waking up from anesthesia in the two study groups, n=120.

Groups	Agitation 30 minutes after waking up from anesthesia		P value (Chi square)
	Calm and quiet	Mild but relievable	
Intervention Number (%)	58 (96.7)	2 (3.3)	0.24
Control Number (%)	60 (100)	0 (0)	
Total Number (%)	118 (98.3)	2 (1.7)	

4- DISCUSSION

This study was done to investigate the effect of preoperative oral carbohydrates on postoperative agitation in pediatrics between 6 months and 10 years of age who were candidates for elective herniauraphy. In summary, the present study showed 90% of the patients in the intervention group were quiet and silent at the time of entry into the operating room but in the control group 68.3% of the patients were mild but agitated. These results reveal that 5 ml/kg carbohydrate beverage exactly 2 hours before anesthesia may lead to parental satisfaction and improvement in positive behavior of pediatrics at anesthesia induction and waking up from anesthesia. One of the main causes of discomfort and agitation in children before surgery is starvation, which is necessary to minimize the risk of vomiting and aspiration during induction of general anesthesia (19). Preoperative fasting can play a significant role in the consequences of nausea and vomiting, pain, inflammatory response to surgery, and other postoperative reactions (20).

Children who undergo surgery are stressed and out of their normal state, which causes them anxiety and weakness (21, 22). On the other hand, prolonged fasting in the absence of gastrointestinal disorders cannot increase gastric volume or increase immunity, but it also leads to unnecessary discomfort for children and their caregivers that should be avoided (23, 24). In this study, in the intervention group, we gave 5 ml/kg of carbohydrate-containing beverage to children candidates for elective herniauraphy 2 hours before the operation, and finally the consequences of agitation when entering the operating room, and when leaving the anesthesia at 5 minutes, 15 minutes and 30 minutes after surgery and the frequency of vomiting at the time of induction and after wake up from anesthesia in the intervention and control groups to determine the value of carbohydrate drinks in the intervention and control groups. In our study at the time of entering the operating room, children in the intervention group (90%) were quiet compared to the control group (11.7%). Five minutes after surgery in the intervention group, 10% had mild agitation

but were relieved, while in the control group, 55% had mild agitation but were relieved. There was a significant difference between the two groups. Song et al. in their study were satisfied with consuming a carbohydrate-containing beverage two hours before general anesthesia, which reduced stomach volume and reduced children's irritability due to quenching thirst, which ultimately led to parental satisfaction, which was consistent with the results of our study because the reduction of perioperative agitation ultimately led to positive behavior of children when entering the operating room and after waking up from anesthesia (16). Randomized trials have shown that drinking carbohydrate-rich fluids before surgery reduces thirst, hunger, weakness, and postoperative insulin resistance, the results of our study due to reduced perioperative agitation of children in the operating room, and waking up from anesthesia were consistent with these studies (25). In a study by Tudor-Drobjewski et al., the use of carbohydrates before the operation reduces the anxiety in the child, so in 4-year-old children, the use of carbohydrates before the operation can be useful (17). Moyao et al. conducted a study to administer an electrolyte oral solution for prolonged preoperative fasting in forty children aged 3 to 12 years with no history of surgery requiring general anesthesia, and showed in their study that oral use of isosmolar solution of electrolytes leads to the cessation of a long period of preoperative starvation and this reduces the risk of residual gastric volume without disturbing the hypoglycemic balance caused by prolonged starvation in children undergoing surgery, which is consistent with our study because in our study, consumption of carbohydrate-containing beverages two hours before the operation reduced insulin resistance, gastric volume and gastritis risk, but no case of vomiting at the time of induction of anesthesia and waking up from anesthesia

was reported in our study. Finally, carbohydrate consumption has led to a reduction in thirst and hunger in children and, most importantly, the main purpose of our study has been to reduce agitation in children undergoing surgery (26). In our study, no case of vomiting before and after surgery was reported, while in the study of Borland and Murat I, pulmonary aspiration related to anesthesia in children was reported to be 0.1-0.04, which is contrary to the results of our study. Therefore, we not only followed the instructions for fasting in the hours before the operation, but also used carbohydrate drinks to prevent prolonged hunger in children before the operation, which led to quenching thirst, hunger (27, 28). The benefits of preoperative carbohydrates in adults have also been shown in some studies so that consuming preoperative carbohydrate drinks reduces stomach volume, side effects and gastric depletion (29, 30). In a study by Bisgaard et al. and in one by Svanfeldt et al., preoperative carbohydrate intake had no effect on reducing nausea and vomiting in adults undergoing surgery, which is somewhat consistent with the results of our study because in our study, no case of postoperative vomiting was reported in the intervention and control groups. These findings could be one of the benefits of no side effects following consuming carbohydrate drinks 2 hours before the start of anesthesia in children candidates for surgery (31, 32).

4-1. Study Limitations

The sample size of the study was small; hence the obtained results cannot be generalized to other populations.

5- CONCLUSION

Based on the results, 5 ml/kg carbohydrate carbohydrate after long-term cessation of foods in pediatrics before anesthesia lead to parental satisfaction and improved pediatrics' positive behavior

during induction of anesthesia and waking up from anesthesia. Also, the use of carbohydrates does not increase the risk of gastric aspiration and postoperative vomiting. It is recommended that future trials should be involved with a larger number of samples and in different doses.

6- AUTHORS' CONTRIBUTION

TK, NK and SSAH conducted the research. SSAH gathered the data. SSAH and HH analyzed the data. HH and TK prepared the primary draft. NK contributed in writing the manuscript and review of articles. HH edited the manuscript. TK prepared the final paper. All authors read and approved the final manuscript.

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8- CONFLICT OF INTEREST: None.

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