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Effect of Oral Glucose Water Administration 1 Hour Preoperatively in Children with Cyanotic Congenital Heart Disease: A Randomized Controlled Trial

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Statistical Analysis C
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Manuscript Preparation E
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Background: Guidelines recommend a clear liquid fasting time of 2 h before surgery, which is often exceeded, leading to adverse reactions (ARs) such as discomfort, thirst, and dehydration. We assessed the gastric contents and ARs after oral glucose water administration 1 h prior to surgery in children with cyanotic congenital heart disease (CCHD).

Material/Methods: This was a non-inferiority randomized controlled trial of children with CCHD enrolled at the Fujian Medical University Union Hospital from 09/2014 to 05/2017 and randomized to receive oral glucose water (10 g of glucose in 100 ml of warm water, 5 ml/kg) 2 h (2-h group, n=174) or 1 h (1-h group, n=170) before surgery. The primary endpoint was gastric volume. Secondary endpoints included pH of gastric content, preoperative blood glucose, and risk factors for aspiration pneumonia. Pre- and intraoperative ARs were recorded.

Results: The 1-h group showed smaller gastric content volumes (0.34±0.35 (95% CI: 0.29–0.39) *vs.* 0.43±0.33 (95% CI: 0.38–0.48) ml/kg, t=2.55, P<0.05) and higher blood glucose (6.21±0.78 (95% CI: 6.09–6.33) *vs.* 5.59±1.11 (95% CI: 5.43–5.76) mmol/L, t=–5.91, P<0.001). The 95% confidence interval of the volume difference between the 2 groups was 0.017–0.163, the upper limit value was 0.163 <δ=0.2 (P<0.01). The non-inferiority hypothesis was correct. The 1-h group showed lower incidence of crying, thirst and hypoxia (all P<0.05 *vs.* 2-h group). There were no differences in ARs between the 2 groups.

Conclusions: A 1-h fast prior to surgery was not inferior to a 2-h fast in terms of gastric residuals and ARs in pediatric patients with CCHD.

Clinical trial registration: *http://www.chictr.org.cn/showprojen.aspx?proj=9563*
Registration number: ChiCTR-IPR-14005270

MeSH Keywords: Fasting • Heart Diseases • Safety

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Background

Fasting is the main strategy used to avoid perioperative pulmonary aspiration during elective procedures under general anesthesia [1–4], but previous studies focused on adults or children with non-serious diseases [5,6]. Whether a 2-h preoperative fast is an optimal strategy for children with cyanotic congenital heart disease (CCHD) requires further exploration. Indeed, fast too long may lead to dehydration, biochemical imbalance, and hypoglycemia [7], increasing the risk of complications. Crying may lead to severe muscle spasm of the right ventricular outflow tract [8]. It is necessary to keep the preoperative fast as short as possible in children with CCHD, as suggested by a meta-analysis in adults [9] and a study in infants [10]. Among children (0–16 years), a shorter fast improves patients' experience and results in low risk of aspiration [11]. There is a lack of high-quality evidence concerning the preoperative fast management of CCHD children ages 0–3 years, although such children were included in Andersson's study [11].

Schmidt et al. [1] previously showed that there are no differences between 1 h and 2 h of clear fluid fasting in children aged 1–16 years undergoing elective surgery. We hypothesized that a 1-h fast has similar outcomes compared to a 2-h fast in pediatric patients undergoing surgery for CCHD. The present study assessed oral administration of 5 ml/kg of glucose water in children (0–3 years) with CCHD 1 h before surgery, compared with 2 h.

Material and Methods

Study design and patients

This was a non-inferiority prospective randomized trial performed at the Cardiovascular Surgery Department of Fujian Medical University Union Hospital. Children with CCHD were enrolled from 09/2014 to 05/2017. The study was registered (No. ChiCTR-IPR-14005270) and approved by the Ethics Committee of Fujian Medical University Union Hospital (No. 2014006). Written informed consent was obtained from the legal guardians.

The inclusion criteria were: 1) 0–3 years of age; 2) CCHD diagnosed according to blood mixing from the left and right heart due to abnormal right to left shunt, children with persistent cyanosis (SpO_2 <92%) and pulmonary blood flow reduction; and 3) scheduled for heart surgery. The exclusion criteria were: 1) any disease or congenital malformation that affected the structure or function of the digestive system, including surgery to the digestive system; 2) severe liver, kidney, brain or other major organs disease; or 3) history of taking H_2 receptor antagonists or proton pump inhibitors.

Intervention

Randomization (1: 1) was performed using a randomization sequence with a block size of 10, prepared by a statistician using a random number table obtained using SPSS 20.0 (IBM, Armonk, NY, USA). Patients were fasted (food and drink) for 4 h prior to surgery. Sequential opaque envelopes (prepared by an independent statistician) were opened by the physicians 3 h before surgery. The patients were randomized to clear liquid fast of 1 h or 2 h. They only received oral glucose water (10 g of glucose dissolved in 100 ml of warm water, 5 ml/kg) 2 h or 1 h before surgery, according to grouping. The glucose water was given using a nursing bottle. All children received inhaled general anesthesia; no child received premedication or intravenous fluid.

After anesthesia, a disposable gastric tube (Yubei Medical Materials, YZB/Yu 0193-2013) was indwelled and attached to a 20-ml syringe to aspirate the gastric content in the supine, left-lateral, and right-lateral positions until no liquid could be obtained. After measuring its volume, the pH of the gastric content was measured with pH test paper (Sanaisi, Shanghai, China).

Observational indicators

The primary endpoint was gastric content volume. The secondary endpoints included pH of gastric content, preoperative blood glucose (immediately after anesthesia, using a model Freestyle Optium, Abbott, USA), and pre- and intraoperative adverse reactions. The rates of patients with gastric content >0.4 ml/kg of body weight and the rates of patients with pH of gastric content <2.5 were compared.

Adverse reactions included thirst (preoperative), crying (preoperative), hypoxia (preoperative), heart failure (intraoperative), vomiting (intraoperative), and witnessed pulmonary aspiration (intraoperative). Preoperative thirst was evaluated by trained nurses (blinded to the purpose of evaluating thirst and the study itself) between the administration of the glucose water and surgery. Thirst was considered to occur when the child showed dry lips and repeatedly licked his/her lips, and using a numeric scale [12]. A score of >4 indicated thirst. Preoperative hypoxemia was defined by significantly decreased SpO_2 (change of >15% from baseline). SpO_2 was measured using an oximeter (model H100B, EDAN, Shenzhen, China). Heart failure was considered to occur when LVEF was <40% at any time, NT-proBNP was ≥125 pg/ml, BNP was ≥35 pg/ml, and/or with difficulty weaning from cardiopulmonary bypass at first attempt with standard inotropes. The children became suddenly agitated, breathing was more difficult, and they were pale, with cyanosis showing at the mouth and toes. Crying was defined as paroxysms of irritability, and fussing or crying that occurred without an apparent cause. Crying was recorded as

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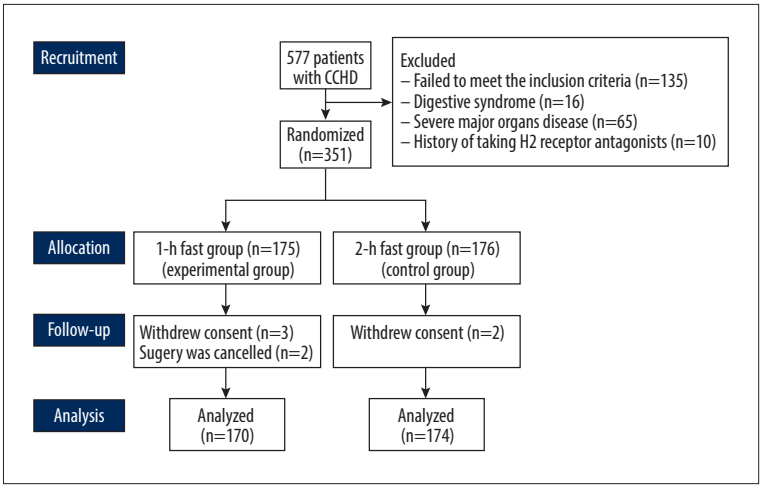

Figure 1. A total of 577 patients were screened. Of these, 351 children diagnosed with cyanotic congenital heart disease (CCHD) who met the inclusion and exclusion criteria were enrolled and randomly allocated to the 2-h fast (control group, 174 patients) or 1-h fast (experimental group, 170 patients) groups. Seven patients were excluded from the final analysis for the following reasons: in the 1-h fast group, the parents of 2 children withdrew consent for their child's data to be used; and in the 2-h fast group, the parents of 3 children withdrew consent for their child's data to be used and surgery was cancelled for 2 children.

yes/no during the 1-h or 2-h period between administration of glucose water and surgery. The final diagnosis of aspiration was based on: 1) hypoxemia of unknown cause, tachypnea or rale, as confirmed by chest radiograph and/or bronchoscopy for the presence of foreign body; and 2) presence of non-pulmonary substances in the throat under direct-vision laryngoscopy or in the trachea under bronchoscopy. Regarding treatment, the airway was reestablished and the children were turned in the right-lateral position with lower head and higher feet. Bronchoscopy was used for suctioning through the nasal cavity. No bronchial washing was allowed. Aminophylline was used to treat bronchospasm. Antibiotics were used for the prevention of pulmonary infection.

Sample size calculation

The differences in volume content caused by fasting timing were considered as the key variable for sample size determination. The sample size was calculated according to the method described by Dalal et al. [13] and Brady et al. [14]. Based on a previous study [1], P is the merged or average rate of the 2 groups, and the critical value was 0.2. The sample size of each group was calculated as n=136. A 20% rate of loss to follow-up (n=164) was considered. Finally, 344 children were included.

Statistical analysis

Data collection and management were performed using EpiData 3.0 (Centers for Disease Control, Atlanta, GA, USA). Statistical analysis was performed with SPSS 20.0 (IBM, Armonk, NY, USA). Continuous variables were assessed by the Kolmogorov-Smirnov test and are presented as mean±standard deviation or median (range). Categorical variables are presented as frequencies. Differences between the 2 groups were evaluated by the *t* test or the Mann-Whitney U test for continuous variables. The chi-square test or the Fisher's exact test was used for categorical data, as appropriate. $P<0.05$ was considered statistically significant.

Results

Patient participation

Among the 577 potential participants, 351 children who met the criteria were enrolled and randomized to the 2-h fast (n=174 after withdrawals) and 1-h fast (n=170 after withdrawals) groups (Figure 1) between 09/2014 and 05/2017. The trial was stopped when recruitment was completed. Table 1 presents the characteristics of the participants.

Volume of gastric content

Gastric content in the 1-h fast group was 0.34±0.35 ml/kg body weight (95% CI: 0.29–0.39), smaller than in the 2-h fast group (0.43±0.33 ml/kg body weight, 95% CI: 0.38–0.48; $t=2.55$, $P=0.011$) (Table 2).

Preoperative blood glucose levels

Blood glucose levels in the 1-h fast group were higher compared with the 2-h fast group ($t=-5.91$, $P<0.001$), but no patient was observed to be hypoglycemic in either group.

Distribution of gastric volume and pH

The rate of patients with gastric content >0.4 ml/kg of body weight was lower in the 1-h fast group compared with the 2-h fast group (10.6% *vs.* 20.1%, $\chi^2=5.988$, $P=0.014$), but there were no differences for pH of gastric content <2.5 (51.8% *vs.* 52.9%, $\chi^2=0.042$, $P=0.837$) and the simultaneous presence of the 2 factors (8.8% *vs.* 10.3%, $\chi^2=0.229$, $P=0.632$) (Table 2).

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Table 1. Characteristics of the patients.

	2-h fast (control) N=174	1-h fast (experimental) N=170
Sex, n (%)		
Male	90 (51.7)	82 (48.2)
Female	84 (48.3)	88 (51.8)
Age (years), n (%)		
0–1	52 (29.9)	48 (28.2)
1–2	59 (33.9)	56 (32.9)
2–3	63 (36.2)	66 (38.8)
Primary disease		
Trilogy of Fallot (ICD-10 Q21-805)	38 (21.8)	36 (21.2)
Tetralogy of Fallot	54 (31.0)	55 (32.4)
Transposition of great arteries	30 (17.2)	31 (18.2)
Atrio-ventricular septal defect	25 (14.3)	22 (12.9)
Total anomalous pulmonary venous drainage	27 (15.5)	26 (15.3)
SPO_2, n (%)		
<70	22 (12.6)	20 (11.8)
70–80	59 (33.9)	62 (36.5)
80–90	69 (39.7)	68 (40.0)
>90	24 (13.8)	20 (11.8)

Pre- and intraoperative adverse reactions

The 1-h fast group showed lower frequencies of crying (40% *vs.* 51.7%, χ^2=4.759, *P*=0.029), thirst (20.6% *vs.* 33.3%, χ^2=7.081, *P*=0.008), and hypoxia (5.3% *vs.* 11.5%, χ^2=4.282, *P*=0.039) compared with the 2-h fast group, but there were no differences for vomiting, witnessed pulmonary aspirations, and heart failure (all *P*>0.05) (Table 3). Four children developed pulmonary infection. After treatment, pneumonia was improved in 3 children and pneumonia recurred in 1 child. All patients were cured before discharge.

Discussion

This randomized trial assessed the gastric residuals after oral glucose water administration 1 h prior to surgery in children with CCHD. The results suggest that a 1-h fast prior to surgery was not inferior to a 2-h fast in terms of gastric residuals and adverse effects in pediatric patients with CCHD.

In 2005, the Scandinavian recommendation suggested using a shorter clear fluid fast of 1 h before anesthesia [14]. Andersson et al. [11] showed that among children 0–16 years of age, shortening the fast duration improved the patients' experience and had a low risk of aspiration, but a certain duration of fasting is required to prevent aspiration [15]. In the present study, the occurrence of aspiration was high, but all children were cured before discharge. Children are prone to crying when uncomfortable and children with CCHD have a higher risk of heart failure and hypoxia when crying because of high right-heart load [16]. Prolonged fasting increases the incidence of thirst and dehydration [17], increasing the risk of thromboembolic events in children with CCHD [18]. The present study showed that compared with a 1-h fast, the 2-h fast led to higher frequencies of crying, thirst, and hypoxia. The American [19], Canadian [20], and European [10] Societies of Anesthesiologists recommend a 2-h fast before anesthesia in infants and young children; "over fasting" in most previous studies refers to >2 h. The results of the present study suggest that a 2-h fast might be too long for children with CCHD.

The historical criteria for the risk of aspiration are: 1) residual gastric fluid volume >0.4 ml/kg body weight (different cutoff values were tried, but 0.4 ml/kg was selected because it is the mean value of the study population); and 2) gastric fluid pH ≤2.5 [21,22]. Some studies suggested that increased gastric content volume and low pH are probable risk factors for pulmonary aspiration [23,24], but this is controversial [12,25]. In this study, the absolute residual gastric content was smaller in the 1-h fast group compared with the 2-h fast group, but no mechanistic insight explaining the difference could be suggested from the design and results of the present study. Nevertheless, there was no difference between the 2 groups regarding the occurrence of gastric residuals >0.4 ml/kg and pH <2.5, as supported by Schmidt et al. [1]. In the present study, the 95% confidence interval of the volume difference between the 2 groups was 0.017-0.163 and the upper limit value was 0.163 <δ=0.2 (*P*<0.01). Thus, the non-inferiority hypothesis was proven to be correct.

In the present study, the rate of pulmonary aspiration was higher than the published rates in children [26], but the American [19], Canadian [20], and European [10] Societies of Anesthesiologists recommend a 2-h fast before anesthesia in infants and young children. The only difference in management between the 2 groups was the duration of the fast, and no difference in the rate of pulmonary aspiration was observed between the 2 groups. It is therefore probable that our high rate of aspiration was due to the criteria we used

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Table 2. Preoperative blood glucose levels and volume and pH of gastric content.

	2-h fast n=174	1-h fast n=170	t/χ^2	P
Gastric content, ml/kg of body weight				
Mean±SD	0.43±0.33	0.34±0.35	2.55	0.011
95% CI	[0.38, 0.48]	[0.29, 0.39]		
Volume of gastric content >0.4 ml/kg of body weight (n, %)	35 (20.1%)	18 (10.6%)	5.988	0.014
pH of gastric content <2.5 (n, %)	92 (52.9%)	88 (51.8%)	0.042	0.837
Gastric content >0.4 ml/kg of body weight and pH <2.5 (n, %)	18 (10.3%)	15 (8.8%)	0.229	0.632
Blood glucose, mmol/L				
Mean±SD	5.59±1.11	6.21±0.78	–5.91	< 0.001
95% CI	[5.43, 5.76]	[6.09, 6.33]		

Table 3. Pre- and intra-operative adverse reactions in the two groups (n, %).

	2-h fast n=174	1-h fast n=170	χ^2/F	P
Crying	90 (51.7%)	68 (40.0%)	4.759	0.029
Thirst	58 (33.3%)	35 (20.6%)	7.081	0.008
Hypoxia	20 (11.5%)	9 (5.3%)	4.282	0.039
Vomiting	6 (3.4%)	7 (4.1%)	0.106	0.745
Witnessed pulmonary aspiration	3 (1.7%)	3 (1.8%)	0.001	0.647*
Heart failure	3 (1.7%)	2 (1.2%)	0.180	0.511*

* Fisher exact test.

to define aspiration, or to the awareness of the medical staff to detect minute aspiration. Supporting these possibilities, Eisler et al. [27] reported underestimation of the rate of perioperative aspiration when using quality insurance reporting; all 4 patients were successfully managed, without signs of infection or affected pulmonary function, but long-term follow-up may be necessary to confirm this.

The present study has some limitations. It only included children with CCHD and from a single hospital, which are selection biases. In addition, postoperative observation and follow-up were not performed. Although care was taken to aspirate all the gastric content by changing the positions of the infants and tube, some residual content could have been left, and suctioning under endoscopic view might provide more reliable results. In addition, the exact pH value was not recorded, only whether it was >2.5 or <2.5. The power analysis was based on the gastric content results of a study by Schmidt et al. [1]. In addition, the present study was powered for the primary endpoint (gastric content volume), and it is probable that the study was underpowered for the secondary endpoints such as adverse events compared between the 2 groups. Furthermore, only patients with CCHD were assessed, and future studies should include more disease types. Finally, the nurses evaluating crying and thirst were blinded to the grouping, but the anesthesiologists and surgeons were not, possibly introducing some bias. In addition, crying was simply defined as yes/no during the 1-h or 2-h preoperative period.

Conclusions

The present study suggests that a 1-h fast prior to surgery was not inferior to a 2-h fast in terms of gastric residuals and adverse effects in pediatric patients with CCHD.

Conflicts of interest

None.

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