Journal of Anesthesia (2024) 38:516–524
https://doi.org/10.1007/s00540-024-03360-2

ORIGINAL ARTICLE

A comparative study using gastric ultrasound to evaluate the safety of shortening the fasting time before pediatric echocardiography: a randomized controlled non-inferiority study

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Received: 4 December 2023 / Accepted: 9 May 2024 / Published online: 8 June 2024

Abstract

Purpose The objective of this study was to demonstrate that the gastric cross-sectional area (CSA) in the right lateral decubitus position (RLDP) during a 2-h fasting period is not larger than that during a conventional 4-h fasting period prior to pediatric echocardiography.

Methods 93 patients aged under 3 years scheduled for echocardiography under sedation were enrolled and randomly allocated into two groups; 2-h fasting vs 4-h fasting. For group 4 h ($n=46$), the patients were asked to be fasted for all types of liquid for more than 4 h, while group 2 h ($n=47$) were asked to be fasted for all types of liquid for 2 h before echocardiography. Gastric ultrasound was performed before echocardiography, and CSA_{RLDP} was measured. We compared $CSA_{RLDP,}$ incidence of at-risk stomach, fasting duration, and the incidence of major (pulmonary aspiration, aspiration pneumonia) and minor complications (nausea, retching, and vomiting, apnea, and bradycardia) between two groups.

Results The mean difference of CSA_{RLDP} (group 2 h–group 4 h) was 0.49 (– 0.18 to 1.17) cm^2, and it was within the non-inferiority margin ($\Delta=2.1$ cm^2). There was no difference in the incidence of at-risk stomach ($P=0.514$). There was no significant difference in the incidence of major and minor complications between the two groups.

Conclusion Two-hour fasting in pediatric patients who need an echocardiography did not increase major and minor complications and CSA significantly.

Keywords Fasting guideline · Fasting time · Sedation · Gastric ultrasound

Introduction

Echocardiography acquires patients' cooperation for precise examination, which is often challenging to achieve in pediatric patients under the age of 3 without sedation [1]. Hence, in many centers, sedation is often performed for echocardiography in children under the age of 3 [1]. Sedation necessitates pre-procedural fasting to reduce gastric residual volume, thereby preventing pulmonary aspiration [2, 3]. American Society of Anesthesiologists (ASA) fasting guidelines provides fasting recommendations based on the types of food, and these are followed in cases involving moderate-to-deep sedation, or general anesthesia [4, 5]. However, when using a single oral sedative for minimal sedation (anxiolysis), there is no standard preparative fasting guidelines [6]. Therefore, many pediatric centers establish their own fasting guidelines for minimal sedation [6]. At our medical center, 8 h (solid) and 4 h (including breast milk, non-human milk, and clear

Presentation: This study was presented as an abstract at the 2023 Annual Meeting of the Korean Pediatric Society.

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liquid) of fasting time are acquired for pediatric patients scheduled for echocardiography under sedation.

In an attempt to comply with the pre-procedural fasting time, it is quite common for the fasting duration to become significantly longer than necessary [7–9]. Moreover, it increases hunger, thirst, irritability, and discomfort in children, causing dissatisfaction of the caregivers [8]. Furthermore, prolonged fasting increases the risk of dehydration and hypoglycemia [6, 10]. Thus, efforts should be made to reduce unnecessary fasting time.

Therefore, we hypothesized that a 2-h fasting time, more aligned with the feeding schedule of children under 3 years of age, could be permissible without significantly increasing the risk of pulmonary aspiration compared to the conventional 4-h fasting period. To assess the risk of pulmonary aspiration, we utilized gastric ultrasound. Gastric ultrasound is a valuable point-of-care tool that allows for the indirect assessment of the risk of pulmonary aspiration [11–13]. In particular, the measurement of gastric cross-sectional area (CSA) in the right lateral decubitus position (RLDP) is known to be well correlated with gastric residual volume [14]. Therefore, in our study, we compared the gastric CSA_{RLDP} between the standard fasting guideline (4 h) and the shortened fasting guideline using gastric ultrasound (2 h) through a non-inferiority trial. We also evaluated the rate of the complication following sedation.

Methods

Ethics

This study was approved by the Institutional Review Board of Samsung Medical Center (IRB No 2023-07-172). Prior to the study participation, written informed consent was achieved from the parents. The informed consent was obtained when the participants visited the outpatient clinic, approximately 1–2 months earlier to the echocardiography date. This study was registered at ClinicalTrials.gov (NCT05757882). This study was conducted in a single tertiary hospital (Samsung Medical Center, Seoul, Republic of Korea) from May 2023 to August 2023.

Study participants

Patients aged less than 3 years, without anatomical deformities in the foregut, scheduled for elective pediatric echocardiography under sedation were included. This study excluded the patients with either of the followings: (1) any conditions with not-permitted oral feeding (tube feeding or gastrostomy feeding), (2) neurologic problems affecting gastric passage with or without medications, (3) any structural abnormalities that prevent gastric ultrasound (ex. abdominal mass), (4) considered as difficult airway, (5) any condition that oral sedation is not applicable, (6) allergic history to chloral hydrate, or (7) when parents refused the participation.

Randomization and blinding

Before the study enrollment, a researcher not directly involved in the study conducted randomization through an Internet-based system (http://www.randomization.com). Following the randomization process, patients were assigned randomly to one of the two groups (group 4 h vs. group 2 h) in a 1:1 ratio, with each group having an equal chance of 50%. A sonographer performing the gastric ultrasound was unaware of the group allocation.

Study process

Once the echocardiography under sedation was decided during the outpatient visit, the parents of the child were informed about the study, and consent forms were obtained. Then, the children were assigned to one of the two groups based on the predetermined sequence. The parents of each child were provided with fasting guidelines according to the allocated group. The group 4 h was instructed to be fasted for all types of liquids (breast milk, non-human milk, and clear liquid), starting from 4 h before the echocardiography. While the group 2 h was instructed to be fasted for all types of liquids (breast milk, non-human milk, and clear liquid) starting from 2 h before the echocardiography. Solid food was fasted for 8 h in both groups (Fig. 1).

Gastric ultrasound

Upon the patient's arrival, oral chloral hydrate (50 mg/kg) was administered for sedation. If successful sedation was achieved, the gastric ultrasound was performed. The gastric ultrasound was conducted by a single sonographer with over 10 years of experience, who was trained and supervised for the gastric ultrasound. VENUGO (GE Healthcare, Wauwatosa, WI, USA) and 4 MHz curved transducer were used. The patients were positioned on the examination bed with their upper body elevated at a 45° angle. Gastric ultrasound was performed in supine position, followed by the RLDP. The ultrasound probe was positioned on the epigastric area, and gastric antrum was explored while moving it in the parasagittal plane toward the right. Gastric antrum was identified between the left lobe of the liver and pancreas, with inferior vena cava being position posteriorly. The gastric antral CSA was determined by measuring the two perpendicular diameters, namely the anteroposterior (AP) and longitudinal (LD) diameters (Fig. 2). Measurements of both diameters were made between peristalsis, and included the serosa layer. CSA was obtained using the formula for the

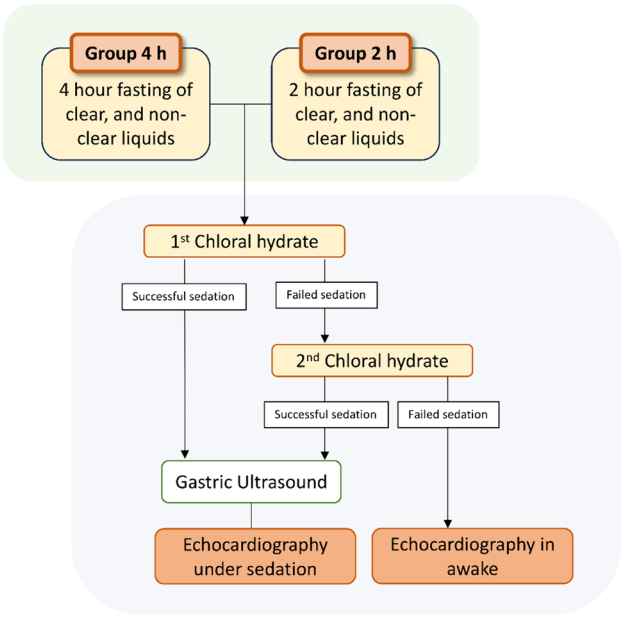

Fig. 1 The flowchart illustrating the study process

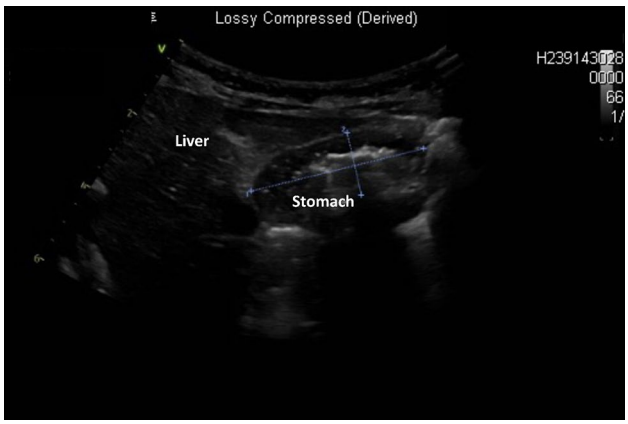

Fig. 2 An example figure depicting gastric measurement

area of an ellipse (AP × LD × π) /4 [15]. Gastric volume was calculated using the following formula for estimating gastric volume in pediatrics [16]:

$$\text{Gastric volume} = -7.8 + \left(3.5 \times \text{CSA}_{\text{RLDP}}\right) + 0.127 \times \text{age (months)}.$$

After dividing gastric volume by weight, an 'at-risk stomach' as a gastric volume exceeding 1.25 mL/kg [17].

Echocardiography and sedation

After the gastric ultrasound examination, the echocardiography was performed. In the event of unsuccessful sedation, or if the oral chloral hydrate was vomited, a repeat dose of oral chloral hydrate (50 mg/kg) was given after a 20-min interval. If sedation failed after the second attempt, echocardiography was performed without sedation and the patients were dropped out from the study.

Secondary outcomes

Data including height, weight, main cardiac diagnosis, and actual time of the patients' last meal were collected. The incidence of major complications (pulmonary aspiration, and aspiration pneumonia), as well as minor complications including nausea, retching, and vomiting, apnea, and bradycardia (< 60 beats per minute) were investigated. The depth of sedation was assessed using the Ramsay Sedation Scale, targeting levels 3 (asleep, response to verbal conversation level) to 4 (asleep, brisk response to light glabellar tap or loud noise) [18]. Inadequate sedation was defined as the failure to reach Ramsay Sedation Scale 3 or 4.

Sample size estimation

The aim of this non-inferiority study was to demonstrate that CSA_{RLDP} after 2 h of fasting (group 2 h) is not larger than that after 4 h of fasting (group 4 h). In pediatric patients, the median difference of CSA_{RLDP} between the grade 2 stomach (known to increase the risk of pulmonary aspiration) and the grade 1 stomach (gastric contents exists but not to the extent to increase the risk of pulmonary aspiration) was 2.1 cm^2 [16]. Therefore, a CSA_{RLDP} of 2.1 cm^2 was selected as a non-inferiority delta. In a previous study, the mean difference of CSA_{RLDP} between the different fasting guidelines was 0.04 cm^2, with a combined standard deviation of 3.203 [15]. The sample size was calculated to test the null hypothesis H_0: $\mu_1 - \mu_0 \geq 2.1$ versus H_1: $\mu_1 - \mu_0 < 2.1$, where μ_0 represents for the CSA_{RLDP} of group 4 h (control group), and μ_1 of group 2 h (test group). According to the allocation ratio of 1, a total of 100 participants (50 participants in each group) were needed using the $\alpha = 0.05$, $\beta = 0.2$, and drop-out rate of 40%.

Statistical analysis

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) v 20.0 software (SPSS, Inc, Chicago, IL) and R version 4.3.1 (R Project for Statistical Computing; R Foundation for Statistical Computing, Vienna, Austria). Continuous variables are expressed as mean and standard deviation (SD), ordinal variables as median and

interquartile range (IQR), and nominal variables as numbers and percentages. Intention-to-treat analysis was used for the cases where the fasting guideline was not adhered to each protocol. Data were compared between the group 4 h and group 2 h using Student's *t* test for normally distributed continuous data, Mann–Whitney *U* test for non-normally distributed data, and Chi-square test or Fisher's exact test for categorical data. $P < 0.05$ was considered statistically si7gnificant. Non-inferiority was declared if the upper limit of the two-sided 95% confidence interval (CI) fell below the non-inferiority margin.

Results

One thousand, four hundred and forty-three patients were assessed for eligibility. Among them, 1343 patients were excluded due to exclusion criteria. Therefore, 100 patients, 50 patients in each group, were randomly allocated to either of the group 4 h or 2 h. Three patients in the group 4 h were lost to follow up, because of cancelation of examination due to fever. One patient in the group 4 h, and three patients in the group 2 h were excluded from the final statistical analysis due to failed sedation (Fig. 3).

The demographic data of the patients are presented in Table 1. The mean age of patients in each group was 13.6 ± 8.2 months in the group 4 h, and 11.1 ± 4.7 months in the group 2 h ($P = 0.073$). There were no differences between the two groups in terms of gender ratio, height, weight, and main cardiac diagnosis. The median fasting hours in the group 4 h were 4.8 ± 1.6 h, while it was 2.3 ± 0.5 h in the group 2 h ($P < 0.001$).

Gastric ultrasound measurements are described in Table 2. CSA_{supine} was 2.22 (1.65–3.26) cm^2 in the group 4 h, and 2.63 (1.88–4.01) cm^2 in the group 2 h, with a median difference and 95% CI of 0.38 (– 0.13 to 0.92) ($P = 0.128$). CSA_{RLDP} was not different between the two groups [2.46 (1.58–3.18) cm^2 in the group 4 h vs. 3.02 (1.86–4.17) cm^2 in the group 2 h, median difference (95% CI) of 0.53 (– 0.01 to 1.13), $P = 0.059$]. There was no significant difference in gastric volume between the two groups ($P = 0.136$). Gastric volume per weight was 0.25 (0–0.64) mL/kg in the group 4 h, and 0.47 (0.02–0.90) mL/kg in the group 2 h, with median difference (95% CI) of 0.11 (0–0.38, $P = 0.108$). The incidence of at-risk stomach in both groups did not show significant difference (8.7% in the group 4 h vs. 10.6% in the group 2 h, $P = 0.514$]. The mean difference of CSA_{RLDP} (group 2 h–group 4 h) was 0.49 (– 0.18 to 1.17) cm^2, and the upper limit of two-sided 95% CI of the differences in means was below the non-inferiority margin of 2.1 (Fig. 4).

There was no difference in sedation scores between the two groups before, during, and after sedation. There was no major complications in both groups. There was one (2.2%) patient complaining nausea in the group 4 h, and two (4.3%) patients in the group 2 h ($P > 0.999$) (Table 3).

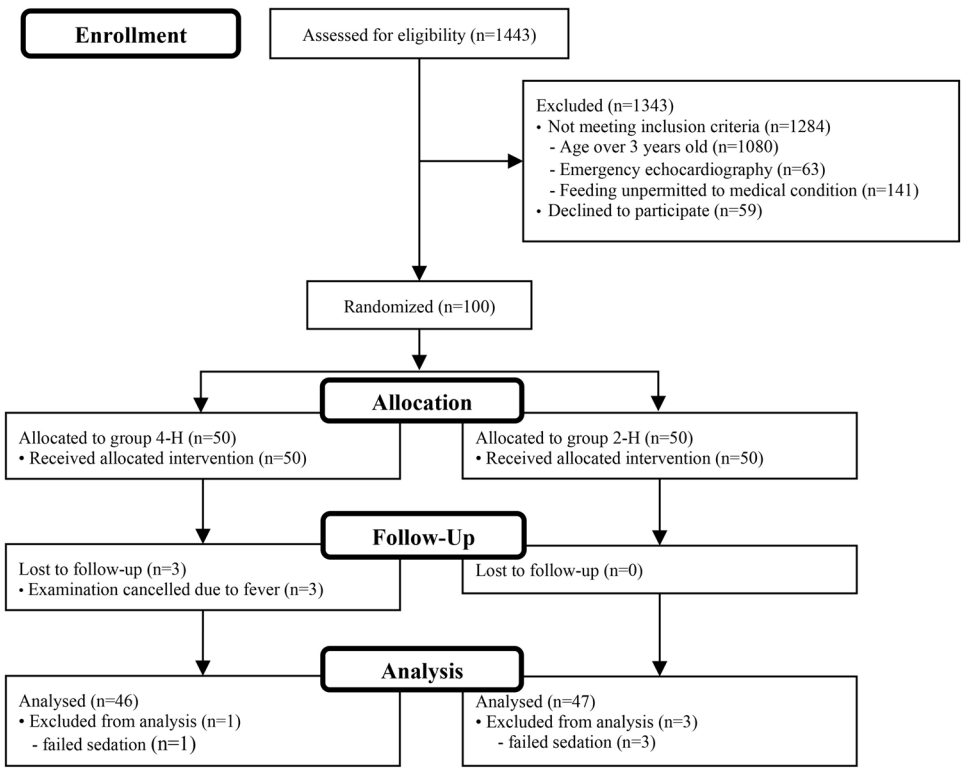

Fig. 3 CONSORT diagram of the present study

Table 1 Baseline characteristics of the study populations

	Group 4 h ($n=46$)	Group 2 h ($n=47$)	P value
Age, month	13.6 ± 8.2	11.1 ± 4.7	0.073
Age distribution			0.210
~ 6 months	8 (17.4)	6 (12.8)	
6 ~ 12 months	19 (41.3)	28 (59.6)	
> 12 months	19 (41.9)	13 (27.7)	
Sex, male	22 (47.8)	20 (42.6)	0.609
Height, cm	75.0 ± 8.8	74.5 ± 8.7	0.777
Weight, kg	9.3 ± 2.3	9.2 ± 1.8	0.803
Main cardiac diagnosis			0.391
Congenital heart disease			
Atrial septal defect	14 (30.4)	7 (14.9)	
Patent foramen ovale	5 (10.9)	5 (10.6)	
Ventricular septal defect	11 (23.9)	17 (36.2)	
Patent ductus arteriosus	2 (4.3)	7 (14.9)	
Pulmonary stenosis	3 (6.5)	2 (4.3)	
Tetralogy of Fallot	4 (8.7)	2 (4.3)	
Atrioventricular septal defect	0 (0)	1 (2.1)	
Acquired heart disease			
Kawasaki disease	4 (8.7)	4 (8.5)	
Dilated cardiomyopathy	2 (4.3)	1 (2.1)	
Miscellaneous	1 (2.2)	1 (2.1)	
Fasting hours, hour	4.8 ± 1.6	2.3 ± 0.5	< 0.001*

Data are presented as mean ± SD, and numbers (%)

*$P < 0.05$

Table 2 Cross-sectional area (CSA) measured by gastric ultrasound in the supine, and right lateral decubitus (RLDP) positions, estimated gastric volume, and the incidence of risk stomach

	Group 4 h ($n=46$)	Group 2 h ($n=47$)	Difference (95% CI)	P value
$CSA_{supine,}$ cm^2	2.22 (1.65–3.26)	2.63 (1.88–4.01)	0.38 (– 0.13 to 0.92)	0.128
$CSA_{RLDP,}$ cm^2	2.46 (1.58–3.18)	3.02 (1.86–4.17)	0.53 (– 0.01 to 1.13)	0.059
Gastric volume, mL	2.18 (0–4.83)	4.17 (0.15–8.97)	0.98 (0 to 3.61)	0.136
Gastric volume per weight, mL/kg	0.25 (0–0.64)	0.47 (0.02–0.90)	0.11 (0 to 0.38)	0.108
At-risk stomach[a]	4 (8.7%)	5 (10.6%)	−0.02 (– 0.10 to 0.10)	0.514

Data are presented as median (interquartile range), and numbers (%)

[a]defined by gastric volume per weight > 1.25 mL/kg

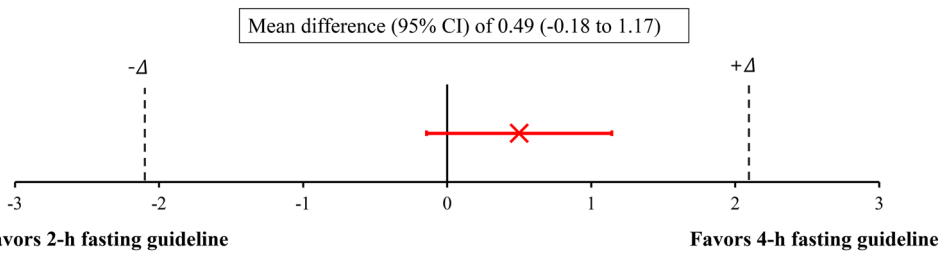

Fig. 4 Non-inferiority diagram of the mean difference of CSA_{RLDP} between 4 h fasting group (group 4 h) and the 2 h fasting group (group 2 h). The dashed line represents the non-inferiority margin ($\Delta = 2.1$). The error bars indicate the 95% CI of the mean CSA_{RLDP} difference (group 2 h–group 4 h). The diagram describes that 2-h fasting is non-inferior to 4-h fasting as to CSA_{RLDP}

Table 3 Sedation score and complications related to sedation

	Group 4 h ($n=46$)	Group 2 h ($n=47$)	P value
Ramsay sedation scale			
Before sedation	2 (2–2)	2 (2–2)	0.163
During sedation	4 (4–4)	4 (4–4)	> 0.999
After sedation	2 (2–2)	2 (2–2)	> 0.999
Major complications			
Pulmonary aspiration	0 (0)	0 (0)	N/A
Aspiration pneumonia	0 (0)	0 (0)	N/A
Minor complications			
Bradycardia	0 (0)	0 (0)	N/A
Nausea, retching, or vomiting	1 (2.2)	2 (4.3)	> 0.999
Apnea	0 (0)	0 (0)	N/A

Data are presented as median (interquartile range), and numbers (%)

N/A not available

Discussion

Our results indicate that there was no difference in CSA, gastric volume, and the incidence of at-risk stomach between the group 4 h and the group 2 h. Furthermore, there was no significant difference in major and minor complications related to sedation. A 2 h liquid fasting period is equivalent to a regular mealtime for patients under 3 years old. Considering that the feeding interval for infants under 2 months of age is typically 2–4 h [19], a 2-h fasting period closely aligns with their normal eating schedule, which can be particularly comfortable for infants during this stage.

There are growing body of research aiming to establish consensus on reducing excessive fasting times. Regarding clear fluids, some studies advocate for encouraging the intake of carbohydrate drinks up to 2 h before surgery to provide energy source [5]. Additionally, there are researches suggesting that the clear fluids can to be consumed up to 1 h before surgery, or even until immediately before surgery [5, 20, 21]. Hence, a consensus among numerous clinicians is emerging to emphasize minimal fasting periods, aimed at averting catabolism, maintaining homeostasis, and mitigating fasting-related complications while enhancing overall outcomes [10, 22, 23].

Since the introduction of gastric ultrasound, studies have introduced the possibility of liberal fasting times for non-human milk or infant formula compared to the previous ASA guidelines of 6 h for non-human milk and infant formula [24–26]. There was no significant difference in gastric fluid volume after infant formula up to 4 h before surgery compared to formula fasting for 6 h, indicating the potential for shortening formula feedings to 4 h before surgery [24]. Another study indicated that there were no significant differences in liquid gastric emptying after taking equal volumes of orange juice or milk, provided that they contained the same caloric content. They suggested that gastric emptying of liquids depends primarily on the total caloric content [25]. Du et al. described that the stomach is cleared by 3–3.5 h after drinking three different drinks (apple juice, 2% milk, and high protein drink). This study does not provide evidence to justify the differentiation between liquids as outlined in the current ASA guidelines [26]. Our study applied an equal fasting time to all types of fluids (breast milk, non-human milk, and formula); however, it may not be feasible to uniformly apply the same fasting time to all types of fluids based on our study findings. Our study suggests that further research using gastric ultrasound to investigate the emptying time of various fluids consumed by children is warranted, which might yield results differing from those of the ASA fasting guidelines.

Echocardiography is characterized by its relatively brief duration, non-invasiveness, and low level of discomfort [1]. Therefore, it does not require deep sedation. However, since minimal sedation also uses sedatives, pre-procedural fasting is still required. Although there is an expectation in clinical practice that minimal sedation may accept short fasting duration, there is a lack of enough research. Therefore, we suggest that our study holds significant importance in investigating fasting times for minimal sedation in children.

Gastric ultrasound is a non-invasive point-of-care tool that is valuable for assessing the risk of pulmonary aspiration [27–29]. It is demonstrated in the prior study investigating the feasibility of gastric ultrasound for assessing gastric content and volume that evaluating the stomach in the right lateral decubitus position allows the gastric contents to localize in the most dependent area, namely the gastric antrum, which is positioned in the right caudal portion of the stomach [30]. Therefore, measuring the CSA of the gastric antrum in the RLDP showed the highest correlation with gastric residual volume [30]. Among various assessment methods, CSA_{RLDP} is the most commonly used for evaluating pulmonary aspiration risk. CSA_{RLDP} is compared to the

cutoff values to examine the risk of pulmonary aspiration, or it can be incorporated into formulas to estimate gastric residual volume [31]. While the calculation of gastric volume can provide valuable information, it can sometimes be imprecise and yield inexact values, occasionally resulting in negative results [31]. Furthermore, since the gastric volume model was developed for pediatric patients with an average age of 11 years, it may not precisely fit our patient population of children under 3 years old [16]. Therefore, we chose CSA_{RLDP} as the primary endpoint to assess pulmonary aspiration risk.

According to our study results, 2-h fasting guideline was non-inferior to 4-h fasting guideline as to CSA $_{RLDP}$. Furthermore, there was no statistically significant difference between the two fasting guidelines in calculated gastric volume and gastric volume per weight. However, since gastric volume was not directly measured, we cannot assert whether actual gastric volume was not increased in 2-h fasting guideline compared to 4-h fasting guideline. Therefore, while CSA $_{RLDP}$ in the group 2 h may not be significantly greater than group 4 h, caution is warranted in interpreting our study as it remains unclear whether actual gastric volume was increased and whether this poses an increased risk of pulmonary aspiration.

This study was conducted in pediatric patients under the age of 3, for whom patient cooperation is crucial during pediatric echocardiography. Obtaining cooperation, particularly in children under 3, can be challenging due to fear and anxiety [1]. Moreover, irritability caused by fasting can further complicate the examination. We shortened the pre-procedural fasting time before pediatric echocardiography, and our findings revealed that there was no significant difference in sedation-related complications or an increase in gastric contents that would elevate the risk of pulmonary aspiration compared to the conventional 4-h fasting period. Therefore, we anticipate that reducing the fasting time before pediatric echocardiography to 2 h, using sedation with oral chloral hydrate, has distinct advantages. Performing echocardiography without sedation is often impractical in children under the age of 3, making the fasting time for echocardiography a critical consideration. Our study, which demonstrated these results in children under 3, is particularly meaningful.

The rationale behind selecting a non-inferiority margin of 2.1 for our study involved thorough consideration of available studies done on similar populations. However, due to the challenges encountered in finding a study precisely matching our patient cohort, we applied the CSA RLDP value from the prior study done on children approximately 11–12 years undergoing elective upper gastrointestinal endoscopy. Therefore, the demographic disparity from our study population must be acknowledged as a limitation. The value of 2.1 was deemed that the non-inferiority delta value should be smaller than the 2.8 used in studies involving adults [15], and larger than the 1.9 difference observed in research conducted on infants under 12 months of age [32]. By selecting a delta value that falls between the ranges observed in studies involving adults and infants, we aimed to strike a balance that reflects the specific requirements of our pediatric population while ensuring the robustness and clinical relevance of our findings.

Our study has several limitations. First, we excluded patients with gastrointestinal disorders, such as foregut anomaly hiatal hernia, gastroesophageal reflux disease, bowel obstruction, enteral tube feeding, ileus, and emergency care gastroparesis from the study. Therefore, it should be noted that a 2-h fasting period should not be applied in cases with such gastrointestinal conditions. Second, in our study, we employed oral chloral hydrate for sedating the patients. Oral chloral hydrate is the one of the commonly used non-intravenous sedatives for pediatric echocardiography, and is known to have rare fatal complications [1, 33, 34]. According to a retrospective study, the incidence of adverse events requiring major intervention was 0.5% [1]. Thus, if different agent was chosen for sedation, the incidence of adverse events, such as nausea, vomiting, and respiratory depression, may vary, potentially leading to different outcomes. Third, the standard fasting protocol of 4 h for all types of fluids, which has been traditionally utilized in our medical center, is more conservative compared to the existing ASA fasting guideline. It was empirically established, considering our medical environment, where it may not be feasible to wait until the fasting period for patients who did not adhere to the fasting instructions. Our study compared the safety of a shortened fasting period of 2 h, in contrast to our institution's standard fasting guideline of 4 h. Therefore, as our guideline does not directly compare to the current widely accepted ASA guideline of 2 h of clear fluid, the safety assessment in comparison to the ASA fasting guideline cannot be made. Finally, this study was conducted on patients undergoing echocardiography. Hence, the dosage of oral chloral hydrate might vary when procedures provoke a gag reflex, involve painful stimulation, or take a long time, potentially leading to varying outcomes. Additionally, when dealing with patients who cannot be present at the bedside for imaging studies like computed tomography or magnetic resonance imaging, caution should be exercised when applying the findings of our study.

In conclusion, shortening the fasting period before echocardiography to 2 h for children under the age of 3 did not increase the gastric CSA compared to the conventional 4-h fasting guideline. In addition, it did not increase the risk of major or minor complications related to sedation. Therefore, we suggest that 2-h fasting time can be safely implemented for pediatric patients undergoing echocardiography under sedation.

Acknowledgements The authors would like to thank Jung Youn Park, Jae Sook Seo, and Hyang Mi Park (sonographer) for their technical assistance with ultrasound imaging.

Data availability The data generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest The authors have no conflict of interest.

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