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ORIGINAL ARTICLE

Ultrasound evaluation of gastric emptying of high-energy semifluid solid beverage in parturients during labor at term: a randomized controlled trial

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Abstract

Purpose What to intake during labor is controversial. The purpose of this study was to compare the gastric emptying of high-energy semifluid solid beverage (HESSB) versus that of carbohydrate (CHO) solution of equal calories and volume by evaluating the gastric antral cross-sectional area (CSA) using ultrasonography in parturients during labor at term.

Methods The study was conducted at a maternity and infant hospital between June and October 2020. Forty parturients scheduled for epidural labor analgesia during labor at term were randomly assigned to receive HESSB (300 mL, $n=20$) or CHO (300 mL, $n=20$). Gastric antral CSA was measured at baseline and 5, 30, 60, 90, and 120 min after consumption of the drink. The primary outcome was gastric antral CSA at 120 min in the HESSB group and CHO group.

Results The gastric antral CSA between the HESSB group and CHO group at 120 min was not statistically significant (2.73 $cm^2 \pm 0.55$ vs. 2.55 $cm^2 \pm 0.72$, $P=0.061$). All patients returned to baseline at 120 min after intake of 300 mL isocaloric HESSB and CHO, confirmed by evaluation of gastric antral CSA. The visual analog scale score for satiety was higher in the HESSB group ($P<0.001$), with better taste satisfaction (7[5–8] vs. 5[4–6], $P<0.001$).

Conclusion The change of gastric antral cross-sectional area after HESSB is similar to the corresponding calories and volume of CHO and the gastric emptying of HESSB can be emptied within 2 h with better taste satisfaction and satiety in pregnant women under labor analgesia.

Keywords Ultrasound · Gastric emptying · Semi-fluid solid beverage · Parturients

Introduction

With significant advances in obstetric analgesia and anesthesia, the use of general anesthesia during labor has become a rare occurrence and the policy of routine oral restriction for all parturients has been questioned [1–3]. Neuraxial anesthesia has become the most common type of anesthesia for cesarean delivery and with these methods, the risk of aspiration is much lower [4]. To some extent, we can prevent the need for general anesthesia in the settings of emergency cesarean delivery with a functioning epidural catheter for analgesia, and may actually be protective against aspiration in some circumstances. We should pay more attention to patients' satisfaction and comfort without compromising safety. It is time to reassess the impact of oral intake restriction during labor given the minimal risk of aspiration in the setting of modern obstetric anesthesia practices.

There has been limited research on the nutritional needs of parturients during labor, but sports medical scientists believed that the process of childbirth is similar to the process of athlete's strenuous exercise and it has been proposed that the energy requirements of labor are similar to that of the continuous moderate aerobic exercise [2]. Allowing a laboring woman to eat and drink at will during labor would contribute to both her comfort and her sense of well-being

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[5]. The study by Bouvet et al. [6] showed that fasting during labor contributes to maternal discomfort. According to an investigation of the status of oral intake management measures of 1213 hospitals in 22 provinces, cities, and autonomous regions during labor in China, different hospitals in China have adopted different oral intake management measures [7]. It is still unknown what kind of food or drink can be allowed to be intake during labor. We should explore suitable oral intake substances to ensure energy and safety for pregnant women.

A recent study [8] showed that maltodextrin is cleared from the stomach faster than coffee with milk and orange juice in laboring women. Gastric emptying depends on factors other than the caloric load and volume of the drink. The physical forms of food, i.e., solid versus liquid or versus semi-solid, may have different effects on the satiation, satisfaction, and gastric emptying of parturient in term [9]. A previous study revealed that gastric emptying time will be within 2 h when 400 ml or less oral carbohydrate (CHO) is taken by term parturient [10] . Researchers in our hospital have developed a kind of high-energy semifluid solid beverage to better ensure the demand for energy and the safe process of childbirth for parturients. This oral intake had applied for the national invention patent (application number was ZL 2019 10197792.9). In this study, we aimed to compare the gastric emptying of HESSB with that of CHO by evaluating the gastric antral cross-sectional area (CSA) using ultrasonography in parturients during labor analgesia.

Methods

Study design and study population

The study was approved by the Ethics Committee of Shanghai First Maternity and Infant Hospital, Shanghai, China (NO.KS 201003; Chairperson Dr. Xiao sheng Feng) on March 20, 2020. The trial was registered at http://www.chictr.org.cn (identifier: ChiCTR2000033311; Principal investigator: X.N.; date of registration: 27 May 2020). This study was designed and conducted according to the Consolidated Standards of Reporting Trials guidelines [11] .

We recruited women with singleton pregnancies more than 37 weeks of gestation and at low risk of potentially requiring general anesthesia in the delivery room in our hospital. The inclusion criteria were an American Society of Anesthesiologists (ASA) physical status II, more than 37 weeks of gestation, more than 18 years old, body mass index of 19–30 $kg.m^{-2}$, ultrasound examination without cephalopelvic disproportion, and minimum fasting duration of 2 h for clear fluids, 6 h for a light meal and 8 h for a high-fat or high-protein meal, pregnant women with an empty stomach at screening. The exclusion criteria were parturients with diabetes mellitus, previous surgical procedures on the esophagus, stomach, or upper abdomen, expected delivery time < 2 h, intolerance to high-energy semifluid solid beverage or carbohydrate.

Study protocol

After written informed consent was obtained, an ultrasound assessment of the antral CSA was performed by one investigator of the study team at the time of admission to the delivery room as a baseline reading using Ultrasound Machine (SonoSite- S-Nerve Ultrasound System, USA) with 2–5 MHz curved probe. An independent statistician used Excel software to generate a random sequence and numbered opaque envelopes. Epidural analgesia was initiated when cervical dilation reached 2 cm, 10 min later, when the VAS of pain score reached 3 or 4, one of the study investigators opened the sealed envelope to determine which study drink was allocated and put the study drink in an opaque container. No other food or drinks were allowed during ultrasound assessments in our study. The main components of the two drinks are listed in Table 1. Both drinks contained 378 kcal in a 300 ml volume. The parturient then consumed the drink within 5 min. Repeated time points of ultrasound measurement were taken at 5, 30, 60, 90, and 120 min after drinking by one investigator of the study team, who was blinded to the drink allocation. The left lobe of the liver, pancreas, aorta and inferior vena cava were the scanning landmarks [8]. The study investigator performing the ultrasound examination had performed at least 150 scans of pregnant women. All patients underwent gastric ultrasound in the right lateral decubitus position at head-up 45 degrees. The CSA of the gastric antral was measured 3 times by the free tracing method, and we averaged the three measurements. The empty stomach of pregnant women was defined by an antral CSA less than 3.00 cm^2 in a semirecumbent position with a 45-degree head-up tilt [12]. Gastric emptying in this study was defined as antral CSA at any time point equal to or less than baseline.

Table 1 Comparison of the main components of the two study drink

	HESSB	CHO
Calories; kcal	378 kcal	378 kcal
Water (diluent); ml	300 ml	300 ml
Protein (kcal); %	7.6%	0
Carbohydrate (kcal); %	90%	100%
Lipid (kcal); %	2.4%	0
The nature of final drink	viscous semifluid	fluid

HESSB high-energy semifluid solid beverage (Beihao; Shanghai Juesheng Biotechnology Co., Ltd, *CHO* carbohydrate (Qingliusu; Shanghai Shouyuan Biotechnology Co., Ltd)

Measurements

The primary outcome was the difference between groups with respect to antral CSA at 120 min. Secondary outcomes were the gastric antral area measured at baseline and at 5, 30, 60, 90 and 120 min in the right lateral decubitus position at 45 degrees, the satiety scores at multiple time points using the visual analog scale(VAS), from 0 (not at all) to 10 (very much) at baseline and at 5, 30, 60, 90 and 120 min after gastric ultrasound assessment. Satisfaction with the taste was assessed at 120 min using the VAS score.

Statistical analysis

GraphPad Prism 6.00 and SPSS 23.0 were used for statistical analysis. Continuous data with normal distribution were represented by mean ± SD, otherwise median, and interquartile range (IQR) were represented. Repeated measures analysis of variance was used to compare the changes of gastric antral CSA among time points after parturients intake of the HESSB and CHO. Wilcoxon signed-rank tests were used to further assess these pairwise comparisons. Bonferroni correction was made for repeated measures where appropriate. Statistical differences were considered significant if $P < 0.05$.

The sample size was determined using online sample size calculations at www.cnstat.org. There was very limited information for sample size estimation. Based on Irwin's study comparing the gastric emptying of tea with milk versus water using ultrasonography in fasted pregnant patients, which showed mean ± SD fasted supine gastric antral CSA 10 $cm^2 \pm 2.9$, they considered a 25% increase in antral CSA would be a significant change [13]. Combined with our pre-experimental results comparing the gastric antral CSA of fasted patients intake HESSB and CHO at 2 h, in which fasted parturients consumed HESSB achieved mean ± SD gastric antral CSA in the right lateral decubitus position at 45 degrees of 3.56 $cm^2 \pm 0.56$ at 2 h, and fasted parturients consumed CHO achieved mean ± SD gastric antral CSA of 3.02 $cm^2 \pm 0.48$ at 2 h, we assumed a difference between the two groups of 0.54 cm^2 and a pooled SD of 0.52. With the α error set at 0.05, and β error set at 0.2 (power of 80%), 16 patients per group were required. To allow for dropouts, the sample size of 20 parturients was randomized to each group.

Results

Forty patients were included in the statistical analyses. Figure 1 shows the recruitment flow diagram. The characteristics of the HESSB group and CHO group are shown in Table 2. There are no significant differences between groups in age, height, weight, or gestational age. Postpartum

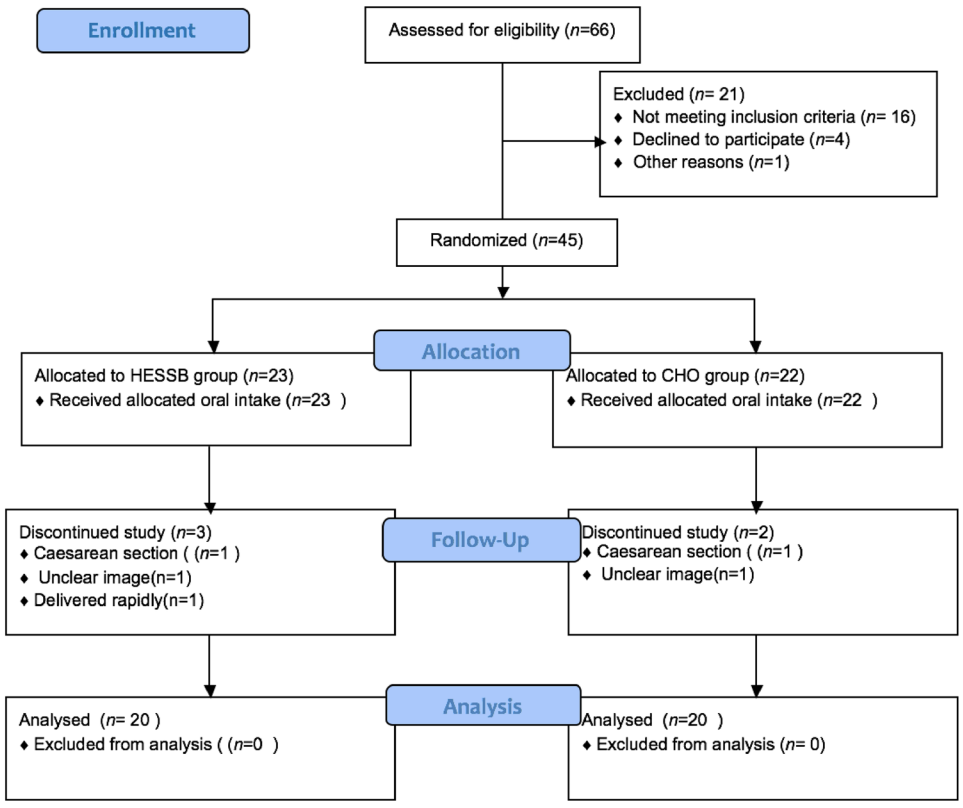

Fig. 1 CONSORT study flowchart

Table 2 Characteristics of the HESSB group and CHO group

	HESSB $n=20$	CHO $n=20$
Age(yr), mean (SD)	29 (3.0)	28 (2.2)
Height(cm), mean (SD)	162 (4.5)	163 (5.3)
Weight(kg), mean (SD)	68.0 (2.1)	70.3 (5.2)
Gestational age(day), mean (SD)	277.3 (4.5)	276.7 (6.3)
Postpartum hemorrhage(ml), median [IQR]	310 [310–386]	365 [314–409]
1 min Apgar score, median [IQR]	9 [9, 10]	9.5 [9, 10]
5 min Apgar score, median [IQR]	10 [10–10]	10 [10–10]

The data are presented as the mean (SD) or median [IQR]

SD standard deviation, *IQR* interquartile range, *HESSB* high-energy semifluid solid beverage, *CHO* carbohydrate

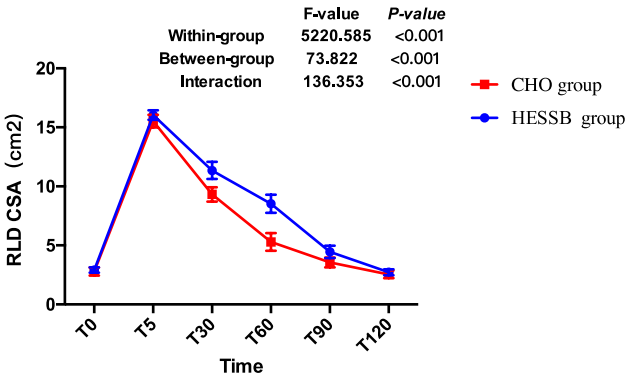

Fig. 2 Changes in gastric antral right lateral decubitus CSA at baseline, 5, 30, 60, 90, 120 min after oral intake comparing the CHO group and HESSB group. The data are presented as the mean ± SD. The *P* values are the results from two-way repeated-measures ANOVA with time and group as two factors to be analyzed. The red line represents the CHO group, the blue line represents the HESSB group. T0, baseline; T5, 5 min after drinking; T30, 30 min after drinking; T60, 60 min after drinking; T90, 90 min after drinking; T120, 120 min after drinking

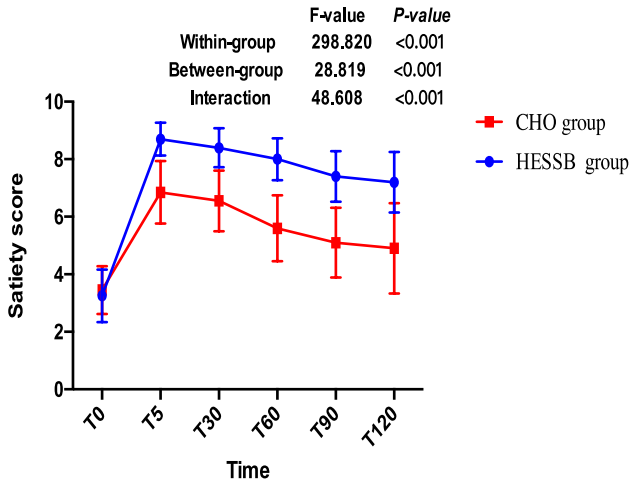

Fig. 3 The visual analog scale score of satiety between the HESSB group and CHO group. The data are presented as the mean ± SD. The *P* values are the results from two-way repeated-measures ANOVA with time and group as two factors to be analyzed. The red line represents the CHO group, the blue line represents the HESSB group. T0, baseline; T5, 5 min after drinking; T30, 30 min after drinking; T60, 60 min after drinking; T90, 90 min after drinking; T120, 120 min after drinking

hemorrhage and neonatal Apgar scores between groups had no difference.

The changes in ultrasound estimated gastric antral CSA over time are presented in Fig. 2. At the baseline scan, the two groups had a similar gastric antral CSA (2.91cm^2 ± 0.22 vs 2.79 cm^2 ± 0.34, $P=0.158$) in the right lateral decubitus position at 45 degrees. All parturients had an empty stomach. At 120 min, the difference of gastric antral CSA between HESSB group and CHO group was not statistically significant (2.73 cm^2 ± 0.55 vs 2.55 cm^2 ± 0.72, $P=0.061$). The gastric antral CSA of HESSB at 30, 60, 90 min were higher than that in the CHO group, all patients in the two groups returned to baseline at 120 min. Both groups achieved a maximum gastric antral CSA at 5 min.

Compared to the CHO group, the HESSB group had a better degree of satiety($P<0.001$; Fig. 3). The interaction between time and group was significant ($P<0.001$; Fig. 3).

The taste satisfaction in the HESSB group was higher than that in the CHO group (7[5–8] vs 5[4–6], $P<0.001$; Fig. 4). Neither group had vomiting or other adverse effects.

Discussion

In this randomized controlled study, we found that residual gastric volume would return to baseline level after 2 h for both the HESSB group and CHO group of equal calories and volume by evaluating the gastric antral CSA using ultrasonography in pregnant women under epidural labor analgesia. Our study also showed that taste satisfaction and satiety were better in the HESSB group.

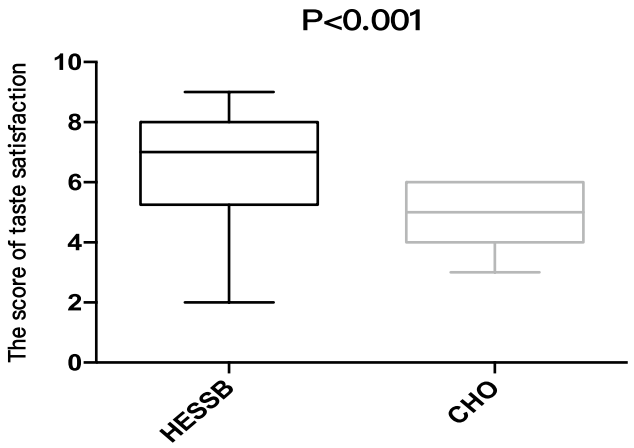

Fig. 4 Comparison of the score of taste satisfaction between the HESSB group and CHO group (7[5–8] vs 5[4–6], $P < 0.001$)

In the culture of China, food and drinks are consumed during labor for nourishment and comfort to help meet the demands of labor [14]. Withholding oral nutrition may result in the development of ketosis and may potentially contribute to a women's stress and dissatisfaction with the birth experience [15]. Less restrictive policies exist in Britain, Australia, and the Netherlands. The American Society of Anesthesiologists recommends that women should be offered modest amounts of clear liquids and avoid intake of solid foods by low-risk laboring women [16]. A policy or guideline regarding oral intake during labor tends to be lacking in many maternity units with a verbal policy controlling this form of labor management [17]. We aimed to enhance the quality of the childbirth process for obstetric patients, improve patient safety and increase patient satisfaction. However, few researchers have explored the appropriate food oral intake during labor in randomized controlled trials. To the best of our knowledge, our study is the first study that assesses a new high-energy semifluid solid beverage for parturients in labor. Our results suggested that the rate of gastric emptying is probably a function of caloric contents as opposed to the compositional content of the fluid, which was in consistent with Okabe's [18]demonstration. In one of their study, 500 ml of milk with a fat content of 3.25 g/dl had a similar rate of gastric emptying to 500 ml of purples orange juice with no fat content but a similar caloric content of about 330 kcal. The degree of viscosity did not seem to alter the rate of gastric emptying [13]. Okabe's research [19] studied the same concept in healthy adults to compare the gastric elimination of a solid meal with water and an equivalent caloric beverage and concluded that gastric elimination did not change as long as the drink quickly became liquid in the stomach, regardless of its content or shape if the calories were the same. In addition, a prospective comparative study concluded that labor epidural analgesia seemed not to worsen but facilitated gastric emptying after a light meal [20], which may explain why all patients in the two groups would return to baseline at 120 min.

Although the difference between HESSB and CHO was only small in protein and lipid content, the satiety and taste satisfaction were better in the HESSB group. A systematic review and meta-analysis [9] on the effects of food texture on satiety concluded that higher viscous food reduced hunger compared to liquid and low viscous food. The HESSB was developed by researchers in our hospital by adjusting the taste and texture as well as the nourishment more suitable for labor parturients. The higher satisfaction of HESSB may be due to its taste and viscous texture. After 120 minutes, although the stomach was already empty, the blood glucose level, the semifluid solid beverage texture of HESSB, the better satiety of HESSB, or other factors may influence the level of satisfaction, which should be further studied.

HESSB may be suitable for women during labor and may have a better influence on their experience of labor. Similarly, some studies have reported that women who ingested the high-protein drink had higher satisfaction scores and the rates of gastric emptying were comparable [5]. Considering the few benefits and the many drawbacks of fasting, a study by O'Sullivan et al. [21] supported the claim that keeping laboring women nothing by mouth is outdated, showing that consumption of a light diet during labor did not influence obstetric or neonatal outcomes in participants, nor did it increase the incidence of vomiting. We also found that there was no significant difference in postpartum hemorrhage and neonatal Apgar scores between the two groups in our study. And neither group had vomiting or other adverse effects.

Some of the strengths of this study include a well-characterized population of epidural labor analgesia, which excluded the impact of pain on gastric emptying. This new high-energy semifluid solid beverage is a new kind of oral intake developed by researchers in our hospital and had applied for the national invention patent (application number was ZL 2019 10197792.9), which is designed for parturients to better ensure the demand for energy and safe process of childbirth. Gastric ultrasound is noninvasive, easy to perform at the bedside with minimal discomfort, and provides reliable quantitative and qualitative information about the nature of gastric contents.

There are also some limitations in our study. First, because the role of CHO already gained recognition by other researchers, we just compared the HESSB with CHO in our study and did not include water or a fasting group as a control group. Second, we only chose the cross-sectional area of the gastric antral in the right lateral decubitus position at head-up 45 degrees due to the inconvenience of the parturients and many studies have shown that the semirecumbent right lateral position is the best position for accurate evaluation. Third, the satisfaction and satiety of patients in

this study are subjective. Some clinical data such as blood glucose level or urine ketone should be included to overcome this limitation and need further consideration. Fourth, HESSB is only available in China, this potentially limits the generalizability of these results to other countries. Finally, this study was conducted in a small, limited population.

In conclusion, the gastric emptying of HESSB and CHO was comparable, and the satiety score was better in patients who consumed the HESSB. Patients favored HESSB taste than CHO. This particular HESSB may not be a safe candidate listed in preoperative fasting guidelines for now, but it may be an appropriate oral food intake during labor in the future. Further studies confirming the optimal component, volume, and interval of HESSB are also required.

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Authors contribution XN and SZ helped to design the study and write the manuscript, and JL helped to collect and analyze the data. QW helped conduct the study, ZX helped to analyze the data, and ZL helped to conduct the trial and design the study. All authors have read and agreed to the published version of the manuscript.

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Data availability The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Conflict of interest The author declare that they have no conflict for interest.

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