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A Randomized Trial of Carbohydrate Preloading in Patients with Type 2 Diabetes Undergoing General Anesthesia

ABSTRACT

Objective: The objective of the study was to determine the efficacy and safety of preoperative carbohydrate (CHO) loading among patients with type 2 diabetes (T2D) undergoing low to intermediate risk surgery.

Materials and methods: A randomized controlled trial was conducted among 50 T2D patients on oral hypoglycemic drugs selected based on the American Society of Anesthesiologists (ASA) grade 2, posted for low to intermediate risk surgeries. Twenty-five participants were randomly allocated to group A (carbohydrate group) and group B (placebo group). Patient well-being in terms of visual analog scale (VAS) scores for hunger, thirst, and postoperative vomiting was assessed. Mean plasma glucose was the primary outcome, gastric volume and pH and VAS scores were secondary outcomes.

Results: Clinical variables such as age, gender, body mass index (BMI), fasting plasma glucose (FPG), random plasma glucose (RPG), glycated hemoglobin (HbA1c), surgical duration, fluids, and opioids administered were comparable between both groups ($p > 0.05$).The mean plasma glucose levels in the postoperative period at 0 hour in group A and group B was 19.32 mg/dL and 30.13 mg/dL respectively and the difference was statistically significant ($p = 0.008$). At 10 hours post-surgery, the mean plasma glucose of group A (20.04 mg/dL) was significantly lower than group B (28.5 mg/dL) ($p = 0.035$). Secondary outcomes in both groups did not show any significant difference ($p > 0.05$).

Conclusions: The improved glycemic control and insulin resistance was observed in the carbohydrate loading group, with no adverse effects, resulting in improved outcomes among patients with T2D undergoing surgery. (Clin Diabetol 2024; 13, 3: 148–155)

Keywords: carbohydrate loading, diabetes, gastric fluid volume, insulin resistance

Introduction

The advent of a starvation period prior to general anesthesia for any elective surgery to avoid chances of regurgitation and/or aspiration has been so deeply engrained into anesthetic practice that it took years to rethink the approach in any way. Due to this, patients have been benefited from significant advances over the past 25 years [1]. The enhanced recovery after surgery (ERAS) is a multidisciplinary, multimodal project which aimed to aid patient recovery post-surgery during the perioperative period with reduction of overall complication occurrences by about 50% when ERAS protocols

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were implemented when compared to the traditional patient management techniques. ERAS protocols involve the concept of preoperative carbohydrate loading which lowers tissue glycosylation and insulin resistance (IR) and enhances postoperative glucose management as well as accelerates recovery post-surgery leading to reduced hospital stay [2].

Diabetes is a potentially devastating disease that is becoming more and more common in low and middle income nations like India. According to projections, by the year 2025, the population of patients with diabetes in India will increase to 69.9 million cases as a great majority of them remain unidentified [3]. In normal individuals, increased tissue resistance to insulin is seen after surgery, along with decreased secretion of anabolic hormones and increased secretion of catabolic hormones like cortisol. These pathophysiological reactions help to explain why even a patient without diabetes might experience perioperative hyperglycemia. This effect will be even more pronounced in patients with diabetes. Based on a study conducted by Albrecht et al., 2019 [4], one out of the 20 study patients with diabetes developed intraoperative hypoglycemia. Due to the lack of symptoms, this complication — along with hyperglycemia — is quite concerning for patients undergoing general anesthesia or for drowsy patients in the recovery area. Two of the major concerns that have led to the exclusion of study participants with diabetes in any research examining patients who received carbohydrate loaded drinks are namely the theoretical increased risk of aspiration due to gastroparesis and an increased risk of pre-operative hyperglycemia leading to deleterious effects including impaired wound healing which could lead to infection [5–7].

The ERAS programs encourage the preoperative consumption of carbohydrate-rich beverages. Given the conflicting data regarding the advent of carbohydrate loading among all patients and the uncertainty surrounding its safety in patients with diabetes, some have urged for a moratorium while more study is conducted [8]. Based on previous studies, we hypothesize that preoperative carbohydrate loading can improve insulin resistance without much interference in glycemic control in the immediate postoperative period. Our study aimed to investigate the effects of preoperative oral carbohydrate administration among perioperative glycemic controls, gastric fluid volume and pH, preoperative discomfort, and postoperative vomiting in American Society of Anesthesiology classification physical status II (ASA 2) patients undergoing elective surgery under general anesthesia. We proposed the following objectives: The primary objective was to ascertain glycemic control based on plasma glucose levels of type 2 diabetes (T2D) patients. The secondary objective was to assess the safety of carbohydrate preloading by measuring gastric fluid volume and pH. Finally, the overall patient well-being by visual analog scale scores for hunger and thirst, and incidence of postoperative vomiting.

Materials and methods

Study design

This was a prospective randomized triple blinded study conducted among T2D patients at a tertiary care multi-specialty hospital located in Coimbatore. The study was conducted after obtaining clearance from the Institutional Human Ethics Committee with project no 21/367. It was also registered with the clinical trials registry of India with reference number CTRI/2023/05/052860.

Study population

Patients with T2D, well controlled on oral hypoglycemic drugs, planned for low to intermediate risk surgeries under general anesthesia and posted first on the list at 8 AM were involved in the study. Patients who were allergic to maltodextrins, pregnant, had a body mass index (BMI) > 40, suffering from any pre-existing condition which can affect gastric motility, or posted for emergency surgeries were excluded from participation in the study.

Procedure

The study participants were allotted to their respective groups: group A which received carbohydrate loaded 50 g sachet in 400 mL water, 47.5 g carbohydrate 190 kcal/kilojoules plus other minerals, and group B which received placebo which was 400 mL of flavored water, three hours before surgery. After obtaining informed consent from the participants, the selected patients were randomized at the first point of contact in outpatient settings by means of computer-generated random numbers and were allotted to one of two groups using sequential sealed envelopes. The sealed envelopes were handed to the dietary department which prepared the drinks accordingly. Neither the attendee handing over the drink, nor the patient was aware of the constituents of the drink. Furthermore, the staff in the ward and operation theatre recording the visual analog scores (VAS) and plasma glucose levels were also not informed about the randomization, thereby making it a triple-blinded study. The investigators were informed of the allocation only after the complete follow-up of the patient was completed. The patients were allowed to take their usual meals until up to 10 PM and were given the carbohydrate or placebo

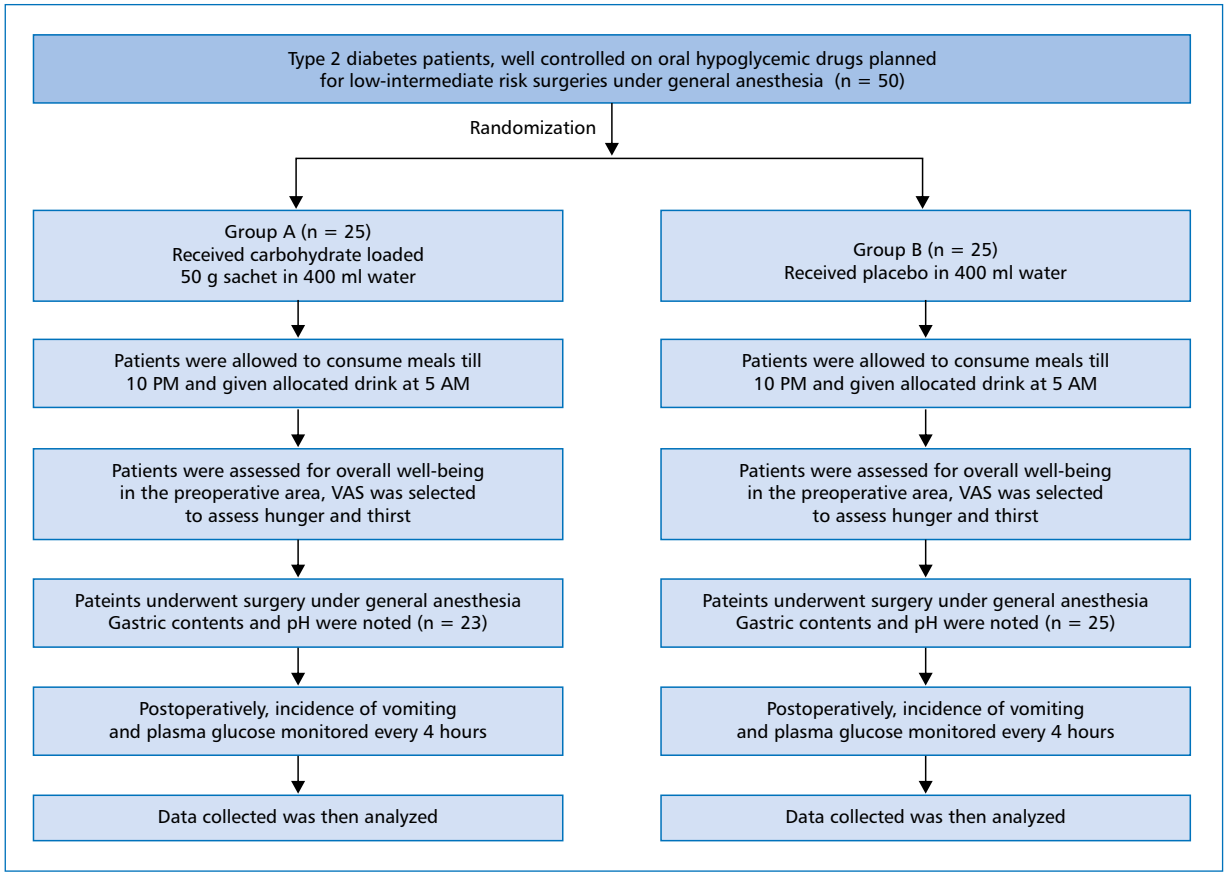

Figure 1. Flow Diagram of the Methodology

drink at 5 AM. All patients were premedicated with tablet Pantoprazole 40 mg and tablet Metoclopramide 10 mg on the morning of surgery. Morning samples for fasting plasma glucose (FPG) and insulin were recorded at 5 AM followed by the post-carbohydrate drink among the intervention group C. Patients were assessed for overall well-being in the preoperative area, VAS was selected to assess hunger and thirst. All patients were administered general anesthesia and glucose levels were noted at the time of induction. Patients were premedicated with Fentanyl 2 mcg/kg and induction of anesthesia was done with Propofol titrated to loss of verbal response. After securing the airway, a nasogastric tube was inserted to measure the gastric contents and the pH of gastric contents was noted. Total opioids administered during the surgery were then recorded, injection ondansetron was administered on completion of the surgery. Hourly monitoring of plasma glucose was done in the intraoperative period and ringer lactate used for maintenance. Steroids were not administered during the surgery. In the postoperative period, any incidence of vomiting was noted in the recovery room where the patient was observed for a minimum of 4 hours and fourth hourly plasma glucose monitoring was done. The next reading for random plasma glucose (RPG) was taken at 3 PM, which is, ten hours after the carbohydrate load. Any plasma glucose value above 200 mg/dL and insulin requirement for correction was noted. The entire methodology was been depicted in a flow diagram (Fig. 1).

A total of fifty patients were enrolled for the study with twenty-five patients allocated into each group with data collected from May 2023 to June 2023. Two patients in group A were not included in the analysis stage because their plasma glucose value on the morning of the surgery was more than 200 mg/dL. Hence, we analyzed 23 patients in group A and 25 patients in group B. There were no cancellations or postponement of surgery in either of the groups. The two patients with morning plasma glucose level more than 200 also underwent surgery on the same day after optimization of glucose level.

Glucose levels were tested for using the Cobas Integra 400 plus which had a precision of 1.61 and HbA1c was tested using Tosoh G8 which a precision of 0.68.

Statistical analysis

Sample size estimation

Sample size estimation was done based on the results of a study conducted by Faria et al. [9], using a confidence interval of 95% and the power of the study 80%. As we have evaluated mean plasma glucose in intraoperative and post-operative period as our primary outcomes, the mean plasma glucose measured at the time of induction of anesthesia, were used to calculate the sample size:

Mean blood glucose (mg/dL) 70 ± 8 (carbohydrate loading group) and 82 ± 17 (control group)

$$n = \frac{2\times SD^2\times (Z_{1-\frac{\alpha}{2}} + Z_{1-\frac{\beta}{2}})2}{(\mu_d)2}$$

$$(Z_{1-\frac{\alpha}{2}} + Z_{1-\frac{\beta}{2}})2 = 7.84$$

μ_d (mean difference) = 82–70) = 12, standard deviation (SD) = 8.17

The calculated sample size approximated to 19 in each group. To account for attrition and drop out, we considered a sample size of 25 participants per group.

The data obtained during the course of the study was analyzed using Statistical Package for the Social Sciences (SPSS) v20. Analysis was conducted using chi-square test and Student's t-test to check for any significant difference with regard to the glycemic control between the two groups. Qualitative variables such as sex, ASA classification and gradings, incidence of aspiration and vomiting and VAS were compared using chi-square test. Quantitative variables such as weight, age, height, duration of surgery, glucose levels, gastric volume, and pH between the groups were compared by means of Student's t-test. Categorical variables were represented by frequency tables and continuous variables were represented as mean ± standard deviation. Categorical data like gender distribution was compared using chi-square test. Continuous data was tested using independent sample t-test for normally distributed and Man-Whitney U-test for non-normally distributed data. Shapiro Wilk test used to test the normality. A p-value less than 0.05 was considered statistically significant at 95% confidence level.

Results

Demographic details

The present study included fifty patients with two groups including twenty-five patients each. Supplementary Table 1 shows that the study included mainly participants who had to undergo laparoscopic cholecystectomy (9 each in both groups). The baseline characteristics such as mean age of the study participants were 59.08 ± 10.25 years in group A and 58.7 ± ± 8.29 years in group B, and this difference was not statistically significant (p = 0.888). The gender distribution showed that the number of male and female participants was not significantly different (p = 0.563). Furthermore, clinical variables such as the reported BMI, FPG, RPG and HbA1c, duration of surgery, intraoperative fluids, and intraoperative opioids administered were also comparable between both groups (p > 0.05) (Tab. 1).

Table 1. The Baseline Characteristics of Participants

		Group A	Group B	p-value
Age [years]		59.08 (10.25)	58.7(8.29)	0.888
Sex CS	Female	15	11	0.563
BMI		27 (4.92)	26.09 (3.72)	0.475
Preoperative FPG [mg/dL]		130.64 ± 46.61	153 ± 38.95	0.101
RBG [mg/dL]		160.71 ± 49.22	190 ± 50.99	0.072
HBA1c M [mmol/mol]		21.50	24.71	0.395
Duration of surgery M [minutes]		25.18	23.76	0.713
Intraoperative fluids M [minutes]		23.18	25.93	0.491
Intraoperative opioids administered M [minutes]		25.88	23	0.363

CS indicates testing done using chi square test; M indicates Mann-Whitney U-test results expressed in mean rank; the rest were tested using Student's t-test, expressed as mean ± SD

BMI — body mass index; FPG — fasting blood glucose; HbA1c — glycated hemoglobin; RBG — random blood glucose

Table 2. Intraoperative and Postoperative Glycemic Outcomes, Visual Analog Scores and Gastric Volume, pH of Study Participants

Variables		Group A		Group B		Mean adjusted difference of two groups (95% CI)
Primary outcomes		Mean ± SD	Mean rank	Mean ± SD	Mean rank	
FPG [mg/dL]		125.68 ± 28.41		142.26 ± 27.83		16.58 (0.219, 32.94)
Intraoperative hour 1 M [mg/dL]		139.46 ± 29.44	26.04	144.48 ± 26.127	22.04	4.00 (–11.36, 21.40)
Intraoperative hour 2 [mg/dL]		150.53 ± 37.34		173.17 ± 50.72		22.46 (–1.89, 46.81)
Intraoperative hour 3 M [mg/dL]		150.53 ± 37.34	16.13	173.17 ± 50.72	12.3	3.83 (–12.50, 57.52)
Intraoperative hour 4 [mg/dL]		148.36 ± 33.97		160.83 ± 21.648		–22.52 (–55.69, 10.64)
Postoperative hour 0 M [mg/dL]		146.56 ± 35.44	30.13	167.74 ± 32.6	19.32	10.81 (7.00, 39.00)
Postoperative hour 4 M [mg/dL]		148.36 ± 33.97	28.26	160.83 ± 21.648	21.04	7.22 (–3.97, 28.90)
10th hour M [mg/dL]		146.24 ± 34.07	28.5	158.27 ± 18.67	20.04	8.46 (2.00, 33.00)
Insulin consumption M	Intraoperative	8.41		8.41		–0.29 (–4.26, 4.48)
	Postoperative	6.17		6.83		–0.66 (–2.75, 2.09)
Secondary outcomes						
Gastric volume M [mL]		10.15±6.88	23.37	11.67±5.57	25.54	–0.71 (–4.73, 3.30)
Gastric pH M		6.69±1.18	13.28	7.33±1	10.27	0.64 (–0.34, 1.62)
VAS (hunger) M		26.04	21.87	21.87	26.04	–0.48 (–1.34, 0.39)
VAS (thirst) M		24.96	23	23	24.96	–0.09 (–0.93, 0.74)

M indicates Mann-Whitney U-test results expressed in mean rank; the rest were tested using Student's t-test, expressed as mean ± SD

FPG — fasting blood glucose; SD — standard deviation; VAS — visual analog score

Mean plasma glucose levels

The mean FPG of the participants on the day of procedure was 125.68 ± 28.41 mg/dL in group A which was significantly lower than group B (142.26 ± 27.83 mg/dL) and ($p = 0.047$). The plasma glucose levels at 0 hours in group A was 146.56 ± 35.44 mg/dL which was significantly reduced when compared to group B (167.74 ± ± 32.6 mg/dL), and this difference was statistically significant ($p = 0.008$). The levels at 10 hours postoperative was also significantly different, with group A glucose levels being 146.24 ± 34.07 in group A and 158.27 ± ± 18.67 in group B ($p = 0.035$). Insulin consumption was compared in intraoperative and postoperative periods and was similar between both groups (Tab. 2).

Gastric findings and VAS scores of participants

None of the patients in both groups had any incidence of aspiration. The median gastric volume in group A was 10.15 ± 6.88 mL and 11.67 ± 5.57 mL in group B, the gastric pH in group A was 6.69 ± 1.18 and 7.33 ± 1 in group B, and these variables did not show any statistically significant difference between both groups ($p = 0.558$ and $p = 0.262$). The median VAS score for hunger and thirst between both groups was statistically not significant ($p > 0.05$) (Tab. 2).

With regard to confounding characteristics: Among the included samples, the common co morbidities noted were hypertension (11), anemia (2), coronary artery disease (6), hypothyroidism (3), seizure disorder (1), smoker (1), old cerebral vascular accident (1) in placebo group. Hypertension (11), anemia (2), coronary artery disease (4), hypothyroidism (4), seizure disorder (1), smoker (1), old cerebral vascular accident (2), heart failure with preserved ejection fraction (2) Down syndrome (1) in post carbohydrate loaded drink group.

The amount of insulin administered in the two groups has been mentioned in Table 2 and the two groups were comparable in the regard ($p > 0.05$).

We do not have data of exact medications used in the preoperative period but all the patients were only on oral hypoglycemic agents, morning medications were omitted for all the patients, preoperative blood glucose profiles were comparable in both the groups (Tab. 2) and all surgeries were posted as first case at 8 AM.

Discussion

This randomized controlled trial was conducted to demonstrate the efficacy as well as safety of carbohydrate preloading in patients with T2D undergoing general anesthesia. Implementing carbohydrate preloading protocols in patients with T2D can help optimize glycemic control without compromising patient safety and improve surgical outcomes. Further research, including larger-scale studies, is warranted to establish standardized guidelines for carbohydrate preloading among patients with T2D undergoing general anesthesia.

The baseline investigations of the present study show that the two groups of participants were comparable with regard to demographic variables such as age and sex, clinical and operative variables such as BMI, duration of surgery, intraoperative fluids and intraoperative opioids administered as well as glucose level variables such like preoperative FPG, RPG and HBA1c levels, making them ideal for comparison.

The FPG of the participants on the day of surgery was lower in the carbohydrate group A when compared to the control group, with this difference being statistically significant ($p=0.047$) despite obtaining comparable baseline HbA1c levels in both the groups.

The plasma glucose levels in both groups at 0 hour and 10 hours was significantly much higher in the placebo group when compared to the carbohydrate group, with p-values of 0.008 and 0.035 respectively. Laffin et al., 2018 [10] in their study among patients with diabetes, did not report any increase in the mean preoperative plasma glucose levels within the group getting preoperative carbohydrate drink. The preoperative plasma glucose value of patients compliant to the post carbohydrate drink was found to be non-inferior to the values in non-compliant subjects (p for non-inferiority < 0.01), among both groups who received evening and morning preloading and morning preloading alone. This result points to the longer-term effects of preoperative carbohydrate loading with regard to patients with T2D.

There are currently two possible explanations for the exact mechanism of insulin release after stress: on the one hand, increased catecholamine, growth hormone, glucocorticoid, and tumor necrosis factor release in response to surgical trauma causing an increase in liver glycogen release and IR; on the other hand, glucocorticoids and epinephrine reduce glucose uptake in peripheral tissues, while cytokines such as interleukin-1 and tumor necrosis factor inhibit insulin signal transmission. Reduced glucose absorption and IR are caused by the absence of the insulin signal receptor and glucose transporter 4 [11]. However, the intra operative and postoperative insulin consumption was similar in both groups with regard to the present study. A systematic review by Ge et al., 2020 reported that of the studies that were part of the review, a study conducted by Breuer et al., 2006 did not find any significant difference between the comparison and control groups with regard to insulin resistance ($p > 0.05$) [12, 13]. A study conducted by Lu et al., 2015 [14] also reported that postoperative insulin resistance index was significantly lower in the comparison group ($p < 0.05$).

None of the patients in both groups had any incidence of aspiration. The median gastric volume and pH values did not show a statistically significant difference between both groups ($p = 0.558$ and $p = 0.262$). Results of a previously conducted study showed that with regard to conditions such as intraoperative hypertension ($p = 0.031$) and postoperative nausea and vomiting ($p = 0.034$), the carbohydrate group showed significantly lower incidences when compared to the control group [15]. These findings are similar to the study by Gustafsson et al., 2008 [16] who assessed gastric emptying by co-administration of paracetamol and did not find delayed gastric emptying after intake of a 12.5% CHO-rich drink for preoperative use among patients with well-controlled T2D compared with healthy control subjects. If anything, a slightly increased gastric emptying rate was found in patients with T2D. The residual gastric volume 2 hours after intake of the drink was similar in healthy subjects compared to patients with T2D.

The median VAS score for hunger and thirst between both groups was also found to be statistically

not significant ($p > 0.05$). These results contrasted those reported in a study by Li et al., 2022 [15] wherein VAS scores of preoperative feelings of thirst, hunger, and fatigue, as well as postoperative feeling of thirst, hunger, and fatigue (all $p < 0.05$), were significantly lower in the carbohydrate group when compared with the control group. A study conducted by Hausel et al., 2001 [17] using VAS for a larger sample size of ASA I/II patients undergoing abdominal surgery found no difference in thirst after the morning carbohydrate drink and placebo. However in the study by Faria et al., 2009 [9] the patients' given carbohydrates reported significantly lower rate of hunger and anxiety. Some patients had reported lesser postoperative nausea and vomiting with carbohydrate loading [9]. These results help in affirming the improved comfort of the patients with administration of preoperative carbohydrates. The effects of glucose ingestion two to three hours prior to surgery on insulin resistance in patients with diabetes have been inconsistently reported; however, the data that is currently available indicates a tendency to improve insulin resistance and prevent postoperative hyperglycemia following surgery [12]. The variation in results could also be caused due to patients being given a carbohydrate loading the night before the surgery too which was not done in our study. However, we do not consider it essential as the patient is allowed their usual dinner. This randomized controlled study provides an effective insight into the safety and efficacy of preoperative carbohydrate loading, perioperative glycemic control, and insulin requirements.

While the study showed promising results, some limitations which are to be acknowledged include the appropriate sample size warranting larger multicenter trials for further validation. The study did not involve patients with type 1 diabetes and patients with T2D who were insulin-dependent as results may vary among different diabetes subtypes. However, the study is a triple blinded study which makes it free of bias and did not have any dropouts which makes up the advantages of the study. Future studies could explore the differential effects of carbohydrate preloading based on diabetes type and severity.

Conclusions

The results of the study help provide improved evidence to recommend carbohydrate preloading as part of ERAS protocols to be extended to well-controlled T2D patients. The benefits of improved insulin resistance and glycemic control, reduced preoperative discomfort, and reduced nausea/vomiting, can also be extended to this subset of patients without any increased risk of aspiration.

Article information

Ethics statement

The study was conducted after obtaining clearance from the Institutional Human Ethics Committee with project no 21/367.

Supplementary materials

The Supplementary materials for this article can be found at https://journals.viamedica.pl/clinical_diabetology/article/view/99377.

Data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' institution policy.

Author contributions

Silvy Anna Varughese: conceptualization, methodology, software.

Silvia Anna Varughese, Dhivya D., Sandhya K.: data curation, writing, original draft preparation.

Silvy Anna Varughese, Dhivya D.: visualization, investigation.

Silvy Anna Varughese: project administration.

Silvy Anna Varughese, Dhivya D.: supervision.

Silvy Anna Varughese: formal analysis, software, validation.

Silvy Anna Varughese, Dhivya D., Sandhya K.: writing, reviewing and editing.

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Conflict of interest

The authors declare no conflict of interest.

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