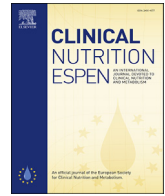




Contents lists available at ScienceDirect

Clinical Nutrition ESPEN

journal homepage: <http://www.clinicalnutritionespen.com>

Original article

Validation of a popsicle as a clear fluid to abbreviate preoperative fasting



Eduardo Fabian Rigo^a, Rosicler Colet^b, Geciane Toniazzo Backes^b, Jamile Zeni^b,
André Keng Wei Hsu^{a,*}

^a Medical School, Universidade Regional Integrada do Alto Uruguai e Missões, URI Erechim, Av. Sete de Setembro, 1621, 99709-910, Erechim, RS, Brazil

^b Department of Food Engineering, Universidade Regional Integrada do Alto Uruguai e Missões, URI Erechim, Av. Sete de Setembro, 1621, 99709-910, Erechim, RS, Brazil

ARTICLE INFO

Article history:

Received 5 May 2023

Accepted 5 December 2023

Keywords:

Enhanced recovery after surgery

Anesthetic procedure

Carbohydrates

SUMMARY

Background & aims: This study is based on the development and validation of a popsicle to reduce preoperative fasting time.

Methods: The study was carried out in two stages, pre-clinical and clinical validation. The first stage consisted of producing a water-based, fat-free, high-calorie fruit-flavored popsicle, characterized by proximal composition and sensory analysis. In the second stage, clinical validation was performed in patients aged between 18 and 65 years before elective surgery, evaluating the incidence of aspiration during anesthesia and the patient's experience in relation to hunger, thirst, anxiety and palatability of the popsicle.

Results: The results of the study showed that the use of popsicle 2 h before the surgical procedure did not cause any adverse reaction in patients and in the anesthetic procedure. Furthermore, the full acceptability of the product by the participants and the control of thirst and satiety during the preoperative period were observed.

Conclusions: The present study showed that with the use of popsicles it was possible to reduce safely the preoperative fasting time to up to 2 h before the surgical procedure.

© 2023 European Society for Clinical Nutrition and Metabolism. Published by Elsevier Ltd. All rights reserved.

1. Introduction

It is widely recognized that the reduction of the preoperative fasting is an important milestone of Enhanced Recovery After Surgery (ERAS) multimodal approach [1]. Prolonged fasting can be harmful to the patient, as it causes some risks and discomforts to patients, such as anxiety, hunger, thirst, and metabolic changes – such as insulin resistance that results in glycemia disorders, interfering the uptake of glucose by the cells. Thus, the metabolic changes can be associated with reduced caloric intake that can lead to malnutrition. This can contribute to decrease the immune system and consequent increase surgical inflammatory response [2].

Drink water before anesthesia reduces dehydration and carbohydrate loading is associated with less insulin resistance [3]. Oral

carbohydrate 2 h before elective surgery in adults attenuates discomfort, mouth dryness, hunger and thirsty with no increase in the incidence of aspiration and infection, leading to a better metabolic profile [4–6]. However, in clinical practice there are few food options to serve as a clear fluid, are those that do not have residues, propose like maltodextrin drink preparations, strained fruit juices and coffee with sugar. Nevertheless, all of them are drinks and cannot deliver the solid bite sensation to the patients. Mastication is one important aspect in oral processing and self-reported hunger [7].

In this scenario, we proposed to develop and validate a popsicle that act as a clear fluid, testing the palatability, acceptance and personal feelings of patients before elective procedures, as well as the incidence of adverse reactions in the anesthetic procedure (vomiting and bronchoaspiration).

2. Materials and methods

The study was approved by the ethics committee, in accordance with Brazilian legislation, under number CAAE 4314532100-

* Corresponding author.

E-mail addresses: e.friego@hotmail.com (E.F. Rigo), rosicler.colet@yahoo.com.br (R. Colet), gtoniazzo@uricer.edu.br (G.T. Backes), jamilenzi@uricer.edu.br (J. Zeni), andrekgeng@hotmail.com (A.K.W. Hsu).

0005351. The formulation and processing of the popsicle followed the methodology described in the patent under registration number BR1020210230410. The development of the popsicle considered the ingredients to characterize it as a clear liquid loaded with fast-absorbing carbohydrates, without fibers, lipids and proteins. The popsicle proximal composition was determined according to the Brazilian resolution RDC n° 359 of December 23, 2003 [8]. All the norms recommended by the Ministry of Health, Department of Sanitary Surveillance, according to Ordinance N° 379, of April 26, 1999, for the preparation of popsicle were followed.

We evaluated acidity, pH, °Brix, viscosity of the mixture, the instrumental color and melting time. In order to guarantee the food safety, microbiological analyzes of *Salmonella* sp. and Enterobacteriaceae were done according to the requirements set out in Normative Instruction n° 161, of 01 of July 2022 [9]. All analyzes were performed in triplicate.

Moisture was determined in an air recirculation oven at 105 °C until constant weight (Fanem model 320-SE, São Paulo, Brazil). The pH reading was performed using a pH meter (Digimed, model DM-22, São Paulo, Brazil) [10]. Fat determination was performed by the Roesse-Gottlieb method using ethyl alcohol and petroleum ether as solvent. Total nitrogen was obtained by the Kjeldahl method and multiplied by a factor of 6.25 to obtain protein (Tecnal, model TE-0344, São Paulo, Brazil). Acidity was determined in Dornic degrees by titration with 0.1 N sodium hydroxide (titratable acidity), following the guidelines of methods 016/IV and 311/IV. Soluble solids were determined by refractometry using a refractometer (Contec, model 0–90 °Brix, São Paulo, Brazil), corrected to 20 °C, results expressed in °Brix. The determination of the total dietary fiber content was carried out using enzymatic-gravimetric method. The total minerals were obtained by the gravimetric method, after calcination at 550 °C for 6 h (Forno Lavoisier, model 400C, Belo Horizonte, Brazil). Results were expressed in g/100 g, on a dry basis.

The residual mineral was diluted in 50 mL of 0.5 % nitric acid, filtered and for the quantification of the mineral component of sodium (Na) and potassium (K) standard concentration of 100 mg/mL (Analyser, model 910, São Paulo, Brazil). For the components zinc (Zn), manganese (Mn), magnesium (Mg), copper (Cu), calcium (Ca), cadmium (Cd) the Sanvanta flame atomic absorption spectrometry method was used (Savantaa, model 6BC 3.11 A, Australia). All the tests followed Adolf Lutz Institute guidelines to food analysis [11].

To decide the best palatable flavor to clinical validation, we did a first step study protocol with a sensorial evaluation analyzing flavor and acceptance of two popsicles formulation prototypes. In this stage, the test was performed by 50 untrained panelists of both sexes, in a sensory analysis laboratory. The tasters had at their disposal two different samples of lemon popsicle flavors. The sensory evaluation of the popsicle was carried out through a consumer acceptance test - structured hedonic scale with 9 points (9 - I liked it a lot and 1 - I hated it a lot) [12].

In the second stage of the study protocol, we offered the popsicle to 40 volunteer patients (n = 40), between 18 and 65 years old, up to 2 h before elective surgery, between July 2021 and February 2022. In this first of the product trial, we excluded obstetric, diabetics, gastropathies and gastroesophageal reflux patients, requiring a new study in this population. Written informed consent was obtained from all subjects participating in pre-clinical and clinical stage in accordance with the Declaration of Helsinki standards and Brazilian regulations (ANVISA) for food manipulation. This manuscript adheres to the applicable Guidelines for the design, conduct and reporting of human intervention studies to evaluate the health benefits of foods [13]. We evaluated the incidence of vomiting aspiration during anesthesia procedure and the experience of the patient with this new product with

questionnaires for the self-completion. In the questionnaire we asked individual data like age, sex, diseases, use of daily medication, and the experience of the popsicle using a numerical analog scale (0 - worst to 10 - best). We evaluated personal feelings of hungry, thirst, anxiety and the palatability experience of the popsicle. In the anxiety and satiety levels evaluations before and after consuming the popsicle, patients answered a questionnaire in which they assigned scores from 1 to 10. In anxiety questionnaire scale: 1 being without anxiety and 10 extremely anxious and in the satiety scale 1 being extremely hungry and 10 totally satisfied.

The statistical analyses were performed using the *GraphPad Prism* 9.2 software. The values of sensory acceptance of the two formulations were compared by *Mann Whitney* test. The correlation among the scores attributed by the patients were plotted one against the other aiming to know their correlations. For all the analysis, *p* values lower than 0.05 were considered as statistically significant.

3. Results

The popsicle had a total solid content of 25.92 (± 0.09) °Brix, pH of 2.5 (± 0.02), acidity of 3.44 (± 0.05) and viscosity of 3.83 (± 0.10) cP. The complete melting time of the popsicle was approximately 70min, and it started thawing after 20 min at a temperature of 29 °C (± 2). Each 200g (3 units) serving of popsicle contains 1.21 mg of Ca (0.12 % of Daily Values - DV), 0.51 mg of Mg (0.12 % of DV), 0.06 mg of Zn (0.54 % of DV) and 0.47 mg K (9.94 % DV). Graphical abstract shows the visual appearance of the popsicle and nutritional label of the product complying with Brazilian resolution RDC n° 359, of December 23, 2003 [8].

During the first step phase, carried out in the laboratory, with 50 people who tasted samples A and B of the popsicle formulations, there was a significant preference for sample B ($p < 0.05$), shown on Fig. 1.

The second phase had 20 male participants and 20 female participants (n = 40). The mean age of patients was around 52 years. Most patients (55 %) had comorbidities and used chronic medication (65 %). The most prevalent group of surgeries was orthopedic, followed by general and urological surgery. General anesthesia (airway manipulation) was the most performed, followed by spinal and plexus block, according to Table 1.

In the personal felling evaluation, 95 % of patients thought the popsicle tasted good or very good. In addition, 90 % reported that, with the consumption of the popsicle, they did not feel thirsty before the surgical procedure. In addition to these findings, 97.5 % of patients were satisfied to be able to consume the product.

In the anxiety evaluation, the scores decreased after the consumption of the product, from average mean value of 5 to

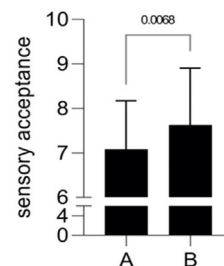


Fig. 1. Sensory acceptance of lemon popsicle formulations (n = 50 untrained panelists). Since B flavor was the most preferred, we choose this flavor formulation to carry the second phase.

Table 1
Characterization of study population (n = 40 patients).

Age (years)		52.35 ± 11.34 (22–65)
Gender	Male (%)	50.0
	Female (%)	50.0
Use of medication	Yes (%)	65.0
	No (%)	35.0
Comorbidity	Yes (%)	55.0
	No (%)	54.0
Surgery	Orthopedics (%)	36.8
	General (%)	26.3
	Urology (%)	21.2
	Others (%)	15.7
Anesthesia	General (%)	78.4
	Spinal (%)	18.9
	Plexus block (%)	2.7

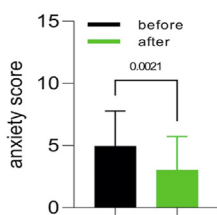


Fig. 2. Diagram representation of anxiety scores before and after the consumption of the popsicle (n = 40 patients).

approximately 2 (p = 0.0021) showing that the popsicle helped to reduce anxiety levels before surgical procedure, according to Fig. 2.

Patients who described that the popsicle had positive effect on thirst and in the evaluation related to anxiety and satiety had better anxiety and satiety levels after the ingestion of the popsicle p < 0.05, according to Fig. 3.

Finally, as it was expected, after the consumption of the popsicle there were no episodes of bronchoaspiration and vomiting during anesthesia procedure.

4. Discussion

Mankind has been enjoying ice cream preparations for thousands of years: 4000 years ago, in China, they mixed powder snow with salt to freeze recipient containing syrup preparation [14]. Ice cream mouth consumption can evoke different sensory perceptions like sweetness, chewiness and smoothness [15]. Palatable food consumption changes dopamine, dopamine receptors and

transporters in the striatum, including GABA (Gamma-Amino-Butyric Acid) and opioids system in food intake reward process [16]. In this study, we tested a new icy palatable food option as a clear fluid that the patients can bite, lick and masticate. In times that patient satisfaction is a possible indicator of quality surgical care [17], this innovative food option can improve patient perception since the popsicle delivered high satisfaction rates and helped to decrease anxiety level before surgery.

It is known that the introduction of a carbohydrate loading before anesthesia not only hydrate but also improves the metabolic state of the surgical patient attenuating trauma response such as insulin resistance [3]. Some studies have also demonstrated an additional benefit in reduction of post operative pain levels when carbohydrates were used to enhance preoperative fasting [18,19].

The main limitation of our research was that the postoperative parameters were not evaluated. We only focused on evaluating the levels of anxiety, thirst, satiety, and adverse reactions with popsicle consumption in the period prior to anesthetic procedure. We also did not the ultrasound evaluation of gastric emptying. In addition, we did not test the popsicle in pregnant and children population and more studies are necessary.

In conclusion, despite all the guidelines and efforts to enhance preoperative fasting, old habits of prolonged fasting are a fact and the adherence of new protocols in hospitals sometimes is difficult [20]. Maybe new palatable food products that act as clear food could catch the attention of patients, anesthesiologists and surgeons to enhance perioperative fasting. Our study revealed that the popsicle had good acceptability by the patients. In addition, there were no episodes of bronchoaspiration or vomiting at the time of anesthetic procedure in any of the study participants. Mostly of the participants were satisfied with being able to consume the popsicle during the preoperative fasting period.

The present study showed that with the use of popsicles it was possible to reduce the preoperative fasting time to up to 2 h before the surgical procedure, without causing adverse reactions to patients and without increasing the risk of bronchoaspiration during the anesthetic procedure. The popsicle promoted a reduction of the levels of anxiety and thirst and provided a feeling of satiety to the participants.

Author contributions

EF Rigo: Methodology, Investigation, Validation, Writing – original draft; R Colet: Methodology, Investigation, Validation, Writing – original draft; GTBackes: Conceptualization, Investigation, Data analyses, Writing – review & editing; J Zeni: Conceptualization, Investigation, Data analyses, Writing – review & editing; AKW Hsu: Conceptualization, Methodology, Investigation, Data analyses, Visualization, Writing – review & editing, Project supervision.

Data sharing statement

Data described in the manuscript is available from the corresponding authors upon reasonable request.

Funding sources

None.

Ethics approval

This study was approved by number CAAE 43145321000005351.

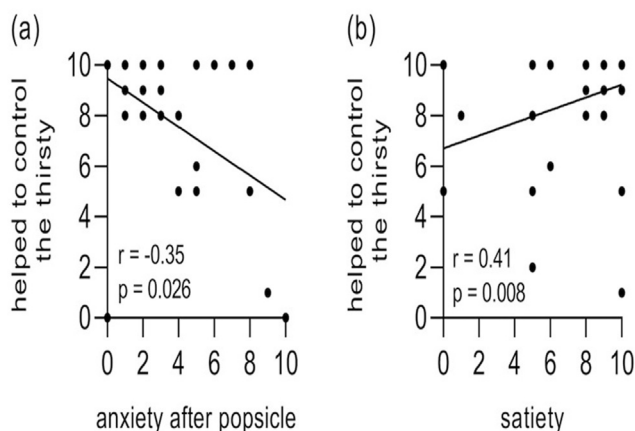


Fig. 3. Scatter Diagram representation of patients who said that the popsicle helped to control the thirst and anxiety and satiety evaluation (n = 40 patients).

Declaration of competing interest

The authors have no conflict of interest to disclose.

Acknowledgements

The authors would like to thank the National Council for Scientific and Technological Development - Brazil (CNPq), Coordination for the Improvement of Higher Education Personnel - Brazil (CAPES) – Finance Code 001, Research Support Foundation of the State of Rio Grande of Sul - Brazil (FAPERGS).

References

- [1] Ljungqvist O, Scott M, Fearon KC. Enhanced Recovery after surgery [Internet] *JAMA Surg* 2017 Mar 1;152(3):292. Available from: <http://archsurg.jamanetwork.com/article.aspx?doi=10.1001/jamasurg.2016.4952>.
- [2] Vieira Pio M, De Queiroz LJ, Moreira Corgozinho M. Abbreviation of preoperative fasting in elective surgeries: integrative review [Internet] *Heal Resid J - HRJ* 2022 Jan 4;3(14):923–40. Available from, <https://escsresidencias.emnuvens.com.br/hrj/article/view/420>.
- [3] Fawcett WJ, Thomas M. Pre-operative fasting in adults and children: clinical practice and guidelines [Internet] *Anaesthesia* 2019 Jan;74(1):83–8. Available from: <https://onlinelibrary.wiley.com/doi/10.1111/anae.14500>.
- [4] Cheng P-L, Loh E-W, Chen J-T, Tam K-W. Effects of preoperative oral carbohydrate on postoperative discomfort in patients undergoing elective surgery: a meta-analysis of randomized controlled trials [Internet] *Langenbeck's Arch Surg* 2021 Jun 25;406(4):993–1005. Available from: <https://link.springer.com/10.1007/s00423-021-02110-2>.
- [5] Noba L, Wakefield A. Are carbohydrate drinks more effective than preoperative fasting: a systematic review of randomised controlled trials [Internet] *J Clin Nurs* 2019 Sep 10;28(17–18):3096–116. Available from: <https://onlinelibrary.wiley.com/doi/10.1111/jocn.14919>.
- [6] Ricci C, Ingaldi C, Alberici L, Serbassi F, Pagano N, De Raffe E, et al. Preoperative carbohydrate loading before elective abdominal surgery: a systematic review and network meta-analysis of phase II/III randomized controlled trials [Internet] *Clin Nutr* 2022 Feb;41(2):313–20. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0261561421005665>.
- [7] Krop EM, Hetherington MM, Nekitsing C, Miquel S, Postelnicu L, Sarkar A. Influence of oral processing on appetite and food intake – a systematic review and meta-analysis [Internet] *Appetite* 2018 Jun;125:253–69. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0195666317315854>.
- [8] Brazil. Resolution No. 359, of december 23. 2003. Technical Regulation of Portions of Packaged Foods for Nutritional Labeling Purposes. [Internet]. 2003. Available from: https://bvsvms.saude.gov.br/bvs/saudelegis/anvisa/2003/rdc0359_23_12_2003.html.
- [9] Brazil. Normative Instruction nº. 161, of July 1, 2022. Establishes microbiological standards of food. Available from: https://antigo.anvisa.gov.br/documents/10181/2718376/IN_161_2022_pdf/b08d70cb-add6-47e3-a5d3-fa317c2d54b2.
- [10] AOAC. Official methods of analysis of the association of official analytical chemists. 2005.
- [11] Summary for policymakers [Internet]. In: *Climate change 2013 – the physical science basis*. Cambridge University Press; 2014. p. 1–30. Available from: https://www.cambridge.org/core/product/identifier/CBO9781107415324A009/type/book_part.
- [12] Dutcosky SD. *Sensory analysis of foods*. 4th ed. 2013.
- [13] Welch RW, Antoine J-M, Berta J-L, Bub A, de Vries J, Guarner F, et al. Guidelines for the design, conduct and reporting of human intervention studies to evaluate the health benefits of foods [Internet] *Br J Nutr* 2011 Nov 1;106(S2):S3. 15. Available from: http://www.journals.cambridge.org/abstract_S00071-14511003606.
- [14] Toussaint-Samat MAB. *History of food*. 1992.
- [15] Doyennette M, Aguayo-Mendoza MG, Williamson AM, Martins SIFS, Stieger M. Capturing the impact of oral processing behaviour on consumption time and dynamic sensory perception of ice creams differing in hardness. *Food Qual Prefer* 2019 Dez;78:103721. <https://doi.org/10.1016/j.foodqual.2019.103721>. Available from: .
- [16] Joshi A, Schott M, la Fleur SE, Barrot M. Role of the striatal dopamine, GABA and opioid systems in mediating feeding and fat intake [Internet] *Neurosci Biobehav Rev* 2022 Aug;139:104726. Available from, <https://linkinghub.elsevier.com/retrieve/pii/S0149763422002159>.
- [17] Lyu H, Wick EC, Housman M, Freischlag JA, Makary MA. Patient satisfaction as a possible indicator of quality surgical care. *JAMA Surg* [Internet] 2013 Apr 1;148(4):362. Available from: <http://archsurg.jamanetwork.com/article.aspx?doi=10.1001/2013.jamasurg.270>.
- [18] Tavalae M, Beigi E, Karbalaiekhani A, Shirzadi A, Ahmadijad I. Evaluation of carbohydrate loading on clinical results and metabolic responses in patients undergoing laparoscopic cholecystectomy [Internet] *Ann Med Surg* 2022 Jun;78. Available from: <https://journals.lww.com/10.1016/j.amsu.2022.103963>.
- [19] Chaudhary NK, Sunuwar DR, Sharma R, Karki M, Timilsena MN, Gurung A, et al. The effect of pre-operative carbohydrate loading in femur fracture: a randomized controlled trial [Internet] *BMC Musculoskel Disord* 2022 Aug 30;23(1):819. Available from: <https://bmcmusculoskeltdisord.biomedcentral.com/articles/10.1186/s12891-022-05766-z>.
- [20] Van Noort HHJ, Eskes AM, Vermeulen H, Besselink MG, Moeling M, Ubbink DT, et al. Fasting habits over a 10-year period: an observational study on adherence to preoperative fasting and postoperative restoration of oral intake in 2 Dutch hospitals [Internet] *Surgery* 2021 Aug;170(2):532–40. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0039606021000751>.