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Research

Use of Mentholated Popsicle in the Management of the Elderly Patient's Thirst in the Immediate Postoperative Period: A Randomized Controlled Trial

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A B S T R A C T

Purpose: This study aimed to compare a mentholated popsicle with usual care (absolute fasting) in the change in thirst intensity and discomfort in elderly patients in the immediate postoperative period (IPP).
Design: A randomized controlled trial.
Methods: The sample consisted of 50 elderly patients (60 years or older) in the IPP who were randomly assigned to two groups: experimental group (20 mL mentholated popsicle) and control group (usual care). The outcomes, thirst intensity and discomfort, were assessed at baseline and 20 minutes after the intervention.
Findings: The mentholated popsicle presented a statistically significant ($P < .001$) decrease in thirst intensity and discomfort by 5.0 in the median and a Cohen's r large effect size for both outcomes. There were no adverse events or side effects.
Conclusions: The use of a mentholated popsicle decreased the intensity and discomfort of the elderly patient's thirst in the IPP.

Thirst is a homeostatic response to increased osmolarity or decreased plasma volume that triggers intense individual motivation to seek, obtain, and consume water.[1] Relevant and complex, thirst is considered a subjective and self-reported symptom according to each patient's experience and is one of the most stressful and challenging symptoms experienced in the perioperative period.[2] Thirst prevalence in the immediate postoperative period (IPP) ranges from 78%,[3] 89.6%[4] to 97.6%[5] in adults; however, prevalence rates of thirst in elderly surgical patients are not evidenced in the literature.

Thirst satiety may occur preabsorptively or postabsorptively. In the surgical patient, preabsorptive satiety is relevant, as it can be achieved using small volumes of cold liquids in the oral cavity, reducing the risk of aspiration of gastric contents in the adult patient.[6,7] Recent studies have shown the effective use of cold and mentholated strategies to mitigate thirst of adult surgical patient's such as menthol chewing gum,[8] mentholated or ice popsicles,[9,10] lip moisturizer, and mentholated popsicles.[5] However, thirst and strategies for reaching satiety are incipiently understood and researched regarding the elderly surgical patients.

The elderly face osmotic and volume alterations in addition to susceptibility to renal function deficiency. This occurs both because of physiological conditions and as a result from surgical trauma, directly affecting their perception of thirst.[11,12] In the literature, there is no consensus on the existence of impaired thirst perception in older adults in the presence of altered serum osmolarity. Studies showed that thirst and fluid ingestion by older adults were lower than by young people,[11] as well as no variation with age in oral water intake and thirst perception, indicating that responses to hyperosmolar stimuli are preserved with aging.[13]

Older adults represent the fastest growing proportion of the population worldwide, leading to a proportional increase in demand for surgical services.[14] In addition, in clinical practice, it is noted that elderly surgical patients do experience thirst symptom intensely.[15] Thus, the relevance of conducting investigations on strategies to reduce thirst of the elderly surgical patients is justified

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to provide proper management of this symptom, especially in the IPP.

Purpose

The purpose of this study was to compare a mentholated popsicle with usual care (absolute fasting) in the change in thirst intensity and discomfort of elderly patients in the IPP.

Methods

Study Design

This study was a randomized controlled trial that followed the recommendations of Consolidated Standards of Reporting Trials.[16] The study was conducted at a public teaching hospital in the state of Paraná, Brazil. The hospital has 316 beds and an operating room with seven surgical suites, where an average of 7.680 elective, urgent, and emergency surgeries per year, of all surgical specialties, are performed.

Participants and Sample Size

Participants consisted of older male and female patients undergoing elective surgery in the postanesthesia care unit (PACU). Inclusion criteria were patients aged 60 years or older, fasting, verbalized thirst, and approved in the assessment of the safety protocol for thirst management (SPTM). This protocol is a validated tool to evaluate safety criteria, allowing the administration of strategies to mitigate thirst of patients in the IPP. SPTM assesses the level of consciousness, coughing, and swallowing reflexes, as well as the absence of nausea and vomiting. To ensure safety for the study participants, they should be approved as per the four-dimension criteria assessed by SPTM to receive the intervention. SPTM obtained a content validity index of 1 and an interobserver reliability for nurses was kappa (κ) = 0.968.[17] Exclusion criteria were patients with restrictions to ingest liquids or inability to swallow and self-reported mint allergy.

To determine the sample size, a pilot study with 25 participants per group was designed following all methodological steps of the randomized controlled trial. A significance level of 0.025 (*Bonferroni* adjustment) for both primary outcomes, thirst intensity and discomfort, was adopted. The statistical power was 0.80 and the method of analysis was the Student *t* test. The sample calculation determined that only five individuals per group would be sufficient to demonstrate the difference in thirst intensity and discomfort between the mentholated popsicle and the usual care. Therefore, it was not necessary to recruit new patients per group in addition to the initial 25 patients. Thus, the final study sample consisted of 50 patients.

Randomization and Blinding

Randomization occurred in seven randomized and balanced blocks through lists generated by GraphPad Software Online (GraphPad Software, Inc La Jolla, CA). The variation in the number of participants in each block was adopted to reduce randomization bias, and the concealment of allocation was observed by sealed sequentially externally numbered, opaque, nontranslucent individual envelopes containing the group information defined by random allocation.

To reduce possible biases, randomization and allocation concealment procedures were performed by a research nurse who was not a member of this research team. One of the researchers enrolled and assigned participants to interventions. Blinding of the participants or the researcher was not possible because of distinct visual and scented characteristics of the mentholated popsicle.

Intervention and Control Groups

Participants were randomized into two groups: the experimental group received a 20 mL mentholated popsicle and the control group received usual care. For the control group, the researchers maintained the usual care performed in the PACU of the study hospital, which is the maintenance of absolute fasting for the elderly patient in the IPP. For the experimental group, the mentholated popsicle followed the formulation proposed in another study,[5] namely, ultrafiltrated water (1,000 mL), 0.05% menthol (5 mg), 0.05% saccharin (5 mg), and 2% cereal alcohol (200 mg), with a popsicle volume of 20 mL.

The enhanced recovery after surgery (ERAS) protocol recommends early intake of oral fluids and solids to be offered in the day of surgery, but without determining a volume limit.[18] A systematic review and meta-analysis with 13 clinical trials and a total of 1,173 patients did not find any drawback of early oral nutrition in IPP. Instead, the authors mentioned that keeping patients “nil by mouth” is without any benefit and patients should be allowed to drink when fully recovered from anesthesia, without volume specification.[19] Evidence indicates that the risk of bronchoaspiration is minimal when the gastric volume is between 50 mL[20] and up to a limit of 1.5 mL/kg.[1,21] Considering that gastric volume is absorbed over time and water has a half-life of about 15 minutes in the stomach,[22] the volume of the mentholated popsicle of 20 mL is considered minimal and safe.

Preabsorptive satiety can be achieved after the ingestion of two 10 mL ice popsicles,[10] justifying the option of adjusting the volume of the mentholated popsicle to 20 mL. The mentholated popsicle was made by the researcher, respecting aseptic care for food handling. The menthol solution was frozen in 20 mL silicone molds. The mentholated popsicle was secured by a small ice cream stick and stored in the freezer in the PACU.

Study Outcomes

The intensity and discomfort of thirst were the primary outcomes analyzed in this randomized controlled trial. Evidence shows that the increase in plasma osmolarity and decrease in vasopressin are related to the perception of thirst measured by numerical scales.[23] Therefore, thirst intensity was assessed using the 11-point numerical scale (0 to 10) with zero being rated as no thirst and 10 the largest thirst ever felt.[24] Thirst discomfort was measured by the Perioperative Thirst Discomfort Scale, in which seven attributes related to thirst discomfort are assessed: dry mouth; dry lips; thick tongue; thick saliva; dry throat, bad taste, and desire to drink water. The score on the scale ranges from zero (no thirst discomfort) to 14 points (most severe thirst-related discomfort).[25] This scale obtained a content validity index of 0.98 and reliability index of 1 for the scale attributes and items. Internal consistency assessed by Cronbach's α was 0.91 and inter-rater equivalence was 1, measured by weighted Kappa coefficient. The patients evaluated the intensity and discomfort of their thirst by answering the questions on the scales used. The researcher read the questions out loud and recorded the answers given by the patients.

Data Collection Procedure

In the PACU, patients were assessed for eligibility. When the patient verbalized thirst spontaneously or when questioned, the SPTM was applied by the researcher. The intensity and discomfort of the patient's thirst were measured only after approval as per this protocol (baseline).

Next, the envelope was opened to identify which group the patient was allocated to. For a patient allocated to the experimental group, a 20 mL mentholated popsicle was offered, and the researcher remained with the patient until the end of the popsicle degustation. The researcher then left the patient's side and returned 20 minutes later to measure thirst intensity and discomfort (final). The time stipulated for the intervention evaluation was delimited based on results of a previous study.[9]

For the patients allocated to the control group, after the initial assessment, the researcher left the patient's side and returned 20 minutes later to measure the investigated outcomes (final). The researcher remained in the PACU (between baseline and final) observing the patient from afar to ensure that fasting was maintained. At the end of study participation, a mentholated popsicle was offered to patients in the control group as well.

The ethical review boards of the University of São Paulo at Ribeirão Preto College of Nursing and of the State University of Londrina approved the study (CAAE Protocols 87689318.4.0000.5393 and 87689318.4.3001.5231, respectively). Participants were invited and instructed as to the objectives of the study signing the informed consent form. The study was registered at ClinicalTrials.gov with the registration number NCT03621800).

Data Analysis

Descriptive analyses were performed for demographic and clinical variables. For quantitative variables the median, first quartile, and third quartile were calculated, and for categorical variables the percentages were calculated. Statistical analysis of the data was performed using IBM SPSS *Statistics* version 23. Data normality was tested using the Shapiro-Wilk test, and the initial thirst intensity and discomfort (baseline) did not demonstrate normal distribution. Thus, the nonparametric Mann-Whitney statistical test was adopted to compare the intensity and discomfort of initial, final, and changes in thirst in the scores on the scales applied both to experimental and control groups.

Considering the nonparametric data, Cohen's r and the proportion of variance (PV) were used to calculate the effect size that can be interpreted as follows: small ($r = 0.10 - PV = 0.01$), medium ($r = 0.30 - PV = 0.09$), or large ($r = 0.50 - PV = 0.25$). For all the analysis, a 5% ($\alpha = 0.05$) significance level and a precision of 95% confidence interval was adopted.[26,27] Statistical analysis was masked by the coding control group as number 1 and the experimental group as number 2, before making the database available to the statistician.

Results

Patient recruitment and data collection took place in June and July 2018. During this period, at the study hospital, 146 surgical procedures were performed on elderly patients, of which 99 were elective and 47 emergency surgeries. Of the 99 patients potentially eligible to participate in the study, 49 did not meet the inclusion criteria. Thus, the sample consisted of 50 participants randomized into the experimental group ($n = 25$) and control group ($n = 25$). There were no losses during follow-up of data collection. Figure 1 presents the eligibility and randomization flow diagram of the study participants.

Table 1 presents the descriptive analysis of the data, and the results of the comparison between demographic and clinical variables showed no statistically significant differences between the groups investigated. Regarding the surgical specialty, for both groups, surgery of the digestive system, orthopaedics, and urology presented the higher frequencies. Spinal anesthesia was the most frequently performed technique in both groups.

Table 2 presents the medians (first and third quartiles) of thirst intensity and discomfort (baseline, final, and changes). The change in thirst intensity had similar behavior to change in thirst

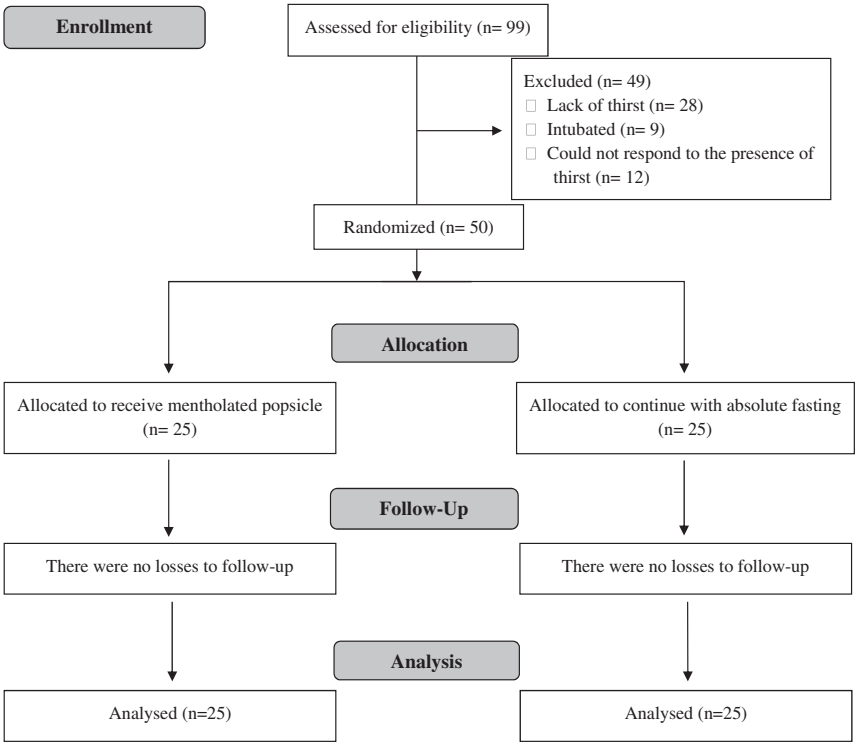

Figure 1. Flow diagram of the study according to the Consolidated Standards of Reporting Trials 2010.

Table 1
Sociodemographic and Clinical Characteristics of the Participants (N = 50)

Characteristics	Groups		*P* Value
	Experimental (n = 25)	Control (n = 25)	
Age (y)			
Median (1st-3rd quartile)	66 (63-71)	69 (64-77)	.199*
Sex n (%)			.259*
Male	12 (48.0)	16 (64.0)	
Female	13 (52.0)	9 (36.0)	
ASA classification n (%)			.236†
ASA I	1 (4.0)	4 (16.0)	
ASA II	17 (68.0)	16 (64.0)	
ASA III	7 (28.0)	5 (20.0)	
Liquid fasting time (h:min), median (1st-3rd quartile)	18:45 (16:12-21:10)	18:25 (15:00-21:20)	.884*
Solid fasting time (h:min), median (1st-3rd quartile)	19:00 (17:10-21:30)	19:50 (15:02-23:20)	.712*

ASA, American Society of Anesthesiologists.
* Mann-Whitney *U* test.
† Kruskal-Wallis test.

discomfort. For both outcomes, the experimental group presented a reduction of 5.0 in the median, which was statistically significant ($P < .001$) with a large size effect (Cohen's r = −0.898 − PV = 0.806) and (Cohen's r = −0.871 − PV = 0.759) for thirst intensity and discomfort, respectively. On the basis of these results, the superiority of the mentholated popsicle in reducing thirst intensity and discomfort when compared with usual care can be affirmed. There were no harms or unintended effects.

Discussion

In the present study, thirst was evaluated through two primary outcomes, intensity and discomfort, and patients receiving the mentholated popsicle presented significant reductions in both measured outcomes, which did not happen with the patients in the control group. In addition, the intervention demonstrated a large effect size in the change both on thirst intensity (Cohen's r = −0.898 − PV = 0.806) and discomfort (Cohen's r = −0.871 − PV = 0.759) after 20 minutes of using only one mentholated popsicle of 20 mL. Furthermore, the PV of change in both outcomes demonstrates the benefits and clinical relevance of the mentholated popsicle, which can be responsible for the reduction of 80.6% in intensity and 75.9% in the discomfort of thirst.

To date, only one study was identified in the literature that evaluated thirst discomfort in adults and older adults in the IPP, and also applied Perioperative Thirst Discomfort Scale. The results demonstrated mean thirst intensity of 6.9 (verbal numerical scale) and mean thirst discomfort of 7.3 (SD = 3.7), as well as the existence of a positive correlation between intensity and thirst discomfort ($P < .05$).[4] These data indicate the relevance of complementarity in the assessment of both outcomes, allowing the measurement of thirst in a plural manner, leading to better understanding of the symptom and consequent appropriate management.

The American Society of Anesthesiologists[28] recommends a 2-hour fast for clear liquids in the preoperative period, and the ERAS protocol[18] endorses early resumption of oral intake in the PACU. However, several health care realities around the world still follow conventional protocols and patients face excessive fasting times both preoperatively and in the IPP.

Studies conducted at public teaching hospitals in Brazil demonstrate this same reality that the fasting time sometimes exceeds even the time prescribed by the surgeon.[29,30] In addition to this, it is troublesome that the average fasting time for elderly surgical patients can be even higher than in younger adults.[30]

Another study, from a regional hospital in Oman, found up to 19 hours of fluid fasting in the preoperative period of adults and elderly patients, with an average of 11.8 hours.[31] In Botswana, another research study reported in the preoperative period, longer fasting times for liquids than those recommended, with an average of 15.3 hours.[32] This prolonged preoperative fasting time and the delay for the reintroduction of fluids in the IPP for the elderly surgical patients reveal that many hospitals around the world are very distant from current protocols based on scientific evidence. This scenario greatly increases patients' discomforts, specially thirst.[3,29] A study shows that even in health care institutions, which have adopted ERAS' recommended practices, the adherence to the evidence of preoperative fasting abbreviation reached only 67.5%.[33]

Table 2
Comparison of Thirst Intensity and Discomfort Over Time by Groups (N = 50)

Outcomes	Experimental Group (n = 25) Median (±1st-3rd Quartile)	Control Group (n = 25) Median (±1st-3rd Quartile)	Mann-Whitney *U* Test			Cohen's r	
			P Value*	*U**	*z**	r (PV)†	95% CI
Thirst intensity							
Baseline value	6.0 (5.0, 8.0)	5.0 (4.0, 7.0)	.082	224.000	−1.742	—	
Final value	0.0 (0.0, 2.0)	5.0 (4.0, 7.0)	<.001	52.500	−5.145	−0.728 (0.529)	−0.837 to −0.564
Change (final − baseline)	−5.0 (−6.5, −3.5)	0.0 (0.0, 0.0)	<.001	0.000	−6.348	−0.898 (0.806)	−0.941 to −0.826
Thirst discomfort							
Baseline value	6.0 (5.0, 7.5)	6.0 (4.0, 8.0)	.590	285.000	−0.539	—	
Final value	1.0 (0.0, 1.0)	6.0 (5.0, 9.0)	<.001	19.000	−5.753	−0.813 (0.661)	−0.890 to −0.691
Change (final − baseline)	−5.0 (−6.5, −4.0)	0.0 (0.0, 1.0)	<.001	0.000	−6.163	−0.871 (0.759)	−0.925 to −0.782

CI, confidence interval; PV, proportion of variance.
* Mann-Whitney *U* test.
† Cohen's r and PV; effect size: small (r = 0.10 − PV = 0.01), medium (r = 0.30 − PV = 0.09), and large (r = 0.50 − PV = 0.25).

Given this complex scenario, studying strategies to manage thirst in the elderly surgical population are of utmost importance. However, to highlight that fasting time is not the only factor that leads to thirst is relevant. Other aspects such as anxiety and fear in the preoperative period, the use of opioids and anticholinergics, orotracheal intubation, and intraoperative bleeding in addition to individual daily intake habits can lead to thirst.[2,34]

A major shift in the understanding of triggering mechanisms for thirst go way beyond osmolar and volumetric imbalance.[34] Therefore, preoperative fasting is in fact a major contributor to thirst genesis but is not the sole factor when it comes to the surgical patient. Thus, even if fasting times are shorter, patients do present thirst during the IPP.

No studies were identified in the literature, which investigated strategies to achieve thirst satiety specifically for the elderly surgical patient in the IPP. However, evidence shows that cold-temperature, solid-water (ice) and menthol-flavored strategies present greater thirst-quenching potential compared with those with liquid products at room temperature or higher and unflavored products in adults.[7,10] In addition, they prevent gastric distension promoting oropharyngeal humidification.[6,10]

These strategies include menthol chewing gum[8] and mentholated popsicle[9] in the preoperative period. In the postoperative period, the ice popsicle[10] and a bundle comprising mentholated ice popsicle and lip moisturizer[5] were effective to significantly decrease thirst intensity and discomfort. The beneficial effects of these strategies can be explained by the activation of anticipatory mechanisms, including the oropharyngeal receptors that can be osmoreceptors, mechanoreceptors, and thermoreceptors.[34] The thermoreceptors known as transient potential melastatin 8 play a relevant role in mitigating thirst for transmitting afferent stimuli in the presence of cold temperature and/or menthol in the oropharynx.[6,35] These stimuli are carried to limbic regions, anterior cingulate, and orbitofrontal cortex where the cold temperature is identified as a pleasant sensation providing a reduction in thirst intensity.[36]

When preabsorptive satiety is achieved through a cold or mentholated strategy, the subfornical organ and the vascular organ of the lamina terminalis that are osmosensitive are able to predict homeostatic restoration in anticipation of hydroelectrolytic imbalance initially detected in the oral cavity.[1,35,37] The discussion of physiological aspects is relevant because the argument of the traditional model that thirst is generated only by osmotic and hypovolemic alterations is being challenged.[34,35] This is clearly observed with elderly surgical patients in clinical practice, for they receive intravenous fluids from the preoperative period on but present thirst in the IPP.

These facts corroborate the importance of using thirst management strategies that act on the oropharynx. Understanding that it is possible to safely quench patient's thirst with a small volume of liquid by activating preabsorptive satiety with cold and mentholated strategies represents a breakthrough for nursing care in the IPP.

Regarding future research and because of the lack of evidence on the management of thirst in elderly surgical patients, the development of new studies to test the mentholated popsicle both preoperatively and in the postoperative period is suggested in different clinical practice scenarios.

Limitations

The main limitation of the present study was the lack of blinding of the participants and researcher responsible for the implementation of the tested intervention. The distinct characteristics of the mentholated popsicle application in comparison with usual care were visually noticeable among the study participants. The randomized clinical trial was a single-center study and some variables such as the length and type of surgery were not controlled. Thus, these aspects can also be considered as limitations of the study.

Conclusions

In the IPP, the use of the mentholated popsicle significantly decreases the intensity and discomfort of thirst in elderly surgical patients with a large size effect. The benefits and clinical relevance of the mentholated popsicle for reducing both thirst intensity and discomfort were also demonstrated in this study by analyzing the PV. Mentholated popsicle is an innovative strategy for application in clinical practice, representing a major shift in comfort and positively affecting the elderly patients' surgical experience.

For safety, patients should be cleared for allergies to menthol before receiving the popsicle. The use of the mentholated popsicle with elderly patients in the IPP was relevant for the population in this health care institution. Therefore, the importance of extending this study to other health care institutions and different regions of the world is highlighted. It is essential to reaffirm that the safety criteria addressed by the SPTM should be met before administering the mentholated popsicle, when patients recover from anesthesia in the PACU.

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