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The use of mentholated popsicle to reduce thirst during preoperative fasting: A randomised controlled trial

Patricia Aroni PhD, RN, Professor[1] | Ligia F. Fonseca PhD, RN, Associate Professor[1] | Marcia A. Ciol PhD, Research Professor[2] | Amanda S. Margatho PhD, RN, Professor[3] | Cristina M. Galvão PhD, RN, Full Professor[3]

[1]Department of Nursing, State University of Londrina, Londrina, Brazil

[2]Department of Rehabilitation Medicine, School of Medicine, University of Washington, Seattle, WA, USA

[3]General and Specialized Nursing Department, Ribeirão Preto College of Nursing, University of São Paulo, Ribeirão Preto, Brazil

Correspondence
Patricia Aroni, Department of Nursing, State University of Londrina, Londrina, PR, Brazil.
Email: aronipatricia@gmail.com

Abstract

Aims and objectives: To compare mentholated popsicle with usual care (absolute fasting) in the change of thirst intensity and discomfort of patients in the preoperative fasting.

Background: Thirst is defined as the desire to drink water, and it is considered to be a multifactorial symptom. In the preoperative fasting, the patient may experience intense thirst, often for a long time, that can lead to feelings of suffocation, desperation, fear and anxiety.

Design: A randomised controlled trial.

Methods: Forty patients, aged between 18–60 years, were randomised to mentholated popsicle group or absolute fasting group (twenty in each). The primary outcomes were thirst intensity, evaluated by a numeric scale ranging from 0 (no thirst)–10 (the worst possible thirst), and discomfort from thirst (evaluated by the Perioperative Thirst Discomfort Scale), both measured twice (baseline and after 20 min of intervention). The CONSORT checklist was used to report this study.

Results: Mean age was similar in both groups (38 years in the mentholated popsicle group and 39 in the absolute fasting group). At baseline, the mentholated popsicle group had higher median for the scales of intensity (6.5) and discomfort (7.5) from thirst than the absolute fasting group (5.0 and 5.0, respectively). At the end of 20 min, the popsicle group had a statistically significant decrease in intensity and discomfort from thirst (median decreases of 5.0 and 7.0 points, respectively) when compared to the absolute fasting group (median increases of 0.5 and 1.0 points, respectively).

Conclusions: The use of mentholated popsicle decreased the intensity and discomfort from thirst, and it is a viable strategy for the management of thirst in the preoperative fasting.

Relevance to clinical practice: In the preoperative fasting, making mentholated popsicles available to patients is an easy strategy to manage thirst, which might lead to better care.

KEYWORDS

fasting, mentha, nursing, nursing care, perioperative nursing, preoperative care, preoperative fasting, randomised controlled trial, thirst

Registration Number Clinical Trials: ClinicalTrials.gov (NCT 03236623).

1 | INTRODUCTION

Thirst is defined as a desire to drink water, and it is a compensation mechanism that aims to re-establish the water balance in the human body. Thirst is a multifactorial symptom that can be stimulated by the necessity of hydration, necessity of normalisation of blood volume and plasma osmolarity, or can be initiated by various personal and cultural characteristics of an individual, such as palatability of ingested liquids and food habits (Leiper, 2005; Stevenson, Mahmut, & Roone, 2015). In addition, thirst can be affected by processes related to health and disease, environment, and life experiences, all of which might influence on how a person perceives and reacts to the symptom (Conchon, Nascimento, Fonseca, & Aroni, 2015). Factors that can affect the intensity and discomfort from thirst include fasting, anxiety, medications, and age, among others (Arai, Stotts, & Puntillo, 2013; Conchon et al., 2015; Leiper, 2005).

Research on the patients' experience of thirst within hospital settings has found a high prevalence of the symptom in surgical patients, varying from 75% (Aroni, Nascimento, & Fonseca, 2012)–98% (Serato et al., 2019) during the postoperative period, and from 43% (Gul, Andsoy, & Ozkaya, 2018)–69% (Francisco, Batista, & Pena, 2015) during the preoperative period. In the surgical patient, the experience of thirst is particularly unpleasant, with reports that it can give the sensation of suffocation, weakness, irritation, desperation, fear and anxiety. (Dessotte, Rodrigues, Furuyall, Rossi, & Dantas, 2016; Silva, Aroni, & Fonseca, 2016; Walker, Bell, Cook, Grocott, & Moonesinghe, 2016). Therefore, it is important that the nursing staff evaluate and treat the symptom to minimise the discomfort of the patient.

To minimise the risk that a surgical patient aspirates the gastric content during the period in which the person is anaesthetised, the American Society of Anesthesiologists (ASA) (2017) recommends that the fasting time is in accordance to the type of food ingested prior to surgery. Their recommendation for fasting is 2 hr prior to surgery for liquids without residues, such as water or tea, 6 hr for light foods, and at least 8 hr for fried or fatty foods as well as meat. The Enhanced Recovery After Surgery (ERAS) protocol describes several strategies for a good surgical recovery of a patient and makes the same recommendations for fasting times for clear liquids and light food as the ASA (Gustafsson et al., 2019).

There is evidence in the literature that surgical patients frequently fast for longer periods than necessary, both on the preoperative and postoperative periods (Abebe et al., 2016; Aguilar-Nascimento et al., 2014; Francisco et al., 2015; Gul et al., 2018; Tosun, Yava, & Açikel, 2015). This procedure negatively affects the surgical recovery and induces thirst in the patient (Abebe et al., 2016; ASA, 2017; Francisco et al., 2015; Gul et al., 2018).

A prolonged fasting might alter the patient's plasmatic osmolarity, while anxiety and some medications promote dryness of the patient's oral cavity (ASA, 2017; Arai et al., 2013; Brunstrom, 2002; Leiper, 2005). Age is another important factor. Usually, the older person presents a diminished perception of thirst, since the ageing process affects the physiological mechanisms of perception and control of this symptom (Kenney & Chiu, 2001; Phillips et al., 1984). All these factors, in isolation or together, might influence and intensify the sensation of thirst, and all of those factors can be easily identified in a surgical patient in the preoperative fasting.

What does this paper contribute to the wider global clinical community?

- This is the first published study on the management of thirst using a cold mentholated strategy of low volume for patients in the preoperative fasting.
- This study demonstrated that mentholated popsicle significantly decreased intensity and discomfort from thirst of patients in the preoperative fasting.
- This study showed that mentholated popsicle is a strategy that nurses could use to alleviate the patient's intensity and discomfort with thirst, with the advantage that it is simple, and it may lead to better care and increased patient's satisfaction.

2 | BACKGROUND

The perception and satiety of thirst are a consequence of interconnected neuronal, physiological and hormonal mechanisms that interact to motivate the ingestion of water according to the necessity of the individual (Leiper, 2005; McKinley & Johnson, 2004). The neuronal modulators involved in the response to thirst work as a reward mechanism, integrating the necessity of water ingestion with the pleasant sensations from that ingestion (Leiper, 2005).

Once the person is thirsty, the human organism has two mechanisms to achieve satiety: pre- and postabsorptive. Preabsorptive satiety is related to baroreceptors, osmoreceptors and thermoreceptors localised in the oropharynx, as well as to gastric receptors that act as measuring instruments of the ingested volume, even before there is absorption of the liquid (Bichet, 2018; Eccles, DuPlessis, Dommels, & Wilkinson, 2013; Zimmerman, Leib, & Knight, 2017; Zimmerman et al., 2016). These receptors can be active by the humidification of the oral mucosa, by the mechanical process of swallowing and by the gastric distention due to the ingestion of liquids, resulting in satiety (Saker, Farrell, Adib, McKinley, & Denton, 2014; Zimmerman et al., 2016). The postabsorptive satiety is initiated after the organism absorbs the water, and there is restauration of the osmotic and/or hypovolemic levels at cellular level (Eccles et al., 2013).

The oropharyngeal stimulus from cold liquids and mentholated substances induces faster sensation of satiety when compared to other stimuli (Eccles et al., 2013). This occurs because of the

presence of thermal receptors in the oropharynx, called transient receptor potential ankyrin 1 (TRPA1) and transient receptor potential melastatin 8 (TRPM8), which are activated in the presence of cold temperatures (Dhaka, Viswanath, & Patapoutian, 2006; McCoy, Knowlton, & McKemy, 2011). TRPM8 is also activated by substances such as menthol and icilin (Latorre, Brauchi, Madrid, & Orio, 2011; McKemy, Neuhausser, & Julius, 2002), and allows one to feel satiety without ingesting large quantities of liquids (Eccles et al., 2013; Leiper, 2005).

Mentholated substances contain menthol, which is a compost of vegetal origin commonly used in candy confectionary, lotions, medications and especially in oral hygiene products, among other uses. There is evidence of the antibacterial potential of menthol against oral pathogens, showing that menthol acts by breaking the cellular membrane of the bacteria in the mouth, and consequently killing the bacteria. However, the antibacterial action of menthol is weaker than other essential oils, such as hinokitiol, carvacrol and thymol. Consequently, the use of menthol in products of oral hygiene is related more to the refreshing sensation it causes than to its antibacterial capacity (Wang et al., 2016). According to the American pharmacopeia, levels below 0.1% are considered safe for human ingestion. In Brazil, where this study was conducted, there is no specific regulation for use of menthol in humans, but other literature shows that the use of mentholated substances varies from 0.003%–2.0% in concentration (Rowe, Sheskey, & Quinn, 2009).

Thirst can be evaluated for intensity and discomfort. For intensity, several researchers have used a numeric scale from 0 (no thirst)–10 (the worst perceived thirst) (Aroni et al., 2012; Puntillo, Arai, Cooper, Stotts, & Nelson, 2014; Stotts, Arai, Cooper, Nelson, & Puntillo, 2015; Yang, Yates, Chin, & Kao, 2010). Higher intensity of thirst was associated with release of antidiuretic hormones related to thirst perception (Arai et al., 2013; Leiper, 2005), validating the use of the patient's self-report as a measure of the symptom (Conchon et al., 2015; Martins, Fonseca, Rossetto, & Mai, 2017; Stevenson et al., 2015). In general, the individual reports thirst when there is dryness in the oral cavity, throat, and lips, the tongue and saliva are thick, there is a unpleasant and bitter taste in their mouth, and a desire to ingest water (Leiper, 2005; Martins et al., 2017).

Understanding the neural mechanisms involved in satiety helps the nursing staff to choose viable and safe strategies to alleviate thirst of patients under their care. In the literature, we found strategies whose primary focus was the humidification of the oral cavity using cold temperatures (Aroni et al., 2012; Cho, Kim, & Park, 2010; Conchon & Fonseca, 2018; Hur et al., 2009; Moon, Lee, & Jeong, 2015; Yoon & Min, 2011). Other authors tested cold strategies with the addition of menthol (Puntillo et al., 2014; Serato et al., 2019). These strategies have been tested in dialysis patients (Fan, Zhang, Luo, Niu, & Gu, 2013; Yang et al., 2010), patients in intensive therapy (Puntillo et al., 2014) and patients in the immediate postoperative period (Cho et al., 2010; Conchon & Fonseca, 2018; Hur et al., 2009; Serato et al., 2019; Yin, Ye, Zhao, Li, & Song, 2014). To date, we found no intervention studies using ice in low volume to alleviate thirst in patients in the preoperative fasting.

Given the lack of studies that focus on alleviating thirst in the preoperative fasting, and the evidence from studies in other populations that the use of menthol creates a sensation of relief from thirst, this study had the objective of comparing mentholated popsicle with usual care (absolute fasting) in the change of thirst intensity and discomfort of patients in the preoperative fasting.

3 | METHODS

3.1 | Design and participants

The study was performed in a large university hospital in the state of Paraná, Brazil. The study was designed as a randomised controlled trial with two parallel groups: one where the patients received a menthol popsicle (denominated mentholated popsicle group) and another who received usual care (denominated absolute fasting group). The study was guided by the CONSORT checklist, see Appendix S1.

Inclusion criteria were as follows: patients admitted to regular wards and reporting thirst in the preoperative fasting, aged between 18–60 years, conscious and oriented to time and space, admitted for an elective surgery, fasting for at least 2 hr at the moment of enrolment in the study, and with a minimum time of 3 hr between the enrolment and the scheduled time for the surgery. Exclusion criteria included the following: patients under preanaesthetic medications, absolute counter-indication for ingestion or swallowing of any substances, mandibular trauma, nausea or vomit, allergy to menthol, dialysis treatment, or Sjogren syndrome (pathology that induces dryness of oral mucosa).

Since there were no previous studies reporting estimates of efficacy of a mentholated popsicle to alleviate thirst in the population of preoperative patients, this study was initially planned as pilot study with 20 individuals in each group. However, given the high efficacy of the intervention (which we will demonstrate below), the current sample size was sufficient to find a difference between the mentholated popsicle and the absolute fasting groups.

The randomisation of the participants followed a computer-generated randomisation list, which was done in blocks to assure that the participants were equally distributed between the two groups over time. The assignments from the randomisation list were inserted in opaque sealed envelopes in the order they were generated. The list and the envelopes were prepared by a researcher who was not involved in any other aspect of this study. Figure 1 shows the flow diagram for the study.

The ethical review board of the university approved the study. Potential participants were approached by the first author and invited to be part of the study. After the study was explained and the individuals agreed to participate, they signed an informed consent prior to randomisation. The study was registered at ClinicalTrials.gov (NCT 03236623).

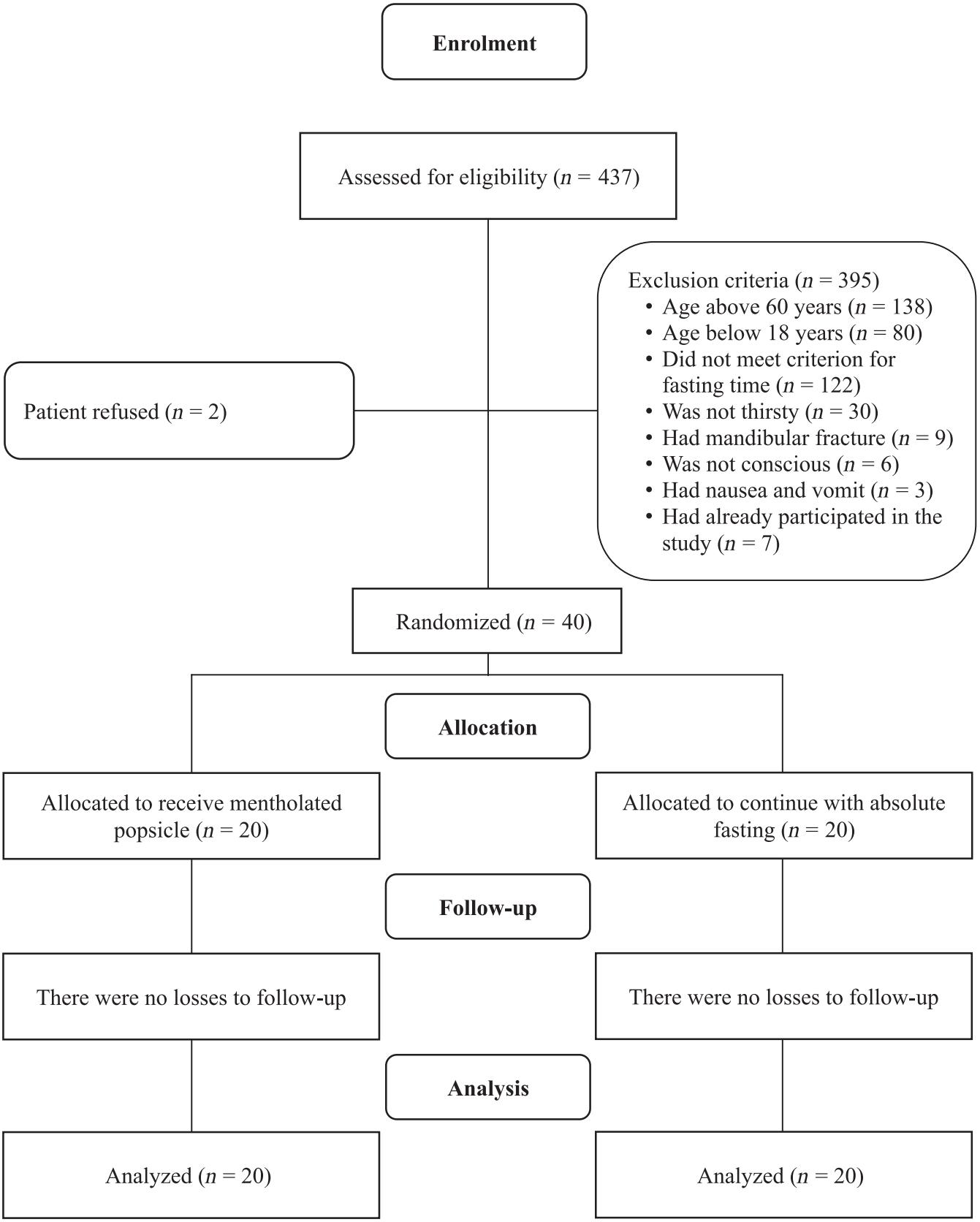

FIGURE 1 Flow diagram according to the Consolidated Standards of Reporting Trials (CONSORT, 2010)

3.2 | Primary outcomes

Primary outcomes were intensity and discomfort with thirst. Intensity of thirst was measured using a numeric scale with values ranging from 0 (no thirst)–10 (the worst possible thirst). Discomfort was measured using the Perioperative Thirst Discomfort Scale (Martins et al., 2017), which includes the following items: dry mouth, dry lips, thick tongue, thick saliva, dry throat, bad taste in the mouth and desire to drink water. Each item was graded as 0 (no), 1 (a little) or 2 (a lot), and the sum of the items is the total scale, varying from 0 (no discomfort from thirst)–14 (most intense discomfort related to perioperative thirst). The Perioperative Thirst Discomfort Scale was selected because it is the only validated instrument for the symptom that we found in the literature (Martins et al., 2017). The patients evaluated their own intensity and discomfort with thirst, by responding to the questions of the two measurement scales. The questions were asked by the first author, who simply read the question and recorded the patient's response.

3.3 | Data collection

3.3.1 | Instrument

In addition to outcome variables, we collected sociodemographic and clinical data from the patient, factors that might predispose to thirst, such as fasting time and medication by an instrument.

3.3.2 | Preparation of the mentholated popsicle

In Brazil, where the study was conducted, there is no specific regulation for the use of menthol in humans. Therefore, our formulation followed the recommendation of the United States Pharmacopeia, which indicates that menthol levels below 0.1% are safe concentrations for human ingestion. Specifically, we based our popsicle in the formulation of Serato and researchers (2019), who used a 10 ml popsicle volume, 0.05% of menthol, 0.05% of saccharine, 2% of cereal alcohol and ultrafiltered water. In our study, we increased the popsicle volume to 30 ml (same concentrations), since in the preoperative fasting the patient is not under anaesthetic medication and the ingestion of this volume does not offer risks to the surgical procedure. Furthermore, this volume prolongates the time for ingestion and, consequently, the duration of the stimulus to the oral receptors related to the preabsorptive satiety. The formulation was prepared in a compounding pharmacy and frozen into popsicles by the first author.

3.3.3 | Time interval for outcome data collection

In a literature review, we found no information on the time necessary for action of menthol in the oral receptors or on the appropriate time for thirst evaluation after the popsicle administration. To resolve those issues, prior to finalising the study protocol, we conducted a small pilot study with nine individuals, with the same inclusion and exclusion criteria as above. We gave a 30 ml menthol popsicle to the first three patients and observed the time they took to ingest it. The time varied from person to person, and we decided that the evaluation time would be counted starting after they finished their popsicle.

The next three patients received the popsicle and had their thirst evaluated 15 min after they finished their popsicle, while the last three patients received the popsicle and had evaluation 20 min after finishing it. Descriptively, the intensity and discomfort from thirst were similar for both groups of patients. Given that the objective was to prolong the satiety sensation, we opted to measure the outcomes at 20 min after the patient finished the mentholated popsicle in the group assigned to receive it. For the absolute fasting group, we evaluated their thirst 20 min after their first evaluation at baseline.

3.3.4 | Procedures

For the safety of all patients, the abstinence of liquids for at least 2 hr was maintained for all of them. To make sure that the group assigned to the popsicle would have time to ingest it completely and we would have time to evaluate their thirst, we only enrolled individuals who had to wait a minimum of 3 hr to the scheduled time of surgery. Individuals whose scheduled surgery was in the morning period were not recruited to avoid that the intervention would awake the patient during early morning hours.

The study was conducted in May and June 2017. Daily surgical schedules were checked for elective surgeries to be performed in the afternoon. Eligible patients were invited to participate in the study, and for the ones who accepted to participate, the intensity and discomfort with thirst were evaluated before they were randomised to one of the two groups. Individuals allocated to the mentholated popsicle group received a popsicle, and the first author stayed with the individuals until they finished ingesting the popsicle. After that, the researcher left and came back 20 min later to measure intensity and discomfort with thirst. For the absolute fasting group, the researcher left after group assignment and returned 20 min later to measure the outcomes. To avoid possible bias in response or loss of follow-up in the absolute fasting group, those patients received a menthol popsicle after the final evaluation. Given the nature of the intervention and control groups, neither patients nor researchers could be blind to the intervention.

3.4 | Statistical analysis

Descriptive analyses were performed for all variables. Participant characteristics that were categorical were reported in percentage by category. For numeric variables (such as age, fasting time and outcomes), we calculated descriptive summaries such as

means, medians, standard deviations, minimums and maximums. Scatterplots of follow-up outcomes by their baseline values and histograms of change in outcome score by intervention groups were created for visualisation of the outcomes. Data were analysed using the Statistical Package for the Social Science (SPSS) (version 24.0 for Mac).

Even though this was a randomised study, given the size of the sample, we compared the two groups on the baseline sociodemographic and clinical variables, to evaluate whether there were differences that could influence the outcomes. Age and fasting time were compared using the test for median of Mann–Whitney. All other variables, which were categorical and had sparse data, were compared using the Fisher exact test, which is appropriate for this type of data.

To compare the median of intensity and discomfort with thirst between the two groups at baseline, and the median changes from baseline to follow-up outcomes between the two groups, we used Mann–Whitney *U* test. The Mann–Whitney *U* test is nonparametric and was chosen because it requires only the assumption that the distribution of the outcomes is the same in both groups, without requiring a specific distribution (such as the Gaussian distribution of the *t* test). With small sample sizes, it is difficult to assume or test whether the data come from a Gaussian distribution, and a nonparametric test is suitable for this situation. In addition, we calculated the 95% confidence interval of the median change per group, using bootstrap (method of bias corrected accelerated) (Davison & Hinkley, 1997).

The significance level for the tests was set to .05, so tests where the *p*-values were smaller than the significance level were considered statistically significant. Recall that a *p*-value is the probability that one would see the difference observed in the data under the null hypothesis of no differences between the two groups.

4 | RESULTS

Of 437 patients screened for eligibility, 388 did not meet eligibility criteria, and two refused to participate. Seven individuals who had already participated once were screened a second time (two patients had reoperations and five had postponement of prior surgery) and were included only in the first time they were screened. The final sample included 20 individuals in each group, and there were no losses to follow-up (Figure 1).

Table 1 shows the descriptive analysis of the data. There were no statistically significant differences between the groups on the observed sociodemographic and clinical variables.

Table 2 shows the summaries for intensity and discomfort with thirst at baseline, final (after 20 min) and change (final - baseline), by group. For initial thirst intensity scale, medians were 6.5 for the mentholated popsicle group and 5.0 for the absolute fasting group ($p = .02$). For final thirsty intensity, medians were 2.0 for the mentholated popsicle group and 6.0 for the absolute fasting group ($p < .001$). The intensity of thirst decreased by 5 points in the mentholated popsicle group (median = −5.0, 95% confidence interval [CI]: −5.5, −4.0), compared to an increase of 0.5 points in the absolute fasting group (median = 0.5, 95% CI: 0.0, 1.0), and the two medians were statistically different ($p < .001$).

For the initial discomfort with thirst scale, medians were 7.5 for the mentholated popsicle group and 5.0 for the absolute fasting group ($p = .02$). For final discomfort with thirst, medians were 0.0 for the mentholated popsicle group and 7.0 for the absolute fasting group ($p < .001$). Discomfort with thirst decreased by 7.0 points in the mentholated popsicle group (median = −7.0, 95% CI: −7.0, −6.0) and increased by 1.0 point for the absolute fasting group (median = 1.0, 95% CI:1.0, 2.0), and the medians were statistically different ($p < .001$).

Figure 2, top, shows a scatterplot of the baseline scores (horizontal axis) by the final scores (vertical axis), with different symbols for each group (triangle for mentholated popsicle group and circle for absolute fasting group). The identity line represents the same value of scores for baseline and final assessments (equivalent to no change in intensity or discomfort). Points above the line represent individuals for whom there was an increase in intensity and discomfort with thirst (worse outcome), while points below the line represent a decrease in the scales (better outcome). A very small random value was added to the initial scores, so that we could distinguish between two or more individuals with the exact same scores at both times. All individuals in the mentholated popsicle group improved on both outcomes, while most individuals in the absolute fasting group worsened or stayed the same, with very few exceptions.

Histograms of the distribution of the changes in scores are shown below the scatterplots (bottom of Figure 2). The two groups present distinct patterns, with negative changes (better symptoms at the follow-up) more prevalent in the mentholated popsicle group and positive changes (worse symptoms at the follow-up) more prevalent in the absolute fasting group.

5 | DISCUSSION

When compared the mentholated popsicle group to the absolute fasting group, the group that received the menthol popsicle had a significant decrease in intensity and discomfort with thirst after a 20-min period.

This study was initially conceived as a pilot study given the lack of previous information on the possible magnitude of the effect of the mentholated popsicle on thirst symptoms. Most pilot studies do not have statistical power to detect a difference between groups, even when one exists, due to large variation within the groups and small sample sizes, which in turn result in small effect sizes. This was not the case with our study. In fact, if one were to use our results to calculate a sample size for a future study, using G*Power (Faul, Erdfelder, Lang, & Buchner, 2007), with a significance level of 0.025 (a Bonferroni adjustment for two tests of hypotheses, one for intensity and another for discomfort), power of 0.95 and the nonparametric

TABLE 1 Sociodemographic and clinical characteristics of the participants

Characteristics	Groups		
	Mentholated popsicle (*n* = 20)	Absolute fastin (*n* = 20)g	*p**
Age in years, mean (standard deviation)	38.4 (12.7)	39.2 (13.1)	
Median (Min., Max.)	38.5 (18, 59)	40.0 (18, 59)	.79
Sex, *n* (%) of males	12 (60)	9 (45)	.52
Presence of chronic diseases, *n* (%) in each category			1.0
No chronic disease	13 (65)	14 (70)	
Hypertension	4 (20)	4 (20)	
Hypertension and heart failure	1 (5)	0 (0)	
Hypertension and diabetes mellitus	1 (5)	0 (0)	
Asthma	1 (5)	0 (0)	
Asthma and emphysema	0 (0)	1 (5)	
Lupus	0 (0)	1 (5)	
Type of opioid, *n* (%) in each category			.06
None	7 (35)	14 (70)	
Tramadol	11 (55)	3 (15)	
Morphine	1 (5)	3 (15)	
Tramadol and morphine	1 (5)	0 (0)	
Type of diuretic medication, *n* (%) in each category			1.0
None	18 (90)	18 (90)	
Hydrochlorothiazide	1 (5)	1 (5)	
Hydrochlorothiazide and furosemide	0 (0)	1 (5)	
Furosemide and spironolactone	1 (5)	0 (0)	
Using anticholinergic medication, *n* (%) yes	0 (0)	1 (5)	1.0
Type of scheduled surgery, *n* (%)			
Orthopaedic	12 (60)	6 (30)	
Urology	2 (10)	7 (35)	
Digestive system	2 (10)	3 (15)	
Otorhinolaryngology	2 (10)	2 (10)	
Head and neck	1 (5)	0 (0)	
Gynaecology and obstetrics	1 (5)	0 (0)	
Thoracic	0 (0)	1 (5)	
Vascular	0 (0)	1 (5)	
ASA physical status classification, *n* (%) in each category			1.0
ASA I: normal healthy patient	14 (70)	14 (70)	
ASA II: patient with mild systemic disease	6 (30)	5 (25)	
ASA III: patient with severe systemic disease	0 (0)	1 (5)	
Fasting time for liquids in hours, mean (standard deviation)	11.6 (7.4)	11.1 (3.3)	
Median (Min., Max.)	10.2 (3.5, 40.7)	11.9 (4.0, 11.8)	.15
Fasting time for solids in hours, mean (standard deviation)	14.4 (7.2)	13.3 (2.2)	
Median (Min., Max.)	12.7 (9.9, 43.2)	13.1 (7.8, 17.9)	.51

Abbreviation: ASA, American Society of Anesthesiologist.

*p-value from Mann–Whitney U test for age and fasting time, and from Fisher exact test for all other variables.

test of Mann–Whitney as statistical analysis, the necessary sample size would be four individuals per group. Therefore, our study already has a large enough sample size to be confirmatory for this of population of individuals in preoperative fasting. However, since this is the first study in this population with this type of intervention, it is important that the study be reproduced to corroborate our results. We would suggest that future studies are conducted with the same or larger sample sizes than ours.

TABLE 2 Comparison of intensity and discomfort with thirst over time, by groups

Outcome measure	Groups		
	Mentholated popsicle (n = 20)	Absolute fasting (n = 20)	p*
Thirst intensity			
Baseline value			
Mean (standard deviation)	6.6 (1.6)	5.3 (1.8)	
Median (Min, Max.)	6.5 (4.0, 10.0)	5.0 (1.0, 9.0)	.02
Final value**			
Mean (standard deviation)	1.8 (1.1)	6.2 (2.2)	
Median (Min, Max.)	2.0 (0.0, 4.0)	6.0 (1.0, 10.0)	<.001
Change (final – baseline)			
Mean (standard deviation)	−4.8 (1.8)	0.8 (1.2)	
Median (Min, Max.)	−5.0 (−8.0, −2.0)	0.5 (0.0, 5.0)	<.001
95% CI for median change***	(−5.5, −4.0)	(0.0, 1.0)	
Discomfort with thirst			
Baseline value			
Mean (standard deviation)	8.0 (3.7)	5.2 (2.9)	
Median (Min, Max.)	7.5 (1.0, 14.0)	5.0 (1.0, 11.0)	.02
Final value**			
Mean (standard deviation)	1.0 (1.6)	6.9 (3.3)	
Median (Min, Max.)	0.0 (0.0, 6.0)	7.0 (2.0, 13.0)	<.001
Change (final – baseline)			
Mean (standard deviation)	−7.0 (3.3)	1.6 (1.2)	
Median (Min, Max.)	−7.0 (−14.0, −1.0)	1.0 (0.0, 4.0)	<.001
95% CI for median change***	(−7.0, −6.0)	(1.0, 2.0)	

*p-value from Mann–Whitney U test.

**20 min after finishing the popsicle in the mentholated popsicle group and 20 min after the baseline evaluation in the absolute fasting group.

***95% confidence interval calculated using bootstrap (method of bias corrected accelerated).

In this study, individuals older than 60 years were not eligible. The rational was that older adults perceive and react to thirst in a different way than younger adults (Kenney & Chiu, 2001; Phillips et al., 1984), and older adults constitute a minority of the surgical patients within the hospital where we conducted the study. Therefore, we cannot generalise the results of this study for older adults and studies of interventions to alleviate thirst during preoperative fasting should be conducted specifically for that population.

Despite the randomisation of the patients into the two groups, there was statistically significant difference in baseline intensity and discomfort between the two groups. It is possible that this can be explained by the larger proportion of individuals in the mentholated popsicle group that were using opioids, which can cause a greater sensation of thirst or oral dryness (Arai et al., 2013; Leiper, 2005; Wiffen, Derry, & Moore, 2014). However, this was the group that reported a large effect of thirst relief, while in the absolute fasting group, the thirst was slightly exacerbated.

The mean times of fasting for solid and liquids prior to a surgery were above the recommended by the ASA (2017) and ERAS protocol (Gustafsson et al., 2019) in both groups, with approximately 8 hr above the recommended for liquids and 7 hr above the recommended for solids. These observations were similar to studies conducted in other countries (Abebe et al., 2016; Aguilar-Nascimento et al., 2014; Francisco et al., 2015; Gul et al., 2018). Thirst in these patients is not only due to the duration of fasting, but can also be influenced by anxiety, medication type and age, for example (Arai et al., 2013; Conchon et al., 2015; Leiper, 2005). It is possible that our results were influenced by the duration of fasting (longer fasting might lead to higher level of thirst), but these are exactly the patients that could benefit from the intervention and are our target population.

To date, we did not find studies of use of mentholated popsicle in the preoperative fasting in the same population of this study, though there is evidence of the benefits of this cold strategy during the postoperative period (Aroni et al., 2012; Cho et al., 2010; Conchon & Fonseca, 2018; Hur et al., 2009; Moon et al., 2015; Puntillo et al.,

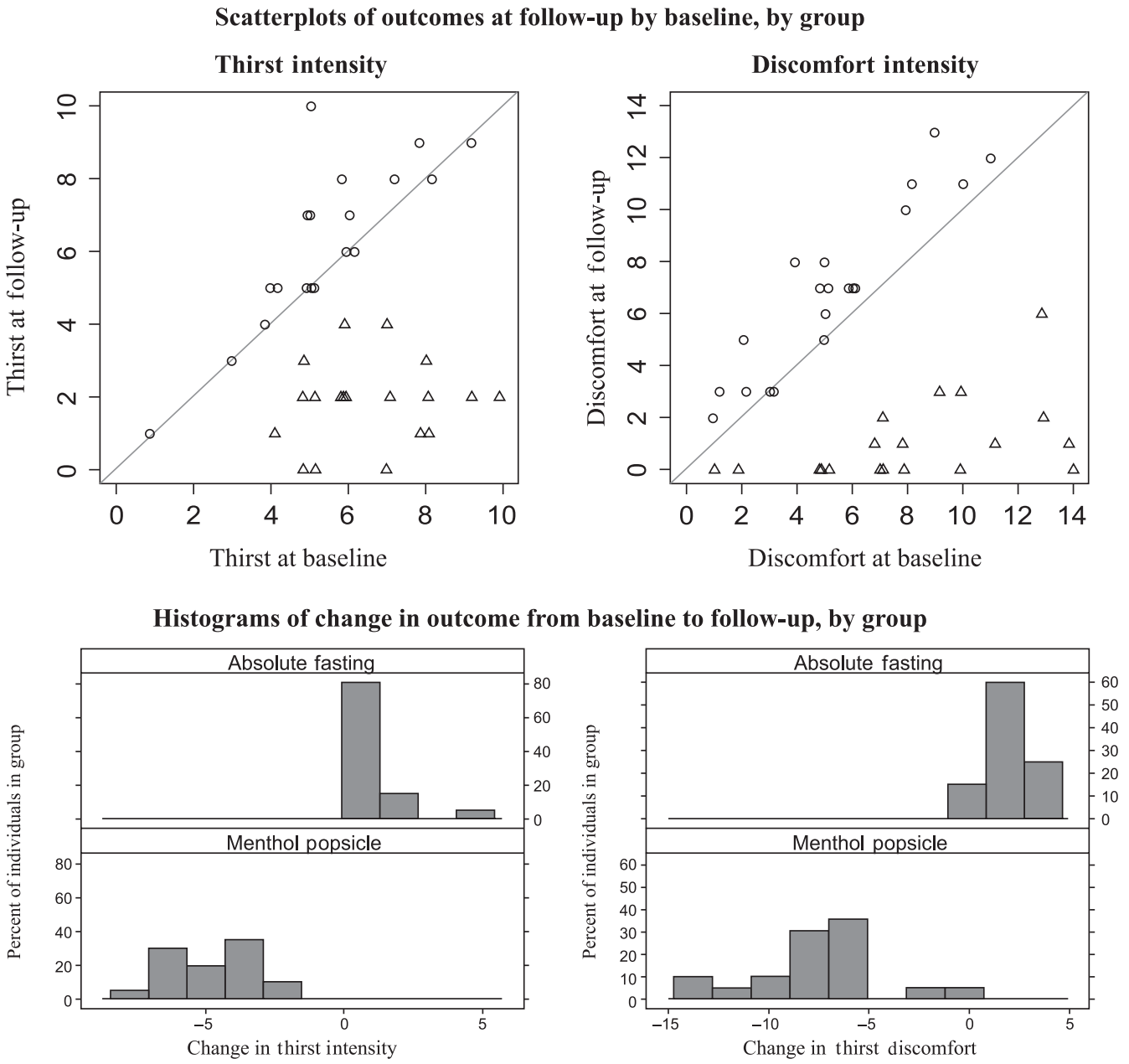

FIGURE 2 The top scatterplots show the scores of intensity and discomfort with thirst at baseline and follow-up (mentholated popsicle group is depicted by triangles, and absolute fasting group is depicted by circles in the scatterplots). The bottom histograms show the changes in scores from baseline to follow-up by group

2014; Serato et al., 2019; Yoon & Min, 2011). In a quasi-experimental study, during the immediate postoperative period, the authors compared the administration of 2 millilitres of water at room temperature with 2 millilitres of ice. Both groups presented a decrease in the intensity of thirst, and there was no statistically significant difference ($p = .56$), although the group receiving ice had a larger decrease (Aroni et al., 2012).

In a randomised controlled trial, researchers evaluated the effectiveness of a 10 ml popsicle of ice against 10 ml of water at room temperature to relief thirst in the immediate postoperative period (Conchon & Fonseca, 2018). The participants could repeat the intervention up to five times (popsicles or water), offered every 15 min. Change in the numeric scale of thirst intensity (final minus baseline) showed a value of five points for the ice popsicle group and three points for the water group, with a statistically significant difference ($p < .01$). In that study, participants could have up to five popsicles, but in our study, we used a single application of the mentholated popsicle, which still showed to be effective.

In another quasi-experimental study, the authors tested gargling with cold water against a gaze wet with cold water to alleviate thirst, improvement of the oral cavity conditions and throat pain in patients in the postoperative period (Yoon & Min, 2011). Gargling with cold water provided a larger decrease in thirst intensity ($p < .001$) and in discomfort with thirst ($p = .003$) when compared to wet gaze.

Another quasi-experimental study compared three groups (frozen wet gaze with saline solution, ice and gaze wetted with water) on the thirst and oral cavity condition in the postoperative period (Cho et al., 2010). Interventions were applied twice to each person. Thirst intensity had larger reduction in the ice group, followed by the frozen gaze ($p < .001$), both of which are recommended to reduce thirst and improve oral cavity conditions. In that study, the researchers evaluated the following discomforts related to thirst: tongue condition, saliva, oral mucosa and gums, all of which presented improvement on the ice and frozen gaze groups, showing that the cold strategies were superior to room temperature strategies.

Few studies using mentholated substances were identified in the literature. In a randomised controlled trial, the effect of a bundle of procedures composed by oral swabs, cold water sprays and mentholated moisturiser was compared to usual care in decreasing intensity and discomfort with thirst and dry mouth in an intensive therapy unit (Puntillo et al., 2014). The bundled procedures decreased intensity and discomfort with thirst ($p < .05$), and the group receiving usual care reported 1.9 times more dry mouth that the group receiving the bundle of procedures ($p < .04$). While the bundled procedures were more effective in decreasing the sensation of thirst, the authors emphasised that the effectiveness of each separated procedure was not investigated and that it is not possible to know whether all procedures are necessary to alleviate thirst.

In another randomised controlled trial, the researchers evaluated a bundle of procedures with menthol (mentholated popsicle and mentholated cold lip moisturiser) versus a bundle on nonmentholated procedures (ice popsicle and cold lip moisturiser) in the management of intensity of thirst, perception of lip hydration, mouth dryness and bad taste in the mouth, in patients in the postoperative period of bariatric surgeries (Serato et al., 2019). Each patient received the assigned intervention three times, with intervals of 30 min between them. The bundle of mentholated procedures was more effective in reducing intensity of thirst after the first application ($p = .04$), but after the second application, both procedures reduced the intensity and the change from baseline was not statistically significant anymore.

In some of the research presented above, the decrease in the intensity of thirst occurred after the patients received various application of the interventions (Cho et al., 2010; Conchon & Fonseca, 2018; Hur et al., 2009; Yoon & Min, 2011).

The mentholated popsicle has several advantages, including a cool sensation due to the activation of the both the thermoreceptors and the taste buds (Eccles et al., 2013; Leiper, 2005; McCoy et al., 2011), in addition to the low cost and the reduction of the thirst intensity and discomfort. When fasting, halitosis and thick saliva are unpleasant, and therefore, the mentholated popsicle can also help with that. We suggest that more studies to corroborate the efficacy of mentholated popsicle for thirst intensity and discomfort should be done and that it might be important to also evaluate the person's satisfaction with its use.

It is noteworthy that the cost of mentholated popsicle is low. The formulation of 1,200 ml (approximately 40 popsicles) costs about US$10 dollars. Forms to freeze the popsicles, popsicles sticks and appropriate equipment to keep the popsicles refrigerated within the clinical unit added some more expenses to a total of about US$13 dollars for 40 popsicles.

5.1 | Limitations

The main limitation of this randomised controlled trial was the lack of blinding of patients and main investigator (who delivered the interventions and collected the outcome data). It is not possible to create a real placebo for the mentholated popsicle, and it is possible that the lack of blinding could bias the response from an individual. However, we believe this was minimised by explaining to the participants that their ratings would be useful in determining if the popsicle was efficacious and by offering the popsicle to individuals in the absolute fasting group after the outcome data were collected.

A second limitation is that we did not study for how long the decrease in the intensity and discomfort of thirst was maintained in the mentholated popsicle group. It might be interesting to study whether the intervention needs to be repeated and how often to maintain the patient with a sensation of satiety. A third limitation is that the minimal significant change in the outcome scores is not yet known. However, the changes in scores in the mentholated popsicle group were seven points in a 0–10 scale and 5 points in a 0–14 scale, both of which are large in relationship to the total possible scores. Studies on the finding the minimal significant difference for each of the scales should be conducted.

Finally, since this was the first study in patients in the preoperative fasting, we did not study whether the fasting time duration or the use of opioids, for example, could act as mediators or moderators in the effect of the mentholated popsicle. Future studies should include these research questions in their design.

6 | CONCLUSIONS

In the preoperative fasting, the experience of thirst of the surgical patient can be intense, sometimes prolongued, and might generate feelings of suffocation, weakness, desperation, irritation, fear and anxiety. The use of mentholated popsicle decreased the intensity and discomfort with thirst. This knowledge advances perioperative nursing, since there are very few studies on thirst and especially during the preoperative fasting.

For safety, it is recommended that the mentholated popsicle is used only for individuals who are not allergic to components of the formulation and that its ingestion occurs at most 2 hr before the scheduled surgery.

7 | RELEVANCE TO CLINICAL PRACTICE

The results of this randomised controlled trial demonstrated that the use of mentholated popsicle significantly decreases the intensity

and discomfort with thirst in patients in the preoperative fasting. The results of this study might help in the nursing staff in the decision-making procedure of choosing interventions to minimise the patient's thirst and consequently increasing the quality of service by implementing a simple strategy of thirst management.

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CONFLICT OF INTEREST

The authors have no conflict of interest to disclose.

ORCID

Patricia Aroni https://orcid.org/0000-0001-5092-2714
Ligia F. Fonseca https://orcid.org/0000-0001-7550-9141
Marcia A. Ciol https://orcid.org/0000-0001-6406-4706
Amanda S. Margatho https://orcid.org/0000-0002-1006-9357
Cristina M. Galvão https://orcid.org/0000-0002-4141-7107

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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