The RAQET Study: the Effect of Eating a Popsicle Directly After Bariatric Surgery on the Quality of Patient Recovery; a Randomised Controlled Trial

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Abstract Quality of recovery could be influenced positively if there is less postoperative sore throat (POST). Eating a popsicle might attenuate this sore throat. Especially for bariatric surgery, early recovery is important. Adding popsicles to the postoperative protocol could be beneficial. Our hypothesis is that offering a popsicle in the recovery room to patients after bariatric surgery will decrease POST and will increase quality of postoperative recovery. Patients undergoing elective bariatric surgery, between the 23 February 2015 and 3 April, were randomised to either the popsicle group or control group. Primary endpoint was the incidence of POST and secondly if a reduction in POST influences quality of recovery at the first day postoperative measured with the Bariatric Quality Of Recovery (BQoR) questionnaire. One hundred and thirty-three patients were assessed for eligibility. For the final analysis, 44 patients in the intervention and 65 in the control group were available. Eating a popsicle after bariatric surgery had no significant effect on the incidence of POST. Significant effects (in favour of the popsicle group) were seen in muscle pain

score ($p = 0.047$) and sore mouth score ($p = 0.012$). Popsicle intragroup analysis revealed that eating the whole popsicle (compared to partially eating the popsicle) has positive effects on nausea ($p = 0.059$), feeling cold ($p = 0.008$), and mean total comfort score ($p = 0.011$). Of the patients who became nauseous and/or had to vomit because of the popsicle, $n = 4$ had more severe pain ($p = 0.04$) and the mean pain score was higher ($p = 0.09$). The present study demonstrates that offering a popsicle early during recovery after bariatric surgery is feasible without adverse effects, although eating popsicle did not reduce postoperative sore throat. There are possible beneficial effects, such as reduced muscle pains and less sore mouth, that may enhance the quality of recovery. More research is necessary to further substantiate the effect of eating popsicles on the quality of recovery in this patient population. Trial Registration: Registration number: NTR4943 (<http://www.trialregister.nl>).

Keywords Bariatric surgery · Popsicle · Quality of recovery · Postoperative sore throat · RAQET

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Introduction

Enhanced recovery programs focus on perioperative strategies that allow fast recovery and early mobilisation after surgery. These programs improve efficiency and reduce postoperative complications, especially after bariatric surgery. Our research group and also others showed that a fast-track approach in the bariatric patient population is safe and efficient [1–5].

An extension to this fast-track approach could be improving direct postoperative well-being. The quality of recovery is influenced by several factors including a sore throat, so-called postoperative sore throat (POST). POST is a common complaint after various types of surgery, with the highest incidence

in patients who have undergone tracheal intubation (ranging between 30 and 70 %) [6, 7].

In the last few years, several studies investigated strategies to reduce POST after surgery using different agents with positive effects: administration of topical tenoxicam [8] and gargling of aspirin and benzydamine [9], ketamine [10], sodium azulene sulfonate [11] and licorice [12]. However, these agents can have possible negative side effects. In this case, the use of a popsicle can be a feasible alternative. The use of popsicles for pain relief after tonsillectomy is well known and without significant side effects [13]. A possible mechanism for pain relief lies in activation of nociceptors in the upper airway and gastrointestinal tract [13].

In this study, we aimed to investigate the effects of eating a popsicle on POST and secondly on the quality of recovery after bariatric surgery, with hypothesis that offering a popsicle in the recovery room to patients after bariatric surgery will decrease POST and will increase quality of postoperative recovery.

Methods

The protocol of this single-blinded randomised clinical trial was approved by the Medical Ethics Committee of the Catharina Hospital in Eindhoven in the Netherlands and was designed in accordance to the Declaration of Helsinki and the principles of Good Clinical Practice. Patients were informed about the purpose of the study, and informed consent was obtained prior to inclusion. The trial was registered at The Netherlands National Trial Register (NTR, www.trialregister.nl) under trial number (NTR4943). The study was performed according to the Consolidated Standards Of Reporting Trials (CONSORT) guidelines.

Patients

Patients aged 18 years and older undergoing elective primary or revisional bariatric surgery at the Catharina Hospital Eindhoven were eligible to participate in this study. Patients with unstable vital signs after surgery, patients who were admitted for re-operation (due to life-threatening complications) within 1 week and patients undergoing adjustable gastric band removal (without an additional bariatric procedure) were excluded. Patients with a history of perioperative nausea and vomiting (PONV) and/or motion sickness and/or problems with the menstrual cycle were excluded from this study.

Intervention

Patients in the intervention group were asked postoperatively if they would like to have a popsicle (Ola® Raket, Unilever Foods, Rotterdam, The Netherlands). The popsicle was offered to patients 1 h after surgery. The recovery nursing staff

documented whether patients had eaten the whole popsicle or just a part of it and whether there were any complaints after eating the popsicle. These complaints were defined as nausea and/or vomiting.

Patients assigned to the control group did receive sips of water postoperatively. All bariatric procedures were standardised, and perioperative care was conducted according to fast-track care protocol, which has been previously described [2, 14].

Ola® Raket Popsicle

The Ola® Raket (Unilever Foods, Rotterdam, The Netherlands) is a flavoured ice based on water and syrup. Exact ingredients are water, sugar, glucose-fructose syrup, citric acid, stabiliser (locust bean gum), pigment (based on sweet pepper) and concentrated red beet juice.

Randomization

Patients provided informed consent before surgery and were randomly assigned to either the intervention or control group (using a cluster randomisation approach). Patients scheduled for bariatric surgery in ‘even’ weeks were assigned to the intervention group, and patients scheduled in the ‘odd’ weeks were assigned to the control group, due to the use fixed teams in the operating rooms in our hospital [14]. The anaesthesiologist, surgeon, the staff of the operating rooms and the outcome assessors (authors SP, PS, MB, RAB, SN) were blinded during the inclusion period. After completing the inclusion for this study, only author SP was de-blinded for the purpose of data analysis.

Outcomes

Our primary endpoint was the incidence of POST and secondly quality of recovery. This item was answered on a five-point Likert scale (5 = ‘none of the time’ to 1 = ‘all the time’).

Bariatric Quality of Recovery Questionnaire

To measure the effect of eating a popsicle postoperatively, the Bariatric Quality of Recovery (BQoR) questionnaire was used. The BQoR questionnaire items are based on the Quality of Recovery-40 (QoR-40) originally developed by Myles et al. [15], omitting items that are not suitable for the bariatric patient population. Each item was answered on a five-point Likert scale, ranging from none of the time to all the time. In total, the BQoR questionnaire is divided in three domains: physical comfort, emotional state and pain. For each domain, the score was defined as the sum of all the scores of all items. The items referred to the past 24 h and aimed at patients during hospital stay.

On the morning after surgery (just before they were discharged from the hospital), the patients in the control and study groups were asked by the bariatric nurse to fill in the questionnaire.

Statistical Analysis

The sample size was calculated using a power analysis including POST [8–12].

Our presumption was that eating of a popsicle gave a mean calculated reduction of 20 % the incidence of POST, based on previous literature [8–12]. Using a two-sided 5 % significance level and a power of 90 % [16], power analysis indicated a sample of 43 patients. Accounting for a dropout rate of 30 % inclusion of 65 patients per group was needed.

The distribution of continuous data was tested using skewness and kurtosis. In case of a normal distribution, variables were analysed with an unpaired Student's *t* test. Otherwise, the Mann-Whitney *U* test was used. Categorical data were analysed with a chi-square test. $P \leq 0.05$ was considered statistically significant. Statistical Package for Social Sciences (SPSS, Chicago, IL, USA Version 20.0) was used to prepare the database and for statistical analysis. The data analysis will be performed according to an 'intention to treat' and a 'per protocol' approach. For the analysis of the effect of eating a

popsicle, only the patients who have eaten the popsicle in total or partially will be used.

Results

From 23 February 2015 to 3 April, 133 patients were assessed for eligibility. Three patients were excluded because they only had gastric band removal without an additional bariatric surgical procedure. In total, 65 patients were randomised to the intervention group and 65 to the control group. Of the patients allocated to intervention, 15 patients refused to eat the popsicle postoperatively (because of nausea, vomiting or they did not want it after surgery), 1 patient was excluded during surgery (because of a major diaphragmatic hernia present and therefore no bariatric surgical procedure was performed) and 5 did not fill in the BQoR questionnaire. For the final analysis, 44 patients (68 %) in the intervention group and 65 patients (100 %) in the control group were available. Forty-four patients completed the study in the popsicle group and 65 in the control group (Fig. 1). Patient characteristics, anthropometric variables, comorbidities and operative details can be found in Table 1.

The intention to treat analysis revealed no significant differences between the popsicle group and the control group, in terms of baseline characteristics and effects of the popsicle on the BQoR. Therefore, a per protocol analysis was conducted.

Fig. 1 CONSORT diagram for the study

Table 1 Baseline characteristics

	Popsicle group (n = 44)	Control group (n = 65)	p value
Age (in years)	43 ± 10	45 ± 11	0.307
Gender			
Male	10 (22.7 %)	13 (20.0 %)	0.812
Female	34 (77.3 %)	52 (80.0 %)	0.812
Weight (in kg)	128 ± 15	124 ± 26	0.593
Height (in cm)	170 ± 9	169 ± 8	0.361
Body mass index (in kg/m ²)	42 ± 6	42 ± 6	0.897
Comorbidities			
Diabetes mellitus	5 (11.4 %)	11 (16.9 %)	0.421
OSAS	7 (15.9 %)	8 (12.3 %)	0.592
Hypertension	19 (43.2 %)	32 (49.2 %)	0.535
Osteoarthritis	14 (31.8 %)	16 (24.6 %)	0.409
Dyslipidaemia	6 (13.6 %)	15 (23.1 %)	0.220
GERD	15 (34.1 %)	23 (35.4 %)	0.843
Smoking status			
Still smoking	6 (13.6 %)	8 (12.3 %)	0.965
Stopped smoking	16 (36.4 %)	23 (35.4 %)	0.965
Never smoked	22 (50.0 %)	34 (52.3 %)	0.965
Mean packed years	14.14 ± 10.64	19.34 ± 14.84	0.169
Surgery			
Primary			
SG	36 (81.9 %)	56 (86.2 %)	0.596
RYGB	16 (36.4 %)	33 (50.8 %)	0.601
RYGB	20 (45.5 %)	23 (35.4 %)	0.601
Revision			
SG → MGB	8 (18.1 %)	9 (13.8 %)	0.596
SG → MGB	1 (2.3 %)	1 (1.5 %)	0.601
AGB → RYGB	3 (6.8 %)	3 (4.6 %)	0.601
AGB → MGB	0	2 (3.1 %)	0.601
SG → RYGB	2 (4.5 %)	2 (3.1 %)	0.601
VBG → RYGB	2 (4.5 %)	1 (1.5 %)	0.601

SG sleeve gastrectomy, RYGB Roux en Y gastric bypass, MGB mini gastric bypass, AGB adjustable gastric band, VBG vertical banded gastroplasty

Incidence of POST

In the popsicle group, of the 44 patients, 17 patients (38.6 %) had a form of POST ranging from sometimes to all the time (scores 4 to 1, according to the BQoR questionnaire) (Table 2). In the control group, of the 65 patients, 19 patients (29.2 %) had a form of POST. There was no significant effect found in eating a popsicle on the incidence of POST (0.299).

Effect of Eating a Popsicle Compared with the Control Group

Table 3 gives an overview of the BQoR scores to assess the effect of eating a popsicle. Significant effects were

found on muscle pain score ($p = 0.047$) and sore mouth ($p = 0.012$) in favour of the popsicle group. The mean total scores per domain (physical comfort, emotional state and pain) were not significantly different between the groups (p values respectively 0.819 0.628 and 0.066).

Popsicle Intragroup Analysis

Of the 44 patients in the popsicle group, 20 patients (45.5 %) ate the whole popsicle and 24 patients (54.5 %) ate the popsicle partially. In this group, eating the popsicle in total was associated with less nausea ($p = 0.059$) and less feeling cold ($p = 0.008$) and the mean total comfort score was higher (27.86 versus 18.06; $p = 0.011$).

Of the 44 patients, 4 patients (3.7 %) had complaints after eating the popsicle (became nauseous and/or had to vomit). These complaints were associated with more severe pain ($p = 0.04$) and a higher mean total pain score (33.00 versus 21.45 (in the group without complaints); $p = 0.09$).

Discussion

This study shows that offering a popsicle early during recovery after bariatric surgery is feasible for most patients without adverse effects. However, eating the popsicle did not reduce the incidence of POST, but patients in the popsicle group experienced less muscle pains and complaints of a sore mouth. Patients eating the whole popsicle had less nausea, felt less cold and were more comfortable compared to patients partially eating the popsicle.

Incidence of POST

POST is a common complaint after various types of surgery, with the highest incidence in patients who have undergone tracheal intubation (ranging between 30 and 70 %) [6]. This wide variation in incidence rates is presumably due to skills and techniques among anaesthesiologists and different

Table 2 Severity of POST (1 day postoperative) in popsicle group and control group

Severity	Popsicle group (n = 44) ^a	Control group (n = 65) ^a
1	2 (4.5 %)	2 (3.1 %)
2	3 (6.8 %)	3 (4.6 %)
3	2 (4.5 %)	2 (3.1 %)
4	10 (22.8 %)	12 (18.4 %)
5	27 (61.4 %)	46 (70.8 %)

5 = none of the time, 4 = small part of the time, 3 = intermittent part of the time, 2 = moderate part of the time, 1 = all the time [15]

^a No significant difference between both groups ($p = 0.299$)

Table 3 The Bariatric Quality of Recovery scores to assess the effect of eating a popsicle after bariatric surgery between the intervention and control group

Mean scores	Popsicle group (n = 44)	Control group (n = 65)	p value
Physical comfort			
Nausea	3.41 ± 1.28	3.35 ± 1.30	0.139
Vomiting	4.43 ± 0.87	4.34 ± 1.04	0.324
Dry retching	4.59 ± 0.90	4.38 ± 1.16	0.548
Feeling restless	4.32 ± 1.11	4.42 ± 1.01	0.271
Shaking or twitching	4.39 ± 1.06	4.52 ± 0.92	0.359
Shivering	4.45 ± 1.11	4.43 ± 1.10	0.846
Feeling too cold	4.36 ± 0.97	4.28 ± 1.15	0.446
Feeling dizzy	3.82 ± 1.21	3.63 ± 1.23	0.232
Mean total score	29.95 ± 4.35	29.72 ± 4.61	0.819
Emotional state			
Bad dreams	4.93 ± 0.33	4.89 ± 0.53	0.895
Feeling anxious	4.75 ± 0.62	4.86 ± 0.39	0.971
Feeling angry	4.93 ± 0.26	4.95 ± 0.28	0.819
Feeling depressive	4.95 ± 0.21	4.92 ± 0.44	0.966
Feeling alone	4.80 ± 0.63	4.89 ± 0.44	0.758
Difficulty falling asleep	3.86 ± 1.39	3.94 ± 1.36	0.604
Mean total score	28.23 ± 2.01	28.46 ± 2.02	0.628
Pain			
Moderate pain	3.16 ± 1.03	3.18 ± 1.09	0.136
Severe pain	3.91 ± 1.16	3.95 ± 1.21	0.375
Headache	4.36 ± 0.92	4.42 ± 1.01	0.874
Muscle pains	4.03 ± 1.24	4.00 ± 0.99	0.047*
Backache	4.52 ± 1.00	4.35 ± 1.12	0.918
Sore throat	4.30 ± 1.13	4.49 ± 0.99	0.299
Sore mouth	4.89 ± 0.44	4.68 ± 0.88	0.012*
Mean total score	29.32 ± 4.16	28.93 ± 3.90	0.066

Values are mean ± SD

*p values < 0.05 are considered significant

definitions of POST [7]. On the other hand, the way of questioning patients is also an important factor. A study by Harding and colleagues [17] found that after indirect questioning of 129 patients, only two complained of POST, and after direct questioning of 113 patients, the incidence of POST was significantly higher (28 patients complained of sore throat) [7, 17]. POST can be a consequence of localised trauma, leading to inflammation of the pharyngeal mucosa secondary to either laryngoscopy or tracheal intubation or as a result of both [7, 9].

Physiological Mechanisms

As mentioned earlier, the use of popsicles for pain relief after tonsillectomy is well known [13], and the physiological mechanism may also apply for POST. It is postulated by others that

‘ice therapy’ may have influence on the activity of the upper airway and gastrointestinal tract [13, 18, 19]. Transient receptor potential ion channel vanilloid (TRPV) receptors are modulators of pain sensation, of which TRPV1 is responsible for the upper airway [18]. Activation of TRPV1 can be induced by capsaicin, by temperatures above 43 °C and by inflammatory mediators (induced by intubation) [19]. Ice therapy by lowering throat temperature may decrease the activity of TRPV1 and thus reduce POST. Transient Receptor Potential Melastin 8 (TRPM8) is a menthol receptor that evokes a cool sensation when activated by temperatures below 25 °C [18, 19]. The activation of TRPM8 has been shown to elicit analgesia in several different pain models [19]. Therefore, we think these mechanisms may be also applicable for the results of our study, in both the central and peripheral analgesic effects of eating a popsicle. Whether these mechanisms explain the differences found between eating the whole popsicle and eating it partially and thus if there is a dose-response mechanism of activation of TRPM8 and TRPV1 receptors is unknown.

Strategies to Reduce the Incidence of POST After Surgery

Recently, several studies investigated strategies to reduce POST after elective surgery. Agarwal et al. [12] investigated the effect of licorice gargle on POST in patients undergoing elective lumbar laminectomy (in a prospective randomised trial). They investigated the effect at rest and while swallowing at different postoperative time points (2, 4 and 24 h postoperatively). They found that licorice gargling reduced POST compared to the control group (who gargled with water) for all time points, except at rest at 24 h. There were no side effects in either group [12]. Ogata and colleagues [11] determined that preoperative gargling with azunol (4 mg in 100 ml water) gives a reduction of the incidence of POST from 65 to 25 %. Canbay et al. [10] reported similar results in patients gargling with a ketamine solution before induction of anaesthesia. They showed that gargling with 40 mg of 30 ml saline mixture significantly reduces the incidence of POST from 78 to 40 % [10]. In another study by Agarwal and colleagues [9], they showed that aspirin and benzydamine hydrochloride gargle made in 30 ml of water performed after patients’ arrival in the operating room for 30 s was equally effective in reducing POST (80 to 26 %, $p < 0.05$). We found no significant effect on POST in our study, which can be explained by two factors. First, we used a different method to measure the effect of our intervention compared to the previously mentioned studies [9–12]. Secondly, previous studies all used soluble agents (solutions of aspirin and benzydamine [9], licorice [12], ketamine [10] azunol [11]) where we used a solid agent (a popsicle) in our study. On the other hand, we investigated the effect of eating a popsicle in a much broader perspective by using our Bariatric Quality

of Recovery questionnaire, and one of our findings was that eating a popsicle significantly reduces the severity of a sore mouth ($p = 0.012$) after bariatric surgery.

Interesting findings of our study were that compared to the control group, the popsicle group had a lower muscle pain score and a better mean total pain score. Secondly, we found that eating the popsicle in total was associated with less feeling cold, less nausea and a higher mean total comfort score. However, whether these observations are explained by eating the popsicle or whether patients accepting it postoperative felt better cannot be distilled from the data.

Limitations

The present study could not be performed in a double-blind fashion, because patients could not be blinded for the sweet taste of the popsicle. Also, for obvious reasons, patients could not be forced to eat a popsicle in the postoperative period and patients were allowed to refuse the offered popsicle, which could have biased the present results. This makes an intention to treat analysis difficult to perform and to interpret. Therefore, we analysed our data according to a per protocol approach, which showed significant differences between the intervention group, but this may give selection bias. This is because patients who have declined the popsicle may have been more or less likely to have POST than the patients who accepted the popsicle.

Secondly, our Bariatric Quality of Recovery questionnaire is not officially validated, which may potentially give bias in the results. But on the other hand, there is no validated questionnaire available in current literature to assess the quality of recovery after bariatric surgery. Thirdly, we only assessed POST on the first day after bariatric surgery and not prior to eating of the popsicle.

Conclusion

The present study demonstrates that offering a popsicle early during recovery after bariatric surgery is feasible without adverse effects, although eating the popsicle did not reduce postoperative sore throat. There are possible beneficial effects, such as reduced muscle pains and less sore mouth, that may enhance the quality of recovery. More research is necessary to further substantiate the effect of eating a popsicle on the quality of recovery in the bariatric patient population.

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Authors' Contributions *Initial idea:* PS
Design of the study: SP, PS, MB, RAB, SN

Data analysis: SP, PS, MB, RAB, SN

Drafting and finalising manuscript: SP, PS, MB, RAB, SN

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

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Research Involving Human Participants/Animals The protocol of this single-blinded randomised clinical trial was approved by the Medical Ethics Committee of the Catharina Hospital in Eindhoven in the Netherlands and was designed in accordance to the Declaration of Helsinki and the principles of Good Clinical Practice.

Informed Consent Patients were informed about the purpose of the study, and informed consent was obtained prior to inclusion.

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