STUDY PROTOCOL

1. **Date: 01.01.2023**
2. **Official Title:**

   THE EFFECT OF A NEWLY FORMULATED PREOPERATIVE ORAL CARBONHYDRATE SOLUTION ON GASTRIC EMPTYING, POSTOPERATIVE NAUSEA AND VOMITING AND STRESS RESPONSE

3. **Method:**

109 patients who underwent elective laparoscopic cholecystectomy, aged 18-65 years and ASA physical state 1-2 were included in the study. The patients were divided into 3 groups: Group A, who would not eat anything 6-8 hours before the operation, Group S, who drank 400 ml of water 2 hours before the operation, and Group K, which drank 400 ml preoperative oral carbohydrate solution (PreOKH) 2 hours before the operation. Before induction of anesthesia (T1), patients antral gastric cross-sectional area (GKA) and gastric volume (GV) were evaluated by gastric ultrasound. The preoperative anxiety level of the patients was determined by the State-Trait Anxiety Inventory (STAI) before the operation (T1), and the symptoms affecting the preoperative patient comfort parameters (thirst, hunger, dry mouth, fatigue) were measured 2 hours before the operation (T0) and before the induction (T1) evaluated with the visual analog scale (VAS). Postoperative nausea and vomiting (PONV) and postoperative pain levels were recorded. Blood glucose, insulin and cortisol levels of the patients were measured 2 hours before the operation (T0), before induction (T1) and postoperative 2nd hour (T3).

Descriptive statistics of qualitative variables in the study will be given as number and percentage, and descriptive statistics of quantitative variables will be given as mean, median, standard deviation, minimum and maximum. Pearson chi-square and Fisher's exact chi-square tests will be used to compare the distribution of the relevant variables between the groups. The conformity of quantitative variables to normal distribution will be examined by Shapiro Wilk test. For normally distributed variables, one-way analysis of variance will be used to compare the means of more than two groups. Tukey test will be used as a posthoc test for pairwise comparisons. For non-normally distributed variables, Kruskall Wallis test will be used in the mean comparison of more than two groups and pairwise comparisons will be examined with Dunn test. Paired t test will be used for the mean comparison of two dependent groups and Wilcoxon signed-rank test will be used for median comparisons. Repeated measures analysis of variance method will be used for mean comparisons of more than two dependent groups and Friedman test will be used for median comparisons. Statistical significance level will be taken as 0.05 and SPSS (Version 28) package program will be used for calculations. For the gastric volume value, at the 95% confidence level, when the significance of a mean difference of 18.18 with 80% power is attributed (means 67.22 and 49.04 with standard deviations 29.49 and 15.4), a minimum of 28 people should be included in the study in each group. [1] Therefore, we planned the number of patients in the study groups as 30 for each group.1

Inclusion Criteria:

1. Between the ages of 18-65
2. Elective laparoscopic cholecystectomy planned under general anesthesia
3. American Society of Anesthesiologists (ASA) class I-II physical condition

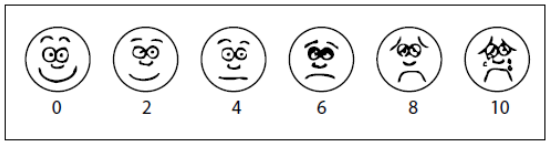
Exclusion Criteria:

1. Patients with gastroesophageal reflux and gastrointestinal motility disorders
2. diabetes mellitus
3. Mental retardation, previous neurological disease symptoms (syncope, dementia, alzheimer etc.)
4. Chronic alcoholism
5. Difficult Intubation
6. Patients with ASA physical status classes ≥III
7. Patients with a body mass index of 35 and above
8. History of meniere and motion sickness
9. Presence of previous history of postoperative nausea and vomiting
10. Smoking

Numerik Rank Score:

0: no vomiting or nausea
1: nausea
2:nausea and once vomiting
3:twice or more vomiting

VAS:



Qualitative evaluation of the antrum with gastric USG:
Grade 0: empty antrum both in the semi-sitting position and in the RLDP
Grade 1: gastric fluid is only visible in RLDP;
Grade 2: gastric fluid can be seen both in the semi-sitting position and in RLDP

	Factor Loading		
Item	I	II	h^2
1. I feel calm	.50	-.21	.41
2. I feel secure	.61	-.10	.45
3. I am tense	.01	.63	.39
4. I am strained	.05	.59	.32
5. I feel at ease	.59	-.05	.38
6. I feel upset	.03	.78	.58
7. I am presently worrying	-.01	.57	.33
8. I feel satisfied	.57	-.10	.39
9. I feel frightened	-.03	.69	.50
10. I feel comfortable	.59	-.19	.51
11. I feel self-confident	.70	.04	.46
12. I feel nervous	.05	.76	.54
13. I feel jittery	.01	.73	.52
14. I feel indecisive	-.09	.55	.37
15. I am relaxed	.58	-.10	.41
16. I feel content	.62	.06	.35
17. I am worried	.12	.79	.54
18. I feel confused	-.10	.62	.45
19. I feel steady	.69	-.01	.47
20. I feel pleasant	.68	.05	.43
21. I feel pleasant	.64	.02	.40
22. I tire nervous and restless	-.32	.44	.44
23. I feel satisfied with myself	.79	.09	.56
24. I wish I could be as happy as others seem	-.20	.23	.14
25. I feel like a failure	-.48	.15	.32
26. I feel rested	.61	.09	.33
27. I am calm, cool, and collected	.67	.03	.43
28. I feel that difficulties are piling...	-.34	.38	.39
29. I worry too much over something...	-.06	.37	.16
30. I am happy	.70	-.05	.52
31. I am inclined to take things hard	-.20	.38	.27
32. I lack self-confidence	-.38	.17	.25
33. I have disturbing thoughts	.78	.03	.59
34. I make decisions easily	.50	.02	.27
35. I feel inadequate	-.38	.21	.27
36. I am content	.70	-.07	.55
37. Some unimportant thought runs...	-.10	.34	.16
38. I take disappointments so keenly...	-.26	.28	.22
39. I am a steady person	.52	-.08	.32
40. I get in a state of tension or turmoil...	-.38	.30	.35

Note. Interfactor correlation = -0.52. Factor loadings are standardized regression coeff

FOLLOW-UP FORM

No:		Duration of operation	
Age-gender		Fasting time	
BMI		Anesthetic agent consumption	Sevoflurane:
GRUP			Remifentanil:
ASA		complications:	
disease		Antiemetic need :	

Gastric examination

Gastrik USG – measurement of CSA in RLPD (CSA = (LD × SD × π)/4)	LD:	SD:	CSA:
Gastric volume (GV = 27,0 + 14,6 × CSA (RLDP'de) − 1,28 × age)			
Qualitative evaluation score			
Gastiric volume (aspiration of ngs)			
Gastric pH			

İntraoperative vital sing

	HR	**SP/DP**	**MAP**	**SpO_2**	**BİS**
Before induction					
İnd +1. min					
10.min					
20. min					
30. min					
40. min					
50. min					
60. min					
Before extubation					
After extubation					

PACU 1. min					
PACU 15.min					

	STAI	**VAS**	**PONK**	**Glucose**	**Insulin**	**cortisole**
Preop 2. hours						
Berofe induction						
PACU						
Postop 2. hours						
Postop 12. hours						
discharge						

Koordinatör: Prof. Dr. Kazım Karaaslan

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References

1) Zhang Z, Wang RK, Duan B, Cheng ZG, Wang E, Guo QL, Luo H. Effects of a Preoperative Carbohydrate-Rich Drink Before Ambulatory Surgery: A Randomized Controlled, Double-Blinded Study. Med Sci Monit. 2020 Aug 28;26:e922837. doi: 10.12659/MSM.922837