Preoperative Nutrition and Postoperative Discomfort in an ERAS Setting: A Randomized Study in Gastric Bypass Surgery.

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Preoperative nutrition and postoperative discomfort in an ERAS setting: A randomized study in Gastric bypass surgery.

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Abstract:

Background: Many patients experience postoperative nausea and vomiting (PONV). Preoperative treatment with carbohydrate solutions seems to improve the course after different types of surgery. This study was undertaken to investigate the potential value of different models for preoperative hydration/nutrition, in addition to our ERAS (enhanced recovery after surgery) protocol.

Patients and Methods: Ninety non-diabetic women planned for elective laparoscopic gastric bypass and aged 18-65 years were included. All were on preoperative low-calorie diet (LCD). They were randomized into three arms, either a carbohydrate-rich drink, a protein-enriched drink or tap water and instructed to drink 800 and 200 mL 16 and 2 hours respectively prior to operation.

Risk factors for PONV were recorded preoperatively. All patients were operated before lunch and received 1500-2000 mL Ringer-Acetate solution during the 24-30 hours postoperative hospital time. Four variables (nausea, pain, tiredness, and headache) were registered on 100 mm visual analogue scales six times over 22 hours. The need for additional medication was registered.

Results: Out of 90 patients, 73 complete datasets were obtained. Nausea peaked at 7 p.m. but with no statistically significant differences between groups for any of the variables. Pain peaked the first 2h postoperatively, remained longer and had not returned to base-line values at 6 a.m. the morning after surgery, but with no difference between groups.

Conclusion: Inside our ERAS protocol, additional preoperative carbohydrate- or protein enriched fluid treatment did not further reduce immediate patient discomfort in laparoscopic gastric bypass surgery.

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Background:

The Enhanced Recovery after Surgery (ERAS) protocol often involves carbohydrate nutrition (CH) preoperatively. Such treatment might attenuate postoperative insulin resistance but possible effects on postoperative well-being have not been clearly established. Preoperative CH has been used with success in gallbladder surgery [1] and in several different types of surgery, as recently reviewed by the Cochrane collaboration [2]. Also bariatric surgery has been the subject of such studies [3]. However, these and other studies look for long term effects, or length of stay [4].

Aleris Obesity specializes in bariatric surgery, doing close to 2000 procedures per year. Our fast-track model includes a completely standardized surgery, anesthesia, and postoperative care with ERAS protocol central in our treatment since year 2009. This has led to a mean hospital time of 1.08 days, with 96 % of patients being able to be discharged home on the first postoperative day [5]. The present study was aimed at examining whether further modifications to our protocol could reduce patient-experienced discomfort after laparoscopic Roux-Y gastric bypass (RYGB) during the first postoperative 24 hours, i.e. until discharge from hospital.

The study was approved by the Institutional Review board and the Lund University ethics committee, and financed by Aleris research funds. Patients were informed according to protocol and consented to participation in writing.

Patients and Methods:

Consecutive female patients were recruited after informed consent from the lists for elective RYGB at Aleris Obesity. Randomization was performed using closed envelopes in blocks of 6. We included only patients with a BMI < 48, because of a different ongoing study on

superobesity running in parallel at our clinic. Patient demographics are given in table 1. An overview of treatment arms is given in Table 2. Plain water was one control substance (negative control), an equicaloric protein liquid was another control (positive control).

A pilot study had previously been performed. Based on the results from that study, we chose to power this study to pick up clinically significant differences of >10 VAS units. To reduce inter-individual differences, only non-diabetic female patients were included. There were three different arms, CH-rich, protein-enriched or plain water (Table 2). Identical patient information to all groups was both verbal and in writing, and signed consent forms were obtained. Liquids were consumed in the patient's home before coming to hospital; no flavor was added in order to enable a comparison between groups for patient compliance.

In the study, altogether 90 patients were originally enrolled. But in four cases time of surgery was changed to an afternoon session. Another 13 patients dropped out of the final analysis for not having consumed their liquids according to protocol (2 water, 7 protein, 4 CH solution). The drop-out rate did not differ between groups (p=0.2821). The analysis is thus based on 73 patients with complete data sets.

Collected variables: In the present study, information on risk factors for postoperative nausea were collected (smoking, previous PONV), and patients' discomfort was assessed using 100 mm visual analogue scales (0=no discomfort; 100 mm=worst imaginable). Measured variables were abdominal pain, nausea, tiredness and headache. Base-line values were obtained 30-60 minutes before anesthesia. Follow-up values were obtained on arrival to the recovery room, 2 and 4 hours later and at 7 p.m., i.e. 6-8 hours postoperatively. Final assessment was the following morning at 6 a.m.

Routine and on-demand medication before operation: The pre- and perioperative drug treatment was made identical by strict adherence to our ERAS protocol. Surgeons, anesthesia staff and ward nurses were blinded to which regimen had been given. All patients were

routinely given 2 g acetaminophen p.o. (Alvedon®, GlaxoSmithKline), 8 mg betamethasone i.v. (Betapred®, SOBI), and 120 mg etoricoxib p.o. (Arcoxia®, MSD) preoperatively.

Surgical procedure and anesthesia: Patients were operated between 8 a.m. and 11:30 a.m. All patients had identical anesthetic technique, with propofol (Propofol®, Lipura, Sweden) and remifentanil (Fentanyl®, Meda, Sweden) in a target controlled infusion, as previously described [6]. The only modification to that protocol was the exclusion of anesthesia gases, but maintaining propofol infusion until three minutes before completion of surgery. At the end of the surgery, 10 mg ketobemidon (Ketogan®, Pfizer) was given i.v., clonidine 22.5 mg i.v. (Catapresan®, Boehringer Ingelheim, Ingelheim am Rhein, Germany) and atracurium 20 mg i.v. (Atracurium-hameln®, Algol Pharma, Kista, Sweden).

A standard Roux-Y gastric bypass with a small, completely separated pouch, a 60 cm biliopancreatic limb and a 150 cm ante-colic, ante-gastric alimentary limb was performed in all patients as previously described [7] using 18 mm Hg intraabdominal pressure during the procedure. No additional procedures, such as cholecystectomy, were performed.

Routine and on-demand medication after operation: All patients were allowed sipping liquids immediately after surgery. In addition they received 1500-2000 mL Ringer's solution over an 18-20 hour time period. Patients spent two hours in the recovery room (RR), where they usually received injections of 0.5-1 mg alfentanil (Rapifen®, Jansen Pharmaceuticals, Sollentuna, Sweden) and 0.5 mg droperidol (Dridol®, Prostrakan AB, Kista, Sweden). Patients were then transferred to the ward. There they received 1 g acetaminophen p.o. (Alvedon®, GlaxoSmithKline) every six hours, and an injection of 10 mg of oxycodone (Oxycontin®, Mundifarma AB, Göteborg, Sweden) at 8 p.m. on the day of operation.

Supplementary medication: If patients scored > 30 for nausea or pain, additional medication was offered. For nausea it was 0.5 mg droperidol i.v. or ondansetron 2 mg i.v.

(Ondansetron®, B Braun), and for pain 10 mg ketobemidon. All such additional medication was recorded, if administered.

Statistics: All data are presented as mean (SE). Differences between groups were calculated using Fisher's exact test or the unpaired Student's T-test using Winstat for Excel® (Kalmia, NY, USA); differences with a p-value < 0.05 were considered significant.

Results

In the study 90 patients were initially included after consent. In the drop-out analysis four patients were found to have changed their operation time to the afternoon session. Another 13 patients had not complied with the protocol for oral intake, 2 in the water arm, 7 in the protein-enriched arm and 4 in the CH arm. This drop-out rate was not different between groups (p=0.2821).

For the 73 participating patients, all operations were completed laparoscopically and no aspiration at intubation recorded. Mean operative time was short and consistent (Table 2). All patients had uneventful recoveries and were discharged to their homes the day after surgery; no patient was readmitted. The prevalence of risk factors for PONV did not differ between groups (data not shown). The need for additional injections of medication (mean (SE)) outside of our routine protocol was 2.3 (0.2) injections for pain, and 1.7 (0.1) for nausea with no significant differences between groups for either variable.

Patient scoring of nausea peaked about 8 hours after surgery (Fig 1), with no differences between groups; the difference between CH-treated vs. protein-treated yielded p=0.2046 and for CH vs. water p= 0.8722. Nausea disappeared overnight and was not different from preoperative values at 6 a.m. on the first postoperative morning. For pain score, the peak values were noted on arrival to the recovery room, remained steady after 2h until 7 p.m. and then diminished somewhat but did not disappear overnight (Fig 2). There were no differences between groups neither in pain score, nor for headache (Fig 3; p=0.1569).

Discussion:

Enhanced Recovery after Surgery (ERAS) protocols often involve carbohydrate nutrition preoperatively. Such treatment has been used with success in several different types of surgery, as recently reviewed by the Cochrane collaboration [2). Also bariatric surgery has been the subject of such studies [3]. The relationship between a preoperative catabolic state and the risk for postoperative nausea has however been refuted [8], as well as any increased risk for short-term complications in gastric surgery [9].

Important reasons for using an ERAS protocol are that nausea and pain prevents patients from mobilization and early return to oral alimentation, for early discharge [10]. However, most studies look for long term effects, or length of stay [4], and not the immediate discomfort that may interfere with early discharge from hospital. Hausel and coworkers [1] investigated in a randomized trial the short term effect (12-24 h) on PONV. They found a beneficial effect from preoperatively administered CH, in gall bladder surgery. Our existing ERAS protocol has already given us short hospital times, as evidenced in the annual publication from the Scandinavian registry [5]. We wanted to study whether further modifications to our protocol would benefit patients in the form of reduced discomfort. Since our surgeons and nursing staff have long time ago passed the learning curve, we work in a situation favorable to evaluating development of an ERAS protocol.

In high-volume surgery such as gastric bypass, there are advantages with preoperative weight loss in order to facilitate the operation [11], and our patients had been on a three-week very low calorie diet (VLCD) before the operation. We examined the effect of three different modalities for preoperative nutrition on the short term outcome of patient-rated problems, such as nausea and pain. These factors are critical to early mobilization of patients and to early discharge [10]. The visual analogue score has been used for patient assessment in similar settings [1]. The present study showed that neither CH, protein-fat or just volume

administration orally in the present setting influenced any of the variables measured postoperatively. Our findings support the view that patients undergoing surgery with short operating times and inside an established ERAS program do not benefit from extra preoperative alimentation. This finding underlines the observation that RYGB can be performed with minor discomfort to patients. This is despite the fact that RYGB is a more complex operation than cholecystectomy, with transection of the gut and possibly more gut-brain interaction. This view is also supported by the fact that all patients could be discharged the following day, without any readmissions.

This study was approved by the Institutional review board and the Lund University Ethics committee, and performed after informed consent by all participants according to the principles of the Helsinki declaration.

Anne Karlsson reports no conflict of interest
Karin Wendel reports no conflict of interest
Sofia Polits reports no conflict of interest
Hjörtur Gislason reports no conflict of interest
Jan L. Hedenbro reports no conflict of interest

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Table 1: Patient demographics. Values given are mean (SE).

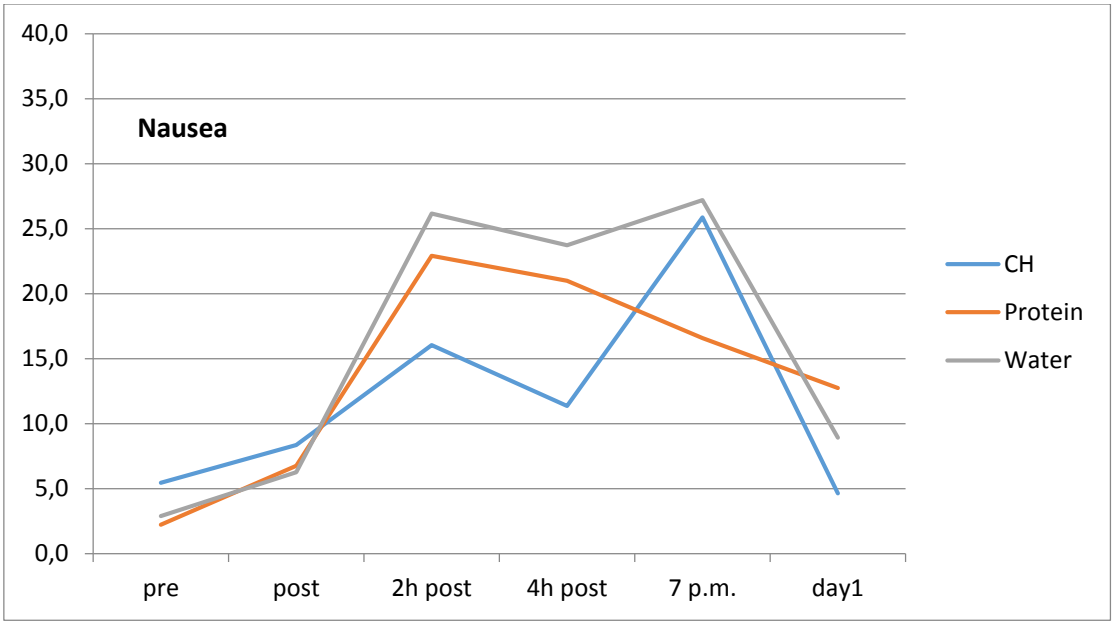
	Age (years)	**Male/Female**	**BMI (kg/m^2)**	**Operating time (mins)**
Group 1: CH-rich; n=25	40.0 (2.0)	0/25	38.0 (0.8)	34 (3.3)
Group 2: Protein-enriched; n=22	41.1 (1.8)	0/22	37.4 (0.8)	33 (2.9)
Group 3: water; n=26	43.7 (1.7)	0/26	37.1 (0.7)	35 (3.0)

Table 2: Oral intake (in grams) prescribed for the different arms.

	Volume ingested	**Total CH content**	**Total protein content**	**Total fat content**
CH-rich n=25 Preop®, Nutricia;	800 + 400 ml	151 g	0 g	0
Protein-enriched n=22; Atkins nutritionals, Denver, CO, USA	800 + 400 ml	8.4 g	55.2 g	33.6 g
Water n=26	800 + 400 ml	0	0	0

Figure 1:

VAS score (mm VA scale), showing levels of nausea for the three groups of patients. No statistically significant differences between groups were identified at any point in time. Maximum possible value is 100; Y-axis formatted to same scale as in all other figures.



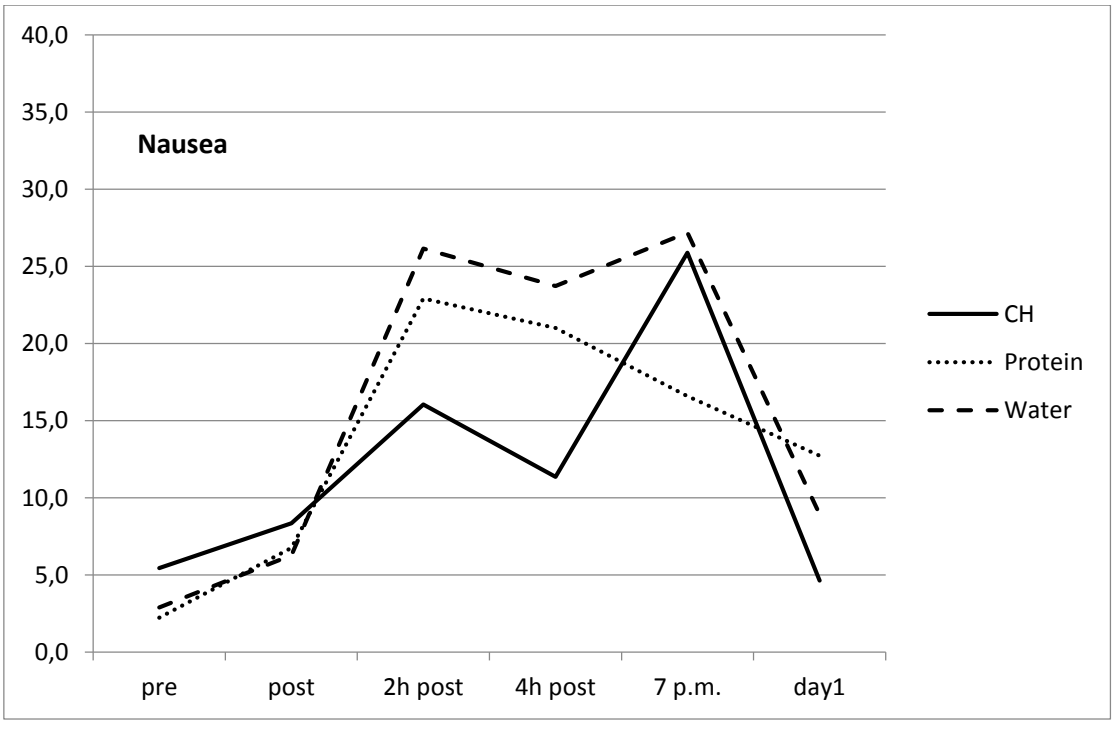
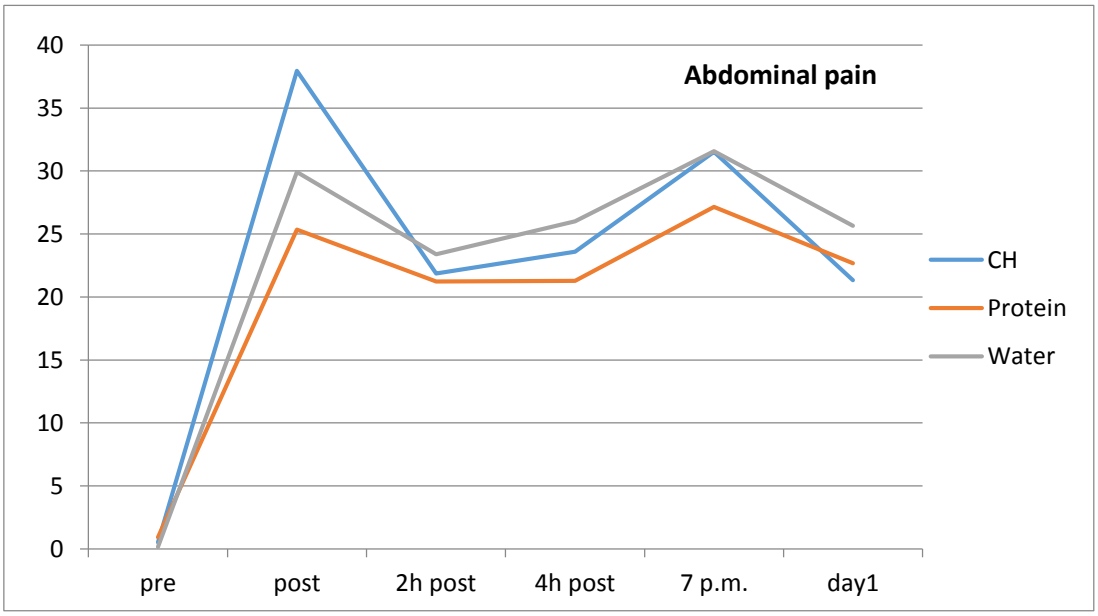


Figure 2:

VAS score (mm VA scale), showing levels of abdominal pain for the three groups of patients. No differences between groups were identified at any point in time. Maximum possible value is 100; Y-axis formatted to same scale as in all other figures.



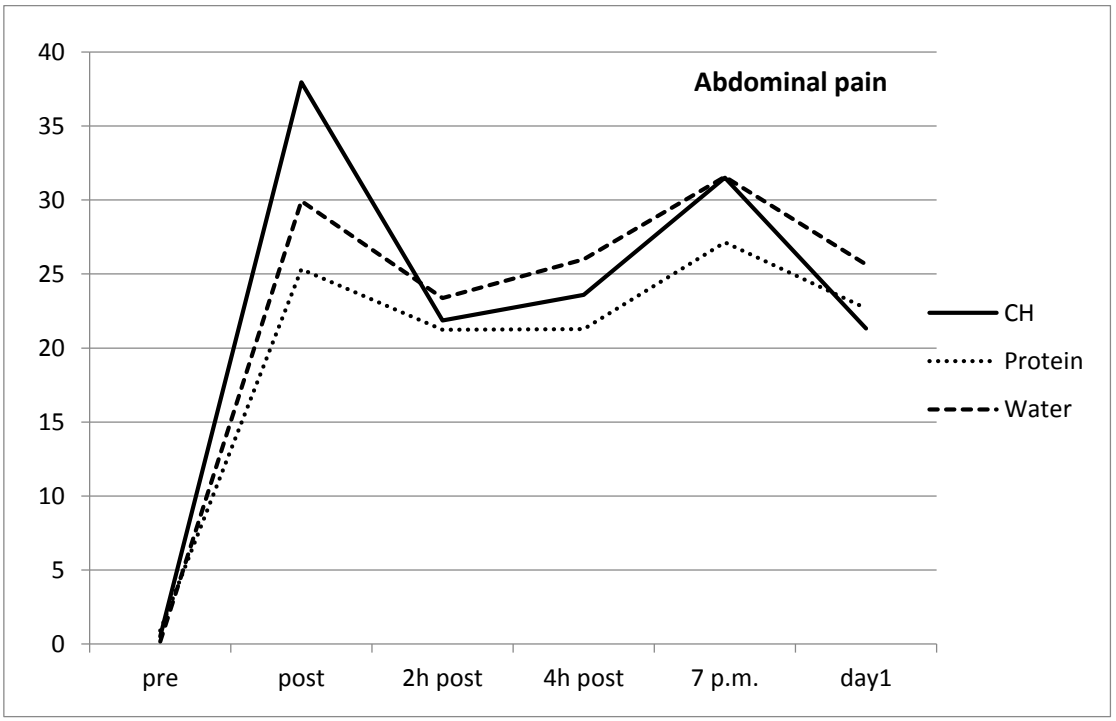


Figure 3:

VAS score (mm VA scale), showing levels of headache for the three groups of patients. No differences between groups were identified at any point in time. Maximum possible value is 100; Y-axis formatted to same scale as in all other figures.