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Effects of preoperative fasting abbreviation with carbohydrate and protein solution on postoperative symptoms of gynecological surgeries: double-blind randomized controlled clinical trial.

Efeitos da abreviação do jejum pré-operatório com solução de carboidrato e proteína em sintomas pós-operatórios de cirurgias ginecológicas: ensaio clínico randomizado controlado duplo-cego.

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ABSTRACT

Objective: to investigate the effects of preoperative fasting abbreviation, a recommendation of Postoperative Accelerated Total Recovery protocol (ACERTO protocol), on postoperative symptoms of patients undergoing gynecological surgeries. **Methods:** a double-blind randomized controlled study of 80 gynecological surgeries performed from January to June 2016. The patients were randomly allocated into two groups: Controle Group, with 42 patients, and Juice Group, with 38 patients, who received 200ml inert solution or 200ml carbohydrate- and protein-enriched liquid, respectively, four hours before surgery. The postoperative symptoms studied were thirst, hunger, pain, agitation, satisfaction, and well-being in both groups. To measure the intensity of symptoms, we used the Visual Analog Scale (VAS), associated with the Facial Scale (FS) for pain, applied ten hours after surgery. **Results:** patients in the Juice Group had less pain (3.51x1.59), thirst (3.63x0.85), hunger (3.86x2.09), and agitation (2.54x0,82) in relation to the Controle Group (P<0.05). Satisfaction (6.89x8.68) and well-being (5.51x7.12) variables were higher (P<0.05) when the carbohydrate- and protein-containing liquid (Juice Group) was ingested in relation to the inert solution (Controle Group). **Conclusion:** the abbreviation of preoperative fasting with carbohydrate- and protein-containing liquid before gynecological surgeries reduces thirst, hunger, pain, agitation, and favors greater satisfaction and well-being than inert solution ingestion.

Keywords: Preoperative Care. Gynecologic Surgical Procedures. Fasting. Carbohydrates. Controlled Clinical Trial.

INTRODUCTION

Enhanced Recovery After Surgery (ERAS) protocols, in Europe, and Accelerated Postoperative Total Recovery (ACERTO), in Latin America and Brazil, are multimodal programs that commonly apply perioperative recommendations and particularly time reduction of preoperative fasting as benefits for patient recovery. Preoperative fasting abbreviation, an intervention recommended by evidence-based medicine, may allow more satisfactory surgical results[1-6].

In addition, current evidence-based guidelines from anesthesiology societies in the United States, Canada, and Europe support the abbreviation of preoperative fasting with clear carbohydrate-enriched liquids with or without protein[7,8]. A contraindication to shortening preoperative fasting is gastroesophageal reflux, since gastroparesis associated with gastroesophageal reflux may delay gastric emptying and predispose to bronchial aspiration[9].

The abbreviation of preoperative fasting, as recommended by ERAS and ACERTO perioperative care protocols, is often related to abdominal[10-14], oncologic[15], and pediatric[16] surgeries. Positive effects are described in terms of satisfaction, recovery improvement, and even muscle strength recovery, suggesting lower muscle proteolysis due to surgical metabolic stress[17].

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However, data on this positive intervention favoring the quality of postoperative recovery in patients undergoing gynecological surgeries are scarce. In addition, there is currently a growing academic interest in the study of anxiety and satisfaction of the surgical patient, as it is the subjective judgment of the quality of perioperative care, and the satisfied patient favors the good surgical outcome since it is more likely to cooperate with the proposed treatment[14,18,19]. Minimizing negative outcomes, such as pain, thirst, hunger, and agitation, may reduce anxiety and promote greater comfort and satisfaction, economically relevant factors, with positive impact on the quality of perioperative care[18,20].

This study aims to evaluate the efficacy of preoperative fasting abbreviation, by administering carbohydrate- and protein-enriched liquid, in minimizing undesirable postoperative outcomes, such as pain, thirst, agitation, and hunger in gynecological surgeries. In addition, it intends to evaluate the possibility of improving positive results, such as satisfaction and well-being, in this area.

METHODS

The research methods of the present study were based on the Consolidated Standards of Reporting Trials (CONSORT) 2010 Statement: Updated guidelines for reporting parallel group randomized trials[21]. This experimental design was a prospective randomized parallel study of two groups, that is, enrollment, intervention allocation, follow-up, and double-blind data analysis, for abbreviation of preoperative fasting in gynecological surgeries.

This study was conducted at Municipal Hospital and Maternity Dr. Odelmo Leão Carneiro (HMMOLC), a medium-complexity general hospital located in Uberlandia, Minas Gerais (MG) state, in partnership with Federal University of Sao Paulo (UNIFESP). It was approved by the board of directors of HMMOLC and the Human Research Ethics Committee of UNIFESP, under protocol n# 1,192,130 and registered in *Plataforma Brasil* with the Certificate of Presentation for Ethical Appraisal - CAAE 48103015,8,0000,5505. It has been included in *Registro Brasileiro de Ensaios Clinicos* (ReBec), the Brazilian Clinical Trials Registry Platform of World Health Organization (WHO) international platform (http://www.who.int/ictrp/en/), under RBR-66gqfs registration. There were no significant changes in the methods after the beginning of the evaluation.

The volunteer participants were patients with indication for gynecological surgery, from January to June 2016 at HMMOLC. Patients were invited to participate in the study after pre-anesthetic release for the procedure, with project clarification meetings and application of exclusion criteria. After excluding patients in special situations or with contraindications to preoperative fasting abbreviation, those who met the eligibility criteria and agreed to participate in the study signed the Informed Consent Form (ICF).

Eligibility criteria were: age between 18 and 70 years, pre-anesthetic evaluation, American Society of Anesthesiologists (ASA) scores I or II, and body mass index (BMI) of 35kg/m^2 or less. Patients with gastroesophageal reflux, infections, steroid use for at least six months before surgery, kidney or liver disease, diabetes *mellitus*, and surgery time longer than four hours were excluded. These latter situations were excluded in the pre-anesthetic evaluation due to a possible analysis bias related to higher metabolic stress.

After recruitment, patients were randomized into two groups. The method and mechanism used to generate the random allocation sequence was developed by Microsoft Excel 2014.

One of the co-authors generated the random allocation sequence, enrolled the participants, and knew about the allocation, not participating in the liquid delivery. Another co-author attributed the intervention to the participants. This co-author did not know which liquid would be offered to the patient. The patient also did not know which liquid to take, characteristic of the double-blind study. Shielding was performed for the patients and authors responsible for the intervention and data collection, with allocation data stored in a sealed envelope, only opened after data collection for result analysis.

The two groups were: Control Group and Juice Group, which received, respectively, four hours before surgery, 200ml inert solution (composed of distilled water, four drops of red dye, and two drops of sucrose sweetener) and 200ml clarified supplement, rich in carbohydrate (89%), and whey protein (11%) produced by a pharmaceutical industry, offered to patients without packaging label.

The following clinical parameters were analyzed: age, weight, height, and body mass index (BMI). The parameters selected for analysis of postoperative symptoms were: thirst, hunger, pain, agitation, satisfaction, and well-being. The instrument used to measure the quality of recovery after surgery was the Visual Analog Scale (VAS), for all parameters, associated with the Facial Scale (FS) for pain. VAS questionnaire was administered ten hours after surgery.

Sample size (at least 30 patients in each group) was determined for identification with 95% confidence level (error a=0.05), a difference if there were at least 5 VAS points between the mean parameters of the two evaluated groups. Descriptive analysis was performed, presenting measures of central tendency and dispersion for continuous variables and frequencies in percentages for qualitative variables. Chi-square test or Fisher's exact test was used to verify the association between groups and qualitative variables. The significance level was of 0.05. Statistical analyses were performed using SPSS 20.0 software (Statistical Package for the Social Sciences).

RESULTS

Of the 124 patients scheduled for gynecological surgery from January to June 2016, 23 did not agree to participate in this study and 22 were excluded. The study began with 79 women and 80 cases (one patient underwent two procedures during the study four months apart and agreed to participate twice). Therefore, the sample consisted of 80 cases, 42 in the Control Group and 38 in the Juice Group. Of these patients, 74 completed the protocol, 40 from the Control Group and 34 from the Juice Group (Figure 1).

Data in table 1 show a paired sample between groups, with no statistical difference in clinical parameters. There were no anesthetic complications.

According to table 2, all variables showed statistically significant differences between the Control and Juice groups, with less pain (3.51x1.59), thirst (3.63x0.85), hunger (3.86x2.09), and agitation (2.54x0.82) in the juice group in relation to the inert solution group (P<0.05). The satisfaction (6.89x8.68) and well-being (5.51x7.12) variables were higher (P<0.05) when carbohydrate- and protein-containing liquid (Juice Group) was ingested compared to the inert solution (Control Group).

DISCUSSION

Although the vast majority of studies derived from ERAS protocol employ carbohydrate-containing liquid, the relevance of this study is that it follows one of the classic recommendations of ACERTO protocol which supports the addition of protein to carbohydrate in the preoperative fasting abbreviation liquid. The mentioned formulation is emphasized in other recent studies to provide the benefits of nocturnal non-starvation before surgery[8]. According to Perrone *et al.*[22], these new formulas may improve postoperative muscle strength and reduce fatigue, anxiety, and discomfort, as well as decrease the metabolic response to trauma.

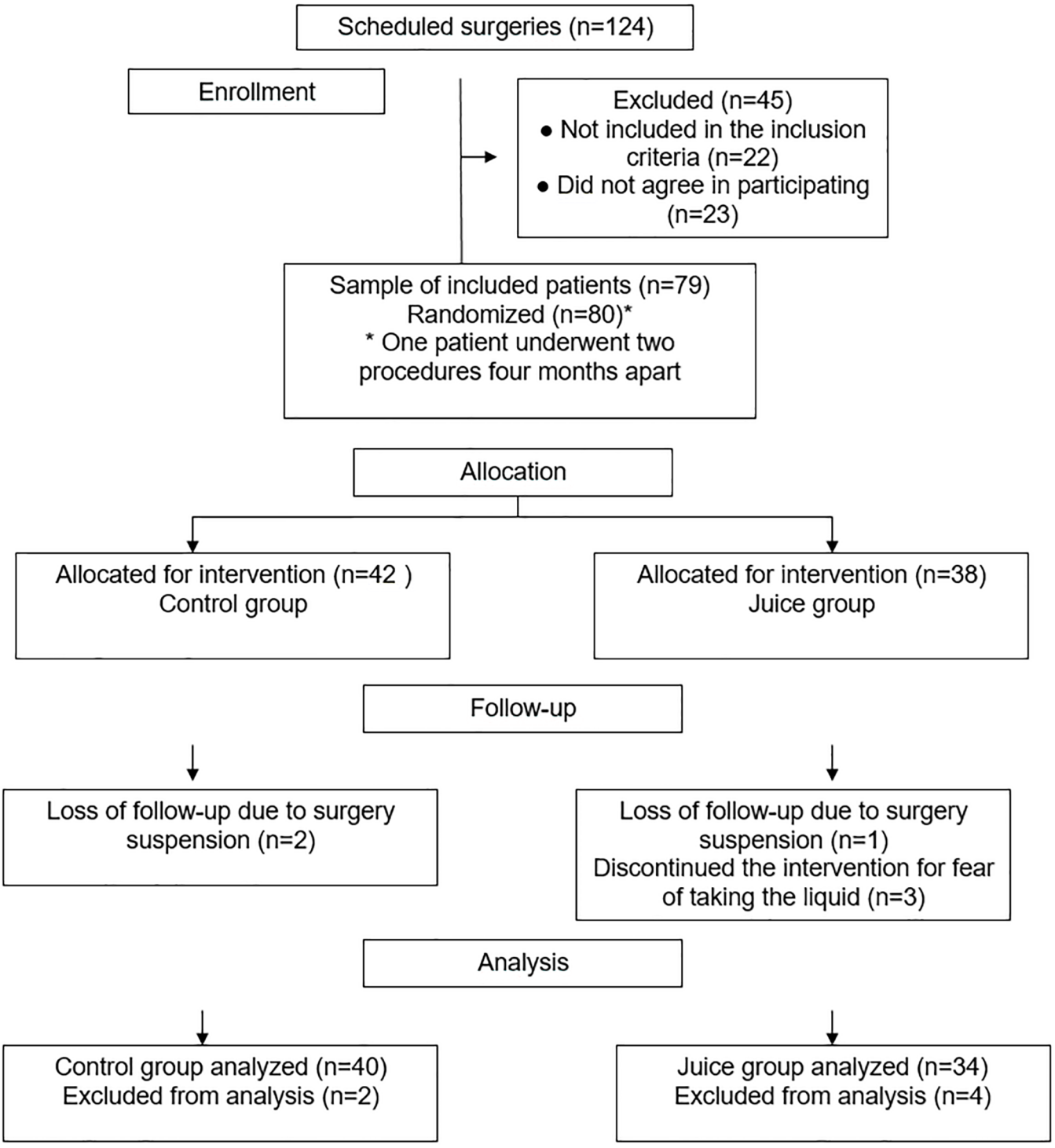

Figure 1. *Flowchart of the prospective double-blind randomized study of preoperative fasting abbreviation in gynecological surgeries.*

They report that whey protein contains a high level of essential amino acids (leucine, isoleucine, and valine) which are rapidly used by skeletal muscle during stress and stimulate protein synthesis. In addition, whey protein has a high degree of digestibility and rapid absorption in the small bowel.

Table 1. *Sample distribution according to clinical variables.*

Variable	Group	Average	95%CI	Median	Min-max	*p-valor*
Age (years)	Control	39.2	36.3-42.1	38.50	25-58	0.552
	Juice	42.5	383-43.4	42.4	22-64	
Surgery time (minutes)	Control	71.4	52.2-90.5	50.0	20-180	0.886
	Juice	77.9	56.8-99.0	60.0	47-132	
Weight (kg)	Control	75.1	70.4-79.7	74	58-104	0.029
	Juice	69.6	62-77.2	68	47-132	
Height (m)	Control	1.64	1.57-1.70	1.61	1.52-1.76	0.039
	Juice	1.58	1.55-1.65	1.58	1.45-1.72	
BMI** (kg/m^2)	Control	27.8	25.5-30.0	27.0	18.1-38.4	0.174
	Juice	27.9	25.2-30.5	26.5	19.8-34.5	

CI= confiance interval; min-max= minimum and maximum; BMI= body mass index; p-valor <0.05.

Table 2. *Differences between groups according to subjective variables measured by VAS.*

Variable	Group	Average	95%CI	Median	Min-max	*p-valor****
Pain	Control	3.51	2.61-4.42	3.0	0.10	0.01
	Juice	1.59	0.57-2.61	0	0-10	
Thirst	Control	3.63	2.77-4.49	4.0	0-8	0.01
	Juice	0.85	0.22-1.49	0	0-8	
Hunger	Control	3.86	2.88-4.83	4.0	0-10	0.04
	Juice	2.09	1.05-3.12	0	0-8	
Agitation	Control	2.54	1.71-3.36	3.0	0-8	0.01
	Juice	0.82	0.14-1.51	0	0-8	
Satisfaction	Control	6.89	6.08-7.69	8.0	2-10	0.012
	Juice	8.68	8.04-9.32	9.0	0-10	
Well-being	Control	5.51	4.50-6.53	5.0	0-10	0.019
	Juice	7.12	6.19-8.05	8.0	0-10	

*CI= confiance interval; min-max= minimum and maximum; * p-valor <0.05.*

de Andrade Gagheggi Ravanini *et al*.[23] corroborate the same results of the present study. The safe and effective addition of whey protein to carbohydrate in the preoperative liquid, under the conditions mentioned before, provides safety and effectiveness. In addition, it improves the metabolic response to trauma compared with only carbohydrate-containing liquid ingestion.

Another particularity of the present study is the 200ml preoperative drink offer as supported by ACERTO protocol, which differs from the 400ml offer published in other studies following ERAS protocol. ACERTO protocol derives from the solid foundations of European ERAS, however, is national, with guidelines supported by the Brazilian College of Surgeons (CBC) and the Brazilian Society of Parenteral and Enteral Nutrition (SBNPE). It therefore offers endorsement of adaptations with practical, safe, and effective functionality to the reality of Latin America, including Brazil[8,24].

Given the current recommendations on perioperative care, it is undeniable that the traditional rules of preoperative fasting subjectively compromise the comfort of the surgical patient, who wants the safe liberalization of these rules[25-27].

Efforts to reduce postoperative symptoms, such as pain, anxiety, and preoperative tension, as well as to value perioperative satisfaction, are highlighted in this study. These measures may provide a positive impact on the quality of perioperative care from the perspective of the surgical patient[26,28].

Imbelloni *et al*.[18] suggest the analysis of practical parameters, such as thirst, hunger, agitation, satisfaction, and well-being, through a simple and objective questionnaire (yes and no), as an instrument for assessing surgical patient's satisfaction. The results of table 2 show that there was statistically significant difference in the quality of surgical recovery between the groups when analyzing these subjective variables. Patients who ingested juice had less pain, thirst, hunger, and agitation, and greater postoperative satisfaction and well-being when compared to those who received inert solution.

Other studies show results of postoperative symptom analysis similar to those of our study. Less perioperative thirst and hunger, due to fasting abbreviation with carbohydrate- and protein-containing liquid, are related to lower undesirable effects and higher satisfaction[25-27,29]. In addition, thirst and hunger are the most important symptoms of preoperative discomfort according to similar perioperative care studies[26]. Efforts to shorten preoperative fasting may result in a measurable reduction in thirst and hunger, as well as in the improvement of patient's well-being[26,27].

The humanization of perioperative care in gynecological surgeries may be favored by the reduction of postoperative symptoms, such as thirst and hunger in this period, as well as by the alleviation of pain. There is a strong correlation in literature on pain management and improvement in surgical care satisfaction[30-33]. Data from this study point to the same findings. Patients who underwent preoperative fasting abbreviation with carbohydrate- and protein-enriched liquid had less pain than patients who ingested the inert solution, with a statistically significant difference ($P<0.05$). This fact may have positively influenced the greater satisfaction of Juice Group in relation to Control Group.

Other studies associate pain and postoperative satisfaction. In a recent systematic review of satisfaction predictors, patient's perception in relation to a good pain management has been the most consistent factor associated with high satisfaction[34,35], which has also favored early mobilization and discharge and, consequently, greater well-being[24]. Thus, the implementation of recovery acceleration has been associated with less pain, reduction of hospital stay, and postoperative morbidity, good satisfaction, and cost reduction[24].

The mistaken fear of undesirable complications, such as bronchial aspiration, may discourage gynecological surgeons from adhering to ACERTO protocol recommendations on preoperative fasting abbreviation. It is important to note that, in this context, anesthesiology guidelines also guarantee these benefits, elucidate this paradigm, and support data security of this study. Anesthesiology societies support that preoperative fasting abbreviation, under the conditions described before, is safe and may decrease perioperative undesirable effects[8].

Our study confirmed that the offer of carbohydrate- and protein-containing liquid up to four hours before the gynecological procedure decreased thirst, hunger, pain, and agitation, and enabled greater patients' satisfaction and well-being.

The practice did not offer additional risks and provided greater comfort and humanization in the perioperative care of gynecological surgeries. It can therefore be encouraged with the aim of accelerating postoperative recovery and adding satisfaction in the quality of hospital care in gynecological surgeries.

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R E S U M O

Objetivo: *investigar os efeitos da abreviação do jejum pré-operatório, uma recomendação do protocolo de "Aceleração da Recuperação Total Pós-operatória" (ACERTO), em sintomas pós-operatórios de pacientes submetidas à cirurgias ginecológicas.* **Métodos:** *estudo controlado, randomizado, duplo-cego, de 80 cirurgias ginecológicas realizadas no período de janeiro a junho de 2016. As pacientes foram aleatoriamente alocadas em dois grupos: Grupo Controle, com 42 pacientes, e Grupo Suco, com 38, e que receberam, respectivamente, 200ml de solução inerte ou 200ml de líquido enriquecido com carboidrato e proteína quatro horas antes da cirurgia. Os sintomas pós-operatórios estudados foram sede, fome, dor, agitação, satisfação e bem-estar, em ambos os grupos. Para medir a intensidade dos sintomas foi utilizada a Escala Visual Analógica (EVA), associada à Escala Facial (EF) para dor, aplicadas dez horas após a cirurgia.* **Resultados:** *as pacientes do Grupo Suco apresentaram menos dor (3,51x1,59), sede (3,63x0,85), fome (3,86x2,09) e agitação (2,54x0,82) em relação ao Grupo Controle (P<0,05). As variáveis satisfação (6,89x8,68) e bem-estar (5,51x7,12) foram maiores (P<0,05) quando houve a ingestão do líquido contendo carboidrato e proteína (Grupo Suco) em relação à solução inerte (Grupo Controle).* **Conclusão:** *a abreviação do jejum pré-operatório com líquido contendo carboidrato e proteína antes de cirurgias ginecológicas reduz sede, fome, dor, agitação e favorece maior satisfação e bem-estar do que a ingestão de solução inerte.*

Descritores: *Cuidados Pré-Operatórios. Procedimentos Cirúrgicos em Ginecologia. Jejum. Carboidratos. Ensaio Clínico Controlado.*

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