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A normocaloric, low-fiber diet for colonoscopy preparation is more acceptable and non-inferior to a liquid, low-calorie diet: a randomized controlled trial

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HIGLIGHTS

- This is the first study in Brazil about diets to prepare for colonoscopy.
- The normocaloric diet was not inferior to the liquid diet regarding the quality of the colonoscopy preparation.
- Both diets were well tolerated, but the normocaloric diet was more accepted than the liquid diet.

ABSTRACT – Background – Several publications have shown greater acceptance of less restrictive diets for colonoscopy preparation, without impairing the quality of the preparation, when compared to the clear liquid diet. **Objective** – To evaluate the quality, tolerance and preference regarding the colonoscopy preparation of a low-fiber, normocaloric diet compared with a hypocaloric liquid diet. **Methods** – This is a randomized, controlled, observer-blind study to compare two low-fiber colonoscopy preparation diets (hypocaloric liquid diet vs. normocaloric diet). The Boston Bowel Preparation Scale was used to evaluate the quality of the preparations, being considered adequate BBPS ≥6 in the global assessment and ≥2 in each segment. The same laxative was used in both groups as well as the "split-dose" regimen. **Results –** A total of 136 individuals were enrolled in each group. Adequate preparation was achieved in 90.4% of the individuals allocated to the liquid diet group and 92.6% to the normocaloric group. There was no significant difference in the quality of preparation and tolerance between groups. A higher patient acceptance to repeat the procedure if necessary was observed in the normocaloric diet group compared with the liquid diet group (P=0.005). **Conclusion** – The normocaloric diet has shown to be not inferior to the liquid diet regarding the quality of the colonoscopy preparation. Patient tolerance rates were similar between both diets, but a higher acceptance rate was observed with the normocaloric diet as compared with the liquid diet.

Keywords – colonoscopy; diet; cathartic.

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INTRODUCTION

Dietary restriction before colonoscopy, either with a clear liquid diet or a low-residue diet, has been the traditional recommendation.

Several publications have shown a greater acceptance of less restrictive diets for colonoscopy preparation, without loss of quality, when compared to the clear liquid diet (CLD)[1-9]. However, the CLD provides approximately 500–600 kcal/day, a value much lower than the caloric intake recommended for a middle-aged adult (1800–2100 kcal/day). Thus, it is easy to understand the greater acceptance of less restrictive diets.

The liquid diet (LD) offers twice the caloric value of the CLD, approximately 1000 kcal/day, and is usually prescribed in the perioperative period, being an interesting option for colonoscopy preparation.

Our study aimed to evaluate the quality, tolerance and acceptance of the colonoscopy preparation of a normocaloric (ND) diet compared to a LD, both of which are low in fiber. The study is pioneer in Brazil and is the first to evaluate the normocaloric diet against the standard recommendation LD.

METHODS

Study design

This was a randomized, controlled, noninferiority, "blinded" endoscopist trial to evaluate the efficacy of a ND with a LD for colonoscopy preparation in outpatients. The study protocol followed the instructions of the National Health Council and was approved by the Ethics Committee of the Federal University of São Paulo (CAAE 23020319.3.00000.5505).

Study population

The study was conducted at the General Hospital of Vitoria da Conquista in southwestern Bahia. Individuals undergoing and outpatient colonoscopy were consecutively invited to participate in the study. The noninclusion criteria were formal contraindications for colonoscopy, patients with inflammatory bowel disease, inability to adequately understand the preparation instructions, previous partial or total colectomy, and incomplete colonoscopy due to contraindications by the endoscopist.

Allocation and masking

The participants were randomized according to the SPSS computer program, following a 1:1 sequence. The nurse in charge explained and provided written guidelines for the diet randomly established for each patient, and subsequently collected signed informed consent forms. The endoscopists responsible for performing the procedures were blinded to the patients' group assignments and watched a video on the evaluation of colonoscopy readiness using the Boston Bowel Preparation Scale (BBPS) to standardize the preparation evaluation.

Intervention

Both diets were prescribed the day before the procedure and prepared by a nutritionist. Each diet contained an average fiber composition of <10 g/day. The LD had a caloric content of 1097.25 kcal, and the ND 2086.12 kcal (FIGURE 1). All participants prepared the cleanse with two sachets of a laxative consisting of 10 mg sodium picosulfate, 3.5 g magnesium oxide and 12 g anhydrous citric acid (PICOPREP®), according to oral and written instructions. All colonoscopies were performed in the afternoon. The preparation regimen used was a "split dose". On the day of the procedure, before performing the exam, a research team nurse was in charge of administering the questionnaires on clinical-epidemiological data and on the quality of preparation, presence of polyps, withdrawal times and total procedure.

Outcomes

Our primary outcome was the rate of adequate bowel preparation measured with the BBPS. Adequacy was defined as a colonoscopy with a score of 2 or 3 points in all colon segments. The secondary outcomes were segment BBPS (right, left and transverse colon), adenoma detection rate, total procedure time and withdrawal time, and "runway" time, defined as the time between ingestion of the last dose of the preparation and the beginning of the colonoscopy. Other outcomes unrelated to the procedure were evaluated, such as acceptance of the diet used, how to use the same preparation protocol if a new procedure was needed, and tolerance (analyzed according to the presence or absence of undesirable symptoms such as abdominal distension and nausea, vomiting,

NORMOCALORIC DIET

BREAKFAST	Mix of: • French bread • Cheese mussarela ligth • Turkey ham • Liquid whole milk	Quantity: • 3 small units • 1 medium thin slice each • 2 medium thin slice each • 1 double cup full (250 mL)
MORNING SNACK	• Liquid whole milk	• 1 double cup full (250 mL)
LUNCH	• Cooked white rice • Lean meat (red meat, pork, fish or chicken) Or • Boiled chicken egg	• 2 medium skimmers • 5 small pieces (200 g) • 2 small units
AFTERNOON SNACK	• Liquid whole milk • Natural yogurt	• 1 double cup full (250 mL) • 2 small cups 120 mL/each
DINNER	• Cooked white rice • Lean meat (red meat, pork, fish or chic Or • Boiled chicken egg	• 2 medium skimmers • 5 small pieces (200 g) • 2 small units
SUPPER	• Whole yogurt	• 2 small cups 120 mL/each

LIQUID DIET

BREAKFAST	Mix of: • Preferred in natura fruit juice (p.e orange, strain the seeds), no sugar • Gelatin	Quantity: • 1 double cup (240 mL) • 3 full soup spoons
MORNING SNACK	• Gelatin • Water • Coconut water	• 5 full soup spoons • Small cup (165 mL) • 1 double cup (240 mL)
LUNCH	• Cooked pasta • Cooked potato • Tea	• 1 medium skimmers • 2 small units (140 g) • 1 cup of tea (200 mL)
AFTERNOON SNACK	• Gelatina • Water • Tea	• 5 full soup spoons • 1 double cup full (250 mL) • 1 cup of tea (200 mL)
DINNER	Vegetables soup and noodles, being: • Water • Noodle • Carrot • English potato • Preferred in natura fruit juice, no sugar	 • 2 small cup full (400 mL) • 1 full skimmer • 1 small unit • 1 small unit • 1 small cup (165 mL)
SUPPER	• Water • Coconut water • Preferred in natura fruit juice, no sugar	• 1 small cup • 1 double cup full (250 mL) • 1 small cup (165 mL)

FIGURE 1. Diets for colonoscopy preparation.

weakness, hunger and interference with daily activities). The following specific questions about the diet were asked: general satisfaction, ease of understanding, ease of preparation, and ease of follow-up, grade using a visual numerical scale from 0 to 10, where 0 to 6 was considered very bad/poor, 7 to 8 fair and 9 to 10 excellent. A question was also asked about overall satisfaction with the diet (without the use of the numerical visual scale), including the following answers: very easy, easy, difficult or very difficult.

Statistical analysis

Qualitative variables are represented as absolute and relative frequencies, and quantitative variables are represented as the mean ± standard deviation (median). All randomly allocated patients were included in the intention-to-treat (ITT) analysis. Missing outcomes of outcome variables were imputed as failures. Patients who completed the preparation protocol and completed the colonoscopy were included in the per-protocol analysis (PP). The association between the primary outcome and the diet groups was assessed using a noninferiority test, which was proven if the lower limit of the 95% confidence interval (CI) for the difference between the diets was equal or greater than -15%. In the case of verification of noninferiority, the superiority test was performed.

Regarding the secondary outcomes, for the association between the diet groups and the qualitative variables, the chi-square test, Fisher's exact test and binary logistic model were used. Student's t test and the Wilcoxon Mann-Whitney test were used to compare the quantitative variables between the two groups, according to the normality of the data distribution (Shapiro-Wilk normality test). The association between sociodemographic and clinical characteristics and the quality of preparation was assessed by univariate logistic regression, with results presented as odds ratios (ORs) and respective 95% CIs. The analyses were performed using the R program, version 4.0.5, and $P<0.05$ was considered significant.

RESULTS

During a period of 8 months, 315 patients were referred for outpatient colonoscopy. Of these pa-

tients, 272 met the inclusion criteria, and 43 were excluded.

All 272 subjects were randomized and analyzed by ITT for efficacy. Two individuals were excluded after randomization, one in each group, due to incomplete colonoscopy due to technical difficulties, and analyzed in the PP.

The type of diet was not associated with sex, age, education, indication for colonoscopy, associated diseases, use of medications or surgical history. A total of 67.3% of participants were female, the mean age was 56.69±12.48 years, and 68.0% completed elementary school. Among the associated diseases, 21.0% had constipation, and previous abdominal surgeries were reported by 19.1% (TABLE 1).

Primary outcome

In the ITT analysis, adequate preparation was 90.4% (95%CI 85.4%; 95.4%) for LD and 92.6% (95%CI 88.2%; 97.0%) for ND. The difference in adequate preparation between the two diets was 2.21% (95%CI -4.40%; 8.81%), so noninferiority was demonstrated because the lower limit of the CI of the differences was higher than -15%. (TABLE 2).

In the PP analysis, the preparation was adequate for 91.1% (95%CI 86.3%; 95.9%) for LD and 93.3% (95%CI 89.1%; 97.5%) for ND. The difference in adequate preparation was 2.22% (95%CI -4.16%; 8.61%), demonstrating noninferiority (the lower limit of the CI was > -15%). Superiority was not demonstrated in either analysis (*P*=0.999).

Secondary outcomes

There was no difference between the diets in the quality of preparation in each segment, as well as in the adenoma detection rate, withdrawal time, "runway" time, presence of diverticula and side effects (TABLES 2 AND 3, FIGURE 2).

TABLE 1. Demographic and clinical characterization of the sample, according to analysis groups.

Characteristics	Liquid diet (n=136)	Normocaloric diet (n=136)	*P*-value	Total (n=272)
Sex			0.796[Q]	
Female	90 (66.2%)	93 (68.4%)		183 (67.3%)
Male	46 (33.8%)	43 (31.6%)		89 (32.7%)
Age (average ± SD (median))	57.63±12.55 (57.00)	55.76±12.38 (56.50)	0.216[T]	56.69±12.48 (57.00)
Schooling			0.899[Q]	
Illiterate	20 (14.7%)	16 (11.8%)		36 (13.2%)
Elementary school I	54 (39.7%)	55 (40.4%)		109 (40.1%)
Elementary school II	21 (15.4%)	19 (14.0%)		40 (14.7%)
High school	37 (27.2%)	40 (29.4%)		77 (28.3%)
University education	4 (2.9%)	6 (4.4%)		10 (3.7%)
Colonoscopy indication			0.712[Q]	
Prevention	71 (52.2%)	72 (52.9%)		143 (52.6%)
Diagnoses	58 (42.6%)	54 (39.7%)		112 (41.2%)
Follow-up after-polipectomy	7 (5.1%)	10 (7.4%)		17 (6.2%)
Associated diseases.				
Diabetes	19 (14.0%)	15 (11.0%)	0.582[Q]	34 (12.5%)
Depression	2 (1.5%)	4 (2.9%)	0.684[F]	6 (2.2%)
Constipation	28 (20.6%)	29 (21.3%)	1.000[Q]	57 (21.0%)
Drugs use.				
Hypoglicemics drugs	17 (12.5%)	13 (9.6%)	0.562[Q]	30 (11.0%)
Antidepressant drugs	4 (2.9%)	7 (5.1%)	0.540[Q]	11 (4.0%)
Surgical background				
Abdominal	32 (23.5%)	20 (14.7%)	0.090[Q]	52 (19.1%)
Gynecológical* (n=183)	46 (51.1%)	49 (52.7%)	0.948[Q]	95 (51.9%)

SD: standard deviation. [Q]Qui-Quadrado test; [F]exact test of Fisher; [T]t-Student test for independent samples; *Gynecological surgery evaluated only in the group of women.

TABLE 2. Evaluation of primary and secondary outcomes of colonoscopy preparation diets, according to analysis groups (intention-to-treat analysis).

Variables	Liquid diet (n=136)	Normocaloric diet (n=136)	*P*-value	Difference (CI95% difference)
Overall quality of preparation				
Adequated (Boston ≥2 in all segments)	123 (90.4%)	126 (92.6%)	0.999[P]	2.21% (-4.40%; 8.81%)
Good quality segment preparation (Boston ≥2)				
Rigth colon Left colon Transverse colon	129 (94.9%) 127 (93.4%) 129 (94.9%)	129 (94.9%) 129 (94.9%) 129 (94.9%)	1.000[Q] 0.797[Q] 1.000[Q]	0.00% (-5.25%; 5.25%) 1.47% (-4.12%; 7.06%) 0.00% (-5.25%; 5.25%)
Adenomas detection rate	38 (27.9%)	36 (26.5%)	0.892[Q]	-1.47% (-12.05; 9.11%)
Female Male	26 (28.9%) 12 (26.1%)	20 (21.5%) 16 (37.2%)	0.326[Q] 0.368[Q]	-7.38% (-19.93%; 5.16%) 11.1% (-8.11%; 30.35%)
Divertícula	37 (27.2%)	30 (22.1%)	0.399[Q]	-5.15% (-15.37%; 5.07%)
Polyps	56 (41.2%)	54 (39.7%)	0.902[Q]	-1.47% (-13.13%; 10.19%)

[Q]Qui-quadrado test, [P]proportion comparison test (non-inferiority).

TABLE 3. Evaluation of procedure times for colonoscopy preparation diets, according to analysis groups.

Variables	Liquid diet (n=136)	Normocaloric diet (n=136)	*P*-value	Total (n=272)
Total time procedure *	15.37±6.36 (14.00)	15.44±6.16 (15.00)	0.687[W]	15.40±6.25 (14.00)
WithdrawalTime *	9.29±5.19 (8.00)	8.88±4.45 (9.00)	0.981[W]	9.09±4.83 (8.00)
Runway time (n=263)			0.689[Q]	
< 5h	31 (23.8%)	30 (22.6%)		61 (23.2%)
5 a 8h	85 (65.4%)	84 (63.2%)		169 (64.3%)
> 8h	14 (10.8%)	19 (14.3%)		33 (12.5%)

*data presented as average ± SD (median). [W]Wilcoxon Mann-Whitney test, [Q]Qui-quadrado test.

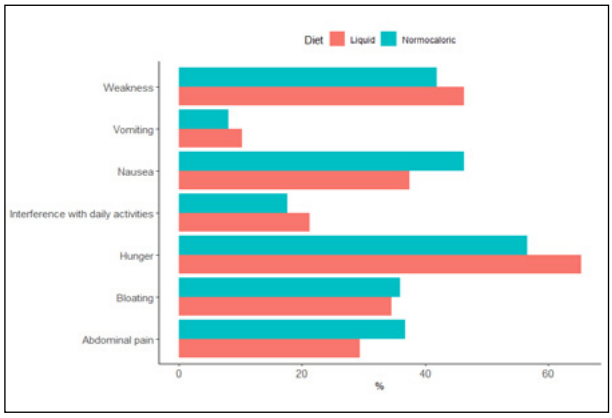

FIGURE 2. Distribution of side effects according to type of diet. There was no significant difference between diets for any of the side effects, so *P*-values were omitted.

Acceptance was 88.2% for the entire sample and higher in ND than in LD (94.1% normocaloric vs 82.2% liquid, *P*=0.005) (TABLE 2).

The LD group had a higher proportion of individuals who considered it difficult in the subjective evaluation (*P*=0.049), as well as poor understanding (*P*=0.002) and follow-up (*P*=0.023) (TABLE 4).

The detection rate of adenomas was higher in the group with adequate preparation (Boston ≥6), 28.9% (95%CI 23.3%; 34.5%) versus 8.7% (95%CI 0.0%; 20.2%) in the inadequate preparation group (Boston <6) (*P*=0.048).

DISCUSSION

In this randomized, controlled, non inferiority study, we demonstrated that an ND is not inferior to an LD for colonoscopy preparation.

LD are frequently prescribed during the perioperative period and offer a caloric intake that is approximately 1000 kcal/day, approximately double the value of CLD (500–600 kcal/day).

All previous publications that addressed diets in colonoscopy preparation used CLD as the "gold standard" and compared it with less restrictive diets[1-9]. Our study, in addition to being a pioneer in Brazil, is the first to compare a composite 1100 kcal/day LD with a 2.100 kcal/day ND.

TABLE 4. Subjective evaluation and using the visual analogue scale of colonoscopy preparation diets, according to analysis groups.

Characteristics	Liquid diet (n=136)	Normocaloric diet (n=136)	*P*-value	Total (n=272)
Subjective evaluation			0.049[L]	
Very easy	4 (2.9%)	4 (2.9%)		8 (2.9%)
Easy	91 (66.9%)	107 (78.7%)		198 (72.8%)
Difficult	38 (27.9%)	23 (16.9%)		61 (22.4%)
Very difficult	3 (2.2%)	2 (1.5%)		5 (1.8%)
Evaluation – numerical scale				
General satisfaction			0.148[Q]	
Bad	23 (16.9%)	17 (12.5%)		40 (14.7%)
Fair	53 (39.0%)	43 (31.6%)		96 (35.3%)
Excellent	60 (44.1%)	76 (55.9%)		136 (50.0%)
Understanding			0.002[Q]	
Bad	25 (18.4%)	10 (7.4%)		35 (12.9%)
Fair	34 (25.0%)	22 (16.2%)		56 (20.6%)
Excellent	77 (56.6%)	104 (76.5%)		181 (66.5%)
Prepare			0.493[Q]	
Bad	14 (10.3%)	9 (6.6%)		23 (8.5%)
Fair	35 (25.7%)	33 (24.3%)		68 (25.0%)
Excellent	87 (64.0%)	94 (69.1%)		181 (66.5%)
Follow-up			0.023[Q]	
Bad	27 (19.9%)	17 (12.5%)		44 (16.2%)
Fair	36 (26.5%)	24 (17.6%)		60 (22.1%)
Excellent	73 (53.7%)	95 (69.9%)		168 (61.8%)

[Q]Qui-quadrado test, [L]binary logistic model.

Even comparing diets with lower differences in caloric values than in previous studies, there was a greater acceptance of ND than LD. A possible explanation is that the ingestion of liquid food causes less satiety than solid food and consequently a lower feeling of satisfaction[10,11].

Although no significant differences in side effects were observed between the diets, there was a trend toward a greater perception of hunger reported by individuals in the LD group. Publications have reported a significantly greater perception of hunger in the CLD compared to the low-residue diet[1,2,4,8].

The detection rate of adenomas has been inversely associated with colorectal cancer mortality[12]. In the present study, we did not observe a difference in this rate between the two diets. Another important finding was that the rate in the group with adequate preparation was 28.9%, which is significantly higher than in the group with inadequate preparation, which was 8.7%. The detection rate of adenomas in the present study, even though it was not designed with this objective in mind, reinforces the importance of the quality of the preparation in the detection of precursor lesions of colorectal cancer.

We recognize the limitations of our study, such as the fact that it was performed in a single center, which may limit the external validation of the results.

CONCLUSION

The normocaloric diet low in fiber is not inferior to the liquid diet in the quality of colonoscopy preparation, with similar tolerance but greater acceptance.

Authors' contribution

Lescano MAL: project management, survey execution, writing of text. Santana LC: survey execution. Gonçalves AFA: data collection. Machado RS, Rohr MR and Miszputen SJ: editing and review.

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RESUMO – Contexto – Diversas publicações têm evidenciado uma maior aceitação de dietas menos restritivas para preparo de colonoscopia, sem prejuízo na sua qualidade, quando comparadas com a dieta de líquidos claros. **Objetivo –** Avaliar a qualidade, tolerância e preferência do preparo para colonoscopia de uma dieta líquida hipocalórica, quando comparada com uma dieta normocalórica, ambas pobres em fibras. **Métodos** – Trata-se de um estudo randomizado, controlado, observador "cego", para comparar duas dietas de preparo para colonoscopia (dieta líquida hipocalórica e dieta normocalórica, ambas pobres em fibras). Foi utilizada a escala de Boston para avaliar a qualidade do preparo, sendo considerado adequado BBPS ≥6 na avaliação global e ≥2 em cada segmento. Foram prescritos o mesmo laxativo e o regime "dose fracionada" para ambos os grupos. **Resultados** – Foram incluídos 136 indivíduos em cada grupo. O preparo adequado foi alcançado em 90,4% dos indivíduos alocados no grupo da dieta líquida e 92,6% da normocalorica. Não houve diferença significativa na qualidade do preparo e na tolerância entre ambas as dietas. Observou-se maior aceitação de repetir o procedimento se necessário, no grupo da dieta normocalórica quando comparado ao da dieta líquida (*P*=0,005). **Conclusão** – A dieta normocalórica não é inferior que à líquida na qualidade do preparo para colonoscopia, ambas apresentam tolerância similar, porém com maior aceitação da dieta normocalórica quando comparada à líquida**.**

Palavras-chave – Colonoscopia; dieta; laxativos.

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