

## Tolerance to colonoscopy preparation with Fortrans and predictors of negative effects

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### ABSTRACT

**Background.** The tolerance of colon cleansing with Fortrans is associated with a number of negative factors. This determines patient compliance and quality of bowel preparation. The relevance of this issue is increasing due to the prevalence of this method in the diagnosis and treatment of colon pathology.

**The aim** of the study was to investigate tolerance to Fortrans in colon preparation for colonoscopy and factors affecting comfort.

**Materials and methods.** Before colonoscopy, a questionnaire method was used to study 84 patients who underwent colon preparation with Fortrans. Patient satisfaction with the preparation was evaluated on the visual analogue scale (VAS).

**Results.** 45 (52.4%) people were satisfied with comfort of the preparation and rated its level as 0–2 points on the VAS. 39 (47.6%) patients were not satisfied with the preparation, a discomfort level of 3–10 points was estimated. Factors affecting patient tolerance of Fortrans administration were determined.

**Conclusion.** Satisfactory tolerance of the colon preparation with Fortrans was observed in half of the patients, which depended on their psychological state and realized expectations of comfort during the procedure. Predictors of intolerance of colon preparation are side effects of Fortrans, which are largely mitigated by its split intake, as well as incorrigible factors, such as higher education, repeated colonoscopy, and history of constipation.

**Key words:** bowel preparation, predictors of tolerance, side effects of Fortrans.

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## Переносимость подготовки к колоноскопии препаратом «Фортранс» и предикторы, влияющие на ее характер

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### РЕЗЮМЕ

**Введение.** Переносимость очищения толстой кишки фортрансом связана с рядом факторов, которые недостаточно исследованы в рамках рассматриваемой проблемы. Она определяет комплаентность пациента и в итоге качество очистки толстой кишки. Значение переносимости подготовки к колоноскопии возрастает из-за распространенности этого метода в диагностике и лечении патологии толстой кишки.

**Цель.** Изучить переносимость фортранса при подготовке толстой кишки к колоноскопии и факторы, влияющие на ее характер.

**Материалы и методы.** На доколоноскопическом этапе методом анкетирования исследованы 84 пациента, прошедшие подготовку толстой кишки фортрансом. По визуально-аналоговой шкале (ВАШ) изучена удовлетворенность пациентами приемом препарата.

**Результаты.** 45 (52,4%) человек удовлетворены комфортом подготовки, самооценка по шкале ВАШ 0–2 балла, 39 (47,6%) пациентов отметили неудовлетворенность приемом препарата, уровень дискомфорта 3–10 баллов. Выявлены факторы, влияющие на переносимость пациентами приема фортранса.

**Заключение.** Удовлетворительная переносимость подготовки толстой кишки фортрансом наблюдается у половины пациентов. Это в определенной мере зависит от их психологического состояния и степени исполнения ожиданий комфорта подготовки. Предикторами непереносимости подготовки толстой кишки являются нежелательные проявления фортранса, которые в значительной мере нивелируются отдельным приемом препарата, а также некорректируемые факторы: высшее образование, повторная колоноскопия, запоры.

**Ключевые слова:** подготовка кишечника, предикторы переносимости, нежелательные явления при подготовке фортрансом.

**Конфликт интересов.** Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, связанных с публикацией настоящей статьи.

**Источник финансирования.** Авторы заявляют об отсутствии финансирования.

**Соответствие принципам этики.** Все пациенты подписали информированное согласие на участие в исследовании. Исследование одобрено локальным этическим комитетом при Тюменском государственном медицинском университете (протокол № 90 от 17.03.2020).

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## INTRODUCTION

Antegrade intestinal lavage is the main preparation method for colon examination. Fortrans, a polyethylene glycol-based medicine, the oldest of this group, remains a common drug for purgation and often serves as a control in various scientific studies which investigate new drugs and ways of

preparing the intestines for various diagnostic and therapeutic procedures [1–3].

Unsatisfactory tolerance of colon cleansing is associated with side effects of medications used for this purpose. This is one of the factors influencing preparation tolerance, and it is important, though not the only one. There are other factors, such as

demographic, social, and clinical ones, which are not sufficiently studied within the issue under consideration.

Tolerance of the preparation process determines the patient's compliance and, as a result, the quality of colon cleansing. This is the key to successful colonoscopy [1, 3, 4]. The study of tolerance predictors, their relationship with compliance, and the quality of colon cleansing will help to correct the colonoscopy preparation plan, which will improve the quality of examination and treatment of patients [5, 6]. Studies on patient satisfaction with their colon cleansing medications preparations are warranted and necessary [7]. These studies are carried out on the basis of analyzed patient questionnaires and assessments of the quality of treatment or its stages [8].

The aim of the study was to investigate tolerance of Fortrans in colonoscopy preparation and factors affecting its quality

## MATERIALS AND METHODS

A total of 84 patients participated in the study. The average age of the patients was  $57.7 \pm 11.8$  years. There were 39 (46.42%) elderly and old patients. The study included 37 men (44.0%) and 47 women (55.9%). In 53 people, the indication for colonoscopy was a screening study with a positive fecal occult blood test, and they took the drug for the first time. In 31 patients, an operation was planned for endoscopic removal of polyps detected in primary health care facilities, and Fortrans was taken for the second time. Patient preparation was carried out at home. Preparation instructions were given by the endoscopist at the pre-colonoscopy appointment.

Patients were admitted to hospital on the day of the study. Before colonoscopy, all patients were interviewed by the co-author of this study, according to the plan presented in the questionnaire. Patients assessed the degree of discomfort in preparation for the examination on the 10-point visual analogue scale (VAS): 0 – no discomfort and 10 – maximum discomfort. Based on the degree of discomfort, 2 groups of patients were formed, who underwent colon cleansing for colonoscopy satisfactorily or unsatisfactorily, according to their self-assessment.

The study was prospective, non-randomized, and single-center.

## RESULTS

Depending on the comfort during preparation, the patients were divided into 2 groups. The 1st group consisted of 45 (52.4%) people, 21 men (46.66%), and 24 women (53.33%), who were satisfied with the comfort during preparation; the VAS scores were 0–2 points. The patients felt no discomfort, or the discomfort was mild. There were 25 (55.55%) people over 60 years old in the first group.

The second group consisted of 39 (47.6%) patients, 16 men (41.0%) and 23 women (59%), and included 14 (35.9%) patients over 60 years old. They noted dissatisfaction with the preparation, the assessment of discomfort on the visual analogue scale was from 3 to 10 points. No statistically significant differences by age and sex were observed in the studied groups,  $p = 0.07$  and  $0.6$ .

The comfort of preparation equal to 0 points was noted by 23 (27.4%) people, 1 point – 15 (17.8%) patients, 2 points – by 7 (8.3%) people. There were 27 (32.1%) patients with the discomfort level of 3–6 points and 12 (14.3%) patients with the discomfort level of 7–10 points. The most common side effects were abdominal syndrome: pain and bloating in 23 (27.4%) people, dyspepsia in 22 (26.2%) patients, including nausea in 18 (21.4%) cases and vomiting in 4 (4.8%) patients. An increase in blood pressure was recorded in 13 (15.5%) patients.

Thus, adverse effects of Fortrans were registered in 58 (69.1%) cases. An increase in the frequency of adverse effects of Fortrans (abdominal pain, dyspeptic syndrome, and increased blood pressure) were statistically significant in patients with an unsatisfactory assessment of tolerance of the medication.

Non-adherence to the instructions for colonoscopy preparation was registered in 28 (33.3%) people (Table 1). In the group with satisfactory tolerance, 12 (26.7%) patients did not follow the preparation methodology, most frequently they noted non-compliance with the diet: 8 (17.8%) people. 16 patients (41.0%) who rated the bowel preparation process as unsatisfactory did not follow the doctor's instructions. The main violations were connected with a decrease in the volume of fluid taken: 11 (28.2%) patients. The differences in non-compliance with the amount of fluid taken were statistically significant ( $p = 0.044$ ) between the groups.

Table 1

Violations of Fortrans intake depending on the preparation tolerance, <i>n</i> (%)				
Parameter	Number of patients	Preparation tolerance		<i>p</i>
		satisfactory, <i>n</i> = 45	unsatisfactory, <i>n</i> = 39	
Non-compliance with the diet	13 (15.5)	8 (17.8)	5 (12.8)	0.531
Decreased fluid intake	15 (17.8)	4 (8.9)	11 (28.2)	0.044
Total	28 (33.3)	12 (26.7)	16 (41.0)	0.146

The number of violations made it possible to determine the compliance of patients for the entire cohort of the studied groups: 84.5% for diet violation and 82.2% for fluid intake. Among patients with satisfactory tolerance, compliance with treatment in terms of the volume of fluid drunk was 91.1%, in terms of adherence to a diet – 82.2%. In the group with unsatisfactory tolerance, compliance was 71.8% and 87.2%, respectively. The general compliance with treatment was 73.3% in the group with satisfactory preparation tolerance and 59% in the group with unsatisfactory preparation.

The results of assessing satisfaction with colon cleansing in patients with prior experience in preparation and those admitted to the department to remove previously detected polyps were significantly worse than in patients who underwent preparation with Fortrans for the first time, 7 (15.5%) and 38 (84.4%) patients, respectively,  $p = 0.001$ . Satisfac-

tory assessment of preparation tolerance among patients suffering from constipation was noted by 12 (26.6%) patients and unsatisfactory assessment – by 21 (53.8%) patients,  $p = 0.02$ . Out of 28 (33.3%) patients with higher and incomplete higher education, 19 (48.7%) people were not satisfied with the preparation, while 9 (20.0%) patients were satisfied,  $p = 0.01$ .

In the studied cohort, 47 (55.9%) patients had one-phase preparation, and 37 (44.1%) patients had two-phase preparation. The split (two-phase) method was preferred. The type of preparation process depended on the patient's ability to take medication in the morning. Assessment of satisfaction with preparation practically did not differ for both methods of colon cleansing. One-phase preparation was characterized as satisfactory by 53% of patients and unsatisfactory by 46% of patients, and two-phase preparation – by 51% and 48% of patients, respectively (Table 2).

Table 2

Adverse effects of Fortrans in various preparation methods, <i>n</i> (%)			
Symptom	One-phase preparation, <i>n</i> = 47	Two-phase preparation, <i>n</i> = 37	<i>p</i>
Abdominal syndrome	13 (27.6)	10 (27.0)	0.949
Dyspepsia	26 (33.9)	6 (16.2)	0.001
Nausea	13 (27.6)	5 (13.5)	0.112
Vomiting	3 (6.3)	1 (2.7)	0.432
Increased blood pressure	9 (19.4)	4 (10.8)	0.295
Total	38 (80.8)	20 (54.1)	0.009

Side effects of Fortrans were detected in 38 (80.8%) patients with one-phase colon preparation and in 20 patients with two-phase colon preparation (54.1%),  $p = 0.009$ . The main adverse effects during one-phase and split preparation were abdominal syndrome, the frequency of which was the same in both groups, 27.6% and 27.0%, respectively, and dyspepsia, whose appearance during split prepa-

ration was two times less frequent than in patients with one-phase preparation, 16.2% and 33.9%, respectively,  $p = 0.001$  (Table 2).

In one-phase preparation, 6 (12.76%) patients reported violation in adherence to the diet and 13 (27.65%) patients to the fluid intake. In split preparation, the same was noted by 7 (18.9%) and 2 (5.4%), patients respectively.

In one-phase preparation, compliance for adherence to the diet was 87.27%, compliance for the volume of fluid taken was 72.35%. In split preparation, the compliance was 81.9% and 94.6%, respectively. The groups with different preparation methods showed statistically significant differences in adherence to fluid intake,  $p = 0.009$ .

## DISCUSSION

The study is focused on the factors that could affect discomfort of patients when preparing for a colonoscopy with Fortans in various situations. They are closely related to such features as intolerance, dissatisfaction, and tolerance – terms that are close in meaning and are used interchangeably. Only a few studies have examined the topic of tolerance during colonoscopy, at the same time, one of the important criteria for assessing the quality of hospital work is patient satisfaction with the treatment [9]. The prevalence of poor tolerance of preparation, which, due to its discomfort, often exceeds the colonoscopy itself, makes the study relevant [10].

The study analyzing the level of discomfort when taking Fortans according to the VAS scale showed that 45 (52.4%) patients noted satisfactory tolerance of preparation. Patient satisfaction with Fortans is reflected in a few publications [11]. The research of S.G. Tereshchenko et al. (2013) studied the level of patient “non-burdensomeness” in preparing for colonoscopy with Fortans, and the obtained result was similar to our studies (55%) [11].

Thus, only slightly more than half of the patients who underwent Fortans colonoscopy preparation were satisfied with its quality. The study of Fortans side effects showed that in the general cohort of patients abdominal pain and bloating were reported by 23 (27.4%) patients. The published studies show significant differences in the incidence of abdominal pain with Fortans, from no pain to 52% [10, 11]. In the group with satisfactory tolerance, pain syndrome occurred in 6 patients (13.3%), and in the group with unsatisfactory tolerance, it was reported much more often, by 17 (43.6%) patients,  $p = 0.002$ . Abdominal pain during colon preparation according to V.M. Ussui et al. was a reliable reason for the patient’s refusal to undergo a second colonoscopy [9]. Dyspepsia was observed in 22 (26.9%) patients: in 1 (2.2%) patient with satisfactory tolerance of prepa-

ration and in 21 (53.8%) people with unsatisfactory tolerance of preparation,  $p = 0.001$ . The incidence of this syndrome for Fortans intake also has significant differences: from 12.9% to 96.4% [3, 10].

In our research, increased blood pressure was recorded in 13 (15.5%) patients: 3 (6.6%) patients with satisfactory tolerance and 10 (25.6%) patients with unsatisfactory tolerance,  $p = 0.037$ . There is a significant relationship between patient dissatisfaction with the preparation and adverse effects of taking the medication. The side effects are the reason for inadequate colon cleansing preparation. Non-adherence to the instructions during colon preparation with Fortans is not uncommon, which is confirmed by various studies [3, 5, 10, 11].

E.D. Fedorov et al., S.G. Tereshchenko et al. found out that 57.1 and 58% of patients, which is more than half of the studied patients, could not drink the entire intended volume of fluid [3, 11]. Due to the large volumes of fluid taken and the need for long-term adherence to the diet, the drugs of the Macrogol group are characterized by lower compliance of patients with prescriptions.

According to Fedorov E.D. et al. [3] and D.A. Svetyash [40], compliance in taking Fortans was 82% and 78%, respectively. In our study, compliance in taking Fortans with satisfactory tolerance was 73% and with unsatisfactory tolerance, it was 59%. There are studies confirming our results: the higher the assessment of satisfaction with the preparation, the greater the adherence to the drug taking, “the patient compliance is influenced by the level of their comfort, confidence and, satisfaction” [9].

Of all the factors that determine preparation tolerance to the chosen medication, the doctor can influence the colon cleansing results only by prescribing a method of its administration: one-phase or two-phase intake of a dose of the drug by the patient. The rest of the factors (demographic, social, clinical) are independent constants determined by patients themselves. Demographic characteristics (age, sex) did not have a significant effect on the preparation tolerance. Of the social factors, only higher education was a statistically significant sign of unsatisfactory tolerance of colon preparation ( $p = 0.01$ ). Adverse effects of Fortans, constipation and repeated colonoscopy were significant clinical features of dissatisfaction with the preparation for colonoscopy.

While examining tolerance to colonoscopy, S. Hazeldine et al. revealed that patients with repeated colonoscopy also significantly more often noted worse results on procedure tolerance on the VAS [13].

Adverse effects of Fortrans were observed in 38 (80.8%) patients with the one-phase preparation method, and in 20 (54.1%) patients with the split method,  $p = 0.009$  (Table 2). Similar results were obtained by other researchers [1]. At the same time, when comparing patient satisfaction in different methods of preparation, the results did not differ. Satisfaction with one-phase preparation was observed in 25 patients (53.1%) and with split preparation in 19 patients (51.3%). Dissatisfaction with the methods was detected in 22 (46.8%) and 18 (48.6%) patients, respectively. There was no difference which would indicate the beneficial impact of any preparation method on comfort of the procedure.

At the same time, the study of the Fortrans adverse effects in groups of patients with different methods of preparation showed their significant differences. In the one-phase method, the side effects were more frequent in comparison with the split method (Table 2). It would be logical to assume that frequent side effects of Fortrans in one-phase preparation method should lead to a decrease in the comfort score in this method of colon cleansing. However, it did not happen, as duration of split preparation, including sleep between phases, was more than 12 hours. There was no quality sleep due to the need to wake up early and take medication for the second time. Then patients had to arrive at the clinic on time and undergo the admission procedure, all this had to be done till 1–3 p.m. (the time of the colonoscopy with the split preparation method).

All nonresident patients risked being late for examination, which did not contribute to their psychological comfort, but, when assessing the tolerance, it was compensated for by less frequent side effects of Fortrans due to a decrease in its intake volume. At the same time, one-phase evening preparation, with its difficulties in taking 4 liters of liquid and high incidence of adverse drug effects, was more convenient for nonresident patients in terms of psychological comfort, which was facilitated by the absence of time pressure, which influenced the overall assessment of the preparation tolerance.

Ultimately, similar assessments of satisfaction with the preparation tolerance were obtained in the groups with one-phase and two-phase preparation for colonoscopy. T. Voiosu et al., using a 10-point visual analogue scale to assess patient satisfaction with the preparation for colon cleansing, also noted that there was no difference in the assessment of comfort depending on the preparation method [12]. L.A. Shafer et al. showed that awakening and taking medication early in the morning in 1/3 of patients preparing for a split colonoscopy caused a negative reaction, which affected the assessment of satisfaction with this preparation method [14].

Patient satisfaction with treatment was defined by M. Tierney et al. as “a multifaceted and individually dependent response with questionable validity” [8]. Analysis of the study results and literature data suggests that the preparation tolerance is not a direct reflection of the degree of adverse drug effects during colon cleansing, but is a multifactorial patient selfassessment of their condition, where the psychological component and its “doubtful validity” are equally important.

The psychological state is formed as a result of patient’s knowledge about the peculiarities of preparation, the need for it, the conditions of being in the clinic, and communication with medical personnel at all stages of preparation and colonoscopy. A lack of assessment of these parameters, understudied comparison of Fortrans tolerance with other medications used for colon cleansing, and single-center nature of the study are the weaknesses of this work.

## CONCLUSION

Satisfactory tolerance of colon preparation with Fortrans is observed in half of the patients. It significantly depends on the adverse effects of the drug, which are to a large extent mitigated by its split intake, and a number of unregulated features associated with characteristics of the patients, such as higher education, repeated colonoscopy, and constipation, which must be taken into account when planning colon cleansing.

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