

WHAT ARE THE MOST IMPORTANT FACTORS REGARDING ACCEPTANCE TO THE COLONOSCOPY?

Study of related tolerance parameters

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ABSTRACT – *Context* - Colonoscopy plays an indubitable role in the setting of clinical practice, however, it is an invasive exam; complex, lengthy, embarrassing, not devoid of risks and discomfort that yields fear and anxiety in the majority of patients. In a new era of rising competition between health institutions, where the quality of health care and client satisfaction are praised, studies regarding tolerance-related colonoscopy issues yield great potential to be explored. In the present study, tolerance is defined as willingness to repeat the exam. *Objectives* - Evaluate information associated to bowel preparation, the exam itself and post-examination period that might interfere with the tolerance to the colonoscopy. *Methods* - Analysis of the tolerance to the colonoscopy at three stages (pre, post, and during) through a checklist: patient's questionnaire and a medical assessment form were used. *Results* - In this present study, 91.2% of 373 patients exhibited positive tolerance to the colonoscopy. Aspects related to a negative level of tolerance were patient gender (12.9% of women versus 3.2% of men would not repeat the exam), age extremes (less than 20 years and greater than 80 years of age), and abdominal pain, both during the bowel preparation and after the procedure. *Conclusions* - Gender, age, patient cooperation and abdominal pain were the decisive components regarding tolerance to the colonoscopy. Notably, in two phases of the exam, the abdominal pain was the most important feature associated to a lessened tolerance.

HEADINGS – Colonoscopy. Patient satisfaction. Abdominal pain.

INTRODUCTION

Colonoscopy has become prominent as a remarkable diagnostic and therapeutic tool, with unique value in colorectal pathologies. Despite this pivotal role, it is recognized as an invasive procedure, yielding anxiety and discomfort, along with the risk of complications. Its ideal accomplishment requires proper technical capacity, adequate colon preparation⁽²⁷⁾ and patient cooperation in order to be considered successful, highly effective and accurate. Therefore, one must first consider and then meet the achievable criteria with respect to the quality of the examination. This can be determined by appropriate indication⁽²⁹⁾, adequate mucosa visibility, minimum discomfort and risk to the patient, low rate of complications and good patient cooperation⁽³⁾. Particularly at higher risk for complications⁽³¹⁾ are the elderly, patients with cardiopathies and thus more prone to desaturation, and those with poor tolerance regarding heart disease and arrhythmias.

Although previous studies on upper digestive en-

doscopies considered patient acceptance to repeating the examination as an indirect measurement of tolerance^(1, 9, 10, 21), few studies have explored the topic of tolerance in colonoscopy^(14, 28, 30).

Compliance to the medical treatment and practice is best attained through a contented patient. Tolerance is a key measure of this fulfillment, enabling such an intricate and subjective issue to be evaluated. Repeated medical visits with surveillance colonoscopies are necessary and critical in the follow-up of patients at higher risk for colorectal cancer, especially in cases of chronic inflammatory bowel disease⁽²⁸⁾. Patient compliance can be affected by the level of their comfort, confidence and satisfaction^(5, 19).

Patient cooperation during colonoscopy has such a considerable repercussion that his/her non-cooperation is considered an absolute contraindication for a colonoscopy⁽⁸⁾.

Likewise, low tolerance to colonoscopy was responsible for approximately 50% of incomplete examinations⁽¹⁵⁾.

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Currently, the assessment of health care quality with respect to satisfaction, and exceeding the client's expectation (patient) as an important marketing tool to attract new clients has become increasingly evident.

The aims of the current study were to evaluate information associated with bowel preparation, the exam itself and post-examination period that might interfere with overall tolerance to the colonoscopy.

METHODS

Study design and setting

Outpatients and inpatients undergoing elective colonoscopy were evaluated in this observational, prospective and longitudinal study, performed from March 2008 to December 2008, in a single-center tertiary teaching hospital (University of São Paulo School of Medicine, Diagnostic Center of Department of Gastroenterology, Clinical Division, Gastroenterology Branch). Patients received colon preparation either at the hospital or at home, with four tablets of bisacodyl by oral route and diet without residue (no fibers) on the day before the colonoscopy. On the day of the procedure, patients were given 500 mL (milliliter) of 20% mannitol solution and dimethicone orally.

Patient selection

The eligibility criteria for patient participation in the study were: 18 years of age or older, comprehension of the procedure and the interview (information regarding when and how the patients would be treated in our institution), and acceptance and agreement to participate in the study. The exclusion criteria included patients less than 18 years of age, insufficient comprehension about the interview or the procedure, denial to participate in the study, and emergency cases.

The present study was approved by the Ethics-Scientific Committee of the Department of Gastroenterology of the University of São Paulo School of Medicine and by the Ethics Committee for Analysis of Research Projects of the USP Clinics Hospital Board of Directors. The study conformed to the principles of the Declaration of Helsinki.

Free and informed consent for this study was obtained from all patients.

Assessment

The study assessed the tolerance of patients undergoing elective colonoscopy through the question: "Are you willing to undergo colonoscopy once more in the future, if necessary?"

The question was asked by the primary researcher after the end of the examination and recovery from sedation, immediately before discharge, on the same day, when the patients were awake and oriented, at least two hours after the procedure. This criterion was based on previously published studies, in order to prevent loss of data^(1, 9, 10, 21, 28, 30). Colonoscopies were performed by a team of 19 physicians, classified in 4 groups based on their experience: up to 2 years (57.8%); between 2 and 5 years (10.5%); between 5 and 10

years (10.5%); more than 10 years (21.2%). The presence of two physicians during the colonoscopy was mandatory; the attending colonoscopist, responsible for the procedure, and one assistant. All colonoscopies were performed with ambient air, since the usage of dioxide carbon is not a standard practice in our country and department, although very common in laparoscopic procedures.

Moderate and deep sedation were achieved when using midazolam and/or fentanyl, and propofol, respectively. The type of association and dosage was used at the discretion of the attending colonoscopist.

The main goal of this study was to prioritize the patients' features and demeanor with regard to their tolerance to the colonoscopy. Therefore, the dosage used from sedatives was explored to a lesser degree.

Relating to the equipment used, Olympus Optical video-colonoscopes were employed, including apparatus models CF-100 and CF-VL, image processor models CV-100 and CV-145, light source models CLV-100 and CLV-160.

The study assessed the patient at three different stages on the same day: 1) pre-examination (during colon preparation); 2) during the colonoscopy; 3) after the examination. Two types of questionnaires were implemented: a) Patient's questionnaire (filled out by the primary researcher, before and after the procedure); b) Medical Assessment Form (filled out by the primary researcher and the attending physician, immediately before and after the examination).

Comparison of results: Tolerance was correlated with the following items:

- a) **Items assessed before the examination:** demographic data, information about previous colonoscopy, explanation about the current examination by the requesting physician, level of anxiety (totally relaxed, relaxed, somewhat anxious, anxious, very anxious, extremely anxious), symptoms during colon preparation: colic, nausea and/or vomiting, dizziness and/or sweating, bloating, previous abdominal surgery and reason for the examination.
- b) **Items assessed during the examination:** type and dose of sedative, use of other medications, degree of difficulty to perform the examination, patient cooperation with the physician (from the physician's point of view), technical aspects (time to reach the cecum, intubation of terminal ileum, abdominal compression and/or change in decubitus) procedures performed (polypectomy, mucosectomy), quality of colon preparation (excellent, very good, regular, poor); complications (abdominal pain, nausea and/or vomiting, oxygen desaturation below 70%, phlebitis, lower gastrointestinal bleeding, intestinal perforation, incomplete examination) and requirement for another physician to complete the examination.
- c) **Items assessed after the examination:** presence and intensity of pain reported by the patient during the examination, patient level of satisfaction with the colonoscopist and overall level of satisfaction,

complications (abdominal pain and distension), and application of medication.

d) Statistical analysis

To analyze the qualitative variables, a Fisher's Exact Test or Chi-square Test was used to verify the association between them. To analyze the quantitative variables, Shapiro-Wilk's Test was used to verify normality. When normality was not rejected, the Student's *t* test was used to compare the means; when normality was rejected, Wilcoxon's test was used.

The multivariate analysis employed the model of logistic regression, including the qualitative variables statistically significant at the univariate analysis and those that were clinically relevant at the "Would you repeat the examination" assertion. After selecting the variables, the Backward technique was applied, based on Wald's test, which selected the most representative variables of the study. To verify the model adjustment, the Hosmer-Lemeshow test was used. *P* values <0.05 were considered statistically significant. All data analyses were conducted with a statistical software package SPSS (Statistical Package for the Social Sciences) Incorporated, Chicago, Illinois, USA.

RESULTS

Sample

Out of 409 total patients referred to colonoscopy, 373 were included in the study. Thirty-six patients were excluded,

TABLE 1. Patient demographic data

Patient characteristic	
Gender	number (%)
Female	217 (58.2)
Male	156 (41.8)
Total	373 (100)
Age, years, mean (±SD*)	57.28 (± 15.57)
Median	60
Categorized age	number (%)
<=20	5 (1.3)
21-40	54 (14.5)
41-60	135 (36.2)
61-80	166 (44.5)
>80	13 (3.5)
Total	373 (100)
Level of schooling	number (%)
None	18 (4.8%)
Literacy	16 (4.3%)
Elementary school	195 (52.3%)
High school	97 (26%)
College or university	42 (11.3%)
Post-graduation	4 (1.0%)
Not informed	1 (0.3%)

*SD, Standard deviation

either due to their lack of interest in participating in the study, or because of missing data during the collection. A majority of the patients (59.8%) had undergone the examination for the first time. Baseline demographic characteristics are summarized in Table 1.

The tolerance of colonoscopy was observed in 91.2% of the patients (n = 340) and not observed in 8.8% of them (n = 33), as shown in Figure 1.

The type and dose of sedatives used are summarized in Table 2.

Comparison of results

The comparison between tolerance and items assessed in the pre-examination period elicited the following statistically significant results, at the univariate analysis:

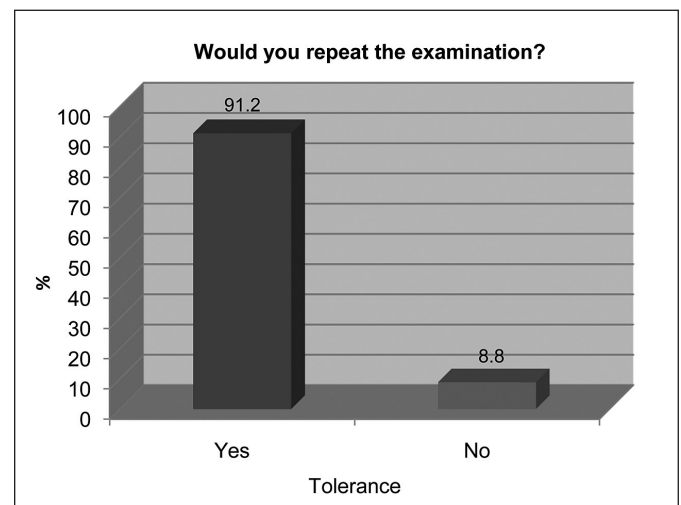


FIGURE 1. Tolerance to colonoscopy

TABLE 2. Type and dose of sedatives

Midazolam (mg)	
Up to 3	112 (30.5%)
3 to 5	228 (62.2%)
>5	27 (7.3%)
Total	367
Fentanyl (mcg)	
Up to 30	97 (28.1%)
30 to 50	237 (68.7%)
>50	11 (3.2%)
Total	345
Propofol (mg)	
Up to 30	40 (40.4%)
30 to 50	37 (37.4%)
>50	22 (22.2%)
Total	99

- a) Men were more tolerant than women ($P = 0.0013$) (Figure 2).
- b) The age range up to 20 years presented a level of tolerance of 60%, when compared to the age ranges of 21 to 40 and 41 to 60 years, which presented levels of tolerance greater than 90% ($P = 0.046$) (Figure 3).
- c) Patients who presented colic were less tolerant ($P = 0.0016$) (Figure 4).
- d) Patients that presented nausea and/or vomiting were less tolerant ($P = 0.0183$).

The following items did not show significance when compared with tolerance: level of schooling, ethnicity, marital

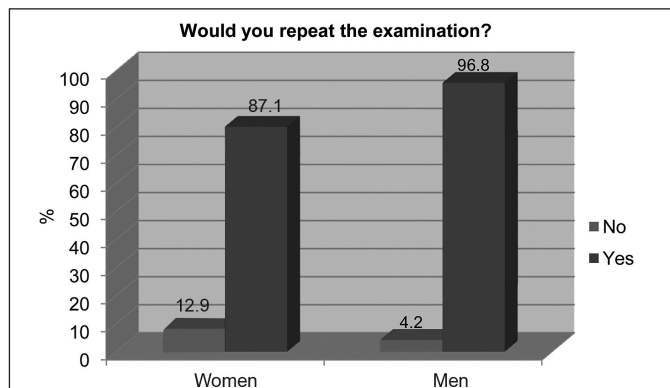


FIGURE 2. Level of tolerance according to gender

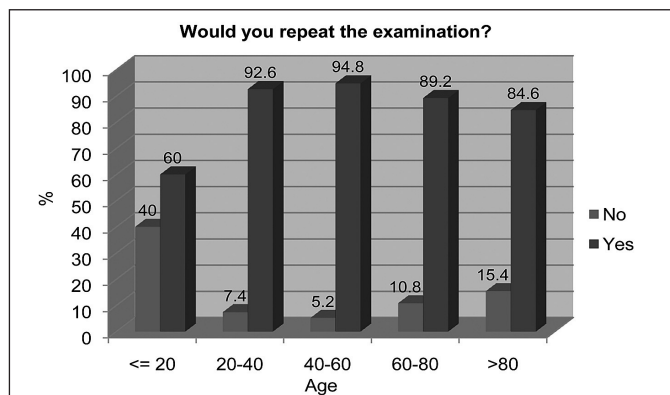


FIGURE 3. Level of tolerance according to age range

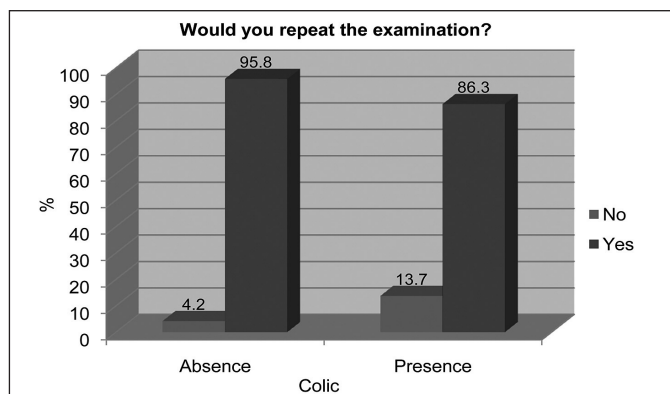


FIGURE 4. Level of tolerance and presence of pre-examination colic

status and various socio-economic features such as residency, wage range and occupation.

Considering the items assessed during the examination, the following were statistically significant at the univariate analysis:

- a) Individuals who experienced pain during the colonoscopy were less tolerant ($P = 0.013$).
- b) Patients that cooperated with the physician during the examination were more tolerant ($P = 0.0050$).
- c) Patients whose exams required an additional physician to complete their examination were less tolerant ($P = 0.0290$).

Considering the items assessed at the post-examination period, the following were statistically significant at the univariate analysis:

- a) Patients exhibiting higher levels of satisfaction with the physician, and overall satisfaction throughout the entire process (from initial scheduling to leaving the hospital) were more tolerant ($P = 0.0010$, $P = 0.0059$, respectively).
- b) Individuals that did not experience post-examination pain from the procedure were more tolerant ($P = 0.041$) (Figure 5).

Multivariate analysis

The items considered at the multivariate analysis are shown in Figure 6.

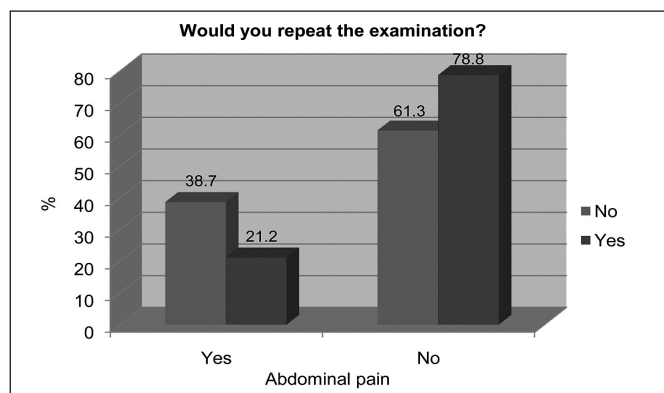


FIGURE 5. Level of tolerance and post-examination pain

1. Gender
2. Categorized age
3. Previous colonoscopy*
4. Nausea during colon preparation
5. Colic during colon preparation
6. Level of abdominal pain during examination
7. Patient cooperation during examination
8. Time until the end of examination*
9. Level of difficulty of the examination given by the physician*
10. Need for another physician to finish examination
11. Post-examination abdominal pain
12. Patient level of satisfaction with the physician
13. Patient overall level of satisfaction
14. Post-examination abdominal distension*
15. Sedation*

* Variables that were non-significant at the univariate analysis, included in the multivariate analysis due to clinical relevance.

FIGURE 6. Multivariate analysis

TABLE 3. Variables selected after the Backward technique

		P value	Odds Ratio	minimum CI	maximum CI
Categorized age (years)	<=20 *	0.057			
	21-40	0.016	32.727	1.919	558.220
	41-60	0.003	56.928	3.864	838.813
	61-80	0.026	17.124	1.412	207.671
	>80	0.059	23.882	.885	644.330
Gender	Female*	0.005	0.071	0.011	0.450
Colic during colon preparation	Presence*	0.013	0.200	0.056	0.713
Patient cooperation	Non-cooperative*	0.042			
	Cooperative	0.013	6.156	1.467	25.832
	Indifferent	0.078	6.373	0.811	50.085
Post-examination pain	Presence*	0.032	0.308	0.105	0.901
Level of overall satisfaction	Very poor*	0.034			
	Poor	1.000	0.000	0.000	
	Regular or indifferent	1.000	0.000	0.000	
	Good	1.000	0.000	0.000	
	Excellent	1.000	0.000	0.000	
Midazolam	Use*	0.056	1.491	0.990	2.246

* reference categories

After the Backward technique had been applied, the variables were selected and are shown in Table 3.

The statistically significant variables were: gender, categorized age, presence of colic during colon preparation, patient cooperation with the physician during the examination and post-examination abdominal pain.

On the other hand, the use of sedatives, regardless of dosage, type of drug, and type of association, did not impair the final outcome regarding tolerance.

DISCUSSION

Thorough scrutinization of the colonic mucosa, yielding an effective and highly accurate analysis, combined with minimal discomfort to the patient, comprise the ideal setting for a colonoscopy⁽³²⁾.

Multiple aspects engender the final outcome: medical indication for the examination, type and quality of the colon preparation, professionalism of the hospital staff involved, colonoscopist skillfulness, reasonable working conditions, and patient tolerance.

Tolerance is a complex and subjective concept, of which currently available factors and data remain controversial and insufficient for an adequate definition and assessment of endoscopic examinations. Previous studies in upper endoscopy (EGD) take into consideration the patients' willingness to repeat the examination as a parameter of tolerance^(1, 6, 9, 10, 21, 28). However, few colonoscopy studies have inquired about this topic^(6, 27, 28, 30).

A similar methodology to interview the patient on the same day of the examination was applied in a study by Hackett et al.⁽¹³⁾, in which a questionnaire was answered by patients under-

going EGD and sedated with IV (intravenous) midazolam, 20 minutes after the end of the examination. Likewise, Akerkar et al.⁽⁴⁾ compared tolerance in the setting of conventional and the virtual colonoscopy, by applying a questionnaire immediately before the patient's discharge from the hospital, on the same day as their procedure. Patients who underwent conventional colonoscopy were given midazolam, meperidine and droperidol. The assessment of tolerance on the same day, prior to hospital discharge, was also accomplished by Hazaldine et al.⁽¹⁴⁾. Sedation with both benzodiazepines and opioids was employed during endoscopic procedures. Finally, Ng Ju-Mei et al.⁽²⁵⁾ evaluated pain related to the colonoscopy 30 minutes after the end of the examination, in patients sedated with midazolam or propofol.

In this study, the majority of patients (91.2%) agreed to undergo additional colonoscopy if medical requirements applied. Similar observation was made in a study by Chartier et al.⁽⁴⁾ and Radaelli et al.⁽²⁸⁾; a systematic review about satisfaction in colonoscopy and a study with colonoscopies under sedation (90.9%), respectively. On the other hand, 67% of the patients were willing to repeat the colonoscopy in the study conducted by Condon et al.⁽⁶⁾.

Although it is widely recognized that pain and tolerance are better assessed by means of a validated visual analogue scale, an unsuccessful attempt to use this scale ensued. Complexity of the scale possibly limited its applicability. Therefore, a simpler questionnaire, which provided more explicit choices, was employed.

Gender

Gender proved to be a statistically significant variable at the univariate and multivariate analyses. Despite the fact that

many previous studies have shown the female sex to be less tolerant^(4, 10, 11, 20, 30); no consensus in the literature has been firmly established to date^(1, 22, 24, 26).

Longer colon, particularly the transverse, which predisposes to a more convoluted sigmoid colon, associated with acute angles due to the narrower pelvic cavity, combine to result in a more difficult procedure in women^(30, 32). Although not evaluated and not significant in the present study, lower pain threshold⁽³⁰⁾ and previous pelvic surgery might also play important roles, respectively. Additionally, cultural concerns and personal issues are expected restrictions for women.

Age

Categorized age was statistically significant in both univariate and multivariate analyses.

The group of younger patients, in the range of 18 to 20 years was the least tolerant of all, whereas patients in the range of 21 to 40 and 41 to 60 years were more tolerant when compared with the first group. Mulcahy et al.⁽²⁵⁾ previously stated that the youngest individuals were the least tolerant.

A study performed by Ristikankare et al.⁽³⁰⁾ showed that the older patients undergoing colonoscopy were more tolerant. Decrease in visceral pain with age⁽¹⁸⁾ can be a plausible explanation why older patients tolerate more. Conversely, a more fixed mesocolon in younger patients might cause more pain and less tolerance for that particular age group⁽³¹⁾.

Higher tolerance with age was gradually observed until 60 years old. Patients above this age showed a decrease in tolerance, when compared to individuals in the range of 21 to 60 years. Potential interpretations are: need for a prolonged colon preparation time, impaired clinical status, higher susceptibility to dehydration and hydro electrolytic disorders⁽²⁾, in addition to increased comorbidities. Furthermore, elderly patients might present a higher degree of psychological difficulty to accept the procedure in general.

Patient cooperation during the examination

Based on studies from Ristikankare et al.⁽³⁰⁾ and DiPalma et al.⁽⁷⁾ in which patient cooperation is listed as one of the aspects of tolerance, our study classifies it (patient cooperation) into three groups (cooperative, non-cooperative and indifferent). The first author evaluated the effects of age and gender concerning tolerance of patients undergoing colonoscopy. The second author performed a study using alfentanil in colonoscopy, considering the following as tolerance factors: procedure facilitation, muscle relaxation, pain, and tolerance itself. In our study, patient cooperation, analyzed from the colonoscopist perspective, was significant at the univariate and multivariate analyses.

Abdominal pain and colic

Presence of abdominal pain during and after the colonoscopy was assessed 2 hours after the procedure, before patients' discharge from the hospital. Patients were given five alternatives to choose from regarding the level of pain during the procedure: nothing, little, medium, very much, extremely; and were allowed to select just one.

The presence of pain during and after the examination showed to be statistically significant at the univariate analysis. However, at the multivariate analysis, only post-examination pain was significant. Prior study supports that pain is the most important feature with regard to procedure acceptability, and yet another author⁽⁴⁾ considered pain and tolerance as the same variable⁽¹¹⁾.

The 30-minute analgesic effect of fentanyl⁽²⁷⁾, along with its half-life of 2 to 4 hours, foster the explanation of the statistical significance of post-examination pain in contrast with the non-significance of the pain experienced during the procedure.

As a result of this optimal window of action, it was expected that the effectiveness of fentanyl be better observed in the periods close to its administration. Longer procedures by themselves did not necessarily imply less tolerance, stressing how relevant the pain is when it comes to evaluating tolerance. Since tablets of bisacodyl were taken one day before the procedure, the association with abdominal pain is very unlikely.

Regarding colon preparation, the standard method utilized in our endoscopy unit includes mannitol, either the day before or the day of the colonoscopy. Although one of the major concerns about mannitol is the risk of gas explosion, its use in our country has been seen as very safe and provides an ultimate bowel cleansing.

Some previous perspectives should be taken into consideration, such as a review by Ladas et al.⁽¹⁶⁾, in which the inadequate quality of bowel preparation and the presence of stools are vital in cases of colonic explosion. Moreover, insufflation of air during colonoscopy standardizes the distribution of combustible gases. A total of 20 cases of colonic gas explosion have been reported. Eleven cases of gas explosion during surgery and nine cases during colonoscopic procedures have been published. Argon plasma coagulation provided the initiating heat source in five of the nine colonoscopic cases whereas the remaining four cases were associated with endoscopic polypectomy⁽¹⁶⁾. Therefore, risk of colonic explosion depends not only on the type of bowel preparation, but also on the presence of stools in the colon and therapeutic procedures.

LIMITATIONS

Questioning reasons why the patient would not repeat the examination could have contributed to a better understanding of tolerance.

Although more detailed information about sedatives, such as prior use of anxiolytics and anti-depressive agents would help correlate patient behavior and tolerance, it was not the aim of this study to scrutinize this topic.

The varied degree of skill wielded by the colonoscopists, the inclusion of outpatients and inpatients undergoing colorectal surgery and the heterogeneity of the sedative drugs made the sample more heterogeneous, albeit more representative of clinical practice.

As abdominal pain was the only significant complication

observed, this might have limited the analysis since it is expected that complications decrease patient tolerance.

FINAL CONSIDERATIONS

The “Second European Symposium on Ethics in Gastroenterology and Digestive Endoscopy” carried out in Greece in 2006, highlights the importance of patient satisfaction with endoscopy. In this symposium, tolerability of the endoscopy is considered as one of the seven possible items of satisfaction. By referencing the tolerability of the procedure as an important aspect for attaining healthcare excellence⁽¹⁷⁾, the inclusion of ‘tolerance’ in the list of indicators of quality in endoscopic examinations can be considered. As a validation of this proposal, Gonzales-Huix Llado F et al.⁽¹²⁾ published a study that values tolerance as one characteristic of quality in colonoscopy.

Some alternatives in the improvement of healthcare quality can prove to be valuable: more detailed explanations given by the colonoscopists to the patients; preventing less experienced physicians to examine less tolerant patients; thorough discussion about the reason for colonoscopy in patients older than 80 years who had never been through an examination before.

Patients that present colic with mannitol who also need to repeat the colonoscopy are strong candidates for using a different method of colon preparation. Post-examination abdominal pain is often caused by the presence of remaining air in the colon due to the repeated insufflations throughout the examination. By adopting a routine measure to remove this air, one can contribute to the minimization of abdominal pain.

This study largely contributed to a better understanding of tolerance and colonoscopy, outlining in greater extent a tolerant and non-tolerant patient’s profile; hence, improving the routine medical practice, particularly since few studies have been published to date on this subject.

CONCLUSIONS

In the present study we observed tolerance to the colonoscopy in 91.2% of the 373 patients. Gender, age, patient cooperation and abdominal pain were the decisive components regarding tolerance to the colonoscopy. Notably, in two phases of the exam, the abdominal pain was the most important feature associated with a lessened tolerance.

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RESUMO – *Contexto* - É inquestionável o papel da colonoscopia na prática clínica, entretanto, trata-se de exame invasivo, complexo, demorado, impudico, não isento de riscos e desconforto, que gera receio e ansiedade à maioria dos pacientes. Em uma nova época de elevada competição entre instituições de saúde, na qual se valoriza a qualidade dos serviços prestados e satisfação dos clientes, estudos sobre fatores relacionados a tolerância à colonoscopia oferecem grande potencial a ser explorado. No presente estudo considerou-se tolerância a disposição de repetir o exame. *Objetivo* - Analisar informações relacionados ao preparo, exame e pós exame que interferem na tolerância à colonoscopia. *Métodos* - Análise da tolerância à colonoscopia em três momentos da colonoscopia (pré, pós e durante) através de check list: “formulário do paciente” e “ficha de avaliação médica”. *Resultados* - No presente estudo 91.2% de 373 pacientes apresentaram tolerância positiva à colonoscopia. Os fatores relacionados à tolerância negativa foram o sexo feminino (12.9% mulheres and 3.2% dos homens não repetiriam o exame), extremos de idade (<20 anos e >80 anos) e dor abdominal durante o preparo intestinal e após o procedimento. *Conclusões* - Gênero, idade, cooperação do paciente e dor abdominal foram fatores determinantes da tolerância à colonoscopia. Significativa em duas fases do exame, a dor abdominal foi o fator mais importante relacionado à redução da tolerância.

DESCRIPTORES – Colonoscopia. Satisfação do paciente. Dor abdominal.

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