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Research Article

Evaluation of the Quality of Informed Consent in Candidate Patients for Endoscopy and Colonoscopy

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Abstract

Background: Given the large number of patients undergoing endoscopy and colonoscopy, the quality of obtaining informed consent and providing accurate, balanced information is crucial for ensuring patient cooperation and informed decision-making. Patients should be provided with comprehensive information about the necessity, benefits, risks, disadvantages, feasibility, alternative methods, and detailed explanations of the procedures.

Objectives: With this in mind, our study aimed to evaluate the quality of informed consent among patients undergoing endoscopy and colonoscopy in Rasht.

Methods: This research was conducted as a descriptive cross-sectional study. The study was performed on patients who were candidates for endoscopy and colonoscopy in Rasht during 2022. A total of 174 patients were examined. Participants were selected using a stratified sampling method. Data were collected through standardized questionnaires and trained interviewers. The collected data were coded and analyzed using SPSS version 22. Descriptive statistics, including mean and standard deviation for quantitative variables and number and percentage for qualitative variables, were used. For inferential analysis, Pearson's correlation test was applied for normally distributed variables, while Spearman's test was used for non-normal distributions. A significance level of $P < 0.05$ was considered.

Results: This study assessed the quality of informed consent among 174 patients undergoing endoscopy and colonoscopy, with an average age of 49.07 ± 15.27 years (50.6% male, 49.4% female). The majority (55.2%) scored in the "average" category for overall informed consent quality, with an average score of 19.98 ± 6.53. Age was negatively correlated with consent quality ($r = -0.248$, $P < 0.001$), while gender showed no significant effect ($P = 0.844$). Education level significantly influenced scores ($P = 0.003$), with higher scores among university graduates compared to illiterate participants. Physician-patient interaction scores averaged 7.83 ± 3.28, with no significant correlation to age or gender but a significant association with education level ($P = 0.044$).

Conclusions: According to the results of the study, it seems that the quality of obtaining consent for endoscopic and colonoscopy procedures for the purpose of diagnosis and treatment decreases significantly with increasing age and low level of education. These patients consent to perform these procedures with less knowledge. The low level of voluntary endoscopy and colonoscopy and its relationship with the factors of age, education, providing information to the patient, and interaction with the attending physician can indicate the need to provide more and more appropriate information about the reasons for performing these measures in order to cooperate and achieve patient satisfaction.

Keywords: Informed Consent, Endoscopy, Colonoscopy

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1. Background

The necessity of performing medical procedures is a crucial topic in medical ethics, as it directly impacts patient care and outcomes (1, 2). In today's healthcare landscape, patients seek to be involved in their healthcare decisions. By following the principles of obtaining results, health providers not only create stronger relationships between patients and providers but can also fulfill their ethics (3). The need to declare consent before treatment is recognized as one of the obvious and legal rights of patients (4). The doctor is obliged to provide the patient with the necessary information about the diagnostic and treatment measures explicitly, clearly, and accurately, and to discuss the effects of treatment complications and appropriate treatment methods, mentioning the benefits and risks of each. The use of complex medical terms and ambiguous words should be avoided as much as possible, and easy understanding should be provided to the patient by methods such as choosing simpler words, shorter sentences, and a more active voice (5). Physicians should allow the patient to use their own judgment while providing the necessary information. The digestive department is also one of the departments that requires informed consent to perform diagnostic and therapeutic procedures (1). Among the important procedures in this section, we can mention colonoscopy and endoscopy. Colonoscopy is one of the procedures that allows direct observation of the large intestine (6, 7). This procedure has many diagnostic benefits and therapeutic applications, and at the same time, it is expensive, uncomfortable, and stressful for most patients (7). Anxiety, fear, worry, and malaise of some patients are among the challenges of informed consent (8). Anxiety may be due to lack of information about the procedure or fear of discomfort and pain during it (9, 10). In fact, colonoscopy may cause anxiety that ultimately leads to the patient avoiding the procedure and reducing their satisfaction (11, 12). Although colonoscopy is considered relatively safe, it can cause complications such as bleeding or perforation, especially in elderly patients and patients with inflammatory bowel disease. Physicians should fully explain the possibility of complications such as perforation to patients before colonoscopy and obtain informed consent (12-14). Upper gastrointestinal tract endoscopy is currently the diagnostic method of choice in many gastrointestinal diseases. This technique is relatively safe, with a mortality rate of 0.03%. The problem with this method is that the patient is more worried and stressed during the procedure because the patient is fully awake during the procedure (7). The necessity of obtaining informed consent is a fundamental aspect of medical ethics and legal rights, ensuring that patients are fully informed about diagnostic and therapeutic procedures. Procedures like endoscopy and colonoscopy, commonly performed in gastroenterology, require comprehensive informed consent due to their diagnostic benefits, potential risks (e.g., bleeding, perforation), and the anxiety they may cause among patients. Despite the importance of informed consent, no prior studies have specifically evaluated the quality of consent obtained for these procedures in Rasht. This study addresses this gap by investigating the quality of informed consent and exploring factors such as age, gender, education level, and physician-patient interaction that may influence it.

2. Objectives

The primary objective of this study is to evaluate the quality of informed consent among patients undergoing endoscopy and colonoscopy in Rasht in 2022. Specifically, the study aims to: (1) Assess the overall quality of informed consent across four domains: Providing information, comprehensibility of consent forms, voluntariness, and physician-patient interaction; (2) examine correlations between patient demographics (age, gender, education level) and the quality of informed consent.

3. Methods

This research was conducted as a descriptive cross-sectional study. The study was performed on patients who were candidates for endoscopy and colonoscopy in Rasht during 2022. A total of 174 patients were examined. Sampling was done by classifying individuals based on private and public centers in Rasht. Patients who were candidates for colonoscopy and endoscopy and consented to participate in the study were included, while those who did not wish to participate were excluded. Data collection was carried out by the patient's physician, who provided a questionnaire to the candidates and requested that they complete it. In case of any ambiguity, the interviewer would explain the questions. The interviewer obtained consent from the participants and assured them that their information would remain confidential. The purpose and method of the study were explained to the participants, and no identifying information was recorded in adherence to ethical principles. The questionnaire used in this study was previously utilized by Sheikhtaheri and Farzandipour on patients undergoing surgery (15). The

Content Validity Index (CVI) of the questionnaire was 0.9, and its content validity ratio (CVR) was 0.8. The reliability of this study was determined by Cronbach's alpha test after completion by 35 individuals who visited intervention centers for colonoscopy in Rasht, resulting in a reliability score of 0.87. The study's questionnaire included 20 questions across four domains: Seven questions related to “providing information regarding consent,” two questions on the “comprehensibility of the consent form,” four questions on “voluntariness,” and seven questions concerning the “interaction between the physician and the patient.” Each question was scored between zero and two, with a score of 2 for "yes," 1 for "somewhat," and 0 for "no." Unanswered or "I don't remember" responses were not scored, resulting in a total questionnaire score ranging from 0 to 40. Scores for specific domains were as follows: Providing information (0 - 18), physician-patient interaction (0 - 14), comprehensibility of the consent form (0 - 4), and voluntariness (0 - 8). Scores below 25%, between 25 - 50%, between 50 - 75%, and above 75% were categorized as “poor,” “average,” “good,” and “excellent,” respectively.

The data obtained from the research were coded and entered into SPSS version 22. Quantitative variables were described using mean and standard deviation, while qualitative variables were described using frequency and percentage. To assess the relationship between variables, Pearson’s correlation test was used for normally distributed variables, and Spearman’s test was used for non-normally distributed variables. A significance level of less than 0.05 was considered significant ($P < 0.05$). The study received approval from the university's ethics committee prior to implementation.

3.1. Ethical Approval

The research conducted in this study adhered to the principles outlined in the Declaration of Helsinki and was approved by the Ethics Committee of Guilan University of Medical Sciences (ethical code No. IR.GUMS.REC.1401.100). The authors have fully complied with ethical issues, such as plagiarism, data fabrication, and double publication.

4. Results

The average age of the participants in the study was 49.07 ± 15.27 years, with the youngest patient being 25 years old and the oldest 89 years old. Among the participants, 50.6% were male and 49.4% were female, with 88 males and 86 females in total. The participants were categorized based on their education levels into three groups: Illiterate (39 people, 22.4%), high school graduates (76 people, 43.7%), and university graduates (59 people, 33.9%).

The analysis of the quality scores of informed consent among patients undergoing endoscopy and colonoscopy showed that 5.2% of participants fell into the "poor" category, 55.2% in the "average" category, 31.6% in the "good" category, and 8% in the "excellent" category. The average quality score of informed consent was 19.98 ± 6.53, with the minimum score being 4 and the maximum 37. The highest frequency was in the "average" category, while the lowest frequency was in the "poor" category. The results indicated an inverse and significant correlation between the quality score of informed consent and the patient's age. As patients got older, their scores on this criterion decreased ($r = -0.248$, $P < 0.001$).

The average quality score of informed consent among men was 20.08 ± 7, and among women, it was 19.88 ± 6.06. The test statistic was 0.20, and the significance level was 0.844, indicating no significant correlation between gender and the quality of informed consent. However, there was a significant correlation between education level and the score on this criterion ($P = 0.003$), with a test statistic of 6.01. The average quality scores of informed consent among illiterate participants, high school graduates, and university graduates were 21.93 ± 6.84, 19.79 ± 6.06, and 17.41 ± 6.13, respectively. Pairwise comparisons using Tukey’s test revealed that the average score of university graduates was significantly higher than that of illiterate participants ($P = 0.002$).

Another goal of the study was to determine the correlation between the average score for providing information to patients and variables such as age, gender, and education level. The results indicated that 6.3% of participants were in the "poor" category, 48.9% in the "average" category, 32.2% in the "good" category, and 12.6% in the "excellent" category. The average score for providing information was 7.31 ± 2.77, with a minimum score of 0 and a maximum of 13. The results showed that older participants received lower scores for providing information. There was a significant inverse correlation between the patient's age and the score on this criterion ($r = -0.279$, $P < 0.001$). In contrast, no significant correlation was found between gender and the score for providing information. The average score for providing information among men was 7.35 ± 2.8, and among women, it was 7.27 ± 2.66, with a test statistic of 0.20 and a significance level of 0.841. There was a significant correlation between education level and the score for providing information, with a significance level of less than 0.001 and a test statistic of 14.91. The scores for

providing information among illiterate participants, high school graduates, and university graduates were 8.75 ± 2.71, 6.82 ± 2.46, and 6.10 ± 2.56, respectively. Pairwise comparisons using Tukey's test revealed that the average score for this criterion was significantly higher among university graduates compared to high school graduates ($P < 0.001$) and illiterate participants ($P < 0.001$).

Now, let's look at the scores for the comprehensibility of the consent forms among patients undergoing endoscopy and colonoscopy, and then examine the relationship between these scores and variables such as age, gender, and education level. The results show that 4% of participants were in the "poor" category, 17.8% in the "average" category, 16.1% in the "good" category, and 62.1% in the "excellent" category. The average score for comprehensibility of the consent forms was 3.31 ± 1, with the minimum score being 0 and the maximum 4.

The results indicate that there was a significant and direct correlation between the patient's age and the comprehensibility score ($r = 0.170$, $P = 0.025$). However, in contrast to age, no significant relationship was found between gender and the comprehensibility score. The average score for comprehensibility was 3.29 ± 1.05 among men and 3.36 ± 0.98 among women. The test statistic was 0.42, and the significance level was 0.674. The results also revealed a significant correlation between the comprehensibility score and education level ($P = 0.030$). Pairwise comparisons using the Games-Howell test showed that the average score among illiterate participants was significantly higher than among high school graduates ($P = 0.030$) and university graduates ($P = 0.005$).

Another objective of our study was to assess the correlation between age, education level, and gender with the average score for voluntariness in obtaining consent from patients. The results demonstrated a significant inverse correlation between the voluntariness score and the patient's age ($r = -0.200$, $P = 0.008$), indicating that as age increased, the voluntariness score decreased. On the other hand, no significant relationship was found between gender and the voluntariness score, with a significance level of 0.455 and a test statistic of 0.75. The average voluntariness score was 2.06 ± 1.39 among women and 1.98 ± 1.62 among men. Moreover, the results indicated a significant correlation between education level and the voluntariness score ($P < 0.001$). Pairwise comparisons using the Games-Howell test showed that the average score among university graduates was significantly higher than among illiterate participants ($P < 0.001$) and high school graduates ($P = 0.019$).

The results also showed that when examining the voluntariness score for obtaining consent from patients, a very high frequency of participants (140 people, 80.5%) fell into the "poor" category. The frequencies for the other categories were as follows: "Average" (12 people, 6.9%), "good" (17 people, 9.8%), and "excellent" (5 people, 2.9%). The average voluntariness score was 2.02 ± 1.51, with a minimum score of 0 and a maximum of 8.

When analyzing the physician-patient interaction score, the highest frequency was in the "average" category (75 people, 43.1%). The average score for this criterion was 7.83 ± 3.28, with a minimum score of 0 and a maximum of 14. The frequencies for the other categories were as follows: "Poor" (13 people, 7.5%), "Good" (47 people, 27%), and "excellent" (39 people, 22.4%).

This study also examined the relationship between the physician-patient interaction score and variables such as age, education level, and gender. The results indicated no significant relationship between the patient's age and the physician-patient interaction score, with a significance level of $P = 0.124$ and $r = 0.17$. Similarly, no significant relationship was found between gender and the physician-patient interaction score ($P = 0.914$). The average score was 7.81 ± 3.53 among men and 7.86 ± 3.02 among women, with a test statistic of 0.11. In contrast to age and gender, there was a significant correlation between education level and the physician-patient interaction score ($P = 0.044$), with a test statistic of 3.19. The average score for this criterion was 6.82 ± 2.75 among illiterate participants and 8.42 ± 3.4 and 7.75 ± 3.22 among high school graduates and university graduates, respectively. Pairwise comparisons using Tukey's test revealed that the average score among high school graduates was significantly higher than among illiterate participants ($P = 0.034$).

5. Discussion

The goal of obtaining informed consent from patients undergoing endoscopy and colonoscopy is to assist patients in making the best possible decision. Providing complete and balanced information not only increases the patient's awareness but also does not negatively affect their anxiety. It is the physician's responsibility to inform the patient about their illness and treatment, and treatment without the patient's consent can have legal consequences (6, 7). The quality of obtaining informed consent is related to patient cooperation and accurate decision-making, and providing information tailored to the patient's age, education level, gender, and socio-economic conditions is important.

This study aimed to evaluate the quality of informed consent among patients undergoing endoscopy and colonoscopy in Rasht, focusing on the impact of age, gender, and education level. The findings reveal a concerning trend: A significant portion of patients (55.2%) falls into the "average" category for overall informed consent quality, indicating a need for improvement in the informed consent process. Only a small fraction of patients (8%) achieved an "excellent" rating, suggesting that optimal informed consent practices are not consistently implemented.

The data and results of this study were compared with a similar study. A 2009 study by Amini et al. aimed to assess the level of informed consent obtained from hospitalized patients in selected hospitals of Tehran University of Medical Sciences (16). The results showed that patients' understanding of the information provided to them, the amount of information they had when making decisions and giving consent, and the overall level of informed consent in selected hospitals were at an undesirable and inappropriate level. Furthermore, the level of informed consent varied significantly according to patients' marital status, education level, and the wards in which they were hospitalized.

The current study identified a significant inverse correlation between age and the quality of informed consent. This finding was similar to the results of previous studies (17-19). As age increased, patients' scores on informed consent quality decreased. This could be attributed to various factors, including cognitive decline, communication barriers, or a perception among healthcare providers that older patients may be less capable of understanding complex medical information. Strategies to enhance comprehension among older patients, such as using simpler language, visual aids, and involving family members, may be beneficial.

While gender did not significantly correlate with overall informed consent quality, education level played a crucial role. Lower education levels were associated with poorer comprehension. Illiterate participants had the lowest average scores for providing information and voluntariness. Interestingly, they had higher scores for comprehensibility of consent forms, possibly indicating a more straightforward approach to the consent process for this group, although it may not equate to better understanding. University graduates scored significantly higher than illiterate participants in voluntariness and the overall quality of information provided, underscoring the importance of education in understanding and actively participating in healthcare decisions. In this regard, reviews of literature demonstrate that lower health literacy (often correlated with lower education) is associated with poorer understanding of medical information and lower rates of informed consent (20-23). This suggests that education plays a significant role in patients' understanding of provided information, affecting the overall informed consent process.

The consistently low scores observed in the "voluntariness" domain are particularly alarming, with over 80% of participants categorized as "poor." This raises serious concerns about the extent to which patients feel autonomous in their decision-making process regarding these procedures. This may indicate subtle coercion, perceived pressure from healthcare providers, or a lack of awareness of their right to refuse the procedure. Further qualitative research is needed to explore the factors contributing to this low sense of voluntariness.

Finally, a significant correlation was observed between education level and the physician-patient interaction score, as well as the correlation between age, education level, and gender with the average score for voluntariness. This can affect the patient's ability to effectively communicate and understand the treatment recommendations, with high school graduates scoring significantly higher than illiterate participants. This highlights the need for healthcare providers to tailor their communication strategies to patients' educational backgrounds to foster better engagement and satisfaction.

The strengths of this study are that it assesses multiple dimensions of informed consent, including providing information, comprehensibility of consent forms, voluntariness, and physician-patient interaction, offering a thorough understanding of the quality of informed consent. The limitations of this study include the following: The study's cross-sectional nature limits its ability to establish causality or assess changes over time. Also, as this study was conducted in Rasht, the findings may not be generalizable to other regions or countries with different healthcare systems or cultural contexts. Despite stratified sampling, certain subgroups within the population may not be fully represented, particularly those with limited access to healthcare services.

5.1. Conclusions

The results of that study showed that the level of participation in clinical decision-making and the interaction between physicians and patients was moderate. The study highlighted the need for strategies

to enhance patients' knowledge and make the comprehension of consent forms easier. Furthermore, the study demonstrated that the comprehensibility of consent forms significantly decreased with age, and there was a significant correlation between education level and the average score of participants, with educated individuals scoring higher than illiterate ones. The quality of obtaining informed consent for endoscopy and colonoscopy was shown to decrease with increasing age and lower education levels. Patients with less knowledge of these procedures had lower levels of consent satisfaction. Given the subjective nature of the current questionnaire, further studies using different questionnaires are recommended. Moreover, it is suggested that sufficient and balanced information be provided to patients before performing these procedures, tailored to their education level and age. Methods such as improved communication with physicians, educational brochures, and audiovisual training are recommended to enhance patient satisfaction.

Footnotes

Authors' Contribution: Conceptualization: S. B. and K. D.; Data curation: M. S. and M. Z.; Formal analysis: G. S.; Investigation: H. B; Methodology: S. B. and K. D.; Project administration: Z. K., S. B., and K. D.; Supervision: S. B. and K. D.; Validation, visualization, and writing–original draft: K. D.; Writing–review and editing: Z. K.

Conflict of Interests Statement: The authors declare that they have no competing interests.

Data Availability: The dataset presented in the study is available on request from the corresponding author during submission or after its publication. The data are not publicly available due to confidentiality of patient information.

Ethical Approval: The research conducted in this study adhered to the principles outlined in the Declaration of Helsinki and was approved by the Ethics Committee of Guilan University of Medical Sciences (ethical code No. IR.GUMS.REC.1401.100). The authors have fully complied with ethical issues, such as plagiarism, data fabrication, and double publication.

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Informed Consent: Written informed consent was obtained from the participants.

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