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How sedation used prior to gastrointestinal endoscopies affects patients' anxiety level for future procedures

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ABSTRACT

Aim: The application of sedoanalgesia during gastrointestinal endoscopic procedures increases the success of the procedure as well as patient comfort and safety. The aims of this study are to investigate the anxiety levels of patients and potential early complications who practised sedoanalgesia in gastrointestinal endoscopic procedures before and two days after.

Material and Method: The study was designed as a prospective, randomized, single-centre clinical trial. Patients over the age of 18 and had American Society of Anaesthesiology (ASA) physical status score 1-3 who were practised elective gastrointestinal endoscopy, between April 2022 and September 2022 were included to the study. The patients who refused to participate, were above ASA 3, and were illiterate, had an Ejection Fraction <30%, and had a diagnosis and treatment of psychiatric disease were excluded from the study. Informed consent obtained from all patients. Anxiety levels of the patients were evaluated with Beck Anxiety Inventory (BAI). Hemodynamic changes, blood test results were recorded and compared before and after the procedure.

Results: One hundred four patients included to the study with the age of 23 to 79. Preoperative and postoperative BAI scores were found statistically significant ($p<0.05$). The patients' satisfactions have seen very high after procedure. The complications have seen on 7 (%6.7) patients. All of the complications were due to nature of the procedure as epistaxis/mucosal trauma (n=3), equipment damage(n=4). There have been no serious or life-threatening complications during procedures.

Conclusion: Reducing anxiety by anaesthesia, patients will be more efficiently persuaded to execute endoscopy and by thus early diagnosis can be achieved. Patients who have undergone an endoscopy procedure while sedated have significantly fewer concerns about the future. This may increase the procedure's chances of success every time.

Keywords: Endoscopy, anaesthesia, anxiety

INTRODUCTION

Patients usually feel anxiousness during medical procedures. Unfamiliar invasive interventions, such as endoscopy, induce anxiety and fear in patients. Anxiety is a state of fear and worry that develops in response to any stimulus (1). Depending on the surgical or interventional procedure, preoperative anxiety, worry, fear and feeling of unease may develop in patients. Reducing anxiety boosts the patient's and physician's comfort throughout the procedure and the intervention's success. Thus, while the success rate of the technique increases, patients are spared from undergoing the same intervention multiple times (2).

The use of sedation in gastroenterological endoscopy has become an integral part of standard therapeutic therapy (2). Sedatives decrease anxiety and pain during trans anal endoscopy, increase patient satisfaction, and enhance examination/treatment performance (3). Also, numerous studies have demonstrated the efficacy of sedation during trans oral endoscopic examinations from the patient's perspective, and meta-analyses have demonstrated the same results (4-6). On the other hand, research suggests that the incidence of adverse outcomes, such as aspiration pneumonia, is higher during trans anal endoscopic examinations performed under general anaesthesia or anesthetic assistance compared to other examinations performed under sedation, and caution should be exercised in this regard (7,8). The American Society of Anaesthesiologists (ASA) recommends that such deep sedation applications be performed by anaesthesiologists (9). Most patients do not express their anxiety unless they are specifically questioned. In the literature has been stated that preoperatively, patients should be carefully evaluated in terms of anxiety, and their preoperative anxiety levels should be determined (10).

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Beck anxiety inventory (BAI) was developed to quantify anxiety irrespective of depressive symptoms (11). BAI includes 21 things. A two-factor model comprising 21-items of physical symptoms and emotional-cognitive symptoms was constructed for this scale. The adequacy of this model was evaluated primarily via validation experiments (12). BAI has a high overall internal consistency and a high test-retest correlation (r = 0.67) in detecting the presence of anxiety (11-15). Therefore, research indicates that the BAI is a trustworthy and valid instrument for measuring anxiety symptoms (16,17). Also, BAI is considered as the gold standard method in the measurement of anxiety due to its brevity, simplicity, and ability to effectively measure general anxiety (18).

As in many centres', in our institute, endoscopic procedures are performed with sedoanalgesia under the control of anaesthesiologists. In this study, the primary aim was to investigate the anxiety levels of patients who underwent sedoanalgesia during and two days after on gastrointestinal endoscopic procedures. Secondary aim of the study was to identify early complications in the patients.

MATERIAL AND METHOD

The study was carried out with the permission of University of Health Sciences Kartal Dr. Lutfi Kirdar City Hospital Scientific Research and Publication Ethics Committee (Date: 30/03/2022, Decision No: 2022/5 l 4/222/18). Informed consent was obtained from all the patients included in the study before they entered the operating room. This study was planned as a prospective, randomized, single-centre, clinical trial. Patients aged over 18 years that were classified as American Society of Anaesthesiologist (ASA) physical status score 1, 2, and 3 and underwent elective gastrointestinal endoscopy between April 2022 and September 2022 were included to the study.

Patients that refused to participate, ASA score above 3, were not literate, with an ejection fraction (EF) of <30%, and diagnosed with or treated for a psychiatric disease were excluded from the study. Patients in whom adequate stomach and intestinal cleansing could not be accomplished and procedure could not be finished due to difficulties were also omitted. Demographic data, such as age, gender, height, weight, comorbidities and medications used by the patients were recorded. The patients were monitored in terms of cardiac apex beat, non-invasive blood pressure (BP), and peripheral oxygen saturation (SpO2). Following cannulation, all patients received intravenous (iv) midazolam premedication, and sedation was provided by titrating the iv propofol and fentanyl combination to a dose that would allow them to experience no pain and maintain drowsiness throughout the surgery.

Preoperative and postoperative evaluations were performed using the Beck Anxiety Inventory (BAI) to determine the anxiety levels of the patients (Annex-1). Before the procedure, patients' anxiety levels were measured using the BAI scale. In addition, in an interview held on the second day after the procedure, BAI was administered to the patients again, and their satisfaction levels were also questioned based on a scale of 1 to 10. The duration of anaesthesia and procedure, length of stay in hospital and intensive care were recorded. The presence of complications was recorded preoperatively and within the first 24 hours.

Statistical Analysis

SPSS version 25 statistical software package was used for statistical analyses. Data were summarized using descriptive statistical methods (mean, frequency, percentage, minimum, and maximum values). The Shapiro-Wilk test was used to test the normality of the distribution of continuous variables. Since the variables did not show a normal distribution, the Kruskal-Wallis Test was conducted for the comparison of three groups and the Mann-Whitney U Test for the comparison of two groups. The difference between the variables obtained from the same participants was investigated using the Wilcoxon signed-rank test due to the sample being dependent and data not being normally distributed.

RESULTS

A total of 104 patients, 53 men and 52 women, who presented to Kartal Dr. Lutfi Kirdar City Hospital, were included in the study. The age of the patients ranged from 23 to 79 years. Gastroscopy was performed in 44 of the patients, colonoscopy in 25, and both (mixed) procedures in 35. According to the results, gastroscopy was the most frequently performed procedure at a rate of 42.31%. The patients were mostly evaluated as ASA class 1 and 2 (96.16%). Hypertension was the most common comorbidity (20.19%), and the rate of medication use was high (41.45%) (**Tables 1, 2**).

Table 3 presents the statistical analysis of the age, satisfaction score, and preoperative and postoperative BAI scores of the patients according to the type of endoscopy procedure performed. It was observed that the patients who underwent colonoscopy were significantly older patients ($p < 0.05$), but patient satisfaction, preoperative and postoperative BAI scores did not significantly differ between the procedures ($p>0.05$). However, there was a significant difference between the patients' preoperative and postoperative BAI scores ($p<0.05$). Accordingly, the mean preoperative BAI score of all the procedures was significantly higher than the mean postoperative BAI score ($p<0.05$). In particular, the patients that underwent gastroscopy had a much larger difference between their preoperative and postoperative BAI scores when compared to the remaining procedure types. Therefore, although the type of procedure did not

result in a significant difference between the mean BAI scores of the patients, there were significant differences in BAI scores between the preoperative and postoperative evaluations within each procedure group.

Table 1: Basic statistics of the categorical variables evaluated in the study

Variable	Group	Frequency	Percentage
Procedure			
	Gastroscopy	44	42.31
	Colonoscopy	25	24.04
	Mixed	35	33.65
Gender			
	Male	53	50.5
	Female	52	49.5
Education level			
	None	3	2.88
	Primary school	27	25.96
	Middle school	10	9.62
	High school	32	30.77
	University	32	30.77
ASA class			
	1	51	49.04
	2	49	47.12
	3	4	3.85
Hypertension			
	Absent	83	79.81
	Present	21	20.19
Diabetes mellitus			
	Absent	85	83.33
	Present	17	16.67
Hypo-hyperthyroidism			
	Absent	98	94.23
	Present	6	5.77
Psychiatric disorder			
	Absent	94	91.26
	Present	9	8.74
Gastrointestinal disease			
	Absent	97	94.17
	Present	6	5.83
Chest disease			
	Absent	97	94.17
	Present	6	5.83
Cardiac disease			
	Absent	99	96.12
	Present	4	3.88
Medication use			
	Absent	61	58.65
	Present	43	41.35
Complication			
	Absent	97	93.27
	Present	7	6.73

ASA: American Society of Anaesthesiologists

Table 2: Basic statistics on the age and anxiety and satisfactions levels of the patients

Variables	Mean	SD	Minimum	Maximum
Age	52.20	12.26	23	79
BAI score (preoperative)	6.53	7.44	0	33
BAI score (postoperative)	1.84	2.26	0	12
Satisfaction score	9.38	0.93	6	10

SD: standard deviation, BAI: Beck Anxiety Inventory

The mean BAI scores significantly differed according to medication use (Table4). The patients that used medications had a statistically higher mean postoperative BAI score than those without medication use($p<0.05$). The Wilcoxon signed-rank test was used to examine the variation in the patients' satisfaction scores according to gender. The results presented in **Table 4** indicate that the satisfaction levels of the patients did not differ between the men and women ($p > 0.05$).

Table 5 presents the results of the cross-evaluation performed to determine how the anxiety classification made according to the BAI score shifted from the preoperative period to the postoperative period. All the patients classified as having very mild anxiety in preoperative BAI evaluation were also classified in the same group in the postoperative test, while most of those that were preoperatively evaluated as having mild, moderate, or high anxiety levels shifted to the minimal anxiety and some to the mild anxiety group in the postoperative period. This demonstrates that sedoanalgesia application was very effective in reducing the patients' anxiety levels.

Table 5: Postoperative changes in patients' anxiety classification according to the BAI scores

	BAI score (postoperative), frequency and percentage	
BAI score (preoperative)	Minimal anxiety	Mild anxiety
Minimal anxiety	74 (100)	0 (0)
Mild anxiety	14 (87,5)	2 (12,5)
Moderate anxiety	8 (88,9)	1 (11,1)
Severe anxiety	4 (80,0)	1 (20,0)
Total	100 (96,2)	4 (3,8)

Table 3: Comparison of age and satisfaction and postoperative changes in anxiety levels between the endoscopic procedure groups

	Procedure			p value
	Gastroscopy	Colonoscopy	Mixed	
Age, mean (min-max)	49.36 (23-73)	58.72 (40-79)	51.11 (29-71)	0.0071
Satisfaction score	9.41(8-10)	9.12 (6-10)	9.54 (8-10)	0.3881
Mean BAI score (preoperative)	7.32	5.56	6.23	0.8961
Mean BAI score (postoperative)	2.25	1.76	1.37	0.0631
p value	0.0002	0.0002	0.0002	0.0001

1Kruskal-Wallis test, 2Wilcoxon signed-rank test, BAI: Beck Anxiety Inventory

Table 4: Mean, minimum, and maximum preoperative and postoperative BAI scores and their comparison according to the investigated variables

	BAI score (preoperative)	BAI score (postoperative)
Gender	Mean (min-max)	
Male	6.98 (0-33)	1.85 (0-12)
Female	6.08 (0-29)	1.83 (0-8)
p value	0.8242	0.7782
Education level	Mean (min-max)	
None	2.67 (2-4)	1.33 (0-3)
Primary school	7.40 (0-33)	1.85 (0-12)
Middle school	3.40 (0-8)	1.5 (0-4)
High school	7.28 (0-29)	1.53 (0-5)
University	6.38 (0-26)	2.28 (0-12)
p value	0.8151	0.6851
ASA class	Mean (min-max)	
1	5.25 (0-20)	1.47 (0-12)
2	7.53 (0-33)	2.31 (0-12)
3	10.5 (3-26)	0.75 (0-2)
p value	0.4311	0.0751
Hypertension	Mean (min-max)	
Absent	6.16 (0-33)	1.55 (0-12)
Present	8 (0-29)	2.95 (0-12)
p value	0.0752	0.0682
DM	Mean (min-max)	
Absent	6.40 (0-33)	1.81 (0-12)
Present	7.59 (0-29)	2.17 (0-12)
p value	0.5342	0.7182
Hypo-hyperthyroidism	Mean (min-max)	
Absent	7.29 (0-33)	2.29 (0-12)
Present	9.67 (0-26)	1.83 (0-5)
p value	0.5342	0.7182
Psychiatric disorder	Mean (min-max)	
Absent	6.15 (0-33)	1.80 (0-12)
Present	10.67 (0-26)	2.22 (0-5)
p value	0.1362	0.2922
Gastrointestinal disease	Mean (min-max)	
Absent	6.39 (0-29)	1.85 (0-12)
Present	9.67 (1-33)	2.00 (1-4)
p value	0.3802	0.3532
Chest disease	Mean (min-max)	
Absent	6.69 (0-33)	1.86 (0-12)
Present	5 (0-15)	2.00 (0-5)
p value	0.2672	0.7442
Cardiac disease	Mean (min-max)	
Absent	6.58 (0-33)	1.82 (0-12)
Present	6.25 (0-16)	2.25 (0-5)
p value	0.9662	0.7652
Medication use	Mean (min-max)	
Absent	5.39 (0-29)	1.44 (0-12)
Present	8.14 (0-33)	2.40 (0-12)
p value	0.0612	0.0382
Complication	Mean (min-max)	
Absent	6.57 (0-33)	1.75 (0-12)
Present	6.00 (2-16)	3.00 (1-5)
p value	0.8202	0.0212

1Kruskal-Wallis test, 2Wilcoxon signed-rank test, BAI: Beck Anxiety Inventory

The complications have seen on 7 (%6.7) patients. All of the complications were due to nature of the procedure as epistaxis/mucosal trauma (n=3), equipment damage(n=4). There have been no serious or life-threatening complications during procedures.

DISCUSSION

The early diagnosis of gastrointestinal system diseases, especially malignancies have a significant effect on patient survival. The gold standard methods for early diagnosis are esophagogastroscopy and colonoscopy for gastrointestinal system diseases (19,20). Anesthesia demand has increased due to patient and endoscopist comfort (21). Anaesthesia management of this patients requires appropriate patient evaluation before and after anaesthesia, unique knowledge, skills, experience, and equipment (22).

In a prior study, it was found that endoscopic applications induced anxiety, and that the level of anxiety was affected by gender and education level, but not by the endoscopic operation itself or patient age (23). Similarly, other studies in the literature have shown that the type of endoscopic procedure does not affect patients' anxiety levels (24,25). In our study, we also found that the type of interventional endoscopic procedure did not affect the anxiety level. Although the postoperative BAI scores were lower for all types of procedures compared to the preoperative evaluation, the decline was most significant for individuals who underwent gastroscopy. In another study, it was determined that patients who underwent gastroscopy had a significantly higher level of anxiety (34%) than those who underwent colonoscopy (26). In a study evaluating patients that underwent colonoscopy, it was observed that the patients' anxiety and post-procedural pain levels were higher among those undergoing colonoscopy for the first time (27). In our study, previous gastrointestinal interventional procedures were not questioned, and therefore we consider that there is a need to include this evaluation in future studies.

It has been stated that the anxiety level of patients depends on many factors, including age, gender, previous surgical experience, education level, type of procedure, extent of the recommended surgery, and current health status (1). A study found that female gender, never having had a gastrointestinal treatment previously, and young age enhanced anxiety during gastrointestinal procedures (24). Another study of the factors causing preoperative anxiety in 592 patients undergoing elective surgery confirmed female gender as a risk factor (28). In the current study, there was no significant correlation between anxiety levels and age, gender, or degree of education.

Similarly, another study reported no significant relationship between gender and anxiety (29). We consider that more significant results can be obtained by increasing the number and diversity of patients. In another study, the authors showed that the level of anxiety in diagnostic gastrointestinal interventional procedures performed in patients with a family history of gastrointestinal cancer was higher than those without a family history (30). The effect of family history on the level of anxiety should be further investigated in future studies.

In a study investigating risk factors that increase patient anxiety in endoscopic interventions, anxiety was higher in female patients and those with gastrointestinal symptoms, such as diarrhoea, dysphagia, and pain (31). We did not observe a significant relationship between the history of gastrointestinal disease and the level of anxiety.

In some studies, investigating the relationship between the education levels of patients and their preoperative anxiety, a significant association was reported (28, 29, 32). This was attributed to patients with higher education levels having higher awareness of anaesthesia and surgery. Other studies that did found a decrease in patients' anxiety levels as education level increased explained these findings by patients with a high education level managing their anxiety better and reducing their anxiety (1,33). In our study, no significant relationship was found between educational status and anxiety level. This can be due to the small number of patients. We consider that better results can be obtained by increasing the number of patients.

In a study, the State and Trait Anxiety Inventory (STAI) was used to compare the anxiety levels of two groups of patients based on whether or not they were going to have anaesthesia-guided endoscopic intervention (34). It was found that the anxiety levels of those who were going to have anaesthesia were lower (34). In our clinic, we routinely apply sedation in the presence of an anaesthesiologist to all our patients scheduled for gastrointestinal endoscopic interventions. Supporting our experience, previous studies showed that performing these procedures under reliable conditions accompanied by anaesthesiologists increases the success of the procedure and patient satisfaction (19,21).

This study has certain limitations. If the sample size had been greater, subgroup analyses could have been performed and provide more significant results. However, there were only limited number of patients that presented to the gastrointestinal processing unit during the study period. In addition, our study lacked a control group because gastrointestinal diagnostic procedures are routinely conducted under the supervision of an anesthesiologist and with the use of sedation in accordance with our institution's quality standards and patient safety measures. Lastly, we did not evaluate whether our patients had previous endoscopy experience, and if they did, whether these procedures had been undertaken with or without anaesthesia. Therefore, the relationship between previous endoscopy experience and anxiety should be investigated in future studies.

CONCLUSION

Considering the importance of endoscopic interventions as gold standard methods in the early diagnosis of gastrointestinal diseases, we consider that reducing anxiety by planning the procedure with sedoanalgesia positively affect the patient's decision to undergo such procedure, and thus help achieve early diagnosis. A sedoanalgesia experiment during gastrointestinal endoscopy can reduce future anxiety, especially in patients who have had multiple endoscopies, which may increase patient compliance and procedure success.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of University of Health Sciences, Kartal Dr. Lutfi Kirdar City Hospital Scientific Research and Publication Ethics Committee (Date: 30/03/2022, Decision No: 2022/5 l 4/222/18).

Informed Consent: Informed consent was obtained from all the patients included in the study before they entered the operating room.

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