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ORIGINAL ARTICLE

KJG

내시경 생검 후 서면 교육자료 제공의 불안 수준 완화: 전향적 무작위 대조연구

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Written Educational Material Relieves Anxiety after Endoscopic Biopsy: A Prospective Randomized Controlled Study

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Background/Aims: Patients who undergo endoscopic biopsy suffer anxiety until results are confirmed. This study assesses the effects of written educational material on the anxiety level of patients following endoscopic biopsy.
Methods: This study was a randomized controlled study trial with 83 patients divided into the following three groups: a biopsy group given written educational material prepared by our institution following the biopsy (intervention group, n=28), a biopsy group without written material (biopsy only group, n=25), and a control group without biopsy (control group, n=30). The anxiety level of each patient was evaluated three times using Spielberger's State-Trait Anxiety Inventory (STAI): for baseline at the first visit to our institution, at the day of endoscopy, one day later, and one week after the procedure. We compared baseline characteristics, STAI scores at each visit, and differences in STAI scores among the three groups.
Results: No difference was found in STAI score among groups at baseline and before and after the endoscopic procedure. However, the STAI-state score of the intervention group was slightly lower than biopsy only group one day post-procedure (40.3±7.7 *vs.* 43.9±7.1, p=0.135). The STAI-state score significantly decreased from pre- to post-procedure only in the intervention group (−2.75±6.1 *vs.* 0.92±4.0, $p < 0.027$).
Conclusions: Use of written educational material for patients having biopsy might lessen their anxiety level. **(Korean J Gastroenterol 2016;67:92-97)**

Key Words: Patient education handout; Biopsy; Test anxiety scale

INTRODUCTION

Endoscopic procedures are commonly performed because they afford an exact diagnosis and guidance regarding proper therapeutic intervention. However, they often give rise to anxiety and stress in patients.[1] Diagnostic gastroscopy and colonoscopy are strongly associated with increases in anxiety.[2] Maguire et al.[3] reported the following reasons for increases in anxiety in patients before endoscopy: (1) fear of procedure-related pain, (2) fear of disease which may be diagnosed, (3) fear of the procedure itself because of insufficient sedation and information, and (4) fear of doctors and other people watching the operation. Many approaches have been tried to lessen patients' anxiety during gastro-

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scopy or colonoscopy, including therapeutic conversation and touch, aromatherapy and music.[4,5] In our experience, patients who underwent biopsy during their gastroscopy or colonoscopy felt more anxiety until they knew the exact diagnosis than patients who did not have a biopsy during the diagnostic procedure. Educating patients about gastroscopy or colonoscopy in advance of the procedure, with written educational material or oral explanation, reduces patients' anxiety.[6] However, there is a lack of research about the effects on patients' anxiety of providing written educational material after biopsy during gastroscopy or colonoscopy.

There are several methods for evaluating the anxiety of patients who undergo endoscopic procedure, including the Spielberger's State-Trait Anxiety Inventory (STAI), Hospital Anxiety and Depression Scale, and the Visual Analog Scale.[7] In this study, we used the Korean version of STAI[8] to examine the effects of providing written educational material on the anxiety level of patients who underwent biopsy during gastroscopy or colonoscopy.

SUBJECTS AND METHODS

1. Subjects

We conducted a randomized controlled trial to evaluate the effects of written educational materials on patients' anxiety. This study included patients who were scheduled for elective gastroscopy or colonoscopy at Gangnam Severance Hospital, Seoul, Korea, between January 2011 and December 2012. The inclusion criteria for this study were as follows: age between 18 and 75 years, no history of any overt or borderline psychiatric disease, not using psychotropic drugs, able to read and comprehend the details of the study in the patient information sheet, and agreed to participate in this study. Written informed consent was obtained from each participant. This study was approved by the Ethics Committee of the Gangnam Severance Hospital, Yonsei University College of Medicine (IRB number: 3-2011-0087).

2. Randomization and study design

A single study physician performed the randomization process, using a computer-generated randomization table. One hundred thirty-six patients were randomly assigned to one of following three groups: the control group, comprised of patients who underwent diagnostic gastroscopy or colonoscopy; the biopsy only group, comprised of patients who underwent biopsy during gastroscopy or colonoscopy and were not provided written educational material; and the intervention group, comprised of patients who underwent biopsy during gastroscopy or colonoscopy and were provided written educational material. Thirty-one patients (22.8%) were excluded from the study because of incomplete questionnaires and lost records, and 22 patients (16.2%) did not participate after the procedure. Eighty-three patients completed the entire study protocol as randomized to the three groups: the

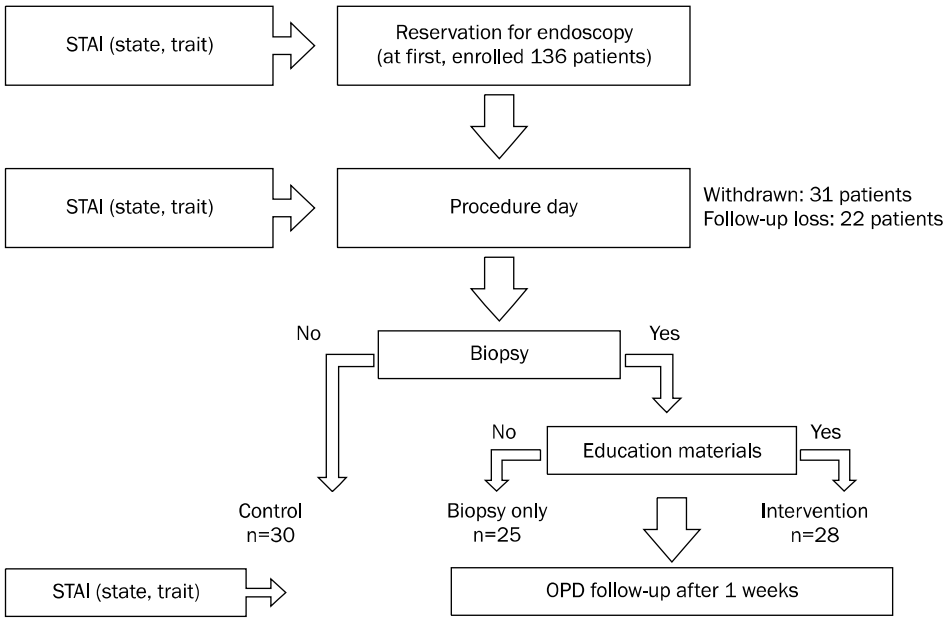

Fig. 1. Flow chart of the study design. Enrolled patients were measured Spielberger's State-Trait Anxiety Inventory (STAI; state, trait) at reservation day for endoscopy, procedure day and follow up day. Only intervention group patients were provided written educational materials after endoscopic biopsy.
OPD, out-patient department.

control group (n=30), the biopsy only group (n=25) and the intervention group (n=28) (Fig. 1). When patients came to schedule an endoscopic procedure, they were asked to complete questionnaires that recorded demographic characteristics and to complete the Korean version of the STAI to evaluate their baseline anxiety level scores. It was translated from STAI, a scale used extensively in research and clinical practice, including Korean populations.[8] STAI scores were also measured on the day of their procedure and one day after. Enrolled patients received oral information about the diagnostic endoscopy and of the probability of biopsy, in some cases before the endoscopic procedure. The patients in the intervention group were provided with written educational material in a handout form prepared by our institution. The oral information content was the same as the written information. The written educational material for the intervention group included information about the procedure, reasons for biopsy, complications that the patient might encounter, and a scheme of what would take place after the procedure (Supplementary Fig. 1, 2, available online only).

3. Measure

1) Spielberger's State-Trait Anxiety Inventory (STAI)

The STAI, a validated test that quantifies the state of anxiety in a patient[9] is simple, generally takes less than five minutes to finish, and is convenient to score. The STAI consists of two parts (20+20 items), with short statements that can be evaluated individually. The two parts are the State portion, an immediate emotional status caused by concern or tension that could be changeable depending on the patient's current status, and the Trait portion, an acquired personality of feeling fear about a safe situation. Each inventory is measured on a four-point scale. Each of the items is rated from 'not at all' (coded as 1) to 'very much so' (coded as 4). An overall score varies between 20 and 80, and higher scores indicate a higher anxiety level. A normative mean STAI score is 35 for adults of varying ages. Some reports define a high anxiety state as one standard deviation above the normative mean, which is a score $\geq$45.[10,11]

4. Statistical analysis

Associations among various categorical variables were evaluated with chi-square and Fisher's exact tests, and the t-test was used for non-categorical variables. ANOVA assessed the anxiety level of patients among the three groups. Null hypotheses of no difference were rejected if p-values were less than 0.05. All analyses were performed using IBM SPSS Statistics software version 20.0 (IBM Co., Armonk, NY, USA).

RESULTS

1. Demographic and other characteristics of patients

There were no significant differences among the three groups in terms of age, sex, socio-demographic variables, comorbid conditions, and previous experience of endoscopy (Table 1).

2. Anxiety levels

Comparisons of STAI-state and STAI-trait scores at baseline, pre-procedure, and post-procedure are shown in Table 2. There were no significant differences in mean STAI-state and STAI-trait scores among the three groups. However, the mean STAI-state score after the procedure decreased modestly compared with baseline and pre-procedure in the biopsy only group and intervention group. Defining a high anxiety STAI score as $\geq$45,[10] the proportion of patients with high state anxiety STAI scores after the procedure was less than that at baseline and pre-procedure (Table 3). In addition, we analyzed the difference in STAI anxiety scores (STAI-state and STAI- trait) between pre- and post-procedure among the three groups (Table 4). The mean STAI-state scores decreased significantly in the group that had biopsies and received written educational material (Fig. 2).

DISCUSSION

Anxiety levels are significantly higher in patients prior to gastroscopy and colonoscopy compared to baseline anxiety level.[12-14] The anxiety of patients who were given written education material before gastroscopy was lower than that of patients not so provided.[15] In our study, we focused on the relation between anxiety and the written educational material for patients who underwent biopsies during gastroscopy and/or colonoscopy. We showed for the first time that written educational material could lessen the anxiety of patients who received biopsies. Drossman et al.[16] explained the reasons for the increase of anxiety level in patients prior to gastroscopy:

Table 1. Demographic Characteristics by Group

Variable	Control (n=30)	Biopsy only (n=25)	Intervention (n=28)	p-value
Age (yr)	44.0±12.0	47.4±13.6	51.1±13.8	0.131
Gender				0.814
Male	12 (40.0)	12 (48.0)	13 (46.4)	
Female	18 (60.0)	13 (52.0)	15 (53.6)	
Educational level				0.762
Primary school graduate	1 (3.3)	2 (8.0)	2 (7.1)	
High school graduate	5 (16.7)	5 (20.0)	5 (17.9)	
University graduate	21 (70.0)	14 (56.0)	20 (71.4)	
Not checked	3 (10.0)	4 (16.0)	1 (3.6)	
Existing conditions				0.223
None	24 (80.0)	10 (40.0)	18 (64.3)	
Diabetes mellitus	0 (0.0)	1 (4.0)	1 (3.6)	
Hypertension	2 (6.7)	3 (12.0)	2 (7.1)	
Thyroid disease	0 (0.0)	2 (8.0)	1 (3.6)	
Gastric ulcer	0 (0.0)	0 (0.0)	2 (7.1)	
Duodenal ulcer	0 (0.0)	1 (4.0)	1 (3.6)	
Gastric cancer	0 (0.0)	1 (4.0)	0 (0.0)	
Liver disease	1 (3.3)	1 (4.0)	0 (0.0)	
Others	3 (10.0)	6 (24.0)	4 (14.3)	
Endoscopy history				0.451
Done	18 (60.0)	19 (76.0)	19 (67.9)	
Not done	12 (40.0)	6 (24.0)	9 (32.1)	
Current endoscopy				0.375
Gastroscopy	9 (30.0)	7 (28.0)	3 (10.7)	
Colonoscopy	8 (26.7)	5 (20.0)	7 (25.0)	
Gastroscopy and colonoscopy	13 (43.3)	13 (52.0)	18 (64.3)	
Type of biopsy[a]				0.394
Gastroscopy		7 (28.0)	6 (21.4)	
Colonoscopy	-	5 (20.0)	14 (50.0)	
Gastroscopy and colonoscopy		13 (52.0)	8 (28.6)	

Values are presented as mean±SD or n (%).
[a]Control group: biopsy was not done.

Table 2. State and Trait Anxiety Scores at Baseline, prior to Gastroscopy and Colonoscopy, and One Day Post-procedure by Group

	Control (n=30)	Biopsy only (n=25)	Intervention (n=28)	p-value
Baseline				
STAI (state anxiety)	44.4±5.9	42.8±9.1	42.2±6.5	0.576
STAI (trait anxiety)	45.6±6.3	45.3±7.7	43.1±7.1	0.358
Pre-procedural				
STAI (state anxiety)	42.8±6.5	43.0±8.8	43.0±9.4	0.967
STAI (trait anxiety)	46.1±6.8	45.0±7.4	44.4±7.8	0.662
Post-procedural				
STAI (state anxiety)	43.1±6.2	43.9±7.1	40.3±7.7	0.135
STAI (trait anxiety)	45.1±6.5	45.2±7.1	43.6±8.7	0.692

Values are presented as mean±SD.
STAI, Spielberger's State-Trait Anxiety Inventory.

(1) sensory discomfort (e.g., pain, gagging and needles), (2) adverse outcomes (e.g., fear of finding cancer), (3) incompetence/inconvenience (not enough sedation, insufficient knowledge of the procedure), and (4) miscellaneous

Table 3. Number of Patients with High State Anxiety Scores at Baseline, prior to Gastroscopy and Colonoscopy, and One Day Post-procedure by Group

	Control (n=30)	Biopsy only (n=25)	Intervention (n=28)	p-value
STAI (state anxiety) ≥45				
Baseline	17 (56.7)	15 (60.0)	9 (32.1)	0.048
Pre-procedural	14 (46.7)	11 (44.0)	12 (42.9)	0.918
Post-procedural	15 (50.0)	12 (48.0)	7 (25.0)	0.099

Values are presented as n (%).
STAI, Spielberger's State-Trait Anxiety Inventory.

Table 4. Comparisons of Differential in STAI Scores between Pre- and Post-procedure by Group

	Control (n=30)	Biopsy only (n=25)	Intervention (n=28)	p-value
STAI (state anxiety)[a]	0.29±5.3	0.92±4.0	−2.75±6.1	0.029
STAI (trait anxiety)	−1.06±7.2	0.25±3.8	−0.71±5.2	0.707

Values are presented as mean±SD.
STAI, Spielberger's State-Trait Anxiety Inventory.
[a]$p<0.05$.

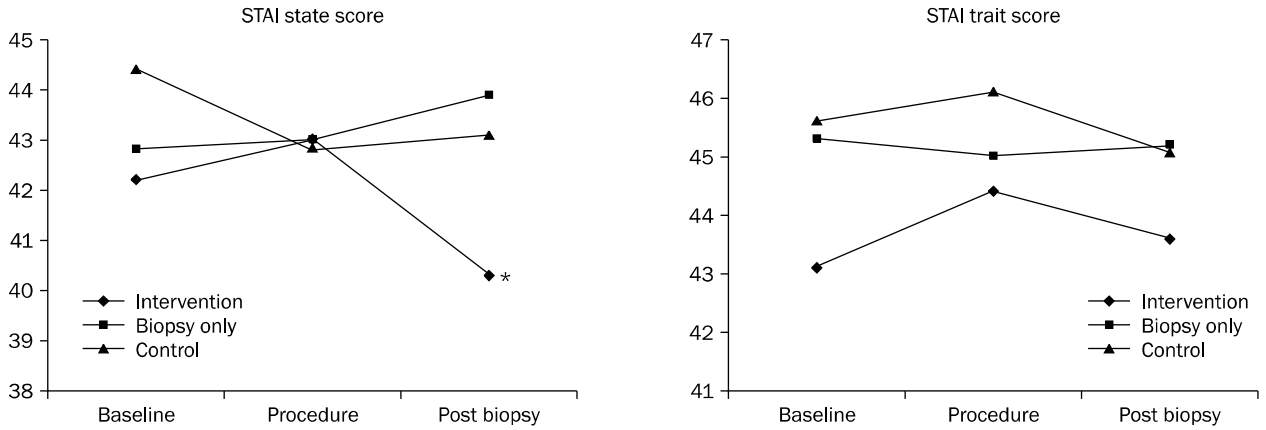

Fig. 2. Comparison of mean state and trait anxiety levels after using of written educational material. *The Spielberger's State-Trait Anxiety Inventory (STAI)-state score was significantly decreased in the intervention group (control, biopsy only, and intervention group; 0.29±5.3, 0.92±4.0, and −2.75±6.1, respectively; p=0.029).

(fear of doctors, concern about others watching the procedure). Furthermore, patients are often fearful of cancer diagnosis after biopsies during gastroscopy and colonoscopy. Anxiety after biopsies might cause unnecessary concern. Morgan et al.[17] reported that a detailed explanation reduced anxiety in patients who usually wanted doctors to talk to them about medical decisions. Additionally, a report in Norway even showed that patients were more interested in potentially alarming information such as complications than in technical aspects of the endoscopic procedures.[18] Therefore, our study team prepared written educational material for patients that includes information about the process of endoscopic biopsy procedure and complication.

The written educational material that we provided effectively lessened the anxiety of patients with biopsy because it included sufficient information about the procedure, the reasons for the biopsy, complications that the patients might encounter, and the plan for after the operation. Informing the patient about the procedure in this manner is very important to decrease the anxiety level of the patient before endoscopy and carry out the procedure smoothly. This written educational material was especially critical to reduce the anxiety level in patients who underwent endoscopic biopsy and were more likely to have fear about a diagnosis of uncertain disease.[6]

The method and timing of providing information to patients prior to endoscopic procedures are most important. If the information is offered to the patients in an inadequate way, the patients' anxiety may increase. However, some studies found that the methods of presenting information to patients prior to endoscopy were not significantly associated with the level of anxiety.[19,20] In contrast, there are also studies indicating that written or oral educational materials provided to patients had an effect on the level of anxiety.[15,21] Our results support the premise that written educational materials alleviate patients' anxiety after endoscopic biopsy, especially the STAI-state domain.

The primary limitation of this study is the small number of patients. With this small sample size, we could not evaluate the influence of other factors on anxiety levels, such as gender, socioeconomic status, education, and types of procedures. Secondly, our study was performed in a well-educated populace, but in areas where the literacy rate is low, the sight of a printed document would surely increase anxiety. Third, although our study was designed as a prospective randomized controlled trial, the high STAI state-anxiety scored patients in the intervention group were fewer than other two groups. This might significantly lessen the mean anxiety level in the intervention group. However, providing detailed information to patients with high anxiety may increase their anxiety by increasing their awareness of the risks and the insertion process.[22]

Nevertheless, this study has several clinical implications. Our study analyzed the use of written educational material to alleviate patients' anxiety after endoscopic biopsy. As we observed that written educational material effectively reduced anxiety, we recommend that clinicians offer such material to patients undergoing biopsy during endoscopy.

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Supplementary Fig. 1. The written educational material for endoscopic biopsy in our study (Korean version).

Tissue biopsy

◆ The figure below shows how a tissue biopsy is performed.

◆ Benign and malignant tumors in various organs can be detected via tissue biopsy, in which a tissue sample is obtained from the lesion. The collected specimen is then examined grossly and histologically.

◆ Tissue biopsy may be performed in order to analyze abnormal findings of the esophagus, stomach, or duodenum. In some cases, even mild inflammation requires tissue biopsy for a more accurate diagnosis of cancer.

◆ In general, endoscopic tissue biopsy is performed for the diagnosis of cancer, inflammation, ulcer, polyp, intestinal metaplasia, Helicobacter pylori infection, and fungal infection.

◆ The test result will be available in 3-5 days. Treatment regimen may vary depending on the result. Please visit the center and discuss with your doctor.

◆ If you experience melena, hematochezia, emesis, or dizziness after a tissue biopsy, please visit the Gastrointestinal Endoscopy Center or Emergency Medical Care Center immediately.

◆ For further inquiries, please contact: Gastrointestinal Endoscopy Center (Telephone number: 2019-2341) or Emergency Medical Care Center (Telephone number: 2019-3333)

Supplementary Fig. 2. The written educational material for endoscopic biopsy in our study (English version).