REVIEW

Improvement of acceptability in patients undergoing esophagogastroduodenoscopy using auditory and visual stimulation

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Abstract : Esophagogastroduodenoscopy (EGD) has become an indispensable examination to discover upper gastrointestinal diseases, including cancer, and perform endoscopic treatment. However, many individuals who undergo the procedure have feelings of anxiety and fear regarding EGD. Although the use of medication for sedation during EGD is useful for reducing anxiety and the stability of hemodynamics, sedation may increase the likelihood of complications. Several noninvasive distractions have been introduced to decrease pain and anxiety during endoscopic examinations ; however, most assessments of these distractions evaluated subjective items such as impression. We herein add the results of our studies using objective items and review the effectiveness of distractions for EGD. J. Med. Invest. 69 : 8-18, February, 2022

Keywords **:** *esophagogastroduodenoscopy, sedation, distraction*

INTRODUCTION

The incidence of gastric cancer has decreased in Japan in recent decades because of the decrease of *Helicobacter pylori* infection, but it remains a major cause of cancer-related mortality (1). Thus, esophagogastroduodenoscopy (EGD) has become an indispensable examination to discover upper gastrointestinal lesion, including gastric cancer, at medical check-ups and screening for cancer. In addition, medical opportunities for the use of EGD for the diagnosis and therapy for etiology of gastrointestinal complaints and upper gastrointestinal cancer have increased. However, many patients and individuals who undergo EGD for the screening of gastric cancer have feelings of vulnerability, fear, and embarrassment (2, 3). This may lead to the patients avoiding EGD and incomplete procedures. As a result, opportunities for the discovery of upper gastrointestinal lesions may be lost. Various inventions have been performed to reduce the unpleasant feeling and pain during EGD such as the development of smaller endoscope diameters, transnasal endoscopy, and the use of medication for sedation. Although sedation is known to increase the success rate of endoscopy and patient satisfaction during the endoscopic procedure (4-8), the use of medication for sedation and analgesia may increase the likelihood of complications such as hypotension and respiratory depression (9-13). The sixth report of endoscopic complications by the Japan Gastroenterological Endoscopy Society Survey showed that the number of complications due to premedication for sedation was 219 cases during 5 years and this number was about 47% of all complications at pretreatment (14). Moreover, there have been several unreported cases, such as fall and traffic accident after endoscopy examination, that should be considered. Various noninvasive methods to improve patient anxiety during endoscopic examinations without sedation were examined. Noninvasive intervention techniques, such as distraction using audio, visual, and olfactory stimulation, were introduced to decrease pain and anxiety during endoscopic examinations. Studies reported that listening to music or watching images was an effective distraction during various endoscopic procedures ; however, the majority of these studies were concerned with decreasing the dose of sedation and improvement of impression of pain, anxiety, and satisfaction (2, 15-17). Although there are several reports on the effectiveness of distractions in subjects undergoing colonoscopy, there are few reports on the effectiveness of distractions for EGD using subjective and objective assessments including vital signs, autonomic nerve function, and psychological questionnaires. Thus, we herein add the results of our randomized controlled trials performed to assess the effectiveness of distractions for EGD using objective items and review their effectiveness.

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1. OUR STUDIES ON THE EFFECTIVENESS OF DISTRACTION FOR EGD

We performed three different prospective single-blind randomized controlled trials to assess the effectiveness of distractions for EGD. The first study was performed to investigate the effectiveness of distractions such audio and visual distraction at pre-EGD (18). The second study was performed to investigate the effectiveness of audio and visual distraction from pre-EGD to post-EGD (19). The third study was performed to investigate the effectiveness of a visual stimulation that was different from the first and second studies on EGD (20).

METHODS

Study design and subjects

Our study protocols are shown in Figure 1. These studies were designed as prospective, single-blinded randomized controlled trials and were performed at Shikoku Central Hospital of the Mutual Aid Association of Public School Teachers. The

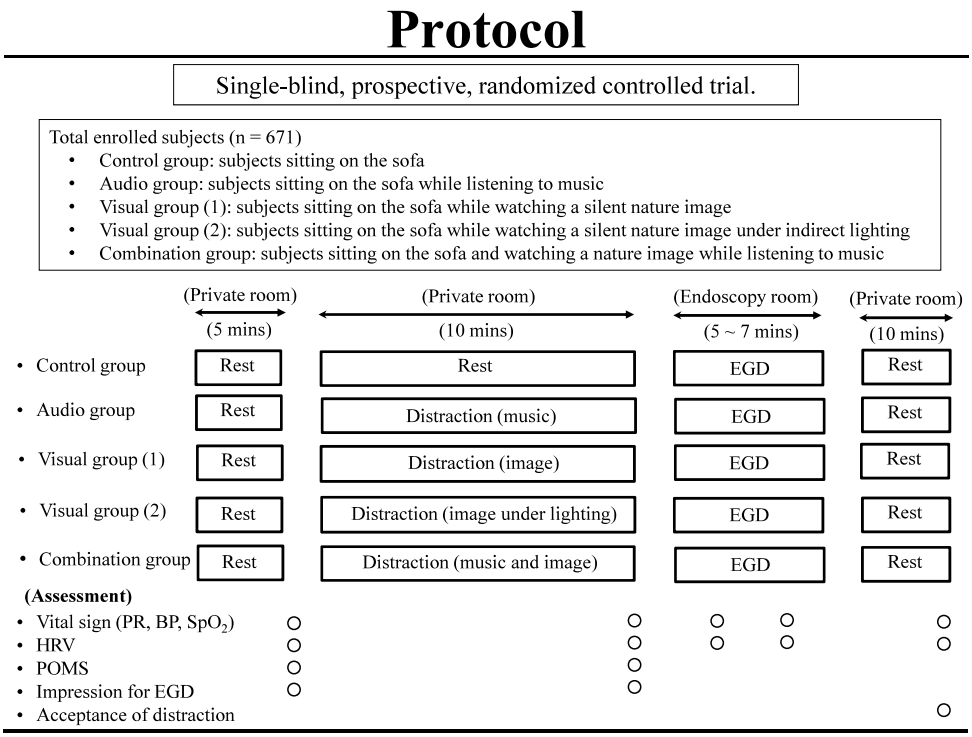

Fig 1. Study protocol.
BP, blood pressure ; EGD, esophagogastroduodenoscopy ; HRV, heart rate variability ; POMS, profile of mood states ; PR, pulse rate ; SpO_2, peripheral blood oxygen saturation.

Ethics Committee of the hospital approved the study protocol, and it was registered in the University Hospital Medical Information Network (UMIN Clinical Trials Registry, number UMIN000022801, UMIN000029637, and UMIN000018579).

The subjects were 671 individuals who underwent a regular health check-up, including EGD, at Shikoku Central Hospital of the Mutual Aid Association of Public School Teachers between September 2015 and March 2018. Each study design was explained, and all subjects provided written informed consent. The exclusion criteria were as follows : (1) current medication use ; (2) a history of severe heart failure, renal failure, hepatic failure, or chronic obstructive pulmonary disease ; (3) previous abdominal surgery, including endoscopic mucosal resection and endoscopic submucosal dissection ; (4) audio or visual disability ; (5) previous experience of bad feelings from audio or visual or lighting stimuli ; (6) a history of anxiety or psychiatric disorders ; (7) pregnant or a possibility of pregnancy ; and (8) receiving a diagnosis of upper gastrointestinal cancer or required biopsy.

Subjects presented in the morning after a longer than 12-h fasting period. An endoscopy nurse performed the randomization and divided patients into two or four groups by selecting sealed, opaque envelopes. All subjects sat on a sofa and rested quietly for 5 min in a private room near the endoscopy room. Subjects in the control group continued to sit on the sofa and rest quietly for 10 min prior to EGD. Subjects in the audio group sat on the sofa and listened to music for 10 min. Subjects in visual group 1 sat on the sofa and watched a silent nature image for 10 min. Subjects in visual group 2 sat on the sofa and watched a silent nature image under indirect lighting for 10 min. Subjects in the combination group sat on the sofa and watched nature images while listening to music for 10 min. The study used music, nature images, and indirect lighting color that were evaluated as good by 20 volunteers in a pre-meeting prior to the start of the present study. Music and nature images were delivered using a wall-type Hivision liquid crystal television (TH-42AS650 ; Panasonic Corporation, Osaka, Japan). Pharyngeal anesthesia with lidocaine pump spray (Xylocaine Pump Spray 8% ; AstraZeneca, Osaka, Japan) without any sedative agents was applied, and five blinded endoscopy specialists with greater than 5 years of experience in endoscopy performed a standard EGD using a conventional single channel endoscope. The profile of mood states (POMS) was performed at pre- and post-distraction. Visual analogue scale (VAS) of the acceptance of distraction was performed after EGD.

Assessment of vital signs

Pulse rate (PR), blood pressure (BP), and peripheral blood oxygen saturation (SpO_2) were measured at the right upper arm and left finger using a monitor unit (BSM-7100 Life Scope ; NIHON KOHDEN CORPORATION, Tokyo, Japan). These parameters were measured 5 and 15 min after sitting on the sofa, during EGD, and 10 min after the EGD procedure. Parameters during EGD were measured just after insertion of the endoscope through the esophagogastric junction (approximately 2 min from the start of EGD) and just after moving the endoscope from the stomach to the esophagogastric junction (approximately 5–7 min from the start of EGD).

Assessment of autonomic nervous function

We assessed autonomic nervous function from pre-EGD to post-EGD using power spectral analysis (PSA). Heart rate variability (HRV) was measured using a Heart Rhythm Scanner (HRV analysis system from Biocom Technologies, Ark Trading Pacific, Inc.) equipped with software that performed algorithms for short-term HRV analysis. A Biocom HRS08 Bluetooth Wireless Pulse Wave Sensor photoplethysmography monitor was clipped to the right earlobe. Data of the average R-R intervals

for 5 min were subjected to PSA using the software of the HRV analysis system. The amplitudes of the low-frequency (LF) range (LF, 0.04-0.15 Hz) and high-frequency (HF) range (HF, 0.15-0.40 Hz) were analyzed using complex demodulation. These LF and HF values were designated as LF power and HF power, respectively. The HF power data were converted to a logarithmic scale for linear regression analysis.

Psychological assessment and impression of EGD

The shortened Japanese version of POMS (POMS2) is a self-report measure that can quickly assess transient, fluctuating feelings and enduring affective states. POMS2 was adapted from the original POMS standard version and was used for psychological assessment at pre- and post-distraction in the distraction groups (21, 22). We also used VAS, which consists of a 100-mm horizontal line scored from 0 to 100, to rate the degrees of strain, anxiety, and fear of EGD at pre- and post-distraction in the distraction groups.

Acceptance of distraction

The degrees of acceptance of the distraction, such as usefulness, satisfaction, and willingness for the use at next EGD, were assessed using VAS in the distraction groups.

Statistical analysis

Based on the requirement of a significant difference among the two or four groups with a significance level of 0.05, power of 80%, and effect size of 0.25, we assumed that the appropriate sample size for the randomized subjects was over 128 or 180 subjects, respectively. By referring to our previous prospective randomized trial on endoscopy, we estimated that the required number of subjects who would receive EGD was over 160 and 225, respectively, in consideration of the exclusion criteria. Quantitative data, including subject characteristics, such as age, number of EGD, and duration of EGD ; vital signs, such as PR, BP, and SpO_2 ; POMS score ; and VAS scores of impressions of EGD and acceptance of distraction are expressed as the means ± standard deviation (SD). Parameters of autonomic nervous function are expressed as means ± standard error of the mean (SEM). All significant differences with a P value less than 0.05 were considered significant. The $\chi 2$-test or Mann-Whitney U-test were used for comparisons between the two groups or pre- and post-distraction among groups. The m × n $\chi 2$-test or Kruskal Wallis test was used to analyze differences among the four groups. If the Kruskal Wallis test revealed differences among the groups, then post-hoc pairwise comparisons were performed using the Mann-Whitney U test with Bonferroni correction. All analyses were performed using Med Calc Software (Broekstraat, Mariakerke, Belgium).

RESULTS

Baseline characteristics of subjects

Baseline characteristics of the subjects in our three studies are shown in Table 1. Although there was a significant difference in PR and SpO_2 among the four groups in Study 1 (both $p < 0.05$), there was no significant difference in age, sex, smoking, drinking, experience, or duration of EGD, POMS, impression of EGD, and vital signs between the control and the distraction group in all studies.

Comparison of vital signs from pre-EGD to post-EGD

Table 2 shows a comparison of vital signs at each point between the control and distraction group. In all studies, although there was no significant difference in most vital signs at pre-EGD (5 min after sitting on the sofa) between the control and distraction group, PR and BP at pre-EGD (15 min after sitting on the sofa) in the distraction group were significantly lower than those in the control group (all $p < 0.05$). In Study 1, although there was a significant difference in PR and SpO_2 at pre-EGD (5 min after sitting on the sofa) between the control and distraction group, the decrease rates of PR, SBP, and DBP between 5 and 15 min after sitting on the sofa in the distraction group were significantly higher than those in the control group (all $p < 0.001$). There was no significant difference in all vital signs during EGD between the control and distraction group in all studies. Furthermore, post-EGD, PR in the distraction group was significantly lower than that in the control group ($p < 0.01$ and $p < 0.05$, respectively) in Studies 2 and 3. In addition, SBP in the distraction group was significantly lower than that in the control group ($p < 0.05$), and SpO_2 in the distraction group was significantly higher than that in the control group in Study 2 ($p < 0.01$).

Comparison of autonomic nervous function from pre-EGD to post-EGD

The comparison of autonomic nerve function from pre- to post-EGD between the control group and distraction group in each study is shown in Figure 2.

In Study 1, there was no significant difference in Log HF power between pre- and post-distraction among the four groups. The LF power/HF power ratio at post-distraction was significantly lower than that at pre-distraction in all distraction groups (all $p < 0.001$).

In Study 2, there was a significant difference in Log HF power during the early and the latter half of EGD, and 10 min after the end of EGD among the four groups ($p < 0.001$, $p < 0.01$, and $p < 0.05$). In addition, post-hoc pairwise comparisons revealed that Log HF power during the early half of EGD in all distraction groups was significantly higher than that in the control group ($p < 0.05$). There was a significant difference in LF power/HF power at pre-EGD (15 min after rest) and 10 min after the end of EGD among the four groups ($p < 0.001$). In addition, post-hoc pairwise comparisons revealed that LF power/HF power at pre-EGD (15 min after rest) and 10 min after the end of EGD in all distraction groups was significantly lower than those in the control group ($p < 0.05$).

In Study 3, Log HF power at pre-EGD (15 min after rest) and 10 min after the end of EGD in the distraction group was significantly higher than in those in the control group (both $p < 0.05$). In addition, LF power/HF power at pre-EGD (15 min after rest) in the distraction group was significantly lower than that in the control group ($p < 0.001$).

Comparison of POMS and the impression of EGD between pre- and post-distraction

Table 3 shows a comparison of POMS and the impression of EGD between pre- and post-distraction among the three distraction groups. Most scores of negative mood at post-distraction were significantly lower than those at pre-distraction in all distraction groups (all $p < 0.05$). However, there was no significant difference in scores of positive mood between pre- and post-distraction in the three distraction groups. In the combination group, all of the VAS scores of impression of EGD at post-distraction were significantly lower than those at pre-distraction (all $p < 0.05$).

Acceptance of distraction after EGD

Table 4 shows a comparison of the acceptance of distraction after EGD among the distraction groups. In Study 1, there was a significant difference in the satisfaction for distraction among the three distraction groups ($p < 0.01$) and the satisfaction for

Table 1. Baseline characteristics of the subjects in our three studies

		Study 1					Study 2					Study 3		
		Control group	Distraction group			P-value	Control group	Distraction group			P-value	Control group	Distraction group	
			(Audio)	(Visual)	(Combination)			(Audio)	(Visual)	(Combination)			(*Visual)	P-value
Content of distraction			Music	Silent image	Music Silent image			Music	Silent image	Music Silent image			Silent image lighting	
	n	51	52	51	52		73	73	72	71		65	65	
Age	(years)	52.4 ± 6.5	52.0 ± 6.3	50.7 ± 7.5	52.1 ± 6.2	NS	52.8 ± 6.7	52.5 ± 6.6	50.7 ± 7.3	52.3 ± 6.2	NS	52.6 ± 7.0	50.6 ± 7.5	NS
Sex	(M/W)	32/19	33/19	29/22	26/26	NS	46/27	45/28	40/32	40/31	NS	40/25	37/28	NS
EGD experience	n	3.9 ± 3.8	4.8 ± 4.1	3.4 ± 2.7	3.7 ± 2.9	NS	4.4 ± 3.9	4.5 ± 3.8	4.1 ± 2.6	4.4 ± 3.3	NS	4.2 ± 3.5	3.0 ± 2.5	NS
Duration of EGD	(sec)	358 ± 104	377 ± 84	371 ± 121	361 ± 86	NS	330 ± 96	351 ± 96	355 ± 116	329 ± 81	NS	326 ± 83	356 ± 111	NS
Smoking	n, (%)		(-)			NS	10 (13.7)	9 (14.1)	12 (16.7)	4 (5.6)	NS	10 (15.4)	11 (16.9)	NS
Drinking	n, (%)		(-)			NS	45 (61.6)	42 (57.5)	40 (55.6)	38 (53.5)	NS	38 (58.5)	36 (55.4)	NS
Vital sign														
PR	(/min)	68.2 ± 8.7	65.4 ± 9.4	62.7 ± 8.2	64.5 ± 9.6	< 0.05	66.8 ± 8.7	65.5 ± 9.7	64.1 ± 8.0	65.4 ± 9.3	NS	66.5 ± 8.3	64.6 ± 8.2	NS
SBP	(mmHg)	125 ± 15	124 ± 15	119 ± 15	128 ± 17	NS	123 ± 15	122 ± 16	121 ± 14	128 ± 17	NS	120 ± 15	119 ± 15	NS
DBP	(mmHg)	82 ± 11	81 ± 13	76 ± 11	82 ± 13	NS			(-)				(-)	
SpO_2	(%)	98.4 ± 1.4	97.9 ± 1.2	98.2 ± 1.3	98.5 ± 1.2	< 0.05	98.2 ± 1.4	98.1 ± 0.9	98.3 ± 1.2	98.5 ± 1.1	NS	98.2 ± 1.4	98.3 ± 1.3	NS
POMS														
(negative mood)														
A-H		46.9 ± 8.4	46.7 ± 7.1	47.8 ± 7.0	45.2 ± 7.7	NS	46.8 ± 8.0	46.2 ± 6.9	46.6 ± 6.5	46.3 ± 8.3	NS		(-)	
C-B		48.1 ± 8.6	49.8 ± 8.4	50.4 ± 7.1	47.5 ± 8.4	NS	48.4 ± 8.5	49.4 ± 8.1	49.6 ± 7.2	48.3 ± 8.2	NS		(-)	
D-D		48.7 ± 7.9	50.1 ± 8.6	49.3 ± 6.8	48.4 ± 6.7	NS	49.0 ± 7.5	49.8 ± 8.2	48.5 ± 6.7	48.5 ± 6.3	NS		(-)	
F-I		45.7 ± 10.0	44.2 ± 8.2	44.2 ± 8.2	44.2 ± 8.2	NS	46.0 ± 9.6	46.2 ± 7.1	45.3 ± 7.1	45.5 ± 9.0	NS		(-)	
T-A		53.0 ± 10.9	51.1 ± 9.0	54.7 ± 9.4	50.3 ± 10.4	NS	53.0 ± 10.9	50.9 ± 8.6	54.1 ± 9.0	51.4 ± 10.5	NS		(-)	
TMD		47.4 ± 9.2	47.8 ± 7.9	48.3 ± 7.0	45.1 ± 7.7	NS	48.0 ± 9.0	47.5 ± 7.6	47.6 ± 6.7	46.2 ± 7.6	NS		(-)	
(positive mood)														
V-V		55.3 ± 10.8	55.9 ± 9.1	56.2 ± 9.1	53.0 ± 10.3	NS	54.4 ± 10.6	55.0 ± 8.8	55.3 ± 9.1	53.5 ± 9.3	NS		(-)	
F		57.2 ± 9.6	59.3 ± 8.5	59.8 ± 8.9	60.2 ± 9.3	NS	56.8 ± 9.7	58.6 ± 8.0	59.2 ± 8.7	59.8 ± 9.2	NS		(-)	
Impression for EGD														
VAS (0~100)														
Strain		45.2 ± 27.7	42.0 ± 25.3	53.9 ± 28.9	41.7 ± 28.7	NS	46.6 ± 26.7	47.1 ± 26.9	53.7 ± 27.9	47.3 ± 30.2	NS		(-)	
Anxiety		34.4 ± 28.2	39.3 ± 25.0	33.8 ± 24.1	31.3 ± 26.7	NS	38.5 ± 28.1	44.5 ± 26.8	39.5 ± 25.8	38.8 ± 30.0	NS		(-)	
Fear		22.3 ± 23.1	28.1 ± 24.4	26.8 ± 18.8	21.8 ± 21.9	NS	29.6 ± 25.3	36.3 ± 28.5	32.3 ± 23.2	31.8 ± 29.6	NS		(-)	

A-H anger-hostility ; C-B confusion-bewilderment ; DBP diastolic blood pressure ; D-D depression-dejection ; EGD esophagogastroduodenoscopy ; F friendship ; F-I fatigue-languid ; n ; number ; M man ; NS no significance ; POMS profile of mood states ; PR pulse rate ; SBP systolic blood pressure ; SpO_2 peripheral blood oxygen saturation ; T-A tension-anxiety ; TMD total mood distress ; VAS visual analog scale ; V-V vigor-vitality ; W women.

* visual stimulation by image and indirect lighting.

Data represent the means ± standard deviation (SD) and number for categorical variables. The $\chi 2$ test or the Mann-Whitney U-test was used to compare between two groups. The m × n $\chi 2$ test or Kruskal Wallis test was used to compare among four groups. Significance is at the 5% level.

Table 2. Comparison of vital signs at four points between control and distraction group

		Study 1					Study 2					Study 3		
		Control group	Distraction group (Audio)	Distraction group (Visual)	Distraction group (Combination)	P-value	Control group	Distraction group (Audio)	Distraction group (Visual)	Distraction group (Combination)	P-value	Control group	Distraction group (*Visual)	P-value
PR	(/min)													
Pre-EGD	5 min after rest	68.2 ± 8.7	65.4 ± 9.4	62.7 ± 8.2	64.5 ± 9.6	< 0.05	66.8 ± 8.7	65.5 ± 9.7	64.1 ± 8.0	65.4 ± 9.3	NS	66.5 ± 8.3	64.6 ± 8.2	NS
	15 min after rest	70.2 ± 8.6	63.9 ± 9.9	60.8 ± 8.9	57.6 ± 7.3	< 0.001	66.7 ± 9.7	62.8 ± 9.8	60.3 ± 8.3	59.1 ± 7.8	< 0.001	66.3 ± 9.3	60.5 ± 8.7	< 0.001
		[Rate of decrease between pre-and post-distraction (mean ± SEM)]												
		-1.98 ± 0.61	1.50 ± 0.37	1.90 ± 0.35	6.92 ± 0.54	< 0.001			(-)				(-)	
During EGD	Early half			(-)			87.5 ± 17.9	84.8 ± 16.4	82.2 ± 16.7	83.2 ± 15.8	NS		(-)	
	Latter half			(-)			76.2 ± 15.3	73.8 ± 13.1	72.5 ± 14.8	70.9 ± 12.8	NS	75.8 ± 15.3	72.9 ± 15.4	NS
Post-EGD				(-)			70.6 ± 10.8	69.0 ± 10.8	65.9 ± 9.4	65.4 ± 8.3	< 0.01	70.4 ± 10.5	66.2 ± 9.8	< 0.05
SBP	(mmHg)													
Pre-EGD	5 min after rest	125 ± 15	124 ± 15	119 ± 15	128 ± 17	NS	123 ± 15	122 ± 16	121 ± 14	128 ± 17	NS	122 ± 15	118 ± 15	NS
	15 min after rest	124 ± 15	117 ± 15	112 ± 12	118 ± 16	< 0.001	122 ± 14	117 ± 15	114 ± 12	120 ± 16	< 0.005	121 ± 13	116 ± 13	< 0.05
		[Rate of decrease between pre-and post-distraction (mean ± SEM)]												
		1.00 ± 0.92	6.77 ± 1.23	6.55 ± 0.98	9.92 ± 1.31	< 0.001			(-)				(-)	
During EGD	Early half			(-)			139 ± 22	139 ± 29	137 ± 27	141 ± 24	(-)		(-)	
	Latter half			(-)			130 ± 19	127 ± 23	125 ± 22	129 ± 18	NS	131 ± 18	125 ± 23	NS
Post-EGD				(-)			129 ± 16	124 ± 15	122 ± 16	126 ± 15	< 0.05	130 ± 16	126 ± 17	NS
DBP	(mmHg)													
Pre-EGD	5 min after rest	82 ± 11	81 ± 13	76 ± 11	82 ± 13	NS			(-)				(-)	
	15 min after rest	80 ± 11	75 ± 12	71 ± 10	74 ± 12	< 0.001			(-)				(-)	
		[Rate of decrease between pre-and post-distraction (mean ± SEM)]												
		1.51 ± 0.59	5.71 ± 1.24	4.77 ± 0.77	7.83 ± 0.81	< 0.001			(-)				(-)	
During EGD	Early half			(-)					(-)				(-)	
	Latter half			(-)					(-)				(-)	
Post-EGD				(-)					(-)				(-)	
SpO_2	(%)													
Pre-EGD	5 min after rest	98.4 ± 1.4	97.9 ± 1.2	98.2 ± 1.3	98.5 ± 1.2	< 0.05	98.2 ± 1.4	98.1 ± 0.9	98.3 ± 1.2	98.5 ± 1.1	NS	98.2 ± 1.4	98.3 ± 1.3	NS
	15 min after rest	98.5 ± 1.2	97.9 ± 1.3	98.0 ± 1.4	98.8 ± 1.1	< 0.001	98.5 ± 1.1	98.3 ± 1.0	98.2 ± 1.3	98.5 ± 0.9	NS	98.5 ± 1.1	98.2 ± 1.3	NS
		[Rate of decrease between pre-and post-distraction (mean ± SEM)]												
		-0.14 ± 0.12	-0.04 ± 0.15	0.12 ± 0.09	-0.25 ± 0.15	NS			(-)				(-)	
During EGD	Early half			(-)			98.2 ± 1.6	98.3 ± 1.0	98.4 ± 1.3	98.6 ± 1.2	NS		(-)	
	Latter half			(-)			98.7 ± 1.5	98.6 ± 1.1	98.8 ± 1.2	98.8 ± 1.2	NS	98.7 ± 1.6	98.8 ± 1.3	NS
Post-EGD				(-)			97.9 ± 1.5	98.1 ± 1.0	98.2 ± 1.2	98.6 ± 1.0	< 0.01	97.9 ± 1.5	98.2 ± 1.3	NS

DBP diastolic blood pressure ; EGD esophagogastroduodenoscopy ; NS no significance ; PR pulse rate ; SBP systolic blood pressure ; SEM standard error of the mean ; SpO_2 peripheral blood oxygen saturation.
* visual stimulation by image and indirect lighting.
Data represent the means ± standard deviation (SD) and number for categorical variables. The $\chi 2$ test or the Mann-Whitney U-test was used to compare between two groups. The m × n $\chi 2$ test or Kruskal Wallis test was used to compare among four groups. Significance is at the 5% level.

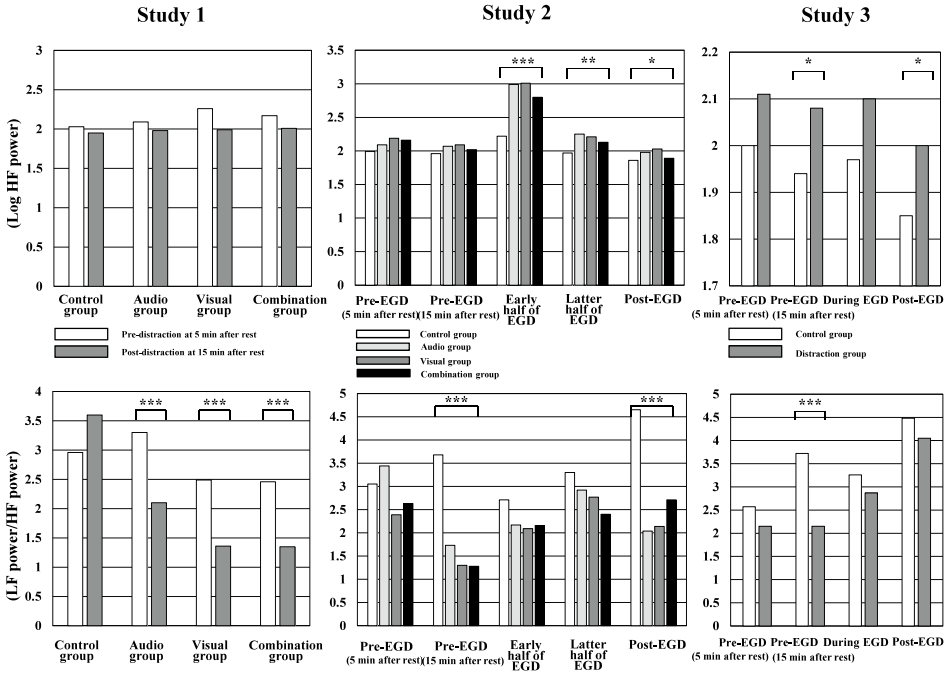

Fig 2. Changes in heart rate variability.
Upper figures Comparisons of Log HF power.
Lower figures Comparisons of LF power/HF power.
In Study 1 and Study 3, the white bar and the gray bar indicate the values of the control group and the audio group, respectively. In Study 2, the white bar, the light gray bar, the dark gray bar, and the black bar indicate the values of the control group, audio group, visual group, and combination group, respectively.
EGD, esophagogastroduodenoscopy ; HF, high-frequency ; LF, low-frequency ; *$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.

distraction in the combination group was highest compared to the other distraction groups ($p < 0.05$). In Study 2, there was a significant difference in the usefulness and the satisfaction for distraction among the three distraction groups (both $p < 0.005$) and the satisfaction for distraction in the combination group was highest compared to other distraction groups ($p < 0.05$). Although there was no significant difference in willingness for the next use of the distraction among the three groups, the degree of willingness for the next use of the distraction was excellent because VAS was more than 70 in all the distraction groups.

2. SUMMARY OF STUDIES FOR THE EFFECTIVENESS OF NONINVASIVE DISTRACTIONS USING AUDITORY AND / OR VISUAL STIMULATION ON EGD

We searched PubMed for reports on the effectiveness of auditory and visual distractions in subjects undergoing EGD up to September 2021. The following search words were used : (a) endoscopy such as : "gastroscopy," "esophagogastroduodenoscopy," and "upper gastrointestinal endoscopy" ; (b) distraction such as : "music," and "visual" ; and (c) randomized controlled trial.

Study profile including kind of distraction, subjects' characteristics, and method of assessment

The study profiles, including kind of the distraction, subjects' characteristics, and method of assessment, are shown in Table 5. These trials of distractions for EGD were conducted in five countries : Australia, India, United States, United Kingdom, and Japan. Auditory, visual, and combination stimulation were six, four, and two studies, respectively. The auditory stimulation distraction consisted of listening to music. The visual stimulation distraction consisted of slow-wave photic stimulation by glasses, watching a movie consisting of nature scenes, and watching a movie of nature scenes under lighting. One study included the use of a sedation agent. The ratio of men and women was 67.1% (745/1,111) and 32.9% (366/1,111), respectively. The subjects' mean age was 50.7-61.3 years. The subjects of two studies were first EGD experience, and the mean number of EGD experiences was 2.7-4.8 in the other studies. Mean duration of EGD was between 326 and 377 seconds. The start time of distraction consisted of pre-EGD (nine studies), pre- and during EGD (two studies), and from pre-EGD to post-EGD (one study). Impression, such as anxiety, was used for subjective assessment in ten studies, and state-trait anxiety inventory (STAI) or POMS was used for objective assessment in eight studies. Vital sign, electroencephalograph (EEG), and autonomic nervous function (ANF) were used for objective assessment in ten, one, and seven studies, respectively.

Effectiveness of noninvasive distractions for EGD

The effectiveness of noninvasive distractions for EGD is shown in Table 6. Bampton *et al*. reported that there was no significant difference in the overall tolerance score between a music group and a no-music group ; however, a significantly higher proportion of patients described the experience of the gastrointestinal endoscopic procedure as being at least moderately unpleasant in the no-music group (23). Desaturation less than 90% occurred three times in the music group and four times in the non-music group ; thus, there may be no significant difference between the two groups. Kotwal *et al*. reported that there was a significant effect of music on the decrease of distress, BP, and respiratory

Table 3. Comparison of POMS and the impression for EGD between pre- and post-distraction among the distraction groups

		Study 1			Study 2		
	POMS and impression for EGD	Pre-distraction	Post-distraction	*P*-value	Pre-distraction	Post-distraction	*P*-value
Audio	(POMS : negative mood)						
group	A-H	46.7 ± 7.1	44.0 ± 6.8	< 0.05	46.2 ± 6.9	44.1 ± 6.9	< 0.05
	C-B	49.8 ± 8.4	47.4 ± 8.0	NS	49.4 ± 8.1	46.8 ± 7.8	< 0.05
	D-D	50.1 ± 8.6	47.5 ± 7.4	NS	49.8 ± 8.2	47.3 ± 7.3	< 0.05
	F-I	46.6 ± 7.2	43.4 ± 7.1	< 0.05	46.2 ± 7.1	43.2 ± 7.6	< 0.01
	T-A	51.1 ± 9.0	45.9 ± 8.9	< 0.01	50.9 ± 8.6	46.0 ± 9.2	< 0.001
	TMD	47.8 ± 7.9	44.0 ± 7.8	< 0.05	47.5 ± 7.6	43.9 ± 7.7	< 0.005
	(POMS : positive mood)						
	V-V	55.9 ± 9.1	56.2 ± 10.0	NS	55.0 ± 8.8	55.4 ± 9.4	NS
	F	59.3 ± 8.5	59.5 ± 10.3	NS	58.6 ± 8.0	58.6 ± 9.8	NS
	(Impression of EGD)						
	Strain	42.0 ± 25.3	32.9 ± 23.2	NS	47.1 ± 26.9	37.5 ± 23.9	< 0.05
	Anxiety	39.3 ± 25.0	27.9 ± 23.5	< 0.05	44.5 ± 26.8	34.3 ± 25.4	< 0.05
	Fear	28.1 ± 24.4	19.5 ± 21.2	NS	36.3 ± 28.5	27.3 ± 25.2	NS
Visual	(POMS : negative mood)						
group	A-H	47.8 ± 7.0	45.7 ± 7.5	NS	46.6 ± 6.5	44.3 ± 6.9	< 0.05
	C-B	50.4 ± 7.1	47.3 ± 7.6	< 0.05	49.6 ± 7.2	46.6 ± 7.0	< 0.005
	D-D	49.3 ± 6.8	46.4 ± 6.4	< 0.01	48.5 ± 6.7	46.0 ± 5.9	< 0.005
	F-I	46.3 ± 7.3	43.3 ± 6.8	< 0.05	45.3 ± 7.1	42.5 ± 6.4	< 0.01
	T-A	54.7 ± 9.4	48.0 ± 8.1	< 0.01	54.1 ± 9.0	47.2 ± 7.9	< 0.001
	TMD	48.3 ± 7.0	44.3 ± 6.8	< 0.01	47.6 ± 6.7	43.7 ± 6.3	< 0.001
	(POMS : positive mood)						
	V-V	56.2 ± 9.1	55.3 ± 11.2	NS	55.3 ± 9.1	54.4 ± 11.1	NS
	F	59.8 ± 8.9	59.4 ± 10.9	NS	59.2 ± 8.7	58.6 ± 10.5	NS
	(Impression of EGD)						
	Strain	53.9 ± 28.9	38.8 ± 21.5	< 0.01	53.7 ± 27.9	40.5 ± 22.0	< 0.005
	Anxiety	33.8 ± 24.1	31.3 ± 23.8	NS	39.5 ± 25.8	34.9 ± 24.4	NS
	Fear	26.8 ± 18.8	27.0 ± 26.4	NS	32.3 ± 23.2	31.0 ± 26.7	NS
Combination	(POMS : negative mood)						
group	A-H	45.2 ± 7.7	41.9 ± 6.5	NS	46.3 ± 8.3	42.6 ± 6.8	< 0.001
	C-B	47.5 ± 8.4	44.1 ± 7.0	< 0.05	48.3 ± 8.2	44.9 ± 6.7	< 0.005
	D-D	48.4 ± 6.7	44.7 ± 6.1	< 0.01	48.5 ± 6.3	45.1 ± 5.9	< 0.001
	F-I	44.2 ± 8.2	39.0 ± 6.1	< 0.01	45.5 ± 9.0	40.5 ± 6.5	< 0.001
	T-A	50.3 ± 10.4	42.6 ± 8.8	< 0.01	51.4 ± 10.5	43.9 ± 8.4	< 0.001
	TMD	45.1 ± 7.7	41.3 ± 6.6	< 0.01	46.2 ± 7.6	42.2 ± 6.6	< 0.001
	(POMS : positive mood)						
	V-V	53.0 ± 10.3	53.2 ± 12.1	NS	53.5 ± 9.3	53.7 ± 10.9	NS
	F	60.2 ± 9.3	60.2 ± 10.5	NS	59.8 ± 9.2	59.8 ± 10.5	NS
	(Impression of EGD)						
	Strain	41.7 ± 28.7	21.5 ± 23.5	< 0.001	47.3 ± 30.2	28.3 ± 25.9	< 0.001
	Anxiety	31.3 ± 26.7	19.2 ± 21.9	< 0.05	38.9 ± 30.0	27.6 ± 26.2	< 0.05
	Fear	21.8 ± 21.9	13.4 ± 19.4	< 0.05	31.8 ± 29.6	22.6 ± 26.5	< 0.05

A-H anger-hostility ; C-B confusion-bewilderment ; D-D depression-dejection ; EGD esophagogastroduodenoscopy ; F friendship ; F-I fatigue-languid ; NS no significance ; POMS profile of mood states ; T-A tension-anxiety ; TMD total mood distress ; V-V vigor-vitality.
Data represent means ± standard deviation (SD). *P*-value is based on the Mann-Whitney U-test. Significance is at the 5% level.

Table 4. Acceptance for distraction after EGD among the distraction groups

	Study 1				Study 2				Study 3
	Distraction group			*P*-value	Distraction group			*P*-value	Distraction group
	(Audio)	(Visual)	(Combination)		(Audio)	(Visual)	(Combination)		(*Visual)
Usefulness of the distraction	(-)	(-)	(-)		72.3 ± 16.5	67.7 ± 15.5	76.4 ± 17.4	< 0.005	72.7 ± 16.3
Satisfaction of the distraction	62.7 ± 17.7[a]	63.4 ± 16.9[a]	72.6 ± 19.1[b]	< 0.01	68.6 ± 19.4[a]	62.4 ± 18.6[a]	74.0 ± 18.6[b]	< 0.005	68.7 ± 21.0
Willingness for the next use of distraction	71.9 ± 16.6	72.4 ± 20.2	76.4 ± 18.3	NS	76.4 ± 17.3	73.1 ± 20.3	78.1 ± 17.7	NS	73.1 ± 21.3

EGD Esophagogastroduodenoscopy ; NS no significance.
* visual stimulation by image and indirect lighting. (-) means no assessment.
Data represent the means ± standard deviation (SD). The P-value is based on the Kruskal Wallis-test. Significance is at the 5% level. Post hoc pairwise comparisons were performed using the Mann-Whitney U test with Bonferroni correction. Different letters indicate a significant difference at the 0.01667 (0.05/3) level.

Table 5. Previous studies' profile including kind of the distraction, subjects' characteristics, and method of assessment

Kind of distraction	Contents of stimulation	Sedation agent	Author (Year)	Country	Number of subjects (C/D)	Sex (M/W)	Age (years)	EGD experience	Duration of EGD (sec)	Start time of distraction	Methods of assessment		
											Psychological assessment		Physical assessment
											Subjectivity	Objectivity	Objectivity
Auditory stimulation	Music	use	Bampton *et al.* (1997)	Australia	*59 (31/28)	?	?	?	?	· Before EGD · During EGD	· Impression (Anxiety, Tolerance)	(-)	· Vital sign (SpO_2 : < 90%)
	Music	No use	Kotwal *et al.* (1998)	India	94 (50/54)	?	?	?	?	· Before EGD · During EGD	· Impression (Uncomfortable feeling)	(-)	· Vital signs (HR, SBP, DBP, RR)
	Music	No use	Hayes *et al.* (2003)	United States	198 (98/100)	193/5	61 ± 10.5	First	?	· Before EGD	(-)	· STAI	· Vital signs (P, SBP, DBP)
	Music	?	El-Hassan *et al.* (2009)	UK	87	?	61.3 ± 17.6	First	?	· Before EGD	(-)	· STAI	(-)
	Music	No use	Sogabe *et al.* (2018)	Japan	103 (51/52)	65/38	(C) 52.4 ± 6.5 (D) 52.0 ± 6.3	(C) 3.9 ± 3.8 (D) 4.8 ± 4.1	(C) 358 ± 104 (D) 377 ± 84	· Before EGD	· Impression 1 (Strain, Anxiety, Fear) · Impression 2 (Satisfaction, Willingness of next use)	· POMS	· Vital signs (PR, SBP, DBP, SpO_2) · ANF (HF, LF/HF)
	Music	No use	Sogabe *et al.* (2020)	Japan	146 (73/73)	91/55	(C) 52.8 ± 6.7 (D) 52.5 ± 6.6	(C) 4.4 ± 3.9 (D) 4.5 ± 3.8	(C) 330 ± 96 (D) 351 ± 96	· Before EGD	· Impression 1 (Strain, Anxiety, Fear) · Impression 2 (Usefulness, Satisfaction, Willingness of next use)	· POMS	· Vital signs (PR, SBP, SpO_2) · ANF (HF, LF/HF)
Visual stimulation	Slow-wave photic stimulation	No use	Nomura *et al.* (2006)	Japan	40 (20/20)	25/15	?	(C) 2.9 ± 1.1 (D) 2.7 ± 0.9	?	· From pre-EGD to post-EGD	· Impression (Pain scores)	(-)	· EEG (Slow-wave activity)
	Natural movie	No use	Sogabe *et al.* (2018)	Japan	102 (51/51)	61/41	(C) 52.4 ± 6.5 (D) 50.7 ± 7.5	(C) 3.9 ± 3.8 (D) 3.4 ± 2.7	(C) 358 ± 104 (D) 371 ± 121	· Before EGD	· Impression 1 (Strain, Anxiety, Fear) · Impression 2 (Satisfaction, Willingness of next use)	· POMS	· Vital signs (PR, SBP, DBP, SpO_2) · ANF (HF, LF/HF)
	Natural movie	No use	Sogabe *et al.* (2020)	Japan	145 (73/72)	86/59	(C) 52.8 ± 6.7 (D) 50.7 ± 7.3	(C) 4.4 ± 3.9 (D) 4.1 ± 2.6	(C) 330 ± 96 (D) 355 ± 116	· Before EGD	· Impression 1 (Strain, Anxiety, Fear) · Impression 2 (Usefulness, Satisfaction, Willingness of next use)	· POMS	· Vital signs (PR, SBP, SpO_2) · ANF (HF, LF/HF)
	Natural movie and indirect lighting	No use	Sogabe *et al.* (2020)	Japan	130 (65/65)	77/53	(C) 52.6 ± 7.0 (D) 50.6 ± 7.5	(C) 4.2 ± 3.5 (D) 3.0 ± 2.5	(C) 326 ± 83 (D) 356 ± 111	· Before EGD	· Impression (Usefulness, Satisfaction, Willingness of next use)	(-)	· Vital signs (PR, SBP, SpO_2) · ANF · (HF, LF/HF)
Combination of auditory and visual stimulation	Music and natural movie	No use	Sogabe *et al.* (2018)	Japan	102 (51/51)	61/41	(C) 52.4 ± 6.5 (D) 50.7 ± 7.5	(C) 3.9 ± 3.8 (D) 3.4 ± 2.7	(C) 358 ± 104 (D) 371 ± 121	· Before EGD	· Impression 1 (Strain, Anxiety, Fear) · Impression 2 (Satisfaction, Willingness of next use)	· POMS	· Vital signs (PR, SBP, DBP, SpO_2) · ANF (HF, LF/HF)
	Music and natural movie	No use	Sogabe *et al.* (2020)	Japan	145 (73/72)	86/59	(C) 52.8 ± 6.7 (D) 50.7 ± 7.3	(C) 4.4 ± 3.9 (D) 4.1 ± 2.6	(C) 330 ± 96 (D) 355 ± 116	· Before EGD	· POMS · Impression 1 (Strain, Anxiety, Fear) · Impression 2 (Usefulness, Satisfaction, Willingness of next use)	· POMS	· Vital signs (PR, SBP, SpO_2) · ANF (HF, LF/HF)

ANF autonomic nervous function ; C control ; CF colon fiber ; D distraction ; DBP diastolic blood pressure ; EEG electroencephalograph ; EGD esophagogastroduodenoscopy ; HF high frequency ; HR heart rate ; LF low frequency ; M man ; POMS profile of mood state ; PR pulse rate ; RR respiratory rate ; SBP systolic blood pressure ; SpO_2 peripheral blood oxygen saturation ; STAI State-Trait Anxiety Inventory ; UK United Kingdom ; W woman.

* means impossibility of distinction between EGD and CF. ? means unclear. (-) means no assessment.

Table 6. List of the influence of noninvasive distractions for EGD

Kind of distraction	Contents of stimulation	Author	Influence			
			Psychological assessment	Physical assessment		
				Vital signs	EEG	ANF
Auditory stimulation	Music	Bampton *et al.**	Anxiety : no effect Tolerance : partial effect	(SpO_2 : < 90%) : no effect	(-)	(-)
	Music	Kotwal *et al.*	Uncomfortable feeling (severe group) : effect	SBP, DBP, RR : effect HR : no effect	(-)	(-)
	Music	Hayes *et al.*	STAI : effect	PR, SBP, DBP : no effect	(-)	(-)
	Music	El-Hassan *et al.**	STAI : effect	(-)	(-)	(-)
	Music	Sogabe *et al.*	POMS : effect Strain, fear : no effect Anxiety : effect Satisfaction, willingness of next use : partial effect	SBP, DBP : effect PR, SpO_2 : no effect	(-)	HF : no effect LF/HF : effect
	Music	Sogabe *et al.*	POMS : effect Strain, anxiety : effect Fear : no effect Usefulness, satisfaction, willingness of next use : partial effect	PR, SBP : effect SpO_2 : no effect	(-)	HF, LF/HF : partial effect
Visual stimulation	Slow-wave photic stimulation	Nomura *et al.*	Pain scores : effect	(-)	Slow-wave activity : effect	(-)
	Nature movie	Sogabe *et al.*	POMS : effect Strain : effect Anxiety, fear : no effect Satisfaction, willingness of next use : partial effect	SBP, DBP : effect PR, SpO_2 : no effect	(-)	HF : no effect LF/HF : effect
	Nature movie	Sogabe *et al.*	POMS : effect Strain : effect Anxiety, fear : no effect Usefulness, satisfaction, willingness of next use : partial effect	PR, SBP : effect SpO_2 : no effect	(-)	HF, LF/HF : partial effect
	Nature movie and indirect lighting	Sogabe *et al.*	Usefulness, satisfaction, willingness of next use : effect	PR, SBP : effect SpO_2 : no effect	(-)	HF, LF/HF : partial effect
Combination of auditory and visual stimulation	Music and natural movie	Sogabe *et al.*	POMS : effect Strain, anxiety, fear : effect Satisfaction : effect Willingness of next use : partial effect	PR, SBP, DBP : effect SpO_2 : no effect	(-)	HF : no effect LF/HF : effect
	Music and natural movie	Sogabe *et al.*	POMS : effect Strain, anxiety, fear : effect Usefulness, satisfaction : effect Willingness of next use : partial effect	PR, SBP : effect SpO_2 : no effect	(-)	HF, LF/HF : partial effect

ANF autonomic nervous function ; DBP diastolic blood pressure ; EEG electroencephalograph ; EGD esophagogastroduodenoscopy ; HF high frequency ; HR heart rate ; LF low frequency ; POMS profile of mood state ; PR pulse rate ; RR respiratory rate ; SBP systolic blood pressure ; SpO_2 peripheral blood oxygen saturation ; STAI State-Trait Anxiety Inventory.
* means impossibility of distinction between EGD and CF. (-) means no assessment.

rate between patients with and without music (24). Hayes *et al*. reported that the rate of reducing anxiety was significantly higher in a music group than that in a non-music group by assessment of STAI ; however, there was no significant difference in PR and BP between the two groups (25). El-Hassan *et al*. reported that being in a music group led to a significant reduction in anxiety scores compared to the control group by assessment of STAI ; however, they did not assess subjects' vital signs (2). Two our studies demonstrated that there was a significant effect of music on negative mood, impression of EGD, and vital signs between a music group and a control group (18, 19). In addition, unlike other studies, we showed that LF/HF, as an index of sympathetic nervous activity at post-distraction and post-EGD, was significantly lower in the music group than in the control group.

Nomura *et al*. reported that there was a significant effect of visual distraction using slow-wave photic stimulation for pain scores compared to a control group (26). In addition, they demonstrated that the mean percentage of slow-wave activity (a high score correlates with less pain) was significantly increased in the distraction group compared to the control group ; however, they did not assess subjects' vital signs. Two our studies using a movie of nature scenes demonstrated that there was a significant effect of visual distraction for negative mood, impression of EGD, vital signs excluding SpO_2, and LF/HF ratio as an index of sympathetic nervous activity compared to the control group (18, 19). Furthermore, another study of our group study using movies of nature scenes and indirect lighting demonstrated that there was a significant effect on the acceptance of distraction ; PR, SBP, and HF as indexes of parasympathetic nervous activity at post-distraction and post-EGD ; in the visual group compared to the control group (20).

Two of our studies using a combination of auditory and visual distraction showed similar results to the above studies using only auditory or visual distraction (18, 19). Although there was no additional effect, such as stability of vital signs and autonomic nervous function in the combination group compared to only auditory or visual distraction, acceptance of distraction in the combination group was better than that in the groups that only received auditory or visual distraction.

The number of studies that found a positive effect of auditory and/or visual distraction on psychological factors, such as anxiety levels, was more than that of studies that found a negative effect. Regarding assessment by vital signs, no effect of distraction was found in two studies and eight studies showed some positive effect. Excluding our studies, there were few reports about the detailed results for the effectiveness of distraction by assessment of autonomic nervous function. Our studies showed that distraction using auditory and visual stimulation contributed to the stability of LF/HF at post-distraction and post-EGD.

CONCLUSIONS

The present review of the effectiveness of auditory and visual distraction on EGD reported that these non-invasive distractions had some positive effect, such as improvement of anxiety and suppression against the elevation of vital signs, in most studies. The necessity of improvements in various physical and psychological conditions at EGD should be considered, as patients who have unpleasant feelings against EGD may avoid undergoing further procedures and miss opportunities for the discovery of upper gastrointestinal lesions. Sedation can increase the success rate of endoscopy and patient satisfaction during the endoscopic procedure (4-8), however, the use of medication for sedation and analgesia may increase the likelihood of complications (9-13). Non-invasive distraction may be able to reduce the medicine dose for sedation at EGD. Lee DW *et al*. reported that the dose of propofol for sedation at sigmoidoscopy in patients with a combination of two (auditive and visual) distractions and use of propofol was significantly smaller than in those with use of propofol alone (17). Further investigation of making a comparison of medicine dose for sedation at EGD between subjects with sedation alone and those with combination of distraction and sedation will be required. Development of more effective and non-invasive distractions is necessary to reduce the medicine dose for sedation and stabilize physical and psychological conditions in patients undergoing EGD.

CONFLICT OF INTEREST

None of the authors has any conflicts of interest to declare.

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