



The effect of presence of family members on the anxiety level of candidates for esophagogastroduodenoscopy: A randomized controlled trial

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Abstract

Background: Anxiety and its control is a public health problem worldwide. This study was conducted to determine the effect of family members' presence on the anxiety level of patients who were candidates for esophagogastroduodenoscopy (EGD).

Methods: This randomized controlled trial study was performed in Shahid Chamran hospital in city of Saveh in IR Iran. In this study, 96 patients who were candidates for EGD and met the inclusion criteria were assigned into control and intervention groups by simple random sampling method. The demographic questionnaire and Spiel Berger's State and Trait Anxiety Questionnaire (STAI) were used to measure anxiety.

Results: No significant difference was found between the 2 groups in the mean level of anxiety before intervention ($p=0.13$). After intervention, the level of anxiety decreased significantly in the intervention group ($p=0.001$). However, the mean level of anxiety was not significant in the control group after intervention ($p=0.09$).

Conclusion: The results of the present study showed that the presence of family members during endoscopy may reduce the patient's anxiety level, and thus it is recommended as a non-pharmaceutical, beneficial, and safe intervention.

Keywords: Anxiety, Family member, Esophagogastroduodenoscopy, Clinical trial

Conflicts of Interest: None declared

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Introduction

Chronic diseases are increasingly developing due to changes in life style and industrialization of communities, particularly in developed countries, and they are considered as one of the main problems in the health systems of countries (1). Gastrointestinal disease is also a chronic disease (2, 3). The complex nature and misguiding symptoms of digestive diseases have made it necessary to discover new diagnostic methods and update the available

methods (4). Some of these diagnostic methods, such as endoscopy, are invasive and expose the patient to a high rate of anxiety (5-8). Endoscopy is a non-surgical method used to study different parts of gastrointestinal system (9, 10). EGD is one endoscopic method and an important tool for examining the upper channel of digestive system. This diagnostic-therapeutic procedure is used frequently in clinical investigations and has many apparent diagnostic

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↑What is "already known" in this topic:

Anxiety and its related problems are known as a common disorder and affect all aspects of a person's life. Anxiety leads to an undesirable condition and affects quality of life.

→What this article adds:

Since anxiety is significantly associated with physiological and psychological health and quality of life, its management with noninvasive methods, such as family member's presence during diagnostic and therapeutical procedures, may help reduce the anxiety level of patients during EGD.

advantages and therapeutic applications (11-14). In this technique, a flexible endoscope is directed into gastric and duodenum organs through the throat to examine the upper part of the digestive system (15). EGD is a fast and safe procedure and can be performed without using sedatives; however, it causes a severe anxiety and creates a feeling of exposure to damaged and unsafe conditions, as well as shame and inconvenience in patients (16, 17). Feeling of anxiety is not normal but necessary for survival; however, when severe anxiety occurs and negatively affects activities of daily living, it is considered as a disorder (18-20).

Previous studies have shown that anxiety level is high of before endoscopy (19). High anxiety can cause many problems for the patients, their family, and the treatment team. It may also complicate the procedure due to using excessive sedation (19), (21, 22). In fact, endoscopy can cause such anxiety in a person that could result in patient's avoiding the procedure (23). The anxiety caused by endoscopy will prolong the endoscopic procedure and increase its side effect. Thus, reducing anxiety is significantly important (9). Eliminating anxiety can ease the process and help physicians perform endoscopy more conveniently (24, 25). Medicinal or nonmedicinal methods can be used to reduce and control anxiety (26). Medicines such as benzodiazepines, serotonin reabsorb inhibitors, narcotics, opioid medicines, and triple ring antidepressant drugs are used to reduce anxiety (27). However, using sedatives is not free of side effects; for example, it increases the patient's medical expenditures 30% to 50% and increases the health care staff's work to relieve, improve, and control the disease (28, 29). Considering the industrialization of modern communities and the increase in the rate of chronic diseases, the need for using diagnostic procedures, such as endoscopy and colonoscopy, is increasing progressively (4, 30, 31). Thus, it is necessary to use noninvasive and nonmedicinal methods to reduce the anxiety and discomfort of patients (32).

The tendency to use nonmedicinal methods is on the rise and presence of one of the family members while the patient undergoes EGD is of great importance. The performed studies on this subject imply that the family members' presence reduces the feeling of pain while the patient undergoes EGD (33). Considering the studies conducted on the high prevalence of anxiety before endoscopy (19), the aim of this study was to determine the effectiveness of family member's presence on the anxiety level of the patient while the patient underwent EGD.

Methods

Study design and main inclusion and exclusion criteria

This was a double-blind randomized controlled trial conducted in Chamran Martyr hospital in city of Saveh, Iran, during February 2015 and April 2016. The study population included the patients who were candidates for EGD. The main inclusion criteria were as follow: willingness to participate in the study; prescription of endoscopy; and no participation in any problem solving training courses, critical thinking, emotional intelligence, and methods of stress control and Yoga in the past 6 months. Incompleteness of questionnaires, recognizing mental

disorder in participants during the study and withdrawing from the study were considered as exclusion criteria.

Sample size and data collection

In this study, 96 patients were selected through purpose-based method and randomly divided into intervention (n=48) and control (n=48) groups (34).

Both groups were homogenized to minimize the intervening parameters, such as age, sex, and study level, and marital status. The participants were entered the study according to Consolidated Standards of Reporting Trials (CONSORT) guideline and were randomly placed into 2 intervention and control groups (35) (Fig. 1).

Instruments

The data gathering tools included demographic questionnaire (age, sex, and level of education, marital status, job status, and other additional information) and Spielberger's State and Trait Anxiety Inventory (STAI). STAI scoring is based on likert (1 to 4) scale and the sum of scores in any part ranges from 20 to 80. STAI has a high scientific validity and is considered as a standard tool for evaluation of anxiety; its scientific validity and reliability were evaluated by Khodayarifard et al. (36). STAI includes separated self-measuring scales for measuring state anxiety (Twenty sentences that evaluate the person's feelings at the moment) and trait anxiety (Twenty sentences that evaluate general feelings).

Intervention

The demographic questionnaire was completed by patients. The intervention group filled out State Anxiety Questionnaire accurately before the endoscopy procedure and at the presence of one of their family members. The control group filled out the Anxiety Questionnaire before the endoscopy procedure without the presence of their family member. Trait Anxiety Questionnaire was filled out by both groups 2 days after the endoscopy procedure at the hospital.

Ethical considerations

This study was registered in Iranian Registry of Clinical Trials [IRCT2017011931522N2] and was approved by the Ethics Committee of Saveh University of Medical Sciences [IR.SAVEHUMS.REC.1394.29].

Statistical analyses

Data were analyzed using SPSS 16 software for both descriptive and analytical statistics. For descriptive statistics, mean and standard deviation were used; and for analytical statistics, unilateral variance analysis, Fisher method, K^2 , independent t test, and paired t test were used. Significance level was set at 0.05.

Results

The demographic information of the participants showed that most participants aged 41-48 years and that most of them were male and married (Table 1). Results of this study showed that the state anxiety level of the patients significantly decreased at the presence of a family

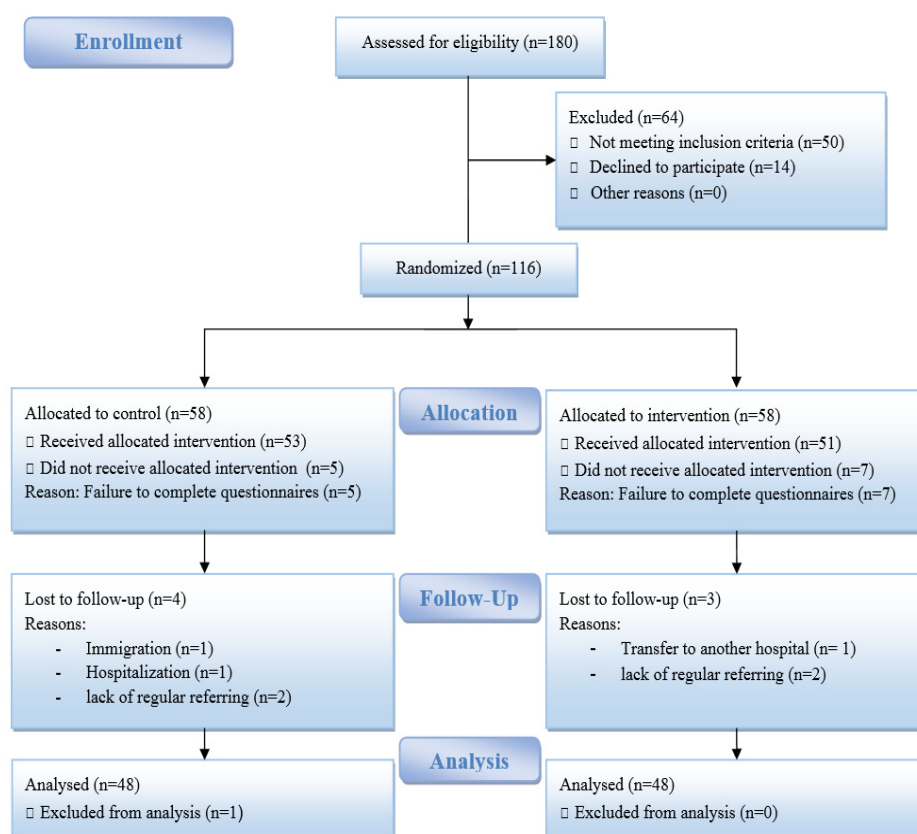


Fig. 1. CONSORT flow diagram of the participants

member during endoscopy in the intervention group ($p=0.001$). However, the level of trait anxiety was not significantly different between the intervention ($p=0.08$) and control ($p=0.09$) groups before and after the intervention (Table 2). According to the results of this study, the level of the state anxiety was decreased among the participants of the intervention group compared to those in the control group. Nevertheless, level of trait anxiety did not show any sign of change between the 2 groups.

Discussion

The present study showed that presence of a family member could reduce the patient's anxiety during endoscopy. Medicinal and nonmedicinal methods are available to reduce patients' anxiety (37). Nowadays, the tendency to use nonmedicinal methods to relieve the pain and anxiety is increasing. Several studies have been performed on the influence of different methods to reduce the patients' anxiety before and during endoscopy of upper part of the digestive system and have reported different results. For

Table 1. Demographic characteristics of participants

Variable		Groups		p	Statistical test
	Mean±SD	Control	Intervention		
		(%) Frequency	(%) Frequency		
Age (year)		54.21±19.26	49.95±19.34	0.38	t-test
Sex				0.60	X ²
Male		(54.2%) 26	(52.1%) 25		
Female		(45.8%) 22	(47.9%) 23		
Marital status				0.13	X ²
Married		(56.2%) 27	(60.4%) 29		
Single		(43.7%) 21	(39.5%) 19		
Level of education				0.25	X ²
Primary education		(66.6%) 32	(66.6%) 32		
High school degree		(20.8%) 10	(18.7%) 9		
Academic degree		(16.6%) 8	(14.5%) 7		

Table 2. Comparison of the mean level of anxiety in patients before and after intervention

Group	Before intervention	After intervention	p	Statistical test
	Mean±SD	Mean±SD		
State anxiety				
Intervention group	42.1±3.75	34.2±3.14	0.001	Pair t-test
Control group	41.08±4.10	42.52±4.47	0.09	Pair t-test
Trait anxiety				
Intervention group	39.1±3.75	38.24±3.14	0.08	Pair t-test
Control group	38.07±4.10	39.52±4.47	0.09	Pair t-test

instance, Eberhardt et al., in their study, entitled, "Information, social support and anxiety before endoscopy of upper part of digestive system" concluded that offering clear information and social support could reduce anxiety in patients before endoscopy (38). Callagan et al., in their study, entitled, "Effect of visual band or written information on patients candidates for endoscopy" found that offering visual information before endoscopy can reduce anxiety in patients (39). Maguire et al., in their study, "Effect of Cognitive and Behavioral Training on Patient's Candidates for Endoscopy" found that offering cognitive and behavioral information before implementation of endoscopy can reduce anxiety in patients (18). Furthermore, Kutluturkan et al. revealed that providing written information about endoscopy can reduce patients' anxiety before the procedure (14). The results of Pehlivan et al. study showed that providing verbal information to patients before implementing the endoscopy procedure has a positive effect on perception, acceptance, and reducing anxiety in these patients (40). Moreover, in Ju-Yeon et al. study, it was shown that preparing patients before endoscopy can significantly reduce their discomfort. Therefore, distracting the patients from the procedure by contact therapy, providing information, observing the endoscopy procedure by patient, Therapeutic relationship between patient and physician, perfume therapy, and listening to music during endoscopy can reduce patients' anxiety (23, 33). In Stanmore's study, it was found that training before endoscopy and listening to music during endoscopy can prevent the increase of diastolic pressure (41). The results of this study on the role of training are in line with previous studies. Maguire et al. concluded that providing information alone can reduce anxiety more than providing information and behavioral training. The results of the present study showed that presence of a family member while the patient is undergoing diagnostic procedures can reduce the patient's anxiety and discomfort. The limitation of this study was that it was performed in one medical center in city of Saveh. Thus, conducting similar studies with larger sample size and multicentral approach is highly recommended.

Conclusion

Patients' candidates for endoscopy experience a high rate of anxiety and based on the findings of previous studies, the presence of family members can be considered a nonmedicinal, beneficial, and effective method to reduce the patient's anxiety before undergoing any invasive therapeutic procedure.

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Conflict of Interests

The authors declare that they have no competing interests.

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