ORIGINAL ARTICLE

Comparison of dialectical behavior therapy and anti-anxiety medication on anxiety and digestive symptoms in patients with functional dyspepsia

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Background: Functional dyspepsia is a common chronic digestive disorder. The purpose of this study was to compare the effectiveness of dialectical behavior therapy and anti-anxiety medication in patients with functional dyspepsia. **Materials and Methods:** The present study was a randomized, controlled clinical trial with sixty patients who were suffering from functional dyspepsia that identified by the ROME III criteria. Patients were divided into three groups by using pre- and posttest design, including Group A (dialectal treatment and pantoprazole), Group B (anxiolytic drug treatment and pantoprazole), and Group C (no intervention, only pantoprazole were used). The Beck Anxiety Inventory and the patient assessment of Gastrointestinal Symptom Severity Index Questionnaire were completed by the patients after receiving the written consent. Finally, the data were analyzed using the Statistical Package for the Social Sciences software version 20. **Results:** There was a significant improvement in the severity of dyspepsia after intervention in all three groups. The greatest decrease in the severity of functional dyspepsia was observed in the dialectical behavioral therapy group as compared to the other groups (Group A: −15.4 ± 6.61, Group B: −3.85 ± 2.77, and Group C: −7.8 ± 4.02; $P = 0.001$). Furthermore, the Beck Anxiety Inventory scores were statistically significantly improved in all three groups (Group A: −5.75 ± 2.53, Group B: −7.3 ± 3.19, and Group C: −2.60 ± 1.5; $P = 0.001$). There was a positive correlation between the change in dyspepsia score and change in anxiety score across different intervention groups ($r = 0.55$; $P < 0.001$). **Conclusion:** Dialectical behavioral therapy can be effective in reducing anxiety and improving the dyspepsia symptoms in patients with functional dyspepsia compared to anti-anxiety medication or conventional therapy. Therefore, communication between the physicians and psychologists and psychiatrists can have positive effects on the treatment of these patients.

Key words: Anxiety, CREDIT ROME III, dialectical behavioral therapy

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INTRODUCTION

Dyspepsia refers to discomfort or pain felt in the upper abdomen.[1] Discomfort may be characterized by or related to bloating, abdominal fullness, early satiety, or nausea, which are usually accompanied by the component of upper abdominal distress.[2] The term "functional dyspepsia" is often regarded as a synonym for nonnuclear dyspepsia or nonorganic or essential dyspepsia.[3] This disease is one of the most common chronic digestive disorders affecting humans, with an incidence rate ranging from 7% to 41%.[4] Although dyspepsia is not a life-threatening state, it may reduce the quality of life[5] and controlling its symptoms is important. As the cause of dyspepsia is not identified completely, its efficient treatment is not yet possible.[6,7] This may be explained in part by the fact that dyspepsia

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is a heterogeneous syndrome, patients with irritable bowel syndrome, biliary tract disease, esophagitis, and other disorders may complain of ulcer-like symptoms, resulting in the broad and nonspecific diagnosis of dyspepsia.[8,9] There is no acceptable drug treatment for this disease.[10] Some related studies have reported that the patient response rate to anti-acid therapy equaled the response rate to placebo.[11] Others have shown no significant difference between the efficacy of H2 blockers and a placebo[12,13] or between the effectiveness of prokinetic and sucralfate and the placebo effect.[10,14] Recent studies have shown that social and psychological effects can affect the ratio of symptoms and healthcare-seeking behaviors in patients with functional gastrointestinal disorders such as dyspepsia.[15] Functional dyspepsia is a syndrome with a multifactorial etiology which is related to irritable bowel syndrome.[16,17] Since psychological factors and disorders affect the acuteness of symptoms in these patients, researchers have shown a greater tendency toward utilizing the psychological approaches for such patients.[18]

Dialectical behavior therapy (DBT) is one type of cognitive-behavioral therapy (CBT)[19] that synthesizes CBT change strategies with acceptance-based strategies which assist the patient in gaining greater awareness and acceptance of his/her current situation. This approach has numerous benefits, including increasing the commitment to treatment.[20-24] DBT has also been adjusted and well-studied in multidelinquent adolescents.[25] It is one of the finest effective methods in the treatment of various disorders.[26] In addition, studies have shown that digestive problems, such as irritable bowel syndrome and functional dyspepsia, have features against which DBT can be beneficial[27] by reducing anxiety levels and improving sleep quality. In this study, we compared the efficacy of DBT with that of anti-anxiety medication on anxiety and digestive symptoms in patients with functional dyspepsia which has not been evaluated yet.

METHODS

This study is a randomized, controlled clinical trial with pre- and posttest assessments which registered in the Iranian Registry of Clinical Trial (20171022036938-N2). This study utilized the convenience sampling method to select 60 patients from those referring to the Gastrointestinal Clinic of University Hospital from September 2016 to April 2017. After a definite diagnosis of functional dyspepsia was made, the goals of the plan and the disadvantages and advantages of the two available therapies were fully explained to the patients who met the inclusion criteria and volunteers entered the study. To observe ethical principles, written consent was obtained from each participant. The inclusion criteria included a diagnosis of functional dyspepsia based on the ROME III protocol, aged between 18 and 50 years, lack of any psychological treatment before entering the study, lack of concurrent structural gastrological or psychotic disorders, and lack of risk factors such as gastrointestinal bleeding, melena, fever, weight loss, anemia, and diarrhea. Any patients developing such unwanted effects during the study were excluded from the study. All patients underwent endoscopy, and based on normal endoscopy and other diagnostic tests, they were diagnosed with "functional dyspepsia". The sample size was determined based on the study by Azizi and Mohamadi.[28] The mean score of anxiety between the control and the dialectical behavioral therapy groups was based on the mean comparison formula. Patients were randomly divided into three independent groups: Group A (dialectal treatment and pantoprazole), Group B (anxiolytic drug treatment and pantoprazole), and Group C (no intervention, only pantoprazole were used). Sixty patients were selected based on the convenience sampling and randomization method used for group member selecting (A, B, and C).

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) software version 16, IBM (SPSS Inc., Armonk, New York) as well as GraphPad Prism version 3 software (GraphPad Software Inc., California, USA). Variables are presented as mean ± standard deviation or mean ± standard error of the mean. The Chi-square, one-way ANOVA, and *post hoc* Tukey test were performed for the comparison of data between the groups. Obtained anxiety and dyspepsia scores before and after trial were compared using the two-way ANCOVA repeated measures and Bonferroni test. For normally distributed variable, a paired sample *t*-test was used. We also use bivariate correlation for the evaluation of association between the change of dyspepsia score and change in the anxiety score. $P < 0.05$ was considered statistically significant.

Research tools

Demographic information

The demographic characteristics of patients included gender, age, type of diagnosed disease, and disease history.

ROME III diagnostic criteria for functional dyspepsia

The Rome III criteria for dyspepsia are the episodes of epigastric burning or pain, early satiation after eating, or early dryness in the nonappearance of an underlying organic sickness which should remain for at least 3 months.[29]

Functional Dyspepsia Symptom Severity Scale

The Gastrointestinal Symptom Severity Index (PAGI-SYM in patients with upper gastrointestinal symptoms (presented by Rentz *et al*. (2004) was used in this study. It contains 20 items scored from 0 to 5 (asymptote to extreme). A total

score of 0–20 indicates asymptote, 21–40 indicates mild grade, 41–60 indicates average grade, 61–80 indicates severe grade, and 81–100 indicates extreme grade.

Internal consistency reliability was assessed by the Cronbach's alpha coefficient. The Cronbach's alpha coefficient for the PAGI questionnaire was 0.80 in all participants and was 0.78, 0.76, and 0.87, in each group A, B, and C, respectively. The Cronbach's alpha coefficient for the Beck Anxiety Inventory was 0.87 in all participants, 0.90, 0.82, and 0.71 in each group, respectively. The coefficient of validity of the questionnaire was evaluated in the Rentz 82/0-6/0 study with the reliability of 0.79–1.95.[30]

Beck's Anxiety Questionnaire, introduced by Beck *et al*. in 1996,[31] contains 21 items and is used to determine the anxiety signs in patients over 2 weeks. Each point in this questionnaire is scored on a 4-point scale (0 = never to 3 = severe to intolerable level).[31,32] The dependability test of Beck's Anxiety Questionnaire among Iranian samples indicated that the total dependability coefficient of the questionnaire is equal to 0.91.[33]

Intervention protocols

Patients were asked to attend an explanatory session in which the aims of the research were clarified. All participants completed the relevant scales in the pretest step (before experimental interventions) and again at the end of interventions in the posttest step to measure the impact of the interventions.

Dialectical behavioral therapy protocol

Dialectical behavioral therapy was conducted in eight, 90-min weekly sessions [Table 1]. Each session included the presentation of the goals and topics of discussion related to that session, discussions and internship sessions, and out-of-class exercises. From the second session onward, each session began with a 5-min exercise of mindfulness through breathing followed by a review of the exercises related to the previous session.[34]

Anti-anxiety therapy protocol

Group B was treated with 100 mg sertraline tablet/daily for 2 months. In addition to the treatments described, pantoprazole was also given. Group C was considered the control group and given pantoprazole tablet 40 mg/daily for 2 months.

RESULTS

In the present study, sixty patients diagnosed with functional dyspepsia based on the ROME–III criteria completed the Beck Anxiety Inventory and were then assigned to three different groups: the dialectical behavior group (twenty patients), the anxiolytic drug treatment group (twenty patients), and the control group (twenty patients). There was no significant difference between the age of patients in different groups (P = 0.23). The mean age of patients in the behavioral therapy group was 25.7 ± 6.7 years, and 4 (20%) were male and 16 (80%) were female. The mean age of patients in the anti-anxiety drug therapy group was 29.1 ± 7.7 years, and 6 (30%) were male and 14 (70%) were female. The mean age of patients in the control group was 29.4 ± 7.9 years. In this group, 9 (45%) were male and 11 (55%) were female. Overall, 31.7% of patients were male and 68.3% were female. The Chi-square test showed no statistically significant difference between the groups regarding gender (P = 0.23).

Table 1: Summary of the educational package of dialectical behavioral therapy

Session	Topic
1	Step 1: Awareness of goals and rules of the group Step 2: Presentation of the definition of dialectics Step 3: Understanding the concept of mindfulness (rational mind; mindfulness and rational mind)
2	Step 1: Skills necessary for the individual to reach the conscious mind observing, describing, and participating Step 2: Instruction on how to perform the skills (adopting a nonpropositional stance, the mind of comprehensible and efficient action)
3-5	Step 1: Crisis survival strategies (1. Distraction strategies, 2. Self-discipline with the five senses, 3. Refinement of skill moments, and 4. Profit technique)
6	Step 1: Distress tolerance skills (1. Admission, 2. Return of mind, and 3. Satisfaction)
7	Step 1: Discussion of the emotional adjustment component (what excitement is and what its components are; learning the pattern for identifying emotions and tagging them, which increases the ability to control emotions; accepting emotions even negative ones; self-teaching of skills; ways to reduce vulnerability to negative emotions)
8	Step 1: Discussion of topics related to the emotional adjustment component (1. Teaching positive emotional experiences by creating short-term positive emotional experiences through working on life goals, relationships, and a common-sense awareness of positive experiences, 2. Teaching how to relieve emotional suffering by accepting emotions and changing negative emotions through antagonistic action)

No statistically significant differences in the Beck Anxiety Inventory score among the three groups before or after intervention were observed ($P > 0.05$). However, a significant decrease in the mean anxiety score of all three groups after intervention compared to preintervention was observed ($P < 0.001$). The Beck Anxiety Inventory scores were statistically significantly improved in the dialectic behavior therapy group compared with the other two groups [Table 2].

A significant difference was observed in the mean scores of severity of dyspeptic symptoms in the dialectic behavior

Table 2: Beck depression and dyspepsia scores before and after trial stratified by the intervention group

	Variables	Group	Mean±SD	*P**	*Post hoc* Tukey		
					$P_{A \text{ and } B}$	$P_{A \text{ and } C}$	$P_{B \text{ and } C}$
Before intervention	Beck score	A	20.60±6.37	0.48	-	-	-
		B	21.05±6.38				
		C	18.85±5.25				
	Dyspepsia scores	A	46.4±10.94	0.32	-	-	-
		B	47.65±10.09				
		C	42.75±10.53				
After intervention	Beck score	A	14.85±5.16	0.33	-	-	-
		B	13.75±5.14				
		C	16.25±5.32				
	Dyspepsia scores	A	30.95±10.80	<0.001	0.017	0.408	<0.001
		B	43.8±9.4				
		C	34.95±9.20				
Changes in parameters at baseline and after intervention	Beck score	A	−5.75±2.53	<0.001	0.133	0.001	<0.001
		B	−7.3±3.19				
		C	−2.60±1.5				
	Dyspepsia scores	A	−15.4±6.61	<0.001	0.029	<0.001	<0.001
		B	−3.85±2.77				
		C	−7.8±4.02				

*By using the ANOVA test. SD=Standard deviation

therapy group (P = 0.01) and anti-anxiety treatment group (P = 0.01) at the beginning, and the end of the study, but no significant differences were seen in the mean scores of severity in dyspepsia symptoms in the control group between the baseline and the outcome of the study (P = 0.2). There was a statistically significant difference between the mean Beck anxiety scores in the dialectic behavioral therapy group (P = 0.01) and the anti-anxiety treatment group (P = 0.001) at the beginning and the end of the study [Table 2]. Furthermore, there was a statistically significant reduction in the mean score of severity of symptoms after intervention in all three groups (P < 0.001).

A comparison of the average changes in anxiety score in the three groups showed that the highest reduction in anxiety score was observed in the drug therapy group and the lowest reduction was observed in the control group. The mean Beck Anxiety Inventory scores in the control group at the beginning and the end of the study showed no statistically significant difference (P = 0.08) [Table 2].

The greatest decrease in the severity of dyspepsia symptoms was observed in the dialectical behavioral therapy group (P < 0.001). Moreover, the lowest reduction was observed in the control group (P < 0.001). Consequently, the results showed that the mean changes in the Beck Anxiety Inventory score (P = 0.01) and the severity of dyspepsia symptoms score (P = 0.01) in the three groups before and after intervention were significantly different. There was a positive correlation between the change in dyspepsia score and change in anxiety score across different intervention groups [r = 0.55; P < 0.001; Figure 1].

It should be mentioned that we did not find complications in patients of all three groups.

DISCUSSION

We compared the effectiveness of dialectical behavioral therapy and anti-anxiety therapy on anxiety and digestive symptoms in patients with functional dyspepsia. The results indicated that although the mean scores of the severity of dyspepsia symptoms in the three study groups did not differ significantly at the beginning of the study (P = 0.32), they became significantly different after intervention in all three groups (P = 0.001). After the intervention, the mean score of severity of dyspepsia symptoms was improved in the dialectical behavioral therapy group and the anti-anxiety drug treatment group. It should be noted that the means of changes in severity scores of dyspeptic symptoms in the three groups were statistically significantly different before and after the study (P = 0.001), more obviously so in the dialectic behavioral group. This finding is in agreement with those of previous studies. A study conducted by Faramarzi *et al*. showed that the average severity of dyspeptic symptoms in patients with functional dyspepsia after psychodynamic treatment (5.8±5.5) was reduced compared with the beginning of the study (12.8 ± 8.1). In fact, intervention improved all gastrointestinal symptoms in patients, including heartburn, nausea, fever, bloating, and upper and lower abdominal pain. In addition, their results indicated a significant improvement in the psychosocial symptoms of patients, such as complete defense mechanisms, neurotic and immature behavior, difficulty in identifying and expressing the feelings, difficulty in describing emotions, and alexithymia. Calvert *et al*. showed

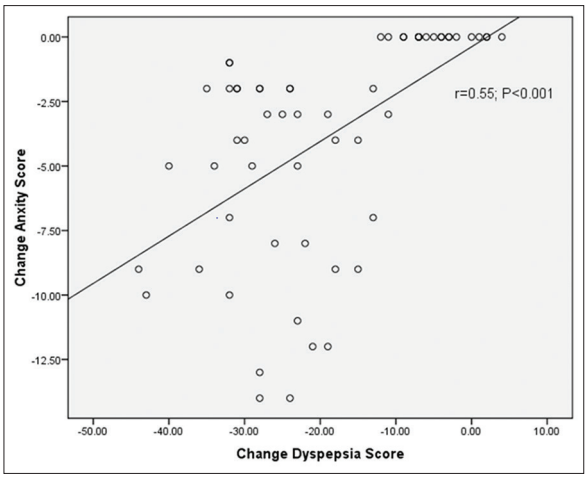

Figure 1: Correlation between the change in dyspepsia score and change in anxiety score in different intervention groups ($r = 0.55$; $P < 0.001$)

that after 16 weeks of intervention, symptoms were more greatly improved in the hypnotherapy group than in the other groups. Improvement rates of 59% in the hypnotherapy group, 41% in the support group ($P = 0.01$), and 33% in the treatment group ($P = 0.057$) were observed. Furthermore, it was shown that long-term intervention (after 56 weeks) led to a more significant improvement in the symptoms of functional dyspepsia in the hypnotherapy group than in the other groups (73% improvement in the hypnotherapy group, 34% in the supportive care group [$P < 0.02$], and 43% in the treatment group [$P < 0.01$]). Therefore, the researchers concluded that patients in the hypnotherapy group had less need to visit the physician during the study period than those in the other groups ($P < 0.001$).[35]

In our study, there was no statistically significant difference in the mean scores of anxiety patients in the three groups before intervention ($P = 0.32$); however, after intervention, the Beck Anxiety Inventory scores in the anti-anxiety drug therapy and dialectical behavioral therapy groups were improved. It should be noted that the mean changes in the Beck Anxiety Inventory scores in the three groups were statistically significantly different before and after intervention ($P = 0.001$). The Beck Anxiety Inventory scores were higher in the anti-anxiety drug therapy and the dialectical behavioral therapy groups. These results are in consistent with the study performed by Mohammadi *et al*. and indicated that the average perceived stress score in the preintervention group was 87.0 ± 31.3 and after behavior therapy was 27.7 ± 6.37. Their findings showed that dialectical behavioral therapy can increase sleep quality and decrease anxiety levels in patients with irritable bowel syndrome.[26] Haghayegh *et al*. showed that dialectical behavioral therapy can be used as effective psychotherapy to improve the psychological status of patients with irritable bowel syndrome.[36] Orive *et al*. indicated that adding psychotherapy to the medical treatment for patients with dyspepsia significantly improved the short-term outcomes in these patients and could have long-lasting effects.[37] Bonnert *et al*. showed that psychotherapy had a significant effect on the reduction of symptoms in functional dyspepsia patients.[38] Xiaoping *et al*. also showed that psychological factors such as depression and anxiety are involved in the etiology of the disease and claimed that the role of anxiety in this disease is more noticeable than depression.[39] In addition, Lee *et al*. found that individual symptoms associated with gastric motility and visceral sensitivity under the influence of psychological stressors could lead to functional dyspepsia. Therefore, extensive interventions such as psychotherapy or cognitive therapy may be effective in reducing the symptoms of indigestion in patients with functional dyspepsia.[40] It seems that the intermediary between the environmental factors and gastrointestinal reactions is a change in the emotional state, in particular, the aggravation or reduction of anxiety. Consequently, dialectic behavioral therapy increases the ability of individuals to reduce the anxiety and adapt to stressful situations, and subsequently to improve symptom relief. Patients with functional dyspepsia are less likely to seek social support and be less able to find flexible solutions. Therefore, dialectical behavioral therapy leaves these patients more able to successfully deal with their disease.

Limitations

Performing research in a single center and short-term follow-up of the patients are the limitations of our study.

CONCLUSION

Dialectic behavioral therapy can be effective in reducing anxiety and improving the dyspepsia symptoms in patients with functional dyspepsia compared to anti-anxiety medication or conventional therapy. Therefore, communication between the physicians and psychologists and psychiatrists can have positive effects on the treatment of these patients.

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Conflicts of interest

There are no conflicts of interest.

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