The effects of cognitive behavioral therapy and drug therapy on quality of life and symptoms of patients with irritable bowel syndrome

Ali Hassanpour Dehkordi, Kamal Solati
Department of Medical-surgical Nursing, Faculty of Nursing and Midwifery, Shahrekord University of Medical Sciences, 1Department of Psychiatry, Shahrekord University of Medical Sciences, Shahrekord, Iran

INTRODUCTION

Irritable bowel syndrome (IBS) is a disorder of bowel functioning which is characterized by chronic abdominal pain and altered bowel habit.[1] Chronic disease affects the quality of life (QOL).[2] Depending on these symptoms' severity, the patients' QOL may be variously affected so that this disease makes most patients absent from their work, leads to disorders in interpersonal relations, and prevents them from having sexual intercourse and even attending social activity and traveling due to fear of symptoms occurrence. Moreover, level of life quality of these patients was reported lower than the general population and healthy people.[3-5] This syndrome is accompanied by psychological disorders. Furthermore, this disease is associated with higher frequency of anxiety, depression, and somatoform disorders.[6] IBS significantly affects QOL and imposes a profound burden on aspects of mental health, physicians, and the health-care system.[7] Higher frequency of IBS symptoms was reported

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in patients with fear, epidemic anxiety, and depression disorders.\textsuperscript{[9]}

Most studies have shown the effectiveness of anti-depressant drugs in decreasing symptoms and improving QOL in patients with IBS.\textsuperscript{[9,10]} However, other studies did not report these results. For instance, in a paper, the therapy with citalopram and amitriptyline was not successful to reduce IBS symptoms in comparison with other medications.\textsuperscript{[10]} Regarding digestion, scholars have highlighted the importance of psychotherapy in controlling IBS symptoms.\textsuperscript{[12,13]} Cognitive behavioral therapy (CBT) can be useful for chronic disease\textsuperscript{[14,15]} and was examined based on self-management with standard therapy (drug therapy) in comparison with control group (only-drug therapy). CBT based on self-management with the standard therapy led to significant reduction of symptoms in patients with IBS after the study period and follow-up step (6 months after therapy) compared with control group (only-drug therapy).\textsuperscript{[16]} The effect of cognitive behavior, gradual relaxation, and daily clinical care was investigated on physical and psychological symptoms of nondepressed patients with IBS. Physical and psychological symptoms of patients were reduced, but there was no significant difference among the three groups.\textsuperscript{[17]} Rapid effect of CBT was revealed in patients' symptoms. In this study, patients with IBS had medium to severe symptoms and were treated during ten sessions (every session with 1 h treatment) through CBT. Quick responses of patients were based on 4-week period and pain relief and reduction of patient's extreme symptoms. In the cited study, 30% of patients treated with CBT responded to therapy quickly and 90%–95% of the remaining patients responded after 6 months of follow-up.\textsuperscript{[18]}

Other studies demonstrated that combined impact of psychological therapies with drug therapy (especially antidepressants) was influential in improving the patients’ QOL with IBS.\textsuperscript{[19]} Other papers also focused that CBT and relaxation were effective in decreasing IBS.\textsuperscript{[20-22]} Concerning the findings of some studies related to the effect of psychological therapy and drug therapy in reducing symptoms in patients with IBS and improving their life quality and the fact that other paper did not report such results, doing research on Iranian samples seems necessary. Hence, this study was conducted to examine the effect of CBT which is considered the most efficient psychological therapies with drug therapy (citalopram) on QOL and the frequency and severity of symptoms in patients with IBS with diarrhea predominance.

**METHODOLOGY**

Clinical trial method was adopted in this study, and samples were all digestive patients referred to Psychosomatic Clinic of Noor Hospital in Isfahan who were selected after disease diagnosis by a gastroenterologist according to interview and clinical examination as well as diagnosis criteria (Rome III). Random sampling continued until completion of group sample size during the study period. The selected sample for this study was 64 patients with IBS and diarrhea predominance who were divided into two groups of CBT with drug therapy and drug therapy alone through simple random sampling. CBT was applied during eight sessions (each 1.5 h) and 2 months on patients individually by a clinical psychiatrist. This therapy was relied on the basis that psychological disorders are specified through disorders in a thinking way. As a best example, depression and anxiety were determined by negative automatic thought and distortion in event interpretation.

Due to the fact that patients with IBS suffered from disorders such as depression, anxiety, cognitive distortion, and negative thoughts of these symptoms (for example, I am sure that my sickness is dangerous and incurable and I am never treated and also extreme diarrhea makes my body dispose water and vital minerals, and as a result, it leads to my death), the patients’ thoughts were manipulated during the sessions and psychological and physical disorders of these patients were eliminated through CBT and homework presentation. Drug therapy was based on citalopram administration that was started by 10 mg dose in the 1st day and increased to 40 mg after 3 weeks which was prescribed by a psychiatrist. This study was single-blind so that a psychologist conducted the evaluation and therapists of two groups were not aware of other affairs. Instruments of this study consisted of two scales:

a. Bowel symptom severity-frequency scale: This scale was made depending on recognition criteria (Rome III) for patients with IBS-D which included 10 questions concerning symptom frequency and 10 questions associated with symptom severity with 5° scale. At first, this test was performed on 40 patients with IBS-D and some cases that were not understandable eliminated and test questions were reformed necessarily. After preparation of the final form, validity of test was confirmed by several digestion specialists. To achieve the test validity, 40 patients with IBS-D were chosen randomly, and mentioned test was executed twice in gap between 2 weeks by retrial that overall correlation of obtained scores was 81%.

b. QOL test of patients with IBS: This test was explored by Patrick and Drossman in 1998 which included 34 questions and eight subscales consisting dysphoria, activities interference, body image, health worry, food abstinence, social reaction, sexual worry, and interpersonal relation. This test has high reliability and its therapy was approved in various studies. Overall validity of this test was reported in America, Europe, and Asian countries 95%, 96%, and 96%, respectively.

**Study protocol**

This study involved with three stages. The first stage was pretreatment in which patients were divided into
two groups (total 32 patients) randomly after possessing permission criteria. The second stage associated with after treatment in which therapy interference (CBT and drug therapy) was executed on patients during 8 weeks period. The third stage was called follow-up level which was appeared in 6 months after therapy interference. At the end of each stage, the patients were examined by study instruments. Statistical data were analyzed by SPSS Inc. Released 2007. SPSS for Windows, Version 16.0. (Chicago, SPSS Inc.) software. Statistical instruments consisted of Pearson’s correlation ratio to determine correlation among demographic attributes and disease background with IBS-D as well as descriptive statistics and MANCOVA.

RESULTS

From the total patients with IBS-D, 24 patients were male and 40 patients were female; 50 patients were married and 14 patients were single. Education level of most patients was diploma level in both groups. The patients’ age ranged from 17 to 65 years with mean age of 37 ± 15.42 years. Age limitation of patients with IBS-D in CBT with drug therapy was between 1 and 28 number and in that of only-drug therapy group was between 1 and 18 [Table 1].

Correlation was not obtained between demographic characteristics and scores of pretests (QOL and IBS), but the correlation was attained among patient with IBS-D with pretest scores in QOL (\( r = 0.27 \)), symptom frequency \( (r = 0.44) \), and symptom severity \( (r = 0.38) \), which were significant statistically \( (P < 0.05) \). Concerning the finding, patient’s background was employed as covariate variable involved with pretest scores in MANCOVA analysis. The results of Box’s and Leven’s tests demonstrated that default consistency of covariance and variance related to dependent variables in CBT and drug therapy with CBT. Regarding this conclusion and similarity of sample size, MANCOVA was used as a best statistical method for data analysis.

Other findings of this study showed that management of covariate variables of pretest and disease background influenced on dependent variables so that there were significant differences between mean score of life quality in CBT group and group of CBT with drug therapy by managing disease background and pretest scores both in posttest and follow-up stages \( (P < 0.05) \). Significant difference was also obtained between mean scores of frequency and symptom severity of IBS in both groups in posttest stage. However, the difference was not significant in follow-up stage \( (P < 0.05) \). Degree of \( \eta^2 \) effect was 67% in relation to QOL variable in posttest stage, which revealed that 67% of changes in dependent variables referred to variety in group membership or therapy type. In other words, this degree showed the higher impact of psychological interference (CBT) on improving QOL of patients. The higher degree of \( \eta^2 \) was shown, the lesser effects of disease background and pretests were appeared on findings which resulted from therapy interference. Moreover, statistical square = 1 number which demonstrated qualification of sample size [Table 2].

Comparison of group differences in dependent variables showed that there were significant differences between two groups of CBT with drug therapy and only-drug therapy in QOL scale both in after treatment and follow-up stage \( (P = 0.001 \text{ vs. } P = 0.07) \). Considering severity and frequency of IBS symptoms, differences were significant in both groups in after treatment stage \( (P = 0.001 \text{ vs. } P = 0.014) \), while the difference was not significant in follow-up stage \( (P = 0.47 \text{ vs. } P = 0.17) \) [Table 3].

DISCUSSION

In the present study, most patients were female that showed the higher prevalence of this disease among women, confirmed by other studies.\(^{23,24}\) Disease background in patients with IBS were obtained from 1 year to 23 years which demonstrated the severity and incurable condition of this disease.\(^{25}\) Another findings of this paper revealed that CBT with drug therapy influenced more than only-drug therapy on improving QOL in patients with IBS both in after treatment and follow-up stages, which was consistent with studies of Drossman et al.\(^{19}\) and Shen and Nahas\(^{26}\) in terms of effectiveness of psychological therapy associated with anti-depression drugs on improving QOL and reducing symptoms in patients with IBS. Therefore, this paper suggested that it was not sufficient to apply drug therapy in recovering QOL of patients and psychological therapies as CBT was required to be executed regarding the results of other research papers in terms of disease simultaneity.
Findings of other articles claimed the influential situation of CBT on improving QOL in patients with IBS, which were in congruent with results of the present study.\[27,28\]

In other section of the present study, it was indicated that CBT with drug therapy was effective in reducing frequency and severity of patient symptoms with IBS in after treatment stage so that decreasing score mean of CBT with the drug therapy group was significant in comparison with only-drug therapy group. In a similar study, CBT based on self-management with the standard therapy was compared with the standard therapy on patients with IBS, which symptoms in patients with IBS in the first group decreased significantly compared to the second group (control group) in after treatment stage.\[16\]

Sources of mentioned paper were as same as the present study. Rapid response to CBT was explored on patient symptoms with IBS in other articles, which obtained findings were indicators of rapid reduction of patient symptoms after 4-week period of CBT interference,\[18\] which were confirmed the results of the present study. Other findings demonstrated the similar effect of CBT, relaxation, and daily clinical caring as three treatment methods on patient symptoms with IBS with no significant differences among the three therapies,\[17\] which is not consistent with the present study. One of the reasons might be the application of CBT without drug interference in the mentioned paper. However, in the present study, cognitive behavior with drug therapy was executed on patients, which approved pathophysiology and psychology aspect of patients.

Some papers revealed effectiveness of anti-depression drugs on reducing symptoms and improving QOL in patients with IBS,\[10,29\] which were in congruent with the present study so that the patient symptoms with IBS reduced in only-drug therapy group after interference in the present study. However, a study indicated that anti-depression drugs were not successful in reducing patient symptoms with IBS compared to placebo.\[11\]

Findings of above-mentioned studies were not in accordance with the present paper and the reason behind this issue resulted from the fact that above-mentioned papers employed just drug therapy, whereas, in the present study, a combination of CBT therapy and drug therapy was employed in patients with IBS. Consequently, there was significant reduction in frequency and severity of symptoms in patients with IBS.

Other results derived from the present study demonstrated that CBT with drug therapy was not influential on frequency and severity of patients with IBS 6 months after therapy interference or follow-up stages, and as a result, degree of frequency and severity of symptoms were decreased extremely in follow-up stage that were in line with results of other research papers, which indicated rapid decrease of symptoms during 6 months after treatment.\[30,31\]

| Table 2: Covariance analysis, comparison of therapy groups with dependent variables by managing of disease background variable and pretest scores in posttest and follow-up stages |

<table>
<thead>
<tr>
<th>Variable</th>
<th>Source</th>
<th>Disease background</th>
<th>QOL</th>
<th>BSSS</th>
<th>BSFS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dependent variables</strong></td>
<td></td>
<td>Posttest Follow-up</td>
<td>Posttest Follow-up</td>
<td>Posttest Follow-up</td>
<td>Posttest Follow-up</td>
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<tr>
<td><strong>Square mean</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>QOL</td>
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<tr>
<td>BSSS</td>
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<td>1</td>
<td>4.93</td>
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<tr>
<td>BSFS</td>
<td>8.64</td>
<td>8.75</td>
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<td>1</td>
<td>3.25</td>
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<tr>
<td>Pretest</td>
<td>256.04</td>
<td>302.8</td>
<td>1</td>
<td>1</td>
<td>3.51</td>
</tr>
<tr>
<td>QOL</td>
<td>31.61</td>
<td>45.7</td>
<td>1</td>
<td>1</td>
<td>4.51</td>
</tr>
<tr>
<td>BSSS</td>
<td>4.53</td>
<td>6.63</td>
<td>1</td>
<td>1</td>
<td>2.63</td>
</tr>
<tr>
<td>BSFS</td>
<td>6.84</td>
<td>8.45</td>
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<td>1</td>
<td>1.95</td>
</tr>
<tr>
<td>Group membership</td>
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<tr>
<td>QOL</td>
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<td>536.4</td>
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<td>1</td>
<td>3.6</td>
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<tr>
<td>BSSS</td>
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<td>8.45</td>
<td>1</td>
<td>1</td>
<td>9.3</td>
</tr>
<tr>
<td>BSFS</td>
<td>4.53</td>
<td>6.63</td>
<td>1</td>
<td>1</td>
<td>5.12</td>
</tr>
</tbody>
</table>

QOL: Quality of Life, BSSS: Bowel Symptom Severity Scale, BSFS: Bowel Symptom Frequency Scale.
### Table 3: Pair-wise comparison of two groups in quality of life, severity, and frequency scales of symptoms of irritable bowel syndrome in three study stage

<table>
<thead>
<tr>
<th>Dependent scales</th>
<th>Therapy groups</th>
<th>Adjusted score (mean±SD)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pretreatment</td>
<td>Posttreatment</td>
<td>Follow-up</td>
</tr>
<tr>
<td>QOL</td>
<td>CBT + DT</td>
<td>82.4±11.02</td>
<td>62.87±9.9</td>
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<tr>
<td></td>
<td>DT</td>
<td>83.2±11.84</td>
<td>74.3±10.01</td>
</tr>
<tr>
<td>BSSS</td>
<td>CBT + DT</td>
<td>12.10±1.2</td>
<td>6.84±1.4</td>
</tr>
<tr>
<td></td>
<td>DT</td>
<td>13.04±2.7</td>
<td>10.75±1.8</td>
</tr>
<tr>
<td>BSFS</td>
<td>CBT + DT</td>
<td>11.57±2.6</td>
<td>6.01±1.1</td>
</tr>
<tr>
<td></td>
<td>DT</td>
<td>11.07±2.05</td>
<td>9.09±1.4</td>
</tr>
</tbody>
</table>

CBT: Cognitive behavioral therapy, SD: Standard deviation, DT: Drug therapy, QOL: Quality of Life, BSSS: Bowel Symptom Severity Scale, BSFS: Bowel Symptom Frequency Scale

### CONCLUSION

The results of the present study revealed the effect of biopsychosocial factors on outbreak and therapy of most medical diseases such as IBS. Hence, the cooperation of internists and circulatory specialists with psychiatrists and psychologists seem as required issue in terms of therapy of some digestion diseases, in which psychological factors play a significant role in outbreak and severity of symptoms. In the other hand, continuity of psychological therapies besides consumption of drug will be prevented from symptom recurrence. The important limitation of the present study was lack of waiting list group that we could not kept such group during 6 months without therapy interference due to moral issues, and as a matter of fact, drug therapy was executed on two groups to evaluate CBT impact.

**Limitations of the study**

Small sample size enrolled in this study limits the generalization of the study findings.

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**Conflicts of interest**

There are no conflicts of interest.

**REFERENCES**


