Guided Imagery for Women with Interstitial Cystitis: Results of a Prospective, Randomized Controlled Pilot Study

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ABSTRACT

Introduction: In the United States, more than 1 million women and men are affected with interstitial cystitis (IC), which is a clinical syndrome involving urinary urgency, frequency, and pelvic pain. A review of the literature revealed that there are no studies showing the effect of guided imagery in women with IC. The purpose of this clinical investigation was to explore the effect of guided imagery on pelvic pain and urinary symptoms in women with IC symptoms.

Methodology: Thirty (30) women with diagnosed IC were randomized into 2 equal groups. One group (treatment) listened to a 25-minute guided imagery compact disc (CD), that was created specifically for women with pelvic pain and IC, twice a day for 8 weeks. The control group rested for 25 minutes twice daily for 8 weeks. Because no guided imagery CDs specifically for women with IC were found on the commercial market, the authors created a script and recorded the CD specifically for women with IC and pelvic pain. The focus of this guided imagery CD was on healing the bladder, relaxing the pelvic-floor muscles, and quieting the nerves specifically involved in IC. Baseline and end-of-study assessment questionnaires (Interstitial Cystitis Symptom Index & Problem Index [IC-SIPI], IC Self-Efficacy Scale, a visual analogue [VAS] scale for pain, and a global response assessment [GRA]), 2-day voiding diaries, and 24-hour pain diaries were completed by the subjects and were evaluated using SPSS (Chicago, IL).

Results: More than 45% of the treatment group were responders to guided imagery therapy noting a moderate or marked improvement on the GRA. Pain scores and episodes of urgency significantly decreased in the treatment group. Responders had significant reductions in IC-SIPI scores (problem index, \( p = 0.006 \); symptom index, \( p = 0.004 \)). In addition, responders on the GRA had significant (\( p = 0.039 \)) improvements in mean pain scores from 5.50 to 2.57 at the end of the study in contrast to the nonresponders, whose pain levels remained the same (4.89 to 4.39).

Conclusions: This is the first study providing preliminary data supporting the use of guided imagery as a potential therapy for IC. Guided imagery may be a useful tool to offer women with IC for pain and IC symptom management. It is an intervention without negative side-effects, is readily available, and shows a trend toward improvement of IC symptoms.

INTRODUCTION

Guided imagery uses words to direct one’s thoughts and attention to imagined visual, auditory, tactile, or olfactory sensations to elicit the psychologic and physiologic response of relaxation.¹ The physiologic effects of guided imagery may be related to the Gate Control Theory of pain by Melzack and Wall.² This theory states that only one impulse can travel up the spinal cord to the brain at a time. If this pathway is occupied with other thoughts, then the sensations

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of pain cannot be sent to the brain, and therefore the pain is reduced. Another theory supports the impact of guided imagery on endorphin release from the brain. Endorphins are the body’s natural analgesics. The endorphins released in response to using guided imagery promote relaxation, decreased pain, and an increased pain threshold. This activates the parasympathetic nervous system to decrease blood pressure, respirations, and heart rate and increase relaxation. Guided imagery has demonstrated efficacy in reducing pain related to many conditions including cancer pain, chronic low-back pain, and postoperative pain. A review of 46 guided imagery intervention studies reported that 87% of these studies found that guided imagery resulted in improvements in the psychologic or physiologic outcomes examined. However, there is a need for more randomized, controlled clinical studies to provide findings that lead to evidence-based practice in a variety of areas.

In urology, many people worldwide suffer with interstitial cystitis (IC) or painful bladder syndrome, which is a chronic condition. In the United States, more than 1 million women are affected as well as a significant number of men. IC is a clinical syndrome of urinary urgency, frequency, and pelvic pain that may occur in a variety of locations such as the lower abdomen and back, as well as the inguinal, urethral, vaginal, or suprapubic areas. Urinary frequency may be up to 60 times per day and every 20–30 minutes during the night. This can lead to chronic sleep deprivation and depression. Currently, in women in the United States, the incidence of IC is 52–67 cases per 100,000. IC is three times more prevalent in the United States than in Europe; however, there are differences in diagnostic criteria that may account for this variation in prevalence. The majority of women with IC are Caucasian, with a median age at diagnosis of 42–46 years.

Chronic pain, particularly neuropathic pain, may alter one’s emotional well-being, family and social relationships, and ability to work. It has been hypothesized that patients with IC who have been unable to obtain adequate relief from medical remedies would value a psychotherapeutic intervention that could diminish some of their pain. In general, women who used biofeedback, self-hypnosis, heat, or cold to alleviate mild-to-moderate pain found the effectiveness of these techniques to be comparable to the effectiveness of medications, including narcotics. However, a review of the literature revealed that there are no studies showing the effect of guided imagery in women with IC.

The purpose of this clinical investigation was to explore the effect of guided imagery on pelvic pain and urinary symptoms in women with IC.

METHODOLOGY

This was a prospective, randomized, controlled pilot study conducted with institutional review board approval from July 2005 to August 2006 at a large community hospital in Royal Oak, Michigan in the hospital’s urology research department. Each subject had an established medical diagnosis of IC confirmed by cystoscopy and hydrodistention performed by a board-certified urologist. All subjects reported urgency, and/or frequency, and pain. Some subjects reported histories of ulcerative IC; however, this was not confirmed by source-document review for this study.

Subjects were referred to the nurse practitioner (NP) in the Beaumont WISH [Women’s Initiative for Pelvic Pain and Sexual Health] program for treatment, and subjects 18 or older with pelvic pain confirmed at that visit by way of levator examination were invited to enroll in the study. The levator examination was done by the NP during a vaginal examination by pressing with the index finger laterally to the levator pelvic floor muscles. Pain was rated on a 0–10 visual analogue scale (VAS). Participants also had stable medication regimens, had not participated in other clinical trials in the last 30 days, and did not have neuromodulation devices implanted in the last 90 days prior to the study.

At their first visits, 30 women were individually randomized by a blinded research staff member not involved in the study by drawing from a shuffled set of folders that included hidden notations of “Treatment group” or “Control group.” Because this was a pilot study and internally funded, it was decided that 15 subjects in each arm would be adequate to provide some preliminary data that could then provide a basis for a larger-powered study in the future. Baseline assessment questionnaires (Interstitial Cystitis Symptom Index & Problem Index [IC-SIPI], IC Self-Efficacy Scale, a VAS for pain, and a global response assessment [GRA]), 2-day voiding diaries, and 24-hour pain diaries were completed by each subject. Both groups were maintained on their IC regimens as prescribed by their own health care providers. One group (treatment) listened to a 25-minute guided imagery compact disc (CD), that was created specifically for women with pelvic pain and IC, twice a day for 8 weeks. Because no guided imagery CDs specifically for women with IC were found on the commercial market, the script for this CD‡ was written by the NP, who had extensive experience in utilizing guided imagery in women’s health and also was knowledgeable about IC. The foci were on healing the bladder, relaxing the pelvic floor muscles, and quieting the nerves specifically involved in IC. Phrases were included such as: “imagine the warm sunshine soaking into your body and gently glowing in your abdomen . . . you may begin to feel healing warmth melt into your bladder . . . coating the inside and outer surfaces . . . letting each and every cell relax and release its tension . . . soothing any painful areas with its gentle golden glow.” (See Appendix 1). The script was reviewed and edited by the hos-

‡Information on the contents and how to obtain this CD are included in Appendix 1.
hospital’s director of integrative medicine, who is a certified hypnotherapist and expert in guided imagery. The other group (comprised of wait-list controls) rested by sitting or lying down for 25 minutes, twice a day, for 8 weeks. Pain and medication diaries were kept by all subjects twice per week—one on a weekday and one on a weekend day. The 2-day voiding diaries and assessment questionnaires were completed again at 8 weeks. The control group members received copies of the guided imagery CD at the end of the study.

**Outcome measures**

The objective of this study was to explore the effect of guided imagery in women with IC. The hypothesis was that guided imagery would decrease IC symptoms and improve self-efficacy in these women. To evaluate the primary endpoint of reduction of IC symptoms, the GRA was used. This is a 7-category scale that includes responses ranging from “markedly worse” to “markedly improved.” A “moderate or marked improvement” response was needed for a subject to be designated as a responder to the therapy. Secondary outcome measures included the information gathered via the 2-day voiding diary and the IC-SIPI both pre- and post study intervention. The IC-SIPI is a validated tool to assess the severity and impact of IC symptoms. The IC symptom index is comprised of 4 questions with responses scored from 0 to 5. The IC problem index has 4 questions that are scored from 0 to 4. A higher score on each is positively correlated with IC symptoms or problems. Finally, for this endpoint, pain was measured by a VAS from 0 to 10.

A tertiary endpoint of improved self-efficacy was evaluated by the IC Self-Efficacy Scale. This tool assesses the degree of confidence that women with IC have in managing a variety of IC symptoms successfully. Each response is noted on a scale from 0 to 100 (“not certain” to “very certain”). The subscales of Manage Pain (α = 0.86), Fatigue (α = 0.82), Distress (α = 0.90), and Activity (α = 0.88) were used in this study. In addition, overall well-being was quantified by a Guided Imagery/Relaxation Response Assessment developed by the researchers that asked how the subject felt overall at the end of the study as compared to the start of the study. This was a 7-point scale that included responses ranging from “markedly worse” to “markedly improved.”

**Data analysis**

All data were analyzed using SPSS software (SPSS version 13.0.1, 2004; Chicago, IL). A Student’s \( t \)-test was used to compare treatment to control and a paired \( t \)-test was used to compare baseline to post-treatment. A participant was considered to be a responder to this treatment if she reported a “moderate” or “marked” improvement on the GRA. Statistical significance was judged using an alpha level (\( p \)-value) of 0.05. The variables of interest in this study were the different measurements of IC symptoms, pain severity, and self-efficacy across the treatment and control groups with the objective of finding out the difference between the two groups.

Standard scoring systems were used for the study instruments to quantify the variables of interest to carry out the statistical analysis. Data analysis was carried out at descriptive and analytical levels. For descriptive purposes, summary statistics such as means and standard deviations for continuous variable and median, mode, and/or frequencies for discrete variables were calculated for the variables of interest. For analytical purposes, statistical distribution assumptions were examined and parametric and nonparametric tests were applied as needed with the principle of using \( t \)-test and analysis of variance for continuous variables, and Chi-square or Fisher’s exact tests were applied to categorical variables.

**RESULTS**

The two groups were similar with respect to age, ethnicity, and educational level. The average age was 44, all were Caucasian, and 93% had more than a high-school education. Seventy-three percent (73%) were married and more than half (57%) did not work outside the home. Although 30 women enrolled in the study, 5 withdrew before completing the study for personal reasons (too busy, not able to follow protocol). This analysis is on the remaining 25 women (Fig. 1).
Forty-five and a half percent (45.5%; 5/11) of the treatment group compared to 14.3% (2/14) of controls noted on their GRAs (Fig. 2) a “moderate or marked improvement” (i.e., reduction) of IC symptoms although this was not statistically significant. This may be a reflection of a lack of power of this study, given that this was a pilot study.

The IC-SIPI scores declined in each group as a whole from the start to the end of the study but this was not statistically significant (Table 1).

The mean overall IC Self-Efficacy Scale scores from the start to the end of the study improved in both groups—the treatment group scores improved from 33.64 to 38.30, and the control group scores went from 38.75 to 40.51; however, this was not statistically significant.

The 24-hour 10-point VAS pain score for the treatment group was statistically significantly improved \( (p = 0.027) \) from 5 at the start to 3 at the end of the study, with a non-significant improvement in the controls from 5 to 4 \( (p = 0.187; \text{Fig. 3}) \). The average episodes of urgency on the voiding diaries significantly declined from the start to the end of the study in the treatment group from 16 to 12 \( (p = 0.02) \), with no significant change (9.77–9.04) in the controls \( (p = 0.684) \). The voiding diaries did not show any other significant difference in number of voids per day or night, volume voided, fluid intake, or bowel movements between the groups.

To assess our definition of a responder as “moderately” or “markedly” improved, we looked at secondary-outcome variables to see if improvements were seen in subjects we defined as responders compared to nonresponders. Responders had significant reductions in IC-SIPI scores (problem index, \( p = 0.006; \) symptom index, \( p = 0.004 \)). In addition, responders on the GRA had a significant \( (p = 0.039) \) improvement in mean pain scores from 5.50 to 2.57 at the end of the study in contrast to the nonresponders whose pain levels remained essentially the same (4.89–4.39).

**DISCUSSION**

This pilot study examined the effect of utilizing a complementary therapy, guided imagery, to manage the urinary symptoms and pelvic pain of women with IC.

Many theories have evolved regarding the etiology of symptoms of IC. Some of the proposed theories include: increased urothelial permeability; increased mast-cell activity; neuroimmune abnormalities; neuroplasticity of the nervous system; and infectious etiologies. Myofascial pain and hypertonc pelvic floor dysfunction are present in as many as 85% of patients with IC and/or chronic-pain syndromes. These muscles may trigger neurogenic inflammation of the bladder wall, which increases urothelial permeability thus resulting in IC symptoms.16

Levator ani muscle myalgia can also be a cause of dyspareunia and chronic pelvic pain for these patients.17 IC is usually associated with dyspareunia and flareups after sexual activity18 while 44% of the lower urinary tract symptoms (LUTS) patients reported sexual pain disorders.19 Chronic pelvic pain often motivates women to seek treatment but the etiology of this pain is often difficult to identify resulting in many medical and surgical treatments (i.e., hysterectomies).20 Patients are often misdiagnosed before an accurate diagnosis of IC is made.21

In relation to pelvic pain, consideration must be given to other gynecologic or gastrointestinal disorders that may contribute to the pelvic pain a patient with IC experiences. Mul-

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**TABLE 1. INTERSTITIAL CYSTITIS SYMPTOM INDEX & PROBLEM INDEX RESULTS**

<table>
<thead>
<tr>
<th></th>
<th>Symptom index (0–20)</th>
<th>Problem index (0–16)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treatment</td>
<td>Controls</td>
</tr>
<tr>
<td>Start of the study</td>
<td>13.40</td>
<td>12.26</td>
</tr>
<tr>
<td>End of the study</td>
<td>11.63</td>
<td>10.71</td>
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tidisciplinary approaches can be used to address the biologic, psychosexual, psychosocial, and spiritual factors that contribute to the pain. Vaginitis/infections should be treated, vaginal pH restored to normal, pelvic floor relaxation exercises taught, hormones adjusted if necessary, pain controlled via medications or other therapies, and counseling recommended as needed.22

There are a variety of medications and intravesical therapies used to treat IC. In addition, other therapies used are transcutaneous electrical nerve stimulation, InterStim,® (Medtronic, Minneapolis, MN) and various surgical procedures.23 However, the efficacy of these therapies is variable and the results are often not long-term. Often, health care providers in various specialties are not familiar with complementary therapies and depend solely on pharmaceutical, medical, or surgical interventions for healing. Other therapies directed at the pelvic floor and not the bladder itself may be key in the multimodal management of IC.

Given that many people with IC (up to 85%) have pelvic floor dysfunction, utilizing guided imagery to relax the pelvic floor muscles may make an impact on bladder symptoms and pain. As health care providers, it seems reasonable to offer this option as a potential therapeutic modality for managing IC symptoms.

Key interventions for people with chronic pain include keeping a pain diary, mastering relaxation techniques, using imagery or hypnosis, and restructuring thoughts.24 In this study, pain and voiding diaries were kept along with utilizing relaxation and guided imagery techniques. More than 45% of the treatment group were responders to guided imagery therapy. In addition, pain scores and episodes of urgency decreased significantly in the treatment group. The exact mechanism of how this guided imagery helped to decrease pain and urgency remains to be seen. One limitation of this study was that cystoscopy was not repeated after treatment for comparison to pretreatment findings. A future study could include pre- and post-treatment cystoscopy, laboratory work, or brain imaging in addition to urodynamic testing.

Although this pilot study had a small sample size, it demonstrated a trend toward reduction of IC symptoms. Given that IC is a syndrome, there is no single marker to define a positive response. A “moderate” or “marked” improvement on the GRA to define a responder in IC has been routinely used.25 This is a subjective measure; however, secondary outcomes improved in subjects defined as responders compared to nonresponders, supporting this definition of response. The use of guided imagery in this population to help alleviate dyspareunia and sexual dysfunction was not explored in this study but would be an interesting area to explore in future research. The trend toward reduction of voiding symptoms and pain, and improving quality of life supports the need for further research in this area.

CONCLUSIONS

This is the first study providing preliminary data supporting the use of guided imagery as a potential therapy for IC. Guided imagery may be a useful tool to offer women with IC for pain and IC symptom management. It is an intervention without negative side-effects, it is readily available, and it shows a trend toward reduction of IC symptoms.

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APPENDIX 1: EXCERPT FROM COMPACT DISC FOR WILLIAM BEAUMONT HOSPITAL WISH [WOMEN'S INITIATIVE FOR PELVIC PAIN AND SEXUAL HEALTH] PROGRAM'S GUIDED IMAGERY FOR WOMEN WITH INTERSTITIAL CYSTITIS AND PELVIC PAIN “LETTING GO”

This 30-minute compact disc (CD)* was written by Donna Carrico, R.N.C., M.S., N.P., at the WISH program at William Beaumont Hospital in Royal Oak, MI, and edited and narrated by Gail Elliott Evo. The copyrighted CD includes some of the following statements for patients to help them relax and participate in guided imagery to relieve their pelvic pain:

The purpose of this exercise is to allow yourself to relax—letting go of any tension you may feel in your body. Relaxation has been shown to be beneficial for one’s health. This CD was created specifically for women with pelvic pain and interstitial cystitis. Please do not listen to this CD while driving or operating machinery. When you are ready, find a comfortable place to sit or lie down . . . it would be ideal if you were undisturbed for about 25 minutes. . . . And as you settle in to your comfortable place, gently invite your eyes to close . . . and then at your own pace, take a deep breath in and slowly let it out . . . just let your breathing settle into its own rhythm. . . . Take a moment and become aware of the breath in . . . and out . . . in . . . and out . . . You can begin to let go of any tension or discomfort that you may have. . . . Continue to breathe. . . . If your mind wanders, simply return your attention to your breath, resting more and more comfortably in your safe place. . . . As you breathe, feel the oxygen entering each and every cell in your body . . . floating in through your nose, and traveling down your through your neck, lungs, your abdomen, back, pelvis and both of your legs . . . fresh, clean air flowing into each and every cell . . . relaxing and nourishing each cell with every breath. You may notice that your head and neck are completely relaxed—loosely resting on your comfortable surface. And as you continue to breathe in . . . and out . . . your shoulders and arms are resting comfortably . . . without tension. And as you continue to breathe in . . . and out . . . notice your back and abdomen resting more comfortably—relaxing more deeply as you continue to breathe. Your legs feel heavy and warm as you become more and more relaxed. . . . Now that your body is relaxed you may use your imagination and envision yourself at the top of a small hill that leads to a meadow—there are 10 steps winding down this gentle slope—. . . .

In a moment, I’m going to gently lead you down the stairs . . . with each step down you will become deeper and deeper relaxed. Approach the steps, and gently stepping down—10 . . . down . . . 9 . . . more comfortably relaxed . . . down . . . 8 . . . and . . . 7 . . . deeper . . . and deeper down . . . 6 . . . 5 . . . 4 . . . feeling more and more relaxed . . . 3 . . . 2 . . . 1. . . You find yourself in a beautiful meadow. You feel sunshine warming your skin from your head to your toes. The air smells so fresh and clean. There are beautiful flowers everywhere—perhaps buttercups, poppies, or gardenias. . . . Butterflies are floating from flower to flower. . . . A few steps ahead you notice a puffy quilt lying in a cozy corner of this meadow. You go and lie down on this soft, comfortable quilt—the green grass is so plush and low, forming a beautiful bed. . . . And as you breathe in, feel your body relaxing more and more into the softness of this space. . . . You may hear sounds like—the birds singing . . . the river flowing peacefully under the nearby footbridge . . . wind chimes in the distance are like lullabies caressing your soul.

You may begin to notice how warm and relaxed you feel as the sunshine surrounds your body and soothes away any discomfort . . . you feel calm, comfortable and cared for. . . .

If you wish, imagine the warm sunshine soaking into your body and gently glowing in your abdomen. Perhaps you imagine this glow to be yellow or gold. You may begin to feel healing warmth melt into your bladder . . . coating the inside and outer surfaces . . . letting each and every cell relax and release its tension . . . soothing any painful areas with its gentle golden glow. And as your bladder feels this warmth and relaxation, your bladder does not need to feel any sense of urgency—you just continue to rest, and enjoy this moment of peaceful healing. . . . Gradually, you feel the warmth continue to flow through your pelvis, vagina and back . . . letting each and every muscle release its tension, becoming loose . . . open . . . and relaxed, allowing your pelvis to sink more comfortably into the soft quilt, feeling soothed by the lullaby of birds in your meadow. . . . And as you breathe in the refreshing, clean air of the meadow, become aware of the oxygen flowing rapidly to these warm, open cells and muscles in your pelvis, vagina and back . . . allowing them to heal . . . allowing their tension to melt away. As you continue to breathe slowly, imagine your blood vessels bringing oxygen and healing compounds to your bladder. Imagine your own pain blockers—your endorphins—gently wrapping around the nerve endings to the bladder like fluffy cotton, insulating your body from the pain. . . .

*This copyrighted CD can be obtained from Ms. Carrico, R.N.C., M.S., N.P. (see reprint address).
You may wish to place your hands gently on your lower abdomen . . . feel the warmth and relaxation in this area of your body.

Notice the enjoyable feeling of letting go—the warmth in your muscles—relaxing more deeply . . . resting safely and comfortably in your meadow. Remember this healing and soothing sensation and know that you can experience this any time. . . .

You may begin to experience many feelings—perhaps kindness . . . understanding . . . self-acceptance . . . forgiveness . . . inner peace. . . .

At your own pace, breathe in . . . and out. . . . Letting go. . . . Really letting go. . . . Accepting these feelings. . . . Accepting yourself just as you are . . . feeling safe. . . .

And as you observe this experience, let go of any expectations about your body or yourself, these are just ideas—let them drop away . . . really go away . . . and just observe your body as it is. . . . Relaxing, . . . letting go. . . . Breathing in . . . aware of the breath in, and breathing out, aware of the breath out. . . .

Let yourself drift. . . . For a moment, be aware of how relaxed your mind and body feel right now. . . . How deeply soothed your pelvis, vagina, bladder and back feel right now. . . . Healed . . . relaxed . . . and how very healthy you feel. . . . You may remember this place anytime you need to soothe away your pain. This is a place where rest, healing and peace are always available . . . a place that is always with you. . . .

In your meadow, you are surrounded by beautiful flowers and butterflies. You feel healing rays of sunshine on your body, and smell the fresh, clean smells of this meadow. You slowly stand up and feel the soft grass beneath your feet. You follow a butterfly to a footpath in your meadow . . . and in a moment I am going to count from 1 to 5, and when I reach 5 you will open your eyes, and feel very refreshed, alert, relaxed and peaceful. . . . If you were listening to this CD and fell asleep, you will have a wonderful rest and awaken and feel re-vitalized, like a new person. . . .

Counting slowly . . . 1 . . . and . . . 2 . . . , becoming more alert . . . 3 . . . aware of your surroundings . . . 4 . . . even more alert, . . . 5 . . . you gently open your eyes. . . . You may wish to gently stretch your body in a way that feels most natural for you. . . . When you are ready, open your eyes—feeling refreshed and alert, knowing you can take these feelings of relaxation and comfort with you into your daily life. . . .

The CD ends with 5 minutes of music.