The Effect of Guided Imagery Therapy in Children with Functional Abdominal Pain in Quiescent Inflammatory Bowel Diseases (IBD).

Introduction

Inflammatory bowel diseases (IBD) impact a significant number of children and adolescents in the United States. Within this patient population, approximately 43 per 100,000 individuals are diagnosed with Crohn’s disease (CD), and 28 per 100,000 are diagnosed with ulcerative colitis (UC). Nearly one fourth of patients with IBD develop their illness during childhood or adolescence and depending on the patient, the subsequent course of illness varies significantly. A subset of IBD patients whose illness is in remission continue to suffer from gastrointestinal symptoms, with no evidence of organic disease and thus of presumed functional origin. The functional gastrointestinal symptoms, specifically abdominal pain, impinge upon the physical and social development of children, and decrease the quality of life for both patients and their families. Traditional medical treatment is not always successful in safely and effectively treating these patients; therefore, the child with functional abdominal pain is best evaluated and treated in the context of a biopsychosocial model of care. Stress, psychosocial factors, depression, and anxiety can aggravate the physiological symptoms of both organic and functional gastrointestinal disease (ie. hyperalgesia), and can be related to disease severity and course. Thus it is important to address these factors in the diagnostic evaluation and management. Combining medical care with behavioral therapies such as guided imagery has been shown to be very effective in reducing abdominal pain, disability and quality of life in children with functional abdominal pain and the innovation of home based therapy addresses issues of accessibility, time, and cost. However, the efficacy of these type of treatment has not been tested in quiescent but symptomatic IBD disease.

Hypothesis and Specific Aims

We hypothesize that home based guided imagery therapy, in addition to traditional medical treatment provided by their physician, will be more effective in treating pediatric IBD patients who are in remission but are experiencing functional gastrointestinal symptoms, than traditional medical treatment supplemented by placebo relaxation exercises. We predict that guided imagery will result in an increase in quality of life (the primary outcome variable) and a decrease in pain and disability.

The aim of the summer project is to design and implement a pilot study that will provide preliminary data on the effect of guided imagery in the treatment of functional abdominal pain in patients whose IBD is in remission. If successful, the results from this project will be used in a future, larger study, with hope of providing effective, affordable, and easily accessible treatment for abdominal pain in these patients. Guided imagery therapy is not meant to replace conventional medical care, but rather to supplement it to obtain more effective treatment.

Background

Inflammatory bowel diseases (IBD) are characterized by inflammation of the gastrointestinal tract. Symptoms associated with IBD in children include abdominal pain, bloody diarrhea, weight loss, growth retardation, and delayed onset of puberty. Abdominal pain is a primary symptom of IBD, but it is also experienced by some patients with quiescent disease. Pain, diarrhea, bloating, and fecal incontinence, are commonly experienced in these patients without the presence of inflammation, ulceration, or obstruction. These symptoms are similar to symptoms of patients who suffer from functional gastrointestinal disorders such as Irritable Bowel Syndrome (IBS), a disorder characterized by abdominal pain with changes in stool. Functional gastrointestinal symptoms are caused by abnormal,
but not pathological, functioning of the GI tract, such as changes in motility or hypersensitivity to normal gut processes. Children with quiescent but symptomatic Crohn’s disease show increased visceral hypersensitivity compared to healthy controls, indicating that pain in the absence of inflammation is of functional origin.  

Children suffering from functional gastrointestinal symptoms, primary or secondary to IBD, experience reduced quality of life as a result of their chronic pain and are often forced to miss school and social activities. Therefore, effective treatment is important; however, no uniform standard of care is available for symptomatic IBD patients who have minimal or no presence of inflammation. The symptoms may be attributed to active disease and patients are prescribed potentially harmful medications such as steroids. Or patients may be reassured that there is no infection and the family is left to cope with the pain and associated disability. Neither one of these approaches is optimal; therefore, there is a need for a proven treatment to treat functional symptoms in patients with IBD, especially in children.

Medical treatment consists of reassurance that the pain is real but not caused by a disease such as inflammation and medications for accompanying symptoms. This can be successful, but additional therapy is required for many patients. Because gastrointestinal disorders also have associated psychosocial factors which can trigger symptoms, cognitive behavioral strategies intended to influence psychological and physiological processes have been tested, and the results have been positive. Specifically, guided imagery techniques are effective and widely used for abdominal pain in pediatric and adolescent patients with IBD, IBS, functional dyspepsia, functional abdominal pain, and abdominal migraine. In guided imagery the therapist uses verbal guidance to help the patient experience specific detailed vivid imagery that has beneficial effects on their behavior, cognitions, emotions or physiology. It is a commonly used technique for the treatment of chronic pain and can be combined with other established behavioral treatments such as cognitive behavioral therapy, progressive muscle relaxation or self-hypnosis. In pediatric patients with functional gastrointestinal disorders, specifically gastrointestinal pain, guided imagery is a useful coping mechanism that is quickly obtained and maintained. Weydert et al showed that patients undergoing guided imagery treatment with progressive muscle relaxation experienced fewer days of pain and missed less days of activities than patients treated with relaxing breathing exercises, exemplifying the validity of guided imagery itself rather than relaxation techniques in general.

Even though guided imagery is widely used to control pain and data has shown its effectiveness for reducing abdominal pain of functional origin, it currently is unavailable to most patients due to the lack of trained therapists outside of academic institutions and costs, particularly for those whose insurance does not cover their treatment. It also is unavailable for many individuals due to the time commitment needed from the family, including absences from work and school for weekly treatment sessions. To increase availability of this treatment, Dr. van Tilburg and colleagues developed a audio recorded guided imagery treatment to treat functional abdominal pain in pediatric patients that is easy to use, low in cost and can be prescribed by any clinician without training in these techniques for use at the comfort of the patient’s home. Although the study group was small, the results indicate that audio guided imagery therapy, in conjunction with regular medical treatment, is more effective than medical treatment alone. Guided imagery resulted in reduced abdominal pain, disability and number of medical visits, as well as an improvement in quality of life. Effects of the therapy were maintained at the six month follow-up. The positive outcomes of this guided imagery method for pediatric patients having disease symptoms similar to IBD patients in remission with chronic abdominal pain suggest this therapy as a potentially effective treatment to be added to conventional medical care.
Methods

Dr. van Tilburg has developed a method for using audio guided imagery in children for treatment of abdominal pain. Her home based methods will be specifically applied to hospitalized pediatric patients in IBD remission who are experiencing abdominal pain severe enough to disrupt functioning.

Subjects

From June 2009 through mid July 2009 N=20 patients aged 6-15 years old with a physician diagnosis of IBD, who are clinically determined to be in remission but are experiencing IBS-like symptoms, will be recruited through pediatric gastroenterologists at the North Carolina Children’s Hospital/Division of Pediatric Gastroenterology. The UNC Pediatric IBD group currently follows approximately 300 patients.

Inclusion criteria

Following referral by a pediatric gastroenterologist, the subjects will be screened by personal interview with one of the parents for the following inclusion and exclusion criteria: (1) Age range: 6-15 yrs; (2) Abdominal pain severe enough to disrupt activities at least once weekly in the previous month; (3) No previous experience with guided imagery for the treatment of abdominal pain; (4) No disability that could interfere with understanding the audio/visual material; (5) No psychiatric disorder with psychotic elements.

Design of the study

From the subjects recruited, patients will be randomly selected to receive treatment or placebo. At the start of the study children and parents of will be assented/ consented and complete baseline questionnaires (detailed in Evaluation section) in separate rooms. Families will receive instructions on how to use the treatment for one month. Patients will be introduced to the therapy in the hospital, but will continue the treatment at home. At the end of the one month period families will be asked to complete the same questionnaires.

Description of the treatment

The guided imagery treatment consists of an instructional DVD (25 minutes), 3 weekly sessions recorded on CD (25 minutes) and daily sessions recorded on CDS (10 minutes a day). For four weeks children will be asked to listen to the CDs at least 5 days out of seven.

Patients in the placebo group will be asked to spend 10 minutes each day listening to music in a relaxing environment. Children will receive written instructional materials explaining when to listen to music of their own choice.

Evaluation

The following questionnaires and procedures will be used to evaluate the treatment results. Questionnaires will only be completed by parents as children under the age of 10 do not have the cognitive abilities to complete most of the questionnaires and our small sample size does not allow for
analyses by age group. All questionnaires are completed pre and post treatment unless indicated otherwise

a. IBD-health related quality of life
   IMPACT is a questionnaire specifically for pediatric patients with inflammatory bowel disease in assessing disease-related quality of life. IMPACT has been shown to have excellent reliability (e.g. for internal consistency of the total score, α=.96) and validity. This is the primary outcome variable in our study.

b. Abdominal pain
   Abdominal pain frequency and intensity will be assessed by two questions derived from the Abdominal Pain Index: (1) During the last week, how often have you(r child) had abdominal pain (stomach aches)? (not at all, 1-2 days, 3-4 days, 5-6 days, every day), and (2) In the last week, when your (child’s) stomach hurt, how much did it usually hurt? (10 - point interval scale ranging from “no pain” to “the most pain possible”).

c. Functional Disability Inventory
   The FDI is a 15-item questionnaire assessing the impact of physical health on children’s functioning. The FDI possesses good internal consistency (α=0.89) and test-retest reliability (r=0.60). This questionnaire will be completed pre- and post- treatment.

d. Treatment Compliance
   To assess adherence to the treatment plan, children will be asked to attach a sticker to their treatment calendar on each day they listened to an audio recorded session or music.

Analysis
   The primary purpose is not to test the efficacy of guided imagery but to provide estimates of effect sizes and variance which will permit us to design an adequately powered trial of the efficacy of guided imagery in the treatment of functional abdominal pain in quiescent IBD. Accordingly, the primary analyses will be descriptive: Means, medians, and standard deviations will be calculated for all outcome measures and for change scores from baseline to post treatment. The distributions of variables will also be examined to insure that the requirements for parametric tests are met.
   However, based on results in our previous study we should have adequate power (83%) to detect differences in quality of life (our primary outcome variable) with an alpha set at .05 and N=20. Therefore, exploratory analyses of group differences will be tested. Group differences at baseline will be tested using independent T-tests and Chi-square tests. An ANCOVA will compare guided imagery to placebo at post treatment. Baseline scores of the dependent variables will serve as covariates to control possible baseline differences within this small sample. The dependent variables will be quality of life, pain and disability post treatment, and the independent variable is group (guided imagery versus placebo).

Time Line
   IRB approval: Full protocol will be submitted to UNC IRB later this spring. Ease of approval is expected since the treatment design imposes no harm on subjects.

   Recruitment of Patients, Introduction to Treatment, Treatment: June 2009 to mid July 2009 (6 weeks)
Analyze data: end of July 2009 (2 weeks)

Write abstract for a scientific meeting and prepare grant for a larger study: August 2009

Bibliography


