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The feasibility and acceptability of esophageal-directed hypnotherapy for functional heartburn

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SUMMARY

Functional Heartburn (FH) is a benign but burdensome condition characterized by painful, burning epigastric sensations in the absence of acid reflux or symptom-reflux correlation. Esophageal hypersensitivity and its psychological counterpart, esophageal hypervigilance (EHv) drive symptom experience. Hypnotherapy (HYP) is an established and preferred intervention for refractory symptoms in functional gastrointestinal disorders (FGIDs) and could be applied to FH. The objective of this study was to determine the feasibility, acceptability and clinical utility of 7 weekly sessions of esophageal-directed hypnotherapy (EHYP) on heartburn symptoms, quality of life and EHv. Similar to other work in FGIDs and regardless of hypnotizability, there were consistent and significant changes in heartburn symptoms, visceral anxiety and quality of life and a trend for improvement in catastrophizing. We would recommend EHYP in FH patients who are either non-responsive to medications or who would prefer a lifestyle intervention.

Keywords

functional heartburn; hypnosis; esophageal hypervigilance; relaxation

INTRODUCTION

Functional heartburn is defined in the Rome III diagnostic criteria as retrosternal burning in the absence of gastroesophageal reflux disease (GERD) and any other histopathology-based esophageal motility disorders.¹ Heartburn is a common symptom, affecting up to 20% of the general population at least once per week.^{2,3} While still considered a disorder of exclusion, a diagnostic workup which includes upper endoscopy to rule out esophagitis, lack of response on proton pump inhibitor (PPI) therapy, and impedance and pH monitoring to measure acid

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reflux, are recommended to make an accurate diagnosis.⁴ Advances in the field, particularly due to the application of esophageal pH-impedance testing, now allow for better diagnosis and characterization for patients presenting with heartburn—these advances have highlighted the inadequacy of one-size-fits-all treatments (modify diet, trial PPI therapy) in the setting of functional heartburn.

Two factors contribute to the onset and maintenance of functional heartburn. The first factor is hypersensitivity to acid in the esophagus—indeed, 75% of patients with non-cardiac chest pain, a disease of similar pathogenesis to functional heartburn, demonstrate esophageal hypersensitivity on balloon distention and experience decreased thresholds for the perception, discomfort and pain when compared to controls.⁵ When hypersensitivity is suspected, symptom management may shift towards pain modulation—commonly with tricyclic antidepressants, selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors or trazodone⁴—unfortunately it is important to note the paucity of pharmaceutical trials in patients with functional heartburn and these medications tend to be poorly tolerated and with limited efficacy.

Another factor that drives FH symptom experience is hypervigilance to esophageal sensations. Esophageal hypervigilance can be conceptualized as a learned behavior involving hyperawareness and early cue detection of future esophageal discomfort. Much like behaviors seen in panic disorder after an initial panic attack has occurred, this hypervigilance is *out of proportion* to prior symptom experience but is nevertheless reinforced when symptoms do not occur as the patient predicted. Instead of enjoying symptom free periods, the patient falsely attributes the lack of symptoms to his/her careful attempt to avoid their perceived triggers, increasing the likelihood of continued hypervigilance—over time these cues become synonymous with heartburn itself. Novel targets for intervention could include any or all of the cognitive-affective processes that make up the construct of esophageal hypervigilance (EHv), most notably 1) esophageal-specific anxiety, or visceral anxiety, manifesting as fear of normal esophageal sensations and the conditions in which these occur;⁴ and/or 2) catastrophizing, which amplifies the heartburn symptoms experience by fostering rumination about symptoms while maintaining a sense of helplessness.

Despite the significant role that the cognitive-affective processes play in the onset and maintenance of functional heartburn, few studies have examined the effects of behavioral interventions, such as hypnotherapy (HYP), in its management. Advances in hypnotherapy research highlight brain imaging studies where HYP modulates brain activation patterns associated with pain processing, patterns strongly believed to be involved in the underlying pathophysiology of functional GI disorders.⁶ There is also evidence that central pain can be modulated through hypnotic suggestion through the visceral sensory pathway.⁷ Interestingly, it has been demonstrated experimentally that gastric acid can be significantly suppressed (as well as increased) by means of hypnosis,⁸ and gastric emptying times can be shortened.⁹ Whorwell and colleagues demonstrated in a small randomized controlled trial that a course of hypnotherapy is highly effective in reducing functional chest pain¹⁰-- a disorder where the pain is thought to generally be of esophageal origin -- and that the therapeutic benefit is well maintained over two years without further intervention.¹¹ Furthermore, Kiebles *et al.*

demonstrated that hypnosis can significantly reduce symptoms of globus, another upper GI functional disorder.¹²

Given the success of HYP in other FGIDs¹³ and the role of EHv in FH, we wondered whether a specific esophageal-directed hypnotherapy protocol might be clinically useful in patients with refractory FH. Aim 1 was to determine the feasibility and acceptability of esophageal-directed hypnotherapy (EHYP) amongst FH patients participating in a NIDDK-funded PPI non-responder phenotyping study. Aim 2 was to estimate effect sizes with respect to symptom reduction, well-being and esophageal hypervigilance for a future randomized controlled trial.

MATERIALS AND METHODS

This was an open-label, controlled trial conducted at an ambulatory, academic, tertiary-care GI faculty practice. Patients enrolled in a PPI non-responder phenotyping study (1R01DK092217) were identified by their gastroenterologist endoscopy, ph-impedence and HRM testing as meeting criteria for FH and were referred for behavioral intervention. Patients were permitted to maintain their current treatment regimen, including their proton pump inhibitor, while participating in the study. Approval from the institutional ethics board was obtained.

Recruitment of subjects

We recruited 9 consecutive patients with FH to participate in this clinical protocol. One patient (intent to treat) did not complete post treatment questionnaires, but we included that individual's data in outcome analyses by adopting a last observation carried forward (LOCF) approach. Inclusion criteria included adults (18–75 years old) with current diagnosis of functional heartburn (meeting Rome III criteria). Exclusion criteria included history of gastrointestinal surgery of the esophagus or stomach; history or present throat or esophageal cancer; history of fundoplication; untreated gastroesophageal reflux disease (GERD); severe esophagitis (LA Grade C or above); Barrett's metaplasia or eosinophilic esophagitis, achalasia or spastic motor disorder; pregnancy; history of significant physical or sexual trauma which has been untreated in terms of psychological wellbeing; past or current significant psychiatric disturbance; cognitive or intellectual impairment; alcohol or other substance dependence and/or abuse; and religious or moral conflict with the use of hypnosis. A description of the study was provided to patients and after consenting, each subject completed a series of questionnaires to assess esophageal symptoms, psychological functioning, perceived stress, health-related quality of life and hypnotizability. All questionnaires were repeated at post-treatment except the Tellegen Absorption Scale. A Global Impression of Change rating was obtained once at post-treatment.

Self-report questionnaires

The Quality Of Life in Reflux and Dyspepsia (QOLRAD)¹⁴ is a well-validated disease-specific QOL measure for heartburn and dyspepsia. Each of the 25 questions is scored on a 7-point Likert scale with a lower score indicating a more severe impact on daily functioning. An average of the 25 question scores can yield a score ranging from 0 to 7.

The Visceral Sensitivity Index (VSI)¹⁵ is a widely used 15-item measure of gastrointestinal symptom-specific anxiety within 5 domains of GI related behaviors and cognitions: worry, fear, vigilance, sensitivity, and avoidance. Two items were slightly modified to capture anxiety about heartburn instead of bowels. Items are rated on a 6-point Likert scale ranging from Strongly Agree to Strongly Disagree and produce an overall score. When reverse scored, higher scores indicate greater anxiety.

The Short Form 12v2 Health survey (SF-12v2)¹⁶ is a validated 12-item health-related quality of life measure that includes a measure of overall perceived health. The SF-12v2 yields two sub-scales, the mental component summary (MCS) and the physical component summary (PCS). Higher scores are indicative of better perceived health and functioning.

The Heartburn Catastrophizing Scale was adapted from the well-validated Pain Catastrophizing Scale (PCS),^{17,18} a 13-item measure of exaggerated negative cognitions related to anticipated or actual painful experiences. For this study, “pain” was replaced by “heartburn symptoms” in the instructions to gauge the participants’ catastrophizing related to heartburn. The measure yields a score from 0 to 52 with three subscales assessing the components of catastrophizing around the experience of heartburn: rumination, magnification and helplessness. Higher scores indicate greater catastrophizing.

The Tellegen Absorption Scale (TAS)¹⁹ is a 34-item self-report questionnaire assessing absorption, or openness to absorbing and self-altering experiences, which is the most frequently studied correlate of hypnotizability and was included as a proxy measure of hypnotizability. Participants with scores between zero and 9 were classified as having low hypnotic ability, 10–19 moderate, and 20 and above as high hypnotic ability.

A Global Impression of Change rating was adapted from the Clinical Global Impressions Scale (CGI)²⁰ which is widely used and validated to assess symptom severity. The rating was collected post-treatment to assess patient reported symptom improvement. Seven choices ranging from 1 (substantially improved) to 7 (substantially worse) were provided to answer the question: Compared to how you felt prior to entering the study, how would you rate the esophageal symptoms for which you sought treatment during the PAST 7 DAYS? Participants provided one response.

Treatment protocol

Following a standardized, semi-structured clinical intake conducted by a trained clinical health psychologist (MER), each subject underwent 7 weekly sessions of an EHYP protocol. The protocol was adapted from the North Carolina Hypnosis for IBS Protocol by LK and OP for the purposes of this study. Each of the 7 sessions of EHYP followed written session scripts. Briefly, they consisted of a similar process of induction: beginning by finding a comfortable position in the relaxation chair, initiating focus on the psychologist’s voice and the subject’s bodily sensations, inducing passive muscle relaxation using mindfulness based strategies, deepening the relaxation using a numerical counting method (1–20) with a visual metaphor (i.e. going down a staircase), using visual imagery to induce comfort and relaxation localized to the esophagus and chest, and re-alerting by counting back from 20 to 1 and achieving a state of full alertness. At the conclusion of the second treatment visit, the

participant received a compact disk (CD) with a recorded (16 minute) hypnosis exercise with content similar to that of the in-session interventions. Participants were instructed to use the CD for guidance in daily home (approximately 5 times per week) practice of EHYP for the remainder of the treatment protocol. For the first two weeks of home practice (weeks 2 and 3), patients kept a home practice log to develop a routine for practice. After week 3, participants had developed a routine that was discussed with MR at the beginning of each session to assess ongoing compliance and consistency with home practice. Consistent with other studies of hypnotherapy in FGIDs, 4 sessions or more was considered an adequate dose to consider complete treatment to have been delivered.

Statistical analysis

Statistical analyses were completed using SPSS 18.0 for Windows (Chicago, IL). Descriptive statistics around demographic and disease characteristics are presented as means and standard deviations. Paired sample t-tests comparing pre and post treatment scores on all questionnaires were the primary statistical test used. Last observation carried forward was used in the one case when post-treatment data was not available.

RESULTS

Demographic data

Nine (8 women, 1 man) functional heartburn patients aged 32–60 years (mean=44.9) enrolled in this pilot study. All were married with at least a high school education. Six of 9 completed the entire 7-session clinical protocol and one more patient completed 4 sessions and was therefore considered a treatment completer. The remaining two patients completed 3 and 2 sessions of the treatment, respectively. There were no differences between patients who completed all 7 sessions and those who completed less other than one of the two non-completers was male. Baseline demographics and clinical characteristics of the sample are shown in Table 1.

Baseline data and treatment response

At baseline, the severity of heartburn symptoms varied widely, ranging from 2.12 to 5.52 on the QOLRAD (with a total possible range from 0 to 7). Commonly described symptoms included burning sensation in throat and chest, acidic taste, esophageal pain/discomfort after eating, difficulty sleeping. Paired sample t-tests were performed for the outcome measures. There was a decrease in visceral anxiety ($p=.01$), an increase in emotional QOL ($p=.05$), a decrease in symptom severity ($p=.01$) and a trend for reduction in heartburn catastrophizing ($p=.06$) (see Table 1 for pre- and post-treatment values). There was no significant change in physical QOL. Hypnotizability was not correlated with outcome measures. All participants reported improvement in symptoms post-treatment; 50% reported their esophageal symptoms as “Substantially Improved”, while 50% reported their symptoms as “Slightly Improved” at the conclusion of treatment. Table 1.

DISCUSSION

The goal of this study was to evaluate the feasibility, acceptability and potential clinical utility of esophageal-directed hypnotherapy in the treatment of 9 adult patients with functional heartburn. Overall, patients found this approach to treatment acceptable—participants tolerated the technique well and showed an appreciation for the esophageal-directed imagery described in sessions. It was also interesting to note that hypnotizability does not appear to be a factor in achieving clinically significant outcomes in terms of decreasing heartburn symptomatology, supporting the wide range of patients for whom this may be useful, however our data set is small and larger trials in the future will be needed to confirm.

The key goal of EHYP is to promote a deep state of relaxation with focused attention. Also, patients are learning through verbal suggestions and imagery to modulate symptoms and physiological sensations that are not easily targeted with traditional medical intervention.²¹ Similarly to the work of Kiebles and colleagues¹² working with patients presenting with globus sensation, we focused our visual imagery scripts on the esophageal physiology and metaphoric imagery related to the transformation of heartburn sensations. Participants engaged in home practice and demonstrated appropriate learning progression with relaxation techniques throughout the course of treatment. Participants became reinforced by their home practice efforts throughout the duration of the study as it provided them with an effective coping strategy.

Clinical and statistical significance was achieved with respect to reduction in heartburn symptoms, EHv, and improvement in emotional quality of life. The changes observed at the completion of the intervention are very much associated with changes to underlying processes of esophageal hypervigilance. All measures except for physical health changed, indicating that participants in this study may still have significant physical health ailments; however the experience of the heartburn symptoms was less burdensome as they learned an adaptive coping strategy.

Once an FH patient has failed PPI therapy, there are very limited treatment options. Early work by Clouse *et al.*²² explored the use of low-dose (100–150 mg) trazodone in a group with symptomatic esophageal contraction abnormalities. At post-treatment of the 6-week, double-blind placebo-controlled trial, patients who received trazodone reported less residual distress over their esophageal symptoms compared to the placebo group (59% +/- 9% vs. 108% +/- 19%, $p = 0.03$). Further, studies have looked at the use of imipramine to decrease esophageal pain perception²³ and improve symptoms related to non-cardiac chest pain, likely through a visceral analgesic effect.²⁴ More recently, Viazis *et al.*²⁵ investigated the use of selective serotonin reuptake inhibitors (SSRIs) for patients with hypersensitive esophagus. Participants were randomized to receive citalopram 20mg or placebo once daily (off PPI) for 6 months. At follow-up, 15 of 39 participants (38.5%) who received citalopram and 24 of 36 controls (66.7%) reported continued reflux symptoms (i.e. heartburn, regurgitation, chest pain) concluding that SSRIs were effective for a select group of individuals with hypersensitive esophagus. Despite limited data and absence of controlled trials specifically

addressing FH, antidepressant agents and SSRIs may be prescribed to target the visceral hypersensitivity aspect of functional heartburn which is based on current literature.^{1,26}

Worst-case scenario for a patient with a functional condition is to undergo an unnecessary and potentially damaging surgery, such as a fundoplication when it is not warranted.³ While medications may address visceral hypersensitivity, our results indicated a reduction in this area after the completion of the EHYP, a behavioral, non-drug alternative. The use of a relaxation technique to decrease physiological arousal through modifiable sympathetic nervous system pathways provides evidence for the utility of hypnotherapy to regulate alterations in gastrointestinal symptoms.¹² Gut-directed hypnotherapy (HYP) is a cost-effective,^{27,28} durable^{27,28} and preferred treatment for several refractory functional gastrointestinal disorders^{29,30} including irritable bowel syndrome (IBS).^{31–34} In IBS, HYP reduces abdominal pain, improves bowel patterns and reduces bloating^{35–37} by normalizing rectal sensitivity thresholds,³⁸ decreasing somatization and visceral anxiety,³⁹ and reducing catastrophizing.⁴⁰ In the upper GI tract, HYP has demonstrated efficacy in functional dyspepsia,⁴¹ non-cardiac chest pain^{10,11,33,42} and globus sensation¹² although less is known about the mechanisms through which this occurs.

There are some limitations which should be addressed in regards to this open-label pilot study. First, our small sample size of 9 consisted of 8 females and 1 male. Despite the sample size, we detected change in our primary endpoints over time, as well as change in EHv, the factor we believed was driving the FH. We also had varying levels of hypnotizability (ranging from low to high) as well as heterogeneity in terms of other medical illnesses among participants, but relatively uniform outcomes. Notably, the male participant only received 2 doses of the EHYP and thus post-treatment data really only reflects the female sample—this may be reflective of bias in referrals and/or willingness to participate in the behavioral intervention. Finally, 6 of 9 patients maintained their PPI therapy despite the exclusion of GERD. We observed patients to remain hesitant and anxious about decreasing their reliance of this medication despite the fact that it was not improving their symptoms. Future research can assess the psychological aspects of these patient beliefs and behaviors.

In conclusion, esophageal-directed hypnotherapy was well tolerated by the patients in our study and the reported substantial improvement in functional heartburn symptomatology from pre to post treatment. To receive this form of treatment, the patient does need to work with a clinician with expertise in hypnotherapy and the behavioral treatment of gastrointestinal disorders, as well as have the availability to attend up to 7 sessions of treatment. We suggest that this is an acceptable and effective intervention for patients who have failed traditional pharmacotherapy or are interested in less invasive treatment alternatives for their symptoms. In the future, we will focus on abbreviated and self-administered protocols to take into consideration patients with limited availability or who are restricted by other medical problems.

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Table 1
Demographic and clinical characteristics of sample before and after esophageal-directed hypnotherapy (N=9)

Participant characteristics and Global Impression of Change Rating [†]	Tellegen Absorption Scale [‡]		Short Form Health Survey Version 2 [§]				QOLRAD		Visceral Sensitivity Index ^{††}		Heartburn Catastrophizing Scale ^{‡‡}	
	Score	Hypnotizability	PCS		MCS		Pre	Post	Pre	Post	Pre	Post
32-year-old, married, female with advanced degree, off PPI, slightly improved	23	High	53	55	37	53	3.68	5.24	39	54	32	8
38-year-old, married, female with advanced degree, on PPI, substantially improved	20	High	45	56	60	60	5.48	6.88	90	90	17	7
36-year-old, married, female with some college education, on PPI, slightly improved	23	High	44	43	24	51	2.96	3.88	25	34	37	25
50-year-old, married, female with high school education, on PPI, slightly improved	15	Moderate	30	26	32	34	3.36	3.40	25	28	25	32
56-year-old, married, female with college education, self-referred, on PPI, slightly improved	19	Moderate	41	50	57	59	5.52	5.80	77	82	8	5
57-year-old, married, female with Associate's	22	High	33	28	52	62	4.56	6.64	59	75	11	3

Participant characteristics and Global Impression of Change Rating [†]	Tellegen Absorption Scale [‡]		Short Form Health Survey Version 2 [§]				QOLRAD [¶]		Visceral Sensitivity Index ^{††}		Heartburn Catastrophizing Scale ^{‡‡}	
	Score	Hypnotizability	PCS		MCS		Pre	Post	Pre	Post	Pre	Post
degree, off PPI, substantially improved												
60-year-old, married, female with Associate's degree, on PPI, substantially improved	16	Moderate	40	45	55	58	4.04	4.72	72	74	30	14
42-year-old, married, female with college degree, on PPI, substantially improved	8	Low	30	27	47	51	3.28	6.56	58	78	6	8
33-year-old, married, male with high school education, self-referred, off PPI	10	Moderate	30	-	28	-	2.12	-	37	-	41	-
Mean age = 45(11), 89% F, 100% married, 44% college +, 100% White, 67% on PPI			M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)
			39.5 (8.1)	41.3 (12.6)	45.5(13.1)	53.5 (8.9)	4.1 (.99)	5.4 (1.3)	55.6 (24.1)	64.4 (23)	20.7 (11.9)	12.8 (10.4)
			t(8) = -.82, p = ns	t(8) = -2.4, p = .05*	t(8) = -3.4, p = .01*	t(8) = -3.3 p = .01*					t(8) = 2.3, p = .06	

Notes.

[†] Participants were asked to rate symptom improvement on the Global Impression of Change scale ranging from 1 (substantially improved) to 7 (substantially worse) at post-treatment.

[‡] Higher scores on the Tellegen Absorption Scale represent a higher degree of hypnotic ability.

[§] Higher scores are indicative of better perceived health and functioning for the PCS and MCS.

[¶] QOLRAD, Quality of Life in Reflux and Dysphagia. Lower score indicates more severe impact of symptoms on daily functioning.

^{††} Higher score on the VSI represent greater symptom related anxiety.

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Higher score indicates greater heartburn symptom catastrophizing.

* statistically significant. PPI, proton pump inhibitor; Pre, Pre-treatment; Post, Post-treatment; PCS, physical component summary; MCS, mental health component summary