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Hypnotherapy for Treatment of Overactive Bladder: An RCT Pilot Study

YM Komesu¹, RE Sapien², RG Rogers³, and LH Ketai⁴

¹Yuko M Komesu MD, Department Obstetrics and Gynecology University of New Mexico Health Sciences Center

²Robert E Sapien MD, Department of Emergency Room Medicine University of New Mexico Health Sciences Center

³Rebecca G Rogers MD, Department Obstetrics and Gynecology University of New Mexico Health Sciences Center

⁴Loren H Ketai MD, Department of Radiology University of New Mexico Health Sciences Center

Abstract

Objectives—To obtain pilot data comparing hypnotherapy & behavioral therapy (hypnotherapy) to behavioral therapy alone (behavioral therapy) in overactive bladder (OAB) treatment.

Methods—Women with OAB were randomized to hypnotherapy or behavioral therapy treatments. Patient Global Impression of Improvement, the OAB-q Short Form questionnaire and voiding diaries were recorded, and within and between group differences compared.

Results—Twenty women enrolled in and completed the study. Both hypnotherapy and behavioral therapy groups improved their mean number of voids ($P=.005$, $P=.01$, respectively) and their OABq-Short Form distress scores ($P=.002$, $P=.03$). The hypnotherapy group had significant improvement in quality of life scores ($P<.001$) whereas the behavioral group did not ($P=.05$). Between group comparisons showed the hypnotherapy group had superior Patient Global Impression of Improvement scores compared to the behavioral group ($P<.009$). The hypnotherapy group trended toward greater improvement in OAB-q quality of life scores compared to the behavioral therapy group (67% versus 42% improvement) though this did not reach statistical significance ($P=.07$). Number of voids and OAB-q Short Form distress scores improved in both groups with no difference between groups.

Conclusions—Both groups improved with treatment. Hypnotherapy resulted in superior Patient Global Impression of Improvement scores compared to behavioral therapy. Voiding and OAB-q Short Form results trended toward greater improvement with hypnotherapy. As a pilot study, recruitment was underpowered to find statistical differences between groups' voids and OAB

Corresponding author: Yuko M Komesu, MD., MSC 10-5580 1 University, Albuquerque, New Mexico 87131, ykomesu@salud.unm.edu, Telephone: 505-925-4395 or 505-272-9702, Fax: 505-272-1336.

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scores. These findings support the need for an expanded trial which could likely show hypnotherapy to be superior in OAB treatment.

Keywords

Hypnotherapy; overactive bladder; complementary alternative medicine

Introduction

Overactive Bladder (OAB) Syndrome is a functional disorder of bladder storage and is defined by the International Continence Society as urinary urgency, usually accompanied by frequency and nocturia, with or without urinary incontinence. ^[1] OAB is common and affects approximately 17% of women in the U.S. ^[2] It is also expensive and will cost society 7.2 billion dollar per annum by 2015. ^[3] On a personal level, its sufferers not only experience decreased self-esteem, it also results in significant distress and embarrassment for family members.^[4] Because of the scope of its effects, OAB has spawned development of numerous therapies, many pharmacologic. Although medications to treat OAB are efficacious in clinical trials, in clinical practice they are costly and continuation rates at twelve months have been reported to be as low as 13%.^[5] Side-effects of medications, including dry mouth and constipation, are well recognized factors which contribute to their discontinuation.

Behavioral therapy, including fluid management, timed voiding and suppression of urge with distraction or relaxation has been equally or more effective than medications in treatment of older women with OAB.^[6] Behavioral therapy is an intervention based on the premise that maladaptive behavior can be modified or unlearned. Bladder retraining's success "is based on the assumption that conscious efforts to suppress sensory stimuli will re-establish cortical control over an uninhibited bladder...re-establishing normal voiding patterns."^[7] Behavioral therapy's proven effectiveness in OAB treatment underscores the importance of the mind's central role in response to and control of this syndrome.

Hypnotherapy, similar to behavioral therapy, may be used to modify behavior and has potential in treating OAB. Hypnosis, a state of inner absorption, concentration and focused attention has been used to promote "suggestions for changes in subjective experience, alterations in...emotion, thought, or behavior."^[8] To date, a single case series has reported hypnotherapy's effectiveness in treating women with OAB.^[9] In this series, 50 participants with urgency incontinence completed 12 weekly hypnotherapy sessions. Following treatment, 86% of women in this non-comparative study reported they were improved or cured; 29 were "entirely symptom free" and 14 were "considerably improved."^[9] Patient reported outcomes and other validated measures were not included in the report. The purpose of our current pilot trial was to further explore hypnotherapy's potential role in OAB treatment. Our objective was to obtain preliminary efficacy data using validated outcomes to compare hypnotherapy to a proven standard treatment, behavioral therapy. "

Materials and Methods

In this exploratory study, we compared hypnotherapy & behavioral therapy to behavioral therapy alone in treatment of OAB. Outcome measures included results of the Patient Global Impression of Improvement (PGI-I),^[10] the OAB-q^[11] Short Form (OAB-q SF) questionnaires and voiding frequency based on voiding diaries. The study was approved by the University of New Mexico Hospital (UNMH) Internal Review Board (HRRC # 08-102). All subjects gave written informed consent prior to study participation.

Women who presented to the UNMH Urogynecology Clinic with complaints of urinary urgency and frequency with or without incontinence were invited to participate in the study. Women with untreated urinary tract infections, vaginal descent past the hymen with Valsalva or elevated post-void residuals were excluded from participation. Non-English speaking women, pregnant or incarcerated women, women <18 years old or those with a history of psychosis, were also excluded. Potential subjects completed the OAB Awareness Tool, a questionnaire validated to identify women with bothersome OAB symptoms.^[12] Women with scores ≥ 8 were eligible for enrollment in this study. Scores ≥ 8 have been found to be sensitive and specific in screening for women with OAB.^[12]

This pilot study was a parallel group randomized controlled trial ("Hypnotherapy for Treatment of Overactive Bladder", Clinical Trials.gov, NCT #00793611). After informed consent was obtained women were randomized to the hypnotherapy group or to the behavioral therapy group. A computer generated allocation sequence was used and subjects were assigned to either of the two interventions. Block randomization in groups of 10 in a final 1:1 ratio ensured similar distributions of subjects between groups. Allocation concealment was performed. Assignments were kept in sequentially numbered, tamperproof, sealed opaque envelopes in the UNM Clinical Trials Science Center (CTSC). Subjects were sent to the CTSC after study enrollment and randomized by CTSC personnel who distributed the envelopes and notified participants of their group assignment. The subjects, the hypnotherapist, and the research nurses who administered the interventions were not blinded to the treatment interventions. Data entry personnel and investigators who performed data analysis were blinded to subjects' group assignments.

Prior to randomization and treatment initiation, subjects answered the OAB-q SF Questionnaire, a questionnaire validated for use in OAB subjects^[11] which consists of a 6-item symptom bother scale and 13-item health related quality of life scale. Subjects also underwent a pelvic exam to ensure that the leading edge of the vagina did not descend past the hymen with Valsalva and answered pertinent demographic and medical history questions. Following randomization, but prior to initiating treatment, subjects recorded voiding frequency with a 3 day voiding diary. The principal investigator instructed both the research nurses and the hypnotherapist regarding an approach to discussion of behavioral interventions (review of voiding diaries, fluid management, voiding schedules, time voiding, distraction techniques and pelvic floor exercise, as noted subsequently). The research nurses and hypnotherapist had the freedom to customize counseling to fit individual patient needs such as addressing OAB triggers and stressors and suggesting changes to prior ineffective coping mechanisms.

Subjects randomized to behavioral therapy were scheduled to see a research nurse for three 30-60 minute counseling sessions over 6-8 weeks. At the first visit the subject and research nurse reviewed the voiding diary, discussed fluid management and suggested changes in voiding schedules. Timed voiding, a method of desensitization resulting in incremental increases in time between voids, was initiated. Urge distraction techniques were also introduced during these sessions. Pelvic floor exercises were discussed and their practice emphasized. Similar discussions occurred during the 2nd and 3rd sessions.

Subjects randomized to hypnotherapy were scheduled to see a certified clinical hypnotherapist (RS) for three 60 minute sessions over 6-8 weeks. The hypnotherapist is a board certified hypnotherapist (board certification requires >300 hours of hypnotherapy training from a state licensed school, successful completion of a written test and review of clinical skills). During each session the hypnotherapist replicated the patient counseling provided in the behavioral therapy session, including review of the voiding diary, timed voiding and pelvic floor exercise. Additionally, during the first hypnotherapy session, the hypnotherapist explained hypnotherapeutic principles, used illustrations of the bladder to help visualize the goal of relaxing and stretching the bladder and subjects underwent hypnotic induction using guided imagery (for bladder relaxation) and therapeutic suggestion (regarding responses to OAB symptoms). These individualized therapeutic suggestions and imagery sessions were developed by the clinical hypnotherapist based upon statements provided by the subjects to the hypnotherapist regarding their perceptions and impressions of their OAB problems. Subjects were instructed to practice these relaxation responses at home prior to the next session. During the 2nd session, timed voiding and pelvic floor exercise were again discussed. Emotional responses to OAB symptoms were discussed and hypnotic induction performed. Subjects were taught guided imagery for use as a relaxation technique in response to urinary urgency. During hypnosis potential emotions blocking OAB improvement were identified. Subjects were instructed on self-hypnosis and were encouraged to practice these daily until the next session. During the 3rd session, OAB symptoms and voiding patterns were reviewed. Subjects were hypnotized and were read a standardized guided imagery script on health and healing.

At the end of the hypnotherapy and behavioral therapy alone treatments, subjects repeated a 3 day voiding diary, completed the OAB-q SF and, in addition, answered the Patient Global Impression of Improvement (PGI-I) question. The PGI-I, validated for use in urinary incontinence and pelvic organ prolapse, [10],[13] asked subjects to... "Check the number that best describes how your urinary condition is now compared with how it was before you began this study." Answers varied from 'very much better=1' to 'very much worse=7' on a 7 point Likert scale. Subjects were also asked to rate the helpfulness of their intervention on a 0-10 Likert scale (0=not helpful, 10=extremely helpful). Outcome measures included within and between group comparisons of the questionnaires and voiding diaries.

Statistical Analysis

Analysis was performed using Fisher's Exact test for categorical variables, t-tests assuming unequal variance for continuous variables, and Wilcoxon Rank test for ordinal variables with significance set at P<.05 (SAS® version 9.2, Copyright© 2009, SAS Institute, Cary,

NC). Differences between groups' OABq-SF scores and voiding frequencies at baseline and follow-up were evaluated and changes were compared.

Results

Thirty-two women were invited to participate in the study and ten declined citing time constraints as the reason. Twenty-two women were enrolled in this exploratory study. Eleven were randomized to the hypnotherapy group and eleven to the behavioral therapy alone group (Figure 1). Two women, one assigned to the hypnotherapy group and the other assigned to the behavioral therapy group, withdrew from the study prior to receiving their assigned therapies; they cited inability to keep their scheduled appointments as the reason. The two drop-outs did not differ from the subjects who continued the study regarding age (40.5+/-16.3 versus 53.6+/-11.2 years, $P=.14$) or baseline OAB-qSF distress scores (63.3+/-14.1 versus 54.7+/-19.3, $P=.5$) or quality of life scores (42.3+/-23.2 versus 42.3+/-18.5, $P=.78$). The two women who withdrew from the study did not receive any treatment and were excluded from the analysis. Twenty women completed the study and kept all scheduled appointments. At study completion, there were no reported complications or complaints regarding either of the treatment interventions.

There were no differences between the hypnotherapy and the behavioral therapy groups' ages, ethnicity and parity (Table 1). Neither were there differences between the groups' medical history, history of hysterectomy or incontinence surgery (Table 1). There were no differences between groups' history of prior OAB treatment except in prior use of pelvic floor exercise where the majority of subjects treated with behavioral therapy alone had previously performed pelvic floor exercise (Table 1). None of the subjects had a history of prolapse surgery.

OAB-qSF distress scores improved significantly in both groups following treatment (Table 2). The behavioral therapy alone group's distress scores improved 37% and the hypnotherapy group improved 53% over baseline ($P=.03$, $P=.0002$, respectively). The hypnotherapy group had significant improvement in OAB-qSF quality of life scores (67% over baseline, $P<.001$) whereas the behavioral therapy group did not (42% over baseline, $P=.05$). Both groups decreased their voiding frequency following treatment. Mean voids decreased 15% in the behavioral therapy alone group and 21% in the hypnotherapy group (Table 2)

Between group comparisons were also performed. Following treatment, the hypnotherapy group had significantly greater improvement in their global impression of improvement (PGI-I) scores than the behavioral therapy group (Table 3). The hypnotherapy group's global impression of improvement mean score represented answers of "much better" and the behavioral therapy group's mean score represented answers of "a little better". There were no differences between group's baseline OABq-SF distress ($P=.55$) and quality of life scores ($P=.66$) (baseline and follow-up scores noted in Table 2). Similarly, there were no differences between groups change in OAB-qSF distress or quality of life scores following treatment, nor were there differences between the two groups' baseline voiding frequency ($P=.16$)(Baseline frequency noted in Table 2) and change in voiding frequency ($P=.17$)

(Post-treatment voiding frequency noted in Table 2, between group differences noted in Table 3).

Discussion

Patients had significant improvement in OAB based on validated questionnaires (37-67% improvement from baseline scores) and voiding diaries (15-21% improvement) following both hypnotherapy and behavioral therapy alone. This pilot study is notable in that the hypnotherapy group had superior global improvement in their OAB symptoms compared to behavioral therapy alone. Thus, hypnotherapy is a useful adjunct to behavioral therapy, a proven and accepted first-line treatment of OAB. [14]

Prior data regarding hypnotherapy's use in lower urinary tract storage disorders are limited. In small trials, hypnotherapy has been reported to be useful in treating childhood enuresis.[15] Only a single study has described hypnotherapy's efficacy in treating women with OAB. In Freeman's [9] observational study, urge incontinent women were treated with 12 hypnotherapy sessions administered over one month. Despite a much less intense regimen in our study we were able to show benefit over standard therapy. Additional hypnotherapy sessions may have resulted in greater therapeutic benefit and we plan to further evaluate their potential benefit in future studies.

This pilot study was designed as an exploratory evaluation of hypnotherapy and is therefore limited by the relatively small number of participants. Post-hoc evaluation of the OAB-qSF quality of life scores indicates that 72 subjects (36 per group) would have been necessary to find the 25% difference that existed between the hypnotherapy and behavioral therapy group's scores to be significant, assuming 80% power and $\alpha=.05$ with the observed effect size=.68. The finding of superior patient global impression of improvement scores following hypnotherapy compared to behavioral therapy alone is remarkable given the small number of patients in this study. The finding is noteworthy as patient global ratings provide the single best measure of the significance of change from the individual perspective, particularly when used as a longitudinal disease-related measure.[16]

A limitation of the current study was absence of double blinding. Subjects knew which interventions they received. Absent monetary or other incentives, we believed recruitment would have been hindered had subjects received a sham intervention without known treatment benefit. A larger trial offering appropriate patient incentives would make sham therapies more acceptable. Additionally, as in any randomized trial, selection bias may have occurred as subjects were willing to participate in randomization so these subjects may not represent the general population. Last, due to the smaller numbers of subjects in this pilot, randomization did not equalize all baseline variables (e.g. history of prior OAB treatments) which could have also introduced bias into the study.

The study has several strengths; subjects were randomized to the interventions, both groups received individualized treatment sessions and validated outcome measures were used to quantify the effects of the treatments. Given these strengths, the study offers encouraging

preliminary data regarding efficacy and acceptance of hypnotherapy as a novel treatment of OAB.

Hypnotherapy's therapeutic effect on urinary urgency is unknown though it is likely mediated by central effects on the brain. Recent work with functional brain imaging has highlighted the importance of the brain in coordinating responses to bladder sensation and has shown that patients with urge incontinence differ from controls in cerebral cortical response to bladder distension.^[17] Hypnotherapy may, as postulated to occur following sacral neuromodulation, modify the brain's response to bladder storage sensations.^[18] The brain and its possible up-regulation to afferent signal is increasingly hypothesized to play a central role in OAB pathophysiology.^[17] This suggests that OAB treatment should be refocused upon the brain and its down-regulation. Direct modification of the brain's response to bladder filling with hypnosis offers a novel approach to a prevalent problem often refractory to treatment. A larger trial comparing hypnotherapy to accepted OAB therapies could potentially add complementary alternative medicine techniques to the OAB armamentarium and increase insight into the role of the mind in OAB treatment.

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Figure 1.
Consort Flow Diagram

Table 1

Patient Characteristics

	Behavioral therapy alone group N=10 Mean (+/-Standard Deviation) or (%)	Hypnotherapy and behavioral therapy group N=10 Mean (+/-Standard Deviation) or (%)	P value
Age mean	56 (7.4)	51.1 (14.0)	.34*
Ethnicity			
Non- Hispanic White	9 (90%)	6 (60%)	.3 [†]
Hispanic White	1 (10%)	3 (30%)	
Native American	0	1 (10%)	
Parity			
0	2 (20%)	3 (30%)	1.0 [†]
1	3 (30%)	3 (30%)	
2	1 (10%)	1 (10%)	
3	3 (30%)	2 (20%)	
4	1 (10%)	1(10%)	
Prior Incontinence Surgery	7 (70%)	0	.21 [†]
History of Hysterectomy	5 (50%)	6 (60%)	1.0 [†]
Past OAB Therapy			
Physical Therapy	5 (50%)	5(50%)	.14 [†]
Anticholinergics	5(50%)	7(70%)	.65 [†]
Voiding diary	6(60%)	2(20%)	.17 [†]
Pelvic Floor Exercises	9(90%)	3(30%)	.02 [†]
Timed Voiding	4(40%)	0(0%)	.09 [†]

* Satterthwaite t-test

[†] Fisher's Exact Test

Table 2

Changes within groups before and after treatment

	Baseline OABq-SF mean distress scores (+/-SD) *	Final oab-qSF distress score mean (+/- SD) *	Change in OABq-SF distress mean scores (+/-SD) *	P[†]
Behavioral therapy alone group (N=10)	57.3 (22.7)	36 (23.9)	21.3 (25.3)	.03
Hypnotherapy + behavioral therapy group (N=10)	52.0 (15.9)	24.3 (12.6)	27.7 (14.4)	.0002

	Baseline OABq-SF mean qol score (+/- SD) *	Final OABq-SF mean qol score (+/- SD) *	Change in OAB-qSF mean qol score (+/-SD) *	P[†]
Behavioral therapy alone group (N=10)	44.6 (25.3)	63.8 (20.3)	19.0 (24.9)	.05
Hypnotherapy+ behavioral therapy group (N=10)	49.5 (22.2)	82.9 (15.0)	33.4 (15.2)	p<.001

	Initial mean # voids (+/-SD) *	Final mean # voids (+/-SD) *	Change mean # voids (+/-SD) *	P[†]
Behavioral therapy alone group (N=10)	9.2 (2.7)	7.8 (2.3)	1.4 (1.4)	.013
Hypnotherapy+ behavioral therapy group (N=10)	11.2 (3.4)	8.8 (1.9)	2.4 (2.0)	.005

* Standard Deviation

[†] Satterthwaite t-test

Table 3

Differences between Behavioral Therapy Alone and Hypnotherapy+Behavioral Therapy Group's scores

	Behavioral therapy alone group N=10 (+/-Standard Deviation)	Hypnotherapy + Behavioral therapy group N=10 (+/-Standard Deviation)	P[*]
Global Impression of Improvement 1=very much better 7=very much worse	3.40 (.97)	2.15 (.30)	.009
Change in mean OABq-SF quality of life score	19.0 (24.9)	33.4 (15.2)	.07
Change in mean OABq-SF distress score	21.3 (25.3)	27.7 (14.4)	.5
Change in mean # voids	1.4 (1.4)	2.6 (2.0)	.17
Helpfulness of treatment 0=not helpful 10=extremely helpful	4.7 (3.5)	7.5 (2.1)	.09

*
Satterthwaite T-test