

Acupuncture for Overactive Bladder

A Randomized Controlled Trial

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Objective: To compare acupuncture treatment for overactive bladder with urge incontinence with a placebo acupuncture treatment.

Methods: Eighty-five women enrolled in this randomized, placebo-controlled trial. Women were randomly assigned to either receive an acupuncture treatment expected to improve their bladder symptoms, or a placebo acupuncture treatment designed to promote relaxation. They underwent cystometric testing, completed a 3-day voiding diary, and completed the urinary distress inventory and incontinence impact questionnaire, validated quality-of-life inventories, before and after 4 weekly acupuncture treatments. The primary endpoint was number of incontinent episodes over 3 days. Secondary endpoints included voiding frequency and urgency, cystometric bladder capacity, maximum voided volume, and the urinary distress inventory and incontinence impact questionnaire symptom scores.

Results: Seventy-four women completed all aspects of the study. Women in both treatment and placebo groups had significant decreases in number of incontinent episodes (59% for treatment, 40% for placebo) without a significant difference in the change between the groups. Women in the treatment group had a 14% reduction in urinary frequency ($P = .013$), a 30% reduction in the proportion of voids associated with urgency ($P = .016$), and a 13% increase in both maximum voided volume and maximum cystometric capacity ($P = .01$). Both groups also had an improvement in the urinary distress inventory and incontinence impact questionnaire scores (54% decrease for treatment, 30%

decrease for placebo, $P < .001$ for the difference in change between the groups).

Conclusion: Women who received 4 weekly bladder-specific acupuncture treatments had significant improvements in bladder capacity, urgency, frequency, and quality-of-life scores as compared with women who received placebo acupuncture treatments.

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Level of Evidence: I

Seventeen percent of American men and women suffer from overactive bladder syndrome, and about one half of these women also have incontinence.¹ Social isolation, loss of productivity, and lowered self-image are common consequences of this condition.^{2–5}

Women complain of a desperate urgency to empty their bladder that is often accompanied by large-volume urinary leakage. It has been estimated that 16–26 billion dollars are spent annually in the United States for products to manage urinary incontinence.^{2,6}

Current therapy for the overactive bladder is only partially effective. Anticholinergic medication is 50–70% effective⁷ and has significant side effects. Because of these side effects, only 18% of patients are compliant with medications after 6 months of treatment.⁸ Behavioral therapy and physical therapy can be equally or more effective than medications initially; however, results fall off by 3 months after treatment.⁸

Several studies support acupuncture as a potentially successful treatment of urinary urgency, frequency, and urgency incontinence. Minni et al⁹ reported that 11 of 20 children suffering from enuresis had cystometrically proven suppression of uninhibited detrusor contractions after acupuncture therapy. Chang¹⁰ concluded that acupuncture reduced symptoms of bladder urgency and frequency in 77% of treated patients and 20% of placebo patients. Berg-

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strom demonstrated reduced incontinent episodes in a small group of elderly women.¹¹ These trials were neither randomized nor blinded.

We hypothesized that acupuncture treatments directed at overactive bladder would reduce urinary incontinence, frequency, and urgency as reported by voiding diary, and would reduce the psychological distress of overactive bladder as captured by the urinary distress inventory and the incontinence inventory questionnaire.¹²

MATERIALS AND METHODS

The study design was a randomized, single-blind, placebo-control trial comparing acupuncture for the treatment of overactive bladder with urge incontinence with a placebo acupuncture treatment designed to promote relaxation. The study was approved by Oregon Health and Science University institutional review board (IRB #5861). Women were recruited through advertisements placed in women's health clinics and primary care clinics at Oregon Health and Science University and through a radio advertisement within the Portland area. Women were eligible to participate if they were aged older than 18 years, were not pregnant, and had symptoms of overactive bladder with urge incontinence.

For the study, overactive bladder with urge incontinence was defined as greater than 8 voids per day, subjective urgency to void, and urge-associated incontinence at least twice during a 3-day period of time. Any woman meeting these criteria could participate, regardless of whether she also had symptoms of genuine stress incontinence. Women were excluded if they were taking medications for overactive bladder or receiving acupuncture treatments for any condition. They were also excluded if they were unable to ambulate or unable to complete a 3-day voiding diary and if they had hematuria or untreated urinary tract infection.

Patients meeting the clinical criteria of overactive bladder with urge incontinence gave informed consent. They were randomly assigned into 1 of 2 treatment arms. A computer-generated random number table assigned the type of acupuncture treatment, with assignments contained in sealed opaque and sequentially numbered envelopes. The number of treatment and placebo allocations was equalized every 20 allocations. Only the OHSU statistician who devised the code and the physician (S.E.) who performed the acupuncture knew the randomization code. The research nurses interacting with the participants and interpreting the voiding diaries and the physician involved in the urodynamic assessment of bladder function were blinded to treatment group.

Patients were assigned their treatment group when they presented for their first acupuncture treatment.

Treatment and placebo acupuncture treatments were based on the reports of Chang,¹⁰ and developed in consensus with the physicians of the Oregon chapter of the American Academy of Medical Acupuncture. A board-certified obstetrician-gynecologist who was trained in medical acupuncture performed all the acupuncture for this study. The treatment group received an acupuncture treatment designed to address overactive bladder with urge incontinence. Needles were placed bilaterally at sites SP6 (inner legs), BL39 (outer knee fold), and BL28 (low back) and midline at CV4 (low-abdomen). Needles were placed and rotated clockwise until the patient reported a sensation of warmth or tightening (the sensation of *deqi*), then were retained without further stimulation for 20 minutes. The same 7 points were used at each of the 4 weekly sessions. The placebo group received a placebo acupuncture treatment designed for relaxation, using bilateral sites GB31 (outer thigh), ST36 (outer legs) and BL12 (upper back) and mid-line CV12 (epigastrium). Needles were placed and retained as for the treatment group. Participants did not know to which group they were assigned.

At enrollment, all women completed demographic information and the short forms of the urinary distress inventory and incontinence impact questionnaire.^{12,13} In addition they completed a 3-day voiding diary, noting the number of voids, the number of incontinent episodes, and the volume of each void. Women also noted whether the void or leak was associated with "an overwhelming urge to empty your bladder." Finally they had a postvoid residual measured, a urinalysis performed, and underwent multichannel cystometric testing with a LuMax Fiber Optic Cystometry System (Cooper Surgical Medamicus Inc, Trumbull, CT) in the 45-degree seated position and in accordance with the International Continence Society guidelines.⁴ Filling cystometry was performed using room temperature normal saline at a rate of 50 mL/min. Patients were asked to identify first desire to void, strong desire to void, and when they could hold no more (maximum cystometric capacity). Detrusor contractions that occurred during filling were noted. Patients did not undergo testing for genuine stress incontinence or for urethral dysfunction.

Two to 4 weeks after completing the 4 acupuncture treatments, participants repeated the 3-day voiding diary, had repeat cystometric testing, and completed follow-up urinary distress inventory and incontinence impact questionnaires. They also completed a standardized adverse-effect questionnaire. Although all women enrolled in this study had frequent contact with study personnel, they did not



receive any directed education about behavioral changes to help with overactive bladder symptoms.

Results were entered into a password-protected database, and analysis was performed using SPSS 11.5 (SPSS, Chicago, IL), using Student *t* and paired Student *t* tests for continuous variables and χ^2 tests for dichotomous variables. Sample size calculation for difference in response rates was done as described by Ellenberg.¹⁴ Assuming, as was found by Burgio et al⁸ when using a medication placebo, a 40% reduction in incontinent episodes among women receiving placebo acupuncture and a 75% reduction in incontinent episodes among women treated with acupuncture for incontinence, we required 40 women per arm to achieve a power of 80% and significance of 5%.

RESULTS

Eighty-five women were entered into the study between July 2000 and October 2002. The flow of the study is shown in Figure 1. A total of 74 women completed all aspects of the study and were analyzed, 36 in the placebo group and 38 in the treatment group. There were no significant differences in demographics between the women who were assigned but did not complete the study and those who did complete the study.

Demographic information and baseline characteristics of the study population are shown in Table 1. We found no significant differences in any of these characteristics. The age range was 22–82 years, with a median of 51 years. Seven percent of participants were from ethnic minority groups. Fifty-six percent were menopausal, and 45% were using estrogen replacement. Fifty percent previously had a hysterectomy, and 18% previously had antiincontinence surgery.

There were no significant adverse effects from the acupuncture. Twenty-three percent noted either bleeding or bruising from the acupuncture needles, but all rated it as insignificant. Twenty-five percent noted minor discomfort with needle placement, but

Table 1. Demographic Information

Characteristic	Treatment Group (n = 38)	Placebo Group (n = 36)
Age (y)	53 ± 13	51 ± 12
Parity	1.8 ± 1.6	1.8 ± 1.6
Vaginal deliveries	1.4 ± 1.8	1.6 ± 1.7
Menopausal	21 (56)	20 (56)
Estrogen users	14 (37)	19 (54)
Hysterectomy	19 (49)	18 (51)
Incontinence surgery	8 (21)	6 (15)
Back surgery	2 (5)	1 (3)

Values are mean ± standard deviation or n (%).

none reported discomfort lasting past the time of the treatment. No one withdrew from the study because of adverse effects. The 3 women who began acupuncture treatments but did not complete them all withdrew because of difficulty in scheduling the treatments around their work schedules.

Voiding characteristics at entry to the study and after acupuncture are shown in Table 2. Treatment results were analyzed both within each group and between groups. Number of incontinent episodes was reduced by 59% in the treatment group and by 40% in the placebo group. However, the difference between the 2 groups did not reach significance. In the treatment group, but not the placebo group, there were significant reductions in urinary frequency and urgency and significant increases in maximum cystometric capacity and maximum voided volume.

Scores on both the urinary distress inventory and the incontinence impact questionnaire were improved in both groups, with the difference between the 2 groups also significant for both scores. There were no significant differences in cystometric measurements.

DISCUSSION

In this placebo-controlled study, 4 sessions of weekly acupuncture treatment for overactive bladder with urge incontinence produced significant improvements in incontinence episodes, voiding frequency, urinary urgency, and bladder capacity in a randomly assigned group of women with overactive bladder. The acupuncture sessions designed to promote relaxation also produced a significant decrease in incontinence episodes but the patients in this group saw no difference in the other important symptoms of overactive bladder. The urinary distress inventory and incontinence impact questionnaire scores reflecting the degree of symptom bother showed significantly more improvement in the group receiving the treatment acupuncture than in the group receiving the placebo acupuncture.

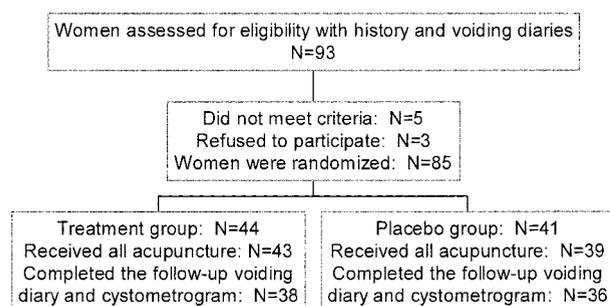


Fig. 1. Flow diagram of the study.

Emmons. *Acupuncture for Overactive Bladder*. *Obstet Gynecol* 2005.



Table 2. Effect of Acupuncture on Voiding Characteristics

	Treatment Group (n = 38)	Placebo Group (n = 36)	P*
Leaks (no. incontinent episodes/3 days)			
Before	6.3 ± 7.3	8.9 ± 9.2	.09
After	2.6 ± 3.1†	5.3 ± 5.9†	
% change	59	40	.71
Frequency (no. voids/3 days)			
Before	30.4 ± 7.8	32.7 ± 11.5	.40
After	26.2 ± 7.1	33.1 ± 16.1	
% change	14	4	.03
Urge (no. urge episodes/3 days)			
Before	16.2 ± 11.1	15.4 ± 10.2	.68
After	11.4 ± 8.8†	15.0 ± 9.4	
% change	30	3	.016
Functional bladder capacity			
Before	210 ± 88	199 ± 84	.50
After	236 ± 99‡	196 ± 85	
% change	12	-2	.01
Urinary distress inventory score			
Before	8.4 ± 3.6	8.6 ± 5.5	.87
After	3.6 ± 3.2†	5.8 ± 4.8†	
% change	57	32	.05
Incontinence impact questionnaire score			
Before	8.9 ± 2.8	9.1 ± 2.6	.80
After	4.3 ± 2.7†	7.0 ± 3.5†	
% change	52	23	.004
Cystometric maximum capacity (mL)			
Before	371 ± 161	341 ± 126	.49
After	415 ± 205	356 ± 193	
% change	12	4	.049
Cystometric volume at first urge to void (mL)			
Before	61 ± 67	69 ± 62	.84
After	65 ± 80	57 ± 75	
% change	6	-19	.47
Cystometric volume at strong urge to void (mL)			
Before	274 ± 144	241 ± 100	.26
After	297 ± 167‡	276 ± 156‡	
% change	8	14	.75
Detrusor contractions during cystometry (no. subjects)			
Before	7/38 (19)	11/36 (31)	.22
After	6/38 (16)	10/36 (28)	
% change	3	3	.98

Values are mean ± standard deviation or n/N (%).

* Significance of the difference between placebo and treatment groups.

† Significant difference between before and after values within groups; $P < .003$.

‡ Significant difference between before and after values within groups; $P < .03$.

There are several potential weaknesses in this study. Due to the 11 incomplete evaluations, we did not meet the necessary number of patients to achieve an 80% power to detect a 75% reduction in incontinent episodes. Although we did find the postulated 40% placebo effect, our treatment effect was just 59%. The study would have required 44 subjects per group to have significant power to validate this change in incontinent episodes.

Another limitation to the study design was the 3-day voiding diary. Although the 3-day diary has been shown to be nearly as accurate as the 7-day diary for studying stress and urge incontinence,^{15,16} our

results might have been more precise if we had chosen a 7-day interval. However, even the 3-day diary is difficult to maintain, particularly in a population that tended to be employed and active. Several women commented that they felt the results might differ depending on whether they kept the diary on workdays or non-work days.

Our study also is limited by the availability of a good placebo for acupuncture. Some critics state that any acupuncture treatment will have some physiologic effect, and so a true placebo cannot involve inserting needles.^{17,18} However, it is very difficult to keep patients blinded to their treatment group with



sham needling, particularly when the treatment protocol calls for leaving the needles in place for 20 minutes. Others argue that nonacupuncture sites should be used, with very shallow needling to give the most minimal effect. Although this may make for a better placebo, we wanted to subject acupuncture to closer scrutiny. If needling points unrelated to overactive bladder resulted in the same degree of improvement as needling specific bladder points, then there would be little scientific merit to the acupuncture. So we chose to use a real but unrelated treatment as the placebo. This had the added benefit of being potentially beneficial to study participants, in promoting relaxation even if it did not improve overactive bladder symptoms.

A review of commonly recommended treatments for overactive bladder reveals similar statistics to our own. A placebo effect range of 33% to 56% has been generally reported in the overactive bladder literature^{8,19–23} and perhaps reflects the strong effect that an increased self-awareness through bladder diaries, multiple supportive interactions with health care providers, and a strong motivation to improve can have on this condition. Treatments such as physical and behavioral therapy describe a reduction in urge incontinent episodes of 80%.²³ Medications such as oxybutynin, tolterodine, and tiroprium chloride are noted to improve urge incontinent episodes by 69%,⁸ 50%,²⁰ and 59%,²² respectively.

Goode et al²³ showed that urinary frequency was reduced by 18% by behavioral intervention, 19% by oxybutynin, and 3% by placebo. Medication studies also show increase in maximum voided volume of about 20%,^{7,21} compared with minimal change in the placebo group. Our results are again very similar.

Patients found acupuncture to be acceptable despite the session frequency. One problem of physical and behavioral treatments has been the rapid fall-off after an intensive program due to the patient's inability to sustain the intense effort demanded for success.⁸ Many in our hectic society would prefer a once-a-day pill with no additional effort required. Acupuncture perhaps can offer a middle ground for the appropriate patient who prefers not to take a daily medication but is unable to commit to the active involvement in behavioral therapy. Burgio et al²⁴ showed that combining behavioral therapy and medication has an additive effect, and quite possibly combining acupuncture with medication or behavior therapy would also promote long-term success.

In this study, acupuncture had a significant short-term effect on overactive bladder, similar in scope to the improvement offered by drug therapy and phys-

ical or behavioral therapy. These results need to be confirmed with a larger sample, and extended to see whether the effect is sustained.

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