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Is Acupuncture Effective in the Prophylaxis of Recurrent Urinary Tract Infections in Adult Women?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies Philadelphia College of Osteopathic Medicine Philadelphia, Pennsylvania

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ABSTRACT

<u>Objective</u>: The objective of this selective EBM review is to determine whether or not acupuncture is effective in the prophylaxis of recurrent urinary infections in adult women.

<u>Study Design</u>: Systematic review of three English language primary studies, published between 1998 and 2003.

<u>Data Sources</u>: Three randomized, controlled trials published after 1996, comparing acupuncture to placebo in the prophylaxis of urinary tract infections were obtained using EBSCOhost and PubMed.

<u>Outcomes Measured</u>: All three studies measured incidence or absence of urinary tract infections, as defined by distal urinary symptoms and/or bacteriuria of $\ge 10^5$ cfu/ml.

<u>Results</u>: Three randomized, controlled studies found that acupuncture treatment significantly decreased the incidence of urinary tract infections as compared to no treatment. Alraek et al 2003 additionally showed that Kidney *qi/yang xu* acupuncture was significantly more effective in UTI prophylaxis than Spleen *yang/qui xu* acupuncture and Liver qui stagnation.

<u>Conclusions</u>: Data suggests that acupuncture therapy, specifically for Kidney *qi/yang xu*, is effective in the prophylaxis of recurrent urinary tract infections in adult women, as evidenced by statistically significant reductions in the incidence of UTIs, as well as low NNT. Acupuncture may be considered as an option for UTI prophylaxis prior to long-term antibiotic therapy. However, further research is needed to determine the mechanism by which acupuncture affects the pathogenesis of UTIs, as well as the cost effectiveness of these acupuncture treatments.

Key Words: Acupuncture, urinary tract infection, cystitis

INTRODUCTION

A urinary tract infection, or UTI, is a bacterial infection of the urinary tract, most commonly caused by *Escherichia coli*. Lower UTI refers specifically to infection of the urinary bladder (cystitis) and urethra (urethritis). The most common route of infection is ascension of bacteria from the urethra into the bladder.¹ Urinary tract infections are considerably more common in women than in men, due to the shorter female urethra, as well as the proximity of the urethral orifice to the vagina and anus.¹ For this reason, many adult females suffer from recurrent cystitis, which is typically defined as 3 or more episodes of acute lower UTI over a 12-month period.^{2,3} Certain factors, such as anatomic variations and behavioral patterns may increase the risk of recurrent UTI.

UTIs are among the most common infections encountered in medical practice; accounting for 6.5-7 million office visits and 1 million emergency department visits per year.^{1,4} Nearly half of all women will experience at least one urinary tract infection in her lifetime,¹ and as many as 3-6% of adult females experience recurrent UTIs.^{2,3} Though most uncomplicated urinary tract infections are successfully treated with a short course of antibiotics, the frequency of these infections comes at an expense. In 2002, it was estimated that 1.6 billion dollars a year is spent on treatment of urinary tract infections alone.⁴

Acute urinary tract infections are typically treated with a 3-7 day course of antibiotics.¹ Prophylaxis for recurrent infections is commonly achieved with single doses of TMP-SMX, nitrofurantoin, or cephalexin at bedtime or at times of intercourse.¹ Other prophylactic measures include behavioral approaches, such as maintaining periurethral hygiene and urinating after intercourse. Cranberry juice and supplements are also frequently used to prevent recurrent infections; however, current research shows mixed results regarding their efficacy.⁵ Because recurrent urinary tract infections require frequent antibiotic treatment, uropathogens are becoming increasingly antibiotic-resistant.⁶ This suggests a need to explore non-pharmacological methods of UTI prophylaxis.

Acupuncture is a traditional form of Chinese medicine that has a growing presence in Western medical practice. Acupuncture has been proven to be an effective treatment for conditions such as nausea and vomiting, post-operative pain, headache prophylaxis, and musculoskeletal pain.⁷ While the exact mechanism of action of acupuncture is unknown, it is generally regarded as very safe. In the United States and Europe, the incidence of adverse events associated with acupuncture is as low as 1 in 10,000 to 1 in 100,000 needle insertions.⁷ Scandinavian research has suggested that acupuncture may also be useful in UTI prevention. This paper evaluates three randomized, controlled trials assessing acupuncture as a prophylactic treatment for recurrent lower urinary tract infections.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not acupuncture is effective in the prophylaxis of recurrent urinary infections in adult women.

METHODS

Criteria used for the selection of articles for this review included randomized controlled trials with adult female participants (age 18 or older) who experience recurrent lower urinary tract infections (3 or more episodes of acute lower UTI over a 12-month period). All studies evaluated incidence of urinary tract infections in treatment groups receiving acupuncture therapy, as compared to control groups receiving no treatment. Studies utilized in this review were obtained using PubMed and EBSCOhost databases. Research was conducted by the author, and key words used in database searches included "acupuncture," "urinary tract infection," and "cystitis." Articles were selected based on their relevance to the clinical question, as well as outcome measures that were patientoriented. Inclusion criteria included randomized controlled trials, published in peer-reviewed journals. Studies were limited to the English language and published in 1996 or later. Exclusion criteria included patients under the age of 18, male patients, and disease-oriented outcome measures. Ultimately, three randomized controlled trials were selected for this review. Statistics reported in these studies included percent reduction, incidence rate ratios (IRR), 95% confidence intervals, and p-values. The author calculated numbers needed to treat (NNT), relative risk reduction (RRR) and absolute risk reduction (ARR) using the dichotomous data found in these studies.

Study	Туре	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Alraek, 2003 ⁸	RCT	98	18-60	Otherwise healthy, cystitis- prone women age 18-60 with 3 or more self- reported episodes of cystitis in previous 12 months (at least 2 diagnosed and treated by a doctor)	Antibiotics in previous 3 weeks, use of cranberries as prophylactic treatment, pregnancy, known complicating illness (i.e. diabetes)	4	Kidney qi/yang xu acupuncture vs. Spleen yang/qi xu vs. Liver qui vs. No treatment
Alraek, 2002 ²	RCT	98	18-60	Women age 18- 60 with 3 or more episodes of distal urinary symptoms in previous 12 months (at least 2 diagnosed and treated by a doctor)	Pregnancy, known complicating illness	4	Acupuncture vs. No treatment
Aune, 1998 ³	RCT	73	18-60	Women age 18- 60 with 3 or more episodes of distal urinary symptoms in previous 12 months (at least 2 diagnosed and treated by a doctor)	Antibiotics in previous 3 weeks, pregnancy, diaphragm use, known complicating illness	us 3 , ancy, agm use, 1 icating	

Table 1: Demographics and characteristics of included studies

OUTCOMES MEASURED

All three studies measured incidence or absence of lower urinary tract infection, as defined by the presence or absence of distal urinary symptoms and bacteriuria. Distal urinary symptoms were defined as dysuria, urinary frequency, and/or suprapubic discomfort, and bacteriuria was defined as 10^5 or more colony-forming units per ml or any amount of *Staphylococcus saphrophyticus* in the urine.

RESULTS

The three randomized controlled trials included in this review compare acupuncture therapy to various control interventions, including different forms of acupuncture, sham acupuncture, and no treatment. One study compares different diagnostic categories of acupuncture to each other, as well as to placebo. All of the included studies have common authors and similar study designs, with relevant findings presented as dichotomous data.

The specific characteristics and demographics of each study are displayed in Table 1. All of the included studies focus on otherwise healthy women ages 18-60, who had experienced 3 or more episodes of cystitis in the previous 12 months (at least two diagnosed and treated by a doctor).^{2,3,8} All three studies excluded pregnant women and those with known complicating illnesses, such as diabetes, cancer, or urinary tract obstructions, due to the complicated nature of urinary tract infections in these populations.^{2,3,8} Two studies excluded patients who had been on antibiotics in the previous 3 weeks, and one study excluded patients using cranberries as prophylactic treatment, presumably to reduce the potential for confounding variables.^{3,8}

Aune et al (1998) randomized 67 women with recurrent urinary tract infections into groups receiving acupuncture, sham acupuncture, or no treatment. Acupuncture was

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performed in 20-minute intervals, twice weekly for 4 weeks.³ The subjects were then followed for signs and symptoms of UTI for 6 months. The study found that 85% of women in the acupuncture group were free of lower UTI during the 6-month observation period, versus 58% in the sham acupuncture group (p < 0.05) and 36% of the control group (p < 0.01).³ This data demonstrated a relative risk reduction (RRR) of 1.36, and an absolute risk reduction (ARR) of 49% when comparing the acupuncture group to the control group receiving no treatment. The number needed to treat (NNT) was 3, meaning three women need to be treated with acupuncture in order for 1 more woman to be free from recurrent UTI (Table 2). Additionally, using incidence rate ratios, this trial found that there were roughly half as many UTI episodes per person-half-year in the acupuncture group as in the sham acupuncture group (IRR = 0.47 95% CI = 0.19-1.16), and one third as many as in the control group (IRR = 0.38 95% CI = 0.13-0.90, p < 0.05)³ (Table 3).

Table 2. Percent reduction, relative and absolute risk reduction, and numbers needed to treat

	% UTI Free (Acupuncture Group)	% UTI Free (Control Group)	р	RRR*	ARR*	NNT*
Aune et al (1998)	85%	36%	< 0.01	1.36	49%	3
Alraek et al (2002)	73%	52%	0.08	0.4	37%	3
Alraek et al (2003)**	78%	17%	≤ 0.01	3.59	61%	2

* RRR= relative risk reduction, ARR= absolute risk reduction, NNT= number needed to treat ** Acupuncture group = Kidney *yang/qi xu*, Control Group = no treatment

(Table displays percentage free of cystitis symptoms regardless of bacteriuria)

	UTI Incidence Rate (Acupuncture)	UTI Incidence Rate (Control)	IRR	95% CI	р
Aune et al (1998*	0.26	0.71	0.38	0.13-0.90	< 0.05
Alraek et al (2002)*	0.27	0.67	0.45	0.23-0.86	≤ 0.05
Alraek et al (2003**	0.12	0.69	0.17	0.04-0.74	≤ 0.001

Table 3. Incidence rate ratios

*Control group = no treatment

** Acupuncture group = Kidney *qi/yang xu*, Control group = no treatment (Table displays incidence rates of cystitis with bacteriuria)

Alraek et al (2002) expanded on the previous study by following a similar design with a slightly larger sample size (n=98).² After meeting inclusion criteria for recurrent UTIs, women were randomized into groups of acupuncture treatment or no treatment in a ratio of $3:1.^2$ In this trial, there were half as many UTI episodes per person-month in the acupuncture group as compared to the control group (IRR = 0.45, 95% CI = 0.23-0.86, p ≤ 0.05)² (Table 3). This same data set demonstrated that 73% of women in the acupuncture group were free of urinary tract infections during the 6-month observation period, as compared to 52% of those receiving no treatment (p = 0.08).² In this case, the RRR was 0.40 and the ARR was 37%. Numbers needed to treat was calculated to be 3 based on this data set (Table 2).

Following the findings in these trials, the third study, Alraek et al (2003) explores specific diagnostic categories of acupuncture, questioning which approach is most effective for UTI prophylaxis.⁸ Using the same study design as above, 98 women were randomly assigned to groups acupuncture therapy or no treatment. Those assigned to acupuncture were then evaluated by trained acupuncturists and placed into 1 of 3 diagnostic categories: Spleen *yang/qi xu*, Kidney *yang/qi xu*, or Liver *qi* stagnation.⁸ Patients were again monitored for UTI

symptoms and bacteriuria for 6 months following treatment. Of the patients in the Kidney *yang/qi xu* group, 78% were free of UTIs as compared to 44% in the Liver group ($p \le 0.05$), 45% in the Spleen group ($p \le 0.05$), and 17% in the control group ($p \le 0.01$, versus all treated patients).⁸ Comparison of the Kidney group to the control group demonstrated an RRR of 3.59, an ARR of 61% and NNT of 2, suggesting that for Kidney *yang/qi xu* patients, only 2 women need to be treated with acupuncture to prevent 1 more from recurrent urinary tract infection (Table 2). Incidence rate ratios further support the effectiveness of acupuncture for Kidney *yang/qi xu* patients, as there were one sixth as many episodes of acute cystitis in the acupuncture group when compared to no treatment (IRR = 0.17, 95% CI = 0.04-0.74, $p \le 0.001$)⁸ (Table 3).

DISCUSSION

The randomized controlled trials in this review propose acupuncture as an alternative to conventional forms of prophylaxis for recurrent urinary tract infections. With a threshold for statistical significance set at $p \le 0.05$, two out of the three studies demonstrated significantly higher percentages of UTI prevention with acupuncture therapy as compared to no treatment. All three studies showed statistically significant reductions in the incidence rate of UTIs per person-time in acupuncture groups versus no treatment.

However, it is important to note that several limitations exist in this review, as well as the individual trials themselves. Though all of the studies were of a randomized, controlled design, sample sizes were relatively small, and limited to a population of women that was self-selected based on newspaper recruitment. Additionally, the trials were not double blinded, as it was obvious to the control groups that they were not receiving acupuncture treatment. Only Aune et al (1998) attempted to address this issue by including a sham acupuncture group. All three of the trials included in this review had common authors and similar study designs, which may have lead to an unintentional bias in results. As for the author's search, this systematic review was limited by restricting articles to those published in the English language. This narrowed the field of available studies, due to the fact that the body of research on acupuncture comes from a variety of different countries, not all of which are predominantly English speaking.

Acupuncture continues to have a growing presence in Western medicine. The acupuncture needle is FDA approved as a medical device and certain insurance plans are beginning to cover acupuncture therapy on a case-by-case basis.^{9,10} However, it is important to note that acupuncture for urinary tract disorders is still considered experimental, and is unlikely to be covered by any insurance plan. Medicare does not currently recognize acupuncture therapy for any medical condition.¹⁰ The cost of acupuncture is widely variable, but patients should expect to pay \$45-60 per treatment session, amounting to several hundred dollars for a course of treatment.¹⁰ Despite the out-of-pocket cost, acupuncture is associated with a low incidence of adverse events and is known to be very safe.⁷ The few contraindications to acupuncture procedures include skin infection or lymphedema at the sites of needle insertion, allergies to needle components, severe immunosuppression, and uncontrolled or unstable diabetes, epilepsy, or cardiac arrhythmias.⁹

CONCLUSIONS

The three randomized controlled trials in this EBM review provide statistically significant evidence that acupuncture is effective in the prophylaxis of recurrent urinary tract infections in adult women. It is noted that patients within the diagnostic category of Kidney *yang/qi xu* achieve the best outcomes with acupuncture therapy for UTI prophylaxis. Based

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on these results, acupuncture may be considered in patients who have failed conventional prophylactic measures, or in patients who are not amenable to long-term antibiotic treatment.

Despite the compelling evidence, further research is warranted to determine the physiologic mechanism by which acupuncture prevents recurrent infections. Additional studies are needed to evaluate the cost-effectiveness of acupuncture versus existing methods of UTI prophylaxis, as well as to formulate recommendations for ideal frequency and duration of acupuncture treatments.

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