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INSIDE

Urinary Stress Incontinence and Biofeedback

By Carmen Tamayo, MD

URINARY INCONTINENCE IS DEFINED AS AN INABILITY TO HOLD URINE until getting to the toilet. It is a symptom, not a disease, and the treatment method depends on the severity of the problem.

Women experience incontinence twice as often as men. Pregnancy and childbirth, menopause, and the structure of the female urinary tract account for this difference. Neurologic injuries, birth defects, strokes, multiple sclerosis, and physical problems associated with aging can cause both women and men to become incontinent.[1] Urinary incontinence has been reported to affect 35% of American women 50 years of age or older, and almost 15% of these women experience leakage daily.[2] Incontinence is a distressing condition with significant medical, social, and economic implications.

The two most common types of urinary incontinence are stress urinary incontinence (SUI) and urge incontinence. Approximately 60% of women with incontinence will have SUI caused by problems with the muscles that help hold and release urine. SUI usually is caused by anatomical defects in the structures that support the bladder and the urethra. Leakage results when the urethra is not closed off properly during exertion because of dysfunction of the neuromuscular components that help control urethral pressure. In women with genuine SUI, the symptoms include involuntary but frequent leakage of small amounts of urine during physical exertion with increased intra-abdominal pressure, such as coughing, sneezing, laughing, exercise, lifting, or sitting.

Urge incontinence is the leakage of large amounts of urine at unexpected times, including during sleep, for no apparent reason. Sufferers often report feeling the sudden need or urge to urinate. The most common cause of urge incontinence is inappropriate and involuntary bladder contractions that occur as a result of damage to the nerves of the bladder, to the nervous system, or to the muscles themselves. Multiple sclerosis, Parkinson's disease, Alzheimer's disease, stroke, and injury—including injury that occurs during surgery—all can harm bladder nerves or muscles.

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Regardless of the cause, incontinence is controllable and in most cases treatable at all ages. Approximately 80% of those affected by urinary incontinence can be cured or improved through diet, changes in medications, or a combination of medicine, behavioral modification, pelvic muscle re-education, collection devices, absorbent products, and physical therapies.[3]

Biofeedback and Physical Therapies

Physical therapies—such as Kegel exercises, pelvic floor muscle (PFM) training, weighted vaginal cones, pelvic floor electric microstimulation therapy, bladder retraining, magnetic therapy, and biofeedback—have been used to treat SUI. The aim of PFM training is to improve the strength and/or timing of voluntary PFM contractions by strengthening the external urethral sphincter.

Biofeedback has been defined as "a group of experimental procedures where an external sensor is used to give an indication on bodily processes, usually in purpose of changing the measured quality."[4] Biofeedback is not a treatment on its own, but rather is a "teaching technique that facilitates learning by providing patients with immediate and observable information about physical performance."[5] Biofeedback is also a component of behavioral interventions, including physical therapies, bladder training, educational sessions, and voiding diaries, that are used to control or treat urinary incontinence. A wide variety of biofeedback apparatus, including pressure perineometers with visual or auditory display and electromyography from vaginal probes, are used commonly in clinical practice to assist with PFM training. Biofeedback can be visual or verbal. Voluntary control of PFMs during voiding can be obtained by relaxation biofeedback (visualization of the electromyographic registration of relaxation and contraction of the pelvic floor by a curve on a display), uroflow biofeedback (observation of the flow curve during voiding), and electromyographic (EMG) biofeedback (bio-electrical muscle activity that is recorded through surface or needle electrodes placed directly against or inside the target muscle's sensory signals and is used to induce a motor-learning process).

Evidence of Effectiveness

Systematic Reviews. To date several systematic and narrative reviews have been conducted to assess the efficacy of physical therapies for first-line use in the treatment and prevention of SUI in women. Four of these concluded that PFM training is of benefit to women with urinary leakage.[6-9]

The effect of biofeedback with PFM training also has been evaluated in systematic reviews in women with SUI. De Kruif and van Wegen reviewed four randomized trials (n = 189), two quasi-experimental studies (n = 47), and four uncontrolled studies (n = 522).[10] Six of these studies compared exercise therapy with and without myofeedback, with two of these studies reporting significant differences in improvement. The combined interventions produced the largest improvement. However, only one of the 10 studies in the review looked at improvement in continence. The authors concluded that exercise therapy with EMG myofeedback has to be considered as a possible treatment method for women suffering from SUI.

A systematic review of 11 randomized controlled trials (RCTs) studying prevention and treatment of SUI with PFM exercises found strong evidence supporting the use of PFM exercises for reducing SUI symptoms.[7] The authors found no apparent benefit of biofeedback-assisted training over PFM training alone at post-treatment assessment. However, the findings suggested that the biofeedback group experienced more rapid improvement. There was limited evidence for the efficacy of a high-intensity vs. a low-intensity regimen of PFM exercises and there was no evidence that PFM exercises with biofeedback are more effective than PFM exercises

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Table

Potential U.S. incontinence treatment patient pool

Patients with incontinence	15 million
Female patients	12.8 million
Female patients with SUI	8.3 million
Total # of patients in potential pool	7 million
Patients getting surgery	200,000
Patients available for other therapies	6.8 million

Source: Tucker D. Less-invasive SUI treatments are goal for many in sector. *The BBI Newsletter* 2002;25:12.

alone. The authors indicated that biofeedback alone seems to be more effective in controlling urge incontinence than SUI.

Weatherall et al questioned the conclusion reached by Berghmans and re-evaluated the findings using pooled data from three of the five trials that examined biofeedback combined with PFM exercises compared to PFM exercises alone.[11] The odds ratio for biofeedback combined with PFM exercises leading to cure was 2.1 (95% confidence interval 0.99-4.4). Although the effect of biofeedback-assisted PFM training did not reach statistical significance, the authors concluded that there was a trend in favor of biofeedback.[11]

The Cochrane Incontinence Group conducted a systematic review of RCTs published from 1983 to 1999.[9] The authors evaluated 43 trials that compared the effects of PFM training to no treatment or other treatment options in women with symptoms or urodynamic diagnoses of stress, urge, and mixed incontinence. Thirty-one trials involved women with SUI but only 23 trials included women with a urodynamic diagnosis of genuine SUI. Ten randomized trials compared PFM training with biofeedback (n = 209) vs. PFM training alone (n = 180). The number of treatments, methods, and duration of biofeedback treatments was highly variable. In the trials with clinic-based biofeedback, the number of sessions per week ranged from one to 12 weeks. The daily home-based programs ranged from two weeks to three months. Half of the trials used biofeedback from a vaginal probe with EMG electrode and the other half used a pressure-sensitive intravaginal device. None of the three measured outcomes (self-reported cure, self-reported cure/improvement, and leakage episodes in 24 hours) found any statistically significant difference between PFM training and PFM training/biofeedback groups.

Three trials, all in women with SUI only, included a short pad test. All found significant reductions in leakage in both groups. In two trials this favored the biofeedback group although the difference was not significant.

One of the two trials that included women with genuine SUI, with or without detrusor muscle instability, measured PFM activity and found that sustained contraction strength was greater in the biofeedback than PFM training group. Overall, the authors concluded that PFM training appeared to be consistently better than no treatment and placebo treatments for women with both stress and/or mixed incontinence. It appears that adding biofeedback to PFM training does not increase the benefit. Anecdotally, many clinicians report that biofeedback is a useful addition to PFM training, but from the review it is not clear what benefit it offers. Long-term outcomes of PFM training are unclear. Side effects were uncommon and reversible.

Recent Clinical Trials. The largest clinical trial comparing PFM training with and without biofeedback to date was conducted in Norway.[12] In this single-blind, randomized trial, 103 women between ages 30 and 70 years and who had experienced symptoms from 1-25 years completed six months of PFM training that consisted of doing three sets of 10 contractions three times per day under a physical therapist's supervision. One group trained with a biofeedback apparatus at home, the other without biofeedback. Data from 94 women were analyzed. Women training with and without biofeedback showed a statistically significant reduction in leakage on pad test ($P < 0.01$) after six months of PFM training. Objective cure (2 g or less of leakage) in the total group was 58% in women training with biofeedback and 46% in women training without biofeedback. In the subgroup of women with urodynamic SUI alone, objective cure was seen in 69% of women training with biofeedback and 50% of women training without biofeedback. Cure rate was high, and the reduction in urinary leakage after treatment was statistically significant in both groups. However, there was no statistically significant difference in the effect of individual pelvic floor muscle training with and without biofeedback.

A prospective randomized pilot study compared EMG-assisted biofeedback to PFM training alone in female patients with SUI.[13] Participants were 31-69 years of age and had no previous incontinence operations. The biofeedback group received an EMG-guided biofeedback device for home training and the PFM group trained without any device at home. All patients were advised to practice for 20 minutes per day five times a week for 12 weeks. Muscle forces increased significantly in both supine ($P < 0.001$) and standing ($P < 0.001$) positions. In the supine position, the increase was significantly higher in the biofeedback group ($P = 0.024$). The results showed close to a significant decrease in the leakage index in the biofeedback group ($P = 0.068$), but no change occurred in the PFM group. The results of this study demonstrate

the efficacy of PFM exercises alone and in combination with a biofeedback device in increasing muscle activity. The decrease in the leakage index and the increase in PFM activity were better in the biofeedback group, a clear indication that adjunctive biofeedback is more effective than PFM training alone. The authors conclude that the biofeedback group showed a significant improvement in PFM training outcome measures (PFM activity, leakage index) compared to the patients doing PFM training alone. The benefit of the EMG feedback is that this device facilitates the acquisition of physiologic responses that otherwise are undetected.

A three-year long-term efficacy study evaluated pelvic floor re-education (PFR) with EMG-controlled biofeedback in the treatment of female genuine SUI or mixed incontinence.[14] Between 1995 and 1998, 36 women completed three to six months of PFM training with a biofeedback device. A mean of 26 months later, a follow-up examination was performed. Immediately after the program, 25 women reported cure or improvement of stress incontinence, but at the long-term follow-up, only 17 women reported the same result. About half of the patients receiving PFR with biofeedback remain cured after 26 months.

Other studies have suggested that biofeedback therapy, particularly with electrical stimulation, produces better subjective outcomes, improvements in quality of life, and higher contraction pressures of PFMs.[15,16] However, the effect on continence has not been evaluated thoroughly.

Conclusion

Biofeedback is clearly an effective tool for teaching proper PFM training techniques. In addition, biofeedback may help the patient learn how to contract faster by use of either EMG or pressure measurements.

Based on evidence from systematic reviews and meta-analyses, it seems that PFM training exercises are effective for stress incontinence, but adding biofeedback to PFM training may not result in additional improvement. The effectiveness of biofeedback-assisted PFM training is not clear, but on the basis of the evidence available there did not appear to be any benefit over PFM alone. Nevertheless, recent clinical trials suggest that the positive effect of biofeedback using electrical stimulation may last over longer periods of time, particularly in women who maintain regular training. The efficacy of PFM exercises, with or without other adjuncts, for the prevention of SUI is uncertain.

Most trials to date have studied the effect of treatment in younger, premenopausal women. Very few trials have addressed cost-benefit analysis. Interestingly, since October 2002, the Centers for Medicare and Medicaid Services approved a national coverage for the use of biofeedback and PFM electrical stimulation for the treatment of urinary incontinence.[17]

Large multicenter studies using the same inclusion and exclusion criteria, biofeedback protocol, and methodology are needed to demonstrate the real effectiveness of biofeedback.[18] Trials measuring the effect of biofeedback-assisted PFM training in women with SUI who are not able to voluntarily contract their PFMs are needed. In addition the rate of improvement in biofeedback-assisted training vs. PFM training alone should be evaluated.

Hay-Smith et al recommend that future research trials should select or develop outcomes that matter to women and that cover a range of outcome domains, and use tools that have established reliability and validity for women with urinary incontinence.[9] Domains that require particular attention in future research are quality of life and socioeconomics.

Urinary incontinence is a distressing and life-altering condition that has significant medical, social, and psychologic implications for women. Continence management requires a sensitive, comprehensive, and holistic approach.[19] More research of high methodological quality is required to further evaluate the effects of physical therapies used to treat and prevent SUI. ❖

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Use of *Lactobacillus* for the Treatment of Vulvovaginitis

Source: Jeavons HS. Prevention and treatment of vulvovaginal candidiasis using exogenous *Lactobacillus*. *J Obstet Gynecol Neonatal Nurs* 2003;32:287-296.

Abstract: The author reviewed literature examining exogenous *Lactobacillus* therapy for vulvovaginal candidiasis and discusses recommendations for clinical practice and future research. Computerized searches on MEDLINE and CINAHL were done in November 2000, September 2001, and March 2002, with search terms including *Lactobacillus*, acidophilus, *Candida*, and yeast infections. Relevant English-language articles from the past 10 years were included in the analysis, and unique or seminal studies included where pertinent. Data are organized under the following headings: endogenous *Lactobacillus*, exogenous *Lactobacillus*, *Candida*, studies of intravaginal *Lactobacillus* therapy for vulvovaginal candidiasis, studies of oral *Lactobacillus* therapy for vulvovaginal candidiasis. The author concluded that vaginally administered or orally ingested *Lactobacillus* is able to colonize the vaginal ecosystem. Controlled intervention studies regarding the effect of such colonization on vulvovaginal candidiasis are promising but few. These studies had small numbers of participants, were inconsistent in the form of *Lactobacillus* used, and reported conflicting results. Further randomized controlled trials involving large numbers of women are imperative. In the meantime, health care providers should discuss potential benefits with affected patients while clarifying the current lack of conclusive evidence. Without further research into currently available sources and brands of *Lactobacillus* and without governmental regulation of supplements and their contents, however, it is difficult to make recommendations regarding appropriate product choice.

■ COMMENTS BY MARY L. HARDY, MD

Vaginitis or symptoms of vaginal irritation account for millions of office visits a year and *Candida* sp. are the most common etiologic agents identified. Effective oral and topical therapies exist for fungal vulvovaginitis, but treatments are not universally effective. Patients commonly turn to over-the-counter (OTC) remedies, including alternative therapies such as probiotics, for relief especially of chronic symptoms. Dr. Jeavons suggested in her recent review that therapy with *Lactobacillus* "represents low risk of therapeutic resistance and side effects, low financial cost, and greater appeal for women who prefer natural methods for their health maintenance." Her recent article reviews the research on the use of exogenous *Lactobacillus* for treatment and prevention of vulvovaginal candidiasis (VVC) and makes clinical recommendations regarding appropriate clinical use.

A recent study focused on the use of OTC and complementary and alternative medicine (CAM) therapies for chronic vaginal symptoms.[1] Most patients thought they had candidiasis and 74% treated with OTC antifungal preparations. About half as many patients (42%) used the following CAM therapies, in descending order of frequency of use: acidophilus pills orally (50%), yogurt orally (20.5%), yogurt vaginally (18%), vinegar douche (14%), boric acid (14%), and acidophilus pills

vaginally (11%). Significantly, less than a third of the women (28%) actually had candidiasis and those women who were correct in their self diagnosis were twice as likely to have used CAM therapies. Patients also were less likely to disclose use of CAM products than OTC products to their health care provider.

Lactobacillus sp. have been used to treat or prevent a variety of conditions such as urinary tract infections, traveler's diarrhea, *C. difficile,* and other bacterial diarrheas as well as VVC.[2] In normal vaginal flora, a complex mixture, *Lactobacillus* is the most commonly identified species. However, *L. acidophilus,* the species most commonly available commercially, is not the only species present in healthy vaginal flora and may not be the dominant species in vivo. The use of active lactobacillus cultures is biologically plausible as there are a number of mechanisms by which lactobacilli can prevent overgrowth of potentially pathogenic species of yeast and bacteria. First, they all produce lactic acid as a byproduct of glucose metabolism, thus acidifying the vagina. Some species produce hydrogen peroxide or other antibacterial compounds and compete with pathogens for binding sites in vaginal epithelium.

According to Dr. Jeavons' review, evidence does exist that exogenously provided *Lactobacillus* sp. can colonize the vagina when given either orally or intravaginally both in dairy products as well as dietary supplements. Most supplementation needs to continue chronically to sustain continued colonization. Several species have been tested and have shown that a relatively long duration of treatment is necessary, on the order of 2-6 months. There is likely a difference in effect based on species chosen and possibly on vehicle of delivery (yogurt-based bacteria were shown in one trial to be less likely to adhere to the vaginal wall). Some studies have also looked at the rate of rectal colonization to determine if vaginal bacteria are seeded into the vagina from the rectum (probably) and if the action of the bacteria in the colon on yeast populations there is definitive for vaginal colonization (unclear from present data). Clinical evidence at this point is insufficient to answer these questions definitively.

Most clinical testing of exogenous *Lactobacillus* is concerned with the ability of these bacteria to relieve current symptoms (with or without a confirmed diagnosis of VVC) and to prevent recurrent attacks. The data are generally scanty as reported by Dr. Jeavons, but encouraging. Most studies had problems with small numbers of subjects, inadequate controls, or lack of blinding, as well as high attrition rates. Encouragingly, one well-done recent trial examined recurrent episodes of VVC in HIV-positive women who were treated weekly for an average of 21 months with placebo, clotrimazole, or *L. acidophilus* administered vaginally.[3] The women in the acidophilus group had only half the risk of developing VVC compared to the placebo group. This reduction in risk is excellent compared to the 60% reduction in risk of the clotrimazole-treated group in these immunocompromised patients. Additional clinical research is urgently needed to clarify how to use these probiotic foods and products to effectively treat patients.

For practicing clinicians, relevant information can be gleaned from this review. First, there is a plausible biologic rationale for the use of exogenous *Lactobacillus* sp. Prophylaxis is probably a better indication for these products than acute treatment, although there is no evidence of toxicity in acute care. Clinical evidence, while not yet sufficiently strong for a firm recommendation, is encouraging. Given, the low toxicity and relatively low cost of these interventions (especially the yogurt), including this therapy in the options discussed with patients is reasonable. In fact, for patients with chronic symptoms or recurrent infections, it is recommended that clinicians actively solicit information about their patients' use of CAM therapies, since patients may not volunteer this information.

Patient adherence may be a limiting factor for the use of probiotic products or foods with active cultures. Treatment may need to be of long duration. Clinical trials documented that large numbers of patients failed to adhere to the clinical regimens. Oral therapies were better tolerated than topical or intravaginal products. Choice of a commercial product should be made based on the amount of live bacteria of an appropriate species the product provides. Some products have been reported

to be contaminated with other bacteria than the target organisms. Yogurt preparations generally have been found to contain single species and can be therapeutically useful. So in summary, for patients with recurrent symptoms or repeated infections of VVC, the choice of an appropriate product given for a sufficient amount of time represents a reasonable addition to the clinical armamentarium in this area. ❖

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CE Objectives

After reading *Alternative Therapies in Women's Health*, the health care professional will be able to:

1. evaluate alternative medicine and complementary therapies for women's health concerns;
2. identify risks and interactions associated with alternative therapies;
3. discuss alternative medicine options with patients; and
4. offer guidance to patients based on the latest science and clinical studies regarding alternative and complementary therapies.

CE/CME Instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the article, using the provided references for further research, and studying the questions at the end of the article. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity, you must complete the evaluation form provided and return it in the reply envelope provided at the end of the semester to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

Correction

On page 43 of the June 2003 issue, the following statement is incorrect: "No infants in either group had an Apgar score of > 7 at five minutes." The sentence should have said: "No infants in either group had an Apgar score of < 7 at five minutes."

CME Questions

1. Stress urinary incontinence usually is caused by:
   a. anatomical defects in the structures that support the bladder and the urethra.
   b. leakage of large amounts of urine at unexpected times, including during sleep, for no apparent reason.
   c. inappropriate and involuntary bladder contractions that occur as a result of damage to the nerves of the bladder, to the nervous system, or to the muscles themselves.

2. What percent of those affected by urinary incontinence can be cured or improved through diet, changes in medications, or a combination of medicine, behavioral modification, pelvic muscle re-education, collection devices, absorbent products, and physical therapies?
   a. 50%
   b. 65%
   c. 80%
   d. 95%

3. What therapies are commonly used to treat stress urinary incontinence?
   a. Kegal exercises
   b. pelvic floor muscle training
   c. biofeedback
   d. All of the above

4. In one study of women with recurrent episodes of vulvovaginal candidiasis, women taking *Lactobacillus acidophilus* had half the risk of developing VVC than women in the placebo group.
   a. True
   b. False

5. *Lactobacillus acidophilus* is a reasonable over-the-counter treatment for VVC because:
   a. it has low toxicity.
   b. it is inexpensive.
   c. it is appealing to women who prefer natural remedies for health maintenance.
   d. All of the above

Answers: 1.a, 2. c, 3. d, 4. a, 5. d.

In the News

Caregivers Give Children Herbal Remedies Without Knowing Adverse Effects

Nearly half of the caregivers surveyed in a large urban hospital reported giving their children herbal products or home remedies, even though they know little about potentially harmful side effects or adverse reactions with other medications, according to an Emory University study that was published in the May issue of *Pediatrics*.

The researchers from the Emory University School of Medicine in Atlanta, GA, interviewed 142 families at a pediatric emergency department at an urban tertiary care children's hospital between October 2001 and December 2001. Using a questionnaire developed by the investigators, caregivers responded to a series of questions about herbal and alternative therapies given to their children (ranging in age from 3 weeks to 18 years old). For the purposes of this study, herbal products were defined as substances used as health treatments that were not approved by the U.S. Food and Drug Administration and were not considered prescription or over-the-counter medications.

Forty-five percent of the caregivers interviewed reported using herbal or alternative remedies for their children. The most common therapies were aloe plant/juice (44%), echinacea (33%), and sweet oil (25%). The most common reasons for use of herbal therapies were colds, burns or cuts, immune stimulation, and relaxation.

Seventy-seven percent of the caregivers either were uncertain about or did not believe there were any side effects from herbal products. Of those who believed side effects were possible, only 27% could name a potential side effect. Furthermore, 66% of the caregivers were unsure or thought that herbal products could not potentially interact with other medications. Only two of the responders who thought interactions could occur correctly identified a potential drug interaction.

Researchers found that 61% percent of children on an herbal therapy were reportedly taking a prescription medication at the same time. The most dangerous potential herbal and prescription medication combination reported was the simultaneous use of ephedra and albuterol in an adolescent with asthma. That combination could result in a dangerously elevated heart rate.

Although 80% of people who used the therapies reported friends or relatives as their primary source of information, only 45% of those giving herbal products to children discussed the use with the child's primary care provider.

FTC Says Claims of Coral Calcium Supreme Supplement Unsubstantiated

The Federal Trade Commission (FTC) has charged the marketers of the dietary supplement Coral Calcium Supreme with making false and unsubstantiated claims about the product's health benefits. In a complaint filed in federal district court, the FTC alleges that Kevin Trudeau, Robert Barefoot, Shop America (USA) LLC, and Deonna Enterprises violated the FTC Act by claiming, falsely and without substantiation, that Coral Calcium Supreme can treat or cure cancer and other diseases, such as multiple sclerosis and heart disease. The FTC charges that these and other claims go far beyond existing scientific evidence regarding the recognized health benefits of calcium.

The defendants promote the product primarily through a nationally televised 30-minute infomercial featuring Trudeau and Barefoot, and through statements made in brochures accompanying the product. The informercial has aired on cable channels such as Women's Entertainment, Comedy Central, the Discovery Channel, and Bravo.

In related law enforcement efforts, the FTC and the U.S. Food and Drug Administration (FDA) are sending strong warning letters to web site operators who are marketing coral calcium products claiming that coral calcium is an effective treatment or cure for cancer and/or other diseases. Accordingly, the FTC is instructing the web site operators to remove any false or deceptive claims from their sites immediately. In a similar action, the FDA warned web site operators that disease claims and unsubstantiated structure/function claims cause their products to be in violation of the Federal Food, Drug, and Cosmetic Act. ❖

In Future Issues:

Chaste Tree Berry for Premenstrual Syndrome

Alternative Treatments for Vaginitis