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Electrical Stimulation For The Management Of Bladder And Bowel Incontinence

Introduction

1.1.1 Who is affected by urinary incontinence?

Urinary incontinence (UI) affects an estimated 13 million Americans. Six out of every seven cases of adult incontinence occur in women, and between 15% and 30% of women experience incontinence during their lifetimes.

Younger women are generally more at risk for urinary incontinence than younger men because of child bearing and the comparative shortness of their urethras (around two inches versus ten in men). The more children a woman has the greater the risk, although it is highest with the first child. Women who have their first child over age 30 are also at higher risk for incontinence. Women who used the drug oxytocin for inducing labor also appear to be at increased risk for urinary incontinence later on, probably because such medically-induced labor tends to subject the muscles and nerves in the pelvis to greater force than does natural labor.

Women who perform high-impact exercise are susceptible to urinary leakage, particularly those with a low foot arch, which, on impact, increases the shock to the pelvic area. Those at highest risk for urinary leakage are gymnasts, followed by softball, volleyball, and basketball players. One study of 600 women indicated that smokers and former smokers are twice as likely to develop incontinence than women who never smoked are [Bump, 1992].

Although the prevalence of UI increases with age, UI should not be considered a normal part of the aging process. For non-institutionalized people older than 60 years of age, the prevalence of UI ranges from 15 to 35%, with women having twice the prevalence of men [Burgio, 1991]. UI is one of the major reasons for institutionalization of the elderly, and it affects an estimated 50% of nursing home residents [AHCPR, 1996].

1.1.2 Types of Incontinence

Urinary incontinence is the inability to control urination. It may be temporary or permanent and can result from a variety of problems in the urinary tract. Urinary incontinence is generally divided into four groups according to the malfunction involved: stress, urge, overflow, and functional incontinence. Sometimes more than one type of incontinence is present; approximately 40% of incontinence cases fall into more than one of the four categories.

Stress Incontinence

Stress incontinence occurs when the sphincter of the bladder does not close completely. In many people with this condition, the muscles of the pelvic floor are weak, allowing the sphincter and the muscles supporting the bladder to relax unduly. In other words, stress incontinence is often caused by weak or overly relaxed muscles in the pelvic floor.

The primary symptom is minor leakage from activities, such as coughing, sneezing, laughing, running, lifting, or even standing, that apply pressure to a full bladder. Leakage stops when the activity stops. (If it persists, the condition is more likely to be urge incontinence.)

Urge Incontinence

People with urge incontinence (also called hyperactive bladder or irritable bladder) need to urinate frequently or are unable to reach the bathroom before leakage. Urge incontinence may cause a person to lose urine when he or she hears or touches running water or when he or she is fumbling with the keys to get through the front door.

In these cases, the bladder is overactive; when it reaches capacity the nerves appropriately signal the brain that the bladder is full, but the urge to void cannot be voluntarily suppressed, even temporarily. Thus, urge incontinence is thought to be primarily a disorder of nerves; this is in contrast to stress incontinence, which is thought to be primarily a disorder of muscles.

In a variant type of urge incontinence known as *reflex incontinence*, the sensation of fullness is not adequately communicated to the brain, and, in the absence of the brain's inhibition of this automatic process, the bladder releases urine.

1.1.3 Mixed (Stress and Urge) Incontinence

Many people with UI have a combination of urge and stress incontinence. When symptoms of both stress and urge incontinence are present, the incontinence is called mixed incontinence. Mixed incontinence is common in women, especially older women. Often, however, one symptom (urge or stress) is more bothersome than the other. Identifying the most bothersome symptom is important in targeting diagnostic and therapeutic interventions.

Overflow Incontinence

Overflow incontinence results when the bladder cannot empty completely, generally because of partial obstruction or an inactive bladder muscle. In contrast to urge incontinence, the bladder is less active than normal. It cannot empty properly and so becomes distended. Eventually this distention stretches the internal sphincter until it opens partially and leakage occurs.

Functional Incontinence

Functional, or environmental, incontinence encompasses a variety of conditions in which a person is unable to use the bathroom because of physical or emotional impairments.

1.1.4 Treatment Of Incontinence By Electrical Stimulation

Transcutaneous Electrical Muscle Stimulation of the Pelvic Floor

Electrical muscle stimulation (EMS) of the pelvic floor is a non-invasive method of producing contraction of pelvic floor muscles. Pelvic floor EMS devices use a (non-implantable) device that produces electrical pulses to cause pelvic floor muscle contraction. The device is attached to the pelvic floor via electrodes. There are several different types of electrodes that may be used. Some electrodes are coated with conductive adhesive and attach to the skin of the pelvic floor. Other electrodes are designed for placement in the vagina or in the anus; these electrodes may be referred to as vaginal plug electrodes or anal plug electrodes.

When the electrodes are attached and the EMS device is activated, it supplies electrical pulses to the muscles of the pelvic floor. (Since the current passes through the skin to reach the underlying muscles, this type of therapy is sometimes referred to as *transcutaneous*.) The electrical pulses cause contraction of the pelvic floor muscles. The device typically maintains the contraction for 5-30 seconds, then it allows the muscles to relax for 5-30 seconds. This contraction-relaxation cycle is typically applied for 30 minutes to an hour per session, but some people apply electrical stimulation for significantly longer periods, up to 20 hours per day. The length and frequency of sessions depends on the severity of the incontinence.

EMS is also believed to produce some inhibition of the bladder, allowing the bladder to reach a greater volume. This is believed to occur because electrical stimulation also stimulates nerves in the pelvic floor. In most people, bladder voiding is inhibited when the skin of the pelvis is touched or otherwise manipulated. This inhibition is via a reflex in the spinal cord that may have evolved to inhibit voiding during sexual contact. The pelvic floor nerves are responsible for transmitting the sensation of touch from the pelvis to the spinal cord. Electrical stimulation of these nerves thus activates sensory fibers that cause inhibition of bladder voiding via a reflex mechanism in the spinal cord. This may explain EMS is an effective treatment for some people with urge incontinence. People report that electrical stimulation of the pelvic floor nerves causes a tingling sensation that is not unpleasant.

Research indicates that pelvic floor EMS can significantly reduce symptoms in women with stress incontinence. It may also be effective in men and women with mixed and urge incontinence. Studies have indicated that 54-77% of people using EMS reported significant relief from symptoms of incontinence, including a decrease in the number of incontinence episodes and a decrease in the volume of a leak [Caputo, 1993]. Side effects of EMS are minimal; some people report some discomfort or pain when a high level of electrical stimulation is applied. The effects of therapy may be sustained for 6 weeks to 2 years. Treatment using

stimulation generally requires monitoring by a health care provider to determine effectiveness.

Implantable Electrical Stimulation Systems

Implantable electrical stimulation devices have been researched and used for bladder control for over two decades. Only one such device is currently available, the Medtronic InterStim Therapy for Urinary Control, which was approved in Europe in 1994 and in the US in 1997.

1.1.5 Medtronic InterStim Therapy for Urinary Control

The Medtronic InterStim device can eliminate or greatly reduce urinary symptoms for many people who suffer from urge incontinence. Several thousand people have been implanted with this device.

Medtronic InterStim Therapy uses a small device to send mild electrical pulses to a nerve located in the lower back (just above the tailbone). The device measures 2.4 inches (6.1 cm) wide x 2.2 inches (5.6 cm) high x 0.4 inches (1 cm) thick. The stimulated nerve, called the sacral nerve, influences the bladder and surrounding muscles that manage urinary function. The electrical stimulation may eliminate or reduce urge incontinence in some people. The system is surgically placed under the skin, typically in the lower abdomen and lower back. It is completely reversible and can be discontinued at any time with no permanent damage to the nerves. The sensation of stimulation varies from person to person, but most people describe it as a slight pulling sensation in the pelvic area. Stimulation is not painful.

The potential benefit of InterStim Therapy can be demonstrated with a temporary test stimulation. The procedure uses an external stimulator and test lead system. During the testing period, a person keeps track of his or her urinary symptoms in a special diary for several days. If the symptoms are significantly reduced or eliminated during the testing period, then he or she may benefit from long-term use of an InterStim Therapy System.

In clinical studies, InterStim Therapy successfully treated urge incontinence in people who had failed or could not tolerate other treatments. InterStim Therapy is not a cure for bladder control problems, but it may help people suffering from these conditions. Several clinical studies of one year or more have shown good results in many people.

Clinical Improvement in Urge Incontinence

- 45% were completely dry
- 34% had 50% or greater reduction in number of wetting episodes
- 70% eliminated heavy leaking episodes

Clinical Improvement in Symptoms of Urinary Urgency and Frequency

- 33% reduced the number of voids by 50% or more
- 31% reduced the number of voids per day to a normal range (4-7 per day)
- 82% improved degree of urgency before a void

52% of clinical study participants experienced therapy-related adverse events, including pain at the implant site, electrode migration, and infection. 54% of these required hospitalization or surgery to resolve. The surgical revision rate was 33%. No adverse events resulted in permanent injury.

A packet of information about InterStim Therapy for Urinary Control may be requested directly from the Medtronic toll-free Help line at (800) 664-5111, ext. 3000 or from the Medtronic web site, http://www.Medtronic.com.

1.1.6 Implantable Systems Under Development

Advanced Bionics Corporation (http://www.AdvancedBionics.com) has entered clinical trials with a small implantable electrical stimulation device for the treatment of urge incontinence. The cylindrical device measures approximately 3 mm in diameter and 25 mm in length. The device contains the electrodes required for stimulation, so no additional lead is necessary. The device is implanted adjacent to a nerve in the pelvis (called the pudendal nerve). In a clinical pilot study of 5 patients, all patients reported a decrease in incontinence episodes of 80-90% or greater. This system is expected to enter a larger clinical trial in 2002.

Several university research programs are also exploring systems for the treatment of urge and stress incontinence. Some of these systems are designed for the treatment of bladder symptoms in people who have suffered a spinal cord injury. NeuroControl (http://www.NeuroControl.com) and Finetech (http://www.finetech-medical.co.uk) both distribute the VOCARE system, which is also designed for the treatment of bladder symptoms in people who have suffered a spinal cord injury.

1.1.7 Companion Therapies

The companion therapies described below are often categorized together as *behavioral techniques*. These techniques may offer effective management and control of incontinence for motivated individuals who wish to avoid more invasive procedures or dependence on protective garments, external devices, and medications. Behavioral techniques generally focus on increasing a person's understanding of lower urinary tract function and the environmental factors affecting symptoms. These techniques can improve control of bladder and pelvic muscle function [AHCPR, 1996].

However, behavioral techniques require patient or caregiver involvement and continued practice. If motivated, most people treated with behavioral techniques show improvement ranging from complete dryness to decreased incontinence episodes. Behavioral techniques have few reported side effects and do not limit future treatment options. Behavioral techniques can also be used safely and effectively in combination with other therapies for incontinence.

Bladder Training

Bladder training (also known as bladder retraining) has many variations but generally consists of three primary components: education, scheduled voiding with systematic delay of voiding, and positive reinforcement. Bladder training is most commonly used to manage UI caused by urge incontinence [AHCPR, 1996].

The education program usually combines written, visual, and verbal instruction that addresses the physiology and pathophysiology of the lower urinary tract. A bladder training program requires a person to resist or inhibit the sensation of urgency, to postpone voiding, and to urinate according to a timetable rather than according to the urinary urge [McCormick, 1984]. Bladder training may involve tactics that help distend the bladder, such as adjustment in fluid loads and delayed voiding to provide progressively larger voiding volumes and longer intervals between voids.

Bladder training can be used in combination with other therapies for incontinence, including external and implantable electrical stimulation systems.

Pelvic Floor Exercise

Pelvic floor exercises, also called Kegel exercises and pelvic muscle exercises, are performed to strengthen the voluntary muscles that contribute to the closing force of the urethra and to the support of the pelvic organs. The first step in pelvic muscle re-education is to establish better awareness of pelvic muscle function. Pelvic floor exercises are performed by “drawing in” or “lifting up” of the muscles between and around the vagina and the anus, as if to control urination or defecation with minimal contraction of abdominal, buttock, or inner thigh muscles. People are generally told to sustain a contraction for at least 10 seconds, followed by an equal period of relaxation. The exercises should be performed about 30-80 times a day for at least 8 weeks and may need to be continued indefinitely. Elderly people may require a longer time to train. To condition the muscle to contract with increases in intra-abdominal pressure, the pelvic muscles should be contracted before and during situations when leakage may occur [AHCPR, 1996].

Pelvic floor exercises are most commonly recommended for women with stress incontinence. However, these exercises may also help to control the symptoms of urge incontinence. The vast majority of people report at least some benefit from such exercises. The intensity of the exercise program affects physiological and functional outcomes. In a 1990 study [Bo, 1990], a group of people who receive ongoing guidance in performing maximum contractions of the pelvic

muscle that increased in intensity over 6 months reported significantly greater reduction in incontinence (and changes in pelvic floor strength) compared with a group that received only a single session of instruction and a home exercise program.

Pelvic floor exercises have virtually no side effects and do not limit future treatment options. They can generally be used in combination with other therapies for incontinence, including external and implantable electrical stimulation systems.

Biofeedback

Biofeedback therapy typically involves the use of electronic or mechanical instruments to relay information to people about their bladder activity. The goal of the therapy is to improve bladder dysfunction by teaching people to change reflexes and other responses that mediate bladder control.

Most biofeedback devices utilize auditory or visual display of information about muscle contraction or sphincter pressure. As pelvic floor exercises are performed, a person receives a signal from a device and attempts to increase muscle contraction in order to maximize this signal. Without biofeedback, weak pelvic muscles may provide limited sensation or feedback following a pelvic muscle contraction, and as a result people do not achieve a maximum muscle contraction. Biofeedback for UI typically is based on measurement of either the electrical activity of the pelvic floor muscles (referred to as an EMG measurement) or of the pressure generated by the vagina or the anus (referred to as manometric measurement). Some biofeedback systems combine multiple measurements.

Pelvic muscle rehabilitation and bladder inhibition using biofeedback therapy may be used for the control of stress, urge, and mixed UI. Studies on the various applications of biofeedback combined with pelvic floor exercises or bladder training report a range of 54-87% improvement in incontinence across various patient groups using different biofeedback and behavioral procedures. The biofeedback protocol that has been associated with the largest and most consistent symptom reduction is one that reinforces pelvic muscle contraction concurrently with inhibition of abdominal and bladder contraction [AHCPR, 1996].

A 1987 study demonstrated that biofeedback may reduce the number of pad changes per day by approximately 50%. This improvement was attained in an approximate average of 11 sessions of approximately 1 hour each [Wilson, 1987]. Another study [Susset, 1990] used biofeedback over six weekly clinic visits, supplemented with a home training device for daily practice. These people demonstrated an 87% reduction of leakage on pad test, suggesting that a home training device may provide an added benefit to clinic biofeedback visits.

Biofeedback is commonly used in conjunction with other behavioral techniques such as pelvic floor exercises and bladder training. Biofeedback can also be used in combination with external and implantable electrical stimulation systems.

Vaginal Weight Training

Specially designed vaginal weights for strengthening the pelvic muscles can augment pelvic floor exercises. People use a set of vaginal weights of identical shape and volume but of increasing weight (20-100 grams). As part of a structured progressive resistive exercise program, women insert the weight into the vagina and attempt to retain it by contracting the pelvic muscles up to 15 minutes. The weight may be worn while the woman is standing or walking, and the exercise is done twice daily. Such exercises are believed to increases the strength of the pelvic muscles. Additionally, the weight may provide heightened sensory feedback during pelvic muscle contraction [AHCPR, 1996].

Vaginal weight training is recommended primarily for premenopausal women with stress incontinence. It can be used in combination with other therapies for incontinence, including external and implantable electrical stimulation systems.

Surgical Alternatives And Compatibility With Electrical Stimulation

Surgery is generally accepted as a beneficial therapy for stress incontinence in men and women and may be recommended as first-line treatment for appropriately selected people who are unable to comply with other non-surgical therapies.

The purpose of a surgical procedure is to correct, compensate for, or circumvent the underlying disorder causing urinary loss. Some people have more than one disorder and thus may undergo a combined procedure or more than one procedure. Surgical procedures generally attempt to achieve one or more of the following goals:

(1) Increase the resistance to urine flow out of the bladder (used for stress incontinence, but may be used for mixed or urge incontinence in some cases)

(2) Decrease the number of spontaneous bladder contractions (in people with urge incontinence)

(3) Remove anatomical obstruction to the bladder, such as prostate tissue (used for overflow incontinence, and may be used for urge incontinence in some cases)

Some types of surgical procedures may be augmented with electrical stimulation therapy before or after the procedure. In people with stress incontinence, pre-surgical electrical muscle stimulation can be used to strengthen the pelvic floor muscles, which may in turn improve surgical recovery and therapeutic outcome. After healing from a surgical procedure, electrical muscle stimulation may be used to strengthen pelvic floor muscles, which may also improve surgical outcome.

For urge incontinence, surgical interventions may be less compatible with electrical stimulation following surgery. In some surgical procedures for urge incontinence, a small piece of intestine is surgically removed and used to augment the bladder, thus hopefully restoring some greater control over the bladder. While transcutaneous EMS is unlikely to be harmful following such a

procedure, the benefit of EMS following this procedure is unknown. In other surgical procedures for urge incontinence, some of the nerves to the bladder or to the pelvis are severed. Following such procedures, EMS may still have some benefit, as it provides direct stimulation to muscles independent of the nerve supply.

All surgical procedures for urge incontinence are likely to alter or disrupt the nerve supply to the bladder or the pelvic floor. Implantable electrical stimulation systems for the treatment of urge incontinence rely on these nerves being at least somewhat intact. Therefore, implantable systems may provide less or no benefit following a surgical procedure for urge incontinence.

For people with mixed incontinence, surgical correction of stress incontinence combined with an implantable electrical stimulation system for treatment of urge incontinence is likely to provide a very effective (if highly invasive) combination therapy.

References

[AHCPR, 1996] "Urinary Incontinence in Adults: Acute and Chronic Management." Clinical Practice Guideline No. 2, 1996 Update. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service, Agency for Health Care Policy and Research. AHCPR Publication No. 96-0682. March 1996. (http://www.medscape.com/govmt/AHCPR/1999/guidelines/AHCPR.urincont/urincont-toc.html)

[Bo, 1990] Bo K, Hagen RM, Kvarstein B, Jorgensen J, Larsen S. "Pelvic floor muscle exercises for the treatment of female stress urinary incontinence III. Effects of two different degrees of pelvic floor muscle exercises." Neurourol Urodyn 1990; 9 (5): 489-502.

[Burgio, 1991] Burgio KL, Matthews KA, Engel BT. "Prevalence, incidence and correlates of urinary incontinence in healthy, middle-aged women." J Urol 1991; 146: 1255-9.

[Bump, 1992] Bump RC; McClish DK. "Cigarette smoking and urinary incontinence in women." Am J Obstet Gynecol 1992 Nov;167(5):1213-8.

[Caputo, 1993] Caputo RM; Benson JT; McClellan E. "Intravaginal maximal electrical stimulation in the treatment of urinary incontinence." J Reprod Med 1993 Sep;38(9):667-71.

[McCormick, 1984] McCormick KA, Burgio K. "Incontinence: an update on nursing care measures." J Gerontol Nurs 1984; 10 (10): 16-23.

[Susset, 1990] Susset JG, Galea G, Read L. "Biofeedback therapy for female incontinence due to low urethral resistance." J Urol 1990 Jun; 143 (6): 1205-8.

[Wilson, 1987] Wilson PD, Faragher B, Butler B, Bullock D, Robinson EL, Brown AD. “Treatment with oral piperazine oestrone sulphate for genuine stress incontinence in postmenopausal women.” Br J Obstet Gynaecol 1987 Jun; 94 (6): 568-74.

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See:
General Considerations in the Clinical Application of Electrical Stimulation
Muscle weakness or paralysis with compromise of the peripheral nerve.

References:
ES in the Management of Bladder and Bowel Incontinence
Comfort in Electrical Stimulation
ES in Muscle Denervation
ES in Muscle Reinnervation