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Pelvic Floor Muscle Biofeedback in the Treatment of Urinary Incontinence: A Literature Review

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Biofeedback is efficacious in the training of the pelvic floor musculature in order to enhance continence. This article reviews the anatomy and physiology of micturition as the underlying rationale for pelvic floor muscle biofeedback in the treatment of urinary incontinence. It critically reviews 28 studies published in peer reviewed journals from 1975 to 2005 that were prospective, randomized studies with parametric statistical analyses, operationally defined patient selection criteria, treatment protocols and outcome measures. The overall mean treatment improvement for patients undergoing biofeedback for urinary incontinence was 72.61%. In 21 of 35 (60%) paired comparisons, biofeedback demonstrated superior symptomatic outcome to control or alternate treatment groups. Larger studies and a standardization of technology and methodology are required for more conclusive determinations.

KEY WORDS: biofeedback; urinary incontinence; pelvic floor muscle.

INTRODUCTION

The International Continence Society has defined urinary incontinence as the involuntary loss of urine which is both objectively demonstrable and a social or hygienic problem (Abrams, Blaivas, Stanton, & Andersen, 1988). The incidence in women has been reported at over 50% (Harrison & Memel, 1994; Brown et al., 1999), with pregnancy increasing the likelihood. The incontinence rate in men over 60 years has been found to be 10% to 25% (Sueppel, Kreder, & See, 2001). Post-radical prostatectomy incontinence ranges from 6% to 87%, depending on the definition used (Wille, Sobottka, Heidenreich, & Hofmann, 2003). Factors contributing to incontinence include aging, childbirth, and surgery. Urinary incontinence can have a serious impact on the quality of life, restricting social engagement, impacting the self-image, contributing to depression and other health problems (Fantl et al., 1996). Approaches to management include behavioral, such as strengthening the pelvic floor musculature with exercises and prompted voiding; pharmaceutical; and surgical treatment options. Fantl et al. (1996) suggested the first choice, as a general rule,

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should be the least invasive treatment with the fewest potential adverse complications that is appropriate for the patient; behavioral techniques meet these criteria for many forms of urinary incontinence. Kegel (1948) was the first to report the efficacy of pelvic floor muscle exercises in treating urinary incontinence in women. Since then, manometric pressure measures and surface electromyography (sEMG) instrumentation have been used as a biofeedback adjunct to pelvic muscle rehabilitation. This feedback helps to isolate the specific muscles and can assist in motivation by visibly displaying pelvic floor muscle activity and progress. sEMG electrodes placed on the abdomen can help prevent the inadvertent overuse of the abdominal muscles when attempting pelvic floor contractions and help train abdominopelvic synergy in contracting the pelvic floor muscles while experiencing intra-abdominal pressures, such as coughing (Brown, 2001). Although the actual mechanisms responsible for the therapeutic effect of pelvic floor muscle biofeedback, or for the therapeutic effect of pharmacotherapy, have not yet been identified (Goode, 2004; Andersson & Wein, 2004), the behavioral approach of biofeedback-assisted pelvic floor rehabilitation focuses on the healthy functioning of the pelvic floor musculature which sets the tone for the whole mictuation process.

ANATOMY AND PHYSIOLOGY OF MICTURITION

The anatomy and physiology of micturition underlies the rationale for biofeedback. Knowledge of the structures, control systems and functions of the abdominal and urovesicular muscles are essential prerequisites to the clinical application of biofeedback assisted rehabilitation. A thorough discussion can be found in DeLancey (2001) and Haab, Sebe, Mondet, and Ciofu (2001). The lower urinary tract controlling micturition is composed of the bladder and the urethra, forming one functional unit. This unit includes the distal portions of the ureters and their ureterovesical junction at the detrusor muscle. The detrusor is smooth muscle and forms the bladder wall. It provides the propulsive force that expels urine through the urethra. The prostate in the male and the smooth and striated muscle of the urethra are also part of the lower urinary system. The pelvic floor muscles connect to and support the bladder neck, the vaginal and the anal canal. The pelvic floor muscles also comprise the external urethral and anal sphincters and have significant influence on bladder control.

A complex set of learned and reflexive control mechanisms govern the functions of urine storage and micturation. These processes involve efferent and afferent activity from the sympathetic and parasympathetic branches of the autonomic nervous system. When experiencing a need to urinate the sympathetic and somatic activities diminish and parasympathetic activity increases. This causes detrusor contractions. The brain stem and cortical centers mediate these peripheral processes. With learning, the cerebral and cerebellar influences become the predominant inhibitory control over bladder contractions. At maturity, micturition is coordinated at several levels of the nervous system extending from the frontal lobe and sensorimotor cortex to the peripheral nervous system. Normal bladder function depends upon the integrative functions of the frontal lobes, the sensorimotor cortex, the thalamus, the hypothalamus, the basal ganglia, the cerebellum, specific centers in the brain stem, the spinal cord, nerve roots and the peripheral nerves.

Several studies have reviewed the components that interact to maintain normal bladder functioning (see Hald & Bradley, 1982; Chung, Peters, & Diokno, 2001; and Myers, 2001). These factors help understanding the pathophysiology of various types of voiding dysfunction. To maintain continence during filling the pressure within the bladder must remain low compared to urethral pressure. Disruption of the low intravesical pressure by bladder noncompliance can lead to urine overflow. The base of the bladder is the bladder neck or trigone which is flat during urine storage and forms a funnel during voiding. The integrity of the vesicourethral angle during storage provides a barrier to urine loss when pressure is transmitted to the bladder and the bladder neck through activities which increase intra abdominal pressure, such as laughing, coughing, sneezing, standing and lifting. The proper functioning of the bladder neck depends on elastic tissues in the submucosa, the tone of the urethral muscles, and sufficient support of the levator ani muscle. Smooth muscle comprises the innermost layers of the bladder neck and the proximal urethra. Appropriate functioning of the urethra depends on the integrity of these smooth muscles. Striated muscles in the distal one third of the urethra, periurethral area and levator ani complex are critical for bladder support and urethral closure. Collagen and elastin connective tissue within the urethral tissue are critical in maintaining the compliance of the urethral lumen for purposes of closure. Vascular, epithelial and hormonal factors also play an important role in the compliance of the urethra. Finally, all of these peripheral factors are interdependent with both central and peripheral nervous system factors that control their functions.

PELVIC FLOOR MUSCLE ANATOMY

The pelvic floor musculature is a key component in the mictuation function. Anatomy of the human pelvic floor musculature involved in urinary control has been extensively studied and described (Shafik, Ahmed, Shafik, El-Ghamrawy, & El-Sibai, 2005; Critchley, Dixon, & Gosling, 1980; Singh, Reid, & Berger, 2002). The bilateral muscles of the levator ani meet in the midline to form the pelvic diaphragm across the floor of the pelvis. The urogenital hiatus and the anal hiatus pierce through the pelvic diaphragm. The levator ani muscle includes the more anterior and inferior pubococcygeus and the more posterior and superior iliococcygeus. The pubococcygeus attaches to the dorsal surface of the pubic bone and laterally to the arcus tendonius levator ani, or muscle white line. It forms a sling around the anus, prostate or vagina, and urethra. The most anterior fibers are the pubovaginalis, and the more posterior fibers are the puborectalis. The posterior of the levator ani, the iliococcygeus muscle, anchors above the tendinous arch of the levator ani muscle and to the spine of the ischium and below attaches to the anococcygeal body and to the last two segments of the coccyx. The coccygeus muscle, also referred to as the ischiococcygeus, lies adjacent to, and forms a continuous plane with, the iliococcygeus. Laterally the coccygeus is anchored to the spine of the ischium and the fibers of the sacrospinous ligament. Medially it fans out to end on the margin of the coccyx and on the side of the lowest piece of the sacrum. The Internal obturator muscle forms the muscular sidewalls of the pelvis and narrows down to a tendinous band which exits the pelvic below the ischial spines to attach to the greater trochanter of the femurs. The bulbospongiosis, ischiocavernosus and transversus perinei superficialis muscles on each side of the body form a traingle. The medial leg of the triangle is the bulbospongiosus, also known as the bulbocavernosus or the sphincter vagina which surrounds the vaginal opening. This muscle attaches anteriorly to the copora cavernosa clitoridis with a muscular fasciculus that also crosses over the body of the clitoris and compresses its deep dorsal vein. Posteriorly the bulbospongiosus anchors to the perineal body where it interdigitates with the external anal sphincter and the transversus perinei superficialis. The ischiocavernosus, also known as the erector clitoridis, is located along the lateral boundary of the perineum next to the bony ridge of the anterior pubic ramus between the pubic symphysis and the ischial tuberosity. The ischiocavernosus anteriorally blends with the sides of the crus clitoridis and posteriorly it anchors to the surface of the crus clitoridids and to the ischal tuberosity. The transversus perinei superficialis muscle spans the perineum laterally between the ischail tuberosities joining the sphincter ani and the bulbospongiosi in the midline at the perineal body. This complex anatomy contributes to the current lack of clarity as to the urodynamic mechanisms involved in achieving continence through various therapies (Goode, 2004).

TYPES OF URINARY INCONTINENCE

Urge incontinence is the involuntary loss of urine associated with an abrupt and strong desire to void (Abrams et al., 1988). Urge incontinence is usually associated with the urodynamic findings of involuntary detrusor contractions. Urgency in the absence of detrusor contractions is often referred to as sensory urge contrasted with detrusor hyperactivity or motor urge. Ideopathic detrusor hyperactivity is referred to as detrusor instability while detrusor contractions caused by neurologic deficits are referred to as detrusor hyperflexia or neurogenic bladder (Abrams et al., 1988). In patients with neurogenic bladder, urge is often accompanied by external urethral sphincter dyssenergia or an inappropriate contraction of the external sphincter which can cause some degree of urinary retention. Urge may also result from involuntary urethral relaxation, known as urethral instability. Urgency can also occur with detrusor hyperactivity with impaired bladder contractility (Resnick & Yalla, 1987) which leads to urge incontinence and elevated post void residuals.

Stress incontinence is the involuntary loss of urine associated with coughing, sneezing, laughing or other physical activities which increase abdominal pressure (Abrams et al., 1988). This symptom may be confirmed by observing urine loss coincident with an increase in abdominal pressure, in the absence of a detrusor contraction or an overdistended bladder. Most commonly, the abdominal pressure causes hypermobility or significant displacement of the urethra and bladder neck during exertion. Stress incontinence can also result from urethral sphincter deficiency (ISD) due to congenital or acquired weakness, most often associated with multiple anti-incontinence surgeries (Blaivas, 1985).

Overflow incontinence is the involuntary loss of urine associated with overdistension of the bladder (Abrams et al., 1988). This may present as constant dribbling or may have urge and stress incontinence symptoms. Overflow incontinence may result from an acontractile bladder due to drugs, spinal cord injury, neuropathy, or fecal impaction or may be due to bladder outlet or urethral obstruction leading to an overdistended bladder and overflow.

It is common for patients to present with a combination of both urge and stress incontinence. When symptoms of both types of incontinence are present it is referred to as mixed incontinence.

Finally it should be noted that male urinary incontinence is most often associated with prostate surgery, primarily a radical prostatectomy for prostate cancer (Wille et al., 2003).

INTAKE PROCEDURES

History

Patient evaluation should start with a history of the patient's urinary patterns and symptoms (Khullar & Cardozo, 2001). Any pertinent medical history should be reviewed including hospitalizations, surgeries, family history, chronic illness, medication and allergies. Urinary symptoms should be evaluated in the following areas:

1. Symptom onset, duration and course of symptoms.
2. Precipitating events
3. Frequency and volume of voluntary and involuntary voids (voiding diary)
4. Patterns of straining during voids, pain, and incomplete voids with incontinence after voiding
5. Food and fluid intake as a factor in voiding
6. Occurrence of urgency and control of voids or flatus
7. Timing of incontinence, e.g. nocturnal, diurnal, food/fluid ingestion, activities, emotional state, etc
8. Type and number of protective pads used
9. Medication being used such as bladder stabilizing medications or laxatives
10. Pelvic floor, penile/vaginal or rectal pain
11. Suprapubic or abdominal cramping

Physical Examination

Clinical practice recommendations for identifying and evaluating urinary incontinence have been made by Fantl et al. (1996) and Schick (2001). The physical examination should include andominal exam to detect masses, suprapubic tenderness or fullness and estimation of urinary flow and post void residuals. Genital examination in men to detect abnormalities of foreskin, glans penis and perineal skin. Pelvic exam in women to assess perineal skin, atrophy, prolapse, pelvic mass, paravaginal muscle tone, urethral hypermobility and bladder neck angle. A rectal exam should be conducted for perineal sensation, sphincter tone, bulbocavernosis reflex and prostate status in men. If indicated a general exam should be conducted to detect edemetous conditions and neurological abnormalities.

Additional Tests

Additional urinary testing may include post void residual (PVR) estimation, provocative stress testing, urinalysis, urine cytology, testing for blood urea nitrogen (BUN), voiding record, evaluation of environmental and social factors and observation of urination to detect hesitancy and straining. Specialized testing may include uroflow, cystometry, urodynamics, urethral pressure profilometry (UPP), cystoscopy and upper and lower urinary tract imaging. In addition, pelvic floor muscle sEMG has been demonstrated to be clinically reliable and predictively valid in identifying subtypes of urinary incontinence (Glazer, Romanzi, & Polaneczky, 1999; Romanzi, Poleneczky, & Glazer, 1999) and therefore may be a standard part of an initial evaluation for urinary voiding dysfunctions.

In the office practice of biofeedback by non-physicians, it is essential that patients be fully medically evaluated prior to initiating treatment so that, by history and examination, all factors such as physiological, anatomical, pharmacological, neurological, infectious, hormonal, oncological can be identified and appropriately treated or ruled out before initiating biofeedback. It could be asserted that external urethral and anal sphincter surface biofeedback is a noninvasive, benign intervention, and therefore is rarely contraindicated and does not require prior medical consultation. However, these authors strongly believe in requiring patients to undergo appropriate medical evaluation prior to initiating biofeedback as failure to do so may lead to poor clinical outcomes and delay in the identification and appropriate treatment of medical conditions, including degenerative neurological diseases such as diabetic neuropathy or multiple sclerosis, a wide range of infectious diseases, or even the identification of potential malignancies, all of which may manifest as voiding disorders. In the following literature review, therefore, only those studies employing medical evaluation of the patients prior to the administration of biofeedback are included.

LITERATURE REVIEW

Selection Criteria

Medline was searched from 1975 to 2005 using the combined keywords of "biofeedback" and "urinary incontinence." Pediatric and adult studies were included. Additional requirements were the use of operationally defined independent and dependant variables, prospective randomized trials using parametric statistical analyses, and patient selection criteria including medical history and intake to rule out organic causation of urinary incontinence.

Study Inclusion/Exclusion

The Medline search using combined keywords of "biofeedback" and "urinary incontinence" yielded 326 studies. Twenty-eight studies met the selection criteria for inclusion in the review. The remaining studies were review papers, meta-analyses, editorials, individual case histories, single group with single or nonrandomized multiple treatments, and studies not meeting criteria for patient evaluation or not using objective operationally defined independent and dependant variables.

Study Designs and Subjects

Twenty-seven of the studies were prospective randomized between group studies and one was a biofeedback versus no treatment control, randomized crossover design (McDowell et al., 1999). The study sample sizes varied from 16 to 227 with a mean of 94. There were no pediatric studies meeting selection criteria for inclusion. Eight of the studies used male patients with an average age of 62 years (see Tables I and II for references). Seven of these eight studies treated incontinence related to radical prostatectomy and one study treated post-micturition dribble in men with erectile dysfunction. Twenty of the studies

Table I. Paired Comparisons of Biofeedback Groups to Comparative Treatment and Control Groups Showing the Number of Studies producing Different Statistical Outcomes

Paired comparison	Total # paired comparisons	# Studies biofeedback greater symptom relief	# Studies biofeedback no difference symptom relief	# Studies biofeedback less symptom relief
Total	35	21 (60%)	14 (40%)	0 (0%)
Biofeedback v no treatment control	7	6 (86%)[a]	1 (14%)[b]	0 (0%)
Biofeedback v unassisted exercise	19	9 (47%)[c]	10 (53%)[d]	0 (0%)
Biofeedback v oxybutynin	2	2 (100%)[e]	0 (0%)	0 (0%)
Biofeedback v oral placebo	2	2 (100%)[f]	0 (0%)	0 (0%)
Biofeedback v vaginal cones	2	0 (0%)	2 (100%)[g]	0 (0%)
Biofeedback v electrical stimulation	2	1 (50%)[h]	1 (50%)[i]	0 (0%)
Biofeedback pre v post prostatectomy	1	1 (100%)[j]	Presurgery biofeedback results in superior continence outcomes to postsurgery biofeedback	

[a] Aksac et al., 2003; Burns et al., 1993; Dorey et al., 2004; Dougherty et al., 2002; McDowell et al., 1999; Parekh et al., 2003.
[b] Franke et al, 2000.
[c] Aksac et al., 2003; Aukee et al., 2002; Berghmans et al., 1996; Burgio et al., 1986; Burns et al., 1993; Pages et al., 2001; Sung et al., 2000; Van Kampen et al., 2000; Wang et al., 2004.
[d] Aukee et al., 2004; Bales et al., 2000; Burgio et al., 2002; Burton et al., 1988; Floratos et al., 2002; Laycock et al., 2001; Morkved et al., 2002; Sherman et al., 1997; Wille et al., 2004; Wyman et al., 1998.
[e] Burgio et al., 1998; Johnson et al., 2005.
[f] Burgio et al., 1998; Johnson et al., 2005.
[g] Laycock et al., 2001; Seo et al., 2004.
[h] Wang et al., 2004.
[i] Wille et al., 2003.
[j] Sueppel, 2001.

Table II. Paired Comparisons of Biofeedback and Alternative Treatment Groups by Secondary Variables Showing the Number of Studies Producing Different Statistical Outcomes

	Total # studies	# Studies biofeedback greater symptom relief	# Studies biofeedback no difference symptom relief	# Studies biofeedback less symptom relief
All male studies	8	4 (50%)[a]	4 (50%)[b]	0 (0%)
Post prostatectomy	7	3 (43%)[c]	4 (57%)[d]	0 (0%)
Post void dribble	1	1 (100%)[e]	0 (0%)	0 (0%)
All female studies	20	12 (60%)[f]	8 (40%)[g]	0 (0%)
Stress incontinence	12	8 (67%)[h]	4 (33%)[i]	0 (0%)
Urge incontinence	3	2 (67%)[j]	1 (33%)[k]	0 (0%)
Mixed incontinence	5	2 (40%)[l]	3 (60%)[m]	0 (0%)
Biofeedback type				
Manometry	13	6 (46%)[n]	7 (54%)[o]	0 (0%)
Surface electromyography	15	10 (67%)[p]	5 (33%)[q]	0 (0%)
Home training protocols				
No home training	6	4 (67%)[r]	2 (33%)[s]	0 (0%)
Unassisted exercise	19	11 (58%)[t]	8 (42%)[u]	0 (0%)
Biofeedback assisted	3	1 (33%)[v]	2 (66%)[w]	0 (0%)

[a]Dorey et al., 2004; Parekh et al., 2003; Sueppel, 2001; Van Kampen et al., 2000.
[b]Bales et al., 2000; Floratos et al., 2002; Franke et al., 2000; Wille et al., 2003.
[c]Parekh et al., 2003; Sueppel, 2001; Van Kampen et al., 2000.
[d]Bales et al., 2000; Floratos et al., 2002; Franke et al., 2000; Wille et al., 200.
[e]Dorey et al., 2004.
[f]Aksac et al., 2003; Aukee et al., 2002; Berghmans et al., 1996; Burgio et al., 1986; Burgio et al., 1998; Burns et al., 1993; Dougherty et al., 2002; Johnson et al., 2005; McDowell et al., 1999; Pages et al., 2001; Sung et al., 2000; Wang et al., 2004.
[g]Aukee et al., 2004; Burgio et al., 2002; Burton et al., 1988; Laycock et al., 2001; Morkved et al., 2002; Seo et al., 2004; Sherman et al., 1997; Wyman et al., 1998.
[h]Aksac et al., 2003; Aukee et al., 2002; Berghmans et al., 1996; Burgio et al., 1986; Burns et al., 1993; McDowell et al., 1999; Pages et al., 2001; Sung et al., 2000.
[i]Aukee et al., 2004; Burton et al., 1988; Laycock et al., 2001; Seo et al., 2004.
[j]Johnson et al., 2005; Wang et al., 2004.
[k]Burgio et al., 2002.
[l]Burgio et al., 1998; Dougherty et al., 2002.
[m]Morkved et al., 2002; Sherman et al., 1997; Wyman et al., 1998.
[n]Burgio et al., 1986; Burgio et al., 1998; Dorey et al., 2004; Pages et al., 2001; Sueppel, 2001; Sung et al., 2000;.
[o]Burgio et al., 2002; Burton et al., 1988; Laycock et al., 2001; Morkved et al., 2002; Seo et al., 2004; Wille et al., 2003; Wyman et al., 1998.
[p]Aksac et al., 2003; Aukee et al., 2002; Berghmans et al., 1996; Burns et al., 1993; Dougherty et al., 2002; Johnson et al., 2005; McDowell et al., 1999; Parekh et al., 2003; Van Kampen et al., 2000; Wang et al., 2004 .
[q]Aukee et al., 2004; Bales et al., 2000; Floratos et al., 2002; Franke et al., 2000; Sherman et al., 1997 .
[r]Berghmans et al., 1996; Burgio et al., 1986; Burns et al., 1993; Wang et al., 2004.
[s]Burton et al., 1988; Seo et al., 2004.
[t]Aksac et al., 2003; Burgio et al., 1998; Dorey et al., 2004; Dougherty et al., 2002; Johnson et al., 2005; McDowell et al., 1999; Pages et al., 2001; Parekh et al., 2003; Sueppel et al., 2001; Sung et al., 2000; Van Kampen et al., 2000.
[u]Aukee et al., 2004; Bales et al., 2000; Burgio et al., 2002; Floratos et al., 2002; Franke et al., 2000; Morkved et al., 2002; Wille et al., 2003; Wyman et al.,1998.
[v]Aukee et al., 2002.
[w]Laycock et al., 2001; Sherman et al., 1997.

used female patients. Of these 20 studies, 12 used patients with stress urinary incontinence with an average age of 60 years. Three studies used patients with urge urinary incontinence with an average age of 57 years, and five studies used patients with mixed or both stress and urge urinary incontinence with an average age of 59 years.

Operational Definitions of Variables

Studies varied in their operational definitions of incontinence subtypes. All studies employed history and medical exams to rule out organic causes of urinary incontinence. Additionally, 15 studies employed urodynamics, 11 studies employed the pad test, nine studies employed voiding diaries, and nine studies employed standardized questionnaires in defining the incontinence subtype under study. Outcome variables also covered a wide range of measures including 20 studies using voiding diaries, 17 using pad tests, six using physical examinations, eight using pelvic floor muscle measurements by manometry or electromyography, four using urodynamics or cystometry, and 13 using patient self-report standardized scales.

Independent, or treatment, variables also showed a wide range of operational definitions. While all twenty-eight studies included a pelvic floor muscle biofeedback group, 13 studies employed manometric biofeedback, anal in males and vaginal in females, and 15 studies employed surface electromyographic biofeedback, anal in males and vaginal in females. Six of the studies did not use any home training of pelvic floor muscles in the biofeedback group, while 19 of the studies used unassisted pelvic floor muscle home training along with office biofeedback, and three studies used pelvic floor muscle biofeedback assisted home training.

Biofeedback protocols varied widely using different patient education, contraction parameters, numbers of training sessions, numbers of repetitions, duration of training, use of accessory muscles, patient positioning, and so forth. Nineteen studies compared biofeedback to unassisted pelvic floor muscle training. Like biofeedback, unassisted pelvic floor muscle training protocols were highly variable between studies. Seven of the studies compared biofeedback to an untreated control group. Two studies compared biofeedback, drug therapy with oxybutynin, and placebo in the treatment of urge incontinence. One study compared biofeedback administered before versus after surgery in post prostatectomy incontinence, and two studies compared biofeedback, electrical stimulation and unassisted pelvic floor muscle training. Of the four remaining studies one compared biofeedback to vaginal cones, one compared biofeedback to vaginal cones and to unassisted pelvic floor muscle training, one compared biofeedback to unassisted pelvic floor muscle training and to a no treatment control group, and the final study compared biofeedback to bladder retraining and to a combined biofeedback and bladder retraining group.

Paired Comparisons of Biofeedback vs. Comparative Treatment and Control Groups

Paired comparisons of biofeedback groups to all other groups, and paired comparisons of biofeedback groups to other treatment groups by secondary variables are presented in Tables 1 and 2, respectively. The total number of biofeedback, comparative treatment and control groups in the 28 studies is 61 and the total number of paired comparisons of the biofeedback groups compared to each other group within each study is 35. All 28 biofeedback groups showed statistically significant symptom reduction over the course of treatment. In 21 of the 35 paired group comparisons, the biofeedback group showed statistically significant greater symptomatic improvement. In 14 of the 35 paired group comparisons, the biofeedback group and the comparison group showed no statistical differences in symptomatic improvement. In no comparison was biofeedback less effective than no-treatment controls or comparative treatments, including unassisted pelvic muscle exercises, medication, electrical stimulation, vaginal cones or behavioral bladder training.

Biofeedback vs. No Treatment Controls

In the seven studies which included both biofeedback and no-treatment control groups, the biofeedback groups all showed statistically significant improvement, and in six of the seven studies the biofeedback treatment resulted in statistically significant superior outcomes compared to the no-treatment control groups. Of the no-treatment control groups, six of the seven showed no statistically significant symptomatic improvement, and one no-treatment control group did show statistically significant improvement. The study in which both biofeedback and no-treatment controls showed statistically significant and equal improvement compares post-prostatectomy biofeedback to no-treatment controls (Franke et al., 2000). Both groups achieved in excess of 85% improvement. Notably the authors state that control subjects were provided detailed literature including postoperative instructions and may have performed pelvic floor muscle exercises without being directed to do so.

Biofeedback vs. Unassisted Pelvic Floor Muscle Exercises

A total of 18 studies included both biofeedback and unassisted pelvic floor muscle exercise groups. All biofeedback and unassisted pelvic floor muscle exercise groups showed statistically significant improvement. In nine of the 18 studies, biofeedback demonstrated statistically significant superior outcomes; and in the remaining nine studies, biofeedback and unassisted pelvic floor muscle exercises demonstrated no statistical difference in degree of improvement. In no studies did pelvic floor muscle exercises produce statistically superior improvement to biofeedback.

Biofeedback vs. Oxybutyinin vs. Placebo

Two studies compared biofeedback, oxybutynin, and placebo groups for the treatment of urge incontinence. In both studies, all three groups showed statistically significant improvement. In both studies, biofeedback was statistically superior to both oxybutynin and placebo, and oxybutynin was statistically superior to placebo.

Biofeedback vs. Vaginal Cones

Two studies compare biofeedback to vaginal cones. One study shows statistically significant symptomatic improvement in both treatment groups and no statistical difference between the treatment modalities, and the second study shows statistically greater symptom benefit for biofeedback over vaginal cones.

Biofeedback vs. Electrical Stimulation

Two studies compared biofeedback to both electrical stimulation and unassisted pelvic floor muscle exercises, showing statistically significant symptomatic improvement in all groups. Both the biofeedback and electrical stimulation groups were statistically superior to the unassisted pelvic floor muscle exercise group but showed no statistical difference between each other.

Paired Comparisons of Biofeedback vs. Alternative Treatments by Secondary Variables

Males

Eight studies employed male subjects. Seven of the eight studies employed pelvic floor biofeedback and one or more comparison groups in the treatment of urinary incontinence associated with radical prostatectomy. Of these seven studies, three demonstrated biofeedback to be statistically superior to a no treatment control group, a placebo electrotherapy group, and an unassisted pelvic floor muscle exercise group. One study demonstrated biofeedback administered both before and after surgery to be statistically superior to biofeedback administered only after surgery. Two of the seven studies on prostatectomy patients demonstrated statistically successful outcomes using biofeedback, but equally successful outcomes using unassisted pelvic floor muscle exercises. One study demonstrated statistically significant successful outcomes for both biofeedback and a no treatment control group. The final study employing male subjects demonstrates biofeedback to be effective in the treatment of post void dribble in men with erectile dysfunction while a no-treatment control showed no improvement. In summary, four of the eight male studies demonstrated statistically both efficacy and superiority of biofeedback, and four of the studies demonstrated efficacy.

Females - Incontinence Subtypes

Twenty studies employed females. Twelve of the 20 studies employed subjects with stress urinary incontinence, three studies employed urge incontinence subjects and five studies employed subjects with mixed incontinence. Biofeedback produced statistically significant symptom improvement in all 12 studies of stress incontinence. In eight of the 12 studies, biofeedback produced statistically superior results to comparison treatment groups and statistically non-differential results in the remaining four studies. Two of the three studies on urge incontinent patients showed efficacy and superiority of biofeedback over oxybutynin and placebo and over electrical stimulation and exercises. The other study on urge incontinent patients showed non-differential efficacy over unassisted exercises. Of the five studies on mixed incontinence subjects, biofeedback showed statistical efficacy in all studies and statistical superiority in two of the five studies. Over all female incontinence subtypes, biofeedback demonstrated statistically significant clinical efficacy in all

20 studies and statistically significant superiority in 12 of the 20 studies and statistically non-differential efficacy in eight of the 20 studies.

Manometry vs. Surface Electromyography (sEMG)

Thirteen of the 28 studies employed manometric biofeedback, and 15 studies employed surface electromyographic biofeedback. Of the 13 studies employing manometric biofeedback, six studies demonstrated statistical superiority of biofeedback over the comparison group(s) with no statistical difference demonstrated in the remaining seven studies. Of the 15 studies employing surface electromyographic biofeedback, 10 studies demonstrated statistical superiority of biofeedback over the comparison group(s) with no statistical difference demonstrated in the remaining five studies.

Home Training

Six of the 28 studies employed in-office biofeedback treatments only and prescribed no home training, 19 studies employed in-office biofeedback and prescribed unassisted pelvic floor muscle home training and three studies employed in-office biofeedback and prescribed biofeedback assisted home training. In four of the six studies using no home training, the biofeedback groups were statistically superior in symptom reduction to the comparison treatment group(s); and in the remaining two studies, biofeedback groups were not statistically different from their comparison treatment group(s). In 11 of the 19 studies using unassisted home training, the biofeedback groups were statistically superior in symptom reduction to the comparison treatment group(s); and in the remaining eight studies, biofeedback groups were not statistically different from their comparison treatment group(s). In two of the studies employing biofeedback assisted home training, the biofeedback groups were not statistically different from their comparison treatment group(s) in symptomatic outcomes.

Protocols/Researchers/Biofeedback Equipment

Biofeedback protocols and equipment employed were consistent over studies only within researchers having multiple studies included in this review. Of the 28 studies reviewed, two researchers (Aukee and Burgio) have two and three studies, respectively, included; and the remaining 23 studies are each by different researchers and employ different biofeedback assessment and treatment protocols and equipment.

Summary of Findings

In summary, all biofeedback groups included in this review showed statistically significant symptomatic improvement. Biofeedback was superior to controls and/or alternate treatments in the majority of studies and demonstrated statistical superiority over no treatment, unassisted pelvic muscle exercises, oxybutynin, placebo, intravaginal electrical stimulation, and equal efficacy to vaginal cones. Biofeedback demonstrated statistically superior efficacy in post prostatectomy incontinence as well as in female stress, urge and mixed incontinence. Surface electromyographic biofeedback more frequently showed statistically greater efficacy than manometric biofeedback, and neither unassisted nor biofeedback assisted home training improved the outcomes of office administered biofeedback.

CONCLUSION

It is notable that the Medline review yielded only 28 studies in the span of 30 years which met traditional scientific criteria for research design and data analysis. Equally notable and likely related is the complete absence of standardization of both biofeedback technology and the methodology for its application to pelvic floor muscle assessment and rehabilitation. Both the small number of studies and the lack of standardized technology and protocols are limiting factors in generalizing our findings. It must also be noted that to date, the mechanisms responsible for therapeutic efficacy have not been identified, making more difficult a focused approach to intervention. In spite of these difficulties, this review consistently demonstrates that pelvic floor muscle biofeedback is efficacious in the treatment of urinary incontinence. In the majority of studies, biofeedback is statistically superior to comparison treatments and controls; and in no studies were any other treatments superior to biofeedback. A more conclusive determination of the role of pelvic floor muscle biofeedback in the medically integrated diagnosis and treatment of urinary incontinence requires further scientifically sound investigations and standardization of technology and procedures.

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