

BIOFEEDBACK IN THE TREATMENT OF URINARY INCONTINENCE IN ADULTS

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OBJECTIVE

For patients with the most common types of urinary incontinence, first line therapy consists of behavioral treatments, such as bladder training and pelvic floor muscle exercises (PME). The patient learns to strengthen the pelvic floor musculature and to better control bladder emptying. Biofeedback itself is not a treatment for urinary incontinence, but can be used as an adjunct to pelvic floor muscle exercises. By providing patients with concurrent feedback on muscle tone, biofeedback is intended to improve the patients' ability to perform pelvic muscle exercises. If patients can learn to exercise more effectively with biofeedback, greater improvement in self-control of incontinence may result.

The objective of this technology assessment is to determine whether adding biofeedback as an aid to performing pelvic floor muscle exercise results in a greater improvement in urinary incontinence, as compared to pelvic floor muscle exercises alone. Stress incontinence and urge incontinence are the most common types of urinary incontinence treated with behavioral techniques and are the main focus of this assessment. The use of biofeedback in treatment of post-prostatectomy incontinence is also addressed in this assessment, as this is a common cause of incontinence in the Medicare population. The treatment of urinary incontinence that is due to neurologic injury or disease is not addressed as part of this assessment.

BACKGROUND

Urinary Incontinence

Urinary incontinence is a common problem, estimated to affect 13 million adults in the U.S., and to account for costs exceeding \$15 billion per year (Fantl et al. 1996; Urinary Incontinence Guideline Panel 1992). In 1994 dollars, it was estimated that \$11.2 million was spent on the direct treatment of incontinence, and \$5.2 million on associated nursing home costs. For older adults living in the community, the prevalence of urinary incontinence is between 15% and 35%, with women affected twice as often as men. The condition is even more common among residents of nursing homes, where more than half of the residents experience urinary incontinence. In addition, urinary incontinence has been cited as one of the major precipitants for placement in a nursing home (Ouslander et al. 1982). Thus, among the elderly Medicare population, this condition is associated with a high burden of illness, high costs, and has a substantial effect on quality of life.

The two major categories of urinary incontinence addressed in this Assessment are stress incontinence (SI) and urge incontinence (UI). Stress incontinence is characterized as loss of urine that occurs with activities that increase intra-abdominal pressure, such as coughing, sneezing, or lifting heavy objects. The majority of stress incontinence is acquired, through weakening of the pelvic floor support structures as a result of aging, childbirth or other factors (NIH Consensus Statement 1989). Urge incontinence occurs when patients are unable to hold urine in response to the urge to urinate. This most commonly results from uninhibited bladder

contractions as a result of instability of the detrusor muscle. Often, features of both stress and urge incontinence co-exist, in this case the term “mixed incontinence” (MI) is used.

Within the categories of stress incontinence and urge incontinence, further diagnostic distinctions can be made. The underlying abnormality in stress incontinence can be either hypermotility of the bladder neck, intrinsic deficiency of the urinary sphincter, or both (Fantl et al. 1996; Urinary Incontinence Guideline Panel 1992). For urge incontinence, the etiology is not understood although subcategories are distinguished as detrusor instability when no underlying cause is identified or as detrusor hyperreflexia when an obvious neurologic cause such as a cerebrovascular accident is evident. The response to various treatment options may theoretically differ with the underlying disorder present.

Post-prostatectomy incontinence is also a common condition among elderly Medicare patients, especially as detection and subsequent treatment of prostate cancer increases. Post-prostatectomy incontinence may be predominantly stress or urge incontinence, depending on the indication for surgery and the type of procedure performed, and many patients may be good candidates for pelvic floor muscle exercises (Johnson and Ouslander 1999). Two recent large cohort studies examined the long-term rates of incontinence following radical prostatectomy. Stanford et al. (2000) followed 1291 men for 18 months and reported that 8.4% of patients were incontinent at that time point. Catalona et al. (1999) reported a similar incontinence rate of 8% in 1,870 men followed for 2 years. Some evidence exists that treatment of post-prostatectomy incontinence with PME is efficacious. A recent randomized controlled trial of PME in this group of patients reported a significantly increased rate of continence at 3 months in the PME group as compared to the control group (88% vs. 56%, $p < 0.001$) (Van Kampen et al. 2000).

Numerous other etiologies of incontinence exist. A variety of neurologic disorders or injuries can interrupt innervation of the bladder and lead to incontinence. Reversible causes, such as urinary tract infection or medications, are managed by treating the underlying cause. A variety of neurogenic causes of incontinence exist, resulting from either a central nervous system disorder or injury that interferes with the innervation of the bladder and associated structures. Overflow incontinence occurs when the bladder cannot empty normally and becomes overdistended, such as occurs with bladder outlet obstruction as a result of prostate hypertrophy. Functional incontinence refers to the situation where no physiologic pathology is present, but incontinence occurs as a result of immobility or severe cognitive dysfunction. For these other etiologies, however, biofeedback is not considered an appropriate treatment option.

For stress, urge, and mixed incontinence, a number of treatment options exist, ranging from behavioral measures to surgical procedures. In general, a staged approach to treatment is recommended for most patients, beginning with the most conservative techniques, and progressing to pharmacologic or surgical treatments if initial measures are not successful (Fantl et al. 1996; Urinary Incontinence Guideline Panel 1992). The Agency for Health Care Policy and Research (AHCPR) issued the most recent guidelines for the management of urinary incontinence in 1996 (Fantl et al. 1996; Urinary Incontinence Guideline Panel 1992). These guidelines recommend that a trial of behavioral intervention be applied to all appropriate patients prior to the use of drugs or surgery.

Behavioral Treatments for Urinary Incontinence

Behavioral treatments for urinary incontinence include toileting assistance, bladder training, and pelvic floor muscle exercises (PME). The 1996 AHCPR guidelines on treatment of incontinence supported the use of behavioral therapy as first-line treatment in patients with stress incontinence or urge incontinence. Their recommendations stated that “Pelvic muscle rehabilitation and bladder inhibition using biofeedback therapy are recommended for patients with stress UI, urge UI, or mixed UI.” The strength of evidence behind this recommendation was rated “A,” meaning that the recommendation was supported by scientific evidence from properly designed and implemented controlled trials providing statistical results that consistently support the guideline statement. However, the guidelines did not specifically address the issue of whether the addition of biofeedback to PMEs is more effective than PME alone.

The most simple of behavioral interventions, toileting assistance, is intended for patients who are disabled or cognitively impaired, and who require the assistance of a caregiver for their activities of daily living. For other categories of patients, behavioral treatments may consist of bladder training, pelvic muscle exercises (PME), or a combination of the two. Biofeedback has been used as an adjunct to PME with the goal of improving patients’ ability to learn these exercises.

Behavioral techniques are generally tailored to the specific etiology of incontinence. For stress incontinence, PMEs are the main component of treatment. PMEs derive from the Kegel exercises developed in the 1940s and 1950s. The first step in this approach is to re-educate the patient to become aware of contraction of the pelvic floor muscle. Once the patient can adequately sense the state of muscle contractions in this area, a graded exercise program is used. Patients are taught to contract these muscles for a defined time period, for example, 10 seconds, followed by a period of relaxation. This is repeated at a prescribed frequency, which increases over time. The AHCPR guidelines recommend that contractions be performed 30–80 times per day for a period of 8 weeks or longer (Fantl et al. 1996; Urinary Incontinence Guideline Panel 1992).

For patients with urge incontinence, bladder training is employed, with or without PME. The primary goal of bladder training is to teach the patient to inhibit contractions of the detrusor muscle, thereby reducing the sense of urgency associated with uninhibited bladder contractions. Education in the form of written, verbal or visual instruction is provided. Patients are placed on a systematic voiding schedule which allows the bladder to adjust to increasing levels of distension. The program may also use distraction or relaxation techniques to achieve these goals. Control of fluid intake is sometimes used to aid in adhering to a voiding schedule.

Treatment with PME or bladder training requires that patients be cognitively intact and motivated to learn and practice the techniques. This was demonstrated empirically by Castleden et al. (1985). These authors studied the factors which were predictive of success with these treatments in an elderly population, and reported that mental ability was the factor most strongly related to a positive outcome.

The delivery of behavioral treatments is not standardized. The method and intensity of instruction for bladder training and PME may vary. The method of delivery may range from

brief verbal instruction by a physician in the office setting, to written materials, to individual session(s) with a clinical specialist trained in delivering this treatment. The intensity of the treatment will vary both as a function of the number of training sessions employed, and with the frequency with which the patient practices the techniques at home. A trial comparing home exercise alone to home exercise with weekly training sessions found that the more intensive PME training regimen was more effective (Bo et al. 1990).

Although behavioral techniques are widely accepted as the most appropriate first-line therapy for stress and urge incontinence, there are few controlled trials of these techniques in the literature. However, several controlled trials of PME exist; and collectively these trials establish the effectiveness of PME. In a randomized, controlled, trial, Wells et al. (1991) treated 82 patients with PME and 75 patients with phenylpropanolamine, a standard first-line medication for stress incontinence. This study reported found outcomes of PME to be similar to drug treatment, with 77% of the exercise group and 84% of the drug group reporting improvement. Burns et al. (1993) compared both PME alone and PME plus biofeedback to a waiting list control group. Both treatment groups had a significantly greater improvement (54% and 61% respectively) than the waiting list control (6%, $p < 0.001$). This limited evidence suggests that PME is more effective than no treatment and roughly equivalent to medications for these patient groups.

Other controlled trials have compared biofeedback-assisted PME with a control group. Burgio et al. (1998) studied 197 cognitively intact, community-dwelling women with urge or mixed incontinence. Patients were randomized to biofeedback-assisted PME, drug treatment with oxybutynin, or placebo. PME plus biofeedback was more effective than drug treatment (80.7% improvement vs. 68.5% improvement, $p < 0.04$), and both active treatments were superior to placebo (39.4% improvement, $p < 0.01$). In a similar study in patients who were cognitively intact but homebound, McDowell et al. (1999) randomized 105 adults, aged 60 years and older, to biofeedback assisted PME or a waiting list control. The percent improvement in the PME plus biofeedback was 75% as compared to 6.5% in the control group. These trials demonstrate that biofeedback-assisted PME is more effective than no treatment but do not address the independent impact of biofeedback on outcomes.

Biofeedback

Biofeedback is a technique developed over the last 3 decades, which is intended to teach subjects to bring certain physiologic processes under voluntary control. Application of this technique to medical conditions was popularized during the 1970s, along with a variety of other behavioral therapies (Subcommittee on Nonpharmacologic Therapy Report 1986). These therapies were primarily directed toward disorders that were thought to include a component of stress, psychosomatic, or psychophysiologic features.

The rationale for biofeedback arose from observations that trained yogis, and other practitioners of eastern philosophies, were able to alter physiologic processes which are not typically under conscious control, such as heart rate and hand temperature. While initially used primarily to induce a state of deep relaxation, the approach has been broadened to the modification of a wide range of physiologic processes.

Biofeedback in conjunction with PME targets skeletal muscles that are under voluntary control, unlike the physiologic measures of heart rate or blood pressure. However, many patients have difficulty identifying, controlling, and coordinating the function of pelvic floor muscle group. When verbally instructed in pelvic floor exercises, patients may perform them ineffectively (Burgio and Engel 1990). With biofeedback, these exercises are performed with simultaneous electromyographic feedback given to the patient to help facilitate awareness of the state of muscle contraction.

For the purpose of this assessment, the following definition of biofeedback will be used: therapy that uses an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone, in order to improve awareness of pelvic floor musculature and to assist patients in the performance of pelvic floor muscle exercises.

FDA Status. Biofeedback is a technique that uses cognitive and behavioral methods to teach patients self-regulation of a physiologic process, and is not specifically subject to FDA approval. The various monitoring devices for biofeedback, such as manometric or electromyographic monitors, may or may not be subject to FDA approval.

Prior Evidence-based Reviews

Literature review identified three published, evidence-based reviews of the effectiveness of biofeedback as an addition to PME for stress incontinence (de Kruif and van Wegen 1996; Berghmans et al. 1998; Weatherall 1999). There were no evidence-based reviews identified that addressed the diagnoses of urge or post-prostatectomy incontinence. Two of these reports were systematic reviews with qualitative data synthesis (de Kruif and van Wegen 1996; Berghmans et al. 1998), while the third (Weatherall 1999) was a quantitative meta-analysis based on the systematic review by Berghmans et al. (1998).

Berghmans et al. (1998) used a comprehensive search strategy with multiple databases to identify all the published literature on this topic between 1980 and 1998 published in English, German, or Dutch. Their criteria for inclusion were: 1) randomized, controlled trial, 2) reported results exclusively or separately on women with stress incontinence, 3) the intervention or reference group consisted of PME with or without other interventions, 4) the outcome measures were clinically relevant and reliable for the problem. Their analysis included a formal assessment of methodologic quality, with division of studies into the categories of “sufficient quality” or of “low quality.”

The authors identified five trials that compared PME alone with PME plus biofeedback, three of which are included in this current assessment (Burns et al. 1993; Berghmans et al. 1996; Glavind et al. 1996). The final two trials included in the Berghmans review did not meet the selection criteria for this assessment—Castleden et al. (1984) had no concurrent control group and reported no relevant outcomes and Taylor and Henderson (1986) reported no relevant outcomes. Two additional studies that met the inclusion criteria for this review were not included in the Berghmans systematic review (Shepherd et al. 1983; Ceresoli et al. 1993).

Two of the 6 trials met the authors' criteria for "sufficient quality" (Burns et al. 1993; Berghmans et al. 1996) and both of these reported no additional benefit in the biofeedback group. Of the three trials deemed to be of "low quality" (Castleden et al. 1984; Taylor and Henderson 1986; Glavind et al. 1996), one demonstrated a statistically significant difference in favor of the biofeedback group, while two did not show a statistically significant difference. The authors thus concluded that there is strong evidence to support that the addition of biofeedback to PME does not offer additional benefits over PME alone.

In a brief report, Weatherall (1999) performed a quantitative meta-analysis of the data included in the systematic review by Berghmans et al. (1998), using the outcome of number of patients cured of incontinence. In two of the five randomized controlled trials (Castleden et al. 1984; Taylor and Henderson 1986), data was not sufficiently reported on this outcome to allow quantitative data synthesis, leaving three trials for meta-analysis (Burns et al. 1993; Berghmans et al. 1996; Glavind et al. 1996). Among these three trials, the definition of cure used was not consistent. Results were combined by pooled analysis of the odds ratios for cure in each of the individual studies. Odds ratios and 95% confidence intervals for cure in each of these three studies were: Burns -- 1.5 (0.5–4.3); Berghmans -- 1.8 (0.4–8.0); Glavind -- 4.8 (1.1–21.1). Combined analysis of these results revealed a pooled odds ratio of 2.1 (0.99–4.4) in favor of biofeedback, a result that reached marginal statistical significance. Weatherall concluded that his results differed from the systematic review mainly due to low power to detect differences in the individual trials, a limitation partially ameliorated by quantitative meta-analysis.

A second systematic review was performed by de Kruif and van Wegen (1996). These authors searched MEDLINE and *Excerpta Medica* and identified six trials that compared PME alone to PME plus biofeedback (Shepherd et al. 1983; Castleden et al. 1984; Taylor and Henderson 1986; Burgio et al. 1986; Burton et al. 1988; Burns et al. 1993). Four of these 6 trials were included in the current Assessment (Shepherd et al. 1983; Burgio et al. 1986; Burton et al. 1988; Burns et al. 1993), while the additional two trials (Castleden et al. 1984; Taylor and Henderson 1986) were excluded for the reasons enumerated previously. Two trials included in the current Assessment (Glavind et al. 1996, Berghmans et al. 1996) were not included in the de Kruif and van Wegen study, most likely because they had not yet been published. These studies were systematically analyzed on the following factors: 1) type of control; 2) subjects; 3) interventions; 4) outcomes; and 5) validity.

Of these 6 trials, only 2 reported statistically significant differences between groups on any outcome measure (Burgio et al. 1986; Burns et al. 1993), and in one of these two studies (Burns et al. 1993), the only outcome showing a difference was the intermediate outcome of perineal muscle strength. Three of the studies which reported better outcomes for the biofeedback group were not considered statistically valid by the authors. The authors conclude from this review that there is limited evidence of high statistical and internal validity, and that the evidence regarding the effect of biofeedback is not conclusive. However, they point out that there is a trend toward greater improvement in most of the studies for the biofeedback group and that this treatment may be an effective adjunct to PME.

Methodologic Considerations

The available literature evidence consists of numerous clinical series of treatment with biofeedback-assisted PME, and a small number of controlled trials. Evidence reported from such single-armed clinical studies tends to overestimate treatment effect (Sacks et al. 1983; Colditz et al. 1989). The pretest-posttest design (the “before-after” study), often employed in clinical series, is the comparison of observations at baseline to observations that occur after an intervention. A major limitation in this type of study design is that rival sources of explanation for changes in outcomes are numerous and uncontrolled. For example, before-after studies do not account for placebo effects, the natural history of the disorder being studied, or other modifying factors that may have an effect on outcomes. For incontinence, there are numerous factors that may impact on the outcomes that are measured, such as education, medication use, activity level, and expectations for treatment. In a trial without concurrent controls, it is impossible to ascertain how much of the improvement seen is due to these types of factors, as opposed to the effect of the intervention.

Campbell and Stanley published a classic handbook on research methodology that still provides a solid framework for evaluating the validity and generalizability of scientific evidence (Campbell and Stanley 1966). The Campbell and Stanley framework classifies clinical series research design as pre-experimental. All the pre-experimental designs are weak forms of scientific research design because they are subject to extraneous factors that provide alternative explanations of the results. When alternative explanations are present, an experiment is ambiguous because the extraneous factors interfere with the conclusion or inferences to be drawn. While clinical series often provide descriptive information and the historical interest in framing a research question, the lack of internal validity excludes studies using a clinical series design as scientific evidence (Guyatt et al. 1994; Sackett 1979; Feinstein 1985; Campbell and Stanley 1966). Clinical series may also provide some information on the durability of a treatment effect, given that efficacy has been established in well-designed, controlled trials of shorter duration. Expert panels in reviewing scientific evidence have ranked the quality of this type of evidence in the lowest category of rigor (Fantl et al. 1996).

In addition there are several concerns specific to the evaluation of efficacy in incontinence. The measurement of the frequency of incontinence is limited both by inherent variability in the condition itself, and by potential inaccuracies in the available measurement instruments. For patients with stress incontinence, the specific activities performed during a given time period will impact on the frequency of incontinence. Day to day variability in activities may be associated with variability in the frequency of incontinence. Other variables, such as fluid or caffeine intake, may also contribute to underlying variability in the condition.

Also, the measurement instruments available to quantitate outcomes of incontinence are not ideal (Fantl et al. 1996). Patient recorded diaries have a fair amount of subjectivity. Adequacy of documentation may introduce an additional level of variability to the data. The pad test, while perhaps more objective than patient reported diaries, may be less useful clinically since the maneuvers performed during this test may or may not correspond to the usual types of activities performed by patients. The precision and reproducibility of the pad test is not well reported in the literature.

As with most medical interventions, there is expected to be some degree of placebo response in clinical trials of treatment for incontinence. For example, in a recent well-designed trial comparing PME to drugs (Burgio et al. 1998), a placebo drug group was included. This placebo group had a 39.4% improvement in the frequency of incontinence by patient-reported diary. The majority of studies of pelvic floor electrical stimulation for urinary incontinence versus sham pelvic floor electrical stimulation report a substantial placebo effect, ranging up to 28% improvement in the frequency of incontinence.

Because of the above methodologic considerations, clinical trials with concurrent controls are needed to demonstrate the efficacy of biofeedback as an adjunct to PME. Randomized controlled trials with adequate numbers of patients are the ideal types of studies that minimize bias and confounding. Controlled trials that are nonrandomized, while prone to selection bias, may also provide sufficient evidence of efficacy if the comparability of the treatment arms can be adequately assessed. Trials without concurrent controls, however, have too great a potential for bias to allow conclusions on the relevant assessment questions. This assessment thus will thus be restricted to controlled trials, either randomized or nonrandomized, involving biofeedback as a adjunct to treatment with PME.

METHODS

Search Methods

The MEDLINE database was searched for the periods of 1976 through January 2000 using the keyword “urinary incontinence/therapy.” This was cross-referenced with the textwords “biofeedback,” “pelvic muscle exercise,” and “bladder training.” The search was limited to English-language articles reporting on human subjects. All articles reporting clinical outcomes of patients with urinary incontinence treated by one of the 3 methods (biofeedback, PME, bladder training) were retrieved. Bibliographies of recent review articles and clinical trials were reviewed and *Current Contents* was also searched to supplement the computerized search.

Study Selection

Selection criteria for inclusion in the Assessment included the following:

- 1) full-length, peer-reviewed articles reporting on outcomes of treatment for urinary incontinence using biofeedback in conjunction with behavioral techniques;
- 2) included patients with documented stress, urge, or mixed incontinence (by physician diagnosis and/or urodynamic testing) or post-prostatectomy incontinence, and the methods used for diagnosis are adequately described;
- 3) included a concurrent comparison group of patients treated with pelvic floor muscle exercises without biofeedback;
- 4) included objective measures of health outcome (percent change in incontinent episodes by patient diary, percent decrease in volume of urine loss on pad test, percent of patients dry, percent of patients with at least 50% reduction in incontinence);
- 5) adequately described of the patient population, including diagnostic categories of incontinence;

- 6) adequately described course and delivery of treatment, including length of treatment, number of sessions, etc.

A total of 8 controlled trials were identified that met the inclusion criteria for this review. Six of these trials reported on patients with stress incontinence, or included a mixed population with the majority having stress incontinence (Shepherd et al. 1983; Burgio et al. 1986; Ceresoli et al. 1993; Burns et al. 1993; Glavind et al. 1996; Berghmans et al. 1996). One controlled trial compared PME alone to biofeedback plus PME in a population primarily consisting of urge incontinence (Burton et al. 1988). The final controlled trial meeting the inclusion criteria enrolled patients with post-prostatectomy incontinence (Franke et al. 2000). One additional controlled trial which met the selection criteria (Burns et al. 1990) appeared to be an earlier version of a later article (Burns et al. 1993) reporting on the same population, and was excluded from analysis.

FORMULATION OF THE ASSESSMENT

Patient Indications

Adults with self-reported involuntary loss of urine, with an objective diagnosis of stress urinary incontinence, urge incontinence, or mixed incontinence that is not of neurogenic origin. A second patient group is males with post-prostatectomy incontinence. Patients must be cognitively intact, and sufficiently motivated to expect that they will learn and practice the exercise regimen(s). Patients with neurologic causes of incontinence are not included in this patient population.

Technologies to Be Compared

Biofeedback, in addition to pelvic floor muscle exercises, will be compared to pelvic floor muscle exercise alone. Pelvic floor muscle exercise is delivered as behavioral treatment for stress and urge incontinence. Delivery of a behavioral treatment includes the following components:

- 1) educational session(s), performed either individually or in a group setting, in which patient is instructed in the techniques of PME, bladder training, or a combination of the two;
- 2) prescribed regimen for performing the exercises at home; and
- 3) follow-up session(s) to review adequacy of performance, reinforce aspects of regimen as needed.

The individual components of behavioral treatment may vary among studies. The type of exercise instruction may vary according to diagnosis (e.g., bladder training for urge incontinence but not stress incontinence), across treating centers, and even may be further individualized to patient characteristics within a single treating center. The length, number, and duration of training sessions may also vary. Since the available literature does not allow precise analysis of outcomes according to variations in patient diagnostic mix and type of training, this assessment will not attempt to address these components individually. However, within each study the treatment arms differ only with respect to whether biofeedback was added to the PME regimen.

Biofeedback training will include the above components, with the addition of a biofeedback component to the training session(s). For the purpose of this assessment, “biofeedback” techniques will refer to the use of specially designed instrumentation that provides visual or auditory information to the patient concurrently with practice of the exercises. This will primarily consist of electromyographic or manometric readings of pelvic muscle(s) tone which are directly monitored by the patient as they are performing the exercises.

The use of pelvic floor muscle electrical stimulation is sometimes referred to as a biofeedback technique. However, this is a distinct technology, with a different mechanism of action in that it is a treatment intervention that stimulates contractions of the pelvic floor muscles. This technology is a method for passive stimulation of pelvic floor muscle exercises. Studies of pelvic floor muscle stimulation are not included in this assessment. The use of electrical stimulation in the treatment of urinary incontinence will be evaluated in a separate technology assessment.

Health Outcomes

Beneficial Outcomes. The desired health outcomes are elimination of incontinent episodes or clinically significant reduction in the frequency and severity of incontinent episodes. The main outcome measure used in studies of incontinence is the percentage change in the number of incontinent episodes, usually measured as leaks per day or leaks per week. Study patients keep voiding diaries that include recording the episodes of voiding and urinary incontinence, number of pads used per day, nocturnal voids and urgency episodes without incontinence. The percent change in the frequency of incontinent episodes is calculated using the following equation:

$$\frac{\text{pretreatment episodes/period} - \text{posttreatment episodes/period}}{\text{pretreatment episodes/period}} \times 100$$

This outcome measure, *percent change* in the frequency of incontinence, is the most consistently reported outcome in the reviewed studies and will be used as the main outcome measure for comparing results across studies. Derived from the percentage change in the number of incontinent episodes are percent cure and/or percent of patients who improve. Patients who become dry (i.e., no longer experience incontinence following treatment) are considered cured of incontinence. The proportion of patients with 100% reduction in incontinence is the *percent cure* reported in a study. A reduction of leakage episodes by 50% has been defined by the International Continence Society as a clinically significant improvement (Blaivas et al. 1997). The proportion of patients with 50% or greater reduction in incontinent episodes is the *percent of patients with improvement* reported in a study.

A standardized pad test may also be used for patients with stress incontinence. This test measures urine loss during standardized maneuvers that are expected to induce urinary incontinence in patients with stress incontinence. Percent improvement on the pad test can be calculated in a manner similar to frequency of incontinence, as follows:

$$\frac{\text{pretreatment pad weight difference} - \text{posttreatment pad weight difference}}{\text{pretreatment pad weight difference}} \times 100$$

pretreatment pad weight difference

In addition to these outcomes measures, clinical examinations often include measuring perineal muscle strength and/or urodynamic testing. These physiologic measures are intermediate outcomes that may or may not be directly related to health outcomes of interest to this assessment, and are not analyzed in this review of evidence.

Subjective assessments include such measures as improvement on visual-analogue scales, subjective judgements of improvement without quantitation, and/or validated disease-specific symptom scales such as the Incontinence Impact Questionnaire (Shumaker et al. 1994). Subjective outcomes that are not quantitated are not considered valid outcome measures for this review. Validated, disease-specific symptom scales have not been commonly used in studies to date.

Specific Assessment Question

For urinary incontinence patients, does adding biofeedback to PME result in greater improvement in health outcomes than the use of PME alone?

REVIEW OF EVIDENCE

Stress Incontinence

Six controlled trials were reviewed for this diagnosis. The methodologic features of these trials are summarized in Table 1 and the outcomes are described in Table 2. All of these studies were relatively small, with the largest including approximately 40 patients in each arm (Burns et al. 1993). Four of the six trials described randomized group allocation (Burns et al. 1993; Glavind et al. 1996; Berghmans et al. 1996), while the other two trials were nonrandomized (Burgio et al. 1986; Ceresoli et al. 1993) or did not report the group allocation process (Shepherd et al. 1983). Two of the trials were very brief reports (Shepherd et al. 1983; Ceresoli et al. 1993), in which the population and methods were not described in detail. In four of the trials, one or more potential sources of bias was identified (Shepherd et al. 1983; Burgio et al. 1986; Ceresoli et al. 1993; Glavind et al. 1996), while in two trials no obvious potential sources of bias were identified (Burns et al. 1993; Berghmans et al. 1996).

Table 1. Controlled trials comparing PME plus biofeedback with PME alone for SI – methodologic features

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Shepherd 1983	22 women randomly assigned to one of two treatment groups. Mean age 48.3, range 23-67	Blinding NR Randomization process not described.	BF plus PME - Biofeedback with perineometer and PME. Mean number of sessions 5.7 PME alone - PME alone. Mean number of sessions 3.5.	BF – 0/11 PME – 3/11 (27%)	Pt recorded diaries	Potential for performance bias. Potential for attrition bias. Patient population and methods not well-described. Tests of statistical significance not performed.
Burgio 1986	24 women with complaints of involuntary urinary loss and urodynamically proven stress incontinence. Mean age 47.9 , range 29-64	Blinding NR Nonrandomized. Pts assigned to groups to balance on age and baseline frequency of incontinence.	BF plus PME - PME with EMG biofeedback PME alone - PME with verbal feedback by therapist. Treatment consisted of 8 one hour sessions for each group.	BF – 0/13 PME – 0/11	Pt recorded diaries completed four weeks prior to treatment and four weeks following treatment.	Potential for selection bias
Ceresoli 1993	60 women with incontinence, treated in referral center in nonrandomized fashion. 17 pts with SI 14 pts with DI 28 pts with MI Mean age NR	Blinding NR Nonrandomized.	BF plus PME - PME with EMG biofeedback for 6 week trial PME alone - PME alone for 3 month trial	NR	Pad test	Potential for performance bias. Potential for selection bias.
Burns 1993	135 elderly female volunteers with SI, 12 with MI Mean age 63	Single blind trial Randomized in blocks of 12 to one of three treatment groups.	<u>BF plus PME</u> – EMG BF with vaginal probe. Eight weekly sessions with trained therapist. <u>PME alone</u> – Eight weekly sessions with trained therapist. <u>Control</u> – Waiting list (no treatment) control group	12/135 (9%) NR by group	Pt recorded diaries completed throughout study and two weeks after treatment completed.	

Table 1. Controlled trials comparing PME plus biofeedback with PME alone for SI – methodologic features (cont'd)

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Glavind 1996	40 women with urodynamically proven SI Median age 45, range 40-48	Blinding not reported. Randomization by sealed envelopes.	<u>BF plus PME</u> – 2-3 individual sessions of PME instruction with therapist plus four sessions of BF. <u>PME alone</u> – 2-3 individual sessions of PME instruction with therapist. Length of trial 4 weeks with 3 month follow-up	BF – 1/20 PME – 5/20 (25%)	Standardized pad test at one month and three months.	Potential for performance bias. Potential for attrition bias.
Berghmans 1996	40 women referred by either a general practitioner or urologist with urodynamically proven SI. Mean age 48.4 years.	Single blind trial Randomized by sealed envelope, stratified for severity of illness.	<u>BF plus PME</u> – EMG BF via vaginal probe with visual and auditory feedback, sessions three times/wk for four weeks.. PME alone – Individual sessions with therapist three times/wk for four weeks.	BF – 0/20 PME – 0/20	Standardized 48 hour pad test. Pt recorded diaries. Symptoms Questionnaire	

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Table 2. Controlled trials comparing PME plus biofeedback with PME alone for SI – outcomes

Study/yr	Patients/Groups	Pt recorded diaries						Pad test					Comments
		Measure	Pre-	Post-	% change ¹	% Pts improv ²	Dry ³	Pre-	Post-	% Change ⁴	% Pts improv ⁵	% Dry ⁶	
Shepherd 1983	PME plus BF (n=11)	Leaks/wk	6.5	1.1	83%	NR	NR	--	--	--	--	--	
	PME alone (n=8)	Leaks/wk	5.5	4.1	25%	NR	NR	--	--	--	--	--	
		Tests of significance not performed											
Burgio 1986	PME plus BF (n=13)	Leaks/wk	6.9	1.8	75.9%*	92%	--	--	--	--	--	--	
	PME alone (n=11)	Leaks/wk	5.8	2.5	51.0%	55%	--	--	--	--	--	--	
		* Significantly greater improvement in PME plus BF group, p<0.05 No statistical test reported for percent of pts with improvement											
Ceresoli 1993	PME plus BF (n=38)			--	--	--	--	52	20	62%	NR	NR	
	PME alone (n=22)			--	--	--	--	25	10	60%	NR	NR	
								No significant differences between groups					
Burns 1993	PME plus BF (n=40)	Leaks/wk	13	5	61%	68%	23%	--	--	--	--	--	
	PME alone (n=43)	Leaks/wk	18	8	54%	60%	16%	--	--	--	--	--	
	Control (n=39)	Leaks/wk	18	17	6%	15%	8%						
		Both treatment groups significantly superior to control (p<0.001) No significant difference between PME plus BF and PME groups.											

Table 2. Controlled trials comparing PME plus biofeedback with PME alone for SI – outcomes (cont'd)

Study/yr	Patients/Groups	Pt recorded diaries						Pad test					Comments
		Measure	Pre-	Post-	% change ¹	% Pts improv ²	Dry ³	Pre-	Post-	% Change ⁴	% Pts improv ⁵	% Dry ⁶	
Glavind 1996	PME plus BF (n=19)			--	--	--	--	1 mon th 9	2.5	72%	NR	58%	
	PME alone (n=15)			--	--	--	--	12.8	19.0	-48%	NR	20%	
								3 mon th 9	0.8	91%	NR	NR	
								12.8	10.0	22%	NR	NR	
								Significant difference over time in favor of BF plus PME group (p<0.02)					
Berghmans 1996	PME plus BF (n=20)	Leaks/day	3.0	1.4	53%	NR	NR	26.6	12.2	54%	NR	NR	
	PME alone (n=20)	Leaks/day	2.0	0.8	60%	NR	NR	29.0	12.5	57%	NR	NR	
		No significant differences between groups											

1 % change – Defined as the percent decrease in the frequency of incontinence over a specified time period, calculated by the following equation:

$\frac{\text{pretreatment episodes/period} - \text{posttreatment episodes/period}}{\text{pretreatment episodes/period}} \times 100$

2 % pts improv – Defined as the percentage of patients with 50% or greater decrease in the frequency of incontinence, as calculated

by the previous equation. 3 % cure – Defined as the percentage of patients with 100% decrease in frequency of incontinence, i.e., no incontinent episodes over the specified time period.

4 % change – Defined as the percent decrease in the amount of urine lost in grams, following provocative maneuvers, calculated by the following equation:

$\frac{\text{pretreatment pad weight difference} - \text{posttreatment pad weight difference}}{\text{pretreatment pad weight difference}} \times 100$

5 % pts improv – Defined as the percentage of patients with 50% or greater decrease in the amount of urine lost in grams

following provocative maneuvers. 6 % cure – Defined as the percentage of patients with 100% decrease urine loss, ie no urine lost following the provocative maneuvers.

Key to Tables

BF:	biofeedback
DI	detrusor instability
ICS	International Continence Society
MI	mixed incontinence (stress and urge incontinence)
%change	percent change in incontinence (frequency by pt recorded diary or urine loss on pad test)
%cure	percent of patients with no further incontinence
% pts improv	percent of patients with >50% decrease in incontinence (frequency by pt recorded diary or urine loss on pad test)
PFES	pelvic floor electrical stimulation
PME	pelvic floor muscle exercise
SI	stress incontinence
UI	urge incontinence
Selection bias	Imbalances in patient characteristics between groups with potential for differences to affect outcomes
Performance bias	Inequality in the intensity of treatment given between groups
Attrition bias	Significant number of dropouts in one or more study arms, not taken into account in the statistical analysis

Of the 6 controlled trials, 3 reported no significant differences between groups on the outcomes of interest (Ceresoli et al. 1993; Burns et al. 1993, Berghmans et al. 1996). Two trials reported a significantly greater improvement in the biofeedback plus PME group as compared to the PME alone group (Burgio et al. 1986; Glavind et al. 1986). In the sixth trial (Shepherd et al. 1983), no statistical tests of significance were reported. Of the three trials with randomized group assignment, two showed no significant improvement with biofeedback (Burns et al. 1993; Ceresoli et al. 1993) while one reported significantly greater improvement in the biofeedback group (Glavind et al. 1996). Of the two trials that were judged least prone to bias (Burns et al. 1993; Berghmans et al. 1996), neither showed a significant benefit of biofeedback. Of the four trials with potential biases identified, two showed a benefit of biofeedback (Burgio et al. 1986; Glavind et al. 1996), one found no significant difference (Ceresoli et al. 1993), and one did not report on statistical significance (Shepherd et al. 1983).

The largest study comparing PME alone to PME plus biofeedback (Burns et al. 1993), recruited 135 women through newspaper advertisements and a poster campaign. Most of the women in the study had a diagnosis of stress incontinence (n=123); however, a few had mixed incontinence (n=12). Subjects were randomized to 1 of 3 arms: PME with biofeedback, PME alone, and waiting list control (no treatment). Both treatment arms were given similar intensity of training; weekly sessions of 25–35 minutes for 8 weeks. The major outcome measure was patient self-reported urine loss via a symptom diary. This outcome was assessed each week during treatment, 2 weeks, 3 months, and 6 months following the completion of treatment. Both treatment groups improved significantly over time as compared with waiting list control subjects, but there was no significant difference in percent improvement between the biofeedback plus PME and the PME alone groups (61% vs. 54%, p=NS).

The Burns et al. (1993) study is also of note because the age range of the subjects permits inferences to the Medicare population. Participants were female volunteers age 55 and older recruited through newspaper advertisements. Burns and co-workers describe their subjects as "cognitively intact, middle-class, community-dwelling women" (Burns et al. 1993). The mean age of participants was 63 years (range: 57–69 years) and 34% of participants were age 65 and older. The results show that older women with stress incontinence improve with PME alone or PME plus biofeedback compared to no treatment; but do not demonstrate additional benefit from biofeedback over PME alone in this population.

The next largest study, Ceresoli et al. (1993) was a nonrandomized comparison between 22 women who were treated with PME alone and 38 women treated with PME and biofeedback. There were some data to suggest that the two groups might not be comparable. In the biofeedback group, 47% of subjects had no cystocele, as compared to 14% of the PME group, while only 32% of the biofeedback group had a grade II cystocele, as compared to 47% of the PME group. This implied that the PME group may have had more severe anatomical abnormalities related to their incontinence. In contrast, baseline pad use was markedly higher in the biofeedback group as compared to the PME group: 52 pads/day versus 25 pads/day, suggesting that the biofeedback group had more severe urine loss overall. Eighty-nine percent of women in the biofeedback had at least 60% improvement in urinary loss, as compared to 82% of the PME patients. Number of pads used decreased 62% in the biofeedback group and 60% in the PME group. Neither of these differences was statistically significant. There was a statistically

significant difference in favor of biofeedback on the intermediate outcome of perineal muscle strength.

Glavind et al. (1996) randomized 40 patients to PME alone or PME plus biofeedback for 4 weeks of treatment. All patients received 2–3 sessions of instruction in PME, the biofeedback group received an additional 4 sessions of biofeedback. Dropouts were higher in the PME alone group compared with the biofeedback group (25% vs. 5%). Outcomes were assessed via a standardized pad test at the end of the 4-week trial and at 3 months follow-up. The percent improvement on the pad test was significantly greater for the biofeedback group at the completion of treatment (72% vs. –48%) and at the three month follow-up (91% vs. 22%). Statistical testing by repeated measures ANOVA showed a greater improvement in the biofeedback group over time ($p < 0.02$). The results of this trial are subject to performance bias related to the greater intensity of treatment in the PME plus biofeedback arm; and to attrition bias related to the higher drop out rate (25% vs. 5%) in the PME alone arm.

Berghmans et al. (1996) recruited 44 patients with stress incontinence from urologists and general practitioners in the Netherlands. After a one-week diagnostic phase, 40 patients were randomized to PME alone or PME plus biofeedback. All patients received 3 sessions of instruction per week for a 4-week period. Outcome measures reported included both frequency of incontinence by a patient-reported diary and a standardized pad test. There were no statistically significant differences between the PME and the PME plus biofeedback groups on the frequency of incontinence (60% vs. 53% respectively) and on the standardized pad test (57% vs. 54%).

The remaining 2 studies were of smaller size (Shepherd et al. 1983 -- $n=22$; Burgio et al. 1986 -- $n=24$). The nonrandomized trial by Burgio et al. (1986) assigned 24 patients to PME alone or PME plus biofeedback after stratifying by age and frequency of incontinence. The authors reported a significantly greater percent improvement in incontinent episodes for patients treated with PME plus biofeedback (76% improvement versus 51%, $p < 0.05$). Shepherd et al. (1983) randomized 22 women with documented stress incontinence to PME alone or PME plus biofeedback. In this small study, there was a greater percent improvement in incontinent episodes for the PME plus biofeedback group (83% improvement versus 25%) but no statistical test was performed, nor was sufficient detail given to allow calculation of statistical significance. The results are subject to attrition bias as 27% of patients dropped out of the PME alone group, compared to none in the PME plus biofeedback group.

In summary, it is not possible to draw conclusions from this body of evidence on whether the addition of biofeedback to PME results in improved outcomes as compared to PME alone. It is possible that there is no additional benefit to the addition of biofeedback to PME, and that the statistically significant results reported in the trials by Burgio et al. (1986) and Glavind et al. (1996) arise from bias. The small trial by Glavind et al., although randomized, is subject to both performance and attrition bias; treatment intensity was greater in the PME plus biofeedback group while drop-outs were greater in the PME-alone group. The trial by Burgio et al. (1986), while stratified to balance the arms on age and frequency of incontinence, was not randomized. It is also possible that there is some additional benefit to biofeedback, and that the studies that found no significant difference in outcomes (Ceresoli et al. 1993, Burns et al. 1993, Berghmans

et al. 1996) lacked sufficient power to detect group differences due to inadequate sample size. Another possibility is that biofeedback is effective for a subset of patients who have difficulty performing PME, but that this benefit is not apparent when the entire group of treated patients is analyzed. Although the available evidence cannot distinguish among these possibilities, this body of evidence certainly fails to demonstrate that the addition of biofeedback to PME is superior to PME alone.

Urge Incontinence

A single trial was identified that met the study selection criteria for this Assessment and reported primarily on patients with urge incontinence (Burton et al. 1988, Tables 3 and 4). This was a small trial that enrolled 32 elderly (age range 64–83 years) volunteers, 74% of whom had a diagnosis of urge incontinence. All patients were ambulatory and without significant cognitive impairment. Patients were assigned to PME alone or PME plus biofeedback in a nonrandomized fashion to balance the groups on age, baseline frequency of incontinence, and type of incontinence. Each patient received up to 6 training sessions over a one-month period. There was a statistically significant improvement in the frequency of incontinence in both the PME alone and the PME plus biofeedback groups (82% and 79% respectively), with no significant difference between groups. Thus, this trial suggests that there is no additional benefit to the addition of biofeedback to PME for patients with urge incontinence. This trial also suggests benefit of behavioral treatment of urinary incontinence in a Medicare-aged population, but does not demonstrate superior results with the addition of biofeedback.

Post-prostatectomy Incontinence

A single trial of patients with post-prostatectomy incontinence was identified that met the selection criteria for this Assessment (Franke et al. 2000, Tables 5 and 6). Thirty patients with a mean age of 61.5 years who had incontinence following radical prostatectomy were randomized to usual care or biofeedback plus PME. Usual care consisted of educational materials and follow-up that may or may not have included biofeedback. The PME plus biofeedback group received usual care plus five 45-minute sessions in biofeedback over a 10-week period. While it was not possible to determine the extent to which the control group actually was treated with PME, the study selection criteria for this review were interpreted liberally due to the lack of other controlled trials in this patient population. Results were reported on frequency of incontinence and standardized pad test. Both groups improved significantly over time, but there was no difference between groups in the magnitude of improvement. This single trial, although limited by the uncertainty regarding treatment in the control group, suggests that the addition of biofeedback to PME does not result in an additional benefit for patients with post-prostatectomy incontinence.

Table 3. Controlled trials comparing PME plus biofeedback with PME alone for DI – methodologic features

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Burton 1988	32 elderly, ambulatory women without cognitive impairment referred from practitioners and ads. 74% with DI 26% pts with SI Mean age 72.6, range 64-83	Blinding NR Nonrandomized. Pts assigned to groups to balance on age, baseline frequency, and type of incontinence.	<u>Group 1</u> - PME with EMG biofeedback <u>Group 2</u> - PME alone Treatment course consisted of six total sessions in each group.	5/32 (16%) NR by group	Pt recorded diaries maintained throughout study.	Potential for selection bias.

Table bibliography:

Burton JR, Pearce KL, Burgio KL et al. (1988). Behavioral training for urinary incontinence in elderly ambulatory patients. J Am Geriatr Soc, 36(8):693-8.

Table 4. Controlled trials comparing PME plus biofeedback with PME alone for DI – outcomes

Study/year	Patients/Groups	Pt recorded diaries					Pad test					Comments	
		Measure	Pre-	Post-	change ¹	pts improv ²	dry ³	Pre-	Post-	change ⁴	pts improv ⁵		dry ⁶
Burton 1988	PME plus BF (n=13)	Leaks/wk	15	2	79%	NR	NR	--	--	--	NR	NR	
	PME alone (n=14)	Leaks/wk	20	2	82%	NR	NR	--	--	--	NR	NR	
No significant differences between groups													

%

Table 5. Controlled trials comparing PME plus biofeedback with PME alone for post-prostatectomy incontinence – methodologic features

Study/year	Patient characteristics	Group Allocation	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Franke 2000	30 patients out of 114 patients undergoing radical prostatectomy. Mean age 61.5 years	Blinding NR Pts randomized into one of two groups. Randomization process not described.	Biofeedback plus PME – Five 45 min sessions over 16 weeks PME alone – educational materials given, no specific instruction in PME. Unclear how many pts practiced PME	BF – 5/15 (33%) (13%)	Pt recorded diaries completed at 6,12, and 24 weeks post-op. Pt recorded diaries completed at 6,12, and 24 weeks post-op.	Potential for attrition bias. Effect of treatment possibly diluted by spontaneous improvement in both groups.

Table bibliography:

Franke JJ, Gilbert WB, Grier J et al. (2000). Early post-prostatectomy pelvic floor biofeedback. J Urol, 163(1):191-3.

Table 6. Controlled trials comparing PME plus biofeedback with PME alone for post-prostatectomy incontinence – outcomes

Study/year	Patients/Groups	Pt recorded diaries					Pad test					Comments				
		Measure	Pre-	Post-	change ¹	2	3	Pre-	Post-	change ⁴	5		6			
Franke 2000	BF plus PME (n=10)	Leaks/day	7.2	1.3	82%	pts improv	NR	dry	NR	162	58	64%	pts improv	NR	dry	NR
	PME alone (n=13)	Leaks/day	5.2	0.8	85%	NR	NR	NR	152	93	39%	NR	NR	NR	NR	NR
		No significant differences among groups					No significant differences among groups									

%

SUMMARY

This Assessment sought controlled trials to determine whether adding biofeedback as an aid to performing pelvic floor muscle exercise results in a greater improvement in urinary incontinence, compared to pelvic floor muscle exercises alone. Eight controlled trials (n=383) were identified that concurrently compared a group of patients treated with pelvic floor muscle exercises plus biofeedback to a control group treated with pelvic floor muscle exercises alone. One of these trials (Burns et al. 1993) included a comparison with a no-treatment control group. Six of these trials reported on patients with stress incontinence, and one report each addressed patients with urge incontinence and post-prostatectomy incontinence. It is not possible to draw conclusions from this body of evidence on whether the addition of biofeedback to PME results in improved outcomes as compared to PME alone.

Summarizing the six trials of patients with stress incontinence, it is possible that there is no additional benefit to the addition of biofeedback to PME, and that the statistically significant results reported in two small trials are explained by bias. One of these trials, although randomized, is subject to both performance and attrition bias; treatment intensity was greater in the PME plus biofeedback group while drop-outs were greater in the PME alone group (Glavind et al. 1996). The other, while stratified to balance the arms on age and frequency of incontinence, was not randomized (Burgio et al. 1986).

It is also possible that there is some additional benefit to biofeedback, and that the three studies that found no significant difference in outcomes (Ceresoli et al. 1993; Burns et al. 1993; Berghmans et al. 1996) lacked sufficient power to detect group differences due to inadequate sample size. However, in one of these trials (Burns et al. 1993) there was adequate power to detect a difference between the treatment groups and a third group that received no treatment. Another possibility is that biofeedback is effective for a subset of patients who have difficulty in performing PME, but that this benefit is not apparent when the entire group of treated patients is analyzed. Although the available evidence cannot distinguish among these possibilities, this body of evidence certainly fails to demonstrate that the addition of biofeedback to PME is superior to PME alone.

For the diagnoses of urge incontinence and post-prostatectomy incontinence, only one small trial was identified in each category. There was no statistically significant improvement in outcomes for the biofeedback plus PME group as compared to the PME alone group in either study. Therefore, the evidence is not sufficient to conclude that the addition of biofeedback to PME improves outcomes in these patient groups.

Thus, the evidence is not sufficient to demonstrate an additional benefit for biofeedback above that obtained with PME alone. It is possible that there is an additional benefit to biofeedback, but the data from the controlled trials is insufficient to demonstrate this conclusion. If so, this benefit is small, and may not be clinically important. Larger randomized, controlled trials would be required to answer this question more definitively.

In three trials the age range of the subjects permits inferences to the Medicare population. Most useful is a 3-arm trial of cognitively intact, middle-class, community-dwelling women that

included a no-treatment control group. The mean age of participants was 63 (range: 57–69 years) and 34% of participants were age 65 and older. The results show that older women with stress incontinence improve with PME or PME plus biofeedback compared to no treatment; but do not demonstrate additional benefit from biofeedback in this population.

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