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Medical Policy Manual

Topic: Biofeedback

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION[1-5]

Biofeedback is a technique intended to teach patients self-regulation of certain physiologic processes not normally considered to be under voluntary control. The technique involves the feedback of a variety of types of information not normally available to the patient, followed by a concerted effort on the part of the patient to use this feedback to help alter the physiological process in some specific way. Biofeedback training is done either in individual or group sessions, alone, or in combination with other behavioral therapies designed to teach relaxation. A typical program consists of 10 to 20 training sessions of 30 minutes each. Training sessions are performed in a quiet, non-arousing environment. Subjects are instructed to use mental techniques to affect the physiologic variable monitored, and feedback is provided for successful alteration of that physiologic parameter. The feedback may be in the form of lights or tone, verbal praise, or other auditory or visual stimuli.

A variety of biofeedback devices are cleared for marketing though the Food and Drug Administration's (FDA) 510(k) process. These devices are designated by the FDA as class II with special controls, and are exempt from the premarket notification requirements. The FDA defines a biofeedback device as "an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters".

MEDICAL POLICY CRITERIA

I. Biofeedback as part of the overall treatment plan may be **medically necessary** for either of the following indications:

A. Migraine or tension headaches

B. Dyssynergia-type constipation in adults: Up to six biofeedback sessions over three months when *all* of the following criteria (1-3) are met:

1. Symptoms of functional constipation that meet all (a-c) of the following ROME III criteria:

a. Two or more of the following symptoms (i-vi) have been present for the past three months, with symptom onset at least six months prior to diagnosis:

i. Straining during at least 25% of defecations

ii. Lumpy or hard stools in at least 25% of defecations

iii. Sensation of incomplete evacuation for at least 25% of defecations

iv. Sensation of anorectal obstruction/blockage for at least 25% of defecations

v. Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor)

vi. Fewer than three defecations per week

b. Loose stools are rarely present without the use of laxatives

c. Insufficient criteria for irritable bowel syndrome

2. Objective physiologic evidence of pelvic floor dyssynergia when one or both of the following criteria are met:

i. Inappropriate contraction of the pelvic floor muscles

ii. Less than 20% relaxation of basal resting sphincter pressure by manometry, imaging, or EMG

3. Failed 3-month trial of standard treatments for constipation including laxatives, dietary changes, and pelvic floor exercises

II. Unsupervised biofeedback in the home setting is considered **investigational**.

III. Biofeedback is considered **investigational** for all other indications, including but not limited to the following:

Abdominal pain, recurrent

Anxiety disorders

Arthritis

Asthma

Autism

Back pain

Bell's palsy

Bruxism and sleep bruxism

Cardiovascular disorders

Chronic fatigue

Chronic pain

Chronic obstructive pulmonary disease (COPD)

Depression

Epilepsy

Facial palsy

Fecal incontinence, encopresis, and constipation *other than* dyssynergia type in adults

Fibromyalgia

Hand hemiplegia

Headaches other than migraine and tension (e.g., cluster headaches)

Hypertension

Insomnia

Knee pain

Low back pain

Low vision

Lupus [systemic lupus erythematosus (SLE)]

Motor function after stroke, injury, or lower limb surgery

Movement disorders

Myalgia or muscle pain

Neck pain

Orofacial pain

Orthostatic hypotension in patients with a spinal cord injury

Post-traumatic stress disorder (PTSD)

Raynaud's disease

Shoulder Pain

Side effects of cancer chemotherapy

Temporomandibular joint disorders

Tinnitus

Urinary disorders

- Post-prostatectomy urinary dysfunction
- Urinary incontinence in adults
- Urinary retention
- Vesicoureteral reflux
- Voiding dysfunction

Vestibulodynia, vulvodynia, vulvar vestibulitis

SCIENTIFIC EVIDENCE

Background

There are several methodologic difficulties that arise in assessing biofeedback for any indication. For example, most interventions that include biofeedback are multimodal and include relaxation and behavioral instruction, which may have effects separate from those that may occur due to biofeedback. While studies may report a beneficial effect of multimodality treatment, without appropriate control conditions, it is impossible to isolate the specific contribution of biofeedback to the overall treatment effect. In addition, behavioral therapies, i.e., non-drug treatments including biofeedback result in both nonspecific and specific therapeutic effects. Nonspecific effects, sometimes called placebo effects, occur as a result of therapist contact, positive expectancies on the part of the patient and therapist, and other beneficial effects that occur as a result of being a patient in a therapeutic environment. Specific effects are those that occur only because of the active treatment, above any nonspecific effects that may be present.

In order to isolate the independent contribution of biofeedback on health outcomes (specific effects) and

properly control for nonspecific treatment effects, well-designed clinical trials with the following attributes are necessary:

- Randomization
  Randomization helps to achieve equal distribution of individual differences by randomly assigning patients to either biofeedback or sham-biofeedback treatment groups. This promotes the equal distribution of patient characteristics across the two study groups. Consequently, any observed differences in the outcome may, with reasonable assuredness, be attributed to the treatment under investigation.
- Sham control group
  A comparable sham control group helps control for expected high placebo effects as well as for the variable natural history of the condition being treated.
- Blinding
  Blinding of study participants, caregivers, and investigators to active or sham assignments helps control for bias for or against the treatment. Blinding assures that placebo effects do not get interpreted as true treatment effects.
- Large study population
  Small studies limit the ability to rule out chance as an explanation of study findings.
- Adequate follow-up
  Follow-up periods must be long enough to determine the durability of any treatment effects.

The focus of the evidence review for biofeedback for all indications is on randomized controlled trials with the attributes noted above.

Literature Appraisal

Technology Assessment

This policy was initially based on a 1995 BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessment that evaluated the use of biofeedback in the treatment of nine different conditions: anxiety disorders, headaches, hypertension, movement disorders, incontinence, pain, asthma, Raynaud's disease, and insomnia.[6] The Assessment reported the following conclusions:

- While a substantial number of studies reported improvement in the biofeedback group relative to the no-treatment group, there were generally no differences when the isolated effect of biofeedback was compared with relaxation or behavioral therapy alone.

- While there was evidence that feedback on physiological processes provided patients with an enhanced ability to control these processes, there was, nevertheless, no consistent evidence of any relationship between a patient's ability to exert control over the targeted physiological process and any health benefits of the intervention. These findings underscore the importance of seeking controlled studies showing whether use of biofeedback improves disease-related health outcomes, as opposed to physiological, intermediate outcomes.

- Studies failed to consistently address the durability of effects beyond the initial, short-term biofeedback training period.

- The literature suggested that the outcomes of biofeedback relative to no treatment were due to the other components of therapy or to the nonspecific effects of the therapeutic setting, not a result of the biofeedback training, per se.

The following is a summary of the current evidence for the use of biofeedback for specific indications.

Anxiety Disorders **Back to Criteria**

The current published clinical trial data is insufficient to allow scientific conclusions concerning the contribution of biofeedback to improvements in health outcomes in the treatment of anxiety disorders.

The 1995 TEC Assessment concluded that evidence was insufficient to demonstrate the effectiveness of biofeedback for treatment of anxiety disorders.[6]

Since the 1995 TEC Assessment, no well-designed randomized, controlled clinical trial data has been published.

Asthma **Back to Criteria**

Lehrer and colleagues[7] reported the results of a trial of 94 asthma patients randomized to one of the following four groups:

1. "Full protocol" including heart rate variability (HRV) biofeedback and training in pursed-lips abdominal breathing with prolonged exhalation
2. HRV biofeedback alone
3. Placebo biofeedback involving bogus "subliminal suggestions designed to help asthma", with no other details provided and no actual suggestions given plus biofeedback training to alternately increase and decrease frontal EEG alpha rhythms
4. A waiting list control group

Although reported improvement was greater in the two treatment groups, scientific conclusions cannot be drawn from this data due to several limitations, as discussed in the Background section above, including possible selection bias due to lack of randomization, short study duration, lack of follow-up to assess long-term effects, and differences between groups in task involvement and assessment frequency. The authors concluded that further research is needed. They advise caution in the use biofeedback for the treatment of asthma until the mechanisms of action are better understood and the long-term effects have been documented.

Autism Spectrum Disorder (ASD) **Back to Criteria**

There is insufficient evidence from RCTs that biofeedback improves outcomes in individuals with ASDs. The scientific evidence on the effectiveness of biofeedback for treatment of autism consists of one small randomized controlled trial (RCT) and a limited number of small, non-randomized studies. The RCT did not find a benefit of biofeedback on autism-related symptoms.

Each individual autism patient is highly different from the next and those differences – clinical and demographic, known and unknown – may impact the treatment outcome in ways that cannot be quantified without a systematic study that controls for bias as discussed in the Background section

above. Therefore, the following literature review for biofeedback as a treatment of ASD focuses on systematic reviews and randomized controlled trials.

Systematic Review

A 2010 article by Coben and Myers reviewed the literature on EEG biofeedback for autistic disorders.[8] The authors identified 2 published small, non-randomized controlled studies evaluating EEG biofeedback in the treatment of autistic disorders. As described in the review, a study published by Jarusiewicz and colleagues in 2002 compared treatment with 20 to 69 sessions of biofeedback in 12 autistic children to a matched control group that did not receive biofeedback. Mean reduction in autistic symptoms, as measured by the Autism Treatment Evaluation Checklist (ATEC), was 26% in the biofeedback group and 3% in the comparison group; this difference was statistically significant. The other study was published by Coben and Padolsky in 2007. It compared 20 sessions of EEG biofeedback in 37 patients to a waiting-list control group. After treatment, parents reported reduction in symptoms in 89% of the treatment group compared to 17% of the control group (p-value not reported). Studies differed in their biofeedback protocols and number of sessions. The review article concluded that RCTs are needed to determine the effectiveness of biofeedback to treat autism.

Randomized Controlled Trials

In 2013, Kouijzer and colleagues published an RCT evaluating electroencephalography (EEG) biofeedback as a treatment for ASD.[9] The trial included 35 teenagers between 12 and 18 years-old with confirmed diagnoses of ASD. Participants were randomly assigned to receive EEG biofeedback (n=13), skin conductance biofeedback (n=12), or a waiting-list control group (n=13). The biofeedback interventions included 40 sessions provided twice a week. Patients and parents in the biofeedback groups but not on the waiting-list were blinded to treatment allocation. The primary outcome measure was change in symptoms at 3 months as measured by the total score on the Social Communication Questionnaire (SCQ) which has a potential range of 0 to 36. In the primary analysis, the investigators only included participants who successfully influenced their EEG activity (called “EEG-regulators”) in the primary analysis. The justification for this was to be able to identify the specific effects of biofeedback on symptoms. Among the 19 of 35 (54%) regulators, there was no statistically significant difference in the SCQ scores between participants treated with EEG- or skin-conductance biofeedback. The investigators evaluated non-specific effects of EEG biofeedback by examining the SCQ scores among EEG-non-regulators as rated by the parents. There was no statistically significant difference in scores among participants in the EEG biofeedback group, the skin conductance biofeedback group and the control group.

Bell’s Palsy **Back to Criteria**

Systematic Review

Cardoso et al. examined the effects of facial exercises associated either with mirror or EMG biofeedback with respect to complications of delayed recovery in Bell's palsy.[10] Patients with unilateral idiopathic facial palsy treated with facial exercises associated with mirror and/or EMG biofeedback were included in this review. Four studies (n=132) met the eligibility criteria. The studies described mime therapy versus control (n=50), mirror biofeedback exercise versus control (n=27), "small" mirror movements versus conventional neuromuscular retraining (n=10), and EMG biofeedback plus mirror training versus mirror training alone. The treatment length varied from 1 to 12 months. The authors concluded that “…because of the small number of randomized controlled trials, it was not possible to analyze if the

exercises, associated either with mirror or EMG biofeedback, were effective. In summary, the available evidence from randomized controlled trials is not yet strong enough to become integrated into clinical practice."

No RCTs have been published since the above systematic review.

Conclusion

Current evidence from small RCTs with variable biofeedback protocols and type of comparison interventions is insufficient to permit conclusions on the impact of biofeedback on Bell's palsy.

Bruxism and Sleep Bruxism **Back to Criteria**

Systematic Review

In 2013, Wang and colleagues published a systematic review of randomized and non-randomized controlled trials on biofeedback treatment for sleep bruxism.[11] The full text of 17 articles was reviewed and 7 studies with a total of 240 participants met the inclusion criteria. Studies were generally small; only 2 included more than 50 participants. Four studies used audio biofeedback, 2 used contingent electrical stimulation and 1 used visual biofeedback. Treatment duration ranged from 1 night to 6 weeks. In 4 of the studies, the duration of treatment was 2 weeks. Three of the studies were considered to be at moderate risk of bias and the other 4 were considered to be at high-risk of bias. The primary outcome of the analysis was the number of sleep bruxism episodes per hour detected by EMG recording. Only 2 studies (total n=27) reported this outcome and had data suitable for meta-analysis. A pooled analysis did not find a statistically significant difference between the biofeedback and control groups; mean difference: -4.47 (95% CI: -12.33 to 3.38). Findings were not pooled for any other outcomes.

Randomized Controlled Trials

No RCTs have been published since the above systematic review.

Conclusion

Current evidence is limited to small, relatively low-quality RCTs with variable interventions and lack of finding of benefit. This evidence is insufficient to permit conclusions on the impact of biofeedback on sleep bruxism.

Chronic Pain (Non-headache) **Back to Criteria**

As discussed in the Background section above, the focus of the evidence review was on RCTs. This study design is particularly important when studying treatments for pain. The most clinically relevant outcomes of therapy for pain are improvement in symptoms, function, and quality of life. These outcomes are subjective and can be influenced by nonspecific effects such as placebo response and the natural history of the disease. Randomized treatment allocation and the inclusion of a control group for comparison are needed to isolate the effect of biofeedback therapy.

The current published clinical trial data is insufficient to allow scientific conclusions concerning the contribution of biofeedback to improvements in health outcomes in the treatment of chronic non-headache pain. (Headache is discussed separately below.)

A Cochrane review by Williams and colleagues on psychological therapies (cognitive-behavioral therapy [CBT] and behavioral therapy, including biofeedback) for chronic non-headache pain in adults was updated in 2012.[12] Forty-two trials provided analyzable data, thirteen of which had not been included in previous updates of this review. The systematic review found that although the quality of trial design had improved over time, the quality of treatments, of their reporting, or both has not improved. CBT but not behavioral therapy had weak effects in improving pain, but only immediately following treatment. CBT also had small effects on pain-related disability, altering mood, and catastrophizing outcomes compared with usual treatment or waiting list patients, with some maintenance at six months follow-up. Behavioral therapy had no effect on mood but showed an effect on catastrophizing immediately post-treatment. The authors recommended against future general RCTs, recommending instead, studies to identify which components of CBT work for which type of patient.

Another Cochrane review by Eccleston and colleagues evaluated psychological therapies for the management of chronic and recurrent pain in children and adolescents.[13] Included studies were RCTs with at least 10 participants in each arm. Although psychological therapies were found to improve pain, only 1 of the 5 studies on non-headache pain evaluated biofeedback.

An updated meta-analysis of studies on psychological therapies for management of chronic pain in children and adolescents was published by Palermo and colleagues in 2010.[14] The review did not identify any new randomized trials on biofeedback for managing non-headache pain.

Arthritis **Back to Criteria**

In a meta-analysis of psychological interventions for rheumatoid arthritis including relaxation, biofeedback, and cognitive-behavioral therapy, Astin and colleagues concluded that psychological interventions may be important adjunctive therapies in rheumatoid arthritis treatment.[15] In the 25 studies analyzed, significant pooled effect sizes were found for pain after an intervention. However, the same effect was not seen long term, and the meta-analysis did not isolate biofeedback from other psychological interventions. Therefore, the specific effects of biofeedback, as discussed in the Background section above, could not be isolated.

Knee Pain **Back to Criteria**

A number of systematic reviews have been published that included trials of biofeedback in the treatment of anterior knee pain[16], patellofemoral pain syndrome,[17] and in post-meniscal repair rehabilitation.[17] Mixed results have been reported, but no standardized treatment protocols or patient selection criteria have been established for biofeedback for knee pain of any etiology.

Low Back Pain **Back to Criteria**

A 2010 Cochrane review on behavioral treatments for chronic low-back pain included a meta-analysis of 3 small randomized trials comparing electromyography (EMG) biofeedback to a waiting-list control group.[18] In the pooled analysis there were a total of 34 patients in the intervention group and 30 patients in the control group. The standard mean difference in short-term pain was -0.80 (95% confidence interval [CI]:-1.32 to -0.28); this difference was statistically significant favoring the

biofeedback group. The Cochrane review did not conduct meta-analyses of trials comparing biofeedback to sham biofeedback and therefore did not control for any non-specific effects of treatment.

Two randomized trials have compared biofeedback to a sham intervention for treatment of lower back pain; neither found a statistically significantly benefit with real biofeedback. Bush and colleagues who randomized 62 patients to receive either EMG biofeedback, sham biofeedback, or a no treatment control.[19] At the conclusion of the trial, all three groups showed significant improvement in multiple measures of pain. There were no significant effects found for treatment type, leading the authors to conclude that biofeedback is not superior to placebo in controlling chronic pain. In 2010, Kapitza and colleagues compared the efficacy of respiratory biofeedback to sham biofeedback in 42 patients with lower back pain.[20] All participants were instructed to perform daily breathing exercises with a portable respiratory feedback machine; exercises were performed for 30 minutes on 15 consecutive days. Patients were randomized to an intervention group that received visual and auditory feedback of their breathing exercises or a control group that received a proxy signal imitating breathing biofeedback. Patients recorded pain levels in a diary 3 times a day, measuring pain on a visual analogue scale (VAS). Both groups showed reduction in pain levels at the end of the intervention period and at the 3 month follow-up, but there were no significant differences in pain between groups. For example, the mean change in pain with activity 3 months after the intervention was a reduction in 1.12 points on a 10-point VAS scale in the intervention group and 0.96 points in the sham control group; $p>0.05$. The mean change in pain at rest after 3 months was a reduction of 0.79 points in the intervention group and 0.49 points in the control group; $p>0.05$.

Another randomized trial, by Glombiewski and colleagues, assessed whether the addition of EMG biofeedback to CBT improved outcomes in 128 patients with lower back pain.[21] Patients with musculoskeletal pain of the low, mid, or upper back, with pain duration of at least 6 months on most days of the week, were randomized to CBT, CBT plus biofeedback, or a waiting-list control; 116 patients began the 1-hour weekly sessions (17-25 treatments) and were included in the final analysis. CBT alone included breathing exercises and progressive muscle relaxation; biofeedback was used for 40% of the CBT treatment time in the combined treatment condition. Both treatments were found to improve outcomes including pain intensity compared to a waiting-list control (moderate effect size of 0.66 for pain intensity in the CBT plus biofeedback group). However, the addition of biofeedback did not improve outcomes over CBT alone.

Neck and Shoulder Pain **Back to Criteria**

In 2011, Ma and colleagues in Hong Kong published an RCT that included 72 patients with chronic (at least 3 months) computer work-related neck and shoulder pain.[22] Patients were randomized to one of four 6-week interventions: Biofeedback, exercise, passive treatment (e.g., hot packs), or a control group receiving only an educational pamphlet. Members of the biofeedback group were given a portable EMG biofeedback machine and were instructed to use it for two hours daily while performing computer work. The active exercise group was given an exercise routine to perform on their own for no longer than 20 minutes, four times a day. Sixty of 72 (83%) participants were available for the post-intervention follow-up assessment (n=15 per group). At the end of the intervention, the average VAS score and neck disability index (NDI) scores were significantly lower in the biofeedback group than in the other three groups. For example, the mean VAS post-intervention was 1.87 (standard deviation [SD]: 0.74) in the biofeedback group and 2.10 (SD: 1.34) in the active exercise group, $p<0.05$.

This study found a short-term benefit of a biofeedback intervention, but the magnitude of difference in the VAS scores and the NDI index was small and of uncertain clinical significance. In addition, there

were several methodologic limitations. The study was of small size and had a substantial number of dropouts; data were available on only 39 of 72 (54%) of participants at 6 months. The interventions were not balanced in intensity, as the biofeedback intervention was more intensive (two hours per day) than the other interventions, such as the passive treatment arm, which received two 15-minute sessions per week. Long-term data were not available due to the low follow-up rate, which at 6 months was too small for meaningful analysis.

Orofacial Pain (including temporomandibular joint disorder) **Back to Criteria**

A 2011 Cochrane review identified 17 trials evaluating non-pharmacological psychological interventions for adults with chronic orofacial pain, e.g., temporomandibular joint (TMJ) disorder.[23] For the outcome short-term pain relief (three months or less), there was a significantly greater reduction in pain with interventions that combined cognitive-behavioral therapy (CBT) and biofeedback compared to usual care (two studies). However, there was not a significant benefit of a combined CBT/biofeedback on longer-term i.e., 6-month pain relief, and there were no studies that compared CBT alone to CBT combined with biofeedback. For biofeedback-only interventions, a pooled analysis of two studies on short-term pain relief did not find a significant benefit compared to usual care. There was only one study reporting long-term pain relief after a biofeedback-only intervention, so a pooled analysis could not be conducted. The authors concluded that there is weak evidence to support psychosocial interventions for managing chronic orofacial pain and the most promising evidence is for CBT, with or without biofeedback. They noted that the trials in the review were few in number and had a high risk of bias, and they recommended additional high-quality trials.

The conclusions of the Cochrane review are similar to previous systematic reviews on treatment of TMJ disorder. They also concluded that there is weak evidence that psychosocial/physical therapy interventions, including biofeedback among others, are beneficial for treating TMJ but that there were few studies and they tended to be of poor methodologic quality. Medlicott and colleagues recommended caution in interpreting results due to heterogeneity in study design and interventions used.[24] Since biofeedback was not isolated from other therapies, no conclusions could be reached for biofeedback alone. Based on two poor-quality randomized controlled trials, McNeely and colleagues concluded that biofeedback did not reduce pain more than relaxation or occlusal splint therapy for TMJ, but did improve oral opening when compared with occlusal splints.[25]

Systemic Lupus Erythematosus **Back to Criteria**

In a randomized controlled trial of 92 patients with systemic lupus erythematosus (SLE), Greco and colleagues reported that patients treated with six sessions of biofeedback-assisted cognitive-behavioral treatment for stress reduction had a statistically significant greater improvement in pain post treatment than a symptom-monitoring support group ($p=0.044$) and a usual care group ($p=0.028$).[26] However, these improvements in pain were not sustained at nine month follow-up and further studies are needed to determine the incremental benefits of biofeedback-assisted cognitive-behavioral treatment over other interventions in SLE patients.

Recurrent Abdominal Pain **Back to Criteria**

Humphrey's and Everts randomly assigned 64 patients with recurrent abdominal pain to groups treated with: 1) increased dietary fiber; 2) fiber and biofeedback; 3) fiber, biofeedback, and cognitive-behavioral therapy; and 4) fiber, biofeedback, cognitive-behavioral therapy, and parental support.[27] The three multi-component treatment groups were similar and had better pain reduction than the fiber-only

group. This study does not address placebo effects. In a systematic review of recurrent abdominal pain therapies in children, Weider and colleagues concluded that behavioral interventions (cognitive-behavioral therapy and biofeedback) had a general positive effect on nonspecific recurrent abdominal pain and were safe.[28] However, the specific effects of biofeedback were not isolated in this systematic review.

Vulvar Vestibulitis **Back to Criteria**

A randomized study by Bergeron of 78 patients with vulvar vestibulitis compared biofeedback, surgery and cognitive-behavioral therapy.[29] Surgery patients had significantly better pain scores than patients who received biofeedback or cognitive-behavioral therapy. No placebo treatment was used.

Other Chronic Pain **Back to Criteria**

Other pain for which there are no clinical trial publications sufficient to demonstrate the effectiveness of biofeedback include muscle pain or myalgia.

Fecal Incontinence and Constipation With or Without Encopresis **Back to Criteria**

The relevant clinical outcome in studies of biofeedback as a treatment of fecal incontinence, encopresis, and constipation should be the overall change in the bowel symptoms. Changes in anorectal physiological assessment (e.g., anal pressure, sensory threshold) often do not correlate with symptom relief (i.e., clinical outcomes). Reduction in episodes of fecal incontinence, encopresis, and constipation, and increase in voluntary bowel movements are the primary clinical outcome. Patient symptoms are usually assessed through diary, questionnaire, or interview.

Although there is a relatively large body of literature evaluating the efficacy of biofeedback for treating fecal incontinence and constipation, current evidence is insufficient to assess the effects of biofeedback for the management of these conditions.

- There is no reliable, long-term evidence from well-designed, well-executed, placebo-controlled, prospective, randomized controlled trials on the effectiveness of biofeedback as a treatment of fecal incontinence in adults and children. Current studies consist of unreliable case series, observational studies, and systematic review.
- Due to numerous methodological limitations, the few available randomized controlled trials (RCTs) are insufficient to permit conclusions on the effect of biofeedback on fecal incontinence. These study design limitations include inadequate or lack of randomization or blinding, lack of appropriate control groups for comparison, small sample size, short follow-up period, nonspecific treatment effects, and lack of validated outcome measures.
- Between-study comparisons are difficult for the following reasons:

    1. Lack of uniform criteria for patient inclusion.
        - Some studies included only chronic constipation patients, some only encopresis, and some constipation with encopresis.
        - Studies often failed to specify the characteristics of the population and the subgroups with different symptoms and diseases. Patients with weak pelvic floor muscles and normal rectal sensation may only need strength training, while patients with normal pelvic floor muscle strength and poor rectal sensation may only need sensory or coordination training.

- Most studies did not identify and report the cause of incontinence and did not conduct analysis on patient subgroups.

2. Lack of standardized criteria for assessing outcome.
   - Studies reported cure rates and improvement rates, but the outcomes and methods underlying their measurement varied across studies.
   - The criterion for success ranged widely from 25% to 90% reduction in episodes across studies.

3. Diversity among treatment protocols.

In summary, stronger research with more rigorous quality, as discussed in the Background section above, is needed to allow a reliable assessment of biofeedback therapy in the management of adults with fecal incontinence. This includes sham-placebo, randomized controlled trials that:

1. Have replicable standardized interventions
2. Control for confounding factors and bias
3. Provide valid short and long-term outcome measures and adequate power

Fecal Incontinence in Adults **Back to Criteria**

- Systematic Reviews

  In 2012, an updated Cochrane review of randomized and quasi-randomized trials of biofeedback and/or sphincter exercises for the treatment of fecal incontinence in adults was published.[30] About half of the 21 trials were considered low risk for bias. Due to the variety of different treatment combinations, treatment delivery techniques, and outcome measures, comparison between studies was difficult. In addition, most studies reported immediate post-treatment outcomes with follow-up of only a few weeks. The authors reached the following conclusions:

  - Biofeedback or electrical stimulation "may offer an advantage over exercises alone" in patients who have failed conservative management (e.g., diet changes, medications).
  - Biofeedback following surgical sphincter repair does not improve health outcomes.
  - The evidence is does not permit conclusions about best practices in the clinical setting, including but not limited to the technique for biofeedback delivery and which patients are suitable for and most likely to benefit from biofeedback.
  - Biofeedback is unlikely to cause harm as no study has reported any adverse events or worsening of symptoms.
  - There is a need for large, long-term, well-designed randomized controlled trials that use validated outcome measures to compare outcomes of biofeedback with other treatments.

- Randomized Controlled Trials
  No new reports from randomized controlled trials were identified since this recent systematic review.

- Clinical Practice Guidelines and Position Statements
  - An American Society of Colon and Rectal Surgeons practice parameter recommended biofeedback "as an initial treatment for motivated patients with incontinence with some voluntary sphincter contraction.[31] Biofeedback may be considered a first-line option for many

patients with fecal incontinence who have not responded to simple dietary modification or medication. Supportive counseling and practical advice regarding diet and skin care can improve the success of biofeedback. Biofeedback may be considered before attempting sphincter repair or for those who have persistent or recurrent symptoms after sphincter repair. It may have a role in the early postpartum period in females with symptomatic sphincter weakness. Biofeedback and a pelvic floor exercise program can produce improvement that lasts more than two years. Biofeedback home training is an alternative to ambulatory training programs, especially in the elderly." The authors assigned a level of evidence of III and grade of recommendation B, defined as well-designed, quasi-experimental nonrandomized studies with generally consistent findings.

Fecal Incontinence in Children **Back to Criteria**

A 2011 updated Cochrane review[32] combined the results of nine trials that compared conventional treatment (i.e., laxatives, toilet training, and dietary advice) with versus without biofeedback in children with fecal incontinence.[33-41] The majority of the trials included fewer than 50 participants. Pooling of data was difficult due to the variety of outcome measures; the only outcome reported by all nine trials was the number of children not cured or improved. Combined results of nine trials showed higher rather than lower rates of persisting symptoms of fecal incontinence up to 12 months when biofeedback was added to conventional treatment. In addition, any short-term benefit from biofeedback training did not correspond with later treatment success. The authors concluded that there is no evidence that biofeedback training added any benefit to conventional treatment in the management of functional fecal incontinence in children. These results confirm the conclusions of prior versions of this Cochrane review and other systematic literature reviews.[42-44]

Since these meta-analyses, one additional randomized trial was published in which the authors reported that the results at 6-months follow-up did not differ between biofeedback and customary care.[33]

The conclusions from the above four systematic reviews of the randomized, comparative studies are similar to that reached for adults:

- There is insufficient evidence from controlled trials to evaluate whether biofeedback treatments are helpful
- The evidence for biofeedback based on observational studies and methodologically weak controlled trials can be viewed only as tentative

Constipation in Adults **Back to Criteria**

For the treatment of constipation, a systematic review of RCTs found a benefit of biofeedback as a treatment of constipation in adults.[45] Conclusions of the systematic review were limited by variability in patient populations, comparison treatments, and outcomes measures. However, detailed examination of several well-conducted RCTs focusing on patients with dyssynergia-type constipation suggested benefits in a sub-group of patients who met criteria similar to trial participants.[46-48] Studies for other types of constipation were limited to poorly-designed randomized trials and case series. These unreliable studies do not permit conclusions on the effect of biofeedback on constipation in adults.

The American Gastroenterological Association (AGA) position statement notes that, "formal evaluations of biofeedback training in constipation are sparse, and important practical details of individual programs are often not stated."[49,50] In spite of this statement, the AGA guidelines consider biofeedback a possible treatment for patients with severe symptoms and proven pelvic floor dysfunction

"to train patients to relax their pelvic floor muscles during straining and to correlate relaxation and pushing to achieve defecation."

The American Society of Colon and Rectal Surgeons practice parameters recommend biofeedback in patients with symptomatic pelvic floor dyssynergia [Evidence level Class II, Grade B, defined as at least one well-designed experimental study with high false-positive or high false-negative errors or both (low power), and generally consistent findings.][51]

Constipation in Children **Back to Criteria**

One randomized controlled trial was found for biofeedback in the treatment of constipation in children.[52] Groups included standard treatment i.e., education, laxatives (n=111) or standard treatment plus two sessions of anorectal manometry (n=91). Manometry measurements were viewed by the child and parent during measurement sessions and the data discussed after each session with instructions in home exercises. At 6 weeks follow-up, there was no significant different in success between the standard treatment group (4%) and the biofeedback group (7%). At the final 104 week follow-up, 43% of the standard treatment group and 35% of the biofeedback group were considered treatment successes. This difference was not significant. The authors noted that 30% of the randomized patients were missing at the final follow-up.

The American Gastroenterological Association (AGA) guideline notes that results of biofeedback in children have been "disappointing."[49,50] The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHN) considers biofeedback to be effective in short-term treatment in selected children with intractable constipation, but does not consider it to be a long-term solution.[53]

Fibromyalgia **Back to Criteria**

In 2013 Glombiewski et al. published the results of a meta-analysis that included 7 studies (total n=321) on EEG- and EMG-biofeedback for fibromyalgia. While EMG-biofeedback was reported to have significantly reduced pain intensity compared to control groups, the interpretation of the results were "limited because of a lack of studies on long-term effects…" The authors recommended further research focused on long-term effects and predictors of treatment response. Since this meta-analysis, no RCTs have been published.

Headache **Back to Criteria**

Tension and Migraine Headache

Despite the poor quality of case series and randomized controlled trials, biofeedback has evolved into a standard of care as part of comprehensive regimens, including medication and relaxation techniques, for treatment and prevention of tension-type headaches, and the prevention of migraine headaches.

- Data from case series and randomized controlled trials is difficult to interpret due to poor study design, high drop-out rates, and inconsistent outcomes.[54-59]
- A number of systematic reviews, including 2 Cochrane reviews, have reported small beneficial effects in children and medium to large beneficial effects in adults when biofeedback is used in conjunction with other prevention measures such as relaxation techniques.[14,60-66]
- Clinical practice guidelines from professional associations include biofeedback in their recommendations for prevention of tension and migraine headaches.[67-71]

Other Headache

The evidence is insufficient to determine the effect of biofeedback for the prevention or treatment of headaches other than migraine and tension headaches, including but not limited to cluster headaches.

Cluster Headache

Due to the lack of clinical trial data, the evidence is insufficient to determine the efficacy of biofeedback in the management of cluster headaches.

- No clinical trial reports were found that focus on the efficacy of biofeedback alone or as part of a comprehensive treatment program.
- Few clinical practice guidelines or position statements from professional associations mention cluster headache, and none recommended biofeedback for management of cluster headache.

Hypertension **Back to Criteria**

Systematic Review

A 2013 the American Heart Association published a statement based on a systematic literature review on alternatives to diet and medication for lowering blood pressure (BP) in patients with hypertension. The report found meta-analyses to have had mixed results, though some recent trials showed reduction in BP with certain biofeedback techniques. However, recommendations for any specific techniques could not be made due to the paucity of data. The statement recommended that biofeedback could be considered for treatment of hypertension. This recommendation was rated as Class IIB, Level of Evidence B recommendation, defined as usefulness/efficacy less well-defined based on conflicting evidence from a single RCT or nonrandomized studies; additional studies with broad objectives needed.

In a 2010 systematic review, Greenhalgh and colleagues concluded, "…we found no convincing evidence that consistently demonstrates the effectiveness of the use of any particular biofeedback treatment in the control of essential hypertension when compared with pharmacotherapy, placebo, no intervention or other behavioral therapies."[72] Trials generally had small sample sizes; only 4 included more than 100 patients. Trials included a variety of biofeedback techniques, and some included more than one modality. Results were not pooled due to differences in interventions and outcomes and the generally poor quality of the studies. Only 1 trial was identified that compared a biofeedback combination intervention to sham biofeedback, and this study did not find a significant difference in the efficacy of the 2 interventions. Only 4 studies on biofeedback alone and 4 on a combined biofeedback intervention reported data beyond 6 months; most of these found no significant differences in efficacy between the biofeedback and control groups. Rainforth and colleagues reviewed randomized, controlled trials and all previous meta-analyses related to stress reduction programs including biofeedback.[73] Each type of therapy was analyzed separately. No significant reduction in blood pressure was achieved using biofeedback alone or biofeedback combined with relaxation training.

Randomized Controlled Trial

In 2013, Landman et al. conducted a randomized, double-blind, sham-controlled trial comparing the effects on blood pressure of lowering breathing frequency in patients with type 2 diabetes and hypertension using active (n=21) and sham (n=24) biofeedback. The changes in systolic blood pressure

from baseline favored the control group while differences in diastolic blood pressure favored the intervention group. However, these differences from baseline, and the differences between the two groups were not statistically significant.

Conclusion

Randomized controlled trials are currently limited to small, short-term studies that do not permit scientific conclusions (see the Background section above). Although there are a large number of RCTs evaluating biofeedback for treating hypertension, evidence is insufficient due to the shortage of studies isolating the effect of biofeedback, the generally poor quality of the trials, and the variability among interventions.

Insomnia **Back to Criteria**

In 2008, an American Academy of Sleep Medicine (AASM) special committee released a guideline on evaluation and management of chronic insomnia in adults.[74] The AASM considers biofeedback as one of a number of common therapies that are "effective and recommended in the treatment of chronic primary and comorbid (secondary) insomnia (Guideline)" The AASM definition for guideline is "a patient-care strategy, which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level 2 Evidence (randomized trials with high alpha and beta error) or a consensus of Level 3 Evidence (non-randomized concurrently controlled studies)."

No other relevant guidelines or clinical trial data were identified.

Motor Function after Stroke, Injury, or Lower Limb Surgery **Back to Criteria**

Systematic Reviews and Meta-analyses

Several systematic reviews have been published; none of these conducted quantitative pooling of results due to heterogeneity among study populations, interventions, and outcome measures. A 2010 systematic review by Silkman and McKeon evaluated the effectiveness of electromyography (EMG) biofeedback for improving muscle function during knee rehabilitation after injury.[75] Four RCTs that compared knee rehabilitation exercise programs with and without biofeedback were identified. Sample sizes in individual studies ranged from 26 to 60 patients. Two of the 4 studies found a statistically significantly greater benefit in the programs that included biofeedback, and the other 2 did not find a significant difference between groups. The positive studies assessed intermediate outcomes e.g., contraction values of the quadriceps muscles. None of the studies were designed to assess functional outcomes.

In 2011, Stanton and colleagues conducted a systematic review and meta-analysis of RCTs evaluating biofeedback to improve activities involving lower limb function after stroke.[76] A total of 22 trials with 591 participants met inclusion criteria. All of the trials had relatively small sample sizes; the largest trial had 54 participants and 15 trials had 30 or fewer participants. The majority of trials (n=17) compared biofeedback plus usual therapy to usual therapy alone. The specific interventions varied; the types of biofeedback included biofeedback of ground reaction force from a force platform with visual and/or auditory feedback (13 trials), muscle activity via visual and/or auditory feedback (5 trials), joint position from an electrogoniometer via visual and/or auditory feedback (3 trials), and limb position via auditory feedback (1 trial). The duration of interventions ranged from 2 to 8 weeks, and intensity ranged between 1 to 5 days per week.

A pooled analysis of data from 17 trials on short-term effect (i.e. 1 month or less) found that biofeedback significantly improved lower limb activities compared to usual care or placebo (standardized mean difference [SMD]: 0.41; 95% CI: 0.21 to 0.62). Outcomes included activities such as directional control during standing, weight distribution between the lower limbs, and gait parameters such as stride length. There was heterogeneity among studies. Trials did not report functional outcomes such as ability to perform activities of daily living (ADL). A sensitivity analysis determined that the heterogeneity was best explained by study quality. When lower quality trials were excluded, biofeedback was still found to improve lower limb activity compared to control conditions (SMD: 0.49, 95% CI: 0.22 to 0.75). A sub-group analysis was also done by type of activity. There was only 1 high-quality trial on standing up (n=40). A pooled analysis of 5 high-quality trials on short-term effect found that biofeedback significantly improved standing outcomes compared to control (SMD: 0.42, 95% CI: 0.05 to 0.78). A pooled analysis of 4 short-term trials on walking also found better outcomes with biofeedback compared to control (SMD: 0.57, 95% CI: 0.10 to 1.03). Five high-quality trials with a total sample size of 136 contributed data to an analysis of long-term term efficacy i.e., 1-5 months after cessation of the intervention. In this pooled analysis, biofeedback was found to improve outcomes compared to control (SMD: 0.41, 95% CI: 0.06 to 0.75).

A Cochrane review that assessed EMG biofeedback for the recovery of motor function after stroke was published in 2007.[77] It included 13 randomized or quasi-randomized studies with a total of 269 patients. All of the trials compared EMG biofeedback plus standard physiotherapy to standard physiotherapy; in addition to standard physiotherapy, several studies also included a sham biofeedback group. The studies tended to be small and poorly designed. The authors did not find support for EMG biofeedback to improve motor power, functional recovery, or gait quality when compared to physiotherapy alone.

A 2010 systematic review by Zijlstra and colleagues searched for studies evaluating biofeedback-based training to improve mobility and balance in adults older than 60 years of age.[78] Although the review was not limited to studies on motor function after stroke, more than half of the studies included older adults post-stroke. For inclusion in this review, studies needed to include a control group of patients who did not receive biofeedback and to assess at least 1 objective outcome measure. A total of 97 potentially relevant articles were identified, and 21 (22%) studies, including 17 RCTs, met the selection criteria. Twelve of the 21 (57%) studies included individuals post-stroke; 3 included older adults who had lower-limb surgery and 6 included frail older adults without a specific medical condition. Individual studies were small with sample sizes that ranged from 5 to 30 patients. The added benefit of using biofeedback could be evaluated in 13 of 21 (62%) studies. Nine of the 13 studies found a significantly greater benefit with interventions that used biofeedback compared to control interventions. However, the outcomes assessed were generally not clinical outcomes but were laboratory-based measures related to executing a task, e.g., moving from sitting to standing in a laboratory setting and platform-based measures of postural sway. The applicability of improvements in these types of measures to clinical outcomes such as the ability to perform activities of daily living or the rate of falls is unknown. Only 1 study cited in this review reported an improvement in fall rates, and this trial could not isolate the effect of biofeedback from other components of treatment. In addition, only 3 studies reported long-term outcomes, and none of these reported a significant effect of biofeedback. Conclusions about the efficacy of biofeedback for improving mobility and balance in older adults cannot be drawn from these data due to the lack of evidence on clinical outcomes. Other methodologic limitations included limited data on the durability of effects and the inability to isolate the effect of biofeedback in many studies.

Randomized Controlled Trials

A 2010 RCT, not included in the Zijlstra et al. review, evaluated biofeedback to improve motor function in patients who were at least 6 months post-stroke.[79] The study, conducted in Italy by Jonsdottir and colleagues, randomized 20 patients to 20 sessions of EMG biofeedback (n=10) or standard rehabilitation (n=10). Patients in both groups received sessions lasting 45 minutes 3 times a week. The biofeedback consisted of an acoustic signal; patients in the intervention group wore a biofeedback belt device. All patients completed the 20 sessions, and 9 in each group (a total of 90%) were available for the follow-up 6 weeks after completion of the intervention. The analyses found statistically significant effects of the biofeedback intervention on the outcome variables ankle power, peak velocity, and stride length but not knee flexion peak from baseline evaluation to the final follow-up. For example, in the treatment group, stride length (percent height per second) increased from 44.1 pre-treatment to 51.1 at final follow-up, and stride length in the control group increased from 33.4 pre-treatment to 35.2 at final follow-up. Although positive, data from this study alone cannot change the conclusion of an insufficient body of evidence on biofeedback to improve motor function after stroke. Moreover, the study did not evaluate outcomes related to activities of daily living, and the biofeedback protocol used in the study has not been replicated in other studies.

In another small RCT, Barcala et al. randomized 20 adults with hemiplegia following stroke to balance training with visual biofeedback or to conventional physical therapy alone.[80] Patients received interventions twice a week for 5 weeks. Both groups demonstrated significant improvement, but no statistically significant differences were found between the 2 groups.

Conclusion

The evidence on biofeedback for improving motor function after stroke is limited by small studies, most of which are not of high-quality and there is variability in the type, duration, and intensity of interventions. In addition, the outcome measured used were primarily assessments of motor activity that were based in a laboratory or research setting. The applicability of improvements in these types of measures to clinical outcomes, such as the ability to perform ADLs or the rate of falls, is unknown. In addition, few studies have reported long-term outcomes. Conclusions about the efficacy of biofeedback for improving mobility and balance in older adults cannot be drawn from the evidence published to date for the reasons discussed above.

Movement Disorders **Back to Criteria**

Since the 1995 TEC assessment, randomized, controlled trials either failed to show any beneficial impact of biofeedback or had design flaws that leave the durability of effects in question or create uncertainty about the contribution of nonspecific factors such as attention or placebo effects.[81-84] A Cochrane review assessing EMG biofeedback for the recovery of motor function after stroke included thirteen randomized or quasi-randomized studies.[77] The authors did not find support for EMG biofeedback to improve motor power, functional recovery, or gait quality when compared to physiotherapy alone, although the results were limited due to small, poorly designed trials. Use of different assessment scales made pooling data for meta-analysis impossible.

Orthostatic Hypotension in Patients with a Spinal Cord Injury **Back to Criteria**

Gillis et al. conducted a systematic review to identify and describe the body of literature pertaining to nonpharmacologic management of orthostatic hypotension during the early rehabilitation of persons with a spinal cord injury.[85] Participants with any level or degree of completeness of spinal cord injury and any time elapsed since their injuries were included. Interventions must have measured at least

systolic blood pressure and have induced orthostatic stress in a controlled manner and have attempted to control orthostatic hypotension during an orthostatic challenge. Four distinct nonpharmacologic interventions for orthostatic hypotension were identified: application of compression and pressure to the abdominal region and/or legs, upper body exercise, functional electrical stimulation applied to the legs, and biofeedback. Methodologic quality varied dramatically between studies. The authors concluded that "…The clinical usefulness of compression/pressure, upper body exercise and biofeedback for treating OH [orthostatic hypotension] has not been proven."

Conclusion

There is insufficient evidence from high-quality controlled studies to permit conclusions about the impact of biofeedback on orthostatic hypotension in patients with a spinal cord injury.

Raynaud's Phenomenon **Back to Criteria**

The Raynaud's Treatment Study Investigators conducted a randomized comparison of sustained-release nifedipine and thermal biofeedback in 313 patients with primary Raynaud's phenomenon.[86] In addition to these two treatment groups, there were two control treatments: pill placebo and EMG biofeedback. EMG biofeedback was chosen as a control because it did not address the physiological mechanism of Raynaud's phenomenon. Nifedipine significantly reduced Raynaud's attacks compared with placebo pill ($p<0.001$), but thermal biofeedback did not differ from EMG biofeedback ($p=0.37$). Better outcome for nifedipine relative to thermal biofeedback was nearly significant ($p=0.08$). With a larger sample size, the rate of 56% fewer attacks with nifedipine relative to thermal biofeedback would likely have been statistically significant. Thus, it cannot be concluded that thermal biofeedback is as effective as this form of medical therapy. A 2009 systematic review identified 5 trials that reported a variety of outcomes. A pooled analysis from 4 trials (total n=110) on the change in frequency of attacks favored the sham control group over the biofeedback group.[87]

Conclusion

There is insufficient evidence from a small number of RCTs that biofeedback is effective as a treatment of Raynaud's disease. A meta-analysis of the available trials did not find that biofeedback was more effective than the control intervention.

Tinnitus **Back to Criteria**

Weise et al. investigated the efficacy of a biofeedback-based cognitive-behavioral treatment for tinnitus in Germany. Tinnitus patients (n=130) were randomly assigned to an intervention or a wait-list control group.[88] Treatment consisted of 12 sessions of a biofeedback-based behavioral intervention over a 3-month period. The primary outcome measures were global tinnitus annoyance and a daily rating of tinnitus disturbance measured by a Tinnitus Questionnaire (TQ) and a daily diary using visual analog scale (VAS) scores. Patients in the wait-list group participated in the treatment after the intervention group had completed the treatment. Results showed improvements regarding the following: tinnitus annoyance; diary ratings of loudness; feelings of controllability; changes in coping cognitions; changes in depressive symptoms; TQ: total score (range 0–84) preassessment mean 54.7, postassessment mean 32.52; TQ: emotional distress (range 0–24) preassessment mean 16.00, postassessment mean 8.15; and diary: loudness VAS (range 0–10) preassessment mean 5.68, postassessment mean 4.38. Improvements were maintained over a 6-month follow-up period in which variable effect sizes were observed. The

study did not investigate the possible additive effect of biofeedback with cognitive-behavioral therapy and did not include an active treatment control group.

Conclusion

These data are insufficient to draw clinical conclusions regarding the role of biofeedback for the treatment of tinnitus.

Urinary Incontinence **Back to Criteria**

Technology Assessments

A 1997 BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessments focused on the independent contribution of biofeedback as an adjunct to pelvic floor muscular exercises for the treatment of urinary incontinence. The 1997 TEC Assessment concluded that while the controlled trials that isolated the contribution of biofeedback reported conflicting results, the weight of the evidence suggested no additional benefit for biofeedback above that obtained with pelvic floor muscle exercises alone.[89] All of the trials had low power to detect a small difference in outcomes; therefore, the possibility exists that larger trials with improved statistical power could demonstrate a beneficial effect of biofeedback. However, the TEC Assessment concluded that based on the available data, any such benefit, if present, was likely to be small and may not be clinically significant.

The conclusions of a 2000 TEC Assessment[90] were similar to the 1997 assessment, i.e., that the evidence was not sufficient to demonstrate an additional benefit for biofeedback above that obtained with pelvic floor muscle exercises (PME) alone:

1. Six controlled trials reported outcomes of biofeedback for the treatment of stress incontinence.

   These trials failed to demonstrate that the addition of biofeedback was superior to PME alone

2. One small, non-randomized study focused on patients with urge incontinence.

   There was no statistically significant improvement in outcomes for the biofeedback plus PME group as compared to the PME-alone group.

3. One randomized trial investigated biofeedback in men with post-prostatectomy incontinence, a relatively uncommon indication for biofeedback at that time.[91]

   A total of 30 patients were randomized to usual care or usual care plus biofeedback. Both groups improved significantly over time, but there was no difference between groups in the magnitude of improvement.

The focus of the both the 1997 and 2000 TEC Assessments contrasted with the 1996 assessment on treatment of incontinence published by the Agency for Healthcare Research and Quality (formerly the Agency for Health Care Policy and Research, AHCPR)[92] While the AHCPR assessment endorsed the use of behavioral therapy as a first-line treatment of incontinence, and identified biofeedback as a component of behavioral therapy, the AHCPR did not specifically evaluate the independent contribution of biofeedback to an overall behavioral approach.

Systematic Reviews

A 2011 Cochrane review evaluated feedback or biofeedback in conjunction with pelvic floor muscle training (PFMT) for treating urinary incontinence (UI) in women.[93] The review included randomized controlled trials (RCTs) in women with stress, urge or mixed UI in which at least two arms of the study included exercise training and at least one arm included feedback and/or biofeedback. Feedback was defined as verbal feedback by a clinician, whereas biofeedback involved use of an instrument or device. After examining 36 full-text articles, 24 trials were found to meet the review's inclusion criteria and 17 contributed data to the analysis of at least one primary outcome measure. Sixteen of the 24 trials included a comparison of PFMT plus biofeedback to PFMT alone; nine of these included the same PFMT programs in both groups. The primary outcomes of the review were quality of life and improvement or cure. Nine trials used one of several validated quality-of-life instruments; however, only four of these reported data in a form that could be used for meta-analysis. Thus, quality-of-life results were not pooled. Data were pooled for the other primary outcome, improvement or cure, but there were a sufficient number of studies only for the comparison between PFMT with and without biofeedback. In a pooled analysis of seven studies, there was a significant reduction in the proportion of women reporting 'no improvement or cure' when biofeedback was added to muscle exercise (risk ratio [RR]: 0.75, confidence interval [CI]: 0.66 to 0.86). The authors noted that there may have been other differences between groups, such as more frequent contact with a healthcare professional or a greater number of treatment sessions, which might partially explain the difference in the improvement or cure rate in women who did or did not receive biofeedback. Moreover, when only the outcome 'no cure' was examined, there was not a significant difference between groups that did and did not receive biofeedback (5 studies: RR: 0.92, 95% CI: 0.81-1.05). Among secondary outcomes, a pooled analysis of seven trials did not find a significant difference in leakage episodes in a 24-hour period after treatment (mean difference: -0.01, 95% CI: -0.21 to 0.01). For the outcomes frequency and nocturia, data could not be combined but the review authors reported that the pattern was one of no difference between groups.

A number of significant design flaws in the 24 trials that met inclusion criteria (1583 women total) limit the reliability of the reported outcomes. These flaws included:

- It was common for the women in the biofeedback arm to have more contact with healthcare professionals than those who did not receive biofeedback.
- Many of the trials were at moderate to high risk of bias.
- There was significant variation in the regimens proposed for feedback and biofeedback, and the intervention's purpose and composition were often unclear.

The authors concluded that feedback or biofeedback may provide additional benefit to PME alone; however, further research is needed to differentiate whether the beneficial effect was due to feedback, biofeedback, or some other difference between the trial arms.

Randomized Controlled Trials

Numerous RCTs have evaluated biofeedback as a treatment of urinary incontinence (UI) in women. However, the methodology of the studies varied, and many were not able to isolate the potential contribution of biofeedback.

One double-blind, sham-controlled RCT was found that compared transvaginal electrical stimulation (TVES) with active (n=68) or sham (n=34) EMG-biofeedback in premenopausal women with stress urinary incontinence (SUI).[94] The group receiving active biofeedback had significantly better results than the sham group for reduction in urinary leakage, pelvic floor muscle strength, and incontinence-related quality of life. No significant between group difference was found in urodynamic data. The authors concluded that TVES with active EMG biofeedback "is a trustworthy method for treating premenopausal women with stress urinary incontinence; however reliability needs to be established."

Nonrandomized Trials

In a 2010 article that was not included in the 2011 Cochrane review, Huebner and colleagues compared biofeedback-assisted PME with conventional electrical stimulation, biofeedback-assisted PME with dynamic electrical stimulation, and biofeedback-assisted PME alone.[95] With conventional electrical stimulation, the electrical stimulation was applied when the patient was at rest, whereas dynamic electrical stimulation involved applying the stimulation while the patient was actively contracting. The study included 108 women with stress or mixed incontinence. The treatment period was 3 months, at which time 88 of 108 (81.5%) were evaluated. The primary outcome, change in quality of life, as measured by the King's health questionnaire, did not differ significantly among groups. The quality of life scores decreased by a mean of 20.7 points in the group with conventional electrical stimulation, 24.8 points in the group with dynamic electrical stimulation, and 20.2 points in the group with only biofeedback-assisted PME. The groups also did not differ significantly on other outcome measures. This study did not include a group that received PME alone without biofeedback.

The National Institutes of Health released a conference statement stating that, "Pelvic floor muscle training and biofeedback are effective in preventing and reversing some pregnancy-related fecal and urinary incontinence for the first year after delivery.[96] There is insufficient research on the sustained long-term benefits of pelvic floor muscle training or biofeedback on preventing fecal or urinary incontinence."

Clinical practice guidelines from the American College of Obstetricians and Gynecologists recommended behavioral therapy that included bladder training and prompted voiding.[97] Biofeedback was not included in this recommendation. Data show that behavioral training with biofeedback results in a 63 percent mean reduction in incontinence episodes, compared with a 69 percent mean reduction following verbal feedback and a 59 percent mean reduction after receiving a self-help booklet.

Post-Prostatectomy Urinary Incontinence **Back to Criteria**

Systematic Reviews

A systematic review of PME to improve post-prostatectomy urinary incontinence identified three studies (281 men) that focused on the incremental value of biofeedback over written/verbal PME.[98] Although PME appeared to reduce the time to recover continence compared to no training, there was no evidence for an advantage of training with biofeedback over written/verbal instructions. None of the individual trials found a statistically significant difference in outcomes between groups.

Randomized Controlled Trials

Several RCTs have been published since the MacDonald review. In 2012, Tienforti and colleagues in Italy compared biofeedback (a session before and after surgery) in combination with written/verbal

instructions on performing pelvic floor muscle exercises to a control intervention of written/verbal instructions alone.[99] The study included 34 patients, 32 of whom (16 in each group) were available for the final 6-month analysis. By 6 months, 10 of 16 patients (62.5%) in the treatment group and 1 of 16 patients (6.3%) in the control group had achieved continence; this difference was statistically significant (p value not reported). The mean number of incontinence episodes per week was also significantly lower in the intervention group (2.7) than the control group (13.1) at 6 months.

Two trials, summarized in detail below, have evaluated the combination of biofeedback and electrical stimulation in men with post-prostatectomy incontinence. The two trials had mixed findings. Mariotti et al. (2009) found a beneficial effect of the combined intervention of biofeedback and electrical stimulation, whereas the Goode et al. study did not find a benefit compared to behavioral therapy alone. Both studies were limited in that they did not isolate the effect of biofeedback, and thus the independent effect of biofeedback on outcomes cannot be determined.

- Mariotti and colleagues conducted a randomized controlled trial comparing a program of pelvic floor electrical stimulation and electromyographic biofeedback (treatment group, n=30) to written/verbal instructions for pelvic muscle exercises (control group, n=30) with 6 months follow-up.[100] The mean time to regain continence was significantly shorter in the treatment group (8.0 weeks) than the control group (13.9 weeks), p=0.003. The continence rate was significantly higher in the treatment group beginning at the 4-week visit and continuing through the 20-week visit at which time 29 of 30 (96.7%) in the treatment group and 18 of 30 (60%) in the control group were continent. The difference in the rate of continence was not statistically significantly different at the final, 6-month visit at which time 29 patients in the treatment group continued to be continent and 20 of 30 (66.7%) in the control group. This is one study suggesting that biofeedback in combination with pelvic electrical stimulation may shorten the time to continence after prostatectomy; however, the effect of biofeedback without electrical stimulation compared to written/verbal instructions to perform pelvic floor muscle exercises was not evaluated.

- In 2011, Goode and colleagues published the results of a randomized trial comparing behavioral therapy alone to behavioral therapy in combination with biofeedback and pelvic floor electrical stimulation.[101] The trial included 208 men with urinary incontinence (UI) persisting at least 1 year after radical prostatectomy. Men with pre-prostatectomy incontinence were excluded. Participants were randomized to 1 of 3 groups; 8 weeks of behavioral therapy (pelvic floor muscle training and bladder control exercises) (n=70), behavioral therapy plus biofeedback and electrical stimulation (n=70), and a delayed-treatment control group (n=68). The biofeedback and electrical stimulation intervention, called "behavior-plus," consisted of in-office electrical stimulation with biofeedback using an anal probe and daily home pelvic floor electrical stimulation. After 8 weeks, patients in the 2 active treatment groups were given instructions for a maintenance program of pelvic floor exercises and fluid control and were followed up at 6 and 12 months. The primary efficacy outcome was reduction in the number of incontinent episodes at 8 weeks, as measured by a 7-day bladder diary. A total of 176 of 208 (85%) randomized men completed the 8 weeks of treatment. In an intention-to-treat analysis of the primary outcome, the mean reduction in incontinent episodes was 55% (28 to 13 episodes per week) in the behavioral therapy group, 51% (26 to 12 episodes per week) in the behavior-plus group, and 24% (25 to 20 episodes per week) in the control group. The overall difference between groups was statistically significant (p=0.001), but the behavior-plus intervention did not result in a significantly better outcome than behavioral therapy alone. Findings were similar on other outcomes. For example, at the end of 8 weeks, there was a significantly higher rate of complete continence in the active treatment groups (11 of 70, 16% in the behavior group and 12 of 70, 17% in the behavior-plus group) than the control group (4 of 68, 6%), but the group

receiving biofeedback and electrical stimulation did not have a significantly higher continence rate than the group receiving behavioral therapy alone.

One RCT compared the effect of preoperative pelvic floor muscle therapy plus biofeedback (n=65) with standard care (n=56) of SUI in men undergoing laparoscopic radical prostatectomy.[102] Follow-up was 1-year, with 19 patients excluded due to early drop-out. No significant difference was found between the two groups for leakage and quality of life. Continence was achieved in 77.2% of patients at 1-year following prostatectomy.

Other Urinary Incontinence **Back to Criteria**

A randomized study of 74 patients with multiple sclerosis reported that the addition of neuromuscular electrical stimulation with biofeedback training resulted in 85% incontinence reduction, compared to a 47% incontinence reduction in the control group trained only with biofeedback.[103]

Other Indications

Other indications for which there are no clinical trial publications sufficient to demonstrate the effectiveness of biofeedback include, but are not limited to the following:

- Cardiovascular disorders **Back to Criteria**
- Chronic fatigue syndrome **Back to Criteria**
- Chronic obstructive pulmonary disease (COPD) **Back to Criteria**
- Depression **Back to Criteria**
- Epilepsy **Back to Criteria**
- Facial palsy **Back to Criteria**
- Hand hemiplegia **Back to Criteria**
- Low vision **Back to Criteria**
- Post-traumatic stress disorder **Back to Criteria**
- Side-effects of cancer chemotherapy **Back to Criteria**

Summary

Despite the poor quality of case series and randomized controlled trials, biofeedback has evolved into a standard of care as part of comprehensive regimens, including medication and relaxation techniques, for treatment and prevention of tension-type headaches, and the prevention of migraine headaches. Therefore, biofeedback may be considered medically necessary for those indications.

Several well-conducted randomized controlled trials that focused on patients with dyssynergia-type constipation suggested benefits in a sub-group of patients who meet criteria similar to trial participants. In addition, two U.S. clinical practice guidelines consider biofeedback to be an option for pelvic floor training for dyssynergia constipation. Therefore, biofeedback may be considered medically necessary in adult patients with dyssynergia-type constipation who meet selection criteria.

Biofeedback has been studied for a wide variety of clinical indications, a majority of which are considered investigational. For the investigational indications discussed above, the evidence is not sufficient to permit conclusions concerning the independent effects of biofeedback on final health outcomes. Studies for these indications are limited and often suffer from methodologic limitations which impact the reliability of the reported results. In some cases, no beneficial results are reported, or conflicting results are reported from different studies for the same indication. For all of the investigational indications discussed above, well-designed randomized controlled trials are needed to determine whether biofeedback results in improved health outcomes compared with standard therapies.

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CROSS REFERENCES

Neurofeedback, Medicine, Policy No. 65

Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence, Surgery, Policy No. 130

Posterior Tibial Nerve Stimulation for Voiding Dysfunction, Surgery Policy No. 154

CODES	NUMBER	DESCRIPTION
CPT	90875-90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying, or supportive psychotherapy); code range
	90901	Biofeedback training by any modality
	90911	Biofeedback training, perineal muscles, anorectal, or urethral sphincter, including EMG and/or manometry
HCPCS	E0746	Electromyography (EMG), biofeedback device