Ethical and Practice Considerations for Biofeedback Therapists in the Treatment of Urinary Incontinence

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The treatment of incontinence presents many unique issues for biofeedback therapists that are routine for professionals in fields such as nursing or medicine. Although all professional practice is guided by ethical standards, the unique circumstances encountered during biofeedback treatments for this disorder warrant the development of specific guidelines. This is true whether insertable or surface EMG devices are used. Therefore, the purpose of this article is to propose a set of ethical guidelines for biofeedback therapists. The intended audience includes professionals such as psychologists, clinical psychophysiologicals, and other mental health-care providers who use biofeedback techniques. These are not formally endorsed by any professional organizations (e.g., APA, AAPB) at this time. Ethical considerations include proper medical evaluation, informed consent, patient instruction, disrobing, nonerotic physical contact, patient safety, and patient satisfaction.

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Biofeedback treatment of urinary incontinence (UI) involves procedures that can present issues not typically seen in a psychotherapeutic relationship. The purpose of this article is to propose a set of ethical guidelines for such treatments. Ethical considerations for biofeedback therapists will also be discussed in relation to defensive practice. The intended audience includes professionals such as psychologists, clinical psychophysiologists, biofeedback technicians, and other mental health-care providers who use biofeedback techniques (Schwartz, 1995). The major issues are proper medical evaluation, informed consent, patient instruction, disrobing, non-erotic physical contact, patient safety, and patient satisfaction.

The uniqueness of biofeedback treatment for UI can be illustrated with a description of some of the major equipment involved. Often, vaginal or rectal probes connected to computerized biofeedback instruments are inserted into the client. These probes transduce the muscular activity of the pelvic floor or the abdomen depending on their placement.

Five different types of instruments are currently used. One of the most common instruments used in biofeedback treatment of UI is the rectal tube. As described by Middaugh, Whitehead, Burgio, and Engel (1989), this method simultaneously assesses pelvic floor and abdominal muscle pressure. The tube is comprised of three balloons. Increases in pressure in the balloons are highly correlated with nearby muscle contractions. The first balloon measures pressure at the external anal sphincter, the second balloon serves to hold the tube in place, and the third balloon measures rectal and abdominal pressure.

A second type of device is a specially designed electromyography (EMG) sensor, called the perineometer (Perry & Hullett, 1990; Tries & Eisman, 1995). This probe is designed to directly measure pelvic floor muscle activity. It can be inserted either vaginally or rectally. The perineometer transduces the electrical activity produced during muscle contractions. This probe has also been used in home practice protocols with portable feedback apparatus. In these instances the patient inserts the probe herself.

A third type of instrument includes the fluid-filled intravaginal balloon device (IVBD). The IVBD is inserted vaginally and connected to a pressure transducer. Like the rectal tube, the IVBD provides measurement of pressure changes associated with nearby pelvic contractions (Dougherty, Abrams, & McKey, 1986). A fourth device related to the IVBD, termed a posterior balloon device, has been developed to measure intraabdominal pressure. It, too, is a fluid-filled balloon that is inserted vaginally, but it is placed at the back of the vagina near the fornix (Dougherty, Bishop, Abrams, Batich, & Gimotty, 1989).

A fifth type of assessment approach is based on more traditional surface EMG techniques. Standard pediatric disposable EKG electrodes are
placed on the perianal region. This approach has been applied successfully in several clinical trials (Drew, 1990; O'Donnell & Doyle, 1991). A related approach uses surface fabric electrodes to measure pelvic floor EMG (Workman, Cassisi, & Dougherty, 1993). This type of sensor holds promise because it may be woven into undergarments and may be more convenient for both therapists and patients (Watt, 1995). In an initial validation study, this type of electrode was shown to correlate \( r = .75 \) with the IVBD (Workman, Cassisi, & Dougherty, 1993). Clearly more research is needed before fabric electrodes can be widely advocated.

All psychological and biofeedback-related practice is guided by ethical standards (Association for Applied Psychophysiology and Biofeedback [AAPB], 1992; American Psychological Association Ethics Committee, 1992; Biofeedback Certification Institute of America [BCIA], 1992). The unique and intrusive circumstances created by these specialized procedures along with the anticipated increase in referrals for behavioral treatment warrant the development of additional specific guidelines for biofeedback therapists. These are not formally endorsed by any professional organizations (e.g., APA, AAPB) at this time. They were derived from the authors' clinical experiences, the literature for related treatment programs (e.g., sex therapy), and the literature from related professions (e.g., gynecology).

**MEDICAL EVALUATION**

There are a number of serious medical conditions that can lead to UI; therefore a collaborative model of health care service delivery is required (Olsen, 1995). A gynecologic/urologic screening is the first step in assessment. This is not, however, to say that the client must be a direct referral from a physician. Often the biofeedback therapist will be referring clients to physicians for the first time. Thus the referral process works both ways. If a client has been recently evaluated by an appropriate physician, records must be obtained regarding previous gynecologic/urologic examinations. If no recent examination has been conducted, the therapist maintains the responsibility to refer the client for such examination. If not functioning within the scope of a multidisciplinary practice, the therapist should cultivate close referral relationships with other medical personnel (BCIA, 1992).

The therapist has ultimate responsibility for evaluations, including verification of patient testing for medical causes of UI (e.g., yeast infection, chlamydia). Furthermore, “the individual must have the cognitive and perceptual motor ability and emotional readiness to participate in training” (AAPB, 1992, p. 23). This may require screening of expectations and cog-
nitive status. Additionally, behavioral analysis of the antecedents and consequences of incontinence episodes should also be evaluated. All requests for patient records require signatures for the release of information. Request for the release of patient records can be followed up via verbal consultation if necessary.

INFORMED CONSENT

Room for patient misunderstanding with this type of treatment is an obvious concern. Therefore, it is important that a detailed informed consent be secured. A formal consent document is not typically required within the scope of psychotherapy and behavior therapy; however, these unusual circumstances warrant its necessity. This issue is analogous to in vivo desensitization, for example, where the therapist may be required to accompany a patient into a public bathroom when treating parauresis (Goisman & Gutheil, 1992). Percival and Striefel (1994) indicate that surveyed members of the Association for Applied Psychophysiology and Biofeedback (AAPB) find both written consent (84%) and verbal instruction (94%) to be highly ethical behaviors, thereby, advocating usage in the clinical setting. An example consent outlining methods, techniques, and expectations, as well as fees is presented in Figure 1. It is more than a document; it is a dialogue (Goisman & Gutheil, 1992).

The right to informed consent was first judicially recognized in the case Scholendorff v. Society of N.Y. Hospital (1914). In 1972, some modifications were made in that doctrine which, according to Brakel, Parry, and Weiner (1985), shifted "the burden of obtaining information toward the treatment provider, holding that prior to treatment, the patient must be apprised of the diagnosis, the nature of the contemplated treatment, the risks inherent in such treatment, his prognosis with and without the treatment and any possible alternative approaches to alleviate the problem (p. 340)." Thus, the practitioner holds responsibility to secure understanding from the client. Full discussion of therapy, methods, and techniques is paramount (Society for the Scientific Study of Sex [SSSS], 1991; Woody, Alperstein, Daily, Earle, Gilmore, Hotchner, Lunquist, & Tatum, 1992). Patients should also be completely informed in advance about per use fees for home equipment and how charges are billed. It can become problematic if the consent form is worded in such a way as to heighten client expectations of the equipment or the outcome (Keifer, 1993), or mislead the client about the charges for equipment usage and services rendered.

Not every patient can demonstrate the ability to provide informed consent (SSSS, 1991). Hence, the practitioner must ensure that informed
INFORMED CONSENT FORM

I, __________________, consent to receive biofeedback treatment for my bladder control problem (urinary incontinence). The risks, benefits, and alternatives of this treatment were explained to me by Dr. ______________.

I was told that my treatment includes undressing in private. I understand that a sensor device will be placed vaginally (or rectally) by my therapist. Wires coming from the sensor will then be connected to a computer that measures muscle tension. From this computer, I will be better able to tell which muscles to squeeze during exercise. Also, I will see and hear how much I am squeezing those muscles.

I understand I should practice my exercises as shown to me at the office at least three times a day. I know that the results of this treatment vary from person to person and that any benefits may not be noticeable for several weeks.

Any devices given me for use at home will be washed, safely stored, and kept away from children.

I know that I will be charged $_______ per session for this treatment. I understand that if I do not return the equipment, I will be billed $_______ for its replacement.

I have read and understand the above consent and I have been given an opportunity to ask questions about bladder control problems and this treatment. If I have future questions I know I can call Dr. ______________ at ________.

I voluntarily choose to particulate in this treatment as described to me. I understand that I may stop this treatment at any time for any reason.

__________________________  __________________________
Patient’s Signature   Date

__________________________  __________________________
Witness   Date

Fig. 1. A sample informed consent form for a legally competent adult. Two copies are signed. The patient is given one copy and the other is kept in the clinic chart. The authors do not warrant that this document meets requirements in any particular jurisdiction. Local variations in application of the doctrine of informed consent do exist. Local rules, including Institutional Review Board approval, should be observed. This form requires a 9th grade reading level as indicated by the Flesch-Kincaid index (Kincaid, Fishburne, Rogers, & Chissom, 1975).
is the key to obtaining informed consent. How the information is presented is just as important as what is presented.

PATIENT INSTRUCTION

Despite a large literature on the treatment of UI, not many sources contain detailed instructions to give patients for proper execution of the exercises. Specific treatment protocols are described in Corcos, Drew, and West (1992), Perry (1990), Tries and Eisman (1995), and Watt (1995); other variants exist. The percentage of individuals who have difficulty in correctly performing pelvic floor exercises is unknown. Therefore, no matter which instructional protocol one follows, it should include both face-to-face training and continuous monitoring of progress.

The optimal number and duration of in-clinic training sessions prior to assigning home practice with portable units is an open empirical question. Initial evidence suggests that brief and informal instruction in pelvic floor exercises do not generalize over time for most patients (Watt, 1995). Furthermore, issuing home trainers until primary face-to-face training has been undertaken is not permitted by current AAPB standards (1992, p. 15).

DISROBING

Surveyed AAPB members also indicated that they felt it is unethical for the client to disrobe in the presence of the biofeedback therapist (Percival & Striefel, 1994). As in some sexual therapy cases, biofeedback therapy with UI patients requires the patient to disrobe. Patients generally recognize the necessity for disrobing when visiting certain health professionals, such as physicians or nurses, but not for psychologists or other types of counselors. The former professions have developed practices to deal specifically with this issue (Court, 1987). Similar procedures for biofeedback therapists are becoming increasingly necessary as referrals for UI increase.

Accepted standards and procedures for patient disrobing while in biofeedback therapy should follow the basic principle of preserving the patient's dignity. Something as simple as providing a private changing room serves this end. Sometimes, however, additional dressing space is not available. Other alternatives include draping or screening off a section of the biofeedback room, or merely leaving the room while the patient is disrobing. Court (1987) advocates the use of a clear contract outlining these issues to eliminate any misunderstanding or confusion.
NONEROTIC PHYSICAL CONTACT

Nonerotic physical contact is also necessary when working with biofeedback. With the recent media attention to improper conduct by various health care professionals, the issue of touch within the therapeutic session can be somewhat uncomfortable for both client and therapist. The situation can become even more amplified when the practitioner is working with a patient of the opposite gender (Holub & Lee, 1990). That is, however, not to discount the importance of this issue when the therapist and the client are of the same gender. Unexpected touching could compromise the patient’s compliance with the treatment program or, at worst, the situation could be twisted into an issue of sexual misconduct (Goisman & Gutheil, 1992). One solution is to require the presence of a third party during treatment (Court, 1987).

Modern biofeedback equipment typically allows for home practice between office visits. Home practice via the portable biofeedback unit has been shown to improve the likelihood of success in cases of severe UI (Burns, Pranikoff, Nochajski, Hadley, Levy, & Ory, 1993). However, home trainers require that the patient properly attach the probe to herself. This requires in-office demonstrations, which can be problematic for the biofeedback therapist who is not also a M.D., R.N., or L.P.N. Biofeedback therapists should be trained in this particular aspect of patient care before they conduct in-office demonstrations.

Until a biofeedback therapist receives proper training in the implementation of insertable devices, a collaborative or multidisciplinary team approach should be used (Olsen, 1995). This approach offers several advantages. For example, as part of the team, a gynecologist or urologist conducts the initial pelvic examination and screening tests, an R.N. or L.P.N. conducts equipment demonstrations to patients, and the biofeedback therapist conducts thrice weekly training sessions. On first glance this may appear to be an inefficient and expensive use of personnel. However, if staff are staggered properly, the majority of training sessions can actually be conducted by supervised technicians, thereby significantly increasing cost effectiveness. Percival and Striefel (1994) have found that there are no significant differences in ethical beliefs across health care disciplines; therefore, from an ethical standpoint, this approach should not be difficult to implement.

In the future, the use of female urinary catheterization simulators (e.g., No. 956, Denoyer-Geppert, Chicago, IL) may be adapted for patient training to ensure proper insertion of the probe. Alternatively, mannequins may be used to illustrate proper placement of sensor undergarments. These may prove to be viable options for the biofeedback therapist to directly placing
a probe or sensor himself or herself. However, the effectiveness of these options needs to be empirically evaluated in terms of patient accuracy.

**PATIENT SAFETY**

The client's safety must also be addressed in terms of environmental influences endemic to this specific therapy. The physical environment must be appropriate to support the equipment and procedures (Court, 1987). As well as the changing room, hardware issues (e.g., electrical wiring) should be anticipated. Generally accepted guidelines for psychophysiological laboratory safety should be followed (AAPB, 1992, p. 78; Andreassi, 1989, pp. 455-458). Widespread use of equipment not approved by the appropriate authorities could potentially pose a threat to both client and clinician. For example, many hospitals require approval from a Department of Biomedical Engineering to ensure equipment safety. If available, safety approval from the appropriate authority in the primary place of practice should be obtained.

Proper infection control procedures must be observed at all times. Insertable devices must be sterilized between patients. While not necessarily the most cost-effective approach, the therapist may decide to issue vaginal or rectal probes to each patient individually and not reuse them across patients. In addition, areas for thorough handwashing, and proper disposal receptacles must be provided. Furthermore, patients should be instructed in proper cleaning and maintenance of equipment between uses at home.

The issue of client safety can also be addressed through a collaborative team approach. Complications may occur during insertion or removal of either vaginal or rectal probes which would necessitate medical attention. One scenario that may be encountered is the presence of blood on the probe upon removal. While there are many possible explanations for this occurrence, it would be to the advantage of both the client and the therapist to have medical personnel available.

**PATIENT SATISFACTION**

Monitoring patient satisfaction is an additional measure in the pursuit of ethical responsibility. Scott (1992) discusses the importance of (1) listening to the patient, (2) maintaining an understanding attitude, and (3) looking for signs of dissatisfaction (e.g., frequent phone calls because the patient feels he/she is “not getting better”). By maintaining the appropriate attitude and listening to what the client is saying, issues related to this
therapeutic alternative can be remedied before they become problematic. Furthermore, clients can be hesitant to complain for fear that it will impact the quality of care received. Adequate time should be allotted at the beginning and end of each session to allow for face-to-face verbal interaction. By careful listening and prompting during that time, costly misunderstandings can be avoided. It is also important to continually monitor home progress to assure compliance with the program and satisfaction with the outcomes.

CONTINUING EDUCATION AND CERTIFICATION

Whereas a compliant patient is an integral factor related to the success of biofeedback treatment, success is ultimately reliant upon the knowledge and skill of the provider (Urinary Incontinence Guideline Panel, 1992). Supervised practice and training requirements for certification should be observed (Court, 1987; SSSS, 1991). General certification, such as that supplied through the BCIA, further assures competent and thoroughly trained practitioners (AAPB, 1992, p. 112-113). In addition, the therapist retains responsibility for obtaining continuing education (BCIA, 1992). Lastly, the therapist must recognize the limitations of his/her competence and act upon that accordingly (Woody et al., 1992).

A need for advanced certification in biofeedback for urinary incontinence may eventually be necessary. The BCIA currently does not have any established advanced biofeedback certification programs. A potential curriculum for this specific treatment area would include training in placement of insertable devices and pelvic floor muscle strength evaluation. The parameters of coursework in terms of content and duration need to be established by BCIA. The content and duration should be parallel to that required by other related disciplines (e.g., occupational therapy, physical therapy).

CONCLUSIONS

Ethical responsibility and defensive practice can reduce the risk of liability related to biofeedback therapy (Ennis, Clark, & Grudzinskas, 1991; Goisman & Gutheil, 1992). Ethical behavior includes "keeping updated on ethical principles and state laws that affect the practice of biofeedback" (Percival & Striefel, 1994). Under the directive to "do no harm," ethical and defensive practice strategies should always be in place. In any case of liability, the complainant must prove that "as a direct causal result of ne-
Table I. Recommended Procedures for the Psychologist Using Biofeedback Treatment for Urinary Incontinence

1. Obtain gynecologic/urologic screening to verify medical causes of incontinence.
2. Obtain informed consent, including verbal verification of patient understanding.
3. Ensure patients receive sufficient face-to-face training and instruction for proper performance of exercises and operation of home trainers.
4. Maximize patient privacy during patient dressing/undressing.
5. Minimize physical contact and have a third party present during treatment.
6. Follow laboratory safety guidelines and maintain proper infection control procedures.
7. Assess patient satisfaction through both continuous dialogue, active listening, and home practice monitoring.
8. Stay current with advances in treatment practices through continuing education.

glect, the therapist breached a duty of care to the patient and specific damages resulted" (Goisman & Gutheil, 1992). While this definition represents a worst case scenario, the therapist, at the very least, wants to avoid bad feelings (Goisman & Gutheil, 1992). Again, detailed informed consent, clear lines of communication, and concise documentation (Goisman & Gutheil, 1992) are the best methods to ensure commitment to ethical responsibility. Table I summarizes the key points presented in this article.

In summary, the treatment of incontinent patients with biofeedback presents many unique issues to the therapeutic setting. As biofeedback technology equipment advances, less invasive alternatives will become available to therapists. Nevertheless, whether using insertable (e.g., vaginal probes) or surface EMG equipment, this behavioral treatment raises unique issues. As outlined, a collaborative team approach and awareness of these special issues (e.g., disrobing and touching) can ensure a more successful outcome. Lastly, informed consent, which should include both a written contract and a dialogue of understanding, is one of the best tools available to secure the most effective therapeutic environment.

REFERENCES

Ethical and Practice Considerations


Scholendorff v. Society of N.Y. Hospital, 211 N.Y. 125, 105 N.E.92 (1914).


