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SPECIAL SECTION

The Glazer Protocol: Evidence-Based Medicine Pelvic Floor Muscle (PFM) Surface Electromyography (SEMG)

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The authors cite a Medline review article of biofeedback for urinary incontinence to demonstrate the pervasive lack of standardized operationally defined variables, which precludes the application of evidence-based-medicine standards to the field. As an example of an early-stage evidence-based-medicine model, the Glazer Protocol demonstrates how empirically derived and operationally defined SEMG characteristics hold great promise for a better understanding of the pathophysiology of urinary incontinence and can assist in both diagnosis and treatment of this disorder.

Introduction

Case studies, clinical experience, patient experiences, and expert opinions are not scientific evidence. This doesn't take away from the importance of clinical thinking. Often experiences in clinical practice are the incubator of hypotheses, which are then subject to evidence-based-medicine research. The cycle is completed with evidence-based research findings returning to clinical practice, where implementation can benefit clinician thinking and patient care. Evidence-based medicine applies scientific methodology to health care practices. It assesses the quality of evidence relating to risks and benefits of treatments. The power of evidence-based data lies in freedom from bias. The most powerful evidence for therapeutic efficacy comes from prospective, randomized, double-blind, placebo-controlled trials with all dependent, independent, and intervening variables operationally defined. The application of these scientific standards to the assessment of biofeedback efficacy presents significant challenges. Very little of the published literature in biofeedback demonstrates this highest level of evidence-based efficacy, with double-blind randomized control trials. Biofeedback focuses on altering physiology, associated experiential states, and functionality, by learning to voluntarily self-regulate a signal derived from the continuous measurement of a defined organic tissue or system, such as muscle, brain, blood flow, or respiration. By its very nature, biofeedback stands at the crossroads of subjective experience (e.g., cognition, perception, motivation, affect) on one hand, and organic tissue and process (e.g., anatomy, physiology, organic chemistry), on the other hand. This makes the historical philosophical issues of dualism, mind-body, and reductionism, reducing unique internal experiences to organic events (Kenny, 1968), a core problem in applying evidence-based-medicine rules to a process melding both scientific technology and individual experience.

The argument can therefore be made that biofeedback, by its very nature, cannot reach the highest levels of evidence-based medicine. However, taking this position concedes that biofeedback can never be subject to the true standards of modern science to determine its efficacy. Although some evidence-based techniques to control bias, such as double blind, present obvious challenges to their use in biofeedback research, other evidence-based-medicine standards, such as operationalizing research variables, can create a more unbiased study of biofeedback and increase recognition of its merit.

Biofeedback research is subject to bias, primarily due to the lack of standardization of technology and techniques and failure to employ operationalized protocols, procedures, and

definitions. This bias is exemplified in a recent review article (Glazer & Laine, 2007), summarizing the peer-reviewed literature in the use of pelvic floor muscle (PFM) biofeedback for the treatment of functional urinary incontinence. This review reported a total of 326 studies found in Medline between 1975 and 2005. Only 8.6% of these studies operationally defined independent and dependent variables, utilized prospective randomized trials with parametric statistical analyses (statistical tests making assumptions, such as normal distribution and equal variance, when comparing two populations, about the parameters of the entire population from which they are drawn), and used specific patient selection criteria to rule out organic causes of urinary incontinence. Among these 27 studies were six different operational definitions for the diagnosis, eight operational definitions for treatments, 12 operational definitions for biofeedback protocols, and six operational definitions for treatment outcome. In 30 years of peer-reviewed literature, only seven studies reported a comparison of biofeedback to a matched, no-treatment, control group. For these seven studies, differences in biofeedback instrumentation, signal processing, assessment and treatment protocols, biofeedback modalities, and multiple uncontrolled intervening variables made each of these groups so different that there was no standardized definition of biofeedback. The same was true in studies employing within-group variables, since the treatments being compared also included many intervening variables, which were neither controlled nor randomized. This pervasive lack of standardization has hampered the scientific assessment of biofeedback by effectively precluding the application of evidence-based-medicine standards to the field.

Intake forms can be standardized for systems review and disorder-related history taking. All disorders and interventions under investigation can be operationalized by use of diagnostic and procedural coding provided by ICD-9-CM (Ingenix, 2012), DSM (American Psychiatric Association, 2000), and CPT (American Medical Association, 2010) systems. Measurement technology, such as SEMG signal processing, evaluation by performance of defined activity sequencing, data recording and storage, database development, and statistical analyses can also be standardized. All hold promise for the introduction of operationalized, evidence-based-medicine data into the field of biofeedback. Specific examples of how the Glazer Protocol standardizes levels of variables in clinical research can be found in a recently published book chapter entitled "Biofeedback in the Diagnosis and Treatment of Chronic Essential Pelvic Pain Disorders" (Glazer & Gilbert, 2011) in the book *Chronic Pelvic Pain and Dysfunction: Practical Physical Medicine* (Chaitow & Jones, 2011).

Patient Selection and Preparation

The Glazer Protocol is an early-stage evidence-based-medicine PFM surface electromyography (SEMG) biofeedback assessment and therapeutic tool with application to a wide range of functional genitourinary (female reproductive and urinary system), gastrointestinal, sexual, and pain disorders. These functional or essential disorders first require ruling out established structural and physiological pathology, therefore requiring all patients to undergo a medical assessment prior to initiating biofeedback. Patients also must have intact sensory-motor pathways and sufficient motivation and discipline to conduct daily biofeedback-assisted exercise sessions for periods of time up to 20 minutes, twice daily, for 6 to 12 months. Noncompliance and dropout rates are significant. Clinicians should be cautious in initiating this biofeedback protocol for patients expressing a preference for treatments involving less commitment of time and discipline.

The Glazer Protocol is a software application installed into a computer equipped with signal processing hardware (Myotrac Infiniti^{TM}, Thought Technology Ltd., Montreal, Quebec, Canada) and its operating system software (Biograph Infiniti^{TM}). The Glazer Protocol operationally defines the intrapelvic PFM SEMG assessment and rehabilitation applications. The assessment protocol includes patient education on the structure and function of the PFM, as related to one's individual symptoms, with a scripted presentation and standardized responses to frequent patient questions. The presentation includes instructions on private self-insertion of the intrapelvic sensor, body positioning as a critical factor in PFM SEMG measurement, and teaching the patient the correct method for contracting and relaxing the PFM. These instructions focus on creating the intrapelvic lifting sensation associated with the correct use of PFM, while permitting limited co-contractions, or overflow (Glazer & MacConkey, 1996) to offset fatigue during the initial stages of exercise (Glazer, 2005).

Bioengineering of Hardware and Software for Glazer Protocol

The engineering of the intrapelvic sensor, signal processor hardware, and operating system software are critical elements in the Protocol. Only by understanding the engineering of the instrument (differential amplification, common mode rejection sensitivity, impedance, rectification, bandpass and notch filtration, analog-to-digital conversion, power density spectral frequency analysis via fast Fourier transformation [FFT], signal reintegration methods, etc.) can the clinician understand both the utility and the

limits of the PFM SEMG data that they are observing and interpreting. Characteristics of the intrapelvic (vaginal and anal) sensing devices (size, shape, configuration of sensor plates and ground lead, material used for SEMG sensors, separation distance, orientation to striate muscle, etc.) are also critical factors to be operationally defined for within- and between-group study consistency.

Glazer Protocol Event Sequencing and PFM SEMG Measurements and Reports

The intrapelvic PFM SEMG assessment consists of a fixed series of contractions and relaxations, directed via an on-screen written script and simultaneous voice-over presentation. The fixed sequence of muscle activity includes pre-baseline rest, phasic contractions, tonic contractions, endurance contraction, and post-baseline rest. This traditional series of PFM assessment contractions was originally intended to reflect sexual, sphincteric, and support functions of the pubococcygeus muscle (Kegel, 1948, 1952). In the Glazer Protocol, PFM SEMG measures taken continuously throughout the Protocol include average SEMG amplitude, recruitment and recovery latencies, median power density spectral frequency, and two measures of PFM SEMG variability: raw (standard deviation) and amplitude corrected (coefficient of variability).

The raw PFM SEMG data (2,048 samples per second) are stored throughout the entire Glazer Protocol Assessment, which takes approximately 8 minutes to conduct. At the completion of the Glazer Protocol the raw data are processed to produce the PFM SEMG measures for each PFM muscle activity segment described above. This initially processed data are then exported to a database incorporating patient demographics, symptom reports, and medical diagnostic findings along with the segmented PFM SEMG data. A Glazer Protocol PFM SEMG report is also produced in which the PFM SEMG values for each of the assessment segments are shown in both numeric and graphic form, along with a summary and interpretation of the findings and recommendation for treatment. A copy of the report is electronically stored in the patient records, and a hard copy is given to the patient and sent to the referring source.

Use of Glazer Protocol to Identify PFM Electrophysiological Abnormalities in a Specified Patient Population by Between- and Within-Group Analysis of PFM SEMG Data

Sufficient PFM SEMG sample sizes are currently being collected from clinicians trained in the use of the Protocol. The next step will be to create PFM SEMG profiles from the database by comparing each symptomatic group's initial evaluation to its asymptomatic matched control group (Glazer et al., 1999; Romanzi et al., 1999). At this time data are being collected for 20 ICD diagnoses related to pelvic floor dysfunction and the Glazer Protocol. PFM SEMG sample sizes for these diagnostic groups vary from $n = 70$ for asymptomatic males to $n = 170$ for vulvar vestibulitis syndrome. Although these data are useful for clinical practice, increasing specificity of operationally defined data collection procedures, quality assurance of data from all sources, and increased sample sizes are necessary before this database can be presented as a standard against which individual assessment data can be compared. Comparing within-group PFM SEMG profile changes over treatment sessions is used with a regression analysis to identify PFM SEMG changes, which significantly predict symptomatic improvement. These findings can then be used to develop training protocols to change the PFM SEMG patterns predictive of symptom reduction (Glazer & Rodke, 1995).

Use of Glazer Protocol PFM SEMG Abnormalities in a Specified Patient Population to Generate Evidence-Based-Medicine Hypotheses Concerning Pathophysiology

PFM SEMG is a direct measure of striate muscle motor unit action potential trains, but it also reflects the complex integrated activity of a wide range of related physiological processes. As described by Mense (2004), sustained contractile amplitude and muscle fatigue are accompanied by a median power density spectral frequency shift toward the lower range of the frequency spectrum. Several studies (Alfonsi et al., 1999; Dimitrov et al., 2006; Hug et al., 2004; Mense, 2004; Tachi et al., 2004; Yoshitake et al., 2001) have shown that elevated contractile amplitude and lower median power density spectral frequency are associated with subjective muscle fatigue, hypoxia, reduced blood flow, and a localized inflammatory response (including the neurochemical release of cytokines, neurokines, lactic acid, substance P, interleukin and TNF alpha), resulting in increased pain sensitivity.

These studies demonstrate that SEMG electrophysiology may reflect more than simple muscle states such as weakness, tension, and asymmetry. SEMG measures have been found to correlate with a wide range of systems from the most molecular cellular level, such as localized microvascular (Sekula et al., 2009) or neuro-chemical changes (Li et al., 2009), to the most molar level of striate muscle events, such as limb articulation, and even autonomic events such as sympathetic nervous system

activity, and its experiential counterparts of cognition, memory, attention, and emotion (Kauff et al., 2012). All of these events can be seen as parts of an integrated multifaceted, multilevel, biopsychosocial response, in which all its elements, including SEMG events, are related to all other elements.

One very exciting early-stage finding of the Glazer Protocol is that a wide variety of diverse PFM-related functional disorders, such as urinary incontinence, fecal constipation, hormonal and menstrual status, genital pain, and sexual disorders, appear to share PFM SEMG electrophysiological abnormalities of elevated sustained contractile coefficients of variability and shifts to the left in power density median spectral frequency, as measured by FFT. Amplitude-related PFM SEMG variables have little statistical significance in predicting disorders, symptoms, or functionality. Furthermore, early findings suggest that variability and spectral frequency measures are modifiable by PFM SEMG training, and their normalization does lead to symptomatic and functional improvement (Akasaka et al., 1997).

In summary, using advanced SEMG technology to "see" previously unobserved muscle-related events that show promise in both operationally defining and treating disorders is only one example of how biofeedback can adopt evidence-based-medicine practices to produce a significant "value added." The following article presents case histories of two patients evaluated and treated in collaboration with Claudia Hacad, a physical therapist with extensive training in the Glazer Protocol, practicing in São Paulo, Brazil.

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