Urgency or urgency urinary incontinence (UUI) is a prevalent, morbid, and costly problem, especially for older women (Abrams, Cardozo, Khoury, & Wein, 2009; Resnick, Tadic, & Yalla, 2012). It is often assumed that UUI is due to an underlying bladder abnormality, detrusor overactivity (DO), the involuntary bladder contraction observed during urodynamics. Drugs aimed at suppressing DO are widely used for treatment. They are easy to administer, but their success rate remains modest despite recent innovations (Hartmann, et al., 2009; Shamliyan, Wyman, & Kane, 2012). Moreover, very few patients continue on medications after a year, due in part to side-effects and limited efficacy (Benner et al., 2010; Shaya, Blume, Gu, Zyczynski, & Jamadilova, 2005). Behavioral therapy, including biofeedback, is the recommended first-line treatment (Abrams, Andersson et al., 2009; Fantl, Newman, & Colling, 1996). It can be as successful as drug treatment and is without side effects (Burgio et al., 1998). However, as presently practiced, it requires expertise, equipment, adherence to a schedule, and sufficient time for several clinic visits, and is therefore rarely used. A current research priority is simplification; shortening or better targeting of biofeedback therapy would help to make it more acceptable and more widely available (Buckley, Grant, Tincello, Wagg, & Firkins, 2010).

Although numerous authors have addressed the treatment of urinary incontinence by pelvic floor muscle training, few have specifically targeted biofeedback or urge incontinence, as is apparent from recent reviews (Herderschee, Hay-Smith, Herbison, Roovers, & Heineman, 2011; Greer, Smith, & Arya, 2012). Further, little is known about the long-term durability of objective improvement in UUI. Burgio et al. (1998) noted that improvement during biofeedback was initially rapid and then slowed down, but drew no conclusion about optimum duration of treatment. Subjectively, 96.5% of Burgio and colleagues’ (1998) patients receiving biofeedback-assisted pelvic floor muscle training were prepared to continue treatment indefinitely. Weinberger, Goodman, & Carnes (1999) suggested that patient-reported improvement after a wide variety of non-surgical treatments was durable at 21-month follow up, but they did not include an objective assessment of improvement. Borello-France et al., (2010) showed that adherence to exercises and urge suppression and pelvic floor muscle exercises were most beneficial. Responders can be identified early in treatment, allowing for fewer sessions.

**Key Words:** Biofeedback, urge suppression, urge urinary incontinence, pelvic floor muscle exercises.
Introduction
Urge urinary incontinence (UUI) is a common, costly, distressing issue for older women. Biofeedback is a form of behavioral therapy that has been successful for treatment, but it is costly, and requires expertise and several visits to learn.

Purpose
The purpose of this secondary analysis was to determine the most effective elements of pelvic floor muscle training and the optimal number of biofeedback sessions to reduce the episodes of UUI.

Methods
This study was a secondary analysis of a non-controlled trial of biofeedback-assisted pelvic floor muscle exercises. Of 183 subjects, 130 completed the seven-day bladder diaries and were eligible for the secondary analysis. The primary outcome measure was the mean reduction in the number of UUI episodes based on the pre- and post-treatment bladder diaries.

Findings
Pelvic floor muscle exercises utilizing biofeedback reduced incontinence episodes from 3.2/24 hours pre-treatment to 1.0/24 hours post-treatment (p < 0.001) for the 183 subjects. The main improvement for the 130 subjects that completed seven-day bladder diaries occurred after the first biofeedback session.

Conclusions
Biofeedback therapy is a useful strategy in older women to reduce UUI that can be taught in two visits, and in a small sub-group of subjects, the therapy was durable after six months.

Level of Evidence: VI
(Polt & Beck, 2012)

Materials and Methods
Subjects were community-dwelling women aged 60 years or older, without overt neurological disease, who were recruited by newspaper advertising or word of mouth. On history, they had to indicate symptomatic UUI (including urge-predominant mixed incontinence) twice a week for at least three months. In addition, their baseline three-day bladder diary had to reveal at least one episode of urgency-related leakage. Any urinary tract infection was treated, and the subject then reassessed.

Exclusion criteria included stress-predominant incontinence by history or physical examination (performed by a trained nurse practitioner), prolapse beyond the hymen; interstitial cystitis; cognitive impairment (mini mental state examination [MMSE] score less than 24/30, or inability to accurately complete a three-day bladder diary, perform a 24-hour pad test, or understand biofeedback instructions); spinal cord injury; history of pelvic irradiation, or advanced uterine or bladder cancer; multiple sclerosis; urethral obstruction; urinary retention (post-void residual urine greater than 200 ml); medical instability or expected change in medication during the study; clinically apparent neurological lesion; and any condition that mandated intravenous antibacterial prophylaxis before urodynamics. Prior exposure to biofeedback-assisted pelvic floor muscle training was not a formal exclusion criterion. The study was approved by the University of Pittsburgh Institution Review Board. All subjects gave written informed consent prior to study procedures.

Clinical Assessment
Following the protocol of the parent study, at baseline, subjects completed a three-day bladder diary with voiding times, voided volumes, and estimated amounts of leakage and circumstances of leakage episodes. On the third day, they also performed a 24-hour pad test to measure the weight of urine lost. Clinical assessment included medical and bladder history, physical examination (including stress and neurological testing, and cognitive testing using the MMSE), and videourodynamic assessment. Clinical and urodynamic assessment, three-day bladder diary, and pad test were repeated after the intervention (as required for the parent study).

Intervention: Biofeedback-Assisted Pelvic Floor Muscle Training
Following the timeline described by Burgio et al. (1998,
subjects attended four biweekly biofeedback-assisted pelvic floor muscle-training sessions over an eight- to 12-week period as shown in Figure 1. Biofeedback-assisted pelvic floor muscle-training sessions included training in pelvic floor muscle exercises and urge-suppression strategies, administered via four biweekly clinic visits (Visits 1 through 4) and home practice between the visits. All treatment was administered by the same highly experienced continence nurse practitioner (LO), who had been trained by Dr. Burgio. To track progress, subjects were asked to maintain daily bladder diaries at home throughout the treatment period, as in Burgio and colleagues’ 1998 and 2002 studies. The daily bladder diaries kept in the week prior to each session were used to determine progress and guide treatment.

Outcome Measures
The analyses in this study were based on the three-day baseline and post-intervention diaries completed prior to Visits 1 and 5, and the seven-day bladder diaries completed prior to Visits 2, 3, and 4 (see Figure 1). Improvement was expressed as the mean reduction in the number of UUI episodes per 24 hours determined from the pre- and post-biofeedback-assisted pelvic floor muscle-training bladder diaries, either raw or expressed as a percentage of the baseline pre-biofeedback-assisted pelvic floor muscle-training value. Post-intervention, all subjects were asked to estimate their subjective perception of the percentage improvement in incontinence. They also answered an open-ended question about which parts of the treatment they found most helpful.

Statistical Methods
We operationally classified subjects with 50% or greater reduction in incontinence frequency as responders, choosing this value for convenience rather than clinical significance because it yielded similar numbers of responders and non-responders. Since the 24-hour frequency of UUI episodes had a skewed distribution, we displayed median values in the table and graphs. We tested postulated associations between responder/non-responder status and other variables using Mann-Whitney and other non-parametric statistical tests, with two-tailed threshold for significance set at \( p < 0.05 \). Estimates from preliminary data suggested that 180 subjects would yield at least 80% statistical power to detect such associations (Resnick, Perera et al., 2012). SPSS® v.18 was used for analyses.

Results
Baseline Data
Demographic, clinical, and urodynamic data are shown in Table 1 for the 183 subjects who followed the protocol of the parent study and completed baseline and post-biofeedback-assisted pelvic floor muscle-training bladder diaries. Of these, 130 subjects also completed bladder diaries prior to Visits 2, 3 and 4 (see Figure 1), enabling analysis of the time course of objective improvement. The total of 130 subjects slightly reduced the sta-
Biographical power for the secondary analysis, but power was still adequate for analysis.

**Improvement in Incontinence**

For the 183 subjects, baseline median frequency of incontinence episodes was 3.2/24 hours. After treatment, it decreased to 1.0/24 hours ($p < 0.001$) (see Table 1). Fifty-five percent (55%) ($n = 101$) of subjects were classified as responders ($\geq 50\%$ improvement). Thirty-four percent (34%) ($n = 62$) of subjects improved by at least 75%, and 13% ($n = 24$) of subjects were entirely continent on the three-day bladder diary and pad test at the end of the study. On pad testing, the median weight of urine lost per 24 hours was reduced from 36 grams to 5 grams ($p < 0.001$).

In reply to the question “From 0% to 100%, rate the improvement in your incontinence (leakage) after biofeedback therapy,” the median estimate of subjective improvement was 60% (research question 3). Among responders, it was 65%, while among non-responders, it was 60%, not significantly different. There was no significant correlation between this subjective estimate of improvement and the objective improvement measured by the percentage reduction in incontinence episodes on bladder diary (Spearman’s $r = 0.11$, $p = 0.20$).

Urge suppression (by appropriately timed pelvic floor and sphincter squeezes) was the aspect of treatment most often identified by patients as helpful (by 65%). Pelvic floor muscle exercises were also highly valued (by 55%). Other elements were mentioned much less frequently (see Figure 2). There was no significant difference in the elements identified as valuable by responders and non-responders.

**Time Course of Improvement**

Based on data from the 130 subjects who completed all five bladder diaries shown in Figure 1, the greatest reduction in incontinence episodes/24 hours occurred after the first biofeedback-

| Table 1. Baseline and Post-Intervention Values of Demographic, Clinical, and Urodynamic Variables in 183 Subjects |
|-------------------------------------------------|-------------------------------------------------|----------------------|
| **Baseline Median (IQR)* or %** | **Post-BFB Median (IQR)* or %** | **p-Value of Difference (Post-Baseline)** |
| Age (Years) | 74 (12.0) | – | – |
| MMSE/30 | 29 (1.0) | – | – |
| Number of UUI episodes/24 hours | 3.2 (3.4) | 1.0 (2.6) | 0.000 |
| Pad weight gain/24 hours (grams) | 36 (94.0) | 5 (53.0) | 0.000 |
| Number of voids/24 hours | 8.4 (3.2) | 7.7 (2.7) | 0.000 |
| Fluid excretion /24 hours (ml) (including estimated leakage) | 1758 (1035.0) | 1646 (974.0) | 0.003 |
| Percentage with DO on urodynamics | 43% | 42% | 0.800 |

*IQR = interquartile range.*

**Figure 2.** Elements of BFB Treatment Identified as Helpful in an Open Question at the End of the Study, with the Percentage of Subjects Identifying Each Element

Note: Some subjects identified more than one element. BFB = biofeedback-assisted pelvic floor muscle-training sessions.
assisted pelvic floor muscle-training session \((p < 0.001)\) (see Figure 3). There was a further substantial decrease after the second session \((p < 0.001)\). After visit three, there was little further improvement or relapse, although some changes remained significant. Figure 4 shows the same data stratified for responders and non-responders. Among responders, the improvement occurred rapidly and was essentially complete by Visit 3. The improvement in non-responders was smaller and less well-sustained.

At the third visit, there was an easily identifiable group of subjects who would go on to be responders at end of study (see Figure 5). Nearly all participants who had 50% or greater improvement at Visit 3 remained responders at the end of the study. For this group, continuing biofeedback-assisted pelvic floor muscle-training therapy beyond the third visit led to little further improvement. By contrast, many of those with less than 50% improvement at Visit 3 remained non-responders at the end of the study.

Thus, the principal improvements thus occurred after the introduction of pelvic floor muscle exercises (Visit 1) or in combination after urge suppression techniques had been added at Visit 2 (see Figure 1).

**Follow-Up Subgroup**

Thirty-five consecutive subjects were contacted for greater than six month follow-up. Thirty-eight percent reported they were still doing pelvic muscle exercises regularly, and 62% were still practicing urge suppression. Thirty subjects agreed to keep a three-day bladder diary, and 25 completed it, a response rate of 71%. These 25 did not differ significantly from the other subjects in the study in age (median 76 vs. 73 years, \(p = 0.30\)) or baseline frequency of incontinence episodes (median 3.2 vs. 3.1/24 hours, \(p = 0.50\)), but they had a slightly higher MMSE (median 29 vs. 28.5/30, \(p = 0.03\)). Among these 25 subjects, the
The median frequency of incontinence episodes at follow-up did not differ significantly from the parent end-study value (1.0/24 hours vs. 0.7/24 hours, \( p = 0.70, n = 25 \)).

Figure 6 shows the UUI frequency determined from successive sets of bladder diaries from each individual in the follow-up subgroup stratified by response to treatment. Among responders, the expected reduction from baseline frequency had occurred by Visit 4, and it was sustained at the end-study Visit 5 and even six months post-treatment. For non-responders, the baseline value tended to be higher, and there was only a slight reduction at Visit 4; thereafter, the UUI frequency fluctuated with no clear trend.

**Discussion**

This study shows that among older women with urge incontinence, there is a substantial group that responds well to treatment with biofeedback-assisted pelvic floor muscle-training. In these responders, treatment is essentially complete after two treatment sessions. Those who do not respond after two sessions are unlikely to respond after four sessions. Consistent with this finding, Burgio et al. (1998) have shown that the greatest improvement occurs after one or two sessions, while another study (Engberg, McDowell, Engberg, & Sereika, 1996) concluded that the greatest improvement occurred during the first three weeks of behavioral therapy, with minimal improvement after session four.

These statistical improvements in UUI were mirrored by individual patients’ experience. Objectively, responders improved quickly and maintained the improvement for six months, and most non-responders failed early on to improve significantly. Patients’ own subjective perception of the success of treatment was satisfactory (median percentage improvement 62%) but had at best a weak relation to objective measurements of improvement. Informal questioning revealed that the sense of increased control provided by the therapy – how to react to urgency even if there was ultimately little change in actual leakage – was highly valued.

The element of biofeedback therapy that was most helpful, as judged by the patients, was the technique of urge suppression, in particular, the use of quick pelvic floor muscle squeezes to control the bladder when urgency is experienced. Biofeedback-assisted pelvic floor muscle-training aided instruction in pelvic floor exercises was also judged helpful. Suggestively, the principal improvements in UUI frequency occurred after the biofeedback-assisted pelvic floor muscle-training sessions in which these two techniques were sequentially introduced. Moreover, at six-month follow up, more than one-third of the subjects surveyed were still doing pelvic floor muscle exercises, and nearly two-thirds were practicing urge suppression, confirming the value of these techniques in real life. The contrast with pharmacological therapy, which is rarely continued even for six months because of side-effects and lack of efficacy (Benner et al., 2010), is striking.

Important implications from these results indicate that once a patient has learned to use her

![Figure 5. Number of Subjects Versus Percentage Reduction in UUI Frequency at Visit 3](image-url)
pelvic floor and sphincter muscles appropriately, they are brought into play whenever UUI threatens; consequently, the behavior is self-reinforcing. In contrast, most of those who do not quickly learn appropriate use of pelvic floor and sphincter muscles remain non-responders in spite of further clinic sessions and home practice.

Based on these findings, a rational clinical approach is suggested to treat all UUI patients with a streamlined therapy composed of a baseline bladder diary followed by two biofeedback-assisted pelvic floor muscle-training sessions, each followed by two weeks of home practice and bladder diaries. At the first session, biofeedback-assisted pelvic floor muscle-training therapy would be used to identify the pelvic floor muscles and their correct use in pelvic floor muscle exercises. At the second session, urge strategies (including quick squeezes of the pelvic floor with relaxation of other muscles) would be taught. A final short visit could be added, and responders (50% or greater reduction in UUI episodes) would be told of their success, encouraged to continue home practice, and followed up by telephone at six months. Non-responders should be informed that further biofeedback-assisted pelvic floor muscle-training therapy was unlikely to be helpful and that they might switch to another behavioral therapy, such as scheduled voiding, or to a drug treatment trial. A controlled trial of such a therapeutic program is desirable.

**Limitations**

The lack of a control group for the parent study implies that the response to therapy may represent a placebo effect, but this is arguably an intrinsic part of any behavioral treatment. The seven-day bladder diaries used during the intervention differed in length from the three-day diaries used at baseline and post-intervention because they were designed to be part of treatment rather than assessment. Moreover, fully com-

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**Figure 6.**

UUI Frequency at Selected Visits in Each of the Individuals in the Follow-Up Subgroup: (A) Responders and (B) Non-Responders to BFB Therapy

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**Note:** BFB = biofeedback-assisted pelvic floor muscle-training sessions, UUI = urge urinary incontinence.
pleted seven-day diaries were available for fewer than the number planned for the parent study. Although six-month follow up was performed in relatively few patients, who differed slightly from the rest in cognition, they provided a convenient cohort in which to graphically follow individual changes during the whole course of the study, as in Figure 2. Results and conclusions are specific to community-dwelling older women and may not be applicable to younger, more frail, or male patients. Power calculations for the primary study were amply fulfilled, and the slightly reduced power for the secondary analysis was still adequate, as shown post hoc by significant p-values. All interventions were performed by one individual; therefore the results may be due to the individual versus the actual intervention. This study would need to be repeated to substantiate results.

Conclusions

Biofeedback-assisted pelvic floor muscle training for urge incontinence is effective in a substantial group of older female patients, is highly valued by patients, and can very probably be streamlined. Non-responders can be identified early and switched to a different treatment. The role of the nurse practitioner in managing urinary incontinence utilizing biofeedback was a key element to the success of the intervention. The nurse practitioner can intervene with non-responders by offering alternative interventions and preventing a prolonged and costly treatment course with biofeedback that will not be beneficial to the patient. The expertise of the nurse is a major factor in teaching patients, especially the elderly, not only to perform pelvic floor muscle exercises correctly but also methods to maintain and increase adherence. Further investigation in regard to reductions in visits is suggested such as combining the instruction for pelvic floor muscle exercise training and urge suppression strategies into one session.

References


