Improving Treatment of Urinary Incontinence

More than 15 million persons in the United States have urinary incontinence,[1] a condition more prevalent than diabetes mellitus. Urinary incontinence not only causes considerable medical and psychosocial morbidity but it also engenders enormous costs. Conservative projections for costs related to diagnosis and treatment of urinary incontinence exceed $26 billion annually,[2] more than is expended by Medicare on dialysis (O. Cohen, oral communication, November 1998) and coronary bypass grafting combined.[3] Moreover, these costs apply only to individuals older than 65 years, who constitute less than half of those with urinary incontinence. Unfortunately, most physicians have received little education about incontinence, fail to screen for it, and view the likelihood of successful treatment as low.[1] Thus, it is fitting that the study by Burgio et al, which examines the efficacy of biofeedback for urge incontinence, should appear in *JAMA*.[4]

See also p 1995.

Urinary incontinence has a broad differential diagnosis, including causes within and beyond the lower urinary tract.[1,5] Within the urinary tract, overactive bladder (detrusor overactivity) is the most common cause of urinary incontinence in the elderly and also contributes to urine leakage in many women with stress incontinence. Although behavioral interventions are recommended by most authoritative groups,[1,6,7] pharmacological therapy remains the most frequently used treatment for patients with overactive bladders. Several factors may contribute to this practice. There are multiple behavioral techniques and protocols, but their comparative efficacy is unknown. Because technical aspects cannot be detailed sufficiently in reports of clinical trials, behavioral interventions also are difficult to replicate in practice. One behavioral technique, biofeedback, has been even less widely used for urge incontinence because it often has required repeated instrumentation of the bladder and urinary sphincter. Moreover, despite the expertise and time entailed, behavioral techniques are poorly reimbursed. By contrast, pharmacotherapy works more quickly and also requires no behavioral expertise, less physician time, and less patient participation. Nonetheless, although drugs help most patients, no drug restores continence to the majority. Furthermore, all of the agents currently used engender adverse effects, expense, and inconvenience,[1] and most must be taken several times daily and indefinitely. Thus, an equally or more effective one-time intervention would be welcome.

The study by Burgio et al[4] demonstrates that a less-invasive biofeedback approach can achieve these goals. The study also serves as a rich source of information and provides valuable lessons for clinicians. The investigators' decision to begin therapy with oxybutynin at 2.5 mg 3 times daily was wise. The effect of oxybutynin was equivalent to that achieved in trials using higher dosages, but it caused far fewer adverse effects and a lower rate of subject attrition.[1] Equally important, efficacy continued to increase beyond 2 weeks, longer than previously reported, but consistent with other recent data.[8,9] Thus, clinicians should avoid escalating dosages of oxybutynin too quickly or abandoning pharmacotherapy too soon.

The decision to use oxybutynin at this dosage, frequency, and duration should have enhanced its benefit, thereby making the biofeedback findings even more impressive. However, it is premature to conclude that biofeedback is superior for patients with urge incontinence. Half the subjects had a component of stress incontinence, which responds well to biofeedback but not to a bladder relaxant medication and which may even worsen as bladder capacity and residual urine volume increase. In addition, the decision to include patients with residual urine volume as high as 200 mL may have affected the results, since such patients may be less responsive to a drug that further impairs detrusor muscle contractility. This approach also may explain the higher proportion of subjects who reported "inability to void" while receiving therapy. Thus, oxybutynin may work as well as or even better than biofeedback for subjects who have pure urge incontinence and low residual urine volume.

Nonetheless, the efficacy of biofeedback was impressive, and it was equal or superior to oxybutynin on every measure of outcome in this group of patients. This finding highlights another strength of the trial: inclusion of patients' perspectives although they may not have been gathered blindly. Patients taking oxybutynin correctly perceived a 68% reduction in leakage and, in 80% of cases, described themselves as better or much better. Yet, only half of these subjects were willing to continue oxybutynin indefinitely and 75% wished to receive another form of therapy (proportions that are not much better than those for individuals receiving placebo). These data contrast strikingly with results from individuals randomized to biofeedback, nearly all of whom were comfortable continuing it and only 14% of whom desired another therapy. Furthermore, since biofeedback is effective for subjects with mixed (ie, urge plus stress) incontinence, and for those with pure urge incontinence, it may be more widely applicable. The feasibility of biofeedback is further enhanced by the fact that a much less invasive, staged approach was as effective as the traditional method.

The traditional approach to urge incontinence is bladder training, which involves increasing the voiding interval and teaching strategies to cope with urgency.[1] By avoiding the expensive equipment and expertise required for biofeedback, bladder training is easier to implement and less expensive, but its comparative efficacy is unknown. Equally important is whether adding biofeedback for those who fail bladder training would be as efficacious as using biofeedback for all patients with incontinence. Similarly, it would be useful to know whether combining biofeedback with pharmacotherapy would provide additive or even synergistic effects. Also, it is important to determine whether biofeedback works as well for subjects with severe

From the Geriatrics Section of General Medicine, Brigham and Women's Hospital, Boston, the Geriatric Research Education and Clinical Center and Division of Urology at the Brockton/West Roxbury Veteran's Affairs Medical Center, West Roxbury, and the Hebrew Rehabilitation Center for Aged and Division on Aging, Harvard Medical School, Boston, Mass.

Corresponding author: Neil M. Resnick, MD, Chief of Geriatrics, Brigham and Women's Hospital, 75 Francis St, Boston, MA 02115.

incontinence as for those with milder forms, how durable the effects are, and how often "refresher courses" will be required.

Because the mechanisms mediating the effects of biofeedback are unknown, whether or how it could be further optimized or streamlined cannot be surmised. Because all the therapists were nurse practitioners who were trained and supervised by Dr Burgio, it is difficult to determine the generalizability of biofeedback to nurses without such training, to different types of therapists, and to therapists outside a clinical trial setting. Additionally, because participants were all volunteers and comprised fewer than half of those recruited over several years, the technique's efficacy in routinely encountered patients is less certain. And, as the authors note, the study subjects were relatively young, cognitively intact, and relatively free of comorbidity, all factors that limit applicability of this technique to other groups of patients.

Nonetheless, with other research on incontinence, this well-conceived trial underscores the fact that therapeutic nihilism is no longer tenable. Given the hidden nature of the condition, primary care clinicians should redouble their efforts toward identifying the majority of patients in their practice who, unbeknownst to the physician, are incontinent and toward addressing the causes related to medications (eg, anticholinergic, sedative, loop diuretic, and adrenergic agents and angiotensin-converting enzyme inhibitors) and diseases outside the urinary tract (eg, heart failure) that they already know how to treat.[1,6,10]

The increasing array of simple algorithms and guidelines[1,5-7,10] also makes empiric management of many patients feasible for primary care clinicians. Even simple interventions can be effective. Moreover, all studies document a high placebo response. Although the mechanisms have not been well studied, they may include patients' learning that incontinence is not untreatable, drinking a little less, voiding a little more often, and becoming more aware of bladder fullness. Importantly, the role of a concerned caregiver's encouragement should not be minimized. Despite the need for continued research to advance and refine treatment of urinary incontinence, at present physicians probably should be less concerned about the relative benefits of various types of behavioral interventions or drugs (all of which appear to have equivalent efficacy)[1] and more concerned that every patient receives *some* individualized intervention.

Neil M. Resnick, MD

Dr Resnick has received a grant from Pharmacia & Upjohn, Bridgewater, NJ, to devise management modules for primary care physicians to treat urinary incontinence. This work is supported in part by the National Institutes of Health grants AG08812, AG4390, and R01-DK49482.

1. Fantl JA, Newman DK, Coiling J, et al. *Urinary Incontinence in Adults: Acute and Chronic Management*. Rockville, Md: US Dept of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research; 1996. Clinical Practice Guideline No. 2, 1996 Update. AHCPR publication No. 96-0682.
2. Wagner TH, Hu T-W. Economic costs of urinary incontinence in 1995. *Urology*. 1998;51:355-361.
3. *Health Care Financing Review, Medicare and Medicaid Statistical Supplement*. 1997:78.
4. Burgio KL, Locher JL, Goode PS, et al. Behavioral vs drug treatment for urge urinary incontinence in older women: a randomized controlled trial. *JAMA*. 1998;280:1995-2000.
5. Resnick NM. Urinary incontinence. *Lancet*. 1995;346:94-99.
6. Urinary incontinence in adults [Consensus Conference]. *JAMA*. 1989;261:2685-2690.
7. World Health Organization. *Report of the First International Consultation on Incontinence in Adults*. Geneva, Switzerland: World Health Organization Press. In press.
8. Appell RA. Clinical efficacy and safety of tolterodine in the treatment of overactive bladder. *Urology*. 1997;50(suppl 6A):90-96.
9. Abrams PH, Freeman R, Anderström C, Mattiasson A. Tolterodine, a new antimuscarinic agent. *Br J Urol*. 1998;81:801-810.
10. Resnick NM. Urinary incontinence in an 89-year-old woman. *JAMA*. 1996;276:1832-1840.

Reporting of Public Health Hazards or Major Advances—Revision of Uniform Requirements

Most medical journals do not wish to publish work that has already been released or published in print or electronic media. The Uniform Requirements for Manuscripts Submitted to Biomedical Journals[1] (URM) of the International Committee of Medical Journal Editors (ICMJE) already indicate that such policies should not preclude consideration of a complete report following publication of an abstract or a presentation at a professional meeting, even if such presentations are covered in the media. However, authors are sometimes concerned whether reporting a public health hazard or major therapeutic advance directly to public media or governmental agencies will jeopardize subsequent medical journal publication of an article or letter to the editor dealing with the same topic.

Since 1994, the *JAMA* "Instructions for Authors" have stated, "Authors submitting manuscripts or letters to the editor regarding adverse drug or medical device reactions, reportable diseases, and the like should also report such to the relevant government agency."[2] At the request of the US Food and Drug Administration, this issue was also discussed at the last meeting of the ICMJE, and the following paragraph was recently approved as a substitute final paragraph of the section on Redundant or Duplicate Publication of the URM[1(p928)]:

Preliminary reporting to public media, governmental agencies, or manufacturers, of scientific information described in a paper or a letter to the editor that has been accepted but not yet published violates the policies of many journals. Such reporting may be warranted when the paper or letter describes major therapeutic advances or public health hazards such as serious adverse effects of drugs, vaccines, other biological products, or medical devices, or reportable diseases. This reporting should not jeopardize publication, but should be discussed with and agreed upon by the editor in advance.

The intent of this revision of the URM is to encourage timely reporting of urgent public health hazards or advances. Authors interested in publishing in a biomedical journal should discuss the possibility of such reporting with the editor in advance.

Richard M. Glass, MD

Dr Glass is Deputy Editor, *JAMA*.
Reprints: Richard M. Glass, MD, *JAMA*, 515 N State St, Chicago, IL 60610 (e-mail: richard_glass@ama-assn.org).

1. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. *JAMA*. 1997;277:927-934.
2. *JAMA* instructions for authors. *JAMA*. 1998;280:19-26.