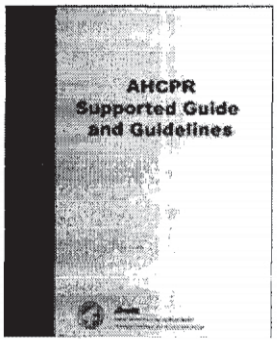

Urinary Incontinence in Adults: Acute and Chronic Management: 1996 Update

AHCPR Clinical Practice Guidelines, No. 2

JA Fantl, DK Newman, and J Colling.

Rockville (MD): Agency for Health Care Policy and Research (AHCPR); 1996 Mar.
Report No.: 96-0682

Despite the prevalence of urinary incontinence (UI), the condition is widely underdiagnosed and underreported. Many health care providers remain uneducated about this condition, and individuals are often ashamed or embarrassed to seek professional help. Furthermore, UI diagnostic and treatment practices as well as associated medical costs vary widely. These factors prompted the selection of UI in adults as a topic for guideline development. A panel of experts used an extensive review of scientific literature as well as expert judgment and group consensus to develop this guideline. Findings and recommendations are presented for (1) prevention, identification, and evaluation of UI; (2) use of behavioral, pharmacologic, and surgical treatment as well as supportive devices; (3) long-term management of chronic intractable UI; and (4) education of health professionals and the public. The panel found evidence in the literature that the treatment of UI can improve or "cure" most patients. They concluded that all patients with UI should have a basic diagnostic evaluation and that behavioral and pharmacologic therapies are usually reasonable first steps in management. In addition, vigorous efforts should be made to educate the professional and lay public.

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[About AHCPR]

The Agency for Health Care Policy and Research (AHCPR) was established in December 1989 under Public Law 101-239 (Omnibus Budget Reconciliation Act of 1989) to enhance the quality, appropriateness, and effectiveness of health care services and access to these services. AHCPR carries out its mission by conducting and supporting general health services research, including medical effectiveness research, facilitating development of clinical practice guidelines, and disseminating research findings and guidelines to health care providers, policymakers, and the public.

The legislation also established within AHCPR the Office of the Forum for Quality and Effectiveness in Health Care (the Forum). The Forum has primary responsibility for facilitating the development, periodic review, and updating of clinical practice guidelines. The guidelines will assist practitioners in the prevention, diagnosis, treatment, and management of clinical conditions.

Guidelines are available in formats suitable for health care practitioners, the scientific community, educators, and consumers. AHCPR invites comments and suggestions from users for consideration in development and updating of future guidelines. Please send written comments to Director, Office of the Forum for Quality and Effectiveness in Health Care, AHCPR, Willco Building, Suite 310, 6000 Executive Boulevard, Rockville, MD 20852.

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Guideline Development and Use

Guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical conditions. This guideline update was developed by a private-sector panel convened by the Agency for Health Care Policy and Research (AHCPR). The panel employed an explicit, science-based methodology and expert clinical judgment to develop specific statements on patient assessment and management for the clinical condition selected.

Extensive literature searches were conducted and critical reviews and syntheses were used to evaluate empirical evidence and significant outcomes. Peer review and field review were undertaken to evaluate the validity, reliability, and utility of the guideline in clinical practice. The panel's recommendations are primarily based on the published scientific literature. When the scientific literature was incomplete or inconsistent in a particular area, the recommendations reflect the professional judgment of panel members and consultants.

Guideline updates are a result of periodic review of the state of scientific information and technology. Updates reflect new research findings, experience, or technologies and provide specific recommendations in the field.

We believe that the AHCPR-assisted clinical practice guidelines will make positive contributions to the quality of care in the United States. We encourage practitioners and patients to use the information provided in this *Clinical Practice Guideline Update.* The recommendations may not be appropriate for use in all circumstances. Decisions to adopt any particular recommendation must be made by the practitioner in light of available resources and circumstances presented by individual patients.

Clifton R. Gaus, ScD

Administrator

Agency for Health Care Policy and Research

Publication of this guideline does not necessarily represent endorsement by the U.S. Department of Health and Human Services.

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Many other organizations and individuals also made significant contribution during the development of this guideline. Although they are too numerous to mention here, the Contributors section, which appears later in this document, lists

individual consultants, peer reviewers, and support staff. Publication of this guideline would not have been possible without their collaborative efforts.

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Foreword

Urinary incontinence (UI) affects approximately 13 million Americans in community and institutional settings. Despite its prevalence, and an estimated annual cost of more than $15 billion, most affected individuals do not seek help for incontinence, primarily because of embarrassment or because they are not aware that help is available. When individuals do seek help, evidence exists that practitioners are hesitant or ill prepared to discuss, diagnose, or treat the problem.

A number of Federal and private organizations have provided research funding for the study of UI. Data from these studies indicate that treatment of UI is effective in most people, but there is an increased need for efforts to inform and educate the public and health care providers about the condition. Furthermore, there are wide variations in the actual costs and methods of providing care for UI, in the actual costs per procedure, and the charges within each diagnostic group.

It is expected that UI will continue to be a significant health care problem in the elderly and institutionalized populations, and will increase as the population of America continues to age.

This *Clinical Practice Guideline Update* addresses major evaluative, diagnostic, treatment, and management issues of UI. It was developed under the sponsorship of the Agency for Health Care Policy and Research (AHCPR), Public Health Service, U.S. Department of Health and Human Services. To develop the guideline, AHCPR convened a multidisciplinary, expert panel of physicians, nurses, other allied health care providers, and consumers. The panel first undertook an extensive and interdisciplinary clinical review of current needs, therapeutic practices and principles, and emerging technologies for diagnosis and treatment of UI. Second, the panel conducted a comprehensive review of the field to define the existing knowledge base and critically evaluate the assumptions and common wisdom in the field. Third, the panel initiated peer review of guideline drafts with intended users in clinical sites. Comments from these reviews were assessed and used in developing the guideline.

This is an update of the *Clinical Practice Guideline on Urinary Incontinence in Adults*, first published in March 1992. This update reflects new research findings and experience with emerging technologies for UI diagnosis and treatment, and provides *specific* recommendations for diagnosing and managing adult patients with UI.

Urinary Incontinence in Adults Guideline Update Panel

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Executive Summary

Urinary incontinence (UI) plagues 10-35 percent of adults and at least half of the 1.5 million nursing home residents in the United States. Because of the social stigma of UI, many sufferers do not even report the problem to a health care provider. In addition, when it is reported, many physicians and nurses, who need to be educated in this area, fail to pursue investigation of UI. As a result, this medical problem is vastly underdiagnosed and underreported.

The prevalence of UI, its toll on physical and psychological health, large variations in UI care practices and costs, and the urgent need to educate health care providers and the public about this condition prompted the selection of UI as a clinical guideline topic.

The purpose of this guideline is to improve reporting, diagnosis, and treatment of UI; reduce variations in clinical practice; educate health care providers and consumers about this condition; and, finally, encourage further biomedical, clinical, and cost research on UI. The guideline should help clinicians, caregivers, patients, and patients' families understand the assessment, management, and treatment of UI in adults. Specific reimbursement issues are not addressed.

The guideline recommendations apply to the diagnosis and treatment of acquired incontinence in ambulatory and nonambulatory patients in outpatient, inpatient, and long-term care settings. Not addressed are extraurethral UI, which is involuntary loss of urine through channels other than the urethra, UI in children, and UI due to neuropathic conditions.

To develop and update the guideline AHCPR convened a multidisciplinary, private-sector panel of physicians, nurses, allied health professionals, and health care consumers. The panel conducted extensive literature reviews of UI in adults, heard public testimony at national hearings, and examined information gathered from consultants. It studied the effectiveness and appropriateness of diagnostic and treatment procedures for UI, how they affect outcomes important to patients, their benefits and adverse consequences, and costs incurred from their use.

The panel found evidence in the literature that the treatment of UI can improve or "cure" most patients. It determined that UI in the adult requires a comprehensive approach by health professionals in the initial evaluation and treatment with behavioral and pharmacologic interventions and requires specialists for further diagnostic evaluation and surgical intervention.

The guideline provides practice recommendations in three areas:

- **Prevention, identification, and evaluation.** Specific risk factors for incontinence can be both identified and remediated with targeted interventions and prevention programs. The identification and documentation of UI can be improved with more thorough medical history taking, physical examination, and recordkeeping. Routine tests of lower urinary tract function should be performed for initial identification of UI. Situations that require further evaluation by qualified specialists include uncertain diagnosis, lack of correlation between symptoms and clinical findings, failure to respond to adequate therapeutic trial, hematuria without infection, presence of other comorbid conditions, and confirmation of diagnosis of incontinent patients being considered for surgical therapy. The specialized tests recommended for further diagnosis are detailed.

- **Selection of appropriate therapy.** The guideline provides an informed framework for selecting appropriate behavioral, pharmacologic, and surgical treatments and supportive devices that can be used to manage UI. The panel concluded that behavioral techniques such as bladder retraining and pelvic muscle rehabilitation are

effective, low-risk interventions that can reduce incontinence significantly in varied populations. The guideline outlines what drugs can be used effectively for certain types of incontinence, including dosages and possible side effects. The panel recognizes the effectiveness of surgical interventions in well-selected cases. Behavioral and pharmacologic treatments may reduce the need for surgical interventions and may be considered in the initial management. A new chapter on long-term management of chronic intractable UI has been added to the updated chapters from the 1992 guideline. Specific recommendations on management of patients with this condition are provided.

- **Education of health professionals and the public.** Finally, the guideline calls for continued efforts to educate health care providers about this condition so that they are sufficiently knowledgeable to diagnose and treat it. It recommends that the public be advised to report incontinence problems once they occur and be informed that incontinence is not inevitable or shameful but is a treatable or at least manageable condition.

This is an update of the guideline, *Urinary Incontinence in Adults* first published in March 1992. This update reflects new research findings and experience with emerging technologies and innovative approaches for UI assessment and relief. The Agency for Health Care Policy and Research and the guideline development panel welcome comments and suggestions regarding the current guideline. Please address written comments to: Director, Office of the Forum for Quality and Effectiveness in Health Care, Agency for Health Care Policy and Research, 6000 Executive Boulevard, Suite 310, Rockville, MD 20852.

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1 Overview

Incidence and Prevalence

UI affects approximately 13 million Americans, with the highest prevalence in the elderly in both community and institutional settings (National Kidney and Urologic Diseases Advisory Board, 1994). The high prevalence of UI and its significant adverse physical, psychological, and financial effects clearly justify more aggressive efforts to identify, evaluate, and treat UI in all settings. Growing evidence indicates that appropriate management can reduce the morbidity and cost of UI, particularly in institutionalized populations (Ouslander, Palmer, Rovner, et al., 1993).

Although the prevalence of UI increases with age, UI should not be considered a normal part of the aging process. Reported prevalence rates of UI vary considerably, depending on the population studied, the definition of UI, and how the information is obtained (Diokno, Brock, Herzog, et al., 1990). Among the population between 15 and 64 years of age, the prevalence of UI in men ranges from 1.5 to 5 percent and in women from 10 to 30 percent (Burgio, Matthews, and Engel, 1991; Harrison and Memel, 1994). Although UI is usually regarded as a condition affecting older multiparous women, it is also common in young, nulliparous women, particularly during physical activity (Bo, Maehlum, Oseid, et al., 1989; Nygaard, Thompson, Svengalis, et al., 1994)

For noninstitutionalized persons older than 60 years of age, the prevalence of UI ranges from 15 to 35 percent, with women having twice the prevalence of men. Between 25 and 30 percent of those identified as incontinent have frequent incontinence episodes, usually daily or weekly (Burgio, Matthews, and Engel, 1991; Diokno, Brock, Brown, et al., 1986).

Survey data from caregivers of the elderly show that approximately 53 percent of the homebound elderly are incontinent (Noelker, 1987). A random sampling of hospitalized elderly patients identified 11 percent as having persistent UI at admission and 23 percent at discharge (Palmer, McCormick, Langford, et al., 1992).

UI is generally recognized as one of the major causes of institutionalization of the elderly. Among the more than 1.5 million nursing facility residents, the prevalence of UI is 50 percent or greater, with the majority of nursing home residents having frequent UI (Ouslander, Kane, and Abrass, 1982; Palmer, German, and Ouslander, 1991). The annual incidence of UI in nursing home residents who are admitted continent was recently reported to be 27 percent and is higher in males; it is strongly associated with dementia, fecal incontinence, and inability to walk and transfer independently (Ouslander, Kane, and Abrass, 1982; Palmer, German, and Ouslander, 1991). Additional information about the prevalence of UI in nursing home residents and homebound persons is provided in Chapter 4.

Quality of Life

UI imposes a significant psychosocial impact on individuals, their families, and caregivers. UI results in a loss of self-esteem and a decrease in ability to maintain an independent lifestyle. Dependence on caregivers for activities of daily life increases as incontinence worsens. Consequently, excursions outside the home, social interaction with friends and family, and sexual activity may be restricted or avoided entirely (Grimby, Milsom, Molander, et al., 1993; Harris, 1986; Noelker, 1987). Quality-of-life and symptom distress questionnaires for women with UI have been validated for use (Shumaker, Wyman, Uebersax, et al., 1994; Uebersax, Wyman, Shumaker, et al., 1995).

Underreporting/Undertreatment

Fewer than half of individuals with UI living in the community consult health care providers about the problem (Burgio, Ives, Locher, et al., 1994). The reasons for this could be the availability of absorbent products, low

expectations of benefit from reporting the condition to health care providers, and lack of information regarding management options. There is a lack of understanding about UI, especially among men, those age 85 or older, and those with lower levels of education Branch, Walker, Wetle, et al., 1994).

Studies show significant variation in performance of adequate examination, assessment, and management of UI. UI is often undetected and underreported by hospital and nursing home personnel, masking its true extent and clinical impact and reducing the opportunity for effective management. Assessment tools with cue words for continence status significantly improve identification of UI in nursing homes and increase the opportunity for effective management (Palmer, McCormick, Langford, et al., 1992).

Risk Factors and Prevention

The incidence of incontinence is sufficiently high that the development of an effective prevention program would reduce new cases of incontinence in community-dwelling women alone by approximately 50,000 cases annually (Siu, Beers, and Morgenstern, 1993). There is good evidence that specific risk factors for incontinence can be both identified and remediated with targeted interventions. However, no controlled clinical trial data exist showing that these interventions reduce incontinence incidence, severity, or prevalence. Table 1 provides a summary of risk factors associated with incontinence that have been documented in the literature. Some of the risk factors for UI are discussed further in Chapter 2. Only one reference has been listed for each risk factor, although in most cases multiple studies have described the same factor. Several of the studies described interventions that have modified these risk factors successfully.

Costs

A recent estimate of the direct costs of caring for persons of all ages with incontinence is $11.2 billion annually in the community and $5.2 billion in nursing homes (based on 1994 dollars) Hu, 1994). This cost estimate is more than 60 percent greater than a previous estimate (Hu, 1990), an increase greater than that for the cost of services in the medical care sector. Data show that costs of providing care for UI vary widely (Baker and Bice, 1995; Hu, Gabelko, Weiss, et al., 1994).

The guideline does not address specific reimbursement issues, which are being evaluated by other groups (National Kidney and Urologic Diseases Advisory Board, 1994).

Purpose and Scope

The original *Clinical Practice Guideline on Urinary Incontinence in Adults* was published in March 1992. The purpose and scope of the 1992 guideline and the methodology for its development are outlined below. The process used for updating the original guideline, which resulted in the publication of this *Clinical Practice Guideline Update on Urinary Incontinence in Adults: Acute and Chronic Management* is also outlined.

1992 Guideline

The original UI guideline panel defined UI as involuntary loss of urine that is sufficient to be a problem. The panel agreed that the guideline, which sought to improve the care of incontinent adults, should be directed toward acquired incontinence in ambulatory and nonambulatory patients in outpatient, inpatient, home care, and long-term care settings. Extraurethral UI, which is involuntary loss of urine through channels other than the urethra, was not addressed in the document. The guideline was targeted to all practitioners who encounter UI, with the primary outcome of elimination or reduction of UI.

The original panel also agreed on the components of the evaluation and management of UI, which were considered to be the management model for the guideline. The original guideline made seven broad-based recommendations, as follows:

1. Improve the education and dissemination of UI diagnosis and treatment alternatives to the public and to health care providers.
2. Educate the consumer to report incontinence problems once they occur.
3. Improve the detection and documentation of UI through better medical histories and health care recordkeeping.
4. Establish appropriate basic evaluation and criteria for further evaluation.
5. Delineate the steps of appropriate management.
6. Where appropriate, reduce variations among health care providers, while maintaining flexibility to individualize treatment to individual patients.
7. Encourage further biomedical and clinical research on prevention, diagnosis, and treatment of UI in adults and encourage further research into the costs of UI diagnosis and treatment and the cost benefit of prevention programs.

The original panel conducted an extensive literature review on UI in adults, heard public testimony at a national hearing, and reviewed information from consultants. It also sought further evidence of the costs of UI, variations in practice and payments, the prevalence of incontinence in hospitals, and the incidence of UI in outpatient, rehabilitation, and home settings. Previous research data and expert opinions helped to provide insight into the problem within communities, acute care facilities, and nursing homes. The draft guideline was also extensively peer-reviewed by individual experts and representatives of the various professional and public organizations, and many of their recommendations were incorporated into the document.

The panel found evidence that treatment of UI is effective in most people; however, the condition was underreported, services were improperly or poorly documented, and major variations in diagnosis and treatment were identified as significant problems.

The original UI panel also recommended that review of the guideline respond to new developments in UI research, training, product developments, practice, and patient participation. Because of the magnitude of literature produced each year, the panel recommended that the guideline be updated annually.

Updating the Guideline

Because the recommendations were so broad-based, AHCPR recommended updating the guideline to include recent literature and to provide specific recommendations for managing UI in adults. AHCPR provided the general parameters for this update of the guideline. An update can be in the form of amendments to the guideline or a more complete update and reprinting. In the months following release of a guideline, the Office of the Forum surveys subsequently published scientific literature in the topic areas addressed by the guideline to determine the volume of new scientific evidence, its quality, and the likelihood that such information would cause a change in the guideline recommendations. Comments are also solicited from the public regarding the availability of new scientific evidence or new technologies that may warrant an update. Other relevant information may be obtained from evaluation studies conducted to examine the implementation or effects of the guidelines. When sufficient data are obtained to indicate that a guideline update may be needed, a public meeting to address the need for and timing of an update is convened.

After reviewing and analyzing the findings from the update literature review and analysis since 1992, the Office of the Forum recommended a complete update and reprinting of the guideline. The primary goals of the update process were to present new developments in UI research that affect diagnosis and management of the condition and to develop specific recommendations for each assessment and treatment method. The algorithm for management of UI in primary care was revised to reflect the findings and recommendations of the panel (see Attachment A).

Methodology for Updating the Guideline

The following specific activities were undertaken to update the original UI guideline.

Formation of the Panel

AHCPR initiated formation of the update panel and appointed its chairperson and members. A notice published in the Federal Register invited nominations of new candidates to replace the departing panel members. The original panel chairs reviewed nominations received by AHCPR and provided their recommendations to AHCPR to replace departing members. Following these recommendations, AHCPR selected and appointed the replacement members for the update period. The update panel comprised 16 members representing the multidisciplinary areas included in the original panel -- the departing cochairs were replaced by two of the original panel members, six other original members remained, and eight new members joined. Several consultants with expertise in nursing and primary care, methodology, literature review and analysis, and cost analysis, as well as a representative of the Centers for Disease Control and Prevention (CDC), were appointed to the panel. Over the course of the update process the panel also sought the advice and assistance of 22 technical specialists to evaluate the literature and develop revisions to the original guideline.

Public Comment and Peer Review

An open forum was held September 20, 1993, to give interested individuals, organizations, and agencies the opportunity to present written or verbal testimony. Later in the process, drafts of the revised guideline were sent out for peer review. AHCPR selected peer reviewers from those who had expressed interest in the guideline, participated in the open forum, or were nominated by professional organizations or panel members. The 22 technical specialists were included among the peer reviewers. The reviewers were asked to evaluate the comprehensiveness of the literature review as well as the panel's findings and recommendations. The panel incorporated their comments into the final revision of the guideline.

Literature Search

The panel initiated a comprehensive literature search of topics relating to adult UI. The bibliography from the original guideline was the starting point for this literature search.

The search for literature published since the final literature search conducted for the 1992 guideline was performed through the National Library of Medicine. Over the course of the update process, three searches were conducted. Abstracts of approximately 1,500 articles that met the search criteria were each independently evaluated by panel members for scientific quality and relevance to the guideline update. Approximately 1,200 articles were obtained for further evaluation.

Additional articles came from panel members, from the open forum process, and from unsolicited sources. All articles were entered into a comprehensive bibliography, classified by topic, and screened systematically to determine if they contained information of use to the update panel.

Literature Review and Data Abstraction

The articles were categorized and assigned to corresponding subcommittees for screening and further review. These categories were prevalence, prevention, and quality of life; cost; causes and diagnostic evaluation; behavioral treatment; pharmacological treatment; surgery; supportive devices; and professional and public education. The methodology to identify and evaluate the scientific evidence on each assessment and treatment method included a systematic evaluation of each study's quality and its applicability to adult patients with UI. The panel screened all articles, using minimum article selection criteria to select articles for data abstraction. The panel subcommittees used a common data abstraction method, but because of the varied nature of the subject, each subcommittee determined its own inclusion/exclusion criteria. The pharmacology subcommittee restricted review to clinical efficacy studies of drugs likely to be available in the United States. Because few such studies exist in other areas, it was not possible to place similar restrictions on the review of behavioral and surgical interventions. Minimum criteria generally required that articles represent a designed study (not a case report) with outcome defined in some manner. The articles selected were then sent to technical specialists for review for data abstraction and for confirmation of the data abstraction

process. The technical specialists followed the same data abstraction process to evaluate the quality and to abstract pertinent data from each article. The articles on behavioral, pharmacologic, and surgical treatments were further reviewed and summaries of results (with total number of subjects and a range or average of improvement or success rates) provided. The papers on diagnostic, supportive, and health education were not judged applicable for meta-analysis.The panel then reviewed the available data to decide how much weight to give each study in developing the recommendation statements for the update guideline.

Outcome Measures

The panel was aware of the limits of and issues surrounding current outcome measures while evaluating the available data on assessment and treatment methods for UI. The current outcome measure of UI treatment is to stop urine leakage or to reduce its amount, frequency, or both. Measuring urine leakage or wetting is difficult, however. The panel agreed that UI outcome can be measured in many domains (e.g., patients' opinions, diaries, pad tests, quality-of-life scales, urodynamic tests) and that each of these domains is continuous and not discrete. The International Continence Society and other groups are considering standardization of outcome measures.

The wide variability in outcomes measured in different articles made it difficult to choose a single outcome measure to assess treatment. Because the subjective outcome of "cure," improvement, or both was cited in studies much more often than objective measures, this was the outcome the panel generally relied on. When sufficient articles presented results on incontinent episodes, these were also noted.

Developing the Guideline Recommendations

To develop recommendations for each assessment and treatment method, the panel considered (1) the quality and amount of evidence, (2) the consistency of findings among studies, (3) the clinical applicability of the evidence to adult patients with UI, and (4) the evidence on harms or costs.

Specific recommendation statements were developed by the panel collectively. The panel rated the strength of evidence supporting each recommendation, based on the following criteria:

A.

The recommendation is supported by scientific evidence from properly designed and implemented controlled trials providing statistical results that consistently support the guideline statement.

B.

The recommendation is supported by scientific evidence from properly designed and implemented clinical series that support the guideline statement.

C.

The recommendation is supported by expert opinion.

Please note that these ratings represent the strength of the supporting research evidence, not the strength of the recommendation itself. The strength of each recommendation is conveyed in the language describing it.

Clinical Algorithm

The overview algorithm in Attachment A provides the health care provider with a visual display of the conceptual organization, procedural flow, decision points, and preferred management pathways discussed in the guideline.

Tables

Table 1. Risk factors associated with incontinence

Risk factor	Reference
Immobility/chronic degenerative disease	Ouslander, Palmer, Rovner, et al., 1993; Adams, Lorish, Cushing, et al., 1994
Impaired cognition	Morris, Browne, and Saltmarche, 1992; Skelly and Flint, 1995
Medications	Dwyer and Teele, 1992
Morbid obesity	Bump and McClish, 1994
Diuretics	Diokno, Brock, Herzog, et al., 1990
Smoking	Bump and McClish, 1994
Fecal impaction	Resnick and Yalla, 1985
Delirium	Resnick, 1988
Low fluid intake	Colling, Owen, and McCreedy, 1994
Environmental barriers	Wyman, Elswick, Ory, et al., 1993
High-impact physical activities	Nygaard, Thompson, Svengalis, et al., 1994
Diabetes	Appell and Baum, 1990
Stroke	Benbow, Sangster, and Barer, 1991
Estrogen depletion	Burns, Nochajski, and Pranifoff, 1993
Pelvic muscle weakness	Burns, Nochajski, and Pranifoff, 1993
Childhood nocturnal enuresis	Moore, Richmond, and Parys, 1991
Race	Burgio, Matthews, and Engel, 1991
Pregnancy/vaginal delivery/episiotomy	Foldspang, Mommsen, Lam, et al., 1992; Klein, Gauthier, Robbins, et al., 1994

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This publication is provided for historical reference only and the information may be out of date.

2 Identifying and Evaluating Urinary Incontinence

Symptoms and Subtypes

UI can be caused by anatomic, physiologic, and pathologic (genitourinary) factors affecting the urinary tract, as well as external (nongenitourinary) factors. Multiple and interacting factors often contribute to UI development, especially in frail, older patients (Ouslander and Bruskewitz, 1989). In such patients, the diagnostic evaluation must be comprehensive, focusing not only on the lower urinary tract but also on the patient's general medical and functional status.

Several conditions that cause or contribute to UI are potentially reversible (see Table 2). Management of one or more of these conditions can sometimes lead to the resolution of the UI. This potentially reversible type of UI has been referred to as transient incontinence. In other patients, treatment of these conditions will reduce the severity of UI but will not totally resolve it. Several different nosologies have been used to classify the various types of UI. The classification of subtypes of UI used here is based on symptoms so as to facilitate use of this guideline by primary health care providers. Often, classifications used by specialists incorporate primarily pathophysiologic characteristics.

Urge Incontinence

The symptom of urge incontinence is the involuntary loss of urine associated with a strong desire to void (urgency). Urge incontinence is usually, but not always, associated with the urodynamic finding of involuntary detrusor contractions, referred to as detrusor instability (DI). Although DI can be associated with neurologic disorders, it also occurs in individuals who appear to be neurologically normal. The uninhibited bladder contractions associated with DI can cause UI with and without symptoms of urgency; it can also cause symptoms of urgency without concomitant incontinence (Fantl, Wyman, McClish, et al., 1991). When a causative neurologic lesion is established, the DI is called detrusor hyperreflexia (DH) (Abrams, Blaivas, Stanton, et al., 1988). A common neurologic disorder associated with DH is stroke. In patients with suprasacral spinal cord lesions and multiple sclerosis, DH is commonly accompanied by detrusor sphincter dyssynergia (DSD) (inappropriate contraction of the external sphincter with detrusor contraction). This can result in the development of urinary retention, vesicoureteral reflux, and subsequent renal damage (McGuire, Woodside, Borden, et al., 1981).

Another urodynamic diagnosis associated with the symptom of urge incontinence in frail, elderly patients is detrusor hyperactivity with impaired bladder contractility (DHIC) (Resnick and Yalla, 1985). Patients with DHIC have involuntary detrusor contractions, yet must strain to empty their bladders either incompletely or completely. Clinically, patients with DHIC generally have symptoms of urge incontinence and an elevated postvoid residual (PVR) volume, but they may also have symptoms of obstruction, stress incontinence, or overflow incontinence. DHIC must be distinguished from other types of UI because it can mimic them, resulting in inappropriate diagnosis and treatment.

Stress Incontinence

The symptom of stress urinary incontinence (SUI) presents clinically as the involuntary loss of urine during coughing, sneezing, laughing, or other physical activities that increase intra-abdominal pressure. SUI is defined as urine loss coincident with an increase in intra-abdominal pressure, in the absence of a detrusor contraction or an overdistended bladder. The most common cause of SUI in women is urethral hypermobility, or significant displacement of the urethra and bladder neck during exertion when intra-abdominal pressure is raised.

SUI may also be caused by an intrinsic urethral sphincter deficiency (ISD), which may be due to congenital sphincter weakness in patients with myelomeningocele, epispadias, or pelvic denervation, or may be acquired after prostatectomy, trauma, radiation therapy, or a sacral cord lesion. In women, ISD is commonly associated with multiple incontinence surgical procedures, as well as with hypoestrogenism, aging, or both. In this condition, the urethral sphincter is unable to generate enough resistance to retain urine in the bladder, especially during stress maneuvers (Blaivas, 1985; Staskin, Zimmern, Hadley, et al., 1985). Patients with ISD often leak continuously or with minimal exertion. In some patients, stress incontinence results from coexisting ISD and hypermobility of the urethra and bladder neck.

Mixed Incontinence

It is not unusual for patients to present with a combination of urge and stress incontinence (Fantl, Wyman, McClish, et al., 1990; Ouslander, Hepps, Raz, et al., 1986). When both symptoms are present, the incontinence is called mixed UI. Mixed UI is common in women, especially older women. Often, however, one symptom (urge or stress) is more bothersome to the patient than the other. Identifying the most bothersome symptom is important in targeting diagnostic and therapeutic interventions.

Overflow Incontinence

Involuntary loss of urine associated with overdistension of the bladder is termed overflow incontinence. This type of incontinence may have a variety of presentations, including frequent or constant dribbling, or urge or stress incontinence symptoms. Overflow UI may be caused by an underactive or acontractile detrusor, or to bladder outlet or urethral obstruction leading to overdistension and overflow. The bladder may be underactive or acontractile secondary to drugs, neurologic conditions such as diabetic neuropathy, low spinal cord injury, or radical pelvic surgery that interrupts the motor innervation of the detrusor muscle. The detrusor muscle may also be underactive from idiopathic causes.

In men, overflow incontinence associated with obstruction is commonly caused by prostatic hyperplasia and, less frequently, prostatic carcinoma or urethral stricture. Although an outlet obstruction is rare in women, it can occur as a complication of an anti-incontinence operation and because of severe pelvic organ prolapse, in which the organ involved protrudes to or beyond the vaginal orifice (e.g., prolapsing cystocele, uterine prolapse). In patients with suprasacral spinal cord injury or multiple sclerosis, DSD can cause obstruction when the external sphincter muscle inappropriately and involuntarily contracts rather than relaxes at the same time the detrusor contracts (Blaivas, 1985).

Other Causes and Types

Functional Incontinence

Urine loss may be caused by factors outside the lower urinary tract such as chronic impairment of physical or cognitive functioning, or both, a condition commonly termed "functional incontinence" Williams and Pannill, 1982). This diagnosis should be one of exclusion, however, because some immobile and cognitively impaired individuals have other types and causes of UI that may respond to specific therapies (Skelly and Flint, 1995). For example, most nursing home residents have not only functional limitations that interfere with their ability to toilet but also urge UI with detrusor instability or DH. In addition, UI can often be improved or "cured" by improving the patient's functional status, treating other medical conditions, discontinuing certain types of medication, adjusting the hydration status, reducing environmental barriers, or all of the above -- even if a lower urinary tract abnormality is present.

Unconscious or Reflex Incontinence

Urine loss may also occur without any warning or sensory awareness such as in paraplegics and some patients without overt neurologic dysfunction. This condition, which also has been termed unconscious incontinence, presents as either postmicturitional or constant (continuous) dribbling. Extraurethral UI (i.e., fistulas), UI in children, and neuropathic conditions are not specifically addressed in this guideline.

Another urodynamic finding that may be associated with UI is decreased bladder compliance. This abnormal bladder condition may result from radiation cystitis, inflammatory bladder conditions such as chemical cystitis or interstitial cystitis, and some neurologic bladder disorders such as those that occur following radical pelvic surgery and in myelomeningocele. Many of the patients with a nonneurogenic etiology for their decreased bladder compliance (e.g., chemical or radiation cystitis) have severe urgency associated with bladder hypersensitivity and with no demonstrable DI. This is termed "sensory urgency." Both loss of bladder wall elasticity and lack of bladder accommodation produce a steep rise in intravesical pressure during bladder filling without detrusor contraction. In patients in whom the urethral sphincter mechanism may already be compromised by the condition that produced the inelastic bladder (e.g., radiation, neurologic dysfunction), the abnormal increase in bladder pressure may overcome the urethral pressure and produce UI. A major concern in patients with a poorly compliant bladder, especially those who are neurologically impaired, is the development of vesicoureteral reflux and hydronephrosis.

Identifying Urinary Incontinence

Because many people with UI delay or do not seek professional help (Herzog, Fultz, Normolle, et al., 1989; Norton, MacDonald, Sedgwick, et al., 1988), primary health care providers should question their patients regularly to identify UI. Open-ended requests such as "Tell me about the problems you are having with your bladder" and "Tell me about the trouble you are having holding your urine (water)" are a useful initial approach. If the patient responds negatively, more specific questions such as "How often do you lose urine when you don't want to?" and "How often do you wear a pad or other protective device to collect your urine?" may help identify UI. In licensed nursing facilities, assessment of continence status using the Minimum Data Set (MDS) is required within 14 days of admission and every 3 months thereafter (Morris, Hawes, Murphy, et al., 1990).

If UI is identified by questioning, detecting an odor, observing wetness, or by a patient complaint, and represents a problem for the patient or caregiver, evaluation should be undertaken as described below.

General Principles of Diagnostic Evaluation

Health care providers are encouraged to be knowledgeable about and initiate the basic evaluation of patients with UI. (Strength of Evidence = C.)

When UI is a problem for the patient or caregiver, the patient should undergo a basic evaluation by a health care provider. UI has traditionally been evaluated by specialists, including gynecologists and urologists, and in some rehabilitation settings, by physiatrists. Given the high prevalence of UI in the general population, however, limiting UI evaluation and management to these specialists is not feasible. The panel encourages primary health care providers, such as family physicians, general internists, geriatricians, nurse practitioners and specialists, and physician assistants, to be knowledgeable about and able to initiate the basic evaluation of UI.

Basic Evaluation

All patients with UI should undergo a basic evaluation that includes a history, physical examination, measurement of postvoid residual volume, and urinalysis. (Strength of Evidence = B.)

Risk factors that are associated with UI should be identified and attempts made to modify them. (Strength of Evidence = B.)

Purpose

UI is a symptom and not a condition in itself. Thus, the purposes of the basic evaluation are to

1. Confirm the presence of UI.
2. Identify conditions, including potentially reversible ones (see Table 2), that may be contributing to the UI.

3. Identify patients who require further evaluation before any therapeutic interventions are attempted and patients who may receive initial treatment without further testing.
4. Identify a presumptive diagnosis, if possible.

Components

The basic evaluation should include a history, physical examination, estimation of PVR volume, and urinalysis. The basic evaluation may not be appropriate for every patient, and every health care provider may not have the background to complete this assessment for some patients. At any time during the basic evaluation, the health care provider may refer the patient for further evaluation by a specialist.

History

The history should include (1) a focused medical, neurologic, and genitourinary history that includes an assessment of risk factors (see Table 1) and a review of medications (including nonprescription medications) and (2) a detailed exploration of the symptoms of the UI and associated symptoms and factors, including

- Duration and characteristics of UI (stress, urge, dribbling, others).
- Most bothersome symptom(s) to the patient (which may be especially important in guiding therapy and determining response).
- Frequency, timing, and amount of continent voids and incontinent episodes.
- Precipitants of incontinence (e.g., situational antecedents, cough, certain types of exercises, surgery, injury, previous pelvic radiation therapy, trauma, new onset of diseases, new medications).
- Other lower urinary tract symptoms (e.g., nocturia, dysuria, hesitancy, poor or interrupted stream, straining, hematuria, suprapubic or perineal pain).
- Fluid intake pattern, including caffeine-containing or other diuretic fluids.
- Alterations in bowel habits or sexual function.
- Previous treatments and their effects on UI.
- Amount and types of pads, briefs, and protective devices.
- Expectations for outcomes of treatment.
- A bladder record.
- A mental status evaluation and assessment of mobility, living environment, and social factors, especially in elderly patients.

Bladder records are helpful supplements to the history in many patients (Diokno, Wells, and Brink, 1987; Larson and Victor, 1992; Wyman, Choi, Harkins, et al., 1988). These written records are used to determine the frequency, timing, and amount of voiding, as well as other factors associated with UI. Such a record can be kept by the patient or a caregiver for a few days before the basic evaluation. The record may provide clues about the underlying cause of UI, as well as information on fluid intake and voiding patterns that may be helpful for behavioral interventions, and can serve as a baseline to gauge severity and treatment efficacy (see sample records, Attachments B and C.

A mental status examination should be performed when appropriate. Assessment of mobility and living environment is also especially important in certain individuals. Questions should be asked about access to toilets or toilet substitutes, and about social factors such as living arrangements, social contacts, or caregiver involvement (Williams and Gaylord, 1990).

Physical Examination

The physical examination should include the following:

- *General examination* if indicated to detect conditions such as edema that may contribute to nocturia and nocturnal UI; to detect neurologic abnormalities that may suggest multiple sclerosis, stroke, spinal cord compression, or other neurologic conditions; and to assess mobility, cognition, and manual dexterity related to toileting skills among frail and functionally impaired patients Williams and Gaylord, 1990).
- *Abdominal examination* to check for diastasis rectii, organomegaly, masses, peritonitis, fluid collections, and so on. Abnormality of abdominal contents may influence intraabdominal pressure and detrusor physiology.
- *Rectal examination* to test for perineal sensation, sphincter tone (both resting and active), fecal impaction, or rectal mass, and to evaluate the consistency and contour of the prostate in men. The size of the prostate on digital examination does not exclude or imply obstruction and is usually helpful only for the surgeon in determining the surgical approach if an operation is contemplated.
- *Genital examination in men* to evaluate skin condition and detect abnormalities of the foreskin, glans penis, and perineal skin.
- *Pelvic examination in women* to assess perineal skin condition, genital atrophy, pelvic organ prolapse (cystocele, rectocele, uterine prolapse), pelvic mass, paravaginal muscle tone, or other abnormalities. Palpation of the anterior vaginal wall and urethra may elicit urethral discharge or tenderness that suggests a urethral diverticulum, carcinoma, or inflammatory condition of the urethra. Pelvic organ prolapse may not relate to urinary symptoms, especially in the elderly (Ouslander, Hepps, Raz, et al., 1986).
- *Direct observation of urine loss* using the cough stress test. Observation of urine loss can be performed by having the individual cough vigorously while the examiner observes for urine loss from the urethra. Optimally, testing should be done when the patient's bladder is full but before the patient has a precipitant urge to void Kadar, 1988). In women who are being evaluated for specific treatments for stress incontinence, this test is important for objective demonstration of urine loss and identification of provoking factors. In other patients, particularly those with physical or cognitive impairment, direct observation may be difficult to carry out, and this documentation may not be critical in determining initial treatment of incontinence. If an instantaneous leakage occurs with cough, then SUI is likely; if leakage is delayed or persists after the cough, DI should be suspected. If the test is initially performed in the lithotomy position and no leakage is observed, the test should be repeated in the upright position (Kadar, 1988). If bladder filling is needed to perform stress testing, it may be conveniently performed in conjunction with the catheterization method of measurement of PVR volume.

Estimation of PVR Volume

Accurate measurement of PVR can be accomplished either by catheterization or by pelvic ultrasound (Coombes and Millard, 1994; Haylen, Frazer, and MacDonald, 1989; Ireton, Krieger, Cardenas, et al., 1990). Some health care providers may use abdominal palpation or bimanual pelvic examination to suspect elevated PVR; however, the exact amount of volume or confirmation usually requires other methods (catheterization, ultrasound) (Norton, Peattie, and Stanton, 1989).

Before PVR is measured, the patient should void in the most comfortable and private environment possible. Voiding can be observed at this time to detect signs of hesitancy, straining, or slow or interrupted stream, which may indicate urethral obstruction, a bladder contractility problem, or both.

Measurement of PVR volume is generally done within a few minutes after voiding by catheterizing the patient or by pelvic ultrasound. Review of the literature failed to indicate a specific maximum PVR volume considered normal, nor is there any documentation of the minimal PVR considered abnormal. In general, PVRs of less than 50 mL are considered adequate bladder emptying. Repetitive PVRs ranging from 100 to 200 or higher are considered inadequate

emptying. Clinical judgment must be exercised and all other clinical information included in interpreting the significance of PVR volume, especially in the intermediate range of 50-199 mL.

The PVR urine may be influenced by such factors as the volume voided before PVR measurement, whether the patient is "ready" to void or strains to void, the efforts made to drain the bladder completely, and the environment or clinical setting. Because PVR volume may vary, one measurement of PVR may not be sufficient and repeated measurements may be of value in some patients.

Urethral catheterization in men with prostate obstruction may cause urinary tract infection. Therefore, catheterization in men should be performed only with clear indication and by a health care provider who is prepared to manage abnormal findings.

An alternative to catheterization is the use of pelvic ultrasound. Portable ultrasound devices that estimate PVR with reasonable accuracy are now available (Ireton, Krieger, Cardenas, et al., 1990; Ouslander, Simmons, Tuico, et al., 1994; Topper, Holliday, and Fernie, 1993).

Urinalysis

This test is used to detect conditions that are associated with or contributing to UI such as hematuria (suggestive of infection, cancer, or stone), glucosuria (which may cause polyuria and contribute to UI symptoms), pyuria, and bacteriuria, as well as glycosuria and proteinuria. If catheterization is performed for PVR measurement, a sample of the residual urine can be used for the urinalysis and microscopic examination. Careful cleaning of the glans penis in men and the periurethral area in women with an antiseptic solution allows collection of a spontaneously voided specimen that accurately reflects bladder urine.

Dipstick methods are available to detect bacteriuria and pyuria. The diagnostic accuracy of these methods varies considerably among methods and different patient populations (Lachs, Nachamkin, Edelstein, et al., 1992). Therefore, urine cultures should be obtained in incontinent patients when dipstick tests indicate infection or when symptoms suggest infection.

Among chronically incontinent nursing home residents, eradication of bacteriuria (with or without pyuria) has no effect on morbidity, mortality, or the severity of UI (Boscia, Kobasa, Abrutyn, et al., 1986). Thus, unless UI is of recent onset, has recently worsened, or is accompanied by other symptoms of infection (e.g., dysuria, hematuria, fever, sudden decline in mental or physical functioning), bacteriuria (with or without pyuria) does not need to be treated in this patient population. Among noninstitutionalized patients, the relationship of bacteriuria (with or without pyuria) to UI is unclear. Further research is needed to clarify this relationship. Until such data are available, infection should be treated when the incontinent patient is initially evaluated and the effect observed before further diagnostic or therapeutic interventions are undertaken (Ouslander, 1989).

Supplementary Assessments

The use of blood tests (BUN, creatinine, glucose, and calcium) and urine cytology in the assessment of the incontinent patient was also evaluated.

> Blood testing (BUN, creatinine, glucose, and calcium) is recommended if compromised renal function is suspected or if polyuria (in the absence of diuretics) is present. (Strength of Evidence = C.)

Blood tests that may be helpful in the basic evaluation of the incontinent patient include creatinine levels in patients suspected of having obstruction, noncompliant bladders, or urinary retention. However, normal creatinine levels do not rule out hydronephrosis. Patients with polyuria in the absence of diuretic agents should be evaluated for excess intake (diabetes insipidus), hyperglycemia, and hypercalcemia if indicated.

Urine cytology is not recommended in the routine evaluation of the incontinent patient. (Strength of Evidence = B.)

There is no evidence in the literature to support urine cytology testing in patients with UI. Individuals with incontinence are at no higher risk of bladder cancer than the continent population Mohr, Offord, Owen, et al., 1986). Urine cytology is a poor screening test for bladder cancer, with sensitivities ranging from approximately 20-70 percent (Curling, Broome, and Gendry, 1986; Murphy, 1990; Rife, Farrow, and Utz, 1979). Patients with hematuria (2-5 RBC/hpf) or acute onset of irritative voiding symptoms in the absence of urinary tract infection (UTI) require cystoscopy and cytology to exclude bladder neoplasm (Utz and Zincke, 1974).

Further Evaluation

After the basic evaluation, treatment for the presumed type of urinary incontinence should be initiated unless there is an indication for further evaluation. (Strength of Evidence = B.)

After the basic evaluation, all incontinent patients in whom transient (reversible) causes of UI have been detected should be treated appropriately (see Table 2). If UI persists after the transient causes are identified and treated, further evaluation may be helpful before therapy is initiated.

Examples of patients who may not need further evaluation before initiating treatment follow:

- Patients with SUI, normal PVR volume, and no complicating features.
- Patients with urge UI, normal PVR volume, and no complicating features.
- Women with mixed urge-stress UI with normal PVR volume and no complicating features for whom behavioral or pharmacologic therapy, or both, is preferred.

Initial management options for these patients are outlined in Table 3.

Patients requiring further evaluation include those who meet any of the criteria in Table 4. Because of their general medical condition, some of these patients may not be appropriate for further evaluation, particularly if it is not desired by the patient or feasible.

After the basic evaluation and initial treatment, patients who fail or those who are not appropriate for treatment based on presumptive diagnosis should undergo further evaluation. (Strength of Evidence = C.)

The objectives of further evaluation are as follows:

- Identify the specific cause or causes of UI with reproduction of leakage during testing.
- Identify conditions that cause similar symptoms but require different treatments, such as outlet obstruction, detrusor muscle weakness, urethral hypermobility, ISD, and urethral diverticulum.
- Detect functional, neurologic, or anatomic lesions affecting the lower urinary tract.
- Help obtain specific informtion necessary for choosing the appropriate therapy.
- Identify risk factors that may influence the outcome of a specific treatment.

Specialized Tests

Specialized tests are not intended to be part of the basic evaluation of UI. (Strength of Evidence = B.)

Numerous specialized diagnostic tests are available, and the evaluation must be tailored to the question to be answered. Specialized tests include the following:

- Urodynamic tests.
- Endoscopic tests.
- Imaging tests.

Table 5 summarizes the major symptoms of incontinence, associated factors, conditions, and diagnostic test options. Although the primary care physician is not expected to be an expert in these techniques, health care providers should be familiar with the diagnostic tests that may be used in evaluating the symptoms of UI.

Urodynamic Tests

These tests are designed to determine the anatomic and functional status of the urinary bladder and urethra. The tests are performed by qualified professionals trained in the specific definitions and procedures.

In the further evaluation of UI, simple cystometry is appropriate for detecting abnormalities of detrusor compliance and contractability, measuring PVR, and determining capacity. (Strength of Evidence = A.)

In some instances of complicated diagnostic situations or involved therapeutic plans, multichannel cystometric tests are appropriate. (Strength of Evidence = B.)

When performing urodynamic studies, the health care provider should attempt to reproduce the patient's symptoms. (Strength of Evidence = C.)

No published research supports a need for cystometric testing in routine or basic evaluation of UI. However, cystometric tests remain important in certain clinical conditions, such as the ones delineated in Table 4.

Cystometry is a test of detrusor function. Depending on the technique used, cystometry can be used to assess bladder sensation, capacity, and compliance, and to determine the presence and magnitude of both voluntary and involuntary detrusor contractions. The patient's symptoms should be reproduced at the time of cystometry, because involuntary DI may be observed in asymptomatic patients and symptomatic patients may show no evidence of involuntary ventrusial contractions. On the other hand, cystometry may be falsely negative in a patient with a genuinely overactive bladder (McGuire, 1994). This is caused by heightened psychological inhibition of reflex activity or lack of measurable increase of detrusor pressure, urethral pressure, or electromyographic activity, which may be dissipated by poor urethral resistance and must therefore be examined closely.

Simple cystometry can be used to detect detrusor contractions and abnormalities of bladder compliance, and to measure PVR and determine bladder capacity (Ouslander, Leach, and Staskin, 1989; Sand, Brubaker, and Novak, 1991). This procedure is performed by filling the bladder to capacity by means of a urethral catheter. Because a rectal or vaginal catheter is not used to monitor the abdominal pressure, results must be interpreted with caution, especially in uncooperative or demented patients. Compared with multichannel studies, simple cystometry has a reported 75-100 percent sensitivity, 69-89 percent specificity, and 74-91 percent positive predictive value for the diagnosis of DI (Fonda, Brimage, and D'Astoli, 1993; Sand, Brubaker, and Novak, 1991; Sutherst and Brown, 1984).

A multichannel or subtracted cystometrogram (CMG) with simultaneous measurement of intra-abdominal, total bladder, and true detrusor pressures can differentiate an involuntary detrusor contraction or deversed bladder compliance from an increase in intra-abdominal pressure. However, few data are available comparing multichannel cystometrics with other measures of intravesical pressure, and it is suspected that false positives may be a problem, especially in elderly populations (Diokno, Brown, Brock, et al., 1988). Likewise, ambulatory continuous monitoring may reveal detrusor contractions missed during a provocative subtracted CMG (McGuire, 1994).

A voiding CMG or pressure flow study can measure detrusor contractility and detect outlet obstruction if the patient is able to void. Simultaneous measurement of detrusor and urethral pressures during voiding is especially helpful in diagnosing urodynamic obstruction (Diokno, 1990).

Uroflowmetry measures the urine flow rate visually, electronically, or with the use of a disposable unit. An electronically generated flow curve is considered helpful in identifying abnormal voiding patterns. Uroflowmetry is not helpful in diagnosing the types of incontinence found in women (Diokno, Normolle, Brown, et al., 1990; Fantl, Smith, Schneider, et al., 1983), but it may be helpful in patients who have difficulty with bladder emptying. However, this test cannot distinguish between obstruction and detrusor weakness without a simultaneous measurement of detrusor function.

Urethral pressure profilometry (UPP). The urethral function test measures resting and dynamic pressures in the urethra. Passive measurement of urethral pressures has been used by some investigators to help identify ISD, especially in women who have had previous operations. However, no specific measurement to date has been found to be discriminatory, especially in the elderly because of the normal decline of urethral pressures with age (Diokno, Normolle, Brown, et al., 1990). Dynamic measurements of urethral and bladder pressures may be used to measure the effect of exertion on the urethral closure mechanism. Sphincter function can also be assessed by measuring the abdominal or vesical pressure needed to overcome the urethral resistance (McGuire, Fitzpatrick, Wan, et al., 1993; McGuire, Woodside, Borden, et al., 1981; Wan, McGuire, Bloom, et al., 1993). The relative usefulness of the UPP versus that of Abdominal Leak Point Pressure (ALPP) has not been adequately studied.

Electromyography (EMG) of the striated urethral sphincter measures the integrity and function of its innervation. Both needle and surface EMG, in conjunction with CMG, may be helpful in diagnosing DSD Diokno, Koff, and Anderson, 1976). However, this condition should be diagnosed only after common artifacts such as volitional tightening of the sphincter during involuntary detrusor contraction are excluded.

Endoscopic Tests

> Cystoscopy is not recommended in the basic evaluation of UI. (Strength of Evidence = B.) However, cystoscopy may be indicated in the further evaluation when the following situations are present: (a) sterile hematuria or pyuria (Strength of Evidence = B); (b) when urodynamics fail to duplicate symptoms (Strength of Evidence = C); (c) new onset of irritative voiding symptoms, bladder pain, recurrent cystitis, or suspected foreign body. (Strength of Evidence = B.)

Cystourethroscopy is a procedure that may help in identifying bladder lesions and foreign bodies, as well as urethral diverticula, fistula, strictures, or ISD. Most experts agree that cystoscopy is indicated for the evaluation of incontinent patients who have sterile hematuria or pyuria; recent (weeks to months) onset of irritative voiding symptoms such as frequency, urgency, and urge incontinence in the absence of any reversible causes (seeTable 2); bladder pain; recurrent cystitis; or suspected intravesical foreign body; and when urodynamics fail to duplicate symptoms of UI.

A literature search revealed that in studies involving more than 600 incontinent patients selectively cystoscoped, only 11 (less than 2 percent) metaplastic or neoplastic lesions were identified (Awad, Gajewski, Katz, et al., 1992; Benson, 1985; Fischer-Rasmussen, Hansen, and Stage, 1986; Ouslander, Hepps, Raz, et al., 1986; Ouslander, Leach, Staskin, et al., 1989; Vehkalahti, Kivela, and Seppanen, 1986). Even in elderly, incontinent populations, the yield from selected cystoscopy is less than 1 percent Ouslander, Hepps, Raz, et al., 1986). Therefore, cystoscopy should not be performed routinely in incontinent patients to exclude neoplasm.

The precise role of cystoscopy in the evaluation of incontinent patients is controversial. Data are scarce in the literature on this issue, and studies have a referral bias. Furthermore, urethroscopy is not as useful as urodynamic tests in diagnosing SUI Scotti and Ostergard, 1993). Because this test is not performed during voiding, its usefulness in corroborating or excluding outlet obstruction is limited. Given the large numbers of patients with UI, and given the fact that the majority of UI patients are currently not cystoscoped, cystoscopy cannot be recommended as part of the

routine evaluation until data are available to support its performance (Ouslander, Leach, and Staskin, 1989; Fischer-Rasmussen, Hansen, and Stage 1986).

Imaging Tests

Radiographic, ultrasonographic, and other imaging tests should be used for the evaluation of anatomic conditions associated with UI when clinically needed. (Strength of Evidence = C.)

Upper tract imaging is not a routine test to evaluate UI. Ultrasound of the kidneys, bladder, or both can help identify dilation of the upper urinary tract and renal pathology, especially in patients with urinary retention, abnormal renal function, or poorly compliant bladders. Excretory urography (i.e., intravenous pyelography) or other imaging modalities are indicated for incontinent patients with sterile hematuria or for further evaluation of upper tract obstruction or other pathology identified by ultrasound (Kumar and Schreib, 1985).

Lower tract imaging with and without voiding is helpful in examining the anatomy of the urinary bladder and urethra. Nonvoiding lateral cystourethrography in the resting and straining view can identify mobility or fixation of the bladder neck, funneling of the bladder neck and proximal urethra, and degree of cystocele. The voiding component can identify a urethral diverticulum, obstruction, and vesicoureteral reflux. Ultrasonography for assessing the dynamics of the bladder neck and urethra is still under investigation, and its clinical utility remains to be confirmed (Benson and Sumners, 1990; Mouritsen, Standberg, Jensen, et al., 1993; Quinn, Beynon, Mortensen, et al., 1988; Richmond and Sutherst, 1989b).

Videourodynamics is a technique that combines the various urodynamic tests with simultaneous fluoroscopy. The technique is helpful in sorting out causes of complex incontinence problems.

Tables

Table 2. Identification and management of reversible conditions that cause or contribute to urinary incontinence

Condition	Management
Conditions affecting the lower urinary tract	
Urinary tract infection (symptomatic with frequency, urgency,dysuria, etc.)	Antimicrobial therapy
Atrophic vaginitis/urethritis	Oral or topical estrogen (see Chapter 3 section on Pharmacologic Treatment)
Pregnancy/vaginal delivery/episiotomy	Behavioral intervention. Avoid surgical therapy postpartum as condition may be self-limiting
Postprostatectomy	Behavioral intervention. Avoid surgical therapy until clear condition will not resolve.
Stool impaction	Disimpaction; appropriate use of stool softeners, bulk-forming agents, and laxatives if necessary; implement high fiber intake, adequate mobility and fluid intake
Drug side effects [a]	
Diuretics:	With all medications discontinue or change therapy, as clinically possible. Dosage reduction or modification (e.g., flexible scheduling of rapid- acting diuretics) may also help.
causing polyuria, frequency, and urgency	
Caffeine:	
causing aggravation or precipitation of UI	
Anticholinergic agents:	
causing urinary retention, overflow incontinence, impaction	
Psychotropics:	
- Antidepressants: causing anticholinergic actions, sedation	
- Antipsychotics: causing anticholinergic actions, sedation, rigidity, and immobility	
- Sedatives/hypnotics/CNS depressants: causing sedation, delirium, immobility, muscle relaxation	
Narcotic analgesics:	
causing urinary retention, fecal impaction, sedation, delirium	
Alpha-adrenergic blockers:	
causing urethral relaxation	
Alpha-adrenergic agonists:	

causing urinary retention (present in many cold and diet over-the-counter (OTC) preparations)	
Beta-adrenergic agonists:	
causing urinary retention	
Calcium channel blockers:	
causing urinary retention	
Alcohol:	
causing polyuria, frequency, urgency, sedation, delirium, immobility	
Increased urine production	
Metabolic (hyperglycemia, hypercalcemia)	Better control of diabetes mellitus. Therapy for hypercalcemia depends on underlying cause.
Excess fluid intake	Reduction in intake of diuretic fluids (e.g., caffeinated beverages)
Volume overload	
Venous insufficiency with edema	Support stocking Leg elevation Sodium restriction Diuretic therapy
Congestive heart failure	Medical therapy
Impaired ability or willingness to reach a toilet	
Delirium	Diagnosis and treatment of underlying cause(s) of acute confusional state
Chronic illness, injury, or restraint that interferes with mobility	Regular toileting Use of toilet substitutes Environmental alterations (e.g., bedside commode, urinal)
Psychological	Remove restraints if possible. Appropriate pharmacologic and/or nonpharmacologic treatment

a Many side effects are seen with over-the-counter (OTC) drugs, the use of which may not be reported by some patients.

Table 3. Management options after basic evaluation

Type of UI	Characteristics	Management options
Urge	Detrusor instability With normal PVR, no complicating factors	Behavioral techniques: -Bladder training -Pelvic muscle rehabilitation -Other (e.g., fluid management) Pharmacologic interventions: -Anticholinergic medications, tricyclic antidepressants as alternative
Stress	With normal PVR, no complicating factors	Behavioral techniques: -Pelvic muscle rehabilitation -Bladder training Pharmacologic techniques: -Alpha-adrenergic medications or tricyclic antidepressants; estrogen; combination if needed Surgical techniques: -Uncomplicated, nonrecurrent SUI due to hypermobility
Mixed (Urge-Stress)	With normal PVR, no complicating factors	Combinations of above excluding surgical options in most cases

Table 4. Criteria for further evaluation [a]

- **Uncertain diagnosis and inability to develop a reasonable treatment plan based on the basic diagnostic evaluation. Uncertainty in diagnosis may occur when there is lack of correlation between symptoms and clinical findings.**
- **Failure to respond to the patient's satisfaction to an adequate therapeutic trial, and the patient is interested in pursuing further therapy.**
- **Consideration of surgical intervention, particularly if previous surgery failed or the patient is a high surgical risk.**
- **Hematuria without infection.**
- **The presence of other comorbid conditions, such as:**

- incontinence associated with recurrent symptomatic UTI

- persistent symptoms of difficult bladder emptying

- history of previous anti-incontinence surgery or radical pelvic surgery

- beyond hymen and symptomatic pelvic prolapse

- prostate nodule, asymmetry, or other suspicion of prostate cancer

- abnormal PVR urine

- neurologic condition, such as multiple sclerosis and spinal cord lesions or injury.

[a] Some patients who meet the criteria may not be appropriate for further evaluation and treatment if such evaluation and/or treatment is not desired by or feasible for the patient.

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Fantl JA, Newman DK, Colling J. Urinary Incontinence in Adults: Acute and Chronic Management: 1996 Update. Rockville (MD): Agency for Health Care Policy and Research (AHCPR); 1996 Mar. (AHCPR Clinical Practice Guidelines, No. 2.)

3 Treatment of Urinary Incontinence

The three major categories of treatment are

- Behavioral.
- Pharmacologic.
- Surgical.

Treatment options including their risks, benefits, and outcomes should be discussed with the patient so that informed choices can be made. As a general rule, the first choice should be the least invasive treatment with the fewest potential adverse complications that is appropriate for the patient. For many forms of UI, behavioral techniques meet these criteria. However, an informed patient's preference must be respected. A combination of surgical, behavioral, and pharmacologic interventions may be appropriate, but more research is required to determine the optimum treatment combinations for specific patient groups.

The role of other measures and supportive devices used in the management or treatment of UI is considered at the end of this chapter.

Behavioral Techniques

Behavioral techniques decrease the frequency of UI in most individuals when provided by knowledgeable health care providers, have no reported side effects, and do not limit future treatment options. Behavioral therapies can be divided into (1) caregiver-dependent techniques for patients with cognitive and motor deficits and (2) those requiring active rehabilitation and education techniques. These distinctions are arbitrary, however, and any individual's ability to actively participate varies on a continuum from complete dependence to full participation in the most complex behavioral therapies. For example, physically impaired patients who are cognitively intact may benefit from bladder training, pelvic muscle exercises (PMEs), and biofeedback therapy, but may depend on caregivers for assistance to the toilet.

Behavioral techniques are listed below in the order of those requiring passive involvement to those requiring active participation:

- Toileting assistance -- routine/scheduled toileting, habit training, and prompted voiding.
- Bladder retraining.
- Pelvic muscle rehabilitation -- PMEs, PMEs and bladder inhibition augmented by biofeedback therapy, PMEs augmented with vaginal weight training, and pelvic floor electrical stimulation.

All behavioral techniques involve educating the patient, the caregiver, or both, and provide positive reinforcement for effort and progress. Behavioral techniques should be offered to motivated individuals who wish to avoid more invasive procedures or dependence on protective garments, external devices, and medications. Behavioral techniques have few reported side effects and do not limit future treatment options. Behavioral techniques can increase patient understanding of lower urinary tract function and the environmental factors affecting symptoms. These techniques can improve control of detrusor and pelvic muscle function. They generally require patient or caregiver involvement and continued practice. If motivated, most people treated with behavioral techniques show improvement ranging from complete dryness to decreased incontinence episodes. Improved bladder control can occur even in the cognitively

impaired individual (Colling, Ouslander, Hadley, et al., 1992; Engel, Burgio, McCormick, et al., 1990; McCormick, Cella, Scheve, et al., 1990; Schnelle, 1990). Behavioral techniques can also be used in combination with other therapies for UI.

Published results indicate that determining the precise level of effectiveness of behavioral interventions is limited by the following factors:

- Use of different outcome criteria.
- Variability in number, duration, and frequency of and adherence to treatment sessions.
- Variability of comprehensiveness in training procedures.
- Absence or variability in followup data.
- Concurrent application of multiple interventions that confound outcomes.
- Unspecified criteria for group assignment.
- Use of heterogeneous samples.
- Lack of measurement of independent variables.
- Uncontrolled inclusion of patients who had failed previous incontinence treatments.
- Lack of standardized terminology for the various behavioral techniques. (Because of the lack of standardized terminology, the reader must examine each study carefully and be alert to differences even in studies that appear to use the same terms.)

In general, however, studies show that behavioral interventions are effective in reducing incontinence. The cost of behavioral treatments compared with other treatments has not been studied, but two reports showed that the behavioral techniques enabled a considerable number of patients to avoid or postpone surgery (Cammu, Van Nylen, Derde, et al., 1991; Mouritsen, Frimodt, and Moller, 1991).

Assessment Before Behavioral Intervention

Before implementing behavioral therapy, patients should undergo the basic evaluation. Behavioral approaches must be tailored to the patient's underlying problem, such as bladder training or habit training for urge UI and pelvic muscle rehabilitation for SUI. Patients with overflow UI are not primary candidates for behavioral intervention.

Toileting Assistance

Toileting assistance interventions include routine or scheduled toileting, habit training, and prompted voiding.

> Routine or scheduled toileting should be offered to incontinent patients on a consistent schedule. This technique is recommended for patients who cannot participate in independent toileting. (Strength of Evidence = C.)

Routine or scheduled toileting is provided by the caregiver on a fixed schedule at regular intervals. The caregiver takes the patient to void every 2-4 hours including at night. The goal is to keep the patient dry. No systematic effort is made to motivate the patient to delay voiding and resist urge, unlike in bladder retraining. In an uncontrolled, descriptive study of 161 male institutionalized patients, 20 patients who received a 4-week regimen of toileting every 2 hours eight times per day experienced an 85-percent improvement and were incontinent less than 20 percent of the time (Sogbein and Awad, 1982). In an uncontrolled, descriptive study of 20 females aged 24-94 years who were instructed to void every 2 hours regardless of urge for a period of 2 weeks, patients reported a 79-percent success rate (Godec, 1994). Burgio, Stutzman, and Engel (1989) studied 20 men postprostatectomy who followed a 2-hour voiding

program for 2 weeks and reported a 33-percent increase in urgency, 29-percent decrease in stress UI, and no change in continual leakage.

> Habit training is recommended for patients for whom a natural voiding pattern can be determined. (Strength of Evidence = B.)

Habit training is toileting scheduled to match the patient's voiding habits. One controlled study of habit training identified voiding patterns of 51 nursing home residents with an electronic monitoring device (Colling, Ouslander, Hadley, et al., 1992). The nursing home staff were taught to toilet the residents during the periods of greatest voiding frequency based on individual patterns identified by monitoring. A significant reduction in UI occurred during the 3-month intervention in 86 percent of the subjects, with one-third of this group showing 25 percent or greater improvement over baseline compared with an increase in UI observed in the control group. In addition, the volume of urine loss decreased significantly in the experimental group only. No side effects of habit training were reported. Nursing staff compliance was a problem, however, because of resistance to changes in care routines.

Habit training is an excellent technique for patients in the home living with a caregiver.

> Prompted voiding is recommended in patients who can learn to recognize some degree of bladder fullness or the need to void, or who can ask for assistance or respond when prompted to toilet. Patients who are appropriate for prompted voiding may not have sufficient cognitive ability to participate in other, more complex behavioral therapies. (Strength of Evidence = A.)

The three major elements of prompted voiding are as follows:

- Monitoring -- The patient is checked by caregivers on a regular basis and asked to report verbally if wet or dry.
- Prompting -- The patient is asked (prompted) to try to use the toilet.
- Praising -- The patient is praised for maintaining continence and for trying to toilet.

Prompted voiding has been shown to be effective in dependent or cognitively impaired nursing home incontinent patients (Schnelle, 1990; Hu, Igou, Kaltreider, et al., 1989; Burgio, McCormick, Scheve, et al., 1994; McCormick, Burgio, Engel, et al., 1992). Used as a supplement to habit training, prompted voiding reinforces discrimination of continence status, the need to urinate, and requests for toileting assistance from caregivers.

Four clinical trials, three controlled (Creason, Grybowski, Burgener, et al., 1989; Hu, Igou, Kaltreider, et al., 1989; Schnelle, 1990) and one uncontrolled (Burgio, McCormick, Scheve, et al., 1994), evaluated prompted voiding in nursing homes. The combined trials used prompted voiding for 251 residents and demonstrated significant reductions in incontinence with no reported side effects. An average reduction of 0.8-1.8 incontinence episodes per patient per day was reported. In contrast, the baseline number of incontinence episodes in control group subjects of approximately 4.5 times per 12-hour period remained unchanged over the course of the clinical trial. Residents with lower voiding frequencies (less than four in a 12-hour period) and those who toileted appropriately more than 75 percent of the time during a brief 2- to 6-day prompted voiding trial were the most likely to show long-term benefits with prompted voiding.

A clinical trial in seven nursing homes reported that nursing staff were able to maintain improved resident continence levels for 6 months in 76 residents who were identified as highly responsive to prompted voiding (Schnelle, Newman, White, et al., 1993). An earlier study showed that the behavioral training resulted in an estimated 76 percent savings per day per patient, and the investigators recommended that such training be instituted early after admission to maximize savings (Schnelle, Sowell, Hu, et al., 1988). Because nursing home staff administer the prompted voiding and habit training protocols, program success relies on training, compliance, and incentives for active staff

participation. A 3-hour prompted voiding schedule can improve dryness in residents with mild to moderate UI (Burgio, McCormick, Scheve, et al., 1994).

Bladder Training

Bladder training is strongly recommended for management of urge (DI) and mixed incontinence. Bladder training is also recommended for management of SUI. (Strength of Evidence = A.)

Bladder training (also termed "bladder retraining") has many variations but generally consists of three primary components:

- Education.
- Scheduled voiding with systematic delay of voiding.
- Positive reinforcement.

The education program usually combines written, visual, and verbal instruction that addresses the physiology and pathophysiology of the lower urinary tract. A bladder training program requires the patient to resist or inhibit the sensation of urgency, to postpone voiding, and to urinate according to a timetable rather than according to the urinary urge (McCormick and Burgio, 1984).

Bladder training may involve tactics that help distend the bladder, such as adjustment in fluid loads and delayed voiding to provide progressively larger voiding volumes and longer intervals between voids (Keating, Schulte, and Miller, 1988).

Initially, the interval goal is usually set between 2 and 3 hours or determined by the patient's present interval, and is not enforced during sleeping hours. The voiding schedule progressively increases the interval between mandatory voids with concomitant distraction or relaxation techniques. The patient is thus taught to delay voiding when the urge to void occurs. If the patient is unable to delay voiding between scheduled toileting times, the schedule is adjusted and the interval time is reset from the time of the last void. Another method is to keep the prearranged schedule and disregard the unscheduled void between schedules. The training may continue for several months, during which time the therapist provides positive reinforcement and instruction.

Bladder training has been used primarily to manage UI caused by DI. This form of training has few side effects but is difficult to implement in cognitively impaired persons. It may not be successful in frail, elderly patients.

Several reports demonstrate that bladder training is effective in reducing UI (Fantl, Wyman, McClish, et al., 1991; Ferrie, Smith, Logan, et al., 1984; Pengelly and Booth, 1980). Fantl, Wyman, McClish, et al. (1991) conducted a controlled, randomized study of 131 women with sphincteric incompetence and unstable detrusor function, 123 of whom had some followup data. Subjects receiving treatment participated in a bladder training program that included behavioral strategies to decrease urge, patient education, and a schedule of voiding. Of the 60 women in the treatment group, 12 percent became dry and 75 percent had at least a 50-percent reduction in the number of incontinent episodes. The magnitude of the effect was somewhat larger in the women with DI. The effect of bladder training was maintained after 6 months. Control subjects did not have significant changes in incontinent episodes. To date, no urodynamic variable has been shown to relate directly to the observed beneficial clinical effects.

Pelvic Muscle Rehabilitation

PMEs may be used alone or augmented with bladder inhibition biofeedback therapy or with vaginal weight training. Pelvic floor electrical stimulation is another method of pelvic muscle rehabilitation. Health care providers must teach patients the correct method of distinguishing and contracting the pelvic muscles through digital vaginal examination to verify appropriate muscle use, verbal feedback, or use of vaginal weights and biofeedback therapy to ensure accurate

performance (Benvenuti, Caputo, Bandinelli, et al., 1987; Bump, Hurt, Fantl, et al., 1991; Burns, Marecki, Dittmar, et al., 1985; Dougherty, Abrams, and McKey, 1986; Keating, Schulte, and Miller, 1988).

Pelvic Muscle Exercise

Teaching women PMEs may prevent UI. (Strength of Evidence = C.)

Teaching exercises to strengthen pelvic muscles may decrease the incidence of UI. (Strength of Evidence = C.)

PMEs are strongly recommended for women with SUI. (Strength of Evidence = A.)

PMEs are also recommended in men and women in conjunction with bladder training for urge incontinence. (Strength of Evidence = B.)

PMEs may also benefit men who develop urinary incontinence following prostatectomy (Strength of Evidence = C.)

PMEs, also called Kegel exercises and pelvic floor exercises, are performed to strengthen the voluntary periurethral and perivaginal muscles (i.e., voluntary urinary sphincters and levator ani) that contribute to the closing force of the urethra and to the support of the pelvic visceral structures.

The first step in pelvic muscle re-education is to establish better awareness of pelvic muscle function. PMEs are performed by "drawing in" or "lifting up" of the perivaginal muscles and anal sphincter as if to control urination or defecation with minimal contraction of abdominal, buttock, or inner thigh muscles (Rose, Baigis-Smith, Smith, et al., 1990). Patients are generally told to sustain a contraction for at least 10 seconds, followed by an equal period of relaxation. The exercises should be performed about 30-80 times a day for at least 8 weeks and may need to be continued indefinitely. Elderly patients may require a longer time to train. In general, an individualized program of exercises and repetitions should be tailored to enhance muscle strength progressively (Ferguson, McKey, Bishop, et al., 1990). To condition the muscle to contract with increases in intra-abdominal pressure, patients should be taught to contract the pelvic muscles before and during situations when leakage may occur.

The specific effects of PMEs on actual lower urinary muscle function is not completely understood; some studies show a relationship between changes in various measures of pelvic floor strength, such as anal sphincter strength or maximum urethral closure pressure, and reduction in incontinence (Benvenuti, Caputo, Bandinelli, et al., 1987; Bo, Hagen, Kvarstein, et al.,1990; Ferguson, McKey, Bishop, et al., 1990; Dougherty, Bishop, Mooney, et al., 1993).

PMEs are indicated for women with stress incontinence and can reduce urgency and prevent urge UI (Burgio and Engel, 1990; Burgio, Robinson, and Engel, 1986; Burgio, Stutzman, and Engel, 1989; Burton, Pearce, Burgio, et al., 1988; Castleden, Duffin, Asher, et al., 1985; Klarskov, Nielsen, Kromman-Andersen, et al., 1991; McDowell, Burgio, Dombrowski, et al., 1992). They may be effective in reducing incontinence following prostatic surgery in men, but to date have only been tested for postprostatectomy in conjunction with a biofeedback component (Burgio, Stutzman, and Engel, 1989). PMEs are effective in reducing UI even after multiple surgical repairs in women (Baigis-Smith, Smith, Rose, et al., 1989; Brink, Wells, and Diokno, 1987; Burgio and Engel, 1990; Castleden, Duffin, and Mitchell, 1984; Ferguson, McKey, Bishop, et al.,1990; Heller, Whitehead, and Johnson, 1989; Henalla, Kirwan, Castleden, et al., 1988; Pearson and Droessler, 1988; Rose, Baigis-Smith, Smith, et al., 1990; Stoddart, 1983).

The effects of PME alone have been well documented in the medical literature. A summary of outcome findings from well-conducted studies follows.

Dougherty, Bishop, Mooney, et al. 1993) studied 65 women 35-75 years of age (mean age 51.3) and obtained a 62-percent reduction in UI episodes, and Ferguson, McKey, Bishop, et al. (1990)studied 20 women and demonstrated a 56- to 58-percent reduction in leakage as measured by 24-hour pad test using audiotape instruction in PME. Telephone

contact and ongoing use of a bladder record may have contributed to the greater success found in these studies compared with others using a one-time instruction session.

To date, the most effective use of PME has been reported in an uncontrolled study by Benvenuti, Caputo, Bandinelli, et al. 1987), who provided 20 sessions of PME and other behavioral strategies and an intensive home program for a total of 10 contact hours to 20 women aged 35-65 years (mean age 50.8). In addition to a 95-percent reduction in incontinent episodes, significant changes were also reported FUL and MUCP at rest and during maximal voluntary contraction. A significant clinical benefit was consistent with changes in several physical measures of bladder function.

In a randomized clinical trial comparing PME and phenylpropanolamine hydrochloride (PPA), PME was found to be an effective alternative treatment for SUI comparable to PPA (Wells, Brink, Diokno, et al., 1991). Of the 54 subjects who completed the exercise program and the 64 who completed the drug protocol, 77 percent of the exercise subjects and 84 percent of the drug subjects reported improvement. The PME protocol involved 6 months of active PME taught with only written instruction, followed by monthly monitoring visits. The PPA was administered in doses of 50 mg daily for 2 weeks, increasing to twice daily if wetting continued. Adherence to the drug treatment was greater than to the exercise protocol.

Indications are that the intensity of the exercise program affects physiological and functional outcomes. Bo, Hagen, Kvarstein, et al. (1990) found that 52 subjects of mean age 45.9 years (range 24-64) randomized into a group receiving ongoing guidance in performing maximum contractions of the pelvic muscle that increased in intensity over 6 months reportedsignificantly greater reduction in incontinence and changes in physiological measures of pelvic floor strength compared with a group that received only a single session of instruction and a home exercise program. The group receiving the ongoing instruction reported a 60.1-percent cure/improvement rate compared with 17.3 percent attained in the home exercise group. This work also indicates a possible systematic relationship between symptom reduction and objective physical changes. Based on the data presented (Benvenuti, Caputo, Bandinelli, et al., 1987; Elia and Bergman, 1993; Mouritsen, Frimodt, and Moller, 1991), there is evidence that pelvic muscle re-education has the potential to change muscle physiology. Standards for assessment of change in pelvic muscle function have yet to be established, however.

PME also appears to be effective in the treatment of older adults. Flynn, Cell, and Luisi (1994) provided treatment for transient UI in 37 older adults receiving home nursing care (mean age 76) and behavioral strategies that included education in the maintenance of bowel regularity, bladder and habit training, fluid intake management, and PME. An 82.4-percent decrease in UI was attained with an average of five nursing visits. Because those patients with transient UI were not separated in the final analysis, the specific effect of the behavioral treatment is difficult to determine. Nonetheless, this report and others (Scheve, Engel, McCormick, et al., 1991) demonstrate the overall effectiveness of a well-directed nursing program, which includes PME for UI in the homebound and long-term chronically ill patients.

Summary of findings. Evidence demonstrates that patients require repeated guidance over an extended period of time to derive optimal benefit from PME. Kegel himself recommended that patients be seen weekly to ensure that the exercises were being performed correctly. Further controlled studies are needed to demonstrate the most efficient method of teaching PME, exercise prescription, and the conditions in which biofeedback provides an added benefit to PME alone. It should also be noted that the majority of the research on PME is in women only.

PME and Bladder Inhibition Augmented by Biofeedback Therapy

> Pelvic muscle rehabilitation and bladder inhibition using biofeedback therapy are recommended for patients with stress UI, urge UI, and mixed UI. (Strength of Evidence = A.)

Some type of biofeedback device is often used to assist patients to gain function and pelvic muscle awareness { Burns, Pranikoff, Nochajski, et al., 1990). The aim of biofeedback therapy, which uses electronic or mechanical instruments to relay information to patients about their physiologic activity, is to improve bladder dysfunction by teaching people

to change physiologic responses that mediate bladder control (Burgio and Engel, 1990). Auditory or visual display of this information forms the core of biofeedback procedures (Schwartz, 1995). Biofeedback for UI typically uses single measurement (surface, needle, vaginal, or anal probe) EMG or manometric methods. Biofeedback using multimeasurement feedback methods involves simultaneous measurement of pelvic and abdominal/detrusor muscle activity. Biofeedback should be used in conjunction with other behavioral techniques such as PME and bladder training. As with all of the behavioral techniques, successful application of biofeedback depends greatly on the knowledge and skill of the health care provider, whose knowledge must include familiarity with evaluation techniques, anatomic and physiologic correlates of the different forms and symptoms of bladder dysfunction, instrumentation, and behavioral principles that guide the procedure.

Studies on the various applications of biofeedback combined with behavioral treatment report a range of 54-87 percent improvement in incontinence across various patient groups using different biofeedback and behavioral procedures. Some biofeedback protocols use only one measure for reinforcement of pelvic muscle contraction, whereas others use up to three, and include measures of abdominal and detrusor activity. The biofeedback protocol that has been associated with the largest and most consistent symptom reduction is one that reinforces pelvic muscle contraction concurrently with inhibition of abdominal and detrusor contraction. Reports using this multimeasurement method show a 75.9-82 percent reduction in UI across six studies involving 166 subjects Burgio, Robinson, and Engel, 1986; Burgio, Stutzman, and Engel, 1989;(Burgio, Whitehead, and Engel, 1985; Burton, Pearce, Burgio, et al., 1988; McDowell, Burgio, Dombrowski, et al., 1992). The presumed benefit of the multimeasurement procedure is that it reinforces pelvic floor contraction directly with moment-to-moment feedback, which characterizes for the patient the quality and intensity of the contraction. Without biofeedback, weak pelvic muscles may provide limited kinesthetic feedback to the desired contraction, and as a result the patient uses an attenuated internal reference to upgrade muscle contractions. Combining bladder and sphincter biofeedback also allows teaching pelvic muscle contraction in response to increasing bladder volume and observed detrusor activity.

In a controlled study, Burgio, Robinson, and Engel (1986) found that 13 subjects (mean age 47.9) receiving multimeasurement biofeedback reduced incontinence by 75.9 percent compared with a 51-percent reduction obtained in 11 subjects (mean age 40.7) who received only verbal feedback and instruction for PME with digital palpation. The multimeasurement biofeedback method has also been used successfully in the treatment of UI in postprostatectomy patients with urge and intermittent stress incontinence (Burgio, Stutzman, and Engel, 1989). However, another study demonstrated that when subjects complained primarily of urge incontinence, no benefit was obtained with the addition of biofeedback to behavioral training and PME, which was provided by a well-trained clinician over an average of five clinic sessions (Burton, Pearce, Burgio, et al., 1988). The results of this study should be interpreted with caution, however, because the groups differed in severity before treatment.

Several studies have also demonstrated significant reductions in UI associated with neurologic disease and in the frail elderly using a combination of multimeasurement biofeedback and other behavioral techniques such as bladder training (McDowell, Engberg, Weber, et al., 1994; Middaugh, Whitehead, Burgio, et al., 1989; O'Donnell and Doyle, 1991). Because multimeasurement biofeedback can provide specific reinforcement for pelvic muscle contraction that is isolated from counterproductive abdominal contraction, it is assumed that awareness of pelvic muscle contraction can be achieved more efficiently than from vaginal palpation alone.

In contrast to multimeasurement methods, the reduction in number of pad changes per 24 hours ranged from 43 to 54 percent when single-measurement biofeedback is used, when excluding a subgroup who had received only one biofeedback session (Wilson, Faragher, Butler, et al., 1987). This improvement was attained in an approximate average of 11 sessions (0.5 to 1.5 hours each). Another study (Susset, Galea, and Read, 1990) used single-channel biofeedback over six weekly clinic visits and a home trainer with which the subjects practiced daily. These subjects demonstrated an 87-percent reduction of leakage on pad test, suggesting that a home training device may provide an added benefit to clinic biofeedback visits, especially when only single-channel biofeedback is used.

In a randomized controlled study, Burns, Pranifoff, Nochajski, et al. (1993) studied 135 women (age range 55-75 years) with primary stress incontinence in three groups. One group received PME, and another group received single-

measurement EMG biofeedback to perivaginal contraction for 20 minutes per week. The two treatment groups demonstrated a 54-61 percent reduction in incontinent episodes, compared with a 6-percent reduction of incontinence in the control group, but no difference between the two treatment groups was found. The improvements were maintained over a 6-month followup, and patients with moderate-to-severe symptoms showed even more improvement in the posttreatment phase. This study demonstrated that PME reduces incontinence and provided evidence that symptom severity has a role in response.

Further research is needed to determine which biofeedback protocols ensure that optimal outcomes are achieved in individual conditions and what methods provide the most valid measures of pelvic muscle function. The multimeasurement biofeedback appears to produce greater reduction in incontinence compared with PME alone or single measurement biofeedback. It is not known, however, to what degree detrusor or intra-abdominal pressure biofeedback individually contributes to the outcomes reported.

Summary of findings. Overall, the literature indicates that PME and other behavioral strategies, with or without biofeedback, can "cure" or reduce incontinence. Maximum benefit is derived from any pelvic muscle rehabilitation and education program when ongoing reinforcement and guidance are provided. Also, the intensity of the exercise program seems to influence both functional and physiological outcomes, and multimeasurement biofeedback protocols seem to yield the greatest and most consistent reductions in UI (Bo, Hagen, Kvarstein, et al., 1990; Burgio, Robinson, and Engel, 1986; Elia and Bergman, 1993; McDowell, Burgio, Dombrowski, et al., 1992).

Pelvic Muscle Exercises Augmented with Vaginal Weight Training

Vaginal weight training is recommended for SUI in premenopausal women. (Strength of Evidence = B.)

Specially designed vaginal weights for strengthening the pelvic muscles can augment PME. The patient receives a set of vaginal weights of identical shape and volume but of increasing weight (20-100 grams). As part of a structured progressive resistive exercise program, women insert the weight intravaginally, with the tapered portion resting on the superior surface of the perineal muscle and attempt to retain it by contracting the pelvic muscles up to 15 minutes. The weight is worn while the patient is ambulatory, and the exercise is done twice daily. The hypothesized mechanism of action is that the sustained contraction required to retain the weight increases the strength of the pelvic muscles, and the weight is assumed to provide heightened proprioceptive feedback to desired pelvic muscle contraction.

Available literature on this technique includes observations made in premenopausal women with SUI. Initial observations from four studies including 103 premenopausal women indicate subjective "cure" or greatly improved status of 68-80 percent after 4-6 weeks of treatment (Bridges, Denning, Olah, et al., 1988; Olah, Bridges, Denning, et al., 1990; Peattie and Plevnik, 1988; Peattie, Plevnik, and Stanton, 1988; Wilson and Borland, 1990). Objective outcome measures included reduction of urine loss on pad test, improvement in ability to hold heavier weights intravaginally, increased pelvic muscle strength (perineometer), and significant reduction in incontinence episodes. There were minimal or no adverse reactions. However, in several studies, PMEs were performed at the same time.

Although vaginal weight training may be useful in the treatment of stress incontinence, issues of applicability to other populations, particularly postmenopausal women with pelvic organ prolapse or other comorbid conditions, must be evaluated in terms of treatment protocols and long-term effects.

Pelvic Floor Electrical Stimulation

Pelvic floor electrical stimulation has been shown to decrease incontinence in women with SUI. (Strength of Evidence = B.)

Pelvic floor electrical stimulation may be useful for urge and mixed incontinence. (Strength of Evidence = B.)

Pelvic floor electrical stimulation (nonimplantable) produces a contraction of the levator ani, external urethral and anal sphincters, accompanied by a reflex inhibition of the detrusor; this activity depends on a preserved reflex arc through the sacral micturition center (Vodusek, Plevnik, Vrtacnik, et al., 1988). Nonimplantable pelvic floor electrical stimulation uses vaginal or anal sensors or surface electrodes (Vodusek, Plevnik, Vrtacnik, et al., 1988). Adverse reactions are minimal and include pain and discomfort. Studies vary regarding the type and placement of electrodes; frequency, duration, and amplitude of voltage; and whether the stimulation was phasic, intermittent, or continuous. Several of these studies address long-term followup with reports that the effects for cured or improved patients ranged from 54 to 77 percent (Bent, Sand, Ostergard, et al., 1993; Bergmann and Eriksen, 1986; Blowman, Pickles, Emery, et al., 1991; Caputo, Bensen, McClellan, et al., 1993; Eriksen, 1990; Eriksen, Bergmann, and Mjolnerod, 1987; Eriksen, Bergmann, and Eik-Nes, 1989; Esa, Kiwamoto, Sugiyama, et al., 1991; Fall, Ahlstrom, Carlsson, et al., 1986; Fossberg, Sorensen, Ruutu, et al., 1990; Green and Laycock, 1990; Hahn, Sommar, and Fall, 1991; Lamhut, Jackson, and Wall, 1992; Leach and Bavendam, 1989; Lose, Andersen, and Kristensen, 1986; McIntosh, Frahm, Mallett, et al., 1993; Meyer, Dhenin, Schmidt, et al., 1992; Eriksen and Mjolnerod, 1987; Nakamura, Sakurai, Tsujimoto, et al., 1986; Nakamura, Sakurai, Sugao, et al., 1987; Ohlsson, Fall, and Frankenberg-Sommar, 1989; Plevnik, Joney, Vrtacnik, et al., 1986; Sand, Richardson, Staskin, et al., 1995; Wilson, 1990; Zollner-Nielsen and Samuelsson, 1992).

Two randomized controlled trials have been conducted. Using active and placebo perianal surface patch neurostimulation for SUI in patients, Blowman, Pickles, Emergy, et al. 1991) reported a "cure" or improvement rate of 86 percent in the active group (N=7) and 33 percent in the placebo group (N=6). Electrical stimulation was not used as a single therapy, however; both groups also received instruction in PME. Using active and inactive vaginal plug devices in 52 women with SUI, Sand, Richardson, Staskin, et al. (1995) reported objective "cure" or improvement in 48 percent of the active device group and in 13 percent of the placebo group. Active device patients had significant improvements in UI episodes, leakage volume, and vaginal muscle strength and in subjective improvement measures when compared with the placebo group.

In other studies with similar settings, anal or vaginal plug devices were used for maximal electrical stimulation for 4 weeks to 3.5 months, 20 minutes to 20 hours/day. "Cure" or improvement rates ranged from 48 to 94 percent in 842 patients with stress, urge, or mixed incontinence. The effects of therapy were sustained 6 weeks to 2 years in 54-77 percent of patients, especially if patients continued to do PME after treatment (Bergman and Eriksen, 1986; Blowman, Pickles, Emery, et al., 1991; Bridges, Denning, Olah, et al., 1988; Caputo, Bensen, McClellan, et al., 1993; Eriksen, Bergmann, and Eik-Nes, 1989; Eriksen, Bergmann, and Mjolnerod, 1987; Eriksen and Eik-Nes, 1989; Esa, Kiwamoto, Sugiyama, et al., 1991; Fossberg, Sorensen, Ruutu, et al., 1990; Kunkle, Payne, and Whitmore, 1993; Meyer, Dhenin, Schmidt, et al., 1992; Plevnik, Joney, Vrtacnik, et al., 1986; Sand, Richardson, Staskin, et al., 1995; Zollner-Nielsen and Samuelsson, 1992). One study of cognitively impaired patients in a nursing home showed no significant effect of stimulation, with a trend toward increased wetness (Lamhut, Jackson, and Wall, 1992).

Summary of findings. Research indicates that pelvic floor electrical stimulation can significantly reduce UI in women with SUI, and may be effective in men and women with mixed and urge UI. Stimulation may be effective when augmented with other pelvic muscle rehabilitation therapies. Minimal adverse side effects occur with this treatment. Treatment using stimulation requires monitoring by a health care provider to determine effectiveness. Further research is needed to determine the efficacy of pelvic floor stimulation used alone or in combination with other therapies. Standardization of the parameters of the techniques used, such as that proposed by the International Continence Society, is necessary to allow further comparison of study results.

Pharmacologic Treatment[a,b]

[a] Of the pharmacologic treatments discussed in this chapter, only oxybutynin and flavoxate have been officially approved by the FDA for the indicated use. The remainder are not approved but are commonly used.
[b] Imipramine is officially approved by the FDA for enuresis in children but not adults.

Several medications have proven to be beneficial for treating UI, although their risk-to-benefit ratios are difficult to gauge precisely because of deficiencies in study design. Some of the limitations of published trials include variable

inclusion and exclusion criteria or inadequate (small) sample size; inconsistent definition of outcome criteria; short study durations; fixed drug dosages that may have been excessive or inadequate; analyses confounded by other interventions such as behavioral manipulations; and limited compliance data and nonuniform methods for collecting, reporting, and comparing side effects. Summarized below are data derived from randomized controlled trials of orally administered medications, vaginally administered medications, or both, used to treat UI. Recommendations pertaining to the benefits, risks, and utility of pharmacologic therapies are noted, including the strength of evidence.

Urge Incontinence: Detrusor Instability

The following pharmacologic agents are reported to be useful in DI as observed in clinical practice. (Strength of Evidence = B.) Anticholinergic agents: oxybutynin, dicyclomine hydrochloride, and propantheline. Tricyclic antidepressants: imipramine, doxepin, desipramine, and nortriptyline.

Anticholinergic Agents

Anticholinergic agents are the first-line pharmacologic therapy for patients with DI. (Strength of Evidence = A.)

When pharmacologic therapy is to be used for patients with DI, oxybutynin is the anticholinergic agent of choice. The recommended dosage is 2.5-5 mg taken orally three or four times per day. (Strength of Evidence = A.)

Propantheline is the second-line anticholinergic agent in the treatment of patients with DI who can tolerate the full dosage. The recommended dosages are 7.5-30 mg administered three to five times per day; higher dosages (15-60 mg qid) may be required. (Strength of Evidence = B.)

Flavoxate is not recommended for the treatment of patients with DI. (Strength of Evidence = A.)

Anticholinergic agents are effective as treatment for UI because they block contraction of the normal bladder and probably the unstable bladder as well. All anticholinergic drugs are contraindicated in patients with documented narrow-angle, but not wide-angle, glaucoma.

Oxybutynin has both anticholinergic and direct smooth muscle relaxant properties. Seven randomized controlled studies of the use of this agent for UI were identified. Oxybutynin proved superior to placebo in six studies of middle-aged outpatients, reducing incontinence frequency by 15-58 percent over the response to placebo (Holmes, Montz, and Stanton, 1989; Moore, Hay, Imrie, et al., 1990; Riva and Casolati, 1984; Tapp, Cardozo, Versi, et al., 1990; Thuroff, Bunke, Ebner, et al., 1991; Zeegers, Kiesswetter, Kramer, et al., 1987). In two of these studies, 43 percent and 67 percent of subjects became subjectively continent, a much better result than occurred with placebo (Moore, Hay, Imrie, et al., 1990; Riva and Casolati, 1984). Only one study reported a benefit with a dosage of 15 mg tid-qid Holmes, Montz, and Stanton, 1989), whereas a second showed no improvement over placebo (Thuroff, Bunke, Ebner, et al., 1991). In the only trial that failed to note a benefit, oxybutynin was used less frequently (5 mg bid) in elderly nursing home residents (Zorzitto, Holliday, Jewett, et al., 1989). Oxbutynin has also been effective and well tolerated when instilled into the bladder of study patients, primary those with neuropathic bladder (Mizunaga, Miyata, Kaneko, et al., 1994).

Side effects were noted in all studies and included dry skin, blurred vision, change in mental status, nausea, constipation, and marked xerostomia (dry mouth). Severity increased with dosage, with severe xerostomia occurring in 84 percent of subjects receiving 5 mg of oxybutynin four times per day (Tapp, Cardozo, Versi, et al., 1990).

Propantheline is the prototype for anticholinergic agents used for urologic conditions. No agent better approximates atropine's effect on the bladder in vitro, although its central nervous system side effects are less marked. Moreover, propantheline is inexpensive and has been widely used over time.

Despite propantheline's success in uncontrolled case series, only five adequately controlled trials could be identified Blaivas, Labib, Michalik, et al., 1980; Dequeker, 1965; Holmes, Montz, and Stanton, 1989; Thuroff, Burke, Ebner, et al., 1991; Zorzitto, Jewett, Fernie, et al., 1986), three of which included only elderly nursing home residents with advanced dementia. Only one study reported a benefit with a dosage of 15 mg tid-qid (Holmes, Montz, and Stanton, 1989). Two of the nursing home studies evaluated higher dosages of propantheline (30 mg qid; 15 mg tid + 60 mg at bedtime (hs)) and found that incontinence frequency was reduced by 13-17 percent over placebo -- a small but statistically significant improvement in both studies Dequeker, 1965; Zorzitto, Jewett, Fernie, et al., 1986). In one of these trials, side effects were reported in half of the subjects, one-fifth of whom withdrew because of severe side effects Zorzitto, Jewett, Fernie, et al., 1986); no side effects were reported in the trial using the 60 mg hs dosage. In a dose titration study, dosages up to 60 mg qid were associated with complete response in 25 of 26 patients (Blaivas, Labib, Michalik, et al., 1980).

In addition to urinary retention, side effects associated with propantheline, as with all anticholinergic agents, include visual blurring, xerostomia, nausea, constipation, tachycardia, drowsiness, and confusion; the most common of these was xerostomia.

Despite the lack of adequate trials, consensus among experts is that at least for less impaired patients who can tolerate full dosages, propantheline is effective (Andersson, 1988; Wein, 1990).

Dicyclomine hydrochloride is an anticholinergic agent with smooth muscle relaxant properties. Studies on the use of this drug for UI are limited, and the populations that have been studied were small. One pilot trial and one larger randomized controlled trial were identified Beck, Arnusch, and King, 1976; Castleden, Duffin, and Millar, 1987). In the larger study, 62 percent of subjects improved on dicyclomine 10 mg tid (90 percent of whom became continent) compared with 20 percent on placebo (65 percent of whom became continent); statistical significance was not specified, and side effects were not mentioned Beck, Arnush, and King, 1976). Results were similar in the smaller pilot study (Castleton, Duffin, and Millar, 1987).

Studies comparing dicyclomine with other anticholinergic agents are not available. This agent may be used as an alternative treatment for UI, however, pending further research. The dosage is 10-20 mg taken orally three times daily.

Flavoxate is a tertiary amine that has demonstrated smooth muscle relaxant properties in vitro. Although flavoxate is widely used for incontinence, only four randomized controlled studies of its efficacy for UI could be identified (Meyhoff, Gerstenberg, and Nordling, 1983; Robinson and Brocklehurst, 1983; Zeegers, Kiesswetter, Kramer, et al., 1987; Chapple, Parkhouse, Gardener, et al., 1990). None demonstrated a significant benefit. At present, this drug is not recommended for the treatment of UI.

Hyoscyamine and other oral anticholinergics are known to be used in clinical practice in the treatment of DI; however, no scientific literature that met the panel's criteria addressed the use of these agents for patients with UI. The panel therefore is not making recommendations regarding these drugs.

Calcium Channel - Blocking Agents

Influx of extracellular calcium is important for detrusor muscle contraction and can be blocked by calcium channel antagonists. Although such agents are often advocated for bladder storage disorders, only a few small, but favorable, case series were identified in the literature. No controlled studies could be found for marketed agents (e.g., nifedipine, diltiazem, verapamil). One placebo-controlled study of flunarizine that showed a positive effect was identified; however, in a subsequent 1-month controlled trial by the same investigators, its efficacy diminished, and the high (but unreported) rate of side effects led the investigators to temper their original enthusiasm Palmer, Worth, and Exton-Smith, 1981). At this time, these agents are not recommended for general use for the treatment of detrusor instability.

Terodiline. An investigational drug in the United States, terodiline possesses calcium channel - blocking and anticholinergic properties. It has demonstrated in vivo activity in the treatment of DI. However, recent reports of

serious ventricular arrhythmias have resulted in its temporary removal from the European market and discontinuation of trials in the United States.

Tricyclic Agents

> The use of tricyclic agents (TCAs) should be reserved for carefully evaluated patients. The usual oral dosages are 10-25 mg initially administered one to three times per day, but less frequent administration is usually possible because of the long half-life of these drugs. The daily total dosage is usually 25-100 mg. (Strength of Evidence = B.)

Although TCAs are widely used, they produce many adverse effects (e.g., cardiac and anticholinergic), with the risk more likely in elderly patients. Limited research on the use of TCAs is available. Only three randomized controlled studies were identified. One conducted with psychiatric inpatients in whom the type of UI was not established showed that imipramine, desipramine, and nortriptyline each resulted in a statistically significant reduction in the number of "wet nights" (Milner and Hills, 1968). Side effects were rare and minor except for paralytic ileus in one case.

The other two studies, one using doxepin Lose, Jorgensen, and Thunedborg, 1989) and the other imipramine (Castleden, Duffin, and Gulati, 1986), documented decreases in incontinence frequency. However, the results were statistically significant only for reducing nocturnal incontinence and overall patient preference for doxepin. Side effects in these studies included fatigue, xerostomia, dizziness, and blurred vision in the doxepin group and nausea and insomnia in the imipramine group.

Nonsteroidal Anti-Inflammatory Drugs

> Nonsteroidal anti-inflammatory drugs (NSAIDs) are not recommended for the primary treatment of DI. (Strength of Evidence = C.)

NSAIDs are theorized to be effective for UI because of their inhibition of prostaglandin "synthetase," which interferes with prostaglandin-mediated bladder contractions. However, limited research on the use of NSAIDs for patients with UI is available. Two controlled trials in women have been conducted (Cardozo and Stanton, 1979; Cardozo, Stanton, Robinson, et al., 1980). In a non-placebo-controlled trial, patients receiving indomethacin 100 mg po bid experienced comparable resolution of UI compared with those receiving bromocriptine (Cardozo and Stanton, 1979). A placebo-controlled trial demonstrated 55-percent continence with flurbiprofen 50 mg po tid versus 29 percent with placebo (Cardozo, Stanton, Robinson, et al., 1980). In both studies, side effects were frequent, although no patient stopped use of NSAIDs. When NSAIDs are used, close monitoring for drug toxicity (e.g., gastrointestinal hemorrhage, renal dysfunction) should be performed, especially in elderly patients.

Other Drugs of Possible Benefit

Other drugs used for detrusor instability include a beta-adrenergic agonist (terbutaline) (Lindholm and Lose, 1986) and a spinal synaptic inhibitor (baclofen) (Taylor and Bates, 1979). Limited studies and clinical experience with these agents suggest that further studies must be done before they can be recommended for general use.

Summary of findings. Pharmacotherapy, at least in short-term trials, appears to benefit some patients with UI due to detrusor instability. However, regardless of the agent chosen, involuntary bladder contractions are usually not abolished, the "warning time" between appreciation of the need to void and the onset of bladder contraction is usually not affected, the degree of improvement is modest, and "cure" is uncommon. In addition, many of these medications are costly, and most have bothersome side effects. These drugs should be used only in conjunction with a voiding schedule or behavioral intervention and only after other factors contributing to incontinence have been addressed.

To date, oxybutynin possesses the most favorable efficacy, safety, and pharmacokinetics profile of the agents for DI. However, selection of an agent must be individualized and based on patient considerations (i.e., contraindications) and

cost as well as on drug considerations (i.e., kinetics, drug interactions, and side effects). For example, an antidepressant may be the preferred drug for UI in a depressed patient but not for a patient with orthostatic hypotension who is prone to falling. A drug with a rapid onset of action may be useful for a patient who desires protection only for certain events (e.g., going out for the afternoon), whereas a drug with a longer half-life may be preferable for a patient who desires continuous protection.

Regardless of the agent selected, the initial dosage should be relatively low. The dosage should be increased slowly, consistent with the drug's half-life, and titrated to balance efficacy with side effects. Patients must be closely monitored for urinary retention. Combining agents with different mechanisms of action may increase their efficacy and reduce side effects, but few relevant data are available. Although the long-term efficacy of bladder relaxants is largely unknown, Moore, Hay, Imrie, et al. (1990) have reported that once incontinence responded to pharmacologic and behavioral interventions, improvement persisted even if the medication was withdrawn after a few months.

Stress Incontinence: Urethral Sphincter Insufficiency

The rationale for pharmacologic therapy for UI due to urethral sphincter insufficiency (stress incontinence, SUI) is based on selection of agents that affect the high concentration of alpha-adrenergic receptors in the bladder neck, bladder base, and proximal urethra. Sympathomimetic drugs with alpha-adrenergic agonist activity presumably cause muscle contraction in these areas and thereby increase bladder outlet resistance. Pharmacotherapeutic strategies that are designed to increase bladder outlet resistance include the use of drugs with direct alpha-adrenergic agonist activity, estrogen supplementation both for direct effect on urethral mucosal and periurethral tissues and for enhancement of alpha-adrenergic response, and beta-adrenergic-blocking drugs that may allow unopposed stimulation of alpha-receptor-mediated contractile muscle responses.

Alpha-Adrenergic Agonist Drugs

> Phenylpropanolamine (PPA) or pseudoephedrine is the first-line pharmacologic therapy for women with SUI who have no contraindications for its use, particularly hypertension. The recommended dosage for PPA is 25-100 mg in sustained-release form, administered orally, twice daily. The usual dosage of pseudoephedrine is 15-30 mg, orally, three times daily. (Strength of Evidence = A.)

PPA in sustained-release form is the major alpha-adrenergic agonist drug studied in women with stress incontinence. Seven prospective randomized controlled studies of middle-aged, normotensive women with stress incontinence were reviewed. In three studies (Collste and Lindskog, 1987; Fossberg, Beisland, and Lundgren, 1983; Lehtonen, Rannikko, Lindell, et al., 1986) no patients became continent, but 31-45 percent of patients given PPA had decreased incontinence over placebo response (PPA minus placebo "improved" response). In four studies (Ek, Andersson, Gullberg, et al., 1978; Hilton, Tweddell, and Mayne, 1990; Walter, Kjaergaard, Lose, et al., 1990; Wells, Brink, Diokno, et al., 1991), 9-14 percent of women became dry, and 19-60 percent of patients experienced significant reduction of incontinence over the number of similar responses in the placebo group. In studies in which the improvement rate was reported, the reduction in leakage with PPA ranged from 31 to 60 percent over the response with placebo.

Side effects were minimal and included nausea, xerostomia, insomnia, rash, itching, and restlessness. PPA did not cause significant increases in blood pressure during the evaluation period.

Summary of findings. Pharmacologic therapy of incontinence caused by sphincter insufficiency (stress incontinence) using PPA appears to result in few cures or dryness (0-14 percent) but may cause subjective improvement in 20-60 percent of patients over placebo response. It is unclear whether patient age or the severity of leakage affects the likelihood of response. Possible side effects from alpha-adrenergic agonist drugs include anxiety, insomnia, agitation, respiratory difficulty, headache, sweating, hypertension, and cardiac arrhythmias, all of which may occur more commonly in elderly patients. The risk of PPA use in hypertensive women and its efficacy in women taking antihypertensive drugs have not been determined. PPA should be used with caution in patients with hypertension,

hyperthyroidism, cardiac arrhythmias, and angina. The sustained-release form is advocated because of its routine use by investigators in clinical trials. Whether the immediate-release form produces similar results has not been established.

Estrogen Therapy

Estrogen (oral or vaginal) may be considered as an adjunctive pharmacologic agent for postmenopausal women with SUI or mixed incontinence. Conjugated estrogen is usually administered either orally (0.3-1.25 mg/day) or vaginally (2 g or fraction/day). Progestin (e.g., medroxyprogesterone 2.5-10 mg/day) may be given continuously or intermittently. (Strength of Evidence = B.)

Because the vagina and urethra are of similar embryologic origin, estrogen supplementation in postmenopausal women may restore urethral mucosal coaptation and increase vascularity, tone, and the alpha-adrenergic responsiveness of urethral muscle, which in turn may increase bladder outlet resistance and decrease stress incontinence. However, the exact role of estrogen, as well as its mechanism of action, is still unknown and deserves further research. Most clinical trials have been conducted with estrogen products available abroad; but their data are included in this report because of the paucity of research using marketed products in the United States and the similarities between estrogens.

Estriol derivatives. Two studies of postmenopausal women with stress incontinence compared effects of placebo and estriol, 4 mg/day, on continence (Samsioe, Jansson, Mellstrom, et al., 1985; Walter, Kjaergaard, Lose, et al., 1990). Results showed that 0-14 percent of patients on estriol became dry, and 29 percent of patients experienced improved continence compared with patients who received placebo. One study showed that the response to estriol was significantly better than to placebo (Walter, Kjaergaard, Lose, et al., 1990), whereas the other study showed that the response to active drug was not significantly better than to placebo (Samsioe, Jansson, Mellstrom, et al., 1985). In the latter study, 66 percent of patients with UI reported improvement.

A trial of quinestradol, an estriol derivative, in female incontinent nursing home residents did not result in continence, but 89 percent of patients had a significant reduction of leakage episodes while taking quinestradol compared with 0 percent while on placebo (Judge, 1969).

Estrone derivatives. A 3-month prospective study of postmenopausal stress-incontinent women who received placebo or piperazine estrone sulfate for 3 weeks with one drug-free week per cycle revealed that subjective and objective improvements at 3 months were greater, but not statistically significant, while on estrogen (Wilson, Faragher, Butler, et al., 1987).

Fantl, Cardozo, McClish, et al. (1994) provided a meta-analysis from 6 randomized controlled trials and 17 uncontrolled clinical series. Favorable effects on incontinence in postmenopausal women were found with estrogen therapy ($P<0.01$ for all subjects and $P< 0.05$ for those with SUI).

Summary of findings. Limited evidence suggests that estrogen therapy by oral or vaginal administration may benefit some patients with SUI and mixed UI. Its effect on urge UI has not been reported in most of the available literature.

Other beneficial effects of long-term estrogen may include decreased risk of stroke, ischemic heart disease, and osteoporosis. Estrogen replacement should be given with a progestin when the uterus is present to avoid unopposed estrogen stimulation of the endometrium, particularly if prolonged therapy is anticipated. The dosages of estrogen and progestin used vary. Risks of estrogen therapy given in this manner include neoplasia of estrogen-responsive organs. Thus, estrogen therapy is contraindicated in patients with known or suspected cancer of the breast or uterus.

Alpha-Adrenergic Agonist and Estrogen Supplementation

Combination therapy of oral or vaginal estrogens and PPA is recommended in the treatment of SUI in postmenopausal women when initial single-drug therapy has proven inadequate. (Strength of Evidence = A.)

The rationale supporting combined estrogen supplementation and alpha-adrenergic agonist therapy in postmenopausal women with incontinence due to sphincteric insufficiency is based on an estrogen-induced increased number, sensitivity of alpha-adrenergic receptors in the urethra, or both, which potentiates the alpha-adrenergic contractile response to drug stimulation.

Review of four controlled studies that combined estrogen and alpha-adrenergic agonist therapy suggests that the combined therapy may be more effective than alpha-adrenergic agonist therapy alone (Ek, Andersson, Gullberg, et al., 1978, 1980; Hilton, Tweddell, and Mayne, 1990; Walter, Kjaergaard, Lose, et al., 1990). However, the studies are limited, and based on these results, combination therapy should be considered when initial single-drug therapy fails. The possible risks of alpha-adrenergic agonist drugs and estrogen do not appear to be increased when used together. Patients should be carefully monitored when combination therapy is prescribed, however.

Other Drugs of Possible Benefit

> Imipramine is recommended as an alternative pharmacologic therapy for SUI when first-line agents have proven unsatisfactory. (Strength of Evidence = C.)

Imipramine. A tricyclic antidepressant that possesses both alpha-adrenergic agonist activity (presumably mediated by blocking reuptake of norepinephrine) and anticholinergic properties has been reported to benefit women with stress incontinence. In a nonrandomized, uncontrolled study, 30 women (28-64 years old) with pure stress incontinence received imipramine at 75 mg daily for 4 weeks; 21 of the 30 (70 percent) claimed continence (Gilja, Radej, Kovacic, et al., 1984). Side effects reported included nausea, insomnia, weakness, fatigue, and postural hypotension. Prospective controlled studies are not available, and thus further research is necessary.

> The use of propranolol or other beta-blockers cannot be recommended for treatment of SUI because of lack of clinical experience and clinical studies. (Strength of Evidence = C.)

Propranolol. Limited research on the use of beta-blockers for treatment of SUI is available. In one uncontrolled study, a beta-adrenergic-blocking drug was reported to improve symptoms of SUI (Gleason, Reilly, Bottaccini, et al., 1974). The use of this and other beta-blockers cannot be recommended for treatment of incontinence at this time.

Antidiuretic hormone. Desmopressin (desmopressin diacetate arginine vasopressin (DDAVP)) is used mainly in the treatment of nocturnal enuresis and night-time polyuria. Available research on this drug has been conducted mainly in children and in patients with neuropathic conditions. Because few data exist in adults, DDAVP is not discussed in detail in this guideline.

Surgical Treatment

The decision to perform surgery for the treatment of UI should be made only after a precise, focused assessment that includes a comprehensive clinical evaluation with an objective confirmation of the pathophysiologic diagnosis and severity of urinary loss, a correlation of the anatomic and physiologic findings with the surgical plan, an estimation of surgical risk, and an estimation of the impact of the proposed surgery on the patient's quality of life.

Several caveats must be considered when reviewing the literature on the surgical treatment of UI. Standards have not been established for describing the patient population, the type of incontinence, the methods for accurate diagnosis, the techniques of the surgical procedure, or the outcome in different domains (e.g., symptoms, anatomophysiologic outcomes, quantity of fluid loss, quality of life). There may be difficulty in comparing surgical procedures because of intentional modifications or variations in technique and the experience and expertise of the surgeon. Postoperative reporting is often biased by variations in the definitions for failure, improvement, and success, and similarly for the degree and incidence of operative morbidity, early and late complications, and length of followup. These variations make precise comparisons of studies including different surgeons performing the same procedure, or multiple surgeons performing different procedures, impossible. Retrospective comparison of different techniques may contain

unknown selection biases. Prospective comparisons often include different surgeons with different degrees of experience and expertise. Terminology should be standardized for classification of incontinence, description and execution of surgical procedures, and reporting of surgical outcomes. In reports of series, complications should be reported individually, and the criteria for patient selection should be described. Comparison of different techniques should be made by prospective randomized studies using similar inclusion criteria for each technique.

This guideline is primarily directed toward the primary care provider, and the level of detail provided is not sufficient to direct surgical therapy. The inherent variability in surgical technique and the way in which operations are performed make it impossible to direct surgical practice in a guideline of this scope.

The objectives of surgical treatment of incontinence depend on the specific etiology. A given patient may have more than one etiology. In this guideline, each etiology is addressed separately. The purpose of a surgical procedure is to correct, compensate for, or circumvent the underlying pathology causing urinary loss. Stress incontinence in women may be caused by urethral hypermobility or ISD. Men with stress incontinence suffer solely from ISD. Inappropriate elevations in bladder pressure may result from uninhibited bladder contractions or a loss of bladder compliance. Poor bladder emptying that leads to retention may result from an impaired or absent bladder contraction or from outlet obstruction.

The surgical procedures described in this section are divided into three sections: (1) surgeries that *increase outlet resistance* and relieve SUI and ISD, (2) procedures that *decrease detrusor instability* and correct urge incontinence, and (3) operations that *remove outlet obstruction*, thereby correcting overflow incontinence or reversing detrusor instability that is secondary to the outlet obstruction.

> Surgery is recommended for treatment of stress incontinence in men and women and may be recommended as first-line treatment for appropriately selected patients who are unable to comply with other nonsurgical therapies. (Strength of Evidence = B.)

Stress Incontinence in Women: Hypermobility or Intrinsic Sphincter Deficiency

The surgical objective in cases of hypermobility is to improve the support of the sphincter unit without obstruction. On the other hand, the goal of surgery for ISD is to increase urethral coaptation and resistance. Although many operations result in both improved support and compression of the proximal urethra, a primarily supportive procedure is less likely to succeed for a patient with ISD than for a patient with only hypermobility.

Preoperative Evaluation

A preoperative evaluation is important to ensure proper patient selection and to determine the appropriate surgical procedure. The evaluation should include a comprehensive history, physical examination, urinalysis, urine culture, and measurement of PVR volume. It is important to document the incontinence objectively by direct observation of a positive stress test (direct visualization). Some multiparous women may have stress incontinence on physical examination but are not troubled by this; therefore, the patient should be asked if the incontinence visible on examination is the type of incontinence that led her to seek care. Because CMGs may be falsely negative in many women with DI, simply using a negative CMG to diagnose SUI is not acceptable. When further corroboration is needed, cystoscopy, a cystogram with straining, measurement of Valsalva leak point pressure, dynamic UPP, or a combination may be used.

Although patients with symptoms of DI may be more likely to remain incontinent after surgery, it is not clear whether a preoperative CMG to search for asymptomatic instability is necessary. If symptomatic instability is present, some health care providers may attempt behavioral or pharmacologic treatment before surgical correction of the stress incontinence. Others may not because many patients experience resolution of DI once stress incontinence is corrected. This decision must be made on an individual basis, using clinical judgment and considering the patient's informed preference.

To select the appropriate surgical procedure, one must assess the position of the urethra and the degree of axial urethral mobility by physical examination, cystogram, ultrasound, or cystoscopy. Factors that may be associated with an increased risk of failure, such as symptomatic DI, obesity, prior surgery, hypoestrogenism, chronic cough, strenuous physical activity, previous radiation therapy, advanced age, or poor nutrition, must be identified. Pelvic organ prolapse or other pathology that would require surgical treatment at the same time as the anti-incontinence procedure should also be identified. The approach required to treat the concurrent pathology will influence the choice of approach for the anti-incontinence procedure. The extent of the evaluation depends on the complexity of the presentation.

The degree of ISD should be assessed preoperatively using a combination of assessment tools. In the history, patients who have only hypermobility describe leakage with vigorous activity, whereas patients with ISD tend to have leakage with minimal activity. On physical examination, patients with incontinence due to hypermobility have descent of the urethra and bladder neck during stress maneuvers. On the other hand, reproducible demonstration of stress incontinence through a normally supported urethra is suggestive of ISD. Corroboration of ISD may be established by a variety of tests, including leak point pressure, passive urethral profilometry, imaging techniques such as fluoroscopy, and on occasion cystoscopic assessment. Most of these assessment tools do not provide a definitive diagnosis alone, especially if the patient has coexistent DI, which can cause a functional opening of the bladder neck at rest. Therefore, the entire clinical presentation must be considered.

Procedures for Hypermobility

After complete evaluation, if the primary pathophysiologic defect appears to be urethral hypermobility or displacement, three main types of procedures are used:

- Retropubic suspension.
- Needle bladder neck suspension.
- Anterior vaginal repair.

Retropubic or needle suspension is recommended for women with hypermobility when SUI is the primary indication for surgery. On the basis of greater efficacy, these procedures are recommended over anterior vaginal repair for hypermobility. (Strength of Evidence = B.)

Review of the available literature shows that in general retropubic and needle suspension procedures produce a superior result to that of anterior repair in "curing" UI. This analysis of results usually focuses exclusively on the symptom of stress incontinence and does not account for postoperative problems such as the new development of an enterocele or rectocele large enough to require surgery, persistent voiding difficulty, or DI. Therefore, although the reported cure rate for stress incontinence is high, the number of women with an entirely satisfactory outcome may not be. Treatment must be individualized for each patient as well as standard recommendations about which operation will be best. The option selected depends on the surgeon's training and expertise and on the presence of concurrent pathology that would require correction by a vaginal or abdominal approach.

For hypermobility with coexisting ISD the surgical procedure should stabilize the anatomic support and compress the urethra, which invariably means using one of the sling procedures (see Procedures for ISD below). The choice must be individualized for each patient. Women who have severely damaged urethras require special procedures such as urethral or bladder neck reconstruction, urethral substitution, continent vesicotomy, or urinary diversion.

Management must be individualized for women whose primary problem is prolapse of the pelvic organs but who have SUI or in whom temporary replacement of the prolapse during preoperative evaluation uncovers SUI. In these circumstances, a decision about the most appropriate anti-incontinence procedure to be combined with repair of the prolapse should account for the type of SUI present (hypermobility or ISD), the operation chosen to repair the prolapse (abdominal or vaginal), and additional morbidity from the continence operation weighed against the degree

of incontinence. Preoperative urodynamic examination should be performed if this information is needed to choose the type of operation to be performed.

Retropubic suspension. Retropubic suspension procedures include several different techniques performed through a low abdominal incision (i.e., retropubic approach). All techniques have in common elevation of the lower urinary tract, particularly the urethrovesical junction, within the retropubic space. The procedures differ according to what structures are used to achieve the elevation. For the Marshall-Marchetti-Krantz procedure, the periurethral tissue is approximated to the symphysis pubis. For the Burch colposuspension, the vaginal wall lateral to the urethra and bladder neck is elevated toward Cooper's ligament. The paravaginal repair involves reapproximating the endopelvic fascia to the pelvic wall at the arcus tendineus.

To evaluate this category of procedures, 45 studies incorporating 3,882 patients were reviewed (Baker and Drutz, 1992; Beck, Thomas, and Maughan, 1968; Bergman, Ballard, and Koonings, 1989; Bergman, Koonings, and Ballard, 1989a; Bergman, Koonings, and Ballard, 1989b; Bergman, Koonings, and Ballard, 1989c; Brieger and Korda, 1992; Duncan, Nurse, and Mundy, 1992; Eriksen, Hagen, Eik-Nes, et al., 1990; Fall, Erlandson, and Pettersson, 1984; Ferriani, de Sa, de Moura, et al., 1990; Francis, Sand, Hamrang, et al., 1987; Goodno and Powers, 1992; Green, McGuire, and Lytton, 1986; Hilton and Stanton, 1983; Iosif, 1985; Jouppila, Kauppila, Ylikorkala, et al., 1977; Kiilholma, Makinen, Chancellor, et al., 1993; Kil, Hoekstra, Van der Meijden, et al., 1991; Korda, Ferry, and Hunter, 1989; Kujansuu, 1983; Langer, Ron-El, Newman, et al., 1988; Langer, Ron-El, Bukovsky, et al., 1988; Lockhart, Maggiolo, and Politano, 1983; Lose, Jorgensen, and Johnsen, 1988; Milani, Scalambrino, Quadri, et al., 1985; Morgan, 1973; Nielsen and Lundvall, 1973; Park and Miller, 1988; Penttinen, Kaar, and Kauppila, 1989; Penttinen, Lindholm, Kaar, et al., 1989; Pow-Sang, Lockhart, Suarez, et al., 1986; Richardson, Ramahi, and Chalas, 1991; Richmond and Sutherst, 1989a; Sand, Bowen, Ostergard, et al., 1988; Shull and Baden, 1989; Spencer, O'Conor, and Schaeffer, 1987; Stanton, Williams, and Ritchie, 1976; Stanton and Cardozo, 1979; Steel, Cox, and Stanton, 1985; Thunedborg, Fischer-Rasmussen, and Jensen, 1990; Van Geelen, Theeuwes, Eskes, et al., 1988; Vordermark, Brannen, Wettlauffer, et al., 1979; Wheelahan, 1990). Total "cure" rates averaged 79 percent, and 84 percent were "cured" or improved.

Overall complication rates reported for retropubic operations average 18 percent (6-57 percent). In the recent literature, complications reported among the studies of retropubic urethral suspensions were sparse, being included in only 6 of 13 papers with insufficient information and consistency to allow accurate statistical reporting. Wound infections, urinary retention, de novo DI, and dyspareunia were all noted in the 3-15 percent range. The cause of postoperative symptomatic enterocele/rectocele with anterior traction on the anterior wall seems to be most prominent after the Burch operation, occurring in up to 12 percent of patients (Kiilholma, Makinen, Chancellor, et al., 1993). Recently, some of these retropubic procedures have been performed laparoscopically.

Needle bladder neck suspension. Another type of anatomic correction employs needle suspension of the bladder neck. Variations of this procedure are all performed through a vaginal approach, and most utilize small suprapubic skin incisions (Cobb and Ragde, 1978; Gittes and Laughlin, 1987; Pereyra, Lebherz, Growdon, et al., 1982; Stamey, 1980; Raz, 1981). Anchoring tissues adjacent to the urethra and bladder neck are held by suspending sutures.

Of the 3,015 patients studied in the reviewed research, most had the Stamey procedure; the others had the Pereyra-Raz procedure Abbassian, 1989; Ashken, 1990; Benderev, 1992; Benson, Agosta, and McClellan, 1990; Bergman, Ballard, and Koonings, 1989; Bergman, Koonings, and Ballard, 1989a; Bergman, Koonings, and Ballard, 1989c; Bhatia and Bergman, 1985a; Bosman, Vierhout, and Huikeshoven, 1993; Cobb and Ragde, 1978; Dijkman and Friese, 1984; Duncan, Nurse, and Mundy, 1992; Foster and O'Reilly, 1989; Ganabathi, Abrams, Mundy, et al., 1992; Gaum, Ricciotti, and Fair, 1984; Griffith-Jones and Abrams, 1990; Hilton, 1989; Huland and Bucher, 1984; Jones, Shah, and Worth, 1989; Juma, Little, and Raz, 1992; Kil, Hoekstra, et al., 1991; Kirby and Whiteway, 1989; Kursh, 1992; Kursh, Angell, and Resnick, 1991; Leach and Raz, 1984; Lopez Lopez, Valdivia Uria, and Uca Terran, 1992; Loughlin, Whitmore, et al., 1990; Mundy, 1983; Netto, Lemos, Palma, et al., 1988; Nitti, Bregg, et al., 1993; Parra and Shaker, 1990; Penttinen, Kaar, and Kauppila, 1989; Pereyra, Lebherz, Growdon, et al., 1982; Pope, Shaw, Coptcoat, et al., 1990; Pow-Sang, Lockhart, Suarez, et al., 1986; Ramon, Mekras, and Webster, 1990; Raz, Sussman, Erickson, et al.,

1992; Richardson, Ramahi, and Chalas, 1991; Shah and Holder, 1989; Spencer, O'Conor, and Schaeffer, 1987; Stamey, 1980; Varner, 1990; Walker and Texter, 1992; Wujanto and O'Reilley, 1989). For the combined series, 74 percent were continent postoperatively and 84 percent were "cured" or improved; followup varied. Complications included UTI, urinary retention longer than 3 weeks' duration, obstructive symptoms, suture abscess, wound infection or vaginal granuloma, vesicocutaneous fistula, hematoma, sutures pulling out of the vaginal fascia, sepsis, new onset of symptomatic DI, and prolonged suprapubic pain and de novo pelvic floor defects.

Anterior vaginal repair. The anterior vaginal repair category of treatments includes several modifications of the original Kelly plication. All techniques include some degree of dissection of the anterior vaginal wall from the overlying bladder base and urethra, and plication of the pubocervical fascia. The extent of the dissection and the location and extent of the placating (elevating) sutures vary substantially among these techniques. Although the success of these operations as a group is somewhat lower than retropubic or needle suspensions, some specific techniques achieve excellent success, on objective followup indicating the need to discriminate the actual technical details of each of these different operations before making generalizations (Beck, McCormick, and Nordstrom, 1991).

Review of 11 studies incorporating 957 patients reveals an overall "cure" rate of 65 percent (range = 31-91 percent) and a "cure" or improvement rate of 74 percent (range = 31-98 percent); followup varied (Beck, McCormick, and Nordstrom, 1991; Beck, Thomas, and Maughan, 1968; Bergman, Ballard, and Koonings, 1989; Bergman, Koonings, and Ballard, 1989c; Jouppila, Kauppila, Ylikorkala, et al., 1977; Kujansuu, 1983; Lose, Jorgensen, and Johnsen, 1988; Park and Miller, 1988; Stanton, Hilton, Norton, et al., 1982; Thunedborg, Fischer-Raumussen, and Jansen, 1990; Van Geelen, Theeuwes, Eskes, et al., 1988). Complication rates were provided for only two studies; the average was 14 percent.

Procedures for Intrinsic Sphincter Deficiency

Procedures for management of ISD include

- Sling procedures.
- Periurethral bulking injections.
- Placement of an artificial sphincter.

Sling procedures are recommended for women who have ISD with coexisting hypermobility or as first-line treatment for ISD. (Strength of Evidence = B.)

Periurethral bulking injections are recommended as first-line treatment for women with ISD who do not have coexisting hypermobility. (Strength of Evidence = B.)

Artificial sphincter is recommended for ISD patients who are unable to perform intermittent catheterization and have severe SUI that is unresponsive to other surgical treatments. Because of the high complication rate, this treatment is rarely used as primary therapy. (Strength of Evidence = B.)

Sling procedures. The various sling procedures all involve placing a sling, made of either autologous or heterologous material, under the urethrovesical junction and anchoring it to retropubic or abdominal structures or both. The operation can be performed through an abdominal approach, a vaginal approach, or a combined abdominal and vaginal approach. Sling operations are often performed in women with complicated incontinence, many of whom have failed previous attempts at surgical correction. The success and complication rate should be viewed with this fact in mind.

Data from a series of 9 studies of 434 patients with fascial slings indicated that 89 percent were "cured," and 92 percent were "cured" or improved (Beck, McCormick, and Nordstrom, 1988; Deppe, Castro-Marin, Nachamie, et al., 1978; Low, 1969; McGuire and Lytton, 1978; McIndoe, Jones, and Grieve, 1987; Narik and Palmrich, 1962; Ogundipe and Rosenzweig, 1992; Richmond and Sutherst, 1989a; Ridley, 1966). Combined analysis of 298 patients

from six studies that used a synthetic sling indicated that 78 percent were "cured," and 84 percent were "cured" or improved (Brieger and Korda, 1992; Bryans, 1979; Kersey, 1983; Korda, Peat, and Hunter, 1989).

Although the total complication rate given for the fascial sling series was higher than that for the synthetic sling series, the synthetic sling caused more severe complications, many of which were directly attributable to local effects of the sling (i.e., erosion, nonhealing of the vaginal wall, abscess, vesicovaginal fistula). Fascial slings are preferable to synthetic slings because of the lower rate of local complications.

Data from 32 patients treated with the vaginal wall sling showed that 81 percent were dry, 9 percent were improved, and 9 percent showed no improvement (Ogundpipe and Rosenzweig, 1992; Ridley, 1966). Complications included urinary retention and new onset of irritative voiding symptoms.

Periurethral bulking injections involve the injection of materials such as polytetrafluoroethylene (PTFE), collagen, or autologous fat under cystoscopic guidance into an incompetent periurethral area. Patients being considered for periurethral collagen injection require a skin test for sensitivity to the material. Injection of the material appears to be technically easier because the number of patients requiring anesthesia or sedation is less than that reported with PTFE. The longevity of PTFE versus collagen has not been studied. Urinary tract infection and transient urethral irritation are the most common side effects after periurethral collagen injection. The procedures for periurethral bulking injections are described below in the section on male incontinence caused by ISD. In women, these injections are easily performed under local anesthesia. Combined data from 15 studies of 528 women indicate that after followup for up to 2 years 49 percent of patients were "cured" (range = 8-100 percent), and 67 percent were either "cured" or improved (Beckingham, Wemyss-Holden, and Lawrence, 1992; Berg, 1973; Deane, English, Hehir, et al., 1985; Eckford and Abrams, 1991; Harrison, Brown, and O'Boyle, 1993; Kiilhoma and Makinen, 1991; Lewis, Lockhart, and Politano, 1984; Lotenfoe, O'Kelly, Helal, et al., 1993; McGuire and Appell, 1994; O'Connell, McGuire, Aboseif, et al., in press; Santarosa and Blaivas, 1994; Schulman, Simon, Wespes, et al., 1983; Smart, 1991; Stricker and Haylen, 1993; Vesey, Rivett, and O'Boyle, 1988). Complications included urgency, UTI, and urinary retention.

Although documentation of teflon migration to the lung persisted (Claes and Stroobants, 1989) adverse reactions to this material in other sites has not been found. Increasing experience with collagen has established its efficacy in the short term, but, as with Teflon injection, long-term results beyond 5 years are not available.

Artificial sphincter. Artificial sphincter placement, described below in the section on ISD in men, has been used for women with ISD. Combined data from 8 studies of 192 women with ISD treated with artificial sphincter placement indicated that 77 percent were dry, and 80 percent were "cured" or improved (Appell, 1988; Light and Scott, 1985; Diokno, Hollander, and Alderson, 1987; Duncan, Nurse, and Mundy, 1992; Karram, Rosenzweig, and Bhatia, 1993; Motley and Barrett, 1990; Parulkar and Barrett, 1990; Webster, Perez, Khoury, et al., 1992). Complications included fluid leak, loose cuff, erosion or atrophy of the cuff site, tubing kink, and infection.

Stress Incontinence in Men: Intrinsic Sphincter Deficiency

An underactive outlet in men may result from a congenital defect or from direct or indirect trauma to the anatomy or physiology of the bladder outlet. Direct trauma due to prostatectomy is the most common cause of sphincter insufficiency. Neurologic dysfunction (e.g., sympathetic innervation to the bladder neck, pelvic nerve to the intrinsic sphincter, pudendal nerve to the external sphincter) may be a primary or contributory etiology. Devascularization or fibrosis, most commonly following radiation therapy or surgery, may also contribute to decreased closure pressure of the bladder outlet. The high incidence of mixed incontinence requires that an alteration in bladder function be considered and diagnosed before surgical intervention for decreased outlet resistance. Postprostatectomy incontinence is not always due to sphincter insufficiency but sometimes to detrusor dysfunction or both. Patients must be evaluated for other possible causes of incontinence, including obstruction, DI, and poor bladder compliance.

The choices for surgical treatment of male sphincter insufficiency include

- Periurethral bulking injections.