3. Effectiveness and Safety of Devices and Other Treatments

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Few studies have systematically examined the efficacy and long-term cost effectiveness of the various treatments for urinary incontinence. Most published studies are reports of case series. The relative efficacy of various treatments has rarely been examined. In this chapter, we review in detail the published reports of the effectiveness of treatments for urinary incontinence, focusing especially on devices.

ARTIFICIAL SPHINCTERS

Several types of artificial sphincters have been developed and tested over the last two decades. The historical development of and the mechanisms by which these devices maintain continence are described in detail later in this case study. The most extensively tested types of sphincters are surgically implanted cuffs, which fit around the urethra and are controlled externally by the patient. Earlier models such as the AS 721, manufactured by American Medical Systems, required patients to both inflate and deflate the cuff. Later models, such as the AS 791 and AMS **800** TM, manufactured by American Medical Systems, require patients to deflate the cuff only when they desire to urinate; the cuff automatically inflates gradually after urination. These devices are implanted primarily for weakness or total dysfunction of the bladder outlet and urethral sphincter mechanisms. Patients with unstable bladders or urinary retention (secondary to anatomic obstruction of urine flow or an inadequately contracting bladder) are not appropriate candidates for an implantable sphincter and therefore must be excluded by preoperative urologic evaluation. In addition, candidates for artificial sphincters must be mentally and physically capable of managing the device and be motivated to do so (or have a caregiver available who will manipulate the device for them).

As shown in table 3-1, all published reports of artificial sphincters have been case series, not controlled clinical trials. Most commonly, artificial sphincters have been tested in males with incontinence following prostate surgery, in women with stress incontinence (many of whom have had previous unsuccessful surgical procedures to correct incontinence), and in children with spinal-cord abnormalities (myelomeningocele).

As the table demonstrates, artificial sphincters appear to improve or cure incontinence in **40** to 80 percent of patients. The duration of followup has ranged from a few months to longer than 3 years. Many patients developed complications from the procedure—primarily erosion of the sphincter cuff into the urethra. This was often a very serious and irreversible complication, occurring in up to one-quarter of treatment failures. Other complications included persistent infection and mechanical failure requiring removal and/or replacement of the device. A newer technique (primary deactivation), designed to minimize cuff erosion, involved leaving the cuff deflated for up to 3 months after the implantation to allow tissue healing.

In addition to the surgically implantable devices, other approaches to the artificial sphincter have been developed. A prosthesis made of a silicone gel has been implanted in patients with postprostatectomy incontinence. In the fewer than **200** cases reported, approximately 70 percent benefited from the prosthesis over a 1- to 2-year

Table 3-1.—Sphincter Devices

Sphincter device	Reference	Study design	Diagnosis	Criteria for Improvement	Results	Comments
AS 721	Scott Bradley and Timm (1973)	Case Series (N = 5 1 m 4 fe) 10-day follow-up	4 neurologic disorder	Radiologlc office examination urodynamics tissue acceptance	100% success, all dry and void freely, voiding flow rates as good as or better than preoperative results, no discomfort after 10 days	
AS 721	Hald, Bystrom, and Alfthan (1975)	Case Series (N = 8, 6 m 2 fe) 2-10 month follow-up	5 neurogenic bladder, 3 postsurgery	Continence	6 continent	
AS 721	Furlow (1976)	Case Series (N = 31. 29 m. 2 fe) Ages 22-78, 24-month follow-up	Most post-prostate surgery, 6 pelvic trauma	Continence	68% success	Major complications, 3 Infections around prosthesis, 2 urethral erosions, 1 vesical neck erosion, 1 vesicorectal fistula, 1 defective cuff 9/26 continent patients required more than one revisit to maintain device function
AS 761	Balloon Sphincter Clinical Study Group (1977)	Case Series (N = 82)		Continence	57% successful Initially, 2% Improved, 41 % failed	Failures from mechanical complications (e g , valve failure), surgical failure (e g Infection), patient selection (e g , uninhibited bladder contractions)
AS 742	Balloon Sphincter Clinical Study Group (1978)	Case Series (N = 90)		Continence	68% success, 5% improved, 27% failed	Failures from surgical error (11), patient selection (3), mechanical failure (1)
AS 721 AS 742	Scott (1978)	Case series (N = 41)	Most past-prostate surgery, 10 pelvic fracture	Patient should not require bedpad, be continent with stress. and be able to urinate easily	Success rate = AS 721, 59%, AS 742, 92%, Overall, 78%	Success rate = 100% for incontinence resulting from urethral surgery or following radical prostatectomy Success rate = 50% for those with pelvic fracture causing disruption to membranous urethra 6/41 required removal of prostheses because of surgical contamination and Infection
742 A,B. C	Bruskewitz, et al (1980)	Case Series comparing AS 742A with AS 742B or C Group I (N = 21, 19 m 2 fe) Ages 7-83	Most post-prostate surgery, 2 female stress Incontinence	Excellent = none or slight Incontinence Improved = Improvement but still moderate incontinence	14% excellent, 24% Improved, 62% failure	Failures associated with cuff erosion (24%), Infection (24%) patient's inability to operate the device and continued Incontinence (24%)
		Group II (N = 17) Ages 9-81	Most post-prostate surgery, 15 had neurologlc disorders, 2 pelvic trauma	Failure = unimproved	44% excellent, 6% Improved, 50% failure	Failures associated with cuff erosion (33%), infection (11 %), continued Incontinence (6%) The higher balloon pressures in 742B and C were associated with increased rates of erosion
AS 742 A,B,C	Furlow (1981)	Case Series (N = 47, 41 m, 6 fe) Ages = 6-81, mean = 55	17 radical prostatectomy 13 neurogenic bladder, 4 female stress incontinence	Continence	81% continent, 19% erosion	Device malfunction was not a significant cause of failure, half the failures were corrected by cuff replacement and deactivation
AMS 791 /792	Scott, et al (1981)	Case Series (N = 203, 129 m, 74 fe) Ages 5-84: 27-month follow-up	88 neurological disorders, 68 postoperative, 47 others	Failure = complications or persistent Incontinence	85% success rate	Mechanical failures (26) mainly caused by cuff failure: 96 percent chance of success after first 6 months

Table 3-1 .—Sphincter Devices—Continued

Sphincter device	Reference	Study design	Diagnosis	Criteria for Improvement	Results	Comments
AS 742	Lindner, Kaufman, and Raz (1983)	Nonrandomized comparison of primary activation with delayed activation (N = 78, 76 m, 2 fe) Ages 6-83, mean = 60 Follow-up Group I mean = 268 months, Group II mean = 92 months	Most post-prostate surgery	Dry Minimal stress Incontinence Failure	Primary activation (N = 53), 40% dry, 15% minimal: 45% failed Delayed activation 58% dry, 7% minimal, 35% failed	Reasons for failure, Group I erosion 19%, Incontinent 13%, infection, 11 % tube leaked, 2%, Group 11 erosion 24% Incontinent 12%
AMS 791/792	Reimenschneider and Moon (1983)	Case Series (N = 16) 2-12 month follow-up	Most post-prostate surgery	Patient dry between voiding residual under 100 cc; unchanged or Improved upper urinary tracts, no complications for more than 90 days	*8* success, 3 failure, 5 unknown (follow-up less than 90 days)	Best results occurred in patients with normal bladders and Incompetent sphincters Urethral erosion was major complication
Rosen prostheses	Rosen (1978)	Case Series (N = 23)	Most post-prostatectomy	Continence	77% success	8 patients had second operation 3 had device successfully changed 5 had device removed because of infection (4) or urethral damage (1)
Rosen prosthesis	Rosen (1978)	Case Series (N = 16)	14 post-prostate surgery	Cured = continent most of the time	11	Five failures included failure of scrotal reserve, urethral and Derineal fistula, persistent perineal pain, persistent incontinence
Rosen prosthesis	Augspurger (1981)	Case Series (N = 17) O-26 month follow-up	Post-prostate surgery	Proper prosthesis function regardless of number of operations	53% success	Half of failures (4) had a possibility of replacement (e. g mechanical failure), other half caused by perineal pain (2) and multiple complications (2), 15 patients had major complications requiring another operation with replacement or removal of prosthesis
Silicone-gel prosthesis	Kaufman (1978)	Case Series (N = 184) 6-1 2-month follow-up	168 post-prostate surgery	Excellent = patient satisfaction and no pads used Good = patient uses fewer than four pads a day for stress incontinence Failure = no Improvement or patient uses more than four pads a day	169 excellent or good 15 failure	11'Yo had major complications (mostly urethral erosions) After 1 year with one or more injection 33% excellent, 28% good, 390/$_0$ failure Overall, 69% benefit
Silicone-gel prosthesis	Confer and Bean (1981)	Case Series (N = 8) 30-month follow-up	Post-prostate surgery	Continence without Complications regardless of number of injections	100% success	One patient required a second injection 2'/2 years later
Periurethral Teflon Injection	Politano (1978)	Case Series (N = 125, 77 m, 43 fe) Ages 6-84	75 post-prostate surgery, variety of other conditions	Excellent = total continence with no protective device Good = collecting device not necessary Poor = little or no Improvement	70% good/excellent	
Periurethral Teflon injection	Lim, Ball, and Feneley (1983)	Case Series (N = 28) Ages 20-84, Mean = 569, 3-12 month follow-up	All Incontinent, 26 had previous surgery to relieve incontinence	Cured = total continence Temporary Improvement = good control of continence with only minimal leakage	21% cured, 54% temporary Improvement, 2570 no Improvement	'Patients with weak sphincters and stable bladders responded best

Table 3-1 .—Sphincter Devices—Continued

Sphincter device	Reference	Study design	Diagnosis	criteria for Improvement	Results	Comments
Four recent studies [a]						
	Light	Case Series (N = 58) Ages 12-67, 3-36 month follow-up	All spinal cord	Continence without complications	70%	
	Diokno	Case Series (N = 23) Follow-up mean = 35 years		Continence without complications	70%	6 failures from tissue erosion 1 from infection
	Mulcahy	Case Series (N = 70)		Continence without complications	89%	Complications Included 11 cuff erosion 4 tubing kinks 3 cuff leaks 3 pump erosions
	Barnett	Case Series (N = 262)	All had previous surgery for incontinence	Continence without complications	50%	
		(N = 30)	None had previous surgery for Incontinence		95%	

apresented at the 1983 Annual Meeting of the American Urological Association and reported in Hager 1983

SOURCE J Ouslander and R Kane University of California at Los Angeles 1984

period. Some of the patients required repeated injections, and urethral erosion (similar to complications described with artificial sphincters) occurred in a few patients (38,88).

In addition to the silicone-gel prosthesis, a method of periurethral injection of Teflon has been developed (31). This procedure is quite simple and requires only local anesthesia and the injection of a Teflon paste around the urethra. As with the silicone-gel prosthesis, fewer than 200 cases have been reported; approximately 70 percent achieved favorable results. Experiments with dogs have indicated that the Teflon particles can migrate: They have been found in the dogs' lungs and other major organs (97'). Thus, before this technique can be widely instituted, larger sized Teflon particles may have to be developed to prevent migration and any potential long-term adverse effects of these articles in various areas of the body.

ELECTRICAL STIMULATION

Several different approaches involving electrical impulses for the treatment of incontinence have been tested over the last 20 years (149). In the earliest investigations, electrodes were implanted into the pelvic floor musculature and electrical current was used to stimulate muscle contraction and maintain continence in patients with stress incontinence. Difficulties with mechanical failure and migration of the surgically implanted electrodes led to the development of external electrical stimulation. External techniques include anal plugs and pessary-like devices with electrodes.

Electrical stimulation has been used for both acute and chronic conditions. In acute situations, the maximum voltage that does not produce discomfort is used to stimulate for periods of approximately 30 minutes. Stimulation can be repeated on several occasions over the course of a few weeks. In chronic situations, the device is left in place for most of a 24-hour period and the pelvic floor musculature is intermittently stimulated as the current is turned on and off for several seconds at a time.

Scandinavian studies done in cats and humans have shown that these devices can be used for both stress incontinence and incontinence associated with bladder instability (.50,51,53,54). In stress incontinence, stimulation appears to work by causing contraction of the pelvic floor musculature through stimulation of the nerves that innervate (i. e., control) the muscles. For bladder instability, the device stimulates sensory nerve fibers, which then cause reflex relaxation of the bladder, mediated by the spinal cord.

These different effects occur at different frequencies of stimulation. Thus, it appears that optimal design of the device involves the ability to vary the stimulation frequency. Because the effects are mediated by nerve fibers, the electrodes must be placed and maintained in the proper position for nerve stimulation to be effective. Recently developed electrical stimulators are inflated in the vagina to minimize electrode movement.

Patient selection is important in the success of these devices. Urologic examination must be performed to determine the type of incontinence and rule out abnormalities treatable by other means. Patients with stress incontinence must have intact pelvic floor musculature to be eligible. Patients with unstable bladders must have an intact nervous reflex arc. Patients with disorders that have completely destroyed the peripheral nerves or lower spinal cord are not appropriate candidates. In addition, patients must be willing and able to use and manage this device on an acute or chronic basis.

Results of several reported case series (shown in table 3-2) vary, depending on the nature of the electrical stimulation. In general, between .50 and 80 percent of individuals derive some short-term benefit from the treatment. A much smaller proportion of patients enjoy long-term benefits. Although there were few serious complications re-

Table 3.2—Electrical Stimulators

Electrical stimulator device	Reference	Study design	Diagnosis	Criteria for improvement	Results	Comments
Implantable pelvic floor stimulate?	Merrill, Conway, and DeWolf (1975)	Case Series (N = 14; 9 m, 5 fe) Ages 3-70	Most had necrologic disorders; 6 postoperative	Dry for at least 3 hours for several days in a row	3 cured; 4 Improved	No surgical complications; procedure uniformly unsuccessful for those with lower motor neuron lesions or meningomyelocoele: equipment failures (fractured antenna leads (4); faulty power supply (2)) occurred In 43% of failures
Implanted electrical stimulators	Alexander (1976)	Case Series (N = 22 fe) 3-24 month follow-up	Stress incontinence, usually with coexisting urge incontinence	Cure =continence Improved = subjects relieved but not totally continence	8 cured after surgery without using implant, 13 Improved with surgery and Implant stimulation	Relapses associated with Influenza, gallbladder surgery, bladder uncomfortable, blow on the abdomen, domestic strife
Transrectal external pelvic floor stimulator	Merrill, Conway, and DeWolf (1975)	Case Series (N = 6 fe)	Stress, congenital iatrogenic postoperative incontinence	Continence	50%	Abdominal cramps and mild diarrhea occurred during stimulation: no equipment failure
Transrectal stimulator	Merrill (1979)	Case Series (N = 20) 5-12 month follow-up	Urinary incontinence and detrusor hyperreflexia	Cure = continence without stimulator Benefit = symptoms less than before Implant	O cured: 4 benefited	Patient Instructed to activate device continually except when voiding, 3/4 successes after frost day
External stimulating device	Doyle, et al. (1974)	Case Series (N = 120)	104 sphincter weakness 12 bladder dysfunction 4 both	Success = continence	370/o success 42% success 75% success	Success rate highest in young, nulliparous patients who had not had surgery and was lowest in older patients who had had pregnancies and previous surgery
Maximal perineal stimulation	Glen, et al (1976)	Case Series (N = 19)	Urinary incontinence, 17 poor urethral pressure profiles	Subjective	O reported benefit	
Chrome electrical stimulation	Godec, Cass, and Ayala (1976)	Case series (N = 72; 34 m, 38 fe)	38 hyperreflexive bladder; 12 pelvic floor weakness: 16 both	Cured = dry when off device one month Improved = less wet than before stimulation	17 cured, 49 Improved, 6 failure 12% success rate overall	Failures caused by urethral stricture (2): urinary tract infection (2), radiation cystitis (l), mental retardation (1)
Acute electrical stimulation	Godec and Cass (1978)	Nonrandomized study of different types (N = 29, 8 m, 21 fe) 4-17 month follow-up	8 stress incontinence, most others had necrologic disorders	relief = dry Improved = less wet	Overall 1 7/20 relief or improvement, 5/17 relapsed, requiring repeat treatment	

Table 3-2.—Electrical Stimulators-Continued

Electrical stimulator device	Reference	Study design	Diagnosis	Criteria for Improvement	Results	Comments
Maximal electrccal “ stimulation (M ES)	Plevnik and Janez (1979)	Case Series (N = 98)	37 mixed stress and urge Incontinence, 11 postprostate surgery, remainder had various types of neurogenic bladder	Success = continence	Overall 7% cured, 50% Improved, 43% no effect	In some patients, 3 MES sessions resulted in sustained Improvements
Electronic pessary	Harrison and Paterson (1970)	Case Series (N = 21 fe) Ages 37-70	15 stress Incontinence, 5 urge Incontinence, 1 dribbling incontinence (duration of symptoms = 9 mo to 38 yrs)	Symptoms cured or Improved	11 success	
Electric pessary	HiIl, et al (1968)	Case Series (N = 5 fe) 12 week follow-up	2 stress incontinence, 1 urge incontinence, 1 postsurgical Incontinence	Continence	4 Improved	
Intravaginal electrical stimulation (IVS)	Erlandson, Fall, and Sundin (1977)	Case Series (N = 50 fe) Ages 19-82	24 stress incontinence, 22 urgency with or without incontinence	Urethral pressure profile used to determine effect of electrical stimulation on urethral closure	20-50 Hz for 15 mins was most effective for urethral closure	Carefully selected positions of electrodes and proper frequency of electrical Impulse were necessary for optimal urethral response
Ivs	Fall, et al. (1977)	Case Series (N = 17 fe) Ages 27-60, mean = 46	Idiopathic urinary urgency without incontinence	Bladder capacity increase before urination	Bladder capacity less than 300 ml 7/9 Increased, 2/9 decreased Bladder capacity more than 300 ml 3/8 Increased, 5/8 decreased	
Long-term IVS (4-9 months)	Fall, et al (1977)	Case Series (N = 24 fe) Ages 30-60, mean = 46, 2-8 month follow-up	9 urge incontinence, 9 stress incontinence; 6 both	Cured, free from symptoms or marked improvement, no Improvement	Urge incontinence 1/9 cured, 8/9 Improved Stress Incontinence 3/9 cured, 4/9 improved, 2/9 not Improved Both types 1/6 cured, 5/6 Improved	

“Not defined

SOURCE J Ouslander and R Kane, University of California at Los Angeles 1984

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ported with these devices, the long-term effects of chronic electrical stimulation are unknown. Several reports indicated that patients simply refused to use the device for a long period of time.

Several features of the case series reviewed in table 3-2 should be emphasized. Many of these series were done before information on optimal frequencies and durations of stimulation for the different types of incontinence were known. Thus, the success rate using optimal parameters of stimulation is unknown. Unlike the situation for artificial sphincters, which requires a sham operation to design a true controlled trial, a controlled trial of intravaginal electrical stimulation to test possible placebo effects is much more feasible. Despite the possibility, no controlled studies have been reported. Comparing the effects of the functioning intravaginal electrical stimulator with the effects achieved by simply placing the device without the electrical stimulation would be of great interest in light of reports in which patients had prolonged cures after single treatments or claimed success when batteries were malfunctioning.

CATHETERS

There are three basic types of catheter techniques used to manage incontinence: chronic indwelling catheterization, intermittent bladder catheterization, and external catheters (for men). Chronic in-dwelling catheterization involves the placement of a catheter in the bladder, held in place by an inflated balloon. The catheter is attached to plastic tubing, draining urine into a drainage bag, which is emptied at regular intervals. The drainage bag can be strapped to the leg and hidden beneath clothing to avoid embarrassment. Despite improved techniques of chronic indwelling catheterization, this type of treatment is associated with several potentially severe complications and is probably overused in the management of incontinence (especially for elderly patients in long-term care institutions) (98,110, 120,166).

Continuous in-dwelling catheterization is appropriate for managing established incontinence in only a limited number of patients. They include individuals with urinary retention (caused by either anatomic or functional obstruction or poor bladder emptying) that cannot be relieved surgically, pharmacologically, or by intermittent catheterization, and patients with skin conditions that are worsened by contact with urine. Surveys of long-term care institutions in this country and Canada indicate that 10 to 30 percent of incontinent individuals are managed by continuous indwelling catheterization (85,98,111,120). This number probably far exceeds the number of patients with the above-mentioned conditions, but catheters are probably used for staff convenience and because of cost considerations (if one ignores the costs of treating complications that result from catheterization). The cost implications are discussed later in this study.

The primary risk of chronic in-dwelling catheterization is urinary tract infection. Virtually all patients with in-dwelling catheters for periods over 2 weeks will have urinary tract infections; however, not all these patients will become symptomatic and require treatment (166). Urinary catheterization has been shown to be the major cause of nosocomial infections in acute care hospitals (77,144) and are associated with increased mortality in this setting (116).

Studies over the last two decades have shown that maintaining a closed drainage system and adeptly handling the catheter and draining its bag are critically important in preventing infection (68,177). Other techniques, such as one-way valves in the catheter tubing to prevent backflow of urine and separate ports added to the catheter for urine sampling, have also decreased the risk of infection. Prophylactic antibiotic therapy, either directly instilled into the bladder or taken orally, does not prevent urinary infections and, in fact, appears to predispose to infection with more resistant bacteria (70,91,106,165). Frequent cleaning of the area of catheter entry with antimicrobial substances increases rather than decreases the incidence of infection (26). Thus it

appears that techniques involving frequent manipulation of the catheter or breaking of the draining system increase the risk of infection and should be avoided. A few recent reports indicate that antimicrobial substances, such as peroxide and iodine solutions, instilled regularly into the drainage bag, diminish the incidence of infection (39, 96,143). The ability of these techniques to prevent symptomatic infections to patients continuously catheterized for years is still unproven.

An alternative approach to continuous in-dwelling catheterization is intermittent self-catheterization. This technique has been applied mainly in younger individuals with paraplegia or other necrologic disorders (e. g., spina bifida) whose bladders do not contractor empty properly (92). It is also applicable for patients with other causes of chronic urinary retention such as a diabetic neuropathic bladder. These patients are taught to catheterize themselves at regular intervals. The procedure involves no special equipment except a catheter, which is kept in an antiseptic solution between catheterizations. This technique has been shown to reduce the incidence of infection and other complications compared with continuous in-dwelling catheterization in younger patients (92). Intermittent catheterization is less often used in the elderly incontinent patient; however, it would be applicable in those whose incontinence is associated with urinary retention not correctable by other means. Either the patient or the caregiver must be trained in the technique. Because complications with this technique might be more frequent in this patient population than in others, studies comparing the efficacy of chronic in-dwelling versus intermittent catheterization in the elderly population would be of value.

External catheters (condom catheters) are used exclusively in men. Although this technique is thought to diminish the risk of urinary tract infection, no studies have confirmed this impression. External catheters require changing every 24 to 48 hours, and they frequently fall off, requiring reapplication. Certain types of catheters and application techniques reduce the frequency with which the catheter falls off. A substantial proportion of patients develop skin irritation on the penis (balanitis), which precludes the use of these catheters; the patient then requires an in-dwelling catheter until the skin lesions heal. External catheters, like intermittent catheterization, require either the patient or, more commonly, a caregiver to be available and trained in the proper management techniques.

BEDPADS AND UNDERGARMENTS

Most acute care hospitals and long-term care institutions use “blue pads” for managing incontinence, despite their relatively poor absorbency and lack of odor control. A variety of other products are available for keeping patients’ bedding, clothing, and furniture dry in these settings. Specially designed incontinence undergarments and bedpads have been used for several years in Great Britain, other European countries, and Australia, but only over the last 2 to 3 years have several of these products been marketed intensely in the United States.

Ideally, an incontinence bedpad or undergarment should be highly absorbent, nonallergenic, and relatively easy for patients or caregivers to change. It should control odor, not wrinkle (which predisposes to skin irritation and impairs healing of pressure sores), and require fewer changings than simply using drawsheets or other types of padding (152,171). The most innovative bedpad is the Kylie pad, which was developed in Australia. This pad is launderable, has a porous top layer that allows urine to pass freely into a more absorbent middle layer, and a moisture-resistant backing that keeps the bed dry. Unlike other types of bedpads, the Kylie pad’s special design helps keep both the patient and the bed or furniture dry (24,175).

Incontinence undergarments come in many shapes and forms. Some are completely disposable; others are launderable briefs into which a disposable pad is inserted. An increasing number of these products is being marketed in this country. Most are designed along the lines of the Kylie

bedpad, with a permeable layer close to the patient, a highly absorbent middle layer or pad (which generally contains a polymer with tremendous absorptive capacity), and an outer layer, which prevents soiling of clothing.

Several small-scale studies have examined the impact of these products on patient comfort and health (table 3-3). Most of the studies are uncontrolled and do not account for patient cross-overs between treated and untreated groups.

As might be expected, most patients responded favorably. A few studies suggested that costs decreased because the reduced amounts of clothing and bedding required decreased the laundry and labor needs, thus lowering costs. These types of products can clearly make life more comfortable for incontinent persons and diminish the burden on their caregivers by keeping the affected individuals dry and more mobile and by enhancing their ability to interact socially. However, carefully designed, controlled studies with objective outcomes that compare these products with other strategies to manage incontinence would be of great value, especially in the incontinent population now in long-term care institutions, No studies have carefully assessed the effectiveness of these products in diminishing such complications of incontinence as skin irritation and urinary tract infection. Studies that examine the effectiveness of these products in diminishing the burden on caregivers of community-dwelling elderly and in delaying or preventing institutionalization would also be of great interest.

SURGERY

Surgical treatment is essential in the management of certain types of incontinence and effective, but not essential, for other types. For those patients with overflow incontinence caused by an anatomic obstruction to urine flow (e. g., an enlarged prostate in men or a urethral stricture), surgery is necessary to relieve the obstruction. Although this type of surgery may not always cure the incontinence (in fact, in some instances, the incontinence may persist or even worsen), urinary obstruction cannot be left untreated. Continuous retention of urine will predispose the patient to recurrent urinary tract infections and could eventually lead to renal failure and death. In some patients, pathologic conditions in the lower genitourinary tract, which irritate the bladder or urethra and cause incontinence, can be corrected surgically. Examples of such conditions include bladder tumors, bladder stones, and diverticuli of the bladder or urethra, as well as several other, less common conditions.

The most common surgical procedure for incontinence is bladder-neck suspension. In this operation in women with stress incontinence, the bladder neck and urethra are repositioned. Several modifications of the original bladder-neck suspension procedure have been developed, and the procedure can now be done in less than an hour, under local or spinal anesthesia (124). Hospital stays can be as short as 3 days. Because women with symptoms of stress incontinence can also have other abnormalities of genitourinary tract function (e.g., bladder instability and urinary retention), careful preoperative evaluation and appropriate patient selection are critical to success. Most published series have shown a 70 to 90 percent success rate (99,123,124,146). No prospective, randomized, controlled study has been done to compare bladder-neck suspension to other treatments for stress incontinence—e.g., electrical stimulation or drug treatment—in similar groups of patients.

DRUG TREATMENT

Drugs can be used to treat overflow, stress, and urge incontinence (14,109,122). For those patients with overflow incontinence caused by poor bladder contraction (rather than anatomical obstruction to urine flow), cholinergic drugs that promote bladder contraction can be used. The most com-

Table 3-3.— Bedpads and Undergarments

Device	Reference	Study design	Diagnosis	Criteria for Improvement	Results	Comments
Launderable bed pad (Kylie)	Broughten (1979)	Nonrandomlzed crossover study of drawsheet and disposable pads vs Kylie pad (N = 18), age = 65+	85% incontinent of urine, 50% incontinent of urine and stool	Nurses' reactions, patient's reactions, skin condition and costs	Kylie pads decreased odor, made patients more comfortable, Improved skin conditions, reduced laundry by 45%	Estimated cost savings per patient per night = $2420
Launderable bed pad (Kylie)	Smith (1979)	Uncontrolled (N = 8) age = 65+	All Incontinent of urine at night and prone to pressure sores	Nurses' assessments of Kylie pad's ability to absorb large volume of urine, retain moisture under pressure, keep patient's skin dry, keep bed dry reduce risk of bed sores, avoid wrinkling; give patient comfort, reduce odor, be economical	Kylie pads allowed patients to sleep better, saved time, saved linen, decreased cost by $1.25 per patient per night	Study performed m two acute-care hospitals
Launderable bed pad (Kylie)	Williams, et al (1981)	Comparison of disposable bed pads and Kylie with crossover design (N = 36: 11 m, 25 fe) Ages = male 52-87, mean = 73; female 34-101, mean = 77	Most had neurologlc disorder causing incontlnence	Skin dryness, lack of creasing, less need to change bed hnen; less odor, cost savings	Kylie pads reduced skin wetness, creased less often, decreased bed changes, Improved odor; reduced cost 39% ($1 25 per patient per day)	
Launderable undergarments with disposable pads (Kanga, Molnlyche, and Sandra pants)	Shepherd and Blannin (1980)	Each subject wore each garment for a month (N = 20; 2 m, 18 fe) Ages 4-84	Necrologic disorders	Subject's opinion of garment	Kanga was most satisfactory; Molnlyche was difficult to handle, Sandra was associated with skin Irritation, sweating, and discomfort	Most subjects were living in homes and attended by a community nurse
Launderable bedsheet (Kylie pad)	Silberberg (1977)	Randomized comparison of absorbent pad, pad and antimicrobial agent, and drawsheet (N = 32)	Urinary and stool incontinence	Lack of skin moisture, skin inflammation, creasing or wrinkling of pad; odor	Groups with pads had less skin irritation (77% vs. 37%), dryer skin (750/976 vs. 387/1046): less wrinkling (14% vs. 41%), less odor (5% vs. 27%)	Subjects living in long-term care ward
Disposable undergarments (Attends)	Beber (1980)	Randomized comparison of Attends and disposable bedpads, no crossover (N = 276) Age = 65+	Persistent incontinence (3 or more uncontrolled urinations per day)	Nursing staff rate skin conditions and quality of life	40/53 staff judged patient's quality of life as Improved (based on social activities and expressed confidence with Attends)	All were nursing-home patients; reduced patient changes, gave some patients greater mobility and less embarrassment: Improved odor, appearance, and mood of ward
Launderable brief with disposable pad (Molnlyche pant)	Watson (1980)	Uncontrolled (N = 54; 15 m, 39 fe) Age 60-99	22 "heavy' incontinence; 17 "moderate", 8 "slight", 21 also had stool incontinence	Patient comfort, acceptance, and effect on skin	Reduced staff workload, laundry, odor; increased patient dignity, response to toilet training	Subjects in chronic hospital; estimated 90% cost savings for all wards, increase in visitors

SOURCE J Ouslander and R Kane, University of California at Los Angeles, 1984

monly used drug, bethanechol (Urecholine), stimulates bladder contraction and emptying, prevents recurrent urinary tract infections caused by urinary retention, and, in theory, helps resolve the overflow incontinence. In many patients, especially in the elderly age group, this type of treatment may worsen incontinence by creating urinary frequency and urgency. In addition, bethanechol has several adverse side effects, including gastrointestinal cramping, diarrhea, and increased bronchial secretions. Thus, intermittent catheterization may be a better alternative for many of these patients.

Drugs that promote contraction of the smooth muscle around the bladder outlet have been used to treat stress incontinence. These drugs include pseudoephedrine and phenylopropanolamine, both found in over-the-counter cold preparations. No carefully designed studies have been done to compare the effectiveness and risks of drug versus surgical therapy for stress incontinence. Drugs for stress incontinence must be used carefully, especially in elderly women in whom they can exacerbate hypertension and cardiovascular disease. Topical or oral estrogens are frequently chosen to treat stress incontinence in elderly women. Although estrogens strengthen the tissues around the bladder outlet, few studies have objectively documented that this physiologic effect results from estrogen therapy alone, and estrogens do carry the risk of exacerbating hypertension and thromboembolic disease, as well as an increased risk of endometrial cancer (86,169). They are probably useful in women with stress incontinence in whom there are no major contraindications to their use and should be used cyclically in the lowest doses possible. Some experts recommend that they be used in a topical vaginal cream in combination with a progestational agent taken orally to diminish the risk of complications, although topical intravaginal estrogens are absorbed to pharmacologic blood levels, and the relative safety of this mode of administration remains unclear (86).

The most common and effective drug treatment is that for urge incontinence (122,174). Various drugs have been tested for their ability to diminish bladder contractility and thereby improve symptoms associated with bladder instability (table 3-4). Most studies have shown these drugs to be effective in over 50 percent of the patients.

Several caveats are important. The majority of studies have been either uncontrolled or placebo controlled without adequate concern for patient cross-overs between treatments. The patients, their genitourinary abnormalities, their presenting symptoms, and the specific outcomes of treatments have generally been poorly defined. Interestingly, several of the studies mentioned that symptomatic improvement does not always correlate with objective changes in lower genitourinary function (as measured by urodynamic techniques). Most studies did not control for other simultaneous interventions that can also affect outcomes, such as instructions to delay the urge to void, to schedule toileting, and to restrict fluid intake. Finally, most of the drugs used to treat bladder instability have bothersome side effects, including dry mouth, constipation, and blurred vision (122,174).

Several newer classes of drugs, such as prostaglandin inhibitors and calcium antagonists, have also been studied in small numbers of patients. Carefully controlled studies of newer drugs, studies comparing drug treatment to other forms of treatment for detrusor instability, and the development of new pharmacologic agents for this condition would be of great value.

TRAINING PROCEDURES

Several techniques, broadly labeled here as "training procedures, " have been reported as successful in managing various types of incontinence (71,74). These techniques include pelvic floor exercises, biofeedback bladder retraining, habit training, and behavioral modification.

Repetitive contraction of muscles of the pelvis and vaginal wall (Kegel exercises) have been used for several decades in the management of stress incontinence in females (89). Although these exercises are often not curative and can only be used by patients with adequate cognitive function, in-

Table 3-4.—Drugs in Incontinence Treatment

Drug	Reference	Study design	Diagnosis	Criteria for Improvement	Results	Comments
Diminish bladder contractions:						
Propantheline 30 mg orally aid or more	Tulloch (1978)	Uncontrolled (N = 33), ages = 14-79, mean = 62	Unstable detrusor	Symptoms	2 symptomatic Improvements	14/20 needed long-term therapy to maintain Improvement
Propantheline 60 mg IV Imipramine 25-75 mg IM	Diokno, et al (1972)	Uncontrolled (N = 11)	Uninhibited bladder contractions	Urodynamic	Propantheline abolished uninhibited bladder contractions, Imipramine did not	
Propantheline 15 mg orally weeks Oxybutinin 5 mg orally 4-6 weeks	Thompson and Lauvetz (1976)	Double-blind: placebo controlled (N = 14)	Uninhibited neurogenic bladder	Urodynamic	Both delayed reflex contractions, Increased bladder volume at first contraction, and subjectively decreased urge incontinence	Oxybutinin was better than propantheline, had fewer side effects over 4-6 week period
Propantheline 30 mg po Flavoxate 200 mg PO	Kohler and Morales (1968)	Double-blind, no placebo (N =, 23 m, 2 fe)	21 bladder spasticity 4 flaccid bladder	Urodynamic	Both raised bladder capacity 2 hours after dose, 13/21 flavoxate, 8/21 propantheline	No change In Intra-ocular pressure
Propantheline 30 mg orally qid 7 days Flavoxate 200 mg orally qid 7 days	Badley and Cazort (1970)	Double-blind; no placebo (N = 46; 18 m, 28 fe)	Urinary symptoms	Symptoms	Both Improved symptoms	11 urinary Infection, 25 cystitis, no change m ocular pressure
Propantheline 15 mg orally qid 3 weeks Dicyclomine 10 mg orally 3 weeks	Beck, Aruusch, and King (1976)	Uncontrolled (N = 82)	Detrusor overactivity, stress Incontinence	Symptoms Urodynamic	76% of 64 propantheline, 67% of 18 dicyclomine Improved or cured	
Propantheline 15 mg orally qid 3 weeks Dicyclomine 10 mg orally qid 3 weeks	Beck, Aruusch, and King (1976)	Placebo; controlled (N = 51)	Detrusor overactivity; stress inactivity	Symptoms	75% of 15 propantheline, 62% of 13 dicyclomine; 15% of 15 placebo Improved	
Propantheline 15 mg orally Atropine 0,6 mg IM Ephedrine 15 mg orally Orphenodrine 50-100 mg orally Others	Brocklehurst and Dillane (1967)	Uncontrolled; All subjects elderly	Incontinence	Incontinence charts, urodynamics	Combination of propantheline and orphenadrine gave best clinical and urodynamic improvement	Total of 13 drug combinations Clinical Improvement did not correlate with urodynamic changes
Propantheline 15 mg orally combined with Imipramine 25 mg qid orally	Fliegner and Glenning (1979)	Uncontrolled (N = 258)	Urge and stress incontinence	Symptoms	90% with urge Incontinence Improved	Not all subjects received both drugs; some received other agents
Propantheline 15 mg adults IM, 7.5 mg children IM	Blaivas, et al. (1980)	Uncontrolled (N = 42, 9 m, 33 fe) ages = 5-79, mean = 62	Uninhibited detrusor contractions	Urodynamic	79% positive response to propantheline, 50% urinary retention	No patient who failed to respond to parenteral medication had favorable response to drug when administered orally
Emepronium bromide 50 mg orally qid 2-4 weeks	Brocklehurst, Armetage, and Jouhar (1972)	Placebo controlled, crossover unblinded (N = 43) ages = 57-90; mean = 82	Incontinence	Nursing records	Small reduction In Incontinence with active drug	
Emepronium bromide 200 mg orally qid for one month	Nordling, et al. (1979)	Uncontrolled (N = 38) ages = 18-90, mean = 51	30 uninhibited contractions	Symptoms	66% Improved	
Emepronium bromide 50 mg IM dose 200 mg orally qid 7-10 days	Ritch, et al (1977)	Uncontrolled (N = 9, 6 m, 3 fe) ages = 71-94, mean = 82	Established Incontinence, uninhibited contractions	Urodynamic	Only IM decreased contractions and a raised bladder capacity and had little effect on urodynamics	

Table 3.4.—Drugs in Incontinence Treatment—Continued

Drug	Reference	Study design	Diagnosis	Criteria for Improvement	Results	Comments
Emepronwm bromide 200 mg qid orally Flavoxate hydrochloride 200 mg orally qid	Stanton (1973)	Double-blind randomized crossover, no placebo (N = 38; 6 m, 32 fe) mean age = 47	Urinary symptoms and Incontinence	Symptoms Urodynamlc	Flavoxate better for relief of symptoms, no change m urethral pressure profiles	38% showed no clinical effect from either drug
Emepronium bromide 200 mg orally qid 21 days	Williams, Prematalake, and Palmer (1981)	Double-blind placebo controlled (N = 30, 8 m, 22 fe) mean age = 74	Organic brain disease; functional psychiatric disorder; incontinence	Symptoms	No significant difference between placebo and emepronium	
Emepronium bromide 200 mg tId Propantheline 3 x 30 mg for 12 weeks	Gaudenz and Weil (1980)	Placebo controlled (N = 70)	Motor urge incontinence	Symptoms Urodynamic	Emepronium bromide, 34% excellent; flavoxate, 50% excellent; propantheline, 15% excellent; placebo, O%	Uninhibited detrusor contractions persisted
Emepronium bromide 200 mg tid OR placebo in two 4-week periods	Walter, et al. (1982)	Double-blind crossover (N = 20; 8 m, 12 fe) ages = 64-88; mean = 74	Urinary incontinence and frequency	Symptoms Urodynamic	No statistically significant difference between effects of emepronium bromide and placebo; overall subjective cure rate = 79%	
Emepronium bromide 200 mg qid OR Flavoxate chloride 200 mg qid OR Placebo	Meyhoff, Gerstenberg, and Nordling (1983)	Double-blind crossover (N = 20) ages = 22-79, median = 51	Motor urge incontinence without bladder suspension defect	Subjective	79% claimed good effects from one or more drugs; 47% preferred placebo Only placebo had statistically significant decrease m frequency of voidings, incontinence, and nocturia No differences demonstrated between emepronium bromide and flavoxate chloride	
Flavoxate 100 mg IV 200 mg orally qid 7 days	Briggs, Castleden, and Asher (1980)	Uncontrolled (N = 6; 2 m, 4 fe) ages = 72-84	Uninhibited contractions	Symptoms Urodynamic	No consistent effect on symptoms or urodynamic parameters	
Flavoxate 200 mg IV Emepronium bromide 50 mg IM Imipramine 50 mg IM	Cardozo and Stanton (1979)	Uncontrolled (N = 15)	Detrusor instability	Urodynamic	Emepronium significantly Improved urodynamic parameters; flavoxate and imipramine had no significant effect	
Flavoxate 50 mg orally qid 14 days Methanteline 50 mg orally qid 14 days Meiadrazine 150 mg orally aid 14 days	Hebjorn (1977)	Double-blind crossover, no placebo (N = 34; 8 m, 26 fe) ages = 23-65; mean = 47	Multiple sclerosis; incontinence; detrusor hyperreflexia	Symptoms as recorded m a patient diary Urodynamic	27/32 had improved symptoms, 18/27 preferred methanteline	9 chronic urinary infection, patient satisfaction did not correlate well with urodynamic changes
Flavoxate 200 mg qid	Younglove, Newman, and Wall (1980)	Uncontrolled (N = 25)	Unstable bladder	Symptoms	21 cured	
Methanteline 50 mg orally qid 6 months	Walter (1978)	Uncontrolled (N = 54) ages = 29-82, mean = 54	Uninhibited contractions	Symptoms Urodynamic	27/53 Improved or free of symptoms	Only half those Improved had increased bladder by cytometry, no other urodynamic changes
Dicyclomine 20 mg IM 20 mg orally tid 8 weeks	Awad, et al. (1977)	Uncontrolled (N = 27; 14 m, 13 fe) ages = 10-90	Uninhibited neurogenic bladder	Symptoms Urodynamic	Most had increased bladder capacity with oral or IM; 26 increased bladder capacity an average of 21 see, 24 had symotomatic improvement	No significant side effects; improvement started at 7-10 days and continued after 4 weeks, females had more symptomatic Improvement
Dicyclomine 20 mg orally	Fischer, et al (1978)	Uncontrolled (N = 14; 6 m, 8 fe)	Uninhibited neurogenic bladder	Urodynamic	17% excellent; 7% good, 22% fair	No complications

Table 3-4.—Drugs in Incontinence Treatment—Continued

Drug	Reference	Study design	Diagnosis	Criterla for Improvement	Results	Comments
Imipramine 50-100 mg orally in divided doses 1-2 weeks	Cole and Fried (1971)	Uncontrolled (N = 9)	Spinal cord injury or disease and neurogenic bladder	Symptoms Urodynamic	6 improved continence	3 with urodynamic follow UP had Increased bladder capacity
Imipramine 50-150 mg for up to 2 weeks	Castelden, et al (1981)	Uncontrolled (N = 10, 2 m, 3 fe) ages = 63-88, mean = 88	Detrusor instability	Symptoms Urodynamic	6 became continent urodynamics Improved	2 had symptomatic postural hypotension no correlation with plasma drug levels
Oxybutinin	Moisey, Stephenson, and Brenoler (1980)	Double-blind placebo controlled crossover (N = 26; 10 m, 13 fe) ages = 20-79	Detrusor instability	Symptoms Urodynamic	69% had symptomatic Improvement, 40% had urodynamic Improvement	8% placebo response, Symptomatic improvement not correlated with urodynamic changes, dry mouth common side effect
Oxybutinin	Younglove, Newman, and Wall (1980)	Uncontrolled (N = 3)	Unstable bladder	Symptoms	100% improved	
Oxybutinin (a) 5 mg oral dose (b) 5 mg orally bid or tid 7-14 weeks	Diokno and Lapides (1972)	Uncontrolled (N = 8)	Uninhibited bladder contractions	Symptoms Urodynamic	7 had decreased frequency or amplitude of uninhibited contractions Improved symptoms	3 given 15 mg propantheline orally in separate trial this also decreased contractions
Strengthen bladder outlet: Norephedrine 100 mg orally bid	Ek, et al (1978)	Double-blind placebo controlled crossover (N = 25) mean age = 54	Stress incontinence	Symptoms Urodynamic	12/22 Improved, 2 became continent, urethral pressure Increased in erect and supine positions	Urodynamic changes correlated with symptomatic Improvement
Norephedrine 100 mg orally bid 3 weeks	Obrink and Bunne (1978)	Uncontrolled (N = 10) ages = 33-67, mean = 52	Stress incontinence	Symptoms Urodynamic	1 Improved, no change in bladder or urethral pressure	7 got headaches, all subjects on estrogens
Norephedrine 75-100 mg orally 1 dose	Ek, Andersson and Ulmsten (1978)	Uncontrolled (N = 6) ages = 39-66, mean = 55	Stress incontinence	Urodynamic	Urethral pressure increased in all subjects	2 got headaches, mean blood pressure Increased from 130/83 to 178/96
Ephedrine 25 mg orally bid 1-18 mos	Rashbaum and Mandlebaum (1948)	Uncontrolled (N = 82) ages = 41-70	Incontinence	Symptoms	41% of 68 improved, 40% of 68 cured	52 had previous pelvic surgery
Ephedrine 44-200 mg orally in divided doses for 1-17 mos	Diokno and Taub (1975)	Uncontrolled (N = 38, 20 m, 18 fe) ages = 7-77	Incontinence	Symptoms	27 good to excellent response	
Ephedrine 15-30 orally 3 x daily 2-6 weeks	Castleden, et al (1982)	Uncontrolled (N = 24, 8 m, 16 fe) ages = 68-90, mean = 79.5	Unstable detrusor contractions	Symptoms Urodynamic	32% Continent, 55% improved, 13% same	Urodynamic Improvement did not reach statistical significance, tralnlng techniques also used
Phenypropanalamine 50 mg orally (1 spansule Ornade)	Montague and Stewart (1979)	Uncontrolled (N = 12)	Stress incontinence	Urodynamic	11 had at least 20% Increase in urethral pressure	
Chlorpheniramine maleaxe and phenylpronolamine (twice daily	Younglove, Newman, and Wall (1980)	Uncontrolled (N = 14)	Unstable bladder	Symptoms	~~ cured	
Phenylpropanalamine 50 mg orally bid (1 spansule Ornade) for 3 mos to 3 yrs	Stewart, Banowsky, and Montague (1976)	Uncontrolled (N = 88, 11 m. 77 fe)	Females–stress Incontinence (documented in 32), males–prostatectomy incontinence	symptoms	59% females and 27% males had significant Improvement	
Phenylpropanalamine 50 mg orally bid for up to 4 weeks	Awad, et al (1978)	Uncontrolled (N = 20, 7 m, 13 fe)	Females–stress incontinence, males—post-prostatectomy Incontinence	Symptoms Urodynamic	11 females improved or became continent, 6 men Improved, all with urodynamic follow up had Increased urethral pressure	

Table 3-4.— Drugs in Incontinence Treatment—Continued

Drug	Reference	Study design	Diagnosis	Criteria for Improvement	Results	Comments
Estrogen therapy:						
Estradiol 2 mg + estradiol 1 mg daily	Walter, et al. (1978)	Double-blind controlled, no crossover (N = 29) ages = 56-69, mean = 56	All postmenopausal stress Incontinence but no detrusor hyperreflexia	Symptoms Urodynamic	8 cured (of these 1 had placebo), no significant urodynamic changes	No one experienced side effects: significant difference betwen placebo and estrogen, demonstrated influence of estrogen on urethral and vaginal mucosa
Estriol 2 mg day for 2-4 months	Faber and Heidenreich (1977)	Controlled (N = 41)	All postmenopausal with stress incontinence grades II and III (clinical categories after Ingelman-Sundberq)	Urodynamic Symptoms	95% had significant urodynamic Improvement, 34% subjective Improvement	No patient maintained complete continence
Estradiol Benzoate 4,000-10,000 RU 2-3-wk Estradiol Depropionate 1-2 mg 3/wk IM	Salmon, Walter, and Geist (1941)	Uncontrolled (N = 16) ages = 57-72	10 stress incontmence, 6 urinary frequency	Symptoms	12 had relief over 4-month follow-up	Symptoms returned 6 weeks to 9 months after treatment, recurrent symptoms responded to estrogen therapy
Estradiol 2 mg/day for 3 wks then 1 mg/day	Ek, et al (1980)	Uncontrolled (N = 16) ages = 38-71; mean = 61	All postmenopausal stress incontinence	Urodynamic Symptoms	No statistical urodynamic change, 1 /13 improved, 10/13 no change, 2/1 3 got worse	
Estradiol 2 mg/day for 3 wks OR Estriol 8 mg/day for 3 wks	Rud (1980)	Uncontrolled (N = 30) ages = 37-78; mean = 61	24 stress incontinence 27 postmenopausal	Subjective Urodynamic	17/24 Improved, no significant change m urodynamic parameters	
Estriol rejection 80 mg every 4 wks with phenylpropanolamine 50 mg twice daily	Belsland, Fossberg, and Sander (1981)	Uncontrolled (N = 14) ages = 54-94; mean = 77	Urinary incontinence from recomplete urethral closure mechanism	Symptoms Good = continent Improved = continent occasionally Unchanged	8 good. 4 improved	No serious side effects
Other drugs:						
Baclofen 5 mg orally per day for 28 days	Taylor and Bates (1979)	Double-blind, placebo-controlled crossover (N = 40, 13 m, 27 fe)	Unstable bladder	Symptoms	Improved symptoms	Some Improvement also noted with placebo
Nifedipine 10-20 mg orally bid for 1 week	Rud. Andersson, and Ulmsten (1979)	Uncontrolled (N = 10) ages = 9-63, mean = 33	Urge incontinence	Symptoms Urodynamic	All had symptomatic improvement; uninhibited contractions abohshed	
Methyldopa 250-2,000 mg day m divided doses for up to six months	Raz, et al (1977)	Uncontrolled (N = 50)	Neurogenic bladder with residual urine: 38 upper motor neuron (mostly multiple scleroses), 12 lower motor neuron	Symptoms Urodynamic	19/38 Improved, 5/12 Improved, urodynamics unchanged after one week	
Bromocriptine up to 25 mg orally bid Indomethacin up to 100 mg orally bid	Cardozo and Stanton (1980)	Single-blind crossover (N = 40) mean age = 53	Detrusor instability	Symptoms	More symptomatic Improvement with inmdomethacm	Prominent side effects with both drugs
Bromocriptine 5 mg/day	Farrar and Osborne (1976)	Uncontrolled (N = 24, 7 m, 17 fe) ages = 17-22	Detrusor instability	Symptoms	14 benefited	Of 10 studied, 5 had marked side effects
Bromocriptine 5 mg/day	Farrar and Osborne (1976)	Double-blind (N = 10)	Detrusor instability	Symptoms	Too small for statistical analysts but those on placebos subsequently improved on Bromocriptine	

Table 3-4.—Drugs in Incontinence Treatment—Continued

Drug	Reference	Study design	Diagnosis	Criteria for Improvement	Results	Comments
Bromocriptine 75 mg/day OR placebo in a six-week period	Abrams and Dunn (1979)	Double-blind (N = 51, 6 m, 45 fe) ages = 20-68)	Bladder instability	Symptoms Urodynamic	No significant Improvement in either symptoms or urodynamic findings seen in bromocriptine compared to control group	
Flurbiprofen 50 mg orally bld for 2 wks	'Cardozo, et al (1980)	Double-blind placebo, controlled crossover (N = 30) ages = 21-74, mean = 49	Detrusor instability, 27 idiopathic, 3 multiple sclerosis	Symptoms Urodynamic	Significant symptomatic Improvement, increased bladder volume at first contraction, 6 cured symptomatically and urodynamically	43% side effects (mostly minor)
Flunarazine 20 mg	Palmer, et al (1981)	Double-blind placebo controlled crossover (N = 14) ages = 35-81	Detrusor Instability	Symptoms Urodynamics	11 symptomatic cure with active drug, no significant urodynamic change	No correlation between symptomatic and urodynamic change

KEY IM = By Intramuscular injection
qid = Four times a day
PO = by mouth orally
tid = three times a day
OR = operating room

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tact pelvic-floor musculature, and motivation to perform them, they can be useful adjuncts to other forms of therapy, such as surgery, drugs, or electrical stimulation.

Biofeedback has been used in the treatment of both urge and stress urinary incontinence, as well as in fecal incontinence (49,168,172). This procedure involves placing pressure transducers in the bladder or rectum and having the patients try to either inhibit bladder contraction or contract pelvic-floor musculature, depending on the nature of the condition being treated. The pressure transducers can supply both visual and auditory feedback on these physiologic processes. The treatments are performed repeatedly over several weeks and require specialized equipment and personnel and well-motivated patients with adequate cognitive function.

Bladder *retraining* refers to techniques that help restore normal voiding pattern and continence. These techniques are generally useful after bladder function has been acutely altered. For patients who have had over-distention injuries from acute urinary retention, techniques to stimulate voiding (e.g., running tap water and stroking the lower abdomen and inner thigh) and to help complete bladder emptying (e.g., bending forward and pressing on the lower abdomen) are used, often in combination with intermittent catheterization, until the patient can void properly on his or her own. For those patients who have urge incontinence from a shrunken, inflamed bladder (such as might occur after removal of an indwelling catheter), bladder retraining involves having the patient attempt to delay voiding as long as possible and gradually extend the intervals between voiding. This technique (sometimes referred to in the literature as "bladder drill") has also been used to treat urge incontinence. For bladder retraining to be successful, the patient must have adequate cognitive and physical function, and both the patient and staff must be sufficiently motivated.

Habit training is most useful for patients with functional incontinence, although the techniques may also be useful for those with urge and stress incontinence. In contrast to bladder retraining, the primary objective of habit training is to avoid incontinent episodes, rather than to restore a completely normal pattern of voiding. The procedure involves a toileting schedule modified by the patient's responses and may include techniques for stimulating or inhibiting voiding and complete bladder emptying (similar to bladder retraining). Unlike bladder retraining, habit training can be successful in patients with impaired mental and physical function and is more dependent on the motivation of the staff performing the procedure. It is referred to in the literature as "bladder training, " "habit retraining, " and "scheduled toileting. "

Behavioral modification involves procedures similar to habit training with the addition of positive and negative reinforcers. This technique has been used mainly in children with persistent bedwetting and in chronically mentally impaired patients (37,119).

Carefully controlled studies of training procedures are exceedingly difficult to perform. Several clinical series using training procedures have been reported; however, many have not carefully defined the training procedure, and few have been adequately controlled. Most have involved some type of bladder retraining or habit training for urge incontinence, with 50 to 80 percent of subjects cured or substantially improved (35,48,56, 63,74 ,82,83,84,95,115,150). Studies that would carefully define training interventions and compare them to other treatments in patients with similar types and degrees of incontinence could lead to better patient selection and more effective treatment.