

Guidelines

Guidelines for management of urinary incontinence

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In Japan, only the following two guidelines are available: 'Guidelines on Urinary Incontinence in the Elderly' based on research funded by the Longevity Sciences Research Grant (chief investigator: Kikuo Okamura) and 'Guidelines on Urinary Incontinence in Women' based on 'Research on Treatment Standardization in the Urological Field' funded by the Health Sciences Research Grant (group leader: Osamu Nishizawa). This paper is an English translation of these two guidelines originally published in Japanese.

Key words: urinary incontinence, guideline, algorithm.

Introduction

Guidelines on Urinary Incontinence in the Elderly

The frequency of urinary incontinence in the elderly is extremely high. It is found in about 10% of the elderly at home and in 50% or more of the elderly admitted to hospitals and nursing homes. In Japan, it has been reported that more than 50% of people over 60 years of age have urinary incontinence;¹ the actual population reportedly reached 3 to 4 million. Oshima *et al.* investigated the frequency of elderly people wearing diapers because of urinary incontinence in nursing homes for the aged, special nursing homes for the aged and health service facilities for the aged in Aichi prefecture and reported that the frequencies were 8.5%, 54.5% and 58.6%, respectively.²

Urinary incontinence is generally not related directly to survival, but in patients with threats to their quality of life (QOL), mental distress and reduced activities of daily living occur. Conversely, if treatment for urinary incontinence alleviates or cures it, the distress can be eliminated and the range of activities expanded, and a return to an active life is possible.

Many elderly people do not have anyone to consult about urinary incontinence because they are ashamed and even if they do consult someone, they are often told that it is just due to aging. General internists and urologists unfortunately do not have a very high interest in aged urinary incontinence. From a social standpoint, the expenses incurred by urinary incontinence in Japan with its rapidly aging population are becoming huge.³ However, examinations of patients in nursing homes by urologists are limited due to the introduction of the nursing care insurance system and the increasing burden of direct healthcare payments by the elderly. Under such conditions, a system that permits more efficient diagnosis and treatment of urinary incontinence in both medical and economic terms is necessary. A system must be established that assures: (i) diagnosis of the type of urinary incontinence at the individual, caregiver, nurse or general physician levels and provision of treatment or care depending on the type; and (ii) examination by a specialist when the urinary incontinence does not improve.

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Various clinical trials have been conducted on the treatment of urinary incontinence and effective treatment methods have been verified. Based on the results, Guidelines on Urinary Incontinence in Adults were prepared by the Agency for Health Care Policy and Research in 1992 in the United States and the guidelines were revised in 1996. However, in Japan, almost no progress has been made at present on publicity activities by urologists aimed at the general public, caregivers and general internists. In this document, the proper methods of diagnosis, evaluation, treatment and care for urinary incontinence in the elderly based on scientific evidence are presented.

The papers in reference were classified into five levels as follows. Level I: papers with clear results from a large-scale RCT; Level II: papers with clear results from a small-scale RCT; Level III: papers on trials with a non-randomized concurrent control group; Level IV: papers on trials with a non-randomized retrospective control group and with opinions of specialists added; and Level V: case-driven research (no control group) with opinions of specialists added. In these guidelines, only Level I and Level II papers are covered. The 'strength of evidence' was classified as Rank A for therapy that was statistically effective in multiple (at least two) papers of Levels I and II; Rank B for therapy that was statistically effective in only one paper of Levels I and II; and Rank C for therapy verified to be effective only in research at Levels III to V.

Evaluation

Many elderly people with urinary incontinence have already recognized that it cannot be helped and they rarely consult with their physicians about urinary incontinence even when they are examined at medical institutions for other diseases. It is important for treatment providers to regularly ask if patients have urinary incontinence or not.

Mainly urology and gynecology departments handle urinary incontinence, but with the sharp increase in the elderly population at present, it is recommended that general internists and nurses become actively involved in evaluation and treatment of urinary incontinence.

The basic objectives of the evaluation are: (i) confirmation of whether or not urinary incontinence is present; (ii) understanding of the disease state of urinary incontinence; (iii) determination of whether or not improvement can easily be achieved by elimination of factors related to urinary incontinence (Table 1); (iv) determination of patients that require evaluation before the start of treatment; and (v) determination of the diagnosis if possible.

Table 1 Causes and treatment of urinary incontinence

	Factors	Treatment
Bladder, prostate, urethra	Urinary tract infections (associated with pollakiuria, micturition pain and urinary urgency) Atrophic vaginitis, urethritis After prostate surgery Constipation, stool impaction	Antibiotic treatment Oral or transvaginal estrogen Lower urinary tract rehabilitation (pelvic floor exercise) Manual removal of feces, laxatives, exercise, dietary fiber, suspension of water intake, weight reduction
Adverse reactions of drugs or other articles of taste	Diuretics (cause of excessive urine output, pollakiuria and urinary urgency) Caffeine Anticholinergic agents (cause of urinary retention, overflow urinary incontinence and constipation) Psychotropic drugs Antidepressants Antipsychotics Sedatives Narcotic analgesics (cause of urinary retention, constipation, sedation and delirium) α -sympatholytic agents (cause of reduced tonus of the urethra) α -sympathomimetic agents (cause of urinary retention, overflow urinary incontinence: included in many cold remedies) β -sympathomimetic agents (cause of urinary retention and overflow urinary incontinence) Antiarrhythmic agents (Rythmodan, etc.: cause of urinary retention and overflow urinary incontinence) Calcium channel blockers (cause of urinary retention and overflow urinary incontinence) Alcohol (cause of excessive urine output, pollakiuria, urinary urgency, constipation, sedation and delirium)	
Excessive urine output	Excessive drink due to diabetes mellitus	Treatment of diabetes mellitus Restriction on drinking water (standard daily urinary volume of 1600–1800 mL)
Edema	Impaired venous drainage Heart failure	Compression stockings, Na restriction, diuretics Treatment of heart failure
Reduced volition and activity	Delirium Chronic disease, fracture, etc. Mental disease	Treatment of underlying disease

Basic evaluation

The basic items for evaluation of urinary incontinence are: (i) disease history; (ii) examination; (iii) residual urine; and (iv) urinalysis.

Disease history

The following points are included.

- Period from onset of urinary incontinence
- How does urinary incontinence occur? (urinary urgency, coughing, exercise, etc.)
- Which symptoms cause the most discomfort?
- Frequency, prevalent time range, urine volume and incontinence levels
- Opportunities for urinary incontinence to occur (surgery, trauma, radiation treatment of pelvis, change of drugs)
- Other urinary tract symptoms (nocturia, sensation of residual urine, intermittent stream, straining, hematuria, micturition pain, etc.)
- Water intake, tea and coffee intake
- Medication history (for example, administration status of diuretics)
- History of treatment of urinary incontinence and its effects
- Number (quantity) of pads and diapers used
- Expectation of disappearance or alleviation of urinary incontinence
- Urination/urinary incontinence diaries
- Cognitive function, physical function, environment of activities, social environment

In the urination/urinary incontinence diaries, the urination time, amount, incontinence period and incontinence level (large, medium,

small) within 24 hours are entered by the patient or caregivers for 2 to 3 days. These diaries are useful in diagnosis of the type of incontinence and provide important information for setting of drinking water restrictions and timing, and setting of periods of timed induction of urination from the drinking and urination patterns.

Examinations

- General examination
The presence/absence of edema that causes nocturia and nocturnal urinary incontinence, the presence/absence of neurological disorders such as spinal disorders and cerebrovascular disorders caused by spinal compression fractures and spinal stenosis; and the presence/absence of cognitive function caused by cerebrovascular disorders, and activities of daily living (ADL) disorders are examined.
- Abdominal examination
The presence/absence of a bulging bladder, abnormalities in other organs and presence/absence of ascites are examined. In cases of decreased bladder compliance due to bladder outlet obstruction caused by prostatic hypertrophy or neurogenic bladder, etc. and in cases of urinary retention or overflow urinary incontinence, renal functional disorders can occur. The presence/absence of hydronephrosis is confirmed by ultrasound.
- Rectal examination
The pudendal sensation, tonus of the rectal sphincter muscle (when relaxed and when contracted), presence/absence of lumps of feces, and in males, the size and hardness of the prostate are examined.

There is not necessarily any correlation between the size of the prostate and voiding disturbances.

- Perineal examination
Whether or not skin abnormalities due to urinary incontinence are present is examined
- Examination of female genitalia
Atrophy of the perineum, ptosis of the pelvic organs (cystoceles, rectoceles, uterine prolapse), pelvic tumors and tonus of the muscles around the vaginal wall are examined.
- Stress test (direct confirmation of urinal leakage by coughing)
The stress test is performed when the bladder is full. It is necessary to induce a large cough. When a large cough cannot be achieved, applying pressure to the lower abdomen is also possible. When nothing is confirmed in the lithotomy position, it is repeated in the standing position. When the bladder is not full, the test can be performed by injection of physiological saline after measurement of the residual urine.

Measurement of residual urine

The residual urine after urination is measured using ultrasound from the lower abdomen or a catheter. Residual urine of less than 50 mL presents no problem. Mild voiding disturbances occur when the residual urine is 50 to 100 mL and moderate to severe voiding disturbances occur when more than 100 mL of residual urine is present. The amount of residual urine is affected by the amount voided before measurement of residual urine. Usually, it is necessary to urinate 150 mL or more immediately before measurement of residual urine. When residual urine is present, it is necessary to measure the residual urine several times.

Urinalysis

Hematuria (urinary tract infections, cancer, calculus), urinary sugar (urinary incontinence due to excessive urine output), pyuria and bacteriuria are tested. In both men and women, if the white blood cell count (WBC) is less than 1–4/high power field (hpf) in midstream urine, a urinary tract infection can be ruled out. However, if the WBC is 4–10/hpf or higher in urinary sedimentation in the midstream urine, there is a strong possibility of contamination with vulvar bacteria or vaginal excreta and there is no evidence of urinary tract infection. In such cases, urinary sedimentation and a bacterial culture test using urine collected with a catheter should be performed.

In aged patients with chronic diseases in hospitals or nursing homes, asymptomatic bacteriuria (both with and without pyuria) has no pathological significance and treatment is not required.⁴ In the elderly with urinary incontinence treated in the outpatient clinic, it is recommended to perform treatment with antibiotics or antibacterial agents and examine the effects of bacteriuria before evaluation and treatment.

Diagnosis algorithm

Most urinary incontinence is based on storage disturbances but it can also be based on voiding disturbances. In patients with bladder outlet obstruction related to prostatic hypertrophy or bladder neck sclerosis, a feeling of urinary urgency, nocturia and urge urinary incontinence often occur. The elderly often have uninhibited contraction of the bladder detrusor muscle and detrusor hyperactivity with impaired contractile function (DHIC). When such patients are administered anticholinergic drugs without caution, increased residual urine, urinary retention and

overflow urinary incontinence can occur. Treatment of urge urinary incontinence or overflow urinary incontinence when a bladder outlet obstruction occurs differs completely from treatment of ordinary urge or stress urinary incontinence and it is essential to determine initially if the incontinence is caused by voiding disturbances or not.

For reliable treatment, it is necessary to determine if the urinary incontinence is urge, stress, reflex, overflow or functional or if several factors are involved. The elderly patients usually have multiple factors.

When the incontinence is considered transient or reversible from the basic evaluation, treatment can be started immediately (Table 1). Detailed testing of the patients shown below is unnecessary and treatment can be initiated immediately.

- Patients with stress urinary incontinence with residual urine of less than 50 mL
- Patients with urge urinary incontinence with residual urine of less than 50 mL
- Patients with mixed stress and urge urinary incontinence with residual urine of less than 50 mL and considered appropriately indicated for behavioral therapy or drug therapy

Figure 1 shows the algorithm for diagnosis.

Detailed examinations

The purposes of detailed examinations are as follows.

- Identify the cause of the urinary incontinence
- Detect diseases with completely different treatments such as bladder outlet obstruction, reduced detrusor contractility, hypermobility or intrinsic sphincter deficiency
- Detect neurological or anatomical abnormalities that affect the lower urinary tract
- Obtain information required to select appropriate treatment
- Identify risk factors affecting therapeutic results (research objective)

If urinary incontinence cannot be improved or eliminated by removing the cause, a detailed examination by a specialist is required.

If one of the following criteria is met, an emergency detailed examination is required. However, elderly people often put off examinations based on their systemic condition or they do not want to be examined.

- In the basic evaluation, the diagnosis cannot be determined (symptoms and findings do not match) and treatment policies cannot be established
- Patients are not satisfied with treatment and are interested in other treatment
- Surgery is under consideration, especially when previous surgery failed or risk is high
- Hematuria is present with or without infections
- Cases with the following pathological conditions:
 - Urinary incontinence associated with recurrence of symptomatic urinary tract infections
 - Persistent feeling of residual urine and residual urine of 50 mL or more
 - History of treatment of urinary incontinence or radical surgery for cancer of pelvic organs
 - Prostate hypertrophy or prostate cancer suspected from asymmetry or elevated prostate specific antigen (PSA)
 - Suspected spinal nerve lesions

The detailed examination includes a urodynamic study, endoscopic examination, imaging examinations such as X-ray examination and ultrasound. Specialist knowledge is required to perform and interpret these examinations.

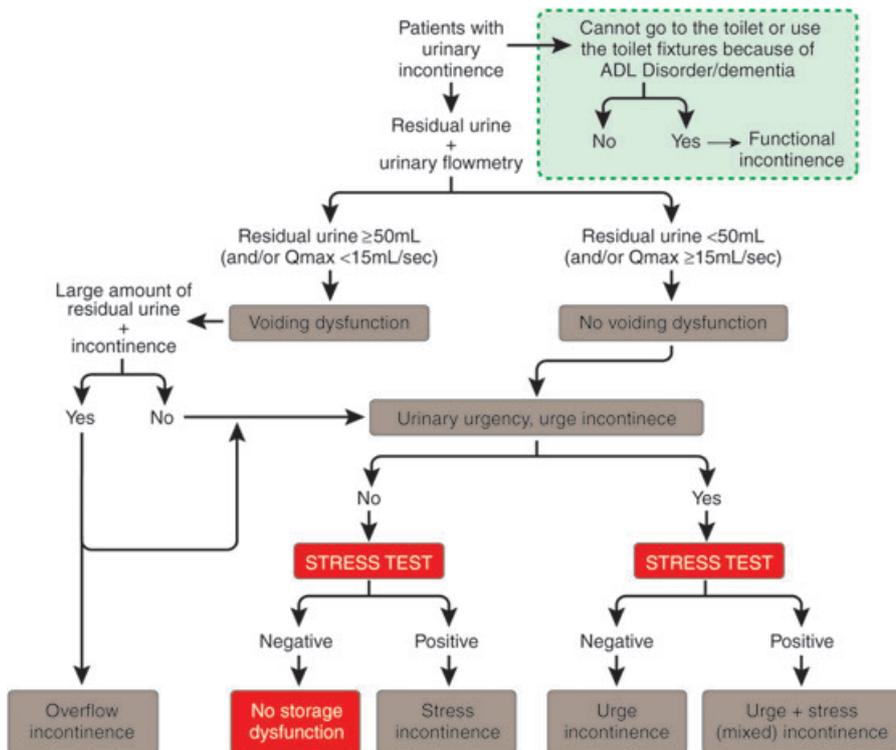


Fig. 1 Algorithm for diagnosis of urinary incontinence.

Evaluation of severity

It is necessary to set evaluation criteria to determine the efficacy of treatment of urinary incontinence, but no standard evaluation method is available at present. In reports published before 1990, there were many subjective evaluations for urinary incontinence such as disappeared, improved, unchanged or worse, but recently the quantitative level and frequency of urinary incontinence have been used. In elderly patients with cognitive functional disorders and physical functional disorders, it is very difficult to measure the amount of each episode of urinary incontinence and it is also very difficult with current manpower deficiencies in Japan to evaluate the frequency of urinary incontinence by having nurses check whether or not incontinence has occurred every hour.

If no cognitive functional disorder is present, urination and incontinence records or QOL questionnaires (Quality of Life in Persons with Urinary Incontinence [IQOL] or King's Health Questionnaire [KHQ]) completed by the patients themselves should be used for evaluation of urinary incontinence. In highly academic research, it is necessary not only to evaluate the severity of urinary incontinence but also to include urodynamic studies. At present, the International Continence Society (ICS) is undertaking standardization of severity evaluations.

Treatment

Treatment of urinary incontinence can be classified as: (i) lower urinary tract rehabilitation; (ii) drug treatment; and (iii) surgical treatment. It is necessary to carefully explain to patients the inherent advantages, effects and risks of each method of treatment. The intentions of the patients should be strictly respected and the method of first choice should be that with the fewest complications and the lowest invasiveness. In this sense,

behavioral therapy is appropriate, but behavioral therapy associated with training may be difficult in the elderly because of the need to understand the significance and methods of training, to maintain motivation and to be able to act as required. Combinations of the three types of treatment can be effective, but in the future, it will be necessary to study which treatments should be combined in which way to increase efficacy.

The following shows simple treatment options that can be used for patients encountered in routine practice (refer to Table 2 for details).

- Urge urinary incontinence with residual urine of less than 50 mL
 - Lower urinary tract rehabilitation: bladder training, pelvic floor exercise
 - Drug therapy: anticholinergic drugs
- Stress or mixed incontinence with residual urine of less than 50 mL
 - Lower urinary tract rehabilitation: pelvic floor exercise, bladder training
 - Drug therapy: α -sympatholytic agents, estrogen, α -sympatholytic agents + estrogen
 - Surgical therapy

Lower urinary tract rehabilitation

The frequency of urinary incontinence can be reduced without complications. A clear understanding of the concept of behavioral therapy by the caregiver and skilful use of the handbook and experts such as urologists play a major role in achieving the effects of behavioral treatment. (Intensity of evidence: A)

Gorman *et al.* (1995) studied the effects of the handbook and the expert system in spreading knowledge to urinary incontinence outpatients using a randomized clinical trial and said that the skilful use of

Table 2 Classification and treatment of urinary incontinence

Type of urinary incontinence	Lower urinary tract rehabilitation	Drug therapy	Surgical therapy	Remarks
Urge urinary incontinence (residual urine <50 mL)	Toileting assistance† Timed toileting guidance Patterned toileting guidance Reeducation for toileting habits Bladder training† Pelvic floor exercise†	Anticholinergic agents Propiverine hydrochloride† Oxybutynin chloride† Proprantheline bromide Imipramine hydrochloride Flavoxate hydrochloride	Cases of urge urinary incontinence caused by bladder outlet obstruction due to prostatic hypertrophy, etc. Transurethral prostatectomy, etc.†	Re-evaluation of degree of urinary incontinence and residual urine every 1–3 months. Examination by a urologist when incontinence is not improved by drug therapy or residual urine increases to 50 mL or more.
Stress urinary incontinence (residual urine <50 mL)	Toileting assistance† Timed toileting guidance Patterned toileting guidance Re-education for toileting habits Bladder training† Pelvic floor exercise†	Estrogen therapy† β-Sympathomimetic agents α-Sympathomimetic agents‡	Transvaginal bladder neck suspension† Retropubic bladder neck suspension† Anterior colpoplasty† Sling operation† Periurethral collagen injections† Artificial urethral sphincter implantation‡	Also possible to use bladder neck support device† Re-evaluation of degree of urinary incontinence and residual urine every 1–3 months. Examination by a urologist when urinary incontinence is not improved by drug therapy.
Overflow urinary incontinence		Cases of bladder outlet obstruction α-Sympatholytic agents	Cases of bladder outlet obstruction Transurethral prostatectomy, etc.†	Intermittent catheterization† Urethral catheterization‡ Examination by a urologist
Functional urinary incontinence	Toileting assistance† Timed toileting guidance Patterned toileting guidance Re-education on toileting habits			Adjustment of the environment (sign on the toilet, elimination of level differences and obstructions, use of portable toilets and urinals)

†Treatment that should be tried first. ‡Should be applied with caution because of many complications. When residual urine is 50 mL or more, the patient should consult with a urologist.

knowledge of experts was effective.⁵ Williams *et al.* (1997) compared groups of nurses given and not given the urinary incontinence handbook and stated that the level of knowledge of nurses improved significantly in the group given the handbook.⁶ Beguin *et al.* (1977) studied 245 patients who received health training on urination problems, especially urinary incontinence, for about 30 min and 451 patients who did not receive such training. They found that the rate of consultation of specialists and rates of undergoing testing and treatment were significantly higher in the group receiving training, indicating that such health training is useful in improving awareness of urinary incontinence.⁷

Behavioral therapy is classified into two types depending on the relation of the patient to the treatment.

- 1 Treatment provided by the caregiver to patients with activities of daily living (ADL) disorders (passive).
- 2 Treatment that requires the patient to actively participate in education and rehabilitation (active).

In clinical practice, however, there is no clear division between the two types. For example, in patients with normal cognitive function and only ADL disorders, stress urinary incontinence or urge urinary incontinence are improved by bladder training, pelvic floor exercise and biofeedback treatment but toileting guidance by caregivers is often necessary to achieve complete prevention.

Lower urinary tract rehabilitation consists of the following three parts.

Toileting assistance

- 1 Timed toileting guidance
- 2 Toileting guidance matching urination patterns of each patient (patterned toileting guidance)
- 3 Re-education on toileting habits

Bladder training

Pelvic floor exercise

- 1 Pelvic floor exercise
- 2 Pelvic floor exercise combined with biofeedback
- 3 Pelvic floor exercise using a vaginal cone
- 4 Electrical stimulation of the pelvic floor.

No adverse drug reactions due to lower urinary tract rehabilitation have been reported. It is possible to combine with other methods of treatment such as drug therapy and surgical therapy. If the patient's motivation is clear, support is obtained from caregivers and rehabilitation can be continued, it is possible to completely eliminate urinary incon-

tinence by behavioral therapy alone. Even in patients with some level of cognitive disorder, it is known that bladder control is possible although it may not be complete.

Many papers had the following problems that: results were reported using different scales, the number of times, periods and frequency of therapeutic training were different, there were subtle differences in training methods, results of long-term observations were lacking, concomitant therapy was used, patient characteristics differed, names of each type of behavioral therapy were not uniform, and no information on how many patients who had shown no response to previous therapy were included. Because of such problems, the usefulness of behavioral therapy is not always clear. Generally speaking, behavioral therapy reduces urinary incontinence and surgery is not usually necessary in patients with stress urinary incontinence.

Before behavioral therapy, it is necessary to evaluate the type of urinary incontinence. Overflow urinary incontinence must be excluded.

Drug therapy

Many randomized clinical trials reported to date presented various problems; they did not have clearly recorded patient characteristics, few patients were enrolled in the research, unclear efficacy evaluation criteria were used and observation periods were short. The number of randomized clinical trials on the elderly is increasing, but in the future, efforts must be made to improve the quality of the research.

In Japan, the Ministry of Health, Labour and Welfare have approved the following drugs for treatment of urinary incontinence and pollakiuria (storage disturbances).

- 1 Anticholinergic drugs that improve pollakiuria and urge urinary incontinence by inhibiting involuntary contraction of the detrusor muscle and expanding the bladder volume (oxybutynin chloride, propiverine hydrochloride, propantheline bromide)
- 2 Flavoxate hydrochloride that acts directly on the detrusor muscle
- 3 Clenbuterol chloride that increases the tonus of the urethral sphincter by β_2 -sympathomimetic action and is effective against stress urinary incontinence

The following unapproved drugs are also used.

- 4 α -Agonists that increase urethral resistance (ephedrine hydrochloride, methylephedrine hydrochloride)
- 5 Tricyclic antidepressants with anticholinergic action and α -stimulant action (imipramine hydrochloride, amitriptyline hydrochloride)

Urge urinary incontinence

Oxybutynin chloride, propiverine hydrochloride and propantheline bromide with anticholinergic action are effective against urge urinary incontinence associated with uninhibited detrusor contraction. Oxybutynin chloride and propiverine hydrochloride also have direct contraction inhibitory action on the detrusor muscle. Propantheline bromide is almost never used at present. In the United States, a new anticholinergic drug, tolterodine tartrate, with fewer adverse drug reactions such as dry mouth has been marketed. A clinical trial is also being performed on a sustained release formulation of oxybutynin chloride with effects maintained by a single daily dose. The effects of flavoxate hydrochloride on urge urinary incontinence have not been recognized in the Agency for Health Care Policy and Research (AHCPR) guidelines, but one report indicated that it is equivalent to oxybutynin chloride. Imipramine hydrochloride, which is useful for nocturia in children, is also useful for urge urinary incontinence. The calcium channel blocker

terodiline has also been reported as useful, but it is not marketed at present because of cardiovascular adverse reactions.

Stress urinary incontinence

Useful drug therapy of urinary incontinence caused by urethral sphincter deficiency includes: (i) treatment that stimulates the α -sympathetic nerve receptors distributed at a high density from the bladder neck to the proximal urethra and increases resistance at the bladder outlet by increasing the tonus; (ii) treatment that results in recovery of the elasticity of the urethral mucosa and periurethral support tissue by female hormone replacement during menopause; and (iii) combination therapy with α -sympathomimetic agents and female hormones. However, in the opinion of specialists, drug treatment should not be considered as the main treatment of stress urinary incontinence and behavioral therapy or surgery should be attempted first. Drug therapy can be used as supplemental treatment, but long-term use when no effects are observed is not recommended.

Clenbuterol chloride that increases the tonus of the urethral sphincter by β -sympathomimetic action is effective against stress urinary incontinence.

Surgical treatment

Surgical treatment of urinary incontinence includes: (i) operations to correct the hypermobility of the bladder outlet and increase resistance in stress urinary incontinence in women; (ii) operations on hyperactive bladders in cases of urge urinary incontinence, and (iii) operations to eliminate bladder outlet or urethral obstructions that cause overflow urinary incontinence or bladder irritation symptoms.

Other treatments and assist devices

Adjustment of the environment

It is possible to improve the level of urinary incontinence by adjusting the environment in terms of both cognitive and physical functions. (Strength of evidence: C)

Urinary incontinence in the elderly with reduced cognitive and physical functions can be improved by elimination of level differences and obstructions and setting handrails on the way to the toilet and placing a sign on the toilet. In patients who cannot hold back urination until they reach the toilet, urinary incontinence can be prevented by using portable toilets and urinals.

Clothing

It is possible to improve the level of urinary incontinence by adjusting clothing to match both cognitive and physical functions. (Strength of evidence: C)

Clothing that can be removed quickly such as underwear that opens in the front is being designed. Especially for patients with severe urine urgency, wearing too many layers or thick clothing often makes it difficult for them to open or remove their clothing in time for proper urination. Thick clothing can be avoided by creating a pleasant indoor environment using heating, etc.

Intermittent catheterization

Intermittent catheterization is used in cases of chronic urinary retention caused by impaired detrusor contractility or bladder outlet obstruction. (Strength of evidence: C)

This is standard therapy when the contractility of the detrusor muscle is impaired because of peripheral neurological disorders or when residual urine occurs because of spinal injuries. Complications such as urinary tract infections can occur, but this is less common than with catheter implantation. If patients are young or have normal immunity, a clean technique is adequate, but in the elderly with reduced immunity, catheterization by sterile procedures is recommended by some physicians to avoid urinary tract infections. Long-term administration of antibiotics to prevent urinary tract infections should be avoided because of the appearance of resistant bacteria. When symptoms of urinary tract infections appear, treatment is performed as a rule. If the patients have no cognitive disorders and want such treatment, intermittent self-catheterization is also possible in elderly patients.

Urethral catheterization

When patients have bladder outlet obstruction causing urinary incontinence and other treatment cannot be performed to eliminate the obstruction (inoperable patients, etc.), when the systemic condition become serious or terminal and no caregivers are present to perform intermittent catheterization, urethral catheterization can be used. (Strength of evidence: C)

McMurdo *et al.* (1992) compared catheterization and management with pads in 78 elderly women with refractory urinary incontinence and found that about 30% of patients with catheterization wanted catheterization. Although the cost was high, they said it should be attempted in patients with refractory urinary incontinence.⁸

When problems arise in the pudendal skin because of urinary incontinence and urinary incontinence has an adverse effect on decubitus, temporary catheterization can be considered, but it should not be used for urinary incontinence other than the overflow type as a rule. When catheterization is performed, closed-type urine collection bags can be used.

Catheterization is apt to cause urinary tract infections and septicemia.⁹ Catheters should be replaced every 30 days, but if stones are lodged in catheters and they become obstructed, the replacement frequency should be shortened. Catheters with thickness of 14 to 18 F are appropriate for implantation and balloons are inflated with 10 mL of distilled water. Not only is it impossible to eliminate bacteriuria by periodic bladder washing, but also the bladder mucosa can be damaged and the opportunities for bacterial infections to occur are increased. Therefore, washing is not performed unless the catheter is blocked. Muncie *et al.* (1989) conducted a randomized clinical trial on 32 women with catheterization who underwent bladder washing once a day for 10 weeks. They reported that the catheter obstruction frequency and incidences of fever and bacteriuria were the same as in the group without washing.¹⁰ No conclusion has been reached about which catheter materials, including latex, silicone and Teflon, are best. Catheters coated on the surface with hydrophilic lubricant materials widely used in recent years, antibacterial agents or silver can reduce complications such as clogging with stones. Bull *et al.* (1991) compared the Dow Corning silicone elastomer catheter and the Bard Biocath catheter and found significant differences in the mean implantation periods, 89.6

days for the Bard catheter and 56.7 days for the Dow Corning catheter. Catheters coated with the hydrophilic lubricant material were reported to be better than silicone catheters.¹¹

Suprapubic (bladder fistula) catheters

Catheterization of the bladder from the suprapubic abdominal wall is sometimes used after urological surgery. In overflow urinary incontinence, it can replace urethral implanted catheters. (Strength of evidence: C)

This catheterization is not indicated for patients with urge or reflex incontinence. Since the catheter is not implanted in the urethra, it is better than a urethral catheter for eliminating complications in the urethra. However, complications on catheterization (bleeding, intestinal injuries) and trouble when catheters are replaced occur. Problems are also caused by insufficient knowledge of general practitioners and nurses about suprapubic (bladder fistula) catheter management and measures to solve problems such as spontaneous dislodging of catheters.

External urinary appliances

External urinary appliances are effective in patients who can empty their bladders. (Strength of evidence: C)

In men, condom-type external urinary appliances are used. Before use, it is necessary to confirm that there are no urinary tract infections, dysuria or abnormalities in the upper urinary tract. Abnormalities are likely to occur in the skin because the devices cover the penis and are attached so that they do not come off. Penile abnormalities should be checked everyday. Women also use external urinary appliances but evaluation of their usefulness has made little progress.

Bladder neck support devices

Silicone devices to support the bladder neck from the vagina are effective in patients with stress urinary incontinence. (Strength of evidence: C)

No randomized clinical trials on the effectiveness of bladder neck support devices for stress urinary incontinence have been reported. The patients themselves must insert and remove the devices from the vagina every day. It is necessary for the cognitive function to be normal, the patient to be willing to use the devices, and the fingers to be moved skillfully.

Urine absorbent products

Urine absorbent products are effective in the care of urinary incontinence. (Strength of evidence: C)

Depending on the severity of the incontinence, various sizes of pads, combinations with pants, diapers for adults and bed pads are used. The costs of these urine absorbent products are increasing every year.

These products can be used as supplements with other treatments such as behavioral therapy. When they are used from an early stage, the patients become strongly dependent on the pads, the pads are not removed to prevent patient anxiety and it is possible that the patients will show less desire to cure their incontinence.

The performance and convenience of such materials are improving, but no comparative trials have been performed on which products are the best.^{12,13}

Drinking water and diet

Constipation causes the level of urinary incontinence to become worse in the elderly. Constipation can be improved by appropriate intake of dietary fiber and water. (Strength of evidence: C)

The bladder is rapidly filled and urinary incontinence occurs due to the diuretic effects of caffeine present in tea and coffee. Urinary incontinence is not improved by restricting water intake and it is not only possible that constipation will occur but also that dehydration will appear. It is important to have a diet with high levels of dietary fiber and to drink sufficient amounts of water. Dowd *et al.* (1996) randomly assigned 32 women to a group with the water intake 500 mL higher than normal, a group with normal intake or a group with a 300 mL reduction in water intake. Although the difference was not significant, the importance of increasing drinking water intake was stressed.¹⁴

Handling nocturnal pollakiuria and urinary incontinence

The number of nocturnal urinations and urinary incontinence can be decreased by limiting drinking of water and beverages containing caffeine from the evening. (Strength of evidence: C)

Appropriate levels of water should be drunk before the evening hours. Taking diuretics in the morning is useful to reduce nocturnal urination levels.

Skin care

If urinary incontinence occurs, it is recommended to wipe the pudendal area in the morning and keep it clean. (Strength of evidence: C)

Urinary incontinence can cause decubitus. It is necessary to be concerned about cleanliness and dryness, pad and diaper materials that are gentle on the skin and posture changing methods.

Guidelines on Urinary Incontinence in Women

Diagnosis

Most urinary incontinence in healthy women can be classified as stress urinary incontinence, urge urinary incontinence and mixed urinary incontinence based on interviews about disease history, and a physical examination and conservative treatment is initiated depending on the type (Fig. 2).

Initial evaluation (evaluation by general practitioners)

Interview (essential item)

It is necessary to adequately interview urinary incontinence patients and it is convenient to use the interview form.

Onset conditions and timing

For urinary incontinence in women, it is important to clarify under what conditions the urinary incontinence occurred and in many patients the type can be evaluated only in an interview. In classical stress urinary incontinence, urine leaks only when pressure is applied to the abdomen (coughing, sneezing, running, walking, lifting heavy materials, sports, etc.) and does not occur when the patient is at rest lying down. However, urge urinary incontinence involves cases where the patient 'cannot hold back the urine in spite of trying' with strong urinary urgency and is often associated with pollakiuria. The mixed type requires checking of which symptoms are more troublesome for the patient, the stress type or urge type. Understanding of the time from onset and the status (frequency, severity, time range, number of changes of underwear, pads or diapers, and effects on daily life) of urinary incontinence can serve as a reference for indications of treatment and selection of treatment methods.

Disease history and complications

Patients should be asked if they have a history of childbirth, menopause or hormone replacement therapy. A sufficient understanding of histories of diseases that affect urination such as cerebrovascular disorders, spinal diseases and diabetes mellitus, as well as pelvic surgery or surgery to treat urinary incontinence in the past obtained from interviews including conditions before and after the onset of urinary incontinence is necessary.

Medication history

Drugs such as diuretics, anticholinergic agents, psychotropic drugs, calcium channel blockers and sympatholytic and sympathomimetic agents are used at relatively high frequencies and may have an effect on urinary incontinence. Therefore, it is necessary to understand the conditions of use. It is recommended to consult with specialists as required about whether or not to continue administration of a drug.

Others

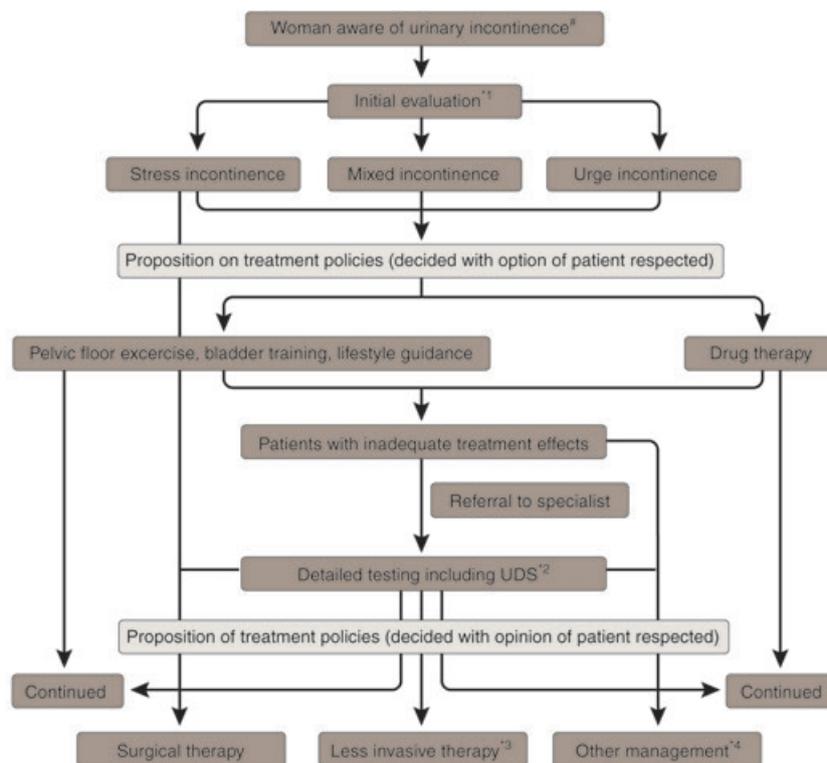
Interviews should also include diseases other than urinary incontinence such as a feeling of genital ptosis, dysuria, micturition pain, and hematuria, as well as intake of water and alcohol, urinary function and sexual function.

Especially in the elderly, it is necessary to ask about decreases in activities of daily living, mental condition (presence/absence of mental disease as a complication, reduced cognitive function and dementia), and precautions related to the living and social environment.

Quantification of symptoms and QOL

Bladder diary (essential item)

Patients are given a cup that can measure the amount of urine and a diary to enter the time and amount of each urination, the number of episodes of urinary incontinence, the number of pads used and other events for a minimum of 24 hours (several days to 1 week if possible) during activities of daily living. By using the diary, it is possible to understand relatively easily the number of urinations and amounts each time both day and night, and the frequency and severity of urinary incontinence.^{15,16}



#: The algorithm is applied to patients with urinary incontinence that has been diagnosed objectively and poses social hygiene problem.

*1: Interviews (including urination conditions and menstrual conditions); bladder diary, pad test, QOL physical testing (neurological testing, vaginal examination); stress test, urinalysis, presence/absence of residual urine.

*2: Measurement of residual urine, uroflowmetry, cystometry, ALPP, imaging (abdominal ultrasound, cystography)

*3: Biofeedback therapy, electrical stimulation therapy.

*4: Absorbents, devices

Fig. 2 Algorithm for urinary incontinence in women.

Pad test (optional item)

The pad test is an objective index of urinary incontinence. After drinking 500 mL of water, patients perform movement for 1 hour to induce stress urinary incontinence, and the 1-hour pad test in which the amount of urinary incontinence is obtained from the difference in pad weights before and after the test and the 24-hour pad test in which the amount of urinary incontinence for 24 hours during daily living is obtained are performed. It has been reported that the 1-hour pad test is more often false-negative than the 24-hour pad test¹⁷ and it is recommended to inject a fixed volume into the bladder to compensate for this demerit.¹⁸

QOL evaluation (essential item)

The effect of urinary incontinence on QOL differs greatly depending on the patient's sense of values and lifestyle even when the severity is the same and this governs the necessity and selection of treatment. Since the purpose of treatment of urinary incontinence, a benign disease, is improvement of QOL, it is necessary to evaluate accurately the effect on QOL and the International Consultation on Incontinence Questionnaire covering a QOL evaluation is under investigation.

Physical tests (essential item)

Palpation of abdomen and neurological tests

Abdominal distension and obesity and the presence/absence of surgical scars are checked. It is recommended to observe the sense of touch, heat and pain and evaluate the tonus and contraction of the anal sphincter muscle by digital rectal examination.

Vaginal examination and stress test

When stress urinary incontinence is suspected from the disease history, a vaginal examination when urine is present is important. Whether or not urine flows at the same time as coughing or strain (stress test) or hypermobility of the urethra occurs is observed. When urinary incontinence is not induced, useful measures include increasing the volume of the bladder by physiological saline injection or repeating the examination in both the lithotomy and standing positions.¹⁹ When flow of urine is delayed a moment after coughing, it is possible that urge urinary incontinence will be induced with uninhibited contraction of the bladder by coughing and caution is required. An overall examination of relaxation of the pelvic floor includes evaluation of genital prolapse (cystoceles, rectoceles or uterine prolapse) and tonus of the

muscle around the vaginal wall and the presence/absence of atrophic vaginitis, vesicovaginal fistulas or urethral diverticulum.

Other

Urinalysis (essential item)

Screening for urinary tract infections, calculus, bladder tumors (especially carcinoma *in situ*) and diabetes mellitus is performed. When urinary tract infections are found, antibacterial agents are administered before the evaluation or treatment of urinary incontinence to eliminate the effects of the infection.

Measurement of residual urine (essential item)

The residual urine after urination is measured using ultrasound from the lower abdomen or catheterization. For patients with major complaints of urinary incontinence and pollakiuria associated with a large volume of residual urine, overflow urinary incontinence is suspected. Repeated measurements of the urinary volume should be performed because of the large discrepancies among measured values, but the analysis is complex and if residual urine of more than 50 mL persists, it is recommended to be examined by a specialist.

Secondary evaluation (evaluation by a specialist)

Urodynamic study

Cystometry (Essential Item). Cystometry is important for reproducing urinary incontinence conditions during daily life and correctly diagnosing the cause of the urinary incontinence. According to a study on women with urinary incontinence that compared diagnosis by disease history and physical findings and diagnosis after a urodynamic study, the two results matched in 65% of women and the results of the urodynamic study caused a change in the subsequent treatment method in 31% of women.²⁰ By measuring rectal pressure at the same time and using the formula ‘intravesical pressure – rectal pressure = detrusor muscle pressure,’ it is possible to more strictly differentiate between contraction of the detrusor muscle and abdominal pressure.

- **Diagnosis of urodynamic stress urinary incontinence**
When stress urinary incontinence is suspected, coughing or strain is induced in the storage phase of cystometry and the induction of urinary incontinence is examined. If it is confirmed that urine leaks due to an increase in abdominal pressure without the detrusor muscle contraction, then genuine stress urinary incontinence can be diagnosed. The abdominal leak pressure (ALPP) is the differential pressure at which urinary incontinence appears when the abdominal pressure increases. It serves as an index correlated with the severity of urinary incontinence. If the ALPP is 60 cm H₂O or less, then intrinsic sphincter deficiency (ISD) is present.^{21–23}
- **Diagnosis of urinary incontinence by a hyperactive bladder**
Cystometry is very useful in the diagnosis of urge urinary incontinence. Uninhibited contraction is not found in all patients with urge urinary incontinence,²⁴ but if it is confirmed that detrusor hyperactivity is present in the cystometry in the storage phase and the maximum cystometric capacity and compliance have decreased, the diagnosis is more definite. To increase the detection rate of uninhibited contraction, it is recommended to relieve the stress on the patient and perform various induction tests (postural changes, abdominal pressure load or cold water stimulation).²⁵

Uroflowmetry (Optional Item). Uroflowmetry is a more useful method together with measurement of residual urine for screening of voiding disturbances than diagnosis of urinary incontinence itself. Since a voiding disturbance is suspected when there is a definite drop in the urine flow rate and significant residual urine is present, it is recommended to perform a detailed examination including a pressure-flow study as described below.

Pressure-Flow Study (Optional Item). The pressure-flow study is a useful test for screening the cause when a urine voiding disturbance is suspected from uroflowmetry and residual urine measurements. It is an advantage to be able to estimate quantitatively bladder outlet obstruction and detrusor contractility by simultaneous intravesical pressure and urine flow measurements, but the usefulness in women has not been adequately established.

Imaging studies

Video urodynamics (optional item)

This is a method for an overall diagnosis of the function and morphology of the lower urinary tract including urethral hyperactivity and bladder neck expansion by performing an X-ray guided urodynamic study. In this study, bladder neck expansion when standing at rest without detrusor contraction, a classical finding of intrinsic sphincter deficiency, can be diagnosed.²⁶

Cystourethrography (optional item)

This has only a supplemental significance for the diagnosis of urinary incontinence,²⁷ but observations of the posterior urethrovesical angle, the position of the bladder neck and morphology in chain cystourethrography have some usefulness in evaluation of urethral hypermobility, ISD and cystoceles. It is also useful in evaluation of recurrent or refractory urinary incontinence and comparisons before and after urinary incontinence surgery.

Pelvic ultrasound (optional item)

Pelvic ultrasound (transvaginal, tranrectal or transperineal) shows major overlapping between stress urinary incontinence and normal groups and its diagnostic significance is limited.²⁸ It has been reported to be as useful as cystourethrography in the evaluation of urethral hypermobility, the position of the bladder neck and morphology.²⁹ Cystourethrography more clearly images expansion of the bladder neck and the bladder as a whole, but one advantage of ultrasound is obtaining information of tumors, etc. in the pelvic region without using X-rays.

Others (optional items)

Excretion pyelography, upper urinary tract ultrasound and CT are not usually recommended for diagnosis of female urinary incontinence, but they can be useful in evaluation of the upper urinary tract in overflow urinary incontinence or neurogenic bladder and diagnosis of ureteral urinary incontinence such as in ureterovaginal fistulas.

Cystourethroscopy (optional item)

When abnormalities such as hematuria appear in urinary sedimentation, cystourethroscopy should be used for diagnosis of bladder tumors, calculus and foreign matter. This method has some usefulness for

screening the cause of recurrent refractory urinary incontinence including vesicovaginal and ureterovaginal fistulas.

Treatment of stress urinary incontinence

Treatment of stress urinary incontinence includes lower urinary tract rehabilitation, drug therapy, surgical therapy and treatment using therapeutic devices for urinary incontinence. Lower urinary tract rehabilitation is usually performed first in mild to moderate cases and surgical therapy is indicated for moderate to severe cases. Drug therapy of stress urinary incontinence is only considered as supplemental treatment because evaluation of efficacy in randomized clinical trials has been inadequate to date. Urinary incontinence is a QOL disease and since severity and necessity of treatment are greatly affected by the patient's own individuality and sense of values, it is important to consider the wishes of the patients themselves in addition to the efficacy, invasiveness and economics when selecting the treatment. This also applies to urinary incontinence in the parturient stage.

Lower urinary tract rehabilitation

Lower urinary tract rehabilitation is one of the treatment categories for stress urinary incontinence in women. The main procedures are: (i) pelvic floor exercises; (ii) bladder training; (iii) pelvic floor muscle electrical stimulation; and (iv) lifestyle guidance, either alone or in combination.

At present, lower urinary tract rehabilitation is the treatment of choice for stress urinary incontinence, but there have been no reports to date on selection of surgical therapy and non-surgical therapy such as lower urinary tract rehabilitation based on severity. In Japan, health insurance reimbursement prices are not specified for lower urinary tract rehabilitation to treat urinary incontinence. Another problem is that therapeutic devices required to assist in treatment have not been approved.

Methods of lower urinary tract rehabilitation

Pelvic floor exercise

Pelvic floor exercise is one type of lower urinary tract rehabilitation with voluntary contraction of the levator muscles of the anus and the sphincter muscles around the urethra and the vagina.

Pelvic floor exercise has two goals: (i) learning a method of reflexive contraction of the urethral sphincter muscles when pressure is applied to the abdomen; and (ii) increasing the urethral closure pressure by strengthening the muscle power of the pelvic floor muscles. Few reports on indication criteria for pelvic floor exercise by severity and distress of stress urinary incontinence have been published³⁰ but as a rule, all patients who want to continue and understand the exercise methods are indicated.

The mechanisms (anatomical and physiological) by which stress urinary incontinence occurs are first explained to the patients and the exercise methods are provided. An oral explanation of the exercise methods is insufficient.³¹ The instructors perform a vaginal examination to confirm the position of the pelvic floor muscles and the patients are taught the correct contraction method (manual instruction method). The basic training program consists of the maintenance of contraction at maximum strength for 8 to 12 seconds and the relaxation for the same time as the contraction and this is repeated 80 to 100 times a day. The contraction time and number of contractions are reduced as required based on the muscle power of the

patients at the start of exercise. The patients are instructed on how to deliberately contract the pelvic floor at the time of abdominal pressure (for example, cough, sneezing, exercise, etc.) that causes urinary incontinence.

Supplementary methods to strengthen the effects of pelvic floor exercise include periodic concentrated exercise by instructors,³² biofeedback methods³³ and the use of vaginal cones.³⁴

In concentrated exercise by instructors, patients who have learned pelvic floor exercises are examined periodically in medical institutions and undergo exercise for a certain time by instructors each time. The instructors show the patients how to achieve the maximum contraction in various body positions and motivate them so that they can continue with the same exercises at home.

Biofeedback treatment is training that involves electrical or mechanical monitoring of contraction of the pelvic floor muscles in which the patients use devices that can be understood visually and audibly. Typical examples are the method using an intravaginal pressure gauge or the method using an electromyograph connected to intravaginal or intra-anal electrodes or surface electrodes. In recent years, several guidance systems in which the electromyographic information is displayed on a personal computer have been marketed but they have not been approved in Japan. A simple method involves insertion of a very small diameter cylinder into the vagina and confirmation of contraction from movement of the cylinder at the time of pelvic floor muscle contraction.

A vaginal cone is a tampon-shaped molded weight that is inserted into the vagina. When the patient walks, the pelvic floor muscles are contracted to prevent the cone from falling out. Walking for 15 min is standard. The cones are weights of the same shape weighing from 20 to 100 g and they are selected in accordance with the pelvic floor muscle strength in each patient.

Bladder training

Bladder training is defined as 'a learning and behavioral therapy type training method for the purpose of control of urinary incontinence in adults.' The basic method differs depending on the reporter, but as a rule, it consists of: (i) learning about urinary continence and urinary incontinence; (ii) planned urination and prolonging intervals between urination in stages; (iii) control of urination urgency by diverting the patient's attention and physical/mental relaxation; (iv) self-evaluation of urination habits; and (v) assistance by physicians.³⁵ Step (ii) has been reported to range from strict adherence to a plan to less strict adherence, and intervals between urination are not fixed. The basic methods for self-control of urinary urgency in Step (iii) that have been reported include methods requiring mental concentration such as deep breathing and doing calculations, auto-suggestion and the perineal pressure method, and contraction of the pelvic floor muscles as required.

Pelvic floor electrical stimulation method

Electrical stimulation of the pelvic floor muscle involves contraction of the levator muscles of the anus and the sphincter muscles around the urethra and the vagina in the same location. The route of electrical stimulation includes transvaginal, transanal and percutaneous electrodes. There are various reports on selection of electrodes and treatment schedules (stimulation frequency, number of stimulations and frequency of treatment), but to strengthen the closure function of the external urethral sphincter in patients with stress urinary incontinence, the stimulation is performed two or three times a day at 20 to 50 Hz for 4 to 8 weeks.^{36,37} Adverse reactions include a feeling of discomfort in

the vagina and anus and pain, but they are not serious. The main contraindications for electrical stimulation include pregnant women or women who might be pregnant, patients with vaginitis, vaginal fistulas or uterine prolapse, patients with pacemakers and those with arrhythmia. The electrical stimulators used in this method are not approved in Japan.

Lifestyle guidance

Risk factors for stress urinary incontinence in lifestyles include obesity, constipation, smoking and excessive water intake, and guidance is given to improve these factors. It is also necessary to consider the possibility that this is caused by drugs being administered. Various absorptive pads are also used as a passive method against stress urinary incontinence. However, the pads should not hastily be used; they should be used carefully only in the evaluation period before the start of treatment or the period before the onset of therapeutic effects.

Treatment results

Pelvic floor exercises

Pelvic floor exercises are useful as a non-surgical method to treat stress urinary incontinence and significant improvements have been found in comparison with untreated groups in RCTs.³⁸

When concentrated training by instructors was introduced for pelvic floor exercises, no differences appeared in the first month when compared with the group with exercises only at home, but after 6 months, only the concentrated training group showed significant improvements both subjectively and objectively in the urinary continence.³² When biofeedback was added as a supplemental method to pelvic floor exercises, the effects were also higher than with pelvic floor exercises alone.^{33,38,39} In many cases, pelvic floor exercises were performed at the same time as the use of vaginal cones. Urinary incontinence improved after treatment when only vaginal cones were used, but in a comparison with pelvic floor exercises with an instructor, the improvement was significantly better in the pelvic floor exercise group.⁴⁰

Bladder training

Few trials on bladder training in patients with only stress urinary incontinence have been performed. The frequency of urinary incontinence decreased in a trial on a pooled population with stress urinary incontinence, urge urinary incontinence or mixed urinary incontinence.⁴¹

Electrical stimulation of pelvic floor muscles

Improvement in urinary incontinence was observed in an RCT on electrical stimulation of pelvic floor muscles with a sham electrode group, but the results were not always significant.^{36,42–44} However, in an RCT comparing an electrical stimulation group with a pelvic floor exercise group, vaginal cone group and untreated group, a significantly better improvement rate was found only in the pelvic floor exercise group.⁴⁰ In a trial of the usefulness of combining pelvic floor exercise with electrical stimulation, the frequency of urinary incontinence improved significantly in the concomitant electrical stimulation group when compared with the concomitant sham electrode group.⁴⁵

Drug therapy

α -Adrenergic agents

Many α -adrenergic receptors are distributed in the bladder base, bladder neck and proximal urethra and α -adrenergic agents strengthen the contraction of urethral sphincter muscles. Therefore, in patients with stress urinary incontinence caused by ISD, α -adrenergic agents supplement the insufficient flow resistance and stress urinary incontinence can be reduced by proper administration. In Japan, there are no α -adrenergic agents covered by health insurance to treat stress urinary incontinence, but various adrenergic agents to treat asthma and orthostatic hypotension are on the market. It is possible that these drugs will be used off-label by patients not contraindicated for cardiovascular disease. However, in recent surveys centered on the measurement of urethral pressure, a subjective improvement feeling was obtained by administration of midodrine hydrochloride with potent α_1 -adrenergic action, but no significant change in the maximum urethral closure pressure was reported.⁴⁶

Estrogen replacement

When estrogen replacement was given to women with genitourinary atrophy after menopause, the nutritional conditions in the urethral mucosa improved, the urethral wall thickness increased and the response to α -adrenergic agents was strengthened, suggesting that the urethral obstruction might be improved. In a meta-analysis of six reports on estrogen replacement in postmenopausal women with urinary incontinence, a subjective improvement feeling by estrogen replacement was seen in surveys only on stress urinary incontinence as well as in surveys on urinary incontinence in general. However, as an objective index, urine leakage levels did not decrease in any of the surveys and in one of the six surveys, a significant increase in maximum urethral closure pressure was obtained.⁴⁷ In subsequent RCT, efficacy of estrogen replacement on stress urinary incontinence as well as urinary incontinence in general was not confirmed from frequency and amounts of urine leakage and from pad test results.^{48,49}

Drugs currently marketed in Japan include conjugated estrogens and estriols for oral use, estradiol for percutaneous use and estriol for transvaginal use. The doses have mainly been reported in surveys from Western countries, and it will be necessary to set appropriate doses in the future for Japanese women with a smaller physique because of racial differences. When estrogens are administered for long periods, consideration must be given to the onset of endometrial cancer or breast cancer.

β -Adrenergic drugs

Clenbuterol hydrochloride, a β -adrenergic drug, has long been used to treat asthma, but at present it is also covered by health insurance for treatment of stress urinary incontinence. β -Adrenergic drugs increase outflow resistance in the bladder neck by raising tension in the striated muscle of the pelvic floor. When clenbuterol hydrochloride at 20–40 μ g/day was administered to 32 women with stress urinary incontinence for 2 weeks, efficacy related to the frequency and amounts of urine leakage was 75% for both marked and moderate improvement. Adverse reactions such as tremor and palpitations were observed in 32%.⁵⁰ In the other two surveys, decreases in the frequency and amounts of urine leakage for oral administration of clenbuterol hydrochloride at 20–40 μ g/day were reported.^{51,52} Since clenbuterol hydro-

chloride has blood pressure increasing and blood glucose increasing actions, it is not indicated for patients with hypertension or diabetes mellitus.

Surgical therapy

In the selection of surgical therapy for female stress urinary incontinence, not only subjective symptoms but also objective findings from urodynamic studies and cystography are required for evaluation of bladder neck hypermobility and ISD and screening of detrusor hypermobility as causes of stress urinary incontinence.

Surgical therapy in female stress urinary incontinence includes various operative techniques and modifications of them, but the main methods are retropubic bladder neck suspension, transvaginal bladder neck suspension, the sling operation and periurethral collagen injections.

Bladder neck suspensions are intended to support or raise the bladder neck from the proximal urethra and prevent ptosis. They are indicated for patients with bladder neck hypermobility and a normal bladder sphincter function. The sling operation is used not only to prevent bladder neck ptosis but also to provide close adhesion between the proximal urethra and bladder neck region in ISD. It is indicated for patients with ISD or bladder neck hypermobility. Periurethral collagen injections are intended to achieve close adhesion between the proximal urethra and bladder neck region and are indicated for ISD patients as a rule.

Operative techniques

Retropubic bladder neck suspension

Retropubic bladder neck suspension raises, supports and fixes the periurethral and bladder neck tissue using Cooper's ligament or pubic periosteum as an anchor by means of a retraction operation using a lower abdominal incision. Typical techniques include the Marshall-Marchetti-Kranz method in which the tissue around the urethra and bladder neck and the vagina are sutured to the retropubic periosteum and the Burch method with suturing to Cooper's ligament. These techniques are indicated for patients with bladder neck hypermobility.

Transvaginal bladder neck suspension

The Stamey, Gittes and Raz methods are used. From about the middle of the 1980s in Japan, the Stamey method has been widely used and it is indicated for patients with bladder neck hypermobility. The short-term postoperative results are excellent, but in recent years, decreases in long-term results have been reported.⁵³ Recently, the sling operation is selected for patients with bladder neck hypermobility.⁵⁴ This technique is indicated for patients with bladder neck hypermobility and the improvement rates in patients with ISD are poor.⁵⁵

Bladder neck (urethral) sling operations

Sling operations include transabdominal and transvaginal methods but for female stress urinary incontinence, the transvaginal sling operation with its low invasiveness is generally used. Patients with ISD and patients in whom other urinary incontinence operations have failed are indicated. In recent years, patients with bladder neck hypermobility have also been indicated.⁵⁴ Materials used for slings include fascia (rectus muscle fascia or fascia lata), biomaterials such as vaginal wall,

and synthetic materials such as Marlex mesh or polytetrafluoroethylene. Long-term results are good but problems include postoperative bladder outlet obstruction and newly appearing urinary urgency. In recent years, the concept of bladder neck or urethral slings has changed from 'suspension' to 'support,' and operations with no tension applied to the sling are used. Prolene mesh tape is used for slings and tension-free vaginal tape (TVT) sling operations to support the center of the urethra are used because of the low invasiveness and use of local anesthetics.

Periurethral collagen injections

Glutaraldehyde cross-linked (GAX) collagen is injected submucosally into the bladder neck or proximal urethra to achieve close adhesion between the proximal urethra and bladder neck region and is indicated for ISD patients. The injection is performed by inserting the needle under transurethral endoscopy or around the exterior urethral meatus. The recurrence rate is high and to achieve stable results, injections must often be performed twice or more.

Operative results

Comparison of the results for various methods of surgical therapy of female stress urinary incontinence is not easy because of major discrepancies in the definition of urinary incontinence improvement, few papers on long-term results, lack of fixed operative techniques with many modifications made by surgeons and very few randomized comparative trials. The surgical results described below are based on trials of long-term follow-up by a meta-analysis performed in the guidelines on surgical therapy of stress urinary incontinence in women prepared by the American Urological Association in 1997⁵⁶ and recently reported randomized comparative trials.

Although it is not described here, anterior colpoplasty, the main treatment for cystoceles, showed poorer urinary incontinence elimination rates than Burch retropubic bladder neck suspension both in short-term and long-term results.^{57,58} Comparison of the results for different techniques of transvaginal bladder neck suspension is difficult, but it has been noted that the results are comparable to those of Burch retropubic bladder neck suspension in the short-term^{59,60} but the long-term results are worse.⁴⁰ The results for transvaginal bladder neck suspension in ISD patients were inferior to those for bladder neck hypermobility.⁵⁵ The results for the endoscopic Burch retropubic bladder neck suspension are under investigation^{61,62} and the long-term results are unknown. On the other hand, the sling operation has shown good stable results for both short-term and long-term elimination of urinary incontinence no matter what the disease state. Few reports on the TVT sling operation have appeared in the literature, but in the short-term, a large randomized clinical trial showed comparable results to the Burch method⁶³ and in the long-term, good results with a urinary incontinence elimination rate of 91% over 3 years have been reported.⁶⁴ In long-term results for more than 4 years based on a meta-analysis, the urinary incontinence elimination rate (median value) was 84% for retropubic bladder neck suspension, 67% for transvaginal bladder neck suspension, 61% for anterior colpoplasty and 83% for sling operations. Retropubic bladder neck suspension and sling operations were more effective than other operative techniques.⁵⁶ The recurrence rate for periurethral collagen injections is high, the urinary incontinence elimination rate is lower than that for other methods and long-term results are unknown.

Complications

The main surgical complications for urinary incontinence are voiding disturbances based on bladder outlet obstruction and urinary urgency newly appearing after the operation. The results of a meta-analysis showed that the incidence of transient urinary retention continuing for 4 weeks or longer was about 5% for retropubic and transvaginal bladder neck suspensions and about 8% for sling operations.⁵⁶ Data on the incidence of permanent urinary retention is not adequate. The incidence of postoperative urinary urgency was slightly higher with retropubic bladder neck suspension and sling operations than with transvaginal bladder neck suspension.⁵⁶ No differences in complications related to urinary tract infections and surgical wounds based on the operative technique have been found, but for the sling operation, complications such as vaginal erosion, urethral erosion, fistulas and wound infections tend to be more common when artificial materials are used than with biomaterials.⁵⁶

Absorbents and devices

Various forms of absorbents for absorbing leaked urine (pads and diapers) are widely used in the management of urinary incontinence. With technological advances, a major drop in skin disorders associated with the use of absorbents has recently been observed. It is useful to obtain data on voiding function such as voiding records and quantitative values for urine leakage during a fixed period of use of absorbents. However, it must be noted that in patients using absorbents for very long periods, a psychological burden from 'untreated physical defects that induce urine leakage,' decrease in QOL and severe limitations on a range of activities occur.

Although they differ slightly from absorbents, there are devices such as pessaries that support the bladder neck when inserted into the vagina, covers fitted over the external urethral meatus and urethral plugs inserted into the urethra. These devices are similar to absorbents in that they improve the physical conditions related to urine leakage, but they differ from absorbents in that they are intended to reduce involuntary urine leakage via the urethra.

Treatment of urge urinary incontinence

Treatment of urge urinary incontinence consists of lower urinary tract rehabilitation, drug therapy and surgical therapy. Lower urinary tract rehabilitation and drug therapy are usually performed first in mild to moderate cases and surgical therapy is indicated for severe cases that do not respond to the above therapy. Several drugs have shown efficacy for drug therapy of urge urinary incontinence in randomized clinical trials and drug therapy has become core treatment.

Lower urinary tract rehabilitation

Bladder training

Several randomized controlled trials have been performed, but when the results were analyzed, it was found that the details of the bladder training were not the same in each trial, which must be taken into consideration.

The usefulness of bladder training for urge urinary incontinence was reported in two of the randomized controlled trials that used an untreated group as the control. It was reported that the urinary continence rate after 6 months was 90% and the urinary incontinence improvement rate after 6 weeks was 67%.^{41,65} In one of these trials,

patients with stress urinary incontinence and with mixed urinary incontinence were included. The results showed that bladder training is useful and that it should also be applied from the standpoints of low invasiveness and economy.

In a randomized controlled trial that compared the results of bladder training and pelvic floor exercise in 145 patients with genuine stress urinary incontinence and 59 patients with detrusor overactivity, the urinary incontinence elimination rates at 3 months and 6 months were 18% and 16% for the bladder training group and 13% and 20% for the pelvic floor exercise group, showing no differences between the groups.⁶⁶

In a randomized controlled trial that compared bladder training and drug therapy in 50 patients with detrusor overactivity, inpatient bladder training was compared with outpatient combination therapy with flavoxate hydrochloride 200 mg and imipramine hydrochloride 25 mg. The subjective urinary continence rate and symptom disappearance rate were 84% and 76% in the bladder training group and 56% and 48% in the drug therapy group.⁶⁷ In a trial comparing the effects of bladder training and oxybutynin hydrochloride 15 mg in 75 patients, the urinary incontinence elimination rates after completion of 6 weeks of treatment were 73% and 74%, respectively. After 6 months of treatment, the rate was 70% in the bladder training group but had dropped to 42% in the drug therapy group.⁶⁸ It is difficult to draw a conclusion at present on a comparison of bladder training and other treatment methods and concomitant effects of bladder training and other treatment methods and more randomized controlled trials are needed.

Electrical stimulation therapy (excluding the electrode implantation method)

Four randomized controlled trials have been conducted on the usefulness of electrical stimulation therapy for urge urinary incontinence and they all reported significant effects.⁶⁹⁻⁷² The numbers of patients in these trials were 22, 121, 47 and 68. The sites of stimulation were transvaginal electrical stimulation in two cases, percutaneous electrical stimulation in the pubic or sacral regions in one case and stimulation with electrodes inserted in the vagina and anus in one case. The observation period was a maximum of 8.4 months.

In the future, electrical stimulation to treat urge urinary incontinence will require a randomized controlled trial to investigate optimal conditions related to stimulation conditions and sites and to determine whether or not this treatment is useful in the long term. This treatment method is not covered by health insurance in Japan.

Lifestyle guidance

Many trials have been performed on the relation of urinary incontinence with obesity, strenuous exercise, smoking, fluid intake and constipation, mainly with respect to stress urinary incontinence.⁷³⁻⁸⁴ There have been no randomized controlled trials that have proven any connection between correction of these factors and improvement of urinary incontinence.

Drug therapy

Drugs with mixed pharmacological actions

Oxybutynin Hydrochloride. In addition to its action on muscarinic receptors, oxybutynin hydrochloride also has direct detrusor muscle relaxation effects and local anesthetic effects.

The results of a double-blind trial comparing oxybutynin hydrochloride with propantheline bromide in 169 patients with overactive bladder showed symptom improvement rates of 58.2% for oxybutynin hydrochloride, 44.7% for propantheline bromide and 43.4% for placebo. The improvement rate for oxybutynin hydrochloride was significantly higher.⁸⁵ In a double-blind trial on 366 patients with propiverine hydrochloride as the positive control, both propiverine hydrochloride and oxybutynin hydrochloride were effective when compared with placebo, but thirst as an adverse reaction was reported to be more intense with oxybutynin hydrochloride.⁸⁶ In a double-blind trial on oxybutynin hydrochloride monotherapy and oxybutynin hydrochloride and behavioral therapy concomitantly, the symptom improvement rate was 72.7% in the monotherapy group, but became significantly higher at 84.3% in the concomitant behavioral therapy group.^{87,88} There have been other reports that concomitant therapy is useful.⁸⁹

Propiverine Hydrochloride. Propiverine hydrochloride has both antimuscarinic action and calcium channel blocking action.

In a double-blind trial on administration of propiverine hydrochloride to 98 patients with urge urinary incontinence or urge and stress urinary incontinence, the frequencies of urination and urinary incontinence were significantly reduced, effects on the heart showed no significant differences with placebo and the incidence of thirst as an adverse reaction was reported as 2%.⁹⁰ In a double-blind trial on 185 patients with urinary urgency or urge urinary incontinence, an 80% improvement rate was obtained at a dose of 30 mg/day.⁹¹ In a comparison of propiverine hydrochloride 45 mg/day and oxybutynin hydrochloride 10 mg/day in a double-blind trial on 366 patients, almost the same effects can be expected when compared with the placebo, but propiverine hydrochloride had fewer adverse reactions.⁹² It was also reported that this drug can be used safely in patients with mild to moderate hepatic function disorders.⁹³

Flavoxate Hydrochloride. In a crossover trial with propiverine hydrochloride in 46 patients with urinary urgency or urge urinary incontinence, improvement was found for urinary frequency and bladder compliance when compared with placebo.⁹⁴ In a double-blind trial on 27 patients, it was reported that a dose of 1200 mg/day was more effective than 600 mg/day (in Japan, doses up to 600 mg/day are approved).⁹⁵

In a comparative trial with clenbuterol hydrochloride on 39 patients with urge urinary incontinence, clenbuterol hydrochloride was reported to be more effective⁹⁶ and in a double-blind crossover trial on 41 patients with unstable bladder, the results did not show a significant difference in comparison with placebo.⁹⁷ In a double-blind trial on 70 patients with bladder irritation symptoms associated with prostatic hypertrophy, improvement rates were reported to show no significant difference between the flavoxate hydrochloride 1200 mg/day group and the placebo group.⁹⁸

Anticholinergic agents

Propantheline bromide, a quaternary ammonium salt, shows no selectivity and acts on all subtypes of muscarinic receptors.

In 110 patients with bladder overactivity who took parasympatholytic agents such as propantheline bromide, symptoms improved in 80 (72.7%), but in only 20% in the placebo group.⁹⁹ The results of a randomized double-blind trial on oxybutynin hydrochloride 15 mg/day, propantheline bromide 15 mg/day and placebo showed no differences in the improvement rates between the propantheline bromide 15 mg/day and placebo.¹⁰⁰

Tricyclic antidepressants

Antidepressants such as imipramine hydrochloride are used to treat urinary incontinence due to their antimuscarinic action.

In a placebo-controlled double-blind trial on 19 elderly patients with urinary incontinence, improvements were reported in 14 patients in the imipramine group and in six in the placebo group.¹⁰¹ In a comparison of groups of 105 women with urge urinary incontinence taking an antispasmodic, an antispasmodic and calcium channel blocker, and imipramine, the antispasmodic group showed the fewest adverse reactions, but also the lowest effects.¹⁰²

Drugs of the same type include clomipramine hydrochloride and amitriptyline hydrochloride.

Hormone treatment

Hormones are used to treat postmenopausal urinary urgency and urge urinary incontinence.

In a double-blind trial on 64 women with urge urinary incontinence given estriol 3 mg/day, symptoms were improved but the effects were not significant.¹⁰³

Intravesical injection treatment

In a double-blind trial on 39 women with urge urinary incontinence, the group with oxybutynin hydrochloride 20 mg injected into the bladder showed significant improvement of symptoms when compared with placebo.¹⁰⁴

Surgical therapy

Several reports have appeared on the results of augmentation enterocystoplasty in patients showing no improvement with conservative treatment such as bladder training, electrical stimulation and drug therapy.^{105–110} The number of patients with no clear neurogenic bladder among the patients in these reports ranged from 3 to 46. In all reports, excellent effects on urinary incontinence were obtained, but when it is considered that intermittent catheterization was required postoperatively in 44% to 70% of patients and the degree of surgical invasiveness was high, this should be considered only a treatment of last resort.

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†References 1–14 are Main papers used in preparation of the Guidelines on Urinary Incontinence in the Elderly, and references 15–110 are Main papers used in preparation of the Guidelines on Urinary Incontinence in Women.

The following papers are ranked by levels as follows.

Clinical research paper levels

Level I: Papers with clear results from a large-scale randomized controlled trial (RCT)

Level II: Papers with clear results from a small-scale RCT

Level III: Papers on trials with a non-randomized concurrent control group

Level IV: Papers on trials with a non-randomized retrospective control group and with opinions of specialists added

Level V: Case-driven research (no control group) with opinions of specialists added.