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Practice Guidelines

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## Japanese Practice Guidelines for Fecal Incontinence Part 2 -Examination and Conservative Treatment for Fecal Incontinence- English Version

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### Abstract

Examination for fecal incontinence is performed in order to evaluate the condition of each patient. As there is no single method that perfectly assesses this condition, there are several tests that need to be conducted. These are as follows: anal manometry, recto anal sensitivity test, pudendal nerve terminal motor latency, electromyogram, anal endosonography, pelvic magnetic resonance imaging (MRI) scan, and defecography. In addition, the mental and physical stress most patients experience during all these examinations needs to be taken into consideration. Although some of these examinations mostly apply for patients with constipation, we hereby describe these tests as tools for the assessment of fecal incontinence.

Conservative therapies for fecal incontinence include diet, lifestyle, and bowel habit modification, pharmacotherapy, pelvic floor muscle training, biofeedback therapy, anal insert device, trans anal irrigation, and so on. These interventions have been identified to improve the symptoms of fecal incontinence by determining the mechanisms resulting in firmer stool consistency; strengthening the pelvic floor muscles, including the external anal sphincter; normalizing the rectal sensation; or periodic emptying of the colon and rectum.

Among these interventions, diet, lifestyle, and bowel habit modifications and pharmacotherapy can be performed with some degree of knowledge and experience. These two therapies, therefore, can be conducted by all physicians, including general practitioners and other physicians not specializing in fecal incontinence. However, patients with fecal incontinence who did not improve following these initial therapies should be referred to specialized institutions. Contrary to the initial therapies, specialized therapies, including pelvic floor muscle training, biofeedback therapy, anal insert device, and trans anal irrigation, should be conducted in specialized institutions as these require patient education and instructions based on expert knowledge and experience.

In general, conservative therapies should be performed for fecal incontinence before surgery because its pathophysiologies are mostly attributed to benign conditions. All Japanese healthcare professionals who take care of patients with fecal incontinence are expected to understand the characteristics of each conservative therapy, so that appropriate therapies will be selected and performed. Therefore, in this chapter, the characteristics of each conservative therapy for fecal incontinence are described.

### Keywords

fecal incontinence, practice guideline, defecation disorders, examination, conservative treatments, Japanese practice guidelines

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## Introduction

Introductory comments on the Japanese Practice Guidelines for Fecal Incontinence have been provided in part 1[1]. These guidelines contain a number of items and volumes; thus, we divided them into three parts:

Part 1: Definition, Epidemiology, Etiology, Pathophysiology and Causes, Risk factors, Clinical Evaluations, and Symptomatic scores and QoL questionnaire for Clinical Evaluations[1]

Part 2: Examination and Conservative Treatments

Part 3: Surgical Treatment and Fecal Incontinence under Special Conditions

On this part 2 issue, Examination and Conservative Treatments are described.

The Fecal Incontinence Guideline Preparation Committee has proposed two algorithms to simplify the understanding of practice flow: an algorithm for primary and specialist practices (Figure 1) and an algorithm for surgical practice (Figure 2).

## Methodology

The methodology of this literature research is described in Japanese Practice Guidelines for Fecal Incontinence Part 1[1].

### Grade of Recommendation Assessment

There are many different categories for recommendations. As for this study, we used the most recent ones, which were adopted in the “JSSCR Guidelines 2010 for the Treatment of Colorectal Cancer”; we have also used those in the “Japanese Practice Guidelines for Anal Disorders.” Therefore, in the chapters on treatment and in the CQs, we have attached the evidence for classification and recommendation assessments that have been established after the Guideline Preparation Committee members have reached a consensus.

Consensus of committee members was obtained through

the following steps:

1. Voted “agree,” “oppose,” or “abstain” to each statement.

When “oppose” and “abstain” were selected, Step 2 was omitted.

2. When “agree” was selected, members explained whether the evidence level to support the statement was high (recommendation level A) or low (recommendation level B).

The following method was used in deciding the category of recommendation:

1. If all committee members agreed with the statement, the category of recommendation was determined to be either A or B, according to the evidence level. The category had to be supported by a majority of members. In case of a tie, it will be decided by the committee chairman.

2. If at least one member opposed the statement, the level of recommendation was determined to be either C or D. If more than 70% of members agreed, the recommendation was categorized as C and as D if less than 70% agreed.

Grade of Recommendation A: Based on high levels of evidence, the Guideline Preparation Committee members concur in their opinions (i.e., there are a multitude of documents, and some indicate a high level of evidence).

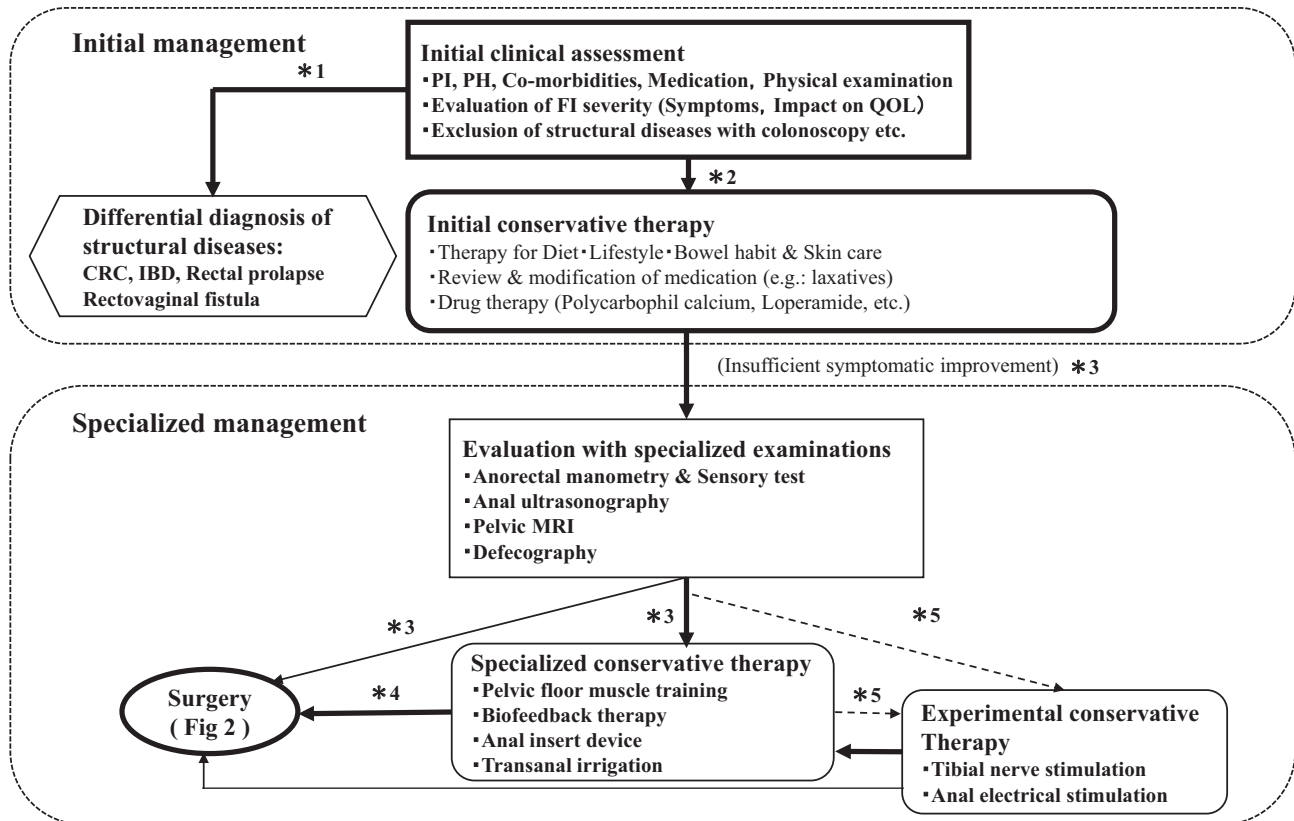
Grade of Recommendation B: Based on a low level of evidence, the Guideline Preparation Committee members concur in their opinions (i.e., only a few documents exist, and some are considered to have a low level of evidence).

Grade of Recommendation C: Regardless of the level of evidence, the Guideline Preparation Committee members do not agree.

Grade of Recommendation D: The Guideline Preparation Committee members have widely varying opinions.

## VII. Examination for Fecal Incontinence

Examination for fecal incontinence is performed in order to evaluate the condition of each patient. As there is no single examination that perfectly assesses this condition, there are several examinations that need to be performed. These



PI: present illness, PH: past history, FI: fecal incontinence, QOL: quality of life, CRC: colorectal cancer, IBD: inflammatory bowel disease

**Figure 1.** Algorithm for the Management of Fecal Incontinence. Algorithm of the Initial Management and Specialized Examination & Conservative Therapy for Fecal Incontinence.

\*1 If patients with fecal incontinence (FI) have some alarm signs on initial clinical assessment, including blood stool, recent changes of bowel habits, unexpected body weight loss, and palpable abdominal and/or rectal tumor, structural diseases should be differentiated with colonoscopy etc. Colonoscopy is also recommended if patients aged 50 years or over have never undergone it within the last 3 years.

\*2 If the examinations such as colonoscopy reveal some structural diseases including colorectal cancer, inflammatory bowel disease, rectal prolapse and rectovaginal fistula, they should be treated at first. Otherwise, patients with FI are to be treated with initial conservative therapies.

\*3 If sufficient symptomatic improvement is not achieved with the initial conservative therapies, specialized examinations are to be performed, followed by specialized conservative therapies and/or surgery.

The bold line, thin line and broken line mean that it has higher recommendation in this order.

\*4 If sufficient symptomatic improvement is not achieved with the specialized conservative therapies, surgery is to be considered.

\*5 Tibial nerve stimulation and anal electrical stimulation may be performed as experimental therapies only in clinical trials.

are as follows: anal manometry, recto anal sensitivity test, pudendal nerve terminal motor latency, electromyogram, anal endosonography, pelvic MRI scan, and defecography. In addition, the mental and physical stress the patients experience during all these examinations needs to be taken into consideration. Although some of these are used for assessment in patients with constipation, we also hereby describe these tests as tools for the assessment of fecal incontinence.

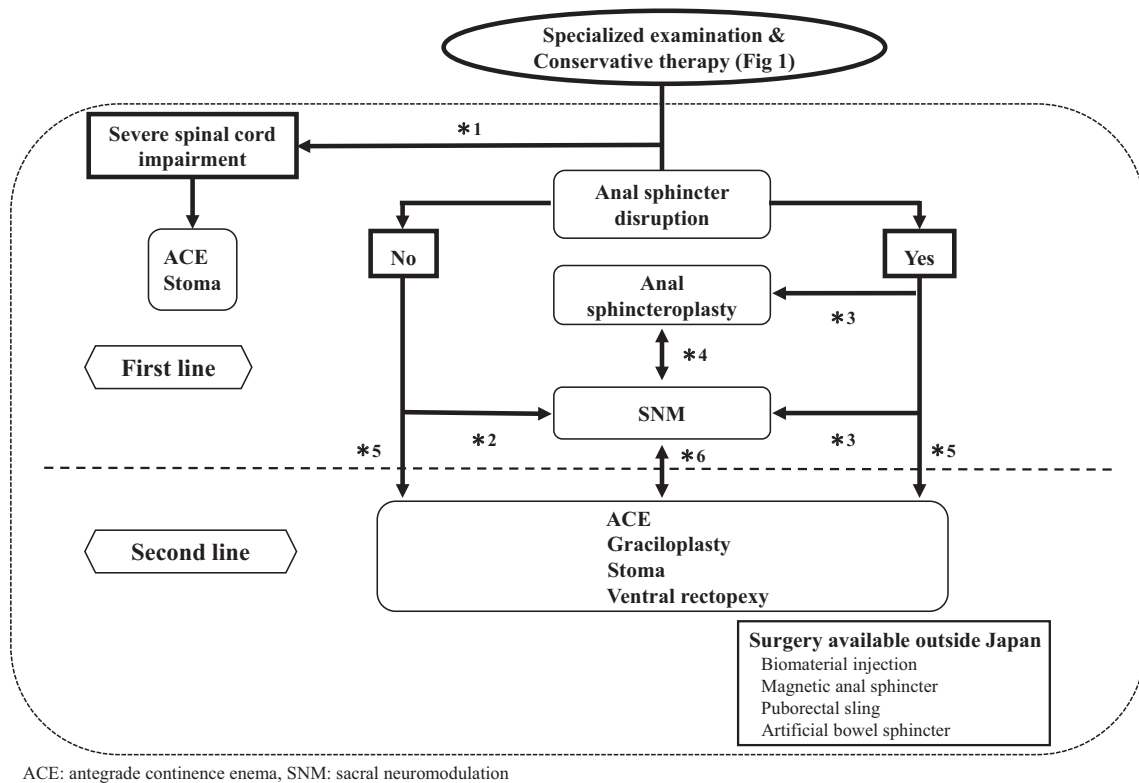
## A. Physiological Test

### 1. Anorectal manometry

#### Statement

The main parameters of this measurement include the functional length of the anal canal, resting anal canal pressure, and the voluntary contraction pressure. Resting anal canal pressure refers to the internal anal sphincter function, but it also comprises 15 to 30% of the external anal sphincter function.

#### Discussion



ACE: antegrade continence enema, SNM: sacral neuromodulation

**Figure 2.** Algorithm for the Management of Fecal Incontinence. Algorithm of Surgery for Fecal Incontinence.

\* 1 Antegrade continence enema or stoma is to be considered if fecal incontinence (FI) is caused by sever spinal cord impairment.

\* 2 Sacral neuromodulation is the first line surgical therapy for FI if it is not caused by anal sphincter disruption.

\* 3 If FI is mainly caused by anal sphincter disruption, either anal sphincteroplasty or sacral neuromodulation is to be performed.

Its decision is to be made after full discussion with patients with FI, referring to the Clinical Question 3.

\* 4 If sufficient symptomatic improvement is not achieved with one of the anal sphincteroplasty and sacral neuromodulation, the other one might be performed.

\* 5 The surgery in the second line can be performed without the surgery in the first line being performed, depending on the preference and conditions of each patient with FI.

\* 6 If the first line surgical therapies fail to achieve sufficient symptomatic improvement, the surgery in the second line is to be considered. On the other hand, the second line can be tired first depending on the preference and conditions of each patient with FI. If the second line fails, the first line can follow it.

Anorectal manometry is often performed by inserting a measurement probe into the rectum and the anal canal in order to measure the pressures. Although various items are used for pressure measurement, the basic premise is that the pressure obtained from the probe is measured via the recorder, which is then connected through the transducer. The patients are usually placed in a left lateral position during the measurement. Two kinds of pressure are measured: resting anal canal pressure at rest and squeeze pressure during contraction.

When the balloon inserted in the rectum is inflated, the anal canal pressure instantly increases and then decreases lower than the resting anal canal pressure, eventually returning to the level of resting anal canal pressure. The increased

pressure phenomenon is referred to as the recto anal excitatory reflex, while the pressure observed on the return to the baseline pressure is the recto anal inhibitory reflex[2].

Although it has been reported that the external anal sphincter contributes 15% of the resting anal canal pressure[3], the internal anal sphincter does not necessarily contribute all the remaining 85% of the pressure. Other than the contribution of the internal and external anal sphincters, the cushion element has also been identified to play a role in the anal canal pressure. Considering this, there has been a report suggesting that the ratio of each element is as follows: internal anal sphincter, 55%; external anal sphincter, 30%; and anal cushion, 15%[4].

In patients with fecal incontinence, both their resting and

squeeze anal pressures are having found to be lower compared to control subjects. Bharucha et al.[5] have reported that, in comparison to control, among the 51 female patients with fecal incontinence, 35% had reduced resting anal canal pressure and 73% had reduced squeeze pressure. Lowered resting anal canal pressure can also be observed in male patients with fecal incontinence; however, the pressure observed is higher than those of the female patients[6]. When the anal sphincter dysfunction is determined to be the main reason for fecal incontinence, resting anal canal pressure decreases in patients with passive fecal incontinence, whereas squeeze pressure decreases in patients with urge fecal incontinence. Given this, the symptoms of fecal incontinence and anal canal pressures have been determined to be associated[7].

## 2. Rectoanal sensation tests

### Statement

For the rectoanal sensation tests, methods involving the use of a balloon, electrical stimulation, etc. have been performed. In some patients with fecal incontinence, rectal sensation may significantly increase or decrease, in comparison with control subjects. On the other hand, in some cases of fecal incontinence, anal sensation has been determined to significantly decrease compared with the control subjects.

### Discussion

Among the methods utilized for the objective assessment of rectoanal sensation, there are procedures to evaluate the sensation of pressure on the rectal wall, anal mucosal sensation, and tactile sensation around the anus using a device or temperature sensation[8]. In this chapter, rectal balloon sensation and anal mucosal electro sensitivity test shall be described.

#### 1) Rectal balloon sensation test

This method is often used to objectively assess the rectal sensation, wherein a balloon is inserted into the rectum and inflated step-by-step using a volume-measurable injection connected to the balloon. The following are recorded in relation to the volume of the balloon: threshold volume, which initiates the sensation of pressure in the rectum; the desire to defecate volume, which induces the patient to defecate; and lastly, maximum tolerable volume, at which they feel the strongest tolerable urge to defecate or develop pain. The level of rectal sensation can be considered a condition of hypersensitivity when the threshold volume in patients with fecal incontinence is lower than those of the control group[5], with rectal volume also being reduced[9]. Conversely, when the maximum tolerable volume in patients with fecal incontinence is determined to be greater than that of the control subjects, it is a condition determined to be of hyposensitivity.

#### 2) Anal mucosal electro sensitivity test

After the catheter attached to the stimulation electrode is

placed on the anal mucosa, electrical stimulation is then gradually increased. The level of electrical stimulation at which the subject initially feels the stimulation is then recorded. Although normal values depend on each stimulator, when the recorded value is greater than the normal value, the sensation is judged to be decreased. In patients with fecal incontinence due to diabetes mellitus, the stimulation threshold has been found to significantly increase compared with the control subjects[10].

## 3. Pudendal nerve terminal motor latency (PNTML)

### Statement

PNTML is significantly prolonged in patients with idiopathic fecal incontinence compared with the control group. Currently, this test has low clinical significance because of its low reliability.

### Discussion

In conducting PNTML, an examiner wears a special glove that is attached with an electrode on the finger and inserts it into the rectum to stimulate both sides of the pudendal nerve. The examiner then measures the time between the initiation of the electrical stimulation and the response of the external anal sphincter. Although prolonged transmission time is assessed as a neurological dysfunction, the cutoff times may slightly vary among different institutes. It is generally assessed as abnormal when the prolonged time is more than 2.2 msec[11]. This is usually prolonged in patients with idiopathic fecal incontinence compared with the control group[10]. The different frequencies of one- or two-sided prolonged pudendal nerve latencies have been reported. In patients with idiopathic fecal incontinence, PNTML is within the normal range in both sides in 66% of patients, prolonged in both sides in 15%, and prolonged in only one side in 20%[12]. The clinical significance of this test is low because the reliability of the test is low or perhaps because PNTML itself may not be related with fecal incontinence[13].

## 4. Anal electromyogram

### Statement

The electrical activities of the external anal sphincter and the puborectalis muscles have been determined to decrease in many patients with fecal incontinence compared with the control group.

### Discussion

This is a test to assess the electrical activities of the external anal sphincter and the puborectalis muscles. This measurement is performed using a surface or needle electrode, with patients lying in a left lateral position. In a normal anal electromyogram, a motor unit potential (MUP: electrical activity with some voltage and width) can be observed in the external anal sphincter when it is contracted or during the bearing down action; however, the MUP disappears or sig-

nificantly decreases during defecation. When the electrical activity during anal sphincter contraction or coughing decreases, damage to the nerve fiber is suggested[14]. In most patients with fecal incontinence, the electrical activities of the external anal sphincter and the puborectalis muscles tend to decrease when compared with the control group[15]. When the electromyogram was performed in patients with idiopathic fecal incontinence, abnormal findings was detected in 65% of anal sphincters and in 43% of puborectalis muscles[5].

## B. Morphological Examination

### 1. Anal endosonography

#### Statement

Anal endosonography allows an objective evaluation in terms of the presence and extent of anal sphincter damage. Anal sphincter damage can be identified when a low echo portion is detected in a high echo area. The size of the damage is often correlated with the degree of fecal incontinence.

#### Discussion

In an anal endosonography, an anal probe is inserted into the anal canal in order to directly depict the morphology of the internal and external anal sphincters using sonography. In the endosonographic visualization, the internal anal sphincter is often represented by a uniformly hypoechoic area, while the outer hyperechoic area represents the external anal sphincter[16]. Clinical assessment could be achieved by measuring the width of the anal sphincter or by visualizing the defect of the anal sphincter. Defects in the external anal sphincter are identified as losses of the continuity of the normal internal hypoechoic ring; the size of the defect is often correlated with the severity of fecal incontinence[17]. It has been reported that, among patients with fecal incontinence secondary to sphincter damage, when the defective portion of the anal sphincter was depicted by endosonography prior to sphincter repair, 86% of those defective portions were identified during the operation[18].

### 2. Pelvic MRI

#### Statement

Pelvic MRI is performed in order to evaluate the thinning of anal sphincter muscle fibers or the replacement of atrophied sphincter muscle with fat. Endoanal MRI is useful in identifying the defective portion of the anal sphincter defect.

#### Discussion

Different contrast imaging can be obtained using T1- and T2-weighted imaging, while three-dimensional imaging can be obtained using coronal or sagittal images. Furthermore, dynamic MRI is useful in determining any changes of the pelvic movement[5]. From the obtained image, the thinning of anal sphincter muscle fibers or replacement of sphincter

muscle with fat can be evaluated as atrophy. The sphincter defect is also detected as a deformity or as a disruption of muscle fiber continuity[19]. Endoanal MRI can obtain a 360-degree image by inserting the coil into the anal canal. It has been reported that, when the endoanal MRI was performed in patients with fecal incontinence due to sphincter damage before sphincter repair, the sensitivity and specificity were 81% and 40%, respectively[18].

### 3. Defecography

#### Statement

Defecography is a test performed to assess the morphological movement of the rectum and pelvic floor muscles during defecation. It can also assess rectal morphological movement and detect the presence of dyssynergia, rectocele, enterocele, and rectal intussusception.

#### Discussion

Defecography has been identified as a test, which utilizes barium contrast, used for assessing the morphological movement of the rectal and the pelvic floor muscles during defecation. After inserting a mixture of contrast agent and a material for maintaining viscosity into the rectum, lateral radiographies are taken at rest, during maximum pelvic floor contraction, and during attempted defecation in a patient with sitting position. Various parameters are used for assessment among different institutes. The angle between the rectum and the anal canal is referred to as the anorectal angle, while the distance between anorectal junction and pubococcygeal line is called the perineal descent[20]. Defecography can also be used to assess the rectal morphological movement and check for the presence of dyssynergia, rectocele, enterocele, and rectal intussusception[21]. Among the different observers, the reproducibility of the morphological assessment for enterocele and rectocele is good, but is only fair to moderate for rectal intussusception cases[22].

It was reported that when defecography was performed in 50 women, aged between 30 and 87, suffering from anal incontinence, it identified 25 patients with perineal descent at rest, 28 with perineal descent at straining, 30 with rectocele, 30 with rectal intussusception, and 14 with enterocele (duplicate cases); furthermore, it was useful for assessing pathology related with these pelvic floor disorders[23].

#### CQ1. How is anal sphincter disruption assessed?

##### Statement

Large anal sphincter disruptions could be palpable by anorectal finger examination.

(Grade of recommendation C)

Anal endosonography and endoanal MRI have been both determined to be useful in diagnosing anal sphincter disruption.

(Grade of recommendation B)

### Discussion

Assessment of anal sphincter disruption is performed as follows: medical history taking, inspection, digital anorectal examination, anal endosonography, and endoanal MRI. In most cases, in medical history taking, there is often a history of traffic accident, anal surgery, or injury at delivery in many, which could be attributed as the cause of the anal sphincter disruption. Meanwhile, inspection could detect obvious trauma-induced scars around the anus, and when the defect is deemed large, the injured area could be palpable through an anorectal finger examination. Other tests, for example, anal endosonography, can depict anal sphincter damage, and it has been reported that the size of the damage is often correlated with the degree of fecal incontinence[17]. In a pelvic MRI, the sphincter defect is also detected as a disruption of muscle fiber continuity or deformity[19]. It has been reported that the sensitivity and specificity of the endoanal MRI are 81% and 40%, respectively[18].

## VIII. Conservative Therapies for Fecal Incontinence

Conservative therapies for fecal incontinence include diet, lifestyle, and bowel habit modification, pharmacotherapy, pelvic floor muscle training, biofeedback therapy, anal insert device, trans anal irrigation, and so on. These interventions have been identified to improve the symptoms of fecal incontinence by determining the mechanisms resulting in firmer stool consistency; strengthening the pelvic floor muscles, including the external anal sphincter; normalizing the rectal sensation; or periodic emptying of the colon and rectum.

Among these interventions, diet, lifestyle, and bowel habit modifications and pharmacotherapy can be performed with some degree of knowledge and experience. These two therapies, therefore, can be performed by all physicians, including general practitioners and other physicians who do not specialize in fecal incontinence. Patients with fecal incontinence who did not improve following the initial therapies should be referred to specialized institutions. Contrary to the initial approaches mentioned earlier, specialized therapies, including pelvic floor muscle training, biofeedback therapy, anal insert device, and transanal irrigation, should be performed at specialized institutions because these require patient education and instructions based on expert knowledge and experience.

In general, conservative therapies should be performed for fecal incontinence before surgery as its pathophysiologies are mostly attributed to benign conditions. This principle is exemplified in the package insert of the device for sacral neuromodulation (SNM), where it is explicitly stated that “sacral neuromodulation is indicated only for patients who have failed or are not suitable for conservative therapies.”

SNM has been defined as a surgical therapy approved by the Japanese National Health Service in 2014 for the treatment of fecal incontinence. All Japanese healthcare professionals who take care of patients with fecal incontinence are expected to understand the characteristics of each conservative therapy, so that appropriate therapies will be selected and performed. Therefore, in this chapter, the characteristics of each of the conservative therapies for fecal incontinence are described.

### A. Diet, Lifestyle, Bowel Habit Modification, and Skin Care

#### Statement

Intake of dietary fiber has been determined to be useful in treating fecal incontinence that is associated with loose stool (*Grade of recommendation A*).

Meanwhile, it is useful to refrain from taking alcohol and food that could make stool looser in treating fecal incontinence associated with loose stool (*Grade of recommendation B*).

Bowel habit instructions and skin care are useful in preventing fecal incontinence-associated dermatitis (*Grade of recommendation B*).

#### Discussion

For patients with fecal incontinence, it is advised that they should refrain from taking caffeine, citrus fruits, spicy foods, and alcoholic beverages as these could act as stool softeners[24]. A randomized controlled trial (RCT) demonstrated that the use of psyllium, a dietary fiber supplement, was able to alleviate fecal incontinence by improving stool consistency[25]. Further, another RCT reported that fecal incontinence was improved by fiber supplementation when combined with loperamide hydrochloride, an anti-diarrheal agent[26]. On the other hand, in an RCT where clinical and educational nurse intervention was made for stroke survivors to modify the diet and fluid intake for the treatment of fecal incontinence and constipation, the percentage of bowel frequency graded as “normal” by participants has significantly increased, while fecal incontinence did not improve significantly.

Instructions on proper bowel habits have been identified as one of the important methods for the management of fecal incontinence. In subjects who have normal rectal sensation, it is advised that they go to the toilet only when they feel the urge to defecate and to do so as soon as possible without unnecessary holding. On the other hand, in patients with rectal hypo sensation that could be associated with fecal incontinence, it is advised that they should plan to go to the toilet even when they do not feel the urge to defecate; this is to prevent fecal incontinence[28,29]. For example,

due to rectal hypo sensation, the elderly and/or those with spinal cord impairment will not feel any urge to defecate even when the rectum is already filled with stool. This condition, which is referred to as “rectal fecal impaction,” could lead to passive fecal incontinence through an overflow mechanism. For such patients, bowel habit instructions could be useful, wherein they are advised to go to the toilet to attempt to defecate (abdominal pressure defecation), twice a day (30 minutes after breakfast and dinner), even if they do not feel the urge to do so.

Nurse-led education and advice about diet, lifestyle, and bowel habits could alleviate fecal incontinence and are useful for both patients with fecal incontinence and their caregivers[29]. When fecal incontinence is refractory and its management is difficult, perianal skin erythema, erosion, ulceration, and fungal infection could occur. This condition, often referred to as “incontinence-associated dermatitis (IAD),” could be prevented and alleviated by appropriate skin care, including skin moisturization and protection with a slightly acidic cleanser and a skin protector. An indwelling rectal catheter and fecal collector with skin barrier could be useful to alleviate severe and refractory IAD at the perianal and perineal regions[29].

## B. Pharmacotherapy

### Statement

Calcium polycarbophil has been identified to be a useful treatment for fecal incontinence associated with loose stool (*Grade of recommendation B*).

Loperamide hydrochloride is also useful in treating fecal incontinence associated with loose stool. It is important to titrate its dosage depending on individual patients to avoid constipation as a side effect (*Grade of recommendation A*).

Ramosetron hydrochloride is useful for the treatment of urge fecal incontinence in patients with irritable bowel syndrome, associated predominantly with diarrhea (*Grade of recommendation B*).

Antidepressants (amitriptyline hydrochloride) and anxiolytics (diazepam) could be used in some patients with fecal incontinence which is not associated with loose stool (*Grade of recommendation C*).

Periodic emptying of the rectum with suppository and/or enema, in addition to bowel habit instructions, could be useful in patients with overflow passive fecal incontinence associated with rectal fecal impaction (*Grade of recommendation B*).

### Indications and concept

Patients with fecal incontinence are often determined to be in a state of slight diarrhea, irrespective of its causes, with frequent bowel motions and loose stool, characterized

by Bristol stool form scale (BSFS) types 5 to 7. Thus, the purpose of pharmacotherapy for fecal incontinence is to put patients in a state of pseudo-constipation without actually causing any symptoms of constipation, such as abdominal bloating, abdominal pain, and evacuation difficulty. This intervention aims to decrease bowel frequency and make the stool firmer by inhibiting colonic motility. To fulfill these purposes, some drugs like calcium polycarbophil, loperamide hydrochloride (loperamide), as well as ramosetron hydrochloride for irritable bowel syndrome with predominant diarrhea (IBS-D) can be used. Specifically, amitriptyline hydrochloride (a tricyclic antidepressant) and diazepam (an anxiolytic) could be useful in some patients with fecal incontinence.

Some patients with rectal hyposensation due to spinal cord impairment or aging do not feel the urge to defecate even when the rectum is filled with stool, which could often lead to overflow fecal incontinence. Meanwhile, other patients cannot empty their rectum completely on evacuation, which could lead to post-defecatory passive fecal incontinence. In such patients, periodic emptying of the rectum with judicious usage of suppository and/or enema, in addition to bowel habit instructions, could improve overflow fecal incontinence associated with rectal fecal impaction as well as post-defecatory passive fecal incontinence.

### Discussion

In total, 12 RCTs have been reported on pharmacotherapy for fecal incontinence associated with loose stool[30-32]. These studies have evaluated the efficacy of loperamide, psyllium (dietary fiber supplement), diphenoxylate, codeine phosphate, tricyclic antidepressants, sucralfate, and methyl cellulose. Among these, only loperamide had hard evidence for its efficacy[33-37]; meanwhile, one RCT had recently reported that psyllium is as effective as loperamide[32].

At present, the National Health Service in Japan has not approved any drug for the treatment of fecal incontinence. However, calcium polycarbophil and loperamide are deemed effective and can be practically used in Japan for the treatment of fecal incontinence associated with loose stool.

Calcium polycarbophil has been approved for the treatment of IBS and is effective for both IBS-D and IBS with predominant constipation (IBS-C). It is defined as a synthetic polymer of polyacrylic acid that is cross-linked with calcium. By releasing the calcium ion inside the acidic condition in the stomach, it is modified to polycarbophil, which exerts its effect as a bulking agent by absorbing intestinal liquid, in both the small and large intestines that is more than 35 times of its original weight under a neutral condition. Nearly 100% of its intake is evacuated in the stool without being absorbed in the gastrointestinal tract. As a stool stabilizer, therefore, it is expected to be effective in treating fecal incontinence through the same mechanisms as



dietary fiber[30,32]. In fact, in Japan, it has been reported that calcium polycarbophil was effective in 68% of 72 patients with FI[38]. Calcium polycarbophil was also observed to improve FI symptoms by making loose stool firmer in patients with fecal incontinence, while rarely causing constipation symptoms related to an overly firm stool, which could happen with loperamide as is discussed later. Therefore, calcium polycarbophil is recommended to be used as a first-line medication.

Loperamide has been identified as a strong anti-diarrheal agent that acts on the opioid receptors of the small and large intestines. It decreases bowel frequency by inhibiting intestinal motility, while it makes stool firmer by inhibiting the secretion and, at the same time, facilitating the absorption of water and other electrolytes in the intestine. It is useful for the treatment of patients with fecal incontinence associated with loose stool. As it can cause constipation symptoms as side effects, its dosage should be titrated depending on individual patients, so that the bowel frequency ideally ranges from every other day to twice a day and the stool consistency is between types 3 and 4 of BSFS[31,32,39]. Even just a daily intake of a 1 mg loperamide capsule is enough to cause constipation symptoms. As such, dosage should be started with 0.5 mg/day of its granule, and then, it can gradually be increased or decreased as needed. According to the guideline set by NICE (National Institute for Health and Clinical Excellence), loperamide is relatively safe and effective in a dose-dependent manner, wherein it can be used up to 16 mg per day until the ideal stool consistency and frequency have been achieved[39]. On the contrary, its upper limit approved by the Japanese National Health Service is only 2 mg/day. However, the usage of loperamide requires an extra caution as the US Food and Drug Administration has already issued a warning in June 2016 that the abuse or misuse of loperamide (average dosage: 195 mg/day in cases with adverse events) could cause an adverse event of serious arrhythmia[40]. In an RCT, which compared the efficacy for fecal incontinence between loperamide and psyllium, both were determined to be equally effective in approximately 60% of the patients with fecal incontinence, but the incidence of constipation symptoms was significantly higher in loperamide (29%) than in psyllium (10%)[32]. Loperamide achieves these improvements through its reported direct effect on anal sphincter function and its anti-diarrheal action[34,35]. In a cross-over RCT, which compared loperamide with placebo among 26 patients with fecal incontinence, loperamide has significantly decreased the incidence of fecal incontinence episodes and fecal urgency as well as bowel frequency[34]. In addition, on anal manometry, both the maximum resting and squeeze pressures have significantly increased in patients treated with loperamide for fecal incontinence whose anal sphincter function had been impaired. It is speculated that loperamide improves the anal

sphincter function due its direct actions of increasing the smooth muscle tone, inhibiting acetylcholine release from presynaptic nerve terminals, and inhibiting the biosynthesis of prostaglandin[34].

Meanwhile, ramosetron hydrochloride, a 5-HT<sub>3</sub> antagonist, is useful for the treatment of urge fecal incontinence in patients with IBS-D. In a randomized, double-blind, placebo-controlled clinical trial, which compared ramosetron hydrochloride and placebo during a 12-week study period in 442 patients with IBS-D, ramosetron hydrochloride has significantly decreased bowel frequency, made the stool firmer, and improved fecal urgency[41].

Amitriptyline hydrochloride, a tricyclic antidepressant, has also been reported to be effective for idiopathic fecal incontinence[42]. In this study, where 18 patients with idiopathic fecal incontinence were treated with low-dose amitriptyline hydrochloride (20 mg once daily before sleep) for 4 weeks, fecal incontinence symptoms significantly improved in 16 patients (89%), with the fecal incontinence score and bowel frequency having decreased significantly. The mechanisms of its efficacy are speculated to include inhibition of rectal activity and improvement of anal sphincter function on rectal contraction through the anti-cholinergic, anti-muscarinic, and serotonin-related actions of the amitriptyline hydrochloride. It is also reported that diazepam, an anxiolytic, could be used for fecal incontinence after a low anterior resection[43]. In this study, five patients with fecal incontinence after a low anterior resection for rectal cancer showed improvements within a week after being treated with diazepam (2 mg once daily).

No high-quality studies exist examining the efficacy of bowel habit instructions, usage of suppositories, and enema for the treatment of fecal incontinence. Some patients with rectal hyposensation due to spinal cord impairment or aging do not feel the urge to defecate even when the rectum is filled with stool, which could lead to overflow passive fecal incontinence. For such patients, bowel habit instructions could be useful, in which they are advised to go to the toilet and attempt to defecate even if they do not feel the urge to do so (Refer to section A: Diet · Lifestyle · Bowl habit modification and Skin care). For patients who do not respond to the bowel habit instructions and are unable to evacuate a sufficient amount of stool on defecation, periodic emptying of the rectum using a suppository (once daily after breakfast) could alleviate the frequency of bowel motions and the severity of fecal incontinence[30,44]. Some patients require an enema due to their inability to evacuate enough stool even with the daily usage of a suppository. This enema is recommended to be used at most twice a week, as it could cause rectal injury with its nozzle and could further induce the evacuation of loose stool in the descending colon that is not supposed to be evacuated at the time of the enema usage.

## CQ2. How to properly use calcium polycarbophil and loperamide hydrochloride for the treatment of fecal incontinence

### Statement

Calcium polycarbophil has been recommended as a first-line treatment for fecal incontinence associated with loose stool, aiming for BSFS type 3 or 4 as appropriate stool consistency (*Grade of recommendation B*).

Loperamide hydrochloride is recommended to be used together with calcium polycarbophil, aiming for type 3 or 4 of BSFS as appropriate stool consistency, for the treatment of fecal incontinence associated with loose stool and when fecal incontinence symptoms have not sufficiently improved even with the highest dosage of calcium polycarbophil at 3 g daily (*Grade of recommendation A*).

### Discussion

Patients with fecal incontinence are often in a state of slight diarrhea, irrespective of its causes, having frequent bowel motions and loose stools with BSFS types 5 to 7. Thus, pharmacotherapy is used to put patients in a state of pseudo-constipation without causing any symptoms of constipation. Specifically, it aims to decrease bowel frequency and make stool firmer by inhibiting colonic motility. Calcium polycarbophil[38] and loperamide hydrochloride (loperamide)[33-37] have been identified to be useful drugs for these purposes.

Patients with fecal incontinence, which is associated with loose stool with types 5 to 7 of BSFS, are to be treated at first with calcium polycarbophil 0.5-1 g, twice or thrice a day (daily dosage of 1.5-3 g) for 2-4 weeks. If fecal incontinence symptoms persist and the stool is still loose (without reaching type 3 or 4 of BSFS) even with the intake of calcium polycarbophil, a sachet of loperamide granule 0.5 mg once daily is to be added in the morning. Then, its dosage should be titrated as needed, aiming for a bowel frequency of every other day up to twice a day and a stool consistency between type 3 and 4 of BSFS. When its daily dosage has reached 2 mg, the loperamide can be prescribed as 1 mg capsule that should be taken twice daily. As has been mentioned, caution should be exercised with the administration of loperamide.

## C. Pelvic Floor Muscle Training

### Statement

Pelvic floor muscle training (PFMT), when properly instructed, can be beneficial for patients suffering from fecal incontinence (*Grade of recommendation C*).

### Indications and concept

PFMT has been determined to improve fecal incontinence by increasing the contractile function of the external anal sphincter and the pelvic floor muscles, including the levator ani, through contraction training.

It is yet to be determined what kind of patients with fecal incontinence benefit from PFMT. It is, therefore, indicated that patients understand the instructions for PFMT and be fully motivated to continue the PFMT self-training at home.

The success rate of PFMT in treating fecal incontinence has been reported to be between 41% and 66%, if properly instructed.

### Discussion

PFMT is also called “Kegel exercise” after the name of its advocate, Dr. Arnold H. Kegel[45]. In a typical PFMT, patients are instructed to contract the pelvic floor muscle for 10 seconds with 20 minutes interval for rest, while breathing normally with relaxed abdominal muscles. In a single set, this contraction is repeated up to 10 to 20 times at one time, and patients are instructed to perform 3 to 5 sets of this exercise every day[30]. Although this instruction can be given verbally or with a brochure, a therapist is recommended to make sure that patients are actually squeezing their anal sphincter by inspecting their perineum or inserting an index finger into their anus. At the same time, the therapist also instructs not to flex their abdominal muscles when squeezing their anal sphincter and further inspects this by putting a hand on their abdomen[30]. This should be given special attention because some patients with fecal incontinence, particularly those with urge fecal incontinence, tend to flex their abdominal muscles when trying to hold the urge to defecate. This contraction of the abdominal muscles could result in the increase of the intraabdominal pressure, by which patients are practically making a motion to defecate, which is contrary to their efforts to hold their stool.

In most RCTs that have evaluated the efficacy of PFMT for fecal incontinence, it has been evaluated as a control against biofeedback therapy[30,46]. The success rate of PFMT for fecal incontinence has been reported to be between 41% and 66%. However, in another study, PFMT was reported to be less effective than biofeedback therapy[47], while some studies reported no significant differences on their efficacies[48,49].

Although PFMT could be less effective than biofeedback therapy, PFMT alone improved fecal incontinence in 41% of patients who had not responded sufficiently to other conservative therapies[47]. Therefore, PFMT is beneficial as a simple therapy for the treatment of fecal incontinence.

## D. Biofeedback Therapy (BF)

### Statement

Biofeedback therapy (BF) is useful for the treatment of fecal incontinence (*Grade of recommendation C*).

### Indications and concept

BF has been determined to increase the contractile function of the external anal sphincter and the pelvic floor muscles and normalize the rectal sensation by pelvic floor muscle training, coordination training, and normalization training of the rectal sensation.

It is unknown which patients with fecal incontinence will benefit from BF. Therefore, it is indicated that patients understand the instructions for BF and are fully motivated to continue the PFMT self-training at home.

The success rate of BF for fecal incontinence has been reported to be approximately 70%, with an odds ratio of 1.2 (0.7-2.1), according to a meta-analysis which compared the efficacy of BF with other therapies.

### Discussion

Biofeedback has been defined as “a general term to describe a technique or phenomenon, in which body conditions can be consciously controlled by feed backing the unrecognizable bioinformation upon the consciousness with some engineering measures.” BF has been applied in various pathophysiologies, such as hypertension, asthma, urinary incontinence, etc., since it was first advocated by Skinner and Miller in the 1960s. Since its first reported usage for fecal incontinence, as performed by Engel et al. in 1974[50], BF was further developed and has become popular in Western countries.

In BF for PFMT, patients visually recognize the contractile activity of their own pelvic floor muscle through the use of anal electromyography or manometry, so that PFMT can be effectively instructed by a therapist and performed by patients. In a typical BF for PFMT, patients, in an outpatient setting, are instructed to perform three kinds of contraction of the pelvic floor muscle, which consist of the strongest, prolonged, and quick contractions. These contractions are then visualized using a BF device. At the same time, effectiveness is enhanced if they are instructed not to flex their abdominal muscles by visually feed backing the abdominal muscle contractile activity to them, using surface electrodes on their flank muscles. This outpatient instruction session is given once or twice a month, with an average total number of five sessions, while patients perform their self-training of PFMT at home between the sessions. During self-training, patients are required to contract their pelvic floor muscle 30 times in total to complete a set of the exercise, consisting of 10 times each of the strongest, prolonged, and quick con-

tractions. They are then instructed to perform three to five sets of the exercise every day. Therefore, when PFMT is effectively instructed, BF can be considered as a form of rehabilitation. Similar to the PFMT alone, it is very important for patients to continue their self-training at home.

In BF for coordination training, patients are asked to perform the PFMT exercises as usual, but with a balloon placed in the rectum. As the rectal balloon is expanded with air, patients would feel the urge to defecate. Then, they are instructed to perform the PFMT, in coordination with the urge sensation.

The normalization training of the rectal sensation is not performed on its own, as it is given in addition to PFMT or coordination training. In patients whose rectum is diagnosed as hypersensitive (with the maximum tolerated volume <150 mL in the rectal sensory examination to balloon distension), they are trained using a rectal balloon. A small and tolerable volume is used initially and is then gradually increased, so that patients can finally tolerate a volume of more than 200 mL. On the contrary, in patients whose rectum is diagnosed as hyposensitive (with the first sensation volume >100 mL), the opposite is done with the rectal balloon. Patients start with a large volume, and it is then gradually decreased, so that they can finally feel the first sensation between 50 and 100 mL[30].

A systematic review in 2001, mainly of case series and cohort studies, demonstrated that the success rate of BF for fecal incontinence was approximately 70%; furthermore, no difference was found between PFMT and the coordination training[51]. In a study, which examined the relationship between the effectiveness of BF for fecal incontinence and the anal sphincter damage on endoanal ultrasonography, its outcome was deemed good (improved rate: 80%) in patients who had both internal and external anal sphincters intact, whereas it was poor (improved rate: 45%) in those who had both anal sphincters damaged[52]. The RCTs published thereafter have not conclusively determined the usefulness of BF for fecal incontinence, because one RCT has demonstrated that BF was significantly effective than PFMT alone (improved rate: 76% vs. 41%)[47], while another reported that BF was as effective as pharmacotherapy or PFMT alone[48]. According to a meta-analysis of six RCTs in 2009, the odds ratio of BF regarding its efficacy for fecal incontinence was determined to be 1.2 (0.7-2.1) compared to other therapies[53]. A Cochrane review in 2012 also concluded that the definitive assessment of the role of BF for fecal incontinence was not possible[46].

Nevertheless, a good long-term result of BF for fecal incontinence has been reported, demonstrating that fecal incontinence significantly improved in the BF group compared with an untreated control group (improved rate: 85% vs. 26%), and its effects lasted for 5 years after the BF[54]. Although BF requires some specialized devices, it can be rec-

ommended for patients with fecal incontinence who do not respond to other conservative therapies because PFMT can be effectively instructed and completed without any adverse events[30,55].

### E. Anal Insert Device (Anal Plug)

#### Statement

Anal plugs can be beneficial for the management of fecal incontinence, as long as patients can keep using these without experiencing any intolerable psychological or physical discomforts, which may be caused by their retention in their anorectum (*Grade of recommendation C*).

#### Indications and concept

An anal plug refers to an anal insert device that is plugged into the anus and retained in the rectum. It is also another type of modality used to prevent fecal incontinence.

It is mainly indicated for patients with reduced anorectal sensation, such as the elderly and/or those with spinal cord impairment, because most patients who have normal anorectal sensation cannot tolerate the discomfort it may cause in the anorectal area. However, some patients with normal anorectal sensation are able to tolerate and use it without much discomfort. It is, therefore, recommended to discuss information regarding the anal plug to patients who do not respond or are ineligible for other conservative therapies as fecal incontinence can be effectively prevented by anal plugs if they can tolerate the discomfort that comes with it.

#### Discussion

Peristeen<sup>®</sup> Anal Plug (Anal Plug<sup>®</sup>) has been identified as the only anal insert device commercially available in Japan at present, although various shapes and materials of anal insert devices have been developed and reported before[56,57].

Anal Plug<sup>®</sup> is made of polyurethane and comes in two sizes, either S or L. It is covered with a dissolvable film, which keeps the plug in a columnar shape (diameter S:12 mm, L:13 mm). After it is inserted into the rectum, moisture and mucus from the rectal mucosa dissolves the film, and the anal plug then expands into a reverse conical shape (diameter S:37 mm, L:45 mm). It has a string attached to the tip of the plug, leaving the other end of it outside of the anus. By gently pulling the string outside of the anus, the expanded conical plug is fitted to the upper end of the anus which consequently plugs it, so that fecal incontinence can be prevented. It can stay in place for up 8 to 12 hours, but it must be removed by pulling the string with slight force in order to pass stool in the toilet. It can be disposed of as a household waste, but not into the toilet.

Four RCTs have been reported regarding the usage of

anal plugs[57],but only one RCT had adults as its subjects[58].In an RCT[58], which compared the two sizes of Anal Plug<sup>®</sup>, out of the 34 patients with fecal incontinence who were offered Anal Plug<sup>®</sup>, 4 declined to participate due to psychological discomfort, 2 did not attend the next visit, and 8 discontinued Anal Plug<sup>®</sup> due to discomfort after its initial or second trial. As a result, its efficacy was evaluated in only 20 patients (59%) who used it for at least 3 times. Among them, nine patients (26%) declined to use the second size of Anal Plug<sup>®</sup> due to their experience of discomfort with the first size. Consequently, only 11 patients used both sizes for 2 weeks each; therefore, it was impossible to compare their usefulness in terms of size, which was the original purpose of this study. After the study, 14 patients (41%) declined to keep using it due to discomfort or its ineffectiveness, while 4 (12%) wished to continue using it, and 2 (6%) wanted its occasional usage. As long as Anal Plug<sup>®</sup> was tolerated and used, fecal incontinence was remarkably improved.

In a prospective study, which evaluated the efficacy of a 3-week use of Anal Plug<sup>®</sup> in 30 adult patients with fecal incontinence, 7 (23%) stopped using it due to discomfort within a week, while 23 (77%) continued its usage for 3 weeks, out of whom 21 (70%) wished to keep using it after the study[59]. Among the 21 patients who wished for its continued usage, the ability to control fecal incontinence achieved 9 points (0: worst - 10: best) at the end of the study, median duration of its usage per one Anal Plug<sup>®</sup> was 8 hours, and median number of used Anal Plug<sup>®</sup> per day was 2 pieces.

As has been reported above, only 18 to 70% of patients with fecal incontinence continued to use Anal Plug<sup>®</sup> when offered. Nevertheless, Anal Plug<sup>®</sup> is useful for the management of fecal incontinence, as long as patients can keep using it without experiencing any intolerable psychological or physical discomfort.

Recently, the efficacy of a new anal insert device, called Renew<sup>®</sup>, has been reported[60].Out of the 91 patients suffering from fecal incontinence, 73 (80%) continued to use it for 12 weeks. Among them, 56 (77%) achieved 50% or significant reduction of fecal incontinence frequency. Compared with the conventional Anal Plug<sup>®</sup>, Renew<sup>®</sup> was better tolerated by patients as they reportedly felt less discomfort when using it as the volume it occupies in the rectum is much less (regular size: 0.5 mL,large size: 0.8 mL vs Anal Plug<sup>®</sup> S: 8 mL,L: 13mL). If Renew<sup>®</sup> will be introduced in Japan in the future, we would have greater choice of therapies for fecal incontinence.

## F. Transanal Irrigation (Retrograde Colonic Irrigation)

### Statement

Transanal irrigation (TAI) can be used in the management of refractory fecal incontinence, which is severe enough for much time and labor it requires (*Grade of recommendation B*).

### Indications and concept

TAI, also called “retrograde colonic irrigation”, is a therapy used to prevent fecal incontinence, in which the rectum and left colon are regularly emptied by their transanal lavage with warm water. It is also applied to refractory constipation. As it consumes much time and labor, it is indicated mostly for refractory fecal incontinence and constipation. It is often used in patients with spinal cord impairment and in children with spina bifida who have both symptoms of fecal incontinence and constipation. It is also useful for patients who have severe symptoms of bowel and anorectal disorders after low anterior resection, referred to as low anterior resection syndrome (LARS).

### Discussion

TAI is a therapy utilized to prevent fecal incontinence, in which the rectum and the left colon are emptied daily or every other day after infusing 500-1,500 mL of warm water into the anus. It requires so much time and labor that only patients with refractory fecal incontinence and/or constipation continue the therapy, because the water infusion takes approximately 15 minutes and its complete evacuation with stool requires approximately 45 minutes. If it is continued without significant psychological or physical burden, it can improve a severe case of fecal incontinence, which can lead to a better quality of life (QOL). Although dedicated devices for this therapy, such as Peristeen<sup>®</sup> anal irrigation system, are available in foreign countries, there is no such device in Japan at the time of the publication of this guideline that can be used for the medical application of TAI.

Only one RCT has been reported regarding the use of TAI[61-63], in which its effectiveness was compared by randomizing 87 patients with spinal cord injury into 2 intervention groups: TAI and other conservative bowel management. Out of the 42 patients who underwent TAI in this RCT, 30 (71%) continuously used it throughout the entirety of the 10-week study period. Both fecal incontinence symptoms and fecal incontinence-specific QOL evaluated using Fecal Incontinence Quality of Life (FIQL) scale significantly improved, compared with the control group of conservative bowel management[61]. It was also demonstrated in this study that TAI was more cost-effective than the other conservative bowel management[64].

In a retrospective study, in which 348 patients with fecal incontinence and/or constipation underwent TAI, 145 (42%) continued its use, with a mean follow-up of 21 months[65]. The continued rate, which is usually regarded as a “success rate” in this therapy, was higher in patients with neurogenic bowel dysfunction (63%) and anal insufficiency (51%), while it was lower in those with idiopathic constipation (34%) and sequela to anorectal surgery (29%). In this study, one case of rectal and another case of sigmoid colon perforations were reported out of the total 110,000 irrigations. Despite its low incidence, the presence of an intestinal perforation warrants extra caution as it may be a serious adverse event.

TAI is also useful for patients with LARS. In a retrospective study, in which 26 patients with LARS underwent TAI, 21 (81%) continued its use, and fecal incontinence symptoms were completely resolved in 15 (71%) patients[66]. In a prospective study that followed 14 patients with LARS who underwent TAI, all patients continued its usage for a median follow-up of 29 months[67]. In this study, median bowel frequency significantly decreased both during the daytime (eight times to once a day) and the nighttime (thrice to none in a day). Furthermore, the Cleveland Clinic Florida Fecal Incontinence Score significantly improved from 17 to 5, so did the QOL, as evaluated using FIQL and SF-36.

As has been stated above, many patients discontinue TAI, because it is time-consuming and laborious. However, it is still considered useful for patients with refractory fecal incontinence, which is severe enough for the time and labor required. The reasonably good outcomes described above are based on the studies reported from foreign countries, where some dedicated devices for TAI are available. We must bear in mind that similar results might not be achieved in Japan, where the necessary devices are not available at present. It is expected that medical devices dedicated for TAI will be introduced to or developed in Japan in the near future.

## G. Other Conservative Therapies

### 1. Tibial nerve stimulation (TNS)

#### Statement

Tibial nerve stimulation (TNS) is often not recommended as a useful therapy for fecal incontinence because the evidence level for its efficacy is low, although it is less invasive and less expensive than SNM.

#### Indications and concept

TNS is a mode of therapy in treating fecal incontinence by using an external nerve stimulator to electrically stimulate the tibial nerve, which runs behind the ankle medial malleolus. There are two kinds of TNS: percutaneous TNS

(PTNS), in which a needle electrode is inserted through the skin, and transcutaneous TNS (TTNS), in which an electrode pad is placed on the skin. TNS should be performed only in clinical trials at the moment because the evidence level for its efficacy is low, and there is no dedicated medical device available for this therapy in Japan at present.

#### *Discussion*

TNS is considered to work by electrically stimulating sacral nerve plexus, similar to SNM, as the tibial nerve originates from the sacral nerve. Although it is obvious that TNS is less expensive and less invasive with less adverse events compared with SNM, the evaluations of TNS have not conclusively determined its efficacy to improve fecal incontinence. One reason for this uncertainty is that there is no consensus regarding the optimal stimulation conditions and methods of this therapy.

A systematic review regarding TNS identified 6, 5, and 1 studies for PTNS, TTNS, and both, respectively[68]. Among them, 2 studies were RCTs and 10 were case series. According to the systematic review, the success rates of PTNS and TTNS ranged from 63 to 82% and from 0 to 45%, respectively. In an RCT for TTNS, which was compared with sham stimulation in 144 patients with fecal incontinence, the superiority of TTNS was not validated, suggesting that its efficacy could be just a placebo effect[69]. No similar study was performed for PTNS. This systematic review, therefore, stated that no reliable conclusion could be drawn regarding the efficacy of TNS, although both PTNS and TTNS might improve fecal incontinence to some extent. Afterward, however, one RCT studied the effect of PTNS, in comparison with sham stimulation among 227 patients with fecal incontinence[70]. No significant differences were noted in the success rate between the groups.

## **2. Anal electrical stimulation**

### *Statement*

Anal electrical stimulation is often not recommended as a useful therapy in treating fecal incontinence as the evidence level for its efficacy is low, although it is a low-cost and minimally invasive therapy.

### *Indications and concept*

Anal electrical stimulation is defined as a therapy used to treat fecal incontinence by electrically stimulating anal sphincters with an anal plug electrode inserted into the anal canal. It is unknown what kind of patients with fecal incontinence benefit from this therapy, and the evidence level for its efficacy is currently low. Anal electrical stimulation should be performed only in clinical trials at the moment because it is not approved by the National Health Service and no dedicated medical device is available for this therapy in Japan at present.

### *Discussion*

Anal electrical stimulation seems to improve fecal inconti-

nence by increasing the contractile strength of the anal sphincters during passive contraction through electrical stimulation of their neuro-muscular junction. However, an RCT has reported that the main effect of this therapy might not be sphincter contraction, but actually sensitization of patients to the anal area. Furthermore, it might simply be a placebo effect because a similar improvement of fecal incontinence was achieved by sham stimulation at 1 Hz, with which anal sphincters were not contracted, compared with active stimulation at 35 Hz, with which they were contracted[71].

The efficacy of anal electrical stimulation as a treatment for fecal incontinence is yet to be evaluated due to the varying stimulation conditions and methods used in most studies, leading to a lack of consensus on these matters. Several case studies have reported that this therapy is effective on its own with a 60 to 70% success rate[72-74], while an RCT did not detect any statistically significant difference between the active and sham stimulation regarding their efficacy to improve fecal incontinence[71]. In addition, a Cochrane review of this therapy also concluded that "At present, there are insufficient data to allow reliable conclusions to be drawn on the effects of electrical stimulation in the management of FI. There is a suggestion that electrical stimulation may have a therapeutic effect, but this is not certain."[75]

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