Practice Guidelines

Japanese Practice Guidelines for Fecal Incontinence Part 3 -Surgical Treatment for Fecal Incontinence, Fecal Incontinence in a Special Conditions- English Version

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Abstract

In Japan, the surgical treatment for fecal incontinence (FI) can be performed using minimally invasive surgery, such as anal sphincteroplasty and sacral neuromodulation (SNM), as well as antegrade continence enema (ACE), graciloplasty, and stoma construction. In addition, currently, several other procedures, including biomaterial injection therapy, artificial bowel sphincter (ABS), and magnetic anal sphincter (MAS), are unavailable in Japan but are performed in Western countries. The evidence level of surgical treatment for FI is generally low, except for novel procedures, such as SNM, which was covered by health insurance in Japan since 2014. Although the surgical treatment algorithm for FI has been chronologically modified, it should be sequentially selected, starting from the most minimally invasive procedure, as FI is a benign condition.

Injuries to the neural system or spinal cord often cause disorders of the sensory and motor nerves that innervate the anus, rectum, and pelvic floor, leading to the difficulty in controlling bowel movement or FI and/or constipation. FI and constipation are closely associated; when one improves, the other tends to deteriorate.

Patients with severe cognitive impairment may present with active soiling, referred to as "incontinence" episodes that occur as a consequence of abnormal behavior, and may also experience passive soiling.

Keywords

fecal incontinence, practice guideline, defecation disorders, surgical treatments, fecal incontinence in a special condition, Japanese guidelines

Introduction

The introductory comments of the Japanese Practice Guidelines for Fecal Incontinence (FI) have been described in Part 1[1]. These guidelines contain numerous items and are large in volume; therefore, we have reported them in three parts: Part 1: Definition, Epidemiology, Etiology, Pathophysiology and Causes, Risk Factors, Clinical Evaluations, and Symptomatic Scores and Quality of Life (QOL) Questionnaire for Clinical Evaluations[1]; Part 2: Examination and Conservative Treatment[2]; and Part 3: Surgical Treatment and Fecal Incontinence Under Special Conditions. This document describes Part 3 of the guidelines.

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 literature research has been described in the Japanese Practice Guidelines for Fecal Incontinence Part 1[1].

Grade of Recommendation Assessment

There are several categorizations for the recommendations. We used the most recent ones, which are adapted from the "JSSCR Guidelines 2010 for the Treatment of Colorectal Cancer," and also those described 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 through a consensus of the Guideline Preparation Committee members.

The consensus of the 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 to decide the category of recommendation:

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

2. If at least one member opposed the statement, the level of recommendation was determined as C or D. The recom-

mendation was categorized as C or 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 low-level 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.

IX. Surgical Treatment for FI

Introduction

In Japan, the surgical treatment for FI can be performed using minimally invasive surgery, such as anal sphincteroplasty and sacral neuromodulation (SNM), as well as antegrade continence enema (ACE), graciloplasty, and stoma construction. In addition, currently, several other procedures, including biomaterial injection, artificial bowel sphincter (ABS), and magnetic anal sphincter (MAS), are unavailable in Japan but are performed in Western countries.

However, the evidence level of surgical treatment for FI is generally low, except for novel procedures, such as SNM, which were covered by health insurance in Japan in 2014; this could be because randomized controlled trials and large-scale clinical trials are difficult to conduct owing to the nature of the surgical treatment. In addition, the definitions of FI and fecal continence have not been standardized in the past, as well as the assessment method for incontinence severity.

Although the surgical treatment algorithm for FI has been chronologically modified, it should be selected in order, starting with the most minimally invasive procedure, since FI is a benign condition.

In Japan, to properly select and perform these surgical treatments, the characteristics of each treatment should be well known to general practitioners and specialist surgeons. This section describes the statement and discussion of each treatment.

A. Anal Sphincter Repair/Sphincteroplasty

Statement

Anal sphincter repair and sphincteroplasty are useful for the treatment of FI due to lacerations of the anal sphincter.
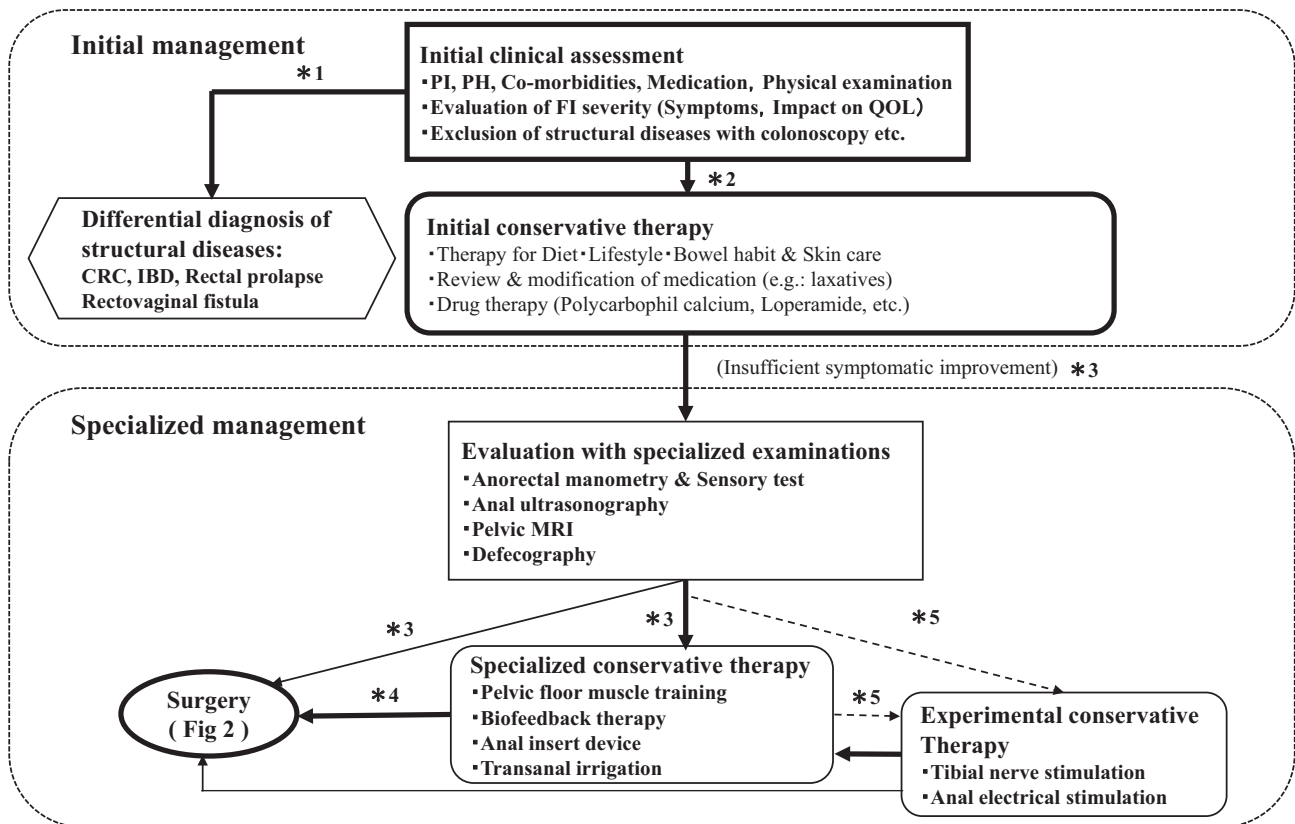
PI: present illness, PH: past history, FI: fecal incontinence, QOL: quality of life, CRC: colorectal cancer, IBD: inflammatory bowel disease

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 withing 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.

The short-term outcomes of these surgical treatments are favorable; however, the results deteriorate in the long term. (*Grade of recommendation B*)

Indications and concept

These surgical procedures, including the anatomical repair of lacerated anal sphincter, are indicated for patients with FI due to sphincter impairment. The most common cause of sphincter impairment is perineal laceration during delivery, as well as postoperative anal fistula and road traffic injuries. Anal sphincter repair includes suturing the freshly lacerated sphincter stump, while sphincteroplasty is the procedure used to repair residual lacerations with previously sutured edges or spontaneously healed sphincter lacerations that have become scar tissue. However, both medical terms are often used interchangeably.

Discussion

The common surgical procedure in both is overlapping sphincteroplasty that involves suturing the superimposed sphincter and scar tissue with each other; it was first reported in 1971[3]. However, a randomized controlled trial
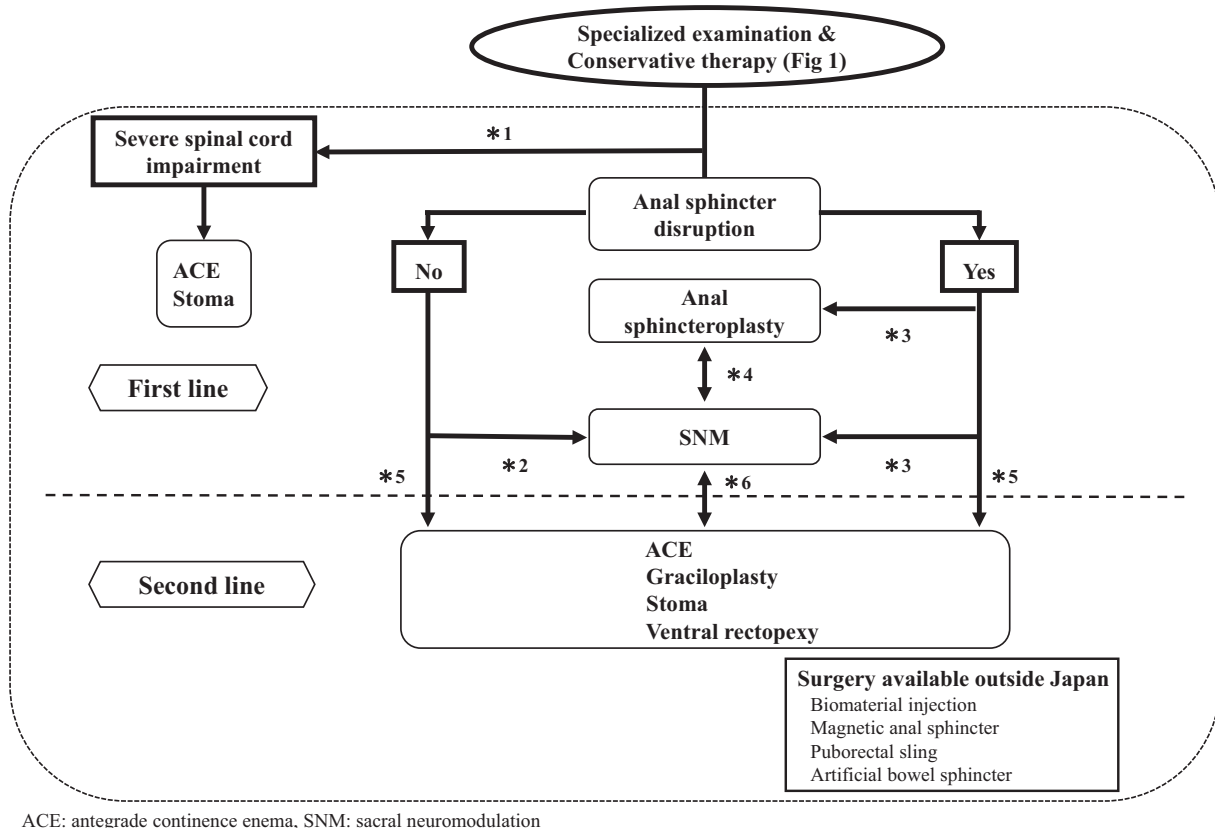
ACE: antegrade continence enema, SNM: sacral neuromodulation

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.

reported that the outcomes of direct repair[4], which involves direct suturing without overlapping the stumps, are comparable to those of overlapping sphincteroplasty.

Short-term outcomes of less than 3 years after surgery have been reported with a 60%-85% success rate[5,6]. The Cleveland Clinic Florida Fecal Incontinence Score (CCFIS) and maximum squeezing pressure at 3 months postoperatively were significantly lower and higher, respectively, than those before surgery in Japan[7]. However, long-term outcomes of 5 years or more have a success rate of 10%-46%[6,8,9]. The etiologies of poor long-term outcomes include sphincter atrophy caused by mobilization of the normal anal sphincter during surgery, sphincter degeneration due to aging, tissue extension, and pudendal nerve dysfunction.

The efficacy of sphincteroplasty is low for FI developed long after injury during delivery[6]. For such cases, studies recommend that SNM precede sphincteroplasty[10]; however, at present, no direct comparison study of the two surgical treatment exists. In addition, reoperation is not recommended due to unfavorable surgical outcomes in patients with FI without improvement or relapse after sphincteroplasty[6].

With respect to preoperative prognostic factors for predicting surgical outcomes, there are reports stating that the outcomes are excellent among young people[11], but reports

denying the relationship with age also exist[12]. Similarly, there are studies that report the duration of symptoms[13] and pudendal neuropathy[14] as predictive factors and studies that deny this claim[12]. Therefore, there is no robust evidence concerning prognostic factors.

In terms of postoperative complications, the incidence of wound infection is high (24%), which might lead to wound dehiscence. A case of rectovaginal fistula owing to wound infection has been reported[15]. Wound infection may affect sexual function and cause secondary fecal impaction or urinary tract infection.

B. Sacral Neuromodulation: SNM

Statement

SNM is a minimally invasive and reversible surgical treatment for FI. (*Grade of recommendation A*)

Indications and concept

SNM is a surgical treatment that uses electrical stimulation of the sacral nerve for FI and constipation; lower urinary tract dysfunction, including urinary incontinence and dysuria; and pelvic floor dysfunction, including chronic pelvic pain. In Japan, reimbursement for the treatment of FI was started in April 2014.

SNM is divided into two stages, and the stimulation lead is placed in the first stage. The efficacy of the procedure is evaluated over a test stimulation period of approximately 2 weeks, and the nerve stimulation device is implanted only in effective cases through a second operation. In contrast, the stimulation lead is removed in ineffective cases. The features of SNM are effective case selection using this test stimulation, and reversibility, such that return to the original condition without deterioration of symptoms is possible in invalid cases. In the Japanese medical insurance system, these two-step SNM procedures have been individually reimbursed from 2014.

SNM is indicated for patients in whom conservative treatment is ineffective or inapplicable, and surgeons performing SNM are required to attend a seminar to obtain the certification for the procedure.

Discussion

The efficacy of SNM for urinary incontinence was first reported in 1982[16], while the implantation of a stimulation device for FI was first performed in 1995[17]. SNM has already been approved as a surgical treatment device for FI in 27 countries of the European Union and the United States (USA). Moreover, SNM has been performed worldwide in about 200,000 patients (as of December 2015) with pelvic floor dysfunction.

Regarding the effect on FI, in the US clinical trial[18],

test stimulation was performed in 133 patients, and the stimulator was implanted in 120 patients (90%). Of these, 88 patients (83%) were successfully treated (patients in whom the frequency of FI decreased by 50% or more), it could be evaluated 1 year after surgery in 106 patients, and complete continence was obtained in 43 patients (41%). FI-specific QOL also significantly improved. A 89% success rate was seen in a clinical study on 76 patients with a follow-up period of 5 years, and complete continence was maintained at 36%[19].

In a multi-institutional study in Japan[20], test stimulation and implantation were performed in 22 and 21 patients (95%), respectively, of which 18 (86%) were successfully treated after 6 months and complete continence was observed in 4 (19%).

Regarding the cause-specific outcomes of SNM for FI, the success rate for idiopathic FI without sphincter injury was 75%[21], while favorable outcomes have also been reported in patients without sphincter injury[22]. In a systematic review of the effects of SNM on FI after surgery for rectal cancer[23], 43 patients (79%) underwent test stimulation, and the stimulator was implanted in 34 patients (79%). The symptoms improved in 32 patients (74%), indicating that the results were similar to those of other studies. In addition, the efficacy of SNM for FI due to postoperative rectal prolapse[24], Crohn's disease[25], ulcerative colitis[26], and cauda equina syndrome[27] has been reported.

In other words, the cause of FI does not determine the indication for SNM. SNM is indicated for all patients in whom conservative therapy is ineffective and test stimulation can be safely performed.

The most common adverse effect was pain at the implantation site in about 25% of patients, followed by infection at the implantation site in about 10%[18,20]. In the US clinical trials[18], stimulator modification was observed in 6%, replacement in 7%, and removal in 11% of patients. However, numerous other adverse effects could be addressed with conservative therapy or program adjustments.

Magnetic resonance imaging (MRI) can be performed only with head MRI that meets the criteria, and other sites of MRI is contraindicated for SNM. Hyperthermia (diathermy) with an ultra-shortwave or microwave treatment device is contraindicated due to the risk of tissue damage and damage to stimulator caused by heat generation at the electrode implantation site.

Although the exact mechanism of SNM is unclear, it is thought to be multifactorial in nature, including contraction of the anal sphincter and levator ani muscle via the pudendal nerve, involvement of the autonomic nervous system via the pelvic nerve plexus, and effects on the central nervous system via the spinal cord by electrical stimulation of the sacral plexus[28].

C. Antegrade Continence Enema: ACE

Statement

Although ACE for FI has some morbidities, such as wound infection and postoperative stenosis, it is useful because it can be performed in a shorter time with lesser lavage fluid than with transanal irrigation. (*Grade of recommendation C*)

Indications and concept

ACE is a useful surgical treatment for FI that involves keeping the large bowel empty with its periodic antegrade lavage via an appendiceal or cecal fistula created by laparotomy, laparoscopic surgery, or endoscopic placement[29]. Retrograde colonic irrigation takes time and effort to flush the bowels and is indicated for serious defecation disorders, such as frequent bowel movements and severe FI. Compared with retrograde colonic irrigation, ACE has the advantages of lesser amount of liquid and shorter cleansing time. However, despite it being minimally invasive, a surgical procedure is required, and the problem of body image, like a stoma, can be a disadvantage of ACE.

Discussion

ACE was initially reported by Malone et al. in the UK in 1990[30] and was mainly performed for pediatric neurogenic defecation disorders[31]. Subsequently, it has been applied for the surgical treatment of adult FI and constipation[32].

Long-term outcomes regarding the assessment of bowel function, social life, and QOL showed significant improvements in FI as well as in chronic constipation and neurogenic defecation disorders[33]. In a systematic review of studies on adults[34], 78%-100% of patients continued ACE during a follow-up period of 22.5-48 months. Moreover, in a retrospective study of 75 patients[35], 64 (85%) continued ACE after a median follow-up period of 48 months, and the postoperative CCFIS significantly improved from 14.3 to 3.4. The reasons for ACE discontinuation were abdominal pain during the procedure and prolonged FI.

The most common postoperative complication is wound infection (45%)[36], and other early complications, such as intestinal perforation, have been reported[33]. Late complications include increased incidence of postoperative stenosis[33] requiring bougie dilatation or reoperation[37]. However, these complications are attributed to the conventional appendiceal fistula, and in the recent years, the gastrostomy kits utilized in adults may considerably reduce these complications.

ACE is often performed daily or every other day, and when it is not in use, it can be covered with a dressing or the button of a gastrostomy kit. Regarding the adverse effects of ACE, pain during catheter insertion, nausea, malaise, and skin disorders have been reported[33].

D. Gracioplasty

Statement

Gracioplasty is a surgical treatment option for FI that should be performed in highly specialized institutions due to the difficulty of the technique and the need of some number of patients for technical acquisition. (*Grade of recommendation D*)

Indications and concept

When performing gracioplasty, the gracilis muscle is mobilized and wrapped around the anus, and the tendon on the distal side of the gracilis is sewn to the opposite sciatic bone to achieve optimal pressure in the anal canal and to maintain fecal continence[38]. The procedure is often selected for severe FI, where other surgical treatments are ineffective, and there is no other alternative to constructing a stoma.

Discussion

This surgical procedure was first reported in 1952 for FI in children[39] and was subsequently applied in the treatment of adult incontinence[40]. There are two types of surgery: adynamic gracioplasty (AG)[41], which simply includes muscle grafting, and dynamic gracioplasty (DG)[40], which refers to the muscle grafting with an electrical stimulation device. To obtain good response with the procedure, gracilis muscles composed of type II muscle fibers (fast muscles) that tend to cause contraction fatigue should contract for a long time, like the type I external sphincter muscles. Although DG was conventionally used to modify type II into type I muscles, the electrical stimulator has not been used for DG after the introduction of SNM. Therefore, DG was not implemented in Europe and USA. However, in the recent years, it has been reported that the effect of DG could be obtained in AG by performing transanal electrical stimulation for 6 months after the operation[42].

In a multicenter study on 123 patients with FI, DG was efficacious in 81 (66%) 18 months after the operation[40]. A systematic review revealed that the efficacy of DG is 42%-85%[43]. Among the 31 patients who underwent DG after abdominoperineal resection for rectal cancer, 26 were able to evaluate bowel function after the operation, of which 22 (71%) retained fecal continence on a median follow-up of 37 months[44]. According to a report in Japan[38], 15 patients with severe FI underwent gracioplasty (AG, 12 cases; DG, 3 cases); Kirwan classification grade 2 (gas incontinence only) or higher was maintained in 8 (67%) out of 12 patients (excluding 3 with stoma construction).

Complications occurred 189 times in 91 patients (74%),

and in a multicenter study of 123 patients, surgery for complications was performed in 49 (40%)[40]. A systematic review of DG reported an average of 1.12 complications per patient with a surgery-related mortality of 2%[43]. As described above, graciloplasty is a surgical treatment option that should be performed in a highly specialized facility because the procedure is particularly complicated and difficult, and numerous operations for the treatment of FI are required to master the surgical technique.

E. Stoma Construction

Statement

Stoma construction is a useful surgical treatment option for severe FI. (*Grade of recommendation B*)

Indications and concept

Stoma construction is considered to be the last resort for severe FI. However, it is not necessarily a failure as a FI treatment. It is one of the surgical treatment options for severe FI and is the simplest and most fundamental procedure if the patient does not mind the psychological aspect of body image being different from others. A well-shaped and well-placed stoma in an appropriate location can favorably control FI.

Discussion

In the recent years, advanced stoma appliances are available, and environmental maintenance, such as management guidance by wound, ostomy, and continence nurses, has also progressed. Consequently, the QOL of an ostomate has also improved. Although there are no reports of high levels of evidence, such as randomized controlled trials, a cross-sectional survey showed that 39 ostomates had a significantly higher QOL than 71 patients with FI, including those with postoperative rectal cancer, diverticulitis, and FI[45]. According to the results of a questionnaire survey of 69 ostomates with stoma construction for the treatment of FI[46], the median value was 8 points when the postoperative ability of physical activity was evaluated on a scale of 10. In addition, 83% of patients replied that stoma construction limited their daily life "slightly" or "not at all," indicating that the QOL improved after stoma construction as compared with severe FI.

A systematic review of the cost-effectiveness of the stoma construction group[47], ABS group, and graciloplasty group for FI revealed that the stoma construction group was the most cost-effective at 5 years postoperatively.

In addition to general skin problems, stoma complications include diversion colitis associated with Hartmann's operation[48], parastomal hernia, and stoma prolapse, which may require abdominoperineal resection or stoma reconstruction.

F. Other Surgical Treatments

1. Biomaterial injection

Statement

Although biomaterial injection has been reported to be effective for FI in a few patients in Europe and the USA, reports of complications, such as anal pain and ulceration, also exist. This procedure has not been approved in Japan.

Indications and concept

This procedure, which is unapproved in Japan for FI, involves injecting a biomaterial substance into the anal submucosa and inter-sphincteric space with bulging and appropriate closing of the anal canal.

Discussion

The injected material should be biocompatible, nonallergenic, easy to inject, and non-tissue transferable. Since it was reported in 1993 that injecting polytetrafluoroethylene into the anal submucosa was effective for FI in 64% of patients[49], various biocompatible substances have been used[50]. However, the number of patients has been small, and complications, such as anal pain and ulceration, have been reported.

Currently, Gatekeeper™ (THD, Correggio, Italy) is approved in the EU, and Solesta® (Salix, Raleigh, USA) is approved in the USA. Gatekeeper™ is a solid substance made from a polyacrylonitrile, which is injected under ultrasound guidance between the internal and external anal sphincter muscles to close the anal canal. During a median follow-up period of 33.5 months, injecting Gatekeeper™ in 14 patients for FI improved the frequency of incontinence from 7.1 to 0.4 times/week and the CCFIS from 12.7 to 5.1[51].

Solesta®, which is approved in the USA in 2011, is a liquid substance of dextranomer beads/stabilized sodium hyaluronate gel, which is injected in 1 ml doses in 4 directions under the anal mucosa, 5 mm orally from the dentate line, and closes the anal canal. Comparison of a double-blind study 6 months after the injection[52] showed that 71 (52%) of the 136 patients in the Solesta group had improved incontinence with significant difference, compared with 22 (31%) of the 70 patients in the Sham group having improved. In this study, 136 patients who had received Solesta® were followed up for 3 years[53], and the frequency of FI improved by 50% or more in 52%, 57%, and 52% of patients 6 months, 1 year, and 3 years after surgery, respectively.

2. Artificial bowel sphincter (ABS)

Statement

A multicenter study in North America reported that ABS was effective. However, complications, such as infection and equipment malfunction, have been reported. ABS is an unapproved surgical treatment in Japan.

Indications and concept

The device used for FI is Acticon Neosphincter® (American Medical Systems, Minneapolis, USA), a modified version of urinary incontinence, with a closed cuff around the anal canal and a switch implanted in the labia majora or scrotum. It is a technique to open and close the anus with an implanted switch; however, it is not approved in Japan.

Discussion

Artificial sphincter surgery was first performed as a procedure for urinary incontinence in 1973, and in Japan, it was covered by health insurance in April 2012 for severe urinary incontinence after radical prostatectomy. Since it was first implemented as an artificial anal sphincter for FI in 1987[54], the device has been continuously improved and was commercialized as Acticon Neosphincter® in 1996. A randomized controlled trial of 14 patients with FI[55] showed a significant improvement in CCFIS and QOL scores in the ABS group compared with the conservative therapy group, and complications included perineal infection and rectal fecal impaction. In a comparison study between eight patients who underwent ABS and eight who underwent gracioplasty[56], the FI score in the ABS group was significantly lower than that in the gracioplasty group. However, there were more patients with infection and more patients requiring removal or repositioning of the device due to erosion or pain. In a large multicenter study of 115 patients[57], the incidence of infection and device-related complications was extremely high at 87%, and 35% of the devices were removed. In the remaining 65% of patients, 85% had a significant success rate with markedly improved FI and QOL. As a result, the success rate for all patients who underwent ABS was approximately 50%. At present, this surgical procedure has numerous problems, including equipment malfunction.

3. Magnetic anal sphincter (MAS)

Statement

MAS is a minimally invasive surgical treatment approved in the EU and USA and has shown to be useful in a small number of cases. However, the long-term outcomes and complications are unknown, and it is an unapproved surgical treatment in Japan.

Indications and concept

This surgical treatment utilizes magnetic force: 14-20 titanium magnetic beads are connected with a wire and placed around the anal canal[58]. The anal canal is closed according to the contraction force generated by the magnetic attracting force between the beads, and fecal continence is obtained. The abdominal pressure opens the magnetically closed anal canal and allows for defecation. It was approved in the EU in 2011 and was used under the product name FENIX™ (Torax Medical Inc, Shoreview, USA); however, it is unapproved in Japan.

Discussion

A magnetic device was originally developed for the treatment of gastroesophageal reflux disease. Regarding FI, MAS was performed in 23 women[59], and the CCFIS significantly improved from a median of 15.2 (preoperatively) to 5.3 (36 months postoperatively), and FIQL also significantly improved from 1.97 to 2.93. In addition, 16 patients (70%) were satisfied with the outcome, and 14 (61%) said that they would likely recommend it to other patients. However, the complications included anal bleeding and fecal impaction. The device was removed due to complications in two cases (8.7%) with a median follow-up period of 18 months. Although it is a less-invasive surgical procedure, evaluating the long-term outcomes and complications in patients is necessary.

4. Puborectal sling

Statement

Puborectal sling is one of the surgical treatment methods for FI that uses meshes; the evaluation of this technique has not yet been established.

Indications and concept

Puborectal sling is a surgical procedure for improving FI by pulling the upper edge of the anal canal from the posterior to the pubic bone in a sling shape using an elastic polyester mesh to sharpen the recto-anal angle.

Discussion

In a study with eight patients[60], a mesh was placed between the internal and external anal sphincter muscles, and rectal ulcer developed in one patient, necessitating sling removal. In the remaining seven patients, the FI score (FISI, CCFIS) and QOL score (FIQL) significantly improved. Thereafter, the procedure was modified to prevent anal ulcers by placing a mesh outside the external anal sphincter[61]. A modified procedure was performed in four patients, and refractory deep peripubicitis was observed in one. Furthermore, to avoid the risk of blind manipulation on the dorsal side of the pubis, the procedure was modified by guiding the sling to the front side of the pubis with a subcutaneous tunnel and fixing it. The symptoms of FI improved in three patients.

In a multicenter study conducted by 14 institutions in the USA, trans-obturator postanal sling (TOPAS®, American Medical Systems, Minneapolis, USA) was developed and performed in 152 female patients with FI[62]. Twelve months after surgery, the frequency of FI improved by 50% or more in 69% of patients; complete continence was seen in 19% of patients, and CCFIS and FIQL significantly improved. There were 66 patients and 104 events with complications, most of which were short-term complications and 97% of patients conservatively improved without the need to expose or replace the sling. Although TOPAS® has not been approved in Japan, evaluating the long-term outcomes and

complications in the USA in the future is necessary.

5. Ventral rectopexy

Statement

Although ventral rectopexy is a useful surgical treatment for FI caused by rectal intussusception and rectocele, its evaluation in a large number of patients has not yet been conducted.

Indications and concept

Ventral rectopexy is a surgical procedure in which the rectum is fixed after intraperitoneally mobilizing the right side of the rectum and anterior wall (rectovaginal septum), and both ends of the mesh are sutured to the ventral side of the lower rectum and sacral promontory, respectively. It was first reported by D'Hoore et al. in 2004[63] originally as a surgery for rectal prolapse. It has the advantage of preserving the autonomic nerve. The procedure is indicated for rectal intussusception or rectocele, which may cause FI, and is often performed in female patients.

Discussion

Recent research suggests that rectal intussusception may be a precursor lesion of rectal prolapse, and clinical etiologies are considered to be common[64]. Although the mechanism by which rectal intussusception causes FI is unclear, it has been suggested that the recto-anal inhibitory reflex is induced[65], and resting pressure of the anus is decreased[66].

In Japan, short-term outcomes regarding FI were reported in 21 patients[67], and FISI scores decreased by 50% or more in 14 patients (67%). However, FI persisted in four patients (10%).

One year after surgery for FI in 26 patients with rectal intussusception grade III (advanced part down to the upper end of the anal canal) and in 46 patients with grade IV (advanced part into the anal canal), the FISI score was significantly improved from 31 to 15[65].

Regarding postoperative complications, urination disorder was observed in seven patients (11%), and one patient with exposure of the mesh to the vagina, which required removal, was reported, as well as another patient with vaginal exposure of the mesh causing infection and requiring removal[65].

CQ3. Which should be applied first for laceration of anal sphincter: sphincteroplasty or SNM?

Statement

Currently, it is unclear which surgical treatment should be performed first.

The treatment method should be selected in each case after explaining all treatment methods and characteristics. (*Grade of recommendation B*)

Discussion

At present, there are no reports of randomized controlled trials of sphincteroplasty and SNM for lacerations of the sphincter. Therefore, it is controversial as to which surgical treatment should be performed first.

In a study on SNM in 91 patients without sphincter laceration and in 54 patients with mean 105° sphincter laceration[13], FI scores were similar 12 months after surgery. Moreover, in a prospective study on SNM in 21 patients with sphincter laceration up to 120° and in 32 patients without laceration[22], the FI and QOL scores were similar in the 12-month follow-up period. In a systematic review of SNM for patients with sphincter lacerations[10], the FI score decreased from 16.5 to 3.8. However, 9 articles, other than the abovementioned prospective study, are retrospective studies, and there is a problem of low evidence level.

In contrast, 5 years after surgery, the long-term outcomes of sphincteroplasty for sphincter laceration remain at an effective rate of 10%-46%[6,9]. Since the evaluation method is not constant, comparing the surgical outcomes of sphincteroplasty with those of SNM is difficult. However, in the long-term outcomes of 160 patients of sphincteroplasty (median, 9 years and 3 months), the frequency of FI decreased by more than 50% (the patient judged to be effective by SNM) in 60% of patients. This was comparable to the long-term outcomes of SNM[68].

One of the advantages of SNM is its reversibility, in that the patient can be restored to the original condition by removing the stimulation lead if the test stimulus is not effective without morphologically changing the anal sphincter itself. In contrast, the disadvantages are that MRI examinations, other than those of the head, are contraindicated and thermotherapy (diathermy) cannot be undertaken (Table 1). The surgical procedure should be determined by considering the clinical outcomes and characteristics of sphincteroplasty and SNM.

X. FI in Special Conditions

A. Neurogenic and spinal cord diseases (injuries)

Injuries to the neural system or spinal cord often cause disorders of the sensory and motor nerves that innervate the anus, rectum, and pelvic floor, leading to the difficulty in controlling bowel movement, or FI, and/or constipation. FI and constipation act in close association: when one improves, the other tends to deteriorate. Based on the mechanisms of the onset of the neurological and spinal cord diseases, they are classified into congenital, traumatic, regenerative, ischemic, oncologic, etc. The reported incidences of FI as per diseases are 70% in patients with spinal cord injury or multiple sclerosis[69,70], 34% in those with spinal bifida[71], and 24% in those with Parkinson's disease[72].

There are two distinct patterns in the clinical presentation of bowel dysfunction, determined by the site of the spinal cord injury. Injury above the conus medullaris (a caudal

Table 1.   Comparison of Sphincteroplasty and Sacral Neuromodulation (SNM).

Methods	Advantage	Disadvantage
Sphincteroplasty	Enable morphological repair of the sphincter muscles	Long-term deterioration of the results
SNM	Preoperative evaluation of the effect	Contraindication for MRI
	Reversible method	Need two times of admission
	Good long-term results	Foreign body in the body
	Controllable method of on/off	Need change of stimulator
		High cost

edge of the taper spinal cord, located as high as the first lumbar vertebra) is characterized by increased tone of the colonic wall and anus, leading to constipation or fecal retention, and may cause overflow FI[73]. Injury at the conus medullaris and cauda equina is characterized by the loss of colonic peristalsis and atonic external anal sphincter and levator muscles, leading to passive FI[73]. Bowel dysfunction, such as FI and/or constipation, is perceived to be more serious than bladder and sexual dysfunction[70] and may cause anxiety and QOL impairment[74]. However, the usual management of bowel dysfunction is empirical with limited evidence[75].

The following assessments are required in patients with neurogenic and spinal cord diseases, besides the usual FI evaluation:

1. Clinical history: patient's request, QOL assessment, problem in accessing the toilet, behavior of caregivers

2. Physical findings: cognitive function; motor, sensation, and reflexes of the anus; spastic paralysis severity of the upper and lower limbs; palpation of the abdomen and digital examination of the rectum; working ability of the hand and finger; walking and ambulating ability; ability to hold sitting position

Conservative treatment

1）Initial management

1. Fiber-rich diet and adequate fluid intake

2. Stimulation of the anorectum and use of suppository

3. Timely trigger or assistive technique for defecation

4. Prescription of medications

5. Abdominal massage

6. Manual evacuation

2）Specialized management

1. Transanal irrigation

2. Biofeedback treatment

3. Anal plug

4. Posterior tibial nerve stimulation

The initial treatment aims to completely empty the bowels on a regular basis, leading to the prevention of FI and/or constipation. The abovementioned initial management should be individually expanded in stages. Basically, adequate fiber diet and fluid intake can produce satisfactory stool form. Digital rectal stimulation and suppository can be

helpful. Indeed, previous studies have reported that peristalsis of the left colon was enhanced following digital rectal stimulation[76], and polyethylene glycol-based bisacodyl suppository used in patients with spinal cord injury reduced time consumption on bowel management procedure[77]. Regarding the timing to trigger defecation, stroke patients assigned to morning bowel training groups were significantly more efficient than those assigned to evening bowel training groups[78]. The mechanism is unclear, but gastro-colonic reflexes following breakfast may be associated with positive results. Bulk-forming laxatives or isosmotic macrogol electrolyte solution used for treating constipation in Parkinson's disease increased stool frequency and helped in bowel care[79,80]. Previous reports showed that abdominal massage had positive effects on the symptoms of constipation in patients with multiple sclerosis or spinal cord injury[81,82]. Accordingly, a combination of initial managements[1-5] reduced the time required for bowel management procedure and use of laxatives in patients with spinal cord injury.

Digital evacuation is helpful for the management of fecal impaction. As bowel management, digital evacuation was used to treat 56% of community-dwelling individuals with spinal cord injuries[83].

Specialized management is provided when the initial management is unsuccessful. Most of the literature on this subject reports the outcome of treatment in patients with spinal cord injury. Transanal irrigation, injection of warm water into the rectum and left colon, can stimulate a patient to evacuate (cf. VIII-F). A randomized controlled trial in spinal cord-injured patients showed that transanal irrigation improved FI and constipation, compared with conservative bowel management (initial management on this head)[84]. Similarly, successful bowel management was reported in patients with spina bifida who were managed by means of a large-volume saline enema[85]. Literature of biofeedback treatment in patients with neurogenic and spinal cord diseases is scarce. A previous study reported that biofeedback for the treatment of FI was effective in patients with mild to moderate multiple sclerosis[86]. Anal plugs are used as supplementary measures, which can be seen in VIII-E. Posterior tibial nerve stimulation (cf. VIII-G-1) was reported to be effective for the treatment of FI caused by partial spinal cord

injury[87].

Surgical treatment

   1. Sacral nerve stimulation

   2. ACE

   3. Stoma

Surgical treatment is selected when conservative treatment of FI has been unsuccessful. The probability of bowel function improvement in patients with spinal cord injury with conservative management was estimated to be 63%[88]. So, surgical treatment may be an option when FI has not improved or chronic severe constipation has persisted after conservative management. Sacral nerve stimulation can be seen in CQ4. ACE is a simple operation that involves appendicostomy or cecostomy. Through the small stoma, patients can introduce a catheter and administrate an enema (cf. IX-C). In patients with spinal cord injury who underwent ACE, FI or constipation improved in seven out of eight patients[89].

Fashing a stoma is a surgery in which the colon or ileum is passed through the anterior abdominal wall and is opened (cf. IX-E. Stoma). In patients with spinal cord injury who underwent a stoma, the duration of bowel care was reduced[90] and QOL improved following surgery[91].

CQ4. Is sacral nerve stimulation therapy recommended for the treatment of FI in patients with spinal cord injury?

Statement

Sacral nerve stimulation therapy should be considered for the treatment of FI in patients with incomplete spinal cord injury or spina bifida because it is of value in select patients.

Commentary

Sacral nerve stimulation is used in treating disorders of defecation and lower urinary function (cf. IX-B). A previous study showed that 8 out of 11 patients suffering from cauda equina syndrome (injured cauda equina results in the laxness of the anal sphincter muscle and levator muscle) who underwent percutaneous nerve evaluation had successful outcomes. Five of the eight patients proceeded to permanent implantation of a neurostimulation device, which led to improved continence in all cases[27]. None of the three patients with complete spinal cord injury showed any improvement of FI after sacral nerve stimulation[92]. Meanwhile, previous studies have reported that sacral nerve stimulation therapy was effective for the treatment of FI in patients with incomplete spinal cord injury or spina bifida[93-96]. The latest report showed that 29 of 36 patients with neurological FI had permanent implants, which led to improved continence and QOL in 28 patients[95]. In a pediatric population suffering from congenital spinal cord injury, including spina bifida, sacral nerve stimulation therapy was effective for FI in 78% (14/18) of patients and for urinary incontinence in 81% (17/21)[97].

B. Patients with severe cognitive impairment and frail or bedridden older adults

1. Patients with severe cognitive impairment

Patients with severe cognitive impairment may present with active soiling, which refers to "incontinence" episodes that occur as a consequence of an abnormal behavior. Examples of these include defecating not at the toilet or in an inappropriate receptacle. Meanwhile, these patients may suffer from passive soiling, which refers to episodes when they have loss of awareness of the fullness of feces in the rectum and its subsequent leakage.

A comprehensive treatment of severe cognitive impairment has been described in the Guidelines of the Treatment of Severe Cognitive Impairment[98]. Symptoms of severe cognitive impairment are divided into core symptoms (memory impairment, conjecture impairment, aphasia, apraxia, agnosia, etc.) and behavioral and physiological symptoms (BPSD) (behavioral symptoms: violent language, violence, wandering, rejection, disinhibition, FI, etc.; physiological symptoms: sense of anxiety, depression, apathy, hallucination, delusion, etc.). The core symptoms can cause secondary BPSD in which the appearance is deeply involved in the physiological, environmental, and psychosocial factors (the symptoms may be triggered by unfamiliar and uncomfortable circumstances or inappropriate caregivers[99]). The cause of FI or playing with stool (to think of stool as a different thing or to fiddle with stool in the toilet seat), which is regarded as one of the behavioral symptoms, can be similarly explained.

Treatment policy

The initial management is basically followed as per VIII. Conservative Treatment of Fecal Incontinence.

Assessment

If the baseline assessment and initial management have failed to resolve FI, patients should be referred for behavioral analysis after interviewing patients, their families, and caregivers, to determine if there is any behavioral reason for FI. The relationship between the environment and FI is examined (this may lead to FI because patients cannot find the toilet). This will determine the exact location where FI occurred, frequency of FI, context in which FI occurred, and patients' and others' reaction to FI. Patients may feel discomfort after having a dirty diaper and therefore may try to take the stool out and stain clothes using their hands. To analyze patient behavioral, a daily record of patient's defecation may be helpful.

Moreover, whether the correspondence of caregivers to patients is appropriate or not should also be assessed. If the caregiver blames the patient or becomes angry with the patient, this inappropriate handling may hurt the patient's pride or cause anger and the patient may feel bad; this may lead to the deterioration of behavioral symptoms, including

FI[100].

Meanwhile, the causes of FI in severe cognitive impairment are often multifactorial, and local neurological symptoms or cognitive and psychological functions should be assessed. Abnormality of the dominant nerves to the rectum (the cause of fecal impaction), aphasia, agnosia, apraxia, apathy, and clinical depression need to be evaluated. "Playing with stool" may result from the misunderstanding of the stool.

Management and correspondence

After conducting behavioral and functional analyses, healthcare professionals should offer patients with appropriate severe cognitive impairment management individually. Making the locations of toilets clear to the individual, leading patients to go to the toilet timely, checking surroundings such as lighting adjustment, and reviewing the correspondence of caregivers to patients are fundamentals in the management of FI. Because patients may have a sense of shame for unclear behavior (they may hide an underwear soiled with stool), they should be respected and provided preventive care of pride. If patients feel discomfort due to fecal impaction and try to extract the stool from the rectum, the treatment of constipation can prevent this behavior[99]. Caregivers should remain calm if patients play with stool and quickly deal with the stool. Specialized treatment is not suitable[101].

In contrast, caregivers should be supported and protected by organizations that do not isolate them, because caregivers are heavily burdened psychologically and physically and may fall into depression[100]. The behavioral symptoms of patients can be reduced if caregivers are relaxed and build a good relationship with them.

2. Frail or bedridden elderly

FI was reported in up to 10% of community-dwelling older adults and approximately 50% of nursing home residents[102,103]. FI experienced by nursing home residents is rarely treated as a serious matter, and bowel care or management of FI is not actively provided. FI in older adults is associated with increasing disability, which may cause them to become isolated from the society and result in the deterioration of their QOL[104]. Understanding and assessing the pathophysiology that causes FI enable treatment.

1) Causes of FI

Characteristically, frail people suffer from neurological FI, which is caused by stroke[105], cognitive impairment, diabetes mellitus[106], fecal impaction, etc. Additionally, mobility problems[107] and visual impairment are associated with FI. Anal sphincter injury due to a history of anal surgery or obstetric anal sphincter injury may cause FI late in life. Further causes of FI in frail people include perineal descent, rectocele, rectal intussusception, and rectal prolapse.

2) Assessment

The initial management of FI is planned by assessing the history and physical examination[108]. Advanced tests for FI should be considered in older adults, if the results of testing could impact specialized treatment[109].

1. History: frequency of bowel movements, frequency of FI, comorbidities, prior colon cancer screening and its time, evaluation of drug-drug interactions, lactose malabsorption, checking on products containing more sorbitol, etc.

2. Physical finding: assessment of cognition, vision, and mobility; digital rectal examination; etc.

3) Initial management

Planned bowel evacuations using laxative, suppository, or enema should be provided in a timely manner, if appropriate. The equipment to help people gain access to a toilet should be provided, and appropriate disposable products should be offered.

Discussion

The initial management is basically followed as per "VIII Conservative Treatment of Fecal Incontinence." A practicable treatment plan should be individually formulated after having an interview with the family and caregivers[110].

Fecal impaction, which may specifically occur in frail or bedridden older adults, should be managed or prevented. There are numerous causes of fecal impaction in these people, including being bedridden or in a sitting position for a long time; weak straining ability; shortage of intake of water or dietary fiber; metabolic diseases, such as hypothyroidism or potassium deficiency; use of drugs that may inhibit bowel motility; and neurological diseases, such as stroke or Parkinson's disease[111]. Patients with severe cognitive impairment or bedridden older adults who live in nursing homes experience frequent fecal impaction[112], which may cause passive FI. A previous study reported that more than 80% of nursing home residents had bowel movements less than three times a week, and 71% of them had FI[113].

An understanding of bowel habits and scheduled defecation on a regular basis should be conducted to prevent fecal impaction. Controlling the physical nature of the stool and enema in people with FI who live in residential homes resulted in an improvement in FI[114]. Meanwhile, a trial of exercise intervention and guidance of defecation in frail people showed a significant improvement in FI[115]. In addition, the equipment for facilitating toilet access and the use of portable chamber pots are helpful. Skin care using disposable body-worn pads was also useful in community-dwelling care-dependent residents[116]. Timely checking of diapers should be provided in bedridden older adults; however, if they can report the need to defecate, caregivers can lead them to evacuate into a pot on the bed, which may decrease the burden on the caregiver[117]. The use of continence anal plug was reported to be an effective method in managing FI in bedridden older adults with loose or watery stool[118].

Specialized treatment

The causes of FI should be determined if the initial management of FI has not been effective. There is little evidence of specialized treatment for FI in frail or bedridden older adults, which is scarcely adapted to these people.

1) Conservative treatment

1. Biofeedback

Biofeedback treatment of FI is suitable in people with intact external anal sphincter who do not show impaired cognitive function. This treatment should be considered in community-dwelling frail people if the initial management of FI has not been effective[119].

2) Surgical treatment

1. Stoma

As stoma provides ease of defecation and hygiene, it may be effective in frail and older people who are less mobile, cognitively impaired, and at risk of skin breakdown[109].

"Notation"

Frailty is a common geriatric syndrome that embodies an elevated risk of decline in the reserve of physiologic ability, which may fall into a physiological function disorder, need of nursing care, and death; however, it can be reversed to more sound conditions by appropriate intervention (The Japan Geriatrics Society, 2014).

Conflicts of Interest

There are no conflicts of interest.

Author Contributions

KM, MS, YT, AT, TM, TY, KY, and HK: Substantial contribution to the conception or design of the work, and the acquisition and interpretation of data for the work.

Disclaimer

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The original version is available at https://www.nankodo.co.jp/g/g9784524258963/.

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