Clinical practice guideline for colonic fecal retention assessment during constipation for nursing care: Japan edition

Supervised by the Japan Academy of Nursing Science

Edited by the Nursing Care Development/Standardization Committee

2023 Edition

Clinical practice guideline for colonic fecal retention assessment during constipation for nursing care

(English version 2023)

JANS

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Preface

In 2017, the Japan Academy of Nursing Science, a public interest incorporated association, established the Nursing Care Development and Standardization Committee with the mandate to establish a system to translate nursing research evidence into clinical practice, under the stewardship of then-President Yayoi Kamakura. The first chairperson of the committee was Hiromi Sanada (President for 2019–2020), who was succeeded by Junko Sugama in 2019.

The first model project of this committee was the development of "Clinical Practice Guideline for Aspiration and Pharyngeal Residual Assessment during Eating and Swallowing for Nursing Care." This was the first guideline development effort by the Japan Academy of Nursing Science, and adhering to the "Minds Practice Guideline Development Manual 2017," a steering committee, a guideline development group, and a systematic review team were formed to carry out the work. Since many aspects were not explicitly stated in the manual, the work proceeded through an in-depth review of technical books regarding guideline formulation, video tutorials, and consultation with experts in guideline development, and it took approximately two and a half years from the start to publication.

This "Clinical Practice Guideline for Colonic Fecal Retention Assessment during Constipation for Nursing Care" is the second guideline to be published. The guideline development protocol was compliant with the "Minds Medical Practice Guideline Development Manual 2020 ver. 3.0." Benefiting from the experience of previous guideline formulation, the process was completed in a considerably shorter time of approximately 1 year and 8 months. This medical practice guideline was also adopted by the Japan Agency for Medical Research and Development (AMED) for research on the creation of Medical Arts (development of new medical technologies and software for surgery, oncology, nursing, rehabilitation, etc.) field 1 Medical Technology Development, which was conducted from FY2016 to FY2018, and was entitled "Advanced Nursing Technology Construction of a Multidisciplinary Cooperative System to Support Eating, Swallowing, and Defecation of Patients Treated at Home and in Nursing Facilities by Introducing Advanced Nursing Technology (Principal Investigator: Hiromi Sanada, Professor Emeritus, University of Tokyo; President, Ishikawa Prefectural College of Nursing)."

The formulation of clinical practice guideline for the assessment of aspiration and pharyngeal residual assessment and the assessment of colonic fecal retention has enabled standardization of nursing care related to eating and defecation. We believe this is a tangible step toward translating research evidence into clinical practice, which was the goal of establishing the committee. Further research is required to identify the best approach for implementing and disseminating standardized assessments.

We would like to express our sincere gratitude to the members of the guideline development steering committee, the guideline development group, the systematic review team, and the panel that determined the degree of recommendation, to have patiently provided guidance and encouragement over a long period

during the development of this guideline. We would also like to express our sincere appreciation to all external committee members for their dedication to this project. We thank Shigeko Horiuchi, President of the Japan Academy of Nursing Science, the board of directors, the auditors, the external reviewers who reviewed the report before its publication and provided advice, and the members of the Japan Academy of Nursing Science who provided their invaluable inputs in the guideline development group. We would also like to thank Takayuki Arita, Director of the Office of the Japanese Society of Nursing Science, and the staff for their administrative support during the process of preparing and publishing this guideline.

We hope that this guideline will help improve the quality of defecation care for subjects who are not always able to communicate their discomfort and needs regarding defecation.

May 2023

Chairperson of the Nursing Care Development /Standardization Committee

Junko Sugama

Contents

Preface ····ii
Clinical question and recommendation ····ix

Executive summary ····1

1. Title ····2
2. Purpose ····2
3. Scope ····2
4. Target patients ····2
5. Target audience ····3
6. Constituent organizations ····3
7. Organization members and roles ····5
   1) Guideline development steering committee ····5
   2) Guideline development group ····5
   3) Systematic review team ····6
   4) Panel members ····7
   5) Cooperative member ····7
   6) Secretariat ····7
   7) External evaluation committee ····8
8. Conflicts of interest (COI) ····8
9. Guideline development process ····9
   1) Development policy ····9
   2) Development process ····9
      (1) Organizational structure for creation ····9
      (2) Scoping ····11
      (3) Systematic review ····11
      (4) Creation of recommendations ····12
      (5) Finalization ····13
10. Clinical question and summary of recommendation ····14
   1) Assessments covered by the guidelines ····14
   2) List of CQs and recommendations ····14

11. Glossary ····18
1) Important term ····18
2) List of abbreviations ····18
12. Scope of coverage and focus of the guideline ····18
13. Relationship to existing guidelines ····19
14. Results of external evaluation and reflection in guidelines ····19
15. MINDS preliminary evaluation and reflection in guidelines ····20
16. Public comments and reflection in guidelines ····23
17. Funds ····23
18. Audit Standards ····24
19. Dissemination and implementation of the guideline ····24
20. Post-publication efforts ····24
1) Organizational structure after release ····24
2) Efficacy evaluation and monitoring ····24
3) Revision cycle ····24

Part 1. Constipation ····27

1. Clinical characteristics ····28
1) Definition ····28
2) Classification ····28
3) Pathophysiology of constipation ····29
4) Anatomy and functions of defecation ····29
5) Diagnosis ····31
2. Epidemiological characteristics ····32
3. Constipation assessment ····33
1) Assessment and nursing care objectives and methods ····33
2) Algorithm for assessment-based nursing care ····34
3) Assessment methodology ····36
(1) Interview ····36
(2) Defecation diary ····36
(3) Assessment of stool form, volume, etc. ····37
(4) Self-assessment chart for the presence and severity of constipation ····38
(5) Quality of life assessment ····39
(6) Physical examination ····40
(7) Rectal and anal visual examination, perianal palpation, and rectal and anal digital examination ····41
(8) Ultrasonography ····41

4. Assessment-based nursing care ····43
1) Care to promote stool mass discharge ····43
(1) Digital impaction ····43
(2) Enema, suppository ····43
(3) Biofeedback ····43
(4) Pelvic floor muscle exercises ····44
(5) Transanal irrigation ····44
2) Care to promote intestinal peristalsis ····44
(1) Lifestyle modification ····44
3) Diet modification and pharmacotherapy ····45
(1) Diet modification ····45
(2) Probiotics ····45
(3) Pharmacotherapy ····45

Part 2. Recommendation statements and systematic reviews for each CQ ····49

1. CQ 1 ····50
1) Recommendation ····50
2) Background and aims ····50
3) Commentary ····50
4) Database search results ····51
5) Literature search flowchart ····52
2. CQ 2 ····53
1) Recommendation ····53
2) Background and aims ····53
3) Commentary ····53
4) Database search results ····53
5) Literature search flowchart ····54
3. CQ 3 ····55
1) Recommendation ····55
2) Background and aims ····55
3) Commentary ····55
4) Database search results ····56
5) Literature search flowchart ····57
4. CQ 4 ····58
1) Recommendation ····58
2) Background and aims ····58
3) Commentary ····58

4) Database search results ····60
5) Literature search flowchart ····61
6) Reference standards: BSFS, defecation cycle, digital impaction ····62
7) Reference standards: digital impaction, enema, stool form ····64
8) Reference standard: Hard stool (BSFS1 or 2) ····66
5. CQ 5 ····70
1) Recommendation ····70
2) Background and aims ····70
3) Commentary ····70
4) Database search results ····71
5) Literature search flowchart ····72
6) List after secondary screening ····72
7) List of included papers ····73
8) Evaluation of the evidence in individuar studies ····73
9) Evaluation of body of evidence ····73
10) Qualitative systematic review ····74
6. CQ 6 ····75
1) Recommendation ····75
2) Background and aims ····75
3) Commentary ····75
4) Database search results ····76
5) Literature search flowchart ····76
7. CQ 7 ····77
1) Recommendation ····77
2) Background and aims ····77
3) Commentary ····77
4) Database search results ····78
5) Literature search flowchart ····78
8. CQ 8 ····79
1) Recommendation ····79
2) Background and aims ····79
3) Commentary ····79
4) Database search results ····80
5) Literature search flowchart ····81
6) List after secondary screening ····82
7) List of included papers ····82
8) Evaluation of the evidence in individuar studies ····83
9) Evaluation of body of evidence ····87
10) Qualitative systematic review ····88

Appendix ·····91

1. Key clinical issues·····92
   Key clinical issue 1 ·····92
   Key clinical issue 2 ·····93
   Key clinical issue 3 ·····94
   Key clinical issue 4 ·····95
2. Database search formula ·····96
3. The conflict of interest statuses ·····98

Clinical question and recommendation

Strength of recommendation	
strong	1
weak	2
Recommendation by the expert panel	—

Overall certainty (strength) of evidence on overall outcomes for recommendation decisions	
A (Strong)	Strong confidence in the appropriateness of the effect estimate to support recommendations
B (Moderate)	Moderate confidence in the appropriateness of the effect estimate to support recommendations
C (Weak)	Limited confidence in the appropriateness of the effect estimate to support recommendations
D (Very weak)	Little confidence in the appropriateness of the effect estimate to support recommendations

(Adapted from the Minds Manual for Guideline Development 2020 ver. 3.0., p. 117)

CQ 1

Is a systematic assessment using defecation diaries and interviews useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort and need for defecation?

Recommendation - In adult patients who are not always able to communicate their discomfort or need for defecation, a systematic assessment using a defecation diary, which is noninvasive, and a medical interview is recommended.

Recommendation by the expert panel

CQ 2

Is systematic assessment using physical examination techniques (inspection, auscultation, palpation, and percussion) useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort or need for bowel movements?

Recommendation - In adult patients who are not always able to communicate their discomfort or need for defecation, it is recommended that a systematic assessment be performed using noninvasive physical examination techniques (inspection, auscultation, palpation, and percussion).

Recommendation by the expert panel

CQ 3

Is assessment by digital rectal examination useful in the evaluation of rectal fecal impaction during constipation in adult patients who are not always able to communicate their discomfort or need for defecation?

Recommendation - In adult patients who are not always able to communicate their discomfort or need for defecation, it is strongly recommended that a digital rectal assessment be performed to evaluate rectal fecal retention during constipation.

GRADE 1D

CQ 4

Is the assessment of rectal stool retention by ultrasound imaging useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort or need for defecation?

Recommendation - In adult patients who are not always able to communicate their discomfort or need for defecation, it is strongly recommended that rectal fecal impaction be assessed by ultrasound imaging to determine rectal fecal impaction.

GRADE 1C

CQ 5

Is defecation care based on systematic assessment using defecation diaries and interviews useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort and need regarding defecation?

Recommendation - We propose the implementation of defecation care based on systematic assessment using defecation diaries and interviews with adult patients who are not always able to communicate their discomfort or need regarding defecation.

GRADE 2D

CQ 6

Is defecation care based on systematic assessment using physical examination techniques (inspection, auscultation, palpation, and percussion) useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort or need for defecation?

Recommendation - In adult patients who are not always able to communicate their discomfort or need for defecation, it is recommended that defecation care be based on systematic assessment using abdominal physical examination techniques (inspection, auscultation, palpation, and percussion).

Recommendation by the expert panel

CQ 7

Is defecation care based on the assessment by digital rectal examination useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort or need for defecation?

Recommendation - Defecation care based on digital rectal examination is strongly recommended in adult patients who are not always able to communicate their discomfort or need for defecation.

GRADE 1D

CQ 8

Is defecation care based on observation of rectal stool retention by ultrasound imaging useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort and need for defecation?

Recommendation - In adult patients who are not always able to communicate their discomfort or need for defecation, it is strongly recommended to implement defecation care based on ultrasound imaging to detect rectal stool retention.

GRADE 1C

Executive summary

1. Title

Clinical practice guideline for colonic fecal retention assessment during constipation for nursing care

2. Purpose

Constipation is a common symptom in the general population. However, in our hyper-aged society, it has become a chronic health problem.

This guideline aims to provide and recommend methods for the assessment, selection, and implementation of nursing care for colonic retention during constipation in adults who are not always able to communicate their discomfort or need for defecation. This guideline would enable the nurses to provide appropriate care to alleviate constipation at an early stage, thus providing patient comfort and preventing serious complications, such as bowel obstruction, perforation, ulceration, and bleeding. This guideline deals with defecation assessment performed by nurses as part of medical care under the Act on Public Health Nurses, Midwives, and Nurses.

The recommended levels in this guideline are not mandatory and are only a reference document to present assessment methods in defecation care.

3. Scope

Assessment of colonic fecal retention during constipation in adults

4. Target patients

The target patients are individuals aged over 18 years who are not always able to communicate their discomfort or need for defecation. These include patients with cerebrovascular disease, cerebral dysfunction, impaired consciousness, dementia, intractable diseases, and terminally-ill patients. Adult patients who require defecation support, such as patients with spinal cord injury, are also considered targets. Furthermore, these guidelines are also applicable to those with an elevated rectal sensory threshold due to aging or other factors (rectal sensory insensitivity) and those who have lost the strong urge to defecate due to continuous defecation suppression.

5. Target audience

The target audience of this guideline are nurses who provide defecation care in hospitals, long-term care facilities, and homes in collaboration with physicians, pharmacists, physical therapists, occupational therapists, radiology technicians, clinical technologists, care workers, and other professionals.

6. Constituent organizations (Figure 1)

The "Clinical Practice Guideline for Colonic Fecal Retention Assessment for Nursing Care" were developed under the Japan Academy of Nursing Science (JANS). The following three divisions formed by the "Nursing

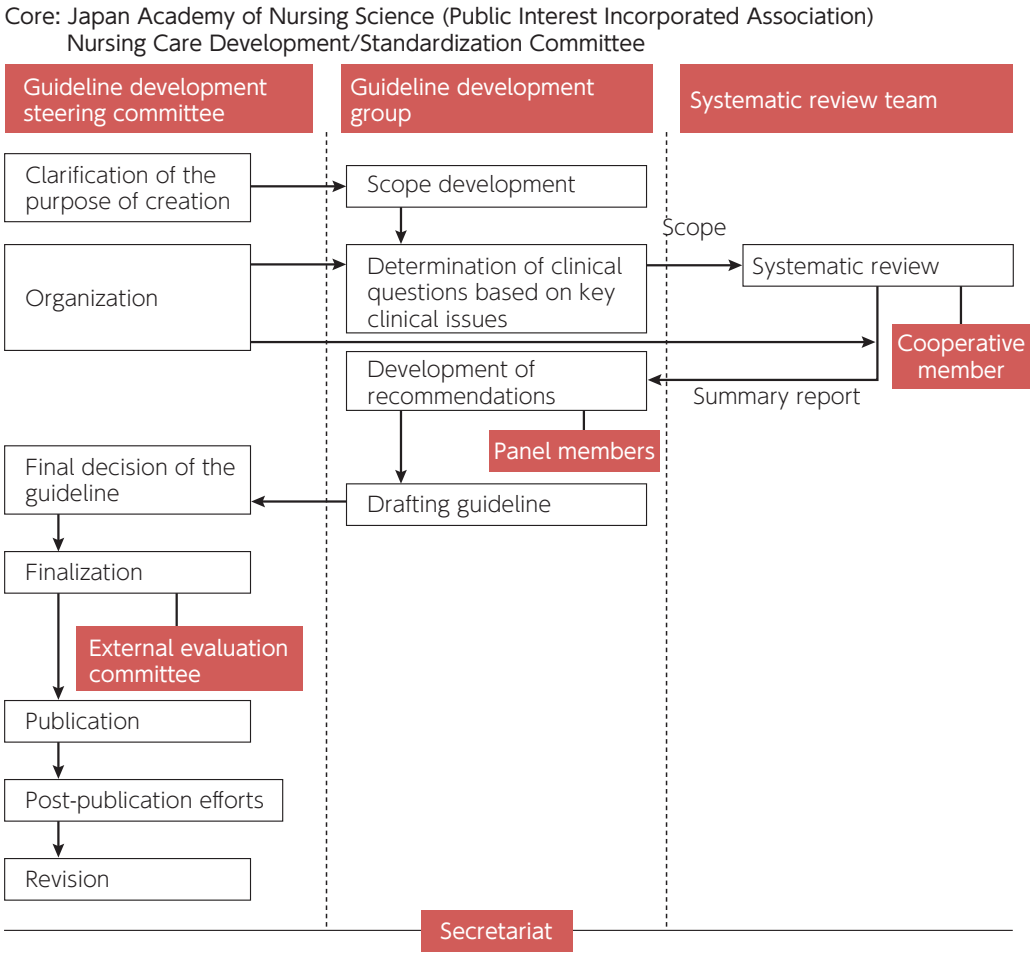

Figure 1: Organizational structure for developing the clinical practice guideline

Care Development/Standardization Committee" were involved in the development of the guideline: the guideline development steering committee, the guideline development group, and the systematic review team.

The guideline development steering committee was formed in October 2021 and comprised experts in nursing technology development, geriatric nursing, imaging nursing, continence care, gastroenterology, home health care, and clinical practice guideline development. The guideline development group comprised of experts in nursing technology development, geriatric nursing, home care nursing, continence care, imaging nursing, gastroenterology, diagnostic imaging, and guideline development who had the necessary expertise to develop this guideline. The systematic review team was independent of the guideline development group, and its members were selected from among the members recommended by the guideline development steering committee and members of the JANS based on the selection criteria. The members of the systemic review team were appointed in December 2021 with the approval of the board of directors. In principle, the minimum criteria for the systematic review team were: a doctoral degree, at least one original research paper in English published as the first author, and experience attending seminars on systematic review or guideline development.

In addition to the three divisions, panel members, cooperating members, secretariat, and external evaluation committee members were appointed. In addition to the 10 members of the guideline development group, the panel members included a Certified Nurse in Wound, Ostomy and Continence Nursing who provides dermatology/ continence care at home, a Certified Nurse in Wound, Ostomy and Continence Nursing affiliated with a hospital with a recovery-phase rehabilitation ward for patients with spinal cord injury and stroke, a faculty member of a nursing college specializing in the field of psychiatric nursing, and a physician in the department of palliative medicine. The cooperating members were a librarian at a nursing college who had the necessary expertise to perform a literature search for the systematic review. The secretariat was a member of the JANS tasked with managing all organizations involved in the development of the guidelines. These organizations included non-members of the JANS, who were referred to as external cooperative members. After the completion of the draft, an external evaluation committee was formed consisting of experts independent of the above organizations. The external evaluation committee were experts recommended by medical societies related to gastroenterological diseases, medical and nursing societies related to excretion, geriatrics and gerontological nursing, and home health care and home nursing. In addition, the guideline was preliminarily evaluated by Minds.

7. Organization members and roles

For each member of the clinical practice guideline organization shown in **Figure 1**, the name, affiliation, location, and role are listed in the table.

1) Guideline development steering committee

Name	Affiliation	Location	Role
Junko Sugama (Chair)	Research Center for Implementation Nursing Science Initiative, Fujita Health University	Toyoake, Aichi	Nursing technology development
Miyuki Ishibashi	Graduate School of Nursing, Chiba University	Chiba City, Chiba	Gerontological nursing
Shingo Okada*	Kitamihara Clinic	Hakodate, Hokkaido	Home health care
Hiromi Sanada	Ishikawa Prefectural Nursing University	Kahoku, Ishikawa	Imaging nursing, Gerontological nursing, Continence care
Atsushi Nakajima*	Department of Gastroenterology and Hepatology, Graduate School of Medicine, Yohokama City University	Yokohama, Kanagawa	Gastroenterology
Takeo Nakayama*	Health Management Course, Kyoto University School of Public Health	Kyoto City, Kyoto	Expert in creating clinical practice guidelines
Kaoru Nishimura	Continence Japan Co., Ltd.	Suginami, Tokyo	Continence care

*: External cooperative members

2) Guideline development group

Name	Affiliation	Location	Role
Junko Sugama(leader)	Research Center for Implementation Nursing Science Initiative, Fujita Health University	Toyoake, Aichi	Nursing technology development
Nao Tamai (sub-leader)	Department of Nursing, Graduate School of Medicine, Yokohama City University	Yokohama, Kanagawa	Imaging nursing
Erika Ota	Global Health Nursing, St. Luke's International University	Chuo, Tokyo	Expert in creating clinical practice guidelines
Atsuo Kawamoto	Department of Radiology, Tokyo Medical University Hospital	Shinjuku, Tokyo	Image technology
Hiroe Koyanagi	Innovation Promotion Division, Research Promotion Headquarters, Fujita Health University	Toyoake, Aichi	Continence care
Chiaki Sakakibara	Home-visit nursing agency Yaya's House	Komatsu, Ishikawa	Continence care, Home care nursing
Mihoko Seki *	Nursing Department, JCHO Tokyo Yamate Medical Center	Shinjuku, Tokyo	Continence care
Momoko Tsuda *	Hokkaido Cancer Society	Sapporo, Hokkaido	Gastroenterology
Masaru Matsumoto	Graduate School of Adult Nursing, Ishikawa Prefectural University of Nursing	Kahoku, Ishikawa	Imaging nursing
Noboru Misawa*	Department of Gastroenterology and Hepatology, Graduate School of Medicine, Yohokama City University	Yokohama, Kanagawa	Gastroenterology

*: External cooperative members, JCHO: Japan Community Health Care Organization

3) Systematic review team

Name	Affiliation	Location	Clinical Question
Aya Kitamura*	Graduate School of Medicine, The University of Tokyo	Bunkyo, Tokyo	CQ 2
Ayano Nakai	School of Health Sciences, Fujita Health University	Toyoake, Aichi	CQ 3,4,7
Ayumi Amemiya	School of Nursing, Chiba University	Chiba City, Chiba	CQ 2
Beniko Itokawa	Japanese Red Cross Akita College of Nursing	Akita City, Akita	CQ 4,6
Chikoto Suzuki	Department of Nursing, Saiseikai Yokohamashi Tobu Hospital	Yokohama, Kanagawa	CQ 1,4,5
Fumiko Ishimitsu	School of Nursing & Health, Aichi Prefectural University	Nagoya, Aichi	CQ 3,4,7
Masashi Katogi	School of Nursing, Kanagawa University of Human Service	Yokosuka, Kanagawa	CQ 2,8
Mayumi Hamada	The Jikei University School of Nursing	Chofu, Tokyo	CQ 1,4,5
Mikiko Shimizu	School of Health Sciences, Fujita Health University	Toyoaki, Aichi	CQ 3,4,7
Miku Aoki	School of Medical Sciences, University of Fukui	Yoshida, Fukui	CQ 4,8
Misako Dai*	Graduate School of Adult Nursing, Ishikawa Prefectural University of Nursing	Kahoku, Ishikawa	CQ 3,4,7
Nozomi Sonoda	School of Nursing, Takarazuka University	Osaka City, Osaka	CQ 4,8
Rumi Tanaka	School of Nursing, Kitasato University	Sagamihara, Kanagawa	CQ 1,4,5
Taiki Teshima	Faculty of Nursing, Kansai Medical University	Hirakata, Osaka	CQ4, 8
Tamae Urai	Faculty of Nursing, Toyama Prefectural University	Toyama City, Toyama	CQ 4,6
Tamami Mori	JCHO Tokyo Shinjuku Medical Center Affiliated Nursing School	Shinjuku, Tokyo	CQ 2, 4
Tomohiro Ishinuki	School of Nursing, Sapporo Medical University	Sapporo, Hokkaido	CQ 4,6
Toshiaki Takahashi*	Graduate School of Medicine, The University of Tokyo	Bunkyo, Tokyo	CQ 4,6
Yuka Miura*	Research Center for Implementation Nursing Science Initiative, Fujita Health University	Toyoake, Aichi	CQ 4,8
Yuko Mugita*	Graduate School of Medicine, The University of Tokyo	Bunkyo, Tokyo	CQ 1,4,5

*: Team leader, JCHO: Japan Community Health Care Organization

4) Panel members

Name	Affiliation	Location	Role
Junko Sugama	Research Center for Implementation Nursing Science Initiative, Fujita Health University	Toyoake, Aichi	Nursing technology development
Nao Tamai	Department of Nursing, Graduate School of Medicine, Yokohama City University	Yokohama, Kanagawa	Imaging nursing
Keiko Ishihama*	Nursing Department, JCHO Hoshigaoka Medical Center	Hirakata, Osaka	Specialist in spinal cord injury and stroke, Rehabilitation nursing, Continence care
Erika Ota	Global Health Nursing, St. Luke's International University	Chuo, Tokyo	Expert in creating clinical practice guidelines
Miho Okabe*	Wound and skin home care station	Maebashi, Gunma	Home care nursing, Continence care
Atsuo Kawamoto*	Department of Radiology, Tokyo Medical University Hospital	Shinjuku, Tokyo	Imaging technology
Yoshifumi Kido	Faculty of Nursing, School of Medicine, Hamamatsu University	Hamamatsu, Shizuoka	Psychiatric nursing
Takaomi Kessoku*	Department of Palliative Medicine, The International University of Health and Welfare Narita Hospital	Narita, Chiba	Gastroenterology, Palliative medicine
Hiroe Koyanagi	Research Center for Implementation Nursing Science Initiative, Fujita Health University	Toyoake, Aichi	Continence care
Chiaki Sakakibara	Home-visit nursing agency Yaya's House	Komatsu, Ishikawa	Continence care, Home care nursing
Mihoko Seki*	Nursing Department, JCHO Tokyo Yamate Medical Center	Shinjuku, Tokyo	Continence care
Momoko Tsuda*	Hokkaido Cancer Society	Sapporo, Hokkaido	Gastroenterology
Masaru Matsumoto	Graduate School of Adult Nursing, Ishikawa Prefectural University of Nursing	Kahoku, Ishikawa	Imaging nursing
Noboru Misawa*	Department of Gastroenterology and Hepatology, Graduate School of Medicine, Yohokama City University	Yokohama, Kanagawa	Gastroenterology

*: External cooperative members, JCHO: Japan Community Health Care Organization

5) Cooperative member

Name	Affiliation	Location
Kuniko Sato	Center for Academic Resources, St. Luke's International University	Chuo, Tokyo

6) Secretariat

Name	Affiliation	Location
Masaru Matsumoto	Graduate School of Adult Nursing, Ishikawa Prefectural University of Nursing	Kahoku, Ishikawa

7) External evaluation committee

Name	Affiliation	Location	Recommended Society
Eikichi Ihara	Department of Medicine and Bioregulatory Science, Graduate School of Medical Sciences, Kyushu University	Fukuoka City, Fukuoka	The Japanese Gastroenterological Association
Hiroyuki Imaeda	Department of Gastrointestinal Medicine, Saitama Medical University Hospital	Iruma, Saitama	The Japanese Society of Gastroenterology
Michio Maruyama	Tanashi hospital	Nishitokyo, Tokyo	Japanese Association for Home Care Medicine
Takashi Kawazoe	Carepro, Inc	Nakano, Tokyo	Japan Academy of Nursing for Home Care
Takeya Yasushi	Graduate School of Medicine, Osaka University	Suita, Osaka	The Japan Geriatrics Society
Toshiki Mimura	Department of Surgery, Division of Gastroenterological, General and Transplant Surgery, Jichi Medical University	Shimono, Tochigi	Japanese Society of Stoma and Continence Rehabilitation
Toshiko Kaitani	Department of Gerontological Nursing, Graduate School of Nursing, Sapporo City University	Sapporo, Hokkaido	Japanese Society of Wound, Ostomy & Continence Management
Yu Maruyama	Department of Nursing, Saitama Prefectual University	Koshigaya, Saitama	Japan Academy of Gerontological Nursing

8. Conflicts of interest (COI)

Economic COI and academic COI related to the development of this guideline were declared.

Method of investigation of potential COI: COI declarations were made according to the guideline of the JANS. The table at the end of this report shows the status of COI for each participant for the three years immediately preceding the development of the guideline.

Description of economic COI: The following items were requested to be declared. Directorships and advisory positions (1 million JPY or more), shareholdings (profits of 1 million JPY or more, 5% or more of all shares), patent royalties (1 million JPY or more), lecture fees (500,000 JPY or more), manuscript fees (1 million JPY or more), research funds from companies and organizations (2 million JPY or more), scholarship donations (incentive donations), endowed courses (affiliation), and other rewards (more than 100,000 JPY).

Description of Academic COI: Experts in multiple fields and professions were invited to participate in the development of this guideline as members of the guideline development group or systematic review team, and efforts were made to eliminate the influence of individual expertise, the professional societies, academic development, and competition among organizations. All members were required to report any previous involvement in the development of this guideline related to this subject or other similar guidelines.

Before initiating the development of this guideline, the members of the each committee were asked to submit a COI declaration form to rule out any potential conflicts of interest that may affect the preparation of this guideline. However, members who were authors of any published studies that were subject to the systematic review were not assigned to the systematic review team. The first author was excluded from the panel meeting when determining recommendations for clinical questions (CQs). In addition, we requested the submission of conflict of interest reports in different years and verified any changes.

9. Guideline development process

1) Development policy

Chronic constipation may occur in hospital in-patients, nursing home residents, and in the home care setting. The symptoms of difficulty in defecation experienced by patients with chronic constipation are straining, a feeling of residual stools, frequent stools, and a feeling of blockage at the perineum. In patients with chronic constipation, excessive straining to expel hard stools can cause a sudden rise in blood pressure, which may trigger potentially life-threatening cardiovascular events. In addition, abdominal pain and bloating cause a decrease in food intake, affecting the nutritional status of the patient. Of note, in adults who are not always able to communicate their discomfort or need for defecation, chronic constipation may cause complications such as bowel obstruction, rectal ulcer, and perforation of the gastrointestinal tract [1]. On the other hand, excessive use of laxatives to treat constipation may lead to watery stool, which is not a healthy bowel movement, because it typically does not lead to a feeling of well-being after defecation.

Nurses are required to support patients with chronic constipation in their daily lives to restore and maintain normal bowel movements. Appropriate assessment is necessary for the treatment and care of constipation. The conventional assessment methods include interview of the patient/caregivers and physical assessment. However, it is difficult to obtain accurate information from adults who are not always able to communicate their discomfort and needs regarding bowel movements. In recent years, there has been an increased impetus for research and training programs regarding the use of point-of-care ultrasound imaging by nurses for the assessment of rectal bowel movements. Therefore, there is a need to develop standardized guideline for ultrasound-based techniques for the assessment of constipation that can be used in any setting, such as hospitals, nursing homes, and home, and that can guide the selection of care in cooperation with physicians and other professionals.

Given this background, this guideline was developed in accordance with the "Minds Manual for Guideline Development 2020 ver. 3.0"[2] to facilitate decision-making regarding care selection based on research evidence and multifaceted factors such as the balance of benefits and harms and the patient's value system. The CQs are those that are encountered in actual situations of care selection for constipation, those that are difficult to decide, and those that are expected to improve clinical outcomes. Recommendations were made by panel members from various decision-making positions. Due care was taken to ensure neutrality and transparency throughout the guideline development process.

A systematic literature search to address the CQs was conducted in both English and Japanese journals, and recommendations were made after including a wide range of overseas evidence. When utilizing clinical guidelines published overseas, due cognizance was taken of the differences in medical systems between Japan and other countries.

2) Development process **(Figure 2)**

This guideline was developed in compliance with the Minds Manual for Guideline Development 2020 ver. 3.0 which adopts the internationally accepted GRADE framework (Grading of Recommendations Assessment, Development, and Evaluation) for the classification of the strength of evidence.

(1) Organizational structure for creation

After the JANS clarified the purpose of creating this guideline, a guideline development steering committee

Figure 2: Guideline development process

was formed to initiate the process for the creation of clinical practice guideline. In accordance with the Minds Manual for Guideline Development 2020 ver. 3.0 [2], a guideline development group was formed in October 2021, a secretariat was set up, a systematic review team was formed, and a clinical practice guideline development organization was formed by deciding on cooperating committee members.

(2) Scoping

After the guideline development steering committee decided on the overall scoping policy, the guideline development group outlined the basic characteristics of the symptom topic (constipation) and selected the candidate CQs. The selected candidate CQs were narrowed down to eight CQs under the supervision of the guideline development steering committee (see Appendix). The guideline development group listed the clinically important outcomes for each important clinical issue. Each member then scored the outcomes on a 9-point scale (from 1 to 9), and the average of the scores was calculated. For each narrowed-down CQ, items related to the systematic review were determined. The items related to the systematic review included evidence search methods (evidence type, database, search method, and search period), criteria for selecting and excluding references, and methods for evaluating evidence and integrating results. After these steps, the scope was determined. Following the basic characteristics of constipation, especially functional constipation, and the algorithm for constipation assessment and care selection, three main items were determined as the specific contents of the scope (items related to the contents covered by clinical guidelines, items related to systematic reviews, and items related to the process from making recommendations to finalization and publication). The first item, the content covered by the guideline, includes the title, purpose, scope, target patients, target audience, relationship with existing guidelines, important clinical issues, the scope of the clinical guideline, and a list of CQs. The second item, systematic review, includes the review schedule, evidence search, literature selection criteria, inclusion/exclusion criteria, evidence evaluation, and methods for integrating the results. The third item, from recommendation development to finalization and publication, includes the basic policy for recommendation development, finalization, specific methods of external evaluation, and publication schedule.

(3) Systematic review

A systematic review team member was appointed and a systematic review of each CQ was requested beginning in February 2022. During evidence collection, scoping-based evidence searches were conducted with the assistance of the university library librarian who had the necessary expertise and skills for the literature search strategy for systematic reviews. After the primary and secondary screening, the evidence was individually evaluated by performing a qualitative systematic review, and these were combined for a general evaluation of the evidence. The list of articles that were the subject of the qualitative systematic review was shared with the guideline development committee members and the guideline development steering committee specializing in defecation management to confirm that the list contained references that should be included. Based on the results, a systematic review report was prepared. Qualitative integration was used as the basis of the systematic review, in accordance with the Minds Manual for Guideline Development 2020 ver. 3.0 [2], but quantitative integration (meta-analysis) was used for some CQs because there were several studies with similar methods of evaluation. The systematic review was completed in October 2022.

①Search for evidence

ⅰ. Evidence Type

Original Articles: Randomized controlled trials, Non-randomized controlled trials, Observational studies, Case studies

Review Articles: Systematic Review

Existing guidelines: the "Evidence-based clinical practice guidelines for chronic constipation 2017 "[3] (Research society for the diagnosis and treatment of chronic constipation/ affiliated to the Japanese society of gastroenterology) was referred to for scoping and setting the CQs. However, for the systematic review, we did not use the results of this existing guideline as they were but conducted an all-new systematic review.

ⅱ. Databases

PubMed, Embase, CINAHL, Cochrane Library, Ichushi-Web (Japanese)

ⅲ. Search Methods

The Patient, Intervention, Control, Outcome format was used to search for interventions. P and I were used as the basis, and C and O were not specified.

ⅳ. Reference Period for Literature Search

All databases were searched until November 3, 2020.

②Criteria for selection and exclusion of references

Owing to the lack of any existing clinical guideline or systematic review article corresponding to the CQs in this guideline that were prepared in accordance with the Minds Manual for Guideline Development 2020 ver. 3.0 [2], a new systematic review was conducted for all of the CQs. For CQs on care selection interventions, priority was accorded to randomized controlled trials that met the inclusion criteria for the systematic review, but observational studies and case studies were also included if there were no relevant randomized controlled trials. For CQs on the sensitivity and specificity of assessments for care selection, observational studies that qualified the selection criteria were included.

③Evaluation of evidence and integration of results

The methods for evaluation of the aggregate evidence and the method for expressing the strength of the aggregate evidence were in accordance with the “Minds Manual for Guideline Development for 2020 Ver. 3.0." [2] Although qualitative integration was the basic method, quantitative integration (meta-analysis) was conducted for CQ 4 because several studies had used similar evaluation methods.

(4) Creation of recommendations

The basic policy for making recommendations was based on the “Minds Manual for Guideline Development 2020 ver. 3.0."[2] Considering that constipation requires care in a variety of clinical nursing settings, the panel members were nurses certified in Wound, Ostomy, and Continence Nursing or nurses who provide excretory care in any medical facility or at home, whether inpatient or outpatient. In addition, the panel members were composed of opinion leaders in their field, including a nurse certified in Wound, Ostomy, and Continence Nursing providing recovery care for spinal cord injury and stroke patients,

a researcher specializing in psychiatric nursing, gastroenterology physicians, a palliative medicine physician, and a radiology technician. A panel meeting was held in February 2023 to determine the recommendations for each CQ. The panel members discussed the draft recommendations prepared by the guideline development group in accordance with the modified Delphi method, and the panel members agreed on the recommendations. The panel members who were the first authors of the articles adopted as evidence did not participate in the determination of the recommendations for the CQs in question. However, the co-authors participated in the decision on the recommendation of the CQ in a restrained and self-reflective manner, taking COI into account, as required by the proceedings of the panel meeting.

The recommendation panel made its decision based on the certainty of the evidence for all outcomes for CQ

(**Table 1**), the balance of benefits and harms, and a comprehensive consideration of the patient and clinical situation, including the values, intentions, burden, medical costs, and resources of the caregivers. The strength of the recommendation is indicated by the certainty (strength) of the evidence, with 1 indicating “strongly recommended" and 2 indicating “weakly recommended." When a clear recommendation could not be made, it was indicated as “None." In the description of recommendations, “Suggested" indicates a weak recommendation.

For assessment techniques for which there is no clear evidence, but which are considered important, the recommended level was determined as “recommendation by consensus of experts," reflecting the consensus among the panel members based on the balance of benefits and harms, the values and intentions of the patient, burden, medical costs and resources, and actual clinical experience.

Table 1: Certainty (strength) of evidence on overall outcomes for recommendation decisions

A (Strong)	Strong confidence in the appropriateness of the effect estimate to support recommendations
B (Moderate)	Moderate confidence in the appropriateness of the effect estimate to support recommendations
C (Weak)	Limited confidence in the appropriateness of the effect estimate to support recommendations
D (Very weak)	Little confidence in the appropriateness of the effect estimate to support recommendations

(Adapted from the Minds Manual for Guideline Development 2020 ver. 3.0., p. 117)

(5) Finalization

After completion of the draft in February 2023, it was reviewed by the guideline development steering committee and revised in March 2023. External evaluation and public comments were collected from March to April 2023. The guideline development group examined the results of the external evaluation and public comments and made revisions reflecting the results. In May 2023, the Nursing Care Development and Standardization Committee finalized and published the draft.

10. Clinical question and summary of recommendation

1) Assessments covered by the guidelines

Assessments covered in this guideline include medical interview, defecation diary, physical examination techniques, digital rectal examination, and ultrasound imaging. Please refer to Part 1 for the specific details of each of these assessments.

2) List of CQs and recommendations

CQ 1

Is a systematic assessment using defecation diaries and interviews useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort and need for defecation?

Recommendation

○In adult patients who are not always able to communicate their discomfort or need for defecation, a systematic assessment using a defecation diary, which is noninvasive, and a medical interview is recommended.

Strength of recommendation▶**Recommendation by the expert panel**

[Note] Although there is insufficient evidence to recommend a systematic assessment using defecation diaries and interviews, the panel committee decided to make a recommendation based on expert opinion. Since patients themselves are not always able to communicate, care should be taken to seek information from family members and caregivers who understand the patient's daily life.

CQ 2

Is systematic assessment using physical examination techniques (inspection, auscultation, palpation, and percussion) useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort or need for bowel movements?

Recommendation

○In adult patients who are not always able to communicate their discomfort or need for defecation, it is recommended that a systematic assessment be performed using noninvasive physical examination techniques (inspection, auscultation, palpation, and percussion).

Strength of recommendation▶**Recommendation by the expert panel**

[Note] Although there is insufficient evidence to recommend an assessment using physical examination techniques (inspection, auscultation, palpation, and percus-

sion), the panel committee decided to make a recommendation based on expert opinion.

CQ 3

Is assessment by digital rectal examination useful in the evaluation of rectal fecal impaction during constipation in adult patients who are not always able to communicate their discomfort or need for defecation?

Recommendation

○In adult patients who are not always able to communicate their discomfort or need for defecation, it is strongly recommended that a digital rectal assessment be performed to evaluate rectal fecal retention during constipation.

GRADE 1D (Strength of recommendation : strong, Certainty of evidence (strength) : very weak)

[Note] Although there is insufficient evidence to recommend assessment by digital rectal examination, we decided to recommend it based on expert opinion because digital rectal examination can assess the presence or absence of stool in the rectum and is a reference standard for other CQs. The target patients of this guideline may not always be able to communicate their discomfort or need regarding defecation. When performing digital rectal examination, due consideration should be given to the stress induced by the procedure due to feelings of shame, pain, and discomfort.

CQ 4

Is the assessment of rectal stool retention by ultrasound imaging useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort or need for defecation?

Recommendation

○In adult patients who are not always able to communicate their discomfort or need for defecation, it is strongly recommended that rectal fecal impaction be assessed by ultrasound imaging to determine rectal fecal impaction.

GRADE 1C (Strength of recommendation : strong, Certainty of evidence (strength) : weak)

[Note] It is assumed that the patient understands how constipation can be assessed by means of a medical interview, defecation diary, and physical examination techniques. Ultrasound imaging for the detection of rectal fecal impaction should be performed by a nurse who has received specific training in this technique. In addition, the ultrasound imaging should be compatible with a convex

probe as a prerequisite for adequate rectal observation. The probe should have a frequency in the range of 3.5 to 5 MHz and a resolution level that can delineate the bladder, uterus/vagina, prostate, and rectum.

CQ 5

Is defecation care based on systematic assessment using defecation diaries and interviews useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort and need regarding defecation?

Recommendation

○We propose the implementation of defecation care based on systematic assessment using defecation diaries and interviews with adult patients who are not always able to communicate their discomfort or need regarding defecation.

GRADE **2D** (Strength of recommendation : **week**,
Certainty of evidence (strength) : **very weak**)

[Note] Since patients themselves are not always able to communicate, care should be taken to seek information from family members and caregivers who understand the patient's daily life.

CQ 6

Is defecation care based on systematic assessment using physical examination techniques (inspection, auscultation, palpation, and percussion) useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort or need for defecation?

Recommendation

○In adult patients who are not always able to communicate their discomfort or need for defecation, it is recommended that defecation care be based on systematic assessment using abdominal physical examination techniques (inspection, auscultation, palpation, and percussion).

Strength of recommendation▶**Recommendation by the expert panel**

[Note] Although there is insufficient evidence to recommend defecation care based on a systematic system assessment using physical examination techniques (inspection, auscultation, palpation, and percussion), the panel committee made this recommendation based on expert opinion.

CQ 7

Is defecation care based on the assessment by digital rectal examination useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort or need for defecation?

Recommendation

○Defecation care based on digital rectal examination is strongly recommended in adult patients who are not always able to communicate their discomfort or need for defecation.

GRADE 1D (Strength of recommendation : strong, Certainty of evidence (strength) : very weak)

[Note] Although there is insufficient evidence to recommend assessment by digital rectal examination, we decided to recommend it based on expert opinion because it can enable the assessment of the presence or absence of stool in the rectum and is a reference standard for other CQs. The target patients of this guideline may not always be able to communicate their discomfort need regarding defecation. When performing digital rectal examination, due consideration should be given to the stress induced by digital rectal examination due to feelings of shame, pain, and discomfort.

CQ 8

Is defecation care based on observation of rectal stool retention by ultrasound imaging useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort and need for defecation?

Recommendation

○In adult patients who are not always able to communicate their discomfort or need for defecation, it is strongly recommended to implement defecation care based on ultrasound imaging to detect rectal stool retention.

GRADE 1C (Strength of recommendation : strong, Certainty of evidence (strength) : weak)

[Note] Ultrasound imaging should be performed by nurses trained in the observation of rectal fecal impaction. The ultrasound imaging should be compatible with a convex probe as a prerequisite for adequate rectal observation. The probe should have a frequency in the range of 3.5 to 5 MHz and a resolution level that can delineate the bladder, uterus/vagina, prostate, and rectum.

11. Glossary

1) Important term

○ Rome Ⅳ

ROME IV criteria describe the disease concept and diagnostic criteria for functional gastrointestinal disorders. The Rome I criteria were developed in 1992 and have been revised since then, with the Rome VI criteria published in 2016 [4]. The criteria are relevant to functional bowel disorders. The content of this guideline falls within the purview of functional bowel disorders, including disease concepts and diagnostic criteria for irritable bowel syndrome, functional constipation, functional diarrhea, functional bloating, nonspecific functional bowel disorders, and opioid-induced constipation.

2) List of abbreviations (Table 2)

The abbreviations used in this guideline are listed below.

Table 2: Abbreviation list

Abbreviation	Full spell
AS	Acoustic shadow
BSFS	Bristol stool form scale
CAS	Constipation assessment scale
CDSR	The Cochrane Database of Systematic Reviews
CENTRAL	The Cochrane Central Register of Controlled Trials
CSS	Constipation scoring system
Minds	Medical Information Distribution Service
JPAC-QOL	Japanese version of the patient assessment of constipation quality of life
PAC-SYM	Patient assessment of constipation–symptom questionnaire

12. Scope of coverage and focus of the guideline

This guideline covers the assessment of colonic fecal retention performed as part of nursing care for constipation. Specimens, abdominal radiography, enteral radiography, endoscopy, and specialized functional tests for the diagnosis of constipation performed by professionals other than nurses are beyond the scope of this guideline.

Ultrasound imaging for detecting rectal stool retention should only be performed at facilities or hospitals with a compatible ultrasound device and should be performed by nurses who are adequately trained in the observation technique.

13. Relationship to existing guidelines

There are no guidelines for the assessment of colonic retention during constipation in adults in Japan or overseas, which are designed to be used by nurses to select care.

In Japan, “Evidence-based clinical practice guidelines for chronic constipation 2017"[3] (edited by Research society for the diagnosis and treatment of chronic constipation/ Affiliated to the Japanese society of gastroenterology) and “Evidence-based clinical practice guidelines for chronic constipation 2023"[5] (edited by the Japanese gastroenterological association" have been published as clinical guidelines for physicians on chronic constipation. Clinical guidelines mainly cover diagnostic evaluation tests such as medical history, physical examination, routine examination, and specialized functional tests. However, these do not cover point-of-care ultrasound performed by nurses. The Japanese Society of Wound, Ostomy, and Continence Management, The Society for Nursing Science and Engineering, and the members of the Consensus Meeting of the 22nd Annual Meeting of the Japanese Society of Neurogastroenterology published a book titled the “Best Practices for Observation of Rectal Stool Retention Using Ultrasonography "[6] in 2021. The book focuses on observation using ultrasound imaging and does not discuss other interviewing and physical examination techniques performed by nurses.

Overseas, the World Gastroenterology Organization Global Guideline titled “Constipation: a global perspective"[7] was published in 2010. The guideline discusses various examinations for diagnostic evaluation of constipation in adults. However, it does not cover ultrasound imaging performed by nurses. This guideline was developed with reference to these existing publications to promote the assessment of colonic fecal retention during nursing care for constipation.

14. Results of external evaluation and reflection in the guideline

The draft of this guideline was externally evaluated by representative academic organizations specializing in gastroenterology, geriatrics, gerontology, gerontological nursing, continence rehabilitation, continence care, home health care, and home health care nursing, as well as by experts in the development of clinical guidelines, prior to its release to the public.

These representative academic organizations provided written evaluations and comments from the perspective of the clinical significance and practical application of the draft as a whole.

In addition to the word correction, the following two issues were pointed out for consideration.

●Question

Does the target population for this guideline include those with an elevated rectal sensory threshold (rectal sensory insensitivity)?

【Answer】

It was decided to add the following to the list of target populations: (1) those with rectal sensory insensitivity and (2) those with defecation suppression.

●Opinion

Since the digital rectal examination covered in CQ3 and CQ6 can evaluate the presence or absence of stool in the rectum and is used as a reference standard for other CQs, it is recommended that the level of recommendation be changed from “recommendation by expert panel" to GRADE 1D (Strength of recommendation: Strong; Certainty (strength) of evidence: Very weak).

【Answer】

This opinion of external committee members was reviewed by the guideline development steering committee and the recommended change was approved for incorporation in the guideline.

15. Minds preliminary evaluation and reflection in the guideline

A pre-publication evaluation was received on May 2 from four members of the Clinical Guideline Evaluation Committee (date of approval of the evaluation results: May 15, 2023). The general comments of the responsible subcommittees were as follows. The AGREE II evaluation table is shown in **Table 3**, and as much as possible, the comments from Minds are reflected in this guideline.

●Advanced reviews

In the AGREE II evaluation, the description of the subject and purpose areas was highly rated and is seen as a model for other clinical guidelines. The purpose of the clinical guideline is described in detail. The method of making recommendations is also described in detail, and the disclosure of the materials used from the literature search to the determination of recommendations is highly evaluated. The content of this guideline is described in two parts, the general and CQ parts, which is seen as useful for users of this guideline. For further improvement of the clinical guideline, the process of making recommendations should be more clearly described in detail. In particular, it would be helpful to present the results of the modified Delphi method. As for the search formula, there is a statement that it is included as an Appendix (e.g., p. 52), and it would be more transparent to disclose it as supplementary material to enhance the transparency of the preparation process. Regarding external evaluations, the results of the evaluations should be described, and the methodology used to integrate these in the process of developing the clinical guideline should be described in detail.

Please consider responding to the items pointed out in the public comments and the revisions made, as stated on the website of the Society (p. 18). Regarding revisions to the clinical guideline, it would be helpful to provide more specific information on the revision procedures (e.g., the system for reviewing revisions). Another issue is to consider and describe factors that promote or hinder the use of the clinical guideline, tools to support their application, cost information, and standards and methods for monitoring and auditing to evaluate the dissemination and use of the clinical guideline. Efforts made to reflect the values and wishes of patients and families in the process of developing the clinical guideline is expected. It would be desirable to describe the methods and results of the efforts, and how they were reflected in the clinical guideline in detail. In addition, since the overall impression is that the document is difficult to read, it is recommended to devise a layout that makes it easier to find recommendations, such as by framing recommendations with a frame or coloring them.

Table 3: Summary of the results of AGREEII's external evaluation of the pre-publication draft

Domain				
1	Scope and Purpose	1	The overall objective(s) of the guideline is (are) specifically described.	6.5
		2	The health question(s) covered by the guideline is (are) specifically described.	5.75
		3	The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	6.25
2	Stakeholder Involvement	4	The guideline development group includes individuals from all the relevant professional groups.	6.75
		5	The views and preferences of the target population (patients, public, etc.) have been sought.	2.75
		6	The target users of the guideline are clearly defined.	5.75
3	Rigour of Development	7	Systematic methods were used to search for evidence.	5.75
		8	The criteria for selecting the evidence are clearly described.	5.5
		9	The strengths and limitations of the body of evidence are clearly described.	6.5
		10	The methods for formulating the recommendations are clearly described.	4.75
		11	The health benefits, side effects, and risks have been considered in formulating the recommendations.	5.75
		12	There is an explicit link between the recommendations and the supporting evidence.	6
		13	The guideline has been externally reviewed by experts prior to its publication.	4.25
		14	A procedure for updating the guideline is provided.	4.75
4	Clarity of Presentation	15	The recommendations are specific and unambiguous.	5.25
		16	The different options for management of the condition or health issue are clearly presented.	3.75
		17	Key recommendations are easily identifiable.	3.25
5	Applicability	18	The guideline describes facilitators and barriers to its application.	4.5
		19	The guideline provides advice and/or tools on how the recommendations can be put into practice.	4
		20	The potential resource implications of applying the recommendations have been considered.	4.25
		21	The guideline presents monitoring and/ or auditing criteria.	5
6	Editorial Independence	22	The views of the funding body have not influenced the content of the guideline.	5.25
		23	Competing interests of guideline development group members have been recorded and addressed.	6.25

●Comment 1

It would be good to have a structure to survey and reflect the values and wishes of the target population.

【Answer】

The target population for this guideline is "adult patients who are not always able to communicate their discomfort or need regarding defecation." This makes it difficult to find evidence regarding values and wishes. This is an important perspective for determining recommendations and should be an issue for the Nursing Care Development and Standardization Committee.

●Comment 2

The addition of an evidence search formula would make the creation process more transparent.

【Answer】

Evidence search formulas have been added to the Appendix.

●Comment 3

It would be good to have a description of the results of the modified Delphi method.

【Answer】

In this guideline, the following notation was made. “The decision was made by consensus of the panel members after discussion at a panel meeting on a draft recommendation prepared by the guideline development group in accordance with the modified Delphi method."

●Comment 4

Please consider describing the content of the public comments and external evaluation and how you responded to them.

【Answer】

Response to comments received from public comments and external evaluation is included in the finalization section.

●Comment 5

For CQs and recommendations, we recommend incorporating double quotation marks, coloring, or other devices to make them easier to find.

【Answer】

The background of the CQ is now red to make it easier to find. Also, the recommended text is now in bold.

●Comment 6

There is a section listing key clinical issues, CQs, and recommended statements, but it would be easier to read if they were presented in a table.

【Answer】

See response to comment 7.

●Comment 7

It would be more convenient if the list of important clinical issues, CQs, and recommendation statements were listed at the beginning of the document, following the Table of Contents.

【Answer】

A list of CQs and recommended statements are included at the beginning following the Table of Contents.

●Comment 8

It was mentioned that COI are indicated in the Appendix at the end of the book, so it would be a good idea to mention them in the final version.

【Answer】

A list of COI has been added to the Appendix.

16. Public comments and reflection in the guideline

Public comments were solicited after preparing the draft, in parallel with the external evaluation and prior to its release to the public. The invitation for public comments was disseminated to the members of the JANS by e-mail, and the draft was posted on the members' page of the JANS from March 23 to March 31, 2023. Comments were obtained in the form of open-ended responses.

Public comments were submitted by two persons. The comments and the responses are listed below. The comments and responses were also posted on the JANS website.

●Opinion

I think it is very comprehensive. I think this nursing care guideline can be used in all aspects of nursing, but I suspect that when reviewing the content on the web, some will find it difficult to use because of the large number of words and long sentences. In the future, it would be helpful if the structure could be made so that the content can be used while using a tablet device.

【Answer】

We plan to publish this guideline in print and upload a PDF of the print version on our website. We believe that the readability of the guideline is a major influencing factor for its dissemination. After publication, we would like to work with the Public Relations Committee to consider the structure of the guideline to make it easier to use in electronic media.

●Question

If there is a blunting of rectal sensation due to chronicity in relation to “awareness of rectal fecal impaction," it would be easier to understand if the perspective of assessment of sensory function regarding awareness of rectal impaction could be clarified.

(e.g., “awareness of rectal retention" should be added to the subject's conditions, such as excluding cases of constipation with rectal sensory blunting due to chronicity).

【Answer】

Thank you for your important comments regarding the target population for this guideline. We have decided to add (1) those with rectal sensory insensitivity, and (2) those with defecation suppression, to the list of subjects.

17. Funds

Funding for the development of this guideline was provided by the JANS. No funding was received from other private companies or organizations. Self-reported COI were collected from the committee members and examined in accordance with the regulations of the JANS. It was confirmed that there were no COI issues. Conflicts of interest that should be disclosed are listed in the clinical guideline “Outline 8: COI."

18. Audit Standards

The relationship between the assessment and the care choices made, and the relationship between chronic constipation (functional constipation), defecation management in the form desired by the patient, and other factors will be monitored every six months to one year.

19. Dissemination and implementation of the guideline

This guideline concisely summarizes the recommendations for the eight CQs, clearly indicating what is important in an easy-to-understand manner. The interview and physical examination techniques which are useful for patients with suspected chronic constipation (functional constipation) and do not require special equipment are facilitating factors in the application of the clinical practice guidelines. On the other hand, digital rectal examination and ultrasound examination for observation of rectal stools must be performed by adequately trained persons. Therefore, the limited number of facilities that have the necessary equipment and trained personnel for these examinations are potential barriers. The training of personnel in these observation techniques is an important issue for the future.

Both the Japanese and English versions of this guideline will be published in full on the websites of the JANS and Minds. Further, the Japanese version will also be published as a book. This guideline also include a summary for the public. In addition, a systematic review will be published in the Japan Journal of Nursing Science. Moreover, we aim to promote the use of this guideline by holding lectures at various academic meetings and other events.

20. Post-publication efforts

1) Organizational structure after release

After the release of the clinical guideline, the guideline development steering committee and the guideline development group will continue their activities to promote the introduction of this guideline, evaluate its effectiveness, and check for new research findings that may affect the recommendations in this guideline.

2) Efficacy evaluation and monitoring

To evaluate the effectiveness of this guideline, we plan to assess whether the introduction of the guideline has improved patient outcomes in terms of stool characteristics, rectal retention, laxative use, and other outcomes. These will be measured every year from the time of introduction of the clinical guideline.

3) Revision cycle

This guideline will be revised periodically according to new evidence and changes in the medical care system. Revisions will be considered approximately every three to four years. Revisions may be considered earlier if new

physical examination techniques, screening tests, definitive diagnostic methods, or assessment criteria are proposed.

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6) The Japanese Society of Wound, Ostomy & Continence Management, and The Society for Nursing Science and Engineering ed.. Best Practice for observation of rectal fecal impaction using ultrasonography, Shorinsha Inc., Tokyo, 2021. (in Japansese)
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Part 1.

Constipation

The purpose of this guideline is to guide the assessment of defecation, especially constipation, in adult patients who may not always be able to communicate their discomfort or need for defecation. Adoption of these guidelines can enable nurses to provide early and appropriate constipation care, prevent bowel obstruction and perforation, and help patients comfortably expel feces that should otherwise be expelled. These guidelines are particularly relevant during the nursing care of patients with dementia, stroke, brain injury, spinal cord injury, and Parkinson's disease. These guidelines may also apply to patients receiving opioid medications for palliative care. Additionally, these can be used for patients with rectal hypersensitivity (e.g., due to aging), and for those who have lost the urge to defecate due to continuous suppression of defecation.

Note that organic constipation caused by physical gut obstruction, due to lesions such as cancer, rectal, mass, or rectal prolapse, is not covered by these guidelines.

1. Clinical characteristics

1) Definition

The Evidence-based clinical practice guidelines for chronic constipation 2023 [1], published in 2023, defines constipation as a condition characterized by fecal impaction or hard stools, decreased frequency of defecation, excessive irritation due to inability to defecate comfortably, a feeling of residual feces, blockage of the rectum and anus, and difficulty in defecation due to retention of feces in the large intestine. Chronic constipation is defined as "a condition that can interfere with the daily life or cause various physical disturbances due to chronic persistent constipation" (Evidence-based clinical practice guidelines for chronic constipation 2023). **Table 1** lists the diagnostic criteria for chronic constipation.

Table 1: Diagnostic criteria for chronic constipation (based on Rome IV diagnostic criteria)

1. Diagnostic criteria for functional constipation (FC)
The symptoms of FC must include two or more of the following: Defecation core symptom - C1 (Stool form) Lumpy or hard stools (BSFS type 1 or 2) more than25% of defecations. - C2 (Frequency of bowel movements) Fewer than three spontaneous bowel movements per week Defecation peripheral symptom - P1 (Straining) Straining more than 25% of defecations. - P2 (Sensation of incomplete evacuation) Sensation of incomplete evacuation more than one-fourth (25%) of defecations. - P3 (Sensation of anorectal obstruction/blockage ensation of anorectal obstruction/blockage more than one-fourth (25%) of defecations - P4 (Manual maneuver) Manual maneuvers to facilitate more than one-fourth (25%) of defecations.
2. Diagnostic criteria for chronicity
Symptoms must have been present for at least 6 months and have met the above criteria for the last 3 months. However, in “routine medical care," this is left to descrition of the physician examining the patient.

BSFS: Bristol stool form scale
(Lacy BE, et al. Gastroenterology 2016; 150: 1393-1407)
(The Japanese Gastroenterological Association (edit). Evidence-Based Clinical Practice Guidelines for Chronic Constipation 2023. Nankodo Co., Ltd., Tokyo, 2023. (in Japanese))

2) Classification

The classification of chronic constipation is shown in **Table 2** [2]. Constipation is broadly classified into organic constipation with morphological changes and functional constipation without morphological changes,

Table 2: Classification and mechanism of constipation

Organic constipation	
Stenotic constipation	Physical passage obstruction due to cancer or other causes
Non-stenotic constipation	Constipation due to organic fecal discharge disorders such as rectal mass or rectal prolapse.
Functional constipation	
Constipation with decreased stool frequency	- Slow transit constipation: Delays the time for the stool to pass through the colon - Normal transit constipation: Constipation type of hypersensitivity hypersyndrome, etc.
Difficult to defecate constipation	Impaired stool evacuation at the rectum and anus
Secondary (symptomatic) constipation is due to underlying diseases such as endocrine disorders, collagen diseases, neurological diseases, etc.	
Drug-induced constipation is due to psychotropic drugs, anticholinergics, opioids, etc.	
Idiopathic constipation has no identifiable cause	

(The Japanese Society of Wound, Ostomy, and Continence Management (edit). New Edition Excretory Care Guidebook. Shorinsha Inc., Tokyo, 2023. (in Japanese))

depending on the cause of constipation. Organic constipation is further classified into stenotic constipation caused by colorectal cancer or intestinal inflammation and non-stenotic organic constipation (small intestine/colon type and rectum/anal type) caused by lesions obstructing fecal discharge such as rectal mass or rectal prolapse. Functional constipation is classified into "decreased stool frequency type" and "difficult defecation type" based on the symptoms. Decreased stool frequency refers to the condition wherein the feces are retained in the colon, while difficulty in defecation refers to the condition wherein the feces present in the rectum cannot be comfortably excreted. Note that there is a possibility of overlap between the decreased stool frequency type and the difficult defecation type. Other types of constipation include secondary (symptomatic), drug-induced (including opioid-induced constipation), and idiopathic.

3) Pathophysiology of constipation

The pathophysiology of constipation is believed to involve a combination of three main factors: (1) inadequate dietary intake leading to insufficient amount of feces; (2) decreased gastrointestinal transport capacity; and (3) failure to excrete stool mass in the rectum due to abnormal rectoanal function, such as intentional inhibition of bowel movements, decreased bowel movements, and failure to relax the anal sphincter muscle. Elderly patients are prone to constipation because of the inability to apply adequate abdominal pressure due to decreased strength of the abdominal muscles.

Changes in the living environment, such as underlying disease, oral medications, decreased physical activity, and decreased fluid intake, may also cause constipation.

4) Anatomy and functions of defecation

The organs involved in defecation include the small intestine, colon, rectum, and anus (**Figure 1**)[3].

The final part of the rectum is called the ampulla, which narrows abruptly to form the anal canal (**Figure 2**)[3]. The anal canal is a double-layered structure consisting of the internal anal sphincter, an involuntary muscle, and the external anal sphincter, a voluntary muscle. The internal anal sphincter constantly tightens the anus with a constant force. The external anal sphincter surrounds the internal anal sphincter and plays an important role in the voluntary closure of the anal canal.

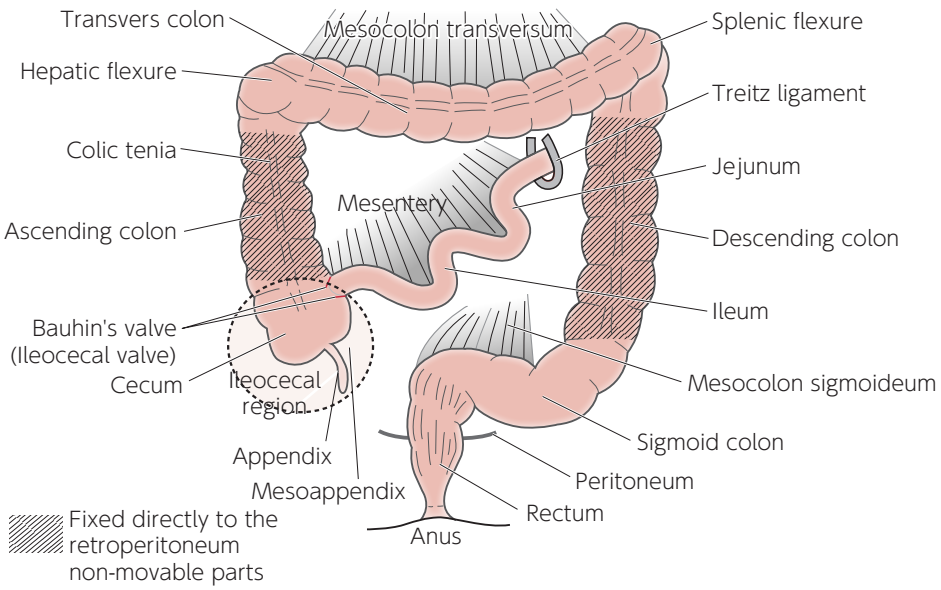


Figure 1: Schematic illustration of the lower gastrointestinal tract

(Anazawa S., et al (edit). Excretion Rehabilitation: Theoretical and Clinical. Nakayama Shoten Co., Ltd., Tokyo, 2009. (in Japanese))

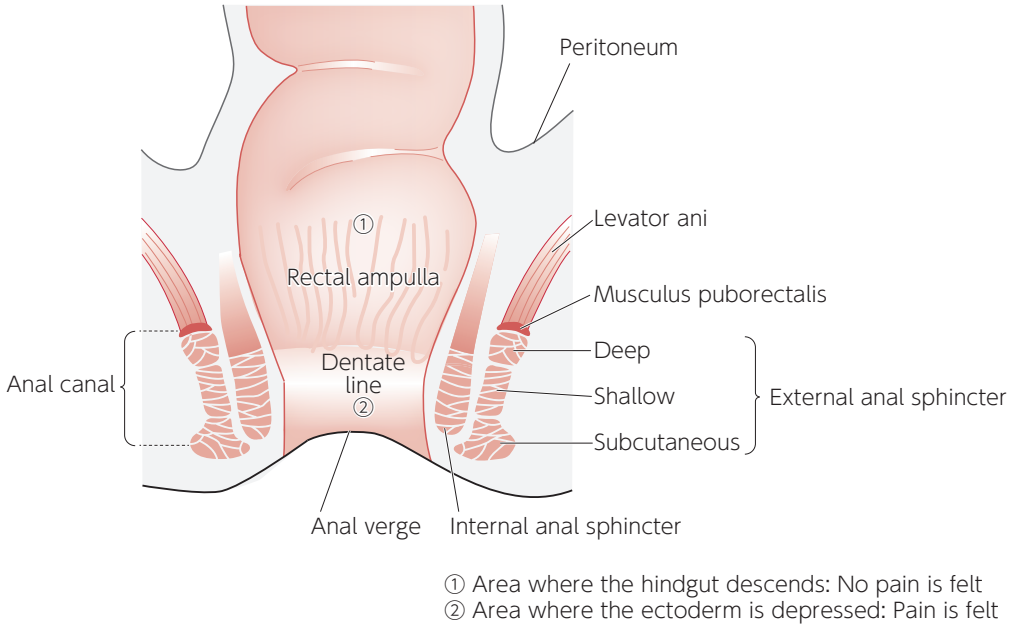


Figure 2: Anatomy and origin of the rectoanal region

(Anazawa S., et al (edit). Excretion Rehabilitation: Theoretical and Clinical. Nakayama Shoten Co., Ltd., Tokyo, 2009. (in Japanese))

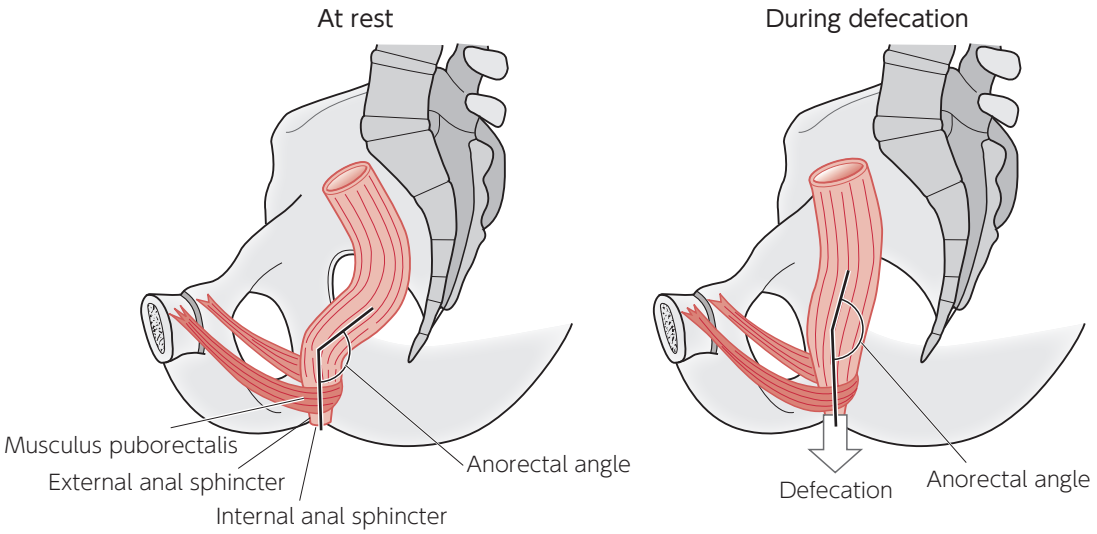


Figure 3: Schema at rest and during defecation
(Lembo A, Camiller M. N Engl J Med 2003; 349 (14): 1360-1368)

Food that enters the mouth is digested in the stomach and the nutrients are digested and absorbed in the small intestine. Entry of the food into the stomach induces the gastrocolic reflex, causing peristalsis of the colon, which results in the propulsion of the food from the small intestine to the large intestine. From the sigmoid colon, the stool is transported to the rectoanal region, where it is temporarily retained before its expulsion (**Figure 3**)[4].

The normal sequence of defecation is as follows. Entry of stool into the rectum stretches the rectal wall and the internal anal sphincter, increasing rectal pressure. When the rectal pressure reaches approximately 40–50 mmHg, the brain senses the need for defecation via the pelvic nerve, leading to the relaxation of the internal anal sphincter. Simultaneously, the external anal sphincter and the puborectal muscles contract strongly via the pubic nerves to hold the stool. This is referred to as the rectoanal reflex. In conditions that are unsuitable for defecation, the external anal sphincter and puborectalis muscles contract, and the rectoanal angle is sharply angled to prevent the stool from leaking out (**Figure 3**, left, at rest).

When defecation is possible, deliberate application of abdominal pressure and simultaneous relaxation of the external anal sphincter and puborectal muscles causes the perineum to descend and the rectoanal angle to become obtunded, which straightens the rectum and facilitates defecation (**Figure 3**, right, during defecation).

At the end of defecation, the anus, which had been dilated by the passage of stool, contracts, and under normal conditions, there is no residual stool in the rectum after defecation (**Figure 3**, left, at rest).

Functional constipation occurs due to the impairment of the coordinated movement of pelvic floor muscles or rectal sensation.

5) Diagnosis [1]

Chronic constipation, diagnosed based on symptoms, can be classified as primary or secondary, as described above. The underlying disease or condition is inferred from the interview and physical examination, and the necessity of further investigations (blood tests, colonoscopy, abdominal X-ray, and enteroscopy) are individually

determined and performed to differentiate secondary constipation (drug-induced constipation, symptomatic constipation, and stenosing organic constipation).

Although blood tests are useful in identifying secondary constipation, the need for further investigations should be performed only after careful evaluation of the medical history and physical examination, which often provide clues to the underlying condition. Fecal occult blood test is a screening test for colorectal cancer.

Colonoscopy is useful mainly for differential diagnosis of stenosing organic constipation associated with neoplastic and inflammatory diseases.

Abdominal radiography is useful for the early detection or exclusion of organic diseases such as intestinal obstruction and colonic axis torsion by observing intestinal gas retention and bowel compression due to masses. Similar to colonoscopy, enteral radiography is used in patients in whom stenosing organic constipation must be ruled out.

CT and MRI are used to evaluate colonic fecal impaction, and recently, the usefulness of abdominal ultrasonography in the diagnosis and treatment of constipation has been reported [1, 5].

In addition, to evaluate the pathophysiology, especially in patients with intractable chronic constipation, specialized functional tests such as colon transit time test, defecography, balloon emptying test, rectoanal pressure test, and rectal sensory test are performed. The colonic transit time test objectively evaluates the peristalsis of the large intestine and is useful for classifying constipation with decreased frequency into delayed colonic transit type and normal colonic transit type. The radiopaque marker method is the most widespread worldwide; however, SITZMARK®, which is used as the marker, has not been approved by the pharmaceutical affairs bodies or listed on the health care registry in Japan as of March 2023. The time from oral ingestion of the marker to its expulsion from the anus is evaluated. Defecography is a dynamic intrarectal radiographic examination in which pseudo feces are injected transanally into the rectum with a contrast medium to observe the dynamics of the rectum, sigmoid colon, and pelvic floor musculature during the act of defecation. In the balloon voiding test, a water-filled balloon is implanted in the rectum to evaluate the voiding ability in the sitting position. It evaluates the presence or absence of functional fecal discharge disorders such as pelvic floor muscle dyskinesia. Rectal and anal manometry measures the internal pressure in the rectum and anal canal to evaluate the contractility of the anal sphincter, changes in rectal pressure during effort, and the rectoanal reflexes. Rectal sensory testing evaluates the sensory capacity of the rectum and includes rectal balloon sensory testing and rectal mucosal stimulation threshold testing.

2. Epidemiological characteristics

In the National Survey of Living Conditions, constipation is included as one of the digestive system symptoms in response to the question "Do you have any symptoms of illness or injury in the past few days that make you feel sick (subjective symptoms)?" Based on the results of the 2019 National Survey of Living Conditions [6], the prevalence of constipation (per 1000 population) disaggregated by gender and age group was prepared (**Figure 4**). From teens to 50s, the prevalence rate of constipation in women was higher than that in men. The prevalence of constipation in patients aged ≥65 years (per 1,000 population) was 164 for men and 181 for women.

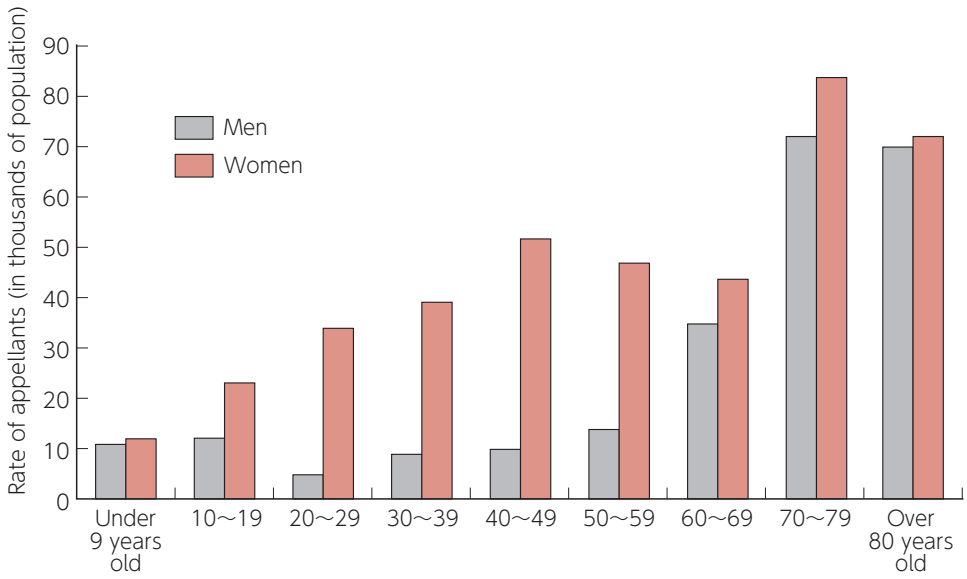


Figure 4: Percentage of constipation prevalence by age group and gender

(Comprehensive survey of living conditions 06 Statistical Tables (2nd Revision 0629) (mhlw.go.jp). (in Japanese))

The prevalence of constipation in post-stroke patients was 48% (95% confidence interval [CI] 33–63%)[7]. The prevalence rates differed by stroke type: ischemic stroke, 51% (95% CI 27–75); hemorrhagic stroke, 66% (95% CI 40–91). In terms of stage of disease, the prevalence was 45% (95% CI 36–54) in the acute phase and 48% (95% CI 23–73%) in the rehabilitation phase.

In a survey [8] of 202 inpatients in the convalescent group, 168 (83%) were prescribed laxatives, either daily or intermittently. Laxatives were prescribed to more than 70% of the patients regardless of their method of defecation, especially to diaper users (159 patients), 86% of whom were prescribed laxatives. Laxatives were prescribed to 87% (119/137) of patients with cerebrovascular disease.

3. Constipation assessment

1) Assessment and nursing care objectives and methods

The purpose of constipation assessment and defecation care in nursing is to assess and recommend defecation in adult patients who may not always be able to communicate their discomfort or need for defecation. The goal is to provide early and appropriate constipation care to prevent complications such as bowel obstruction and bowel perforation, as well as to enable the patient to pass stools in sufficient volume and comfort.

In the defecation care system, the presence or absence of suspected constipation is determined, followed by a comprehensive assessment of abdominal and anal symptoms, the underlying cause, imaging studies, defecation movements, and lifestyle. Based on the assessment results, a defecation care plan is developed and implemented. The goal of these measures is to achieve as safe, comfortable, and independent defecation as possible (**Figure 5**).

Constipation assessment and defecation care are ideally performed by a multidisciplinary team comprising of

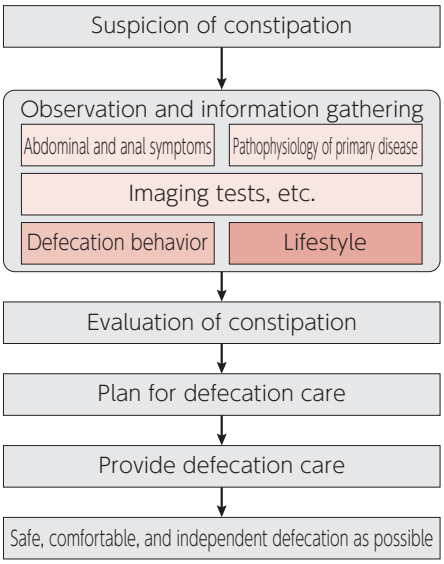


Figure 5: System of defecation care

a physician, nurse, pharmacist, physical therapist, occupational therapist, dietitian, nursing staff, medical social worker, and family members.

2) Algorithm for assessment-based nursing care

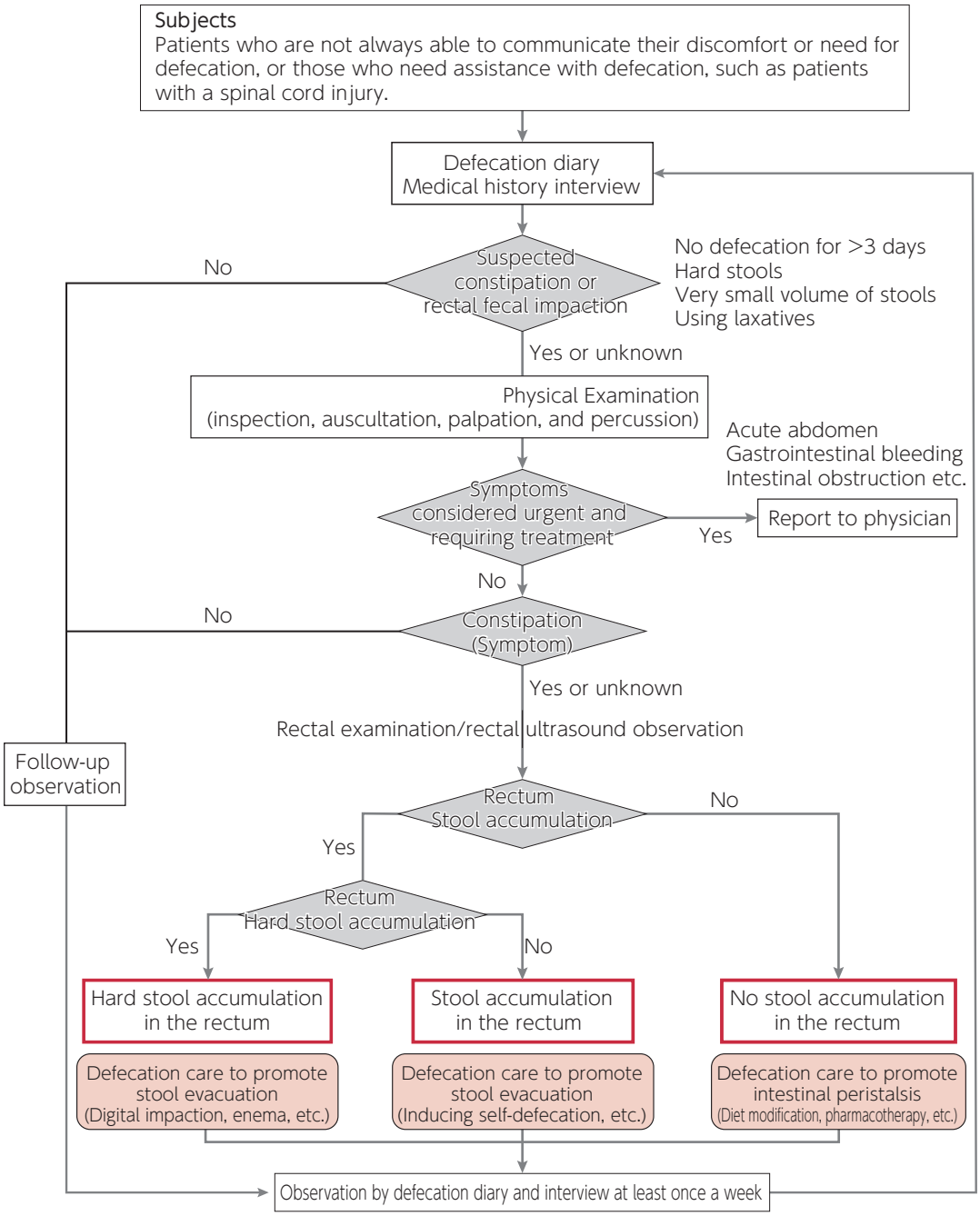
Figure 6 shows the flow chart of information collection and assessment, goal setting based on these assessments, and selection of care to be implemented, to realize safe and comfortable defecation. This algorithm was developed under the AMED ("Japan Agency for Medical Research and Development") Longevity Science Research and Development Project "Construction of a Multidisciplinary Collaboration System to Support Eating, Swallowing, and Defecation for People Cared for at Home and in Nursing Homes by Introducing Advanced Nursing Techniques." In the study, standardization was conducted in "care selection" by ultrasound examination.

The algorithms were targeted at individuals aged ≥18 years who have discomfort or needs related to defecation but do not always communicate them correctly, or who need assistance with defecation, such as patients with spinal cord injuries.

Specifically, patients with cerebrovascular disease, brain dysfunction, impaired consciousness, dementia, spinal cord injury, Parkinson's disease, patients with intractable diseases, and terminally-ill patients are assumed to be those who have discomfort or need but are not always able to communicate their discomfort or need. In addition, individuals with sensory insensitivity of the rectum (e.g., due to aging) and those who have lost the strong urge to defecate due to continuous defecation suppression are also included.

The CQs in this guideline follow this algorithmic flow. The nurse confirms the presence or absence of suspected constipation from the patient's interview and defecation diary.

If constipation is suspected, the presence of bowel obstruction should be ruled out first. Bowel obstruction refers to a physical blockage of the intestinal lumen caused by stool retention. The symptoms of bowel obstruction may include abdominal distention, abdominal pain, nausea/vomiting, and absence of bowel movements.



Note: If constipation cannot be determined despite the presence of fecal impaction based on assessment results, the patient should be comprehensively evaluated, including other assessment results, and followed up.

Figure 6: Algorithm for selecting nursing care based on constipation assessment

The physical signs may include increased peristalsis and metallic bowel sounds or decreased peristalsis by auscultation. The presence of these signs and symptoms is an indication for an abdominal X-ray or CT/MRI scan, upon recommendation by the physician. The typical imaging signs of bowel obstruction are dilated bowel and bowel collapse distal to the site of obstruction.

If no complications are determined, a systematic physical examination (inspection, auscultation, palpation, and percussion) should be performed to identify signs related to constipation, and a digital rectal examination or ultrasound imaging should be performed to rule out rectal fecal impaction.

In this systematic review of the guidelines, physical examination techniques included information obtained from interviews with patient, caregivers, and family members. A constipation scale was also included. Examination techniques to detect rectal fecal impaction included digital rectal–anal examination and ultrasound imaging. Since the above-mentioned assessments cannot necessarily determine the pathophysiology of constipation, a specialized defecatory function test is performed under the direction of a physician, if deemed necessary by the primary caregiver.

3) Assessment methodology

(1) Interview [1)]

Interview the patient, family members, or caregiver about symptoms, medical history, medication use, defecation patterns and environment related to defecation, warning signs, and risk factors.

The key aspects include frequency of defecation, stool characteristics, abdominal symptoms, and anal symptoms. The patient's medical history should include the duration of illness, onset of illness, comorbidities, medication use, history of surgery, and history of childbirth. Defecation patterns and the environment related to defecation refer to the defecation rhythm, breakfast intake, toilet environment, and defecation posture. Dietary factors and any potential stressors should also be enquired.

Regarding warning signs and symptoms, the patient is asked about any sudden change in defecation habits, unexpected weight loss (>3 kg within 6 months), bloody stools, fever, joint pain, and any abnormal physical findings (palpable abdominal mass, abdominal wave, palpable mass detected by digital rectal examination, blood clots). Risk factors include onset of disease at the age of ≥50 years, and history or family history of colorectal organic disease.

If warning symptoms or risk factors are present, necessary investigations for differential diagnosis of neoplastic or inflammatory disease are performed under the physician's direction.

If there is a hard, large fecal plug (fecal embolus) blocking the anus, soft or liquid stool may leak out from the sides, or only the liquid component of the fecal plug may flow out, soiling the underwear and perianal area. In this case, there is a risk that the patient will be incorrectly deemed as not being constipated.

(2) Defecation diary

The defecation diary is used to monitor the patient's defecation status and determine whether or not constipation is suspected. There is no standardized format for defecation diary. Different facilities or care providers may use different formats depending on the ease of use. The items noted in the log include time of defecation, bowel movement, stool consistency, volume of defecation, use of medications (laxatives, enemas, suppositories), and stool removal.

In general, constipation is evaluated based on the following criteria: defecation cycle of 3 days or more, stool consistency is hard, stool volume is small, and there is a sensation of residual stool. Since direct observation of

stools and subjective symptoms such as a feeling of residual stools are not always available, a defecation cycle of 3 days or longer is used as a guideline for judging the suspicion of constipation. As a precaution in recording, days without a bowel movement should be noted as such, so that the patient can visually identify when a bowel movement has occurred.

(3) Assessment of stool form, volume, etc.

①Bristol stool form scale: BSFS

The Bristol Stool Shape Scale [9-11] is widely used for objective assessment (**Figure 7**). Types 3 through 5 are healthy feces, types 1 and 2 are constipated feces, and types 6 and 7 feces indicate diarrhea. It can be assumed that the harder the stool is, the longer the transit time through the digestive tract, and the softer the stool is, the shorter the transit time.

②Assessment of stool volume

There is no uniform method for evaluating stool volume. Specifically, the various descriptions used are "very small amount, about the size of a quail egg, about the size of a chicken egg, about the size of a banana, a lot,"[2] and "about adherence, about the size of rabbit feces, about the size of a quail egg, about the size of a chicken egg, about the size of a banana, more than one banana, watery stool,"[12] to name a few. There is also one paper [13] that sets a guideline for the amount of stool according to its hardness, ranging from 1 (SS) to 5 (LL). In addition, there is a King's Stool Chart [14] that uses a combination of stool hardness and stool volume, and a simplified Cent Scale [15]. In addition, the validity of the Gut-Mieru-Sheet®, which evaluates stool volume, stool color, and stool shape as a stool shape evaluation tool, has been reported [16, 17].

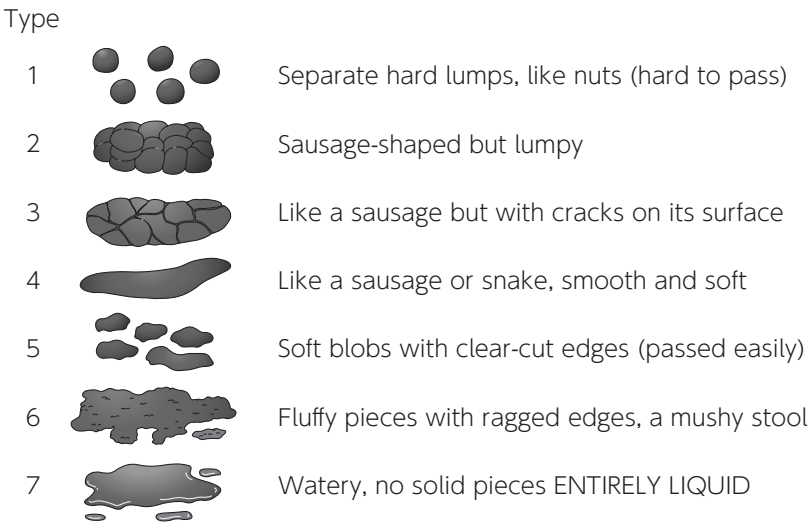


Figure 7: Bristol stool form scale

(O'Donnell LJD, et al. Br Med J 1990; 300: 439-440, Longstreth GF, et al. Gastroenterology 2006; 130: 1480-1491)

(4) Self-assessment chart for the presence and severity of constipation [18, 19]

There are several self-assessment tools, but we will discuss three that are commonly used.

①Constipation assessment scale (CAS)[20]

It was developed to care for cancer patients who experience constipation as a side effect of opioids. The scale consists of the following 8 items: feeling of abdominal fullness or bloating, change in voiding volume, decreased frequency of bowel movements, feeling of rectal contents filling up, anal pain during bowel movements, fewer bowel movements, condition of stool, diarrhea or watery, and more. Each item is rated on a scale of 0 (no problem) to 2 (very problematic). The total score for the past week is calculated and it ranges from 0 to 1. Individuals scoring ≥1 point are considered constipated.

Fukai et al. developed a Japanese version of the constipation rating scale and tested its reliability and validity in healthy students [21], healthy elderly persons [22], and disabled elderly persons without dementia [22] (**Table 3**). A score of 5 or higher indicates constipation which should be considered a nursing problem. To make the scale available to a variety of subjects, it is divided into three different time periods. Specifically, the LT version evaluates bowel movements over the past month (long term), the MT version evaluates bowel movements over the past week (medium term), and the ST version evaluates bowel movements on the same day or over several days (short term).

Table 3: Response form for Japanese version of constipation assessment scale version 2

Questionnaire	Three choices	
	ST version	MT version and LT version
1.Abdominal distension or bloating	-None -A little -Very much	-None of the above -Sometimes -All the time
2.Change in amount of gas passed rectally	-Normal or large -Less -Very little	-Normal or large -Sometimes less -Always less
3.Less frequent bowel movements	-Normal or large -Less -Very little	-Normal or large -less -Very little
4.Rectal fullness or pressure	-Not at all -A little -Very much	-Not at all -Sometimes -All the time
5.Rectal pain with bowel movement	-Not at all -A little -Very much	-Not at all -Sometimes -All the time
6.Smaller stool size	-Normal or large -Less -Very little	-Normal or large -less -Very little
7.Urge but inability to pass stool	-Easy to discharge -Slightly difficult to discharge -Very difficult to discharge	-Very difficult to discharge -Sometimes difficult to discharge -Always difficult to discharge
8.Oozing liquid stool	-None -A little -Very much	-None of the above -Sometimes -All the time

ST: short term (On the day or during the past few DAYS), MT: middle term (Past 1 week), LT: long term (Past 1 month)
(Fukai K., et al. Nursing Research. 1995;28:209-216. (in Japanese))

②Constipation scoring system (CSS)[23]

Constipation scoring system consists of 8 items: frequency of defecation, difficult or painful defecation, residual stool sensation, abdominal pain, time required for defecation, assistance in defecation, number of attempts to defecate/24 hours, and duration of constipation (in years)(**Table 4**). All items, except for the defecation assistance item, are scored on a scale of 0 to 4, while the defecation assistance item is scored on a scale of 0 to 2. The total CSS score range is from 0 to 30, and a total score of ≥15 indicates constipation.

Table 4: Constipation scoring system

Evaluation item	0	1	2	3	4
Frequency of bowel movements	1-2 times per 1-2 days	2 times per week	Once per week	Less than once per week	Less than once per month
Difficulty: painful evacuation effort	Never	Rarely(Less than once/ month)	Sometimes(More than once/month but less than once/week)	Usually(More than once/week but less than once/day)	Always(More than once/day)
Completeness: feeling incomplete evacuation	Never	Rarely(Less than 1 time/ month)	Sometimes(More than once/month but less than once/week)	Usually(More than once/week but less than once/day)	Always(More than 1 time/day)
Pain: abdominal pain	Never	Rarely(Less than 1 time/ month)	Sometimes(More than once/month but less than once/week)	Usually(More than once/week but less than once/day)	Always(More than 1 time/day)
Time: minutes in lavatory per attempt	Less than 5	5-9	10-19	20-29	More than 30
Assistance: type of assistance	Without assistance	Stimulative laxatives	Digital assistance or enema	-	-
Failure: unsuccessful attempts for evacuation per 24 hours	Never	1-3	4-6	7-9	More than 10
History: duration of constipation (yr)	0	1-5	6-10	11-20	More than 21
Total score (Minimum score, 0; Maximum score, 30)					

(The Japanese Society of Wound, Ostomy, and Continence Management (edit). New Edition Excretory Care Guidebook. Shorinsha Inc., Tokyo, 2023. (in Japanese))

③Patient assessment of constipation – symptom questionnaire (PAC- SYM)[24, 25]

PAC-SYM was developed to assess the frequency and severity of chronic constipation. Patients self-assess the degree of 12 symptoms experienced over the last 2 weeks: abdominal symptoms (4 items), rectal symptoms (3 items), and defecation status (5 items). The severity is rated on a Likert scale ranging from 1 to 4 (0: absent, 1: mild, 2: moderate, 3: severe, and 4: very severe), with a total score of 0–48. It has been used in Japan to evaluate cancer patients with opioid-induced chronic constipation[26].

(5) Quality of life assessment

Disease-specific measures of quality of life for subjects with constipation symptoms include the Patient Assessment of Constipation Quality of Life (PAC-QOL)[27] and the Constipation-related Quality of Life measure [28]. The reliability and validity of the Japanese version of PAC-QOL (JPAC-QOL) have been demonstrated (**Table 5**)[29]. It is a 28-item questionnaire consisting of four constipation-related domains and their subscales, with a 5-point scale ranging from “0: not at all" to “4: extremely" for symptoms in the past 2 weeks. Lower scores indicate a higher quality of life. Since only the 18th item is positive, we recommend changing this item to the following when using the questionnaire. “Did you feel that you did not have control over your situation?" Alternatively, one can choose to reverse the coding.

Table 5: JPAC-QOL

Physical discomfort score
1.felt bloated to the point of bursting? 2.felt heavy because of your constipation? 3.felt any physical discomfort? 4. felt the need to have a bowl movement but not been able to?
Psychosocial discomfort score
5.been embarrassed to be with other people? 6.been eating less and less because of not being able to have bowel movements? 7.had to be careful about what you eat? 8.had a decreased appetite? 9.been worried about not being able to choose what you eat (for example, at afriend's house)? 10.been embarrassed about staying in the bathroom for so long when you were away from home? 11.been embarrassed about having to go to the bathroom so often when you were away from home? 12.been worried about having to change your daily routine (for example, traveling, being away from home)?
Worries/concerns score
13.felt irritable because of your condition? 14.been upset by your condition? 15.felt obsessed by your condition? 16.felt stressed by your condition? 17.felt less self-confident because of your condition? 18.felt in control of your situation? 19.been worried about not knowing when you are going to be able to have a bowel movement? 20.been worried about not being able to have a bowel movement? 21.been more and more bothered by not being able to have a bowel movement? 22.been worried that your condition will get worse? 23.felt that your body was not working properly?
Satisfaction score
24.had fewer bowel movements than you would like? 25.satisfied with how often you have a bowel movement? 26.satisfied with the regularity of your bowel movements? 27.satisfied with the time it takes for food to pass through the intestines? 28.satisfied with your treatment?
Rate symptoms for the past 2 weeks on a 5-point scale from "0: not at all" to "4: extremely." Lower scores indicate higher QOL (items 18 and 25–28 were reversed and tabulated in the analysis because lower scores also indicate lower QOL)

(Kira I. Journal of Japanese Society of Nursing Research. 2013;36:119-127. (in Japanese))

(6) Physical examination

Inspection, auscultation, palpation, and percussion of the abdomen are performed in this order. On visual examination, observe skin abnormalities (e.g., surgical scars), presence or absence of venous engorgement, external shape and contour of the abdomen (abdominal distention), surface movements (peristalsis), and position, color, tone, and shape of the umbilicus.

Auscultation is used to confirm the sound of bowel peristalsis. The observer should place the stethoscope membrane over the right lower abdomen and listen for at least 1 minute. Normal peristalsis is heard irregularly every 5 to 15 seconds. The nature of the sound varies with the contents, and it is also influenced by diet, defecation, and stress, therefore, it varies from person to person.

On percussion, a flatulence sound is heard in the intestinal tract, while a turbid sound is heard at sites of fecal impaction. In case of increased intestinal peristalsis and gas retention, flatulence and percussion are increased, along with the increase in the number of resonant areas. If there is an intestinal obstruction or stricture, a metallic sound is heard, but a turbid sound may also be heard due to the retention of intestinal fluid or fecal masses caused by obstruction.

On palpation, a fecal mass can be felt in the left lower abdominal quadrant (near the sigmoid colon) in constipated patients. A fecal mass in the sigmoid colon may be palpable even in thin individuals.

(7) Rectal and anal visual examination, perianal palpation, and rectal and anal digital examination

On visual examination, the anal area and the surrounding skin should be observed. Look for the presence and extent of perianal skin disorders, scarring, and deformities, and the presence and extent of anal looseness. Check for the presence of rectal prolapse, mucus or stool leakage, perineal prolapse, uterine prolapse, vaginal prolapse, sentinel tag, and scarring. Observe the patient both at rest and while exerting intraabdominal pressure.

On palpation, observe the presence and degree of perianal skin induration and swelling, and the presence and degree of tenderness. Rectal and anal digital examination should be performed to observe the presence or absence of fecal mass and the state of contraction of the anal sphincter. The finger with which the rectoanal digital examination was performed should also be observed for any blood.

(8) Ultrasonography

In recent years, bedside ultrasound imaging to detect fecal impaction in the rectum is being increasingly performed [30].

For this examination, the subject adopts the supine position and the ultrasound probe is applied to the suprapubic border (**Figure 8**). In a transverse scan, the detection of a semilunar or crescent-shaped high echo area located dorsal to the bladder is considered indicative of fecal mass accumulation in the rectum (**Figure 9**). If a hard fecal mass is present, both a strong crescent-shaped high echo area and an acoustic shadow (AS) are observed. If the crescent-shaped, strongly high echo area has a diameter of 4.5 cm or greater, a fecal embolus is suspected, as it is difficult to expel the stool by itself. A fecal embolus is a situation in which a large hard stool occupies the rectum and cannot pass through the anus.

A transabdominal approach is generally utilized, but may not be possible in case of an empty urinary bladder or if there is a lot of gastrointestinal gas. In such cases, the transgluteal approach can be chosen [30]. In the transgluteal approach, the subject is placed in a supine position with the knees flexed and the ultrasound probe is placed over the gluteal cleft. As with the transabdominal approach, observation of a high echo area is considered indicative of fecal impaction (**Figure 10**).

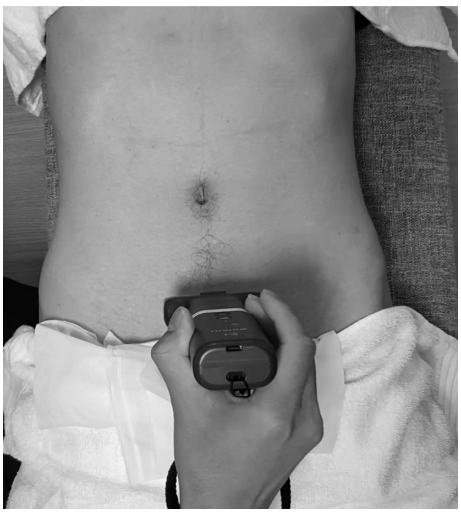


Figure 8: Ultrasound probe scanning during rectal observation
(Ultrasound probe being applied to the suprapubic margin in a transverse scan.)

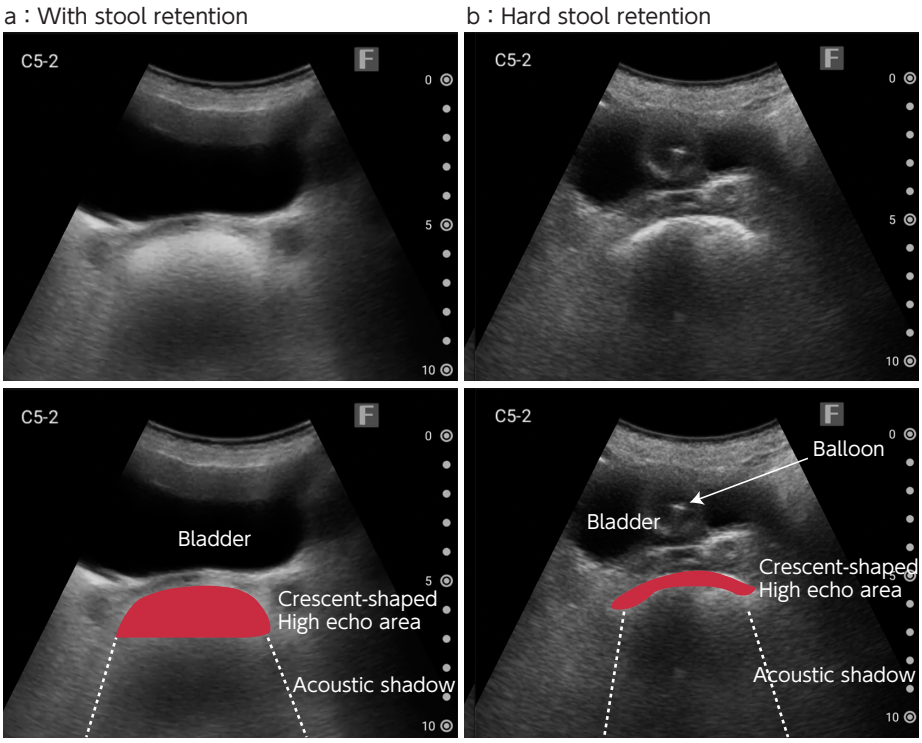


Figure 9: Ultrasound image (transverse view) of fecal impaction in the rectum

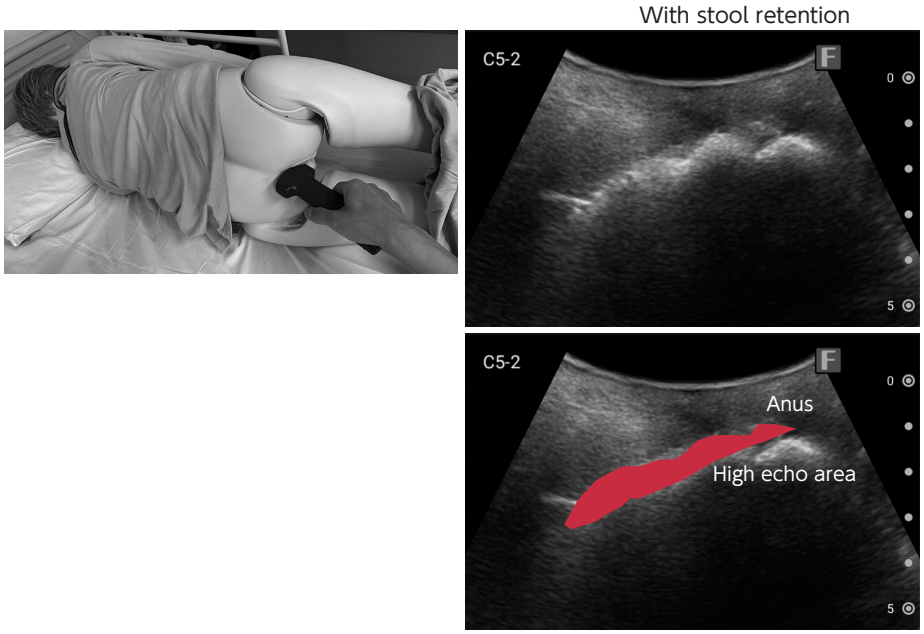


Figure 10: Ultrasound scanning and ultrasound images in the transgluteal approach.

4. Assessment-based nursing care

Assessment-based care includes care to promote stool mass evacuation, care to promote intestinal peristalsis, and diet modification and pharmacotherapy.

1) Care to promote stool mass discharge

(1) Digital impaction

Digital impaction is performed for patients who are unable to defecate spontaneously or who are unable to apply abdominal pressure, for example, due to paralysis or rectal–anal dysfunction. It is especially indicated for patients with suspected fecal embolization and those with difficult-to-defecate constipation who fail to defecate even after the use of suppositories and enemas. The procedure for digital impaction may lead to complications such as bleeding due to damage to the rectal mucosa, perforation of the rectum, and hypotension due to vagal reflex. Therefore, the procedure should be performed with extreme caution.

First, lubricate the gloved fingers with a lubricant. In the left lateral recumbent position, tap the anus with the finger, and when the anus relaxes, insert the finger gently and slowly for 6 to 8 cm. Remove the stool clumps from the rectal wall, and break up any large clumps before their removal.

(2) Enema, suppository

In the left lateral recumbent position, insert a tube and slowly inject a small amount of enema solution (up to 50 mL) warmed to approximately 40°C. In the case of fecal embolization (hard and large feces blocking the anus), stretching of the intestinal tract by the enema solution may cause bleeding or rectal perforation because of decreased blood flow in the intestinal tract. In case of bleeding, glycerin may enter the blood vessels and cause hemolysis, so the procedure should be performed with caution. In addition, in patients with age-related decline in the external anal sphincter contractility or cognitive impairment, the patient may not be able to hold the bowel movement after injection leading to fecal incontinence.

There are two types of suppositories: suppositories that promote fecal evacuation by generating carbon dioxide in the rectum to increase the intrarectal pressure and suppositories that promote fecal evacuation by acting directly on the rectal mucosa to promote peristalsis.

(3) Biofeedback

This method effectively reinforces training by using science and technology to convert invisible biological responses into light, sound, and other forms, and by providing visual and auditory feedback of this information. In practice, pelvic floor muscle dyscoordination is improved by teaching patients how to apply abdominal pressure when leaning forward and straining during defecation, and by making them aware of their anorectal movements using an anal electromyograph, an anal manometry, and a rectal balloon. The indication for biofeedback is described in Evidence-based clinical practice guidelines for chronic constipation 2017 [1] as functional defecation disorder due to pelvic floor muscle incoordination disorder. Pelvic floor muscle coordination disorder is a condition characterized by the failure of the pelvic floor muscles, including the puborectalis and anal sphincter muscles, to relax properly during defecation.

A training method using electromyography biofeedback training equipment with a medical electromyography system for generating an anal electromyograph is used. To ensure that the abdominal muscles are sufficiently contracted to increase abdominal pressure while simultaneously keeping the pelvic floor muscles relaxed without

contracting them, or for their proper guidance, one channel is used for the abdominal muscles and the other for the pelvic floor muscles to simultaneously display and measure both surface electromyograms. When using an anal manometer, an anal pressure microtransducer is used, the sensor is inserted into the anus, and the actual movement of the anal sphincter is monitored with the patient during training. When a rectal balloon is used, training is performed by inserting a balloon into the rectum and pushing it out as if it were a stool.

Biofeedback therapy is effective in the treatment of chronic constipation caused by pelvic floor muscle dyskinesia. However, because it is a highly specialized treatment, it should be performed at a specialized facility (Evidence-based clinical practice guidelines for chronic constipation 2023).

(4) Pelvic floor muscle exercises

Pelvic floor muscle exercises refer to pelvic floor muscle contraction training for the prevention and treatment of urinary and fecal incontinence and pelvic organ prolapse. Pelvic floor muscle relaxation training in biofeedback therapy for pelvic floor muscle incoordination may have a secondary effect, but there is a lack of evidence that it improves constipation [31].

(5) Transanal irrigation [2]

The common goal of forced defecation is periodic emptying of the colon, with an adequate amount of stool expelled at once to eliminate residual stool. There are retrograde and progressive ablutions.

In retrograde colon irrigation, water injected through the anus is allowed to reach the cecum, with the goal of excreting the entire colon content at once. Forced defecation, which is currently covered by insurance, is called “transanal self-irrigation," and is medically referred to as “transanal irrigation" or “retrograde colon irrigation." It is a treatment to prevent fecal incontinence and improve constipation symptoms by injecting 300–1000 mL of slightly warm water into the rectum transanally, once every 1–2 days, to enable evacuation of the contents of the rectum and left-side colon as much as possible.

In Japan, the Peristine anal irrigation system was approved by the Japanese pharmaceutical affairs in 2016 for use in transanal bowel cleansing therapy. The reimbursement has been approved for calculation as “home transanal self-bowel cleansing instruction and management fee" since 2018, and an additional fee for materials has been added since 2021. The indication for this treatment is defecation disorders caused by spinal cord disorders that do not improve sufficiently after more than three months of conservative treatment.

Antegrade continence enema, on the other hand, is performed by connecting an abdominal inlet to the colon and injecting enema solution into the ascending colon, to excrete feces from the entire colon at once. The appendix is surgically separated from the cecum, that part is sutured, the appendix is reversed, and the distal side is sutured through the submucosal tunnel of the cecum. The appendage is then placed in an anti-reflux mechanism, and one end of the appendage is placed as an inlet into a hole in the abdomen. Through this narrow passage, the colon can be accessed via a catheter. These procedures are sometimes performed by pediatric urologists and surgeons for patients with spina bifida who require treatment in childhood.

2) Care to promote intestinal peristalsis

(1) Lifestyle modification

The “Evidence-based clinical practice guidelines for chronic constipation 2017"[1] recommend “appropriate diet, exercise, and abdominal wall massage" for improving symptoms of chronic constipation. Exercise therapy for chronic constipation has been reported to be effective in improving symptoms, especially aerobic exercises [32]. In addition, abdominal wall massage 15 minutes a day, 5 times a week has been reported to be effective in relieving chronic constipation [33]. Furthermore, although not mentioned in the aforementioned guidelines, warm

compresses of the lower abdomen or back of the lumbar region have been reported to be effective in alleviating chronic constipation [34, 35].

3) Diet modification and pharmacotherapy

(1) Diet modification

The diet should include foods that soften the stool and stimulate bowel movements, such as insoluble fiber, soluble fiber, and fermented foods. Supplements should be prescribed to patients who have problems chewing or swallowing and those who cannot consume sufficient amounts of food or fiber.

(2) Probiotics

Probiotics are defined as “live microorganisms that have a beneficial effect on the health of the host when taken in appropriate amounts." The beneficial effects of probiotics are attributed to the improved hemostasis of the intestinal microflora. According to the “Evidence-based clinical practice guidelines for chronic constipation 2023,"[1] “certain probiotics are effective in increasing the frequency of defecation and improving abdominal symptoms in patients with chronic constipation."

(3) Pharmacotherapy

Also called laxatives. The type, action, and marketed generic names of each drug are summarized in **Table 6**.

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Table 6: Types of laxatives, actions, trade name/generic name

Types of laxatives		Actions	Trade name/generic name
1. Probiotics		Improve the intestinal environment for good bacteria	(Trade names) Enteronon-R, Lac B-R, etc. (lactic acid bacteria) Biofermin, Lac B (Bifidobacteria) Mya BM (Butyric acid bacteria)
2. Inflammatory laxatives		A cellulose preparation that is indigestible by human digestive enzymes. It transfers water from the intestinal epithelium to the stools, increases stool volume, and stimulates the intestinal tract to induce peristalsis.	(Generic name) Carboxymethylcellulose Polycarbophil calcium
3. Osmotic laxative	Saline laxatives	Salts, which are not easily absorbed from the intestine, increase osmotic pressure in the intestine, transfer water from the intestinal epithelium to stools, increase stool volume, and stimulate peristalsis.	(Generic name) Magnesium oxide Magnesium citrate Magnesium hydroxide Magnesium sulfate
	Saccharide laxatives	Disaccharides, which are indigestible by human digestive enzymes, increase osmotic pressure in the intestines, transfer water from the intestinal epithelium to stools, increase stool volume, stimulate the intestinal tract, and cause peristalsis.	(Generic Name) Lactulose D-sorbitol Lactitol
	Infiltrating laxative	Reduces the surface tension of stools by its surfactant action and enables water to permeate into hard stools with low water content.	(Generic name) Dioctylsodium sulfosuccinate
	Osmotic laxative (polymer compound)	Aqueous solution, with special composition electrolyte, mechanically cleanses the intestinal tract.	(Generic name) Polyethylene glycol
4. Stimulant laxative	Anthraquinones	Hydrolyzed by intestinal bacteria and enzymes in the digestive tract. It becomes active and acts on the intermuscular plexus of the large intestine to promote high amplitude colonic contraction waves, thereby inhibiting water absorption from the intestinal tract and causing a lucid laxative effect.	(Generic name) Sennoside Senna Aloe
	Diphenyl		(Generic name) Bisacodyl Sodium picosulfate
5. Epithelial function altering drug	Chloride channel activator	A functional fatty acid compound that activates the CIC-2 chloride channel on the lumenal side of the small intestine and stimulates osmotic water secretion into the intestinal tract, thereby softening the stool and boosting fecal transport in the small intestinal tract to promote defecation	(Generic Name.) Lubiprostone
	Guanylate cyclase C receptor agonist	Synthetic peptide consisting of 14 amino acids that increases the amount of cGMP in mesenteric epithelial cells via stimulation of the guanylate cyclase C receptor. Increased cGMP promotes intestinal fluid secretion via CFTR activation.	(Generic Name.) Linaclotide
6. Gastroprokinetic agent	5-HT_4 receptor stimulator	Selectively activates 5-HT receptors in the Auerbach plexus within the gastrointestinal wall	This drug is unavailable in Japan
7. Kampo medicine		Varies with each Kampo drug	(Generic name) Daewang Ganoderma Tang, Asonin Maru, Daiken Zhong Tang, etc.
8. Bile acid transporter inhibitors		Inhibits bile acid absorption and increases water secretion and colonic motility.	(Generic name) Elobixibat

Agonist: A drug that increases the action or expression when it binds to a receptor

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Part 2.

Recommendation statements and systematic reviews for each CQ

CQ 1

Is a systematic assessment using defecation diaries and interviews useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort and need for defecation?

1) Recommendation

○In adult patients who are not always able to communicate their discomfort or need for defecation, a systematic assessment using a defecation diary, which is noninvasive, and a medical interview is recommended.

Strength of recommendation▶**Recommendation by the expert panel**

[Note] Although there is insufficient evidence to recommend a systematic assessment using defecation diaries and interviews, the panel committee decided to make a recommendation based on expert opinion. Since patients themselves are not always able to communicate, care should be taken to seek information from family members and caregivers who understand the patient's daily life.

2) Background and aims

In adult patients who are not always able to communicate their discomfort and needs regarding defecation, systematic assessment using defecation diaries and questionnaires is useful for the evaluation, treatment, and care of constipation. However, the usefulness of systematic assessment using defecation diaries and questionnaires in actual clinical practice is not clear because of the diversity of practitioners and contents. Therefore, we examined the sensitivity and specificity of systematic assessment using defecation diaries and interviews based on domestic and overseas literature.

3) Commentary

A systematic review was planned to assess the sensitivity and specificity of systematic assessment using defecation diaries and interviews. However, no relevant articles were identified in literature search. The “Clinical guideline for abnormal bowel movements-Chronic constipation" (Japanese Society of Gastroenterology, 2023) recommends the use of a questionnaire. However, no study was found to have investigated the sensitivity and specificity for this CQ.

In clinical practice, systematic assessment using defecation diaries and questionnaires is an indispensable technique to identify patients with suspected constipation and to conduct subsequent physical examinations. However, it may be difficult to obtain accurate information from adults who are not always able to communicate their discomfort and needs regarding defecation, and there is a risk of delay in treatment and care for constipation. In such cases, it is necessary to solicit information from family members, caregivers, or other persons who understand the patient's daily life. In addition, the physical examinations listed in CQ2 below should also be conducted to evaluate constipation. For specific questions and physical examination techniques, please refer to

In addition to the certainty of the evidence, the panel meeting to determine the recommendation primarily discussed the balance of benefits and harms, the subject's sense of value for the primary outcome, cost, and feasibility. Defecation diaries and interviews are assessment methods already used in general practice. There is no need for new equipment or facilities, and there is no extra cost involved. In addition, in the case of patients who are not always able to communicate their discomfort or need, medical personnel or family members are likely to maintain records. Therefore, it was judged that there would be a limited impact on the values, intentions, and wishes of the target patients or groups and that the burden would not be great. Furthermore, since the benefits of correct classification outweigh the possible harms of incorrect classification, there is no impact on medical inequity. Moreover, since the assessment method is already widely used in clinical practice, the reliability and feasibility of the assessment were judged to be high.

The facilitating factor for the application of the clinical guideline is that the defecation diary/questionnaire is already a widely used assessment method in clinical practice, and does not require the use of any special equipment. A limitation is that assessment by defecation diaries/questionnaires requires a certain level of education and experience.

Given the above, despite insufficient evidence, a recommendation was decided by the panel committee based on expert opinion.

4) Database search results

The keywords used were: Constipation, physical examination, physical assessment, defecation care. The following databases were searched for articles published as of November 3, 2020: PubMed, Embase, Cochrane Database of Systematic Reviews, The Cochrane Library/CENTRAL, CINAHL, and ICHUSHI. A total of 27 papers were selected from out of the 2013 papers in the primary screening, and no papers were selected after the secondary screening. The database search strategy is presented in the Appendix.

5) Literature search flowchart

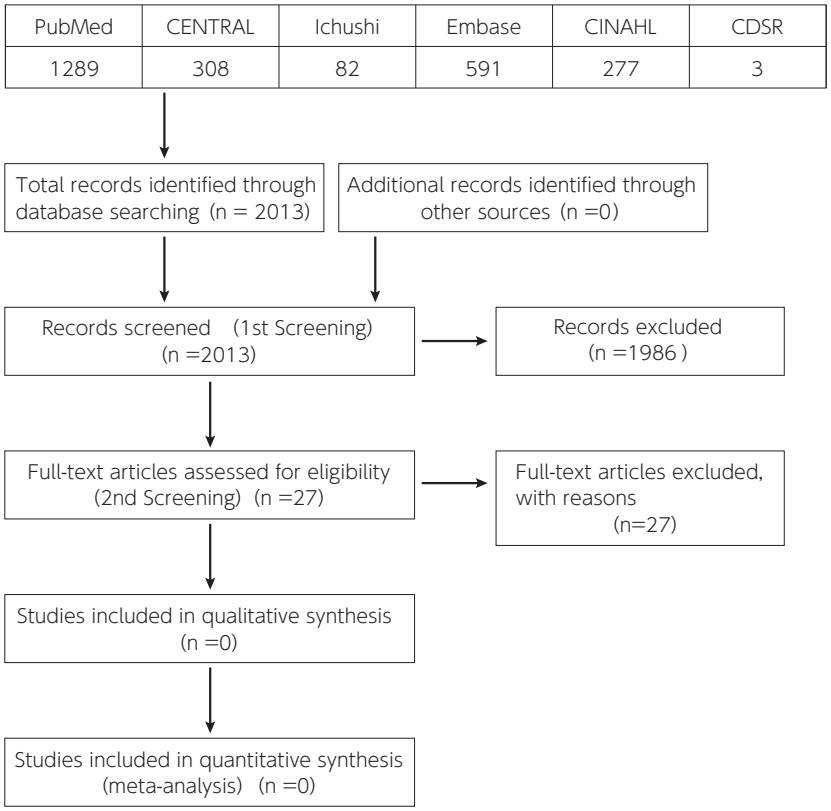

Figure 1: Literature search flowchart

2. CQ 2

CQ 2

Is systematic assessment using physical examination techniques (inspection, auscultation, palpation, and percussion) useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort or need for bowel movements?

1) Recommendation

○In adult patients who are not always able to communicate their discomfort or need for defecation, it is recommended that a systematic assessment be performed using noninvasive physical examination techniques (inspection, auscultation, palpation, and percussion).

Strength of recommendation▶**Recommendation by the expert panel**

[Note] Although there is insufficient evidence to recommend an assessment using physical examination techniques (inspection, auscultation, palpation, and percussion), the panel committee decided to make a recommendation based on expert opinion.

2) Background and aims

It is unclear whether systematic assessment using physical examination techniques, a noninvasive procedure, is useful in the evaluation of constipation. Therefore, we examined the usefulness of systematic assessment using physical examination techniques for evaluating constipation in persons aged 18 years or older with suspected constipation based on domestic and overseas literature.

3) Commentary

A systematic review was planned to evaluate the usefulness of physical examination techniques for the evaluation of constipation in adult patients who are not always able to communicate their discomfort or need for defecation. However, no relevant articles were obtained in literature search.

In addition to the certainty of the evidence, the panel meeting to determine the recommendation primarily discussed the balance of benefits and harms, the subject's sense of value for the primary outcome, cost, and feasibility. Despite the lack of evidence, physical examination techniques for the evaluation of constipation are already used in general practice. These are also useful for adult patients who are not always able to communicate their discomfort or need for defecation. For specific physical examination techniques, please refer to Part 1: Constipation.

Given the above, despite insufficient evidence, a recommendation was made by the panel committee based on expert opinion.

4) Database search results

Constipation, physical examination, physical assessment, and defecation care were used as keywords. The following databases were searched for articles published as of November 3, 2020: PubMed, Embase, Cochrane Database of Systematic Reviews), The Cochrane Library/CENTRAL, CINAHL, and ICHUSHI. Thirty-four papers were selected out of the 2013 papers retrieved in the primary screening. However, none of the papers qualified the criteria in the secondary screening. The database search strategy is presented in the Appendix.

5) Literature search flowchart

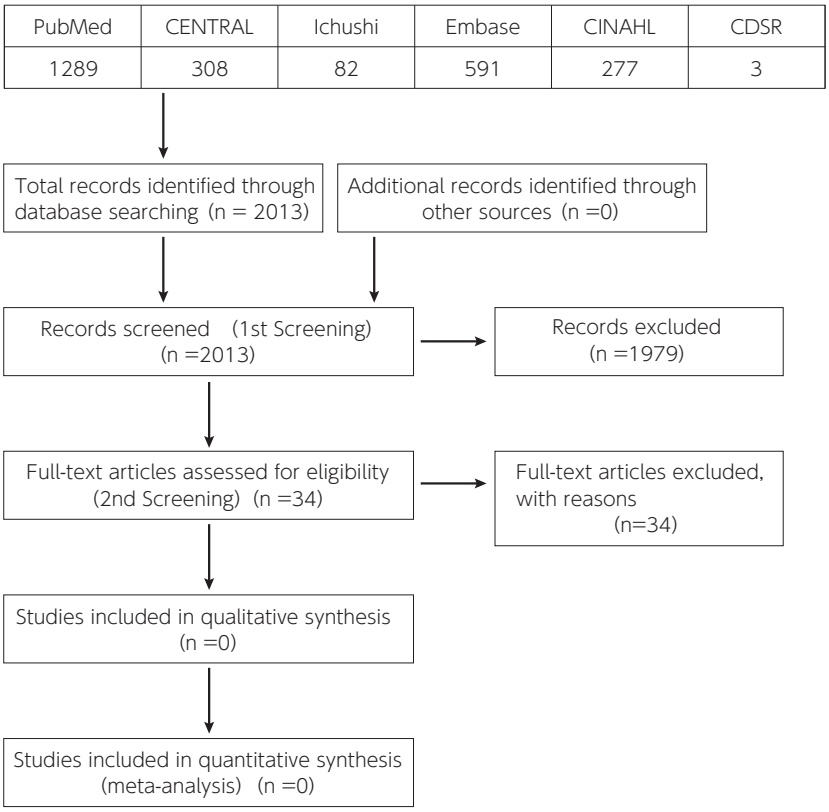

Figure 2: Literature search flowchart

3. CQ 3

CQ 3

Is assessment by digital rectal examination useful in the evaluation of rectal fecal impaction during constipation in adult patients who are not always able to communicate their discomfort or need for defecation?

1) Recommendation

○ In adult patients who are not always able to communicate their discomfort or need for defecation, it is strongly recommended that a digital rectal assessment be performed to evaluate rectal fecal retention during constipation.

GRADE **1D** (Strength of recommendation : **strong**, Certainty of evidence (strength) : **very weak**)

[Note] Although there is insufficient evidence to recommend assessment by digital rectal examination, we decided to recommend it based on expert opinion because digital rectal examination can assess the presence or absence of stool in the rectum and is a reference standard for other CQs. The target patients of this guideline may not always be able to communicate their discomfort or need regarding defecation. When performing digital rectal examination, due consideration should be given to the stress induced by the procedure due to feelings of shame, pain, and discomfort.

2) Background and aims

Under normal conditions, when there is no bowel movement, the rectum is empty of feces, and feces are retained in the gut proximal to the sigmoid colon. Occurrence of large peristalsis in the left semicolon causes movement of the feces stored in the sigmoid colon to the rectum, stretching the rectal wall. The stretch stimulus is transmitted to the cerebral cortex via the sacral nerve, causing a bowel movement. However, adult patients who are not always able to communicate discomfort or need for defecation may not feel the presence of feces in the rectum and constipation may be suspected. However, it is unclear whether assessment by digital rectal examination is useful in evaluating constipation. Therefore, we examined the sensitivity and specificity of the assessment by digital rectal examination in persons aged ≥18 years suspected of constipation without subjective symptoms based on domestic and overseas literature.

3) Commentary

The criterion for selecting evidence was randomized controlled trials. However, observational studies were also eligible for inclusion if no studies met this criterion. Literature search did not identify any articles presenting evidence for this CQ that met the criteria.

Impairment of one of the rectoanal functions results in the so-called “fecal emptying disorders" wherein the rectum is unable to comfortably expel feces. In rectal hypoesthesia, the patient does not feel the urge to defecate

even if there is fecal matter in the rectum. In addition to hypoesthesia of the rectal wall itself, other causes include increased rectal compliance and increased rectal capacity. In some cases, the patient does not feel the urge to defecate, resulting in decreased frequency of defecation and leakage of a small amount of fecal matter from the anus, resulting in leaky fecal incontinence. It often occurs in adults who are unable to complain of subjective symptoms.

Rectal digital examination has traditionally been performed as a method for assessing fecal retention/stool characteristics. It provides objective information regarding the rectum, which cannot be assessed by information from defecation diaries, interviews, or abdominal physical examination techniques.

In the panel meeting to determine the recommendation, in addition to the certainty of the evidence, the main issues discussed were the balance of benefits and harms, the sense of value for the main outcome of the target population, cost, and feasibility. Patients covered by this guideline may not always be able to communicate their discomfort or need regarding defecation. When performing the digital rectal examination, the need for such an examination should be determined from information in the defecation diary, interview, and per abdominal physical examination. In addition, due consideration should be accorded to stress induced by the examination, such as embarrassment, pain, and discomfort.

Rectal digital examination is performed in the left lateral recumbent position using the index finger. Usually, the rectum up to 6 to 8 cm from the anal verge can be examined. In patients with functional abnormalities of the rectum, the rectum can be observed for distension and the presence of fecal impaction. It can also detect scarring, rectal stenosis, and neoplastic lesions that may cause defecation difficulty, but these assessments require specialized education and skills in rectal examination (visual and finger examinations).

Therefore, despite insufficient evidence, the panel committee made a recommendation based on expert opinion.

4) Database search results

Constipation, Physical Examination, Physical Assessment, and Defecation Care were used as keywords.

The following databases were used: PubMed (through November 3, 2020), Embase (through November 3, 2020), Cochrane Database of Systematic Reviews (through November 3, 2020), The Cochrane Library/CENTRAL (through November 3, 2020), CINAHL (until November 3, 2020), and ICHUSHI (until 2021). A total of 162 articles were selected from the 2013 articles in the primary screening, and no article was selected in the secondary screening. The database search strategy is presented in the Appendix.

5) Literature search flowchart

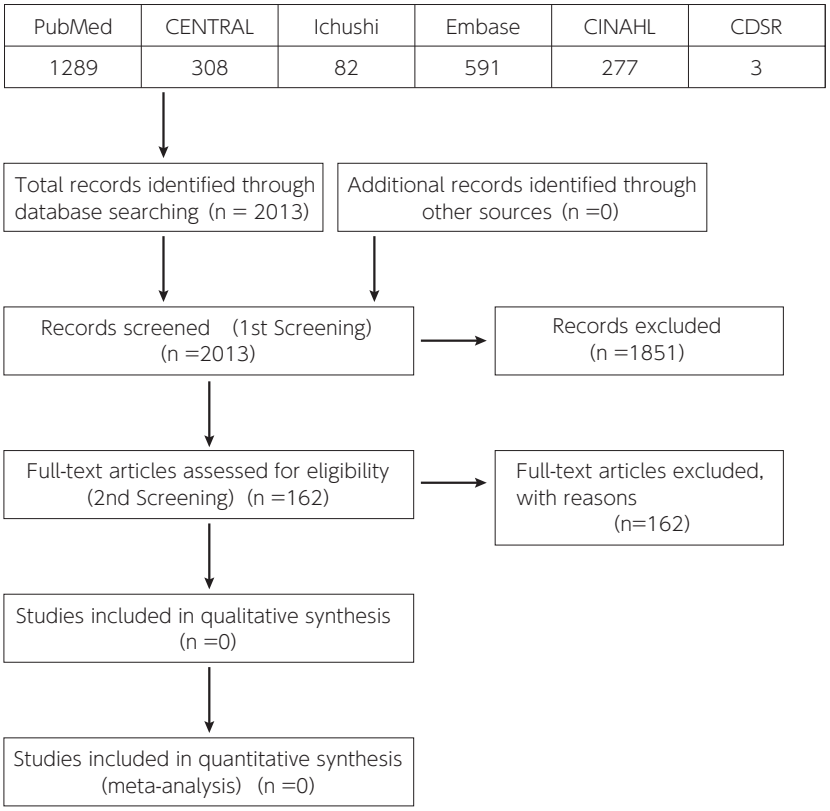

Figure 3: Literature search flowchart

4. CQ 4

CQ 4

Is the assessment of rectal stool retention by ultrasound imaging useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort or need for defecation?

1) Recommendation

○ In adult patients who are not always able to communicate their discomfort or need for defecation, it is strongly recommended that rectal fecal impaction be assessed by ultrasound imaging to determine rectal fecal impaction.

GRADE **1C** (Strength of recommendation : **strong**, Certainty of evidence (strength) : **weak**)

[Note] It is assumed that the patient understands how constipation can be assessed by means of a medical interview, defecation diary, and physical examination techniques. Ultrasound imaging for the detection of rectal fecal impaction should be performed by a nurse who has received specific training in this technique. In addition, the ultrasound imaging should be compatible with a convex probe as a prerequisite for adequate rectal observation. The probe should have a frequency in the range of 3.5 to 5 MHz and a resolution level that can delineate the bladder, uterus/vagina, prostate, and rectum.

2) Background and aims

Ultrasound imaging for assessment of fecal impaction in the rectum is a noninvasive method. In particular, portable ultrasound imaging have recently become widely available and can be easily used at the patient's bedside or in home health care settings. Since the presence or absence of stool retention in the rectum can be confirmed on the spot, it is expected to be an objective assessment method for adult patients who may not always be able to communicate their discomfort or need for defecation. However, it is unclear whether assessment based on rectal observation with ultrasound imaging is useful in assessing constipation. Therefore, we examined the sensitivity and specificity of ultrasound imaging for the assessment of rectal contents based on domestic and overseas literature.

3) Commentary

After a systematic review, two case-control studies, one prospective cohort study, and four cross-sectional studies were selected. The ultrasound imaging equipment used in each study was different. Image acquisition and interpretation were performed by ultrasound technologists* or trained nurses. In addition, the site where the probe was applied for image acquisition was the hallux valgus in addition to the lower abdomen. The sensitivity and specificity of ultrasound imaging for detecting rectal fecal impaction in the selected references are described below.

* Registered medical sonographer: A certification established by the Japan Society of Ultrasonics in Medicine to certify the knowledge and skills necessary for ultrasonography and to improve ultrasound medicine and medical care. Certified as a Registered Nurse, Licensed Practical Nurse, Clinical Laboratory Technician, and Radiologic Technologist as a professional medical examiner.

(1) Detection of constipation

One case report [1] and one cross-sectional study [2] were adopted as reference criteria. The pooled sensitivity was 0.45 (95% confidence interval [CI]: 0.27–0.64) and specificity was 0.93 (95% CI: 0.77–0.99).

Although the study subjects had normal cognitive function and were able to report subjective symptoms, it was determined that this did not affect the outcomes (sensitivity and specificity). Non-directness was “low (0)" and selection bias was unknown. Because some of the included studies did not adequately describe the evaluation of echographic images, the risk of bias was evaluated as “medium/suspicious (-1)," the sensitivity and specificity were varied and inconsistency was set to “medium/suspicious (-1)," and the noncertainty was set to “medium/suspicious (-1)" due to the small sample size. Based on the above, the certainty of evidence was assigned a grade of C (weak).

(2) Detection of rectal fecal impaction

One case report [3] and one cross-sectional study [4] were adopted as reference criteria. The pooled sensitivity was 1.00 (95% CI: 0.87–1.00) and pooled specificity was 1.00 (95% CI: 0.48–1.00). Owing to the high sensitivity and specificity, the possibility that the ultrasound images were analyzed after the results of the bowel movements were known cannot be ruled out.

Although the subjects included had normal cognitive function and were able to report subjective symptoms, it was determined that this did not affect the outcome. Non-directness was “low (0)," as the included studies were rated as “uncertain" with respect to selection bias and the timing of ultrasound image assessment, and studies whose reference criterion was the degree of adhesion with stool retention by excision. The risk of bias was set at “medium/suspicious (-1)," the sensitivity and specificity were not varied and inconsistency was set at “low (0)," and the imprecision was set at “medium/suspicious (-1)" due to the small sample size. Based on the above, the certainty of evidence was assigned as “C" (weak).

(3) Detection of hard stools

Reference criteria were stool characteristics (Bristol Stool Shape Scale) type 1 (hard, colossal, rabbit-feces-like (difficult to defecate) stool) or type 2 (sausage-like but hard stool). One case report [1], four cross-sectional studies [4-7], and one cohort study [2] qualified the criteria. A meta-analysis of six references was conducted. The sensitivity and specificity of imaging finding of “crescent-shaped high echo areas with acoustic shadows" for indicating hard stools were 0.93 (95% CI: 0.63–0.99) and 0.81 (95% CI: 0.60–0.92), respectively. Furthermore, in a paper [7] that used rectal observation with an artificial intelligence (AI)-equipped ultrasound imaging system, the sensitivity was 0.86 (95% CI: 0.57–0.98) and specificity was 0.88 (95% CI: 0.64–0.99). In addition, the sensitivity and specificity of rectal observation by the sonographer and AI-equipped ultrasound system were 1.00 (95% CI: 0.89–1.00) and 1.00 (95% CI: 0.72–1.00), respectively [7].

Non-directivity was set to “low (0)" because the subjects included those who could complain of subjective symptoms, but this was not deemed to have affected the outcome. The risk of bias was set to “medium/suspicious (-1)" because it included studies with “unknown" selection bias and studies with “unknown" blinding of

index test and reference criteria. Inconsistency was set at “Medium/suspicious (-1)" due to variations in sensitivity and specificity. Inconsistency was set to “low (0)" because the total number of patients was more than 100. Based on the above, the certainty of evidence was set at “C" (weak).

In addition to the certainty of the evidence, the panel meeting to determine the recommendation primarily discussed the balance of benefits and harms, the subject's sense of value for the primary outcome, cost, and feasibility. Since a healthy state is one in which there is little or no stool or gas in the rectum, if stool is present in the rectum, it should be expelled as soon as possible by appropriate means. The target audience for this guideline is adult patients who are not always able to communicate their discomfort or need for defecation. All panelists discussed the desirable benefits of ultrasound imaging to detect stool retention in the rectum. Negative reactions such as patient embarrassment and time burden were discussed as undesirable effects. Although no studies have investigated patient reactions to ultrasound examination, physicians and nurses who use ultrasound in their clinical practice for detecting rectal stool retention said that patients typically do not object to the use of ultrasound for this purpose. In addition, the procedure is not time-intensive and can be performed quickly. Regarding cost and feasibility, the cost of purchasing an ultrasound imaging and the cost of training personnel for detection of rectal fecal impaction were discussed. Although both of these costs are initial costs, it was decided to consider the weight of the disadvantage of the costs in determining the strength of the recommendation, since the maintenance costs involve purchase of relatively inexpensive consumables, such as echogel, and these costs are not directly borne by the patient.

Based on the above, the certainty of evidence is weak, but considering the benefit to the subject, and based on the expert opinion, the recommendation and strength of evidence for this CQ is GRADE 1C (strength of recommendation: strong; certainty of evidence (strength): weak).

4) Database search results

Constipation, physical examination, physical assessment, defecation care were the keywords for literature search. The following databases were searched for articles published as of November 3, 2020: PubMed, Embase, Cochrane Database of Systematic Reviews, The Cochrane Library/CENTRAL, CINAHL, and ICHUSHI. As a result, 65 articles were selected from the 2013 articles in the primary screening, and 7 articles were included after the secondary screening. The database search strategy is presented in the Appendix.

5) Literature search flowchart

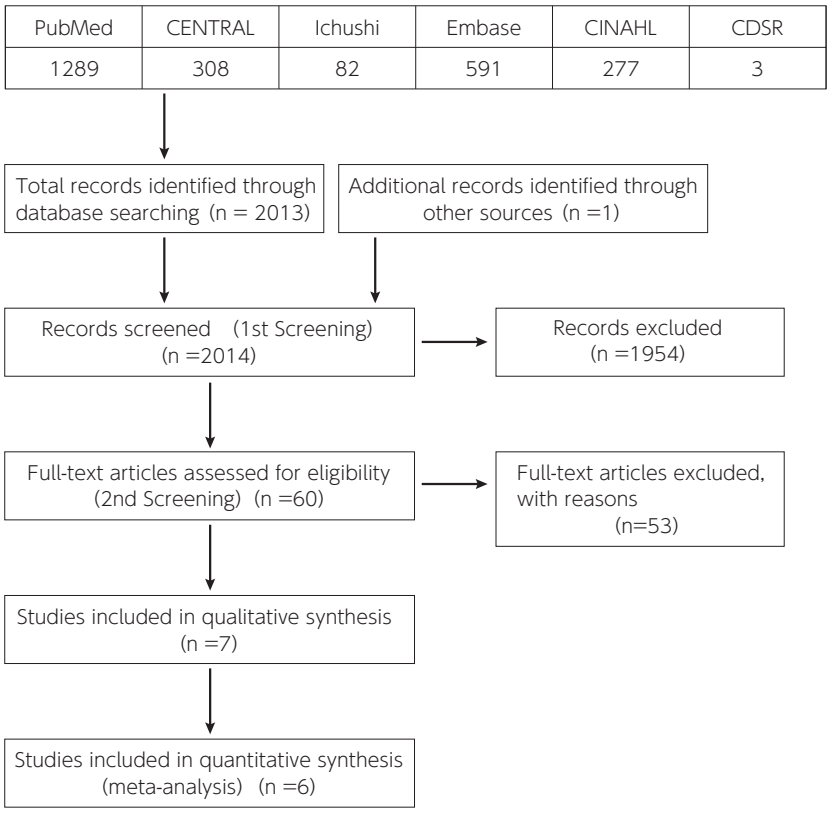

Figure 4: Literature search flowchart

6) Reference standards: BSFS, defecation cycle, digital impaction

(1) List after secondary screening

Table 1: List after secondary screening

Reference Documents	Research Designs	P	Index test	Reference Standards	O
Matsumoto, 2018	Case series	3 elderly patients admitted to a long-term care facility	Observation of stool shape by ultrasound imaging system	BSFS, defecation cycle and digital impaction	Sensitivity and specificity for constipation, sensitivity and specificity for hard stools
Tanaka, 2018	Cohort study	Inpatients 65 years and older with constipation	Observation of stool shape evaluation by ultrasound imaging system: R3 is constipation, R1,2 is not constipation	Defecation cycle: Less bowel movement frequency is considered constipation, and the rest is not constipation	Sensitivity and specificity of the presence or absence of constipation Sensitivity and specificity of the Hard stools

BSFS: Bristol stool form scale

(2) List of accepted papers

Table 2: List of included papers

Author	Title, refrence, year of publication, volume and page
Matsumoto M, Yabunaka K, Tanaka S, et al	The evaluation of stored feces in elderly patients by ultrasonography: Three case studies. The evaluation of stored feces in elderly patients by ultrasonography: Three case studies, Nippon Ronen Igakkai Zasshi. Japanese Journal of Geriatrics 2018; 55 (4): 657-662.
Tanaka S, Tabunaka K, Matsumoto M, et al	Fecal distribution changes using colorectal ultrasonography in older people with physical and cognitive impairment living in long-term care facilities: a longitudinal observational study. Healthcare (Basel) 2018; 6 (2): 55.

(3) Evidence evaluation of individual research

Table 3: Evidence evaluation of individual research

CQ	CQ4-1
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Index test	Observation of rectal stool retention by ultrasound imaging
Control test	not specified
Reference standard	Bristol stool form scale, frequecy of bowel movement, rectal and anal digital examination

*1 Each domain was ratedn in 3 levels; "high", "low" and unclear".
*2 The summary was reflected in the body of evidence in 3 levels; "serious ", "unlikely", and "none".

Outcome			Sensitivity & specificity in assessment of constipation									Number of participants												
Study			Risk of bias*1					Indirectness *1																
ID	Study design	Reference standard	Participant selection	Index test	Reference standard	Flow and timing	Summary *2	Participant	Index test	Reference standard	Summary	TP	FP	TN	FN	Prevalence	95%CI	Sensitivity	95%CI	specificity	95%CI	Accuracy	95%CI	ROC AUC	95%CI	P
Matsumoto, 2018	Case series	BSFS, frequecy of bowel movement, digital impaction	unclear	unclear	low	unclear	unlikely	low	low	low	none	1	1	1	0	0.33	0.008, 1.00	1.00	0.025, 1.00	0.50	0.01, 0.99	0.67	0.09, 0.99	NA	NA	NA
Tanaka, 2018	Cohort study	frequecy of bowel movement	unclear	unclear	low	low	unlikely	low	low	low	none	13	1	26	17	0.53	0.39, 0.66	0.43	0.25, 0.63	0.96	0.81, 1.00	0.68	0.55, 0.80	NA	NA	NA

BSFS: Bristol stool form scale, TP: true positive, FP: false positive, TN: true negative, FN: false negative, ROC: receiver operating characteristic curve, AUC: area under curve

(4) Evaluation of body of evidence

Table 4: Evaluation of body of evidence

CQ	CQ4-1
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Index test	Observation of rectal stool retention by ultrasound imaging
Control test	not specified
Reference standard	Bristol stool form scale, frequecy of bowel movement, rectal and anal digital examination

*1. Each domain was ratedn in 3 levels; "very serious (-2)", "serious (-1)" and "non (0)".
*2. Strength of evidence was rated on four levels; "strong (A)", "moderate (B)", "weak (C)"and "very weak (D)".
*3. Importance is rated on a sale of 1 to 9, with higher scores indicating greater importance.

body of evidence								Number of participants																
Outcome	Studies (No. of studies)	Reference standard	Risk of bias *1	Inconsistency *1	Imprecision *1	Indirectness *1	Others (publication bias, etc) *1	TP	FP	FN	TN	Prevalence	95%CI	Sensitivity	95%CI	specificity	95%CI	Accuracy	95%CI	ROC/AUC	95%CI	P	Strength of evidence *2	Importance *3
Sensitivity & specificity in assessment of constipation	Case report(1), cross-sectional study(1)	BSFS, frequency of bowel movement, rectal and anal digital examination	− 1	− 1	− 1	0	0	14	2	17	27	0.52	0.38, 0.65	0.45	0.27, 0.64	0.93	0.77, 0.99	0.68	0.55, 0.80	NA	NA	NA	D	7.8

BSFS: Bristol stool form scale, TP: true positive, FP: false positive, TN: true negative, FN: false negative, ROC: receiver operating characteristic curve, AUC: area under curve

(5) Qualitative systematic review

Table 5: Qualitative systematic review

CQ	4-1	Is the assessment of rectal stool retention by ultrasound imaging useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort or need for defecation?
P	Patients over 18 years of age who are not always able to communicate their discomfort or need regarding defecation.	
I	Observation using ultrasound imaging system.	
C	None	
Clinical contexts	In assessing for constipation, first determine whether or not constipation is suspected by interview and defecation diary, followed by observation and information gathering. Observation and information gathering include assessment of constipation by observing abdominal and anal symptoms, pathophysiology of the underlying disease, gastrointestinal function based on defecatory function tests and imaging studies, defecatory movements, and lifestyle habits. Based on the evaluation, appropriate defecation care is implemented. In recent years, observation using ultrasound imaging is becoming more common in clinical practice as a means of evaluating fecal retention. This method evaluates the presence or absence of stool retention and hard stools based on the presence or absence of hyperechoic or acoustic shadows.	
01	True positive, true negative, suspicious positive, and false negative results in constipation identification (stool shape, defecation cycle, stool removal, glycerin enema).	
Summary of Indirectness	Although the subjects included those who were able to report subjective symptoms without cognitive decline, the non-directiveness was set to Low (0) because it was judged not to affect the outcome.	
Summary of Bias Risk	Studies with unknown selection bias and studies with unknown timing of ultrasound image evaluation were included, with a Medium/Suspicious (-1) risk of bias.	
Inconsistency and Other summaries	Sensitivity and specificity varied and inconsistency was rated as Medium/Suspicious (-1). Inconsistency was rated as Medium/Suspicious (-1) due to small sample size.	
Commentary		

7) Reference standards: digital impaction, enema, stool form

(1) List of secondary screenings

Table 6: List of secondary screenings

Reference Documents	Research Designs	P	Index test	Reference Standards	O
Yabunaka, 2017	Case series	One female with rectal fecal impaction and one male without rectal retention	Ultrasound imaging	Stool extraction and glycerin enema	Defecation findings on ultrasound images
Sano, 2020	Cross sectional study	8 dialysis patients with defecation problems	Ultrasound imaging, observation of stool form	BSFS	Sensitivity and specificity for stool retention (Group1-3) and no stool retention (Group4) Sensitivity and specificity for hard stool (BSFS divided into 1 or otherwise)

(2) List of included studies

Table 7: List of included studies

Author	Title, reference, year of publication, volume and page
Yabunaka K, Nakagami G, Komagata K, et al	Ultrasonographic follow-up of functional chronic constipation in adults: a report of two cases. SAGE Open Medical Case Reports. 2017; 5: 2050313X17694234.
Sano Y, Muto M, Urata K, et al	The study of faces property assessment with ultrasonogrphy: usefullness of lower rectum assessment by intergluteal cleft approach scanning method. Japanese Journal of Medical Ultrasound Technology. 2020; 45 (2): 168-174.

(3) Evidence evaluation of individual research

Table 8: Evidence evaluation of individual research

CQ	CQ4-2
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Index test	Observation of rectal stool retention by ultrasound imaging
Control test	not specified
Reference standard	Bristol stool form scale, rectal and anal digital examination, implementation of glycerin enema

*1. Each domain was ratedn in 3 levels; "high", "low" and unclear".
*2. The summary was reflected in the body of evidence in 3 levels; "serious ", "unlikely", and "none".

Outcome			Sensitivity & specificity in assessment of rectal stool retention																						
Study			Risk of bias *1					Indirectness *1				Number of participants													
ID	Study design	Reference standard	Partici-pant selection	Index test	Reference standard	Flow and timing	Summary *2	Partici-pant	Index test	Reference standard	Summary *2	TP	FP	TN	FN	Preva-lence	95%CI	Sensi-tivity	95%CI	speci-ficity	95%CI	Accu-racy	95%CI	ROC AUC	95%CI	P
Yabunaka, 2017	case series	BSFS, rectal and anal digital examination	unclear	unclear	low	low	none	low	low	low	none	1	0	1	0	0.50	0.01, 0.99	1.00	0.03-1.00	1.00	0.03-1.00	1.00	0.03-1.00	NA	NA	NA
Sano, 2020	cross-sectional study	BSFS	unclear	unclear	high	unclear	unlikely	low	low	low	none	26	0	4	0	0.87	0.69, 0.96	1.00	0.87, 1.00	1.00	0.40, 1.00	1.00	0.88, 1.00	NA	NA	NA

BSFS: Bristol soot form scale, TP: true positive, FP: false positive, TN: true negative, FN: false negative, ROC: receiver operating characteristic curve, AUC: area under curve

(4) Evaluation of body of evidence

Table 9: Evaluation of body of evidence

CQ	CQ4-2
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Index test	Observation of rectal stool retention by ultrasound imaging
Control test	not specified
Reference standard	Bristol stool form scale, digital evacuation, Implementation of glycerin enema

*1. Each domain was ratedn in 3 levels; "very serious (-2)", "serious (-1)" and "non (0)".
*2. Strength of evidence was rated on four levels; "strong (A)", "moderate (B)", "weak (C)"and "very weak (D)".
*3. Importance is rated on a sale of 1 to 9, with higher scores indicating greater importance.

body of evidence								Number of participants																
Outcome	Studies (No. of studies)	Reference standard	Risk of bias *1	Inconsistency *1	Imprecision *1	Indirectness *1	Others (publication bias, etc) *1	TP	FP	FN	TN	Prevalence	95%CI	Sensitivity	95%CI	specificity	95%CI	Accuracy	95%CI	ROC/AUC	95%CI	P	Strength of evidence *2	Importance *3
Sensitivity & specificity in assessment of rectal stool retention	Case series(1), Cross-sectional study(1)	BSFS, digital impaction, Imlementation of glycerin enema	− 1	0	− 1	0	0	27	0	0	5	0.84	0.67, 0.95	1.00	0.87, 1.00	1.00	0.48, 1.00	1.00	0.89, 1.00	NA	NA	NA	D	7.5

BSFS: Bristol stool form scale

(5) Qualitative systematic review

Table 10: Qualitative systematic review

CQ	4-2	Is the assessment of rectal stool retention by ultrasound imaging useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort or need for defecation?
P	Patients over 18 years of age who are not always able to communicate their discomfort or need regarding defecation.	
I	Observation using ultrasound equipment.	
C	None.	
Clinical contexts	In assessing for constipation, first determine whether or not constipation is suspected by interview and defecation diary, followed by observation and information gathering. Observation and information gathering include abdominal and anorectal symptoms, pathophysiology of the underlying disease, and gastrointestinal function through defecatory function tests and imaging studies, as well as defecatory movements and lifestyle. Based on the classification of constipation, appropriate defecation care should be provided. In recent years, observation using ultrasound equipment is becoming popular in clinical practice as one of the ways to evaluate fecal retention. This method evaluates the presence or absence of fecal retention and hard stools based on the presence or absence of hyper-echogenicity or acoustic shadows.	
01	True positive, true negative, false positive, and false negative in rectal fecal impaction identification (stool extraction, glycerin enema, and stool shape).	
Summary of Indirectness	Although the subjects did not have cognitive decline and may have included some who were able to report subjective symptoms, it was determined that this would not affect the outcome, and the non-directiveness was set to Low (0).	
Summary of Bias Risk	Selection bias included studies that were unknown, studies that were uncertain about the timing of echographic evaluation, and studies in which the reference criterion was stool removal and degree of adhesion with stool retention. Therefore, the risk of bias was set at Medium/Suspicious (-1).	
Inconsistency and Other summaries	There was no variation in sensitivity and specificity, and inconsistency was considered Low (0). Due to the small sample size, the imprecision was set as Medium/Doubtful (-1).	
Commentary		

8) Reference standard: Hard stool (BSFS1 or 2)

(1) List of secondary screenings

Table 11: List of secondary screenings

Reference Documents	Research Designs	P	Index test	Reference Standards	O
Matsumoto, 2018	Case series	3 elderly patients admitted to a long-term care facility	Ultrasound Imaging System (Hyperechoic area)	BSFS	Sensitivity and specificity of hard stools
Yabunaka, 2018a	Cross sectional study	Eleven healthy adults	Ultrasound imaging system (Hyperechoic area or acoustic shadow)	BSFS	Sensitivity and specificity of hard stools
Yabunaka, 2018b	Cross sectional study	32 elderly patients admitted to a long-term care facility and meeting the criteria for chronic constipation	Ultrasound imaging system (Transverse sectional image: Hyperechoic area with acoustic shadows, Longitudinal image:Hyperechoic area)	BSFS	Sensitivity and specificity of hard stools
Tabnaka, 2018	Cohort study	Inpatients 65 years of age or older who are able to take oral intake and are scheduled to be hospitalized for at least one week	Ultrasound imaging system (Hyperechoic area or acoustic shadow)	BSFS	Sensitivity and specificity of hard stools
Matsumoto, 2020	Cross sectional study	Inpatients 65 years of age or older who are able to take oral intake and are scheduled to be hospitalized for at least one week	Ultrasound Imaging System (Hyperechoic area with acoustic shading)	BSFS	Sensitivity and specificity of hard stools
Sano, 2020	Cross sectional study	8 dialysis patients with defecation problems	Ultrasound imaging system (Hyperechoic area or acoustic shadow)	BSFS	Sensitivity and specificity of hard stools (BSFS1 or otherwise)

BSFS: Bristol stool form scale

(2) List of included papers

Table 12: List of included papers

Authors	Title, reference, year of publication, volume and page
Matsumoto M, Yabunaka K, Tanaka S, et al	The evaluation of stored feces in elderly patients by ultrasonography: Three case studies. The evaluation of stored feces in elderly patients by ultrasonography: Three case studies, Nippon Ronen Igakkai Zasshi. Japanese Journal of Geriatrics 2018; 55 (4): 657-662.
Yabunaka K, Matsumoto M, Yoshida M, et al	Assessment of rectal feces storage condition by a point-of-care pocket-size ultrasound device for healthy adult subjects: A preliminary study. Drug Discov Ther 2018a; 12 (1): 42-46.
Yabunaka K, Nakagami G, Komagata K, et al	Constipation in the elderly in a Japanese long-term medical facility: An ultrasonographic investigation. Drug Discov Ther 2018b; 12 (4): 233-238.
Tanaka S, Yabunaka K, Matsumoto M, et al	Fecal distribution changes using colorectal ultrasonography in older people with physical and cognitive impairment living in long-term care facilities: a longitudinal observational study. Healthcare (Basel) 2018; 6 (2): 55.
Matsumoto M, Tsutaoka T, Nakagami G, et al	Deep learning-based classification of rectal fecal retention and analysis of fecal properties using ultrasound images in older adult patients. Japan journal of nursing science. Jpn J Nursing Sci 2020; 17 (4): e12340.
Sano Y, Muto M, Urata K, et al	The study of faces property assessment with ultrasonogrphy: usefullness of lower rectum assessment by intergluteal cleft approach scanning method. Japanese Journal of Medical Ultrasound Technology. 2020; 45 (2): 168-174.

(3) Evaluation of evidence in individual studies

Table 13: Evaluation of evidence in individual studies

CQ	CQ4-3
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Index test	Observation of rectal stool retention by ultrasound imaging
Control test	not specified
Reference standard	Bristol stool form scale

*1. Each domain was ratedn in 3 levels; "high", "low" and unclear".
*2. The summary was reflected in the body of evidence in 3 levels; "serious ", "unlikely", and "none".

Outcome			Sensitivity & specificity in assessment of hard stool																						
Study			Risk of bias *1					Indirectness *1				Number of participants													
ID	Study design	Reference standard	Partici-pant selection	Index test	Reference standard	Flow and timing	Summary *2	Partici-pant	Index test	Reference standard	Summary *2	TP	FP	TN	FN	Preva-lence	95%CI	Sensi-tivity	95%CI	speci-ficity	95%CI	Accu-racy	95%CI	ROC AUC	95%CI	P
Matsumoto, 2018	Case series	BSFS	unclear	unclear	unclear	low	unlikely	low	low	low	none	1	1	1	0	0.33	0.01, 0.91	1	0.03, 1.00	0.5	0.01, 0.99	0.667	0.94, 0.99	NA	NA	NA
Yabunaka, 2018a	Cross-sectional study	BSFS	unclear	low	unclear	low	unlikely	high	low	low	none	3	8	0	0	0.27	0.60, 0.61	1	0.29, 1.00	0	0.00, 0.37	0.273	0.60, 0.61	NA	NA	NA
Yabunaka, 2018b	Cross-sectional study	BSFS	unclear	low	low	low	unlikely	low	low	low	none	3	2	25	2	0.16	0.53, 0.33	0.6	0.15, 0.95	0.926	0.76, 0.99	0.875	0.71, 0.96	NA	NA	NA
Tanaka, 2018	Cohort study	BSFS	unclear	unclear	unclear	low	unlikely	low	low	low	none	16	20	18	3	0.33	0.21, 0.47	0.842	0.60, 0.97	0.474	0.31, 0.64	0.596	0.46, 0.72	NA	NA	NA
Matumoto, 2020	Cross-sectional study	BSFS	unclear	low	low	low	unlikely	low	low	low	none	14	2	15	0	0.45	0.27, 0.64	1	0.77, 1.00	0.882	0.64, 0.99	0.935	0.79, 0.99	NA	NA	NA
Sano, 2020	Cross-sectional study	BSFS	unclear	unclear	unclear	low	unlikely	low	low	low	none	8	18	4	0	0.27	0.12, 0.46	1	0.63, 1.00	0.182	0.05, 0.40	0.4	0.23, 0.59	NA	NA	NA

BSFS: Bristol soot form scale, TP: true positive, FP: false positive, TN: true negative, FN: false negative, ROC: receiver operating characteristic curve, AUC: area under curve

(4) Evaluation of body of evidence

Table 14: Evaluation of body of evidence

CQ	CQ4-3
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Index test	Observation of rectal stool retention by ultrasound imaging
Control test	not specified
Reference standard	Bristol stool form scale

*1. Each domain was ratedn in 3 levels; "very serious (-2)", "serious (-1)" and "non (0)".
*2. Strngth of evidence was rated on four levels; "strong (A)", "moderate (B)", "weak (C)"and "very weak (D)".
*3. Importance is rated on a sale of 1 to 9, with higher scores indicating greater importance.

								Number of participants																
Outcome	Studies (No. of studies)	Reference standard	Risk of bias *1	Inconsistency *1	Imprecision *1	Indirectness *1	Others (publication bias, etc) *1	TP	FP	FN	TN	Prevalence	95%CI	Sensitivity	95%CI	specificity	95%CI	Accuracy	95%CI	ROC/AUC	95%CI	P	Strength of evidence *2	Importance *3
Sensitivity & specificity in assessment of hard stool	case series (1), cross-sectional study (4), cohort study (1)	BSFS	− 1	− 1	0	0	0	45	51	5	63	0.31	0.24, 0.38	0.90	0.78, 0.97	0.55	0.46, 0.65	0.66	0.58, 0.73	0.91	0.88 0.93,		C	7.5

BSFS: Bristol stool form scale, TP: true positive, FP: false positive, TN: true negative, FN: false negative, ROC: receiver operating characteristic curve, AUC: area under curve

(5) Meta-analysis

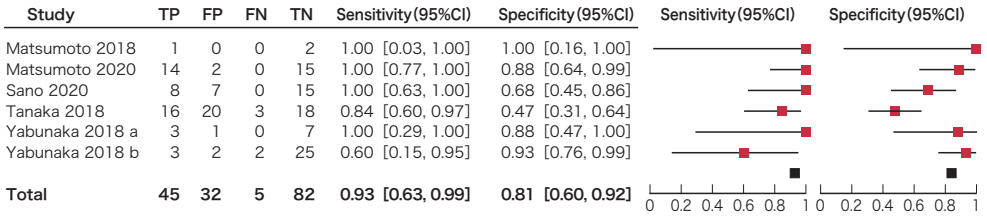

Figure 5: Meta-analysis

(6) Qualitative systematic review

Table 15: Qualitative systematic review

CQ	4-3	Is the assessment of rectal stool retention by ultrasound imaging useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort or need for defecation?
P	Patients over 18 years of age who are not always able to communicate their discomfort or need regarding defecation.	
I	Observation using ultrasound imaging equipment.	
C	None.	
Clinical contexts	In assessing for constipation, first determine whether or not constipation is suspected by interview and defecation diary, followed by observation and information gathering. Observation and information gathering include abdominal and anorectal symptoms, pathophysiology of the underlying disease, and gastrointestinal function through defecatory function tests and imaging studies, as well as defecatory movements and lifestyle. Based on the classification of constipation, appropriate defecation care should be provided. In recent years, observation using ultrasound imaging is becoming popular in clinical practice as one of the methods to evaluate fecal retention. This method evaluates the presence or absence of fecal retention and hard stools based on the presence or absence of hyper-echogenicity or acoustic shadows.	
01	True positive, true negative, false positive, and false negative in rectal fecal impaction identification (hard stool).	
Summary of Indirectness	Although it was possible that some of the subjects had no cognitive decline and were able to report subjective symptoms, it was determined that this would not affect the outcome and the non-directiveness was set to Low (0).	
Summary of Bias Risk	Selection bias included studies that were unknown, studies with unknown timings for evaluation of ultrasound imaging, and studies in which the reference criterion was the degree of adherence with stool retention by stool extraction, with a Medium/Suspicious (-1) risk of bias.	
Inconsistency and Other summaries	Sensitivity and specificity were set to Medium/Suspicious (-1) for Inconsistency due to variation in sensitivity and specificity. Inconsistency was set as Low (0) because there were more than 100 total cases.	
Commentary		

References

1) Matsumoto M, Yabunaka K, Tanaka S, et al. The evaluation of stored feces in elderly patients by ultrasonography: Three case studies. The evaluation of stored feces in elderly patients by ultrasonography: Three case studies, Nippon Ronen Igakkai Zasshi. Japanese Journal of Geriatrics. 2018; **55** (4): 657-662.
2) Tanaka S, Yabunaka K, Matsumoto M, et al. Fecal distribution changes using colorectal ultrasonography in older people with physical and cognitive impairment living in long-term care facilities: a longitudinal observational study. Healthcare (Basel) 2018; **6**: 55.
3) Yabunaka K, Nakagami G, Komagata K, et al. Ultrasonographic follow-up of functional chronic constipation in adults: a report of two cases. SAGE Open Med Case Rep 2017; **5**: 2050313X17694234.
4) Sano Y, Muto M, Urata K, et al. The study of faces property assessment with ultrasonogrphy: usefullness of lower rectum assessment by intergluteal cleft approach scanning method. Japanese Journal of Medical Ultrasound Technology. 2020; **45** (2): 168-174.
5) Yabunaka K, Matsumoto M, Yoshida M, et al. Assessment of rectal feces storage condition by a point-of-care pocket-size ultrasound device for healthy adult subjects: A preliminary study. Drug Discov Ther 2018a; **12**: 42-46.
6) Yabunaka K, Nakagami G, Tabata K,et al. Constipation in the elderly in a Japanese long-term medical facility: an ultrasonographic investigation. Drug Discov Ther 2018b; **12**: 233-238.
7) Matsumoto M, Tsutaoka T, Nakagami G, et al. Deep learning-based classification of rectal fecal retention and analysis of fecal properties using ultrasound images in older adult patients. Jpn J Nurs Sci 2020; **17**: e12340.

5. CQ 5

CQ 5

Is defecation care based on systematic assessment using defecation diaries and interviews useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort and need regarding defecation?

1) Recommendation

○ We propose the implementation of defecation care based on systematic assessment using defecation diaries and interviews with adult patients who are not always able to communicate their discomfort or need regarding defecation.

GRADE **2D** (Strength of recommendation : **week**, Certainty of evidence (strength) : **very weak**)

[Note] Since patients themselves are not always able to communicate, care should be taken to seek information from family members and caregivers who understand the patient's daily life.

2) Background and aims

In adult patients who are not always able to communicate their discomfort or need regarding defecation, defecation care based on systematic assessment using defecation diaries and interviews can help inform appropriate drug therapy and lead to the selection of appropriate defecation care.

However, it is unclear whether defecation care based on systematic assessment using defecation diaries and interviews contributes to improved patient outcomes. Therefore, we examined the usefulness of defecation care based on systematic assessment using defecation diaries and interviews from the domestic and overseas literature.

3) Commentary

A systematic literature search regarding defecation care based on systematic assessment using defecation diaries and interviews was conducted. After the systematic review, one prospective cohort study was selected for review.

The study population consisted of 52 patients (age range, 65–89 years) with chronic constipation and lower urinary tract symptoms who were attending a gastroenterology or urology clinic. Chronic constipation was defined as having less than three bowel movements per week and hard stools. The number of bowel movements per week, time spent in the toilet per day, and six other symptoms related to urination were prospectively surveyed using a questionnaire. After the survey entry, a constipation treatment (oral medication) was prescribed. The number of bowel movements per week showed a significant increase ($p < 0.01$) and the time spent in the toilet per day decreased ($p < 0.01$) compared to before the start of constipation treatment. There was a significant improvement in the scoring for urgency, frequency, and burning sensation during urination ($p < 0.01$).

The purpose of this study is to examine the effect of treatment of constipation on lower urinary tract symptoms. Therefore, for all outcome measures, subjects were those who could report subjective symptoms, and outcomes were reported using self-reported questionnaires. Since the data from defecation diaries and question-

naires were measured as outcome data rather than being used for the intervention, and it is unclear whether the constipation assessment methods differ before and after the intervention, the non-directiveness was set at “-1" (medium/suspicious). This was a single-arm observational study with no control group. The amount of medication used to treat constipation was customized for each individual. The outcome was a self-reported questionnaire (once a month). The risk of bias was set as high “-2." Inconsistency was set to low “0" because only one observational study was included. All the other studies were assigned a score of -2 (high) due to insufficient power. From the above, the certainty of evidence was set as D (very weak).

In addition to the certainty of the evidence, the main issues discussed at the panel meeting to determine the recommendation were the balance of benefits and harms, the subject's sense of value for the main outcome, cost, and feasibility. Since defecation diaries and interviews are already used in general practice, there is essentially no cost involved. In addition, it was determined that the burden would not be too great for patients who are not always able to communicate their discomfort or need, although there is some variation in their values, intentions, and wishes regarding outcomes for themselves. Furthermore, the reliability and feasibility of the assessment method were judged to be high because the benefits of correct classification outweigh the possible harms of incorrect classification, there is no impact on medical inequity, and the assessment method is already widely used in clinical practice.

The facilitating factor for the application of the guideline is that the defecation diary/questionnaire is already widely used in clinical practice, and this method does not require any special equipment. A potential limitation is that assessment requires a certain level of education and experience.

Based on the above, the strength of recommendation and evidence for this CQ is GRADE 2D (strength of recommendation: weak; certainty of evidence (strength): very low).

4) Database search results

Constipation, physical examination, physical assessment, defecation care were the keywords. The following databases were searched for articles published as of November 3, 2020: PubMed, Embase, Cochrane Database of Systematic Reviews, The Cochrane Library/ CENTRAL, CINAHL, and ICHUSHI. A total of 39 articles were selected from 2013 articles in the primary screening, and one article was selected after the secondary screening. The database search strategy is presented in the Appendix.

5) Literature search flowchart

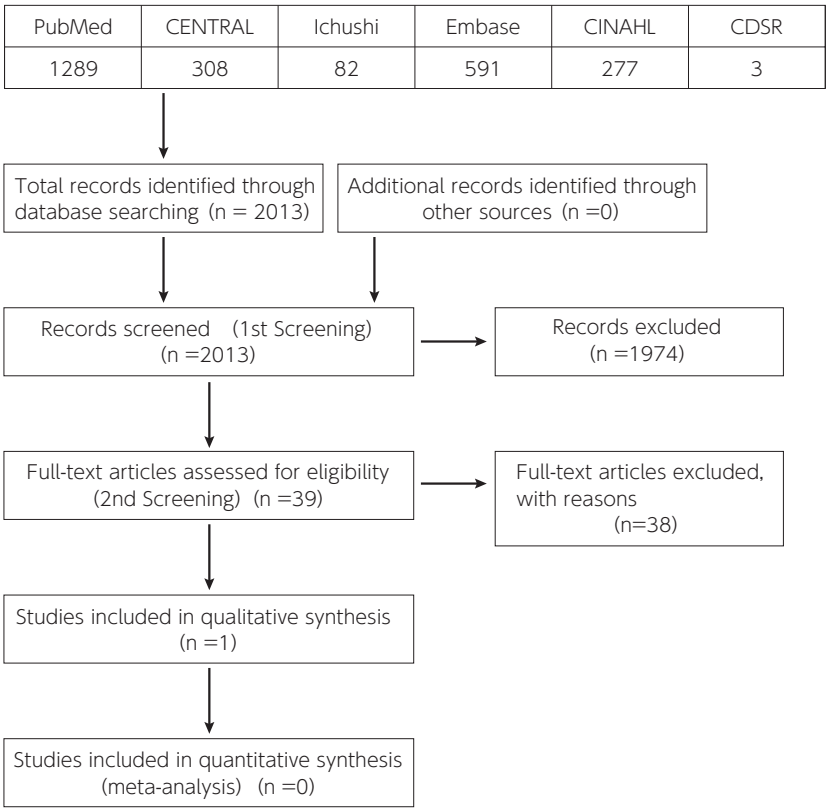

Figure 6: Literature search flowchart

6) List after secondary screening

Table 16: List of secondary screenings

Reference Documents	Research Designs	P	I	C	O
Charach G, 2001	Cohort study	Patients 65-89 years old with chronic constipation and lower urinary tract symptoms	Determination of constipation based on defecation patterns (number of bowel movements per week, abdominal bloating, time spent in the toilet per day) and treatment of constipation (oral medication) based on these patterns	Before the start of constipation treatment	Frequency of bowel movements per week, abdominal bloating, and time spent in the bathroom per day

7) List of included papers

Table 17: List of included papers

Author	Title, reference, year of publication, volume, and page
Charach G, Greenstein A, Rabinovich P, et al.	Alleviating constipation in the elderly improves lower urinary tract symptoms. Gerontology 2001; 47: 72-76.

8) Evaluation of the evidence in individuar studies

Table 18: Evaluation of the evidence in individuar studies

CQ	CQ5
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Intervention	Defecation care based on systematic assessment using defecation diaries and interviews
Control	Defecation care based on conventional assessment for constipation

*1. Each domain was ratedn in 3 levels; "high(-2)", "moderate/suspected (-1)" and "low (0)".
*2. The summary was reflected in the body of evidence in 3 levels; "high (-2)", "moderate (-1)", and "low(0)".
*3. Each domain was rated in 3 levels; "high (+2), "moderate (+1) , "low (0)".
*4. The summary wsd refrected in the body of evidence in 3 levels; "high (+2) ", "moderate (+1) ", "low (0)".

Outcome		No of defication per week																							
Study		Risk of bias*1							Upgrade factor *3				Indirectness*1					Number at risk/Mean/Standard deviation (SD)							
		Selection bias	Performance bias	Detection bias	Attrition bias	Others																			
ID	Study design	Differences in participant chracteristics	Differences in care	Inadequate outcome measure-ment	Incomolete outocome data	Insufficient confounding adjust	Other bias	Sum-mary *2	Dose-response gradient	Plausible con-founders	Magni-tude of effect	Sum-mary *4	Partici-pation	Inter-vention	Con-trol	Out-come	Sum-mary *2	Con-trol	Mean	SD	Inter-vention	Mean	SD	Mean difference/ Standardized mean difference: SMD	SD	95% CI
Charach, 2001	Cohort study	− 2	− 2	− 1	− 1	− 2	0	− 2	0	0	0	0	− 1	− 2	− 1	− 1	− 1	NA	NA	NA	52	4.7	1.2	can not be calculated	can not be calucu-lated	can not be calucu-lated

9) Evaluation of body of evidence

Table 19: Evaluation of body of evidence

CQ	CQ5
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Intervention	Defecation care based on systematic assessment using defecation diaries and interviews
Control	defecation care based on conventional assessment for constipation

*1. Each domain was ratedn in 3 levels; "high(-2)", "moderate/suspected (-1)" and "low (0)".
*2. Upgarade factor was described in 3 levels; "high(+2)", "moderate (+1)" and "low (0)".
*3. Thee were 4 levels of evidence strengths; "strong (A)", "moderate (B)", "weak (C) ", and "very weak (D)".
*4. The importance ranged from 1to 9. The higher score indicated greater importance.

Body of evidence								Number at risk/Mean/Standard deviation (SD)										
Outcome	Study design/ Number of studies	Risk of bias *1	Inconsist-ency *1	Impre-cision *1	Indirect-ness *1	Others (publication bias, etc) *1	Upgrade factor *2	Control group	Mean	SD	Inter-vention	Mean	SD	Mean difference/ Stndardized mean difference: SMD	SD	95% CI	Strength of evidence *3	Impor-tance *4
No of defication per week	Cohort study (1)	− 2	0	− 2	− 1	− 2	0	NA	NA	NA	52	4.7	1.2	NA	NA	NA	D	7
abdominal bloating	Cohort study (1)	− 2	0	− 2	− 1	− 2	0	NA	NA	NA	52	5	9.6154	NA	NA	NA	D	6

SMB study: single-case, multiple-baseline study

10) Qualitative systematic review

Table 20: Qualitative systematic review

CQ	5	Is defecation care based on systematic assessment using defecation diaries and interviews useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort and need regarding defecation?
P	Adults 18 years and older who cannot complain of subjective symptoms (cerebrovascular disease, brain damage, consciousness disorder, dementia, spinal injury, intractable disease, terminal stage, etc.)	
I	If defecation care is provided based on an evaluation using a defecation diary and medical interview.	
C	Conventional observation of constipation only (or none).	
Clinical contexts	The constipation treatment process is categorized as diagnostic (assessment). The first step in the assessment of constipation is to determine whether or not constipation is suspected by interview and defecation diary. Next, observation and information gathering are conducted. During observation and information gathering, defecation is assessed by observing abdominal and anorectal symptoms, pathophysiology of the underlying disease, gastrointestinal function through defecatory function tests and imaging examinations, as well as defecatory movements and lifestyle habits. Appropriate defecation care is provided based on the assessed classification of constipation. Does defecation care based on the assessment by defecation diary and interview in adults who cannot complain of subjective symptoms contribute to the improvement of patient outcomes?	
01	Frequency of bowel movements/week	
Summary of Indirectness	Subjects are those who can report subjective symptoms, and outcomes are reported using a self-report questionnaire. Since the data from the defecation diary/questionnaire were measured as outcome data rather than being used for the intervention, and it is unclear whether the constipation assessment method differed before and after the intervention, the non-directiveness was rated as Medium/ Suspicious (-1).	
Summary of Bias Risk	This is a single group observational study with no control group. The amount of medication used to treat constipation was not protocolized and customized to the individual. The outcome is a self-report questionnaire (once a month), which may lead to recall bias. Based on the above, the risk of bias was set at High (-2).	
Inconsistency and Other summaries	Inconsistency was set to Low (0) because the included study was a single observational study. All others were set to -2 (High) as underpowered.	
Commentary		
02	abdominal bloating	
Summary of Indirectness	Subjects are those who can report subjective symptoms, and outcomes are reported using a self-report questionnaire. Since the data from the defecation diary/questionnaire were measured as outcome data rather than being used for the intervention, and it is unclear whether the constipation assessment method differed before and after the intervention, the non-directiveness was rated as Medium/ Suspicious (-1).	
Summary of Bias Risk	This is a single group observational study with no control group. The amount of medication used to treat constipation was not protocolized and customized to the individual. The outcome is a self-report questionnaire (once a month), which may lead to recall bias. Based on the above, the risk of bias was set at High (-2).	
Inconsistency and Other summaries	Inconsistency was set to Low (0) because the included study was a single observational study. All others were set to -2 (High) as underpowered.	
Commentary		

References

1) Charach G, Greenstein A, Rabinovich P, et al. Alleviating constipation in the elderly improves lower urinary tract symptoms. Gerontology 2001; 47: 72-76.

6. CQ 6

CQ 6

Is defecation care based on systematic assessment using physical examination techniques (inspection, auscultation, palpation, and percussion) useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort or need for defecation?

1) Recommendation

○In adult patients who are not always able to communicate their discomfort or need for defecation, it is recommended that defecation care be based on systematic assessment using abdominal physical examination techniques (inspection, auscultation, palpation, and percussion).

Strength of recommendation▶**Recommendation by the expert panel**

[Note] Although there is insufficient evidence to recommend defecation care based on a systematic system assessment using physical examination techniques (inspection, auscultation, palpation, and percussion), the panel committee made this recommendation based on expert opinion.

2) Background and aims

Physical examination techniques (inspection, auscultation, palpation, and percussion) for abdominal examination are performed in addition to the interview to assess constipation symptoms such as decreased bowel motility and abdominal distension and to identify potential organic diseases such as cancer and gastrointestinal obstruction. Therefore, it is commonly used as a physical assessment for constipation.

However, the impact of defecation care based on assessment by physical examination techniques (inspection, auscultation, palpation, and percussion) on patient outcomes has not been clarified. In this study, we examined the usefulness of defecation care based on physical examination techniques (inspection, auscultation, palpation, and percussion) by nurses.

3) Commentary

The criterion for selecting evidence was randomized controlled trials. Observational studies were also eligible for inclusion if no studies met the criterion. None of the articles retrieved on literature search presented evidence for this CQ.

Thus, the panel meeting to determine the recommendation focused primarily on the balance of benefits and harms, the subject's sense of value for the primary outcome, cost, and feasibility. Per abdominal physical examination techniques include palpation for detection of abdominal distention and tenderness in the supine position, percussion to assess flatulence, and auscultation of bowel sounds. These are commonly used to identify organic disease and obstacles to stool evacuation. In addition, training in defecation care based on systematic assessment using physical examination techniques is an integral part of basic nursing education. Physical examination does

not cause patient discomfort or pain. However, the selection of physical examination techniques and assessment-based defecation care may vary among individuals, such as experts and newcomers. Since the physical examination techniques are already a part of general physical examination, the feasibility of conducting a study with a control group is low.

Given the above, there is insufficient evidence to recommend care, but the panel committee made the recommendation based on expert opinion.

4) Database search results

The following keywords were used for literature search: Constipation, physical examination, physical assessment, defecation care. The following databases were searched: PubMed (until November 3, 2020), Embase (until November 3, 2020), Cochrane Database of Systematic Reviews (until November 3, 2020), The Cochrane Library/ CENTRAL (until November 3, 2020), CINAHL (until November 3, 2020), and the Central Journal of Medicine (until 2021). A total of 110 articles were selected from the 2013 articles in the primary screening, and no articles were selected after the secondary screening. The database search strategy is presented in the Appendix.

5) Literature search flowchart

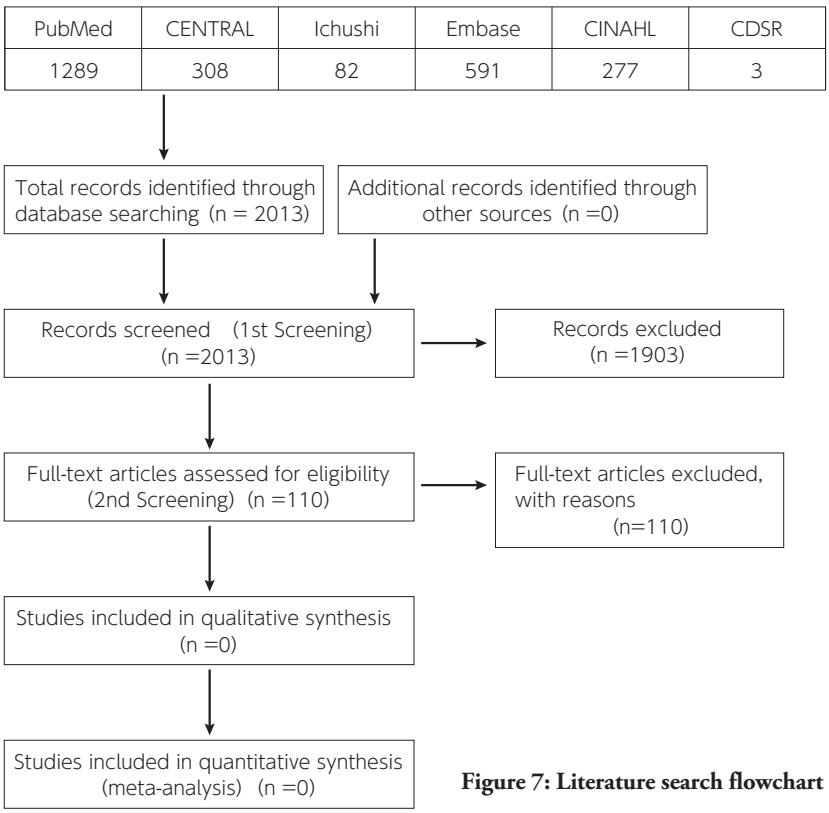

Figure 7: Literature search flowchart

4. CQ 7

CQ 7

Is defecation care based on the assessment by digital rectal examination useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort or need for defecation?

1) Recommendation

○ Defecation care based on digital rectal examination is strongly recommended in adult patients who are not always able to communicate their discomfort or need for defecation.

GRADE **1D** (Strength of recommendation : **strong**,
Certainty of evidence (strength) : **very weak**)

[Note] Although there is insufficient evidence to recommend assessment by digital rectal examination, we decided to recommend it based on expert opinion because it can enable the assessment of the presence or absence of stool in the rectum and is a reference standard for other CQs. The target patients of this guideline may not always be able to communicate their discomfort need regarding defecation. When performing digital rectal examination, due consideration should be given to the stress induced by digital rectal examination due to feelings of shame, pain, and discomfort.

2) Background and aims

In the absence of bowel movement, the rectum is normally empty of feces, and the feces are stored on the oral side of the sigmoid colon. Occurrence of large peristalsis in the left semicolon causes propulsion of the feces from the sigmoid colon to the rectum, stretching the rectal wall. The stretch stimulus is transmitted to the cerebral cortex via the sacral nerve, causing a bowel movement. However, adult patients, who are not always able to communicate discomfort or need for defecation, may not feel the presence of feces in the rectum and constipation may be suspected. In such cases, digital rectal examination can provide useful information regarding the need for defecation care.

3) Commentary

The criterion for selecting evidence was randomized controlled trials. Observational studies were also eligible for inclusion if no studies met the criterion. A systematic literature search did not identify any eligible articles presenting evidence for this CQ.

Therefore, the panel meeting to determine the recommendation primarily discussed the balance of benefits and harms, the subject's sense of value for the primary outcome, cost, and feasibility. It is unclear whether defecation care based on assessment by digital rectal examination to assess rectal fecal impaction during constipation is useful in improving patient outcomes, but observation of rectal sensation and rectal reflexes by digital rectal

examination may be useful for guiding defecation care. In the absence of any evidence, the effectiveness and certainty of the evidence could not be evaluated. However, the feasibility of the intervention was considered high because it is already a commonly implemented intervention method. It is necessary to obtain adequate training to ensure that it is performed safely without causing pain to the subject and that the necessary information on rectal sensation and reflexes is obtained.

Based on the above, there is insufficient evidence to recommend care, but the panel decided to make a recommendation based on expert opinion.

4) Database search results

The following keywords were used for the literature search: constipation, physical examination, physical assessment, defecation care.

The following databases were searched: PubMed (until November 3, 2020), Embase (until November 3, 2020), Cochrane Database of Systematic Reviews (until November 3, 2020), The Cochrane Library/ CENTRAL (until November 3, 2020), CINAHL (until November 3, 2020), and ICHUSHI (until 2021). A total of 8 papers were selected from 2013 papers in the primary screening, and no papers were selected after the secondary screening. The database search strategy is presented in the Appendix.

5) Literature search flowchart

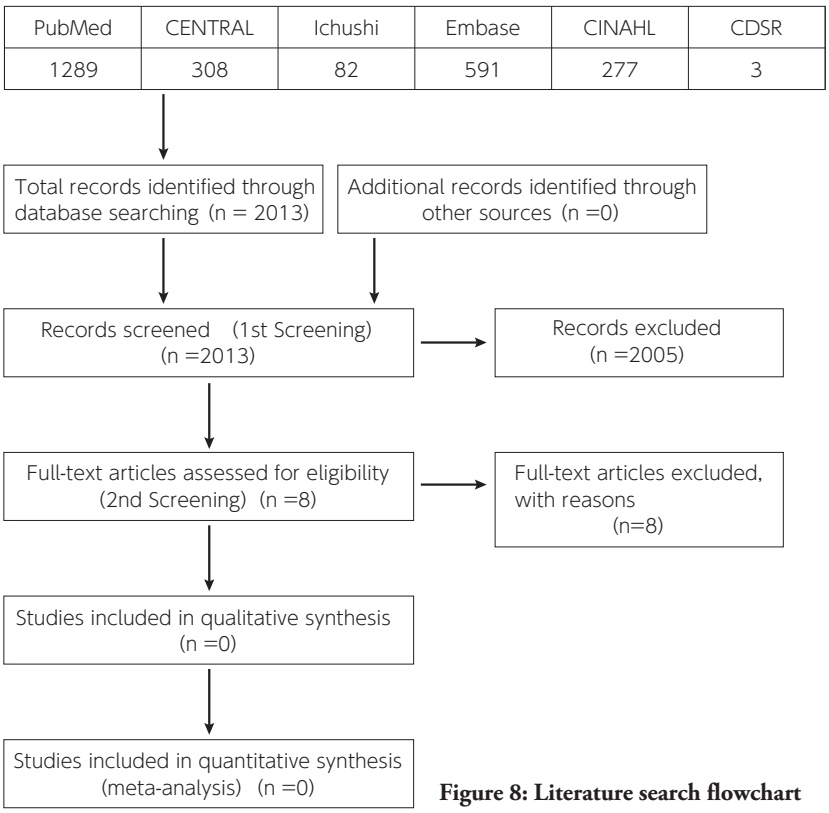

Figure 8: Literature search flowchart

8. CQ 8

CQ 8

Is defecation care based on observation of rectal stool retention by ultrasound imaging useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort and need for defecation?

1) Recommendation

○ In adult patients who are not always able to communicate their discomfort or need for defecation, it is strongly recommended to implement defecation care based on ultrasound imaging to detect rectal stool retention.

GRADE **1C** (Strength of recommendation : **strong**, Certainty of evidence (strength) : **weak**)

[Note] Ultrasound imaging should be performed by nurses trained in the observation of rectal fecal impaction. The ultrasound imaging should be compatible with a convex probe as a prerequisite for adequate rectal observation. The probe should have a frequency in the range of 3.5 to 5 MHz and a resolution level that can delineate the bladder, uterus/vagina, prostate, and rectum.

2) Background and aims

In adult patients who are not always able to communicate their discomfort or need for defecation, it is useful to use ultrasound imaging to observe the presence of stool retention in the rectum and provide appropriate medication and defecation care based on the results. However, it is unclear whether defecation care based on assessment using ultrasound imaging contributes to improved patient outcomes. Therefore, we examined the usefulness of defecation care based on ultrasound imaging findings from domestic and overseas literature.

3) Commentary

Systematic literature search identified one single-case, multiple-baseline study and one case report.

The former examined the effectiveness of an algorithm in which home health care nurses who had undergone training added ultrasound imaging observations to traditional physical assessment and implemented care based on the results of the observations [1].

In 15 home care patients, comparison of the baseline and intervention periods showed a significant reduction in the frequency of hard stools ($p < 0.01$), manual defecation ($p < 0.01$), stimulant laxative use ($p < 0.01$), and glycerin enema use ($p = 0.04$). The Tau-U of the intervention effect ranged from 0.34 to 0.56, suggesting a moderate change. In the latter case study, a home health care nurse who received educational program added ultrasound imaging to the traditional physical assessment and provided care based on the observations to an 86-year-old male prostate cancer patient who was being treated at home [2]. Following the intervention, stool characteristics changed from hard stools (BSFS1) to normal stools (BSFS3-5), eliminating the need for stool removal, and the patient was able to defecate on his own in the toilet after an enema. A meta-analysis could not be con-

ducted because of the nature of the studies.

All outcome measures were reported by patients with the ability to report subjective symptoms. Therefore, it was determined to have a non-directiveness of “low (0)," the risk of bias was rated as “medium/suspicious (-1)" due to the home care nurse's knowledge of the echo results, inconsistency was rated as “low (0)" due to the small number of articles, and imprecision was rated as “medium/suspicious (-1)." Based on the above, the certainty of evidence was assigned as C (weak).

In addition to the certainty of the evidence, the main issues discussed at the panel meeting were the balance of benefits and harms, the subject's sense of value for the main outcome, cost, and feasibility. Since a healthy state is one in which there is little or no stool or gas in the rectum, if stool is present in the rectum, it should be expelled as soon as possible by appropriate means. The target population for this guideline is adult patients who are not always able to communicate their discomfort or need for defecation, and all panelists discussed the desirable benefits of ultrasound imaging for detecting stool retention in the rectum. Negative reactions such as patient embarrassment and time burden were discussed as undesirable effects. Although no papers had describe patient reactions to ultrasound observation, physicians and nurses who use ultrasound in their clinical practice to observe stool retention in the rectum reported that patients typically do not object to the use of ultrasound. In addition, it was also commented that the procedure is not time-consuming. Regarding cost and feasibility, the purchase cost of the ultrasound device and the cost of training in detecting rectal fecal impaction were discussed. However, these are initial costs, and since the maintenance cost is relatively low (including relatively inexpensive consumables such as echogel) and these costs are not directly borne by the patient, it was decided to consider the weight of the disadvantageous aspects of the costs when determining the strength of the recommendation.

Based on the above, although the certainty of the evidence is weak, the recommendation and strength of evidence for this CQ is GRADE 1C (strength of recommendation: strong; certainty of evidence (strength): weak) based on the expert opinion, taking into consideration the benefit to the target population.

4) Database search results

Constipation, physical examination, physical assessment, defecation care were the keywords used for literature search. The following databases were searched for articles published as of November 3, 2020: PubMed, Embase, Cochrane Database of Systematic Reviews, The Cochrane Library/ CENTRAL, CINAHL, and ICHUSHI. A total of 130 articles were selected from 2013 articles in the primary screening, and 2 articles were selected after the secondary screening. The database search strategy is presented in the Appendix.

5) Literature search flowchart

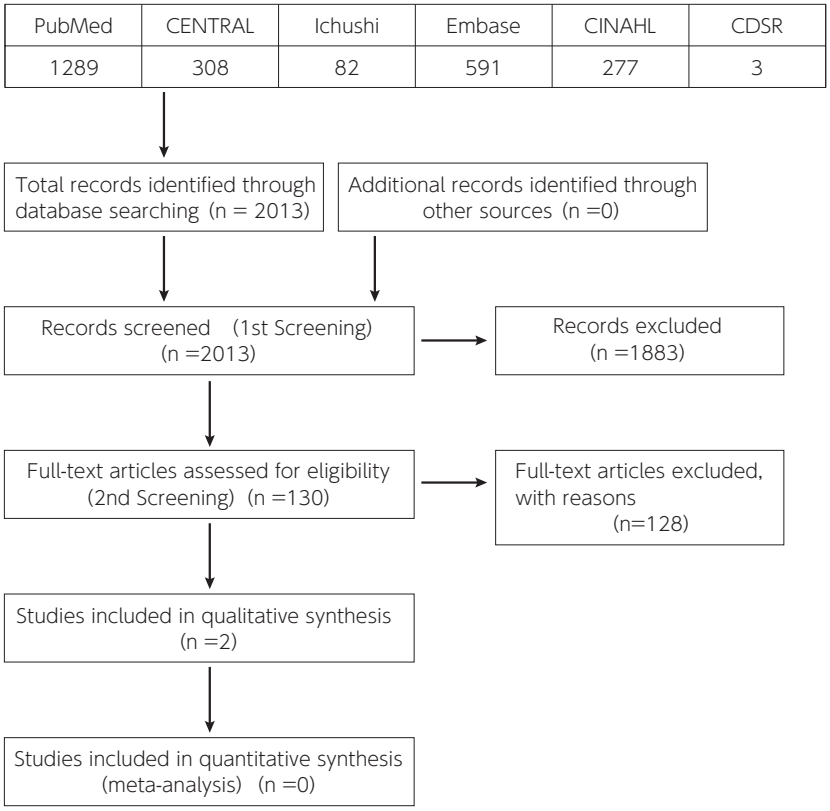

Figure 9: Literature search flowchart

6) List of secondary screenings

Table 21: List of secondary screenings

Reference Documents	Research Designs	P	I	C	O
Matsumoto M, 2020a	Single-case, multiple-baseline study	15 home care patients Eligibility criteria: (1) defecation difficulty due to cognitive or physical decline, (2) defecation interval of 3 days or more or BSFS 1 or 2 points, (3) low stool volume, Exclusion criteria: (1) no intention by the patient or family to change defecation care, (2) history of organic bowel disease, (3) risk of bleeding from the colon	Defecation care based also on assessment with the addition of rectal fecal impaction observation by ultrasound imaging to the physical examination	Defecation care based on assessment of medical interview and physical examination	Number of non-manual defecation (per week) Number of hard stools (BSFS1-2) defecation (per week) Number of manual defecation (per week) Number of manual defecations (per week) Stimulant laxative use (per week) Glycerin enema use (per week) Amount of suppositories used (per week)
Matsumoto M, 2020b	Case report	85 years old, prostate cancer, recovering at home	Defecation care based also on assessment with the addition of rectal stool retention observation by ultrasound imaging to the physical examination	Defecation care based on the assessment of medical interview and physical examination	BSFS (median) Number of stool extractions Amount of osmotic laxatives used Amount of glycerin enema used

BSFS: Bristol stool form scale

7) List of included papers

Table 22: List of included papers

Author	Title, reference, year of publication, volume, and page
Matsumoto M, Yoshida M, Yabunaka K, et al	Safety and efficacy of a defecation care algorithm based on ultrasonographic bowel observation in Japanese home-care settings: a single-case, multiple-baseline study. Geriatr Gerontol Int 2020a; 20: 187-194.
Matsumoto M, Yabunaka K, Yoshida M, et al	Improvement of constipation symptoms in an older adult patient by defecation care based on using a handheld ultrasound device in home care settings: a case report. J Wound Ostomy Continence Nurs 2020b; 47: 75-78.

8) Evaluation of the evidence in individuar studies

(1) Outcome: Score of Bristrol stool form scale

Table 23: Evaluation of the evidence in individuar studies - Score of Bristrol stool form scale

CQ	CQ8-1
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Intervention	Defecation care based on observation of rectal stool retention by ultrasound imaging
Control	Defecation care based on conventional assessment for constipation

*1. Each domain was ratedn in 3 levels; "high(-2)", "moderate/suspected (-1)" and "low (0)".
*2. The summary was reflected in the body of evidence in 3 levels; "high (-2)", "moderate (-1)", and "low(0)".
*3. Each domain was rated in 3 levels; "high (+2), "moderate (+1) , "low (0)".
*4. The summary wsd refrected in the body of evidence in 3 levels; "high (+2) ", "moderate (+1) ", "low (0)".

Outcome		Score of Bristrol stool form scale																								
Study		Risk of bias *1							Upgrade factor *3				Indirectness *1					Number at risk//Mean/ Standard deviation (SD)								
		Selection bias	Performance bias	Detection bias	Attrition bias	Others																				
ID	Study design	Differences in participant chracteristics	Differences in care	Inadequate outcome measure-ment	Incomolete outcome data	Insufficient con-founding adjust	Other bias	Sum-mary *2	Dose-response gradient	Plausible con-founders	Magni-tude of effect	Sum-mary *4	Partici-pation	Inter-vention	Con-trol	Out-come	Sum-mary *2	Con-trol	Mean	SD	Inter-vention	Mean	SD	Mean difference/ Standardized mean difference: SMD	SD	95% CI
Matsumoto M, 2020b	Case report	0	0	− 2	0	0	0	− 1	0	0	0	0	− 1	0	0	0	0	2	1.00	0	8	3.70	0.35	2.7	can not be calucu-lated	can not be calucu-lated

(2) Outcome: Number of non-manual defecations

Table 24: Evaluation of the evidence in individuar studies - Number of non-manual defecations

CQ	CQ8-2
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Intervention	Defecation care based on observation of rectal stool retention by ultrasound imaging
Control	Defecation care based on conventional assessment for constipation

*1. Each domain was ratedn in 3 levels; "high(-2)", "moderate/suspected (-1)" and "low (0)".
*2. The summary was reflected in the body of evidence in 3 levels; "high (-2)", "moderate (-1)", and "low(0)".
*3. Each domain was rated in 3 levels; "high (+2), "moderate (+1) , "low (0)".
*4. The summary wsd refrected in the body of evidence in 3 levels; "high (+2) ", "moderate (+1) ", "low (0)".

Outcome		Number of non-artificial defecation per week																								
Study		Risk of bias *1							Upgrade factor *3				Indirectness *1					Number at risk/Mean/ Standard deviation (SD)								
		Selection bias	Performance bias	Detection bias	Attrition bias	Others																				
ID	Study design	Differences in participant chracteristics	Differences in care	Inadequate outcome measure-ment	Incomolete outcome data	Insufficient con-founding adjust	Other bias	Sum-mary *2	Dose-response gradient	Plausible con-founders	Magni-tude of effect	Sum-mary *4	Partici-pation	Inter-vention	Con-trol	Out-come	Sum-mary *2	Con-trol	Mean	SD	Inter-vention	Mean	SD	Mean difference/ Standardized mean difference: SMD	SD	95% CI
Matsumoto M, 2020a	SMB Study	0	0	− 2	− 1	0	0	− 1	0	0	0	0	− 1	0	0	0	0	69	1.25	1.94	73	1.85	1.86	0.60	0.32	[-0.03, -1.23]

SMB study: single-case, multiple-baseline study

(3) Outcome: Frequency of hard stool defecation

Table 25: Evaluation of the evidence in individuar studies - Frequency of hard stool defecation

CQ	CQ8-3
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Intervention	Defecation care based on observation of rectal stool retention by ultrasound imaging
Control	Defecation care based on conventional assessment for constipation

*1. Each domain was ratedn in 3 levels; "high(-2)", "moderate/suspected (-1)" and "low (0)".
*2. The summary was reflected in the body of evidence in 3 levels; "high (-2)", "moderate (-1)", and "low(0)".
*3. Each domain was rated in 3 levels; "high (+2), "moderate (+1) , "low (0)".
*4. The summary wsd refrected in the body of evidence in 3 levels; "high (+2) ", "moderate (+1) ", "low (0)".

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Outcome		Number of hard stool defecation per week																								
Study		Risk of bias *1							Upgrade factor *3				Indirectness *1					Number at risk//Mean/ Standard deviation (SD)								
		Selection bias	Performance bias	Detection bias	Attrition bias	Others																				
ID	Study design	Differences in participant chracteristics	Differences in care	Inadequate outcome measure-ment	Incomolete outocome data	Insufficient con-founding adjust	Other bias	Sum-mary *2	Dose-response gradient	Plausible con-founders	Magni-tude of effect	Sum-mary *4	Partici-pation	Inter-vention	Con-trol	Out-come	Sum-mary *2	Con-trol	Mean	SD	Inter-vention	Mean	SD	Mean difference/ Standardized mean difference: SMD	SD	95% CI
Matsumoto M, 2020a	SMB Study	0	0	− 2	− 1	0	0	− 1	0	0	0	0	− 1	0	0	0	0	69	0.59	0.94	73	0.18	0.51	− 0.41	0.16	[-0.66, -0.16]

SMB study: single-case, multiple-baseline study

(4) Outcome: Number of bowel movement

Table 26: Evaluation of the evidence in individuar studies - Number of bowel movement

CQ	CQ8-4
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Intervention	Defecation care based on observation of rectal stool retention by ultrasound imaging
Control	Defecation care based on conventional assessment for constipation

*1. Each domain was ratedn in 3 levels; "high(-2)", "moderate/suspected (-1)" and "low (0)".
*2. The summary was reflected in the body of evidence in 3 levels; "high (-2)", "moderate (-1)", and "low(0)".
*3. Each domain was rated in 3 levels; "high (+2), "moderate (+1) , "low (0)".
*4. The summary wsd refrected in the body of evidence in 3 levels; "high (+2) ", "moderate (+1) ", "low (0)".

Outcome		Number of artificial defecation per week																								
Study		Risk of bias *1							Upgrade factor *3				Indirectness *1					Number at risk//Mean/ Standard deviation (SD)								
		Selection bias	Performance bias	Detection bias	Attrition bias	Others																				
ID	Study design	Differences in participant chracteristics	Differences in care	Inadequate outcome measure-ment	Incomolete outocome data	Insufficient con-founding adjust	Other bias	Sum-mary *2	Dose-response gradient	Plausible con-founders	Magni-tude of effect	Sum-mary *4	Partici-pation	Inter-vention	Con-trol	Out-come	Sum-mary *2	Con-trol	Mean	SD	Inter-vention	Mean	SD	Mean difference/ Standardized mean difference: SMD	SD	95% CI
Matsumoto M, 2020a	SMB Study	0	0	− 2	− 1	− 1	0	− 1	0	0	0	0	− 1	0	0	− 1	0	69	1.46	1.03	73	0.88	0.96	-0.58	0.11	[-0.91, -0.25]
Matsumoto M, 2020b	Case report	0	0	− 2	0	− 1	0	− 1	0	0	0	0	− 1	0	0	0	0	2	3.00	0.00	8	0.38	0.48	-2.63	0.12	can not be calucu-lated

SMB study: single-case, multiple-baseline study

(5) Outcome: Amount of non-stimulant laxatives

Table 27: Evaluation of the evidence in individuar studies - Amount of non-stimulant laxatives

CQ	CQ8-5
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Intervention	Defecation care based on observation of rectal stool retention by ultrasound imaging
Control	Defecation care based on conventional assessment for constipation

*1. Each domain was ratedn in 3 levels; "high(-2)", "moderate/suspected (-1)" and "low (0)".
*2. The summary was reflected in the body of evidence in 3 levels; "high (-2)", "moderate (-1)", and "low(0)".
*3. Each domain was rated in 3 levels; "high (+2), "moderate (+1) , "low (0)".
*4. The summary wsd refrected in the body of evidence in 3 levels; "high (+2) ", "moderate (+1) ", "low (0)".

Outcome		Amount of non-stimulant laxative per week (mg)																							
Study		Risk of bias *1							Upgrade factor *3				Indirectness *1					Number at risk/Mean/ Standard deviation (SD)							
		Selection bias	Performance bias	Detection bias	Attrition bias	Others																			
ID	Study design	Differences in participant chracteristics	Differences in care	Inadequate outcome measure-ment	Incomolete outocome data	Insufficient con-founding adjust	Other bias	Sum-mary *2	Dose-response gradient	Plausible con-founders	Magni-tude of effect	Sum-mary *4	Partici-pation	Inter-vention	Con-trol	Out-come	Sum-mary *2	Con-trol	Mean	SD	Inter-vention	Mean	SD	Mean difference/ Standardized mean difference: SMD	SD	95% CI
Matsumoto M, 2020a	SMB Study	0	0	− 2	− 1	− 1	0	− 1	0	0	0	0	− 1	0	0	0	0	69	3589	3609	76	4041	4304	452.0	434.5	[-836.98, 1740.98]
Matsumoto M, 2020b	Case report	0	0	− 2	0	− 1	0	− 1	0	0	0	0	− 1	0	0	0	0	2	1414	94.29	8	1680	62.09	265.5	493.7	[128.42, 403.58]

(6) Outcome: Amount of stimulant laxative

Table 28: Evaluation of the evidence in individuar studies - Amount of stimulant laxative

CQ	CQ8-6
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Intervention	Defecation care based on observation of rectal stool retention by ultrasound imaging
Control	Defecation care based on conventional assessment for constipation

*1. Each domain was ratedn in 3 levels; "high(-2)", "moderate/suspected (-1)" and "low (0)".
*2. The summary was reflected in the body of evidence in 3 levels; "high (-2)", "moderate (-1)", and "low(0)".
*3. Each domain was rated in 3 levels; "high (+2), "moderate (+1) , "low (0)".
*4. The summary wsd refrected in the body of evidence in 3 levels; "high (+2) ", "moderate (+1) ", "low (0)".

Outcome		Amount of stimulant laxative per week (mg)																							
Study		Risk of bias *1							Upgrade factor *3				Indirectness *1					Number at risk/Mean/ Standard deviation (SD)							
		Selection bias	Performance bias	Detection bias	Attrition bias	Others																			
ID	Study design	Differences in participant chracteristics	Differences in care	Inadequate outcome measure-ment	Incomolete outocome data	Insufficient con-founding adjust	Other bias	Sum-mary *2	Dose-response gradient	Plausible con-founders	Magni-tude of effect	Sum-mary *4	Partici-pation	Inter-vention	Con-trol	Out-come	Sum-mary *2	Con-trol	Mean	SD	Inter-vention	Mean	SD	Mean difference/ Standardized mean difference: SMD	SD	95% CI
Matsumoto M, 2020a	SMB study	0	0	− 2	− 1	− 1	0	− 1	0	0	0	0	− 1	0	0	0	0	69	22.7	44.6	76	14.1	34.2	− 8.6	3.92	[-21.63, 4.43]

SMB study: single-case, multiple-baseline study

(7) Outcome: Amount of glycerin enema

Table 29: Evaluation of the evidence in individuar studies - Amount of glycerin enema

CQ	CQ8-7
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Intervention	Defecation care based on observation of rectal stool retention by ultrasound imaging
Control	Defecation care based on conventional assessment for constipation

*1. Each domain was ratedn in 3 levels; "high(-2)", "moderate/suspected (-1)" and "low (0)".
*2. The summary was reflected in the body of evidence in 3 levels; "high (-2)", "moderate (-1)", and "low(0)".
*3. Each domain was rated in 3 levels; "high (+2), "moderate (+1) , "low (0)".
*4. The summary wsd refrected in the body of evidence in 3 levels; "high (+2) ", "moderate (+1) ", "low (0)".

Outcome		Amount of glycerin enema per wek (ml)																								
Study		Risk of bias *1							Upgrade factor *3				Indirectness *1					Number at risk/Mean/ Standard deviation (SD)								
		Selection bias	Performance bias	Detection bias	Attrition bias	Others																				
ID	Study design	Differences in participant chracteristics	Differences in care	Inadequate outcome measure-ment	Incomolete outocome data	Insufficient con-founding adjust	Other bias	Sum-mary *2	Dose-response gradient	Plausible con-founders	Magni-tude of effect	Sum-mary *4	Partici-pation	Inter-vention	Con-trol	Out-come	Sum-mary *2	Con-trol	Mean	SD	Inter-vention	Mean	SD	Mean difference/ Standardized mean difference: SMD	SD	95% CI
Matsumoto M, 2020a	SMB Study	0	0	− 2	− 1	− 1	0	− 1	0	0	0	0	− 1	0	0	0	0	69	58.3	62.1	73	45.2	59.4	− 13.1	7.48	[-33.11, 6.91]
Matsumoto M, 2020b	Case report	0	0	− 2	0	− 1	0	− 1	0	0	0	0	− 1	0	0	0	0	2	180.0	0	8	97.5	59.5	− 82.5	計算不可	計算不可

SMB study: single-case, multiple-baseline study

(8) Outcome: Amount of suppository

Table 30: Evaluation of the evidence in individuar studies - Amount of suppository

CQ	CQ8-8
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Intervention	Defecation care based on observation of rectal stool retention by ultrasound imaging
Control	Defecation care based on conventional assessment for constipation

*1. Each domain was ratedn in 3 levels; "high(-2)", "moderate/suspected (-1)" and "low (0)".
*2. The summary was reflected in the body of evidence in 3 levels; "high (-2)", "moderate (-1)", and "low(0)".
*3. Each domain was rated in 3 levels; "high (+2), "moderate (+1) , "low (0)".
*4. The summary wsd refrected in the body of evidence in 3 levels; "high (+2) ", "moderate (+1) ", "low (0)".

Outcome		Amount of suppository per wek (mg)																								
Study		Risk of bias *1							Upgrade factor *3				Indirectness *1					Number at risk/Mean/ Standard deviation (SD)								
		Selection bias	Performance bias	Detection bias	Attrition bias	Others																				
ID	Study design	Differences in participant chracteristics	Differences in care	Inadequate outcome measure-ment	Incomolete outocome data	Insufficient con-founding adjust	Other bias	Sum-mary *2	Dose-response gradient	Plausible con-founders	Magni-tude of effect	Sum-mary *4	Partici-pation	Inter-vention	Con-trol	Out-come	Sum-mary *2	Con-trol	Mean	SD	Inter-vention	Mean	SD	Mean difference/ Standardized mean difference: SMD	SD	95% CI
Matsumoto M, 2020a	SMB Study	0	0	− 2	− 1	− 1	0	− 1	0	0	0	0	− 1	0	0	0	0	69	0.36	1.22	79	0.16	0.61	− 0.20	0.15	[-0.52, 0.12]

SMB study: single-case, multiple-baseline study

9) Evaluation of body of evidence

Table 31: Evaluation of body of evidence

CQ	CQ8
Participant	Adult patients who are not always able to communicate their discomfort and need for defecation
Intervention	defecation care based on observation of rectal stool retention by ultrasound imaging
Control	defecation care based on conventional assessment for constipation

*1. Each domain was ratedn in 3 levels; "high(-2)", "moderate/suspected (-1)" and "low (0)".
*2. Upgarade factor was described in 3 levels; "high(+2)", "moderate (+1)" and "low (0)".
*3. Thee were 4 levels of evidence strengths; "strong (A)", "moderate (B)", "weak (C) ", and "very weak (D)".
*4. The importance ranged from 1to 9. The higher score indicated greater importance.

Body of evidence								Number at risk/Mean/Standard deviation (SD)										
Outcome	Study design/ Number of studies	Risk of bias *1	Inconsist-ency *1	Impre-cision *1	Indirect-ness *1	Others (Publication bias, etc.) *1	Upgrade factor *2	Control	Mean	SD	Inter-vention	Mean	SD	Mean difference/ Stndardized mean difference: SMD	SD	95% CI	Strength of evidence *3	Impor-tance *4
Score of Bristol stool form scale	Case report(1)	− 1	0	− 1	0	0	0	2	1.00	0	8	3.70	0.35	2.70	NA	NA	C	7.4
Number of non-artificial defecation per week	SMB study(1)	− 1	0	− 1	0	0	0	69	1.25	1.94	73	1.85	1.86	0.60	0.32	[− 0.03, 1.23]	C	7.4
Number of hard stool defecation per week	SMB study(1), Case report(1)	− 1	0	− 1	0	0	0	69	0.59	0.94	73	0.18	0.51	− 0.42	0.16	[− 0.66, − 0.16]	C	7.4
Number of artificial defecation per week	SMB study(1), Case report(1)	− 1	0	− 1	0	0	0	71	1.50	1.05	81	0.83	0.94	− 0.67	0.16	[− 0.91, − 0.25]	C	7
Amount of non-stimulant laxative per week (mg)	SMB study(1), Case report(1)	− 1	0	− 1	0	0	0	71	3527.73	35756	84	3816.1	4152.2	288.37	657.7	[131.29, 404.90]	C	6.4
Amount of stimulant laxative per week (mg)	SMB study(1)	− 1	0	− 1	0	0	0	69	22.7	44.6	76	14.1	34.2	− 8.60	3.92	[− 21.63, 4.43]	C	6.4
Amount of glycerin enema per wek (ml)	SMB study(1), Case report(1)	− 1	0	− 1	0	0	0	71	61.7	64.4	81	50.4	61.4	− 11.30	10.21	[− 33.11, 6.91]	C	6.5
Amount of suppository per wek (mg)	SMB study(1)	− 1	0	− 1	0	0	0	69	0.36	1.22	79	0.16	0.61	− 0.20	0.15	[− 0.52, 0.12]	C	6.5

SMB study: single-case, multiple-baseline study

10) Qualitative systematic review

Table 32: Qualitative systematic review

CQ	8	Is defecation care based on observation of rectal stool retention by ultrasound imaging useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort and need for defecation?
P	Adult patients who are not always able to communicate their discomfort or need regarding defecation.	
I	Defecation care based on observation using ultrasound imaging equipment.	
C	Defecation care based on medical interview and physical examination.	
Clinical contexts	In assessing for constipation, first determine whether or not constipation is suspected by interview and defecation diary, followed by observation and information gathering. Observation and information gathering include abdominal and anorectal symptoms, pathophysiology of the underlying disease, and gastrointestinal function through defecatory function tests and imaging examinations, as well as defecatory movements and lifestyle. Based on the classification of constipation, appropriate defecation care should be provided. In recent years, observation using ultrasound imaging is becoming popular in clinical practice as one of the methods to evaluate fecal retention. This method evaluates the presence or absence of fecal retention and hard stools based on the presence or absence of hyper-echogenicity and acoustic shadows.	
01	Bristol stool form scale scores.	
Summary of Indirectness	Subjects can report subjective symptoms, which may affect outcomes somewhat. Judged Low (0).	
Summary of Bias Risk	If the home care nurse knew the results of the echo, it could warp the observations of the stool shape, resulting in a detection bias. The patient was judged to be Medium/Suspicious (-1).	
Inconsistency and Other summaries	Inconsistency was determined to be Low (0) due to only one literature. The sample size was small and the imprecision was judged to be Medium/Suspicious (-1).	
Commentary		
02	Number of non-manual defecations.	
Summary of Indirectness	Patients who can report subjective symptoms are included, which may affect outcomes somewhat. It was determined to be Low (0).	
Summary of Bias Risk	If the home care nurse knew the results of the echo, she might intentionally encourage non-useful defecation, which would be a detection bias. The patient was judged to be Medium/Suspicious (-1).	
Inconsistency and Other summaries	Inconsistency was determined to be Low (0) due to only one literature. The sample size was small, and inconsistency was judged as Medium/Suspicious (-1).	
Commentary		
03	Frequency of hard stool defecation.	
Summary of Indirectness	Patients who can report subjective symptoms are included, which may affect outcomes somewhat. It was determined to be Low (0).	
Summary of Bias Risk	If the home care nurse knew the results of the echo, it could warp the observations of the stool condition, resulting in a detection bias. The patient was judged to be Medium/Suspicious (-1).	
Inconsistency and Other summaries	Inconsistency was determined to be Low (0) due to only one literature. The sample size was small and the imprecision was judged to be Medium/Suspicious (-1).	
Commentary		
04	Number of bowel movement	
Summary of Indirectness	Patients who can report subjective symptoms were included, which may affect the outcome somewhat. In addition, one literature review included manual defecation, including suppositories and enemas in addition to bowel movements, which was judged to be Low (0).	
Summary of Bias Risk	If the home care nurse knew the results of the echo, she might intentionally reduce the number of stool samples, which would be a detection bias. The patient was judged to be Medium/Suspicious (-1).	
Inconsistency and Other summaries	In both of the two references, the number of bowel movements tended to decrease in the intervention group, and the inconsistency was determined to be Low (0). The sample size was small, and inconsistency was judged to be Medium/Suspicious (-1).	
Commentary		

Table 32: Qualitative systematic review

05	Amount of non-stimulant laxatives
Summary of Indirectness	Patients who can report subjective symptoms are included, which may affect outcomes somewhat. It was determined to be Low (0).
Summary of Bias Risk	If the home care nurse knew the results of the echo, she might intentionally increase the non-stimulant laxative, which would be a detection bias. The patient was judged to be Medium/Suspicious (-1).
Inconsistency and Other summaries	In both of the two references, the use of non-stimulant laxatives showed an increasing trend in the intervention group and was judged to be Low (0) for inconsistency. The sample size was small, and inconsistency was judged to be Medium/Suspicious (-1).
Commentary	
06	Amount of stimulant laxative
Summary of Indirectness	Patients who can report subjective symptoms are included, which may affect outcomes somewhat. It was determined to be Low (0).
Summary of Bias Risk	If the home care nurse knew the results of the echo, there is a possibility of intentionally reducing the stimulant laxative, which would result in a detection bias. The patient was judged to be Medium/Suspicious (-1).
Inconsistency and Other summaries	Only one literature was found, and the inconsistency was determined to be Low (0). The sample size was small, and the imprecision was judged to be Medium/Suspicious (-1).
Commentary	
07	Amount of glycerin enema
Summary of Summary of Indirectness	Patients who can report subjective symptoms are included, which may affect outcomes somewhat. It was determined to be Low (0).
Summary of Bias Risk	If the home care nurse knew the results of the echo, there is a possibility of intentionally reducing the use of enemas, which would result in a detection bias. The patient was judged to be Medium/Suspicious (-1).
Inconsistency and Other summaries	In both of the two references, the amount of enema use tended to decrease in the intervention group, and inconsistency was judged to be Low (0). Due to the small sample size, inconsistency was judged to be Medium/Suspicious (-1).
Commentary	
08	Amount of suppository
Summary of Indirectness	Patients who can report subjective symptoms are included, which may affect outcomes somewhat. It was determined to be Low (0).
Summary of Bias Risk	If the home care nurse knew the results of the echo, there is a possibility of intentionally reducing the use of suppositories, which is a detection bias. The patient was judged to be Medium/Suspicious (-1).
Inconsistency and Other summaries	Only one literature was found, and the inconsistency was determined to be Low (0). The sample size was small, and the imprecision was judged to be Medium/Suspicious (-1).
Commentary	

References

1) Matsumoto M, Yoshida M, Yabunaka K, et al. Safety and efficacy of a defecation care algorithm based on ultrasonographic bowel observation in Japanese home-care settings: a single-case, multiple-baseline study. Geriatr Gerontol Int 2020a; **20**: 187-194.
2) Matsumoto M, Yabunaka K, Yoshida M, et al. Improvement of constipation symptoms in an older adult patient by defecation care based on using a handheld ultrasound device in home care settings: a case report. J Wound Ostomy Continence Nurs 2020b; **47**: 75-78.

Appendix

1. Key clinical issues

Key clinical issue 1

Key clinical issues addreses in the scope				
Key clinical issue 1: Is it useful to conduct a systemic assement of colonic stool retention during constipation for adults who are not always able to communicate their discomfort and need for defecation, using a defecation diary and interview?				
Components of CQ				
P (Patients,Problem,Population)				
Gender	not specified			
Age	over 18 years old			
Dieases and conditions	adults who are not always able to communicate their discomfort and need for defecation			
Geographic requirements	not specified			
Others	not specified			
I (Interventions) /C (Comparisons,Controls) list				
I: systemic assessment using a defecation diary and interview C: observayion of conventional constipation, or none Outcomes are adopted with a score 5 or more.				
O (Outcomes) list				
	Outcome	Benefit or harm	Priority	Included or excluded
O1	Sensitivity and specificity of constipation identification	Benefit	7.8	○
O2	Sensitivity and specificity of colonic stool retention	Benefit	7.5	○
O3	Stool form	Benefit	7.4	○
O4	Feeling of imcomlete defecation	Benefit	7.1	○
O5	Patient satisfaction	Benefit	7.1	○
O6	Number of bowel movement (ferequency or times/week)	Benefit	7	○
O7	Diarhearia	Benefit	6.8	○
O8	Number of digital evacuaion	Benefit	6.8	○
O9	Amount of stool	Benefit	6.6	○
O10	Pain during bowel movement	Benefit	6.6	○
O11	Amount of laxative (oral medicine)	Benefit	6.5	○
O12	Amount of laxative (suppository or enema)	Benefit	6.5	○
O13	Number of successful defecation attempts	Benefit	6.5	○
O14	Abdominal pain	Benefit	6.4	○
O15	Sensation of abdominal distension	Benefit	6	○
O16	Time required for bowel movement	Benefit	5.9	○
CQ				
CQ 1: Is a systematic assessment using defecation diaries and interviews useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort and need for defecation? CQ 5: Is defecation care based on systematic assessment using defecation diaries and interviews useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort and need regarding defecation?				

Key clinical issue 2

Key clinical issues addreses in the scope				
Key clinical issue 2: Is it useful to conduct a systemic physical assement of colonic stool retention during constipation for adults who are not always able to communicate their discomfort and need for defecation, using inspection, auscultation, palpation, and percussion?				
Components of CQ				
P (Patients,Problem,Population)				
Gender	not specified			
Age	over 18 years old			
Dieases and conditions	adults who are not always able to communicate their discomfort and need for defecation			
Geographic requirements	not specified			
Others	not specified			
I (Interventions) /C (Comparisons,Controls) list				
I: systemic physical assessment using inspection, auscultation, palpation, and percussion C: observayion of conventional constipation, or none Outcomes are adopted with a score 5 or more.				
O (Outcomes) list				
	Outcome	Benefit or harm	Priority	Included or excluded
O1	Sensitivity and specificity of constipation identification	Benefit	7.8	○
O2	Sensitivity and specificity of colonic stool retention	Benefit	7.5	○
O3	Stool form	Benefit	7.4	○
O4	Feelings of imcomlete detecation	Benefit	7.1	○
O5	Patient satisfaction	Benefit	7.1	○
O6	Number of bowel movement (ferequency or times/week)	Benefit	7	○
O7	Diarhearia	Benefit	6.8	○
O8	Number of digital evacuaion	Benefit	6.8	○
O9	Amount of stool	Benefit	6.6	○
O10	Pain during bowel movement	Benefit	6.6	○
O11	Amount of laxative (oral medicine)	Benefit	6.5	○
O12	Amount of laxative (suppository or enema)	Benefit	6.5	○
O13	Number of successful defecation attempts	Benefit	6.5	○
O14	Abdominal pain	Benefit	6.4	○
O15	Sensation of abdominal distension	Benefit	6	○
O16	Time required for bowel movement	Benefit	5.9	○
CQ				
CQ 2: Is systematic assessment using physical examination techniques (inspection, auscultation, palpation, and percussion) useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort or need for bowel movements? CQ 6: Is defecation care based on systematic assessment using physical examination techniques (inspection, auscultation, palpation, and percussion) useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort or need for defecation?				

Key clinical issue 3

Key clinical issues addreses in the scope				
Key clinical issue 3: Is it useful to conduct a digital rectal examination for rectal stool retention during constipation for adults who are not always able to communicate their discomfort and need for defecationn?				
Components of CQ				
P (Patients,Problem,Population)				
Gender	not specified			
Age	over 18 years old			
Dieases and conditions	adults who are not always able to communicate their discomfort and need for defecation			
Geographic requirements	not specified			
Others	not specified			
I (Interventions) /C (Comparisons,Controls) list				
I: digital rectal examination C: observation of conventional constipation, or none Outcomes are adopted with a score 5 or more.				
O (Outcomes) list				
	Outcome	Benefit or harm	Priority	Included or excluded
O1	Sensitivity and specificity of constipation identification	Benefit	7.8	○
O2	Sensitivity and specificity of colonic stool retention	Benefit	7.5	○
O3	Stool form	Benefit	7.4	○
O4	Feelings of imcomlete defecation	Benefit	7.1	○
O5	Patient satisfaction	Benefit	7.1	○
O6	Number of bowel movement (ferequency or times/week)	Benefit	7	○
O7	Diarhearia	Benefit	6.8	○
O8	Number of digital evacuaion	Benefit	6.8	○
O9	Amount of stool	Benefit	6.6	○
O10	Pain during bowel movement	Benefit	6.6	○
O11	Amount of laxative (oral medicine)	Benefit	6.5	○
O12	Amount of laxative (suppository or enema)	Benefit	6.5	○
O13	Number of successful defecation attempts	Benefit	6.5	○
O14	Abdominal pain	Benefit	6.4	○
O15	Sensation of abdominal distension	Benefit	6	○
O16	Time required for bowel movement	Benefit	5.9	○
CQ				
CQ 3: Is assessment by digital rectal examination useful in the evaluation of rectal fecal impaction during constipation in adult patients who are not always able to communicate their discomfort or need for defecation? CQ 7: Is defecation care based on the assessment by digital rectal examination useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort or need for defecation?				

Key clinical issue 4

Key clinical issues addreses in the scope				
Key clinical issue 4: Is it useful to conduct a observation using ultrasonography for rectal stool retention during constipation for adults who are not always able to communicate their discomfort and need for defecation?				
Components of CQ				
P (Patients,Problem,Population)				
Gender	not specified			
Age	over 18 years old			
Dieases and conditions	adults who are not always able to communicate their discomfort and need for defecationcommunicate			
Geographic requirements	not specified			
Others	not specified			
I (Interventions) /C (Comparisons,Controls) list				
I: observation using ultrasonography C: observation of conventional constipation, or none Outcomes are adopted with a score 5 or more.				
O (Outcomes) list				
	Outcome	Benefit or harm	Priority	Included or excluded
O1	Sensitivity and specificity of constipation identification	Benefit	7.8	○
O2	Sensitivity and specificity of colonic stool retention	Benefit	7.5	○
O3	Stool form	Benefit	7.4	○
O4	Feelings of imcomlete defecation	Benefit	7.4	○
O5	Patient satisfaction	Benefit	7.1	○
O6	Number of bowel movement (ferequency or times/week)	Benefit	7	○
O7	Diarhearia	Benefit	6.8	○
O8	Number of digital evacuaion	Benefit	6.6	○
O9	Amount of stool	Benefit	6.6	○
O10	Pain during bowel movement	Benefit	6.6	○
O11	Amount of laxative (oral medicine)	Benefit	6.5	○
O12	Amount of laxative (suppository or enema)	Benefit	6.5	○
O13	Number of successful defecation attempts	Benefit	6.4	○
O14	Abdominal pain	Benefit	6.4	○
O15	Sensation of abdominal distension	Benefit	6.3	○
O16	Time required for bowel movement	Benefit	6.3	○
CQ				
CQ 4: Is the assessment of rectal stool retention by ultrasound imaging useful in the evaluation of constipation in adult patients who are not always able to communicate their discomfort or need for defecation? CQ 8: Is defecation care based on observation of rectal stool retention by ultrasound imaging useful for improving patient outcomes in adult patients who are not always able to communicate their discomfort and need for defecation?				

2. Database search formula

PubMed, CINAHL, Cochrane Library

#1	"defecation"[MeSH Terms] OR "defaecat*"[Title/Abstract] OR "defecat*"[Title/Abstract] OR "dyschezia"[Title/Abstract] OR "hard stool*"[Title/Abstract] OR "obstipation*"[Title/Abstract] OR "fecal impaction"[MeSH Terms] OR (("feces"[MeSH Terms] OR "feces"[Title/Abstract] OR "fecal"[Title/Abstract] OR "faecal"[Title/Abstract]) AND ("impaction"[Title/Abstract] OR "retention"[Title/Abstract] OR "evacuation"[Title/Abstract]))
#2	"ultrasonography"[MeSH Terms] OR "ultrasonograph*"[Title/Abstract] OR "ultra sonograph*"[Title/Abstract] OR "doptone"[Title/Abstract] OR "echogram*"[Title/Abstract] OR "echograph*"[Title/Abstract] OR "echo graph*"[Title/Abstract] OR "echoscop*"[Title/Abstract] OR "echosound*"[Title/Abstract] OR "echo sound*"[Title/Abstract] OR "echotomograph*"[Title/Abstract] OR "echo tomograph*"[Title/Abstract] OR "sonogram*"[Title/Abstract] OR "sonograph*"[Title/Abstract] OR "ultrasonic*"[Title/Abstract] OR "ultra sonic*"[Title/Abstract] OR "ultrasound*"[Title/Abstract] OR "ultra sound*"[Title/Abstract] OR "acoustic"[Title/Abstract] OR "B-mode"[Title/Abstract] OR "gray scale*"[Title/Abstract] OR "b scan*"[Title/Abstract]
#3	#1 and #2
#4	"english"[Language] OR "japanese"[Language]
#5	#3 and #4

Embase

#1	'constipation'/exp OR 'constipation' OR constipat*:ti,ab OR coprostasis:ti,ab OR costiveness:ti,ab OR 'defecation'/exp OR 'defecation' OR defecat*:ti,ab OR dyschezia:ti,ab OR 'hard stool*':ti,ab OR obstipation*:ti,ab OR 'feces impaction'/exp OR 'feces impaction' OR ((feces OR fecal OR faecal) NEAR/3 (impaction OR retention OR evacuation)) OR defaecat*:ti,ab
#2	'echography'/exp OR 'echography' OR ultrasonograph*:ab,ti OR 'ultra sonograph*':ab,ti OR doptone:ab,ti OR echogram*:ab,ti OR echograph*:ab,ti OR 'echo graph*':ab,ti OR echoscop*:ab,ti OR 'echo scop*':ab,ti OR echosound*:ab,ti OR 'echo sound*':ab,ti OR echotomograph*:ab,ti OR 'echo tomograph*':ab,ti OR sonogram*:ab,ti OR sonograph*:ab,ti OR ultrasonic*:ab,ti OR 'ultra sonic*':ab,ti OR ultrasound*:ab,ti OR 'ultra sound*':ab,ti OR acoustic:ab,ti OR b-mode:ab,ti OR 'b scan*':ab,ti OR 'gray scale*':ab,ti
#3	english:la OR japanese:la
#4	#1 AND #2 AND #3
#5	#4 AND ('Conference Abstract'/it OR 'Conference Paper'/it OR 'Editorial'/it OR 'Letter'/it OR 'Note'/it)
#6	#4 NOT #5
#7	#6 AND ([adolescent]/lim OR [child]/lim OR [embryo]/lim OR [fetus]/lim OR [infant]/lim OR [newborn]/lim OR [preschool]/lim OR [school]/lim)
#8	#6 NOT #7
#9	#8 AND ('animal tissue'/de OR 'human cell'/de OR 'human tissue'/de OR 'nonhuman'/de)
#10	#8 NOT #9
#11	#10 AND ('case control study'/de OR 'comparative effectiveness'/de OR 'controlled clinical trial'/de OR 'controlled study'/de OR 'diagnostic test accuracy study'/de OR 'meta analysis topic'/de OR 'practice guideline'/de OR 'randomized controlled trial'/de OR 'randomized controlled trial topic'/de OR 'systematic review'/de)

Ichushi-Web

#1	((ultrasound/TA) or (ultrasound endoscopy /TH) or (ultrasonography/TA) or (doptone/TA) or (echogram/TA) or (echograph/TA) or (echoscop/TA) or (echosound/TA) or (echotomograph/TA) or (sonogram/TA) or (sonograph/TA) or (ultrasonic/TA) or (ultrasound/TA))
#2	(constipation/TH) or (constipation/TA) or (defecation/TH) or (defecation/TA) or (fecal impaction/TH) or (fecal impaction/TA) or (feces/TH) or (feces/TA) or (bowel movement/TA)
#3	#1 and #2
#4	(#3) and (PT=exclude case report)
#5	(#4) and (PT=explanation, diagram, conference proceeding)
#6	#4 not #5
#7	(#6) and (CK=animal)
#8	#6 not #7
#9	(#8) and (CK=fetus, neonate, infant(1-23 months),toddler(2-5 years old),pediatric (6-12 years old))
#10	#8 not #9

3. The conflict of interest statuses

Organizational members and roles

	Name (Organization)	Economic COI	Academic COI
Guideline development steering committee	Junko Sugama (Fujita Health University)	None	None
	Miyuki Ishibashi (Chiba University)	None	None
	Shingo Okada* (Kitamihara Clinic)	None	None
	Hiromi Sanada (Ishikawa Prefectural Nursing University)	None	None
	Atsushi Nakajima* (Yohokama City University)	-Lecture fees: EA Pharma Co., Ltd., Astellas Pharma Inc., Mochida Pharma Co., Ltd., Mylan EPD, Biofermin Pharma Co., Ltd. (2020-2021) -Research funding: EA Pharma Co., Ltd., Astellas Pharma Inc., Mochida Pharma Co., Ltd., Mylan EPD. (2020-2021) - Scholarship Donations (2,000,000 JPN or more): EA Pharma Co., Ltd.	None
	Takeo Nakayama* (Kyoto University)	None	None
	Kaoru Nishimura (Continence Japan Co., Ltd.)	None	None
Guideline development group	Junko Sugama (Fujita Health University)	None	None
	Nao Tamai (Yokohama City University)	-Endowed chairs (affiliations): From April 2019 to March 2022: Social cooperation course (Investor: FUJIFILM Corporation)	None
	Erika Ota (St. Luke's International University)	None	None
	Atsuo Kawamoto (Tokyo Medical University Hospital)	None	None
	Hiroe Koyanagi (Fujita Health University)	None	None
	Chiaki Sakakibara (Home-visit Nursing Agency Yaya's House)	None	None
	Mihoko Seki* (JCHO Tokyo Yamate Medical Center)	None	None
	Momoko Tsuda* (Hokkaido Cancer Society)	None	None
	Masaru Matsumoto (Ishikawa Prefectural Nursing University)	-Endowed chairs (affiliations): From April 2017 to August 2021: Social cooperation course (Investor: FUJIFILM Corporation)	None
	Noboru Misawa* (Yohokama City University)	None	None

Systematic review team	Miku Aoki (University of Fukui)	None	None
	Ayumi Amemiya (Chiba University)	None	None
	Fumiko Ishimitsu (Aichi Prefectural University)	None	None
	Tomohiro Ishinuki (Sapporo Medical University)	None	None
	Beniko Itokawa (Japanese Red Cross Akita College of Nursing)	None	None
	Tamae Urai (Toyama Prefectural University)	None	None
	Masashi Katogi (Kanagawa University of Human Services)	None	None
	Aya Kitamura (The University of Tokyo)	None	None
	Shimizu Mikiko (Fujita Health University)	None	None
	Chikoto Suzuki (Saiseikai Yokohama-shi Tobu Hospital)	None	None
	Nozomi Sonoda (Takarazuka University)	None	None
	Misako Dai (Ishikawa Prefectural Nursing University)	-Endowed chairs (affiliations): From April 2019 to March 2021: Social cooperation course (Investor: Saraya Corporation)	None
	Toshiaki Takahashi (The University of Tokyo)	-Endowed chairs (affiliations): From April 2018 to September 2020: Social cooperation course (Investor: Molten corporation)	None
	Rumi Tanaka (Kitasato University)	None	None
	Taiki Teshima (Kansai Medical University)	None	None
	Ayano Nakai (Fujita Health University)	None	None
	Mayumi Hamada (Tokyo Jikei University)	None	None
	Yuka Miura (Fujita Health University)	-Endowed chairs (affiliations): From April 2019 to March 2022: Social cooperation course (Investor: FUJIFILM Corporation)	None
	Yuko Mugita (The University of Tokyo)	None	None
	Tamami Mori (Tokyo Shinjuku Medical Center Affiliated Nursing School)	None	None

Panel members	Junko Sugama (Fujita Health University)	None	None
	Nao Tamai (Yokohama City University)	-Endowed chairs (affiliations): From April 2017 to August 2021: Social cooperation course (Investor: FUJIFILM Corporation)	None
	Keiko Ishihama* (JCHO Hoshigaoka Medical Center)	None	None
	Erika Ota (St. Luke's International University)	None	None
	Miho Okabe* (Wound and skin home care station)	None	None
	Atsuo Kawamoto* (Tokyo Medical University Hospital)	None	None
	Yoshifumi Kido (Hamamatsu University School of Medicine)	None	None
	Takaomi Kessoku* (the International University of Health and Welfare Narita Hospital)	-Research funding (2,000,000JPN or more): EA Pharma Co., Ltd., Mochida Pharma Co., Ltd.	None
	Hiroe Koyanagi (Fujita Health University)	None	None
	Chiaki Sakakibara (Home-visit Nursing Agency Yaya's House)	None	None
	Mihoko Seki* (JCHO Tokyo Yamate Medical Center)	None	None
	Momoko Tsuda* (Hokkaido Cancer Society)	None	None
	Masaru Matsumoto (Ishikawa Prefectural Nursing University)	-Endowed chairs (affiliations): From April 2017 to August 2021: Social cooperation course (Investor: FUJIFILM Corporation)	None
	Noboru Misawa* (Yohokama City Un iversity)	None	None
Cooperating member	Kuniko Sato (St. Luke's International University)	None	None
Secretariat	Masaru Matsumoto (Ishikawa Prefectural Nursing University)	-Endowed chairs (affiliations): From April 2017 to August 2021: Social cooperation course (Investor: FUJIFILM Corporation)	None

External evaluation committee	Eikichi Ihara (Kyushu University)	-Lecture fees: Takeda Pharma Co., Ltd. -Endowed chairs (affiliations): Ono Pharma Co., Ltd., Miyarisan Pharma Co., Ltd., Sanwa Kagaku Kenkyusho Co., Ltd., Otsuka Pharmaceutical Factory, Inc., FUJIFILM Medical Co., Ltd., Terumo Corp., Fancl Corp., OHGA Pharmacy Co., Ltd.	None
	Hiroyuki Imaeda (Saitama Medical University Hospital)	-Lecture fees (500,000 JPN or more): SHINDAN TO CHIRYO SHA, Inc.	None
	Toshiko Kaitani (Sapporo City University)	None	None
	Takashi Kawazoe (Carepro Inc.)	-Employment/ Advisory role: Carepro, Inc. representative director -Stock ownership: Carepro, Inc.	None
	Takeya Yasushi (Osaka University)	-Lecture fees: Daiichi Sankyo, Inc., Astellas Pharma Inc.	None
	Michio Maruyama (Tanashi Hospital)	None	None
	Yu Maruyama (Saitama Prefectual University)	None	None
	Toshiki Mimura (Jichi Medical University)	None	Related clinical guideline preparation members: Vice-Chair, The Japan Society of Coloproctology