

ORIGINAL ARTICLE

International bowel function extended spinal cord injury data set

K Krogh^{1,2}, I Perlash³, SA Stiens⁴ and F Biering-Sørensen⁵

¹Neurogastroenterology Unit, Department of Hepatology and Gastroenterology V, Aarhus University Hospital, Aarhus, Denmark; ²Department of Surgery P, Aarhus University Hospital, Aarhus, Denmark; ³Stanford University and Va Palo Alto Health Care System, Palo Alto, CA, USA; ⁴VA Puget Sound Health Care System, Spinal Cord Injury Service, Seattle, WA, USA and ⁵Clinic for Spinal Cord Injuries, Neuroscience Centre, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark

Study design: International expert working group.

Objective: To develop an International Bowel Function Extended Spinal Cord Injury (SCI) Data Set presenting a standardized format for the collection and reporting of an extended amount of information on bowel function.

Setting: Working group consisting of members appointed by the American Spinal Injury Association (ASIA) and the International Spinal Cord Society (ISCoS).

Methods: A draft prepared by the working group was reviewed by Executive Committee of the International SCI Standards and Data Sets and later by the ISCoS Scientific Committee and the ASIA Board. Relevant and interested scientific and professional organizations and societies (around 40) were also invited to review the data set and it was posted on the ISCoS and ASIA websites for 3 months to allow comments and suggestions. The ISCoS Scientific Committee, ISCoS Council and ASIA Board received the data set for final review and approval.

Results: The International Bowel Function Basic SCI Data Set includes 26 items providing a thorough description of bowel-related symptoms as well as clinical assessment of anal sphincter function and description of total gastrointestinal or segmental colorectal transit times.

Conclusion: An International Bowel Function Extended SCI Data Set has been developed. This Data Set is mainly for research purposes and it should be used in combination with the information obtained from the International SCI Core Data Set and the International Bowel Function Basic SCI Data Set.

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Introduction

Neurogenic bowel dysfunction including constipation, fecal incontinence and abdominal pain or discomfort affects the majority of individuals with spinal cord injury (SCI).^{1–4} Symptoms often restrict social activities and impair quality of life.^{2,3} Colonic transit times are usually prolonged^{5–8} and anorectal sensibility and voluntary control of the external anal sphincter is reduced or lost.^{5,9,10} The severity of colorectal and anal sphincter dysfunction depends on the completeness of SCI³ and constipation-related symptoms become significantly more severe with time since injury.^{1,11}

A Bowel Function Basic SCI Data Set (Krogh K *et al.*, submitted) has been developed to facilitate comparison of symptoms and outcomes between patients, various centers and countries through the collection of data in a standardized manner. Furthermore, background information about

age, gender, level of lesion and so on is collected within the International SCI Core Data Set.¹²

A Cochrane review concluded that the treatment of bowel dysfunction in patients with central neurological diseases must remain empirical until well-designed clinical trials have been performed.¹³ Such trials, as well as other studies on bowel function after SCI, may benefit from detailed collection of data in a standardized manner. In accordance with the aim and vision of the International Spinal Cord Injury Data Sets,¹⁴ the following International Bowel Function Extended SCI Data Set has been developed mainly for this purpose. Accordingly, information within the Bowel Function Extended SCI Data Set is mainly for research purposes and should be used in connection with information from the International SCI Core Data Set¹² and the Bowel Function Basic SCI Data Set.

Correspondence: Dr K Krogh, Department of Hepatology and Gastroenterology V, Aarhus University Hospital, Norrebrogade 44, Aarhus 8000, Denmark. E-mail: krogh@as.aaa.dk

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Methods

The development of the International Bowel Function Extended SCI Data Set by the working group appointed by

the American Spinal Injury Association (ASIA) and the International Spinal Cord Society (ISCoS), together with a representative of the Executive Committee of the International Spinal Cord Injury Standards and Data Sets, followed the lines described for the International Bowel Function Basic SCI Data Set (Krogh K *et al.*, submitted).

Results

The complete International Bowel Function Extended SCI Data form is included in the Appendix. The complete data syllabus, data sheet and training cases will be available at the respective websites of ISCoS (<http://www.iscos.org.uk>) and ASIA (<http://www.asia-spinalinjury.org>). The following items are included in the Data Set:

Date of data collection

As the collection of data on bowel function may be carried out at any time since SCI, the date of data collection is imperative to compute time since injury and to identify the data collected in relation to other data collected on the same individual at various time points (that is, in the International SCI Core Data Set).¹²

Duration of constipation

Functional constipation is usually defined according to the Rome II¹⁵ or Rome III¹⁶ criteria. Accordingly, within a specified period of time, individuals should report at least one of the following: straining $>\frac{1}{4}$ of defecations, lumpy or hard stools $>\frac{1}{4}$ of defecations, sensation of incomplete evacuation $>\frac{1}{4}$ of defecations, sensation of anorectal obstruction/blockade $>\frac{1}{4}$ of defecations, manual maneuvers to facilitate defecation $>\frac{1}{4}$ defecations, or <3 defecations per week. The Rome criteria have not been specifically developed for individuals with SCI. However, in this data set, they are used to define the term constipation. In most individuals with SCI, the duration of constipation is equal to the time since SCI. However, constipation-related symptoms may become more severe with time after SCI and some individuals may develop constipation years later.¹¹

Unsuccessful attempts at defecation

This variable documents the average number of daily unsuccessful attempts at defecation within the last 3 months. Unsuccessful attempt at defecation is a common sign of obstructed defecation. To be considered as one attempt, the bowel emptying procedure should be separated from the previous bowel emptying procedure by some other activity.

Incomplete rectal emptying after defecation

This variable documents the presence of any sense of incomplete rectal emptying after defecation within the last 3 months. A sense of incomplete rectal emptying after defecation is a common sign of obstructed defecation.

Abdominal bloating

This variable documents the presence of abdominal bloating within the last 3 months. Abdominal bloating is a common

symptom in chronic constipation and other motility disorders. In this data set, bloating is either a subjective feeling of excessive intra-abdominal gas or visible/palpable abdominal distension due to gas.

Abdominal pain/discomfort

This variable documents the presence of abdominal pain or discomfort within the last 3 months. Abdominal pain or discomfort is a common symptom not only in individuals with SCI⁴ but also in chronic constipation or irritable bowel syndrome and in the general population.^{17,18} It should be documented separately from abdominal bloating and perianal symptoms covered by those specific variables. In some individuals, abdominal pain is an indirect signal of the need to defecate. In such cases, it is covered both by that specific variable in the Bowel Function Basic SCI Data Set and here. In subjects unable to feel abdominal pain, the term 'Never' should be used.

Respiratory discomfort due to a distended abdomen

This variable documents any respiratory discomfort (shortness of breath/difficulty in taking a deep breath) considered to be entirely or partly due to a distended abdomen. Constipation and bloating may cause or contribute to respiratory discomfort. This is defined as a feeling of shortness of breath or difficulty in taking a deep breath entirely or partly due to a distended abdomen. Accordingly, patients do not have to be able to clearly differentiate between bowel and other causes of respiratory discomfort. However, respiratory symptoms entirely due to higher level SCI are not included in this variable.

Perianal pain during defecation

This variable documents the presence of perianal pain during defecation within the last 3 months. Perianal pain during defecation is a common sign of difficult bowel evacuation. Most individuals with complete SCI are unable to feel perianal pain during defecation. In such cases, the code 'Never' and not the code 'Unknown' should be used. Indirect indicators of perianal pain during defecation such as perspiration, spasms or headache are not registered here.

Frequency of flatus incontinence

This variable documents the frequency of flatus incontinence within the last 3 months. Flatus incontinence is defined as involuntary passage of flatus.

Frequency of fecal incontinence to liquid stools

This variable documents frequency of fecal incontinence to liquid stools within the last 3 months. Fecal incontinence is defined as involuntary passage of stools. It has profound influence on quality of life and may cause severe restriction on social activities.^{3,19}

Frequency of fecal incontinence to solid stools

This variable documents frequency of fecal incontinence to solid stools within the last 3 months.

Ability to defer defecation for 15 min or more

This variable documents the ability to defer defecation for 15 min or more within the last 3 months. Inability to defer defecation may cause fecal incontinence and restrict social activities.

Position for bowel care

This variable documents the position for bowel care used within the last 3 months. The position for bowel care is important for bowel management. Whenever appropriate more than one code could be used for the same individual.

Degree of independence during bowel management

The degree of independence during bowel management is important to most individuals with SCI. The codes used are identical to those used in the Spinal Cord Independence Measure III (SCIM III).²⁰

Bowel care facilitators

Individuals with SCI may use a number of maneuvers to facilitate bowel care. Digital anorectal stimulation is digital triggering of rectal contractions and anal relaxation and thus rectal emptying. Digital evacuation is the need to dig out stools with a finger. Although the effect is not much validated, abdominal massage is recommended by some to improve colorectal transit. The gastrocolonic response stimulates colorectal motility after the intake of a meal. It remains after SCI, and many individuals with SCI use this response by performing bowel care shortly after breakfast.

Events and intervals of defecation (1): Average time from the initiation of bowel care to first stool coming out

This variable is an attempt to describe the time spent at bowel care in more detail than just total time spent at defecation.²¹ The code given in minutes is based on each individual's own assessment of average time consumption.

Events and intervals of defecation (2): Average time during bowel movement when stool comes out

This variable begins when the previous variable stops and documents average time during bowel movement when stool intermittently or continuously (in the case of a single defecation) comes out with or without assistance. It is an attempt to describe the time spent at bowel care in more detail than just total time spent at defecation.²¹ The code given in minutes is based on each individual's own assessment of time consumption.

Events and intervals of defecation (3): Time spent waiting after last stool passes before ending bowel care

This variable begins when the previous variable ends. In line with the two previous items this variable is also an attempt to describe the time spent at bowel care in more detail. End of bowel care is defined as end of dressing. If this is not applicable, end of bowel care is end of clean up.

Lifestyle alteration due to anal incontinence

Anal incontinence covers fecal incontinence and flatus incontinence. This variable only covers altered lifestyle due to anal incontinence or the risk of anal incontinence. Examples may be avoidance of social activities, traveling, sexual activities and so on.

Lifestyle alteration due to constipation

This variable only covers altered lifestyle due to constipation. Constipation-related symptoms included difficult bowel evacuation. Examples may be avoidance of social activities, traveling and so on.

Self-reported impact on the quality of life caused by neurogenic bowel dysfunction

Self-reported impact on the quality of life caused by neurogenic bowel dysfunction covers the patient's own assessment of the impact of all aspects of neurogenic bowel dysfunction. This parameter is important for any choice of treatment modality.

Anal tone

Digital examination of anal tone mainly provides information about the anal resting pressure. Under normal circumstances, it is estimated that the internal anal sphincter muscle, consisting of smooth muscle cells, contributes to 55–85% of the anal resting pressure. The remaining is from the striated external anal sphincter muscle and the pressure within the hemorrhoidal plexus.²²

Sympathetic innervation is believed to increase the tone of the external anal sphincter.²³ Accordingly, anal resting pressure is generally lower in individuals with spinal cord lesions at or above the second lumbar vertebrae than in those with lower lesions.¹⁰ However, spasms of the striated external anal sphincter muscle may cause an excessively high pressure. The resting anal pressure is highly variable between individuals,^{24,25} and the reproducibility and validity of digital anal examination of individuals with SCI remains to be tested. Accordingly, this variable depends on the subjective assessment of the examiner and only three options are given for this.

Evidence suggests that the amplitude of rectoanal inhibitory reflex mediating relaxation of the internal anal sphincter muscle during stretch of the rectal wall is affected by the level of SCI.¹⁰ Therefore, it is recommended that the tone of the anal canal is evaluated before and not after digital examination of the rectum is performed.

Voluntary contraction of the anal canal

Digital evaluation of voluntary contraction of the anal canal is an assessment of the voluntary function of the external anal sphincter muscle. The comments about intersubjective variation and validity of the examination given above are also true for this variable. Accordingly, it is only assessed whether there is voluntary contraction of the anal canal or not.

Voluntary anal contraction may be confused with spasms or reflex activity of the external anal sphincter muscle. Accordingly, it is recommended to ask the patient to contract the anal canal two times or more during the examination.

Total gastrointestinal or colonic transit time

This variable documents total gastrointestinal or colonic transit time assessed by means of radio-opaque markers and a plain abdominal X-ray. Total gastrointestinal and colonic transit times are prolonged in many individuals with SCI.⁵⁻⁸ Transit time through the stomach and the small intestine is usually just a few hours. Colonic transit time is, however, much longer. Some authors present transit times as total gastrointestinal transit time and others prefer colonic transit time. Unless multiple X-rays are taken, the most correct term is total gastrointestinal transit time.

Generally, transit time is prolonged throughout the colon in individuals with supraconal SCI. In contrast, individuals with conal or cauda equina lesions often have severely prolonged rectosigmoid or left colonic transit times.⁸ The intrasubjective variation remains to be studied and due to poor correlations between total gastrointestinal/colonic transit time and colorectal symptoms after SCI, the clinical relevance of transit time measurement has been questioned.²⁶ Several types of radio-opaque markers and protocols for determining total gastrointestinal and colonic transit times exist. However, no evidence exists to recommend one from the others.

Right colonic transit time

This variable documents transit time of the cecum, ascending and transverse colon assessed by means of radio-opaque markers. The comments given about total gastrointestinal or colonic transit time are applicable to this item too.

Left colonic transit time

This variable documents transit time of the descending colon (including the splenic flexure) and the rectosigmoid assessed by means of radio-opaque markers.

Discussion

The data within this International Bowel Function Extended SCI Data Set shall be seen in conjunction with data in the International SCI Core Data Set¹² and the International Bowel Function Basic SCI Data Set. The International SCI Core Data Set includes information on date of birth and injury, gender, the cause of spinal cord lesion, and neurologic status among others. The Bowel Function Basic SCI Data Set was mainly developed for clinical use and the number of items included ($n=12$) was kept as small as possible. In contrast, the present International Bowel Function Extended SCI Data Set is mainly intended for research and should provide a standardized format for the collection and reporting of extended information on bowel function after SCI.¹⁴ However, the working group recognizes that information within the Bowel Data Sets could be extended by other clinically important information whenever appropriate. We are also aware that not all items in the Data Set will be relevant in all studies and researchers may choose to use only those relevant in a given setting.

Several scores have been developed for fecal incontinence,^{27,28} constipation¹⁹ or neurogenic bowel dysfunction²⁹

but none have yet been generally accepted for use in individuals with SCI. The working group found it important to make results from studies using the SCI Bowel Data Sets as comparable as possible to results from other patient groups and we recognize that treatment of bowel dysfunction after SCI should be multidisciplinary. Therefore, the combined Basic and Extended Data Sets cover the most commonly used scores even if this means including a few items that could otherwise have been left out. This also explains why the time period used for some items is four weeks while it is 3 months in others.

The present International Bowel Function Extended SCI Data Set mainly includes colorectal symptoms. This reflects the paucity of validated objective measures for bowel dysfunction after SCI. However, the working group found that objective parameters should be included if valid and if available at most institutions. The most basic objective measure is anal tone and contraction force assessed by digital examination. To keep it as simple as possible, these two parameters are described as normal, reduced or excessive and present or not present. Anorectal sensibility is covered by the International SCI Core Data Set.¹² Radiographically determined gastrointestinal or total and segmental colorectal transit times were included as objective parameters for colorectal function as they are easily performed. The correlation between transit times and symptoms is poor,²⁶ and symptoms and objective measures should complement each other. We also considered including anorectal physiology tests but chose not to do so. This was mainly for the following two reasons: equipment for anorectal physiology testing is not available at most centers and variation in the parameters commonly used is extremely large.³⁰

To facilitate the use of the International SCI Data Sets, this Bowel Function Extended Data Set and its data collection form (Appendix) have been developed much along the lines of the International Lower Urinary Tract Function Basic SCI Data Set.³¹

The International Bowel Function Basic and Extended SCI Data Sets were developed by a working group of experts with clinical and research experience within the field, and a large number of organizations and societies were asked for comments. The general outline of the Bowel Data Sets was accepted by almost all those giving their comments, and nearly all comments received were about specific details and clarification. However, the validity and reproducibility of most items included is unknown and the usefulness of the Bowel Data Sets needs to be shown. Much work is still needed to validate and translate these data sets, and the authors invite all interested to participate in this open and ongoing process.

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Appendix

**INTERNATIONAL SPINAL CORD INJURY DATA SETS
BOWEL FUNCTION EXTENDED SCI DATA SET—DATA FORM**

Date of data collection: YYYYMMDD Unknown

Duration of constipation:

- Less than a year 1–5 years 6–10 years 11–20 years
 More than 20 years Not applicable Unknown

Unsuccessful attempts at defecation (within the last 3 months):

- Never Less than once per month Less than once per week but at least once per month Once or more per week but not every day
 1–3 per day 4–6 per day 7–9 per day 10 times or more per day
 Not applicable Unknown

Incomplete rectal emptying after defecation (within the last 3 months):

- Daily Not every day but at least once per week
 Not every week but at least once per month
 Less than once per month Never Not applicable Unknown

Abdominal bloating (within the last 3 months):

- Daily Not every day but at least once per week
 Not every week but at least once per month
 Less than once per month Never Unknown

Abdominal pain/discomfort (within the last 3 months):

- Daily Not every day but at least once per week
 Not every week but at least once per month
 Less than once per month Never Unknown

Any respiratory discomfort (shortness of breath/difficulty in taking a deep breath considered to be entirely or partly due to a distended abdomen) (within the last 3 months):

- Daily Not every day but at least once per week
 Not every week but at least once per month
 Less than once per month Never Not applicable Unknown

Perianal pain during defecation (within the last 3 months):

- Daily Not every day but at least once per week
 Not every week but at least once per month
 Less than once per month Never Not applicable Unknown

Frequency of flatus incontinence (within the last 3 months):

- Daily Not every day but at least once per week
 Not every week but more than once per month
 Once per month Less than once per month Never
 Not applicable Unknown

Frequency of incontinence to *liquid* stools (within the last 3 months):

- Two or more episodes per day Once daily
 Not every day but at least once per week
 Not every week but more than once per month
 Once per month Less than once per month Never
 Not applicable Unknown

Frequency of incontinence to *solid* stools (within the last 3 months):

- Two or more episodes per day Once daily
 Not every day but at least once per week
 Not every week but more than once per month
 Once per month Less than once per month Never
 Not applicable Unknown

Ability to defer defecation for 15 min or more (within the last 3 months):

- Yes No Not applicable Unknown

Position for bowel care (within the last 3 months):

- Bed Toilet chair/Commode Raised toilet seat
 Conventional toilet Other, specify: _____ Unknown

Degree of independency during bowel management (within the last 3 months):

- Requires total assistance Requires partial assistance; does not clean self
 Requires partial assistance; cleans self independently
 Uses toilet independently in all tasks but needs adaptive devices or special setting (e.g. bars)
 Uses toilet independently; does not need adaptive devices or special setting
 Unknown

Bowel care facilitators (within the last 3 months):

- Digital stimulation Abdominal massage
 Gastrocolonic response Other, specify: _____
 None Unknown

Events and intervals of defecation (1): Average time from initiation of bowel care to stool comes out (within the last 3 months):

_____minute(s)

- Not applicable Unknown

Events and intervals of defecation (2): Average time during bowel movement that stool intermittently or continuously comes out with or without assistance (within the last 3 months):

_____minute(s)

- Not applicable Unknown

Events and intervals of defecation (3): Average time spent waiting after last stool passes before ending bowel care (within the last 3 months):

_____minute(s)

- Not applicable Unknown

Lifestyle alteration due to *anal incontinence* (within the last 3 months):

- Lifestyle altered each day Lifestyle altered at least once per week but not every day
 Lifestyle altered more than once per month but not every week
 Lifestyle altered once per month Lifestyle altered less than once per month
 Life style not altered Not applicable Unknown

Lifestyle alteration due to *constipation* (within the last 3 months):

- Lifestyle altered each day Lifestyle altered at least once per week but not every day
 Lifestyle altered more than once per month but not every week
 Lifestyle altered once per month Lifestyle altered less than once per month
 Life style not altered Not applicable Unknown

Self-reported impact on quality of life due to bowel dysfunction:

- Major impact Some impact Little impact No impact
 Unknown

To be collected after physical examination:

Anal tone:

- Normal Reduced Excessive Not tested Not applicable

Voluntary contraction of the anal canal:

- Yes No Not tested Not applicable

To be collected after X-ray investigation:

Total gastrointestinal or colonic transit time:

_____days _____hours Not tested

Right colonic transit time:

_____days _____hours Not tested

Left colonic transit time:

_____days _____hours Not tested