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Accidental Bowel Leakage Evaluation: A New Patient-Centered Validated Measure of Accidental Bowel Leakage Symptoms in Women

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Abstract

BACKGROUND—Questionnaires assessing accidental bowel leakage lack important patient-centered symptoms.

OBJECTIVE—We aimed to create a valid measure of accidental bowel leakage symptoms.

DESIGN—We previously created a conceptual framework capturing patient-centered accidental bowel leakage symptoms. The framework included bowel leakage type, severity and bother and ancillary bowel symptoms, including predictability, awareness, leakage control, emptying disorders and discomfort.

SETTINGS—Outpatient clinics.

PATIENTS—Women with at least monthly accidental bowel leakage.

INTERVENTIONS—Participants completed the Accidental Bowel Leakage Evaluation at baseline, 12 and 24 weeks, as well as bowel diaries, and other validated pelvic floor questionnaires. A subset completed items twice before treatment. Final item selection was based on psychometric properties and clinical importance.

MAIN OUTCOME MEASURES—Psychometric analyses included Cronbach's alphas, confirmatory factor, and item response theory analyses. Construct validity was based on correlations with measures of similar constructs.

RESULTS—A total of 296 women completed baseline items and 70 provided test-retest data. The cohort was predominately White (79%) and middle aged (64 +/− 11 years). Confirmatory factor analyses supported the conceptual framework. The final 18-item scale demonstrated good internal consistency (Cronbach's alpha=0.77 −0.90) and test-retest reliability (intraclass correlation=0.80). Construct validity was demonstrated with baseline,12- and 24-week scale scores which correlated with the Vaizey (r=0.52, 0.68 and 0.69), Colo-rectal Anal Distress Inventory (r=0.54, 0.65, 0.71), Colo-rectal Anal Impact Questionnaire (r=0.48, 0.53, 0.53), and hygiene (r=0.39, 0.43, 0.49) and avoidance subscales scores of the adaptive index (r=0.45, 0.44, 0.43) and average number of pad changes per day on bowel diaries (r=0.35, 0.38, 0.31), all p<.001.

LIMITATIONS—Validation in a care-seeking population.

CONCLUSIONS—The Accidental Bowel Leakage Evaluation instrument is a reliable, patient-centered measure with good validity properties. This instrument improves on currently available measures by adding patient- important domains of predictability, awareness, control, emptying and discomfort. See **Video Abstract** at http://links.lww.com/DCR/B172.

Abstract

Los cuestionarios que evalúan la fuga intestinal accidental, carecen de síntomas centrados en el paciente.

Nuestro objetivo fue crear una medida válida de síntomas de fuga intestinal accidental

Previamente creamos un marco conceptual centrado en el paciente, para capturar síntomas de fuga intestinal accidental. El marco incluía tipo de fuga intestinal, gravedad, molestia, y síntomas intestinales auxiliares, incluyendo previsibilidad, conciencia, control de fugas, trastornos de vaciado e incomodidad.

Clínicas de pacientes externos.

Mujeres con al menos una fuga intestinal accidental mensual.

Las participantes completaron la Evaluación de Fuga Intestinal Accidental al inicio del estudio y a las 12 y 24 semanas, así como diarios intestinales y otros cuestionarios validados del piso pélvico. Un subconjunto completó los elementos dos veces antes del tratamiento. La selección final del elemento se basó en las propiedades psicométricas y la importancia clínica.

Los análisis psicométricos incluyeron el Alfa de Cronbach, factor confirmatorio y análisis de la teoría de respuesta al elemento. La validez de constructo se basó en correlaciones con medidas de constructos similares.

Un total de 296 mujeres completaron los elementos de referencia y 70 proporcionaron datos de test-retest. La cohorte fue predominantemente blanca (79%) y de mediana edad (64 +/− 11 años). Análisis factorial confirmatorio respaldó el marco conceptual. La escala final de 18 elementos, demostró una buena consistencia interna (Alfa de Cronbach = 0,77–0,90) y fiabilidad test-retest (correlación intraclase = 0,80). La validez de constructo se demostró con puntajes de escala de referencia de 12 y 24 semanas que se correlacionaron con Vaizey (r = 0,52, 0,68 y 0,69), Inventario de Ansiedad colo-recto anal (r = 0,54, 0,65, 0,71), Cuestionarios de Impacto colo-recto anal (r = 0,48, 0,53, 0,53) e higiene (r = 0,39, 0,43, 0,49), puntuaciones de subescalas de evitación del índice adaptativo (r = 0,45, 0,44, 0,43), número promedio de cambios de almohadilla por día, de los diarios intestinales (r = 0.35, 0.38, 0.31), todos p <.001.

Validación de una población en busca de atención.

El instrumento de Evaluación de Fuga Intestinal Accidental es una medida confiable, centrada en el paciente y con buenas propiedades de validez. Este instrumento mejora las medidas actualmente disponibles, al agregar dominios importantes para el paciente de previsibilidad, conciencia, control, vaciado e incomodidad. Consulte **Video Resumen** en http://links.lww.com/DCR/B172.

Keywords

Accidental bowel leakage; Anal incontinence; Questionnaire

INTRODUCTION

Accidental bowel leakage (ABL), also known as fecal incontinence (FI), is the involuntary loss of stool, mucous, and fluid.[1] The prevalence of ABL varies based on population and definition applied; by recent estimates, ABL occurs in up to 12.5% of community dwelling adults.[2] The impact of ABL on patient quality of life is profound, leading to embarrassment, social isolation, and depression.[3] From a public health standpoint, ABL is associated with increased healthcare costs and is a common indication for nursing home placement.[3–5]

Evaluation and treatment of ABL is complex, due to the multifactorial nature of the disease and variation in severity and impact of patient symptoms. An ideal ABL symptom questionnaire should be based on factors that patients identify as important,[6] be responsive to changes in their condition, and reliably measure symptoms. Other ABL measures such as the Pescatori Incontinence Scale, Wexner (Cleveland Clinic) Scale, St. Marks (Vaizey) Scale and Fecal Incontinence Severity Index were developed with limited patient input and may not capture all symptoms important to patients.[7–10] In order to better understand what constructs should be included in a patient-centered ABL scale, in prior work we used qualitative methods to develop a comprehensive conceptual framework capturing symptoms important to women struggling with ABL. This work identified gaps in our current ABL measures, including predictability, awareness, control, emptying and discomfort as important constructs.[6]

To improve on existing ABL symptom measures, our objective was to develop and validate a new patient-centered measure of ABL symptom severity for women for use in clinical and research settings.

MATERIALS AND METHODS

This was a planned ancillary study to an ongoing multi-centered randomized trial evaluating primary treatment for ABL. All women gave written informed consent and all sites obtained Institutional Review Board approval for study procedures across eight sites in the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development sponsored Pelvic Floor Disorders Network (PFDN).

The current study builds on our previous work that resulted in a comprehensive conceptual framework capturing patient-important ABL symptoms informed by focus groups and

cognitive interviews.[6] In brief, a literature search of existing ABL questionnaires was conducted. All items were “binned” by domains which informed a working conceptual framework. Face and content validity and conceptual gaps were identified through focus groups. Based on the final conceptual framework, representative existing items were selected to optimize domain coverage (winnowing). These items were modified as needed for consistency and clarity. New items were created to cover domain gaps leading to a candidate item list.

We conducted cognitive interviews with women with ABL to evaluate the candidate items to determine if respondents interpreted terminology differently than intended and identify items that were unclear or difficult to understand. This allowed us to identify potential problems and improve the quality of the items before reliability and validity testing. Cognitive interviews were conducted on an in-person one-on-one basis using a think-aloud process to try to identify problems with items along the question response process (comprehension -> retrieval -> judgment -> response).[11] Cognitive interviews were conducted in two rounds. The first round of interviews identified potential problems with the items. Items were revised based on the findings in the first round and then the revised items were tested in the second round to ensure that the revisions corrected problems. We used the cognitive interviews to explore ceiling and floor effects of response categories. Women who participated in the focus groups and cognitive interviews were recruited from PFDN sites, and interviews were conducted by trained personnel at each site. Women were eligible for participation in the focus groups and cognitive interviews if they were >/= 18 years of age, diagnosed with ABL, had bothersome ABL symptoms for at least 3 months, and were able to speak, read and comprehend English. Women were excluded if they reported either watery stools (consistent with a Bristol Stool Index designation of “7”) or hard, lumpy stools (Bristol Stool Index designation of “1”). In addition, women were excluded if they had diagnosis or history of colorectal or anal malignancy, inflammatory bowel disease, rectovaginal fistula, rectal prolapse or history of pelvic floor or abdominal radiation.

Women recruited to an ongoing trial comparing treatments for ABL were included in this validation study. (Figure 1) In the parent study, 296 women with ABL completed bowel diaries, the St. Mark’s (Vaizey) score, the Pelvic Floor Distress Inventory (PFDI) short form (including the subscales Colo-Rectal Anal Distress Inventory (CRADI), Urinary Distress Inventory (UDI), and the Pelvic Organ Prolapse Distress Inventory (POPDI)),[12] the Pelvic Floor Impact Questionnaire (PFIQ) short form (including the subscales Urinary Impact Questionnaire (UIQ), Colorectal Anal Impact Questionnaire (CRAIQ) and Pelvic Organ Prolapse Impact Questionnaire (POPQI)),[12] the Fecal Incontinence Adaptation Index,[13] and the Short Form-12 (SF-12).[14] Women completed measures prior to treatment and again at 12 weeks and 24 weeks after enrollment in the interventional trail. Inclusion and exclusion criteria were similar to those for the focus groups and cognitive interviews, except that all women reported fecal incontinence, while for the focus groups and cognitive interviews women could have incontinence of flatus as well. Specific inclusion and exclusion criteria for the parent trial were previously published.[15]

First, we confirmed that the candidate items grouped into seven subscales as published in our conceptual model including the specific type of leakage (solid stool, liquid stool, mucus,

gas), conditions when leakage occurs (predictability/awareness, control), and ancillary bowel symptoms.[6] Specifically, using the Mplus software program we fit a higher-order confirmatory factor model to test whether the items group into seven first-order factors, representing the individual subscales, and then whether those factors could be combined into one second-order factor representing the overall scale.[16] The fit of the model to our data was assessed using three model fit indices: the comparative fit index (CFI), Tucker-Lewis fit index (TLI), and the Root Mean Square Error of Approximation (RMSEA). The CFI and TLI are measures that compare the fit of our hypothesized model with a baseline model. The RMSEA quantifies the difference (i.e., the amount of error) between the covariance matrix based on our sample data and the covariance matrix that would occur if our hypothesized model is correct. Values of CFI and TLI greater than 0.95 and RMSEA less than 0.08 indicate an acceptable model fit.[17,18]

After establishing the factor structure of the items, we examined item-level characteristics to identify items for inclusion in the final ABLE scale. Items were coded so values ranged from zero to four with higher values indicating more severe symptoms. We reviewed the item distributions to determine if items had sufficient variability in responses and did not exhibit floor or ceiling effects. We then examined the item-total correlations and factor loadings to determine how well each item relates to the other items on the subscale; ideally, items should have values of 0.4 or higher.

We also conducted item response theory (IRT) analyses using the IRTPRO program.[19] We fitted a graded response IRT model for ordinal items which estimates two types of parameters for each item, including a slope parameter which indicates how well the item discriminates among patients with different levels of symptom severity and a set of threshold parameters that place the individual response options along a continuum representing level of symptom severity. The number of thresholds is equal to the number of response options minus one. Items should have slopes of one or higher and thresholds spread across the continuum.

Final item selection was performed by creating a matrix with the characteristics of each item displayed, so that poorly performing items could be deleted. A few items which did not perform as well as others were retained as they were felt to be clinically important by the working group. Following item selection, we assessed the reliability and validity of the final ABLE scale and subscales. Scale and subscale scores were computed as the mean of the recoded items with possible values ranging from zero to four. Cronbach's alphas were computed to assess internal consistency reliability at each of the time points. Alpha values should be 0.70 or greater but not larger than 0.90 so that items form cohesive factors without being overly redundant. A subset of women completed the items twice before initiating therapies. Test-retest reliability was computed as the intraclass correlation between those two measurements.

Construct validity was assessed by computing Pearson's correlations between the ABLE scale and clinical and self-report measures of fecal incontinence, the bowel diaries and related constructs. These measures included patient bowel diaries, the PFDI and its subscales, the PFIQ and its subscales,[12] Fecal Incontinence Adaptation Index,[13] and the

SF-12.[14] We expected that the ABLE scale would be highly correlated with bowel diaries and Vaizey scores and moderately correlated with the Adaptation Index. We expected that correlations with bowel symptom and QOL measures, such as the CRADI and CRAIQ scores, would have weaker correlations and that correlation with clinical measures such as manometry and physical exam findings would have the lowest correlations. As a rule of thumb, 10 subjects per item are adequate to validate a measure.[20] The parent study aimed to enroll 294 women, which was adequate to evaluate 30 items.

RESULTS

We conducted 4 focus groups and 20 cognitive interviews. At the conclusion of the focus groups and cognitive interviews, 35 candidate items were identified as representative of the domains previously identified in our conceptual framework (Supplemental Table 1, http://links.lww.com/DCR/B173). These items were administered to the women enrolled in the primary study. Baseline demographics are represented in Table 1. In brief, these women were middle-aged with a mean age of 63.75 +/− 11.14 years and the majority were White (79%). Over half of women were privately insured (61%) and had, on average, 1.59 +/− 1.78 incontinence episodes per day, representing women severely affected with ABL. Women reported significant bother from their ABL as reflected in their CRADI scores. A total of 296 women gave baseline data, 274 at 12 weeks follow-up and 266 at 24 weeks. Ten of the 274 women at 12 weeks did not have data for the ABLE instrument and are excluded from these analyses.

The results of the confirmatory factor analyses supported the grouping of the items into both individual subscales and an overall scale. The fit indices met or exceeded the criterion for acceptable model fit at each time point: Baseline (CFI=0.98, TLI=0.97, RMSEA=0.06), Week 12 (CFI=0.97, TLI=0.96, RMSEA=0.08), and Week 24 (CFI=0.98, TLI=0.98, and RMSEA=0.07). The first-order factor loadings for all items except A16 at baseline had values greater than 0.4 (Table 2). The liquid stool subscale had the highest loadings on the overall factor with average loading of 0.81 across the time points and predictability/awareness was lowest with an average loading of 0.36.

Similar to the factor loadings, almost all items had moderate to high-item total correlations (> 0.4), indicating that they are related to the other items on the corresponding subscale (Table 2). The items selected for the final scale demonstrated good discrimination with IRT slopes of one or higher (Supplemental Table 2, http://links.lww.com/DCR/B174).

A subset of 70 participants completed the items twice before initiating therapies within a mean interval of 39.18 ± 29.18 days. The overall scale demonstrated good test-retest reliability (ICC=0.80) and internal consistency (alphas of 0.77 to 0.90) (Table 3). The subscales demonstrated acceptable reliability with ICCs of 0.63 (Mucus) to 0.78 (Ancillary Bowel Symptoms) with nearly all Cronbach's alphas at or above 0.70.

The patterns of correlations in Table 4 support the construct validity of the ABLE measures. Using data from patient bowel diaries, ABLE scores were positively related to average number of leaks (r=0.32 to 0.36) and pad changes per day (r=0.31 to 0.38) and negatively

related to the number of accident-free days per week (r=−0.30 to −0.48). Among the self-report questionnaires, ABLE scale scores are more highly correlated with the CRADI, CRAIQ, and Fecal Adaptation Index and less highly correlated with the quality of life measures not focused on bowel symptoms, such as the SF-12. After this iterative process, 18 items were retained in the final scale. (Exhibit)

DISCUSSION

The ABLE instrument was developed using rigorous methods to ensure patient-centeredness and comprehensive coverage of symptom domains important to women with ABL. We used a stepwise process, building on existing questionnaires and utilized mixed qualitative and quantitative methods. The ABLE demonstrates good face, content and construct validity properties and contains 18 items (Figure 2).

Although other patient subjective measures for ABL exist, our primary goal was to develop a measure that captured aspects of ABL important to women. By including symptoms that women identified as important through focus groups and cognitive interviews, we have been able to create a new scale that reflects a new definition of treatment “success” for women. We identified several novel domains which are covered in the ABLE including predictability, awareness, control, emptying and discomfort symptoms, work that was previously published.[6] This is a unique aspect of the ABLE questionnaire as these domains are generally not addressed in existing measures.

ABLE scores were positively correlated to patient bowel diaries, although only moderately. This may be due to several factors. First, the frequency of bowel leakage may be only weakly related to patient bother with ABL. Second, bowel diaries do not capture all of the associated symptoms related to ABL, underscoring the importance of a patient-centered measure that captures the full range of symptoms of women suffering from ABL.

There are limitations to our study. We only included women seeking care for ABL for the validity testing. This may limit the external validity of our findings in less severely affected patients or for population-based research. In addition, the validity of this measure is untested in men. In its current format, the ABLE is intended to be a fixed format, self-administered questionnaire without the ability to be adaptive. Further research is needed to establish alternative methods of administering the measure as well as the use of modern item response theory methodologies to diminish patient burden in completing the questionnaire. Finally, ABLE focuses on FI symptoms and does not measure quality of life. The strengths of our study include that our subjects were recruited from eight diverse clinical sites across the country. Also, ABLE addresses an existing gap in the literature, and includes novel symptoms that patients identify as important. We plan to test responsiveness of the instrument in the near future to assess its usefulness as an outcome measure.

CONCLUSIONS

In summary, we have utilized rigorous qualitative and quantitative methodologies to create a measure that represents an array of ABL symptoms important to women. Further work

continues on evaluating the responsiveness and performance of the instrument and establishing minimum important differences.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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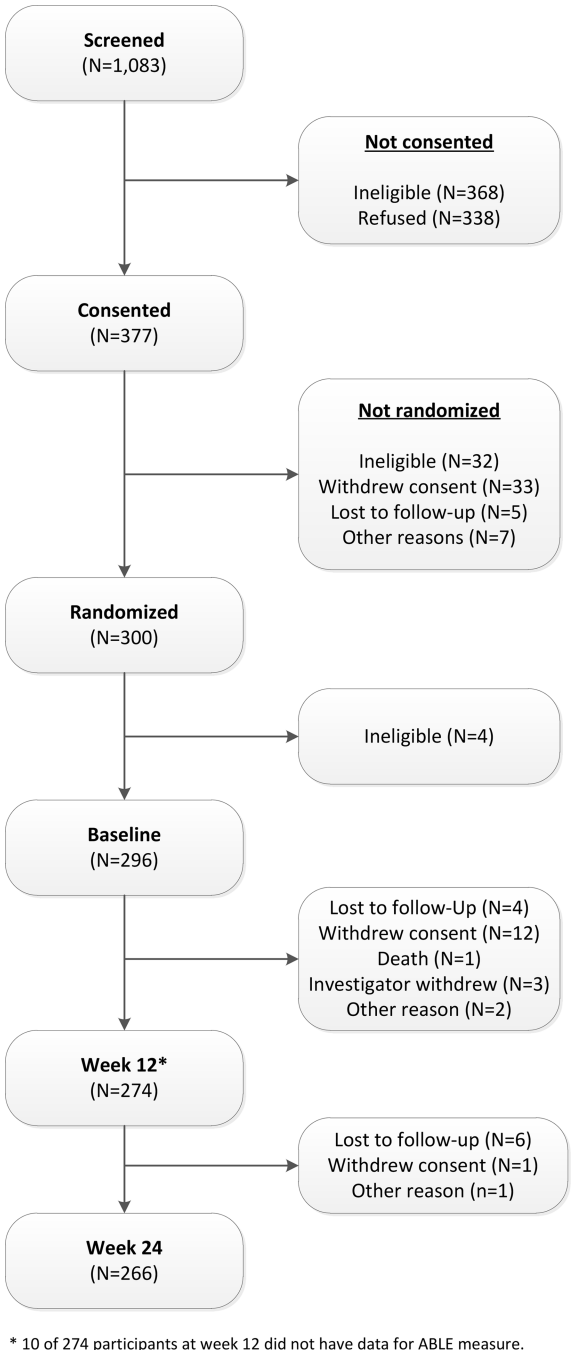

Figure 1:
Patient flow chart.

Section A: **The following items ask about accidental bowel leakage symptoms you may have experienced. These may include accidental leakage of liquid stool, solid stool, mucus or gas. We recognize that your symptoms may vary. Please complete the questionnaire based on your symptoms as best you recall them. Please complete each statement by indicating how often you experienced each of these symptoms and how much they bother you.**

A1. When I have accidental leakage of liquid stool it is usually...

- A large amount of liquid stool (4)
- A moderate amount of liquid stool (3)
- A small amount of liquid stool (2)
- Staining only (1)
- I do not have leakage of liquid stool (0)

A2. I experience accidental leakage of liquid stool...

- Daily (4)
- Weekly (3)
- Monthly (2)
- Less than monthly (1)
- I never experience accidental leakage of liquid stool (0)

A3. I am bothered by accidental leakage of liquid stool

- Very bothered (4)
- Somewhat bothered (3)
- A little bothered (2)
- Not at all bothered (1)
- I do not have leakage of liquid stool (0)

A4. When I have accidental leakage of solid stool, it is usually…

- A large amount of solid stool (4)
- A moderate amount of solid stool (3)
- A small amount of solid stool (2)
- Staining only (1)
- I do not have leakage of solid stool (0)

A5. I experience accidental leakage of solid stool...

- Daily (4)
- Weekly (3)
- Monthly (2)
- Less than monthly (1)

□I never experience accidental leakage of solid stool (0)

A6. I am bothered by accidental leakage of solid stool…

□Very bothered (4)

□Somewhat bothered (3)

□A little bothered (2)

□Not at all bothered (1)

□I do not have leakage of solid stool (0)

A7. When I have accidental leakage of mucus, it is usually…

□A large amount of mucus (4)

□A moderate amount of mucus (3)

□A small amount of mucus (2)

□Staining only (1)

□I do not have leakage of mucus (0)

A8. I experience accidental bowel leakage that consists of mucus...

□Daily (4)

□Weekly (3)

□Monthly (2)

□Less than monthly (1)

□I never experience leakage of mucus (0)

A9. I am bothered by accidental mucus leakage...

□Very bothered (4)

□Somewhat bothered (3)

□A little bothered (2)

□Not at all bothered (1)

□I do not have leakage of mucus (0)

A10. I lose gas from my rectum beyond my control...

□Daily (4)

□Weekly (3)

□Monthly (2)

□Less than monthly (1)

□I never lose gas from my rectum beyond my control (0)

A11. I am bothered by accidental leakage of gas…

□Very bothered (4)

Somewhat bothered (3)

A little bothered (2)

Not at all bothered (1)

I do not have leakage of gas (0)

A12. My accidental bowel leakage is predictable. Is this true for you…

All of the time (0.8)

Most of the time (1.6)

Some of the time (2.4)

A little of the time (3.2)

None of the time (4)

I do not have accidental bowel leakage (0)

A13. When I have accidental bowel leakage, I leak without knowing it:

Almost always (4)

Often (3.2)

Sometimes (2.4)

Rarely (1.6)

□I never have leakage without knowing it happened (0.8)

□I do not have accidental bowel leakage (0)

A14. I get a sudden urge to move my bowels with little or no warning:

□Almost always (4)

□Often (3)

□Sometimes (2)

□Rarely (1)

□Never (0)

A15. I am bothered by a sudden urge to empty my bowels with little or no warning:

□Very bothered (4)

□Somewhat bothered (3)

□A little bothered (2)

□Not at all bothered (1)

□I do not have sudden urges to empty my bowels (0)

A16. I feel that I am completely empty after a bowel movement:

□Almost always (0)

□Often (1)

□Sometimes (2)

□Rarely (3)

□Never (4)

A17. I am bothered because I cannot completely empty my bowels:

□Very bothered (4)

□Somewhat bothered (3)

□A little bothered (2)

□Not at all bothered (1)

□I do not have difficulty with completely emptying my bowels (0)

Section B: Many women experience pain and discomfort along with accidental bowel leakage. We would like to focus on the physical symptoms that may be related to your accidental bowel leakage. The physical symptoms may include the following: generalized pain, specific pain, cramping, burning and/or discomfort.

B1. I have pain (may also be cramping, burning, and/or discomfort) related to my accidental bowel leakage:

□Almost always (4)

□Often (3)

Figure 2:
Final 18-Item ABLE Scale.

Table 1.

Baseline Demographic Characteristics and Scale Scores of Study Participants (N=296)

Characteristic	N	%
Demographics		
Age (years)		
< 40	7	2
40–49	28	9
50–59	68	23
60–69	106	36
70–79	68	23
80+	19	6
Race		
American Indian/Alaskan Native	3	1
Black/African American	46	16
White	234	79
Other	8	3
More than one race	5	2
Ethnicity		
Hispanic/Latina	26	9
Not Hispanic/Latina	265	90
Unknown/Not reported	5	2
Primary Language		
English	283	96
Spanish	8	3
Other	1	0
Unknown	4	1
Health Insurance (check all that apply)		
Private insurance	181	61
Medicaid/Medicare	158	53
Self-pay (without insurance)	4	1
Other	22	7
Unknown	3	1
Scale Scores	**Mean**	**SD** *
St. Mark's (Vaizey) Score	14.21	4.09
Urogenital/Urinary Distress Inventory (UDI)	40.32	29.02
Pelvic Organ Prolapse Distress Inventory (POPDI)	26.41	22.60
Colorectal Anal Distress Inventory (CRADI)	50.36	22.04
Pelvic Floor Distress Inventory (PFDI)	117.09	61.37
Urinary Impact Questionnaire (UIQ)	33.13	28.97
Colorectal Anal Impact Questionnaire (CRAIQ)	43.36	28.28
Pelvic Organ Prolapse Impact Questionnaire (POPIQ)	27.09	28.60

Pelvic Floor Impact Questionnaire (PFIQ)	103.57	78.88
Fecal Incontinence Adaptation index		
Hygiene	47.40	21.49
Avoidance	35.76	23.59
Short Form-12 (SF-12)		
Physical	43.71	11.10
Mental	48.43	10.11
Bowel diary		
Number of accident-free days per week	2.89	2.16
Average number of leaks per day	1.59	1.78
Average number of pad changes per day	0.64	0.97

* SD = Standard Deviation

Table 2.

Descriptive Statistics of ABLE Items

Item	Mean (SD)	Item-Total Correlations			Factor Loadings		
	Baseline N=296	Baseline N=296	Week 12 N=264	Week 24 N=266	Baseline N=296	Week 12 N=264	Week 24 N=266
Liquid Stool							
A1. When I have accidental leakage of liquid stool, it is usually...	2.2 (1.2)	0.66	0.68	0.68	0.86	0.76	0.79
A2. I experience accidental leakage of liquid stool...	2.3 (1.3)	0.70	0.68	0.74	0.72	0.82	0.84
A3. I am bothered by accidental leakage of liquid stool	3.0 (1.4)	0.81	0.79	0.82	0.86	0.95	0.97
Solid Stool							
A4. When I have accidental leakage of solid stool, it is usually...	2.0 (1.2)	0.63	0.66	0.73	0.68	0.68	0.78
A5. I experience accidental leakage of solid stool...	2.2 (1.3)	0.69	0.72	0.73	0.74	0.82	0.84
A6. I am bothered by accidental leakage of solid stool	3.1 (1.4)	0.75	0.80	0.81	0.98	0.99	1.00
Mucus							
A7. When I have accidental leakage of mucus, it is usually...	1.0 (1.1)	0.85	0.80	0.82	0.91	0.88	0.91
A8. I experience accidental leakage of mucus...	1.1 (1.3)	0.85	0.82	0.88	0.93	0.92	0.97
A9. I am bothered by accidental leakage of mucus	1.5 (1.7)	0.88	0.85	0.85	0.96	0.96	0.96
Gas							
A10. I lose gas from my rectum beyond my control...	3.0 (1.2)	0.75	0.79	0.74	0.88	0.91	0.90
A11. I am bothered by accidental leakage of gas	3.3 (1.1)	0.75	0.79	0.74	0.93	0.91	0.90
Predictability/Awareness							
A12. My accidental bowel leakage is predictable	3.7 (1.2)	0.26	0.59	0.61	0.57	1.00	0.92
A13. When I have accidental bowel leakage, I leak without knowing it	3.4 (1.3)	0.26	0.59	0.61	0.57	0.61	0.70
Control							
A14. I get a sudden urge to move my bowels with little or no warning	2.4 (1.1)	0.58	0.63	0.69	0.76	0.75	0.80
A15. I am bothered by a sudden urge to empty bowels with little or no warning	3.3 (1.1)	0.58	0.63	0.69	0.91	0.93	0.94
Ancillary Bowel Symptoms							
A16. I feel that I am completely empty after a bowel movement	1.8 (1.1)	0.59	0.63	0.60	0.37	0.53	0.59
A17. I am bothered because I cannot completely empty my bowels	2.6 (1.3)	0.57	0.64	0.68	0.53	0.69	0.68
B1. I have pain (may also be cramping, burning, and/or discomfort) related to my accidental bowel leakage	1.5 (1.3)	0.34	0.36	0.36	0.77	0.63	0.66

Table 3.

Reliability of ABLE Scales/Subscales

Scale	Test-Retest Reliability	Internal Consistency (Cronbach's Alpha)		
	N=70	N=296	N=264	N=266
	(ICC)	Baseline	Week 12	Week 24
Overall	0.80	0.77	0.89	0.90
Liquid Stool	0.74	0.85	0.84	0.86
Solid Stool	0.68	0.83	0.84	0.86
Mucus	0.63	0.92	0.90	0.91
Gas	0.76	0.85	0.88	0.85
Predictability/Awareness	0.67	0.42	0.75	0.76
Control	0.77	0.73	0.76	0.80
Ancillary Bowel Symptoms	0.78	0.68	0.71	0.71

Table 4.

Correlations of ABLE Scores with Related Measures

Measure	ABLE		
	Baseline N=296	Week 12 N=264	Week 24 N=266
St. Mark's (Vaizey) Score	0.52	0.68	0.69
Urogenital/Urinary Distress Inventory (UDI)	0.26	0.40	0.33
Pelvic Organ Prolapse Distress Inventory (POPDI)	0.49	0.54	0.38
Colorectal Anal Distress Inventory (CRADI)	0.54	0.65	0.71
Pelvic Floor Distress Inventory (PFDI)	0.50	0.61	0.56
Urinary Impact Questionnaire (UIQ)	0.37	0.46	0.37
Colorectal Anal Impact Questionnaire (CRAIQ)	0.48	0.53	0.53
Pelvic Organ Prolapse Impact Questionnaire (POPIQ)	0.34	0.40	0.34
Pelvic Floor Impact Questionnaire (PFIQ)	0.43	0.50	0.45
Fecal Incontinence Adaptation index			
Hygiene	0.39	0.43	0.49
Avoidance	0.45	0.44	0.43
Short Form-12 (SF-12)			
Physical	−0.29	−0.25	−0.07
Mental	−0.30	−0.32	−0.27
Bowel diary			
Number of accident-free days per week	−0.30	−0.48	−0.47
Average number of leaks per day	0.33	0.36	0.32
Average number of pad changes per day	0.35	0.38	0.31

Note: All correlations except SF-12 Physical score at 24 weeks ($r=-0.07$) significant at $p < 0.001$.