



Development of the Painful Periods Screening Tool for endometriosis

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ABSTRACT

Objectives: Diagnostic delay is common in endometriosis. There is an unmet need for a symptom-based, patient-completed screening tool to facilitate discussions between patients and physicians about potential endometriosis symptoms. The objective of this study was to develop and assess the patient-completed Painful Periods Screening Tool (PPST) to assess the presence of potential endometriosis symptoms.

Methods: To develop and refine the PPST, a cross-sectional qualitative study was conducted with women with endometriosis and healthy controls. Following identification of potentially relevant concepts in the literature and input from clinical experts, a draft version of the PPST was tested during in-depth individual interviews with 16 women: 11 with endometriosis and 5 healthy controls.

Results: The six draft items of the PPST were refined iteratively in two rounds of interviews, and one item was deleted following the second set of interviews. All concepts included in the final five-item PPST were found to be relevant to women with endometriosis, and all 11 participants with endometriosis endorsed at least one of the items. No core symptoms of endometriosis were noted as missing from the PPST.

Conclusion: The PPST assesses the most important endometriosis-related symptoms and may help facilitate discussions between patients and physicians, promoting earlier diagnosis and treatment of endometriosis.

ARTICLE HISTORY

Received 25 July 2018
Accepted 18 September 2018

KEYWORDS

Endometriosis; Painful Periods Screening Tool; patient-completed; screening; symptom

1. Introduction

Endometriosis is estimated to affect 6–10% of women of reproductive age [1]. Symptoms of endometriosis include dysmenorrhea, dyspareunia, pelvic pain, infertility, heavy menstrual bleeding, and painful bowel and/or bladder symptoms [1,2]. Endometriosis has significant social and psychological impacts across several domains, including health-related quality of life (HRQOL), intimate relationships, planning for and having children, productivity at work and home, and emotional well-being [3,4]. The HRQOL impairment associated with endometriosis increases as the number and severity of symptoms increases [5]. Endometriosis also causes significant economic burden, with hospitalizations being the main direct-cost driver [6–11].

Many women with endometriosis experience delayed diagnosis [12], typically occurring 6 or more years after patients initially present with symptoms [13]. Previous research has found discordance between patients' and physicians' descriptions and perceptions of endometriosis symptoms [14], potentially contributing to diagnostic delays. Time to diagnosis also may be greater for women seeking care from generalists (vs. gynecologists), those diagnosed during routine care (vs. those seeking treatment for symptoms), those who did not undergo

an imaging procedure (vs. those who did), those with symptom onset in adolescence (vs. adulthood), and white women (vs. women of other ethnicities) [12,15]. Moreover, a differential diagnosis of endometriosis is challenging because its clinical presentation is variable, it may affect multiple pelvic organs, and its symptoms may overlap with those of other diseases [16]. Traditionally, endometriosis has been definitively diagnosed only via surgical means (i.e. laparoscopy or laparotomy, coupled with histopathology) [17].

There is a need for a tool to help patients recognize potential endometriosis symptoms and consult with their physicians to seek diagnosis and treatment if applicable. A recent review sought to identify existing patient-completed symptom-based endometriosis screening tools to facilitate patient–physician communications [18]. None of the measures identified were found to be fit for purpose, primarily because of their length and complexity or because they lacked patient input or adequate validation. Thus, the objective of this study was to develop and evaluate the content validity of the Painful Periods Screening Tool (PPST), a brief, patient-completed screening tool to assess the presence of potential endometriosis symptoms.

2. Materials and methods

Development of the PPST was in accordance with the U.S. Food and Drug Administration's (FDA's) guidance for the development of patient-reported outcome (PRO) measures [19].

2.1. Item development

In a targeted literature review [18], potential concepts for the new tool were identified. Standard survey methodological principles were applied to draft items designed to assess the hallmark symptoms of endometriosis. The PPST was designed as an assessment of typical symptoms based on a single administration versus as a diagnostic tool.

The draft items were evaluated by four clinical experts (S.K. A., C.C.C., E.S.S., and H.S.T.) and an experienced endometriosis patients' advocacy board representative. Using a semi-structured interview guide, D.B.D. led a 1-h telephone discussion with each expert, who provided feedback on the clarity, importance, and relevance of each item. This feedback informed revisions to the items, which then were tested with patients in cognitive debriefing interviews – a qualitative research technique used in this case to elicit patients' understanding of and feedback on the PPST concepts and items.

2.2. Study participants

Interview participants were recruited by qualitative research facilities in two U.S. cities (Raleigh, NC, and Dallas, TX). Trained medical recruiters screened women who self-reported a clinical diagnosis of endometriosis, as well as healthy controls. Sample sizes of 10–12 women with endometriosis and 4–6 healthy controls were considered adequate to achieve sufficient saturation and address the study objectives [19].

Eligible individuals were pre- or perimenopausal females aged 18–49 years who could read and understand English. Participants with endometriosis were also required to have self-reported laparoscopic or other surgically confirmed endometriosis to be eligible. Individuals were ineligible if they were postmenopausal; self-reported history of a hysterectomy, oophorectomy (unilateral or bilateral), and/or current pregnancy; or self-reported cessation of menstrual periods for 1 year or more. For the healthy control group, individuals who self-reported a diagnosis of endometriosis or pain with functional impairment during or near their periods were ineligible.

2.3. Interview methods

Two iterative rounds of 1-h, in-person interviews were led by two experienced female interviewers (C.E. and/or D.B.D.), following a semi-structured guide.

For women self-reporting a diagnosis of endometriosis, each interview began with a brief study overview and general questions about participants' experience with endometriosis. For women in the healthy control group, the discussion briefly focused on age at first menses and the participant's knowledge about endometriosis, if any. Interviewers then asked all

participants to 'think aloud' as they responded to each PPST item, posing probe questions as needed to further explore how participants interpreted the items. All interviews were conducted in June 2017 and were audio-recorded and transcribed.

2.4. Statistical analyses

Qualitative analysis focused on identifying and comparing dominant trends within and across interviews to generate themes or patterns in participants' descriptions of their symptoms and feedback on the draft PPST. Descriptive statistics (e.g. frequency of symptom reports) were summarized.

2.5. Ethical approval

All study procedures were in accordance with the ethical standards of the Declaration of Helsinki. The study was reviewed and approved by RTI's institutional review board, and all participants provided written informed consent.

3. Results

3.1. Participant characteristics

A total of 16 women participated in the interviews: 11 women with endometriosis and 5 healthy controls (Table 1). All 11 participants with endometriosis self-reported a laparoscopically confirmed diagnosis, and average time since diagnosis was 11.3 years.

Participants with endometriosis described the onset of their symptoms and the diagnosis process. Most women described symptoms (most commonly pelvic/abdominal pain) that started within a few years of menses onset (adolescence)

Table 1. Participant characteristics.

Characteristic	Patients with endometriosis (n = 11)	Controls (n = 5)	Total (N = 16)
Age in years, mean (range)	37.2 (24–48)	34.0 (27–42)	36.2 (24–48)
Age at first period, mean (range)	12.3 (10–14)	11.2 (9–14)	11.9 (9–14)
Time since diagnosis, mean (range)	11.3 (2–23)	N/A	11.3 (2–23)
Comorbidities, n (%)			
Allergies	9 (81.8)	2 (40.0)	11 (68.8)
Uterine fibroids	5 (45.5)	0 (0.0)	5 (31.3)
Asthma	5 (45.5)	0 (0.0)	5 (31.3)
IBS/IBD	2 (18.2)	0 (0.0)	2 (12.5)
Race/ethnicity, n (%)			
White	4 (36.4)	2 (40.0)	6 (37.5)
African American	6 (54.5)	2 (40.0)	8 (50.0)
Hispanic	1 (9.1)	1 (20.0)	2 (12.5)
Education, n (%)			
Some college	5 (45.5)	2 (40.0)	7 (43.8)
College degree	2 (18.2)	2 (40.0)	4 (25.0)
Advanced degree	4 (36.4)	1 (20.0)	5 (31.3)

IBD: inflammatory bowel disease; IBS: irritable bowel syndrome; N/A: not applicable.

and increased in severity over time, prompting them to seek medical help. The time from symptom onset to accurate diagnosis for most women was lengthy, sometimes spanning years. These women commonly reported seeing multiple physicians and receiving various diagnoses prior to confirmation of endometriosis via surgery. Almost half of the women with endometriosis voiced frustration and sadness when describing the diagnosis process and the significant impact of their symptoms. Specifically, many women noted that endometriosis had affected their ability to feel 'well' or 'normal', exercise, go to school and/or work, and conceive.

Participants with endometriosis were asked to report their endometriosis-related symptoms and the treatments they had received. The most commonly reported symptoms included pelvic/abdominal pain and/or cramping ($n = 9$, 81.8%) and heavy bleeding ($n = 6$, 54.5%; of note, five women reported a clinical diagnosis of uterine fibroids in addition to their endometriosis diagnosis; Table 2). Women with endometriosis described having taken a variety of treatments, including surgical treatment ($n = 7$, 64%), birth control (i.e. hormonal contraceptives; $n = 7$, 64%), and Lupron ($n = 3$, 27%). Although all healthy controls ($n = 5$) noted that they had heard of endometriosis, none of these women knew much (if anything) about its symptoms.

3.2. Cognitive debriefing

Table 3 presents the draft versions of the instructions, response options, and items that were tested during both rounds of patient interviews; Table 4 presents participants' verbatim feedback on these elements. The supplemental appendix presents the final PPST.

No items except for the dyspareunia item were endorsed by any control subject during cognitive debriefing, supporting the ability of the PPST to differentiate between women with endometriosis and healthy controls. (The one control subject who endorsed dyspareunia attributed it to another condition.)

3.2.1. Instructions

Based on feedback from participants in both interview rounds, the final PPST instructions reference pelvic, abdominal, or

lower back pain days 'before, during, or after' periods (see Table 3).

3.2.2. Response options

Most PPST items use a dichotomous 'yes/no' response scale. Based on participant feedback, a 'Not applicable, I am not sexually active' response option was included for the items about dyspareunia and avoidance of sexual intercourse in the final PPST.

3.2.3. Often or typically

In Round 1, two terms assessing frequency of symptoms were tested ('often' or 'typically') across the items. Although participants easily understood both terms, nearly all preferred 'often', and it was retained in all but one item (Item 4) in the final PPST.

3.2.4. Pelvic pain-related symptoms

3.2.4.1. Item 1: dysmenorrhea. In Round 1, two versions of an item assessing dysmenorrhea severe enough to limit activities or require medication were tested. One focused on specific types (locations) of pain before or during periods, and the other asked about 'painful periods'. Most participants with endometriosis deemed dysmenorrhea highly relevant (except one participant who experienced symptoms only during intercourse and urination), and all found the items easy to understand and answer. Women with endometriosis preferred the version denoting the location of pain, and this version was retained for testing in Round 2. All Round 2 participants again easily understood and answered the item and found it highly relevant.

3.2.4.2. Item 2: pelvic pain. In Round 1, feedback on two options for a pelvic pain item was similar to that for the dysmenorrhea item: participants overwhelmingly preferred the version with specific pain locations noted, and this version was retained for further testing in Round 2. All participants understood the difference between Item 1 (pain before and/or during periods) and Item 2 (pain between periods). This item proved highly relevant for women who experienced pelvic pain continuously, not only in association with their periods. In Round 1, four of five participants with endometriosis endorsed this symptom, and all Round 2 participants with endometriosis indicated that this item was highly relevant. In fact, one participant reported that pain between her periods is what finally persuaded her that something was wrong.

3.2.5. Symptoms related to sexual intercourse

3.2.5.1. Item 3: dyspareunia. Several alternative versions of an item assessing dyspareunia were tested. In Round 1, two versions of an item assessing 'pain with sexual intercourse and certain sexual activities' were tested: one with a reference period of 'often' and the other without. Women consistently described pain with sexual intercourse as pain in the pelvic area with (most typically) penile penetration. Approximately half of participants with endometriosis in Round 1 endorsed this symptom, and one of three control participants endorsed this symptom (but attributed this

Table 2. Endometriosis symptom frequency.

Symptom	Round 1 ($n = 5$)	Round 2 ($n = 6$)	Total ($N = 11$)
Pelvic/abdominal pain/ cramping	5 (100%)	4 (67%)	9 (82%)
Heavy bleeding	2 (40%)	4 (67%)	6 (55%)
Pain with sex	3 (60%)	3 (50%)	6 (66%)
Vomiting/nausea	2 (40%)	2 (33%)	4 (36%)
Back pain	1 (20%)	3 (50%)	4 (36%)
Long cycles ^a	1 (20%)	2 (33%)	3 (27%)
Blood clots	2 (40%)	0 (0%)	2 (18%)
Infertility	1 (20%)	1 (17%)	2 (18%)
Mood swings	1 (20%)	1 (17%)	2 (18%)
Diarrhea	1 (20%)	1 (17%)	2 (18%)
Bloating	1 (20%)	1 (17%)	2 (18%)
Painful bowel movements	1 (20%)	0 (0%)	1 (9%)
Pain with urination	1 (20%)	0 (0%)	1 (9%)
Frequent urination	1 (20%)	0 (0%)	1 (9%)
Constipation	0 (0%)	1 (17%)	1 (9%)
Bruising (thigh/legs)	0 (0%)	1 (17%)	1 (9%)

^a Bleeding for a long time; long menstrual flow.

Table 3. Iterative development of the endometriosis screening tool.

	Round 1	Round 2	Final
Instructions ^a	If you frequently have pelvic, abdominal, or lower back pain days before or during your period, you may have a condition called endometriosis. Complete the following questions to see if this is something you might want to discuss with your doctor.	Option A: If you frequently have pelvic, abdominal, or lower back pain days before or during your period, you may have a condition called endometriosis. Complete the following questions to see if this is something you might want to discuss with your doctor. Option B: If you have frequent or chronic pelvic, abdominal, or lower back pain associated with your periods, you may have a condition called endometriosis. Complete the following questions to see if this is something you might want to discuss with your doctor.	If you frequently have pelvic, abdominal, or lower back pain before, during, or after your period, you may have a condition called endometriosis. Complete the following questions to see if this is something you might want to discuss with your doctor.
Item 1: dysmenorrhea	1a. Do you typically experience pelvic/abdominal or lower back pain before or during your periods that limits your activities or requires medication? 1b. Do you often have painful periods that limit your activities or require medication?	1. Do you often experience pelvic/abdominal or lower back pain before or during your periods that limits your activities or requires medication?	1. Do you often experience pelvic/abdominal or lower back pain before or during your periods that limits your activities or requires medication? 2. Do you often experience pelvic/abdominal or lower back pain between your periods that limits your activities or requires medication?
Item 2: pelvic pain	2a. Do you often experience pelvic/abdominal or lower back pain between your periods that limits your activities or requires medication? 2b. Do you typically experience pain between your periods that limits your activities or requires medication?	2. Do you often experience pelvic/abdominal or lower back pain between your periods that limits your activities or requires medication?	2. Do you often experience pelvic/abdominal or lower back pain between your periods that limits your activities or requires medication?
Item 3: dyspareunia ^b	3a. Do you often experience pain with sexual intercourse or certain sexual activities? <input type="checkbox"/> Yes <input type="checkbox"/> No 3b. Do you experience pain with sexual intercourse or certain sexual activities? <input type="checkbox"/> Yes <input type="checkbox"/> No	3a. Do you often experience pain with sexual intercourse? <input type="checkbox"/> Yes <input type="checkbox"/> No 3b. Do you often experience pain with sexual intercourse or certain sexual activities? <input type="checkbox"/> Yes <input type="checkbox"/> No 3c. Do you often experience pain with sexual intercourse or certain sexual activities? <input type="checkbox"/> Yes <input type="checkbox"/> No 3d. Do you often experience pain with sexual intercourse or certain sexual activities? <input type="checkbox"/> Yes <input type="checkbox"/> No	3a. Do you often experience pain with sexual intercourse? <input type="checkbox"/> Yes <input type="checkbox"/> No 3b. Do you often experience pain with sexual intercourse or certain sexual activities? <input type="checkbox"/> Yes <input type="checkbox"/> No 3c. Do you often experience pain with sexual intercourse or certain sexual activities? <input type="checkbox"/> Yes <input type="checkbox"/> No 3d. Do you often experience pain with sexual intercourse or certain sexual activities? <input type="checkbox"/> Yes <input type="checkbox"/> No

(Continued)

Table 3. (Continued).

	Round 1	Round 2	Final
Item 4: avoidance of sexual intercourse ^b	4a. Do you avoid sexual intercourse or certain sexual activities to avoid pain? <input type="checkbox"/> Yes <input type="checkbox"/> No 4b. Do you typically avoid sexual intercourse or certain sexual activities to avoid pain? <input type="checkbox"/> Yes <input type="checkbox"/> No	4. Do you sometimes avoid sexual intercourse to avoid pain? <input type="checkbox"/> Yes <input type="checkbox"/> No	4. Do you sometimes avoid sexual intercourse to avoid pain? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable, I am not sexually active
Item 5: dysuria	5. Do you often have painful urination before and/or during your periods?	5. Do you often have painful urination before and/or during your periods?	Deleted
Item 6: dyschezia	6. Do you typically have pain or difficulty with bowel movements before and/or during your periods?	6a. Do you often have pain or difficulty with bowel movements before and/or during your periods? 6b. Do you often have pain with bowel movements before and/or during your periods?	5. Do you often have pain with bowel movements before and/or during your periods? Deleted

^aOne version of the instructions, referencing 'pelvic, abdominal or lower back pain days before or during your period', was tested in both rounds of interviews and found to be clear and easy to understand. In Round 1, of the five participants with endometriosis, three noted experiencing 'chronic' symptoms unrelated to menstruation or their menstrual cycle. In the second round of interviews, an alternative set of instructions referencing 'frequent or chronic pelvic, abdominal or lower back pain associated with your periods' was tested. Round 2 participants overwhelmingly reported that a revised instruction set, targeting the time 'before, during or after' periods, would be the most inclusive. The most inclusive reference period was retained in the final instructions.

^bFor the items about dyspareunia and avoidance of sexual intercourse, 'not applicable'-type responses were tested following feedback from participants in Round 1 that they were not currently sexually active and thus did not know how to select an answer to the question. A 'Not applicable, I am not sexually active' response option for women who were not sexually active was added to the final Painful Periods Screening Tool after Round 2 interviews, based on feedback from the interviews.

Table 4. Verbatim participant feedback on the Painful Periods Screening Tool (PPST).

PPST element/item	Quotations
Instructions	'It's saying like if you're having any type of stomach pains or pelvic pains or if your back is hurting during your period, then you might want to consult with your doctor because you could have endometriosis ... It was easy ... [the instructions are] pretty self-explanatory to me'. 'Because that way [referencing before, during, and after] you're including basically everybody ... [Option B] that was more of a wide range, I'd be like, "Well, you know, that doesn't apply to me because I don't have pain other than just at this point".'
Item 1: dysmenorrhea	'Well this one [painful periods item] is not being specific about what type of pains are you having. Are you having headaches, are you having arm pains?...This one [Item 1a] is more like identifying the problem ... pelvic, abdomen, lower back, and stuff like that'. 'Um, that's asking me ... do you miss any days out of work?...Can you not get out of bed? I've had this issue where it limits work, absolutely limits my activities ... I missed time out of work, normal household stuff, cooking, cleaning, everything that ... because I'd just lay in bed all day in a fetal position'. 'Totally applies to me ... I wouldn't change anything' [about the question]. 'And I like the way [the item] explains. Do you often experience ... it doesn't say "typically experience" – pelvic/abdomen pain or lower back pains between your periods that limit your activities or require medication ... I know the pains that they're talking about, but a person that's trying to figure out if they have endometriosis, they'll be trying to figure out what pains they're talking about [in 2b]'. 'That [item] would make perfect sense and you would help with diagnosis because it's somebody that has the pain in between periods, then you know there is something is there ... So I do prefer 2a, you know, just says "pelvic/abdominal or lower back pain"'. 'I don't know if you want to specify certain sexual activities ... Somebody is probably going to ask, "Well, what do you mean by that?" So I think you might want to explain what exactly [the phrase "certain sexual activities" means]'. 'Do you often experience pain with sexual intercourse or certain sexual activities? I wasn't sexually active for a lot of that time. So, depending on when I would have answered this question, it wouldn't be relevant to me at the time'. '... certain sexual activities? [laughter] I like the first question better ... so what sexual activity are they talking about? That would be my first question, like, what in the world?' 'I don't know about that one [certain sexual activities] ... because for me it's with penetration, so I don't know ... well, I haven't experienced anything else to know if there's pain in any other forms of sex'.
Item 2: pelvic pain	
Item 3: dyspareunia	
Item 4: avoidance of sexual intercourse	'This tells you how bad the pain really is'. 'And I answered yes [to avoiding intercourse due to pain] because even though it didn't ... bother me all the time ... certain times of the month I knew I could not get past that because I knew I'd be in pain ... For me, the "sometimes" was okay just because it was not an all-the-time thing'. 'I feel like if you're not sexually active, then those questions just don't pertain to you'. 'There would be times when it was just like, "Okay, I don't want to do this [intercourse]". And you don't want to upset your partner, but at the same time it's kind of hard to tell them, "Hey. When you're doing what you're doing, everything hurts". So, it's just like, "I can't". So sometimes, yeah, you just nip it in the bud. Not at all'. 'Yeah, I would have said yes just because that was a huge symptom for me. Like I felt like I had a UTI for 6 months'. 'That's a weird question. I'm thinking about a burning sensation'.
Item 5: dysuria	
Item 6: dyschezia	'[Is there a difference to you between pain and difficulty?] Difficulty means you might be straining or constipated, maybe. I guess. Pain means while you're doing it, there is pain. It's hurting'. 'Before my period, I do [have pain or difficulty with bowel movements]. But during my period, I have diarrhea'. '[Item 6a] is basically asking, you know, do you experience constipation, diarrhea, anything like that during or around your periods ... [it is] a more broad statement saying "difficulty" because it made me think of constipation or diarrhea. The 6b, it just says "Do you often have pain with bowel movements?" It's just asking me, am I having pain with my bowel movements during my period, and I wouldn't have pain with the bowel movements. It was just the difficulty'.
Title	'Since I've never heard of endometriosis, I don't think, like I wouldn't even look at it'. 'I think maybe something alluding to the fact of maybe like, you know, Painful Period? Is It Something More Than Just a Painful ... just something to get them thinking, I think, to actually look at it, yeah. But I don't know how you would word that'.
Overall measure	'Made me go sooner [to OB-GYN] if I had this [tool]'. 'So, the questions would help you to know that you have something that you actually do need to discuss with your doctor and sort of be your own advocate because they have busy days and they're not going to know to ask you about it'. 'I'm having this problem and I don't know what it means ... you know, this is wrong ... but you don't know the words to necessarily use ... Having a questionnaire, that does help because you can go into the doctor and you may not even have to say [words]. You can just read through it'. 'I think [the tool is] great. I think, you know, you've pinpointed the bigger things and the most obvious things that someone would more than likely recognize if they had endometriosis. And even if not, you picked the top things, and that question – that blurb at the end saying if you answered yes to one of these things you need to talk to your doctor – that's going to cover everything else. I like it'. 'Covers all the most important symptoms'. 'Conveys a lot'. 'Straight to the point'. 'Really good. Not too long'.

pain to a different condition). However, all eight Round 1 participants found the phrase 'certain sexual activities' unclear, and most said it was unnecessary. Additionally, two of the eight participants indicated that they were not currently sexually active, prompting the addition of a 'not applicable' response option for this item. In Round 2, two versions were tested – the first assessing pain with sexual intercourse and the second assessing 'sexual intercourse or

certain sexual activities' (to obtain additional feedback on the phrase). All Round 2 participants easily understood and answered the item assessing pain with sexual intercourse but again expressed confusion about or discomfort with the phrase 'certain sexual activities'. Almost all participants ($n = 7$, including all six participants with endometriosis) reported that the item assessing only sexual intercourse was clearer and more relevant.

3.2.5.2. Item 4: avoidance of sexual intercourse. In Round 1, two versions of an item assessing avoidance of sexual intercourse were tested, and all women generally understood and easily answered both versions. The three Round 1 participants with endometriosis who experienced dyspareunia found the concept highly relevant, and all would have endorsed this item when they were sexually active (two were currently not). However, as with Item 3, Round 1 participants found the phrase ‘certain sexual activities’ disconcerting and unclear; thus, this alternative was deleted. In addition, a Round 1 participant suggested an alternative frequency of ‘sometimes’ (instead of ‘typically’). The revised frequency tested well in subsequent interviews across Rounds 1 and 2; several women indicated that ‘sometimes’ most accurately portrayed their experiences given that they still had sexual intercourse, often for relationship reasons. Round 2 participants also found this concept to be important. The three Round 2 participants with endometriosis who reported dyspareunia (Item 3) also responded affirmatively to this item. Participants further indicated that the item was both relevant and important.

3.2.6. Urinary and bowel symptoms

3.2.6.1. Item 5: dysuria. One item assessing dysuria was tested across both rounds of interviews, with highly consistent results. Only 1 of the 11 participants with endometriosis reported experiencing this symptom and described it as pelvic pressure and pain when urinating (before or during periods). All remaining Round 1 participants interpreted painful urination as a burning or stinging sensation similar to that associated with a urinary tract infection or sexually transmitted disease.

Although the one participant with endometriosis who reported this symptom thought it was impactful and important to treat, she also reported at least one other endometriosis symptom included in the PPST. This concept was retained for further testing in Round 2, which yielded similar results. The concept of painful urination is noted in the literature and was identified as a potential (but uncommon) endometriosis symptom by clinical experts; however, it was not highly endorsed or clearly understood by interview participants and was not retained in the final PPST.

3.2.6.2. Item 6: dyschezia. One item assessing this concept was tested in Round 1. All Round 1 participants found the dyschezia item easy to answer. However, all but one participant (four with endometriosis and the three controls) equated ‘difficulty with bowel movements’ with constipation. In contrast, most women did not directly correlate ‘pain with bowel movements’ with constipation, and a few women described this concept as abdominal pain or cramping that was distinguishable from menstrual pain. Although three participants with endometriosis positively endorsed this item, only one woman described actual dyschezia (bowel movements that ‘hurt’ during her period) as a symptom she experienced; in fact, this participant described painful bowel movements as her most bothersome symptom.

Two dyschezia items were subsequently tested in Round 2: the original version with slight modifications (replacing ‘typically’ with ‘often’) and an alternative version focusing only on

‘pain with bowel movements’. In Round 2, all participants easily answered both versions and again generally interpreted ‘difficulty with bowel movements’ as ‘constipation’ or in some cases. When provided the intent of the question, most women (seven of eight) reported that version of the item focusing solely on pain would be most appropriate.

3.2.7. Scoring

The clinical experts who provided input on the items before the patient interviews each suggested that patients answering ‘Yes’ to any single item should discuss their symptoms with a physician to explore the possibility that they might have endometriosis. The same set of scoring instructions was tested across each round of interviews and deemed clear, easy to understand, and appropriate.

3.2.8. Screening tool review

All participants found the PPST clear, comprehensible, and easy to use, and all indicated that it assessed the most important symptoms associated with endometriosis. When probed about whether any important concepts were missing from the PPST, the only concepts reported by more than one participant were the bleeding symptoms of heavy bleeding and passing clots ($n = 2$ for each). Participants also reported that the short length and the yes/no response options facilitated completion of the PPST. Additionally, all women with endometriosis saw great value in the tool and would have used something like it to initiate discussions with their doctors.

4. Discussion

Concepts for inclusion in the draft PPST were based on the hallmark symptoms of endometriosis identified in a literature review [18], with the addition of a urinary item based on expert input. Clinicians and advocacy board representatives provided feedback on an early draft of the items before the draft PPST was tested with patients.

All items in the final five-item PPST tested well during cognitive debriefing interviews, and the study sample found the tool to be clear and to reflect the most important concepts associated with endometriosis. Although bleeding-related concepts were considered for the tool, due to the low number of patients who noted these concepts as missing and the fact that heavy bleeding is not considered by clinical experts to be a core symptom of endometriosis, items assessing these symptoms were not included in the final PPST. All concepts included in the final PPST were deemed relevant to women with endometriosis, and all 11 participants with endometriosis endorsed at least one item. Conversely, only one of five control participants answered any item affirmatively (pain with intercourse), which the participant attributed to another condition. These results suggest that the final PPST clearly and concisely assesses the core symptoms of endometriosis and support the face and content validity of the tool [19].

Some limitations of this study must be acknowledged. The sample size was adequate to support saturation and qualitative analysis (e.g. assessing the item wording, content, and item revisions) [19,20] and was consistent with those used in other qualitative studies, including the development of other screening or communication tools [21–24]. The results may be subject to

selection bias, in that patients who choose to participate in studies such as this one may experience greater symptom severity or may be more likely to initiate contact with a health-care provider. Thus, caution should be used in generalizing these findings to a larger endometriosis population. Nevertheless, interviews were conducted at two geographical locations to ensure some diversity in demographics and replicability. In addition, participants' symptoms and other clinical characteristics were self-reported, and the potential for confounding variables (e.g. uterine fibroids, reported by five participants, and other comorbidities) must be considered.

In comparison with existing endometriosis screening tools, which are lengthy, complex to complete and score, and/or inadequately validated [18], the PPST is short and uses patient-friendly language. Existing screening tools may have clinical utility in some settings (e.g. to complement surgical diagnostic techniques and imaging) but may be less useful in promoting discussions of a potential endometriosis diagnosis early in the disease course. The PPST is intended to facilitate discussions between patients and clinicians about potential endometriosis symptoms, thus promoting earlier diagnosis. For women with a diagnosis of endometriosis, validated tools are available to assess HRQOL, symptoms, and other PROs (e.g. the Endometriosis Health Profile short-form questionnaire (EHP-5) [25] and the Endometriosis Treatment Satisfaction Questionnaire (ETSQ) [26])

Previous research indicates that delayed diagnosis is a significant issue in endometriosis. The PPST was designed to address an unmet need by providing a structured measure to help patients recognize potential symptoms of endometriosis, thus facilitating initial discussions between patients and their physicians. Considerations for widespread use of the PPST include patient education about the symptoms of endometriosis, physician education, and encouraging physicians to consider endometriosis at the onset of a clinical presentation of symptoms. Prospective research should evaluate whether uptake of the screening tool shortens time to diagnosis.

5. Conclusion

Results of this qualitative work indicate that the PPST addresses and adequately measures the most important endometriosis-related symptoms. The PPST clearly addresses an unmet need and may potentially be used to help facilitate earlier diagnosis and treatment of endometriosis.

Acknowledgments

The authors gratefully acknowledge Mary Lou Ballweg of the Endometriosis Association for her insights during development of the screening tool and her insightful review of this manuscript. Ms. Ballweg is a paid consultant for AbbVie.

Geolocation information

This study was conducted in the United States.

Funding

This study was funded by AbbVie. AbbVie participated in data analysis; in interpretation of data; and in review, approval of, and decision to submit the manuscript.

Declaration of interest

This research was performed under a contract between AbbVie and RTI Health Solutions. D.B. DiBenedetti, C. Ervin, and E. Evans are employees of RTI Health Solutions, which was funded by AbbVie to conduct this project. A.M. Soliman is an employee of AbbVie and may own AbbVie stocks/stock options. C.C. Coddington, S.K. Agarwal, E.S. Surrey, and H.S. Taylor are consultants for AbbVie and may own AbbVie stocks/stock options. Medical writing services were provided by Kate Lothman of RTI Health Solutions. Medical writing services were funded by AbbVie, Inc. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties. Peer reviewers on this manuscript have no relevant financial relationships to disclose.

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APPENDIX: Painful Periods Screening Tool (PPST)

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If you frequently have pelvic, abdominal or lower back pain before, during or after your period, you may have a condition called endometriosis. Complete the following questions to see if this is something you might want to discuss with your doctor.

1. Do you **often** experience pelvic/abdominal or lower back pain before or during your periods that limits your activities or requires medication?
 - Yes
 - No
2. Do you **often** experience pelvic/abdominal or lower back pain between your periods that limits your activities or requires medication?
 - Yes
 - No
3. Do you **often** experience pain with sexual intercourse?
 - Yes
 - No
 - Not applicable, I am not sexually active
4. Do you **sometimes** avoid sexual intercourse to avoid pain?
 - Yes
 - No
 - Not applicable, I am not sexually active
5. Do you **often** have pain with bowel movements before and/or during your periods?
 - Yes
 - No

Scoring: If you answered 'Yes' to one or more of these questions, you could have a condition called endometriosis. Please talk to your doctor or health-care professional.