Bowel Endometriosis Syndrome: a new scoring system for pelvic organ dysfunction and quality of life

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STUDY QUESTION: Is it possible to develop a validated score that can identify women with Bowel Endometriosis Syndrome (BENS) and be used to monitor the effect of medical and surgical treatment?

SUMMARY ANSWER: The BENS score can be used to identify women with BENS and to monitor the effect of medical and surgical treatment of women suffering from bowel endometriosis.

WHAT IS KNOWN ALREADY: Endometriosis is a heterogeneous disease with extensive variation in anatomical and clinical presentation, and symptoms do not always correspond to the disease burden. Current endometriosis scoring systems are mainly based on anatomical and surgical findings.

STUDY DESIGN, SIZE, DURATION: The score was developed and validated from a cohort of 525 women with medically or surgically treated bowel endometriosis from Aarhus and Copenhagen University Hospitals, Denmark.

PARTICIPANTS/MATERIALS, SETTING AND METHODS: Patients filled in questionnaires on pelvic pain, quality of life (QoL) and urinary, sexual and bowel function. Items were selected for the final score using clinical and statistical criteria. The chosen variables were included in a multivariate analysis. Individual score values were designated items to form the BENS score, which was divided into 'no BENS', 'minor BENS' and 'major BENS.' Internal and external validations were performed.

MAIN RESULTS AND THE ROLE OF CHANCE: The six most important items were 'pelvic pain', 'use of analgesics', 'dyschezia', 'straining to urinate', 'fecal urgency' and 'satisfaction with sexual life'. The range of the BENS score (0–28) was divided into 0–8 (no BENS), 9–16 (minor BENS) and 17–28 (major BENS). External validation showed a significant association between BENS score and QoL ($P = 0.0001$).

LIMITATIONS, REASONS FOR CAUTION: The BENS scoring system is limited by the fact that it was developed from a single endometriosis unit in Denmark, making it susceptible to social, cultural and demographic bias.

WIDER IMPLICATIONS OF THE FINDINGS: It is the first endometriosis classification system to be based directly on the symptomatology of the patient. Validation in other languages will promote comparison of treatments and results across borders.

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Key words: endometriosis / surgery / quality control / bowel / classification

Introduction

Endometriosis is a heterogeneous disease with extensive variation in anatomical and clinical presentation, and symptoms do not necessarily correspond to the disease burden (Dunselman *et al.*, 2014). This complicates comparison of treatment and results, and a harmonization in the reporting of clinical outcome has been called for (Meuleman *et al.*, 2011, 2012; Hirsch *et al.*, 2016). A number of classification systems for endometriosis exist, the most widely used being the revised American Society for Reproductive Medicine (ASRM) score (ASRM, 1997). The score is widely accepted and easy to use but has been criticized for omitting retroperitoneal manifestations of the disease (Haas *et al.*, 2013a,b). The ENZIAN score (Tuttlies *et al.*, 2005) aims to take the presence of deep infiltrating endometriosis into account and has been shown to display superior correlation with clinical symptoms compared with the ASRM score (Haas *et al.*, 2013a,b), but it has not gained wider acceptance outside German speaking countries. Finally, the Endometriosis Fertility Index (EFI) has proven useful in predicting fertility outcome (Adamson and Pasta, 2010; Adamson, 2013).

A recent consensus paper from the World Endometriosis Society has summed up the status and challenges in the classification of endometriosis (Johnson *et al.*, 2017).

These classification systems have in common that they are mainly constructed on the basis of anatomical and surgical findings, although the EFI combines surgical findings with the patients' history of infertility. Consequently, none of them take the patients' symptoms into account. This could be considered a serious lack in the literature, as almost any decision made by doctors dealing with women suffering from endometriosis is based on the symptomatology of the patient. Another approach is the The Endometriosis Health Profile (EHP) (Jones *et al.*, 2004). Although very useful for evaluating the psychological and social aspects of endometriosis, it does not combine the self-reported quality of life (QoL) with organ-specific symptoms.

Recently, patient-centered scoring systems based on symptoms and their impact on QoL have emerged in the field of colorectal surgery (Brandsborg *et al.*, 2013; Thyo *et al.*, 2017). Most notable is the Low Anterior Resection Syndrome (LARS) score (Emmertsen and Laurberg, 2012), which has presently been validated in 29 languages, enabling colorectal surgeons round the world to monitor their patients and report results in a consistent and applicable manner. These scores are based on large cohorts of patients and have the advantage that the 'relative' impact of the different symptoms on QoL have been computed by regression analyses, and they have proven useful in the assessment of symptoms originating from one organ system; the gastro-intestinal tract.

The scientific focus of our group in recent years has been women suffering from bowel endometriosis. These patients often experience symptoms from multiple organ systems, including the urinary, genital and gastrointestinal tract, such as painful urination, urgency, irregular bleeding, dysmenorrhea, constipation or diarrhea (Ferrero *et al.*, 2011; Panel *et al.*, 2016). We propose to denote this syndrome 'Bowel Endometriosis Syndrome' (BENS). We have published our results on the effect of rectosigmoid resection in these patients (Riiskjaer *et al.*, In Press, 2016). Moreover, the symptoms of our cohort with conservatively treated bowel endometriosis have been monitored prospectively (Egekvist *et al.*, 2017). Thus, we have established a large cohort of patients with comprehensive data on QoL, pelvic pain as well as urinary, sexual and bowel dysfunction.

The aims of the present study were to develop and validate a simple, reproducible score for clinical evaluation of the severity of BENS, and to identify which aspects of the disease have the greatest impact on health-related QoL as perceived by the patient.

Materials and Methods

Study design

The cohort included women from Aarhus University Hospital and Rigshospitalet, Copenhagen University Hospital, with conservatively and surgically treated bowel endometriosis. The diagnosis was verified by transvaginal ultrasonography and/or magnetic resonance imaging (Riiskjaer *et al.*, 2016). Details on localization and dimension of the endometriotic lesions have been described elsewhere (Riiskjaer *et al.*, In Press; Egekvist *et al.*, 2017). From our cohort of surgically treated patients, we had questionnaires before and 1-year after surgery. From our cohort of conservatively treated women with endometriosis we had information from up to three questionnaires during the study period (unpublished data). These questionnaires were included, as the score was intended to be sensitive to changes in the symptomatology in women with both surgically and conservatively treated disease.

All patients were asked to fill in questionnaires about pelvic organ functioning, pelvic pain and QoL. The International Consultation on Incontinence Modular Questionnaire–Female Lower Urinary Tract Symptoms (ICIQ–FLUTS) (Brookes *et al.*, 2004) was used to evaluate urinary tract function (12 items). The Sexual function-Vaginal Changes Questionnaire (SVQ) was used to assess sexual and vaginal problems (17 items) (Jensen *et al.*, 2004). The LARS score questionnaire was used to evaluate bowel function (five items) (Emmertsen and Laurberg, 2012). The women were asked to report the frequency of analgesic use and to evaluate dysmenorrhea, intermenstrual pain and dyschezia using the Numerical Rating Scale (NRS). Finally, health-related QoL was measured using the RAND SF-36 (Short Form-36) questionnaire. The SF-36 questionnaire yields two summary scales: Physical Component Summary and Mental Component Summary (Mishra *et al.*, 2014).

Ethical approval

All patients signed an informed consent, and the study was approved by the Danish Data Protection Agency (no. 1–16- 02-221–13) and the Danish Patient Safety Authority (no. 3-3013-969/1).

Data analysis

QoL was addressed by a single question—'In general, would you say your health is?' with five possible answers: 'Excellent'/'Very good'/'Good'/ 'Fair'/'Poor'. Each basic questionnaire item was correlated to QoL by odds ratio (OR). Standard logistic regression is only valid to a binary outcome. In order to use all the information inherent in the five answer categories of the QoL-scale, we, therefore, performed ordinal logistic regression with QoL as the dependent variable. Only items with an overall significant contribution ($P < 0.05$) were included.

We aimed to develop a score that is easily applicable in the busy daily clinical setting. Therefore, a comprehensive reduction in the number of items was performed using the following criteria:

- Statistically significant association with QoL. All items with a *P*-value above 0.05 were excluded.
- Preservation of at least one item from each questionnaire. This was a priority in order to cover facets from all aspects of the disease.
- The questions should be easy to understand and non-intimidating for the patients. Thus, detailed questions about sexual practice were excluded.

- All questions should be non-exclusive. Therefore, the item "dysmenorrhea" was not included, as a significant part of these patients have had a hysterectomy or have amenorrhea due to hormonal treatment. A question about sexual function had to include women who are not sexually active.
- Finally, an expert panel of five Danish gynecologys with special interest in endometriosis and covering five different departments of different size and geographically distributed throughout the country were asked to review the questionnaires and affirm, which items they thought to be the most relevant for this group of patients.

The final selection of items for the score was made on the basis of these criteria, the highest ORs and an estimation of clinical relevancy.

The chosen variables were included into a multivariate analysis. A response category in the multivariate model with none or few answers was combined with a neighboring category. Items using the NRS scale were grouped into categories of none (0), mild (1–3), moderate (4–6) and severe (7–10) pain (Krebs *et al.*, 2007). When the final model was determined, multivariate ordinal logistic regression was performed, the coefficients were logarithmically transformed, multiplied by five and rounded off to obtain an additive score value for each symptom.

We aimed to ensure both internal and external validations of the score, facilitated by the large number of patients included. Thus, the score was developed using only the questionnaires from Aarhus University Hospital. Internal validation was obtained by comparing the pre- and post-operative scores from our group of patients having undergone laparoscopic bowel resection. External validation was attained by applying the score to the cohort of women from Rigshospitalet, Copenhagen University Hospital.

The individual maximal scores for each symptom were summed to provide the maximal BENS score. The sensitivity and specificity of the BENS score in predicting the impact on QoL was assessed by receiver operating characteristic (ROC) curves of the score versus the patients' self-reported QoL ('Excellent'/'Very good'/'Good' versus 'Fair'/'Poor'). On the basis of this plot and the mean BENS score for each group the score was divided into groups of 'no BENS', 'minor BENS' and 'major BENS'. A three-by-three table showing BENS-group versus the self-reported QoL ('Excellent'/'Very good' versus 'Good' versus 'Fair'/'Poor') was used to assess the prediction model by calculating the percentage of perfect fit, moderate fit and no fit.

Comparison between pre- and post-operative BENS score was performed using paired *t*-test. Differences in BENS score between QoL-groups in the external validation cohort were tested by the Kruskal–Wallis test. All statistical analyses were performed using STATA (STATA 12, StataCorp LP, TX, USA).

Results

At Aarhus University Hospital questionnaires were retrieved prospectively from February 2011 until April 2017. In this period, 265 women underwent laparoscopic bowel resection, and 252 (95.1%) women filled in the questionnaires before surgery. At the end of the study period, 59 women had been operated within the last year and had, therefore, not yet attended a 1-year follow-up. The remaining 206 women had attended a 1-year follow-up and out of these, 196 women (95.1%, a 74.0% participation rate from the originally recruited women) had returned the questionnaire. Furthermore, we asked the women who had been operated before February 2011 (*n* = 62) to fill in the questionnaires. Thirty-one (50.0%) of these women returned the form. The questionnaries from the cohort of conservatively treated patients (*n* = 98) were filled in between April 2014 and December 2016. During this time period each woman filled in between one and three questionnaires, representing a total of 263 questionnaires.

At Copenhagen University Hospital all women with rectosigmoid endometriosis were identified (*n* = 283). This cohort consisted of 211 women with conservatively treated disease, whereas 72 women had undergone laparoscopic bowel resection in the period between December 2010 and November 2016. Response rates were 102 (48.3%) in the conservative treatment group and 42 (58.3%) in the surgery group. In the Copenhagen cohort, there was no statistically significant difference in the age distribution among the women who responded and those who did not.

Thus, a total of 886 questionnaires from 525 patients constituted the final data set. Details of the cohort are shown in Table I.

Based on the regression analyses, these six final items were selected for the score:

- Pelvic pain.
- Analgesics consumption.
- Dyschezia.
- Straining to urinate.
- Fecal urgency.
- Satisfaction with sexual life.

ORs from multivariate analyses and adjusted score values for each of the six items are shown in Table II. The score ranges from 0 to 28 points.

The ROC curve (Fig. 1) of the BENS score versus the patients' self-reported QoL showed an area under curve = 0.8165. With a cut off at 17 points, the BENS score had a sensitivity of 57.37% and a specificity of 87.29% for identifying patients reporting 'Fair' or 'Poor' QoL. Moreover, the BENS score was plotted against the impact on QoL ('Excellent'/'Very good' versus 'Good' versus 'Fair'/'Poor') (Fig. 2), and on the basis of this plot and the ROC curve, the range of the score was divided into groups of 'no BENS' (0–8), 'minor BENS' (9–16) and 'major BENS' (17–28). The prediction model showed a perfect fit in 53.9%, moderate fit in 41.5% and no fit in 4.6% (Table III).

The internal validity was evaluated by testing whether the score was able to show differences between women before and after laparoscopic bowel resection for rectosigmoid endometriosis. The mean BENS score before surgery was 15.8 (SD 6.2) and the mean BENS score 1-year after surgery was 10.2 (SD 6.1). The difference between the pre- and post-operative BENS scores was statistically significant (*P* < 0.0001).

The external validity of the BENS score was tested on the study population from Copenhagen University Hospital (*n* = 144). The score was plotted against each of the five categories of QoL (Fig. 3) showing a significant association between BENS score and QoL (*P* = 0.0001).

In order to validate the BENS score further, we compared the BENS score with QoL data using the more comprehensive SF-36 questionnaire. A significant association between the three BENS score categories and the SF-36 summary scales was observed (both *P* = 0.0001).

Discussion

In 2004, Garry described endometriosis classification as being in as state of 'etiological confusion and therapeutic anarchy' (Garry, 2004). Our study represents an unprecedented change in this field. The BENS score is the first classification system within the field of endometriosis to be based on patient reported symptoms and QoL.

Except for the rare cases of endometriosis of the sacral nerves, bowel endometriosis comprises the most advanced form of the disease, and the surgical treatment carries a significant risk of short- and

Table I Patient characteristics of the development and validation cohorts.

	Development group (Aarhus University Hospital)	Validation group (Copenhagen University Hospital)	Total
Age (years) at the time of survey, mean (range)	35.6 (22.7–57.5)	37.6 (24.7–53.1)	
No of patients	381	144	525
No of questionnaires	742	144	886
Conservative treatment*	263	102	365
Prior to surgery	252	0	252
After surgery	227	42	269

*This cohort consisted of 98 women with conservatively treated bowel endometriosis. Each woman filled in between one and three questionnaires during the study period.

Table II The BENS score.

BENS score	OR	P	Adjusted OR	Log OR	Log OR × 5	Score
Pelvic pain						
No pain	1		1	0	0.0	0
Mild	2.78	<0.001	1.64	0.49	2.5	2
Moderate	8.50	<0.001	3.32	1.20	6.0	6
Severe	15.71	<0.001	4.90	1.59	7.9	8
Analgesics						
0–1 days/week	1		1	0	0.0	0
>1 day/week	3.76	<0.001	2.32	0.84	4.2	4
Everyday	8.36	<0.001	3.91	1.36	6.8	7
Dyschezia						
No pain	1		1	0	0.0	0
Mild	2.92	<0.001	1.19	0.17	0.9	1
Moderate	6.08	<0.001	1.54	0.43	2.2	2
Severe	8.95	<0.001	1.63	0.49	2.5	2
Straining to urinate						
Never	1		1	0	0.0	0
Occasionally	2.48	<0.001	1.86	0.62	3.1	3
Often	4.16	<0.001	2.24	0.81	4.0	4
Fecal urgency						
Never	1		1	0	0.0	0
<Once a week	1.70	0.005	1.34	0.29	1.5	1
>Once a week	3.46	<0.001	1.55	0.44	2.2	2
Sexual satisfaction						
Satisfied	1		1	0	0.0	0
Neither nor	1.91	0.001	1.47	0.39	1.9	2
Dissatisfied	4.84	<0.001	2.72	1.00	5.0	5
					Maximum score	28

BENS, Bowel Endometriosis Syndrome; OR, odds ratio.
OR and score values for each selected item.

long-term complications. This makes selection of indications for surgery and comparison of treatment modalities and results important. The BENS score offers this opportunity.

For such a score to gain acceptance it is essential that it is valid to bowel endometriosis patients in another setting than the one it was developed from. Moreover, there is a risk of circular arguments if development and validation are achieved using the same cohort. The score was developed from the cohort of patients at Aarhus University Hospital. A way to test for generalizability is employing the score to a separate, but comparable population. The endometriosis clinics in
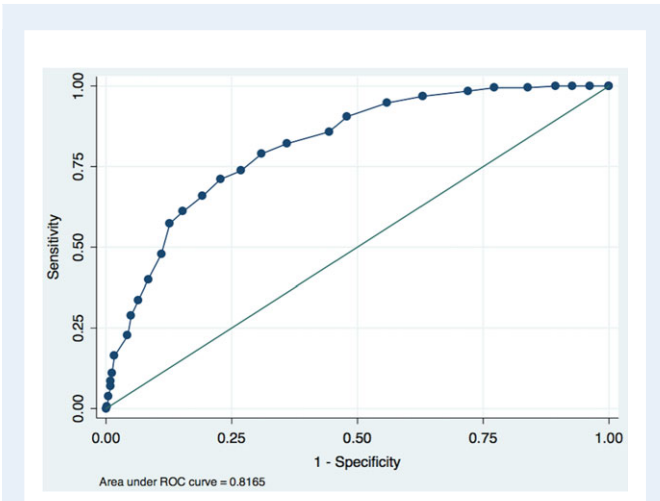
Figure 1 ROC curve showing relation between score and 'Fair' or 'Poor' QoL. QoL, quality of life.
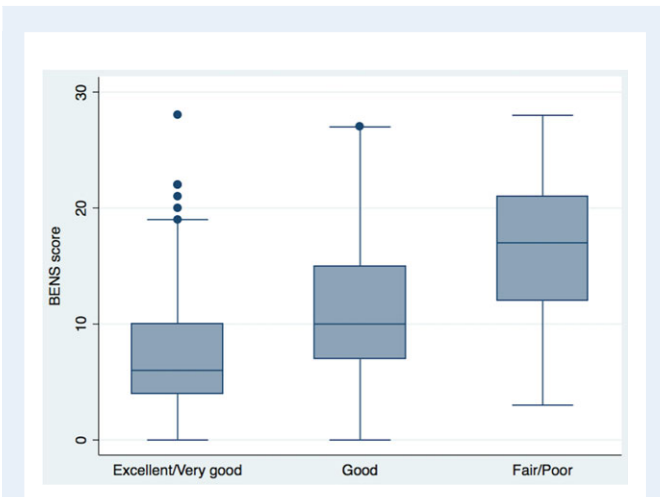

Figure 2 BENS score plotted against QoL in the entire cohort. The midline of the box represents the median, the top and bottom of the box represent the 25 and 75 percentiles, while the adjacent lines represent the upper and lower quartile ±1.5 inter quartile range. BENS, Bowel Endometriosis Syndrome.

Aarhus and Copenhagen are the only tertiary referral centers for advanced endometriosis in Denmark. When applied to women with bowel endometriosis from Copenhagen University Hospital the BENS score was significantly associated to poor QoL, underlining the potential utility value of the score in different clinical settings.

In addition, we tested the score on our prospective cohort of patients having undergone rectosigmoid resection for endometriosis. In agreement with our published results (Riiskjaer *et al.*, In Press, 2016), the score was sensitive to the improvements in self-reported QoL experienced by these patients, indicating that the score is clinically valid and useful.

The strengths of the study are the well-defined definitions of all included items, the stringent methodological development of the scoring system, and the large number of patients in the cohort. It is limited by the fact that it was developed from a single endometriosis unit in Denmark, making it susceptible to social, cultural and demographic bias. Also, it was partly based on retrospective data. We hope that the score will be tested and validated, including test–retest, in other languages and cultures enabling gynecologists around the world to compare results. The non-validated English translation of the BENS score and the scoring instructions are provided in the Supplementary Data. Please await validation before use.

The indication for surgery in bowel endometriosis is almost always relative. An NRS score above six has been suggested as an indication for surgery (Abrao *et al.*, 2015), but the authors conclude that all aspects of the disease should be addressed before deciding to perform bowel resection. The BENS score aims to take the whole complex of symptoms into account, including dysfunction of the pelvic organs and sexual health. It has the advantage of combining the 'relative' impact of the different symptoms into an overall score. Likewise, consisting of only six items it offers a quick and easy evaluation of the patients' symptoms in the busy out-patient setting.

A review from 2011 (Martin *et al.*, 2011) stated: 'Our data suggest that endometriosis is a complex condition in which the traditional one-dimensional focus on end-organ gynecological factors may not be sufficient in advancing our understanding of the optimal treatment of this condition.' In this we concur. Pain symptoms constitutes the largest part of the score, which is barely surprising for clinicians dealing with these patients. Strikingly, dis-satisfaction with sexual life makes up for a major part of the score emanating from pelvic organ dysfunctions. Along with the questionnaires, we received several personal letters from the affected women thanking us for taking an interest in their functional problems. In agreement with a recent review (Barbara *et al.*, 2017) this emphasizes that sexual health plays a major role for the

Table III Prediction model fit.

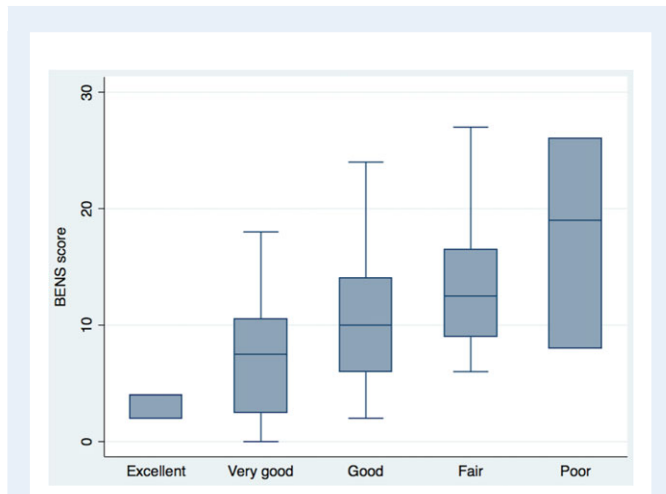|	No BENS	Minor BENS	Major BENS	Total
QoL				
Excellent/Very good	133	62	10	205
Good	84	85	43	212
Fair/Poor	18	63	109	190
Total	235	210	162	607

QoL, quality of life.

Figure 3 BENS score plotted against QoL in the validation cohort. The midline of the box represents the median, the top and bottom of the box represent the 25 and 75 percentiles, while the adjacent lines represent the upper and lower quartile ±1.5 inter quartile range.

health-related QoL in bowel endometriosis patients, and that these matters should also be taken into account when deciding the need for medical and surgical treatment.

In addition to the comparison of pre- and post-operative status, the BENS score has a potential utility in monitoring women with conservatively treated bowel endometriosis. The ease by which the score can be filled in, makes it an ideal starting point for discussion of the patients' symptoms in the out-patient clinic. The potential of the score in predicting the need for medical and/or surgical treatment could be a topic for a future study.

In conclusion, we have developed a score that can be used in the everyday clinical practice to identify women with BENS and to monitor the effect of medical and surgical management of women suffering from bowel endometriosis. It is the first endometriosis classification system to be based directly on the symptomatology of the patient. Validation in other languages will promote comparison of treatments and results across borders.

Supplementary data

Supplementary data are available at *Human Reproduction* online.

Acknowledgements

Authors' roles

M.R. designed the study, collected the data, performed the statistical analyses and drafted the manuscript. U.S.K. designed the study, performed the statistical analyses and drafted the manuscript. A.G.E., D.H., A.F. and M.S-.H. collected the data and revised the manuscript for important intellectual content. All authors approved the final version of the manuscript.

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Conflict of interest

A.F. is an investigator for Bayer, outside this work.

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