Measuring the symptoms and impacts of endometriosis: Psychometric validation of the Endometriosis Symptom Diary and Endometriosis Impact Scale

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Background and Objectives

Objective 1: To develop and validate a daily symptom diary assessing the three core symptoms of endometriosis (pelvic pain, dysmenorrhoea and dyspareunia) related to menstrual cycle (MC). Objective 2: To develop and validate a weekly patient-rated questionnaire assessing the core impacts of endometriosis. Objective 3: To investigate the psychometric validity of the ESD and EIS, a non-interventional real-world study was conducted. Validity study to Endometriosis PRQ (WPRO).

Methods

Study design

A prospective, observational validation study was conducted in the US and Germany (n=268). Study design: Diary and Endometriosis Impact Scale (EIS). Study period: 28 days (range 21-29). Other relevant PRO and Clinician-Reported Outcome (ClinRO) measures were also completed at various intervals to support the evaluation (Table 1).

Overview of scoring algorithms

1. Pain: Pain is assessed on a daily basis using a score of 0-10 NRS and can be used to derive the following scores: Mean score of pain (mean 0-10); Mean of worst pain (mean 0-10); Mean of pain on bleeding days (bleeding days only); Mean of pain on bleeding days (28-days only); Percentage of days with worst pain ≥4; Percentage of days with worst pain ≥7; Percentage of days with bleeding and pain ≥4; Percentage of days with bleeding and pain ≥7.

2. Dysmenorrhea: Menstrual bleeding is rated using a 0-10 NRS (where 0 = no bleeding and 10 = maximum bleeding). Pain associated with bleeding is assessed using a 0-10 NRS, with a minimum score of 5 to identify pain severity.

3. Dyspareunia: Pain associated with sexual intercourse is assessed using a 0-10 NRS, with a minimum score of 5 to identify pain severity.

4. Emotional well-being: Emotional well-being is assessed using the Biberoglu and Behrman Scale (modified B&B).

5. Cost of healthcare: Costs related to the management of endometriosis are assessed using the Oxford University Health Economic Evaluation Data Set.

6. Labour Force Participation: The impact of endometriosis on work productivity is assessed using the Oxford University Health Economic Evaluation Data Set.

Results

The ESD provides daily assessment of the three core symptoms of endometriosis (pelvic pain, dysmenorrhoea and dyspareunia related to menstrual cycle). A prospective, observational validation study was conducted in the US and Germany (n=268). Findings were consistent regardless of the concurrent measure (PGI-S, NRS, VAS or CGI-C) used to categorize patients as 'improved' or 'no change/not improved'.

Convergent validity

- ESD and EIS scores were strongly correlated with self-rated assessment of endometriosis-associated pain at its worst in the last 24 hours (using a 0-10 NRS where 0 = no pain and 10 = pain unbearable). Findings were consistent regardless of the concurrent measure (PGI-S, NRS, VAS or CGI-C) used to categorize patients as ‘improved’ or ‘no change/not improved'.

Responsiveness

- Participants categorized as ‘improved’ according to patient-reported (PGI-S, NRS, VAS) and Clinician-Reported (CGI-C) measures of disease severity all demonstrated a reduction (i.e. negative mean change) in ESD and EIS scores.

- For all ESD and EIS scores (with the exception of dysmenorrhoea score) the magnitude of change observed in participants categorized as ‘improved’ was significantly greater (p<.05) than those categorized as ‘no change/not improved’.

- Findings were consistent regardless of the concurrent measure (PGI-S, NRS, VAS or CGI-C) used to categorize patients as ‘improved’ or ‘no change/not improved’.

Limitations And Perspective

- The study presented was observational and non-interventional in nature. Future work will need to determine the clinical validity of endometriosis impact scales and the role of self-reported symptoms, disability and healthcare utilization in the management of endometriosis.

Conclusions

- There is strong evidence for the reliability and validity of scores derived from the ESD and EIS.

- Future research will need to further explore responsiveness and the evaluation of meaningful change in ESD and EIS scores using data from clinical trials.

References

- Data from the ESD study was used to assess the reliability, validity and responsiveness of ESD and EIS scores (Table 5).

Declarations

- This study was funded by Bayer Healthcare AG.