Clinical and Economic Burden of Women With Endometriosis (EM)

RWD105

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Background

- Endometriosis (EM) is a chronic systemic condition characterized by the presence of endometrial tissue outside the uterine cavity[1-3]
- EM affects approximately 10% of women of reproductive age,[2,3] with age of onset in the early 20s[4]
- Approximately 75%–80% of diagnosed women experience EM-related symptoms,[5] most frequently chronic pain[6]
  - EM-associated chronic pain includes back pain, menstrual and nonmenstrual pelvic pain, dysmenorrhea, dyspareunia, and dyschezia[6]
- Surgeries for the management of EM, such as laparoscopy, ablation, and hysterectomy, are frequently performed but not always curative[7]
- 2 gonadotropin-releasing hormone (GnRH) antagonists (elagolix and relugolix/estradiol/norethindrone acetate) were recently approved by the US Food and Drug Administration (FDA) for the treatment of moderate to severe EM-associated pain
- With the approval of GnRH antagonists, it is important to review the clinical and economic burden among women with EM

Objective

- To provide recent insight into the clinical burden and healthcare resource utilization (HCRU), including costs, of women with EM

Methods

Study Design and Patient Identification

- This cross-sectional retrospective analysis used claims data from the Merative™ MarketScan® Research Database—a large, US-based administrative claims database—for claims occurring during the 2021 calendar year
  - The database provides representative, patient-level deidentified claims data with records for >273 million individuals
- The analysis compared women with an EM diagnosis to a control cohort of women of similar age with no EM diagnosis
- Women in both cohorts were 18–55 years old who self-selected gender as female and had continuous medical and pharmacy coverage during 2021
- Women in the EM cohort had ≥1 diagnosis code for EM during 2021 and ≥2 diagnosis codes between January 1, 2016, and December 31, 2021 (data availability period)
- Women in the control cohort had no diagnosis code for EM during the data availability period and did not have evidence of likely EM based on prescriptions for hormonal treatments and EM-related pain; women were removed at random to match the age distribution of the EM cohort
- Women were excluded if they had evidence of any type of cancer or a diagnosis for uterine fibroids during the study period

Assessments and Statistical Analysis

- Demographics were assessed at the beginning of 2021, and baseline clinical characteristics are representative of any diagnoses from January 1, 2021, to December 31, 2021
- EM-related signs and symptoms of interest were identified via diagnosis codes
- HCRU and costs were calculated on a per-patient basis averaged across the cohort for calendar year 2021
- Statistical significance was assessed using chi-squared tests (categorical measures) or Wilcoxon rank-sum test (continuous measures), without imputation or adjustment

Results

Patient Selection and Characteristics

- A total of 15,228 women with EM were included in the EM cohort, and 37,596 women without EM diagnoses were included in the control cohort
- Mean age in both cohorts was 36.2 years, and 40% of women were 30–39 years of age (**Table**)

EM-Associated Symptoms

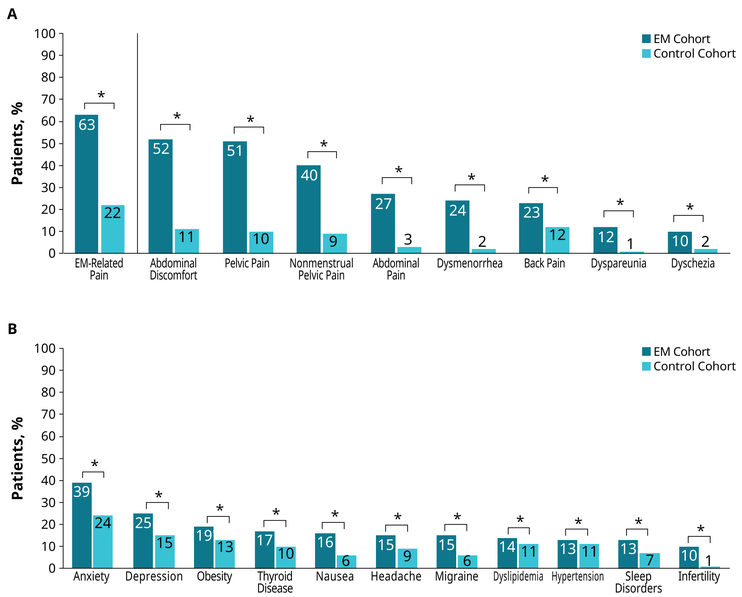
- Women with EM were significantly more likely than those in the control cohort to be diagnosed with:
  - EM-related pain and associated pain symptoms, including abdominal pain or discomfort, back pain, menstrual and nonmenstrual pelvic pain, dyschezia, dysmenorrhea, and dyspareunia (all *P*<0.01) (**Figure 1A**)
  - Infertility, anxiety, and depression (all *P*<0.01) (**Figure 1B**)

Table. Patient Demographics and Clinical Characteristics

Characteristic	EM Cohort (N=15,228)	Control Cohort (N=37,596)
Mean (SD) age, y	36.2 (8.6)	36.2 (9.1)
Age category, y, n (%)		
18–29	3518 (23)	8686 (23)
30–39	6119 (40)	15,107 (40)
40–49	4636 (30)	11,445 (30)
≥50	955 (6)	2358 (6)
Insurance type, n (%)		
PPO	7759 (51)	17,886 (48)
HMO	2044 (13)	5544 (15)
HDHP	1764 (12)	4745 (13)
CDHP	1674 (11)	4123 (11)
POS	1488 (10)	4073 (11)
Comprehensive	303 (2)	691 (2)
EPO	110 (1)	304 (1)

CDHP, consumer-directed health plan; EM, endometriosis; EPO, exclusive provider organization; HDHP, high-deductible health plan; HMO, health maintenance organization; POS, point of service; PPO, preferred provider organization.

Figure 1. (A) EM-Related Pain† and Pain Symptoms and (B) EM-Associated Symptoms and Comorbidities of Interest Occurring in ≥10% of Women in Either Cohort

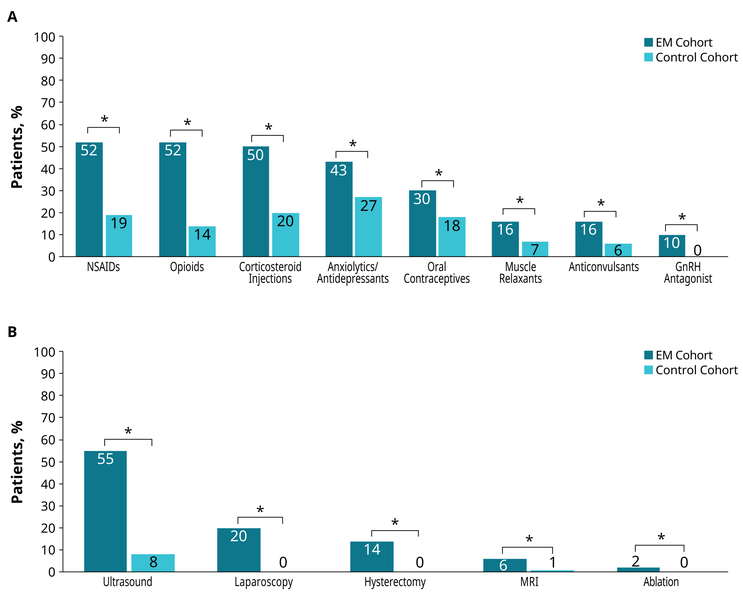


EM, endometriosis.
*P<0.01.
†EM-related pain includes all of the pain symptoms noted on the right-hand side of the graph.

HCRU in Women With vs Without EM

- Women with EM were significantly more likely than those in the control cohort to:
  - Be treated with nonopioid pain medications, opioids, oral contraceptives, and GnRH antagonists (**Figure 2A**)
  - Undergo ultrasound, laparoscopy, hysterectomy, magnetic resonance imaging, and ablation (**Figure 2B**)

Figure 2. (A) Treatments‡ and (B) Procedures of Interest Among Women With vs Without EM

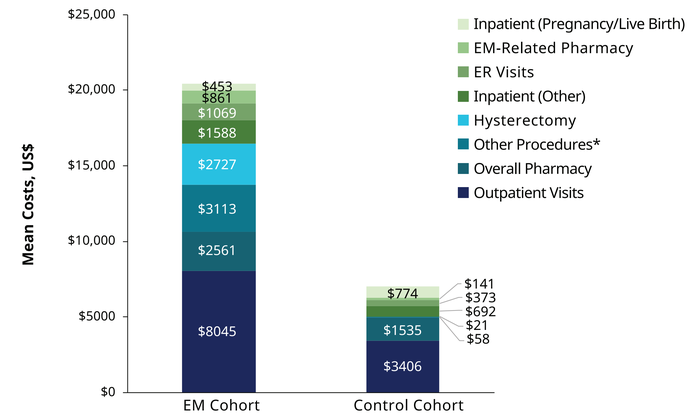


EM, endometriosis; GnRH, gonadotropin-releasing hormone; MRI, magnetic resonance imaging; NSAID, nonsteroidal anti-inflammatory drug.
*P<0.01.
‡Occurring in ≥10% of women in either cohort.

Healthcare Costs in Women With vs Without EM

- Women with EM experienced approximately 3 times greater healthcare costs than women in the control cohort ($20,381 vs $7000; **Figure 3**)
  - Outpatient procedures and total pharmacy costs were the 2 largest cost expenditures
  - Inpatient costs related to pregnancy and live birth were lower among women with EM than controls, consistent with increased infertility in women with EM

Figure 3. EM-Associated Per-Patient Healthcare Costs in 2021



EM, endometriosis; ER, emergency room.
*Other procedures included ablation and laparoscopy.

Limitations

- This study was retrospective and descriptive, which limits conclusions regarding causality and outcomes in women beyond the age and time constraints
- Claims data may be subject to coding errors
- National Drug Code claims are not associated with a diagnosis, and pharmacotherapy or procedures may have been given for reasons other than EM

Conclusions

- In this 2021 cross-sectional analysis, women with EM were more likely than the age-matched control group to be diagnosed with burdensome symptoms including pain, dyspareunia, and infertility
- EM symptoms were associated with greater HCRU and higher overall costs, which were primarily driven by outpatient procedures and pharmacy costs
- Women with EM commonly underwent surgical procedures, whereas FDA-approved medications for EM-associated pain were less commonly used
- New pharmacologic therapies for EM-associated pain may reduce clinical burden and associated HCRU for many women with EM

References

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Disclosures

Gregory Christman has nothing to disclose. **Michele Cole** and **Cassandra Lickert** are employees of Sumitomo Pharma America, Inc. **Kaitlyn Austin** and **Caroline Schuler** are employees of Charles River Associates. **Simon DePaauw-Holt** is an employee of Sumitomo Pharma Switzerland, GmbH.