

EE324

Describing the Clinical and Economic Burden of Women Diagnosed With Uterine Fibroid (UF) and Heavy Menstrual Bleeding (HMB) in a United States (US) Commercial Database 2015–2022

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Background

- Uterine fibroids (UF) are common, benign uterine tumors that affect approximately 70% of women of reproductive age¹
- UF symptoms include pain, bulk symptoms such as pelvic pressure and increased urination, fertility issues, and heavy menstrual bleeding (HMB); HMB is the most common symptom of UF²
- Treatment for UF is typically individualized and includes watchful waiting, pharmacotherapy, and surgical procedures depending on symptom burden, desire for maintenance of fertility, patient age, and tumor size and location²
- Pharmacologic treatment options include hormonal contraceptives, nonsteroidal anti-inflammatory drugs, tranexamic acid, selective progesterone receptor modulators, and gonadotropin-releasing hormone (GnRH) agonists³; GnRH antagonists have been approved more recently for HMB associated with UF based on clinical studies in which HMB was reduced^{3,4}
- The overall cost of care and the additional incremental burden of HMB in UF remain unclear

Objective

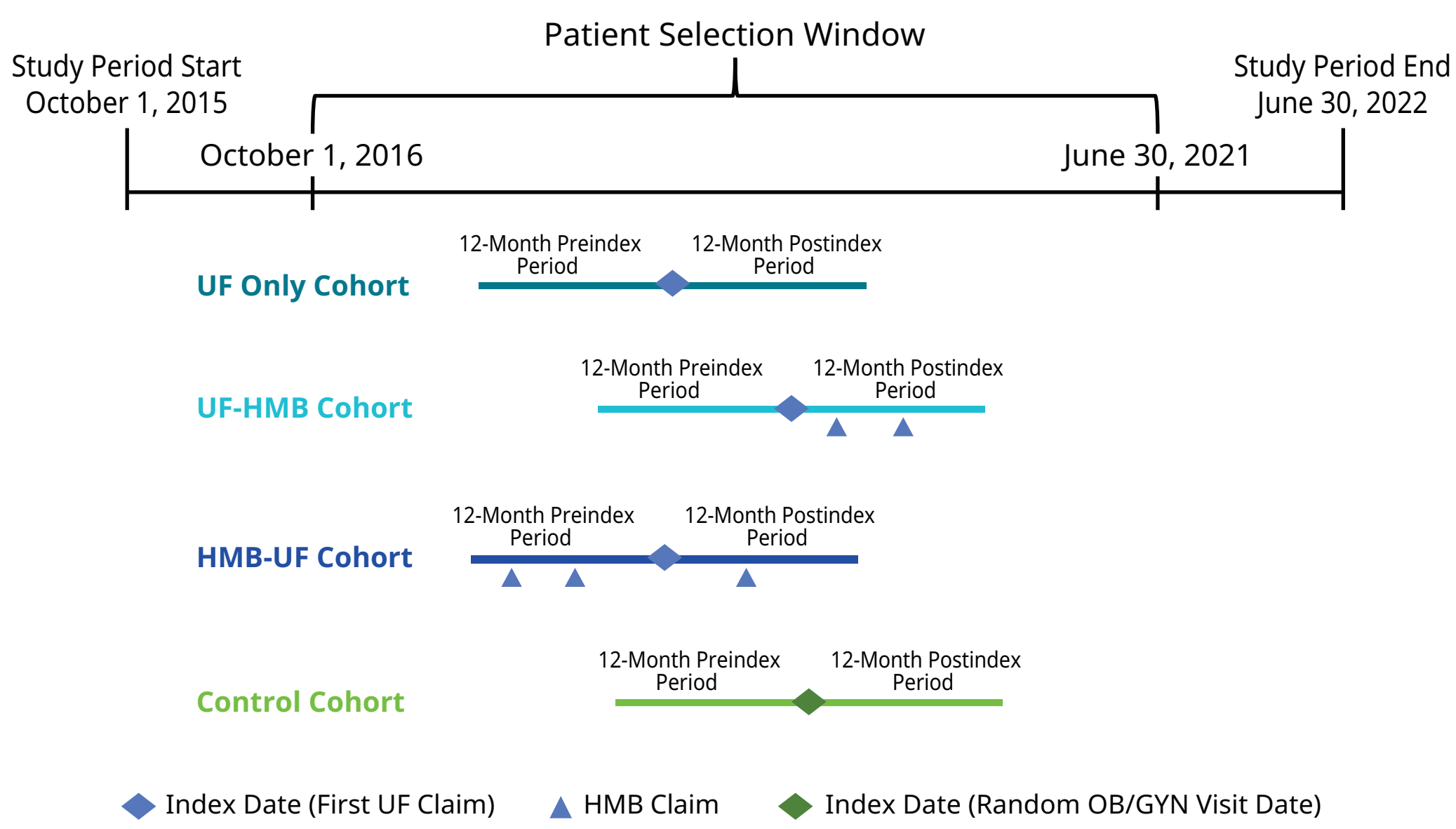
- To describe the current clinical and economic burden of women diagnosed with UF with or without HMB and to determine the incremental burden of care compared with women without UF or HMB

Methods

Study Design and Patient Identification

- This retrospective observational study used claims data from the Merative™ MarketScan® Commercial Database (October 1, 2015, to June 30, 2022) linked at the geographic level with the Robert Wood Johnson Foundation County Rankings database for social determinants of health, including race
- Included women were 18–55 years old with ≥1 inpatient claim for UF or ≥2 nondiagnostic outpatient claims for UF occurring ≥30 days apart
- Women with UF were categorized into cohorts based on the presence and order of HMB claims: UF only, UF then HMB (UF-HMB), and HMB then UF (HMB-UF)
 - UF cohorts were matched 1:1:1 on age and race
- A control (non-UF/non-HMB) cohort was identified, which included women with no evidence of claims for UF or HMB during the study period
 - The control cohort was matched 5:1 to the 3 UF cohorts based on age and race
- For the UF cohorts, the index date was defined as the first UF claim; for the control cohort, the index date was a random obstetrician/gynecology visit that occurred over the same period as the UF cohort dates (**Figure 1**)
- All women had continuous eligibility with medical and pharmacy benefits for 12 months pre- and postindex

Figure 1. Study Period



HMB, heavy menstrual bleeding; OB/GYN, obstetrics and gynecology; UF, uterine fibroids.

Assessments and Statistical Analysis

- Demographic characteristics were assessed at index
- Clinical characteristics, treatment characteristics (UF cohorts only), HCRU, and cost outcomes were assessed during the 12-month pre- and postindex periods
 - Treatment characteristics included pharmacy and procedure claims
 - HCRU included measures of inpatient visits, ER visits, outpatient office visits, other outpatient services, and outpatient pharmacy claims
 - Cost outcomes were based on the paid amounts of adjudicated claims and included costs related to HCRU outcomes
- Chi-square or Fisher's exact test (categorical variables) and t-tests (continuous variables) were used to compare differences in outcomes between UF and control cohorts

Results

Patient Selection and Characteristics

- The study included 22,057 women in each UF cohort and 110,285 women in the control cohort with an overall mean (SD) age of 43.5 (5.9) years (**Table 1**)
- Cohort baseline demographics were well balanced with respect to age, geographic Black race, median household income, education level, and ratio of primary care physicians to residents
 - Slight imbalances remained with respect to geographic non-Black race, region of residence, and health plan type in the UF cohorts compared with the control cohort
- All cohorts had mean Charlson comorbidity index (CCI) scores of either 0.2 or 0.3 at baseline
 - The most common preindex CCI component comorbidities were chronic pulmonary disease and diabetes

Table 1. Patient Demographics and Baseline Clinical Characteristics

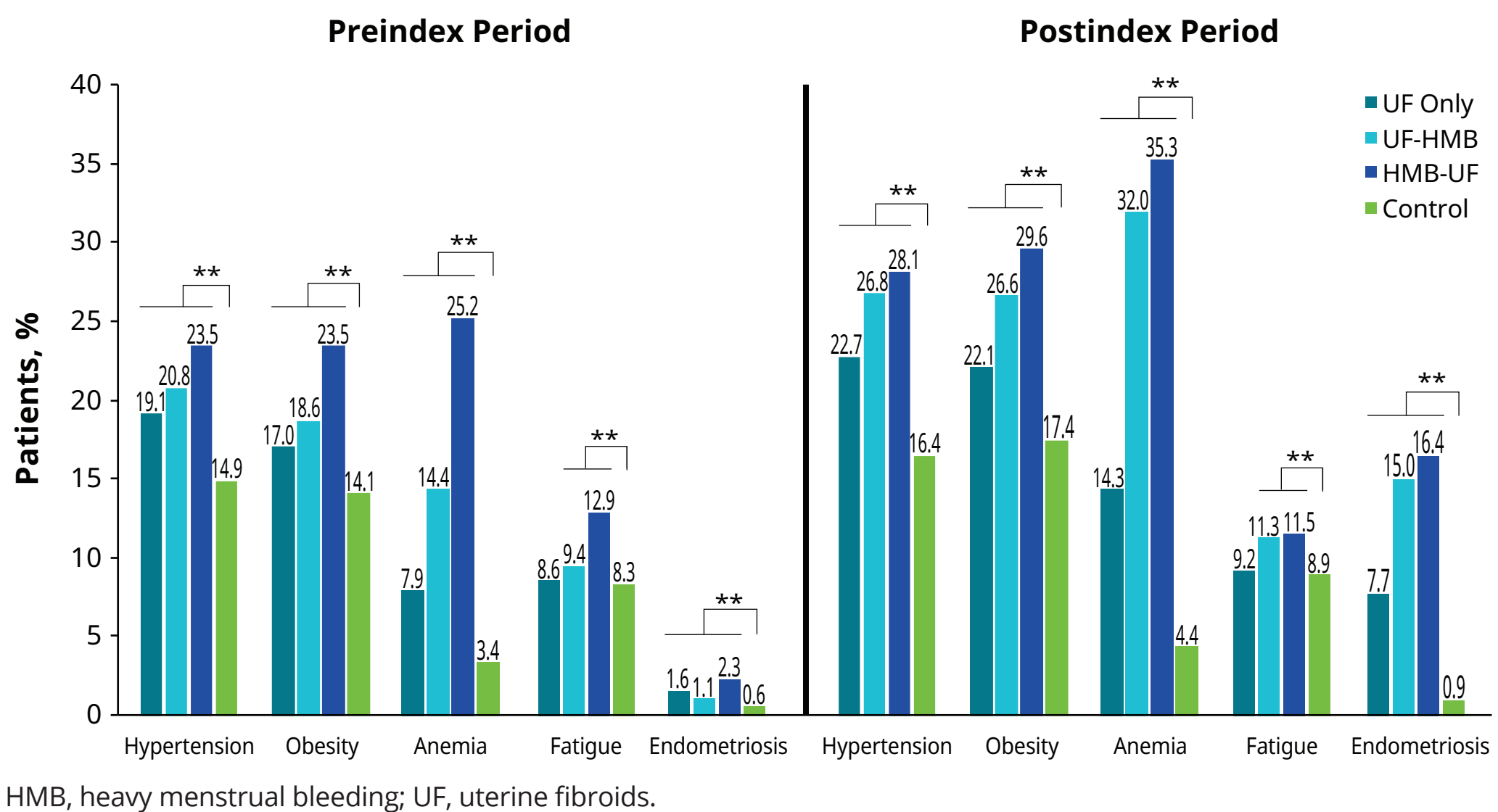
Characteristic	UF Only Cohort (N=22,057)	UF-HMB Cohort (N=22,057)	HMB-UF Cohort (N=22,057)	Control Cohort (N=110,285)
Mean (SD) age, y	43.5 (5.9)	43.5 (5.9)	43.5 (5.9)	43.5 (5.9)
Age category, y, n (%)				
18–25	69 (0.3)	69 (0.3)	69 (0.3)	345 (0.3)
26–35	2182 (9.9)	2182 (9.9)	2182 (9.9)	10,910 (9.9)
36–45	10,651 (48.3)	10,651 (48.3)	10,651 (48.3)	53,255 (48.3)
46–55	9155 (41.5)	9155 (41.5)	9155 (41.5)	45,775 (41.5)
Region, n (%)				
South	11,995 (54.4)	12,766 (57.9)	12,520 (56.8)	63,143 (57.3)
North Central	3589 (16.3)	3445 (15.6)	3991 (18.1)	20,794 (18.9)
Northeast	2696 (12.2)	2392 (10.8)	1964 (8.9)	13,294 (12.1)
West	3777 (17.1)	3454 (15.7)	3585 (16.2)	13,054 (11.8)
Insurance type, n (%)				
EPO/PPO	10,096 (45.8)	10,352 (46.9)	10,333 (46.9)	53,745 (48.7)
CDHP/HDHP	5795 (26.3)	5314 (24.1)	5408 (24.5)	28,628 (26.0)
HMO	4065 (18.4)	3783 (17.2)	3952 (17.9)	15,554 (14.4)
POS	1214 (5.5)	1690 (7.7)	1442 (6.5)	8297 (7.5)
Comprehensive/indemnity	568 (2.6)	485 (2.2)	516 (2.3)	2125 (1.9)
Other/unknown	319 (1.5)	433 (2.0)	406 (1.8)	1936 (1.8)
Mean (SD) percentage of race per county residence				
White	54.7 (20.9)	55.4 (20.8)	56.2 (20.6)	58.4 (20.3)
Black	18.3 (14.9)	18.3 (14.9)	18.3 (14.9)	18.3 (14.9)
Hispanic	17.9 (16.4)	17.7 (16.3)	17.1 (16.0)	15.3 (14.6)
Asian	6.7 (7.1)	6.1 (6.6)	5.8 (6.2)	5.5 (5.9)
Native Hawaiian/Pacific Islander	0.2 (0.2)	0.2 (0.2)	0.2 (0.2)	0.2 (0.2)
American Indian/Alaska Native	0.9 (1.2)	0.9 (1.3)	0.9 (1.2)	0.8 (1.4)
Median household income, 2022 USD	69,545	68,964	66,791	67,054
Mean (SD) preindex CCI score	0.2 (0.7)	0.2 (0.7)	0.3 (0.7)	0.2 (0.6)
Preindex CCI conditions occurring in ≥2% of women in any cohort, n (%)				
Chronic pulmonary disease	1770 (8.0)	1904 (8.6)	2066 (9.4)	8170 (7.4)
Diabetes (mild or moderate)	1178 (5.3)	1257 (5.7)	1313 (6.0)	5278 (4.8)
Rheumatic disease	369 (1.7)	400 (1.8)	434 (2.0)	2132 (1.9)

CCI, Charlson comorbidity index; CDHP, consumer-directed health plan; EPO, exclusive provider organization; HDHP, high-deductible health plan; HMB, heavy menstrual bleeding; HMO, health maintenance organization; POS, point of service; PPO, preferred provider organization; UF, uterine fibroid; USD, US dollar.

Clinical Characteristics of Women With vs Without UF

- A significantly greater percentage of women in the UF cohorts had hypertension ($P<0.001$) or obesity ($P<0.001$) in both the pre- and postindex periods compared with the control cohort (**Figure 2**)
- Rates of endometriosis were significantly higher ($P<0.001$) in the 3 UF cohorts compared with the control cohort, and rates of endometriosis increased from the pre- to postindex period among the UF cohorts

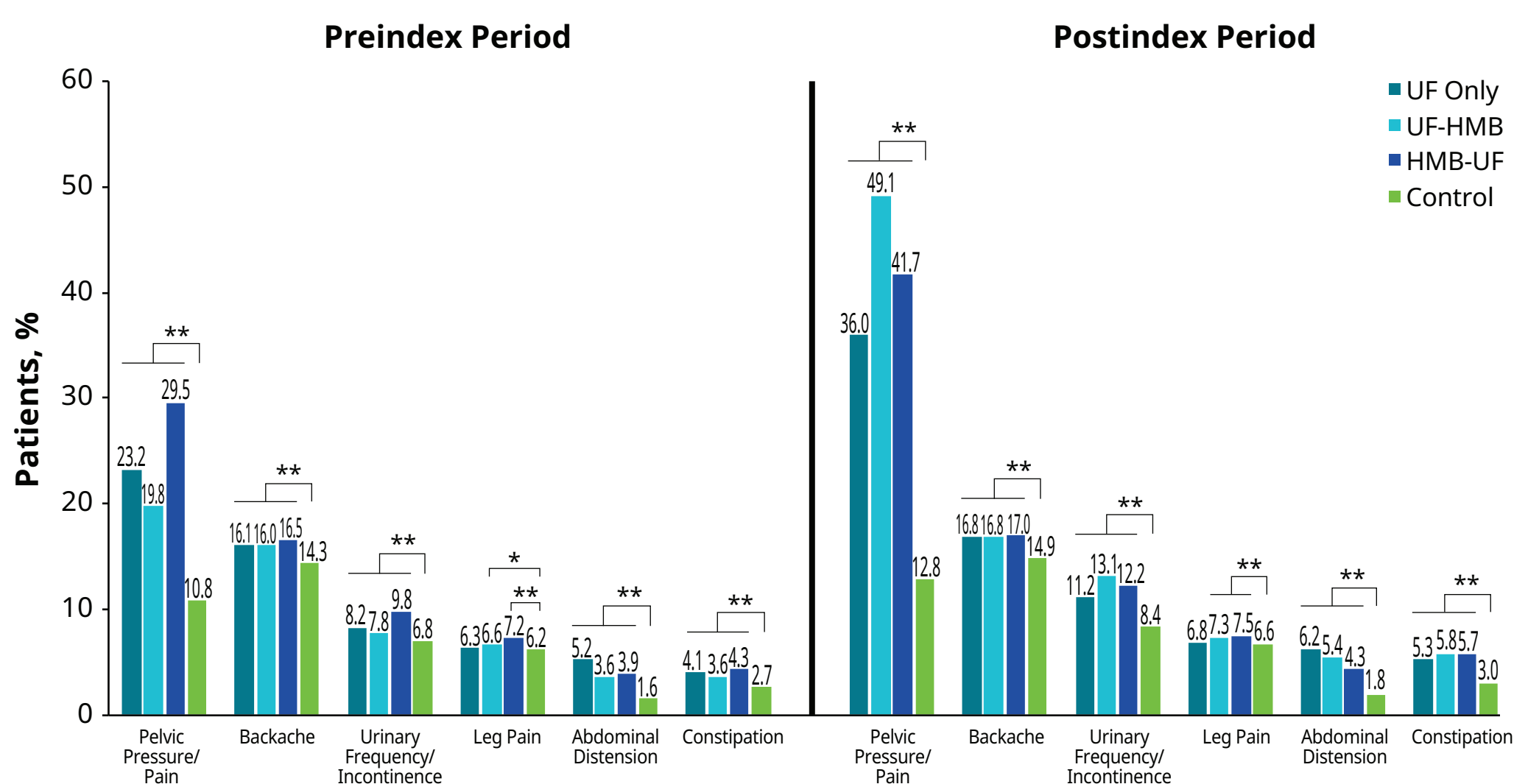
Figure 2. Comorbidities of Interest in the UF vs Control Cohorts



HMB, heavy menstrual bleeding; UF, uterine fibroids.
** $P<0.001$.

- Before UF diagnosis, 40.6%–49.7% of women in the UF cohorts had >1 bulk symptom compared with 31.3% in the control cohort; after UF diagnosis, bulk symptoms increased to 54.4%–64.1% in the UF cohorts compared with 34.7% in the control cohort
- The most common bulk symptoms after UF diagnosis were pelvic pressure/pain, backache, and urinary frequency/incontinence (**Figure 3**)
 - The HMB cohorts generally had the highest clinical burden post-UF diagnosis compared with the UF only and control cohorts

Figure 3. Rates of UF-Associated Bulk Symptoms in UF vs Control Cohorts

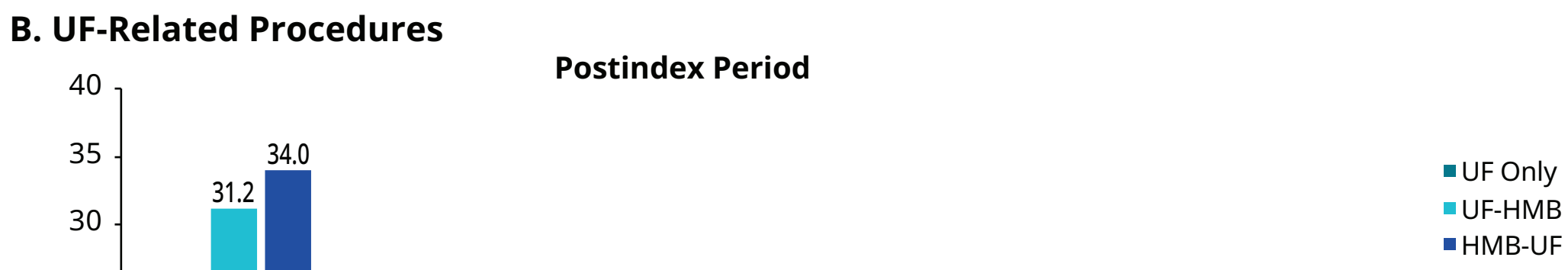
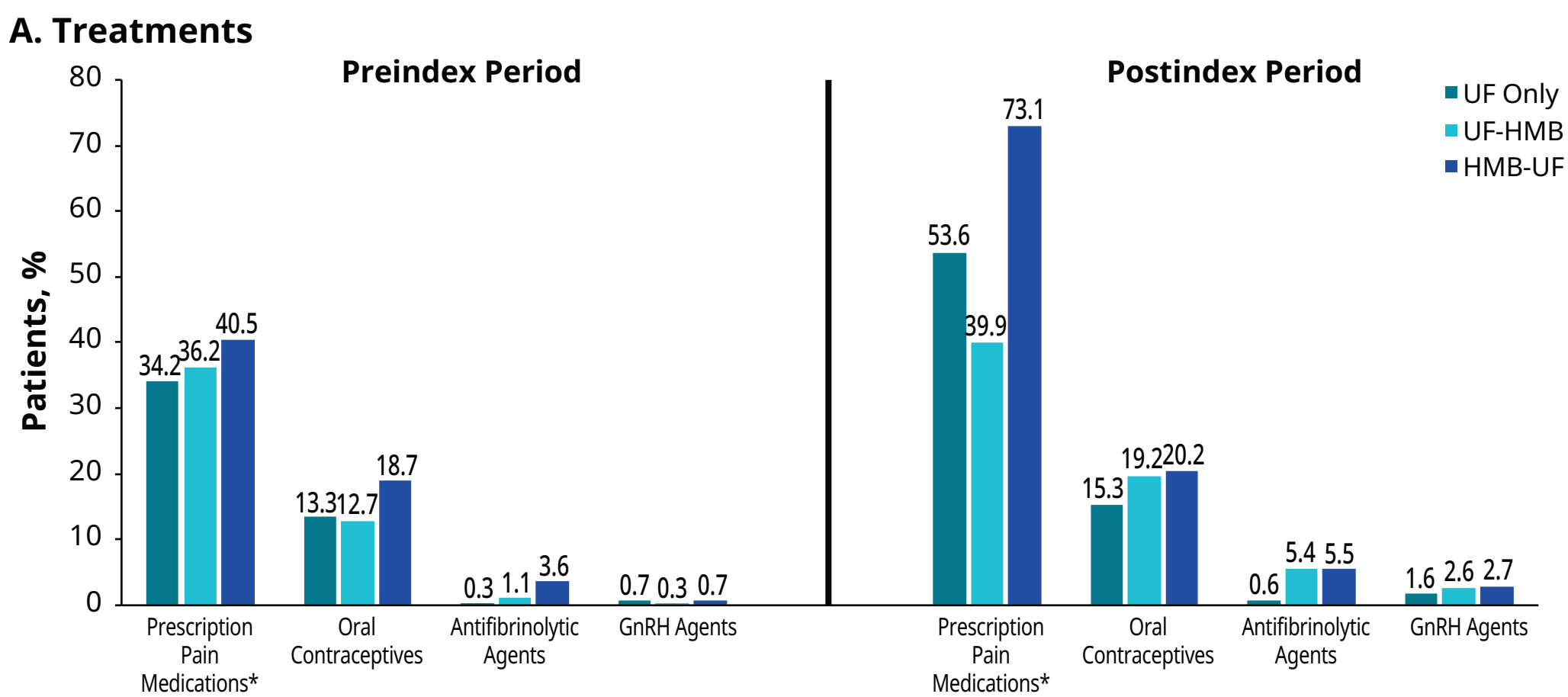


HMB, heavy menstrual bleeding; UF, uterine fibroids.
* $P<0.05$; ** $P<0.001$.

Treatment Patterns and HCRU in Women With vs Without UF

- Overall, 18%–38% of women received no pharmacologic therapy of interest; <30% received hormonal therapy, with oral contraceptives (13%–20%) being the most common
- Before UF diagnosis, prescription pain medications were the most common UF-related pharmacologic treatments; after UF diagnosis, a greater proportion of women received any type of UF-related pharmacologic treatment (**Figure 4A**)
- Overall, <57% had a surgical/gynecologic procedure, with hysterectomy (11%–34%) being the most common (**Figure 4B**)
- A greater percentage of women in the UF-HMB and HMB-UF cohorts had a UF-related procedure postindex compared with the UF only cohort (49.1% and 56.1% vs 17.0%)

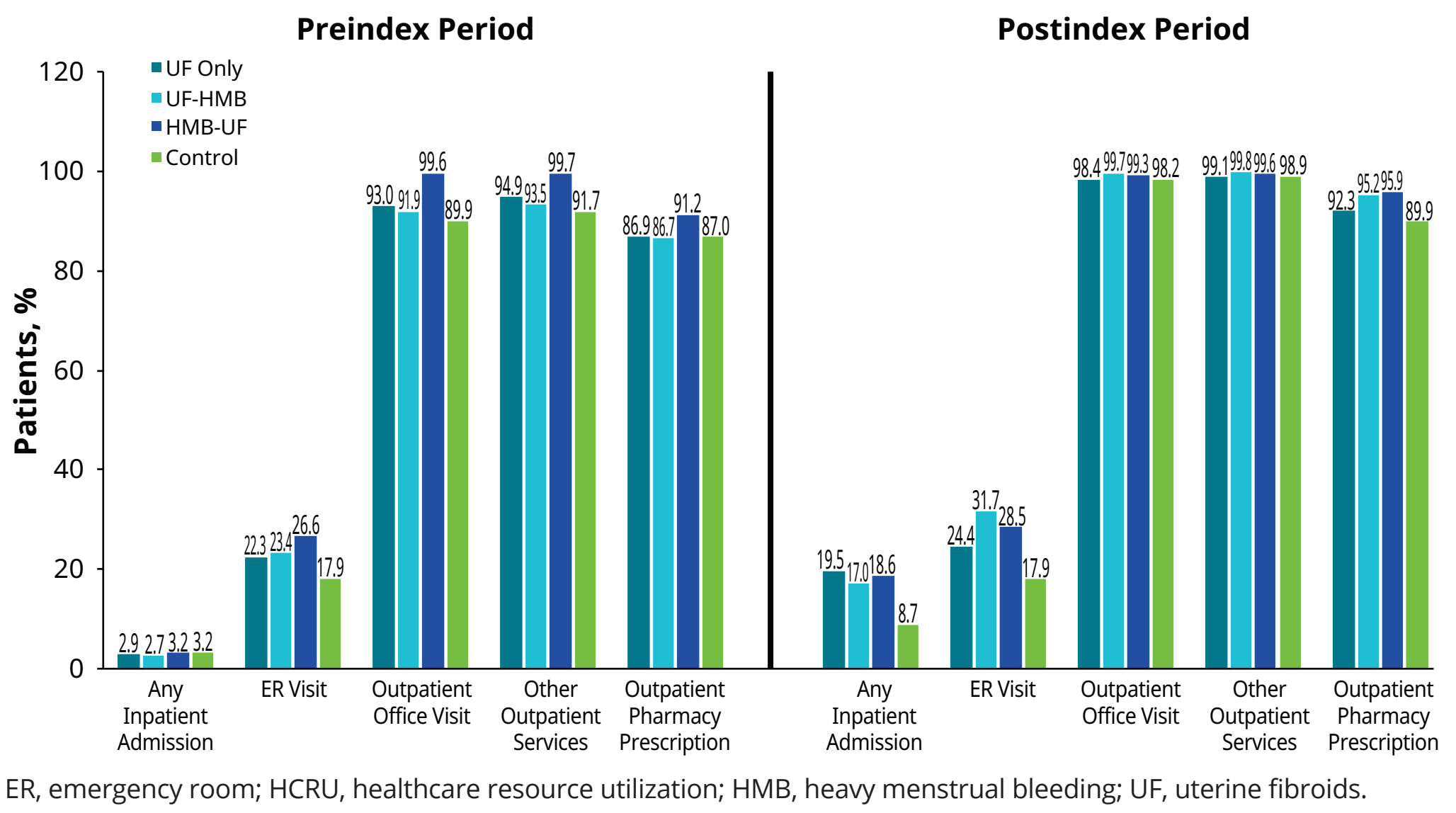
Figure 4. (A) Pre- and Postindex Treatments and (B) Postindex UF-Related Procedures Among Women With UF



GnRH, gonadotropin-releasing hormone; HMB, heavy menstrual bleeding; UF, uterine fibroids.
*Includes nonsteroidal anti-inflammatory drugs, opioids, and cox-2 inhibitors.

- The 3 UF cohorts generally had increased HCRU compared with the control cohort; the greatest differences between the UF and control cohorts were in emergency room visits and postindex inpatient admissions (**Figure 5**)

Figure 5. Rates of HCRU Claims Among Women With vs Without UF

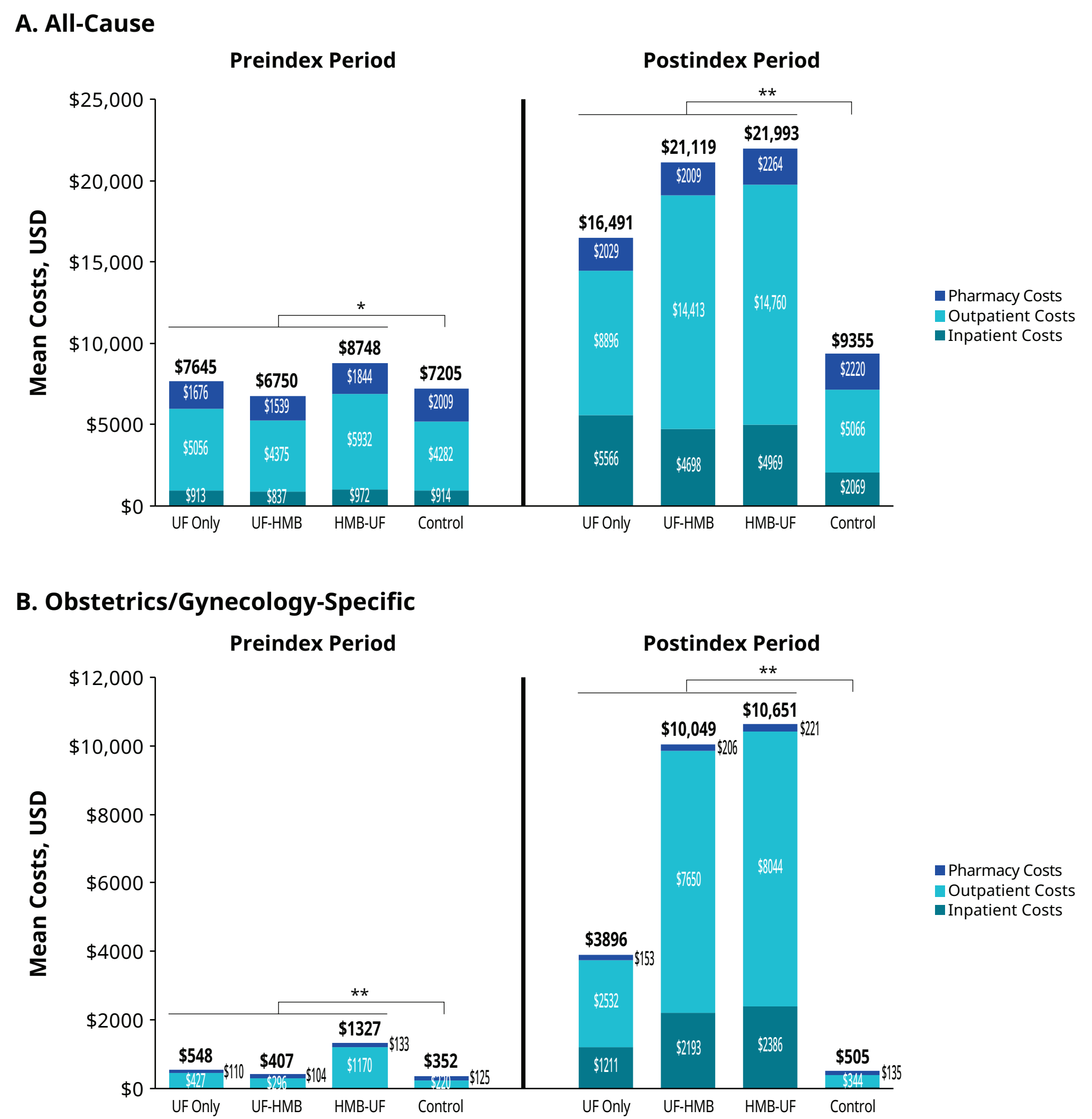


ER, emergency room; HCRU, healthcare resource utilization; HMB, heavy menstrual bleeding; UF, uterine fibroids.

Healthcare Costs in Women With vs Without UF

- All-cause and obstetrics/gynecology-related total costs increased >2 fold from the pre- to postindex periods for all UF cohorts (**Figure 6**)
- Women in the UF cohorts had significantly higher all-cause and obstetrics/gynecology-related postindex total costs compared with women in the control cohort; the 2 cohorts with both UF and HMB had the highest costs of care during the postindex period
- Outpatient costs accounted for >50% of total costs pre- and postindex for all cohorts

Figure 6. (A) All-Cause and (B) Obstetrics/Gynecology-Specific Per-Patient Healthcare Costs



HMB, heavy menstrual bleeding; UF, uterine fibroids.
Bold numbers above each bar indicate total costs (ie, inpatient + outpatient + pharmacy).
* $P<0.01$; ** $P<0.001$.

Limitations

- This analysis was retrospective and descriptive, which limits conclusions regarding causality and outcomes in women beyond the age and time constraints
- This study was limited to women with commercial health coverage; therefore, results may not be generalizable to those with other insurance or without healthcare coverage
- Claims data may be subject to coding errors due to billing processes being the primary source of collection
- Potential misclassification of UF and HMB is possible because women were identified through administrative claims as opposed to medical records

Conclusions

- Results of this study show that UF, with or without HMB, is associated with a notable clinical and economic burden and emphasize the importance of recognizing signs and symptoms that may lead to the diagnosis of UF
- HMB generally exacerbates the incremental burden over UF alone
- Diagnosis of UF and HMB is associated with shifts in management practices, leading to increased cost of care
- Results from this study shed light on differential pathways to UF and HMB diagnosis, highlighting the importance of ongoing patient and provider education and discussions around shared decision-making

References

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Disclosures

Laura McKain is an employee of McKain Consulting LLC. Brenna L. Brady and Anh Thu Tran are employees of Merative. Cassandra Lickert is an employee of Sumitomo Pharma America, Inc.

