Comparison of Health Care Costs for Women With Treated vs Untreated Vasomotor Symptoms Due to Menopause

RWD61

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INTRODUCTION

- Women undergo physiologic and psychosocial changes that are associated with hot flashes, night sweats, and other symptoms during menopause[1]
- During menopause, up to 80% of US women experience vasomotor symptoms (VMS) due to menopause and may receive on-label or off-label treatment; however, VMS is frequently left untreated by most women, while others use alternative treatments, such as herbal supplements and nonprescription medications[2,3]
- Although several studies report higher health care resource use and costs among women with untreated VMS due to menopause, costs for on-label and off-label treatment have not been previously quantified[1,4]

OBJECTIVES

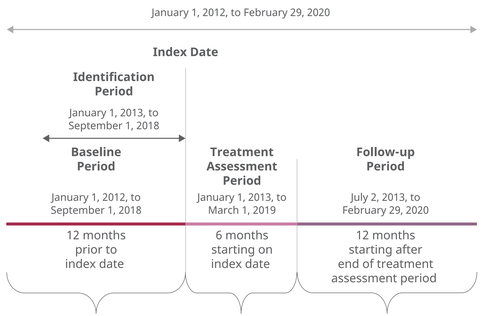
- To estimate and compare health care costs for treated vs untreated women with VMS and for subgroups receiving on-label and off-label treatments

METHODS

Study Design and Data Source

- The Optum Research and integrated claims-clinical databases were used in this retrospective analysis of US administrative claims data (medical and pharmacy) from commercial enrollees and Medicare Advantage with Part D beneficiaries who were diagnosed with VMS during the study period from January 1, 2012, through February 29, 2020 (**Figure 1**)

Figure 1. Study Design



Study Population

- Patients were included if they had ≥1 VMS diagnosis claim in any position for (1) natural or surgical menopause/female climacteric states (ICD-9-CM 627.2, 627.4/ICD-10-CM N95.1, E89.41) OR (2) flushing (ICD-9-CM 782.62/ICD-10-CM R23.2) or hyperhidrosis (ICD-9-CM 780.08/ICD-10-CM R61) AND ≥1 claim with diagnosis code for natural menopause or procedure/diagnosis code for surgical menopause on the same date or in the prior 12 months during the identification period from January 1, 2013, through September 1, 2018
- Treated patients received systemic hormone therapy or paroxetine 7.5 mg (on-label) or off-label treatments, including selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, gabapentin, pregabalin, clonidine, oxybutynin, or compounded estradiol pellet
  - Other inclusion criteria were as follows:
    - Females
    - Aged 40–63 years in the year of the index date
    - Had ≥12 months (365 days) of continuous enrollment with medical and pharmacy benefits prior to the index date and ≥18 months (547 days) starting on the index date

Outcomes

- Main outcomes included total cost of care (TCC; including and excluding costs of VMS treatment) and all-cause health care resource utilization (HCRU)
- Individual components of TCC comprising pharmacy costs, other medical costs, inpatient stays, emergency department visits, outpatient visits, office visits, ambulatory costs, and medical costs were also reported

Statistical Analysis

- Distributions of baseline patient and clinical characteristics across cohorts of interest were evaluated using standardized differences (SDIFF)
- A 1:1 ratio propensity score (PS) matching of treated and untreated patients was used to control for potential confounding of the association between outcomes and treatment pattern characteristics; following the matching procedure, descriptive analyses and generalized linear model analyses were performed
  - Covariates included in PS matching were baseline patient demographics, comorbidities, Quan-Charlson Comorbidity Index score, HCRU, and health care costs

RESULTS

- Of 117,582 eligible women in the pre-PS matched group, 12.8% (n=15,077) received on-label VMS treatment, 7.6% (n=8992) received off-label VMS treatment, and 79.5% (n=93,513) were untreated; among 48,114 women in the post-PS matched group, 31.3% (n=15,069) received on-label VMS treatment, 18.7% (n=8988) received off-label VMS treatment, and 50.0% (n=24,057) remained untreated (**Table 1**)

Table 1. Study Population Pre- and Post-PS Matching

Study Population	Pre-PS Matching, n	Post-PS Matching, n
Treated cohort	24,069	24,057
On-label treatment subgroup	15,077	15,069
Off-label treatment subgroup	8992	8988
Untreated cohort	93,513	24,057
Overall	117,582	48,114

PS, propensity score.

- The PS-matched sample was balanced on all measured baseline characteristics (SDIFF <10%). Of 48,114 PS-matched treated and untreated patients, the mean (SD) age was 51.6 (4.8) years. Over 40% of patients in the post-PS matched sample were aged 50–54 years (n=19,557), followed by 26% (n=12,368) aged 45–49 years and 20% (n=9605) aged 55–59 years (**Table 2**)

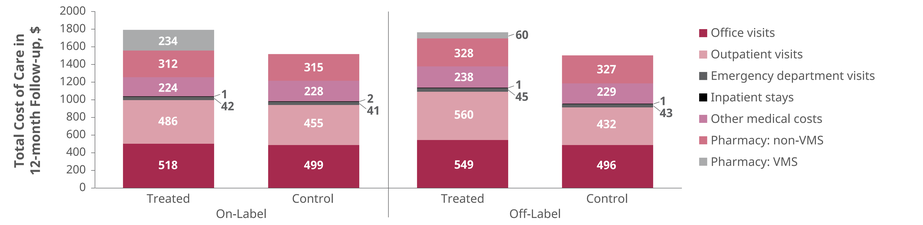
Table 2. Demographic Characteristics Post-PS Matching

Demographics			Post-PS Matching Treated (n=24,057)	Post-PS Matching Untreated (n=24,057)	Post-PS Matching Treated vs Untreated SDIFF, %
Age Group, years	40–44	n	1915	1725	2.99
		%	7.96	7.17	
	45–49	n	5961	6407	–4.24
		%	24.78	26.63	
	50–54	n	9923	9634	2.45
		%	41.25	40.05	
	55–59	n	4772	4833	–0.63
		%	19.84	20.09	
	60–63	n	1486	1458	0.49
		%	6.18	6.06	
Region	Northeast	n	1298	1229	1.29
		%	5.40	5.11	
	Midwest	n	6131	6092	0.37
		%	25.49	25.32	
	South	n	11,674	11,856	–1.51
		%	48.53	49.28	
	West	n	4940	4868	0.74
		%	20.53	20.24	
	Other	n	14	12	0.36
		%	0.06	0.05	
Index Year	2013	n	5671	5673	–0.02
		%	23.57	23.58	
	2014	n	4784	4800	–0.17
		%	19.89	19.95	
	2015	n	3966	3961	0.06
		%	16.49	16.47	
	2016	n	3626	3648	–0.26
		%	15.07	15.16	
	2017	n	3445	3421	0.29
		%	14.32	14.22	
	2018	n	2565	2554	0.15
		%	10.66	10.62	

PS, propensity score; SDIFF, standardized difference.

- The post-PS matched sample (n=48,114) was balanced by patient demographics, comorbidities including Quan-Charlson Comorbidity Index score, health care utilization, and health care costs (all SDIFFs <10%)
- During the follow-up period, the on-label treated subgroup had significantly higher all-cause total costs than their untreated controls (TCC ratio 1.18 [$1816 vs $1541, SDIFF 12.6%, *P*<.001]) and pharmacy costs ($546 vs $315, SDIFF 38.6% *P*<.001); the cost difference between the two groups was driven mainly by increases in the on-label group's pharmacy costs (**Figure 2**)
- The off-label treated subgroup had higher total costs than their untreated controls (TCC ratio 1.17 [$1781 vs $1528, SDIFF 12.7%, *P*<.001]), medical costs ($1393 vs $1201, SDIFF 10.4%, *P*<.001), and pharmacy costs ($388 vs $327, SDIFF 10.8%, *P*<.001); the cost difference in the follow-up between the two groups was driven mainly by increases in ambulatory visit costs (**Figure 2**)
  - Excluding VMS medication costs, the TCC ratio was 1.03 for on-label ($1582 vs $1529, SDIFF 2.5%, *P*=.03) and 1.13 for off-label ($1721 vs $1517, SDIFF 10.2%, *P*<.001) VMS treatment (**Figure 2**)

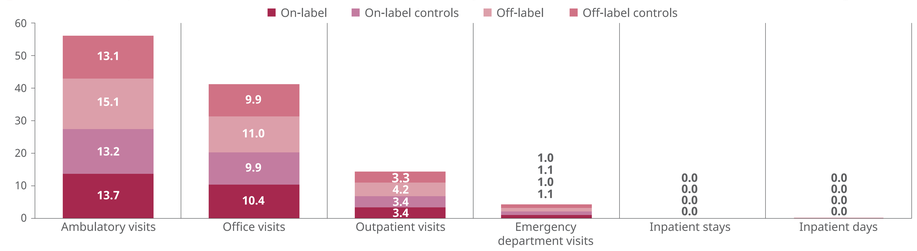
Figure 2. Follow-up All-Cause Health Care Cost[a] by On-Label, Off-Label Treatment[b] Post-PS Matching



PS, propensity score; VMS, vasomotor symptoms.
[a]Mean.
[b]Stratified by health care cost components.

- There was little difference in all-cause HCRU between the on-label cohort and the untreated subgroup; a higher number of ambulatory visits were observed in the on-label treated cohort than in untreated controls during the follow-up period (13.7 vs 13.2, SDIFF 3.2%, *P*<.001; **Figure 3**)
- During the follow-up period, mean all-cause HCRU difference between off-label and untreated subgroups was driven mainly by increases in outpatient visits (4.2 in off-label vs 3.3 in untreated, SDIFF 13.9%, *P*<.001) and office visits (11.0 in off-label vs 9.9 in untreated, SDIFF 9.9%, *P*<.001) (**Figure 3**)

Figure 3. Follow-up All-Cause Health Care Resource Utilization[a] by On-Label, Off-Label Treatment[b] Post-PS Matching



PS, propensity score.
[a]Mean number per patient per year.
[b]Stratified by HCRU components.

LIMITATIONS

- The analytic sample included women with commercial coverage; therefore, results may not be generalizable to women with other types of coverage (eg, Medicaid) or those without health insurance
- Healthcare claims data only capture condition information if a patient seeks diagnosis or care; therefore, women with VMS who did not seek treatment were excluded from the study population
- Reliance on self-report of over-the-counter medication could result in misclassification of exposure

CONCLUSIONS

- Most patients with VMS remain untreated
- VMS treatment, both on-label and off-label, was associated with higher TCC
- Unmeasured confounders that may affect costs, including VMS severity and frequency and socioeconomic status, warrant further research
- On-label treatment costs were driven by pharmacy costs, whereas off-label treatment costs were driven by medical costs
- Results of this study suggest that on-label treatment may be more cost-effective than off-label treatment, despite higher pharmacy costs

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AUTHOR DISCLOSURES

A. Shiozawa, S. Mancuso, and **C. Young:** Employees of Astellas Pharma, Inc. **J. Friderici, S. Tran,** and **H.M. Trenz:** Employees of Optum, which received funding for the current study.

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