

Understanding mHealth Patient-Reported Priority Symptoms for Gynecologic Cancer During Chemotherapy: A Secondary Analysis

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OBJECTIVES: To determine the percentage of and the most prevalent moderate to severe symptoms and to analyze longitudinal patterns and co-occurrence of symptoms during the first three cycles of chemotherapy.

SAMPLE & SETTING: A secondary analysis of 26 women with gynecologic cancer who reported daily symptoms.

METHODS & VARIABLES: Moderate to severe symptom presence and severity levels were calculated as proportions. Symptoms for each patient were graphed during three cycles and analyzed for patterns of onset, duration, and clustering.

RESULTS: Patients completed 1,562 calls to the remote symptom monitoring system. The most commonly reported moderate to severe symptoms were pain, fatigue, and trouble sleeping. Pain and fatigue co-occurred with trouble sleeping in one symptom pattern. Patterns included no moderate to severe symptoms, moderate to severe symptoms during one cycle, moderate to severe symptoms during two cycles, and moderate to severe symptoms during all cycles.

IMPLICATIONS FOR NURSING: Nurses should consistently assess symptoms across cycles. To verify distinct classes of symptoms and better target interventions, further study is warranted.

KEYWORDS female genital neoplasms; symptoms; chemotherapy

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Gynecologic cancers account for more than 114,000 diagnoses and 34,000 deaths annually in the United States (Siegel et al., 2023). The five major types of gynecologic cancers, which are cancers of the female reproductive system, are cervical, ovarian, uterine, vaginal, and vulvar. Ovarian cancer has the highest mortality rate at more than 13,000 individuals each year because it is typically diagnosed in postmenopausal women and at later stages, making it difficult to treat and conferring a poorer prognosis (Siegel et al., 2023). Cancers of the uterus are the most common, accounting for about 66,000 new diagnoses and more than 13,000 deaths annually (Siegel et al., 2023). Uterine cancer is a broad term, encompassing any cancer of or related to the uterus, including uterine sarcomas and endometrial cancer.

Treatments for women with gynecologic cancer vary based on the type and stage of disease and include surgical procedures, radiation therapy, chemotherapy, and immunotherapy. Each of these treatment modalities has its own set of side effects and symptoms. The theory of unpleasant symptoms describes the interactions among symptoms and how they can affect and compound the symptom experience (Lenz et al., 1997). Therefore, in this analysis, the authors focused on patients who underwent multiple cycles of chemotherapy as part of their treatment plan. Chemotherapy, in particular, can have a range of adverse effects on patients, including anemia, nausea, vomiting, fatigue, pain, loss of appetite, and alopecia (Olsen et al., 2018). Although these symptoms are commonly experienced by patients, each chemotherapy regimen has its own symptom pattern of frequency and severity.

Symptoms commonly reported by women receiving chemotherapy for gynecologic cancer have been

studied, but studies of symptom clusters during chemotherapy are less common, and most often are limited to ovarian cancer (Huang et al., 2016; Hwang et al., 2016; Nho et al., 2017). However, research is expanding into all gynecologic cancers (Pozzar et al., 2021, 2022). Existing research on symptom clusters in patients with gynecologic cancer shows that abdominal, respiratory, weight change, psychological, and menstrual/hormonal symptom clusters have been identified (Huang et al., 2016; Hwang et al., 2016; Nho et al., 2017; Pozzar et al., 2022). In prior studies, symptoms have been assessed via a cross-sectional design using one time point (Hwang et al., 2016; Nho et al., 2017) or a longitudinal design (Huang et al., 2016; Pozzar et al., 2022). Within the longitudinal studies, Huang et al. (2016) examined symptoms once prior to each treatment cycle, whereas Pozzar et al. (2022) examined symptoms at the following three time points: once prior to chemotherapy, once the week after chemotherapy, and once two weeks after chemotherapy. Although establishing symptom clusters through cross-sectional, monthly, or weekly assessments is important, patients can experience chemotherapy symptoms daily and with a variety of longitudinal patterns. These symptoms vary in onset, duration, and intensity over time; however, they are not typically captured on a daily basis during chemotherapy cycles so that the peaks and ebbs and co-occurrence can be understood. Past studies have not examined these patterns based on daily reports of symptoms over the course of three chemotherapy cycles. In addition, these studies did not employ remote patient monitoring systems. Remote patient monitoring systems can efficiently capture daily symptom patterns, providing an avenue to better understand and treat chemotherapy side effects (Mooney, Berry, et al., 2017). Patient engagement is a key component of successful remote patient symptom monitoring and requires symptom capture through a platform that is acceptable to patients.

The purpose of this study was to better understand daily symptoms and their patterns in women undergoing chemotherapy for gynecologic cancer during their first three chemotherapy cycles. The specific aims of the study were to (a) determine the percentage of moderate to severe symptoms (a rating of 4 or higher on a 0–10 numeric rating scale), (b) determine the most prevalent moderate to severe symptoms, and (c) analyze the pattern and co-occurrence of moderate to severe symptoms during the first three chemotherapy cycles.

Methods

Design, Sample, and Setting

This was a secondary analysis of a randomized controlled trial conducted at the University of Utah in Salt Lake City and Vanderbilt University in Nashville, Tennessee. The parent study evaluated the efficacy of the automated, interactive voice-recorded Symptom Care at Home monitoring system, which provided coaching and clinician notifications for moderate to severe symptoms. The design and results of this study have been published elsewhere (Mooney, Beck, et al., 2017). The current analysis focused on a subset of patients with gynecologic cancer randomized to the usual care arm. Patients in the usual care arm reported daily symptoms to the Symptom Care at Home monitoring system and were encouraged to contact the oncology team about symptom concerns. Usual care did not receive the intervention that included automated coaching and clinician notifications in response to poorly controlled symptom reports. Only patients in the usual care arm were included in this analysis because the Symptom Care at Home intervention demonstrated superiority in reducing symptom burden over usual care, and the current study aimed to describe usual care symptom patterns.

Data Collection

All participants called into the Symptom Care at Home monitoring system to report their symptoms daily. Patients were greeted and then asked systematically about the presence and the severity (if there were symptoms present) of 11 symptoms consisting of fatigue, pain, trouble sleeping, nausea, sore mouth, numbness and tingling, difficulty thinking, diarrhea, feeling blue, feeling nervous or anxious, and distress over appearance changes.

Data Analysis

Demographic and clinical data were reported using descriptive statistics. Proportions were used to determine call adherence and usage rates for patients. Proportions of symptom reports for each patient were used to calculate presence and severity levels and averaged across patients. Symptoms that were reported during three (25%) or more calls were graphed for each patient during the first three cycles of chemotherapy and analyzed for patterns of onset, persistence over time (duration), and clustering by cycle. Two independent reviewers examined symptom patterns for days where symptoms were moderate to severe and separately by cycle. A moderate to severe

TABLE 1. Patient Clinical and Demographic Characteristics (N = 26)

Characteristic	n
Cancer stage	
I	4
II	4
III	10
IV	8
Cancer type	
Ovarian	14
Endometrial	5
Uterine	4
Cervical	2
Vulvar	-
Other ^a	1
Education level	
High school diploma or GED	6
Some college or technical school	10
Associate degree	1
Bachelor's degree	5
Postgraduate degree	4
Employment status	
Not employed	10
Full-time	7
Too sick or on disability	5
Retired	3
Part-time	1
Marital status	
Married	15
Divorced	5
Single	4
Separated	1
Widowed	1
Net income (\$)	
Less than 9,999	2
10,000-19,999	3
20,000-29,999	2
30,000-39,999	2
40,000-49,999	4
50,000-69,999	2
More than 70,000	9
Did not know	2
Declined to answer	-
Race	
Asian	1
Black or African American	-

*Continued in the next column***TABLE 1. Patient Clinical and Demographic Characteristics (N = 26) (Continued)**

Characteristic	n
Race (continued)	
Native American or Alaska Native	1
White	23
Missing data	1
Religion	
Latter-day Saint	14
Protestant	2
Catholic	1
No religion	5
Other	4

^a Included fallopian tube**Note.** The mean age of patients was 58.5 years (SD = 7.9, median = 59, range = 40-76).

pattern was defined as three or more days of one or more of the top three symptoms with a severity rating of 4 or higher on the numeric rating scale (0 = no pain, 1-3 = mild pain, 4-7 = moderate pain, 8-10 = severe pain). This definition was selected to indicate clinically meaningful repeating moderate to severe symptoms common to most patients, which would suggest moderate to severe symptoms occurred about once per week because most cycles lasted 21 days. Therefore, three or more symptom days were chosen to establish an ongoing pattern of moderate to severe fatigue, pain, and sleep disturbance that would need to be addressed by a clinician. Patterns were characterized as (a) not frequently having moderate to severe symptoms for any of the top three symptoms, (b) three or more days with moderate to severe symptoms during one cycle, (c) frequent moderate to severe symptoms during two cycles, and (d) frequent moderate to severe symptoms during all cycles. Summary of classifications included which symptoms qualified as moderate to severe symptoms. If there was a discrepancy between reviewers, they reviewed symptoms together to reach concordance.

Results

Sample Characteristics and Use of mHealth Symptom Reporting

Twenty-eight patients with gynecologic cancer were identified from the usual care arm of the parent study. Of those, 26 participants had data for three or more cycles and were included in this analysis. Most patients were White (n = 23), married (n = 15), and

diagnosed with ovarian cancer (n = 14). Eighteen patients had stage III or IV cancer. All demographic and clinical characteristics are reported in Table 1.

Patients were in the study for an average of 65.7 days (SD = 12.8, range = 22–95) and completed an average of 60.1 calls (SD = 11.8, range = 21–88), with an average call adherence for expected call days of 92% (SD = 6%, range = 68%–99%). A total of 1,562 calls were completed, with 61% (n = 950) of calls reporting at least one symptom with a severity rating of 1 or higher and 39% (n = 608) of calls having at least one symptom reported with a severity rating of 4 or higher.

Most Prevalent Symptoms

Across 1,562 total calls from patients, the most prevalent symptoms overall included fatigue (n = 738, 47%), pain (n = 647, 41%), and trouble sleeping (n = 391, 25%) of calls. The most prevalent moderate (rating of 4–7) to severe (rating of 8–10) symptoms across the first three cycles of chemotherapy were fatigue (n = 471, 30%), pain (n = 378, 24%), and trouble sleeping (n = 283, 18%). Table 2 presents symptom prevalence overall and by cycle. Only fatigue, pain, and trouble sleeping were reported in more than 10% of calls in which symptoms were identified as moderate to severe. Of note, among the top three symptoms, if

TABLE 2. Prevalence of Symptoms Reported by Patients During Each Chemotherapy Cycle

Symptom	Cycle 1 (N = 536)				Cycle 2 (N = 538)				Cycle 3 (N = 498)				All Cycles (N = 1,562)			
	With Symptom		With Mod/Sev Symptom		With Symptom		With Mod/Sev Symptom		With Symptom		With Mod/Sev Symptom		With Symptom		With Mod/Sev Symptom	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any	324	60	203	38	327	61	214	40	298	60	191	38	949	61	608	39
Fatigue	248	46	152	28	253	47	147	27	237	48	172	35	738	47	471	30
Pain/ discomfort	215	40	105	20	222	41	143	27	210	42	130	26	647	41	378	24
Trouble sleeping	143	27	103	19	137	25	101	19	111	22	79	16	391	25	283	18
Nausea	123	23	35	7	122	23	40	7	119	24	42	8	364	23	117	7
Difficulty thinking	90	17	36	7	74	14	23	4	64	13	36	7	228	15	95	6
Numbness/ tingling	84	16	34	6	112	21	39	7	92	18	28	6	288	18	101	6
Sore mouth	75	14	16	3	112	21	39	7	76	15	30	6	263	17	85	5
Feeling blue	61	11	34	6	39	7	19	4	27	5	17	3	127	8	70	4
Distress about appearance	58	11	19	4	58	11	17	3	29	6	14	3	145	9	50	3
Nervous/ anxious	57	11	25	5	41	8	23	4	33	7	18	4	131	8	66	4
Diarrhea	43	8	27	5	44	8	20	4	41	8	22	4	128	8	69	4

mod—moderate; sev—severe

Note. Mod to sev symptoms were identified based on a rating of 4 or higher on a numeric rating scale (0 = no pain, 1–3 = mild pain, 4–7 = mod pain, 8–10 = sev pain).

Note. Patients could report more than 1 symptom.

patients reported a symptom, the severity in more than half of these calls was in the moderate to severe range. For example, 47% (n = 738) of calls reported fatigue, with 64% (n = 471) of these calls reporting moderate to severe fatigue. Finally, all patients called

to report at least one moderate to severe symptom at some point during the study, with 25 of 26 patients reporting at least one moderate to severe symptom related to fatigue, pain, or sleep. The least prevalent symptoms included numbness and tingling, which

TABLE 3. Findings Related to Patient Remote Symptom Monitoring Call Data

Patient Record	More Than 3 Days ^a	Cycle	Fatigue	Pain	Trouble Sleeping	Class
1021	No	None	None	None	None	Pattern 1
1158	No	None	None	None	None	Pattern 1
1269	No	None	None	None	None	Pattern 1
1294	No	None	None	None	None	Pattern 1
1330 ^b	No	None	None	None	None	Pattern 1
1363	No	None	None	None	None	Pattern 1
1160	Yes	Cycle 1	Yes	Yes	None	Pattern 2
1139 ^b	Yes	Cycle 2	None	Yes	None	Pattern 2
1066	Yes	Cycles 1 and 2	Yes	None	Yes	Pattern 3
1267 ^b	Yes	Cycles 1 and 2	None	Yes	None	Pattern 3
1367	Yes	Cycles 1 and 2	Yes	Yes	None	Pattern 3
1379 ^b	Yes	Cycles 2 and 3	Yes	Yes	None	Pattern 3
1042	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1086	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1097	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1099	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1185	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1219	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1226	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1234	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1273	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1277	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1336	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1339 ^b	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1352	Yes	Cycles 1-3	Yes	Yes	Yes	Pattern 4
1373	Yes	Cycles 1-3	Yes	Yes	None	Pattern 4

^a At least 1 moderate to severe symptom in 1 cycle

^b Indicates reviewer discrepancy that was resolved for final class

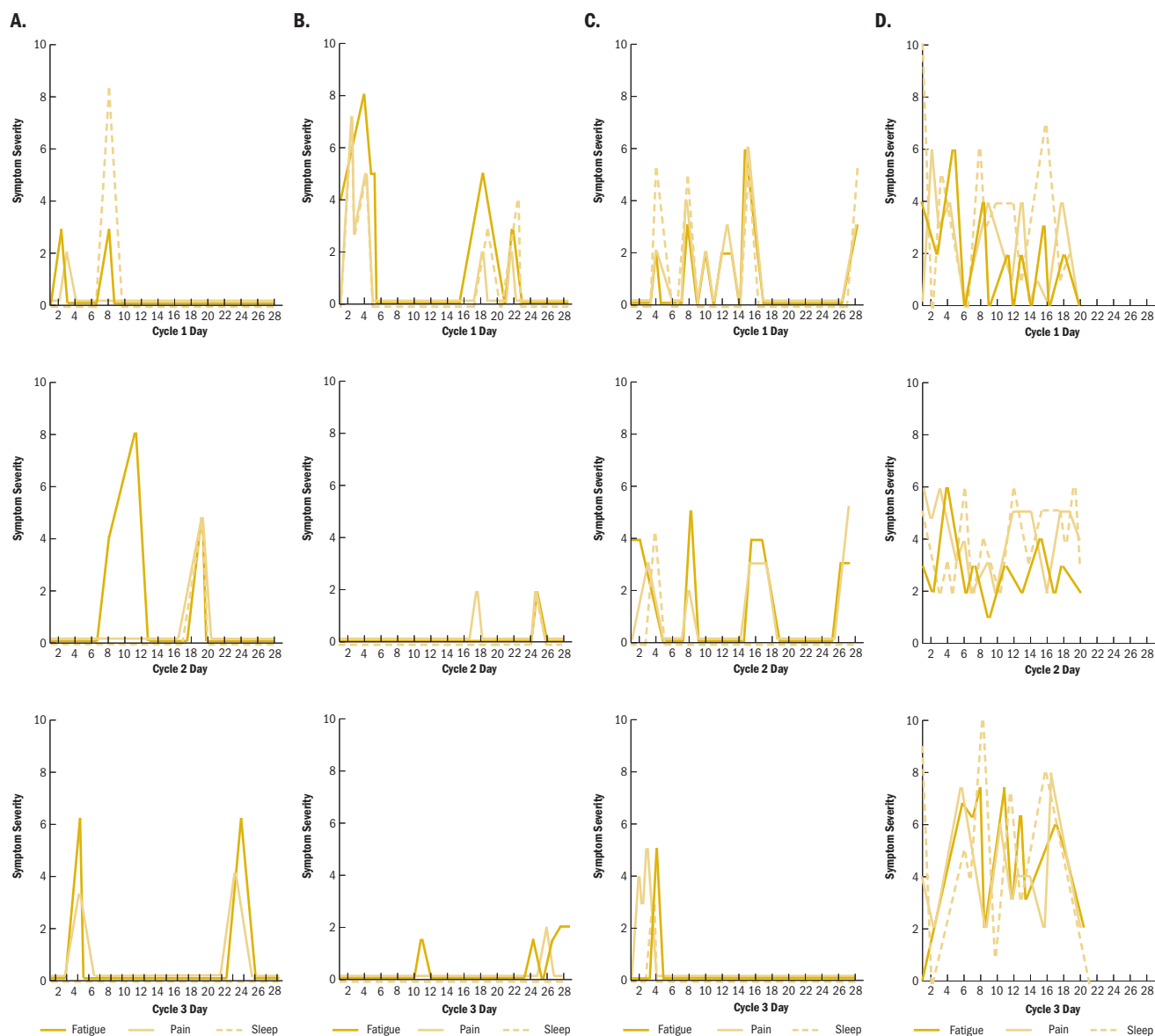
was reported by 10 patients, and depressed mood, which was reported by 16 patients.

Patterns and Co-Occurrence of Symptoms

Daily patient data for the three most common symptoms, fatigue, pain, and trouble sleeping, were graphed separately for each patient to examine changes within

and between cycles. The two independent reviewers had similar findings on 21 of 26 patients. The remaining five patients were discussed by both reviewers, and concordance was reached. The results of the review of patterns and co-occurring symptoms are provided in Table 3. All three symptoms tended to co-occur, although trouble sleeping co-occurred in

FIGURE 1. Daily Symptom Report Patterns for Fatigue, Pain, and Trouble Sleeping Across 3 Chemotherapy Cycles



Note. Symptom severity was rated daily for 28 days across 3 chemotherapy cycles using a numeric rating scale (0 = no pain, 1–3 = mild pain, 4–7 = moderate pain, 8–10 = severe pain). The stacked graphs represent 4 distinct symptom patterns across the 3 cycles (A = sporadic moderate to severe symptoms, B = several days of moderate to severe symptoms during only 1 cycle, C = several days of moderate to severe symptoms during 2 cycles, and D = consistent moderate to severe symptoms during all 3 cycles).

only a subset of patients. Using visual analysis, graphs were classified into the following four general patterns: (a) sporadic moderate to severe symptoms (n = 6), (b) several days of moderate to severe symptoms during only one cycle (n = 2), (c) several days of moderate to severe symptoms during two cycles (n = 4), and (d) consistent moderate to severe symptoms during all cycles (n = 14). Examples of these patterns are presented in Figure 1, specifically the same-day co-occurrence of these symptoms.

Discussion

Daily remote symptom monitoring can be beneficial to patients and providers and allow for symptom monitoring over time. However, the time burden for patients to report symptoms during the course of cancer treatment must also be considered. In this study, the average call adherence for expected daily reports from patients with gynecologic cancer during three cycles of chemotherapy (about 90 days) was 92%. This aligns with the call adherence (90%) found in the parent study, which included a variety of cancers (Mooney, Beck, et al., 2017), indicating that patients with gynecologic cancer are willing to report symptoms, including potentially sensitive symptoms such as psychosocial symptoms, on a daily basis. Patients with gynecologic cancer can experience menstrual, menopausal, and sexual symptoms (Abbott-Anderson & Kwekkeboom, 2012; Wilson et al., 2020). Although these symptoms were not assessed in the current study, it has been frequently reported that patients may be hesitant to discuss sexual symptoms face to face (Wilson et al., 2022). A more anonymous remote symptom monitoring system can be an optimal way to examine these symptoms in patients.

To monitor and treat chemotherapy side effects, the symptom trajectories of patients undergoing treatment for gynecologic cancer need to be anticipated, and greater understanding of whether there is variation and subtypes at risk for higher symptom burden is essential. Although the sample in the current study was too small to evaluate differences based on variables such as cancer type, these differences should be explored further in future studies. The results from this study indicate that women with gynecologic cancer experience different patterns of chemotherapy-related symptoms throughout the course of their first three cycles of treatment, demonstrating the importance of daily assessment and recognition of symptom patterns during each cycle. Automated patient-reported outcome monitoring platforms can provide an efficient and scalable

KNOWLEDGE TRANSLATION

- Pain, fatigue, and trouble sleeping are the most reported generalized moderate to severe symptoms in patients with gynecologic cancer receiving chemotherapy.
 - Patients can experience different patterns of symptoms throughout the course of multiple cycles of chemotherapy.
 - Nurses should consistently assess for symptoms over time to account for variations in pain across treatment cycles.
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method for daily assessment. Therefore, advocacy by clinicians for implementation of such devices in oncology clinics should be undertaken to better track patient symptoms (Wilson & Mooney, 2020).

Previous studies have examined symptom clusters or patterns in patients with ovarian cancer; however, these were cross-sectional studies or examined single monthly time points (Huang et al., 2016; Hwang et al., 2016; Nho et al., 2017). In addition, Pozzar et al. (2022) expanded their study to include all gynecologic cancers but focused only on weekly time points. These previous studies primarily identified psychological, abdominal, respiratory, weight change, and menstrual/hormonal symptom clusters (Huang et al., 2016; Hwang et al., 2016; Nho et al., 2017; Pozzar et al., 2022). In another study, Pozzar et al. (2021) examined distinct sleep trajectories over multiple cycles of chemotherapy; however, these were measured over six time points. One strength of the current study is that it examined daily symptoms using more than 1,550 call reports. Similar to the results of Pozzar et al. (2021), trouble sleeping was found to be a prevalent symptom with distinct trajectories in this study. This study's results differ from those of other studies that did not examine daily patterns in that fatigue and pain were the most prevalent symptoms with greater severity, which may have not been captured in prior studies because less frequent assessments may have missed peak symptom days. The unique aspect of this study is that it examined trajectories of symptoms on a daily basis, documenting severity and co-occurrence with other symptoms, which, as a group, compounds symptom burden. Other studies have examined daily symptom reporting, as well as symptom patterns, but they were limited to patients with breast cancer (Whisenant et al., 2017, 2019). Similar to the current study, distinct patterns were identified related to sleep and fatigue, but latent class analyses were able to be conducted because of the larger sample size, which should be considered in future studies of

patients with gynecologic cancers (Whisenant et al., 2017, 2019).

Similar to a previous study that examined daily symptom reports in patients with various cancers receiving chemotherapy (Mooney, Beck, et al., 2017), the patients in the current study reported pain, fatigue, and trouble sleeping as the top three moderate to severe symptoms. Nausea was the fourth most common symptom in the Mooney, Beck, et al. (2017) study, with 60% of individuals reporting moderate to severe nausea and vomiting. However, the current analysis showed that patients with gynecologic cancer experienced nausea, but it was often not moderate or severe. Patients with gynecologic cancer often experience gastrointestinal symptoms as part of their disease trajectory, but this may have been adequately addressed by medications prior to chemotherapy.

Of note, only two patients reported distress about appearance changes, which was the least reported moderate to severe symptom in this study. Appearance changes are common among patients in the gynecologic cancer population and are typically associated with gastrointestinal, depression, and sexuality-related symptoms (Kirchheiner et al., 2016; McCorkle et al., 2006; Wilson et al., 2020). Appearance changes and distress are also commonly reported in conjunction with menopause symptoms and found to be related to menopause-related symptom clusters, such as hot flashes, trouble sleeping, and fatigue (Huang et al., 2016; Kirchheiner et al., 2016). In the current study, reports of moderate to severe trouble sleeping and fatigue symptoms were noteworthy, but distress was not reported with appearance changes.

This preliminary exploration of daily symptom patterns and co-occurrences with other symptoms underscores the need for daily assessment and management of patients in the gynecologic cancer population to address symptoms as they emerge and before they escalate to severe levels. An overall benefit has been shown in reducing symptom burden in patients with cancer through daily remote symptom monitoring and management using technology-enabled platforms (Mooney, Beck, et al., 2017; Mooney et al., 2019).

Although this study was a preliminary investigation of daily symptom trajectories, the three distinct symptom patterns identified indicate a need for further examination and analyses with a larger sample size. For example, the use of latent class analysis could help to identify subgroups of patients displaying specific symptom patterns and their relationships to clinical and demographic factors, similar to

analyses previously conducted in patients with breast cancer (Whisenant et al., 2017, 2019). Interventions that are directed at a single symptom may not address the cumulative burden of symptoms. Understanding symptom clusters allows for testing interventions aimed at disrupting the cluster and more effectively addressing symptom burden.

Limitations

Although this study has notable strengths, including an intensive longitudinal data collection that revealed symptom pattern outcomes from more than 1,550 reports, there are several noteworthy limitations. First, as a secondary data analysis, the variables able to be assessed were limited. Of note, assessing the unique sexual and menstrual symptoms related to gynecologic cancers and their treatment, particularly from radiation therapy, was absent. Second, with the small sample size, certain analyses (e.g., latent class analyses) were restricted, limiting more in-depth investigations that warrant further study.

Implications for Nursing

Women who receive treatment for gynecologic cancers frequently experience moderate to severe symptoms during multiple cycles of chemotherapy. Based on preliminary evidence, several patterns of onset and duration may occur. Symptom clustering of pain, fatigue, and trouble sleeping has been reported. Because of the varying patterns of onset and duration of these symptoms, nurses should regularly assess patients' symptoms over time. Additional research is needed to confirm distinct classes of symptoms to ensure targeted symptom care.

Conclusion

Overall, the examination of daily remote symptom reporting is crucial to better understand and monitor patient symptoms, trajectories, and clusters. In this study, patients with gynecologic cancer had three priority symptoms (fatigue, pain, and trouble sleeping), which were found to have four distinct patterns when examined qualitatively. This analysis demonstrates that patients may have different and distinct experiences when undergoing treatment. Further investigation into daily symptom patterns and clusters, including the addition of sexual and menstrual symptoms, is warranted to improve symptom care.

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