

Remote Symptom Alerts and Patient-Reported Outcomes (PROs) in Real-World Breast Cancer Practice: Innovative Data to Derive Symptom Burden and Quality of Life

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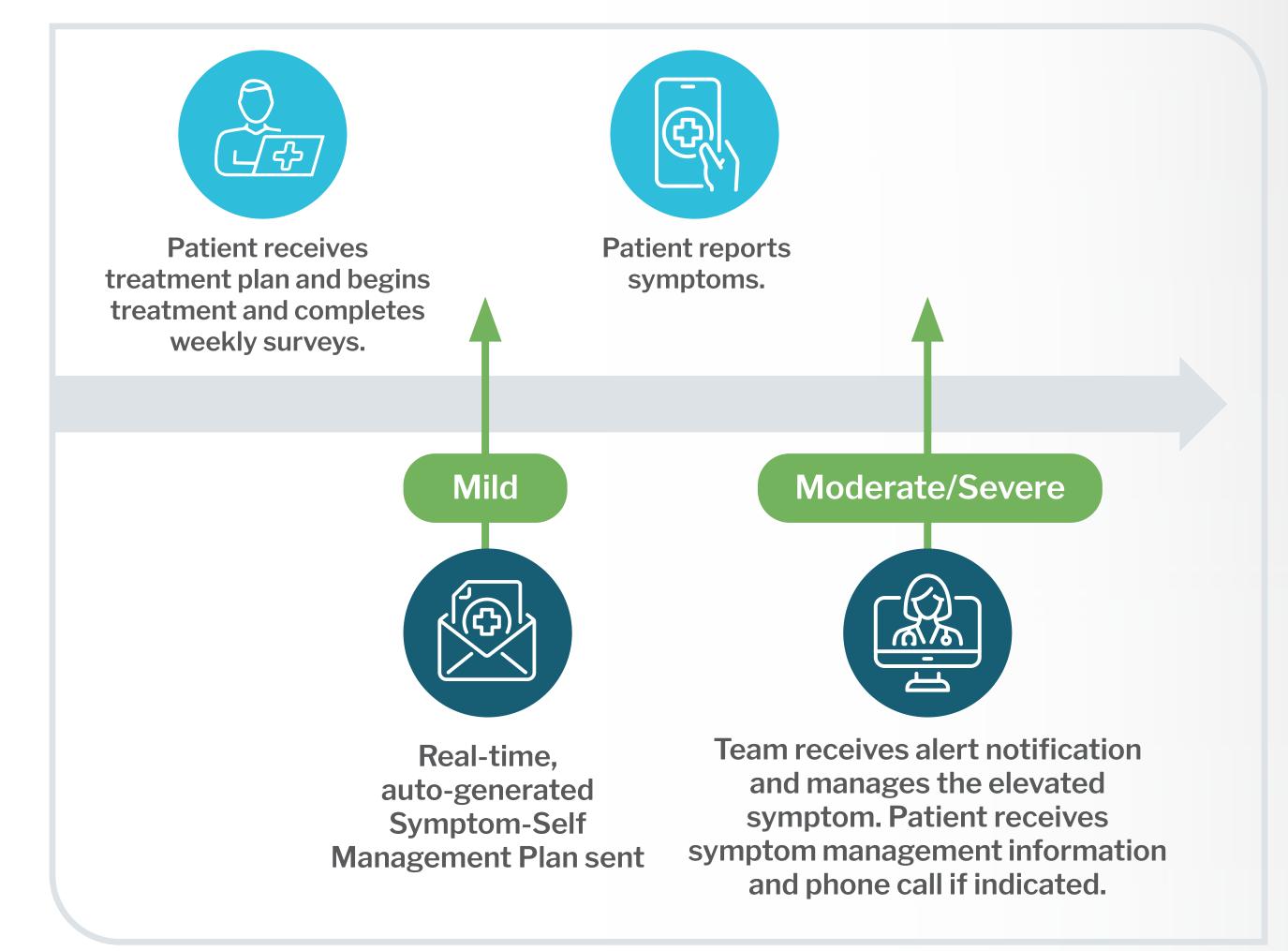
BACKGROUND

- Prior studies have shown the value of routine symptom monitoring and patientreported outcomes (PROs) assessments on oncology patient outcomes.1,2,3
- Women undergoing breast cancer treatment may experience debilitating symptoms that can significantly reduce quality-of-life (QoL).4
- Continued monitoring using remote symptom monitoring platform (RSM) with an alert system allows patients to report symptoms and inform the healthcare team in real time.
- Insights on patient experiences with symptom prevalence and their impact to daily function and QoL, particularly in patients with poor functional status⁵, is essential for treatment decision making.
- This research aims to highlight the use of data collected via PRO-generated alerts system to characterize symptom burden and QoL in real-world breast cancer population.

METHODS

- Breast cancer patients enrolled in Carevive PROmpt®, an RSM platform, between September 2020 and November 2023 with evidence of therapy were included.
- Patients received weekly surveys to report any symptoms (derived from PRO-CTCAE®) experienced during treatment. When a patient reported a moderate or severe symptom, an algorithm-based system would generate an "alert" notification to the healthcare team.
- The healthcare team was notified and documented the clinical action(s) taken to address the symptoms. Patient-reported quality of life and physical function data were visible to the care team upon alert generation.
- Patients were followed from the baseline survey completion to the last completed survey or end of study period (whichever is earliest).
- Symptom burden, measured by the number of alerts/week and symptom prevalence, as well as QoL (measured by the Global health/QOL items of EORTC QLQ-C30) at alerts were characterized.
- Results were explored by stage (early or late), biomarker (Her2+/HR+, Her2-/HR+ or TNBC), age, frailty (Frail, Intermediate, or Fit) and ECOG status (0, 1, or 2+).

Figure 1: Carevive PromPT® Remote Symptom Alerts



RESULTS

Table 1: Demographic and Baseline Characteristics

	All patients (n = 646)	Had ≥1 symptom alerts (n=519)
No. of patients who generated at least one symptom alerts, n (%)	519 (80.3)	519 (100)
No. of alerts generated during observation period	7,641	7,641
No. of symptoms reported during observation period	19,425	18,506
PROs follow-up time (weeks), Median	12.3	16,506
1		
Age at enrollment (years), Mean (SD) Median	55.6 (12.6) 56	54.8 (12.7) 55
	36	<u> </u>
Age at enrollment n (%)	200 (21 0)	174 (22 5)
<50 years old	200 (31.0)	174 (33.5)
50-64 years old	270 (41.8)	211 (40.7)
65-75 years old	154 (23.8)	118 (22.7)
>75 years old	22 (3.4)	16 (3.1)
Female, n (%)	646 (100)	519 (100)
Race, n (%)	7 (1.1)	F (1.0)
American Indian or Alaskan Native	7 (1.1)	5 (1.0)
Asian	11 (1.7)	10 (1.9)
Black or African American	132 (20.4)	107 (20.6)
Native Hawaiian or Other Pacific Islander	1 (0.2)	1 (0.2)
White	466 (72.1)	370 (71.3)
Other	9 (1.4)	7 (1.3)
Unknown	20 (3.1)	19 (3.7)
Biomarker status, n (%)		
HR+/HER2-	305 (47.2)	247 (47.6)
HR+/HER2+	100 (15.5)	85 (16.4)
Triple negative	119 (18.4)	90 (17.3)
Unknown	122 (18.9)	97 (18.7)
Stage, n (%)		
Early stage (0-IIIA)	399 (61.8)	325 (62.6)
Late stage (IIIB-IV)	147 (22.8)	114 (22.0)
Unknown	100 (15.4)	80 (15.4)
Baseline frailty status		
Fit	503 (77.9)	393 (75.7)
Intermediate	77 (11.9)	69 (13.3)
Frail	44 (6.8)	41 (7.9)
Unknown	22 (3.4)	16 (3.1)
ECOG status		
0	144 (22.2)	120 (23.1)
1	134 (20.7)	108 (20.8)
2+	61 (9.4)	58 (11.2)
Unknown	307 (47.7)	233 (44.9)
Treatment closest to first symptom alert, n (%)	, ,	,
Chemotherapy	164 (25.4)	164 (31.6)
Anti-HER2 therapy	101 (15.6)	101 (19.5)
Mono Endocrine therapy (ET)	91 (14.1)	91 (17.5)
PD-1/L1 inhibitors	45 (7.0)	45 (8.7)
CDK 4/6 inhibitors	36 (5.6)	36 (6.9)
Other	33 (5.1)	33 (6.4)
	127 (19.7)	0 (0.0)
Did not generate alerts	14 \1J.//	0 (0.0)

- A total of 646 female breast cancer patients reported 19,425 symptoms over a median 12.3 weeks. Median age was 56, 72.1% were white, and 22.8% were late stage (**Table 1**).
- About 80.3% of patients (n=519) reported a moderate/severe symptom at least once, generating 7,641 total alerts (**Table 1**).
- Pain (26.4%), nausea/vomiting (11.4%), neuropathy (10.5%), fatigue (10%), and constipation (7.9%) were most prevalent symptoms that triggered an alert (Figure 2).
- Patients generated an average of 2 alerts (SD=1.5) per week, with a median of 1 alert per patient per week (Figure 3).

- Average number of alerts per patient per week were similar by stage, biomarker, or age.
- Frail patients, on average, reported more moderate/severe symptoms per week than Fit or Intermediate. Similar trend was observed when comparing ECOG 2+ vs. ECOG 1 or 0. (**Table 2**).
- Quality of life, physical function, and treatment bother were consistently worse for Frail than Fit or Intermediate (Figure 4).

Table 2: No. of Alerts per Patient per Week by Clnical Characteristic

	All	Early stage	Late stage	HER2-/ HR+	HER2+/ HR+	TNBC	Fit	Int.	Frail	<50	50-64	65-75	>75	ECOG 0	ECOG 1	ECOG 2+
No. of patients with alerts	519	325	114	247	85	90	393	69	41	174	211	118	16	120	108	58
No. of alerts	7641	4439	2088	3671	1245	1403	5319	1400	621	2547	3398	1520	176	1235	1579	1145
No. of alerts per patient																
Mean (SD)	2.0 (1.5)	2.1 (1.5)	2.1 (1.6)	2.0 (1.6)	2.0 (1.5)	2.1 (1.7)	2.0 (1.5)	2.1 (1.4)	2.5 (1.5)	2.0 (1.6)	2.1 (1.5)	1.9 (1.4)	1.7 (1.0)	1.5 (0.9)	1.9 (1.1)	2.1 (1.3)
Median	1	1	1	1	1	2	1	2	2	1	2	1	1	1	2	2

Figure 2: Overall Symptom Prevalence

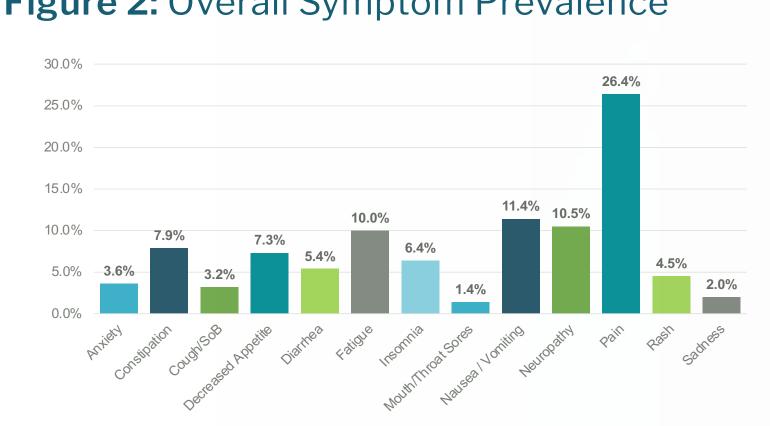


Figure 3: Average Number of Alerts per Patient over time

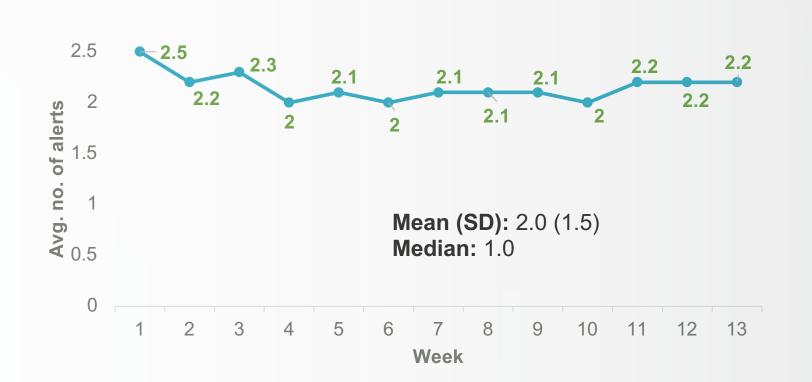
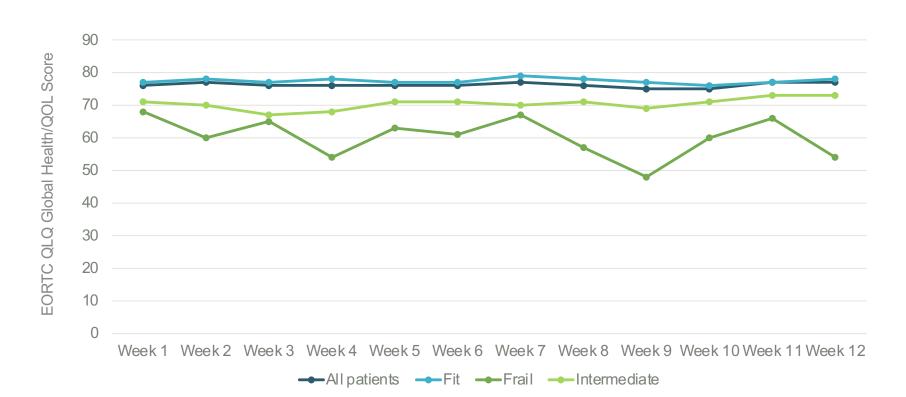


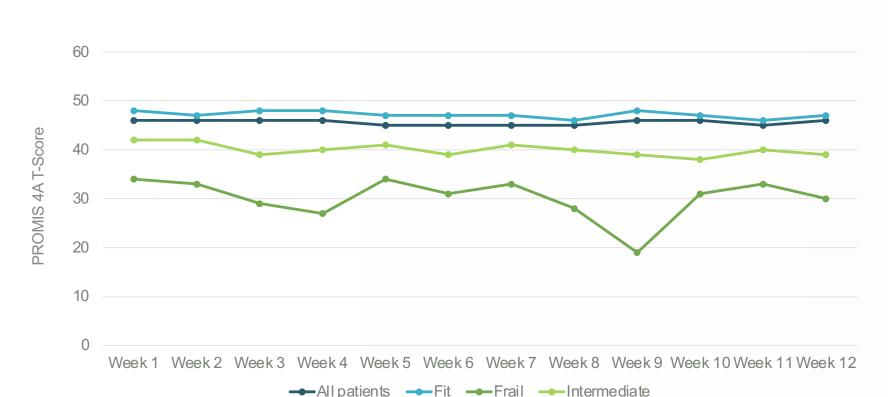
Figure 4: Quality-of-Life, Physical Function, and Treatment Bother by Frailty Status

Quality-of-Life by Frailty Status



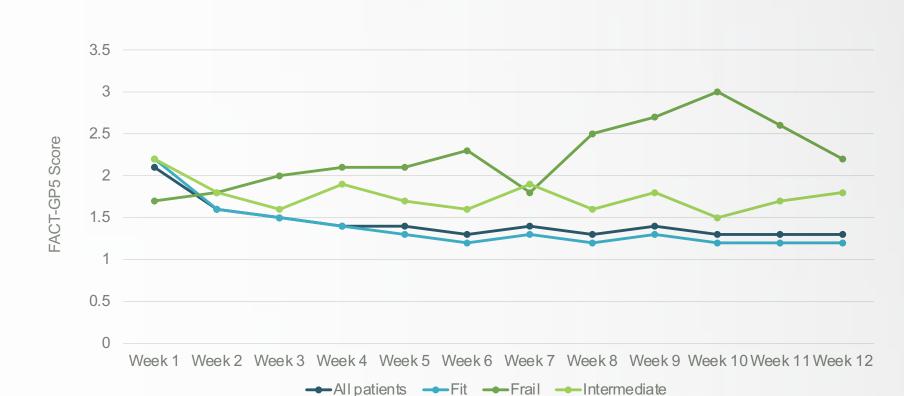
Measured by Global health/QoL items of EORTC QLQ-C30 score (range: 0-100). Higher score indicates higher, more positive perception of overall health and QoL.

Physical Function by Frailty Status



Measured by PROMIS 4A Physical Function T-score (range: 22.5-57.0). Higher score indicates greater overall function.

Degree of Treatment Bother by Frailty Status



Measured by single item FACT-GP5 (range: 0-4). Higher score indicates higher degree of treatment bother.

CONCLUSION

- Data collected from PRO-generated alerts system can be used to characterize symptom burden and quality of life in breast cancer.
- Frail and ECOG 2+ patients generated more alerts per patient per week, indicative of higher symptom burden.
- Patients with poor functional status may greatly benefit from continuous monitoring of symptoms, function, and quality-of-life over time.
- Early identification of patients with poor functional status allows clinicians to tailor monitoring frequency.
- Results can inform future studies on interventions to mitigate symptoms in high-risk breast cancer patients with poor functional status.

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