Feasibility of Telemonitoring of Personalized Circadian Rhythms in Patients with Early-Stage Hormone Receptor–Positive Breast Cancer Receiving Endocrine Therapy

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Introduction

- Endocrine therapy (ET) is an integral adjuvant treatment for early-stage hormone receptor positive (HR+) breast cancer, but significant side effect burden can lead to decreased adherence and increased risk of recurrence.[1]
- Chronotherapy, or aligning medication timing with circadian rhythms, has shown promise in reducing toxicity and improving efficacy of medications in other malignancies, but remains underexplored in breast cancer and ET.[2,3]
- We conducted a pilot study to evaluate the feasibility of monitoring circadian rhythms in patients receiving ET using wearable digital health sensors and validated patient-reported outcomes (PROs).

Methods

- Patients with early-stage HR+ breast cancer already receiving or planning to initiate standard ET were eligible.
- For 14-days, patients wore a wristwatch (LEAP Actigraph) and chest sensor (Movisense) to capture continuous physiologic data, including rest-activity, sleep-wake cycles, skin temperature, and heart rate 24 hours a day.

Figure 1: Study Wearables



- The Pittsburgh Sleep Quality Index (PSQI) was administered as a baseline PRO. Daily PROs were administered including the Karolinska Sleepiness Scale (KSS) and Functional Assessment of Cancer Therapy–Endocrine Subscale (FACT-ES).
- Patients who took their ET between 05:00h and 13:00h were classified as "early"
- Patients who took their ET between 20:00h and 22:00h were classified as "late"

Results

As of 11/21/25, 13 of the 20 patients have completed the study.
12 of 13 (93%) patients reported "very easy" or "easy" to participate in the study while continuing daily life.

Table 1: Patient Demographics

Characteristic	All Patients	Early group	Late group	p-value
	N = 13	N = 5	N = 8	
Age, years	56.6 (15.7)	61.4 (12.8)	53.6 (17.4)	0.38
Sex, n (%)				
Female	13 (100)	5 (100)	8 (100)	
Race, n (%)				0.12
Black n (%)	2 (15.4)	2 (0.4)	0 (0)	
White	11 (84.6)	3 (0.6)	8 (100)	
BMI, kg/m2	27.6 (4.1)	27.6 (2.5)	27.5 (5)	0.96
Menopausal Status, n (%)				1.0
Postmenopausal	9 (69.2)	4 (80)	5 (62.5)	
Premenopausal	4 (30.8)	1 (20)	3 (37.5)	
Neoadjuvant Treatment, n (%)				1.0
No	7 (53.8)	3 (0.6)	4 (50)	
Yes	6 (46.2)	2 (0.4)	4 (50)	
Radiation, n (%)				0.12
No	2 (15.4)	2 (0.4)	0 (0)	
Yes	11 (84.6)	3 (0.6)	8 (100)	
Endocrine Therapy, n (%)				1.0
Anastrozole	5 (40)	2 (40)	3 (40)	
Exemestane	2 (20)	1 (20)	1 (10)	
Letrozole	4 (30)	1 (20)	3 (40)	
Tamoxifen	2 (20)	1 (20)	1 (10)	
ET duration at start of study, months	8.7 (12.7)	14.9 (18)	4.8 (6.7)	0.14
OFS, n (%)				1.0
No	9 (69.2)	4 (80)	5 (62.5)	
Yes	4 (30.8)	1 (20)	3 (37.5)	
CDK4/6i, n (%)				1.0
No	12 (90)	5 (100)	7 (90)	
Yes	1 (10)	0 (0)	1 (10)	
Bisphosphonate, n (%)				1.0
No	11 (84.6)	4 (80)	7 (90)	
Yes	2 (15.4)	1 (20)	1 (10)	

Figure 2: Average KSS and FACT-ES Scores for Early vs. Late Groups

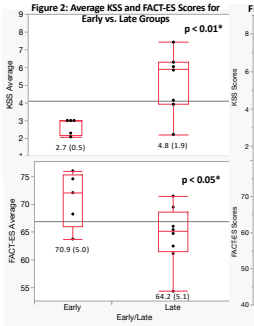


Figure 3: Average Daily KSS and FACT-ES Scores for Early vs. Late Groups

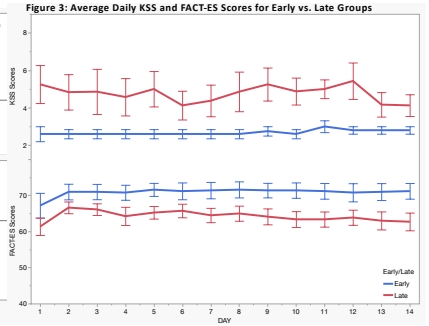


Figure 1: Average PRO scores for Early vs Late groups. Higher KSS scores indicate increased sleepiness, and lower FACT-ES scores indicate worse endocrine symptoms.

Figure 2: Average daily KSS (upper panel) and FACT-ES (lower panel) scores over the 14-day study period, stratified by early vs late ET administration.

Patient 1: Early ET

Patient 2: Late ET

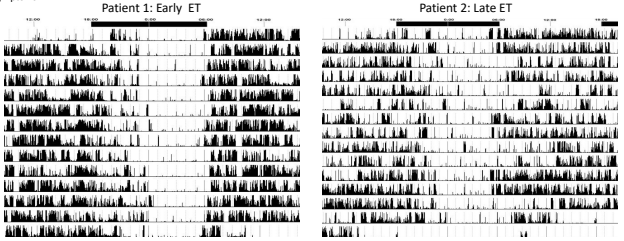


Figure 4: Sleep-wake cycles for two patients during the 14-day pilot. Patient 1 (left) experienced more consistent or regular sleep-wake cycles. Patient 2 (right) had more disrupted rest-activity rhythms with variable sleep and wake times and night awakenings, suggesting increased sleep fragmentation and overall circadian disruption.

Discussion

Telemonitoring of circadian rhythms using wearables is feasible and well-tolerated in patients receiving ET for HR+ breast cancer. Preliminary data suggest excellent patient adherence and feasibility of the approach, with 12/13 patients reporting it was "easy" or "very easy" to continue daily life while on study, and 97% of all surveys completed.

In this pilot, time-of-day of ET administration was associated with emerging group differences with early vs. late administration of ET and individual differences in sleep and circadian patterns and endocrine-related symptom scores.

- The late ET group reported greater daytime sleepiness, with KSS scores, on average >2 points higher than the early ET group.
- Late ET group reported worse endocrine symptom burden, with FACT-ES scores on average 6.7 points lower than early ET, greater than established minimally clinically important difference of 4.25 points.[4]
- Baseline PSQI score, a validated subjective sleep quality metric, was on average 2.6 higher in the late ET group (8.8 vs 6.2 in the early ET group).[5]
- Limitations of this work include small sample size and potential confounding from unmeasured factors.

Conclusions and Future Directions

Preliminary pilot results support further evaluation of chronotherapy-informed dosing strategies for ET in larger, prospective cohorts. Planned analysis will explore additional circadian metrics and larger scale randomized studies are planned in the future.

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