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Wearable Derived Sleep Metrics Differentiate Responders From Non-Responders Following Biologic Therapy in Inflammatory Bowel Disease

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INTRODUCTION

- Biologic therapies are central to inflammatory bowel disease (IBD) treatment, yet only ~40% of patients respond.[1]
- Monitoring relies on intermittent clinical assessments and lab tests, limiting timely detection of therapeutic effect. Wearable sensors provide continuous, objective data, including sleep, which is often impaired during active IBD.
- We evaluated whether wearable-derived sleep metrics can differentiate responders from non-responders after biologic initiation.

AIM

- To determine whether wearable-derived sleep metrics can distinguish biologic therapy responders from non-responders and reflect inflammatory disease activity in patients with IBD. The reported findings offer initial insights into this ongoing research.

METHOD

- Adults (≥18 years) with IBD starting biologic therapy, with active inflammation, were followed pre-treatment through 14 weeks after initiation, while continuously using a wearable device (Oura Ring) collecting daily sleep data.
- Inflammation was assessed using C-reactive protein (CRP) at baseline (drug initiation day) and weeks 2, 6, and 14 (active inflammation defined as CRP >5 mg/L).
- Fatigue and sleep were assessed using the Patient Global Impression of Change (PGIC) and Patient Global Impression of Severity (PGIS) measures. PGIS was collected at baseline, and PGIC/PGIS at weeks 2, 4, 6, 8, and 14.
- Responders were defined as participants achieving remission (CRP ≤5 mg/L) after initiation and maintaining remission through week 14.
- Associations between sleep and inflammatory status were evaluated using a mixed-effects model adjusting for age, sex, body mass index, and steroid use, with participant as a random effect.
- Sleep differences between responders and non-responders were assessed using a mixed-effects model also including time, responder group, and their interaction. Sixty participants contributed longitudinal wearable data.

RESULTS

- Sixty participants were followed for 14 weeks after biologic initiation.
- Awake time in bed decreased significantly at week 6 and week 14 (-2.9%, p<0.01; -3.8%, p<0.01), and sleep efficiency significantly increased at week 14 compared to pre-treatment (+3.6%; p<0.05) (n=60) (**Figure 1**).
- Participants reported significant improvements in sleep (PGIC-sleep) and fatigue (PGIC-fatigue) at each time point throughout the study (p<0.01 at week 2, 4, 6, 8, 14), with maximum reported improvement at week 14.
- There was significant interaction between time and responder status for sleep efficiency and time awake in bed. Responders (n=12) showed greater reductions in time awake in bed at week 6 and week 14 (-4.7% and -4.4%, p<0.01) and greater improvements in sleep efficiency (+5.5% and +6.4%, p<0.01) compared with non-responders (n=17) (**Figure 2**).
- During remission, participants had higher sleep efficiency, less time awake in bed, reduced light sleep, and greater deep sleep compared to inflammation periods (Δ=1.5–2%; p<0.05) (**Figure 3**).

Table 1. Demographic information for study participants

Demographics	UC (n=27) (Mean ± SD)	CD (n=33) (Mean ± SD)	Combined (n=60) (Mean ± SD)
Female Sex, (%)	17 (62.9)	15 (45.4)	32 (53.3)
Age (years)	34.7 ± 11.1	34.3 ± 10.6	34.5 ± 10.8
Time in Study (days)	116.8 ± 3.9	127.5 ± 17.8	122.7 ± 15.3

CONCLUSIONS

- Wearable-derived sleep measures differentiated responders from non-responders and distinguished active inflammation from remission.
- These findings support digital sleep biomarkers as sensitive indicators of therapeutic response and highlight their potential role in remote monitoring of IBD.

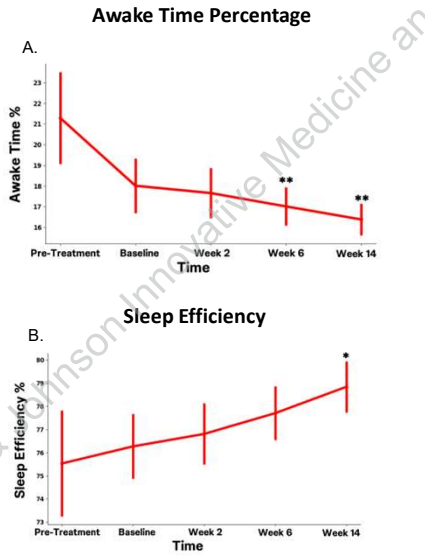

Figure 1. Trend of digital measures of sleep in all IBD participants starting from pre-treatment to end of study (n=60). (A) Awake time in bed decreased over the course of the study. Statistically significant decrease in awake time in bed was observed at week 6 and week 14 compared to pre-treatment. (B) Sleep efficiency increased over the course of the study. Statistically significant increase in sleep efficiency was observed at week 14 compared to pre-treatment *p < 0.05; **p < 0.01

REFERENCES

1. Peyrin-Biroulet L, et al. Review article: remission rates achievable by current therapies for inflammatory bowel disease. Aliment Pharmacol Ther. 2011 Apr;33(8):870-9.

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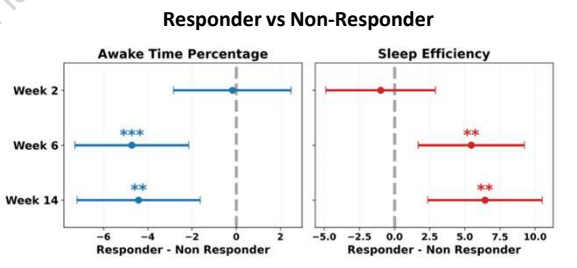

Figure 2. Differences in digital sleep measures between responders and non-responders. Responders showed a greater improvement in awake time in bed and sleep efficiency compared to non-responders at week 6 and week 14. Improvement was assessed with respect to baseline. *p < 0.05; **p < 0.01; ***p < 0.001

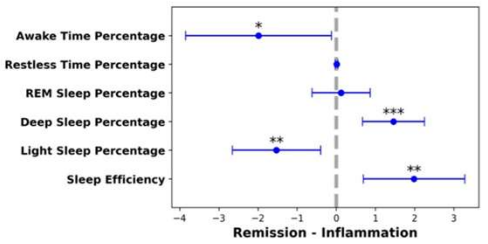

Figure 3. Compared to inflammation, participants in remission had better quality of sleep as demonstrated through higher sleep efficiency, less time awakee in bed, reduced light sleep, and greater deep sleep. *p < 0.05; **p < 0.01; ***p < 0.001

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