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Harnessing Wearable Devices and Patient-Captured Outcomes for Subjective Health Monitoring in Waldenstrom Macroglobulinemia: A Longitudinal Remote Approach is Feasible.

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Background

Waldenstrom macroglobulinemia (WM) is a rare, indolent B-cell lymphoma characterised by the overproduction of monoclonal IgM antibodies. This leads to a range of clinical manifestations, many of which significantly affect quality of life (QoL). With the development of novel targeted therapies, accurately assessing QoL is critical. Existing patient-reported outcome (PRO) measures lack specificity for WM, necessitating the creation of tailored assessment tools addressing the unique symptoms and treatment impacts experienced by WM patients.

Aims

To enhance the understanding of daily life for WM patients by remotely monitoring physical activity, sleep patterns, and QoL, to identify WM-specific metrics and explore variations across patient subgroups.

Methods

75 patients with WM provided informed consent for data capture and analysis using a CE-marked smartwatch to monitor activity, sleep, and heart rate (HR). Data were recorded via a specialised mobile app within a digital ecosystem to track QoL-linked ePROs, including EQ-5D-5L assessments and symptoms (scored 1-5). Wearable data were continuously captured, and patients input daily ePRO data. This information was integrated into a digital platform and analysed at a cohort level/across subgroups by age, sex, and treatment (patient-reported at onboarding and patient-updated through the app). A previous version of this work was presented at ASCO Breakthrough, Yokohama, Japan. Data have been extended since.

Results

The median±SD (range) age was 67±10 (43-88) years and 51% were female; 16% (12/75) receiving BTKi, 3% chemotherapy, 3% clinical trial treatment, 7% other WM medications, and 7% a combination of these treatments (multiple). Completion rates of daily ePROs over a 254-day snapshot was 49%, and for synced wearables (84%, 63/75) this was 68% for sleep and 79% for activity.

At a cohort level, patients reported a median EQ-5D-5L score of 0.796±0.188; 'Health State' of 78±19. 'Fatigue' (2.0/5) had the highest median symptom severity score. From a wearables perspective, patients recorded a median of 3,675±3,595 steps, active HR of 71±16, sleep duration of 07:25:00±01:56:12, and sleep HR of 61±11.

Increasing activity levels showed a statistically significant correlation with decreasing symptom severities and increasing EQ-5D scores. Similarly, sleep quality including higher sleep duration and lower wakeup counts correlated with lower symptom severity and higher EQ-5D scores. Increasing age was significantly correlated with increasing wakeup counts and duration; increasing breathlessness, weakness, and dizziness/light-headedness; and increasing usual activities and mobility disruption.

Females recorded significantly lower expended total calories (1,379 vs. 1,727, p<0.001) and durations in HR zone 0 (04:32:27 vs. 08:24:57, p<0.001), but longer in HR zones 1 (06:03:08 vs. 03:17:48, p=0.002) and 2 (00:34:34 vs. 00:10:04, p<0.001) than males. Between treatment groups, significant differences in wearable metrics were predominantly regarding heart rates and sleep disruptions (Table 1).

Table 1. Summary of statistically significant differences between treatment groups.

	Variable	BTKi	Chemotherapy	Clinical Trial	Other WM	Multiple	None	Treatment Group Comparison
Wearables | Activity	HR Zone 0	06:10:02	07:03:42	-	06:43:04	10:37:20	06:58:03	**BTKi vs. Multiple**, p=0.018 **Multiple vs. None**, p=0.033
	HR Zone 1	06:42:21	02:59:59	-	05:41:11	02:58:31	04:44:25	**BTKi vs. Multiple**, p=0.018 **Multiple vs. None**, p=0.041
	HR Zone 2	00:15:10	00:18:24	-	00:07:45	00:05:01	00:17:42	**BTKi vs. Multiple**, p=0.018 **Multiple vs. None**, p=0.041
	Steps	4,865	7,112	-	2,602	3,131	4,321	**Multiple vs. None**, p=0.041
Wearables | Sleep	Night SpO_2	97.5	-	-	96.8	-	96.2	**BTKi vs. None**, p=0.033
	Sleep Heart Rate	61	70	-	68	58	62	**Other WM vs. Multiple**, p=0.016 **Other WM vs. None**, p=0.018
	Wakeup Count	2.2	2.2	-	1.5	2.0	1.7	**BTKi vs. Other**, p=0.010 **BTKi vs. None**, p=0.030
	Wakeup Duration	00:20:30	00:17:14	-	00:13:07	00:17:29	00:16:14	**BTKi vs. Other**, p=0.010 **BTKi vs. None**, p=0.030
ePROs	Quality of Life (EQ-5D-5L)	0.722	0.871	0.676	0.847	0.724	0.800	**Chemotherapy vs. Clinical Trial**, p=0.046
	Anxiety / Depression	2.0	1.1	2.3	1.5	1.5	1.6	**Chemotherapy vs. Clinical Trial**, p=0.046

Conclusions

Our data indicate potential differences in remotely trackable metrics with age, between sexes, and treatment pathways. However, the number of patients within each treatment group is currently low. Overall, this supports the feasibility of utilising wearables and ePROs within a supported digital ecosystem to better understand patient experiences, building an underlying metric baseline in WM to expand future work with larger, more representative cohorts.