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EXPLORING SMARTPHONE-BASED DIGITAL ENDPOINTS FOR RHEUMATIC CONDITIONS

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Background: The care of rheumatic diseases is currently episodic, based on visits every 3-6 months at the rheumatologist, which may fail to characterize the condition state. To address this issue, the research community is investigating ways to use smartphones and sensors to monitor conditions passively.

Objectives: Explore associations between smartphone-generated data, standardized functional tests, and Patient Reported Outcome Measures (PROMS) to support the creation of digital endpoints.

Methods: Participants from Portugal and Austria participated in a Data Collection that included: (i) physical activities, such as walking with a smartphone in the pocket; (ii) hand dexterity exercises, such as copying text sentences with the smartphone keyboard; (iii) downloading and processing sociability data from the participants' smartphone; (iv) performing functional tests, such as Moberg Pickup Test (Moberg) and Timed Up-and-Go (TUG); and (v) answering validated PROMS, such as MD-HAQ, EQ-5D-5L, and visual analogue scale (VAS) for pain, fatigue, and disease activity. Statistical analysis focused on the correlation between smartphone-collected data and functional tests or PROMS, and independent t-test for between-group comparison.

Results: We collected data from 59 participants (76% female, 24% male). From this set, 31 were patients diagnosed with osteoarthritis (45%), rheumatoid arthritis (26%), or psoriatic arthritis (29%). The remaining 28 were age-matched healthy controls. In terms of age, 17% of participants were under 41 years old, 52% were between 41 and 60, and 31% were 61 or older. Most patients reported stiffness or pain in the upper (90%) and lower (83%) parts of the body. Subjective health status was high (M=77.95, SD= 16.31) in the VAS of EQ-5D-5L. Independent t-tests (Table 1) showed significant differences between patient and control groups regarding Mobility (M= 1.90, SD= 0.77), Pain/Well-Being (M= 2.48, SD= 0.81), and Mental Health (M= 1.68, SD=0.83) with higher difficulty levels reported by rheumatic patients compared to controls. Rheumatic patients also rated worse in HADS anxiety (M= 5.90, SD= 3.74) but not depression. We found significant differences between patients and controls in the variability of key pressing time (ms), with less variability among patients than controls (M= 30.71, SD= 11.99). The inter-key typing time was lower in participants below 50 years than above. A moderate correlation was found between the number of character deletions and the Moberg test (r= 0.44, p = 0.02) in patients with hand joint pain. Regarding Mobility associations, TUG total time (s) was positively correlated with the number of total steps (r=0.81, p <.001), the average duration (s) of each step (r= 0.35, p <.001), the average speed (m/s) of walking (r= -0.92, p <.001), as well as the standing up (r= 0.59, p <.001) and sitting down (r=0.55, p <.001) times (s).

Table 1. – Group comparison through independent t-test applied to some of the collected variables.

Dimension	Variable	Significance	Effect Size (d)	Patient Group (mean±SD)	Control Group (mean±SD)
Functional and disease assessment (EQ-5D-5L)	Mobility	0.018	-0.63	1.90±0.77	1.32±0.77
	Self-Care	0.981	-	1.39±0.76	1.39±1.10
	Daily Activities	0.116	-	1.71±0.78	1.36±0.91
	Pain/Well-Being	<.001	-1.02	2.48±0.81	1.68±0.82
	Mental Health	0.014	0.39	1.68±0.83	1.25±0.59
Mental health (HADS)	Subject H. Status	0.200	-	75.10±16.31	81.22±19.67
	Anxiety	0.005	-0.68	5.90±3.744	3.75±2.40
TUG	Depression	0.124	-	3.83±3.10	2.43±3.75
	Standing time (s)	0.001	-0.72	1.26±0.364	0.98±0.24
	Sitting time (s)	0.045	-0.53	2.215±0.922	1.80±0.58
Moberg	Avg. number of steps in curves	0.035	-0.56	3.419±0.847	2.93±.90
	Dominant hand time (s)	0.004	-7.20	19.813±6.21	15.856±4.58
Transcriptions	Key pressing time variability (ms)	0.005	0.78	30.71±11.99	22.996±7.71

Conclusion: Data collection with smartphone appears to have face, construct and discriminative validity, able to support future trials in patients with rheumatic diseases, to validate smartphone-based data vs objective measures of disease activity and quality of life over time.

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THE GLUCOCORTICOID TOXICITY INDEX-METABOLIC DOMAINS: AN ABRIDGED VERSION OF THE GLUCOCORTICOID TOXICITY INDEX

Keywords: Outcome measures

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Background: Measurement of glucocorticoid (GC) toxicity is critical to efforts to reduce it. In clinical trials, the Glucocorticoid Toxicity Index (GTI)[1] measures toxicity effectively using two scores, the Cumulative Worsening Score (CWS) and the Aggregate Improvement Score (AIS). In clinical practice, high patient volumes limit time available to perform the full GTI. An abbreviated GTI version – the GTI-Metabolic Domains (GTI-MD) – may address this issue by including only data that are collected routinely at clinic visits, requiring no additional physician time. The GTI-MD includes four domains: Body Mass Index, Glucose Tolerance, Blood Pressure, and Lipid Metabolism.

Objectives: We evaluated the correlations between the GTI-MD, overall GTI scores, and the remaining GTI domains to determine if the GTI-MD differentiates patients effectively according to GC toxicity.

Methods: We used data from ADVOCATE[2], a phase 3 trial in which avacopan replaced a standard GC taper in ANCA-associated vasculitis, to test the correlation of the GTI-MD with overall GTI scores. We evaluated the ability of the GTI-MD to differentiate the treatment groups by GC toxicity, comparing GTI-MD scores between groups at weeks 13 and 26.

Results: The abilities of the full GTI domains to differentiate the treatment groups according to GC toxicity have been reported[3]. The Spearman rank correlation coefficient for the GTI-MD CWS with GTI CWS was 0.78 (p<0.0001). The corresponding correlation for the AIS was 0.73 (p<0.0001). The GTI-MD distinguished the two groups by GC toxicity at both 13 and 26 weeks (Table 1). The mean GTI-MD CWS was lower in the avacopan group, consistent with less toxicity (15.9 versus 23.0 at 13 weeks [p=0.001]; 26.7 versus 31.7 at 26 weeks [p=0.009]). The GTI-MD AIS values were also consistent with less toxicity in the avacopan group (2.5 versus 13.0 at 13 weeks [p=0.0003], 4.4 versus 10.1 at 26 weeks [p=0.03]). Contributions of the four GTI-MD domains were balanced (Figure 1). A GTI-MD score of zero correlated with low toxicity in other domains.

Table 1. Differentiation of the two treatment groups in ADVOCATE by glucocorticoid toxicity, as measured by the Glucocorticoid Toxicity Index-Metabolic Domains.

GTI-MD Score	Week	Treatment Group	N	Mean Score	Standard Deviation	P-value
AIS	13	Avacopan	160	2.5	23.4	0.0003
		Prednisone	161	13.0	27.3	
	26	Avacopan	154	4.4	25.7	0.03
Prednisone	153	10.1	26.1			
CWS	13	Avacopan	160	15.9	15.7	0.001
		Prednisone	161	23.0	19.2	
	26	Avacopan	154	26.7	20.1	0.009
Prednisone	153	31.7	20.3			

GC, glucocorticoid; GTI-MD, Glucocorticoid Toxicity Index-Metabolic Domains; AIS, Aggregate Improvement Score; CWS; Cumulative Worsening Score