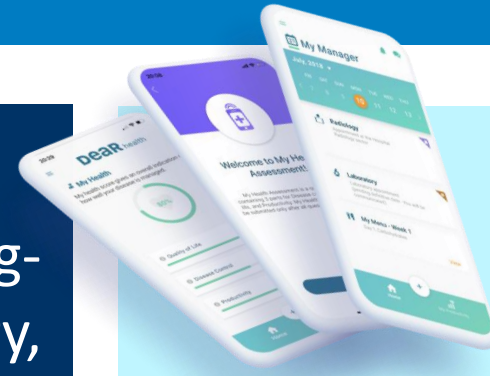


Predictive Value of a Patient-Reported Outcome Measure in Different Risk Groups in Inflammatory Bowel Diseases: Six-Month Outcomes of a Prospective Cohort Study

Introduction

Patients with inflammatory bowel disease (IBD) require long-term, intensive care. To optimise future healthcare delivery, identifying patients suitable for remote monitoring is crucial. Patient-reported outcome measures integrated within eHealth systems, such as the 4-item Mobile Health Index (mHI)¹, offer potential for predicting disease activity. This study explores the predictive value of the mHI within the e-health system DEARhealth² at a Dutch university medical centre.



eHealth System

This multi-center prospective cohort study tracked IBD patients within the e-health system. Patients were categorized into high-, intermediate-, and low-risk groups based on current and past biochemical disease activity. High-risk patients had current biochemical disease activity (FCP > 150 µg/g and/or CRP > 5 mg/L), intermediate-risk patients were in remission but experienced a biochemical flare within the last three years, while low-risk patients had been in biochemical remission for at least three years. A personalized care pathway, considering both risk group and medication usage, dictated the frequency of outpatient visits and lab tests.

Aims and Methods

Over a 12-month period, patients are monitored according to standard of care (biochemical disease activity; endoscopic disease activity) and with mHI scores at both pre-defined time points and patient-initiated moments. These preliminary results focus on assessing the predictive value of a mHI score above a validated cut-off value¹ at baseline for predicting a flare within six months in the group of patients in biochemical remission. Sensitivity, specificity, and predictive values are calculated alongside simple logistic regression and Kaplan-Meier analyses

Table 1: Baseline Characteristics

	Total n = 319	Biochemical Disease Activity		p-value
		Remission n=230	Active n = 89	
Age at inclusion (y)	43 [33 - 57]	44 [34-59]	42 [32 - 54]	0.08
Sex (female)	173 (54.2)	124 (53.9)	49 (55.1)	0.85
IBD type (CD)	181 (56.7)	134 (58.3)	47 (52.8)	0.38
Smoking (smoker)	30 (11)	23 (11.7)	7 (9.1)	0.68
Disease duration (y)	15 [8 - 26]	16 [9 - 26]	14 [7 - 22]	0.08
CRP	1.7 [0.8 - 4.5]	1.3 [0.7 - 3.4]	3.4 [1.2 - 8.2]	<0.01
FCP	60 [20 - 242]	31 [14 - 97]	283 [161 - 1409]	<0.01
mHI-score above cut-off point	99 (32.5)	51 (23.0)	48 (57.8)	<0.01
CD-mHI	59 (33.0)	32 (24.4)	27 (56.3)	<0.01
UC-mHI	40 (31.7)	19 (20.9)	21 (60.0)	<0.01

Data are presented as median [interquartile ranges] or as frequencies (n) and percentages (%). y = year; CD = Crohn's Disease; CRP = C-reactive protein; FCP = Faecal Calprotectin; UC = Ulcerative Colitis; mHI = mobile Health Index.

Table 2: Predictive Value of Baseline mHI Above Cut-off for Disease Activity

	Diagnostic Metrics				
	RR (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Ulcerative Colitis	2.44	24.1	82.4	40.0	83.6
Crohn's Disease	1.62	38.5	73.4	14.7	90.0

RR = Relative Risk; PPV = Positive Predicting Value; NPV = Negative Predicting Value

Results

Study Cohort

- 230 patients in remission at baseline
- 79 (34.3%) experienced a biochemical flare-up within six months

Predictive value of the mobile Health Index score

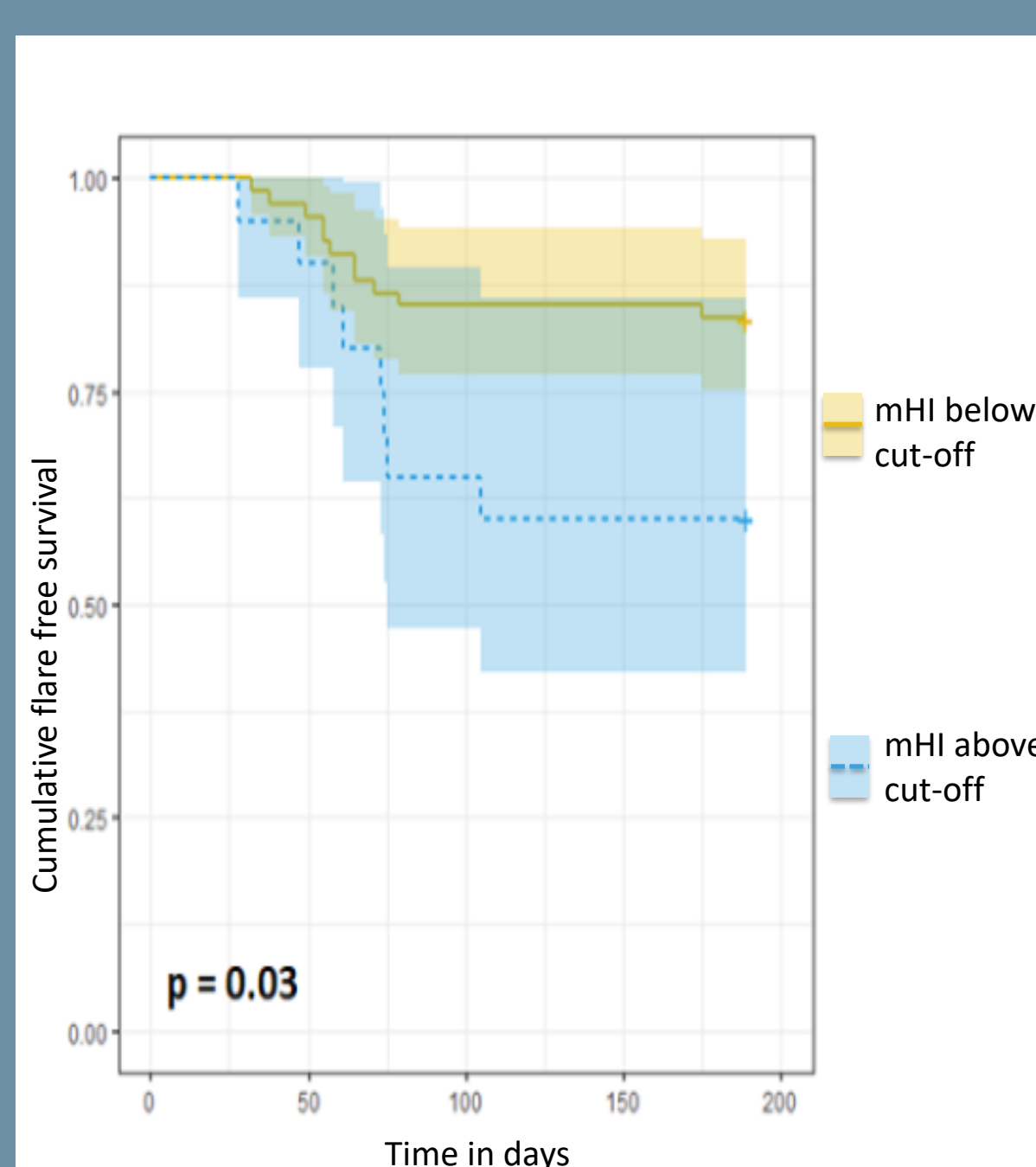
Ulcerative Colitis

- Patients with a baseline mHI score above the cut-off are 2.44 times more likely to experience a flare within six months compared to those with a score below the cut-off (p = 0.04)
- Significant association of mHI score above cut-off with disease flares (OR = 3.394; 95% CI: 1.110-10.330; p = 0.03)
- Longer flare-free survival with mHI score below cut-off (p = 0.03)

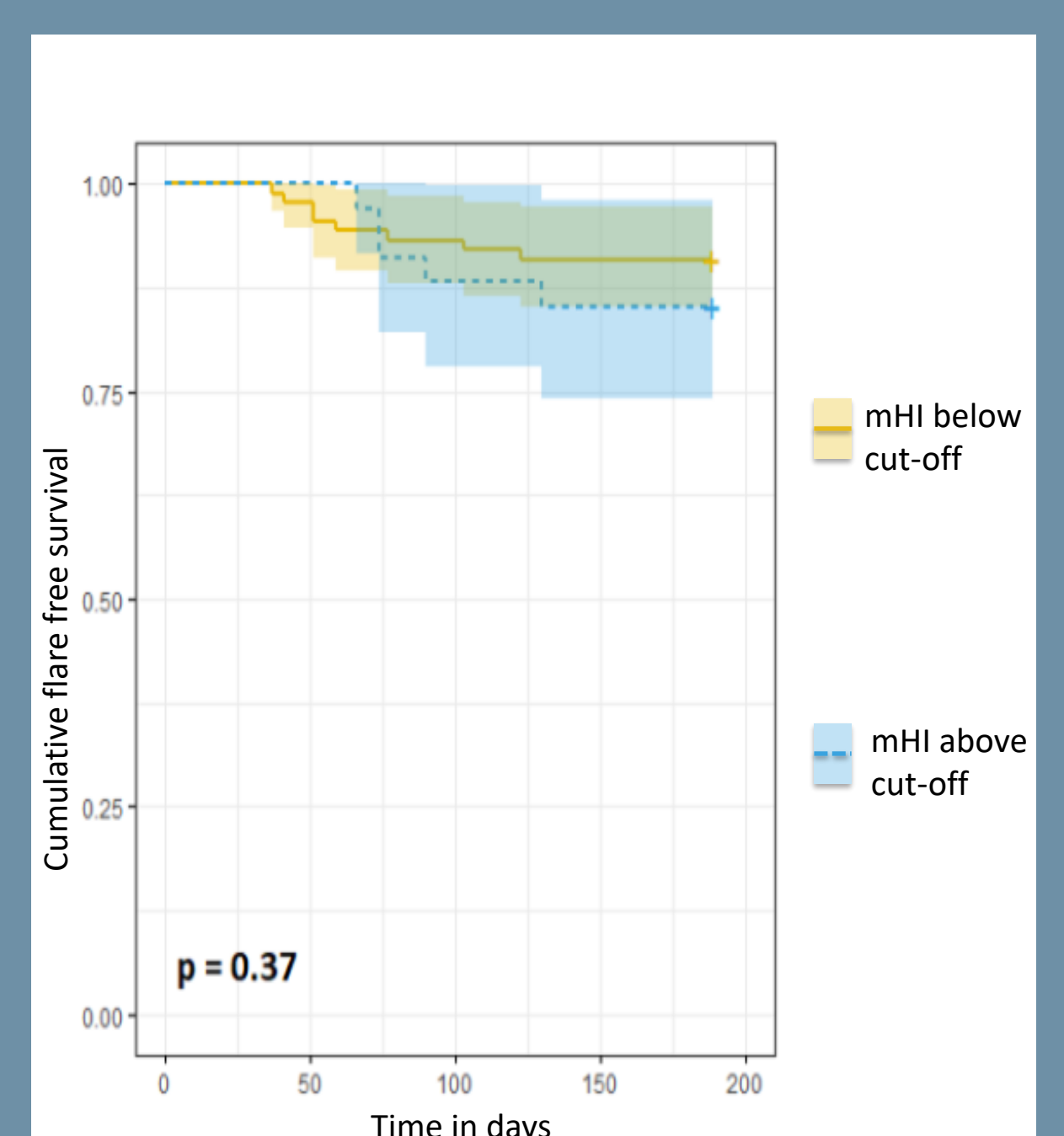
Crohn's Disease

- Patients with a baseline mHI score above the cut-off are not significantly more likely to experience a disease flare within six months compared to those with a score below the cut-off (RR: 1.62; p = 0.39)
- No association of mHI score above cut-off with disease flares (OR = 1.724; 95% CI: 0.487-5.603; p = 0.37)
- No significant flare-free survival with mHI score below cut-off (p = 0.14)

Ulcerative Colitis



Crohn's Disease



Conclusion

The mobile Health Index could be a valuable tool for predicting disease activity, and particularly quiescent disease, in UC patients.

These results underscore the potential utility of mHI in enhancing the management of IBD patients, with implications for personalized care and resource allocation within healthcare systems.

Further aims: The study will follow patients for a year to develop a personalized prediction model, exploring repeated mHI measurements and the addition of CRP and FCP. Moreover, the potential improvement of PPV and NPV over a 2-month versus a 6-month period will be investigated.

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