HOME vs HOSPITAL-BASED ANALYSIS OF STOOL CALPROTECTIN

COMPARISON OF TWO DIAGNOSTIC METHODS FOR MONITORING INFLAMMATORY BOWEL DISEASE

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BACKGROUND AND AIM

Fecal **calprotectin** measurements are increasingly used to monitor patients with **inflammatory bowel diseases**. Recently a **home-used lateral flow-based rapid test** for the analysis of stool calprotectin was launched. It comes together with an application (IB*Doc*®, BÜHLMANN Laboratories AG, Switzerland) that turns an ordinary **smartphone** camera into a reader for quantitative measurements.
We compared the new IB*Doc*® method with the established enzyme-linked immuno sorbent assay (ELISA) to assess the agreement between the two.

METHODS

Eligible teenagers and adults, who had a smartphone validated for the IB*Doc*® app, received an instruction manual to perform the calprotectin stool test at home (**Figure 1**). The residual of the stool specimen was sent to the hospital for ELISA measurement (BÜHLMANN Laboratories AG). We assessed agreement by Bland-Altman plot and evaluated concordance between our clinically relevant calprotectin ranges (<250, 250-500, >500 µg/g). Predefined acceptable limits of agreement were ±100 µg/g in the lower range of calprotectin and ±200 µg/g in the higher range.

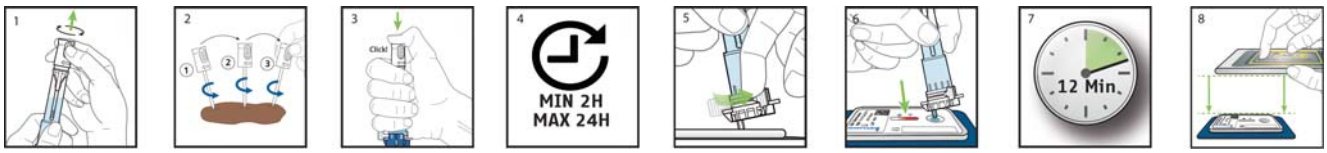

Figure 1: IB*Doc*® procedure

CONCLUSION

We found sufficient agreement between IB*Doc*® home test and hospital-based ELISA in the lower ranges of calprotectin to use this new test for disease monitoring. We suggest that ELISA confirmation of positive IB*Doc*® findings is done before therapy adjustment is considered. We expect that misclassification will reduce when patients receive face-to-face training of an expert before the first IB*Doc*® measurement.

RESULTS

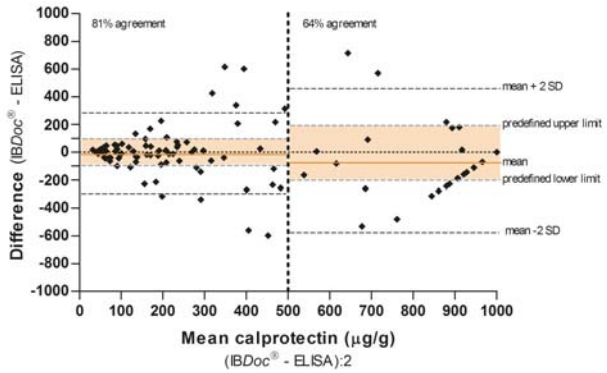

Figure 2: Bland-Altman plot showing difference against mean

We analyzed **152 paired samples**. We found 81% agreement (100 of 124 samples) in the lower range of calprotectin and 64% (18 of 28 samples) in the higher range (**Figure 2**).
The concordance between methods is presented in **Figure 3**. 108 of 152 test pairs (71%) were concordant. Two of six discordant test pairs, depicted in the right lower corner of were caused by one participant who did not observe the advised incubation time.

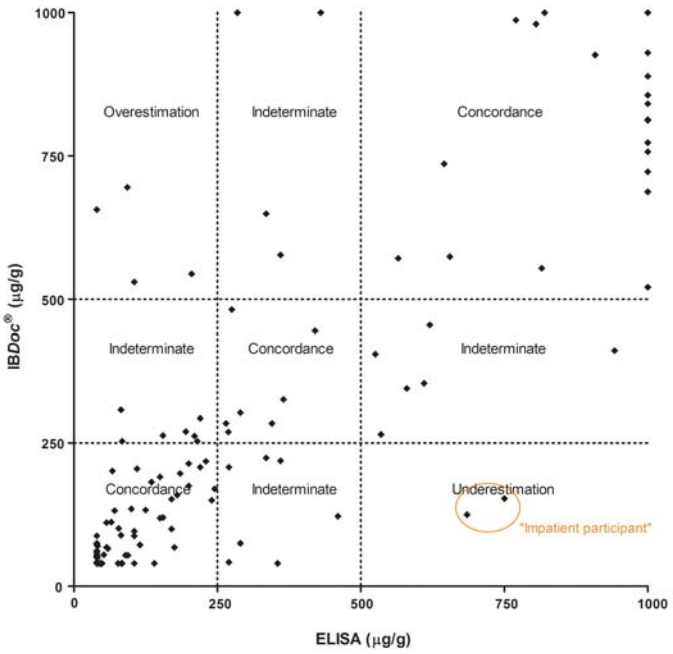

Figure 3: Scatterplot showing concordance between IB*Doc*® against ELISA results

Disclosure

This project was supported by BÜHLMANN Laboratories AG, producer of both the IB*Doc*® method and the ELISA assay used in this study. BÜHLMANN did not have a role in the design, execution, analyses, and interpretation of the data, or in the decision to submit the results.

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