Home-testing of faecal calprotectin using the IBDoc™ system: a comparative pilot study

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Introduction

Faecal calprotectin (FCAL) is a useful test for monitoring of inflammatory bowel disease (IBD) activity. Providing a stool sample in person to the hospital laboratory is an anecdotally unpopular method with poor uptake. A new FCAL kit (IBDoc™, Bühlmann) enables self-testing using a proprietary collection tube, camera smartphone and app. The aim of this study was to assess patient's adherence to, and experience of, a testing regimen using IBDoc™, as well as benchmarking the assay to the standard laboratory test.

Methods

After focussed training, participants were asked to test using IBDoc™ (fig 1) once a month for four months and provide a standard stool sample which was posted to the hospital laboratory overnight and refrigerated on receipt, to be tested with standard ELISA (Bühlmann). The following questionnaires were applied before and after testing: GAD-7 (anxiety), PHQ-9 (depression), IBD-control-8, Multi-dimensional Health Locus of control (MHLC) and Cognitive Behavioural Responses to Symptoms (CBSRQ). Patients were also asked to record their experiences and preferences for testing on a proprietary questionnaire.

Sample kits were provided FOC by Alpha Laboratories, UK and the project was supported by an unrestricted grant from AbbVie, UK. REC reference 15/WA/0168.

Results

54 consecutive patients (Crohn's: 23, UC: 31, F=28, mean age 36.0 ± 9.2 yrs) were enrolled. Participants completed a median of 3 tests (0-4) during the study with 19/54 (35%) completing all four set time points and 17/54 (32%) returning no samples, despite active reminders. There was no difference in any of the questionnaire scores between compliant and non-compliant patients.

There was moderate correlation of numerical FCAL results between the two methods (r=0.77, 95%CI 0.68-0.84, p<0.0001, fig. 2). Categorising results into disease activity categories (no inflammation [1], mild [2], moderate [3], severe [4]) produced a similar result (weighted κ= 0.57, p<0.0001, fig. 3).

63% of respondents stated a preference for IBDoc™, but stated that (in a routine clinical scenario) they would require timely contact from the hospital team in the event of an abnormal result (24-72 hours). A further 22% of patients preferred the IBDoc™ test, but stated that they would not require contact until their next scheduled appointment.

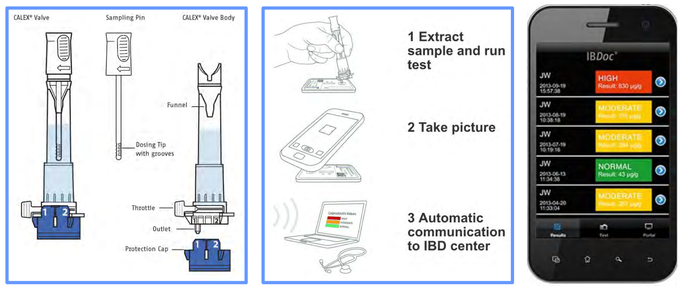

Figure 1. *Components and schematic of the IBDoc™ test.* The proprietary Calex™ valve tube is used to collect and prepare a sample for analysis. A predetermined volume is applied to a calibrated test reading strip which is imaged by the App, generating a result which is communicated immediately via web portal to the team.

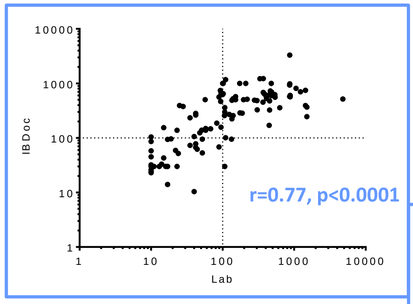

Figure 2. *Numerical correlation of Lab to IBDoc™ tests.* Dotted lines at calpro 100µg/g ('no inflammation').

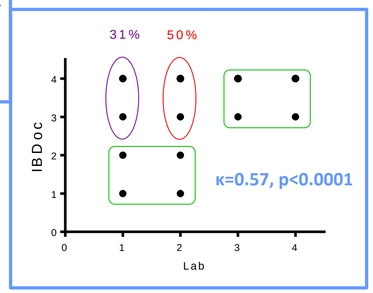

Figure 3. *Categorical correlation of Lab to IBDoc™ tests.* Lilac and red circle denotes data points at which the lab test result was either no or mild inflammation, respectively, while IBDoc™ showed moderate or severe. Green: categorically concordant.

Discussion

While there was good correlation at the upper and lower margins, a significant proportion of discordant results were obtained which, in a clinical scenario, might have led to a treatment change. It is not clear from our current data which test is more predictive, and while the lab test has been subject to over a decade of clinical validation, pre-analytic factors may have affected these results.

Conclusions

There was reasonable uptake and adherence to a demanding testing regimen (more frequent testing than might be required in routine clinical care) **with 85% of respondents preferring the IBDoc™ test over other methods**. While this is a promising and popular technology, further studies are warranted to correlate results to clinical outcomes and gauge workload impact, in a treatment pathway.