Home testing for faecal calprotectin: follow-up results from the first UK trial

King's College Hospital NHS Foundation Trust

Johanna Raker, Charlotte Ford, Polychronis Pavlidis, Lucy Medcalf, Lee Meng Choong, Guy Chung-Faye, Patrick Dubois, Bu'Hussain Hayee

Introduction

Faecal calprotectin (FCAL) is a useful test for monitoring inflammatory bowel disease (IBD) activity.

Providing a stool sample in person to the hospital laboratory is anecdotally unpopular.

A new FCAL kit (IBDoc™, Bühlmann) enables self-testing using a proprietary collection tube, camera smartphone and app.

The aims of this study were to:

- assess patients' adherence to and experience of using IBDoc™
- compare the assay to the standard laboratory test
- determine if IBDoc™ can be used to predict a flare of IBD within four months.

Methods

Patients tested stool using IBDoc™ (figure 1) once a month for four months and provided a standard stool sample to be tested with standard ELISA (Bühlmann).

The following questionnaires were completed 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 asked to record their experiences and preferences for testing on a proprietary questionnaire.

Electronic records were retrospectively reviewed to assess FCAL as a predictor of a flare. An FCAL of > 100 µg/g was defined as a positive result.

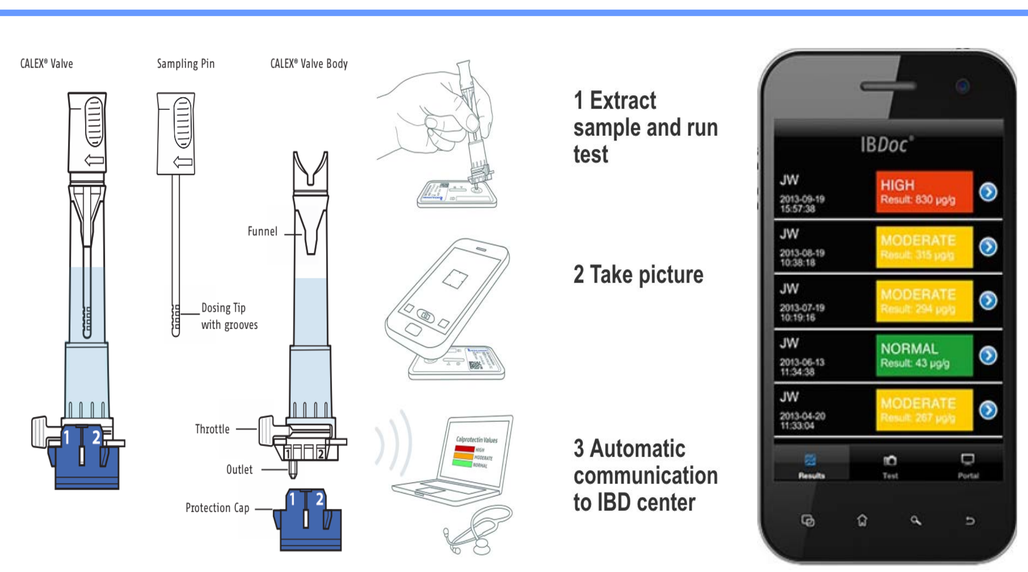

Figure 1. *Components and schematic of the IBDoc™ test.* The proprietary Calex™ valve tube is used to collect and prepare a sample for analysis. A predetermined volume is applied to a calibrated test reading strip which is imaged by the App, generating a result which is communicated immediately via web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

Results

54 consecutive patients (Crohn's: 23, UC: 31, F=28, mean age 36 years) were enrolled.

Participants completed a median of 3 tests during the study with 35% completing all four set time points and 32% returning no samples.

There was no difference in any of the questionnaire scores between compliant and non-compliant patients.

Overall, 85% of respondents stated a preference for IBDoc™ of which 74% would want this to be in the context of prompt contact from the hospital team in the event of a positive result.

There was moderate correlation of FCAL results between the two methods (r=0.47, p<0.0001 (fig 2)).

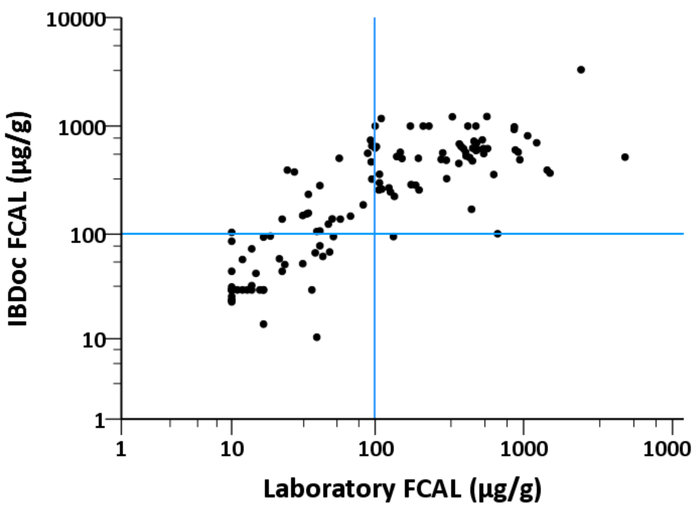

Figure 2. *Correlation of Lab to IBDoc™ tests.* Blue lines at cut-off for positive test (100µg/g).

37 patients had at least one paired IBDoc™ and laboratory FCAL result, of which 30 were in remission at the time of the test. To predict a flare within four months IBDoc™ showed greater sensitivity than the laboratory test but a low specificity (table 1).

Table 1. *Sensitivity and specificity of IBDoc™ and lab FCAL.*

	Sensitivity	Specificity	NPV
IBDoc™	89%	33%	88%
Laboratory	78%	57%	86%

Conclusions

Home faecal calprotectin testing demonstrated acceptability with patients, with 85% preferring this to other methods.

While IBDoc™ showed only moderate correlation to laboratory FCAL, a negative FCAL of < 100 µg/g by either method is a useful test to exclude a flare within four months.

Positive results should be interpreted with caution and repeat testing may be advisable prior to treatment escalation.