Does extraction of faeces by the patient at home impact on the precision of faecal calprotectin analysis?

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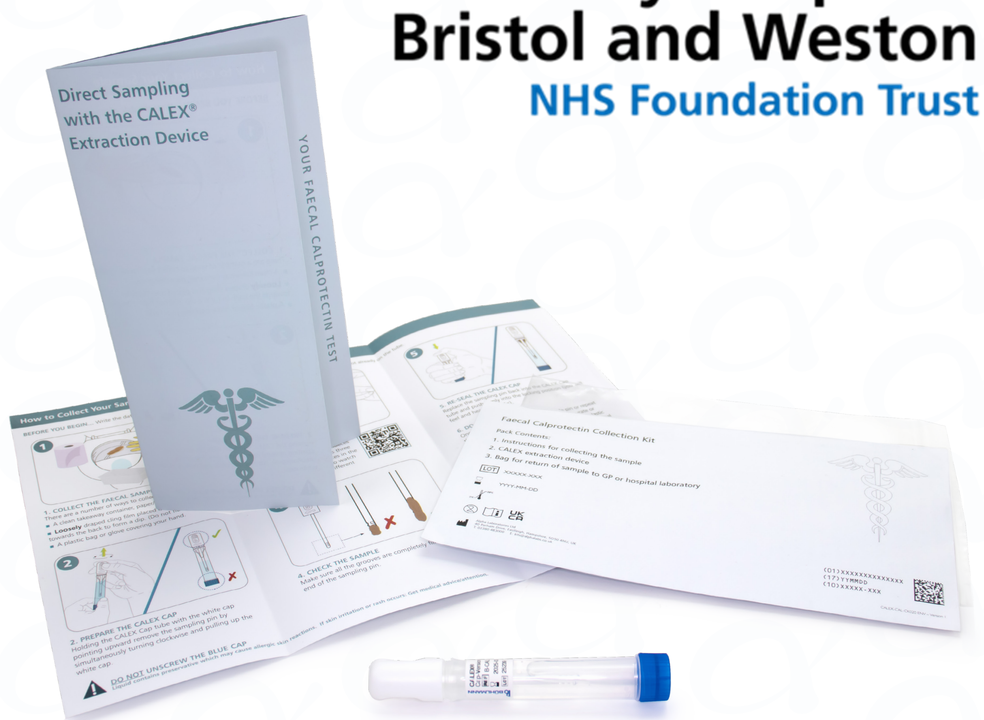

Introduction

Calprotectin, a protein released by neutrophils during an inflammatory response, is detected in faeces of patients with inflammatory bowel diseases (IBD). Measurement of faecal calprotectin (FC) is used for screening and monitoring of IBD. Analytical methods for FC require extraction of calprotectin from faeces, typically performed in clinical laboratories by trained technicians. The introduction of simple devices for faecal extraction not requiring accurate weighing (e.g. BÜHLMANN CALEX® tube) has recently allowed patients to extract the faeces themselves. Measurement of FC suffers from poor reproducibility, even in experienced hands. It is unknown whether performing faecal extraction outside of a laboratory would worsen precision. This study attempted to answer this question.

Methods

Packs containing 2x CALEX tubes, a stool-pot and instructions were distributed to 47 patients attending IBD clinic at Bristol Royal Infirmary. FC was measured by the BÜHLMANN ELISA method, with reportable range of 30-1800 μg/g. Within the lab, faecal pools are extracted with every batch for quality control (QC) purposes. The coefficient of variation (CV_a=SD/mean) was calculated for duplicate patient extractions and for lab extracted faecal pool QC. Patient and lab extracted CV was compared by Wilcoxon-Mann-Whitney test.

Results

CALEX tubes were returned by 32 patients. 10 had at least one FC result outside the reportable range, such that the CV_a could not be calculated. CV_a for the remaining 22 duplicate patient extractions and for 23 lab extracted faecal pools over the last 2 years are shown in Figure 1. There was no statistically significant difference between patient and lab extracted CV_a: median 19% and 22%, p=0.204. The spread of CV_a was greater for patient extracted (0.1 – 44%) than lab extracted (5.3% – 36%). Repeat analysis of extract QC gave CV_a of 7.4% and 9.5%.

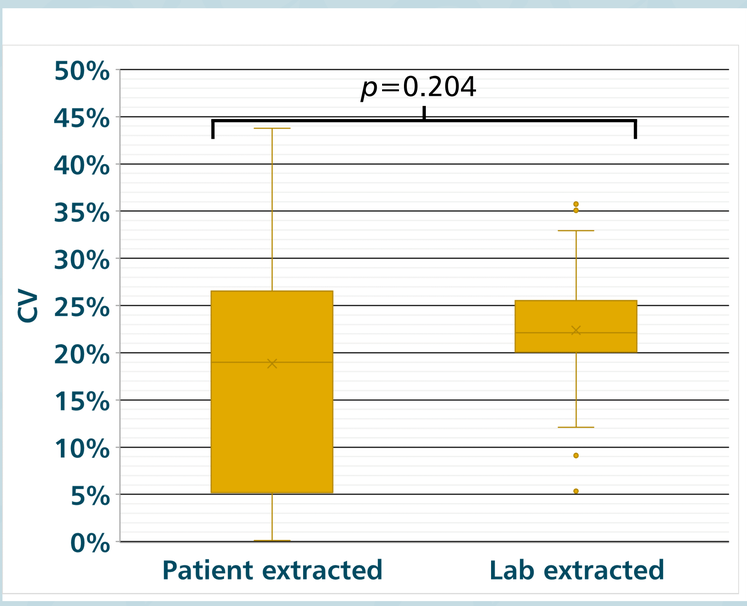

Figure 1: Box and whisker plot of CV_a for duplicate patient extracts and lab extracted faecal pools.

Discussion

Our data demonstrate that CV_a for duplicate patient extractions is variable, but on average of similar magnitude to CV_a for faecal extraction obtained by trained lab technicians. The ELISA step itself has a lower CV_a. This confirms that poor reproducibility of FC analysis is from the faecal extraction step itself; however, the identity of the person performing it makes no difference.

In conclusion, patient extraction of faeces for FC analysis is workable and does not adversely impact on result precision.