Home based fecal calprotectin testing: a Canadian user performance evaluation study of IBDoc®

BACKGROUND _______________________
• Fecal calprotectin (FC) is a stool biomarker that has previously been shown to be sensitive and specific for mucosal inflammation in patients with Inflammatory Bowel Disease (IBD) (1).
• FC is useful to diagnose or monitor IBD activity, although the test is limited by the requirement for patients to collect and return stool samples.
• Previous study showed sample return rate of 78% (2). Therefore, a home based FC test may improve patient adherence and the sample return rate.

OBJECTIVE __________________________
• Determine the usability of a FC home kit (IBDoc®)
• Determine the comprehensibility of instructions provided to an independent non-healthcare professional

METHODS __________________________
• Included participants were ≥19 years of age, diagnosed with IBD (ulcerative colitis or Crohn’s disease) and at least 30% of participants demonstrated active disease (defined by Harvey-Bradshaw Index (CD) >5 or partial Mayo score (UC) >2).
• Participants with acute, severe diarrhea or chronic use of non-steroidal anti-inflammatory drugs were excluded.
• Participants were given a demonstration at the clinic on how to use the FC kit to assay their stool extract at home.
• Participants completed the IBDoc® kit as well as provided samples to be used by study coordinator for comparative ELISA measurement.

CONCLUSION _______________________
• The IBDoc® test kit was understood by participants, with a majority of participants finding it easy to use, with an understandable display and a product that they are likely to use in the future.
• FC measurements obtained by participants using the IBDoc® were strongly correlated with the standard FC ELISA measurements.
• Further studies are needed to determine whether patients will continue to use it outside of a clinical trial setting and whether it will positively impact patient care for those with known or suspected IBD.

RESULTS __________________________
• Total of 61 participants were enrolled in the study with 34% (21) being male with an average age of 34.8 +/- 9.0 years.
• 97% (59/61) agree that they understand the instruction of the app with 80% (49/61) strongly agreeing, giving an average rating of 4.8 +/- 0.50, suggesting that a majority of participants understood the instructions.
• 77% (47/61) participants agree that they understand the way the result is displayed with 59% (36/61) of participants strongly agreeing with an average rating of 4.3 +/- 1.1.
• 78% (48/61) agree that the home kit is easy to use with 59% (36/61) of participants strongly agreeing with an average rating of 4.4 +/- 1.00.

Table comparing FC values from patient IBDoc® and ELISA reference measurement

No false positives or negatives

Table comparing FC values from ELISA reference measurement and patient prepared ELISA reference measurement

No false positives or negatives

Total Target Agreement: 88 %