Poo-tentially better? Faecal calprotectin and elastase stability in different sample collection devices and a trial of at home patient-led extraction.

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Background

Stool analysis for biomarkers such as faecal calprotectin and elastase provides a non-invasive tool to investigate the condition of a patient's digestive health and help diagnose disease, such as inflammatory bowel disease and pancreatic insufficiency respectively.

Delay in the receipt or processing of stool samples in the current way (a sample in a brown top stool container) could potentially lead to false results. Faecal calprotectin could degrade and so produce falsely low results therefore providing a false exclusion of IBD in unknown patients and false reassurance for both the patient and clinician in known patients being monitored.

Delay in sample processing for faecal elastase on the other hand can give a falsely low result which may lead to inappropriate treatment with costly enzyme replacement therapy.

Aims

- Determine faecal calprotectin and elastase stability in various sample collection devices at room temperature over 7 days

-Faecal calprotectin: Brown stool pot, Calex extraction device and Werfen extraction device

-Faecal elastase: Brown stool pot and Calex extraction device

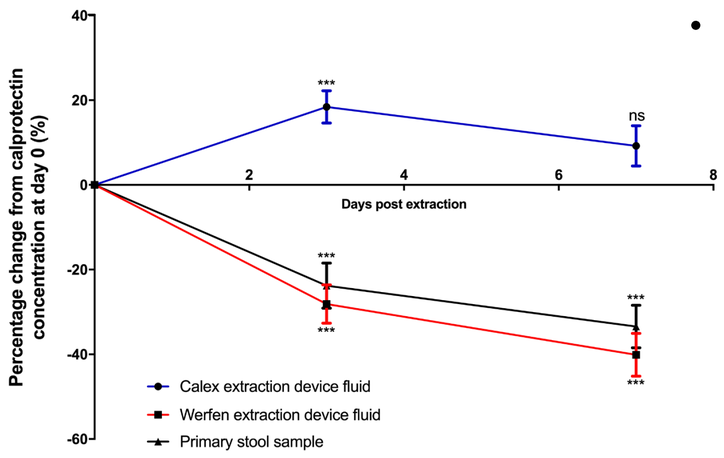
- Trial patient led at home faecal calprotectin extraction

-Can patients extract as well as laboratory staff

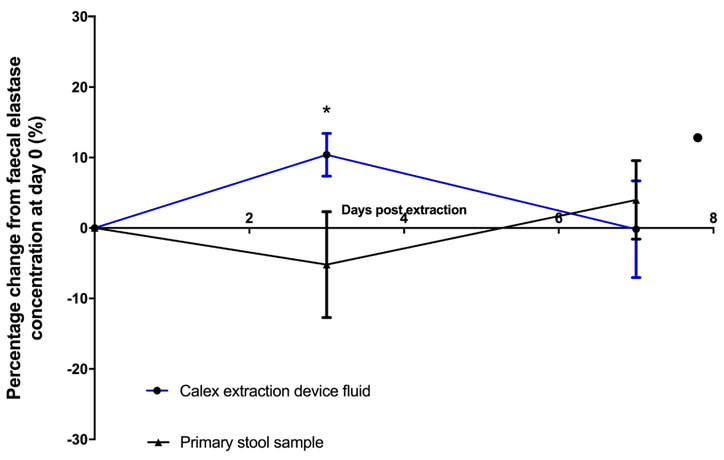
-Determine patient acceptability of alternative collection devices

Collection device from left to right: brown standard stool pot, Calex device, Werfen device

Faecal markers stability at RT



- Faecal calprotectin stability in current brown top pot and extraction devices for 2 different calprotectin assay: Inova QUANTA flash (Werfen device) and BÜHLMANN fCAL turbo (Calex device). Increase in fCAL in Calex device presumably due to release of fCAL from white blood cells



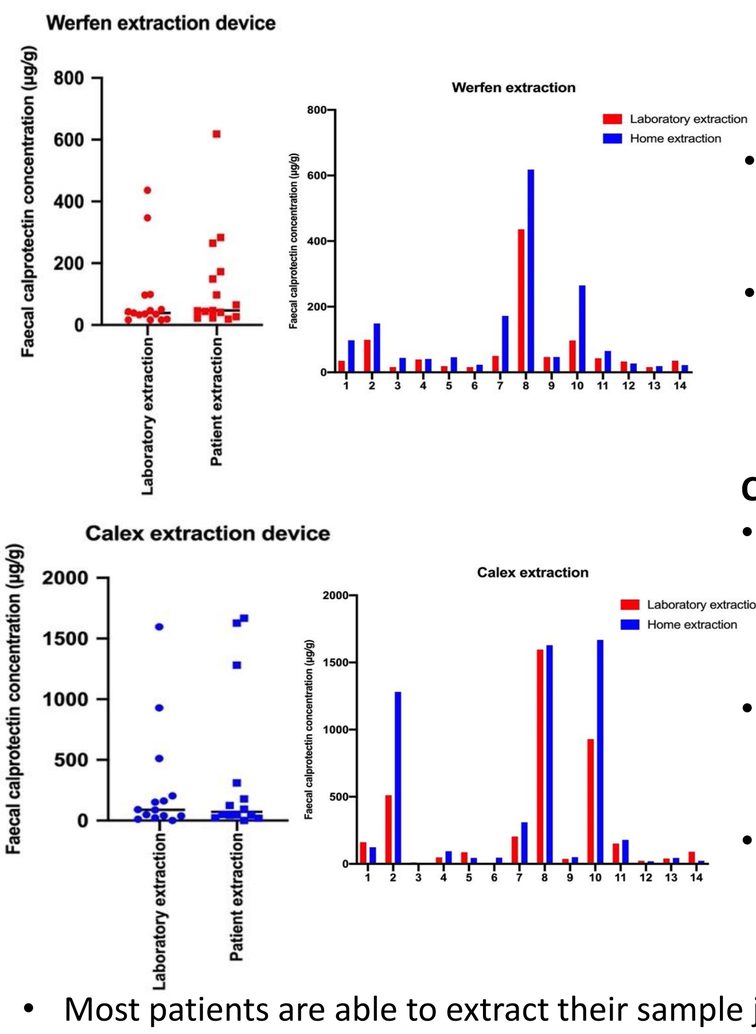
- Faecal elastase stability in current brown top pot and extraction device for BÜHLMANN fPELA turbo (Calex device)

20 patient samples. Each sample homogenised and the primary sample extracted into each sample collection device. The primary sample and extracts are measured immediately after extraction (day 0) and at day 3 and day 7. Percentage change of faecal marker concentration compared to day 0 calculated.

At home patient-led faecal calprotectin extraction trial

- Selected cohort of patients: known IBD patients
- Provided a kit with a cover letter, questionnaire and 3 sample collection devices
- Ask patients to collect the same stool sample using the three different stool collection devices
- Kits returned to laboratory where stool sample in brown top pot was extracted using additional Werfen and Calex devices and samples run on their corresponding analysers
- Faecal calprotectin values in patient and laboratory extractions were compared

- Poor return rate for kits (14/45)



Werfen extraction tubes

- 86% of samples had a higher faecal calprotectin concentration in the home extraction
- Lab extraction: mean 70 µg/g; median 37 µg/g; range: <16.1-436 µg/g
- Home extraction: mean 117 µg/g; median 47 µg/g; range: 18.8-618 µg/g

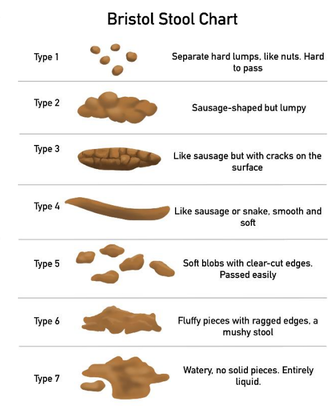
Calex extraction tubes

- 71% of samples had a higher faecal calprotectin concentration in the home extraction
- Lab extraction: mean 278 µg/g; median 89 µg/g; range: 0-1596 µg/g
- Home extraction: mean 394µg/g; median 72µg/g; range: 0-1668 µg/g

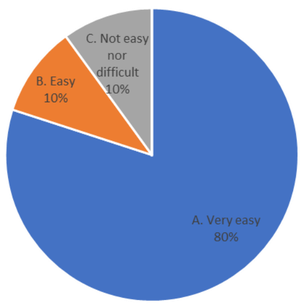
- Most patients are able to extract their sample just as well as laboratory trained staff
- In samples where faecal calprotectin concentration was higher in laboratory extracted samples the difference didn't change which management or diagnostic pathway the patient would have been entered in to

Patient acceptability

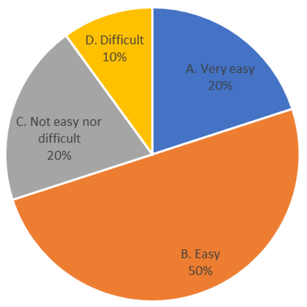
- Only 10/14 filled out the preference and acceptability questionnaire
- 50% male, 50% female
- 16-80 years old (median age: 47 years old)
- 6% of patients reported blood to be present in their stool
- 13% of patient reported mucus to be present in their stool
- Stool consistency 2-6 on Bristol stool chart



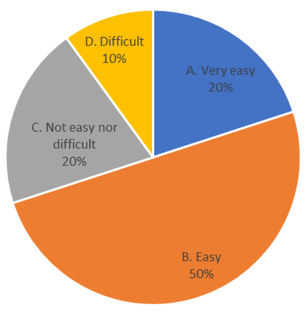
How easy or difficult did you find it to use the standard stool pot scoop to take a sample of your stool



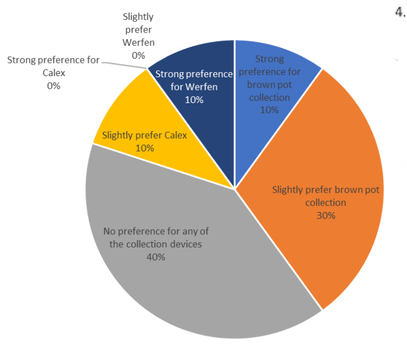
How easy or difficult did you find it to use the Werfen device to take a sample of your stool



How easy or difficult did you find it to use the Calex device to take a sample of your stool



Preference



4. Which collection tube did you prefer?
   a. **Strong preference for standard brown pot collection**
   b. **Slightly prefer standard brown pot collection**
   c. No preference for any of the test pots
   d. **Slightly prefer Calex tube**
   e. **Strong preference for Calex tube**
   f. Slightly prefer Werfen tube
   g. Strong preference for Werfen tube

Conclusions

- Potential to decrease work load in stretched laboratories by patients performing home extraction
- Significant degradation of faecal calprotectin at RT in brown stool pots and Werfen extraction devices
- Samples extracted using Calex device prevents faecal calprotectin from degrading
- Majority of patients able to extract as well as laboratory staff
- Mixed ease of use and patient acceptability for all devices
- Poor response to trial and this is possibly due to patients deeming 3 collection devices being too many
- Requires larger study to draw definitive conclusion