FIT for Purpose

Faecal Immunochemical Tests (FIT) for Diagnosis of Significant Bowel Disease

In June 2015, NICE published the NG12 guidelines and advocated the introduction of tests for “occult blood in faeces” for certain patients presenting in primary care with lower abdominal symptoms but with a low risk of colorectal cancer. This sparked much controversy regarding the different types of tests available for occult blood detection, since many hospital laboratories had discontinued the provision of guaiac-based tests and did not want to go back to this old technology with its very poor analytical and clinical sensitivity and specificity.

Whilst newer quantitative Faecal Immunochemical Test (FIT) methods have been widely introduced for bowel screening, publications on the use of this methodology in assessment of patients with lower abdominal symptoms have been increasing since 2012. Unfortunately, these had not been part of the data review for the June 2015 NG12 publication. In consequence, NICE have now reviewed the evidence for FIT in this clinical setting and are due to publish new guidelines in June 2017 entitled: “Quantitative faecal immunochemical tests to assess symptomatic people who are at low risk of colorectal cancer in primary care”.

This assessment is focused on peer-reviewed publications on quantitative FIT methods in this particular clinical setting. These publications are concerned with studies on symptomatic patients being planned or considered for colonoscopy on whom a FIT had been performed1-3. The quantitative FIT results were compared against the clinical findings. These publications identified that the FIT result could be used as a “rule out” test for significant colorectal disease (SCD), that is, colorectal cancer (CRC) plus higher risk adenoma (HRA; sometimes precursors of cancer) and inflammatory bowel disease (IBD: Crohn’s and ulcerative colitis), since they have a very high negative predictive value (NPV) for SCD. In fact, using a cut-off of <10 µg Hb/g faeces, the NPV was almost 100% for cancer and >90% for SCD.

The NICE Diagnostics Assessment Committee has published a number of documents, including the draft diagnostic guidance, on the internet: www.nice.org.uk/guidance/indevelopment/gid-dg10005/documents

Differentiating patients with serious bowel disease from those with benign functional disorders, such as irritable bowel syndrome, and minor colorectal disease such as haemorrhoids, hyperplastic polyps and simple diverticular disease, can be very challenging since the symptoms are very common and overlap in these conditions. The ability to use a simple, easy to use inexpensive diagnostic test will provide additional assistance in determining the appropriate patient pathway for further investigation. Ahead of this publication, several hospitals and CCGs have already committed to the provision of FIT as a means of triaging all patients presenting in primary (and secondary) care with lower abdominal symptoms.

The introduction of new quantitative FIT methods has also vastly improved the method of faecal sample collection. This is an important aspect of the process since the clinical outcomes are dependent on the ability of the method to detect faecal haemoglobin at very low versus undetectable concentrations.

Haemoglobin in native faeces is very unstable and degrades rapidly at physiological and ambient temperatures. In passed faeces, which contains digestive enzymes, bacteria and fungi, it will degrade even more quickly. Therefore, to protect the integrity of any haemoglobin in a faecal sample, it is vital to stabilise the haemoglobin present in the specimen collection device prior to analysis. Some FIT devices such as that used with the HM-JACKarc analytical system can ensure stability for up to 120 days at 4°C or at 14 days at ambient temperature.

Consistency of sample collection is another key consideration. Results are expressed as µg Hb/g faeces and, thus, any variation in sample size could potentially impact the clinical outcomes. The HM-JACKarc sample collection device has been specifically designed to consistently collect the same amount of faeces, irrespective of the person collecting the sample or the consistency. The unique dimpled collection probe ensures uniform sampling.

The excellent clinical outcome data demonstrated in many publications require faecal haemoglobin cut-offs for referral for further investigation at the low end of the analytical range of the available analytical systems. The choice of laboratory method is therefore important to the objective evaluation of patients not only for haemoglobin stability in the specimen collection device, but also for its low bias and small imprecision at the lower limit of the analytical working range.

Four FIT analytical systems were evaluated by the Guildford Medical Evaluations Centre (GMEC) in 2013. The resulting report is available online: http://194.97.148.137/assets/downloads/pdf/activities/fit_reports/gmec_fit_evaluation_report.pdf

In this study, the HM-JACKarc was described as one of the more precise methods and its analytical working range correlated well to the expected values of spiked faecal samples. The ability to detect haemoglobin at both the lower and higher limits of the analytical range was confirmed as was the sample stability.

References:


For more information about the HM-JACKarc FIT system and how this could help with your clinical practice, please visit www.alphalabs.co.uk/fit