Calprotectin Self-Testing Four Years On

The Benefits for Patients and Healthcare Staff of Routine IB*Doc* Use

Kathleen Sugrue, Advanced Nurse Practitioner at Mercy University Hospital, Cork

C S case study

The Mercy University Hospital in Cork is a designated Gastroenterology Centre of Excellence and has one of the largest cohorts of IBD patients in Ireland. It was the first hospital to introduce the BÜHLMANN IB*Doc*® calprotectin patient self-testing into routine practice. This was back in the summer of 2015 and after 4 years the team there has gained a wealth of experience in the value of this test for monitoring their IBD patients.

Kathleen Sugrue, the advanced nurse practitioner in IBD at the Mercy talks to us about how implementing IB*Doc* testing has positively impacted the patients and the clinic.

Historically we used an external laboratory for calprotectin testing (Biomnis). However, this was extremely expensive and we were waiting 6-8 weeks for the results. This is too long to wait for clinical decision making.

We first introduced use of the IBDoc test in the summer of 2015. After an initial trial period it was rolled out to all IBD patients that have compatible phones for reading the results. There are now over 50 devices that support the CalApp® and so we now have over 650 patients that are regularly using the system.

All initial patient screening tests are now performed in our own laboratory, since calprotectin has been introduced in-house. This is using the BÜHLMANN fCAL turbo assay which has the advantage of being standardised with IBDoc. Once a patient has been diagnosed we would hope to get them onto the IBDoc system for monitoring. However, we don't have funding for all patients and there are some that don't have compatible phones, so we still use the lab as a fall back for these patients. Costs are similar for the two test formats but we do prefer to have patients on IBDoc, in terms of ease of testing and speed of the result. Thus we always try to use IBDoc as a priority wherever possible.

Initially patients can be a little taken aback when they realise that they will do the test themselves but you explain that it isn't much different from them taking their sample for the lab test. Most of them are familiar with having to provide the samples anyway so it is okay.

The only extra bit they have to do is reading the result with the phone and actually they embrace it. For patients that are well, we use IBDoc to monitor their disease and we explain that without it they will require a colonoscopy; the vast majority are happy to do the test – the chance of avoiding a colonoscopy is a good motivator.

Display of Results

In the beginning we started with the traffic light system of results, but we found it somewhat restrictive. For example a patient could have a red result and a few weeks later test again and still get a red reading. What they didn't see was that their actual calprotectin level had reduced from >3000µg/g down to 700µg/g, so it was in fact trending in the right direction.

In the interests of transparency, self-management and having a better understanding of their disease, patients are now able to see the numerical result which is very important for reassurance.

Patients who are using IBDoc generally test a base line level on initiating their treatment with biologics and then re-test every four months. As a general rule we use four tests per patient, per year. The 4th test they keep at home to use if they having symptoms. Thus, if they aren't sure if they are flaring or not they can use the test for reassurance.

Kathleen Sugrue (3rd from the left) and the IBD team at Mercy Hospital

Funding

The biggest issue we have at the moment is funding, despite the fact that IBDoc is cheaper than the previous method of testing and we are making significant savings on the use of biologics. We still don't have a direct source of funding for the test (although we have had agreed an additional member of staff which will help significantly). Some of the pharma companies will fund patients on their drugs, and I am in discussion with some others so that all the biologics patients have access.

However I would like the IBDoc for all IBD patients as it isn't fair to have the test available for one cohort of patients and not another. I am hoping that it will become part of the care programme for all patients, but there is currently no funding for this.

Patients love the IBDoc and have become reliant on it for self-managing their disease.

Patients love the IBDoc and have become reliant on it for self-managing their disease. Once they get started on it they don't want to stop using it. I have even had patients enquiring about self-funding the tests because the cost isn't huge for 3 – 4 tests a year. Unfortunately we currently don't have the ability to bill patients for it so this isn't happening here.

The feedback from the Gastro team and other IBD nurses is also extremely positive:

- *Patients are more confident at self-managing*
- *We aren't having to chase results*
- *Patients email if they get results they are concerned about, so it is a very safe system*

Sometimes you are investing a little bit more to make sure the longer term outcome is better. We do have a conversation with them about the testing and this takes a bit of time, but it is worth it in the long run as patients are with us for life. It saves us time going forward as we are not chasing results from the lab all the time.

Initially we went through the formal training, but now we give the patients the kit and say watch the video and 9 out of 10 don't have any issues with these instructions.

Reduced Helpline Calls

Since introducing IBDoc we get less calls on the helpline because patients can check themselves if they are concerned they are flaring. More than fifty percent of the time they do not have active disease – perhaps it is something they have eaten or they have a bug. Once they know it isn't their disease then they don't contact us.

The other really big positive for us is the fast track clinic. We ask patients to do the IBDoc test before they come to clinic. When we have the calprotectin result readily available to make clinical decisions we can make a definite plan immediately. Previously they would have come to clinic and we would have been waiting 6-8 weeks for a result, so it is much more efficient for them to come in with their own result.

During the two month period from February to March 2019, 27 patients who experienced symptoms of a flare-up did the IBDoc test and had normal results. Therefore they did not need to come to clinic. This is an example of considerable saving in terms of both financial cost to the hospital and also Gastroenterologist and IBD nurse time.

Dr Elsafi from the Mercy conducted a study using IBDoc to indicate mucosal healing in IBD patients starting biologics[1]. Traditionally patients starting biologics have follow-up clinic appointments at 3 months and a colonoscopy at 6 months to assess mucosal healing.

During the study 131 patients were provided with IBDoc kits, enabling them to test their own calprotectin levels at home at the 3 and 6 months post induction of biological agents. This avoided the need to attend hospital appointments to obtain a calprotectin result. Results from the IBDoc tests were transferred to the gastroenterology team's database. At the 3 month assessments the IBDoc results showed that 40% of the patients had normal calprotectin levels. After 6 months 75% of the patients showed normal calprotectin levels [Figure 1].

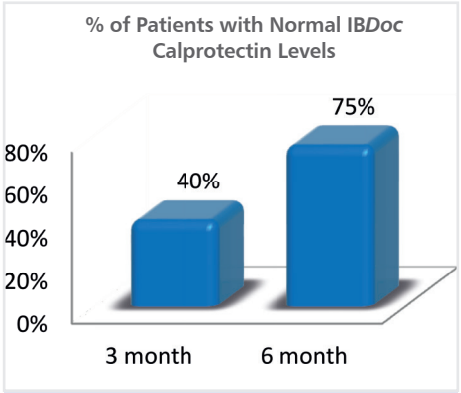

Figure 1.
Normal IBDoc results in IBD patients 3 and 6 months following initiation of anti-TNFα therapy.

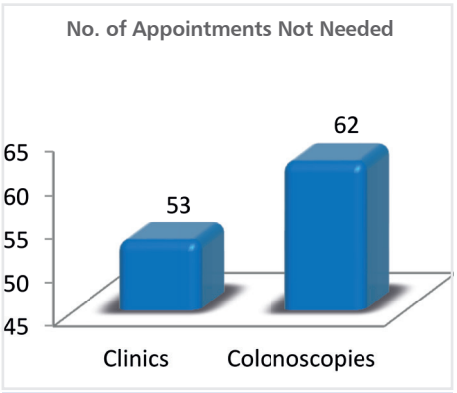

Figure 2.
Clinics and colonoscopies saved through patients using IBDoc calprotectin home tests.

Of the 78 patients that had a raised IBDoc calprotectin at 3 months, 28% of these had a normal reading after 6 months.

Overall, using the IBDoc calprotectin results as indicators of mucosal healing, a total of 53 clinic visits and 62 colonoscopies were not required because the calprotectin results were within normal limits [Figure 2].

This represents a significant cost saving plus the benefits of better managed healthcare resources, reducing demand and therefore the waiting times for both clinic visits and colonoscopies, plus an improved patient experience.

Guidance on Treatment Plans

We also use IBDoc to guide decision making on switching treatments if a patient is on a biologic and isn't doing so well from a symptom point of view. If the IBDoc result shows the calprotectin is high or continues to stay high then we would use this as justification to switch to another medication or for treatment escalation.

Virtual Clinics

At the Mercy we hold virtual clinics for patients who are in remission for at least six months and IBDoc is an essential component of being able to do this. The patients are sent an IBDoc kit in the post and an IBD questionnaire; they also get bloods done by their GP. A date is arranged for a call and we go through the results, ensure they are doing well and that no changes are required to the medication. After the call I dictate a letter to the GP to say they have been reviewed at a virtual clinic and outline what the outcomes are.

Cost Savings

We currently have more than 100 patients who are assessed on a virtual clinic basis. This is expected to increase as there are significant resource and cost savings using this approach. The cost of an outpatient clinic appointment in Ireland is €129.50 and that is without lab work or anything; with this level of saving it is definitely the way forward and the ability for remote testing is a key element of this.

If clinics are considering implementing patient self-testing, my advice is - just do it.

If clinics are considering implementing patient self-testing, my advice is - just do it. Talk to other clinics who have been using it and you will see very quickly how easy it is. The buy in from patients is very positive and overall it makes things easier from a healthcare point of view.

Reference

1. G Elsafi. UEGW 2017. Cost effectiveness of IBDoc as a surrogate marker of mucosal healing in IBD patients post induction of biological agents.