Questionnaire: treatment for chronic diarrhoea in patients with BAM and IBS

Introduction

KSR has been commissioned by NICE to evaluate the clinical and cost effectiveness of [^{75}Se] tauroselcholic acid (SeHCAT) in diagnosing bile acid malabsorption (BAM). The current BSG guideline for chronic diarrhoea places SeHCAT at the end of the diagnostic algorithm.

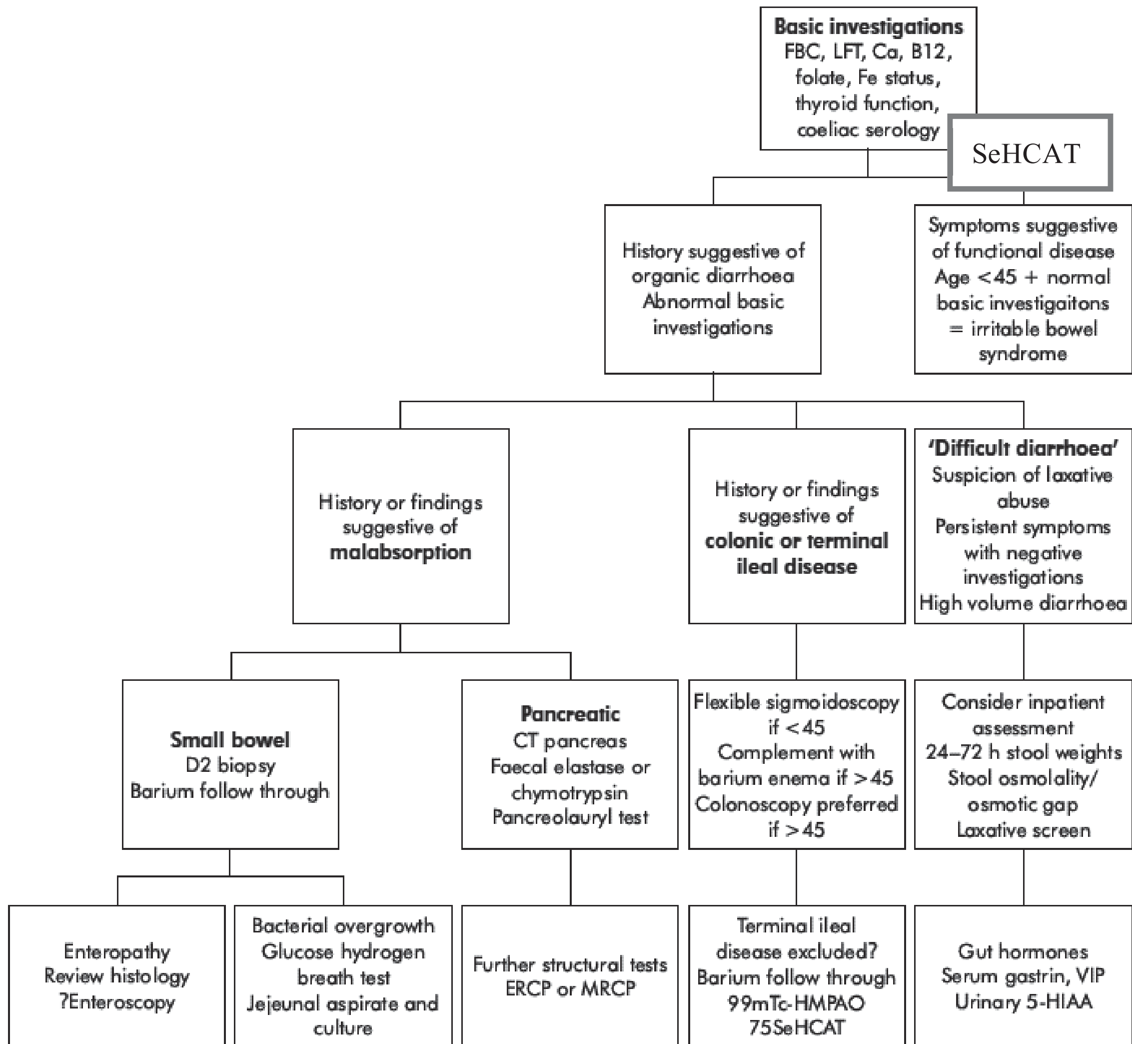
After the scoping phase, it was decided that the current evaluation will be limited to two populations for investigation:

1. People presenting with chronic diarrhoea with unknown cause and symptoms suggestive of functional disease (who would, without diagnosis of BAM, be diagnosed as IBS-D);
2. People with Crohn's disease and chronic diarrhoea with unknown cause (i.e. before resection of the terminal ileum).

It has been discovered that little published evidence would be available to inform this evaluation. Thus, expert opinion is of key importance to the success of the current project. The length of this questionnaire is rather long (10 pages) but given the lack of formal evidence this was unavoidable. If you think other sources, such as published literature, conference abstracts, databases etc., are available for one or more of the questions, could you please indicate this?

First population – chronic diarrhoea with unknown origin

The place for SeHCAT that is currently under investigation is after blood work, patient history etc, where in the current approach the patient is thought to have IBS-D. See also figure below for the placement of SeHCAT. The purpose is to compare the current scenario without SeHCAT, where these patients receive some form of treatment (or not) for their IBS-D, with the new scenario where these patients undergo SeHCAT testing for BAM.



In the current scenario, where patients are diagnosed as having IBS-D, many treatment options are possible. We have several questions regarding the typical approach in managing IBS-D.

No SeHCAT available

1. Do all patients start with some form of treatment for their chronic diarrhoea/IBS-D? If no then go to Q2)

2. If not, which percentage does not receive any treatment? (please also provide a range [lowest and highest] reflecting your uncertainty about the percentage)

% of patients	Lowest	Highest

3. Why do they not receive treatment?

4. From the whole group of patients with IBS-D, which percentage receives a pharmaceutical? (please also provide a range reflecting your uncertainty about the percentage)

% of patients	Lowest	Highest

5. Can you please provide more details about the pharmaceutical treatment:

Type drug	% of patients	lowest	highest	dosage	Duration (If chronic use, please state 'chronic'. If limited period please indicate duration)

6. From the whole group of patients with IBS-D, which percentage will be given diet instructions at some point? (please also provide a range reflecting your uncertainty about the percentage)

% of patients	Lowest	Highest

7. Regarding the diet instructions, will these be simple instructions regarding e.g. the use of fibre, or do they entail visits to a dietician? In the latter case, please indicate how often.

Only simple diet instructions during regular consultation	%
Visits dietician	% .... visits

8. From the whole group of patients with IBS-D, which percentage receives some form of psychological treatment (e.g. cognitive behavioural therapy, hypnotherapy) at some point? (please also provide a range reflecting your uncertainty about the percentage)

% of patients	Lowest	Highest

9. Can you please provide more details about the psychological treatment:

Type of therapy	% of patients	Lowest	Highest	Duration

10. Can you indicate what, in general, the order is in which the various options are prescribed? For example, most patients start with X, if not (fully) successful then Y, etc.

11. Can you indicate what percentage of IBS-D patients will eventually be considered "successfully treated"?

% of patients	Lowest	Highest

12. And can you also indicate how long that process of reaching success may take (e.g. 6 months, 1 year, longer than a year)?

Time	Lowest	Highest

Until now, we have considered the situation that SeHCAT is not a diagnostic option. In the following questions, we will assume the new scenario, i.e. patients have had a SeHCAT test. Assume that the test finding was negative (i.e. the percentage bile acid absorption was > 15%). However, the SeHCAT test does not have a 100% sensitivity and specificity, so it is reasonable to assume that some of these 'negative' patients do in fact have BAM. However, because of the negative test result, they are now diagnosed as IBS-D.

SeHCAT BAM negative patients

13. Which treatments that are commonly used in IBS-D patients may also have a positive effect on patients with BAM?

14. Would the success percentage of treatment be approximately equal for BAM and IBS-D patients or would that be different (please indicate more or less effective in BAM than in IBS-D, if possible with percentage)

15. Would this patient with the wrong diagnosis eventually be correctly diagnosed as BAM, or is this unlikely to happen given the negative SeHCAT result.

16. If eventually the patient is diagnosed with BAM, how long would the delay approximately be (e.g. 6 months, 1 year, 3 years)?

Finally we consider the patients with a positive test result, i.e. a percentage bile acid absorption < 15%. In general, these patients can be treated with bile acid sequestrants (BAS). However, in studies in patients with BAM, positive patients are treated with cholestyramine and we see that a certain percentage of patients do not want to use that drug and another group does not tolerate the drug.

SeHCAT BAM positive patients

17. Do you have any idea what the long-term adherence to cholestyramine is for patients that started the treatment?

18. When cholestyramine is not an option or is not tolerated, which, if any, other BAS treatments considered for BAM patients?

19. Do you know which percentage of patients with BAM<15% treated with such BAS alternative is "successfully" treated?

% of patients	Lowest	Highest

20. When none of the BAS treatments is an option or tolerated, which, if any, other treatments considered for BAM patients?

21. Do you know which percentage of patients with BAM<15% treated with such non-BAS alternative is "successfully" treated?

% of patients	Lowest	Highest

Second population – Crohn's disease without ileum resection

The second population for which SeHCAT testing is under consideration is for patients with Crohn's disease without ileum resection who have chronic diarrhoea. We have some questions that are similar to the earlier questions, but now concern this very different second population. We start with the 'current' situation, in which SeHCAT is not an option.

No SeHCAT available

1. Do all patients initially receive some form of treatment for their chronic diarrhoea?

2. If not, which percentage does not receive any treatment? (please also provide a range reflecting your uncertainty about the percentage)

% of patients	Lowest	Highest

3. Why do they not receive treatment?

4. From the whole group of patients considered here (chronic diarrhoea in Crohn's disease), which percentage receives a pharmaceutical? (please also provide a range reflecting your uncertainty about the percentage)

% of patients	Lowest	Highest

5. Can you please provide more details about the pharmaceutical treatment:

Type drug	% of patients	Lowest	Highest	dosage

6. Which, if any, non-pharmaceutical treatment options available for these patients?

7. Can you indicate what, in general, the order is in which the various options are prescribed? For example, most patients start with X, if not (fully) successful then Y, etc.

8. Can you indicate what percentage of Crohn's patients will eventually be considered "successfully treated" for the chronic diarrhoea?

% of patients	Lowest	Highest

9. Can you also indicate how long that process of reaching success may take (e.g. 1 months, 3 months, a year)?

Time	Lowest	Highest

Now suppose patients with Crohn's disease without ileum resection who have chronic diarrhoea are tested with SeHCAT. Again, it is reasonable to assume that some of the 'negative' patients do in fact have BAM. However, because of the negative test result, they are now considered to have a chronic diarrhoea with no known cause.

SeHCAT BAM negative patients

10. Is the treatment of the negative SeHCAT patients the same as above in the situation without SeHCAT? If no, please describe.

11. Which of these treatments would also have a positive effect on patients with BAM (i.e. the false negatives)?

12. Would the success percentage of treatment be approximately equal for BAM and non-BAM patients or would that be different (please indicate more or less effective in BAM than in non-BAM, if possible with percentage)

13. Would this patient with the wrong diagnosis eventually be correctly diagnosed as BAM, or is this unlikely to happen given the negative test SeHCAT result.

14. If eventually the patient is diagnosed with BAM, how long would the delay approximately be (e.g. 1 month, 6 months, 1 year, 3 years)?

Time	Lowest	Highest

Finally we consider the patients with a positive test result, i.e. a percentage bile acid absorption < 15%. Again we want to know what alternatives are available for patients unwilling or unable to take cholestyramine.

SeHCAT BAM positive patients

15. When cholestyramine is not an option or is not tolerated, which, if any, other BAS treatments considered for BAM+ Crohn's patients?

16. Do you know which percentage of Crohn's patients with BAM<15% treated with such BAS alternative is "successfully" treated?

% of patients	Lowest	Highest

17. When none of the BAS treatments is an option or tolerated, which, if any, other treatments considered for BAM+ Crohn's patients?

18. Do you know which percentage of Crohn's patients with BAM<15% treated with such non-BAS alternative is "successfully" treated?

% of patients	Lowest	Highest