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Outcomes from treating bile acid malabsorption (BAM) using a multidisciplinary approach

Gupta A *et al.* Support Care Cancer. 2015 Oct;23(10):2881-90

Prescribing information can be found at the end of this presentation

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08-2017 JB7347 | UK Communication Tool

Background

- Irritable bowel syndrome (IBS) is one of the most common GI functional disorders
- Affects up to 20% of the Western population
- Pathophysiology of IBS not completely understood
- Response to bile acids on colonic motor and secretory functions seems to be exaggerated in patients with IBS
- In different IBS subgroups, modulating the colonic bile acid exposure has been an effective treatment strategy

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Background & Study aims

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Diagnostic criteria for BAM are controversial and fewer than 1% of patients are thought to be correctly diagnosed

- SeHCAT is the gold standard for diagnosis, because of its safety profile, relatively low cost, low radiation exposure, and high sensitivity and specificity

There are no recognised published guidelines for the treatment of BAM; options include:

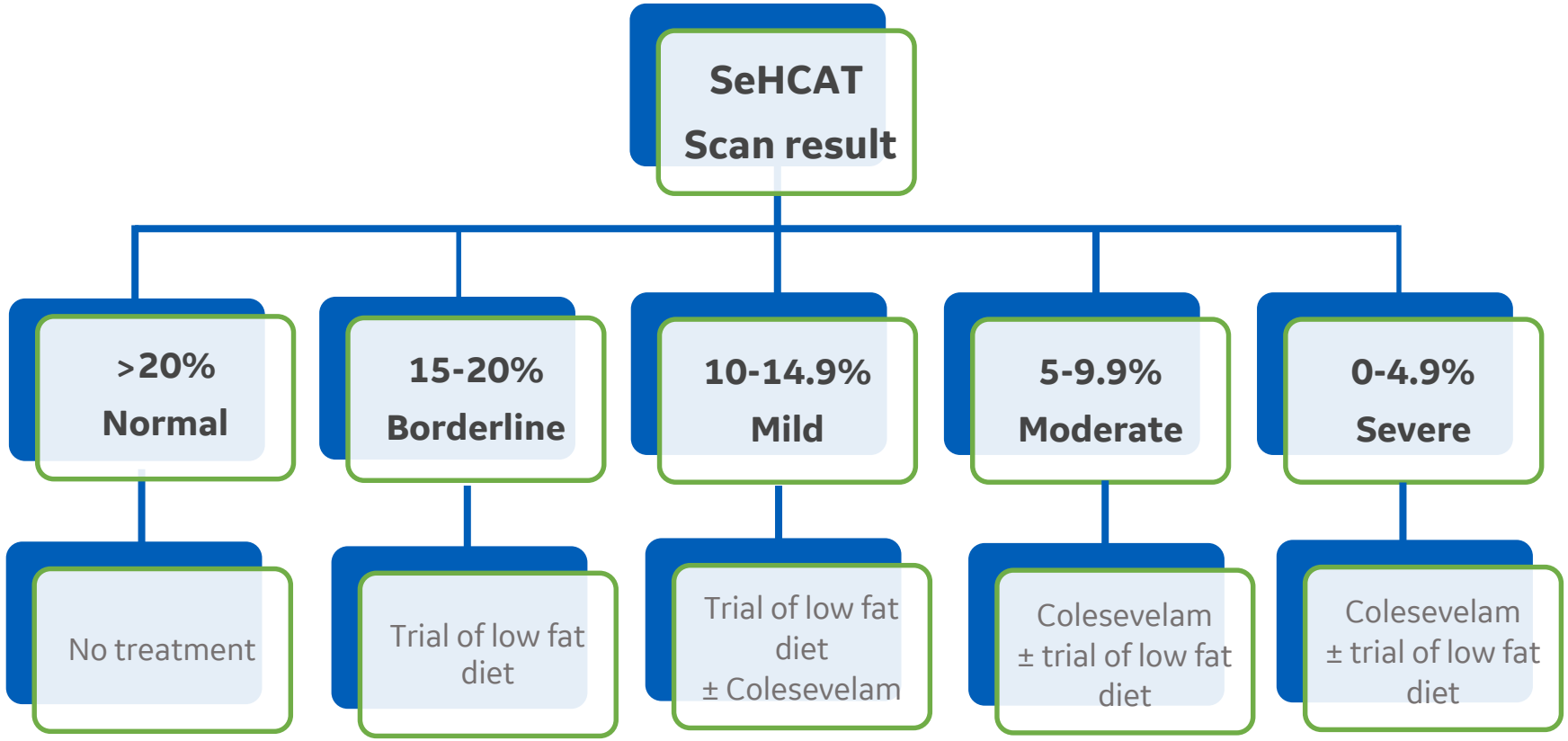
- Bile acid sequestrants (BAS): colestyramine, colestipol and colesevelam
- Budesonide, which may increase uptake of bile in the terminal ileum
- Antidiarrhoea and stool bulking agents to help alleviate symptoms
- Reduced dietary fat intake (rarely recommended)

Aiming to assess the effectiveness of structured intervention following a specific treatment algorithm for BAM in people previously treated for cancer

Methods

- A retrospective assessment of prospectively, systematically recorded data of patients referred to a specialist gastrointestinal (GI) "consequences-of-cancer-treatment" clinic
- Patients completed a 7-day food diary, a GSRS questionnaire and a Bristol stool chart before first clinic appointment and the GSRS questionnaire and Bristol stool chart again before every subsequent visit
- All patients with abnormal GI symptoms were assessed and treated with a peer-reviewed management algorithm

Methods



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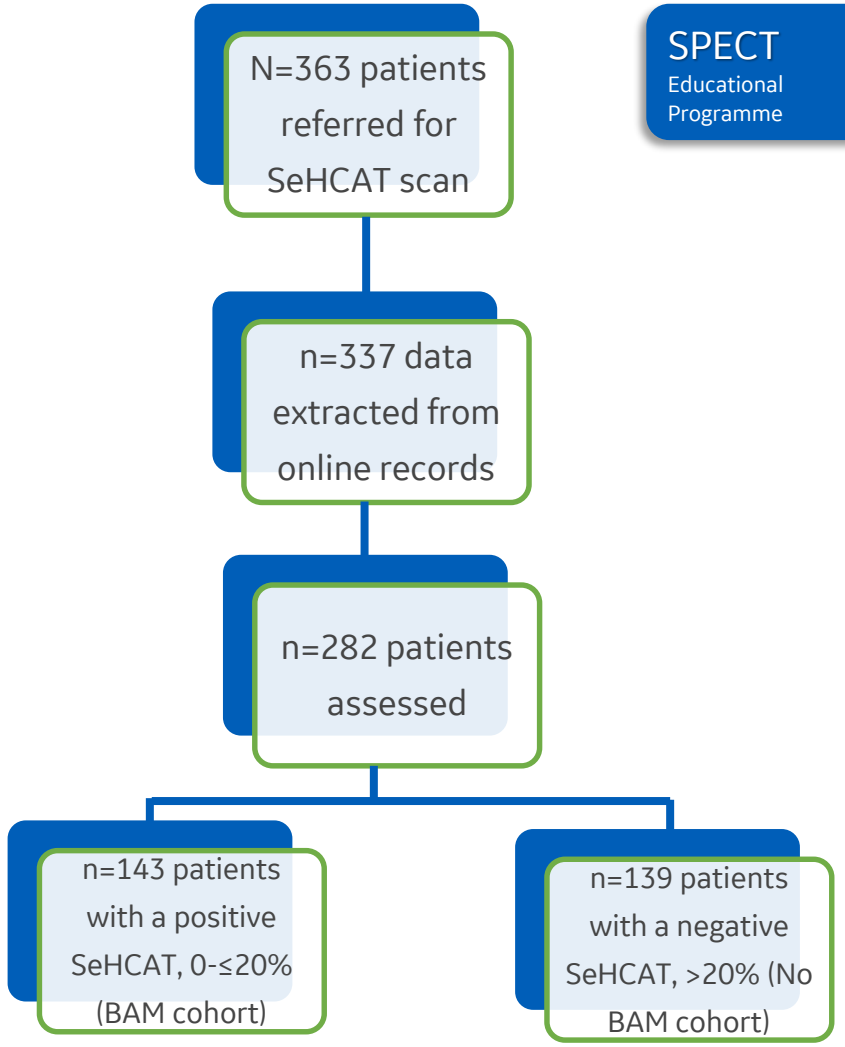
Results

- Trial profile is shown to the right; male:female ratio roughly equal, median age 66 years (range 19-89)
- 51% (n=143) had SeHCAT of ≤20%; 73% (n=105) had previously undergone pelvic radiotherapy and 47% (n=67) GI surgery
- 86% (n=123) were treated with low fat diets, 55% (n=79) with a BAS, 51% (n=73) with both
- On discharge, 70% (n=100) of patients reported a significant overall symptom improvement
- Patients reported a clinically significant improvement in urgency, faecal incontinence, wind, nocturnal defecation, tiredness, abdominal pain, bloating, and steatorrhoea (p=<0.0005)
- Stool frequency was reduced and stool consistency improved



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Conclusions

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- In this complex group (>66% have GI symptoms arising from multiple causes), **patients who report even occasional mushy or liquid stools have a high frequency of BAM** if investigated with SeHCAT; given the importance of a differential diagnosis for patient management, **routine use of SeHCAT in this group could have a meaningful clinical impact**
- It is noteworthy that **BAM does not only affect people misdiagnosed as having irritable bowel syndrome**; large (unquantified) numbers of people have secondary BAM as a result of surgery, radiotherapy, chemotherapy, and diseases of the GI tract
- **The treatment algorithm improves symptoms of BAM**, in particular urgency and faecal incontinence; dietary restriction appears useful, though further study is needed. This approach could offer an **option that is cheap to implement, avoids side effects associated with drugs and may have significant health benefits** (in terms of weight loss and improved cardiovascular status) beyond BAM management

Implications for clinical practice

The treatment algorithm presented supports a multidisciplinary approach to managing GI symptoms related to BAM. Further research is needed to investigate the long-term

PRESCRIBING INFORMATION SeHCAT 370kBq Capsules ([^{75}Se]tauroselcholic acid)
Please refer to full national Summary of Product Characteristics (SPC) before prescribing.
Indications and approvals may vary in different countries. Further information available on request.

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PRESENTATION Hard gelatin capsule containing [^{75}Se]tauroselcholic acid [370kBq at the activity reference date].

INDICATIONS This medicinal product is for diagnostic use only. Used for the investigation of bile acid malabsorption and measurement of bile acid pool loss. It may be used in the assessment of ileal function, in the investigation of inflammatory bowel disease and chronic diarrhoea and in the study of entero-hepatic circulation.

DOSAGE AND METHOD OF ADMINISTRATION Normal adult and elderly dose is one capsule administered orally. No paediatric dosage form or clinical experience of the use of this product in children. The same dose used adults should be used in children. A careful assessment of the risk/benefit ratio should be undertaken before use of the product in children due to increased effective dose equivalent. Careful consideration of the activity to be administered to patients with hepatic impairment is required since increased radiation exposure is possible. Drinks of 15 ml of water are recommended before, during and after swallowing capsule to ensure passage to the stomach. Patient should be in standing or sitting position.

CONTRAINDICATIONS Hypersensitivity to the active substance or to any of the excipients.

WARNINGS AND PRECAUTIONS If hypersensitivity or anaphylactic reactions occur, administration must be discontinued immediately and if required, intravenous treatment initiated. The necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available. Caution advised in administration of SeHCAT to patients with severe hepatic dysfunction or biliary tract obstruction. Radiation dose to liver will be significantly increased in these patients. Exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting radiation dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic or therapeutic result. For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should be as low as reasonably achievable to obtain the required diagnostic information. Careful consideration of the benefit risk ratio in patients with hepatic impairment is required since increased radiation exposure is possible. No data are available for the paediatric population however careful consideration of the indication is required since the effective dose per MBq is higher than in adults. This medicinal product contains 3.01 mmol (71.04 mg) sodium in each capsule which should be taken into account in patients on a low sodium diet.

INTERACTIONS No interaction studies have been performed and no interactions reported to date.

PREGNANCY AND LACTATION When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about the potential pregnancy, alternative techniques not using ionising radiation (if there are any) should be offered to the patient. No data are available on the use in human pregnancy. Animal reproduction studies have not been carried out. Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. Only essential investigations should therefore be carried out when the likely benefit exceeds the risk to the mother and foetus. Before administration to a breastfeeding mother, consideration should be given as to whether the investigation could be reasonably delayed until after the mother has ceased breastfeeding and as to whether the most appropriate choice of radiopharmaceutical has been made, bearing in mind the secretion of activity in breast milk. If administration is considered necessary, breastfeeding should be interrupted and breast milk discarded for three to four hours after administration, after which breastfeeding can be resumed.

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UNDESIRABLE EFFECTS Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 0.26 mSv when the maximal recommended activity of 370 kBq is administered these adverse reactions are expected to occur with a low probability.
Immune system disorders: Hypersensitivity (unknown frequency).
DOSIMETRY Effective dose for a healthy adult administered one 370kBq capsule of SeHCAT is typically 0.26mSv. In most clinical investigations for which this substance is used (e.g. Crohn's disease) the effects of impaired ileal absorption and shorter gastrointestinal transit time tend to reduce the dose commitment compared with the normal case. However, in patients with severe cholestatic jaundice, the liver dose has been estimated to be about 100 times the normal value.
MARKETING AUTHORISATION HOLDER GE Healthcare Limited, Amersham Place, Little Chalfont, HP7 9NA, UK.
CLASSIFICATION FOR SUPPLY Subject to medical prescription (POM).
UK MARKETING AUTHORISATION NUMBER PL 0221/0105.
PRICE £195.
DATE OF REVISION OF TEXT 28 April 2017.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to GE Healthcare.

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