

EUropean consensus on the Resolution Of SympToms After oesophago-gastric Resection (EUROSTAR): Peri-Operative Quality Initiative (POQI) consensus statement

Sowrav Barman ^{1,2} Mickael Chevallay,^{1,3} Suzanne S Gisbertz,^{4,5} Mieke Van Hemelrijck,^{2,6} Ben E Byrne ^{7,8} Bas Wijnhoven,⁹ Sheraz Markar,^{10,11} Jessie A Elliott,¹² Jan Bornschein,^{13,14} Mark Pritchard,¹⁵ Magnus Nilsson,^{16,17} Donald Low,¹⁸ Christian Alexander Gutschow,¹⁹ Jason M Dunn,²⁰ Sebastian Zeki ²⁰, Sam H Ahmedzai,²¹ Barry Laird,²² Jafar Jafari,²⁰ Orla Evans,¹ Christopher J Peters,²³ Pernilla Lagergren ^{23,24,25} Jesper Lagergren,^{1,2,25} Manuel Pera Roman,²⁶ Maria Dolors Muns Cornellàs,²⁶ Fiona Huddy,²⁷ Anthony Hobson,²⁸ Zainab Noor,²⁹ Andrew J Cockbain,^{30,31} Fredrik Klevebro,^{17,32} Louis Fox,⁶ Charlotte Moss,⁶ Kellie Owen,³³ Anne-Margrethe Phillips,¹¹ Chantal T Hoen,^{4,5} Elizabeth Ward,³⁴ Cathy White,³⁵ Mark I van Berge Henegouwen ^{4,5} Stefan Möning,³ Loes Noteboom,^{4,5} Kiran Purushothaman,³⁶ Thibaud Koessler,^{37,38} Marcel André Schneider ¹⁹ Gwen Masclee,³⁹ Christian Geroïn,⁴⁰ Jacopo Weindelmayer,⁴⁰ Silvia Lazzaris,⁴⁰ Misha Luyer,⁴¹ Jakob Hedberg,⁴² Visvakanth Sivanathan,⁴³ John Reynolds,^{12,44} Arnulf H Hölscher,^{45,46} Guillaume Piessen,⁴⁷ Timothy E Miller,⁴⁸ Mike Grocott,^{49,50} Jervoise Andreyev ^{51,52}, Andrew Davies,^{1,2} EUROSTAR Study Faculty Members

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For numbered affiliations see end of article.

Correspondence to Professor Andrew Davies; Andrew.davies57@nhs.net

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ABSTRACT

Background Symptoms after upper gastrointestinal (UGI) cancer surgery are common, frequently overlap, and can substantially affect quality of life. Despite increasing recognition of this problem, there is limited standardisation in the definition, investigation and management of the postoperative conditions responsible for these symptoms.

Methods A society-endorsed, European-wide series of consensus meetings was conducted using a modified Delphi process developed by the PeriOperative Quality Initiative (POQI). A multidisciplinary panel of experts from 10 European countries, selected for their expertise in UGI cancer survivorship, participated in the development of consensus-based recommendations for symptoms following major UGI cancer surgery. Independent oversight was provided by POQI, and statements and recommendations were graded using a modified GRADE methodology informed by a comprehensive literature review.

Results A total of 8 statements and 13 recommendations relating to symptom monitoring and service provision after major UGI cancer surgery were developed, refined and agreed upon through a preliminary meeting and two semistructured POQI consensus meetings. Diagnostic criteria, investigation pathways and management recommendations for the common postoperative conditions encountered after UGI cancer surgery were also developed and refined through

multidisciplinary discussion before achieving consensus. 16 future research priorities were identified.

Conclusions The EUROSTAR consensus provides guidance on symptom monitoring, service provision and the investigation and management of common postoperative conditions following UGI cancer surgery. These recommendations represent an important step towards standardising survivorship care and supporting future research in this patient population.

INTRODUCTION

Symptoms after major upper gastrointestinal (UGI) cancer surgery are common and significantly affect quality of life.¹ Curatively intended treatment often includes a combination of chemo(radio)therapy and surgery, resulting in irreversible changes to the anatomy and physiology of the gastrointestinal tract.^{2–4} The ensuing symptoms are often multiple and under-appreciated, given that routine postoperative symptom monitoring is not a standard of care in most centres. Patients may feel unsupported in dealing with these consequences. Until recently, there has been a conspicuous lack of standardisation regarding the definition, investigation and management of the conditions frequently responsible for these symptoms.^{5,6} Some patients can have multiple conditions acting at the same

time, and clinical acumen alone is poor at diagnosing these.⁷ Timely identification of symptoms aligned with a consistent approach to investigation and management may facilitate earlier diagnosis and treatment of the underlying conditions, improve quality of life and have health economic benefits. Standardisation would also allow for comparison between units and a benchmark from which prospective trials may be launched.

Expanding on the work of the UK based RESTORE (REsolution of SympToms after Oesophago-gastric REsection) study, a series of society endorsed meetings were conducted using a modified Delphi process, as developed by the Peri-Operative Quality Initiative (POQI).^{8,9} The aim was to produce guidance statements based on current evidence and expert opinion to inform service provision and the definition, investigation and management of the common symptoms and conditions encountered after UGI cancer surgery. Future research questions were also identified as part of the process.

METHODS

POQI is an international, multidisciplinary, non-profit organisation that facilitates consensus conferences on clinically relevant perioperative topics. The POQI conferences included a multidisciplinary, diverse group of experts from across 10 European countries to develop consensus based recommendations pertaining to symptoms after major UGI cancer surgery (oesophagectomy or gastrectomy). A modified Delphi method was used as previously described.⁹ Societal support was obtained from the British Society of Gastroenterology, the European Society for Diseases of the Esophagus, the Association of Upper GI Surgeons of Great Britain and Ireland, the UK and Ireland Oncology Group and the Oesophageal Patients Association. Healthcare professionals were recruited based on their expertise in the field of survivorship in UGI cancer. Participants were divided into three groups, each with clinical chairs and a representative from POQI who, together, acted as moderators. Each subgroup discussed predefined topics incorporating statements and recommendations on service specifications after UGI cancer surgery and an assigned list of conditions. A 'statement' was defined as a stated fact supported by evidence, while a 'recommendation' was defined as a suggested course of action supported by evidence and expert opinion. An extensive literature review was conducted before the meetings to inform the evidence base for discussion.

The POQI conferences were held virtually using the Microsoft Teams (Microsoft Corp, Redmond, Washington, USA) online platform. An initial preparatory meeting explained the process to participants, expanded the invitees to ensure a diverse group of multidisciplinary professionals and agreed a longlist of statements and recommendations. Two subsequent POQI conferences followed a standard structure: an initial plenary session to introduce the range of statements for discussion, subgroup discussions to refine the allocated list of statements and a final plenary discussion where each subgroup presented proposed changes to the wider group. Statements were presented alongside contemporaneous data to support or refute each statement. Groups assigned quality of evidence using a modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) structure taking into account the whole body of the literature, in keeping with previous POQI guidance.⁹

The quality of evidence was graded between 'high' and 'very low', and the strength of recommendation (recommendations only) was allocated as either 'strong' or 'weak' for or against the proposal (online supplemental table 1).

After the first conference, the working groups further refined the statements and recommendations to ensure consistency of wording ahead of a second conference. This followed the same format as the first. At the end of the second conference, refined and graded POQI statements were either accepted (100% participant agreement) or rejected if consensus could not be reached.

RESULTS

Consensus statements and recommendations (general statements and service provision)

Table 1 summarises the agreed statements and recommendations related to symptom monitoring and service provision after major UGI cancer surgery. Several service recommendations gained strong support. These included an acknowledgement of the high frequency of patient symptoms and, as a result, the need to document these prospectively during follow-up. While numerous follow-up models exist, with little evidence to support one over another, it was unanimously agreed that patients should have access to a multidisciplinary care team for as long as required following surgery and that this team should have access to the appropriate investigative tests. The availability of a multidisciplinary team meeting to discuss complex cases was considered important. Follow-up should be multifaceted and holistic, designed to address symptoms proactively while also surveying for cancer recurrence and addressing the wide range of nutritional, psychological, social and financial issues encountered in this patient group. Dietetic input was highlighted as a core component of follow-up.

General principles for investigating, diagnosing and managing conditions

Diagnostic criteria for each condition followed the same structure. The guidance was deliberately intended to be pragmatic and helpful in day-to-day clinical practice. Candidate symptoms for each condition were long listed and refined during the group discussions. The presence of symptoms was felt to be a prerequisite for investigation and intervention in this setting. However, it was acknowledged that conditions could be asymptomatic or subclinical (ie, the absence of symptoms did not necessarily preclude the presence of an underlying condition). Variations in patient symptom reporting were acknowledged, hence the desire for validated, objective symptom questionnaires in addition to the more tailored patient history taking that might be performed in an outpatient setting. While testing was generally considered preferable to obtain a definitive diagnosis, it was accepted that many conditions were often treated empirically. A prospectively documented symptom response to treatment was felt to be a good indicator of a correct diagnosis in routine clinical practice or, alternatively, a potential outcome measure in prospective clinical trials.¹⁰

Acid reflux

Gastro-oesophageal reflux is a common issue after oesophagectomy, owing to the disruption of the hiatus and removal of the gastro-oesophageal junction which form natural antireflux barriers. Lifestyle advice was advocated,

Table 1 Agreed statements and recommendations developed using a modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) structure, with quality of evidence and strength of recommendation related to service provision and symptom monitoring after major upper gastrointestinal cancer surgery. Unless otherwise stated, strength of recommendation is FOR the proposal

Statement (S) or recommendation (R) After major upper GI cancer surgery...	Quality of evidence	Strength of recommendation	Evidence
S: Symptoms are common and affect patients' quality of life.	High	N/A	1 93 97 98
S: Symptoms may overlap between conditions and patients can have multiple underlying conditions acting at the same time.	High	N/A	1 93 97 98
R: A systematic approach to assessment, investigation and management is recommended as this may lead to a faster resolution of symptoms and, therefore, improved quality of life.	Moderate	Strong	1 21 95 97
R: Given significant symptom overlap between conditions, testing is recommended prior to treatment. Empirical treatment may be considered for certain conditions, provided response to treatment is documented.	Moderate	Strong	1 21 95
R: Changes to the GI tract anatomy and physiology as a result of surgery, oncological treatments (eg chemotherapy/radiotherapy/immunotherapy), other iatrogenic causes (eg, medications) and pre-existing conditions may all contribute to the development of symptoms and these should be considered when investigating symptoms.	High	Strong	95 99 100
R: Symptom questionnaires (patient reported outcome measures) are recommended to document the symptom burden and trajectory.	High	Strong	101–104
R: In initiating management of postoperative conditions, contemporaneous recording of the symptomatic response to treatment is recommended. This may provide important information on the efficacy of treatment and likelihood of the proposed diagnosis being correct.	Low	Strong	1 8 10 21
R: Regular follow-up and access to clinical teams after surgery is recommended. This may identify important symptoms for investigation, monitor patients for possible recurrence and provide an opportunity for holistic patient care to improve quality of life.	Low	Strong	1 95 105
S: The optimal follow-up model to improve postoperative quality of life and survival is unknown but may combine routine face-to-face, remote/virtual and 'as required' (patient or questionnaire initiated) contacts.	Low	N/A	1 106 107
R: Follow-up should be individualised after surgery and may need to be long term in some patients.	Very low	Strong	1 87 108
S: The timely availability of multidisciplinary expertise including upper GI surgery, gastroenterology, oncology (medical and clinical/radiation), nursing, dietetics, psychology and other allied health professionals may benefit some patients.	Moderate	N/A	1 107 109 110
S: The availability of key investigations at point of care is desirable; however, initiating empirical treatment may be appropriate if investigation is not available in a timely manner.	Moderate	N/A	21 95 107
R: Access to a designated multidisciplinary team meeting for patients in follow-up is recommended to provide a forum to discuss complex cases.	Low	Strong	87 109–111
R: A full history, incorporating dietary history, the pattern and timing of symptoms and any underlying pre-existing conditions is recommended.	High	Strong	1 95 112
R: Nutritional issues are common and specialist dietitian input during follow-up is recommended.	Moderate	Strong	96 113–115
R: Weight loss and micronutrient deficiency are common. It is recommended that patients are monitored following surgery to ensure that they are meeting their micronutrient requirements and to mitigate the risk of developing micronutrient deficiencies.	High	Strong	116–119
R: A complete multivitamin and mineral supplement (containing iron, selenium, zinc and copper) should be considered for all patients following oesophagectomy or gastrectomy. Additional administration of a combined calcium and vitamin D supplement should also be considered.	Low	Weak	119–122
R: Long term supplementation of vitamin B12 (parenteral) is recommended for all patients following total gastrectomy with close monitoring and appropriate supplementation after subtotal gastrectomy or oesophagectomy.	High	Strong	123–125
S: A holistic postoperative follow-up approach should include issues beyond basic symptom assessment.	High	N/A	1 8 95 126
S: Needs based supportive care and education may complement the benefits of medical treatment on postoperative symptoms.	Moderate	N/A	1 127 128
S: Recurrent cancer should be considered in patients whose symptoms deviate significantly from their postoperative baseline	Moderate	N/A	8 95 105 107 129
N/A, not applicable.			

including the avoidance of dietary triggers, refraining from late meals, use of specialist pillows, raising the head end of the bed and the correct timing of medication in relation to meals. As outlined in [box 1](#), empirical treatment with proton pump inhibitors (PPI) was the recommended first line treatment,^{11 12} while acknowledging that endoscopy can be helpful in assessing and managing other conditions

which may have a significant symptom overlap (eg, anastomotic stricture and delayed gastric emptying).^{13 14} Alternative PPIs may be used to good effect in patients with inadequate symptom control or side effects from a particular PPI.^{15 16} While formal pH studies are commonly used to quantify reflux in the benign setting, these are seldom used following resectional surgery. The second line use of

Box 1 A Management of acid reflux

Suggestive symptoms: Typical: retrosternal chest pain/burning, reflux/heartburn, regurgitation, acid in mouth, gravity dependent reflux/regurgitation. Atypical: cough, hoarse voice.

Diagnostic criteria:

1. Suggestive symptoms
AND ...
Either
- 2a. Conclusive evidence of gastro-oesophageal reflux disease at endoscopy (Los Angeles classification system grade A–D)
OR ...
- 2b. Pathological oesophageal acid exposure on pH monitoring (acid exposure time >6%)
AND/OR
3. Symptomatic response to adequate acid suppression therapy.

First line investigation: Upper GI endoscopy/OGD (oesophago-gastro-duodenoscopy) (high evidence, strong recommendation)

First line treatment: Proton pump inhibitor (high evidence, strong recommendation)

Second line treatment: Additional H2 receptor antagonist (eg, famotidine) (high evidence, strong recommendation)

H2 receptor antagonists, such as famotidine, was considered well established.^{17 18} Oral alginates (eg, Gaviscon advanced formula) were supported as an evidence based adjunct to acid suppressing medication.^{19 20} The use of prokinetics is discussed in the later section on delayed gastric emptying (DGE). Following gastrectomy procedures, acid production

Box 2 Management of non-acid (bile) reflux

Suggestive symptoms: Retrosternal chest pain/burning, reflux/heartburn, regurgitation, burning in mouth, cough, nocturnal/postural symptoms.

Diagnostic criteria:

1. Suggestive symptoms
AND ...
2. Evidence of inflammation and bile in the oesophagus or stomach at endoscopy.
AND/OR ...
3. Symptomatic response to treatment.

First line investigation: Upper GI endoscopy/OGD (oesophago-gastro-duodenoscopy) (high evidence, strong recommendation)

Second line investigation: Oesophageal impedance monitoring (very low evidence, weak recommendation)

First line treatment: Sucralfate suspension (or alternative if not available) (moderate evidence, strong recommendation)

Second line treatments: Alginates, prokinetic agents, ursodeoxycholic acid, topical anaesthetic agents (eg, oxetacaine/mucaine) (very low evidence, weak recommendation)

Box 3 Management of anastomotic stricture

Suggestive symptoms: Dysphagia (dysphagia score ≥ 2),²⁶ odynophagia, regurgitation, nausea and vomiting, early satiety (especially gastrectomy), reduced dietary intake, weight loss, chest pain.

Diagnostic criteria:

1. Suggestive symptoms
AND ...
Either
- 2a. Anastomotic stricture on oesophago-gastro-duodenoscopy (OGD): severe=inability to pass a standard 8–10 mm diagnostic gastroscope through the anastomosis; moderate=clear narrowing of the lumen but able to pass standard 8–10 mm diameter diagnostic gastroscope through the anastomosis.
OR...
- 2b. Anastomotic stricture on contrast study: severe=contrast study showing hold up or proximal dilation at the anastomosis with diameter ≤ 10 mm; moderate=contrast study showing hold up or proximal dilation at the anastomosis with diameter >10 mm.
AND/OR ...
3. Symptomatic response to treatment.

First line investigation: Upper GI endoscopy/OGD (oesophago-gastro-duodenoscopy) (high evidence, strong recommendation)

Second line investigation: Liquid barium/water soluble contrast study (high evidence, strong recommendation)

First line treatment: Balloon (or bougie) dilatation (high evidence, strong recommendation)

Second line treatment: Dilatation with steroid injection (moderate evidence, strong recommendation) or endoscopic stricturoplasty (needle–knife incision) (moderate evidence, strong recommendation)

is either reduced (subtotal) or absent (total gastrectomy), although a symptom overlap with bile reflux (discussed later) was acknowledged.

Non-acid (bile) reflux

Significant symptom overlap with gastro-oesophageal reflux was acknowledged. Bile reflux was often felt to be postural or nocturnal, with a bitter taste of bile in the mouth considered highly suggestive. The presence of excessive bile in the gastric conduit or gastric remnant alongside evidence of inflammation was endorsed as diagnostic, although it was agreed that endoscopy (where used) was principally looking for other causes of patient symptoms and the diagnosis was often made clinically.^{13 21 22} It was accepted that patients could have reflux or regurgitation that was neither acidic nor bilious in nature. Given the similar symptoms, it was felt likely that most patients would be taking, or have already trialled, acid suppressing medication (eg, PPIs). While pH/impedance studies are frequently used to investigate patients in a benign reflux setting,^{22 23} these are very seldom used following resectional surgery. Sucralfate gained strong support as first line therapy with a trial period of 6 weeks felt to be sufficient to assess any benefit.^{21 24} Second line options including alginates, prokinetics, ursodeoxycholic

acid and topical anaesthetic agents (oxetacaine, mucaine) all received weak support acknowledging a very low quality of supporting evidence^{21 25} (outlined in [box 2](#)). Biliary gastritis and biliary reflux gastropathy were acknowledged as separate conditions, although it was felt that symptoms, more often than not, related to the reflux component. Given the identical workup and treatment of these conditions to biliary reflux, it was agreed that they also be considered within this section.

Anastomotic stricture

It was acknowledged that the spectrum of symptoms differs between patients after oesophagectomy (mainly oesophageal symptoms such as dysphagia²⁶ and odynophagia) and partial/subtotal gastrectomy (mainly gastric emptying symptoms such as nausea, vomiting, and early satiety), although with some overlap. Diagnostic criteria acknowledged the need to attempt to quantify anastomotic strictures with an inability to pass a standard diameter endoscope (or equivalent lumen diameter on contrast study) felt to be the most pragmatic solution (outlined in [box 3](#)). It was accepted that some patients could still have narrowing (and symptoms) despite successful passage of a gastroscopy and hence this was acknowledged as a moderate stricture. Endoscopy was the preferred first line investigation and management option, facilitating balloon dilatation.^{27–29} Bougie dilatation was used variably with some centres using it frequently and others not at all. Second line adjuncts to dilatation such as the use of steroid injection (eg, triamcinolone) or needle–knife stricturoplasty were noted to have a good evidence base in benign strictures.^{30–32} These were also identified as potential research topics. Some symptom overlap with delayed gastric conduit emptying after oesophagectomy was noted and this diagnosis should be considered in the absence of a stricture on endoscopy.

Delayed gastric emptying

A distinction was highlighted between delayed gastric emptying (DGE) following partial gastrectomy and delayed gastric conduit emptying (DGCE) after oesophagectomy. Following oesophagectomy, diagnostic criteria for this study focused on late DGCE, whereas a recent Delphi survey addressed both early (in-hospital) and late postoperative gastric conduit emptying.^{5 33} Some amendments to these criteria were advocated by the group. Significant food or liquid residue in the stomach despite fasting was felt to represent sufficient evidence of DGCE and had previously been proposed by the RESTORE Delphi study.⁸ Delayed passage of oral contrast assessed by a specialist radiologist or gastric emptying studies, which may be performed using nuclear medicine imaging or ¹⁴C breath testing, were also supported.^{6 33 34} It was acknowledged that none of these have recognised normal range values following UGI surgery, hence the poor and very poor evidence grades attached, respectively, aligned with weak positive recommendations. Establishing these normal ranges was felt to be an important future research topic to allow for quantification of any delay in gastric conduit emptying, an objective that has been proposed as part of the forthcoming JEDI study. As outlined in [box 4](#), endoscopic evaluation was supported as a first line investigation, allowing for assessment of the anastomosis (all patients), conduit and pylorus (oesophagectomy patients), and facilitating dilatation where appropriate.³⁵ For DGCE post-oesophagectomy, pyloric dilatation and the use of prokinetics were both advocated, although prescribing restrictions on the duration of use of the latter (as outlined in [table 2](#))

Box 4 Management of delayed gastric emptying (DGE)

Suggestive symptoms: Nausea, vomiting, dysphagia, early satiety, regurgitation, reduced dietary intake, weight loss, heartburn, acid/bile in the mouth, abdominal pain, chest pain, belching.

Diagnostic criteria:

1. Suggestive symptoms
AND ...
Either
 - 2a. Significant food/liquid residue in the stomach on oesophago-gastro-duodenoscopy (OGD) despite fasting.
OR ...
 - 2b. Delayed passage of contrast on timed barium/water soluble swallow and meal, as determined by an expert gastrointestinal radiologist*.
 - OR ...
 - 2c. Delayed emptying on gastric emptying study as determined by an expert radiologist/physiologist*
AND/OR ...
3. Symptomatic response to treatment.

**Normal range values need to be established in upper GI cancer surgery patients*

First line investigations: Upper GI endoscopy/OGD (oesophago-gastro-duodenoscopy) (moderate evidence, strong recommendation). Timed liquid barium/water soluble contrast study (swallow and meal) (low evidence, weak recommendation)

Second line investigation: Gastric emptying study (very low evidence, weak recommendation)

First line treatments: Endoscopic pyloric dilatation (high evidence, strong recommendation). Short term and/or intermittent use of prokinetic drugs (low evidence, weak recommendation)

Second line treatments: Surgical pyloroplasty (high evidence, strong recommendation), botulinum toxin type A injection of the pylorus (moderate evidence, strong recommendation), pneumatic dilatation (eg, larger balloon up to 30 mm) (moderate evidence, strong recommendation)

Third line treatment: Gastric per oral endoscopic myotomy (GPOEM), within a research setting (low evidence, weak recommendation)

were acknowledged.^{36–41} A range of second line options, including surgical pyloroplasty, botulinum toxin injection of the pylorus and pneumatic dilatation with a larger calibre balloon, were all strongly supported.^{42–45} Gastric per oral endoscopic myotomy (GPOEM) was weakly supported as a third line option owing to a poorer evidence base, largely in benign patients.⁴⁶ All second line and third line options were felt to be areas in need of research to establish superiority. It was acknowledged that prophylactic measures to prevent DGCE have been extensively reported, including both surgical and endoscopic pyloric interventions.^{47–50} An ongoing randomised trial is exploring the role of preoperative endoscopic dilatation versus controls in preventing DGCE interventions postoperatively.⁵¹

An important additional group of patients with mechanical symptoms, potentially benefiting from surgical revision after oesophagectomy, was recognised. These might include patients with a redundant, dilated conduit (most commonly described in the right chest after Ivor–Lewis

Table 2 Prokinetic and antiemetic drugs used for the treatment of delayed gastric emptying or delayed gastric conduit emptying

Drug	Dose	Duration	Cautions
Metoclopramide	10 mg three times a day before meals	3 months	Risk of tardive dyskinesia with more than 3 months of usage
Erythromycin (syrup)	250–500 mg three times a day before meals	6 weeks	Tachyphylaxis after 6 weeks. Electrolyte disturbances (predisposition to QT interval prolongation) may aggravate myasthenia gravis
Domperidone	10 mg three times a day orally	1 week	Increased risk of ventricular arrhythmia. Risk of cardiac side effects/sudden death; it is recommended not to be used for more than 1 week unless the benefits outweigh the risks. Tachyphylaxis may develop after 6 weeks
Aprepitant	125 mg once daily	4 weeks	No cautions and safe to use long term
Prucalopride	2 mg once daily	Long term if required	Cautions if history of cardiac arrhythmias or ischaemic heart disease
Paroxetine	20 mg once daily	6 months initially	Can increase the risk of bleeding due to their effect on platelet function

oesophagectomy)⁵² or para-conduit hernias, and will be explored further as part of the Revisional Surgery for Delayed Gastric Conduit Emptying (RESTORANT) study.

Dumping syndrome

It was agreed that a diagnosis of dumping syndrome was often reached by a thorough assessment of postprandial symptoms and a positive symptom response to dietary intervention.⁵³ As a result, testing was often not used immediately. Historically, the terms early and late dumping were used to describe symptoms within 60 and 180 min of eating, respectively, with the latter representing reactive hypoglycaemia. Where testing is required, a modified oral glucose tolerance test was advocated, with continuous glucose monitoring reserved for third line^{54 55} (outlined in [box 5](#)). Individually tailored dietary advice and guidance by a specialist dietitian, including (but not limited to) reduced meal size, taking food and fluid separately and a high fibre, high protein, low glycaemic index diet was strongly recommended as first line treatment.^{53 54} The use of octreotide as a second line treatment was strongly recommended.^{56 57} Acarbose as a third line treatment for late dumping symptoms was weakly recommended due to a poor evidence base in UGI surgical patients and the potential for GI side effects, such as bloating, diarrhoea and flatulence.⁵⁸

Bile acid diarrhoea

The diagnostic criteria for bile acid diarrhoea (BAD) using a 75-selenium homocholic acid taurine (SeHCAT) test are well established and received a strong recommendation based on high quality evidence⁵⁹ (outlined in [box 6](#)). Given the significant symptom overlap with other conditions (eg, small

Box 5 Management of dumping

Suggestive symptoms: Postprandial symptoms including abdominal pain, bloating, borborygmi, nausea, diarrhoea, flushing, palpitations, perspiration, tachycardia, hypotension, fatigue, desire to lie down, syncope.

Diagnostic criteria:

1. Suggestive symptoms
AND ...
2. If an oral glucose tolerance test has been performed:
⇒ Early dumping syndrome: rise in haematocrit >3% OR a rise in heart rate >10 bpm, 30 min after ingestion.
⇒ Late dumping syndrome: hypoglycaemia (< 3.3 mmol/l 60–180 min after ingestion).
AND/OR ...
3. Symptomatic response to treatment.

First line investigation: Food and symptom diary, thorough dietary history (moderate evidence, strong recommendation)

Second line investigation: Modified oral glucose tolerance test (75 g glucose in water after overnight fast with measurement of blood glucose, haematocrit, pulse and blood pressure before and at 30 min intervals up to 3 hours after ingestion) (moderate evidence, strong recommendation)

Third line investigation: Continuous glucose monitoring (low evidence, weak recommendation)

First line treatment: Dietary advice and guidance by a specialist dietitian (including reduced meal size, food and fluid separation and a high fibre/high protein diet) (moderate evidence, strong recommendation)

Second line treatment: Octreotide (early dumping) (moderate evidence, strong recommendation)

Third line treatment: Acarbose (late dumping) (low evidence, weak recommendation)

Box 6 Management of bile acid diarrhoea (BAD)

Suggestive symptoms: Diarrhoea, bloating, abdominal pain/cramps, flatulence, incontinence, faecal urgency, nocturnal diarrhoea, borborygmi, frequency of defecation, fatigue, weight loss.

Diagnostic criteria:

1. Suggestive symptoms
AND ...
2. Positive 75-selenium homocholic acid taurine (SeHCAT) scan (preferable): (borderline=15–20% residual bile acid; mild=10–15% residual bile acid; moderate=5–10% residual bile acid; severe=<5% residual bile acid)
AND/OR ...
3. Symptomatic response to treatment.

First line investigation: SeHCAT scan (high evidence, strong recommendation)

First line treatment: Bile acid sequestrants (eg, colestevlam, colestyramine, colestipol) (moderate evidence, strong recommendation), dietary assessment and modification—reduced fat intake (moderate evidence, weak recommendation)

Second line treatment: Antidiarrhoeal agents (eg, loperamide) (moderate evidence, weak recommendation)

intestinal bacterial overgrowth (SIBO)), testing to establish the diagnosis and quantify the deficiency was felt to be preferable before commencing treatment. However, it was noted that this test was not available in all centres. More recently, there has been interest in 7- α -hydroxy-4-cholesten-3-one (7 α HC4) as a potential screening tool for patients with diarrhoea, although its role specifically in complex surgical patients has not been established and access to the test is limited. While low levels make BAD unlikely, high levels lack the sensitivity for a definitive diagnosis and still currently require confirmation with a SeHCAT scan.^{60–63} Bile acid sequestrants⁶⁴ received a strong recommendation as first line treatment along with supervised dietary intervention (reduced fat intake). Antidiarrhoeal agents (eg, loperamide), received a weak recommendation as second line treatment based on moderate evidence.⁶⁵ Glucagon-like peptide-1 agonists (eg, liraglutide or semaglutide) were identified as future research topics.

Carbohydrate malabsorption

A significant symptom overlap with other conditions was again noted and testing to exclude SIBO was recommended before pursuing investigations for carbohydrate (CHO) malabsorption.²¹ The interaction of this diagnosis with altered GI tract motility postoperatively was identified as an area of uncertainty, as similarly noted with SIBO. Although widely accepted as an investigation for CHO malabsorption, fructose/lactose breath testing was a weak positive recommendation based on poor evidence specifically in UGI surgical patients.^{21 66 67} Dietary exclusion of specific carbohydrates (eg, lactose free diet under the supervision of a specialist dietitian) received strong support either following testing or as an empirical 14 day trial^{21 68} (Summarised in box 7).

Box 7 Management of carbohydrate malabsorption

Suggestive symptoms: Bloating, abdominal pain, diarrhoea, weight loss, flatulence, brain fog, frequency of defecation.

Diagnostic criteria:

1. Suggestive symptoms
AND* ...
2. Positive breath test (rise in hydrogen of ≥ 20 ppm from baseline during fructose/lactose breath testing).
AND/OR ...
3. Symptomatic response to treatment.
*Having excluded small intestinal bacterial overgrowth.

First line investigation: Empirical 14 day trial of specific carbohydrate exclusion (eg, lactose free diet) as a diagnostic manoeuvre with response assessment (low evidence, weak recommendation) or fructose/lactose breath test (low evidence, weak recommendation)

First line treatment: Dietary exclusion of carbohydrates under the supervision of a specialist dietitian (moderate evidence, strong recommendation)

Small intestinal bacterial overgrowth

While there were a range of views of participants on the subject of SIBO, there was wide acceptance that dysbiosis because of a surgical intervention and concomitant medications is common. This may occur in the small bowel, colon or both, although treatment strategies are similar. The clinical challenge is that dysbiosis is often persistent and hard to treat, particularly if underlying risk factors are not addressed. SIBO, by definition, is an increased number of bacteria in the small intestine, which is normally low in colony forming units. This can cause aberrant fermentation of (predominantly) carbohydrates and subsequent symptoms. Use of PPIs, postoperative achlorhydria and antibiotic use can all contribute to dysbiosis in the long term. Intestinal methanogen overgrowth, while distinct from SIBO being related to excess anaerobic archaea, was also considered within this section due to the significant overlap of symptoms, investigation and management.

A wide range of symptoms were listed as potentially being caused by SIBO, often overlapping with other conditions. Testing was advocated, acknowledging that even in non-surgical patients the best method of assessment has not been established.⁶⁹ Combined hydrogen and methane breath testing gained the strongest support, although lacking recognised normal range values in UGI surgical patients and acknowledging the limited availability of breath testing across European centres.^{21 69} The optimal substrate for breath testing was unknown. Lactulose (10 g) is widely used as a breath test substrate in non-surgical patients, although the potential for false positive results in the context of accelerated gut transit and reduced specificity compared with glucose breath testing was acknowledged. The presence of a vagotomy and shortening of the functional small bowel length courtesy of a Roux-en-Y configuration after gastrectomy are both potential contributors to this. However, the evidence for accelerated gut transit after oesophagectomy, gastrectomy and bariatric surgery shows significant variation between patients and operation types.^{70–72} Whether oro-caecal transit should be formally tested in parallel with breath tests to contextualise the result remains uncertain. Assessment with glucose (75 g) breath testing gained support as an alternative, being less susceptible to the transit confounding issues highlighted above.⁷³ A summary of the discussion points related to choice of substrate is presented in table 3.

Small bowel bacterial sampling was advocated by some as an alternative to breath tests, particularly as it could be performed at the time of endoscopy, which may be useful in assessing patients with non-specific symptoms.²¹ It was agreed that quantitative bacterial analysis was too

Table 3 Breath test substrate characteristics and impact on potential for false results

Substrate		Reliable result
Lactulose	Non-absorbable, therefore liable to false positives due to colonic fermentation in fast transit. Oro-caecal transit study may be useful	Negative
Glucose	Rapidly absorbed in proximal small bowel. Risks of false negatives in distal SIBO/IMO (which is more common due to greater bacterial colonisation in distal small bowel and proximity of the colon)	Positive results strongly suggest proximal overgrowth
IMO, intestinal methanogen overgrowth; SIBO, small intestinal bacterial overgrowth.		

Guideline

time consuming and expensive for widespread use as well as being limited to sampling of only the proximal small bowel. Simplified culture and sensitivity were used by some centres, treating based on the presence of atypical or colonic bacteria (eg, gram negative and anaerobes) in the small bowel aspirate.

Treatment options (summarised in [box 8](#)) principally included the use of antibiotics with a strong evidence base, accepting the high rates of recurrence reported in the literature.^{74 75} The choice of antibiotics might depend on local prescribing policies, positivity on hydrogen versus methane breath testing and the sensitivity results of any available cultures ([table 4](#)). A positive lactulose hydrogen breath test (LHBT) has been shown to predict efficacy for rifaximin when compared with a negative LHBT.⁷⁶ Interestingly, although methane is present in about 30% of healthy asymptomatic subjects, when this is associated with symptoms of bloating and constipation, reduction of methanogens with dual antibiotic therapy (eg, rifaximin and neomycin) correlates with improvements in symptoms as well as bowel transit times.⁷⁶ Notably, oral iron supplementation can act as a fuel to methanogens and other dysbiotic bacteria, which can exacerbate symptoms via the excessive luminal iron content.⁷⁷

Box 8 Management of small intestinal bacterial overgrowth (SIBO)

Suggestive symptoms: Abdominal pain, bloating, diarrhoea, constipation, reduced dietary intake, weight loss, flatulence, steatorrhoea, borborygmi, faecal urgency, nausea, vomiting, early satiety, dyspepsia, heartburn, belching, brain fog, fatigue, headache, muscle aches, frequency of defecation.

Diagnostic criteria:

1. Suggestive symptoms
AND ...
Either
 - 2a. Positive breath test (rise of ≥ 20 ppm from baseline in hydrogen in 90 min or ≥ 10 ppm for methane)
OR ...
 - 2b. Excessive bacteria ($>10^3$ colony forming units per ml from small bowel aspirate)
OR ...
 - 2c. Growth of colonic / atypical bacteria on small bowel aspirate AND/OR ...
3. Symptomatic response to antibiotics

First line investigation: Breath test (recommended) (moderate evidence, weak recommendation)

Alternative investigation: Small bowel (duodenal/jejunal) aspirate with cultures (low evidence, weak recommendation)

First line management: Antibiotics (high evidence, strong recommendation)

Second line management: Alternative antibiotics (high evidence, strong recommendation)

Third line management: Probiotics, prokinetics, FODMAP (fermentable oligosaccharides, disaccharides, monosaccharides and polyols) diet, correct reversible causes (very low evidence, weak recommendation)

Table 4 Antimicrobial options for treatment of small intestinal bacterial overgrowth (SIBO)

Antimicrobial	Indication	Targeted bacteria	Duration (days)
Rifaximin	Considered first line treatment for SIBO, especially hydrogen dominant cases	Primarily targets gram negative and gram positive bacteria	7–14
Co-amoxiclav, ciprofloxacin/norfloxacin	In resistant cases where rifaximin is ineffective, co-amoxiclav, ciprofloxacin or norfloxacin can be helpful. Bacterial sensitivities can be determined from Small bowel aspirates if performed	Co-amoxiclav for mixed infections (gram positive, gram negative and anaerobes)	7–14
Neomycin* and vancomycin	If methane dominant SIBO/IMO is present, combination therapy appears to be more effective than single agent treatment. Rifaximin combined with neomycin, vancomycin or metronidazole for methane producing bacteria	Vancomycin gram negative (especially methanogens) and some gram positive	7–14
Metronidazole	For cases resistant to initial treatments, or complicated SIBO. Consider small bowel aspirates	Metronidazole for anaerobes	7–14

*Not widely available in Europe.
IMO, intestinal methanogen overgrowth; SB, small bowel.

For empirical treatment, at the time of writing, rifaximin (first line), co-amoxiclav, ciprofloxacin, vancomycin and metronidazole for a duration of 1–2 weeks were considered the most evidence based options.^{78–80} Prospective monitoring of the symptom response to treatment was considered an important adjunct, particularly given the high recurrence rates. Alternative strategies such as rotational antibiotics and longer term antibiotics were also discussed for patients with proven recurrent or persistent SIBO. Additional therapies such as probiotics, prokinetics, low FODMAP (fermentable oligosaccharides, disaccharides, monosaccharides and polyols) diets and correcting underlying causes (eg, medications) were all weakly recommended as third line therapeutic options based on very poor evidence in UGI surgical patients.^{81–83}

Box 9 Management of exocrine pancreatic insufficiency (EPI)

Suggestive symptoms: Weight loss, steatorrhoea, urgency, bloating, foul smelling stool or flatus, abdominal pain, diarrhoea.

Diagnostic criteria:

1. Suggestive symptoms
AND ...
2. Low faecal elastase (<200 $\mu\text{g/g}$ of faeces)
AND/OR ...
3. Symptomatic response to treatment.

First line investigation: Faecal elastase level (high evidence, strong recommendation)

First line treatment: Pancreatic enzyme replacement therapy (eg, Creon, Nutrizym, Pancrease, Pancrex) and dietary advice (high evidence, strong recommendation)

Box 10 Management of recurrence

Suggestive symptoms*: Unexplained or significant (>10%) weight loss, dysphagia, anorexia, abdominal pain, chest pain, lethargy/fatigue, progressive hoarse voice, regurgitation, vomiting, jaundice, malaise.

Diagnostic criteria: Endoscopic, histopathological or radiological evidence of recurrent disease.

First line investigation (luminal symptoms): Upper GI endoscopy/OGD (oesophago-gastro-duodenoscopy) and CT thorax, abdomen and pelvis (high evidence, strong recommendation)

First line investigation (extra-luminal symptoms): CT thorax, abdomen and pelvis (high evidence, strong recommendation)

First line treatment: According to local multidisciplinary team meeting decision (evidence not applicable, strong recommendation)

*Change from postoperative baseline.

The investigation and management of SIBO was identified as an area much in need of further research, particularly in the post-surgical patient.

Exocrine pancreatic insufficiency

Consistent symptoms and a faecal elastase of <200 µg/g of faeces in a solid stool sample or a symptomatic response to empirical treatment gained strong support as diagnostic criteria (summarised in box 9) for exocrine pancreatic insufficiency (EPI).²¹ It was accepted that a low faecal elastase did not always correspond with proven malabsorption of fat measured over 72 hour stool sampling.⁸⁴ Conversely, de-synchrony of pancreatic secretions (functional insufficiency) could also occur after UGI surgery. As a result, faecal elastase could be falsely negative, and the diagnosis could still be considered in the presence of typical symptoms alone or indeterminate faecal elastase levels (eg, 200–500 µg/g of faeces).^{84 85} After a diagnosis of EPI, a comprehensive nutritional assessment, including assessment of fat soluble vitamin status (A, D, E and K) was advocated. Pancreatic enzyme replacement therapy (eg, Creon, Nutrizym, Pancrease, Pancrex) was strongly supported as first line treatment.^{84–86} Response-to-treatment assessment was considered important, with 4 weeks felt to be an appropriate period (provided adequate compliance, patient education and dosage) to assess for a response.

Recurrent cancer

This was defined as endoscopic, histopathological or radiological evidence of recurrent disease. It was acknowledged that symptoms could be variable and non-specific and should be taken in context of the timing after surgery and postoperative histology. A deviation of relevant symptoms from the postoperative baseline was considered concerning. These were broadly categorised into luminal (dysphagia, anorexia, regurgitation and vomiting) and non-luminal (weight loss, abdominal or chest pain, lethargy/fatigue, progressive hoarse voice, jaundice and malaise). First line investigation for luminal symptoms was an upper GI endoscopy with a

recommendation for parallel CT (thorax, abdomen and pelvis, with or without the neck if appropriate) in the case of high clinical suspicion or abnormal findings on endoscopy.^{87 88} (summarised in box 10). A CT was recommended as first line for non-luminal symptoms. Subsequent management should be discussed and agreed at the local multidisciplinary team meeting.^{87–89}

Algorithm development

Algorithms for each of the conditions, based on the agreed investigation and management pathways above, are presented in online supplemental figure 1A–J. These have been consolidated alongside a summary of service recommendations in an infographic (figure 1).

Research topics

Topics identified as future research priorities are included in box 11.

DISCUSSION

This multidisciplinary, society endorsed, European-wide modified Delphi process conducted via a series of POQI conferences has gained broad consensus on eight statements and 13 recommendations relating to follow-up after major UGI cancer surgery. The symptoms, diagnostic criteria, investigation and management of the common conditions encountered after surgery have also been agreed as well as future research topics. This represents a much needed move towards standardisation of patient care in the recovery phase after UGI cancer surgery and forms a benchmark from which prospective studies may be launched.

Several general principles regarding symptoms after major UGI cancer surgery were strongly supported by the participants. These included symptoms being common and under-appreciated, with patients frequently experiencing symptoms which may overlap from multiple conditions acting synchronously.¹⁷ A systematic approach to diagnosis, investigation and management was felt to be of critical importance and routine monitoring of postoperative symptoms, ideally through the administration of patient reported outcome measures, was advocated.^{5 21 58} While testing to confirm a given diagnosis was considered preferable, it was also acknowledged that many symptoms and conditions may be treated empirically.^{21 81 84} In this scenario, the principle of prospectively recording the symptomatic response to treatment (positive or negative) was endorsed.

While the optimal follow-up model remains uncertain, there was strong agreement that patients should have access to multidisciplinary care in the survivorship phase, as required.^{1 90 91} This should be tailored to the individual needs of the patient and continue for as long as necessary after surgery.^{1 91} The availability of a multidisciplinary team meeting to discuss complex cases was supported, as was the accessibility of suitable investigations in units conducting follow-up. It was acknowledged that symptom monitoring was only one aspect of the wider holistic approach required to aid recovery after surgery.

Several methodological issues merit further discussion. The modified Delphi process conducted through POQI conferences is an established method for gaining consensus.^{9 92} The participants represented a diverse, multi-disciplinary group of experts from across a range of health-care systems in Europe. It is acknowledged that enthusiasts

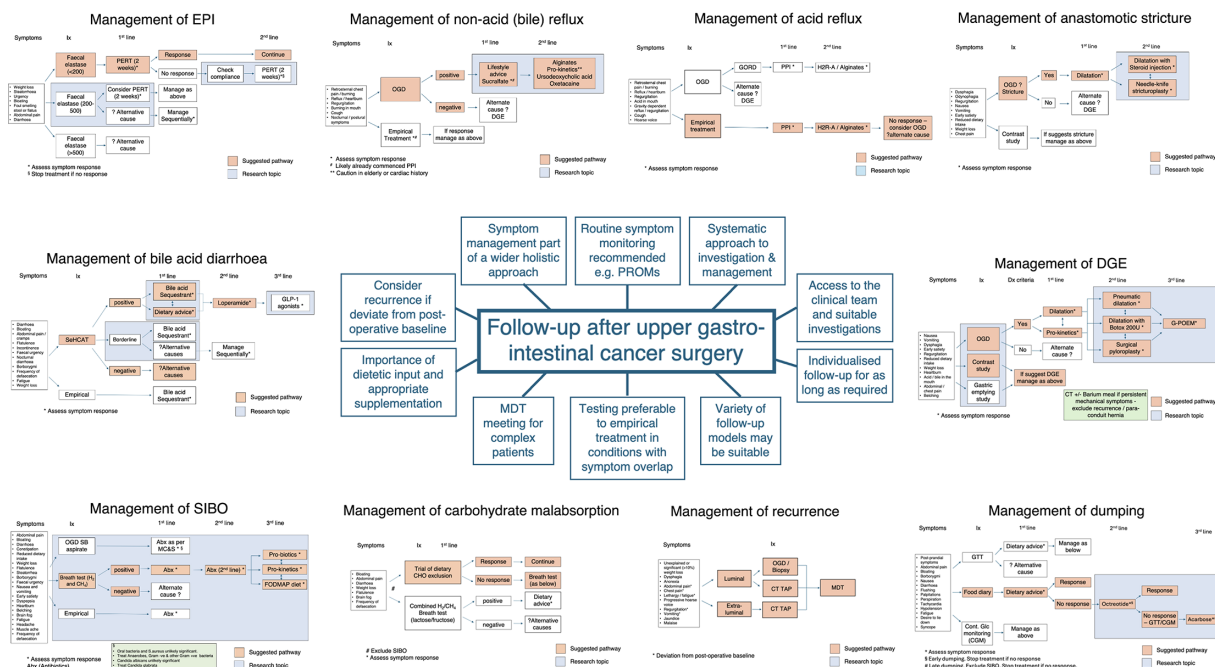


Figure 1 Infographic summarising service recommendations and management algorithms for the common conditions encountered after upper gastrointestinal cancer surgery. CT TAP, CT of the thorax, abdomen and pelvis; DGE, delayed gastric emptying; EPI, exocrine pancreatic insufficiency; GLP-1, glucagon-like peptide-1; GORD, gastro-oesophageal reflux disease; GPOEM, gastric per oral endoscopic myotomy; GTT, Glucose Tolerance Test; H2R-A, H2 receptor antagonist; MC&S, microscopy, culture and sensitivity; MDT, multidisciplinary team; OGD, oesophago-gastro-duodenoscopy; PERT, pancreatic enzyme replacement therapy; PPI, proton pump inhibitor; SB, small bowel; SeHCAT, 75-selenium homocholic acid taurine; SIBO, small intestinal bacterial overgrowth. ©PeriOperative Quality Initiative.

may naturally exhibit stronger support for the principles of proactive symptom follow-up and that the views of sampled participants may not represent all of those in the wider UGI cancer community. Limitations in the strength of the data were acknowledged with relatively few high quality studies available to inform the guidance statements. Nonetheless, a detailed review of the literature, incorporating 162 studies, was conducted before the conferences and referenced during discussions. Careful consideration was given before providing strong recommendations with a poor evidence base, as moderated by the clinical and POQI co-chairs. It is recognised that the management of post-operative symptoms and conditions will inevitably evolve over time and that any guidance will require updating to remain contemporaneous and relevant.

In recent years, there has been increasing interest in the management of symptoms after major UGI cancer surgery. This has been driven by a greater recognition of the scale of the problem, amplified by the improved cancer related survival of these patients, who are living for longer with the side effects of treatment.^{1,2} With an increasing focus on quality of life restoration after surgery, these sequelae need to be acknowledged and managed appropriately by dedicated teams with the requisite experience and resources. The LASER study,⁹³ a pan-European survey, confirmed a high symptom burden in these patients beyond a year from surgery and identified clusters of symptoms that adversely affected quality of life. This was subsequently validated in the LASORS study.⁹⁴ Other large patient surveys have suggested patients, on average, have 10–13 symptoms after UGI cancer surgery which can migrate over time from upper gastrointestinal (early) to lower gastrointestinal (late).^{1,21} The RESTORE study examined the national provision of services in the UK, agreed definitions for

a range of symptoms and conditions after UGI cancer surgery and, by Delphi survey, began to explore a standard set of investigation and management pathways with high levels of consensus.⁸ Other studies have focused on individual conditions, such as DGE and EPI, with the aim of establishing standards.^{5,6} Wider guidelines documents, such as those provided by the British Society of Gastroenterology, have provided a much needed baseline resource, although these have generally catered for the side effects of all cancer therapies and cannot necessarily be expected to address the specific issues encountered after UGI cancer surgery.⁹⁵

The rationale for greater standardisation is twofold. Firstly, in the absence of agreed diagnostic criteria, it remains impossible to compare different treatments or centres' outcomes. Established criteria are a prerequisite for identifying a population of patients with a given condition who may be eligible for enrolment in prospective studies. Secondly, inconsistencies in the investigation and management of symptoms remain a considerable barrier to improving patient care and lead to healthcare inequalities. An agreed, systematic, algorithmic approach might facilitate alternative models of follow-up such as combined specialist nurse and dietitian led clinics and/or patient led surveillance using patient reported outcome measures.⁹⁶ With a prevailing focus on cancer survivorship, it is no longer acceptable for patients to be left unsupported to deal with the consequences of cancer treatment. Given the complexity of these issues, primary care lacks the investigative resources and expertise to adequately manage these patients, mandating ongoing input from the resectional centre.

CONCLUSIONS

This European Delphi survey has agreed unanimously on the importance of symptom monitoring following UGI cancer

Box 11 Research topics

1. What is the symptom burden in this patient group? Can patient reported outcome measures prospectively document the symptom burden?
2. What is the role of routine versus targeted micronutrient supplementation, including bone health (note ongoing LaVida trial)?
3. What is the optimal frequency of vitamin B12 injections? What is the efficacy of oral administration of vitamin B12 after upper gastrointestinal (UGI) cancer surgery?
4. What is the optimal treatment of bile reflux?
5. Comparison of dilatation versus dilatation AND steroid injection versus needle–knife stricturoplasty for the treatment of anastomotic stricture.
6. What are the 'normal range values' for contrast studies or gastric emptying studies investigating delayed gastric (conduit) emptying specifically after UGI cancer surgery?
7. Comparison of dilatation versus dilatation AND Botox versus surgical pyloroplasty versus gastric per oral endoscopic myotomy (GPOEM) for delayed gastric conduit emptying.
8. What is the role of bile acid sequestrants and which sequestrant is optimal, especially in patients with a borderline SeHCAT (75-selenium homocholic acid taurine) result for bile acid diarrhoea (BAD)?
9. What is the role and efficacy of a low fat diet for BAD?
10. What are the 'normal range values' for breath testing for small intestinal bacterial overgrowth (SIBO) specifically after oesophagogastric cancer surgery and what is the optimal substrate?
11. What is the sensitivity and role of small bowel aspirates in diagnosing SIBO?
12. What is the role of probiotics, prokinetics and dietary manipulation (eg, low FODMAP (fermentable oligosaccharides, disaccharides, monosaccharides and polyols) diet) for SIBO?
13. What is the role for pancreatic enzyme replacement therapy (PERT) in patients with a borderline or negative faecal elastase (200–500 µg/g of faeces OR >500 µg/g of faeces)?
14. What is the role of empirical PERT treatment for steatorrhoea, presumed to be exocrine pancreatic insufficiency?
15. What is the duration of a trial period of PERT and when should it be stopped if no clinical response (4 weeks)?
16. Symptom driven versus routine or intensive surveillance for recurrence (note ongoing Surveillance After Resection of Oesophageal and Gastric cancer (SARONG) Trial). Do symptoms predict recurrence?

surgery as well as providing guidance on service provision, investigation and management of the common postoperative conditions and identifying future research priorities. This represents an important step towards greater standardisation of clinical care. It is hoped that the provision of diagnostic criteria provides a springboard for prospective research studies which will in turn facilitate a much needed evolution in the evidence based management of these complex patients. Justifying managerial investment in survivorship programmes remains an important agenda with a clear pathway to patient benefit.

Author affiliations

- ¹Upper GI Surgery, Guy's and St Thomas' Hospitals NHS Trust, London, UK
- ²School of Cancer and Pharmaceutical Sciences, King's College London, London, UK
- ³Division of Digestive and Transplant Surgery, Department of Surgery, Geneva University Hospital Main Building, Geneva, Switzerland
- ⁴Cancer Treatment and Quality of Life, Cancer Center Amsterdam, Amsterdam, Netherlands
- ⁵Department of Surgery, Amsterdam UMC location, University of Amsterdam, Amsterdam, Netherlands
- ⁶Transforming cancer Outcomes through Research (TOUR), School of Cancer and Pharmaceutical Sciences, King's College London, London, UK
- ⁷Population Health Sciences, University of Bristol, Bristol, UK
- ⁸University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, UK
- ⁹Erasmus MC Cancer Institute, Department of Surgery, Erasmus Medical Center, Rotterdam, Netherlands
- ¹⁰Nuffield Department of Surgical Science, University of Oxford, Oxford, UK
- ¹¹Oxford University Hospitals NHS Foundation Trust, Oxford, UK
- ¹²Department of Surgery, Trinity St James's Cancer Institute, Dublin, Ireland
- ¹³Medical Research Council Translational Immune Discovery Unit (MRC TIDU), Weatherall Institute of Molecular Medicine (WIMM), University of Oxford, Oxford, UK
- ¹⁴Translational Gastroenterology and Liver Unit, University of Oxford, John Radcliffe Hospital, Oxford, UK
- ¹⁵Institute of Systems, Molecular and Integrative Biology, University of Liverpool, Liverpool, UK
- ¹⁶Department of Clinical Science, Intervention and Technology (CLINTEC), Karolinska Institutet, Stockholm, Sweden
- ¹⁷Department of Upper Abdominal Diseases, Karolinska University Hospital, Stockholm, Sweden
- ¹⁸Department of Thoracic Surgery, Virginia Mason Franciscan Health, Tacoma, Washington, USA
- ¹⁹Department of Visceral Surgery and Transplantation, University Hospital Zurich, Zurich, Switzerland
- ²⁰Gastroenterology, Guy's and St Thomas' Hospitals NHS Trust, London, UK
- ²¹School of Medicine and Population Health, University of Sheffield, Sheffield, UK
- ²²Department of Palliative and Supportive Care, Institute of Genetics and Cancer, University of Edinburgh Division of Clinical and Surgical Sciences, Edinburgh, UK
- ²³Academic Surgical Unit, Department of Surgery and Cancer, Imperial College London, London, UK
- ²⁴Department of Upper Abdominal Diseases, Karolinska University Hospital, Stockholm, Sweden, Sweden
- ²⁵Department of Molecular Medicine and Surgery, Karolinska Institute, Stockholm, Sweden
- ²⁶Section of Gastrointestinal Surgery, Hospital del Mar, Hospital del Mar Research Institute, Autonomous University of Barcelona, Barcelona, Spain
- ²⁷Department of Nutrition and Dietetics, Royal Surrey NHS Foundation Trust, Guildford, UK
- ²⁸Functional Gut Clinic, London, UK
- ²⁹Guy's and St Thomas' Hospitals NHS Trust, London, UK
- ³⁰St James's University Hospital, Leeds, UK
- ³¹Leeds Teaching Hospitals NHS Trust, Leeds, UK
- ³²Department of Clinical Science, Intervention and Technology (CLINTEC), Karolinska Institutet, Stockholm, Stockholm, Sweden
- ³³Salford Care Organisation, Northern Care Alliance, Salford, UK
- ³⁴Department of Dietetics, Oxford University Hospitals NHS Foundation Trust, Oxford, UK
- ³⁵Department of Nutrition and Dietetics, Beaumont Hospital, Dublin, Ireland
- ³⁶Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK
- ³⁷Oncology Department, Geneva University Hospital, Geneva, Switzerland
- ³⁸Department of Medicine, University of Geneva, Geneva, Switzerland
- ³⁹Department of Gastroenterology and Hepatology, Amsterdam University Medical Centres, Amsterdam, Netherlands
- ⁴⁰University of Verona, Verona, Italy
- ⁴¹Department of Surgery, Catharina Hospital, Eindhoven, Netherlands
- ⁴²Department of Surgical Sciences, Uppsala University, Uppsala, Sweden
- ⁴³Department of Internal Medicine I, Johannes Gutenberg University Mainz, Mainz, Germany
- ⁴⁴Department of Surgery, St James's Hospital, Dublin, Ireland
- ⁴⁵Department for General, Visceral and Trauma Surgery, Elisabeth-Krankenhaus-Essen, Essen, Germany
- ⁴⁶Contilia Center for Esophageal Diseases, Elisabeth Hospital Essen, Essen, Germany
- ⁴⁷Centre Hospitalier Régional Universitaire de Lille, Lille, France
- ⁴⁸Duke University School of Medicine, Duke University Health System, Durham, North Carolina, USA
- ⁴⁹University of Southampton, Southampton, UK
- ⁵⁰NIHR Southampton BRC, University Hospital Southampton NHS Foundation Trust, Southampton, UK
- ⁵¹Gastroenterology, United Lincolnshire Hospitals NHS Trust, Lincoln, UK
- ⁵²University of Nottingham, Nottingham, UK

Collaborators We do not have any collaborator group name. All of our participants are listed as authors, which is outlined above.

Contributors Sowrav Barman (Conceptualisation, Data curation, Formal analysis, Investigation, Project administration, Visualisation, Writing original draft, Writing—review & editing), Mickael Chevallay (Data curation, Formal analysis, Investigation, Project administration, Visualisation, Writing—review & editing), Suzanne S Gisbertz (Conceptualisation, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Visualisation, Writing—original draft, Writing—review & editing), Mieke Van Hemelrijck (Formal analysis, Investigation, Methodology, Project administration, Resources, Writing—review & editing), Ben E Byrne (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—original draft, Writing—review & editing), Bas Wijnhoven (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—review & editing), Sheraz Markar (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—review & editing), Jessie A Elliott (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Writing—review & editing), Jan Bornschein (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—original draft, Writing—review & editing), Mark Pritchard (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—review & editing), Magnus Nilsson (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—review & editing), Donald Low (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Christian Alexander Gutschow (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—review & editing), Jason Dunn (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Sebastian Zeki (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Sam H Ahmedzai (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—review & editing), Barry Laird (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Jafar Jafari (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Orla Evans (Data curation, Formal analysis, Investigation, Writing—review & editing), Christopher J Peters (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Pernilla Lagergren (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Jesper Lagergren (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—review & editing), Manuel Pera Roman (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Maria Dolors Muns Cornellas (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Fiona Huddy (Data curation, Formal analysis, Investigation, Writing—review & editing), Anthony Hobson (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Zainab Noor (Data curation, Formal analysis, Investigation, Writing—review & editing), Andrew J Cockbain (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Fredrik Klevebro (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—review & editing), Louis Fox (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Charlotte Moss (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Kellie Owen (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Anne-Margrethe Phillips (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Chantal T Hoen (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Elizabeth Ward (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Cathy White (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Mark I van Berge Henegouwen (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Stefan Mönig (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Loes Noteboom (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Kiran Purushothaman (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Thibaud Koessler (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Marcel André Schneider (Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—review & editing), Gwen Masclee (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Christian Geroin (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Jacopo Weindelmayer (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Silvia Lazzaris (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Misha Luyer (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Jakob Hedberg (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing),

Visvakanth Sivanathan (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), John Reynolds (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Arnulf H Hölscher (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Guillaume Piessen (Formal analysis, Investigation, Project administration, Resources, Writing—review & editing), Timothy E Miller (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—review & editing), Mike Grocott (Conceptualisation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing—review & editing), Jervoise Andreyev (Conceptualisation, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Visualisation, Writing—original draft, Writing—review & editing), Andrew Davies (Conceptualisation, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Visualisation, Writing—original draft, Writing—review & editing)

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ORCID iDs

Sowrav Barman <https://orcid.org/0009-0008-3949-5385>
Ben E Byrne <https://orcid.org/0000-0002-2183-8166>
Sebastian Zeki <https://orcid.org/0000-0003-1673-2663>
Pernilla Lagergren <https://orcid.org/0000-0002-4634-0233>
Mark I van Berge Henegouwen <https://orcid.org/0000-0001-8689-3134>
Marcel André Schneider <https://orcid.org/0000-0002-6723-8879>
Jervoise Andreyev <https://orcid.org/0000-0002-7165-6352>

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