

The range and suitability of outcome measures used in the assessment of palliative treatment for inoperable malignant bowel obstruction: a systematic review

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What is already known about the topic?

- Malignant bowel obstruction is a complex condition, both in terms of its aetiology and management. For patients nearing the end of their life, multiple options for palliative treatment exist, and the best option is not always clear.
- Recruitment to control arms of randomised clinical trials is difficult in inoperable malignant bowel obstruction when patients are at the end of life.
- Outcome assessment in inoperable malignant bowel obstruction is currently inconsistent.

What this paper adds

- Adverse events and survival are the most prevalent outcomes measured in studies of inoperable malignant bowel obstruction patients, when symptom relief might be the most appropriate objective.
- Definitions of treatment success and methods of measuring key symptoms vary across palliative interventions used to achieve symptom relief.
- Few studies measure patients' quality of life, and those that do struggle to conduct meaningful assessments because of patient deaths in the follow-up period.

Implications for practice, theory or policy

- There is a need for greater consistency in the way that measures of pain, nausea and vomiting are captured in the assessment of palliative interventions for inoperable malignant bowel obstruction.
- Success of treatment should encompass a measure related to patients' wellbeing.
- Quality of life should be measured in a way which is appropriate for palliative settings, and captured in a short window of time in a way that is meaningful and minimises the burden of assessment for patients.

Background

Bowel obstruction is a common complication of advanced cancer^[1,2] which prevents intestinal transit and digestion. This causes severe pain, nausea, abdominal distension and vomiting^[3] and can have profound effects on a person's quality of life^[4,5]. An obstruction can be mechanical (caused by the infiltration of a tumour) or functional (caused by a lack of motility), and can present as a singular blockage or multiple blockages caused by diffuse carcinomatosis. The wide range of definitions of the condition contribute to difficulties in establishing its incidence^[6,7,8]. It is most prevalent in colorectal cancer, affecting up to 29 per cent of patients^[9], and in ovarian cancer, affecting up to up to 51 per cent of patients^[6].

The management of malignant bowel obstruction is complex and controversial^[10]. Surgery to remove the blockage is often not an option in advanced disease^[3] because symptom relief is often short term, and patients are at risk of complications and an increased length of hospital stay^[11,12]. Use of nasogastric tube decompression can relieve the symptoms, but is often uncomfortable for patients^[13,14]. For inoperable malignant bowel obstruction, palliative intervention options include placing an expandable stent or a venting gastrostomy for decompression, or a more conservative approach using medication to reduce intestinal secretions, nausea, vomiting and pain.

There is currently little consensus over how to evaluate the outcome of treatments for inoperable malignant bowel obstruction^[2,10]. A mix of procedural and non-procedural interventions are used to relieve the obstruction and/or its symptoms. Often, symptoms are addressed simultaneously, using drugs such as somatostatin analogues to reduce intestinal secretions, antiemetics to control nausea and vomiting and analgesics for pain relief, but experience in pharmacological interventions is limited and sometimes theoretical when it comes to sequencing and combining medications^[12,15]. There is also a lack of agreement on clinically relevant outcomes and timepoints for measuring symptom control^[15].

The development and use of a standardised set of outcomes across clinical research studies of inoperable malignant bowel obstruction would improve the consistency of outcome reporting, allow comparisons between clinical trials and inform clinical decision-making. The aim of this review was to identify the range and suitability of outcomes currently used to

evaluate palliative treatments for inoperable malignant bowel obstruction, including procedural interventions for intestinal decompression (stenting or venting gastrostomy), non-procedural pharmacological interventions and the administration of parenteral nutrition. It comprises Phase I of a four-phase study developing a core outcome set (COS) for the assessment of inoperable malignant bowel obstruction in research and clinical practice^[16].

Methods

The protocol for this review was registered with the International Prospective Register of Systematic Reviews (PROSPERO ID: CRD42019150648). The review follows methodology recommended by the Core Outcome Measures in Effectiveness Trials (COMET) initiative^[17], and is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement^[18].

Search strategy

The following databases were searched in October 2021 using strategies developed through discussion with an information retrieval specialist: the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane CENTRAL, Embase, MEDLINE and psycINFO. Additional searches were conducted through Caresearch, OpenGrey and BASE. The search was limited to studies of adults, with no date or language restrictions. Search strategies are available via the PROSPERO registry. Reference lists of systematic reviews of studies of palliative interventions for inoperable malignant bowel obstruction were hand searched for relevant primary studies not captured by the database search.

Study eligibility and selection

Given the complex aetiologies of malignant bowel obstruction and the difficulties in comparing studies that this presents, our definition of the condition for the purposes of this review is restricted to the obstruction of the intestines distal to the ligament of Treitz as a result of a cancerous tumour^[8,12]. In order to capture as wide a range as possible of outcomes, the review included RCTs, quasi-RCTs, single arm trials and observational studies reporting outcomes on clearly defined palliative groups or subgroups of patients with advanced, unresectable cancer undergoing pharmacological ('medical' or 'conservative')

treatment, endoscopic or temporary decompression procedures (stents or venting gastrostomy) or parenteral nutrition to treat patients with malignant bowel obstruction without concurrent chemotherapy. Eligible studies included at least one subgroup undergoing a non-surgical intervention with palliative intent, in any study setting, with no restrictions on the period of follow-up.

We excluded studies in which patients with gastric outlet obstruction (above the ligament of Treitz) made up all or the majority of the palliative sample, and studies solely focused on obstructions of benign aetiology (adhesions or radiation enteropathy). We also excluded studies without a clearly defined palliative inoperable malignant bowel obstruction group, studies of interventions including chemotherapy unless a non-chemotherapy group was assessed separately, and studies evaluating the technical success of endoscopic procedures without assessing patient-relevant outcomes. Studies were also excluded if the abstract cited clinical success as the sole outcome with no accompanying patient-relevant definition of 'success'. Qualitative studies were excluded; a systematic review of qualitative studies was undertaken separately (PROSPERO ID: CRD42020176393)^[19].

Papers were collated using Endnote X7 (Thompson Reuters, New York, USA) and duplicates removed. All abstracts were screened independently by AB and GO against eligibility criteria using Abstrackr (Center for Evidence Synthesis in Health, Brown School of Public Health, Providence, Rhode Island, USA). Full texts were also screened independently by AB and GO. Disagreements over inclusion were resolved by discussion (AB, GO, JWB). Abstracts citing outcomes of completed trials meeting the eligibility criteria were included where a published full text was not available. For papers in languages other than English, full texts of methods, results (including tables) and discussion sections of each study were translated using GoogleTranslate and edited for clarity; this produced a level of translation adequate to meet the data extraction requirements of a review of outcome terminology, and enabled the inclusion of a broader range of papers.

Data extraction

Data on study designs, aims, settings, sample sizes, comparison groups/interventions and cancer types were extracted from full text articles by AB and GO using a data extraction form in Microsoft Excel® piloted before extraction commenced. We anticipated that the heterogeneity of study designs and outcomes would not allow the synthesis of statistical

data, and measures of effect were not extracted. The aim of the review was to conduct a descriptive synthesis of outcome reporting^[20].

Indexing of outcomes and domain categorisation

Outcomes, the frequency of their occurrence, outcome definitions, timepoints and patient-relevant statements in descriptive text were extracted verbatim using NVivo 12 (QSR International, Burlington, MA, USA) to retain contextual information, categorised by intervention type. 'Outcome' was defined as any term used in included papers to specify measurement of a clinical endpoint or physiological event, in any domain. Where a primary outcome was not specified, this was inferred as the first outcome reported in study results. Details of patient-reported outcome measures (PROMs) used in included studies were also collected.

Two lists of verbatim outcomes were produced: *Outcomes List 1* included all stand-alone clinical and physiological endpoints (Supplementary File 2), *Outcomes List 2* included individual items extracted from patient-reported outcome measures (Supplementary File 3), as recommended by the Core Outcome Measures in Effectiveness Trials (COMET) initiative^[17]. All outcomes were categorised under the following COMET domains^[21]: physiological/clinical (including gastrointestinal and nutrition outcomes), life impact, resource use, death (including mortality and survival) and adverse events. Synonymous outcomes in each list were pooled and combined into standardised terms, and this process was reviewed by members of the study Steering Group (*[initials of team members]*).

Assessment of bias

The objective of the review was to extract, analyse and pool outcome terms (verbatim), and to count the frequency of their use to indicate which outcome measures are most prevalent in the assessment malignant bowel obstruction. Inclusion criteria focused on gathering as broad a range of outcome measures as possible. The review did not assess the methodological quality of studies as it did not aim to draw any conclusions related to the efficacy of treatments, or to evaluate the research design of included studies.

Results

Search results

Search results are summarised in Figure 1. Of the 80 papers included in the review, 12 reported RCTs (2 papers reporting different outcomes for the same RCT), 3 quasi-RCTs, 8 single-arm trials and 57 observational studies with a total of 13,898 participants. For one single-arm trial not yet published, outcomes were extracted from trial results on *ClinicalTrials.gov* and a published abstract^[22]. Study characteristics are summarised in Supplementary File 1. The distribution of included studies by year and intervention type is shown in Figure 2.

Characteristics of included studies

Participants and interventions

The 23 papers reporting on clinical trials included 1,311 participants, of which 53% took part in pharmacological trials^[22-37], 14% in trials of decompressive procedures (stenting/venting gastrostomy)^[38-42], 4% in a trial of a traditional Chinese remedy (Da-Cheng-Qi)^[43], and 3% in a trial of parenteral nutrition^[44]. The number of participants enrolled on the 11 randomised controlled trials ranged between 17^[34] and 106^[23/29]. One early RCT compared dexamethasone to a placebo^[24], eight RCTs compared treatment with somatostatin analogues to standard pharmacological treatment^[23,26,27,28,30,31,32,34], one compared percutaneous transoesophageal gastrostomy (PTEG) to decompression using a nasogastric tube^[39], and one compared stenting with surgery (resection or stoma)^[42].

The 57 observational studies^[45-101] reported on the treatment of 12,587 patients, 92% of which were patients with malignant bowel obstruction. Of these palliative patients, 27% underwent surgery for their obstruction (initially or after temporary stenting), and 73% were inoperable. Surgery was conducted with the primary intention of relieving symptoms (adhesiolysis, bypass, colostomy, enterostomy, laparotomy, ileostomy, open gastrostomy, resection); outcomes for subgroups of operable patients were not extracted. Of the inoperable patients, 74% underwent pharmacological treatment and 3% unspecified pharmacological or decompressive treatment, 11% underwent stenting, 11% gastrostomy, and 1% parenteral nutrition as a primary intervention. The grouping of samples without distinguishing between operable/inoperable or non-palliative/palliative patients was a

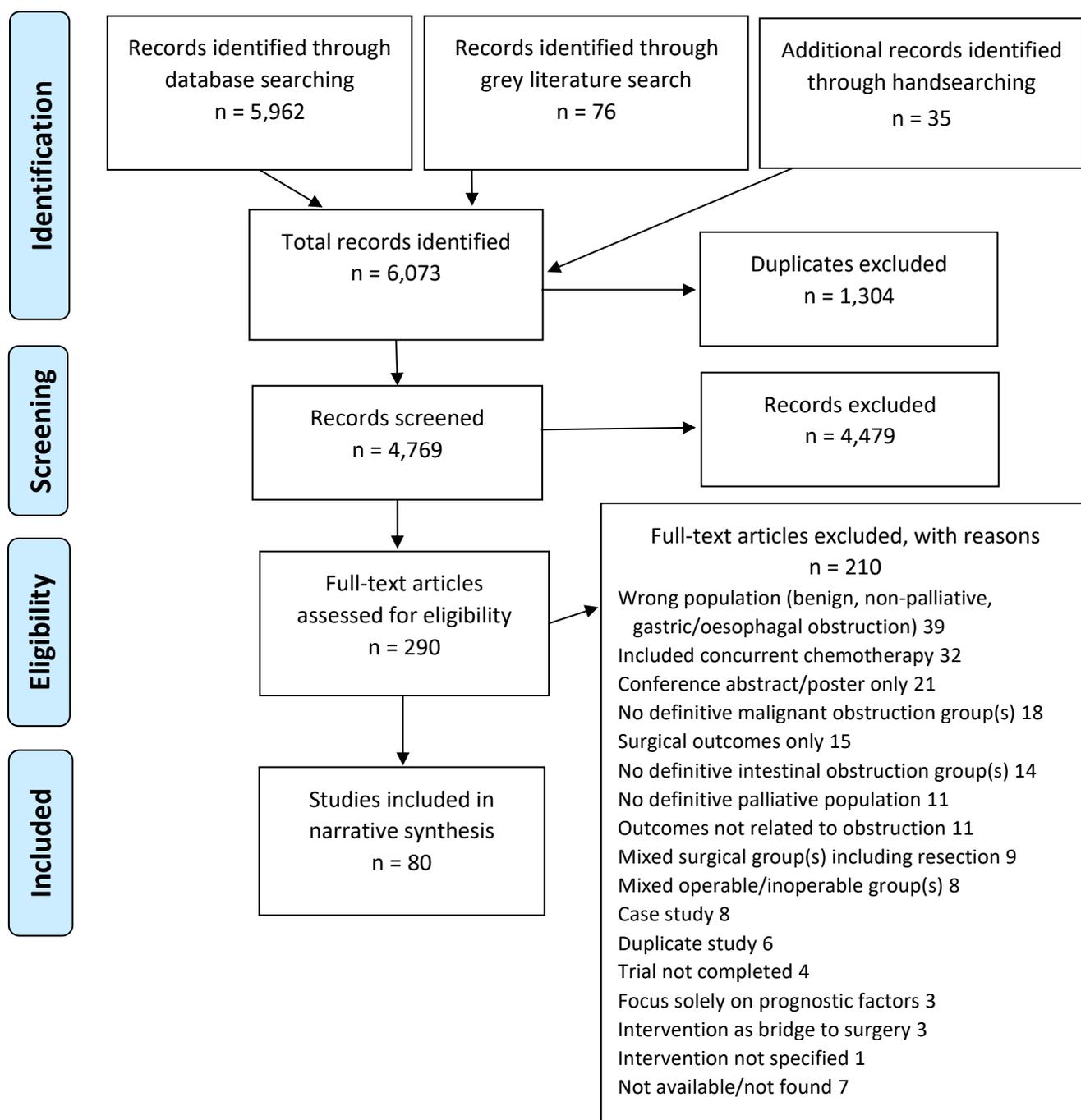


Figure 1 PRISMA diagram of studies investigating palliative treatment of inoperable malignant bowel obstruction.

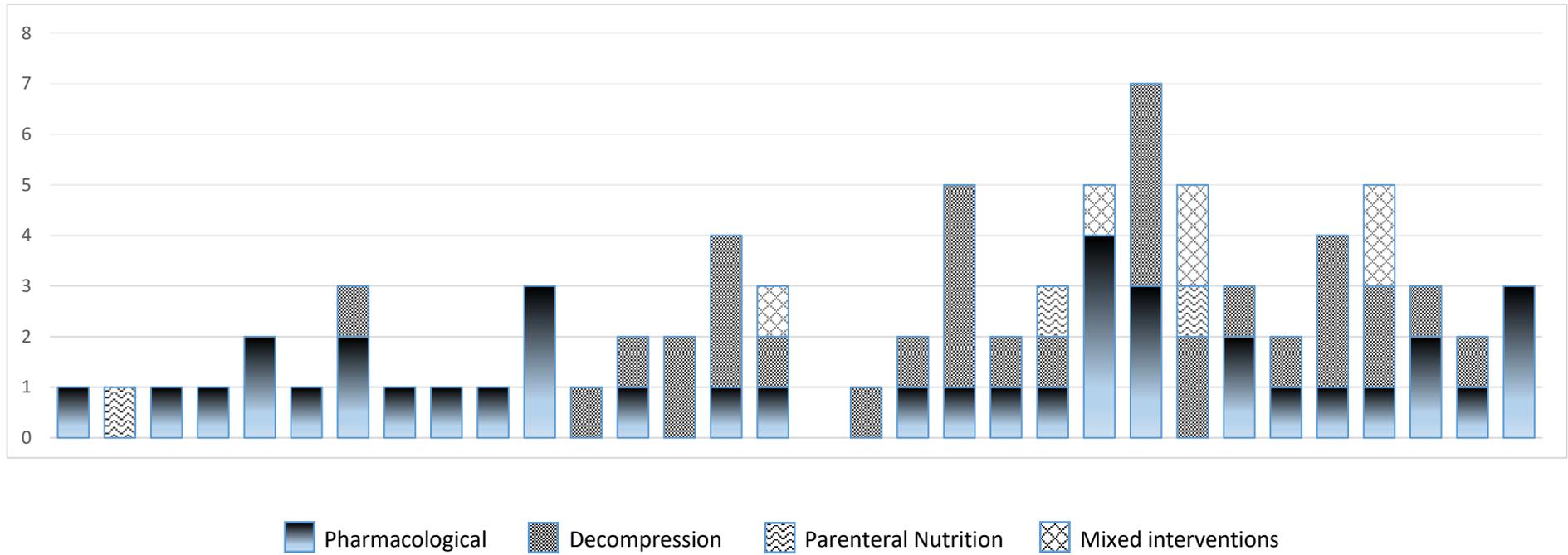


Figure 2 *Distribution of included studies by year and intervention type.*

common reason for exclusion during abstract screening. None of the included observational studies focused exclusively on palliative surgery. Two quasi-RCTs included subgroups undergoing palliative surgery, both comparing defunctioning colostomy with stenting^[40,41].

Settings

The majority of studies took place in hospital settings (88%), 14% of these in specialist cancer centres, 5% reporting the inclusion of patients in palliative care units; 5% included hospice patients and 10% included patients being cared for in their home. Studies took place in Europe (34%), North America (28%), Asia (26%), and remaining studies in Russia and the Middle East. Italy was the source of 48% of the European studies, exploring a mix of palliative interventions and outcomes related to home care.

Cancer types

The primary cancers of study participants are shown in Table 1. The majority of the studies (63%) recruited mixed samples including people with a range of advanced cancers, based on their need for symptom palliation. Nine studies focused exclusively on patients with colorectal cancers^[45,57,60,73,74,77,89,92,93], nine studies focused on patients with gynaecological cancers^[32,37,61,69,79,80,86,87,94].

Study designs	Mixed: multiple cancer types	Mixed: Limited cancer types	Individual cancers/ cancer groups
RCTs, quasi-RCTs and single arm trials	19 ¹	1 colorectal and ovarian	2 ovarian ²
Observational studies	38	1 colorectal/gynaecological 1 pancreatic/ovarian	9 colorectal 4 gynaecological 3 ovarian 1 urological

¹Currow et al, 2015 and McCaffrey et al, 2017^[22,29] covering the same RCT; ²Including Hardy et al, 1998^[24] (majority ovarian).

Table 1 Primary cancers of patients recruited to the 80 studies included in the review.

Identification of outcomes

A total of 343 individual terms reflecting individual and composite outcome measures were extracted verbatim from the 80 studies and categorized under COMET domains^[21].

Synonymous outcomes were pooled into 90 standardised terms (see Supplementary File 2).

The distribution of these outcome measures across COMET core areas and domains is shown in Table 2. A summary of the frequency of outcomes, listed by intervention, is supplied in Supplementary File 4. The majority of outcome measures were related to gastrointestinal symptoms and nutritional intake, reflecting the symptoms of malignant bowel obstruction. Composite quality of life measures were poorly represented. The number of outcomes under the ‘life impact’ domain reflect the reporting of discharge settings or place of death, which were categorised under ‘personal circumstances’, defined by the COMET taxonomy as relevant to the patient’s environment or place of care.

Table 2 *Distribution of the 90 standardised individual outcome terms across COMET domains.*

Core area	Outcome domain	Number of standardised terms
Physiological/Clinical	Gastrointestinal outcomes	30
	Nutrition outcomes	12
Life Impact	Physical functioning	1
	Global quality of life	2
	Delivery of care	2
	Personal circumstances	8
Resource Use	Economic	1
	Hospital	4
	Need for further intervention	10
Adverse events	Adverse events/effects	10
Death	Mortality/Survival	10

Composite outcome measures

A total of 21 patient-reported outcome measures (PROMs) were used across all the studies included in the review, 14 of which used validated measurement tools and eight of which created customised scales. Multiple-item validated scales used to assess physical symptoms and health related quality of life are shown in Table 3. Measurement tool items were separated out into individual items as recommended by COMET^[17]; the distribution of 172 items across domains is shown in Table 4. Synonymous outcomes were recategorised under COMET domains^[21] and pooled into 50 standardised terms (see Supplementary File 3). Table 4 shows a predominance of items assessing physical functioning over items assessing emotional and social functioning.

Table 3 Multiple item assessment scales used in studies.

Outcome Assessed	Assessment scale
Adverse events	National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) ^[22,37,65]
Communication	Japanese version of the Support Team Assessment Schedule (STAS-J) ^[84]
Nutrition	Patient-Generated Subjective Global Assessment (PG-SGA) ^[100]
Pain	Brief Pain Inventory (BPI) ^[23]
Quality of life	European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) ^[29]
	EuroQOL 5-dimension quality of life scale (Euro-QOL EQ-5D) ^[42]
	Functional Assessment of Cancer Therapy – Colorectal (FACT-C) ^[85]
	Functional Assessment of Cancer Therapy – General (FACT-G) ^[49]
	Functional Assessment of Chronic Illness Therapy – Treatment Satisfaction – General Version 1 (FACIT-TS-G) ^[49]
	Global Impression of Change (GIC) ^[23]
Symptoms	Edmonton Symptom Assessment Scale (ESAS) ^[22, 27, 33, 91]
	Rotterdam Symptom Checklist (RSC) ^[91]
	World Health Organisation Control of Vomiting scale ^[25,76,79]
	Visual Analogue Scale (VAS) using graphic representations of emotive faces for patient to indicate feelings ^[22,28,31,62,65,81,86,100]
	Study-specific, customised measurement tool ^[30, 32, 34, 38, 85, 90]

Table 4 Distribution across COMET domains^[21] of the 172 items extracted from PROMs.

Core area	Outcome domain	Number of individual terms
Life Impact	Physical functioning	109
	Social functioning	11
	Role functioning	1
	Emotional functioning/Well-being	32
	Cognitive functioning	2
	Global quality of life	8
	Delivery of care	5
	Personal circumstances	4

Evaluation of outcome definitions

Of the 343 individual outcome terms, 67 were accompanied by a definition: 38 of these definitions were related to measures of overall treatment success or efficacy, 22 to measures of overall symptom control and six to other individual outcomes (complications, lumen patency, readmission, remission rate, resolution of bowel obstruction, hospital-free days). Definitions of success varied according to intervention type. Procedural or technical

success in stenting and venting gastrostomy studies was distinguished from clinical success. Definitions of clinical success for decompression included the resolution of obstruction, the relief of symptoms, and/or the return of normal bowel function accompanied by toleration of oral intake. Symptom control was reported as 'response' in 21% of studies reporting pharmacological interventions. In studies of pharmacological interventions, 'success' and 'response' were defined as the reduction of symptoms, the most prevalent associated measure being a reduction in vomiting.

Approaches considered as 'conservative treatment' or 'medical management' were variously defined as the insertion of a nasogastric tube and administration of fluids^[32], pharmacological treatment^[23,24,25,30,31] or tube decompression with fluids and pharmacological management^[36,51], or undefined^[100]. A rationale offered for including endoscopic procedures under conservative or medical management was that they do not require general anaesthesia or involve the same recovery time as surgery^[51].

Outcome measures

The frequency of occurrence of outcome measures in the 80 included papers is supplied in Supplementary File 4, which lists outcomes by intervention type under COMET taxonomy categories^[21]. Figure 3 shows outcomes ranked by frequency.

Physiological and clinical

The range of approaches taken to the measurement of key symptoms are shown in detail in Supplementary File 4. In the gastrointestinal subdomain, the most prevalent outcome was overall symptom control, or 'response to treatment', measured in 38% of studies. The most prevalent symptoms measured individually or as part of a composite symptom control measure included vomiting (41% of studies), nausea (34%) and abdominal pain (33%). Outcomes related to the use of a nasogastric tube to relieve vomiting were included in 24% studies (15 related to pharmacological interventions). Removal of nasogastric tube/changes in nasogastric tube secretion volume were reported as proxy measures for the control of vomiting (evaluated daily), and requirement for a nasogastric tube indicated a failure to adequately control symptoms.

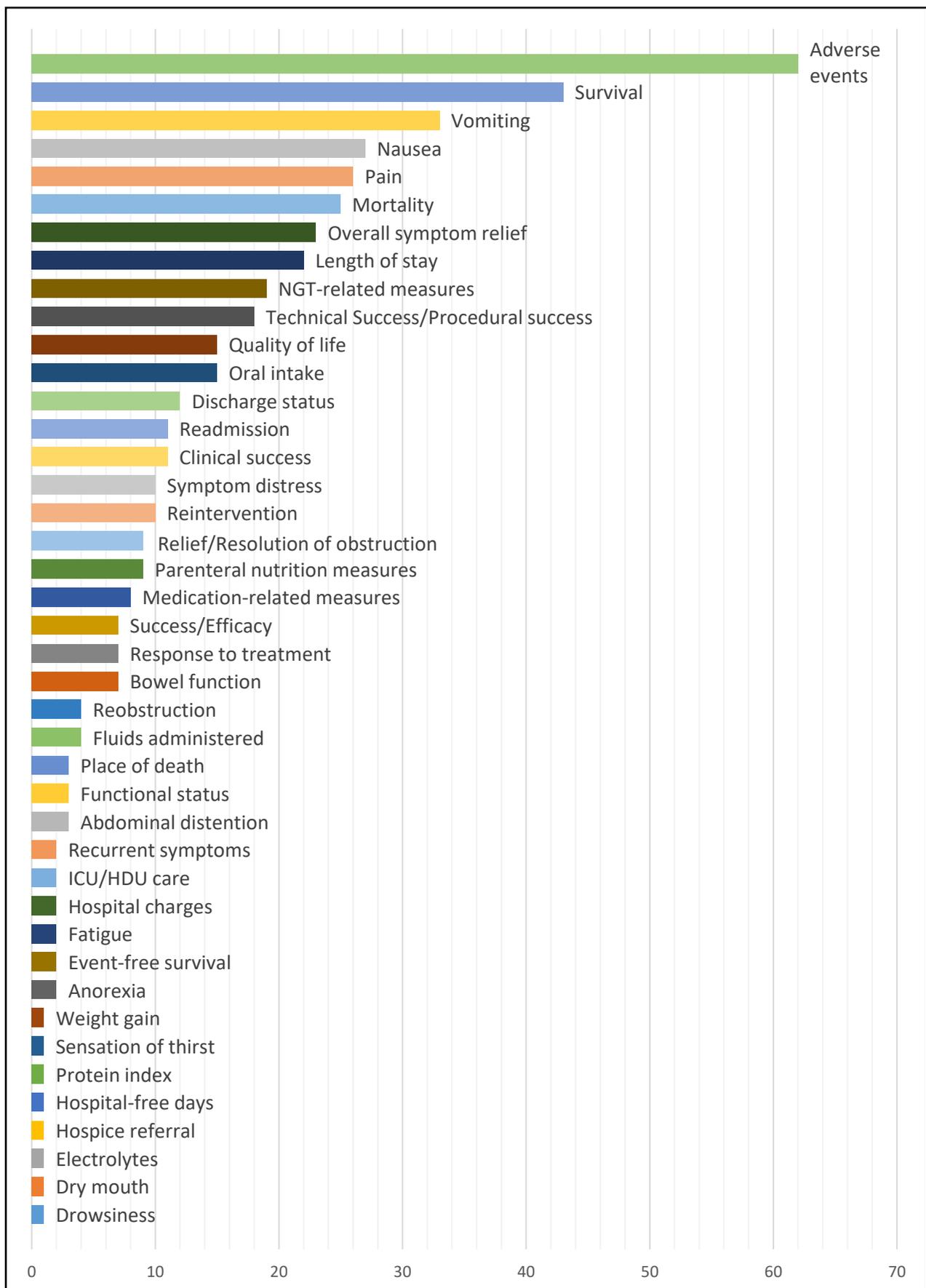


Figure 3 Outcomes used to assess inoperable malignant bowel obstruction in the 80 studies, ranked by frequency of occurrence.

The most prevalent nutritional measure was oral intake (19% of studies), reported as an indicator of symptomatic improvement and most often assessed in three stages: ability to tolerate fluids only, fluids and soft foods, or fluids and solid foods. Measures related to parenteral nutrition were included in 13% of studies^[33,44,45,48,54,69,82,100]; only three papers focused on parenteral nutrition met inclusion criteria for the review^[44,48,56], all of which discussed controversies around its administration and patient and caregiver concerns about death by starvation when parenteral nutrition is withdrawn.

PROMs including measures of physical symptoms were used by 24% of pharmacological studies^[22,23,27,28,29,33,35,65,81,100]. Pharmacological studies assessed a more diverse range of symptom measures than papers exploring decompression procedures (see Supplementary File 4), only four of which made use of PROMs assessing global quality of life^[39,42,85,101]. The majority of pharmacological studies measured key symptoms daily, while studies of decompression conducted weekly assessments. The degree of heterogeneity in timepoints of measurement for symptom-related outcomes is shown in Table 5.

Table 5 *Heterogeneity in timepoints of measurement for symptom-related outcomes in decompression and pharmacological treatments, where timepoints were reported.*

Decompressive interventions	Pharmacological interventions
Within 7 days of procedure ^[58]	On admission and at discharge ^[100]
Within 30 days of procedure ^[57]	Daily until intestinal transit recovered ^[83]
Weekly for 4 weeks ^[38]	Daily to day 3, 4, 6 or 7 ^[23,26,30,32,33,34,35,36,73,76,79,86,88]
Weekly at weeks 1, 2, 4, 8, 12 and 24 ^[85]	Day 1, then every 3 days ^[81]
	Days 1, 3, 7, then weekly ^[90]
	Days 1,7,14,29,57,85 ^[27]
	Days 2 and 3 ^[89]
	Days 2, 4, 8, 15 ^[37,65]
	Days 3 and 6 ^[31]
	Days 3, 7, 10, 20 ^[28]
	Days 4, 8, 15 ^[37]
	Days 7, 14, 28 ^[22]
	At 1 week, 1 month and 3 months ^[91]

Life impact

Life impact is a core area in the COMET taxonomy^[21], and includes domains related to physical, psychological, social, emotional and cognitive functioning, global health related quality of life and personal circumstances. Assessment of quality of life was attempted in 19% of studies. Validated summary measures used to assess quality of life are listed in Table

3, and were used in four studies^[23/29,42,49,85]. Two RCTs^[23/29,42] and two observational studies^[49,85] chose quality of life as a primary outcome, but did not recruit or retain enough patients at follow up to enable successful analyses.

Shima et al^[35] used a customised summary quality of life measure. Implicit composite global quality of life outcomes^[17] were assessed in three studies: '30 good days', defined as days out of hospital subsequent to the date of consultation^[49]; well-being, defined on a VAS from 'I don't feel well at all' to 'I feel very well'^[28]; and quality of life recorded using a VAS^[102] showing faces with graded expressions from unwell/unhappy to well/happy^[65]. Quality of life was assessed at treatment cessation^[29], daily in the week following intervention^[23,35,65], or weekly/monthly^[22,27,42,85,91] (with follow-up to 24 weeks in studies evaluating decompressive procedures). Treatment-related preferences or goals of care expressed by study participants rather than clinicians were referred to in the descriptive text of 15% of studies ^[34,48,50,51,52,59,66,68,69,72,85,86].

Given that one of the aims of palliative care is to support patients achieve their preferred place of care, place of death (which does not appear elsewhere in the COMET taxonomy) was categorised under the life impact domain. This outcome appeared in 4% of studies^[53,59,69] evaluating percutaneous decompression tube/gastrostomy procedures, two of these citing the procedure as facilitating home death^[53,69].

Resource use and adverse events

Studies of procedural interventions reported a higher proportion of resource related outcomes than studies evaluating pharmacological interventions or parenteral nutrition (see Supplementary File 4). Length of hospital stay was the most frequently assessed (28% of studies), the other most prevalent outcomes being discharge status (15%) readmission (14%) and reintervention (13%), reflecting the likelihood of re-obstruction and the recurrence of symptoms, or the occurrence of complications.

The most frequently measured outcomes were adverse events (78% of studies); terminology to describe adverse events included 'adverse effects', 'side effects', 'toxicity' or 'complications'. All papers reporting on decompression procedures reported details of complications (pain or bleeding; stent migration, perforation or tumour overgrowth; tube occlusion or infection at tube insertion site). Early complications were defined as events

occurring within 30 days^[57] of a decompression procedure. Overall, 66% of the pharmacological studies recorded details of adverse effects. The National Cancer Institute Common Terminology Criteria for Adverse Events (CT-CAE v3) was used to record toxicity in 4% of studies^[23,37,65]. Sixteen per cent of studies did not report adverse events, including three RCTs exploring pharmacological interventions^[30,32,34].

Studies focusing on nutrition recorded complications such as bone pain, catheter dislodgement, febrile episodes, hyperkalemia, infection, metabolic complications, pancreatitis and sepsis^[48,56,66], with the exception of one quasi-RCT^[44] which closed early because of poor patient accrual, reporting concerns from patients and families about starvation in the case of allocation to the control arm.

Mortality and survival

Mortality was a more prevalent outcome in evaluations of procedural interventions (56% of decompression studies) than pharmacological studies (8%), with timepoints of follow-up ranging up to 8 months. Survival was assessed in 54% of studies (63% of decompression studies and 42% of pharmacological studies), with variable follow up timepoints (days or months).

Discussion

From the 80 studies included in this review, 343 individual outcomes were extracted and pooled into 90 standardised terms. Items from 21 PROMs were separated out into 175 individual items and pooled into 50 standardised terms. All unique standardised terms were then categorised into six domains: physiological, nutrition, life impact, resource use, mortality, and survival. The highest number of outcomes were categorised under the physiological domain, representing the gastrointestinal symptoms of inoperable malignant bowel obstruction. Other key domains represented in the studies include quality of life, nutrition, the need for further intervention, adverse events, mortality, and survival. Assessment of survival and adverse events is comprehensive, but there is wide variation in the level of detail reported for adverse events, with some studies describing intervention-related events and others recording concomitant major events related to comorbidities.

The outcomes summarised in this review have been used to assess a patient population with advanced cancer, many of whom are approaching the end of life. For this population, survival is not always the most important outcome from the perspective of patients or clinicians – the aim of palliation is ‘a good outcome under...unfavourable circumstances’^[98]. Previous reviews of treatment for malignant bowel obstruction exploring surgery^[103], surgery and medical management^[104,105] and parenteral nutrition^[106] point out that the clinical resolution of bowel obstruction is not an adequate proxy measure for symptom relief or quality of life. These outcomes apply across all interventions (procedural and non-procedural, and parenteral nutrition), and this review indicates a need to be more precise in our definitions of ‘treatment success’ with this population.

Trials of treatments for inoperable malignant bowel obstruction are difficult to conduct – recruitment raises ethical concerns in a population suffering from distressing symptoms towards the end of life, and there is an understandable reticence among patients and caregivers to agree to randomisation^[44,85]. Difficulties also arise where symptom control is the primary outcome and control arms include patients with a poorer prognosis. Currow et al^[23] was the only study to address the issue of pre-consent, where patients who might be expected to develop an obstruction give their permission for inclusion in a trial before it commences.

The review demonstrates a level of consensus across studies on the central importance of pain, nausea and vomiting in bowel obstruction, and how these key symptoms should be measured – the majority of studies assess the severity of pain and nausea, and the severity and frequency (number of daily episodes) of vomiting. Assessing the absence of key symptoms is not sufficient in this population^[19], and placing nausea on a continuum with vomiting may not allow the assessment of the balance between these symptoms for individual patients. The details of this can, however, be difficult to tease out where patient-reported outcome measures fail to focus either on symptoms specific to bowel obstruction or symptoms appropriate to the end of life. The review also indicates that currently, a focus on physical symptom assessment overshadows the measurement of psychological, social and spiritual outcomes in inoperable malignant bowel obstruction.

There is a need for further consideration of which patient-reported outcomes measures might best suit this particular population. Quality of life assessment includes an individual’s

perceptions in the context of their personal values and beliefs, and considers symptom improvement alongside physical deterioration, reflecting the core values of the WHO definition of palliative care^[108]. This can only be meaningful when patients have good communication with health care professionals and reasonable expectations of treatment. Evidence of the improvement of quality of life is important to determining the utility of palliative treatment^[104]. It can be limited in relation to inoperable malignant bowel obstruction because of difficulties in conducting meaningful assessment^[27,42,49], for example because of short windows of time available for measurement. The use of visual analogue scales to assess wellbeing^[27,65] does not consider the challenges this may present to patients who may have difficulty with vision and the interpretation of emotions at the end of life^[109]. Self-report is often feasible, however^[110], and COMET suggest that the scope and nuance of quality of life measurement, in general terms, is often inadequate^[21].

In the studies included in this review, evaluating the assessment of quality of life relies on global measures. In the light of our qualitative review^[19], this fails to capture some of the associations between quality of life and outcomes listed under other COMET categories that are evident from studies of patient experience. For example, the resumption of oral intake, when measured to evidence the mechanical resolution of obstruction, does not reflect the psychological effects on the patient. The inability to eat is often experienced as a deep loss on a social and emotional level^[19], and the degree and duration of its restoration are likely to have deep implications for quality of life. Further, issues to do with patient comfort are rarely discussed in any depth in the discussion sections of study reports. A minority of papers noted patients' physical discomfort with nasogastric tubes, and studies of parenteral nutrition explored patient and caregiver concerns about starvation when treatment is withdrawn.

Strengths and limitations of the review

The search was necessarily broad to catch as wide a spectrum of outcomes as possible from palliative approaches to treatment. Searching by the condition (malignant bowel obstruction) was necessary as searching by intervention proved too indiscriminate, retrieving (for example) multiple papers focused on the treatment of non-malignant obstruction or evaluating procedural techniques. Studies use a variety of approaches in their titles – some specifying obstruction by cancer type, others by its location, many including

benign and malignant obstruction in the same study. Our broad search strategy might have led to the omission of studies which met the eligibility requirements. It is possible that studies where concurrent chemotherapy occurred have been included in the review, if this has not been reported. A strength of the review is that papers reporting on decompression and pharmacological management reached a point of saturation where no new outcomes arose in multiple additional papers. This point was not reached in relation to parenteral nutrition, because of the low number of included studies in this area.

This review cannot demonstrate whether quality of life tools focused on palliative patients may be more suitable for assessing inoperable malignant bowel obstruction than tools focused more generally on symptoms of advanced cancer. For example, the Palliative care Outcome Scale (POS)^[111], developed in 1999 as a successor to the Support Team Assessment Schedule (STAS) for use with patients with advanced disease and refined as the Integrated Palliative care Outcome Scale (IPOS) in 2019^[112], did not appear in the included papers, which date from 1990 to 2021. This may reflect the time lag between uptake of new measurement tools in practice and reports of their use in journal publications.

Conclusion

This review demonstrates that outcome measurement in the majority of studies of palliative interventions for inoperable malignant bowel obstruction currently focuses on survival and adverse events, and that routine assessment of patients' quality of life is scarce. Definitions of treatment success centre around technical aspects of decompressive procedures and the reduction of symptoms by pharmacological interventions, but fail to include measures of wellbeing appropriate to patients at the end of life. A clear distinction needs to be made between studies evaluating the technical success of procedural interventions in resolving obstruction and studies evaluating patient-relevant outcomes related to symptoms and wellbeing. The majority of studies focus on the three key symptoms of pain, nausea and vomiting, assessing them in a variety of ways for their severity, frequency, and/or duration; measures placing nausea and vomiting on a continuum may be inappropriate for the assessment of inoperable malignant bowel obstruction patients because they do not distinguish the balance between these two key symptoms. Three recommendations can be made from the results of the review. In assessing inoperable malignant bowel obstruction,

we need increased patient relevance in definitions of treatment success to align with the aims of end of life care, a more consistent approach to the nuances of symptom assessment, and greater consideration of how to measure wellbeing in this patient population.

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Author contributions

JWB, SN, MJ, FEM, DC, GO, EGB, AN and KS were involved in the conception of the study. All authors contributed to protocol development; SN, JWB, MJ, FEM and DC made significant contributions to the direction of the review. AB and GO led on data collection and analyses, and AB led on writing, with oversight of data collection, analysis and writing by JWB. All authors read and approved the final manuscript.

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Data management and sharing

Data analysis files are available from the corresponding author on reasonable request.

Declaration of Conflicting Interests

The authors declare that there is no conflict of interests.

Research ethics and patient consent

The review did not directly involve human participants and did not require ethical approvals. The overarching core outcome set study of which this is a part was reviewed by the Wales Research Ethics Committee 5 (Wales REC) on 10th December 2019 (Ref 19/WA/0340).

Supplemental material

Supplementary material for this article is available online.

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[See following pages for Supplementary Files]

Supplementary File 1

Characteristics of included studies

Study	Setting & dates	Participants	Intervention (I) Comparator (C) Exposure (E)	Primary cancer/ Site of obstruction	Primary outcomes <i>ns = not specified</i>
RCTs (12 papers representing 11 RCTs):					
Aramaki et al., 2020 ^[22] A randomized controlled trial of the efficacy of percutaneous transoesophageal gastro-tubing (PTEG) as palliative care for patients with malignant bowel obstruction.	5 hospitals, Japan (Oct 2009–Jan 2015).	39 patients with IMBO (14 females, 25 males). Median age: 62 (34–76)	I: Gastrostomy. C: Nasogastric tubing (NGT).	Primary cancer(s): Bile duct, colorectal, gastric, mesothelioma, oesophageal, ovarian, pancreatic, peritoneal unknown. Site of obstruction: Not stated.	Primary outcome: Symptom palliation
Currow et al., 2015 ^[23] Double-blind, placebo-controlled, randomized trial of octreotide in malignant bowel obstruction.	12 palliative care service networks, Australia (Aug 2008–May 2012).	87 patients with IMBO (52 female, 47 male). Mean age (SD): 62.9 (13.6)	I: Octreotide, 600 mcg/24 hours SC. C: Placebo, normal saline SC; standardized therapies – regular parenteral dexamethasone, 8 mg/24 h; ranitidine, 200mg/24 h,	Primary cancer(s): Not stated. Site of obstruction: Gastric outlet/duodenal, small bowel/multi-level, large bowel.	Primary outcome: Vomiting

			and hydration, 10-20 mL/kg/day unless overtly dehydrated at study entry.		
Hardy et al., 1998 ^[24] Pitfalls in placebo-controlled trials in palliative care: dexamethasone for the palliation of malignant bowel obstruction.	Hospital, UK (Trial 1: Dec 1987 for 36 m; Trial 2: Jan 1993 for 24 m).	37 patients with MBO (female). Median age: 59 (38–80)	Cross-over design. I: Dexamethasone, 4 mg IV every 6h for 5 days. C: Placebo.	Primary cancer: Ovarian. Site of obstruction: Not stated.	Primary outcome: Resolution of obstruction
Laval et al., 2000 ^[25] The use of steroids in the management of inoperable intestinal obstruction in terminal cancer patients: do they remove the obstruction?	12 palliative care units, France (Aug 2008–May 2012).	52 patients with IMBO (33 female, 19 male). Median age: 69.4 (range not stated)	I(i): Methylprednisolone 40mg IV over 1 hr for 3 days. I(ii): Methylprednisolone 240mg IV over 1 hr for 3 days. C: Placebo.	Primary cancer: Colorectal, gynaecological, lung, urological. Site of obstruction: Colon, small bowel, upper duodenum, simultaneous small and large bowel.	Primary outcome (ns): Resolution of obstruction

<p>Laval et al., 2012^[26] SALTO: a randomized, multicentre study assessing octreotide LAR in inoperable bowel obstruction.</p>	<p>18 cancer centres, France (Nov 2005–Sep 2008).</p>	<p>64 patients with IMBO (46 female, 18 male). Mean age (SD): 64.2 (11.0)</p>	<p>I: Intramuscular octreotide LAR 30mg on days 1, 29 and 57, and IV or SC octreotide 600 mcg/24h on days 1 to 6. C: Placebo. <i>Concomitant treatments (both groups):</i> methylprednisolone 3-4mg/kg/24 hours intravenous bolus on days 1 to 6.</p>	<p>Primary cancer: Bladder, bile duct, breast, colorectal, gastric, oesophageal, ovarian, pancreatic, uterine, unknown. Site of obstruction: Duodenum, small intestine, colon, unknown.</p>	<p>Primary outcome: Treatment success (absence of a nasogastric tube and vomiting less than twice per day and no use of anticholinergic agents).</p>
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<p>Mariani et al., 2012^[27]</p> <p>Symptomatic treatment with lanreotide microparticles in inoperable bowel obstruction resulting from peritoneal carcinomatosis: a randomized, double-blind, placebo-controlled phase III study.</p>	<p>22 hospitals, Belgium/France /Netherlands (Sep 2003–Sep 2008).</p>	<p>80 patients with IMBO (66 female, 14 male).</p> <p>Mean age (SD): I: 62.5 (10.0) C: 62.2 (13.2)</p>	<p>I(i): Double-blind phase (10 days): intramuscular injection of 30mg lanreotide microparticles.</p> <p>I(ii): Open-label phase: intramuscular injection of 30mg lanreotide microparticles every 10 days until patients decided to stop treatment or died.</p> <p>C: Placebo.</p> <p><i>Concomitant treatments:</i></p> <p>(1) 1 mg/kg/24h methylprednisolone IV (or equivalent for other corticosteroids) for 5 days previously;</p> <p>(2) 40 mg per day omeprazole (or equivalent) for 3 days previously;</p> <p>(3) antispasmodics or antiemetics: used for 3 days previously.</p> <p>Analgesic use unrestricted.</p>	<p>Primary cancer: Breast, cholangio-carcinoma, colorectal, gastric, ovarian, pancreas, uterus, unknown.</p> <p>Site of obstruction: Stomach/duodenum, colon.</p>	<p>Primary outcome: Vomiting</p>
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<p>McCaffrey et al., 2017^[28]</p> <p><i>Secondary outcome from a double-blind, placebo-controlled randomised trial of octreotide (Carrow et al, 2015, above).</i></p> <p>Does octreotide improve Health-related quality of life (HrQOL) in patients with malignant bowel obstruction.</p>	<p>12 palliative care service networks, Australia (Aug 2008–May 2012).</p>	<p>106 patients with IMBO (85 female, 21 male); only 87 completed trial protocol for Carrow et al, 2015.</p> <p>Mean age (SD): I: 62.9 (13.6) C: 66.3 (12.2)</p>	<p>I: Octreotide, 600 mcg/24 hours SC.</p> <p>C: Placebo, normal saline SC.</p> <p><i>Concomitant treatment:</i> dexamethasone 8 mg/24h; ranitidine 200mg/24h; hydration 10-20 mL/kg/24h.</p>	<p>Primary cancers:</p> <p>Not stated.</p> <p>Sites of obstruction: Gastric outlet/duodenal, small bowel/multi-level, large bowel.</p>	<p>Primary outcome:</p> <p>HRQOL</p>
<p>Mercadante et al., 2000^[29]</p> <p>Comparison of octreotide and hyoscine butylbromide in controlling gastrointestinal symptoms due to malignant inoperable bowel obstruction.</p>	<p>Home care and hospital, Italy (dates not specified).</p>	<p>15 adults with IMBO (13 female and 2 male).</p> <p>Median age: 67 (53–81).</p>	<p>I: Octreotide 300 mcg/24 hours SC.</p> <p>C: Hyoscine butylbromide 60 mg/24 hours SC.</p>	<p>Primary cancers:</p> <p>Breast, gastric, liver, ovarian, pancreatic, rectal, small bowel, vulval.</p> <p>Sites of obstruction:</p> <p>Not stated.</p>	<p>Primary outcome (ns):</p> <p>Vomiting</p>
<p>Mystakidou et al., 2002^[30]</p> <p>Comparison of octreotide administration vs conservative treatment in the management of inoperable bowel obstruction in patients</p>	<p>Hospital, Greece (Oct 1995–Jun 1998).</p>	<p>68 adults with IMBO (32 female, 36 male).</p>	<p>I: Octreotide 600-800 mcg/24 hours by SC.</p>	<p>Primary cancers:</p> <p>Bladder, colorectal, gastric, liver, ovarian, pancreatic, uterine.</p>	<p>Primary outcome (ns):</p> <p>Vomiting</p>

with far advanced cancer: a randomised, double blind, controlled clinical trial.		Median age: I: 63 (47–74) C: 64 (42–77)	C: Hyoscine butylbromide 60–80 mg/24 hours by SC. <i>Concomitant treatment:</i> Chlorpromazine 15–25 mg/24 hours SC.	Sites of obstruction: Not stated.	
Peng et al., 2015 ^[31] Randomized clinical trial comparing octreotide and scopolamine butylbromide in symptom control of patients with inoperable bowel obstruction due to advanced ovarian cancer.	Hospital, China (Jan 2010–Dec 2013).	96 patients with IMBO (female). Median age: I: 54 (47–61) C: 53 (45–61)	I: Octreotide 300 mcg/24 hrs by SC. C: Hyoscine (scopolamine) butylbromide 60 mg/24 hrs by SC. <i>Concomitant treatment:</i> NGT and IV fluids.	Primary cancer: Ovarian. Sites of obstruction: Not stated.	Primary outcome (ns): NGT secretions
Ripamonti et al., 2000 ^[32] Role of octreotide, scopolamine butylbromide, and hydration in symptom control of patients with inoperable bowel obstruction and nasogastric tubes: a prospective, randomised trial.	Cancer unit and home care, Italy (Sep 1995–Sep 1997).	17 patients with IMBO (11 female, 6 male). Median age: 61 (45–75)	I: Octreotide 300 mcg/24hrs for 3 days by SC. C: Hyoscine (Scopolamine) butylbromide, 60 mg/24 hours for 3 days by SC. <i>Concomitant treatment:</i> NGT.	Primary cancers: Breast, cholecystic, colorectal, endometrial, gastric, ovarian, pancreatic. Sites of obstruction: Not stated.	Primary outcome (ns): NGT secretions

<p>Young et al., 2015^[33]</p> <p>Improving quality of life for people with incurable large-bowel obstruction: randomized control trial of colonic stent insertion.</p>	<p>2 hospitals in Australia (Sep 2006–Nov 2011).</p>	<p>52 patients with MBO (17 female, 35 male).</p> <p>Mean age: I: 66 (41–83) C: 67 (35–86)</p>	<p>I: Stent insertion.</p> <p>C: Surgery.</p>	<p>Primary cancers: Colorectal, non-colorectal (unspecified).</p> <p>Sites of obstruction: Ascending colon, descending colon, transverse colon, splenic flexure, hepatic flexure, rectosigmoid colon, sigmoid colon, rectum.</p>	<p>Primary outcome: QOL</p>
Quasi-RCTs (3):					
<p>Fiori et al., 2004^[34]</p> <p>Palliative management of malignant rectosigmoidal obstruction. Colostomy vs endoscopic stenting. A randomized prospective trial.</p>	<p>University hospital, Italy (Jan 2001–May 2003).</p>	<p>22 patients with MBO (9 female, 13 male).</p> <p>Mean age: I: 77.2 (73–80) C: 76 (71–80)</p>	<p>I: Colostomy.</p> <p>C: Endoscopic stenting.</p>	<p>Primary cancer: Colorectal.</p> <p>Sites of obstruction: Sigmoid colon, rectum.</p>	<p>Primary outcome (ns): Procedure time</p>
<p>Oh et al., 2014^[35]</p> <p>A randomized phase II study to assess the effectiveness of fluid therapy or intensive nutritional support on survival in patients with advanced cancer who cannot be nourished via enteral route.</p>	<p>University hospital, South Korea (Jun 2011–Dec 2011).</p>	<p>31 patients, 29 with MBO, 2 on bowel rest due to bleeding (22 female, 19 male).</p> <p>Median age:</p>	<p>I: Parenteral nutrition.</p> <p>C: IV fluids (normal saline, half saline, or dextrose water).</p>	<p>Primary cancers: Breast, colorectal, gastric, hepatobiliary and pancreatic, leukemia, lung, melanoma, neuroendocrine, prostate, salivary gland.</p>	<p>Primary outcome: Survival</p>

		59 (40–83).		Sites of obstruction: Not stated.	
Tomiki et al., 2004 ^[36] Comparison of stent placement and colostomy as palliative treatment for inoperable malignant colorectal obstruction.	University hospital, Japan (Jan 1996–Dec 2002).	35 patients with IMBO (I:19 female, 16 male). Median age: I: 67 (47–83) C: 61 (43–82)	I: Stent. C: Colostomy.	Primary cancers: Colorectal, gastric, oesophageal, ovarian. Sites of obstruction: Not stated.	Primary outcome (ns): Technical success
Single-arm trials (8):					
Aramaki et al., 2013 ^[37] Phase II study of percutaneous transesophageal gastrotubing for patients with malignant gastrointestinal obstruction.	Five hospitals/ cancer centres, Japan (Feb 2003–Dec 2005).	33 patients with MBO (21 females and 12 males). Median age: 61 (31–74)	E: Gastrostomy.	Primary cancer: Colorectal, gastric, ovarian, pancreatic, other. Sites of obstruction: Not stated.	Primary outcome: Clinical efficacy

<p>Duck et al., 2019^[38] Study to assess efficacy and safety of lanreotide Autogel® 120 mg in treatment of clinical symptoms associated with inoperable malignant intestinal obstruction.</p> <p>[Abstract only; full paper not available.]</p>	<p>15 hospitals, Belgium (Nov 2014–Nov 2017).</p>	<p>52 participants with IMBO (41 female, 11 male).</p> <p>Age range: 40–70.</p>	<p>I(i): Phase I – lanreotide Autogel® 120 mg by SC. I(ii): (participants who completed the 28 days of Phase 1 and responded) second dose of lanreotide Autogel® 120 mg by SC.</p>	<p>Primary cancers: Not stated.</p> <p>Sites of obstruction: Not stated.</p>	<p>Primary outcome: Response (symptom control)</p>
<p>Khoo et al., 1994^[39] Palliation of malignant intestinal obstruction using octreotide.</p>	<p>Hospital and hospice, UK (Feb 1991–Oct 1992).</p>	<p>24 patients with IMBO.</p> <p>Age range: 38–88.</p>	<p>I: Octreotide, 100 – 600mcg/24h by SC.</p>	<p>Primary cancers: Appendiceal, bile duct, cervical, colorectal, gallbladder, gastric, liver, ovarian, pancreatic.</p> <p>Sites of obstruction: Not stated.</p>	<p>Primary outcome (ns): Response (control of nausea/vomiting)</p>
<p>Porzio et al., 2011^[40] Can malignant bowel obstruction in advanced cancer patients be treated at home?</p>	<p>Home care (rural community), Italy (Aug 2006–Dec 2009).</p>	<p>11 patients with MBO (8 female, 3 male).</p> <p>Median age: 65 (38–84).</p>	<p>I: Octreotide (300 mcg/24 h), metoclopramide (1 mg/kg/24 h), morphine (dose was patient-tailored after titration; transdermal or oral opioids were switched to parenteral morphine) and dexamethasone (16</p>	<p>Primary cancers: Colorectal, gastric, ovarian, pancreatic.</p> <p>Site of obstruction: Not stated.</p>	<p>Primary outcome (ns): Vomiting</p>

			mg/day intravenous bolus).		
Shima et al., 2008 ^[41] Clinical efficacy and safety of octreotide (sms201-995) in terminally ill Japanese cancer patients with malignant bowel obstruction.	Hospital, Japan (dates not specified).	25 patients with IMBO (14 female, 11 male). Median age: 53 (41–67).	I: Octreotide 300mcg/24h by SC.	Primary cancers: Cervical, colorectal, gastric, ovarian, pancreatic. Sites of obstruction: Not stated.	Primary outcome: Response (control of nausea/vomiting)
Tian et al., 2019 ^[42] Topical Delivery of modified Da-Cheng-Qi Decoction using low-frequency ultrasound sonophoresis for refractory metastatic malignant bowel obstruction: an open-label single-arm clinical trial.	Hospital, China (Oct 2014–Jul 2017).	50 patients with IMBO and completion of at least one week of decompression and octreotide therapy with ineffective results (27 female, 23 male). Median age: 55 (41–72).	I: Topical delivery of Da-Cheng-Qi Decoction (DCQD), a Chinese herbal formula, using ultrasound device. <i>Concomitant treatment:</i> fasting, gastrointestinal decompression, glycerol enema, intravenous nutrition, and anti-secretory therapy.	Primary cancers: Breast, colorectal, gastric, liver, ovarian. Sites of obstruction: Not stated.	Primary outcome (ns): Remission of bowel obstruction (absence of abdominal pain/distension, and the presence of a normal appetite and defecation, without abdominal tenderness and rebound pain)
Tuca et al., 2009 ^[43] Efficacy of granisetron in the antiemetic control of nonsurgical intestinal	3 hospitals, Spain (dates not specified).	24 patients with IMBO (14 female, 10 male).	I: Nil by mouth; no NGT; intravenous hydration with saline; granisetron 3 mg/24h by IV;	Primary cancers: Colorectal, gynaecological, other.	Primary outcome (ns): Response (control of vomiting)

obstruction in advanced cancer: a phase II clinical trial.		Mean age: 61 (40–83).	dexamethasone 4 mg/12h by IV. <i>Rescue therapy if required:</i> haloperidol 2.5 mg by SC.	Sites of obstruction: Upper intestinal tract/ lower intestinal tract/ multiple levels.	
Watari et al., 2011 ^[44] A prospective study on the efficacy of octreotide in the management of malignant bowel obstruction in gynecologic cancer.	Multiple hospitals (number not specified), Japan (Mar 2006–Dec 2009).	22 patients with IMBO (female). Median age: 62 (43–79).	I: Octreotide (300 mcg/24 h) by SC, or IV as a continuous injection, for 7 days.	Primary cancers: Cervical, endometrial, ovarian, peritoneal. Sites of obstruction: Small intestine, large intestine, rectum, unknown.	Primary outcome: Response (control of vomiting)

Observational studies (53):					
<p>Abelson et al., 2017^[45]</p> <p>Long-term postprocedural outcomes of palliative emergency stenting vs stoma in malignant large-bowel obstruction.</p>	<p>Multiple hospitals, New York State, USA (Oct 2009–Dec 2013).</p> <p><i>Prospective cohort study</i></p>	<p>345 patients with MBO (168 female, 177 male).</p> <p>Mean age (SD): Stent group 70.9 (6.8); Stoma group 69.9 (4.4).</p>	<p>E: Stent vs stoma.</p>	<p>Primary cancer:</p> <p>Colorectal.</p> <p>Sites of obstruction: Colon, rectum, 'other'.</p>	<p>Primary outcomes:</p> <p>Subsequent operation and readmission within 90-days/1 year</p>
<p>Alford et al., 2014^[46]</p> <p>Clinical outcomes of stenting for colorectal obstruction at a tertiary centre.</p>	<p>Hospital, Canada (August 2005–March 2011).</p> <p><i>Chart review</i></p>	<p>58 patients with MBO (24 female, 34 male).</p> <p>Median age: 70 (34–97).</p>	<p>E: Stent (11 as BTS).</p>	<p>Primary cancers:</p> <p>Colorectal, non-colorectal (not specified).</p> <p>Sites of obstruction:</p> <p>Ascending colon, transverse colon, splenic flexure, descending colon, sigmoid colon, rectum.</p>	<p>Primary outcome (ns):</p> <p>Clinical success (the ability to pass stool and tolerate an oral diet)</p>
<p>Arvieux et al., 2005^[47]</p> <p>Treatment of malignant intestinal obstruction. A prospective study over 80 cases.</p> <p>[French.]</p>	<p>Hospital, France (Jan 2000–Jan 2004).</p> <p><i>Prospective cohort study</i></p>	<p>78 patients with IMBO (51 female, 24 male).</p> <p>Median age: 64 (22–99).</p>	<p>E: <i>Mixed</i></p> <p>Medical management/gastrostomy.</p> <p>Stage I: Steroids, antiemetics, anticholinergic antisecretory and</p>	<p>Primary cancers:</p> <p>Breast, bile duct, colorectal, endometrial, gastric, lung, oesophageal, ovarian, pancreatic, prostate, skin, urological.</p>	<p>Primary outcome (ns):</p> <p>Survival</p>

			analgesics for 5 days. Stage II: In non-responding patients, somatostatin analogue for three days. Stage III: Gastrostomy.	Sites of obstruction: Not stated.	
August et al., 1991 ^[48] Home parenteral nutrition for patients with inoperable malignant bowel obstruction.	Hospital, Connecticut, USA (1980–1989). <i>Chart review</i>	17 patients with IMBO (13 female, 4 males). Median age: 58 (33–79).	E: Home parenteral nutrition (HPN).	Primary cancers: Appendiceal, colorectal, endometrial, gastric, ovarian. Sites of obstruction: Not stated.	Primary outcome (ns): Survival
Badgwell et al., 2014 ^[49] Outcome measures other than morbidity and mortality for patients with incurable cancer and gastrointestinal obstruction.	Hospital and outpatient clinic, Arkansas, USA (Nov 2009–Jul 2012). <i>Prospective cohort study</i>	53 patients with MBO (24 female, 29 males). Median age: 57 (36–86).	E: <i>Mixed</i> Operative and non-operative procedures.	Primary cancers: Colorectal, 'other'. Sites of obstruction: Gastric outlet, small bowel, large bowel.	Primary outcome (ns): QOL

<p>Baerlocher et al., 2007^[50]</p> <p>Safety and efficacy of gastrointestinal stents in cancer patients at a community hospital.</p>	<p>Community hospital, Canada (Jun 2004–Apr 2006).</p> <p><i>Chart review</i></p>	<p>16 patients with MBO (11 female, 5 male).</p> <p>Median age: 65 (41–89).</p>	<p>E: Stent.</p>	<p>Primary cancers:</p> <p>Ampullary, bladder, colorectal, endometrial, kidney, oesophageal, ovarian, pancreatic, stomach.</p> <p>Sites of obstruction:</p> <p>Oesophagus, colon.</p>	<p>Primary outcome (ns):</p> <p>Procedure time</p>
<p>Bateni et al., 2018^[51]</p> <p>Hospital utilization and disposition among patients with malignant bowel obstruction: a population-based comparison of surgical to medical management.</p>	<p>Multiple hospitals, USA (2006–2010).</p> <p><i>Retrospective cohort study</i></p>	<p>4,576 patients with MBO, 3421 under medical management (inc. pharmacological approaches, stenting and venting gastrostomy) (2235 female, 1186 male).</p> <p>Mean age (SD): 63.2 (13.6).</p>	<p>E: <i>Mixed</i></p> <p>Medical/surgical management.</p>	<p>Primary cancers: Colorectal, hepatobiliary, lung/mediastinal, ovarian/non-ovarian urogynaecological, pancreatic, multiple, unknown.</p> <p>Sites of obstruction:</p> <p>Not stated.</p>	<p>Primary outcomes:</p> <p>Discharge home</p> <p>Hospital deaths</p> <p>Hospital-free days</p>
<p>Berger et al., 2016^[52]</p> <p>Medical therapy of malignant bowel obstruction with octreotide, dexamethasone, and metoclopramide.</p>	<p>Hospice/home hospice, USA (Jan 2009–Jun 2012).</p> <p><i>Chart review</i></p>	<p>19 patients, 12 with MBO.</p> <p>Median age: 71 (55–85).</p>	<p>E: Medical management.</p>	<p>Primary cancers:</p> <p>Appendiceal, colorectal, lung, oesophageal, ovarian, pancreatic, peritoneal.</p> <p>Sites of obstruction:</p> <p>Small bowel, large bowel.</p>	<p>Primary outcome (ns):</p> <p>Symptom control (control of nausea/pain + time to resumption of oral intake)</p>

<p>Brooksbank et al., 2002^[53]</p> <p>Palliative venting gastrostomy in malignant intestinal obstruction.</p>	<p>Hospice, Australia (1989–1997).</p> <p><i>Chart review</i></p>	<p>51 patients with IMBO (32 females and 19 males).</p> <p>Mean age: 61 (25–86).</p>	<p>E: Gastrostomy.</p>	<p>Primary cancers: Breast, colorectal, gallbladder, lung, ovarian, pancreas.</p> <p>Sites of obstruction: Not stated.</p>	<p>Primary outcome (ns): Symptom control (nausea/vomiting).</p>
<p>Campagnutta et al., 1996^[54]</p> <p>Palliative treatment of upper intestinal obstruction by gynaecological malignancy: the usefulness of percutaneous endoscopic gastrostomy.</p>	<p>Hospital, Italy (Apr 1993–Aug 1995).</p> <p><i>Retrospective cohort study</i></p>	<p>34 patients with IMBO (female).</p> <p>Mean age: 55.8 (29–74).</p>	<p>I: Gastrostomy.</p>	<p>Primary cancers: Cervical, endometrial, ovarian, uterine.</p> <p>Site of obstruction: Small bowel.</p>	<p>Primary outcome (ns): Procedural success</p>
<p>Chan et al., 1992^[55]</p> <p>Intestinal obstruction in patients with widespread intraabdominal malignancy.</p>	<p>Hospital, Australia (1984–1989).</p> <p><i>Chart review</i></p>	<p>28 patients with MBO (16 female, 12 male).</p> <p>Median age: 66 (32–92).</p>	<p>E: Medical/surgical management.</p>	<p>Primary cancers: Breast, colorectal, lymphoma, ovarian, pancreatic.</p> <p>Sites of obstruction: Small bowel, large bowel.</p>	<p>Primary outcome (ns): Response (cessation of vomiting/colic/distension/constipation and tolerance of normal oral intake)</p>

<p>Chermesh et al., 2011^[56]</p> <p>Home parenteral nutrition (HTPN) for incurable patients with cancer with gastrointestinal obstruction: do the benefits outweigh the risks?</p>	<p>Hospital, Israel (Jan 2003–Jul 2009).</p> <p><i>Prospective cohort study</i></p>	<p>68 patients, including group of 28 with MBO (13 female, 15 male).</p> <p>Mean age (SD): 59.9 (12.7).</p>	<p>E: Home total parenteral nutrition.</p>	<p>Primary cancers: Breast, colorectal, ovarian, stomach, colorectal, laryngeal, pancreatic.</p> <p>Sites of obstruction: Not stated.</p>	<p>Primary outcome (ns): Survival</p>
<p>Dalal et al., 2011^[57]</p> <p>Management of patients with malignant bowel obstruction and stage IV colorectal cancer.</p>	<p>Cancer centre, USA (Jan 2000–Jun 2005).</p> <p><i>Chart review</i></p>	<p>141 patients with MBO (64 female, 77 male).</p> <p>Median age: 58 (29–89)</p>	<p>E: Surgical management or endoscopic procedure (gastrostomy or stent).</p>	<p>Primary cancer: Colorectal.</p> <p>Sites of obstruction: Small bowel, large bowel.</p>	<p>Primary outcome (ns): Symptom relief (nausea/vomiting/pain)</p>
<p>Davies et al., 2005^[58]</p> <p>Bowel function following insertion of self-expanding metallic stents for palliation of colorectal cancer.</p>	<p>Hospital, UK (May 2000–April 2004).</p> <p><i>Chart review</i></p>	<p>21 patients with MBO (9 female, 12 male).</p> <p>Median age: 76 (48–92).</p>	<p>E: Stent.</p>	<p>Primary cancer: Colorectal.</p> <p>Site of obstruction Sigmoid colon, rectosigmoid junction, rectum.</p>	<p>Primary outcome (ns): Technical success</p>
<p>Dittrich et al., 2017^[59]</p> <p>Benefits and risks of percutaneous endoscopic</p>	<p>2 hospitals, Germany (Mar</p>	<p>75 patients with MBO (53 female, 22 male).</p>	<p>E: Gastrostomy.</p>	<p>Primary cancer: Breast, colorectal, hepatobiliary, ovarian,</p>	<p>Primary outcome (ns): Symptom reduction (nausea/vomiting/pain)</p>

gastrostomy (PEG) for decompression in patients with malignant gastrointestinal obstruction.	2002–Oct 2013). <i>Chart review</i>	Median age: 66 (29–86).		pancreatic, stomach, unknown, ‘other’.	
Dronamraju et al., 2009 ^[60] Role of self-expanding metallic stents in the management of malignant obstruction of the proximal colon.	Hospital, UK (2003–2008). <i>Chart review</i>	97 patients with MBO (44 female, 53 male). Median age: 73 (range not specified).	E: Stent (including 5 BTS).	Primary cancer: Colorectal. Site of obstruction: Right-sided – large bowel.	Primary outcome (ns): Technical success
Emmert et al., 1996 ^[61] Intestinal obstruction in patients with advanced gynaecological cancer. A study of 62 cases.	University hospital, Germany (dates not specified). <i>Chart review</i>	62 patients with MBO (female). Median age at first treatment: 55 (31–76).	E: Ileostomy, surgery and/or conservative management.	Primary cancers: Breast, cervical, endometrial, ovarian, tubal, uterine, vaginal. Sites of obstruction: Not stated.	Primary outcome (ns): Survival
Fainsinger et al., 1994 ^[62] Symptom control in terminally ill patients with malignant bowel obstruction (MBO).	Hospital, Canada (Dec 1990–Nov 1991). <i>Chart review</i>	100 patients, 15 with MBO (10 female, 5 male). Mean age (SD): 63 (13).	E: Medical management.	Primary cancers: Breast, colorectal, haematological head and neck, lung, lymphoma, urogenital, unknown. Sites of obstruction: Not stated.	Primary outcome (ns): Length of (hospital) stay

<p>Heng et al., 2018^[63]</p> <p>A retrospective audit on usage of Diatrizoate Meglumine (Gastrografin) for intestinal obstruction or constipation in patients with advanced neoplasms.</p>	<p>Hospital, Australia (Jan 2013–Oct 2015).</p> <p><i>Chart review</i></p>	<p>71 patients with advanced cancer (24 female, 47 male) including group of 42 with MBO (sex not specified).</p> <p>Mean age (all): 63 (29–93).</p>	<p>E: Diatrizoate Meglumine intestinal obstruction or constipation.</p>	<p>Primary cancer:</p> <p>Bladder, colorectal/ upper gastrointestinal, ovarian/other gynaecological, peritoneal, pancreatic, 'other'.</p>	<p>Primary outcome (ns):</p> <p>Resolution of obstruction</p>
<p>Henry et al., 2012^[64]</p> <p>A scoring system for the prognosis and treatment of malignant bowel obstruction.</p>	<p>University hospital, USA (2000–2007).</p> <p><i>Retrospective cohort study</i></p>	<p>523 patients with MBO (306 female, 217 male), including non-surgical group of 199 (140 female, 59 male).</p> <p>Mean age (non-surgical group): 58.6 (29–86).</p>	<p>E: <i>Mixed</i></p> <p>Non-surgical therapy (medical management, temporary NGT, stents, PEG) and surgical management.</p>	<p>Primary cancers:</p> <p>Carcinoid, colorectal, other gastrointestinal (non-colorectal), gynaecological, genitourinary.</p> <p>Sites of obstruction:</p> <p>Small bowel, large bowel.</p>	<p>Primary outcome (ns):</p> <p>Mortality (30-day)</p>
<p>Hisanaga et al., 2010^[65]</p> <p>Multicenter prospective study on efficacy and safety of octreotide for inoperable malignant bowel obstruction.</p>	<p>22 hospitals/ cancer centres, Japan (Oct 2006–Mar 2008).</p>	<p>46 patients with MBO (20 female, 26 male).</p> <p>Median age: 62 (38–87).</p>	<p>I: Octreotide administered at 300mcg/day for 3 days (days1–4), adjusted up to 600mcg/day if required.</p>	<p>Primary cancers:</p> <p>Cervical, colorectal, endometrial, gall bladder/bile duct, stomach, ovarian, pancreatic, 'other'.</p>	<p>Primary outcome:</p> <p>Symptom control (pain/distention/nausea/anorexia/thirst/vomiting/fatigue)</p>

	<i>Prospective cohort study</i>			Sites of obstruction: Small bowel, large bowel.	
Hu et al., 2014 ^[66] Management of malignant bowel obstruction with decompression tubes.	Hospital, China (I: Jan 2009–Oct 2010; C: Jun 2006–Dec 2008). <i>Prospective cohort study</i>	60 patients with MBO (I: 8 women, 22 men). Mean age (SD): I=60 (13); C=61(12).	I: <i>Mixed</i> Small intestinal decompression and enteral nutrition. C: NGT and parenteral nutrition.	Primary cancers: Not stated. Site of obstruction: Lower bowel.	Primary outcome (ns): Weight gain
Hwang et al., 2013 ^[67] Octreotide prescribing patterns in the palliation of symptomatic inoperable malignant bowel obstruction.	Hospital, USA (2008–2011). <i>Chart review</i>	767 patients, 37 with IMBO (24 female, 13 male). Mean age: 56.7 (range not specified).	E: Octreotide.	Primary cancer: Appendiceal, breast, colorectal, endometrial, mesothelioma, non-Hodgkin’s lymphoma, oesophageal, ovarian, pancreatic, stomach, unknown. Sites of obstruction: Not stated.	Primary outcome (ns): Length of (hospital) stay
Issaka et al., 2013 ^[68] Palliative venting percutaneous endoscopic gastrostomy (VPEG) tube is safe and effective in patients with malignant obstruction.	Hospital, USA (1998–2010). <i>Chart review</i>	96 patients with MBO (57 female, 39 male). Mean age (SD): 57 (14)	I: Gastrostomy.	Primary cancers: Appendiceal, cholangiocarcinoma, colorectal, gynaecological, pancreatic, transitional cell carcinoma, ‘other’.	Primary outcome (ns): Technical success

<p>Jolicoeur et al., 2003^[69]</p> <p>Managing bowel obstruction in ovarian cancer using a percutaneous endoscopic gastrostomy (PEG) tube.</p>	<p>Hospital, Canada (1996–1999).</p> <p><i>Chart review</i></p>	<p>24 patients with MBO (sex/age not specified).</p>	<p>I: Gastrostomy.</p>	<p>Primary cancers:</p> <p>Not stated.</p> <p>Sites of obstruction:</p> <p>Not stated.</p>	<p>Primary outcome (ns):</p> <p>Length of (hospital) stay</p>
<p>Kawata et al., 2014^[70]</p> <p>Percutaneous endoscopic gastrostomy for decompression of malignant bowel obstruction.</p>	<p>Cancer centre, Japan (Sep 2002–Dec 2011).</p> <p><i>Chart review</i></p>	<p>76 patients with MBO (32 female, 44 male).</p> <p>Median age:</p> <p>62 (21–83).</p>	<p>I: Gastrostomy.</p>	<p>Primary cancers:</p> <p>Colorectal, gynaecological, pancreatic, stomach, urological, ‘other’.</p> <p>Sites of obstruction:</p> <p>Small bowel, duodenum, other (not specified).</p>	<p>Primary outcome (ns):</p> <p>Procedural success</p>
<p>Keswani et al., 2008^[71]</p> <p>Stenting for malignant colonic obstruction: A comparison of efficacy and complications in colonic versus extracolonic malignancy.</p>	<p>University hospital, USA (Sep 2000–Dec 2007).</p> <p><i>Prospective cohort study</i></p>	<p>49 patients with MBO (23 female, 26 male).</p> <p>Mean age (SD):</p> <p><i>Colorectal cancer group (34):</i> 66.3 (12.8)</p> <p><i>Extracolonic malignancy group (15):</i> 64.1 (6.9).</p>	<p>E: Stent.</p>	<p>Primary cancers:</p> <p>Bladder, gynaecological, lung, pancreatic.</p> <p>Sites of obstruction:</p> <p>Right colon, splenic flexure, descending colon, sigmoid, rectosigmoid.</p>	<p>Primary outcome (ns):</p> <p>Technical success</p>

<p>Kim et al., 2009^[72]</p> <p>Dual-design expandable colorectal stent for malignant colorectal obstruction: comparison of flared ends and bent ends.</p>	<p>Hospital, China (Sep 2001–Jun 2008).</p> <p><i>Prospective cohort study</i></p>	<p>122 patients with MBO (70 female, 52 male).</p> <p>Mean age (SD): (I) 57.52 (16.22) (C) 59.45 (13.24).</p>	<p>I: Flared end stent (27 as BTS).</p> <p>C: Bent end stent (15 as BTS).</p>	<p>Primary cancers:</p> <p>Bladder, cholangiocarcinoma, colorectal, ovarian, renal, stomach, pancreatic.</p> <p>Sites of obstruction:</p> <p>Ascending colon, transverse colon, descending colon, sigmoid, rectosigmoid, rectum.</p>	<p>Primary outcome (ns):</p> <p>Technical success</p>
<p>Kim et al., 2010^[73]</p> <p>Radiologic placement of uncovered stents for the treatment of malignant colorectal obstruction.</p>	<p>University hospital, Korea (May 2003–Jan 2008).</p> <p><i>Chart review</i></p>	<p>116 patients with MBO, including 47 palliative (18 female, 29 male).</p> <p>Mean age: <i>all patients:</i> 65 (28–99); <i>palliative patients:</i> 63 (36–89).</p>	<p>E: Stent.</p>	<p>Primary cancers:</p> <p>Not stated.</p> <p>Sites of obstruction:</p> <p>Not stated.</p>	<p>Primary outcome (ns):</p> <p>Technical success</p>
<p>Kim et al., 2013^[74]</p> <p>The efficacy of self-expanding metal stents for malignant colorectal obstruction by noncolonic malignancy with peritoneal carcinomatosis.</p>	<p>2 university hospitals, South Korea (Jul 2004–Jan 2010).</p>	<p>20 patients with MBO (12 female, 8 male).</p> <p>Mean age: 55.1 (32–75).</p>	<p>E: Stent.</p>	<p>Primary cancers:</p> <p>Cholangiocarcinoma, colorectal, endometrial, germ cell, pancreatic, stomach.</p>	<p>Primary outcome (ns):</p> <p>Technical success</p>

	<i>Chart review</i>			Sites of obstruction: Transverse colon, splenic flexure, descending colon, sigmoid colon, rectum.	
Kim et al., 2018 ^[75] Transjejunostomy stent placement in patients with malignant small-bowel obstructions.	Hospital, South Korea (Mar 2009–Dec 2016). <i>Prospective cohort study</i>	23 patients with MBO (6 female, 17 male). Mean age (SD): 59.5 (13.1).	E: Stent.	Primary cancers: Bladder, breast, cholangiocarcinoma, colorectal, oesophageal, ovarian, pancreatic, prostate. Site of obstruction: Small bowel.	Primary outcome (ns): Procedure time
Kubota et al., 2013 ^[76] Clinical impact of palliative treatment using octreotide for inoperable malignant bowel obstruction caused by advanced urological cancer.	Hospital, Japan (Jul 2008–Jun 2011). <i>Prospective cohort study</i>	14 patients with MBO (4 female, 10 male). Median age: 81 (55–92).	E: Octreotide 300 mcg/24h by SC.	Primary cancers: Bladder, prostate, renal, ureteral. Sites of obstruction: Small bowel, large bowel, 'undetermined'.	Primary outcome (ns): Duration of dosage
Law et al., 2003 ^[77] Comparison of stenting with emergency surgery as palliative treatment for obstructing primary left-sided colorectal cancer.	University hospital, China (Nov 1997–Jun 2002).	61 patients with MBO (I: 10 female, 20 male; C: 11 female, 20 male). Median age:	I: Stent. C: Surgery	Primary cancer: Colorectal. Site of obstruction: Right-sided colon.	Primary outcome (ns): Relief of obstruction

	<i>Prospective cohort study</i>	(I) 75 (36–98); (C) 70 (38–89).			
Lilley et al., 2017 ^[78] Survival, healthcare utilization, and end-of-life care among older adults with malignancy-associated bowel obstruction. Comparative study of surgery, venting gastrostomy, or medical management.	Medical insurance registry database (hospital data), USA (2001–2011). <i>Chart review</i>	3,583 Patients (3,117 females and 466 males). Median age: 75 (71–81).	E: <i>Mixed</i> Surgery, venting gastrostomy, medical management.	Primary cancers: Ovarian, pancreatic.	Primary outcome (ns): Mortality (hospital deaths)
Mangili et al., 1996 ^[79] Octreotide in the management of bowel obstruction in terminal ovarian cancer.	Hospital, Italy (Jan 1992–May 1994). <i>Prospective cohort study</i>	13 patients with MBO (female). Median age: 63 (16–77).	I: Octreotide 3–6 mcg/24h by SC or IV.	Primary cancer: Ovarian. Sites of obstruction: Duodenum, small bowel, large bowel.	Primary outcome (ns): Survival

<p>Mangili et al., 2005^[80] Palliative care for intestinal obstruction in recurrent ovarian cancer: a multivariate analysis.</p>	<p>Hospital, Italy (dates not specified).</p> <p><i>Retrospective cohort study</i></p>	<p>47 patients with MBO (female).</p> <p>Mean age: 58.7 (31–77).</p>	<p>E: Surgery or octreotide 3–6 mcg/24h by SC or IV.</p>	<p>Primary cancer: Ovarian.</p> <p>Site of obstruction: Not stated.</p>	<p>Primary outcome (ns): Mortality</p>
<p>Mercadante et al., 1993^[81] Octreotide in relieving gastrointestinal symptoms due to bowel obstruction.</p>	<p>Hospital and home care, Italy (dates not specified).</p> <p><i>Prospective cohort study</i></p>	<p>14 patients with IMBO (7 female, 7 male).</p> <p>Median age: 61 (45–71).</p>	<p>I: Octreotide 300-600 mcg/24h by SC or IV.</p>	<p>Primary cancers: Colorectal, ovarian, pancreatic, sarcoma, stomach.</p> <p>Sites of obstruction: Duodenum, small bowel, large bowel, multiple.</p>	<p>Primary outcome: Survival</p>
<p>Mercadante et al., 1995^[82] Bowel obstruction in home-care cancer patients: 4 years' experience.</p>	<p>Home care, Italy (Jan 1990–Jan 1994).</p> <p><i>Chart review</i></p>	<p>24 patients with MBO (11 female, 13 male).</p> <p>Mean age: 61 (35–65).</p>	<p>E: Home care</p>	<p>Primary cancers: Colorectal, ovarian, pancreatic, sarcoma, stomach.</p> <p>Sites of obstruction: Not stated.</p>	<p>Primary outcome (ns): Survival</p>

<p>Mercadante et al., 2004^[83]</p> <p>Aggressive pharmacological treatment for reversing malignant bowel obstruction.</p>	<p>Palliative care unit (cancer centre), Italy (dates not specified).</p> <p><i>Prospective cohort study</i></p>	<p>15 Patients, median age 57 y (36 - 72 y). with IMBO</p>	<p>I: Metoclopramide 60 mg/24h, octreotide 300 mcg/24h, and dexamethasone 12 mg/24h.</p>	<p>Primary cancers:</p> <p>Colorectal, ovarian, pancreatic, stomach.</p> <p>Sites of obstruction:</p> <p>Not stated.</p>	<p>Primary outcome (ns):</p> <p>Recovery of intestinal transit</p>
<p>Murakami et al., 2013^[84]</p> <p>Octreotide acetate-steroid combination therapy for malignant gastrointestinal obstruction.</p>	<p>Hospital, Japan (Apr 2008–Dec 2010).</p> <p><i>Retrospective cohort study</i></p>	<p>27 patients with MBO (17 female, 10 male).</p> <p>Mean age (SD): 61.7y (13.8).</p>	<p>E: Octreotide acetate 100–300 mcg/24h by IV.</p>	<p>Primary cancers:</p> <p>Bile duct, colorectal, lung, ovarian, pancreatic, stomach, uterine, unknown.</p> <p>Sites of obstruction:</p> <p>Not stated.</p>	<p>Primary outcome:</p> <p>Response (control of nausea/vomiting)</p>
<p>Nagula et al., 2009^[85]</p> <p>Quality of life and symptom control after stent placement or surgical palliation of malignant colorectal obstruction.</p>	<p>University hospital and cancer centre, USA (Feb 2003–Jul 2006).</p> <p><i>Prospective cohort study</i></p>	<p>44 patients with MBO (31 female, 13 male).</p> <p>Mean age: 57 (range not specified).</p>	<p>I: Stent</p> <p>C: Surgery</p>	<p>Primary cancer:</p> <p>Bladder, breast, colorectal, fallopian tube, gallbladder, ovarian, pancreatic, prostate, stomach, uterine, unknown.</p> <p>Site of obstruction:</p> <p>Large bowel.</p>	<p>Primary outcome:</p> <p>QOL</p>

<p>Philip et al., 1999^[86]</p> <p>Corticosteroids in the management of bowel obstruction on a gynecological oncology unit.</p>	<p>Hospital, Australia (Jan 1994–Jan 1995).</p> <p><i>Prospective cohort study</i></p>	<p>13 patients with MBO (female).</p> <p>Median age: 55 (35–79).</p>	<p>E: Dexamethasone 8mg/24h by SC or IV for 3 days, then reduced by 2mg weekly.</p>	<p>Primary cancer:</p> <p>Colorectal, endometrial, ovarian.</p> <p>Sites of obstruction: Small bowel, large bowel.</p>	<p>Primary outcome (ns):</p> <p>Symptom control (nausea/vomiting/pain)</p>
<p>Pothuri et al., 2004^[87]</p> <p>The use of colorectal stents for palliation of large-bowel obstruction due to recurrent gynecologic cancer.</p>	<p>A tertiary hospital, USA (Aug 2001–Jan 2003).</p> <p><i>Chart review</i></p>	<p>6 patients with MBO (female).</p> <p>Mean age: 51.5 (22–83).</p>	<p>E: Stent.</p>	<p>Primary cancer:</p> <p>Endometrial, ovarian.</p> <p>Sites of obstruction:</p> <p>Descending colon, sigmoid.</p>	<p>Primary outcome (ns):</p> <p>Relief of obstruction</p>
<p>Qi et al., 2021^[88] The effect of compound Da-Cheng_Qi Decoction on the treatment of malignant bowel obstruction with transnasal ileus tube</p>	<p>Hospital, China (July 2018–August 2019).</p> <p><i>Prospective cohort study</i></p>	<p>30 patients with MBO (16 female, 14 male).</p> <p>Mean age (SD): 52.2 (13.8)</p>	<p>I: Compound Da-Cheng-Qi Decoction with transnasal ileus tube (100 ml/12h for 7 days + TPN + octreotide, dosage not specified).</p> <p>C: Plain boiled water with transnasal ileus tube (100 ml/12h for 7 days) + TPN + octreotide, dosage not specified).</p>	<p>Primary cancer:</p> <p>Bladder, cervical, colorectal, gastric, ovarian, pancreatic, peritoneal.</p> <p>Sites of obstruction:</p> <p>Large bowel.</p>	<p>Primary outcome (ns):</p> <p>Effective rate (gas liquid level and waistline reduction)</p>

<p>Reza et al., 2009^[89] Colorectal stenting for management of acute malignant bowel obstruction in advanced colorectal cancer in Iran.</p>	<p>Hospital, Iran (Feb 2005–Mar 2007).</p> <p><i>Prospective cohort study</i></p>	<p>8 IMBO patients (3 female, 5 male).</p> <p>Age range: (58–82).</p>	<p>E: Stent.</p>	<p>Primary cancer: Colorectal.</p> <p>Site of obstruction: Not stated.</p>	<p>Primary outcome: Technical success</p>
<p>Sanchez Perez et al., 2011^[90] Pilot study of characteristics of malignant bowel obstruction in cancer patients treated by a palliative care support team. [Spanish]</p>	<p>Hospital and home care, Spain (2008–2009).</p> <p><i>Chart review</i></p>	<p>12 patients with MBO (9 female, 3 male).</p> <p>Mean age (SD): 72.6 (12.6).</p>	<p>E: Pharmacological management (morphine, metoclopramide, hyoscine butylbromide, octreotide; dosage not specified).</p>	<p>Primary cancers: Cervical, ovarian, stomach, rectum.</p> <p>Site of obstruction: Not stated.</p>	<p>Primary outcome (ns): Survival</p>
<p>Selby et al., 2019^[91] Percutaneous transesophageal gastrostomy (PTEG): A safe and well-tolerated procedure for palliation of end-stage malignant bowel obstruction.</p>	<p>Health sciences centre, Canada (Mar 2018–Nov 2018).</p> <p><i>Chart review</i></p>	<p>10 Patients (9 female, 1 male).</p> <p>Median age: 61.5 (39–76).</p>	<p>E: Gastrostomy.</p>	<p>Primary cancers: Colorectal, ovarian, pancreatic, stomach, vulval.</p> <p>Sites of obstruction: Small bowel, sigmoid, multiple.</p>	<p>Primary outcome (ns): Procedural complications</p>
<p>Siddiqui et al., 2017^[92] Long-term outcomes of palliative colonic stenting versus emergency surgery for</p>	<p>4 university hospitals, USA (Feb 1999–Oct 2015).</p>	<p>105 patients with MBO, (female 47, male 58) including 59 undergoing palliative stenting.</p>	<p>E: Stent (including 10 BTS) or surgery.</p>	<p>Primary cancer: Colorectal.</p>	<p>Primary outcome (ns): Technical success</p>

acute proximal malignant colonic obstruction: A multicenter trial.	<i>Retrospective cohort study</i>	Mean age: <i>surgery: 58; stent: 63.</i>		Sites of obstruction: Ascending colon, transverse colon, hepatic flexure, caecum.	
Spinelli et al., 2001 ^[93] Use of self-expanding metal stents for palliation of rectosigmoid cancer.	Cancer centre, Italy (Nov 1990–Feb 1999). <i>Prospective cohort study</i>	37 patients with MBO (18 female, 19 male). Mean age: 76 (39–95).	E: Stent.	Primary cancer: Rectal. Sites of obstruction: Rectal, rectosigmoid.	Primary outcome (ns): Treatment success (stool number, abdominal pain and distension, the need for laxatives, and the presence of diarrhoea or constipation)
Tigert et al., 2021 ^[94] Factors impacting length of stay and survival in patients with advanced gynaecologic malignancies and malignant bowel obstruction.	Cancer centre, Canada (December 2014–March 2019) <i>Retrospective cohort study</i>	107 patients with MBO (all female). Mean age (SD): 62.8 (12.74)	I: Conservative management (nil by mouth, bowel rest, nasogastric tube, pharmacological treatment (undefined), paracentesis, Teckhoff drain). C: Active management (surgical interventions, chemotherapy, radiology, stents, venting gastronomy).	Primary cancer: Gynaecological. Sites of obstruction: Small bowel and large bowel.	Primary outcomes (ns): Length of stay, survival

<p>Ventafridda et al., 1990^[95]</p> <p>The management of inoperable gastrointestinal obstruction in terminal cancer patients.</p>	<p>Hospital and home care, Italy (May 1987–May 1988).</p> <p><i>Prospective cohort study</i></p>	<p>22 patients with IMBO (16 female, 6 male).</p> <p>Mean age: 57.9 (40–80).</p>	<p>E: Pharmacological management (Morphine 0.5mg/kg, Scopolamine butyl bromide 1mg/kg, Haloperidol 0.05mg/kg Via SC or IV routes)</p>	<p>Primary cancers: Abdominal sarcoma, cervical, colorectal, liver, lung, ovarian, pancreatic, stomach, uterine.</p> <p>Sites of obstruction: Not stated.</p>	<p>Primary outcome (ns): Pain</p>
<p>Vodoleev et al., 2018^[96]</p> <p>Short-term results of colorectal stenting in patients with malignant large bowel obstruction. [Russian.]</p>	<p>Hospital, Russia (Dec 2012–Aug 2017).</p> <p><i>Prospective cohort study</i></p>	<p>102 patients with MBO (55 female, 47 male).</p> <p>Mean age (SD): 70.3 (11.5).</p>	<p>E: Stent.</p>	<p>Primary cancer: Bladder, colorectal, pancreas, prostate.</p> <p>Site of obstruction: Ascending colon, hepatic flexure, transverse colon, splenic flexure, descending colon, sigmoid colon.</p>	<p>Primary outcome (ns): Procedural success</p>
<p>Wey et al., 2020^[97] Palliative medical management of malignant bowel obstruction with ‘triple therapy’: dexamethasone, octreotide and metoclopramide.</p>	<p>Cancer centre (January 2015–December 2018).</p> <p><i>Retrospective cohort study</i></p>	<p>49 patients with MBO (27 female, 22 male).</p> <p>Mean age (SD): (I) 62.2 (13.8) (C) 58.6 (15.1)</p>	<p>I: Triple drug therapy (100-300 mg/8h octreotide, dexamethasone 4-8 mg/6h-12h, metoclopramide 5-10 mg/6h-12h) + standard care (nil by mouth, IV fluids, nasogastric tube, analgesics).</p> <p>C: Standard care only (see above).</p>	<p>Primary cancer: Colorectal, gynaecological, other (not specified).</p> <p>Sites of obstruction: Small bowel and large bowel.</p>	<p>Primary outcome: Deobstruction (resolution of nausea and vomiting and toleration of oral intake)</p>

<p>Woolfson et al., 1997^[98] Management of bowel obstruction in patients with abdominal cancer.</p>	<p>Hospital, USA (Nov 1987–June 1995).</p> <p><i>Chart review</i></p>	<p>75 patients, 48 with MBO (sex not specified), including 16 with IMBO.</p> <p>Age not specified.</p>	<p>E: Surgery/Conservative management.</p>	<p>Primary cancers: Not stated.</p> <p>Sites of obstruction: Not stated.</p>	<p>Primary outcome (ns): Mortality</p>
<p>Yoon et al., 2013^[99] Outcomes of secondary self-expandable metal stents versus surgery after delayed initial palliative stent failure in malignant colorectal obstruction.</p>	<p>Hospital, South Korea (Jul 2005–Dec 2009).</p> <p><i>Chart review</i></p>	<p>115 patients with MBO (39 female, 76 male).</p> <p>Median age: 62 (25–88).</p>	<p>E: Stent/Surgery.</p>	<p>Primary cancers: Colorectal, non-colorectal (not specified).</p> <p>Site of obstruction: Not stated.</p>	<p>Primary outcome: Survival</p>
<p>Yu et al., 2020^[100] Surgical and conservative management of malignant bowel obstruction: Outcome and prognostic factors.</p>	<p>Hospital, China (Jun 2017–Oct 2019).</p> <p><i>Chart review</i></p>	<p>64 patients with MBO (37 female, 27 male).</p>	<p>I: Conservative treatment (not defined).</p> <p>C: Surgery.</p>	<p>Primary cancers: Bladder, colorectal, gallbladder, kidney, ovarian, pancreas, peritoneum, stomach, other (not specified).</p> <p>Sites of obstruction: Small bowel and large bowel.</p>	<p>Primary outcome: Survival</p>

<p>Zucchi et al., 2016^[101] Decompressive percutaneous endoscopic gastrostomy in advanced cancer patients with small-bowel obstruction is feasible and effective: a large prospective study.</p>	<p>Cancer centre, Italy (Sep 2002–Sep 2012).</p> <p><i>Prospective cohort study</i></p>	<p>158 patients with MBO (sex not specified).</p> <p>Age not specified.</p>	<p>E: Gastrostomy.</p>	<p>Primary cancers:</p> <p>Breast, colorectal, endometrial, gallbladder, ovarian, pancreatic, stomach, uterine.</p> <p>Site of obstruction:</p> <p>Small bowel.</p>	<p>Primary outcome (ns):</p> <p>Procedural success</p>
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Note: BTS=Bridge to surgery, C=Comparator, E=Exposure, I=intervention, IMBO=Inoperable malignant bowel obstruction, IV=Intravenous, MBO=Malignant bowel obstruction, NGT=Nasogastric tube, QOL=Quality of life, SC=Subcutaneous, SD=Standard deviation, TPN=Total parenteral nutrition.

Supplementary File 2

Outcomes List 1: Verbatim outcomes and measures (SLR)

PHYSIOLOGICAL/CLINICAL: GASTROINTESTINAL OUTCOMES		
COLUMN 1: <u>Standardised outcome terms</u>	COLUMN 2: <u>Verbatim outcomes</u> Binary: yes/no or % of sample, unless otherwise stated	COLUMN 3: <u>Verbatim measures</u>
Outcomes/measures for treatment success:		
Success of treatment (stenting)	Clinical effect	
	Clinical success	
		Lumen patency
		Stent patency
		Time stent(s) in situ
	Success	
	Success of the procedure	
	Technical success	
		Technical success rate
	Treatment success	
Success of treatment (decompression/venting/ PEG/PTEG)	Clinical success	
	Death with PEG intact	
		Duration of intestinal tube placement
		Efficacy rate
	Gastrostomy in place	
		Primary success rate
	Procedural success	
	Successful PEG tube placement	
		Secondary success rate
	Technical success	
Success of treatment (pharmacological)		Effective rate
		Efficacy of treatment
		Number of days treatment until remission
		Relation between dosage and efficacy
		Reduction in medication dose
	Success	
	Success of treatment	
		Time between first injection and clinical response

Success of treatment (compared across different intervention types)	Success of palliation	
Outcomes/measures for overall symptoms:		
		Days of follow up
Reobstruction	Reobstruction	
		Time to reobstruction
Resolution of obstruction (complete)	Complete remission	
	Complete relief of obstruction	
	Relief of intestinal obstruction	
		Remission rate
	Resolution of obstruction (complete)	
	Resolution of the obstruction	
		Time to deobstruction
Resolution of obstruction (partial)	Resolution of obstruction (partial)	
Response		Maintenance of response until death
		Physician's subjective impression of response
	Response	
		Response rate
	Therapeutic response	
		Time between first injection and clinical response (pharmacological intervention)
Response to treatment (complete)	Response (complete)	
	Response (complete control)	
Response to treatment (none)	Response (no control)	
Response to treatment (partial)	Response (partial)	
	Response (partial control)	
Symptom control	Change in symptoms	
	Change of symptoms	
	Control of symptoms without resolution of obstruction	
		Durability of symptom relief (development of new symptoms)
		Duration of symptom relief
	Immediate relief	
		Intensity of symptoms
	Obstructive symptoms	
		Quality of symptom relief
	Relief of symptoms	
		Subjective symptoms
	Symptomatic improvement	

	Symptomatic relief (PEG)	
		Symptom assessment
		Symptom burden
	Symptom control	
	Symptom control without long-term NGT	
		Symptom distress (intensity)
	Symptom relief	
		Symptom palliation
		Time to onset of symptom improvement
		Time to symptom control without long-term NGT
Outcomes/measures for specific symptoms:		
Anorexia		Anorexia (major/minor)
		Middle upper arm circumference (MUAC)
		Visual assessment by clinician
Abdominal bloating [cramping synonymous with 'pain']		Abdominal cramping/bloating
Abdominal distension		Abdominal distension
		Feeling of abdominal distension
		Release time of abdominal distension
Change in nasogastric aspirate	Change of nasogastric aspirates	
		Daily quantity of gastric secretions through the NGT
		Production of nasogastric drainage
	Reduction of nasogastric aspirate	
	Reduction in volume of nasogastric aspirate	
		Trends in quantity of NGT secretions
		Volume of gastric drainage in the presence of a nasogastric tube
Change in secretions	Reduction in secretions	
		Changes in baseline secretion volume
Disturbance of bowel function		Disturbance of bowel function
Drowsiness	Drowsiness	
Dry mouth	Dry mouth	
Electrolytes [changes in]	Electrolyte measurements (sodium, potassium)	
Nausea control	Nausea	
		Duration of nausea
		Intensity of nausea

		Number of daily episodes of nausea
		Number of nausea episodes per day
		Relief of nausea
		Severity of nausea
Pain reduction		Abdominal pain intensity
		Abdominal pain scores
		Days to tolerable abdominal pain
		Pain intensity
	Pain reduction	
		Release time of abdominal pain
Removal of nasogastric tube	Removal of NGT	
Requirement for nasogastric tube		Days with nasogastric tube
	Nasogastric tube insertion	
	NGT required	
		Number of nasogastric tubes placed [% patients]
		Period of nasogastric tube insertion
	Requirement for nasogastric tube	
Resumption of bowel function		Bowel frequency
		Bowel movement frequency
		Laxative use
	Resumption of bowel frequency within 24 hours	
		Recovery time of defecation
		Recovery time of exhaust
		Stool consistency
		Time to first bowel movement
		Time to first flatus
		Time to intestinal transit
		Time to recovery of bowel movements
Resumption of oral intake (food and liquids)		Time to resumption of oral intake
	Toleration of soft and liquid foods	
Resumption of oral intake (fluids only)	Oral intake of water	
Vomiting control	Vomiting	
		Change in vomiting episodes
		Changes in vomiting frequency
	Control of vomiting	
		Control of vomiting: time to produce an effect
		Episodes of vomiting
	No longer vomiting	
		Number of episodes of vomiting
		Number of vomiting episodes

		Number of vomiting episodes per day
		Number of vomits in 24 hours
		Number of patient-recorded episodes of vomiting per day
		Number of days free of vomiting
		Number of days without vomiting
		Number of episodes of vomiting
		Post-palliation episodes of vomit
		Time to control of vomiting after achieving correct dosage
		Vomiting assessment
		Vomiting control
Weight gain	Gain in body weight	

PHYSIOLOGICAL/CLINICAL: NUTRITION OUTCOMES		
COLUMN 1: <u>Proposed outcome terms for Delphi Survey</u>	COLUMN 2: <u>Verbatim outcomes</u> <u>Binary: yes/no or % of sample,</u> <u>unless otherwise stated</u>	COLUMN 3: <u>Verbatim measures</u>
Ability to resume oral intake	Ability to eat and drink fluids without nausea and vomiting	
	Ability to resume oral intake at discharge	
		Days nothing by mouth
		Days to oral intake resumed
		Oral intake of liquids/soft food
		Period of diet intake
		Rate of oral intake
	Restoration of ability to eat	
	Resumption of oral intake	
		Time to restoration of oral intake
	Tolerating oral diet at discharge	
	Toleration of liquid or soft diet	
Ability to resume fluid intake	Ability to tolerate clear fluids	
	Toleration of oral liquids	
	Toleration of sips or beverages only	
	Progression to full fluid diet	
Content of nutritional intake	Outcomes after palliation - diet: oral/oral + parenteral/ parenteral	
	Receiving enteral nutrition	
Content of oral intake (regular/soft/liquid/tube feed)		Content of oral intake (regular/soft/liquid diet)
	Diet tolerance (regular/soft/liquid/tube feeds	

	only/unable to tolerate dietary intake)	
	Diets tolerated with and without PEG tube being clamped (none/sips/liquids/soft or regular/unknown)	
	Food intake capacity (no oral intake/liquids only/soft solids/low-residue diet or full diet)	
Discontinuation of hydration/ parenteral nutrition	Discontinuation of hydration/ parenteral nutrition	
Fluctuation from full fluid to low-residue diet	Fluctuation from full fluid to low-residue diet	
Gain of albumin		Gain of albumin
Gain of prealbumin		Gain of prealbumin
Receiving parenteral nutrition		Duration of TPN
		Number of patients receiving parenteral nutrition
		Number of patients receiving TPN
Receiving parenteral nutrition or hydration		Duration of parenteral nutrition or hydration
Receiving home parenteral nutrition		Duration of HPN
		Number of patients discharged with parenteral hydration
		Number of patients receiving HPN
	Likelihood of TPN on readmission	
Receiving hydration		Amounts of fluids administered (IV/SC hydration)
		Amount of parenteral hydration through the IV or SC routes
		Hours per day
		Quantity of IV fluids
		Rate per day
		Treatment days (on hypodermoclysis)
		Volume per day
		Days HDC (hypodermoclysis) around the clock
		Days HDC (hypodermoclysis) overnight only

LIFE IMPACT		
COLUMN 1: <u>Standardised outcome terms</u>	COLUMN 2: <u>Verbatim outcomes</u> <u>Binary: yes/no or % of sample,</u> <u>unless otherwise stated</u>	COLUMN 3: <u>Verbatim measures</u>
Quality of Life: (See Outcomes List 2 for granular details)		
Quality of life	Quality of life	
Wellbeing	Wellbeing	
Physical functioning:		
Functional status	Functional status	
	General activity	
	General performance status	
Personal circumstances:		
Discharge to community hospital	Discharge to country hospital	
Discharge to home	Ability to return home	
	Discharge home	
	Discharge to home care	
	Discharge to home with parenteral nutrition	
	Discharge to nursing facility	
	Disposition to home	
		Number of patients able to return home
	Discharge to nursing facility	
Discharge to hospice	Discharge to hospice	
	Discharge to inpatient hospice	
	Discharge to palliative care unit	
	Hospice enrolment	
	Hospice referral	
Hospice referral (patient choice)	Hospice referral (patient choice)	
	Opted for hospice services	
	Pursued hospice care	
Hospital discharge	Discharge from acute care	
	Other than routine discharge status	
	Delay to inpatient discharge	
		Time to discharge
Hospital-free days	Hospital-free days	
Place of death	Differences in death setting	
	Place of death	
Deaths in hospital	Deaths in hospital	
	In-hospital death	
	Hospital deaths	
Delivery of care:		
Catheter removal	Catheter removal (hospital/home)	

Protocol diversions		Number of patients diverting from each treatment protocol before end of study
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RESOURCE USE		
COLUMN 1: <u>Standardised outcome terms</u>	COLUMN 2: <u>Verbatim outcomes</u> Binary: yes/no or % of sample, <u>unless otherwise stated</u>	COLUMN 3: <u>Verbatim measures</u>
Economic:		
Hospital charges		Hospital charges
		Medical costs
Hospital:		
Hospital stay		Hospital stay
		Hospitalization duration
		Length of stay
		Length of hospital stay
		Period of hospitalization for episodes of intestinal obstruction
		Time to discharge
		Total days in the hospital
ICU/HDU stay		ICU care
		ICU care in last days of life
		ICU/HDU stay
Post-operative stay		Postoperative stay
		Post-procedure stay
Procedure time		Fluoroscopy time
		Inpatient treatment duration
		Length of medical management required
		Procedure time
		Procedural time
Need for further intervention:		
Control of recurrent symptoms	Successful treatment of recurrent symptoms	
Emergency surgical intervention	Urgent/emergency surgical intervention	
	Emergency surgical interventions	
Lost to follow up	Lost to follow up	
Readmission		Days to readmission
		Disease-related readmission
		Hospital admissions
		Hospital readmissions
		Number of readmissions
	Readmission	
		Readmission interval
		Readmission rate
		Re-admission for MBO

		Readmissions to hospital related to bowel obstruction
		Re-hospitalization for obstruction
		Rehospitalizations for obstructive symptoms
		Time from discharge to readmission and re-obstruction
		Time to readmission with MBO
Readmissions not related to bowel obstruction		Readmissions to hospital not related to bowel obstruction
Readmissions per patient		Readmissions per patient
Recurrent symptoms	Continued obstructive symptoms	
	Recurrent symptoms	
Repeat procedures	Clinical success of repeat endoscopy	
	Repeated endoscopy	
	Re-stenting	
Need for reintervention	Reinterventions	
	Need for surgical intervention	
	Return to operating room	
	Stoma creation	
	Subsequent operation	
	Technical failure leading to reintervention	
	Time to gastrostomy [drugs unsuccessful]	
Surgery after recurrent symptoms	Surgery	
	Surgery after recurrent symptoms	
	Surgical interventions	

ADVERSE EVENTS		
COLUMN 1: <u>Standardised outcome terms</u>	COLUMN 2: <u>Verbatim outcomes</u> Binary: yes/no or % of sample, unless otherwise stated	COLUMN 3: <u>Verbatim measures</u>
Adverse events	Adverse events	
	Adverse events to grade 3 or higher (NCI-CTCAE)	
	Major events	
Complications	Complications	
	Early complications	
	Major or minor complications	
Complications in the immediate postoperative period	Complications in the immediate postoperative period	
Drug-related adverse events	Drug-related adverse events	
	Drug-related symptoms	

	Premature discontinuation [of drugs]	
	Side effects	
		Toxicity
Emergency department access		Emergency calls
		Number of accesses to emergency department
Morbidity	Morbidity	
Transfusion	Transfusion	
Procedure-related complications	Complications resulting from PEG tube insertion	
	Complications related to PDT placement	
	PEG tube dislodgement	
	Procedural/surgical complications	
	Procedure-related complications	
	TPN related complications	
	VPEG malfunction	
Stent-related complications	Perforation	
	Stent displacement	
	Stent migration	
	Stent occlusion	
Treatment-related adverse events	Treatment-related adverse events	
	Treatment-related laboratory adverse events	

MORTALITY/SURVIVAL		
COLUMN 1: <u>Standardised outcome terms</u>	COLUMN 2: <u>Verbatim outcomes</u> Binary: yes/no or % of sample, <u>unless otherwise stated</u>	COLUMN 3: <u>Verbatim measures</u>
Mortality:		
Cause of death	Cause of death	
Mortality	Deaths	
	Mortality	
		Mortality rates
		30-day all cause mortality
		30-day mortality
		30-day peri-interventional mortality
Hospital deaths		Hospital deaths
		Hospital mortality
		In-hospital deaths
		In-patient mortality rate
		Time to death in hospital
Procedure-related deaths	Death after stent placement	
	Deaths after stenting	

	Deaths in near postoperative period	
	Death secondary to stent placement	
	Mortality directly related to PDT placement	
	Postoperative deaths	
	Procedure-related deaths	
Survival:		
Event-free survival	Event-free survival	
Progression-free survival	Progression-free survival	
Post-procedural survival	Post-procedural survival	
		Duration of survival post the placement of replacement G tube [after occlusion]
		Lifespan from completion of gastrostomy
		Survival after PEG placement
		Survival post-PEG insertion
Survival		Overall survival
	Survival	
		Lifespan from study entry
		Survival from diagnosis of obstruction
		Survival time from diagnosis of occlusion
		Survival stratified by KPS baseline measure
		Survival stratified by setting (home/hospital)
		Survival from discharge
Survival on HPN	Survival on HPN	
Survival not on HPN	Survival not on HPN	
TOTAL pooled terms = 90		
TOTAL standardised terms = 343		

Supplementary File 3

Outcomes List 2: LIFE IMPACT domain

Verbatim patient-reported outcome measures (itemisation of PROMs)

COLUMN 1: <u>Summary themes</u>	COLUMN 2: <u>Verbatim patient reported outcomes</u> <u>(measurement scale in brackets)</u>
25. Physical functioning	
<i>General: [24]</i>	
General activity	Am enjoying the things I usually do for fun (1-5)
	Enjoyment of recreational activities (1-4)
	Have symptoms interfered with...General activity? (0-10)
	How did you complete this questionnaire?
	How has pain interfered with general activity in the last 24 hours? (0-10)
	Over the past month, I would generally rate my activity as: normal with no limitations/not my normal self, but able to be up and about with fairly normal activities/not feeling up to most things, but in bed or chair less than half the day/able to do little activity and spend most of the day in bed or chair/pretty much bedridden, rarely out of bed (multiple choice)
	Problems doing my usual activities (1-4)
Work/Housework	Am able to work (include work at home) (1-5)
	Are you able to...Go to work? (1-4)
	Are you able to...Heavy housework/ household jobs? (1-4)
	Are you able to...Go shopping? (1-4)
	Are you able to...Walk about the house? (1-4)
	Are you able to...Walk out of doors? (1-4)
	How has pain interfered with normal work (outside home and housework) in the last 24 hours? (0-10)
	Light housework/household jobs (1-4)
	Have symptoms interfered with...Work (including work around the house) (0-10)
	Work is fulfilling (1-5)
Mobility	Are you able to...Climb stairs (1-4)
	How has pain interfered with walking ability in the last 24 hours? (0-10)
	Forced to spend time in bed (1-5)
	Problems in walking about (1-4)
	Walking (symptoms interfering with) (0-10)
Self care	Are you able to...Care for myself (wash etc)? (1-4)
	Problems washing or dressing (1-4)
<i>Symptoms/Side Effects: [85]</i>	
Abdominal bloating	Bloated feeling in abdomen (1-4)
Bowel function	Blood in your stools (1-4)
	Constipation (1-4, yes/no)

	Diarrhoea (1-4, yes/no)
	Frequent bowel movements during the day (1-4)
	Frequent bowel movements during the night (1-4)
	Have control of my bowels (1-5)
	Have diarrhoea (1-5)
	Mucus in your stools (1-4)
	Leakage of stools from your back passage (1-4)
	Unintentional release of gas/flatulence from your back passage (1-4)
Dizziness	Dizziness (1-4)
Dry/sore mouth	Dry mouth (1-4, 0-10, yes/no)
	Mouth sores (yes/no)
	Problems swallowing (yes/no)
	Sore mouth/pain when swallowing (1-4)
Dyspnoea	Shortness of breath (1-4, 0-10)
Fatigue	Drowsy (0-10)
	Fatigue (0-10, yes/no)
	Lack of energy (1-5, 1-4)
	Tired (0-10)
	Tiredness (1-4)
General symptoms	Feel ill (1-5)
	Subjective symptoms (comparative rating of PEG against NGT in terms of comfort) (1-5: levels of discomfort)
	Symptom assessment (pharmacological interventions, global assessment) (0-3)
Headache	Headaches (1-4)
Indigestion	Abdominal (stomach) aches (1-4)
	Acid indigestion (1-4)
	Have swelling or cramps in my stomach area (1-5)
Insomnia	Am sleeping well (1-5)
	Difficulty sleeping (1-4)
	How has pain interfered with sleep in the last 24 hours? (0-10)
	Sleep (1-4)
	Sleep issues
Nausea	Frequency and severity of nausea (1-4)
	Have nausea (1-5)
	Nausea (1-4, 0-10, yes/no)
	Nauseated (0-10)
	Smells bother me (yes/no)
Numbness or tingling	Numbness or tingling (0-10)
	Tingling hands or feet (1-4)
Appetite	Appetite (1-10)
	Can digest my food well (1-5)
	Food intake: As compared to my normal intake, I would rate my food intake during the past month as: unchanged/more than usual/less than usual (I am now taking normal food/little solid food/only liquids/only nutritional supplements/very little of anything/only tube feeding or nutrition by vein) (multiple choice)
	Have a good appetite (1-5)
	Lack of appetite (0-10, 1-4)
	Symptoms: no problems eating/no appetite/things taste funny or have no taste/feel full quickly (multiple choice)

Pain	Abdominal pain (1-4)
	Burning/sore eyes (1-4)
	Have you had pain today? (0-10)
	Percentage of relief 0-100
	Rate pain at its worst (last 24 hours) (0-10)
	Rate pain at its least (last 24 hours) (0-10)
	Rate pain on average (0-10)
	Rate pain right now (0-10)
	Where do you feel pain?
	Where you hurt (locate on diagram of front/back of body)
	Have pain (1-5)
	Low back pain (1-4)
	Pain (0-10, yes/no)
	Pain assessment (0-4)
	Pain control (0-4)
	Pain in buttocks/anal area/ rectum (1-4)
	Pain or discomfort (1-4)
	Perceived level of pain, on a continuum 0-100 (Visual Analogue Scale)
	Sore muscles (1-4)
Shivering	Shivering (1-4)
Side effects of treatment	Bothered by side effects of treatment (1-5)
	Loss of hair (1-4)
	Lost hair as a result of your treatment (1-4)
	Problems with your sense of taste (1-4)
	Sore skin around your anal area (1-4)
Urination	Any unintentional release (leakage) of urine (1-4)
	Pain when urinated (1-4)
	Urinate frequently during day (1-4)
	Urinate frequently during night (1-4)
Vomiting	Vomiting (1-4, 0-10, yes/no)
Weight change	Am losing weight
	During the past two weeks my weight has decreased/not changed/increased (multiple choice)
Other	Other problem (0-10)
	Other symptom control (0-4)
Sexual function	Decreased sexual interest (1-4)
	(Men) Difficulty getting or maintaining an erection during past 4 weeks. (Women) Pain or discomfort during intercourse during past 4 weeks. (1-4)
	Satisfied with my sex life (1-5)
	To what extent interested in sex? (1-4)
26. Social functioning [11]	
Family/caregiver relationships	Communication between patient and family (0-4)
	Family anxiety (0-4)
	Family has accepted my illness (1-5)
	Family insight (acceptance of prognosis) (0-4)
	Feel close to my partner (or the person who is my main support) (1-5)
	Get emotional support from my family (1-5)
	Satisfied with family communication about my illness (1-5)

Friendship support	Feel close to my friends (1-5)
	Get emotional support from my friends (1-5)
Social functioning	Relations with other people: How has pain interfered in last 24 hours (0-10)
	Relations with other people (symptoms interfering with) (0-10)
26. Role functioning [1]	
[Family/caregiver relationships]	Have trouble meeting needs of family (1-5)
28. Emotional functioning/well-being [32]	
Anxiety/Worry	Am losing hope in the fight against my illness (1-5)
	Anxiety (1-4)
	Anxious (0-10)
	Anxious or depressed (1-4)
	Feel nervous (1-5)
	Nervousness (1-4)
	Patient anxiety (0-4)
	Tension (1-4)
	Worrying (1-4)
	Worry about dying (1-5)
	Worried about your health in near future (1-4)
	Worried about your weight (1-4)
	Worry that my condition will get worse (1-5)
	Been feeling less feminine/masculine as a result of your disease or treatment (1-4)
	Feel physically less attractive as a result of your disease or treatment (1-4)
	Like the appearance of my body (1-5)
	Satisfied with how I am coping with my illness (1-5)
Depression	Depressed (0-10)
	Depressed mood (0-10)
	Despairing about the future (1-4)
Distressed	Distressed (upset) (0-10)
Embarrassment	Feel embarrassed because of your bowel movement (1-4)
Enjoyment of life	Can you enjoy TV, radio, book, talking? (1-4)
	Enjoyment of life: How has pain interfered in the last 24 hours? (0-10)
Mood	Feel sad (1-5)
	Feeling sad (0-10)
	Irritability (1-4)
	Mood: How has pain interfered in the last 24 hours? (0-10)
	Mood (symptoms interfering with) (1-4)
	Have accepted my illness (1-5)
Prognostic awareness	Patient insight (acceptance of prognosis) (0-4)
Spiritual wellbeing	Spiritual [adjustment] (0-4)
29. Cognitive functioning [2]	
Concentration	Difficulty concentrating (1-4)
Memory	Problem with remembering things (0-10)
30. Global quality of life [8]	
Enjoyment of life	Am able to enjoy life (1-5)
	Enjoyment of life (symptoms interfering with) (0-10)
Wellbeing	Feeling of wellbeing (0-10)

Quality of life	Content with the quality of my life right now (1-5)
	Quality of life (0-10) (Visual Analogue Scale)
	Global Impression of Change (GIC) (0-7: -3 to +3)
	How good or bad your health is TODAY
	Rate your QoL during the past week (0-7)
32. Delivery of care [5]	
Satisfaction with therapy	Satisfaction with therapy (1-4)
Advising professionals	Advising professionals [Amount and speed of advice needed for other professionals]
Communication between professionals	Communication between professionals [Speed, accuracy and depth of information communicated, reflecting any difficulties for patient and family]
Communication between professionals and patient/family	Communication professional to patient and family [Depth of information given]
Professional anxiety	Professional anxiety [Effect of anxiety on other professionals, reflecting difficulties caused for patients and family]
33. Personal circumstances [4]	
Financial	Financial (0-4)
Planning	Planning (0-4)
Practical aid	Practical aid (0-4)
Wasted time	Wasted time (0-4)
TOTAL 50	TOTAL 172

Supplementary File 4

Distribution of most frequent outcomes, listed by intervention type

OUTCOMES	Interventions				Total: 80 papers
	Decompression (<i>stenting/ gastrostomy</i>) (32 papers)	Pharmacological (39 papers)	Parenteral Nutrition (3 papers)	Mixed (<i>comparing interventions</i>) (6 papers)	
GASTROINTESTINAL					
Clinical success	11	-	-	-	11 (14%)
Technical Success/ Procedural success	18	-	-	-	18 (23%)
Success/Efficacy	4	3	-	-	7 (9%)
Relief/Resolution of obstruction	1	6	-	2	9 (11%)
Recurrent symptoms	-	2	-	-	2 (3%)
Reobstruction	-	3	-	1	4 (5%)
Overall symptom measures:					
Symptom relief/ symptom control	11	9	-	3	23 (29%)
Response to treatment	-	8	-	-	8 (10%)
Symptom distress	1	10	-	-	11 (14%)
Measures reported for key symptoms (includes outcomes reported as part of overall symptom control assessment):					
Pain:					26 (33%)
<i>absence/relief of</i>	2	-	-	-	2
<i>severity</i>	5	14	-	-	19
<i>severity and type (continuous or colicky)</i>	-	3	-	-	3
<i>time to relief of</i>	-	2	-	-	2
Nausea:					27 (34%)
<i>absence/relief of</i>	6	-	-	-	6
<i>severity</i>	1	13	-	-	14
<i>frequency</i>	-	1	-	-	1
<i>severity + frequency</i>	-	1	-	-	1
<i>severity + duration of</i>	-	1	-	-	1
<i>lowest score on continuum with vomiting</i>	-	4	-	-	4
Vomiting:					33 (41%)
<i>absence/relief of</i>	5	3	-	1	9
<i>frequency</i>	1	9	-	-	10
<i>severity</i>	1	5	-	-	6
<i>severity + frequency</i>	-	3	-	-	3
<i>absence + frequency</i>	-	3	-	-	3
<i>time to control of</i>	-	1	-	-	1
<i>frequency + time to control of</i>	-	1	-	-	1
Secondary symptoms:					
Anorexia	-	2	-	-	2 (3%)
Abdominal distention	1	2	-	-	3 (4%)
Drowsiness	-	1	-	-	1 (1%)
Dry mouth	-	1	-	-	1 (1%)

Fatigue	-	2	-	-	2 (3%)
Sensation of thirst	-	1	-	-	1 (1%)
Related measures:					
Bowel function	4	3	-	-	7 (9%)
Medication-related measures:					
					8 (10%)
<i>duration of dose/ time to symptom relief</i>	-	4	-	-	4
<i>reduction in dose</i>	-	1	-	-	1
<i>premature discontinuation</i>	-	1	-	-	1
<i>relation between dosage and efficacy</i>	-	1	-	-	1
<i>need for rescue dose</i>	-	1	-	-	1
NGT-related measures:					
					19 (24%)
<i>duration of NGT use</i>	-	1	-	-	1
<i>reduction in secretions (aspirate volume)</i>	-	6	-	-	6
<i>requirement for NGT</i>	-	4	-	-	4
<i>removal of NGT</i>	2	4	-	1	7
<i>symptoms more/less comfortable than with NGT</i>	1	-	-	-	1
LIFE IMPACT					
Quality of life:					15 (19%)
<i>global QOL (validated scales)</i>	4	5	-	1	11
<i>study-specific customised QOL scale</i>	-	1	-	1	2
<i>visual analogue scale (VAS) (‘Face scale’)</i>	-	2	-	-	2
Functional status	-	3	-	-	2 (3%)
Place of death	3	-	-	-	3 (4%)
NUTRITION					
Electrolytes	-	1	-	-	1 (1%)
Fluids administered	1	3	-	-	4 (5%)
Oral intake:					
					15 (19%)
<i>resumption of</i>	6	2	-	2	10
<i>resumption + content (fluids/soft foods/ solid foods)</i>	3	2	-	-	5
Protein index	-	-	-	1	1 (1%)
Parenteral nutrition:					
					9 (11%)
<i>no. patients receiving/ discharged with</i>	3	3	-	-	6
<i>duration of</i>	-	1	-	-	1
<i>calories administered</i>	-	-	1	-	1
<i>perceived value of</i>	-	-	1	-	1
<i>No. patients receiving enteral nutrition</i>	-	1	-	-	
Weight gain	-	-	-	1	1 (1%)

RESOURCE USE					
Hospital charges	1	1	-	-	2 (3%)
Length of stay	14	8	-	-	22 (28%)
ICU/HDU care	1	-	-	1	2 (2.5%)
Discharge status	7	1	1	3	12 (15%)
Hospital-free days	-	-	-	1	1 (1%)
Hospice referral	-	-	-	1	1 (1%)
Readmission	6	3	-	2	11 (14%)
Reintervention	8	1	-	1	10 (13%)
Adverse events: (78%)					62
Adverse effects/ Side effects	2	14	-	-	16
Complications	29	4	3	2	38
Adverse events + Complications	1	1	-	-	2
Toxicity	-	6	-	-	6
MORTALITY					
Mortality	18	3	-	4	25 (31%)
SURVIVAL					
Survival	20	16	3	4	43 (54%)
Event-free/ progression-free survival	2	-	-	-	2 (3%)