Complete Summary

GUIDELINE TITLE

Management of oesophageal and gastric cancer. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Management of oesophageal and gastric cancer. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2006 Jun. 69 p. (SIGN publication; no. 87). [393 references]

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on Scottish Intercollegiate Guidelines Network (SIGN) Web site.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- July 31, 2008, Erythropoiesis Stimulating Agents (ESAs): Amgen and the U.S. Food and Drug Administration (FDA) informed healthcare professionals of modifications to certain sections of the Boxed Warnings, Indications and Usage, and Dosage and Administration sections of prescribing information for Erythropoiesis Stimulating Agents (ESAs). The changes clarify the FDA-approved conditions for use of ESAs in patients with cancer and revise directions for dosing to state the hemoglobin level at which treatment with an ESA should be initiated.
- November 8, 2007 and January 3, 2008 Update, Erythropoiesis Stimulating Agents (ESAs): The U.S. Food and Drug Administration (FDA) notified healthcare professionals of revised boxed warnings and other safety-related product labeling changes for erythropoiesis-stimulating agents (ESAs) stating serious adverse events, such as tumor growth and shortened survival in patients with advanced cancer and chronic kidney failure.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Oesophageal cancer and gastric cancer

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Oncology
Radiation Oncology
Radiology
Surgery

INTENDED USERS

Advanced Practice Nurses
Dietitians
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To improve care and outcomes for patients with oesophageal and gastric cancer
- To provide guidance in patient management in order to reduce the wide variations in current practice observed throughout Scotland
- To encourage appropriate referral and early diagnosis in the general population and in high risk groups

- To optimise care delivery for oesophageal and gastric cancer patients at all stages of their disease by informing local protocols for implementation by managed clinical networks
- To ensure that all patients with oesophageal or gastric cancer are offered the best chance of cure or palliation irrespective of where they present or are treated

TARGET POPULATION

Adults with oesophageal or gastric cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis, Assessment, and Evaluation

1. Assessment for risk factors
2. Helicobacter pylori testing
3. Diagnosis
    - Upper gastrointestinal (GI) endoscopy
    - Biopsy
    - Pathological assessment
4. Staging using computed tomography (CT), endoscopic ultrasound (US) (+/- fine needle aspiration), laparoscopy, magnetic resonance imaging (MRI), bronchoscopy (+/- bronchoscopic ultrasound +/- biopsy), thoracoscopy, and neck imaging (US or CT)
5. Assessment of pre-operative fitness
6. Follow-up monitoring

Treatment/Management

1. Surgery
    - Resection (oesophagectomy, gastrectomy)
    - Reconstruction following oesophagectomy or gastrectomy
    - Lymphadenectomy
    - Epidural analgesia
    - Pre- and post-operative nutritional support
    - Endoscopic mucosal resection (EMR)
    - Mucosal ablation (photodynamic therapy [PDT], argon plasma coagulation, laser) for management of residual disease
2. Preoperative adjuvant chemotherapy
3. Non-surgical treatment (chemoradiotherapy, radiotherapy)
4. Palliative care
    - Endoscopic ablative therapies for oesophageal obstruction (laser therapy, PDT)
    - Stenting
    - Palliative surgery, including resection and gastric bypass
    - Palliative chemotherapy, external beam radiotherapy, and brachytherapy
5. Control of other symptoms
    - Pain (analgesia, including celiac axis plexus block)
    - Anorexia (corticosteroids, megestrol acetate)
    - Nausea and vomiting (octreotide, corticosteroids)

- Anaemia (blood transfusion, erythropoietin)

MAJOR OUTCOMES CONSIDERED

- Survival
- Disease recurrence
- Treatment related morbidity and mortality

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence base for this guideline was synthesised in accordance with Scottish Intercollegiate Guidelines Network (SIGN) methodology. A systematic review of the literature was carried out using a search strategy devised by a SIGN Information Officer. Databases searched include Medline, Embase, Cinahl, PsychINFO, and the Cochrane Library. For most searches, the year range covered was 1994–2004. Internet searches were carried out on various websites including the New Zealand Guidelines Programme, NELH Guidelines Finder, and the US National Guidelines Clearinghouse. The Medline version of the main search strategies can be found on the SIGN website, in the section covering supplementary guideline material. The main searches were supplemented by material identified by individual members of the development group.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies (e.g. case reports, case series)

4: Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports.

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. Scottish Intercollegiate Guidelines Network (SIGN) has based its assessments on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health, which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use.

The assessment process inevitably involves a degree of subjective judgment. The extent to which a study meets a particular criterion - e.g., an acceptable level of loss to follow up - and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two group members. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer or an experienced member of SIGN Executive staff will arbitrate to reach an agreed quality assessment

Evidence Tables

Evidence tables are compiled by SIGN executive staff based on the quality assessments of individual studies provided by guideline development group

members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Synthesising the Evidence

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgment is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgment on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence-based, but which is relevant to the way in which health care is delivered in Scotland and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Considered Judgment

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, SIGN has introduced the concept of considered judgment.

Under the heading of considered judgment, guideline development groups summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence

- Generalisability of study findings
- Directness of application to the target population for the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources needed to treat them)
- Implementability (i.e., how practical it would be for the NHS in Scotland to implement the recommendation)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgment. Once they have considered these issues, the group is asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

Additional detail about SIGN's process for formulating guideline recommendations is provided in Section 6 of the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN Web site.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; *or*

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4*; or*

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The national open meeting is the main consultative phase of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development, at which the guideline development group presents its draft recommendations for the first time. The national open meeting for this guideline was held in February 2005 and was attended by 181 representatives of all the key specialties relevant to the guideline. The draft guideline was also available on the SIGN website for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

This guideline was also reviewed in draft form by independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline.

As a final quality control check, the guideline is reviewed by an editorial group comprising the relevant specialty representatives on SIGN Council to ensure that the specialist reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC)*: In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.*

The grades of recommendations (A–D) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Risk Factors and Risk Factor Modification

Risk Factors

B - A healthy lifestyle (not smoking, not consuming excess alcohol, avoiding obesity, and maintaining a good dietary intake of fibre, fruit, and vegetables) is associated with reduced risk of oesophageal and gastric cancer and should be encouraged.

Risk Factor Modification

C - Reduction of risk of progression to adenocarcinoma is not an indication for anti-reflux surgery in patients with Barrett's oesophagus.

Chemoprevention

D - Aspirin or non-steroidal anti-inflammatory drugs (NSAIDs) should not be used for chemoprevention of oesophageal and gastric cancer.

Presentation and Referral

Uncomplicated Dyspepsia

B - A test and treat policy for *Helicobacter pylori* should be employed in the initial management of patients with uncomplicated dyspepsia.

C - Irrespective of age, patients should be reviewed after *H. pylori* eradication treatment. For those with recurrent or persistent symptoms the need for further assessment, including endoscopy, should be considered.

Symptoms of Gastro-oesophageal Reflux

C - In patients with gastro-oesophageal reflux symptoms, endoscopy with the intention of identifying cancer is not indicated unless an alarm symptom is also present.

Alarm Symptoms

B - Patients presenting with any of the following alarm symptoms should be referred for early endoscopy:

- Dysphagia
- Recurrent vomiting
- Anorexia
- Weight loss
- Gastrointestinal blood loss

Diagnosis

Upper Gastrointestinal (GI) Endoscopy

C - Flexible upper GI endoscopy is recommended as the diagnostic procedure of choice in patients with suspected oesophageal or gastric cancer.

Chromoendoscopy

D - Routine use of chromoendoscopy during upper GI endoscopy is not recommended, but may be of value in selected patients at high risk of oesophageal or gastric malignancy.

Histological Diagnosis

Biopsy Technique

C - A minimum of eight biopsies should be taken to achieve a diagnosis of oesophageal malignancy.

C - In patients with Barrett's oesophagus there should be a structured biopsy protocol with quadrantic biopsies every two centimetres and biopsy of any visible lesion.

Histopathology

C - Pathologists should follow the revised Vienna classification for reporting dysplasia.

C - Where radical intervention is contemplated on the basis of high grade dysplasia or early adenocarcinoma the diagnosis should be validated by a second pathologist experienced in this area and further biopsies should be taken if there is uncertainty.

C - Evaluation of suspected high grade dysplasia in Barrett's oesophagus biopsies should be undertaken with knowledge of the clinical and endoscopic background and biopsies should be reviewed at a multidisciplinary meeting with access to the clinical information.

Assessment and Staging

Staging Modalities and Techniques

Computerised Tomography (CT)

B - In patients with oesophageal or gastric cancer CT scan of the chest and abdomen with intravenous contrast and gastric distension with oral contrast or water should be performed routinely. The liver should be imaged in the portal venous phase.

Endoscopic Ultrasound

B - Patients with oesophageal or oesophagogastric junction cancers who are candidates for any curative therapy should have their tumours staged with endoscopic ultrasound (EUS) +/- fine needle aspiration.

Laparoscopy, Cytology and Ultrasound

C - Laparoscopy should be considered in patients with oesophageal tumours with a gastric component, and in patients with gastric tumours being considered for surgery where full thickness gastric wall involvement is suspected.

Magnetic Resonance Imaging

C - Magnetic resonance imaging (MRI) should be reserved for those patients who cannot undergo CT, or used for additional investigation following CT/EUS.

Bronchoscopy

D - Bronchoscopy +/- bronchoscopic ultrasound (BUS) +/- biopsy should be undertaken in patients with clinical or imaging features suspicious of tracheobronchial invasion.

Thoracoscopy

D - Thoracoscopy may be considered for patients where a tissue diagnosis of suspicious nodes (not possible by either EUS or CT guided techniques) is required to determine optimum management.

Positron Emission Tomography (PET)

C - PET is not routinely indicated in the staging of oesophageal and gastric cancers.

Neck Imaging

D - Neck imaging either by US or CT is recommended as part of the staging of oesophageal cancer.

Implications of Tumor Stage

Tumor Stage, Treatment, and Survival

B - Patients with gastric or oesophageal cancer should undergo careful preoperative staging to enable targeting of potentially curative treatment to those likely to benefit.

B - Patients with gastric or oesophageal cancer who have distant metastases or patients with oesophageal cancer who have metastatic lymph nodes in three compartments (neck, mediastinum, and abdomen) on preoperative staging are not candidates for curative treatment.

C - When M1a nodal involvement in oesophageal cancer, or extensive lymphadenopathy in any cancer, is identified on preoperative staging, the anticipated poor prognosis should be carefully considered when discussing treatment options.

Tumor Stage and Quality of Life

D - The possibility of reduction in quality of life after surgery should be considered when discussing treatment options, particularly when preoperative staging suggests that surgery would be unlikely to be curative.

Assessment of Preoperative Fitness

B - All patients being considered for surgery should undergo careful assessment of fitness with emphasis on performance status and respiratory function.

Pathological Staging of Resected Specimens

Important Pathological Parameters

B - Resection specimens of oesophageal and gastric cancer resections should be reported according to, or supplemented by, the Royal College of Pathologists' minimum data sets.

Treatment Principles

Information, Communication, and Support

D - Information relating to local and national support services should be made available to both patients and carers.

Ongoing Support/Follow Up

D - Follow up of patients with oesophageal or gastric cancer should monitor symptoms, signs and nutritional status.

Surgery

Service Delivery

B - Oesophageal and gastric cancer resectional surgery should be carried out in high volume specialist surgical units by frequent operators.

Type Of Operation

B - Surgery for oesophageal or gastric cancer should be aimed at achieving an R0 resection (proximal, distal, and circumferential margin clearance).

Reconstruction

After Oesophagectomy

B - Following oesophagectomy, the route of reconstruction and potential use of pyloric drainage procedure should be determined by the surgeon based on their individual experience.

After Gastrectomy

B - Consideration should be given to pouch formation after total gastrectomy.

Lymphadenectomy

Oesphagus

D - Two-field lymphadenectomy should be considered during oesophagectomy to improve staging and local disease control.

B - Routine extension of lymphadenectomy into the superior mediastinum or neck should not be carried out.

Stomach

B - D2 lymphadenectomy, with a minimum of 25 lymph nodes removed, considered for patients undergoing gastrectomy. Routine resection of additional organs (spleen and pancreas) during gastrectomy is not recommended.

Anaesthetic Management

D - The routine use of epidural analgesia is recommended in gastric and oesophageal cancer surgery.

Perioperative Nutritional Status

B - Patients undergoing surgery for oesophageal or gastric cancer who are identified as being at high nutritional risk should be considered for preoperative nutritional support.

B - All patients undergoing surgery for oesophageal or gastric cancer should be considered for early postoperative nutritional support preferably by the enteral route.

Endoscopic Treatments With Curative Intent

High Grade Dysplasia

B - Patients diagnosed with high grade dysplasia should have careful assessment (CT, EUS, rigorous biopsy protocol +/- endoscopic mucosal resection [EMR]) to exclude coexisting cancer.

B - In the absence of invasive cancer, patients with high grade dysplasia should be offered endoscopic treatment.

C - The assessment and management of patients with high grade dysplasia should be centralised to units with the appropriate endoscopic facilities and expertise.

Early Cancer

B - Superficial oesophageal cancer limited to the mucosa and early gastric cancer limited to the superficial submucosa should be treated by EMR.

D - Mucosal ablative techniques such as photodynamic therapy (PDT), argon plasma coagulation (APC), or laser should be reserved for the management of residual disease after EMR and not for initial management if invasive disease is present in patients fit for surgery.

Neoadjuvant and Adjuvant Therapies

Oesophageal Cancer

Neoadjuvant (Preoperative) Therapies

Chemotherapy In Patients With Oesophageal Cancer

B - Patients with operable oesophageal cancer, who are treated surgically, should be considered for two cycles of preoperative chemotherapy with cisplatin and 5-fluorouracil or offered entry into a clinical trial.

Chemoradiotherapy in Patients with Oesophageal Cancer

B - Preoperative chemoradiotherapy for patients with oesophageal cancer is not recommended outside clinical trials.

Radiotherapy in Patients with Oesophageal Cancer

A - Preoperative radiotherapy is not recommended for patients with oesophageal cancer

Adjuvant (Postoperative) Therapies

Chemotherapy in patients with oesophageal cancer

A - Postoperative adjuvant chemotherapy is not recommended for patients with oesophageal cancer

Gastric Cancer

Neoadjuvant (Preoperative) Therapies

A - The neoadjuvant use of either chemotherapy or radiotherapy for patients with gastric cancer is not recommended outside clinical trials.

Adjuvant (Postoperative) Therapies

Chemotherapy in Patients with Gastric Cancer

B - Postoperative chemotherapy for patients with gastric cancer is not recommended outside a clinical trial.

C - Intraperitoneal chemotherapy and immunotherapy for patients with gastric cancer are not recommended outside a clinical trial.

Downstaging Advanced Oesophageal and Gastric Cancers

D - Patients with locally advanced disease having chemotherapy/chemoradiotherapy should have their response assessed for an

impact on the potential to operate; following a good response the patient should be restaged and the role of surgery re-evaluated by the multidisciplinary team.

Non-Surgical Treatments with Curative Intent

Chemoradiotherapy

C - Chemoradiotherapy should be considered in patients with oesophageal cancer who have locally advanced disease, those unfit for surgery, or those who decline surgery.

Radiotherapy

D - In patients with oesophageal cancer who are not suitable for surgery and intolerant to chemoradiotherapy, single modality radiotherapy can be used as a curative treatment in localised disease.

Palliative Care

Changing Priorities: Quality Of Life, Comorbidity and Performance Status

C - Studies of palliative treatments in patients with oesophageal or gastric cancer should use validated questionnaires to measure quality of life outcomes and should include comorbidity and performance status.

Supportive and Palliative Care

D - Studies of supportive care should clearly define interventions and use validated quality of life end points.

Role of Palliative Care Teams

C - Patients with oesophageal or gastric cancer should have access to a specialist palliative care team.

Endoscopic Ablative Therapies

B - Laser or photodynamic therapy should be used for initial control of obstructive symptoms caused by exophytic tumours in the oesophagus including tumours near the upper oesophageal sphincter.

D - Laser or photodynamic therapy should be considered for control of tumour overgrowth in stented patients.

Stenting

Oesophagus

B - Partially covered self expanding metal stents are the intubation of choice for patients with obstructive oesophageal symptoms.

C - Partially covered self expanding metal stents should be used to control obstructive oesophageal symptoms either following or instead of laser therapy, depending on the availability of local expertise.

Dilatation

D - The use of oesophageal dilatation alone should be avoided.

Palliative Surgery

Palliative Resection of the Oesphagus

C - Oesophagectomy (transthoracic or transhiatal) should not be performed with palliative intent in patients with oesophageal cancer.

Palliative Bypass For Oesophageal Cancer

D - Substernal bypass for oesophageal cancer should not be performed with palliative intent.

Palliative Resection of the Stomach

C - Palliative gastrectomy should be avoided in patients with gastric cancer who have disseminated peritoneal disease.

D - D2 lymphadenectomy should be avoided in patients with gastric cancer in the palliative setting.

D - Health professionals should take the following factors into account when considering palliative gastric resection:

- Peritoneal disease (favour minimal)
- Tumour diameter (favour <100 mm)
- Histological type (favour Lauren intestinal type)
- Degree of differentiation (favour moderate to good differentiation)

Palliative Gastric Bypass

D - Laparoscopic bypass or gastric outlet stenting are alternatives to palliative gastric bypass.

D - Palliative gastric bypass should be avoided when malignant ascites or small bowel obstruction are present.

Exploratory Laparotomy

D - Exploratory laparotomy alone should be avoided.

Palliative Chemotherapy and Radiotherapy

Palliative Chemotherapy

B - In patients with locally advanced or metastatic cancer of the oesophagus or stomach with good performance status combination chemotherapy including cisplatin and infusional 5-FU (such as epirubicin, cisplatin and continuous 5-fluorouracil [ECF] or mitomycin C, cisplatin and continuous 5-fluorouracil [MCF]) should be considered.

External-Beam Radiotherapy

D - Palliative external-beam radiotherapy is an appropriate option for the treatment of mild dysphagia in patients with oesophageal cancer.

Brachytherapy

D - Endoluminal brachytherapy is an option for patients with dysphagia from oesophageal cancer.

Control of Other Symptoms

Pain

D - The principles of treatment outlined in the World Health Organisation pain relief programme should be followed (WHO analgesic ladder).

C - Coeliac axis plexus block should be considered in patients with severe upper abdominal pain who are intolerant of, or have pain unresponsive to, other analgesic measures.

Anorexia and Cachexia

D - Corticosteroids or megestrol acetate should be considered for patients with advanced oesophageal or gastric cancer who are anorexic.

Nausea and Vomiting

D - Octreotide and corticosteroids should be considered to relieve symptoms of bowel obstruction caused by malignancy where interventional therapy is not possible or appropriate.

Anemia

C - Blood transfusion is recommended as the standard treatment for symptomatic anaemia.

D - Erythropoietin use should be considered in accordance with agreed guidelines.

Definitions:

Grades of Recommendations

Grade A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

Grade B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

Grade C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

Grade D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies (e.g., case reports, case series)

4: Expert opinion

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and management of patients with gastric and oesophageal cancer

POTENTIAL HARMS

- Procedure-related mortality for upper gastrointestinal endoscopy is approximately 1 in 10,000 and significant complications (mostly sedation related) occur in approximately in 1,000 cases. Minor complications such as sore throat occur in up to 10% of cases
- Adverse effects of chemotherapy and other pharmacological agents
- Morbidity associated with surgery (especially cardiovascular and respiratory complications)
- The main disadvantage of radical radiotherapy is the development of a fibrous stricture in 44% of patients treated.
- Photodynamic therapy may result in "minor" side effects (photosensitisation).
- Side effects of laser therapy may include perforations
- The main complications of endoscopic mucosal resection (EMR) are bleeding and perforation.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to radical radiotherapy include long tumour length and/or the presence of a tracheo- or bronchooesophageal fistula.

Stents are contraindicated near the upper oesophageal sphincter.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of

care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is, however, advised that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Local Implementation and Managed Clinical Networks

Implementation of national clinical guidelines is the responsibility of each National Health Service (NHS) Board and is an essential part of clinical governance. It is acknowledged that every Board cannot implement every guideline immediately on publication, but mechanisms should be in place to ensure that the care provided is reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units, and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

Three regional managed clinical networks (MCNs) for upper gastrointestinal (GI) cancer are in place to ensure equitable provision of high quality clinically effective services throughout Scotland. These MCNs also cover hepatic, pancreatic, and biliary cancers. The implementation of this guideline by the regional MCNs will facilitate their role in bringing about demonstrable improvement in patient outcomes. The MCNs' role in promoting equitable access to specialist services for patients with potentially curable disease and improved selection for and local delivery of palliative therapies is central to this process.

Key Points for Audit

Audit of the patient journey and clinical outcomes is integral to improving care for patients with oesophageal and gastric cancer.

- Implementation of a nationally acceptable minimum dataset should be supported and resourced on a Scotland wide basis
- All patients diagnosed with oesophageal or gastric cancer should be entered into clinical audit
- Clinicians and multidisciplinary teams should be aware of their individual outcomes with oesophageal or gastric cancer patients
- The three upper GI cancer clinical networks in Scotland should review and quality assure audit data nationally with a view to setting standards and ultimately removing regional differences in care

- Clinical audit of patients with potentially curable disease should emphasise medium and long term outcomes
- For patients with incurable disease at time of diagnosis the audit process should emphasise quality of life and symptom palliation.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Management of oesophageal and gastric cancer. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2006 Jun. 69 p. (SIGN publication; no. 87). [393 references]

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Not applicable: The guideline was not adapted from another source.

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GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

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GUIDELINE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Declarations of interests were made by all members of the guideline development group. Further details are available from the Scottish Intercollegiate Guidelines Network (SIGN) Executive.

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Management of oesophageal and gastric cancer. Scottish Intercollegiate Guidelines Network, 2006 Jun 11 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research & Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.

PATIENT RESOURCES

None available

NGC STATUS

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