Complete Summary

GUIDELINE TITLE

Management of transitional cell carcinoma of the bladder. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Management of transitional cell carcinoma of the bladder. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2005 Dec. 45 p. (SIGN publication; no. 85). [161 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.

COMPLETE SUMMARY CONTENT

SCOPE
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SCOPE

DISEASE/CONDITION(S)

Transitional cell carcinoma (TCC) of the bladder

Note: Less common tumours such as squamous cell carcinomas or adenocarcinomas and management of metastatic disease are not within the scope of this guideline.

GUIDELINE CATEGORY

Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Oncology
Radiation Oncology
Surgery
Urology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To present evidence-based recommendations on management of transitional cell carcinoma (TCC) of the bladder

TARGET POPULATION

Patients with transitional cell carcinoma (TCC) of the bladder

INTERVENTIONS AND PRACTICES CONSIDERED

Management/Treatment

1. Assess risk factors such as occupational exposure to industrial chemicals and prior radiotherapy and/or chemotherapy
2. Involve patient in decision-making process
3. Management of superficial bladder cancer
    - Photodynamic (fluorescence) aided transurethral resection of bladder tumor
    - Follow-up with annual cystoscopy
    - Intravesical chemotherapy
    - Bacille Calmette-Guerin (BCG) therapy (induction and maintenance)
    - Microstaging of pT1 disease
4. Surgical treatment
    - Cross-sectional imaging prior to treatment (magnetic resonance imaging [MRI] and computed tomography [CT])
    - Urethrectomy
    - Bilateral pelvic lymph node dissection
    - Bladder reconstruction
5. Non-surgical treatment
    - Palliative radiotherapy

    - Chemotherapy (neoadjuvant with a combination chemotherapy regimen containing cisplatin)
6. Lifestyle modifications (smoking cessation, diet)
7. Patient education and support

Note: Radiotherapy and cystectomy were considered but not specifically recommended.

MAJOR OUTCOMES CONSIDERED

Patient outcomes including:

- Morbidity and mortality
- Disease-free and overall survival rate
- Recurrence rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary 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 an explicit search strategy devised by the SIGN Information Officer in collaboration with members of the guideline development group. Literature searches were initially conducted in Medline, Embase, Cinahl, and the Cochrane Library using the year range 1998-2003. The literature search was updated to cover the period up to October 2004. Key websites on the Internet were also used, such as the National Guidelines Clearinghouse. These searches were supplemented by the reference lists of relevant papers and group members' own files. The Medline version of the main search strategies can be found on the Scottish Intercollegiate Guideline Network (SIGN) website.

NUMBER OF SOURCE DOCUMENTS

294

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

Review of Published Meta-Analyses
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 Scottish Intercollegiate Guidelines Network (SIGN) guideline development.

Peer Review

All SIGN guidelines are reviewed in draft form by independent expert referees, who are asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. A number of general practitioners (GPs) and other primary care practitioners also provide comments on the guideline from the primary care perspective, concentrating particularly on the clarity of the recommendations and their assessment of the usefulness of the guideline as a working tool for the primary care team. The draft is also sent to a lay reviewer in order to obtain comments from the patient's perspective. The comments received from peer reviewers and others are carefully tabulated and discussed with the chairman and with the guideline development group. Each point must be addressed and any changes to the guideline as a result noted or, if no change is made, the reasons for this recorded.

As a final quality control check prior to publication, the guideline and the summary of peer reviewers' comments are reviewed by the SIGN Editorial Group for that guideline to ensure that each point has been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. Each member of the guideline development group is then asked formally to approve the final guideline for publication.

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.

Lifestyle Issues

Smoking

B - Smoking should be discouraged.

Diet

B - People should be encouraged to:

- Eat more fruit and vegetables
- Reduce the amount of animal fat in their diet

Other Risks

B - Clinicians should be aware that previous treatments with radiotherapy and certain chemotherapy may predispose patients to transitional cell carcinoma of the bladder.

Referral

Timing of Treatment

C - For optimum survival benefit, cystectomy for patients with muscle invasive bladder cancer should be performed within three months of diagnosis.

Involving the Patient in the Decision Making Process

D - Healthcare professionals should involve patients in making decisions about their treatment, if the patient expresses a wish to do so.

Management of Superficial Bladder Cancer

Imaging During Follow Up

B - Only patients with high grade tumours (including carcinoma in situ [CIS]) at time of diagnosis should have regular upper tract surveillance.

Photodynamic Aided Resection

B - Fluorescence cystoscopy under blue/violet light (wavelength 400 nm) which causes tumours to fluoresce red should be used to improve the completeness of resection of superficial bladder tumours.

Follow Up

C - Patients with a single pTa G1/G2 tumour at the time of diagnosis and who are recurrence free at three months after the original resection should have annual cystoscopy.

Intravesical Therapy

A - A single instillation of intravesical chemotherapy should be used to reduce the risk of recurrent disease following resection in all patients considered to be at high risk of recurrence.

Random Biopsy of Normal Mucosa

C - Normal looking areas of the bladder need not be routinely biopsied at the time of diagnosis or follow up.

Management Strategies

C - Patients with CIS of the bladder should be treated with bacille Calmette-Guerin (BCG).

B - Maintenance therapy with BCG should be considered in patients with CIS to improve local control and reduce the incidence of progression.

Progression to Muscle Invasive Disease (pT2-4)

C - Routine pathological reporting should include microstaging of pT1 disease, where possible.

Surgical Treatment

Imaging for Staging of Invasive Disease

C - Patients with muscle invasive bladder cancer should have cross-sectional imaging prior to treatment.

C - Magnetic resonance imaging (MRI) is the best staging modality to assess invasion into or through bladder muscle.

Indications for Removal of the Urethra

C - Urethrectomy should be performed in high-risk patients having cystectomy and urinary diversion.

C - If frozen section biopsies of the urethral margin are negative the urethra can be preserved for orthotopic reconstruction.

Indications for Removal of the Lymph Nodes

C - All patients having curative radical cystectomy should have bilateral pelvic lymph node dissection.

C - A meticulous lymph node dissection should be performed for retrieval of the maximum number of nodes.

Bladder Reconstruction

C - Where appropriate, patients should be given the option of bladder reconstruction after radical cystectomy.

Non-Surgical Treatment

Radiotherapy

B - Radiotherapy using 21Gy in three fractions in one week should be considered for palliation of patients with bladder cancer.

Chemotherapy

A - Neoadjuvant chemotherapy should be offered to suitable patients prior to definitive radical therapy for patients with T2-T4 transitional cell carcinoma of the bladder.

A - A combination chemotherapy regimen containing cisplatin should be used.

Information for Discussion with Patients and Carers

Support Needs of Patients, Families and Carers

C - Patients should be offered verbal and written information throughout their journey of care and should be made aware of the support mechanisms that are in place and how to access them.

C - Structured emotional support should be available to all patients and carers.

Methods and Sources of Communication

B - Healthcare professionals in cancer care should be trained in listening and communication skills.

B - Healthcare professionals in cancer care should consider giving either written summaries or audiotapes of consultations to people who have expressed a preference for them.

Definitions:

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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

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

General Benefits

Appropriate management of transitional cell carcinoma (TCC) of the bladder

POTENTIAL HARMS

- Bacille Calmette-Guerin (BCG) instillations are as effective as mitomycin C, but have a greater potential toxicity.
- Toxicity from MVAC (methotrexate + vinblastine + doxorubicin + cisplatin) chemotherapy was greater in patients treated adjuvantly. In elderly patients or those with significant comorbid illness treatment related toxicity may outweigh any advantages to chemotherapy.
- The disadvantages of bladder reconstruction include risk of nocturnal leakage and failure of voiding requiring catheterisation or intermittent self catheterisation. In female patients bladder reconstruction carries a risk of neobladder-vaginal fistula and of urethral recurrence.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications for radical cystectomy are:

- Advanced disease (T4b or distant metastases)
- Patient unfit for major surgery
- Patient preference

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guideline is not intended to be construed or to serve as a standard of medical 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 regarding a particular clinical procedure or treatment plan must be made by the appropriate healthcare professional following discussion of the options with the patient, in light of the diagnostic and treatment choices available. It is advised however, 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.

- There is no agreement as to whether muscle invasive disease is best managed by surgery or by radiotherapy. The role of lymph node dissection and orthotopic reconstruction in patients undergoing cystectomy needs to be defined, as does the optimum radiotherapy regimen. New data on the effectiveness of neoadjuvant chemotherapy may lead to a change in routine practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of local National Health Service (NHS) organizations and is an essential part of clinical governance. It is acknowledged that not every guideline can be implemented 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.

Key points for audit are identified in the original guideline document.

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

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Management of transitional cell carcinoma of the bladder. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2005 Dec. 45 p. (SIGN publication; no. 85). [161 references]

ADAPTATION

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

DATE RELEASED

2005 Dec

GUIDELINE DEVELOPER(S)

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

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Dr Grahame Howard Consultant Radiation Oncologist (Co-chair) Western General Hospital, Edinburgh; Professor David Kirk Consultant Urologist, Gartnavel General Hospital, Glasgow (Co-chair); Dr John Brush Consultant Radiologist, Western General Hospital, Edinburgh; Ms Kirsty Carrie Oncology Dietitian, Beatson Oncology Centre, Glasgow; Dr Dermot Gorman Consultant in Public Health, Edinburgh; Dr Ken Grigor Consultant Pathologist, Western General Hospital, Edinburgh; Dr Roberta James Programme Manager, SIGN; Mr John MacFarlane Consultant Urologist, Queen Margaret Hospital, Dunfermline; Mr Hamish Mackie Lay Representative, Edinburgh; Dr Duncan McLaren Consultant Oncologist, Western General Hospital, Edinburgh; Mr Stewart Orr Consultant Urologist, Monklands Hospital, Airdrie; Dr Martin Russell Consultant Clinical Oncologist, Beatson Oncology Centre, Glasgow; Mr Duncan Service Information Officer, SIGN; Mrs Mary Squires Lay Representative,

Raigmore Hospital Patients Council, Inverness; Mr David Tulloch Consultant Urologist, Western General Hospital, Edinburgh

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 transitional cell carcinoma of the bladder, Scottish Intercollegiate Guidelines Network, 2005. 2 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.
- An example Referral Proforma can be found in Annex 6 of the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 6, 2006. The information was verified by the guideline developer on May 1, 2006.

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