Complete Summary

GUIDELINE TITLE

Skin melanoma.

BIBLIOGRAPHIC SOURCE(S)

Dutch Working Group on Melanoma. Skin melanoma. Utrecht, The Netherlands: Association of Comprehensive Cancer Centres (ACCC); 2006 Jul 14. 9 p.

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis **RECOMMENDATIONS** EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS **CONTRAINDICATIONS** IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT **CATEGORIES** IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Melanoma

DISCLAIMER

GUIDELINE CATEGORY

Diagnosis Management Screening Treatment

CLINICAL SPECIALTY

Dermatology Family Practice Internal Medicine Oncology Pathology Plastic Surgery Surgery

INTENDED USERS

Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

To provide guidance on the management of patients with melanoma

TARGET POPULATION

Patients with pigmented skin lesions and skin melanoma

INTERVENTIONS AND PRACTICES CONSIDERED

Screening

- 1. Routine assessment of individuals with a known familial or otherwise increased risk of melanoma
- 2. Population-based screening (considered but not recommended)

Diagnosis/Evaluation

- 1. Dermatoscopy
- 2. Histopathological diagnostic evaluation
 - Pathology report documentation
- 3. Sentinel node biopsy
 - Pathological assessment of the sentinel node
 - Optimal number of sections
 - Optimal distance between sections
 - Immunohistochemistry
- 4. Supplemental tests for staging assessment
- 5. American Joint Committee of Cancer (AJCC) staging system

Management/Treatment

- 1. Excision margins of primary melanoma
 - In situ
 - Breslow thickness
- 2. Pathological assessment of re-excised sections
- 3. Adjuvant treatment
 - Radiation therapy following lymph node dissection
 - Systemic therapy in patients with a poor prognosis (not recommended outside a clinical trial)
- 4. Treatment of metastases
 - Clinical trials

- Dacarbazine
- 5. Follow-up for primary melanoma
 - Frequency based on Breslow thickness

MAJOR OUTCOMES CONSIDERED

- Incidence of melanoma
- Incidence of metastasis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Relevant subjects were identified, and literature concerning each subject was extensively reviewed by teams of two members of the responsible committee. Each team prepared a report that was discussed in plenary sessions of the committee.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Relevant subjects were identified, and literature concerning each subject was extensively reviewed by teams of two members of the responsible committee. Each team prepared a report that was discussed in plenary sessions of the committee.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Recommendations were formulated after extensive discussion within the committee responsible for the guidelines preparation and after approval of the Dutch Melanoma Working Group.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Screening

Is screening for skin melanoma useful?

The working group is of the opinion that routine checking for pigmented lesions warrants recommendation in cases with a known familial increased risk of melanoma. One check-up every 6 to 12 months is considered sufficient.

According to the working group, increased attentiveness is advisable for individuals with a combination of risk factors resulting in a substantially increased risk of melanoma.

The working group is of the opinion that population-based screening for melanoma is not warranted in the Netherlands.

Diagnosis

Does dermatoscopy increase the accuracy of clinical diagnosis?

Dermatoscopy has an established role in the clinical diagnosis of pigmented skin disorders. Physicians who are unfamiliar with dermatoscopy are advised to become proficient with the technique before applying it.

Pathological assessment of diagnostic excisions

Each pigmented skin lesion removed should be submitted for histopathological diagnostic evaluation.

The pathology request form should include at least the following information: personal details, location of the lesion, reason for removal (cosmetic versus diagnostic) and the excisional margin. For excisions made for diagnostic purposes, the reason why malignancy was suspected should be included (e.g., irregular macroscopic features, changes over time, itching).

The pathology report should contain a conclusion statement which, for cases of melanoma, should include at least the following information:

- Anatomical location
- Type of procedure (shave, punch, elliptical or incisional biopsy)
- Excisional margin
- Diagnosis of melanoma (including the histologic subtype, if possible)
- Breslow thickness
- Presence/absence of ulceration
- Clark level
- Presence/absence of microsatellitosis
- Presence/absence of regression or partial regression
- Completeness of the removal

If the diagnosis of melanoma is uncertain, the case should be presented to a pathologist with special expertise in the diagnosis of melanocytic tumours.

Sentinel Node Procedure

What is the indication for sentinel node biopsy?

According to the working group, sentinel node biopsy should be reserved for patients who desire the most complete information possible regarding their prognosis. This procedure is not considered part of standard diagnostic evaluation. If sentinel node biopsy is proposed, the low risk of complications, the rather high percentage of false-negative results, and the possible increased incidence of intransit metastases should be considered.

How should pathological assessment of the sentinel node be conducted?

Intraoperative frozen section assessment of the sentinel node is contraindicated in melanoma.

In addition to haematoxylin-eosin (HE) stained sections, evaluation of the sentinel node requires immunostaining for S-100 and at least one additional, more specific marker, preferably MART-1.

Assessment of more than one section of the sentinel node is necessary for optimal detection of melanoma metastases. At this time, definitive statements cannot be made regarding the optimal number of sections to assess or the optimal distance between sections. The working group advises that at least three sections from each paraffin block are assessed, including immunohistochemistry of each section; however, assessment of six sections is preferred, in accordance with the European Organisation for Research and Treatment of Cancer (EORTC) guidelines.

The optimal distance between sections depends on the total number of sections and varies between 50 microns for six sections and 150 microns for three sections. Measuring the number and size of melanoma metastases in the sentinel node is not necessary at this time, as confirmation of the possible therapeutic relevance of these findings is pending.

The sentinel node should be fixed *in toto* and prepared completely for microscopic histopathological evaluation.

Supplemental Investigation

For localised melanoma (American Joint Committee of Cancer [AJCC] stage I and II), does supplemental testing (other than sentinel node evaluation) influence the prognosis?

Supplemental tests for staging assessment are not routinely indicated for patients with clinically localized melanoma. Supplemental testing can be used when indicated, such as the use of lymph node ultrasound when palpation of the lymph node regions yields inconclusive results.

Treatment

What are the recommended margins for therapeutic re-excision of a primary melanoma?

The following margins of unaffected skin surrounding the biopsy are recommended for the therapeutic re-excision of melanoma:

Melanoma in situ: 0.5 cm

Breslow thickness ≤2 mm: 1 cm
 Breslow thickness >2 mm: 2 cm

Pathological Assessment of Re-excised Skin Sections

- Assessment of three blocks of scar tissue in re-excised sections of skin/subcutis is sufficient following complete excision of the melanoma.
- Complete embedment of the scar tissue is required if the melanoma is not removed completely during diagnostic excision and residual tumour is revealed by the resection margin analysis of the re-excision.
- Pigmented lesions and other focal abnormalities should always be evaluated histologically.

Adjuvant Treatment

Is adjuvant radiation therapy indicated following lymph node dissection?

Adjuvant radiation therapy is not considered standard treatment following lymph node dissection. Whether radiation therapy is applied and how it is applied depends on the prognosis and the risk of recurrent disease in the area of the removed lymph nodes.

Is there a systemic adjuvant therapy that has proven efficacy in patients with prognostically unfavourable characteristics?

Systemic adjuvant treatment of patients with melanoma is not recommended outside the context of a clinical trial. This also applies to adjuvant treatment with interferon a (IFNa).

Treatment of Metastases

Which systemic therapy is the treatment of choice for melanoma with distant metastases?

Patients with metastatic melanoma are preferably treated in a clinical trial. If treatment outside the context of a clinical trial is to be considered, there is no better alternative to dacarbazine (DTIC).

Follow-Up

What is adequate follow-up for primary melanoma?

Breslow thickness <1 mm:

- A single check-up 1 month after treatment for primary melanoma, providing
 the patient with the opportunity to ask questions and learn self-checking
 techniques. It should be explained to the patient that additional check-ups do
 not improve the chance of cure, but that an appointment can always be made
 at short notice if symptoms occur.
- If desired, additional check-ups can be scheduled for counselling, checking one's own work, educational purposes, or scientific research.
- The frequency and extent of evaluation is then determined by need.

Breslow thickness >1 mm:

- Year 1: check-up once every 3 months
- Year 2: check-up once every 4 months
- Years 3 to 5: check-up once every 6 months

Breslow thickness > 2 mm:

• Same as Breslow thickness > 1 mm plus annual check-ups years 6 to 10.

Supplemental tests as indicated.

Staging

Which staging system should be used for melanoma in the Netherlands?

The working group is of the opinion that the American Joint Committee of Cancer (AJCC) staging system — unabridged and unmodified — should be adopted in the Netherlands.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved quality of care in patients with melanoma
- Better results from treatment
- Decreased metastases
- Decreased mortality

POTENTIAL HARMS

If sentinel node biopsy is proposed, the low risk of complications, the rather high percentage of false-negative results, and the possible increased incidence of intransit metastases should be considered.

CONTRAINDICATIONS

CONTRAINDICATIONS

Intraoperative frozen section assessment of the sentinel node is contraindicated in melanoma.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations Personal Digital Assistant (PDA) Downloads

For information about <u>availability</u>, 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 Staying Healthy

IOM DOMAIN

Effectiveness Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

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

DATE RELEASED

2006 Jul

GUIDELINE DEVELOPER(S)

Association of Comprehensive Cancer Centres - Disease Specific Society

SOURCE(S) OF FUNDING

Association of Comprehensive Cancer Centres

GUIDELINE COMMITTEE

Dutch Working Group on Melanoma

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in English and Dutch from the <u>Association of</u> Comprehensive Cancer Centres Web site.

Print copies: Available from the Association of Comprehensive Cancer Centres PO Box 19001, 3501 DA Utrecht, The Netherlands

AVAILABILITY OF COMPANION DOCUMENTS

A version of the guideline for Personal Digital Assistants (PDAs) is also available at the Association of Comprehensive Cancer Centres Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on May 8, 2008. The information was verified by the guideline developer on July 1, 2008.

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