Complete Summary

GUIDELINE TITLE

Treatment of cutaneous melanoma.

BIBLIOGRAPHIC SOURCE(S)

American Society of Plastic Surgeons. Evidence-based clinical practice guideline: treatment of cutaneous melanoma. Arlington Heights (IL): American Society of Plastic Surgeons; 2007 May. 14 p. [81 references]

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
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Cutaneous melanoma

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Dermatology
Family Practice
Oncology

Plastic Surgery
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To address the assessment and treatment of cutaneous melanoma and to develop a set of recommendations that fairly reflect current accepted medical standards

TARGET POPULATION

Patients with cutaneous melanoma

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment

1. Patient history, including assessment of risk factors
2. Physical examination, including examination of entire skin, focused examination of pigmented lesions, and palpitation of major lymph node bases
3. Biopsy of primary lesion (excisional or incisional)
4. Pathological staging of the primary melanoma
5. Other assessments (blood work, chest x-ray or other radiological examination, screening for molecular markers)
6. Follow-up assessment, including regular physical examinations and diagnostic tests

Treatment/Management

1. Surgical excision of primary melanoma
2. Sentinel lymph node biopsy using multiple imaging techniques
3. Complete lymph node dissection
4. Referral to oncologist for systemic treatment
5. Surveillance, including patient education and adequate follow-up

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search and Admission of Evidence

This study was carried out with a prospective, systematic method for identifying and evaluating current literature on the treatment of cutaneous melanoma. To identify relevant literature, a comprehensive search of Medline, the Cochrane Database of Systematic Reviews, and the National Guideline Clearinghouse™ was performed by using various combinations of the following search terms: melanoma, cutaneous melanoma, diagnosis, staging, biopsy, treatment, excision margins, sentinel node biopsy, as well as a wide range of indexing terms, free text words and word variants. Search limits restricted results to English-language manuscripts that were published from 1997 to 2007 and also indexed as human studies, clinical trials, randomized controlled trials, systematic reviews, and/or guidelines.

Articles were selected if they were relevant to clinical questions about patient assessment, staging, prognosis, treatment, follow-up and surveillance. Excluded from the literature selection were articles that specifically addressed assessment and treatment of patients with non-cutaneous melanoma.

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

Evidence Rating Scale for Diagnostic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, cohort study validating a diagnostic test (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies
II	Exploratory cohort study developing diagnostic criteria (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies
III	Diagnostic study in nonconsecutive patients (without consistently applied "gold" standard as reference); or a systematic review of these studies
IV	Case-control study; or any of the above diagnostic studies in the absence of a universally accepted "gold" standard
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

Evidence Rating Scale for Prognostic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, prospective cohort study with adequate power; or a systematic review of these studies
II	Lesser-quality prospective cohort study; retrospective study; untreated controls from a randomized controlled trial; or a systematic review of these studies
III	Case-control study; or a systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

Evidence Rating Scale for Therapeutic Studies

Level of Evidence	Qualifying Studies
I	High-quality, multi-centered or single-centered, randomized controlled trial with adequate power; or a systematic review of these studies
II	Lesser-quality, randomized controlled trial; prospective cohort study; or a systematic review of these studies
III	Retrospective comparative study; case-control study; or a systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Critical Appraisal of the Literature

Relevant articles were categorized by study type: randomized controlled trial, systematic review, cohort study, case-control study, case series, and case report. Each article was critically appraised for study quality according to criteria referenced in key publications on evidence-based medicine. Depending on type (prognostic, diagnostic, or therapeutic) and quality of study, each article was assigned a corresponding level of evidence according to the American Society of Plastic Surgeons (ASPS) Evidence Rating Scales (see "Rating Scheme for the Strength of the Evidence" above), which were modified from scales developed by other surgical specialties and authorities on evidence-based medicine.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Development of Clinical Practice Recommendations

Practice recommendations were developed through critical appraisal of the literature and consensus of the American Society of Plastic Surgeons (ASPS) Health Policy Committee. Recommendations are based on the strength of supporting evidence and were graded according to the ASPS Grades of Recommendation Scale (see "Rating Scheme for the Strength of the Recommendations" below), which was modified from scales used by other surgical specialties and authorities in the practice of evidence-based medicine.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade	Descriptor	Qualifying Evidence	Implications for Practice
A	Strong Recommendation	Level I evidence or consistent findings from multiple studies of levels II, III, or IV	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
B	Recommendation	Levels II, III, or IV evidence and findings are generally consistent	Generally, clinicians should follow a recommendation but should remain alert to new information and sensitive to patient preference.
C	Option	Levels II, III, or IV evidence, but findings are inconsistent	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
D	Option	Level V; little or no systematic empirical evidence	Clinicians should consider all options in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Approved by the Executive Committee of the American Society of Plastic Surgeons, May 2007

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the levels of evidence for diagnostic, prognostic, and therapeutic studies (I–V) and the strength of the recommendations (A–D) are provided at the end of the "Major Recommendations" field.

Recommendations for Patient Assessment	Supporting Evidence	Grade
Patient History Assess risk factors: • Skin type I or II • Presence of multiple common nevi (>30) • Presence of atypical nevi (≥3) • Personal or family history of melanoma • Prior significant sun exposure (blistering sunburns)	(Carli et al., 2003; Naldi et al., 2005; Gandini et al., 2005)	**B**
Physical Exam Exam should include: • Thorough inspection of entire skin, including mucous membranes, for pigmented lesions • Focused exam of pigmented lesions (ABCDEF criteria*) • Careful palpation of major lymph node basins	(Hazen et al., 1999; Abbasi et al., 2004)	**B**
Biopsy of the Primary Lesion For pigmented lesions suspect for melanoma: • Excisional biopsy recommended when possible • Only when excisional biopsy is impractical, should incisional biopsy be considered	(Lorusso, Sarma, & Sarwar, 2005; Karimipour et al., 2005; Bong, Herd, & Hunter, 2002)	**B**
Other Clinical and Diagnostic Assessments		
For all patients, consider: • Blood work (serum lactate dehydrogenase, alkaline phosphatase) • Chest x-ray	(Wang et al., 2004; Tsao et al., 2004; Hofmann et al., 2002)	**C**

Recommendations for Patient Assessment	Supporting Evidence	Grade
For patients with more advanced disease, consider: • Blood work (serum lactate dehydrogenase, alkaline phosphatase, S100B) • Radiologic exams (chest x-ray, chest and abdominal computed tomography [CT], positron emission tomography [PET] scan, brain magnetic resonance imaging [MRI]) • Screening tests for molecular markers (reverse transcriptase-polymerase chain reaction [RT-PCR])	(Hoffmann et al., 2002; Deichmann et al., 2004; Banfalvi et al., 2002; Mohammed et al., 2001; Keilholz et al., 2004)	**C**

*ABCDEF criteria include the following factors:

- **A**symmetry
- **B**order irregularity
- **C**olor variegation or changes
- **D**iameter greater than 6 mm,
- **E**volutionary changes in color, size, symmetry, surface characteristics, and symptoms
- **F**unny-looking lesions

Recommendations for Treatment	Supporting Evidence	Grade
Surgical Excision of Primary Melanoma • In situ, 0.5 to 1 mm lesion: 0.5 cm margin • <1 mm lesion: 1 cm margin • 1 to 2 mm lesion: consider 1 to 2 cm margin • 1 to 4 mm lesion: 2 cm margin • >4 mm lesion: ≥2 cm margin	(Balch et al., 2001; Cohn-Cedermark et al., 2000; Haigh, DiFronzo, & McCready, 2003; Khayat et al., 2003; Thomas et al., 2004)	**A**
Sentinel Lymph Node Biopsy (SNLB)		
SNLB should be considered for patients with: • Primary melanoma ≥1 mm • Primary melanoma <1 mm, but with negative prognostic features (i.e., ulceration, Clark level IV/V, vertical growth phase [VGP])	(Estourgie et al., 2003; Essner et al., 1999; Morton et al., 2006; Landi et al., 2000; Bedrosian et al., 2000; Wagner et al., 2000; Morton et al., 2005)	**B**
Recommend use of multiple imaging techniques: • Blue vital dye	(Estourgie et al., 2003; Essner et al., 1999; Morton et al., 2006; Landi et al., 2000; Duprat et al., 2005; Cafiero et al., 1998; Rossi	**B**

Recommendations for Treatment	Supporting Evidence	Grade
• Radioactive colloid • Gamma probe	et al., 2006; Morton et al., 2005)	
Measures to minimize probability of missed sentinel node metastasis include: • Serial sectioning • Hematoxylin and eosin staining • Immunohistochemistry • RT-PCR	(Estourgie et al., 2003; Essner et al., 1999; Morton et al., 2006; Landi et al., 2000; Duprat et al., 2005; Cafiero et al., 1998; Rossi et al., 2006; Giese et al., 2005; Gradilone et al., 2004; Kammula et al., 2004; Morton et al., 2005)	**B**
Complete Lymph Node Dissection (CLND) CLND is recommended for patients with: • Positive sentinel lymph node (determined by biopsy) • Clinically obvious metastatic melanoma in regional lymph nodes, even when multiple basins are involved • Distant metastasis (as palliative treatment)	(Morton et al., 2006; Pu et al., 2003; Balch et al., 2000; Morton et al., 2005; Kretschmer et al., 2004)	**C**
Systemic Treatment • Patients who cannot be successfully treated with surgery should be referred to an oncologist for further treatment options.	Expert Opinion	**D**

Recommendations for Follow-up	Supporting Evidence	Grade
Physical Exam		
Perform every 3 months for the first year; every 6 months for 5 years, then at least yearly thereafter: • Full skin assessment • Lymph node palpation	(DiFronzo et al., 1999; DiFronzo, Wanek, & Morton, 2001; Brobeil et al., 1997)	**B**
For patients with the following high-risk features, more frequent visits may be necessary: • Greater tumor thickness	(DiFronzo et al., 1999; DiFronzo, Wanek, & Morton, 2001; Ferrone et al., 2005)	**B**

Recommendations for Follow-up	Supporting Evidence	Grade
• Multiple melanomas • Presence of clinically atypical nevi • Family history of melanoma • Sentinel lymph node metastasis		
Diagnostic Tests For patients with at least stage II or III disease, or signs/symptoms of possible systemic involvement, consider: • Routine blood work (serum lactate dehydrogenase, serum alkaline phosphatase, serum albumin, plasma hemoglobin) • Radiology (chest x-ray, etc)	(Miranda et al., 2004; Wang et al., 2004; Tsao et al., 2004; Hofmann et al., 2002; Deichmann et al., 2004; Banfalvi et al., 2002; Mohammed et al., 2001; Keilholz et al., 2004)	**C**

Recommendations for Surveillance	Supporting Evidence	Grade
Educational Intervention Patients and family members should be educated about: • Self-examination of skin and lymph nodes • Signs and symptoms of recurrence	(DiFronzo, Wanek, & Morton, 2001; Uliasz & Lebwohl, 2007; Brady et al., 2000)	**B**
Adequate Follow-up Physicians should assess patients for symptoms of recurrence and risk factors associated with recurrence: • Sentinel lymph node metastasis • Metastasis to multiple sentinel lymph nodes • Greater Breslow thickness • Ulceration • Clark level IV/V	(Estourgie et al., 2003; DiFronzo et al., 1999; Brobeil et al., 1997; Cerovac et al., 2006; Chao et al., 2002)	**B**

Definitions:

Scale for Grading Recommendations

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Level of Evidence	Qualifying Studies
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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate treatment and management of cutaneous melanoma

POTENTIAL HARMS

- Incisional biopsies that leave at least 50% of the clinical lesion are sometimes inadequate for accurate melanoma staging, and upstaging may be required after complete excision of the residual lesion.
- Chest x-ray and blood work-up for various protein markers may have limited value in the initial assessment of asymptomatic patients with primary cutaneous melanoma that is 4 mm or less in thickness. These tests may be associated with a high false-positive rate, and initial imaging studies are insensitive and nonspecific for the detection of clinically occult and distant disease.
- Surgical excision can cause functional or cosmetic disfigurement.
- As with any medical procedure, there are several possible complications that may arise in association with surgical treatment of melanoma:
    - Lymphedema
    - Hematoma and/or seroma formation
    - Wound infection
    - Sensory nerve injury, typically transient
    - Allergic reactions to isosulfan blue dye
    - Edema

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Clinical practice guidelines are strategies for patient management and are developed to assist physicians in clinical decision making. This guideline, based on a thorough evaluation of the scientific literature and relevant clinical experience, describes a range of generally acceptable approaches to diagnosis, management, or prevention of specific diseases or conditions. This guideline attempts to define principles of practice that should generally meet the needs of most patients in most circumstances.
- However, this guideline should not be construed as a rule, nor should it be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the appropriate results. It is anticipated that it will be necessary to approach some patients' needs in different ways. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of all circumstances presented by the patient, the available diagnostic and treatment options, and other available resources.
- This guideline is not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all facts or circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance, and as practice patterns evolve. This guideline reflects the state of knowledge current at the time of publication. Given the inevitable changes in the state of scientific information and technology, periodic review, updating and revision will be done.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

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)

American Society of Plastic Surgeons. Evidence-based clinical practice guideline: treatment of cutaneous melanoma. Arlington Heights (IL): American Society of Plastic Surgeons; 2007 May. 14 p. [81 references]

ADAPTATION

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

DATE RELEASED

2007 May

GUIDELINE DEVELOPER(S)

American Society of Plastic Surgeons - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Plastic Surgeons

GUIDELINE COMMITTEE

Health Policy Committee of the American Society of Plastic Surgeons

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 Portable Document Format (PDF) from the American Society of Plastic Surgeons Web site.

Print copies: Available from the American Society of Plastic Surgeons, 444 East Algonquin Road, Arlington Heights, IL 6005-4664

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Description and development of evidence-based practice guidelines. American Society for Plastic Surgeons. Electronic copies: Available from the American Society of Plastic Surgeons Web site.

Print copies: Available from the American Society of Plastic Surgeons, 444 East Algonquin Road, Arlington Heights, IL 6005-4664

PATIENT RESOURCES

None available

NGC STATUS

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