Complete Summary

GUIDELINE TITLE

Postmenopausal uterine bleeding.

BIBLIOGRAPHIC SOURCE(S)

Amann M, Anguino H, Bauman RA, Cheung ML, Harris S, Kennedy J, Kivnick S, Lim A, Moore D, Munro M, Musoke L, Solh S. Postmenopausal uterine bleeding. Pasadena (CA): Kaiser Permanente Southern California; 2006 Dec. 27 p. [62 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Postmenopausal uterine bleeding

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology

Oncology
Pathology
Radiology

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To develop evidence based, consensus guidelines for the management of abnormal uterine bleeding (AUB) for women in the Southern California Region

TARGET POPULATION

Women with postmenopausal uterine bleeding

INTERVENTIONS AND PRACTICES CONSIDERED

1. Risk assessment
2. Referral to a specialist
3. Sequencing of investigations
4. Clinical investigations
    - Physical examination
    - Endometrial biopsy and histological assessment
    - Transvaginal sonography (TVS)
    - Saline infusion sonography (SIS)
    - Hysteroscopy with curettage
    - Dilation and curettage
5. Follow-up

MAJOR OUTCOMES CONSIDERED

- Incidence of endometrial cancer
- Sensitivity and specificity of diagnostic tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature searches were performed in MEDLINE and the Cochrane Database of systematic reviews using the following search terms: Postmenopausal Uterine Bleeding; Transvaginal Ultrasound; Sonohysterography; Saline Infusion Sonography; Hysteroscopy; Endometrial Biopsy; Tamoxifen; Hormone

Replacement Therapy. Also searched were the websites of the American College of Obstetricians and Gynecologists, the Society of Obstetricians and Gynecologists of Canada, the New Zealand Guidelines Group, the Royal College of Obstetricians and Gynaecologists, and the Geneva Foundation for Medical Education and Research, (http://www.gfmer.ch/000_Homepage_En.htm) each a repository of web-published guidelines.

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

Classification of Evidence

Modified US Preventive Services Task Force Hierarchy of Research Design

I-1: Evidence obtained from at least one meta analysis or systematic review of randomized clinical trials.

I-2: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III: Descriptive studies and case reports.

IV: Opinions of respected authorities, consensus committees, clinical experience

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

The guideline was developed using the available evidence identified from literature searches and a consensus process with which to classify, interpret, and, where necessary develop components of the guideline not evaluated adequately by the literature. Evidence was classified using a modification of the system adopted by the U.S Preventive Services Task Force of the Agency for Health Research and Quality (AHRQ) adding a subgroup for Class I evidence to allow for meta analysis of randomized controlled trials, such as a Cochrane review. An additional modification was to create a Class IV grouping that isolated expert opinion, including that from guidelines or other consensus documents from national or international organizations or from the collective opinion of the members of the Abnormal Uterine Bleeding Working Group (AUBWG) itself.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Chair of the Committee was selected by the Regional Chief of Obstetrics and Gynecology for Kaiser Permanente Southern California. The remaining members of the Committee were selected by the chairs of each of the 12 medical centers.

Face to face meetings were planned monthly with ad hoc face to face or teleconference-based meetings held as necessary.

After an introductory discussion on the general and Southern California Permanente Medical Group (SCPMG)-specific issues involved in the general problem of post menopausal bleeding (PMB), the committee met as a whole to review methods of guideline development, agree on terms for evidence classification, and to come to consensus on the scope of the guideline(s) to be developed. The Working Group Chair prepared a shell document to aid the guideline development process.

A subgroup of three individuals was charged with leading the investigation and developing draft documents for meetings of the whole group. Drafts were electronically distributed to the whole group and monthly face to face meetings were used to obtain feedback from each of the members of the committee.

The recommendations were created and classified according to the strength of the evidence, classified according to the system used by the American College of Obstetricians and Gynecologists (see rating scheme below).

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations are based according to the following classification used by the American College of Obstetricians and Gynecologists:

Level A. Recommendations are based on good and consistent scientific evidence

Level B. Recommendations are based on limited or inconsistent scientific evidence

Level C. Recommendations are based primarily on consensus and expert opinion

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

The consensus document was created, approved by the members of the Abnormal Uterine Bleeding Working Group (AUBWG) on October 2004 and then submitted to the Southern California Regional Chiefs for review, comment, and approval.

Minor modifications of the guideline were made following presentation to the Regional Chiefs and to the Southern California gynecologic oncology group each of whom approved the final version.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (**I-1 – IV**) and levels of recommendations (**A-C**) are defined at the end of the "Major Recommendations" field.

- Postmenopausal bleeding (PMB) shall be defined to be spontaneous vaginal bleeding that occurs more than one year after the date of the last menstrual period. **(Grade C)**
- Breakthrough bleeding is unscheduled uterine bleeding encountered in any woman using hormone replacement therapy (HRT). **(Grade C)**
- Women with spontaneous PMB should be primarily evaluated with *either* endometrial biopsy (EB), or transvaginal sonography (TVS) to measure the thickness of the endometrial echo complex (EEC). **(Grade A)**
- When TVS or saline infusion sonography (SIS) is used as a technique for assessing the endometrium of women with PMB, photographs of the sagittal and transverse images should be placed in the chart with a suitable note describing the findings. **(Grade C)**
- Practitioners without adequate training in either office-based EB or TVS should refer patients with PMB or breakthrough bleeding to an individual, usually a gynecologist, appropriately trained in these techniques. **(Grade C)**
- Women with spontaneous PMB and an EEC of >5 mm should be further evaluated with endometrial sampling. **(Grade B)**
- A satisfactory endometrial biopsy comprises perceptible passage of the sampling device through the cervical canal into the endometrial cavity and appropriate functioning of the aspiration mechanism. Adequacy of the

specimen for histological interpretation is determined by the pathologist. **(Grade C)**

- Women with persistent spontaneous PMB require further evaluation of the endometrial cavity for focal lesions with one or a combination of office-based SIS and hysteroscopy. Such an approach is necessary even if there is a satisfactory/adequate endometrial biopsy without evidence of hyperplasia, and regardless of the EEC thickness. **(Grade B)**
- Operating room-based dilation and curettage (D&C) of women with PMB should be performed only when office based endometrial biopsy is indicated and cannot be performed for technical reasons, or when it is inconclusive and sonographic techniques (TVS, SIS) are non reassuring. **(Grade B)**
- Women taken to the operating room for D&C should have concomitant hysteroscopy with ancillary instruments that allow for the removal of focal lesions such as endometrial polyps. **(Grade C)**
- Only selected women with bleeding associated with estrogen and progestin containing HRT require assessment of the endometrium. Uterine bleeding or spotting may be expected depending in part on the dose of HRT administered, in part on the schedule of progestin administration, and in part on the duration of therapy. **(Grade A)**
- It is not necessary to routinely evaluate the endometrium of women with uterine spotting or light uterine bleeding in the first six months of continuous estrogen and progestin therapy. Endometrial assessment of such women is recommended if spotting or bleeding persists beyond six months, although there is a very low incidence of endometrial hyperplasia or neoplasia. **(Grade A)**
- Women on doses of unopposed estrogen will have a much higher incidence of endometrial hyperplasia and neoplasia and require appropriate investigation of the endometrium. **(Grade A)**
- Women on estrogen and cyclical progestins can be expected to have indefinite progestin withdrawal bleeding provided the dose and duration of cyclic progestins is adequate. **(Grade A)**
- For women using cyclic progestins, bleeding outside the time of progestin withdrawal is considered abnormal and requires appropriate investigation. **(Grade B)**
- It is apparent that EEC thresholds used for spontaneous bleeding can be applied to patients with HRT-related bleeding, but with a higher incidence of false positive evaluations. **(Grade A)**
- Women experiencing uterine bleeding on tamoxifen (usually used as an adjuvant for breast cancer) should be assessed primarily with endometrial sampling as, in such patients, TVS is neither sensitive nor specific for neoplasia. **(Grade A)**
- Women with persisting bleeding on tamoxifen, and who have already undergone endometrial sampling, should be assessed with one or a combination of SIS and hysteroscopy with appropriate sampling or excision of polyps if found. **(Grade B)**
- Women with repeated bleeding on tamoxifen, and who have been demonstrated to have normal histology and a structurally normal endometrial cavity, should have EB repeated annually. **(Grade C)**
- Postmenopausal bleeding can be a presenting symptom of cancer in the cervical canal. Consequently, if there is no endometrial explanation for PMB, appropriate steps to evaluate patients for cervical cancer should be undertaken considering Pap smear, colposcopy, and curettage of the endocervical canal. **(Grade C)**

Definitions:

Support for Recommendations

Based on the American College of Obstetricians and Gynecologists Strength of Recommendation Classification:

Level A. Recommendations are based on good and consistent scientific evidence

Level B. Recommendations are based on limited or inconsistent scientific evidence

Level C. Recommendations are based primarily on consensus and expert opinion

Classification of Evidence

Modified US Preventive Services Task Force Hierarchy of Research Design

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II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III: Descriptive studies and case reports.

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CLINICAL ALGORITHM(S)

Clinical algorithms are provided in the original guideline document, titled:

- Postmenopausal Bleeding - Investigation Endometrial Echo Complex (EEC) Thickness First
- Postmenopausal Uterine Bleeding Investigation – Endometrial Biopsy First
- Postmenopausal Bleeding – Tamoxifen

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

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

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate evaluation and management of postmenopausal uterine bleeding

POTENTIAL HARMS

False positive and false negative test results

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The recommendations in this guideline are for informational purposes only. They are not intended nor designed as a substitute for the reasonable exercise of independent clinical judgment by practitioners, considering each patient's needs on an individual basis. Guideline recommendations apply to populations of patients. Clinical judgment is necessary to design treatment plans for individual patients.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

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

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

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

DATE RELEASED

2006 Dec

GUIDELINE DEVELOPER(S)

Kaiser Permanente-Southern California - Managed Care Organization

SOURCE(S) OF FUNDING

Kaiser Permanente Southern California

GUIDELINE COMMITTEE

Southern California Permanente Medical Group, Abnormal Uterine Bleeding Working Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Clinical Lead: Malcolm Munro, MD (*Chair*)

Kaiser Permanente Southern California Abnormal Uterine Bleeding Working Group Members: Michael Amann, MD; Hector Anguino, MD; Roselie A. Bauman, MD; Mon-Lai Cheung, MD; Selena Harris, MD; John Kennedy, MD; Seth Kivnick, MD; Aaron Lim, MD; Damien Moore, MD; Lois Musoke, MD; Saad Solh, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from Marguerite Koster, Practice Leader, Technology Assessment and Guidelines Unit, Kaiser Permanente Southern California; Email: Marguerite.A.Koster@kp.org

Print copies: Available from Malcolm G. Munro, MD, FRCS(c), FACOG, Department of Obstetrics and Gynecology, Kaiser Permanente Southern California, Professor, Department of Obstetrics & Gynecology, David Geffen School of Medicine at UCLA; Email: M.G.Munro@kp.org

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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