Complete Summary

GUIDELINE TITLE

Venous thromboembolism and hormonal contraception.

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Venous thromboembolism and hormonal contraception. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 Oct. 13 p. (Guideline; no. 40). [71 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Venous thromboembolism associated with hormonal contraception

GUIDELINE CATEGORY

Counseling
Management
Prevention
Risk Assessment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To present evidence-based recommendations and statements on venous thromboembolism (VTE) and hormonal contraception

TARGET POPULATION

Women using hormonal contraception

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment/Counseling

1. Assessment of medical eligibility for hormonal contraception and counseling concerning use
    - Women with current or previous venous thromboembolism
    - Postpartum
    - Breastfeeding
    - Post abortion
    - Smokers
    - Body mass index >30
    - Surgery
    - Other conditions which may predispose to venous thromboembolism (e.g., sickle cell disease, inflammatory bowel disease)
2. Thrombophilia screen (where indicated; not recommended routinely)

Oral Contraception

1. Combined
    - Levonorgestrel- containing
    - Norethisterone-containing
    - Desogestrel-containing
    - Gestodene-containing
2. Progestogen-only (pills, injectables, implant and intrauterine system)

MAJOR OUTCOMES CONSIDERED

- Absolute and relative risk of venous thromboembolism with oral contraception use
- Mortality and morbidity associated with combined oral contraceptive use

- Health risks and benefits of hormonal contraception

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

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

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Electronic searches were performed for Medline (Ovid version) 1996-2003; Embase (1996-2003); PubMed (1996-2003); the Cochrane Library (to 2003), and the US National Guideline Clearing House. Searches used relevant medical subject headings (MeSH) terms and text words. The Cochrane Library was searched for systematic reviews, meta-analyses, and controlled trials. Previous guidance from the Royal College of Obstetricians and Gynaecologists (RCOG), the Faculty of Family Planning and Reproductive Health Care (FFPRHC), and the World Health Organization (WHO) was reviewed. Key publications were appraised according to standard methodological checklists before conclusions were considered as evidence.

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

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

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

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The recommendations were graded according to the level of evidence upon which they were based.

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)

Grade B - Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendations (evidence levels IIa, IIb, III)

Grade C - Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

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

Following discussion in the Guidelines and Audit Committee, each green-top guideline is formally peer reviewed. At the same time the draft guideline is

published on the Royal College of Obstetricians and Gynaecologists (RCOG) website for further peer discussion before final publication.

The names of author(s) and nominated peer reviewers are included in the original guideline document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

Levels of evidence (**Ia-IV**) and grading of recommendations (**A-C**) are defined at the end of the "Major Recommendations" field.

Does Combined Oral Contraception Increase the Risk of Venous Thromboembolism (VTE)?

B - The relative risk of venous thromboembolism is increased with combined oral contraceptive use. Nevertheless, the rarity of venous thromboembolism in women of reproductive age means that the absolute risk remains small.

Risk of Venous Thromboembolism

B - Combined oral contraceptives containing levonorgestrel or norethisterone are associated with a lower risk of venous thromboembolism than those containing desogestrel or gestodene.

B - A levonorgestrel- or norethisterone-containing combined oral contraceptive should be advised as a pill of first choice. However, after counselling, a woman may choose a desogestrel- or gestodene-containing combined pill.

B - The relative risk of venous thromboembolism increases in the first 4 months after starting combined oral contraception. This risk decreases with increasing duration of use, although it remains above that of non-users. After discontinuation, VTE risk falls to that of non-users within 3 months.

Does Progestogen-Only Contraception Increase the Risk of Venous Thromboembolism?

Progestogen-Only Contraception

B - Progestogen-only pills, injectables, and levonorgestrel implants do not increase the risk of venous thromboembolism.

Medical Eligibility for Hormonal Contraceptive Use

C - Assessing medical eligibility before prescribing allows contraception to be provided appropriately and safely without introducing unnecessary medical barriers.

The World Health Organization (WHO) *Medical Eligibility Criteria for Contraceptive Use* (WHOMEC) provides systematically developed, evidence-based recommendations to facilitate selection of the most appropriate method of contraception without unnecessary medical barriers. **Eligibility**, rather than **ineligibility** (or contraindication), is described. (WHO category 1: "unrestricted use"; WHO category 2: "benefits generally outweigh risks"; WHO category 3: "risks usually outweigh benefits"; WHO category 4: "unacceptable health risk"). Eligibility criteria for combined contraception (oral and transdermal) and progestogen-only, relevant to VTE, are summarised in Table 2 in the original guideline document.

Current or Previous Venous Thromboembolism

C - Women with current venous thromboembolism should not use hormonal contraception.

C - Women with a personal history of venous thromboembolism should not use combined oral contraception but may use progestogen-only methods.

Postpartum

C - A woman who is less than 21 days postpartum should not use combined oral contraception.

C - Combined oral contraception can be used after day 21 postpartum if a woman is not breastfeeding.

C - The progestogen-only pill, implant, or injection can be used safely before day 21 postpartum, even if a woman is breastfeeding.

Combined oral contraceptives affect the quality and quantity of breast milk and are not advised for breastfeeding women [Evidence level IV]

Post-Abortion

C - Combined oral contraception can be commenced immediately following first- or second-trimester abortion.

C - Progestogen-only contraception can be commenced immediately following first- or second-trimester abortion.

Smoking

B - Smokers over the age of 35 years should not use combined oral contraception but progestogen-only methods can be used.

Body Mass Index

B - Women with a body mass index over 30 should first consider progestogen-only methods, but combined oral contraception can be used after counselling.

Surgery

C - Combined oral contraception should be discontinued at least 4 weeks before major surgery where immobilisation is expected.

C - Progestogen-only methods need not be discontinued prior to surgery even when immobilisation is expected.

C - Hormonal methods do not need to be discontinued before minor surgery without immobilisation.

Other Conditions Which May Predispose to Venous Thromboembolism

Superficial Venous Thrombosis

The WHOMEC recommends that the benefits of combined oral contraception (COC) and progestogen-only contraception (POC) outweigh the risks in women with varicose veins and superficial thrombophlebitis (WHO 1 and WHO 2, respectively).

Sickle Cell Disease

WHOMEC advises that benefits of combined contraception and POC use by women with sickle cell disease outweigh the risks (WHO 2 and WHO 1, respectively).

Women with pulmonary hypertension should be advised against the use of combined contraception.

Inflammatory Bowel Disease

WHOMEC does not address inflammatory bowel disease. Faculty of Family Planning and Reproductive Health Care (FFPRHC) guidance suggests that women with inflammatory bowel disease should be offered the same contraceptive choices as other women. Women who are immobilised due to disease exacerbation require counselling regarding stopping COC.

Is Screening for Thrombophilia Needed Before Prescribing Hormonal Contraception?

C - Routine thrombophilia screening prior to hormonal contraceptive use is not recommended.

C - A thrombophilia screen may be considered in a woman with a history of venous thromboembolism in a first-degree relative under the age of 45 years who, after counselling, still wishes to use combined oral contraception.

Summary

- For most women, COC is a safe method of contraception. Although the relative risk of VTE is increased, the absolute risk remains very small.
- Progestogen-only methods (pills, injectables, implant, and intrauterine system) do not appear to be associated with increased risk of VTE. However, evidence regarding these methods is limited and absence of evidence does not equate to absence of risk.
- Heavy smoking, obesity, and underlying thrombophilia increase the risk of VTE and these factors must be taken into account when making contraceptive choices.
- Women with previous VTE should be advised against the use of COC but a progestogen-only method may be used.
- There is no place for routine screening for thrombophilia prior to contraceptive prescribing.

Definitions:

Grading of Recommendations

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)

Grade B - Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendations (evidence levels IIa, IIb, III)

Grade C - Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

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" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of women using oral contraception to minimize the risk of venous embolism

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Clinical guidelines are "systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions." Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1: *Guidance for the Development of Royal College of Obstetricians & Gynaecologists (RCOG) Green-top Guidelines*.
- These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

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

Staying Healthy

IOM DOMAIN

Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Venous thromboembolism and hormonal contraception. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 Oct. 13 p. (Guideline; no. 40). [71 references]

ADAPTATION

This guideline was partially adapted from World Health Organization. *Medical Eligibility Criteria for Contraceptive Use*. 3rd ed. Geneva: WHO; 2000.

DATE RELEASED

2004 Oct

GUIDELINE DEVELOPER(S)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

Royal College of Obstetricians and Gynaecologists

GUIDELINE COMMITTEE

Guidelines and Audit Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Professor Deirdre J Murphy, MRCOG (Chair); Lizzy Dijeh (Secretary); Ms Toni Belfield, Consumers' Representative; Professor P R Braude, FRCOG, Chairman, Scientific Advisory Committee; Mrs C Dhillon, Head of Clinical Governance and Standards Dept.; Dr Martin Dougherty, A. Director NCC-WCH; Miss L M M Duley, FRCOG, Chairman, Patient Information Subgroup; Mr Alan S Evans, FRCOG; Dr Mehmet R Gazvani, MRCOG; Dr Rhona G Hughes, FRCOG; Mr Anthony J Kelly MRCOG; Dr Gwyneth Lewis, FRCOG, Department of Health; Dr Mary A C Macintosh, MRCOG, CEMACH; Dr Tahir A Mahmood, FRCOG; Mrs Caroline E Overton, MRCOG, Reproductive medicine; Dr David Parkin, FRCOG; Oncology; Ms Wendy Riches, NICE; Mr Mark C Slack, MRCOG, Urogynaecology; Mr Stephen A Walkinshaw, FRCOG, Maternal and Fetal Medicine; Dr Eleni Mavrides, Trainees Representative

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Guideline authors are required to complete a "declaration of interests" form.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

Print copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Bookshop, 27 Sussex Place, Regent's Park, London NW1 4RG; Telephone: +44 020 7772 6276; Fax, +44 020 7772 5991; e-mail: bookshop@rcog.org.uk. A listing and order form are available from the RCOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guidance for the development of RCOG green-top guidelines. Clinical Governance Advice No 1. 2000 Jan. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.
- Searching for evidence. Clinical Governance Advice No 3. 2001 Oct. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

PATIENT RESOURCES

None available

NGC STATUS

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