Complete Summary

GUIDELINE TITLE

The management of tubal pregnancy.

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). The management of tubal pregnancy. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 May. 10 p. (Guideline; no. 21). [60 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Tubal pregnancy (ectopic pregnancy)

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide guidance on the management of tubal pregnancy
- To discuss the methods and techniques that may be used once a diagnosis of ectopic pregnancy has been made

TARGET POPULATION

Women with ectopic (tubal) pregnancy

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment

1. Transvaginal ultrasonography
2. Serum human chorionic gonadotrophin (hCG) levels

Management

1. Surgical
    - Laparoscopic approach
    - Open approach (laparotomy)
    - Salpingectomy
    - Salpingotomy
2. Medical
    - Intramuscular methotrexate
3. Expectant management
    - Patient follow up and serum hCG level monitoring
4. Patient education regarding treatment and adverse effects of interventions

MAJOR OUTCOMES CONSIDERED

- Tubal patency rates
- Rates of persistent trophoblast
- Rates of repeat tubal pregnancy
- Adverse effects of medical and surgical interventions
- Cost effectiveness of treatment
- Future intrauterine pregnancy rate
- Spontaneous resolution rate
- Predictive value of human chorionic gonadotrophin serum levels

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

Previous guidelines within this subject area were sought using the sites and gateways laid out in the Royal College of Obstetricians and Gynaecologists (RCOG) clinical governance advice document *Searching for Evidence*. The Cochrane Library (including the Database of Systematic Reviews, DARE, and the trials registry) and Medline were searched using a combination of Medical Subject Heading (MeSH) terms and keywords. The keywords used were "ectopic pregnancy," "tubal pregnancy," "laparoscopy," "laparoscopic," "salpingectomy," "salpingotomy," "methotrexate," "persistent trophoblast," and "beta human chorionic gonadotrophin (beta-hCG)." Reference lists of the articles identified were hand searched for additional articles, and some experts within the field were contacted.

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

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

One important advantage of medical therapy is the potential for considerable savings in treatment costs. Economic evaluations undertaken alongside randomised trials comparing methotrexate and laparoscopic surgery have shown direct costs for medical therapy to be less than half of those associated with laparoscopy. Indirect costs are also less with women and their carers losing less time from work. However, in both these randomised trials no cost saving was seen at serum human chorionic gonadotrophin (hCG) levels above 1500 IU/L due to the increased need for further treatment and prolonged follow-up.

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.

Surgical Management of Tubal Pregnancy

A - A laparoscopic approach to the surgical management of tubal pregnancy, in the haemodynamically stable patient, is preferable to an open approach.

C - Management of tubal pregnancy in the presence of haemodynamic instability should be by the most expedient method. In most cases this will be laparotomy.

There is no role for medical management in the treatment of tubal pregnancy or suspected tubal pregnancy when a patient shows signs of hypovolaemic shock. Transvaginal ultrasonography can rapidly confirm the presence of haemoperitoneum if there is any diagnostic uncertainty but expedient resuscitation and surgery should be undertaken. Experienced operators may be able to manage laparoscopically women with even a large haemoperitoneum safely but the surgical procedure which prevents further blood loss most quickly should be used. In most centres this will be laparotomy. [Evidence level IV]

B - In the presence of a healthy contralateral tube there is no clear evidence that salpingotomy should be used in preference to salpingectomy.

The use of conservative surgical techniques exposes women to a small risk of tubal bleeding in the immediate postoperative period and the potential need for further treatment for persistent trophoblast. Both these risks and the possibility of further ectopic pregnancies in the conserved tube should be discussed if salpingotomy is being considered by the surgeon or requested by the patient. [Evidence level IIa]

B - Laparoscopic salpingotomy should be considered as the primary treatment when managing tubal pregnancy in the presence of contralateral tubal disease and the desire for future fertility.

In women with a damaged or absent contralateral tube, in vitro fertilisation is likely to be required if salpingectomy is performed. Because of the requirement for postoperative follow-up and the treatment of persistent trophoblast, the short-term costs of salpingotomy are greater than salpingectomy. However, if the subsequent need for assisted conception is taken into account, an increase in intrauterine pregnancy rate of only 3% would make salpingotomy more cost effective than salpingectomy. In the presence of contralateral tubal disease the use of more conservative surgery is appropriate. Women must be made aware of the risk of a further ectopic pregnancy. [Evidence level IIa]

Medical Management of Tubal Pregnancy

B - Medical therapy should be offered to suitable women, and units should have treatment and follow-up protocols for the use of methotrexate in the treatment of ectopic pregnancy.

B - If medical therapy is offered, women should be given clear information (preferably written) about the possible need for further treatment and adverse effects following treatment. Women should be able to return easily for assessment at any time during follow-up.

Differentiating so-called "separation pain" due to a tubal abortion from pain due to tubal rupture can be difficult, and a proportion of women will need to be admitted for observation and assessment by transvaginal ultrasound following methotrexate therapy. Women should also be advised to avoid sexual intercourse during treatment, to maintain ample fluid intake, and to use reliable contraception for three months after methotrexate has been given, because of a possible teratogenic risk. [Evidence level IIa]

B - Women most suitable for methotrexate therapy are those with a serum human chorionic gonadotrophin (hCG) below 3000 IU/L, and minimal symptoms.

The presence of cardiac activity in an ectopic pregnancy is associated with a reduced chance of success following medical therapy and should be considered a contraindication to medical therapy. [Evidence level IIa]

A - Outpatient medical therapy with single-dose methotrexate is associated with a saving in treatment costs.

Expectant Management of Pregnancy of Unknown Location

C - Expectant management is an option for clinically stable women with minimal symptoms and a pregnancy of unknown location.

In the management of suspected ectopic pregnancy there is a serum hCG level at which it is assumed that all viable intrauterine pregnancies will be visualised by transvaginal ultrasound. This is referred to as the discriminatory zone. When

serum hCG levels are below the discriminatory zone (<1000 IU) and there is no pregnancy (intra- or extrauterine) visible on transvaginal ultrasound scan, the pregnancy can be described as being of unknown location.

The concept of a discriminatory zone has limitations. Levels of hCG of 1000 IU/L, 1500 IU/L, and 2000 IU/L have been used as discriminatory levels. These levels are dependent upon the quality of the ultrasound equipment, the experience of the sonographer, prior knowledge of the woman's risks and symptoms, and the presence of physical factors such as uterine fibroids and multiple pregnancy. For specialised units performing high resolution vaginal ultrasound with prior knowledge of the woman's symptoms and serum hCG, a discriminatory zone of 1000 IU/L can be used. In other units offering a diagnostic transvaginal scan without prior clinical or biochemical knowledge a discriminatory zone of 1500 IU/L or 2000 IU/L is acceptable.

Using an initial upper level of serum hCG of 1000-1500 IU/L to diagnose pregnancy of unknown location, women with minimal or no symptoms at risk of ectopic pregnancy should be managed expectantly with 48-72 hours of follow-up and should be considered for active intervention if symptoms of ectopic pregnancy occur, serum hCG levels rise above the discriminatory level (1000 IU/L) or levels start to plateau.

If women are managed expectantly, serial serum hCG measurements should be performed until hCG levels are less than 20 IU/L. In addition, women selected for expectant management of pregnancy of unknown location should be given clear information (preferably written) about the importance of compliance with follow-up and should be within easy access to the hospital treating them. [Evidence level III]

C - Expectant management is an option for clinically stable asymptomatic women with an ultrasound diagnosis of ectopic pregnancy and a decreasing serum hCG, initially less than serum 1000 IU/L.

Expectant management is a useful form of treatment management for ectopic pregnancy in selected cases. It is however only acceptable if it involves minimal risks to the woman. Expectant management should only be used for asymptomatic women with an ultrasound diagnosis of ectopic pregnancy, with no evidence of blood in the pouch of Douglas, and decreasing hCG levels that are less than hCG 1000 IU/L at initial presentation and less than 100 mL fluid in the pouch of Douglas. Women managed expectantly should be followed twice weekly with serial hCG measurements and weekly by transvaginal examinations to ensure a rapidly decreasing hCG level (ideally less than 50% of its initial level within seven days) and a reduction in the size of adnexal mass by seven days. Thereafter, weekly hCG and transvaginal ultrasound examinations are advised until serum hCG levels are less than 20 IU/L as there are case reports of tubal rupture at low levels of beta-hCG. In addition, women selected for expectant management of pregnancy of unknown origin should be counselled about the importance of compliance with follow-up and should be within easy access to the hospital in question. [Evidence level III]

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 and successful treatment of ectopic pregnancy, with minimal adverse effects on the patient

POTENTIAL HARMS

Adverse effects of medical and surgical interventions

CONTRAINDICATIONS

CONTRAINDICATIONS

The presence of cardiac activity in an ectopic pregnancy is associated with a reduced chance of success following medical therapy and should be considered a contraindication to medical therapy.

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.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

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
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). The management of tubal pregnancy. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 May. 10 p. (Guideline; no. 21). [60 references]

ADAPTATION

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

DATE RELEASED

2004 May

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

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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 1. 2001 Oct. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

Additionally, Audit Criteria can be found in section 10 of the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

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