Royal College of Obstetricians and Gynaecologists

Consent Advice No. 8

June 2010

LAPAROSCOPIC MANAGEMENT OF TUBAL ECTOPIC PREGNANCY

This is the first edition of this guidance.

This paper provides advice for clinicians in obtaining consent of women undergoing laparoscopic salpingectomy or salpingotomy for ectopic pregnancy. This paper is intended to be appropriate for a number of procedures and combinations and the consent form should be carefully edited under the heading 'Name of proposed procedure or course of treatment' to accurately describe the exact procedure to be performed, after discussion with the woman. The paper follows the structure of Consent Form 1 of the Department of Health, England/Welsh Assembly Government/Scottish Government/Department of Health, Social Services and Public Safety, Northern Ireland. It should be used in conjunction with RCOG Clinical Governance Advice No. 6: *Obtaining Valid Consent.*[1] Please refer to RCOG Green-top guideline No. 21 *The Management of Tubal Pregnancy*[2] and RCOG Patient Information *An ectopic pregnancy: information for you*.[3]

The aim of this advice is to ensure that all women are given consistent and adequate information for consent; it is intended to be used together with dedicated patient information. After discharge, women should have clear direction for obtaining help if there are unforeseen problems.

Clinicians should be prepared to discuss with the woman any of the points listed on the following pages.

Presenting information on risk

Term	Equivalent numerical ratio	Colloquial equivalent
Very common	1/1 to 1/10	A person in family
Common	1/10 to 1/100	A person in street
Uncommon	1/100 to 1/1000	A person in village
Rare	1/1000 to 1/10 000	A person in small town
Very rare	Less than 1/10 000	A person in large town

The above descriptors are based on the RCOG Clinical Governance Advice, *Presenting Information on Risk*.[4] They are used throughout this document.

To assist clinicians at a local level, we have included at the end of this document a fully printable page 2 of the Department of Health, England/Welsh Assembly Government/Scottish Government/Department of Health, Social Services and Public Safety, Northern Ireland, Consent Form 1. This page can be incorporated into local trust documents, subject to local trust governance approval.

CONSENT FORM

1. Name of proposed procedure or course of treatment

Laparoscopic salpingectomy or salpingotomy after confirmation of tubal ectopic pregnancy.

2. The proposed procedure

Describe the nature of laparoscopy and salpingectomy or salpingotomy.The laparoscopic approach is preferred to an open (laparotomy) procedure unless the patient is haemodynamically unstable or either suitable equipment or surgical expertise is not available. Salpingectomy is the preferred surgical option with the possible exception of a diseased or absent contralateral tube. Explain the procedure as described in the patient information.

Note: If any other procedures are anticipated, these must be discussed and consent obtained.

3. Intended benefits

To remove the ectopic pregnancy if it is confirmed by laparoscopy.

4. Serious and frequently occurring risks

It is recommended that clinicians make every effort to separate serious from frequently occurring risks.Women who are obese, have significant pathology, have had previous surgery or who have pre-existing medical conditions must understand that the quoted risks for serious or frequent complications will be increased.

4.1 Serious risks

Serious risks include:[5,6,7]

- damage to bowel, bladder, uterus or major blood vessels which would require immediate repair by laparoscopy or laparotomy (uncommon); however, up to 15% of bowel injuries might not be diagnosed at the time of laparoscopy
- failure to gain entry to abdominal cavity and complete intended procedure laparoscopically, requiring laparotomy instead
- the overall risk of serious complications from diagnostic laparoscopy is approximately two in 1000
- three to eight women in every 100 000 undergoing laparoscopy die as a result of complications (very rare).

4.2 Frequent risks

Frequent risks include:[8,9]

- inability to identify an obvious cause for presenting complaint
- bruising
- shoulder-tip pain
- wound gaping
- wound infection
- persistent trophoblastic tissue, when salpingotomy performed (4–8 in 100)
- hernia at site of entry.

5. Any extra procedures which may become necessary during the procedure

- Laparotomy.
- Salpingectomy.
- Repair of damage to bowel, bladder, uterus or blood vessels.
- Blood transfusion.
- Oophorectomy.

6. What the procedure is likely to involve, the benefits and risks of any available alternative treatments, including no treatment[2,8–10]

Insertion of a laparoscope through a small incision to confirm the presence of the ectopic pregnancy, following which additional instruments may be inserted through two additional small incisions to remove the tube containing the ectopic pregnancy.

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 women who are asymptomatic with an ultrasound diagnosis of ectopic pregnancy, with no evidence of blood in the pouch of Douglas and decreasing serum hCG levels that are lower than 1000 iu/l at initial presentation.

In women with an early ectopic pregnancy who are stable, treatment with a single intramuscular injection of methotrexate is often successful without recourse to surgery. Women most suitable for methotrexate therapy are those with a serum hCG below 3000 iu/l with minimal symptoms and no fetal heart pulsations visible. About 14% of women will require more than one dose of methotrexate and fewer than 10% of women treated with this regimen will require surgical intervention.

Persistent trophoblast is detected by the failure of serum hCG levels to fall as expected after initial treatment. It is primarily a problem occurring after salpingotomy rather than following salpingectomy. Although, even in the presence of persistent trophoblast, hCG levels may return uneventfully to normal, cases of delayed haemorrhage owing to persistent trophoblast have been described and this provides the rationale for following women with serial hCG measurements after treatment and administering methotrexate if levels fail to fall as expected.

7. Statement of patient: procedures which should not be carried out without further discussion

Other procedures which may be appropriate but not essential at the time should be discussed and the woman's wishes recorded.

8. Preoperative information

A record should be made of any sources of information (such as RCOG or locally produced information leaflets) given to the woman prior to surgery. Please refer to RCOG Patient Information: *An ectopic pregnancy: information for you*.[3]

9. Anaesthesia

Where possible, the woman must be aware of the form of anaesthesia planned and be given an opportunity to discuss this in detail with the anaesthetist before surgery. It should be noted that with obesity there are increased risks, both surgical and anaesthetic.

References

1. Royal College of Obstetricians and Gynaecologists. *Obtaining Valid Consent*. Clinical Governance Advice No. 6. London: RCOG; 2008 [www.rcog.org.uk/womens-health/clinical-guidance/obtaining-valid-consent].
2. Royal College of Obstetricians and Gynaecologists. *The Management of Tubal Pregnancy*. Green-top Guideline No. 21. London: RCOG; 2004 [www.rcog.org.uk/womens-health/clinical-guidance/management-tubal-pregnancy-21-may-2004].
3. Royal College of Obstetricians and Gynaecologists. *An Ectopic Pregnancy: Information for You*. London: RCOG [in press].
4. Royal College of Obstetricians and Gynaecologists. *Presenting Information on Risk*. Clinical Governance Advice No. 7. London: RCOG; 2008 [www.rcog.org.uk/womens-health/clinical-guidance/presenting-information-risk].
5. Brosens I, Gordon A, Campo R, Gordts S. Bowel injury in gynecologic laparoscopy. *J Am Assoc Gynecol Laparosc* 2003;10:9–13.
6. Chapron C, Querleu D, Bruhat MA, Madelenat P, Fernandez H, Pierre F, *et al*. Surgical complications of diagnostic and operative gynaecological laparoscopy: a series of 29,966 cases. *Hum Reprod* 1998;13:867–72.
7. Jansen FW, Kapiteyn K, Trimbos-Kemper T, Hermans J, Trimbos JB. Complications of laparoscopy: a prospective multicentre observational study. *Br J Obstet Gynaecol* 1997;104:595–600.
8. Lipscomb GH, Bran D, McCord ML, Portera JC, Ling FW. Analysis of three hundred fifteen ectopic pregnancies treated with single-dose methotrexate. *Am J Obstet Gynecol* 1998:178:1354–8.
9. Lipscomb GH, McCord ML, Stovall TG, Huff G, Portera SG, Ling FW. Predictors of success of methotrexate treatment in women with tubal ectopic pregnancies. *N Engl J Med* 1999;341:1974–8.
10. Royal College of Obstetricians and Gynaecologists. *Preventing Entry-Related Gynaecological Laparoscopic Injuries*. Green-top Guideline No. 49 London: RCOG; 2008[http://www.rcog.org.uk/womens-health/clinical-guidance/preventing-entry-related-gynaecological-laparoscopic-injuries-green-].

This Consent Advice was produced by Mr M Read FRCOG, with the support of the Consent Group of the Royal College of Obstetricians and Gynaecologists.

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Final version is the responsibility of the Consent Group of the RCOG.

The Consent Advice review process will commence in 2013 unless otherwise indicated

Patient identifier/label

Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear) *Laparoscopic salpingectomy (removal of a fallopian tube containing an ectopic pregnancy)* or laparoscopic salpingotomy (removal of an ectopic pregnancy through an incision in the fallopian tube)*.*

** Delete as appropriate.*

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient, in particular, I have explained:

The intended benefits: *To remove the ectopic pregnancy if it is confirmed by laparoscopy.*

Serious risks:

- *Damage to bowel, bladder, uterus or major blood vessels, which would require immediate repair by laparoscopy or laparotomy (uncommon); up to 15% of bowel injuries might not be diagnosed at the time of laparoscopy.*
- *Failure to gain entry to abdominal cavity and complete the procedure.*
- *The overall risk of serious complications from diagnostic laparoscopy is approximately two in 1000.*
- *Three to eight women in every 100 000 undergoing laparoscopy could die as a result of complications (very rare).*
- *Hernia at site of entry.*

Frequent risks:

- *Inability to identify an obvious cause for presenting complaint.*
- *Bruising.*
- *Shoulder-tip pain.*
- *Wound gaping.*
- *Wound infection.*
- *Persistent trophoblastic tissue.*

Any extra procedures which may become necessary during the procedure

☐ Blood transfusion

☐ other procedure (please specify): *Laparotomy, repair of damage to bowel, bladder, uterus or blood vessels, salpingectomy (when salpingotomy planned)*

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet/tape has been provided: *Please refer to patient information An Ectopic Pregnancy: Information for You*

This procedure will involve:

☐ general and/or regional anaesthesia ☐ local anaesthesia ☐ sedation

Signed ..... Date .....

Name (PRINT)..... Job title.....

Contact details (if patient wishes to discuss options later)

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand

Signed ..... Date .....

Name (PRINT).....

Top copy accepted by patient: yes/no (please ring)