Royal College of Obstetricians and Gynaecologists

Consent Advice No. 5

October 2009

VAGINAL SURGERY FOR PROLAPSE

This is the second edition of this guidance, which was previously published in 2004 under the title *Pelvic Floor Repair and Vaginal Hysterectomy for Prolapse*.

This paper provides advice for clinicians in obtaining the consent of women undergoing vaginal surgery for prolapse. 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]

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*.[2] 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

Vaginal surgery for prolapse, with or without vaginal hysterectomy. Surgery using mesh or suspensory techniques, such as colpopexy or colposuspension, is not covered in this guidance.

2. The proposed procedure

Describe the nature of the patient's complaint and the significance of the prolapse, as well as the extent of the planned surgery, locations of incisions and possible effects on fertility. Explain the procedure as described in the patient information. Explain additional safety measures to be taken, such as antibiotics and thromboprophylaxis. Great caution should be exercised in advising surgery in women who are asymptomatic.

Note: If any other procedures are anticipated, these must be discussed and a separate consent obtained. If a decision to perform vaginal hysterectomy is made intraoperatively, the woman should be aware of this possibility.

3. Intended benefits

To improve or resolve the symptoms of prolapse (e.g. to remove the feeling of a lump within the vagina).

4. Serious and frequently occurring risks[3–5]

It is recommended that clinicians make every effort to separate serious from frequently occurring risks. Women who are obese, who have significant pathology, who 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:

- damage to bladder/urinary tract, two women in every 1000 (uncommon)
- damage to bowel, five women in every 1000 (uncommon)
- excessive bleeding requiring transfusion or return to theatre, two women in every 100 (common)
- new or continuing bladder dysfunction (variable – related to underlying problem)
- pelvic abscess, three women in every 1000 (uncommon)
- failure to achieve desired results; recurrence of prolapse (common)
- although venous thrombosis (common) and pulmonary embolism (uncommon) may contribute to mortality, the overall risk of death within 6 weeks is 37 women in every 100 000 (rare).

4.2 Frequent risks

Frequent risks include:

- urinary infection, retention and/or frequency
- vaginal bleeding
- postoperative pain and difficulty and/or pain with intercourse
- wound infection.

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

- blood transfusion: two women in every 100 undergoing vaginal hysterectomy will require intraoperative blood transfusion
- other procedures:
  - repair of bladder and bowel damage
  - laparotomy and conversion to abdominal approach.

6. What the procedure is likely to involve, the benefits and risks of any available alternative treatments, including no treatment

Involves pelvic floor repair ± vaginal hysterectomy and attempt at restoring normal pelvic anatomy. For women who are premenopausal, the additional significance of a hysterectomy should be made clear and their attitude to pregnancy clearly known and documented. Further RCOG guidance on hysterectomy consent is available.[6]

The option of no treatment and other therapies, such as physiotherapy and pessaries, should have been discussed.

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, such as removal of benign lesions, should be discussed and the woman's wishes recorded.

8. Preoperative information

A record should be made of any sources of information (e.g. RCOG or locally produced information leaflets/tapes) given to the woman prior to surgery.

9. Anaesthesia

Where possible, the woman must be aware of the form of anaesthesia planned and should be given an opportunity to discuss this and its risks 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. *Presenting Information on Risk*. Clinical Governance Advice No. 7. London: RCOG; 2008 [**www.rcog.org.uk/womens-health/clinical-guidance/presenting-information-risk**].
3. Mäkinen J, Johansson J, Tomás C, Tomás E, Heinonen PK, Laatikainen T, *et al*. Morbidity of 10 110 hysterectomies by type of approach. *Hum Reprod* 2001;**16**:1473–8.
4. Nieboer TE, Johnson N, Lethaby A, Tavender E, Curr E, Garry R, *et al*. Surgical approach to hysterectomy for benign gynaecological disease. *Cochrane Database Syst Rev* 2008:CD003677. DOI: 10.1002/14651858.CD003677.
5. McPherson K, Metcalfe MA, Herbert A, Maresh M, Casbard A, Hargreaves J, *et al*. Severe complications of hysterectomy: the VALUE study. *BJOG* 2004; **111**:688–94. (Additional data from Dr M J A Maresh FRCOG, Manchester.)
6. Royal College of Obstetricians and Gynaecologists. *Abdominal Hysterectomy for Benign Conditions*. Consent Advice No. 4. London: RCOG; 2009 [**www.rcog.org.uk/abdominal-hysterectomy-benign-conditions**].

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

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) *Vaginal surgery for prolapse ± vaginal hysterectomy*

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 improve the symptoms of prolapse of the bladder/bowel/uterus. If hysterectomy is performed no further children or menstrual cycles are possible*

Serious risks:

- *damage to bladder/urinary tract, 2 women in every 1000 (uncommon)*
- *damage to bowel, 5 women in every 1000 (uncommon)*
- *excessive bleeding requiring transfusion or return to theatre, 2 women in every 100 (common)*
- *new or continuing bladder dysfunction (variable – related to underlying problem)*
- *pelvic abscess, 3 women in every 1000 (uncommon)*
- *failure to achieve desired results; recurrence of prolapse. (common)*
- *although venous thrombosis (common) and pulmonary embolism (uncommon) may contribute to mortality, the overall risk of death within six weeks is 37 women in every 100 000 (rare)*

Frequent risks:

- *urinary infection, retention and/or frequency*
- *vaginal bleeding*
- *postoperative pain and difficulty and/or pain with intercourse*
- *wound infection*

Any extra procedures which may become necessary during the procedure

☐ blood transfusion *required in 2 women in every 100 (common)*

☐ other procedure (please specify) *If any damage to bowel or bladder occurs it may be by repaired by opening your abdomen*

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

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)