



Complete Summary

GUIDELINE TITLE

Surgical treatment of urodynamic stress incontinence.

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Surgical treatment of urodynamic stress incontinence. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2003 Oct. 9 p. (Guideline; no. 35). [53 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [October 22, 2008, Surgical mesh devices](#): The U.S. Food and Drug Administration (FDA) informed healthcare professionals of serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The FDA provided recommended actions for both physicians and patients to reduce the risks.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

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DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Urodynamic stress incontinence

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Surgery
Urology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To highlight the evidence for different surgical approaches for stress incontinence

TARGET POPULATION

Women with urodynamic stress incontinence

INTERVENTIONS AND PRACTICES CONSIDERED

Preoperative Management

1. Urodynamic investigations (including cystometry)
2. Assessment of type of incontinence
3. Assessment for the presence of any complicating factors (e.g., voiding difficulty, detrusor overactivity)

Surgical Procedures

1. Anterior vaginal repair
2. Burch colposuspension
3. Other suprapubic operations such as Marshall-Marchetti-Krantz, paravaginal repair, and laparoscopic colposuspension.

4. Sling procedures using autologous or synthetic materials
5. Injectable agents (collagen, Teflon®, fat, silicon, Durasphere®)
6. Artificial sphincter implantation

Note: Needle suspension procedures were considered but not recommended.

MAJOR OUTCOMES CONSIDERED

- Surgical complication rate
- Mortality rate
- Length of hospital stay
- Procedure success and failure rates
- Continence rate
- Voiding difficulty
- Postoperative detrusor overactivity
- Urethral and vaginal erosion
- Long-term self-catheterisation rate

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

The Cochrane Database of Systematic Reviews and Cochrane Register of Controlled Trials were searched for relevant randomised controlled trials (RCT), systematic reviews, and meta-analyses. A search of the Medline (PubMed) electronic database from 1966 to 2002 was also carried out. The date of the last search was May 2002. In addition conference proceedings and relevant abstracts were searched.

The databases were searched using the relevant Medical Subject Heading (MeSH) terms including all subheadings and this was combined with a keyword search using "human," "female," "incontinence," "bladder," "repair," "surgery," "sutures," "anterior repair," "anterior colporrhaphy," "Burch colposuspension," "retropubic," "Marshall–Marchetti–Krantz," "paravaginal repair," "laparoscopic colposuspension," "Stamey," "Pereyra," "needle suspension," "tension-free vaginal tape," "sling," "Martius," "fascia lata," "cadaveric," "Macroplastique," "injectable," "collagen," "artificial sphincter," "randomised controlled trials," and "meta-analysis."

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

This guideline is based on recommendations formulated by the 2nd International Consultation on Incontinence, Paris 2001, which provided a worldwide panel of experts, and a summary of Cochrane and National Institute of Clinical Excellence (NICE) reviews from 2003.

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.

Surgical Procedures

Anterior Vaginal Repair

A - Anterior repair is less successful as an operation for continence than retropubic procedures and has been superseded by sling procedures. Anterior repair still has a role in the treatment of prolapse without incontinence.

Burch Colposuspension

A - Burch colposuspension is the most effective surgical procedure for stress incontinence, with a continence rate of 85–90% at one year. The continence rate falls to 70% at five years; this shows better longevity than other methods of treatment.

Alternative Suprapubic Surgery

B - The role of other suprapubic operations such as Marshall-Marchetti-Krantz, paravaginal repair, and laparoscopic colposuspension, is unclear.

Needle Suspension Procedures

A - Needle suspension procedures should not be performed: initial success rates are not maintained with time and the risk of failure is higher than for retropubic suspension procedures.

Sling Procedures

A - Sling procedures, using autologous or synthetic materials, produce a continence rate of approximately 80% and an improvement rate of 90%, with little reduction in continence over time. Only one synthetic sling procedure (tension-free vaginal tape) has been subjected to randomised study to date.

Numerous materials are available for use in a suburethral sling. As a generalization, autologous material is associated with a greater continence rate and fewer complications than either cadaveric material or synthetic materials [Evidence level Ia].

Injectable Agents

B - Injectable agents have a lower success rate than other procedures: a short-term continence rate of 48% and an improvement rate of 76%. Long term, there is a continued decline in continence. However, the procedure has a low morbidity and may have a role after other procedures have failed (e.g., when a diagnosis of intrinsic sphincter deficiency is made).

Artificial Sphincters

B - Artificial sphincters can be successfully used after previous failed continence surgery but have a high morbidity and need for further surgery (17%).

Preoperative Management

It is recommended that women undergoing surgery for urodynamic stress incontinence should have urodynamic investigations prior to treatment (including cystometry). There was a paucity of data on urodynamics prior to surgery identified in a 2003 Cochrane review; one small study showed that women were more likely to be treated with drugs or surgery as a result of testing. Nevertheless, prior to performing irreversible bladder-neck surgery, it would

appear to be beneficial to have assessed objectively the type of incontinence and the presence of any complicating factors such as voiding difficulty or detrusor overactivity, which may affect the surgical decision and provide the basis for informed consent. Surgery should be performed by a surgeon who has been trained in the operation and who has a caseload that enables him or her to provide a suitable level of expertise, especially when any repeat surgery is considered.

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 selected recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate surgical intervention to reduce or eliminate symptoms in women with urodynamic stress incontinence

POTENTIAL HARMS

Complications and side effects associated with surgical interventions and materials

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.
- The literature on surgery for stress incontinence is extensive but is mainly based on case series rather than randomised trials. Cure is defined in many different ways, both subjective and objective. The difficulty of assessing cure rates in studies of continence surgery has been highlighted in a review of stress incontinence surgery. Overall, 83% of women reported improvement three months after continence surgery, 5% had no change, and 8% reported a worsening in their condition. The impact of complications from bladder-neck surgery has been studied only recently; for example, the occurrence of urge incontinence or voiding difficulty postoperatively can greatly affect the woman's perception of "cure." While not underestimating the difficulty in conducting well constructed, prospective, randomised trials of surgical treatment, this review highlights the need for such trials to be performed. In this guideline, the developers have attempted to provide consistency in definition of cure, using "continence rate" after surgery to indicate the woman's dryness reported by the surgical team. If objective measurements have been performed, an "objective continence rate" is quoted. Too few of the available studies provided subjective data on women's perception of continence (such as quality-of-life data), although this is often markedly different from the surgical perception of "cure."

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources

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). Surgical treatment of urodynamic stress incontinence. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2003 Oct. 9 p. (Guideline; no. 35). [53 references]

ADAPTATION

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

DATE RELEASED

2003 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. 2001 Oct. Available from the [Royal College of Obstetricians and Gynaecologists \(RCOG\) Web site](#).

Additionally, Audit Criteria are provided in section 5 of the [original guideline document](#).

PATIENT RESOURCES

The following is available:

- Surgery for stress incontinence: information for you. Royal College of Obstetricians and Gynaecologists, 2005 Feb. 8 p. Electronic copies: Available from the [Royal College of Obstetricians and Gynaecologists Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on October 18, 2005. This summary was updated by ECRI Institute on October 27, 2008 following the U.S. Food and Drug Administration (FDA) advisory on surgical mesh devices.

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