



Complete Summary

GUIDELINE TITLE

Hypospadias. In: Guidelines on paediatric urology.

BIBLIOGRAPHIC SOURCE(S)

Hypospadias. In: Tekgul S, Riedmiller H, Gerharz E, Hoebeke P, Kocvara R, Nijman R, Radmayr C, Stein R. Guidelines on paediatric urology. Arnhem, The Netherlands: European Association of Urology, European Society for Paediatric Urology; 2008 Mar. p. 19-24. [28 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
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EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
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SCOPE

DISEASE/CONDITION(S)

Hypospadias

GUIDELINE CATEGORY

Counseling
Diagnosis
Risk Assessment
Treatment

CLINICAL SPECIALTY

Pediatrics
Surgery
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To outline a practical and preliminary approach to paediatric urological problems
- To increase the quality of care for children with urological problems

TARGET POPULATION

Infants and children with hypospadias

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment/Diagnosis

1. Assessment of risk factors: genetic, placental, environmental
2. Description of local findings
3. Genetic and endocrine workup

Treatment

1. Hypospadias repair
 - Differentiation between functionally necessary and esthetically feasible operative procedures
 - Establishing therapeutic objectives
 - Preoperative hormonal treatment
2. Special considerations for surgery
 - Age at surgery
 - Penile curvature
 - Preservation of the well-vascularized urethral plate
 - Re-do hypospadias repairs
 - Urethral reconstruction
 - Urine drainage and wound dressing

MAJOR OUTCOMES CONSIDERED

- Adolescent satisfaction with penis size
- Rate of fistula formation

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guidelines were based on current literature following a systematic review using MEDLINE.

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

1a Evidence obtained from meta-analysis of randomized trials

1b Evidence obtained from at least one randomized trial

2a Evidence obtained from at least one well-designed controlled study without randomization

2b Evidence obtained from at least one other type of well-designed quasi-experimental study

3 Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports

4 Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Application of a structured analysis of the literature was not possible due to a lack of well-designed studies. Whenever possible, statements have been classified in terms of level of evidence and grade of recommendation. Due to the limited availability of large randomized controlled trials – influenced also by the fact that a considerable number of treatment options relate to surgical interventions on a large spectrum of different congenital problems – this document is therefore largely a consensus document.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

- The first step in the European Association of Urology (EAU) guidelines procedure is to define the main topic.
- The second step is to establish a working group. The working groups comprise about 4-8 members, from several countries. Most of the working group members are academic urologists with a special interest in the topic. In general, general practitioners or patient representatives are not part of the working groups. A chairman leads each group. A collaborative working group consisting of members representing the European Society for Paediatric Urology (ESPU) and the EAU has gathered in an effort to produce the current update of the paediatric urology guidelines.
- The third step is to collect and evaluate the underlying evidence from the published literature.
- The fourth step is to structure and present the information. The strength of the recommendation is clearly marked in three grades (A-C), depending on the evidence source upon which the recommendation is based. Every possible effort is made to make the linkage between the level of evidence and grade of recommendation as transparent as possible.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

- A. Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomized trial
- B. Based on well-conducted clinical studies, but without randomized clinical studies
- C. Made despite the absence of directly applicable clinical studies of good quality

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

There is no formal external review prior to publication.

The Appraisal of Guidelines for Research and Evaluation (AGREE) instrument was used to analyse and assess a range of specific attributes contributing to the validity of a specific clinical guideline.

The AGREE instrument, to be used by two to four appraisers, was developed by the AGREE collaboration (www.agreecollaboration.org) using referenced sources for the evaluation of specific guidelines. (See the "Availability of Companion Documents" field for further methodology information).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (**1a-4**) and grades of recommendation (**A-C**) are defined at the end of the "Major Recommendations" field.

Risk Factors

Risk factors associated with hypospadias are likely to be genetic, placental and/or environmental (**Level of evidence: 2b**):

- Endocrine disorders can be detected in a very few cases.
- Babies of young or old mothers and babies with a low birth weight have a higher risk of hypospadias.
- A significant increase in the incidence of hypospadias over the last 20 years suggests a role for environmental factors (hormonal disruptors and pesticides).

The use of oral contraceptives during pregnancy has not been associated with an increased risk of hypospadias in the offspring (**Level of evidence: 2a; Grade of recommendation; B**).

Diagnosis

Patients with hypospadias should be diagnosed at birth (except for the megameatus intact prepuce variant).

Diagnosis includes a description of the local findings:

- Position, shape and width of the orifice
- Presence of atretic urethra and division of corpus spongiosum
- Appearance of the preputial hood and scrotum
- Size of the penis
- Curvature of the penis on erection

The diagnostic evaluation also includes an assessment of associated anomalies, which are:

- Cryptorchidism (in up to 10% of cases of hypospadias)
- Open processus vaginalis or inguinal hernia (in 9%-15%)

Severe hypospadias with unilaterally or bilaterally impalpable testis, or with ambiguous genitalia, require a complete genetic and endocrine work-up

immediately after birth to exclude intersexuality, especially congenital adrenal hyperplasia.

Urine trickling and ballooning of the urethra requires exclusion of meatal stenosis.

The incidence of anomalies of the upper urinary tract does not differ from the general population, except in very severe forms of hypospadias.

Treatment

Differentiation between functionally necessary and aesthetically feasible operative procedures is important for therapeutic decision making. The functional indications for surgery are:

- Proximally located meatus
- Ventrally deflected urinary stream
- Meatal stenosis
- Curved penis

The cosmetic indications, which are strongly linked to the psychology of the parent or future patient's psychology, are:

- Abnormally located meatus
- Cleft glans
- Rotated penis with abnormal cutaneous raphe
- Preputial hood
- Penoscrotal transposition
- Split scrotum

As all surgical procedures carry the risk of complications, thorough pre-operative counselling of the parents is crucial.

The therapeutic objectives are to correct the penile curvature, to form a neo-urethra of an adequate size, to bring the neomeatus to the tip of the glans, if possible, and to achieve an overall acceptable cosmetic appearance of the boy's genitalia (**Level of evidence: 4; Grade of recommendation: C**) (see Figure 1 in the original guideline document).

The use of magnifying spectacles and special fine synthetic absorbable suture materials (6/0-7/0) is required. As in any penile surgery, an exceptional prudence should be adopted with the use of cautery. Knowledge of a variety of surgical reconstructive techniques, wound care and post-operative treatment are essential for a satisfactory outcome. Pre-operative hormonal treatment with local or parenteral application of testosterone, dihydrotestosterone or beta-chorionic gonadotropin can be helpful in patients with a small penis or for repeat surgery.

Age at Surgery

The age at surgery for primary hypospadias repair is usually 6-18 months (**Level of evidence: 4; Grade of recommendation: C**). However, earlier repair

between 4 and 6 months of age has been reported recently (**Level of evidence: 3; Grade of recommendation: B**).

Penile Curvature

If present, penile curvature is often released by degloving the penis (skin chordee) and by excision of the connective tissue of the genuine chordee on the ventral aspect of the penis. The urethral plate has well-vascularized connective tissue and does not cause curvature in most cases. The residual chordee (curvature) is caused by corporeal disproportion and requires straightening of the penis, mostly using dorsal orthoplasty (modification of Nesbit dorsal corporeal plication) (**Level of evidence: 3; Grade of recommendation: B**).

Preservation of the Well-Vascularized Urethral Plate

The mainstay of hypospadias repair is preservation of the well-vascularized urethral plate and its use for urethral reconstruction has become the mainstay of hypospadias repair.

If the urethral plate is wide, it can be tubularized following the Thiersch-Duplay technique. If the plate is too narrow to be simply tubularized, it is recommended that a midline-relaxing incision of the plate, followed by reconstruction according to the Snodgrass-Orkiszewski technique, is performed in distal hypospadias, as well as in proximal hypospadias (though the complication rate is higher).

The onlay technique is preferred in proximal hypospadias and in cases of a plate that is unhealthy or too narrow. For distal forms of hypospadias, a range of other techniques is available (e.g., Mathieu, urethral advancement, etc.) (**Level of evidence: 2b; Grade of recommendation: B**).

If the continuity of the urethral plate cannot be preserved, a modification of the tubularized flap, such as a tube-onlay or an inlay-onlay flap, is used to prevent urethral stricture (**Level of evidence: 3; Grade of recommendation: C**). In this situation, as well as in severe scrotal or penoscrotal hypospadias, the Koyanagi technique or two-stage procedure may be an option.

If preputial or penile skin is not available, or has signs of balanitis xerotica obliterans, a buccal mucosa graft is used in an onlay or two-stage repair (**Level of evidence: 3; Grade of recommendation: C**). The use of inlay skin grafts may allow an increased number of single-stage repairs to be performed.

Re-do Hypospadias Repairs

For re-do hypospadias repairs, no definitive guidelines can be given. All the above-mentioned procedures are used in different ways and are often modified according to the individual needs of the patient.

Urethral Reconstruction

Following formation of the neo-urethra, the procedure is completed by glansplasty and by reconstruction of the penile skin. If there is a shortage of skin covering,

the preputial double-face technique or placement of the suture line into the scrotum may be used. In countries where circumcision is not routinely performed, preputial reconstruction can be considered. However, in the tubularized incised urethral plate (TIP) repair, the parents should be advised that use of a preputial dartos flap reduces the fistula rate (**Level of evidence: 2; Grade of recommendation: B**).

Urine Drainage and Wound Dressing

Urine is drained with a transurethral dripping stent, or with a suprapubic tube. Some surgeons use no drainage after distal hypospadias repair. Circular dressing with slight compression, as well as prophylactic antibiotics, are established procedures.

A large variety of duration of stenting and dressing is described. No recommendation can be given due to the low level of evidence.

Outcome

Adolescents, who have undergone hypospadias repair in childhood, have a slightly higher rate of dissatisfaction with penile size, but their sexual behaviour is not different from that in control subjects (**Level of evidence: 2a**).

Definitions:

Levels of Evidence

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CLINICAL ALGORITHM(S)

The original guideline document contains a clinical algorithm for the management of hypospadias.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for some of the recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate and timely diagnosis and treatment of hypospadias
- Overall acceptable cosmetic appearance of the genitalia

POTENTIAL HARMS

- Surgical complications
- Patient dissatisfaction with size of penis

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The purpose of these texts is not to be proscriptive in the way a clinician should treat a patient but rather to provide access to the best contemporaneous consensus view on the most appropriate management currently available. European Association of Urology (EAU) guidelines are not meant to be legal documents but are produced with the ultimate aim to help urologists with their day-to-day practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The European Association of Urology (EAU) Guidelines long version (containing all 19 guidelines) is reprinted annually in one book. Each text is dated. This means that if the latest edition of the book is read, one will know that this is the most updated version available. The same text is also made available on a CD (with hyperlinks to PubMed for most references) and posted on the EAU websites Uroweb and Urosource (www.uroweb.org/professional-resources/guidelines/ & <http://www.urosource.com/diseases/>).

Condensed pocket versions, containing mainly flow-charts and summaries, are also printed annually. All these publications are distributed free of charge to all

(more than 10,000) members of the Association. Abridged versions of the guidelines are published in European Urology as original papers. Furthermore, many important websites list links to the relevant EAU guidelines sections on the association websites and all, or individual, guidelines have been translated to some 15 languages.

IMPLEMENTATION TOOLS

Clinical Algorithm

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)

Hypospadias. In: Tekgul S, Riedmiller H, Gerharz E, Hoebeke P, Kocvara R, Nijman R, Radmayr C, Stein R. Guidelines on paediatric urology. Arnhem, The Netherlands: European Association of Urology, European Society for Paediatric Urology; 2008 Mar. p. 19-24. [28 references]

ADAPTATION

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

DATE RELEASED

2008 Mar

GUIDELINE DEVELOPER(S)

European Association of Urology - Medical Specialty Society
European Society for Paediatric Urology - Medical Specialty Society

SOURCE(S) OF FUNDING

European Association of Urology

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: S. Tekgül; H. Riedmiller; E. Gerharz; P. Hoebeke; R. Kocvara; R. Nijman; Chr. Radmayr; R. Stein

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the working group submit a conflict of interest form. The information is kept on file in the European Association of Urology (EAU) Central Office database. This guidelines document was developed with the financial support of the EAU. No external sources of funding and support have been involved. The EAU is a non-profit organisation and funding is limited to administrative assistance, travel, and meeting expenses. No honoraria or other reimbursements have been provided.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [European Association of Urology Web site](#).

Print copies: Available from the European Association of Urology, PO Box 30016, NL-6803, AA ARNHEM, The Netherlands.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- EAU guidelines office template. Arnhem, The Netherlands: European Association of Urology (EAU); 2007. 4 p.
- The European Association of Urology (EAU) guidelines methodology: a critical evaluation. Arnhem, The Netherlands: European Association of Urology (EAU); 18 p.

Print copies: Available from the European Association of Urology, PO Box 30016, NL-6803, AA ARNHEM, The Netherlands.

PATIENT RESOURCES

None available

NGC STATUS

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