Surgical Management of Primary Distal Shaft to Midshaft Hypospadias in Infants <1 Year Clinical Guideline

March 10, 2017

This guideline was adapted from clinical standards at Texas Children's Hospital as part of the Pediatric Initiative for Clinical Standards (PICS) Collaborative.
Definition

Hypospadias is a congenital anomaly of the male urethra that results in abnormal ventral placement of the urethral opening. (UpToDate 2016) The location of the meatus may range from the glans to the perineum.

Epidemiology

Hypospadias is one of the most common congenital anomalies with an incidence that varies from 0.3% to 0.7% of male live births. (UpToDate 2016)

Guideline Eligibility Criteria

Infants <1 year with primary distal shaft to midshaft hypospadias

Guideline Exclusion Criteria

- Proximal hypospadias
- Hypospadias reoperation
- Patients with androgen insensitivity
- Patients with gynecologic involvement
## Methods

### Existing External Guidelines/Clinical Pathways

<table>
<thead>
<tr>
<th>Existing External Guideline/Clinical Pathway</th>
<th>Organization and Author</th>
<th>Last Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
<td></td>
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</tbody>
</table>

Any published clinical guidelines have been evaluated for this review using the [AGREE II criteria](#). The comparisons of these guidelines are found at the end of this document. [AGREE II criteria](#) include evaluation of: Guideline Scope and Purpose, Stakeholder Involvement, Rigor of Development, Clarity of Presentation, Applicability, and Editorial Independence.

### Review of Relevant Evidence: Search Strategies and Databases Reviewed

#### Search Strategies

<table>
<thead>
<tr>
<th>Search Terms Used:</th>
<th>Document Strategies Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>hypospadias AND: testosterone, antibiotics, pain, acetaminophen, hydrocodone, catheter, dressing, technique, suture, flap, fistula, infection, surgery, penile block, urine culture, glans, weight, age, shallow plate, flap AND second primary closure, pain AND oxycodone, pain AND acetaminophen, pain AND ibuprofen</td>
<td></td>
</tr>
</tbody>
</table>

#### Years Searched - All Questions

February 2006 - July 2016

#### Language

English

#### Age of Subjects

0-18 years

#### Search Engines

PubMed, Cochrane Collaboration, Google

#### EBP Web Sites

Professional Organizations

<table>
<thead>
<tr>
<th>Joint Commission</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Guideline Clearinghouse</td>
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</table>

#### Other

<table>
<thead>
<tr>
<th>Government/State Agencies</th>
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</thead>
<tbody>
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<td>National Guideline Clearinghouse</td>
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</tbody>
</table>

### Evidence Found with Searches

<table>
<thead>
<tr>
<th>Check Type of Evidence Found</th>
<th>Summary of Evidence – All Questions</th>
<th>Number of Articles Obtained</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>Systematic Reviews</td>
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</tr>
<tr>
<td>☒</td>
<td>Meta-analysis articles</td>
<td>1</td>
</tr>
<tr>
<td>☒</td>
<td>Randomized Controlled Trials</td>
<td>18</td>
</tr>
<tr>
<td>☒</td>
<td>Non-randomized studies</td>
<td>48</td>
</tr>
<tr>
<td>☐</td>
<td>Review articles</td>
<td>0</td>
</tr>
<tr>
<td>☐</td>
<td>Government/State agency regulations</td>
<td>0</td>
</tr>
<tr>
<td>☐</td>
<td>Professional organization guidelines, white papers, etc.</td>
<td>0</td>
</tr>
<tr>
<td>☐</td>
<td>Other:</td>
<td>0</td>
</tr>
</tbody>
</table>
**Evaluating the Quality of the Evidence**

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. The table below defines how the quality of evidence is rated and how a strong versus a weak recommendation is established.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Type of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong</td>
<td>Desirable effects clearly outweigh undesirable effects or vice versa</td>
</tr>
<tr>
<td>Weak</td>
<td>Desirable effects closely balanced with undesirable effects</td>
</tr>
<tr>
<td><strong>High</strong></td>
<td>Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies</td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>Evidence from RCTs with important limitations (e.g., inconsistent results, methodological flaws, indirect evidence, or imprecise results) or unusually strong evidence from unbiased observational studies</td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>Evidence for at least 1 critical outcome from observational studies, from RCTs with serious flaws or indirect evidence</td>
</tr>
<tr>
<td><strong>Very Low</strong></td>
<td>Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence</td>
</tr>
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</table>
### Recommendations

<table>
<thead>
<tr>
<th>Evidence Supports</th>
<th>Evidence Lacking/Inconclusive</th>
<th>Evidence Against</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consider the use of preoperative testosterone in patients with a small-appearing penis and a stretched penile length 1-2 SD below the mean, adjusted for patient age. (Ahmad 2011, Asgari 2015, Bastos 2011, Kaya 2008, Luo 2003, Snodgrass 2011)</td>
<td>Do not give a penile block prior to the time of surgery in patients who require a penile block. – Consensus recommendation</td>
<td>Do not use a compressive dressing without clinical indications (e.g., postoperative bleeding). (Hosseini 2012, McLorie 2001, Narci 2011)</td>
</tr>
<tr>
<td>Administer preoperative testosterone intramuscularly when its use is indicated. The lowest effective dose (testosterone enanthate 2 mg/kg or 25 mg, whichever is lower) should be given IM at 6 weeks and 3 weeks prior to surgery. (Chalapathi 2003, Nerli 2009)</td>
<td>Avoid opioids for postoperative pain management. Alternate acetaminophen and ibuprofen for post-operative pain management. – Consensus recommendation</td>
<td></td>
</tr>
<tr>
<td>Consider using a fine (6-zero or 7-zero), absorbable suture for urethroplasty. (Guarino 2009)</td>
<td></td>
<td>Weak recommendation, moderate quality evidence</td>
</tr>
<tr>
<td>Use a silastic catheter, &lt;8 French in size. (Karakus 2013)</td>
<td></td>
<td>Strong recommendation, very low quality evidence</td>
</tr>
<tr>
<td>Use a catheter (vs. unstented repair) to avoid postoperative retention. The catheter should stay in place for at least 8 weeks if planned. (Hayashi 2007)</td>
<td></td>
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</tbody>
</table>
Clinical Management

**General:**
Hypospadias is often diagnosed in the newborn center. Treatment of distal shaft to midshaft hypospadias requires surgical intervention.

**Consults/Referrals:**
Refer to endocrinology if stretched penile length >2 SD below the mean, adjusted for patient age.

**Follow-Up Care:**
Follow-up care is recommended for all children after hypospadias repair.
Algorithm

Hypospadias
Surgical Management of Primary Distal Shaft to Midshaft
Evidence Based Outcome Center

GUIDELINE EXCLUSION CRITERIA
- Proximal hypospadias
- Hypospadias reoperation
- Patients with androgen insensitivity
- Patients with gynecologic involvement

GUIDELINE INCLUSION CRITERIA
- Patient diagnosed with primary distal shaft to midshaft hypospadias
- Infant < 1 year of age

Small appearing penis

Stretched penile length > 2 standard deviations below the patient age adjusted mean?

YES → Administer: IM preoperative testosterone at 6 weeks and 3 weeks prior to surgery

NO → Consider: IM preoperative testosterone at 6 weeks and 3 weeks prior to surgery

Stretched penile length 3 - 2 standard deviations below the patient age adjusted mean?

YES → Operation:
- Perform TIP repair (if possible)
  - Utilize:
    - At minimum a single-layer neurocutaneous coverage (e.g. flap)
    - Sialo catheter ≤ 8 French in size
    - Interrupted sub-epithelial closure for urethroplasty and subcuticular skin cover sutures
    - Non-compressive dressing
    - Contraindication: Postoperative bleeding indicates compressive dressing
    - Consider using a fine (6-zero or 7-zero) absorbable suture for urethroplasty

NO → Post Operation:
- Pain Management:
  - Alternate Acetaminophen and ibuprofen
- Bladder spasms:
  - Oxybutynin 3 times daily as needed
- Antibiotics Prophylaxis (Consider):
  - Bactrim 2 times daily while catheter is in place

Remove catheter and dressing after 5-10 days

For questions concerning this pathway, Click Here
Last Updated March 10, 2017
References


UpToDate 2016.


Clinical Standards Preparation
This clinical standard was prepared by the Evidence-Based Outcomes Center (EBOC) team in collaboration with content experts at Texas Children’s Hospital (TCH) and the Pediatric Initiative for Clinical Standards (PICS) Collaborative.

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Recommendations
Practice recommendations were directed by the existing evidence and consensus amongst the content experts. Patient and family preferences were included when possible. The TCH Content Expert Team and DCMC EBOC team remain aware of the controversies in the surgical management of hypospadias in infants <1 year. When evidence is lacking, options in care are provided in the clinical standard.

Approval Process
PIICS guidelines are reviewed by DCMC content experts, the EBOC committee, and are subject to a hospital wide review prior to implementation. Recommendations are reviewed and adjusted based on local expertise.

Evaluating the Quality of the Evidence
Published clinical guidelines were evaluated for this review using the AGREE II criteria. The summary of these guidelines are included in the literature appraisal. AGREE II criteria evaluate Guideline Scope and Purpose, Stakeholder Involvement, Rigor of Development, Clarity and Presentation, Applicability, and Editorial Independence using a 4-point Likert scale. The higher the score, the more comprehensive the guideline.

The GRADE criteria were utilized to evaluate the body of evidence used to make practice recommendations. The table below defines how the quality of the evidence is rated and how a strong versus weak recommendation is established. The literature appraisal reflects the critical points of evidence.

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