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

Existing External Guideline/Clinical Pathway	Organization and Author	Last Update
N/A		

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	Document Strategies Used
Search Terms Used:	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
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	
Joint Commission	
Government/State Agencies	National Guideline Clearinghouse
Other	

Evidence Found with Searches

Check Type of Evidence Found	Summary of Evidence – All Questions	Number of Articles Obtained
☐	Systematic Reviews	0
☒	Meta-analysis articles	1
☒	Randomized Controlled Trials	18
☒	Non-randomized studies	48
☐	Review articles	0
☐	Government/State agency regulations	0
☐	Professional organization guidelines, white papers, ect.	0
☐	Other:	0

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.

Recommendation	
Strong	Desirable effects clearly outweigh undesirable effects or vice versa
Weak	Desirable effects closely balanced with undesirable effects
Type of Evidence	
High	Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies
Moderate	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
Low	Evidence for at least 1 critical outcome from observational studies, from RCTs with serious flaws or indirect evidence
Very Low	Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence

Recommendations

Evidence Supports	Evidence Lacking/Inconclusive	Evidence Against
Use preoperative testosterone in patients with a small-appearing penis and a stretched penile length >2 SD below the mean, adjusted for patient age. **(Ahmad 2011, Asgari 2015, Bastos 2011, Kaya 2008, Luo 2003, Snodgrass 2011)** – Strong recommendation, low quality evidence	Do not use a balloon catheter. – Consensus recommendation	Do not routinely use preoperative testosterone in patients with a normal-sized penis. **(Ahmad 2011, Asgari 2015, Bastos 2011, Kaya 2008, Luo 2003, Snodgrass 2011)** – Strong recommendation, very low quality evidence
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)** – Weak recommendation, low quality evidence	Do not give a penile block prior to the time of surgery in patients who require a penile block. – Consensus recommendation	Do not use a compressive dressing without clinical indications (e.g., postoperative bleeding). **(Hosseini 2012, McLorie 2001, Narci 2011)** – Strong recommendation, low quality evidence
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)** – Strong recommendation, very low quality evidence	Avoid opioids for postoperative pain management. Alternate acetaminophen and ibuprofen for post-operative pain management. – Consensus recommendation	
Use the TIP procedure in infants with a distal shaft to midshaft primary hypospadias. **(Abdel-Hamid Mohamid El-Hawy 2013, Acimi 2011, Akbiyik 2009, Aminsharifi 2008, Andersson 2011, Andersson 2015, Asanuma 2007, Aslam 2013, ElGanainy 2010, ElGanainy 2012, Hadidi 2012, Liem 2006, Mouravas 2014, Pfistermuller 2015, Prat 2012, Sarhan 2009, Scarpa 2010, Silay 2012, Snodgrass 2010, Sujijantararat 2009)** – Strong recommendation, moderate quality evidence	Do not obtain a urine culture at the time of catheter removal. – Consensus recommendation	
Utilize at least a single-layer neourethral coverage for all TIP repairs. **(Abolyosr 2010, Appignani 2009, Babu 2013, Bakan 2007, Bertozzi 2011, Bilici 2011, Braga 2010, Cimador 2013, Dhua 2012, Djordjevic 2006, El-Kassaby 2008, Hayashi 2007, Kureel 2008, Mustafa 2008, Pfistermuller 2015, Savanelli 2007, Snodgrass 2010, Tayakkoli Tabassi 2010, Thomas 2015, Yigiter 2010, Yildiz 2010)** – Strong recommendation, moderate quality evidence		
Consider using a fine (6-zero or 7-zero), absorbable suture for urethroplasty. **(Guarino 2009)** – Weak recommendation, moderate quality evidence		
Use a silastic catheter, <8 French in size. **(Karakus 2013)** – Strong recommendation, very low quality evidence		
Use a catheter (vs. unstented repair) to avoid postoperative retention. The catheter should stay		

in place for 2-7 days postoperatively. **(Aslan 2007, Leclair 2004, Lorenz 2004, Ritch 2010)** – Strong recommendation, very low quality evidence		
Consider administering cephalexin three times daily while the catheter is in place for prophylaxis. **(Kanaroglou 2013, Meir 2004)** – Weak recommendation, very low quality evidence		

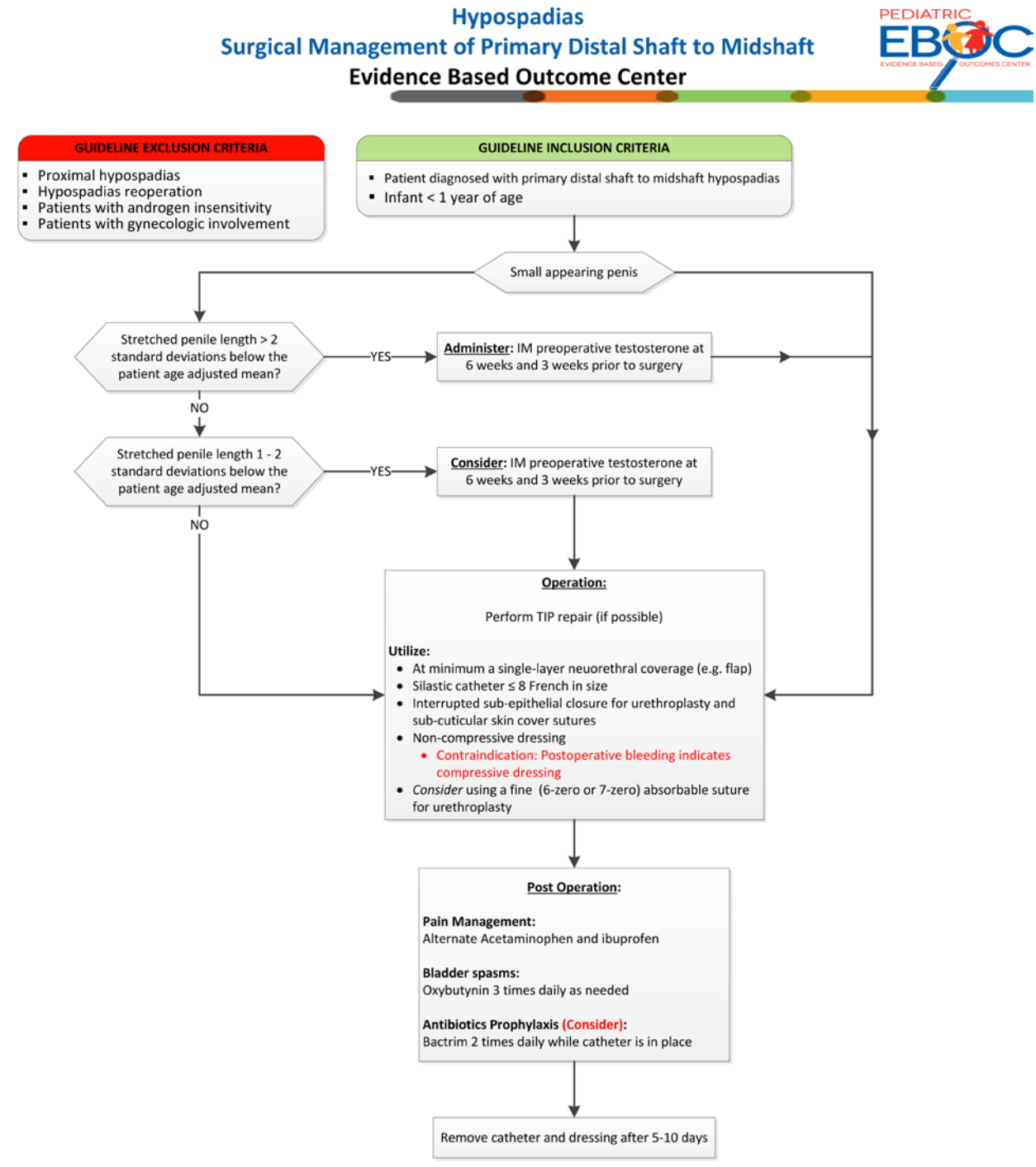
Clinical Management

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



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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

PICS 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.
This clinical standard specifically summarizes the evidence *in support of* or *against* specific interventions and identifies where evidence is *lacking/inconclusive*. The following categories describe how research findings provide support for treatment interventions.
"Evidence Supports" provides evidence to support an intervention
"Evidence Against" provides evidence against an intervention.
"Evidence Lacking/Inconclusive" indicates there is insufficient evidence to support or refute an intervention and no conclusion can be drawn *from the evidence.*

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.

Recommendation	
STRONG	Desirable effects clearly outweigh undesirable effects or vice versa
WEAK	Desirable effects closely balanced with undesirable effects
Quality	**Type of Evidence**
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Moderate	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
Low	Evidence for at least 1 critical outcome from observational studies, RCTs with serious flaws or indirect evidence
Very Low	Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence

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