

Patient Reported Outcomes in Preoperative and Postoperative Patients with Hypospadias

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Purpose: Current outcome tools for hypospadias have limited focus on the caregiver or patient perspective of important patient centered outcomes. In this study we collaborated with patients, caregivers, and lay and medical experts to develop and pilot a patient reported outcome measure for hypospadias.

Materials and Methods: We developed a patient reported outcome measure based on systematic review of the literature and focus group input. The patient reported outcome measure was piloted in caregivers for boys younger than 8 years and in patients older than 8 years who presented for urology consultation before meeting with the surgeon. Patients were classified with uncorrected hypospadias, successful repair or failed repair based on the presence or absence of complications (fistula, diverticulum, meatal stenosis/stricture, greater than 30-degree recurrent curvature, glans dehiscence and/or skin reoperation).

Results: A patient reported outcome measure was developed and administered to 347 patients and/or caregivers-proxies, including 105 uncorrected cases, 162 successful repair cases and 80 failed cases. Satisfaction with appearance was highest in those with successful hypospadias repair compared to failed repair and uncorrected hypospadias (93% vs 77% and 67%, respectively). Voiding symptoms such as spraying or a deviated stream were highest in failed and uncorrected cases (39% and 37%, respectively). Overall dissatisfaction with voiding was highest for uncorrected hypospadias and failed repair compared to successful cases (54% and 47%, respectively, vs 15%).

Conclusions: The evaluation of patient and caregiver-proxy reported outcomes in preoperative and postoperative patients with hypospadias allows for the quantification of benefits derived from hypospadias repair and may ultimately represent the gold standard outcome measure for hypospadias. This pilot study identified preliminary patient centered themes and demonstrated the feasibility of administering hypospadias patient reported outcome measures in clinical practice.

Key Words: urethra, hypospadias, outcome assessment (health care), questionnaires, evaluation studies as topic

Abbreviation and Acronym

I-PSS = International Prostate Symptom Score

PROM = patient reported outcome measure

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SURGICAL outcomes of the correction of hypospadias vary widely with important physical and psychosocial consequences for patients who experience

complications. Modern advances in surgical technique have improved surgical outcomes in hypospadias but 15% of boys experience a complication.

This risk doubles in boys with proximal defects or prior complications.^{1,2} Poor cosmetic or functional outcomes can lead to considerable long-term behavioral and psychosocial consequences,³ including negative genital perception^{4,5} and sexual avoidance.^{6,7} This is especially concerning when cosmetic appearance is an indication for operative treatment.⁸

Current outcomes tools for hypospadias repair do not adequately assess important patient centered outcomes. A systematic review of patient reported outcomes in hypospadias revealed multiple ad hoc questionnaires that primarily focus on cosmetic and urinary function. None were developed with patient input such as interviews or focus groups and these surveys do not address self-perception, embarrassment, satisfaction with voiding/sexual function or quality of life.⁹ Several small cross-sectional studies have assessed the long-term urinary, sexual, cosmetic and self-esteem outcomes of individuals with hypospadias.^{4,10} However, it is difficult to draw conclusions from these studies due to different definitions of success and limited patient input on priority outcomes. When reported, poor outcomes of hypospadias consistently had a significant impact on the psychosocial well-being of individuals.¹¹ Open-ended studies tend to reveal more negative patient perceptions than standardized questionnaires.¹²

Our study objectives were to work with patients and families to develop a pilot PROM and assess feasibility in developing and administering a PROM in a pediatric urology population.

METHODS

An initial pool of potential questions for a PROM was generated by a critical review of the literature, 2 focus group of 10 lay experts including hypospadias advocacy organization members, social workers, nurses and a sex therapist, a focus group of 3 pediatric urologists and open-ended interviews with 5 patients and caregivers. We then identified preliminary themes, leading to theme consolidation and extraction with subsequent iterative discussion and analysis.^{12,13} Survey items were generated after identifying priority domains through interviews, literature review and incorporation of items from the validated I-PSS voiding questionnaire, which we modified for a pediatric population.¹⁴ Item reduction was done through consensus of lay experts and medical experts to cover priority domains and maintain a brief survey. Survey items were piloted in a small group of patients, caregivers and physicians for face validity. English and Spanish language versions of a caregiver-proxy and a patient version of the survey were developed (see figure).

The survey was field tested in consecutive patients seen at a pediatric urology practice that also cares for adults with hypospadias. Postoperative questionnaires were administered at 6-week, 8-month and annual followup visits. Surgery was classified as successful repair if

no urethroplasty or reoperative skin complications were noted by the surgeon or the caregiver/patient. Patients between stages for planned 2-stage repair and incomplete surveys were excluded from analysis. Surveys were self-administered in clinic before surgical consultation and nurses were available to answer questions.

Patient clinical characteristics and survey responses were analyzed using SAS®, version 9.3. Significant differences were determined by the independent samples t-test, the Pearson chi-square, Mann-Whitney and Kruskal-Wallis tests, and ANOVA.

RESULTS

Priority domains identified included satisfaction with urination, appearance and erection, and overall well-being. The pilot survey incorporated questions in the relevant domains and was further refined with patient, caregiver, and lay and medical expert feedback (see figure).

Survey Respondents

A total of 347 surveys were completed by the 296 caregivers and 51 patients 8 years old or older. Of the patients 105 had uncorrected hypospadias, 162 underwent successful repair, including a prior surgical complication and successful reoperation in 28, and 80 had an active surgical complication. Complications included fistula in 35% of cases, glans dehiscence in 28%, multiple failed hypospadias operations in 12%, stricture/meatal stenosis in 8%, reoperative skin complication in 8%, greater than 30-degree recurrent ventral curvature in 4% and diverticulum in 1%.

Postoperative patients were older than preoperative patients and those with complications were older (see table). Disease severity differed. Most preoperative and successful postoperative patients had distal hypospadias compared to more than half of those with failure, who had proximal hypospadias at baseline.

The surgical group without complications was most satisfied with the appearance of the genitals (93%). However, there remained relatively high satisfaction rates in postoperative patients with failure and uncorrected hypospadias (77% and 67%, respectively, $p < 0.0001$). Patients and caregivers continued to have concerns about what others might think about the appearance of their genitals or those of their son despite successful surgical correction in 38% to 44% across groups. At all time points almost half of the patients had been teased about the appearance of the genitals (40% to 46% across groups).

Dissatisfaction with voiding was highest in patients with uncorrected hypospadias (54%) and failed repair (47%), although there was some dissatisfaction with voiding in those with successful

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