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Application of the STROBE statement to the hypospadias literature: Report of the international pediatric urology task force on hypospadias

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Summary

Introduction
Observational studies, particularly case series, represent the majority of the current hypospadias research. As a result, this literature lacks standardization of surgical techniques, uniform definitions of hypospadias complications, and consistency of outcome reporting, which may make it difficult to compare results across studies. A modified version of the STROBE statement, containing 20 items, was presented at the International Pediatric Urology Task Force on Hypospadias meeting to assist with clear and transparent reporting of hypospadias studies. The adoption and implementation of this modified tool will allow investigators and health care providers to critically evaluate quality and identify bias within the literature. In addition this instrument will ensure consistency of reporting, improving objective comparisons between studies, unification of results, and development of evidence-based clinical guidelines.

Methods
In this article, we have applied the modified STROBE statement to the hypospadias literature, aiming to create a guide on study reporting for pediatric urologists, and ultimately improve the quality of research in our field. We present itemized recommendations for adequate reporting of hypospadias studies and case series, ranging from drafting the abstract to addressing biases and potential sources of confounding. Included with each item is a brief explanation of its importance and potential effect on the study, as well as pertinent examples of hypospadias articles.

Results
A modified STROBE summary table containing 20 items is presented in (Supplementary Table 1).

Conclusions
If properly conducted and reported, hypospadias studies have the potential to provide useful information to clinicians and surgeons. However, authors should recognize the inherent limitations of these observational studies, especially in the form of bias, which may introduce invalid data or limit generalizability. Thus, we expect that the use of this guiding tool will not only improve transparency of hypospadias reporting, but also improve its methodological quality, allowing proper comparison and interpretation of data across different institutions.

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Supplementary Table 1 Strobe Summary table.

		Item	Description
Title and Abstract	1	Title	Use the PICOT format (**P**opulation, **I**ntervention, **C**omparative intervention, **O**utcome, **T**ime horizon).
		Abstract	Provide a brief but detailed summary of the study. Include methodology, results and interpretation.
Introduction	2	Background/Rationale	Explain the purpose of conducting the research.
	3	Objectives	Specify the objectives of the study and state the predetermined hypotheses.
Methods	4	Study design	Present the general study design and indicate the primary and secondary outcomes.
	5	Setting	Description of the location of the study and relevant dates.
	6	Eligibility criteria	Include both the inclusion and exclusion criteria and describe patient selection process.
	7	Variables	Include all outcome measures, interventions, risk factors, predictors, potential confounders, and other applicable variables.
	8	Data sources/management	Describe how each variable was recorded, the source and methods of data and how the data was collected.
	9	Bias	Acknowledge and explain how potential sources of bias were addressed.
	10	Study size	Describe and explain how sample size was reached.
	11	Statistical methods	Clear explanation of all statistical methods.
		Control for confounding	Outline the methods used to control for confounding.
		Subgroup/Interaction analysis	Identify if these were *a priori* or *post hoc* analyses.
		Handling of missing data	Evaluate and explain if missing data is random or systematic.
		Sensitivity analyses	Describe any sensitivity analyses.
Results	12	No. of participants at each stage	State the number of subjects included in each stage of the study.
		Reason for non-participation	State why participants were excluded at each phase of the study.
		Flow diagram	Use a flow diagram to display information efficiently.
	13	Study participants	Include baseline patient characteristics table.
		Missing data	Provide the number of subjects with missing data for each outcome.
	14	Outcome data	Report the number of outcome events or summary measures.
	15	Unadjusted and adjusted estimates	Report both adjusted and unadjusted estimates of your main results. Clarify which confounders were included or excluded, and why.
Discussion	16	Key results	Describe the main results highlighting the original goals and objectives.
	17	Limitations	Acknowledge possible sources of bias, and other study limitations.
	18	Generalizability	Indicate the extent to which study results are generalizable.
Other information	19	Funding	State the funding sources and the role of the funders.
	20	Summary of findings table	Use a standardized Summary of findings table to effectively communicate key study findings.

Introduction

Even though randomized controlled trials (RCTs) are considered to be the gold standard for systematically evaluating interventions, this type of study design accounts for only 1% of the pediatric urological literature [1]. This paucity is due, at least in part, from the ethical and logistical challenges imposed by blinding and randomizing patients, especially children, to different surgical interventions, the high costs associated with conducting experimental studies, and the need for clinical equipoise [2]. Given these challenges, observational studies (particularly case series) represent the majority of the current urological literature [3].

Although non-experimental (observational) research strategies can provide valuable information on surgical outcomes, they are often prone to confounding, interactions from unmeasured factors and different biases (such as sampling or recall bias) [2]. Confidence in employing observational studies to inform clinical