Journal of Plastic, Reconstructive & Aesthetic Surgery (2015) 68, 1647—1655

JPRAS
An International Journal of Surgical Reconstruction
www.JPRASurg.com

REVIEW

Fistula after single-stage primary hypospadias repair — A systematic review of the literature

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Received 26 February 2015; accepted 21 July 2015

KEYWORDS
Complications;
Fistula;
Stenosis;
Stricture;
Dehiscence;
Hypospadias

Summary *Background:* The reporting of fistula after hypospadias repair varies greatly in the worldwide literature, with incidence ranging from 0% to over 35%. With multiple techniques employed within a heterogeneous patient cohort, to date, no "average" incidence of fistula has been reported.
Methods: A systematic review of the contemporary English-language literature from 2005 to 2015 identifying articles reporting complications after primary, single-stage hypospadias repair (the most commonly performed hypospadias operation) was performed. Identified reports were reviewed according to the Consolidated Standards of Reporting Trials (CONSORT) and the Methodological Index or Non-Randomized Studies (MINORS). A random effects analysis model was produced, in order to calculate a pooled outcome rates across the included studies. Separate models were then produced for subgroups of studies, with the resulting pooled rates compared.
Results: After application of inclusion and exclusion criteria, 44 articles progressed to the final analysis. A total of 6603 patients were included. The incidence of fistula was 7.5% (95% CI: 5.8—9.4), stricture or stenosis 4.4% (95% CI: 3.1—5.8) and dehiscence 2.1% (95% CI: 1.3—3.1).

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http://dx.doi.org/10.1016/j.bjps.2015.07.024

Conclusions: With pooled proportions of complications from over 6600 patients over a 10-year period, a standard may be set for outcomes after single-stage primary hypospadias repair for surgeons to audit their own outcomes against.

Introduction

Over 400 techniques have been described for hypospadias repair.[1] Many other variables are also encountered in the management of hypospadias: pre-operative hormonal manipulation; timing of surgery; correction of chordee; post-operative urinary diversion; and medications such as antibiotics and antispasmodics. With a limited pool of high quality evidence available, recommendations from the European Association of Urology (EAU) for the treatment of hypospadias[2] are not definitive, and have changed little in recent revisions.[3] The guidelines allow many factors influence the choice of surgical technique, including ''personal taste, upbringing, situational preference, training, experience and personal success''.[4] As such, the reporting of common post-operative outcomes from a very heterogeneous patient population is diverse: for example, the incidence of post-operative fistula ranges from 0% to over 35%.[5,6] Specific commonly reported outcomes including fistula, urethral stricture or meatal stenosis may require revision surgery and so it is essential to highlight these during the pre-operative counseling and consenting of parents and patients. The "acceptable" complication rate is historically based upon expert opinion[7,8] and the EAU current recommendation to benchmark complications below 10% is based upon level 2b evidence,[9] but this is not specific to the type of complication. Revision surgery for a complex proximal urethrocutaneous fistula is wholly different to that for mild meatal stenosis.

Hypospadias surgery is not alone with respect to a poor evidence base, a highly variable patient cohort and diverse surgical and post-operative management regimens. Cleft palate reconstruction has a wide range of treatment protocols, with optimum age at primary surgery and technique historically based largely upon low quality evidence.[10] It is also prone to post-operative fistula akin to hypospadias repair. Digital flexor tendon reconstruction is another example of a heterogeneous patient cohort with repair technique variable in respect to suture material and configuration, management of the extra-tendinous soft tissues and post-operative rehabilitation.[11,12] By pooling the outcomes of different studies, the incidence of specific complications from the worldwide literature can be reported. In an aim to improve outcomes, standards can be set to allow individual audit of complications, highlight areas of deficiency and instigate change.

Rather than suggesting the optimum method or management regimen for hypospadias repair, the aim of this review will be pool outcomes from multiple worldwide studies that have reported complications after hypospadias surgery. This review will provide an "average" incidence of individual post-operative complications, regardless of patient or surgical factors. If standards are not being met, changes can be made to protocols in order to improve patient outcome. A contemporary review of the available literature and systematic analysis of the reported data will provide information about the incidence of fistula and other complications after single-stage primary hypospadias repair, the most commonly performed procedure.[13]

Materials and methods

Data sources

A systematic literature review of publications in English of the following electronic databases was conducted: Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, MEDLINE and EMBASE. The following keywords were used: (primary) AND (hypospadias) AND (repair OR urethroplasty) AND (fistula). The publication date range for studies was from 01/01/2005 to 31/12/2014. A decision was made to limit the search to fistula as the primary outcome measure as it is widely reported in a categorical manner (either present or absent).

Study selection

Two researchers independently selected articles for each review. We defined study eligibility using the population, intervention, comparator, outcome, and study design approach (PICOS).[14] The inclusion criteria and exclusion criteria are summarized in Table 1. Articles were included if a subgroup of patients fulfilling the exclusion criteria could be extracted from the reported cohort (e.g. complications of primary cases extracted from a mixed cohort of primary and secondary surgeries). If primary single-stage repair data was not available from a mixed cohort, it was deemed non-extractable and excluded.

Study selection was performed through two levels of screening. In the first level, abstracts were reviewed for the inclusion and exclusion criteria. In the second level screening, all articles filtered through the first level were read in their entirety and the same inclusion and exclusion criteria applied. Only studies that successfully passed both levels of screening were included in our analysis. The final list of included articles was selected with the consensus of all the authors, verifying that inclusion criteria were met. Our procedure for evaluating records identified during the literature search followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) criteria.[14]