

# INPLASY PROTOCOL

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**Corresponding author:**  
Nitinkumar Borkar

drnitinborkar25@aiimsraipur.edu.in

**Author Affiliation:**  
All India Institute of Medical sciences Raipur.

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None declared.

## Use of an autologous platelet -rich concentrate in hypospadias repair : a systematic review and meta-analysis

Borkar, NB<sup>1</sup>; Sharma, C<sup>2</sup>; Mohanty, D<sup>3</sup>; Upadhyay, VD<sup>4</sup>; Sinha, A<sup>5</sup>.

**Review question / Objective:** To systematically compare outcomes of hypospadias surgery in children with or without use of autologous platelet concentrates (APC).

**Information sources:** Preliminary literature search was done in PubMed and Cochrane central register of controlled trials (CENTRAL) to confirm the absence of published metanalysis of this topic. Detailed electronic searches were be done in the electronic database including Medline , CENTRAL, Embase , Scopus and Google scholar by two authors independently till 15 September 2022. Also clinical trial registry ( clinicaltrials.gov ) and major conference proceedings, was searched till 15 September 2022, with no language restrictions

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 September 2022 and was last updated on 20 September 2022 (registration number INPLASY202290098).

### INTRODUCTION

**Review question / Objective:** To systematically compare outcomes of hypospadias surgery in children with or without use of autologous platelet concentrates (APC).

**Rationale:** Though repair of hypospadias done by many technique and offered by many surgical discipline, unanimous agreement among them is on the use of intermediate layer to cover the neourethra. There are different technique to cover the neourethra. Literature describes the use of various tissues such as de-epithelised overlap skin flap, dartos fascia, corpus

spongiosum , tunica vaginalis (TV) flap and tunica vaginalis graft to provide cover to neourethra. Dartos fascia and tunica vaginalis flaps are the commoner to use as a intermediate layer. It has been proved that use of intermediate layer in hypospadias repair reduce the incidence of postoperative complications. Snow BW. was the first to introduce the use of TV as a blanket wrap to cover reconstructed neourethra. Tiwari et al. reported tunica vaginalis can be used as a graft also to cover neourethra. Though dissection of TV flap is easy and it is well vascularised , TV flap sometimes may be limited by its length to reach up to the apex of urethroplasty also it will not be available in re do surgeries once used . Local dartos considered more physiological but it will limited to use in redo surgeries or in staged surgeries . Tissue glue , sealants and biomaterial are useful in such conditions. Tissue sealants are one such option that has gained significant attention in the recent past. Covering neourethra tissue sealant during the operative repair of hypospadias provides an additional coverage to neourethra and reduce the complications like urethrocutaneous fistula. However , these sealants are blood derived products and infectious and allergic risk cannot be ruled out. Also these products are costly. An autologous concentrate of human platelets in small volume of plasma containing biologically active factors , responsible for hemostasis , synthesis of new connective tissue and revascularisation. Autologous platelet concentrate is used for wound healing , soft tissue reconstruction, bone healing and found to be safe. It was first used in hypospadias surgery for closure of urethrocutaneous fistula by Soyer et al., Guinto A et al. was the first to use autologous platelet rich fibrin (PRF) membrane for urethroplasty coverage with encouraging results.

**Condition being studied:** Hypospadias is the most common congenital anomaly of penis. It is the second most common genital birth defect in boys after cryptorchidism. It has an incidence of 200 to 250 per male live births. Clinical

spectrum hypospadias is based on the location of the meatus and associated chordee. There are around 300 different surgical techniques described in literature for repair of hypospadias.

## METHODS

**Search strategy:** This systematic review and meta- analysis was conducted as per the preferred reporting items for systematic review/ and meta-analyses (PRISMA) guidelines. The search term were used (Autologous platelet rich plasma OR autologous platelet rich fibrin membrane OR Autologous platelet gel OR Platelet rich plasma OR PRP AND Hypospadias OR Hypospadias repair ). Hand search were also done with related references list in the studies.

**Participant or population:** Operated hypospadias patients.

**Intervention:** Autologous platelet concentrate to cover neourethra.

**Comparator:** Tissue covers to neourethra.

**Study designs to be included:** We included any randomised studied or comparative studies for our metanalysis . We included studies reported as full text or published as abstract only where sufficient data are available, and unpublished data from completed studies if available.

**Eligibility criteria:** Operated hypospadias patients in whom autologous platelet rich fibrin membrane is used to cover neourethra.

**Information sources:** Preliminary literature search was done in PubMed and Cochrane central register of controlled trials (CENTRAL) to confirm the absence of published metanalysis of this topic. Detailed electronic searches were be done in the electronic database including Medline , CENTRAL, Embase , Scopus and Google scholar by two authors independently till 15 September 2022. Also clinical trial registry ( clinicaltrials.gov ) and major conference proceedings, was

searched till 15 September 2022, with no language restrictions

**Main outcome(s):** Urethrocutaneous fistula, meatal stenosis, stricture, wound infection, mean operative time.

**Data management:** Study selection- Two authors independently reviewed for abstract and title of the identified article. After removing any duplicates in the search results, full texts of the potentially eligible studies were retrieved. Two authors independently assessed the full-text articles to identify eligible studies for inclusion. Any disagreement between authors was resolved through discussion and a third author was consulted if consensus was not achieved. Excluded studies and the reasons for exclusion were documented. This selection process is presented in a PRISMA flow diagram. We measured Cohen's Kappa coefficient for estimation of the interrater reliability for selection of potentially relevant studies. Data extraction- After the selection of the relevant studies, data extraction will be performed by two authors independently. Baseline information about study (Information of the author, year of publication), number of patients per study, number of patients in each group, mean/median age, age range, along with abovementioned outcomes will be extracted in a data extraction table using MS Excel (Version 16.16.27). Any discrepancies among the observers will be resolved through consensus and consultation with another author.

**Quality assessment / Risk of bias analysis:** The methodological quality of the included studies was independently assessed by two authors utilising the modified Downs and Black scale. This 27-item validated scale (score ranging from 0 to 28) was adopted to include studies other than randomized controlled trials (RCTs) also. The measurement of the interrater reliability agreement was done using kappa statistics. Based on the kappa values, the level of agreement was defined as almost perfect (0.81- 1.00), substantial (0.6- 0.80),

moderate (0.41-.60), fair (0.21-0.40), slight (0.00-0.20) and poor (<0.00).

**Strategy of data synthesis:** Data was analysed using RevMan 5.4. Continuous variables such as mean operative time were analysed as mean differences with 95% confidence intervals (CIs). Dichotomous variables were analysed as risk ratios (RRs) with 95% CIs. The individual was the preferred unit of analysis. Heterogeneity was identified by visual assessment of the confidence intervals of the studies in the forest plot (eyeball test). Heterogeneity will be specifically examined with  $I^2$  statistics. To quantify the heterogeneity, the following ranges of  $I^2$  statistic will be used to guide the interpretation.

**Subgroup analysis:** Between the type of hypospadias repair and type of hypospadias.

**Sensitivity analysis:** For heterogeneity  $I^2 > 50\%$ .

**Country(ies) involved:** India.

**Keywords:** Hypospadias; repair; platelet rich plasma; platelet rich gel.

**Contributions of each author:**

Author 1 - Nitinkumar Borkar - Drafted manuscript, Statistical analysis.

Email: drnitinborkar25@aiimsraipur.edu.in

Author 2 - Charu Sharma - Search literature.

Email: drcharusharma18@gmail.com

Author 3 - Debajyoti Mohanty - Search, methodological assessment.

Email: debajyotimohanty@aiimsraipur.edu.in

Author 4 - Vijay Upadhyay - methodological assessment.

Email: upadhyayavj@rediffmail.com

Author 5 - Arvind Sinha - preliminary search, statistical analysis.

Email: drarvindsinha@gmail.com