



# The effect of parenteral testosterone administration prior to hypospadias surgery: A prospective, randomized and controlled study

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## Summary

### Introduction

The goal of hypospadias surgery is to provide a functionally and cosmetically normal penis. Whether this goal will be to the patient's satisfaction depends largely on the original anatomy, surgical technique and surgeon's experience. It has been suggested that androgen administration is associated with better outcomes in hypospadias repair; however, few studies have included control groups and the issue is still controversial.

### Purpose

To evaluate the effects of parenteral testosterone administration on the results of hypospadias repair in children with untreated hypospadias.

### Materials and methods

A total of 182 children with midshaft or distal hypospadias and a mean age of 30 months (range 18–52 months) were enrolled in this study. Consecutive children were randomly allocated to the study group (testosterone administration) (Group 1,  $n = 91$ ) or control group (Group 2,  $n = 91$ ). Only children with a flat urethral plate were included in this study. The control group did not receive any pre-operative treatment. Children with a previous history of hypospadias repair and any proven endocrine disorder were excluded. The study children received 2 mg/kg testosterone enanthate monthly for two months before surgery. Tubularized incised plate (TIP) urethroplasty, with or without chordee correction, was performed for all children in both groups by the same urologist. Hypospadias repair was performed 4 weeks after the second dose of testosterone administration. Postoperative complications were recorded, including: urethrocutaneous fistulas, urethral diverticula, meatal stenosis, and glanular dehiscence. The mean stretched penile length and circumference were measured at baseline and at 1 month and 2 months post operation. All children were examined every month for any adverse affects to testosterone treatment, like pubic and axillary hair, and height acceleration, up to 3 months post operation.

## Results

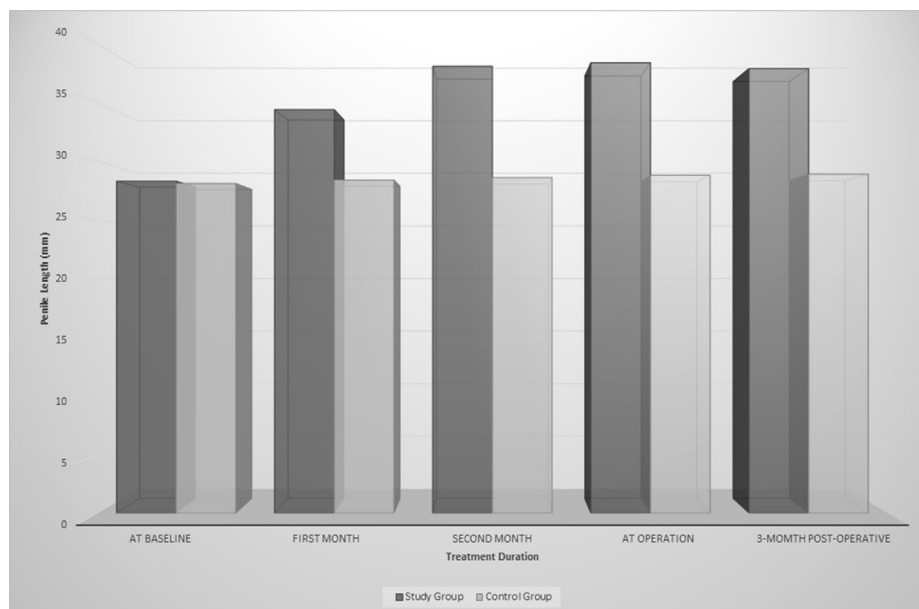
An increase in penile length (from  $28.1 \pm 2.2$  mm to  $38.5 \pm 2.6$  mm) ( $P = 0.001$ ) and penile circumference (from  $35.1 \pm 1.6$  mm to  $45.5 \pm 2.2$  mm) ( $P = 0.001$ ) were noticed in all but four children in Group 1. The actual values for increase in penile length in the study group were, 22.0%, 35.0% and 36.0%, at postinjection months 1, 2 and 3, respectively ( $P = 0.01$ ,  $P = 0.001$  and  $P = 0.001$ , respectively) (Figure). The actual values for increase in penile circumference in the study group were, 16.0%, 27.0% and 29.0%, at postinjection months 1, 2 and 3, respectively ( $P = 0.01$ ,  $P = 0.001$  and  $P = 0.001$ , respectively). The overall complication rates were significantly higher in Group 2 [12 children, 13.18%] compared to Group 1 (five children, 5.45%) ( $P = 0.03$ ). Urethrocutaneous fistula was the most common complication in both groups (four children [4.39%] in Group 1 and seven children [7.69%] in Group 2) ( $P = 0.02$ ), followed by meatal stenosis (one child [1.09%] in Group 1 and three children [3.29%] in Group 2) ( $P = 0.03$ ). All children in Group 1 developed pigmentation of the genitalia, and scant pubic hair appeared in 14 of them. These side effects disappeared by the 3 months postoperation follow-up visit.

## Discussion

Tubularized incised plate urethroplasty is a popular reconstructive method for hypospadias repair and is widely accepted by pediatric urologists. It is a reliable and simple technique with low complication rates. Testosterone administration before hypospadias repair decreases complication rates, reduces the need for reoperation and results in better cosmetic outcomes. Some studies have demonstrated temporary side effects like pubic hair growth and aggressive behavior, which gradually became normalized after treatment cessation. Nowadays, many pediatric urologists administer testosterone prior to hypospadias surgery; however, this can be variable.

## Conclusion

Parenteral testosterone administration before hypospadias repair is beneficial in decreasing complication rates.



## Introduction

Surgical repair of hypospadias is a challenging reconstructive surgery. The principal goals of this surgery are good cosmetic results and better functional outcomes [1]. A number of complications, including urethrocutaneous fistula, meatal stenosis, urethral diverticulum and wound dehiscence, have been reported for different techniques of hypospadias repair [2–4]. Androgen stimulation is often used to increase the penile size before hypospadias surgery [5,6]. It is believed that the temporary increase in penile length, glans circumference and tissue vascularity that are induced by androgen administration make the hypospadias repair easier and improve functional and cosmetic results [5,7,8]. The therapeutic effect of testosterone to increase the length of the penis is significantly greater than human chorionic gonadotropin (HCG) [9]. Both systemic and local administration of testosterone are capable of significantly increasing penile length, but the clinical outcomes in local form are unpredictable due to variability in the volumes applied and, therefore, absorbed [10].

The existing published literature on pre-operative hormonal stimulation in hypospadias repair is controversial. In a randomized study by Kaya et al., patients who received dihydrotestosterone (DHT) gel had fewer complications and better cosmesis than those who underwent surgery alone [11]. In a study by Nerli et al., 21 consecutive children with microphallic hypospadias were randomized to receive either topical or parenteral testosterone prior to surgery [8]. They noticed significant penile growth in both groups of children. Ahmad et al. reported that parenteral testosterone can be safely used to improve the surgical outcome of hypospadias repair [12]. In another study by Ishii et al., there was significantly increased penile length in prepubertal boys with hypospadias [13]. Bastos et al. demonstrated that the use of 1% topical testosterone propionate

before hypospadias repair yields neovascularization in absolute numbers and in volume density [14].

Although the previously published studies have suggested that androgen administration is associated with better outcomes in hypospadias repair, few have included control groups.

In addition, the sample size in most of the non-randomized studies is too small. In a systematic review, Netto et al. addressed the issue of hormone therapy in hypospadias surgery [15]. They concluded that ‘although pre-operative hormone therapy is currently used before hypospadias surgery, its real benefit in terms of improvement of the penis and surgical results has not been defined’.

Therefore, the present prospective, randomized, controlled study was designed to address the safety and efficacy of parenteral testosterone enanthate administration on hypospadias repair. The hypothesis of the study was that children with hypospadias who receive parenteral testosterone prior to reconstructive surgery would have better surgical outcomes than children who do not receive parenteral testosterone.

## Materials and methods

### Study participants

From December 2003 to January 2013 a total of 335 children with primary distal and mid-shaft hypospadias underwent surgical repair in the present institute. Of these 335 children, 182 with a mean age of 30 months (range 18–52 months), who met the study criteria, were enrolled in this study. Inclusion criteria were children with midshaft or distal hypospadias and superficial shallow urethral plates. Following the classification made by Nguyen et al. [16] the

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