

Role of intramuscular testosterone therapy for the position of meatus as well as the changes in the degree of chordee on proximal penile hypospadias in children: a non-randomized clinical trial

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ABSTRACT

Aims: The aim of the current study was to evaluate and compare the changes in meatal position and degree of chordee in children with proximal penile hypospadias before and after intramuscular testosterone therapy.

Methods: This was a single center, parallel arm, non-randomized clinical trial which was conducted in the surgery out-patient department (SOPD) of Bangladesh Shishu Hospital & Institute, Dhaka, Bangladesh from June 2022 to March 2024 for a period of 22 months. Patients with proximal penile hypospadias attended in SOPD in Bangladesh Shishu Hospital & Institute during the study period. Several variables were recorded like position of meatus as well as the degree of chordee. A preparation of testosterone depot, containing testosterone propionate, phenylpropionate, isocaproate, and decanoate, was administered via intramuscular injection in the buttock to a patient with proximal penile hypospadias. The dosage was 2 mg/kg of body weight, following the specified flowchart. If the desired effect was achieved, either by the growth of the penile length proximal to the meatus resulting in a change in the severity from proximal penile to mid/distal penile hypospadias, or by a reduction in the degree of chordee to less than 30°, or both, the testosterone therapy was discontinued.

Results: A total number of 20 children presented with hypospadias were recruited for this study after fulfilling the inclusion and exclusion criteria. The mean age with the SD of the study population was 42.10±25.37 months. All the position of the meatus of the study population were in the proximal position which was 20(100.0%) cases before intramuscular testosterone therapy. However, After the therapy, the proximal position was found in 10(50.0%) cases and mid position was in 10(50.0%) cases ($p=0.002$). During testosterone therapy, the mean with the SD of degree of chordee was 55.0±8.73 mm and 43.25±14.26 mm in before and after intramuscular testosterone injection respectively ($p=0.0001$).

Conclusion: In conclusion the degree of chordee is significantly change before and after intramuscular testosterone injection.

Keywords: Hypospadias, proximal penile hypospadias, chordee, testosterone

INTRODUCTION

Hypospadias is a congenital defect resulting from an abnormal penile development, which leads to the urethral meatus being situated abnormally along the penile shaft, scrotum, or perineum instead of its usual location at the tip of the glans. It is the second most common birth anomaly, occurring in approximately 1 out of every 300 males.¹

The condition arises due to arrest in normal development of the urethra, foreskin, and the ventral aspect of the penis.² Hypospadias classification is based on factors such as the positioning of the urethral opening, the presence of penile curvature (chordee), and the extent of related abnormalities.³ Proximal hypospadias which account for 20% of all cases of

hypospadias among them one-fourth of the hypospadias are associated with chordee.^{4,5} The position of the meatus and degree of chordee determine the severity of hypospadias.⁶

Hypospadias was classified according to position of meatus into four categories: first-degree (with the urethral opening at the coronal or distal area of the penis), second-degree (with the urethral opening located between the mid-penile and sub-coronal area), third-degree (with the urethral opening in the perineum or proximal penile area), or categorized as not otherwise specified (NOS).⁷ The degree of the chordee can be classified according to the angle of the chordee, with mild chordee defined as <20°, moderate chordee as 20-30°, and



severe chordee as $>30^\circ$.⁸ So, according to classification the more proximal the meatal opening more severe the hypospadias additionally degree of chordee is directly proportional to the severity of hypospadias.

Surgical correction is advised to achieve optimal functionality, cosmetic appearance, and minimal complications, addressing the primary objectives of correcting chordee and ensuring an aesthetically pleasing penis.⁹ The likelihood of surgical success remains significantly challenging in children with proximal hypospadias with chordee compared to those with a less severe deformity.⁵ To enhance the size of the penis and to achieve satisfactory repair, preoperative testosterone is commonly used as androgen therapy.¹⁰

In order to increase penile length, temporary stimulation has been attempted through the local application of testosterone or dihydrotestosterone (DHT) cream; however, the outcomes were not only irregular but also exhibited variability in absorption.¹¹ The benefit of using intramuscular (IM) testosterone application over topical is that it ensures an increase in serum testosterone level.¹⁰

Therefore, IM testosterone stimulation ensures the development of high-quality tissue by promoting an increase in total penile length, the amount of preputial and penile shaft skin.¹² Testosterone also enhances the vascularity of the corpus spongiosum that facilitates to reconstruct a neourethra within the glans penis, allowing for low-pressure voiding within a distensible tube as well as minimizes potential complications.¹³

However, a few effects as secondary sexual characteristics, like the appearance of pubic hair, changes in genital pigmentation, and aggressive behavior were noted following testosterone stimulation.¹⁴ Nonetheless, these effects were observed to regress once hormonal therapy was discontinued. The most common effect of secondary sexual characteristics of IM testosterone found was the appearance of pubic hair.¹⁵⁻¹⁷ A survey indicated that 76% of respondents believed that the side effects could be minimized by administering IM testosterone at a dosage of 2mg/kg body weight.¹⁷

Despite an increase in total penile length, it has been observed that the distance from the hypospadiac meatus to the tip of the glans does not increase proportionately with the entire length of the penis.⁹ However, this study used topical testosterone and measured total penile length and meatus to glans distance but didn't specifically measure penile length proximal to the meatus.

Testosterone stimulation results in a disproportionate increase in penile length, with more significant growth in tissues proximal to the hypospadiac meatus.¹² Furthermore, their research highlights that the increase in tissues proximal to the meatus is greater than that observed in distal tissues which eventually alters the degree of hypospadias. However, this study was done in a single center on a very small number of patients and didn't mention the effect of IM testosterone on the degree of chordee. Considering these facts about IM testosterone, the present study was conducted to evaluate the effect of intramuscular testosterone on proximal penile hypospadias. The purpose to the present study was to observe and compare the changes in the position of meatus as well as the changes in the degree of chordee before and after IM testosterone therapy.

METHODS

Ethical Consideration

Keeping compliance with the Helsinki Declaration for Medical Research Involving Human Subjects, 1964 a consent form was constructed describing the title, objectives, and procedure of the study, the expected outcome, any potential risk to the subject undergoing intervention, and ways to minimize. These statements were written and described in an easily understandable clear local language. Parents or caregivers decided themselves to be or not to be included in the study. This written informed consent was signed duly by the caregiver and the principal investigator. All information from the patients was kept confidential under the responsibility of the principal investigator. An identification number was given instead of using a name for each member of the study group. No other than the investigator, regulatory authorities, and the ethical review committee would have access to collected data. The patient's identity was not disclosed while analyzing or publishing the results of the study. Ethical clearance was taken from the ethical review committee (Date: 19.10.2022, Decision No: 2022692) of Bangladesh Shishu Hospital and Institute, Dhaka. Every ethical issue was discussed with the patient's parents regarding the study and informed written consent was obtained. The study did not involve any social, psychological, or legal risk to the subject or any invasion of privacy. The study did not involve using hospital or medical records. There was no chance of disclosure of any information that was harmful to the patients or others. The patient's parents were informed about the nature and purpose of the study, procedures followed, risks associated with it, and benefits from the study. They were also informed about the right to participate or to withdraw from the study at any time. No compensation for risk or loss of work time was provided. Confidentiality was strictly maintained regarding all data.

Study Settings and Population

This was a single center, parallel arm, non-randomized clinical trial. The study was conducted in the surgery outpatient department (SOPD) of Bangladesh Shishu Hospital & Institute, Dhaka, Bangladesh. This study was carried out from June 2022 to March 2024 for a period of 22 months. Patients with proximal penile hypospadias attended SOPD in Bangladesh Shishu Hospital & Institute during the study period. A purposive sampling technique was used. Out of the study population, the individual sample units were selected according to clinical judgment until the desired sample size was attained.

Selection Criteria

Patients who had proximal penile hypospadias with age ranging from 1 year to 10 years were included in this study. Patients who developed secondary sexual characteristics, patients who underwent some surgical repair of penis in the past, patients who had taken prior hormonal therapy for penile growth and patient who had a disorder of sexual development were excluded from this study.

Study Procedure

Several variables were recorded like total length of the penis, penile length proximal to meatus, penile length distal to the meatus, position of meatus and degree of chordee. Proximal



penile hypospadias was defined as the urethral opening located proximal to halfway from the tip of the penis to penoscrotal junctions on the ventral aspect of the shaft of the penis will be 'proximal penile' hypospadias. Severe chordee was recorded when chordee was more than 30°. Position the meatus and degree of chordee was used to define severity of hypospadias. The growth of the penile length proximal to the meatus resulting in a change either in position of the meatus from proximal penile to mid/distal penile hypospadias, or by a reduction in the degree of chordee to less than 30°, or both were considered as reduced severity.

At first, the patient attended the SOPD, Bangladesh Shishu Hospital & Institute, was assessed and the diagnosis was established based on clinical grounds and by history taking and proper physical examination. Then they were approached to participate in the study. Before enrollment in the study, all attendants of patients were described about the titles, study aim and objectives, procedure, benefits, and potential dangers of the study. Face-to-face interviews with patient guardians were conducted by using a semi-structured questionnaire.

Measurements

The degree of chordee measurements was taken by a geometric protractor after stretching the penis. Total penile length, penile length proximal to the meatus and penile length distal to the meatus were measured by placing the jaw of the ruler at the penoscrotal junction after stretching the penis.

Intervention

A preparation of testosterone depot, containing testosterone propionate, phenylpropionate, isocaproate, and decanoate, was administered via intramuscular injection in the buttock to a patient with proximal penile hypospadias. The dosage was 2 mg/kg of body weight, following the specified **Figure 1**.

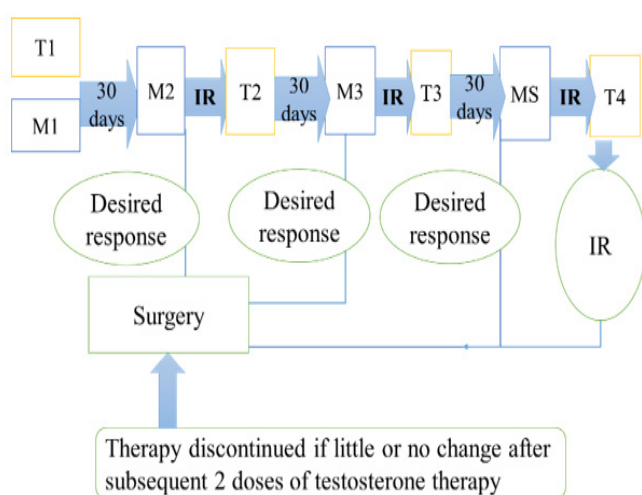


Figure 1. Follow up and outcomes measures

M1: Measurement before 1st injection, T1: 1st dose of testosterone injection, M2: Measurement before 2nd injection, T2: 2nd dose of testosterone injection, M3: Measurement before 3rd injection, T3: 3rd dose of testosterone injection, M4: Measurement before 4th injection, T4: 4th dose of testosterone injection, IR: Inadequate response.

Follow Up and Outcomes Measures

All patient were followed up and effects of IM testosterone measured according to specified flowchart. If the desired effect was achieved, either by the growth of the penile length proximal to the meatus resulting in a change in the severity from proximal penile to mid/distal penile hypospadias, or by a reduction in the degree of chordee to less than 30°, or

both, the testosterone therapy was discontinued and patients were referred to consultant for surgical correction. If there was little to no change in the penile length proximal to the meatus or degree of chordee during subsequent two dosage of testosterone therapy, the therapy was also terminated and patients were referred for surgical consultation as well. Appearance secondary sexual characteristics following IM testosterone therapy like the appearance of pubic hair, genital pigmentation, and aggressive behavior were also observed after therapy. All patients underwent surgical correction within 60 days due to the temporary effects of the intervention. Since this study focused solely on the effects of intramuscular testosterone on penile growth, postoperative outcomes were not assessed.

Quality Assurance Strategy

All the study population was selected very carefully under the close supervision of the guide and inclusion-exclusion criteria was strictly followed. The completeness and quality of the collected data were ensured by regular and routine supervision, checking, and monitoring. The guide randomly scrutinized the data collection procedure. The gathered information from the patient was checked and rechecked with the medical record. Schedule meetings were arranged with the guide at every monthly interval to discuss the progress of data collection. Data cleaning was done before editing in the computer for analysis. After obtaining the results of one-quarter of the study subjects, a review meeting was arranged with the guide, and emerged issues were addressed properly. Before entering data in the computer for analysis random checking of data was done by the guide. Irrelevant and inconsistent data was discarded. After the completion of the data collection, a meeting was arranged with a guide and co-guide to discuss the progress of thesis writing and submission.

Statistical Analysis

The collected data from the participants were analyzed. To maintain consistency, the data were manually checked, edited, and verified before tabulation. The data was then coded, entered, and analyzed using SPSS (Statistical Package for Social Science) version 26 statistical software. The categorical variables were presented as n (% of cases), and the continuous variables were presented as mean±SD. Paired t-tests were carried out to determine the significance of the differences between pre-treatment and post-treatment outcome variables for total penile length, penile length proximal to meatus, penile length distal to the meatus, ratio of distal & proximal penile length and degree of chordee. On the other hand, the McNemar test was used as a test of significance for change in the position of the meatus. A significance level of $p < 0.01$ was considered to be statistically significant. All hypotheses were formulated using two-tailed alternatives against each null hypothesis (hypothesis of no difference).

RESULTS

Twenty children with hypospadias were included in this study after meeting the inclusion and exclusion criteria. The age of the participants ranged from 16 to 108 months, with a mean age of 42.10 ± 25.37 months (**Table 1**). Before testosterone therapy, the mean total penile length and proximal penile length were 20.10 ± 4.96 mm and 5.15 ± 2.60 mm, respectively. Following therapy, significant increases ($p=0.0001$) were observed, with

**Table 1.** Age Distribution of the study population (n=20)

Age	Values
Mean±SD	42.10±25.37 months
Age range	16.0 to 108.0 months

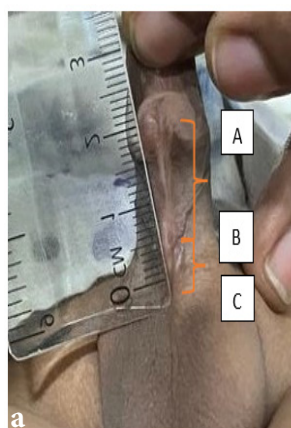
SD: Standard deviation

the total penile length reaching 29.20±5.35 mm (**Table 2**). The length before and after the testosterone is shown in **Figures 2a, 2b** and the proximal penile length increasing to 12.15±4.22 mm (**Table 3**).

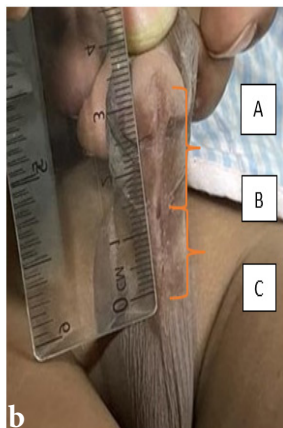
Table 2. Comparison of total penile length (AC) before and after testosterone therapy

Testosterone therapy	Total penile length (mean±SD)	99% CI	p value
Before testosterone	20.10±4.96	6.68 to 11.61	0.0001
After testosterone	29.20±5.35		

Results were expressed as mean±SD, paired t-test was done as a test of significance, p value <0.01 was considered as significant, CI: Confidence interval, SD: Standard deviation



a. Before testosterone



b. After testosterone

Figure 2. Comparison of penile length; total penile length (AC) and proximal penile length (AB)**Table 3.** Comparison of proximal penile length (AB) before and after testosterone therapy

Testosterone therapy	Proximal penile length (mean±SD)	99% CI	p value
Before testosterone	5.15±2.60	4.88-9.11	0.0001
After testosterone	12.15±4.22		

Results were expressed as mean±SD, paired t-test was done as a test of significance, p value <0.01 was considered as significant, CI: Confidence interval, SD: Standard deviation

Before intramuscular testosterone therapy, all 20 participants (100.0%) had the meatus located in the proximal penile position. After therapy, the meatal position was proximal in 10 cases (50.0%) and mid-penile in 10 cases (50.0%), with the change in meatal position being statistically significant ($p=0.002$) (**Table 4**). Additionally, the mean degree of chordee decreased significantly, from 55.0±8.73 mm before therapy to 43.25±14.26 mm after therapy. The 99% confidence interval for the mean difference in chordee was 7.44 to 16.06 mm, with the improvement being statistically significant ($p=0.0001$) (**Table 5**). The degree of chordee before and after the testosterone therapy are as shown in **Figure 3a, 3b**.

Table 4. Position of meatus before and after testosterone therapy

Testosterone therapy	Position	n (%)	p value
Before testosterone	Proximal	20 (100.0%)	0.002
After testosterone	Proximal	10 (50.0%)	
	Mid	10 (50.0%)	

McNemar's test was done as a test of significance, p value <0.01 was considered as significant

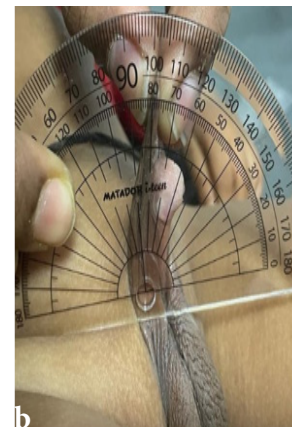
Table 5. Comparison of degree of chordee before and after testosterone therapy

Testosterone therapy	Degree of chordee (mean±SD)	99% CI	p value
Before testosterone	55.0±8.73	7.44 to 16.06	0.0001
After testosterone	43.25±14.26		

Results were expressed as mean±SD, paired t-test was done as a test of significance, p value <0.01 was considered as significant, CI: Confidence interval, SD: Standard deviation



a. Before testosterone



b. After testosterone

Figure 3. Comparison of degree of chordee

DISCUSSION

The administration of intramuscular testosterone therapy for proximal penile hypospadias has been a subject of considerable interest due to its potential to influence penile growth by promoting cell proliferation and tissue expansion, resulting in a larger and more vascular penis, which may help reduce surgical complications.¹⁸

In this study total penile length and proximal penile length before testosterone therapy were 20.10±4.96 and 5.15±2.60, respectively. However, total penile length and proximal penile length showed significant increments ($p=0.0001$) after testosterone therapy, resulting in 29.20±5.35 and 12.15±4.22, respectively. Following this observation, as the penile length increases while the distance from the meatus to the tip of the glans does not grow, similarly to the distance from the meatus to the penoscrotal junction in proximal type, the hypospadias condition effectively shifts to a more distal position compared to its status before treatment.^{9,12,19}

All the positions of the meatus of the study population were in the proximal position which was 20 (100.0%) cases before intramuscular testosterone therapy. However, after the therapy, the proximal position was found in 10 (50.0%) cases, and the mid position was found in 10 (50.0%) cases. The difference in the position of the meatus before and after therapy was statistically significant ($p=0.002$). This finding is also consistent with the findings of another study which showed that the distance from the meatus to the tip did not increase proportionately with the entire penile length, even after testosterone therapy.¹² It has been suggested that the dysplastic nature of the tissue distal to the meatus could be the reason for this discrepancy¹³

Some authors use hormonal stimulation on proximal hypospadias with severe chordee after correcting the chordee due to dysplastic nature of the tissue.¹³ Conversely, testosterone stimulation ensures the development of high-quality tissue by enhancing the vascularity of the corpus spongiosum which



alters the severity of hypospadias.¹² In this study, it was found that testosterone therapy significantly reduced the average degree of chordee from 55.0 ± 8.73 degrees to 43.25 ± 14.26 degrees. Similar findings were found by a study who used gonadotropins for hormonal stimulation to reduce the degree of chordee.²⁰ May be that resulted due to disproportionate growth of penile length proximal and distal to the meatus.^{9,19}

The study involved administering IM testosterone to twenty patients, and only one patient (5%) developed pubic hair growth as a result of secondary sexual characteristics. The remaining 95% of the patients showed no signs of pubic hair growth, aggressive behavior, or genital pigmentation. These findings are consistent with few studies which reported similar results with intramuscular testosterone therapy.^{15,16,21} These effects could be caused by various factors such as the choice of hormone therapy, timing of administration, appropriate dosage, and method of application (topical or parenteral). A survey reported that administering intramuscular testosterone at a dosage of 2mg/kg body weight could help minimize these effects.¹⁷ Moreover, the single patient who developed pubic hair was the oldest among all the study participants, aged 108 months.

This study did not assess key parameters such as glans width, urethral plate dimensions, and penile shaft diameter, which are essential for a comprehensive understanding of the effects of intramuscular testosterone on proximal penile hypospadias. Additionally, no hormonal tests, such as measuring testosterone levels, were conducted to provide a biological explanation for the observed changes. Hormonal evaluations are needed to establish a link between endogenous testosterone levels and treatment effectiveness. Despite its limitations, this study offers important preliminary evidence that IM testosterone therapy, when used at an appropriate dosage, can reduce the severity of proximal penile hypospadias and minimize side effects. It sets the stage for more extensive research in the future. Well-designed studies are necessary to validate these findings and develop practical clinical guidelines.

CONCLUSION

In conclusion, all patients showed significant increases in proximal penile length, resulting in changes in the position of the meatus more distally. The difference in the position of the meatus before and after therapy is statistically significant. The comparison of the degree of chordee before and after testosterone therapy is also statistically significant.

ETHICAL DECLARATIONS

Ethics Committee Approval

The study was conducted with the permission of the Ethics Committee of Bangladesh Shishu Hospital and Institute (Date: 19.10.2022, Decision No: 2022692).

Informed Consent

Parents of all patients signed a free and informed consent form.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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