

---

**“A ONE YEAR RANDOMIZED CONTROLLED TRIAL TO  
COMPARE THE OUTCOME OF PRIMARY REPAIR OF  
HYPOSPADIAS WITH VASCULAR COVER USING TUNICA  
VAGINALIS FLAP WITH THOSE USING PREPUTIAL  
DARTOS FASCIA”**

---

**By**

**REG.NO. BH0115011**

# **Dissertation**

**Submitted to the  
KLE University, Belagavi, Karnataka  
In partial fulfillment  
Of the requirements for the degree of**

**M.S in**

**GENERAL SURGERY**

**DEPARTMENT OF GENERAL SURGERY,  
J. N. MEDICAL COLLEGE,  
BELAGAVI - 590010.KARNATAKA**

---

**APRIL - 2018**

---

**KLE UNIVERSITY, BELAGAVI,  
KARNATAKA**

**ENDORSEMENT BY THE HOD/PRINCIPAL/  
HEAD OF THE INSTITUTION**

This is to certify that the dissertation entitled “ **A ONE YEAR  
RANDOMIZED CONTROLLED TRIAL TO COMPARE THE  
OUTCOME OF PRIMARY REPAIR OF HYPOSPADIAS WITH  
VASCULAR COVER USING TUNICA VAGINALIS FLAP  
WITH THOSE USING PREPUTIAL DARTOS FASCIA**” is a  
bonafide research work done by **REG.NO. BH0115011**.

**Dr. S.S.SHIMIKORE** MS  
Professor and Head,  
Department of Surgery,  
J. N. Medical College,  
Nehru Nagar, Belagavi – 10

**Dr. N.S. MAHANTASHETTI** MD  
Principal,  
J. N. Medical College,  
Nehru Nagar, Belagavi – 10

Date:  
Place: Belagavi

Date:  
Place: Belagavi

## **LIST OF ABBREVIATIONS USED**

DSD	–	Disorders of Sexual Development
F	-	French scale
IV	–	Intravenous
MAGPI	–	Meatal advancement and glanuloplasty incorporated
mm	-	millimetres
PD	–	Preputial Dartos
TIP	–	Tubularized Incised Plate
TV	–	Tunica Vaginalis

## **ABSTRACT**

### **Background and Objectives**

Tubularized incised plate (TIP) urethroplasty, also called as Snodgrass Urethroplasty is the most common technique noted to correct hypospadias. But, urethrocutaneous fistula is still the most common complication of this technique which usually requires reoperation. Several techniques of providing vascularized flaps to the neourethra have been recommended to decrease this complication rate. The objective of this study was to assess the complication rate and outcome in patients undergoing primary hypospadias repair using tunica vaginalis flap with those using preputial dartos fascia.

### **Methodology**

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from January 2016 to December 2016. A total of 40 children who came for primary hypospadias repair were randomized into two groups of 20 each based on the type of vascular cover as group PD (Preputial dartos cover) and group TV (Tunica Vaginalis flap cover).

### **Results**

In the present study, the mean age of the children was 4.8yrs, youngest child being 1yr old and oldest being 16yrs old. The mean of the children in preputial dartos group was 4.17yrs and in that of tunica vaginalis group was 5.25yrs. After intra-operative correction of chordee, there were 20 cases of distal hypospadias, 8 cases of middle hypospadias and 12 cases of proximal hypospadias. Chordee was absent in 26

children. In 14 children, chordee was present, out of which it was <30 degree in 6 children and >30 degree among the rest. All the patients were followed up for minimum of 6 months. Two (10%) patient developed meatal stenosis and one (5%) patient developed mild torsion of testis in preputial dartos group. Two (10%) patient in tunica vaginalis group developed meatal stenosis. In the present study, two (10%) patients in preputial dartos group developed urethrocutaneous fistula and one (5%) patient developed stricture urethra in the follow up period. None of the patients developed urethrocutaneous fistula in the tunica vaginalis group. One (5%) patient had stricture urethra in tunica vaginalis group. However, no significant difference was noted between the two groups for major complications (P value – 0.442).

### **Conclusion and interpretation**

Use of tunica vaginalis flap is associated with acceptable results, cosmesis and less complications compared to those occurring with preputial dartos cover. However, further long term studies are required for concluding.

### **Keywords**

Hypospadias, Tubularized incised plate (TIP) urethroplasty; tunica vaginalis; preputial dartos; fistula

## CONTENTS

<b>SL. NO.</b>	<b>TOPIC</b>	<b>PAGE NO.</b>
<b>1</b>	<b>INTRODUCTION</b>	<b>1</b>
<b>2</b>	<b>OBJECTIVES</b>	<b>3</b>
<b>3</b>	<b>REVIEW OF LITERATURE</b>	<b>4</b>
<b>4</b>	<b>METHODOLOGY</b>	<b>16</b>
<b>5</b>	<b>RESULTS</b>	<b>24</b>
<b>6</b>	<b>DISCUSSION</b>	<b>46</b>
<b>7</b>	<b>CONCLUSION</b>	<b>50</b>
<b>8</b>	<b>SUMMARY</b>	<b>51</b>
<b>9</b>	<b>BIBLIOGRAPHY</b>	<b>53</b>
<b>10</b>	<b>ANNEXURES</b>	
	<b>ANNEXURE I – CONSENT FORM</b>	<b>58</b>
	<b>ANNEXURE II – PROFORMA</b>	<b>62</b>
	<b>ANNEXURE III – MASTERCHART</b>	<b>65</b>

## LIST OF TABLES

TABLE NO.	DESCRIPTION	PAGE NO.
1	Mean age	25
2	Mean age in each group	25
3	Frequency of meatal position	26
4	Distribution of meatal position	26
5	Frequency of characteristics of meatus	27
6	Frequency of shape of glans	28
7	Frequency of degree of chordee	29
8	Distribution of degree of chordee	29
9	Frequency of corporal bodies	30
10	Distribution of each clinical findings	31
11	Frequency of intraoperative diagnosis	35
12	Frequency of type of anesthesia given	36
13	Frequency of supplementation of anesthesia	37
14	Frequency of blood loss during surgery	37
15	Minor complications	38
16	Major complications	39

## LIST OF GRAPHS

GRAPH NO.	DESCRIPTION	PAGE NO.
1	Number of patients in each group	24
2	Mean age	25
3	Frequency of meatal position	27
4	Frequency of shape of glans	28
5	Frequency of degree of chordee	30
6	Distribution of meatal position	32
7	Distribution of characteristics of meatus	32
8	Distribution of shape of glans	33
9	Distribution of degree of chordee	33
10	Distribution of corporal bodies	34
11	Diagnosis of introporative correction of chordee	35
12	Type of anesthesia given	36
13	Minor Complications	38
14	Major Complications	39

## LIST OF FIGURES

<b>FIGURE NO.</b>	<b>DESCRIPTION</b>	<b>PAGE NO.</b>
1	Human urogenital embryology	5
2	Duckett classification of hypospadias	7
3	Algorithm for hypospadias repair	9
4	TIP with PD cover – Intra-operative	20
5	TIP with PD cover – Immediate post operative	21
6	TIP with TV cover – Intra-operative	22
7	TIP with TV cover – Immediate post operative	23
8	Well healed scar of TIP repair with PD	41
9	Well healed scar of TIP repair with TV	42
10	Good urinary stream of TIP repair with PD	43
11	Good urinary stream of TIP repair with TV	44
12	Post operative urethrocutaneous fistula	45

## **INTRODUCTION**

Hypospadias surgery is one of the challenging areas in pediatric urology and has undergone continuous evolution. This is because of the unacceptable high complication rate, poor functional and cosmetic results of the previously existing surgeries. Multiple factors influence the outcome of surgical correction, which include size of the penis, size of glans, and urethral plate, presence of curvature, age at surgery, surgical technique like using loops, fine instruments and suture material used.

Hypospadias surgery has evolved from multi-staged repair to single stage repair. But the choice of technique depends on the surgeon and degree of hypospadias, urethral plate, size and shape of glans, corporal bodies and prepuce, degree of chordee and preputial hood. Introduction of Tubularized incised plate(TIP) urethroplasty, described by Dr Warren Snodgrass in 1994, has revolutionized the surgical management of hypospadias. Since then Tubularized incised plate(TIP) urethroplasty has become the choice of repair because of low complication rate and good functional and cosmetic result. However, urethrocutaneous fistula is still a bothersome complication following this technique along with meatal stenosis. Various interposition flaps have been proposed to decrease the complication rate but ideal flap yet eludes us.

There are various studies which support tunica vaginalis flap repair as an excellent technique for the treatment of urethrocutaneous fistula after initial failed tubularized incised plate repair. But there have been few studies involving the usage of tunica vaginalis flap as vascular cover in primary hypospadias repair. Till date,

there is only sparse data available comparing the preputial dartos fascia and tunica vaginalis flap vascular covers for primary hypospadias repair.

The proposed study is being conducted to compare the outcome of primary hypospadias repair using tunica vaginalis as a vascular cover with those using preputial dartos flap.

## **AIM AND OBJECTIVES**

**AIM:** - To assess the outcome primary repair of hypospadias using tunica vaginalis flap with those using preputial dartos fascia.

**OBJECTIVES:** - To assess the results and complications in patients undergoing primary hypospadias repair using tunica vaginalis flap with those using preputial dartos fascia.

## **REVIEW OF LITERATURE**

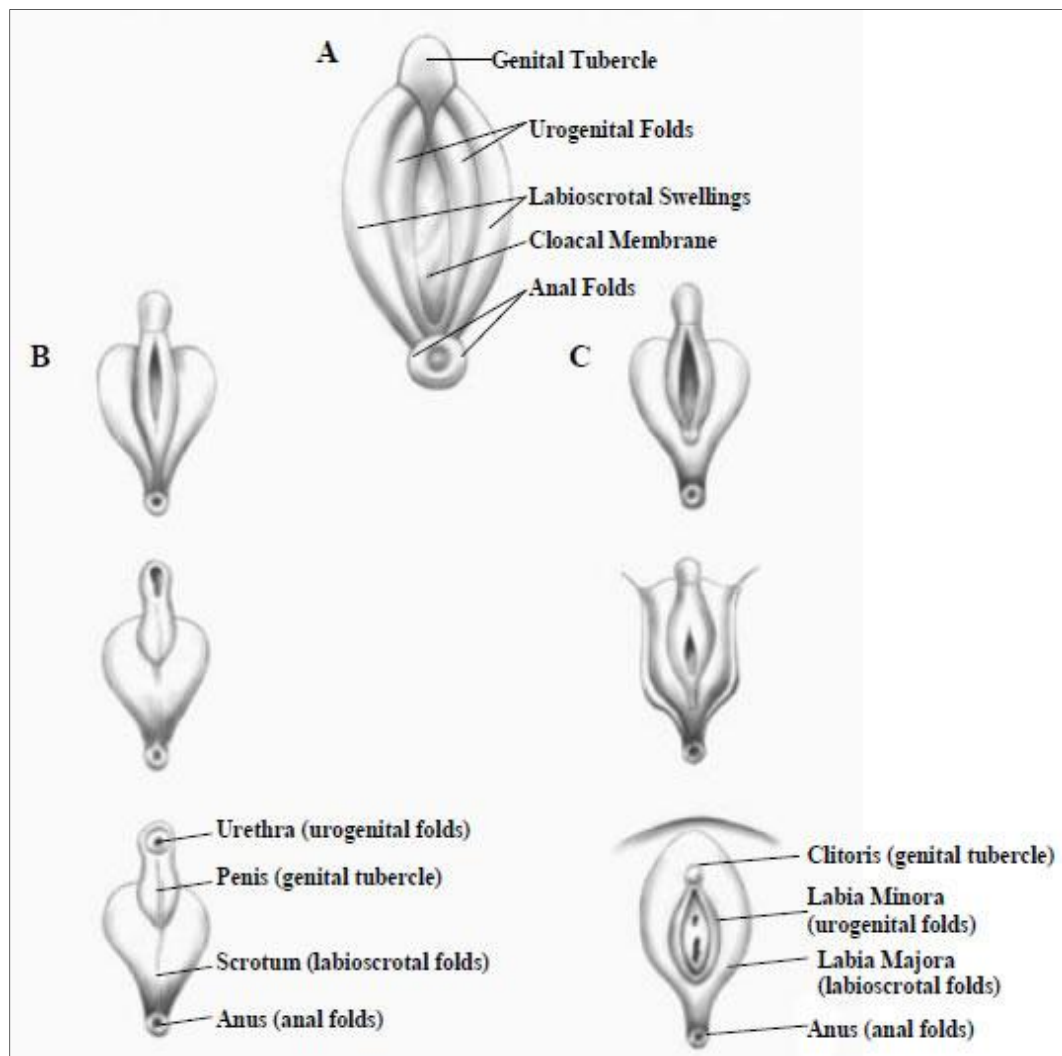
Hypospadias (*hypo* - 'under' and *spadizo* [Gr] - 'to tear off') is the most common congenital malformation of the penis. Incidence of hypospadias is on the rise with a present incidence of 1 in 700 live births. It occurs due to abnormal development of the urethral spongiosum and ventral part of prepuce, along with a failure of correction of the embryological penile curvature. This results in the urethral opening being arrested along the ventral side of the penis.

Majority of affected children have the aberrant urethral meatus at the subcoronal margin, corona, or on the glans penis. Moderate and severe cases of hypospadias are characterized by a more proximal urethral opening located on the penile shaft and scrotum/ perineum, respectively. In general, the severe forms of hypospadias tend to be associated with a higher degree of penile curvature, called *chordee*, as well as peno–scrotal transposition.

**Anatomy and Embryology** – The anatomy of the hypospadiac penis is similar to the normal penis except on the ventral aspect where the foreskin is abortive, urethra is arrested and urethral spongiosum is deficient distally. Histological analysis has shown that the urethral plate in hypospadias is well vascularized, with sinusoids of abortive urethral spongiosum, and without any scar tissue <sup>[1]</sup>. These features may explain the successful use of incorporating the urethral plate or abortive spongiosum into hypospadias reconstruction <sup>[2]</sup>.

Formation of genital tubercle, which occurs at 8-12 weeks of gestational age in both male and female fetuses, is a hormone independent process. Further development of external genitalia in males is under the influence of fetal testicular

androgens. Genital tubercle becomes cylindrical to form *phallus*, which elongates to become penis in males. As the solid epithelial urethral plate elongates towards the tip of the genital tubercle, it canalizes to form a groove on the ventral surface of the genital tubercle known as *definitive urethral groove*, bounded by urethral folds called as *definitive urethral fold*. These urethral folds fuse in the midline forming penile urethra. Failure of fusion of the urethral folds results in *hypospadias*.

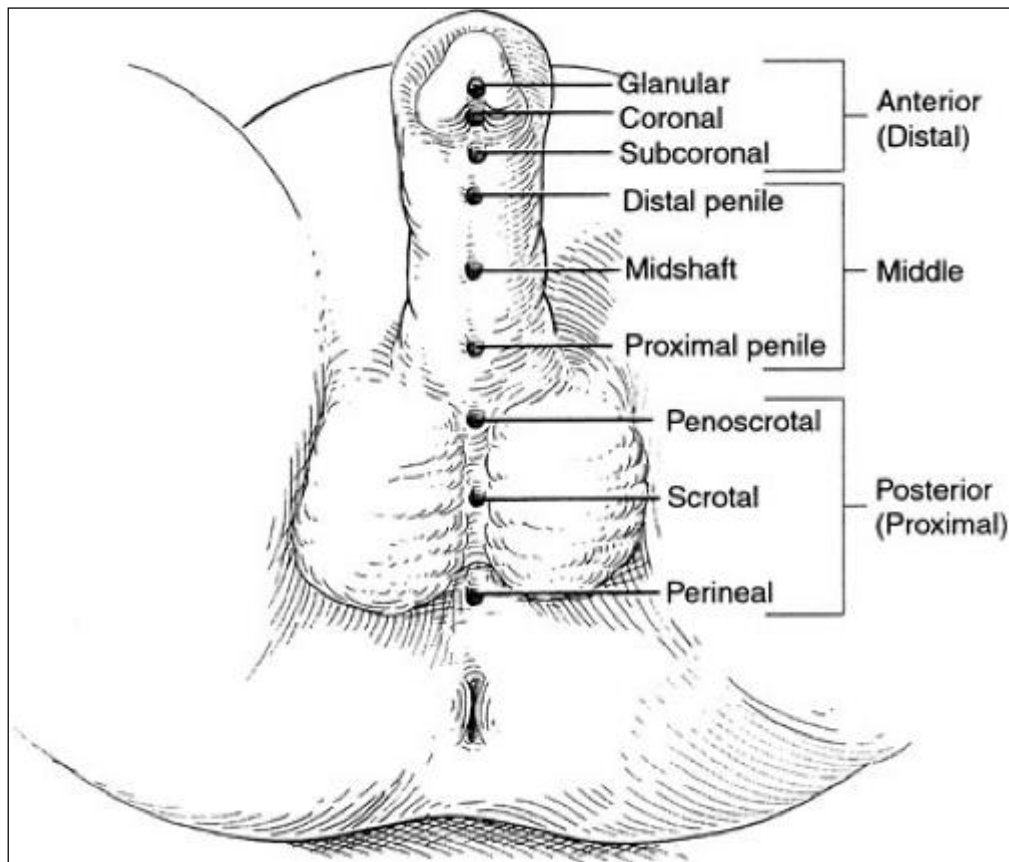


**Figure 1 - Human urogenital embryology. (A) Sex undifferentiated precursors prior to 7 weeks gestational age. (B) Male development in gestational weeks 7–17 from precursors shown in (A). (C) Female development in weeks 7–17 from precursors shown in (A)**

**Etiology** – Many hypotheses have been proposed to explain the etiology of hypospadias. These include genetic predisposition, inadequate prenatal hormonal stimulation, maternal-placental factors and environmental factors. Less than 5% of all patients with hypospadias can be explained by androgen metabolism (5 alpha-reductase type II deficiency) abnormalities, androgen receptor defects, or genetic defects <sup>[3]</sup>. A significant increase in the incidence of hypospadias in the population over the last 20 years has raised the possibility of a role for environmental factors (hormonal disrupters and pesticides). Genetic syndromes, such as hand-foot-genital syndrome, an extremely rare autosomal-dominant disorder characterized by a mutation in HOXA13 gene, exhibit hypospadias of variable severity. Rarely, they are also associated with disorders of sexual development(DSD). The incidence of DSD is increased in patients with proximal or complex hypospadias <sup>[4]</sup>.

**Diagnosis** - Hypospadias is usually diagnosed by physical examination, first suspected with the presence of ventrally deficient prepuce and confirmed by the proximal meatus. Other abnormal findings potentially include ventral glans tilt, deviation of the median penile raphe, ventral curvature called chordee, scrotal encroachment onto the penile shaft, midline scrotal cleft and penoscrotal transposition.

**Classification of Hypospadias** - Hypospadias is classified according to the level of meatus without taking into account curvature. The most common classification was given by Duckett in 1996 <sup>[5]</sup>. He divided them into anterior (50%), middle (30%) and posterior (20%) hypospadias. These are further classified according to the location of meatus - Anterior – glandular, coronal and distal penile; Middle – midshaft and proximal penile; Posterior – Penoscrotal, scrotal and perineal.



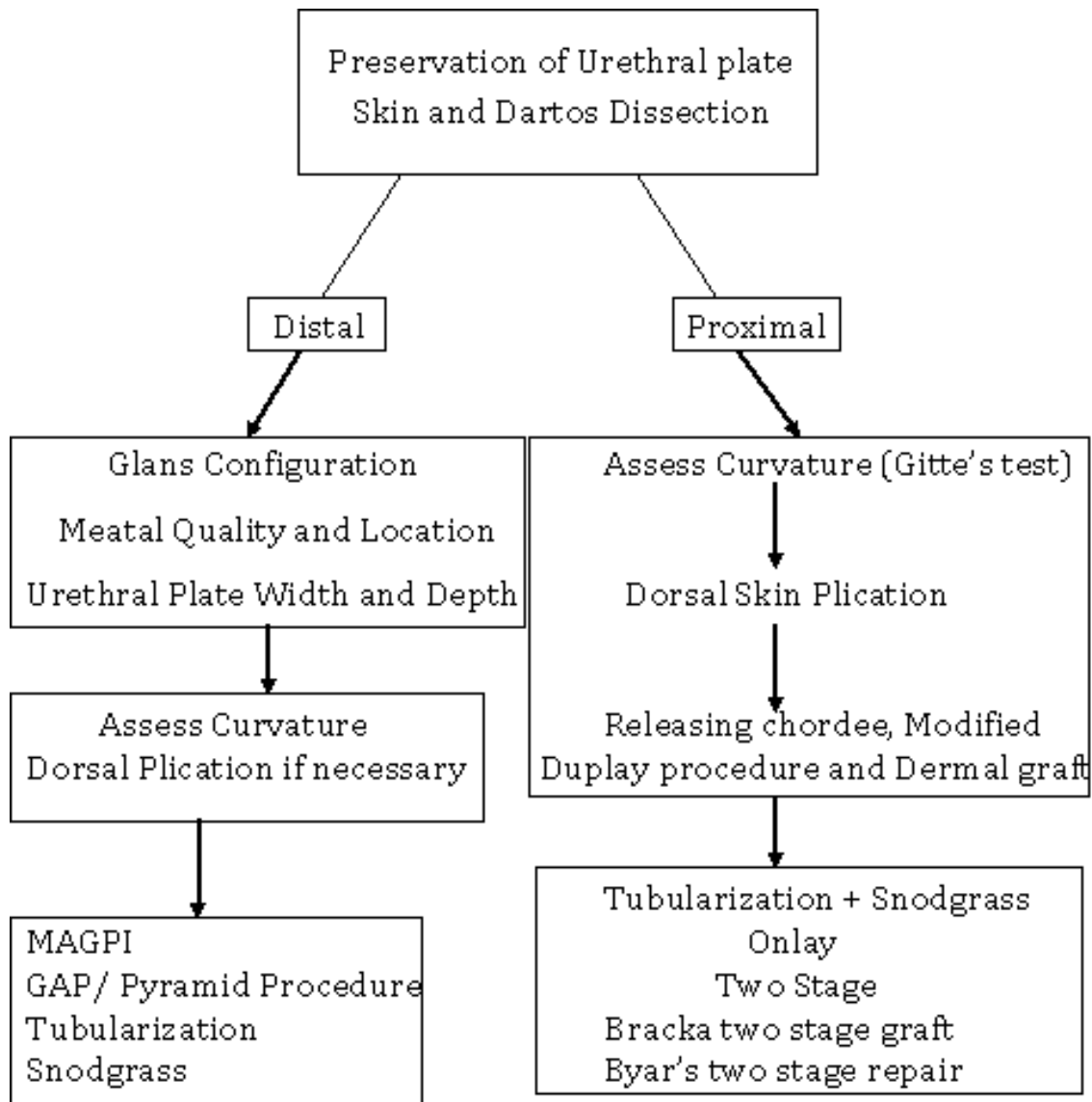
**Figure 2 – Duckett classification of Hypospadias**

Uncorrected hypospadias will result in deflected or spraying of urinary stream, impaired insemination due to proximal meatus and chordee, painful erection because of chordee and can lead to psychosocial issues relating to abnormal looking penis with difficulty in sexual activity in the affected males at a later age. The goal of modern repair of hypospadias is to achieve functional and cosmetically normal penis. Currently, surgery is recommended between 6 and 18 months of age, however, it can be corrected at any age with comparable complication risk, functional and cosmetic outcomes.

Surgical repair of hypospadias began quite early, to extend the urethra to the normal terminus. First successful repair of hypospadias was performed by Anger in 1874<sup>[6]</sup>. Surgical techniques have evolved since then and over 200 techniques have been described because of an unacceptable complication rate or poor functional or aesthetic results. In the beginning, this reconstructive surgery was limited to boys with proximal defects, which causes most morbidity. Eventually, hypospadias surgery was expanded to include less severe distal defects as well.

Multistaged repairs were in vogue when the reconstructive surgery was limited to correction of proximal defects. Staged repair includes orthoplasty (penile straightening/chordee correction), urethroplasty, meatoplasty and glanuloplasty, scrotoplasty and skin coverage.

As the surgery was expanded to include the distal defects, single-staged repairs were popularized with Asopa's and Duckett's island preputial flap urethroplasties. Other surgeries included preputial free grafts, flip-flaps, onlay preputial island flaps and meatal advancement and glanuloplasty incorporated (MAGPI) surgeries.



**Figure 3 - Algorithm For Hypospadias Repair**

**Tubularized Incised Plate (TIP) urethroplasty**, also called as Snodgrass Urethroplasty, has been widely accepted due to its technical simplicity, good results, acceptable cosmetic results and low complication rate. Today, tubularization of the urethral plate after the dorsal incision to widen it, is the most common technique to correct distal hypospadias and is also an option to repair middle and proximal hypospadias cases. Tubularized incised plate (TIP) urethroplasty was first described by Warren Snodgrass in 1994 for distal hypospadias repair. Off late, this technique

has been extended for the correction of mid-penile and proximal hypospadias with promising results.

The two major principles of tubularized incised plate urethroplasty are midline incision made from within the meatus to the distal extent of the urethral plate followed by creation of tension free neourethra, and dartos flap which reinforces the neourethra and hence decreases the incidence of fistula. Hence, tubularized incised plate urethroplasty is found to be superior to other techniques. But, two contraindications to tubularized incised plate urethroplasty are severe chordee and an unhealthy urethral plate that appears thin or in insufficiently widened after incision.

Even though tubularized incised plate urethroplasty is surgery of choice for hypospadias repair with good urethral plate, this procedure is not completely devoid of complications. Urethrocutaneous fistula is the most common complication with variable rates <sup>[7]</sup>, followed by meatal stenosis. Other complications include urethral stricture and wound dehiscence.

Snodgrass has tried various technical modifications since then to improve the outcomes of surgery. Although Warren Snodgrass made changes to distal tubularized incised plate urethroplasty, primarily moving from chromic to polygalactin sutures and epithelial to subepithelial suturing, these technical changes did not impact his urethroplasty complications, occurring in 4-8% in various analyses <sup>[8-10]</sup>, which is not statistically different.

However, Snodgrass also made changes in proximal tubularized incised plate urethroplasty that did result in a significant reduction in fistulas. The urethral plate was tubularized in the first cases in a single layer using continuous epithelial chromic

catgut. The neourethra was then covered with a dorsal dartos flap. Database review found that 33% developed fistulas. He then made several changes, from one-layer epithelial chromic to two-layer subepithelial urethroplasty using interrupted polyglactin and continuous polydioxanone sutures, and adding spongioplasty. A dartos flap again covered the entire repair. Subsequent outcomes review showed a reduction of fistulas to 10% in the next series of patients. In the last published series a tunica vaginalis flap replaced dartos as the barrier layer and no fistulas occurred during mean follow-up of 12 months<sup>[11]</sup>.

**Intermediate barrier Layer** - One of the major principle of tubularized incised plate urethroplasty is the interposition of a barrier layer between the neourethra and overlying skin, which helps in reducing the incidence of urethrocutaneous fistula. The use of interposition flaps is well documented in the literature. Maintaining the vascularity of the barrier layer is one of the major factors for a successful outcome. Various modifications have been tried to provide protective intermediate vascular cover to the neourethra to prevent fistula formation and other complications, for example – Smith’s flap<sup>[12]</sup>, Buck’s fascial flap<sup>[13]</sup>, buccal mucosa<sup>[14]</sup>, dorsal dartos flap from the prepuce, dartos flap from the scrotum<sup>[15]</sup> and tunica vaginalis<sup>[16]</sup>. Yamataka *et al.*, described method of using gubernaculum as vascular cover to cover neourethra in hypospadias patient with concomitant undescended testis<sup>[17]</sup>. Although various options are available for providing vascular cover to the neourethra, ideal one which significantly reduces complication rates still eludes us.

**Tunica Vaginalis Flap** - Use of tunica vaginalis flap is credited to Snow et al, who was first to describe it in 1986 <sup>[16]</sup>. Snow et al used tunica vaginalis as interposition graft. The fistula rate reported was 9%. Since then, many authors have used tunica vaginalis flap for the repair of urethrocutaneous fistula with satisfactory results<sup>[18-25]</sup>. It has a dependable blood supply from the cremasteric vessels, easy to mobilize, easily available, not being affected by penile disorders and its pedicle length can be safely increased upto the external inguinal ring. Routh et al. described the use of tunica vaginalis flap and reported that urethrocutaneous fistula rate was 0% with only 2.2% complication rate of scrotal haematoma and abscess <sup>[25]</sup>.

Significant studies have supported the use of tunica vaginalis flap for the repair of urethrocutaneous fistula following hypospadias surgery with satisfactory results. Shanker *et al.* <sup>[26]</sup> had a similar experience with the use of tunica vaginalis flap. They reported a success rate of 50% with fistula of >2 mm but without the use of tunica vaginalis and had only one recurrence in six cases when tunica was used in a third attempt for fistula repair. They reported success in 71% cases in first attempt for fistula repair, 70% in second attempt and 50% in third and subsequent repairs. Five fistulas were successfully closed using tunica vaginalis flap without any recurrence by Handoo *et al* <sup>[18]</sup>.

Kadian *et al.* successfully repaired all cases of recurrent fistulas except in one, who had leak from fistula site. One (7%) of the patients developed scrotal haematoma <sup>[19]</sup>. Landau *et al.* studied the results of fistula closure using tunica vaginalis flap reinforcement in 14 cases and observed no fistula <sup>[24]</sup>. Sharma *et al.* reported a success rate of 80% with tunica vaginalis flap in management of recurrent fistula cases <sup>[20]</sup>. Muruganandham *et al.* in their study concluded that application of tunica vaginalis

flap after fistula repair gave excellent results as compared to simple closure of urethrocutaneous fistula <sup>[21]</sup>. Ezkiel *et al.* reported a good outcome a fistula rate of 1.6 % over a follow up of 44 months <sup>[22]</sup>. Hence, it is pretty evident that tunica vaginalis flap cover was superior to any other tissue cover in the management of urethrocutaneous fistula following hypospadias repair.

The relatively high success rate of urethrocutaneous fistula repair with tunica vaginalis flap led to another modification in tubularized incised plate urethroplasty, i.e. the use of tunica vaginalis flap in primary hypospadias repair to prevent the incidence of urethrocutaneous fistula. Hamid *et al.* conducted a similar study where tunica vaginalis flap was used as a vascular cover following tubularized incised plate urethroplasty. They reported fistula rate of 2.85% other complications included meatal stenosis, wound infection and scrotal abscess <sup>[23]</sup>. There are limited studies comparing the tunica vaginalis flap with dartos flap following tubularised incised plate urethroplasty.

Chatterjee *et al.* conducted a study where the two techniques of neourethral coverage after tubularized incised plate procedure were prospectively compared, and reported 0% fistula rate with tunica vaginalis, as opposed to 15% in dartos group <sup>[27]</sup>. In a recent study by Anjan Kumar Dhua, comparing the tunica vaginalis and dartos as soft tissue vascular covers, the fistula rate for dartos flap was 12% and that of tunica vaginalis flap was 0% <sup>[13]</sup>.

Similar study conducted by Babu R *et al.* reported higher complications with dartos flap. The percentage of higher ventral skin necrosis and urethrocutaneous fistula was 23% and 30.7% with preputial daros flap and 0% and 4.7% with tunica vaginalis flap respectively <sup>[28]</sup>.

There are various studies which support tunica vaginalis flap repair as an excellent technique for the treatment of urethrocutaneous fistula after initial failed tubularized incised plate repair.

**Dartos Flap** - Dartos flap as vascular cover is being used since many decades. In 1993, Motiwala described the use of a dartos flap as an aid to urethral reconstruction <sup>[15]</sup>. Churchill *et al.*, in 1996, reported their experience in eight patients who underwent urethral reconstruction without a single fistula. They recommended the use of a dartos flap in secondary proximal hypospadias and complex urethral repair <sup>[29]</sup>.

Dartos flap is simple to isolate and exists in both scrotal compartments. It is distinct from the scrotal skin, or the visceral or parietal layers of the tunica vaginalis. Since the dartos flap can be raised from either side of the scrotum, it may also be used on more than one occasion should the need arise. The dartos flap is advantageous in redo hypospadias repair and complex urethral repair for several reasons. It is uniformly available, even in patients with previous scrotal surgical manipulation.

It is well vascularized with small branches from the superficial and deep external pudendal branches of the femoral artery, the superficial perineal branch of the internal pudendal artery and the cremasteric branch from the inferior epigastric artery. These branches are from the internal and external iliac arterial trees and, thus, they are more reliable than a flap based on a single end artery. Limitations of the dartos flap include the need for a penoscrotal incision, and so it is not suitable for distal urethroplasty.

Snodgrass originally used the dartos fascia flap dissected from the preputial and shaft skin, button-holed, and brought ventrally to act as a blanket between the neourethra and skin closure in order to decrease the incidence of fistula formation, however he still had 4 % incidence of fistula in his series, which was actually low when compared with other techniques. Two technical factors in fashioning the dartos fascia flap might be responsible for the incidence of fistula. Vascularity of the dorsal skin may become compromised during dartos fascia dissection which usually needed for covering ventral skin deficiency. On the other hand, the vascularity of the central part of the dartos fascia flap may become compromised after button- holing of the fascia.

Wafa *et al.* dissected the dartos fascia flap from one of the Byar's preputial flaps (preserving the other for coverage for ventral skin deficiency) as an axial proximally based flap to cover the repair <sup>[30]</sup>. He reported that his technique will provide two advantages, avoid button-holing of dartos flap so preserving vascularity of the flap which promote rapid healing of the repair and also act as a barrier between the repair and skin. In addition, it will leave part of the dorsal skin intact for additional coverage.

Till date, there are very few studies comparing the preputial dartos fascia and tunica vaginalis flap vascular covers for primary hypospadias repair.

## **METHODOLOGY**

### **SOURCE OF DATA**

All children with diagnosis of hypospadias who were admitted for urethroplasty in the Department of Surgery, KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Belagavi from 1<sup>st</sup> January 2016 to 31<sup>st</sup> December 2016 were eligible for the study. Consent was taken for participation in the study.

**STUDY DESIGN:** - The study design was a randomized controlled trial.

**STUDY PERIOD:** The study was conducted for duration of 1 year from 1<sup>st</sup> January, 2016 to 31<sup>st</sup> December, 2016.

### **SAMPLE SIZE AND SAMPLE SIZE CALCULATION:**

Sample size was calculated using the formula :

$$\begin{aligned}\text{Sample size} &= \text{Number of cases operated in last 3 years}/3 \times 0.8 \\ &= 37.86\end{aligned}$$

Sample size of 40 was appropriate for the study (20 in each group).

**SAMPLING TECHNIQUE:-** All the children who came for primary hypospadias repair to the hospital were considered in the study.

### **SELECTION CRITERIA:-**

#### **Inclusion Criteria:**

Hypospadias

Age – 9 months to 18 years.

**Exclusion Criteria: -**

Failed Hypospadias Repairs.

Previous inguino-scrotal surgery i.e. hernia or hydrocoele repair or orchidopexy.

Associated undescended testis.

Patients who have undergone circumcision surgery.

Glandular hypospadias

Severe chordee

No or poor urethral plate

Disorders of sexual development

**ETHICAL CLEARANCE:-**

The study was approved from the Ethical and Research Committee, Jawaharlal Nehru Medical College, Belagavi prior to the commencement of the study.

**INFORMED CONSENT:-**

The parents or guardians of children fulfilling the selection criteria were informed in detail about the nature of the study and a written informed consent was obtained (Annexure I).

**METHOD OF RANDOMIZATION:-**

The children who had fulfilled the criteria were randomly divided into 2 groups by computerized randomization technique.

- Children undergoing Snodgrass urethroplasty with preputial dartos vascular cover were included in group PD.

- Children undergoing Snodgrass urethroplasty with tunica vaginalis vascular cover were included in group TV.

#### **METHOD OF COLLECTION OF DATA:-**

Demographic data such as age and history was obtained through an interview. Further these children were subjected to clinical examination and findings such as meatal position, characteristics of meatus, shape of glans, preputial fold, chordee and corporal bodies were noted on a predesigned and pretested proforma (Annexure II).

#### **INVESTIGATIONS:-**

Complete blood counts were done in all the children prior to surgery.

#### **OPERATIVE PROCEDURE:-**

In both the groups, the initial technique was same.

- Patient was catheterized with 6 to 10 number feeding tube according to age and urethral plate. A circumscribing incision was made 1 to 2mm proximal to the hypospadiac meatus and the penis is then degloved to the penoscrotal junction. If the skin overlying the distal urethra is thin, the incision is extended proximally and the urethra is opened to this level before tubularization.
- An artificial erection test is done if chordee was present.
- Parallel longitudinal incision approximately 6 to 8 mm. apart to define the urethral plate.
- The glandular wings are dissected laterally to facilitate subsequent glans closure.

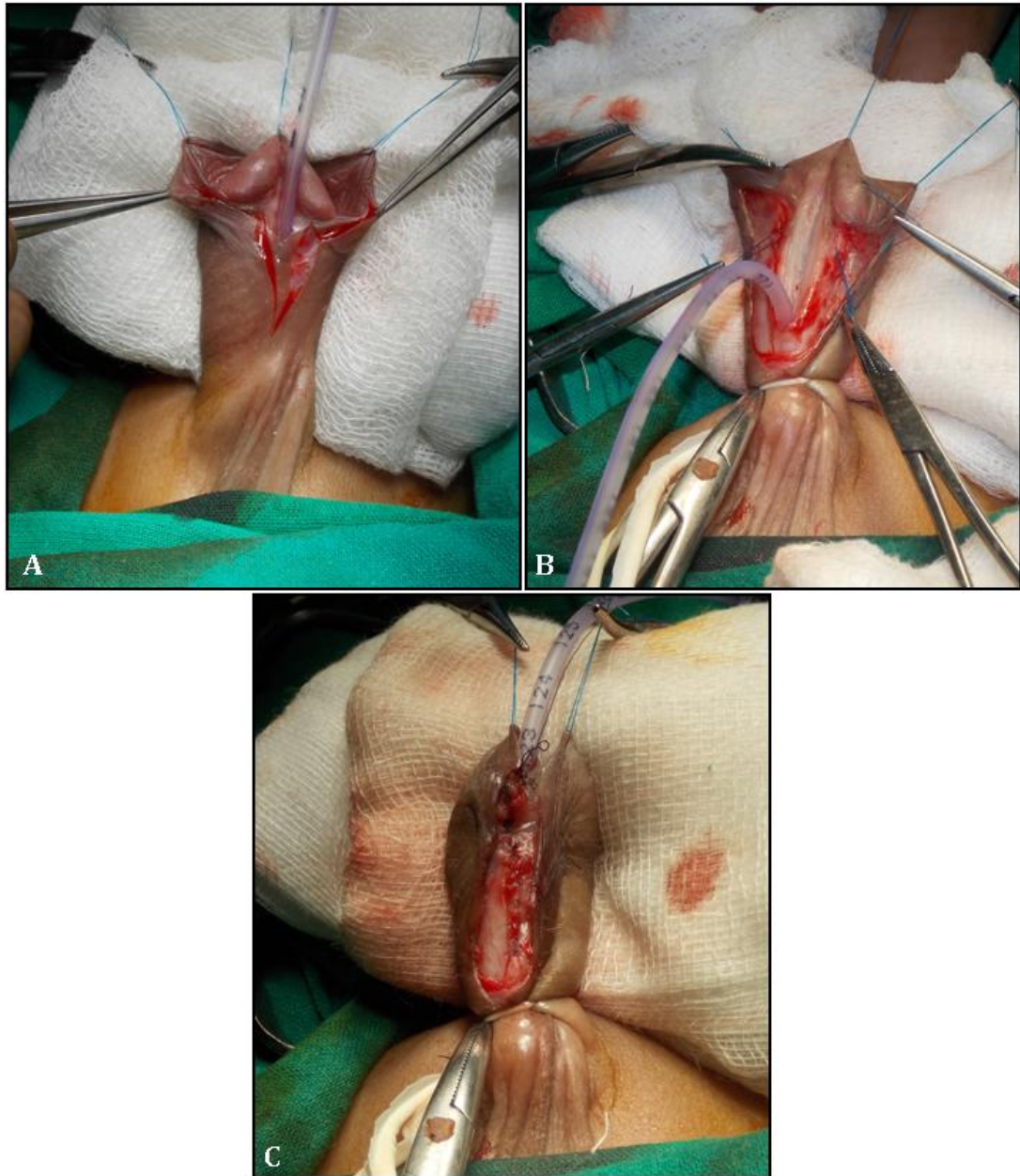
- The edges of the urethral plate are gently elevated and retracted laterally with fine forceps. The plate is then incised in the midline from the meatus to the tip of the glans. This incision is carried deeply, dividing all transverse webs and exposing the underlying corporeal bodies. The epithelial strips created by longitudinal incision of the plate are mobile.
- Consequently, the urethral plate was tubularized with a diameter exceeding 6 to 10F. Interrupted 6-0 vicryl suture with taper cut needle was used to close the plate over a 6 to 10F infant feeding tube catheter, which provides urinary drainage for 10 days.
- Neourethra was then covered with preputial dartos flap or tunica vaginalis flap depending on which group the child belonged to.
- Skin closure was achieved.
- Aseptic dressing was done and was removed on post operative day 10.

**FOLLOW UP:-**

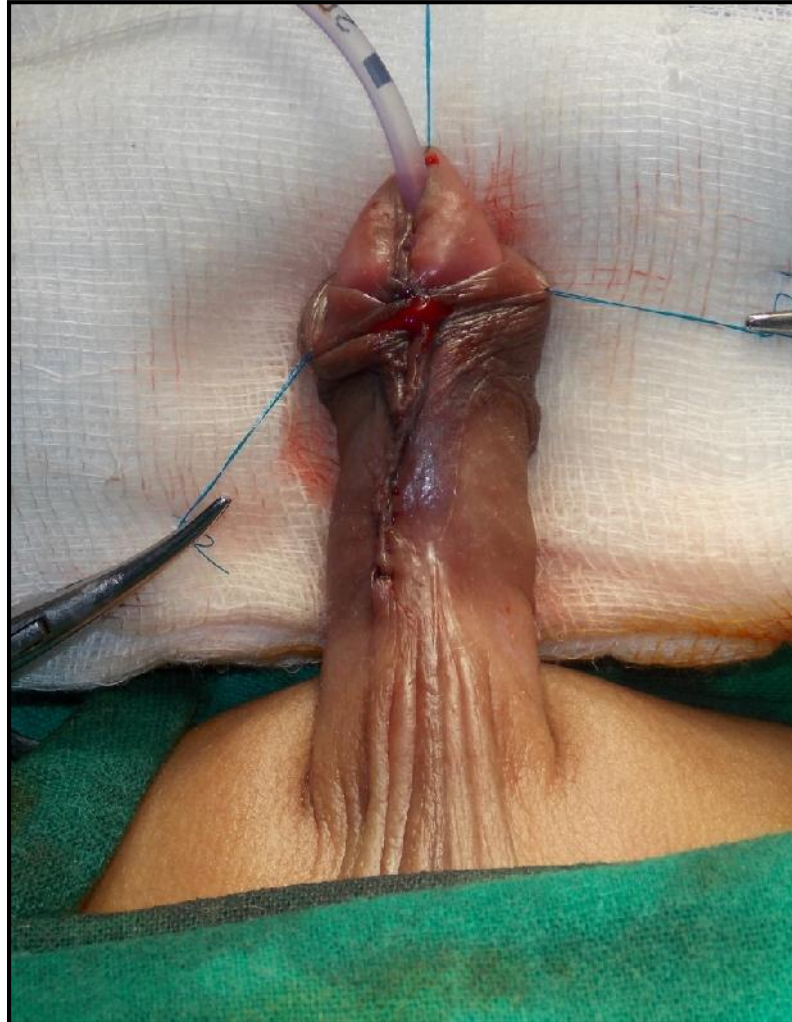
All the children were followed up for a minimum period of 6 months.

**STATITICAL ANALYSIS:-**

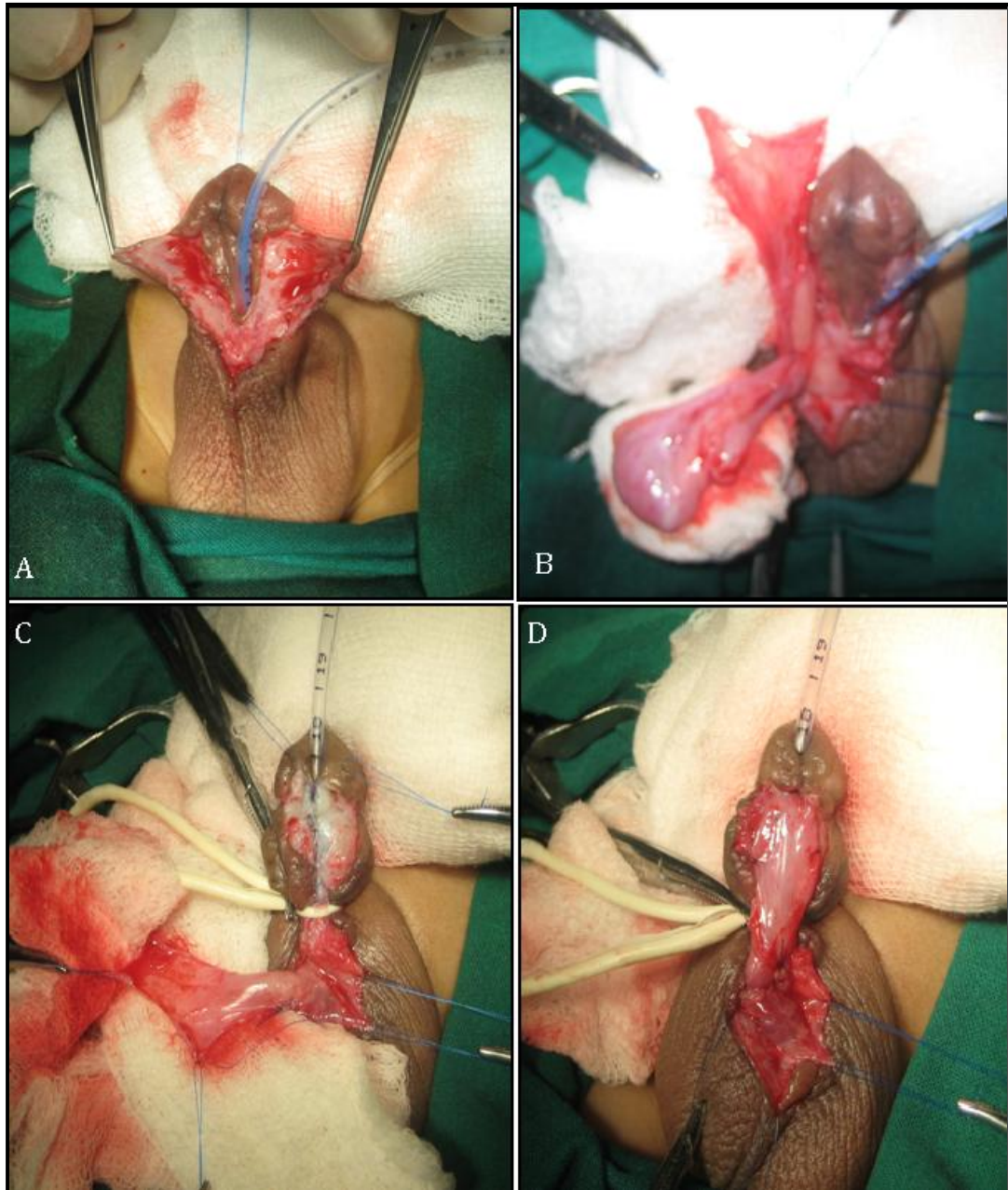
Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean and SD. Quantitative variables were compared using unpaired t-test between two groups. Qualitative variables were compared using Chi-Square test /Fisher's exact test as appropriate. A p value of <0.05 was considered statistically significant. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.



**Figure 4 – Intraoperative photographs of TIP Urethroplasty with Preputial dartos vascular cover. (A) Skin incision for dissecting the skin flaps. (B) Incised urethral plate. (C) Neourethra covered with preputial dartos vascular cover.**



**Figure 5 - Immediate post-operative photograph of TIP Urethroplasty with preputial dartos vascular cover showing completed repair.**



**Figure 6 – Intraoperative photographs of TIP Urethroplasty with Tunica Vaginalis vascular cover. (A) Dissected skin flaps. (B) Testis being delivered into operative field for harvesting tunica vaginalis flap. (C) Harvested tunica vaginalis flap. (D) Tunica vaginalis flap covering neourethra.**



**Figure 7 - Immediate post-operative photograph of TIP Urethroplasty with tunica vaginalis flap showing completed repair.**

---

---

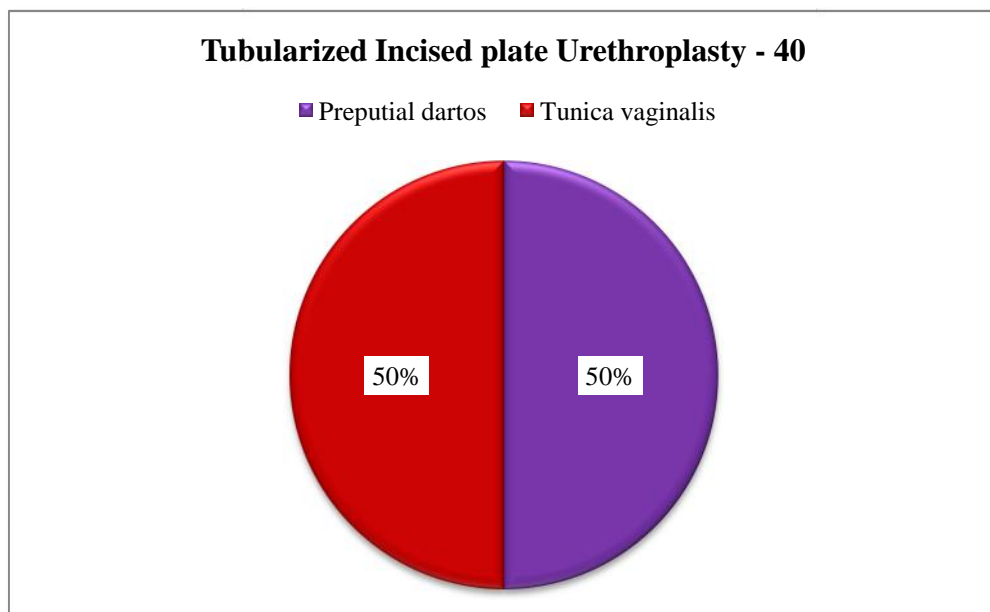
## RESULTS AND OBSERVATIONS

A one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from 1st January 2016 to 31st December 2016.

During the course of the study, total 40 children were included who fulfilled inclusion criteria, who underwent Snodgrass tubularized incised plate urethroplasty among, which 20 patients underwent tubularized incised plate urethroplasty with preputial dartos vascular cover and 20 patients underwent tubularized incised urethroplasty with tunica vaginalis vascular cover.

The data obtained was entered in Microsoft Excel Spreadsheet. The data was analyzed and the observations were tabulated as below.

**Graph 1 – Graph representing number of patients undergoing tubularized incised plate urethroplasty with preputial dartos vascular cover and tunica vaginalis vascular cover.**



**MEAN AGE**

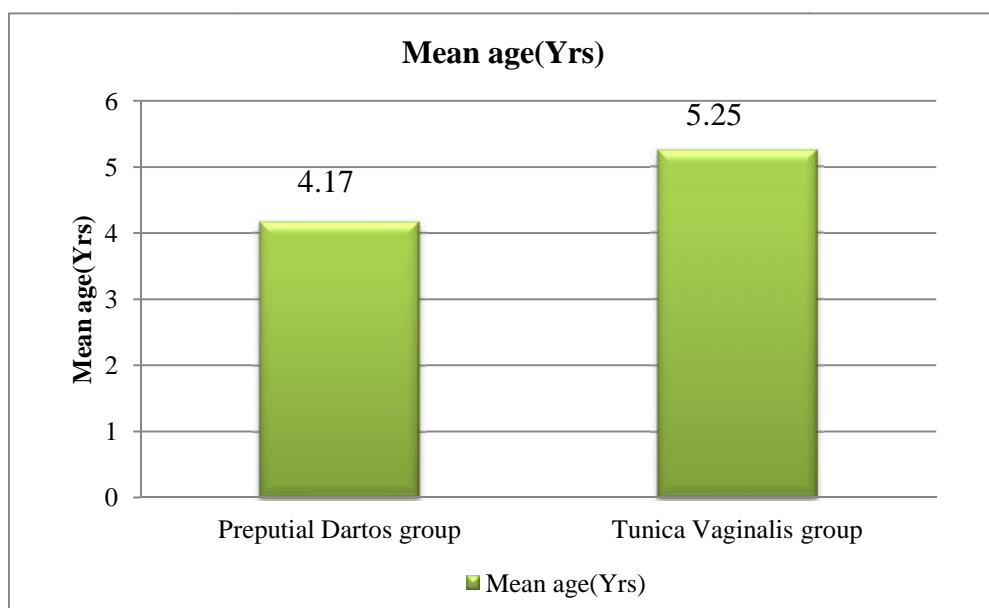
**Table 1 – Mean age of the children considered in the study.**

	N	Minimum	Maximum	Mean
Age(yrs)	40	1.0	16.0	4.850

**Table 2 – Mean age of the children in each group.**

Vascular cover	Mean Age (yrs)	Standard Deviation
Preputial Dartos	4.17yrs	3.112
Tunica Vaginalis	5.25yrs	4.97

**Graph 2 – Distribution of mean age group between two groups.**



**CLINICAL FINDINGS –**

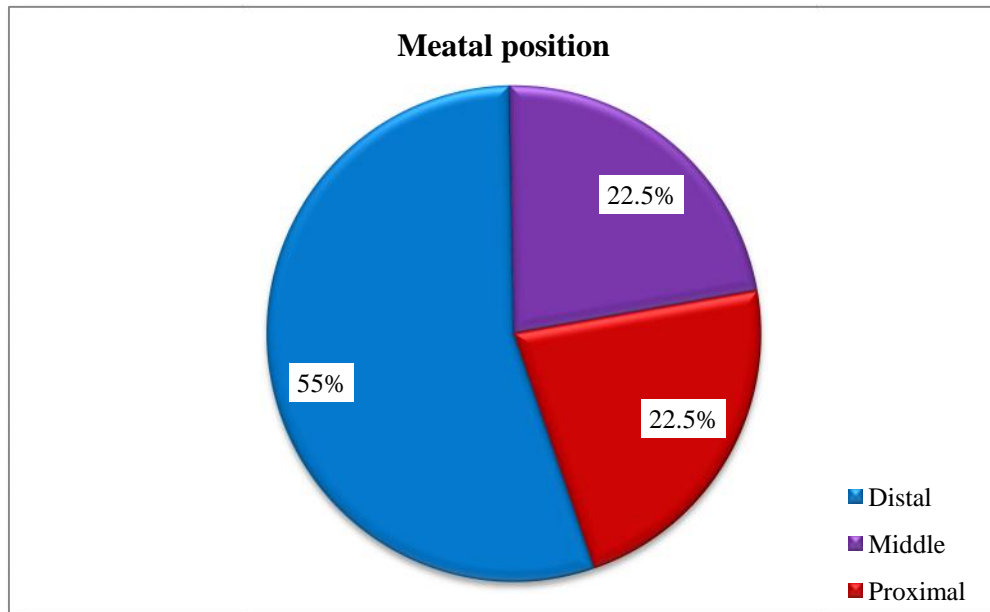
**Table 3 – Frequency of clinical findings – meatal position.**

<b>Meatal position</b>	<b>Frequency (No.)</b>	<b>Percentage (%)</b>
Distal	22	55
Middle	9	22.5
Proximal	9	22.5
Total	40	100.0

**Table 4 – Distribution of meatal position between the two groups.**

		Vascular cover		Total
		Preputial dartos	Tunica vaginalis	
Meatal Position	Distal	13	9	22
		65.0%	45.0%	55.0%
	Middle	2	7	9
		10.0%	35.0%	22.5%
	Proximal	5	4	9
		25.0%	20.0%	22.5%
Total		20	20	40
		100.0%	100.0%	100.0%

**Graph 3 – Graph representing frequency of meatal position.**



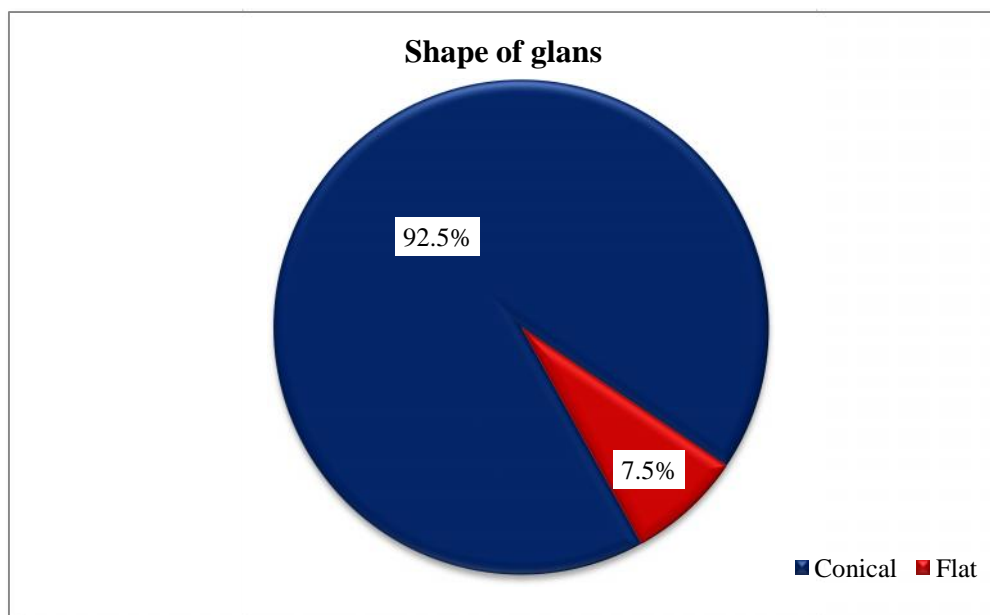
**Table 5 – Frequency of clinical findings -characteristics of meatus.**

Characteristics of Meatus	Frequency (No.)	Percentage (%)
Normal	32	80.0
Stenotic	8	20.0
Total	40	100.0

**Table 6 – Frequency of clinical findings - shape of glans.**

Shape of glans	Frequency (No.)	Percentage (%)
Conical	37	92.5
Flat	3	7.5
Total	40	100.0

**Graph 4 – Graph representing frequency of shape of glans.**



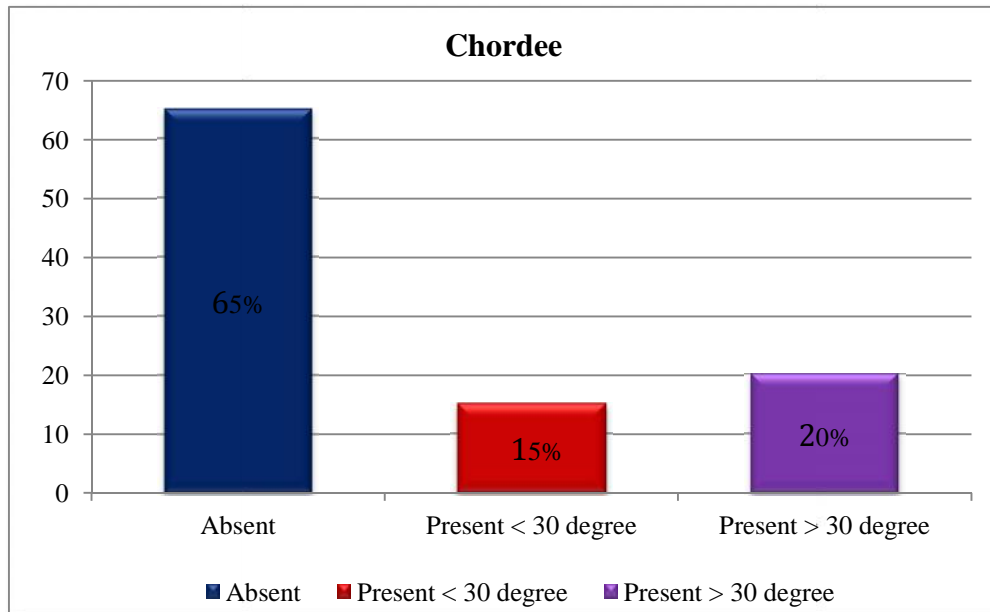
**Table 7 – Frequency of clinical findings – degree of chordee.**

<b>Degree of Chordee</b>	<b>Frequency (No.)</b>	<b>Percentage (%)</b>
Absent	26	65.0
Present < 30 degree	6	15.0
Present > 30 degree	8	20.0
<b>Total</b>	<b>40</b>	<b>100.0</b>

**Table 8 – Distribution of degree of chordee between the two groups.**

		Vascular cover		Total
		Preputial dartos	Tunica vaginalis	
Chordee	Absent	15	11	26
		75.0%	55.0%	65.0%
	Present < 30 degree	3	3	6
		15.0%	15.0%	15.0%
	Present >=30 degree	2	6	8
		10.0%	30.0%	20.0%
<b>Total</b>		<b>20</b>	<b>20</b>	<b>40</b>
		100.0%	100.0%	100.0%

**Graph 5 – Graph showing frequency of degree of chordee.**



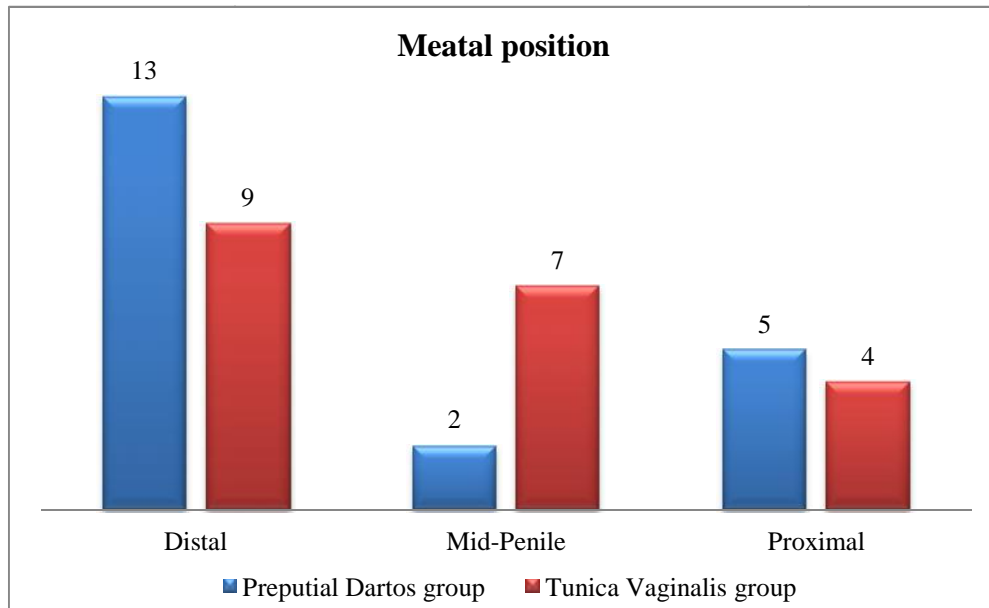
**Table 9 – Frequency of clinical findings – Corporal bodies.**

Corporal Bodies	Frequency (No.)	Percentage (%)
Good	38	95.0
Poor	2	5.0
Total	40	100.0

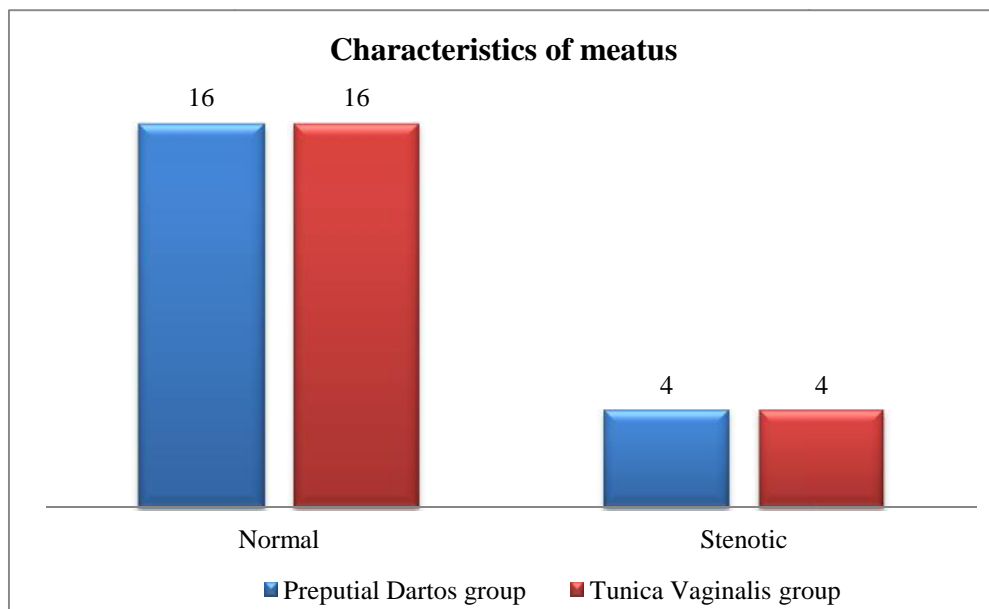
**Table 10 – Detailed distribution of clinical findings between two groups. There was no statistical significance noted between the two groups.**

	Vascular Cover		P value
	Group PD (n = 20)	Group TV (n = 20)	
Meatal position	Distal - 13	Distal – 9	0.164
	Mid-penile - 2	Mid-penile - 7	
	Proximal - 5	Proximal – 4	
Characteristics of meatus	Normal - 16	Normal – 16	1.00
	Stenotic - 4	Stenotic – 4	
Shape of glans	Conical - 18	Conical – 19	0.548
	Flat - 2	Flat – 1	
Chordee	Absent - 14	Absent – 13	0.270
	Present <30 degree - 1	Present <30 degree – 4	
	Present >30 degree - 5	Present >30 degree - 3	
Corporal bodies	Good - 19	Good – 19	1.00
	Poor - 1	Poor – 1	

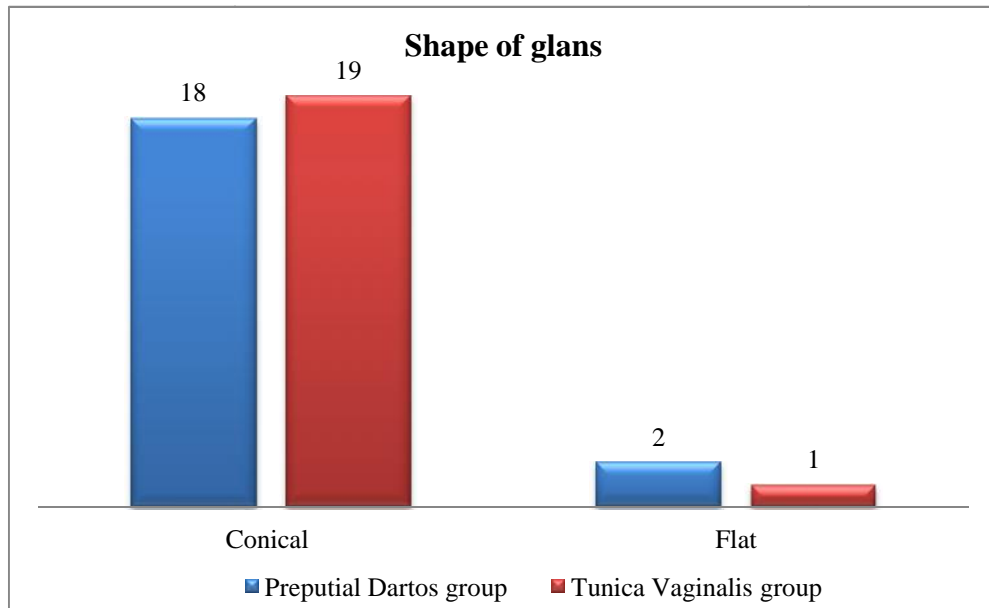
Graph 6 - Distribution of meatal position between two groups.



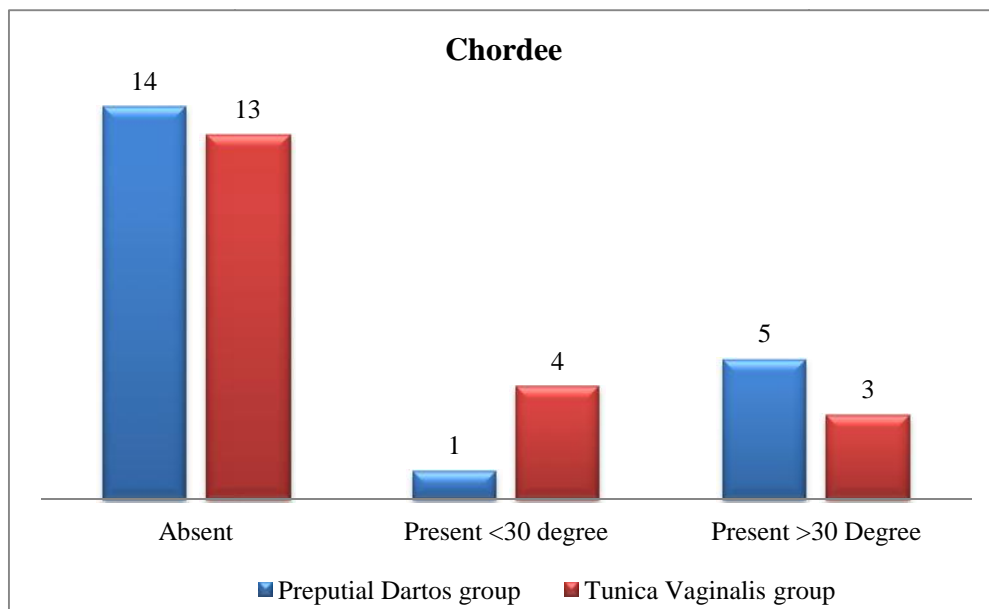
Graph 7 - Distribution of characteristics of meatus between two groups.



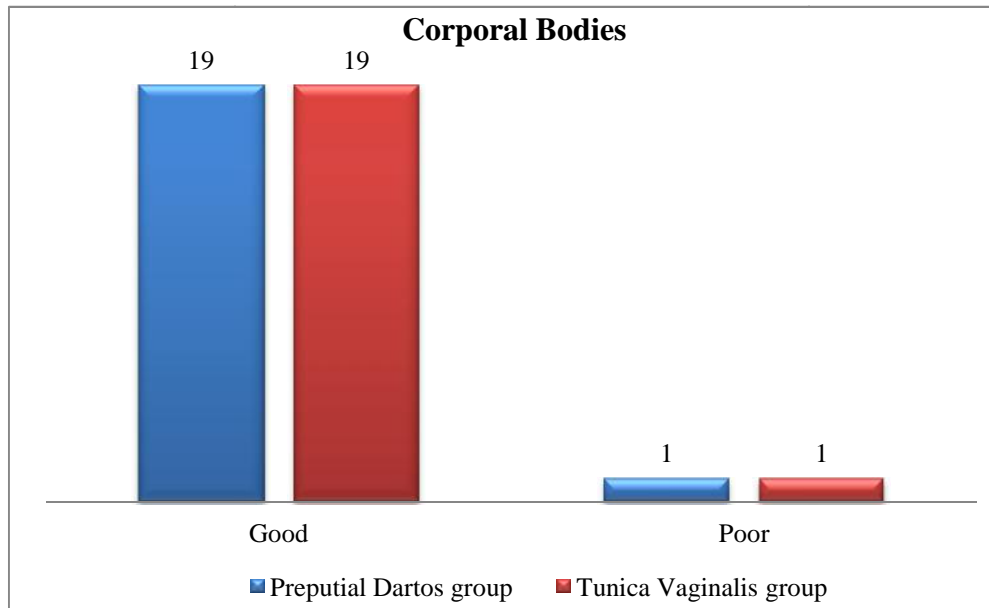
Graph 8 – Distribution of Shape of glans between two groups.



Graph 9 – Distribution of chordee between two groups.



Graph 10 – Distribution of corporal bodies between two groups.

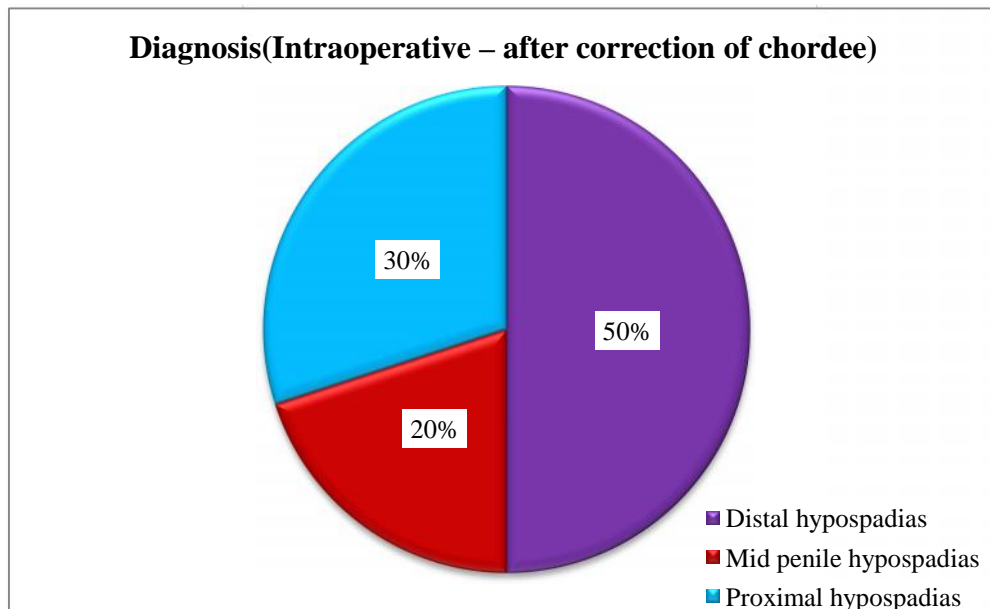


**INTRAOPERATIVE FINDINGS –**

**Table 11 – Frequency of intraoperative diagnosis.**

<b>Diagnosis (Intraoperative – after correction of chordee)</b>	<b>Frequency (No.)</b>	<b>Percentage (%)</b>
Distal hypospadias	20	50.0
Mid penile hypospadias	8	20.0
Proximal hypospadias	12	30.0
Total	40	100.0

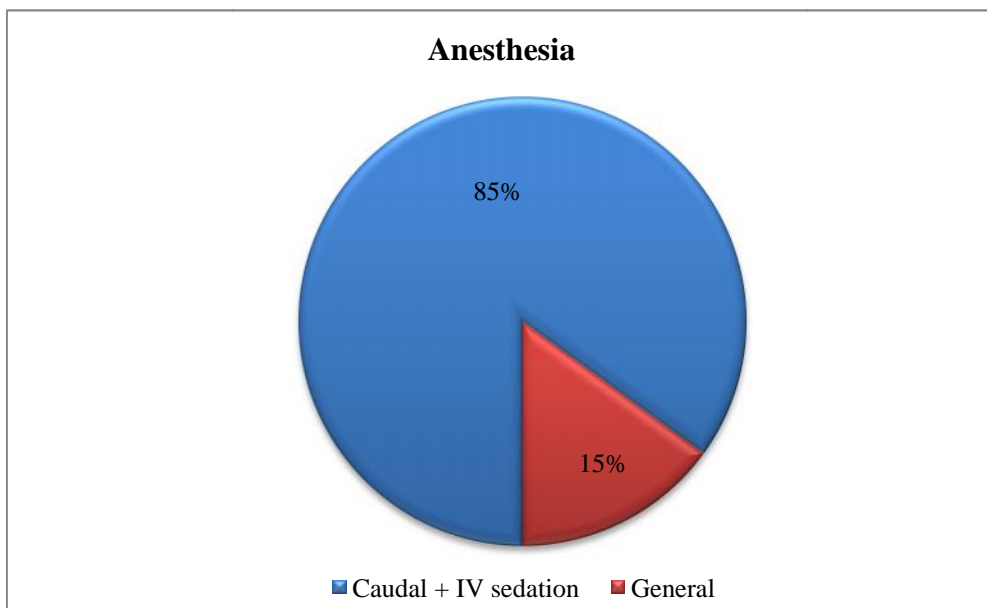
**Graph 11 – Graph depicting frequency of diagnosis after intraoperative correction of chordee.**



**Table 12 – Frequency of type of anaesthesia given.**

Type of anaesthesia given	Frequency (No.)	Percentage (%)
Caudal + IV sedation	34	85
General	6	15.0
Total	40	100.0

**Graph 12– Graph representing frequency of type of anesthesia given.**



**Table 13 – Frequency of supplementation of anesthesia given.**

<b>Supplementation of Anesthesia</b>	<b>Frequency (No.)</b>	<b>Percentage (%)</b>
General	8	20.0
None	32	80.0
Total	40	100.0

**Table 14 – Frequency of blood loss during surgery.**

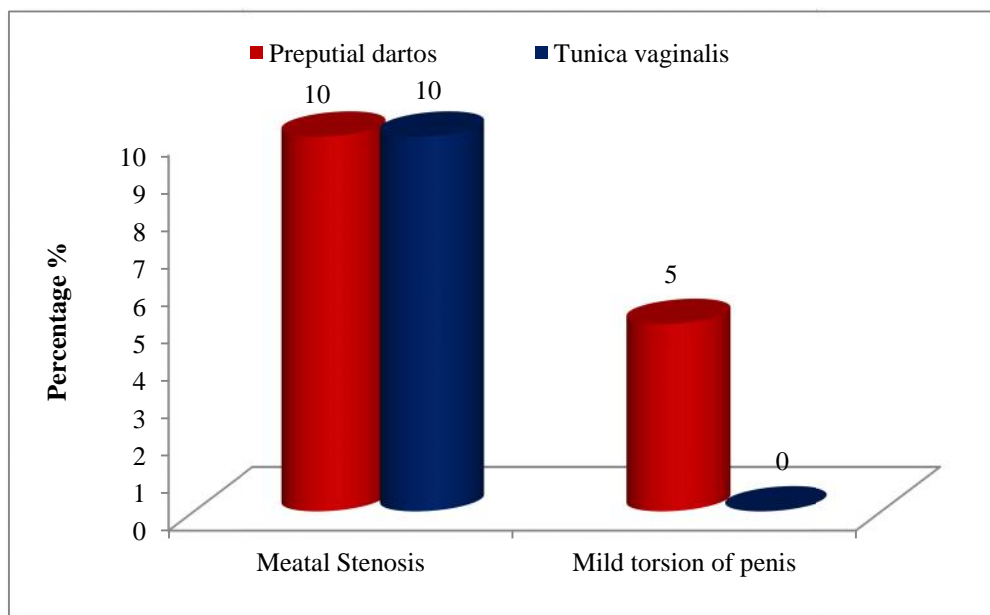
<b>Blood Loss during surgery</b>	<b>Frequency (No.)</b>	<b>Percentage (%)</b>
Acceptable	33	82.5
Excessive	7	17.5
Total	40	100.0

**COMPLICATIONS –**

**Table 15 – Comparison of minor complications between the two groups.**

Complications Minor Category		Vascular cover		Total
		Preputial dartos	Tunica vaginalis	
Meatal Stenosis		2	2	4
		10.0%	10.0%	10.0%
Mild torsion of penis		1	0	1
		5.0%	.0%	2.5%

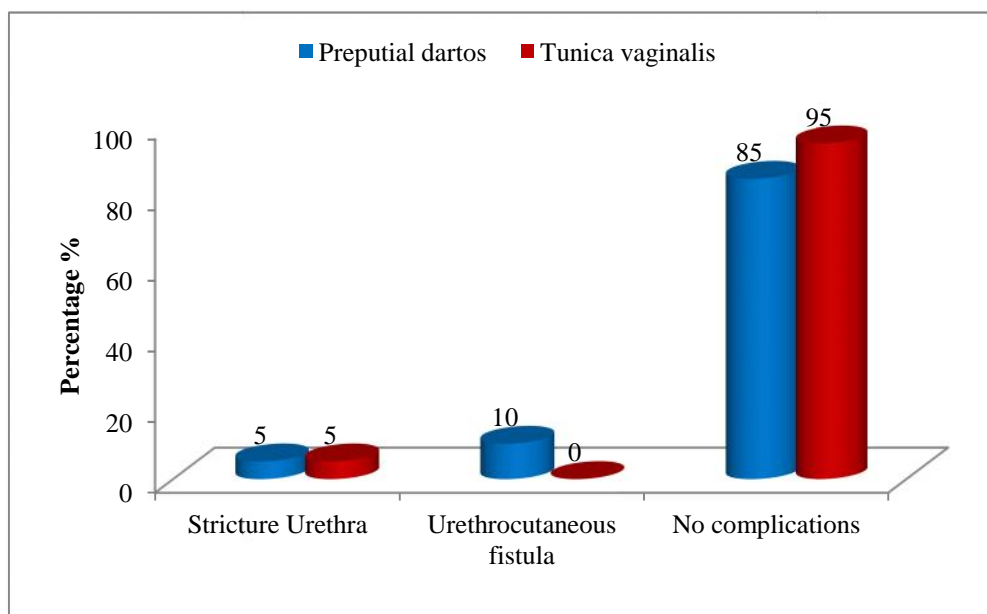
**Graph 13 – Graph comparing the minor complications between the two groups**



**Table 16 – Comparison of major complications between the two groups ( P value – 0.442)**

Complications Major Category		Vascular cover		Total
		Preputial dartos	Tunica vaginalis	
	Stricture Urethra	1	1	2
		5.0%	5.0%	5.0%
	Urethrocutaneous fistula	2	0	2
		10.0%	.0%	5.0%
	No complications	17	19	36
		85.0%	95.0%	90.0%
Total		20	20	40
		100.0%	100.0%	100.0%

**Graph 14 – Graph comparing the major complications between two groups.**



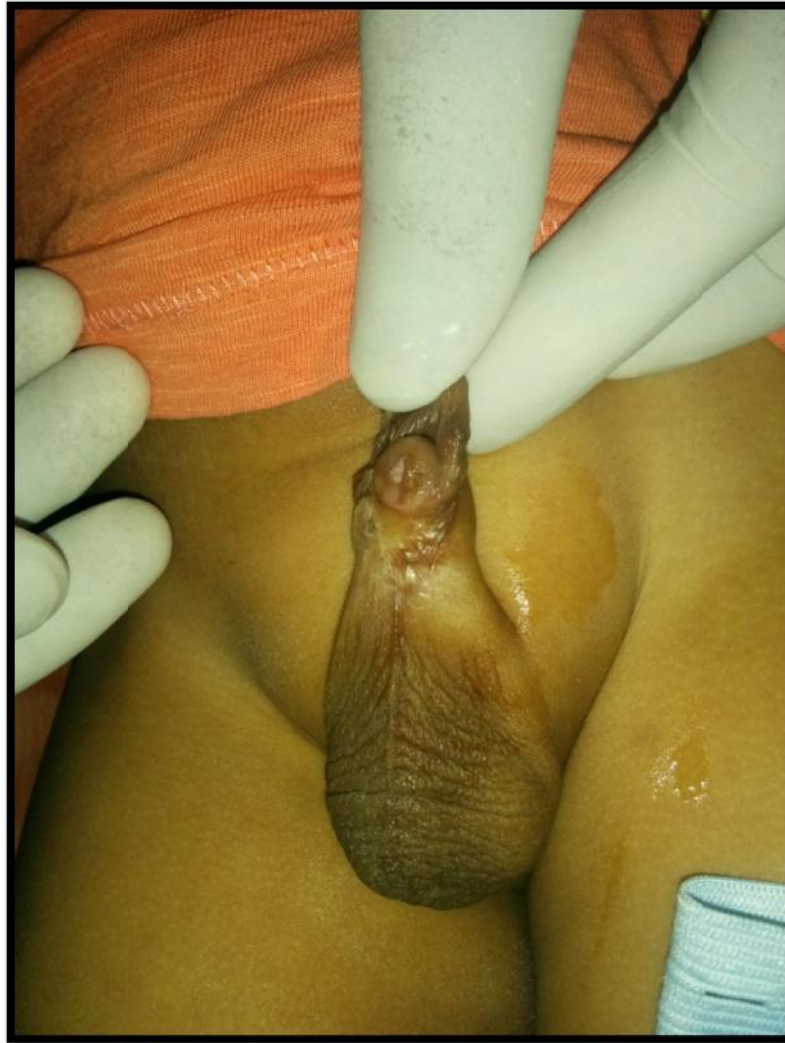
In the present study, the mean age of the children considered was 4.8yrs, youngest child being 1yr old and oldest being 16yrs old. The mean age of the children in preputial dartos group was 4.17yrs and in that of tunica vaginalis group was 5.25yrs. The position of meatus was distal in 22, middle in 9 and proximal in 9. Chordee was absent in 26 children. In 14 children, chordee was present, out of which it was <30 degree in 6 children and >30 degree among the rest. After the intraoperative correction of chordee, 2 distally placed meatus were found to be middle hypospadias and 3 middle hypospadias was found to be proximal hypospadias. So in the present study, there were 20 cases of distal hypospadias, 8 cases of middle hypospadias and 12 cases of proximal hypospadias. Detailed distribution of each clinical finding is summarized in table 10.

In 34 patients, hypospadias repair was done under caudal anesthesia with IV sedation and in the remaining patients it was done under general anesthesia. Of the 34 children, 8 children required general anesthesia intraoperatively. Excessive blood loss was noted in 7 children, but none of the children required post operative blood transfusion.

In our study, all the patients were followed up for minimum of 6 months. Two (10%) patient developed meatal stenosis and one (5%) patient developed mild torsion of testis in preputial dartos group. Two (10%) patient in tunica vaginalis group developed meatal stenosis. In the present study, two (10%) patients in preputial dartos group developed urethrocutaneous fistula and one (5%) patient developed stricture urethra in the follow up period. None of the patients developed urethrocutaneous fistula in the tunica vaginalis group. One (5%) patient had stricture urethra in tunica vaginalis group. However, no significant difference was noted between the two groups for major complications (P value – 0.442).



**Figure 8 – Clinical photograph of a follow up patient of preputial dartos flap repair showing well healed scar.**



**Figure 9 – Clinical photograph of follow up patient of tunica vaginalis flap repair showing well healed scar.**



**Figure 10 – Clinical photograph of a follow up patient who underwent TIP Urethroplasty with preputial dartos vascular cover showing good caliber single urinary stream.**



**Figure 11 – Clinical photograph of a follow up patient who underwent TIP Urethroplasty with tunica vaginalis vascular cover showing good caliber single urinary stream.**



**Figure 12 – Clinical photograph of a follow up patient of preputial dartos repair showing urethrocutaneous fistula (arrow), 3 months after surgery.**

## **DISCUSSION**

Several techniques have been described for hypospadias repair, but no single surgery is considered ideal because of the unacceptable complication rates. Introduction of tubularized incised plate urethroplasty by Snodgrass has revolutionized the outcome of hypospadias surgery, especially with reference to urethrocutaneous fistula. One of the major principles of tubularized incised plate urethroplasty repair was to provide additional coverage to the neourethra to decrease the incidence of fistula formation. Various modifications have been tried to provide protective intermediate vascular cover to the neourethra, for example – Smith’s flap, Buck’s fascial flap, buccal mucosa, dorsal dartos flap from the prepuce, dartos flap from the scrotum and tunica vaginalis.

Snodgrass<sup>[31]</sup> described the use of vascularised subcutaneous tissue, dissected from dorsal preputial and shaft skin, for providing additional coverage to the neourethra. Dartos based flaps require skillful dissection and there are high chances that the vascularity of the overlying skin may get compromised leading to dermal necrosis. The advantage of dartos based flaps is that they are locally available and are the conventional and is universally practiced method.

Snow<sup>[16]</sup> first described the use of tunica vaginalis as interposition graft and reported a fistula rate of 9%. Since then many authors have used tunica vaginalis as interposition graft and have reported similar results<sup>[18, 26]</sup>. Tunica Vaginalis vascular cover has several advantages. Tunica vaginalis is thin, elastic in nature, expandable, easy to harvest and close to penile shaft. It has an independent blood supply from the

cremasteric vessels and its pedicle length can safely be increased even up to the external inguinal ring<sup>[18]</sup>.

In our study, total 40 children were considered in the study with a mean age of 5yrs. Children requiring any kind of augmentation with either local application of testosterone cream or intramuscular testosterone injection were not considered in the study. Chordee was present in 6 patients in preputial dartos group and in 7 patients in tunica vaginalis group. The correlation of age, position of the meatus, presence or absence of chordee and preputial skin with the occurrence of complications as independent factors did not have any statistical significance. After intraoperative correction of chordee, 20 children had distal, 8 had mid-penile and 12 had proximal hypospadias. 8 children required general anesthesia in addition to the initially given anesthesia. Excessive blood loss was present in 7 children but none of the children required blood transfusion.

All the children were followed up for a minimum period of 6 months. Children were assessed for major complications, which included urethrocutaneous fistula, stricture urethra, complete wound dehiscence and glans breakdown; and minor complications like skin necrosis, local infection and meatal stenosis.

In preputial dartos group, 2(10%) patients had urethrocutaneous fistula. There was no fistula reported in tunica vaginalis group. Similar results were reported by other authors as well. Snodgrass reported zero fistula rate in 14 patients with proximal hypospadias who were treated with double-layered urethroplasty and tunica vaginalis vascular cover<sup>[31]</sup>. Fistula formation and other complications were found to be low with the use of tunica vaginalis vascular cover as demonstrated by Guralnick ML *et al.*<sup>[32]</sup> and Landau EH *et al.*<sup>[24]</sup>. Routh *et al.* reported fistula rate of 0% when tunica

vaginalis flap was used along with operative microscope. Chatterjee *et al.* [27] reported fistula rate of 0% and 15-20% for cases with tunica vaginalis flap and dartos flap respectively. Dhua *et al.* [13] in their study found a fistula rate of 12% with dartos flap and 0% with tunica vaginalis flap. Hamid *et al.* [23] reported fistula rate of 2.85% with tunica vaginalis flap cover. With respect to fistula rate, our results were found to be similar to other reported series. Decreased fistula rate in our study might be due to shorter duration of follow up. Both the patients with urethrocutaneous fistula required re-do surgery. Re-do surgery was done with tunica vaginalis flap cover and follow up period was uneventful.

Meatal stenosis occurred in four (10%) patients, two in each group and required surgical management with ventral meatoplasty. Meatal stenosis was reported in one patient (2.85%) in study conducted by Hamid *et al.* [23] where tunica vaginalis flap was used. Babu *et al.* [28] encountered 4(6.4%) and 1(4.77%) cases of meatal stenosis in dartos flap and tunica vaginalis group respectively. Chatterjee *et al.* [27] did not report any cases of metal stenosis in their study.

Stricture urethra occurred in two patients, one in each group, and was adequately managed with urethral dilatation/calibration. One (5%) patient in preputial dartos group had mild torsion of penis. However, there was no statistical significance noted between the two groups with respect to major (P value - 0.442) complications.

Use of dartos flap is associated with higher morbidity. Complications such as dermal necrosis, complete breakdown of repair are known. This is because of the compromise in the blood supply to the dorsal skin while dissection of dartos fascia. In cases of distal hypospadias, the ventral skin cover is adequate. However in midshaft and proximal hypospadias, there is insufficient skin and ventral cover is provided by

rotating the dorsal outer foreskin. If the blood supply to this gets compromised while dissecting dartos flap it can result in ventral skin necrosis and urethrocutaneous fistula [28]. Total breakdown of repair is also known in repair with dartos flap. However, tunica vaginalis flap is easier to dissect and has an independent blood supply. Since the outcome of hypospadias surgery depends on the vascularity of the flap used to cover neourethra, tunica vaginalis flap is a good alternative to dartos flap. Tunica vaginalis flap can be used as waterproofing layer in previously circumscised patients as well [13].

The limitation of our study was small sample size and shorter duration of follow up. There are no guidelines specifying the duration of follow up following hypospadias repair. A study was conducted by Snodgrass et al. to determine the timing of diagnosis of urethroplasty complications in patients undergoing primary and reoperative TIP repair. They concluded that majority of urethroplasty complications are diagnosed at the first postoperative visit or within the first year following TIP hypospadias repair [37].

The strength of our study is that it is a randomized controlled trial, procedures were performed by a single surgeon and most variables were matched including similar population was included in the study.

## **CONCLUSION**

In our study, repair with tunica vaginalis flap was associated with lesser complications, however it was statistically not significant, as compared to that of preputial dartos repair. Use of tunica vaginalis flap has been extended for use in primary repair along with redo hypospadias repair. In difficult cases where preputial dartos is unavailable, or where it is difficult to give vascular cover, tunica vaginalis may be used with ease and is also efficacious and even safe. The time and skill required to create a preputial dartos flap is more, compared to tunica vaginalis flap which was found in this study. The complications specifically arising due to dissection of flap are rare with tunica vaginalis and treatable, even if complications occur. Hence, it is advisable to judiciously choose one of the vascular cover – either tunica vaginalis or preputial dartos.

Tunica vaginalis flap could be an alternative to preputial dartos flap for covering the neourethra with vascularised flap, resulting in fewer complications. However, long term studies are required to conclude the same.

## **SUMMARY**

Tubularized incised plate (TIP) urethroplasty, also called as Snodgrass Urethroplasty is the most common technique to correct all types of hypospadias. But, urethrocutaneous fistula is still the most common complication of this technique which usually requires reoperation. The use of vascularized flaps for covering neourethra in hypospadias surgery is widely accepted as an important factor leading to better results in terms of postoperative complications, especially with regard to dehiscence and urethrocutaneous fistula formation. The objective of this study was to assess the complication rate and outcome in patients undergoing primary hypospadias repair using tunica vaginalis flap with those using preputial dartos fascia.

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi from 1<sup>st</sup> January 2016 to 31<sup>st</sup> December 2016. A total of 40 children who came for primary hypospadias repair were randomized into two groups of 20 each based on the type of vascular cover as group PD (Preputial dartos cover) and group TV (Tunica Vaginalis flap cover).

In the present study, the mean age of the children considered in the study was 4.8yrs, youngest child being 1yr old and oldest being 16yrs old. The mean of the children in preputial dartos group was 4.17yrs and in that of tunica vaginalis group was 5.25yrs. After intraoperative correction of chordee, there were 20 cases of distal hypospadias, 8 cases of middle hypospadias and 12 cases of proximal hypospadias. Chordee was absent in 26 children. In 14 children, chordee was present, out of which it was <30 degree in 6 children and >30 degree among the rest. all the patients were

followed up for minimum of 6 months. Two (10%) patient developed meatal stenosis and one (5%) patient developed mild torsion of testis in preputial dartos group. Two (10%) patient in tunica vaginalis group developed meatal stenosis. In the present study, two (10%) patients in preputial dartos group developed urethrocutaneous fistula and one (5%) patient developed stricture urethra in the follow up period. None of the patients developed urethrocutaneous fistula in the tunica vaginalis group. One (5%) patient had stricture urethra in tunica vaginalis group. However, no significant difference was noted between the two groups for major complications (P value – 0.442).

To conclude, use of tunica vaginalis flap is associated with good results, acceptable complication rate and good cosmetic results as compared to that of preputial dartos cover in Snodgrass repair for hypospadias.

## **BIBLIOGRAPHY**

1. Erol A, Baskin LS, Li YW, et al. Anatomical studies of the urethral plate: why preservation of the urethral plate is important in hypospadias repair. *BJU Int* 2000;85(6):728- 34.
2. Cheng EY, Vemulapalli SN, Kropp BP, et al. Snodgrass hypospadias repair with vascularized dartos flap: the perfect repair for virgin cases of hypospadias? *J Urol* 2002;168(4 Pt 2):1723 - 6.
3. Holmes NM, Miller WL, Baskin LS. Lack of defects in androgen production in children with hypospadias. *J Clin Endocrinol Metab* 2004;89:2811- 6.
4. Manzoni G, Bracka A, Palminteri E, Marrocco G. Hypospadias surgery: when, what and by whom? *BJU Int* 2004; 94: 1188–1195.
5. Van der Horst HJR, de Wall LL. Hypospadias, all there is to know. *Eur J Pediatr* 2017; 176: 435-441.
6. Asopa H S. Newer concepts in the management of hypospadias and its complications. *Ann R Coll Surg Engl* 1998; 80: 161-168.
7. Snodgrass WT. Tubularized incised plate hypospadias repair: Indications, technique, and complications. *Urology* 1999; 54:6-11.
8. Snodgrass WT, Bush N, Cost N. Tubularized incised plate hypospadias repair for distal hypospadias. *J Pediatr Urol* 2010;6:408-13.
9. Bush NC, Holzer M, Zhang S, Snodgrass W. Age does not impact risk for urethroplasty complications after tubularized incised plate repair of hypospadias in prepubertal boys. *J Pediatr Urol* 2012; 9: 252-6.
10. Bush N, Barber T, Dajusta D, Prieto J, Ziada A, Snodgrass W. Results of hypospadias repair after pediatric urology fellowship training: a comparison.

11. Snodgrass W, Bush N: Tubularized incised plate proximal hypospadias repair: Continued evolution and extended applications. *J Pediatr Urol* 2011; 7:2-9.
12. Smith D. A de-epithelialised overlap flap technique in the repair of hypospadias. *Br J Plast Surg.*1973; 26: 106–14.
13. Dhua AK,et al. Soft tissue covers in hypospadias surgery :is tunica vaginalis better than dartos flap? *J Indian Assoc Pediate Surg.*2012 Jan;17(1):16-9.
14. Ahmed S, Gough DC. Buccal mucosal graft for secondary hypospadias repair and urethral replacement. *Br J Urol* 1997; 80: 328-30.
15. Motiwala, H. G. Dartos flap: an aid to urethral reconstruction. *Brit. J. Urol.*, 72: 260, 1993.
16. Snow BW. Use of tunica vaginalis to prevent fistula in hypospadias. *J Urol* 1986;136:861-3.
17. Yamataka A, Kobayashi H, Okada Y, Tsukamoto K, Lane GJ, Miyano T. A novel technique for reinforcing the the neourethra in hypospadias associated with bilateral undescended testis: Use of the gubernaculum. *J Pediatr Surg.* 2003; 38: 1799–801.
18. Handoo YR. Role of tunica vaginalis interposition layer in hypospadias surgery. *Indian J Plast Surg.*2006;39:152-6.
19. Kadain YS, Rattan KN, Singh M, Kajal P, Parihar D. Tunica vaginalis: An aid in hypospadias fistula repair: Our experience of 14 cases. *Afr J Paediatr Surg.* 2011;8:164-7.
20. Sharma N, Bajpai M, Panda SS, Singh A. Tunica vaginalis flap cover in repair of recurrent proximal urethrocutaneous fistula: A final solution. *Afr J Paediatr Surg* 2013;10:311-4.

21. Muruganandham K, Ansari MS, Dubey D, Mandhani A, Srivastava A, Kapoor R, Kumar A. Urethrocutaneous fistula after hypospadias repair: outcome of three types of closure techniques. *Pediatr Surg Int.* 2010; 26: 305-8.
22. Ezekiel H, Offer N, Gofrit, et al. Outcome Analysis of Tunica Vaginalis Flap for the Correction of Recurrent Urethrocutaneous Fistula in Children. *J Urol* 2003; 170: 1596-99.
23. Hamid R, Baba AA, Shera A, Ahmad S. Tunica vaginalis flap following 'Tubularised Incised Plate' urethroplasty to prevent urethrocutaneous fistula. *Indian J Plast Surg* 2015; 48: 187-191.
24. Landau EH, Gofrit ON, Meretyk S, Katz G, Golijanin D, Shenfeld OZ, *et al.* Outcome analysis of tunica vaginalis flap for the correction of recurrent urethrocutaneous fistula in children. *J Urol* 2003; 170:1596-9.
25. Routh JC, Walpeol JJ, Reinberg Y. Tunneled tunica vaginalis flap is an effective technique for recurrent urethrocutaneous fistulas following tubularised incised plate urethroplasty. *J Urol* 2006; 176:1578-81.
26. Shanker KR, Losty PD, Hopper M, Wong L, Rickwood AM. Outcome of hypospadias fistula repair. *BJU Int* 2002; 89:103-5.
27. Chatterjee US, Mandal MK, Basu S, Das R, Majhi T. Comparative study of dartos fascia and tunica vaginalis pedicle wrap for the tubularised incised plate in primary hypospadias repair. *BJU Int.*2004;94:1102-4.
28. Babu R, et al. Tunica vaginalis flap is superior to inner preputial dartos flap as a waterproofing layer for primary TIP repair in midshaft hypospadias. *J Pediatr Urol.* 2013 Dec;9(6 Pt A):804-7.

29. Churchill, Bernard M. et al. The Dartos Flap as an Adjunct in Preventing Urethrocutaneous Fistulas in Repeat Hypospadias Surgery. *J Urol*. 1996; 156: 2047 - 2049.
30. Wafa AM, Fotouh SM, EL-Sherbeni KM. Modified Tubularized Incised Plate (TIP) Hypospadias Repair Using Dartos Fascia Flap. *J Plast Reconstr Surg* 2006; 30: 139-142.
31. Snodgrass WT. Editorial comment. *J Urol*. 2007;178: 1456.
32. Guralnick ML, Al-Shammari A, Williot PE, Leonard MP. Outcome of Hypospadias repair using the tubularized, incised plate urethroplasty. *Can J Urol*. 2000; 7: 986–91.
33. Snodgrass W. Tubularized, incised plate urethroplasty for distal hypospadias. *J Urol* 1994; 151:464-5.
34. Snodgrass W, Koyle M, Manzoni G, Hurwitz R, Caldamone A, Ehrlich R. Tubularized incised plate hypospadias repair for proximal hypospadias. *J Urol* 1998; 159:2129-31.
35. Snodgrass W, Koyle M, Manzoni G, et al. Tubularized incised plate hypospadias repair: results of a multicenter experience. *J Urol* 1996; 156: 839-41.
36. Snow BW, Castwright PC, Unger K. Tunica vaginalis blanket wrap to prevent urethrocutaneous fistula: An 8 years experience. *J Urol* 1995; 153:472-3.
37. Snodgrass W, Vallanueva C, Bush NC. Duration of follow-up to diagnose hypospadias urethroplasty complications. *J Pediatr Urol* 2014; 10: 208-11.
38. Marrocco G, Vallasciani S, Fiocca G, Calisti A. Hypospadias surgery: a 10-year review. *Pediatr Surg Int* 2004; 20: 200-203.

39. Roberts, Julian. Hypospadias surgery past, present and future. *Current Opinion in Urology* 2010; 20: 483-489.
40. Snodgrass W, Bush N. TIP hypospadias repair: A pediatric urology indicator operation. *J Pediatr Urol* 2016; 12: 11-18.
41. Fahmy O, Khairul-Asri MG, Schwentner C, Schubert T, Stenzl A, Zahran MH, Gakis G. Algorithm for Optimal Urethral Coverage in Hypospadias and Fistula Repair : A Systematic Review. *Eur Urol* 2016; 70: 293-298.
42. Jan IA, Mirza F, Yaqoot, Ali M, Arian A, Saleem N, Ahmad, Kumar D. Factors influencing the results of surgery for hypospadias: experience at NICH. *J Pak Med Assoc* 2004; 54:577-579.
43. Baskin LS, Ebbers MB. Hypospadias: anatomy, etiology, and technique. *J Pediatr Surg* 2006; 41: 463-472.
44. Blaschko SD, Cunha GR, Baskin LS. Molecular mechanisms of external genitalia development. *Differentiation* 2012; 84: 261–268.
45. Appeadu-Mensah W, Hesse AA, Glover-Addy H, Osei-Nketiah S, Etwire V, Sarpong PA. Complications of hypospadias surgery: Experience in a tertiary hospital of a developing country. *Afr J Paediatr Surg* 2015;12:211-216.
46. Seo S, Ochi T, Yazaki Y, Okawada M, Doi T, Miyano G, Koga H, Lane GJ, Yamataka A. Soft tissue interposition is effective for protecting the neourethra during hypospadias surgery and preventing postoperative urethrocutaneous fistula: a single surgeon's experience of 243 cases. *Pediatr Surg Int* 2015; 31: 297-303.
47. Thomas DT, et al., The effect of dorsal dartos flaps on complication rates in hypospadias repair: A randomised prospective study. *J Pediatr Urol* 2015; 11: 1-4.

## **ANNEXURE I – CONSENT FORM**

**Title of Research Study : A one year randomized control trial to compare the outcome of primary repair of hypospadias with vascular cover using tunica vaginalis flap with those using preputial dartos fascia.**

Principal Investigator:-

Co-investigator:-

Co-Guide :

**INTRODUCTION AND PURPOSE** :- You are requested to give consent for participation of your child in a study that is an attempt to evaluate the outcome of primary repair of hypospadias using tunica vaginalis flap vascular cover with those patients of repair with preputial dartos fascia vascular cover.

Preputial dartos vascular cover is routinely used in primary hypospadias repair to provide adequate vascularity to the neourethra. However, preputial dartos vascular cover is associated with complications like urethrocutaneous fistula, meatal stenosis, wound dehiscence etc.

In an effort to avoid the above mentioned complications, the study has been undertaken to assess the outcome of alternate vascular cover ie tunica vaginalis flap. In this study, outcomes of primary repair of hypospadias with tunica vaginalis flap vascular cover will be compared with those of preputial dartos fascia vascular cover.

This study will be conducted by Dr. V. Geethika, Post Graduate in Department of Surgery, under the direct supervision and guidance of Dr Ramesh S. Koujalagi, Associate Professor, Department of General Surgery and Dr. Santosh Kurbet, Professor and Head, Department of Paediatric Surgery, J. N. Medical College, Belagavi.

Your child needs to be eligible, meeting all the selection criteria to participate in this study. You should be willing to provide information about your child. All the subjects will be enrolled in this study will be randomized in either of 2 groups (details below).

**PROCEDURE :-** If you give consent for the participation of your child in this study, your child will be randomly allotted into a group (A or B) and accordingly receive either the standard treatment (preputial dartos fascia vascular cover) or the newer treatment (tunica vaginalis flap vascular cover). In the 24 hours following surgery, you will be assessed at fixed intervals for post-operative pain. Your child will be followed up for a minimum of 3 months.

**BENEFITS :-** The tunica vaginalis flap vascular cover is supposed to be associated with less complications as compared to that of preputial dartos vascular cover. But preputial dartos is the conventional method and practiced commonly.

**RISK INVOLVED :-** The risks associated with the hypospadias repair surgery include torsion of testis, testicular complications and other complications of hypospadias repair.

**COMPENSATION:-** Taking part in the study will not affect the cost of treatment i.e. it will be similar to the cost of standard procedure. In the event that your child becomes injured as a result of taking part in this study, treatment will be offered to your child or you will be given information about where to receive medical care: but

you/your insurance company will be responsible for the costs. However, no reimbursement, compensation or free medical care will be given.

**CONFIDENTIALITY :-** Every effort will be made to protect the confidentiality of the information you provide. This means that the researchers will not let anyone, not a part of the study, see the information you provide. Only Dr. V. Geethika, Dr. Ramesh S. Koujalagi and Dr. Santosh Kurbet will have access to the information collected. Results of this study may be published but your name will not be revealed.

**VOLUNTARY PARTICIPATION / WITHDRAWAL :-** Taking part in this study is voluntary; you may choose not to enroll your child in this study. Your decision will not change the present or future health care services offered to you at KLES Dr. Prabhakar Hospital, Belagavi. The alternative that you have is that your child will have to undergo the traditional procedure that is carried out in KLES Hospital.

If you need any further information regarding your rights as a study participant, you may also contact Dr.Ganga Pilli (Mobile No. 9480275601), Chairman of Institutional Ethics Committee on Human Subjects Research, JNMC, Belgaum.

**CONSENT TO PARTICIPATE IN THE STUDY**

I Mr./Mrs. \_\_\_\_\_ , parent/guardian of \_\_\_\_\_ have been explained about the research study, the need of the study, the intervention, their risks, benefits and alternatives available in my own vernacular language.

I voluntarily agree for the participation of my child in this study by signing up this form below. I understand that I may withdraw my child at any time from this study. I have been given adequate time to clarify my doubts about the study and my rights as a parent/ guardian of the study participant.

My signature / thumb impression below indicates that I have read or information in the consent been read to me including the risks and benefits and have cleared my doubts.

Name of parent/guardian:

Signature/LTI:

Representative (if applicable):

Relationship with participant:

Name of witness:

Signature:

Name of investigator:

Signature:

Date:

Place:

## ANNEXURE II – PROFORMA

### PROFORMA / QUESTIONNAIRE USED FOR DATA COLLECION

The proposed proforma / questionnaire to be used for data collection for the study titled  
“A one year randomized control trial to compare the outcome of primary repair of  
hypospadias with vascular cover using tunica vaginalis flap with those using  
preputial dartos fascia.” is as follows :-

#### 1. PATIENT IDENTIFICATION DATA

Group –

Date of admission -

Name –

Date of surgery -

Age –

Date of discharge -

Father’s name –

Mother’s name –

Address –

CHIEF COMPLAINTS –

Antenatal History – History of intake progesterones by mother?

Family History – DSD/ Infertility

**2. General Physical Examination**

Weight –

Pulse –

**3. Local Examination**

Site of meatus – Proximal/ Middle/ Distal hypospadias

Urethral Plate – Present/ Absent

If present, width in mm –

Meatus – Normal/ Stenotic

Shape of Glans – Conical/ Flat

Preputial fold – Adequate/ Inadequate

Chordee – Present/ Absent

If present, degree –

Corporal bodies –

**4. CLINICAL DIAGNOSIS**

**5. INVESTIGATIONS** – Complete Blood Count -

**6. OPERATION DETAILS**

Date of surgery –

Name of Surgery –

Anesthesia –

**7. ASSESSMENT OF COMPLICATIONS -**

COMPLICATIONS	Day 10	Day 14	Day 30	Day 30	Day 90			
Urinary Leakage								
Wound Dehiscence								
Glans Dehiscence								
Infection								
Urethrocutaneous Fistula								
Meatal Stenosis								
Testicular Complications								

	IP number	Age	Clinical Features				Diagnosis	Anesthesia	Supplementation of Anesthesia	Vascular cover	Haemorrhage	Duration	Requirement of blood	Complications		Follow-up	
			Meatal position	Meatus	Shape of glans	Chordee								Corporal Bodies	Minor		Major
1	745435	6yrs	Distal	Normal	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	none	Preputial dartos	Acceptable	42min	No	Nil	Nil	
2	723650	1yr	Distal	Normal	Flat	Absent	Good	Distal hypospadias	Caudal + IV sedation	none	Tunica vaginalis	Acceptable	44min	No	Nil	Nil	
3	768824	2yrs	Distal	Normal	Conical	Present, < 30 degree	Good	Distal hypospadias	Caudal + IV sedation	none	Preputial dartos	Acceptable	50min	No	Nil	Nil	
4	729928	16yrs	Distal	Normal	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	none	Tunica vaginalis	Acceptable	50min	No	Nil	Nil	
5	768211	6yrs	Distal	Stenotic	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	none	Preputial dartos	Acceptable	45min	No	Nil	Nil	
6	765534	15yrs	Proximal	Stenotic	Conical	Absent	Good	Proximal hypospadias	General	none	Tunica vaginalis	Excessive	60min	No	Nil	Nil	
7	767394	4.5yrs	Proximal	Normal	Conical	Present, >30 degree	Poor	Proximal hypospadias	Caudal + IV sedation	none	Preputial dartos	Acceptable	60min	No	Nil	Nil	
8	765503	2yrs	Proximal	Normal	Conical	Present, < 30 degree	Good	Proximal hypospadias	Caudal + IV sedation	none	Tunica vaginalis	Acceptable	68min	No	Nil	Nil	
9	737172	7yrs	Middle	Normal	Flat	Absent	Good	Mid penile hypospadias	Caudal + IV sedation	General	Preputial dartos	Excessive	55min	No	Meatal Stenosis	Nil	Underwent ventral meatoplasty
10	745836	3yrs	Middle	Normal	Conical	Absent	Good	Mid penile hypospadias	Caudal + IV sedation	none	Tunica vaginalis	Acceptable	50min	No	Nil	Nil	
11	724478	4yrs	Distal	Normal	Conical	Absent	Good	Distal hypospadias	General	none	Preputial dartos	Acceptable	55min	No	Nil	Nil	
12	732808	2yrs	Middle	Stenotic	Conical	Present, > 30 degree	Good	Proximal hypospadias	Caudal + IV sedation	none	Tunica vaginalis	Acceptable	50min	No	Meatal Stenosis	Nil	Underwent ventral meatoplasty
13	733382	1.6yrs	Distal	Normal	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	none	Preputial dartos	Acceptable	50min	No	Nil	Nil	
14	726199	2.3yrs	Middle	Normal	Conical	Absent	Good	Mid penile hypospadias	Caudal + IV sedation	none	Tunica vaginalis	Acceptable	45min	No	Nil	Nil	
15	714819	1.2yrs	Distal	Normal	Conical	Present, >30 degree	Good	Mid penile hypospadias	Caudal + IV sedation	none	Preputial dartos	Acceptable	45min	No	Nil	Nil	
16	730008	4yrs	Proximal	Normal	Conical	Present, > 30 degree	Good	Proximal hypospadias	Caudal + IV sedation	none	Tunica vaginalis	Acceptable	55min	No	Nil	Nil	
17	740455	3yrs	Distal	Normal	Conical	Present, >30 degree	Good	Mid penile hypospadias	General	none	Preputial dartos	Acceptable	40min	No	Meatal Stenosis	Stricture Urethra	Underwent dilatation, ventral meatoplasty
18	742534	1.6yrs	Distal	Normal	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	General	Tunica vaginalis	Acceptable	50min	No	Nil	Nil	
19	770075	1.11yrs	Distal	Normal	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	none	Preputial dartos	Acceptable	56min	No	Nil	Nil	
20	710770	1yr	Distal	Normal	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	none	Tunica vaginalis	Excessive	55min	No	Nil	Nil	
21	721867	1yr	Middle	Normal	Conical	Present, >30 degree	Good	Mid penile hypospadias	Caudal + IV sedation	none	Preputial dartos	Acceptable	55min	No	Nil	Urethrocuteaneous fistula	Underwent re-do surgery
22	709499	8yrs	Middle	Normal	Conical	Present, < 30 degree	Poor	Proximal hypospadias	Caudal + IV sedation	none	Tunica vaginalis	Acceptable	58min	No	Nil	Nil	
23	710642	2.6yrs	Distal	Normal	Conical	Absent	Good	Distal hypospadias	General	none	Preputial dartos	Acceptable	60min	No	Mild torsion of penis	Nil	
24	718164	1.6yrs	Distal	Normal	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	General	Tunica vaginalis	Acceptable	40min	No	Nil	Nil	
25	719368	3yrs	Proximal	Stenotic	Conical	Present, > 30 degree	Good	Proximal hypospadias	Caudal + IV sedation	none	Preputial Dartos	Acceptable	44min	No	Nil	Nil	
26	757960	6yrs	Distal	Normal	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	none	Tunica vaginalis	Acceptable	50min	No	Nil	Sticture Urethra	Underwent dilatation
27	716970	5yrs	Proximal	Normal	Conical	Absent	Good	Proximal hypospadias	Caudal + IV sedation	none	Preputial Dartos	Excessive	55min	No	Nil	Nil	
28	708229	11yrs	Middle	Normal	Conical	Present, < 30 degree	Good	Mid penile hypospadias	Caudal + IV sedation	none	Tunica vaginalis	Acceptable	50min	No	Nil	Nil	
29	700456	13yrs	Proximal	Stenotic	Conical	Absent	Good	Proximal hypospadias	Caudal + IV sedation	none	Preputial dartos	Acceptable	48min	No	Nil	Urethrocuteaneous fistula	Underwent re-do surgery
30	764893	1yr	Distal	Normal	Conical	Absent	Good	Distal hypospadias	General	none	Tunica Vaginalis	Excessive	40min	No	Nil	Nil	
31	759367	1yr	Distal	Normal	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	none	Preputial dartos	Acceptable	40min	No	Nil	Nil	
32	725150	2yrs	Proximal	Stenotic	Flat	Present, < 30 degree	Good	Proximal hypospadias	Caudal + IV sedation	none	Tunica vaginalis	Acceptable	60min	No	Nil	Nil	
33	753687	9yrs	Proximal	Normal	Conical	Absent	Good	Proximal hypospadias	Caudal + IV sedation	General	Preputial dartos	Excessive	60min	No	Nil	Nil	
34	732402	13yrs	Middle	Stenotic	Conical	Present, < 30 degree	Good	Proximal hypospadias	Caudal + IV sedation	none	Tunica Vaginalis	Acceptable	50min	No	Meatal Stenosis	Nil	Underwent ventral meatoplasty
35	735316	2.5yrs	Distal	Normal	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	General	Preputial dartos	Acceptable	45min	No	Nil	Nil	
36	762105	2yrs	Distal	Normal	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	General	Tunica vaginalis	Acceptable	45min	No	Nil	Nil	
37	773782	2yrs	Distal	Stenotic	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	none	Preputial dartos	Acceptable	40min	No	Nil	Nil	
38	761247	6yrs	Distal	Normal	Conical	Absent	Good	Distal hypospadias	Caudal + IV sedation	General	Tunica vaginalis	Acceptable	50min	No	Nil	Nil	
39	776913	8yrs	Middle	Normal	Conical	Absent	Good	Mid penile hypospadias	Caudal + IV sedation	none	Preputial dartos	Excessive	56min	No	Nil	Nil	
40	743137	12yrs	Distal	Normal	Conical	Present, < 30 degree	Good	Distal hypospadias	Caudal + IV sedation	General	Tunica vaginalis	Acceptable	55min	No	Nil	Nil	



# *Introduction*

---



# *Objectives*

---



# *Review of Literature*

---



# *Methodology*

---



*Results*

---



# *Discussion*

---



*Conclusion*

---



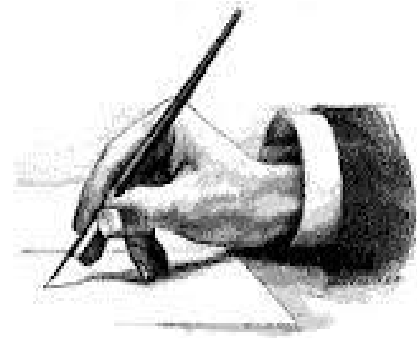
# *Summary*

---



# *Bibliography*

---



## *Annexure-I*

---



## *Annexure-II*

---



## *Annexure-III*

---