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TREATMENT OF CHYLURIA: INSTILLATION OF POVIDONE IODINE IN PELVICALICEAL SYSTEM - A MINIMALLY INVASIVE TECHNIQUE

P SAHA¹, MA SALAM², AKM K ALAM³, KR ABEDIN⁴, Z HASAN⁵, ME HAQUE⁶, KMM KARIM⁷

Abstract

Purpose: We present our experiences in treating patients who had chyluria by instilling povidone iodine into the pyelolymphatic channels, which produces lymphangitis and ultimately fibrosis resulting in obliteration of lymphaticourinary fistula. Povidone iodine is iodine complexed with the non-ionic surfactant polymer polyvinyl pyrrolidone, and has a local sclerosant action.

Materials and methods: 31 patients (16 women and 15 men) with age range 19-58 years who presented with chyluria from July 1999 to June 2004 were included in our study and subjected for treatment. 24 patients presented only with the complaints of chyluria, 3 with haematochyluria, 3 associated with severe malnutrition and recurrent urinary tract infection and the another one presented with post TURP recurrent haematuria & milky urine. Diagnosis was based on urinalysis for the presence of chyle and fat globules, excretory urography and cystoscopy. Cystoscopy was performed under SAB. An ureteric catheter was passed inside the ureteric orifice, effluxing milky white urine. Then 7-10 ml of 5% povidone iodine was pushed through the ureteric catheter into the collecting system. Out of 31 cases there were bilateral efflux of chylous urine in 2 cases and both the sides were treated in the same sitting. The ureteric catheter was removed after 5 minutes in all the cases.

Results: All the patients were followed up periodically ranging from 1st post operative day to 32 months (mean 13 months) with clinical evaluation and urine examination for the presence of chyle and fat globules 2 hours after fatty meal. Chyluria disappeared completely in all the cases within 2 days but one who received second instillation after 5 days and ultimately cured from the symptoms. The post operative complications were unremarkable and general condition with nutritional status improved significantly in all the cases.

Conclusion: Chyluria can successfully be treated by instilling povidone iodine as a sclerosing agent. This procedure is minimally invasive, safe, easy to perform and cost effective. Despite open surgical procedure chyluria commonly recurs whereas this treatment can be repeated safely.

Introduction:

Chyluria is passage of lymphatic fluid or chyle, noted by the patients as passage of milky white urine. Chyluria is a symptom, not a disease representing a lymphatic-urinary system fistula. Most often the cause is obstruction of the renal lymphatics, which results in forniceal rupture and leakage of chyle into the urinary drainage system. Chyluria may be classified as parasitic or non-parasitic. The most common cause is parasitic infestation with filariae. Non-parasitic chyluria is caused by trauma, tuberculosis, pregnancy and retroperitoneal tumors. Filarial chyluria is prevalent in Southeastern Asia. 5--10% of the population in endemic areas are infested of whom 10% eventually have chyluria. In Bangladesh it commonly occurs in the northern and eastern hilly areas.

Chyluria is a late sequelae and usually affects young males and females equally. It is painless, profuse and intermittent because of spontaneous remission and is often worse after a fatty meal. Chylous clots may produce renal colic and urinary retention. Chyluria and haematochyluria causes general fatigue, weight loss, hypoproteinaemia and immunological disorders due to severe proteinuria. Hence the early diagnosis and treatment of chyluria and haematochyluria is necessary.

Mild cases require no therapy only the supportive treatment is necessary and spontaneous cure occurs in 50% of cases. In impaired nutrition instillation of renal pelvis by sclerosing agents may give expectant result and in refractory cases renal decapsulation or resection of renal lymphatics should be performed.

Instillation of povidone iodine as an sclerosing agent is a better treatment option for chyluria. Povidone iodine is iodine complexed with the non-ionic surfactant polymer polyvinyl pyrrolidone and has a local sclerosant action. Passage of 5% povidone iodine into the renal lymphatics through the pyelolymphatic channels, a potential communication that exist between the renal lymphatics and the pelviccaliceal system, produces lymphangitis and finally fibrosis, resulting in obliteration of lymphaticourinary fistula.

Patients and Methods

We observed, recorded and reviewed the results of 31 patients with chyluria treated by instillation of povidone iodine into the pyelolymphatic channels from July 1999 to June 2004. All patients had manifestations of weight loss and fatigue with 3 months to 5 years history of milky urine. 31 patients (16 women and 15 men) with age range 19-58 years (mean age 28++7) who presented with chyluria were included in our study and subjected for treatment by sclerotherapy with povidone iodine. Out of 31 patients 24 presented only with chyluria, 3 with haematochyluria, 3 associated with severe malnutrition and recurrent urinary tract infection and another one presented with post TURP recurrent haematochyluria.

Diagnosis was based on the urine analysis for the presence of chyle and fat globules, excretory urography and cystoscopic evaluation 3 hours after a fatty meal. Lymphangiography was deferred. Cystoscopy was performed under subarachnoid blockade. An ureteric catheter was passed inside the ureteric orifice, effluxing milky white urine. Then 7-10 ml of 5% povidone iodine was pushed through the ureteric catheter into the collecting system. Out of 31 cases there were bilateral efflux of chylous urine in 2 cases and both the sides were treated in the same sitting. The ureteric catheter was removed after 5 minutes in all the cases. All the patients were compliant with follow-up.

Procedure

Cystoscopy was performed 3 hours after a fatty meal consisting of 10 gm of butter and a cup of creamy milk. The procedure was done under regional anesthesia by subarachnoid blockade in all the cases. The patient was placed in lithotomy position. After introduction of cystoscope affected side was confirmed by efflux of milky white urine from the ureteric orifice. Then a 5 Fr. ureteric catheter was introduced up-to 5 cm through the ureteric orifice. 5 ml of 10% povidone iodine aqueous solution was mixed with 5 ml of distilled water to make it 5% solution. Then 5 - 7 ml of prepared 5% povidone iodine was instilled through the ureteric catheter into the collecting system. Ureteric catheter was removed after 5 minutes in all the cases. Bilateral cases were treated in the same sitting with the more affected side irrigated first. Before removing the cystoscope the povidone iodine was washed out from the bladder. All the patients were catheterized with 2 ways Foley's catheter and then sent to the recovery room.

Results

All the patients were compliant with the follow-up from 1st post operative day to 32 months (mean 13 months) and they were followed-up with clinical evaluation and urine examination for the presence of chyle and fat globules even 2 hours after fatty meal. Chyluria disappeared completely in 30 cases within 48 hours of povidone iodine instillation, one case received second instillation after 5 days and ultimately resolved, in all the cases chylous urine did not recur even after ingestion of fatty meal. No complication developed preoperatively or post-operatively. Post operative hospital stay was 2 to 6 days (mean 2.40 days). Chylous urine completely resolved and general condition with nutritional status were significantly improved.

Summary Table

No. (Men/Women)	- 31(15/16)
Mean age	- 28±7 years
Unilateral (Lt./Rt.)	- 29(15/14)
Bilateral	- 2
Mean postoperative hospital stay	- 2.40 days
Mean follow-up	- 13 month
Resolved after 1 st instillation	- 30(96.77%)
2nd instillation needed	- 1(3.23%)
Postoperative complication	- None.

Discussion

In this series 31 patients underwent povidone iodine instillation into the collecting system for chyluria of whom 15(48.38%) were men and 16(51.62%) were women, which shows that either sex was affected almost equally and this ratio is consistent with other international studies1,4,7,8.

The age range of the study population was 19 to 58 years with mean age 28++7 years, indicating that young adults are affected most and is identical with other studies6,7,8.

Out of 31, 2 patients had bilateral involvement and 29 had unilateral with left sided preponderance. The mean post operative hospital stay was 2.4 days which is a small stay and reduces the treatment cost which is similar to other series of study2,4,6.

In 30 patients (96.77%) chyluria resolved after 1st instillation and 1 patient (3.23%) needed 2nd instillation which indicate the high success rate of this treatment procedure and no patient showed any significant post

operative complication but smooth recovery with improvement of general physical condition and nutritional status.

Conclusion

The data retrieved from this study indicate that chyluria can successfully be treated by instilling povidone iodine as a sclerosing agent into the pyelolymphatic channels. This procedure is minimally invasive, safe, easy to perform and cost effective with no significant post operative complication. Chyluria commonly recurs and this treatment can be repeated safely.

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ABSTRACT FROM CURRENT LITERATURE

The Diameter of the Rectum on Ultrasonography as A Diagnostic Tool For Constipation in Children with Dysfunctional Voiding

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Purpose: We proved the accuracy of the transverse diameter of the rectum on ultrasonography as an additional parameter for diagnosing constipation in children with lower urinary tract dysfunction.

Materials and Methods: The diameter of the rectum on bladder ultrasonography in a constipated group of patients with dysfunctional voiding was compared to this diameter in a control group of patients with a normal defecation pattern. A total of 49 children were included. Group 1 consisted of 23 patients with a positive history of dysfunctional voiding and, according to pediatric gastroenterological practice, constipation. Control group 2 consisted of 26 patients without lower urinary tract dysfunction and a normal defecation pattern. In each group a defecation questionnaire was administered and physical examination of the abdomen was done. In all patients a 7.5 MHz probe was used to measure the transverse diameter of the rectum behind the bladder on ultrasonography. The probe was applied on the abdominal skin approximately 2 cm above the symphysis. Measurement was performed with a filled bladder at an angle of about 15 degrees downward from the transverse plane.

Results: In constipated group 1 the mean diameter of the rectum was 4.9 cm (95% CI 4.4 to 5.3). In the control group the mean diameter of the rectum was 2.1 cm (95% CI 1.8 to 2.4). In group 1 the diameter of the rectum was significantly larger than in group 2 ($p < 0.001$). None of the patients had a sensation to defecate during the investigation. There was no significant difference in age between the 2 groups ($p = 0.20$) and no significant difference between them in the period between the last time that stool was passed prior to the time of rectal measurement ($p = 0.16$).

Conclusions: The transverse diameter of the rectum measured by lower abdominal ultrasound provides an additional accurate parameter with which to diagnose constipation in patients with nonneurogenic bladder-sphincter dyssynergia.

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Giant bladder diverticula causing bladder outlet obstruction in children

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Purpose: Congenital giant diverticulum of the bladder is a consequence of deficiency in the detrusor musculature and has been reported in male infants as a rare cause of bladder outlet obstruction.

Materials and Methods: A 10-year retrospective review revealed 4 patients (3 boys and 1 girl) with bladder outlet obstruction due to a giant bladder diverticulum. Prenatal and postnatal clinical and imaging records were reviewed.

Results: Prenatal sonography was unremarkable in all patients. Three males (ages 4 months, 10 months and 3 years) had no medical history of voiding dysfunction, and 1 female (11 years) had the Ehlers-Danlos syndrome. While the girl presented with urinary tract infection, all patients presented with progressively decreasing urinary stream and urinary retention. Each patient underwent voiding cystourethrography (VCUG) and ultrasound. In each patient VCUG showed a giant (greater than 7 cm) bladder diverticulum that descended below the bladder neck and compressed the urethra during voiding. Vesicoureteral reflux was seen in 2 patients. Ultrasonography demonstrated moderate unilateral hydronephrosis in 2 patients. Bladder diverticulectomy was successfully performed in all patients, with ureteral reimplantation in 3.

Conclusions: A giant congenital bladder diverticulum, when noted on VCUG to descend below the bladder neck, may lead to bladder outlet obstruction. To our knowledge we report the first case of a female presenting with bladder outlet obstruction due to a giant bladder diverticulum. Children with connective tissue disorders may be predisposed to this disorder, which must be excluded, regardless of gender, in all patients presenting with voiding abnormalities. Surgical diverticulectomy, often with ureteral reimplantation, is the preferred treatment, with excellent long-term results.

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COMPARISON OF HYPOSPADIAC AND NORMAL PREPUTIAL VASCULAR ANATOMY.

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Purpose: Data about the differences between the vascularization of normal and hypospadiac prepuce are lacking. We investigated the course of the preputial arterial blood vessels in normal controls and children with hypospadias by using transillumination, arterial methylene blue injection and 3-dimensional (3-D) reconstruction of serial histological sections focusing on arterial vessels.

Materials and Methods: Prepuce of 48 normal controls and 15 children with hypospadias was transilluminated by a front and back lighting technique and then photographed. All of the normal and 12 of hypospadiac prepuces not used for urethroplasty or penile body skin reconstruction were removed. The blood vessels of normal prepuce were also identified after arterial injection of methylene blue. Selected prepuce of normal controls and children with hypospadias was serially sectioned, and arterial and venous vessels were histologically distinguished. A 3-D computer reconstruction of the arterial system of normal and hypospadiac prepuces was performed.

Results: We confirmed the reliability of the transillumination technique to describe the arterial vascular anatomy of the prepuce by comparing the transillumination to methylene blue injection and 3-D reconstruction of histological sections. We classified the arterial vascular anatomy of normal prepuce as 1 artery predominant (41.67%), 2 arteries predominant (25%), H-type arching artery (12.5%) and net-like arterial system (20.83%). However, hypospadiac prepuce revealed a net-like arterial system more frequently (50%). We noted that the frequency of net-like arterial system was higher in more severe hypospadiac prepuce.

Conclusions: Understanding the differences between normal and hypospadiac prepuce vascular anatomy is germane to hypospadias surgery. The arterial blood supply of the hypospadiac prepuce is different than normal. A better knowledge of the vascular anatomy of the hypospadiac prepuce may improve the surgical results of hypospadias repair.

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LONG-TERM FOLLOWUP OF BUCCAL MUCOSA ONLY GRAFT FOR HYPOSPADIAS REPAIR: ANALYSIS OF COMPLICATIONS.

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Purpose: We review the long-term results of buccal mucosa onlay grafting for urethral reconstruction in hypospadias surgery in patients with followup of at least 5 years.

Materials and Methods: We retrospectively evaluated 132 patients who underwent buccal mucosa onlay graft for hypospadias repair, including 34 who underwent "salvage" grafting, during a 10-year period at our institution. In 49 cases with available followup longer than 5 years (average 6.2) complications were analyzed in detail.

Results: The overall complication rate was 24% (12 of 49 patients), with all but 3 complications occurring during the first postoperative year (3 fistulas, 1 stricture, 1 meatal stenosis, 2 graft contractures, 2 scars at oral harvesting site). The remaining 3 complications manifested during postoperative years 2 and 3, and encompassed 2 anastomotic strictures at the proximal anastomosis and 1 meatal stenosis.

Conclusions: Buccal mucosa onlay grafts for urethral reconstruction in hypospadias repair seem to provide stable long-term results, with complications occurring primarily during the first 12 months postoperatively.

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Bladder calculi after augmentation cystoplasty: risk factors and prevention strategies

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Purpose: Lower urinary tract reconstruction is an essential tool in the management of severely dysfunctional bladders in children. The incidence of calculi in augmented bladders has been reported in up to 50% of cases. We analyzed our experience with stone formation in this population to assess risk factors and outcomes.

Material and Methods: We performed a retrospective cohort study of all patients who underwent bladder augmentation from 1988 to 2002 at our institution. Patient demographics, risk factors and management were abstracted from the medical record.

Results: A total of 105 patients (58 males and 47 females) were identified. Ileum, colon and stomach were used in 37, 18 and 50 patients, respectively. Median age was 8.0 years. Median followup was 8.4 years. A total of 12 patients (11%) were found to have bladder calculi. Ten patients with ileum (27%), 1 with colon (6%) and 1 with stomach (2%) formed stones. All patients had recurrent urinary tract infections. Nine patients were successfully treated with an endoscopic procedure. Four patients (33%) formed recurrent stones despite saline bladder irrigations. One patient had multiple recurrences but is now stone-free on a daily regimen of 20% urea instillation.

Conclusions: Augmentation cystoplasty carries an overall low risk of bladder calculi. Gastrocystoplasty had a significantly lower rate of stone formation than augmentation with ileum and colon. Urinary tract infection is an independent risk factor for stone formation. Endoscopic management is safe and effective in the majority of patients and it may be facilitated by a percutaneous access. Recurrent stones form in some patients despite aggressive medical management.

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The value of your time: evaluation of effects of changes in medicare reimbursement rates on the practice of urology.

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Purpose: Several reforms to Medicare have changed the reimbursement of physicians from payment based on usual, customary or reasonable charges to a resource based relative value scale. We studied the effect of these changes on hourly reimbursement rates for various services provided by urologists.

Materials and Methods: We used a previously published national survey of urologists who provided information regarding physician time and work required before, during

and after most frequently performed urological services, including during the global period. For comparison mean operative times during the last year at our private hospital for several common urological procedures were obtained. Medicare reimbursement rates for common urological procedures and evaluation and management (E&M) codes for 1995, 1999 and 2004 were acquired from our department's billing office and used to calculate reimbursement rate per hour.

Results: There was a steady increase in reimbursement for outpatient services and a decrease in reimbursement for surgical procedures. For E&M codes the reimbursement rates per hour for 2004 represent a mean 51% increase since 1995. However, surgical procedures have had a mean decrease of 28.5% in reimbursement rates per hour. There was remarkable consistency in rates with 7 of the 9 surgical procedures losing between 25.5% and 32% in reimbursement. In 1995 outpatient E&M services were the least profitable at less than half the hourly rate of operative procedures. In 2004 office cystoscopy and transrectal ultrasound biopsy of the prostate had the highest reimbursement and, with the exception of shock wave lithotripsy, there was a minimal difference in hourly reimbursement rates between common surgical procedures and E&M services.

Conclusions: Changes in Medicare reimbursement during the last decade have resulted in significant changes in rates for different urological services. The near equity in reimbursement rates for E&M and surgical services will likely have an increasingly important role in the future practice of urology.

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A new approach to urology training:: a laboratory model for percutaneous nephrolithotomy.

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Purpose: The efficacy of traditional operating room based training of urology residents is being reevaluated. The development of hands-on laboratory practicums to facilitate the acquisition of skills by surgical residents lessens learning curves and hastens familiarity with tissue and instrument handling. We describe an innovative model for simulated percutaneous renal access and nephrolithotomy.

Materials and Methods: Porcine kidneys pre-implanted with artificial stone material were placed within intact chicken carcasses as a model for percutaneous nephrolithotomy. Urology residents were taught needle access, tract dilation and renal access sheath insertion using fluoroscopy. Training in percutaneous nephrolithotomy with the nephroscope, graspers and stone fragmentation methods followed.

Results: This simple, cost-effective model closely simulates percutaneous nephrolithotomy. Anonymous evaluations submitted by training session participants revealed a high degree of satisfaction with model effectiveness in the application of percutaneous renal access and nephrolithotomy techniques.

Conclusions: Our percutaneous nephrolithotomy laboratory model is an effective means of skills acquisition for a complex endourological procedure. Patient care can safely be of secondary importance with respect to trainee experience in a low stress environment that provides an opportunity for supervised, repetitive performance of essential technical skills. We describe an effective percutaneous renal access and nephrolithotomy surgical training model of original design.

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Prediction of successful outcome of microdissection testicular sperm extraction in men with idiopathic nonobstructive azoospermia.

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Purpose: Microsurgical techniques in testicular sperm extraction can improve sperm retrieval in patients with nonobstructive azoospermia (NOA). However, spermatozoa retrieval rates have still been reported to be around 50% for patients with NOA. Thus, a reliable prediction method for successful outcome is needed to avoid unnecessary surgery. In this retrospective study we determined the diagnostic and predictive values of noninvasive parameters used in the treatment of patients with NOA.

Materials and Methods: We analyzed 9 preoperative factors including patient age, testicular volume and endocrinological data of 100 patients with NOA using

multivariate logistic modeling. Testicular spermatozoa were retrieved successfully in 41 of the 100 patients (41%).

Results: We found that the concentrations of follicle-stimulating hormone (FSH), total testosterone (TT) and inhibin B were considered the most influential preoperative factors. We developed a formula to calculate the probability of successful outcome, $P = [1 + \exp(5.201 - 0.048 \times \text{FSH} - 0.449 \times \text{TT} - 0.021 \times \text{inhibin B})]^{-1}$. Association of predicted probabilities and observed responses was 0.77. A predicted probability of more than 15.7% was found to be the best cutoff. Sensitivity was 71.0% and specificity was 71.4% as determined by receiver operating characteristic analysis.

Conclusions: We concluded that our formula should be useful for doctors considering microdissection testicular sperm extraction for patients with NOA because our equation uses noninvasive parameters without a preoperative testicular biopsy, which is a relatively invasive examination.

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The presence of vasal vessels in men with congenital bilateral absence of the vas deferens.

RAMAN, JAY D.; GOLDSTEIN, MARC *

Purpose: We characterized spermatic cord microanatomy in men with congenital bilateral absence of the vas deferens (CBAVD) presenting for varicocelectomy. We discuss the implications of these findings for varicocele repair.

Materials and Methods: Between 1997 and 2003, 8 men with CBAVD underwent a total of 11 microsurgical subinguinal varicocelectomies at microsurgical epididymal sperm aspiration and cryopreservation. All 8 men had palpable grades II to III varicoceles and in 6 varicoceles were repaired due to painful symptomatology, while 2 had testicular hypotrophy with an abnormal hormonal profile. Three men had bilateral varicoceles repaired, while 5 underwent unilateral varicocelectomy. All patients provided a thorough history and underwent physical examination, hormonal evaluation, semen analysis, genetic testing and renal ultrasonography.

Results: Intraoperative microsurgical dissection confirmed dilated internal and external spermatic veins, and absence of the vas deferens in all 11 spermatic cords. Characteristic tortuous vasal vessels of normal caliber were clearly identified in all 11 (100%) of these spermatic cords between the internal and external spermatic fasciae in the location where the vas deferens is usually found.

Conclusions: Despite the absence of the vas deferens normal sized, orthotopically located vasal vessels were present in 100% of the spermatic cords examined. Furthermore, the caliber of the vasal veins was sufficient to provide adequate venous return from the testis following ligation of the internal and external spermatic veins. In patients with CBAVD presenting for varicocele repair standard microsurgical varicocelectomy with ligation of all internal and external spermatic veins can be performed without the risk of testicular congestion secondary to inadequate venous drainage.

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Randomized, double-blind placebo controlled trial of the once daily antimuscarinic agent solifenacin succinate in patients with overactive bladder.

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Purpose: In this phase 3 trial we assessed the efficacy of solifenacin 5 mg and 10 mg daily in patients with symptoms related to overactive bladder. In addition, we assessed the safety and acceptability of solifenacin.

Materials and Methods: The study was a multicenter, multinational, randomized, double-blind, placebo controlled trial. Patients were randomized to 12-week once daily treatment with solifenacin 5 mg, solifenacin 10 mg or placebo. The primary efficacy variable was changed from baseline to study end point in mean number of micturitions per 24 hours. Secondary efficacy variables included changes from baseline in mean number of urgency, nocturia and incontinence episodes per 24 hours, and mean volume voided per micturition.

Results: Compared with changes obtained with placebo (-1.59), micturitions per 24 hours were statistically

significantly decreased with solifenacin 5 mg (-2.37, $p = 0.0018$) and solifenacin 10 mg (-2.81, $p = 0.0001$). A statistically significant decrease was observed in the number of incontinence episodes with both solifenacin doses (5 mg, $p = 0.002$ and 10 mg, $p = 0.016$). This effect was also seen for episodes of urge incontinence (5 mg, $p = 0.014$ and 10 mg, $p = 0.042$). Of patients reporting incontinence at baseline, fully 50% achieved continence after treatment with solifenacin. Episodes of nocturia were statistically significantly decreased in patients treated with solifenacin 10 mg (-0.71, -38.5%) versus placebo (-0.52, -16.4%, $p = 0.036$). Episodes of urgency were statistically significantly reduced with solifenacin 5 mg (-2.84, -51%, $p = 0.003$) and solifenacin 10 mg (-2.90, -52%, $p = 0.002$). Mean volume voided per micturition was statistically significantly increased with both solifenacin doses ($p = 0.0001$). Treatment with solifenacin was well tolerated. Dry mouth, mostly mild in severity, was reported in 7.7% of patients receiving solifenacin 5 mg and 23% receiving solifenacin 10 mg (vs 2.3% with placebo).

Conclusions: In this study treatment with solifenacin 5 mg and 10 mg once daily significantly improved all the major symptoms of overactive bladder including frequency, urgency and incontinence. Solifenacin 10 mg also decreased the frequency of nocturia. Solifenacin therapy was associated with a favorable tolerability profile and a low incidence of dry mouth, especially at the 5 mg starting dose.

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Detrusor overactivity. Does it represent a difference if patients feel the involuntary contractions?

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Purpose: We evaluated the differences between patients with overactive bladder (OAB) who felt involuntary detrusor contractions during cystometry (detrusor overactivity [DO]) and those who did not feel them.

Materials and Methods: We prospectively studied 45 patients with symptoms of nonneurogenic, nonobstructed overactive bladder and with DO on cystometry. All patients underwent videourodynamics, the ice water test and electrical perception threshold

determination. Continence, urodynamic parameters, data from specific sensory evaluation and outcome of drug treatment were examined.

Results: Almost half of our patients did feel the contractions of DO and half did not. The groups differed significantly. Those without DO sensation were more frequently incontinent, had more involuntary detrusor contractions and these occurred earlier during bladder filling. They had involuntary start of voiding more frequently, more pathological sensation of bladder filling and lower electrical sensory thresholds. The results of drug treatment were better in the group who felt DO.

Conclusions: Contractions of DO are felt by some of the patients and they differ from those patients who do not feel such contractions. It is likely that this finding reflects the existence of different OAB conditions with a different neuropathological cause and a different treatment outcome. Therefore, we suggest that specific tests for the evaluation of sensation in the lower urinary tract should be part of the diagnosis of patients with DO and symptoms of OAB.

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OUTCOME OF RADICAL PROSTATECTOMY AND SHORT TERM FOLLOW-UP RESULT IN LOCALIZED CARCINOMA OF PROSTATE

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Summary :

Objective: To evaluate the short term result of retropubic radical prostatectomy performed by a single surgeon.

Patients and Methods: Between September 1999 to May 2005 thirty two radical retropubic prostatectomy was performed in the university hospital and a private hospital by the same surgeon. Only patients with histologically proven carcinoma prostate of Stage B or less were selected for radical prostatectomy. The patients were followed up regularly with IPSS score, PSA, Uroflowmetry, U/S scan and yearly bone scan and X-ray chest.

Results: The mean age was 58 years. Mean preoperative PSA was 13.5 and mean Gleason score was 5.8. Pre operatively all patients had low libido and significant erectile dysfunction. Mean operating time was taken 2.5 hours. Mean operative blood loss was 150ml. Incontinence was observed in 10 patients in the immediate post operative period of which improved over 3 months time and one eventually recovered in 9 months time. Erectile dysfunction was present in all the cases in the early post operative period. 13 patients were satisfied with the sexual function at three months after surgery. Ten patients were not bothered for the ED. Rest of the patients were given sildenafil citrate 50 mg to 100 mg before sexual intercourse and all showed a good response. The quality of life was assessed and found to be at a satisfactory level in all patients. The patients were followed up to 3 years and found to have bladder neck stricture in 3 cases which was incised with urethrotome and was placed in self dilation programme. There was a recurrence of carcinoma of prostate and was placed on radiation therapy resulting in a good control.

Conclusion: The challenges of incontinence and impotence were found to be overcome in radical retropubic prostatectomy for a localized carcinoma of prostate.

Introduction

Radical retropubic prostatectomy (RRP) is one of the major forms of therapy for localized prostate cancer. Through better anatomical description of the procedure

the morbidity has dramatically decreased. However, incontinence continues to be a significant morbidity in 0.5 -2.5% of patients. Other series with patients operated in an academic institutions indicate that nearly 30% of men wear pads or other devices to deal with incontinence after RRP. The incidence of incontinence is much reduced after introduction of improved techniques and modifications of the surgical technique. Some of the variance in the reported incidence may be related to the definition of incontinence, while other reasons may include patient rather physician reported assessments of incontinence.

Many published series have reported different factors that might be important in incontinence after RRP. These includes, membranous urethral length, bladder neck preservation, puboprostatic ligament (PPL) sparing, patient age, cavernous nerve sparing, seminal vesicle (SV) sparing, intussusceptions of the bladder neck, and control of the deep dorsal vein. None of these methods has been completely successful in eliminating incontinence. We present a combination of sequential, critical and technical steps in the Retro pubic prostatectomy with posterior bladder neck plication technique. We think this may leads to faster recovery of continence.

Patients and Methods

Between September 1999 and May 2005, 32 consecutive patients underwent RRP for clinically localized prostate cancer by same surgeon at our institution. None of the patient had history of incontinence before RRP. The urinary catheter was removed 10 days after RRP. Prospective data on continence were then obtained immediately and at 3, 6, 9, and 12 months after RRP. Incontinence was defined simply as the need to wear diapers, sanitary napkins or a device after RRP. Those patients who only occasionally wore one pad prophylactically before strenuous exercise were considered continent. This information was obtained using a questionnaire or interview.

* The article was presented in 9th National Scientific Conference, 24, June 2005; Dhaka, and awarded one of the best paper award.

Surgical Technique

The retropubic space is opened up through a suitable incision and the structures are displayed clearly. After incising the endopelvic fascia, the exposed fibers of the levator muscles are gently dissected off the sides of the prostate with careful blunt and sharp dissection. A plane is developed between the urethra and the dorsal vein complex. The dorsal vein complex is now divided in between ligature with # 2-0 Dexon / Vicryl. This may follow a brisk bleeding from the dorsal venous complex which can be easily controlled with a running 3/0 dexon or vicryl suture. This allows for a relatively bloodless field with excellent visualization of the rhabdosphincter, urethra and prostatic apex.

The ventral urethra is incised with a no 15 blade over the catheter, exposing the urethral catheter. The catheter is lifted out of the urethrotomy and then divided at its most distal portion between two clamps. The most distal clamp is held under tension, thereby exposing the dorsal part of the urethra, which is then incised sharply. If the nerves are to be spared (based on a preoperative pathological assessment) the fascia overlying the prostate is then removed high and laterally with a fine scissor dissection and the neurovascular bundle pushed posteriorly off the prostate. The rectourethralis and Denonvillier's fascia are separated sharply and a plane developed between the posterior surface of the prostate and the rectum. The lateral pedicle is taken between right angle clamps above the neurovascular bundles when the nerves are spared.

The Denonvillier's fascia over the vas deferens and seminal vesicles is incised; This technique decreases the risk of injury to the inferior hypo gastric plexus near the tip of the seminal vesicles¹². The vasa deferentia are identified, ligated and transected; they are separated from the seminal vesicles with diathermy scissors. The seminal vesicles are simply separated from the posterior surface of bladder by blunt dissection and with the aid of diathermy scissors. The seminal vesicles are dissected to their tip sharply and ligated at the feeding vessels under direct vision.

To preserve the bladder neck a marking suture at the bladder neck at the start of operation is extremely helpful. An incision at this level will expose the lumen. Allis clamps are placed at the bladder neck junction and held upwards, thereby aiding in the identification of the anterior prostate and the bladder neck. With continued blunt and sharp dissection, the prostate is removed with seminal vesicles and terminal portion of vas.

The bladder neck is properly fashioned by putting few interrupted stitches in the posterior end of the bladder neck admitting little finger. The mucosa of the prostatic urethra or bladder is then everted with a series of simple interrupted 4-0 dexon / vicryl sutures. This technique will help mucosa to mucosal anastomosis with the urethra.

A series sutures consisting of six 3-0 dexon / vicryl were placed in the urethra at 1, 3, 5, 7, 9 and 11 O' clock and properly marked. The sutures are now passed through the newly constructed bladder neck taking appropriate measure to carefully pass the sutures through in appropriate place to avoid any distortion. At this stage a three way 20 Fr. Foleys catheter is introduced and the balloon is inflated. The bladder is mobilized downwards aided by the traction on the Foleys catheter to approximate the bladder neck and the urethra. Finally, all six sutures are carefully tied down onto the urethra. Sterile irrigation is started and the bladder is filled to confirm water tight anastomosis. The wound is closed with a 12/14 fr drainage tube in the retropubic space.

Results

The mean age was 58 years and the youngest one was 40 years, who had familial incidence of prostate cancer. Mean preoperative PSA was 13.5 and mean Gleason score was 5.8. Almost all had significant low libido and erectile dysfunction. Mean operating time was 2.5 hours. Initially the time taken for the procedure was about four hours and subsequently the whole procedure could be completed in 1.5 hours with a mean operative blood loss of less than 150 ml. Incontinence was observed in 10 patients in the immediate post operative period which improved over 3 months time in all the cases except one case who eventually recovered in 9 months time. The incidence of incontinence in immediate post operative period was found to be reduced in latter cases in comparison to the initial ones.

In one patient the specimen removed found to have positive margin for carcinoma. Subsequently the patient was submitted to radiotherapy for local control of cancer. Erectile dysfunction was present in all the cases in the early post operative period. 13 patients were satisfied with the sexual function at three month after surgery. Ten patients was not bothered for the ED. Rest of the patient was given sildenafil citrate 50- 100 mg before sexual intercourse and all showed a good response.

The quality of life was assessed and was found to be at

a satisfactory level in all patients. The patients were followed up to 3 years and found to have bladder neck stricture in 3 cases which was incised with urethrotome and was placed in self dilatation programme. There was a relapse of carcinoma of prostate and was placed on radiation therapy with a good control of the recurrence.

Discussion

The method presented herein, we consider that the outcome of radical prostatectomy may lead to a better early continence and increased overall continence if careful dissection of the prostatic apex with avoidance of injury to the sphincter and continence nerves, careful seminal vesical dissection, bladder neck preservation and placing of the posterior plication of bladder neck. Each of these critical steps is important to achieve over all better continence rate. The PPL (posterior pubourethral ligament') is a pyramidal fascia that extends from the undersurface of the pubic symphysis to the anterior portion of the proximal membranous urethra and the prostatic apex. The dorsal vein complex passes between the pillars of this structure. In a small series, Poore et al. reported an improved early return of continence by using a PPL sparing procedure in 25 men, compared with a control group of 18 men who had a standard RRP¹. The median time for return of continence in these groups was 6.5 and 12 weeks, respectively. Although it is truly divided, we refer to this procedure as 'relative' sparing of the PPL, as the ligation is closer to the prostate, leaving the portion of the PPL, under the pubic symphysis intact. In addition, ligating the PPLs away from their insertion into the pubic symphysis may prevent inadvertent injury of the continence nerves (pudendal and pelvic nerve branches)¹². Although not used in our technique, incorporating the anastomotic sutures into this complex of tissue might further serve to support the anastomosis.

The importance of an intact and functional external urinary sphincter after prostatectomy cannot be overemphasized. In the incontinent patient, urodynamic studies show sphincter deficiency in 35-67% as the sole contributing factor and in 64-96% in combination with detrusor instability. We obtained control of the dorsal vein complex by developing a plane between the urethra and dorsal vein complex.

After ligating and dividing the dorsal vein complex, there is clear visualization of the prostatic apex, urethra and rhabdosphincter. This is partly because of the gentle earlier dissection by the sucker tip after incising the endopelvic fascia. Others have suggested the use of

finger dissection, which similarly separates the rhabdosphincter fibers from those of the levator ani muscle. The use of diathermy on a highpower setting serves as a theoretical form of trauma to the sphincter/continence nerves. Our results do not support a negative effect; this makes anatomical sense, as the continence nerves/ sphincter are well below. The careful seminal vesicle (SV) dissection previously described avoids critical nerves located just lateral to the SV at the junction of the lateral rectum. John and Hauri recently went a step further and in a prospective study assessed the SV preservation compared with standard RRP¹⁰. In this small pilot study, they showed that a SV tip sparing procedure gave early restoration of urinary continence. The SV tip sparing group had a 60% 6 week continence rate, compared with 18% in the standard RRP group. Although it is possible to use this SV tips paring procedure, we consider that our results indicate that the entire SV can be removed carefully without compromising the neural continence mechanism.

The bladder neck reconstruction and perfect eversion of mucosa ultimately serves to preserve the bladder neck and prostatic urethra. Numerous previous reports showed that preserving the bladder neck does not increase the likelihood of positive bladder neck margins. This 'internal' sphincter may or may not be important in early continence after RRP⁵ this issue has been controversial; It was stated that the bladder neck alone can maintain continence. In most instances, after a successful bladder neck peel, filling the bladder with sterile saline can show that the bladder is 'continent' at a capacity of 700 ml, with no leak. Although the scientific validation or the clinical significance of 'continent on the table' is unknown, we think that bladder neck sparing might improve early continence. This may be particularly true in those men where the external sphincter or the nerves that supply it are inadvertently traumatized. Recently, in a three armed study comparing the effects of bladder neck sparing, PPL sparing, and a combination of the two, Deliveliotis et al reported the significance of the bladder neck sparing procedure⁹. When comparing patients having bladder neck sparing or not, the former had significantly better earlier continence. The results of this study were statistically significant. The long term continence at 12 months was not significantly different among the three groups. These results might indicate that the contribution of bladder neck sparing could be greater than relative PPL sparing in the return of early continence.

The use of a posterior plicating suture incorporates the posterior lateral edges of the endopelvic fascia and reinforces the bladder neck. The suture is placed 3 cm from the everted edge of the bladder neck in the posterior aspect of the bladder. This imbrication procedure probably serves to prevent opening of the bladder neck as the bladder is filled. Whether or not this leads to an increased proximal urethral length is debatable. This step is similar to that recently described by Walsh. In Walsh's intussusception of the reconstructed bladder, posterior and anteriorly, 2 - 0 polyglyconate sutures are placed to secure the classic 'Tennis racket' closed bladder neck. The continence was 82% vs 54% in an earlier series of 64 men who had not had this bladder neck intussusception. The success of this variation may partly be a result of our use of the bladder neck sparing procedure vs the classic technique used by Walsh.

Others have described the use of various tube formations of the anterior bladder neck, with a statistically significant return of early continence. In both series, comprising 69 and 29 patients respectively, bladder neck retubularization led to an earlier return of urinary continence than in the control group. The bladder neck was resected and not preserved in both series, therefore prompting the need for tabularization. We consider that with bladder neck preservation, this step may be avoided. However, recently Poon et al., in a three armed group study, showed no difference in early return of continence when comparing bladder neck preservation, tennis racket reconstruction and anterior bladder tube reconstruction.

Radical Retropubic Prostatectomy in this series was undertaken by one surgeon in 32 consecutive patients, ensuring a more homogenous technique. The followup of all patients up to 24 months helped to assess the long term results.

Conclusion:

Continued advances in the understanding of the anatomy of prostate, urethra, external sphincter and continence nerves, the morbidity of incontinence after RRP has dramatically decreased. In the last decade, published reports have focused on techniques that help to increase early continence. Importantly, in most contemporary series with acceptable definitions of continence, continence rates are typically >92% at 1 year. This should be reassuring for the patient considering RRP

as a means of definitive therapy for prostate cancer.

In the present series of 32 consecutive patients, the overall continence rate was 100% at 24 months; compared with other recent series, this rate is favorable. Each step of the procedure is important in both early and long term continence. Although the independent contribution of each step to continence might be ill defined, the summation of steps helps to ensure a gradation of protection of continence. A randomized prospective study would be required to critically assess each step of the procedure. The ultimate decision of the technique used for Radical Retropubic Prostatectomy will probably be determined by the surgical training and comfort of the surgeon.

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CASE REPORT

LEFT URETERIC ENDOMETRIOSIS: A CASE REPORT

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A 38 year lady came to Urology outpatient department with complaints of left sided loin pain and occasional hematuria. She also complains of excessive pervaginal bleeding.

USG revealed bulky uterus, normal ovarian system. On October'2003 she underwent abdominal hysterectomy. But her left loin pain, occasional hematuria was not improved. She also complains of cyclical pervaginal bleeding even after hysterectomy.

She again evaluated on June'04, USG showed grossly dilated left kidney; IVU showed nonexcreting left kidney; renogram showed gross parenchymal insufficiency with poor function. She underwent urethroscoposcopic evaluation on September'04 and a ureteral polyp was found on left ureteric orifice and was biopsied. Histopathological examination revealed endometrial polyp.

URS was done on October'04 and D-J stent was given in same sitting with a view to improving renal

function on left side. After removal of stent renogram showed 15% split function on left side with gross parenchymal insufficiency. USG showed gross hydronephrosis and IVU showed nonexcreting left kidney.

She was referred to department of Obstetrics & Gynecology for pervaginal bleeding after hysterectomy and she was advised for transvaginal ultrasonography (TVS) & examination under anesthesia. TVS showed a mixed echogenic mass lesion in base of bladder involving left ureteric orifice containing small flecks of calcification & mass involves the stump.

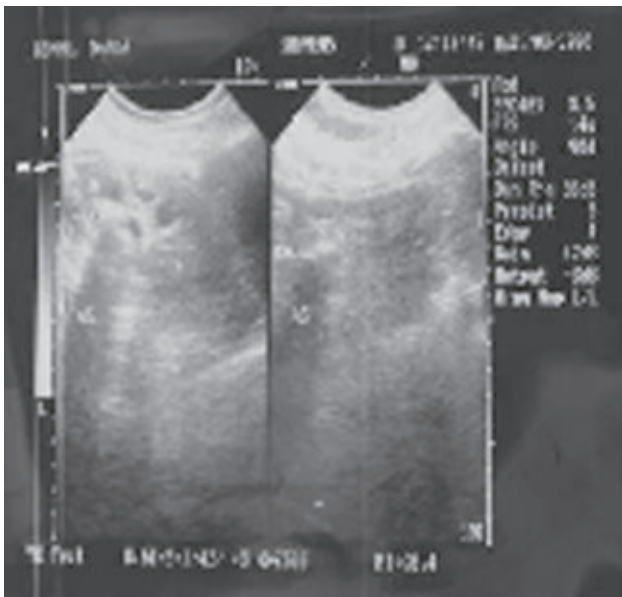


Fig-1 : USG shows gross hydronephrosis of left kidney.



Fig-2 : IVU shows non-excreting left kidney

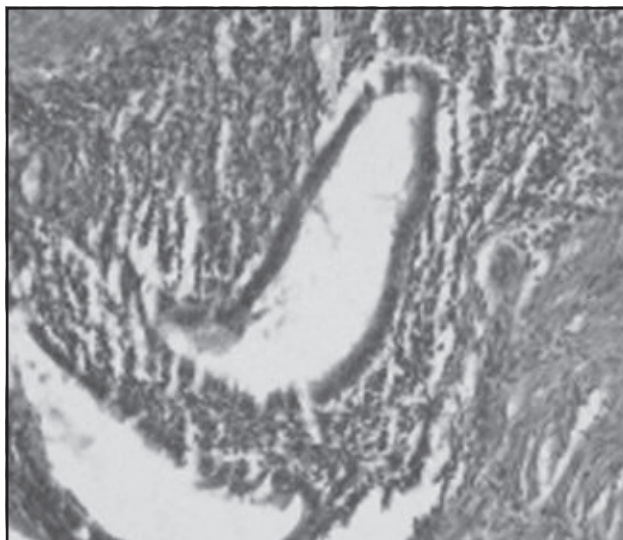
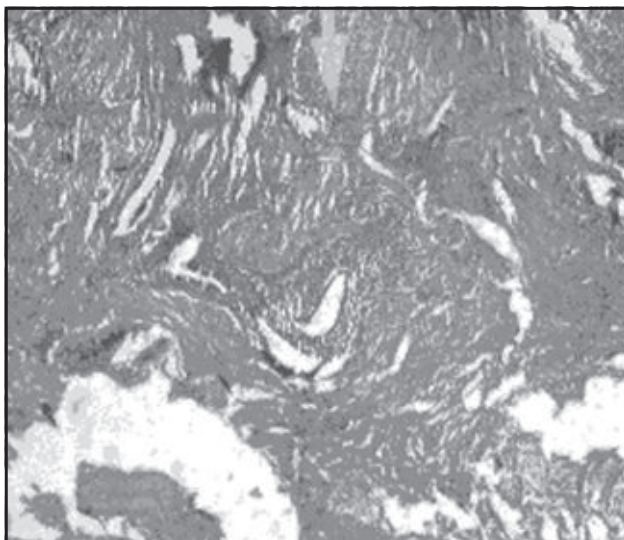


Fig-3 : low power (1x10) and high power (1x20) histopathology of endometriosis of left colonic superficial wall

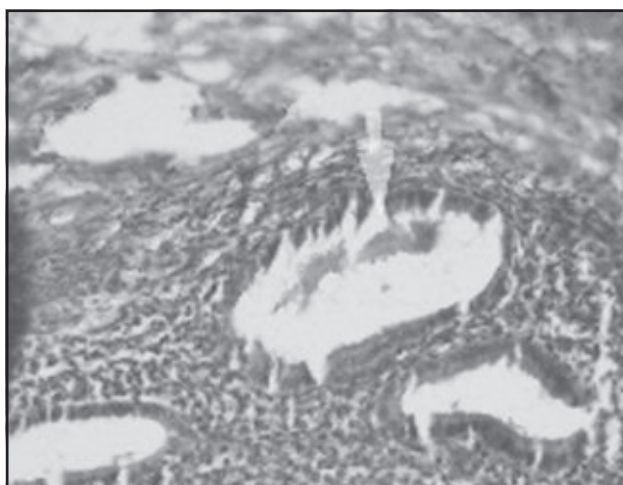
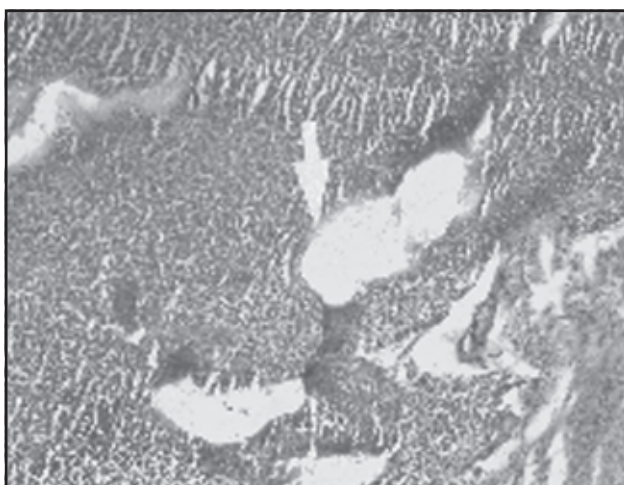


Fig-4 : low power(1x10) and high power (1x20) histopathology of endometriosis of lower end of left ureter

She underwent exploration for left nephroureterectomy. Peroperatively it was found that mass at the lower end of ureter involved the colonic superficial wall, unidentified tubular structure (suspected thrombosed gonadal vein), remaining stump of cervix. Gynecological surgeon examined under anesthesia and pervaginally removed some polypoid tissue by sponge holding forceps as well as vaginal lesion.

Endometriosis is a prevalent problem in premenopausal women with peak age incidence between 25 and 40 years.¹

Endometriosis occasionally involves the urinary tract, and a ureteral obstruction from this order constitutes a rare variant with serious consequences.²

Endometriosis may be extrinsic or intrinsic. Extrinsic involvement results from scarring, fibrosis and dense adhesion associated with the endometrioma and accounts for 75% to 85% of the reported cases.³ Intrinsic ureteric involvement by endometriosis is an exceedingly rare event.⁴ This case report describes intrinsic ureteric involvement by endometriosis and to some extent extrinsic endometriosis as well.

Hormone therapy with estrogen-progestin combination or danazol, a testosterone analogue, relieves the primary symptoms associated with endometriosis but only occasionally relieves the ureteral obstruction (Rivilin et al, 1985).⁵

The scarring and inflammatory reaction associated with the disease also make surgical correction of this problem difficult and hazardous. Surgical correction of endometriosis includes ureterolysis, ureteroureterostomy, ureteric reimplantation, psoas hitch and occasionally nephrectomy. Surgical correction can be done by laparoscopic procedure as well.

Nephrectomy is necessary in those patients with severe hydronephrosis, particularly if there is associated sepsis, the rate of which has been reported to vary from 13% to 44% (Moore et al, 1979).⁶ This case was treated by nephroureterectomy.

Ureteral endometriosis, especially intrinsic endometriosis, is usually silent and results in a high rate of renal loss before recognition, physicians should have a heightened awareness of this uncommon but serious manifestation of endometriosis.

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GENITAL RECONSTRUCTION OF ISOLATED MALE EPISPADIAS: OUR INITIAL EXPERIENCE

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Abstract:

Purpose: The purpose of this study was to evaluate our initial experience of genital reconstruction in patients with isolated male epispadias.

Methods: We performed genital reconstruction with isolated male epispadias on 12 patients between January 1996 and March 2005 in the department of paediatric surgery of Sylhet MAG Osmani Medical College Hospital. The operated procedure was done by modified Cantwell-Ransley epispadias repair technique. Demographic data, surgical reconstructions and their ultimate outcomes were analyzed.

Results: The mean age was 2.5 (SE±1.8) years, and 10 patients belonged to penopubic epispadias. Common complications encountered after repair of epispadias included urethrocutaneous fistula in 25% patients, stricture in 8.3% cases, and minor skin separation of dorsal penile skin closure in 8.3% patients. Reconstruction was successful and the postoperative course was uneventful in 7 (58.4%) cases.

Conclusion: Isolated male epispadias can be successfully repaired in a single stage procedure. With carefully planned and executed surgical procedures can lead to a relatively straight penis with a urethra of adequate caliber and minimum morbidity.

Key Words: Epispadias, Surgical reconstruction.

Introduction:

The term epispadias (Greek *epi* – upon, *spadon* – a rent) describes the malformation in the male in which the urethra opens on the dorsum of the penis.¹

Fortunately, Male epispadias is a rare anomaly, with a reported incidence of 1 in 117,000 males. Most male epispadias patients (about 70%) have complete epispadias with incontinence.² In affected boys, the penis is typically broad, shortened and curved toward the abdomen (dorsal chordee). The penis may be attached to the pelvic bones, which are widely separated, resulting in a penis that is pulled back toward the body. Unlike hypospadias, epispadias can be explained by defective migration of the paired primordia of the genital tubercle that fuse on the midline to form the genital

tubercle at the fifth week of embryologic development. Epispadias and exstrophy of the bladder are considered varying degrees of a single disorder. Another hypothesis relates the defect to the abnormal development of the cloacal membrane.

Classification of epispadias is based on the location of the meatus on the penis. It can be positioned on the glans (glanular), along the shaft of the penis (penile) or near the pubic bone (penopubic). The position of the meatus is important in that it predicts the degree to which the bladder can store urine (continence). The closer the meatus is to the top base of the penis, the more likely the bladder will not hold urine. With the glandular type, the malformation affects the distal part of the urethra. With the penile type, the entire penile urethra is affected, with an external meatus on the dorsal shaft of the penis. With the complete or penopubic type, a total deficiency of the dorsal wall of the urethra and the anterior wall of the bladder is present. The glans is often spatulated, and the prepuce is clefted dorsally with ventral transposition. All forms of epispadias are associated with chordee. The extent of chordee varies.

In most cases of penopubic epispadias, the bones of the pelvis are widely separated. This affects the bladder neck. In this situation, the bladder neck does not close and cannot store urine and the result is a constant dribble of urine. Most boys with penopubic epispadias and approximately two-thirds of those with penile epispadias have leakage of urine with stress (e.g., coughing and strenuous effort). Ultimately, they may require reconstructive surgery of the bladder neck. Almost all of the boys with glanular epispadias have a good bladder neck. They can hold urine and toilet train normally. However, the penis abnormality (upward bend and abnormal opening) still requires surgical repair.

The primary goals of treatment of epispadias are to: maximize penile length and function by correcting dorsal bend and chordee; and create functionally and cosmetically acceptable external genitalia with as few surgical procedures as possible. If the bladder and bladder neck are also involved, surgical treatment is required to establish urinary continence and preserve fertility.

There are two popular surgical techniques that achieve these objectives. The first is the modified Cantwell-Ransley urethroplasty technique, which involves partial disassembly of the penis and placement of the urethra in a more normal position.³ The second technique and most recent evolution of the modern epispadias repair is the Mitchell technique.⁴ It involves complete disassembly of the penis into its three separate components — two corpora cavernosa and a single corpus spongiosum. Following disassembly, the three components are reassembled such that the urethra is in the most functional and normal position and dorsal chordee is corrected. Both techniques provide a straight urethra positioned on the underside of the penis, correction of chordee and an acceptable cosmetic result.

The epispadiac penis can be constructed by the several methods, but the modified Cantwell-Ransley epispadias repair⁵ has enjoyed widespread application with the greatest success. We herein report our experience with aim to evaluate our initial experience of genital reconstruction in patients with male isolated epispadias.

Materials and Methods:

We performed genital reconstruction with isolated male epispadias on 12 patients between January 1996 and March 2005 in the department of paediatric surgery of Sylhet MAG Osmani Medical College Hospital. The operated procedure was done by modified Cantwell-Ransley epispadias repair technique. These patients had not under gone previous operations for epispadias. No other surgical procedures were performed at the time of the epispadias repair. Demographic data, surgical reconstructions and their ultimate outcomes were analyzed.

Surgical Technique:

All epispadias repairs were performed under endotracheal general anaesthesia. Fine noncrushing instruments, traction sutures and skin hook were used to minimize the surgical trauma to the genital skin. Adrenaline injection of 1:100,000 dilutions were used as a haemostatic aid; and, when necessary, meticulous pinpoint haemostasis was achieved with electrocautery. The modified Cantwell-Ransley procedure is begun by placing a 4/0 prolene island stitch through the glans as a traction stitch.

Incisions are made over two parallel lines marked previously on the dorsum of the penis that outline an 18-mm wide strip of urethral mucosa, extending from the prostatic urethral meatus to the tip of the penis (Fig.-1). For this procedure, a deep vertical incision (IPGAM) is made in the urethral plate distally. The incision is then closed with 6-0 polyglycolic sutures in

a transverse fashion in the Heineke-Mikulicz fashion. Glandular mucosal areas of the dorsal glans are excised adjacent to the urethral strip and thick glandar flaps are constructed bilaterally. Lateral skin flaps are mobilized and undermined. A Z-incision of the suprapubic area permits wide exposure. Ventral penile skin is taken down to the level of the scrotum.

Dissection of the corpora is begun ventrally with dissection on the surface of Buck’s fascia covering the corporal bodies. The plan is followed closely until one exits on the dorsum of the penis between the corpus spongiosum and the corporal body, first on one side and then on the other (Fig.-2). This almost separates the penis into three components, the two corpora and the urethral plate. However, complete penile disassembly is not undertaken, and the distal most 1-cm attachment of the mucosal plate to the glans is left intact.

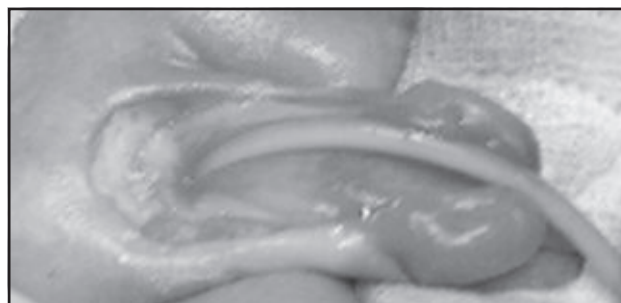


Fig.-1: *Parallel longitudinal incisions that outline an wide strip of urethral mucosa*



Fig.-2: *Dissection between the corpus spongiosum and the corporal bodies*

Then the urethral strip is closed in a linear manner from the prostatic opening to the glans over a No. 8 Fr silicone stent with 6-0 polyglycolic sutures. After this is accomplished, incisions are then made in the corporal bodies at the point of maximum curvature, opening a diamond-shaped effect in the erectile tissue. The corpora are then closed over the neourethra with two running sutures of 5-0 polydioxone, and the diamond-shaped defects in the adjacent area of the corpora are sutured to each other. This procedure effectively displaces the urethra ventrally in a normal position. The glans wings are then closed over the glandular urethra using 5-0 polyglycolic sutures. The ventral skin is then brought up and sutured to the ventral edge of the corona, and the flaps are fashioned to provide adequate coverage and lengthening of the dorsum of the penis. The skin is reapproximated with interrupted 5-0 polyglycolic sutures. A Z-plasty at the base of the penis is closed with interrupted 5-0 polyglycolic acid sutures.



Fig.3: A Z-plasty at the base of the penis is closed

A stent is left indwelling in the neourethra to provide drainage for 10 to 12 days. The dressings remain in place for 4 days if no problems occur. Remove the diverting urinary catheter after 8-10 days. Discharge the patient after removal of the urinary diversion and when spontaneous voiding occurs without difficulty. The patient was followed-up initially 2 weeks after discharge from hospital, thereafter at 1, 3, 6 months, and then yearly. All patients were treated and followed in the same institution.

Results:

Age range from 1.5 years to 12 years and the mean age was 2.5 (SE±1.8) years (Table-I). Of the 12 epispadias patients, 10 (83.3%) patients belonged to penopubic epispadias and 2 (16.7%) had penile epispadias at presentation (Table-II). Reconstruction was successful and the postoperative course was uneventful in 7 (58.4%) cases. These patients had a horizontal or downward-angled penis while standing and the appearance of the penis was acceptable to both parents and children.

Common complications requiring re-operation occurred in five patients (41.6%), of whom three (25%) developed urethrocutaneous fistula, one (8.3%) had urethral stricture of the proximal anastomotic site, and one (8.3%) had minor skin separations of the dorsal skin closure. The fistula was repaired successfully in two boys and one is awaiting for surgery.

Table-I
Age Distribution (n=12)

Age group	Number	%
Before 2 years	02	16.7
2 years– 4 years	06	50.0
4 years – 8 years	02	16.7
8 years – 12 years	01	8.3
Above 12 years	01	8.3

Table-II
Types of Epispadias (n=12)

Type	Number	%
Penopubic	10	83.3
Penile	2	16.7
Glandular	0	0
Total	12	100

Discussion:

Normally, the meatus is located at the tip of the penis; however, in boys with epispadias, it is located on top of the penis. From this abnormal position to the tip, the penis is split and is opened, forming a gutter. It is as if a knife was inserted into the normal meatus and the skin stripped away on the top of the penis. Male epispadias has been categorized by the location of the urethral meatus into complete epispadias (penopubic or subsymphyseal epispadias), penile epispadias, and

glandular (balanitic) epispadias. Of these locations, the complete variety is the most common and glandular is the least common.¹ In the present study, 83% (10) patients belonged to penopubic epispadias and 17% (2) had penile epispadias at presentation, which is similar to other studies.^{6,6} Mollard P, Basset T, Mure PY: Male epispadias: experience with 45 cases. *J Urol* 1998; 160(1): 55-59

The penis is formed by the corpus spongiosum surrounding the urethra and by 2 corpora cavernosa. These structures are composed of erectile tissue surrounded by the tunica albuginea (Buck fascia) and the dartos fascia more superficially, which contains terminal branches of external pudendal arteries and veins and the superficial lymphatics. Patient anatomy, surgeon preference, previous surgical procedures, availability of tertiary care facilities, and access to medical care all play a role in which operative procedure is chosen for a particular patient. None of the current epispadias repairs offer any significant gain in penile length by removal of the entire urethral plate from the glans or even the use of a free graft. Some authors have advised even more aggressive techniques than those proposed originally by Cantwell. Mitchell and Bagley (1996) described a complete penile disassembly technique in which the epispadiac phallus is completely disassembled into three components: the urethral plate and the right and left hemicorporal glandular bodies.⁴

Correction of dorsal chordee can be achieved with corporal rotation, cavemocavernostomy or medial corporal rotation ventrally. In our series, we have observed that the modified Cantwell-Ransley repair effectively corrects corporal chordee and adds some penile length. Persistent dorsal chordee is fairly typical with older reconstructive techniques for epispadias. It is now less common with newer treatment techniques. Epispadias repair does little harm to erectile function.⁷

Controlling bladder spasms is dominant because they are associated with more urinary extravasation and fistula formation. An urethrocutaneous fistula used to be quite common after a major epispadias repair. In present study, three (25%) developed urethrocutaneous fistula, one (8.3%) had urethral stricture of the proximal anastomotic site, and one (8.3%) had minor skin separations of the dorsal skin closure, which findings compare critically with the other series.^{8 & 9} The higher incidence of fistula formation in our studies most likely reflects necessary of controlling bladder spasms and leg restraints postoperatively.

Conclusion:

Children born with isolated epispadias can be successfully surgically corrected in a single stage procedure. With carefully planned and executed surgical procedures can lead to a relatively straight penis with a urethra of adequate caliber and minimum morbidity.

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A DOSE RANGING STUDY OF THE EFFICACY AND SAFETY OF TAMSULOSIN IN PATIENT WITH SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA

M HOSSAIN¹, MS ISLAM¹, AKMK ALAM¹, S ISLAM¹, ATM AMANULLAH¹, SA KHAN², AZM Z HOSSAIN²

ABSTRACT

Objective: The present Placebo controlled dose ranging study was done to evaluate the efficacy and tolerability (safety) of Tamsulosin at doses 0.2 mg, 0.4 mg and 0.6 mg once daily for 4 weeks. The aim of this study is to establish the optimum dose of Tamsulosin and to determine the efficacy and safety of the drug and dose response relationship of the drug comparing the effect with Placebo. Methods: This study was conducted on purposively selected 120 cases with lower urinary tract symptoms associate with benign prostatic hyperplasia. All the cases were selected as per selection criteria and were evaluated initially and 1st week (1st visit), 2nd week (2nd visit) and 4th week (3rd visit) case and control were evaluated by history, physical examination, IPSS scoring by determining peak urinary flow rate, voiding time, measuring post voidal residual urine volume by transabdominal ultrasonogram. During study period drug emergent adverse events were looked for.

Results: The result of the present dose ranging study has established that Tamsulosin 0.4 mg once daily is the optimal dose for the treatment of lower urinary tract symptoms associated with BPH. The efficacy of Tamsulosin were determined by IPSS, peak urine flow rate, voiding time and post voidal residual urine volume. The result indicated that there is a dose response relationship up to 0.4 mg after 4 weeks of therapy. There were changes from base line in Tamsulosin 0.2mg group but these were smaller than those of 0.4mg, whereas the changes in the Tamsulosin 0.6 mg were comparable to those seen in the 0.4 mg.

Conclusion: Tamsulosin is well tolerated and overall incidence of adverse events is similar in Tamsulosin 0.4 mg group and Placebo treated group. More adverse events were reported by patient in the Tamsulosin 0.6 mg group. The most common adverse events were asthenia, dizziness, headache, rhinitis and abnormal ejaculation. The only adverse event that occurred significantly more (3.33%) with Tamsulosin 0.4mg than with Placebo was abnormal ejaculation which was still more (10%) with 0.6mg of Tamsulosin recipient group.

Introduction

Benign Prostatic Hyperplasia (BPH) is a common disease among elderly men and its prevalence increases with age¹ Prostate size has limited clinical significance². Digital rectal examination provides an estimate of prostate size but not accurately. The enlarged transition zone volume can be quantified using transrectal ultrasonography³. There is no guidance regarding the extent of enlargement required to establish the diagnosis of BPH. Although BPH is a histological diagnosis, it can cause benign prostatic enlargement and benign prostatic obstruction (BPO) leading to a variety of lower urinary tract symptoms, often referred to as 'symptomatic' benign prostatic hyperplasia⁴. About 1 in 4 men aged 50 years and over have this condition for which TURP is the most common treatment. However, there is increasing interest in the use of drug therapy rather than surgical intervention, especially in patient with mild to moderate symptoms, in patient who are unable or unwilling to undergo surgery, or in those awaiting surgery^{5,6,7}.

The symptoms of BPH are caused by mechanical and dynamic obstruction of urine flow. The mechanical obstruction is due to compression or intrusion into the urethra by the enlarging nodule of the prostate or by protrusion of the median lobe of prostate into the bladder neck and leading to higher bladder outlet resistance. Dynamic obstruction is caused by increased muscle tone of the bladder neck and prostate, which is regulated by α_1 -adrenergic receptor⁸.

There are many options for treatment of symptomatic BPH like watchful waiting, medical therapy with α -receptor blockers and 5 α -reductase inhibitor, phytotherapy and surgical treatment including minimally invasive therapy. Efficacy of treatment represents the effect of a treatment on symptoms and urinary flow. Symptoms are best assessed by IPSS and peak urine flow rate⁹. Watchful waiting should be considered when a symptom is mild (0-7). Medical treatment is usually chosen, when there are moderate symptoms and no absolute indication for surgical intervention⁷. Medical treatment for BPH may be in the form of α_1 – receptor

blocker or 5 α reductase inhibitor (finasteride). But it is now well known that α_1 – receptor blockers (like Tamsulosin) is safe and more effective than 5 α reductase inhibitor or the combinations of the two¹⁰.

Tamsulosin is a new α_{1A} -adrenoceptor antagonist that is selective for the α_{1A} -adrenoceptor subtype predominantly present and functional in the human prostate^{11,12,13,14}. Furthermore, it appears to be a more selective inhibitor of α_1 -adrenoceptor in human prostatic tissues than in vascular tissues¹⁵. Therefore, Tamsulosin is the first 'prostate selective' α_1 -adrenoceptor antagonist for BPH. It is available in a modified release formulation which has a long elimination half life of 10-13 h, enabling once-daily dosing¹⁶. Tamsulosin 0.1-0.4 mg administered once daily has been shown to be effective in Japanese men with 'symptomatic BPH'. Moreover, it can improve urinary flow and symptoms without causing clinically significant adverse effects on blood pressure and heart rate¹⁷.

The primary aim of this study was to evaluate the efficacy and safety of Tamsulosin in a dose ranging study and to establish the optimum dose of Tamsulosin for patient with symptomatic benign prostatic hyperplasia to be administered in subsequent phase II clinical studies in Europe⁷.

Comparative data have shown that Tamsulosin is as effective as other α_{1a} -adrenoceptor antagonists by increasing Q_{max} and improving symptom scores. Considering all these factors, a hypothesis was formulated: Tamsulosin (α_{1a} -adrenoceptor blocker) is well tolerated (safe) and effective in improving urinary flow rate and relieving lower urinary tract symptoms (LUTS) in patient with symptomatic benign prostatic hyperplasia (BPH) and response of Tamsulosin is dose related¹⁷.

Methods

This was a prospective purposive case control study, conducted in the out patient department of Urology, Dhaka Medical College Hospital, Dhaka from July 2002 June 2004. Total 132 cases were selected purposively according to selection criteria. The selection criteria were - male patient between 50 to 85 years of age with LUTS suggestive of Benign Prostatic Hyperplasia with IPSS score 8 to 19, Peak urine flow rate (Q_{max}) 10-15 ml/sec for a voided volume of 200 ml or more, Post voidal residual urine volume 50-200 ml (by trans abdominal ultrasonogram). The exclusion criteria were refractory urinary retention, carcinoma prostate,

neurogenic bladder, patient undergone surgery to the bladder neck of prostate, urethral stricture, bladder stone, severe diverticulum of the bladder, urinary tract infection which might affect micturition, renal or hepatic insufficiency, ventricular arrhythmias, heart failure, orthostatic hypotension, senile dementia, stroke with in last six months, Patient taking other α -adrenoceptor antagonist, combined a/b-adrenoceptor antagonist, α -adrenoceptor agonist that might interfere the study medication, patient on antidepressant drugs and neuroleptics drugs. Among them 12 cases were not reported at time of base line investigation. Rest 120 cases were divided sequentially into 4 groups, each group comprising 30 cases i.e. 1st case were put in Group-A, 2nd case in Group-B, 3rd case in Group-C and 4th case in Group-D. This sequence was followed among patient of this study group. Tamsulosin 0.2mg was given to each cases of Group-A, Tamsulosin 0.4mg to Group-B, Tamsulosin 0.6mg to Group-C and placebo was given to cases of Group-D.

Each of the patients continued the therapy for four weeks and was followed up at 1st week (1st visit), 2nd week (2nd visit) and 4th week (3rd visit). Before starting the treatment, all the patients were thoroughly evaluated by history, physical examination, and laboratory workup for base line records.

All history and examinations followed a similar protocol. Informed consent was taken from all patients. A detail data sheet was completed and this included particulars of the patient – history, results of physical examinations and relevant baseline investigations. From the supplied sheet IPSS Symptom Score was determined.

After starting the dose of Tamsulosin and Placebo, each patient was then observed and followed up at 1st week (1st visit), 2nd week (2nd visit) and 4th week (3rd visit) of treatment. On each follow up visit, each patient was evaluated by history to find out any adverse event like, dizziness, headache and dyspnoea, and blood pressure recording to see hypotension. IPSS were also recorded and uroflowmetry was done to see the flow of urine and voiding time. Ultrasonography was done to see post voided residual urine volume.

Efficacy was based on the changes from baseline in symptoms, urinary flow rate and amount of post voidal residual urine.

Throughout the study safety was assessed by monitoring adverse events and vital signs (blood pressure and pulse rate both supine and standing). Using a questionnaire,

patient were also asked about the occurrence of a specific series of pre-determined symptoms (adverse events) which included dizziness, nasal stuffiness, blurred vision, skin rash, changes in bowel habit, joint pain, sleepiness, ringing in ears.

Results

Total 132 cases were selected purposively according to selection and exclusion criteria with lower urinary tract symptoms due to benign prostatic hyperplasia. Among them 12 cases were not reported at time of base line investigation.

In group-A, among 30 cases, 10(33.0%) cases were between 50-59 yrs, 14 (47.0%) cases were between 60-69 yrs and 6 (20%) cases were between 70-85 yrs of age. In group-B, among 30 cases, 11(36.67%) cases were between 50-59 yrs, 15(50%) cases were between 60-69 yrs and 4(13.33%) cases were between 70-85 yrs of age. In group-C, among 30 cases, 10(33.33%) cases were between 50-59 yrs, 13(43.33%) cases were between 60-69 yrs and 7(23.33%) cases were between 70-85 yrs of age. In group-D, among 30 cases, 10(33.33%) cases were between 50-59 yrs, 15(50%) cases were between 60-69 yrs and 5(16.67%) cases were between 70-85 yrs of age. Age of the patients of each group were compared and found no significant difference.

Age distribution of the Patients

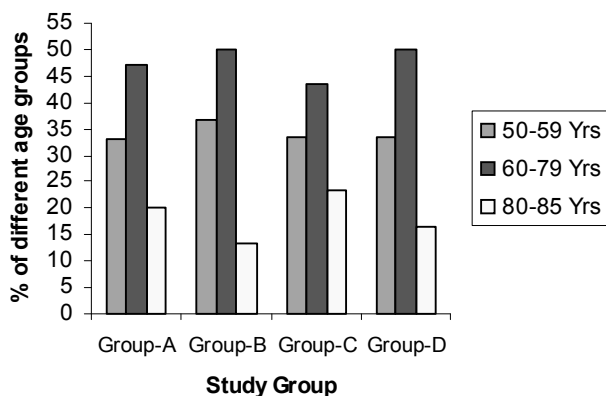


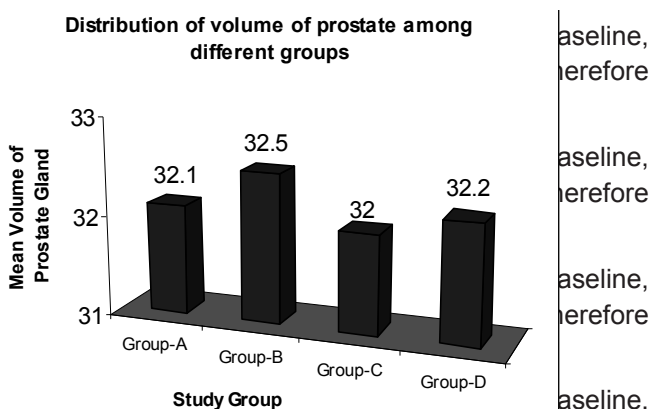
Fig.-01: Bar diagram is showing age distribution of patients among 4 groups.

- Group-A – patients receiving 0.2 mg Tamsulosin.
- Group-B – patients receiving 0.4 mg Tamsulosin.
- Group-C – patients receiving 0.6 mg Tamsulosin.
- Group-D– patients receiving Placebo

Volume of the prostate of each patient was measured by trans abdominal ultrasonogram and were compared.

The range of volume of prostate gland were 28-35 (mean 32.1+1.2) ml in group-A, 27-36 (mean 32.5+1.01) ml in group-B, 26-35 (mean 32+0.75) ml in group-C and 26-36 (mean 32.2+1.1) ml in group-D. There is no significant difference observed in volume distribution among cases and control.

Fig.-02: Bar diagram showing distribution of volume of the prostate of patients among 4 groups.



change of mean IPSS was 0.20+2.54.

Mean change of IPSS in Group-A was 0.20+0.41, in Group-B was 5.20+1.19, in Group-C was 5.40+1.22 & in Group-D was 0.20+0.41.

Hence a significant improvement of IPSS was found after 4 weeks of treatment with 0.4 mg of Tamsulosin (Group-B) and with 0.6 mg Tamsulosin. The change was found statistically significant (P=<.001). Again very minimum change of IPSS was observed between patient taking 0.4 mg of Tamsulosin (Group-B) and patients taking 0.6 mg Tamsulosin (Group-C).

Table-01

Changes in IPSS from baseline to end point during the treatment.

IPSS	Tamsulosin		Placebo	
	Group-A (n=30)	Group-B (n=30)	Group-C (n=30)	Group-D (n=30)
Baseline	15.80+1.44	15.00+1.75	14.80+1.75	15.00+1.44
End Point	14.00+1.37	9.80+0.81	9.40+1.22	14.80+1.35
Change	0.80+0.41	5.20+1.19	5.40+5.93	0.20+0.41
% Change	1.37+2.59	34.78+4.34	36.31+5.93	1.25+2.54
P Value	<0.05	<0.001	<0.001	<0.05

Mean change of IPSS of each group was determined and compared by 'paired student t test'. Again mean change of IPSS among the patients taking Tamsulosin was compared and tested by ANOVA.

Baseline = Score determined before starting the dose of Tamsulosin or Placebo.

End point = Score determined 4 week after the treatment with Tamsulosin or Placebo.

Change = Mean change of International Prostate Symptom Score determined 4 week after the treatment with Tamsulosin or Placebo.

Table- 02

Changes in peak urine flow rate (Q_{max}) from baseline to end point during the treatment.

Q_{max}	Tamsulosin		Placebo	
	Group-A (n=30)	Group-B (n=30)	Group-C (n=30)	Group-D (n=30)
Baseline	10.82+1.42	10.40+1.04	11.40+1.04	10.60+1.22
End Point	10.60+1.22	14.73+1.26	15.70+1.21	10.80+1.49
Change	0.22+0.78	4.33+1.75	4.30+1.60	0.20+0.41
% Change	2.11+7.57	43.20+20.22	42.70+18.70	1.67+3.39
P Value	<0.05	<0.001	<0.001	<0.05

Fig.-04 : Bar Diagram is showing changes in Q_{max} among the patients according to baseline Q_{max} distribution of the patients of 4 groups

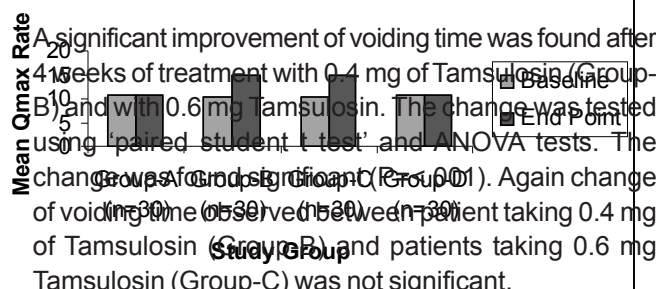


Fig.-03: Bar diagram is showing changes in IPSS from baseline to end point during the treatment.

Mean change of peak urine flow rate (Q_{max}) in Group-A was 0.22+0.78, in Group-B was 4.33+1.75, in Group-C was 4.30+1.60 & in Group-D was 0.20+0.41.

Hence a significant improvement of Q_{max} was found after 4 weeks of treatment with 0.4 mg of Tamsulosin (Group-B) and with 0.6 mg Tamsulosin. The change was found significant ($P<.001$). Again change of Q_{max} observed between patient taking 0.4 mg of Tamsulosin (Group-B) and patients taking 0.6 mg Tamsulosin (Group-C) was not significant.

Table- 03

Changes in voiding time from baseline to end point during the treatment.

Voided Time	Tamsulosin		Placebo	
	Group-A (n=30)	Group-B (n=30)	Group-C (n=30)	Group-D (n=30)
Baseline	65.20+2.57	63.20+1.29	62.40+1.04	65.00+2.57
End Point	64.80+2.75	55.60+1.38	54.80+1.19	64.80+2.68
Change	0.40+0.72	7.60+0.50	7.60+1.38	0.20+0.41
% Change	0.62+1.13	12.03+0.86	12.16+2.08	0.31+0.64
P Value	<0.05	<0.001	<0.001	<0.05

The adverse events observed in study period in Group-C (23.33%) was very much higher than other groups. Hence the difference between the groups were significant.

Figure 05 : Bar Diagram is showing changes in voiding time from baseline to end point during the treatment.

Statistically significant reduction of PVR was found after 4 weeks of treatment with 0.4 mg of Tamsulosin (Group-B) and with 0.6 mg Tamsulosin (P=<.001). Again change of PVR observed between patient taking 0.4 mg of Tamsulosin (Group-B) and patients taking 0.6 mg Tamsulosin (Group-C) was not significant.

Table- 04

Changes in PVR from baseline to end point during the treatment.

PVR	Tamsulosin		Placebo	
	Group-A (n=30)	Group-B (n=30)	Group-C (n=30)	Group-D (n=30)
Baseline	107.80+9.95	119.00+5.93	114.00+8.75	108.80+9.95
End Point	103.17+9.92	50.50+3.04	50.17+6.76	110.80+8.90
Change	4.63+2.67	68.50+6.45	63.83+10.88	2.00+4.07
% Change	4.26+2.41	57.47+3.28	55.75+6.86	2.00+4.07
P Value	<0.001	<0.001	<0.001	<0.05

Figure 06 : Bar diagram is showing changes in PVR from baseline to end point during the treatment.

Table-05

Adverse effects observed in different study groups (Tamsulosin and Placebo).

Adverse effects	Tamsulosin		Placebo	
	Group-A (n=30)	Group-B (n=30)	Group-C (n=30)	Group-D (n=30)
Postural	0	0	0	0
Hypotension				
Dizziness	0	0	1	0
Headache	1	1	1	1
Rhinitis	1	1	1	1
Asthenia	0	0	1	0
Abnormal	1	1	3	0
Ejaculation				
Total	3	3	7	2

Adverse effects observed in different study groups (Tamsulosin and Placebo)

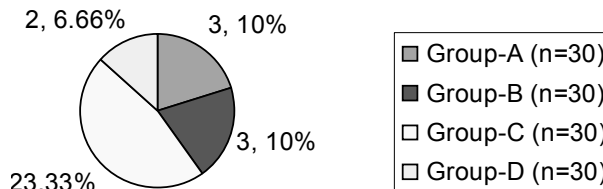


Figure-07: Pie diagram showing adverse effects observed in different study groups (Tamsulosin and Placebo).

Discussion

Recently most of the urologist in Bangladesh has been using Tamsulosin for the medical treatment of BPH. Present study was done to determined the optimum dose, efficacy and safety of the drug. In this study, 0.2 mg, 0.4 mg and 0.6 mg of Tamsulosin and a Placebo tablet were given to 120 patients and were followed up for 4 weeks to determine the optimum dose, efficacy and safety of the drugs. The same type of dose ranging study was done in 1997 with 0.2 mg, 0.4 mg & 0.6 mg once daily for 4 weeks in 126 men with lower urinary tract symptoms associated with BPH. Study was done

to establish the optimum doses of Tamsulosin and to evaluate the efficacy and safety of the drugs ¹⁹.

In this study, all cases were purposively selected with age ranging from 50-85 years who has been suffering from lower urinary tract symptoms due to benign prostatic hyperplasia. The age range of the separate study done in 1997 was 50-85 years and had a diagnosis of lower urinary tract symptoms suggestive of BPO ¹⁹. Another study was done to see the efficacy of Tamsulosin on patient suffering from lower urinary tract symptoms due to BPH in 27 men age ranging from 57-86 years ²⁰. Efficacy and safety of α_1 -blocker was studied in a separate series in 1992 on 421 men age ranging 50-75 years with symptoms of BPH ²¹.

In this study, the range of volume of prostate gland as assessed by trans abdominal ultrasonography was 28-36 ml. Prostatic volume between 28.2 ml and 34.1 ml were observed in a study done by Abrams P. et. al. in 1997 which is the similar to the present study¹⁹.

Mean change of IPSS after 4 weeks of treatment in Group-A was 0.20+0.41, in Group-B was 5.20+1.19, in Group-C was 5.40+1.22 & Group-D was 0.20+0.41. IPSS was significantly decreased to 34.7+4.34% in Group-B and in Group-C decreased to 36.31+5.9. But in Group-A & in Group-D a negligible change of IPSS 1.37+2.58% & 1.25+2.54% respectively were observed.

Mean change of AUA symptoms score was found 6.8+1.7 after 4 weeks of treatment with Tamsulosin (0.4mg) in a study done on 27 men suffering from lower urinary tract symptoms due to BPH ²⁰.

Tamsulosin (0.4 mg) was found to produced is significant improvement in IPSS by 35.8% reduction than did in Placebo 23.7% (P=<0.002) ¹⁸.

Effect of Tamsulosin was again observed in a separate study by evaluating change of IPSS with 0.4 mg Tamsulosin after 4 weeks of treatment. The mean change of IPSS was 9-20% ²².

Mean change of Q_{max} in Group-A was 0.22+0.78 (2.11+7.57%), in Group-B was 4.33+1.75 (43.20+20.22%), in Group-C was 4.30+1.60 (42.70+18.67%) & in Group-D was 0.20+0.41 (1.67+3.39%). The main measure of the efficacy of Tamsulosin were the effects on urinary flow rate which was measured by Peak Urine Flow Rate (Q_{max}). In this study maximum improvement of Q_{max} was found in Group-B (with 0.4 mg of Tamsulosin) by 43.20+20.22% and in Group-C (with 0.6 mg of Tamsulosin) by 42.70+18.67%. But negligible change of Q_{max} were

observed in Group-A (with 0.2mg of Tamsulosin) by 2.11+7.57% and in Group-D (with Placebo) by 1.67+3.39%.

The mean change of Peak Urine Flow (Q_{max}) were also observed in a dose ranging study done on 126 men with lower urinary tract symptoms due to BPH and maximum improvement of Q_{max} (2.2 ml/sec) was observed after 4 weeks of treatment with 0.4 mg of Tamsulosin and 1.8 ml/sec in patient receiving 0.6 mg of Tamsulosin for 4 weeks. But mean change of Q_{max} was 1.2 ml/sec in patient receiving 0.2mg of Tamsulosin and 0.1 ml/sec in patient receiving Placebo were observed ⁷.

The mean Q_{max} significantly improved from 7.8+3.5 ml/sec at base line to 9.80+3.5 ml/sec after 1 week of treatment and improved further to 10+3.8 ml/sec after 2 weeks and 11.1+3.5 ml/sec after 4 weeks of treatment with 0.4 mg Tamsulosin once daily. Thus the efficacy of Tamsulosin was shown by the improvement of from base line to end point of treatment after 4 weeks ²⁰.

A randomized Placebo control, 4 weeks multi center Japanese trial in 218 patient with lower urinary tract symptoms showed mean percentage increase in Q_{max} base line were statistically significant with Tamsulosin 0.1 to 0.4 mg per day but not with Placebo ¹⁷.

The main measures of the efficacy of Tamsulosin were effects on peak urine flow (Q_{max}) and on International Prostate Symptoms Score (IPSS). In this study significant increase of Q_{max} (4.43 ml/sec) and decrease in IPSS (5.20) occurred after 4 weeks in patients receiving 0.4 mg Tamsulosin. Changes in IPSS (5.40) & in Q_{max} (4.30 ml/sec) with 0.6 mg of Tamsulosin per day. Therefore, no significant better effect were observed with 0.6 mg of Tamsulosin. Changes in IPSS (0.2) and in Q_{max} (0.22 ml/sec) occurred in patients receiving 0.2 mg of Tamsulosin per day. Change in IPSS (0.2) and in Q_{max} (0.2 ml/sec) occurred in patients receiving Placebo. Hence no significant changes in IPSS and in Q_{max} were observed between Placebo & 0.2 mg of Tamsulosin group. The results indicated that there is a dose response relationship for Tamsulosin up to 0.4 mg, after 4 weeks of therapy there were changes from base line in the Tamsulosin 0.2 mg group, but these were smaller than those with 0.4 mg, whereas the changes in the Tamsulosin 0.6 mg were comparable to those seen in the 0.4 mg group ¹⁹.

Mean change of voiding time in Group-A was 0.40+0.72 sec, in Group-B was 7.60+0.50 sec, in Group-C was 7.60+1.38 sec & in Group-D was 0.20+0.41 sec.

Hence a significant improvement of voiding time was found after 4 weeks of treatment with 0.4 mg of Tamsulosin (Group-B) and with 0.6 mg Tamsulosin. The change was found significant ($P < .001$). Again change of voiding time observed between patient taking 0.4 mg of Tamsulosin (Group-B) and patients taking 0.6 mg Tamsulosin (Group-C) was not significant.

Similar reduction in voiding time were also observed in a study on 126 patient with lower urinary tract symptoms due to BPH. The change of voiding time were 7.8 sec with 0.4 mg, 4.2 sec with 0.6 mg, 6.3 sec with 0.2 mg of Tamsulosin and 1.7 sec with Placebo after 4 weeks of therapy (¹⁹Abrams P, et al., 1997).

Mean change of PVR in Group-A was 4.60+2.67 ml, in Group-B was 68.50+6.45 ml, in Group-C was 63.83+10.88 ml & in Group-D was 2.00+4.07 ml.

Hence a significant reduction of PVR was found after 4 weeks of treatment with 0.4 mg of Tamsulosin (Group-B) and with 0.6 mg Tamsulosin. The change was found significant ($P < .001$). Again change of PVR observed between patient taking 0.4 mg of Tamsulosin (Group-B) and patients taking 0.6 mg Tamsulosin (Group-C) was not significant.

Significant decrease in post void residual urine volume were greater for patient receiving a-blocker therapy (29.1%) than for those receiving Placebo (0.2%)²³.

In a study, it was observed that, mean PVR rate on base line was 30.9+32.3 ml which was significantly decrease to 10.5+12.1 after 1 week of treatment and became 8.8+12.7 after 2 weeks and 10.5+12.1 after weeks of treatment with 0.4 mg of Tamsulosin per day²⁰.

Total number of adverse events occurred after 4 weeks of study period were in Group-A = 3 (10%), in Group-B = 3 (10%), Group-C = 7 (23.33%) and Group-D = 2(6.66%).

So, the adverse events observed in study period in Group-C (23.33%) was very much higher than other groups. Highest incidence of adverse events was abnormal ejaculation 3 (10%) observed in 0.6 mg Tamsulosin recipient group which was found dose related. Hence the differences between the groups were significant.

Tamsulosin was well tolerated and the overall incidence of adverse events was similar in 0.4 mg of Tamsulosin and Placebo treated groups. The maximum adverse events were reported by the patients in the tamsulosin

0.6mg (Group-C). The most common adverse events were asthenia, dizziness and headache^{24,25}. These adverse events were only reported by few patients with Tamsulosin 0.6mg¹⁹. Other studies confirmed that the incidence of adverse effect is comparable between 0.4 mg Tamsulosin and Placebo group^{18,26}. Tamsulosin was shown as well tolerated drug for the long term treatment of lower urinary tract symptoms¹⁸. The only adverse events that occurred significantly more with Tamsulosin 0.4 mg than with Placebo was abnormal ejaculation (4.5% vs 1%)¹⁹. The incidence of treatment emergent adverse events shown in US and European Placebo controlled trials in which daily doses of 0.1 to 0.8 mg of Tamsulosin were given to 1783 patients and Placebo given to 798 patients. Abnormal ejaculation were complained 8.4% in 0.4 mg Tamsulosin recipient group, 18.1% in 0.8 mg Tamsulosin recipient group & 0.2% in Placebo group. Abnormal ejaculation includes-ejaculation failure, retrograde ejaculation and decrease ejaculation²⁷. The only adverse events that was reported consistently and significantly more frequent with the 0.4 mg dose in both studies was abnormal ejaculation (6% & 11% respectively) VS <1% with the Placebo. The occurrence of the adverse events was dose dependent as it was reported by significantly more patients on 0.8 mg (18%) then 0.4 mg in both in study²⁷.

The present study has been designed to assess the efficacy and safety variables at base lines and after 4 weeks of treatment. Significant effects were seen for Tamsulosin 0.4 mg suggesting that it has a rapid onset of action. The European Phase III study symptoms score and Q_{max} assessment after 4 weeks of Tamsulosin therapy have shown significant improvement compare to Placebo and was also maintained after 16 weeks^{18,26,28}.

The results of this present dose ranging study have established that Tamsulosin 0.4 mg once daily is the optimal dose for the treatment of lower urinary tract symptoms (LUTS) associated with BPH. It was also reported by a separate study on 126 patients and European Phase III studies^{19,26}.

Conclusion

From the present study it can be concluded that the optimal dose for the prostate selective α_{1A} -adrenoceptor antagonist (Tamsulosin) is 0.4 mg once daily. This study inferred that Tamsulosin can be given at its optimal therapeutic dose which is well tolerated and effective in the treatment of lower urinary tract symptoms due to BPH leading to rapid improvements in urinary flow rate

and symptoms within 4 weeks of starting therapy. It also observed that the efficacy and safety of Tamsulosin is dose related.

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INDWELLING JJ URETERAL STENTS-A CURRENT PERSPECTIVE AND REVIEW OF LITERATURE

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Introduction

There are numerous types of stents available in the market today. It is essential that those using them be familiar with their properties, design and demerits. There are no universal guidelines regarding their use, handling and effect. Despite tremendous advances in stent biomaterials and design, JJ stents are not free of complications and problems and the search for an ideal JJ stent may remain utopian.^{1,2}

The ideal stent

A ureteric stent is a specially designed hollow tube, made of a flexible plastic material that is placed in the ureter. An ideal stent is expected to stay up and drain well. It should keep the biological passage open. It is expected to be patient-friendly and comfortable, free of complications even with prolonged indwelling times. It should also be biocompatible, biodurable and radio opaque. With such high expectations, tremendous improvements have taken place in the field of stent biomaterials, design and texture; however, the ideal stent continues to elude us.^{1,2} Thus the goal of ureteral stenting is to have a stent that will slide up, stay there, drain well, be comfortable to the patient, be easily visible on fluoroscopy and provide cost benefit to the patient and hospital.

Stent materials

JJ stents are prone to encrustation, a major problem that may limit its long-term use. Experimental studies have shown that various biomaterials may vary in their tendency towards encrustation. According to one such study,⁴ silicone was found to be the least prone to struvite encrustation, followed by polyurethane, silitek, percutflex and hydrogel-coated polyurethane.³ Similarly, silicone was also least susceptible to hydroxyapatite encrustation, followed by silitek, polyurethane, percutflex and hydrogel-coated polyurethane stents.⁴

According to Cormio et al, hydrogel-coated polyurethane stents such as Hydro-PlusTM cause minimal superficial epithelial destruction, show least ureteric reactive changes and low encrustation rates.⁵ It is believed that PercuflexTM stents (thermoplastic copolymer of polyolefin) have a high tensile strength with the best

internal:outside diameter (ID:OD) ratios and an excellent side hole characteristic. A larger ID/OD ratio predicts an overall improved flow capacity of the stent. Moreover, the PercuflexTM stent has good biodurability and biocompatibility with good surface features and a low friction coefficient even without a hydrogel coating.⁴ According to Mardis et al³ polyurethane stents have questionable bio-durability and biocompatibility, hence these are suitable only for short-term deployment.

Indications for Ureteral Stenting

The indications for ureteral stenting may be divided into two main headings, (a) As adjunct to Ureteral surgery (pre and/or postoperative), and (b) For managing ureteral obstruction (extrinsic and/or intrinsic). The salient indications^{6,7,8,9,10,11,12,13} for ureteral stenting are:

- (i) Adjunct to ESWL, PCNL, ureteroscopy, endopyelotomy, open/laparoscopic ureteral surgery, ureteric injury and renal transplantation.
- (ii) Managing ureteral obstruction (stones, strictures, oedema, fistula, tumours, tuberculosis, retroperitoneal fibrosis-tumours, hydronephrosis) and conservative management of genitourinary fistulas in women.¹⁴
- (iii) Assisting the passage of a guide wire into the ureteric orifice.
- (iv) Passively dilating the ureter before interval ureteroscopy.

Pre-ESWL stenting for renal stones (1-2 cm) and less than 1 cm ureteric stones is most controversial at the moment.¹² It is important that the stenting should be done in selected cases only, even when indications do exist and not on a routine basis. According to Mardis et al² approximately 50% of all extracorporeal lithotripsy and over 90% of all ureteroscopic stone procedures involve an indwelling ureteral stent. Thus the DJ stent is vital to the endourologist. Barely 10% of stenting is related to long-term stenting.²⁴ Percutaneous nephrostomy drainage should be preferred where long-term stenting is anticipated such as in extrinsic obstruction by advanced abdominal malignancies.¹³

Stent complications

The common problems and complications encountered with indwelling ureteral DJ stents are enumerated below. Some of these complications are often related to prolonged indwelling times, especially in forgotten or overlooked stents.^{15,16,17,18,19,20,21,22,23,24,25,26,27}

Early complications

- (i) Bladder storage symptoms and stentcolic
- (ii) Dysuria
- (iii) Haematuria
- (iv) Vesicoureteric reflux²⁷
- (v) Bacteriuria, urosepsis and pyelonephritis
- (vi) Fever and flank pain
- (vii) Loss of stent patency

Late complications

- (i) Hydronephrosis
- (ii) Encrustation and blockage
- (iii) Stuck stents
- (iv) Stent migration
- (v) Stent knotting and fracture
- (vi) Spontaneous fragmentation and stenturia
- (vii) Uretero-arterial and uretero-intestinal fistulae (especially with rigid stents)²⁶

Stent pain

Stent pain refers to a constellation of clinical symptoms associated with the presence of a stent in the urinary tract. One must remember that JJ stents are foreign bodies that are prone to cause irritation and patient discomfort. Although silicone stents were more patient-friendly as these were seen to be better tolerated by patients, they are now almost phased out since they were less rigid, making their handling and insertion a tedious task.¹⁷ All JJ stents tend to cause discomfort on account of several factors such as stent rigidity/stiffness, stasis, long intravesical segments, migration and sepsis.¹⁸ This may lead to stent colic and pain with an impaired health-related quality of life.^{19,20} Soft stents produce significantly less severe stent discomfort than the firm stents.

Stent Encrustation

Polyurethane stents are especially prone to encrustation; this may be due to their higher tensile strength that contributes to their rigidity that may encourage stasis

with periluminal and endoluminal encrustation. Biochemical and optical analyses of stent encrustations by Robert et al²¹ revealed that these encrustations consist mainly of calcium oxalate, calcium phosphate and ammonium magnesium phosphate. According to one study the stent encrustation rate increased from 9.2% at <6 wks, through 47.5% at 6-12 wks to 76.3% at >12 weeks.²¹ Up to a 30% rate of luminal blockage has been documented with indwelling times of up to 3 months and another 4% develop evidence of clinical obstruction.²² This occurs because of a significant persistent drainage continues to occur, rather than urinary flow via the hollow stents. These problems tend to occur especially in those with significant risk factors such as chronic recurrent stone formers with a lithogenic history, uricosuria, chronic renal failure and congenital anomalies.^{2,3} Encrustation may also occur in the absence of underlying urolithiasis suggesting a slow progressive phenomenon induced by urease, urinary tract infection, stasis, dehydration and long indwelling times.²³ Encrustation is generally preceded by the formation of a "biofilm", which refers to the accumulation of urinary mucoprotein (slippery slime) on its surface with subsequent crystalloid deposition. Some studies have shown that hydrogel-coated stents have a higher risk of becoming encrusted in vitro than uncoated stents made of the same material.²⁴

Spontaneous fragmentation

Irrespective of the material, with the passage of time all stents are prone to ageing due to encrustation and loss of tensile strength resulting in stent fracture, breakage and even stenturia.²⁵ Inspection of such stents has shown that these fracture lines generally pass across the stent side holes.²⁸ The tensile elongation (maximal elongation at break point), known to be a sensitive indicator of the aging process of plastic materials, has been shown to be diminished with prolonged deployment. It is possible that the initial event may be "leaching", a dominant reaction caused by a progressive chemical urinary assault on the stent plastic and its integrity.^{29,30} This eventually results in fragmentation of the stent and its expulsion in urine as stenturia.³¹

Forgotten stent

It refers to an overlooked stent^{32,33} that is generally associated with significant complications such as sepsis, renal decompensation, massive encrustation and stent fragmentation.

Stent migration

Refers to the spontaneous stent dislocation either in an upward³⁴ or downward direction. Most polyurethane stents are suspended from the kidney with a pigtail memory at their proximal end so as to prevent migration. Migration may still occur due to the renal ureteral dynamics and peristalsis. Improper placement and incorrect size selection may contribute to stent migration. Proximal migration is most commonly due to the placement of a stent too short for the ureter.^{34,35} It is believed that stents must be inserted into the pelvis rather than into the calyces so as to minimize the chance of migration.³⁶

Sepsis

Sepsis associated with the presence of stents may not be specific to the stent biomaterial. Like other prostheses, DJ stents may also bind to bacteria and promote infections. Despite antibiotic prophylaxis, bio-films tend to form on the ureteric stents in vivo and bacteria tend to cling to them.³⁷ It may be related to the degree of sterility, urinary components, and the underlying disease, and on the properties of the bacteria, especially the presence of P-fimbriae. The presence of bacteria on the stent bio-film may be of no consequence, but their colonization may be associated with urinary tract infection and sepsis.

The late complications of stents (for > three months) are generally associated with increasing morbidity and an increasing frequency of encrustation, infections, secondary stone formation and obstruction of the stented tract.³⁸

Perforation of ureter and erosive damage to bladder due to stent may also occur.

Size selection

JJ stents are available in sizes from 4.8-5.5-6 Fr / 16-24-26-28 cm. The most commonly used adult size is 26cm/16Fr. These generally admit 0.028"-0.035" guide wires. Endopyelotomy stents of 5/10,6/12 and 7/14 Fr calibre (tapering), varying in length from 24-26-28 cm are also available. The 7/14Fr size is the most commonly used endopyelotomy stent. A paediatric patient necessitates the estimation of the ureteric length and then selecting a smaller stent length such as 24/4.8 or 20/4.8. Stents of an incorrect size tend to migrate into the bladder and that may cause severe stent discomfort.

Stent insertion & removal

The usual stent assembly comprises the JJ stent, guide wire, pusher and a clip. The stent is opened under sterile

aseptic conditions and assembled over a guide wire. If it is a close-ended stent the stiff end of the guide wire can be safely inserted into the leading end of the stent, the stent is then made taut over the guide wire and held in place with a clip; next, the pusher is placed over the guide wire flush with the distal end of the stent and is held in place with another clip. In case of an open-ended stent the floppy end of the guide wire should be deployed at the leading end. The assembled stent is then inserted cystoscopically (21F sheath) into the ureter under fluoroscopic guidance (retrograde stenting). As soon as the stent negotiates the distal ureter, the proximal clip is removed and the stent is advanced into the kidney by using the pusher; the distal clip is now disengaged and the guide wire is partially withdrawn until the renal coil of the stent is safely seen in the kidney. The guide wire and pusher are now gently withdrawn till the distal coil of the stent is safely seen in the bladder. Most stents have graduations on them at intervals of 5 cm-this helps in confirming precise stent placement.

Alternatively, antegrade stenting³⁹ can be performed similarly under fluoroscopic guidance through the nephroscope by sliding the stent antegradely over a pre-placed through and through guide wire, following a PCNL, when gravel is expected to choke the ureter and a tubeless PCNL is being contemplated.

Most stents can be safely removed under local anaesthesia using a cystoscope with a two-pronged rigid or flexible biopsy forceps.

Technical problems

Failure to negotiate the ureteric orifice

This may be due to overdistension of the bladder; abnormal ureteric morphology or too rigid a stent being used. Try first placing in a guide wire through a ureteric access catheter (6F MicrovasiveTM) and then slide an open-ended stent retrogradely over it under a fluoroscopic monitor using a pusher. One may inject more lubricant into the ureteric orifice through a ureteric catheter and reattempt the stenting.

Guide wire is stuck

The most likely cause is an incorrect gauge of the guide wire used. Remove and reinsert, try using 0.028" guide wire in place of the 0.035" wire.

Proximal coil fails to open

The most likely cause is that it is in the ureter or PUJ; try pushing the guide wire, straighten the coil, advance it further and then remove the guide wire or remove and reinsert afresh.

Distal coil fails to open

It is most probably due to overinsertion of the stent. It may need repositioning with an ureteroscope under anaesthesia if the guide wire has been removed. Sometimes spontaneous migration may allow the distal end of the stent to pout out when it can be gently pulled out partially.

Managing stent complications

Heavily encrusted stuck stents remain one of the most challenging tasks facing the endourologist, especially when one is confronted with a long overdue forgotten stent. Multimodal endourology remains the cornerstone of management.^{23,40} Most mildly encrusted stuck stents respond to one or two sessions of shockwave lithotripsy.⁴¹ Those with a major proximal stone burden may need a PCNL.⁴² Broken stent fragments in the kidney can also be safely removed by PCNL, while ureteric fragments can be managed by minimally invasive techniques^{23,43,44,45} such as ureteroscopy and intracorporeal lithotripsy. Forgotten stents should be managed endoscopically only by those well trained and sufficiently advanced in endourology.^{46,47} Open surgery has a role where multimodal endourology fails, but one must remember that this is also not easy and is fraught with its own attendant risks of causing further renal impairment and sepsis. Finally, where less than 10% renal function remains, one must consider nephrectomy.²³ It is important that some sort of stent diary or a computerized stent log be maintained and periodically updated by the surgeon himself so as to track overdue stents and remove them at the earliest.^{23,48,49} Two general strategies have been used to minimize stent encrustations associated with bacterial bio-film formation namely, use of surface-active antimicrobial-coated stents and the use of hydrophilic compounds.⁵⁰

Potential risk factors for complications

Not all patients tolerate indwelling ureteral stents and some may be more prone to develop complications directly attributable to them.⁵¹ It is necessary to identify and monitor these patients more closely. Such patients should ideally either undergo an alternative form of urinary diversion or their stents should be removed / changed at the earliest. According to one study at least a third of the patients may develop one of the delayed complications.⁵² It is vital to recognize this high-risk group for medico-legal reasons⁵³ as well as to prevent the occurrence of hazardous complications since this may lead to the loss of a renal unit or life. Patients with

known metabolic problems, recurrent stone formers, chronically compromised renal units, congenital renal anomalies, etc. are some of the 'at risk' groups. Appropriate prophylaxis should be instituted in them such as high fluid intake, timely attention to clinical complaints, aggressive treatment of documented infection and correction of metabolic aberrations with appropriate dietary and medical means. Long-term antibiotic suppression may be indicated in those with a lithogenic history on internal stenting.⁵⁴ Stent malfunction can be avoided and their patency can be maintained by ensuring a high urine output through increased oral fluid intake, by prophylactic oral antibiotics and avoiding stent placement in grossly infected or bloody systems.⁵⁵

Newer experimental stents*Bio-degradable stents*

These stents are "soft, hydrogel-coated plastic stents" capable of spontaneous dissolution in a safe benign manner. They are still in the experimental stage and more research is required to assess the exact time of stent retention, potential adverse symptoms, stent fragment passage and safety in human subjects.^{56,57}

Valve stents

This is a modification in stent design to prevent upward migration. The distal vesical end of the stent is wider than the ureteral orifice. The valvular mechanism comprises two transparent membranes attached to the vesical end of the stent that tend to close and coapt when the intravesical pressure rises due to voiding.

Tail stents

These are tapered distal end stents that tend to thin out distally and hence serve to prevent uretero-vesical reflux.

Dangler stents

These are the usual DJ polyurethane stents that have additional dangler nylon or prolene wire loops dangling out of the stent ends. These may be deployed and pulled to remove the stent without the need of an additional cystoscopic procedure. If not required they may be cut away during their insertion.

Thermo-expandable stents

These are nickel-titanium alloy stents with a thermoexpandable shape memory.⁵⁸ They have been used in the management of ureteric strictures, e.g., Memocath 051TM. The stent is placed in the ureter after prior dilatation (unexpanded state) and later expanded

by injecting sterile heated water at 50°C. The shaft diameter is 9F while the proximal end expands to a calibre of 17F. They have mainly been used in cases where long-term stenting is needed such as in malignant ureteric strictures.

Stain-less steel bead stent These stents have a stainless steel bead attached to their distal end. By using an earth magnet, minimally invasive, non-endoscopic ureteral stent retrieval is possible in several patients.⁵⁹

PVP-coated stents

(Polyvinyl pyrrolidone (PVP)-coated polyurethane stents) PVP coating may be useful in preventing complications due to bacterial bio-film formation and encrustation. These stents are still under evaluation.⁶⁰

Extra-anatomic stents

This refers to the placement of stents through a passage other than the normal ureter. These may be placed intra-abdominally or via a subcutaneous tunnel as an extra-anatomic bypass as in cancer cervix or where a malignant process engulfs the entire ureter, e.g. pyelo-vesical shunt.

Recently, antibiotic impregnated stents (adsorption of antimicrobials)⁶¹ have also hit the market. Double silver and copper-coated stents have been experimented with and they may hold the promise of keeping out sepsis (preventing bio-film formation)⁶² and reducing infection rates, but resistant bacteria, short leaching times and side-effects make it essential that different options be considered. Further encrustation may limit their long-term use. It is likely that surface engineered materials (hydrogels e.g. Aquavene)⁶³ and anti-microbial drug delivery systems will be the next generation of refined stents, however, their efficacy and efficiency needs to be proven clinically.⁶⁴ Hydrogel stents offer the advantage of easy placement and patient comfort.⁶⁵

Duration of stenting

An ideal safe minimal optimal duration for stenting has not been described. No matter what the stenting duration is, all stents will form a bio-film with some degree of bacterial adherence. If left for a sufficiently long time nearly all stents will encrust. However, the safe window period of stenting is probably 6-8 weeks. Stenting following ureteroscopy or SWL for ureteric calculi is generally removed in 2-3 weeks. A difficult PCNL or ESWL associated with a risk of significant "steinstrasse" may necessitate stenting for up to 2-3 months. Patients

with chronic renal failure due to obstructive uropathy or malignant ureteric obstruction may need lifelong stenting with a 3-monthly serial change.

Patients with double-j stent should be told of the importance of appropriate follow up and eventual stent removal.

Stent monitoring

Stent monitoring includes regular monthly urine c/s analysis, serum creatinine and an X-ray KUB. Renal scans may be indicated where renal jeopardy is suspected, but these must be done with an indwelling Foleys catheter to keep the bladder empty, so as to avoid diagnosing a pseudo-obstructive pattern on the scan. Internal ureteral stent patency can be evaluated by colour-coded Doppler sonography (CCDS) or by a micturating cystourethrography. CCDS may have sensitivity up to 100% besides being completely non-invasive; a simultaneous KUB ultrasound scan can be done to detect any hydronephrosis. To establish ureteral patency prior to stent removal, retrograde pyelography may also be attempted via the stent.⁶⁶ At risk stone formers should be additionally screened for metabolic abnormalities.

Suggested guidelines & precautions

- Always take an informed consent for stenting
- Review the indications for stenting as routine stenting has the possibility of increasing complications as well as the cost of the procedure
- Maintain careful documentation with close follow-up using a patient stent card or diary
- Select the appropriate stent size .
- Polyurethane stents are economical and are best suited for short-term use. They are however prone to migration and rapid encrustation if not removed/changed in 2-3 months.
- Reserve expensive coated stents like Percuflex™ (hydrophilic) for prolonged stenting
- If prolonged stenting is mandatory, change the stent at least once every 3 months and earlier in stone formers and chronic renal failure patients
- It is advisable that all patients be kept on a perurethral Foleys catheter for the initial 24-48 hours so as to minimize the inevitable vesico-ureteric reflux
- Prophylactic antibiotic cover is desirable though not absolutely essential. Oral fluoroquinolones such as

ciprofloxacin or ofloxacin may be the drug of choice in a susceptible population

- Severe urosepsis should prompt stent removal and percutaneous nephrostomy
- Broken ureteric stents can be safely removed by ureteroscopy
- Renal stent fragments are best dealt with percutaneous procedure

Conclusions

Indwelling ureteral stenting should not be performed routinely. Its use must be restricted to cases where benefit overrides the complications. It is necessary that the indication for stenting, the type of stent and the size to be used be reviewed selectively. Whenever used they must be tracked closely and removed at the earliest. Late complications of stents are frequent and may appear in up to a third of the patients on long-term stenting. A closer follow-up and frequent periodic monitoring is indicated in them and in the susceptible at risk population. Appropriate prophylaxis and safety guidelines and precautions should be strictly adhered to all cases that undergo indwelling ureteral stenting.

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NEED OF A NATIONAL GUIDELINE IN MANAGING UROLOGICAL PROBLEMS

The need of a guideline in managing clinical problems is universal. In general the guideline in managing various diseases and clinical problems is well described in texts, journals, periodicals, reviews etc. But this information is diffuse, not based objectively on problem solving and not sometime practical in all situations. Efforts have already been taken by prestigious urological societies of the world like American Urological Association and European Urological Association. Their publication as AUA guideline and EUA guideline is followed worldwide.

In contrast to these global guidelines, a local or national guideline may be more appropriate in addressing some problems particular to the locality. A disease, which is prevalent in Bangladesh, may be rare in advanced world and therefore may not be well studied or documented in literature. Among the important reasons to have a local or national guideline, is the fact that, many diseases in urology have unique presentation and course demanding an appropriate treatment protocol. Therefore, special protocols for such cases are needed. More over high-tech advanced technology may be a standard protocol for a particular problem in advanced country but the same facility may not exist in developing center or country. The local guideline should be able to address the problem appropriately and direct towards an effective and easily available treatment protocol that will bear a similar short term and long-term result.

There may be many controversial areas in urological management, which need clarification. The guideline will be helpful in addressing these issues with confidence especially for the junior specialists. To achieve a consensus on controversial issues is not easy and need frequent discussions among the faculty members. The effort is time taking but will bring a milestone of progress of urology in our country.

Constant advancement of technology, knowledge and skill will demand a regular updating the guideline.

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