Aim of this study is to judge effectiveness of new design, temporary, cover, metal selective urethral Allium stents in lower urinary tract symptoms treatment concerning all peri and post procedural complications.

Material and methods: We observed group of 40 patients with longstanding history of lower urinary tract symptom, in which outflow obstruction was localized in bulbar urethra in 24 pts and in prostatic urethra in 13 pts. Residual voiding volume and prostate volume measurements by ultrasonography, urethrocystography, urine culture and uroflowmetry (bulbar urethra stricture PTS) were done before stent insertion. Procedure was done in all cases but one in ambulatory conditions, under local anesthesia with oral antibiotics administration day before and 5 days after. Objective and subjective parameters of stent effectiveness were estimated and statistically revealed.

Results: Majority of pts (32/40) were satisfied with all the aspects of the procedure and with quality of life while urethra was stented. Urinary infection did not happen in any case, encrustation of the migrated stent occurred in 2 cases (6.4%). Emptying of the bladder was adequate while wearing either prostatic or bulbar urethra stent. Residual volume was significantly smaller, urinary flow significantly higher. In pts with bulbar urethra stricture urinary flow and morphology of patent urethra lumen, 6 months after stent extraction suggested prolonged-permanent recanalisation results.

Conclusion: Site specific, metal Allium urethral stents enable adequate emptying of the urinary bladder with minimal and transient patient discomfort. Stent insertion and explantation are simple procedures to perform, when correctly indicated without significant early and late complications.

Key words: Posterior urethra, bulbar urethra, stricture, stent

INTRODUCTION

Recurrent urethral strictures are well known problem in urology and interventional radiology practice. Substitution urethroplasty procedures although complex, expensive and traumatic, in most of the cases have best longtime results\(^1\,^2\). There is obvious disproportion between raising number of pts with chronic urethra stricture and number of experienced urethral surgeons. Expansion and progress of endourology, on the other side resolved majority of patients with posterior urethra outflow obstruction\(^3\). Still there are many, especially elderly patients not suitable for any kind of surgical treatment (ASA grade II and III), who until urethral stents era were dialed with urinary catheters and cystostomy draining tubes.

Many urethral stents of various design, material and expansion modality, for temporary or permanent use are used until nowadays, achieving different degree of success\(^4\,^5\,^6\). Until 1980. year and Fabian’s "partial catheter"\(^7\) rich clinical experience in urethral metal stents and catheter based endoprostheses usage, established field of indications, advantages, limitations and undesirable effects of stent insertion.

GOAL OF THE STUDY:

- To estimate clinical effects of Allium stents in recanalisation urethral obstruction.
- To compare patient comfort, satisfaction and quality of life before and after stent implantation.
- To evaluate eventual early and late complications of procedures.
- To judge preliminary indications and contraindications in the light of final results.
MATERIAL AND METHODS:

Clinical trial was conducted in Institute of radiology and Institute of urology and nephrology, Clinical Centre of Serbia in Belgrade as a prospective and comparative research during a period from August 2003 until June 2013. All relevant approvals from Ethical Committee and individual patient’s consent were taken. Preparatory experimental and laboratory study was done in Israel, in Allium corporation under the leadership of Daniel Yachia and Zeljko Markovic.

Our group included 40 male patients with prolonged history of lower urinary tract symptoms. Fourteen pts had obstructed posterior-prostatic part of the urethra and 26 pts had bulbular-anterior urethra stricture. Not in one case Allium stent insertion was the primary or the first therapeutic option. Concerning pathology, different medication, mechanical successive or balloon catheter dilation, radiotherapeutical or surgical methods preceded stent insertion. We used the flexible and rigid version of the stent (Figure 1 a, b and Figure 2) a procedure performed under imaging guidance (Figure 3)

In all cases but one (39/40) Allium urethral stent implantation was done in ambulatory conditions as well as the following monthly checks. In one pt stent was inserted in stationary 3 days after internal urethrotomy was done. Preliminary medical exams included besides diagnostic procedures connected to the basic pathology, urine analysis, urine culture, urethrocystography (UCG), prostate volume and post voiding volume measurements by ultrasonography. Oral broad spectrum antibiotics were prescribed 12-24 hours before and oral analgesics 1 hour before procedure was planned. In 17 pts with bulbular urethra stricture preliminary balloon catheter dilation (BKD) was performed just before stent insertion. In 14 pts with anterior urethra obstacle BKD was done in 2 cases in order to enable introduction of stent delivery system, which is flexible.

Early control, after the insertion is finished included urethrocystography (Picture 5) and watchful voiding. Urine analysis and post voiding volume measurements were done monthly but UCG was indicated only if some voiding disturbances were complained. Urodynamic examination (uroflowmetry) performed after one and six month period only in pts where Allium bulbular urethra stent was inserted.

Objective and subjective parameters were used for evaluation of stent effectiveness. Descriptive features are shown as frequencies and numerical data as average values ± standard deviation (STD). Difference between average values of numerical data was tested with Student-t test for connected and no connected samples while the difference in descriptive features frequencies was tested with Chi² test. Zero hypothesis is accepted on possibility level greater than 0,05.

RESULTS

Forty patients enrolled in our study have average 67,9±12,25 years (42 to 84 years) and they wear the stent 7,77±3,96 months on an average (1 to 15 months).

Patients with posterior urethra obstruction (14/40) were 77,4±5,1 years old (68-84 years) and had prostatic urethra stent for 4,93±3,17 months (1-13 months). Participants with bulbular urethra stricture (17/40) were 60,06±10,07 years old (42-80 years) and they wear the stent for average period of 10,12±2,89 months (1-15 months).

Patients with Allium prostatic stent were older t=5,5, p<0,01 and had have urethral stent for shorter period of time t=5,5, p<0,01 than pts with bulbular urethra stent.

Ethiology of posterior and anterior urethra obstruction enrolled in dominantly postraumatic (31 pts)
From 40 pts included 25 (80.6%) had one time implanted singular stent (Allium prostatic or bulbar urethra stent), in 3 pts (9.7%) prostatic stent insertion was repeated, while 2 pts (6.5%) had simultaneously two bulbar urethra stents implanted (partially overlapped). Another pt (3.2%) wear one prostatic and one bulbar urethra stent at the same time.

In addition to shorter hematuria (12 cases) and dislocation of the stent forward (6 cases) we had another early complications. Of late complications in 5 cases we had a dislocation of the stent. Effectiveness of the procedure was estimated using objective and subjective parameters. Participants gave their opinion how did they experience stent implantation and explantation procedure, what is their comfort and ability of everyday activities during urethra was stenting. They compared actual situation with the time before intervention and graded it as: satisfied (0), unsatisfied (1) and indecisive (2). Twenty four pts (77.4%) said they are satisfied about all mentioned aspects, 3 pts (9.7%) were not satisfied and 4 pts (12.9%) were undefined about urethra stenting.

Before Allium stent implantation (bulbar or prostatic one) median of pts subjective criteria was 1,00 while after procedure median was 0. That change is statistically highly significant, z=3,9 p<0,01.

As an objective parameter of urethra stenting, after micturation voiding volume was calculated in milliliters by trans-abdominal ultrasound exam. Obtained numerical date are displayed in Diagram 3 and 4. Before intervention, residual voiding volume mediana was 2, after stent insertion mediana was 1, pointing statistically significant change z=-2,0, p<0,05.

In subgroup of 17 participants with obstruction at the level of bulbar part of the urethra, one and six months after Allium stent implantation uroflowmetry was done. Average urinary flow before and six months after stent increased to 4.5 ml/sec. Mean urinary flow was statistically of higher value with Allium bulbar urethra stent inserted, t=-6,8, p<0,01 (Figure 4 and 5).

**DISCUSSION**

Urethral stent implantation, until October 1996. when First International Symposium on Urological Stents was held, took legitimate place as minimally invasive option of therapy of lower urinary tract symptoms. Many clinical studies about metal or catheter based stents, for temporary or permanent usage have been published until nowadays and despite advantages some limitations are pointed.

Good results are published about resorbable urethral stents combined with surgery.

Principal idea of this self-expandable, stent design was that its morphology and lumen cross-section resemble and match real shape of the obstructed urethra and that due to large spaces between nitinol coils stent accomplishes great flexibility and low but sufficient radial force. So the stent should minimally interfere with physiological motions of the urethra. In our study such expectations were fulfilled according to pts quality of life while stent was inserted.

Our subjective criteria (satisfied, unsatisfied, indecisive) differs from quality of life parameter in estimation BPH grade. This subjective parameter refers mostly to stent role in obstructive symptoms releaf, in order to make all participants, from very inhomogeneous group comparable among themselves. Majority of pts (77.4%) said they are satisfied with their comfort of life, that stent did not cause trouble while sitting or limited everyday activities. Transient foreign body feeling and discomfort lasted for first 2 to 5 days. Sexually active pts didn’t complain about erection and ejaculation problems.

Seven pts (21.6%) who judged stent function and insertion and extraction procedures as unsatisfied (3/31 pts=9.7%) and undefined (4/31 pts=12.9%); have had prostate urethra stent. In two of them encrustation of partially and completely migrated stent occurred (Diagram 2) after 13 and 15 months of stenting, what is far longer period than we proposed previously. We suggested 6...
months longest time period of prostate stenting, conducted with data about temporary stenting published in literature. Their unfulfilled expectations can be explained with surgical intervention that followed extraction through cystostomy in one and endoscopic retrieval in the other case). On the other hand late migration rate is rarely published concerning permanent but not so rare talking about temporary stents, according to literature. Partial or complete, late migration (13 and 15 months) in both of pts were accompanied with calcium salt deposition, where stent as foreign body acted as a precipitant.

In rest 5 pts who gave negative or undefined opinion, there were 2 pts who were waiting for the prostate operation and 3 pts with post-irradiation fibrotic changes of the prostate and small bladder capacity. Everything mentioned above when added to possible bladder wall weakness (associated with advanced years), small bladder capacity (after irradiation fibrotic changes) results in often, weak stream urination. Other words, besides prostate urethra lumen is wide open symptoms persist even with the stent.

Participants included in this study were advanced in years, especially those with posterior urethra obstruction (77.4±5.1 years) and according to pathological substrate underwent many different surgical and non surgical treatment options, before urethral stent was indicated. In almost one third (29%) of pts prostate urethra stent was inserted in BPH (benign prostate hyperplasia) pts with permanent contraindications for any kind of surgery due to high ASA grade. In these cases Allium prostate urethra stent served as sophisticated, temporary replacement for urinary catheter, enabling active-voluntary urination, without draining bag. Active urinary tract infection did not occur in our participants while they were stented, although many of them have had bladder catheterization for prolonged period of time associated with bacteriuria, before.

On diagram 2, patho-anatomical substrate of bladder outlet obstruction is presented and this data are equal with indications which we applied in our study. Patients younger than 18, with immune-insufficiency, urinary bladder tumor, atonic urinary bladder, urethral fistulas, penile implants and artificial urethra sphincter were excluded from our study. Temporary contraindications were anticoagulant therapy, urinary infection and urinary bladder calculi. Indications and contraindications for Allium stent implantation are referring to postulate previously established.

In cases of bulbar urethra stricture story goes on the other direction. The role of Allium bulbar urethra stent is therapy, not palliation. When preliminary BKD bursts the scar, regardless the depth of spongiosfibrosis balloon dilation is of sufficient strength, stent is placed over the strictured and teared part of the urethra in order not only to maintain the lumen open but to enable healing around the stent as a tutor.

Participants with Allium bulbar urethra stent inserted were very satisfied with stent function and life comfort, even when minor grade complications occurred. Bulbar urethra stent was advocated to remain in the urethra from 6 to 12 months. In the meantime healing, scarification and scar fixation should happen but the scar retraction and lumen reobliteration should be avoided due to stent tutorial. In 2/31 pts (6.4%) complication-new stricture formation appeared at the distal stent end. In one pt (3.2%) BKD was performed in the other (3.2%) another bulbar urethra stent was implanted, partially overlapping the first. After the stent/stents extraction there was no evidence of stricture relapse on 6 months control exam. We thought this new stricture is due to epithelial proliferation, because irritation from the distal stent margin occurred at the junction of bulbar and penile part where urethra is fixed. Good answer to dilatation indicative is for superficial but not deeper urethra tissue involvement, in new stricture formation.

After urination voiding volume was measured in all pts without indwelling catheter (21/31) before Allium bulb or posterior urethra stent insertion. Using transabdominal ultrasound measurements were done and residual volume graded into 3 grades. Less than 40 ml volume, we considered physiological, because it is really so and also because ultrasound is subjective method and error possibility from technical point of view is significant. Volume
more than 40 ml we considered slightly or highly suggestive of bladder outlet obstruction. In all participants where residuum was measured it was highly suggestive of bladder outflow obstruction. Residual voiding volume was measured in entire group (31/31) including pts with previous longtime bladder catheterization (!). With stent inserted, less than half (14/31=45,2%) had residuum 40-100 ml and only one pt(1/31=3,2%) over 100 ml. In majority of cases, (54,8%) residual volume detected was insignificant. It is obvious (Diagram 3 and 4.) that after Allium bulbar/prostate urethra stent implantation emptying of the urinary bladder drastically improved.

Urine flow analysis, before and after stent insertion were performed only in pts with bulbar urethra stricture (17/31). Thou, they were significantly younger (60,06±10,07 years) we assumed bladder wall contractility preserved which enable both "pump and pipe" sufficient to estimate pathency of urethral lumen with stent. According to literature, average urine flow rate is more real representative of urethra lumen diameter because hyperactive or hypotonic bladder wall have less chance to give false positive and false negative urine flow results. Before intervention, average urinary flow was 6,4±10,07 ml/s and after Allium stent insertion it doubled to 12,8±3,9ml/s. This double raised flow is highly significant and suggestive of less often and more complete emptying of the urinary bladder.

**CONCLUSION**

Allium prostate/bulbar temporary urethra stents while indwelling enable good life quality causing no significant discomfort. Complications are rare but suggest precise work, regular controls and experience ordinaries. During stenting, Allium prostate urethra stent enable efficient bladder emptying while in cases of bulbar urethra stricture, better urinary out put is prolonged (permanent) on 6 and 12 months check ups, after stent extraction.

**SUMMARY**


Zaključak: Metalni stentovi Allium omogućavaju adekvatno pražnjenje bešike uz minimalnu i prolaznu nelagodnost pacijenta. U pacijenata sa irreversible uro-opstrukcijom primene ove metode dobija na značaju kao metoda izbora koja nema značajnijih ranih i kasnih komplikacija

Ključne reči: zadnja uretra, bulbarna uretra, stikure, stent

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