

Urodex Injection (Urethral Bulking Agent) Outcomes In Treatment of Stress Incontinence, Interventional Study

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Abstract: The stress incontinence is caused by internisic sphincter deficiency, or weakness of pelvic floor muscle, which is divided into three stamey grades according to severity, urodex is used to mild to moderate grades. The study is started in February 2017 to July 2018; this study was done on 15 patients in private outpatient clinic, 12 of them presented with GSI and other three patients presented with mixed incontinence. for those patient whom complaining from mixed incontinence were treated with an anticholinergic medication (used to oxybutynin tab 5mg 1x2), the diagnosis is confirmed with cystometry, the other of patients with urodex injection which are containing 1cc in four site (12,3,6,9). The range of age 43 to 62 years old female. Total numbers of patients are 14 (93.3 %) after exclusion one patient respond to oxybutynin. Six of patients (43%) presented with immediate retention, the follow up is done 6 weeks, 3months and 12 months and compare the results with baseline visit. There are significant changes in stamey grade and number of incontinence in next visit. The urodex is good choice as a minimal invasive intervention in mild to moderate stress incontinence

Keyword: Stress Incontinence, Urodex, Urethral Bulking Agent.....

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I. Introduction

Stress Urinary Incontinence (SUI) involuntary loss of urine that occurs when physical forces on the bladder are increased during physical movement of the body (Langford CF, 2011). SUI is caused by weakening of pelvic floor muscles, the urethra or the supporting ligaments of the urethra. Such weakness results in involuntary passing of the urine when intra-abdominal pressure increases, such as during coughing, laughing and sneezing. Using fluorourodynamics, McGuire recognized a different etiology to SUI due to dysfunction of the internal urethral sphincter and called it Type III. Intrinsic Sphincter Deficiency (ISD) or Type III is seen in patients who have little or absent motility of the urethra during the Valsalva maneuver, leakage at smaller increases in abdominal pressure, and often have abnormal opening of the proximal urethral sphincter (Mc Guire EJ, 2004). The most important treatment methods for SUI due to ISD include urethral sling placement and Urethral Bulking Agents (UBAs). The UBA treatment method was initially suggested as a salvage minimally invasive procedure for women with devastated bladder outlet, typically after undergoing many pelvic surgical procedures and/or pelvic radiation therapy. Because of its minimally invasive nature, it was also used in frail, elderly patients and patients experiencing complications with procedures requiring general anesthesia (N.F.Davis, 2013). An ideal bulking agent should be biocompatible, nonimmunogenic, causes no fibrosis after infiltration of the urethral tissue, non-antigenic, and a cellular (N.F.Davis, 2013). Both dextranomer and hyaluronic acid are biocompatible, and a serious tissue reaction is not expected. Hyaluronic acid naturally exists in tissue (M. Bio'ci'c, 2012). Dx/HA has different commercial names, according to the size of the contained microspheres. Deflux contains 80–250 µm dextranomer microspheres and in products like Urodex has a size of 80–120 µm. 1ml Urodex contains (O.Aydogdu, 2012).....

1-Cross-linked hyaluronic acid sodium salt	14.0	mg.....
2-Dextranomer	50.0	mg.....
3-Sodium chloride	6.9	mg.....
4-Water for injection	1.0	ml.....

The use of UBAs has been most effective for patients suffering from stress urinary incontinence due to intrinsic sphincter deficiency. In this condition, the bladder neck does not close properly; therefore, a high intra-abdominal pressure can cause the contents of the bladder to leak involuntarily. Objective assessment techniques characterize ISD by a very low or absent proximal urethral closure pressure (<15cmH₂O), low closing urethral pressure of 20cmH₂O and a Valsalva leak point pressure of <90mmHg (Pajoncini C, Ramsden M, 2003). As

determined by urodynamic studies. There is no standardized set of urodynamic values to diagnose SUI due to ISD; however, Pajoncini et al found that using both maximal urethral closure pressure and Valsalva leak point pressures as parameters to assess incontinence yields more accurate results in identifying patients with genuine stress incontinence (Pajoncini.C, 2003)..... The severity of stress incontinence is classified by Stamey (<http://www.urology-textbook.com>).

Grade1:loss of urine with sudden increases of abdominal pressure: e.g. coughing, sneezing or laughing.
Grade2:loss of urine with lesser degrees of stress: e.g. walking or standing up.
Grade3:loss of urine without any relation to physical activity or position, e.g. while lying in bed.

Patients and methods:- This study was done on 15 patients in private outpatient clinic, 12 of them presented with GSI and other three patients presented with mixed incontinence. The study is started in February 2017 to July 2018. For all of them we do preinjection history, physical examination, urinalysis, abd. US for PVRV, cough test, Q tip test, valsalva leak point pressure (VLPP), detrusor leak point pressure (DLLP), quantitative pad test.....

Inclusion criteria were women >18 years old, with a Stamey grade 1-2 on the Stamey incontinence scale; a patient should not be on anticholinergic treatment unless she has been on stable treatment during the previous month and will continue treatment during the protocol. The bladder capacity should be 300mL or more and post void residual urine of less than 100 mL, and they should have urodynamically proven SUI. Exclusion criteria were women with urodynamic detrusor over activity (DO) or predominately urgency incontinence, pelvic organ prolapse (POP), suspicion of neurogenic bladder, long-term indwelling catheter with local fibrotic urethral/ bladder neck tissues, pregnancy, or plans of conceiving within 2 years after urethral injection therapy. For those patient whom complaining from mixed incontinence were treated with an anticholinergic medication (used to oxybutynin tab 5mg 1x2) to relieve urinary urgency, over one month trial. Procedure: urodex set is composed of four syringe each 1cc, infundibulum, Foleys catheter. Patient is putted in lithotomy position, area is sterilized by povidone, next apply the anesthesia, 1% lidocaine gel into urethra. Then insert Foleys (14 or 16 f) cath. With inflate the balloon, draw the catheter catch the foleys near external urethral meatus to assess length of urethra, and compare that length with infundibulum grade (A, B, C...ect)..... Then according to length insert each injection to 12, 3, 6 and 9 o'clock.

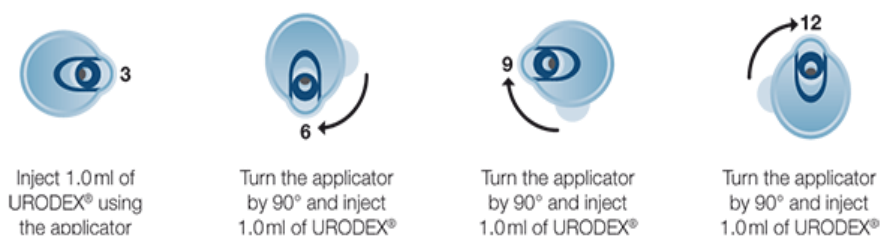


Fig. 1 site of injections in urethra.

For those patients that presented with post injections urinary retention temporarily solved by insertion small caliber catheter to prevent effacement of the bulking agent for few hours. Efficacy of study is evaluated in first baseline visit and regular visits by using stamey grade (take mean of them), number of pads in 48 hours, and the number of incontinence. For assessing of safety; Fellow up to frequency, urgency and post voiding residual volume. Statistics: we use MS excel 2010, if P value < 0.05 is significant.....

II. Results

The range age of patients 42 years to 63 years (the mean is 52.5) , the number of them is 15, three of them (20%) were complaining mixed incontinence and treated with oxybutynin tablet 5mg 1x2 , one of three her incontinence is completely resolved , other 2 patients get no benefit so treated with urodex. Most of these patients presented with mild to moderate incontinence (stamey 1 and 2). The total number of patients that treated with urodex is 14 (93.3 %). The standard procedure is done; give the two hour post procedure to ensure spontaneous voiding. Six of patients (43%) presented with immediate retention (within 2 hours) treated with 8 f catheter for 24 hours then removed allowing the edema subsiding. Post-operative pain treated by diclofinac tab 50 mg for three days, Fellow up done in 6 weeks, 3 month and 12 month. Most of patients get dry in regular visit us show post voiding residual volume few cc to 100 and decrease in next visit.

Table 1: postoperative complications

complications	number of patients	percentage	notes
Postop. retention	6	43%	Small size catheter 24 h
Postop. Pain	11	78 %	Treatment by diclofinac tab 50 mg x3
Bleeding	8	57%	Dressing only

Table 2: efficacy of regular visits

Timing of visit	Stamey grade (Mean)	Number of pads in 48 h.(mean)	Number incontinence in 24 h (mean)
First visit	1.6	15.3	10.7
6 week visit	0.6	7.6	4.7
3 month visit	0.2	1.9	2.6
12 month visit	0.1	0.8	2.1
P value	0.0067	0.015	0.0054

III. Discussion

SUI in women can be either of extrinsic origin is caused by weak pelvic floor support and bladder neck result in urethral hypermobility or may be due to weakness in the urethral sphincteric mechanism that known as intrinsic sphincter deficiency (ISD) (**M. K. Shirvan, 2013**). Surgical correction e.g., transobtrutor or transvaginal slings, can give final solution. But these procedures are invasive and are associated with risk of failure morbidities. Therefore, most of patient seeks for less invasive therapies with lower rate of complications(**D. Robin, 2003**). Bulking agent is formerly given to patients with ISD, but the application of these bulking agents has and also can be used to SUI due to urethral hypermobility(**A.C. Steele, 2000, A.E.Bent, 2001**). In our study we can compare the changes in the results in regular fellow up with Apolikhina et al study(**Apolikhina , A Saidova, 2011**). 14 UI after 1 month in both groups remained high enough: in 1 group – 91.2%, in 2 group –90.3%, after 3 month efficiency has drop by 10%, and after 12 month drop by 30% in both groups. Indicators of the cushioning test after treatment in both groups of patients showed the reduction of urine loss: in 1 group (from 6.83 to 3.63) and in 2 group (from 7.6 to 3.8) (p<0.05) (**Apolikhina , A Saidova, 2011**). The most likely the cause of early urine retention is due postinjection edema, which is subsiding with time. So treatment is few days by small size catheter. The bleeding was accepted as comparative with previous study. Stamey grade had gradual significant change, explain to this results is gradual bulking change in site of injection. The number of pads is decrease. The frequency of incontinence is decrease with significance change. The results are better than some study is due to increase the experience with time

IV. Conclusion

The urodex is good urethral bulking agent with excellent results in treatment mild and moderate severity stress incontinence

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- [9]. **List of abbreviations:-** (SUI) Stress Urinary Incontinence, (ISD) Intrinsic Sphincter Deficiency, (VLPP) valsalva leak point pressure, (DLPP) detrusor leak point pressure, (DO) detrusor over activity, (POP) pelvic organ prolapsed, (UBA) Urethral Bulking Agents.

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