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THE ROLE OF BULKING AGENT HYALURONIC ACID/DEXTRANOMER GEL AT THE THERAPY IN WOMAN WITH STRESS URINARY INCONTINENCE

The role of bulking agent hyaluronic acid/dextranomer gel at the therapy in woman with stress urinary incontinence

Hypothesis/Aims of study: To investigate the efficacy of periurethral injection of bulking agent hyaluronic acid/dextranomer gel (NASHA/dx) – Urodex in women with stress and mixed urinary incontinence (UI).
Materials and methods: Since 2008 30 patients aged 33-70 (mean 54,3±2,9) received therapy in "*Sientific Centre of Obstetrics, Gynecology and Perinatology named after Academician V.I. Kulakov"*. 20 Women with SUI formed group 1 (80%), 10 women with mixed UI (20%) formed group 2. Diagnosis were confirmed by urodynamical tests. BMI was 26,9±1,0 kg/m^2.
Total patients received complex assessment of anamnestic data, gynecological exam with coughing test and Valsalva test, voiding diary, King's Health Questionnaire (KHQ), the Patient Global Impression of Severity (PGI-S), Patient Global Impression of Improvement (PGI-I), assessment of vaginal walls prolapse with POP-Q classification, 3D sonography of paraurethral spatium after injection of NASHA/dx. Patients were attended follow-up assessments at months 1, 2 and 12, volumes of agent was evaluated in 4 locations. Women with mixed UI and urgency received solofenacin (5-10 mg per day). The week before injection of NASHA/dx local vaginal cream - estriol was used (0.25mg x 2 per week).
Injection of NASHA/dx performed in aseptic condition under local anesthesia (instillagel 6ml and lidocain 2%) in 22% cases and intravenous anesthesia in 78% cases. Bladder was catheterized and length of urethra evaluated. 20G needles were inserted via luer applicator to 4 locations, according 3, 6, 9 and 12 hours. Volume of injected agent was 4ml per 1 patient. No perioperative and postoperative complications were observed.
Efficacy of method was evaluated by comparison of subjective and objective data before and after 1,3 and 12 months. Assessment include analysis of symptoms, incontinence episodes, 24 hour pad test and PVR.
Results: 28 out of 30 (98%) patients had improvement at 1 month of follow-up, 26 out of 30(78%) at 3 month of follow-up. Improvement was defined as absence of complaints, negative provocation tests ($p<0.05$), decreasing of number of used pads per 24 hour ($p<0.04$), decreasing of number of stress incontinence episodes per 24 hours($p<0.01$)). In group1 in 4 out of 7 (57%) women with SUI at 1 year of follow-up positive response of treatment was observes (absolute rehabilitation). In 3 (42%) there was no effect at 1 month of follow-up. In group 2 at 1 year of follow-up in 3 out of 4 (75%) patient positive response was observed and in 1 case (25%) retreatment was indicated. In 1 women out of 4 (25%) there was no effect after injection. Assessment of KHQ, PGI-S, PGI-I showed significant improvement, PVR was measures <50ml.
Interpretation of results According to 3D sonography, resorbion of the bulking agent begins in 3 month after injection and it is manifested by individual episodes of incontinence. It is confirmed that efficacy of procedure decreases if vaginal walls prolapse degree ≥2 is observed. The procedure is easy and quick to perform. The safety profile seems unique thus no product specific adverse events were seen.
Concluding message: Periurethral injection of NASHA/dx is a convenient, minimally invasive means of treating stress and mixed incontinence. Injection of this agent significantly improves quality of life and patient satisfaction. Using of modern periurethral methods allows to reach good results and high efficiency at careful selection of patients. Duration of effect on the average makes till 1 year and for its maintenance retreatment are required.

Specify source of funding or grant	**non**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Local Ethics committee and followed the declasation of Helsinki informed concent was obtained from the patients**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**