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Koldewijn, E.L., Streppel, J., Sedelaar, M., Debruyne, F.M.J., Bemelmans, B.L.H.

Department of Urology, University Hospital Nijmegen, The Netherlands.

ULTRASOUND GUIDED IMPLANTATION OF MICROBALLOONS IN FEMALE PATIENTS WITH INTRINSIC SPHINCTER DEFICIENCY

Introduction: Periurethral bulking injections for the treatment of type 3 stress urinary incontinence (intrinsic sphincter deficiency = ISD) should be easy to use, easy to repeat in case of failure, unharmful, not influence the changes of future treatment and financially competitive. Unfortunately, most materials have the disadvantage of migration and absorption and therefore limited success rates. Recently, a new material for urethral bulk injection was introduced. In this study ultrasound guided periurethral implantation of microballoons is evaluated in patients with ISD.

Patients & Methods: In January 2000, 9 patients, mean 54.5 years (range 42 - 67) with urodynamically proven stress urinary incontinence were treated prospectively. All patients had vaginal deliveries, mean 2.6 (range 1-4). In 5 a vaginal or abdominal hysterectomy was performed. All patients, accept one, had previous surgical treatment for stress urinary incontinence: Burch colposuspension in 4, Raz or Stamey suspension in 5 patients. In one patient collagen injections had been used 9 years ago. On physical examination 4 patients had a cystocele, no rectocele or enteroceles were noted. On stress cystogram 6 patients had an open bladder neck and 4 patients had descent of the bladder base of maximum 3 cm. Micturition diaries were filled in for 7 day's. A disease specific quality of life questionnaire was filled in. All patients had a stable cystometry, with a bladder capacity of more than 350 ml. The maximum urethral closure pressure was measured twice and the maximum value was noted: mean was 24.4 cm H_2O, range 20-30.
Microballoons were implanted using the self detachable Urovive balloon system from AMS, USA. The is an elastomeric capsule of silicone with an inflation volume of 0.9 ml. The filling material is normal saline. A check valve prevents the filler material from exiting the balloon. The delivery system consist of a trocar-like needle, sheath, catheter and holder. The procedure is performed under regional or general anaesthesia with the patient placed in lithotomy position. Before the needle is placed, a cystoscopy is performed and the shape of the bladder neck is observed and the bladder is filled with minimum of 100 ml.

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Than, a transrectal ultrasound probe is placed in the vagina. On ultrasound vision the tip of the balloon-delivery-needle is positioned at the bladder neck in a 9, 12 and 3 o'clock position one by one. When after placement of 3 balloons pressure on the suprapubic region revealed stress incontinence and the cystoscopic image showed no closure of the bladder neck additional balloons were placed. After the procedure, the bladder is emptied and no bladder catheter was given. Patients left the hospital within 24 hours after the procedure. Evaluation was performed using a micturition diary, the incontinence questionnaire and a vaginal ultrasound control after 2 months.

Results: Operating time was 15 to 25 minutes. In 6 patients 3 balloons, in 1 patient 4 balloons en in 1 patient 5 balloons were used. In the latter two patients 1 balloon was accidentally punctured during placement. In all patients an acceptable closure of the bladder neck was noted after the procedure. In 4 patients retention occurred for maximum of 24 hours. In one patient hematuria was noted during 12 hours after treatment which recovered spontaneously. Micturition diaries showed no stress-incontinence (dry) after treatment in 4 (44%), improvement in 2 (22%) and unchanged or worse in 3 patients (33%), from whom 1 was dry for only 1 week. The quality of life questionnaire showed no clinical difference before and 2 month after treatment. The ultrasound control 2 month after treatment showed that in 3 out of 4 patients who were dry, at least two balloons were located less than 5 mm. from the bladder neck. In all other patients the balloons were migrated from the original location, more than 1 cm from the bladder neck. None of the patients complaint of discomfort after the procedure in the perineal region.

Conclusion: The implantation of microballoons by ultrasound guidance is an easy and safe procedure, that is well tolerated by patients. Unfortunately, migration occurs and it seems that patients who responded favourable have the implant close to the bladder neck. Placement of the micro balloons is critical for therapeutic success. For this reason ultrasound guided placement seems to be the best technique. Long-term follow-up is needed to judge this treatment. Micro-balloons are a promising new treatment for ISD and ultrasound guided placement surely is a methodological improvement.