Alloussi S1

1. Klinikum Neunkirchen

# NON-ANIMAL STABILISED HYALURONIC ACID/DEXTRANOMER (NASHA/DX) GEL FOR THE TREATMENT OF POST-PROSTATECTOMY INCONTINENCE: EARLY RESULTS

# Hypothesis / aims of study

Urinary incontinence after a radical prostatectomy presents a serious problem for affected patients. It has considerable impact on their daily lives, both from a social and professional point of view. Endoscopic injection into the urethra is a minimally invasive treatment option, which can cure male stress urinary incontinence (SUI). The aim of this study is to investigate the use of non-animal stabilised hyaluronic acid/dextranomer (NASHA/Dx) gel (Deflux®, Q-Med AB, Uppsala, Sweden) in patients with SUI following radical prostatectomy.

## Study design, materials and methods

Thirty-three consecutive patients with post-operative SUI following radical prostatectomy participated in the study. In all cases, incontinence proved refractory to electrostimulation and/or biofeedback (pharmacotherapy not administered). Stress urinary incontinence was urodynamically diagnosed and graded according to the following criteria: grade III (daily urine loss >250 g), grade II (daily urine loss 51–250 g), grade I (16–50 g) or grade 0 (0–15 g). Exclusion criteria included urethral obstruction; post-void residual urine >50 ml; on-going radiotherapy or hormonal therapy; prostate-specific antigen (PSA) level >3 ng/ml; and concurrent neurogenic disease.

All patients underwent endoscopic injection of NASHA/Dx gel into the urethra. Twelve patients were injected after having an epidural, and the bladder was relieved using a suprapubic catheter. The remaining 21 patients were injected under local anaesthetic. Follow-up assessment was performed at 3–6 months post-treatment.

#### **Results**

The patients' mean age was 67 years (range: 57–76 years). Before treatment with NASHA/Dx gel, 23 patients had grade II SUI, and 10 had grade III; all were free from symptoms of urge incontinence. Daily urine loss ranged between 50 and 900 g. None of the patients displayed signs of cancer progression in terms of clinical symptoms and PSA levels (all were <0.1 ng/ml), and there was no clinical evidence of metastases. There were also no problems with bladder voiding, of either an obstructive or neurological kind.

The volume of NASHA/Dx gel injected ranged between 1 and 5 ml. At post-treatment follow-up, 21 of the 23 patients with grade II SUI were reduced to grade 0 and two were reduced to grade I. Six out of the 10 patients with grade III SUI were reduced to grade II, three patients to grade I and one patient to grade 0. Among these patients, mean daily urine loss was reduced by 79%, from 542 g to 116 g.

A further injection is planned for all patients with on-going SUI (grade I–II).

## Interpretation of results

NASHA/Dx gel was shown to be highly effective for the treatment of SUI after radical prostatectomy. The treatment procedure is minimally invasive and can be carried out under local anaesthetic. The outcome of treatment appears dependent on the severity of incontinence and the extent of sphincter damage. Following this initial investigation, long-term follow-up data are awaited with interest. In addition, patient selection criteria and the methods used for the injection procedure remain to be verified.

# **Concluding message**

This preliminary study has demonstrated that endoscopic injection of NASHA/Dx gel is a feasible and effective treatment option for SUI following radical prostatectomy. Further investigation of this approach to treatment, including its effect on quality of life, is clearly warranted.