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ZUIDEX® TREATMENT OF SUI – IMPACT ON QUALITY OF LIFE (KING'S HEALTH QUESTIONNAIRE)

Aims of Study

Stress urinary incontinence (SUI) is the most common form of urinary incontinence in females and the incidence of the condition increases with age. SUI affects the physical, psychological and social well-being of a patient thus having a considerable impact on quality of life (QoL). The patient and physician should discuss all the available options when choosing treatment for SUI and patients should be fully informed of the relative benefits and risks for each option. Presently, surgery is regarded as the only effective treatment for SUI refractory to non-invasive treatment, but patients tend to favour less invasive approaches even if the likelihood of cure is reduced (Robinson D et al. Abstract 115, ICS 2002). Improving patients' overall QoL should be the primary aim of all treatment for SUI.

Dextranomer/hyaluronic acid (Dx/HA) copolymer is widely used as an injectable agent for endoscopic treatment of vesico-ureteral reflux in children and has been approved by the FDA (Deflux®, Q-Med, Uppsala, Sweden). Dx/HA copolymer also has European approval for the treatment of SUI (Zuidex™). In combination with a novel applicator (Implacer™ device), treatment of SUI by transurethral injection of Dx/HA copolymer can be performed as an office procedure, eliminating the need for surgical facilities.

A pilot study was recently undertaken to evaluate the safety and efficacy of Zuidex™ in SUI, during which patients also assessed their QoL using the King's Health Questionnaire. This instrument is specifically designed to measure the impact of incontinence and its effects on a range of lifestyle parameters.

Methods

This was an open, prospective, multi-centre study. Female patients 18 years of age or older with urodynamically verified SUI were recruited, regardless of SUI pathophysiology (hypermobility and/or intrinsic sphincter deficiency). All patients had a history of SUI for at least 12 months and had failed prior non-invasive treatment.

Following administration of local anaesthetic, Dx/HA copolymer injections were administered at the mid-urethra using the Implacer™ device. The device facilitates sequential injection of four injections at the 12, 3, 6 and 9 o'clock positions. Two different injection volumes were investigated: 4 x 1.0 ml and 4 x 0.7 ml. No clinically relevant differences were observed between the two groups, therefore pooled data are presented.

Patients completed the King's Health Questionnaire at the baseline visit and at each of the follow-up visits, 3 and 12 months post-treatment. The domains are evaluated using a four-point scale.

Patient perception of overall bladder condition was assessed at the baseline, and the 3- and 12-month follow-up visits. This was obtained from patients' rating of their overall bladder condition as causing 'none', 'some very minor', 'some minor', 'some', 'some severe' or 'many severe' problems.

Results

A total of 42 patients were recruited into the study (Table 1).

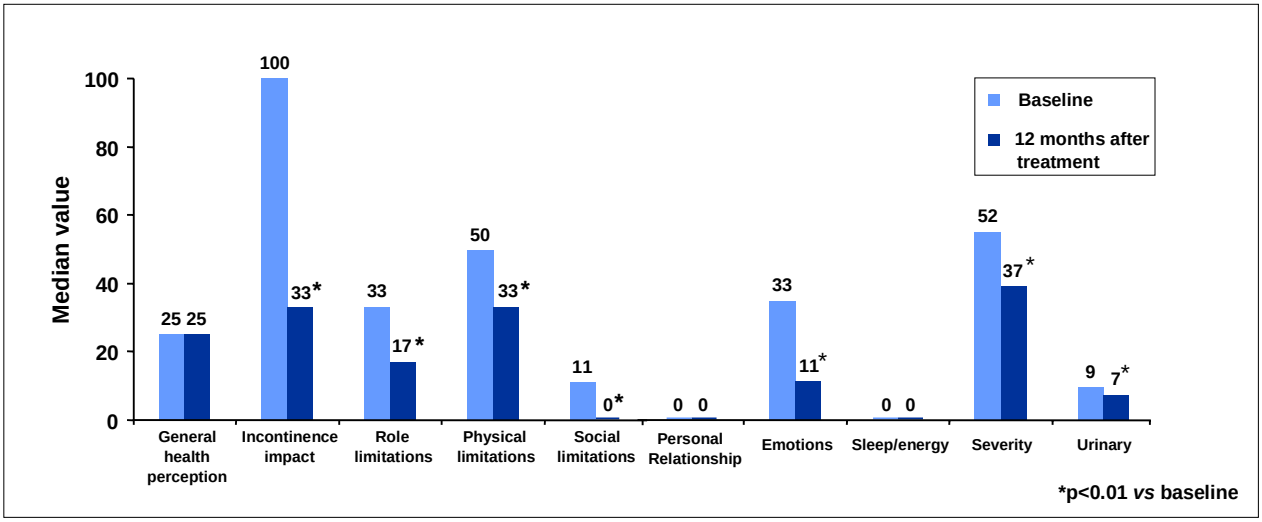
Table 1. Patient characteristics.

Age in years (range)	52.8 (30.5–77.9)
Menopause n (%)	22 (52.4%)
Duration of symptoms >5 years	33 (78.6%)
Severe problems (patient perception)	22 (52.4%)
Previous non-drug therapy for SUI	42 (100.0%)

Clear improvements in QoL were observed within 3 months of treatment and sustained to month 12 (there was little difference between the two timepoints). At month 12, a statistically

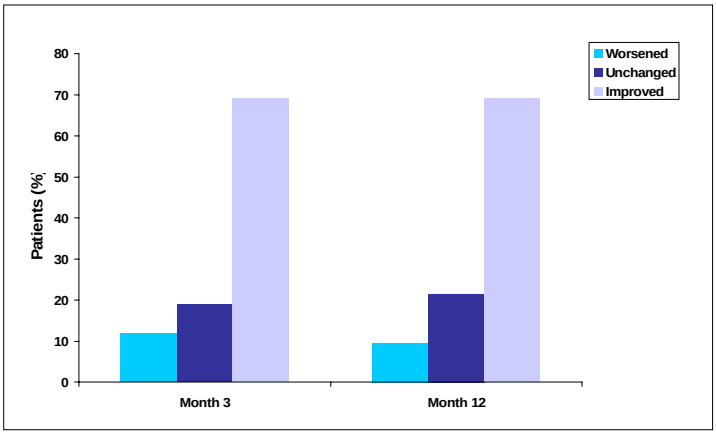
significant improvement relative to baseline was observed in 7 out of the 10 QoL domains of the King's Health Questionnaire: incontinence impact, role limitations, physical limitations, social limitations, emotions, severity measures and urinary symptoms (Figure 1). For two of the three domains for which there was no significant improvement (personal relationship and sleep/energy), the median impact of SUI was zero at both baseline and 12 months.

Figure 1. Effect of Zuidex™ treatment on King's Health Questionnaire domains (baseline vs 12 months).



Twenty-nine patients (69.0%) perceived an overall improvement in their bladder condition at 3 months (Figure 2). There was no deterioration in this response between months 3 and 12.

Figure 2. Patient-perceived changes in bladder condition at 3 and 12 months versus baseline.



Conclusions

This study has shown that treatment with Zuidex™ produces marked improvements in QoL among patients with SUI, as measured by the King's Health Questionnaire. The improvements were apparent within 3 months of treatment and sustained to12 months.

These benefits in QoL, coupled with the convenient and minimally invasive nature of the procedure, suggest that Zuidex™ could become a favoured treatment option among patients failing non-invasive treatment of SUI.