284

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IMPACT OF THE ZUIDEX™ SYSTEM FOR THE TREATMENT OF STRESS URINARY INCONTINENCE ON QUALITY OF LIFE: 6-MONTH RESULTS OF AN OPEN, MULTICENTRE STUDY

Hypothesis / aims of study

Stress urinary incontinence (SUI) is the most common type of incontinence in women. It can often be the cause of significant embarrassment to the patient, with a direct impact on everyday activities. An improvement in the symptoms of SUI can produce a major improvement in the patient's quality of life. Zuidex™ (Q-Med AB, Uppsala, Sweden) is a novel system for treating SUI: an injection device (Implacer™) is used to achieve reproducible urethral injection of non-animal stabilised hyaluronic acid (NASHA)/dextranomer (Dx) gel, without the need for endoscopy. NASHA/Dx gel is a biodegradable and biocompatible injectable agent, whose safety profile has been well documented. The present study was performed to measure the impact of Zuidex injection on patient quality of life over 6 months following treatment.

Study design, materials and methods

One hundred and thirty nine invasive-therapy naïve SUI patients aged 18 years and over, with SUI confirmed by a provocation test, were recruited into an open, multicentre, non-comparative study across 16 European centres. Patients were urodynamically characterised and recruited regardless of the nature of their SUI (hypermobility and/or intrinsic sphincter deficiency). The study was performed in accordance with Good Clinical Practice and applicable regulatory requirements. Local anaesthetic was administered prior to treatment with the Zuidex system (four injections of NASHA/Dx gel delivered via the Implacer device). If a patient was not dry or improved to her satisfaction at week 8, a second treatment was offered. Patients were asked to assess their quality of life by completing the King's Health Questionnaire and providing a global assessment of incontinence problems (no, mild, moderate or severe problems). These assessments were performed at baseline, week 8, week 12 and month 6.

Results

Baseline characteristics of the study participants are shown in Table 1.

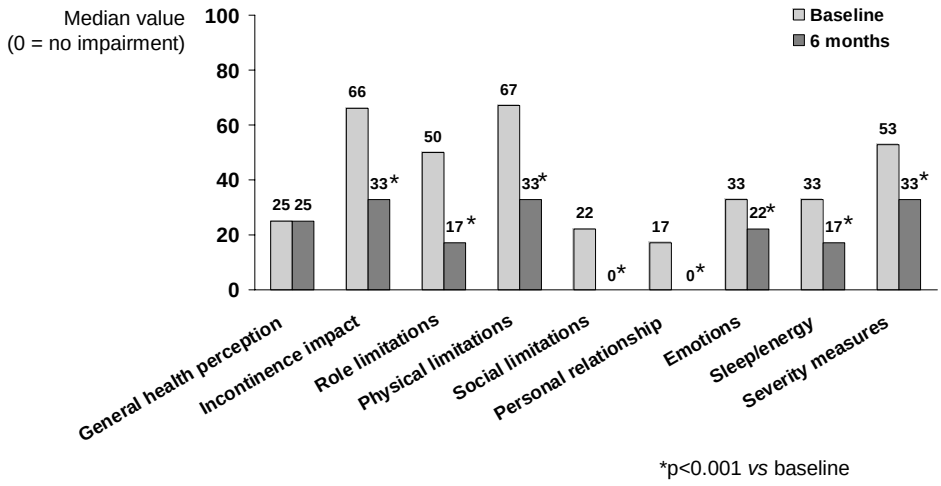
Table 1. Patient demographics (n=139).

Mean age in years (range)	55.3 (27–86)
Mean body mass index in kg/m^2 (range)	25.7 (19.3–33.1)
Post-menopausal (%)	61.9
Mean no. of deliveries (range)	2.1 (0–5)
SUI symptoms for >5 years (%)	49.6

The initial treatment procedure was viewed as acceptable by the large majority (83%) of patients, with only 17% considering the procedure to be unpleasant or very unpleasant. Pain associated with the treatment procedure was the primary reason given by patients reporting the procedure to be unpleasant. An increased proportion of the patients undergoing a second treatment (90%) viewed the re-treatment procedure as acceptable.

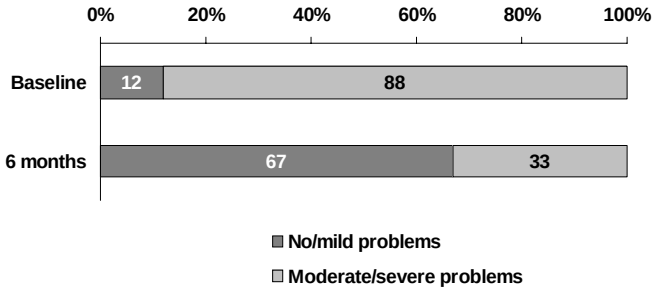
Treatment with Zuidex had a positive impact on patients' quality of life. Significant improvements were noted in eight out of nine King's Health Questionnaire domains (6 months *vs* baseline, Figure 1). Median quality-of-life impairment was reduced to zero at 6 months, in terms of social limitation and personal relationships. At weeks 8 and 12, the improvements in quality of life were similar to those at 6 months (data not shown).

Figure 1. Comparison of King's Health Questionnaire responses at baseline and 6 months after Zuidex treatment.



Patients' general perception, as indicated by global assessment of incontinence problems, showed a correspondingly large improvement at 6 months (Figure 2). Over two-thirds of patients (68%) reported a lower magnitude of incontinence-related problems compared with baseline. Two-thirds of patients reported either mild or no problems at 6 months.

Figure 2. Patients' global assessment of incontinence problems at baseline and 6 months after Zuidex treatment.



Interpretation of results

A large majority of SUI patients treated with Zuidex reported an improvement in their global assessment of incontinence, and found the treatment procedure acceptable. Correspondingly, significant improvements were observed in patients' quality of life assessed by the King's Health Questionnaire. Initial improvements were maintained for 6 months post-treatment. These findings, taken together with patients' preferences for minimally invasive treatment procedures for SUI as opposed to more invasive surgery (1) support the potential use of Zuidex as early intervention for patients presenting with this condition.

Concluding message

The Zuidex system provides a straightforward and effective treatment for SUI that significantly improves patients' quality of life. Zuidex treatment is also highly acceptable to patients.

References

1. What do women want? Interpretation of the concept of cure. *J Pelvic Surg Med* 2003; **9**: 273–7.

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