

RESULTS AFTER SUBMUCOUS BULKING THERAPY WITH NASHA/DX FOR ANAL INCONTINENCE IN RELATION TO PRETREATMENT CLINICAL CHARACTERISTICS

Hypothesis / aims of study

Anal incontinence is a common condition affecting up to 2% of women in the normal population (1). Anorectal bulking therapy is increasingly used as minimal invasive treatment of anal incontinence (2). The aim is to expand the anorectal junction to increase resistance to leakage of feces. Theoretically patients with moderate internal sphincter dysfunction would have most benefit of this treatment. The aim of this study was to assess the results after submucous injection of Nasha/Dx for fecal incontinence and also to evaluate the results in relation to clinical characteristics and pretreatment manometry

Study design, materials and methods

34 patients (29 women, 5 men, mean age 61, 34-80, 5 with endosonographic subtotal sphincter defect) with fecal incontinence were injected with 4 x 1 ml through an anoscope in the submucous layer 5-10 mm above the dentate line. 18 patients received a second treatment after 4 weeks. The patients were followed up after 3 months and thereafter every 6 months with clinical assessment plus registration of incontinence episodes using a 4 weeks diary and a bowel function questionnaire. A response to treatment was defined as a 50% reduction in leak episodes. The results were evaluated separately with patients categorized according to pretreatment clinical characteristics and manometry.

Results

All injections were performed at an out patient setting without anaesthesia and no SAE occurred. 25 pts (74%) stated that they were improved at one year follow-up. The average number of leak episodes during 4 weeks were 25 before treatment and decreased to 15, 14, and 15 after 3, 6 and 12 months respectively ($p < 0.01$, Wilcoxon signed rank test). 21/26 (81%) were improved after 18 months, and 17/19 (89%) after 24 months. After 18 and 24 months the mean no of episodes were 14 and 12, respectively. There was no clear relationship between pre-treatment manometry and outcome. The results were also independent of age, gender, dose, presence of sphincter defect, type and severity of incontinence.

Interpretation of results

The effect was sustained for one year and appears to be stable for two years. The result was independent of pretreatment manometry and clinical characteristics indicating that this treatment might be suitable for various types of incontinence.

Concluding message

Anorectal injection of Dx gel is a safe, durable and effective treatment for fecal incontinence.

References

- 1) Int Urogynecol J Pelvic Floor Dysfunct. (2006) 17; 407-417.
- 1) Br J Surg (2005) 92; 521-527.

FUNDING: The study was supported by a grant from Q-Med AB.

CLINICAL TRIAL REGISTRATION: Swedish Medical Product Agency dnr 461:2003/71862

HUMAN SUBJECTS: This study was approved by the Medicinska Fakultetens Forskningsetikkommitte, Uppsala, Sweden. and followed the Declaration of Helsinki Informed consent was obtained from the patients.