Results after submucous bulking therapy with NASHA/Dx for anal incontinence in relation to pretreatment clinical characteristic

Graf W, Danielsson J, Sonesson AC, Dept of Surgery, Institution of Surgical Science, Akademiska Hospital, Uppsala Sweden

Background
Anal incontinence is a growing problem worldwide with a prevalence of about 2% (1). For many patients the disease has serious impact on quality of life. Many patients avoid seeking help due to embarrassment and the perception that there is a lack of effective treatment options.

Common etiologies are:
- Obstetric injuries
- Neurogenic disorders
- Iatrogenic injuries
- Bowel dysfunctions
- Degenerative disorders

Traditional treatment involves:
- Delay and pharmacological treatment
- Physiotherapy and biofeedback
- Local sphincter surgery
- Reconstrutive colorectal surgery
- Nerve stimulation techniques
- Neuropenther procedures
- Enterostomy

Injectable bulking therapy has been developed in order to delay or avoid invasive therapy or to improve suboptimal results (2). The results after previously used agents (Hyalogel, AlloSilicone, Collegen, Carboncoated beads) has been encouraging although there may be a potential for further improvement.

NASHA/Dx gel is a copolymer of cross-linked deacetein microspheres (diameter 80-250 micrometers) in a 1% carrier of Stabilised Non-Amyloid Hyaluronic Acid. The substance has been CE-approved since December 1998 and FDA-approved since September 2001 for the use in treatment of urinary stress incontinence and vesicouretral reflux. It has proven to be an easily injectable substance and has shown very good tissue tolerance (3).

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.

Materials and Methods
34 patients (29 women, 5 men, mean age 63, 34-80, 5 with endosonographic sublental 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 injection.

The results after previously used agents (Autologous fat, Silicone, Collagene, Carboncoated beads) has been encouraging although there may be a potential for further improvement.

NASHA/Dx gel is a copolymer of cross-linked deacetein microspheres (diameter 80-250 micrometers) in a 1% carrier of Stabilised Non-Amyloid Hyaluronic Acid. The substance has been CE-approved since December 1998 and FDA-approved since September 2001 for the use in treatment of urinary stress incontinence and vesicouretral reflux. It has proven to be an easily injectable substance and has shown very good tissue tolerance (3).

The results were evaluated separately with patients categorized according to pretreatment clinical characteristics and manometry. The trial is still ongoing. All 34 patients have completed the 12 months follow-up. 26 and 19 patients have completed the 18 and 24 months follow-up respectively.

Results
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 follow-up respectively.

The results were independent of dose and presence of sphincter defect (Fig 2) and did not vary in relation to pretreatment manometry (Fig 3).

Discussion and conclusion
Injectable bulking therapy in the submucous layer of the anorectal junction with NASHA/Dx gel might be a safe and effective treatment for anal incontinence. So far the results appear to be independent of the severity and etiology of the disease. In November 2006 NASHA/Dx (SOLESTA™) was CE-approved for the treatment fecal incontinence, based on the result from this trial.

References