International Continence Society | August 22-26, 1999 | 29th Annual Meeting | Denver, Colorado USA

Category No. | Video Demonstration | Ref. No. 521

Abstract Reproduction Form B-1

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Title (type in CAPITAL LETTERS): A NONSURGICAL URETHRAL SUPPORT DEVICE FOR CURE OF STRESS AND MIXED INCONTINENCE

Aims of Study. A new concept in conservative management in stress and mixed urinary incontinence is described. This is an intravaginal tampon like device, when in place, mimics the surgical effects of suburethral sling by supporting urethra and elevating bladder neck without urethral occlusion. The aims of present study were to determine safety and efficacy of this device in subjects with stress and mixed incontinence.Device is made of medical grade Santoprene 241-55, with a FDA Drug Master File Number of 7730.

Methods. A total of 29 subjects were recruited between March 1997 and November 1998.All subjects underwent strict inclusion and exclusion criteria. A baseline frequency volume chart(FVC) was completed over 2 weeks. Women with less than two leakages per week were not included. The number of pads per day and number of urges per day on FVC were recorded as outcome measures. A standard 1-hour pad test was performed to confirm at least 3mls in 1 hour.Patients were offered enrollment if a diagnosis of GSI or MI with primary stress symptoms was reached. Diagnosis was based on history, examination, urodynamics and presence of abdominal leak point pressure. Each subject underwent a video cystourethrogram befor and following insertion of the device to exclude outflow obstruction, and confirm urethral support and continence. Device came in 3 sizes and most of the subjects were fitted with Medium size device. Subjects were reviewed on a weekly basis for the first four weeks. They were asked to keep a bladder diary, any side effects, voiding difficulty, pain or discharge. On fifth visit each subject was evaluated in order to document the effect of the device on urethral and bladder function and incontinence severity. After completion of the initial phase the subjects were enrolled in long term extension of the study.

Results. Of total 29 subjects enrolled in the study there were six drop outs for various reasons. In 23 women who continued for 9 months, median number of leaks/day declined from 4.5 to less than 1.0. Median pad test loss fell from 57mls to 3mls. Cystometry showed a modest reduction in detrusor instability, with no evidence of outflow obstruction. Video cystogram confirmed stabilization and support of hypermobile urethra and elevation of bladder neck. A voiding cystogram confirmed absence of urethral compression and normal voiding. Success was defined when device fitted ccomfortably and subject was completely dry or had both, a 70% improvement in leaks per day and a 70% improvement in pad testing. An overall success rate of 85% demonstrated with 19/23 totally dry at 4 weeks and end of 9 months.

Conclusions. This new urethral support device acts by support and elevation of hypermobile urethra in a retropubic position, in a similar fashion as sub urethral sling or burch colposuspension. This device appears to be a safe and effective predictor of surgical success and will appeal to subjects who wish to defer surgery, or in cases with where surgery had been of little help.

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urethral compressionpresence of normal voiding. Success was defined when device fitted comfortably and subject was completely dry or had both, a 70% improvement in leaks per dayand a 70% improvement in pad testing. An overall success rate of 85% demonstrated with 19/23 totally dry at four weeks as well as end of nine months.

Conclusions.This new urethral support device acts by support and elevation of hypermobile urethra in a retropubic position, in a similar fashion to suburethral sling or Burch colposuspension. The device appears to be a safe andeffective predictor of surgical success and will appeal to subjects who wish to defer surgery or can be either a long term or short term cure for subjects in whim previous surgical results had been less than satisfactory