Abstract Reproduction Form B-1

Author(s): Victor Nitti

Institution: New York University
City: New York, New York
Country: United States

Title (type in CAPITAL LETTERS): NOVEL DEVICE AND TRANSURETHRAL DELIVERY METHOD FOR MALE URINARY STRESS INCONTINENCE

Aims of Study: Effective surgical treatment options for stress urinary incontinence in men following radical prostatectomy has been limited. While several injectable bulking agents have been evaluated, none have shown the efficacy of artificial urinary sphincters. Currently, a new type of minimally invasive device is being evaluated as a treatment option. This paper will describe the initial experience and results of the device which was evaluated under a Phase 1 clinical trial for safety and initial efficacy. A Phase 2 multi-center trial is underway.

Methods: The new device, UroVive™, manufactured by UroSurge, Inc. of Coralville, Iowa, USA, consists of an implantable silicone micro-balloon, hydrogel filler material and transurethral delivery system. The method of implantation involves the creation of a pocket in the submucosa distal to the bladder neck. Once the pocket has been created, the deflated balloon is inserted then inflated resulting in urethral bulking. The micro-balloon after inflation is 2.1cm (length) and .85cm (diameter) and requires a 2.5cm pocket. The inability to achieve the desired insertion plane has led to the creation of a unique cystoscope for delivery of the device. Multiple devices can be implanted to achieve the desired coaptation. Transurethral placement of the device is performed using a custom cystoscope manufactured by Richard Wolf Medical Instruments of Germany.

Results: Seven patients have been treated at NYU with a maximum follow-up of twelve months. Three patients had an initial improvement post-treatment. Two patients have undergone an additional treatment. Presently, two of the most recent patients have shown significant improvement. An evolution in the design of the delivery method has occurred over the course of this study. The ability to insert the device into the desired submucosal plane presented initial difficulties. An additional challenge includes the heavy layers of scar tissue that may have formed as a result of radical prostatectomy.

Conclusion: Development of a unique cystoscope adapter and delivery technique will help to increase the efficacy of the device to potentially become an effective minimally invasive treatment for male stress urinary incontinence. Clinical results from the prospective study to be updated and reported.