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Crivellaro S[1], Tosco L[1], Martinez Bustamante L G[1], Palazzetti A[1], Kocjancic E[2], Frea B[1]
1. *Azienda Ospedaliero- Universitaria di Udine, Udine, Italy,* ***2.*** *University of Illinois, Department of Urology, Chicago, USA*

STEPPER GUIDED TRANSRECTAL ULTRASONOGRAPHY PROACT POSITIONING

Hypothesis / aims of study

Stress urinary incontinence following radical prostatectomy remains a significant problem for both patients and urologists, with an incidence of 5-20%. A recent surgical treatment option includes pro adjustable continence therapy (ProACT). The way used to implant ProACT® employs fluoroscopic control. This doesn't permit to see both the sagittal and transverse section at the same time and may create problems in positioning balloons in the correct section in reference to the bladder neck and bladder-urethral anastomosis. As long as the efficacy of implants is strictly related to the right position beside the bladder neck, we tried to achieve a better placement control using stepper-guided transrectal ultrasonography (TRUS). The aim of this study is to evaluate if stepper-guided TRUS permits a better Pro-ACT placement.

Study design, materials and methods

Between April 2009 and February 2010 a total of 25 patients (range 21-80 years old) underwent ProACT® positioning using stepper-guided TRUS. After positioning the ultrasound probe in place a pre-planning of positioning was made. Distance from the ideal location to the pubic symphisis, ischiopubic rami, urethra and probe in the transversal view and distance to the skin in the longitudinal view have been recorded. The measurements are then reported on the skin and on the trocar. A Chiba needle is then used to verify the path of the trocar based on measurements previously taken and to perform local anesthesia. Subsequently the trocar is inserted and followed by ultrasound to the ideal position and the device inserted through the sheath. All patients enrolled in our study underwent a urodynamic exam to confirm the presence of intrinsic sphincteric insufficiency in the absence of detrusor overactivity. Efficacy of the treatment has been evaluated with daily pads count and with Incontinence Quality of Life questionnaires (IQoL). Moreover, patients' impression has been evaluated using Visual Analogue Scale (VAS from 0 to 10) and Overall Impression (Dry, improved, same, worse). Surgical details and complications balloons volume and number of adjustments have been reported for each patient at follow up visits at 1,3,6 and 12 months.

Results

Mean surgery time was 20 minutes (range 12-35). Mean follow-up time was 6 months (range 2-10). Daily pads count highlighted that after surgery a total of 15 patients (60%) were completely dry and 7 pts (28%) were improved. IQoL increased from an average of 30,2 before ProACT implant to 65 at last follow-up ($p<0,005$). Average VAS score was 7. Overall impression showed 62% Dry and 25% Improved. Complications that required devices removal happened in 3 patients (12%). Reasons were urethral erosion (2 pts), infection (1 pts). Mean balloon volume was 3.1 cc on the right and 3.3 on the left. Number of adjustments was on average 2.5

Interpretation of results

The stepper-guided TRUS permicts a more precise positioning in according with a pre-planning measurements. Additionally it permicts the operator to use both hands on the trocar allowing more control on the procedure. The balloon volume required to reach a good results seems to be slightly lower than the usual one maybe decreasing the risk of erosion over time.

Concluding message

Our study demonstrated that the correct positioning of ProACT® implants benefits from the use of stepper-guided TRUS which permits to achieve a greater precision in reaching the desired location thus reducing wrong placements of balloons that frequently are the cause of the persistence of stress urinary incontinence.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**Because it doesn't cause any harm on patient's.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**