140

Christine B[1], Bivins V M[1], Tully A S[1], Bugg C[1], Bella A[2], McGwin, Jr G[3]
1. *Urology Centers of Alabama, Birmingham, AL, USA,* ***2.*** *University of Ottawa, Ontario, Canada,* ***3.*** *University of Alabama at Birmingham, Birmingham, AL, USA*

TRANSOBTURATOR MALE SLING AT THE TIME OF ROBOTIC ASSISTED, LAPAROSCOPIC RADICAL PROSTATECTOMY YIELDS IMPROVED CONTINENCE OUTCOMES: DATA FROM A RANDOMIZED CLINICAL TRIAL DEMONSTRATING SAFETY AND EFFICACY.

Hypothesis / aims of study

Persistent stress urinary incontinence is a well documented potential complication of radical prostatectomy. Reduction in quality of life secondary to urinary incontinence in these men is also well known. The AdVance transobturator male sling (American Medical Systems) has been shown to be an efficacious and safe treatment option in the patient with mild-to-moderate post-prostatectomy stress incontinence (1). The authors hypothesized that placement of an AdVance transobturator sling at the time of a robotic assisted, laparoscopic radical prostatectomy would positively effect continence outcomes with little risk of increased complications.

Study design, materials and methods

Men diagnosed with prostate cancer and scheduled to undergo robotic assisted, laparoscopic radical prostatectomy were extensively counseled about this study including detailed discussions regarding risks, potential benefits, and alternatives to care associated with the transobturator male sling. After reading and signing appropriate consent documents, patients underwent flexible cystoscopy in the clinic setting to rule out bladder neoplasm and urethral stricture. They were then randomized to one of two treatment arms: robotic prostatectomy with concurrent placement of the male sling, or robotic prostatectomy alone. Simple randomization was carried out so that 20 men were assigned into each of the treatment arms. Neither patients nor care providers were blinded to patient assignment into the two treatment arms. The primary endpoint of the study was time to return to complete continence following urinary catheter removal.

The surgical technique of sling placement has been described elsewhere. In this study, following completion of the robotic prostatectomy, the robot was undocked from the patient and all port incisions closed. Then, the patient was re-prepped, re-draped, and the sling placed in standard fashion through a midline, perineal incision. The only modification to sling placement was that the foley catheter was not removed during sling tensioning. Patients were discharged to home the following morning, and catheter removal was carried out 6 days later per our robotic surgeons' standard protocol.

Patients were followed up in the clinic at 6 weeks, 3 months, 6 months, and 12 months after surgery. Patients were asked to record the day that they attained complete continence and no longer required the use of protective pads. At each visit patients were queried as to continence, pad use and adverse events, Time to return to continence was recorded as number of days since catheter removal; patients who attained continence the same day as catheter removal were recorded as "1 day" time to continence. Patient age and size of the excised prostate were recorded.

Results

The study design called for 40 total patients to be randomized. All 40 randomizations have occurred with 20 men randomized into each treatment arm. However, at the time of this abstract, only 19 men in each arm have undergone surgery. Thus, we can report on 38 total participants. Mean time to return to complete continence and cessation of pad use was 14 days for the patients who had a sling placed concurrent with robotic prostatectomy (range 1-90 days), and 104 days for patients who did not receive a sling (range 1 day to continued leakage at the time of this abstract). P value for this function was <0.0001. Further, all men who received a sling have attained complete continence, while 6/19 (31.6%) men who did not receive a sling have persistent incontinence. 8/19 men (42%) who received a sling at the time of radical prostatectomy attained continence on the day of catheter removal. The power for the time to continence analysis is >0.99. Mean patient age was 64.5 years for patients who received a sling (range 53-74 years), and 63.5 years for those who underwent prostatectomy alone (range 51-75 years). Mean prostate size was 48.9gms for sling patients (range 25- 72 grams), and 47.7gms for men who did not receive a sling (range 29-83 grams). There have been no adverse events associated with sling placement. Specifically, no wound infections, increased bleeding, or episodes of urinary retention have occurred in these patients.

Interpretation of results

This randomized trial has shown that men who received a transobturator male sling concurrent with robotic assisted, laparoscopic radical prostatectomy experienced a significantly shorter time to attain complete continence than men who underwent robotic radical prostatectomy alone. Further, 42% of the patients who received a sling became continent on the day of catheter removal. Patient age and size of the prostate were not significantly different between the treatment groups. We believe the striking difference in continence outcomes is the result of the AdVance sling's ability to provide support to the bulbar urethra and external sphincter. In the patient who has previously undergone a radical prostatectomy, the sling repositions the proximal urethra and external sphincter into a more anatomic position, thus reducing the prolapse of these structures that occurs when the prostate is removed and male pelvic support is altered. In the patients who receive the sling concurrent with radical prostatectomy, the sling is felt to *prevent* this prolapse from occurring. This allows a more rapid, and in some cases an immediate, return to continence.

Concluding message

Continence outcomes following robotic assisted, laparoscopic radical prostatectomy were significantly improved by the concurrent placement of the AdVance transobturator male sling. Mean time to attain complete continence was reduced from

104 days to 14 days, with 42% of sling patients attaining continence on the day of catheter removal. While these outcomes are encouraging, a multicenter study is needed to confirm our findings.

References

1. Rehder P, Mitterberger, Pichler R, Kerschbaumer A, Glodny B. The 1 Year Outcome of the Transobturator Retroluminal Repositioning Sling in the Treatment of Male Stress Urinary Incontinence. BJU Int. 2010, May 26.

Specify source of funding or grant	**American Medical Systems, USA**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Institutional Review Board, St. Vincent's Hospital, Birmingham, Alabama, USA**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**