Functional Recovery, Oncologic Outcomes and Postoperative Complications after Robot-Assisted Radical Prostatectomy: An Evidence-Based Analysis Comparing the Retzius Sparing and Standard Approaches

Mani Menon,* Deepansh Dalela,*,† Marcus Jamil, Mireya Diaz, Christopher Tallman, Firas Abdollah,‡ Akshay Sood, Linda Lehtola, David Miller and Wooju Jeong

From the Vattikuti Urology Institute Center for Outcomes Research, Analytics and Evaluation, Vattikuti Urology Institute, Henry Ford Health System (DD, MJ, MD, CT, FA, AS, LL, WJ) and Departments of Urology, Wayne State University School of Medicine, Detroit (MM) and University of Michigan Medical School (DM), Ann Arbor, Michigan, and Departments of Urology, Case Western Reserve University (MM), Cleveland and University of Toledo (MM), Toledo, Ohio

Abbreviations and Acronyms

BCR = biochemical recurrence

BCRFS = BCR-free survival

MUSIC = Michigan Urological Surgery Improvement Collaborative

RARP = robot-assisted radical prostatectomy

RCT = randomized controlled trial

SHIM = Sexual Health Inventory for Men

VUI = Vattikuti Urology Institute

Purpose: We report a 1-year update of functional urinary and sexual recovery, oncologic outcomes and postoperative complications in patients who completed a randomized controlled trial comparing posterior (Retzius sparing) with anterior robot-assisted radical prostatectomy.

Materials and Methods: A total of 120 patients with clinically low-intermediate risk prostate cancer were randomized to undergo robot-assisted radical prostatectomy via the posterior and anterior approach in 60 each. Surgery was performed by a single surgical team at an academic institution. An independent third party ascertained urinary and sexual function outcomes preoperatively, and 3, 6 and 12 months after surgery. Oncologic outcomes consisted of positive surgical margins and biochemical recurrence-free survival. Biochemical recurrence was defined as 2 postoperative prostate specific antigen values of 0.2 ng/ml or greater.

Results: Median age of the cohort was 61 years and median followup was 12 months. At 12 months in the anterior vs posterior prostatectomy groups there were no statistically significant differences in the urinary continence rate (0 to 1 security pad per day in 93.3% vs 98.3%, p = 0.09), 24-hour pad weight (median 12 vs 7.5 gm, p = 0.3), erection sufficient for intercourse (69.2% vs 86.5%) or postoperative Sexual Health Inventory for Men score 17 or greater (44.6% vs 44.1%). In the posterior vs anterior prostatectomy groups a nonfocal positive surgical margin was found in 11.7% vs 8.3%, biochemical recurrence-free survival probability was 0.84 vs 0.93 and postoperative complications developed in 18.3% vs 11.7%.

Accepted for publication November 29, 2017.

No direct or indirect commercial incentive associated with publishing this article.

The corresponding author certifies that, when applicable, a statement(s) has been included in the manuscript documenting institutional review board, ethics committee or ethical review board study approval; principles of Helsinki Declaration were followed in lieu of formal ethics committee approval; institutional animal care and use committee approval; all human subjects provided written informed consent with guarantees of confidentiality; IRB approved protocol number; animal approved project number.

Supported by Blue Cross Blue Shield of Michigan (Michigan Urological Surgery Improvement Collaborative).

* Equal study contribution.

† Correspondence: Vattikuti Urology Institute Center for Outcomes Research, Analytics and Evaluation, Vattikuti Urology Institute, 2799 West Grand Blvd., K-9, Henry Ford Health System, Detroit, Michigan 48202 (telephone: 586-344-4969; FAX: 313-916-9539; e-mail: ddalela1@hfhs.org).

‡ Financial interest and/or other relationship with GenomeDx Biosciences.

Editor's Note: This article is the third of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 1360 and 1361.

0022-5347/18/1995-1210/0
THE JOURNAL OF UROLOGY®

https://doi.org/10.1016/j.juro.2017.11.115
Vol. 199, 1210-1217, May 2018
Printed in U.S.A.

Conclusions: Among patients with clinically low-intermediate risk prostate cancer randomized to anterior (Menon) or posterior (Bocciardi) approach robot-assisted radical prostatectomy the differences in urinary continence seen at 3 months were muted at the 12-month followup. Sexual function recovery, postoperative complication and biochemical recurrence rates were comparable 1 year postoperatively.

Key Words: prostatic neoplasms, prostatectomy, robotic surgery procedures, morbidity, outcome and process assessment (health care)

Galfano[1,2] and Lim[3] et al recently suggested that the Retzius sparing (posterior) approach to RARP allows for faster recovery of urinary continence after surgery. In an earlier study we reported the results of an open label RCT comparing the anterior (Menon) and the posterior (Bocciardi) techniques of robot-assisted radical prostatectomy.[4] At the 3-month followup superior urinary outcomes were seen in patients who underwent the Bocciardi approach. Accrual of patients was stopped in April 2016 but patients continue to be followed by an independent third party as part of the MUSIC CQI (Collaborative Quality Initiative).

We report the 12-month urinary, sexual, oncologic and postoperative outcomes in patients who participated in the randomized controlled trial. This represents phase 3 of the IDEAL (Idea, Development, Exploration, Assessment and Long-term followup) guidelines for surgical innovation.[5]

MATERIAL AND METHODS

Study Design

Details of study design, patient selection, sample size calculation, randomization, allocation concealment, posterior approach steps and study primary outcomes have been published.[4] Briefly, we randomly assigned 120 patients with low-intermediate risk prostate cancer according to NCCN (National Comprehensive Cancer Network®) Guidelines® to primary RARP performed by a team of 2 surgeons (MM and WJ) to 1 of 2 approaches, including anterior RARP in 60 as the control arm and posterior RARP in 60 as the intervention arm. The anterior approach was done with techniques established by Menon and the posterior approach was done using the Bocciardi technique with minor modifications as previously described.[4] We did not use the Rocco stitch in either patient group. Urinary continence and urinary function outcomes within 3 months of catheter removal have been reported.[4]

Outcome Assessment

We examined urinary and sexual function, BCR and complication rates at a median followup of 12 months postoperatively. Urinary continence outcomes up to 3 months postoperatively were tracked by VUI personnel as part of the RCT.[4] Functional outcomes at 3 months and beyond were prospectively assessed by an independent third party, MUSIC, as part of a quality improvement project. MUSIC, which represents approximately 90% of all urologists in Michigan, is funded by BCBSM (Blue Cross Blue Shield of Michigan). MUSIC collects patient reported functional outcomes in men who undergo RARP at participating centers via electronic/postal anonymous surveys.

During the study period of January 2015 to April 2016 MUSIC assessed urinary and sexual function using the previously validated MSKCC (Memorial Sloan Kettering Cancer Center) STAR (Symptom Tracking and Reporting) questionnaire (supplementary Appendix, http://jurology.com/)[6] at baseline (preoperatively), and 3, 6 and 12 months postoperatively. The results were collected by MUSIC personnel and the results of individual surgeons were reported back to them. In cases in which followup was missing for a given time point, data were obtained through a review of the institutional electronic medical records.

Urinary function scores were summed from responses to individual questions with a maximum score of 21 and a score of 17 or greater indicating good urinary function. Total continence was defined as no pad use or no urinary leakage in a 24-hour period (questionnaire question 1, section A), while social continence was defined as use of 1 pad or less in a 24-hour period. However, MUSIC does not measure pad weight in incontinent patients. Those men were contacted by VUI personnel and asked to record 24-hour pad weight for a week. The average 24-hour pad weight was used for analysis.

The MUSIC sexual function questionnaire was not directly used for analysis. Instead responses to questions on sexual function (questionnaire section B, questions 7, 9, 11 and 12, and section C, question 2) were extrapolated to generate the SHIM score. We used the SHIM score to allow for greater comparability with our historical results. Two definitions of potency were used for study purposes, including a postoperative SHIM score of 17 or greater and erection sufficient for intercourse, defined as a response of 2 or greater to SHIM question 2. Patients who were potent preoperatively, defined as a preoperative SHIM score of 17 or greater, and interested in sexual activity postoperatively were included in potency analyses.

Procedure specific complications were captured comprehensively,[7] prospectively assessed using the Martin-Donat criteria[8] and graded according to the Clavien-Dindo classification.[9] We adhered to the CONSORT (Consolidated Standards of Reporting Trials) reporting of harms criteria to identify and report postoperative complications. Positive surgical margins in the 2 arms were stratified a priori by extent as focal (2 mm or less) vs nonfocal (greater than 2 mm) and location (anterior, posterior or apical) as well as by pathological tumor stage (pT2 organ confined vs pT3a or greater nonorgan confined disease). BCR was defined as 2 consecutive prostate specific antigen values greater than 0.2 ng/ml measured on 2 occasions.