

# **EVOLUTION OF PRACTICE PATTERNS IN TRANSRECTAL ULTRASOUND-GUIDED PROSTATE BIOPSY: A QUESTIONNAIRE SURVEY OF PRACTICING UROLOGISTS**

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(Presentation to be made by Dr. Tadros)

**Objective:** Transrectal ultrasound (TRUS)-guided prostate biopsy is the standard technique for diagnosing prostate cancer and is one of the most commonly performed procedures by practicing urologists. Despite its widespread use, there are still no universally recognized standards for number of biopsy cores obtained, antibiotic and bowel preparation, or PSA threshold for recommending biopsy. In this study, we seek to better define current practice patterns and explore the evolution of these patterns over the last eight years.

**Materials and Methods:** A questionnaire survey was designed to assess prostate biopsy practice patterns. The survey focused primarily on method, number and location of biopsies, anesthesia use, bowel preparation, prostate specific antigen (PSA) thresholds for biopsy and use of other diagnostic criteria. It was mailed initially to members of the WSAUA in 2003. The same survey (identical questionnaire) was repeated by mail to members of the SESUA in 2006 and again to members of the WSAUA in 2011 by electronic survey using SurveyMonkey<sup>®</sup>. To assess trends in biopsy practice patterns, survey results were compared over this 8 year period (2003-2011).

**Results:** The most recent (2011) electronic questionnaire was sent to 1560 members of the WSAUA, with 239 (15%) responding to date, a significantly lower response rate compared to mailed survey responses of 44% in 2006 (SESUA - 1233 members responding) and 42% in 2003 (WSAUA - 568 members responding). Currently (2011), biopsy preparation includes the use of oral antibiotics alone and pre-biopsy enema in 99.5% and 76%, respectively. The mean number of biopsy cores taken on initial biopsy increased from 9.2 in 2003 to 11.2 in 2006 and 12.2 in 2011. In 2003, only 24% of urologists obtained at least 12 cores on initial biopsy. This increased to 51% in 2006 and 67% in 2011. For men aged 40-59 years, a PSA threshold of 2.5 ng/mL was used to recommend biopsy by 45% of urologists in 2003, 51% in 2006, and 65% in 2011. The use of periprostatic Lidocaine block alone or in combination with other anesthesia has increased from 51% in 2003 to 69% in 2006 and 93% in 2011. To select men for repeat prostate biopsy, PSA kinetic measures (PSA velocity and doubling time) are commonly (76%) used, and PCA-3, a relatively new urine-based genetic marker, is currently used by 30% of urologists in this setting.

**Conclusions:** There has been a significant upward trend in the number of biopsy cores obtained at the time of initial prostate biopsy. Clearly, sextant biopsy is no longer the standard of care. Periprostatic Lidocaine block has shown a significant increase in use and is now employed by the vast majority of practicing urologists. While lower age-specific PSA thresholds are becoming more widely adopted to recommend initial biopsy in younger men, a threshold advocated by many (2.5 ng/ml), is still not being used by a significant minority of urologists.

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**REDUCED RATE OF INFECTIVE COMPLICATIONS AFTER INITIAL PROSTATE BIOPSY USING A UNIFORMED PRE-BIOPSY PROTOCOL: SINGLE INSTITUTION EXPERIENCE WITH 3,194 PATIENTS**

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(Presentation to be made by Dr. Zhuang)

**INTRODUCTION AND OBJECTIVES:** A recent population-based study demonstrated an increasing frequency of infectious complications after prostate biopsy procedures with hospitalization rates approaching 5% (Nguyen et al. J Urol 2010). However it is unclear whether this effect is due solely to bacterial resistance and whether pre-procedural or technical modifications can mitigate complication rates. Thus, we sought to review the safety results at our institution where a uniformed pre-biopsy protocol has been in place for nearly two decades.

**METHODS:** The records from 3,194 unique patients in the Portland Veterans Affairs Medical Center (VAMC) database who underwent transrectal ultrasound (TRUS) with initial prostate biopsy were reviewed. All patients had a normal urinalysis and no signs of prostatitis. All patients received a cleansing enema and antibiotic prophylaxis consistent with 2010 AUA guidelines, most commonly a one-day course of an oral flouoroquinolone. All patients received a post-procedure telephone call within 2 weeks and any adverse effects were recorded. Rate of complications were assessed for the entire group and by study period (pre-2001 vs. 2001-2005 vs 2006-2010).

**RESULTS:** Of all 3,194 patients who underwent the initial TRUS biopsy, complications occurred in 27 pts. (0.85%). These were classified as infectious in 18 pts (0.56%), clinically significant hematuria in 4 pts. (0.16%) and urinary retention in 5 pts. (0.13%). Hospital admission was required in 11 pts. (0.34%). There was a slight trend towards increased infectious complications in the two groups undergoing biopsy between 2001-2010 as compared to the pre-2001 group.

**CONCLUSIONS:** Due to the emergence of antimicrobial-resistant organisms pre-procedure strategies that offset infectious complications are desperately needed. In our experience, strict adherence with a uniformed pre-procedure regimen resulted in a reduced rate of infections and hospitalizations as compared to historical controls. Based on these findings, the impact of ancillary measures prior to prostate biopsy procedures as a means of infection control is worthy of further study.

## CONTEMPORARY NATIONALLY-REPRESENTATIVE TRENDS IN PRIMARY TREATMENT FOR LOCALIZED PROSTATE CANCER

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(Presentation to be made by Dr. Cooperberg)

**Background:** Primary treatment trends for localized prostate cancer, including substantial local variation, have previously been documented among selected community-based U.S. practices. We aimed to determine whether these trends are confirmed in larger, more broadly representative databases.

**Methods:** We analyzed treatments in two national administrative datasets including men covered by Medicare in 1998-2006 and by private insurance (i3 database) in 2002-2006. Treatment distributions were determined in each year among watchful waiting/active surveillance (WW), radical prostatectomy (RP), radiation therapy (RT), cryotherapy, and primary androgen deprivation therapy (PADT). Trends in specific modalities were further examined within RP and RT. County-level variation was assessed, and treatment predictors were determined using multinomial regression.

**Results:** Among 54,322 Medicare patients (mean age at diagnosis 75), WW use fell from 30% in 1998 to 22% in 2002 and remained low. PADT use peaked at 24% in 2002 and fell to 17% by 2006. RP use varied between 11% and 13% during the study period, while RT use rose from 35 to 44%. Laparoscopic/robot-assisted RP (LRRP) and intensity-modulated radiation therapy (IMRT) were both first reported in 1999, and rose to 35% of RP and 53% of RT cases, respectively, by 2006. Among 16,161 privately insured patients (mean age 65), WW and PADT fell steadily from 25% and 12% in 2002, respectively, to 12% and 7% in 2006. RT use varied between 30 and 32%, while RP use rose from 33 to 48%. LRRP and IMRT use rose from 1% and 15% of RP and RT cases, respectively, in 2002 to 41% and 48% in 2006. Use of neoadjuvant androgen deprivation therapy (NADT) declined among RP and brachytherapy patients, to 6 and 25%, respectively, among Medicare patients and to 2% and 22% among private insurance patients by 2006. Use of NADT rose to 41% and fell to 37% among external-beam RT patients with Medicare and private insurance, respectively. There was considerable geographic variation in treatment selection. Across counties, use of WW, PADT, RP, and RT ranged, respectively, from 3 to 55%, 0 to 48%, 0 to 50%, and 15 to 71%. Comorbidity, age, income, year of diagnosis, and county-level sociodemographic variables predicted treatment.

**Discussion:** These trends echo those documented in prior studies in smaller datasets, and these data confirm extensive geographic variation. In both databases, there is rapid, ongoing adoption of high-cost technologies among both RP and RT patients. These findings underscore the urgent need for high-quality cost-effectiveness research comparing these treatments.

## PREVENTING MAJOR TO MINOR COMPLICATIONS: EXPERIENCE AFTER 1,000 ROBOTIC-ASSISTED RADICAL PROSTATECTOMIES

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(Presentation by Dr. Ahlering)

**Objective:** After identifying common complications, we refined and developed novel techniques to reduce their incidence during robot-assisted radical prostatectomy (RARP)

**Methods:** We have made a number of technical changes to decrease surgical early and late complications after RARP. For prevention of *PE/DVT* we incorporated pneumatic compression and early aggressive ambulation; for femoral *nerve palsies* we discontinued spreader bars for stirrups to reduce hyper-extension of the femoral nerves over the psoas muscle. *Rectal injury* – do not dissect the prostate retrograde off the rectum, always antegrade. *Fossa strictures* were inadvertently introduced by the use of 22Fr catheters – now we only use 18Fr. Mid line *vertical incisions* were replaced by transverse incisions to prevent primary and secondary hernias. *Corneal abrasions*, are very painful and felt to occur secondary to positional eye edema and irritation from the Trendelenberg positioning. Prevention: foam-based safety eye goggles during surgery and about 90 minutes in the recovery room to prevent inadvertent rubbing causing corneal abrasion. Goggles are removed only when the patient is fully oriented enough not to rub their eyes.

**Results:** Table 1 presents by Clavien score, the comparisons of the initial complication rates to the improved techniques described in the methods . Clavien 3 and 4 complications of fossa strictures, incisional hernias and PE/DVT have all significantly decreased to  $\leq 0.6\%$ . The small incidences of BNC and rectal injury show a statistical trend. Clavien 1 complications of corneal abrasion and nerve palsy do not require reoperation, but can be painful or very slow to heal, they too have significantly decreased to  $\leq 0.1\%$  in this study. Overall the rate for the 71 complications was 7.1% in this RARP group.

**Conclusions:** Identification of complications and proposing insightful working solutions has decreased their incidence in robotic prostatectomy in both major and minor complications. Inclusion of these techniques should improve patient outcomes for robotic surgeons.

Table 1. Complications	Clavien Score	Old rate	Resolution	New rate	P-value
Corneal Abrasion	1	4/200 (2%)	Foam-based safety goggles	1/800 (0.1%)	.002*
Nerve Palsy	2	4/800 (0.5%)	Avoid hyper-extension of the femoral nerve and careful padding	0/200 (0%)	.59*
Rectal Injury	3 a	1/100 (1%)	Meticulous Apical/lateral dissection	0/900	.10
Fossa Strictures	3 a	9/131 (6.9%)	Avoidance $\geq$ 20F Catheters	1/693 (0.1%)	<.001*
Bladder Neck Contractions (BNC)	3 a/3 b	6/592 (1%)	Addition of 'Rocco' Stitch to Van Velthoven Single knot Anastomosis	0/396 (0%)	.09*
Camera Site Hernias	3 b	36/735 (4.9%)	Transverse Incision	1/165 (0.6%)	.008*
Pulmonary Embolus	4 a	6/190 (3.2%)	Thigh-high pneumatic compression	0/810	<.001*

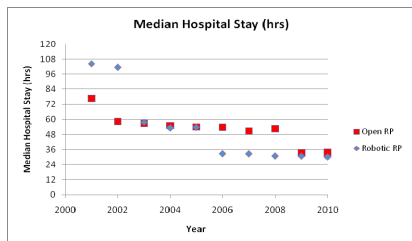
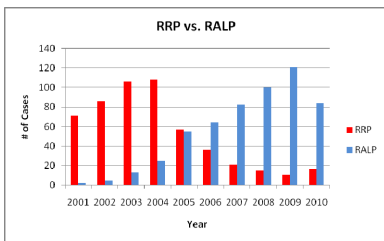
# DO PATIENTS UNDERGOING ROBOTIC PROSTATECTOMY HAVE A SHORTER HOSPITAL STAY THAN OPEN SURGICAL PATIENTS?

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(Presentation to be made by Dr. Corman)

**Objectives:** A primary advantage to minimally invasive prostatectomy is shorter length of hospital stay (LOS). In justifying the additional expense of robotic technology in comparison to open surgical techniques, earlier hospital discharge again is cited as a mitigating rationale. In order to achieve expedited hospital discharge, standard care pathways were established for all patients undergoing surgery for prostate cancer. These pathways dictate diet advancement, pain control, ambulation parameters, and catheter management. This study reviews the pattern of hospital discharges following both open and robotic surgery.

**Material and Methods:** Prospective data from 1105 consecutive patients undergoing radical prostatectomy by a single surgeon (JMC) at Virginia Mason Medical Center (VMMC) between August 2000 and December, 2010 was reviewed. The queried data set is IRB approved and HIPAA compliant. Hospital admission time was recorded as admission check in (typically 150 minutes prior to scheduled surgery). Hospital discharge time was recorded as the time the patient departed the surgical ward. No patient was excluded from analysis:

**Results:** Over the past 7 years there has been a dramatic transition toward minimally invasive surgery (92% of all radical prostatectomies). There is however, no statistically significant difference in the median LOS between the 2 groups over the past 2 years.



**Conclusions:** The last 11 years has witnessed a dramatic conversion to from open to minimally invasive prostate cancer surgery. Care pathways have been developed to facilitate hospital discharge and to minimize costs associated with robotic surgery. When these same pathways are instituted for open surgical patients, hospitalization time similarly declines. There is no statistically significant difference in LOS when common pathways are utilized.

## **RRP VS RALRP: QUALITY OF LIFE COMPARISON**

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(Presentation to be made by Dr. Gannon)

**Purpose:** To evaluate and compare the quality of life outcomes of patients undergoing radical retropubic prostatectomy (RRP) and Robotically Assisted Laparoscopic Radical Prostatectomy (RALRP).

**Materials and Methods:** Eight hundred and seven, non-randomized patients undergoing RRP or RALRP at one institution involving only 2 surgeons were prospectively evaluated using the Expanded Prostate Cancer Index Composite (EPIC). Patients were evaluated preoperatively and post-operatively at 3, 6, 9, 12, 18, and 24 months.

**Results:** Excluding patients with Stage >T3, Gleason score >7 and patients undergoing a non-nerve sparing procedure, 345 patients underwent RALRP and 248 patients underwent RRP by 2 surgeons. Significant differences existed between tumor grade, stage, and Gleason score ( $p < 0.05$ ), reflecting an institutional bias to select higher grade and higher volume tumors for RRP. No significant difference was noted in post-operative complications. Robotic surgery had no significant impact on EPIC urinary function scores. Age had a significant impact on post-operative urinary function. Of the 243 patients who had a nerve sparing procedure and adequate pre-operative sexual function, no significant difference was noted between robotic and open prostatectomy. Age and degree of nerve sparing had a significant impact on post-operative sexual function ( $p < 0.05$ ).

**Conclusions:** Our non-randomized prospective comparison of quality of life outcomes between patients undergoing RRP vs RALRP revealed no significant differences in post-operative urinary and sexual function scores.

## **CURRENT USE OF BRACHYTHERAPY AND CRYOTHERAPY BY RISK LEVEL FOR PROSTATE CANCER IN THE UNITED STATES**

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(Presentation to be made by Dr. Welty)

**Background:** Prior studies have shown that treatment choice in prostate cancer (PCa) is often related to factors other than disease characteristics, perhaps related to lack of certainty in the treatment guidelines. The use of brachytherapy and cryotherapy alone in high-risk PCa is controversial, however there are no definitive trials comparing these two therapies to the more conventional treatments of radical prostatectomy (RP) or external beam radiation therapy (EBRT). In this study, we use population-based cancer registry data to describe the use of brachytherapy and cryotherapy in low, intermediate, and high-risk PCa patients and evaluate non-tumor related factors that affect the use of these two therapies.

**Methods:** We identified incident PCa cases diagnosed from 2003 to 2007 across the 17 Surveillance, Epidemiology and End Results (SEER) population-based cancer registries. Patients receiving primary therapy with brachytherapy only, cryotherapy only, EBRT, and/or RP were identified and included for further analysis. Risk levels were defined according to National Comprehensive Cancer Network guidelines for low, intermediate, and high-risk based on clinical stage, prostate serum antigen, and gleason score. Logistic regression was used to identify demographic factors associated with treatment use within each risk level, while trends in treatment for continuous variables were identified using multivariate linear regression. The treatment of interest was compared to those who received EBRT or RP.

**Results:** A total of 96,588 cases of PCa were identified who underwent local treatment, including 25,786 high risk cases. For all PCa cases, the proportion receiving brachytherapy monotherapy decreased from 15.1% in 2003 to 12.7% in 2007 while the proportion receiving cryotherapy monotherapy increased, from 1.44% to 2.07%. Brachytherapy and cryotherapy monotherapy were used infrequently in high-risk patients (7.6% and 1.4% of those treated, respectively). For all risk levels, use of both brachytherapy and cryotherapy increased with age. Men over 75 years of age had 2.23 times more likely to receive brachytherapy than those less than 55 (95% CI 2.08-2.39) and 15.5 times more likely to receive cryotherapy (95% CI 11.7-20.7). Receipt of brachytherapy and cryotherapy did not vary by race. Men with all risk levels of PCa from wealthier counties were less likely to receive brachytherapy (pTrend<0.001), while for cryotherapy this was only observed among men with intermediate and low-risk disease. Married men with low and intermediate-risk PCa were less likely to receive brachytherapy, while marital status was not associated with the use of cryotherapy. Location also affected treatment use at all risk levels. For example, men with high-risk PCa in Seattle were much more likely to receive brachytherapy or cryotherapy than those in greater Los Angeles (OR 4.0, 95% CI 2.9-5.5 and OR 5.5, 95% CI 2.9-10.2, respectively).

**Conclusions:** Brachytherapy and cryotherapy monotherapy are used for all risk levels of PCa. Although infrequently used in high-risk disease several non-cancer related demographic factors are related to use of these modalities. Further study to identify how patient, provider, and clinical factors influence treatment choices is needed.

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## PROSPECTIVE RANDOMIZED TRIAL COMPARING KTP LASER PVP, BIPOLAR, AND MONOPOLAR TRANSURETHRAL RESECTION OF THE PROSTATE FOR BENIGN PROSTATIC HYPERTROPHY

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(Presentation to be made by Dr. Willis)

**Purpose:** The monopolar transurethral resection of the prostate (TURP) is the gold standard procedure to treat lower urinary tract symptoms (LUTS) secondary to bladder outlet obstruction (BOO) when medical treatment has failed or the patient has sequelae such as bladder calculi. However, this procedure is associated with serious complications. The potassium-titanyl-phosphate (KTP) laser photovaporization of the prostate (PVP) and bipolar TURP are newer modalities available for treating BOO that are purported to have similar efficacy and avoid at least some of the complications associated with the monopolar TURP. The objective of our study is to compare the efficacy and morbidity of the monopolar TURP, bipolar TURP, and KTP laser PVP.

**Materials and Methods:** This is a prospective, three-armed, randomized, single-blinded study to compare the above-mentioned modalities. Patients examined in the Veteran's Administration Hospital of Salt Lake City (VASLC) Urology clinic for LUTS or BOO due to BPH were evaluated for inclusion in the study. The inclusion criteria were: 1) AUA symptom score (AUA SS)  $\geq 8$ , 2) Failure of medical management with alpha-blockers and/or 5-alpha-reductase inhibitors or patient preference to stop medications, 3) No evidence of prostate cancer by digital rectal exam and PSA, 4) Maximum urinary flow rate (Qmax)  $<12$  milliliter/second, and 6) urinalysis with no evidence of infection or microhematuria. Patients who were poor operative candidates, had had previous prostate surgery, diagnosed with concomitant prostate cancer or a neurological process that would confound a diagnosis of LUTS due to BPH were excluded from the study. Select patients with a history of a cerebrovascular accident, multiple sclerosis or diabetes mellitus who had proven BOO on pressure/flow studies were included in the study. Upon enrollment, patients were randomized to undergo monopolar TURP (n=25), bipolar GyruS TURP (n=20), or KTP laser PVP (n=23). The AUA SS, post-void residual of urine (PVR), Qmax, IIEF score, and length of catheterization were measured pre-operatively and at 1 month, 6 months, 1 year and 3 years after surgery. The study was set up to test non-inferiority of bipolar to monopolar TURP, non-inferiority of KTP laser PVP to monopolar TURP, and non-inferiority of laser to bipolar TURP on the primary outcome of AUA SS. The non-inferiority margin was a priori set at a 4 point decrease in AUA SS from baseline. The primary outcome was change in AUA SS at 1 month. The remaining measurements were secondary outcomes and were analyzed using a standard superiority statistical approach. All p values and confidence intervals come from multivariable linear regression models, with treatment group as the primary predictor variable, while controlling for the baseline value of the outcome.

**Results:** For the change in AUA SS, the KTP laser was demonstrated to be non-inferior to both monopolar and bipolar TURP at all time points. Superiority of KTP laser over monopolar or bipolar TURP was not demonstrated. Non-inferiority of the bipolar TURP compared to monopolar TURP was not demonstrated. For the secondary outcomes of change in PVR, Qmax, and length of catheterization, there was no statistically significant difference between the 3 modalities at each of the time points. For IIEF, there was a statistically significant difference in the change in IIEF score after bipolar compared to monopolar at 1 month (-11.2 points, p=0.025) and in the change in IIEF score after KTP laser compared to monopolar at 3 years (+21.6 points, p=0.015). The number of post-operative complications in each arm was too small to allow for meaningful analysis, but there were no obvious differences in complication rates based on preliminary analysis.

**Conclusions:** We conclude that KTP laser PVP is equivalent to but not superior to monopolar and bipolar TURP at all time points for the primary outcome, change in AUA SS. Non-inferiority of bipolar to monopolar TURP could not be demonstrated. The study was not powered for the secondary outcomes, which have much greater variability.

## THE CHANGING NATURE OF BPH TREATMENT: THE EFFECT OF HOLEP ON PATIENT GEOGRAPHIC DISTRIBUTION

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(Presentation to be made by Dr. Nuñez-Nateras)

**Objectives:** Benign prostate hyperplasia (BPH) is the main cause of lower urinary tract symptoms in aging men. The utilization of different treatment options for BPH has changed over time as new technology and techniques have been introduced. Recently we presented an analysis of the patterns of BPH treatment over the past 5 years at our institution. The results showed a temporal increase in the utilization of holmium laser enucleation of the prostate (HoLEP) for definitive surgical management. It was our hypothesis that many of these patients came specifically seeking out this new procedure. To explore this issue further we chose to analyze the geographical origins of all patients that had undergone a HoLEP at our institution.

**Materials and Methods:** A retrospective review of our IRB approved HoLEP database was performed. Patients permanent addresses were analyzed and divide into 2 groups: Group A (permanent Arizona residence) and Group B (permanent residence outside of Arizona). A breakdown per year was done from 2007 to 2010 in order to analyze possible trends.

**Results:** A total of 307 HoLEP procedures for the treatment of BPH have been performed at our institution. Over the study period there was steady increase in the total number of HoLEP procedures performed. Table 1 displays the geographical distribution of our patients that under went the procedure by year. Overall the mean number of patients originating from Arizona was 178 (63.2%), while the number originating from outside the state was 104(36.8%)

**Conclusions:** The acceptance and recognition of HoLEP as a safe and effective therapy has increased the number of patients seeking out this procedure at our institution. Geographical distribution data shows the visibility the HoLEP procedure among potential patients and providers, and may reflect the increasing medical sophistication of patients as they utilize on-line resources and scientific publications to identify their health care providers.

HoLEP	Year							
	2007		2008		2009		2010	
	N	%	N	%	N	%	N	%
Arizona	12	70	56	66	56	63	54	55
Other state	5	30	29	34	26	37	44	45

## **WHAT IS THE PREVALENCE AND IMPACT OF DEPRESSION, ANXIETY, AND DISTRESS IN PATIENTS NEWLY DIAGNOSED WITH LOCALIZED PROSTATE CANCER?**

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(Presentation to be made by Dr. Punnen)

**Introduction:** Despite increased attention towards sexual and urinary outcomes in men with prostate cancer, mental health concerns and their impact on recovery and functional outcomes often go unnoticed. The objective of this study was to determine the prevalence and severity of depression, anxiety, and distress in patients with newly diagnosed prostate cancer, to examine what factors are associated with worse mental health outcomes, and to ascertain if there is an association between mental health functional outcomes.

**Materials and Methods:** The study population consisted of patients referred to the department of Urology at the University of California, San Francisco who were managed with active surveillance (AS) or radical prostatectomy (RP). Baseline levels of depression, anxiety and distress were ascertained using well-validated questionnaires: Patient Health Questionnaire 9 (PHQ-9), Generalized Anxiety Disorder 7 (GAD-7) and the Distress Thermometer (DT), respectively. Multivariate logistic regression was used to examine the associations between baseline factors and mental health measures. Multivariate linear regression was used to examine the association between mental health measures and sexual and urinary outcomes.

**Results:** The study cohort consisted of 943 patients. The prevalence at diagnosis of no, mild, or moderate to severe depression and anxiety were 85% and 82%, 11% and 15%, and 4% and 3%, respectively. Low distress was present in 83% while 17% reported having high distress at baseline. There were no significant differences between AS and RP patients in their distribution of PHQ-9, GAD-7 and DT scores at baseline. Increasing International Prostate Symptom Scores (IPSS) and younger age appeared to be associated with increased depression, anxiety and distress levels, while decreased Sexual Health Inventory for Men (SHIM) scores appeared to be associated with increased depression and being single versus in a relationship appeared to be associated with increased distress. Increased levels of depression, anxiety and distress appeared to be associated with worse IPSS and SHIM scores.

**Conclusion:** Levels of depression, anxiety and distress appeared to be low at baseline. However, these mental health measures do appear to be associated with urinary and sexual outcomes.