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Review Article: National Prostate Cancer Registries: Contemporary Trends of Prostate Cancer in the United States

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Abstract

Introduction: Randomized clinical trials are considered the gold standard for evidence-based practices but strict inclusion and exclusion criteria, costs to perform them and the time required to design and complete them may limit generalizability, followup and timeliness. Observational studies based on well designed, large volume patient registries may be more flexible in that scope. Such registries can be modified with time to incorporate new treatments as they emerge.

Methods: We describe the design, objectives, funding mechanisms and results to date of the major prostate cancer registries in the United States, highlighting as examples PCOS, CaPSURE™, PROST-QA, CEASAR, MUSIC and AQUA.

Results: Registries and collaborations have provided valuable knowledge for prostate cancer regarding oncologic and health related quality of life outcomes among treatments, changes in disease prevalence, staging, national practice trends and health service utilization.

Conclusions: While there are important limitations to observational data, registries will continue to have an important and growing role in advancing prostate cancer care as a complement to data from clinical trials and traditional cohort studies.

Key Words: prostatic neoplasms, registries, epidemiologic research design, observational study as topic, data collection

Abbreviations and Acronyms

ADT = androgen deprivation therapy
AQUA = AUA Quality Registry
AUA = American Urological Association
CAPRA = Cancer of the Prostate Risk Assessment
CaPSURE = Cancer of the Prostate Strategic Urologic Research Endeavor
CEASAR = Comparative Effectiveness Analysis of Surgery and Radiation
EBRT = external beam radiotherapy
EPIC = Expanded Prostate Cancer Index Composite
HRQOL = health related quality of life
MUSIC = Michigan Urological Surgery Improvement Collaborative
PADT = primary ADT
PCa = prostate cancer
PCOS = Prostate Cancer Outcomes Study
PROST-QA = Prostate Cancer Outcomes and Satisfaction with Treatment Quality Assessment study
PSA = prostate specific antigen
RCT = randomized clinical trial
RP = radical prostatectomy
RT = radiation therapy
SEER = Surveillance, Epidemiology and End Results
WW = watchful waiting

Randomized clinical trials are still considered the gold standard for examining the safety and efficacy of new drugs or devices. However, their usefulness for generalizability may be limited due to strict constraints of inclusion and exclusion criteria. RCTs are also costly to perform. A recent study showed that approximately 1 of 4 genitourinary clinical trials terminate prematurely, mainly due to poor accrual.[1] This was the case in the SPIRIT (Surgical Prostatectomy Versus Interstitial Radiation Intervention Trial)[2] and Observation or Radical Treatment in Patients With Prostate Cancer trials.[3] The failure of these and other trials has led to the use by necessity of claims based databases such as Medicare, and national

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databases such as SEER and NCDB (National Cancer Database) for comparative effectiveness and health services research. While such data sources offer ready access to population based data, the depth of their clinical data is limited. In addition, although they are population based, they may only represent a specific subgroup of the entire population. Medicare in particular includes only individuals older than 65 years and it excludes those enrolled in Medicare managed care plans, who may differ in important and nonrandom ways from those in Medicare Fee-for-Service.[4] Finally, because data are reported by billing/coding specialists and/or cancer registrars rather than clinicians, data accuracy is not always assured.

A well designed, prospective patient registry offers a third path, one that is more labor intensive and costly than a claims based database but much less so than a RCT and with excellent data accuracy and depth. A registry can be more flexible in scope and be modified with time to incorporate new treatments as they emerge. A registry can also accomplish long-term followup more easily than a RCT. The result is that different stakeholders may perceive value and benefits from patient registries in different ways, such as clinicians (ie real world perspectives of disease and current treatment practices), physician organizations (ie assessment of the degree to which evidence-based guidelines are implemented) and payer perspectives (ie assessment of the usefulness of procedures or devices at the population level). In addition, other study designs that focus on more limited patient populations and focused research questions, such cohort, case-control and even RCTs, can come from within and be facilitated by registries.[5]

AHRQ (Agency for Healthcare Research and Quality) has sponsored the RoPR (Registries of Patient Registries) initiative since 2005. This suggests that well designed patient registries can be powerful tools to observe the course of disease with time, understand variations in treatments and outcomes, examine factors that influence prognosis and quality of life, describe patterns of care such as disparities in care delivery, and assess care effectiveness.[5] Some of the largest registries and cohorts have been used to track and report PCa outcomes. Key examples (not all) are summarized in this review.

PCOS

PCOS is a population based outcomes study developed at NCI (National Cancer Institute) in 1994 to study variations in treatment strategies in men newly diagnosed with biopsy proven PCa as well as HRQOL outcomes, especially urinary, bowel and sexual function.[6] A total of 11,137 men diagnosed with PCa between 1994 and 1995 from 6 of the 10 SEER cancer registries were eligible for PCOS. Patients were sampled according to a prespecified design to ensure a representative sample of all patients, including different ethnic groups and patients younger than 60 years. Nevertheless, PCOS is a cross-sectional database with a fixed number of patients, which limits the reproducibility of outcomes. Bias may be introduced by the high rate of nonresponders, which may reflect a certain sociodemographic pattern.

Patients reported baseline urinary incontinence but not irritative or obstructive symptoms, and bowel and sexual function 6 months after the initial diagnosis and during the last month. HRQOL questionnaires were collected at 12 and 24 months.[6] The PCOS questionnaire was based on the previously validated SF-36® for general HRQOL and the UCLA-PCI (University of California-Los Angeles Prostate Cancer Index). The survey instrument was also translated and validated in Spanish.[6] PCOS data showed that in 1994 to 1995, 47.6% of patients with localized PCa underwent RP, 23.4% received RT, 10.5% received PADT and 18.5% were treated with WW.[7] Age 75 years or greater was associated with more conservative treatment, defined as PADT or WW.

Another PCOS study showed that black men who had higher risk tumors were less likely to undergo RP than white men (35.2% vs 52.0%) and more likely to receive conservative treatment (38.9% vs 16.3%).[8] A recent PCOS study revealed that in contrast to RT, RP was associated with a significant decrease in overall as well as cancer specific mortality in men diagnosed with localized PCa.[9] This benefit was particularly noted in younger patients (age 65 years or less), healthier patients with a lower Charlson comorbidity index score and those with higher risk cancer. However, these findings should be interpreted cautiously since they may have been the result of residual selection bias rather than a true survival benefit.

Several groups examined comparative posttreatment HRQOL using PCOS. Penson et al noted no statistical difference in general HRQOL domains in patients who received different treatments for localized PCa at 2 years.[10] Another study demonstrated that men who elected RP were more likely to have incontinence and erectile dysfunction than patients who received RT, although each therapy showed decreased rates.[11] Patients who received RT reported more bowel dysfunction. Resnick et al found that at 15 years men who elected RP and those who received RT experienced decreased outcomes in all functional domains.[12] Notably that study did not include an untreated, age matched control group. Therefore, it was not possible to account for the effect of an age related decrease in these domains with time rather than the effect of PCa treatment.

CaPSURE

CaPSURE was initiated on May 10, 1995 as a longitudinal, disease specific, observational registry of men with PCa.[13] As of April 2014, almost 15,000 men have participated in CaPSURE from a total of 43 mostly community based urology practices around the United States. Since each PCa treatment can have a different impact on clinical, economic and HRQOL outcomes, an observational registry such as CaPSURE allows men to be followed in a naturalistic setting to determine treatment effects in the real world. CaPSURE collects clinician reported outcomes as well as patient reported outcomes using validated instruments to assess survival status, duration of disease-free survival, HRQOL, satisfaction with care and the economic burden of treatment. The secure CaPSURE website enables treating urologists to graphically display trends in