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TOPIC PAPER

The example of CaPSURE: lessons learned from a national disease registry

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Abstract
Introduction Although randomized controlled trials (RCTs) remain the gold standard for determining evidence-based clinical practices, large disease registries that enroll large numbers of patients have become paramount as a relatively cost-effective additional tool.
Methods We highlight the advantages of disease registries focusing on the example of prostate cancer and the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE^{TM}) registry.
Results CaPSURE collects approximately 1,000 clinical and patient-reported variables, in over 13,000 men that are enrolled. Thus far, CaPSURE has yielded over 130 peer-reviewed publications, with several others in press, in key areas of risk migration, practice patterns, outcome prediction, and quality of life outcomes.
Conclusions Disease registries, like CaPSURE complement RCTs and CaPSURE, have provided a means to better understand many aspects of prostate cancer epidemiology, practice patterns, oncologic and HRQOL outcomes, and costs of care across populations. Specialized observational disease registries such as CaPSURE provide insight and have broad implications for disease management and policy.

Keywords Prostatic neoplasms · CaPSURE · Disease registries

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Introduction

The randomized controlled trial (RCT) remains the gold standard for informing evidence-based clinical practice, in urology as in other medical domains. Limitations include time, significant expense, stringent inclusion criteria, and resistance to randomization by clinicians and patients. Ultimately, if patients enrolled in a RCT differ from the larger population of patients with a given condition, the external validity of the findings may be questionable. Although these limitations can be mitigated by utilizing specialized RCT designs (Table 1), disease registries have emerged as an important complement to RCTs. Disease registries, which accrue prospectively identified cohorts and follow them regardless of sociodemographic characteristics, clinical variables, treatment details or intermediate outcomes, have emerged as an important complement to RCTs. This reflection of "real world" treatment is a tremendous asset especially in prostate cancer research as it provides a relatively cost-effective tool to shed light on a disease with a long natural history and rapidly changing management practices that are subject to many different clinical, scientific, demographic, and economic dynamics. This article will highlight some advantages of disease registries focusing on the example of prostate cancer and the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE^{TM}) registry.

Table 1 Specialized classifications of randomized controlled trials

Type	Description	Strengths	Limitations
Cluster	Randomization of subjects as a group rather than on individual basis	Can study interventions that cannot be directed toward selected individuals	Needs more subjects to reach statistical power than standard RCT
		Can control for contamination across individuals (i.e., when one individual's behavior can influence another's)	
Explanatory	Individual randomization of very selective subjects in a highly controlled setting	Useful to test efficacy (i.e., whether an intervention causes a specific biologic response)	External validity and applicability to clinical practice is limited due to subject selection
		Patients blinded	
		Excellent internal validity	
		Good for acute disease processes	
Pragmatic	Individual randomization of non-selective group of patients in a regular clinical setting	Useful to test effectiveness of an intervention in everyday practice	Patients unblinded
		Good for chronic disease processes and complex interventions	Internal validity limited due to broad inclusion criteria
		Excellent external validity and directly applicable to clinical practice	
Expertise-based	Individual randomization of subjects to an expertise in the intervention in question	Useful when intervention is non-pharmacologic (i.e., surgical procedures)	External validity limited to only those patients receiving care from a physician with expertise skills

CaPSURE was initiated in 1995 to document national trends in prostate cancer epidemiology, disease management, oncologic outcomes, and health-related quality of life (HRQOL) outcomes. It is a longitudinal, observational database accruing data from a total of 40 urologic practice sites over the history of the registry. The majority of sites are community based, although four university-affiliated centers, and Veterans Affairs (VA) medical centers are included. Men with biopsy-proven cancer are invited to join CaPSURE regardless of disease stage or treatment history. Informed consent for participation is obtained under institutional review board supervision.

CaPSURE collects approximately 1,000 clinical and patient-reported variables. Clinical information is collected by the treating urologist at baseline and with each follow-up visit and includes history of prostate cancer diagnosis, biopsies, pathology, staging tests, primary and subsequent treatments (radical prostatectomy [RP], external beam radiotherapy [EBRT], brachytherapy, primary and neoadjuvant androgen deprivation therapy [PADT and NADT], cryosurgery, and watchful waiting/active surveillance [AS]), Karnofsky performance status scores, clinic procedures, and medications. At enrollment and every 6 months thereafter, a questionnaire is completed documenting sociodemographic parameters, comorbidities, and HRQOL using validated instruments. Other sections of the patient questionnaires assess use of health services, with hospitalization data verified by discharge summary review.

Patients are treated according to their physicians' usual practices and patient preferences and are followed until time of death or withdrawal from the study. Periodic, random sample chart review ensures completeness and accuracy of data collected and entered. Additional details regarding project methodology have been reported previously [1]. CaPSURE is managed by the Department of Urology at the UCSF Helen Diller Family Comprehensive Cancer Center. It was funded from inception to 2007 through an unrestricted education grant from TAP Pharmaceutical Products, Inc., and currently is supported through Abbott Labs (Chicago, IL) and several collaborative Federal grants.

There are currently 13,821 men enrolled in CaPSURE. The median patient age at diagnosis is 67, and 75% of men are between 60 and 79 years of age. Most patients are white, with approximately 10% black representation, and 3.5% Latino, Asian, and other ethnicities. There is a fairly even distribution across socioeconomic strata, based on education and income level. CaPSURE has yielded over 130 peer-reviewed publications, with several others in press. A summary of some key research findings follows.

Trends in prostate cancer presentation and risk

Temporal trends in the PSA era in patient risk at diagnosis are consistent with downward stage migration. In CaPSURE, the proportion of patients presenting with low-risk disease (PSA < 10 ng/mL, Gleason score < 7 with no pattern 4 or 5 disease on biopsy, and clinical stage T1 or T2 disease) has increased from 31% between 1989 and 1990 to 47% of patients between 2001 and 2002 and has remained

relatively stable [2]. However, within this low-risk group, there is a trend toward lower-risk characteristics (based on PSA, clinical stage, and percent positive biopsy). Conversely, during the same time, men with high-risk disease (PSA > 20 ng/mL, Gleason 8-10 on biopsy, or stage T3) have decreased from 41 to 29%. Although the rate of high-risk prostate cancer has fallen, it has remained stable since 2000 and represents approximately 24% of patients in recent studies [3]. There is no evidence in the CaPSURE cohort of meaningful downward risk migration among high-risk patients over the past 15 years.

Despite presentation with lower-risk disease due to increased PSA screening, recent studies have observed a disparity in prostate cancer presentation across sociodemographic groups. Dall'era et al. [4] examined 5,939 men enrolled in CaPSURE from 1995 to 2007, and found that patients who were older, less educated, and had Medicare for insurance (as opposed to VA or private coverage) were more likely to have intermediate or high-risk disease. Non-white race was also associated with high-risk disease at presentation (OR 1.83, 1.47–2.29, $P < 0.01$). Clinically insignificant disease (PSA < 10 ng/mL, <33% of biopsy cores involved, no Gleason pattern 4/5, and stage T1a or T2a) was more common in younger men (<60 years old), higher income/education, and men with private insurance. Within this group, younger age and private insurance were again associated with immediate treatment in lieu of AS.

Health services research and trends in disease management

The majority of patients followed in CaPSURE were diagnosed during the PSA era and treated in community-based settings. One strength of this registry is that participating physicians treat according to their usual practices and patient preferences. CaPSURE provides a mix of locales and practice types, reflecting current contemporary urological practice at a national level. The CaPSURE sites are not a random sample of the US population. However, CaPSURE includes far richer clinical detail than population-based sources such as the Surveillance Epidemiology and End Results (SEER) database and SEER-Medicare and therefore is an excellent data source for national studies of disease management.

Imaging studies performed in men with prostate cancer may serve to facilitate optimal treatment planning. However, staging studies are associated with low but definite risks, significant costs to the health care system, and have minimal benefit in patients with low-risk disease characteristics. One early study from CaPSURE examined the use of imaging tests for staging clinically localized prostate cancer between 1989 and 1997. Kindrick et al. [5] found widespread and consistent overuse in the rates of bone scan, computed tomography, and magnetic resonance imaging among patients with low likelihood of extraprostatic disease. Follow-up analysis through 2001 showed that rates of bone scan and computerized tomography use have decreased in recent years with the greatest decreases in patients with lower-risk cancer [6]. Whereas among early CaPSURE patients, disease risk exerted no influence on the likelihood of imaging, the more recent CaPSURE data have illustrated a trend toward appropriate and evidence-based use of imaging tests. This highlights the value of registries such as CaPSURE that allows evaluation of adherence to guidelines based on high-level evidence into common clinical practice, as well as the extent to which evidence-based medicine is practiced in urology.

Multiple recent CaPSURE studies have examined patterns in treatment selection for patients diagnosed with prostate cancer. An early study examined the use of ADT in patients with localized disease and found a higher than expected use of ADT monotherapy [7]. Among low-, intermediate-, and high-risk patients, ADT monotherapy rose dramatically, from 5 to 14%, 9 to 20%, and 33 to 48%, respectively, from 1989–1990 to 2000–2001. PADT monotherapy is considered to be investigational based on the American Urological Association's clinical practice guidelines [8], and no controlled trials have established efficacy of this approach.

With decreasing risk migration, it would be expected that the use of AS would increase since more men are presenting with favorable risk disease. An early study of temporal trends found that the use of AS reached a nadir of 5.5% in 2000–2001 from 9.5% in 1992–1994, with the largest declines in low-risk patients (6.2%), although recent improvement to 10.2% in 2004–2006 was observed [2]. Another study by Barocas et al. [9] found that between 1999 and 2004, 16.4% of men met strict surveillance criteria (PSA < 10 ng/mL, clinical T1 or T2a, prostate-specific antigen density PSAD < 0.15, <33% biopsy cores positive, and absence of Gleason pattern 4/5 on biopsy), but only 9% of men in this low-risk category chose surveillance, highlighting the underuse of this management strategy in the United States.

In addition to the initial decline in AS, a decrease was observed in EBRT from 13% in 1993–1995 to 7% in 1999–2001 and RP (55–52%) and increases in PADT (7–12%) and brachytherapy (4–22%) in low-risk patients [10]. This treatment trend remained present in men >75 years with the use of surveillance in only 24%, declining from 52%, PADT use increasing from 23 to 30%, and brachytherapy from 3 to 31%. A reversal of this trend was observed with a decrease in brachytherapy to 13% in 2005–2006, a decrease in PADT to 6.6%, and an increase in RP to 60% [2].

Overall, it appears that prostate cancer risk drives treatment selection in conjunction with age, comorbidity, and socioeconomic status. However, a recent analysis in CaPSURE examining practice patterns in the primary treatment of localized prostate cancer confirmed prevalent overtreatment of low-risk disease but also identified what appeared to be a troubling undertreatment of high-risk disease [3, 11]. Interestingly, treatment patterns were found to vary across clinical sites, and much of the variation could be attributed to practice site itself and not solely patient or tumor factors. Clinical practice site alone explained, for example, 13% variation seen in ADT, 30% in RP, 36% in brachytherapy, 20% in EBRT, and 74% in cryoablation [11].

Another unique feature of CaPSURE is the access to resource use data that offer a means of studying health care cost implications of different prostate cancer management strategies. Penson et al. [12] examined adjusted first-year costs associated with various treatment options based on Medicare payment schedules and found a trend toward higher costs for higher-stage patients. The mean cost of prostate cancer treatment in the first year after diagnosis was $6,375 and was not different between patients with RP and EBRT, but was higher for those receiving NADT prior to either treatment. Wilson et al. [13] analyzed all health care utilization of various treatments over a period of 5 years and found that the average annual cost was $7,740. This varied widely with AS costing the least at $5,843 and androgen deprivation therapy the most expensive at $12,590.

Oncologic outcomes

Recent evidence suggests that information beyond Gleason score obtained at diagnostic biopsy contributes significantly to accurate risk assessment among patients with newly diagnosed prostate cancer. The percent of positive biopsy cores was initially validated as a prognostic marker among patients who underwent RP in CaPSURE and was significant across all risk groups, confirming that biopsy data obtained in the community setting using non-standardized techniques and assessed by diverse pathologists offers consistent and useful prognostic information [14].

Cancer of the Prostate Risk Assessment score (CAPRA) was developed using data from the CaPSURE registry. The CAPRA score simply and accurately predicts pathologic status, disease recurrence, and mortality after surgery [15]. Points are assigned based on age, clinical stage, PSA, Gleason grade, and percent of cores positive on biopsy. Scores range from 0 to 10 with each 2-point increase roughly doubling the risk of recurrence and progression. A 9-point variation of the CAPRA scoring system can alternatively be used if data regarding percent positive biopsy cores are not available. The strength of the CAPRA score is not only in its ease of use but in its ability to better discriminate between categories of risk in all practice settings when compared with other nomograms [16, 17]. The CAPRA score has been extensively validated in other disease registries and academic cohorts, both in the United States and Europe [18].

Uncertainty regarding the optimal treatment for localized prostate cancer has led to large variation in practice patterns as reported previously in CaPSURE [11]. To date, no adequate randomized trials have compared active treatments for localized prostate cancer due to difficulties with accrual, randomization, high cost, and need for long follow-up. Disease registries can provide important insights into outcomes and can provide an important source for comparative effectiveness analysis between various treatments. This is highlighted in a recent study by Cooperberg et al. [19] which compared risk-adjusted disease-specific and all-cause mortality after treatment of localized prostate cancer with RP, EBRT, and primary ADT. After adjusting for age, disease risk, and comorbidity, mortality at 10 years was less likely in men who underwent RP than EBRT or primary ADT, especially in men with intermediate or high-risk disease.

Quality of life outcomes

The preservation of health-related quality of Life (HRQOL) is a priority in any discussion of prostate cancer treatment and outcomes due to the long natural history of disease. Any negative impact on quality of life must be minimized, as patients may experience it for an extended period of time. CaPSURE had proved to be an invaluable resource for the prospective, longitudinal assessment of patient-reported outcomes and it has enabled investigators to successfully address a number of questions in this area of prostate cancer research.

CaPSURE HRQOL data are reported by both patients and physicians and provide insight into the differences between outcomes. An early study by Litwin et al. [20] found that physician assessment of treatment impact on HRQOL underestimated the impact experienced by patients, especially within general health parameters. When impairment was noted, urologists reported on urinary and sexual functions more often than pain in men who underwent treatment for localized prostate cancer. Many aspects

Table 2 National registries in the United States used commonly in prostate cancer research

Database	Description
CaPSURE	Community practice-based longitudinal data from 31 sites as reported by urologists and patients
	http://www.capsure.net
CPDR	Longitudinal data on prostate cancer patients treated in the military health care system as reported by medical practitioners (urologists, medical/radiation oncologists)
	http://www.cdpr.org/database.html
Medicare	Population-based data on insurance claims for covered health services for eligible US persons over 65 years old
NIS	A cross-sectional database that is part of HCUP which collects information on over 8 million hospital stays annually
	http://http://www.hucp-us.ahrq.gov
PCOS	Cross-sectional, population-based (SEER) data collected from patient chart abstraction
	http://healthservices.cancer.gov/pcos
PROST-QA	Longitudinal data collected from prostate cancer patients and spouses at 9 US academic medical centers on prostate cancer treatment outcomes
SEARCH	Longitudinal data on men who underwent radical prostatectomy at 4 VA hospitals and 1 military center
SEER	Population-based, longitudinal data collected on approximately 28% of all US cancer patients, including cancer staging
	http://seer.cancer.gov
SEER-Medicare	Linkage of two of the largest US population-based data sources
	http://healthservices.cancer.gov/seermedicare

CaPSURE Cancer of the Prostate Strategic Urologic Research Endeavor

CPDR Center for Prostate Disease Research

HCUP Healthcare Cost and Utilization Project

NIS Nationwide Inpatient Sample

PCOS Prostate Cancer Outcomes Study

PROST-QA The Prostate Cancer Outcomes and Satisfaction with Treatment Quality Assessment

SEARCH Shared Equal Access Regional Cancer Hospital

SEER Surveillance Epidemiology and End Results

VA Veterans Affairs

of patient-reported HRQOL (physical function and general health) have also been significantly associated with survival in a similar cohort of men, over the course of disease from diagnosis to after treatment [21]. These studies highlight the continued importance of multidimensional, patient-reported HRQOL assessment in current prostate cancer treatment.

Using longitudinal HRQOL data within CaPSURE, comparisons can be made between outcomes among treatment options. Men who underwent RP had lower scores on both disease-specific and general HRQOL instruments immediately postoperative, which improved significantly at 1 year after treatment, and continued to improve in the domain of sexual function in the second year. Men who were treated with EBRT, AS, or primary ADT had scores that were relatively stable, except for sexual function, which declined with time. Overall, patients who underwent RP had the greatest decline initially, but also the greatest degree of recovery. Most men experienced the greatest recovery of both urinary and sexual functions within 2 years of treatment, with little change in reported HRQOL scores after 3 years [22]. Those who received multimodal therapy appeared to have greater declines in urinary and sexual functions than those who were treated with monotherapy [23].

Although prostate cancer presentation and treatment patterns vary based on ethnicity, little was known with regards to any differences in HRQOL. Disease registries like CaPSURE are ideal to study ethnic groups that are underrepresented in most clinical studies. Using CaPSURE data, African American men were found to have lower HRQOL scores across many domains of QOL at baseline and after treatment, but had higher sexual function scores [24]. Over time, African American patients never recovered as well as white patients in reported HRQOL scores. Ethnicity was also found to play a role in primary treatment choice in men with equivalent disease characteristics [25].

Although this article focuses primarily on lessons learned from CaPSURE, there are a number of other US national registries and databases available for research. Table 2 highlights the strengths of many of the resources available to study the various aspects of prostate cancer. For example, the Prostate Outcomes Cancer Study (PCOS), which utilizes Surveillance Epidemiology and End Results (SEER)-based data, was initiated by the National Cancer Institute (NCI) and used by investigators to report on HRQOL outcomes in American men diagnosed with prostate cancer [26]. Likewise, the Department of Defense Center for Prostate Disease Research (CPDR) has been used to report on prostate cancer-specific mortality and not only collects data on men with prostate cancer treated within the military medical system but seeks to standardize clinical practice among military sites [27].

Limitations to disease registries in general center on methodology of data collection. The quality of data collected and integrity in data collection and follow-up determine the quality of the disease registry. In addition to bias introduced by data collection, disease registries do not capture a random sample of the population. These biases can be minimized (as in CaPSURE) by including community centers to increase population sampling. Centralizing data collection and analysis with strict monitoring by a statistician ensure quality control. Although CaPSURE does capture a diverse group of men, patients are enrolled by their urologists, rather than medical or radiation oncologists, which may exclude a proportion of men with prostate cancer.

CaPSURE is a research partnership with industry (initially funded by TAP pharmaceuticals) under IRB approval. Data integrity has been maintained free of conflict of interest by thoughtful and transparent methodology and reporting. Data analyses and decision for publication of CaPSURE results have always rested with academic investigators without the influence of industry. Currently, CaPSURE is supported by a combination of gifted funds from Abbott Laboratories along with a growing portfolio of federal grants to ensure registry continuity and maintenance.

Conclusion

While RCTs remain the gold standard for advancing knowledge in medicine, they can be difficult to complete and expensive; moreover, in a disease with a prolonged natural history, treatment strategies may evolve quickly that even a well-executed trial may not be relevant by the time it is published. Disease registries, like CaPSURE, have provided a means to better understand many aspects of prostate cancer epidemiology, practice patterns, outcomes, and costs of care. It remains a robust source of information and provides a cost-effective way of driving evidence-based decisions regarding treatment and health policy. Specialized observational disease registries such as CaPSURE provide insight and have broad implications for disease management and policy.

Conflict of interest Drs. Cooperberg and Carroll are CaPSURE researchers. Drs. Porten and Konety have no disclosures.

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