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The Evolution of Self-Reported Urinary and Sexual Dysfunction over the Last Two Decades: Implications for Comparative Effectiveness Research

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Abstract

Background—Despite the paramount importance of patient-reported outcomes, little is known about the evolution of patient-reported urinary and sexual function over time.

Objective—To evaluate differences in pretreatment urinary and sexual function in two population-based cohorts of men with prostate cancer enrolled nearly 20 yr apart.

Design, setting, and participants—Patients were enrolled in the Prostate Cancer Outcomes Study (PCOS) or the Comparative Effectiveness Analysis of Surgery and Radiation (CEASAR) study, two population-based cohorts that enrolled patients with incident prostate cancer from 1994 to 1995 and from 2011 to 2012, respectively. Participants completed surveys at baseline and various time points thereafter.

Outcome measurements and statistical analysis—We performed multivariable logistic and linear regression analysis to investigate differences in pretreatment function between studies.

Results and limitations—The study comprised 5469 men of whom 2334 (43%) were enrolled in PCOS and 3135 (57%) were enrolled in CEASAR. Self-reported urinary incontinence was higher in CEASAR compared with PCOS (7.7% vs 4.7%; adjusted odds ratio [OR]: 1.83; 95% confidence interval [CI], 1.39–2.43). Similarly, self-reported erectile dysfunction was more common among CEASAR participants (44.7% vs 24.0%) with an adjusted OR of 3.12 (95% CI, 2.68–3.64). Multivariable linear regression models revealed less favorable self-reported baseline function among CEASAR participants in the urinary incontinence and sexual function domains. The study is limited by its observational design and possibility of unmeasured confounding.

Conclusions—Reporting of pretreatment urinary incontinence and erectile dysfunction has increased over the past two decades. These findings may reflect sociological changes including heightened media attention and direct-to-consumer marketing, among other potential explanations.

Patient summary—Patient reporting of urinary and sexual function has evolved and is likely contingent on continually changing societal norms. Recognizing the evolving nature of patient

reporting is essential in efforts to conduct high-quality, impactful comparative effectiveness research.

Keywords

Prostate cancer; Quality of life; Urinary function; Sexual function; Patient-reported outcomes

1. Introduction

Treatment for localized prostate cancer yields potential short- and long-term negative impacts on health-related quality of life (HRQOL), particularly in the urinary, sexual, and bowel function domains [1–4]. However, little is known regarding how the reporting of dysfunction in these domains may have changed over time and how such differences may alter the interpretation of patient-reported outcomes in comparative effectiveness research. The public has certainly become more aware of prostate cancer and the negative effects of its treatment over the past two decades. There has also been rapid expansion of direct-to-consumer (DTC) advertising, possibly reducing the stigma of conditions such as urinary incontinence or erectile dysfunction (ED) that would, in turn, increase patient reporting of such functional deficiencies [1–4]. Although stigma serves as a barrier to seeking treatment and information for a particular illness [5,6], it is not known whether stigma reduction results in meaningful changes in patient reporting.

Patient-reported outcomes (PROs) have become the cornerstone of measurement of the comparative harms of prostate cancer treatment. As such, understanding how patients report function in different time periods is essential in interpreting the results of comparative effectiveness research, and failing to recognize the profound contribution of contemporary norms will, without question, result in study bias. As we begin to use PROs in quality and performance measurement, it will become increasingly important to understand the constructs that contribute to patient reporting in prostate cancer and other disease states. To this end, we sought to evaluate changes in the reporting of pretreatment sexual and urinary dysfunction in two prospective prostate cancer cohorts enrolled nearly 20 yr apart. We hypothesized that patients enrolled in the contemporary Comparative Effectiveness Analysis of Surgery and Radiation (CEASAR) cohort would report less favorable pretreatment urinary and sexual function when compared with patients enrolled in the historical Prostate Cancer Outcome Study (PCOS) cohort.

2. Methods

2.1. Patients

To test our hypothesis we used data from the PCOS and the CEASAR study, two longitudinal population-based prostate cancer cohorts. Using a rapid case ascertainment system, PCOS enrolled incident prostate cancer patients from six participating Surveillance Epidemiology and End Results (SEER) sites (Connecticut, Utah, New Mexico, and the metropolitan areas of Atlanta, Georgia; Los Angeles, California; and Seattle-Puget Sound, Washington) between October 1, 1994, and October 31, 1995. Institutional review boards at all participating sites including the Vanderbilt University coordinating site approved the study. Details of the objectives and methods of PCOS were reported previously [7,8].

The PCOS sampled 5672 subjects from 11–137 eligible cases. We limited the cohort to men ≤75 yr of age with clinically localized (cT1/2N0M0) prostate cancer with a prostate-specific antigen (PSA) ≤50 ng/ml who completed a baseline survey, resulting in an analytic cohort of 2334 PCOS participants. Because of the practical limitation of interviewing men with prostate cancer before diagnosis, baseline assessment was conducted at 6 mo, at which time participants were asked to recall their prediagnosis function. Nearly 90% of patients had initiated treatment at the time of response to the baseline survey. Nonetheless, prior studies demonstrated strong agreement between baseline and 6-mo estimates of prediagnostic urinary and sexual function [9].

CEASAR also used a population-based sampling strategy and recruited men <80 yr with newly diagnosed clinically localized prostate cancer and a PSA ≤50 ng/ml from five SEER registries (Atlanta/Rural, Los Angeles, Louisiana, New Jersey, and Utah) from January 2011 to February 2012. CEASAR was enriched with a sample from Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE), an observational prostate cancer registry [10]. However, given the non-population–based sampling strategy used in CaPSURE participants, these men were excluded from the current study (n = 232). Details and objectives of the CEASAR study were reported previously [11].

During the 1-yr enrollment period, the study contacted 7243 eligible men. Of these, 3691 (51.0%) completed a baseline survey within 6 mo of diagnosis. We limited the current cohort to men ≤75 yr with clinically localized (cT1/2N0M0) prostate cancer who responded to a baseline survey and a 6-mo survey including self-reported comorbidity, resulting in an analytic cohort of 3135 men. Unlike PCOS, fewer patients (49%) had initiated treatment at the time of response to the baseline survey in CEASAR.

2.2. Data collection

After enrollment in PCOS, men completed a survey that included items regarding clinical and sociodemographic issues, comorbid conditions, and disease-specific HRQOL [7,8]. HRQOL was measured using the UCLA Prostate Cancer Index (UCLA-PCI), a reliable and valid instrument [12] that measures the sexual function, urinary incontinence, and bowel function domains relevant to prostate cancer and its treatment.

Similarly, after enrollment in CEASAR, participants completed a baseline survey that contained multiple scales including the Expanded Prostate Cancer Index Composite (EPIC)-26, a reliable and valid instrument derived from the UCLA-PCI, with many common questions regarding disease-specific sexual function, urinary incontinence, and bowel function, as well as additional domains for urinary irritation/obstruction and hormonal function/vitality [13]. In both studies, individual items with multi-item responses were dichotomized to facilitate clinical interpretation.

To ensure appropriateness of the between-study comparison, the current study was limited to items common to both the UCLA-PCI and the EPIC-26. We included four items in the urinary incontinence domain and three items in the sexual function domain. We derived modified domain summary scores based on the common between-study items, scaled 0–100 with 100 representing optimal function.

2.3. Statistical analysis

We compared baseline characteristics using appropriate parametric and nonparametric statistical tests. Multivariable models were fit to determine the main independent effect of the study (ie, PCOS vs CEASAR) on baseline function, both at the individual item and summary score levels. We performed multivariable logistic regression analysis with individual item response as the dependent variable and multiple a priori identified covariates as independent variables. We also performed multivariable linear regression analysis with domain summary score as the dependent variable and included the same a priori identified covariates as independent variables in the linear regression models. Principal analyses were performed on the complete study sample. A sensitivity analysis was performed on the subgroup of CEASAR participants who had initiated treatment at the time of baseline survey completion. Finally, sensitivity analysis was performed using a cohort restricted to common SEER registries between the two studies (Atlanta, Los Angeles, Utah).

All p values were two sided, and p values <0.05 were considered statistically significant. R software v.2.13.0 (R Foundation, Vienna, Austria) and Stata v.12.1 (StataCorp, College Station, TX, USA) were used for all statistical analyses.

3. Results

The final study cohort comprised 5469 men, of whom 2334 (43%) were enrolled in PCOS and 3135 (57%) were enrolled in CEASAR. The mean age of CEASAR participants was 63.2 yr versus 64.1 yr in PCOS; the median age of participants in both study groups was 65 yr. We identified multiple between-study differences in sociodemographic factors. Complete data are presented in Table 1.

PCOS participants had a higher mean pretreatment PSA than CEASAR patients (9.6 vs 6.7; $p < 0.001$). The proportion of patients with Gleason score 7–10 disease was lower in PCOS than CEASAR, likely owing to changes in pathologic reporting between 1994 and 2012 [14]. PCOS participants harbored more comorbid illnesses, with 29% and 22% of PCOS and CEASAR participants reporting two or more comorbid illnesses, respectively ($p < 0.001$). Table 2 presents the complete clinical data.

CEASAR participants were more likely to report pretreatment severe urinary incontinence, defined as having no urinary control or frequent leakage, than PCOS participants (7.7% vs 4.7%; $p < 0.001$). The adjusted odds ratio (OR) of severe urinary incontinence among CEASAR participants compared with PCOS participants was 1.83 (95% confidence interval [CI], 1.39–2.43). Similarly, CEASAR participants were more likely to wear urinary pads before treatment (OR: 2.95; 95% CI, 2.13–4.07). A total of 14.5% and 4.0% of CEASAR and PCOS participants reported moderate or severe bother secondary to urinary symptoms, respectively ($p < 0.001$), with an adjusted OR of 4.73 (95% CI, 3.61–6.19). Table 3 shows the unadjusted percentages and adjusted ORs for individual items in the urinary incontinence and sexual function domains.

At baseline, 24% of CEASAR participants reported using oral medications for ED. The unadjusted risk of ED, defined as being unable to achieve an erection sufficient for

intercourse, among CEASAR and PCOS participants was 44.7% and 24.0% ($p < 0.001$), respectively, with an adjusted OR of 3.12 (95% CI, 2.68–3.64). CEASAR patients were also more likely to report moderate or severe sexual bother than PCOS patients (OR: 1.38; 95% CI, 1.19–1.60).

Results from the domain-specific multivariable linear regression models were consistent with individual item findings. After adjustment for multiple relevant covariates, the sexual function summary score was 7.3 points lower among CEASAR participants than PCOS participants, indicating worse HRQOL related to sexual function (95% CI, 5.50–9.19). Not surprisingly, age, self-reported overall health status, income, marital status, diabetes, heart failure, and hypertension were all independently associated with sexual function. Similar findings were observed in the urinary incontinence model, with CEASAR patients reporting scores 5.1 points lower than PCOS patients (95% CI, 3.95–6.20). Table 4 presents the complete domain-specific models.

Sensitivity analyses including only CEASAR participants who had initiated treatment at the time of response to the baseline survey found no material differences in the main study findings, but they did note increased magnitude of both the absolute and relative between-study differences in the individual item model (Supplementary Table 1) and the summary score model (Supplementary Table 2). Similarly, sensitivity analysis restricted to participants from SEER sites common to both CEASAR and PCOS revealed findings consistent with those derived from the overall cohort (data not shown).

4. Discussion

PROs are essential in the measurement of treatment-related harms in prostate cancer and other disease states. Despite the relative importance placed on PROs, the evolution of patient reporting over time remains poorly characterized. This is particularly germane in domains where cultural norms may change with time, such as sexual and urinary function. The purpose of the current study was to compare differences in baseline reporting of these two domains in two prostate cancer cohorts enrolled nearly 20 yr apart. Patients in the contemporary CEASAR study were more likely to report sexual dysfunction and urinary incontinence than patients enrolled in the historical PCOS study. A number of explanations are plausible for the observed study findings. There are well-documented temporal increases in the prevalence of obesity [15–18] and diabetes mellitus [19,20], both of which have been associated with ED [19,21,22] and urinary symptoms [15,23–25]. We found the proportion of men with two or more comorbidities to be higher in the PCOS cohort than the CEASAR cohort. The distribution of comorbidity between cohorts provides some reassurance that prostate cancer diagnosis and treatment has been appropriately directed at healthier men. However, despite harboring more comorbid illnesses, PCOS participants reported more favorable pretreatment function than CEASAR participants, suggesting that comorbidity does not explain the study findings.

Conversely, the observed findings could reflect differences in reporting due to dynamic changes in sociocultural norms and patient perception of stigmatized conditions. Important sociological changes occurred between the time of PCOS enrollment (1994–1995) and

CEASAR enrollment (2011–2012) that may have contributed to the significant between-study differences. The approval of sildenafil coincided with the relaxation of the US Food and Drug Administration regulations on DTC advertising in 1997. This resulted in considerable investment in DTC marketing during the late 1990s through the first decade of the 21st century [1,5]. Proponents of DTC advertising contend that the practice serves to educate patients, promotes adherence, and enhances the patient–physician relationship [26]. Opponents of the practice believe that DTC advertising encourages inappropriate prescribing practices, promotes overdiagnosis, and ultimately increases health care costs with no net benefit to society [15,17,18].

It is possible that both medicalization and stigma reduction have resulted in the observed study findings. Medicalization and stigma reduction refers to the phenomenon by which "previously non-medical problems are defined and treated as medical problems, usually in terms of illnesses or disorders" [19]. The past two decades have certainly witnessed the medicalization of ED. Stigma reduction in ED was largely accomplished through recategorization [5]. One of the principal components of stigma is a separation between the stigmatized ("them") from the rest of the population ("us") [27]. Recategorization refers to the process by which media contact repositions people from "them" to "us," thereby reducing stigma associated with the condition of interest [5]. Public exposure to DTC advertising through prominent public figures including US senator and presidential candidate Bob Dole and the professional American football player Tony Siragusa may have indeed resulted in recategorization. The effect of celebrity promotional campaigns is well described. Cram et al reported an increase in colonoscopy rates after Katie Couric's televised colorectal cancer awareness campaign [28], and Nattinger et al described changes in breast cancer practice patterns that the authors attributed to Nancy Reagan's public battle with breast cancer [29].

The current study suggests that the reporting of ED and urinary incontinence has increased from 1994–1995 to 2011–2012. It is possible that stigma reduction has resulted in increased reporting of pretreatment sexual and urinary dysfunction, raising the possibility of *underreporting* of baseline dysfunction in historical studies of prostate cancer patient–reported outcomes and thus *overestimation* of treatment-related morbidity. Given the inclusion of treatment-related harms in formulating the US Preventive Services Task Force recommendations surrounding prostate cancer screening [30], identifying dynamic changes in pretreatment urinary and sexual dysfunction is an essential component of estimating the burden of population-level harms attributable to prostate cancer treatment.

These findings are of paramount importance when considering the use of PROs in comparative effectiveness research. Specifically, the use of historical data may not accurately reflect the contemporary landscape and, as such, may result in considerable bias when evaluating differences in PROs over time. The current study suggests that exogenous societal factors may influence reporting of baseline function among men with prostate cancer. Our study findings underscore the need for longitudinal data analysis and raise significant concerns about the use of cross-sectional study designs in the evaluation of comparative effectiveness.

This study has a number of limitations. First, the study uses modified summary scores for the UCLA-PCI and EPIC-26 instruments to compare the PCOS and CEASAR cohorts in the multivariate linear regression analyses. To this end, the psychometric properties of the modified scales have not been established. Acknowledging this, the multivariate logistic regression analyses of the individual items use effectively identical end points between the two studies. The fact that the findings between the two analyses are consistent lends validity to the results. Second, it is possible that other unmeasured factors modulated the relationship between time and baseline disease-specific function in the current study. Neither CEASAR nor PCOS collected data surrounding obesity or prostate volume, which could confound the relationship between pretreatment function and study enrollment. Finally, whether the observed between-study differences are of sufficient effect to achieve clinical significance remain largely unknown.

5. Conclusions

Contemporary patients with newly diagnosed prostate cancer are more likely to report pretreatment urinary and sexual dysfunction than patients diagnosed two decades ago even after adjustment for known confounders. These findings suggest that nonclinical factors may influence patient perception and reporting of disease-specific function, particularly in cases where cultural norms change over time. These data have important implications for study design in comparative effectiveness research.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Demographic characteristics of study cohorts

Variable	CEASAR	PCOS	*p* value
Age, yr			
Mean	63.2	64.1	<0.001
Median	65 (58–69)	65 (59–70)	
Race, % (*n*)			
White	63 (1974)	69 (1601)	<0.001
Black	13 (403)	17 (401)	
Hispanic	6 (203)	14 (332)	
Other	18 (555)	0 (0)	
Inflation-adjusted income, % (*n*)			
<$30 000	22 (551)	24 (522)	<0.001
$30 000–100 000	50 (1276)	58 (1226)	
>$100 000	28 (706)	18 (384)	
Education, % (*n*)			
Less than grade school	5 (133)	9 (199)	<0.001
Less than high school	5 (137)	11 (249)	
High school graduate	21 (573)	21 (476)	
Some college	22 (604)	25 (567)	
College graduate	23 (616)	15 (337)	
Advanced degree	23 (631)	21 (476)	
Employment, % (*n*)			
Works full time	40 (1069)	29 (682)	<0.001
Works part time	8 (209)	9 (221)	
Retired	47 (1272)	56 (1315)	
Other	5 (135)	5 (116)	
Marital status, % (*n*)			0.016
Married	79 (2116)	82 (1892)	
Not married	21 (575)	18 (419)	
Insurance status, % (*n*)			
Private or HMO	51 (1361)	51 (1197)	<0.001
Medicare	38 (1026)	39 (904)	
VA or military	0 (7)	0 (0)	
Medicaid	5 (139)	2 (36)	
Other	4 (105)	8 (184)	
No insurance	1 (40)	1 (13)	

CAESAR = Comparative Effectiveness Analysis of Surgery and Radiation; HMO = health maintenance organization; PCOS = Prostate Cancer Outcomes Study; VA = US Department of Veterans Affairs.

Percentages may not add to 100% due to rounding.

Table 2

Clinical characteristics of study cohorts

Variable	CEASAR	PCOS	*p* value
PSA			
Mean	6.7	9.6	<0.001
Median	5.3 (4.1–7.3)	7.3 (5.2–11.3)	
Gleason score, % (*n*)			
≤6	41 (1297)	43 (1014)	<0.001
7	28 (887)	16 (369)	
8–10	8 (254)	6 (145)	
Missing	22 (697)	35 (805)	
Treatment, % (*n*)			<0.001
Surgery	51 (1592)	58 (1344)	
Radiation	27 (849)	25 (586)	
Active surveillance	11 (346)	12 (275)	
Hormone therapy	2 (75)	6 (129)	
Other	9 (273)	0 (0)	
No. of comorbidities, %(*n*)			<0.001
0	43 (1337)	40 (932)	
1	36 (1122)	31 (732)	
2	15 (464)	16 (376)	
≥3	7 (212)	13 (294)	
Self-reported overall health, % (*n*)			0.017
Excellent	19 (603)	19 (450)	
Very good	38 (1186)	37 (850)	
Good	31 (966)	30 (699)	
Fair	10 (299)	11 (261)	
Poor	2 (74)	2.3 (54)	
Hypertension, % (*n*)	50 (1561)	34 (805)	<0.001
Heart failure, % (*n*)	3 (98)	5 (121)	<0.001
Stroke, % (*n*)	3 (93)	4 (103)	0.001
Heart attack, % (*n*)	6 (217)	7 (161)	0.499
Angina, % (*n*)	3 (111)	7 (168)	<0.001
Diabetes mellitus, % (*n*)	15 (500)	14 (323)	0.285
Colitis, % (*n*)	2 (60)	4 (90)	<0.001

CAESAR = Comparative Effectiveness Analysis of Surgery and Radiation; PCOS = Prostate Cancer Outcomes Study; PSA = prostate-specific antigen.

Percentages may not add to 100% due to rounding.

Table 3

Unadjusted responses to individual items and logistic regression models for individual items

	CEASAR, %	PCOS, %	OR[*, †]	95% CI
Urinary incontinence domain				
No urinary control or frequent leakage	7.7	4.7	1.83	1.39–2.43
Any urinary incontinence	27.3	19.5	1.57	1.35–1.83
Use any incontinence pads	7.4	3.1	2.95	2.13–4.07
Moderate or big problem due to urinary bother	14.5	4.0	4.73	3.61–6.19
Sexual function domain				
Erection insufficient for intercourse	44.7	24.0	3.12	2.68–3.64
Poor quality erections	40.1	38.3	1.12	0.97–1.30
Moderate or big problem due to sexual bother	29.7	23.9	1.38	1.19–1.60

CEASAR = Comparative Effectiveness Analysis of Surgery and Radiation; CI = confidence interval; OR = odds ratio; PCOS = Prostate Cancer Outcomes Study.

[*] PCOS referent.

[†] Adjusted for age, race, self-reported overall health, insurance status, income, employment, education, marital status, diabetes mellitus, colitis, emphysema, heart failure, stroke, hypertension, coronary artery disease, and angina.

Table 4

Multivariable linear regression models for domain summary scores

	Sexual function summary score		Urinary function summary score	
	Coefficient	**95% CI**	**Coefficient**	**95% CI**
CEASAR vs PCOS	−7.34	−9.19 to −5.50	−5.07	−6.20 to −3.95
Age, continuous	−1.02	−1.19 to −0.86	−0.18	−0.28 to −0.08
Race vs white				
Black	0.86	−1.69 to 3.41	−2.75	−3.78 to −0.63
Latino/Hispanic	3.13	−0.07 to 6.32	−1.22	−3.17 to 0.74
Other	−3.47	−9.23 to 2.28	−11.02	−14.57 to −7.47
Overall health vs poor				
Fair	4.63	−2.06 to 11.32	6.58	2.53–10.64
Good	14.26	7.79–20.73	9.37	5.45–13.28
Very good	22.64	16.08–29.20	12.19	8.22–16.16
Excellent	27.80	21.03–34.57	13.87	9.77–17.97
Income vs <$30 000				
$30 000–100 000	4.25	1.67–6.82	1.77	0.18–3.35
>$100 000	7.36	4.00–10.72	2.82	0.76–4.88
Not married vs married	2.68	0.41–4.94	−1.45	−2.83 to −0.69
Diabetes	−7.65	−10.13 to −5.18	−1.88	−3.39 to −0.36
Heart failure	−6.47	−11.34 to −1.62	0.42	−2.55 to 3.39
Hypertension	−3.18	−5.02 to −1.34	0.44	−0.68 to 1.57
Stroke	−1.39	−6.09 to 3.31	−4.67	−7.53 to −1.81
Colitis	−3.88	−9.01 to 1.24	−5.81	−8.90 to −2.71

CEASAR = Comparative Effectiveness Analysis of Surgery and Radiation; CI = confidence interval; PCOS = Prostate Cancer Outcomes Study.

Adjusted for insurance status, employment, education, emphysema, heart attack, and angina.