

Quality of life, sexual function and decisional regret at 1 year after surgical treatment for localized prostate cancer

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OBJECTIVE

To examine the effect of changes in quality of life (QoL) and levels of sexual function on decisional regret after surgical treatment of localized prostate cancer.

PATIENTS AND METHODS

Patients who decided to have a radical prostatectomy (RP) were assessed for health-related QoL using the general European Organization for Research and Treatment of Cancer C30 instrument and disease-specific prostate cancer module, and sexual function using the abbreviated International Index of Erectile Function-5 before and 1 year after RP. Decision control was measured before RP, and decisional regret 1 year afterward, using measures mailed to participants 1 year after treatment.

RESULTS

Of 130 respondents (mean age 62 years), 4% expressed regret over their decision to have surgery. Physical and social functioning, and finances, were compromised, while emotional functioning and treatment-related symptoms improved by 1 year. Higher levels of decisional regret were correlated with decreases in role and social functioning, increased pain and financial difficulty (all $P < 0.01$). Sexual function was decreased ($P < 0.001$) after treatment. Men reported feeling less masculine, having less sexual enjoyment, difficulty in getting and maintaining an erection, and discomfort when being sexually intimate after surgery. Mean scores of decisional regret were similar among patients who reported assuming either active (84%) or collaborative (11%) roles in treatment decision-making. Men who assumed a passive

role reported the most variability and highest scores on decision regret.

CONCLUSIONS

Few men regretted having RP at 1 year after treatment, even though some QoL functions and domains were significantly affected. Ongoing assessment of the effect of surgical treatment on sexual function, sexuality and masculinity certainly deserves further exploration with this group of cancer survivors.

KEYWORDS

prostate cancer, quality of life, decision regret, decision control, sexual function, radical prostatectomy

INTRODUCTION

Radical prostatectomy (RP) remains the standard treatment for men with organ-confined prostate cancer who accept treatment-related complications and have a life-expectancy of >10 years [1]. Improved longevity after curative treatment for clinically localized prostate cancer has resulted in clinicians focusing on methods to decrease treatment-related morbidity. In particular, satisfaction with sexual function remains one of the contributing factors having the greatest impact on the overall quality of life (QoL) of prostate cancer survivors [2]. After RP most men do not regain the sexual function they had before [3] and ≈60% of men rate the condition as distressing [3,4]. The most important prognostic factors for the return of potency after RP are preservation of both

neurovascular nerve bundles, being younger, and having good sexual function before surgery [5].

An important aspect of overall treatment success is whether a patient regrets the decision he has made. Patients vary in the value placed on erectile function before surgery and cure is often considered more important than the effect of treatment on future health-related QoL. Because of these differences the treatment of prostate cancer will always be very patient-specific and most physicians encourage their patients to be involved in treatment decision-making. Lack of patient involvement in treatment decision-making has been identified as a major risk factor for regretting treatment choice [6]. Higher levels of decisional regret have previously been reported to be associated with poorer scores on QoL among a sample of

men with metastatic prostate cancer [7], but it is unknown if this finding would be supported in a group of patients with early-stage prostate cancer after RP.

Davison and Goldenberg [8] previously reported that QoL scores before treatment were similar to levels 18 months after treatment (RP or radiotherapy) for early-stage prostate cancer. Levels of decisional regret were low among men and most reported participating in treatment decision-making at the time of diagnosis. Given the small sample size of this latter study and possible variation due to treatment choice, we focused specifically on the impact of RP on sexual function, QoL and decisional regret; in the present study we examined the effect of changes in levels of sexual function and QoL on decisional regret after RP for localized prostate cancer.

PATIENTS AND METHODS

A consecutive sample of patients was recruited from a patient-education centre at an academic urological clinic from January 2002 to June 2004, after obtaining institutional review board approval. Patients were eligible if they had a confirmed diagnosis of localized prostate cancer as confirmed by their TRUS biopsy results and urological assessment, were scheduled for RP, and able to read and speak English. About 100 patients are referred to the centre annually for preoperative teaching.

Sociodemographic information, baseline disease-specific information and assumed role in treatment decision-making were assessed before surgery. QoL and sexual function were assessed before and 1 year after RP; at 1 year a research nurse telephoned each patient to ask if he would still be willing to complete the follow-up questionnaires, and to gather additional data on treatment status. QoL, sexual function and decisional regret questionnaires were then mailed to participants in a self-addressed envelope. Up to two follow-up telephone calls were made if forms were not returned within a month.

The Decisional Regret Scale (DRS) was used to measure distress or remorse after the decision to have surgery [9]. This scale uses a five-item self-reported Likert Scale (1, 'strongly agree'; 2, 'agree'; 3, 'neither agree nor disagree'; 4, 'disagree'; and 5, 'strongly disagree'). Items 2 and 4 were reverse-coded so that, for each item, a higher value would indicate more regret. Scores were then converted to a 0–100 scale by subtracting one from each item and multiplying by 25. To obtain a final score, each item was summed and averaged. A score of zero meant no regret, and a score of 100 indicated high regret. To date, no score groupings have been developed to indicate high, medium or low levels of regret. A Cronbach's α coefficient of 0.92 was reported previously with this patient population [8].

Decisional control was measured using the five statements of the Control Preferences Scale (CPS). Patients were asked to select the statement that best described the role they assumed in making a treatment decision. The statements ranged from assuming an active (patient makes the decision alone or after consideration of physician opinion), collaborative (patient and physician make the

decision together) or passive (physician makes the decision with or without input from patient) role. The reliability of the CPS 'select one' method was reported previously in studies conducted with this patient population [10,11].

QoL was assessed using the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 (version 3) [12] and accompanying prostate cancer module (EORTC-PC). The EORTC-C30 contain 30 items grouped into five functional domains (physical, role, cognitive, emotional, social), three symptom domains (fatigue, pain, nausea and vomiting), five single-symptom items (dyspnoea, insomnia, anorexia, diarrhoea, constipation), one item dealing with financial concerns, an overall health domain, and an overall QoL domain. The questionnaire uses 28 four-point response scales (1, 'not at all'; 2, 'a little'; 3, 'quite a bit'; 4, 'very much'), and two seven-point response scales for the overall health status and QoL domains. Patients indicate the extent to which they have experienced specific symptoms or functional limitations over the past week. In accordance with the EORTC QLQ-C30 scoring manual, all scores were linearly transformed to a 0–100 scale. For items relating to symptoms, a higher score represents a higher level of symptoms. For scales related to function, a higher score represents a higher level of functioning.

The EORTC-PC module consists of 25 items; nine items measure urinary symptoms and problems, four assess bowel symptoms and function, six assess treatment-related symptoms, and six are related to sexuality. Two of the sexuality items are for all patients, and four are conditional on being sexually active. The questionnaire uses 25 four-point response scales (1, 'not at all'; 2, 'a little'; 3, 'quite a bit'; 4, 'very much'). For scales related to each overall group of items, a higher score represents a lower level of experiencing that particular symptom. Items 50–52 of the PC module were reverse-coded so that scoring would be consistent with the main questionnaire.

The Sexual Health Inventory for Men (SHIM) was used to assess sexual function [13]. This five-item measure is an abridged version of the 15-item International Index of Erectile Function (IIEF) measure used to diagnose the presence and severity of erectile dysfunction (ED). The five sexual function domains include

ED, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction. ED is classified into five severity levels ranging from none (22–25) through severe (5–7). Responses on this questionnaire were based on the previous six months. Rosen *et al.* [13] showed that there is substantial agreement between the predicted and true ED classes (weighted $\kappa = 0.82$).

The EORTC QLQ-C30 and PC module, SHIM and DRS are unidimensional scales and were considered to have interval levels of data. The internal consistency value of the DRS was 0.91 and of the SHIM 0.95, as measured by Cronbach's α coefficient. The EORTC QLQ-C30 measure was analysed according to the instruction manual provided by the authors. Paired Student's *t*-tests were used to compare QoL scores, SHIM, and PC module sexuality items before and after RP. Pearson correlation coefficients were used to assess the degree of relationship between QoL, SHIM, CPS and DRS scores. Current and baseline treatment-related symptoms (specifically sexual and urinary function), age, level of education, assumed role in decision-making, and overall QoL scores were entered into a regression model to predict levels of decisional regret. In all tests, $P < 0.05$ was considered to indicate statistical significance.

RESULTS

Of 155 men, 130 (84%) completed baseline measurement before RP and then at 1 year afterward; 25 men (16%) did not return the questionnaires at 1 year. Men who withdrew from the study did not differ significantly from those who completed it in age, education or sexual function at baseline. All patients had been diagnosed with clinical early-stage prostate cancer, as confirmed by the TRUS biopsy results, and had undergone RP; 39 (30%) received neoadjuvant hormone therapy (NHT). Most (94%) received no additional treatment in the first year after RP. Of the eight men who had adjuvant therapy after RP, two had NHT, two external beam radiation, and four external beam radiation and NHT. The mean (SD) age of the patients was 62.05 (6.02) years, with most having had greater than a high-school education (71%), being married (85%), and employed either full-time or part-time (56%) (Table 1).

All patients in this sample were Caucasian and most (66%) were referred to the centre from

TABLE 1 The baseline characteristics of the 130 study participants

Variable	N (%)
Age, years:	
<60	48 (36.9)
60–65	39 (30.0)
>65	43 (33.1)
Educational attainment:	
<High school	6 (4.6)
High school	32 (24.6)
>High school	92 (70.8)
Marital status:	
Married/cohabiting	111 (85.4)
Single	19 (14.6)
Employment:	
Full-time	61 (46.9)
Part-time	12 (9.2)
Retired	56 (43.1)
Unemployed	1 (0.8)
Referral source:	
Prostate Centre	44 (33.8)
Community urologist	75 (57.7)
Cancer agency	6 (4.6)
Self-referral	5 (3.8)
PSA level, ng/mL:	
<10	107 (82.3)
10–20	20 (15.4)
>20	3 (2.3)
Gleason score:	
3–6	88 (67.7)
7	39 (30.0)
8–9	3 (2.3)
Clinical stage:	
T1	48 (36.9)
T2	82 (63.1)

community urology practices. Of the men, 30% had treatment consultations with two or more urologists and 32% were seen by a radiation oncologist before a final decision was made to have surgery; 84% (109) reported assuming an active role in treatment decision-making with their physician, 11% (14) a collaborative role, and 5% (seven) a passive role.

The mean scores before and after RP for all functioning scales of the EORTC QLQ-C30 and PC module are shown in Table 2. Physical and social functioning was compromised at 1 year, while emotional functioning and appetite were improved at 1 year after RP. Patients reported having significantly more financial difficulties, treatment-related symptoms,

EORTC measure*	Mean (SD) score		P
	Before RP	After RP	
QLQ-C30 items:			
Overall health	81.99 (16.85)	81.41 (15.23)	0.690
Functioning:			
Physical	97.28 (7.27)	95.13 (9.16)	0.008
Role	96.79 (9.97)	94.36 (13.54)	0.071
Emotional	75.51 (19.87)	83.29 (19.45)	0.001
Cognitive	89.49 (16.23)	88.97 (15.19)	0.720
Social	92.05 (14.56)	86.15 (20.03)	0.002
PC module items:			
Urinary incontinence	85.80 (12.65)	85.05 (12.41)	0.570
Bowel symptoms	97.48 (7.03)	96.64 (6.63)	0.220
Treatment-related symptoms	95.02 (8.00)	90.26 (9.83)	0.001
Sexuality	61.71 (25.71)	40.92 (23.60)	0.001
Symptom domains:			
Fatigue	10.09 (15.80)	12.35 (15.43)	0.140
Nausea and vomiting	1.67 (8.00)	0.77 (3.51)	0.180
Pain	6.03 (13.92)	10.38 (18.82)	0.015
Dyspnoea	2.31 (10.33)	4.10 (12.46)	0.160
Insomnia	22.82 (27.23)	20.77 (26.01)	0.410
Anorexia	3.59 (13.92)	1.28 (6.44)	0.028
Constipation	5.38 (13.00)	6.41 (15.02)	0.500
Diarrhoea	5.68 (15.09)	5.94 (14.70)	0.860
Financial difficulty	1.54 (7.02)	5.38 (14.85)	0.005

TABLE 2

A comparison of EORTC QLQ-C30 and EORTC-PC module scores before and after RP

*A higher score on functioning indicates less impairment, while higher scores on symptom and PC modules indicate a higher level of impairment.

TABLE 3 Cross tabulation of SHIM scores in the 130 patients

Sexual function Before RP	At 1 year after RP					Total (%)
	none	mild	mild-moderate	moderate	severe	
No ED (20–25)	6	5	7	5	56	79 (60.8)
Mild ED (17–21)	0	0	0	1	11	12 (9.2)
Mild-moderate ED (12–16)	0	1	0	0	7	8 (6.2)
Moderate ED (8–11)	0	0	0	1	6	7 (5.4)
Severe ED (1–7)	0	1	3	1	19	24 (18.5)
Total (%)	6 (4.6)	7 (5.4)	10 (7.7)	8 (6.2)	99 (76.2)	130

pain, and sexual difficulties at 1 year than before RP.

Overall, self-reported sexual function was significantly decreased ($P < 0.001$) after RP, using the SHIM score. Before RP, 31 (24%) men reported having 'moderate' to 'severe' ED, and 99 (76%) reported having 'none' to 'mild/moderate' ED (Table 3). Seventy-six (77%) of men in this latter group reported having 'moderate' to 'severe' ED at 1 year after RP. Six men who did not have ED before RP reported having no ED after RP. Men who received NHT reported significantly lower ($P = 0.016$) SHIM scores at 1 year than men who did not receive NHT.

A comparison of scores before and after RP on each of the six sexuality items of the EORTC-PC module showed no change in sexual interest after RP, but significantly many men felt less masculine and were less sexually active (with or without intercourse) after treatment. A comparison of patients (who were sexually active over the previous 4 weeks) before and after RP showed that they had significantly less sexual enjoyment, difficulty in getting and maintaining an erection, ejaculation problems, and being more uncomfortable being sexually intimate (Table 4). The total mean scores on the six sexuality items of the PC module were highly correlated with total mean SHIM scores

before ($r = 0.62$) and after ($r = 0.53$, both $P < 0.01$) RP.

Men had no regrets over their decision to have surgery (Table 5); the mean (SD, range) score on the DRS was 16.65 (18.70, 0–80). While 102 (79%) men had scores of < 30 , five (4%) men scored > 65 . There were no significant differences between the mean scores of the DRS and the role assumed in treatment decision-making. The seven men who reported assuming a passive role had the highest variation in scores (SD 31).

Higher levels of decisional regret were significantly correlated with changes in QoL (before and after RP) in men with decreases in role ($r = 0.34$), and social ($r = 0.45$) functioning; increased pain ($r = 0.29$) and financial difficulties ($r = 0.30$, all $P < 0.01$). There was no significant correlation between changes in SHIM scores before and after RP and decisional regret. Regression modelling showed that the role assumed in treatment

decision-making, age, educational attainment, SHIM score, treatment-related symptoms (urinary, bowel), sexuality, and NHT variables had no significant effect on the patients' DRS scores. Urinary function as reported in the QoL measure was not significantly altered at 1 year after RP.

DISCUSSION

The present study has several important findings. First, few patients regretted their decision to have surgery at 1 year after RP. Similarly, Hu *et al.* [14] reported that $< 4\%$ of patients with localized prostate cancer treated with RP expressed regret about their decision at ≈ 3 years afterward. Davison *et al.* [8] also reported that the type of treatment for localized prostate cancer had no effect on decisional regret at ≈ 18 months after treatment. Results from these studies suggest that even over time, patients do not regret their initial treatment decisions. One explanation for this finding is that the present

patients were informed about the potential side-effects associated with surgery, were involved in their treatment selection, and were pleased with the treatment decision made. Similarly, Clark *et al.* [7] concluded that patients who were adequately informed and made their own decisions were less likely to regret their treatment choice than were those whose physicians made the decision for them. In a recent study, Clark and Talcott [15] reported that few (7%) men with localized prostate cancer expressed regret over their treatment decision at 5 years. Regret was related to men being poorly informed and leaving treatment decisions mainly to their physicians [15]. The present patients who reported assuming a passive role in decision-making had high variation in their DRS scores. This latter finding identifies the need to further evaluate this phenomenon.

Second, most (76%) of the present men (who were potent before RP) reported having 'moderate' to 'severe' ED at 1 year after RP, even though sexual interest remained unchanged. Similar rates of ED were previously reported at 1 year [16] and even 5 years after RP [4]. While sexual functioning declines with age, sexuality remains a significant aspect of some men's lives well into their older years. The reported impact of diminished sexual function on QoL after surgical treatment for prostate cancer varies; while some have reported little or no long-lasting effect on the QoL of men after treatment for prostate cancer [3,17], others reported a significant effect. Bokhour *et al.* [2] conducted focus groups with 48 men treated for prostate cancer within the previous 12–24 months, to explore their perceptions of the effect of ED on QoL. Four domains of QoL identified as being relevant to men's experiences included; quality of sexual intimacy, everyday interactions with women, sexual imagining and fantasy life, and men's perceptions of their masculinity. Men reported that erectile problems affected both

TABLE 4 Changes from before to after RP in the EORTC-PC module sexuality items

Item	N	Mean (SD) value before/after RP	P
Over the last 4 weeks ...			
49 Have you felt less masculine as a result of your illness or treatment?	130	1.32 (0.66)/1.77 (0.80)	< 0.001
50 To what extent were you interested in sex?	128	2.33 (0.84)/2.36 (0.90)	0.92
51 To what extent were you sexually active (with or without intercourse)?	129	2.76 (0.86)/2.98 (0.94)	0.01
Answer next four questions only if sexually active over last 4 weeks ...			
52 To what extent was sex enjoyable for you?	64	1.75 (0.74)/2.50 (0.89)	< 0.001
53 Did you have difficulty getting or maintaining an erection?	64	1.52 (0.76)/3.11 (1.01)	< 0.001
54 Did you have ejaculation problems (during ejaculation)?	61	1.28 (0.73)/2.85 (1.22)	< 0.001
55 Have you felt uncomfortable about being sexually intimate?	64	1.34 (0.67)/1.91 (0.97)	< 0.001

TABLE 5 DRS item scores by n (%) of the 130 patients

DRS items	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
1 It was the right decision	78 (60.0)	41 (31.5)	8 (6.2)	2 (1.5)	1 (0.8)
2 I regret the choice that was made	4 (3.1)	5 (3.8)	6 (4.6)	40 (30.8)	75 (57.7)
3 I would make the same choice if I had to do it over again	74 (56.9)	42 (32.3)	9 (6.9)	3 (2.3)	2 (1.5)
4 The choice did me a lot of harm	1 (0.8)	12 (9.2)	20 (15.4)	46 (35.4)	51 (39.2)
5 The decision was a wise one	67 (51.5)	51 (39.2)	8 (6.2)	3 (2.3)	1 (0.8)

their intimate and non-intimate lives, including how they saw themselves as sexual beings. A more recent study conducted with 91 men who had received treatment for prostate cancer within the previous 18 months also showed that both sexual desire and function were necessary for optimal QoL [18]. Respondents in this latter study with lower sexual functioning reported significantly lower QoL scores as the level of sexual desire increased. A tendency for men with better sexual functioning to have higher QoL scores as their level of sexual desire increased was also identified. The results show the psychosocial implications consequential to ED, especially within the first 2 years after treatment for prostate cancer, and the need for healthcare professionals to assist survivors to adjust to treatment-related changes in their sexuality.

Third, this younger group of working men also reported having significant difficulties related to finances at 1 year after treatment. This is one of the first times that financial difficulty has been identified in the QoL assessment as being compromised by RP. Financial difficulties were also related to higher levels of decisional regret. Of the men in the present sample, 67% were aged <65 years and 56% were working at either a full-time or part-time job. Although the men in this Canadian study were well educated and incurred minimal healthcare costs, our results suggest that men perceived the diagnosis and/or treatment of prostate cancer was having an impact on their finances. In a recent study, Harden *et al.* [19] also reported that couples in the 50–64-year age group reported greater disappointment and anger at their inability to reach life goals and establish financial security, after a diagnosis of prostate cancer. The number of men in this study who retired early, were self-employed or lost salary due to sick time is unknown. Several American investigators conducted studies specifically with lower-income men with prostate cancer, but the longitudinal effect of treatment on higher-income men might deserve further study.

The present study has several limitations that might influence the general applicability of the findings. Although the sample consisted of well-educated Caucasian men who reported being actively involved in treatment decision-making, the sample is representative of the type of patients referred by urologists to this education centre over the last 6 years.

Second, the number of men who had nerve-sparing surgery and were prescribed treatment for ED after surgery was not recorded, as the authors had no access to the private medical records of patients referred from community urologists. Third, responses on the SHIM were based on the previous 6 months and the sexuality items in the EORTC-PC module were based on the previous 4 weeks. Despite this discrepancy, the SHIM and EORTC-PC sexuality scores were remarkably similar before and after surgery.

In conclusion, surgery for localized prostate cancer has an effect on men's QoL, but our results show that men who are informed and participate in treatment decision-making do not regret their treatment decision. There is also some indication that men who play passive roles in treatment decision-making with their physician might have more decisional regret. However, this phenomenon deserves further study. Our data also support the need to further examine the effect of surgery on men's sexual function, sexuality and masculinity. There is also a need to identify how treatment effects the financial status of younger men who are still employed.

CONFLICT OF INTEREST

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Abbreviations: **RP**, radical prostatectomy; **QoL**, quality of life; **DRS**, Decisional Regret Scale; **CPS**, Control Preferences Scale; **EORTC**, European Organization for Research and Treatment of Cancer; **PC**, Prostate Cancer (module); **SHIM**, Sexual Health Inventory for Men; **IIEF**, International Index of Erectile Function; **ED**, erectile dysfunction; **NHT**, neoadjuvant hormone therapy.