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Original Article

How informed is our consent? Patient awareness of radiation and radical prostatectomy complications

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ABSTRACT

Objective: To evaluate patient's recall of pretreatment counseling for radical prostatectomy and radiation therapy for the treatment of prostate cancer.

Material and methods: A retrospective review of all patients presenting to our reconstructive urology clinic for the management of the complications of prostate cancer treatment was conducted over 24 months. Patients treated with only surgery or radiotherapy were included in the study. Patients were asked a standard series of questions to assess their recall of their pre-prostate cancer treatment counseling.

Results: We identified 206 patients that met inclusion criteria. Of those, 153 underwent radical prostatectomy and 53 patients received radiation therapy. Median age at presentation was 72 years in the surgery group and 75 in the radiation therapy group. Mean time since treatment was 8.8 years in those that recalled being counseled and 9.9 years in those who did not (p=0.21). In the surgery group, the adverse effects experienced by 119 (77.8%) patients recalled, and counselled were related to the risk of treatment. In the surgical patients that had records with documentation of pretreatment counseling, 41/48 (85.4%) endorsed recall. In the surgery group, 117 (76.5%) stated that their treating physician was aware of their complication. In the radiation group, 5 patients (9.4%) endorsed recall (p<0.0001). In the subgroup of radiation patients with documentation of pre-treatment counseling, no patients endorsed recall. In the surgery group, 117 (76.5%) patients stated that their treating physicians were aware of their complication, while in the radiation group, only 16 (30.2%) of treating physicians were aware of the complications (p<0.0001).

Conclusion: Patient recall of potential complications of prostate cancer treatment is poor. It's unclear if this is secondary to poor recall, selective memory loss or inadequate counseling.

Keywords: Ethics; informed consent; mental recall; postoperative complications; prostate neoplasms.

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Introduction

Prostate cancer (CAP) is the most common non-cutaneous malignancy in men.[1] The most common therapies for treatment of localized prostate cancer are radical prostatectomy (RP) and radiation therapy (RT).[2,3] Each modality comes with risks. Patients rely on appropriate counseling by their physicians in order to make a decision through a process of informed consent. Beauchamp defines informed consent as, "A legal doctrine based on the principle of autonomy in which information about a proposed procedure or treatment, including the risks/benefits/alternatives, must be provided so the patient or surrogate can decide if he/she is willing to participate."[4] For informed consent to be valid, the participant must be given adequate information, have decision-making capacity, and the consent must be voluntary.[4] Concerning patients in our pelvic reconstructive urology clinics seen for CAP-related complications, in many circumstances they did not recall or were not told that certain complications of treatment were possible. Therefore, we sought to evaluate patients' recall of pretreatment counseling for radical prostatectomy and radiation therapy for the treatment of localized prostate cancer and the adequacy of informed consent.

Material and methods

After Institutional Review Board (IRB) approval, a retrospective analysis of all patients presenting to our reconstructive urology clinic for management of CAP-treatment complications from January 1, 2015 to December 31, 2016 was conducted. Patients with clinically localized adenocarcinoma of the prostate treated with only RP or only RT were included in the study. Patients were included if they presented with an adverse effect that could be reasonably attributed to their previous treatment, including, but not limited to, stress urinary incontinence, erectile dysfunction, bladder neck contraction, radiation cystitis, fistula development, urethral stricture formation. Only the primary complaint at the time of the reconstructive urology clinic visit was assessed. Patients who had been treated with both RP and RT, or patients that had been treated with other therapies were excluded. The time interval from the time of presentation to our office to the onset of CAP treatment was also recorded.

Patients were asked a standard series of questions to assess their recall of their pre-CAP treatment consent and their recollection of whether or not the complication they experienced was discussed prior to treatment. Responses were recorded in prospectively collected database. Patients were asked to provide "yes" or "no" answers to following questions:

1. "Do you recall being told that your current condition was a risk of the treatment you received for prostate cancer?"
2. "Does the physician that provided that therapy know that you developed this complication?"
3. "Does the physician that provided that therapy know that you are seeking treatment for this complication?"

Statistical analysis

When available, initial CAP treatment consultation notes were reviewed for documentation of informed consent discussion. Statistical analysis was performed with the t-test for normally distributed data, the Wilcoxon rank-sum test for skewed data, and chi-square test for categorical data with a $p<0.05$ considered to be statistically significant.

Results

We identified 206 patients (153 RP, and 53 RT patients) that met the selection criteria. Results are summarized in Table 1. Median age at presentation was 72 years in the RP and 75 years in the RT group. Median time since treatment was 9.4 years in the RP group and 8.9 years in the RT group (p=0.88). Median time since treatment was 8.8 years in those that recalled being counseled and 9.9 years in those who did not (p=0.21).

Table 1. Patient and treatment demographics

Radical prostatectomy (n=153)	
Age, median (IQR)	72 (66;77)
Time from treatment (years), median (IQR)	9 (3;15)
Approach/Modality	
Open, n (%)	98 (64)
Robotic, n (%)	55 (36)
Presenting complication	
SUI, n (%)	148 (97)
Fistula, n (%)	3 (2)
BNC, n (%)	2 (1)
Radiation therapy (n=53)	
Age, median (IQR)	75 (72;82)
Time from treatment (years), median (IQR)	9 (4;12)
Approach/Modality	
EBRT, n (%)	29 (55)
Brachytherapy, n (%)	15 (28)
EBRT + Brachytherapy, n (%)	9 (17)
Presenting complication	
Hemorrhagic cystitis, n (%)	20 (38)
SUI, n (%)	14 (26)
Urethral stricture, n (%)	9 (17)
Fistula, n (%)	7 (13)
BNC, n (%)	3 (6)

IQR: interquartile range; SUI: stress urinary incontinence; BNC: bladder neck contracture; EBRT: external beam radiation therapy

In the RP group, 119 (77.8%) patients recalled being counseled that the adverse effect they were experiencing was a risk of treatment, compared to 5 (9.4%) patients in the RT group ($p<0.0001$). In those that underwent open RP, the recall rate was not significantly different from patients undergoing robotic RP (75.5% vs 81.8%, p=0.36).

In the RP group, 54 (35.2%) patients had initial CAP treatment consultation notes available. Of these, 48 (88.9%) contained documentation of a discussion of their specific adverse effect. In 48 patients who had specific counseling documented in notes, 41 (85.4%) endorsed recall.

Of the 53 patients that were treated with RT, 20 (37.7%) had initial CAP treatment consultation notes available. Discussion of the presenting adverse effects of 10 (50%) patients was documented in their pretreatment consult notes. The remaining 10 records had generic statements asserting that risks were discussed. In no one of the 10 patients who had specific counseling documented in notes endorsed recall.

In the RP group, the most common presenting chief complaint was stress urinary incontinence (SUI), occurring in 148 men. Of those, 119 (79.7%) recalled counseling about SUI. One of the two patients (50%) with the chief complaint of bladder neck contracture (BNC) recalled counseling, and none of the 3 patients with fistula recalled counseling.

In the RT group, the most common presenting chief complaint was radiation cystitis, occurring in 20 patients. Only 2 patients (10.0%) recalled a discussion about radiation cystitis prior to treatment. Three of 14 men (21.4%) with SUI recalled counseling. None of the patients that presented with fistula (n=7), BNC (n=2), or urethral stricture (n=9) recalled counseling about those adverse effects.

The majority (n= 117, 76.5%) of the patients that underwent RP stated that their treating physicians were aware of their complications, while in the radiation group, 16 (30.2%) of treating physicians were aware of treatment complications ($p<0.0001$). The RP group's treating physicians were also more likely to know that they had been seen for the management of their treatment related complication (46.4 vs 17.0%, $p<0.0001$).

Discussion

The results show that among patients treated with radiation therapy or radical prostatectomy for CAP, the rate of recall of potential adverse effects is poor. This may the result of inadequate disclosure, poor retention of information, or a combination of both.

Perhaps the more troubling explanation would be inadequate counseling. While informed consent must include "adequate disclosure" of the risks associated with therapy, there is no set criteria for which risks must be discussed for each modality of treatment. Instead, ethical principles provide a framework to determine what should be disclosed to a patient in order for them to make an informed decision.

Traditionally, there have been three approaches to determine amount of information considered to be adequate to make an informed decision. The first approach, the reasonable physician standard, is defined as what a reasonably prudent physician would disclose. It is rooted in the ethical principles of paternalism, thereby largely disregarding the patient autonomy which is an imperative of informed consent.

A second approach, the reasonable patient standard, is the most commonly accepted approach and is based on the ethical principle of autonomy. In this approach, the physician must provide the patient with the information that the average patient needs to know in order to make an informed decision. The third approach, the subjective standard, builds on the reasonable patient standard. Not only must physician take into account what a typical patient or physician might need to know and disclose, but the information must be individualized for each particular patient.

A study by Sullivan et al.[5] surveyed providers and patients on how much information patient's wished to know about their disease and treatments. The authors found that physicians underestimated the amount of information that patients wanted, with 62% of the patients wanting all details regarding the illness and treatments. In contrast, only 32% of the physicians felt that patients wanted all details.

The radiation oncology literature has also evaluated the informed consent process.[6-9] Barnett el al.[6] surveyed radiation patients on the amount of information about the risks of treatment that they wished to receive prior to treatment. This survey showed that most patients wished to be informed about adverse effects even if the risk was less than 10 percent. If the adverse effect was severe, 44% of the patients wanted to be informed even if the risk was very low (<0.1%). A more recent study by Jimenez-Jimenez et al.[10] also assessed patient's perceptions of the counseling they received during radiation oncology treatments. Using a survey (EORTC QLQ-INFO25), they found that although patients were generally satisfied about the counseling, a high percentage (43%) wanted more information. The study also found that patients felt well informed regarding their cancer diagnosis, medical tests, and type of treatments, but reported lack of information on certain side effects and social support following treatment. Another notable finding of this study was that older and less educated patients were less satisfied with the information they received. This is important in this patient population, as those treated for prostate cancer are generally older in age.

Freeman et al.[7], evaluated the consent process amongst Canadian radiation treatment centers. They found that only 59% of the centers had obtained written consent prior to radiation. In many cases, consent was considered implied since patients returned for follow-up visits and treatments. The authors did recognize that the lack of written consent does not offer the patient an opportunity to understand what is being told.

In our study, among the patients who underwent RT and for whom records from initial consultation were available, we found that half of the patient's notes contained documentation of discussion of specific risks related to radiation therapy. In the remaining half, there were at least generic statements that risks were discussed. In the RP group, 88.9% of the records available contained documentation of discussion of their specific adverse effects. This would suggest that counseling was provided to patients at a higher rate than our patient's recall rates would imply.

An alternate explanation for the poor recall is poor retention of the information presented to the patient. In our study, only 9.4% of the patients treated with radiation recalled being counseled on the adverse effect they were seeking treatment for. To our knowledge, no previous studies have specifically evaluated recall consent to treatment in the prostate cancer population treated with radiation therapy.

Conversely, in the RP group, 77.8% of the patients recalled counseling on their specific adverse effects. Informed consent recall has been explored extensively in the surgical literature with recall rates of surgical risks ranging from 30 to 77.9 percent.[11-15] While as there is limited data on the phenomenon for radical prostatectomy; information about consent recall has been reported in the urology literature.[16-18] Saw et al.[18] performed a prospective study of consent recall among men undergoing transurethral resection of the prostate (TURP). The authors found that patients had been better informed of the benefits of surgery compared to the risks. Patient's recall of TURP complications was poor with 29%, 47.3%, and 61.8% of the patients did not recall of being informed about the risks of bleeding, infection, and urinary retention, respectively. In addition, 18%, and 49% of the patient did not remember of being informed about the complications of retrograde ejaculation and potential erectile dysfunction, respectively.

The time passed since treatment could have also affected recall. The median time elapsed since treatment in this study was 9.3 years. It is possible that many men were extensively and adequately counseled; yet simply do not recall it. We did not find a significant difference in the average time interval since treatment in those that recalled being counseled compared those who did not (8.8 vs 9.9 years, p=0.21). This would suggest that time alone was not the cause of the lower relative recall rate in the radiation group. It is possible that the recall of adverse effects was influenced by patient follow-up patterns. Many patients are seen back frequently after RP and are asked about complications at each visit. Patients may be recalling discussions of adverse effects at one of their many follow-up visits rather than initial consultation, or the repeated discussions at follow-up visits may have reinforced their memory.

We also found that many treatment providers were unaware of the complications that their patients were experiencing. The rate was much higher in the radiation group (73.3%), compared to the RP group (24.2%). One potential explanation may be that patients with urinary complaints might be more likely to seek consultation with a urologist rather than returning to their radiation oncologists. If this is true, radiation oncologists may underestimate the rate of treatment related side effects and thus be less likely to disclose them at the time of initial counseling. Shakespeare et al.[19] reported on the variability of risk estimation between radiation oncologists. A group of Australian radiation oncologists were asked to estimate risks of RT complications in 49 clinical scenarios. They found considerable variabilities in risk estimates which correlated with the experience of the radiation oncologist. As part of the study, respondents were asked to estimate the risk of erectile dysfunction following radiotherapy of the prostate in a potent 50, and a potent 70-year old patients. Risk estimates varied by 13 and 17-fold respectively. The authors concluded that the variability in risk estimates may be explained by varying experience of physicians and a lack of published evidence on which to base risk estimates.

This study comes with limitations. First is its retrospective nature. Next, the time elapsed since treatment was approximately 9 years in our patients. Certainly, this extended period since treatment in an elderly patient group could have affected recall across both groups. In addition, the patient's cognitive function and health literacy at the time of treatment is unknown and may have influenced their understanding during preoperative counseling which could have affected recall. Furthermore, the patients included in this study received their initial treatment across many centers. Pretreatment records were available for only 36% of the patients. Therefore, we are limited in ability to comment on how much counseling was truly provided to the patients prior to treatment. Besides, this cohort included only patients experiencing adverse effects of their given treatment which might bias the results. To add, patients were only asked about their recall of the adverse effects they were seeking treatment for and not about other risks they might have been counseled on. In addition, there is likely a selection bias in our cohort related to the clinical practice type. Our reconstructive urologist sees high volumes of patients for SUI and consideration for urinary sphincter device implantation. As illustrated in Table 1, the majority of patients in this study were seen for SUI, with most of these occurring in the surgical group. Other common adverse effects of prostate cancer treatment such as erectile dysfunction was not seen in this practice. However, it is also important to reiterate that this study is about recall and counseling rather than the description of complications. Reporting on complication rates is not the intent of this paper.

In conclusion, patient recall of potential complications of localized prostate cancer treatment is poor. It's unclear if the poor recall is secondary to selective memory loss or inadequate counseling. Regardless, of the reason behind the patients' poor recall, it is clear that many patients are unaware of the potential complications. Treating physicians must ensure that patients are not only informed of risks associated with treatment, but also that they understand those risks before a treatment decision is made.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Mayo Clinic (IRB Approval 16-007206, Approval date: 11/10/2016).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

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