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Implications of prostate cancer treatment in men with inflammatory bowel disease

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Abstract

Objectives—To investigate the influences of inflammatory bowel disease (IBD), a rare but morbid disease with increasing incidence, on prostate cancer management decisions. We examined whether prostate cancer treatment differed for men with IBD, and whether treatment choice was associated with risk of IBD flare.

Methods—Using Veterans Health Administration cancer registry and administrative data, we identified 52,311 men diagnosed with prostate cancer from 2005 through 2008. We used ICD–9 codes, pharmacy and utilization data to identify IBD diagnoses, IBD-directed therapy, and flares (glucocorticoid escalation, hospitalization, surgical intervention). We compared characteristics across men with and without IBD, and used multivariable regression to examine IBD flares after treatment according to treatment type.

Results—Two hundred and forty men (0.5%) had IBD prior to prostate cancer diagnosis. Compared to non-IBD patients, IBD patients were more likely Caucasian ($p<0.001$) with lower risk cancer ($p=0.02$). Surgery was more common in IBD patients (41% vs 28%, $p<0.001$). In the year following prostate cancer treatment 18% of IBD patients experienced flares. After adjustment, the only predictor of flare in the year after treatment was flare in the year prior to treatment (adjusted odds ratio, 12.5, 95% confidence interval, 5.4–29.2).

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Conclusions—IBD patients were more likely to have lower risk disease and be treated with surgery. Choice of prostate cancer treatment did not predict flares in the subsequent year. Better understanding the intersection of IBD and prostate cancer can help inform treatment decisions for the increasing number of men managing both diseases.

Keywords

inflammatory bowel disease; prostatic neoplasms; symptom flare; surgery; radiation

INTRODUCTION

Inflammatory bowel disease (IBD) is a morbid, idiopathic disease of the intestinal mucosa. While somewhat rare with an estimated prevalence of 0.5% in the United States, IBD is increasing in incidence and frequently associated with the need for long-term immunosuppressive therapy, and even surgical management of bowel complications.¹⁻⁵ Consequently, IBD is an increasingly relevant comorbidity regarding the medical and surgical management of pelvic cancers.

Prostate cancer is one common condition whose anatomical location and treatment modalities require careful consideration in men with IBD. Most commonly, prostate cancer is managed through surgical removal of the prostate gland or localized radiation.⁶ However, given the possibility of pre-existing inflammation in the pelvis as well as immunosuppressive regimens for many patients, both radiation oncologists and urological surgeons may perceive these patients as being at high risk for complications. Outside of small single-institution studies examining radiation therapy outcomes in IBD patients with prostate cancer, how best to manage these men and how treatment impacts IBD symptom flares remains unclear.^{7,8} Better understanding prostate cancer treatment implications for men with IBD would benefit patient and provider decision-making.

For these reasons, we characterized initial prostate cancer treatment patterns in a large cohort of men with and without IBD. We compared the incidence of IBD flares in the year following radiation and surgical treatment, and explored how IBD symptom control was modulated by prostate cancer treatment choice. We hypothesized that primary treatment would favor surgery for patients with IBD, an increasingly relevant issue given the transition from traditional open extraperitoneal to robotic-assisted intraperitoneal radical prostatectomy. Through this study, we provide a better understanding of treatment patterns for men with both prostate cancer and IBD, as well as how prostate cancer treatments interact with underlying IBD to impact outcomes.

MATERIALS AND METHODS

Study population

We used the Veterans Administration (VA) Central Cancer Registry to identify men diagnosed with pathologically confirmed, incident prostate cancer between the years 2005 and 2008. We linked these records with administrative files to obtain clinical data as previously described.⁹ We excluded records for patients who were enrolled in hospice within

30 days of diagnosis, died within 6 months of diagnosis, were diagnosed at autopsy, or had metastatic cancer from a non-prostate primary site. This resulted in a cohort of 52,311 men with localized prostate cancer.

Characterization of inflammatory bowel disease

We considered several treatment-related implications of bowel inflammation among prostate cancer patients. First, even in otherwise healthy patients radiation can induce bowel inflammation. This effect becomes particularly worrisome when considered in a background of prior and possibly ongoing inflammation. Second, inflammation may make surgery more difficult as it obliterates natural planes and degrades tissue. Further, patients on immunosuppressive medications may be at elevated risk of postsurgical problems involving infection or wound healing. Last, while chronic immunosuppression is an important and often necessary part of the management of moderate to severe IBD, this carries the risk of increasing rates of extra-intestinal malignancy and possibly cancer recurrence.¹⁰

Within our cohort described above, we used a validated approach with ICD-9 codes as well as pharmacy and utilization data to obtain information regarding IBD diagnosis, IBD-directed medical and surgical therapy at baseline, as well as any IBD flares in the year prior to treatment.^{11,12} Briefly, patients were identified if they had at least two IBD-specific ICD-9 codes (Crohn's disease 555.x, ulcerative colitis 556.x) across multiple clinical encounters including at least one outpatient encounter.¹³ Data were extracted on medication use, imaging, and GI specialty care. We categorized patients as having IBD (yes/no) and also recorded IBD subtype (Crohn disease vs ulcerative colitis). Medication use was assessed by comparing use of 5-aminosalicylates (5-ASA), glucocorticoids, immunomodulators (e.g. azathioprine, 6-mercaptopurine, and methotrexate), and biological therapies (tumor necrosis factor alpha inhibitors) during the year prior to prostate cancer treatment.

Outcomes

Our primary outcomes for this study were differences in prostate cancer treatment patterns among IBD patients, and the effects of these treatments on IBD flares in the year following prostate cancer treatment. We defined IBD flares as the need for any of the following based on administrative claims data: glucocorticoid therapy escalation, hospitalization related to IBD morbidity, or the need for surgical intervention for IBD. We also identified IBD flares in the year prior to prostate cancer treatment and included this as a covariate in our analysis. Secondary outcomes included use of IBD-directed therapy during the year prior to prostate cancer treatment across IBD flare categories, tumor characteristics, and differences in staging and risk group.

Statistical Analysis

We used descriptive statistics to assess differences in patient demographics, severity of prostate cancer, and prostate cancer treatment patterns among men with and without IBD, as well as between subtypes of IBD. Demographic variables included: age at prostate cancer diagnosis, race (white, black, other/unknown), ethnicity (Hispanic, non-hispanic, unknown), marital status (married, divorced, single/never married, widowed, unknown), and employment status (full-time, part-time, retired, self-employed, unemployed, active military,

unknown). Prostate cancer was assessed with the following variables: pretreatment prostate-specific antigen (≤ 10 , 10-20, >20 ng/mL), Gleason score (6, 7, 8-10), T-stage (T1, T2, T3), and D'Amico risk group (low, intermediate, high). We assessed comorbidity using the Charlson comorbidity index (0, 1, 2+).^{14,15} Prostate cancer treatment group was determined using the summary treatment variable from the VA Central Cancer Registry, which reflects definitive treatment for localized prostate cancer, and included the following groups: surgery, radiation, or hormone therapy/observation. In examining prostate cancer treatment patterns we excluded patients who received both surgery and radiation, or whose treatments were unknown or other (9,001 patients in the non-IBD group and 35 in the IBD group).

Next, we examined rates and types of IBD therapy in the year prior to prostate cancer treatment. We determined our outcome of any IBD flare during the first year according to prostate cancer treatment group. We used multivariable logistic regression to assess the effects of prostate cancer treatment type on IBD flare, and selected the following variables for inclusion in the model *a priori* based on the univariate comparisons and clinical judgment: IBD flare in the year prior to treatment, D'Amico risk score, and prostate cancer treatment type. To focus our analysis on the effects of radiation therapy, we simplified prostate cancer treatment to a binary variable reflecting whether or not a patient received any radiation therapy.

All analyses were performed in SAS, version 9.4 (SAS Institute, Cary, NC). Statistical significance was evaluated using an $\alpha = 0.05$. This study was approved by the VA Ann Arbor Healthcare System Institutional Review Board.

RESULTS

Within this cohort of 52,311 men with incident prostate cancer, we identified 240 men with IBD (0.5%), similar to the general population. As shown in Table 1, patients with IBD were more likely to be Caucasian and married, but age at prostate cancer diagnosis and employment status did not differ. Patients with IBD were more likely to be diagnosed with lower Gleason score and be in the lower risk group compared to non-IBD patients, though tumor stage and comorbidity measures did not differ. As illustrated in the Figure, compared to non-IBD patients, IBD patients were significantly more likely to undergo surgery than radiation (40% vs. 27%, $p < 0.001$ for overall comparison). Rates of ADT/observation were similar between groups. Comparisons between subtypes of IBD did not reveal any significant differences (data not shown).

We found the use of IBD therapy prior to prostate cancer treatment did not differ significantly between treatment types (Table 2). In the year prior to treatment, 40% of IBD patients were taking 5-ASA medications, 17% glucocorticoids, 10% immunomodulators, 52% no therapy, and none took biologic medications. In the year after prostate cancer treatment 18% of IBD patients experienced a flare. The most common flare type was glucocorticoid escalation, followed by hospitalization and need for surgical intervention. Flare rates were higher in patients receiving radiation therapy (23%) than in those receiving surgery (13%) or ADT or observation (19%), however these differences did not achieve statistical significance ($p = 0.28$). There were also no significant differences in flares in the

year prior to prostate cancer treatment across treatment groups. Distributions between IBD subtypes were similar (data not shown).

In our multivariable model examining IBD flares in the year following initial prostate cancer treatment, we found that radiation therapy was not a significant predictor of IBD flare (adjusted odds ratio, (aOR) 1.5, 95% confidence interval (CI), 0.6 – 3.6, Table 3). The only variable associated with IBD flare in the year after prostate cancer treatment was having experienced a flare in the year prior to treatment (aOR, 12.5, 95% CI, 5.4 – 29.2).

COMMENT

We found that patients with a history of IBD and newly diagnosed prostate cancer were more commonly diagnosed with lower risk disease and that following diagnosis there were significant differences in prostate cancer treatment patterns, with IBD patients undergoing surgical intervention at a higher rate than their non-IBD counterparts. These differences may reflect hesitation on the part of practitioners to utilize radiation in this group of patients perceived to be at higher risk of post-radiotherapy complications. We also found that when adjusted for patient and disease characteristics, prostate cancer treatment type did not significantly influence the risk of IBD flare in the year following treatment. While IBD appears to impact the diagnosis and treatment of prostate cancer, these management differences may not alter ultimate IBD symptom control among these men. Given our study findings, poor IBD control in the year prior to treatment is likely the most powerful indicator of future exacerbations, not prostate cancer treatment type.

The differences in prostate cancer disease characteristics appear unrelated to IBD pathophysiology and instead most likely reflect health care utilization in this integrated delivery system patient cohort. If IBD does exert effects on the development, progression, and aggressiveness of prostate cancer, it was not reflected in our data. It should be noted that the differences in prostate cancer treatment selection may be confounded by variables beyond IBD such as race, shown to be associated with prostate cancer treatment type and which did differ between the IBD and non-IBD groups in our study population.¹⁶ However, using multivariable sensitivity analysis, race was not a significant predictor and our results were essentially unchanged. Some literature has suggested a role for chronic prostate inflammation in the development of prostate cancer, though systemic inflammatory diseases may not manifest similar effects.¹⁷ Population-based data have been conflicting regarding the effect of IBD on prostate cancer risk.^{10,18,19} Emerging literature suggests that IBD treatments may modulate prostate cancer. A recent study found that IBD patients treated with 5-aminosalicylate medications were at significantly lower risk for development of prostate cancer than those who did not receive these medications.²⁰ Conversely, other data suggests that IBD-directed therapy at the time of prostate cancer treatment may confer increased risk of subsequent complications.⁷ The relationship between prostate cancer and IBD may be bidirectional, as ADT use in prostate cancer was found to be associated with lower risk of IBD.²¹ In tandem with existing literature, our work shows that the interplay of comorbid IBD and prostate cancer and their treatments is complex and requires further exploration.

Our findings regarding the lack prostate cancer treatment effects on flares are somewhat surprising given existing single-institution literature indicates IBD patients to be at higher risk of post-radiation complications.^{22,23} While the results of published studies tend to show that external beam radiation is a risk factor for complications in patients with IBD, there have been mixed results with regard to prostate brachytherapy which was uncommon in our study.^{8,24-26} In addition, our study focused on IBD flares, rather than complications more generally, to address this aspect of prostate cancer decision-making and did not show differences across treatment type. Instead, the severity of IBD at prostate cancer treatment seemed to drive flares after treatment. Whether the intraperitoneal robotic-assisted laparoscopic prostatectomy that largely replaced the open extraperitoneal approach examined in our study creates other complication risks for men with IBD also warrants further study.

This work, representing the largest cohort of comorbid IBD and prostate cancer reported, has important clinical implications and builds upon previously published data. The use of radiation in these patients is low, however from an IBD control standpoint this may be less of a concern than previously suspected. Instead, the most important consideration for predicting subsequent IBD severity appears to be past patterns of IBD activity rather than prostate cancer management choice. Thus while providers carefully select among these patients those who they deem good candidates for radiation therapy, these data should help to reduce anxiety about subsequent IBD symptom control. Continued caution appears warranted however as these patients may remain at elevated risk of other treatment-related complications.

There are some important limitations to our work. First, in spite of being the largest cohort study of men with prostate cancer and IBD to date, IBD is sufficiently rare that we had very few cases to allow for robust subgroup analysis and there were few IBD flares during the study period. However, our cohort prevalence rate of IBD is similar to the broader population rate of 0.5%.³ Our results are consistent with the rarity of these events in the community and a study this large nonetheless represents a significant addition to the existing literature on this topic. Our unique, multi-disciplinary focus on the clinically-relevant outcome of IBD flares provides insight into the real-world impact of prostate cancer treatment on IBD control. This focus allows for a nuanced understanding of the effects of treatment on IBD pathophysiology. Additionally, while we did not detect any differences during the post treatment period, we utilized a time horizon of one year which may not capture the late effects of treatment on IBD control. Nonetheless, these short-term outcomes do not appear to be impacted. Last, our study is limited by its retrospective nature rather than a prospective or randomized approach, however multi-variable statistical adjustment strengthens our results.

In spite of these limitations, this study helps to build our understanding of prostate cancer treatment patterns for men with IBD, as well as the effects of these treatments on IBD control. Coordinated, multidisciplinary approaches are crucial to optimize outcomes in this group of patients, and these findings can help inform providers across fields providing high quality, specialized care to patients suffering from IBD and prostate cancer. A better sense of practice patterns across the country may help urologists and radiation oncologists understand

how their own approaches compare to their peers, while insights into the effects of these treatments on flares and symptom control should assist gastroenterologists in planning and medical decision making during the peri- and post-treatment periods. Currently there is little evidence to guide gastroenterologists in planning the management of IBD therapy around cancer treatment. Typically, biologic and immunomodulatory treatments are withheld for at least the first year following cancer treatment and frequently up to five years out of concern for negative impacts on cancer-related outcomes, though existing data do not necessarily suggest higher rates of recurrence.²⁷ Further study assessing the particular risks of IBD-directed therapy in both the pre-and post-treatment cancer stages should help further tailor recommendations for these patients.

CONCLUSIONS

In summary, we found that men suffering from IBD who are diagnosed with prostate cancer tend to be diagnosed with less aggressive disease, treated surgically, and that the success of IBD symptom control following treatment is mainly dictated by pre-treatment IBD severity. One of the most interesting and emerging topics in this area is the effect of IBD medications on prostate cancer outcomes, and continued research in this arena may yield additional insights into the pathophysiological relationship of these diseases. These patients are a unique, highly-selected group necessitating further study to elucidate best practices and minimize IBD symptoms and complications while maximizing cancer control and shared decision-making.

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Abbreviation key

IBD	inflammatory bowel disease
PSA	prostate-specific antigen
ADT	androgen deprivation therapy
ASA	aminosalicylate

Figure 1. Distribution of primary prostate cancer treatment among patients with and without IBD

Among patients with IBD we found most were treated with surgery, with a lower percentage receiving either radiation or ADT/Observation. These numbers differed significantly in patients without IBD, who were more likely to receive radiation and less likely to receive surgery, while rates of ADT/Observation were similar between groups.

Table 1

Demographic characteristics of men with prostate cancer across IBD status.

Demographics	No IBD (n=52,071)	IBD (n=240)	p-value
Age at Diagnosis, y (Mean)	66	66	0.9
Race (%)			<.0001
White	70	86	
Black	26	10	
Other/Unknown	4	4	
Ethnicity (%)			0.14
Hispanic	5	2	
Non-Hispanic	94	97	
Unknown	1	1	
Marital Status (%)			0.04
Married	52	61	
Divorced/Separated	29	21	
Single/Never Married	8	9	
Widowed or Unknown	11	9	
Employment Status (%)			0.13
Full-Time	10	9	
Self-Employed or Part Time	7	11	
Retired	48	49	
Unemployed	34	30	
Active Military or Unknown	1	1	
Pretreatment PSA, ng/mL (%)			0.13
≤10	72	78	
10-20	15	13	
>20	13	9	
Gleason Score (%)			<0.01
6	46	54	
7	37	36	
8-10	17	10	
T-stage (%)			0.10
T1	80	86	
T2	4	3	
T3	16	11	
D'Amico Risk Group (%)			0.02
Low	34	41	
Intermediate	33	34	
High	33	25	
Comorbidity (Charlson Index, %)			0.55

Demographics	No IBD (n=52,071)	IBD (n=240)	p-value
0	45	44	
1	26	29	
2+	29	27	

Table 2

IBD medication use and flares in the year prior to and following treatment compared across prostate cancer treatment groups.

IBD characteristics	Surgery ^{**} (n=85)	Radiation (n=56)	ADT/Observation (n=64)	p-value
IBD medication within 1 year prior to treatment (%) [*]				
None	58	57	45	0.27
5-ASA	38	32	48	0.17
Glucocorticoid	13	20	19	0.49
Immunomodulators	15	7	8	0.21
Any flare in year prior to treatment (%)	13	21	19	0.39
Hospitalization for IBD	5	4	3	0.88
Need for Glucocorticoid Escalation	13	20	19	0.49
Surgical Intervention for IBD	0	0	0	-
Any flare in year following treatment (%)	13	23	19	0.28
Hospitalization for IBD	2	5	3	0.62
Need for Glucocorticoid Escalation	5	23	17	0.20
Surgical Intervention for IBD	1	2	0	0.59

^{*} Percentages do not add to 100% as categories are not mutually exclusive.

^{**} 1 patient treated with robotic-assisted radical prostatectomy, all others open radical prostatectomy

Table 3

Multivariable logistic regression model of IBD flare predictors in one year following prostate cancer treatment.

Covariate	Adjusted Odds Ratio	95% Confidence Interval	p-value
Flare in year prior to prostate cancer treatment	12.5	5.4 – 29.2	< 0.001
D'Amico risk score	0.9	0.5 – 1.5	0.71
Radiation therapy	1.5	0.6 – 3.6	0.37