REPORTS OF PRACTICAL ONCOLOGY AND RADIOTHERAPY 22 (2017) 77–82

Available online at www.sciencedirect.com

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journal homepage: http://www.elsevier.com/locate/rpor

Original research article

Long term clinical toxicity of radiation therapy in prostate cancer patients with Inflammatory Bowel Disease

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ARTICLE INFO

Article history:
Received 15 February 2016
Received in revised form
5 August 2016
Accepted 21 October 2016

Keywords:
Inflammatory Bowel Disease, IBD
Radiation proctitis
Radiation induced bowel toxicity

ABSTRACT

Aim: The study's aim was to examine the clinical impact of radiation therapy (RT) on GI toxicity in Inflammatory Bowel Disease (IBD) patients.
Background: IBD has long been considered a risk factor for increased bowel toxicity from RT; however, minimal evidence exists on patients with prostate cancer (PC) and IBD.
Materials and methods: The tumor registry was queried for patients with IBD and PC from the years 1990–2013. A retrospective review was conducted for patients who received RT. Radiation treatment and toxicity data were collected.
Results: Average length of follow-up was 12 years (median 9.54, range 0.42–19.9). The majority had well controlled baseline bowel function on medical management. Prior to radiation, 60% of patients (9/15) and 40% (6/15) reported grade 0 (G0) and grade (G1) diarrhea at baseline, respectively. No baseline proctitis existed. Following radiation treatment, 78% (14/18) of patients experienced G0 diarrhea while 22% (4/18) reported G1 diarrhea. No patients suffered from greater than G1 diarrhea. Sixty-six percent (12/18), 17% (3/18) and 17% (3/18) of patients experienced G0, G1, and G2 proctitis, respectively. No patients suffered post-radiation stricture formation, and all patients with G2 proctitis received 3dCRT.
Conclusions: Limited published data is available exploring RT for patients with PC and IBD. This analysis offers valuable insight into appropriate counseling for a rare patient subset. Radiation improved late G1 diarrhea rates. Grade 2 proctitis was only encountered in 3dCRT patients. No post-radiation complications occurred. Our findings suggest that IBD patients experience minimal toxicity in the era of IMRT based RT.
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1. Background

Inflammatory Bowel Disease (IBD) is a chronic inflammatory process of the gastrointestinal (GI) tract which currently affects approximately 1.3 million patients in the United States.[1] The disease is associated with reduction in quality of life and other comorbidities, such as increased risk of secondary malignancies.[2] Medical management can decrease flare rates of the disease; however, complete remission is

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http://dx.doi.org/10.1016/j.rpor.2016.10.005
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uncommon.[3,4] As a result, IBD is considered a chronic disease that patients must live with for the duration of their lives. Due to population aging, more patients are carrying a diagnosis of IBD prior to the initiation of cancer treatment.[5,6]

IBD patients generally suffer from worsened baseline bowel functioning, and there has been considerable concern over the acute and late effects cancer treatment can pose to this subset.[7] Particularly, this has been a topic of debate concerning the effects of radiation therapies on these patients.[8,9] Previously published retrospective reviews have demonstrated mixed results, with some studies reporting increased toxicity rates for radiation therapy and others finding little to no change compared to non-IBD patients.[8–13] Due to the severity of toxicity when it did occur, these studies have generally recommended avoidance of radiation. These analyses are limited, however, by small total patient numbers and high heterogeneity of patients in terms of sites and types of cancer grouped into a single analysis.

Prostate cancer is paramount when considering acute and late GI effects of radiation. No other cancer site utilizes the high absolute total doses (>75 Gy) that have been standardized in prostate cancer. Dose escalation has also been proven to yield a higher biochemical control rate.[14,15] Clinical responses for low and intermediate risk disease appear equivalent for primary surgical management versus radiation therapy. Therefore, both are appropriate treatment regimens.[16,17] Historically, fear of increased GI toxicity secondary to close proximity of the rectum and prostate dictated treatment modality. Patients with IBD were more likely to be referred for surgery than for definitive radiation therapy.[8–10] Thus, treatment options were limited for IBD patients presenting with concomitant prostate cancer. Unfortunately, partly due to the paucity of the two diseases occurring together, these management decisions have been based upon assumptions rather than published evidence. To date, there is limited data available for prostate cancer patients with IBD who were treated with definitive radiation therapy other than several reviews of patients treated with low-dose rate (LDR) brachytherapy and one retrospective review of 16 patients treated with external beam.[11,12,15,16]

2. Aim

The aim of our study is to elucidate the clinical impact of radiation therapy on GI toxicity in Inflammatory Bowel Disease patients.

3. Material and methods

Institutional review board approval was obtained prior to conducting a retrospective patient review and the study was conducted in accordance with the ethical standards of the committee on human experimentation. The tumor registry was queried for individuals who held the International Statistical Classification of Diseases, 9th Revision (ICD9) codes for both IBD and prostate cancer between January 1990 and December 2013. Only patients who were diagnosed with non-metastatic prostate cancer and concomitant IBD were included in the study. In addition, patients treated first with surgery and then salvage radiation therapy for biochemical recurrence were also excluded. Patients were also excluded if they were currently having an active flare of IBD. Only patients in remission or currently on medical maintenance therapy for IBD were included in the analysis. Radiation treatment data collected in the present study includes: Intensity Modulated Radiation (IMRT), 3d Conformal Radiation Therapy (3dCRT), brachytherapy, radiation doses, doses received by the rectum/small bowel, and inclusion of the lymphatic system. Pathologic characteristics of the tumor, including clinical stage, pre-treatment prostate specific antigen, and Gleason score, were also examined.

Baseline characteristics for bowel function were recorded. As show in Table 1, Common Terminology Criteria for Adverse Events version 4 (CTCAE v4) scoring criteria were used to code proctitis/diarrhea baseline, acute and late effects.[17] Acute and late effects were defined as within 3 months of treatment and more than 3 month after treatment, respectively. Follow-up was measured from the date radiation was received to the date of last contact. IBD diagnosis and treatment specifics were also noted, including suppressive medication regimen and active vs. dormant disease.

4. Results

4.1. *Patients*

Initial query of the tumor registry revealed that 166 patients carried the diagnosis of IBD and prostate cancer. All 166 charts were reviewed, with only 18 patients meeting the inclusion criteria for IBD diagnoses and prostate cancer treated with radiation therapy. In patients who underwent surgery, the primary reason cited for offering surgery instead of radiation was the concomitant diagnosis of IBD and fear of increased complication rates with radiation. Average length of follow-up for patients meeting inclusion criteria was 12.0 years (median 9.5, range 0.42–19.9). Of these patients, sixteen patients carried the diagnosis of ulcerative colitis, and 2 held the diagnosis of Crohn's disease. Demographic and other patient characteristics may be viewed in Table 2.

4.2. *Baseline bowel functioning*

For the majority of patients, baseline bowel function was well-controlled with medical management prior to treatment. Twenty-two percent were in remission from IBD without receiving any form of treatment. Fifty-six percent of patients were actively taking 5-ASA; 17% were prescribed prednisone; and 5% were taking Remicade. Three patients had no baseline bowel function data available in the chart. Of patients with available pre-treatment bowel function data, sixty percent of patients (9/15) reported grade 0 (G0) diarrhea at baseline prior to radiation therapy. Forty percent of patients (6/15) suffered grade 1(G1) diarrhea at baseline. No baseline proctitis was present. Two patients had ostomy placed prior to the diagnosis of prostate cancer.

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