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Basic Original Report

To prep or not to prep - that is the question: A randomized trial on the use of antiflatulent medication as part of bowel preparation for patients having image guided external beam radiation therapy to the prostate

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Abstract

Introduction: Radiation therapy is a standard treatment option for prostate cancer. With growing use of escalated doses and tighter margins, procedures to limit rectal size variation are needed to reduce prostate motion, increase treatment accuracy, and minimize rectal toxicity. This prospective study was done to determine whether the introduction of an antiflatulent medication would decrease rectal distention at computed tomography (CT) simulation and throughout a course of radiation therapy.

Results were presented at the Canadian Association of Radiation Oncology 2015 Annual Scientific Meeting in Kelowna, Canada and the 12th Annual RTi3 Conference in Toronto, Canada.

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Methods and materials: Patients undergoing a radical course of radiation therapy to the prostate/prostate bed were eligible to participate. Participants were randomly assigned to the intervention arm (antiflatulent medication) or the control arm (no medication). For each participant, the number of CT simulation rescans was recorded. Rectal diameters were measured on CT simulation and treatment cone beam CT scans. Acute rectal toxicities were assessed at baseline and weekly using National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.0. A χ^2 analysis was used to compare the number of participants requiring a rescan in each study arm. Change in rectal diameter over time was assessed using repeated measures analysis of variance.

Results: A total of 78 patients participated, with equal numbers assigned to each study arm. There was no significant difference between arms in the number of participants requiring a CT simulation rescan ($P = .5551$). There was no significant variation in rectal diameter between arms ($P = .8999$); however, there was a significant effect of time ($P = .0017$) and a significant interaction effect between study arm and time on rectal diameter ($P = .0141$). No acute rectal toxicities above grade 2 were reported.

Conclusions: The addition of antiflatulent medication did not affect the frequency of CT simulation rescans. Both time and the interaction between study arm and time had a statistically significant effect on rectal diameter, although neither finding was clinically significant. Instead, standardized bowel preparation education developed for this study may have been sufficient to limit rectal size variation.

Introduction

In Canada, prostate cancer is the most common cancer occurring in men, with approximately 24,000 new cases diagnosed each year.[1] Depending on stage at diagnosis, treatment may include surgery, radiation therapy, and/or hormonal therapy. For early-stage disease, radical conformal radiation therapy to the prostate has been established as an accepted treatment option, with excellent long-term results.[2] Most recently, several published randomized clinical trials have proven the efficacy and improved outcomes of delivering escalated radiation therapy doses.[3-5]

The prostate gland sits directly anterior to the rectum in the pelvis, making rectal toxicity a primary limiting factor to dose escalation.[6] In addition, it has been well established that the prostate moves under the influence of the rectum.[7-14] Varying rectal dimensions caused by feces or gas can substantially displace the prostate during radiation therapy treatment. If the prostate is displaced during treatment delivery, a geographical miss can occur.[15] Furthermore, studies have reported rectal distention during CT simulation can significantly reduce local control.[16,17] For the prostate to be effectively and safely treated with escalated doses, rectal motion must be limited.

There have been multiple studies attempting to reduce variations in rectal size. External fixation using a rectal balloon was proven to be inefficient in reducing prostate motion resulting from the incidence of gas and stool adjacent to the balloon[18]; however, daily enemas have been found to limit variation in rectal filling and decrease the risk of geographic miss.[6,19] Two different reports found a bowel preparation including milk of magnesia paired with an antiflatulent diet had no effect on intrafraction prostate motion or interfraction variation in rectal filling.[20,21] In contrast, Smitsmans et al used a dietary protocol with a daily laxative and observed a significant decrease in feces and moving gas on cone beam computed tomography (CT) scans.[22] Similarly, Ki et al found variations in rectal volume were reduced in patients taking probiotic capsules.[23] To date, no consensus has been reached as to which regime, if any, is most effective.

Current standards of practice dictate that patients receiving external beam radiation therapy to the prostate should have a full bladder and empty rectum at the time of CT simulation and treatment. At our institution, patients undergo CT simulation 2 weeks before image guided radiation therapy using daily cone beam CT (CBCT). If CT simulation or any pretreatment CBCT scan shows there is excess stool or gas displacing the prostate, the patient will be asked to empty the stool/gas and a rescan will be performed. Excess stool/gas is defined as a rectal diameter of greater than 4 cm as measured on the CT simulation scan, or a rectal volume on CBCT that is observed to be much larger than what was present at the time of CT simulation. An institutional audit was completed over a 3-month period in 2010 when a total of 138 patients were simulated for conformal radiation therapy to the prostate. Of these, 43 patients (31%) required at least 1 CT simulation rescan.

Rescans can have significant costs that are largely borne by the patient. Anecdotally, patients express feelings of anxiety, frustration, and embarrassment when they are told a rescan is necessary because of large rectal size. Additionally, the extra time that rescans require is often not accounted for in the daily schedule of a CT simulator or treatment machine. This may result in unexpected delays that affect the treatment of other patients. Overall, rescans can adversely affect the quality of the patient experience during radiation treatment.

Unfortunately, there is no quick and easy remedy for rectal distension, particularly if caused by a bolus of gas sitting at or above the level of the prostate where it is difficult to release. Although this specific problem has not been well studied, some investigators have reported the use of an antiflatulent