Executive Summary

“Evaluation of new Bowel and Bladder Preparation Guidelines for Radical Prostate and Prostate Bed patients receiving Radiation Therapy: A Pilot study at Peel Region Cancer Center (PRCC)”

Investigators
Mina Yaver MRT (T), BSc. (1)
Ann Foo MRT (T), BSc. (1)
Tessa Larsen MRT (T), BSc. (1)
Heather Fineberg MRT (T) BMRSc. (1)
Grace Zeng PhD, FCCPM. (2, 5)
Dr. Thomas McGowan MD, MBA, FRCPC (3, 5)

Consultant/Co-investigator
Dr. Glenn Jones BSc., MD, FRCPC, MSc. (5, 6, 7, 8, 9)

Affiliations
(1) Dept. of Radiation Therapy – Trillium Health Partners – Credit Valley Hospital Site
(2) Dept. of Medical Physics – Trillium Health Partners – Credit Valley Hospital Site
(3) The Cancer Centre Bahamas, the Cancer Center Eastern Caribbean
(4) Dept. of Radiation Oncology – Trillium Health Partners – Credit Valley Hospital Site
(5) Dept. of Radiation Oncology – University of Toronto
(6) University of the West Indies Medical School, School of Clinical Medicine and Research, Nassau
(7) The Partners Clinical Research Center (Bahamas and Antigua)
(8) The Medical Consulting Services Division of the CSB5 Management Company Ltd.
(9) Cancer Center Network, the Cancer Center Eastern Caribbean

Funding:
Canadian Association of Medical Radiation Technologists
Telus’ Ride for Dad – The Prostate Cancer Fight Foundation

Running Header
Summary and project completion report
Bowel and bladder prep
According to 2015 Canadian Cancer Society statistics, approximately 24,000 men are diagnosed with prostate cancer annually in Canada with half receiving curative radiotherapy. The anatomical location of the prostate organ and its proximity to rectum, bladder and small bowel renders delivery of high therapeutic doses to the prostate organ challenging. Literature has shown that the geometry of surrounding organs such as rectum and bladder can affect both tumor control as well as the incidence of treatment related toxicities. Previous studies have investigated the impact of various bowel and bladder preparation methods. However, an informal survey of cancer centers in Ontario demonstrated a lack of consensus in utilization of the most effective preparation guidelines. Furthermore an in-house patient focus group with previously treated prostate patients showed the undesirable impact of preparation instructions on daily patient routine and quality of life.

The Genit-o-urinary disease site team at Mississauga Halton/Central West Regional Cancer Program undertook this study to formulate a patient-centric method of achieving the most desirable and least invasive organ preparation regimen. The new guidelines are designed to reflect the current advanced practice of radiation therapy where treatment is delivered through Volumetric Modulated Arc Therapy and daily localization of the prostate organ is done prior to treatment delivery. The authors recognize that the most effective preparation regimen would provide optimum organ geometry at the time of the planning session but also facilitate patient compliance thus ensuring consistent organ status daily throughout the course of treatment which can extend up to 39 sessions.

This two phase prospective longitudinal study aims to investigate the effect of the two regimens on the consistency of surrounding organ geometry, patient satisfaction and daily operations. A total of 88 patients (41 phase 1 with the existing guidelines, 44 phase two patients with the new guidelines) were consented for this study. Phase one patients were asked to follow the existing departmental guidelines which entailed maintaining an empty rectal status through the use of enema the morning of the planning session and daily use of Milk of Magnesium thereafter during daily treatment appointments. Patients were also asked to drink 500 ml of water 1 hour prior to appointments to ensure maximum displacement of small bowel from the high dose region. Phase 2 patients underwent pre-screening in order to schedule patients’ planning and treatment appointments according to their natural bowel habits consistently within 3 hours of their most regular bowel movement. Phase 2 patients followed the same bladder preparation instruction as phase 1, additionally, clinicians were asked to ensure a minimum displacement of the bowel from the prostate on the initial planning scan, a practice not used previously. In phase 2 patients were asked to hydrate (drink 2 L of water over a period of 24 hours prior to planning session and to continue to do so during daily treatments). Patient planning and pre-treatment mini-CT scans (CBCT) on days 1-3 and weekly thereafter were used to evaluate the impact of both preps on organ geometry. Treatment toxicity information was collected using documented clinician assessments and patient reported outcomes tool, The Expanded Prostate Cancer Index Composite (EPIC) bowel and bladder domains, pre-treatment and on a weekly basis.

**Findings:**
The initial phase of data analysis focused on organ geometry. Patient CBCT scans were exported and rectum, bladder, gas and prostate were outlined on day 1, 2, 3 and weekly CBCTs. A total of 1,335 structures were outlined.
This initial data analysis showed that
Rectal volume consistency can be achieved through a less invasive preparation regimen as no statistical difference in rectal volume was found between the two groups. Therefore we recommend a patient-centred approach that offers patients a choice between using medical interventions such as enema and Milk of Magnesium or bowel status-based appointment times, thus engaging the patient in their care and improving overall patient experience.

The incremental decline in bladder volume can be reduced through the means of introduction of daily patient hydration and better scanning guidelines. As patients progress through the treatment, bladder volume can decrease due to the treatment related side effects. This incremental reduction was noted to be less in phase 2 patients.

Elimination of the use of Milk of Magnesium and enema does not impact target coverage since no significant difference was noted in prostate target coverage between the two groups.

**Future steps:**
Data analysis is still in progress for this study. The next step involves an analysis and comparison of treatment toxicities between the two patient populations.

**Project completion Report:**
Patient acquisition and data collection started Feb 1st, 2013 and ended July 7, 2014. Funds provided through CAMRT were used to fund a temporary clinical radiation therapist position to replace the investigators thus allowing some time to contour rectum, bladder, prostate and gas on the CBCT scans. The provided grant provided 132 hours of coverage.

**Research dissemination activities**
As mentioned above the authors of this study are currently in the process of analyzing the remainder of the data and will be submitting for publications in the near future. Previous publication activities include

- 2014 RTi3 Conference
  - Investigating variations in rectal size on CT planning data set and CBCT for patients undergoing radiation therapy to their prostate/prostate bed during the first thirteen days of treatment.

- Manuscript submission to Journal of Medical Imaging and Radiation Sciences, special "Back to Basics" edition of the Journal of Medical Imaging and Radiation Sciences. publication date; December, 2015
  - Consistency of Organ Geometries During Prostate Radiotherapy with Two Bladder and Bowel Regimens
- Departmental meeting and in-services