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Original research article

Compliance with bladder protocol during concurrent chemoradiation for cancer of the cervix and its impact on enteritis: A prospective observational study



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ABSTRACT

Aim: This prospective study aims to assess the compliance with bladder protocol and the correlation with enteritis during pelvic radiation.

Background: Bladder protocol is routinely used for patients undergoing pelvic radiation to reduce radiation enteritis. It is very difficult to maintain constant volume especially in the last two weeks due to radiation enteritis and cystitis.

Materials and methods: Histologically proven 35 cervical cancer patients treated with concurrent chemoradiation in a tertiary care center were the subjects of this prospective study. Following CT simulation and after every fraction, patients were asked to void urine in a calibrated urine container and the volume was documented. Patients were assessed for the highest grade of radiation enteritis weekly as per common toxicity criteria. The mean voided urine volume was correlated with the radiation enteritis.

Results: The mean urine volume at planning CT scan was 295.85 ± 300 ml (SD) with a range of 75–650. At the end of treatment, it was reduced to 233.14 ± 250 ml (range 50–400 ml), a reduction by 21% ($p < 0.001$). The maximum grade of enteritis was grade I (11%), II (11.4%), III (3–29%) in week 1,2 and 3–5, respectively with a p value of < 0.001 . A mean urine volume of 230 ml was associated with grade III enteritis in the third week.

Conclusions: Urine output volume measured using a calibrated container is a simple, efficient and practical method to monitor bladder distension thereby reducing enteritis in cervical cancer patients treated with concurrent chemoradiation.

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1. Background

The standard treatment for carcinoma cervix from Stage IB2 onwards is concurrent chemo radiation as per National Cancer Institute (NCI) Alert 1999.¹ Radiation therapy along with chemotherapy leads to various acute toxicities, the important ones being radiation enteritis and haematological toxicities. Kirwana et al. observed a twofold increase in acute GI toxicity with concurrent cisplatin administration.² There are various methods to minimise irradiated small bowel volume, like treatment in a prone position, using a belly board and with distended bladder, amongst others. Tae hyun kim et al. have studied the effect of distended bladder and observed that the irradiated small bowel volume was reduced from 82 to 48% for patients undergoing preoperative radiotherapy for rectal cancer.³

Pinkawa et al. conducted a prospective study on prostate cancer correlated bladder volume with questionnaire based assessment of enteritis. A larger initial bladder volume reduced enteritis from 22% to 5% on the last day of radiation.⁴

L.M. Mullaney et al. showed a supine position with distended bladder tends to push the small bowel out of the radiation field and hence can lead to decreased small bowel toxicity.⁵ According to the protocol, 30 min prior to simulation CT scan as well as daily during radiation treatment, the patient will be instructed to evacuate the bladder followed by consumption of 500 ml of water. Our observation is that with progress of the treatment, patients may have acute cystitis and enteritis, it may be difficult to maintain the same bladder distension and hence compliance with the bladder protocol is difficult.

With cumulative radiation doses, enteritis increases and is maximum in the last two weeks of radiation. Due to enteritis associated dehydration, it is very difficult to maintain the same bladder volume for radiation. The decrease in bladder volume will in turn increase the amount of bowel in the irradiated area, which may further increase enteritis. Jee et al. observed a reduction in the median bladder volume by 38% at 6 weeks of radiation therapy which was statistically significant among patients with rectal cancer undergoing concurrent chemoradiation.⁶

Many authors have looked at the compliance with the bladder protocol mostly for cancers of the prostate and rectum. There are different methods to assess the bladder volume, such as ultrasound Ahmad,⁷ Stam et al.⁸ and CT scan Pinkawa et al.⁴, Haiqin et al.⁹ Doing these on all days of radiation is cumbersome and financially not feasible. A simple method to measure the urine volume is to collect the urine in a calibrated container immediately after every fraction and document the reading. Hence, this study was designed with an aim to correlate the measured value with the degree of radiation enteritis.

2. Materials and methods

This prospective observational study was conducted on 35 histopathologically proven cases of carcinoma cervix treated with concurrent chemo radiotherapy from May 2014 to April 2015. Based on Ahmad et al. in a study conducted on

interfraction bladder filling variations, it was found that the mean bladder volume reduced by 71% at week 3. With a power of 90% and significance level of 95%, the minimum sample size required for the present study was estimated to be 35. Patients with postoperative cervical cancer, uterine prolapse and bladder pathology, such as hypotonic bladder and incontinence, were excluded from the study.

Patients were instructed to evacuate the bladder followed by consumption of 500 ml of water. After 30 min, contrast enhanced CT of the abdomen and pelvis scan was done with 5 mm cuts (from L1 vertebra to mid-thigh) with 80 ml of iodinated intravenous contrast. Following the scan, the patient was asked to void urine in a calibrated urine container and the volume was documented.

External Beam Radiation Therapy was delivered with 3D conformal technique to a dose of 45 Gy in 25 fractions (Fr), 5 fractions per week over 5 weeks along with weekly cisplatin 40 mg/m² for 4–5 courses. After each fraction, voided urine was measured and documented. Variations in volume of urine (hereafter also referred to as bladder volume) were measured. Patients were assessed once weekly for the highest grade of radiation enteritis weekly as per common toxicity criteria (CTC version 4.0) and documented.

The mean bladder volume per week was calculated which was correlated with the highest grade of radiation enteritis for that week.

3. Statistical analysis

Descriptive statistical analysis was carried out in the present study. Results of continuous measurements are presented on Mean \pm SD (Min–Max) and results of categorical measurements are presented in number (%). Significance is assessed at a 5% level of significance. Spearman's correlation was used to find the correlation between the amounts of urine output with the grade of enteritis. Fischer exact test was used to find the significance in difference of proportion between different grades of enteritis with respect to week. Repeated measures of anova was used to compare the measurement of urine output from the baseline to the last day of treatment and for the week wise comparison of urine output.

4. Results

The patient characteristics of this prospective observational study are as shown in Table 1. All patients received the

Table 1 – Patient characteristics.

	Range (24–62 years)	No: 35 (%)
Age	20–30	1 (2.85)
Mean: 47 years	31–40	10 (28.57)
	41–50	13 (37.14)
	51–60	8 (22.85)
	61–70	3 (8.57)
Stage (FIGO)	II A	20 (57.14)
	II B	13 (37.14)
	III B	2 (5.71)

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