ABSTRACT

High dose rate (HDR) brachytherapy is an established treatment modality in the treatment of carcinoma of the uterine cervix.

Dose reduction to critical structures such as bladder and rectum will enhance the therapeutic ratio. Many methods are adopted for reducing the rectal and bladder doses. Wet gauze packing is the commonly adopted procedure for immobilizing the applicators and increasing the distance between bladder and rectum thereby reducing the dose to these organs.

The present study is concerned with the design of a new device to reduce rectal and bladder doses. The device can be used as a substitute for gauze packing. The insertion time of applicator can also be reduced.

The study was divided into the following sections

1. The variation of rectal and bladder doses a) between fractions b) when dwell position of first plan is used for the remaining fractions
2. The inter-observer variation in planning using films obtained with gauze packing.
3. Design and development of a latex balloon
4. Evaluation of the balloon in patients
5. Geometrical variation of the applicator within and between fractions
6. Inter-observer variation in planning using films obtained with balloon
1a. It was found that there existed a significant variation in rectal dose ($F=4.811$, $p=0.032$) while bladder dose variation between fractions was not significant ($F=0.032$, $p=0.858$).

b. The study also tried to see the variation of rectal and bladder doses, obtained when the dwell positions of the first plan for the first sitting were simulated on the second ($2\text{bldr1}, 2\text{rtm1}$) and vice-versa ($1\text{bldr2}, 1\text{rtm2}$). These rectal and bladder dose values were compared with the actual rectal and bladder doses of the second ($2\text{B}, 2\text{R}$) and first ($1\text{B}, 1\text{R}$) fractions. No significant differences were found between them.

2. A significant difference was observed on rectal ($F=3.407$, $p=0.01$) and bladder ($F=3.284$, $p=0.013$) doses obtained by different observers.

3. To avoid the differences in packing between fractions, a reproducible device that serves the purpose of packing would be helpful. In the present work, an independently expandable, latex based, rectal and bladder balloon was designed and tested. Water mixed with a contrast medium is pushed into the bladder and rectal parts. This expands the balloon and increases the rectal and bladder distance from the applicator thus reducing the dose to these critical organs.

4. The balloons were used in 102 sittings (45 patients) and the rectal and bladder doses were calculated as per ICRU-38 guidelines. The rectal and bladder doses obtained for the first sitting using the balloon inflated from 20cc (standard volume) to the maximum volume tolerated by the patient (commonly 30cc) were analyzed and showed a significant reduction in rectal doses ($F=3.54$, $p<0.008$) with an average reduction of dose from 78.1% to 62%. Paired t-test done on the bladder doses showed that the reduction was not significant but the average dose was found to reduce from 81.3% to 74.8%. The same trend was observed in second and third sittings also.
A study on the reproducibility of rectal and bladder doses obtained using balloon was done. Patients who completed their first and second fractions (N=35) and all the three fractions (N=21) were considered. The rectal and bladder doses obtained from first and second sittings were compared and no significant difference was found in both rectal (F=0.003, p=0.960) and bladder (F=0.058, p=0.81) doses. The rectal (F=0.624, p=0.539) and bladder doses (F=0.002, p=0.998) obtained from all the three fractions were also compared and no significant variation was seen.

The rectal and bladder doses of 43 patients who had undergone treatment using gauze packing were noted from their records and compared with that of a similar number of patients with balloon. A reduction of 17.9% in rectal dose was obtained using the balloon compared to gauze packing. A significant reduction in bladder dose was also noticed and use of balloon could reduce it by 17%.

5. Geometrical variation studies of applicator within and between fractions was studied. This did not show any significant variation in the parameter studied.

6. Inter-observer variation in the dose of rectum and bladder was also carried out for patients treated with balloon. On analysis of the planned data for 30 patients it was found that there was no significant variation either for bladder (F=0.9, p=0.444) or for rectum (F=2.483, p=0.064).

**Key Words**

Brachytherapy, High Dose Rate, Remote Afterloaders, Uterine cervix, Applicators, Intrauterine tube, ovoids, MicroSelectron HDR, Treatment Planning System, simulator, orthogonal films, rectum, bladder, gauze packing, former/ mould, latex, one-way valves, inflatable balloon, balloon spacer, geometrical variation, interobserver variation, quality assurance, reproducibility, ICRU 38, point A, point B, Manchester system