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## Title

Treatment and prognosis of patients with late rectal bleeding after intensity-modulated radiation therapy for prostate cancer

## Abstract

[Background] Radiation proctitis after intensity-modulated radiation therapy (IMRT) differs from that seen after pelvic irradiation in that this adverse event is a result of high-dose radiation to a very small area in the rectum. We evaluated the results of treatment for hemorrhagic proctitis after IMRT for prostate cancer. [Methods] Between November 2004 and February 2010, 403 patients with prostate cancer were treated with IMRT at 2 institutions. Among these patients, 64 patients who developed late rectal bleeding were evaluated. Forty patients had received IMRT using a linear accelerator and 24 by tomotherapy. Their median age was 72 years. Each patient was assessed clinically and/or endoscopically. Depending on the severity, steroid suppositories or enemas were administered up to twice daily and Argon plasma coagulation (APC) was performed up to 3 times. Response to treatment was evaluated using the Rectal Bleeding Score (RBS), which is the sum of Frequency Score (graded from 1 to 3 by frequency of bleeding) and Amount Score (graded from 1 to 3 by amount of bleeding). Stoppage of bleeding over 3 months was scored as RBS 1. [Results] The median follow-up period for treatment of rectal bleeding was 35 months (range, 12–69 months). Grade of bleeding was 1 in 31 patients, 2 in 26, and 3 in 7. Nineteen of 45 patients (42%) observed without treatment showed improvement and bleeding stopped in 17 (38%), although mean RBS did not change significantly. Eighteen of 29 patients (62%) treated with steroid suppositories or enemas showed improvement (mean RBS, from  $4.1 \pm 1.0$  to  $3.0 \pm 1.8$ ,  $p = 0.003$ ) and bleeding stopped in 9 (31%). One patient treated with steroid enema 0.5-2 times a day for 12 months developed septic shock and died of multiple organ failure. All 12 patients treated with APC showed improvement (mean RBS,  $4.7 \pm 1.2$  to  $2.3 \pm 1.4$ ,  $p < 0.001$ ) and bleeding stopped in 5 (42%). [Conclusions] After adequate periods of observation, steroid suppositories/enemas are expected to be effective. However, short duration of administration with appropriate dosage should be appropriate. Even when patients have no response to pharmacotherapy, APC is effective.