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A randomized placebo-controlled phase I/II trial of famotidine in prostate cancer patients undergoing radiotherapy

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Background & Purpose: Pelvic radiotherapy for prostate cancer causes a series of clinical and hematological toxicities during the radiotherapy course of prostate cancer patients and significantly affects the quality of life as well as treatment efficacy. A variety of novel radioprotectors have been experimentally studied but, hardly any compound has so far led to clinical therapeutic gain. This study was performed to investigate whether famotidine can reduce acute toxicities in prostate cancer patients undergoing radiotherapy.

Patients & Methods: A total of 36 prostate cancer patients were randomized to receive either placebo or famotidine tablets daily before each external beam radiotherapy fraction. Acute clinical and hematological toxicities were evaluated during radiotherapy and once thereafter according to RTOG grading criteria.

Results: Famotidine was well tolerated. Significant differences in clinical endpoints including grade II acute bowel toxicity ($p=0.009$), rectal bleeding ($p=0.046$), and the duration of bowel toxicity ($p=0.027$) in favour of the famotidine group were observed. In addition to clinical toxicities, a significant reduction in radiation-induced lymphopenia was noted in famotidine treated patients ($p=0.006$).

Discussion: This phase I/II randomized controlled trial could have a major role to bridge the gap between experimental and clinical studies using famotidine as a radioprotector to improve the quality of life and treatment efficacy of prostate cancer patients. Compared to known radioprotectors, famotidine benefits from the advantages of being available, inexpensive, and easy route of administration.

Conclusion: We demonstrated for the first time that famotidine is a safe and effective radioprotector for prostate cancer patients undergoing radiotherapy.

Biography

Bahram Mofid, is an Associate Professor of Radiation Oncology at Shahid Beheshti University of Medical Sciences. He obtained his medical degree in 1991 and then completed residency training in Radiation Oncology at Shahid Beheshti University of Medical Sciences. He focused his career on the treatment of prostate cancer patients and his primary research interests include trials and epidemiological studies related to treatment of prostate cancer and improving patient's quality of life. He practices at the Shohada-e-Tajrish Hospital, where he also serves as the chair of Radiation Oncology division as well as the chief of the Hospital.

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