# Lack of radioprotective efficacy of nanocurcumin in prostate cancer patients undergoing radiotherapy

***B. Mofid[1], A. Razzaghdoust[2], A. Sadipour[1], M. Bakhshandeh[1], A. Mahdavi[3], N. Simforoush[2]***

[1]Shohada-e-Tajrish Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[2]Urology and Nephrology Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[3]Shahid Modarres Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran

***Topic: Clinical track/ Prostate***

## *Introduction and Objectives:*

There is a growing body of evidence exploring the role of high-dose curcumin as a radioprotector against radiation-induced toxicities in normal tissues as well as a radiosensitizer in tumor cells [1]. Efficacy of oral curcumin is limited by poor absorption and, thus, its clinical application is hindered [2]. Curcumin nanoformulation is considered as a novel promising approach to overcome low bioavailability of oral curcumin [3]. The aim of this double-blind randomised placebo-controlled trial was to determine the efficacy of oral nanocurcumin in prostate cancer patients undergoing radiotherapy (RT).

## *Methods:*

Between March 2016 and April 2017, 64 prostate cancer patients were randomised to receive either oral nanocurcumin or placebo three days before and during the RT course (120mg/day). The nanocurcumin 40mg or placebo capsules were taken three times daily, so two capsules were administered in the morning and another capsule at bedtime. All patients were stratified by treatment schedule and received either conventional fractionated (70Gy, 2Gy/fraction) or hypofractionated schedule (70.2Gy, 2.7Gy/fraction). All patients received neoadjuvant hormone therapy. An intention to treat approach was used as the analysis strategy. Acute toxicities were assessed weekly during the treatment and once thereafter according to CTCAE grading criteria. The patients are followed to evaluate the treatment response. Pearson's chi-square and fisher's exact test were used to compare the number of patients with acute toxicities in the two groups. The duration of acute toxicities was compared using Mann–Whitney U test. A p value <0.05 (two-sided test) was considered significant.

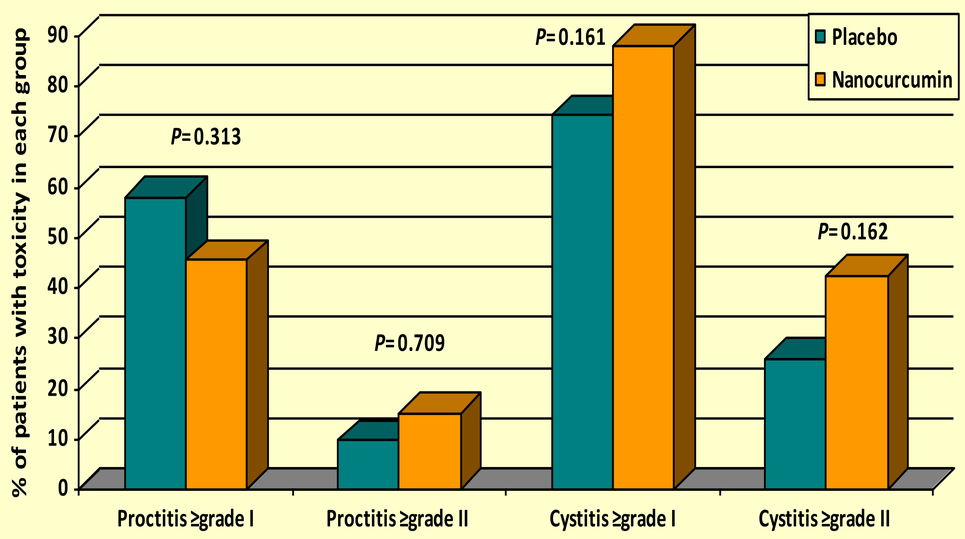


Figure 1. Distribution of clinical toxicities between the two groups

Table 1. Analysis of radiation-induced clinical toxicities

| | Placebo group (n=31) | Nanocurcumin group (n=33) | P value |
|---|---|---|---|
| **Acute toxicity, n (%)** | | | |
| **Proctitis** | 18 (58.1) | 15 (45.5) | 0.313 |
| **Cystitis** | 23 (74.2) | 29 (87.9) | 0.161 |
| **Duration of toxicity, Mean weeks (SD)** | | | |
| **Proctitis** | 1.3 (1.4) | 1.2 (1.5) | 0.651 |
| **Cystitis** | 2.5 (2) | 3.3 (1.6) | 0.309 |

## *Results:*

Nanocurcumin was well tolerated. Differences between the two groups with respect to the bowel and urinary endpoints are illustrated in the Figure and Table above. There was no significant difference between placebo and nanocurcumin group in terms of two major clinical endpoints including proctitis and Cystitis. Furthermore, no significant difference was observed between the two groups in relation to duration of the toxicities. No patient except one in the nanocurcumin group experienced grade 3 or higher acute toxicity during the treatment.

## *Conclusions:*

The present study describes a clinical experience with nanocurcumin and provides insight into future clinical directions. In contrast to encouraging preclinical evidence, we demonstrated that nanocurcumin is not an effective radioprotector for prostate cancer patients undergoing radiotherapy. Therefore, clinical application of nanocurcumin as a promising radioprotector was not confirmed in this setting.

## *References:*

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Bahram Mofid
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