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Are results from intermediate risk prostate cancer patients treated within clinical trials applicable to real life patients?

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Categories: Radiation Oncology
Keywords: prostate, cancer, trial, comorbidity, radiation therapy

How to cite this poster
Liem X, Bahary J, Delouya G, et al. (2015) Are results from intermediate risk prostate cancer patients treated within clinical trials applicable to real life patients? . Cureus 7(9): e.

Abstract

INTRODUCTION: There is some doubt on whether clinical studies (CS) have selective inclusion criteria that might not represent real-life patients (RLP) and may limit their applicability to daily clinical practice. Furthermore, patients in CS and RLP might have different comorbidities which can have an impact on overall survival. We assessed whether patients from CS differ from patients not included in terms of comorbidity, prostate cancer aggressiveness and biochemical recurrence.

PATIENTS AND METHODS: We identified 468 patients with D'Amico intermediate risk prostate cancer from our institutional database all treated with external beam radiotherapy only. 307 patients were treated in a CS, including two, multinational randomized trials (PROFIT and RTOG 0126) each including >80 patients from our center; one in-house phase II with >40 patients and some smaller randomized studies with <13 patients each. These CS patients were compared to 161 patients (RLP) who were not included in any CS. Patients treated with permanent seed brachytherapy were excluded. Patients treated in CS were compared to the RLP using non-parametric tests. Biochemical recurrence rate was estimated using the Kaplan-Meier method and compared using the log-rank test.

RESULTS: Median follow-up was 56 months (inter-quartile range 36-78 months). There was no difference in age (mean 70y for both, p=0.95) or in cancer aggressiveness between both groups: PSA >10 in 28 % of CS patients and in 32 % of RLP (p=0.37). Gleason score 4+3 was found in 29% of CS patients and in 30% of RLP (p=0.58).

There were differences in comorbidity: CS patients had more frequently hypertension (60% CS vs. 46% RLP, p=0.01), and more often hypercholesterolemia (51 % for CS vs. 43 % in RLP, p=0.01). There was no difference in previous myocardial infarction (10% CS vs. 17% RLP p=0.53) or diabetes (18% CS vs. 20 % RLP p=0.71).

Biochemical recurrence free survival was similar between both groups with a 5 year rate of 94 % in both groups (p=0.65).

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Published 09/08/2015

CONCLUSION: In our exploratory analysis, we found that patients treated in CS did not differ from RLP in terms of age, prostate cancer aggressiveness or biochemical outcome. However, there was a trend towards more comorbidity in patients treated within CS, but the impact on overall survival remains unclear. In our institution, conclusion from clinical study can be transferred to daily practice.

65