



Bicalutamide 150 mg as First-Line Monotherapy of Patients with Low and Intermediate Risk Prostatic Cancer

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Abstract

Introduction: Bicalutamide (Casodex) is a competitive androgen receptor antagonist that inactivates androgen-regulated prostate cell growth and function, leading to cell apoptosis and inhibition of prostate cancer growth. In several countries, Bicalutamide 150 mg/day is approved in men with locally advanced non-metastatic prostate cancer as immediate therapy either in adjuvant setting, or as an alternative to surgical or medical castration.

Many patients with prostate cancer for whom hormonal therapy is indicated are physically and sexually active. Quality of life is therefore a critical issue when considering treatment options.

Material and Methods: Seventy-six patients received bicalutamide, 150 mg once daily, as a first-line therapy for low or intermediate risk prostate cancer. The median age of the patients in the study was 73.9 years (range 65-83). 49 pts were low risk (Gleason score 4-9 pts, 5-3 pts, and 6-37 pts.), 26 pts - intermediate risk (Gleason score 7) and 1 patient had metastatic disease.

The average PSA levels at diagnosis was 13.5 ng/ml (range 5.65-45). The average PSA levels at the beginning of the treatment was 11.6 ng/ml (range 0.26-45). The median follow-up was 3.7 years (range 1-5). All pts received prophylactic breast irradiation before the start of treatment.

Results: 90% of patients demonstrated PSA declines of greater than 50%. The average PSA level at end of treatment was 1.02 ng/ml (range 0.01-7.86). The average nadir was 0.9 ng/ml (range 0.01-7.86). The most frequent side effect was mild gynecomastia in 15 (20%) of the pts.

Conclusion: Antiandrogen monotherapy is effective and well tolerated and resulting in significantly lesser loss in sexual interest and a better physical capacity.

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Introduction

Prostate cancer is the most common cancer among men, except for skin cancer. At time of diagnosis, most cases of prostate cancers (93%) are diagnosed when the disease is confined to the prostate and nearby organs. Overall, most men who develop prostate cancer (99%) have a life expectancy of at least five years from the time of diagnosis. Ninety-eight percent (98%) of the patients have a 10 years life expectancy and 94% of them will survive for at least 15 years. However, for men diagnosed with prostate cancer that has spread to other parts of the body, the five-year survival rate drops to 28%. Prostate cancer is the second leading cause of cancer death in men in the United States [1]. In cancer care, multidisciplinary team, to create an overall treatment plan that combines different type of treatments is extremely important. Treatment options and recommendations depend on several factors, including the type and stage of cancer, possible side effects, and the patient's preferences and overall health. The most common treatment options for prostate cancer are: active surveillance for early-stage cancer, surgery, radiation therapy, hormone therapy, chemotherapy, vaccine therapy, and getting care for symptoms and side effects. One of the possible treatment options offered to patients is monotherapy by bicalutamide 150 mg/day. Bicalutamide is a non-steroidal pure anti androgen given at a dosage of 150 mg once daily as monotherapy for the treatment of early (localized or locally advanced) non-metastatic prostate cancer. The efficacy and tolerability of bicalutamide as monotherapy for patients with non-metastatic and metastatic prostate cancer have been evaluated in randomized clinical trials. Combined data from 2 studies revealed no statistically significant difference in overall survival between bicalutamide 150-mg monotherapy and castration in patients with non-metastatic locally advanced disease. In patients with metastatic disease, there was a statistically significant difference (6 weeks) in overall survival in favor of castration [2,3]. In the number of countries, bicalutamide 150 mg/day is approved in men with locally advanced non-metastatic prostate cancer as immediate therapy either as an

adjuvant to active treatment or as monotherapy as an alternative to surgical or medical castration. Bicalutamide monotherapy offers better tolerability and higher Health-Related Quality-Of-Life (HR-QOL) scores for sexual interest and physical capacity compared with surgical or medical castration [4]. In patients with localized or locally advanced prostate cancer, Bicalutamide 150 mg as immediate therapy, alone or as adjuvant to treatment of curative intent significantly reduced the risk of disease progression and the risk for PSA doubling [5]. In patients with metastatic prostate cancer Bicalutamide 150 mg as a monotherapy is less effective than castration regarding the time to treatment failure, time to disease progression and time to death [6].

Material and Methods

Seventy-six patients with low or intermediate risk prostate cancer received Bicalutamide 150 mg once daily, as first-line therapy. The median age was 73.9 years (range 65-83). 49 patients were categorized as low risk (Gleason score 4-9 patients, Gleason score 5-3 patients, and Gleason score 6-37 patients). 26 patients were categorized as intermediate risk (Gleason score of 7). One patient had metastatic disease at the time of diagnosis.

The average PSA level at time of diagnosis was 13.5 ng/ml (range 5.65-45). The average PSA levels at the time the first line of treatment was administered was 11.6 ng/ml (range 0.26-45). The median follow-up was 3.7 years (range 1-5). All patients received prophylactic breast irradiation before treatment with Bicalutamide was administered. Prophylactic breast irradiation was performed by single field electron beam- 800cGy single dose was given.

Results

90% (68) of the patients demonstrated PSA declines of greater than 50%. The average PSA level at end of treatment was 1.02 ng/ml (range 0.01 to 7.86). The average nadir was 0.9 ng/ml (range 0.01 to 7.86). The most frequent side effect was mild gynecomastia in 15 (20%) of patients. The most common reasons for changing of treatment were elevation of PSA level or desire of the patient.

Discussion

Prostate cancer is the most widespread type of cancer in men. Treatment options for prostate cancer are varied- from active surveillance, surgery, radiotherapy, hormonal therapies, chemotherapy, radio nuclide therapy and their combinations. When treatment options are being offered to a patient, ones must take the efficiency and the side effects of the offered treatment into consideration.

Loss of sexual function and incontinence has a major effect on the patient's quality of life. The number of patients diagnosed at younger age with early stages of the disease is rising. Many treatment options are available to those patients and we must choose the most efficient line of treatment while attempting to reduce side effects to minimum. Treatment options should be discussed with the patients in the setup of a multidisciplinary team of oncologists, urologists and radio therapists.

Monotherapy with Bicalutamide 150 mg is one of the treatment options that have been proven to be effective and have a well tolerable side effect profile. At the beginning of the treatment in prostate cancer patients, when trying to avoid a more aggressive line of treatment- monotherapy with Bicalutamide 150 mg may be an appropriate treatment option that will not prejudice the patient health and allows the patients to maintain a good quality of live.

This study describes our clinical experience with treatment with Bicalutamide 150 mg. The patients in our study were not randomized- all patients with low and intermediated risk prostate cancer was enrolled to this study. In daily practice, it is often observed that the efficacy demonstrated in randomized trials is better than in daily practice, when selection of patients isn't made. Therefore, data collected from non-randomized patients is relevant and necessary.

The impact of localized prostate cancer in the elderly depends on disease aggressiveness and life expectancy. In men with localized prostate cancer, those with low-risk disease or a shorter life expectancy should be managed expectantly, whereas those with long life expectancy or more aggressive disease may benefit from curative treatment. Comorbidity and quality-of-life concerns are key considerations during the selection of therapeutic modalities in the elderly in localized and metastatic settings [7].

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