JOJ
Urology & Nephrology
ISSN: 2476-0552

Juniper Publishers
key to the Researchers

Opinion
Volume 3 Issue 5 – July 2017
DOI: 10.19080/JOJUN.2017.03.555624

JOJ uro & nephron

Early Hormonal Therapy Options for Biochemical Recurrence after Radical prostatectomy

Anwar Alesawi*

Department of Urology, DSFH, JEDDAH, Saudi Arabia

Submission: June 21, 2017; **Published:** July 27, 2017

***Corresponding author:** Anwar Alesawi, Consultant Urologist, Uro-oncologist, MIS & Robotic Urologist DSFH, JEDDAH, Saudi Arabia, Telephone: +966505683509; Email: esawi_anwar@yahoo.com

Keywords: Bicalutamide; Prostate cancer; Biochemical recurrence;, Metastasis

Abbreviations: PCa: Prostate Cancer; PSA: Prostate-Specific-Antigen; LHRH: Luteinizing Hormone-Releasing Hormone; PFS: Progression Free Survival; LHRH-A: Luteinizing Hormone-Releasing Hormone Agonist; RP: Radical Prostatectomy

Introduction

Standard care for men with localized prostate cancer (PCa) includes radical prostatectomy, radiotherapy or active surveillance [1]. Prostate-specific-antigen (PSA)-only relapse (biochemical recurrence) after initial local therapy of prostate cancer is a common phenomenon. Furthermore, the majority of patients with biochemical failure are otherwise healthy and need to preserve their quality of life.

Local therapies such as salvage surgery for post-radiation failure, prostate bed radiation for post-surgery recurrence, cryotherapy or brachytherapy are mainly reserved for men with organ-confined disease. Hormonal therapy is frequently given for the management of PSA-only relapses with suspicion of nodal or distant metastasis. Typical approaches include orchiectomy or luteinizing hormone-releasing hormone (LHRH) agonist treatment, (LHRH) antagonist therapy or combined hormonal treatments. However, those therapies are associated with serious side effects [2-4]. Castration based therapy is associated with decreased libido and sexual function, fatigue, loss of bone mineral density and muscle mass, and altered cognitive function [5-9].

In randomized trials, the non steroidal anti-androgen bicalutamide (150mg) showed a lower risk of side effects than castration in terms of maintenance of sexual interest, physical ability and bone mineral density [8-11]. Bicalutamide 150mg therefore offers a hormonal therapy option not based on castration for patients wishing to maintain their sexual and physical activity levels.

There were several studies that described the use of bicalutamide as a treatment option for different stages of prostate cancer. Some of these studies described bicalutamide as a neo-adjuvant to standard care [12], while others used bicalutamide as a monotherapy for localized or locally advanced prostate cancer [10,13].

The Casodex early prostate cancer trialist group investigated casodex as monotherapy or adjuvant to standard care in a prospective double-blind, placebo-controlled trials and concluded that bicalutamide 150mg as adjuvant to standard care, improved progression free survival (PFS) in patients with locally advanced prostate cancer [14].

Bicalutamide was also evaluated as salvage therapy in nonmetastatic castration-resistant prostate cancer, where it was found to induce a second response in almost half of the cohort, with a duration of response more than 1.5 years and a prolonged metastasis-free survival [15].

Several studies described bicalutamide as monotherapy or combined with luteinizing hormone-releasing hormone agonist (LHRH-A) in advanced prostate cancer [16-20].

One study has evaluated bicalutamide 150mg as salvage treatment of biochemical recurrence after radiotherapy with neo-adjuvant hormonal therapy for localized and locally advanced prostate cancer. This study recruited only 20 patients who received bicalutamide for 24 weeks, additional courses of bicalutamide were given to three patients who responded well to the initial course while the others received total androgen

deprivation [21], this is a small cohort with short-term results with the primary definitive treatment being radiotherapy with neo-adjuvant hormonal therapy.

We use bicalutamide as a salvage monotherapy after RP in asymptomatic hormone-naïve patients who present with biochemical recurrence for a certain time, and trying to evaluated the efficacy of bicalutamide 150mg plus tamoxifen 20mg once daily in controlling biochemical recurrence and the duration of prostate-specific antigen (PSA) response after biochemical recurrence after radical prostatectomy (RP) in cases of rapidly rising PSA (i.e. those who had biochemical recurrence within the first six months after RP or fast PSA doubling time suggestive of systemic failure) or those who were not interested in or candidates of salvage radiotherapy. Hopefully we can release our results soon, otherwise, we will need a well designed, controlled (compared to LHRHa for example) prospectively approached to advice with or against the use of bicalutamide as a salvage therapy of biochemical recurrence after RP in all patients.

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How to cite this article: A Alesawi. Early Hormonal Therapy Options for Biochemical Recurrence after Radical prostatectomy. JOJ uro & nephron. 2017; 3(5): 555624. DOI: 10.19080/JOJUN.2017.03.555624.

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