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EDITORIAL

Is there still a place for docetaxel rechallenge in prostate cancer?

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Abstract

Three-weekly docetaxel plus prednisone is the standard first-line cytotoxic treatment for patients with metastatic castrate-resistant prostate cancer (mCRPC). Today, several new treatment options are available for patients with tumor progression after first-line docetaxel: Abiraterone, enzalutamide, cabazitaxel, sipuleucel-T immunotherapy, and the radionuclide radium-223. However, despite the evolving scenario in CRPC treatment, the optimal sequencing of the innovative therapies remains unclear. The reintroduction of docetaxel at the occurrence of disease progression after a drug holiday (docetaxel rechallenge) was often proposed, and this chemotherapeutic agent showed to maintain antitumor activity in mCRPC patients. Docetaxel rechallenge may still constitute a valid treatment option mainly for patients with favorable response to first-line docetaxel, at least > 3 mo progression-free interval, age less than 75 years, good performance status, and acceptable docetaxel toxicity. The risk of cumulative toxicity must be evaluated, since sensory neuropathy, nail disorders and fatigue might occur on docetaxel rechallenge.

Key words: Abiraterone acetate; Docetaxel; Prostate cancer; Prostate-specific antigen; Rechallenge

Core tip: New treatment options are currently available for metastatic castrate-resistant prostate cancer (mCRPC) patients after first-line chemotherapy with docetaxel. The actual role of docetaxel rechallenge in the evolving scenario of mCRPC treatment is discussed in this editorial.

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INTRODUCTION

From 2004, three-weekly docetaxel plus prednisone is the standard first-line cytotoxic treatment for patients with metastatic castrate-resistant prostate cancer (mCRPC)[1,2]. In TAX 327 trial, which compared 3-weekly docetaxel plus prednisone *vs* mitoxantrone plus prednisone, 45% of patients receiving docetaxel and prednisone achieved ⩾ 50% prostatic-specific antigen (PSA) reduction, and the median duration of PSA response was 7.7 mo. The patients received a maximum of 8-10 docetaxel cycles, and more that one third of them discontinued chemotherapy without evidence of disease progression. At 4-year follow-up, 3-weekly docetaxel plus prednisone maintained a statistically significant advantage in overall survival (OS) compared to mitoxantrone plus prednisone (19.2 mo *vs* 16.3 mo, $P = 0.004$)[3].

The reintroduction of docetaxel at the occurrence of disease progression after a drug holiday was often proposed in mCRPC patients, and the drug showed to maintain antitumor activity[4-6]. The truly docetaxel rechallenge consists in the reintroduction of the drug in patients responding to first-line docetaxel who discontinued chemotherapy without evidence of disease progression. Although significant advantages in terms of OS were not demonstrated, all studies reported > 25% PSA response on docetaxel rechallenge in patients achieving an initial good response to first-line treatment with the same drug[4-7].

SUGGESTED ELIGIBILITY CRITERIA FOR DOCETAXEL RECHALLENGE

Docetaxel has been the first drug to report a survival benefit for mCRPC patients. Although these men are usually elderly and with concomitant comorbidities, some of them still have an acceptable performance status and might be proposed for another treatment after docetaxel failure. Today several new treatment options are available for patients with tumor progression after first-line docetaxel: abiraterone, enzalutamide, cabazitaxel, sipuleucel-T immunotherapy, and the radionuclide radium-223[8-12].

Abiraterone acetate, a selective irreversible inhibitor of cytochrome P-450c17, prolonged OS in chemotherapy-naïve or docetaxel-pretreated patients[8,13]. Enzalutamide, a novel androgen receptor signaling inhibitor, significantly prolonged OS and improved quality of life compared to placebo in men with post-docetaxel CRPC[9]. Enzalutamide was recently approved also in pre-docetaxel patients[14].

Cabazitaxel, a second-generation taxane, achieved a statistically significant improvement in OS when added to prednisone *vs* mitoxantrone plus prednisone in mCRPC patients[10]. Sipuleucel-T, an active cellular immunotherapy, prolonged OS among asymptomatic mCRPC patients[11], and Radium-223, which has high bone affinity, improved OS and time to first skeletal-related event[12]. Despite the availability of these new agents in mCRPC patients, their optimal sequencing remains unclear[15].

The possibility of a docetaxel rechallenge has been largely limited by the introduction of abiraterone, enzalutamide and cabazitaxel in the treatment of CRPC patients. Neverthless, it must be considered that the reintroduction of docetaxel can reduce the possibility to administer to the patients one of the new available treatment options. However, a docetaxel rechallenge therapy may be a cheaper option considering the budget impact on health plans of new anticancer agents[16]. Furthermore, the situation is actually complicated by recent trials which might led to early prescription of docetaxel in combination with androgen-deprivation therapy, or for the new indications of abiraterone and enzalutamide in pre-docetaxel patients[13,14,17]. In this setting, some clinical reports suggested a cross-resistance when first-line chemotherapy with docetaxel was administered after the new hormonal agent abiraterone, while there were very few experiences about docetaxel rechallenge after failure to abiraterone or other agents[18-20].

The results of the ongoing randomized phase Ⅱ study CANTATA (EudraCT 2012-003835-40) comparing cabazitaxel with docetaxel rechallenge will add useful informations about the role of docetaxel rechallenge in the mCRPC new agents-era.

Docetaxel rechallenge may still have a role in mCRPC, but a carefull selection of patients has to be performed. Most studies reported that ⩾ 50% PSA response to first-line docetaxel was the main predictive factor for the favorable outcome on the reintroduction of the same drug. A progression free-interval (PFI) of > 6 mo after first-line docetaxel was associated with high fequency of good PSA responses and symptomatic responses on docetaxel rechallenge in a large retrospective study, and encouraging 20.4 mo median OS was reported[21]. Another study described a longer median PFS (6.3 mo *vs* 3.4 mo) and median OS (19.4 mo *vs* 12.8 mo) with docetaxel rechallenge in mCRPC patients progressing at > 3 mo after the last docetaxel cycle with respect to those progressing within 3 mo[22]. In a study of 46 patients with CRPC rechallenged with docetaxel, the PSA response was 66%, and the median OS was 32 mo. In this study a docetaxel rechallenge was safely repeated sveral times, and the good responders had a median PFI of 6 mo[7].

On the other hand, it was reported that PFI < 3 mo was associated with no benefit from docetaxel rechallenge, probably because of early development of complex mechanisms of resistance to the drug[23].

Available findings indicate that docetaxel rechallenge might still constitute a valid treatment option, and some eligibility criteria may be suggested: good response to first-line docetaxel, at least > 3 mo PFI, age less than 75 years, and acceptable docetaxel toxicity (Table

Table 1 Main eligibility criteria for docetaxel rechallenge in metastatic castrate-resistant prostate cancer patients

PFI > 3-6 mo
> 50% PSA response to first-line docetaxel
No cumulative docetaxel-toxicity
Age < 75 yr
ECOG PS 0-1

PFI: Progression free-interval; PSA: Prostatic-specific antigen.

1). On the other hand, very elderly patients and/or men with worsened performance status could benefit from less aggressive treatment options. Furthermore, since the chemotherapy agent cabazitaxel shows low incidence of severe sensory neuropathy, this drug may be a valid treatment choice for patients who exhibit unacceptable toxicity to docetaxel[10].

Another intriguing treatment strategy, especially for patients with PFI 3-6 mo, might be to combine docetaxel rechallenge with another agent which might help to overcome the resistance to docetaxel. Among chemotherapeutic agents which were investigated, epirubicin resulted feasible and tolerable when combined with docetaxel on a weekly schedule[24]. A randomized phase Ⅱ study suggested an advantage in PSA response, PFS, and OS for the combination of docetaxel and epirubicin compared with docetaxel alone in advanced CRPC patients[25]. In a recent clinical study, our research team reported encouraging results with rechallenge of docetaxel combined with weekly epirubicin in 26 men with advanced CRPC following progression on docetaxel and abiraterone acetate, with PSA response in 26.9% of patients, 4.4 mo PFS, and 10.7 median OS[26]. Among the subjects who were symptomatic at baseline, pain was reduced in 9 patients (38.1%) with a significant decrease in analgesic use. The weekly epirubicin/doxorubicin treatment was well tolerated: grade 3 neutropenia occurred in 19.2% of patients, and no grade 4 toxicity or congestive heart failure was observed.

These encouraging results may also suggest that abiraterone treatment after docetaxel failure does not reduce the efficacy of a delayed docetaxel rechallenge. Larger studies should be performed to investigate if epirubicin or other agents may play a role in restoring the sensitivity and reversing the resistance to docetaxel in patients who were previously poor-responders to the same drug.

Despite the addition of a drug to docetaxel rechallenge might led to overcome the resistance to docetaxel, the risk of eventual increase in the occurrence of adverse events must be considered, too[27-29]. Moreover, sensory neuropathy, nail disorders and fatigue might occur on docetaxel rechallenge[6,7,21].

Though the feasibility and activity of docetaxel rechallenge in mCRPC patients have been demonstrated in several studies before the new agents-era, very few data are available about the reintroduction of the drug in heavily pretreated subjects. It might hypothesized that in mCRPC patients with PFI 3-6 mo a delayed rechallenge by intercalation of a non-docetaxel treatment might be effective, with possible restoring of sensitivity to the drug. In this setting, in other tumors such as relapsed ovarian cancer, the PFI prolongation by intercalation by an effective non-platinum regimen resulted in survival advantage with subsequent platinum-based regimens[30,31].

Another interesting point is that docetaxel rechallenge on weekly schedule might be offered, especially for mCRPC patients with some degree of toxicity during 3-weekly docetaxel. Neverthless, a few small experiences suggested that weekly docetaxel schedule might be effective in patients not-responding to first-line 3-weekly docetaxel[7,32]. In conclusion, as we all await additional studies to clarify the optimal sequencing of the new available agents in mCRPC, docetaxel rechallenge may have still a role for well selected patients.

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