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CED-CCO Special Advice Report 23

The Use of Cabazitaxel in Men with Castrate Resistant Metastatic Prostate Cancer Previously Treated with Docetaxel

S. Hotte, A. Haynes, N. Fleshner, and A. Loblaw

Report Date: October 25, 2011

This CED-CCO Special Advice Report consists of a Summary and a Full Report and is available on the CCO website (http://www.cancercare.on.ca)
PEBC CED-CCO page at:
http://www.cancercare.on.ca/toolbox/qualityguidelines/other-reports/evaldrug-rep/

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Report Citation (Vancouver Style): Hotte S, Haynes A, Fleshner N, Loblaw A. The use of cabazitaxel in men with castrate resistant metastatic prostate cancer previously treated with docetaxel. Toronto (ON): Cancer Care Ontario; 2011 Oct 25. Program in Evidence-based Care CED-CCO Special Advice Report No.: 23.

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SUMMARY

QUESTION

Does the use of cabazitaxel, either alone or in combination, for the treatment of patients with castrate resistant metastatic prostate cancer who were previously treated with a docetaxel-containing regimen result in improved outcomes?

Outcomes of interest include overall survival, progression-free survival, time-to-progression, time-to-next treatment, time-to-treatment failure, objective and prostatic-specific antigen (PSA) response rates, pain response rate, palliation, quality of life, and adverse events.

TARGET POPULATION

Adult patients with castrate resistant metastatic prostate cancer who have been previously treated with a docetaxel-containing regimen.

RECOMMENDATIONS

The following recommendations reflect the opinions of the authors of this special advice report.

- Cabazitaxel is recommended to improve survival in patients with metastatic castrate-resistant prostate cancer (CRPC) who have progressed following therapy with a docetaxel-containing regimen. Patients should be counselled on the risk of adverse events, especially hematological adverse events.

- Patient preferences need to be taken into account when considering ANY further therapy in patients with metastatic CRPC who progress following therapy with a docetaxel-containing regimen. Clinicians should discuss with these patients the goals of treatment, including what is most important to them. Increased survival, symptom

relief, and the risk of adverse events associated with each treatment option are important considerations that should be discussed with each patient.

QUALIFYING STATEMENTS

- The evidence regarding the most appropriate patient to receive cabazitaxel is incomplete. However, based on the available evidence and expert opinion, cabazitaxel may be most appropriate for patients who have progressed on or within six to 12 months after completing docetaxel. In patients who have a very prolonged benefit from first-line docetaxel, retreatment with the same agent may be appropriate, but all decisions should be at the discretion of the treating oncologist.

- The evidence regarding the optimal regimen is incomplete. However, based on the available evidence and expert opinion, the regimen from the TROPIC trial (10 cycles or less of cabazitaxel 25 mg/m^2 intravenously (i.v.) over one hour every three weeks plus 10 mg of oral prednisone daily) may be most appropriate for most patients prescribed cabazitaxel. In singular instances—where patients continue to benefit from cabazitaxel with minimal toxicity—more than 10 cycles could be given, at the discretion of the treating physician and the patient.

- According to established guidelines, prophylactic granulocyte-colony stimulating factor (G-CSF) should not be routinely given in patients receiving cabazitaxel and dose reductions should be considered in patients who are felt to be at high risk from febrile neutropenia complications. Use of G-CSF in subsequent cycles should occur according to these same guidelines.

KEY EVIDENCE

One randomized controlled trial was identified that investigated the use of cabazitaxel in men with castrate resistant metastatic prostate cancer (1). Patients were randomized to receive either cabazitaxel and prednisone (n=378) or mitoxantrone and prednisone (n=377). The authors reported a significant difference in overall survival in favour of cabazitaxel compared to mitoxantrone (median, 15.1 months versus [vs.] 12.7 months; hazard ratio [HR] 0.70, p<0.0001). Although the authors did not report whether statistical comparisons were made on the rates of adverse events between the treatment arms, more patients in the cabazitaxel arm experienced hematological adverse events and diarrhea, both of any grade or grade 3/4, than the mitoxantrone arm (see Full Report, Table 4).

RELATED PROGRAM IN EVIDENCE-BASED CARE GUIDELINES

- Evidence-based Series (EBS) 3-15: Non-Hormonal Systemic Therapy in Men with Metastatic Hormone-Refractory Prostate Cancer.
  Available at:
  https://www.cancercare.on.ca/toolbox/qualityguidelines/diseasesite/genito-ebs/.

Funding

The PEBC is a provincial initiative of Cancer Care Ontario supported by the Ontario Ministry of Health and Long-Term Care through Cancer Care Ontario. All work produced by the PEBC is editorially independent from its funding source.

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REFERENCES—SUMMARY

1. de Bono JS, Oudard S, Ozguroglu M, Hansen S, Machiels J-P, Kocak I, et al. Prednisone plus cabazitaxel or mitoxantrone for metastatic castration-resistant prostate cancer progressing after docetaxel treatment: a randomised open-label trial. Lancet. 2010 Oct 2;376(9747):1147-54.