

OCCA Objectives

- Influence regulators (*e.g.*, FDA & EMA) to require companies to optimize doses of drugs
- Publicize evidence where drugs are used at higher than their optimal doses. **Examples:**
 - Ratain et al: Interventional pharmacoeconomics: a new discipline for a cost-constrained environment. *JAMA Oncol* 2019;5: 1097-8.
 - Tannock et al: Near equivalence: Generating evidence to support alternative cost-effective treatments. *J Clin Oncol* 2021;39:950-5.
 - Patel et al: Improving access to immunotherapy in low- and middle-income countries. *Ann Oncol* 2022;33:360-1
- Influence guideline committees **and the WHO EML** to recommend alternative prescribing
- Convene and organize clinical trials of marketed drugs whose labeled dose is likely excessive



**OPTIMAL CANCER
CARE ALLIANCE**
Optimal Dosage. Best Outcome.

Pharmacokinetic and Pharmacodynamic studies and a small RCT have shown that:

Abiraterone 250mg after food gives similar drug levels and anticancer effects to the approved dose of 1000mg fasting

OCCA applied successfully to NCCN to include low dose abiraterone with food in their guidelines

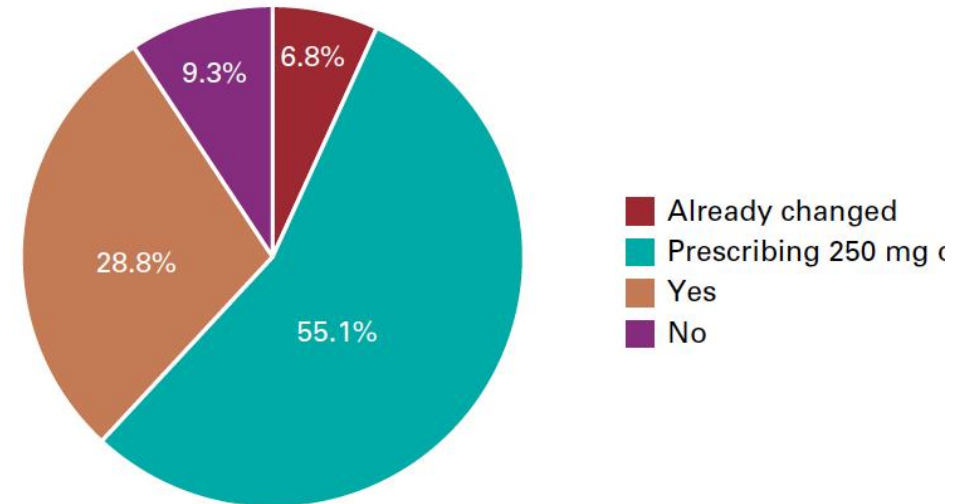
2023-04-24

Low-Dose Abiraterone in Metastatic Prostate Cancer: Is It Practice Changing? Facts and Facets

Amol Patel, MBBS, MD, DM¹; Ian F. Tannock, MD, PhD²; Priyanka Srivastava, MD, DNB³; Bivas Biswas, MD, DM⁴; Vineet Govinda Gupta, MD, DM⁵; Atul Batra, MD, DM⁶; Sainath Bhethanabhotla, MD, DM⁷; Raja Pramanik, MD, DM⁶; Shubh Mahindru, MBBS, DNB⁸; TVSVGK Tilak, DM⁹; Chandan Krishna Das, MD, DM¹⁰; and Prashant Mehta, MD, DM¹¹

Will you change your practice from abiraterone 1,000 mg to abiraterone 250 mg?

118 responses



Average Indian patient would save INR 260,000
Annual saving to Indian Health Service ~US\$182million
(INR 13.5billion)

Clinical Trials

Ongoing

A Randomized Study Investigating the Pharmacokinetics of Standard Interval Dosing Compared to Extended Interval Dosing of Nivolumab or Pembrolizumab in Locally Advanced or Metastatic Cancers
NCT04295863; Sponsor: University of Chicago; Sample size: 264

Planned

The DILUTAMIDE Trial:

A comparison of the registered daily dose with 50% of that dose for treatment of metastatic hormone-sensitive (mHSPC) prostate cancer with enzalutamide, apalutamide or darolutamide.



Our Limitations & Problems

- Lack of funding to support dose-finding studies
 - Trials that evaluate reduced dosing save more money than they cost, but challenge is to persuade payers to finance them
- Persuading patients that reduced dosing will not decrease benefit from treatment – and may increase it
- Limited implementation of lower-dose strategies in high-income countries