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High dose ketoconazole for the treatment of hormone refractory metastatic prostate carcinoma: 16 cases and review of the literature.

[Jubelirer SJ](#)¹, [Hogan T.](#)

⊕ Author information

Abstract

We treated 16 patients who had hormone refractory metastatic prostate cancer with 400 mg. ketoconazole orally every 8 hours. None of the patients had an objective response, although 6 (37.5 per cent) had stable disease (2 of whom had a subjective decrease in bone pain). The median duration of stable disease was 6.8 months (range 2 to 12 months) and side effects were seen in 14 patients. Nausea, vomiting or anorexia was noted in 10 patients, rash and pruritus in 2, transient abnormal liver function tests in 1 and transient pulmonary infiltrates in 1. Nine prior studies investigating the use of ketoconazole in hormone refractory metastatic prostate cancer were reviewed. Only 1 complete response was reported. A partial response was noted in 14 per cent of the patients. Most of the patients had stable or progressive disease. High dose ketoconazole as a single agent appears to have limited use in patients who have failed prior systemic therapy.

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