



REVIEW

Megestrol acetate for the palliation of anorexia in advanced, incurable cancer patients[☆]

Farrah Mateen^a, Aminah Jatoi^{b,*}

^aDepartment of Neurology, Mayo Clinic College of Medicine, Rochester, MN, USA

^bDepartment of Oncology, Mayo Clinic College of Medicine, 200 First Street SE, Rochester, MN 55905, USA

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Summary Anorexia, or loss of appetite, is a troubling symptom for many patients with advanced cancer. The early observation that breast cancer patients, who were prescribed megestrol acetate as a cancer treatment, went on to increase their appetite and gain weight has given rise to a large number of clinical trials that have tested this progestational drug as a palliative agent for the cancer anorexia/weight loss syndrome. This review focuses on these trials, summarizing their findings and providing a practical approach for prescribing megestrol acetate to advanced cancer patients who suffer from the cancer anorexia/weight loss syndrome.

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[☆]This paper is based on the presentation given at the III Cachexia Conference (Rome, 8–10 December 2005). During the conference, experts in wasting diseases, both basic scientists and clinical researchers, discussed relevant topics in the anorexia–cachexia field, including pathogenic mechanisms, diagnostic tools, current therapeutic strategies and future options. More details can be found at www.cachexia.org.

*Corresponding author. Tel.: +1 507 284 3902; fax: +1 507 284 1803.

E-mail address: jatoi.aminah@mayo.edu (A. Jatoi).

Introduction

Sometimes a negative set of circumstances can turn positive. Such was the case with breast cancer patients who complained of weight gain with megestrol acetate, a well-known progestational agent originally prescribed as an antineoplastic agent. In 1987, Tchekmedyian and others reported weight gain ranging between 0.9 and 20.1 km, as well as enhanced appetite, in 28 breast cancer patients who had been prescribed megestrol acetate 480–1600 mg/day.¹ Demonstrating insight and creativity, these investigators went on to capitalize on this side effect profile to advance the proposition that megestrol acetate might be an effective therapy for the cancer anorexia/weight loss syndrome: “Our results suggest a possible role for megestrol acetate in reversing anorexia and weight loss, thereby improving the quality of life of patients with cachexia.” In effect, these preliminary data and this early hypothesis gave rise to a sizable body of literature that has focused on megestrol acetate as a palliative agent for patients suffering from the cancer anorexia/weight loss syndrome and, in turn, led to its prominent role as a standard therapy for select advanced cancer patients who suffer from this syndrome.

The purpose of this review is to summarize this large body of literature. Ironically, although we know a great deal about how and when to prescribe megestrol acetate for palliating the cancer anorexia/weight loss syndrome, we continue to know relatively little about how it works as an appetite stimulant. Thus, the purpose of this review is to summarize the available information, focusing on the following questions. (1) How problematic is anorexia, or loss of appetite, in advanced cancer patients, and why focus on it? (2) How effective is megestrol acetate in palliating anorexia? (3) What works better? and (4) Are there any newer formulations of this drug that might lead to greater efficacy?

How problematic is anorexia in advanced cancer patients, and why focus on it?

There are two main reasons for focusing on anorexia. First, it is a common, upsetting symptom for patients with advanced cancer. Several studies have focused on end-of-life symptoms in patients with cancer, and, invariably, anorexia ranks as one of the top five most distressing symptoms. For example, in a 66-patient study, Tranmer and others found that the majority of patients ranked anorexia

as their fourth most distressing symptom, tied with nausea.² This study is particularly notable because the patients surveyed were no longer receiving chemotherapy, an observation that makes the point that this symptom is not necessarily iatrogenic and in fact can occur as a result of the cancer itself. Moreover, even children with cancer suffer from anorexia. Wolfe and others observed that anorexia was the fourth most problematic symptom among children as well, and among parents, there was an overwhelming perception that this symptom was not being adequately palliated.³ Thus, anorexia is prevalent and troublesome, spanning a wide age range of cancer patients.

Second, anorexia is problematic and deserving of further research because it predicts an early demise for the patient with advanced, incurable cancer. Several studies have made this point. Tamburini and others assessed a 100-patient cohort of cancer patients and found that poor appetite scores were associated with lower median survivals.⁴ In a 1115-patient study that included patients with colorectal and lung cancer, the North Central Cancer Treatment Group observed that quality of life questions that detected poor appetite were able to predict early death better than quality of life questions that focused on other symptoms.⁵ This same powerful prognostic effect has also been observed with patient reported weight loss of >5% of premonitory weight, as shown in the landmark study from Dewys and others.⁶ This investigation employed a robust, multivariate analysis that demonstrated that patient-reported weight loss predicted early demise independently of a variety of other factors, including performance score and tumor burden. In short, both anorexia and weight loss are validated predictive factors of early death for the patient with advanced cancer.

How effective is megestrol acetate in palliating anorexia?

If one relies on well-powered, rigorous trials, megestrol acetate is one of the most effective palliative interventions for the cancer anorexia/weight loss syndrome. In the first-reported, double-blinded, placebo controlled trial to test megestrol acetate as an appetite stimulant, investigators from the North Central Cancer Treatment found that 70% of advanced cancer patients who received megestrol acetate at a dose of 800 mg/day reported an improvement in appetite.⁷ There was even an improvement in weight: a fifteen pound or greater weight gain occurred in 16% of megestrol

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