

REPORT: Canadian Society for the Study of the Aging Male: Response to Health Canada's Position Paper on Testosterone Treatment

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ABSTRACT

Introduction

Testosterone treatment of older symptomatic men with reduced testosterone availability is increasing. There is an expanding body of literature to support such treatment in a large subset of aging men, but there has not yet been a long-term placebo-controlled double-blind study of several thousand men to confirm the efficacy and safety of this treatment as indicated by shorter-term studies. The absence of a long-term study has been used by governmental agencies as a limiting factor in providing full access and payment for this treatment in government-sponsored health care plans. Health Canada issued a

testosterone analysis document to the pharmaceutical industry, the implications of which may make it more difficult for appropriate patients to receive such treatment. The Canadian Society for the Study of the Aging Male (CSSAM) believed it had an obligation to advocate on behalf of men requiring this treatment.

Aim

To provide an international consensus on the use of testosterone treatment in appropriately selected hypogonadal men.

Main Outcome Measure

To determine whether the literature supports the use of testosterone treatment in a selected population of hypogonadal men, to achieve consensus on this point among an international consulting group, and to transmit this view to health care workers and insuring and governmental agencies.

Methods

Email communication among the consulting group to prepare a response to Health Canada, followed by a review of appropriate literature and international practice guidelines, incorporating the literature and guidelines together with the CSSAM letter and Health Canada's response.

Result

The literature and international guidelines support the initiation of testosterone therapy in symptomatic hypogonadal men, recognizing that there is no universal agreement on the criteria for the diagnosis of hypogonadism in each suspected case. The need for careful monitoring of such men is stressed.

Conclusion

CSSAM acted as an advocate for hypogonadal men who may benefit from treatment with testosterone. Short-term studies and 60 years of experience with testosterone therapy attest to its efficacy. Long-term studies are desirable, but it may take many years before results could be forthcoming. There is no evidence to suggest that testosterone treatment increases the risk of prostate cancer or cardiovascular disease. Current evidence suggests, in fact, that testosterone treatment may be cardioprotective. It is important to bring this information to the attention of governments and insuring agencies through the collaboration of groups devoted to the diagnosis and treatment of hypogonadal men. Bain J, Brock G, and Kuzmarov I, for the International Consulting Group. Canadian Society for the Study of the Aging Male: Response to Health Canada's position paper on testosterone treatment.

Introduction

Testosterone therapy for classical male hypogonadism has been available for more than 50 years. "Classical hypogonadism" traditionally consisted of direct damage to, or disease of, the testes (primary hypogonadism), encompassing such conditions as Klinefelter's syndrome, orchitis, trauma, orchidectomy, etc. Classical hypogonadism also included hypothalamic-pituitary dysfunction (secondary/tertiary hypogonadism), in which testicular function was compromised because of tumor formation or various other conditions resulting in inadequate production or action of gonadotropin-releasing hormone or the gonadotropins (leutinizing hormone and follicle stimulating hormone).

During the past decade, there has been increasing interest in the possible clinical relevance of the declining levels of testosterone, and particularly bioavailable testosterone, in men as they age. These questions have been addressed to some extent recently with studies evaluating the physiologic effects of testosterone using innovative animal models and human volunteers [1, 2]. What there is no controversy about is the fact that testosterone production and availability do decrease with age, a decrease that starts in the early 40s. The research group from Harvard has recently demonstrated that response in some individuals is related to the initial extent of hypogonadism and that considerable variation in testing exists [3, 4, 5, 6]. Where the controversy resides is in the debate over whether declining testosterone is associated with clinically important sequelae, and whether symptomatic men with reduced levels of testosterone should be treated. The debate is intensified by the fact that there is yet no long-term study (several years) conducted in a placebo-controlled double-blind fashion in several thousand men. Because of the absence of such an in-depth study, there are, on the one hand, those who say we have either no evidence or insufficient evidence to support treating aging men with testosterone in the absence of classical hypogonadism [7]. Then there are those who, on the other hand, argue that, based on shorter-term studies with smaller numbers of men and based on clinical experience, there is ample reason and evidence to treat men with testosterone who have signs and/or symptoms of hypogonadism, arguing both for its efficacy and safety [8].

The number of physicians who have taken the latter view has increased dramatically within the past decade. The number of studies and articles written on the subject has risen exponentially, describing methods of questioning the patient or examining the causal relationship with forms of erectile dysfunction [9, 10, 11]. This, in turn, has stimulated position papers and guidelines by a number of

professional associations around the world. Finally, governments have entered the discussion either because they are the primary payers of prescription drugs for certain populations, or because they have responsibility for the safety, health, and welfare of their citizens.