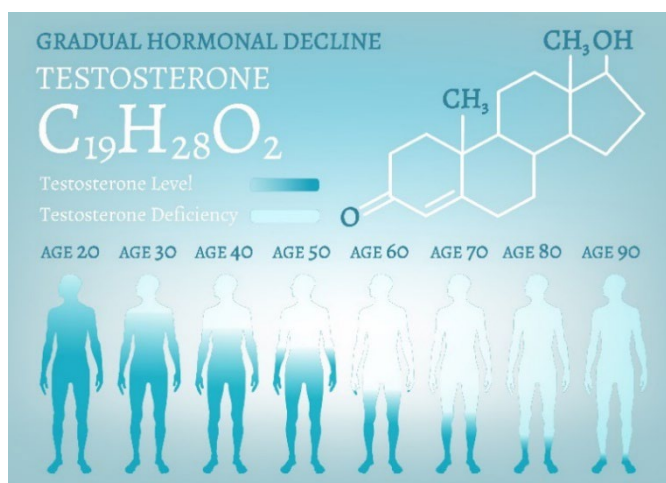


# Testosterone Replacement Therapy in Hypogonadism

**COPYRIGHT DISCLAIMER:** This scientific case study has been published in a peer-reviewed journal as follows: Banov, D., Biundo, B., Ip, K., Shan, A., Banov, F., Song, G., & Carvalho, M. (2024). Testosterone Therapy for Late-Onset Hypogonadism: A Clinical, Biological, and Analytical Approach Using Compounded Testosterone 0.5-20% Topical Gels. *Pharmaceutics*, 16(5), 621. <https://doi.org/10.3390/pharmaceutics16050621>

## Introduction:

Male hypogonadism is a broad term that refers to low testosterone in men. Andropause is a common form of hypogonadism that refers to a gradual testosterone decline in the aging male, as shown in Figure 1. This decline is predominantly due to a failure in the function of the hypothalamic-pituitary unit and thus it is also referred to as hypogonadism.<sup>1</sup> Low testosterone is linked to a complexity of symptoms such as erectile dysfunction, loss of libido (sex drive), depressed mood, lethargy and declining muscle tone. It has been suggested that it is also associated with prostate cancer and benign prostatic hyperplasia.<sup>2</sup> It is very important to consider testosterone replacement therapy to improve the quality of life and long-term health of hypogonadal patients. There are several options for supplementation, such as parenteral dosing, implantable pellets and sublingual or buccal administration. However, the topical administration of testosterone gels at concentrations of 1% to 5% appears to be the most effective way of dosing testosterone.<sup>3</sup> The purpose of this case study is to discuss the management of hypogonadal symptoms with the topical application of testosterone 5% in the PCCA base Atrevis Hydrogel.



**Figure 1.** Testosterone medical illustration and molecular formula (adapted from Double Brain/Shutterstock.com).

## Case Report:

A male in his seventies with hypogonadal symptoms was dispensed testosterone 5% in Atrevis Hydrogel, an advanced topical base designed specifically to deliver testosterone through the skin in male patients.

The topical gel (PCCA Formula 12674, Table 1) was dispensed in a 75 mL MegaPump® (PCCA Item 35-5068), which delivers approximately 0.5 mL of gel per pump. The patient applied two pumps of the gel every morning, in the inner forearm, thus approximately 50 mg of testosterone daily. The treatment was initiated in August 2017 and lasted 6 months, as directed by his physician. In order to accurately assess the therapeutic effect of the compounded medication, the patient checked his level of total serum testosterone in January 2018 (Figure 2) and completed the Androgen Deficiency in Aging Males (ADAM) questionnaire before and after treatment. The patient provided consent to the publication of his results.

Rx	100 g
Testosterone USP Micronized CIII (Soy)	5 g
Propylene Glycol USP	10 g
Base, PCCA Atrevis Hydrogel®	85 g

**Table 1.** PCCA Formula 12674: Testosterone 5% Topical Gel (Atrevis Hydrogel®).

## Methodology:

The ADAM questionnaire is a non-invasive screening test to detect testosterone deficiency in males over 40 years of age. It is a self-reported questionnaire that includes 10 “Yes/No” questions, from libido to work performance. The questionnaire was validated in the general population and was found to have 88% sensitivity and 60% specificity for detecting testosterone deficiency. According to Morley *et al.*, the patient is likely to have low testosterone if he answers “Yes” to question numbers 1 or 7, or if he answers “Yes” to more than 3 questions.<sup>1</sup>

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TESTOSTERONE, TOTAL, LC/MS/MS	
COLLECTION DATE	01/22/2018
Order Date	01/22/2018
Result Date	01/28/2018
Ordering Physician	[REDACTED]
TESTOSTERONE, TOTAL,	1076 (250-1100 ng/dL)

**Figure 2.** Patient laboratory results for total serum testosterone following treatment with PCCA Formula 12674.

### Results and Discussion:

The patient answered all questions of the ADAM questionnaire before and after treatment with the testosterone topical gel. A positive ADAM score was obtained before treatment since the patient answered “Yes” to questions 1 and 7, meaning that the patient reported decreased libido and decreased strength of erections. After treatment, a negative ADAM score was obtained since the patient answered “No” to all 10 questions, as shown in Table 2.

Question Number	Patient's Answers	
	Before Treatment	After Treatment
1	Yes	No
2	Yes	No
3	No	No
4	No	No
5	No	No
6	No	No
7	Yes	No
8	No	No
9	No	No
10	No	No

**Table 2.** ADAM scores before and after treatment.

The laboratory result obtained for the total serum testosterone post-treatment was 1,076 ng/dL (Figure 2). Considering that the healthy range of testosterone is 250–1,100 ng/dL, the level achieved is clinically optimal. The patient and the physician stated that the results obtained were beyond expectations.

In comparison to other treatments, the patient felt that the Atrevis Hydrogel absorbed well without leaving a film or residue, i.e., there was no “greasy mess.” The patient also reported that there was no skin sensitivity, most likely because the Atrevis Hydrogel is a water-based gel and hence it is alcohol-free.

### Conclusions:

Testosterone replacement therapy may be a key treatment option in andropause patients with self-reported hypogonadal symptoms, such as loss of libido and decreased strength of erections. Pharmacists are in a very unique position to work with these patients and physicians in achieving better treatment outcomes by providing personalized, innovative compounded medications. Testosterone in Atrevis Hydrogel is a promising treatment option that is shown in this case report to benefit a complexity of low testosterone symptoms (ADAM questionnaire) and to increase the level of total serum testosterone (laboratory results).

### References:

1. Morley, J.E., Charlton, E., Patrick, P. *et al.* (2000) ‘Validation of a screening questionnaire for androgen deficiency in aging males’, *Metabolism Clinical and Experimental*, 49 (9), p. 1239-42.
2. Biundo, B. (2009) ‘Hormone Treatment Options for Males: What to Do for Men with Low Testosterone’, *International Journal of Pharmaceutical Compounding*, 13 (4), p. 276-9.
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