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Case Study: Testosterone Replacement Therapy in a Premenopausal Woman

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INTRODUCTION

The safety, effectiveness and use of compounded bioidentical hormone replacement therapy (cBHT) has been questioned by the U.S. Food and Drug Administration in the light of the recently published study report by The National Academies of Sciences, Engineering and Medicine (NASEM). A case study was conducted to evaluate the effectiveness of compounded testosterone (T) therapy in a premenopausal woman presented with bothersome psychological symptoms and sexual disfunction, which negatively impacted the patient's Health-Related Quality of Life (HRQoL) . There are myths and misconceptions about T therapy in women as well as gender bias that keep women from receiving equivalent treatment options to their male counterparts[2]. *Myth: Testosterone is a 'male' hormone. Fact: Testosterone is essential for physical, mental and emotional health in both sexes.* The replacement of testosterone is being increasingly used to treat symptoms of hormone deficiency in pre and postmenopausal women[3]. Compounding pharmacists may provide customized topical preparations to meet the patient's individual needs for testosterone and women are thus encouraged to discuss cBHT options with their physicians.

METHODS

The effectiveness of the compounded T-therapy was assessed retrospectively by inviting the patient to complete the Cervantes Scale-Abridged (short-form), a self-administered questionnaire designed to measure the HRQoL in pre and postmenopausal women aged 45-60 years-old. This validated research instrument is composed by 16 items and it is structured in 4 dimensions: menopause and health (comprising the sub-dimensions vasomotor symptoms, health and aging); psychological symptoms; sexuality; and couple relations. Each item is scored in a Likert scale from 0 to 5. The scoring algorithm offers 8 individual scores, all standardized to a 0 to 100 metric, where higher scores represent a worse quality of life[1]. The purpose of this primary outcome measure was to report any HRQoL changes from baseline (before treatment) and, as such, the patient was invited to complete the questionnaire twice, by referring to her symptoms before and after topical treatment. Permission was requested and obtained to use the Cervantes Scale-Abridged for this purpose. The secondary outcome measure of this case study was the salivary laboratory testing of the patient's testosterone levels, also before and after topical treatment. The patient provided informed consent for the publication of this anonymous case study.

RESULTS & DISCUSSION

The premenopausal woman was presented to her physician with bothersome symptoms related to low levels of testosterone, which were later confirmed by salivary testing (<8 pg/mL). The patient was prescribed testosterone 0.75 mg/g topical gel (PCCA Versabase® Anhydrous HRT) to be applied 1 mL QD (Figure 1). PCCA Versabase Anhydrous HRT (Figure 2) is a proprietary anhydrous base (water activity below 0.6) with extended stability, developed specifically for the topical delivery of female hormones into and through the skin. This base has proven to facilitate the percutaneous absorption of testosterone *in vitro* using a dermatomed human skin model[4].

Following 6 months of compounded T-therapy, the patient's salivary testosterone levels increased from <8 pg/mL (low) to 32 pg/mL (optimal) (Figure 3). These results are consistent with the self-reported clinical outcomes: *"The results are great; the physician is keeping me on the same dose for another 6 months."*

According to the Cervantes Scale-Abridged, completed before and after topical treatment, the patient's psychological symptoms decreased from 6.67 to 0 (no impact on a women's HRQoL). The patient's sexuality, on the other hand, improved from 60 to 30 (100 being the worst possible impact on a women's HRQoL). All other dimensions (menopause and health, and couple relations) remained unchanged. These improvements are also consistent with the patient's laboratory results and the self-reported clinical outcomes.

Figure 3. *Patient laboratory results (salivary testosterone) after treatment.*

"Testosterone is the most abundant biologically active hormone in women[2,3]."

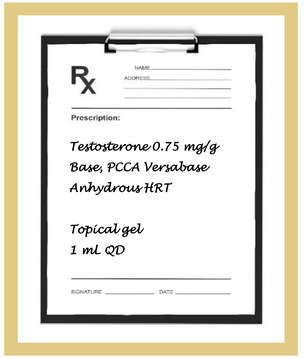

Figure 1. *Sample prescription pad; stock illustration ID: 329147189 (adapted from Gts /Shutterstock.com).*

Figure 2. *Photograph of a PCCA container for the topical base Versabase Anhydrous HRT[4].*

CONCLUSIONS

Despite the myths and misconceptions associated with testosterone, there is scientific evidence to support the safety and effectiveness of compounded T therapy in women. In this case study, not only the patient's salivary testosterone levels increased to an optimal range, but also the patient reported an improvement of her HRQoL following 6 months of topical treatment. It is concluded that cBHT is an effective and essential treatment option for women.

REFERENCES

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