

Converting Men from Clomiphene Citrate to Natesto® for Hypogonadism Improves Libido, Maintains Semen Parameters, and Reduces Estradiol

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INTRODUCTION

Traditional testosterone replacement therapy (TRT) such as gels and injections, suppress the gonadotropins follicle stimulating hormone (FSH) and luteinizing hormone (LH), thereby suppressing spermatogenesis downstream. The selective estrogen receptor modulator, clomiphene citrate (CC) is an off-label treatment for hypogonadism in a spermatogenic preserving manner. Most men achieve normalization of testosterone (T) on CC, but estradiol (E2) levels commonly rise. And symptomatic response is worse on CC than TRT, particularly libido. The intranasal TRT, Natesto®, at more frequent intervals of administration, allows FSH and LH to remain at normal levels. A phase IV clinical trial has shown men treated with Natesto® did not have significant suppression of semen parameters from baseline.

OBJECTIVES

To evaluate the outcomes of men converted from CC to Natesto®.

METHODS

After institutional review board exemption was obtained due to the de-identified nature of the study, a retrospective chart review was performed to assess the outcomes of hypogonadal men desiring to maintain fertility who were converted from CC to Natesto®. Semen analyses (obtained at a single andrology laboratory), T, and E2 levels were obtained on CC and again 3 months after discontinuing CC and initiating Natesto®. Results are reported as means with standard deviations.

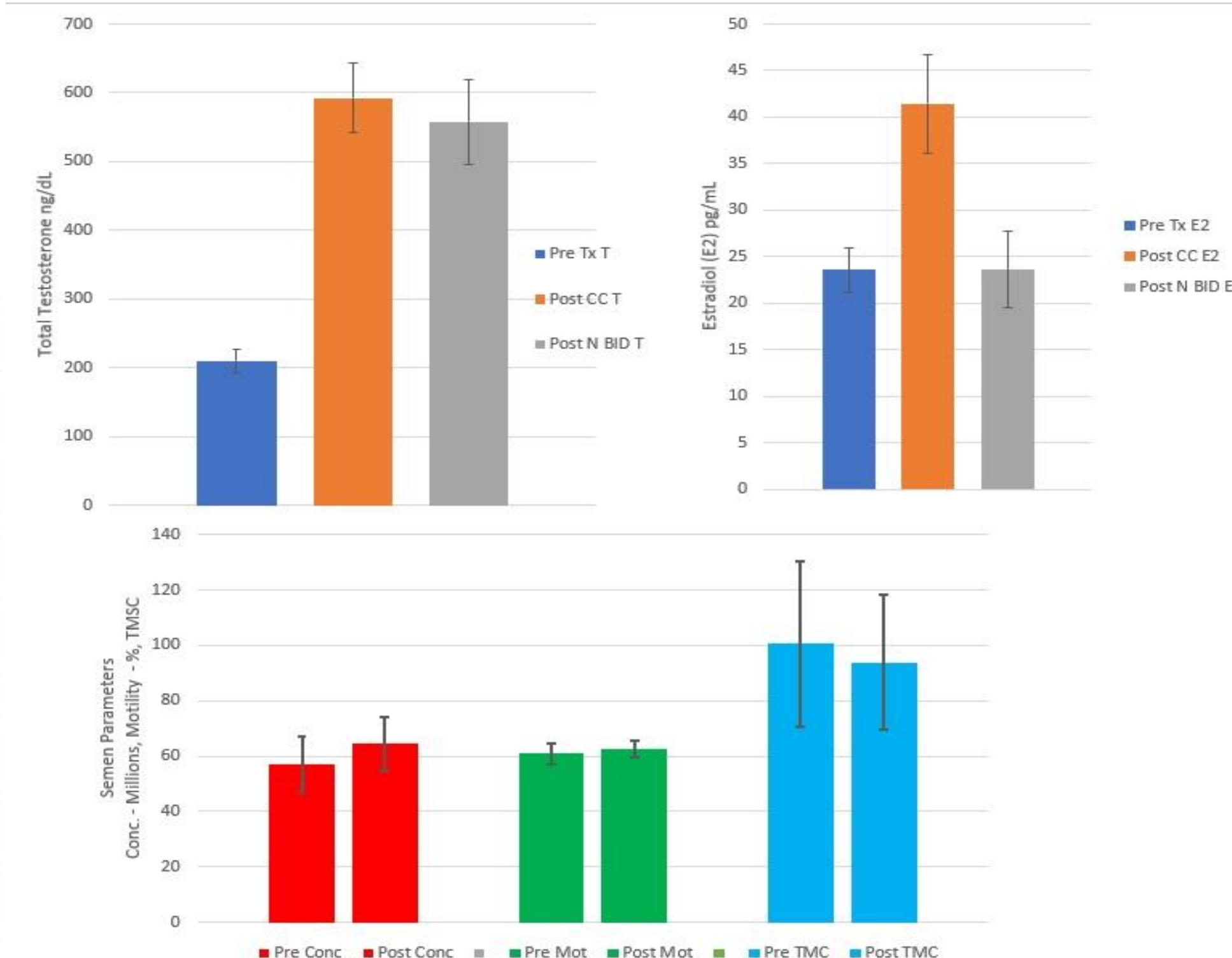
RESULTS

Figure 1: T, E2, and semen parameters on CC versus Natesto®.

	Baseline	CC	Natesto®
Testosterone (ng/dL)	209.6 (61)	592.5 (198)	557.8 (211)
Estradiol (pg/mL)	23.6 (10)	41.4 (21)	23.6 (14)
Semen Volume (mL)		2.9 (2)	2.5 (2)
Concentration (mil/ml)		57 (36)	64.3 (35)
Motility (%)		60.9 (14)	62.4 (11)
Forward Progression (FP)		29.2 (14)	35.7 (8)
Morphology (%)		5.9 (3)	5.9 (3)
Total Motile Count (mil)		100.5 (107)	93.7 (87)

Forty-six men desiring to maintain fertility potential changed from CC to Natesto® and 15 of them had reached the 3 months post-initiation of Natesto® treatment to evaluate their responses. The mean age of these men was 39±7 years and they had improvements in T levels to eugonadal levels on both treatments, but significantly higher E2 levels on CC than baseline or on Natesto®. There was no significant change in any semen parameters comparing them while on CC to after converting to Natesto®. All patients reported improved libido after converting from CC to Natesto®.

Figure 1: T, E2, semen parameters on CC versus Natesto®.



CONCLUSIONS

Although men reach eugonadal T levels on both CC and Natesto®, CC nearly doubled the E2 levels from baseline, and converting men from CC to Natesto® returned E2 to baseline levels. There was not a detrimental effect on semen parameters, and there was subjective reporting of improved libido after converting from CC to Natesto®.

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