Testosterone Prescribing Among Women in the USA, 2002–2017

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INTRODUCTION

Serum testosterone levels in women decline with age, with the largest decrease occurring before menopause.[1] There are no serum testosterone levels that define testosterone deficiency in women, or even an understanding of the extent to which low testosterone is associated with symptoms.[1] Recent randomized controlled trials have reported, however, that testosterone therapy may improve sexual function in women presenting with low libido.[2, 3] Because no testosterone product has ever been approved for women, it is generally prescribed off-label, either in dose-modified form or as a compounded therapy including estrogen.[4] Despite extensive research on testosterone prescription patterns and adverse events in men,[5, 6] no such information is available in women. We therefore conducted a study to examine trends in testosterone prescription among women in the USA.

METHODS

This retrospective cohort study used administrative health data from Optum Clinformatics DataMart (CDM), one of the nation's largest commercial insurance databases. Providers are required to submit complete claims to receive reimbursement. During the study period (2002–2017), a total of 11,650,309 women aged ≥ 30 years were included in the overall study population with a minimum of 1,970,851 women in any year (Fig. 1). We used a combination of outpatient, inpatient, and pharmacy claims data. The pharmacy database contains eligibility and pharmacy claims information for medications from retail pharmacies through a member's pharmacy benefit.

We examined total number of testosterone prescriptions in the 12 months following the first prescription using an incidence cohort from 2017. For new testosterone users in 2002–2017, we searched for a laboratory test for endogenous testosterone and for indications for testosterone use (psychosexual dysfunction, osteoporosis, depression, gender dysphoria) in the previous year. All analyses were performed using SAS (SAS Institute) version 9.4. Statistical tests were 2-tailed and significant at a level of 0.05. This study was approved by the University of Texas Medical Branch Institutional Review Board.

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RESULTS

The overall number of women prescribed testosterone therapy varied between 13.8 per 10,000 and 19.0 per 10,000 between 2002 and 2009, and then decreased to 4 per 10,000 in 2017 (Fig. 2). Women aged 50–59 years had the highest prevalence in all years. Overall, 9 per 10,000 women were prescribed testosterone combined with estrogen compared with 4 per 10,000 women being prescribed testosterone only. Examination of the prevalence of testosterone use by region in 2010 showed that women in the Northeast had the highest use (25 per 10,000) while those in the South had the lowest (6 per 10,000). Overall, 48.0% of new testosterone users filled only 1 prescription in a 12-month period; 52.2% filled ≥ 2; 36.2 filled ≥ 3; and 27.5% filled ≥ 4. Among all new testosterone users (2002–2017), only 35.6% had their testosterone level measured; 67.0% had been given a diagnosis of sexual dysfunction; 0.5%, gender dysphoria; 14.2%, osteoporosis, and 19.7%, depression.

DISCUSSION

Our findings show that testosterone use among women aged ≥ 30 years was relatively stable between 2002 and 2007 before rising in 2008 and 2009, and then decreased substantially over the next 8 years. The majority of women received a form of testosterone that was combined with estrogen. Among women receiving a new testosterone prescription, 48.0% did not receive a subsequent prescription and 64.4% did not receive a laboratory test for testosterone in the prior 12 months.

Our findings must be interpreted in view of limitations. First, commercial insurance data select for employed females;

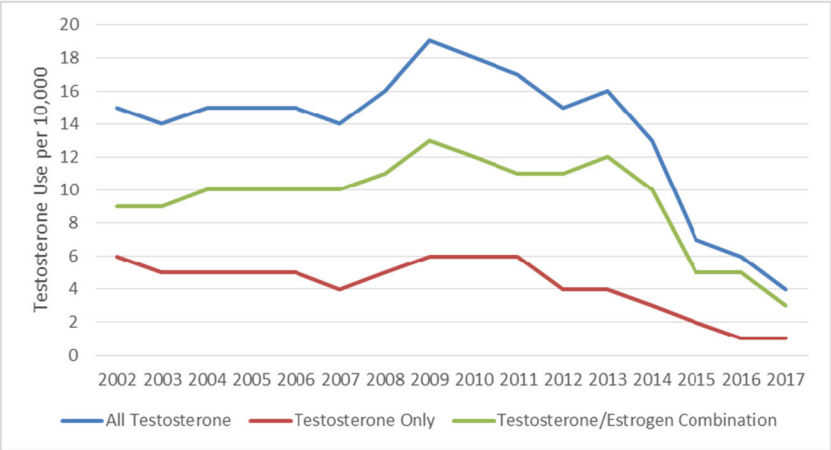

Figure 1 Annual prevalence of testosterone use among women in the USA by year and compound status. Separate denominators were calculated for each calendar year from 2002 to 2017. Each denominator included all women who were ≥30 years at the start of the calendar year with continuous benefits for the entire study year and prior year. The denominators in any year ranged from 1,970,851 to 3,555,864.

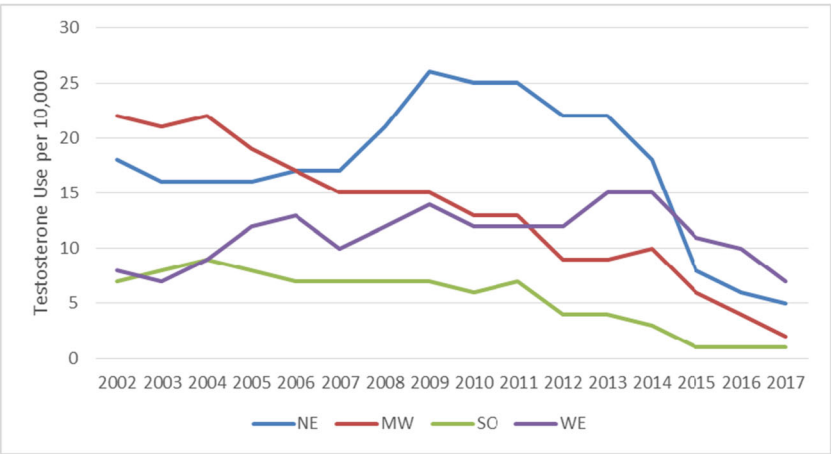

Figure 2 Annual prevalence of testosterone use among women in the USA by year and region. Separate denominators were calculated for each calendar year from 2002 to 2017. Each denominator included all women who were ≥30 years at the start of the calendar year with continuous benefits for the entire study year and prior year. Regions were based on US census regions. NE Northeast, MW Midwest, SO south, WE west. The denominators for any region category in any year ranged from 160,148 to 1,442,522.

in particular, the results for women aged ≥65 are not generalizable. Second, women may have obtained testosterone from clinicians not reimbursed by their insurance. Third, because this was an ecologic study, the reasons for patterns of testosterone use over time cannot be determined.

Similar to the pattern observed in men,[6] the steepest decline of testosterone use in women coincided with published reports of testosterone-associated adverse cardiovascular events.[5] Our finding that almost 50% of new users did not refill their prescription suggests that, for many women, testosterone therapy is either not effective or that the benefits of treatment did not outweigh the adverse effects or concerns about risks. Further studies are needed to examine patterns, indications, and efficacy of testosterone use in women.

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Author Contributions *Dr. Baillargeon had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.*
Study concept and design: Baillargeon, Urban, Raji, Westra, Williams, Lopez, Kuo.
Analysis and interpretation of data: Baillargeon, Westra, Kuo.
Drafting of the manuscript: Baillargeon, Westra, Kuo.
Critical revision of the manuscript for important intellectual content: Baillargeon, Urban, Raji, Westra, Williams, Lopez, Kuo.
Statistical analysis: Baillargeon, Westra, Kuo.
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Administrative, technical, or material support: Baillargeon, Westra, Kuo.
Study supervision: Baillargeon, Kuo.

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Compliance with Ethical Standards:

Conflict of Interest: *Jacques Baillargeon has received payment, for consulting, with AbbVie, GlaxoSmithKline, Endo Pharmaceuticals, and Auxilium Pharmaceuticals. None of the other authors have conflicts to report.*

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