Original Research

Trends of Postmenopausal Estrogen Plus Progestin Prevalence in the United States Between 1970 and 2010

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OBJECTIVE: To estimate long term trends in estrogen–progestin prevalence for the U.S. female population by year and age.

METHODS: We integrated data on oral estrogen–progestin use from the National Health and Nutrition Examination Survey 1999–2010 with data from the National Prescription Audit 1970–2003. Distributions of estrogen–progestin by age from the National Health and Nutrition Examination Survey were applied to the prescription data, and calibration and interpolation procedures were used to generate estrogen–progestin prevalence estimates by single year of age and single calendar year for 1970–2010.

RESULTS: Estimated prevalence of oral estrogen–progestin was below 0.5% in the 1970s, began to rise in the early 1980s, and almost tripled between 1990 and the late 1990s. The age-adjusted prevalence for women aged 45–64 years peaked at 13.5% in 1999 with highest use among 57-year-old women (23.2%). Prevalence of estrogen–progestin use declined dramatically in the early 2000s with only 2.7% of women aged 45–64 years using estrogen–progestin in 2010, which is comparable to prevalence levels in the mid-1980s.

CONCLUSION: The dramatic rise and fall of estrogen–progestin use over the past 40 years provides an illuminating case study of prescription practices before, during, and after the development of evidence regarding benefits and harms.

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LEVEL OF EVIDENCE: II

Use of postmenopausal hormones has varied over the past decades. Until the 1970s, estrogen formulations were most common.[1,2] In 1975, an elevated risk of endometrial cancer from estrogen therapy was recognized,[3–5] and postmenopausal hormone use declined.[6–8] Thereafter, studies demonstrated that adding progestin to estrogen reduced endometrial cancer risk[9,10] and suggested additional benefits.[11,12] The number of estrogen–progestin prescriptions grew rapidly until the early 2000s.[13,14] In 2002, the Women's Health Initiative clinical trial found that estrogen–progestin use among healthy postmenopausal women was associated with elevated risk of breast cancer, coronary heart disease, stroke, and venous thromboembolic disease.[12] Estrogen–progestin use decreased dramatically,[14–18] and in January 2003, the U.S. Food and Drug Administration recommended that manufacturers label estrogen–progestin products with information on possible health risks.[19]

Recent ecological studies showed that breast cancer incidence declined between 2001 and 2004, simultaneously with the decline of estrogen–progestin use,[20–23] igniting a discussion of whether and to what extent changes in estrogen–progestin use contributed to changes in breast cancer incidence.[24–30]

Long-term nationally representative data on estrogen–progestin use are needed to investigate the historical effects of estrogen–progestin use on population-level trends in health outcomes related to its use. Estrogen–progestin prevalence estimates are available from the

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National Health and Nutrition Examination Survey since 1999.[31] Available earlier national prescription sales counts[32–35] are only an indirect measure of prevalence.[6,8,13] We sought to estimate nationally representative trends in estrogen–progestin prevalence for the U.S. female population by calendar year and age by integrating recent National Health and Nutrition Examination Survey prevalence estimates with prescription drug statistics dating back to 1970.

MATERIALS AND METHODS

For our analysis, we used publications based on the National Prescription Audit 1970–2003 and National Health and Nutrition Examination Survey 1999–2010.[6,8,13,14,36] The National Health and Nutrition Examination Survey data are publically available and were validated by the Centers for Disease Control and Prevention. The National Prescription Audit is validated by the IMS Institute. From the National Health and Nutrition Examination Survey data, we calculated odds ratios of estrogen–progestin use between age groups. Using these odds ratios, we split the aggregated prescription data into age specific data. Finally, we combined the two data sources and interpolated estrogen–progestin prevalence estimates by single year of age and single calendar year. This study was determined to be exempt from human subjects review by the University of Wisconsin Health Sciences institutional review board under category 4 because the data are publicly available.

We used data from six National Health and Nutrition Examination Survey survey waves on the percentage of women aged 40 years and older reporting current use of oral estrogen–progestin between 1999 and 2010.[36] The National Health and Nutrition Examination Survey is a program designed to assess the health of the U.S. population and has been conducted annually and published biennially since 1999 with less regular prior waves. It uses a multistage probability sampling design to select a population sample that is representative of the civilian noninstitutionalized U.S. population.[37] A more detailed description of the National Health and Nutrition Examination Survey reproductive health module is given in Sprague et al.[31] Sample sizes of women aged 40 years and older with estrogen–progestin data during the National Health and Nutrition Examination Survey waves in 1999, 2001, 2003, 2005, 2007, and 2009 were 1,329, 1,433, 1,420, 1,276, 1,763, and 1,739, respectively. We calculated the prevalence of current use of oral estrogen–progestin by age (5-year age groups) in 2 calendar-year increments corresponding to the National Health and Nutrition Examination Survey survey waves. The data were analyzed in the R survey package and weighted by the provided sampling weights to account for sampling design to calculate nationally representative estimates.

We relied on publications that reported national counts of postmenopausal hormone prescriptions based on data from the National Prescription Audit to assess the use of estrogen–progestin before 1999. The National Prescription Audit is an industry standard source of national prescription activity for all pharmaceutical products.[38] Data are collected from a representative sample of retail, standard mail service, specialty mail service, and long-term care facilities. Several papers were identified that reported counts of noncontraceptive estrogens, progestins, or both covering the time period 1970–2003.[6,8,13,14] Each study sought to include all noncontraceptive estrogen and progestin preparations used at the time. A more complete description of the specific products included in each study is available in the source publications.

Because information on the number of prescription of both estrogen and progestin used together was not directly available from the National Prescription Audit publications, counts of prescriptions for estrogen–progestin were estimated by multiplying the total number of noncontraceptive postmenopausal estrogen prescriptions by the reported fraction of estrogen prescriptions that were prescribed along with progestin. For years in which no published estrogen prescription data were available (1993–1994), linear interpolation was performed. Similarly, in years in which no estimate of the fraction of coprescribed progestin was available (1970–1973, 1987–1991, 1993–2000), linear interpolation of that fraction was performed. The estrogen–progestin prescription counts were normalized to annual population denominator counts of U.S. women aged 40 years and older as obtained from the U.S. Census.[39]

We used a weighted logistic regression model to measure the association between estrogen–progestin use and age in the National Health and Nutrition Examination Survey 1999–2010 data while adjusting for National Health and Nutrition Examination Survey wave as a measure of calendar year. We tested an interaction term between age group and survey year, which was not statistically significant ($P=.35$) and subsequently excluded the interaction term from the model. In addition to the odds ratios, we calculated biannual probabilities of estrogen–progestin use by age group.

The estrogen–progestin use odds ratios by age were numerically applied to the normalized prescription counts between 1970 and 2003, such that the variation in estrogen–progestin use by age observed

in National Health and Nutrition Examination Surveys 1999–2010 was mirrored in the prescription drug data, resulting in estimated age-specific prescription rates of estrogen–progestin use between 1970 and 2003 by 5-year age group. These prescription rates were then calibrated to the National Health and Nutrition Examination Survey data to produce pre-1999 estimates of estrogen–progestin prevalence.

To generate single calendar year and single year of age prevalence estimates, we implemented a two-step interpolation process. First, the National Health and Nutrition Examination Survey biennial prevalence estimates between 1999 and 2010 from the logistic regression were interpolated to annual probabilities per 5-year age group with 1-year knot per National Health and Nutrition Examination Survey survey. The annual National Health and Nutrition Examination Survey data and the calibrated prescriptions were then combined into one data set in the cutoff year 2003. These prevalence estimates by 5-year age groups that covered the entire period (1970–2010) were then interpolated to single-year age groups with one age knot per 5-year age group.

RESULTS

Estrogen–progestin prescriptions varied substantially over time (Fig. 1). The estimated age-adjusted prevalence of oral estrogen–progestin use was below 1% for all age groups until approximately 1980, began to rise in the early 1980s, and grew by approximately 200% between 1990 and 1999. The absolute increase in estrogen–progestin prevalence for women aged 45–64 years was 4.4% between 1980 and 1990 and 8.8% between 1990 and 2000 (Table 1). Age-adjusted estrogen–progestin prevalence in women aged 45–64 years peaked at 13.5% in 1999. Increases in use were statistically significant ($P<.001$) based on linear trends reported in Wysowski et al.[13] Estrogen–progestin prevalence declined by approximately 85% between 2001 and 2005. The odds ratio of estrogen-progestin use in 2010 was 0.174 (95% confidence interval 0.087–0.346; $P<.001$) compared with use in 2000. Annual change was not significantly different across age groups ($P=.35$). The prevalence in 2010 was similar to that observed in the mid-1980s (Fig. 2).

Estrogen–progestin use varied substantially by age. Estrogen–progestin prevalence was less than 5% across all years among women aged 45 years and younger as well as among women aged 75 years and older. Peak use was observed among women in their late 50s (Fig. 3). Maximum use estimates were reached in 1999 with an estimated 23.2% prevalence among 57-year-old women (12.4% among 50-year-old, 14.6% among 60-year-old, and 10.4% among 65-year-old women). Between 2002 and 2006, estrogen–progestin use decreased steeply in all age groups. Absolute changes during that time varied according to the different levels of estrogen–progestin prevalence per age group (Table 1), but the relative annual decline was similar in all groups and ranged from approximately −43% in 2004 and 2005 to approximately −16% in 2006. Post-2000 use was lowest in the mid-2000s with the lowest prevalence for women aged 45–64 years observed in 2006 at 1.7%. There is some suggestion of a very modest increase that occurred in the late 2000s (Figs. 2 and 3).

DISCUSSION

Our analyses provide age- and year-specific estimates for estrogen–progestin use during 1970–2010 representative

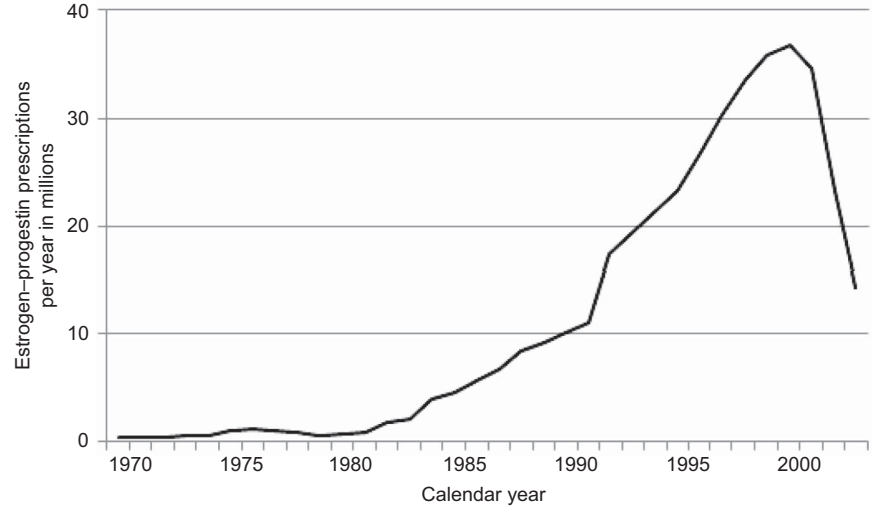

Fig. 1. Postmenopausal estrogen–progestin prescriptions in the United States, 1970–2003.

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Table 1. Estimated Prevalence of Oral Postmenopausal Estrogen–Progestin Use in the United States by Age and Calendar Year, 1970–2010

Age (y)	1970	1980	1990	2000	2010	Absolute Change, 1980–1990	Absolute Change, 1990–2000	Absolute Change,* 2000–2010
40	<0.1	<0.1	0.2	0.6	0.1	0.2	0.4	−0.5
45	<0.1	0.1	1.0	3.2	0.6	0.9	2.2	−2.6
50	0.2	0.3	4.2	12.4	2.4	3.9	8.2	−10.0
55	0.4	0.6	7.9	21.5	4.6	7.3	13.6	−16.9
60	0.2	0.4	5.0	14.5	2.9	4.6	9.5	−11.7
65	0.2	0.2	3.4	10.3	1.9	3.2	6.9	−8.4
70	0.1	0.2	2.9	8.7	1.6	2.7	5.9	−7.1
75	0.1	0.1	1.2	3.8	0.7	1.1	2.6	−3.1
80	<0.1	0.1	0.9	2.9	0.5	0.8	2.0	−2.4
45–64†	0.2	0.3	4.7	13.5	2.7	4.4	8.8	−10.8
40–84‡	0.2	0.2	3.2	9.2	1.8	2.9	6.0	−7.4

Data are %.
* The odds ratio of estrogen-progestin use in 2010 was 0.174 (95% confidence interval 0.087–0.346; $P<.001$) compared with use in 2000. Annual change was not significantly different across age groups ($P=.35$).
† Age-adjusted to the U.S. 2000 (45–64 years old) standard population.
‡ Age-adjusted to the U.S. 2000 (40–84 years old) standard population.

of the U.S. female population. Our estimates of estrogen–progestin use between 1970 and 2010 are unique in the level of detail they provide and could help generate new hypotheses for future research around past and current health outcomes associated with estrogen–progestin use. The population-level effect of estrogen–progestin use on women's health has likely varied according to the changes in estrogen–progestin prevalence in the past decades.

Our estimates are consistent with patterns shown in previous publications among specific study populations during more restricted time periods.[15,17,32–35,40–43] Our modeled estrogen–progestin prevalence trends are nationally representative and more comprehensive by providing estimates per calendar year and single year of age rather than aggregate estimates over time and age groups. In some cases, our estimates are slightly lower compared with previous publications, particularly when comparing them with studies conducted on enrollees of health maintenance organizations. For example, Buist et al[15] reported a 14.6% estrogen–progestin prevalence among women aged 40–80 years in 1999, whereas the corresponding value in our study was 9.5%. This most likely reflects the elevated use of postmenopausal hormones among women enrolled in health maintenance organizations relative to use among the general population, which also includes uninsured women. There is little nationally representative estrogen–progestin data in the published literature with which to compare our results more directly, and we found none that covered comparably long time periods. In a study based on National Health and Nutrition Examination Survey data, Brett et al[43] reported estrogen–progestin prevalence estimates in 1999 quite comparable to ours.

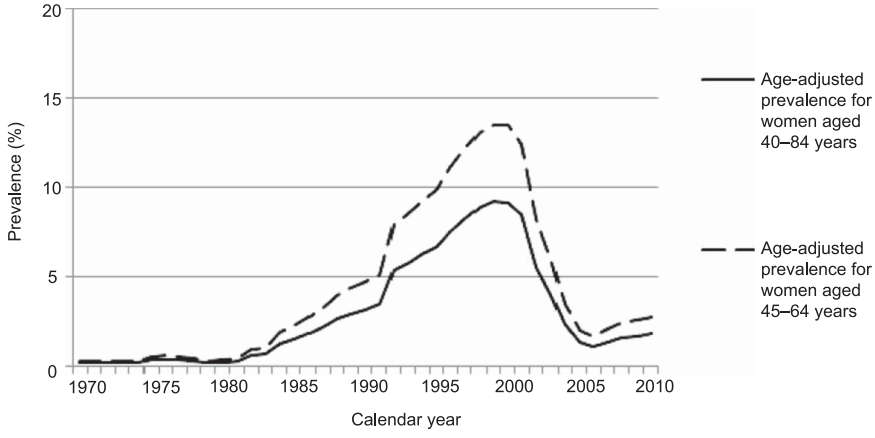

Fig. 2. Estimated age-adjusted prevalence of oral estrogen–progestin use 1970–2010 among women aged 45–64 years (*dashed line*) and aged 40–84 years (*solid line*).

Jewett. Estrogen Plus Progestin Prevalence. Obstet Gynecol 2014.

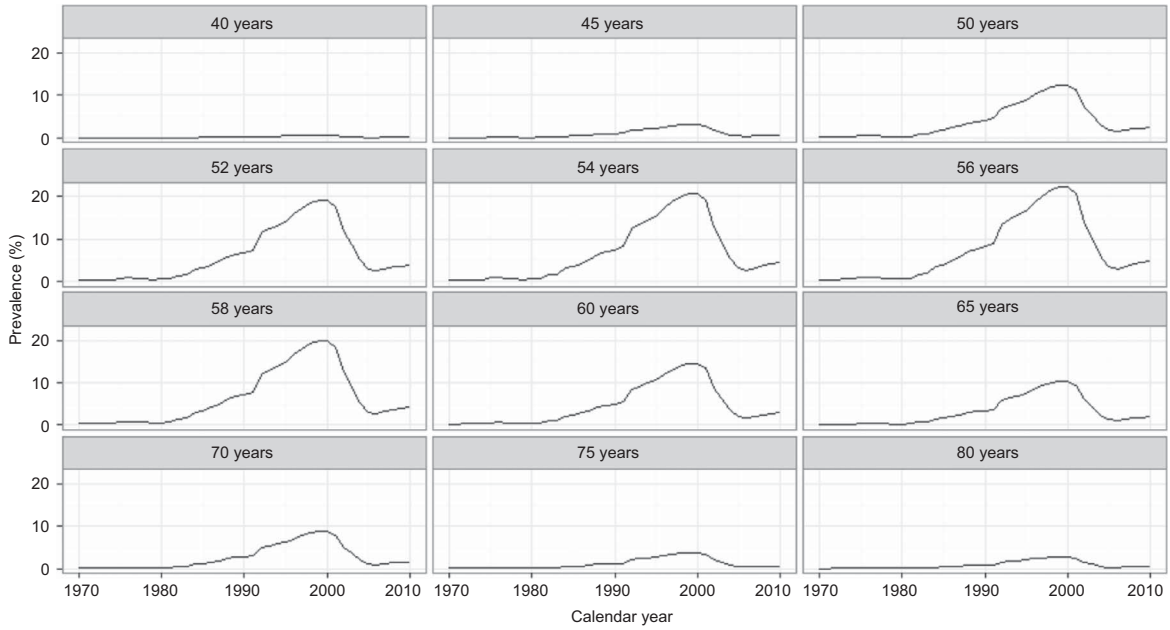

Fig. 3. Estimated prevalence of oral estrogen–progestin use by age, 1970–2010.
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Our study has limitations. First, National Health and Nutrition Examination Survey data on postmenopausal estrogen–progestin use rely on self-reports. However, prior studies indicate good reliability and validity for self-reported hormone use.[44–46] Second, we relied on prescription dispensary data from several publications. Although these data may not precisely reflect actual use because some dispensed prescriptions may not be used, they arise from a broadly representative sample of prescription dispensaries across the United States. To account for unused prescriptions, we calibrated the prescription information to the National Health and Nutrition Examination Survey data. We did not have prescription drug data by age and therefore applied odds ratios between age groups from the National Health and Nutrition Examination Survey 1999–2010 data to the prescription data. This assumes that odds ratios of estrogen–progestin use between age groups were stable over time. We did not find evidence contradicting this, and the test for effect modification between age and time in the National Health and Nutrition Examination Survey data was not statistically significant. We interpolated estrogen use in 1993–1994, and the fraction of progestin among estrogen users in years in which no estimate of that fraction was available. Notably, the fraction of progestin use among estrogen users reported by other authors appears to have been relatively stable during these time periods.[6,8,13,14] Nevertheless, our estimates only approximate true estrogen–progestin use if our assumption of stable odds ratios holds true and if the fraction of progestin use among estrogen users did not fluctuate much in the 1990s. We only modeled estrogen–progestin estimates for age groups 40–84 years, but prevalence in women aged younger than 40 years and 85 years and older is very low.[36] Finally, our results reflect oral estrogen–progestin use, because detailed data on use of patches, creams, suppositories, and injections was not available from the National Health and Nutrition Examination Survey throughout the duration of the study period. Notably, we previously reported that 90% of women reporting use of postmenopausal hormones in the National Health and Nutrition Examination Survey during 1999–2010 used oral preparations.[31]

Our results show the evolution of estrogen–progestin use during a 40-year period in which the evidence base for benefits and harms grew from nearly no evidence to a steadily increasing number of observational studies and finally to randomized trial data.[12,47–51] While demonstrating the capacity for the clinical community to rapidly respond to new evidence, these trends also illustrate susceptibility toward elevated prescription use in the absence of definitive evidence. Future studies evaluating the use of low-dose, short-duration, and other alternative postmenopausal hormone preparations will be needed to study the next chapter of hormone therapy in the United States.

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