message is that agents considered as either biosimilars or follow-on biologics should be regarded as essentially different from the innovator biologic by virtue of subtle differences in the manufacturing and/or purification process. These agents must undergo formal regulatory approval and they should be marketed in the context of a strong pharmacovigilance infrastructure. In this regard, the EMEA has provided a well-thought-out process for regulatory approval, and the European Union, like the United States, has robust pharmacovigilance in place.


Sai R. Keithi-Reddy1 and Ajay K. Singh1
1Renal Division, Brigham and Women’s Hospital, Boston, Massachusetts, USA
Correspondence: Ajay K. Singh, Renal Division, Brigham and Women’s Hospital, 75 Francis Street, Boston, Massachusetts 02115, USA.
E-mail: asingh@partners.org

Hormone therapy and loss of kidney function

To the Editor: We read with interest the stimulating article by Ahmed et al.1 on the association of oral hormone replacement therapy and kidney function in postmenopausal women.

The authors reported the baseline characteristics of the groups by categorical hormone therapy use. There was a significant difference in terms of the use of nonsteroidal anti-inflammatory drugs and diuretics. The groups namely ‘Estrogen only’ (46.8%) and ‘Progestin only’ (52.5%) had a higher percentage of patients on diuretics. The percentage of patients on nonsteroidal anti-inflammatory drugs was higher (45.3%) in the ‘Estrogen only’ group. The elderly (all 66 years old or older) made up the entire data population. This makes the subjects more vulnerable to the effects of both nonsteroidal anti-inflammatory drugs and diuretics on the renal function. Although other factors were analyzed in multivariate analysis, we are surprised that the authors did not include diuretics in the analysis. These drugs are known to affect effective circulating volume and renal function.2,3 Logistic regression analysis has shown the greatest decline of glomerular filtration rate in the ‘Progestin only’ group (Δ, 3.98; confidence interval: −0.30, 8.26) followed by the ‘Estrogen only’ group (Δ, 1.21; confidence interval: 0.28, 2.14), but the ‘Combined group’ had the least decline in glomerular filtration rate (Δ, 0.99; confidence interval: −0.56, 2.54) with large confidence intervals.1 They did not offer a plausible explanation for this discrepancy. We hope that they have a reasonable explanation for this, or is this just a statistical finding? It will be interesting to see their results with the inclusion of diuretic use in the analysis.


Aniruddha V. Palya1, Bulent Cuhaci1 and Karthik M. Ranganna1
1Division of Nephrology, Drexel University College of Medicine, Philadelphia, Pennsylvania, USA
Correspondence: Aniruddha V. Palya, Division of Nephrology, Drexel University College of Medicine, 245 N. 15th Street, 6th Floor, suite 6109, Mailstop 437, Philadelphia, Pennsylvania 19102, USA.
E-mail: Aniruddha.Palya@DrexelMed.edu