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Ethinyl estradiol and levonorgestrel patch phase 3 data clarification

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Letter to the Editor

**Ethinyl estradiol and levonorgestrel patch phase 3 data clarification**

I was excited to see the published results from the Phase 3 study of the transdermal delivery system (patch) with ethinyl estradiol and levonorgestrel by Dr. Nelson and colleagues [1]. The information will be helpful as providers and patients decide if this new option provides additional convenience or benefit as compared to other available combined hormonal methods. Clarification of two points with incomplete data presentation would be helpful for readers.

First, the study reports six venous thromboembolic events (VTEs) in five participants. The authors state the fifth participant did not experience the VTE event while using the patch and considered this VTE unrelated. However, no details are provided as to how remote from treatment the event occurred. For example, if the event occurred one week after treatment, the reader might come to a different conclusion. Without details, readers cannot be reassured by the presented information.

Second, the presentation of unscheduled bleeding data as mean  $\pm$  standard deviation is statistically incorrect as the standard deviation cannot exceed the mean when a negative value cannot occur. In such circumstances, the data is not normally distributed and median (with interquartile range) would be a more appropriate statistic. Use of medians would allow the reader to truly understand the bleeding data and provide appropriate counseling to patients.

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## **Reference**

1. Nelson AL, Kaunitz AM, Kroll R, Simon JA, Poindexter AN, Castaño PM, et al. Efficacy, safety, and tolerability of a levonorgestrel/ethinyl estradiol transdermal system: Phase 3 clinical trial results. *Contraception* 2020, doi: <https://doi.org/10.1016/j.contraception.2020.11.011>.

## **Conflicts of Interest**

Dr. Creinin serves on an Advisory Board for Evofem, Mayne, Merck & Co., Searchlight and TherapeuticsMD and is a consultant for Danco, Estetra, Mayne, Medicines360, and Merck & Co. His department receives research funding for contraceptive research from Daré, HRA Pharma, Medicines360, Merck & Co. and Sebela.