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## Vaginal Leakage: An Unappreciated Influence on Effectiveness of Agents in Vaginal Gels

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### OBJECTIVES

Effectiveness of vaginal gels might differ among women due to vaginal leakage. Our objective was to estimate and explain the variability of leakage of three vaginal products.

### METHODS

Three products were compared in a randomized trial. 48 healthy women were allocated to 2.5 ml Conceptrol, 2.5 ml KY Jelly, 2.5 ml of cellulose sulfate (CS) or 5.0 ml CS. Evaluation of leakage was measured by change in sanitary pad weight during 10 hours after gel insertion at bedtime. We conducted a secondary analysis of factors potentially related to gel leakage.

### RESULTS

Participants' median age was 33 (range:19-47); most were Caucasian (66%) and parous (55%). Median pad weight change was 1.93 gm (range: 0.03 to 6.2 gm). Leakage differed by product, and also differed between women using the same product. There was no significant difference in vaginal leakage by history of vaginal delivery, by duration of time wearing the pad, by age or by product osmolality. Two products had similar osmolalities; the third had higher osmolality but intermediate leakage. Assuming two-fold dilution and looking at only the 2.5 mL doses, average leakage amounts of women in the lowest and highest quintiles were 10% and 71% of the administered doses.

### CONCLUSION

Leakage is variable and difficult to explain. If bioavailability and effectiveness are related to vaginal persistence of gel, then variation of leakage between individuals is a significant issue. Additional research is needed to evaluate other approaches such as nonwoven textile devices or vaginal rings, in order to reduce variability in vaginal drug delivery.