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The Power Of Posture. Aguilar, Naudi. Pharmacokinetics and safety of umbral and non-umbral vaginal rings of estradiol in premenopausal women. To evaluate the safety and pharmacokinetics of 4 weeks of daily vaginal administration of highly pure 17beta-estradiol (E(2)) micro-encapsulated in 3 different polymers (poly(D,L-lactide), poly(DL-lactide-co-glycolide), and poly(DL-lactide/glycolide)) in healthy premenopausal women. Randomized, placebo-controlled trial. The Population Research Centre, Faculty of Health Sciences, McMaster University, Hamilton, Ontario, Canada. Premenopausal women (n=41) were randomly allocated to receive 2 flexible E(2) vaginal rings, which were either umbral or non-umbral, daily for 4 weeks. Blood samples were collected before and after daily insertion, and in week 5. The primary safety endpoint was plasma E(2) concentrations at various timepoints. Plasma E(2) concentrations were measurable within the first hour after insertion of the first E(2) vaginal ring. Plasma concentrations were significantly increased in umbral (2.02 +/- 0.63 pg/ml at 4 h) and non-umbral (2.46 +/- 1.72 pg/ml at 4 h) compared with baseline (1.12 +/- 0.46 pg/ml). There was no significant difference in peak E(2) concentration, area under the curve to 4 h, or half-life between umbral and non-umbral rings. No serious adverse events were reported. The incidence of local adverse events was 15% in the umbral and 22% in the non-umbral groups. The mean E(2) levels in all women who gave informed consent and had at least 2 blood samples were 3.01 +/- 1.75 pg/ml at 4 h after insertion of the first ring, consistent with the steady-state concentrations produced with 10 microg oral E(2). Vaginal E(2) rings are generally well-tolerated in healthy premenopausal women. The incidence of local adverse events was low. There was no difference between umbral and non-umbral rings in plasma concentration or other pharmacokinetic parameters. Both rings produced similar steady-state plasma

concentrations over the 4 weeks of treatment. Tidal Energy About
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