8 WHO RANDOMIZED TRIAL OF VITAMIN C & E SUPPLEMENTATION AMONG WOMEN AT HIGH RISK FOR PREECLAMPSIA AND NUTRITIONAL DEFICIENCY

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OBJECTIVE: Previous trials of Vitamin C & E supplementation of pregnant women at risk for preeclampsia (PE) revealed no protective effect and "overdosing" possibly caused harm. A study paralleling the UK-VIP trial was designed to prevent PE in high risk women that specifically targeted populations with nutritional deficiencies.

STUDY DESIGN: Women at risk for PE and nutritionally deficient were randomized before gestational wk 20 to either daily vitamin C (1 gm) and E (400IU) or placebo in double blind fashion. Primary outcomes were PE, LBW (< 2500 gr.), SGA (<10%) and perinatal mortality. WHO centers in India, Peru, South Africa, and Vietnam participated.

RESULTS: 687 women were randomized to supplements; 678 to placebo. Gestational ages, (18.1 wk), clinical and demographic characteristics and BP were similar at randomization. Differences in risk factors between groups were minor, the most common being previous PE (supplements 41.6 %; placebo 41.3%). Loss to follow-up (<2%) was similar. Supplementation did not reduce PE (RR: 1.0; 95% CI 0.9-1.3), eclampsia (RR: 1.5; 95% CI 0.3-8.9), severe PE (RR: 0.8; 95% CI 0.4-1.3) or severe gestational hypertension (RR: 0.8; 95% CI 0.6-1.1). Adjusting for maternal age didn't alter these results. LBW and SGA and preterm delivery were also similar. (RR: 0.9; 95% CI 0.8-1.1, RR: 0.9; 95 % CI 0.6-1.1 and RR: 0.9; 95% CI 0.8-1.1, respectively). Perinatal mortality tended to be lower with supplementation (RR: 0.8; 95% CI 0.6-1.2) but the trial was underpowerd to test this outcome. Stratified analysis for women with history of PE demonstrated similar rates in both groups (26% supplement; 28% placebo). Women with BMI>30 had marginally less PE (RR: 0.6; 95% CI 0.3-0.99).

CONCLUSION: Supplementation with vitamin C & E did not prevent PE, reduce its severity nor lower adverse neonatal outcomes in this high risk population with low nutritional status.

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