Off-label treatment of hyperemesis gravidarum with transdermal clonidine: safety and clinical outcomes

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**Objective.** Improvement of symptoms of severe persistent Hyperemesis Gravidarum (HG) with use of transdermal (TD) clonidine was described and first reported in a series of cases (Obstetric Medicine 2011) and a randomized controlled pilot study to study the efficacy was completed (BJOG, 2014). A clinical outcome database was set up under permission of the local institutional review board. Informed consent was signed by all participating women.

**Materials and Methods.** n = 270 women were prospectively followed throughout pregnancy until delivery after prescription of TD clonidine in the first and mid trimester for severe unresponsive HG (PUQE score at admission > 12 and no improvement with standard treatments). Median weeks at start: 10 (6-21) with a median duration of treatment of 12 weeks (1-31); 34% continued treatment until delivery.

**Results.** Median gestational age at delivery of the 270 women enrolled was 39 weeks with prematurity < 37 weeks in 5.6%. Cesarean Section rate was 35%. PROM occurred in 12% of pregnancies. Median birthweight was 3260 grams (2010-4300) and median percentile for singletons 48.5; LBW newborns < 2500 grams were 8% SGA < 10th percentile occurred in 7.4%. One intrauterine fetal death and one perinatal death were reported for other causes. Prevalence of major birth defects was < 2% (mainly cardiac septal defects). Side effects were contact dermatitis (24%) and symptomatic hypotension (2%). Dropouts: n = 6 for systemic intolerance (tiredness, fatigue, hypotension).

**Conclusions.** Off-label use of TD clonidine in selected cases of HG appears safe and effective in clinical practice.