Twelve Month Safety and Efficacy of Low Dose Mifepristone for Uterine Fibroids

SH Eisinger,* T Bonfiglio, K Fiscella, S Meldrum, DS Guzick. (University of Rochester School of Medicine & Dentistry)

Objectives: to assess long-term effects of low dose mifepristone on fibroid regression, symptoms, and endometrial pathology.

Methods: Prospective, open-label, randomized, controlled trial of 5 v. 10 mg mifepristone daily for 1 year, in 40 women with large, symptomatic fibroids. Measurements were made by ultrasound determination of the total volume of the uterus. Symptoms were assessed by questionnaire. Endometrial pathology was determined by endometrial biopsy. A subset of subjects was followed after cessation of mifepristone therapy.

Results: Mean uterine volumes decreased by 48-49 % in both groups after 6 months of mifepristone and by 52-53 % in both groups after 12 months. Amenorrhea occurred in 61-65% at 6 months, and 40-70 % at 12 months. Anemia was corrected in all anemic subjects. Eighty endometrial biopsies were performed. Simple hyperplasia was seen in 5 of 36 (13.9 %) subjects at 6 months; all cases occurring in the 10 mg group (Fisher exact P test = 0.04). At 12 months 1 of 21 (4.8 %) subjects had minimal hyperplasia, also in the 10 mg group (Fisher exact P test = 0.48). No endometrial sample showed cytologic atypia. Nine women were followed post-treatment for an average of 5.7 months. Uterine volumes increased among most of these subjects, though remained on average 42% less than baseline.

Conclusions: Long-term administration of low dose mifepristone results in fibroid shrinkage and amelioration of symptoms, modest rates of low-grade endometrial hyperplasia, but no evidence of atypia. Regrowth occurs following cessation of the drug, although slowly in some subjects**.** Mifepristone may be a useful treatment for fibroids. Further studies are required to assess quality of life improvement, to clarify the optimal dose, and to assess the value of interrupted therapy or progestin withdrawal.