

Uterine Leiomyoma Longitudinal Interventions Studies: The Fibroid Growth Study Barbara J. Davis

The Fibroid Growth Study (FGS) was designed to define growth characteristics of uterine leiomyoma in a clinically relevant population of women as a foundation for developing therapeutics for this highly prevalent disease of women. The FGS tested the hypothesis that uterine leiomyomas are heterogeneous in terms of their growth characteristics and in their clinical symptoms or outcomes and that differences in leiomyoma growth dynamics can be discriminated by molecular markers and cellular phenotypes. 120 women, with a minimum of 2 to 5 cm-diameter fibroids determined by ultrasound, completed from 1 to 4 magnetic resonance imaging (MRI) sessions over 1 year at the University of North Carolina. The last MRIs were performed in December 2004. Each participant donated blood and urine and completed an initial extensive medical history followed by monthly questionnaires for the duration of their study participation. 46 participants elected surgical intervention during the study, and 31 women consented to donate tissue for histological and molecular analysis. The average age of study participants was 39.1 (range 24-54) years-old. The ethnic and racial distribution of the participants included 48% African American, 41% White, 4% Hispanic, 1% Asian, 1% Native American, and 8% identified themselves as other. Volumetric analysis was done on MRI studies of 98 women using a computer-aided image analysis program (VETOT). The number of fibroids per participant ranged from 1 to 11. A total of 1076 volumes were calculated. Preliminary data analysis suggested that the change in volume was significantly different depending on size and location of the tumor. Fibroids greater than 50 cm³ ("large" tumors) and between 7 cm³ and 50 cm³ ("medium" tumors) had a significantly greater increase in volume over time than fibroids less than 7 cm³ ("small" tumors). Intramural fibroids increased in volume at a slower rate than fibroids located in the subserosa or submucosa. Rate of growth was similar among women of different races or ethnicity. Rate of tumor growth was not different between women that elected surgery. However, bleeding, pain and discomfort scores were greater in women that elected surgery and decreased after surgery. Women also elected surgery if they were attempting pregnancy. Histologically, large tumors had significantly more fibrous connective tissue than smaller tumors. These data suggest that fibroid growth is dependent on accumulation of fibrous connective tissue but that growth itself is not a determinant of why women elect surgical intervention for therapy.