

## **GS2-06: Patient Reported Outcomes Following Active Monitoring or Surgery (+/- Radiation) for Low Risk DCIS in the Comparing an Operation to Monitoring, with or without Endocrine Therapy (COMET) Study (AFT-25)**

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**Background:** Data comparing patient-reported outcomes (PROs) comparing management strategies for low-risk ductal carcinoma in situ (DCIS) are lacking. Comparing an Operation to Monitoring, with or without Endocrine Therapy (COMET), for low-risk DCIS is a prospective randomized controlled trial that evaluated the effects of active monitoring (AM) compared to breast surgery (lumpectomy followed by radiation vs. unilateral mastectomy vs. bilateral mastectomy) on PROs including quality of life (QOL), anxiety, depression and specific symptoms.

**Methods:** We compared PROs among patients who completed questionnaires at baseline prior to randomization, at 6 months and 1 year after randomization, then annually in years 2-5. Patients completed validated measures that assessed QOL, anxiety and depression and breast cancer treatment-related symptoms using the SF-36, EQ-5D-5L, a modified 19-item version of the Breast Cancer Prevention Trial (BCPT) Symptom Checklist, the Breast-Q, four items from the Quality of Life in Adult Cancer Survivors (QLACS), the State Trait Anxiety Inventory (STAI) scale and the Center for Epidemiologic Studies Depression Scale (CES-D-10), as well as the Breast Cancer Pain and Brief Pain Inventory.

**Results:** We will present patient characteristics for the 997 patients who enrolled in the study and PRO questionnaire completion rates overall and within relevant subgroups to assess response bias. The analysis of differences by randomized group will include differences in the SF-36, STAI and CES-D, as well as the Breast Cancer Pain, Brief Pain Inventory and BCPT symptoms. We will also assess group differences over time and within specific subgroups (e.g., by age).

**Conclusion:** In this analysis of PROs after active monitoring or surgical +/- radiation management for low-risk DCIS, quality of life, anxiety, depression and symptom patterns (severity, recovery, decline etc.) likely differed between the two groups; how they differed will be presented and whether these differences persisted over time.