GS2-05: Early Oncologic Outcomes Following Active Monitoring or Surgery (+/- Radiation) for Low Risk DCIS: the Comparing an Operation to Monitoring, with or without Endocrine Therapy (COMET) Study (AFT-25)

Presenting Author(s): Eun-Sil Hwang

Abstract Number: SESS-3481

Background: Over 50,000 women in the United States will be diagnosed with ductal carcinoma in situ (DCIS) this year alone. Almost all of these diagnoses will be made in completely asymptomatic individuals with a highly variable risk of progression to invasive cancer. In some low-risk malignancies, "watchful waiting," is offered as a treatment option. Such an approach is likely reasonable for some DCIS and could reduce the harms of treatment while helping to identify those most likely to benefit from more aggressive therapy. To date, this approach has not been tested in a clinical trial setting.
Methods: The COMET study (Comparing an Operation to Monitoring, with or without Endocrine Therapy for low risk DCIS; AFT-25) is a large pragmatic randomized non-inferiority trial that compares oncologic outcomes between patients randomized to guideline concordant care (GCC; surgery +/- radiation therapy) or active monitoring (AM). The study population were women seeking treatment for DCIS at one of the Alliance Clinical Trial sites. Eligible participants were age>40 with low-intermediate grade estrogen and/or progesterone receptor positive, HER2 receptor negative (if HER2 tested) DCIS on core biopsy without microinvasive or invasive cancer. The choice for endocrine therapy was offered in both groups. Participants in the AM group had surgical intervention only upon diagnosis of invasive progression. All study endpoints were collected prospectively.
Results: This is the first planned interim Intention-to-Treat (ITT) analysis of the COMET trial primary endpoints at a median follow up of XX months. We will present patient characteristics for the 997 participants who enrolled in the study and were randomized to either GCC or AM. The primary endpoint to be presented is whether the ipsilateral invasive cancer rate for AM is non-inferior to that for GCC. Characteristics of invasive cancer events in the two groups will be compared. Secondary endpoints (rates of mastectomy, radiation, chemotherapy) and survival endpoints between groups will also be presented.
Conclusion: These data will provide the first randomized trial evidence of whether an active monitoring strategy is a safe alternative for women with low-risk DCIS. Longer-term data could support practice changing guidance as to how DCIS is managed and treated and will have future implications for treatment guidelines for these excellent prognosis patients.