

Abstract #51753

The use of Ki67 to predict benefit from adjuvant tamoxifen in node-negative, estrogen receptor-positive patients.

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Abstract Text:

Background: There is a strong evidence in the literature that Ki67 is prognostic for breast cancer-specific survival (BCSS). There are controversial studies regarding its predictive role for adjuvant hormone therapy. We examined whether Ki67 can predict benefit from adjuvant tamoxifen in node-negative, estrogen receptor-positive (ER+) patients. **Methods:** Patients with early-stage breast cancer who were diagnosed between 1986 and 1992 and referred to the British Columbia Cancer Agency were included in this study. All patients were ER (+), node negative, had T1/T2 tumors, and had not received adjuvant chemotherapy. Median follow-up was 12.4 years. Ki67 status was determined by immunohistochemistry using 10% cells staining as a cutoff value. Associations between whether tamoxifen was used as adjuvant chemotherapy, Ki67 status, and BCSS were assessed using Cox proportional-hazards models and Kaplan-Meier plots. **Results:** 710 patients met all criteria. Ki67 was a strong negative prognostic parameter (HR = 1.67, p = 0.01). Overall tamoxifen had no effect, HR = 0.92, p = 0.50. However, in the subset of patients who had a low Ki67, the patients who were treated with tamoxifen benefited, HR = 0.63, p = 0.08, while the subset with high Ki67 did not, HR=1.07, p = 0.65; test for interaction, p=0.01. **Conclusions:** Our study confirms Ki67's role as a prognostic marker. Moreover, low Ki67 predicted benefit from tamoxifen in the ER (+), node-negative patients. We report that low Ki67 expression was associated with a HR of 0.63 for tamoxifen. We estimate that if tamoxifen assignment had been based on randomization, an HR of about 0.70 would be expected based on the EBCTCG data. If future randomized studies using an accepted methodology and cutoff point for Ki67 find it comparable to more costly genetic tests, Ki67 may prove useful in predicting benefit from systemic adjuvant treatment in areas of the world where funding is a concern. **BCSS at 10 years of follow-up for node-negative, ER (+) in patients not receiving adjuvant chemotherapy**

		No tamoxifen		Tamoxifen	
	n	BCSS	s.e.	BCSS	s.e.
All patients	210/710	0.918	0.011	0.892	0.022
Low Ki67	99/408	0.942	0.012	0.979	0.015
High Ki67	111/302	0.887	0.019	0.823	0.038

