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Title: Tamoxifen and contralateral breast cancer (CBC) risk for BRCA1 and BRCA2 mutation carriers: an updated analysis of data from the Kathleen Cuningham Foundation Consortium for Research into Familial Breast Cancer, the International BRCA1 and BRCA2 Carrier Cohort Study and the Breast Cancer Family Registry.

Body: Background: Findings from an analysis published in 2013, using combined retrospective and prospective data pooled from 3 cohort studies, were consistent with tamoxifen use after 1st breast cancer (BC) being associated with reduced CBC risk for both BRCA1 and BRCA2 mutation carriers, although the analysis of prospective data alone (based on 100 incident CBCs) gave inconclusive results. The association did not differ by estrogen receptor (ER) status of the 1st BC, suggesting that tamoxifen may be a useful secondary BC prevention agent for mutation carriers regardless of the ER status of their 1st BC. The aim of this updated analysis was to assess these associations after incorporating data from an additional 1,279 mutation carriers and with further follow-up providing 153 additional prospective CBC events. Methods: Eligible women were BRCA1 and BRCA2 mutation carriers diagnosed with unilateral BC since 1970 and with no other invasive cancer or tamoxifen use before their 1st BC. They were followed up from their 1st BC (or, for the prospective analysis, from the later of recruitment and 1st BC diagnosis) to the development of CBC or censoring (at contralateral mastectomy, death or loss to follow-up). Hazard ratios (HRs) for CBC associated with tamoxifen use were estimated using Cox regression, adjusting for year and age of diagnosis, country and bilateral...
oophorectomy; analyses were also stratified by ER status of the 1st BC. **Results:** This 2017 analysis includes 3,743 mutation carriers (BRCA1 2,343; BRCA2 1,400) with 21,436 person years of follow-up. Compared with the 2013 analysis, the strengths of the inverse associations were attenuated after including the additional data.

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<tr>
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*Combined = retrospective and prospective, N=number, BRCA1 & BRCA2=mutation carriers, Tam 1st BC= Tamoxifen for 1st Breast Cancer

In this updated prospective analysis, the inverse association between tamoxifen use for 1st BC and CBC risk was most apparent for women with ER positive 1st BC, especially for BRCA2 mutation carriers: **BRCA1** ER positive HR=0.45 (95% CI 0.17-1.22, p=0.12), **BRCA1** ER negative HR=0.87 (95% CI 0.45-1.67, p=0.67), **BRCA2** ER positive HR=0.33 (95% CI 0.15-0.74, p<0.007), **BRCA2** ER negative HR=1.12 (95% CI 0.27-4.70, p=0.88).

**Conclusions:** Tamoxifen use for 1st BC might reduce CBC risk for mutation carriers, but predominantly for those with an ER positive 1st BC. These data do not support use of tamoxifen to prevent CBC for mutation carriers with ER negative BC.

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2. - Roger L Milne.
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