Recurrence Following Initiation of Low Dose Tamoxifen for Breast Cancer Prevention: A Real-World Study

Karishma Vijay Rupani[1], Erin Moshier[2], Cao Jin[3], Diana Jaber[4], Nicole Casasanta[5], Catherine Wu[6], Amy Tiersten[7], Rima Patel[7]

1. Division of Hematology and Medical Oncology, Department of Medicine, Icahn School of Medicine at Mount Sinai, New York, NY, 2. Division of Biostatistics, Department of Population Health Science and Policy, Icahn School of Medicine at Mount Sinai, New York, NY, 3. Department of Pathology, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, New Hyde Park, NY, 4. Department of Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL, 5. Division of Hematology and Medical Oncology, Department of Medicine, Yale School of Medicine, Yale Cancer Center, New Haven, CT, 6. Department of Anesthesiology, Perioperative and Pain Medicine, Icahn School of Medicine at Mount Sinai, New York, NY, 7. Denotes co-final authors, Division of Hematology and Medical Oncology, Department of Medicine, Icahn School of Medicine at Mount Sinai, New York, NY

BACKGROUND

- Patients diagnosed with non-invasive breast lesions such as DCIS, LCIS, ADH, and ALH are at increased risk of developing invasive breast cancer.
- The TAM-01 study found that low-dose tamoxifen (LDT) for 3 years for chemoprevention resulted in an approximate 50% risk reduction in breast cancer events compared to placebo.
- A recent study at our institution showed that the uptake of LDT was 19%.[1]

STUDY DESIGN

January 2019 - December 2021

Retrospective Review

Patient cohort: DCIS, LCIS, ADH, and/or ALH patients on LDT

Data Collection:
- Rates of LDT completion
- Recurrence patterns & characteristics

Statistical analysis:
Time-dependent Cox regression model

BASELINE PATIENT CHARACTERISTICS

Table 1: Baseline characteristics of patients initiated on LDT at initial diagnosis

Demographics	Number of Patients (%)
Total number of patients	81 (100)
Postmenopausal	32 (39)
Premenopausal	49 (61)
Pathologic Diagnosis	
DCIS	32 (39)
LCIS / ADH / ALH	49 (61)
LDT Treatment Outcomes	
Completed 3 years of LDT	54 (67)
Discontinued early due to adverse events	24 (30)
Discontinued due to recurrence	1 (1.2)
Discontinued to attempt pregnancy	1 (1.2)
Discontinued due to new malignancy	1 (1.2)

RESULTS

Table 2: Recurrence patterns for patients initiated on LDT at initial diagnosis

Initial Diagnosis	Menopausal Status	Completed 3 years of LDT? Reason for discontinuation	Type of Recurrence	Recurrence Treatment
Recurrence patterns in patients who completed 3 years of LDT (n=3)				
LCIS	Premenopausal	Yes	Contralateral ADH	Continued tamoxifen 5 mg
LCIS	Premenopausal	Yes	Ipsilateral ALH	Surveillance
ALH	Premenopausal	Yes	Contralateral ADH and ALH	Lumpectomy
Recurrence patterns in patients who discontinued LDT early (n=5)				
LCIS and ADH	Premenopausal	No Back pain, headaches, ocular issues, mood changes	Ipsilateral LCIS and ADH	Surveillance
LCIS and ADH	Premenopausal	No Severe migraines	Ipsilateral LCIS, ADH and ALH	Lumpectomy
LCIS and ADH	Premenopausal	No Mood changes, bloating	Ipsilateral LCIS and ADH	Surveillance
LCIS, ADH and ALH	Postmenopausal	No Hot flashes, weight gain	Ipsilateral LCIS	Surveillance
ADH and ALH	Postmenopausal	No Developed recurrence on LDT	Ipsilateral HR, HER2+ IDC, DCIS	Lost to follow up

- At a median follow up time of 4.74 years, the overall recurrence rate was 10% (N=8).
- Among the 27 patients who discontinued LDT early, 19% (N=5) recurred: 4 after discontinuing LDT due to AEs and 1 recurred while on LDT.
- Among 54 patients who completed LDT, 6% (N=3) recurred: 1 during treatment and 2 after 3 years of LDT.

Author Contact: karishma.rupani@mountsinai.org

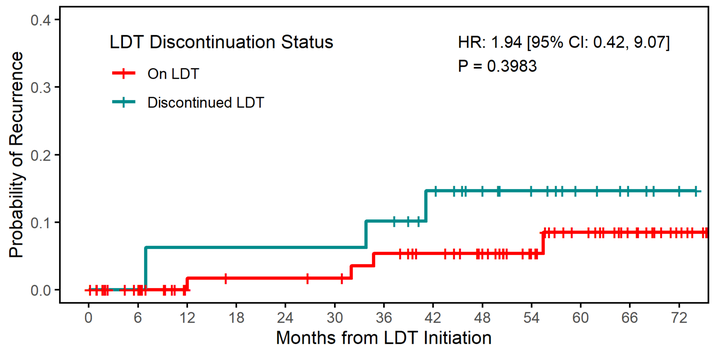


Figure 1: Probability of recurrence for patients initiated on LDT

- Based on the time-dependent Cox model, the estimated 5-year probability of recurrence was 8% for patients who completed LDT and 15% for those who discontinued early.
- Early discontinuation was associated with nearly a two-fold increased risk of recurrence, although this was not statistically significant due to the low event rate [HR: 1.94; 95% CI: 0.42-9.07; p=0.40].
- All recurrences were in patients who had LCIS, ADH, and/or ALH.
- Most recurrences (75%) were in premenopausal patients, and the 3 patients who recurred after completing 3 years of LDT were all premenopausal.
- Except for 1 patient who developed HR-, HER2+ IDC and DCIS while on LDT, all other recurrences, irrespective of completion of 3 years of LDT, were atypia or LCIS.

References:
1. Patel R, Jin C, Jaber D, et al. Low Dose Tamoxifen for Breast Cancer Prevention: A Real-World Experience. Clin Breast Cancer. 2025;25(3):283-290. doi:10.1016/j.clbc.2024.12.020