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Title: **Shall patients' anxiety influence surgical decisions for atypical breast lesions? A substudy of the prospective NOMAT trial.**

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Atypical breast lesions (ABL) identified on image-guided biopsies are associated with both a 10-25% probability of concomitant cancer at surgery, and a long-term increased risk of breast cancer. Many such ABL may be considered as part of the “overdiagnosis” of current breast cancer screening strategies. Proposing a systematic surgery, as has long been done, leads to procedures with no cancer associated on definitive specimen in 75 to 90% of women which can be considered as unnecessary. Current guidelines (from NCCN and (1)) recommend to attempt avoiding surgery of lesions at low risk of upgrading (based on pathological classification or models), with close follow up. However, some patients may be less tolerant to uncertainty and have a lower acceptance of follow-up strategies. NOMAT (clinicaltrials.gov NCT02523612; French Ethics Committee approval 2015-A00045-44) is a national multicenter prospective trial (2) whose primary objective was to validate a prediction model for upgrade at surgery, among women with atypical breast lesions. A secondary objective was to describe the evolution of state anxiety and identify factors associated with this evolution.

Women aged 18 or older were eligible for the study if diagnosed with an ABL (including flat epithelial atypia [FEA], atypical ductal [ADH] or lobular hyperplasia [ALH] and lobular carcinoma in situ [LCIS] of classic type) on image-guided biopsy for breast microcalcifications were included in this trial between July 7, 2015 and May 29, 2018, in 18 French centers (2). The final patients’ diagnoses were classified as “cancer” if either an invasive adenocarcinoma, or a ductal carcinoma in situ (DCIS) or a pleomorphic lobular carcinoma in situ (LCIS) was retrieved on the surgical specimen.

Psychological self-reported outcomes were collected at baseline, including anxiety (State-Trait Anxiety Inventory, STAI) and intolerance of uncertainty (Intolerance of Uncertainty Scale). “Before surgery” was at the end of the surgical consultation meaning after the announcement of ABL on biopsy, the risk of cancer associated and explanation on surgical procedure. Patients completed the state-anxiety scale again post-surgery (between day 21 and day 30).

We compared the state-anxiety scores after versus before surgery using a paired Wilcoxon-Mann-Whitney test. The association between candidate variables and changes in anxiety score levels before versus after surgery were assessed using a Wilcoxon-Mann-Whitney test. Statistical analyses were performed on R version 3.6.1.

Two hundred forty one (80.3%) and 210 (70.0%) women completed the STAI-state inventory questionnaire before and after surgery respectively. The mean state-anxiety score of respondents was significantly lower after surgery in the global population (42.70 [SD 13.07] vs 35.37 [SD 11.68], $p < 0.001$) as well as in patients who did not get a final diagnosis of cancer (42.63 [SD 13.06] vs 33.59 [SD 10.76], $p < 0.001$).

One hundred ninety-nine patients (66.3%) answered both questionnaires. Among them, 118 patients (59.3%) had stable, 65 (32.7%) decreased and 16 (8.0%) increased anxiety levels after surgery (Figure 1). Patients with increased anxiety were younger than patients with decreased or stable levels (n=180) (mean: 50.07 years [SD: 8.06], vs 55.52 years [SD: 9.37], p=0.026). Patients with decreased anxiety had a higher baseline STAI-Trait score than patients with increased or stable levels (n=118) (mean: 46.10 [SD: 8.81] vs 38.88 [SD: 8.84], p<0.001) and a higher baseline level of intolerance of uncertainty (mean: 62.29 [SD: 19.16] vs 53.32 [SD: 16.24], p=0.002). Of note, state anxiety and intolerance to uncertainty are highly correlated (Kruskall-Wallis p= 4.10⁻⁷).

Among 162 women who did not have cancer at surgery, 56 (34.6%) had a decreased, 98 (60.5%) a stable and 8 (4.9%) an increased STAI-state anxiety score. There again, the total score of intolerance to uncertainty at baseline was higher in patients with decreased anxiety as compared to the others (mean: 63.36 [SD: 18.74] vs 52.00 [SD: 14.85], p=0.0002). The form of ABL significantly affected the score of STAI-ETAT before surgery (p=0.004) and after surgery (p=0.01), patients with ADH were more anxious than patients with no ADH.

Overall, surgery allowed a decreased level of anxiety in one third of the women, whether they had a final diagnosis of cancer or not. These women had consistent higher anxiety and intolerance to certainty levels at baseline.

The present design raises, but cannot entirely answer the question whether surgical abstention would preclude such anxiety relief. In addition to clinical and pathological features (i.e age, initial radiological microcalcifications, focus size and complete radiological target excision after biopsy)(2, 3), breast surgeons should take into account psychological aspects, including anxiety associated with the situation, tolerance to uncertainty, and patients preferences overall, in the surgery decision balance. A well-conducted shared decision process appears of critical importance in this situation.

Declarations

Letter to editor

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1 figure

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Author Contribution:

Flore Salviat made data analysis; all authors have contributed to write and review the manuscript

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Figure 1 Evolution of state anxiety before and after surgery in patients who filled both questionnaires

