Breastfeeding After Hormone Receptor–Positive Breast Cancer: Results From the POSITIVE Trial

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ABSTRACT

PURPOSE We investigated breastfeeding patterns, behaviors, and association with breast cancer (BC) outcomes in women with early hormone receptor–positive (HR+) BC who had a live birth in the POSITIVE trial.

PATIENTS AND METHODS POSITIVE is a prospective trial that demonstrated no increased short-term risk of BC events in women with early HR+ BC who interrupted endocrine therapy (ET) to attempt pregnancy. We describe the frequency, duration, and laterality of breastfeeding and estimate the cumulative incidence of BC events by breastfeeding status.

RESULTS At a median follow-up of 41 months, 317 patients had at least one live birth and 313 were eligible for this analysis. A total of 196 of 313 (62.6%) patients breastfed. A total of 130 of the 167 women (77.8%) who had breast-conserving surgery breastfed, and 90 of 130 (69.2%) breastfed from the unaffected breast only. Sixty-six of the 146 women (45.2%) who underwent unilateral mastectomy breastfed. The frequency of breastfeeding was higher in women older than 35 years (67.6% *v* 55.7%) and in those without previous children (66.4% *v* 48.5%). Over half (103 of 196, 52.6%) of women breastfed their first live birth for >4 months (median 4.4 months; 95% CI, 4.0 to 5.3). The cumulative incidence of a BC event at 24 months from first on-study live birth was 3.6% and 3.1% in the breastfeeding and nonbreastfeeding groups, respectively (0.5% difference; 95% CI, −4.3% to 5.2%).

CONCLUSION In POSITIVE, two thirds of women who gave birth after BC diagnosis breastfed, mostly for 4 months or more. In early follow-up, we did not observe differences in BC-related events in women who breastfed compared with those who did not. These results are key for women who wish to pursue pregnancy and breastfeeding after BC.

ACCOMPANYING CONTENT

Appendix

Data Sharing Statement

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INTRODUCTION

With the rising trend of delaying childbearing, more women are diagnosed with breast cancer (BC) before starting or completing their families.[1] These women often inquire into the feasibility of future pregnancy and breastfeeding and whether either could have a detrimental impact on their disease outcomes.

Data on breastfeeding in women with a history of BC are limited to retrospective case series or surveys focused on the feasibility of breastfeeding in this setting.[2-5] Most of the published papers are qualitative analysis on <100 patients[6] or focus on specific patient populations,[7] and thus, the full picture of breastfeeding after BC and its potential impact on prognosis have not been adequately evaluated yet.

Recently, we reported the results of the POSITIVE trial, a prospective single-arm trial evaluating the safety of temporary interruption of endocrine therapy (ET) to attempt pregnancy in young patients with BC.[8] At a median follow-up of 41 months, no higher short-term risk of BC events was

CONTEXT

Key Objectives

Is breastfeeding feasible and safe for patients with breast cancer (BC) interrupting endocrine treatment to seek pregnancy?

Knowledge Generated

A total of 62.6% of included patients breastfed, and 52.6% of them breastfed for more than 4 months. Breastfeeding was more frequent in women who had breast-conserving surgery. In this group, breastfeeding was predominantly from the contralateral breast. The cumulative incidence of BC events at 24 months was 3.6% and 3.1% in the breastfeeding and nonbreastfeeding groups, respectively.

Relevance *(K.D. Miller)*

Breastfeeding is beneficial for babies and mothers but exposes women to higher estrogen levels, raising concern that it may increase the risk of recurrence. The POSITIVE trial provides reassuring data on the safety of pregnancy and the ability to successfully breastfeed after pregnancy without an obvious increased risk.*

*Relevance section written by *JCO* Senior Deputy Editor Kathy D. Miller, MD.

found. Here, we report the results of one of the main secondary end points of the trial: breastfeeding patterns, behavior, and relation to BC outcomes.

PATIENTS AND METHODS

POSITIVE is a prospective, international, multicenter, single-arm trial. Trial design, patient characteristics, and the primary end point analysis were previously published.[8,9] In brief, eligible patients had stage I to III BC, were 42 years or younger at enrollment, and received 18-30 months of ET before inclusion. The trial recruited 518 patients, in 116 centers, across 20 countries from December 2014 to December 2019.

The protocol specified a temporary interruption of ET for up to 2 years to allow for pregnancy, delivery, and breastfeeding, if desired and/or feasible. Data on breastfeeding were prospectively collected for the first pregnancy and included breastfeeding rate, laterality, and duration. All patients were strongly encouraged to resume ET after conclusion of pregnancy or breastfeeding (whichever was later) to complete 5-10 years as planned.

The study was conducted by the International Breast Cancer Study Group (IBCSG), which was responsible for trial design, data collection, management, and statistical analysis. Participating centers were affiliated with cooperative groups of the Breast International Group and the US National Clinical Trials Network.

The study was conducted in accordance with the International Council for Harmonisation Good Clinical Practice guidelines, the Declaration of Helsinki, and local clinical research regulations. The protocol was approved by the institutional review board at all participating centers. All patients provided written informed consent. Study progress was reviewed every 6 months by the IBCSG Data and Safety Monitoring Committee.

The evaluable data set consisted of women who had at least one live birth while on study. The breastfeeding pattern included duration for all patients and laterality in patients who underwent breast-conserving surgery (BCS).

The Kaplan-Meier method was used to estimate the duration of breastfeeding for the first live birth among those who initiated breastfeeding; all women who breastfed did so for at least the first live birth. If an offspring was still being breastfed at the time of the analysis, breastfeeding duration was censored at the most recent follow-up date.

The cumulative incidence of BC events (1 minus Kaplan-Meier) was estimated by breastfeeding status. For this analysis, using a landmark analysis approach, we redefined breast cancer–free interval (BCFI) from the time of first post-treatment live birth to the first invasive local, regional, or distant BC recurrence or the first instance of contralateral disease. Patients without a BCFI event were censored at the date last known to be alive and BC-free.

RESULTS

Patient Characteristics

At database lock, 497 women were evaluable for pregnancy, of whom 317 (63.8%) had at least one live birth (365 babies born; Fig 1). Of the 317 evaluable patients, four (1.2%) had bilateral mastectomy, two for bilateral disease and two for unilateral disease, and were removed from this analysis, leaving 313 eligible patients for breastfeeding analysis.

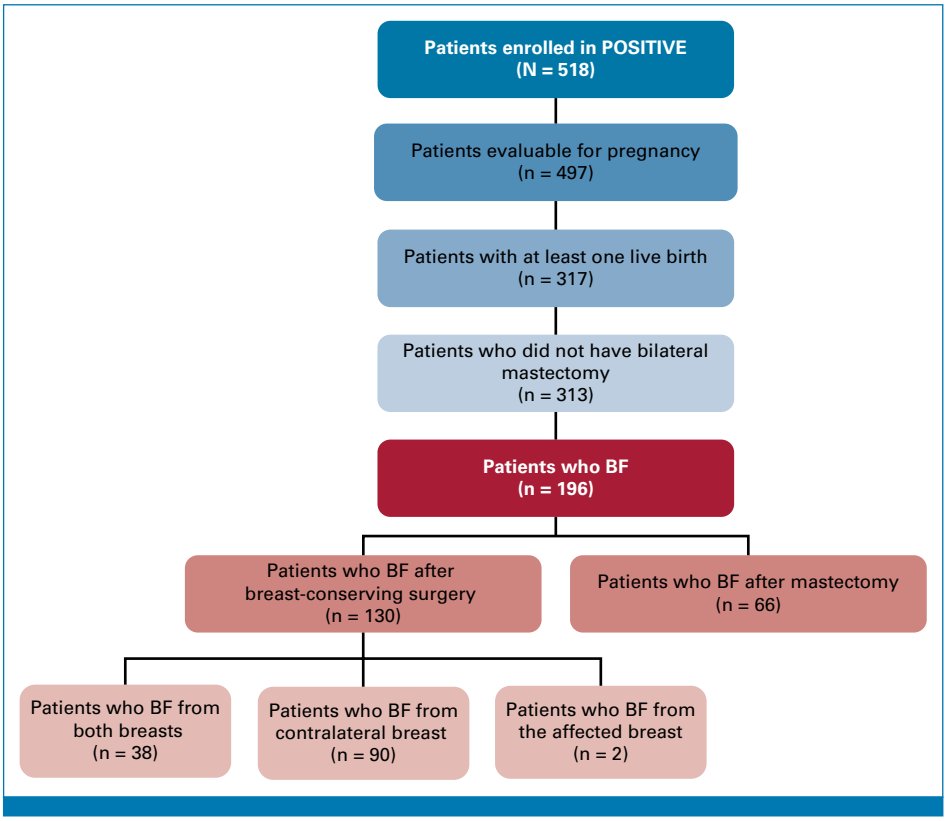

FIG 1. Trial enrollment and analysis population. BF, breastfed.

Among the 313 eligible patients, the median time from enrollment to first live birth was 18 months (IQR, 14-23). A total of 146 of 313 (46.6%) women had unilateral mastectomy, and 167 of 313 (53.4%) BCS. A total of 196 of 313 (62.6%) breastfed at least one child, including 163 who fed exactly one, 31 who fed two children, one who fed three, and one who fed four.

Breastfeeding Behavior

Figure 2 illustrates the frequency of breastfeeding according to patient characteristics, and Appendix Table A1 (online only) shows the underlying percentages. Of the 196 patients who breastfed their first live child, 113 (57.7%) had previously received chemotherapy (mostly anthracycline- and taxane-based), 130 breastfed after BCS (66.3%), 90 of 130 (69.2%) breastfed from the contralateral breast only, 38 of 130 (29.2%) breastfed from both breasts, and two (1.5%) breastfed from the affected breast only. Of the 40 patients who breastfed from the affected breast, 34 (85.0%) had previously received radiation therapy.

The frequency of breastfeeding was higher not only in women who underwent BCS (77.8% *v* 45.2%) but also in those with no previous children (66.4% *v* 48.5%) and those at least 35 years old (67.6% *v* 55.7%). Women from Asia/Pacific/Middle East breastfed with higher frequency (85.7%), compared with those from Europe (62.7%) or North America (51.2%).

The median duration of breastfeeding for the first on-study live birth was 4.4 months (95% CI, 4.0 to 5.3), and the breastfeeding duration was at least 6 months, 1 year, or 2 years in 37.1%, 12.8%, and 1.5% of patients, respectively (Fig 3). Duration of previous ET and time from enrollment to first live birth were not associated with breastfeeding frequency or duration (Table 1 and Appendix Figs A1 and A2).

Breast Cancer Outcomes After First Live Birth

After a median follow-up of 22 months (IQR, 13-34 months) from first live birth, we did not observe a higher cumulative incidence of BCFI events among patients who breastfed in comparison with those who did not (Fig 4). The 12-month estimates of BCFI after live birth were 1.1% (95% CI, 0.3% to 4.4%) and 1.9% (95% CI, 0.5% to 7.5%) in the breastfeeding and nonbreastfeeding cohorts, respectively. At 24 months, the estimates were 3.6% (95% CI, 1.5% to 8.5%) and 3.1% (95% CI, 1.0% to 9.5%), with an absolute difference of 0.4% (95% CI, −4.3% to 5.2%).

A total of nine BC events occurred after the first live birth, six of 196 in the breastfeeding cohort (two local, one contralateral, one regional, and two distant) and three of 117 in the nonbreastfeeding cohort (one local, one regional, and one distant).

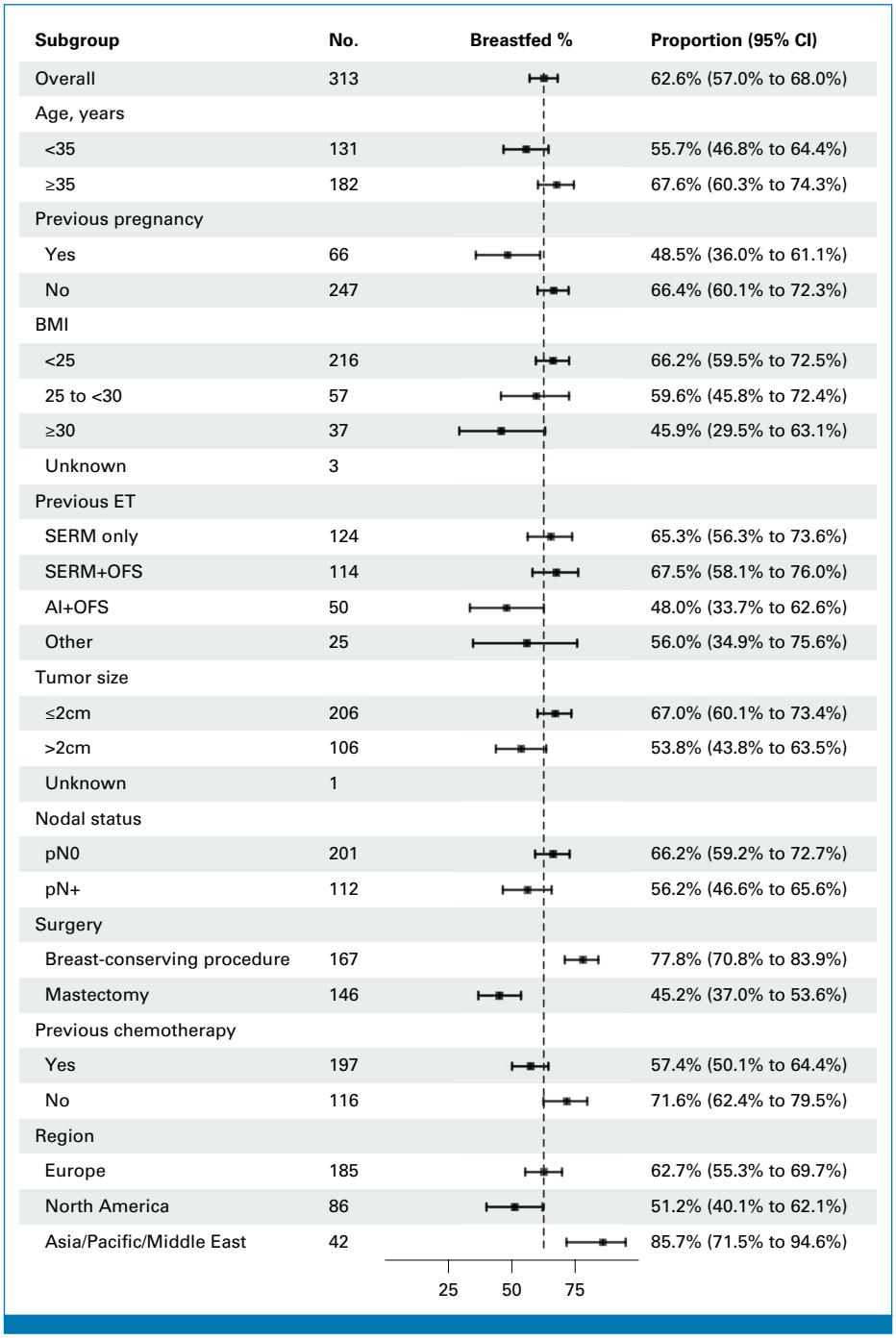

FIG 2. Breastfeeding proportion according to patient characteristics. The dashed line indicates the overall percentage of patients who breastfed (62.6%).

DISCUSSION

To our knowledge, this is the largest prospective study to evaluate breastfeeding frequency, patterns, and relation to BC outcomes in women previously diagnosed with BC, providing valuable information for comprehensive breastfeeding counseling.

With the limitations that the trial had a highly motivated patient and health care provider population, we found that most women who gave birth in the POSITIVE study were able to breastfeed and that those who underwent BCS predominantly breastfed from the contralateral breast. After a median follow-up of 41 months from enrollment (22 months from first live birth), breastfeeding was not associated with a higher incidence of BCFI events.

There is a large body of evidence supporting the health advantages of breastfeeding, for both the mother and the newborn.[10-12] Breastfeeding frequency in the general

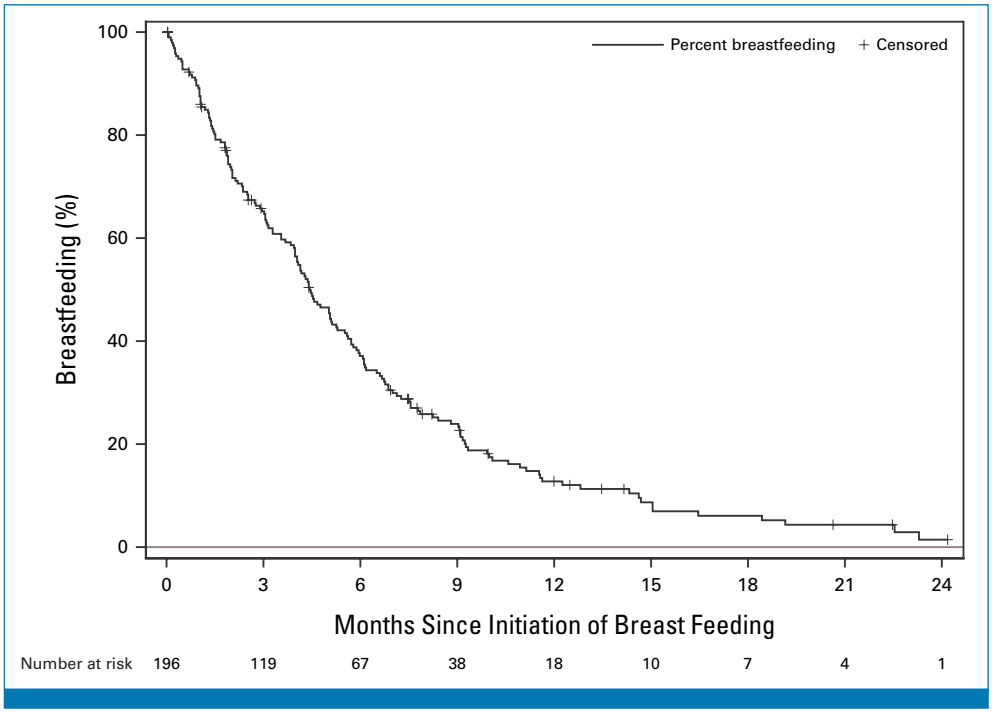

FIG 3. Breastfeeding duration (months) since initiation.

population is highly influenced by breastfeeding counseling and training, community support programs, adherence to the international code of marketing of breast milk substitutes, and maternity protection in the workplace. Globally, 46% of newborns are breastfed within an hour from birth, with striking differences among countries.[13] Women who had a previous diagnosis of BC face additional hurdles, mainly because of the scarce support and lack of counseling, the availability of only one healthy breast to breastfeed, and the prognostic unknowns of breastfeeding after BC.[5,14,15] In our analysis, 196 of 313 (62.6%) women who gave birth and did not have bilateral mastectomy breastfed, a lower percentage than that reported in the study by Sella et al. In their study, 143 young BC survivors who reported one or more live births were surveyed for breastfeeding habits. One hundred fifteen responded, and 94 were included in the analysis cohort. Of these, 39 of 94 had bilateral mastectomy, and of the remaining 55 patients, 52 (95%) breastfed. They were mainly White and non-Hispanic and had high support from lactation consultants and access to online information.[5] In our study, we could not ascertain antenatal psychological and socioeconomic factors that are known to affect successful breastfeeding,[16] nor the exact reasons to start or not to start breastfeeding, but the correlation between higher breastfeeding frequency and age older than 35 years and BCS are consistent with those already reported by others.[3,5] Of note, also, the higher breastfeeding frequency in women from Asia/Pacific/Middle East compared with those from Europe or North America is in line with the reported breastfeeding frequency in the general population.[13] Unfortunately, in our study, granular information on the

TABLE 1. Duration of Previous ET and Time From Enrollment to First Live Birth (months) by Breastfeeding Status

		Duration of Previous ET (months)			Time from Enrollment to First Live Birth (months)		
Breastfeeding Status	No.	P25	Median	P75	P25	Median	P75
Patients who had a live birth and did not have a bilateral mastectomy	313	20	23	27	14	18	23
Breastfed longer than 4 months[a]							
Yes	103	19	23	28	14	16	20
No	93	21	24	27	14	18	23
Did not breastfeed	117	20	23	26	14	18	24

Abbreviation: ET, endocrine therapy.
[a]Among first live births.

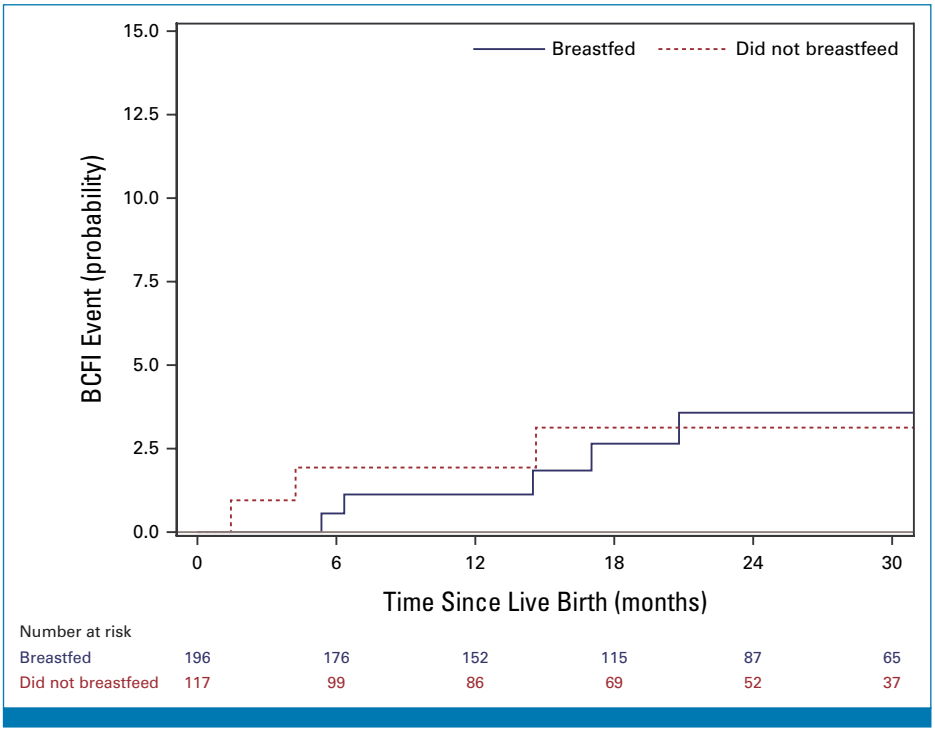

FIG 4. BCFI events among patients who breastfed and did not breastfeed after the first live birth. BCFI was censored at day 1 for 18 patients: because of no disease follow-up through live birth (six and eight for the breastfed and did not breastfeed cohorts, respectively) or because of having a BCFI event before the first live birth (1 and 3, respectively). BCFI, breast cancer–free interval.

barriers and facilitators of breastfeeding and the impact of breastfeeding on quality of life were not available and this should be considered as a limitation.

Among women who underwent BCS and breastfed, the majority (69.2%) breastfed from the unaffected breast only. Even if the reasons for choosing the unaffected breast were not investigated in our study, reduced milk production from the irradiated breast and pain and discomfort during latching could explain this behavior, as described in other studies.[3,5] The reasons for the lower breastfeeding rate among patients with previous mastectomy remain to be elucidated. It is plausible that the negative impact of mastectomy on woman's body image[17] might have potentially contributed to such observation, as might have the lack of appropriate counseling. In addition, women who placed less value on future breastfeeding might have been more likely to accept mastectomy. In the study by Sella et al, one woman who had unilateral mastectomy did not breastfeed because she believed that she would not have sufficient milk supply and two indicated that they were not interested in breastfeeding.[5]

The median duration of breastfeeding in our study was 4.4 months. As all women attempted pregnancy and breastfeeding before completing their 5-10 years of adjuvant ET and were strongly encouraged to resume treatment within a timeframe of 2 years, as per the POSITIVE trial protocol, it is likely that this had an impact on the decision to breastfeed and/or its duration. Another potential limitation to the breastfeeding duration may be the difficulty in interpreting breast imaging (mammography and/or magnetic resonance imaging), even if it is feasible during breastfeeding. This needs to be considered in interpreting the results and underlines the importance of adequate counseling about breastfeeding in women who need to resume adjuvant ET.

As only 30 of 190 patients screened for *BRCA* had a pathogenic variant, we could not correlate *BRCA* status with breastfeeding, but data on breastfeeding after BC in carriers of *BRCA* 1 or 2 pathogenic variants have been recently presented and also confirmed the feasibility and safety of breastfeeding in this special population.[7]

Despite the relatively short follow-up from trial enrollment (median 41 months) and from subsequent first live birth (median 22 months), to our knowledge, this is the first large prospective study that addresses the question of the safety of breastfeeding after BC. We found that, irrespective of breastfeeding status, patients had excellent outcomes, with only nine BCFI events, including three local recurrences, equally distributed in the breastfeeding and nonbreastfeeding group. At 24 months since breastfeeding initiation, the percentage of BCFI events was 3.6% in the breastfeeding group and 3.1% in the nonbreastfeeding group, with an absolute difference of 0.5% and wide 95% confidence intervals (95% CI, −4.3% to 5.2%).

The few BC events observed in our study might in part be related to the relatively short follow-up time, as stated above. As hormone-responsive BC recurrences may occur up to 20 years after diagnosis,[18] the short follow-up remains a limitation of our study. The planned longer follow-up will clarify the long-term BC event patterns in patients who do and do not breastfeed after live birth.

In conclusion, our data provide prospective new evidence on the pattern of breastfeeding and its safety in women with a history of BC. Based on current data, breastfeeding is feasible and is not associated with a higher short-term rate of BC-related events. These results provide much needed information for young women worldwide who are considering pregnancy and breastfeeding after BC diagnosis.

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PRIOR PRESENTATION

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CLINICAL TRIAL INFORMATION

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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DATA SHARING STATEMENT

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Breastfeeding After Hormone Receptor–Positive Breast Cancer: Results From the POSITIVE Trial

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APPENDIX

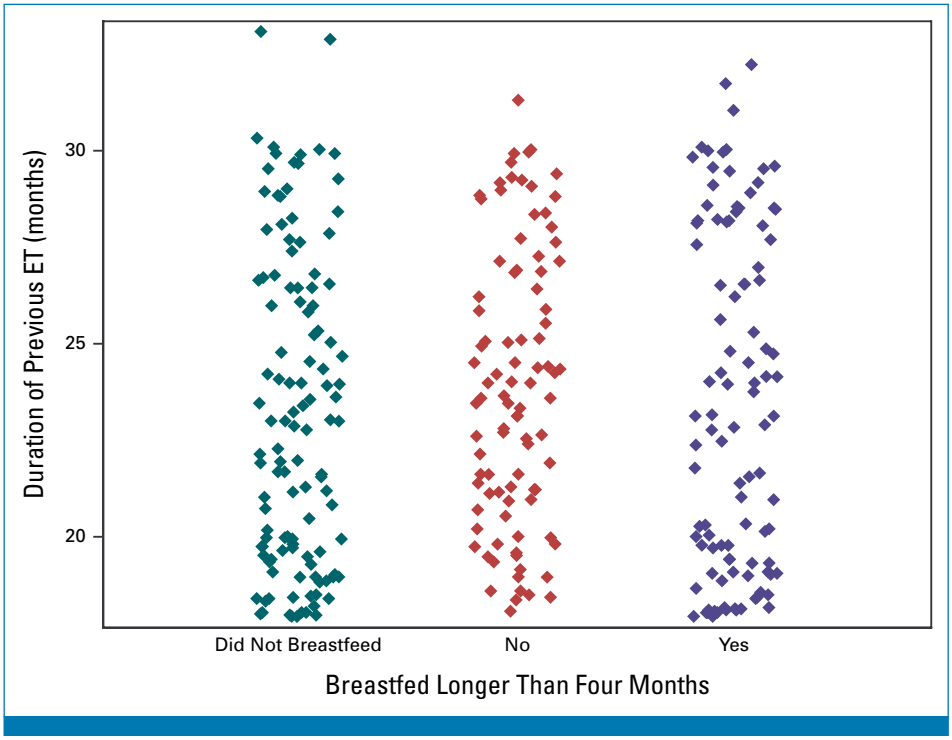

FIG A1. Distribution of duration of previous ET (months) by breastfeeding longer than 4 months. ET, endocrine therapy.

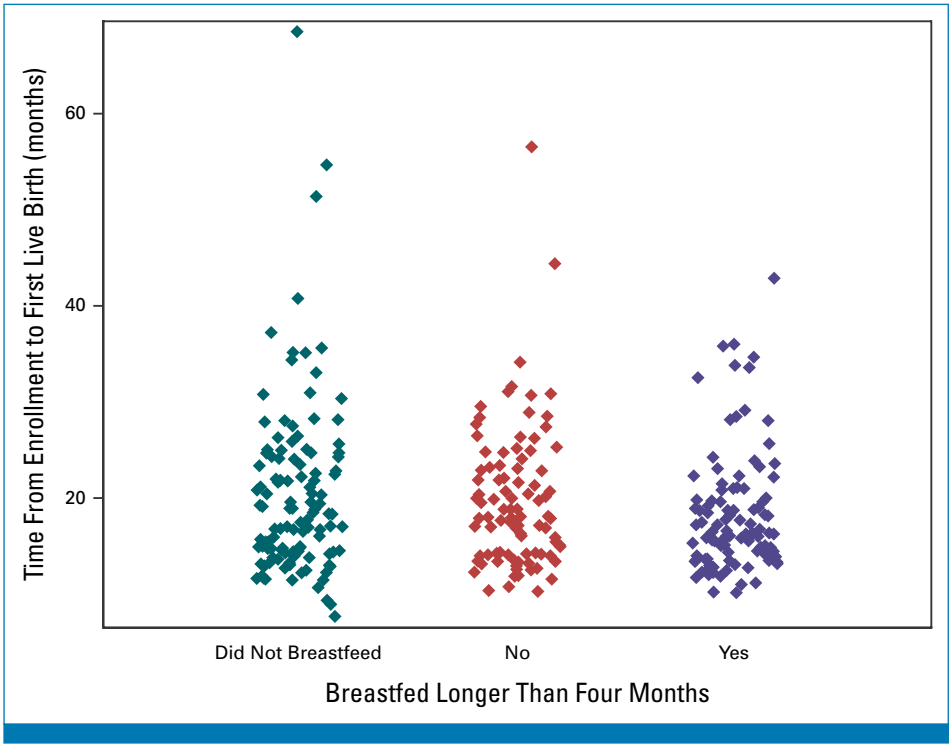

FIG A2. Time from enrollment to first live birth (months) by breastfeeding longer than 4 months.

TABLE A1. Patient Characteristics According to Breastfeeding Status

	Total	Breastfed	Did Not Breastfeed
Characteristic	No.	No. (%)	No. (%)
Patients who had a live birth and did not have a bilateral mastectomy	313	196 (62.6)	117 (37.4)
Age at enrollment, years			
<35	131	73 (55.7)	58 (44.3)
≥35	182	123 (67.6)	59 (32.4)
Previous birth			
Yes	66	32 (48.5)	34 (51.5)
No	247	164 (66.4)	83 (33.6)
BMI			
<25	216	143 (66.2)	73 (33.8)
25 to <30	57	34 (59.6)	23 (40.4)
≥30	37	17 (45.9)	20 (54.1)
Unknown	3	2 (66.7)	1 (33.3)
Tumor size (cm)			
≤2	206	138 (67.0)	68 (33.0)
>2	106	57 (53.8)	49 (46.2)
Unknown	1	1 (100.0)	—
Nodal status			
pN0	201	133 (66.2)	68 (33.8)
pN+	112	63 (56.3)	49 (43.8)
Breast surgery			
Breast-conserving procedure	167	130 (77.8)	37 (22.2)
Mastectomy	146	66 (45.2)	80 (54.8)
Previous chemotherapy			
Yes	197	113 (57.4)	84 (42.6)
No	116	83 (71.6)	33 (28.4)
Adjuvant endocrine therapy			
SERM only	124	81 (65.3)	43 (34.7)
SERM + OFS	114	77 (67.5)	37 (32.5)
AI + OFS	50	24 (48.0)	26 (52.0)
Other	25	14 (56.0)	11 (44.0)
Continent			
Europe	185	116 (62.7)	69 (37.3)
North America	86	44 (51.2)	42 (48.8)
Asia/Pacific/Middle East	42	36 (85.7)	6 (14.3)

Abbreviations: AI, aromatase inhibitors; OFS, ovarian function suppression; SERM, selective estrogen receptor modulator.