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5-year follow-up results from the POSITIVE (Pregnancy Outcome and Safety of Interrupting Therapy for Women with Endocrine Responsive Breast Cancer) trial

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Background

The POSITIVE trial demonstrated in early follow-up (median 41 months) the safety and feasibility of temporary interruption of adjuvant endocrine therapy (ET) for pregnancy in women with hormone receptor-positive early breast cancer. We now present updated results on breast cancer free interval (BCFI), distant recurrence free interval (DRFI), pregnancy and in vitro fertilization (IVF) outcomes, and ET resumption.

Methods

POSITIVE, a single-arm prospective trial evaluating temporary interruption of adjuvant ET (after 18-30 months for up to 2 years) for pregnancy in young BC survivors, enrolled 518 eligible women from 12/2014-12/2019. With comparison to a matched external control group of SOFT/TEXT patients, 5-year BCFI and DRFI event rates were estimated.

Results

At median follow-up of 71 mos and 80 mos in the POSITIVE and SOFT/TEXT control cohorts, respectively, 5-year cumulative incidence of BCFI events was 12.3% in POSITIVE and 13.2% in SOFT/TEXT [-0.9% difference (95% CI: -4.2% to 2.6%)]. 5-year cumulative incidence of DRFI events was 6.2% in POSITIVE and 8.3% in SOFT/TEXT [-2.1% difference (95% CI: -4.5% to 0.4%)]. Among the 497 women followed for pregnancy outcomes, 377 (75.8%) had at least one pregnancy on trial, 343 (69%) had at least one live birth with 440 newborns; 75 patients had more than 1 live birth on trial. An 18-month landmark analysis confirmed that patients who had a pregnancy had similar BCFI events compared to those who did not. Comparing the 180 patients (36%) who had embryo/oocyte cryopreservation prior to enrollment to those who did not, the 5-year cumulative incidences of BCFI events were 14.0% (95% CI: 9.6% to 20.2%) and 11.5% (95% CI: 8.4% to 15.7%), respectively. Of the 429 patients followed for at least 2 years and remaining disease-free, 352 (82%) have resumed ET.

Conclusions

In young BC patients, temporary interruption of ET for pregnancy does not increase risk of breast cancer events at 5-year follow-up. More than two-thirds of women had a live birth and most resumed ET per protocol. Ongoing follow-up is needed to assess long-term outcomes.

Clinical trial identification

NCT02308085.

Legal entity responsible for the study

ETOP IBCSG Partners Foundation.

Funding

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Disclosure

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