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First interim analysis of radiotherapy data after 4.5 years of sentinel lymph node biopsy versus no axillary surgery in early breast cancer clinically and ultrasonographically node-negative: a prospective randomized controlled trial – venus trial

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Objective: VENUS (ClinicalTrials.gov – NCT05315154 and ReBEC – RBR-8g6jbf; ethics approval: CAAE:06805118.2.0000.5404) is an ongoing trial that evaluates omission of sentinel lymph node biopsy (SLNB) in early breast cancer clinically and ultrasonographically node negative. This is a partial report on the first interim radiotherapy data collected up to 4.5 years after the VENUS trial started. The objective was to evaluate whether radiotherapy is uniform between VENUS groups. **Methodology:** This is a prospective, multi-center, non-inferiority randomized controlled clinical trial including T1-2 N0 (clinical/ultrasound) M0 breast cancer patients randomized into SLNB or no axillary surgery. Adjuvant radiotherapy planning was based on local protocols adopted by each study center. In the no-surgery group, axilla status was considered N0 during planning. Radiotherapy features analyzed were: planning, number and location of fields, whole-breast/boost dose, fractioning, and dose distribution in axillary levels I-III. **Results:** Until February 2024, 322 women were randomized. Radiotherapy was performed in 221 (SLNB n=115 and no-surgery n=106). 2D and 3D IMRT and 3D conformational planning were applied for 7, 26, and 173 patients, respectively, with no imbalance across study groups (p=0.23). The mean whole-breast dose was 424742.cGy in SLNB and 4269.95cGy in no-surgery (p=0.67). The mean percentage of total prescribed breast doses distribution in axillary was Level I 5.73% SLNB vs. 2.16% no-surgery (p=0.12), Level II 0.53% SLNB vs 0.07% no-surgery (p=0.86), and Level III 0.96% SLNB vs. 0.00% no-surgery (p=0.06). Radiotherapy fields (axilla, supraclavicular fossa, breast, and internal mammary) and boost are described and were all evenly balanced across study groups. **Conclusion:** Breast radiotherapy has achieved an unintentional low radiation dose in the axilla of some patients, mainly at Level I. However, there was no difference between VENUS trial groups in radiotherapy parameters. So far, with more than 40% of the sample size achieved, there has been no violation of radiotherapy procedure protocol in the VENUS trial.

Keywords: breast neoplasms; breast cancer; sentinel lymph node biopsy; breast cancer treatment; axillary surgery; ultrasound; radiotherapy.