

SIMULTANEOUS ROOM

<https://doi.org/10.29289/259453942024V34S1017>

Immediate postoperative complications associated with sentinel lymph node biopsy in early breast cancer in the context of the sentinel lymph node biopsy versus no axillary surgery in early breast cancer clinically and ultrasonographically node-negative (venus) trial

Amanda Maria Sacilotto Detoni¹, Giuliano Mendes Duarte¹, Danielle Cristina Miyamoto Araújo¹, Rodrigo Menezes Jales¹, Ruffo Freitas-Júnior², Rosemar Macedo Sousa Rahal², Luis Otávio Sarian¹, VENUS TRIAL Group³

¹Universidade Estadual de Campinas, Faculty of Medical Sciences, Department of Obstetrics and Gynecology.

²Universidade Federal de Goiás, Department of Obstetrics and Gynecology.

³VENUS TRIAL Group.

Objective: VENUS is an ongoing trial that evaluates the omission of sentinel lymph node biopsy (SLNB) in early breast cancer clinically and ultrasonographically node negative. Despite SLNB being a low-morbidity procedure compared with axillary dissection, there are complications associated with it that may be underestimated. The aim of this study was to evaluate the first data about immediate and late axillary complications in patients of the VENUS trial. **Methodology:** This is a prospective, multi-center, non-inferiority randomized controlled trial including T1-2 N0 (clinical/ultrasound) M0 breast cancer patients randomized into SLNB or no axillary surgery. Complications were assessed during postoperative follow-up visits and at 6-month intervals. This report focuses on postoperative assessments. The variables included were pain, seroma, paresthesia, arm movement restriction, lymphedema, patent blue tattooing, and others, as well as whether treatments/interventions were required. This study was registered in ClinicalTrials.gov (NCT05315154) and ReBEC (RBR-8g6jbf) and approved by the ethics committee (CAAE:06805118.2.0000.5404). **Results:** Until now, 322 patients were randomized to SLNB (n=170) or no-surgery (n=152). The mean follow-up time so far is 20.6 months (range 3.3–48.6 months). The overall axillary complication rate was 53.5% (SLNB) vs. 5.3% (non-SLNB) ($p < 0.001$). In the immediate postoperative assessment, blue dye tattooing was the most frequent (33.5%) complication, followed by pain (22.4%), paresthesia (8.2%), seroma (6.5%), dehiscence and infection (2.4%), and range of motion restriction (1.8%). Complications were not associated with the number of sentinel nodes resected (regression coef = -0.06, $p = 0.534$). Interventions to treat at least one of the complications were required for 36.9% of the patients, with analgesics being the most frequent (50%) intervention. **Conclusion:** SLNB was associated with a higher rate of complications, which may be overlooked and lead to treatment morbidity, and should not be disregarded.

Keywords: breast cancer; sentinel lymph node biopsy; breast cancer treatment; axillary surgery; complications.