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28615 – CRYOABLATION IN THE TREATMENT OF EARLY BREAST CANCER: RESULTS FROM THE STUDY FREEZING BREAST CANCER IN BRAZIL (FIRST)

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Introduction: Image-guided tumor ablation is a minimally invasive, non-surgical therapy available for local treatment of carcinomas, offering an alternative to surgery. However, studies evaluating this therapy in early breast cancer have reported variable success rates, raising the question of whether omitting surgery is a viable option. Ongoing studies, such as the FROST and ICE3 trials, may alter the landscape of cryoablation in the treatment of early breast cancer. In the era of minimally invasive treatment, the search for ablative therapies like cryoablation has emerged as a treatment option. Methodology: This is a multicenter, non-randomized, single-arm, before-and-after clinical trial. Inclusion criteria include patients with unifocal invasive breast carcinoma, tumors ≤2.5 cm, lesions visualized by ultrasound, and surgery indicated as the primary treatment option. Exclusion criteria include ductal carcinoma in situ, multifocal or multicentric tumors, clinical axillary involvement, lesion-to-skin distance less than 5 mm, presence of distant metastases, and neoadjuvant treatment. All patients will undergo local cryoablation followed by conventional surgical treatment 14 to 28 days later. Imaging exams (mammography, ultrasound, and breast MRI) will be performed before and after ablation. The efficacy of cryoablation will be assessed based on the success rate, defined as the absence of malignant neoplastic cells, both invasive and in situ, in the surgical specimen. If the expected success rate of cryoablation is similar to the 92% rate reported in the ACOSOG Z1072 study for patients without multifocal disease, a minimum of 32 patients will be necessary to determine if the technique is satisfactory (success rate >70%), with 95% statistical power and a 5% significance level. This study was approved by the local Ethics Committee and registered on ClinicalTrials.gov (NCT05398497). Conclusion: The results highlight cryoablation as a promising therapy, providing a viable alternative to surgical approaches in patients with early--stage breast cancer, as demonstrated in this study. The ongoing advancement of minimally invasive therapies consolidates cryoablation as an option in the treatment of early breast cancer.