

Radioactive Seed Localization versus Wire Guided Localization of Nonpalpable Invasive and In Situ Breast Cancer: A Danish Multicenter Randomized Controlled Trial

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Background:

Wire-guided localisation (WGL) is the current standard for localisation of nonpalpable breast lesions in breast conserving surgery (BCS) despite methodological difficulties. Radioactive seed localisation (RSL) was developed to reduce these difficulties. The aim of this trial was to compare the rate of positive resection margins between RSL and WGL in patients with nonpalpable invasive breast cancer (IBC) or ductal carcinoma in situ (DCIS).

Material and Methods:

Patients with nonpalpable IBC or DCIS visible on ultrasound were enrolled in this randomized, multicenter, open-label clinical trial, and randomly assigned to receive either RSL or WGL. The primary outcome was margin status after BCS. Secondary outcomes were duration of the surgical procedure, weight of the excised specimen and patient's pain perception. Analyses were performed by intention-to-treat (ITT) and per protocol. χ^2 -test, Fisher's exact test and Wilcoxon rank-sum test, respectively, were used to test differences between groups. Level of statistical significance was set to 5%.

Results:

Between Jan 1, 2014, and Feb 4, 2016, 444 patients were eligible, of which 413 lesions representing 409 patients were randomized; 207 were allocated to RSL and 206 to WGL. 23 did not meet inclusion criteria, chose to withdraw, or had a change in surgical management and were excluded. The remaining 390 lesions constituted the ITT population. Baseline and pathological characteristics between the two groups were alike, except for significantly more patients with DCIS in the WGL group (5.1% vs 0.5%).

Resection margins were positive in 23 cases (11.8%) in the RSL group compared to 26 cases (13.3%) in the WGL group ($p=0.65$). Allocated intervention was received in 186 cases (89.9%) in the RSL group and in 192 cases (93.2%) in the WGL group ($p=0.08$), and the per-protocol analysis revealed no difference in margin status ($p=0.62$). There was no difference in the duration of the surgical procedure ($p=0.12$), the amount of tissue removed whether the analysis was done on the primary excision ($p=0.32$) or the total weight ($p=0.54$). We did not find any difference in pain perception between the two groups whether patients who received local anesthesia were kept in the analysis ($p=0.28$) or excluded ($p=0.91$).

Conclusions:

We were not able to detect any differences in margin status, patient's pain perception, or duration of the surgical procedure between the two localization methods. RSL offers a major logistic advantage, as localization can be done several days before surgery compared to WGL. The RSL procedure with ultrasound guided implementation of the seed has been found preferable at our institutions.