Clinical analysis of early results of the implementation of intraoperative radiotherapy with the INTRABEAM device during breast-conserving surgery of early breast cancer in a private hospital

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OBJECTIVES

- Results of TARGIT trials increased clinical interest in intraoperative radiotherapy (IORT) during breast-conserving surgery (BCS) in early breast cancer and thus we have evidenced an increase in its use.
- At Assuta Medical Centers we implemented this treatment in a private hospital setting where multiple surgeons use it.
- This report reviews surgical oncology guidelines, the protocol for the treatment as well as the outcomes for breast cancer patients who received IORT as their sole radiation treatment at our hospital

METHODS

➢ **Inclusion criteria (Israel)**

- In Israel we have established our criteria of patients eligible for IORT based

on a combination of the ones made by different national societies (e.g. ESTRO and ASTRO and others), as follows:

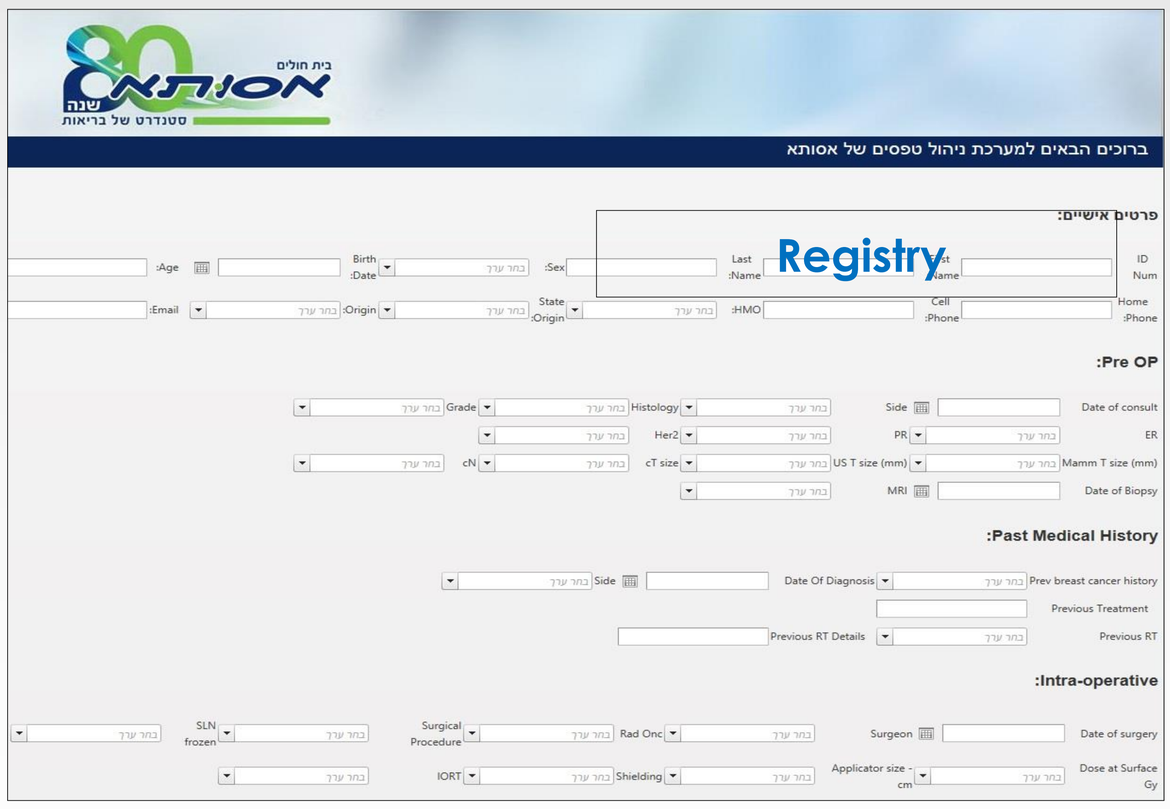
✓ >55 years old
✓ Invasive ductal carcinoma/other favorable histology
✓ T1 (≤2 cm), unifocal
✓ N0
✓ Positive estrogen hormone receptor status
✓ M0

➢ **Exclusion criteria**

✓ Multifocal disease
✓ Presence of EIC
✓ Presence of LVI
✓ Neoadjuvant chemotherapy
✓ N+ disease
✓ BRCA1/2

➢ **Assuta approach**

- Multidisciplinary approach: patient is seen by surgeon and radiation oncologist.
- X-rays are reviewed at tumor board.
- Patients are enrolled in a tumor registry.
- Close follow up by surgeon and radiation oncologist.



PATIENT CHARACTERISTICS

	Median	Range
Age (yrs)	64.5	49 to 79
Applicator size (cm)	4	3 to 5
pTsize (mm)	11.36	1 to 30
Grade	2	1 to 3
#LN removed	2	1 to 10
Surgical margin (mm)	3.3	0 to 10

RESULTS

Out of the 3,702 breast cancer patients, 308 cases (8.3%) were referred for IORT. 232 patients (75%) were eligible and were treated with IORT by Intrabeam. With a median follow-up of 18.8 months (range 2 to 36 months), one patient developed local relapses. There were no metastases and no deaths related to their breast cancer. The average hospital stay was 1.2 days and wound healing time was 7±2 days. Seven patients (3%) developed postoperative infection, two of them had delayed infection, and one patient experienced a hematoma. Two patients needed surgical re-excision. There was no observed excess need for pain medication. The evaluation of cosmetic outcome showed that 84% of the patients graded as excellent or good while 16% patients graded it as fair, one patient had poor cosmetic outcome. 19 patients (8.2 %) needed additional external radiation therapy. We analyzed the reasons for non-treatment in the 25% of referred patients. We found that 32% of these did not meet the eligibility criteria, 26% had positive SLN during surgery and IORT was aborted, 19% of the patients were eligible but the reason for non-treatment was economic due to insurance refusal to pay the cost, in 5% it was due to a technical problem in the Intrabeam machine and in 18% it was due to patients declining IORT.

CONCLUSIONS

✓ **For early-stage breast cancer patients, intraoperative radiotherapy after breast-conserving surgery in a private based center, if done according to a peer reviewed protocol is both safe and reliable and has resulted in very acceptable outcomes.**

✓ **With the larger emerging experience patient selection for IORT should be less restrictive. Patient and physician education is needed in order to increase awareness of this modality. Insurers should be involved in the costs and benefits of this procedure.**

REFERENCES:

Vaidya J.S at al/ Risk-adapted targeted intraoperative radiotherapy versus whole-breast radiotherapy for breast cancer: 5-year results for local control and overall survival from the TARGIT-A randomized trial. The Lancet. 382:Nov. 2013.

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