



## Factsheet for the Press (Clinical)

### CURRENT STATUS OF ELIOT STUDIES ON BREAST CANCER AT THE EUROPEAN INSTITUTE OF ONCOLOGY IN MILAN

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**Context:** The current standard in the management of early stage breast cancer consists of conservative surgery (lumpectomy or quadrantectomy), followed by a course of radiation therapy on the whole remaining breast tissue (whole breast irradiation) given in 5-7 weeks of treatment. In spite of the positive data of this approach in terms of both local control and long term survival, several institutions are trying to revisit the adjuvant irradiation setting, especially with regard to overall treatment time and target volume. This concept has been developed by applying the modern philosophy of partial breast irradiation (PBI). PBI can be realised using external beam RT, brachytherapy or intraoperative RT (IORT). Based on published results, very recently both the American and European Societies of radiation Oncology (ASTRO and ESTRO, respectively) have developed, independently, some recommendations providing a clinical guidance for the use of PBI outside the context of a clinical trial. With some minor differences, ASTRO and ESTRO guidelines proposed the selection criteria to define a low-risk group of patients, suitable to be treated in clinical setting.

**Purpose:** PBI has been extensively tested in Milan, using ELIOT (Electron IntraOperative Therapy). It consists of a single-fraction treatment targeted at the tumour bed, during the surgical procedure, immediately after the removal of the tumour mass. The logistic problem to bring the radiation source and the patient together is solved by the use of mobile accelerators that are brought to the operating room, and produce electron beams with variable energies from 3 up to 12 MeV. In this abstract we report the results observed in more than 2000 patients treated between 1999 and 2008, in different trials, trying to correlate our results with the guidelines of international societies.

**Findings:** In our trials we tried to assess the feasibility and the effectiveness of PBI using ELIOT at the full single dose of 21 Gy. All patients received quadrantectomy followed by sentinel node biopsy and only in cases of positive nodes, axillary dissection. The primary endpoint for analysis was the rate of local recurrence within a 5-year observation period. After 5-years, 2.3% of the patients developed a true local recurrence and 1.3% a second lesion in the other quadrant of the same breast. The 5-years overall survival was 97.5%. The second endpoint was the assessment of late toxicity. Less than 1% of patients developed serious breast fibrosis, with a high (more than 80%) rate of good/excellent cosmetic results.

**Impact:** A large debate about the role (and the limits) of PBI is still ongoing. Our contribution is quite important to confirm PBI as a possible new standard in selected subsets of patients with breast cancer. In our results, the strong impact on local control has been demonstrated with respects to age of patients at diagnosis, size of the tumor and, really important, biological profile of



the disease. In this subsets of patients, which represents at least 20% of all breast cancer patients, PBI (using ELIOT or other techniques) could be applied in clinical setting, allowing to overcome some constraints of long courses of radiation therapy, such as the accessibility to the centres of radiotherapy, the socio-economic impact on the working life and on the personal habits of the patients.

**Indicative of a bigger trend in oncology?** This research fits entirely with the general trend in oncology, based on strict cooperation between different specialists. In addition, shorter schedules of radiation oncology allow to reduce the health cost, optimizing the distribution of resources available in radiation therapy. Further advantages can be considered, mainly in terms of improving quality of life of the patients, without any decrease of possibility to be cured.

*"If 5- and 10-year ipsilateral local relapse rates <5% are consistently reported in current randomised trials, partial breast radiotherapy, including ELIOT, is likely to offer significant clinical benefits in large subpopulations of women with early breast cancer."*

Prof. John Yarnold, Royal Marsden Hospital & Institute of Cancer Research, UK