Use of intra-operative radiotherapy [IORT] alone in breast cancer patients when conventional external beam radiation therapy [EBRT] was not possible

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Although External Beam Radiotherapy (EBRT) is generally regarded as safe for most patients, there are a number of side effects that can limit and in some cases prevent its use in breast cancer patients. We have been using intra-operative radiotherapy [IORT] with the Intrabeam technique in the randomised TARGIT trial since 2000. In special circumstances, we treat patients with IORT alone when EBRT is not feasible. The aim of this study was to avoid unnecessary mastectomy whilst maintaining a high probability of long term local tumour control in this cohort of patients. We present our preliminary results of this non-randomised study of consecutive female patients. Their treatment involved wide local excision (WLE) followed by IORT, in some instances, under local anaesthetic.

IORT is delivered using the Intrabeam system which contains a miniature electron gun and accelerator. Soft x-rays (50kV) are emitted from the point source, delivering 20Gy to the applicator surface located in the tumour bed. 13 patients have been treated in this way, with a mean follow-up of 21 months (range 1-59). The special circumstances and follow-up outcomes are contained in the table below.

In conclusion, we believe that IORT using Intrabeam offers a safe and effective method of delivering radiotherapy to breast cancer patients in whom EBRT is not an option. There were no loco regional recurrences or radiation induced complications in this series however, one patient developed a second primary in the same breast.

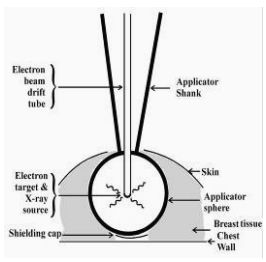
Case No.	Age	Reasons for IORT alone	Outcome
1	53	Patient declined standard radiotherapy (deep concerns about side-effects, long distance to travel)	No recurrence
2	48	Recurrent breast cancer after WLE and EBRT, refused mastectomy	Second primary in different quadrant and metastatic breast carcinoma
3	60	Severe bronchiactasis	No recurrence
4	78	Severe Chronic Obstructive Pulmonary Disease with poor lung function	Died 18 months post-surgery from bronchopneumonia without signs of local recurrence
5	54	Past history of lymphoma and mantle radiotherapy, declined mastectomy	No recurrence
6	56	Myasthenia gravis	Multiple recurrence, mainly bony sites (18m), subsequent local recurrence (24m)
7	90	Co-morbidities	No recurrence
8	68	Severe Parkinson's, wheelchair bound	No recurrence
9	66	Total blindness	No recurrence
10	56	Severe obesity and previous problems with EBRT for treatment of contralateral breast cancer	No recurrence
11	85	Minimal intervention because of age	No recurrence
12	68	Hodgkin's disease, previously treated with mantle radiotherapy	No recurrence
13	40	Brain metastases – IORT was delivered as palliative treatment	No recurrence

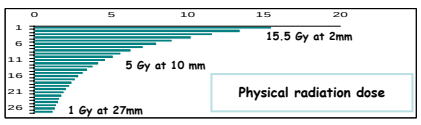
The IORT Technique

PRS400 (Intrabeam) A miniature electron generator and accelerator

Accurately delivers radiotherapy from within the breast

Uniform radiation dose at the surface of the applicator sphere





Soft X-rays
Small 'high-dose' region
Quick attenuation ($1/r^3$)- distance protects normal tissues
Shielding is easy

Applicator (mm)	*Treatment time(min) for 20 Gy at the surface*
15	*7.07*
20	*11.53*
25	*17.43*
30	*24.98*
35	*18.57*
40	*26.80*
45	*36.58*
50	*48.82*

Measurement

Sterile applicator and drape

Applicator in place

Anaesthetist behind shielding

IORT delivery

The end result

The TARGIT Trial

Is a single fraction of IORT (targeted to the tissues at the highest risk of local recurrence) equivalent to standard EBRT, after breast conserving surgery in women with early stage breast cancer, in terms of local relapse within the treated breast?

The TARGIT Trial allows for two randomisation options, which allows efficient use of the equipment whilst evaluation is ongoing

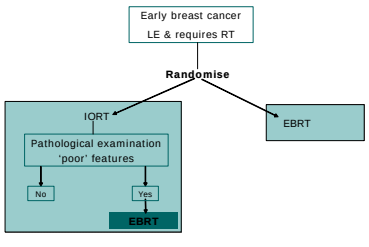
- *Single procedure (pre-pathology), e.g. at centres where the equipment is on site*
- *Second procedure (post-pathology), e.g. for patients referred from other centres*

Concurrent sub-studies:

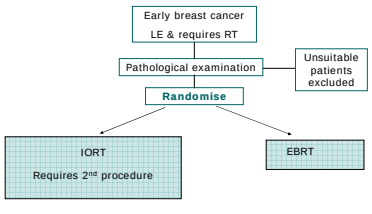
Cosmesis
QoL and impact of disease & treatment
Patient preference study
Health economics

For further details see www.targittrial.org, or contact TARGIT@ctg.ucl.ac.uk

IORT as a single procedure



IORT as a second procedure



TARGIT
Targeted Intra-operative Radiation Therapy