

Breast cancer patients treated with intra-operative radiotherapy alone when conventional external beam radiation therapy was not possible

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Background: Intra-operative radiotherapy (IORT) with Intrabeam system has been piloted since 1998 and used in the randomised TARGIT International trial since 2000. Some patients are suitable for off-trial therapy, particularly where external beam radiotherapy (EBRT) cannot be offered due to various reasons.

Methods: Patients with invasive breast cancer underwent wide local excision followed by IORT (n=75) using the Intrabeam system containing a miniature electron gun and accelerator. Low energy x-rays (50kV) are emitted from the point source, delivering 20Gy to the breast tissue at the surface of the tumour bed using a spherical applicator (Figure 1).

The procedure can be performed in an unmodified operating theatre.


Patients who were deemed unfit for surgery received interstitial radiotherapy alone using Intrabeam, with only the point source placed at the tumour centre under stereo-guidance under local anaesthetic, and were followed up with serial MRI scans.

Results: Over the past 7 years 78 patients have been treated in this way in centres in 3 countries (UK, Germany and Australia). To date there have been no local recurrences. One patient developed a second primary and subsequently died of brain metastases (Table).


Conclusions: This cohort adds to the evidence that targeted radiotherapy using Intrabeam (either IORT or interstitial) could offer a safe and effective method of delivering radiotherapy to breast cancer patients in whom EBRT is not an option.

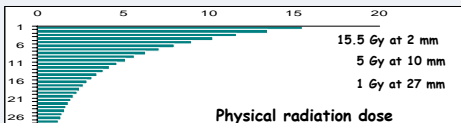
Patients who are suitable for either EBRT or IORT can participate in the TARGIT Trial (Figure 2).

Figure 1. The IORT Technique



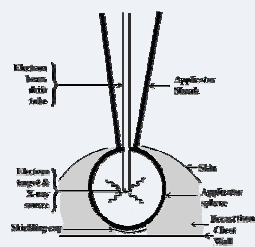
PRS500 (Intrabeam) A miniature electron generator and accelerator
Accurately delivers radiotherapy from within the breast
Uniform radiation dose at the surface of the applicator sphere







Soft X-rays
Small 'high-dose' region
Quick attenuation (1/r²) – 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

Table

Reason for IORT	No. of patients	Age (years)*	Follow-up (months)*	Outcome
Previous EBRT	22	64 (54-74)	35 (15-50)	All free of LR; 2 died
Collagen Vascular Disease	5	63 (57-64)	24 (22-35)	All free of LR
Co-morbidities	24	79 (66-83)	22 (16-35)	All free of LR; 7 died
Other	27	62 (52-73)	29 (22-48)	All free of LR; 1 died

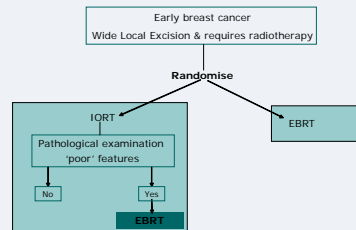
* median (IQR)
LR = local recurrence

Figure 2. 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?

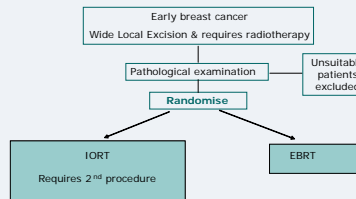
The TARGIT Trial allows for two randomisation options, which allows efficient use of the equipment whilst evaluation is ongoing

IORT as a single procedure



Single procedure (pre-pathology), e.g. at centres where the equipment is on site

IORT as a second procedure



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
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The TARGIT Trial is open to recruitment – of patients and centres!