

## Intraoperative Radiation Therapy in the treatment of breast cancer

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### Background and Aims

**Intraoperative Radiation Therapy (IORT)** allows the administration, at the time of surgery, a large single radiation dose directly to the tumor bed. The aim is to improve local control and decrease the toxicity by lower irradiation of healthy tissues and skin, since sensitive structures are mobilised and shielded of the target. Its use has been described as a conventional treatment **boost** of External Beam Radiation Therapy (EBRT), achieving a higher and more effective radiation doses in the target volume, or as an alternative to EBRT (**single radiation modality**) in early stages of breast cancer.

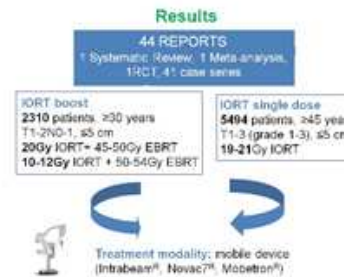
The **aims** of this **systematic review** were to assess the **effectiveness** of IORT boost or single dose in terms of recurrence, survival, cosmetic results and impact on quality of life; and to ascertain the **safety** in terms of acute and late toxicity.

### Methods

**Bibliographic research:** from Jan 2000 to Jan 2013 in:

- Centre for Reviews and Dissemination
- Cochrane Plus Library
- ISI Web of Knowledge
- Clinical Trials Registry
- WHO International Clinical Trials Registry Platform
- General search of quality Internet web pages.
- Medline
- Embase
- CSIC-Índice Médico Español
- Current Controlled Trials

**Selection papers:** two independent reviewers in accordance with pre-established inclusion and exclusion criteria, with any disagreements being resolved by consensus. Manual review was performed of the bibliographic references cited in the papers selected.  
**Data extraction:** were summarised in evidence tables. Study quality was assessed using the National Health and Medical Research Council scale.



### Results

#### IORT boost

- **Effectiveness:** 5-year risk for local recurrence was from 1.3% to 6.5% and 5-7 years overall survival 91%.
- **Cosmetic results:** good and/or excellent in over 90% of patients.
- **Toxicity:** moderate. The most frequent complications were fat necrosis (50%), seroma (48%) and skin toxicity (15%), with worse results after IORT than with EBRT. Incidence of ulcers, fibrosis, oedema and lymphoedema was 5% and regular acute pain 10%.

#### IORT single dose

- **Effectiveness:** recurrence rate from 1.22% at 4-year to 7% at 10-year, slightly higher than EBRT ( $p > 0.05$ ). Overall survival was close on 90% at 10 years.
- **Cosmetic results:** good and/or excellent in 90% of patients.
- **Complications:** higher incidence of ulceration, fat necrosis, infections, seromas and haematomas that required intervention than EBRT, with lower incidence of pain, fibrosis and oedema ( $p > 0.05$ ).

#### Quality of life

Improve daily and professional activity or presence and intensity of pain, as compared to IORT boost or EBRT ( $p > 0.05$ ).

### Conclusions

**IORT boost:** does **not increase** the effectiveness and overall survival, nor does it entail a significant reduction of safety with respect to EBRT. These results are drawn from studies of *low methodological rigour*, and there are no **randomized controlled trials** that would go to confirm them.  
**IORT single dose:** is associated with a **comparable** recurrences and metastasis rate to that of EBRT and, despite showing low toxicity, does **not improve the toxicity** of EBRT to any significant degree. This evidence is based on a single RCT with *certain limitations* and on *observational and descriptive* studies, that considerably reduces the validity of these results.  
Indeed, the studies included give rise to **important doubts** regarding the possible replacement of EBRT by IORT as the treatment of choice in patients with early breast cancer.

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