Associazione Italiana Radioterapia Oncologica
Gruppo di Studio per la Patologia Mammaria

III Zoom Journal Club 2013

Non un Congresso "classico" né un Corso, ma un'occasione per concreti aggiornamenti, confronto e dibattito su alcuni "Hot Topics 2013" dalla letteratura relativa alla radioterapia mammaria.

Bologna
21 Febbraio 2014
NH Hotel De La Gare

Presentazione del Documento del Gruppo di Studio AIRO_IORT

Dr Luigi Tomio, UO Radioterapia Oncologica - Trento

Progetto

- Congresso AIRO_Roma 20-11-2012

  Survey 2011 1500 IORT per ca.mammella (1100e; 400b) in 20 centri

- Riunione Gruppo IORT_Bologna 10-5-2013
- Riunione Gruppo IORT_Bologna 27-9-2013

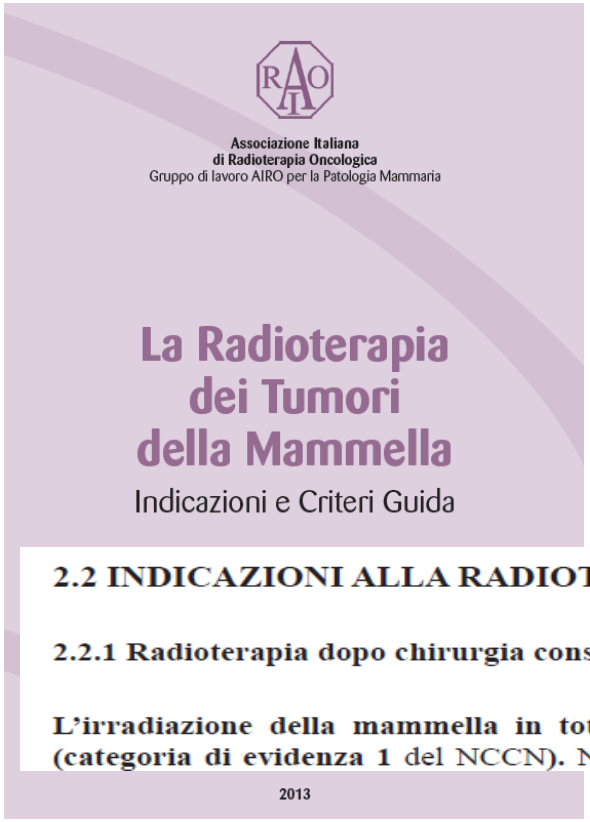
Introduzione

- La metanalisi EBCTCG 2011:

Nel carcinoma infiltrante della mammella, la radioterapia postoperatoria WB riduce le recidive intramammarie e le ricadute regionali con miglioramento della sopravvivenza

Early Breast Cancer Trialists' Collaborative Group (EBCTCG), Darby S, McGale P, Correa C et al (2011) Effect of radiotherapy after breast-conserving surgery on 10-year recurrence and 15-year breast cancer death: meta-analysis of individual patient data for 10,801 women in 17 randomised trials. Lancet 378:1707–1716

Introduzione



Irradiazione parziale

L'irradiazione parziale può essere erogata postoperatoriamente in 1-3 settimane mediante brachiterapia o fasci esterni, o intraoperatoriamente in una seduta unica

Irradiazione limitata di una parte (letto operatorio con un margine di sicurezza) della mammella **non** rappresenta ad oggi uno standard terapeutico

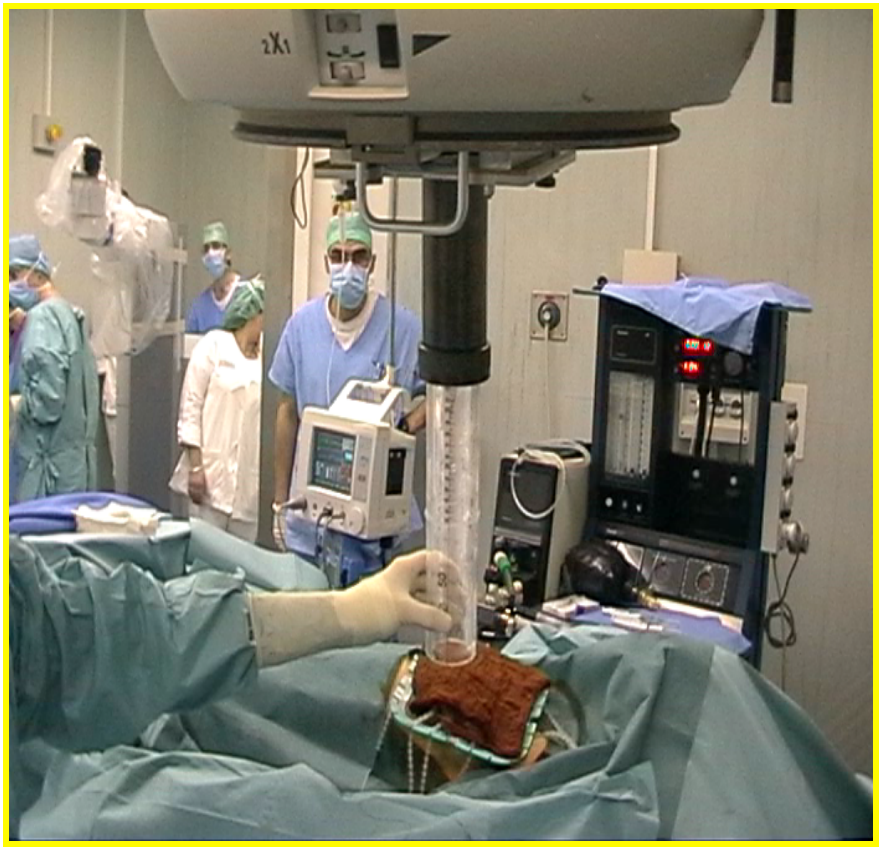
Taccuino IORT Mammella
Istruzioni operative

- INDICAZIONI e CONTROINDICAZIONI
- VALUTAZIONE PRE CHIRURGICA
- CONSENSO INFORMATO
- STEP in SALA OPERATORIA
- FOLLOW UP

IORT

- Unica frazione di radioterapia associata al trattamento chirurgico

- Trattamento esclusivo
- Trattamento di sovradosaggio



CAPPELLO GENERALE

- **Il percorso terapeutico che prevede la IORT, necessariamente multidisciplinare, richiede il parere obbligatorio di ogni singolo specialista coinvolto e il parere quando negativo diviene vincolante**

IORT esclusiva al di fuori di studi clinici

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CONSENSUS STATEMENT

ACCELERATED PARTIAL BREAST IRRADIATION CONSENSUS STATEMENT FROM THE AMERICAN SOCIETY FOR RADIATION ONCOLOGY (ASTRO)

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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 randomised trial

Jayant S Vaidya, Frederik Wenz, Max Bulsara, Jeffrey S Tobias, David J Joseph, Mohammed Keshtgar, Henrik L Flyger, Samuele Massarut, Michael Alvarado, Christobel Saunders, Wolfgang Eiermann, Marinos Metaxas, Elena Sperk, Marc Sütterlin, Douglas Brown, Laura Esserman, Mario Roncadin, Alastair Thompson, John A Dewar, Hafie M F Hilaly, Steffi Pigorsch, Mary Falzon, Eleanor Harris, April Matthews, Chris Brew-Graves, Ingrid Potyka, Tammy Carica, Norman R Williams, Michael Baum, on behalf of the TARGIT trialists' group

Summary

Background The TARGIT-A trial compared risk-adapted radiotherapy using single-dose targeted intraoperative radiotherapy (TARGIT) versus fractionated external beam radiotherapy (EBRT) for breast cancer. We report 5-year results for local recurrence and the first analysis of overall survival.

Methods TARGIT-A was a randomised, non-inferiority trial. Women aged 45 years and older with invasive ductal carcinoma were enrolled and randomly assigned in a 1:1 ratio to receive TARGIT or whole-breast EBRT, with blocks stratified by centre and by timing of delivery of targeted intraoperative radiotherapy: randomisation occurred either before lumpectomy (prepathology stratum, TARGIT concurrent with lumpectomy) or after lumpectomy (postpathology stratum, TARGIT given subsequently by reopening the wound). Patients in the TARGIT group received supplemental EBRT (excluding a boost) if unforeseen adverse features were detected on final pathology, thus radiotherapy was risk-adapted. The primary outcome was absolute difference in local recurrence in the conserved breast, with a prespecified non-inferiority margin of 2·5% at 5 years; prespecified analyses included outcomes as per timing of randomisation in relation to lumpectomy. Secondary outcomes included complications and mortality. This study is registered with ClinicalTrials.gov, number NCT00983684.

Findings Patients were enrolled at 33 centres in 11 countries, between March 24, 2000, and June 25, 2012. 1721 patients were randomised to TARGIT and 1730 to EBRT. Supplemental EBRT after TARGIT was necessary in 15·2% [239 of 1571] of patients who received TARGIT (21·6% prepathology, 3·6% postpathology). 3451 patients had a median follow-up of 2 years and 5 months (IQR 12–52 months), 2020 of 4 years, and 1222 of 5 years. The 5-year risk for local recurrence in the conserved breast was 3·3% (95% CI 2·1–5·1) for TARGIT versus 1·3% (0·7–2·5) for EBRT (p=0·042). TARGIT concurrently with lumpectomy (prepathology, n=2298) had much the same results as EBRT: 2·1% (1·3–4·2) versus 1·1% (0·5–2·5; p=0·31). With delayed TARGIT (postpathology, n=1153) the between-group difference was larger than 2·5% (TARGIT 5·4% [3·0–9·7] vs EBRT 1·7% [0·6–4·9]; p=0·069). Overall, breast cancer mortality was much the same between groups (2·6% [1·5–4·3] for TARGIT vs 1·9% [1·1–3·2] for EBRT; p=0·56) but there were significantly fewer non-breast-cancer deaths with TARGIT (1·4% [0·8–2·5] vs 3·5% [2·3–5·2]; p=0·0086), attributable to fewer deaths from cardiovascular causes and other cancers. Overall mortality was 3·9% (2·7–5·8) for TARGIT versus 5·3% (3·9–7·3) for EBRT (p=0·099). Wound-related complications were much the same between groups but grade 3 or 4 skin complications were significantly reduced with TARGIT (four of 1720 vs 13 of 1731, p=0·029).

Interpretation TARGIT concurrent with lumpectomy within a risk-adapted approach should be considered as an option for eligible patients with breast cancer carefully selected as per the TARGIT-A trial protocol, as an alternative to postoperative EBRT.

Funding University College London Hospitals (UCLH)/UCL Comprehensive Biomedical Research Centre, UCLH Charities, National Institute for Health Research Health Technology Assessment programme, Ninewells Cancer Campaign, National Health and Medical Research Council, and German Federal Ministry of Education and Research.

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GEC-ESTRO Recommendations

Patient selection for accelerated partial-breast irradiation (APBI) after breast-conserving surgery: Recommendations of the Groupe Européen de Curiethérapie-European Society for Therapeutic Radiology and Oncology (GEC-ESTRO) breast cancer working group based on clinical evidence (2009)

Csaba Polgár [a,*], Erik Van Limbergen [b], Richard Pötter [c], György Kovács [d], Alfredo Polo [e], Jaroslaw Lyczek [f], Guido Hildebrandt [g], Peter Niehoff [h], Jose Luis Guinot [i], Ferran Guedea [j], Bengt Johansson [k], Oliver J. Ott [l], Tibor Major [a], Vratislav Strnad [l], On behalf of the GEC-ESTRO breast cancer working group

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Intraoperative radiotherapy versus external radiotherapy for early breast cancer (ELIOT): a randomised controlled equivalence trial

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Summary

Background Intraoperative radiotherapy with electrons allows the substitution of conventional postoperative whole breast irradiation with one session of radiotherapy with the same equivalent dose during surgery. However, its ability to control for recurrence of local disease required confirmation in a randomised controlled trial.

Methods This study was done at the European Institute of Oncology (Milan, Italy). Women aged 48–75 years with early breast cancer, a maximum tumour diameter of up to 2·5 cm, and suitable for breast-conserving surgery were randomly assigned in a 1:1 ratio (using a random permuted block design, stratified for clinical tumour size [<1·0 cm *vs* 1·0–1·4 cm *vs* ≥1·5 cm]) to receive either whole-breast external radiotherapy or intraoperative radiotherapy with electrons. Study coordinators, clinicians, and patients were aware of the assignment. Patients in the intraoperative radiotherapy group received one dose of 21 Gy to the tumour bed during surgery. Those in the external radiotherapy group received 50 Gy in 25 fractions of 2 Gy, followed by a boost of 10 Gy in five fractions. This was an equivalence trial; the prespecified equivalence margin was local recurrence of 7·5% in the intraoperative radiotherapy group. The primary endpoint was occurrence of ipsilateral breast tumour recurrences (IBTR); overall survival was a secondary outcome. The main analysis was by intention to treat. This trial is registered with ClinicalTrials.gov, number NCT01849133.

Findings 1305 patients were randomised (654 to external radiotherapy and 651 to intraoperative radiotherapy) between Nov 20, 2000, and Dec 27, 2007. After a median follow-up of 5·8 years (IQR 4·1–7·7), 35 patients in the intraoperative radiotherapy group and four patients in the external radiotherapy group had had an IBTR (p<0·0001). The 5-year event rate for IBRT was 4·4% (95% CI 2·7–6·1) in the intraoperative radiotherapy group and 0·4% (0·0–1·0) in the external radiotherapy group (hazard ratio 9·3 [95% CI 3·3–26·3]). During the same period, 34 women allocated to intraoperative radiotherapy and 31 to external radiotherapy died (p=0·59). 5-year overall survival was 96·8% (95% CI 95·3–98·3) in the intraoperative radiotherapy group and 96·9% (95·5–98·3) in the external radiotherapy group. In patients with data available (n=464 for intraoperative radiotherapy; n=412 for external radiotherapy) we noted significantly fewer skin side-effects in women in the intraoperative radiotherapy group than in those in the external radiotherapy group (p=0·0002).

Interpretation Although the rate of IBTR in the intraoperative radiotherapy group was within the prespecified equivalence margin, the rate was significantly greater than with external radiotherapy, and overall survival did not differ between groups. Improved selection of patients could reduce the rate of IBTR with intraoperative radiotherapy with electrons.

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See Online for a podcast interview with Umberto Veronesi

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Targit-A e ELIOT

	Events; 5-year cumulative risk (95%CI)		Absolute difference*	
	TARGIT	EBRT		
All patients				
Local recurrence (n=3375)	23; 3·3% (2·1–5·1)	11; 1·3% (0·7–2·5)	12 (2·0%)	0.04
Any other recurrence (n=3375)	46; 4·9% (3·5–6·9)	37; 4·4% (3·0–6·4)	9 (0·5%)	
Death (n=3451)	37; 3·9% (2·7–5·8)	51; 5·3%(3·9–7·3)	−14 (−1·4%)	
Prepathology†				
Local recurrence (n=2234)	10; 2·1% (1·1–4·2)	6; 1·1% (0·5–2·5)	4 (1·0%)	0.3
Any other recurrence (n=2234)	29; 4·8% (3·1–7·3)	25; 4·7% (3·0–7·4)	4 (0·1%)	
Death (n=2298)	29; 4·6% (1·8–6·0)	42; 6·9% (4·3–9·6)	−13 (−2·3%)	
Postpathology‡				
Local recurrence (n=1141)	13; 5·4% (3·0–9·7)	5; 1·7%(0·6–4·9)	8 (3·7%)	0.06
Any other recurrence (n=1141)	17; 5·2% (3·0–8·8)	12; 3·7% (1·9–7·0)	5 (1·5%)	
Death (n=1153)	8; 2·8% (1·3–5·9)	9; 2·3% (1·0–5·2)	−1 (0·5%)	

TARGIT=targeted intraoperative radiotherapy. EBRT=external beam radiotherapy. *In Kaplan-Meier point estimate at 5 years (TARGIT minus EBRT). †TARGIT given at same time as lumpectomy. ‡TARGIT given after lumpectomy, as separate procedure.

Table 1: **Results of primary (local recurrence in the conserved breast), secondary (death), and exploratory (any other recurrence) outcomes for all patients and the two strata as per timing of randomisation and delivery of TARGIT**

	External radiotherapy (n=654)		Intraoperative radiotherapy with electrons (n=651)		Log-rank p value
	Number	5-year event rate (95% CI)	Number	5-year event rate (95% CI)	
Ipsilateral breast tumour recurrence	4	0·4% (0·0–1·0)	35	4·4% (2·7–6·1)	<0·0001
Local relapse	4	0·4% (0·0–1·0)	21	2·5% (1·2–3·8)	0·0003
New ipsilateral breast tumour	0	0	14	1·9% (0·8–3·1)	0·0001
Axillary or other regional lymph node metastasis	2	0·3% (0·0–0·8)	9	1·0% (0·2–1·9)	0·03
Locoregional tumour recurrence	6	0·8% (0·0–1·5)	44	5·4% (3·5–7·2)	<0·0001
Contralateral breast tumour	13	1·7% (0·6–2·7)	8	1·1% (0·2–2·1)	0·34
Distant metastasis*	35	4·8% (3·1–6·5)	33	5·1% (3·3–6·9)	0·94
Other primary cancer	22	3·2% (1·8–4·7)	20	2·5% (1·2–3·8)	0·88
Death as first event	7	0·9% (0·1–1·7)	8	1·0% (0·1–2·0)	0·69
Total deaths	31	3·1% (1·7–4·5)	34	3·2% (1·7–4·7)	0·59
Breast cancer	20	2·0% (0·9–3·2)	23	2·1% (0·9–3·3)	0·56
Other cause	11	1·1% (0·2–2·0)	11	1·1% (0·2–2·0)	0·93

Person-years until last visit 3920 for external radiotherapy, 3716 for intraoperative radiotherapy with electrons. Person years until last contact 4107 for external radiotherapy, 3997 for intraoperative radiotherapy with electrons. *As first or secondary event (including four diagnosed at the time of surgery, all in the intraoperative radiotherapy group).

Table 2: **Events identified during follow-up according to allocated group (intention-to-treat population)**

IORT esclusiva al di fuori di studi clinici

INDICAZIONI

- Età > 50 anni e stato menopausale
- Malattia **unifocale**
- Istotipo invasivo **non** lobulare
- T ≤ 2 cm
- malattia con profilo biologico favorevole (basso indice di proliferazione, recettori ormonali positivi, HER 2 negativo ovvero gruppo fenotipico **luminal A)**
- assenza di metastasi linfonodali (**N0**)
- margini chirurgici **macroscopicamente** negativi

CONTROINDICAZIONI ASSOLUTE

- Malattia multifocale o multicentrica
- T > 2 cm o T4
- N+
- Chemioterapia neoadiuvante
- Mutazione di BRCA
- Gravidanza

CONTROINDICAZIONI RELATIVE

Malattie del connettivo. Alcune malattie del collageno quali lupus, sclerodermia, dermatomiosite se in fase quiescente rappresentano una controindicazione relativa, se in fase attiva assoluta per l'amplificazione delle tossicità segnalate. L'artrite reumatoide non è considerata controindicazione al trattamento

Situazioni cliniche particolari

- Nelle Pazienti che per comorbidità, età avanzata o difficoltà logistiche presentino difficoltà o **impossibilità ad eseguire il ciclo di radioterapia esterna postoperatoria**, anche ove non siano rispettati i criteri di indicazione alla IORT sopra citati, qualora non optino per la mastectomia, **può essere proposta una IORT**. E' necessaria una **valutazione multidisciplinare** e la **condivisione della decisione clinica con la Paziente adeguatamente informata.**

REIRRADIAZIONE

- **L'indicazione chirurgica standard per recidiva mammaria dopo trattamento conservativo è la mastectomia**, ma qualora in accordo con la paziente, previo confronto multidisciplinare, si opti per un approccio conservativo, la **IORT può rappresentare**, una delle possibili tecniche di re-irradiazione parziale insieme a brachiterapia o 3DRTE.
- Tale possibilità terapeutica potrebbe essere presa in considerazione in **situazioni selezionate** in pazienti con recidiva insorta tardivamente, con diametro della lesione limitato, basso grading (10).
- Analogamente in caso di neoplasia insorta dopo **RT per altra patologia** (ad es. per linfoma), nell'impossibilità di una radioterapia dell'intera mammella si potrebbe proporre una irradiazione parziale, anche con metodica IORT.
- La programmazione del trattamento non può prescindere dalla conoscenza dettagliata di dosi e volumi relativi alla RT precedente.

VALUTAZIONE PRECHIRIRGICA MULTIDISCIPLINARE

STADIAZIONE PREOPERATORIA

- Mammografia
- Ecografia mammaria e dei cavi ascellari
- Biopsia della lesione con definizione **dell'istotipo, dello stato recettoriale, del recettore HER 2, del Ki67**
- Valutazione di fattibilità (sede della lesione, volume del seno,…)

RISONANZA MAGNETICA MAMMARIA

CONSENSO INFORMATO

- **Deve essere fornito** sia per le procedure chirurgiche e radioterapiche, fornendo delucidazioni chiare e comprensibili, atte a far comprendere vantaggi e benefici della metodica, possibili complicanze ed effetti collaterali acuti e tardivi.

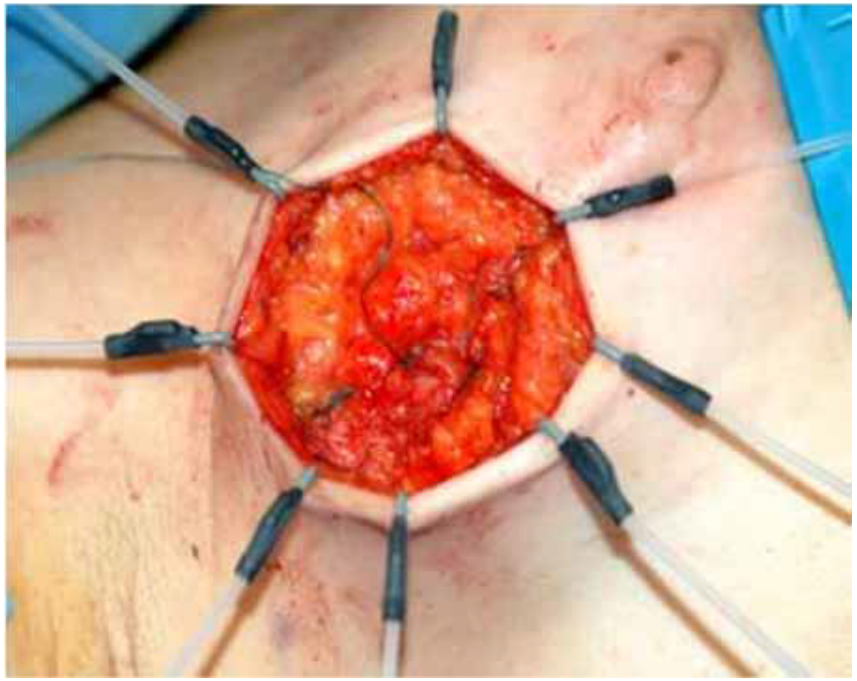
STEP IN SALA OPERATORIA

- Si sottolinea l'importanza di **expertise e coordinamento** tra le figure dello staff, con definizione delle responsabilità e dell'esecuzione delle singole procedure, da parte di ogni centro.
- Si raccomanda che **il radioterapista sia in sala al momento dell'inizio dell'intervento** al fine di ottimizzare l'identificazione del CTV.
- Per l'effettuazione del trattamento è **necessaria** la **presenza del Fisico e del Tecnico di Radioterapia**.

IORT con e-

LA PROCEDURA

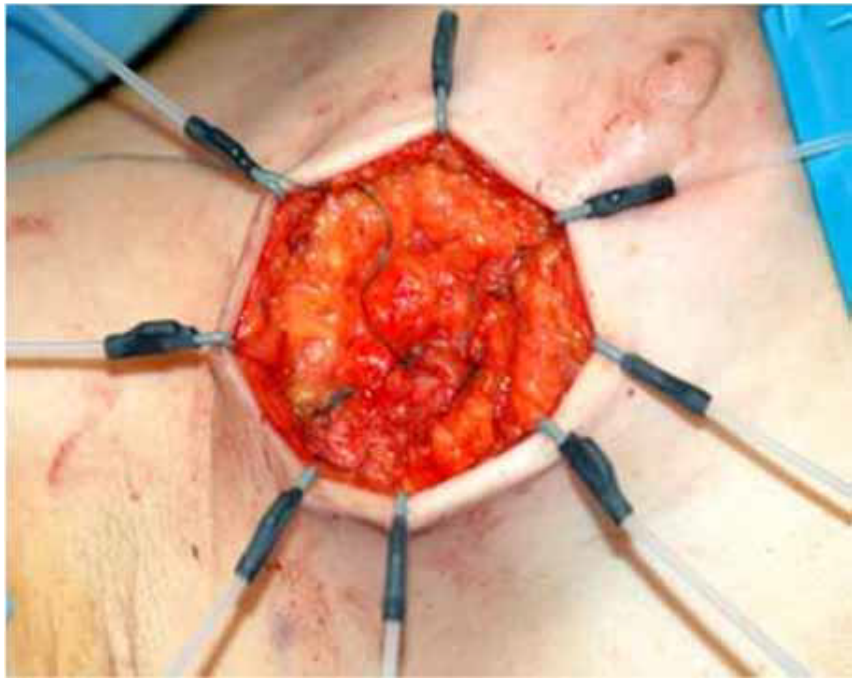
- Preparazione della ghiandola
- Protezione della parete toracica
- Determinazione del volume bersaglio
- Scelta del diametro dei coni di irradiazione
- Posizionamento del collimatore e sua connessione al Linac (mobile o non dedicato)



IORT con e-

ENERGIA E DOSI

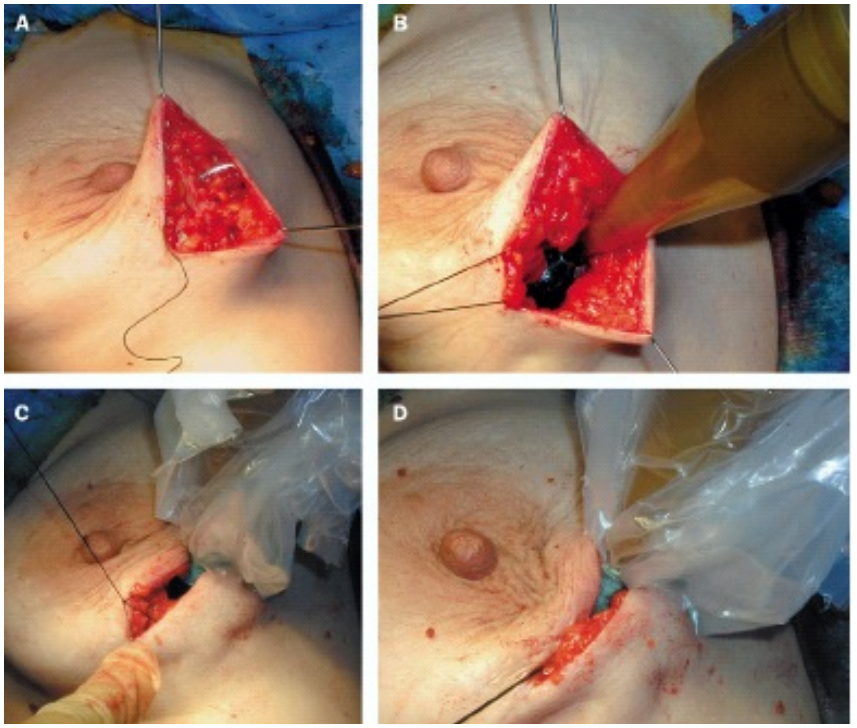
- L'**energia** viene scelta in base allo **spessore del tessuto da irradiare** valutata con ago graduato (su almeno tre punti, al centro e alla periferia del letto operatorio) e/o con ecografia.
- La **dose prescritta** è generalmente di **21Gy**, all'isodose 90%.
- La **durata dell'irradiazione** è intorno ai 2 minuti.



IORT con Intrabeam

- Preparazione della cavità chirurgica
- Scelta dell'applicatore sferico (1,5 a 5 cm)
- Confezionamento di una "borsa di tabacco" attorno all'applicatore con il tessuto che delimita la cavità chirurgica
- sottile **protezione** costituita da una gomma di poliuretano impregnata di tungsteno alla base della cavità per la mammella sinistra

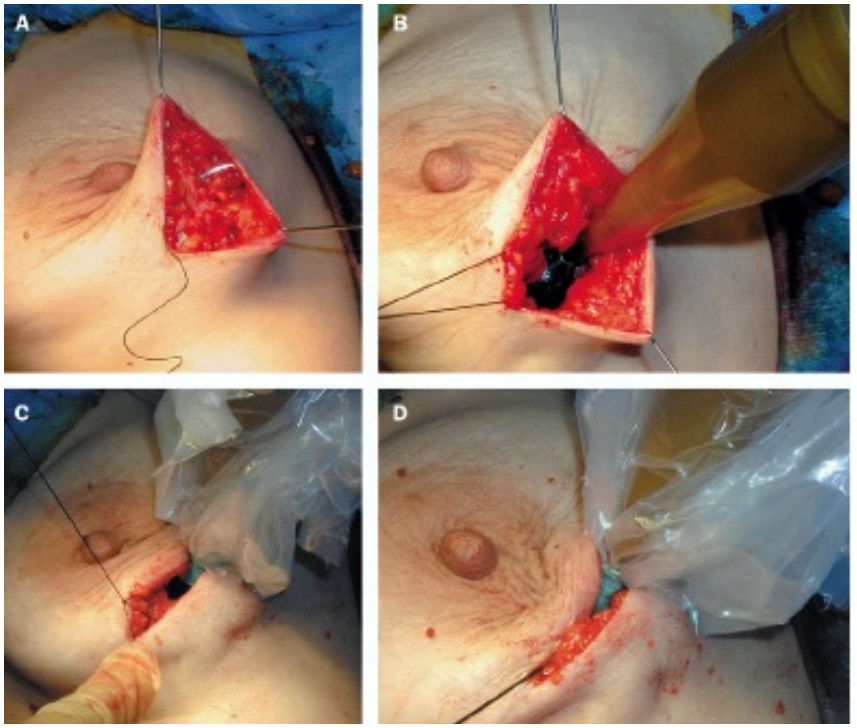
LA PROCEDURA



IORT con Intrabeam

- Raggi X a bassa energia prodotti da elettroni accelerati con una potenza di **50 Kv** e 40 μA su un target d'oro
- La **dose prescritta** è di **6 Gy ad 1 cm** (o **20 Gy alla superficie dell'applicatore**)
- La **durata dell'irradiazione** è di circa 30 minuti

ENERGIA E DOSI



IORT come boost anticipato

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- Fastner G, Sedlmayer F, Merz F, Deutschmann H, Reitsamer R, Menzel C, Stierle C, Farmini A, Fischer T, Ciabattoni A, Mirri A, Hager E, Reinartz G, Lemanski C, Orecchia R, Valentini V. IORT with electrons as boost strategy during breast conserving therapy in limited stage breast cancer: long term results of an ISIORT pooled analysis. Radiother Oncol. 2013 Aug;108(2):279-86

IORT come boost anticipato

- Modalità impiegata per prima nel trattamento intraoperatorio
- Utile per prevenire «geographic miss» soprattutto dopo chirurgia oncoplastica
- Miglior distribuzione della dose
- Buoni risultati in termini di controllo locale, tossicità e risultati cosmetici

IORT come boost anticipato

LA PROCEDURA

- lo scollamento della ghiandola dalla parete toracica che non appare necessario
- l'uso del disco di protezione non è mandatorio
- posizionamento di clips sui margini

ENERGIA E DOSI

- scelta dell'energia come per il trattamento esclusivo
- 10 – 12 Gy all'isodose del 90 -100%

REPORT

- L’indicazione al **trattamento, il consenso informato, i dati tecnici, fisici e dosimetrici del trattamento radiante devono essere registrati e reperibili** nel dossier della paziente secondo le norme vigenti.

FOLLOW UP

- Le pazienti sono avviate al follow up

- Si sottolinea l'importanza del radioterapista oncologo nella valutazione degli effetti acuti e tardivi, legati alla procedura IORT

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