Incontri
di aggiornamento
del Dipartimento
Oncologico

La gestione del paziente oncologico:

Il follow-up nel carcinoma mammario.

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5 novembre 2016

Obiettivi del follow-up:

- Riconoscimento precoce di recidive di malattia potenzialmente suscettibili di trattamento con intento radicale.
- Gestione e monitoraggio degli effetti collaterali (fisici e/o psicosociali) della terapia sia a breve che a lungo termine.
- Aderenza alla terapia anti-ormonale.
- Promozione e mantenimento di uno stile di vita sano.
- Definizione del rischio eredo-famigliare.
- Prevenzione secondaria per i secondi tumori.

- **Riconoscimento precoce di recidive di malattia potenzialmente suscettibili di trattamento con intento radicale.**
- Gestione e monitoraggio degli effetti collaterali (fisici e/o psicosociali) della terapia sia a breve che a lungo termine.
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Esami per la sorveglianza della recidiva di malattia

Cosa ci raccomandano le linee guida?

Esame clinico	Anamnesi ed esame obiettivo dovrebbero essere eseguiti ogni 3-6 mesi nei primi tre anni dal trattamento primario, ogni 6-12 mesi nei successivi 2 anni e poi annualmente[1].
Mammografia	La mammografia dovrebbe essere eseguita entro un anno dalla mammografia che ha diagnosticato la neoplasia (nelle donne sottoposte a chirurgia conservativa, una mammografia dopo almeno 6 mesi dalla fine della radioterapia), poi una volta all'anno[2-3]

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- ✓ Visits every 3-4 months in the first 2 years, every 6 months from years 3-5 and then annually are recommended.
- ✓ Annual ipsilateral (after BCT) and/or controlateral mammography with ultrasound is recommended.

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- ✓ History and physical exam 1-4 times per year as clinically appropriate for 5 years, then annually.
- ✓ Mammography every 12 months.

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Un'accurata visita medica con una dettagliata raccolta anamnestica, associata alla mammografia annuale, rimangono i cardini del follow-up ottimale.

Rojas MP et al., Cochrane Librart 2005.
Grunfeld E at al., Breast 2002.
Lash Tl et al., J Clin Oncol 2007.

….e gli altri esami strumentali?

Procedure non raccomandate	In assenza di indicazioni cliniche i seguenti esami non sono raccomandati: RMN della mammella; TC encefalo-torace-addome; TC-PET con FdG; esami del sangue; radiografia del torace; ecografia addominale, scintigrafia ossea; determinazione dei marcatori tumorali (CEA, CA 15.3, CA 125 ecc.) [6-10]

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- ✓ In asymptomatic patients, there are NO data to indicate that other laboratory or imaging tests (e.g. blood counts, routine chemistry tests, chest X-rays, bone scans, liver ultrasound exams, CT scans, PET/FDG CT or any tumour markers such as CA 15-3 or CEA) produce a survival benefit.

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- ✓ In the absence of clinical signs and symptoms suggestive of recurrent disease, there is NO indication for laboratory or imaging studies for metastases screening.

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Patient education regarding symptoms of recurrence	Physicians should counsel patients about the symptoms of recurrence including: • New lumps • Bone pain • Chest pain • Dyspnea • Abdominal pain • Persistent headaches

Khatcheressian JL et al., JCO 2013.

Follow-up convenzionale versus intensivo:

Impact of follow-up testing on survival and health-related quality of life in breast cancer patients. A multicenter randomized controlled trial.

The GIVIO Investigators, JAMA 1994.

RESULTS:

At a median follow-up of 71 months, **no difference was apparent in overall survival with** 132 deaths (**20%**) **in the intensive group and** 122 deaths (**18%**) **in the control group.** No significant differences were apparent in time to detection of recurrence between the two groups. Measurements of health-related quality of life (ie, overall health and quality-of-life perception, emotional well-being, body image, social functioning, symptoms, and satisfaction with care) at 6, 12, 24, and 60 months of follow-up did not show differences by type of care received.

CONCLUSIONS:

Results of this trial support the view that a protocol of frequent laboratory tests and roentgenography after primary treatment for breast cancer does not improve survival or influence health-related quality of life. **Routine use of these tests should be discouraged.**

Intensive diagnostic follow-up after treatment of primary breast cancer. A randomized trial. National Research Council Project on Breast Cancer follow-up.

Rosselli del Turco et al., JAMA 1994 → Palli D et al., JAMA 1999.

RESULTS:

The 5-year relapse-free survival rate was significantly higher for the clinical follow-up group, with patients in the intensive follow-up group showing earlier detection of recurrences**. No difference in 5-year overall mortality (18.6% vs 19.5%)** was observed between the two follow-up groups. → **At 10-year update**: **no difference in overall mortality (31.5% vs 34.8%) (HR 1.05; 95% CI 0.87-1.26).**

CONCLUSIONS:

Periodic chest roentgenography and bone scan allow earlier detection of distant metastases, but anticipated diagnosis appears to be the only effect of intensive follow-up, and no impact on prognosis is evident after 5 years. **Periodic intensive follow-up** with chest roentgenography and bone scan **should not be recommended as a routine policy.**

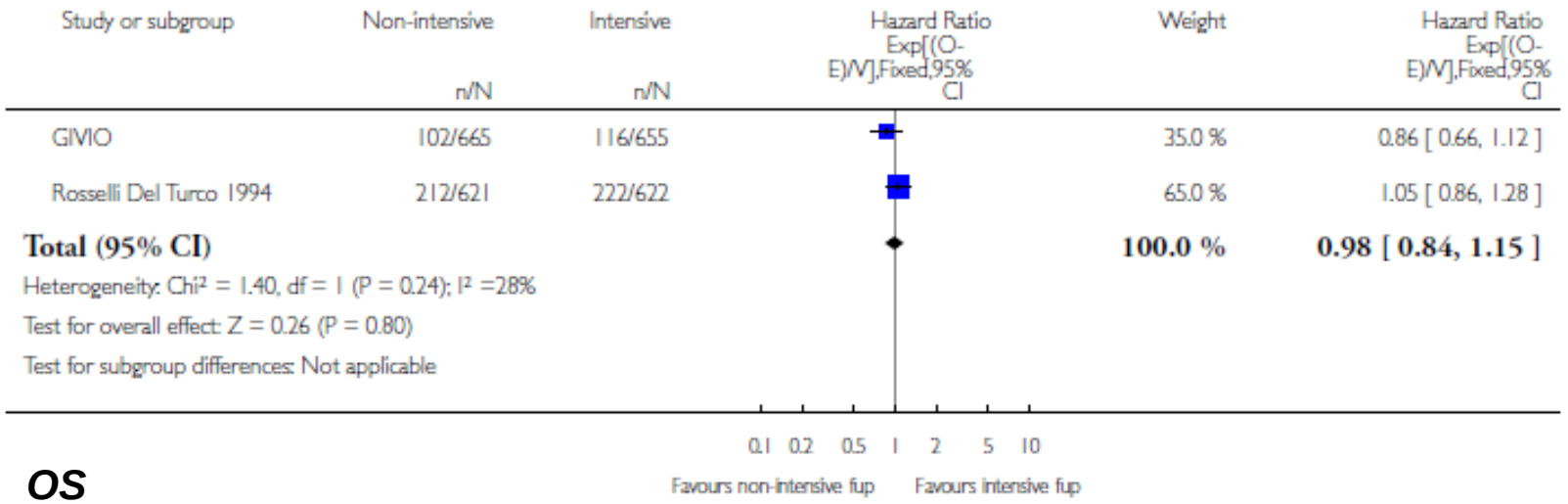
Cochrane Library

Cochrane Database of Systematic Reviews

Main results

Since 2000, one new trial has been published; the updated review now includes five RCTs involving 4023 women with breast cancer (clinical stage I, II or III).

Two trials involving 2563 women compared follow-up based on clinical visits and mammography with a more intensive scheme including radiological and laboratory tests. After pooling the data, no significant differences in overall survival (hazard ratio (HR) 0.98, 95% confidence interval (CI) 0.84 to 1.15, two studies, 2563 participants, *high-quality evidence*), or disease-free survival (HR 0.84, 95% CI 0.71 to 1.00, two studies, 2563 participants, *low-quality evidence*) emerged. No differences in overall survival and disease-free survival emerged in subgroup analyses according to patient age, tumour size and lymph node status before primary treatment. In 1999, 10-year follow-up data became available for one trial of these trials, and no significant differences in overall survival were found. No difference was noted in quality of life measures (one study, 639 participants, *high-quality evidence*).



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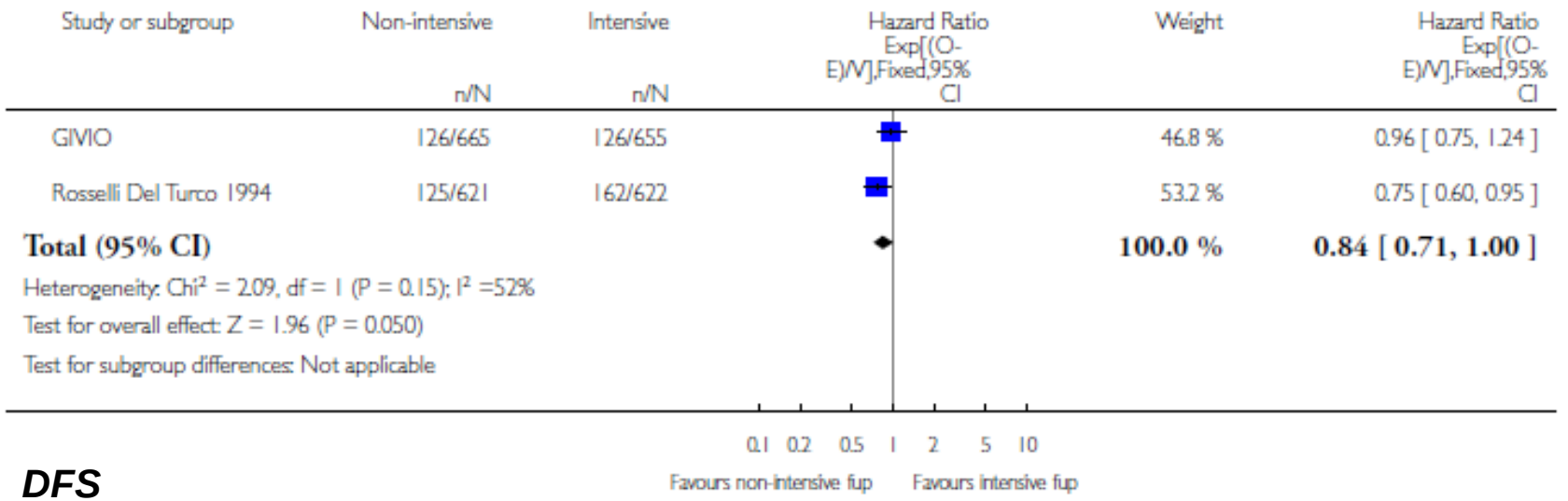
Moschetti I et al., Cochrane Database of Systematic Reviews 2016.



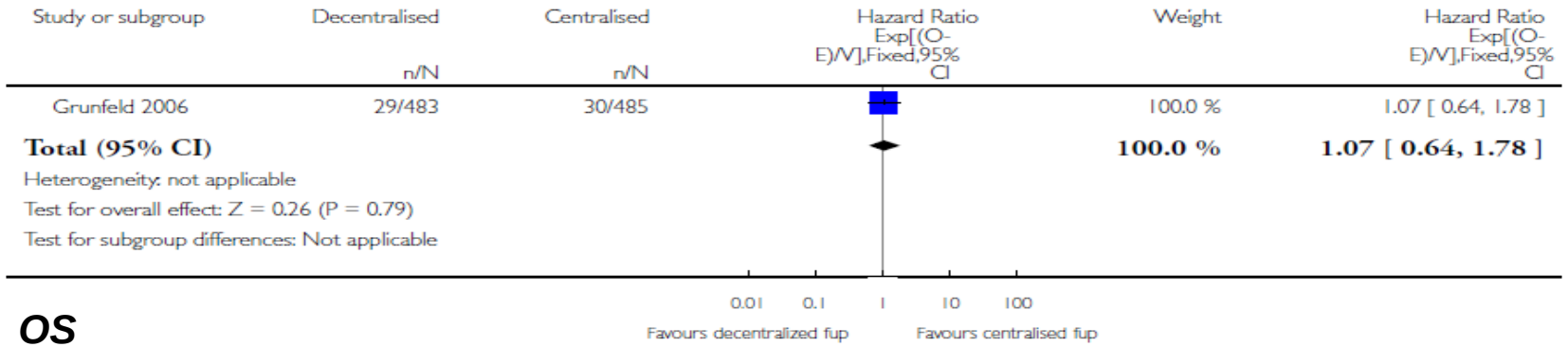
DFS

AUTHORS' CONCLUSIONS

This updated review of RCTs conducted almost 20 years ago suggests that follow-up programs based on regular physical examinations and yearly mammography alone are as effective as more intensive approaches based on regular performance of laboratory and instrumental tests in terms of timeliness of recurrence detection, overall survival and quality of life.

Moschetti I et al., Cochrane Database of Systematic Reviews 2016.

The new included trial, together with a previously included trial involving 1264 women compared follow-up performed by a hospital-based specialist versus follow-up performed by general practitioners. No significant differences were noted in overall survival (HR 1.07, 95% CI 0.64 to 1.78, one study, 968 participants, *moderate-quality evidence*), time to detection of recurrence (HR 1.06, 95% CI 0.76 to 1.47, two studies, 1264 participants, *moderate-quality evidence*), and quality of life (one study, 356 participants, *high-quality evidence*).



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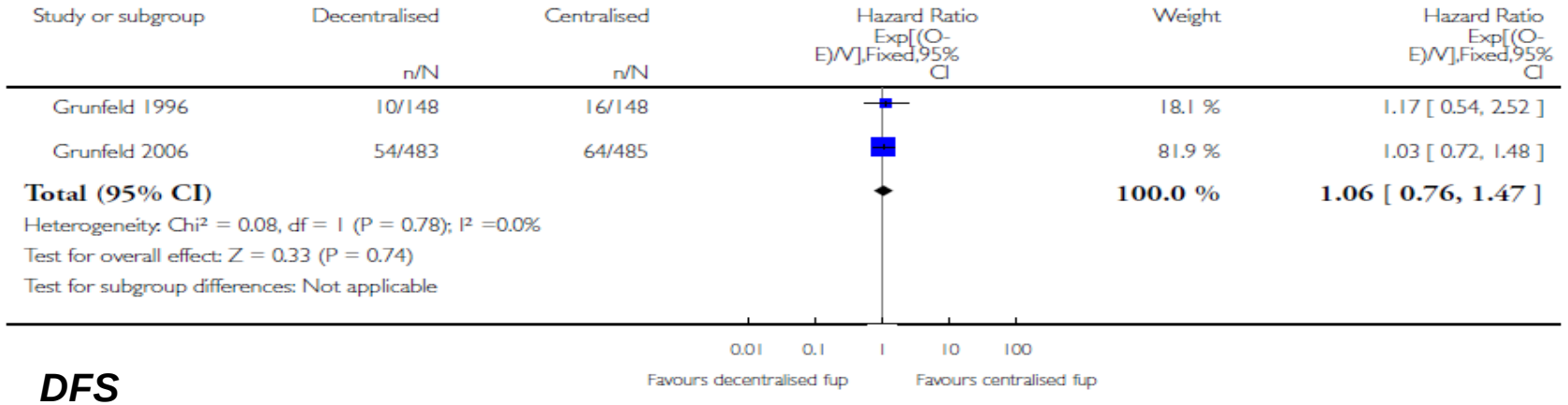

DFS

Moschetti I et al., Cochrane Database of Systematic Reviews 2016.

AUTHORS' CONCLUSIONS

In two RCTs, follow-up care performed by trained and not trained general practitioners working in an organised practice setting had comparable effectiveness to that delivered by hospital-based specialists in terms of overall survival, recurrence detection, and quality of life.

.....but:

Key results: This review of trials found that follow-up programs based on a regular physical examination and a yearly mammogram appear to be as effective as the more intensive approaches and to have similar impact on HRQoL. No significant differences were found between follow-up performed by specialists or family physicians, regularly or on demand. These results should be interpreted with caution bearing in mind that these studies were conducted almost two decades ago; additional trials incorporating new biological knowledge and improved imaging technologies are needed.

Moschetti I et al., Cochrane Database of Systematic Reviews 2016.

- Riconoscimento precoce di recidive di malattia potenzialmente suscettibili di trattamento con intento radicale.
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Cosa ci raccomandano le linee guida?

Monitoraggio degli effetti collaterali dei trattamenti

In caso di terapia con *inibitori dell'aromatasi* è raccomandabile un controllo periodico dei livelli ematici di colesterolo e trigliceridi, così come della densitometria ossea.
In caso di terapia con *tamoxifene*, una valutazione ginecologica annuale (visita ed eventuale ecografia pelvica) può essere presa in considerazione, pur riconoscendo l'assenza di evidenza a sostegno della utilità clinica[4]

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- ✓ For patients on *tamoxifen*, an annual gynaecological examination, possibly with a gynaecological ultrasound is recommended.
- ✓ Regular bone density evaluation is recommended for patients on *aromatase inhinitors*.
- ✓ Routine blood tests are usually indicated to follow-up patients on hormonal therapies due to the potential side-effects to these drugs, namely in the lipid profile.

ESMO European Society for Medical Oncology
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- ✓ Women on *tamoxifen*, annual gynecologic assessment every 12 months if uterus present.
- ✓ Women on *aromatase inhinitors* or who experience ovarian failure secondary to treatment should have monitoring of bone health with a bone mineral density determination at baseline and periodically thereafter.

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Comuni effetti collaterali delle terapie:

Symptom or Problem	Factors Associated with Highest Risk	Recommended Screening	Recommended Interventions*
Hot flashes	Chemotherapy-induced menopause Treatment with tamoxifen or aromatase inhibitors	History	SSRIs†‡ Citalopram, 30 mg Fluoxetine, 20 mg Paroxetine (avoid if patient is receiving tamoxifen), 10–20 mg or 12.5–25 mg continuous release SSNRIs†‡ Venlafaxine, 75 or 100 mg Gabapentin, 300 mg 3 times/day†‡
Sexual dysfunction		History	
Loss of libido (in addition to dyspareunia)	Altered body image due to surgery, irradiation, or systemic therapy; depression		Sexual counseling
Dyspareunia due to vaginal dryness	Chemotherapy-induced menopause; treatment with tamoxifen or aromatase inhibitors		Nonhormonal vaginal moisturizing or lubricating preparation (polycarbophil [Replens] or hydroxyethylcellulose, chlorhexidine gluconate, methylparaben, or glucono delta lactone [Astroglide]); intravaginal estradiol preparations (use with caution)§
Arthralgias and musculoskeletal symptoms	Treatment with tamoxifen or aromatase inhibitors (symptoms are more common with aromatase inhibitors)	History (rule out features suggestive of metastatic disease to bone, such as persistent and progressively more severe long bone or back pain, which would warrant imaging)	Conservative medical management Acetaminophen NSAIDs
Cognitive dysfunction	Diagnosis of breast cancer Of concern but not documented: chemotherapy, treatment with tamoxifen or aromatase inhibitors	History	Evaluate for Alzheimer's disease or other organic cause if progressive and severe
Depression	Diagnosis of breast cancer Of concern but not documented: chemotherapy, treatment with tamoxifen or aromatase inhibitors	History	Usual management (counseling, antidepressants)

Hayes DF, NEJM 2007.

Symptom or Problem	Factors Associated with Highest Risk	Recommended Screening	Recommended Interventions*
Congestive heart failure	Treatment with anthracyclines or trastuzumab	None Monitor left ventricular function during trastuzumab therapy	No known prophylaxis Appropriate medical management if present
Thrombosis (deep vein, cerebrovascular)	Treatment with tamoxifen	History	No proven prophylaxis Appropriate medical management if present
Fatigue	Diagnosis of breast cancer Chemotherapy Of concern but not documented: treatment with tamoxifen or aromatase inhibitors	History	Rule out or treat psychiatric or biologic cause (depression, anemia, hypothyroidism)
Weight gain	Chemotherapy Of concern but not documented: treatment with tamoxifen or aromatase inhibitors	History	Usual management (diet, exercise)
Osteopenia or osteoporosis	Chemotherapy-induced menopause Treatment with aromatase inhibitors Usual risk factors for osteoporosis: lean body habitus, smoking, personal or family history of osteoporotic fracture	Bone densitometry before initiation of aromatase inhibitor and every 1 to 2 years thereafter	Usual management Adequate intake of calcium (1200–1500 mg daily) and vitamin D (400–800 IU daily)¶ Weight-bearing exercise, avoidance of smoking Bisphosphonate if indicated‖
Cardiovascular disease	Irradiation of the left chest wall Of concern but not documented: chemotherapy-induced early menopause, treatment with aromatase inhibitors	History	Appropriate medical and lifestyle risk-reduction strategies

Hayes DF, NEJM 2007.

Cardiotossicità da schemi chemioterapici contenenti antracicline:

- Rischio dose dipendente.
- L'aggiunta della radioterapia sulla parete toracica sinistra incrementa di circa 20-30% il rischio di eventi cardiovascolari a lungo termine.
- Tossicità *acuta* (durante o al termine dell'infusione): in <1% dei casi e generalmente reversibile.
- Tossicità *cronica*: nel 1.6-2.1% dei casi se durante o entro 12 mesi dal termine della chemioterapia o nel 1.6-5.1% dei casi se oltre 12 mesi dal termine del trattamento.
- Non evidenze definitive sull'intervallo ottimale e sulla durata totale del monitoraggio cardiaco → *valutazione a 6 mesi dal termine della chemioterapia, annualmente per 2 o 3 anni e poi ogni 3-5 anni* (Linee guida della Società Europea di Oncologia); se ad alto rischio (ipertensione, displipidemia, diabete, LVEF ridotta al basale) e/o elevata dose cumulativa di antracicline e/o pazienti anziane, possibile monitoraggio più frequente.

Cardiotossicità da chemioterapia e trastuzumab:

- 0.6-4.1% dei casi.
- *Valutazione cardiologica a 3, 6 e 9 mesi durante il trattamento e quindi a 12 e 18 mesi o se clinicamente indicato* (Linee guida della Società Europea di Oncologia).

Curigliano G et al., Annals of Oncology 2012.

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Cosa ci raccomandano le linee guida?

Promozione di corretti stili di vita	Tutte le pazienti dovrebbero essere incoraggiate ad adottare uno stile di vita sano (limitazione del consumo alcolico, astensione dal fumo se fumatrici, attività fisica regolare, riduzione del peso corporeo con opportuno programma nutrizionale se obese o in sovrappeso)[4]

Aiom
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- ✓ *Regular exercise* provides functional and psychological benefits and therefore it should be recommended to all suitable patients after treatment of breast cancer.
- ✓ *Weight gain and obesity* are likely to adversely affect the prognosis of breast cancer → *Nutritional counselling* should be recommended as part of the survivor care for all obese patients.

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- ✓ Evidence suggests that *active lifestyle, health diet, limited alcohol intake and achieving and maintaining an ideal body weight (20-25 BMI)* may lead to optimal breast cancer outcomes.

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Negrar - Verona
Cancer Care Center
Numero Verde
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Numero per la Cura del Tumore

Ambulatorio nutrizionale e psicologico per pazienti oncologici.

- Riconoscimento precoce di recidive di malattia potenzialmente suscettibili di trattamento con intento radicale.
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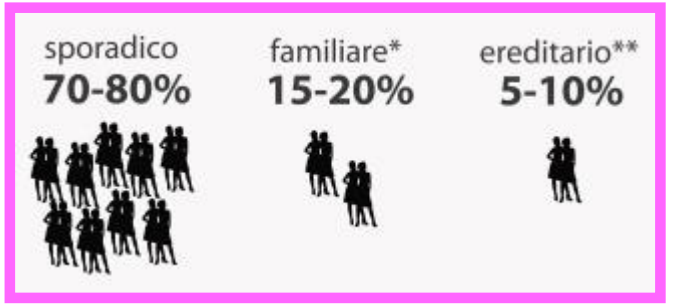

Rischio di secondi tumori

È stato stimato che le pazienti con diagnosi di carcinoma mammario hanno un *aumento del rischio relativo di sviluppare un secondo tumore a 10 anni del 22%:* tale rischio può essere legato a fattori genetici (BRCA e p53), pregressa radioterapia (i.e. angiosarcomi e tumori dell'esofago), terapia ormonale (i.e. rischio di carcinoma endometriale nelle pazienti che assumono tamoxifene) e chemioterapia (leucemie acute, mielodisplasie).

Hayes DF et al., NEJM 2007.
Schaapveld M et al., J Clin Oncol 2008.

Referral for genetic counseling	Women at high risk for familial breast cancer syndromes should be referred for genetic counseling in accordance with clinical guidelines recommended by the US Preventive Services Task Force. Criteria to recommend referral include the following: • Ashkenazi Jewish heritage • History of ovarian cancer at any age in the patient or any first- or second-degree relatives • Any first-degree relative with a history of breast cancer diagnosed before the age of 50 years • Two or more first- or second-degree relatives diagnosed with breast cancer at any age • Patient or relative with diagnosis of bilateral breast cancer • History of breast cancer in a male relative.‡

Khatcheressian JL et al., JCO 2013.

Criteri per l'invio alla consulenza genetica oncologica

(presenza di almeno uno dei seguenti criteri):

- ✓ Mutazione nota in un *gene predisponente* (BRCA1, BRCA2, P53, PTEN etc….).
- ✓ *Maschio* con carcinoma mammario.
- ✓ Donna con *carcinoma mammario e carcinoma ovarico.*
- ✓ Donna con carcinoma mammario < *36 anni.*
- ✓ Donna con carcinoma mammario *triplo negativo* < *60 anni.*
- ✓ Donna con carcinoma mammario *bilaterale* < *50 anni.*
- ✓ Donna con carcinoma mammario < *50 anni e almeno un parente di primo grado* con carcinoma mammario < 50 anni o carcinoma ovarico non mucinoso o borderline a qualsiasi età o carcinoma mammario bilaterale o carcinoma mammario maschile.
- ✓ Donna con carcinoma mammario > *50 anni e storia familiare di carcinoma mammario o ovarico in 2 o più parenti di primo grado tra loro* (di cui uno in primo grado con lei).

Ambulatorio Counseling genetico
Dipartimento Oncologia

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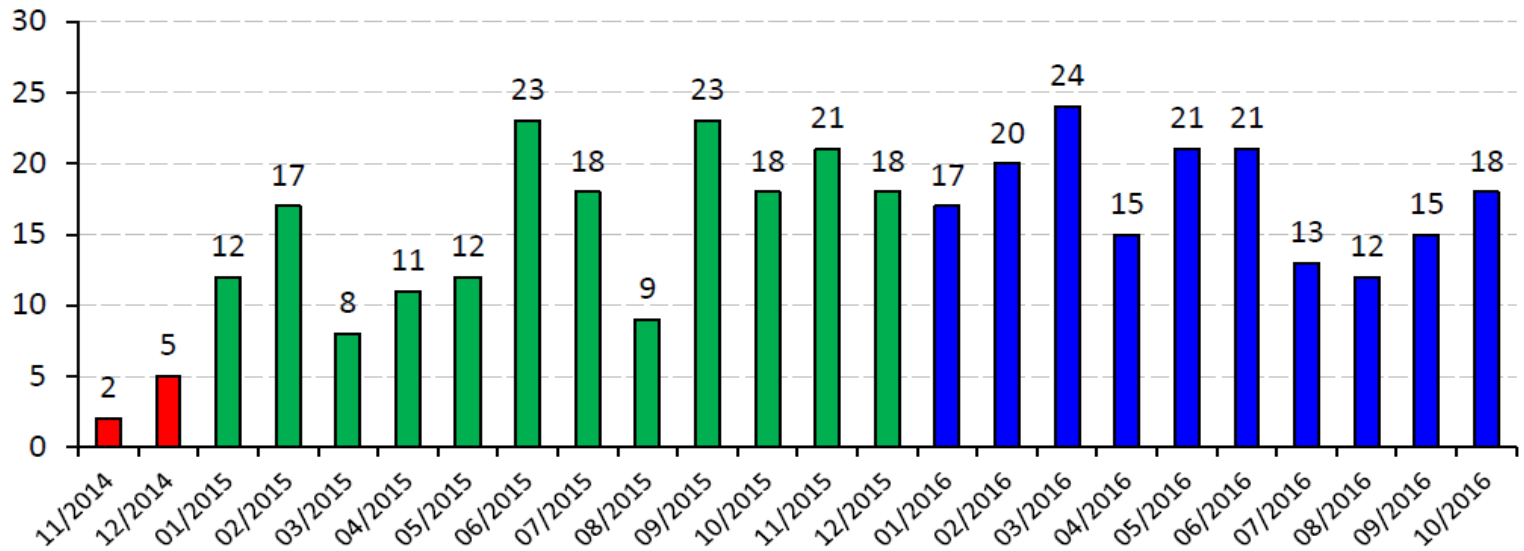
- Andamento mensile:

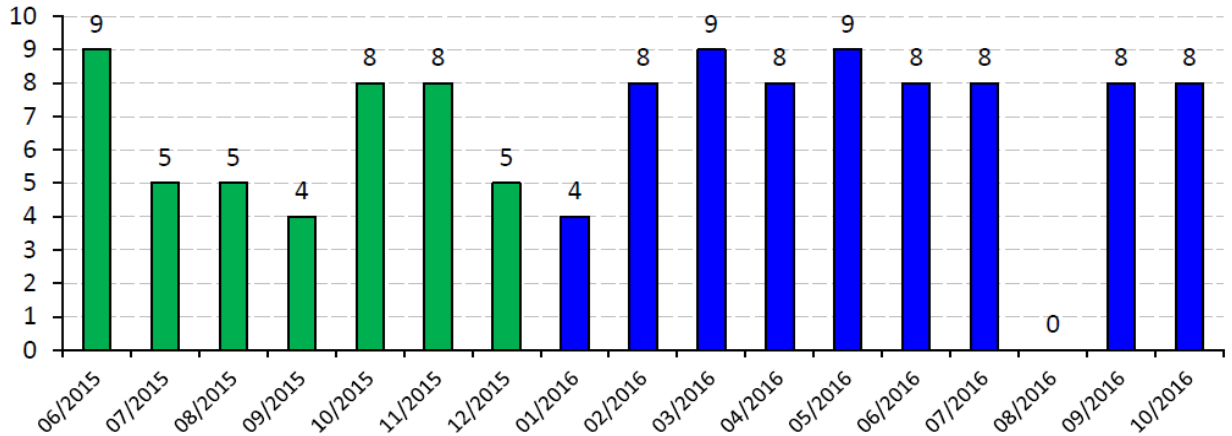


- Riepilogo annuale

2014 (01/11 – 31/12)	2015	2016 (01/01 – 31/10)
7	190	176

Prelievi ematici per valutazione BRCA1/2 inviati allo IOV-Padova (Dott. Montagna) dal 01/06/2015 al 31/10/2016.

- Andamento mensile:



- Riepilogo annuale

	2015 (01/06 – 31/12)			**2016** (01/01 – 31/10)		
	Pts ca mammella	**Pts ca ovaio**	**Totale**	**Pts ca mammella**	**Pts ca ovaio**	**Totale**
Prelievi effettuati	23	21	**44**	38	32	**70**
Risultati pervenuti	6	14	**20**	14	8	**22**
Mutazione BRCA 1/2	3	3	**6**	0	3	**3**

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JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

American Cancer Society/American Society of Clinical Oncology Breast Cancer Survivorship Care Guideline

Carolyn D. Runowicz, Corinne R. Leach, N. Lynn Henry, Karen S. Henry, Heather T. Mackey, Rebecca L. Cowens-Alvarado, Rachel S. Cannady, Mandi L. Pratt-Chapman, Stephen B. Edge, Linda A. Jacobs, Arti Hurria, Lawrence B. Marks, Samuel J. LaMonte, Ellen Warner, Gary H. Lyman, and Patricia A. Ganz

RECOMMENDED MODES OF BREAST CANCER SURVEILLANCE	
History/Physical Exam	Every 3 to 6 months for the first 3 years after primary therapy; every 6 to 12 months for years 4 and 5, then annually.
Patient Education	Counsel patients about the symptoms of recurrence including new lumps, bone pain, chest pain, abdominal pain, dyspnea or persistent headaches.
Referral for Genetic Counseling	Criteria to recommend referral include Ashkenazi Jewish heritage; history of ovarian cancer in patient or any first- or second-degree relative; any first degree relative with a history of breast cancer diagnosed before age 50; two or more first- or second-degree relatives diagnosed with breast cancer; patient or relative with diagnosis of bilateral breast cancer; or, history of breast cancer in a male relative.
Breast Self-Exam	All women should be counseled to perform monthly breast self-examination.
Mammography	First post-treatment mammogram 1 year after the initial mammogram that leads to diagnosis, but no earlier than 6 months after definitive radiation therapy. Subsequent mammograms should be obtained as indicated for surveillance of abnormalities.
Pelvic Examination	Regular gynecologic follow-up is recommended for all women. Patients who receive tamoxifen should be advised to report any vaginal bleeding to their physicians.
Coordination of Care	Continuity of care for breast cancer patients is encouraged and should be performed by a physician experienced in the surveillance of cancer patients and in breast examination, including the examination of irradiated breasts. If follow-up is transferred to a PCP, the PCP and the patient should be informed of the long-term options regarding adjuvant hormonal therapy for the particular patient. This may necessitate re-referral for oncology assessment at an interval consistent with guidelines for adjuvant hormonal therapy.
BREAST CANCER SURVEILLANCE TESTING - NOT RECOMMENDED	
Routine blood tests	CBCs and liver function tests are not recommended
Imaging Studies	Chest x-ray, bone scans, liver ultrasound, CT scans, FDG-PET scans, and breast MRI are not recommended
Tumor markers	CA 15-3, CA 27.29 and CEA are not recommended.

Open questions:

- Il *rischio di recidiva di carcinoma mammario* è più elevato nei primi 5 anni dopo la diagnosi, ma permane ***fino ai 15 anni dalla diagnosi e oltre.***

- Il pattern di recidiva varia in funzione delle caratteristiche biologiche della patologia e del trattamento effettuato: gli ***hazard rates di ricaduta differiscono tra i diversi immunofenotipi*** ai quali corrisponde un beneficio terapeutico distinto.

- Necessità di un follow-up personalizzato sulla base dello stadio e delle caratteristiche biologiche della malattia e di ***modelli prognostici validati*** in grado di selezionare i pazienti a maggior rischio da candidare ad una schema di follow-up più intensivo, al fine di poter intervenire con un intento di guarigione sulla ripresa di malattia (ex HER2-positive, BRCA-positive, triple-negative).

Davies C et al., Lancet 2011.
Dent R et al., Breast Cancer Res Treat 2009.
Untch M et al., Ann Oncol 2008.

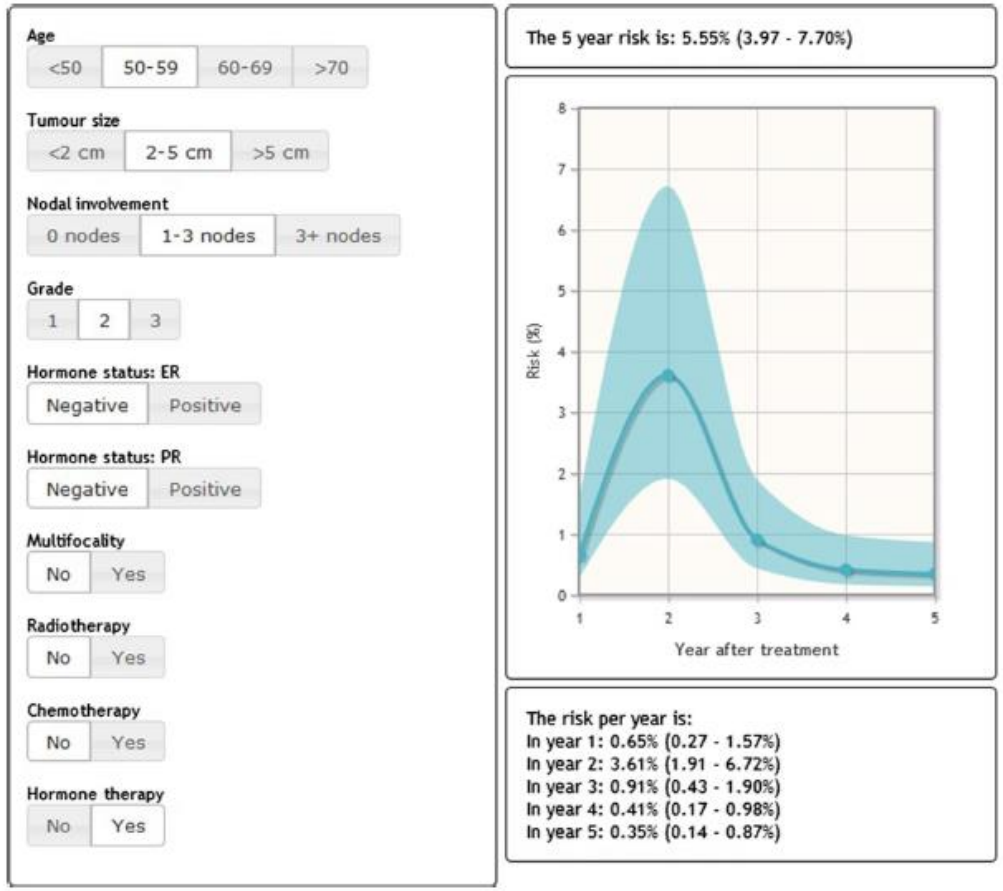
Breast Cancer Res Treat (2015) 152:627–636
DOI 10.1007/s10549-015-3490-4

EPIDEMIOLOGY

Personalisation of breast cancer follow-up: a time-dependent prognostic nomogram for the estimation of annual risk of locoregional recurrence in early breast cancer patients

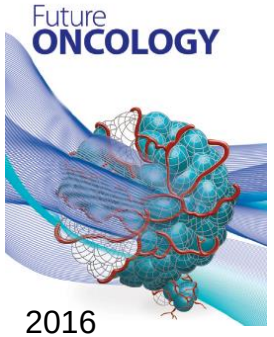
Annemieke Witteveen[1] · Ingrid M. H. Vliegen[2] · Gabe S. Sonke[3] · Joost M. Klaase[4] · Maarten J. IJzerman[1] · Sabine Siesling[1,5]

cohort. The results were incorporated in a web-based nomogram (http://www.utwente.nl/mira/influence). This validated nomogram can be used as an instrument to identify patients with a low or high risk of LRR who might benefit from a less or more intensive follow-up after breast cancer and to aid clinical decision making for personalised follow-up.



Caring for cancer survivors: perspectives of oncologists, general practitioners and patients in Italy

Fabio Puglisi[‡,1,2], Elisa Agostinetto[1,2], Lorenzo Gerratana[*,1,2], Claudia Bozza[1,2], Maurizio Cancian[3], Elisabetta Iannelli[4], Giovanni Ratti[5], Saverio Cinieri[§,6,7] & Gianmauro Numico[‡,8]



2016

- There are a growing number of cancer survivors but a gold standard in surveillance management is currently lacking.
- We conducted a national survey: an online questionnaire was filled by 329 medical oncologists, 380 general practitioners (GPs) and 350 patients.
- The questionnaire included demographic information, adherence to guidelines, continuity and coordination of care, opinion on follow-up strategy and patients' satisfaction.
- Most GPs claim that follow-up should be provided by the collaboration between GPs and medical oncologists, after 2–3 years of disease-free survival.
- The majority of medical oncologists report to have a poor relationship with GPs.
- Patients tend to trust their GPs, but collaboration between medical oncologists and GPs is perceived as poor.
- According to answers provided, the collaboration between oncologists and GPs is considered poor and needs to be improved.
- Analyzing the feedbacks coming from all the actors that take part in this process could help in designing common guidelines that optimize both resources and efficiency.

Un **modello organizzativo condiviso** che integri specialisti oncologi e MMG per l'assistenza in corso di follow-up potrebbe fornire una buona aderenza alle linee guida.

Grazie a tutti per l'attenzione

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