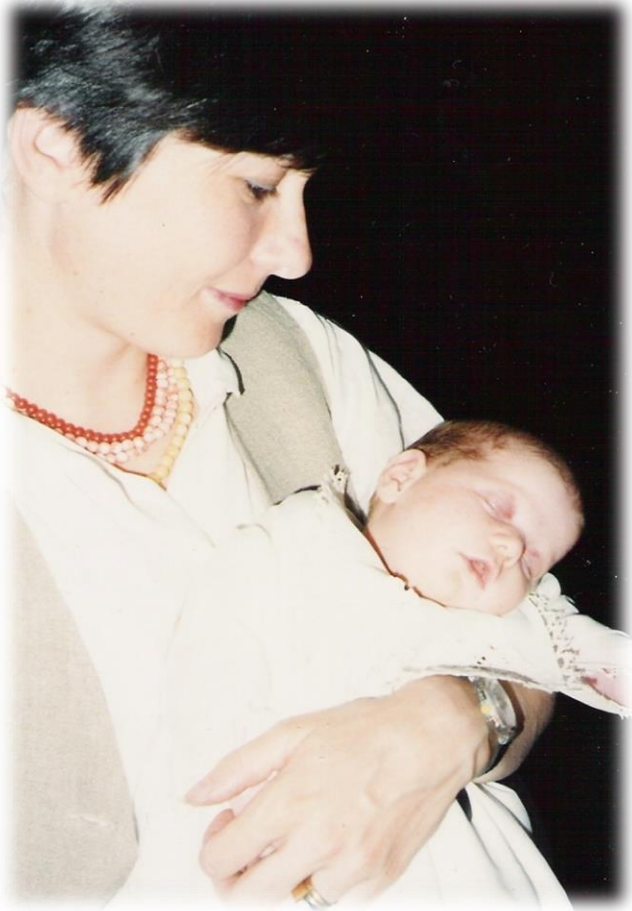


In occasione del primo Fertility Day



Malattia oncologica e preservazione della fertilità

Fedro Alessandro Peccatori, MD PhD
Direttore

Unità Fertilità e Procreazione in Oncologia
Istituto Europeo di Oncologia
Milano



Fertility Day



IEO

Istituto Europeo di Oncologia

I NUMERI DEL CANCRO IN ITALIA 2015



363.000 nuovi casi di tumore ogni anno in ITA

194.000 maschi e 169.000 femmine



Rango	Maschi	Femmine	Tutta la popolazione
1°	Prostata (20%)	Mammella (29%)	Mammella (14%)
2°	Polmone (15%)	Colon-retto (13%)	Colon retto (13%)
3°	Colon-retto (14%)	Polmone (6%)	Prostata (11%)
4°	Vescica* (11%)	Tiroide (5%)	Polmone (11%)
5°	Stomaco (5%)	Utero corpo (5%)	Vescica (7%)

Incidenza 6:1000/anno

1000 persone ogni giorno si ammalano di tumore

177.000 morti di tumore ogni anno in ITA

99.792 maschi e 77.559 femmine



Rango	Maschi	Femmine	Tutta la popolazione
1°	Polmone (26%)	Mammella (17%)	Polmone (20%)
2°	Colon-retto (10%)	Colon-retto (12%)	Colon-retto (11%)
3°	Prostata (8%)	Polmone (11%)	Mammella (7%)
4°	Fegato (7%)	Pancreas (7%)	Stomaco (6%)
5°	Stomaco (6%)	Stomaco (6%)	Pancreas (6%)

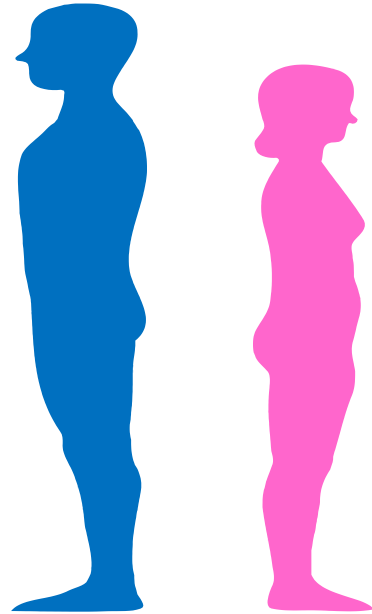
Mortalità 3:1000/anno

485 persone ogni giorno muoiono di tumore

Incidenza dei tumori in età riproduttiva (18-39y)

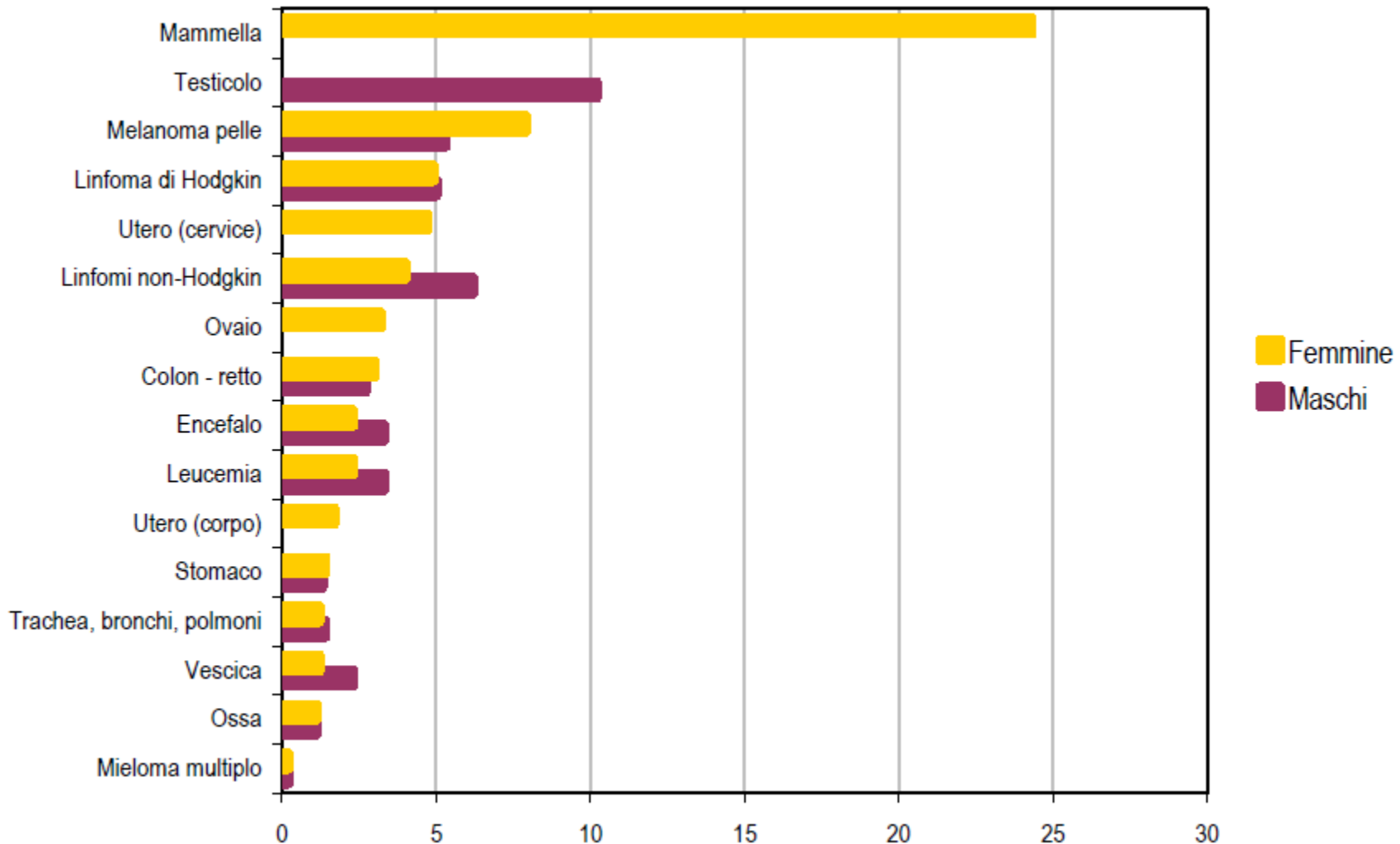
CIRCA 3% di TUTTI I CASI

9.000 nuovi casi ogni anno, 5.000 donne



Incidenza dei tumori in età riproduttiva (18-39y)

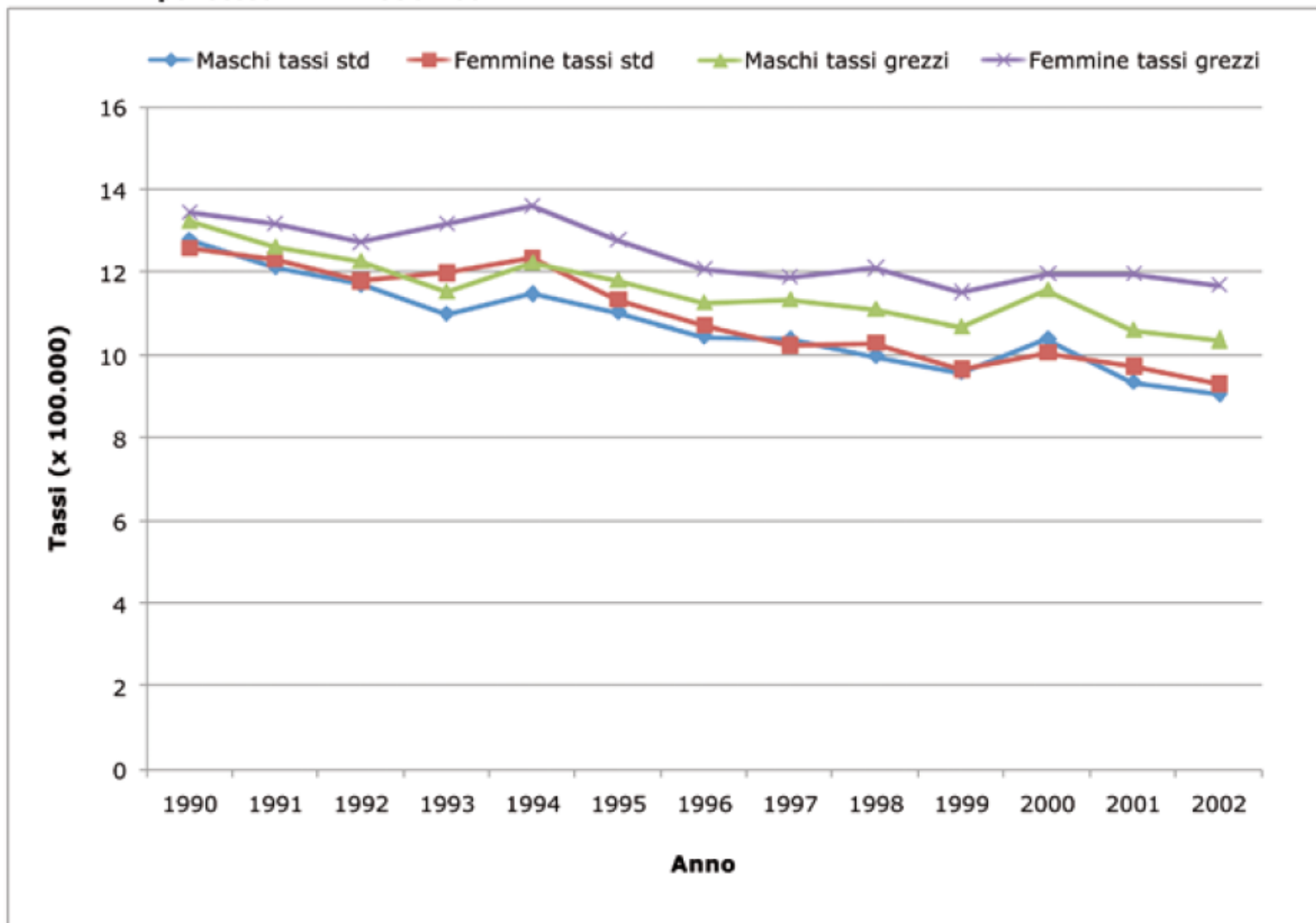
Figura 1 - Tassi per 100.000 abitanti di incidenza annua stimata per tumori maligni a 15-39 anni per sesso e tipo di tumore (ordinati in ordine decrescente) - Anni 1998-2002



I tumori negli adolescenti e nei giovani adulti:
i dati epidemiologici recenti come base per le prospettive future

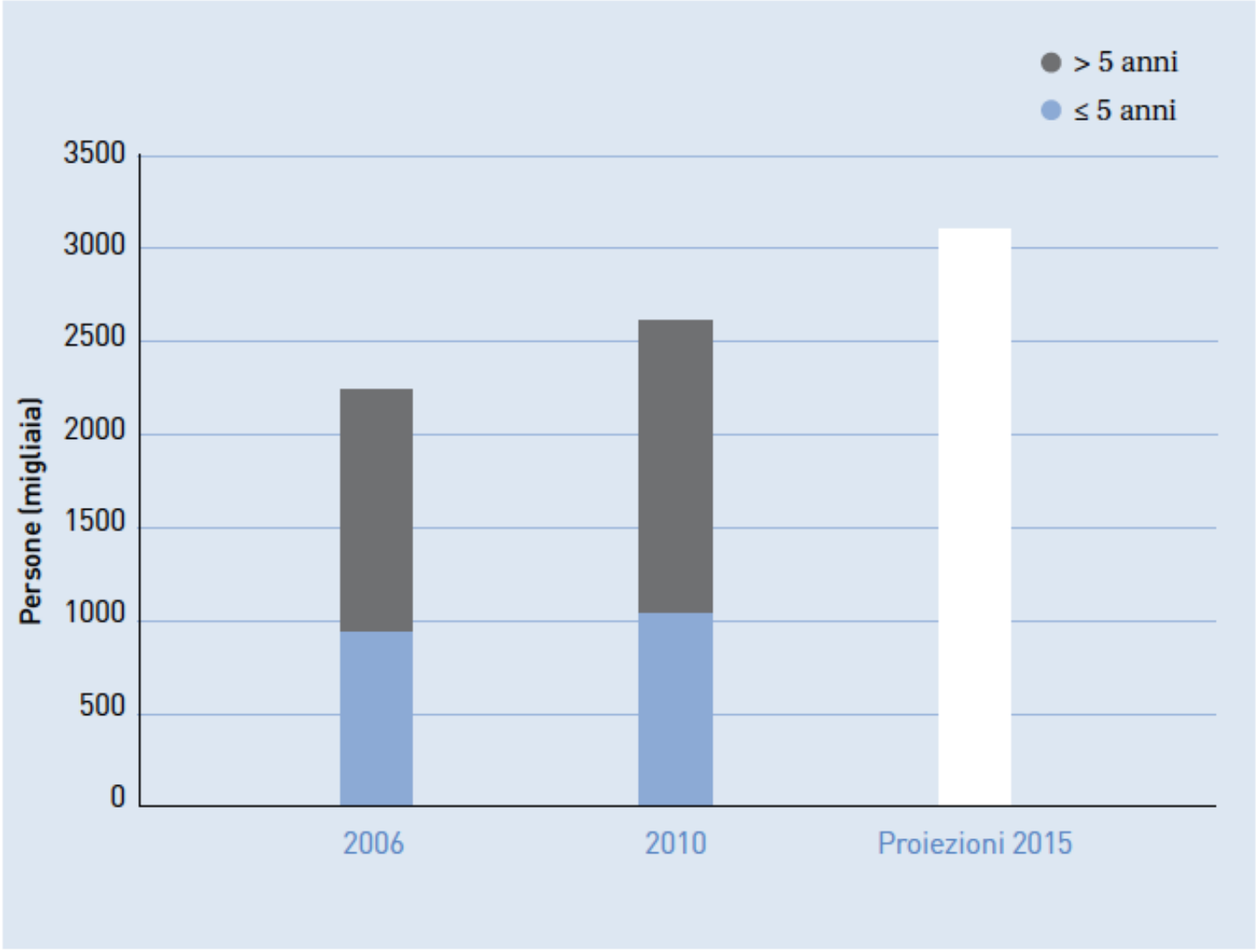
Mortalità dei tumori in età riproduttiva (18-39y)

Figura 3.1 - Tassi grezzi e standardizzati di mortalità per tumore maligno per 100.000 persone di 15-39 anni per sesso - Anni 1990-2002



I tumori negli adolescenti e nei giovani adulti:
i dati epidemiologici recenti come base per le prospettive future

Prevalenza dei tumori in Italia (stime 2015)



Source: AIRTUM

La popolazione dei lungosopravvivenenti in età riproduttiva è di circa 100.000 persone in ITA

Aumentato rischio cardiovascolare

Sindrome metabolica

Secondi tumori

INFERTILITA'



Racial, Socioeconomic, and Demographic Disparities in Access to Fertility Preservation in Young Women Diagnosed With Cancer

Joseph M. Letourneau, MD¹; James F. Smith, MD, MS²; Erin E. Ebbel, BA¹; Amaranta Craig, BA¹; Patricia P. Katz, PhD³; Marcelle I. Cedars, MD¹; and Mitchell P. Rosen, MD, HCLD¹

Characteristic	Total Sample, n=918	Type of Cancer				
		Leukemia, n=121	Hodgkin Disease, n=286 ^a	Non-Hodgkin Lymphoma, n=169 ^a	Breast Cancer, n=223	Gastrointestinal Cancer, n=108
Age at diagnosis, y, mean (SD)	31.5 (6.7)	28.3 (7.2)	27.9 (6.2)	31.6 (6.0)	36.3 (4.0)	34.9 (4.6)
Age at survey, y, mean (SD)	40.9 (8.4)	37.0 (8.3)	36.5 (8.0)	40.5 (7.1)	47.1 (5.9)	44.6 (6.2)
Years since diagnosis, mean (SD)	9.6 (4.4)	8.7 (4.3)	8.6 (4.4)	8.9 (3.9)	10.8 (4.5)	9.7 (4.0)
Children before treatment, No. (%)	478 (52%)	46 (38%)	105 (37%)	88 (52%)	163 (73%)	76 (70%)
Desiring children after treatment, No. (%)	504 (54%)	71 (59%)	181 (63%)	82 (49%)	104 (47%)	61 (56%)

54 % of young patients with cancer want a baby

Web-Based Survey of Fertility Issues in Young Women With Breast Cancer

Ann H. Partridge, Shari Gelber, Jeffrey Peppercorn, Ebonie Sampson, Katherine Knudsen, Marc Laufer, Randi Rosenberg, Michele Przystycki, Alison Rein, and Eric P. Winer

657 patients, median age 32.9 yrs

73% patients worried about fertility issues

57% seriously worried about sterility

29% influenced therapeutic decisions



(Partridge et al JCO 2004)

Perchè l'infertilità dopo tumore?

Panel 1: Estimated risk of gonadal dysfunction with cytotoxic drugs²⁹

High risk

Cyclophosphamide
Ifosfamide
Chlormethine
Busulfan
Melphalan
Procarbazine
Chlorambucil

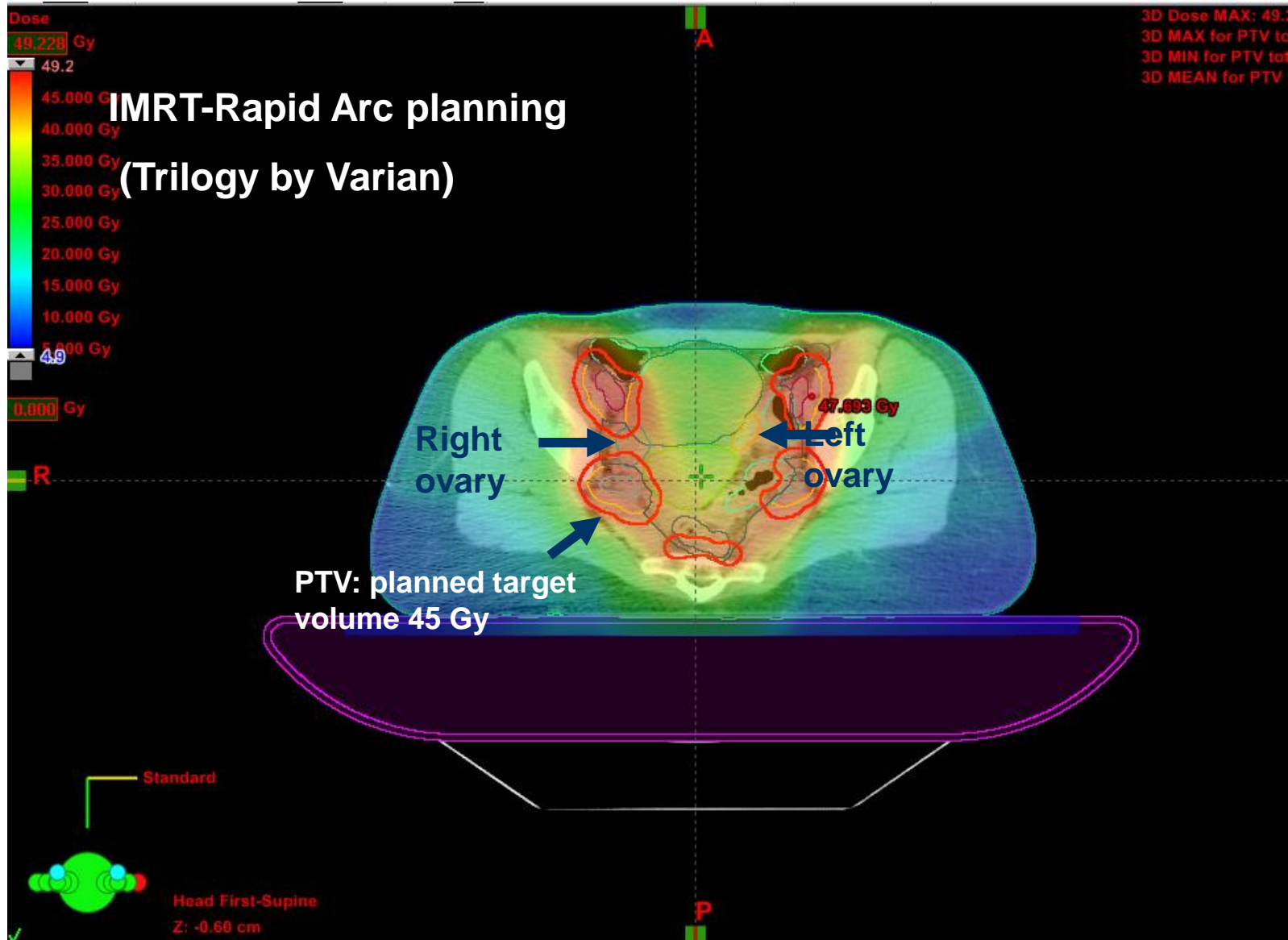
Medium risk

Cisplatin
Carboplatin
Doxorubicin

Low risk

Vincristine
Methotrexate
Dactinomycin
Bleomycin
Mercaptopurine
Vinblastine

Perchè l'infertilità dopo tumore?



Perchè l'infertilità dopo tumore?



E allora, che fare?

- Considerare il problema
cultura e rispetto della centralità del paziente
- Organizzare una rete collaborativa tra oncologi e specialisti in riproduzione umana
il ruolo dell' "early referral" e dei protocolli condivisi
- Offrire la preservazione della fertilità realmente a tutte le interessate e gli interessati
il ruolo delle istituzioni



Considerare il problema e creare cultura



PREVENIRE LA STERILITÀ E CONSERVARE LA FERTILITÀ NELLE DONNE MALATE DI CANCRO

APPELLO AL MINISTERO DELLA SALUTE E ALLA CONFERENZA STATO-REGIONI

Ogni anno in Italia si ammalano di cancro 366.000 persone. Di queste, 169.000 sono donne. Dato che circa il 3% delle neoplasie femminili si verifica tra i 18 e i 39 anni, sono 5.000 le donne che ogni anno devono confrontarsi con un tumore in età riproduttiva. Il carcinoma mammario e i linfomi sono i tumori più frequentemente diagnosticati nelle donne giovani. Rappresentano il 60% di tutti i tumori in età riproduttiva e vengono trattati nella maggior parte dei casi

con chemioterapii e con chemioterapii. Per le giovani donne si fa possibile la soluzione di fertilità da chemioterapia. L'utilizzo di farmaci di fertilità deve essere applicato dopo la guarigione, almeno di 6 mesi e analoghi LHRH, alle pazienti che hanno una probabilità di gravidanza. Quali sono le risorse? Il costo dei farmaci del tutto un onere. Eppure basterebbero



Ministero della Salute

PIANO NAZIONALE PER LA FERTILITÀ

“ Difendi la tua fertilità, prepara una culla nel tuo futuro ”

- 1) Modificare la prevenzione del cancro e agli analoghi LHRH si sottoponesse;
- 2) Implementare di Italia con presidi oncologici, univita ad una rete di pazienti. L'Accordo sancito Trento e di Bolza Nazionale, linea;
- 3) Implementare i pazienti oncologici Superiori di Sani assistenziali dedicati all'utilizzo dei gam sottoposte a ques

Per favorire la natalità, se da un lato è imprescindibile lo sviluppo di politiche intersettoriali e interistituzionali a sostegno della Genitorialità, dall'altro sono indispensabili politiche sanitarie ed educative per la tutela della fertilità che siano in grado di migliorare le conoscenze dei cittadini al fine di promuoverne la consapevolezza e favorire il cambiamento.

Lo scopo del presente Piano è collocare la Fertilità al centro delle politiche sanitarie ed educative del nostro Paese.

A tal fine il Piano si prefigge di:

- 1) **Informare i cittadini sul ruolo della Fertilità nella loro vita, sulla sua durata e su come proteggerla evitando comportamenti che possono metterla a rischio**
- 2) **Fornire assistenza sanitaria qualificata per difendere la Fertilità, promuovere interventi di prevenzione e diagnosi precoce al fine di curare le malattie dell'apparato riproduttivo e intervenire, ove possibile, per ripristinare la fertilità naturale**
- 3) **Sviluppare nelle persone la conoscenza delle caratteristiche funzionali della loro fertilità per poterla usare scegliendo di avere un figlio consapevolmente ed autonomamente.**
- 4) **Operare un capovolgimento della mentalità corrente volto a rileggere la Fertilità come bisogno essenziale non solo della coppia ma dell'intera società, promuovendo un rinnovamento culturale in tema di procreazione.**
- 5) **Celebrare questa rivoluzione culturale istituendo il "Fertility Day", Giornata Nazionale di informazione e formazione sulla Fertilità, dove la parola d'ordine sarà scoprire il "Prestigio della Maternità".**



Prevenire la sterilità e conservare la fertilità nelle donne malate di cancro



Considerare il problema e creare cultura

Annals of Oncology 24 (Supplement 6): vi160–vi170, 2013
doi:10.1093/annonc/mdt198
Published online 27 June 2013

clinical practice guidelines

Cancer, pregnancy and fertility: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up†

F. A. Peccatori¹, H. A. Azim Jr.², R. Orecchia³, H. J. Hoekstra⁴, N. Pavlidis⁵, V. Kesic⁶ & G. Pentheroudakis⁶, on behalf of the ESMO Guidelines Working Group*

¹Fertility and Procreation Unit, Division of Gynaecologic Oncology, European Institute of Oncology, Milan, Italy; ²Department of Medicine, BEAST Data Centre, Institut Jules Bordet, Université Libre de Bruxelles, Brussels, Belgium; ³Department of Radiotherapy, European Institute of Oncology, Milan, Italy; ⁴Department of Surgical Oncology, University Medical Centre Groningen, Groningen, The Netherlands; ⁵Department of Medical Oncology, University of Ioannina, Ioannina, Greece; ⁶Department of Obstetrics and Gynaecology, Faculty of Medicine, University of Belgrade, Belgrade, Serbia;

These Clinical Practice Guidelines are endorsed by the Japanese Society of Medical Oncology (JSMO)



Linee guida

PRESERVAZIONE DELLA FERTILITA' NEI PAZIENTI ONCOLOGICI

Coordinatore: Lucia Del Mastro

Segretario Scientifico: Matteo Lambertini

Estensori:

Paola Anserini,
Maurizio Tomirotti,
Fedro Alessandro Peccatori

Referee AIOM

Referee SIA

Referee SIOG/SIGO

Saverio Cinieri
Luciano Latini

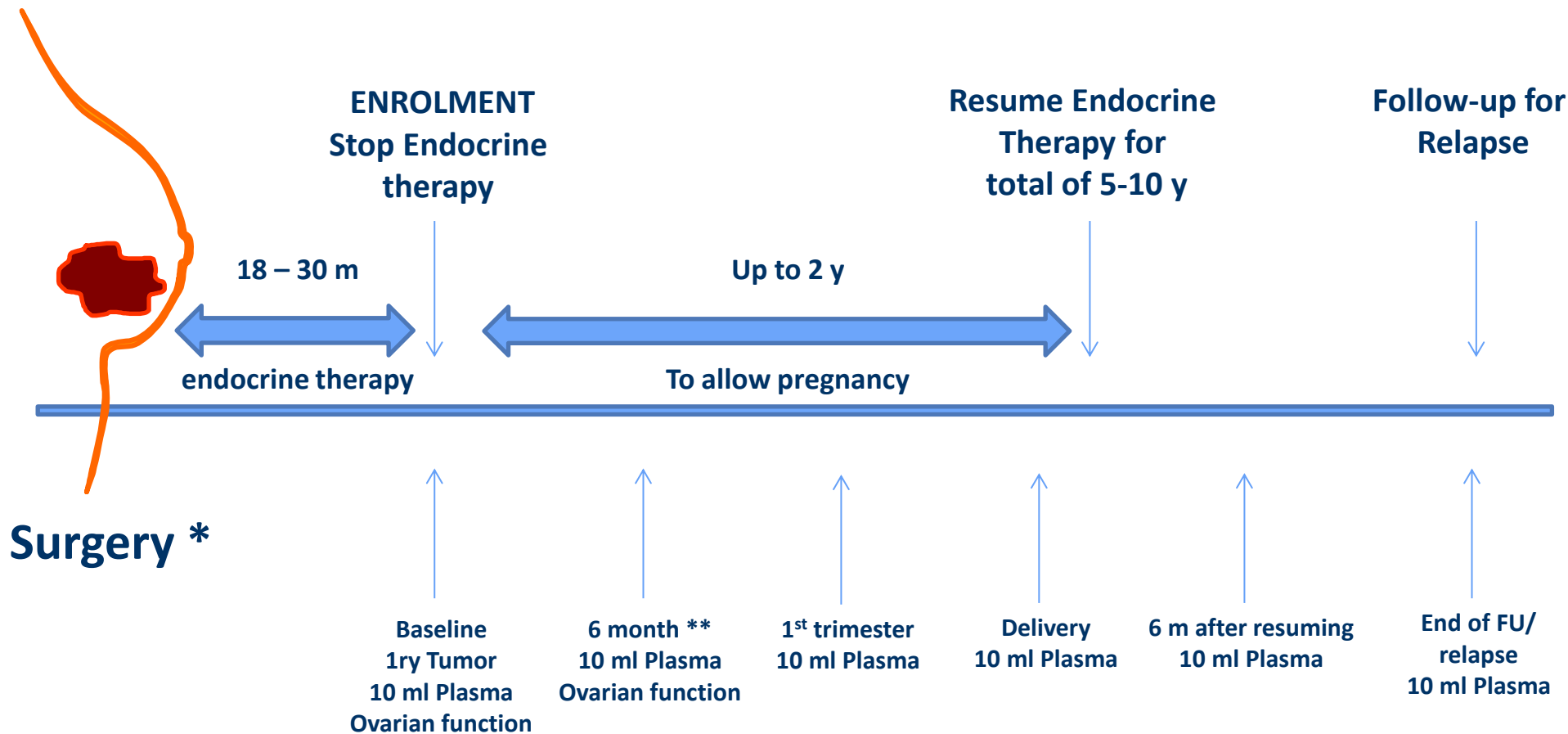
Giancarlo Morrone

Paolo Scollo, Nicola Surico,
Tiziano Maggino



Considerare il problema e creare cultura

IBCSG/BIG: Positive trial



* With or without adjuvant (neo) chemo, at the discretion of the investigator

** if pregnancy did not occur

Organizzare una rete collaborativa tra oncologi e specialisti in riproduzione umana

PERCORSO E + F

Pazienti a rischio e giovani

Donna \leq 38 anni

CONSULTO Fertilità e Procreazione (FPU)

Candidate ad intervento
chirurgico

**Crioconservazione
ovociti**

**Crioconservazione
Tessuto ovarico**

Candidate a
NEOADIUVANTE

Organizzare una rete collaborativa tra oncologi e specialisti in riproduzione umana

Lambertini et al. BMC Medicine (2016) 14:1
DOI 10.1186/s12916-015-0545-7

BMC

CORRESPONDENCE

Cancer and fertility preservation: international recommendations from an expert meeting

Matteo Lambertini^{1*}, Lucia Del Mastro², Maria C. Peccio³, Claus Y. Andersen⁴, Hatem A. Azim Jr⁵, Fedro A. Peccatori⁶, Mauro Costa⁷, Alberto Revelli⁸, Francesca Salvagno⁹, Alessia Gennari⁹, Rilly Giovanni¹⁰, La Sala¹¹, Cristoforo De Stefano¹², W. Hamish Wallace¹³, Ann H. Partridge¹⁴ and Paola

Abstract

In the last years, thanks to the improvement in the prognosis of cancer patients, a growing attention given to the fertility issues. International guidelines on fertility preservation in cancer patients recommend physicians discuss, as early as possible, with all patients of reproductive age their risk of infertility for and/or treatment and their interest in having children after cancer, and help with informed fertility decisions. As recommended by the American Society of Clinical Oncology and the European Society of Oncology, sperm cryopreservation and embryo/ovocyte cryopreservation are standard strategies for preservations in male and female patients, respectively; other strategies (e.g. pharmacological progonads and gonadal tissue cryopreservation) are considered experimental techniques. However, s data have become available, and several issues in this field are still controversial and should be at both patients and their treating physicians.

In April 2015, physicians with expertise in the field of fertility preservation in cancer patients from European countries were invited in Genova (Italy) to participate in a workshop on the topic of "cancer and fertility preservation". A total of ten controversial issues were discussed at the conference. Experts present an up-to-date review of the literature published on these topics and the presentation of own i was encouraged. On the basis of the data presented, as well as the expertise of the invited speakers, a recommendations were discussed and prepared with the aim to help physicians in counselling their patients interested in fertility preservation.

Although there is a great interest in this field, due to the lack of large prospective cohort studies and r on these topics, the level of evidence is not higher than 3 for most of the recommendations highlight further research efforts in many areas of this field. The participation to the ongoing registries and prospect crucial to acquire more robust information in order to provide evidence-based recommendations.

Keywords: Fertility preservation, cancer patients, survivorship issues, sperm cryopreservation, embryo/ovocyte cryopreservation, ovarian tissue cryopreservation, luteinizing hormone-releasing hormone analog

reviews

Annals of Oncology

Annals of Oncology 26: 2406–2418, 2015
doi:10.1093/annonc/mdv374
Published online 7 September 2015

Ovarian suppression using luteinizing hormone-releasing hormone agonists during chemotherapy to preserve ovarian function and fertility of patients: a meta-analysis of randomized

M. Lambertini¹, M. Ceppi², F. Poggio¹, F. A. Peccatori³, H. A. Azim Jr⁴, S. Loib^{5,7}, H. C. F. Moore⁶, A. H. Partridge⁸, P. Bruzzi⁹ & L. Del Mastro¹

¹Department of Medical Oncology, I.I.O. Oncologia Medica 2, IRCCS AOU San Martino-IST, Genova; ²Unit of Clinical Oncology and Prostate Cancer, Department of Oncology, European Institute of Oncology, Milan; ³IRCCS AOU San Martino-IST, Genova; ⁴Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, USA; ⁵Department of Medical Oncology, I.I.O. Oncologia Medica 2, IRCCS AOU San Martino-IST, Genova; ⁶Unit of Clinical Oncology and Prostate Cancer, Department of Oncology, European Institute of Oncology, Milan; ⁷IRCCS AOU San Martino-IST, Genova; ⁸Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, USA; ⁹Department of Medical Oncology, I.I.O. Oncologia Medica 2, IRCCS AOU San Martino-IST, Genova, Italy

Received 7 July 2015; accepted 12 August 2015; accepted 1 September 2015

Background: The role of temporary ovarian suppression with luteinizing hormone-releasing hormone in the prevention of chemotherapy-induced premature ovarian failure (POF) is still controversial. A randomized, controlled trial (RCT) investigate whether the use of LHRHs during chemotherapy in cancer patients reduces treatment-related POF rate, increases pregnancy rate, and impacts disease-free survival. A literature search using PubMed, Embase, and the Cochrane Library, and the prospective was conducted up to 30 April 2015. Odds ratios (ORs) and 95% confidence intervals (CI) study definition, and POF defined as amenorrhea 1 year after chemotherapy completion and/or p for as well hazard ratios (HRs) and 95% CI for DFS, was calculated for each trial. Pooled analysis was fixed- and random-effects models.

Results: A total of 12 RCTs were eligible including 1231 breast cancer patients. The use of L with a significant reduced risk of POF (OR 0.36, 95% CI 0.23–0.57; $P < 0.001$), yet with a $I^2 = 47.1%$, $P_{\text{heterogeneity}} = 0.028$. In eight studies reporting amenorrhea rates 1 year after chemot reduced risk of POF (OR 0.55, 95% CI 0.41–0.73, $P < 0.001$) without h $P_{\text{heterogeneity}} = 0.938$. In five studies reporting pregnancy, more patients treated with LHRH (83 versus 19 women; OR 1.83, 95% CI 1.02–3.28, $P = 0.041$; $I^2 = 0.0%$, $P_{\text{heterogeneity}} = 0.820$). In DFS, no difference was observed (HR 1.00, 95% CI 0.49–2.04, $P = 0.993$, $I^2 = 68.0%$, $P_{\text{heterogeneity}} = 0.020$).

Conclusion: Temporary ovarian suppression with LHRHs in young breast cancer patients is less risk of chemotherapy-induced POF and seems to increase the pregnancy rate, without consequence on prognosis.

Key words: luteinizing hormone-releasing hormone agonists, fertility preservation, ovarian function, premenopausal patients

Introduction

The majority of young premenopausal women diagnosed with early-stage breast cancer are candidates to receive a systemic treatment that includes chemotherapy [1]. Chemotherapy may

cause acute and chronic failure (POF) [2]. Despite to be a favorably associated curence is associated with such as infertility, hot flashes, and osteoporosis, velopment of cardiovascular disease [4, 5]. As a consequence and negatively i

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Controversy

Fertility preservation in women with borderline ovarian tumours

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ABSTRACT

Borderline ovarian tumours (BOT) may occur in young women and have an excellent survival rate. Therefore, there is the obligation to put emphasis on fertility preservation in affected women. On the other hand, it has also been underlined that the disease should be managed with caution because these tumours can relapse and, albeit rare, malignant transformation can also occur. Unfortunately, evidence on fertility preservation in women with BOT is scanty. In this opinion paper, we intend to review some clinical indications based on the few available studies on the clinical management of BOT and their possible relation with controlled ovarian hyper-stimulation (COH). We ultimately came to the following conclusions: (1) Fertility counselling should become an integral part of the clinical management of women with BOT. Conservative management but not pre-surgical oocyte retrieval may expose women without reasonable chances of future conceptions to undue risks. (2) Despite some epidemiological concerns on the possible relation between COH and BOT, the conservative surgical treatment should be associated to oocyte cryopreservation considering the high risk of recurrence of the disease. (3) Intensive during COH should be considered to temper the theoretical risk of increased recurrence. (4) Pregnancy should not be delayed in women at low-moderate risk of recurrence. Fertility preservation may be avoided in these women provided that they start active pregnancy quickly early. (5) Albeit segmental, oocyte retrieval from affected ovaries removed at the time of surgery can be considered. Conversely, over-ovulation cryopreservation is not justified given the possible risks of malignant relapsing.

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Introduction

Borderline ovarian tumours (BOT) have been recognized as a separate diagnostic category of epithelial ovarian tumours [1,2]. They are characterized by features of malignant tumours, including cellular proliferation, stratification of the epithelial lining of the papillae, nuclear atypia, and mitotic activity, but without desmoplastic stromal invasion [3]. They represent about 10–20% of all ovarian epithelial tumours with an estimated incidence ranging from 1.8 to 5.5 per 100,000 women per year [4]. One-third of BOT are observed in patients younger than 40 years of age [5].

BOT are diagnosed at stage I in 82% of cases and have a 5-year survival rate of more than 90% across all tumour stages, with a considerable number of patients cured [6]. However, BOT may relapse and, albeit rare, malignant transformation can occur. FIGO stage, younger age, the presence of peritoneal implants, especially invasive implants, and the type of surgery are the most significant predictive factors of relapse [6, 7].

Overall, given the peculiar epidemiological profile of BOT, there is the indisputable obligation to put emphasis on ovarian function and fertility preservation in affected women.

Fertility-sparing surgery, conservative treatment of BOT

The basic treatment of BOT is surgery. In most cases, this is the exclusive treatment.

The intervention aims at complete resection of the tumour, besides full surgical staging, in postmenopausal or in women who do not wish to preserve fertility the complete staging procedure include: peritoneal washing, bilateral salpingo-oophorectomy,

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Offrire la preservazione della fertilità a tutte le pazienti e i pazienti interessati

- Conservazione dei gameti (ovociti e spermatozoi) prima dell'inizio della chemioterapia
- Facilità di accesso e riconoscimento nei LEA
- Farmaci gonadoprotettori e gonadotropine rimborsate dal SSN attraverso la legge 648

AGENZIA ITALIANA DEL FARMACO

DETERMINA 22 luglio 2016

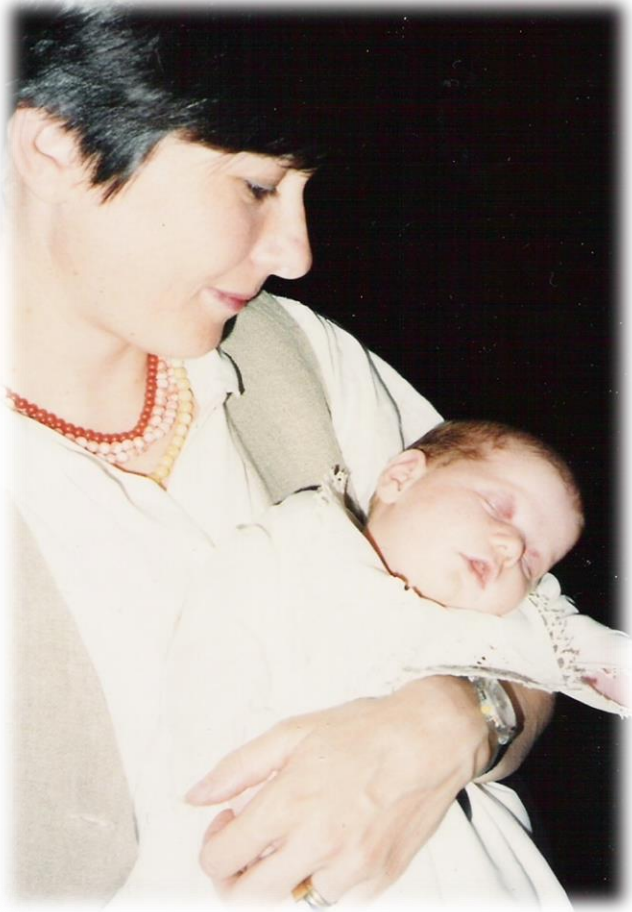
Inserimento degli analoghi dell'ormone di rilascio delle gonadotropine (triptorelina, goserelina, leuprolide) nell'elenco dei medicinali erogabili a totale carico del Servizio sanitario nazionale, ai sensi della legge 23 dicembre 1996, n. 648, per la preservazione della funzionalità pre-menopausa affette da patologie sottoporsi a trattamento chemioterapico precoce e permanente e per le quali o di preservazione della fertilità (cr siano considerate adeguate. (Determin



GAZZETTA
UFFICIALE
DELLA REPUBBLICA ITALIANA

(GU n.183 del 6-8-2016)

In occasione del primo Fertility Day



GRAZIE !

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Fertility Day



IEO
Istituto Europeo di Oncologia