One year of biosimilar filgrastim (EP-2006) in routine clinical practice

Maria Sofia Rosati, Giulia Baciarello, Maria Luisa Basile, Serena Zancla, Ersilia Ranieri

"Sapienza", University of Rome

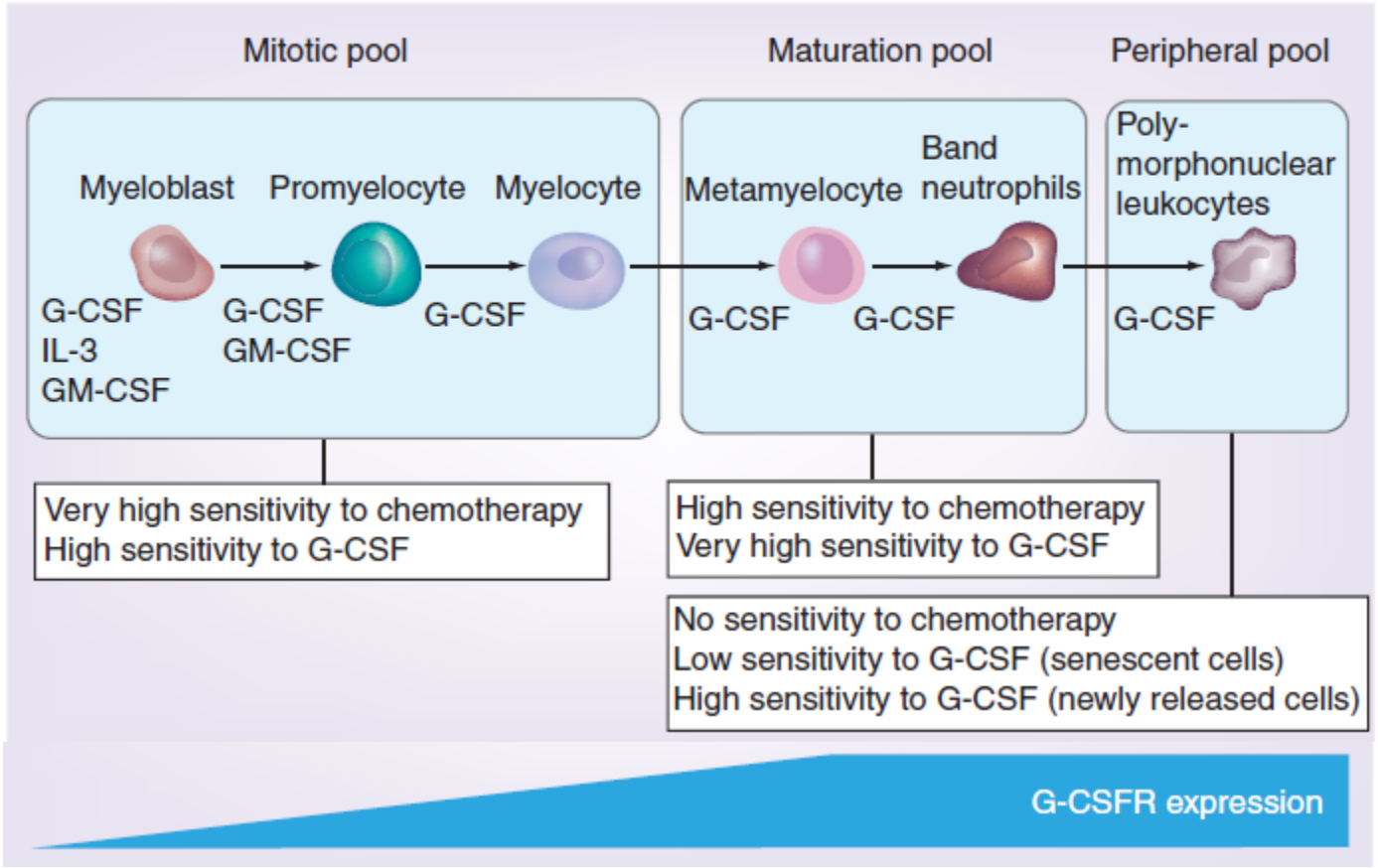
Italy

SAPIENZA
UNIVERSITÀ DI ROMA

Conflict of interest disclosure

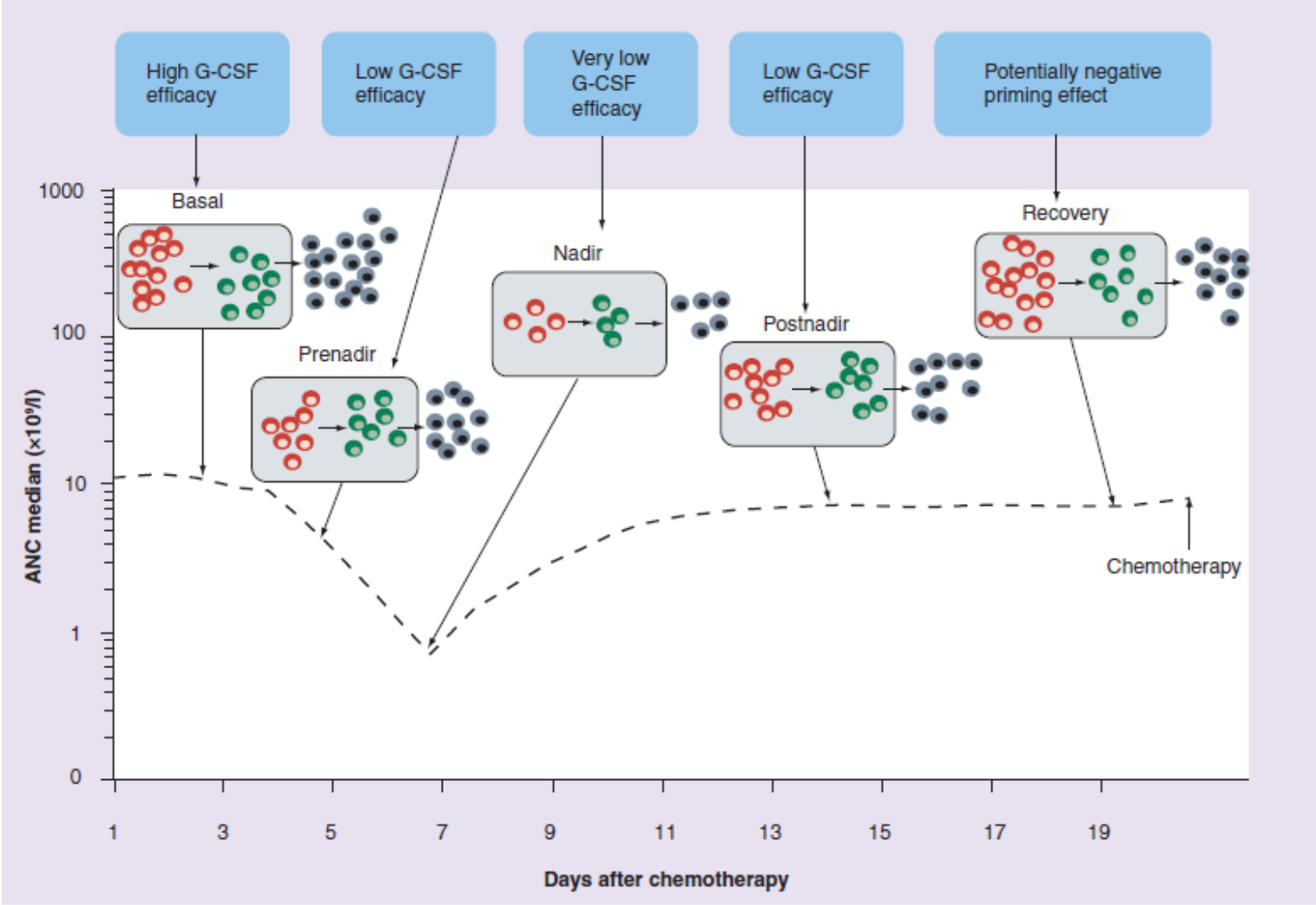
- No financial support for research.
- Sandoz International (Germany) provided logistic support to Dr Rosati for attending MASCC/ISOO 2012

Biological rationale



Courtesy of R. Danesi

Biological rationale



Courtesy of R. Danesi

Biosimilar rG-CSF (EP 2006) administration

original article

Annals of Oncology 21: 1419–1429, 2010
doi:10.1093/annonc/mdp574
Published online 17 December 2009

Development of a new G-CSF product based on biosimilarity assessment

P. Gascon[1], U. Fuhr[2,3], F. Sörgel[4,5], M. Kinzig-Schippers[4], A. Makhson[6], S. Balser[7], S. Einmahl[8] & M. Muenzberg[7*]

[1]Division of Medical Oncology, Hospital Clinic, Barcelona University, Barcelona, Spain; [2]Department of Pharmacology, University Hospital, University of Cologne, Cologne, Germany; [3]Itecra GmbH & Co. KG, Cologne, Germany; [4]IBMP – Institute for Biomedical and Pharmaceutical Research, Nürnberg-Heroldsberg, Germany; [5]Department of Pharmacology, University of Duisburg–Essen, Essen, Germany; [6]Moscow City Oncology Hospital, Moscow, Russia; [7]Sandoz International GmbH, Holzkirchen, Germany and [8]Triskel Integrated Services, Geneva, Switzerland

Received 15 September 2009; accepted 9 November 2009

Support Care Cancer (2010) 18:529–541
DOI 10.1007/s00520-010-0816-y

REVIEW ARTICLE

Prophylaxis of chemotherapy-induced febrile neutropenia with granulocyte colony-stimulating factors: where are we now?

Matti Aapro · Jeffrey Crawford · Didier Kamioner

dicine and Cancer Supportive Care:
of Colony-Stimulating Factor Support

BMC Cancer

Open Access

RESEARCH ARTICLE

Gerlier et al. BMC Cancer 2010, 10:642
http://www.biomedcentral.com/1471-2407/10/642

The use of chemotherapy regimens carrying a moderate or high risk of febrile neutrop the corresponding management of feb neutropenia: an expert survey in breas and non-Hodgkin's lymphoma

Laetitia Gerlier[1*], Mark Lamotte[1], Ahmad Awada[2], André Bosly[3], Greet Bries[4], Véron Christian Focan[6], Stéphanie Henry[7,8], Yassine Lalami[2], Jean-Pascal Machiels[9], Jeroe Didier Verhoeven[12], Luc Somers[13]

ONCOLOGY REPORTS 14: 1405-1412, 2005

Use of granulocyte colony-stimulating factor: A survey among Italian medical oncologists

MARCO DANOVA[1], GIOVANNI ROSTI[2], SABINO DE PLACIDO[3], KATIA BENCARDINO[1] and MARCO VENTURINI[4]

[1]Medical Oncology, Flow Cytometry and Cell Therapy Unit, IRCCS S. Matteo University Hospital, I-27100 Pavia; [2]Department of Oncology, Santa Maria delle Croci Hospital, I-48100 Ravenna; [3]Endocrinology and Experimental and Clinical Oncology Department, Federico II University of Naples, I-80100 Naples; [4]Department of Medical Oncology, National Cancer Research Institute, I-16100 Genoa, Italy

Received May 13, 2005; Accepted July 6, 2005

SAPIENZA
UNIVERSITÀ DI ROMA

PRIMARY END-POINT

- To verify efficacy and safety of biosimilar filgrastim (EP 2006) in “real world” clinical practice .
- To estimate the proportional incidence of FN when 3 days schedule (*short course*) of biosimilar filgrastim was used.

METHODS

- Retrospective data analysis on a routine clinical practice population (n=52 pts)

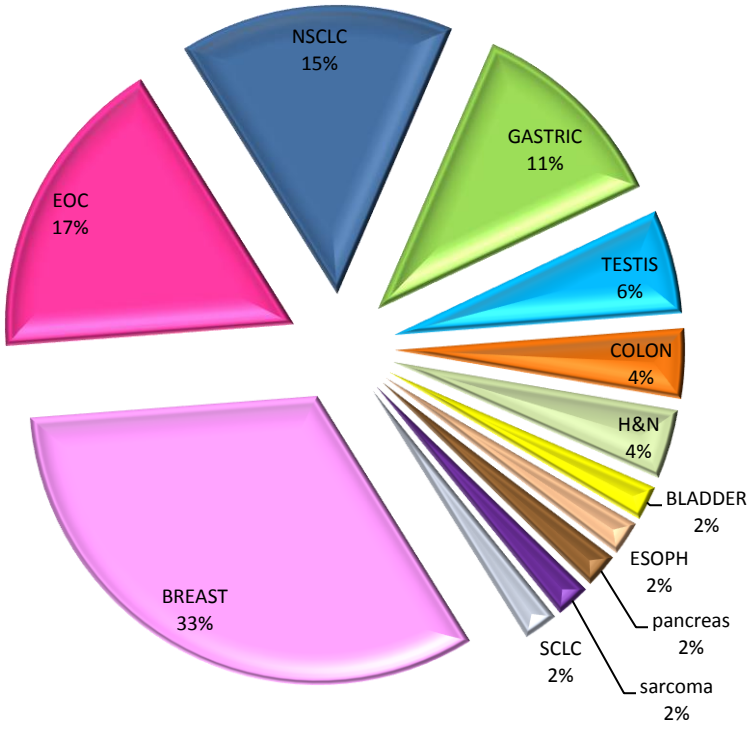
  [from June 2010 to September 2011]

- Analysis is descriptive

PATIENTS AND CHEMOTHERAPY CHARACTERISTIC

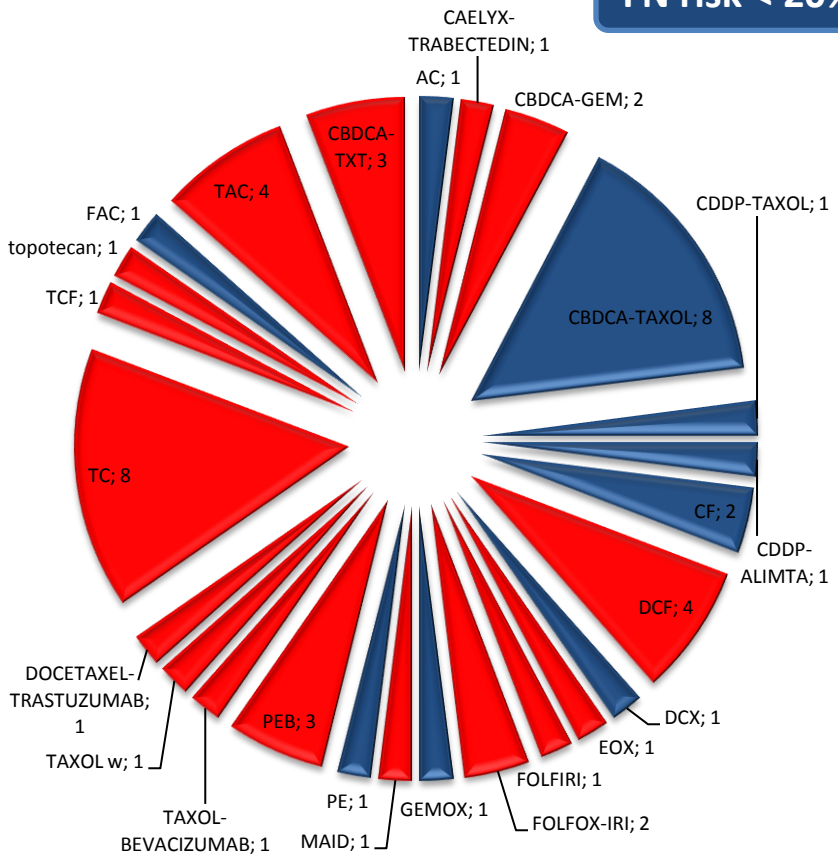
Patients & treatment	
M:F	18:32
Median age	59.2 (26-82)
CHEMOTHERAPY	
Number of chemotherapy cycle	243 (median 4.6 cycle/patient)
Number of bio-filgrastim administrations	651 (median 12.5 administration/patient)
PRIMARY PROPHYLAXIS	
FN> 20% risk	21
FN< 20% at high risk for infection	25
SECONDARY PROPHYLAXIS	6

CANCERS AND CHEMOTHERAPY

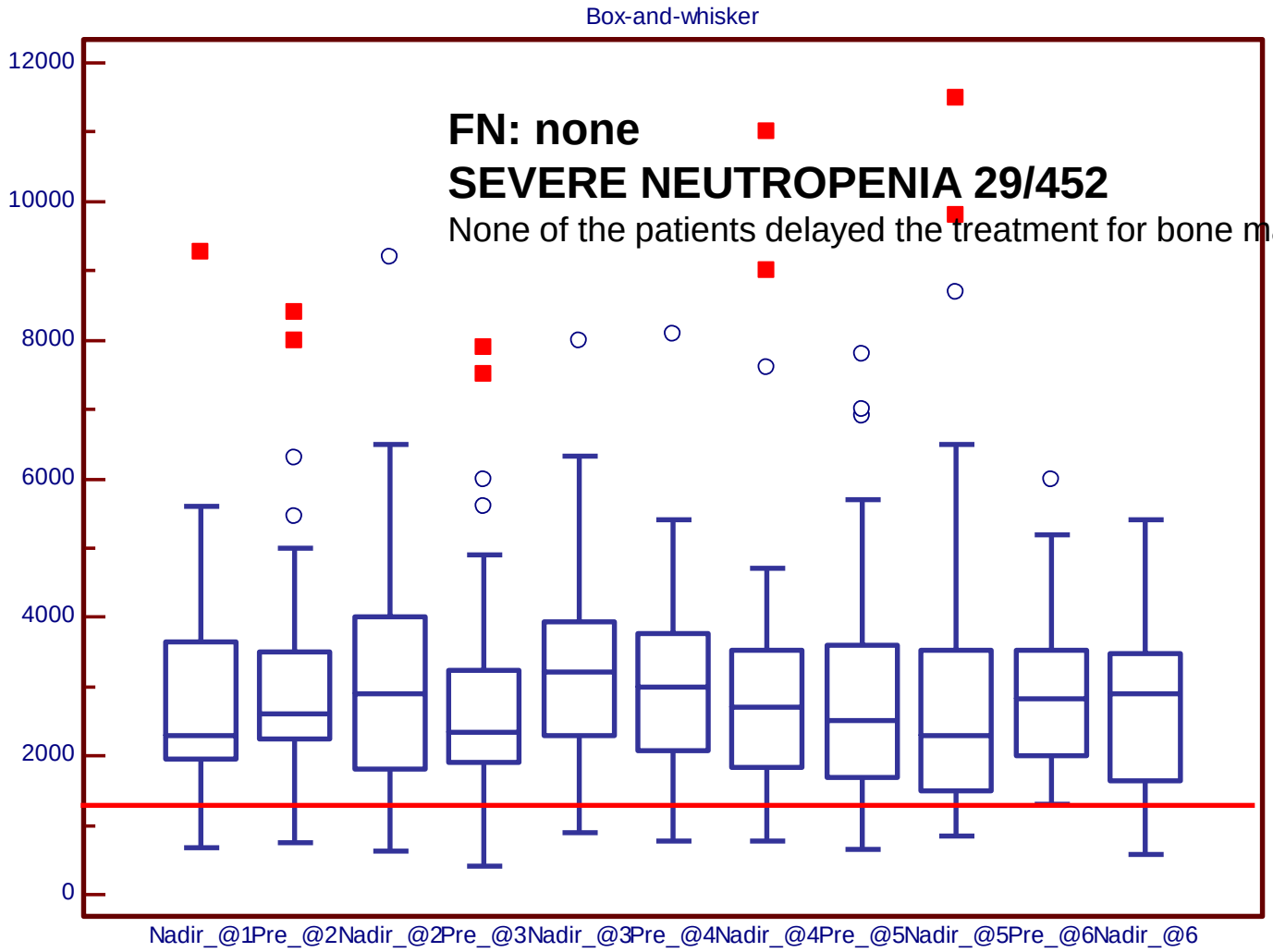


FN risk > 20%

FN risk < 20%



RESULTS



FN: none

SEVERE NEUTROPENIA 29/452

None of the patients delayed the treatment for bone marrow toxicity.

SAPIENZA
UNIVERSITÀ DI ROMA

TOXICITY

Biosimilar filgrastim (EP 2006)	Patients (N=52)	CTC-AE Grade
ALLERGIC REACTION		
Rush, orticaria, edema	2	1
Dyspnea	0	
Cardiovascular (Hypotension, tachycardia)	1	1
Spleen rupture	0	
Respiratory distress syndrome	0	
ADVERSE REACTION		
Medullary Bone Pain	5/32 evaluable patients	1
Cutaneous Vasculitis	0	
Febrile Neutropenia	0	

SEVERE NEUTROPENIC EVENT in ELDERLY (> 65 y)

Over 65y (14 pts) vs under 65 y (38 pts): 11 versus 13 events

[OR: 0.57, 95% CI 0.24−1.31, p= 0.18)]

CONCLUSION

PRO

- Data are from routine clinical practice.
- EP 2006 is a safe, effective, with very low toxicity profile biosimilar myeloid growth factor
- “Short course” prophylaxis is potentially effective to prevent FN.
- Results encourage further investigation on a 3 days schedule.

CONTRAS

- Limited patients number
- Retrospective data analysis
- Unvalidated 3 days G-CSF schedule
- Lack of a 5-10 days G-CSF schedule control