St. Gallen 2015
Tailoring Therapy: Towards Precision Treatment of Patients with Early Breast Cancer

Consensus & Controversy

PROCEDURES
St. Gallen 2015

• Introduction of the Panel
• Introduction of the Process
• Key Areas of Controversy
  – Aim: majority, opinion-based consensus on practical issues for management outside clinical trials
International Consensus Panel
Eric P. Winer, USA & Aron Goldhirsch, CH/I (Chairmen)

Fabrice André (France)  Richard D. Gelber (USA)
José Baselga (USA)  Michael Gnant (Austria)
Jonas Bergh (Sweden)  Pamela J. Goodwin (Canada)
Hervé Bonnefoi (France)  Nadia Harbeck (Germany)
Harold J. Burstein (USA)  Daniel F. Hayes (USA)
Fatima Cardoso (Portugal)  Jens Huober (Germany)
Alberto Costa (Italy)  Clifford A. Hudis (USA)
Monica Castiglione (Switzerland)  James N. Ingle (USA)
Alan S. Coates (Australia)  Jacek Jassem (Poland)
Marco Colleoni (Italy)  Zefei Jiang (PR of China)
Giuseppe Curigliano (Italy)  Per Karlsson (Sweden)
Nancy Davidson (USA)  Monica Morrow (USA)
Angelo Di Leo (Italy)  Roberto Orecchia (Italy)
Bent Ejlertsen (Denmark)  C. Kent Osborne (USA)
John F. Forbes (Australia)  Ann Partridge (USA)
Viviana Galimberti (Italy)  Lorena de la Peña (Spain)
Martine Piccart-Gebhart (Belgium)
Kathleen I. Pritchard (Canada)
Emiel J.T. Rutgers (The Netherlands)
Zhi-Ming Shao (PR of China)
Felix Sedlmayer (Austria)
Vladimir Semiglazov (Russia)
Ian Smith (United Kingdom)
Beat Thürlimann (Switzerland)
Masakazu Toi (Japan)
Andrew Tutt (United Kingdom)
Giuseppe Viale (Italy)
Gunter von Minckwitz (Germany)
Toru Watanabe (Japan)
Timothy Whelan (Canada)
Binghe Xu (PR of China)
Areas of Controversy
Need for Debate

Controversies deserve:

• Debate leading to a consensus
• Debate that can lead to a range of resolutions (because sometimes different approaches are needed in different environments / countries)
• Debate defining need for further trial(s)
Treatment Outside Clinical Trials

• Clinical trials are...
  • ... useful for defining whether one treatment is better than another in a “defined population”
  • ... useful for defining the average improvement in treatment outcome
  • ... do not always define how best to treat an individual patient

• Using available evidence to decide treatment for an individual patient involves interpretation and judgment
Primary Consideration

Primary goal - treatment choice for women with early breast cancer:

- utilize tumor biology to determine responsiveness to various treatments;
- utilize tumor extent to estimate risk of recurrence and magnitude of benefit for the individual patient;
- utilize these factors plus an estimate of the risks of therapy and patient preference to arrive at preferred management.
  - Guidelines and/or decision aids should be provided to patients in appropriate language and format to assist decision-making and optimize informed consent.
  - Assuming that the options are understood, patient preference is paramount and may lead to treatment adjustment.
Questions

Questions should be unambiguous, not directive, and

- Focus on issues for which new evidence exists since 2013
- Lead to the best recommendations for management of typical patients outside of clinical trials.
  - Costs and perceived value vary by country
  - Alternatives for less well-resourced areas/countries should be identified if more costly treatment is only marginally more effective.
  - There will always be exceptions – responses should relate to typical patients, e.g.
    - Refer to usual histologic types (special subtypes require separate consideration);
    - Exclude the treatment of special patient groups such as pregnant patients as well as those with significant co-morbidities;
    - Age cut-offs for “young” and “elderly” may depend on questions.
Panelists’ Answers

• Questions have been prospectively reviewed by the Panelists and revised to be as clear as possible. Semantic discussions on the day are discouraged!!

• Panelists are asked to answer either

  1 Yes or 2 No

for most questions

or in certain cases

Select from mutually exclusive choices, 1, 2, 3, 4, etc.

• Option for 9 Abstain if Panelist has insufficient data, lack of specific expertise on the issue, or conflict of interest. Do not hesitate to abstain if appropriate.
Practice Questions

• The seating capacity of this hall is greater than 1500
  1 Yes  2 No  9 Abstain
• The seating capacity of this hall is (select one):
  1. Not more than 499
  2. From 500 to 999
  3. From 1000 to 1999
  4. At least 2000
  9. Abstain
Key Areas of Controversy

• Surgery of the primary and axilla
• Radiation: partial breast, post-mastectomy, nodal areas
• Pathology: Ki-67, ER, HER2, grade, other markers
• Gene profiling: Oncotype DX®, PAM50/ROR, MammaPrint®/BluePrint®, EndoPredict®, GGI, other
• Endocrine therapies (premenopausal): OFS, TAM, AIs; duration
• Endocrine therapies (postmenopausal): type, duration, role of extended tamoxifen/AIs; chemotherapy
• Postoperative adjuvant chemotherapy for:
  • endocrine responsive disease: duration, regimen
  • HER2 positive: type, duration, combination with anti-HER2
  • Triple-negative: platinums, alkylators, taxanes – role of BRCA
• Neoadjuvant treatments:
  • Role and regimen by subtype
Key Areas of Controversy (continued)

- Anti-HER2 therapies: dual blockade
- Treatments for special types: lobular, special TN types
- Special patient groups
  - Very young women
  - Diagnosis during pregnancy
  - Pregnancy after breast cancer
  - Elderly non-frail patients with indication for chemotherapy
  - Breast cancer after previous malignancy
  - Systemic autoimmune disease
  - Male breast cancer
- Additional therapies
  - Bisphosphonates and denosumab
  - Haemopoietic growth factors
  - Psychological support
  - Physical exercise