6 vs. 3 Cycles of epirubicin/docetaxel + G-CSF in operable breast cancer: Results of ABCSG-14.

Abstract:

Background: Preoperative chemotherapy (PROP) for operable breast cancer is established to downstage tumors primarily not suitable for breast conserving surgery. A pathologic complete response (pCR) after PF surrogate marker for longer overall survival (OS) but the rates of pCR with current treatment regimen and a beneficial effect of PROP upon OS remains to be established. In 1999, the ABCSG set out to test the hypothesis whether prolonging the time of the neoadjuvant treatment period by doubling the number of cycles of the same drugs might raise the rate of pCR after PROP by converting more partial responses into pCR's.

Methods: Patients (pts) with biopsy proven breast cancer T1-4a-c, N+/-, M0 were eligible for this prospectively randomized phase III trial. 282 pts (estimated drop-out rate: 5%) were planned to detect a significant difference (one-sided p < 0,05, Fisher's exact test) with a power of 82%. Pts were randomized to receive either 3 cycles of epirubicin 75mg/m² and docetaxel 75mg/m² on day 1 + G-CSF 30 MU days 3-10 q 21 days (ED+G) or 6 cycles of the identical regimen. Primary end point was the rate of pCR. The pathological nodal status and the rate of breast conserving surgical procedures served as secondary end points.

Results: 292 pts were accrued to the trial between 6/1999 and 12/2002 and 288 pts are eligible. Both trial groups were well balanced for tumor size, clinical nodal status, menopausal status, hormone receptor status, HER2-status, and trial center. The results of the primary and the secondary end points are depicted in the table. There was no significant difference in serious adverse events per patient and per cycle and no patient died while on treatment.

<table>
<thead>
<tr>
<th></th>
<th>3 x ED+G (n=143)</th>
<th>6 x ED+G (n=145)</th>
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</thead>
<tbody>
<tr>
<td>pathological Complete Response</td>
<td>11 (7,7%)</td>
<td>27 (18,6%)</td>
</tr>
<tr>
<td>Negative nodal status</td>
<td>59 (42,8%)</td>
<td>77 (56,6%)</td>
</tr>
<tr>
<td>Breast conserving surgery</td>
<td>93 (66,9%)</td>
<td>104 (75,9%)</td>
</tr>
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Conclusions: Doubeling the number of cycles of neoadjuvant chemotherapy (6 vs. 3 x ED+G) results in higher rates for pCR and negative axillary nodal status with no excess of side effects.
Associated Presentation(s):

1. 6 vs. 3 Cycles of epirubicin/docetaxel + G-CSF in operable breast cancer: Results of ABCSG 14.

Meeting: 2004 ASCO Annual Meeting  
Presenter: Guenther G. Steger  
Session: Breast Cancer I (Poster Discussion Session)

Other Abstracts in this Sub-Category:


Meeting: 2004 ASCO Annual Meeting  
Abstract No: 500  
First Author: M. Yoshimoto  
Category: Breast Cancer - Local-Regional and Adjuvant Therapy - Adjuvant Therapy

2. Changes in gene expression profiling due to primary chemotherapy in patients with locally advanced breast cancer.

Meeting: 2004 ASCO Annual Meeting  
Abstract No: 502  
First Author: J. Hannemann  
Category: Breast Cancer - Local-Regional and Adjuvant Therapy - Adjuvant Therapy

3. The effect of CYP 2D6 genotype and CYP2D6 inhibitors on tamoxifen.

Meeting: 2004 ASCO Annual Meeting  
Abstract No: 508  
First Author: V. Stearns  
Category: Breast Cancer - Local-Regional and Adjuvant Therapy - Adjuvant Therapy

More...

Abstracts by G. G. Steger:


Meeting: 2011 Breast Cancer Symposium  
Abstract No: 41  
First Author: A. Berghoff  
Category: Detection, Screening, and Imaging - Predictive and Prognostic Factors

2. Effect of change of body mass index (BMI) during therapy on the efficacy of endocrine therapy in premenopausal patients with breast cancer: An analysis of the ABCSG-12 trial.

Meeting: 2011 ASCO Annual Meeting  
Abstract No: 514  
First Author: G. Pfeiler  
Category: Breast Cancer - HER2/ER - ER+

3. Impact of HER2-targeted therapy on overall survival (OS) in patients (pts) with HER2-positive (HER2+) metastatic breast cancer (MBC).

Meeting: 2011 ASCO Annual Meeting  
Abstract No: 572  
First Author: A. Berghoff  
Category: Breast Cancer - HER2/ER - HER2+

More...

Presentations by G. G. Steger:

Meeting: 2010 ASCO Annual Meeting
Presenter: Guenther G. Steger
Session: Breast Cancer - Local-Regional and Adjuvant Therapy (Poster Discussion Session)

2. 6 vs. 3 Cycles of epirubicin/docetaxel + G-CSF in operable breast cancer: Results of ABCSG 14.

Meeting: 2004 ASCO Annual Meeting
Presenter: Guenther G. Steger, MD
Session: Breast Cancer I (Poster Discussion Session)

3. Fulvestrant beyond the second hormonal treatment line in metastatic breast cancer

Meeting: 2003 ASCO Annual Meeting
Presenter: Gunther G Steger, MD
Session: Late Breast Cancer (Poster Discussion Session)

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▶ Educational Book Manuscripts by G. G. Steger:

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