PS1-04-29
San Antonio Breast Cancer Symposium® - December 9-12, 2025

# LONGITUDINAL CHANGES IN HEALTH-RELATED QUALITY OF LIFE OF EARLY-STAGE BREAST CANCER PATIENTS TREATED WITH ADJUVANT CHEMOTHERAPY: DATA FROM GEICAM/2003-02 STUDY


Andrea Blasco[1,2], Pilar Zamora-Auñón[1,2,3], Roberto Pastor[4,5], Miguel Martín[1,6,7], Cristina Reboredo[1,8], Ainhara Lahuerta[1,9], Isabel Alvarez[1,9], Sonia Servitja[1,10], María Marín[1,11], Eduardo Martínez de Dueñas[1,12], José Manuel López-Vega[1,13], Agustín Barnadas[1,14], Alvaro Rodríguez-Lescure[1,15], Javier Salvador Bofill[1,16], Jose Ignacio Chacón[1,17], Virginia Lope [1,4,5]

1. GEICAM Spanish Breast Cancer Group, Madrid, Spain. 2. PhD Program in Medicine and Surgery. Doctoral School, Universidad Autónoma de Madrid, Madrid, Spain. 3. Hospital Universitario La Paz, Madrid, Spain. 4. National Centre for Epidemiology, Instituto de Salud Carlos III, Madrid, Spain. 5. Consortium for Biomedical Research in Epidemiology and Public Health (CIBERESP), Madrid, Spain. 6. Instituto de Investigación Sanitaria Gregorio Marañón, Centro de Investigación Biomédica en Red de Oncología, CIBERONC-ISCIII, Madrid, Spain. 7. Hospital Clínico San Carlos, Madrid, Spain. 8. Complejo Hospitalario Universitario A Coruña (CHUAC), A Coruña, Spain. 9. Unidad de Gestión del Cáncer de Guipúzcoa (Osakidetza-OSI Donostialdea_Onkologikoa)-BioDonostia, San Sebastián, Spain. 10. Hospital del Mar, Hospital del Mar Research Institute Barcelona, Spain. 11. Hospital Universitari de Terrasa-Consorci Sanitaria de Terrasa, Barcelona, Spain. 12. Consorcio Hospitalario Provincial de Castellón, Castellón, Spain. 13. Hospital Universitario Marqués de Valdecilla, Instituto de Investigación Valdecilla (IDIVAL), Santander, Spain. 14. Hospital de la Santa Creu i Sant Pau, IR Sant Pau, CIBERONC-ISCIII, Barcelona, Spain. 15. Hospital General Universitario de Elche, Elche, Spain. 16. Hospital Universitario Virgen del Rocio, Sevilla, Spain. 17. Hospital Universitario de Toledo, Toledo, Spain


GEICAM spanish breast cancer group

## BACKGROUND

Multicenter, open-label, randomized phase III GEICAM/2003-02 study compared two regimens as adjuvant therapy for node-negative breast cancer (BC) patients: FACx6 (5-fluorouracil, doxorubicin, cyclophosphamide) vs FACx4 plus weekly paclitaxelx8 (FACx4->wPx8)[1].

GEICAM/2003-02 included patient-reported outcomes (PROs) using EORTC QLQ-C30 questionnaire[2] during adjuvant CT and follow-up visits (post-treatment [3-4 weeks after the last treatment by protocol indication] and 6 months post-treatment).

## OBJECTIVES

The aim is to compare health-related quality of life (HRQoL):

1) Evaluating differences in changes from baseline of QLQ-C30 summary scores (SS) from baseline to post-treatment and 6 months post-treatment between BC patients treated with FACx6 and those treated with FACx4->wPx8.

2) To assess whether there are differences by menopausal status and endocrine-therapy (ET) treatment according to the tumor subtype diagnosis.

## PATIENTS AND METHODS

HRQoL was measured using the EORTC QLQ-C30 v 3.0. A total of 298 early-BC patients from GEICAM/2003-02 who complete the questionnaire at baseline, post-treatment and 6 months follow-up visits were selected:

- FACx6: 157 patients.
- FACx4->wPx8: 141 patients

QLQ-C30 SS were calculated as the mean of 13 scales (excluding Global health status [QL2] and financial difficulties [FI]), with symptom scales reversed, and functional/symptom SS derived accordingly. Changes from baseline to end of treatment and 6 months later were assessed using a random intercept lineal model with two nested levels (hospital and subject) for repeated measures, adjusted by patient and tumor characteristics at diagnosis (body mass index (BMI), age, histopathological grade, surgery type, stage, tumor subtype and menopausal status). Stratified analyses were also performed by menopausal status and ET post-CT.

### Table 1 Baseline characteristics

| | Total (n=298) | FACx6 (n=157) | FACx4 wPx8 (n=141) |
|---|---|---|---|
| **Age (years), n (%)** | | | |
| ≤40 | 38 (12.8) | 14 (8.9) | 24 (17.0) |
| 41 to 50 | 110 (36.9) | 59 (37.6) | 51 (36.2) |
| 51 to 60 | 83 (27.9) | 51 (32.5) | 32 (22.7) |
| >60 | 67 (22.5) | 33 (21.0) | 34 (24.1) |
| **Menopausal status, n (%)** | | | |
| Premenopausal | 155 (52.0) | 77 (49.0) | 78 (55.3) |
| Postmenopausal | 143 (48.0) | 80 (51.0) | 63 (44.7) |
| **BMI categories (kg/m$^2$), n (%)** | | | |
| < 25.0 | 134 (45.0) | 71 (45.2) | 63 (44.7) |
| 25.0 - 29.9 | 96 (32.2) | 54 (34.4) | 42 (29.8) |
| ≥30.0 | 68 (22.8) | 32 (20.4) | 36 (25.5) |
| **Stage at diagnosis, n (%)** | | | |
| I | 196 (65.8) | 104 (66.2) | 92 (65.2) |
| IIA | 101 (33.9) | 53 (33.8) | 48 (34.0) |
| IIB | 1 (0.3) | 0 | 1 (0.7) |
| **Histopathological grade, n (%)** | | | |
| Grade 1-2 | 159 (53.4) | 79 (50.3) | 80 (56.7) |
| Grade 3 | 126 (42.3) | 73 (46.5) | 53 (37.6) |
| Unknown | 13 (4.4) | 5 (3.2) | 8 (5.7) |
| **Tumor subtype, n (%)** | | | |
| HR+ HER2- | 211 (70.8) | 113 (72.0) | 98 (69.5) |
| HER2+ * | 17 (5.7) | 12 (7.6) | 5 (3.5) |
| Triple-negative | 65 (21.8) | 30 (19.1) | 35 (24.8) |
| Unknown | 5 (1.7) | 2 (1.3) | 3 (2.1) |
| **HR+HER2- tumors treated with adjuvant ET (post CT)**** | | | |
| Yes | 196 (92.9) | 106 (93.8) | 90 (91.8) |
| **Surgery type, n (%)** | | | |
| Conservative | 218 (73.2) | 119 (75.8) | 99 (70.2) |
| Mastectomy | 78 (26.2) | 38 (24.2) | 40 (28.4) |
| Unknown | 2 (0.7) | 0 | 2 (1.4) |

*HER2+ irrespective of HR status.
** Percentages over HR+HER2- tumor subtype patients.

**Abbreviatures**: **BC**: Breast Cancer. **BMI**: Body Mass Index. **CI**: Confidence Interval. **CT**: Chemotherapy. **ET**: Endocrine-therapy. **FACx6**: 6 cycles of Fluorouracil, Doxorubicin and Cyclophosphamide. **FACx4->wPx8:** 4 cycles of FAC followed 8 weeks of paclitaxel. **FI**: Financial difficulties. **HER2**: Human Epidermal Growth Factor Receptor 2. **HR:** Hormone Receptor. **HRQoL**: Health-related Quality of Life. **PRO**: Patient-reported outcomes. **QL2**: Global health status. **QLQ-C30:** Quality of life Questionnaire C30. **SD**: Standard Deviation. **SS**: Summary Score.

## RESULTS

The mean age of the 298 analyzed patients was 50 (range: 24-75) years, and 52.0% were premenopausal. The mean BMI was of 26.6 (range: 17-41) kg/m$^2$. Further details are shown in **Table 1.**

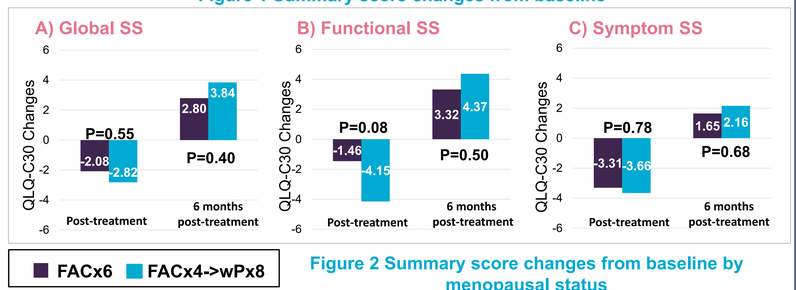
The main results of evaluating differences in SS changes were:

- ✓ QLQ-C30 SS significantly decreased from baseline to end of treatment and FACx4->wPx8: but slightly exceeded baseline scores 6 months post-treatment, with no significant differences between the two arms.
- ✓ Greater deterioration in post-treatment functional SS was observed in the FACx4->wPx8 compared to FACx6.
- ✓ In postmenopausal patients, post-treatment QLQ-C30 SS deterioration was greater in the FACx4->wPx8.
- ✓ HR+HER2- patients treated with ET post-CT showed more pronounced reductions in the QLQ-C30 SS post-treatment than triple-negative patients non treated with ET. Further details are shown in **Table 2** and **Figures 1-3.**

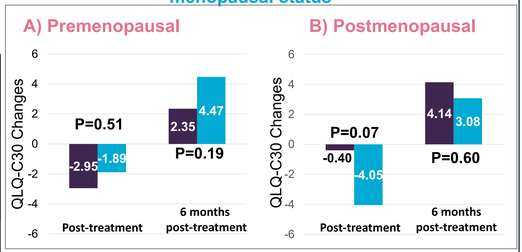
### Table 2 Effect of FACx6 and FACx4->wPx8 on HRQoL changes from baseline to post-treatment and 6 months later

| | QLQ-C30 SS | | Functional SS | | Symptom SS | | Premenopausal QLQ-C30 SS | | Postmenopausal QLQ-C30 SS | | Adjuvant ET (HR+ HER2-) QLQ-C30 SS | | No-Adjuvant ET (Triple-negative) QLQ-C30 SS | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | FACx6 | FACx4 wPx8 | FACx6 | FACx4 wPx8 | FACx6 | FACx4 wPx8 | FACx6 | FACx4 wPx8 | FACx6 | FACx4 wPx8 | FACx6 | FACx4 wPx8 | FACx6 | FACx4 wPx8 |
| Baseline mean (SD) | 87.94 (9.40) | 87.42 (11.47) | 85.87 (11.22) | 84.36 (14.75) | 89.49 (9.58) | 89.40 (10.38) | 88.85 (8.62) | 86.97 (11.41) | 88.85 (8.62) | 86.97 (11.41) | 88.57 (8.89) | 88.69 (10.27) | 87.77 (10.01) | 85.42 (13.13) |
| Post-treatment mean (SD) | 83.86 (13.22) | 82.14 (13.51) | 82.41 (16.08) | 78.49 (17.86) | 84.47 (12.93) | 83.83 (13.48) | 84.68 (13.05) | 82.95 (12.93) | 83.12 (13.42) | 81.05 (14.30) | 84.27 (12.65) | 82.39 (13.99) | 83.87 (13.02) | 82.15 (12.28) |
| Change from baseline (95% CI), *P value* | -2.08 (-7.11, 2.94), *<0.01* | -2.82 (-7.76, 2.13), *<0.01* | -1.46 (-7.78,4.86), *<0.01* | -4.15 (-10.40, 2.11), *<0.01* | -3.31 (-8.58, 1.97), *<0.01* | -3.66 (-8.85, 1.53), *<0.01* | -2.95 (-6.27, 0.37), *<0.01* | -1.89 (-5.33, 1.56), *<0.01* | -0.40 (-6.25, 5.46), *<0.01* | -4.05 (-9.96, 1.86), *<0.01* | -3.58 (-8.42, 1.27), *<0.01* | -5.03 (-9.77, -0.28), *<0.01* | -2.53 (-7.43, 2.37), 0.11 | 1.05 (-4.05, 6.16), 0.91 |
| Difference in change (95% CI), *P value* | 0 (Reference) | -0.74 (-3.18, 1.71), 0.55 | 0 (Reference) | -2.69 (-5.70, 0.33), 0.08 | 0 (Reference) | -0.35 (-2.83, 2.13), 0.78 | 0 (Reference) | 1.06 (-2.13, 4.26), 0.51 | 0 (Reference) | -3.65 (-7.57, 0.27), 0.07 | 0 (Reference) | -1.45 (-4.30, 1.39), 0.32 | 0 (Reference) | 3.58 (-4.05, 6.16), 0.25 |
| 6-month post-treatment mean (SD) | 88.60 (10.04) | 88.69 (10.97) | 87.47 (12.54) | 87.11 (14.22) | 89.15 (9.53) | 89.20 (11.69) | 89.38 (10.12) | 89.32 (10.56) | 87.85 (9.97) | 87.85 (11.54) | 88.68 (9.50) | 88.42 (11.22) | 89.84 (9.56) | 88.43 (11.53) |
| Change from baseline (95% CI), *P value* | 2.80 (-2.23, 7.82), 0.53 | 3.84 (-1.11, 8.79), 0.06 | 3.32 (-3.01. 9.65), 0.25 | 4.37 (-1.88, 10.61), 0.03 | 1.65 (-3.63, 6.92), 0.72 | 2.16 (-3.04, 7.35), 0.61 | 2.35 (-0.99, 5.69), 0.63 | 4.47 (0.99, 7.94), *0.04* | 4.14 (-1.72, 10.01), 0.68 | 3.08 (-2.81, 8.96), 0.55 | 0.74 (-4.13, 5.60), 0.68 | 1.42 (-3.33, 6.17), 0.57 | 4.70 (-0.14, 9.55), 0.21 | 4.21 (-0.67, 9.09), 0.18 |
| Difference in change (95% CI), *P value* | 0 (Reference) | 1.05 (-1.41, 3.50), 0.40 | 0 (Reference) | 1.05 (-1.99, 4.08), 0.50 | 0 (Reference) | 0.51 (-1.97, 2.99), 0.68 | 0 (Reference) | 2.12 (-1.08, 5.32), 0.19 | 0 (Reference) | -1.06 (-5.02, 2.89), 0.60 | 0 (Reference) | 0.68 (-2.20, 3.56), 0.64 | 0 (Reference) | -0.49 (-6.61, 5.62), 0.87 |

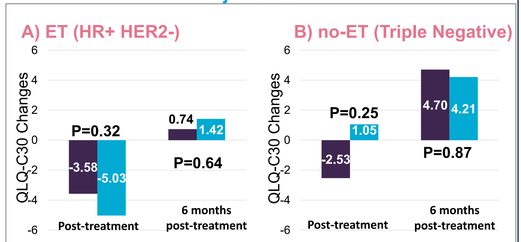
### Figure 1 Summary score changes from baseline




### Figure 2 Summary score changes from baseline by menopausal status




### Figure 3 Summary score changes from baseline by adjuvant ET




## CONCLUSIONS

- Schedules of 8-dose taxane-based do not have a great impact on HRQoL recovery after 6 months of treatment: While temporary deterioration in functional and symptom scales was observed after treatment, patients in both arms recovered their baseline HRQoL 6 months later.
- These results also emphasize the importance of considering patient characteristics when evaluating HRQoL outcomes in BC survivors.

## REFERENCES


1. M. Martín et al., "Fluorouracil, Doxorubicin, and Cyclophosphamide (FAC) Versus FAC Followed by Weekly Paclitaxel As Adjuvant Therapy for High-Risk, Node-Negative Breast Cancer: Results From the GEICAM/2003-02 Study," JCO, vol. 31, no.20, pp. 2593-2599, Jul. 2013.
2. N. K. Aaronson et al., 'The European Organization for Research and Treatment of Cancer QLQ-C30: A Quality-of-Life Instrument for Use in International Clinical Trials in Oncology', JNCI, vol. 85, no.5, pp. 365–376, Mar. 1993.


## ACKNOWLEDGMENTS


We acknowledge all patients, investigators and their teams and all GEICAM staff involved, for their collaboration.



This presentation is the intellectual property of the author/presenter. Contact at: **secretaria-cientifica@geicam.org** for permission to reprint and/or distribute.