Observational retrospective clinical study on the application of the Di Bella Method (DBM) from 2004 to today on breast carcinomas. Preliminary data on survival improvement, objective response and performance status

Giuseppe Di Bella, Vittoria Borghetto, Elena Costanzo, Ilaria Moscato

Giuseppe Di Bella Foundation, Via Marconi 51, 40122 Bologna, Italia

Email: posta@giuseppedibella.it

Keywords: breast cancer, somatostatin, melatonin, retinoids acid, DBM (Di Bella Method)

BACKGROUND & HYPOTHESIS: Overall evaluation and ongoing statistical processing of preliminary data on 502 evaluable cases of breast cancer on 11,300 patients who have been treated with DBM since 2004. METHODS: Administration of DBM to patients with breast cancer: somatostatin / octreotide, estrogenic and prolactin inhibitors, Melatonin, Retinoid solution in vitamin E, Vitamin D3, vitamin C, chondroitin sulfate, glucosamine and metronomic doses of cyclophosphamide. In breast tumors, given the GH receptor co-expression with prolactin and functional coexpression with estrogen, synergistic inhibition of GH and related growth factors with somatostatin/octreotide is indicated; inhibition of prolactin through D2R agonists and estrogen inhibition through FSH-LH analogues and aromatase inhibitors with negative regulation of proliferation, migration and neoplastic angiogenesis. RESULTS: If applied early and with absolute regularity as an exclusive first-line therapy, after seven years the DBM has made it possible to reduce relapses to below 1%. A 5-year survival of 69% was obtained in 297 cases at the IV stage [2]. The first of these cases, under treatment for 15 years, is still in remission of the disease [3-5]. The results obtained in the 441 cases published in previous publications [1-2-3-4] relating to the objective response, survival, quality of life and tolerability of DBM, are consistent and are fully confirmed in the hundreds of cases still under observation. CONCLUSION: In the absence of toxicity, DBM significantly improved quality of life, objective response and survival compared to the same stages of breast cancers treated with conventional cancer protocols. It is clear that the multitherapy synergism of DBM, unlike the high toxicity and reduced efficacy of cytoxic therapies, pursues the restoration of physiobiological functions and inhibits neoplastic proliferation.

REFERENCES: [1] Di Bella G. The Di Bella Method (DBM) improved survival, objective response and performance status in a retrospective observational clinical study on 122 cases of breast cancer. Neuro Endocrinol Lett. 2011;32(6):751-62. PMID: 22167148.

- [2] Di Bella G, Colori B, Scanferlato R. The Synergism of Somatostatin, Melatonin, Vitamins Prolactin and Estrogen Inhibitors Increased Survival, Objective Response and Performance Status In 297 Cases of Breast Cancer. Translational Biomedicine. 2018; Vol.9 No.1:146. DOI: 10.21767/2172-0479.100146.
- [3] Di Bella G, Colori B, Toscano R. Complete objective response, stable for 5 years, with the Di Bella Method, of multiple-metastatic carcinoma of the breast. Neuro Endocrinol Lett. 2017 Dec;38(6):401-407. PMID: 29298280.
- [4] Di Bella G, Mascia F, Ricchi A, Colori B. Evaluation of the safety and efficacy of the first-line treatment with somatostatin combined with melatonin, retinoids, vitamin

- D3, and low doses of cyclophosphamide in 20 cases of breast cancer: a preliminary report. Neuro Endocrinol Lett. 2013;34(7):660-8. PMID: 24464005.
- [5] Di Bella G. Complete objective response to biological therapy of plurifocal breast carcinoma. Neuro Endocrinol Lett. 2008 Dec;29(6):857-66. PMID: 19112416.