

Bologna 01/03/18

Translational Biomedicine Journal,

I submit to your attention the presentation of the article I attach. We performed a retrospective observational study on 297 cases of breast cancer monitored by our Di Bella Foundation (a Non-Profit Organisation, recognised and financed by the Italian government, carrying out scientific and biomedical research). We have already published several retrospective observational studies and case reports on the results obtained in cases of breast cancer treated with the Di Bella Method biological therapy (DBM); these can be accessed at www.pubmed.gov.

[Neuro Endocrinol Lett. 2017 Dec;38(6):401-407. 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. 2013;34(7):660-8. 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. 2011;32(6):751-62. 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. 2008 Dec;29(6):857-66. Di Bella G. Complete objective response to biological therapy of plurifocal breast carcinoma.]

Each of these 297 cases was monitored with hematochemical and instrumental tests, performing histological, immunohistochemical and nuclear grade analyses, according to official oncological criteria. We do not have the financial, organisational and collaborational resources to carry out a prospective observational study with a control group, but we have compared our data with those of the National Cancer Institute for the same type and stage of cancer.

Of the 297 cases studied, 131 were stage 4. The result that we submit to your attention is the improvement in 5-year survival of stage 4 metastatic breast cancer achieved with the DBM: we

achieved a 5-year survival rate of 69.4% compared with the figure of 26.3% reported by the National Cancer.

I would ask you to consider these data which I believe merit some attention since I think the main objective of biomedical research is an increase in life expectancy and an improvement in quality of life. It should be noted that the experiment into the Di Bella Method tested in Italy 20 years ago involved terminal patients with a life expectancy ranging from 11 days to 3 months, with the prospect of a 50% reduction of their tumours in 3 months after following the DBM. A total of 1048 patients were given drugs that had passed their sell-by date and were polluted by acetone: this was confirmed by reports signed by the Anti-Adulteration Unit of the Police. The study was not carried out in double blind with a control group, and the evaluation method applied to the DBM biological therapy was the method for cytotoxic and cytolytic therapies. The numerous and serious irregularities of this study are reported in the publication The Di Bella Method (DBM). Di Bella G. Neuro Endocrinol Lett. 2010;31 Suppl 1:1-42. Review at pages 26-27. The 1998 experiment was contested by doctors, researchers, 50 questions in Parliament and by articles in the BMJ "J. I. Reys, Phil. Physiology, Retired: Compared to what?; 22 January 1999: <http://www.bmj.com> and letters: 3 18/7 178/208-F.I.I."; "Marcus Müller: Di Bella's therapy the last word? BMJ 1999: 318:208-209. "The authors also say that they could not have done randomised trials for ethical reasons, but these are not clear. Indeed some would claim that the inferior design of their studies was unethical".

I believe it is necessary to give you this explanation as you could have thought that the experiment on this method had been performed in a serious way, respecting the scientific procedures foreseen for clinical trials, and then declared ineffective.

I apologise for taking the liberty of sending you this explanation and I thank you for your attention.

Yours sincerely

Giuseppe Di Bella