The Di Bella Method (DBM) improves Survival, Objective Response and Performance Status in Breast Cancer
Breast Cancer treated with DBM therapy

Retrospective observational clinical study
(122 CASES)
This study was conducted by monitoring breast cancer patients who came to the doctor’s office of the G. Di Bella Foundation between 2004-2009 and freely chose to be treated with DBM. All of them gave their written informed consent prior to DBM treatment.

92 = monitored patients (82% inf. ductal – 13% inf. lobul. – 5% other)

The monitoring considered all elements that could be useful to elaborate a statistical study aimed at providing an accurate picture of clinical and therapeutic effects obtained (effectiveness – survival - performance status).

30 case series certified by the Court of Lecce

We are aware that statistics based on a limited number of cases must be regarded carefully. This nonetheless, please consider that by comparison with conventional treatments all parameters have by far been exceeded (including by several percentiles). Most importantly, a series of full, stable and permanent remissions could be observed for the first time, with neither drug or radiation or surgical treatment having been performed previously.
Breast Cancer in DBM therapy

Therapeutic Rationale

Statistical Comparisons

Early Stage Breast Cancer

Metastatic Breast Cancer

First-Line Therapy

Adjuvant Therapy

Locally Advanced

Di Bella Foundation - 2011
DBM therapy sinergically use biological molecules with cytostatic, apoptotic, and anti-proliferative, antiangiogenic differentiating action.

- Somatostatin
- Bromocriptin
- Cabergoline

Melatonin
Retinoids
vit. C - D – E
Condroitinsulfate
Foline

Anti-Proliferative
Anti-Angiogenic

Anti-angiogenic re-differentiating

Pro-apoptotic
anti-angiogenic

Melatonin - Retinoids
vit. D vit E
Cyclophosphamide
(minimal doses)

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Statistical Comparisons
122 cases

First-Line Therapy
(9 cases)

Adjuvant Therapy
(39 cases)

Early Stage
(48 cases)

Metastatic
(39 cases)

No previous treatment
(or only surgery)
(10 cases)

Previously treated
with chemotherapy and surgery
(29 cases)

Locally Advanced
(5 cases)

Overall Survival comparison with
NCI SEER Areas 1988-2001

Metastatic Breast Cancer
30 cases series certified
by the Court of Lecce

Di Bella Foundation - 2011
The inhibition of angiogenesis induced by SST, cabergoline, and bromocriptine is synergistically enhanced by MLT, retinoids, vit. D3, E, C. The same differentiating and apoptotic molecules (melatonin, retinoids, vitamins C, D3, and E) combined with minimal doses of chemotherapy, cause a slow but progressive reduction of the neoplastic concentration, determining significative objective results, until complete remission. MRI-CAD Stream

Tumor mass: 6.3x3.6x3.9 cm. In 7 months: 53% reduction Ø, and 91% volume.
A - Early Stage Breast Cancer (48 cases)
  - First-Line Therapy 9 cases
  - Adjuvant Therapy 39 cases

B - Metastatic Breast Cancer (39 cases)
  - No previous treatment including surgery 10 cases
  - Previously treated with chemotherapy and surgery 29 cases

Locally advanced (5 cases)

STATISTICAL COMPARISONS
122 cases

D - Metastatic Breast Cancer
30 cases series certified by the Court of Lecce

C - Overall Survival comparison with 12 SEER Areas 1988-2001
A - Early Stage Breast Cancer

( clinical results )

DBM as
1 - First-Line Therapy
A - Early Stage

1 - DBM as First-Line Therapy

9 patients chose DBM as first-line therapy, and renounced even to surgery.
4 patients who experienced full remission have been free from disease for several years (2004-2006-2007-2009) and their condition seems to have stabilized.

The other 5 patients are still under treatment.

One of the 4 clinical cases who experienced full remission has been described in detail and published on:

*Neuroendocrinology Letters 2008 Dec 29;29(6).*
## A) Early Stage Breast Cancer

### 1) DBM as First-Line Therapy

<table>
<thead>
<tr>
<th>stage</th>
<th>Initial Condition</th>
<th>Outcome</th>
<th>Current Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Right breast multifocality (1,5 cm - 1 cm) + 2 small brain lesions of uncertain nature</td>
<td>Full Remission</td>
<td>Absence of Disease</td>
</tr>
<tr>
<td>II A</td>
<td>Bilateral lesions – negative biopsy after 6 month DBM treatment</td>
<td>Full Remission</td>
<td>Absence of Disease</td>
</tr>
<tr>
<td>II A</td>
<td>Left breast multifocality and 2 reactive lymph nodes</td>
<td>Full Remission</td>
<td>Absence of Disease</td>
</tr>
<tr>
<td>II B</td>
<td>2 nodules in right breast (2 cm) + positive lymph node</td>
<td>Full Remission</td>
<td>Absence of Disease</td>
</tr>
<tr>
<td>II A</td>
<td>2,5 cm mammary carcinoma + lymph node</td>
<td>Partial Remission</td>
<td>Nodule reduction / Lymph nodes disappeared</td>
</tr>
<tr>
<td>II A</td>
<td>2 cm nodule - lymphadenopathy</td>
<td>Partial Remission</td>
<td>The PET scan shows small residual in mammary area</td>
</tr>
<tr>
<td>II A</td>
<td>35 mm nodule</td>
<td>Partial Remission</td>
<td>12 mm nodule reduction</td>
</tr>
<tr>
<td>I</td>
<td>16 mm nodule</td>
<td>Partial Remission</td>
<td>5 mm nodule</td>
</tr>
<tr>
<td>II B</td>
<td>6,3 x 3.6 x 3.9 cm lesion</td>
<td>Partial Remission</td>
<td>Significant reduction (90%)</td>
</tr>
</tbody>
</table>
A - Early Stage Breast Cancer

2 - DBM as Adjuvant Therapy (post-surgery)
A- Early Stage Breast Cancer

2 - DBM as Adjuvant Therapy (post-surgery)

12 patients showed, upon admission in the treatment trial, evident signs of recovery from disease (local or lymph nodal)

Remissions: 94% (currently all disease-free)

5-year survival: 100%

Only 1 progression was observed in one patient, 2 years after treatment suspension on her request.

Significant results in effectiveness (39 cases)

<table>
<thead>
<tr>
<th>Result</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>remission</td>
<td>36</td>
</tr>
<tr>
<td>stability</td>
<td>2</td>
</tr>
<tr>
<td>progression</td>
<td>1</td>
</tr>
</tbody>
</table>

Di Bella Foundation - 2011
A- Early Stage Breast Cancer

2 - DBM as Adjuvant Therapy (post-surgery)

Clear and significative improvement in Overall Survival (median follow-up: 60 months = 100%)

Di Bella Foundation - 2011
A/2- Early Stage Breast Cancer

Clear and significative improvement in disease-free survival in the adjuvant treatment (post-surgery) (39 patients)

Di Bella Foundation - 2011
## Locally Advanced Breast Cancer

### Stage III b-c

<table>
<thead>
<tr>
<th>arch.</th>
<th>Initial Condition</th>
<th>Outcome</th>
<th>Current Condition</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>799</td>
<td>Advanced stage - inoperable</td>
<td>Progression</td>
<td>Likely to be dead (not possible to get in touch with her)</td>
<td>16 months (at least)</td>
</tr>
<tr>
<td>2680</td>
<td>(morphine) – widespread metastases affecting subclavian-neck and axillas lymph nodes</td>
<td>Progression</td>
<td>Dead 7/2010</td>
<td>7 months</td>
</tr>
<tr>
<td>895</td>
<td>Breast carcinoma 5 cm. + lymph nodes</td>
<td>Progression(incomplete treatment)</td>
<td>Dead 2/2008 (pneumonia)</td>
<td>5 months</td>
</tr>
<tr>
<td>688</td>
<td>1 lung nodule</td>
<td>Full remission</td>
<td>No illness</td>
<td>60 months – alive</td>
</tr>
<tr>
<td>1638</td>
<td>After surgery treated for prevention</td>
<td>Stability</td>
<td>Without changes</td>
<td>28 months – alive</td>
</tr>
</tbody>
</table>
Response to DBM treatment is inversely proportional to the number and intensity of previous chemotherapy cycles, and directly proportional to treatment precocity. Chemotherapy may cause tumor reductions or remissions of variable duration adversely affected by high toxicity and by the mutagenic effect which selects more and more chemo-resistant tumor cell populations in a body severely affected by treatment itself. In many other cases, chemo and/or radiotherapy fail even to obtain such temporary and palliative effects. Conversely, under similar circumstances DBM therapy can produce better results in unimpaired patients in terms of living functions. In all cases and at any stage of disease DBM therapy can improve quality of life and life expectancy compared to median survivals at advanced cancer stages reported in scientific literature. These considerations rest upon the following observations.
### 3 - First-Line Therapy

with no previous treatment  
( including surgery )

4 cases in total  
( 2 remissions – 2 progressions)

<table>
<thead>
<tr>
<th>arch.</th>
<th>Initial Condition</th>
<th>Outcome</th>
<th>Current Condition</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>994</td>
<td>Lymph nodal – retro-pectoral – mediastinic – bone metastases</td>
<td>Partial Remission</td>
<td>Remission everywhere except bone</td>
<td>22 months – living</td>
</tr>
<tr>
<td>586</td>
<td>2 nodules in right breast + lung metastases</td>
<td>Remission</td>
<td>Living</td>
<td>56 months – living</td>
</tr>
<tr>
<td>970</td>
<td>Advanced stage bilateral carcinoma – several bone and lung metastases</td>
<td>Progression</td>
<td>Dead</td>
<td>17 months</td>
</tr>
<tr>
<td>2224</td>
<td>Axillary, breastbone and bone recurrence</td>
<td>Progression</td>
<td>Slow progression</td>
<td>19 months – living</td>
</tr>
</tbody>
</table>
### B - Metastatic Breast Cancer

#### 4 - Adjuvant Therapy

Stage IV patients who were treated with surgery but not with chemotherapy

6 cases in total (3 remissions – 2 stable – 1 progression)

<table>
<thead>
<tr>
<th>arch.</th>
<th>Initial Condition</th>
<th>Outcome</th>
<th>Current condition</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>1826</td>
<td>Lung metastasis + lymph nodes</td>
<td>Full Remission</td>
<td>Absence of Disease</td>
<td>27 months – living</td>
</tr>
<tr>
<td>2440</td>
<td>Axillary infiltration + widespread bone metastases</td>
<td>Partial Remission</td>
<td>Reduction in bone lesions</td>
<td>15 months – living</td>
</tr>
<tr>
<td>2726</td>
<td>Liver and bone metastases</td>
<td>Partial Remission</td>
<td>Reduction in metastases</td>
<td>12 months – living</td>
</tr>
<tr>
<td>1865</td>
<td>Lung + bone + lymph node metastasis</td>
<td>Stability</td>
<td>stability</td>
<td>26 months – living</td>
</tr>
<tr>
<td>2287</td>
<td>Multiple bone lesions</td>
<td>Stability</td>
<td>stability</td>
<td>18 months – living</td>
</tr>
<tr>
<td>1185</td>
<td>Metastases affecting 30 lymph nodes out of 32 + bone metastases</td>
<td>Progression</td>
<td>dead</td>
<td>38 months</td>
</tr>
</tbody>
</table>

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The patient underwent mastectomy in 1997 due to “Infiltrating ductal G2”

Oct. 27th 2009 – Lymph node hystologic test “” Infiltration due to ductal cancer, metastatic””

December, 11th 2009 – PET scan: “”.. High metabolic activity lesions at axillary lymph nodal and bone level (dorsolumbar rachis, right acromion, some ribs bilaterally, right and left iliac regions, right pubic symphysis, left intertrocanteric region). Doubts with respect to right lung

December, 29th 2009 – start of DBM treatment

June, 3rd 2010 – PET scan “disappearance of the tracing focal hyper accumulation in the right nodal axillary region and in some uptake skeletal areas (III front right costal arch, IV back right arch, left iliac ala, right sacroiliac synchondrosis and left intertrochanteric region) uptake gradient reduction at a vertebral level, uptake gradient reduction in the right subareolar region “”
B - Metastatic Breast Cancer

5 - patients previously treated with surgery and chemotherapy

( now under no treatment)

29 cases in total
( 6 stable – 23 progression)

Median survival = 18 months
Clear and significative improvement in Overall Survival (39 patients)
Median = 18 months (30% is alive at 30 months)
Overall Survival

comparison with 12 SEER Areas 1988-2001
30 case series certified by the Court of Lecce
Technical Expert's District Court in Lecce 1999

MDB Response to Breast Cancer

<table>
<thead>
<tr>
<th></th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remis.</td>
<td>20</td>
</tr>
<tr>
<td>Par.Rem.</td>
<td>20</td>
</tr>
<tr>
<td>Stabil.</td>
<td>50</td>
</tr>
<tr>
<td>Progres.</td>
<td>10</td>
</tr>
</tbody>
</table>

Legend:
- Remis.: Remission
- Par.Rem.: Partial Remission
- Stabil.: Stable
- Progres.: Progression
## Overall Survival

<table>
<thead>
<tr>
<th>Initial diagnosis</th>
<th>1 year (90)</th>
<th>3 years (72)</th>
<th>5 years (60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>stage I (18)</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>stage II (47)</td>
<td>100%</td>
<td>100%</td>
<td>94%</td>
</tr>
<tr>
<td>stage III (17)</td>
<td>100%</td>
<td>83%</td>
<td>55%</td>
</tr>
<tr>
<td>stage IV (6)</td>
<td>100%</td>
<td>60%</td>
<td>50%</td>
</tr>
<tr>
<td><strong>MDB total (obs)</strong></td>
<td><strong>100%</strong></td>
<td><strong>93%</strong></td>
<td><strong>82%</strong></td>
</tr>
</tbody>
</table>

## Relative Survival

<table>
<thead>
<tr>
<th>1 year</th>
<th>3 years</th>
<th>5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDB total (rel)</td>
<td>100%</td>
<td>98%</td>
</tr>
</tbody>
</table>
Di Bella Foundation – Italy
website: www.metododibella.org