BIT's 4th World Cancer Congress 2011
People's Republic of China
Dalian

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)

Di Bella Foundation - 2011

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

Locally Advanced

First-Line Therapy

Adjuvant Therapy

DBM therapy
sinergically use **biological**
molecules with **cytostatic, apoptotic, and**
anti-proliferative, antiangiogenic differentiating action

Somatostatin
Bromocriptin
Cabergoline

Anti-Proliferative
Anti -Angiogenic

Melatonin
Retinoids
vit. C - D – E
Condroitinsulfate
Foline

Anti-angiogenic
re-differentiating

Melatonin - Retinoids
vit. D vit E

Cyclophosphamide
(minimal doses)

Pro-apoptotic
anti-angiogenic

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Statistical Comparisons 122 cases

Early Stage (48 cases)

- **First-Line Therapy** *(9 cases)*
- **Adjuvant Therapy** *(39 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

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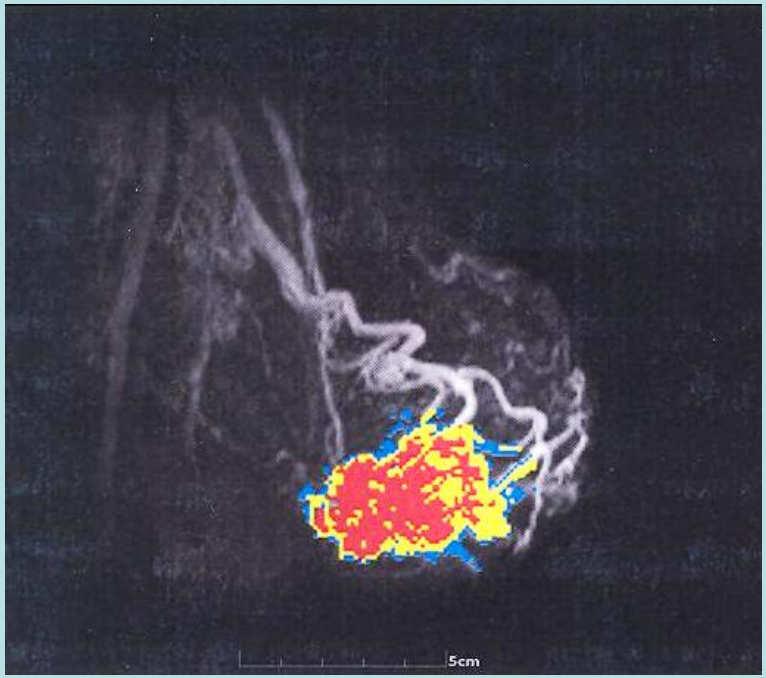
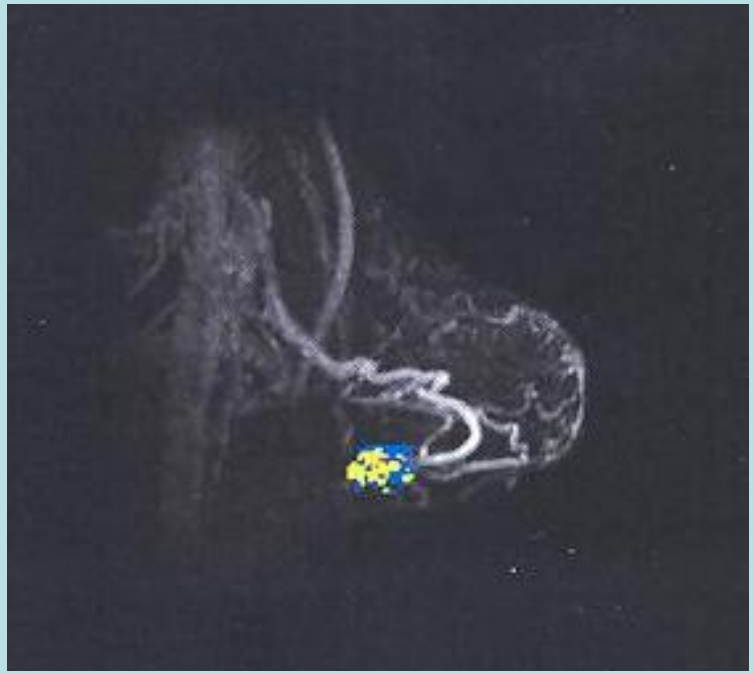
The inhibition of angiogenesis induced by SST, cabergoline, and bromocriptine is synergistically enhanced by MLT, retinoids, vit. D3, E, C.The same differentiating and apoptotic molecules (melatonin, retinoids, vitamins C, D3, and E) combined with minimal doses of chemotherapy, cause a slow but progressive 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

Locally advanced
(5 cases)

B - Metastatic Breast Cancer
(39 cases)

No previous treatment
including surgery
10 cases

Previously treated with chemotherapy and surgery
29 cases

STATISTICAL COMPARISONS
122 cases

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

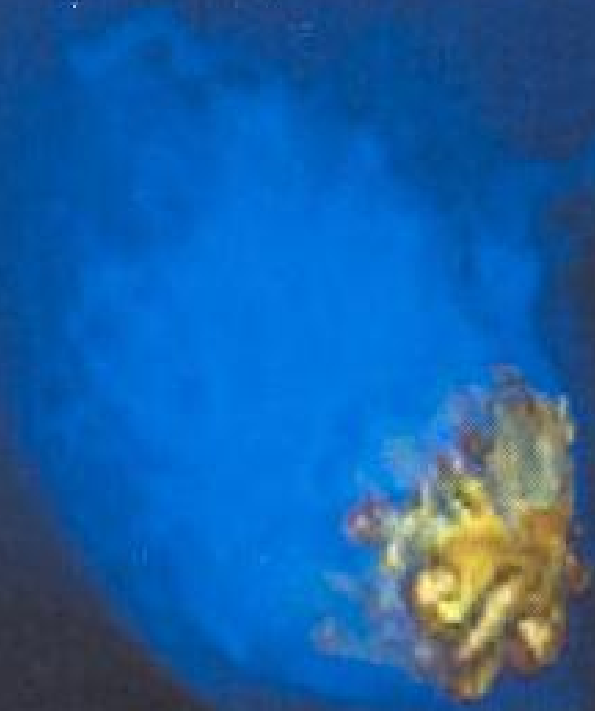
C - Overall Survival comparison with 12 SEER Areas 1988-2001

Breast Cancer
in DBM therapy

A - Early Stage Breast Cancer

(clinical results)

DBM as
1 - First-Line Therapy



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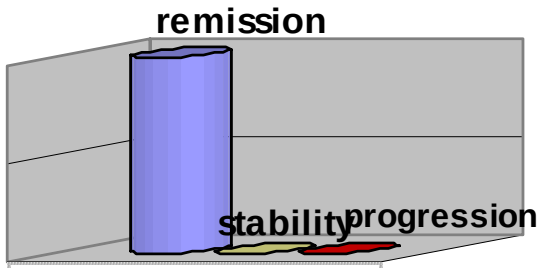
A - Early Stage

Breast Cancer
in DBM therapy

1 - DBM as **First-Line Therapy**

<u>9 patients</u> chose DBM as first-line therapy,
<u>and renounced even to surgery</u>

*BREAST CANCER (**Stage I - II**)*
with DBM as first-line therapy



remission	100,00%
stability	0,00%
progression	0,00%

Breast Cancer
in DBM therapy

A - Early Stage Breast Cancer

1 - DBM as **First-Line Therapy**

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).

Breast Cancer
in DBM therapy

A) Early Stage Breast Cancer

1) DBM as **First-Line Therapy**

stage	Initial Condition	Outcome	Current Condition
I	Right breast multifocality (1,5 cm - 1 cm) + 2 small brain lesions of uncertain nature	Full Remission	Absence of Disease
II A	Bilateral lesions – negative biopsy after 6 month DBM treatment	Full Remission	Absence of Disease
II A	Left breast multifocality and 2 reactive lymph nodes	Full Remission	Absence of Disease
II B	2 nodules in right breast (2 cm) + positive lymph node	Full Remission	Absence of Disease
II A	2,5 cm mammary carcinoma + lymph node	Partial Remission	Nodule reduction / Lymph nodes disappeared
II A	2 cm nodule - lymphadenopathy	Partial Remission	The PET scan shows small residual in mammary area
II A	35 mm nodule	Partial Remission	12 mm nodule reduction
I	16 mm nodule	Partial Remission	5 mm nodule
II B	6,3 x3,6 x 3,9 cm lesion	Partial Remission	Significant reduction (90%)

Breast Cancer
in DBM therapy

A - Early Stage Breast Cancer

2 - DBM as
Adjuvant Therapy
(post-surgery)

A- Early Stage Breast Cancer

Breast Cancer
in DBM therapy

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)

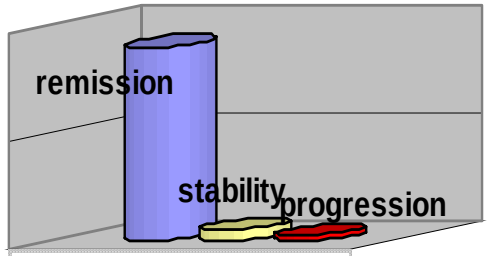
Remissions: 94% (currently all disease-free)

5-year survival : 100%

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

Significative results in effectiveness (39 cases)

Early stage Breast Cancer (stage **I - II - IIIa**)



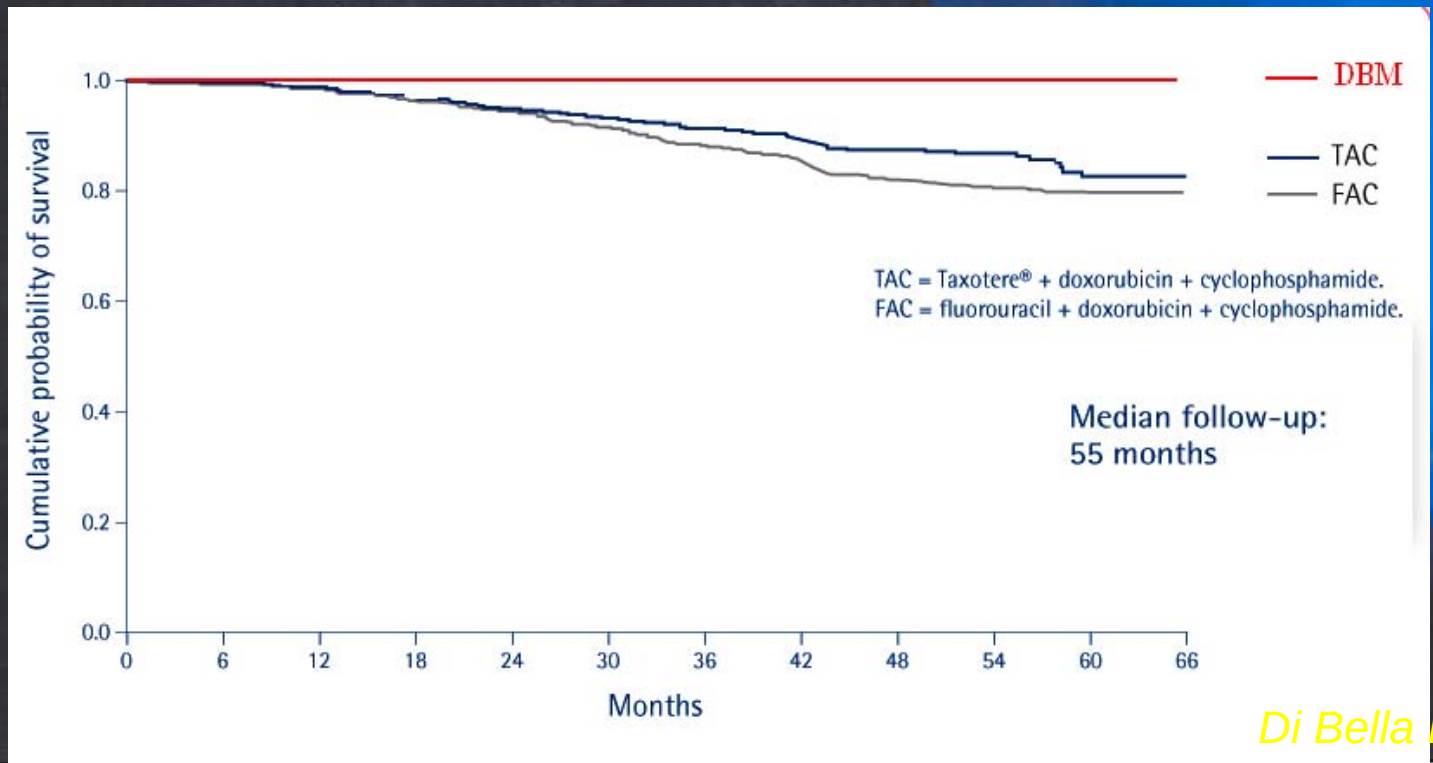
	Result
remission	36
stability	2
progression	1

A- Early Stage Breast Cancer

Breast Cancer
in DBM therapy

2 - DBM as **Adjuvant Therapy (post-surgery)**

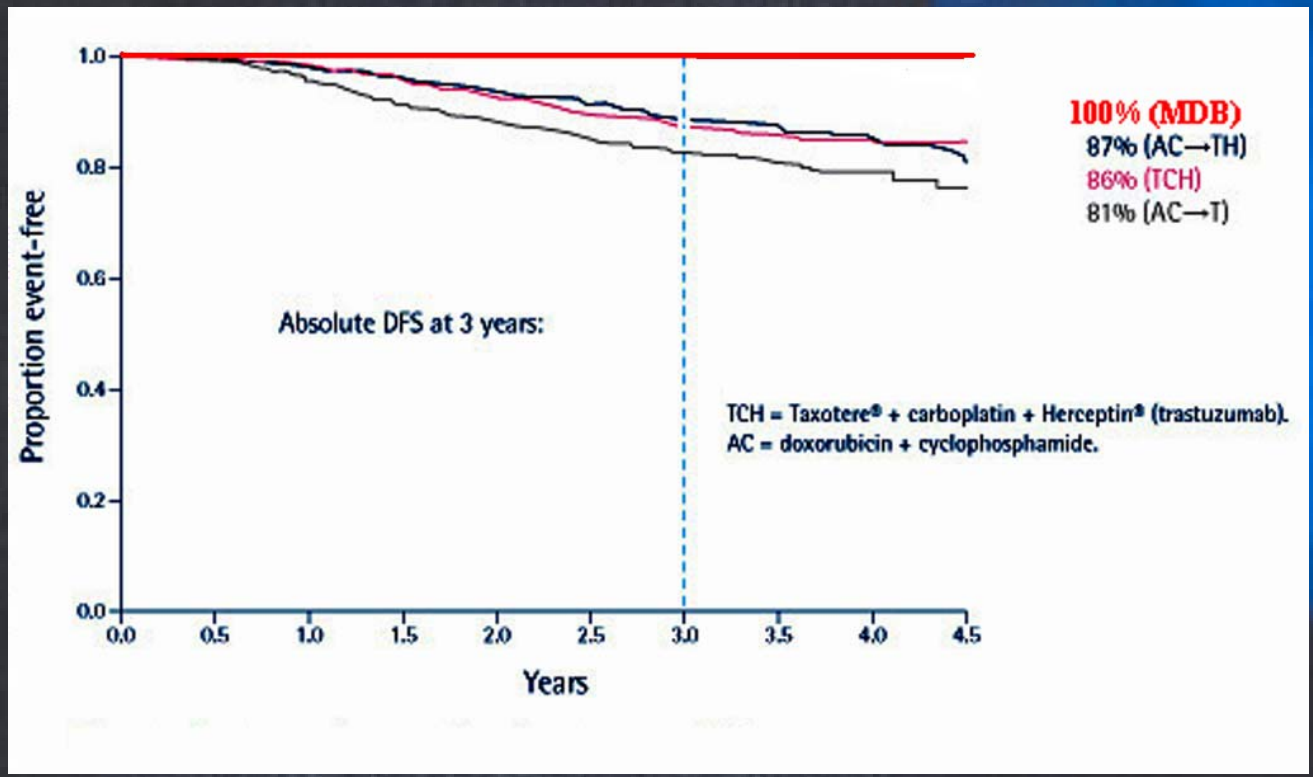
Clear and significative improvement in Overall Survival (median follow-up: 60 months = 100%)



A/2- Early Stage Breast Cancer

Breast Cancer
in DBM therapy

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



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Locally Advanced Breast Cancer

Stage III b-c

arch.	Initial Condition	Outcome	Current Condition	Survival
799	Advanced stage - inoperable	**Progression**	Likely to be dead (not possible to get in touch with her)	**16 months (at least)**
2680	(morphine) – widespread metastases affecting subclavian-neck and axillas lymph nodes	**Progression**	Dead 7/2010	**7 months**
895	Breast carcinoma 5 cm. + lymph nodes	**Progression(incomplete treatment)**	Dead 2/2008 (pneumonia)	**5 months**
688	1 lung nodule	**Full remission**	No illness	**60 months – alive**
1638	After surgery treated for prevention	**Stability**	Without changes	**28 months – alive**

B - Metastatic Breast Cancer

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.

B - Metastatic Breast Cancer

3 - First-Line Therapy

Breast Cancer
in DBM therapy

with no previous treatment
(**including surgery**)

4 cases in total

(2 remissions – 2 progressions)

arch.	Initial Condition	Outcome	Current Condition	Survival
994	Lymph nodal – retro-pectoral – mediastinic – bone metastases	**Partial Remission**	Remission everywhere except bone	**22 months – living**
586	2 nodules in right breast + lung metastases	**Remission**	Living	**56 months – living**
970	Advanced stage bilateral carcinoma – several bone and lung metastases	**Progression**	Dead	**17 months**
2224	Axillary, breastbone and bone recurrence	**Progression**	Slow progression	**19 months – living**

B - Metastatic Breast Cancer

4 - Adjuvant Therapy

Breast Cancer
in DBM therapy

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

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

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

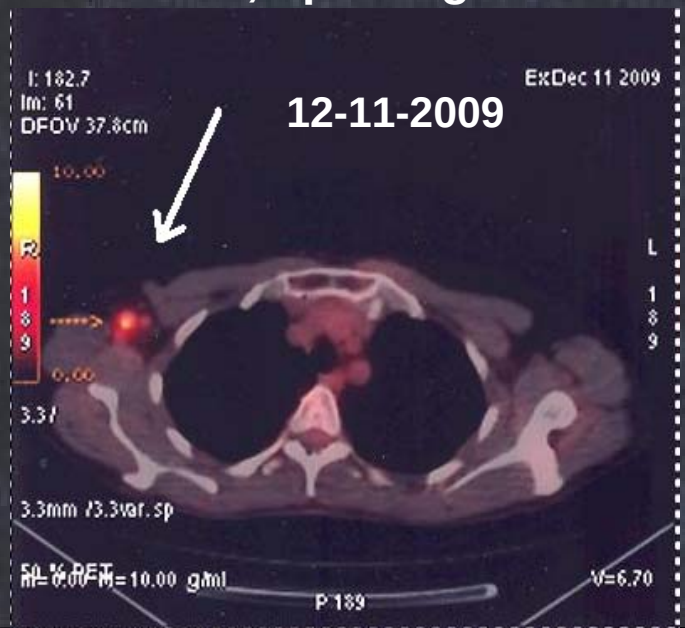
The patient underwent mastectomy in 1997 due to “Infiltrating ductal G2”

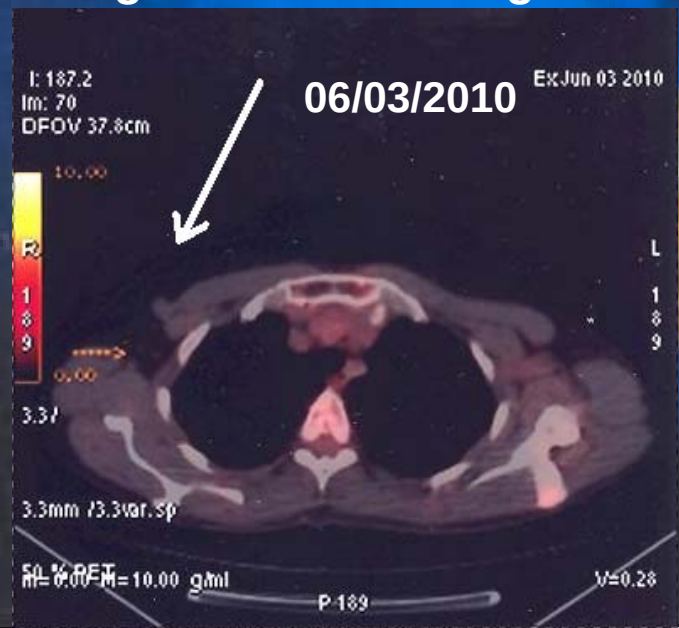
Oct. 27th 2009 – Lymph node hystologic test “” *Infiltration due to ductal cancer, metastatic*””

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

Breast Cancer
in DBM therapy

(now under no treatment)

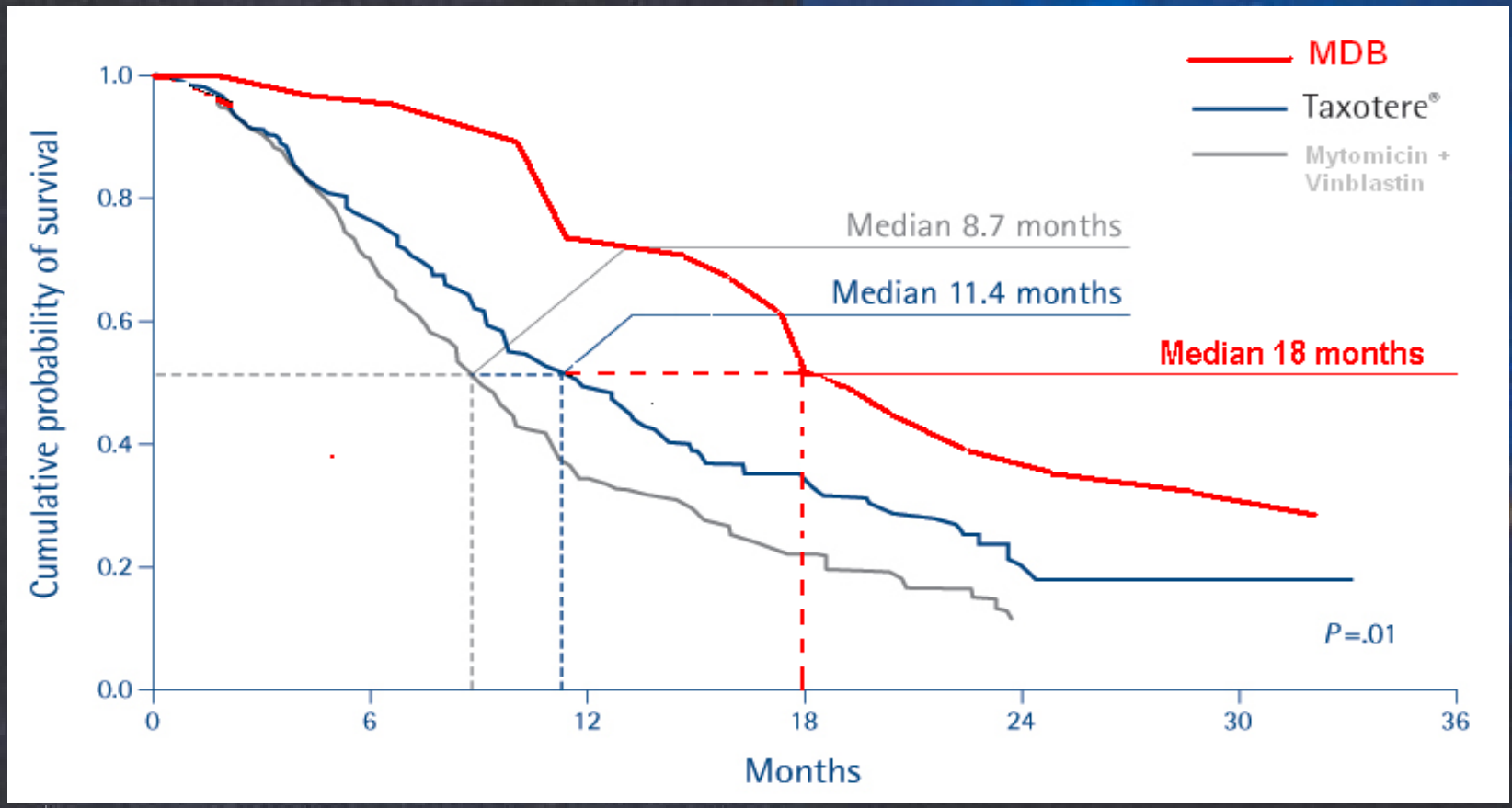
29 cases in total (6 stable – 23 progression)

Median survival = 18 months

Metastatic Breast Cancer
B/3-4-5 clinical results

Breast Cancer
in DBM therapy

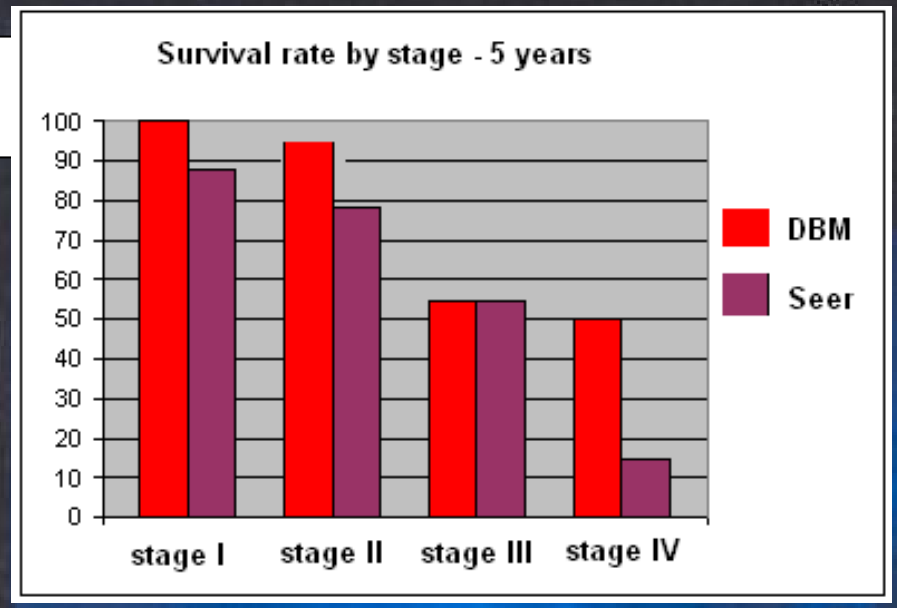
Clear and significative improvement in Overall Survival (39 patients)
Median = 18 months (30% is alive at 30 months)

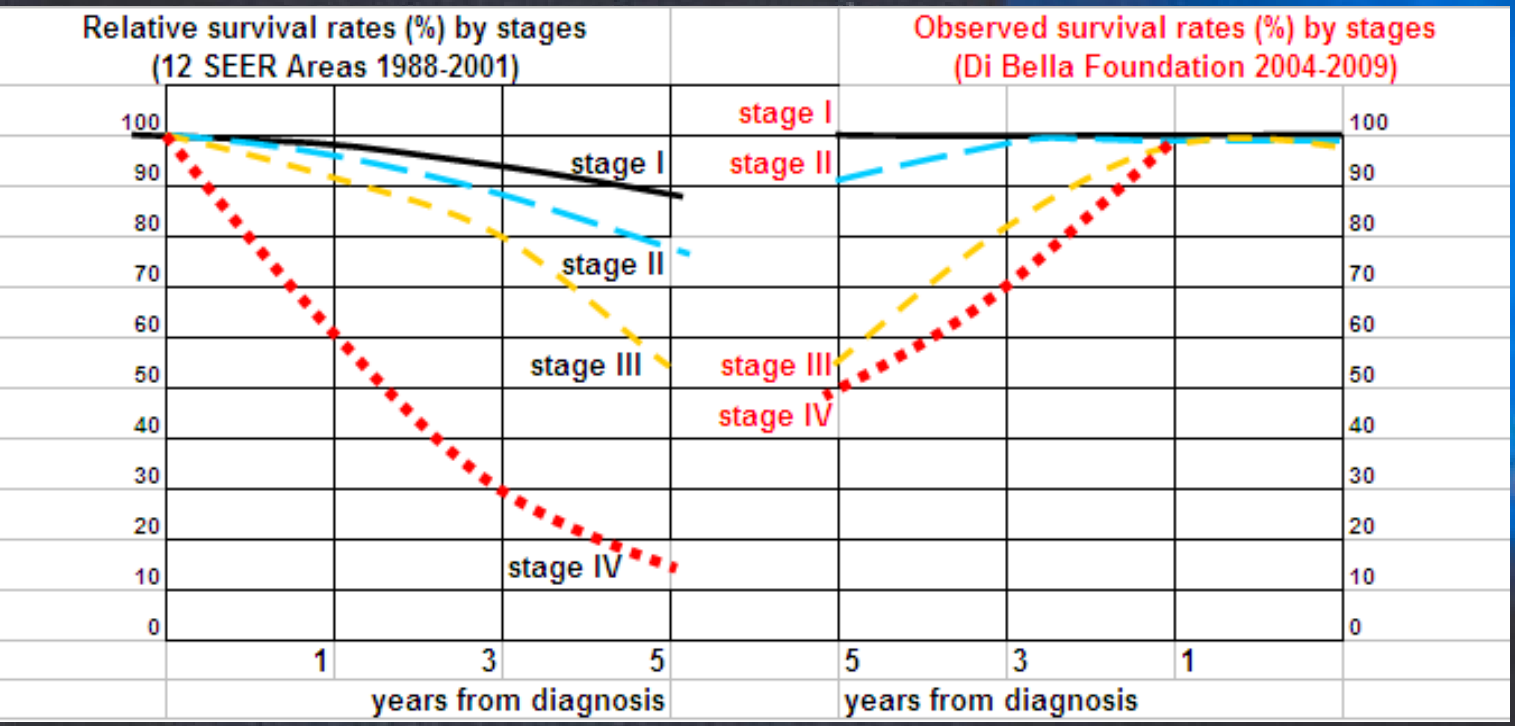


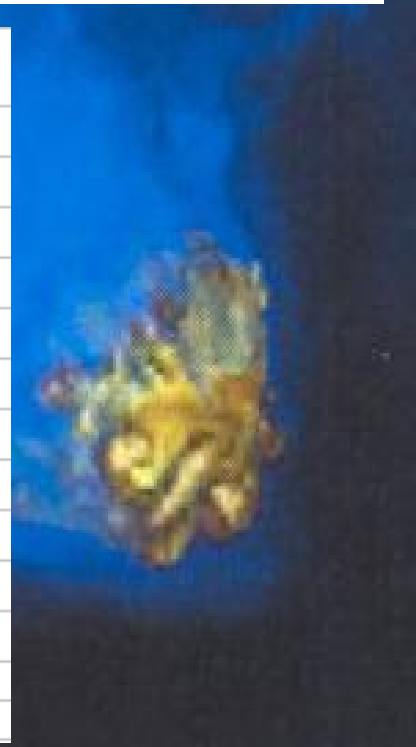
Statistical Comparisons

Overall Survival

comparison with 12 SEER Areas 1988-2001







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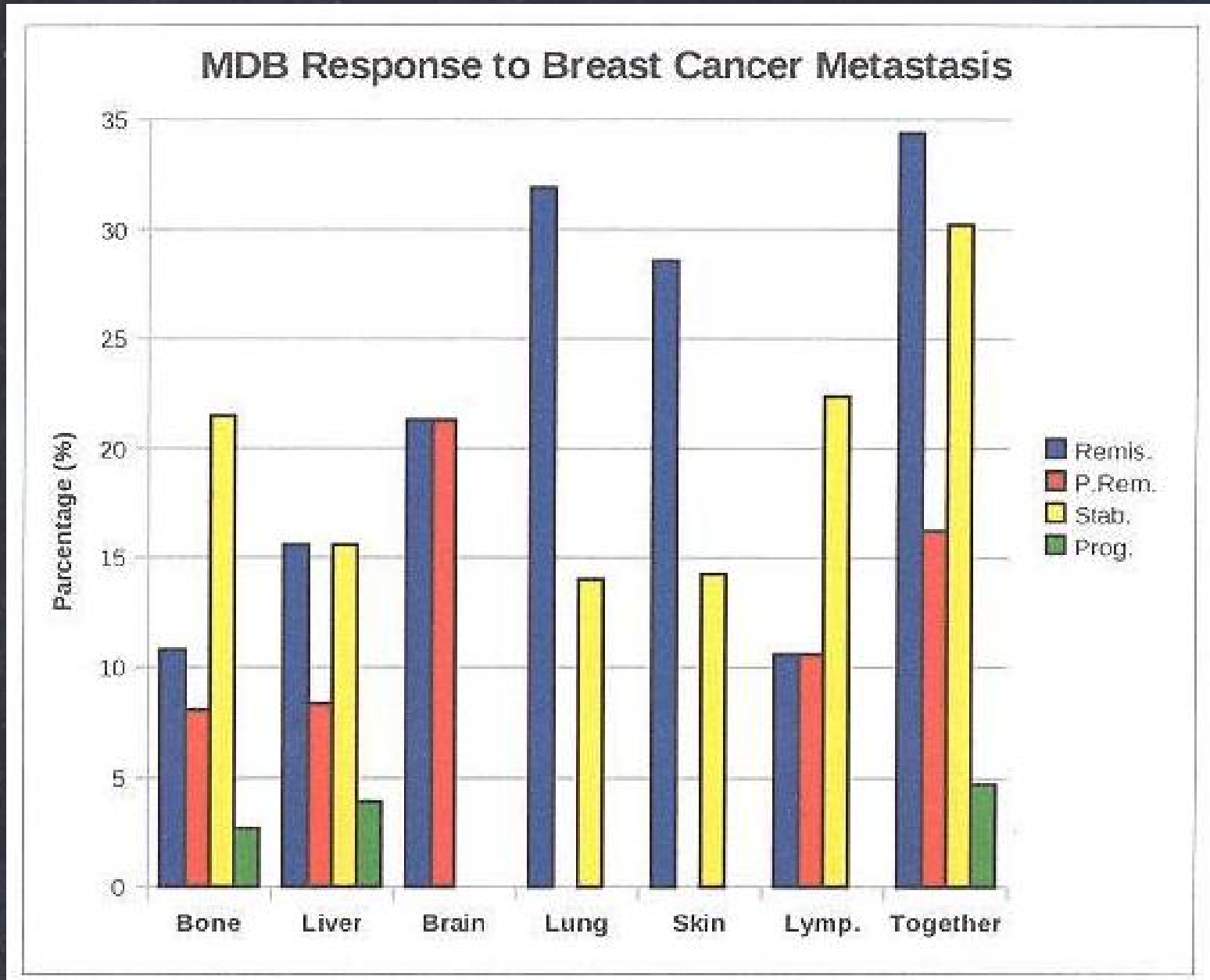
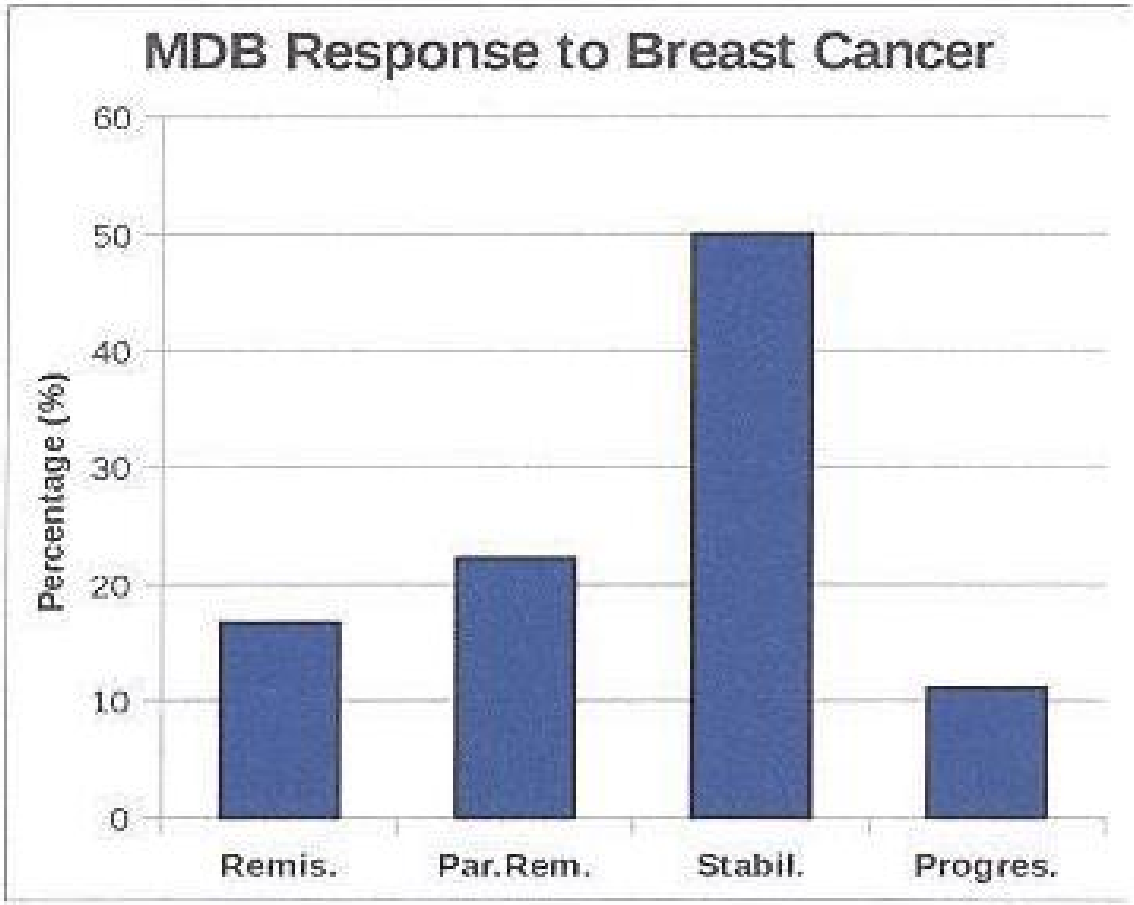
30 case series certified by the Court of Lecce



Technical Expert's District Court in Lecce 1999



Statistical Comparisons

Breast Cancer
in DBM therapy

Overall Survival

Observed Survival (obs) patients treated with MDB			
	1 year (90)	3 years (72)	5 years (60)
Initial diagnosis	%	%	%
stage I (18)	100	100	100
stage II (47)	100	100	94
stage III (17)	100	83	55
stage IV (6)	100	60	50
MDB totale (obs)	100	93	82

Relative Survival (rel) patients treated with DBM			
	1 year	3 years	5 years
	%	%	%
MDB total (rel)	100	98	90

Di Bella Foundation – Italy

website: www.metododibella.org