

MAMMOGRAPHIC BREAST DENSITY EVALUATION AFTER ONE YEAR SOY EXTRACT TREATMENT

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INTRODUCTION AND OBJECTIVES:

Mammographic density is a strong predictor of breast cancer risk and women with high densities are more likely to develop the disease. Whereas soy extracts are taken as post menopausal treatment, only few studies have examined the relation between soy intake and mammographic density. The objective of our study was to analyse the breast density evolution of patients treated with an isoflavone extract during 12 months.

METHODS:

Study design:

This is an international open study with centres located in Australia, Belgium, France and Spain. 395 post menopausal women have been included. Breast density analysis has been performed for the patients from 3 centres: 1 in Belgium and 2 in Spain.

Treatment:

2 capsules in the morning and 2 capsules in the evening of Phyto Soya® corresponding to a daily dose of 70 mg of isoflavone (35 mg daidzin, 21 mg glycitin and 14 mg genistin). Patients were treated for 1 year and they have the possibility to continue 2 additional years.

Main inclusion criteria:

- non hysterectomised women, 45-65 years old, post menopausal since at least 2 years.
- women presenting hot flushes or climacteric symptoms
- wash out of 3 months for HRT, DHEA, tibolone, raloxifene, 2 months for isoflavones.
- BMI < 30 Kg/m,
- No endometrial abnormality, no thromboembolic disease, no uncontrolled arterial hypertension, no history of hormonodependent malignant tumors.
- Classification ACR (classification of abnormality) 0, 3, 4, 5 not included.

Breast density assessment at inclusion and after 1 year:

- 1) Four BI-RADS density categories.
- 2) Computer-aided mammographic density estimation software : breast density analysis was performed on digitized mammograms using the same film scanner. All the breast images were blinded and randomly displayed to the operator. The total breast area was delimited by the radiologist whereas the dense area were determined using an assisted computerized method based in grey scale threshold.

RESULTS AND CONCLUSIONS:

1) Birads results:

175 bilateral mammographies have been collected from the 3 largest centres of the study. 166 patients had interpretable mammographies for inclusion and final visit. They have been classified according to BI-RADS density categories. An increase between T0 and T12 months was observed in only 6 breast whereas a classification decrease was noticed in 13 breasts. No increase from Type 2 to 3, nor type 3 to 4 has been recorded.

	LEFT BREAST		RIGHT BREAST	
	INCLUSION	FINAL VISIT (1 year)	INCLUSION	FINAL VISIT (1 year)
Non interpretable	7	8	8	9
Type 1	65	63	65	65
Type 2	58	63	57	60
Type 3	39	35	39	35
Type 4	6	6	6	6
Total	175	175	175	175

Classification increase	Classification decrease
Type 1 → type 2 : 6 breasts	Type 2 → type 1 : 5 breasts
Type 2 → type 3 : 0 breasts	Type 3 → type 2 : 7 breasts
Type 3 → type 4 : 0 breasts	Type 3 → type 1 : 1 breasts
	Type 4 → type 3 : 0 breasts
Total:	6 breasts / 13 breasts

2) Quantitative method:

Using our computer-assisted method, we didn't observe any significant modification in density percentage after 12 months of treatment.

Conclusions:

No significant change in breast density has been observed after 1 year of treatment, suggesting that intake of our specific and standardized soy extract doesn't increase the risk to develop breast cancer. However, these results are to be confirmed with patients who have accepted to be treated for 3 years.