Long-term safety assessment of a cohort of post-menopausal women treated with Anastrozole as adjuvant treatment for hormone-dependent breast cancer. Baseline data

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Background

The analysis of the ATAC trial, comparing anastrozole to tamoxifen in early breast cancer in postmenopausal women, has shown a significantly higher efficacy (disease-free survival, time to recurrence, time to distant recurrence, incidence of new controlateral breast cancer) for anastrozole, a lower frequency of vascular events and endometrial cancers with anastrozole, but a higher frequency of musculoskeletal adverse events.

As about 25000 women are likely to be treated in France each year by an adjuvant treatment of breast cancer, it was important to assess in a naturalistic situation and in a large population of French patients treated in current clinical practice, the long-term safety of anastrozole and the expression of feelings and complaints raised by the patients over the time.

Thus, a long-term observational, non interventional, longitudinal survey of post-menopausal women with a breast cancer, hormone-receptor positive, treated with anastrozole (1 mg daily during 5 years) as adjuvant therapy has been set-up and the patients' characteristics before starting anastrozole treatment are presented.

Objectives

Main objective: describe long-term tolerability of anastrozole in clinical practice.

Secondary objectives: to describe the available data in an attempt to draw conclusions about their inter-dependence and their impact on tolerance and assess possible changes over time:
- describe the characteristics of breast cancer,
- describe the nature and modalities of care,
- describe intercurrent diseases
- describe the concomitant treatments
- describe patient's reported compliance

The objective of this interim analysis is to describe characteristics of the study population at baseline before treatment with anastrozole.

Materials & Methods

A French observational, non interventional, prospective, multicentre, longitudinal survey is ongoing since October 2005.

Eligibility criteria:

The population targeted by the survey includes women followed within their usual healthcare visit for their disease. The decision to treat these women with anastrozole was taken by their physicians (adjuvant treatment of breast cancer in postmenopausal women with hormone receptor positive).

Safety data are collected:
- during scheduled consultations (every 6 months during the first 2 years, and annually during 3 years)
- through a self questionnaire each year
- each year, in the first 3 months after the scheduled consultation during a phone call

Results

A cohort of 1567 women, recruited by 117 specialists was constituted.

Demographic and clinical patients characteristics:

At study entry, mean age of patients was 63.6 ± 8.5 years with mean menopause duration of 14.1 ± 9.7 years.
Breast cancer treatment is considered to be, in 5.9% of the cases, responsible for the menopause onset.

	Cohort	Effective analysed *(missing data)*
Mean age, years *(SD)*	63.6 *(± 8.5)*	n=1565 *(2)*
Mean length of menopause, years *(SD)*	14.1 *(± 9.7)*	n=1564 *(3)*
Mean body mass index, kg/m² *(SD)*	26.4 *(± 5.2)*	n=1542 *(25)*

Patient's disease history:

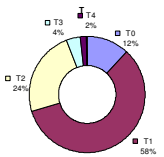
Diagnosis:

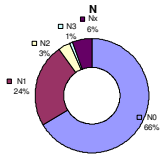
Most patients were diagnosed during a screening mammography.

Screening mammography	69 % (n=1083)
During a consultation	6.3% (n=98)
Patient herself	25.1 % (n=393)

Primary tumour was located in the right breast for 48.2 % of the women, in the left breast for 50.2 % and both for 1.6 %.

TNM classification:





Hormone-receptor:

			Effective analysed *(missing data)*
Estrogen-receptor (%)	positive	98.9	n=1567 *(0)*
	negative	1.1	
Progesterone-receptor (%)	positive	77.4	n=1560 *(7)*
	negative	20.6	
	unknown	2	

Breast cancer treatment

			Effective analysis data *(missing data)*
Surgery	mastectomy	23.2%	n=1560 *(7)*
	conservative	75.8%	
	both	1.0%	
Radiotherapy	No	6.5%	n=1567
	Yes	93.5%	
Chemotherapy	No	63.5%	n=1567
	yes	36.5%	

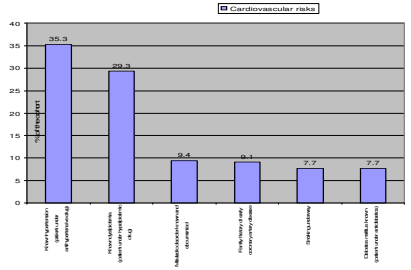
36.5% of patients had adjuvant or neoadjuvant chemotherapy (anthracyline :96.7%, taxanes : 69.2%).

Anastrozole was mostly introduced after radiotherapy and/or chemotherapy.

Introduction of anastrozole			Effective analysed *(missing data)*
Radiotherapy	During	18.8 %	n=1434 *(143)*
	After	81.2 %	
Chemotherapy	During	0.9 %	n=333 *(1234)*
	After	99.1 %	

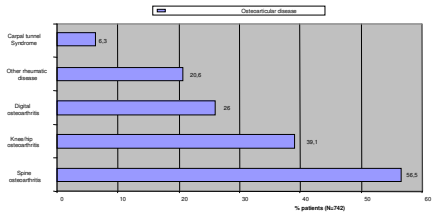
Cardiovascular risk factors at baseline:

A wide range of cardiovascular risk factors is found in this survey: about 1 woman out of 3 is treated for hypertension, 1 out of 3 has dyslipidemia disorders.



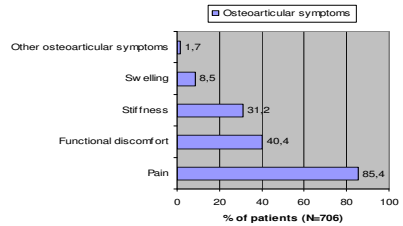
Osteoarticular assessment at baseline:

An osteoarticular disease was present in 47.4 % of the patients (742 patients).



Osteoarticular symptoms at baseline :

Osteoarticular symptoms were present in 46% of patients (706 patients) prior to any treatment with anastrozole .
Patients experienced these symptoms since a mean of 4.5 ± 8.3 years.



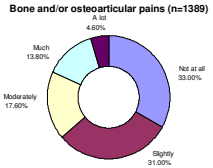
Localisation of the osteoarticular symptoms at baseline:

Spine	Knee	Hands	Shoulder	Wrist	Hip	Feet	Leg	Elbow	Arm
29,6 %	18 %	12,6 %	12,1 %	6,6 %	6,6 %	6,3 %	3,4 %	2,8 %	2 %

Treatment of osteoarticular symptoms at baseline : patients are treated with
NSAID (7.6%)
Corticosteroids (1.7%)
Opioids (3.4%)
Other analgesics and antipyretics (6.9%)
Topical products for joint and muscular pain (1.4%)
Drugs affecting bone structure and mineralization (15.1%)

Symptoms patients assessment (Self questionnaire) at baseline:

Patients were asked to evaluate their bone and osteoarticular pains prior to any intake of anastrozole: 67% of subjects reported pre-existing osteoarticular pain, about 1 out of 3 qualified their pain as "moderately" to "a lot" (cf. figure 7).



Conclusion

A high percentage of patients showed osteoarticular symptoms, osteoporosis and cardiovascular risk factors at baseline prior to receiving anastrozole.
These data should be taken into account when interpreting the long-term tolerability of treatment during the 5 years follow-up.