Abstract #2085:

Bone health and anastrozole adverse events in Japan Sagara Y, et al.

Patients : 656 postmenopausal women who received anastrozole as adjuvant hormone therapy.
Study design: Retrospective analysis.
Results:
Bone fracture rate was 1.3% at the median follow-up period of 17 months. Annual bone fracture rate of 0.8% was lower than that of Western population. (ATAC : 2.26%, BIG1-98: 2.2%).

Title;

The effects of exemestane, anastrozole and tamoxifen on bone mineral density and bone turnover markers in postmenopausal early breast cancer patients: preliminary results of N-SAS BC04, the TEAM Japan sub-study.

Authors;

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Aims

We aimed to investigate the difference among exemestane, anastrozole and tamoxifen in the effect on bone mineral density (BMD) and bone turnover markers in patients with postmenopausal primary breast cancer treated with those agents as adjuvant endocrine therapy.

Patients/Methods:

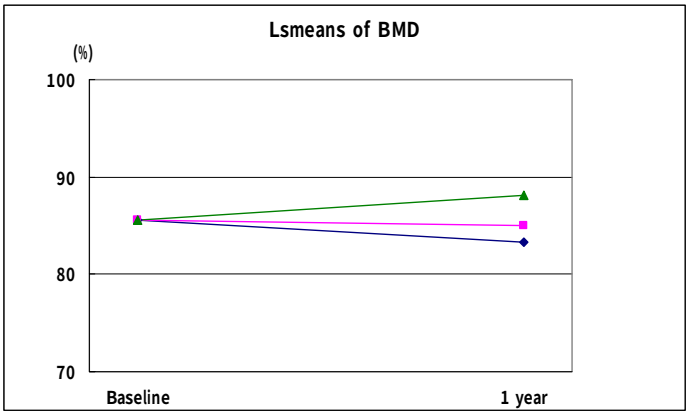
Exemestane arm; n=27, Anastrozole arm; n=23, Tamoxifen arm; n=26. (N-SAS BC04: n=247 in total.)

BMD : DEXA at baseline and 12 months after treatment initiation.

Bone turnover marker:Urinary type I collagen cross-linked N-telopeptide (NTX, bone absorption) and serum bone specific alkaline phosphatase (BAP, bone formation) at baseline and 3, 6, 12 months after treatment initiation.

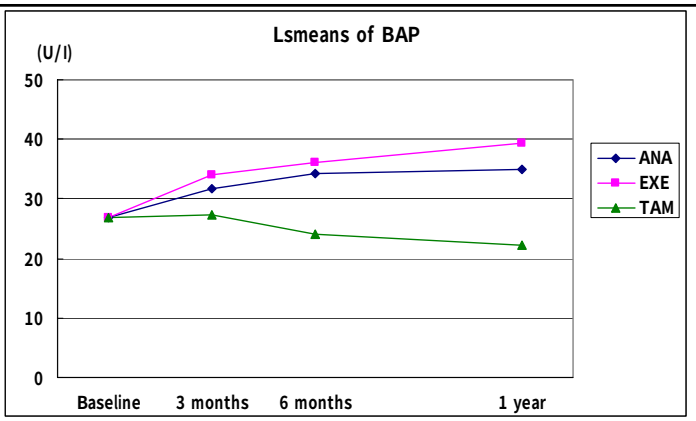
Patient characteristics

		Exemestane n=27	Tamoxifen n=23	Anastrozole n=26	Total n=76
Age	Mean±S.D.	64.1±7.7	61.1±6.9	61.0±6.6	62.1±7.2
Stage	Ⅰ	5(18.5%)	5(21.7%)	8(30.8%)	18(23.7%)
	ⅡA	13(48.1%)	11(47.8%)	14(53.8%)	38(50.0%)
	ⅡB	6(22.2%)	6(26.1%)	4(15.4%)	16(21.1%)
	ⅢA	3(11.1%)	1(4.3%)	0(0.0%)	4(5.3%)
Type of surgery	Breast Conserving	16(59.3%)	12(52.2%)	18(69.2%)	46(60.5%)
	Mastectomy	11(40.7%)	11(47.8%)	8(30.8%)	30(39.5%)
Tumor size	MEAN±S.D.	2.56±1.68	2.56±0.89	2.15±0.73	2.42±1.20
ER	(+)	26(96.3%)	23(100.0%)	26(100.0%)	75(98.7%)
	(−)	1(3.7%)	0(0.0%)	0(0.0%)	1(1.3%)
PR	(+)	20(74.1%)	18(78.3%)	19(73.1%)	57(75.0%)
	(−)	7(25.9%)	5(21.7%)	7(26.9%)	19(25.0%)
Chemotherapy	No	14(51.9%)	11(47.8%)	14(53.8%)	39(51.3%)
	Yes	13(48.1%)	12(52.2%)	12(46.2%)	37(48.7%)
Lymph node	No	9(33.3%)	7(30.4%)	10(38.5%)	26(34.2%)
metastases	Yes	18(66.7%)	16(69.6%)	16(61.5%)	50(65.8%)
Radiation	No	13(48.1%)	12(52.2%)	12(46.2%)	37(48.7%)
	Yes	14(51.9%)	11(47.8%)	14(53.8%)	39(51.3%)



	N	Baseline Mean	Baseline SD	1 year Mean	1 year SD
ANA	19	83.4	11.5	80.5	10.9
EXE	19	88.9	13.4	87.3	13.8
TAM	13	87.2	10.9	88.8	12.0

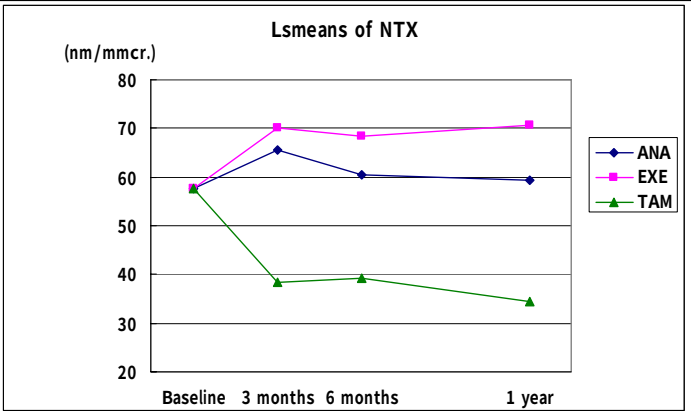
The results of repeated-measures ANOVA was as follows; F value 2.79, P value 0.0712.



Analysis of GEE

	DF	F value	P value
Baseline score	1	113.59	<.0001
group	2	22.73	<.0001
time	2	0.96	0.3853
group*time	4	9.61	<.0001

The number of the patients whose BAP could be measured at baseline, 3, 6 months and 1 year was as follows; EXE (n=26) TAM (n=23) ANA (n=26).



Analysis of GEE

	DF	F value	P value
Baseline score	1	9.24	0.0033
group	2	14.23	<.0001
time	2	0.50	0.6073
group*time	4	0.34	0.8528

The number of the patients whose NTX could be measured at baseline, 3, 6 months and 1 year was as follows; EXE (n=26) TAM (n=23) ANA (n=26).

Results

There was no significant difference in BMD level at 12 months among 3 arms.

NTX level did not change during 12 months period in exemestane and anastrozole arm, while it sharply decreased at 3 months and maintained low level thereafter in tamoxifen arm.

BAP level constantly increased in exemestane as well as anastrozole arm, while it decreased constantly in tamoxifen arm.

Conclusion

Although there was no significant change in the BMD level at 12 months among 3 arms, favorable effect of tamoxifen in bone turnover marker profile was observed.