THE VIENNA TERIPARATIDE DATABASE – CLINICAL EXPERIENCE WITH 158 PATIENTS

Ch. Muschitz[1], T. Pirker[1], L. Milassin[1], I. Pollhammer[1], E. Edlmayr[1], E. Buchinger[1], J. Patsch[1, 3], G. Nirnberger[2], H. Resch[1]

[1] St. Vincent Hospital - Medical Department II, Vienna, Austria
[2] Bioconsult Ltd, Perchtoldsdorf, Austria
[3] Department of Pathophysiology, Medical University Vienna, Austria

KRANKENHAUS BARMHERZIGE SCHWESTERN Wien

EIN UNTERNEHMEN DER VINZENZ GRUPPE WIEN

Objectives:

Patients with progressive osteoporosis and no response to antiresorptive therapeutic regimens benefit from 18 months teriparatide therapy (rhPTH [1-34]).
We established a prospective single-center open-label database to obtain a documentation system of all our patients to evaluate parameters of bone metabolism and treatment efficacy.

Patients & Methods:

The database consists of 158 patients (141 females, 17 males). 78.4% were considered as bisphosphonate non-responder and 9.6% as bisphosphonate incompatibility. 1.2% had steroid induced osteoporosis. At 10.8% we performed a bone biopsy due to uncertain diagnostic findings. All patients were subject to standardised diagnostic examinations (BMD, serum and urine parameters, X-ray, side effects). Due to pre-existing spine deformities 44% of vertebral DXA scans were not applicable for evaluation.
The majority of our patients are still under treatment therefore results are presented at baseline and after 9 months.

Results:

Mean age was 71.94 ± 9.97 years (females 72.64 ± 9.44, range 26-89; males 65.40 ± 12.57). 86 % presented more than 1 vertebral fracture (mean: 3.6 fractured vertebrae including vertebral impressions) [fig 1].

	Females	Males
Mean ± SD	3.66 ± 2.22	3.00 ± 4.32
Median	4	2
Minimum	0	0
Maximum	11	15

Fig 1: Number of vertebral fractures at baseline including vertebral impressions

Serum parameters of calcium, phosphorus, alkaline phosphatase, PTH, P1NP, osteocalcin (S-OC), S-CTX and 25OH Vit D were within normal range at baseline [fig 2].

	Females	Males	Reference
Ca (mval/l)	4.64 ± 0.57	4.78 ± 0.28	4.00 -5.20
Ph (mg/dl)	3.54 ± 0.66	3.60 ± 0.73	2.50 - 4.80
AP (U/l)	76.24 ± 29.05	70.90 ± 22.23	32 - 104
S-OC (ng/ml)	17.64 ± 8.68	18.58 ± 10.51	11 - 48
SCTX (ng/ml)	0.32 ± 0.22	0.41 ± 0.24	0.00 - 1.01
PTH (pg/ml)	45.22 ± 15.48	39.42 ± 22.64	15.0 - 65.0
25OH Vit D (ng/ml)	43.62 ± 34.42	49.29 ± 41.03	7.50 - 120
P1NP (ng/ml)	37.38 ± 22.38	67.83 ± 71.80	16.00 - 74.00
TSH (µU/ml)	1.75 ± 2.03	1.45 ± 0.70	0.27 - 4.20

Fig 2: Baseline laboratory characteristics (mean ± SD)

Lowest T-score of all 158 patients at hip was -2.86 ± 1.01, lowest T-score at spine was -3.20 ± 1.09 [fig 3].

	Females	Males
T-Score Hip	-2.21 ± 0.92	-2.33 ± 1.00
T-Score Hip lowest value	-2.87 ± 1.00	-2.85 ± 1.19
T-Score L1-L4	-2.06 ± 1.51	-1.96 ± 1.05
T-Score L1-L4 lowest value	-3.24 ± 1.06	-2.72 ± 1.31

Fig 3: DXA at Baseline (mean ± SD)

After nine months we found no statistically significant variations of serum calcium, phosphorus, vitamin D levels and 24 hour calcium excretion. Alkaline phosphatase increased from 68.87 ± 87 to 93.77 ± 38.36 U/l ($p < 0.001$), S-OC (ng/ml) changed from 17.21 ± 12.82 at baseline to 71.70 ± 34.90 ($p < 0.001$), S-CTX (ng/ml) increased from 0.25 ± 0.14 to 0.80 ± 0.49 ($p < 0.001$), P1NP (ng/ml) increased from 39.12 ± 25.76 to 144.87 ± 22.18 ($p < 0.05$) and PTH (pg/ml) decreased from 41.65 ± 14.56 to 28.83 ± 12.87 ($p < 0.001$), respectively [figs 4-8].
Lowest T-score at hip (44 patients) enhanced from -3.08 ± 1.10 to -2.55 ± 0.91 ($p < 0.001$), lowest T-score at spine (32 patients) improved from -3.38 ± 1.09 to -3.23 ± 1.18 (n.s.) after 9 months of treatment [figs 9-10]. However, in a large number of patients DXA of spine could not be assessed due to pre-existing fractures. The percentage of new vertebral fractures under PTH-therapy was < 7%.
Drop out rate was < 4%, mostly due to disability of using pen.

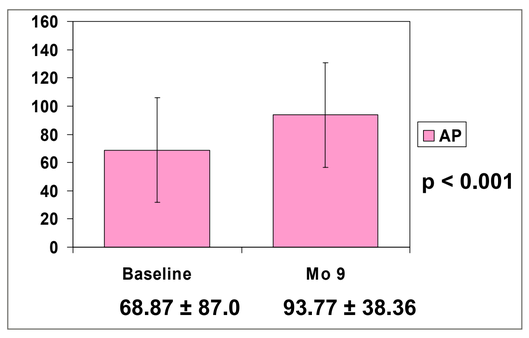

Fig 4: Alkaline Phosphatase (U/l)

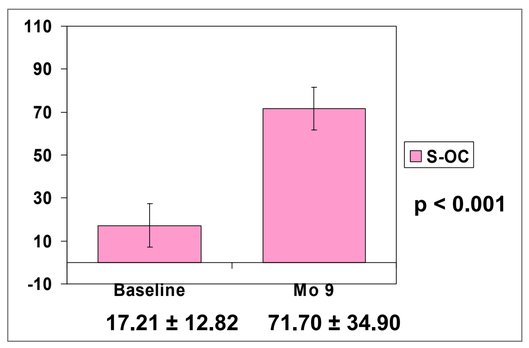

Fig 5: Osteocalcin (ng/ml)

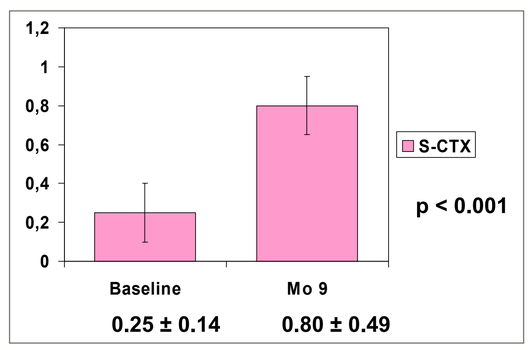

Fig 6: S-CTX (ng/ml)

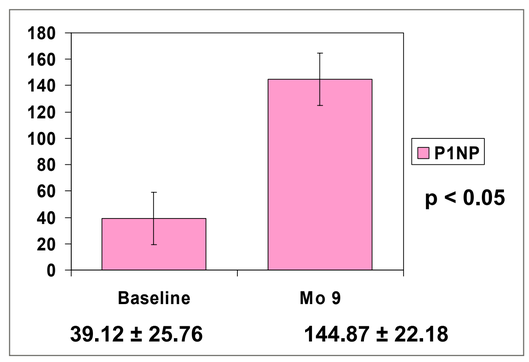

Fig 7: P1NP (ng/ml)

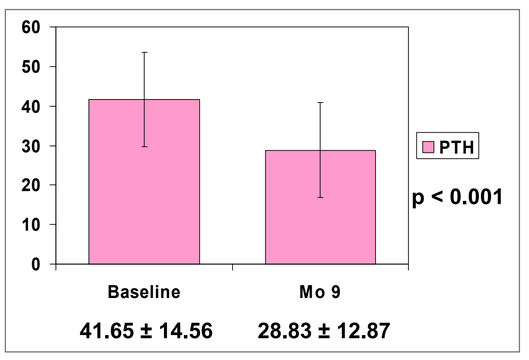

Fig 8: Parathyroid Hormone (pg/ml)

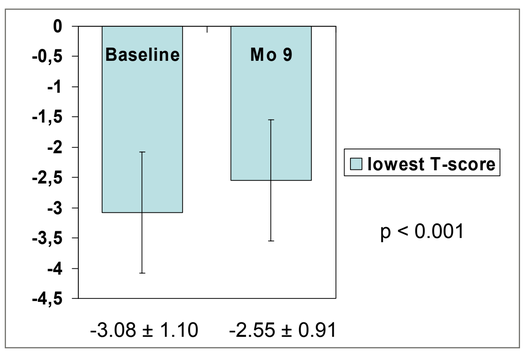

Fig 9: DXA Hip (T-score)

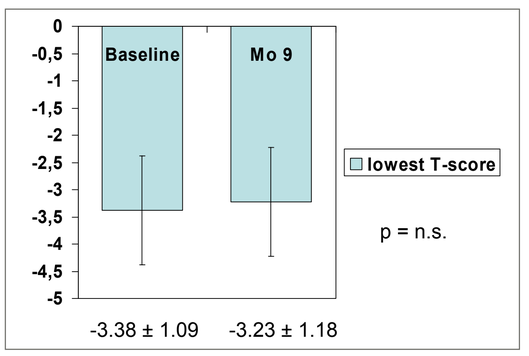

Fig 10: DXA Spine (T-score)

Conclusion:

Our database offers a specific standardized documentation system in daily clinical use for patients suffering from progressive osteoporosis and prior less effective treatment who are not randomized to controlled clinical trials.
For these patients treatment with rhPTH [1-34] is effective and safe leading to increased BMD and serum markers of bone metabolism.

Corresponding author:

Christian Muschitz, M.D.
E-Mail: christian.muschitz@bhs.at