Biochemical Parameters in Patients Using Teriparatide

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Teriparatide (TPT) is the active 1-34 amino acid sequence with osteoanabolic use for severe osteoporosis. Our aim is to analyze the biochemical and clinical profile of patients treated with TPT based on Romanian protocol. The inclusion and exclusion criteria are based on specific country protocol for TPT 20 µg/day, for 2 years, once in life time based on self administration. This is a transversal study including data of a tertiary centre of endocrinology on patients who signed the informed consent. This is a real life study, of observational type (the intervention meaning the TPT recommendation was done by individual decision of each clinician). Normal total and ionic calcium is associated with low 25-hydroxyvitamin D levels and a mean lumbar T-score of -3.1±0.7SD. 50% of patients treated with TPT have digestive conditions, less than 10% are first time users, a high severity profile is based on a median of 4 years regarding prior anti-osteoporotic medication and of 3 previous fragility fractures.

Keywords: teriparatide, osteoporosis, calcium

Parathormone is a parathyroid gland product aiming bone health and disturbing it when primary hyperparathyroidism is registered, and also secondary parathormone raise as feedback to low vitamin D levels [1-4]. Teriparatide (TPT) is the active 1-34 section of the hormone which represents a potent osteoanabolic agent, independent of metabolic events in human body [5-9]. The indication is mainly for severe primary osteoporosis (hypogonadism- or age-related) and glucocorticoid induced bone loss which are typically seen in association with other conditions of skeleton, some with increased severity [8-17].

Experimental part

Aim of the study

The aim of this study is to analyse the biochemical and clinical profile of patients treated with TPT based on Romanian protocol [18].

Materials and method

This is a transversal study including data of a tertiary centre of endocrinology on patients who signed the informed consent. This is a real life study, of observational type (the intervention meaning the TPT recommendation was done by individual decision of each clinician). The inclusion and exclusion criteria of the patients are based on Romanian protocol for TPT 20 µg/day, for 2 years, once in life time based on self-administration [18].

The baseline assessment was clinical, biochemical, and also based on central DXA (Dual X-Ray Absorptiometry), using a GE Lunar Prodigy device as mentioned in national protocol.

Data were introduced in Excel/SPSS. The parameters were expressed as mean, median, standard deviation, minimum and maximum.

Results and discussions

43 patients were included (female/male ratio was 41/2). Baseline parameters of age at TPT start, number of years since menopause and body mass index (BMI) are introduced in table 1. Numerous co-morbidities were identified at baseline as seen in table 2.

The patients were introduced based on Romanian protocol: either de novo, either *non-DXA responders, fracture-responders*, meaning they lost BMD (Bone Mineral Density under a prior medication for osteoporosis), either *non-DXA, non-fracture responders*, meaning they lost BMD

	Age at TPT start (yrs)	Years since menopause	BMI (KG/sqm)
Mean	67.093	21.951	24.569
SD	8.348	10.151	4.826
Min	47	4	17
Max	83	44	37
Median	66	21	24

Table 1
STUDIED POPULATION: AGE AT TERIPARATIDE START, YEARS SINCE MENOPAUSE AND BODY MASS INDEX (BMI)

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Co-morbidities	N(%)
Digestive conditions	20(46.51)
Active corticotherapy	4 (9.30)
Autoimmune conditions	11 (25.58)
Arterial hypertension	24 (55.81)
Hyperlipemia	23 (53.48)
Chronic heart conditions	7 (16.27)
Diabetes mellitus	4 (9.3)
Thyroid conditions	18 (41.86)
Active smokers	6 (13.95)

Table 2
THE BASELINE CO-MORBIDITIES OF THE PATIENTS TREATED WITH TPT

and had a fracture under specific medication, or *DXA, non-fracture responders*, as seen in table 3.

The prior number of fragility fractures and years of specific anti-osteporosis drugs exposure are introduced in table 4.

Baseline biochemistry panel is introduced in table 5. The DXA report is centralised in table 6. Bone turnover markers and hormones are displayed in table 7. Collateral panel of endocrine evaluation required by protocol is introduced in table 8.

Table 3
TYPES OF PATIENTS TREATED WITH TPT

Type	N(%)
De novo	4 (9.3)
Non-DXA, non-fracture	13 (30.23)
DXA, fracture	10 (23.25)
DXA, non-fracture	14 (32.55)

	Years of medication	Prior fractures	Age at first fracture
Mean	4.651	3.264	62.666
SD	3.221	2.004	9.076
Min	0	1	45
Max	14	9	80
Median	4	3	64

Table 4
THE PRIOR NUMBER OF FRAGILITY FRACTURES AND YEARS OF SPECIFIC ANTI-OSTEPOROSIS DRUGS EXPOSURE ON PATIENTS TREATED WITH TPT

	Ionic calcium	Total calcium	24h urinary calcium	Phosphorus	HbA1c
Mean	4.062	9.476	0.153	3.538	5.811
Sd	0.319	0.352	0.102	0.69	0.902
Min	3.1	8.8	0.03	2.1	4.8
Max	4.5	10.2	0.36	4.8	8.9
Median	4.1	9.5	0.12	3.53	5.6
Unit	Mg/dl	Mg/dl	g/24h	Mg/dl	%
Normal	3.9-4.9	8.5-10.2	0.07-0.3	2.5-4.5	4.8-5.9

Table 5
BASELINE BIOCHEMISTRY PANEL

Table 6
THE DXA REPORT

	Lumbar		Femoral neck		Total Hip		1/3 radius	
	BMD	T-score	BMD	T-score	BMD	T-score	BMD	T-score
Mean	0.806	-3.146	0.706125	-2.3725	0.743	-2.09	0.503	-2.908
SD	0.088	0.727	0088239	0.69022	0.099	0.812	0.089	1.279
Min	0.638	-4.5	0.508	-3.9	0.494	-4.1	0.262	-6.3
Max	1.026	-1.3	0.851	-1.1	0.892	-0.5	0.651	-0.9
Median	0.793	-3.2	0.725	-2.25	0.774	-1.9	0.514	-2.8

	AP	P1NP	CL	OC	25OHD	PTH
Mean	71.131	41.841	0.326	17.169	29.719	43.743
SD	22.561	28.208	0.176	7.725	13.785	10.918
Min	45	13	0.07	0.32	6	24.16
Max	152	153	0.885	43	58	65
Median	65	31.685	0.28	16.58	29.7	43
Unit	U/L	Ng/ml	Ng/ml	Ng/ml	Ng/ml	Pg/ml
Normal	38-105	15-74	0.336-1.008	14-46	20-100	15-65

Table 7
BONE TURNOVER MARKERS AND HORMONES

AP = alkaline phosphatase, CL = CrossLaps, OC = ostecalcin, 25OHD=25-hydroxyvitamin D, PTH = parathormone

	TSH	FT4	TPOAb`	ACTH	PLASMA CORTISOL
Mean	1.929	13.517	31.621	23.263	13.955
SD	3.072	2.5	94.333	9.499	5.663
Min	0.1	8	10	5.6	5.7
Max	20	21.6	577	44	26.92
Median	1.1	13.3	10	23	12.955
Unit	µUI/ml	pmol/L	U/l	pg/ml	µg/dl
Normal	0.5-4.5	10.3-24.4	<10	15-65	6-21

Table 8
COLLATERAL PANEL OF ENDOCRINE EVALUATION REQUIRED BY PROTOCOL

Where: TSH = Thyroid Stimulation Hormone, FT4 = Freethyroxine, TPOAb = Thyroperoxidase antibodies, ACTH = AdrenoCorticotropic Hormone

The limits of the study are single centre experience and the need of follow-up data.

The strength of the study is the component of real life medicine regarding a particular protocol of an anti-osteoporotic drug.

Conclusions

50% of patients treated with PTP have digestive conditions, less than 10% are first time users, a high severity profile is based on a median of 14 years regarding prior anti-osteoporotic medication and of 3 previous fractures.

Abbreviations

AP = alkaline phosphatase
CL = CrossLaps
OC = ostecalcin
25OHD = 25-hydroxyvitamin D
PTH = parathormone
BMI = Body Mass Index
BTM = Bone Turnover Markers
BMD = Bone Mineral Density
DXA = Dual-Energy X-Ray Absorptiometry
TPT = teriparatide
TSH = Thyroid Stimulation Hormone
FT4 = Freethyroxine
TPOAb = Thyroperoxidase antibodies
ACTH = AdrenoCorticotropic Hormone

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