Baseline characteristics of Greek patients enrolled in the ExFOS study

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ABSTRACT

Introduction: ExFOS is a multinational, non-interventional, prospective, observational study to evaluate fracture outcomes, back pain, compliance and health-related quality of life in osteoporotic patients treated with teriparatide for up to 24 months. We present the baseline characteristics of the Hellenic subpopulation.

Methods: In Greece, 439 consenting patients with osteoporosis (92.3% female), suitable for prescribing teriparatide in the course of normal clinical practice, were enrolled in the study and provided medical history, clinical data, estimations on back pain and quality of life through validated questionnaires, for which descriptive statistics were calculated.

Results: These were rather elderly (mean(SD) age 70.1(9.8)years (36.4% aged 75 years or older)), slightly overweight (BMI 26.7(4.3)kg/cm^2), with predisposing factors for fracture: hip fracture in biological mother(18.1%), falls in the last year(37.1%), no exercise(49.2%), current smoking(12.1%), sight problems(37.9%), immobilization for > 12 months(1.6%), muscle weakness recorded as assistance with arms when standing up from chair(41.3%). Public health insurance coverage for reimbursement of the medicine is almost complete.

Low bone mineral density with T-score <-3 in lumbar spine or total hip and at least one fracture in 55.1% of patients have been recorded (70.2% of patients had vertebral and 44.2% non vertebral fractures) while 21.6% had two or more fractures.

Of enrollers, 19.8% were antiosteoporotic treatment naïve, 69.5% used at least one osteoporosis/falls related medication (specifically glucocorticoids were reported by 8.9% of patients).

88.4% experienced back pain during the last 12 months while 68.1% experienced back pain at least fairly often during the last month. Moderate to severe limitation of activities was reported by half the participants with mean 4.2(7.7) bed days because of back pain during the previous to enrollment month.

Conclusions: Greek patients enrolled in ExFOS are severely osteoporotic with increased risk of fractures and back pain. Results should be interpreted in the context of observational studies.

INTRODUCTION

ExFOS is an observational study to evaluate fracture outcomes, back pain, compliance and health-related quality of life in osteoporotic patients treated with teriparatide for up to 24 months. We present the baseline characteristics of the Hellenic subpopulation.

METHODS

Multinational, non-interventional, prospective, observational study incorporating teriparatide new indications (24 m, male, GIOP)
GREECE: 439 patients (92.3% female)
32 investigative sites enrolling 0.94 pts/site/month
Medical history, clinical data and estimations on back pain and quality of life through validated questionnaires recorded
Descriptive statistics calculated
Post-hoc by sex analysis for Greece implemented

RESULTS

Number of Greek participants 439 (405 females, 34 males)
Elderly (mean(SD) age 70.1(9.8) years, 36.4% aged 75 years or older),
Slightly **overweight** (BMI 26.7(4.3) kg/cm^2)
Almost complete public health insurance **coverage**

PREDISPOSING FACTORS for fracture:

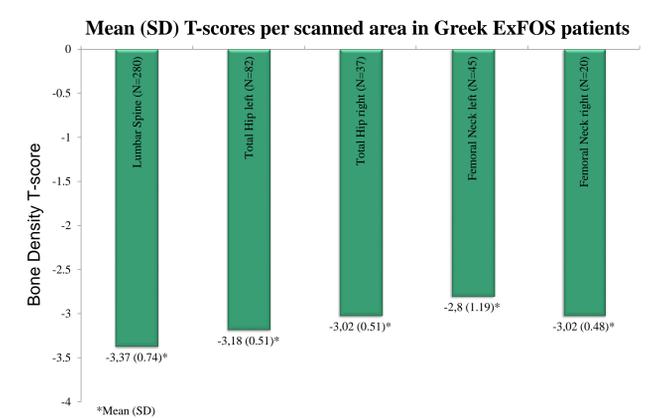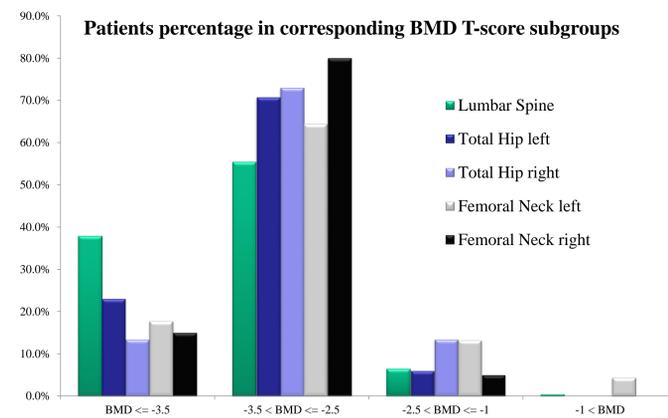|			
Hip fracture in biological mother	57/315 (18.1%),	Falls in the last year	153/413 (37.1%)
No exercise	209/425 (49.2%)	Current smoking	52/429 (12.1%)
Sight problems	162/427 (37.9%)	Muscle weakness*	180/436 (41.3%)
Immobilization for > 12 months	7/433 (1.6%)		

* recorded as assistance with arms when standing up from chair

BONE HEALTH

Very low **bone mineral density** (T-score <-3)

At least one **fracture** in 55.1% of patients (242/439). 21.6% had two or more fractures (95/439). *70.2% of patients had vertebral fractures (170/242) *44.2% had non vertebral fractures (107/242)
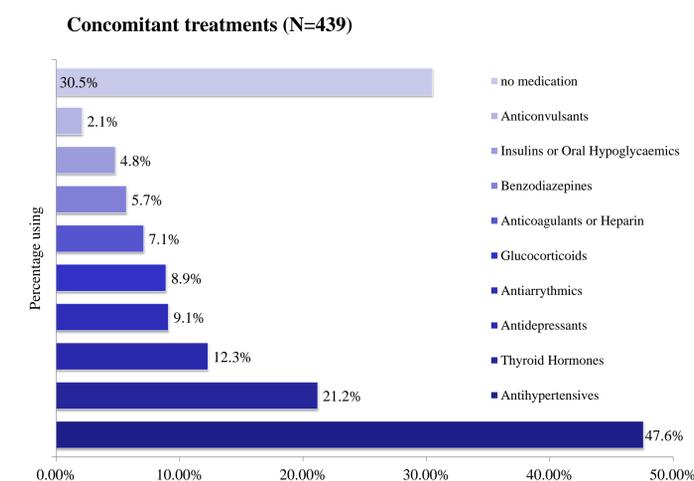

Patients percentage in corresponding BMD T-score subgroups

Mean (SD) T-scores per scanned area in Greek ExFOS patients

CONCOMITANT MEDICATION
Of 439 patients, 352 (80.2%) had recorded OP medication
69.5% used at least one **osteoporosis/falls related medication**
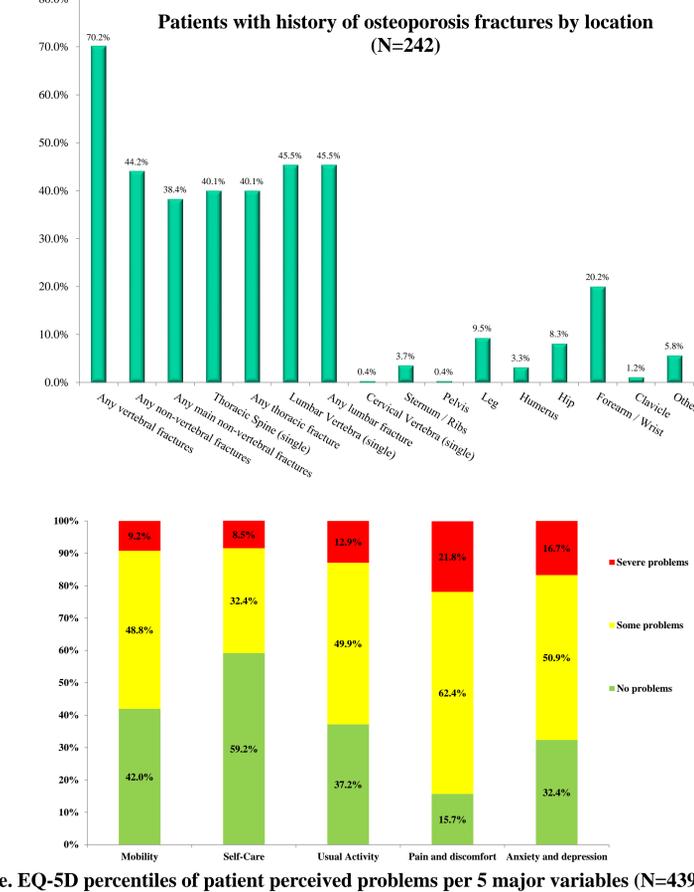8.9% of patients reported prior **glucocorticoid use**

Concomitant treatments (N=439)

Patients with history of osteoporosis fractures by location (N=242)

BACK PAIN (BP)
*88.4% (388/439): BP during the last 12 months
*68.1% (256/376): BP at least fairly often during the last month
*4.2(7.7) days in bed because of BP

Quality of life. EQ-5D percentiles of patient perceived problems per 5 major variables (N=439)

CONCLUSIONS

Greek patients prescribed TPTD in ExFOS are severely osteoporotic with increased risk of fractures and back pain. Differences between sexes may reflect different sex-driven patterns of diagnosis and treatment of osteoporosis. Results should be interpreted in the context of an observational study.