

Treatment outcomes during Teriparatide use in Greece: Country sub-analysis of the ExFOS observational study.

K. Aloumanis¹, M. Savvidis², A. Repousis², H. Lianou¹, V. Drossinos¹, G. Kapetanios³, for the Hellenic ExFOS study group

¹Department of Medical Research, Pharmaserve Lilly SACI ²Private Medical office ³3rd Orthopedics University clinic, Papageorgiou General Hospital, Thessaloniki, Greece.

ABSTRACT

Scope: Extended Forsteo Observational Study (ExFOS), a multinational, non-interventional, prospective, observational study aims to evaluate fracture outcomes, back pain (BP), compliance and health-related Quality of Life (QoL) in osteoporotic patients prescribed teriparatide (TPTD). We present treatment outcomes for patients (male or female) treated for up to 24 months in Greece.

Methods: Of the 440 patients enrolled in the study 416 (mean age 69.9±9.7 years) have performed at least one active treatment post-baseline visit. These were predominantly women (92.1%), at postmenopausal stage (99.7%). Self-reported parameters of health perception have been recorded throughout the study through validated questionnaires (EQ-5D). We report the observed percent and mean responses.

Results: 17 (4.1%) patients had an incident clinical fracture during follow-up. Adherence: 80% of subjects used the treatment through Month 23; 45% continued use through Month 24. BMD numerically increased in all sites. Indicatively, Lumbar BMD T-score (mean (SD)) increased from -3.39 (0.73) at baseline to -2.36 (0.63) at study end. BP history the last year before enrollment was reported by 88.9%. During treatment, all self-reported variables improved. Examples of BP frequency (% of patients with BP fairly often or almost daily) and BP severity (% with moderate-severe BP), EQ-5D Visual Analogue Scale (VAS) score and EQ-5D mobility (% reporting some or extreme problems) are depicted below:

	Baseline	3 m.	6 m.	12 m.	18 m.	24 m.
BP frequency	68.2%	33.5%	22.6%	14.1%	17%	11.6%
BP severity	76.2%	50.4%	32.8%	20.9%	22.2%	18.6%
EQ-5D VAS	57.4	66.2	71.3	75.4	76.7	83
EQ-5D Mobility	57.9%	39.0%	29.9%	22.5%	17.7%	16.2%

Conclusions: Use of TPTD remains high almost throughout the follow-up. A decrease at month 24 may be due to prescribing (24months/26cartridges) particularities. Patients experience improvement in BP and QoL. Fracture rate was low. Results should be interpreted in the context of an observational study.

INTRODUCTION

- Extended Forsteo Observational Study ExFOS evaluates fractures, back pain, compliance and health-related Quality of Life in osteoporotic patients prescribed teriparatide.
- We present treatment outcomes for patients treated for up to 24 months in Greece.
- Methods and Hellenic baseline data have been published (Aloumanis et al, BMC Musculoskelet Disord. 2015, 16:136).

CONCLUSIONS

- Use of TPTD remains high almost throughout the follow-up.
- A decrease at month 24 may be due to prescribing (24months / 26cartridges) details and timing of completion in the study.
- Patients experience improvement in BP and QoL. Fracture rate was low.
- Results should be interpreted in the context of an observational study

*The Hellenic ExFOS Study Group:

Adam A, Alexandridis T, Athanasakopoulos P, Bintas S, Dimopoulos N, Dionysiotti Y, Georgountzos A, Giannadakis P, Gouvas G, Kapetanios G, Kaplanoglou T, Karagiannis A, Kleisiounis A, Kokkoris P, Kosmidis C, Kossyvakis K, Krallis N, Matsouka A, Matzaroglou C, Meleteas E, Milonas C, Papaioannou N, Papazisis Z, Repousis AP, Savvidis M, Temekonidis T, Trovas G, Tsakiri V, Tzoutou M, Tzoutzopoulos A, Vandoros G, Ziabaras K

METHODS

- We present data of the **416 Active treatment (AT)** out of 440 enrolled Greek patients (mean age(±SD) 69.9±9.7 years) who performed at least one active treatment post-baseline visit.
- Self-reported parameters of health perception have been recorded throughout the study through validated questionnaires.
- No statistical analyses of the Hellenic data have been performed at this point.

RESULTS

Adherence

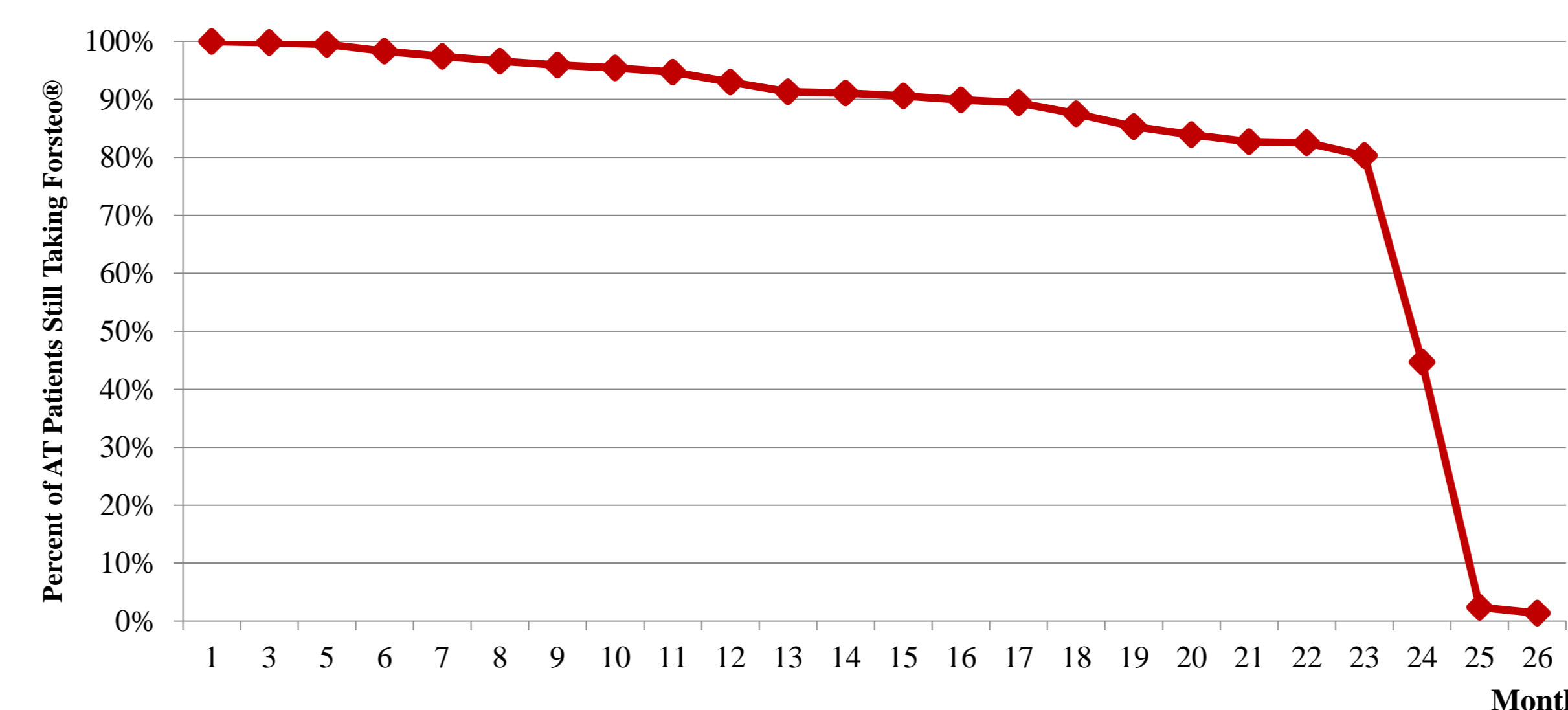


Fig 1. Percent of AT Patients Still Taking Forsteo® by Month (N=416)

Back Pain (BP)

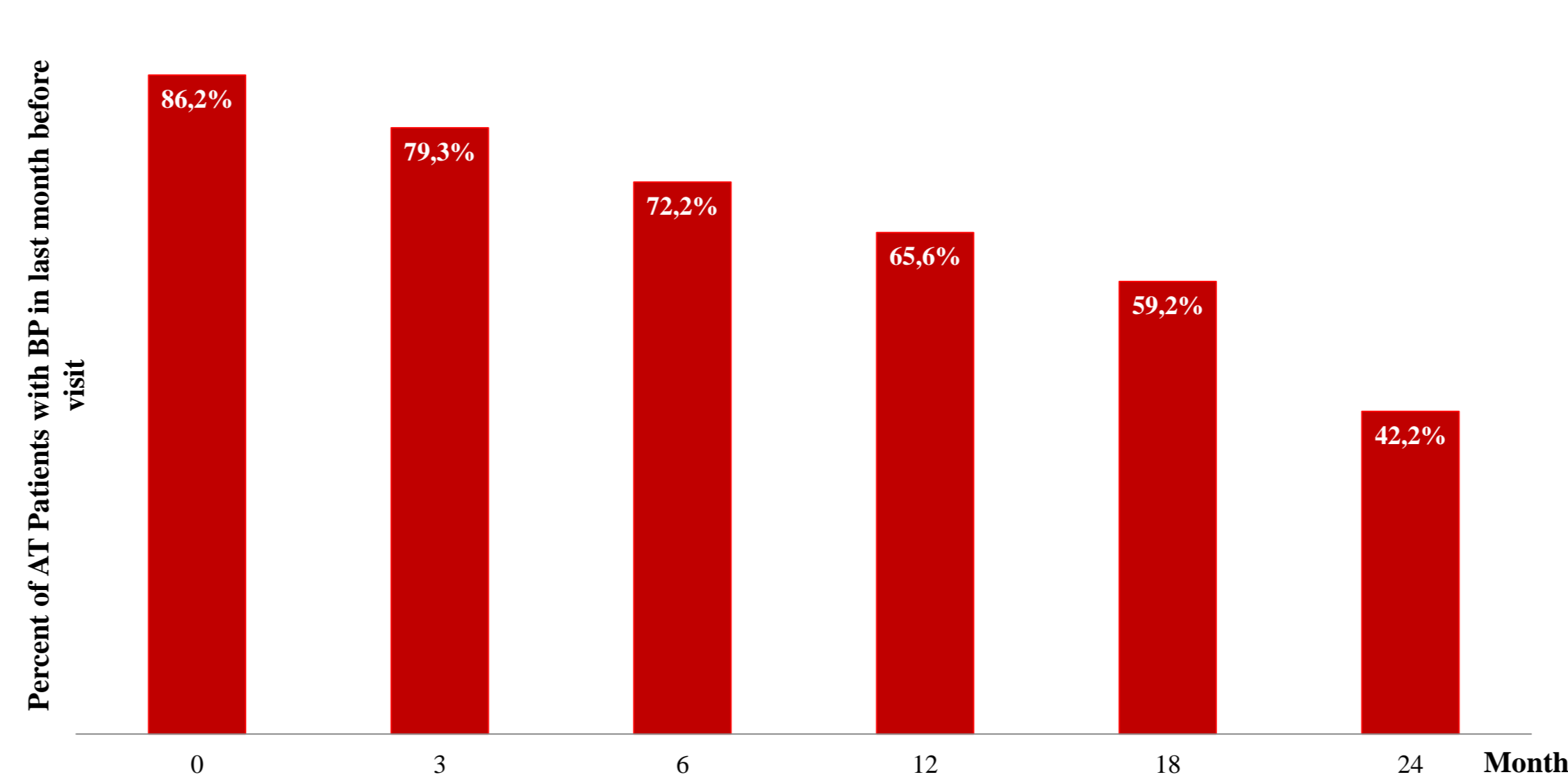


Fig 2. Percent of Patients with BP in the Prior Month by Time (AT cohort)

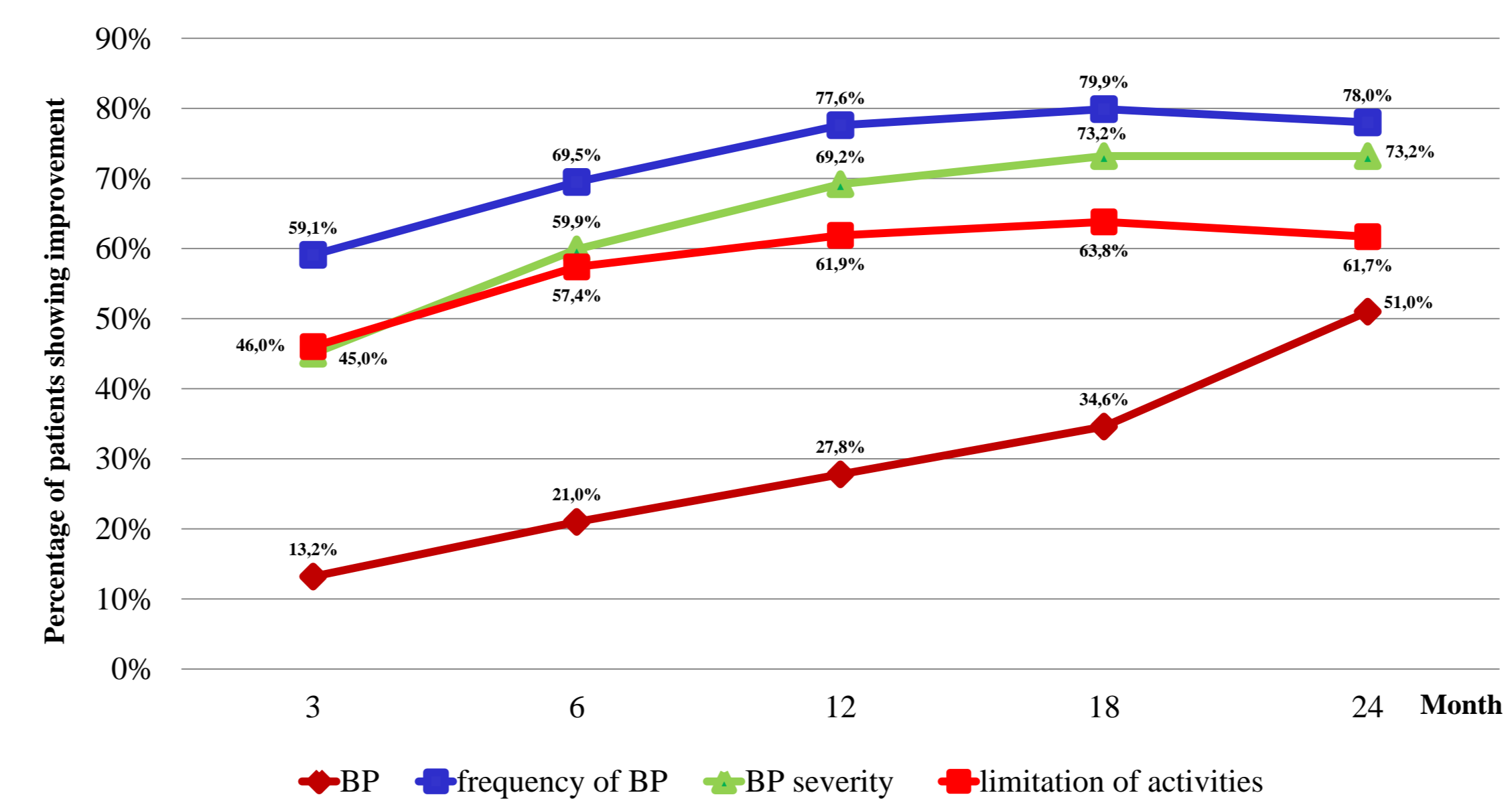


Fig 4. Percentage of patients with improvement in BP characteristics from baseline to the Prior Month by Time (AT cohort)

Health-related Quality of Life (EQ-5D)

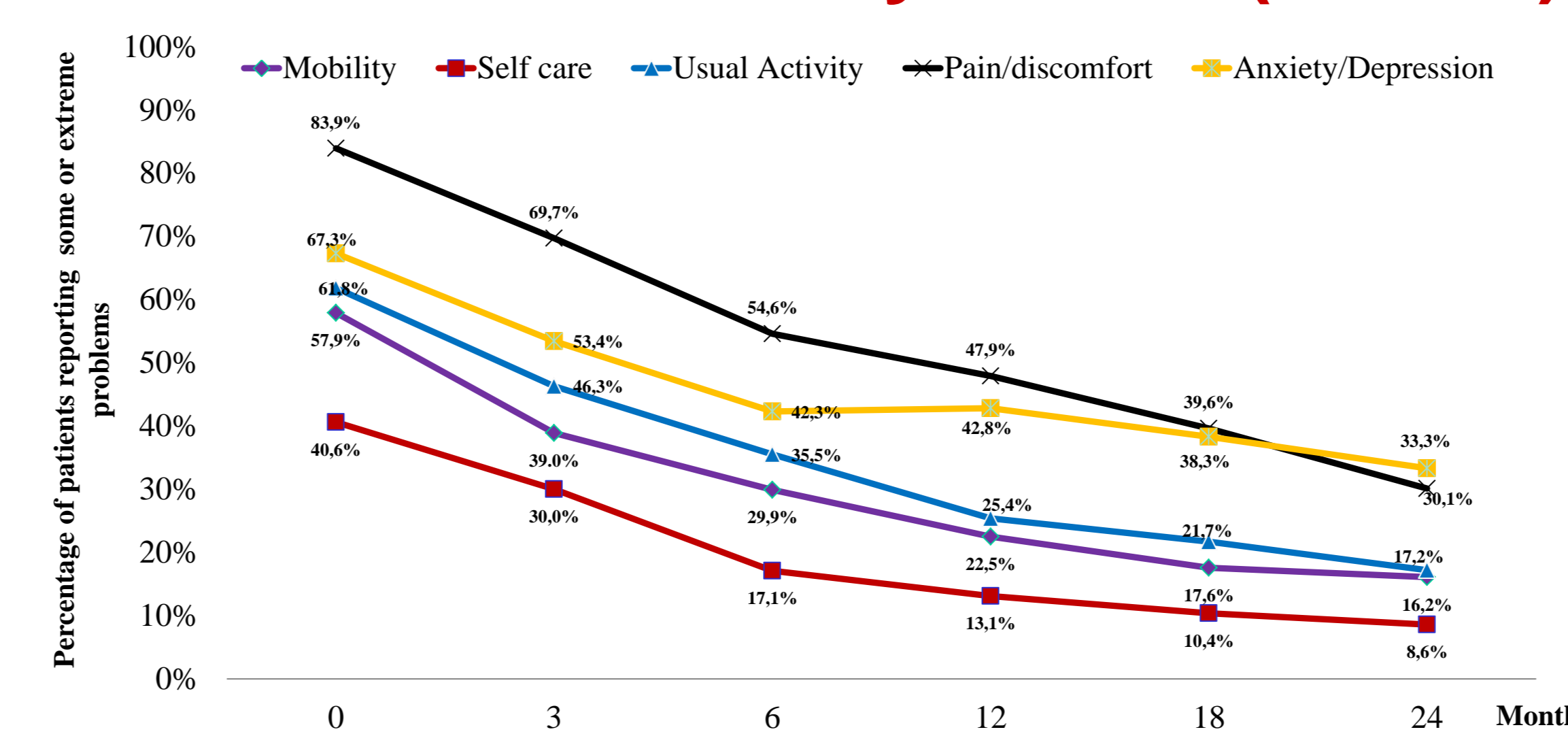


Fig 6. Percentage of patients reporting some or extreme problems in the 5 dimensions of the EQ-5D questionnaire by Time (AT cohort)

Visual Analogue Scale scores* (VAS)

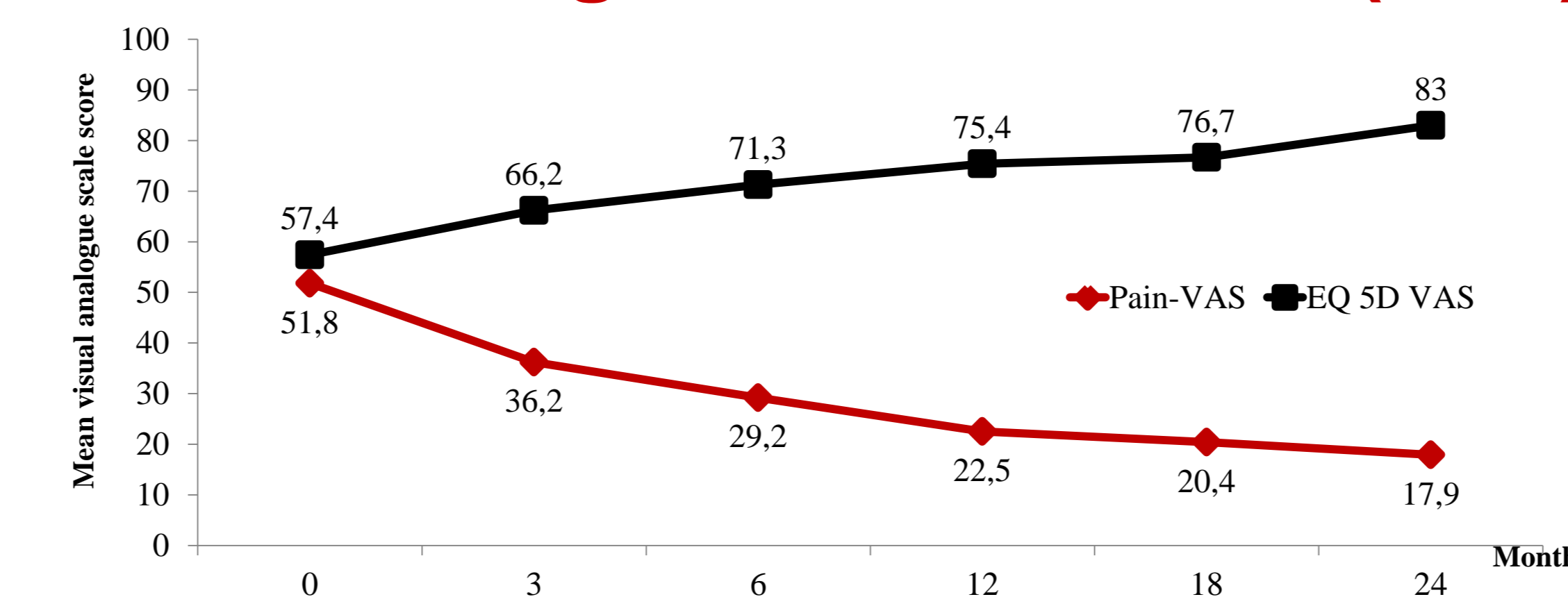


Fig 7. Pain* and EQ-5D Visual analogue scale (VAS) by Time (AT cohort)

* Pain VAS depicts data from AT patients excluding those with rheumatoid arthritis

- Adherence:** At least 80% of subjects continued treatment through Month 23; 45% continued use through the entirety of Month 24 (Fig 1).
- Back Pain:** In the active treatment (AT) cohort, numerical improvement was recorded in BP frequency and severity, as well as in consequent limitations of activities (Fig 2-4).

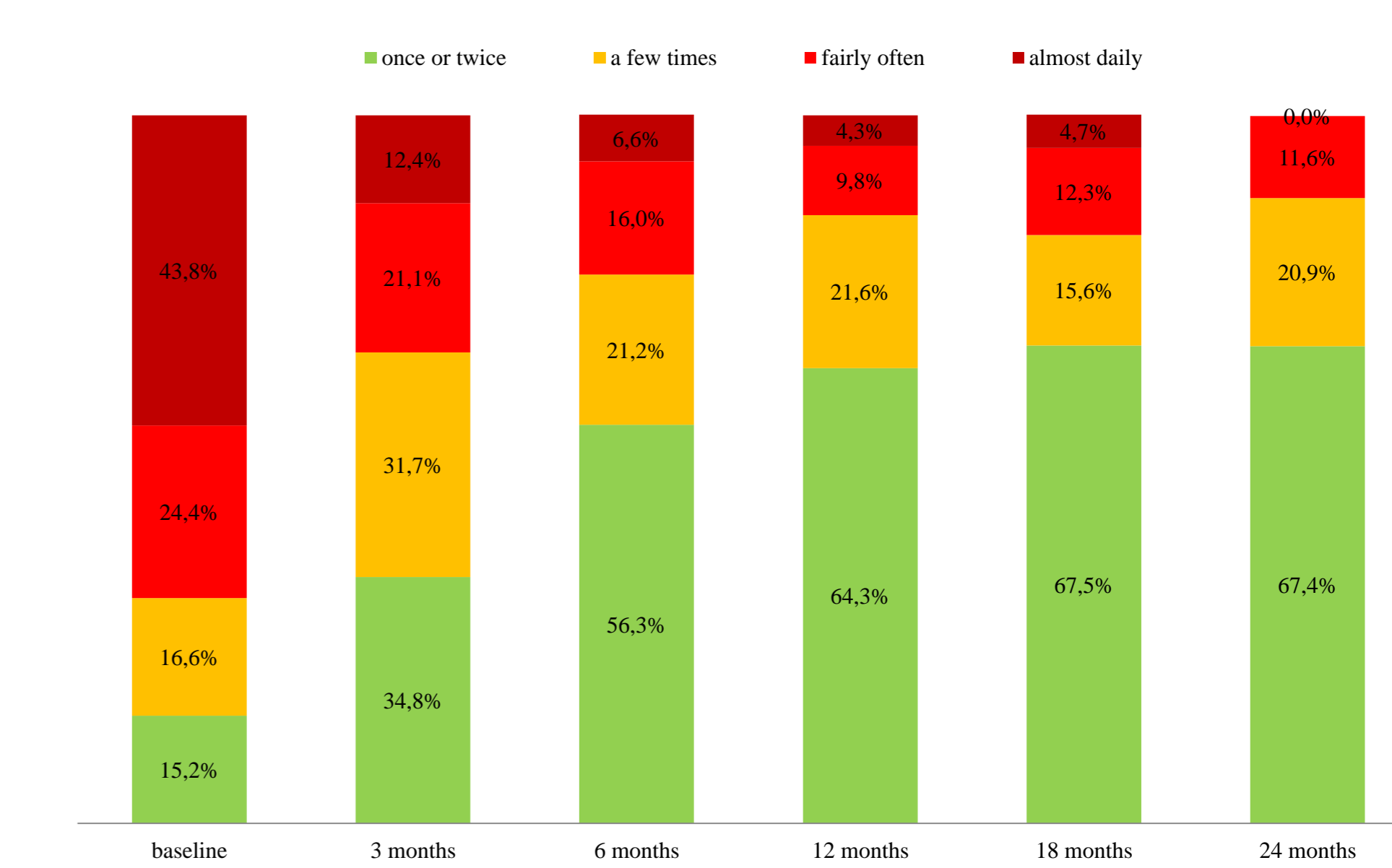


Fig 3. Frequency of BP in the Prior Month by Time (AT cohort)

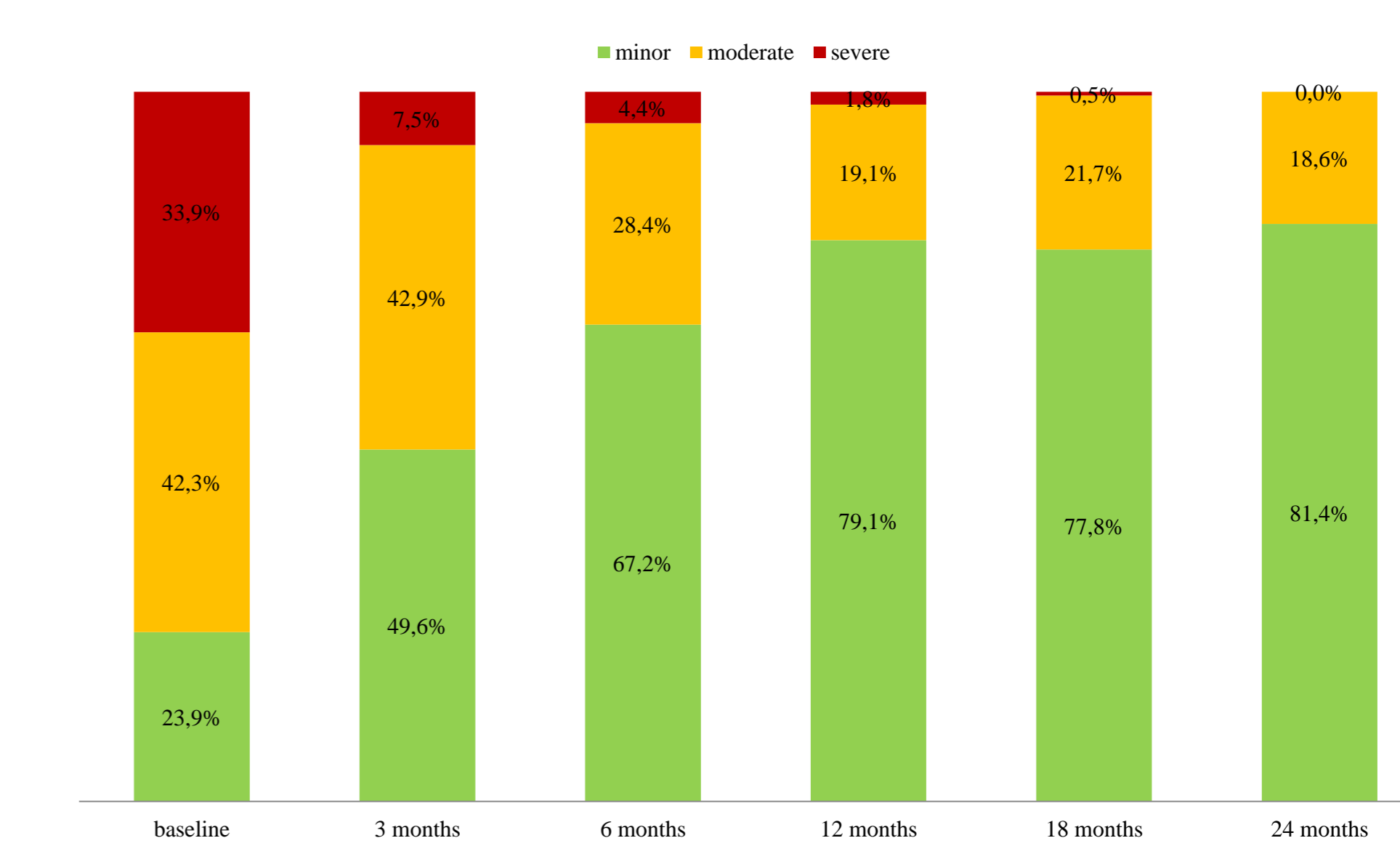


Fig 5. Severity of BP in the Prior Month: Percent in Category by Time (AT cohort)

- Health-related Quality of Life:** The percentage of AT patients reporting "some or extreme problems" in the 5 dimensions of the EQ-5D questionnaire shows numerical improvement (fig. 6).
- Visual Analogue Scale (VAS):** numerical decrease for back pain VAS and improvement in EQ-5D VAS was recorded (fig 7).

Bone Mineral Density (BMD)

- BMD:** numerical increase in all sites. Indicatively, Lumbar BMD T-score (mean (SD)) increased from -3.39 (0.73) at baseline to -2.36 (0.63) at study end.
- Fractures:** Fracture rate was low (non-interpretive).