Quality of life of prostate cancer (PCa) patients with testosterone deficiency symptoms (TDS) before initiation of gonadotropin-releasing hormone (GnRH) agonist therapy, subgroup analysis of EQUINOXE study

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Disclosures

Author	Disclosure
Stéphane Droupy	Occasionally consultant or guest in meeting and congress for/with Ipsen, Menarini, Majorelle, AMS, Intuitive Surgical, Sanofi, Pierre Fabre, Takeda, Ferring
Marie-Hélène Colson	Occasionally consultant or guest in meeting and congress or member of scientific committee for/with Allergan, Astellas, Astra -Zeneca, Bayer santé familiale, Biopharm, Boston, Bouchara-Recordati, Ferring SA, Genévrier, Ipsen, Lilly SA, Majorelle, Menarini, Novartis, Pfizer santé de la famille
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Rationale of the present subgroup analysis

Context

- Both prostate cancer (PCa) and testosterone deficiency symptoms (TDS) risk increase with age
- Patients may therefore suffer from both conditions, and their quality of life (QoL) be reduced

EQUINOXE (NCT02630641) [1-3]

- Observational study in PCa patients initiating GnRh agonist therapy, n = 492 patients and their partners
- Final analysis identified QLQ-PR25 Treatment-related symptom score ≥ 25/100 at baseline as a predictive criteria of improvement of both patient's and partner's QoL after a 6-month follow up

Objective of this post-hoc subgroup analysis

- This complementary analysis aimed to describe baseline parameters of those patients with testosterone deficiency symptoms (TDS) at baseline

1. Droupy S et al. 34th Annual EAU Congress; 2019 March 15-19; Barcelona, Spain, Eur Urol Suppl 2019;18(1);e1399:1041.
2. Descazeaud A et al. 34th Annual EAU Congress; 2019 March 15-19; Barcelona, Spain, Eur Urol Suppl 2019;18(1);e1573:1167.
3. Droupy S et al. 114th Annual AUA Congress; 2019 May 3-6; Chicago, Illinois, USA, J Urol Suppl 2019;201(4S):e321-322:MP22-13.

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EQUINOXE study: methods

Methods

- Prospective, multicenter, longitudinal, non-interventional study conducted in France
- Patients with histologically confirmed PCa and eligible to start GnRH agonist therapy and their partners
- Baseline and 6-month follow-up data, patients and partners, on self-questionnaires
- Objective: to evaluate the evolution of QoL after a 6-month agonist therapy

Questionnaires

- **WHOQOL-BREF*:*** *World Health Organization Quality of Life-Brief Instrument* => 2 single items and 4 dimensions
- **DAS-16*:*** *Dyadic Adjustment Scale* (perception of cohesion between patient and partner)
- **B-IPQ*:*** *Brief Illness Perception Questionnaire*
- **QLQ-PR25:** *Quality of Life Questionnaire Specific to Prostate Cancer* (Patients' symptoms related to the disease) => 1 single item and 5 domains (including Hormonal treatment-related symptoms)

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EQUINOXE study: results on patient's and partner's QoL

Improvement of patient's QoL during the 6-month study

- An improvement in at least 1 of the 4 dimensions of patient's WHOQOL-BREF (physical, psychological, social, environment) was reported by **66.8%** of patients (primary analysis criteria)

Improvement of partner's QoL during the 6-month study

- An improvement of the 1st single item (level of QoL) of partner's WHOQOL-BREF was reported by **15.2%** of partners

Multivariate analyses on patient's and partner's QoL improvement

- Both analyses identified **QLQ-PR25 Treatment-related symptom score ≥ 25/100 at baseline** as a significant factor of QoL improvement after a 6-month follow-up: **OR [95% CI]** = **3.00 [1.46 ; 6.17]** (p = 0.0117) for patient's QoL, and **5.99 [2.40 ; 14.93]** (p = 0.0001) for partner's QoL
- As patients were not receiving any hormonal treatment at baseline, those patients with treatment-related symptoms at baseline **were considered to have testosterone deficiency symptoms (TDS) at baseline**

OR: odds ratio; CI: confidence interval.

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EQUINOXE study: results on patient's QoL

Logistic regression: Factors associated with an improvement in patient's quality of life

Parameters (n = 434)	**Reference**	**OR [95% CI]**	**p**
QLQ-PR25: treatment-related symptoms			
Between 0 and 25/100	0/100 (no symptom)	1.68 [0.95 ; 2.97]	0.0117
≥25/100	0/100 (no symptom)	**3.00 [1.46 ; 6.17]**	
QLQ-PR25: sexual activity			
Between 50 and 100/100	<50/100	2.04 [1.12 ; 3.72]	0.0388
100/100 (no activity)	<50/100	2.23 [1.11 ; 4.50]	

OR: odds ratio; CI: confidence interval.

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EQUINOXE study: results on partner's QoL

Logistic regression: Factors associated with an improvement in partner's quality of life

Parameters (n = 369)	**Reference**	**OR [95% CI]**	**p**
Dyadic adjustment of the partner (DAS-16 total score)			
Poor adjustment	Good adjustment	9.61 [3.18 ; 29.01]	<.0001
Medium adjustment	Good adjustment	1.68 [0.46 ; 6.16]	
QLQ-PR25: treatment-related symptoms			
≥25/100	<25/100 (no or few symptoms)	**5.99 [2.40 ; 14.93]**	0.0001
QLQ-PR25: sexual functioning			
Between 50 and 100/100	<50/100	0.64 [0.25 ; 1.60]	0.0039
100/100 (no activity)	<50/100	14.95 [2.49 ; 89.92]	

OR: odds ratio; CI: confidence interval.

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Results of the present subgroup analysis

Baseline medical and demographic data

(n = 487 without missing data on QLQ-PR25 at baseline)

- **Patients with TDS** (n = 127) accounted for 26% of patients (QLQ-PR25 Treatment-related symptom score ≥ 25/100) vs **Patients without TDS** (QLQ-PR25 Treatment-related symptom score < 25/100) (n = 360)

- **QLQ-PR25 Treatment-related symptoms score** (mean ± SD): 38.2 ± 12.3 in the subgroup with TDS vs 8.5 ± 7.1 in the subgroup without TDS
- **Symptoms of patients with TDS** were (quite a bit or very much): feeling of less masculinity (55.2%), hot flushes (41%), weight gain (40.1%) and enlarged nipples (23.1%)

- **Patients with TDS** were slightly older than those without TDS (not significantly) and had significantly worse performance status (p=0.0153)
- **They suffered** more frequently from recurrent PCa (35.7% vs 24.7%, p=0.0175). Clinical symptoms other than urinary and sexual, i.e. including asthenia, anorexia and bone pain, were more frequent (33.3% vs 21.9%, p=0.0126)

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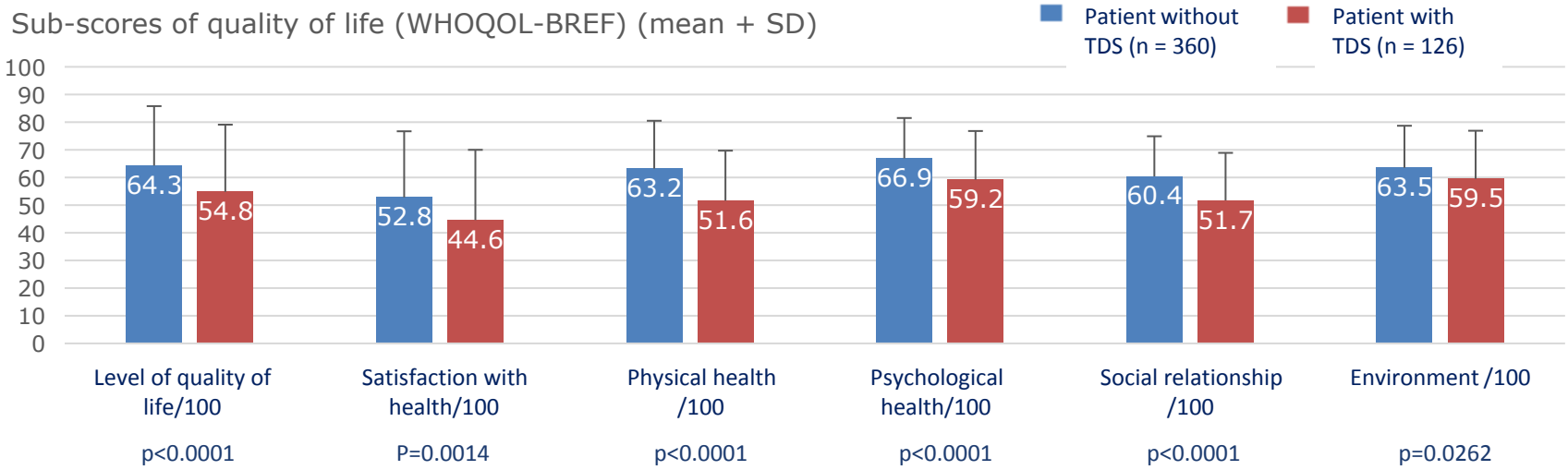
Results of the present subgroup analysis

Patient's quality of life (WHOQOL-BREF) at baseline

- All dimensions of WHOQOL-BREF at baseline were rated significantly worse in patients with TDS at baseline than in patients without TDS at baseline



Higher scores = better assessment; SD: standard deviation; p = Mann-Whitney test.

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Results of the present subgroup analysis

Other parameters from patient's self-questionnaires at baseline

- Total score of illness (B-IPQ) and cohesion in the couple (DAS score) were both significantly worse at baseline in patients with TDS at baseline

Scores (mean ± SD)	Patients without TDS (n = 360)	Patients with TDS (n = 127)	p
Total score of illness (B-IPQ) [range: 0-80]*	39.1 ± 9.4	42.2 ± 8.2	0.004
Cohesion in the couple (DAS score) [range: 0-154]**	107.3 ± 20.9	98.6 ± 22.3	0.0006

* Higher scores = worse assessment; ** higher scores = better assessment; SD: standard deviation; p = Mann-Whitney test.

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Conclusions and Acknowledgements

Conclusions of this subgroup analysis

- 26% of the EQUINOXE patients had TDS at baseline
- This subgroup analysis of EQUINOXE study showed that patients with TDS at baseline experienced at baseline a worse cohesion of the couple and a lower QoL than patients without TDS
- Patients with TDS at baseline benefited relatively more from androgen deprivation therapy with GnRH agonist in term of QoL, as showed in the final analysis of EQUINOXE study (6-month follow up)

Consequences for PCa patients with TDS

- These data suggest ways to better evaluate patients at initiation of androgen deprivation therapy and to improve personalized supportive care in order to improve their quality of life

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