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The improvement of nocturia after treatment mostly affects the improvement of quality of life.

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Introduction

- The QoL item of IPSS is an independent item, because the symptom severity does not always account for the bothersomeness and its negative impact on QoL
- Some men might show high Qol score in spite of having severe LUTS, and some men might show low Qol score although they have mild LUTS
- Some men show improved Qol score proportional to the improvement in LUTS
- However, some men show constant or worse Qol score in spite of improvement in LUTS after treatment.
- To date, there is no reliable explanation for this discrepancy in a subset of patients.

Aim of In this study
to evaluate the symptoms or factors which affect the Qol score at baseline and the change in Qol score after treatment

Materials and Method

- Pooled data analysis
  - Data collection from 5 previously performed study
- Data collection
  - Baseline Data
    - Demographic details (age, height, weight)
    - Past medical history
    - Baseline IPSS score
    - Baseline BPH profile (PSA, prostate volume, Qmax, PVR)
  - Post-treatment Data (3 months)
    - Post-treatment IPSS score
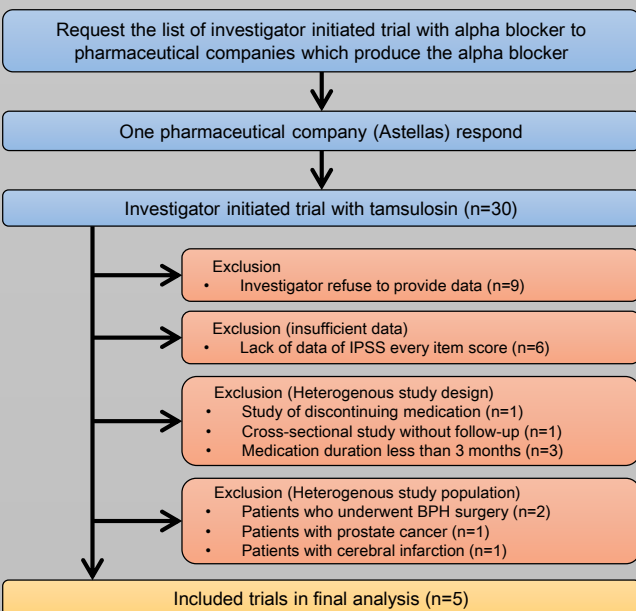   - Qmax, PVR
- Analysis
  - Factors that had an influence on baseline Qol scores (linear regression analysis)
  - Change in variables (baseline scores – post-treatment scores)
  - Factors that had an influence on the change in Qol (linear regression analysis)
- Subgroup analysis according to the change in nocturia
  - Men with nocturia ≥ 2 at baseline
  - Men who showed improvement in IPSS total ≥ 5
    - Aggravation Group (change in nocturia < 0)
    - Stationary Group (change in nocturia = 0)
    - Improvement Group 1 (change in nocturia = 1)
    - Improvement Group 2 (change in nocturia ≥ 2)
  - Qol score improvement was defined as a decrease in score by 1 or more points.

Figure 1. Flowchart of study selection

Request the list of investigator initiated trial with alpha blocker to pharmaceutical companies which produce the alpha blocker

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One pharmaceutical company (Astellas) respond

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Investigator initiated trial with tamsulosin (n=30)

Exclusion
- Investigator refuse to provide data (n=9)

Exclusion (insufficient data)
- Lack of data of IPSS every item score (n=6)

Exclusion (Heterogenous study design)
- Study of discontinuing medication (n=1)
- Cross-sectional study without follow-up (n=1)
- Medication duration less than 3 months (n=3)

Exclusion (Heterogenous study population)
- Patients who underwent BPH surgery (n=2)
- Patients with prostate cancer (n=1)
- Patients with cerebral infarction (n=1)

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Included trials in final analysis (n=5)

Results

Table 1. Baseline characteristics and post-treatment change

Variables	Baseline	3M Follow-up	p-value
Age (y)	62.5 ± 8.5		
Height (cm)	167.7 ± 6.3		
Weight (kg)	68.3 ± 8.3		
Medical disease			
Hypertension	98 (22.1%)		
Diabetes	45 (10.1%)		
Serum PSA (ng/dl)	1.7 ± 1.9		
Prostate volume (cc)	32.7 ± 12.6		
IPSS scores			
IPSS item 1	2.8 ± 1.7	1.7 ± 1.4	< 0.001
IPSS item 2	3.0 ± 1.5	1.9 ± 1.3	< 0.001
IPSS item 3	2.8 ± 1.7	1.9 ± 1.6	< 0.001
IPSS item 4	2.5 ± 1.6	1.3 ± 1.3	< 0.001
IPSS item 5	3.1 ± 1.6	2.1 ± 1.5	< 0.001
IPSS item 6	2.0 ± 1.6	1.3 ± 1.3	< 0.001
IPSS item 7	2.3 ± 1.2	1.6 ± 1.1	< 0.001
QoL	4.0 ± 0.9	2.9 ± 1.2	< 0.001
Voiding symptom sum	10.8 ± 4.8	7.0 ± 4.4	< 0.001
Storage symptom sum	7.8 ± 3.2	4.8 ± 2.7	< 0.001
Total IPSS scores	18.6 ± 6.7	11.7 ± 6.4	< 0.001
Uroflowmetry			
Maximum flow rate (ml/sec)	12.5 ± 5.8	15.2 ± 7.1	< 0.001
Voided volume (ml)	201.3 ± 108.6	226.8 ± 126.1	0.005
PVR (ml)	32.3 ± 34.9	29.3 ± 37.1	0.061

Table 2. Factors that were related to the baseline QoL score

Variables	Univariate			Multivariate		
	B	95%CI	p	B	95%CI	P
Age	-0.009	-0.020 – 0.001	0.074			
Height	-0.013	-0.031 – 0.004	0.143			
Weight	0.002	-0.009 – 0.013	0.756			
Hypertension	-0.234	-0.442 – -0.026	0.027	-0.178	-0.361 – 0.004	0.055
Diabetes	-0.356	-0.642 – -0.071	0.015	-0.115	-0.364 – 0.134	0.363
PSA	-0.027	-0.08 – 0.025	0.309			
Prostate volume	-0.005	-0.013 – 0.003	0.193			
Baseline IPSS item 1	0.197	0.148 – 0.246	< 0.001	0.070	0.018 – 0.121	0.009
Baseline IPSS item 2	0.222	0.167 – 0.278	< 0.001	0.058	0.001 – 0.115	0.047
Baseline IPSS item 3	0.115	0.064 – 0.166	< 0.001	-0.014	-0.064 – 0.037	0.598
Baseline IPSS item 4	0.215	0.164 – 0.266	< 0.001	0.106	0.055 – 0.158	< 0.001
Baseline IPSS item 5	0.215	0.165 – 0.265	< 0.001	0.096	0.044 – 0.147	< 0.001
Baseline IPSS item 6	0.171	0.120 – 0.222	< 0.001	0.073	0.021 – 0.125	0.006
Baseline IPSS item 7	0.273	0.208 – 0.338	< 0.001	0.179	0.118 – 0.24	< 0.001
Maximum flow rate	0.007	-0.009 – 0.022	0.388			
Voided volume	0.000	-0.001 – 0.001	0.988			
PVR volume	-0.002	-0.004 – 0.001	0.155			

Table 3. Factors that were related to the improvement in QoL score after medication

Variables	Univariate			Multivariate		
	B	95%CI	p	B	95%CI	P
Age	0.003	-0.011 – 0.017	0.664			
Height	-0.008	-0.033 – 0.016	0.495			
Weight	0.002	-0.013 – 0.017	0.777			
Hypertension	0.020	-0.263 – 0.303	0.888			
Diabetes	-0.052	-0.440 – 0.337	0.793			
PSA	0.012	-0.060 – 0.084	0.742			
Prostate volume	0.009	-0.002 – 0.020	0.127			
Change in IPSS item 1	0.230	0.162 – 0.298	<0.001	0.036	-0.029 – 0.102	0.276
Change in IPSS item 2	0.319	0.248 – 0.391	<0.001	0.140	0.071 – 0.210	<0.001
Change in IPSS item 3	0.196	0.124 – 0.268	<0.001	0.04	-0.027 – 0.108	0.238
Change in IPSS item 4	0.318	0.252 – 0.383	<0.001	0.148	0.081 – 0.214	<0.001
Change in IPSS item 5	0.273	0.205 – 0.341	<0.001	0.125	0.060 – 0.190	<0.001
Change in IPSS item 6	0.181	0.104 – 0.258	<0.001	0.047	-0.023 – 0.116	0.188
Change in IPSS item 7	0.358	0.254 – 0.463	<0.001	0.171	0.079 – 0.263	<0.001
Baseline Qol score	0.514	0.397 – 0.631	<0.001	0.328	0.222 – 0.433	<0.001
Change in Qmax	-0.015	-0.033 – 0.003	0.104			
Change in VV	0.000	-0.001 – 0.001	0.841			
Change in PVR volume	-0.001	-0.004 – 0.002	0.655			

Table 4. Improvement in Qol score according to improvement in nocturia among patients who had pretreatment nocturia ≥ 2 and showed improvement in IPSS ≥ 5 or points

Change in nocturia	Stationary Qol	Improved Qol
Aggravation Group	1 (50%)	1 (50%)
Stationary Group	9 (32%)	19 (68%)
Improvement Group 1	24 (23%)	80 (77%)
Improvement Group 2	4 (5%)	76 (95%)
P for trend	< 0.001	

*Qol score improvement was defined as a decrease in score of 1 or more points

Conclusions

- Baseline Qol score in the IPSS was affected by almost each item score of IPSS.
- Among the seven items of the IPSS, IPSS item 7 (nocturia) had the maximum influence on Qol scores.
- The post-treatment improvement in IPSS items 2, 4, 5, and 7 had an influence on the improvement in Qol scores.
- Among them, the change in IPSS 7 (nocturia) had the maximum impact on the change in Qol scores.
- When nocturia was not improved, a large proportion of men replied that Qol was not improved, even though other symptoms were improved.