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1 IPSS «bother question» score predicts health-related quality of life 2 better than total IPSS score

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5 **Florin V Hopland-Nechita, MD¹; John R Andersen, PhD^{1,2}; Christian Beisland, MD, PhD^{3,4}**

6 ¹Urology Department, Førde Central Hospital, Førde, Norway

7 ²Western Norway University of Applied Sciences, Førde, Norway

8 ³Department of Clinical Medicine, University of Bergen, Bergen, Norway

9 ⁴Department of Urology, Haukeland University Hospital, Bergen, Norway

10

11 Abstract

12

13 *Objective*

14 To investigate the role of bothersomeness of urinary symptoms on the general health-related quality
15 of life (HRQoL) of patients with benign prostatic hyperplasia. We hypothesized that a higher
16 International Prostate Symptom Score (IPSS) would be associated with a higher score on the IPSS
17 bother question (IPSS-BQ), and a higher IPSS-BQ score would be the dominant factor associated with
18 poorer general HRQoL.

19 *Materials and methods*

20 A case control, cross-sectional study design was used. Patients were selected according to strict
21 inclusion and exclusion criteria and stratified by IPSS severity group (controls: IPSS < 8; moderately
22 symptomatic: IPSS = 8-18; and severely symptomatic: IPSS > 18). The IPSS-BQ was used to analyse
23 bothersomeness of urinary symptoms. A standardised, multidimensional measure of HRQoL (RAND-
24 36) was used. Data were collected on prostate size, uroflowmetry parameters, prostate specific
25 antigen and comorbidities that were quantified using the Charlson Index and the American Association
26 of Anaesthesiologists (ASA) score. Multiple linear regression models were used to assess the impact of
27 bothersomeness of urinary symptoms on physical and mental HRQoL. Cohen's d was used to
28 determine the effect size.

29 *Results*

30 We included 83 patients in the statistical analysis. Linear regression analyses showed that the IPSS was
31 not an independent predictor of HRQoL. Only the highest IPSS-BQ score was associated with both
32 worse physical (P = 0.021) and mental (P = 0.011) HRQoL in the final model. The effect sizes were small
33 to moderate.

34 *Conclusion*

35 The IPSS-BQ score is an important predictor of HRQoL. The IPSS-BQ score as a proxy should be regarded
36 as a standard outcome measure and reported in all LUTS-related research.

37

38 *Keywords: IPSS “bother question”, RAND-36, Health-related quality of life, Bothersomeness of LUTS*

39

40 **Introduction**

41 Benign prostatic hyperplasia (BPH) is a progressive disease and the main cause of lower urinary tract
42 symptoms (LUTS) in aging men[1]. The presence of moderate to severe LUTS is associated with
43 decrements in general health related quality of life (QoL)[2], which refers to “how health impacts on
44 an individual’s ability to function and his or her perceived well-being in physical, mental and social
45 domains of life”[3] The degree to which these symptoms bother patients (bothersomeness) is a key
46 decision point in the diagnosis and treatment algorithm of the European Association of Urology 2020
47 Guidelines for non-neurogenic male-LUTS[4]. Most of the studies on BPH treatment have used
48 improvement in symptoms, as quantified by the International Prostate Symptom Score (IPSS), as
49 primary or secondary endpoints to evaluate efficacy[5-8]. However, the IPSS alone is not a strong
50 predictor of general health-related quality of life (HRQoL)[9]. Improved HRQoL should be the main
51 endpoint of any proposed treatment modality for BPH. Therefore, comprehending the level of
52 impairment in HRQoL due to LUTS for a unique patient should be valuable adjunct information in all
53 treatment-evaluation research[10]. The IPSS bother question (IPSS-BQ) is the most used measure of
54 disease-specific quality of life QoL in the evaluation of men with BPH[11]. Various studies have
55 demonstrated the reliability and validity of the IPSS-BQ and have reported a strong positive correlation
56 with other disease-specific QoL instruments with more items[12, 13]. However, to our best knowledge,
57 no published studies have investigated the role of the IPSS-BQ as a predictor of general HRQoL. The
58 most widely used questionnaire for assessing general HRQoL is the RAND 36. Although evaluations of
59 the general HRQoL of patients with LUTS using the standardised SF-36/RAND-36 questionnaire have
60 been published, these studies have only addressed the association between symptoms (IPSS= and
61 general HRQoL and not the association between bothersomeness og LUTS (IPSS-BQ) and HRQoL [9, 14].
62 The aim of this study was to investigate the role of bothersomeness of urinary symptoms on the
63 general HRQoL of patients with LUTS, secondary to BPH. We hypothesised that a higher IPPS would be
64 associated with a higher IPSS-BQ, while a higher IPSS-BQ would be the dominant factor associated with
65 a poorer general HRQoL.

66

67 Material and Methods

68 *Study design*

69 A cross-sectional design was applied. The study was conducted in the Urologic Outpatient Clinic of
70 Førde Central Hospital. The inclusion period was 20 November 2018 – 17 February 2021.

71

72 *Participants*

73 Patients were referred by their general practitioners (GPs) and selected by the first author if they met
74 the study criteria (Table 1).

75 We did not impose limits on the inclusion criteria regarding prostate size, prostate specific antigen
76 (PSA) value or maximum flow rate (Q-max) because we wanted our study population to be as
77 representative as possible of the general population. Knowing that different categories of patients
78 have different experiences of LUTS, we needed to have wide variation in our data in order to find weak
79 correlations in our analysis of the link between patients' reports of bothersomeness of LUTS and
80 perceived HRQoL. Reference data for HRQoL were derived from a representative survey of general
81 population of Norwegian adults from 2015. The sample consisted of 947 males who completed the
82 Norwegian version of the RAND-36.

83 Please see Table 1 for patient selection, workup and data collection.

84

85 *Measurements*

86 To assess symptom severity, we used the standard 7-item IPSS questionnaire. The eighth question of
87 the IPSS, IPSS-BQ (i.e. 'If you were to spend the rest of your life with your urinary condition just the
88 way it is now, how would you feel about that?') was scored on a 6-point scale: 0 (delighted), 1
89 (pleased), 2 (mostly satisfied), 3 (mixed about equally satisfied and dissatisfied), 4 (mostly dissatisfied)
90 and 5 (unhappy), with higher scores indicating worse QoL. Patients were initially divided in accordance
91 with the scores of the standard IPSS groups: control group (0-7) moderately symptomatic group (8-19)
92 and severely symptomatic group (20-35)[15].

93 The RAND-36 is a widely used HRQoL survey and a reliable tool for analysing group comparisons based
94 on its internal consistency and test-retest reliability indexes[3, 16]. The instrument consists of 36 items
95 that assess eight health concepts: physical functioning, physical role functioning, physical pain, general
96 health, vitality, social functioning, emotional role functioning and mental health. The RAND-36 is not
97 specific for any population or disease. Each subscale is converted to a 100-point scale, with 100
98 representing optimal HRQoL. The eight scales of the RAND-36 are calculated to yield overall physical
99 and mental HRQoL summary scores[17].

100 The presence of comorbidities was assessed using the American Society of Anaesthesiology (ASA) score
101 and the Charlson Index[18].

102

103 *Sample size*

104 Given a power level of 80%, a two-tailed P-value of 0.05 and N = 83, a Pearson correlation of 0.3 is
105 likely to be statistically significant[19]. An effect-size of 0.3 indicates an threshold for effects that are
106 clinically relevant and potentially powerfull in bothe the short and the long run.[20]

107

108 *Statistical method*

109 To examine the associations between the different variables, we used analysis of variance (ANOVA) to
110 examine differences between the parameters of the three IPSS groups. Linear regression was used to
111 analyse the relationship between scores on the IPSS, IPSS-BQ and physical and mental domains of the
112 HRQoL based on the RAND-36. We used both an unadjusted and an adjusted model for age and
113 comorbidities as quantified by the ASA score and the Charlson Index. We then stratified the patients
114 according to the degree to which their symptoms were bothersome, as assessed using the IPSS-BQ.
115 Comparisons were analysed between the IPSS severity groups, the IPSS-BQ and an age-matched
116 sample of males from the general population of Norway[16]. To assess differences between the
117 groups, we used Cohen's d effect size calculation model, where a 0.2 difference in the standard
118 deviation is considered a small difference, 0.5 is a medium difference and 0.8 is a large difference[21].
119 We reported two-tailed P-values and 95% confidence intervals. The IBM SPSS Statistics Version 26
120 software was used for the statistical analyses.

121

122 **Results**

123 Among the 169 patients that met the study's criteria, 91 (53%) signed forms indicating their informed
124 consent to participate in the study. Eight patients were excluded (5 with a prostate cancer diagnosis;
125 1 with an acute leukaemia diagnosis; 1 with a bladder cancer diagnosis; and 1 who withdrew informed
126 consent, all of them within one month of the inclusion date). Thus, 83 patients were considered for
127 the statistical analysis. The general characteristics of the patients are summarised in Table 2. The
128 cohort is typical of patients referred to urologists for LUTS examinations. The control group represents
129 an average representation of typical men between 50 and 80 years of age in Norway. Initial analysis of
130 the IPSS-BQ as an independent predictor of HRQoL revealed that a decrease in mental HRQoL with an
131 increase in bothersomeness of urinary symptoms was not a linear function, but there was a clear
132 reduction in mental HRQoL from the IPSS-BQ score of 2, to an IPSS-BQ score of 3. This reduction was

133 present but not obvious for physical HRQoL on the RAND-36. Consequently, we divided the patients in
134 two groups: IPSS-BQ = 0-2, n = 35 and IPSS-BQ = 3-5, n = 48 (see Supplementary Tables for details).
135 The results of the linear regression showed that the IPSS is a strong predictor of the IPSS-BQ in an
136 unadjusted model and that the association was preserved when adjusting for age and comorbidity.
137 However, when the regression model was used to assess the impact of the IPSS on mental and physical
138 HRQoL, the IPSS score had no significant effect on either of these two parameters. When the IPSS-BQ
139 was added to the model, significant effects on the mental and physical HRQoL scores were observed.
140 The details are summarised in Table 3. Cohen's effect sizes for the physical (d = 0.5) and mental (d =
141 0.7) HRQoL domains were medium and large, respectively. The effect sizes of all the domains of the
142 RAND-36 are presented in the Supplementary Tables.
143 We then compared the study population with Norwegian normed data. The age-adjusted mental
144 HRQoL of the Norwegian population was 81.3 (SD = 15.9), and the physical HRQoL was 76.6 (SD = 20.8).
145 When the study population was stratified by IPSS group there were only small differences, as evaluated
146 using Cohen's d, in mental and physical HRQoL between the three study groups and the normed data.
147 However, there were medium size differences in the vitality domain. The details are illustrated in
148 Figure 1A. When the study population was stratified by IPSS-BQ group, moderate differences were
149 found in mental and physical HRQoL compared to the normed data, and again, a medium size effect
150 was found in the vitality domain (Figure 1B).

151

152 Discussion

153 We explored the role of bothersomeness of urinary symptoms and its relationship with HRQoL and
154 urinary symptom status. The degree to which symptoms become bothersome or worrisome to a
155 patient usually provides the basis for his decision to seek medical treatment. Numerous studies have
156 shown that the "bother question" provides a reproducible valid tool for evaluating changes in the
157 status of LUTS[13, 22, 23]. We have developed a model showing that the objective quantification of
158 symptoms (using the IPSS) may influence the assessment of bothersomeness of urinary symptoms
159 (IPSS-BQ), which in turn, may influence the HRQoL of patients (RAND-36). The IPSS alone showed no
160 significant associations with patients' HRQoL. The IPSS-BQ was the only variable that correlated with
161 patients' mental and physical HRQoL. As the primary goal of LUTS treatment is an improvement in
162 HRQoL, evaluations of new treatment methods based only on an improved IPSS are probably
163 insufficient to conclude that these treatments cause consequent improvement in HRQoL.
164 Although numerous articles have been published on the bother question's association with LUTS, none
165 has addressed the relationship between that the degree to which it is bothersome to the patient and
166 general HRQoL.

167 Salinas-Sanches (2001) investigated the HRQoL of patients on the waiting list for BPH surgery using the
168 SF-36, and found they had a poorer HRQoL than the general population of the same age. A major
169 limitation of this study is bias in the selection of patients with indications for surgical treatment. Thus,
170 it could be expected that these patients would be likely to have poorer HRQoL. However, this study is
171 one of the first studies that objectively quantified the HRQoL of the study group using a validated tool
172 (SF-36) and compared the results with normed data from an age-matched national population[14].
173 Welch (2002) conducted a large survey of United States (US) men participating in the Health
174 Professionals Follow-Up Study. Although they did not use the two composite scores that we used their
175 findings are similar to ours. The patients with severe LUTS had small to moderate differences from the
176 age-matched sample from the general population of the US with regard to vitality/energy and the
177 ability to work and perform daily tasks because of their illness. These findings were consistent when
178 they were adjusted for confounding factors, such as comorbidities However, they did not specifically
179 address the relationship among the scores on the IPSS, IPSS-BQ and SF-36[9].
180 One possible explanation for our findings is that symptoms, per se, have different meanings for
181 different patients. It is only when the subjective experience of these symptoms becomes bothersome
182 that there is a consequent reduction in HRQoL. This is the main driver for patients to seek medical
183 attention. It is improvement in their HRQoL and resolution of their bothersome urinary symptoms that
184 patients expect from the treatment. Neither improved symptom scores nor urinary flow rate are
185 parameters that are directly acknowledged by the patients.
186 The strengths of this study include its strict inclusion and exclusion criteria that narrowed down
187 patients' signs and symptoms to BPH as the most probable aetiology of LUTS; the inclusion of a control
188 group; the homogeneity of the groups that allowed for good comparisons; the use of only one
189 investigator to perform transrectal prostate measurements, thereby eliminating observer bias; and the
190 completeness of the data and comparisons of HRQoL between the patients and the age-matched
191 sample from the general population of Norway. The limitations of the study include its cross-sectional
192 design and small sample of patients that were previously referred to a urologist by a GP. This study
193 population mainly included urology patients and might not reflect an accurate picture of patients in
194 the general population. Another drawback is the use of the IPSS because it does not assess the
195 incontinence aspects of LUTS, which are known to be extremely bothersome[24].
196 Last, as this is a cross-sectional study, it provides only a static picture of IPSS-BQ as a parameter for
197 HRQoL.

198

199 Conclusion

200 The IPSS-BQ is a better predictor of HRQoL than the total IPSS. The IPSS-BQ as a proxy for HRQoL should
201 be regarded as the standard outcome measure and reported in all LUTS-related research. Further
202 longitudinal studies are needed to examine the reliability of this parameter as an instrument for
203 assessing changes over time and responses to treatment.

204

205 Author contributions

206 **FHN:** Project/Protocol development, Data collection and management, Data analysis, Manuscript
207 writing/editing.

208 **JRA:** Project/Protocol development, Data management, Data analysis, Manuscript writing/editing,
209 Supervision

210 **CB:** Project/Protocol development, Data analysis, Manuscript writing/editing, Supervision.

211 All authors have approved the submitted version of the manuscript.

212

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215

216 Compliance with ethical standards

217

218 **Conflicts of interest:** None of the authors report conflicts of interest

219

220 **Ethical approval:** The project is approved by the Norwegian South-East Regional Ethics Committee
221 (REC reference number: 2018/114). In accordance with the approval, all participating patients signed
222 an informed consent form prior to inclusion.

223

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225

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290

Table 1. Patient Selection, Workup and Collected Data

Inclusion Criteria
<ul style="list-style-type: none"> • Male age between 50 and 80 years • Willingness to sign the informed consent form • IIEF-5 score >5 • ECOG performance status 0-1
Exclusion Criteria
<ul style="list-style-type: none"> • Unwilling to sign the informed consent form • Drug treatment for LUTS or sexual dysfunction • Any additional drug treatment with a known effect on BPH symptoms (diuretics, antihistamines, calcium channel blockers, phytotherapy or tricyclic antidepressants) for any length of time in the four weeks prior to inclusion • Presence of other urinary disorders – chronic pelvic pain, urethral strictures, bladder cancer, previous TUR-P or laser procedure, pelvic radiation or surgery, urinary tract infection • Any known cancer diagnosis except non-malignant melanoma of the skin within the last 5 years • Severe cardiac comorbidities – ASA score >3 • Presence of neurodegenerative disorders (i.e. Parkinson’s disease, Alzheimer’s disease, etc.) • Unwilling to report sexual function • Penile conditions that prevent sexual act (i.e. penis cancer) • ECOG performance status > 1
Workup and Collected data
<pre> graph LR A["• Blood samples • Questionnaires: ○ IPSS ○ IIEF ○ RAND-36 • Medical history ○ ASA ○ Charlson index • Demographic data"] --> B["• Uroflowmetry • Post-void residual urine (scanner) • Digital rectal examination • Transrectal ultrasound of the prostate ○ Volume ○ Abnormalities"] B --> C["Discretionary tests (if indicated) • Cystoscopy • Imaging of upper urinary tract • Bladder diary • Urodynamic testing"] B --> D["Treatment according to the clinical situation"] C --> D </pre>

Note: ASA = American Society of Anaesthesiologists; ECOG = Eastern Cooperative Oncology Group; LUTS = lower urinary tract symptoms; TUR-P = Transurethral resection of the prostate; BPH = benign prostatic hyperplasia; IPSS = International Prostate Symptom Score; IIEF-5 = International Index of Erectile Function 5-item version; RAND-36 = RAND 36-Item Health Survey

Table 2. Patients' Characteristics

Variables	Control Group (IPSS <8) n = 20 Mean (SD)*	Moderately Symptomatic (IPSS 8-18) n = 35 Mean (SD) *	Severely Symptomatic (IPSS>18) n = 28 Mean (SD) *	P-value
Age (years)	63.4 (7.1)	65.2 (5.9)	63.4 (6.8)	0.458
IPSS-BQ	1.1 (0.9)	2.7 (1.1)	3.6 (0.9)	<0.001
ASA Classification	1: 14 (70%) 2: 5 (25%) 3: 1 (5%)	1: 11 (31.4%) 2: 21 (60%) 3: 3 (8.6%)	1: 10 (35.7%) 2: 18 (64.3%)	0.031
Charlson Index	0: 13 (65%) 1: 6 (30%) 2: 1 (5%)	0: 23 (65.7%) 1: 7 (20%) 2: 5 (14.3%)	0: 20 (71.4%) 1: 6 (21.4%) 2: 2 (7.1%)	0.742
Prostate Volume (cm ³)	56.7 (28.4)	53.9 (23.4)	50.0 (21.9)	0.629
Residual Urine (ml)	81.6 (36.2)	95.5 (122.3)	121.8 (144.7)	0.614
Q-max (ml/sec)	21.3 (11.4)	16.8 (10.3)	14.0 (7.3)	0.134
PSA (µg/L)	3.5 (3.4)	3.1 (3)	3.2 (3.2)	0.877
Body Mass Index (kg/m ²)	26.9 (3.2)	27.5 (4.4)	26.9 (3.6)	0.768
Rand 36 domains				
Physical Function	92.0 (13.2)	91.6 (8.1)	88.0 (18.4)	0.503
Role Physical	83.8 (32.7)	79.3 (32.4)	74.1 (38.8)	0.632
Bodily Pain	73.6 (21.8)	66.6 (20.3)	70.8 (27.4)	0.534
General Health	75.8 (17.9)	67.1 (16.1)	67.3 (20.7)	0.195
Vitality	74.0 (19.2)	69.6 (14.5)	58.8 (20.1)	0.009
Social Function	88.8 (15.7)	87.1 (16.7)	84.4 (21.7)	0.699
Role Emotional	91.7 (26.2)	86.7 (28.2)	85.7 (32)	0.763
Mental Health	86.2 (13.8)	84.2 (10)	82.7 (12)	0.597
Physical HRQoL	81.3 (18.6)	76.1 (15.3)	75.1 (23.4)	0.511
Mental HRQoL	85.2 (16.7)	81.9 (14.5)	77.9 (16.5)	0.282

Note: P-values are for the ANOVA results; *The ASA Classification, Charlson Index, reports the number of patients in each category not mean and standard deviation; IPSS-BQ = Bothersomeness of urinary symptoms as reported in question 8 of the IPSS; IIEF = International Index of Erectile Function; Q-Max = peak urinary flow ; HRQoL = health related quality of life .

Table 3. Linear Regression Models

Variables	Unadjusted			Adjusted		
	B (95% CI)	Beta	P-value	B (95% CI)	Beta	P-value
Model 1: IPSS-BQ (IV)						
IPSS	0.13 (0.10 – 0.15)	0.72	<0.001	0.13 (0.10 – 0.15)	0.73	<0.001
Age	-0.03 (-0.08 – 0.02)	-0.14	0.196	-0.03 (-0.07 – 0.00)	-0.16	0.060
Charlson Index	0.06 (-0.39 – 0.52)	0.03	0.778	0.13 (-0.24 – 0.50)	0.06	0.496
ASA	0.16 (-0.36 – 0.68)	0.07	0.550	0.00 (-0.46 – 0.46)	0.00	0.991
Model 2: Physical HRQoL (IV)						
IPSS	-0.24 (-0.78 – 0.29)	-0.10	0.369	0.40 (-0.33 – 1.13)	0.17	0.275
IPSS-BQ	-10.22 (-18.40 – -2.03)	-0.27	0.015	-13.61 (-25.07 – -2.15)	-0.35	0.021
Age	0.24 (-0.40 – 0.89)	0.08	0.458	0.28 (-0.41 – 0.98)	0.10	0.418
Charlson Index	-4.02 (-10.30 – 2.26)	-0.14	0.206	-0.52 (-7.84 – 6.80)	-0.02	0.888
ASA	-5.88 (-13.05 – 1.30)	-0.18	0.107	-6.88 (-15.88 – 2.12)	-0.21	0.132
Model 3: Mental HRQoL (IV)						
IPSS	-0.40 (-0.83 – 0.04)	-0.20	0.075	0.19 (-0.41 – 0.78)	0.09	0.537
IPSS-BQ	-10.64 (-17.26 – -4.03)	-0.34	0.002	-12.27 (-21.66 – -2.88)	-0.39	0.011
Age	0.06 (-0.48 – 0.60)	0.03	0.821	0.08(-0.49 – 0.64)	0.03	0.792
Charlson Index	-1.71 (-6.94 – 3.53)	-0.07	0.518	1.01 (-4.98 – 7.01)	0.04	0.737
ASA	-4.59 (-10.54 – 1.36)	-0.17	0.129	-5.37 (-12.74 – (2.00)	-0.20	0.151

Note: IPSS-BQ = Botherome urinary symptoms, as assessed using question 8 of the IPSS; IV = independent variable. Age and IPSS were treated as continuous independent variables and IPSS-BQ was treated as a binary variable (score $\leq 2 = 0$ and $> 2 = 1$).

The variance explained by the adjusted models are as follows: Model 1 = 52.7%, Model 2 = 6.9% and Model 3 = 8.7%.

Figure 1. Cohen's d effect sizes for the three IPSS groups vs the Norwegian normed data

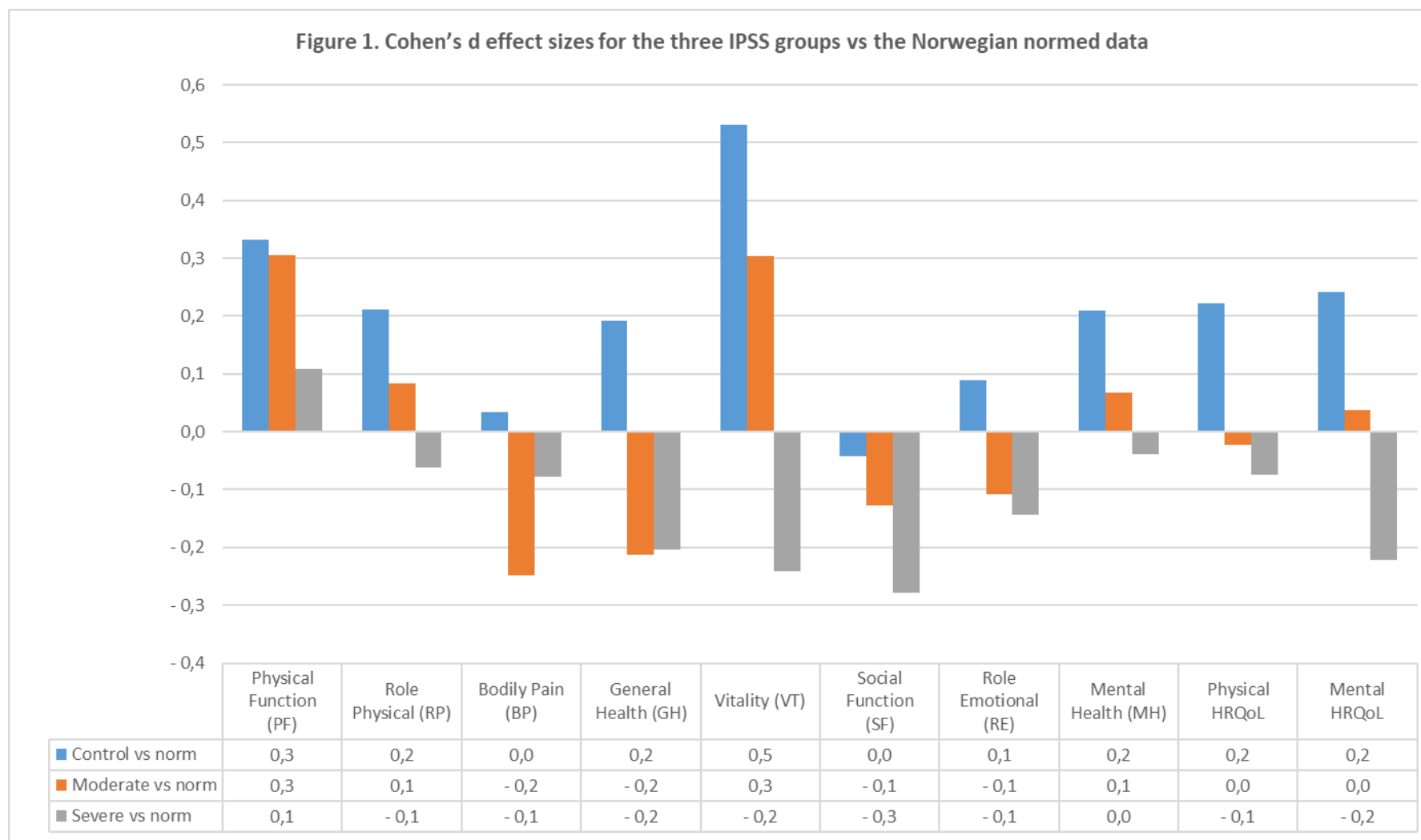


Figure 2. Cohen's d effect sizes for the two IPSS-BQ groups vs the Norwegian normed data

