Transcultural adaptation and validation of the questionnaire "Urgency, Weak stream, Incomplete emptying and Nocturia (UWIN)" for the Brazilian Portuguese

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Lower urinary tract symptoms (LUTS) are common complaints in the adult male population and have a negative affect in the quality of life and represent an economic burden for the healthcare system worldwide. The International Prostatism Symptom Score (IPSS) is a validated tool for assessing these symptoms, but patients with low literacy may have difficulties comprehending and completing it accurately. The Urgency, Weak Stream, Incomplete Emptying, and Nocturia (UWIN) questionnaire was developed as a shorter tool in the assessment of LUTS to improve accuracy and minimize error. This study aimed at performing cross-cultural adaptation to Brazilian Portuguese and validation of UWIN questionnaire for patients with LUTS. The cross-cultural adaptation followed the steps of conceptual, item, semantic, operational, and pre-test equivalence to obtain the UWIN-Br version. The IPSS (gold standard) and UWIN-Br were coadministered, and information regarding the uroflowmetry examination was also recorded. We evaluated 306 men, median age 59 [52-66] years .There was a positive correlation r = 0.804 (p <0.001) between the total IPSS score and the total UWIN-Br score, as well as the quality of life question (r = 0.761) (p <0.001). The Bland-Altman plot showed good agreement between. Also, we observed that the maximum flow values decreased with the severity of the LUTS. UWIN-Br demonstrated excellent diagnostic accuracy in detecting the most severe cases. The area under the ROC curve was 89% [81 - 97%] 95% CI. 280 (91.5%) subjects completed the questionnaires without help, while 26 (8.5%) did so through an interview. The response time was 1.2 [1.0-1.5] min for UWIN-Br and 2.8 [2.2-3.4] min for IPSS (p <0.001). UWIN-Br presents satisfactory and similar psychometric properties to the IPSS in the evaluation of LUTS and quality of life and is suitable for use in both clinical practice and research in our country.

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ABSTRACT

Lower urinary tract symptoms (LUTS) are common complaints in the adult male population and have a negative affect their quality of life and represent an economic burden for the healthcare system worldwide. The International Prostate Symptom Score (IPSS) is a validated tool for assessing these symptoms, but patients with low literacy may have difficulties comprehending and completing it accurately. The Urgency, Weak Stream, Incomplete Emptying, and Nocturia (UWIN) questionnaire was developed as a shorter tool in the assessment of LUTS to improve accuracy and minimize error. This study aimed at performing cross-cultural adaptation to Brazilian Portuguese and validation of UWIN questionnaire for patients with LUTS. The cross-cultural adaptation followed the steps of conceptual, item, semantic, operational, and pre-test equivalence to obtain the UWIN-Br version. The IPSS (gold standard) and UWIN-Br were coadministered, and information regarding the uroflowmetry examination was also recorded. We evaluated 306 men, median age 59 [52-66] years .There was a positive correlation r = 0.804 (p <0.001) between the total IPSS score and the total UWIN-Br score, as well as the quality of life question (r = 0.761) (p <0.001). The Bland-Altman plot showed good agreement between. Also, we observed that the maximum flow values decreased with the severity of the LUTS. UWIN-Br demonstrated excellent diagnostic accuracy in detecting the most severe cases. The area under the ROC curve was 89% [81 - 97%] 95% CI. 280 (91.5%) subjects completed the questionnaires without help, while 26 (8.5%) did so through an interview. The response time was 1.2 [1.0-1.5] min for UWIN-Br and 2.8 [2.2-3.4] min for IPSS (p <0.001). UWIN-Br presents satisfactory and similar psychometric properties to the IPSS in the

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41   research in our country.

42

43   **INTRODUCTION**

44

45   Lower urinary tract symptoms (LUTS) is a broad term that describes storage, voiding,

46   and postmicturition symptoms, according to the definition of the International Continence

47   Society. The prevalence of LUTS in men older than 40 years of age exceeds 60% and increases

48   with age(Irwin et al. 2006; Coyne et al. 2009; Soler et al. 2018).LUTS may be very bothersome

49   to patients and may have a negative impact on work productivity, health-related quality of life,

50   and social functioning(Coyne et al. 2008, 2011).

51   The initial evaluation of men with LUTS includes history and physical examination,

52   urinalysis, a subjective assessment with a survey of symptoms and objective tests, including

53   uroflowmetry and measurement of postvoid residual urine volume(Gravas et al. 2015).

54   The International Prostate Symptom Score (IPSS) is a validated, well-established

55   instrument, which enables the stratification of patients according to the severity of symptoms and

56   allows for the assessment of both responses to treatment and disease progression. In Brazil, the

57   instrument was validated by Berger and Cols in 1999, from the application of the same group of

58   281 participants with benign prostatic hyperplasia. However, patients with a low education level

59   have been demonstrated to report difficulty completing it accurately(Johnson et al. 2008).

60   Simplified questionnaires have been developed and validated and may be more

61   appropriate for the evaluation of subjects with lower education level(Van Der Walt et al. 2011;

62   Eid et al. 2014; Stothers et al. 2017; Mallya et al. 2017; Moses et al. 2017). Among these

63   instruments is the UWIN (Urgency, Weak Stream, Incomplete Emptying and Nocturia), which

64   was developed to facilitate the completion of the IPSS questionnaire, thus making the

65   administration of the questionnaire more efficient. The UWIN is essentially a simplified, shorter

66   version of the IPSS and consists of questions about the four most significant lower urinary tract

67   symptoms, with partial scores ranging from 0 to 3, instead of 0 to 5. The final maximum score is

68   12, instead of 35, the simplified score classifies the intensity of symptoms based on the score into

69   three degrees: mild 0 to 3, moderate 4 to 7, and severe 8 to 12. As with the IPSS, there is an

70   additional simplified question regarding the quality of life(Crawford et al. 2011).

71   The reduction of items in an instrument may cause it to lose sensitivity while potentially

72   gaining specificity, which allows for the detection of more severe cases, even at the expense of

73   failing to recognize some of them. These properties may be considered acceptable when aiming

74   to identify more severe cases for further evaluation. Also, these features are particularly desirable

75   in the primary care setting when limited resources are available, and a considerable proportion of

76   subjects have low health literacy level.

77   The UWIN has been demonstrated to be a valid and reliable tool for the evaluation of

78   LUTS in men(Crawford et al. 2011; Eid et al. 2014; Mallya et al. 2017; Ramaraju et al. 2016),

79   lessening the respondent burden and enhancing the applicability of the IPSS(Johnson et al.

80   2008). The aim of the present study was to perform the cross-cultural adaptation to Brazilian

81   Portuguese and validation of the Urgency, Weak Stream, Incomplete Emptying, and Nocturia

82   (UWIN) for use in Brazil.

83

84   **METHODS**

85

86   The process of cross-cultural adaptation followed the most stringent guidelines on

87   translation and adaptation of health status measures(McDowell 2006; Beaton et al. 2000).

88   Followed the recommended steps to achieve conceptual, between-item, semantic, operational,

89   and pretest equivalence to obtain a Brazilian Portuguese version intended for local use. The

90   instrument validity was subsequently tested through the administration of the questionnaire to

91   men living in the metropolitan region of Feira de Santana, Bahia, Brazil, in 2018. To guide the

92   execution of this stage, we followed the quality assessment tool for diagnostic accuracy studies

93   QUADAS-2(Whiting et al. 2011) and the international consensus on health-related patient-

94   reported outcomes, COSMIN(Mokkink et al. 2010).

95   **Stage 1: Cross-cultural adaptation**

96   Because the instrument includes clinical components, the initial translation was carried

97   out individually by a committee composed of 3 health professionals to obtain the translated

98   versions T1, T2, and T3. The members of the committee were urologists proficient in the English

99   language and familiar with the topic in question. Following the process of individual translation,

100   a synthesis of the three translations was produced (T4). This version was reassessed by an expert

101   committee, which resolved discrepancies by consensus to create the first Brazilian Portuguese

102   version of the survey (T5), which was, in turn, translated back into the English language (BT1)

103   by a bilingual Brazilian physician. The back-translation (BT1) was again retranslated into

104   Brazilian Portuguese (T6) by the expert committee and evaluated by two medical practitioners.

105   In the absence of alterations, this was considered the adapted version of the survey for pilot

106   testing.

107   The UWIN in its pretest version (T6) was self-administered to 50 participants so that

108   interpretation issues could be identified. A researcher was responsible for appraising the

109   adequacy of the instructions and the adopted scoring system. The decision about the number of

110   participants included in this stage confirmed to the literature(Coluci, Alexandre, and Milani

111   2015).

112   Finally, operational equivalence was assessed in the pilot testing stage. In this study, the

113   relevance, adequacy, and format of the instrument, the instructions on how to use it, its modes of

114   administration, scenarios, and categorization were discussed by the expert committee and the

115   research group to reach consensus and improve results. In the absence of modifications, the final

116   version (T6) was termed **UWIN-Br** and utilized for the validation stage.

117   **Stage 2: Validation**

118   The study sample was a convenience sample of 306 consective men older than 40 years

119   included between January and June 2018.

120   Eligible participants were approached at the clinic reception and invited to participate in

121   the study by an adequately trained researcher. The questionnaire was completed individually in a

122   private location, but the participants were able to ask a researcher for help in case of need. As for

123   illiterate participants and those who had difficulty completing it on their own, the survey was

124   administered by a researcher in the form of a structured interview. This number is superior to the

125   mean sample size of similar studies.

126   Both the IPSS and the UWIN-Br, both in Brazilian Portuguese, were utilized for data

127   collection. The total score for each instrument was recorded for each patient to later classify

128   them as having mild, moderate, or severe symptoms. An IPSS score of 0 to 7 indicates mild

129   symptoms, 8 to 19 indicates moderate symptoms, and 20 to 35 indicates severe symptoms. For

130   UWIN-Br, the total score ranges from 0 to 12, with mild, moderate, and severe categories being

131   0 to 3, 4 to 7 and 8 to 12, respectively.

132   For the measurement of completion times, a researcher used a stopwatch and recorded the

133   time in minutes individually spent on the task. Uroflowmetry data were obtained from the

134   electronic patient records.

135   This project was approved by the Research Ethics Committee of the State University of

136   Feira de Santana under the protocol number 64704017.7.0000.0053, position statement

137   2.052.761 (ANNEX D) and all subjects provided written informed consent.

138   **Data analysis**

139   Collected data were inputted into two databases to allow for the cross-checking of

140   information and the detection of typing errors. The Statistical Package for the Social Sciences

141   (SPSS) software for Windows, version 22.0, was used for these purposes. GraphPad Prism,

142   version 8.02, was used for data analysis.

143   Quantitative variables were expressed as medians and interquartile ranges, while

144   qualitative variables were expressed as absolute values, percentages, or proportions(Vickers and

145   Sjoberg 2015).

146   The total IPSS (0 to 35) and UWIN-Br (0 to 12) scores were determined for each

147   participant, and Spearman correlation coefficients were used to assess criterion validity. As the

148   correlation coefficients measure only the strength of the linear relationship between the two

149   scores, we also used Bland-Altman analysis(Bland and Altman 1990) to determine if the IPSS

150   and UWIN-Br scores were in agreement with each other. The Bland-Altman plot represents the

151   average of the two scores (IPSS + UWIN-Br)/2 versus the difference between them (IPSS –

152   UWIN-Br) for each participant. This method requires the scores of both instruments to be

153   expressed on the same scale. Since the IPSS score ranges from 0 to 35 and the UWIN-Br ranges

154   from 0 to 12, each index was divided by its maximum value, and each score was normalized to

155   values between 0 and 1.

156   Uroflowmetry was used as a reference standard for the construct validity analysis of

157   UWIN-Br through hypothesis testing. The urinary flow rate was expected to decrease as the

158   score increased, i.e., for patients with more severe symptoms. The maximum urinary flow was

159   determined by uroflowmetry for each of the three categories of symptom severity, then ANOVA

160   was used to compare these data and evaluate the between-group differences and linear trends.

161   We also assessed the diagnostic accuracy of UWIN-Br for the detection of severe cases as

162   defined by the gold standard (IPSS).

163   Time spent completing the survey (completion time) and need for assistance (for both

164   self-completed questionnaires and interviews) were recorded as a measure of the respondent

165   burden associated with each instrument (UWIN-Br and IPSS)(Andresen 2000; Committee

166   2002).P-values < 0.05 were considered statistically significant.

167

168   **RESULTS**

169   The final study sample comprised 306 men with a median age of 59 [52-87] years.

170   General and demographic data are detailed in Table 1. There was a positive correlation (r = 0.81;

171   p < 0.0001) between the total IPSS score and the total UWIN-Br score (Figure 1), which were

172   also positively correlated regarding quality of life (r = 0.76; p < 0.001). Examination of the

173   instrument's ceiling and floor effects indicates that 9.4% of patients had lower scores (floor

174   effect) and 1.9% had higher scores (ceiling effect).

175   Bland-Altman analysis showed good agreement between the two questionnaires and

176   UWIN-Br scores were on the whole slightly higher (Figure 2), with bias of 0.06 ± 0.13

177   (bias±SD). Maximum urinary flow rate values decreased in inverse proportion to the severity of

178   symptoms: 12 [8-16] ml/s in severe cases, 13 [10-19] ml/s in moderate cases and 17 [11-24] ml/s

179   in those with minimal symptoms (p for trend < 0.001) (Figure 3).

180   UWIN-Br had excellent diagnostic accuracy in detecting the most severe cases, with an

181   area under the ROC curve of 89% (95% CI: [81-97%]; p < 0.001).The diagnostic properties are

182   detailed in Table 2. The cut-off value of ≥ 8 points yielded a sensitivity of 50% and a specificity

183   of 96%, which represent a negative predictive value of 95% and a positive predictive value of

184   52% in this scenario.

185   Median completion time was 1.2 [1.0-1.5] minute for UWIN-Br and 2.8 [2.2-3.4] minutes

186   for IPSS (p < 0.001). Of the total 306 participants, 280 subjects (91.5%) managed to complete

187   the questionnaires with no help, while the other 26 (8.5%) had to be interviewed. The group of

188   participants who needed assistance were significantly older (72 [62-74] versus 58 [51-64] years;

189   p < 0.001) and had a lower education level (4 [2-7] versus 11 [8-14] years of education; p <

190   0.001).

191

192   **DISCUSSION**

193

194   Patient Reported Outcome Assessments (PROs) are useful tools for characterizing

195   symptom burden and health-related quality of life (QoL). They are becoming increasingly

196   relevant in the context of clinical and epidemiological research but also in clinical decision-

197   making. Most questionnaires are developed in English(Vickers and Sjoberg 2015), and their

198   proper use in other languages requires a systematic and standardized process of cultural

199   adaptation and validation. This is a necessary demand to assure the appropriateness of the new

200   version of the questionnaire, considering the linguistic and cultural differences(Crawford et al.

201   2011).

202   The UWIN is a validated instrument for the diagnosis of LUTS(Eid et al. 2014),

203   comprising five questions(Barqawi et al. 2011; Crawford et al. 2011). It has been developed as a

204   simplified questionnaire based on the International Prostate Symptom Score (IPSS). The IPSS is

205   the most used questionnaire for the evaluation of LUTS in men, but subjects with low education

206   level have been shown to have difficulties in completing it accurately(Johnson et al. 2008)(Barry

207   et al. 1992). Following the original publications describing the development(Barqawi et al. 2011)

208   and validation(Crawford et al. 2011) of the UWIN, other studies used the simplified tool to

209   evaluate its validity and applicability compared to the IPSS(Eid et al. 2014; Mallya et al. 2017;

210   Ramaraju et al. 2016). The UWIN provide results comparable to the IPSS while using a more

211   straightforward format and taking less time to complete and needing lesser assistance even when

212   completed by subjects with lower educational status.

213   When comparing the UWIN-Br with the IPSS, we found a strong and positive

214   correlation. Also, a high level of agreement was demonstrated in the Bland-Altman plot,

215   indicating that the UWIN-Br has diagnostic properties that are similar to those of the IPSS. Our

216   results are nearly identical to those of the original study and of subsequent validations reported

217   by Crawford et al., Eid et al. and Mallya et al.(Crawford et al. 2011; Eid et al. 2014; Mallya et al.

218   2017), which reinforces the notion that the UWIN is a reliable shorter alternative to the golden

219   standard. There was good agreement between the quality of life measured by the IPSS and the

220   one measured by the UWIN-Br.

221   The high specificity yielded by the UWIN-Br survey with a cut-off score of ≥ 8 points

222   (classified as severe) enables this instrument as a useful screening tool, as it neglects those at

223 lower risk and allows for the selective referral of individuals at higher risk to specialized, more

224 complex care.

225   To our knowledge, this is the first study to validate this instrument in Latin America and

226 the first to adapt it to Brazilian Portuguese. Also moreover, we are the first to compare the

227 UWIN scores with uroflow. This was an essential accomplishment of the present study as it

228 represents the first time the construct validity of the questionnaire was evaluated in comparison

229 to an objective and widely accepted measure of LUTS. Although its use has been recommended

230 by the original author of the instrument(Crawford et al. 2011), no studies had performed such

231 evaluation previously.

232   Uroflowmetry measures the urinary flow rate over time. It is a noninvasive evaluation

233 and represents the most widely used urodynamic test for the assessment of the voiding function.

234 It has been used in most studies evaluating medical and surgical treatments for LUTS-BPH and

235 is used as inclusion criteria for most of these studies. The maximum urinary flow rate (Qmax) is

236 the most widely used variable, despite to have moderate accuracy. Uroflowmetry with a

237 maximum flow rate of <10ml/s was reported to have lower median sensitivity and specificity of

238 68% and 70%, respectively(Malde et al. 2016).

239   Most patients answered the questionnaire by themselves without assistance. The

240 comprehension analysis demonstrated that the UWIN-Br is a self-applicable questionnaire,

241 simple and easy to answer.

242   LUTS are shown to be very common, especially among older patients(Irwin et al. 2006;

243 Van Den Eeden et al. 2012; Gravas et al. 2015). In a USA population-based study, the general

244 prevalence of LUTS was 28%, of which 40% had moderate or severe symptoms(Glasser et al.

245   2007). Another study using a telephone-based survey in Canada, Germany, Italy, Sweden, and

246   the UK found the general prevalence of LUTS to be 62.5%(Irwin et al. 2006).

247   A recently conducted study in five large Brazilian cities found the prevalence of LUTS in

248   men older than 40 years of being 69%. About 30% of participants had severe symptoms, and

249   40% were very dissatisfied with their condition(Soler et al. 2017). In our study, we found the

250   prevalence of moderate and severe symptoms to be 40% in the studied age group. These

251   differences can be explained for two reasons: Our population is older, and our sample was

252   collected in a urological clinic, which adds possible selection bias.

253   Simplified questionnaires have been recommended in the clinical practice of primary care

254   health professionals as screening instruments, particularly for patients with known risk factors, to

255   aid in the stratification of a problem and the subsequent investigation into the potential

256   worsening of detrimental health issues such as alcohol consumption and depression(Zheng et al.,

257   n.d.; Le and Dubertret 2013; Smith et al. 2009). The adoption of simplified instruments to detect

258   LUTS in primary care settings has also been reported(Martin et al. 2011; Sahai et al. 2014;

259   Kajimotu and Bowa 2018).

260   In primary care settings with limited resources and serving patients with a low education

261   level, a common scenario in Brazil, we believe that it is common sense and that health authorities

262   should recommend the following path. First, the simplified instrument should be used to stratify

263   the symptoms, and then the selected subjects recognized to be at higher risk would be referred to

264   specialists according to appropriate, specific guidelines(Zheng et al., n.d.).

265   In accord with other studies, the UWIN-Br survey was completed more rapidly and was

266   preferred by a significant proportion of respondents, who found it easier to understand(Mallya et

267   al. 2017). Its applicability, simplicity in describing the symptoms and diagnostic properties

268   enable the UWIN-Br as an alternative to the IPSS and may warrant its comprehensive

269   implementation in primary care settings. We believe the actions of this kind would considerably

270   benefit men's health, particularly in the screening of more severe cases. Simplified instruments,

271   like UWIN-Br, reduce respondent burden and increase applicability, optimizing data

272   collection18.

273   Further research is needed to evaluate how this potential advantage of the UWIN-Br in

274   primary care settings with a low prevalence of severe cases and scarce resources could be

275   reproduced in the longitudinal assessment of symptoms, in the evaluation of new therapies and

276   the detection of LUTS in different age groups and women.

277   Cross-cultural adaptation and validation of UWIN-Br for use in Brazil seemed relevant to

278   us, as the standardization and implementation of simplified self-report instruments that can be

279   understood by the greatest number of people regardless of education level will in time allow for

280   the adoption of strategies designed to bring men closer to healthcare services in Brazil, mainly in

281   primary care. Such actions are instrumental in expanding and consolidating the Brazilian

282   National Policy of Men's Health Integral Care to lessen health issues among men.

283

284   **CONCLUSION**

285

286   The UWIN-Br has adequate psychometric properties and achieves results similar to those

287   of the IPSS in the evaluation of LUTS and quality of life, but in a simplified format and with

288   better applicability. These features increase the application possibilities of this instrument,

289   especially in the context of men's health actions, enabling the early detection of men at risk of

290   LUTS worsening and their timely referral to specialized care. The UWIN-Br seems appropriate

291   for use in both clinical and research settings

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General and demographic characteristics

	Median [IQR]
Age (years)	59[52-66]
Schooling (years)	11[8-13.7]
IPSS score	6[3-12]
UWIN-Br score	3[1-5]
Marital status n (%)	
Not married	35(11.4%)
Married	247(80.7%)
Divorced	20(6.5%)
Widower	4(1.3%)

Diagnostic properties of UWIN-Br score.

UWIN Score	Sensitivity%	95% CI	Specificity%	95% CI
1	96,15	80,4% to 99,9%	9,9	6,7% to 14,1%
2	96,15	80,4% to 99,9%	29,4	24,2% to 35,1%
3	96,15	80,4% to 99,9%	43,9	38,1% to 49,9%
4	92,31	74,9% to 99,1%	62,7	56,8% to 68,4%
5	92,31	74,9% to 99,1%	75,5	70,1% to 80,4%
6	80,77	60,6% to 93,4%	84,4	79,6% to 88,4%
7	65,38	44,3% to 82,8%	91,8	88,0% to 94,7%
8	50	29,9% to 70,1%	95,7	92,6% to 97,7%
9	42,31	23,3% to 63,1%	98,2	95,9% to 99,4%
10	26,92	11,5% to 47,8%	98,9	96,9% to 99,7%
11	15,38	4,3% to 34,8%	99,3	97,4% to 99,9%
12	11,54	2,4% to 30,1%	99,7	98,1% to 99,9%

Figure 1

Spearman correlation between the IPSS and the UWIN-Br.
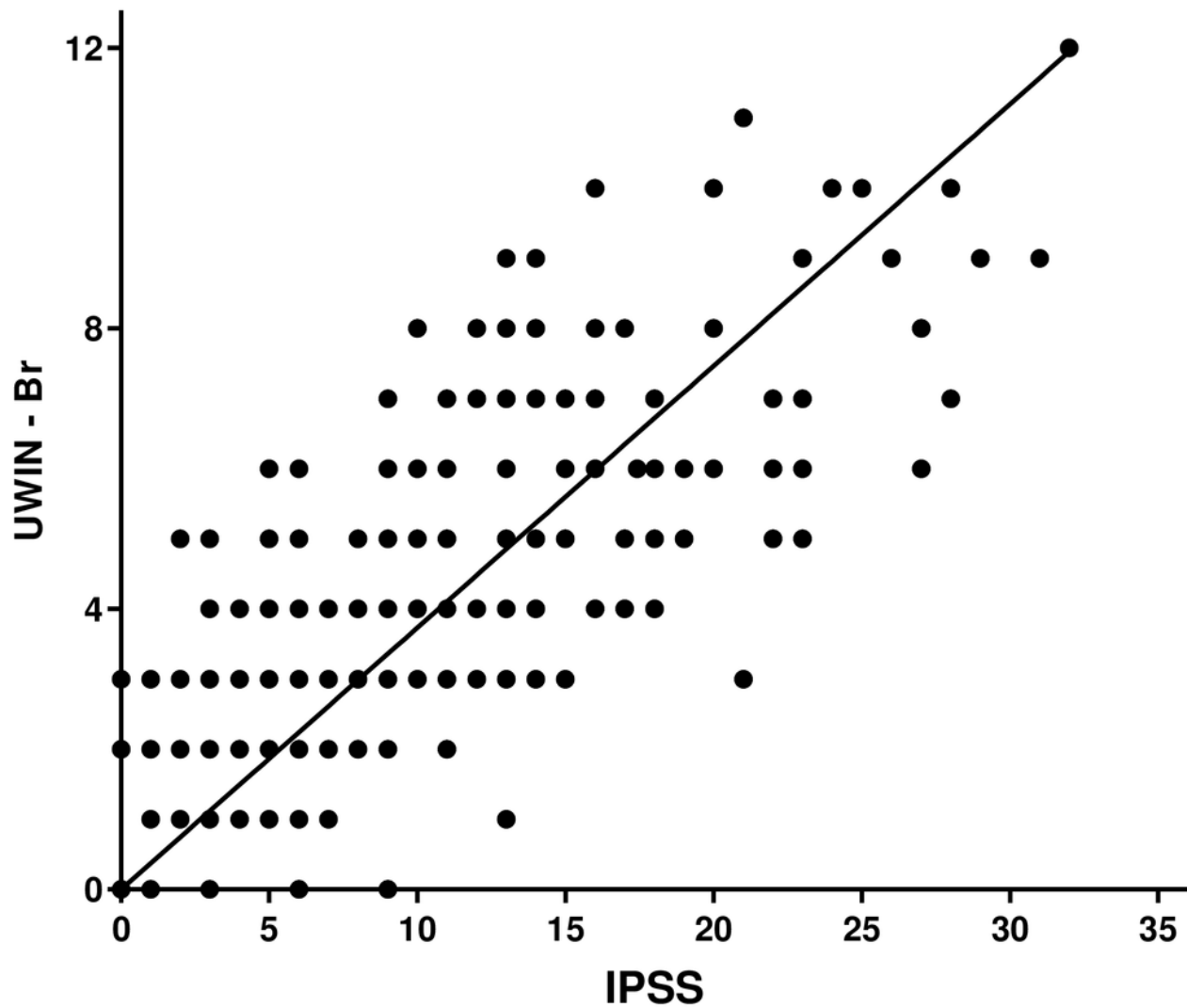
Figure 2

Bland-Altman plot shows agreement between the IPSS and the UWIN-Br.
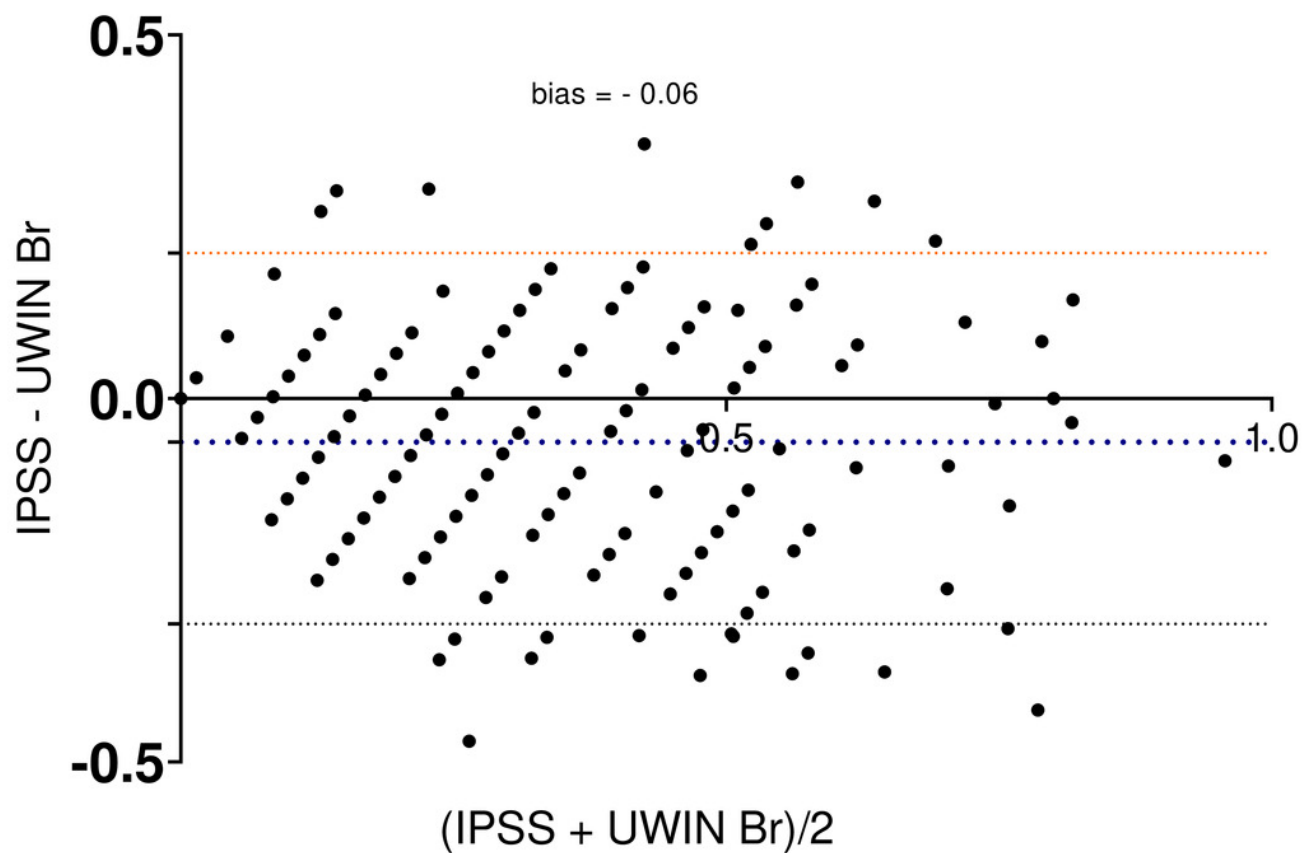
Figure 3

The relationship between symptom severity according to the UWIN-Br and maximum urinary flow rate (ml/s) determined by uroflowmetry, exhibiting a linear trend (arrow).