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RELIABILITY OF THE INTERNATIONAL PROSTATE SYMPTOM SCORE IN THE ASSESSMENT OF PATIENTS WITH LOWER URINARY TRACT SYMPTOMS AND/OR BENIGN PROSTATIC HYPERPLASIA

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ABSTRACT

Purpose: The reliability of the International Prostate Symptom Score (I-PSS) was tested in patients with lower urinary tract symptoms and/or benign prostatic hyperplasia.

Materials and Methods: A total of 71 consecutive men with benign prostatic hyperplasia and/or lower urinary tract symptoms was asked to complete the I-PSS at baseline and 8 weeks later. At the second visit the physician also completed the I-PSS according to the complaints of the patient. Variability between both scores was evaluated by calculation of duplo errors and results were compared to the clinical data.

Results: A considerable variability existed between the I-PSS results obtained at baseline and 8 weeks. The duplo error was 4.3. In a regression analysis of I-PSS, including all clinical parameters, only free flow had some predictive value for I-PSS outcomes.

Conclusions: It is important to consider the variability of the I-PSS score when making decisions concerning treatment.

KEY WORDS: prostatic hypertrophy, urination disorders, urinary tract, urologic diseases, questionnaires

Benign prostatic hyperplasia (BPH) is a common condition among elderly men.¹ Histologically, BPH has been reported in 50% of all men by age 60 years, and in nearly 100% of men older than 80 years.² BPH impacts significantly on quality of life for the aging man primarily by producing bothersome urinary symptoms. Obviously, the majority of patients seek medical attention because of symptoms.³ Consequently, symptoms have become the major focus in management of bladder outlet obstruction due to BPH.⁴ Many urologists use symptoms as the basis for diagnosis of outlet obstruction and for assessing the effects of treatment. Therefore, a number of symptom scores have been designed to permit a more objective and structured history of lower urinary tract symptoms and/or BPH.

There are several advantages in having common symptom scores, such as assessing the efficacy of treatment of BPH, and facilitating comparison of the outcomes of different treatment modalities conducted at different sites and at different times.⁵ Boyarsky et al first developed such a score,⁶ followed by Madsen and Iversen,⁷ and Fowler et al.⁸ More recently, Hald et al developed the Danish symptom score.⁹ In 1992 the American Urological Association symptom score was reported and it has been adopted by the World Health Organization as the International Prostate Symptom Score (I-PSS).¹⁰ The score has been integrated into the evaluation of patients with lower urinary tract symptoms and/or BPH, and has been recommended as a precise tool for diagnosis in these patients.¹¹ On the other hand, little is known about the natural history of patients with lower urinary tract symptoms and/or BPH, but it appears that the course is not necessarily one of deterioration. A considerable fraction of patients may show spontaneous improvement or stabilization of symptoms.¹² Also, the individual perception about the severity of disease may vary. Therefore, it is justified to question whether the clinician dealing with individual patients can rely on 1 measurement of I-PSS to recommend therapy.

PATIENTS AND METHODS

A total of 71 consecutive men with BPH and/or lower urinary tract symptoms who were referred to our prostate center participated in the study. Before therapy the patients presented twice to our department. During visit 1 a medical history (including I-PSS) was obtained, and physical examination, free uroflowmetry study, post-void residual measurement, biochemistry examinations (including prostate specific antigen), urinalysis, urine culture, renal ultrasound and transrectal ultrasonography of the prostate were performed. Two months (median 8 weeks) following visit 1 all patients underwent urodynamic investigation, including pressure-flow study analysis, and flexible urethrocytoscopy, and possible treatment options were discussed. All patients completed the I-PSS at both visits. During visit 2 the physician also completed the I-PSS according to the complaints of the patient.

Transrectal ultrasound was performed using an ultrasound scanner with a 7.5 MHz. transrectal probe (multi-3-dimensional VRW 77 AK). The prostate was imaged from base to apex, documenting the presence of prostate abnormalities and measuring the prostate volume using the planimetric method. During the same session renal ultrasound was performed with the same scanner in combination with the abdominal probe (sector AWP, 3.5 MHz.). With the same probe the post-void residual also was measured using the ellipsoid formula.

The urodynamic evaluation was performed using an 8F transurethral lumen catheter with an 8F intravesical microtip pressure sensor. The digitally stored data were recorded with equipment developed at our department. To obtain useful information from pressure-flow study curves it is necessary to relate detrusor pressure to the corresponding flow. To quantify the grade of outlet obstruction the concept of the linear passive urethral resistance relation, connecting minimal urethral opening pressure with pressure at maximum flow, was used: classes 0 and 1—no urodynamic ob-

TABLE 1. Clinical parameters and results of total I-PSS at visit 1 as completed by the patients, and at visit 2 as completed by the patients and physicians

	Mean \pm SD
Pt. age (yrs.)	63 \pm 9
Prostate vol. (cm. ³)	43 \pm 22
Maximum flow rate (ml./sec.)	10.9 \pm 4.2
Residual vol. (ml.)	56 \pm 73
Linear passive urethral resistance relation	2.2 \pm 1.4
I-PSS:	
Visit 1 (51 pts.)	16.9 \pm 5.9
Visit 2 (67 pts.)	15.6 \pm 7.46
Visit 2 (68 physicians)	15.2 \pm 6.41

struction, classes 2 and 3—moderate bladder outlet obstruction, and higher classes—severe obstruction.¹³

Systematic errors in the completion of the I-PSS were evaluated by calculating the mean difference of the total score between visits 1 and 2 as noted by the patient and physician. Statistical significance of these 2 mean differences was determined by Student's *t* test as well as by calculating 95% confidence intervals. Random variability of the I-PSS was evaluated by calculation of the duplo error according to: $\sqrt{\Sigma(d_i - d')^2/2(n - 1)}$, where d_i is the difference between measurements 1 and 2, d' is the systematic error and n is the number of patients. When the systematic error is 0, this formula reduces to: $\sqrt{\Sigma(d_i^2)/2n}$. If the interpretation of the duplo error is estimated to be 4 and the I-PSS is 20 at visit 1, then the score might be $20 \pm (2 \times 4) = 12$ to 28 at visit 2 due to random variation alone.

The independent influence of objective parameters on the I-PSS was evaluated with multivariate linear regression models. With multiple linear regression analyses we also evaluated whether any of the objective parameters could predict a difference in the I-PSS at both visits. In these latter analyses the absolute differences were modeled as a dependent variable.

RESULTS

Patient age ranged from 44 to 83 years (mean plus or minus standard deviation 63 \pm 9). Mean prostate volume

was 43 \pm 22 cm.³ (range 16 to 113), mean free maximum flow was 10.9 \pm 4.2 ml. per second (range 1.9 to 22.0) and mean voided volume was 270 \pm 158 ml. (range 60 to 859 ml.). Post-void residual ranged from 0 to 280 ml. (mean 56 \pm 73) and mean linear passive urethral resistance relation was 2.2 \pm 1.4 (range 0 to 5). The results of the I-PSS at visit 1 as completed by the patients, and at visit 2 as completed by the patients and physicians are shown in table 1. There appeared to be no statistically significant systematic difference between the I-PSS at both visits. Patient scores at visit 1 minus those at visit 2 resulted in a mean difference (systematic error) of 1.6 points with a standard error of 0.9 and a 95% confidence interval of -0.1 to 3.2. Since 0 lay in this interval there was no statistically significant systematic error ($p = 0.07$). However, when patient scores were evaluated at visit 1 minus those at visit 2 some considerable differences were noted (fig. 1). Cases with higher and lower scores tend to skew to the right of figure 1, indicating a somewhat lower I-PSS result at visit 2. Questions 1 and 4 had the highest and question 7 had the lowest random variation (fig. 2). The duplo error between visits 1 and 2 was 4.3.

Concerning patient scores minus physician scores at visit 2, the systematic error was 0.5 with a 95% confidence interval of -0.6 to 1.6, which was not significant. Again, a significant number of patients had a different score at visit 2 as noted by patients and physicians, with patient scores somewhat higher than physician scores (fig. 3). Question 4 had the highest and question 7 had the lowest random variation.

When comparing I-PSS patient scores at visits 1 and 2 the correlation was 63% (Pearson test). The correlation between patient and physician scores at visit 2 was 77% (Pearson test). The duplo error between the total score as noted by the patient and physician at visit 2 was 3.4. In a linear regression analysis of I-PSS related to patient age, maximum free flow, post-void residual, prostate volume and linear passive urethral resistance relation only free flow had some predictive value for I-PSS (table 2). There was a statistically significant inverse correlation between the standard I-PSS and free flow. If a patient scored 1 point higher on the maximum free flow scale, he scored 0.82 point lower on the I-PSS. Moreover, none of the objective parameters predicted a difference in the I-PSS at either visit.

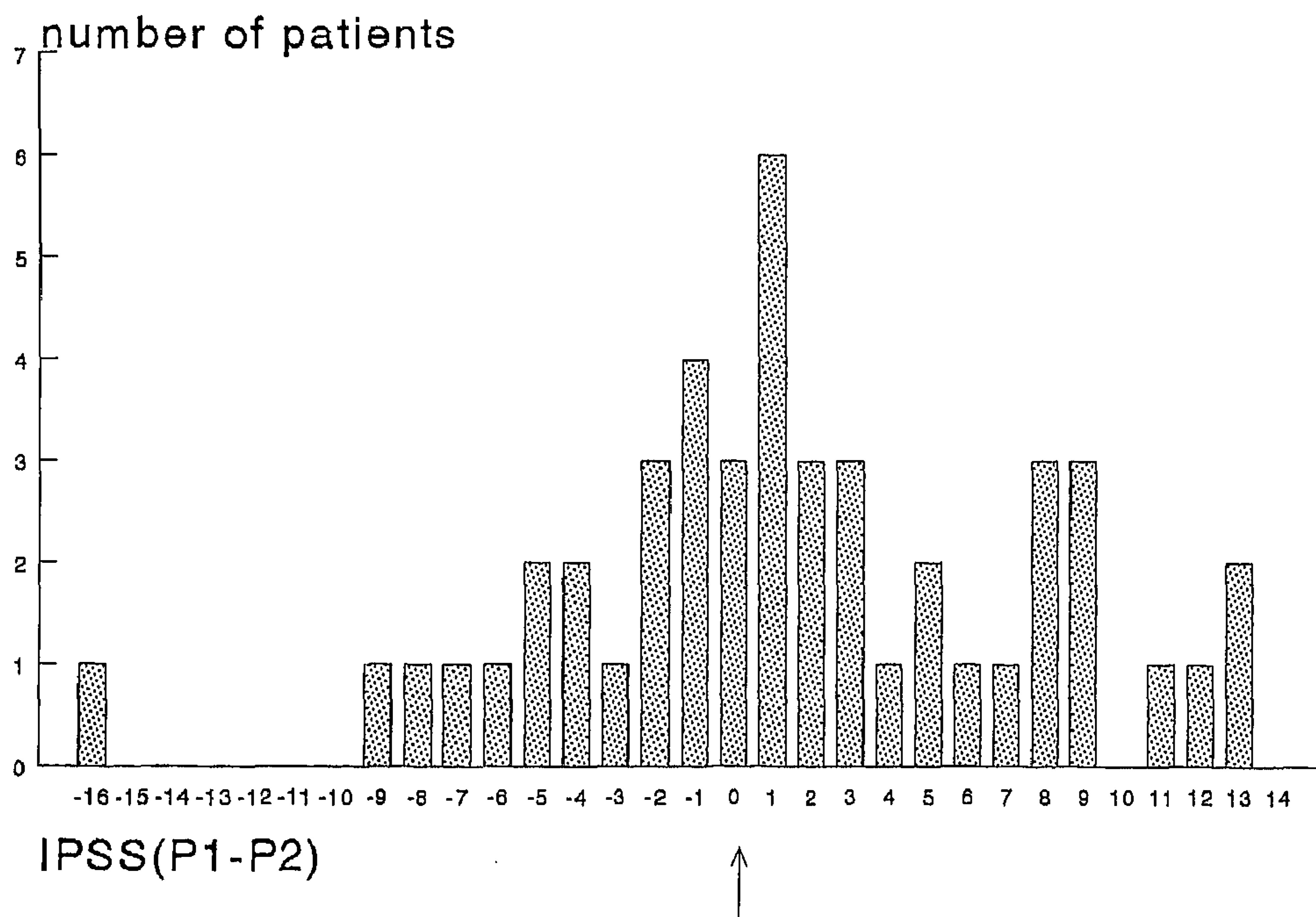


FIG. 1. Histogram for difference between patient (P) I-PSS scores at visits 1 and 2

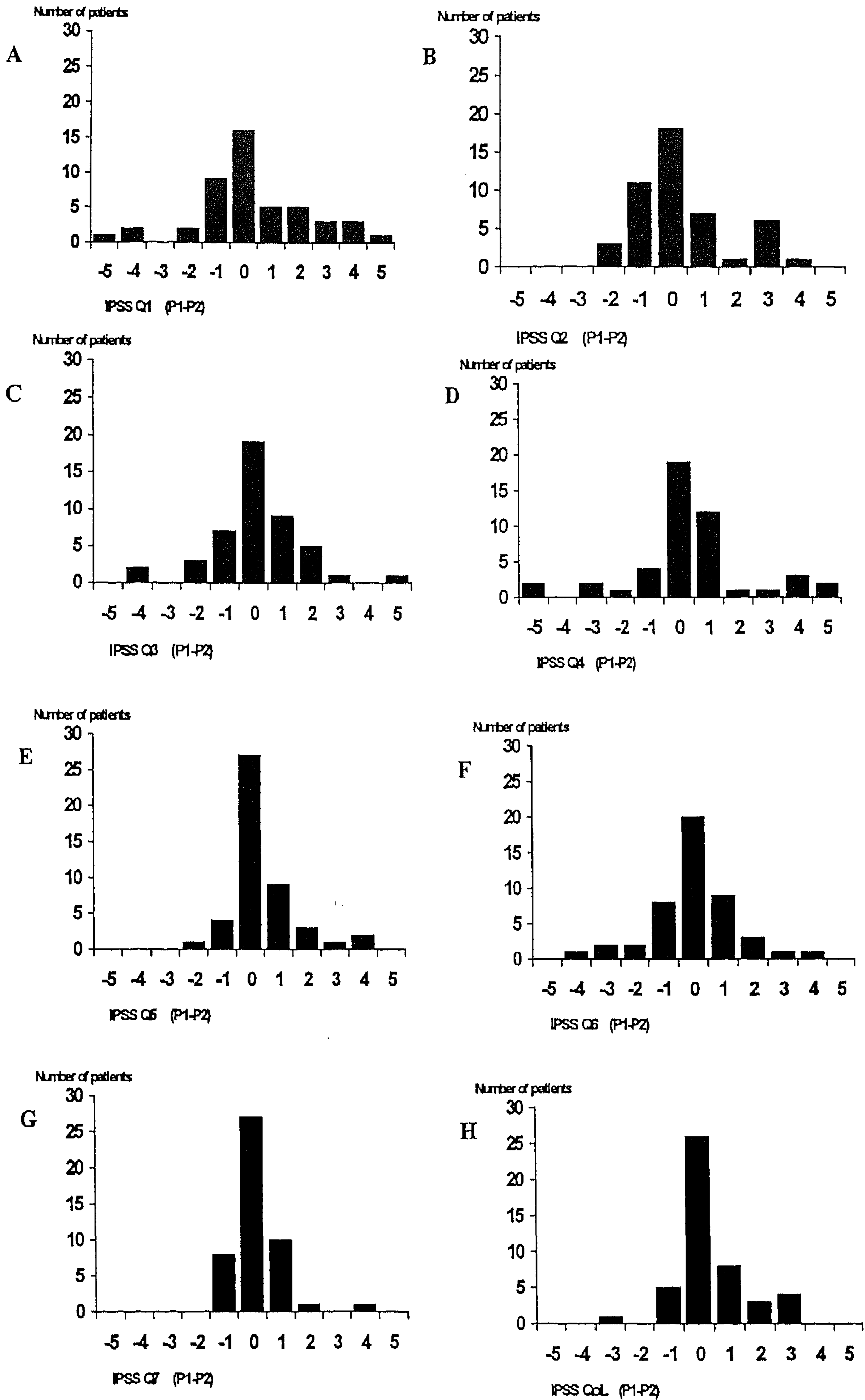


FIG. 2. Histogram for difference between patient (P) I-PSS scores at visits 1 and 2 regarding questions (Q) 1 to 7 of I-PSS score (A to G) and quality of life (QOL) question (H).

DISCUSSION

The most widely used symptom score in the assessment and followup of patients with lower urinary tract symptoms and BPH is the I-PSS (table 3). To rely on this questionnaire, it is mandatory to evaluate test reliability. Barry et al noted that test reliability can be increased by basing decisions on the mean of 2 or more measurements from the same pa-

tient.¹⁴ Because symptoms can vary data to estimate within patient variability must come from repeated measures of the variable during a period short enough so that it is unlikely that true consistent changes in patient condition have occurred.

In our study the majority of measurements were repeated within 8 weeks, since the waiting list for visit 2 takes that

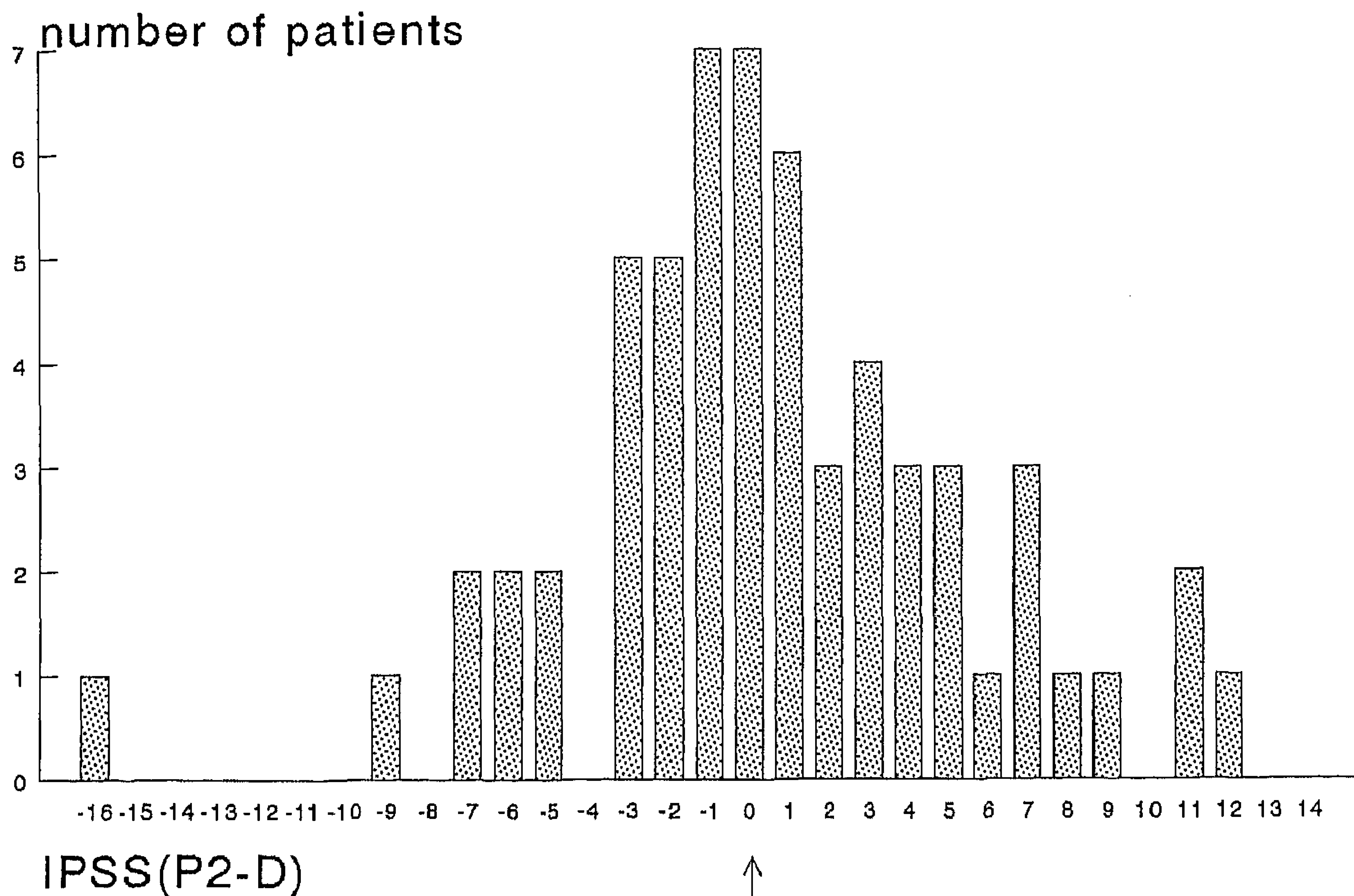


FIG. 3. Histogram for difference between patient (*P*) and physician (*D*) I-PSS scores at visit 2

TABLE 2. Linear regression analysis on I-PSS of different clinical and urodynamic parameters

	$\beta_{\text{coefficient}}$	SE	p Value
Intercept	21.04	8.04	0.01
Pt. age (yrs.)	0.04	0.12	0.73
Maximum flow rate (ml./sec.)	-0.82	0.24	0.001
Residual vol. (ml.)	-0.01	0.01	0.44
Prostate vol. (cm. ³)	0.04	0.05	0.35
Linear passive urethral resistance relation	-1.04	2.69	0.70

The explained variance of this model is 0.22.

long. We observed a tendency for lower scores at visit 2, 8 weeks after visit 1, which is difficult to explain. The learning effect may result in a lower score or the patient may better observe voiding and document it more accurately. Also, patients may believe the complaints to be more serious than they actually are, and they may initially be worried about prostate cancer and become less concerned when carcinoma is ruled out. Indeed, patients tend to overestimate the complaints, which is illustrated by the higher score obtained by the patient than by the physician (table 1). In general, however, our results are within the 95% confidence intervals. Therefore we concluded that no statistically significant systematic error exists. Although we do not expect a systematic error we do expect a significant random variation. In our study the duplo error for the difference between total I-PSS patient scores at visits 1 and 2 was 4.3. A similar conclusion can be made when measuring the duplo error of patient and physician scores at visit 2. This error was somewhat smaller than the duplo error of patient scores at both visits.

The changes found in total patient I-PSS scores at both visits, and between patient and physician scores at visit 2 are presented in figure 4. If a score of more than 12 is mandatory for inclusion in a treatment protocol, then 12 patients (24%) did and did not comply with this requirement at visits 1 and 2, respectively, which is significant. Therefore, we believe that the decision on whether to treat the patient using symptom scores as the sole criterion should be made at an interval of 8 weeks. Also, we learned from a study in a large number of patients followed according to a watchful waiting protocol

that those without urologically proved obstruction had fewer complaints at 6 months of followup, while those with obstruction still had a symptom score at the same level.¹² Therefore, we should perhaps include the results of urodynamic studies with pressure-flow study analysis to improve the reliability of the I-PSS results. However, in a considerable number of studies no significant correlation was found between the results of symptom scores and urodynamic studies.¹⁵ Also, in our study a regression analysis showed that the grade of bladder outlet obstruction (expressed by the linear passive urethral resistance relation result) had no predictive value for I-PSS.

The diagnosis of patients with BPH and/or lower urinary tract symptoms, and the decision to treat are based largely on the nature and severity of the presenting symptoms.³ During recent years we learned that the presenting complaints are not caused by a single factor but by a combination of factors. The recommendation that objective evaluations are optional may tempt clinicians to refrain from their use and, thus, only rely on symptoms. In view of the emerging newer and more complex technologies in our armamentarium,¹⁶⁻¹⁹ all efforts must be made to obtain accurate tools for assessment and evaluation of patients who present with complaints. From our study we learned that at an interval of 8 weeks, one-quarter of all patients no longer complied with the inclusion criteria for treatment used at our department, which is in accordance with previous findings.¹⁴

CONCLUSIONS

We agree that the I-PSS can be an important tool in assessing patient perception of the clinical problem, and should be used only for baseline and followup evaluation of these patients. Moreover, one must keep in mind the variability of the I-PSS when making decisions concerning (surgical) treatment. Therefore, we recommend that at the baseline preferably 2 I-PSS questionnaires be completed and that the second score be used as the baseline. In case of a significant difference in scores, a third I-PSS questionnaire should possibly be completed at an 8-week interval before deciding whether to treat the patient.

TABLE 3. I-PSS score

Question	Not at All	Less Than 1 Time in 5	Less Than Half the Time	About Half the Time	More Than Half the Time	Almost Always
1. Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
2. Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
3. Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
4. Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
5. Over the past month, how often have you had a weak urinary system?	0	1	2	3	4	5
6. Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
	None	1 Time	2 Times	3 Times	4 Times	5 or More Times
7. Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0	1	2	3	4	5

Total I-PPS Score S =

Quality of Life Due to Urinary Symptoms

	Delighted	Pleased	Mostly Satisfied	Mixed, About Equality Satisfied and Dissatisfied	Mostly Dissatisfied	Unhappy	Terrible
1. If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	0	1	2	3	4	5	6

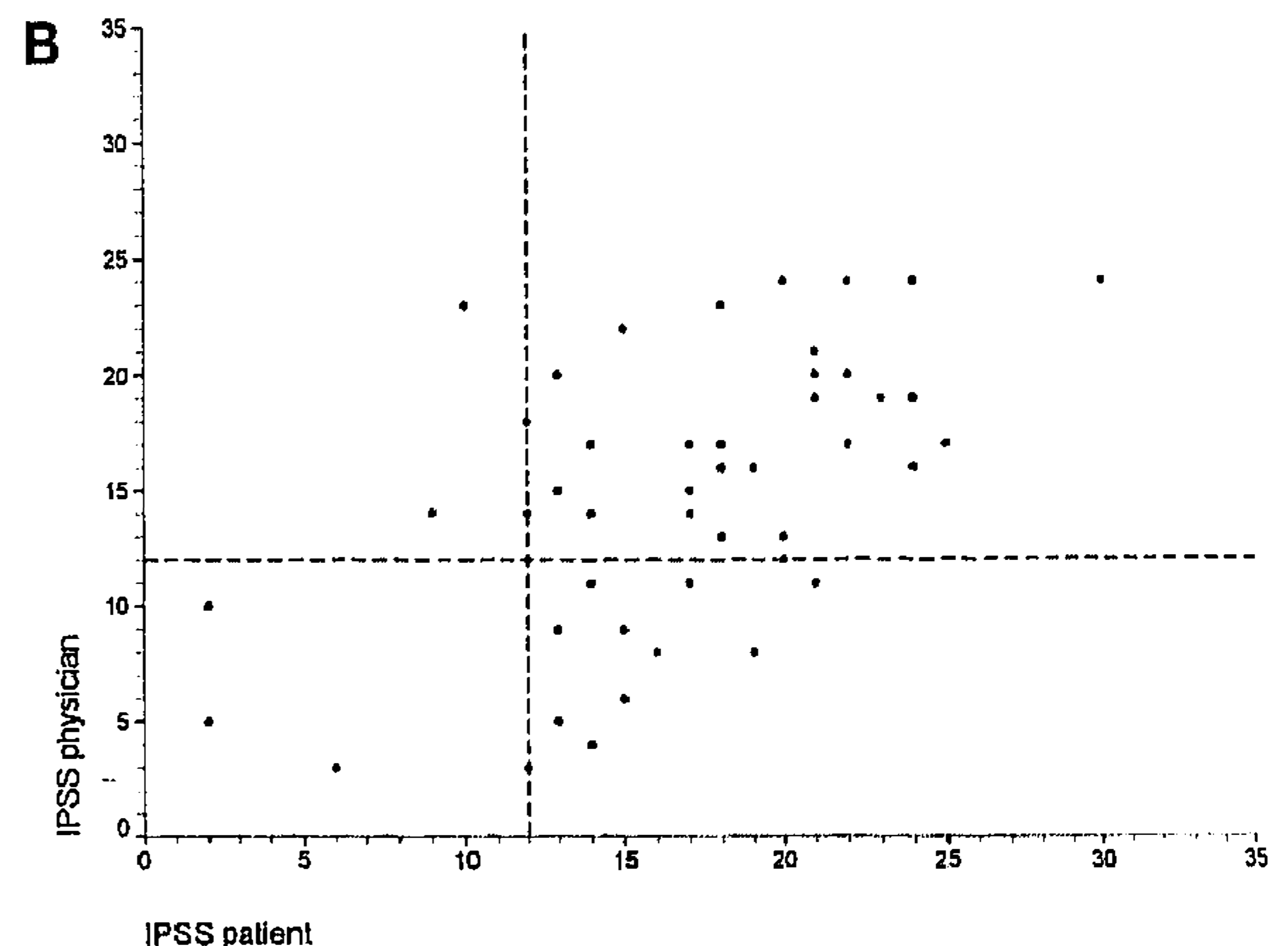
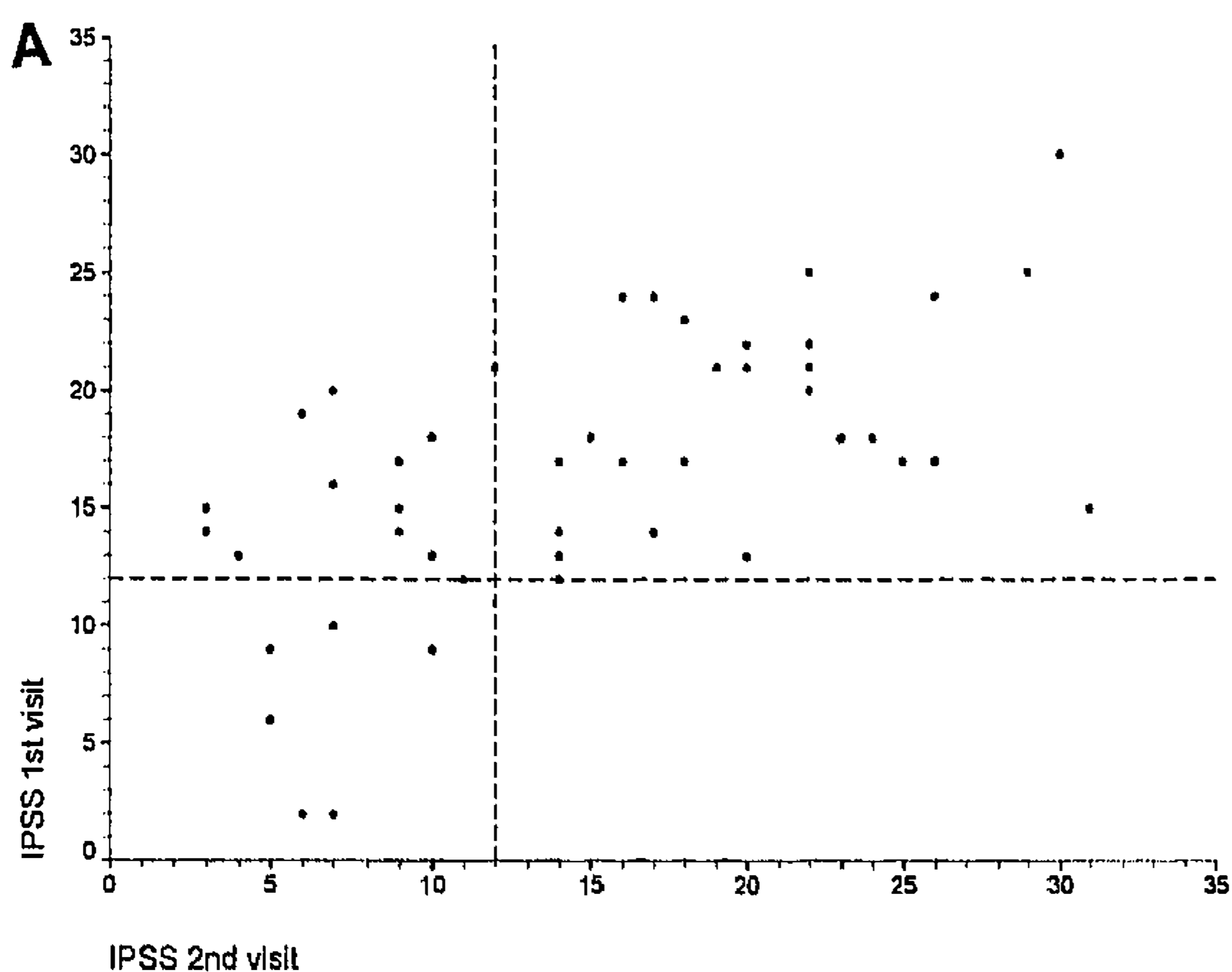


FIG. 4. A, scatterplot of patient I-PSS scores at visits 1 and 2 for 49 patients. Correlation coefficient is 0.63. B, scatterplot of patient and physician I-PSS scores at visit 2 for 66 patients. Correlation coefficient is 0.77.

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EDITORIAL COMMENT

It is clear that many patients with BPH do not understand the symptom score index. The American terminology used also is not always understandable to some men. Moreover, the translation of the symptom score into another language may not be clear.

In our studies focusing on black men with BPH we found it necessary to assist the patient so that he could understand each of the symptoms. Classification of the I-PSS by the patient was enhanced at visit 2 when the volunteer or nurse who presented the symptom score questionnaire to the patient had better interaction with the patient and repeated the questions. Only after the third symptom score presentation was the patient confident of the symptoms and a more reliable score was obtained.

I reviewed a previous article from Brazil in which the urologist interviewed natives, semi-illiterate and illiterate, who did not understand the BPH symptom score. Only after a recommended third evaluation of the I-PSS, which we suggested, did we believe that the native men would have a more complete and better understanding of the questions related to BPH. We believe they needed assistance at all 3 evaluations. We recommended that the evaluations be done 2 months apart. Inclusion of a urodynamic evaluation also enhances the article.

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