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ORIGINAL ARTICLE

Validation study of new clinical scoring — "Apollo Clinical Scoring system" for bladder pain syndrome/interstitial cystitis and comparison of outcome with standard "O'Leary–Sant score"

Rajesh Taneja[1] · Ashutosh Kumar Singh[1] · Ankur Sharma[1] · Nilesh Taneja[1] · Apeksha Raheja[1]

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Abstract

Aim Validation of the recently published newer clinical scoring system for bladder pain syndrome/interstitial cystitis and comparison of the results with the pre-existing standard O'Leary–Sant score.

Introduction The symptoms are our primary guide to disease severity analysis, treatment, and response monitoring. The combined ICSI/ICPI (O'Leary–Sant Interstitial Cystitis Symptom and Problem Index) consist of a four-item symptom and problem index focusing on urgency, frequency, nocturia, and pain. A new scale, assigning more weight to pain and nocturia and adding the domains of sexual dysfunction and psychological impact, has been published by one of the authors (El Khoudary et al. J Women's Health 2002. 18:1361-1368; 7).

Material and methods This is a prospective study conducted to validate a newer clinical scoring system, namedht e 'Apollo Clinical Scoring' (ACS) system for patients with bladder pain syndrome/ interstitial cystitis (BPS/IC), and to compare its outcome with the simultaneously applied standard O'Leary–Sant (OLS) score. Thirty-five patients of BPS/IC diagnosed using the ESSIC definition were enrolled in the study and followed for 6 months. Intraclass correlation coefficient (ICC) for test–retest reliability, and Cronbach's α for measure of internal consistency, were applied to both scoring systems.

Results Intraclass correlation coefficient for ACS was 0.715 and for OLS was 0.689. Cronbach's α for ACS was 0.736 and for OLS was 0.698.

Conclusion The present study suggests that the recently devised Apollo Clinical Scoring (ACS) system for patients of BPS/IC is internally consistent and a reliable scoring system. When compared with OLS in parallel setting, the newer ACS appeared to be marginally better.

Keywords Interstitial cystitis · Bladder pain syndrome · Clinical scoring

Aims and objectives

The aims of the present study were to apply simultaneously the recently published new scoring system for patients with BPS/IC along with the O'Leary–Sant score in a prospective observational study. Further, statistical validation methods were applied to both the systems and their outcomes compared. The newly used scoring system has been named the 'Apollo Clinical Scoring' system, after the institution where this study was carried out.

Introduction

Bladder pain syndrome, earlier known as interstitial cystitis [1], is a chronic bladder disease characterized by combination of symptoms, mainly pelvic pain including urogenital areas associated with urinary symptoms such as frequency, urgency. Bladder pain syndrome/interstitial cystitis (BPS/IC) is a clinical diagnosis based on symptoms and exclusion of other diseases associated with pelvic pain [2].

Quantification of symptoms is essential for disease severity analysis, treatment, and response monitoring. The existing self-administered symptom scores for BPS/IC which

✉ Rajesh Taneja
rajeshtanejadr@yahoo.com

[1] Department of Urology and Robotic Surgery, Indraprastha Apollo Hospitals, Room number 1019, New Delhi 110070, India

have been in use to quantify this disease process include the O'Leary–Sant Symptom and Problem Index, Wisconsin Interstitial Cystitis scale (UW-IC), Pain Urgency Frequency scale (PUF), and Bladder Pain Symptom Score (BPS-SS) [3–6]. Of these, the combined O'Leary–Sant Symptom and Problem Index is most widely used. The UW-IC is a validated scale, but has not been used extensively in clinical practice. The PUF score has additional domains of pelvic pain and dyspareunia. This scale has not been subjected to validation process. BPS-SS was proposed in 2012 by Humphrey et al. [6]. However, it is yet to be used widely.

O´Leary–Sant scale (OLS)

The combined ICSI/ICPI (O'Leary–Sant Symptom and Problem Index) consists of a four-item symptom and problem index focusing on urgency, frequency, nocturia, and pain. It has been in use since 1997, and has been shown to be effective both as a screening tool and an outcome measure [3]. It has four domains examining urinary urgency, frequency, nocturia, and pain, and gives a total score based on the sum from 0–20 (Fig. 1). However, the scale has certain points of weakness that need to be considered.

The domains of pain and nocturia

The domains of pain and nocturia, while being part of the questionnaire, play larger roles in the condition than their mere inclusion accounts for. Both these domains have been independently linked to poor quality of life in BPS/IC patients [7].

Pain in BPS/IC has been linked to poorer mental health, depression, greater disability and overall poor quality of life [8, 9]. Pain is central to the condition, and its severity should carry the most weight in the classification of a patient's syndrome. Nocturnal symptoms of BPS/IC affect the quality of life of BPS/IC by more than one count. A study of 3,397 women with BPS/IC found that short sleep duration was significantly associated with a higher level of life impairment and poorer self-reported physical health [10].

Domain of sexual dysfunction

Some form of sexual dysfunction is present in as much as 90% of patients. According to a survey of 1469 women with BPS/IC, it can present as general sexual dysfunction, lack of sexual interest, arousal difficulties, or bladder pain before or after sex [10, 11]. The addition of a sexual dysfunction domain to the alternative survey UPOINT was actually found to improve the scale's association with symptom severity [12]. Multiple studies have tied the condition to decreased sexual function [10, 13].These symptoms are intricately related to the other symptoms of BPS/IC and to the condition as a whole.

Domain of psychological impact of BPS/IC

BPS/IC is, by definition, a chronic pain syndrome. Chronic pain is known to be correlated with increased rates of depression and other psychological comorbidities [14]. Similarly, studies have now identified increased rates of depression in patients with BPS/IC [15–20].The UPOINT scale developed by Nickel et al. acknowledges the need for a psychosocial component, but limits its analysis to an inclusion into or exclusion from each domain [21].

In order to have a better and more accurate understanding of a patient's clinical condition, the BPS/IC questionnaire should be adapted to include both sexual dysfunction and psychological impact, and to give proper weighting to pain, the most central condition, and nocturia, the only other condition found to be independently correlated with quality of life [22].

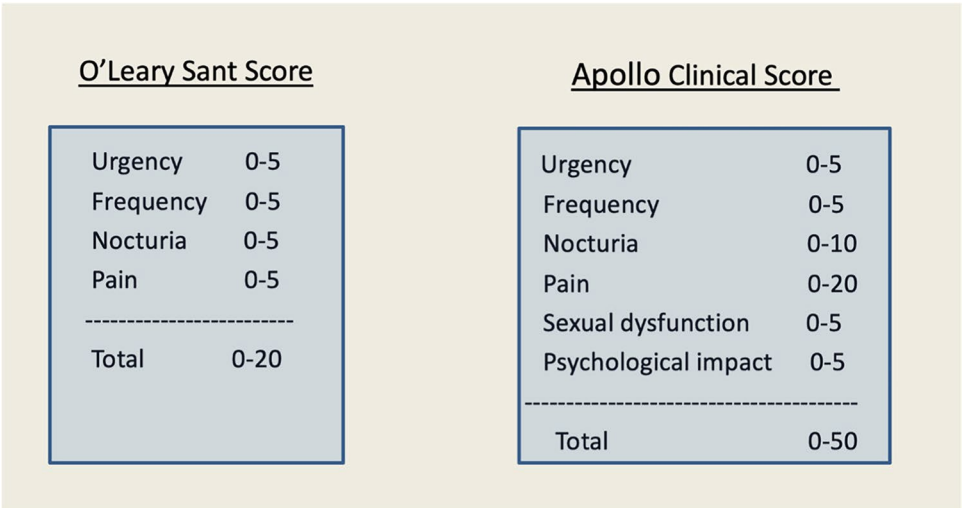

Fig. 1 The scoring systems

Taneja and Massand have proposed a modified scoring system which addresses the above concerns [23]. It uses the four domains used by OLS and adds two new domains — sexual dysfunction and psychological impact. In order to emphasize the impact of pain and nocturia on the quality of life, the weighting of their scores have been increased. While the scoring of pain is from 4–20, it is from 2–10 for nocturia. The scoring for the domains of frequency, urgency, sexual dysfunction, and psychological impact have been assigned from 1–5. This makes a maximum score of 50 (Fig. 2).

The current article is a prospective study based on the above-mentioned scoring system, with an attempt to validate it and compare with OLS. This system of scoring has been referred to and named as the Apollo Clinical Scoring (ACS) system, after the name of the institution where this work has been carried out.

Material and methods

This is a single centre, prospective, observational, and comparative study , including 35 patients who had been diagnosed with bladder pain syndrome as per the ESSIC definition. The inclusion criteria were any patients diagnosed with bladder pain syndrome strictly as per the ESSIC criteria after carefully excluding the probable causes listed by Van de Merwe et al. [2]. The study was approved by the Ethics committee of the Institution-wide registration number '313-20120-192-230417', dated 27 November 2019.

Standard work-up included detailed history and physical examination. Bladder diary, urine analysis, and screening ultrasound examination with estimation of post-void residual urine were performed in all patients. The intravesical anaesthetic challenge test [24] was done only if required.

All patients underwent cystoscopy and bladder biopsy under general anaesthesia as per the institution protocol [25]. Hydrodistension and electro ablation of Hunner's lesion was done if indicated. Treatment was administered as per institute protocol [23].

The clinical presentation of patients were assessed using two parallel scoring systems, the standard O'Leary–Sant score (OLS) and the new Apollo Clinical Score (ACS). Follow-up scores were taken at 1, 3, and 6 months on both scoring systems.

Statistical methods

The data was presented in terms of descriptive statistics: range (minimum, maximum), mean [± SD)/ median (interquartile range (IQR)] for the quantitative variable at baseline and at monthly follow up period for 6 months.

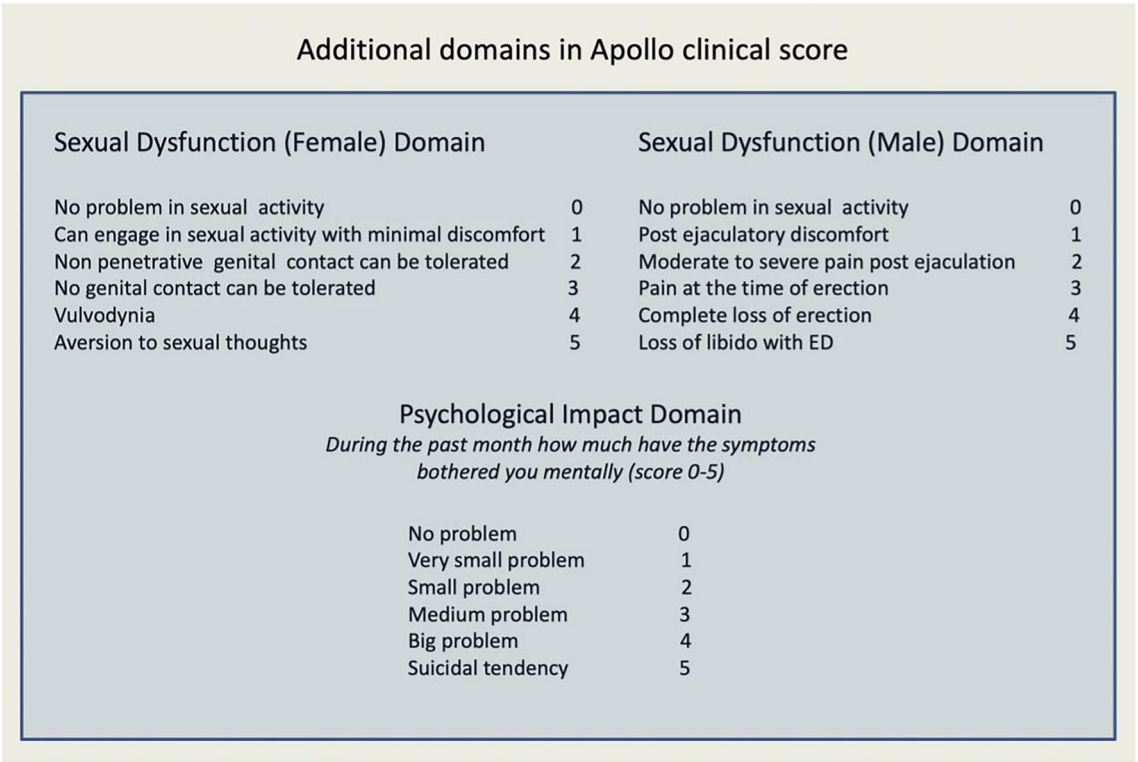

Fig. 2 The additional domains in the Apollo Clinical Score

Table 1 Mean ACS score

	ACS at 0 months	ACS at 1 month	ACS at 3 months	ACS at 6 months
Minimum	27	7	4	6
Maximum	50	45	44	45
Mean	39.06	23.03	19.80	22.59
Std. deviation	6.695	9.057	9.251	11.450
Median	41.00	20.00	19.00	18.50
Std. error of mean	1.132	1.531	1.564	2.441

The qualitative variables were presented in terms of frequency (%) under different categories at the time of baseline and follow-up.

The Pearson's correlation coefficient/non parametric Spearman's rank correlation and intra- class correlation coefficient were calculated to assess test–retest reliability, along with statistical significance for sub and total scores. Cronbach's α statistics was calculated to evaluate internal consistency among the item in individual domains.

The level of statistical significance was taken as *p* value less /equal to 0.05. The data was analysed using SPSS statistical software version 22.0.

Observations

In the present study, 35 patients of BPS/IC diagnosed using the ESSIC definition were enrolled.

On cystoscopy, 11/35 patients (31.42%) were found to have Hunner's lesions; 4/35 (11.42%) had only glomerulations.

Mean ACS score at baseline was 39.06; mean ACS score at 1 month was 23.03, at 3 months was 19.80, and at 6 months was 22.59 (Table 1). Mean OLS score at baseline was 16.97, at 1 month was 10.11, at 3 months was 8.69, and at 6 months was 9.45 (Table 2).

Change in score during follow-up on ACS scale

Maximum change in ACS score from 0 to 1 month was 33, from 0 to 3 months was 37, from 0 to 6 months was 35. Mean changes in ACS score from 0 to 1 month was 16.03, from 0 to 3 months was 19.26, and from 0 to 6 months was 17.27 ($n = 22$). Percentage change in ACS score from 0 to 1 month was 81.06%, from 1 to 3 months was 85.71%, and from 0 to 6 months was 82.78%.

Change in score during follow-up on OLS scale

Maximum change in OLS score from 0 to 1 month was 13, from 0 to 3 months was 15, and 0 to 6 months was 14 . Mean changes on OLS score from 0 to 1 month was 6.86, from 0 to 3 months was 8.29, from 0 to 6 months was 7.73. Percentage change in OLS score from 0 to 1 month was 68.42%, from 0 to 3 months was 80% and from 0 to 6 months was 73.68%.

Comparison of clinical score at baseline and follow up

Mean score on ACS and OLS in present study was 39.06 vs 16.97 at baseline, 23.03 vs 10.11 at 1 month, 19.80 vs 8.69 at 3 months and 22.95 vs 9.45 at 6 months.

Mean change in score on ACS and OLS scale in present study was 16.03 vs 6.86 from 0 to 1 month, 19.26 vs 8.29 from 1 to 3 months and 17.27 vs 7.73 from 3 to 6 months. Percentage of mean change on ACS and OLS was 41.70% vs 40.75% from 0 to 1 month, 49.39% vs 47.87% from 1 to 3 months and 43.65% vs 44.65% from 3 to 6 months. Mean score and changes in mean score on the two scoring systems were different due to different total sum score (50 vs 20) and different domains (six vs four) in ACS vs OLS respectively. But the percentage of mean changes on the two scoring systems were almost the same. (Fig. 3)

Validation analysis

Test–retest reliability

The intraclass correlation coefficient (ICC) measures test–retest reliability of instruments. It refers to the stability of responses to repeated measures of the same

Table 2 Mean OLS score

	OLS at 0 months	OLS at 1 month	OLS at 3 months	OLS at 6 months
Minimum	8	3	3	4
Maximum	20	18	18	19
Mean	16.97	10.11	8.69	9.45
Std. deviation	2.945	3.579	3.411	4.688
Median	17.00	9.00	8.00	8.00
Std. error of mean	.498	.605	.577	.999

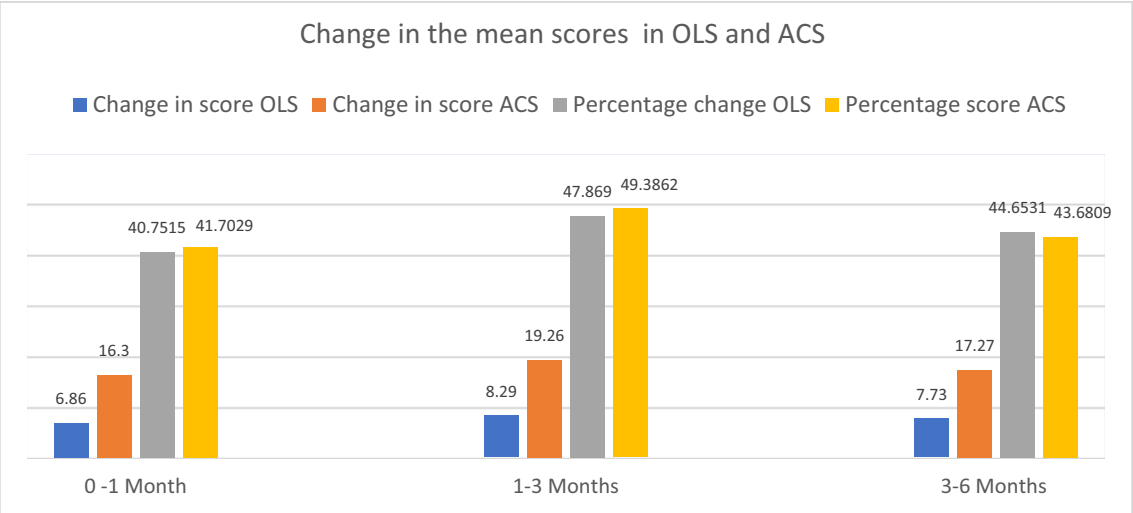

Fig. 3 Change in the mean scores in OLS and ACS

questionnaires. The ICC ranges from 0.0 to 1.0, where values less than 0.5 are indicative of poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability, and values greater than 0.90 indicate excellent reliability.

Internal consistency

Cronbach's coefficient α is the statistic for reporting internal consistency of instruments which measures the homogeneity of items in a scale, and the extent to which the scale is free of random errors. The coefficient may range from a low of 0.0 to a maximum of 1.0, with the desired range of scores between 0.70 and 0.95.

Validity of both instruments (ACS and OLS) was analysed using the intraclass correlation coefficient (ICC) (measure of test–retest reliability) and Cronbach's α (measure of internal consistency). Intraclass correlation coefficient (ICC) and Cronbach's α were calculated using baseline score and score at 1 month for both the scales ACS and OLS.

Reliability statistics for ACS

Cronbach's α for ACS in the present study was 0.736, which appears to be in the desired range.

Intraclass correlation coefficient for ACS was 0.715, which indicates moderate reliability with domain-wise ICC varying from 0.486 to 0.867 (Tables 3 and 4).

Reliability statistics for OLS

Cronbach's α for OLS in present study was 0.698, which appears slightly less than the level of desired range. The intraclass correlation coefficient was 0.689, which indicates moderate reliability, with individual item ICCs varying from 0.479 to 0.725.

Discussion

Pain and nocturia create an important distinction between the two major subsets of bladder pain syndrome, and therefore the current scoring system being discussed here may be capable of differentiating patients with or without Hunner's lesions (HL). Patients with HL are usually as uncomfortable at night as during the day, while the other subset of non-Hunner's lesion usually have very few or no incidences of nocturia. The next logical step after validation of

Table 3 Intraclass correlation coefficient for ACS

	Intraclass correlation	95% confidence interval		F test with true value = 0			
		Lower bound	Upper bound	Value	df1	df2	Sig.
Single measures	.556	.278	.748	3.509	34	34	.000
Average measures	.715	.435	.856	3.509	34	34	.000

Table 4 Intraclass correlation coefficient for OLS

	Intraclass correlation	95% confidence interval		F test with true value = 0			
		Lower bound	Upper bound	Value	df1	df2	Sig
Single Measures	.526	.238	.729	3.219	34	34	.000
Average Measures	.689	.385	.843	3.219	34	34	.000

this scoring system could be to analyze the scores of both these subsets at the entry level and see if this system can be used to predict the presence of HL in the patients. The domain of nocturia may be a reflection of bladder capacity, and this can be correlated in further studies.

Validation characteristics of OLS and ACS were studied and compared. The mean score changes are almost the same in both ACS and OLS scales when considered as a percentage. Since the number of domains is greater and total score is high in ACS, the absolute numbers are different, hence percentage is used for comparison. (Fig. 4 and 5)

The existing literature on validation of various clinical scoring systems for BPS/IC has been reviewed. (Table 5)

Lubeck et al. [26] evaluated the psychometric properties of O'Leary–Sant ICSI in a randomized double-blind study of three different daily doses of PPS in 376 patients. They used the intraclass correlation coefficient (ICC) as a measure of test–retest reliability, and found that ICC for ICSI score was 0.80, and Cronbach's α as a measure of internal consistency, and found the coefficient was 0.72 for the OLS ICSI score. In the present study, ICC for both OLS (0.689) and ACS (0.715) was lower and Cronbach's α for OLS (0.698) was lower but for ACS (0.736) was marginally higher.

Marcella LV et al. [28] in their study evaluated the test-retest reliability for the Brazilian version of the Interstitial Cystitis Symptom Index and Problem Index and Pelvic Pain and Urgency/Frequency (PUF) Patient Symptom Scale. They evaluated 30 patients of BPS/IC using OLS ICSI, ICPI,and PUF score to calculate ICC, and found that ICC for ICSI was 0.56, for ICPI was 0.48, and for PUF was 0.49, which did not did not reach appropriate values for reliability. In the present study, the value of ICC was better for both OLS and ACS.

Arlandis et al. [29] in their study evaluated the validity of the Spanish version of the Bladder Pain/Interstitial Cystitis-Symptom Score (BPS-SS). They evaluated 243 patients of BPS/IC using BPIC-SS questionnaire to calculate ICC and Cronbach's α. They found that ICC for BPIC-SS score was 0.82, with individual ICC items of the score ranging from 0.5–0.9 per item showing good reliability for the instrument. The value of Cronbach's α was 0.92 for the BPIC-SS score, which met the criterion of good internal consistency. In the present study, both ICC and Cronbach's α for OLS and ACS were lower than reported in this study.

Esen et al. [27] in their study evaluated reliability and validity of Turkish versions of the Interstitial Cystitis Symptom Index and Interstitial Cystitis Problem Index. They evaluated 79 patients of BPS/IC using a translated Turkish version of ICSI

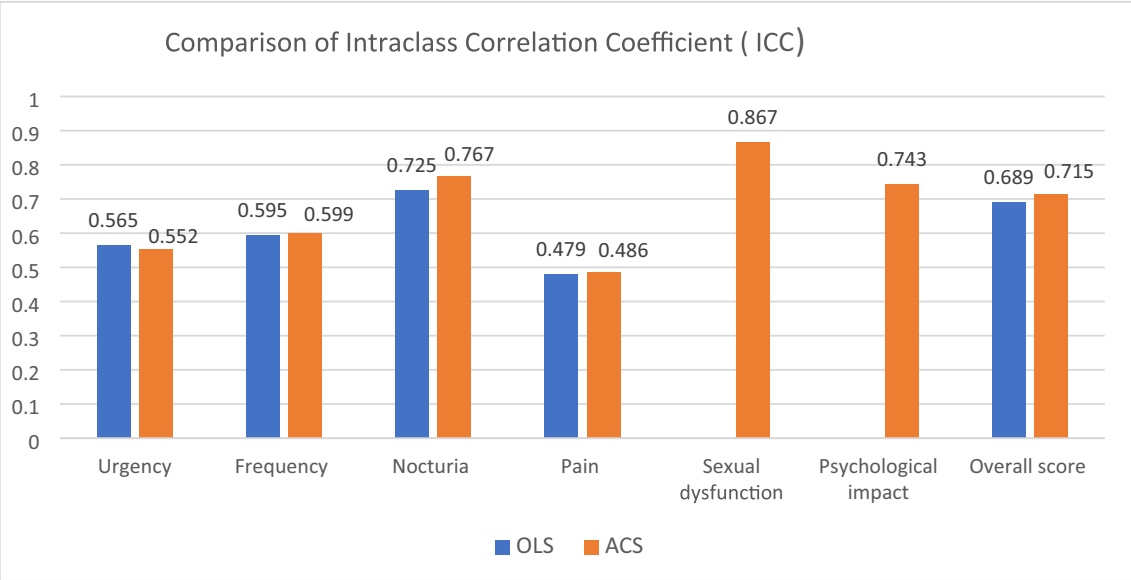

Fig. 4 Comparison of intraclass correlation coefficient (ICC) in OLS and ACS

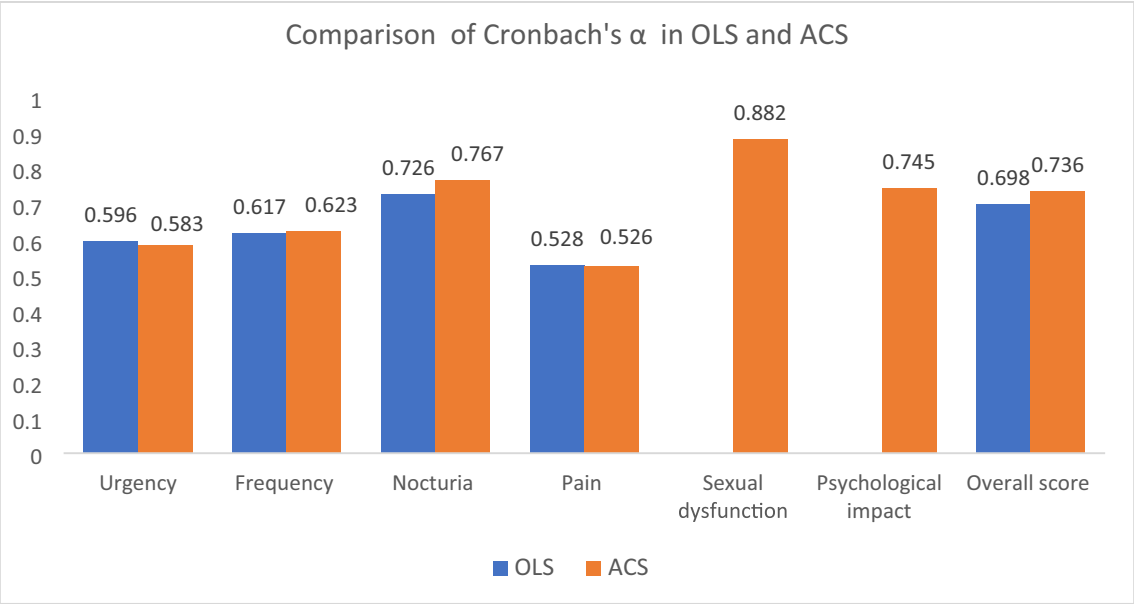

Fig. 5 Comparison of Cronbach's α in OLS and ACS

and ICPI, and calculated ICC and Cronbach's α. They found ICC was 0.722 for ICSI and 0.777 for ICPI, and Cronbach's α for ICSI and ICPI was 0.879 and 0.923 respectively, which met the criterion of good test–retest reliability and internal consistency. In the present study, results of ICC was 0.689 and 0.715 and Cronbach's α were 0.698 and 0.736 for OLS ICSI and ACS respectively. These results meet the criterion of good test–retest reliability and internal consistency, even though the values are slightly lower than reported in earlier studies.

In the present study, compared with OLS, ACS seems to have better test–retest reliability and internal consistency, both overall and domain-wise, as apparent in the values of ICC and Cronbach's α. In view of the low prevalence of the disease, statistically a number above 30 patients was deemed sufficient by the consulting statistician in this this study. It is necessary to point out that another study by Marcell et al, quoted for comparison had enrolled 30 patients. Calculating these statistical values in 35 patients may thus be acceptable.

Conclusion

The validation of ACS was studied by applying test–retest reliability using Intraclass Correlation Coefficient (ICC) and internal consistency using Cronbach's α. Using these methods appeared to be statistically reliable and internally consistent. When these statistical tests were applied to the OLS on the same group of patients in a parallel setting, it was found that ACS performed marginally better than OLS

The present study suggests that the newly devised Apollo Clinical Scoring System (ACS) for use of management of patients of BPS/IC is an internally consistent and reliable scoring system.

Table 5 Validation studies of BPS/IC scoring

Results of various validation studies			
Study	Scoring system	ICC	Cronbach's α
Lubeck et al. [26] (2001) ($n = 376$)	ICSI	0.80	0.72
Baris Esen et al. [27] (2020) ($n = 79$)	ICSI	0.772	0.879
	ICPI	0.777	0.923
Marcella LV et al. [28] (2015) ($n = 30$)	ICSI	0.56	-
	ICPI	0.48	-
	PUF	0.49	-
Arlandis et al. [29] (2018) ($n = 243$)	BPIC-SS	0.82	0.92
Present study (2019–2021)($n = 35$)	OLS-ICSI	0.689	0.698
	ACS	0.715	0.736

Author contributions Rajesh Taneja — concept, direction, guidance overall supervision.

Ashutosh Kumar Singh — collection of data and statistical analysis.

Ankur Sharma & Nilesh Taneja — tabulation of data, writing of manuscript draft.

Apeksha Raheja — draft corrections and final proof reading.

Declarations

Conflicts of interest None.

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