

Sensitivity and Specificity of International Prostate Symptom Score (IPSS) for the Screening of Iranian Patients with Prostate Cancer

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Abstract- We assessed the lower urinary tract symptoms (LUTS) in prostatic cancer patients and investigated the sensitivity and specificity of international prostate symptom score (IPSS) in the screening of these patients. A total number of 132 prostatic cancer patients as the case group who were confirmed by the pathologists and 101 noncancerous men as the control group, aged 50 or older, responded to a questionnaire which included seven questions regarding urination, named the International Prostate Symptom Score (IPSS). Then, two groups were assessed and compared with each other and also the sensitivity and specificity of IPSS tool for screening of prostatic cancer patients were calculated. All participants filled out the questionnaire. 60 (59.4%) noncancerous men and 29 (22.0%) cases had mild LUTS, and 41 (40.6%) noncancerous men and 103 (78.0%) cases had moderate to severe LUTS. Moreover, the sensitivity and specificity of the IPSS tool were 78% and 59.4%, respectively. Urination status and problems could be easily assessed by IPSS and it is a sensitive and specific tool for screening of prostatic cancer patients. It appears that IPSS is a cost beneficial, sensitive, specific and easily-used screening tool to diagnose the prostate cancer cases. Therefore, it can be used more extensively by the health care providers as well as by men ≥ 50 years old themselves.

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Introduction

Prostate cancer is the sixth most common type of cancer worldwide (1), and is both the second leading cause of cancer death among men and a high prevalent cancer that leads to high mortality and high prevalence of urinary problems in men ≥ 50 years old, and increases with aging (2). Prostate cancer is the third most frequent cancer among men and still a major cause of morbidity and mortality in Iran, ranking the seventh most common underlying cause of cancer death for men (3). Isolated prostate specific antigen (PSA) determinations in asymptomatic individuals have not demonstrated sufficient sensitivity (71.9%) and specificity (90.0%) to be useful in the routine evaluation of prostate disease (4,5). The lack of specificity with the most widely applied cutoff of 4.0 ng/mL as the upper limit of normal results in a cancer detection rate of only about 30% for patients with serum PSA between 4.0 and 10.0 ng/ml

and 50% to 70% for patients with PSA greater than 10.0 ng/ml (6). As the population ages rapidly, prostate cancer and related problems like lower urinary tract symptoms (LUTS) have been drawing great attention (7-11). LUTS can be the first signs of prostate cancer (12); therefore, it is very important to be assessed as early indicators of prostate cancer. Assessing the LUTS in men ≥ 50 by a simple screening tool which is cost beneficial, could lead to early diagnosis and even prevention of disease, and will help the health care providers and patients to be aware of the disease status.

International Prostate Symptom Score (IPSS), which was created in 1992 by the American Urological Association (13), is a simple questionnaire, including three questions regarding filling problems (daytime frequency, urgency, nocturia), and four questions regarding voiding problems (emptying, intermittency, weak stream, hesitancy). This scoring system has been reported to be clinically sensible, reliable, valid and

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responsive for benign prostate hyperplasia (7,14,15), but has not been studied for prostate cancer.

In this study, we investigated the urination status in elderly Iranian men with, and without prostate cancer and compared them using IPSS and investigated how the IPSS questionnaire could be a sensitive and specific tool in the screening of patients with prostate cancer.

Patients and Methods

The data is part of a case-control study on risk factors for prostate cancer conducted between 2005 and 2008 in Iran, Mazandaran province (3). 132 male histologically confirmed prostate cancers, and 101 noncancerous male living in the neighborhood, aged 50 years and older, were enrolled to this study. The noncancerous men had normal digital rectal examination (DRE), and negative PSA (Prostate specific antigen) test results (PSA level < 4 ng/mL). Furthermore, we ruled out prostatitis, and urinary infections by urinary tests in the control group.

Trained interviewers filled the same questionnaire by visiting cases and noncancerous men. A written informed consent was provided to each subject. In addition to data on demographic characteristics, and main risk factors for prostate cancer, the International Prostate Symptoms Score questions were asked from both cases and noncancerous.

Data were entered and analyzed using STATA (8.0). After preliminary description of the data, the mean filling subscore, the voiding subscores and the total score of IPSS were compared in cases and noncancerous men using Student's t-test. We also classified total score of IPSS (0-35), filling (0-15), and voiding subscore (0-

20) into three categories and compared them in case and noncancerous males, and also their different sub-categories of age using Chi-square, and Fisher Exact tests. The total score of IPSS was categorized into 0-7, 8-19, 20-35; filling subscore into 0-5, 6-9 and 10-15; voiding score into 0-6, 7-13 and 14-20 as mild, moderate and severe, respectively. A $P < 0.05$ was considered statistically significant.

Results

132 prostatic cancer patients and 101 noncancerous men were studied. The distribution of age groups: 50-59, 60-69, 70-79 and ≥ 80 yr in case and control groups were 5.3%, 22.0%, 51.5%, 21.2% and 7.9%, 32.7%, 59.4%, 0.0%, respectively. The mean age difference of case and controls were 3.8 yr. 13 (9.9%) of cases and 11 (10.9%) of noncancerous persons had secondary education or more. All of the participants were married.

As Table 1 shows, in our study 40 (30.3%) of 132 patients with prostate cancer, and 4 (4.0%) of 101 noncancerous males had severe LUTS, and 63 (47.7%) and 37 (36.6%) had moderate LUTS, respectively ($P < 0.001$). The mean \pm SD IPSS score of cases, and noncancerous men with mild LUTS were 3.16 ± 2.31 and 2.65 ± 2.31 ; and those with moderate LUTS were 13.00 ± 3.11 and 11.19 ± 2.70 ; and with severe scores were 30.33 ± 4.91 and 29.00 ± 6.63 , respectively. In general, the mean score of IPSS in different categories of severity were higher in prostatic cancer patients. There was a significant difference in the IPSS score as a whole between cases and noncancerous males (16.1 ± 10.9 versus 6.7 ± 6.6 ; $P < 0.0001$).

Table 1. The relationship between LUTS severity and IPSS score

LUTS severity	Prostatic cancer patients	Noncancerous
	N (%)	N (%)
Mild	29 (22.0%)	60 (59.4%)
	3.31 \pm 2.30	2.68 \pm 2.27
Moderate	63 (47.7%)	37 (36.6%)
	13.00 \pm 3.11	11.19 \pm 2.70
Severe	40* (30.3%)	4 (4.0%)
	30.10 \pm 4.92	29.00 \pm 6.63
Total	132 (100%)	101 (100%)
	16.05 \pm 10.66**	6.84 \pm 6.63

* LUTS Severity is significantly different in two groups; $\chi^2 = 43.7$, d.f. = 2, $P < 0.0001$

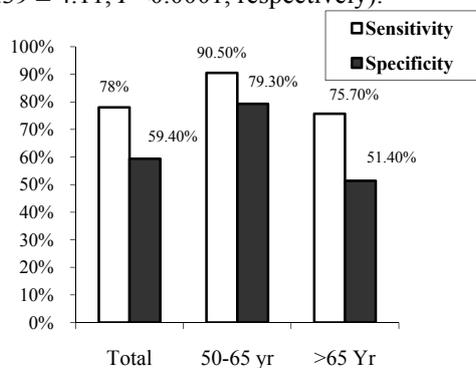
** Mean of IPSS scores is significantly different in two groups, $P < 0.0001$

Table 2. Filling, voiding subscores and IPSS, according to the severity of filling and voiding problems

Category	Filling problem		Voiding problem	
	Prostatic cancer	Noncancerous	Prostatic cancer	Noncancerous
	N (%) Mean IPSS ± SD	N (%) Mean IPSS ± SD	N (%) Mean IPSS ± SD	N (%) Mean IPSS ± SD
Mild	56 (42.4%) 3.36±1.66	83 (81.2%) 2.20±1.56	53 (40.2%) 2.43±2.40	81 (80.2%) 1.84±2.15
Moderate	37 (28.0%) 6.78±0.95	10 (9.9%) 6.8±1.14	47 (35.6%) 9.40±1.72	16 (15.8%) 7.75±1.12
Severe	39 (29.6%) 13.28±1.79	8 (7.9%) 12.25±1.98	32 (24.2%) 18.47±2.18	4 (4.0%) 17.25±3.20
Total	132 (100.0%) 7.25±4.44	101 (100.0%) 3.45 ± 3.32	132 (100.0%) 8.80 ± 6.62	101 (100.0%) 3.39 ± 4.11

When we combined the two categories of severe and moderate LUTS as the determination point to study the sensitivity and specificity of IPSS in the screening of prostatic cancer patients, the sensitivity and specificity of the IPSS score were 78% and 59.4%, respectively. The sensitivity and specificity of the IPSS score as defined above for the age group 50-65 yr increased, and were 90.5% and 79.3% and for older than 65 yr were 75.7%, and 51.4%, respectively (Figure 1). Analysis showed that the specificity of IPSS score was significantly higher ($\chi^2=6.68$, d.f. =1, $P=0.01$) in younger group (50-65 yr); However, sensitivities were not different in the age groups (Fisher Exact test, $P=0.16$).

The severity classification and the mean \pm SD of filling and voiding subscores in the case and noncancerous groups are presented in Table 2. 39 (29.63%) of 132 patients with prostate cancer, and 8 (7.9%) of 101 noncancerous men had severe filling problem ($P<0.001$). Also, 32 (24.2%) of 132 prostatic cancer patients, and only 4 (4.0%) of 101 noncancerous persons had severe voiding problem ($P<0.001$). The mean filling and voiding subscores as a whole were higher among patients with prostate cancer (7.25 ± 4.44 versus 3.45 ± 3.32 , $P<0.0001$ and 8.80 ± 6.62 versus 3.39 ± 4.11 , $P<0.0001$, respectively).

**Figure 1.** Sensitivity and specificity of IPSS

Discussion

Prostate cancer is the most prevalent cancer among men that leads to a lot of medical problems and nonmedical problems like economical problems due to the high costs of medical treatments (1). This disease grows rapidly with aging (2). However, the shortage of sensitive, specific, cost beneficial and easily-used screening tools for diagnosing this disease is obvious and tangible. Logically, it is clear that using this kind of screening tools like the IPSS by the health care providers and the elders themselves could lead to the earlier diagnosis of the disease and the reduction of the disease induced problems and the costs as well.

One of the important features of a screening tool is its sensitivity and specificity. The IPSS tool has been used in several studies to determine the LUTS severity (7,16,17), but its sensitivity and specificity have not been investigated in any studies. It is obvious that if a screening tool is significantly sensitive and specific, its accuracy in the diagnosing of the disease will be significantly high.

Also, LUTS severity has not been investigated in the prostatic cancer patients until now. In the present study, the LUTS severity in the prostatic cancer patients, and also the sensitivity and specificity of IPSS tool were investigated as well. The goal of this study was to develop a pertinent tool for health care providers to screen patients with prostate cancer, and for the elders to note that their symptoms should not be given up, but treated. Several authors reported that a lot of the elderly had urination problems, but that only small percentages of them consulted physicians (8).

Okamura *et al.*, (7) reported in their study that 72.3% of men and 64.7% of women with some medical problems, had moderate to severe LUTS, and the IPSS scores were very similar to LUTS severity in both genders, but they reported nothing about the sensitivity

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and specificity of IPSS tool. Moreover, they reported that IPSS could also be used for assessing urination of elderly men who does not have benign prostatic hyperplasia. Van Haarst *et al.* (16) suggested that the IPSS in both genders has a gradual significant increase in consecutive age groups and men in the third age decade have a mean score of 2.8, while men older than 70 years of age have a score of 7.0.

In addition, in the present study the voiding and filling subscores of the IPSS were evaluated in both cancerous and noncancerous participants. Sommer *et al.* (18) assessed men, and found a significant increase in voiding, filling and total score in the fifth and sixth decade.

Van Haarst *et al.* (16) showed that LUTS are prevalent in all age categories above 20 years in men. However, none of the above studies have included and investigated the prostatic cancer patients. The results of the present study showed that the total IPSS score was significantly higher in the cancerous patients, and also the mean score of IPSS in different categories of severity were higher in them, but in the severe category, the IPSS score was significantly higher in the case group. Also, results showed that the mean filling and voiding subscores as a whole were higher among patients with prostate cancer.

In this study for assessing the severity and specificity of IPSS, we combined the two categories of severe and moderate LUTS as the determination point, and the results showed that the sensitivity and specificity of IPSS tool were significantly high (78% and 59.4%, respectively), and also these findings were higher than total in the age group of 50-65 years old (90.5% and 79.3%, respectively).

One of the main factors in the filling out of this kind of tool that could affect the level of accuracy of acquired data is the level of clients' literacy and education. In other words, if the literacy and educational level of patients in the cases, and control group is different, so that could be an altering factor in determination of sensitivity and specificity of a screening tool. In this study, to eliminate this altering factor we equalized the two groups, so that they had equal educational level. Therefore, we could conclude that the existing difference between the two groups that was determined by the IPSS tool was only due to the severity of LUTS and the severity of patients' disease, not due to their educational level. Thus, we could conclude that the IPSS tool is a sensitive and specific tool for screening of prostatic cancer patients. Also, results of the present study showed that the mean filling and voiding

subscores as a whole were higher among prostatic cancer patients.

We recognized a limitation in the study which prostate cancer usually shows urinary symptoms in the late stages (12). So, in the early stages, we may not be able to determine and diagnose the symptoms by this tool. Despite the limitation, considering the economical and cognitional problems of elder people, using screening tools like the IPSS that is a sensitive, specific, easily-used and very cost beneficial tool, is very important and helpful and can help the health care providers and elders themselves to screen, and diagnose the disease as soon as possible and subsequently decrease the disease induced problems and mitigate the costs of the medical treatments. According to our findings we can strongly suggest that the IPSS tool is a sensitive and specific tool for screening of prostatic cancer patients. Finally, clinicians are able to follow the patients by this tool for evaluation of treatment efficacy.

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