

# The role of noninvasive penile cuff test in patients with bladder outlet obstruction

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**Purpose:** The aim of this study was to compare the penile cuff test (PCT) and standard pressure-flow study (PFS) in patients with bladder outlet obstruction.

**Materials and Methods:** A total of 58 male patients with moderate to severe lower urinary tract symptoms (LUTS) were selected. Seven patients were excluded; thus, 51 patients were finally enrolled. Each of the patients underwent a PCT and a subsequent PFS. The sensitivity (SE), specificity (SP), positive predictive value (PPV), negative predictive value (NPV), and likelihood ratio were calculated. Chi-square and Fisher exact test were used to evaluate relationships between PCT results and maximal urine flow (Q<sub>max</sub>); a  $p < 0.05$  was considered statistically significant.

**Results:** The mean ( $\pm$ standard deviation) age of the study group was  $65.5 \pm 10.4$  years. Overall, by use of the PCT, 24 patients were diagnosed as being obstructed and 27 patients as unobstructed. At the subsequent PFS, 16 of the 24 patients diagnosed as obstructed by the PCT were confirmed to be obstructed, 4 were diagnosed as unobstructed, and the remaining 4 patients appeared equivocal. Of the 27 patients shown to be unobstructed by the PCT, 25 were confirmed to not be obstructed by PFS, with 13 equivocal and 12 unobstructed. Two patients were diagnosed as being obstructed. For detecting obstruction, the PCT showed an SE of 88.9% and an SP of 75.7%. The PPV was 66.7% and the NPV was 93%.

**Conclusions:** The PCT is a beneficial test for evaluating patients with LUTS. In particular, this instrument has an acceptable ability to reject obstruction caused by benign prostatic hyperplasia.

**Keywords:** Lower urinary tract symptoms; Nomograms; Penis; Urinary bladder neck obstruction; Urodynamics

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## INTRODUCTION

Approximately 50% to 60% of elderly men experience lower urinary tract symptoms (LUTS) [1]. Numerous etiological factors may cause urinary symptoms in men. These include bladder outlet obstruction (BOO), weak bladder contraction, and detrusor overactivity [2]. In the case of BOO

caused by an enlarged prostate, if diagnosed accurately and surgical intervention is carried out, acceptable results can be obtained in most cases [3]. Flowmetry is recommended as one of the initial assessments in the evaluation of patients with LUTS. A maximal urine flow rate (Q<sub>max</sub>) of 15 to 20 mL/s is considered normal and a rate of less than 10 mL/s is considered abnormal [2,4]. However, research suggests

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that 50% to 60% of  $Q_{max}$  of 15 to 20 mL/s is due to BOO and 33% of patients with obstruction have a  $Q_{max} > 15$  mL/s [2,3]. Therefore, additional diagnostic tests must be conducted in cases where flowmetry is unable to distinguish between cases of obstruction and no obstruction [1].

Pressure-flow study (PFS) is considered the gold standard for diagnosing BOO [2]. The bladder outlet obstruction index (BOOI) and bladder contractility index (BCI) are indexes used to determine BOO when examining the resultant graphs of the PFS [3,4]. A BOOI greater than 40 indicates BOO. Also, a BCI [ $P_{det}Q_{max} + 5(Q_{max})$ ] indicates poor detrusor contractions when it is less than 100 [5]. Despite this, the methods used to measure the internal pressure of the bladder through conventional PFS are time-consuming, invasive, and expensive and may have a 5% risk of severe urinary infection [5]. Moreover, the results rely on the person who is taking the test, the graphs are complicated, and most patients feel discomfort during the test. Therefore, noninvasive methods like the penile cuff test (PCT) may be an ideal alternative for BOO diagnosis [2,4].

The basic mechanism of the noninvasive PCT is similar to that of measuring blood pressure. The cuff of an infant sphygmomanometer is tied around the penis and is gradually inflated while the patient urinates [6]. This continues to the point at which the urine flow stops. The cuff is then deflated for the urine flow to be restored. This cycle continues throughout the time the patient is urinating and the mean of the obtained figures is calculated as equal to the detrusor pressure while voiding [7]. The cuff test is based on three key principles: (1) the pressure formed in the penile cuff is transferred to the urinary urethra, (2) the bladder remains contracted during the test, and (3) the urinary duct acts as a fluid-filled catheter, which means a stream of liquid must exist between the bladder and the duct when the flow stops [6,8].

A modified nomogram was designed to be used and examined in a noninvasive method. Patients can be categorized into two groups of obstructed and unobstructed in accordance with this nomogram and based on the figures obtained from  $Q_{max}$  and pressure cuff ( $P_{cuff}$ ) [9,10]. The present study was conducted to examine the accuracy, specification, and the positive and negative predictive value of this noninvasive method in comparison with conventional PFS in diagnosing BOO.

## MATERIALS AND METHODS

This study, which was carried out in Shariati Hospital of Tehran from 2013 to 2015, compared the noninvasive PCT

with the PFS method. Men who applied to the hospital's infirmary and met the criteria for participating in the study were selected for the research.

The inclusion criteria were moderate or severe LUTS, which was defined on the basis of an International Prostate Symptom Score  $\geq 8$ , and the patient's willingness to take the test. The exclusion criteria were as follows: active urinary infection, long-term diabetes, small penis or hidden penis due to excess fat in obese people (for a large penis, this is not a problem because there is a proper cuff that can be used), neurologic diseases affecting the bladder, taking medicines that disturb bladder contraction, use of a urinary catheter in the past 6 months, suspected prostate or bladder malignancy, the presence of any obvious factor for obstruction of the duct, or weakness of the bladder muscle (narrowness of the duct or bladder augmentation).

The study protocol was approved by the Research Ethics Committee of Tehran University of Medical Sciences. Recommendations of the Declarations of Helsinki and Tokyo were considered. Informed consent was obtained from all participants. The anonymity and the confidentiality of participants' information were assured.

Note that on the basis of the present study's inclusion and exclusion criteria, all participants with under- or hyperactivity activity of the detrusor were omitted. The volunteer patients entered the study after the researcher explained the manner in which the test was conducted and after the consent forms were filled out by the patients.

A urine sample was taken from the patients during the 7 days before the test to reject the presence of infection in the patient. If there was an infection, antibiotic treatment was carried out based on the results of the cultivation and the intended urine test was conducted after the urine cultivation became negative.

The PCT was carried out by using an infant sphygmomanometer. The patients first drank liquids and after making sure that their bladder was full (300 mL), the sphygmomanometer cuff was attached around the penis and in the shaft area (Fig. 1). The urodynamic machine was then turned on and the patient began to urinate in the special container of the machine. The sphygmomanometer cuff was slowly inflated at a rate of 10 cm/s until the urine flow stopped. The obtained data were recorded and the cuff was opened again and the patient would start urinating again. The cuff would be inflated again and the obtained digits from when the urine flow stopped were recorded. This cycle continued throughout urination and the mean of the digits was recorded as  $P_{cuff}$ . The test was stopped for safety purposes if the urine flow continued up to 200-

cm water pressure. Also, the test was conducted again if the amount of urine was less than 150 mL. The flowmetry graph was registered during the test and the obtained  $Q_{max}$  was collected. The PCT was conducted again on all patients 1 week later and the mean of the obtained figures was recorded as  $Q_{max}$  and  $P_{cuff}$ .

The PFS was carried out in the next phase. In this stage, residual urine in the bladder was measured after the bladder catheter was evacuated. This test was carried out by use of a SIRIUS 8000 urodynamic machine and was based on the recommendations of the International Continence Society. The patient would lie down on the special bed and the genitalia were sterilized. Two special catheters were inserted in the bladder and one balloon catheter was inserted in the rectum. The bladder was then washed with serum fluid (not cold) at a rate of 30 to 50 mL/s and was filled to almost 300 mL. The bladder internal pressure ( $P_{det}$ ) was then calculated and registered while the bladder was voided.

PFS data were plotted on the Abrams-Griffiths modified nomogram, whereas PCT results were plotted on the nomogram proposed by Griffiths [9,10]. For each of two categories, obstructed versus unobstructed, patients were subdivided into two subgroups according to their  $Q_{max}$ , with a threshold of 10 mL/s, in order to evaluate if  $Q_{max}$  was able to improve accuracy. Then sensitivity, specificity, and positive and negative predictive values were calculated based on cross tables by use of SPSS. Fisher exact test was used to examine the relationship between the PCT and  $Q_{max}$ . As mentioned, we divided the patients into 3 groups in the PFS, based the on Abrams-Griffiths modified nomogram and the

following equation:  $BOOI = P_{det}Q_{max} - 2(Q_{max})$

- 1 =  $BOOI > 40$ , obstructed
- 2 =  $BOOI 20-40$ , equivocal
- 3 =  $BOOI < 20$ , unobstructed

This classification is based on the recommendations of the International Continence Society [11].

## RESULTS

A total of 58 patients who met the criteria for participation in the study were examined. Seven patients were excluded during the PCT for technical reasons such as not being able to urinate or  $P_{cuff} > 200$  cmH<sub>2</sub>O. A total of 51 patients were finally statistically analyzed after PCT and PFS.

The mean age of the patients was  $66.5 \pm 10.4$  years. The mean PSA of the patients was estimated to be  $2.8 \pm 1.1$  ng/dL and the mean postvoid residual (PVR) calculated by sonography was  $31.3 \pm 14.2$ . The mean  $Q_{max}$  of the patients was  $10.32 \pm 2.85$  mL/s by flowmetry (Table 1).

In general, on the basis of PCT and the Griffiths nomogram, 24 patients were obstructed and 27 patients had no obstruction. On the basis of the PFS and the International Continence Society (ICS) nomogram, 16 of the 24 patients identified by the PCT were shown to be obstructed, whereas 4 patients were identified as unobstructed and 4 patients were identified as equivocal. Moreover, 18 patients were placed in the obstructed group, 16 individuals were placed in the unobstructed group, and 17 individuals were placed in the equivocal group on the basis of the PFS findings and the ICS nomogram (Table 2). When the patients were classified according to  $Q_{max}$ , 17 of the 24 obstructed patients based on PCT had a  $Q_{max} < 10$  mL/s, whereas 7 patients had a  $Q_{max}$  greater than or equal to 10 mL/s. On the other hand, 12 of the 27 unobstructed patients identified on the basis of PCT had a  $Q_{max}$  lower than 10 mL/s and 15 patients had a  $Q_{max}$  equal to or exceeding 10 mL/s.

The results of the Fisher exact test indicated that the

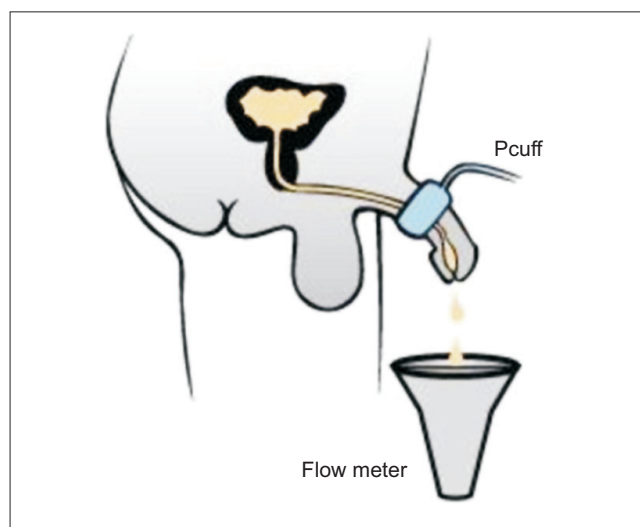


Fig. 1. The sphygmomanometer cuff that was attached around the penis and in the shaft area.

Table 1. Patients' demographic and clinical characteristics

| Variable                  | Mean±SD (range)       |
|---------------------------|-----------------------|
| Age (y)                   | 66.58±10.45 (89-50)   |
| Prostate-specific antigen | 2.83±1.17 (5.4-0.4)   |
| Postvoid residual         | 31.31±14.22 (60-10)   |
| Pdet                      | 52.19±16.30 (86-30)   |
| Penile cuff               | 144.11±33.59 (180-50) |
| Maximal urine flow rate   | 10.32±2.85 (17-5)     |

SD, standard deviation; Pdet, pressure detresor.

**Table 2.** Classification of patients based on penile cuff tests

|                     | Penile cuff test |              | Total, n (%) |
|---------------------|------------------|--------------|--------------|
|                     | Obstructed       | Unobstructed |              |
| Pressure-flow study |                  |              |              |
| Obstructed          | 16               | 2            | 18 (35.3)    |
| Unobstructed        | 4                | 12           | 16 (31.4)    |
| Equivocal           | 4                | 13           | 17 (33.3)    |
| Total, n (%)        | 24 (47.1)        | 27 (52.9)    | 51 (100)     |

**Table 3.** Examine the sensitivity, specificity, positive & negative predictive value, positive & negative likelihood (PCT)

| Variable                      | Value |
|-------------------------------|-------|
| PCT obstructed (n)            |       |
| PFS obstructed                | 16    |
| PFS unobstructed              | 8     |
| PCT unobstructed (n)          |       |
| PFS obstructed                | 2     |
| PFS unobstructed              | 25    |
| Sensitivity (%)               | 88.9  |
| Specificity (%)               | 75.7  |
| Positive predictive value (%) | 66.7  |
| Negative predictive value (%) | 93.0  |
| Negative likelihood ratio (%) | 3.67  |
| Positive likelihood ratio (%) | 0.15  |

PCT, penile cuff test; PFS, pressure-flow study.

sensitivity of the test did not change ( $p=0.059$ ) when the patients were classified on the basis of a  $Q_{max}$  less than or greater than 10 mL/s, whereas the specificity of the test improved ( $p=0.015$ ), which means that the power to rule out unobstructed cases increased. The sensitivity, specificity, positive and negative predictive value, and positive and negative likelihood ratio of the PCT were also calculated. Sensitivity was 88.9% (95% confidence interval [CI], 65.29–98.62) and specificity was 75.7% (95% CI, 57.7–88.9). The positive predictive value was 66.7% (95% CI, 44.6–84.3), and the negative predictive value was 93% (95% CI, 75.7–99.09). The positive likelihood ratio was 3.67 (95% CI, 1.9–6.85) and the negative likelihood ratio was 0.15 (95% CI, 0.04–0.5) (Table 3). In the present study there were no remarkable missing data because the whole process was conducted under the direct supervision of researchers.

## DISCUSSION

Simple PVR assessment was considered a practical instrument for diagnosing BOO during the past century. However, a high PVR could also be due to detrusor underactivity [12]. It is in fact clear today that up to half of unobstructed patients with LUTS may have a high PVR,

whereas one quarter of patients with severe obstruction may not show any residual urine volume [2]. The relationship between high PVR and BOO is therefore not reliable enough to be used as a beneficial clinical instrument [13].

The role of simple flowmetry as a criterion for BOO has been examined in some articles, but no acceptable relationship has been found to date [10,14]. Some researchers have demonstrated that flowmetry can assess the presence of BOO in most patients with a  $Q_{max}$  below 10 mL/s, whereas this ability is significantly reduced in cases with a  $Q_{max}$  greater than 15 mL/s [13,15]. Therefore, the guidelines of the European Association of Urology (2013) present the PFS as an optimal presurgical test for BOO that is commonly used in presurgical assessment in patients with a  $Q_{max}>15$  mL/s [16]. About 25% to 30% of patients with a low  $Q_{max}$  in flowmetry are in fact unobstructed. Moreover, the decrease in urine flow could be caused by weak contractions of the bladder or BOO [14]. Therefore, measuring detrusor pressure is the only method that can distinguish between these two conditions [15]. In addition, it is not possible to judge BOO-related matters or detrusor malfunction correctly regarding the flowmetry curves. On the other hand, a normal flowmetry test result does not exclude the presence of obstruction caused by an enlarged prostate [17]. PFS is still, however, considered the gold standard for accurately assessing BOO in male patients, especially when detrusor underactivity is considered. Despite that, PFS is not routinely used before prostate surgery [16].

The nomogram designed by Abrams & Griffiths is widely used in clinical cases [10]. Another nomogram designed by Abrams aims at classifying patients more accurately on the basis of the two indexes of BOOI and BCI [8]. No simple instrument has been announced as the official and acceptable instrument for distinguishing between obstruction caused by an enlarged prostate and that caused by detrusor underactivity in the past 30 years. Methods of examining detrusor pressure by use of noninvasive instruments such as the PCT have been presented as alternatives for PFS, but their clinical applications are still not specified and few data have been published about the

relationship between the results of the PCT and PFS [15].

The aim of the recent study was to compare the results of the PCT and PFS in diagnostic examinations of patients with moderate to severe LUTS. In summary, the present study made it clear that the PCT has an accuracy of 88.9%, specificity of 75.7%, positive predictive value of 66.7%, and negative predictive value of 93%.

Griffiths et al. [10] also obtained a positive predictive value equal to 68% and a negative predictive value of 78% in a study using the modified nomogram for the noninvasive PCT method. Those authors also specified that the predictive value for obstruction increases by adding the  $Q_{max} < 10$  mL/s criterion and reaches 88% regarding positive predictive value and 86% regarding negative predictive value [10].

An accuracy of 100%, specificity of 63%, positive predictive value of 68%, and negative predictive value of 100% was calculated for the PCT method in the study conducted by Bianchi et al. [13]. However, in contrast to the study of Griffiths and also the results obtained from our studies, Bianchi et al. [13]'s research indicated that classifying the patients on the basis of a  $Q_{max}$  greater than or less than 10 mL/s does not present more information and will not be helpful. The reason for this difference may be the difference in how the patients were selected. In Griffiths' study, the patients were examined when they complained of LUTS, whereas the patients participating in Bianchi's study were TURP candidates. In our study, patients who complained of LUTS were examined and the results were closer to the results of Griffiths' study [10,13].

It therefore seems like a combination of the PCT and  $Q_{max}$  could present more beneficial information on the cause of the disease in the routine assessment of patients complaining from LUTS. This matter must be researched more for better understanding. It is worth mentioning that other anatomical and functional aspects such as prostatic enlargement and a higher prostatic urethral angle were not investigated in our study because of their low role in causing BOO.

In another recent conducted study by Borrini, which was carried out on 30 patients complaining from LUTS, the PCT positive and negative predictive value were calculated to be 82% and 88%, respectively [4]. Thus, the results of the present research are consistent with that study [4].

The average age of the patients in our study was 66.5 years and the mean PSA of the patients was 2.8 ng/dL. The mean residual urine volume calculated through sonography was 31.3 mL and the mean  $Q_{max}$  of the patients was equal to 10.32 mL/s in flowmetry and in the study conducted by Bianchi et al. [13]. The average age of the patients was also

61.5 years, the mean PSA was 2.35 ng/dL, the mean residual urine volume by sonography was 42 mL, and the mean  $Q_{max}$  was 11.6 mL/s. It can be concluded with regard to comparison of the above-mentioned figures that the presence of PVR or PSA is weakly linked to the presence or absence of obstruction. It cannot be determined whether the patient is suffering from obstruction or not on the basis of merely the volume of the residual urine.

The present research and other studies suggest that noninvasive methods of examining detrusor pressure and especially the PCT could be beneficial in examining patients with LUTS and those who are candidates for surgery [18,19]. This could also work as a solution to the problems related to carrying out standard urodynamic study. In fact, compared to PFS, PCT is a prompt and accurate instrument for ruling out obstructions caused by an enlarged prostate because it has great negative predictive value. This test could therefore be used in selecting unobstructed patients with suspected detrusor underactivity. The main issue in examining patients with LUTS before surgery in fact is to separate the patients suffering from detrusor underactivity, because studies suggest that nearly one-quarter of these patients will show no signs of improvement in their symptoms after surgery. Therefore, taking into consideration the high cost of surgery and also the relevant dangers, it is helpful and beneficial to identify the group of patients who will not benefit from surgical procedures. One of the differences between our study and previous studies is that in the present study PCT was done completely manually without the use of conventional digital devices, which reduced the cost of the study.

A total of 208 patients underwent the PCT before transurethral resection of the prostate surgery in Harding et al. [20]'s study, and the results showed that 87% of the patients diagnosed with obstruction had noticeably improved clinically after surgery, whereas only 56% of the patients who were identified as unobstructed through the PCT had improved. This easy diagnostic method can identify patients without obstruction (probably caused by detrusor underactivity) without the need to conduct the challenging and expensive PFS. Thus, proper recommendations and counseling can be offered to patients regarding relative or insignificant improvement of symptoms after surgery. Moreover, the patients were accurately classified on the basis of the PCT, which indicates that most patients with obstruction can be assessed correctly by use of this method.

Regarding the patients classified in the equivocal group on the basis of PFS, it could be that dividing them on the basis of the PCT cannot accurately identify this group of

patients. In any case, only the patients with an unclear diagnosis can undergo PFS, and in other cases, the patients can correctly be classified with only the simple PCT. Although there were some limitations to the present study, such as unwillingness of patients to participate because of cultural issues, the low number of samples, and the small penis size in some cases, the results were acceptable and largely confirmed the study hypothesis that the PCT has better performance than the PFS. In short, conducting the simple and inexpensive PCT along with other noninvasive methods such as the residual volume of urine and flowmetry can evaluate the performance of the detrusor and the condition of the duct more precisely. The functioning of the detrusor, however, will remain unknown in a number of patients, in which case conducting the standard urodynamic study can distinguish between obstruction caused by an enlarged prostate and detrusor underactivity.

## CONCLUSIONS

The PCT is a beneficial instrument for assessing patients with LUTS and in comparison with other noninvasive methods and PFS has a higher diagnostic power. Another advantage of the PCT in addition to the economical benefits and decreased complications resulting from surgery is that patient satisfaction will be met with a high rate of correctly classified patients overall. Also, this instrument has acceptable reliability in ruling out obstruction caused by benign prostatic hyperplasia. In this regard there is no clear mechanism, however, so further studies in this area seem necessary. In addition, this method should be studied more in larger samples to make it an alternative for conventional PFS.

## CONFLICTS OF INTEREST

The authors have nothing to disclose.

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