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DIAGNOSTIC ACCURACY OF NON-INVASIVE PENILE CUFF TEST FOR THE ASSESSMENT OF BLADDER OUTLET OBSTRUCTION COMPARING BY PRESSURE FLOW STUDY IN MEN WITH LOWER URINARY TRACT SYMPTOM

Hypothesis / aims of study

Pressure-flow study (PFS) is the current standard diagnostic test to evaluate the bladder outlet obstruction (BOO). However, PFS has risks related to the procedure. In order to replace the PFS, penile cuff test (PCT) was introduced which in a non-invasive manner to determine the isovolumetric bladder pressure with flow rate. The aim of this study was to evaluate the diagnostic accuracy and the acceptability of the PCT for the assessment of BOO in men comparing to the PFS

Study design, materials and methods

This was prospective, diagnostic study conducted at a single center from December 2013 through February 2015. Men who complained about LUTS presumably due to BPH for ≥ 6 mo based on medical history were screened to determine their eligibility for the study. Inclusion criteria included male patients who had an International Prostate Symptom Score (IPSS) > 12 for over 6 months and patients scheduled to have PFS and able to give fully informed consent. There were two study visits: visit 1 (screening and baseline); and visit 2 (urodynamics). At visit 1, patients were checked by inclusion and exclusion criteria to confirm study eligibility. Vital sign, urinalysis, urine culture, serum PSA, TRUS, digital rectal examination (DRE), UFM with postvoid residual (PVR), and IPSS were evaluated. Observed and spontaneously reported adverse events (AEs) were assessed at all visits. At visit 2, all patients were scheduled to undergo PCT prior to PFS within 4 weeks of visit 1, both of which were performed at the same day and visual analogue scale (VAS) for pain was assessed. Descriptive statistics were used to evaluate patient characteristics. Measures of diagnostic accuracy (sensitivity, specificity, PPV, NPV, likelihood ratio [LR], and accuracy) were determined for the PCT. Comparisons of VAS for pain and procedure time after PCT and PFS were evaluated with Wilcoxon singed rank test.

Results

A total of 193 men were enrolled for the study (Fig 1). Of these, 158 men (81.9%) were had at least 1 acceptable cuff inflation cycle that meet the exclusion criteria. Among them, 12 men whose voided volume was less then 100ml were excluded. Overall 146 of the 193 enrolled men (75.6%) had available full data. According to the PCT nomogram, 48 men were categorized as obstructed and 59 were not obstructed. The use of PFS data classified 35 men as obstructed, with 50 equivocal and 61 non-obstructed. The sensitivity of the PCT based on the PFS results was 89.7%, the PPV was 54.2%, the specificity was 71.8% and the NPV was 94.9%. The positive and negative likelihood ratios were 3.18 and 0.14, respectively. The mean pain VAS for the PFS and PCT were 5.04 ± 2.17 and 1.83 ± 1.98, respectively ($p<0.0001$). The mean procedure time for PCT (6.3 ± 0.6 min) were shorter than PFS (23.3 ± 2.2 min) ($p<0.0001$). There were no occurrences of adverse events during the PCT.

Interpretation of results

PCT can be an efficient screening test for BOO in men because of its high NPV. And, PCT has the advantage of being safe, having a short procedure duration with a non-invasive manner. The position of PCT as diagnostic tool is a diagnostic procedure that is conducted before surgical treatment for BOO on male patients, and is a viable alternative to PFS, and it is determined that further research on PCT should be conducted.

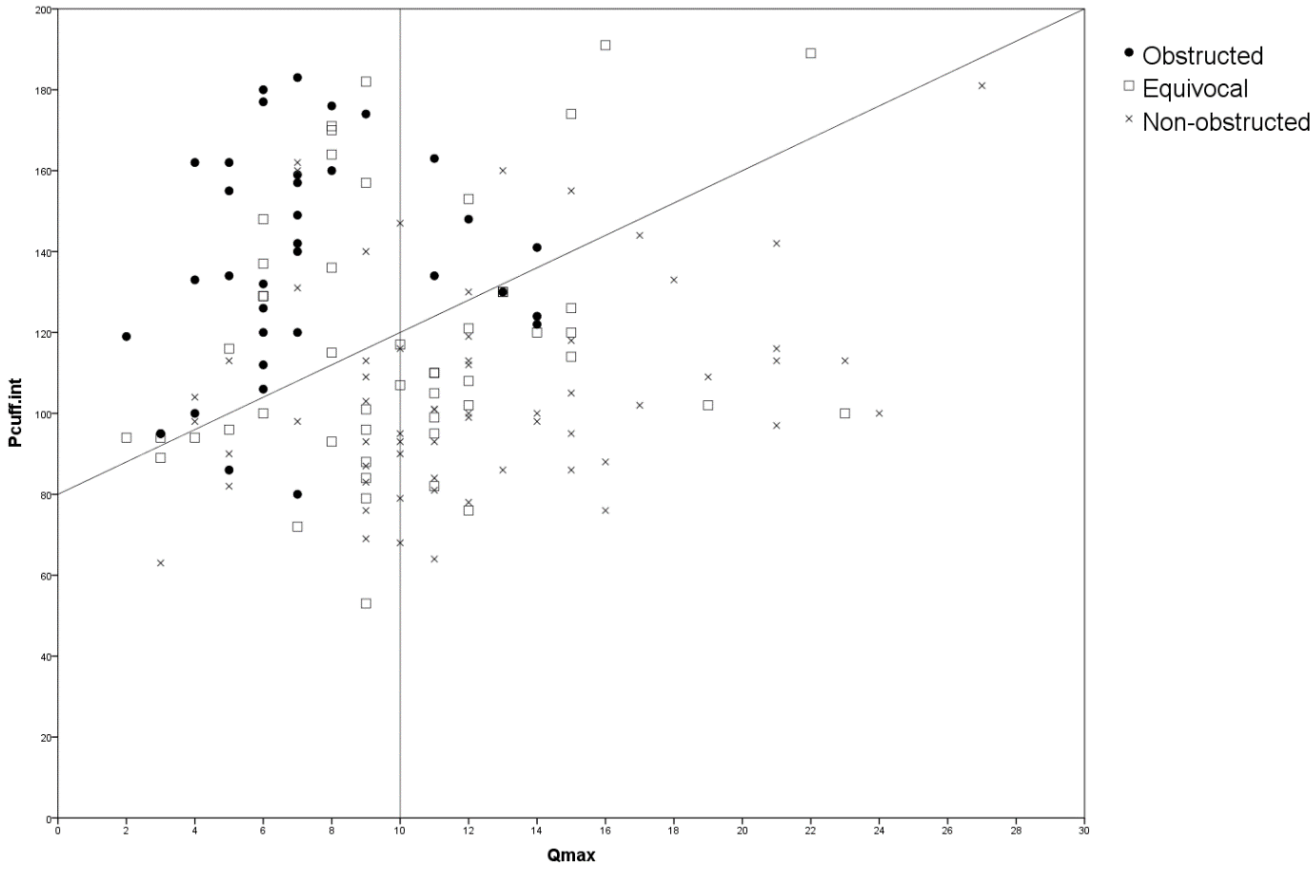
Concluding message

PCT can be an efficient screening test for BOO in men because of its high NPV. And, PCT has the advantage of short procedure time and good tolerability than PFS with safely.

Table 1. Statistical performance characteristics of penile cuff test

Parameter	Estimate (%)	95% confidence interval (%)
Sensitivity	89.7	74.0-97.2
Specificity	71.8	66.0-74.6
Accuracy	76.6	68.2-80.7
Positive predictive value (PPV)	54.2	44.7-58.7
Negative predictive value (NPV)	94.9	87.2-98.6
Positive likelihood ratio (LR+)	3.18	2.18-3.83
Negative likelihood ratio (LR-)	0.14	0.04-0.39

Figure 1. Modified nomogram with data on 146 patients showing classification from PFS using ICS nomogram



Disclosures

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