135

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SPHINCTER RETROGRADE OPENING PRESSURE (PARE). A NEW TEST TO ASSESS URETHRAL SPHINCTER COMPETENCE AFTER RADICAL PROSTATECTOMY? DATA FROM PARE PROJECT

Hypothesis / aims of study

Despite advances in surgical technique, urinary incontinence after radical prostatectomy is not a rare condition.

Evaluation for urinary incontinence (UI) due to urethral sphincter deficiency (USD) after prostatic surgery is not well standardised. There are not diagnostic urodynamic or clinical parameters which clearly define this condition. Sphincter Retrograde Opening Pressure (PARE) could reflect the pressure exerted to overcome urethral resistance during void and therefore sphincter residual function in patients with UI after radical prostatectomy. PARE is the acronym in Spanish of Sphincter Retrograde Opening Pressure: "Presión de Apertura Retrógrada Esfinteriana".

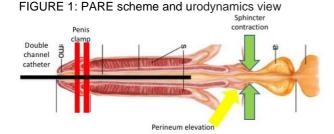
This is the first step to validate this technique. Our aims are: 1° evaluate the reproducibility; and 2° evaluate the relationship with the therapeutic decision.

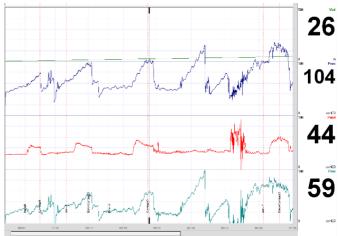
Study design, materials and methods

Case series type, observational, multicentric, prospective study. All men with UI after radical prostatectomy were recruited in three urodynamic departments between December 2011 and December 2015. They all had thorough complete, urological evaluation, including symptoms assessment using a specific questionnaire ICIQ-SF, voiding diary, Pad-test 24 hours, physical examination, urine analysis, cystoscopy with repositioning test and urodynamic testing.

Multichannel urodynamic studies included uroflowmetry, cystometry and pressure/flow study. Stress test during urodynamic evaluation determining Valsalva leak point pressure (VLPP) was used to assess the severity of UI. All procedures and definitions conform to those of International Continence Society.

After we took a therapeutic decision, at the end of urodynamic testing, as a part of the same procedure, we determined PARE as follows: first we moved the urodynamic urethral catheter to the bulbar urethra and we placed a penile clamp for creating a urethral pressure chamber. With the pump at 7mL per minute into the urethra, we determined the urethral pressure at 4 times: 1-BASAL PARE: pressure at which the graph was stabilized. 2-CONTRACTION PARE: we asked the patient to perform a voluntary contraction of the sphincter to determine the maximum pressure that sphincter holds. 3- ELEVATION PARE: we elevated patient perineum to establish the resistance that this maneuver adds to basal PARE. 4- CONTRACTION + ELEVATION PARE: finally we performed simultaneously elevation of the perineum and voluntary contraction to determine the resistance that adds to voluntary contraction. We repeated the complete procedure twice. (Figure 1)





Men presenting with urodynamic diagnosis of detrusor overactivity and previous pelvic floor surgery were excluded.

Software STATA v. 13 was used. Each paramether reproductibility was calculated by Cronbach's alpha test. We cannot calculate reliability because the absence of a gold standard. To evaluate the contents validity of the test we compared the results with the therapeutic decision.

Results

A total of 50 men were enrolled. Mean age was 68 years old. 42 (84%) had undergone laparoscopic procedures and 8 (16%) open radical prostatectomy. The average ICIQ-SF score was 15 points. 49 (98%) patients used some type of pad. The average Pad-test weigh was 400 grams in 24 hours (10-1900 g).

We can observe the perineum elevation maneuver improves pressure values in around 40-50 H₂0 cm. (Table 1)

The Cronbach's alpha test varies from 0.8 to 0.97. (good = 0.8-0-9; excellent >0.9) (Table 2)

No relationship was observed between PARE values and therapeutic decision to implant artificial sphincter or other antincontinence technique (Table 3)

TABLE 1: PARE values. (mean value ± Standard Deviation)

| BASAL | CONTRACTION | ELEVATION | CONTRACTION + ELEVATION |
|---------|-------------|-----------|----------------------------|
| 47 ± 14 | 84 ± 34 | 91 ± 24 | 122 ± 40 |

TABLE 2: Cronbach's alpha test for PARE

| 17.12-12. 0.101104011 0 41.0114 1001101 17.114 | | | | | |
|--|-------------|-----------|---------------|--|--|
| BASAL | CONTRACTION | ELEVATION | CONTRACTION + | | |
| | | | ELEVATION | | |
| 0.84 | 0.96 | 0.97 | 0.92 | | |

TABLE 3: Correlation between PARE values and surgical technique decision (artificial urinary sphincter or others).

| ELEVATION -BASAL | (CONTRACTION+ | | (CONTRACTION | + |
|------------------|---------------|---|--------------|---|
| | ELEVATION) | - | ELEVATION) | - |
| | ELEVATION | | CONTRACTION | |
| P=0.9 | P=0.4 | | P=0.6 | |

Interpretation of results

In the absence of reliable and standardised diagnostic parameters for postprostectomy UI, we suggest that PARE could determine sphincter competence. This measurement, obtainable from a routine urodynamic examination, should reflect the degree of residual rhabdosphincter function as an indirect objective and numerical method.

Our data showed that PARE has a high reproductibility. This is a necessary condition to continue investigating on this technique. The no-correlation with the surgical technique decision means PARE give to us a independent-different information from factors clinically used (pad test, urethroscopy, VLPP) to make the choice of the treatment.

For now, we can not make a terapheutic choice based in PARE values. In the future, we will continue working to assess whether it is a good predictor of surgical success (content validity).

Concluding message

PARE is a reproducible test. It provides new and different (independent) data from those used today in male incontinence assessment.

In the future, it could play a role in diagnosis and treatment of postprostatectomy UI.

Disclosures

Funding: No funding or grant Clinical Trial: No Subjects: HUMAN Ethics not Req'd: This a observational study. The evaluation is a part of urodynamics study, does not add any risk nor bother to the patient and does not interfere with the therapeutic decision Helsinki: Yes Informed Consent: Yes