

URODYNAMIC EVALUATION BEFORE SURGERY FOR FEMALE STRESS INCONTINENCE: IN HOW MANY PATIENTS COULD IT BE CONSIDERED UNNECESSARY?

Hypothesis / aims of study

A urodynamic evaluation is recommended prior surgery for urinary stress incontinence in female patients, according to the recommendation of the International Consultation on Incontinence (1). This recommendation has been recently questioned by the results of the VALUE trial (2), a multicenter, randomized, noninferiority trial aimed to compare outcomes of incontinence surgery after preoperative office evaluation and urodynamic tests or office evaluation only. The conclusion of this study was that, for women with uncomplicated, demonstrable stress urinary incontinence, preoperative office evaluation alone was not inferior to evaluation with urodynamic testing for outcomes at 1 year.

Aim of the present retrospective study was to investigate how many women coming to our urodynamic service to be evaluated prior surgery for stress incontinence can be defined as presenting “uncomplicated, demonstrable stress urinary incontinence”, according to the inclusion/exclusions criteria of the VALUE trial. Secondary aim of this study was to assess in how many women (in both groups of patients eligible or not eligible for the VALUE trial) the urodynamic investigation obtains urodynamic observations that differ from the pre-urodynamic clinical picture.

Study design, materials and methods

This is a retrospective single center study. Data were extracted from the database of the center; history, objective examination, urodynamic report and traces of female patients who underwent an urodynamic evaluation prior surgery for stress urinary incontinence in the years 2008-2012 were considered. Patients considered were classified according to the VALUE trial inclusion/exclusion criteria (2) in patients with “uncomplicated, demonstrable stress urinary incontinence” (briefly, “uncomplicated”) or “complicated”.

Inclusion criteria were: women with urinary incontinence; 21 years of age or older; a history of symptoms of stress urinary incontinence for at least 3 months; clinically predominantly stress urinary incontinence (if mixed incontinence was present); postvoiding residual urine volume of less than 150 ml; negative urinalysis or urine culture; a clinical assessment of urethral mobility, a desire for surgery for stress urinary incontinence; a positive provocative stress test (defined as an observed transurethral loss of urine that was simultaneous with a cough or Valsalva maneuver at any bladder volume). Please note that in the VALUE study the Medical, Epidemiological, and Social Aspects of Aging (MESA) questionnaire had been used to assess the prevalent type of incontinence when mixed incontinence was present: in our retrospective evaluation we were not able to use data of this questionnaire.

Exclusion criteria were: Exclusion criteria were previous surgery for incontinence, a history of pelvic irradiation, pelvic surgery within the previous 3 months, and anterior or apical pelvic-organ prolapse of 1 cm or more distal to the hymen.

The urodynamic observations were compared with pre-urodynamic data and considered different if: a different type of incontinence was diagnosed (e.g. stress instead of mixed or vice versa) or a voiding dysfunction was diagnosed. Different urodynamic observations were separately evaluated in the group of patients “uncomplicated” and “complicated”.

Results

Data of 244 female patients (on a database of around 2750 urodynamic studies) were considered. Thirty-three patients were excluded from the evaluation for incomplete data. Of the remaining 211 patients, only 47 (22.3%) were considered “uncomplicated” according to the definition used in the VALUE trial. The 164 “complicated” patients (77.7%) did not present at least one of the following inclusion criteria or presented at least one of the following exclusion criteria. Inclusion criterion failed: prevalent stress incontinence (in 52 patients), positive stress test (in 49 patients); post-void residual urine >150 ml (in 12 patients). Exclusion criterion present: significant anterior or apical pelvic-organ prolapsed (in 77 patients), previous surgery for incontinence (19 patients).

The urodynamic observations were considered different from the pre-urodynamic data in 134 out of 211 patients (63.5%). This percentage was statistically significantly higher in the “complicated” vs the “uncomplicated” patients (70.1% vs 40.4%, $p=0.0003$). It is worthy to note that a voiding dysfunction was diagnosed in 43 “complicated” patients (26.2%) and 11 “uncomplicated” patients (23.4%): this difference is not statistically significant. The group in which the diagnosis of voiding dysfunction seems to be less likely is the one of “uncomplicated” patients with pure stress urinary incontinence (15% vs 26.7% of prevalence in the remaining patients); nevertheless, this difference is not significant ($p=0.20$).

Interpretation of results

Despite the limitations of a retrospective study, this paper provides, to our opinion, some interesting data.

The huge majority (77.7%) of the female patients coming to our urodynamic lab before surgery for stress urinary incontinence seem to be “complicated”, according to the VALUE inclusion/exclusion criteria. This finding is not completely unexpected, considering that about 66% of patients evaluated in that trial were excluded because they did not meet inclusion criteria. Nevertheless, it seems very useful to underline that the results of the VALUE trial (“preoperative office evaluation alone was not inferior to evaluation with urodynamic testing” for post surgery outcomes at 1 year) should be applied only, as correctly stated by the Authors, to “women with uncomplicated, demonstrable stress urinary incontinence”. These patients, according to the VALUE trial and to the present retrospective study are a minority (34% in the VALUE trial and 22.3% in the present study). For the remaining majority of patients a non inferiority of “simple” office evaluation in comparison to a “complex” evaluation including

urodynamic has not been demonstrated, up to now. On the contrary, a urodynamic evaluation seems to give some new information in as much as 70.1% of “complicated” patients (according to the present study).

Furthermore, according to our data, it seems that a diagnosis of voiding dysfunction could be obtained, only by the urodynamic evaluation, in about 25.6% of patients and the prevalence of this observation is not significantly different in the “complicated” and the “uncomplicated” group. Again, this is not a surprising finding, considering that also in the VALUE trial the urodynamic examination had been able to unmask around 10% of patients with an undiagnosed voiding dysfunction; the interesting data coming from our study is that the proportion of patients diagnosed with voiding dysfunction (higher than in the VALUE trial) is comparable in both groups (“complicated” and “uncomplicated”). Patients with voiding dysfunction seem to show worse results after surgery, according to a subanalysis of the VALUE trial (3): shouldn't we inform the patients consequently before surgery? How to do that without performing urodynamics even in the “uncomplicated” patients?

Concluding message

According to the present study, the huge majority (77.7%) of the female patients coming to our urodynamic lab before surgery for stress urinary incontinence seem to be “complicated”. For these patients, a non inferiority of “simple” office evaluation in comparison to a “complex” evaluation including urodynamic has not been demonstrated and a urodynamic evaluation seems to give some new information in as much as 70.1% of cases.

A diagnosis of voiding dysfunction can be obtained, only by the urodynamic evaluation, in about 25.6% of patients (with comparable prevalence in “complicated” and “uncomplicated” patients); this diagnosis could be related to a worse post surgical outcome. In our opinion, this is a good reason to perform a urodynamic evaluation before surgery even in the “uncomplicated” patients.

References

1. Abrams P, Cardozo L, Khoury S, Wein A.: Incontinence; Health Publication Ltd 2009
2. N Engl J Med 366;21: 1987-97, 2012
3. Neurourol Urodyn. 32:3; 303-4, 2013

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** Retrospectiva study on a database of urodynamics examination; patients signed an informed consent and agreed to the anonymous registration and use of their clinical and urodynamic data. Local ethics committee aware of the existence of the database. **Helsinki:** Yes **Informed Consent:** Yes