PAIN PERCEPTION DURING AMBULATORY CYSTOSCOPY AND URODYNAMICS

Hypothesis / aims of study

To investigate patients' pain perception during cystoscopy and urodynamics.

Study design, materials and methods

Our local ethics committee approved the study. As part of the diagnostic work-up, patients with urinary incontinence who had been scheduled to undergo cystoscopy or urodynamics, completed a questionnaire before and immediately after examination. It included a visual analog scale (VAS; 0 to 10 centimeters) to assess both, their expected and actual amount of perceived pain. Additionally, patients were called one day after the examination and asked about pain and their general state of health. Cystoscopy was performed after instillation of a chlorhexidine and lidocaine containing lubricant (Cathejell[™]) into the urethra, using a rigid cystoscope, charrière 17, with a 70 degree angle of view at bladder filling with 300 milliliters (ml) of 0.9% saline. Urodynamics was performed using a standard transurethral microtip catheter, charrière 8 and a rectal pressure balloon. Urodynamics was also done after Cathejell[™] instillation.

Power calculation yieled a sample size of 52 patients per group, assuming a 2 centimeter difference in pain scores (VAS) as a clinically significant with 95% power and a two-sided significance level of 0.05.

Our Null Hypothesis was: There is no difference in pain perception between a group of patients undergoing ambulatory cystoscopy and another group undergoing urodynamics.

Secondary Null Hypothesis: There is no difference in patients' expectation of pain and the actually experienced pain during cystoscopy and urodynamics.

Exclusion criteria were age \leq 18 years, insufficient ability to understand German, and the participation in another clinical study at the same time. Study design: comparative, non-randomised cohort study.

<u>Results</u>

A total of 109 patients were included into the study. 57 patients underwent cystoscopy and 52 underwent urodynamics. The mean VAS score for patients` pain perception during cystoscopy was 1.9 ± 1.8 (mean \pm standard deviation) and 1.2 ± 1.6 for urodynamics (significant, p=0.03). The mean VAS score for the actually experienced pain in both groups together was 1.5 ± 1.7 (minimum: 0, maximum: 8.8). In both groups, patients expected more pain than they actually experienced: 2.7 ± 2.4 versus 1.9 ± 1.8 for cystoscopy (p=0.03) and 2.1 ± 2.4 versus 1.2 ± 1.6 (p=0.02) for urodynamics. The amount of difference between expected and actually experienced pain in each group was not statistically different between the cystoscopy and the urodynamics group (p=0.87). 20 patients still felt pain on the following day (12 after cystoscopy, 8 after urodynamics), four of whom took analgetics. 106 out of 109 patients (97%) would opt to have the examination again.

Interpretation of results

Both, ambulatory rigid diagnostic cystoscopy and urodynamics cause relatively little pain in urogynecologic patients. Patients experience cystoscopy as more painful than urodynamics and this effects last at least until the following day. Patients anticipate both, cystoscopy and urodynamics to be more painful than they actually are.

Concluding message

Rigid cystoscopy and urodynamics are well tolerated by most patients and 97% are prepared to undergo the test again.

References

1. Erkal S. Patients experiences at home after day case cystoscopy. J Clin Nurs 2007;16:1118-1124

2. Siracusano S, Knez R, Tiberio A, Alfano V, Giannantoni A, Pappagallo G.The usefulness of antibiotic prophylaxis in invasive urodynamics in postmenopausal female subjects. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:939-942

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Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Ethik-Kommission der Medizinischen Universität Wien und des
	Allgemeinen Krankenhauses der Stadt Wien AKH
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes