

## **RANDOMIZED TRIAL COMPARING OUTPATIENT FLEXIBLE TO RIGID CYSTOSCOPY IN FEMALES**

### Hypothesis / aims of study

To compare outpatient rigid versus flexible cystoscopy in females pertaining to (1) pain scored, (2) post procedural complications, (3) de novo symptoms, (3) time to resolution of symptoms, and (5) physician's perception of patient discomfort.

### Study design, materials and methods

This was a randomized clinical trial of women scheduled for outpatient cystoscopy at a tertiary care center urogynecology clinic. Block randomization allocated patients to either flexible cystoscopy (FC), or rigid cytoscopy (RC). Sample size was calculated based on the prior observation that symptoms with outpatient flexible cystoscopy occur in 24% of patients and there was a three-fold increase in morbidity with rigid cystoscopy. 50 patients in each group provide 80% power to detect a difference of this magnitude with 95% confidence. Each patient recorded levels of pain immediately after procedure and 5 minutes later. Pain was measured by a Visual Analogue Scale (VAS) and a 5 point verbal descriptor scale (VDS) addressing: "Which word describes your pain right now?", "Which word describes your pain at its worst?", and "Which word describes it as least?" Physician's perception of patient pain was measured by a VAS. Potential post procedure complications, symptoms, and time to resolution were assessed by a self administered questionnaire within 1 week of the cystoscopy.

### Results

100 women were enrolled in this IRB approved study. The mean age of participants was 59.7years (+ SD 14.6), and 91% were Caucasian. This was the first cystoscopy for 86% of patients. The majority of cystoscopies were performed for evaluation of hematuria, recurrent urinary infections, and urinary incontinence. Duration of procedure was slightly faster for the FC group (4.6 min,  $\pm 1.8$  v. 5.7 min,  $\pm 3.4$ ,  $p=0.046$ ). Average VAS scores was not different between groups ( $1.44 \pm 1.75$  v.  $1.68 \pm 2.14$   $p= 0.5437$ ). Frequency distribution of participant VAS for pain is shown in Figure 1. There were no significant differences in patient response assessed through the VDS. There was also no significant score differences between patient and physician perception of pain (RC group,  $p= 0.383$ ; FC group,  $p= 0.3528$ ). In the one week post procedure questionnaire, which had an 85% response rate, participants in the FC group, reported urinary frequency more often than in the RC group ( $p=0.041$ ). When asked about symptom duration, the FC group reported burning with urination lasting 1-2 days, significantly more often than the RC group ( $p=0.009$ ). There were no other differences when asked about duration of urinary frequency, urgency, and blood in the urine. There were no self reported urinary infections.

### Interpretation of results

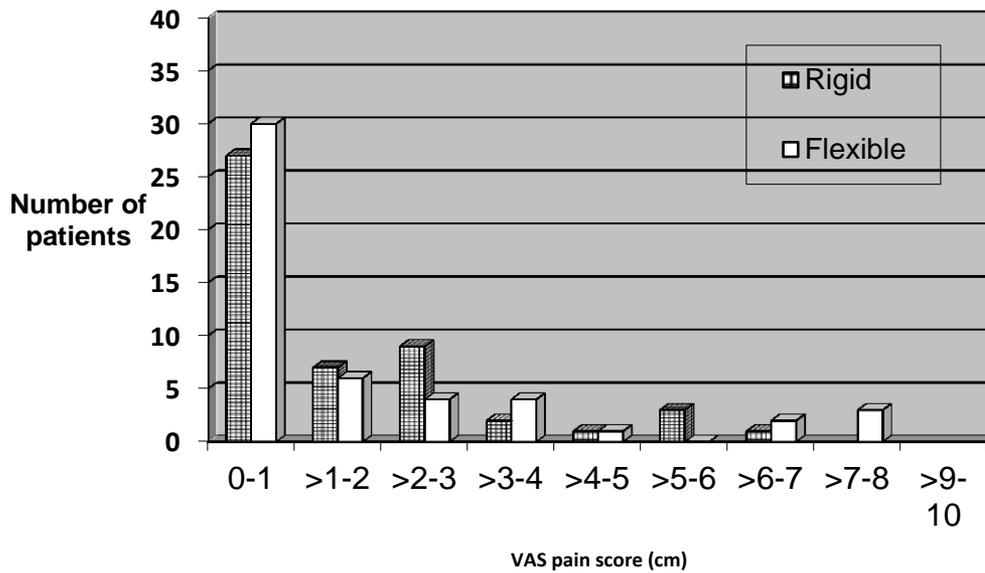
Outpatient flexible and rigid cystoscopies are generally well tolerated in females. Physician perception and patient perception of pain did not significantly differ. Urinary frequency and duration of urinary burning occurred more frequently in the FC group.

### Concluding message

Patient counseling prior to performing flexible cystoscopy should include information about potential development urinary burning and frequency.

Figure 1. Frequency distribution of VAS scores for pain perception by treatment group

## Pain Level During Cystoscopy



<i>Specify source of funding or grant</i>	None
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	Yes
<i>Specify Name of Public Registry, Registration Number</i>	clinicaltrials.gov, registration # NCT00945594
<i>Is this a Randomised Controlled Trial (RCT)?</i>	Yes
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	OUHSC Institutional Review Board
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes