NO PAIN, LOTS OF GAIN:
TOPICAL LIDOCAINE FOR URODYNAMIC TESTING, DOUBLE BLINDED RANDOMIZED CONTROL TRIAL

Hypothesis / aims of study
1. Determine whether the use of topical lidocaine during urodynamic testing decreases patient discomfort during the procedure.
2. Evaluate whether the use of topical lidocaine affects the urodynamic results.

Study design, materials and methods
The hospital Institutional Review Board approved the study. Women with symptoms of stress urinary incontinence scheduled for an urodynamic study (UDS) were eligible to participate. Women presenting with predominant overactive bladder symptoms were excluded. After informed consent, participants were randomized on the day of the procedure using Random Allocation Software Version 1.0. The study participants, the nurses performing the test and the interpreting urogynecologist physicians were all blinded to the study arms until completion of final data analysis. Participant randomization assignment was only known to an independent research nurse and the dispensing pharmacist. The study consisted of transurethral insertion of 5 ml lidocaine 2% or surgilube in the study and control arms, respectively, 10 minutes prior to testing. Prior to testing, a 24 hour bladder diary and the Pelvic Floor Distress Inventory – Short Form 20 were completed by each study participant. The multichannel urodynamic testing was performed per the usual protocol. During bladder filling all participants were asked for sensory information including desire to void and maximal cystometric capacity (MCC). Urethral pressure profiles were obtained at an infused volume of 200 ml. Provocative coughing and valsalva were performed to assess stress urinary incontinence. Using a Likert scale, pain was assessed prior to and after catheter insertion, after performing the urethral pressure profile, and at the completion of the study. Comparisons of the bladder diary and UDS results were made between study and control arms individually and in-between groups.

Statistical methods: Comparisons were done using t-tests for continuous variables, Chi-squared test for categorical variables, Wilcoxon rank-sum test, Lin's Concordance Correlation Coefficient (CCC), and a z-test. Power calculations determined a total sample size of 110 participants was needed to detect significant differences between the groups with at least 94% statistical power.

Results
Data from 110 participants was included for analysis after completion of the study. No differences in demographics except for prior hysterectomy were noted between the groups. Stress urinary incontinence was demonstrated equally in the study and control arms. There was statistically significant less pain in the study arm receiving lidocaine vs. control; pain after UPP minus baseline pain; 1.17 +/- 2.04 vs. 2.05 +/- 2.23 (p=0.032), pain at MCC 1.74 +/- 2.50 vs. 2.96 +/- 3.04 (p=0.023), and pain at MCC minus baseline pain 1.44 +/- 2.54 vs. 2.80 +/- 3.01 (p=0.012). Pain over time by group was significantly lower in the lidocaine arm vs. control at all measured time points following baseline measurements. The administration of lidocaine did not alter MCC during the UDS compared to maximum voided volume on bladder diary (Lin's CCC = 0.467 p=0.0235) between the two groups.

Interpretation of results
During all stages of the UDS, the group administered transurethral lidocaine showed statistically significant lower pain scores than the control group receiving surgilube. Maximum cystometric capacity on UDS correlated with maximal voided volume on bladder diary and did not change between the lidocaine group and the control group, indicating that the lidocaine did not alter bladder capacity.

Concluding message
Use of topical lidocaine during urodynamic testing significantly decreases patient discomfort without affecting UDS results. Consideration should be given to routine application of 2% lidocaine gel intraurethrally 10 minutes prior to performing UDS.

References

Disclosures
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