

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

Zinkgraf K<sup>1</sup>, Aschkenazi S<sup>1</sup>, Anderson R<sup>1</sup>, Stevenson, K<sup>1</sup>

1. Waukesha Memorial Hospital

## 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 IRB approved the study. Women with symptoms of stress urinary incontinence (SUI) scheduled for a urodynamic study (UDS) were eligible to participate. Women presenting with predominant overactive bladder symptoms were excluded. Participants were randomized on the day of the procedure using Random Allocation Software Version 1.0. All were blinded to the study arms until completion of final data analysis. Participant randomization assignment was known only to an independent research nurse and the dispensing pharmacist. The study consisted of transurethral administration of 5 ml lidocaine 2% gel or surgilube gel, in the study and control arms, respectively, 10 minutes before catheter insertion. Prior to testing, a 24 hour bladder diary and the Pelvic Floor Distress Inventory – Short Form 20 were completed. During the UDS 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 measures were performed to assess SUI. 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. The primary outcome; pain after urethral pressure profile (UPP), was compared between the two groups. Comparisons of the bladder diary and UDS results were made between study and control arms individually and in-between groups.

## Statistical methods

The effect of lidocaine on patient pain as reported during multiple time-points during the UDS was evaluated using repeated measures analysis via mixed effects regression with a random patient-specific intercept. This approach allows the evaluation of the overall pain experience, as well as baseline-adjusted comparison at individual time-points. 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. The CCC provides a generalization of Pearson's correlation coefficient that measures how well the data align with the diagonal representing equal values for the two measurements (as opposed to any straight line). Agreement is stronger than correlation. Specifically, the agreement between mean void volume and volume at strong desire, as well as between maximum void volume and volume at MCC were computed separately for each study group. The CCC values were compared between the study groups using 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.

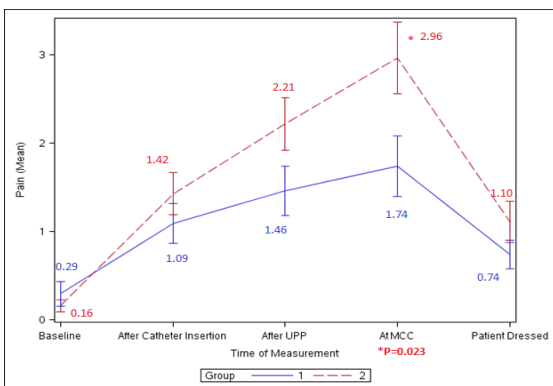
No differences in demographics were noted between the groups except for prior hysterectomy. Stress urinary incontinence was demonstrated equally in the study and control arms.

Without adjustment of baseline pain, pain at MCC was significantly lower in the lidocaine group (Graph 1): 1.74+/-2.50 vs. 2.96 +/-3.04 (p=0.023). After baseline pain adjustment, this finding persisted with statistically significant less pain in the lidocaine group than the control group in the following measurements; pain after UPP: 1.17+/-2.04 vs. 2.05 +/- 2.23 (p=0.032), and pain at MCC: 1.44 +/- 2.54 vs. 2.80 +/- 3.01 (p=0.012).

When comparing bladder diary mean volume and desire to void volume on the UDS, there was similar agreement between both groups (Lin's CCC lidocaine = 0.385 vs., 0.319, p=0.687).

In the lidocaine group, there was statistically significant greater agreement between the diary maximum volume and the UDS MCC vs. the control group (Lin's CCC lidocaine 0.646 vs. 0.313, p=0.0235). This reinforces the notion that lidocaine did not change maximum bladder volumes as the volumes remain similar before and after lidocaine administration. Confirmation of stress urinary incontinence was demonstrated equally in both groups (p=0.73)

Graph 1: Comparison of pain at different time points between study (transurethral lidocaine) and control group (no lidocaine administration) unadjusted for baseline pain.



## Interpretation of results

During all stages of the UDS, the lidocaine group showed lower pain scores than the control group receiving surgilube only. MCC on UDS correlated with maximal voided volume on bladder diary to a greater extent in the lidocaine group, indicating that the lidocaine did not alter maximum bladder capacity.

## Concluding message

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

There are no financial disclosures to report for all study investigators.