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A RANDOMIZED, DOUBLE-BLIND COMPARISON OF BUPIVACAINE CONTAINING SALINE WITH SALINE ONLY FOR HYDRODISSECTION ON VOIDING FUNCTION AND PAIN CONTROL IN THE POSTOPERATIVE INTERVAL FOLLOWING PLACEMENT OF TENSION-FREE VAGINAL TAPE

Hypothesis / aims of study. Tension-free vaginal tape treatment of urinary incontinence has come into common use with some complications. A frequent patient concern is the potential to complete this day-surgery procedure only to require the continued use of a catheter for one or more days after failing a post-operative voiding trial. We noted a tendency for a reduction in failed voiding trials in a retrospective study when the type of local anesthetic agent in the hydrodissection medium was altered. This study was planned to compare the proportion of successful post-operative voiding trials and post-operative pain control when 1/8% bupivacaine containing saline versus saline only is utilized for hydrodissection in the Space of Retzius while placing tension-free vaginal tape midurethral slings.

Study design, materials and methods. A prospective, randomized, double-blind trial was performed after review and approval by the institutional review board. Sixty consenting patients undergoing tension-free vaginal tape placement as their only pelvic floor procedure in a day-surgery unit were randomized using sealed envelopes to receive either bupivacaine containing saline or saline alone. The solution formulation was performed such that subjects, surgeons, and research assistants who interacted with the subjects were blind to treatment. Proportions of subjects with a successful post-operative voiding trial along with measurements of post-operative pain and analgesic use were compared using Student's *t* test, Pearson's chi-square, and Mann-Whitney U. The study was powered to detect differences in voiding trial success from an estimated 55% to greater than 90% with $p<0.05$ and 0.8 power using 25 subjects per group. Additional subjects were allotted to allow for dropouts. An improvement of 35% was considered clinically important as previous experience had also shown a majority of patients failing the post-operative voiding trial, but they only required catheter use for one day. Voiding trials were conducted in the post-operative recovery unit using a standardized method. Post-void residual was also measured as was each subject's pain perception using a visual analog scale. All patients were followed 24 hours after surgery by phone contact to obtain information on additional pain medication use and at the six week post-operative check-up for total length of catheter use and post-operative complications.

Results. Thirty subjects were allocated to each group as planned using sealed envelopes. One subject was excluded after randomization into the saline only group when a second pelvic floor procedure was performed intra-operatively. The treatment groups did not differ in height, weight, BMI, age or pre-operative post-void residual ($p > 0.47$, Student's *t* test) nor numbers of pregnancies, vaginal deliveries, c-sections, and gynecologic surgeries ($p > 0.24$, Mann-Whitney U tests). Groups did not differ in duration of anesthetic ($p = 0.54$), volume of hydrodissection fluid ($p = 0.83$), estimated blood loss ($p = 0.18$), intra-operative complications ($p = 0.32$), and post-operative interval to start of voiding trial ($p = 0.08$). Use of additional pain medications during this interval did not differ ($p = 0.08$) with 86% of those receiving saline only requiring medications compared to 67% of those receiving bupivacaine containing saline. The visual analog score (0-100), a measure of degree of post-operative pain at the time of the voiding trial, did not differ between groups (31 in saline only group versus 36, $p = 0.43$). The total bladder volume was also similar (384 mL for the saline only group versus 413 mL for the bupivacaine containing solution, $p = 0.88$). The percentage of subjects who passed the post-operative voiding trial did not differ (66% for those using saline only versus 47%, $p = 0.14$). The post-void residuals did differ (140 mL in those using saline only versus 225mL, $p = 0.043$ by Mann-Whitney U test). There was no correlation (correlation coefficient of 0.031, $p = 0.82$) of post-void residual to interval from extubation to the voiding trial for the interval from 26 to 230 minutes). The median duration of catheter use in patients failing the initial voiding trial was 1 day in both groups. There was no difference in pain medicine use by patients during the first 24-hours. At the 6-week follow-up visit, there were no differences between groups in complications ($p = 0.97$), urinary tract infections ($p = 0.74$) and satisfaction scores ($p = 0.59$).

Interpretation of results. The results show that addition of bupivacaine to the hydrodissection fluid did not significantly reduce post-operative pain nor did it significantly increase the risk of failing a post-operative voiding trial to a level felt to be clinically important. A power analysis with the data from this study estimates that 118 subjects per group would be required to find a difference of the magnitude measured as significant at the $p < 0.05$ and a power of 0.80. In light of the 85 mL increase in post-void residual which was found to be significant and felt to be clinically important, bupivacaine was left out of the hydrodissection solutions for subsequent cases in our clinic. Since the conclusion of this study, 29 patients have undergone similar procedures and been assessed using the standardized post-operative voiding trial. Twenty of 29 (69% with 95% confidence interval of 49% to 85%) did not require catheter use for an additional day similar to the 66% of those in the saline only group of this trial. Therefore, we feel our conclusions are warranted.

Concluding message. Because bupivacaine was not seen to improve post-operative pain following placement of a tension-free vaginal tape midurethral sling, did not increase the risk of failing a post-operative voiding trial, and was associated with increased post-void residuals, prudence suggests that saline only be preferred over bupivacaine containing solutions for hydrodissection.

Specify source of funding or grant **Funding provided by Enderly Endowment for Research in Urogynecology and Noble Centennial Endowment for Research**

	in Obstetrics and Gynecology.
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Scott & White Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**