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A RANDOMIZED DOUBLE-BLIND PLACEBO CONTROLLED COMPARISON OF THE EFFECT OF NITROFURANTOIN MONOHYDRATE ON THE DEVELOPMENT OF URINARY TRACT INFECTIONS FOLLOWING SURGERY FOR PELVIC ORGAN PROLAPSE AND/OR GENUINE STRESS URINARY INCONTINENCE WITH SUPRAPUBIC CATHETER

Aims of Study

To determine whether antibiotic prophylaxis with nitrofurantoin monohydrate following pelvic organ prolapse and/or urinary incontinence surgery with suprapubic catheterization decreases urinary tract infection compared to placebo in a randomized, double blind, multi-center trial.

Methods

Six centers participated. Subjects were randomized to receive Study Drug A or B through the lead institution. All patients had a negative preoperative urine culture. History, surgical and postoperative course, urine culture and symptoms at suprapubic catheter (SPC) removal and at 6-8 weeks postoperative, treated urinary tract infection (UTI) at any other time up to 6-8 weeks postoperative, and compliance were recorded. Assuming a 20% bacteruria rate in patients without antibiotic prophylaxis, 438 patients are required to demonstrate a 50% decrease in the bacteruria rate with 80% power and α equal to 0.05. Data was evaluated using Student t-test and Fisher's exact test.

Results

A total of 449 patients were enrolled. Thirty-three patients withdrew or were excluded, leaving 416 study subjects, with 202 randomized to nitrofurantoin monohydrate (Drug A) and 212 randomized to Placebo (Drug B). There were no demographic, surgical, compliance, or perioperative differences, including complications, between the two groups ($p > 0.05$). Antibiotic prophylaxis with nitrofurantoin monohydrate was associated with a decrease in any positive urine culture compared to placebo (45% vs 61%, $p=0.002$), symptomatic UTI at SPC removal (7.4% vs 18.8%, $p=0.002$), and any symptomatic UTI (18.4% vs 32.1%, $p=0.002$). However, antibiotic prophylaxis did not significantly decrease symptomatic UTI at the 6-8 week postoperative visit (2% vs 5.5%, $p=0.10$). Preoperative variables, including grade/stage of prolapse, elevated postvoid residual > 100 cc, and past medical history were not related to UTI ($p>0.05$). However, intraoperative estimated blood loss, postoperative infectious complication, and length of SPC were associated with increased risk of UTI ($p<0.05$).

Conclusions

Antibiotic prophylaxis with nitrofurantoin monohydrate decreases UTI compared to placebo following pelvic organ prolapse and/or urinary incontinence surgery with suprapubic catheterization.