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DOUBLE-BLINDED RANDOMIZED TRIAL OF PREOPERATIVE ANTIBIOTICS IN MIDURETHRAL SLING PROCEDURES

TOPIC: SURGERY FOR STRESS INCONTINENCE

Hypothesis / aims of study

To determine if the use of prophylactic antibiotics before Midurethral sling procedures reduces postoperative infectious complications.

Study design, materials and methods

We received institutional IRB approval for this study. All women scheduled to undergo a mid-urethral sling procedure (retropubic or transobturator approach) were eligible for enrollment. Exclusion criteria included; those receiving antibiotics within preoperative 3 days, concomitant surgical procedures, penicillin or cephalosporin allergy, risk factors for endocarditis, and immunosuppression. Patients were randomized to receive Cefazolin or placebo preoperatively in a double-blinded randomized fashion. Patient demographics and surgical outcomes were recorded. The primary outcome was postoperative wound infection. Secondary outcome measures included urinary tract infections, febrile illness, hospital readmission, and mesh exposure. Logistic regression was used to determine differences between the two groups. The baseline risk of surgical site infection is 5%. A power analysis was performed to detect a difference of 50% in infection rate. To achieve 80% power, a total of 200 patients will be necessary with a two sided 5% significance level.

Results

We enrolled 59 women between April 2005 and May 2006: 29 in the Cefazolin, and 30 in the placebo group. Total follow up was 6 (3-24) months .The groups were similar with respect of age, parity, body mass index, race distribution, smoking history, and medical conditions such as diabetes. There were no infections in the placebo group and 1 in the treatment group, (0 vs. 3.3 %). There was 1 mesh exposure in the placebo group and 0 in the treatment group, (3.5 v. 0%). Urinary tract infection was more common in Cefazolin group (3/30, 10%) than the placebo group (1/29, 3.5%), this difference was not statistically significant. There were no other relevant complications.

Interpretation of results

Preliminary data suggests that there is no difference in infectious outcomes between the women who received preoperative antibiotic and placebo.

Concluding message

As it is difficult to achieve adequate power in a single institution due to very low wound infection rates seen in this study, we decided to end recruitment. Consequently, we believe that it is justifiable not to use preoperative antibiotics routinely.

Specify source of funding or grant	**No funding**
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	**Baystate Medical Center IRB**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**