Postoperative Infection Rates in Low Risk Patients Undergoing Percutaneous Nephrolithotomy With and Without Antibiotic Prophylaxis: A Matched Case Control Study

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Purpose: Current guidelines recommend prophylactic antibiotic therapy for all patients undergoing percutaneous nephrolithotomy. We examined the effects of antibiotic prophylaxis in patients undergoing percutaneous nephrolithotomy with negative preoperative urine cultures.

Materials and Methods: Of the 5,803 patients in the CROES (Clinical Research Office of the Endourological Society) Percutaneous Nephrolithotomy Global Study database, a group of 162 patients undergoing percutaneous nephrolithotomy with a negative baseline urine culture who did not receive antibiotic prophylaxis were matched on preoperative nephrostomy, the presence of staghorn calculi and diabetes status with an equal number of patients who received antibiotic prophylaxis. Comparisons were made between the 2 groups in terms of operative and postoperative outcomes, including the incidence of fever and other complications.

Results: Patients who received antibiotic prophylaxis had a lower mean (SD) age at 44.9 (14.2) vs 50.1 (14.4) years ($p = 0.001$). They were also more likely to be in the prone position during the procedure (71.6% vs 39.5%, $p < 0.001$) but less likely to receive postoperative stenting (17.3% vs 32.7%, $p = 0.002$) than those who did not receive prophylaxis. The 2 groups were comparable in terms of all other baseline characteristics and operative factors. Patients who received antibiotic prophylaxis were less likely to experience fever (2.5% vs 7.4%, $p = 0.040$) and other postoperative complications (1.9% vs 22.0%, $p < 0.0001$), and had a higher stone-free rate after percutaneous nephrolithotomy (86.3% vs 74.4%, $p = 0.006$).

Conclusions: Antibiotic prophylaxis of patients undergoing percutaneous nephrolithotomy with a negative baseline urine culture is associated with a significant reduction in the rate of postoperative fever and other complications.

Key Words: nephrostomy, percutaneous; antibiotic prophylaxis; infection; postoperative complications

Abbreviations and Acronyms

PCNL = percutaneous nephrolithotomy

UTI = urinary tract infection

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SINCE its first successful application in the 1970s,[1] percutaneous nephrolithotomy has become the preferred method of removing renal calculi in patients with a large or complex stone burden.[2] Fever secondary to UTI remains a common sequela of PCNL, occurring in 21% to 39.8% of patients.[3,4] Although the majority of temperature increases after PCNL are transient, potentially life

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threatening sepsis can develop in up to 9.3% of patients.[3] Bacterial release from the surgical manipulation and/or fragmentation of calculi, or the introduction of bacteria via the nephrostomy tract, are the basic ingredients necessary for the development of UTIs after PCNL.[5] However, numerous patient and operative factors can increase the risk of infection after PCNL.[3,5–7]

The AUA (American Urological Association)[8] and EAU (European Association of Urology)[9] guidelines recommend prophylactic antibiotic therapy for all patients undergoing PCNL. Unfortunately little evidence exists to support the systematic antibiotic prophylaxis of patients undergoing PCNL, particularly those with negative urine cultures.[10] One randomized placebo controlled trial evaluated the utility of antibiotic prophylaxis in patients undergoing PCNL with a low risk for infection.[11] However, due to a limited sample size, this study was unable to demonstrate a statistically significant reduction in rates of post-PCNL bacteriuria or fever in response to cefotaxime vs placebo. Thus, while an antibiotic prophylaxis policy for PCNL should be based on high levels of evidence, the extent to which antibiotic prophylaxis in low risk patients undergoing PCNL may be clinically beneficial remains largely unknown. Additionally, the current recommendations for antibiotic prophylaxis of all patients undergoing PCNL raise concerns regarding the risk of possible side effects and the development of microbial antibiotic resistance.

CROES, an established unit of the Endourological Society, is responsible for organizing, structuring and facilitating a global network for endourological research.[12] A major initiative by CROES led to the development of the PCNL Global Study. In the current investigation we compared the incidence of fever in patients with negative urine cultures who underwent PCNL with vs without antibiotic prophylaxis.

MATERIALS AND METHODS

Between November 2007 and December 2009, 5,803 consecutive patients treated during a 1-year period at 1 of 96 participating global centers were included in the PNCL Global Study. Patients eligible for inclusion in the study were all those who were candidates for PCNL treatment as the primary indication or after failure of previous treatment. For the current analysis only patients with a negative preoperative urine culture were included.

The background for the development of CROES[12] and the organizational details of the CROES PCNL Global Study have been previously reported.[13] A CROES Steering Committee was set up with the objective of recruiting 100 centers worldwide with an assortment of sites, particularly with different PCNL treatment volumes. Each center was invited to include all patients treated consecutively for 1 year, with the study period at each site starting with the treatment of the first included patient. The authors are representative of the sites that enrolled patients in the PCNL Global Study.

The treatment of patients with PCNL was based on the presence of symptoms of flank pain, hematuria, fever and/or sepsis, and/or dilatation of the upper urinary tract. Bladder urine samples were obtained before the surgical procedure at the discretion of the treating physician and were subsequently tested for the presence of bacterial cultures. Of the 5,803 patients participating in the Global PCNL study 162 (2.8%) did not receive antibiotic prophylaxis as deemed appropriate by their physician.[13] For those patients who received antibiotic prophylaxis, individual centers used their local antibiotic protocols based on antibiotic resistance patterns, antibiotic committee guidance, and local and national guidelines.

During PCNL the patients were positioned in the supine or prone position as determined by the treating physician. Access to the upper tract was guided by ultrasound and/or x-ray combined with (retrograde) intrarenal contrast injection. Once access was obtained, a guidewire was inserted and maneuvered toward the ureter. Dilation was performed with balloon or telescopic dilators along with application of an Amplatz sheath. On followup, the system was inspected by a rigid nephroscope and the stones were disintegrated by laser, ultrasound or ballistic devices, or removed entirely with graspers. The procedure was considered completed when all removable stones had been removed. Internal and/or external drain(s) were positioned according to surgeon judgment.

The presence of a postoperative fever of greater than 38.5C was assessed according to the established protocols at each participating center. All patients received regular followup of perioperative and postoperative complications, stone-free rates and re-treatment rates. Perioperative complications were assessed and scored according to the modified Clavien classification system as applied to PCNL. Data were collected in a central database held at the CROES office. At each participating center institutional review board approval was obtained if required. Otherwise, the lead investigator was responsible for ensuring the quality of the clinical data collected. Each center appointed a staff member to coordinate data collection and handling, and to provide regular updates of the data from their center to the central database.

To provide an unbiased estimation of the effect of antibiotic prophylaxis on postoperative outcomes, we used propensity score matching of patients who underwent PCNL with or without antibiotic prophylaxis in a ratio of 1:1. The matching variables included the presence of preoperative nephrostomy, staghorn calculi and diabetes. Subsequently various demographic, operative and postoperative factors were compared between patients undergoing PCNL who did vs did not receive antibiotic prophylaxis before treatment, but who were otherwise matched on risk factors for fever after PCNL. The chi-square and Student t tests were used to assess group differences in categorical and continuous variables, respectively. Categorical variables were expressed as patient numbers and proportions, while continuous variables were expressed as means and SD. The level of significance was defined as