

Barretos Cancer Hospital

Antibiotic prophylaxis in urinary tract clearance by percutaneous nephrostomy and catheter changes in patients with malignant ureteral obstruction: Retrospective cohort study and systematic review with meta-analysis

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Area of Concentration: Oncology

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Statistical Analysis Plan

Study variables

The study variables make up the research instrument used for data collection.

Sociodemographic and clinical variables: gender, color, age, weight, height, underlying neoplastic disease, performance status and number of organs affected by metastases. Presence of fever, low back pain, pain at the wrist-percussion of the lumbar region, pain in the hypogastrium, dysuria and polyuria, presence of cloudy urine and organ dysfunction. The presence of leukocyturia (elevated white blood cell count on urine sediment examination), leukocytosis (elevated white blood cell count on blood count examination) and positive uroculture will also be checked if they have been used as a therapeutic decision for urinary infection.

Radiological data: degree of urinary tract obstruction.

Dates of diagnosis of underlying neoplasm and diagnosis of malignant ureteral obstruction.

Laboratory data: blood count, creatinine, urea, type I urine, uroculture and antibiogram.

Antibiotics: for the prophylaxis or treatment of urinary tract infection and sensitivity of the first antibiotic used for prophylaxis and/or treatment.

Colonizing and infecting agents and their classification in terms of multidrug-resistant organisms

Period of use of catheter(s); removal of catheter(s); other complications, such as mobility of catheter(s) and/or obstructions.

Data Storage Plan

The data was stored on the REDCap platform, which is among the best platforms for collecting, managing and storing data for research and multi-institutional studies. It complies with the American laws on the protection of patient data, the Health Insurance Portability and Accountability Act (HIPAA). In addition to secure data storage and management, research data is stored on the institution's own server.

Statistical analysis

The data was extracted from the REDCap platform into the SPSS statistical program. The study population was characterized using descriptive statistics, using the mean,

median, standard deviation, minimum, maximum and quartiles for quantitative variables and frequency tables for qualitative variables.

The database was made up of patient information and procedure information, but with a unique identifier for each patient, allowing information to be linked between them.

For the purposes of this study, nephrostomy procedures were considered independent.

The Shapiro-Wilk normality test confirmed the non-normal distribution of the continuous variables. These non-parametric variables were described as the median and the respective interquartile range (from the 25th to the 75th percentile). The Mann-Whitney test was used to compare two independent samples. Categorical variables were presented in absolute and relative frequencies using chi-square association tests or Fisher's exact tests when the expected result was less than five in more than 20% of the cells in the association tables. Post-hoc analysis was carried out using Bonferroni's adjusted p-value for comparisons between more than two independent groups of categorical variables. Multiple analysis was carried out using multiple variable logistic regression. To this end, only the variables that obtained a p-value of less than 0.20 in the simple logistic regression analysis were selected for the model. The analyses were carried out using IBM-SPSS v.26.0 software with a significant level of 5%, two-sided. G*Power v.3.1.9.4 software was used to calculate the statistical power of the sample in the analysis for urinary tract infection.