ORIGINAL ARTICLE

Incidence of fever and bleeding after percutaneous nephrolithotomy: a prospective cohort study

Incidencia de fiebre y hemorragia post nefrolitotomía percutánea: un estudio de cohorte prospectivo

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Abstract

Objective*: Despite relative agreement on the need for immediate peri-operative antibiotic prophylaxis in percutaneous nephrolithotomy (PCNL), there is no consensus regarding antibiotic use the days leading up to PCNL. This study aimed to report the incidence of complications during and after PCNL based on a cohort study design.* **Material and methods***: We included 101 patients in a prospective schedule for PCNL. Patients were divided into 2 groups. In the exposed patients (positive urine culture) the antibiotic was indicated according to the antibiogram report, 7 days before surgery, and 7 days after surgery, and in the non-exposed patient's intravenous antibiotic empirically was administered 8 h and 1 h before surgery.* **Results***: The incidence of complications for both groups was 19%. The exposed group presented complications in 27%, and 16% for the non-exposed. The relative risk of complications, in general, was 1.68 (95% CI, 0.77-3.6), the attributable risk was 11.09, and the percentage of attributable risk was 40.68%.* **Conclusions***: The presence of positive urine culture is the main risk factor for the development of post-PCNL fever. Each treatment center needs to standardize its protocols to reduce the morbidity associated with surgery and to identify the main risk factors.*

Keywords: *Percutaneous nephrolithotomy (PCNL). Post-operative fever. Trans-operative bleeding. Antimicrobial prophylaxis. Prospective cohort. Relative risk complications.*

Resumen

Objetivo: *El objetivo de este estudio es reportar la incidencia de complicaciones durante y después de la nefrolitotomía percutánea (NLP) con base en un diseño de cohorte prospectivo.* **Material y métodos:** *Se incluyeron 101 pacientes de forma prospectiva programados para NLP. Los pacientes fueron divididos en 2 grupos. En el grupo de expuestos (cultivo de orina positivo) el antibiótico se indicó según el reporte del antibiograma, 7 días antes y 7 días después de la cirugía. En los pacientes no expuestos (cultivo de orina negativo) se administró empíricamente antibiótico intravenoso 8 h y 1 h antes de la cirugía.* **Resultados:** *La incidencia de complicaciones para ambos grupos fue del 19%. El grupo de expuestos presentó complicaciones*

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en 27% mientras que para los no expuestos fue de 16%. El riesgo relativo de complicaciones en general fue de 1.68 (IC 95%, 0.77-3.6), el riesgo atribuible fue de 11.09 y el porcentaje de riesgo atribuible fue de 40.68%. **Conclusiones:** *la presencia de urocultivo positivo es el principal factor de riesgo para el desarrollo de fiebre post-NLP. Es importante que cada centro de tratamiento estandarice sus protocolos para reducir la morbilidad asociada con la cirugía e identificar los principales factores de riesgo.*

Palabras clave: *Nefrolitotomía percutánea (NLP). Fiebre post-operatoria. Hemorragia transoperatoria. Profilaxis con antibióticos. Cohorte prospectiva. Riesgo relativo de complicaciones*

Introduction

Nephrolithiasis is a highly prevalent disease worldwide, with rates ranging from 7-13% in North America, 5-9% in Europe, and from 1-5% in Asia[1]. In 2002, a survey reported the prevalence of kidney stones of 5.5% in Southern Mexico, and one of even up to 11% in subjects aged more than 50 years[2]. Heritability and modifiable factors, especially environmental and dietary, have been reported to be associated with the risk of stones, including overweight and obesity, the amount and composition of fluid intake, a diet high in fruits, vegetables, and low-fat dairy products and amounts of dietary calcium intake[3].

Before 2000, rates and distribution of minimally invasive surgical procedures, namely Extracorporeal Shock Wave Lithotripsy (ESWL), UReteroScopy (URS), and PerCutaneous NephroLithotomy (PCNL) were relative stable in Medicare population. ESWL comprised 51-54%, URS 40-41%, and PCNL 3-4% of these procedures[4]. However, over time, PCNL has come to be used more frequently, especially for stones over 2 cm in size[5].

Minimally invasive patterns regarding kidney stone management vary by country and region. In Mexico, PCNL is performed throughout the country in secondary- and tertiary-care medical centers as a favorable option for patients and physicians. The Centro Medico Nacional de Occidente (IMSS) is a tertiary reference center for patients with kidney stones from western Mexico. In 2014, the number of PCNL performed was around 126. In 2015, the number increased to 215 and, during the first half of 2016, nearly 100 PCLN were carried out.

The purpose of this study was to report the incidence of complications during and after PCNL based on a cohort study design.

Material and Methods

The research project was presented to the Local Committee for Research and Research Ethics in Health number 1301 of The Western National Medical Center of Mexican Social Security Institute with registration number 13 CI 14 039 204 according to COFEPRIS (Federal Commission for Protection of Health Risks) as a prospective cohort design projected at 18 months (Authorization R-2016-1301-108). The cohort included patients with a diagnosis of renal lithiasis treated at the Department of Urology of the Hospital de Especialidades del Centro Medico Nacional de Occidente in Guadalajara, Jalisco, Mexico. All procedures were performed based on national and international standards and guidelines in order to protect patient's safety. An informed consent was obtained from all patients and if patients were under 18, from a parent and/or legal guardian.

Inclusion criteria for the cohort comprised men and women older than 16 years of age with non-complex kidney stones (staghorn calculi, associated encrusted or calcified double J stents and kidney malformations) and who were candidates for PCNL. All patients complied with the pre-surgical protocol of the institution (pre-anesthetic assessment, Internal Medicine or Cardiology). Two study groups were formed. The first was for patients of both genders, older than 16 years of age, with a positive pre-operative urine culture (exposed). The second group was made up of patients with the same characteristics as those of the first one, but with a negative urine culture report (non-exposed). The first group was given antibiotics 7 days before surgery based on the antibiogram report and continued with the same management during and 7 days after the surgery. The second group was given intravenous (i.v.) antibiotic empirically (Cefuroxime and Ciprofloxacin in case of allergy to beta lactams), two doses, 8 h and 1 h before surgery.

The procedures in both groups regarding technique were the same (same surgeon, general anesthesia, and double-flex prone position). For puncture and dilation of the tract, the bull's eye technique and the one-shot method (Amplatz sheath 26F dilators; Boston Scientific, Marlborough, MA, USA) were used,

respectively, with the assistance of fluoroscopy. Details in the technique, such as fluoroscopy time and radiation received by medical personnel, may be consulted elsewhere[6].

Patients with horseshoe kidney or other congenital malformations, those who were transplanted, and surgeries that required two or more times were not included in the study.

For the statistical analysis, univariate methods were used for absolute and relative frequencies, while means and Standard Deviation (SD) were employed for quantitative variables. The bivariate analysis-estimated Relative Risk (RR), Attributable Risk (RA), and Percentage of Attributable Risk (PRA) were utilized for complications between the two groups. The relationship between dependent and independent variables was calculated based on a crude model using a multivariate analysis. All stages of the statistical analysis were calculated with a 95% Confidence Interval (95% CI). Statistical inference was calculated with an alpha value of 0.05. The calculations were made with the Excel, Epi-Info, SPSS, and Open Epi statistical software.

Table 1. Demographic data

Variable (means)	Female	Male
Age (years)	43.3	49.1
Weight (Kilograms)	71.9	80.4
Height (meters)	1.58	1.70
Corporal Mass Index	28.77	27.93
Exposed (positive urine culture)	15	18

Table 2. Isolated microorganism from exposed group (n=33)

Microorganism	Number of cases (%)
Escherichia coli	23 (69.7)
Acinetobacter baumannii	2 (6.06)
Pseudomonas aeruginosa	4 (12.12)
Klebsiella pneumoniae	3 (9.09)
Staphylococcus saprophyticus	1 (3.03)

Results

A total of 101 patients were included for the study. The age range was 34 to 75 years, with an average of 49.8 years for both groups. The exposed group (positive urine culture prior to surgery) was composed of 33 patients (33.67%) and the non-exposed group (negative urine culture) was composed of 68 patients (1:2.06). Table 1 shows demographic data from groups. Isolated bacteria from infected patients (exposed group) is shown in Table 2.

Forty-eight procedures were performed on the right side. Average stone volume was 6.89 cm3 for both groups (8.4 cc men, and 5.8 cc women). Average stone density was 913 Hounsfield Units (HU), and average surgical time was 40.79 min (men 45.9, and women 37.1). Table 3 summarizes general data about surgical variables.

Trans-operative bleeding requiring transfusion and post-operative fever were the complications considered. Both of these were grade II according to the modified Clavien grading system[7].

Trans-operative bleeding (transfusion required) and post-operative fever were considered as dependent variables for the study. Regarding the former, it only presented in four patients (3.96%). In two of these patients (1.98%), the bleeding persisted for more than 72 h; therefore, nephrectomy was necessary (Clavien grading system IV). Both of these patients were women. One of these had a pre-PCNL diagnosis of chronic kidney failure (in the kidney transplantation protocol), thus, she was not a candidate for endovascular therapy. The second patient presented hypovolemic shock and elevated levels of creatinine and urea, so neither was she selected for endovascular management.

Fever was present in 14 patients (13.86%) during the first 48 h post-PCNL (five men and nine women). An extended hospitalization time, ranging from 3-days on average, was required. No other type of complication was presented.

The nephrostomy tube was removed at 24-36 h after surgery. After hospital discharge, no patient required hospital readmission. The stone-free rate was 84%, and this was verified 1 month after surgery with a non-contrast abdominal Computed Tomography (CT) scan.

In general terms, total incidence of complications for both groups was 19%. The exposed group presented complications in 27%, while complications were found in 16% of the non-exposed group. RR of complications in general was 1.68 (95% CI, 0.77-3.6), AR was 11.09, and PAR was 40.68 of complications.

Regarding transfusion, total incidence was 3% (exposed 6%, and non-exposed 2.9%). Patients with

Table 3. Arithmetic mean of study variables

Stone volume	Stone density	Surgery time*	Used water (NS0.9%)	Fluoroscopy time*
6.89 cm^2	913 HU	40.79 minutes	4.94 liters	57 seconds
SD 7.04	SD 368.04	SD 26.88	SD 4.5	SD 24.90
95%CI 5.50-8.27	95%CI 840.3-985.6	95%CI 35.48-46.09	95%CI 4.05-5.82	95%CI 52.08-61.91

*The surgery time was measured from puncture to nephrostomy tube colocation
*The fluoroscope was adjusted to minimal dosage (10 mSv per minute)
CI: Confidence interval (t test); SD: Standard deviation.

Table 4. Multivariate analysis results (crude model)

Dependent variable	Independent variable	P value (Chi squared test)	Dependent variable	Independent variable	P value (Chi squared test)
Fever	Diabetes mellitus	>0,05	Transfusion	Diabetes mellitus	>0,05
	Chronic hypertension	>0,05		Chronic hypertension	>0,05
	Chronic kidney disease	>0,05		Chronic kidney disease	>0,05
	Amount of water	>0,05		Amount of water	>0,05
	Surgery time	>0,05		Surgery time	>0,05
	Number of tracts	>0,05		Number of tracts	>0,05

positive urine cultures presented an RR of 2.06 (95% CI, 0.30-13.9), an RA of 2.1, and a PRA of 51.47.

The incidence of fever in both groups was 13.8% (18.1% in exposed and 11.7% in non-exposed). RR was 1.54 (95% CI, 0.58-4.0), RA was 6.41, and PRA was 35.29.

Multivariate analysis included fever and transfusion as dependent variables. To complete the model as independent variables, diabetes mellitus, hypertension, chronic kidney disease, surgery time, amount of water used, and number of tracts were employed obtaining a crude model without no p <0.05 between dependent and independent variables; thus, it was not possible to construct an adjusted model. Table 4 shows results of crude model.

Discussion

The results obtained in our study clearly showed that the frequency of bleeding and fever in patients submitted to a PCNL procedure is higher when the pre-operative urine culture is positive, despite the antibiotic treatment administered. The latter questions whether a 7-day antibiotic treatment prior to surgery is sufficient to avoid these two specific complications.

In 2013, a study reviewed the incidence of Urinary Tract Infections (UTI), post-operative fever, and risk factors of post-PCNL in 96 centers[8]. A total of 5,803 patients were included in the study, in which 10% of the cases (n = 550) presented fever after PCNL despite receiving antibiotic prophylaxis. A total of 865 cases (16.2%) presented positive urine culture, and of these, 18.2% presented fever. Only 8.8% of patients with negative urine culture had fever[8]. These results are similar to those reported in our work; however, a multicenter study tends to entertain greater variability with regard to the results obtained. The strength in our study lies in that it was performed at a single center with the same protocol for all of patients included in the study. Another difference is that our work did not reveal a significant relationship between fever and diabetes (Odds Ratio [OR], 1.9; 95% Confidence Interval [CI], 0.70-5.5; p = 0.2). Our study also demonstrated a higher RR for fever in exposed patients; however, the PAR was 35.29, indicating that about 65% of fever episodes can be attributed to another cause (OR, 1.5; 95% CI, 0.58-4.0; p = 0.3).

In 2016, a study was published that included 138 patients with negative urine culture, renal lithiasis greater than 2 cm, hydronephrosis, and a history of previous UTI[9]. The authors considered these latter three variables as high-risk factors. Twenty-seven of these patients were treated with 7 days of

prophylaxis, other 39 patients received 2 days of prophylaxis, and 72 did not receive pre-operative antibiotics. The authors concluded that prophylaxis extended to 7 days revealed no decrease in risk of fever or tachycardia (p >0.05). The analysis between groups only showed a statistically significant difference in terms of the leukocyte count (p >0.02)[9]. In our study, the non-exposed group had only one of these high-risk factors, which was renal lithiasis, which was greater than 2 cm. None of the non-exposed patients presented hydronephrosis or had a history of previous UTI. A total of eight patients presented fever after PCNL (11.7%), unlike 1 patients (1.4%) in the group reported in the study by Potretzke et al[9]. The difference between the studies regarding this percentage is evident; therefore, it is not possible to consider the same recommendation.

The meta-analysis conducted by de Jonge et al.[10] included 14 studies with 54,552 patients who underwent various surgical procedures. The authors concluded that risk of surgical-site infection is nearly twice that when the prophylactic antibiotic is administered 0-60 min prior to the incision (OR, 1.89; 95 CI, 1.05-3.40) and five times higher when administered 2 h before the incision (OR, 5.26; 95% CI, 3.29-8.39)[10]. It is noteworthy that this report included the four types of surgical procedures described by the CDC (Centers for Disease Control and Prevention)[11]. Our work included only clean contaminated surgery. Regarding patients who presented fever, none of these required more than 48 extra h of hospitalization, in that they registered a single peak higher than 38°C. Hospital discharge was ordered 24 h after fever, and oral antibiotics management was extended to 10 days maximum, while for those without fever, the antibiotic was administered for 7 days post-operatively in both groups.

Lojanapiwat et al., in a PCNL review study, defines the procedure in two ways: clean contaminated (uncomplicated stone without obstruction, stent, or UTI history), or contaminated (complex stone, with obstruction, nephrostomy tube, or double J stent placement). The authors also suggest that, despite a pre-operative negative urine culture, prophylaxis must be administered routinely and a culture must be performed in the presence of fever[12]. Our cohort included only patients considered as clean contaminated. Despite the two prophylactic schemes used, fever was present in both groups. Although the proportion was higher in the exposed group, there was no statistically significant difference (p = 0.6).

Multiple authors have recommended treatment schemes based on their research, such as Chew et al., who conducted a multicenter study in 2018 that included 86 PCNL candidates considered low-risk patients. Low risk was defined as a negative pre-operative urine culture and no history of urinary drain. Forty-three patients were managed with Nitrofurantoin 100 mg every 12 h for 7 days prior to PCNL. The control group did not receive Nitrofurantoin. All patients received Ampicillin or Gentamicin in a single pre-operative dose. No statistically significant difference was shown between groups in relation to sepsis (12% vs. 14%; 95% CI, 0.163-0.122; p = 1.0)[13].

Regarding European guidelines, it has been mentioned that the risk of infection in PCNL is high, that the use of antimicrobial prophylaxis has shown to reduce the risk of infectious complications in a significant manner, and that a single dose has demonstrated to be sufficient[14]. American Urological Association (AUA) Guidelines (Surgical Management of Stones). Statement 37, considered as a clinical principle, states that antibiotic prophylaxis should be administered even with a negative urine culture. The panel argues in this section that there is not sufficient evidence to recommend 1 week of prophylactic antibiotics in patients with a negative urine culture[15].

The exposed group included in our cohort received targeted prophylaxis based on the urine culture. Despite management, the incidence of fever was greater than that of the non-exposed group. But it is important to mention that none of the patients presented fever for more than 24 h, in addition to that in two patients, the fever was probably secondary to atelectasis due to the degree of obesity. Ambulation started 24 h after PCNL.

It is very complicated to measure trans-operative bleeding due to the amount of water used in the procedure. We considered it to be a complication as long as the patient presented hypotension data during the trans-operative period and the need for transfusion. RR and PAR have already been mentioned, that is, close to 50%. The bivariate analysis of risk factors for transfusion did not show statistically significant data: diabetes mellitus (OR, 5.4; 95% CI, 0.71-41.8; p = 0.70); hypertension (OR, 2.7; 95% CI 0.36-20; p = 0.3), and chronic kidney disease (OR, 2.1; 95% CI, 0.28-15; p = 0.4). Other variables, such as surgical time, amount of water used, stone volume, gender, and

Body Mass Index (BMI), did not show any statistically significant relationship (p >0.05).

Our study design allowed us to calculate the RR of the two complications that presented in the cohort. The results are reliable due to the standardization of the peri-operative protocol of patients with stone disease. This protocol complied with the norms of safe surgery since, despite the presence of fever and bleeding in some patients, the final results were satisfactory, achieving a very acceptable free rate of morbidity and a mortality of zero.

A few months ago, we reported the microbiological profile of urinary tract infections in our institution[16]. Our report showed a high resistance for most available antibiotics, such as ciprofloxacin, levofloxacin and ceftriaxone with resistances of 72.87, 69.36 and 49.27% respectively. This report allows us now to prescribe the best option of antibiotics based on antibiogram and in an empirical way for those patients who are not infected previous to PCNL.

It is clear in our results that the comorbidity plays a null role in the complications related to infection, and we agree that the presence of a positive pre-surgical urine culture comprises the main risk factor for the development of post-NLP fever. Based on the results obtained and those reported by other authors, it should be possible to investigate the use of pre-surgical treatment schemes for more than 7 days and to look for other factors that cause post-PCNL fever. The main limitations of this study were the sample (n=101), and the non-significative RR based on the confidence intervals. It is necessary to perform prospective, randomized cohort studies that define whether longer-term schedules are convenient, in addition to analyzing the relationship of complications with the various confounders related to PCNL.

Conclusion

To date, there is no international consensus on the ideal prophylactic scheme for PCNL with the intention of reducing complications. There are many studies that suggest prophylactic schemes; however, the variability of peri-operative protocols and confounder factors renders it difficult to generalize its application in various places. It is important for each center to standardize its protocols in order to reduce the morbidity associated with the surgery and to identify the main associated risk factors. If the latter could be achieved, it would be possible to formalize a consensus and define the best prophylaxis and treatment scheme for reducing the incidence of post-PCNL complications.

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Conflicts of interest

The authors declare no conflicts of interest.

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Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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