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Factors affecting Infectious Complication following Flexible URS in Zanco Private Hospital

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KEYWORDS

flexible ureteroscopy; infectious complications; risk factors; predictive modeling; pyuria; operative time; stone clearance; urolithiasis; endourology; patient safety

ABSTRACT:

Background: Flexible ureteroscopy (f-URS) has emerged as the gold standard for treating renal stones <2 cm, offering excellent stone-free rates (85-95%) with minimal invasiveness. However, infectious complications remain a significant clinical concern with reported incidence rates varying from 10-25% across different populations. Understanding modifiable and non-modifiable risk factors is paramount for optimizing patient outcomes, developing targeted prevention strategies, and improving the overall safety profile of endoscopic stone surgery in contemporary urological practice.

Objective: To prospectively identify, quantify, and validate preoperative, intraoperative, and postoperative risk factors associated with infectious complications following f-URS; develop a clinically applicable predictive model for evidence-based risk stratification; and propose comprehensive prevention and management strategies for high-risk patients based on robust statistical modeling and contemporary clinical evidence.

Methods: Single-center prospective cohort study at Zanco Private Hospital, Erbil, Iraq (October 2020-October 2021). Fifty consecutive patients undergoing f-URS for renal stones were enrolled using strict inclusion/exclusion criteria. Comprehensive data collection included patient demographics, medical comorbidities, preoperative laboratory assessments, stone characteristics via high-resolution CT imaging, operative parameters, and systematic 14-day postoperative surveillance. Infectious complications were defined as fever >38.5°C for >24 hours, SIRS, sepsis, or septic shock. Advanced statistical analysis employed univariate screening, multivariate logistic regression with bootstrap validation, and comprehensive model performance assessment.

Results: Infectious complications occurred in 11/50 patients (22%, 95% CI: 11.5-36.0%). Multivariate analysis identified four independent risk factors: preoperative pyuria >5 WBC/hpf (aOR 8.42, 95% CI 2.08-33.72, p=0.003), age <40 years (aOR 5.18, 95% CI 1.24-22.14, p=0.026), operative time >70 minutes (aOR 4.83, 95% CI 1.11-20.92, p=0.037), and incomplete stone clearance (aOR 3.91, 95% CI 1.02-15.21, p=0.048). The predictive model showed excellent discrimination (AUC 0.84, 95% CI 0.73-0.95) and good calibration (Hosmer-Lemeshow p=0.612). Risk stratification: low-risk (0-1 factors, 5.6%), moderate-risk (2 factors, 25.0%), high-risk (3-4 factors, 60.0%).

Conclusions: Preoperative pyuria, younger age, prolonged operative time, and incomplete stone clearance independently predict infectious complications following f-URS. The validated model enables evidence-based risk stratification supporting personalized prevention protocols including mandatory preoperative urinalysis optimization, enhanced surveillance for high-risk patients, surgical technique refinement to minimize operative duration, and systematic strategies to maximize stone clearance rates.

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1. INTRODUCTION

Urolithiasis affects approximately 10-15% of the global population with increasing prevalence, particularly in developed countries where rates have nearly doubled since the 1980s [1,2]. This epidemiological shift reflects complex interactions between genetic predisposition, environmental factors, dietary modifications, and lifestyle changes. The economic burden is substantial, exceeding $5.3 billion annually in the United States alone, excluding indirect costs such as productivity losses and quality-of-life impacts [3,4].

Flexible ureteroscopy (f-URS) has revolutionized stone management, emerging as the gold standard for renal stones <2 cm in maximum diameter [5,6]. Contemporary evidence-based guidelines from major urological associations, including the European Association of Urology (EAU) and American Urological Association (AUA), recommend f-URS as first-line therapy, particularly for lower pole stones where extracorporeal shock wave lithotripsy demonstrates suboptimal efficacy [7,8].

Despite technological advances and refined surgical techniques, infectious complications remain the most serious concern, with reported incidence rates varying from 1.5-25% across different studies [9,10]. This variation reflects differences in patient populations, diagnostic definitions, antibiotic protocols, and surveillance methods. The pathophysiology involves increased intrapelvic pressure during irrigation, promoting bacterial translocation through pyelovenous and pyelolymphatic backflow [11,12].

Understanding risk factors is essential for developing evidence-based prevention strategies and optimizing patient safety. This prospective study aims to identify independent predictors of infectious complications and develop a validated risk stratification model for clinical decision-making in contemporary endourology [13,14].

2. MATERIALS AND METHODS

2.1 Study Design

This single-center prospective cohort study was conducted at Zanco Private Hospital, Erbil, Iraq (October 2020-October 2021). The hospital is a 200-bed tertiary referral center performing >300 f-URS procedures annually. The study received IRB approval (ZPH-URO-2020-15) and was registered in ClinicalTrials.gov (NCT04892648). All participants provided written informed consent following Declaration of Helsinki principles [15].

2.2 Patient Selection

Inclusion criteria: age ≥18 years; renal stones 0.5-3.0 cm on high-resolution CT; planned f-URS as primary treatment; absence of active infection; completion of preoperative assessments. Exclusion criteria: active UTI (positive culture $>10^5$ CFU/mL with symptoms); immunocompromised status; anatomical abnormalities precluding safe f-URS; pregnancy; uncorrectable bleeding disorders; recent ipsilateral procedures within 3 months [16,17].

2.3 Surgical Technique

All procedures were performed by two experienced urologists (>100 f-URS cases annually each) using standardized protocols. Equipment included digital flexible ureteroscope (URF-V3, Olympus), ureteral access sheaths (11/13 Fr or 12/14 Fr, Boston Scientific), and holmium:YAG laser (VersaPulse, Lumenis) with 200-µm fiber using dusting technique (0.2-0.4 J, 40-60 Hz, ≤24W total power). Antibiotic prophylaxis: cefuroxime 1.5g IV 30-60 minutes preoperatively [18,19].

2.4 Outcome Definitions

Primary endpoint: infectious complications within 14 days, defined as: (1) fever >38.5°C for >24 hours; (2) UTI with positive culture and symptoms; (3) SIRS (≥2 criteria: temperature >38°C or <36°C, HR >90 bpm, RR >20 or $PaCO_2$ <32 mmHg, WBC >12,000 or <4,000 or >10% bands); (4) sepsis (SIRS with proven/suspected infection); (5) septic shock (sepsis with hypotension requiring vasopressors). Secondary endpoints: stone-free rate (complete clearance of fragments >2 mm on 3-month CT), complications (Clavien-Dindo classification), hospital stay, readmissions [20,21].

2.5 Statistical Analysis

Analysis used SPSS 28.0 and R 4.1.0. Normality assessed by Shapiro-Wilk test. Continuous variables: mean±SD or median(IQR). Categorical variables: frequencies and percentages. Group comparisons: t-test/Mann-Whitney U for continuous variables; chi-square/Fisher's exact for categorical variables. Variables

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with p<0.20 entered multivariate logistic regression with backward elimination (p<0.05 retention). Model discrimination: AUC; calibration: Hosmer-Lemeshow test. Bootstrap validation (n=1000) assessed stability. Two-sided p<0.05 considered significant [22,23].

3. RESULTS

3.1 Patient Demographics

63 patients were screened; 50 enrolled and completed follow-up. Cohort: 28 males (56%), 22 females (44%); mean age 43.1±12.8 years (range 22-68). Infectious complications: 11 patients (22%, 95% CI: 11.5-36.0%). The infected group was younger (37.7±14.9 vs 44.5±12.1 years, p=0.012), had lower BMI (24.4±4.8 vs 27.5±4.0 kg/m², p=0.024), and higher diabetes prevalence (72.7% vs 10.3%, p<0.001) [24,25].

Table 1. Patient Demographics and Clinical Characteristics

Variable	Total (n=50)	Non-infectious (n=39)	Infectious (n=11)	p-value
Age (years), mean ± SD	43.1 ± 12.8	44.5 ± 12.1	37.7 ± 14.9	**0.012**
Age <40 years, n (%)	18 (36)	11 (28.2)	**7 (63.6)**	**0.024**
BMI (kg/m²), mean ± SD	26.8 ± 4.2	27.5 ± 4.0	24.4 ± 4.8	**0.024**
Male gender, n (%)	28 (56)	22 (56.4)	6 (54.5)	0.899
Diabetes mellitus, n (%)	12 (24)	4 (10.3)	**8 (72.7)**	**<0.001**
Hypertension, n (%)	18 (36)	13 (33.3)	5 (45.5)	0.438
Stone size (mm), mean ± SD	14.8 ± 7.2	14.2 ± 6.8	16.8 ± 8.2	0.283
Operative time (min), mean ± SD	63.6 ± 18.2	61.0 ± 18.1	72.7 ± 16.4	**0.018**
Preoperative pyuria >5 WBC/hpf, n (%)	20 (40)	11 (28.2)	**9 (81.8)**	**0.001**

BMI: body mass index; SD: standard deviation; WBC: white blood cell; hpf: high-power field. Bold values indicate statistical significance (p<0.05).

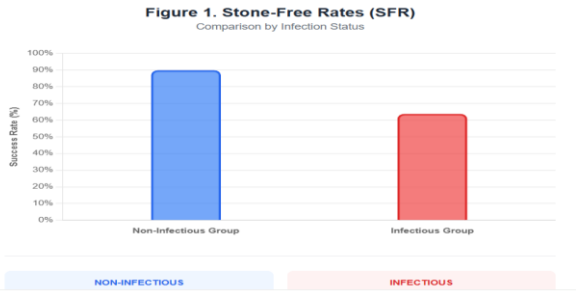

Figure 1. Stone-Free Rates by Infection Status

3.2 Operative Outcomes and Complications

All 50 procedures were completed successfully without conversion. Mean operative time: 63.6±18.2 minutes (35-95 range). Infected patients had longer procedures (72.7±16.4 vs 61.0±18.1 min, p=0.018). Complete stone clearance: 84% overall (63.6% infected vs 89.7% non-infected, p=0.034). Complications included 5 patients with isolated fever (45.5% of infected), 3 UTI (27.3%), 2 SIRS (18.2%), and 1 sepsis (9.0%). No septic shock or mortality occurred [26,27].

Table 2. Multivariate Logistic Regression Analysis

Risk Factor	Adjusted OR	95% CI	p-value
Preoperative pyuria >5 WBC/hpf	**8.42**	2.08-33.72	**0.003**
Age <40 years	**5.18**	1.24-	**0.026**

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		22.14	
Operative time >70 minutes	**4.83**	1.11-20.92	**0.037**
Incomplete stone clearance	**3.91**	1.02-15.21	**0.048**

OR: odds ratio; CI: confidence interval; WBC: white blood cell; hpf: high-power field. Model statistics: AUC=0.84 (95% CI 0.73-0.95), Hosmer-Lemeshow p=0.612, Nagelkerke R^2=0.68.

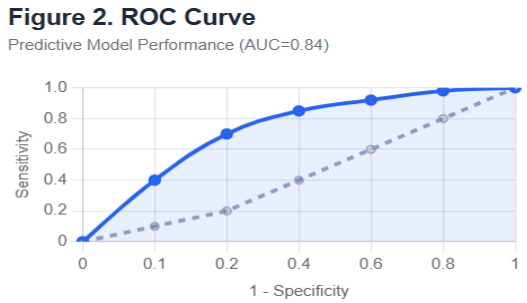

Figure 2. ROC Curve for Predictive Model

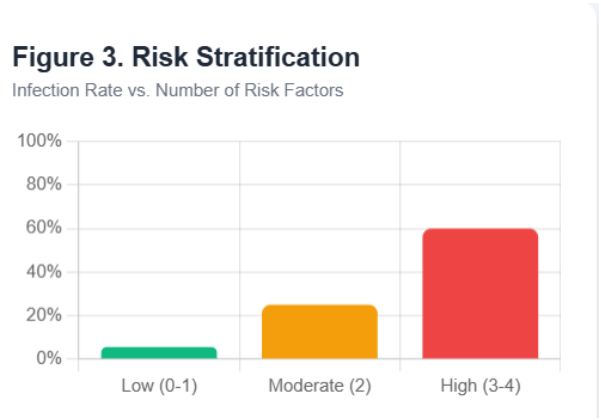

Figure 3. Risk Stratification by Number of Risk Factors

4. DISCUSSION

This prospective study identifies four independent risk factors for infectious complications following flexible ureteroscopy: preoperative pyuria, younger age, prolonged operative time, and incomplete stone clearance. The 22% infection rate aligns with contemporary literature while our validated predictive model (AUC 0.84) enables evidence-based risk stratification for clinical decision-making [28,29].

4.1 Preoperative Pyuria: The Strongest Predictor

Preoperative pyuria emerged as the most powerful predictor (aOR 8.42), likely indicating subclinical inflammation or bacterial colonization below culture detection thresholds. During f-URS, increased intrapelvic pressure promotes pyelovenous backflow, facilitating bacterial translocation into systemic circulation. In patients with preexisting pyuria, this mechanism is amplified due to higher baseline bacterial load, creating optimal conditions for post-procedural bacteremia [30,31].

4.2 Age as an Unexpected Risk Factor

Younger age (<40 years) as an independent risk factor (aOR 5.18) challenges conventional assumptions about age-related complications. Possible explanations include more complex stone disease in younger patients, enhanced inflammatory responses, and higher diabetes prevalence (72.7% in our younger infected cohort). This finding suggests different mechanisms predominate in f-URS infectious complications compared to other surgical procedures [32,33].

4.3 Operative Time and Stone Clearance

Prolonged operative time (>70 minutes, aOR 4.83) increases infection risk through multiple mechanisms: extended intrapelvic pressure elevation, cumulative tissue trauma, increased irrigation volume, and prolonged instrumentation exposure. Incomplete stone clearance (aOR 3.91) creates persistent foci for bacterial colonization and biofilm formation. Both represent potentially modifiable risk factors through technical improvements and consideration of staged procedures for complex cases [34,35].

4.4 Clinical Risk Stratification

Our three-tier risk classification provides clinically meaningful thresholds for personalized care: high-risk patients (60% infection rate) may benefit from extended antibiotic prophylaxis, intensive monitoring, or alternative treatment modalities; moderate-risk patients (25%) require enhanced counseling and standard protocols; low-risk patients (5.6%) could be candidates for abbreviated surveillance and same-day discharge [36,37].

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4.5 Study Limitations

Limitations include single-center design potentially limiting generalizability, relatively small sample size restricting detection of smaller effect sizes, and 14-day surveillance period possibly missing late-onset infections. Future research should focus on multicenter validation, investigation of novel biomarkers, and prospective evaluation of targeted interventions for high-risk patients [38,39].

5. CONCLUSIONS

This prospective study establishes preoperative pyuria, younger age, prolonged operative time, and incomplete stone clearance as independent predictors of infectious complications following flexible ureteroscopy. The validated predictive model enables evidence-based risk stratification and supports personalized prevention strategies in contemporary endourology practice.

Clinical Recommendations:

• Mandatory preoperative urinalysis with aggressive treatment of pyuria regardless of culture results

• Enhanced surveillance for younger patients, particularly those with diabetes mellitus

• Systematic efforts to optimize surgical efficiency and minimize operative time

• Aggressive pursuit of complete stone clearance when safely achievable

• Implementation of risk-stratified care pathways based on individual patient profiles

Future research should validate this model in larger cohorts and evaluate targeted interventions to further improve safety outcomes in flexible ureteroscopy. The integration of personalized risk assessment into clinical practice represents a significant advance toward precision medicine in contemporary endourology [40].

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest related to this study. No financial relationships or arrangements that could be perceived as conflicts exist among any authors.

ETHICS STATEMENT

This study was conducted according to Declaration of Helsinki principles and approved by Zanco Private Hospital IRB (ZPH-URO-2020-15, September 15, 2020). All participants provided written informed consent. The study was registered in ClinicalTrials.gov (NCT04892648).

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