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# Risk Factors for Sepsis after Retrograde Intrarenal Surgery: Single Center Experience

**Jinseok Kang, Koo Han Yoo, Taesoo Choi, Gyeong Eun Min, Dong-Gi Lee, Hyung-Lae Lee, Jeonghyouk Choi**

*Department of Urology, Kyung Hee University Hospital at Gangdong, College of Medicine, Kyung Hee University, Seoul, Korea*

**Purpose:** To evaluate risk factors for sepsis after retrograde intrarenal surgery for treatment of renal stones.

**Materials and Methods:** We analyzed the clinical data of 243 patients with kidney stones who visited our institution between April 2017 and April 2023. Age, sex, body mass index, underlying disease, location and size of stones, previous history of stones, previous history of urinary tract infections, duration of surgery, preoperative drainage, application of ureteral balloon dilation, and laboratory test results were included in the analysis.

**Results:** The mean age of the patients was 58.4 (±15.0) years; there were more men (53.1%) than women (46.9%). Of the 243 patients, the overall rate of sepsis was 5.8% (n=14) and the total mortality rate was 0.4% (n=1). In univariate analysis, history of urinary tract infection (p=0.019), positive preoperative urine culture test (p=0.009), operative duration of more than 90 min (p=0.004), and application of ureter balloon dilation (p=0.016) were statistically significant. In multivariate analysis, positive finding in the urine culture test performed before surgery (p=0.003), operation duration >90 min (p=0.005), and use of balloon dilation during surgery (p=0.011) were statistically significant.

**Conclusions:** There is a risk of progression to postoperative sepsis if bacteria are detected in the urine culture before surgery, if the operative time exceeds 90 min, or if balloon dilation is performed during surgery. Given that the probability of progression to sepsis is approximately 6%, close observation and active treatment are needed for patients with these risk factors.

**Keywords:** Endoscopy; Kidney calculi; Sepsis

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**Correspondence to:** Jeonghyouk Choi
https://orcid.org/0000-0003-0650-7569
Department of Urology, Kyung Hee University Hospital at Gangdong, College of Medicine, Kyung Hee University, 892 Dongnam-ro, Gangdong-gu, Seoul 05278, Korea
Tel: +82-2-440-7736, Fax: +82-2-440-7744
E-mail: jhchoi0@gmail.com

## INTRODUCTION

The incidence of urolithiasis is increasing and is currently estimated at approximately 10% worldwide [1]. The prevalence of urolithiasis ranges from 1% to 20% globally [2]. More specifically, its prevalence varies from 5 to 9% in Europe, 8-13% in the United States, and 1-5% in Asia [3]. The occurrence of renal stones varies according to geographical conditions, genetic factors, diet, climate, and race. The risk of recurrence is determined by the underlying disorder affecting the formation of the stones. With the increase in prevalence and incidence worldwide in recent years, renal stones are a major healthcare concern. It is important to treat stones effectively and safely, to reduce morbidity due to the condition.

Three common options for resolving stones in the upper

urinary tract are shock wave lithotripsy, percutaneous nephrolithotomy, and retrograde intrarenal surgery (RIRS) [4,5]. An analysis of recent trends has shown that RIRS is selectively preferred by healthcare providers and patients [6]. RIRS is a minimally invasive procedure that uses a holmium laser and flexible ureteroscope and has a high stone-free rate and relatively low morbidity. The overall probability of complications following ureteroscopy, including RIRS, ranges from 9% to 25% [7,8]. Most complications do not require intervention and are classified as Clavien grade I or II [9]. However, complications due to infections may occur after surgery. Infectious complications may range from localized urinary tract infections to sepsis and systemic inflammatory response syndrome (SIRS) [10]. Sepsis resulting from urosepsis is the most severe complication of RIRS, with an estimated risk of up to 5% [10-12].

Sepsis is a life-threatening complication, and it is essential to identify the risk factors related to sepsis before and after surgery. In this study, we evaluated the risk factors associated with sepsis after RIRS in nephrolithiasis.

## MATERIALS AND METHODS

A retrospective study was conducted based on the data from the medical records of patients who visited our institution between April 2017 and April 2023 and underwent RIRS for kidney stones. Patients who had kidney stones on computed tomography but in whom the stones were not detected during surgery, resulting in termination of the operation, or who had only a ureteral catheter inserted without surgery because the stones were found to be mud stones were excluded. If a patient scheduled for surgery had a positive preoperative culture test indicative of infection, the patient was treated with appropriate antibiotics based on the susceptibility of the identified pathogens for at least one week before surgery. The patients were classified into postoperative sepsis-occurrence and sepsis non-occurrence groups, and the clinical characteristics of the patients, laboratory test results before the operation, and the characteristics of stones were compared. The analyzed data included age, body mass index (BMI), sex, underlying disease (ischemic heart disease, hypertension, diabetes mellitus, cerebrovascular disease, and chronic kidney disease), history of anticoagulant use, history of stones in the urinary tract, history of urinary tract infection, use of antibiotics before surgery, characteristics of the stones (size and location), drainage before surgery, duration of surgery, ureteral balloon dilatation performed at the time of surgery, positive blood and urine culture, and serum laboratory tests (white blood cell [WBC] count, hematocrit, hemoglobin, platelet count, albumin, creatinine, blood urea nitrogen, alanine transaminase, aspartate transaminase, potassium, and sodium levels). This study was approved by the Institutional Review Board (IRB) of Kyung Hee University Hospital at Gangdong (IRB no. 2023-08-022).

Sepsis was defined according to the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). Sepsis was diagnosed when infection was suspected after surgery and included two or more of the following factors according to the SIRS criteria for defining sepsis:1) body temperature greater than 38℃ or less than 36℃; 2) heart rate >90/min; 3) respiratory rate >20/min or PaCO2 l <32 mmHg (4.2 kPa); and 4) WBC count >12,000/$mm^3$ or <4,000/$mm^3$ in blood tests, or the proportion of immature neutrophils >10% [12-15].

An Olympus flexible fiberoptic ureteroscope (URF-P6) was used in all surgeries. The fibers used were S200 and S365 from FleMAX™ holmium optical fibers. The laser system used was the Trimedyne® 1210-VHP OmniPulse Max™ holmium laser system.

Patient data were analyzed using PASW Statistics ver. 18.0 (SPSS Inc.). Continuous variables were compared using an independent sample t-test, and non-continuous variables were compared using Pearson's Chi-square and Fisher's exact tests. For each risk factor, p-values, odds ratios (OR), and relative risks were calculated. Statistical significance was set at $p<0.05$. Multivariate model analysis was performed using forward selection to identify factors involved in the progression of sepsis among patients who underwent renal stone surgery.

## RESULTS

The medical records of 243 patients were retrospectively reviewed. Table 1 summarizes the detailed patient characteristics. The mean BMI was 24.9±4.59 and the mean age was 58.4±15.0 years. In the distribution of male and female participants, there were more males (53.1% males vs. 46.9% females). The underlying diseases present in the patients were hypertension (n=117, 48.1%), diabetes mellitus (n=70,

Table 1. Baseline characteristics of the patients

| Characteristics | Mean or number of patients (n=243) |
|---|---|
| Age (y) | 58.4±15.0 |
| BMI (kg/m$^2$) | 24.9±4.6 |
| Sex | |
| Male | 129 (53.1) |
| Female | 114 (46.9) |
| Underlying disease | |
| HTN | 117 (48.1) |
| DM | 70 (28.8) |
| IHD | 10 (4.1) |
| CVA | 24 (9.9) |
| CKD | 22 (9.1) |
| Stone | |
| Size (mm) | 10.2±6.5 |
| Location (main) | |
| Upper pole | 36 (14.8) |
| Mid pole | 45 (18.5) |
| Lower pole | 78 (32.1) |
| Pelvis | 57 (23.5) |
| UPJ or Proximal ureter | 27 (11.1) |
| Operation time (min) | 72.1±42.7 |
| Sepsis | 14 (5.8) |
| Mortality | 1 (0.4) |

Values are presented as mean±standard deviation or number (%).
BMI: body mass index, HTN: hypertension, DM: diabetes mellitus, IHD: ischemic heart disease, CVA: cerebrovascular disease, CKD: chronic kidney disease, UPJ: ureteropelvic junction.

28.8%), ischemic heart disease (n=10, 4.1%), cerebrovascular disease (n=24, 9.9%), and chronic kidney disease (n=22, 9.1%). The mean stone size was 10.2±6.51 mm. Analysis of the location of the largest main stone revealed that the stone was found in the upper pole of the kidney in 36 cases (14.8%), the mid-pole in 45 cases (18.5%), the lower pole in 78 cases (32.1%), the pelvis in 57 cases (23.5%), and the ureteropelvic junction or proximal ureter in 27 cases (11.1%). Of the 243 patients who underwent surgery, 14 (5.8%) developed sepsis and one (0.4%) died.

Table 2 summarizes the features of the patients classified according to the presence or absence of sepsis. In the sepsis group, there were more cases with a history of urinary tract infection (21.4% vs. 4.8%; p=0.038), longer operative time (median, 107 min vs. 60 min; p=0.004), application of balloon dilation (28.6% vs. 7.9%; p=0.028), and a higher prevalence of positive preoperative urine cultures (57.1% vs. 23.6%; p=0.005).

A summary of the strains identified in the sepsis and non-sepsis groups is shown in Table 3. In the sepsis group, extended-spectrum beta-lactamase-producing *Escherichia coli* (*E. coli*) was the most frequently identified pathogen in urine and blood culture tests at 25% and 50%, respectively. In the group without sepsis, *E. coli* was identified in 33.3% of the urine culture tests, and *E. coli* and *Proteus mirabilis* were both identified in 28.6% of the blood culture tests.

Variables related to sepsis after RIRS were evaluated using logistic regression analysis. The results are shown in Table 4. In the univariate analysis, a history of urinary tract infection (OR, 5.405; 95% confidence interval [CI], 1.316-22.205; p=0.019), positive preoperative urine culture (OR, 4.321; 95% CI, 1.436-13.002; p=0.009), operative time of more than 90 min (OR, 5.186; 95% CI, 1.671-16.098; p=0.004), and ureter balloon dilation at the time of surgery (OR, 4.689; 95% CI, 1.336-16.455; p=0.016) were statistically significant predictors of sepsis after surgery. In the multivariate analysis, positive findings in the urine culture test prior to surgery (OR, 6.927; 95% CI, 1.968-24.380; p=0.003), operative time of 90 min or longer (OR, 5.659; 95% CI, 1.704-18.794; p=0.005), and the performance of balloon dilation (OR, 6.564; 95% CI, 1.545-27.878; p=0.011) were meaningful risk factors for sepsis after RIRS. The history of urinary tract infection, which was statistically relevant in the univariate analysis, was not statistically meaningful in the multivariate analysis. In addition, sex, stone size, pyuria before surgery, and age were not risk factors for sepsis after surgery for stone removal.

## DISCUSSION

RIRS and percutaneous nephrolithotomy are widely used procedures for removing kidney stones. Percutaneous nephrolithotomy results in greater blood loss, higher complication rates, and a longer hospital stay [16]. In addition, antegrade access is limited, such as in the case of impacted large proximal ureteral stones or in cases where the retrograde method cannot access the stone through the ureter [17]. In contrast, the employment of a flexible ureteroscope is preferred because of improved technology and the availability of digital scopes. RIRS is a non-invasive procedure with low morbidity. However, in rare cases, infectious complications may occur after surgery and may lead to sepsis [8]. In this study, the data of patients who underwent RIRS were retrospectively analyzed, and the risk factors for sepsis after surgery were evaluated.

A positive finding in the urine culture test performed before surgery was identified as a risk factor for the development of sepsis after RIRS, which was also observed in other studies. Blackmur et al. [18] assessed the correlation

**Table 2.** Comparative characteristics of patients with and without sepsis

| Variables | Sepsis (−) (n=229) | Sepsis (+) (n=14) | p-value |
|---|---|---|---|
| Age (y) | 59.0 (14-90) | 52.5 (21-87) | 0.178 |
| BMI (kg/m$^2$) | 24.7 (14.3-48.2) | 23.2 (20.0-31.5) | 0.542 |
| Sex | | | 0.387 |
| Male | 120 (52.4) | 9 (64.3) | |
| Female | 109 (47.6) | 5 (35.7) | |
| Underlying disease | | | |
| HTN | 111 (48.5) | 6 (42.9) | 0.683 |
| DM | 65 (28.4) | 5 (35.7) | 0.557 |
| IHD | 9 (3.9) | 1 (7.1) | 0.454 |
| CVA | 22 (9.6) | 2 (14.3) | 0.636 |
| CKD | 20 (8.7) | 2 (14.3) | 0.368 |
| Medical history Hx. | | | |
| Stone Hx. | 72 (31.4) | 4 (28.6) | 1.000 |
| UTI Hx. | 11 (4.8) | 3 (21.4) | 0.038* |
| Antithrombotic agent | 43 (18.8) | 2 (14.3) | 1.000 |
| Preoperative antibiotics | 90 (39.3) | 8 (57.1) | 0.186 |
| Stone | | | |
| Size (mm) | 9.00 (2.00-35.0) | 10.2 (3.00-40.0) | 0.241 |
| Location (main) | | | 0.366 |
| Upper pole | 35 (15.3) | 1 (7.1) | |
| Mid pole | 43 (18.8) | 2 (14.3) | |
| Lower pole | 70 (30.5) | 8 (57.1) | |
| Pelvis | 54 (23.6) | 3 (21.4) | |
| UPJ or Proximal ureter | 27 (11.8) | 0 (0.0) | |
| RIRS | | | |
| Operation time (min) | 60 (12-227) | 107 (35-229) | 0.004* |
| Laterality | | | 0.181 |
| Left | 106 (46.3) | 5 (35.7) | |
| Right | 88 (38.4) | 4 (28.6) | |
| Both | 35 (15.3) | 5 (35.7) | |
| Preoperative drainage | | | |
| Ureteral stent | 58 (25.3) | 5 (35.7) | 0.389 |
| PCN | 11 (4.8) | 0 (0.0) | 1.000 |
| None | 160 (69.9) | 9 (64.3) | |
| Balloon dilation | | | 0.028* |
| Yes | 18 (7.9) | 4 (28.6) | |
| No | 211 (92.1) | 10 (71.4) | |
| Operative techniques | | | 0.090 |
| Dusting only | 1 (0.4) | 1 (7.1) | |
| Basketing only | 27 (11.8) | 2 (14.3) | |
| Both | 201 (87.8) | 11 (78.6) | |
| Preoperative culture | | | |
| Positive urine culture | 54 (23.6) | 8 (57.1) | 0.005* |
| Bacteremia | 14 (6.1) | 2 (14.3) | 0.233 |
| Preoperative urinalysis | | | |
| Positive nitrite | 14 (6.1) | 2 (14.3) | 0.233 |
| Positive pyuria | 167 (72.9) | 9 (64.3) | 0.483 |
| Positive bacteriuria | 36 (15.7) | 3 (21.4) | 0.476 |
| Mortality | 0 (0.0) | 1 (7.1) | |

between these factors and postoperative urinary tract sepsis in a prospective cohort from a single institution of the National Health Service, UK. A total of 462 patients were involved in the study. Thirty-four (7.4%) patients developed urinary tract sepsis within 28 days of surgery. Patients with a positive finding in preoperative urine culture reported an OR of 4.88, 95% CI of 2.11, 11.31 ($p<0.001$) [18]. Díaz Pérez et al. [19] conducted a retrospective study of patients who underwent ureteroscopy to treat stones between 2015 and 2017. Ureteroscopy was performed in 246 patients, and urinary tract sepsis occurred in 18 (7.3%) patients after surgery, of which sepsis occurred within the first 24 hours in 10 patients (55.5%). Urine cultures demonstrated the presence of *Enterobacteriaceae* (61.1%) and enterococci (38.9%), and pathogens demonstrated higher sensitivity to nitrofurantoin (100%) and quinolones (72%) [19]. Similarly, *Enterobacteriaceae* (63%) were present in the highest proportion in the non-sepsis group of our study.

Previous studies investigated the relationship between surgical time and sepsis. Sugihara et al. [20] investigated

**Table 2.** Continued

| Variables | Sepsis (−) (n=229) | Sepsis (+) (n=14) | p-value |
|---|---|---|---|
| Preoperative laboratory data | | | |
| WBC ($\times10^3/\mu l$) | 7.42 (2.89-15.8) | 7.42 (5.14-11.9) | 0.912 |
| Hemoglobin (g/dl) | 13.4 (8.3-18.2) | 12.75 (10.2-17.2) | 0.629 |
| Hematocrit (%) | 39.7 (25.8-54.7) | 38.7 (30.8-53.1) | 0.875 |
| Platelet count ($\times10^3/\mu l$) | 255 (14-682) | 277 (213-459) | 0.157 |
| BUN (mg/dl) | 15 (5-40) | 16 (8-28) | 0.622 |
| Cr (mg/dl) | 0.86 (0.27-5.33) | 0.76 (0.24-1.97) | 0.557 |
| Albumin (g/dl) | 4.30 (2.20-5.20) | 4.45 (2.50-4.90) | 0.377 |
| AST (U/L) | 23 (10-197) | 19 (11-37) | 0.349 |
| ALT (U/L) | 20 (5-96) | 20 (7-114) | 0.689 |
| Na (mEq/L) | 139 (130-148) | 139 (135-143) | 0.648 |
| K (mEq/L) | 4.0 (2.60-5.20) | 4.15 (3.50-4.90) | 0.265 |

Values are presented as median (range) or number (%).
BMI: body mass index, HTN: hypertension, DM: diabetes mellitus, IHD: ischemic heart disease, CVA: cerebrovascular disease, CKD: chronic kidney disease, Hx.: history, UTI: urinary tract infection, UPJ: ureteropelvic junction, RIRS: retrograde intrarenal surgery, PCN: percutaneous nephrostomy, WBC: white blood cell, BUN: blood urea nitrogen, Cr: creatinine, AST: aspartate aminotransferase, ALT: alanine transaminase.
*$p<0.05$ indicates statistical significance.

**Table 3.** Comparison of urine and blood culture strains between the sepsis and non-sepsis groups

| Strains from urine culture | Sepsis (−) (n=54) | Sepsis (+) (n=8) |
|---|---|---|
| *Escherichia coli* | 18 | 1 |
| Extended-spectrum beta-lactamase-producing *Escherichia coli* | 6 | 2 |
| *Proteus mirabilis* | 7 | 1 |
| *Klebsiella pneumoniae* | 3 | 0 |
| *Pseudomonas aeruginosa* | 1 | 0 |
| *Enterobacter asburiae* | 1 | 0 |
| *Enterococcus faecalis* | 2 | 1 |
| *Enterococcus faecium* | 1 | 1 |
| *Staphylococcus aureus* | 1 | 1 |
| Coagulase-negative Staphylococcus | 3 | 1 |
| *Streptococcus agalatiae* | 2 | 0 |
| *Streptococcus anginosus* | 1 | 0 |
| *Streptococcus mitis* | 1 | 0 |
| *Streptococcus viridans* | 1 | 0 |
| *Bacillus* spp | 1 | 0 |
| *Corynebacterium* spp | 3 | 0 |
| *Candida glabrata* | 2 | 0 |
| **Strains from blood culture** | **Sepsis (−) (n=14)** | **Sepsis (+) (n=2)** |
| *Escherichia coli* | 4 | 0 |
| Extended-spectrum beta-lactamase-producing *Escherichia coli* | 2 | 1 |
| *Proteus mirabilis* | 4 | 0 |
| *Klebsiella pneumoniae* | 2 | 0 |
| *Enterococcus faecalis* | 1 | 0 |
| *Staphylococcus hominis* | 1 | 0 |
| *Staphylococcus saprophyticus* | 0 | 1 |

Values are presented as number only.

12,372 cases included in the Japanese Inpatient Administrative Claims Database between 2007 and 2010. Complication rates increased with operative time, particularly for operative times longer than 90 min. Of the 12,372 patients, 296 (2.39%) experienced severe adverse reactions. Multivariate analysis demonstrated the outcome of surgery duration and moderate adverse events (OR, 1.58 for 90–119 minutes; OR, 4.28 for ≥210 minutes measured against ≤59 minutes; each $p<0.05$) [20]. In a prospective study, Ozgor et al. [21] reviewed the medical records of patients who underwent flexible ureterorenoscopy for kidney stones between 2014 and 2018. A standardized flexible ureterorenoscopy procedure was carried out for all patients. In total, 463 patients who did not experience infectious complications and 31 who experienced infectious complications were included in the study. The average operative time of patients with infectious complications was 65.3 minutes, which was much longer than that of patients without infectious complications (47.8 min; $p<0.001$). Multivariate regression analysis showed that a long operative time of ≥60 min, age ≤40 years, and the presence of renal abnormalities were predictors of infectious complications after flexible ureterorenoscopy [21]. In our study, surgery time longer than 90 minutes was observed to be a significant risk factor for the development of postoperative sepsis. In addition, it was seen that performing balloon dilation also contributes significantly to the risk. This is at variance with the conclusion by Kuntz et al. [22] in a previous study that balloon expansion was associated with fewer complications. If balloon dilation is performed due to a structural abnormality of the ureter, the surgical time will inevitably be prolonged, which will influence the risk of postoperative sepsis.

Our results revealed that the presence of pyuria in

Table 4. Risk factors of sepsis after retrograde intrarenal surgery

| Variables | Univariate analysis | | | Multivariate analysis | | |
|---|---|---|---|---|---|---|
| | OR | 95% CI | p-value | OR | 95% CI | p-value |
| Sex (male vs. female) | 0.612 | 0.199-1.881 | 0.391 | | | |
| Age (<65 vs. ≥65) | 0.498 | 0.135-1.838 | 0.296 | | | |
| UTI History (no vs. yes) | 5.405 | 1.316-22.205 | 0.019* | | | |
| Preoperative pyuria (negative vs. positive) | 0.668 | 0.216-2.072 | 0.485 | | | |
| Preoperative urine culture (negative vs. positive) | 4.321 | 1.436-13.002 | 0.009* | 6.927 | 1.968-24.380 | 0.003* |
| Stone size (<20 mm vs. ≥20 mm) | 2.850 | 0.734-11.066 | 0.130 | | | |
| Operation time (<90 min vs. ≥90 min) | 5.186 | 1.671-16.098 | 0.004* | 5.659 | 1.704-18.794 | 0.005* |
| Balloon dilation (no vs. yes) | 4.689 | 1.336-16.455 | 0.016* | 6.564 | 1.545-27.878 | 0.011* |

OR: odds ratios, 95% CI: 95% confidence intervals, UTI: urinary tract infection.
*$p<0.05$ indicates statistical significance.

preoperative urinalysis was not associated with sepsis. However, some studies have reported that pyuria is a risk factor for sepsis. Kim et al. [8] investigated 150 patients to assess the risk factors for febrile urinary tract infection after RIRS for the treatment of renal stones. Seventeen patients (11.3%) developed febrile urinary tract infections after RIRS. The average patient age was 56.6±13.9 years and the distribution of male and female was equal. The average stone size was 14.2±5.89 mm. The average operative time was 74.5±42.6 min. In the univariate and multivariate logistic regression analyses, the presence of pyuria in preoperative urinalysis was the sole independent risk factor for infectious complications after RIRS (OR, 8.311; 95% CI, 1.759-39.275; p=0.008). BMI, sex, age, comorbidities, hydronephrosis, preoperative bacteriuria, renal stone features, and operative time were not associated with febrile urinary tract infection after RIRS. However, it was found that the presence of pyuria in preoperative urinalysis was the sole risk factor for infectious complications after RIRS [8]. The reason for the contradictory results of the Kim et al. [8] study and our study could be attributed to the differences in the definition of pyuria in the two studies. We had defined pyuria as two or more WBCs detected in a high-power field. However, Kim et al. [8] defined pyuria as five or more WBCs per high-power field.

As mentioned earlier, if a patient scheduled for surgery had a positive urine or blood culture test prior to surgery, antibiotics were administered for at least 1 week according to the pathogen sensitivity to the antibiotic before surgery was performed. If the culture test is not negative, it is likely that surgery will be performed using the method above rather than considering other procedures.

Risk factors that affect surgery time include the size of the stone and the structural abnormalities of the ureter. However, this study found that the size of the stone was not significant in the occurrence of postoperative sepsis. If balloon dilation is performed due to an abnormality in the ureteral structure, the surgery time increases, which increases the risk of developing sepsis after surgery. Contraindications for RIRS should therefore include patients with symptomatic urinary tract infection, patients with developing sepsis, and patients with a liver disease that affects coagulation.

A limitation of our study was that it was a retrospective study conducted at a single institution with a small number of patients. In addition, as the procedure was performed by different surgeons, there may have been differences in the surgical proficiencies, which could have altered the outcomes. In addition, high intrarenal pressure is a factor that leads to complications after ureteroscopic surgery [23]. However, the intraoperative renal pressure was not measured in the participants.

## CONCLUSIONS

A positive finding in a preoperative urine culture test, surgery time exceeding 90 min, and application of intraoperative balloon dilation are risk factors for sepsis after kidney stone surgery. To prevent postoperative sepsis, it is necessary to assess the patient adequately before surgery and minimize the operative time.

## CONFLICT OF INTEREST

No potential conflicts of interest relevant to this article have been reported.

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## AUTHOR CONTRIBUTIONS

J.C. and J.K. designed the study. T.C. and J.K. gathered data and did the analyses. J.K. and K.H.Y. wrote the document with the support of G.E.M. and D.G.L., and H.L.L. provided crucial feedback and contributed to the final version of the document.

## ORCID

Jinseok Kang, https://orcid.org/0009-0007-0480-4443
Koo Han Yoo, https://orcid.org/0000-0001-7952-7902
Taesoo Choi, https://orcid.org/0000-0002-2800-5773
Gyeong Eun Min, https://orcid.org/0000-0003-3881-7481
Dong-Gi Lee, https://orcid.org/0000-0001-7369-9252
Hyung-Lae Lee, https://orcid.org/0000-0002-4338-7423
Jeonghyouk Choi, https://orcid.org/0000-0003-0650-7569

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